

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ROGER P. JACKSON
Patent Owner

Patent No. 11,129,646
Filing Date: December 16, 2020
Issue Date: September 28, 2021
Title: MEDICAL IMPLANT THREADED PLUG HAVING A START
STRUCTURE WITH SYMMETRICALLY SHAPED CONCAVE AND
CONVEX LEADING SURFACES

Inter Partes Review No. IPR 2023-01433

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. 11,129,646 (“the ’646 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 ’646 Patent, (2) the general knowledge a person of ordinary skill in the art (“a POSA”) had at the effective filing date of the ’646 Patent (which I have been asked to assume is January 10, 2012), (3) the meaning a POSA would ascribe to the claims of the ’646 Patent, (4) the scope and content of the prior art references, and (5) whether any of the Challenged Claims of the ’646 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 '646 Patent are obvious. As explained further below, the '646 Patent relates to a closure top (also known as a cap, plug, closure, closure plug, or set screw) used to capture a rod in the U-shaped receiver of a spinal bone screw (commonly known as a polyaxial pedicle screw). This basic construct was well known in the prior art, as the '646 Patent admits. The '646 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. From my review of the prosecution history of the '646 Patent, the claims of the patent appear to have been allowed based on the use of a substantially flat bottom surface with an annular outer edge (which should properly be construed as a downwardly projecting rim), spaced below the start of the threads. But downwardly projecting rims spaced below the thread starts were a well-known feature of prior art closure tops. The '646 Patent also claims thread starting surfaces with a partially planar or bottom beveled surface, but planar or beveled thread starting surfaces have long been known to help center the start of the threads such as the thread starts noted in 1891 by U.S. Patent No. 447,775 to Higbee (EX1015), which states that a thread “may be cut off on an oblique plane.”

EX1015, 1:92. The additional features claimed in the '646 Patent, including curvate leading thread faces, upper thread surfaces that slope rearward from the root towards the crest (i.e., reverse angle threads), breakoff drive mechanisms on the closure top, and breakoff receiver arms, were all conventional features readily available to a POSA when designing a pedicle screw system. Nothing of an inventive nature was taught by simply enumerating many of the various common set screw thread forms, screw head forms, and receiver arm types that could be used in the design of spinal systems. The '646 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 '646 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 a closure top used to capture a rod in the U-shaped receiver of a spinal bone screw. The closure tops of the '477 Publication have many of the features claimed in the '646 Patent, including a thread with a curvate leading face, a substantially flat bottom surface with an arcuate outer edge spaced below the thread start, and a breakoff drive mechanism. 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 closure tops 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), dated December 28, 2010. The ’477 Publication further expressly teaches that “it is foreseen” that its closure tops may be modified in numerous ways, including a closure top where the bottom surface is “flat” and that includes a “lateral rim.” EX1005, ¶[0029]; *see also id.*, ¶[0040]. Because the ’477 Publication does not actually depict such a lateral rim, a POSA would naturally have looked to other prior art references that did teach a lateral rim on the bottom of a closure top. Therefore, a POSA would naturally combine the teachings of the ’477 Publication regarding closure tops with known closure top bottom configurations with a lateral rim on the bottom, such as the closure top of U.S. Patent Application Publication No. 2011/0152947 (“Kirschman”) (EX1007). The ’477 Publication was not cited or discussed during the prosecution of the ’646 Patent.

5. Boschert discloses a polyaxial bone screw with a U-shaped receiver and teaches that dual-start threads offer a benefit over single-start threads when threading a closure top into an open bone screw receiver. 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.”). This is disclosed both

the Boschert patent, which was filed on June 14, 2004, as Application No. 10/874,785, and Boschert patent application publication, U.S. Patent Application Publication No. 2005/0277928, which published on December 15, 2005. Boschert also expressly invites modifications to its closure top, noting that “[t]he embodiments of the locking arrangements disclosed here (e.g., the set screw⁷⁰[]) 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 receivers with known set screws (i.e., closure tops), 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 not discussed during the prosecution of the ’646 Patent and was not relied on by the Examiner until the prosecution of later patent family members when it was used to reject the proposed claims, as is further discussed below.

6. Kirschman discloses a polyaxial bone screw with a U-shaped receiver and teaches the benefits of using curvate leading faces at the start of closure top threads and of spacing the thread starts above the annular outer edge of a substantially flat bottom surface of the closure top. EX1007, ¶¶[0034], [0039], [0043]. Kirschman discloses that an “object of [its] embodiment is to provide a cap comprising at least one deformable area, such as a deformable ring, for

facilitating locking the cap on the receiver and thereby locking a rod to a screw.” *Id.*, ¶[0016]. Kirschman was cited during the prosecution of the ’646 Patent, but its disclosures relating to a flat bottom surface with an annular outer edge spaced below the thread starts were never discussed in any office actions or responses.

7. Finally, U.S. Patent Application Publication No. 2007/0088357 (“Johnson”) (EX1008), is one of many prior art references that disclose the conventional feature of breakoff receiver arm extensions that can be added to any known receiver, such as the receivers disclosed in Boschert or the ’477 Publication, to accommodate severe spinal deformities. Johnson was not cited or discussed during the prosecution of the ’646 Patent.

8. The ’477 Publication, Kirschman, and Johnson was never discussed in any rejection during prosecution of the ’646 Patent, either alone or in combination with Boschert. Instead, the Challenged Claims were allowed on the basis of conventional prior art closure top features without the benefit of the combinations discussed herein. In my opinion, the ’477 Publication with its curvate leading thread face and substantially flat bottom surface with an annular outer edge spaced below the thread start, anticipated or rendered obvious Claims 1-2 and 4-9 of the ’646 Patent. Moreover, the ’477 Publication, in combination with the dual start threads taught by Boschert, rendered obvious Claims 3, 12-18, and 20 of the ’646 Patent. Such a combination would have included every feature claimed in the ’646

Patent with the exception of conventional breakoff receiver arm extensions described in Claims 10, 11, and 19. If there were any doubt that the '477 Publication/Boschert combination disclosed spacing the thread starts above the annular outer edge of a flat bottom surface, this doubt is resolved by Kirschman, which teaches the benefits of doing exactly that. Finally, Claims 10, 11, and 19 were also obvious, because breakoff receiver arm extensions were a conventional design option, as disclosed by Johnson.

9. Furthermore, nothing in the teachings of the '646 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 or not to use breakoff closure tops; breakoff arm extensions; the particular type of thread 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; and the shape of the bottom surface of the closure top that interfaces with the rod. No specific features were taught to be particularly useful and no combination of the features were taught to be superior to any other combination of features. Therefore, in my opinion, each of the Challenged Claims of the '646 Patent are obvious.

10. I reserve the right to supplement this declaration as permitted to address any issues raised by expert(s) engaged by Patent Owner or resulting from

further discovery. Additionally, I reserve my right to supplement this section if new information that would affect my opinions becomes available to me.

II. RELEVANT EXPERIENCE

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

12. From 1989 to 1997, I held positions as Senior Scientist, Director of Polymer Laboratory and Director of R&D at AcroMed Corporation in Cleveland, Ohio. In these roles, I conducted and directed research, development, evaluation and commercialization of many metal, polymer, polymer/carbon fiber composite and elastomer material based orthopedic products, primarily for the spine. During my time at AcroMed, I was involved in some of the design and implementation of the Isola spine screw and rod system, which used spinal pedicle screws that captured a rod to correct, reduce, or stabilize spinal deformities. The Isola System, along with the Texas Scottish Rite Hospital System (“TSRH”) were the first pedicle screw and rod systems introduced worldwide—mostly replacing the Harrington rod and hook system in use from around 1975. These two systems

rapidly evolved into many different polyaxial pedicle screw and rod systems such as the ones described in the Jackson patents.

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

14. I helped develop rod bending systems used to bend stainless steel and titanium rods into the curvatures required for use in pedicle screw and rod systems intraoperatively and have scrubbed into operations where rods were bent and

rebut (sometimes to failure) in order to conform with patient's anatomy. Both polyaxial pedicle screws and pedicle screw extensions with appropriate instruments were developed to make this fitting easier.

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

16. In 2020, I was inducted as a Fellow of the International Union of Societies for Biomaterials Science and Engineering and am entitled to add FBSE after my PhD on my business cards. I am the Recipient of the 2015 C. William Hall lifetime achievement award from the Society for Biomaterials "For significant contributions to the Society for Biomaterials and an outstanding record in

establishing, developing, maintaining, and promoting the objectives and goals of the Society.” I was a Delegate on the first People-to-People program on Biomaterials to the Peoples Republic of China (2010). I was member of the Edison Biotechnology Center Omeris (State of Ohio) from 1992 through 2002, the Commercialization Cabinet from 1997-2002, the Scientific Advisory Council from 1992 through 1994, and the Executive Advisory Committee from 1992-1996. I was also a member of the External Advisory Board at the Center for Cardiovascular Biomaterials, Case Western Reserve University, Cleveland, OH, from 1994 through 1998. And I was an Executive Editor (U.S.A.) of the international journal, *Bio-Medical Materials and Engineering*, Pergamon Press, from 1990-1996.

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

III. COMPENSATION

18. I have been retained by Petitioners as an expert in the above-captioned proceeding. I am being compensated at a rate of \$325 per hour through United

Expert Holdings, LLC dba Round Table Group which collects additional fees. I am also being reimbursed for reasonable and customary expenses associated with my work and testimony in this matter. My compensation is not contingent on the outcome of this matter or the specifics of my testimony.

IV. DOCUMENTS AND INFORMATION CONSIDERED

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

V. APPLICABLE LEGAL STANDARDS

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

A. Invalidity

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

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

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

23. I understand that to be considered prior art under the applicable version of 35 U.S.C. § 102(b), a reference must have been patented or described in a printed publication in the United States or a foreign country or in public use or on sale in the United States, more than one year prior to the date of the application in the United States for the patent at issue. For purposes of this declaration, I have been asked to assume that the effective application date for the ’646 Patent is January 10, 2012.

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.

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 have assumed a date of first invention of the claimed subject matter by Dr. Roger Jackson (the named inventor of the '646 Patent) on January 10, 2012. If later presented with evidence purporting to support an earlier invention date, I will consider it.

25. I understand that to be considered prior art under the applicable version of 35 U.S.C. § 102(e) the invention must be described in a published patent application that was filed in the United States before the invention thereof by the applicant for patent. For purposes of this declaration, I have assumed a date of first invention of the claimed subject matter by Dr. Roger Jackson (the named inventor of the '646 Patent) on January 10, 2012. If later presented with evidence purporting to support an earlier invention date, I will consider it.

26. I understand that a prior art reference is prior art for all that it teaches to a skilled artisan. I further understand that, when determining whether a single item of prior art anticipates a patent claim, one may consider not only what is expressly disclosed in that prior art, but also what is inherently present in that prior art. I understand that claim limitations that are not expressly found in a prior art

reference are inherent if the prior art necessarily functions in accordance with, or includes, the claim limitations, or if the missing element or feature would be the natural result of following what the prior art teaches to persons of ordinary skill in the art. I also understand that it is acceptable to examine evidence outside the prior art reference, in determining whether a feature, while not expressly discussed in the reference, is necessarily present in the reference. I understand that mere probabilities that an element is present are not enough, but it is not required that persons of ordinary skill actually recognized the inherent disclosure at the time the prior art was first known or used.

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

28. I understand that for a reference to be used in an obviousness combination, it must be analogous art to the claimed invention. There are two ways to determine whether prior art is analogous. First, the art can be from the same field of endeavor as the claimed invention. Second, if the reference is not within the same field of endeavor, the reference can still be analogous if it is reasonably pertinent to the particular problem faced by the inventor of the claimed invention such that a POSA would reasonably have sought a solution to the problem in that outside field.

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

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

31. I understand that an obviousness analysis need not seek out precise teachings directed to the specific subject matter of the claimed invention, and that the Board can take account of the inferences and creative steps that a POSA would have employed at the time of the alleged invention. I understand that it is often necessary to look to interrelated teachings of multiple prior art references; the effects of demands known to those working in the relevant field of art or present in the marketplace; and the background knowledge possessed by a POSA, all to determine whether there was an apparent reason for a POSA to have combined elements in the manner claimed. I understand that any need or problem known in the field of endeavor at the time of the alleged invention or addressed by the patent-at-issue can provide a reason for a POSA to have combined elements in the manner claimed. I understand that one way in which a patent's subject matter can

be proven obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims. I understand that when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a POSA has good reason to pursue the known options within his or her technical grasp. I further understand that, if this leads to the anticipated success, it is likely the result not of innovation but of ordinary skill and common sense and, as such, likely is obvious.

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

each separately function or operate effectively, a POSA would have been less likely to combine the features of both devices into a single device.

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

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

35. I understand that, before assessing the issue of obviousness, one must also consider certain objective factors—sometimes referred to as secondary

considerations or indicia—that, if established, may indicate that the claimed invention may not have been obvious. Such secondary considerations include: (a) Were products covered by the claim commercially successful due to the merits of the claimed invention rather than due to other, unrelated factors, such as, for example, advertising, promotion or marketing, salesmanship, or unclaimed features of the product?; (b) Was there a long-felt but unresolved need for a solution to the problem facing the inventors, which was resolved by the claimed invention?; (c) Did others try, but fail, to solve the problem solved by the claimed invention?; (d) Did others copy the claimed invention?; (e) Did the claimed invention achieve unexpectedly superior results over the closest prior art?; (f) Did others in the field praise the claimed invention or express surprise at the making of the claimed invention?; and (g) Did others accept licenses under the patent-at-issue because of the merits of the claimed invention? I understand that these factors are only relevant to obviousness if there is a connection, or nexus, between each of them and the claimed subject matter. I understand that, even if one could conclude that some of the above factors have been established, those factors should be considered along with all other available evidence when determining whether the claimed invention would have been obvious to a POSA at the time of the alleged invention.

B. Claim Construction

36. I understand that to date no court has construed the claim terms of the '646 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 '646 Patent are based on the ordinary and customary meaning of the claim terms in the context of the entire '646 Patent, including its specification and prosecution history.

VI. THE PERSON OF ORDINARY SKILL IN THE ART

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

37. It is my opinion that the relevant field of the invention of the '646 Patent is spinal implants with threaded connections.

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

level of active workers in the field. I considered these factors in arriving at my opinion regarding the qualifications of a person of ordinary skill in the art.

39. I understand that Dr. Roger Jackson, the named inventor of the '646 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.

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

41. Based on my experience and my review of the relevant prior art, it is my opinion that technology for spinal implants with threaded connections, as of January 10, 2012, was not particularly complex. As I will discuss in more detail below (*see* Section VI.B), as of January 10, 2012, the basic framework of the device that the '646 Patent claims—i.e., an open-headed bone screw receiver and a closure top for locking a stabilization rod—was well-known. Within this framework, the technology for threaded connections for spinal implants in particular would have been relatively straightforward and simple. Indeed, as I discussed, the problems encountered in conceiving of and/or designing threaded connections for spinal implants were typically mechanical engineering problems with a defined set of known solutions. In my opinion, as long as a POSA possessed a baseline understanding of the basics in mechanical engineering, innovations and alterations related to spinal implants and threaded connections between various implant components were relatively straightforward.

42. Based on my experience and my review of the relevant prior art, it is my opinion that the education level of active workers in the field as of January 10, 2012, covered a range of educational backgrounds and experience. Most workers in this field had at least a bachelor's degree in mechanical engineering, biomedical engineering, materials science, or an equivalent discipline, but some, including myself, had terminal degrees. Those working in this field also had a range of

experience within the field, from newly hired engineers to those who had been designing or implanting spinal implants with threaded connections for decades. Medical doctors also frequently contributed to spinal implant and instrument designs, most often by defining the need for an instrument or an implant encountered in the operating room. For example, a doctor may suggest that they need a spinal screw with a wire coming out of it.

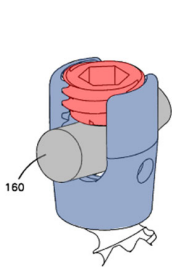
43. In view of the non-exhaustive list of factors discussed above, it is my opinion that a POSA would have had a bachelor's degree in mechanical engineering, or an equivalent discipline, and at least two years of experience designing or implanting spinal implants with threaded connections. More education could substitute for less experience, and vice versa. 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

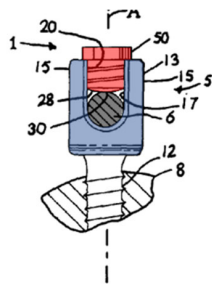
44. I understand that a POSA is presumed to have known the relevant art at the time of the invention. Below is a brief description of some of the knowledge that a POSA would have had as of January 10, 2012.

45. As the '646 Patent concedes, at least as of January 10, 2012, "[b]one anchors, such as bone screws and hooks," were well-known. EX1001, 1:32-35.

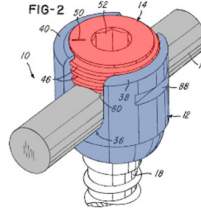
Known bone anchors included polyaxial bone screw assemblies. *Id.*, 1:49-53; *see also* EX1006, 4:44-47, 5:2-11, Figs. 4, 9, 7, 17; EX1005, ¶¶[0018], [0025]-[0027], [0039], Figs. 5-6; EX1007, ¶¶[0004], [0010]-[0011], [0012]-[0013], [0017]-[0018], [0020]-[0021], [0034]-[0036], [0047], [0049], Figs. 1-10; EX1008, ¶¶[0001]-[0004], [0046]-[0047], Fig. 7. Sample depictions of these representative prior art bone screws are shown with annotations below to highlight the receiver (**blue**), closure top (**red**), and rod (**grey**):



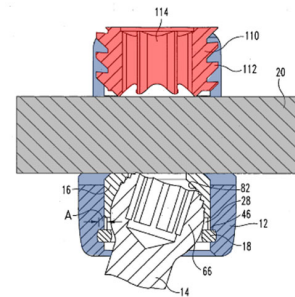
EX1006, Fig. 7



EX1005, Fig. 6



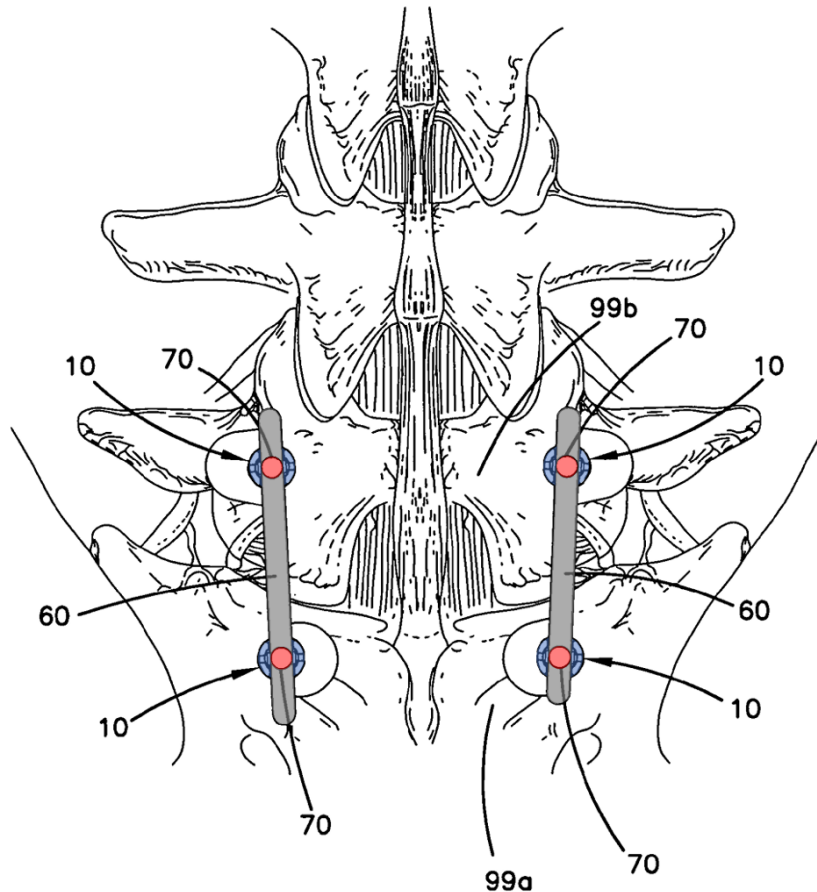
EX1007, Fig. 2



EX1008, Fig. 7

46. In addition, at least as of January 10, 2012, using a rod with bone screws for “providing vertebral support” was a “common mechanism.” EX1001, 1:35-38. It was also known that, “[a]lthough both close-ended and open-ended bone anchors” were known, open-ended anchors were “particularly well suited for connections to longitudinal connecting members such as hard, soft or deformable rods, dynamic or elastic connectors and connector arms, because such rods or other connector members do not need to be passed through a closed bore, but rather can be laid or urged into an open channel within a receiver or head of such a bone

anchor.” *Id.*, 1:39-46. Fig. 2 of Boschert, annotated below, shows how open-ended anchors (**blue**) and set screws (**red**) can be used together with a longitudinal rod (**grey**) to correct and/or stabilize spinal deformities.

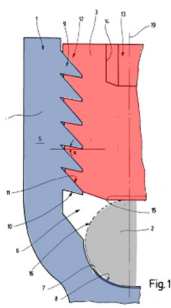


EX1006, Fig. 2.

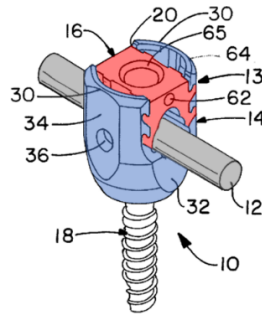
47. “Typical open-ended bone screws included a threaded shank with a head or receiver having a pair of parallel projecting branches or arms which form a yoke with a U-shaped slot or channel to receive a rod or other longitudinal connecting member.” EX1001, 1:54-58; *see also* EX1006, Abstract, 4:13-28,

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, 1:61-65. 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.*, 1:65-2:4; *see also* EX1005, Abstract, Figs. 1-10, ¶¶[0005]-[0011], [0025]-[0046]; U.S. Patent No. 6,296,642 to Morrison (“Morrison”) (EX1016), Abstract, 1:6-10, 2:30-34, 3:49-51, 3:64-4:61, 5:14-28, Figs. 1, 3-6C; U.S. Patent No. 6,302,888 to Mellinger (EX1017), Abstract, 1:63-65, 2:10-22, 4:38-60, 5:53-57, Figs. 1-2, 5-7, 9-10. In addition to those shown above, sample depictions of representative prior art receiver (**blue**) and closure top (**red**) constructs with a longitudinal rod (**gray**) are shown below, along with their publication dates:

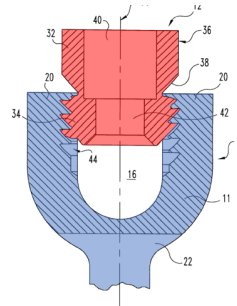
² Closure members have been referred to with a variety of terms in the prior art, including closure, closure top, closure plug, plug, set screw, and the like.



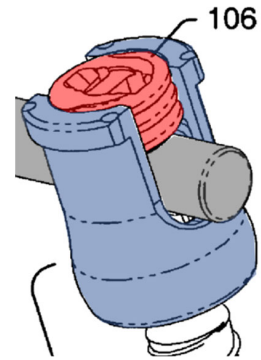
1999
EX1018, Fig. 1



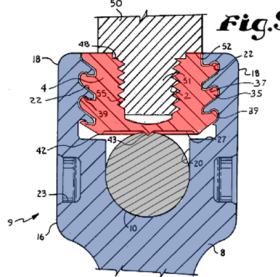
2001
EX1017, Fig. 1



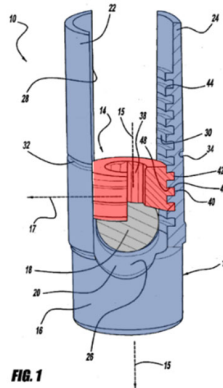
2001
EX1016, Fig. 1



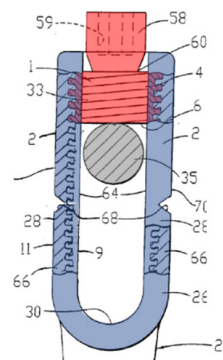
2004
EX1019, Fig. 1



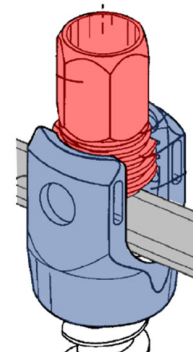
2004
EX1020, Fig. 9



2004
EX1021, Fig. 1



2006
EX1023, Fig. 1



2011
EX1022, Fig. 1

48. Thus, before January 10, 2012, the general environment of a polyaxial bone screw assembly, including open-ended bone screws with a pair of spaced arms forming a channel, longitudinal connecting members such as rods, and 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 a POSA would have applied to a polyaxial bone screw assembly.

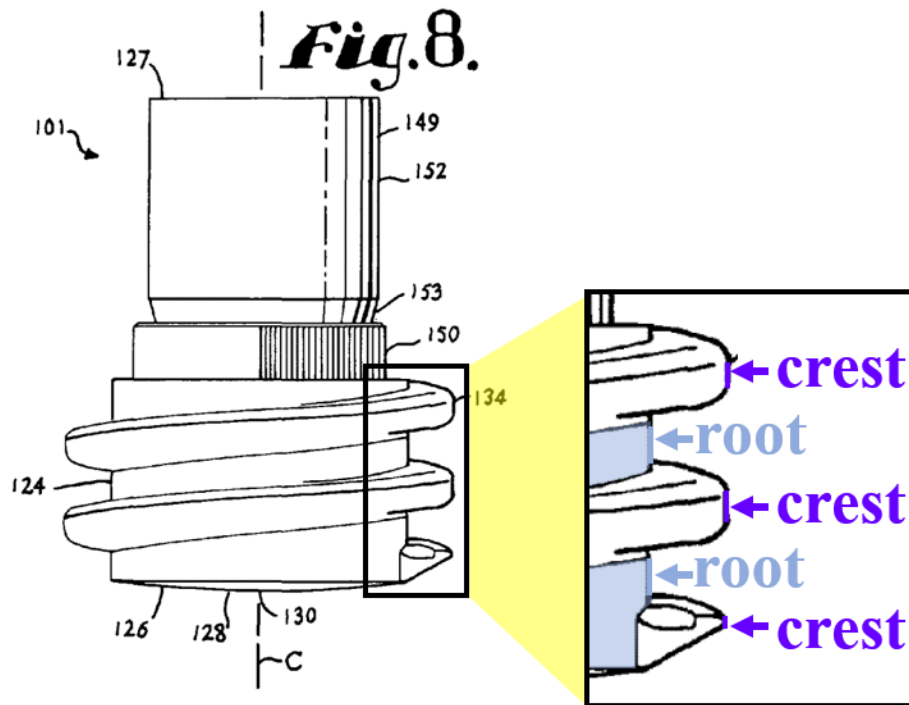
1. Threaded Connectors

49. Before January 10, 2012, threaded connectors were well known in the art. In particular, it was well known that spine correction and stabilization could be accomplished by screws placed into the pedicles of spinal vertebrae joined together by plates or rods. If a rod system was used (particularly for longer vertebral segments or multi-directional correction such as in scoliosis) pedicle screws with U-shaped heads to contain the rod could be used to connect a series of vertebral bodies to each other—generally on both sides of the spine. The rods could be contoured or bent to match the desired curvature of the spine. Although the Acromed/DePuy Isola system used a sliding cap, the most common method of holding the rod within the channels of the screws was with a threaded connector either as a cap over the top of the screw or as a set screw within the top of the screw.

50. In designing a threaded connector, including a closure top for a spinal implant, a POSA would have had the opportunity to choose the type of thread, 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.*

51. The ’477 Publication describes the root and crest of a thread. EX1005, ¶[0031]. As shown in the annotated and enlarged Figure 8, below, the root is the surface of the thread which joins the flanks of adjacent threads and is immediately adjacent the cylindrical body from which the thread projects, and the crest is the surface of a thread which joins the flanks of the thread and is the furthest point from the cylindrical body from which the thread projects. *Id.*, Fig. 8.



a. Multi-Start Threading

52. 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 would have been advantageous 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.

53. 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

54. 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.

55. 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 (“Handbook H28”) (EX1024), 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.

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

57. 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 (EX1014) ("Machinery's Handbook"). 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

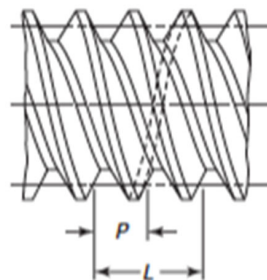
⁴ Emphases and text coloring added unless specified throughout.

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 be synonymous with each other.

degrees. In other words, the Machinery's Handbook teaches that the starts of a dual-start thread should be diametrically opposed with respect to one another. The Machinery's Handbook further taught that one advantage of multi-start threads is that they "provide fast relative traversing motion when this is necessary." *Id.* at 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.

58. Double lead threads were well known well before 2012, as evidenced by their description in the ASME standard B1.7-2006. "On a single lead thread, the lead is equal to the pitch. On a double lead thread (double start), the lead is equal to twice the pitch." 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

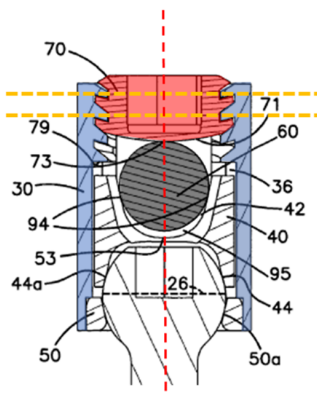
Id. at 9.

59. Before January 10, 2012, it was known that multi-start threading could be used in spinal implants. For example, U.S. Patent No. 6,010,502 to Bagby (EX1026) (“Bagby”), which was filed on September 29, 1997, and issued on January 4, 2000, disclosed a “bone joining implant” that includes a “base[d] 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.

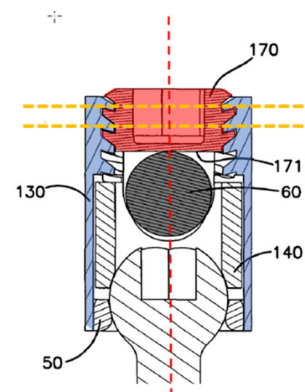
60. Moreover, before January 10, 2012, it was known that multi-start threads were beneficial, for the reasons discussed below, in the specific context of a set screw that needs to hold a rod in place in polyaxial spinal pedicle screw and rod spinal implants, the same as described by Jackson in the ‘646 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, 48-50. Boschert further disclosed that the threads of the set screw can include two thread leads, rather than one, in order “to start more easily than with a single lead.” *Id.*, 7:21-23.

61. 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 threads leads are 180 apart (as illustrated by the yellow horizontal lines that are perpendicular to the red longitudinal line). EX1006, Figs. 3, 15.

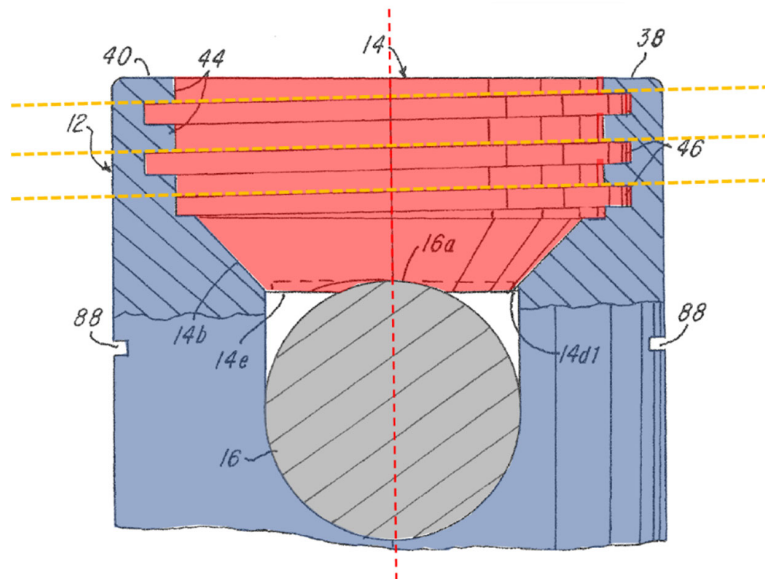


EX1006, Fig. 3



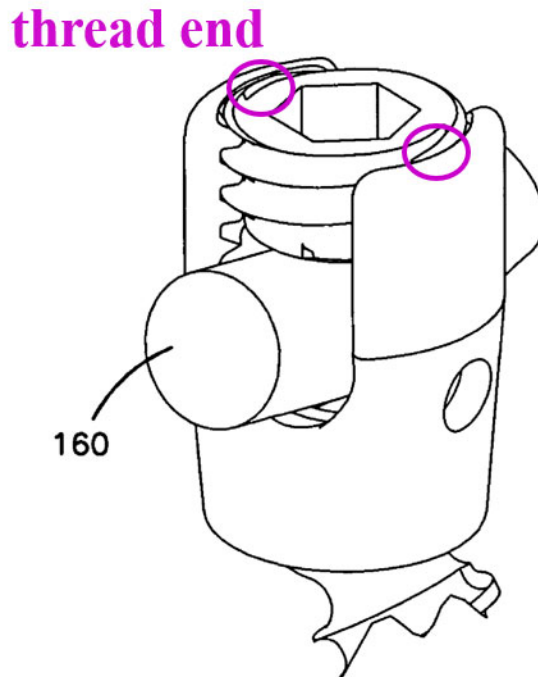
EX1006, Fig. 15

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). EX1007, Fig. 7.



EX1007, Fig. 7

62. 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 have understood that diametrically opposed thread ends are the result of diametrically opposed thread starts. EX1006, Fig. 7.



EX1006, Fig. 7

Therefore, in my opinion, Boschert discloses 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.

63. A POSA would further have understood that for double start threads on the setscrew to engage with the symmetrical, diametrically opposed receiver threads, (1) the receiver threads would necessarily have to mirror each other, and (2) the start and end structures would necessarily be spread equidistant around their respective ends. This understanding 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* ¶¶ 55-62. Further, diametrically opposed thread starts would have been the obvious choice when threading a dual start closure under the threads of two symmetrical, diametrically opposed receiver arms. Specifically, a POSA would have understood that each of the thread starts on the closure top would be designed to simultaneously thread under the corresponding threads at the edge of each diametrically opposed receiver arm. This can only be accomplished by diametrically opposing the thread starts on the closure top.

64. 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

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



Tapered Start



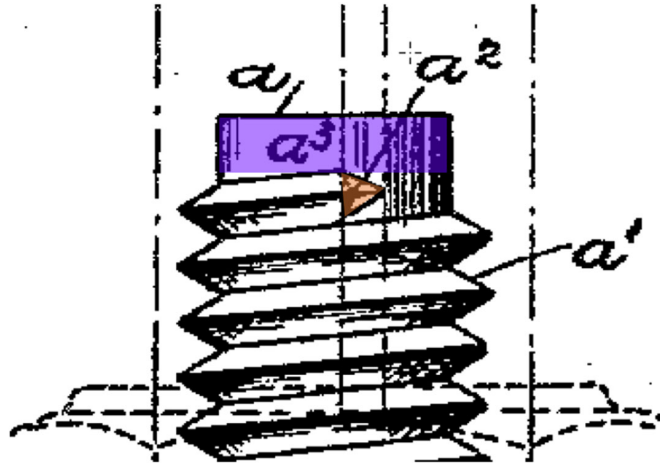
Truncated Start

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 left 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.

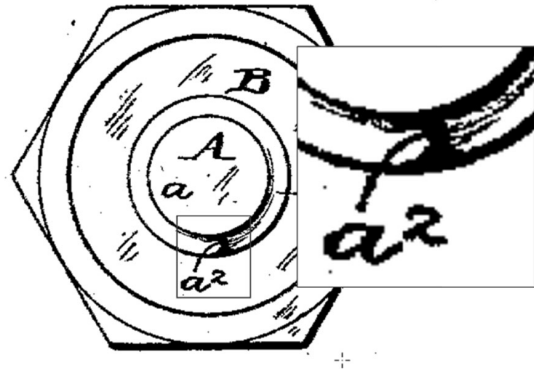
66. U.S. Patent No. 447,775 to Higbee ("Higbee") (EX1015), entitled "Screw bolt and nut," issued in 1891 and disclosed a thread-start cut that is known today as the Higbee cut. Higbee noted that an issue in prior-art thread starts was that, "[i]n threaded couplings of the kind described the thread is 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.

67. Higbee disclosed that, in its figures, “A is the bolt, a its end, a' its thread, and a^2 the thread end.” *Id.*, 1:67-68. 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.*, 1:77-80. “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.* 1:83-88. 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).



68. 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.*, 1:88-94.



The rounded thread end a^2 is shown in enlarged Figure 6 at right.

69. 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):

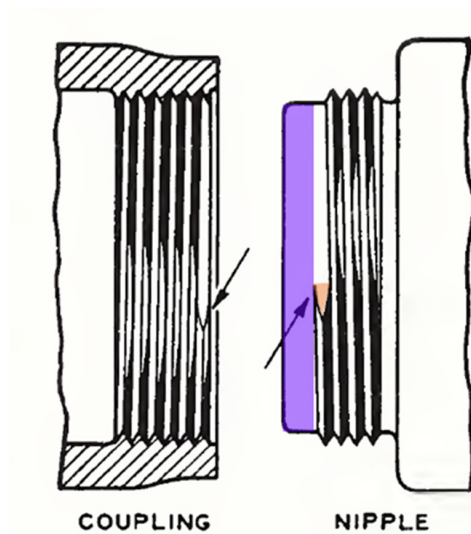


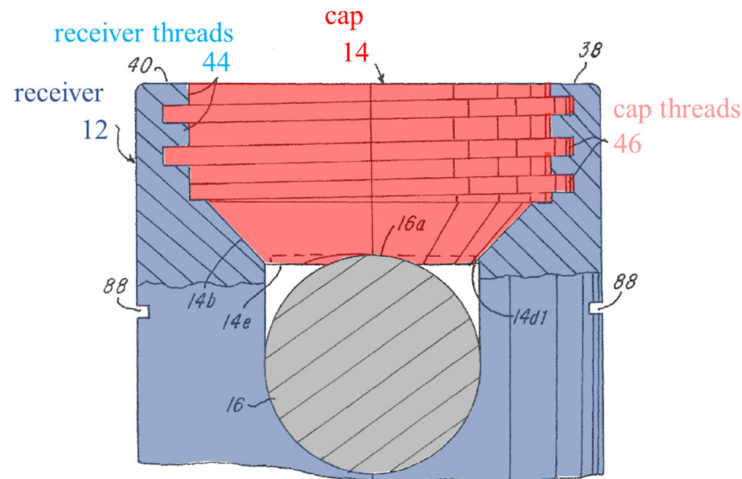
FIGURE 1.1. *Blunt start*

EX1204 at 1.04. This depiction also clearly shows the smooth extension of the nipple (shown in purple) extending below the thread start to facilitate alignment, as was taught by Higbee.

70. 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 '646 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.” EX1007,

Abstract. Kirschman disclosed that, while the “purpose of the threaded locking cap is to affix a spinal stabilizing element,” *id.*, ¶[0004], the “threads of the locking cap and tulip must bear high torque loading which can result in cross-threading and/or thread failure upon initial thread engagement,” *id.*, ¶[0005], and 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].

71. In response to this need, Kirschman disclosed truncated thread starts on the closure top of polyaxial screws with some additional features. 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. the 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 structure), 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.*, ¶[0039]. As shown below in annotated Figures 3 and 4, Kirschman shows the truncated, curved end of the cap thread, highlighted in orange below. *Id.*, Figs. 3-4.

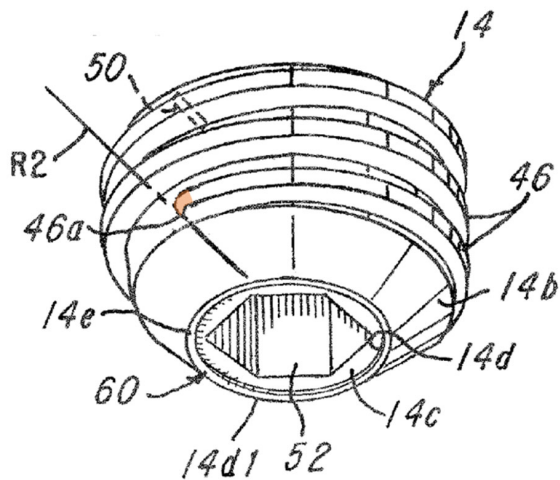


Fig. 3

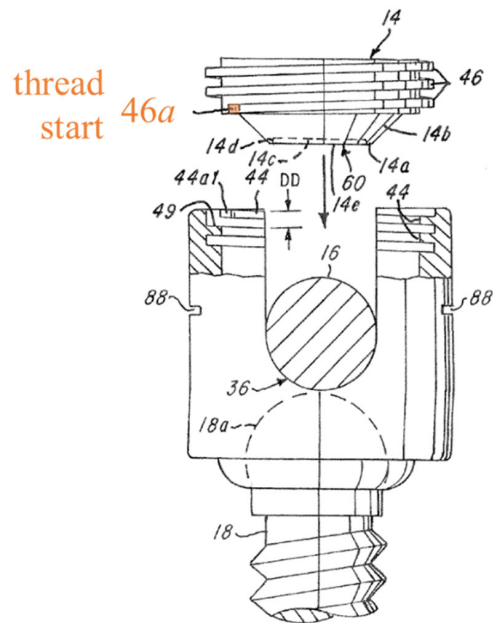
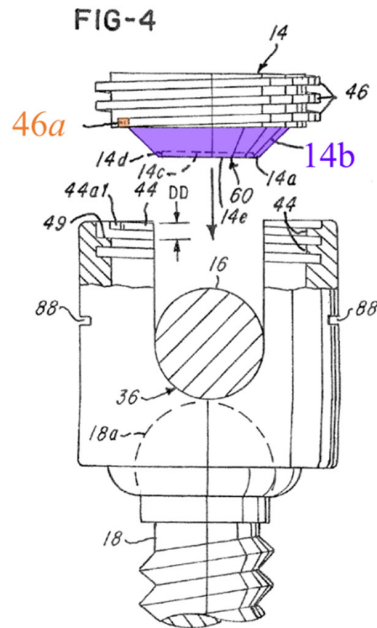


Fig. 4

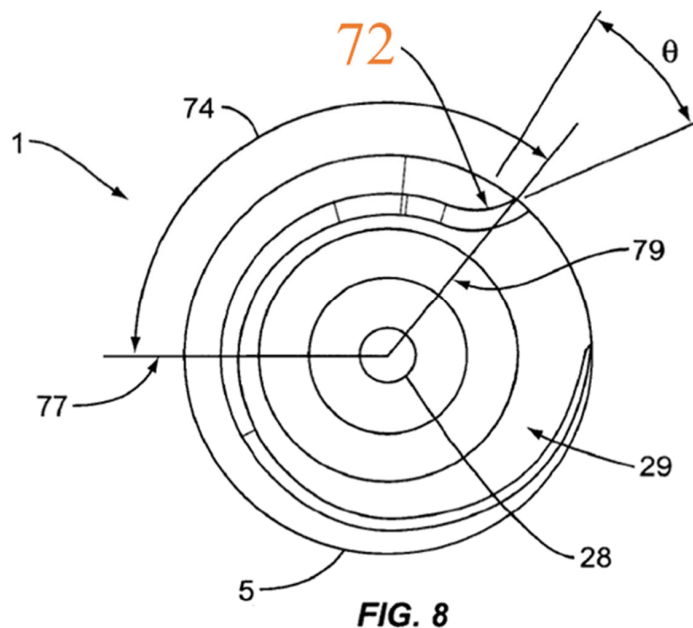
EX1007

72. As shown in annotated Fig. 4 below, by truncating the thread, as was previously taught by Higbee, Kirschman also left a segment 14b of unthreaded surface on the closure top 14, below the thread start 46a. *Id.*, Fig. 4.



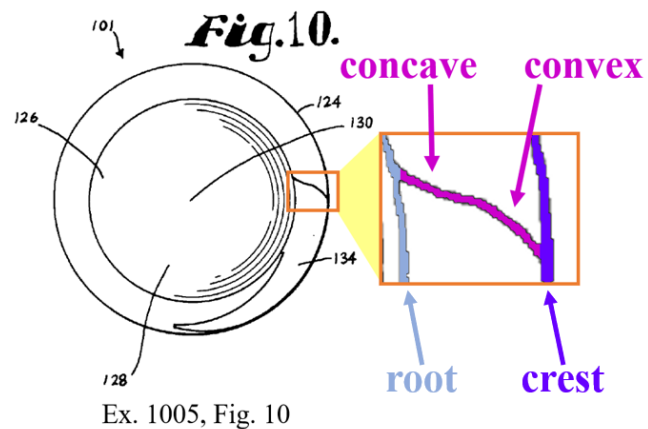
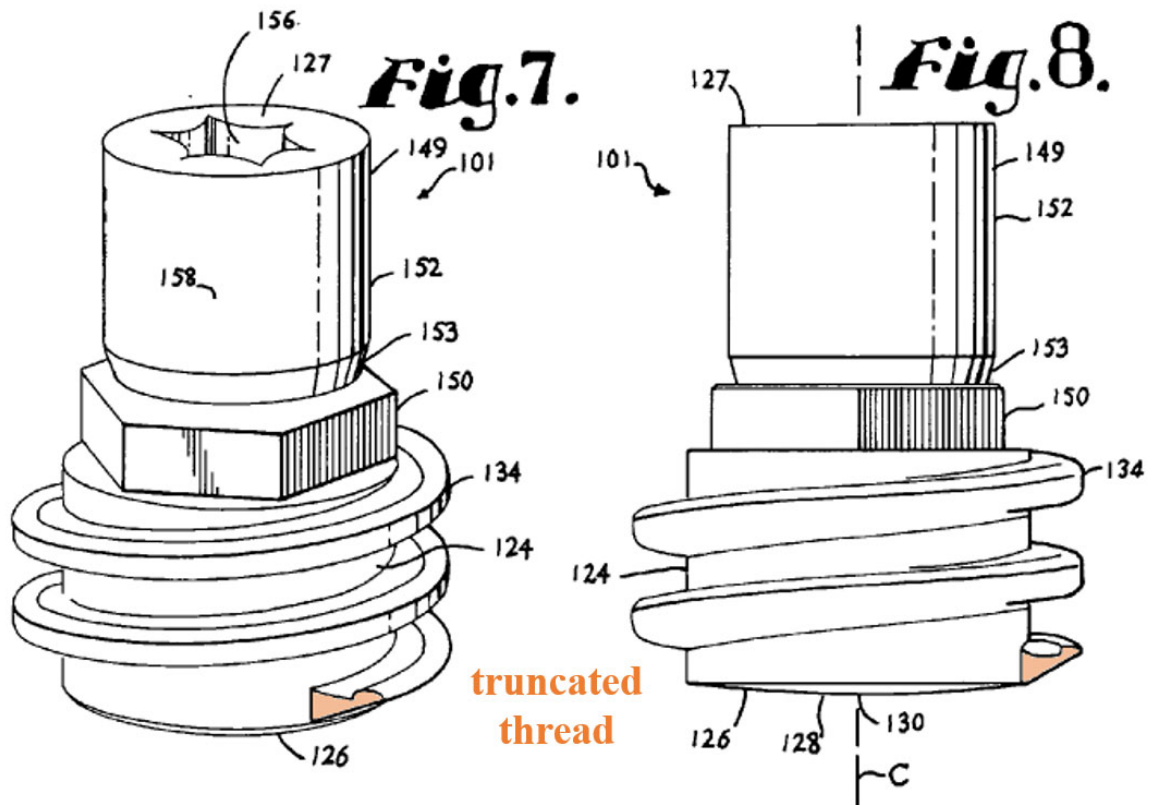
In the preferred embodiment, this segment is frusto-conical, but Kirschman describes that “it should be understood that the surface shape could be any suitable shape adapted to guide the cap 14 into the bore 22 and onto the receiver 12.” *Id.*, ¶[0043]. Thus, Kirschman notes that this unthreaded segment provides an advantage because it “engages and guides the cap 14 as it engages the second arcuate wall threads 44 in the receiver 12 and guides the cap 14 into alignment for threading in the receiver 12.” *Id.*, ¶[0049]. As evidenced by Kirschman’s identification of the 1891 patent to Higbee (U.S. Patent No. 447,775) 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. EX1007, ¶[0009].

73. Another example of prior art recognizing the advantage of truncated leading edge is Patent Application Pub. No. 2011/0106179 to Prevost (“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].



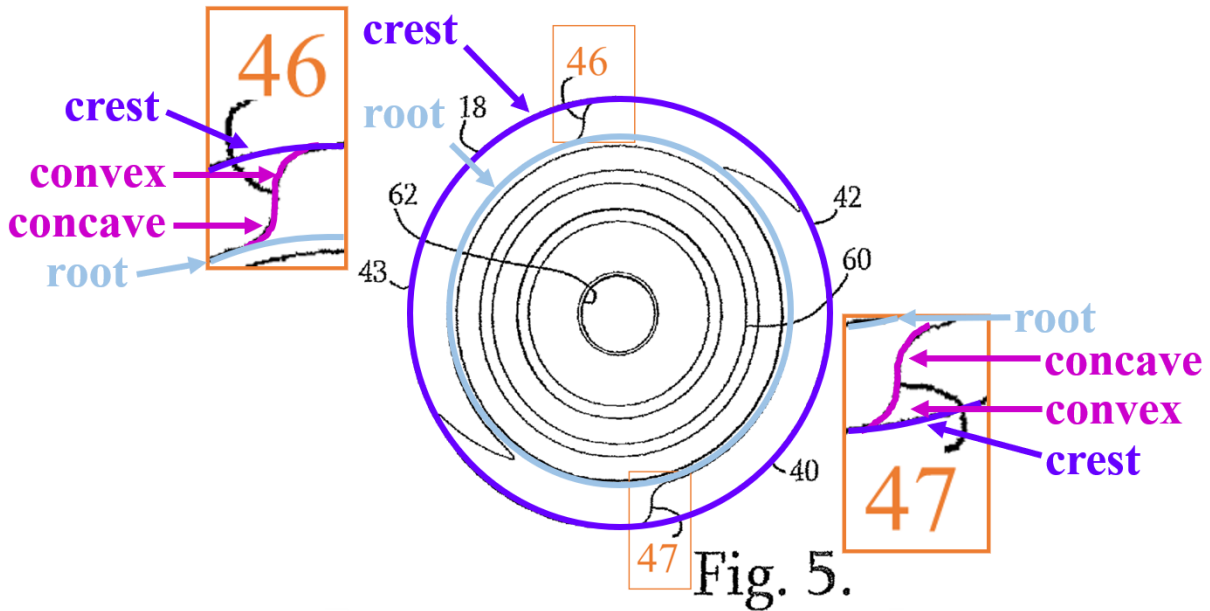
Prevost disclosed the advantages of the truncation of the leading edge of the screw thread and shows the curvate (curved) leading edge 72 shown on his Figure 8. *Id.* Prevost also describes set screws with heads designed to break off at designated torques and different thread types. *Id.*, ¶¶[0005], [0030].

74. 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 breakoff 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, 8, 10.



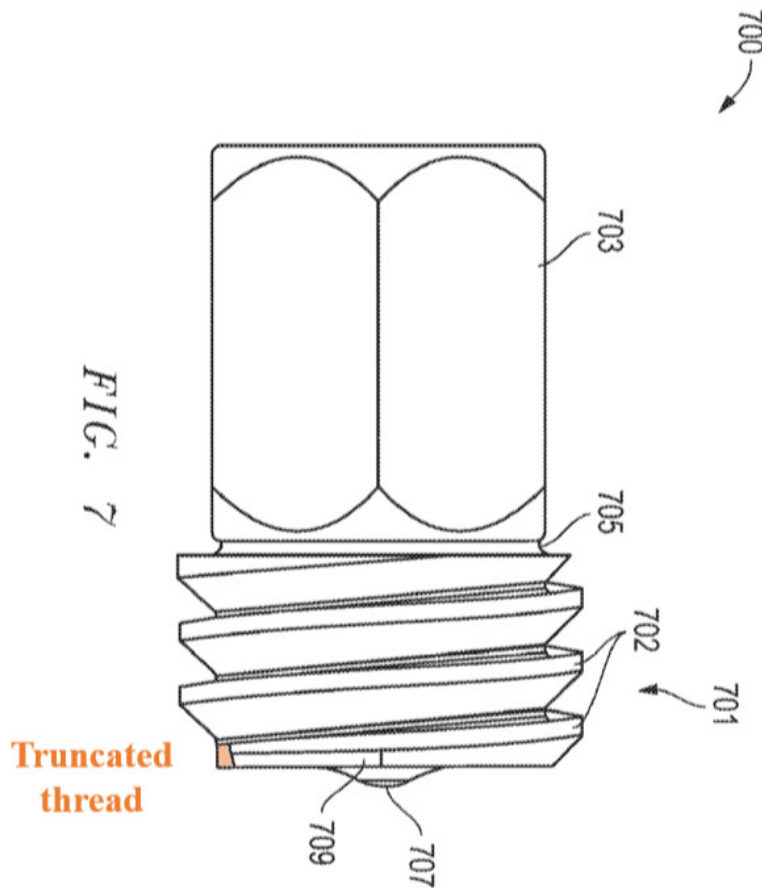
As shown in annotated Figure 5 below, this is quite similar to the concave segment near the thread root and convex segment near the thread crest of thread faces 46

and 47 shown in Figure 5 of the '646 Patent, which is “a reduced bottom plan view of the closure of FIG. 1.” EX1001, 3:55-56, Fig. 5.



75. As a further example, U.S. Patent Application Publication No. 2010/0137918 to Wilcox et al. (“Wilcox”) (EX1012), which published on June 3, 2010, discloses a “method for 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 “couple[e] the rod within the receiving portion.” EX1012, ¶[0010]. As shown below in annotated Figure 7, Wilcox discloses that its set screw has a threaded portion 701 that “includes a Higbee-style truncation 709 of the initial thread 702 which facilitates easier threading of the set screw 700 within the head portion 307. The Higbee-

style truncation 709 is manufactured such that the leading razor edge of the thread is removed.” *Id.*, ¶[0050].



76. 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, a curvate leading face for a thread, and a leading face spaced above the bottom of the closure 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

77. 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 the crest of a thread 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 that the root of a thread 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.

78. Before January 10, 2012, a POSA would have understood that there were several ways to manufacture threads, including thread cutting, thread milling, thread grinding, 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 cylindrical metal rod. To form a thread, a POSA would have understood that a tool cuts or grinds grooves into the cylinder, based on desired thread parameters, to form ridges that comprise the thread. The result of this process would most often be the formation of thread that continues to the bottom of the original cylinder. Due to the way that threads are created, the bottom end of the threading would be relatively thin and sharp.

79. 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, breaking, or cross-threading as taught by Higbee. 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.

80. 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 Pub. No. 2005/0286984 to Weise (EX1013), ¶¶[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.

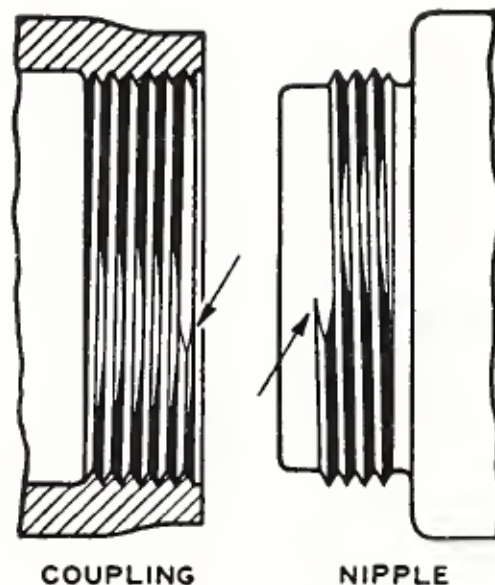


FIGURE 1.1. *Blunt start*

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. EX1013, ¶[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.

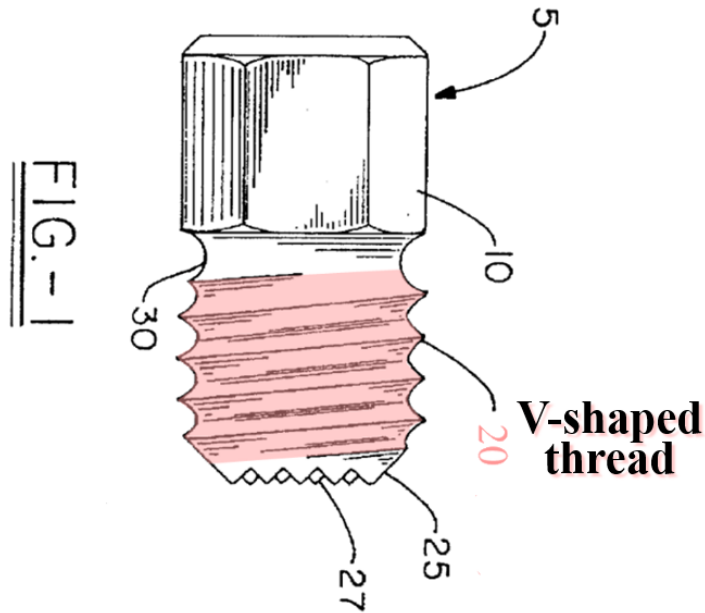
81. As discussed above, before January 10, 2012, a POSA would have understood the benefit of avoiding a thread leading face that is sharp or pointed. A POSA would also have understood that, if the groove tool exits the thread in such a way that the leading face is only concave, the result would be a sharp or pointed edge of the thread adjacent the crest of the thread. 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

82. As the '646 Patent admits, before January 10, 2012, “[*k*]nown *closures include* ... a variety of single start helically wound guide and advancement structures, including, for example, *thread forms having v-thread, reverse-angle buttress or square thread forms*, to name a few, as well as other non-threadlike helically wound forms.” EX1001, 1:64-2:4.

83. 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.



84. While V-shaped threads were the oldest thread configuration, a number of alternative thread designs were also well known well-before the '646 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 rearward surface [52], or pressure angle is negative.” *Id.*, 2:48-51; *id.*, 4:43-5:13, Fig. 3.

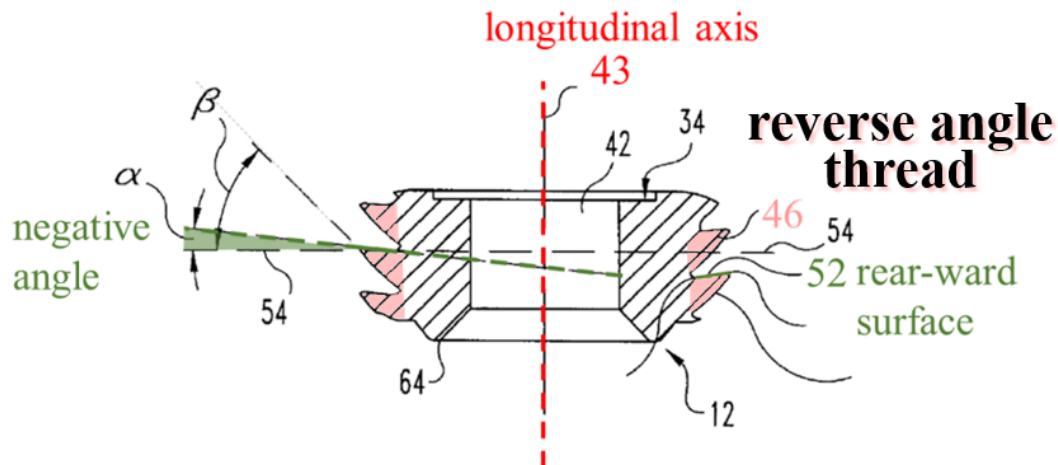
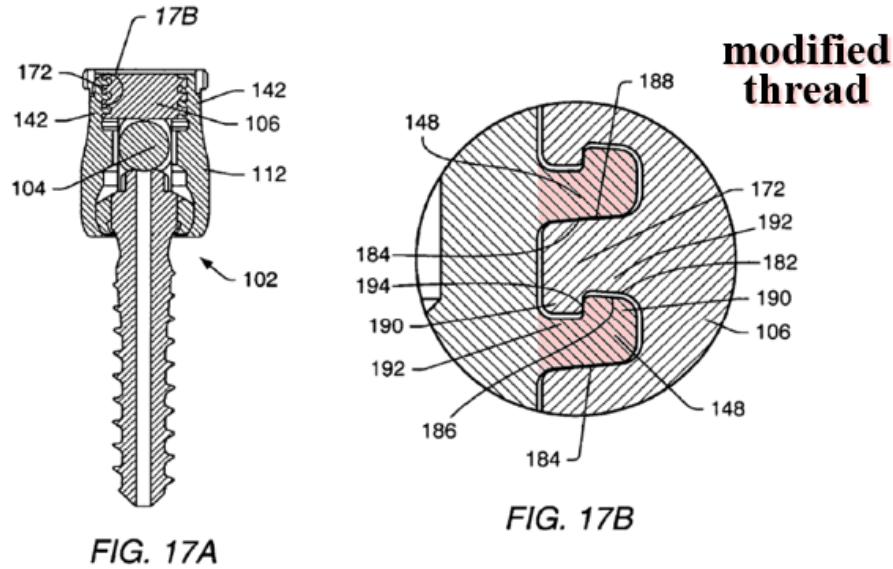


Fig. 3

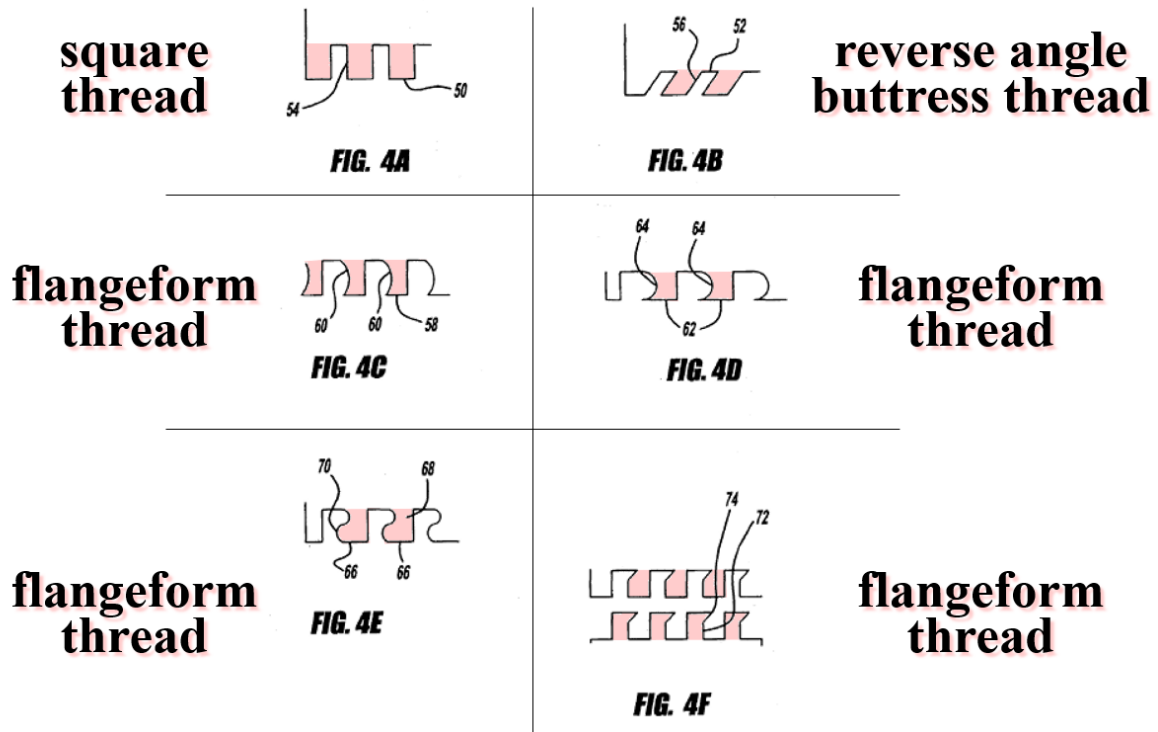
EX1016, Fig. 3. Specifically, Morrison teaches that the “pressure angle is between -1 and -40 degrees. In a currently more-preferred embodiment, the pressure angle is -5 degrees.” *Id.*, 2:53-56. In such a configuration, “*splaying* of the medical device is *prevented*.” *Id.*, 2:60-62.

85. Alternatively, helical flange threads 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). Landy discloses various “modified threads” for use on a closure top. EX1019, 17:22-36. As shown in Figure 17A and annotated Figure 17 B below, these modified threads have “[r]aised portions 190 and recessed portions 192 ... on male distal surface 182 and female proximal surface 186. Cooperating surfaces 194 of modified threads 172 and 148 may contact or be proximate to one another during use.” *Id.*, 17:38-41. “Engagement of cooperating surfaces 194 may *inhibit spreading of arms 142 away from each other*.” *Id.* 17:45-47.



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

86. 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 thread types for spinal implant set screws, including square threads (Fig. 4A), reverse angle buttress threads (Fig. 4B), and a variety of flange form threads that provide a “gripping function” (Figs. 4C-F). EX1021, ¶¶[0028]-[0029].)



87. Jackson himself acknowledged that all of these alternative thread types were well-known in the prior art in his own prior art publications. *See, e.g.*, 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.”); U.S. Patent Application Publication No. 2010/0312287 to Jackson (EX1032), ¶[0151] (“However, it is foreseen that the guide and advancement structure 162 could

alternatively be *a buttress thread, a square thread, a reverse angle thread or thread like or non-thread like helically wound advancement structures* for operably guiding under rotation and advancing the closure 30 downward between the arms 152[.]”). Thus, each of these known thread types had known advantages, and a POSA would have been readily able to choose between these conventional thread types for any given application.

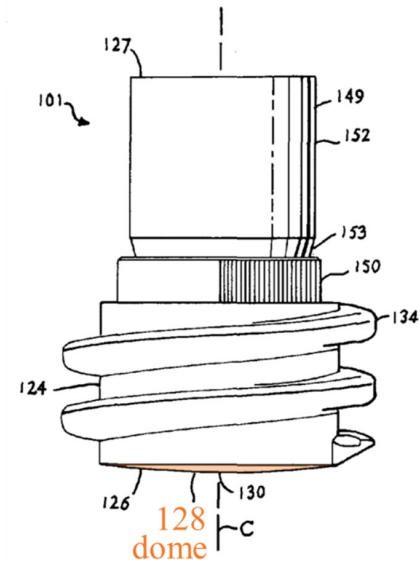
2. Other Aspects of Spinal Implant Design

88. 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 design options related to the shape of closure top bottoms, the use of breakoff closure tops, and the use of breakoff receiver arm extensions.

a. Closure Bottoms

89. Before January 10, 2012, various design options for closure top (i.e. set screw) bottoms were well-known. It was known that different design options for the closure top bottom surface had certain advantages. Among the most commonly known choices for closure top bottoms were domed bottoms, flat bottoms, pointed bottoms, and bottoms that included a downwardly projecting rim. Each of these options provided alternative ways for a POSA to facilitate engagement of the closure top's bottom surface with a stabilizing rod.

90. As one example, the '477 Publication disclosed a closure top bottom surface that may include “a convex shaped region or dome 128 that projects outwardly from the body 124 along the axis B (downwardly in FIG. 8) and has an apex 130 where the dome 128 intersects the axis B” or “may be flat and may have a central point and a lateral rim.” EX1005, ¶[0040]. The '477 Publication illustrates the domed bottom surface, for example in annotated Fig. 8 below, but does not include a figure showing the disclosed rimmed alternative.



EX1005, Fig. 8

91. As a further example, Boschert discloses that the bottom of the closure top “may include a curved bottom surface 71,” EX1006 7:16-17, or a “flat bottom surface 171 for contacting the rod 60 when the rod is clamped within the device 110,” *id.*, 7:40-43. These known alternatives are illustrated in annotated Figs. 3 and 15 respectively below.

EX1006

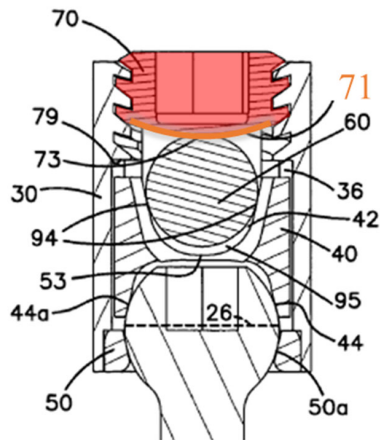


Fig. 3

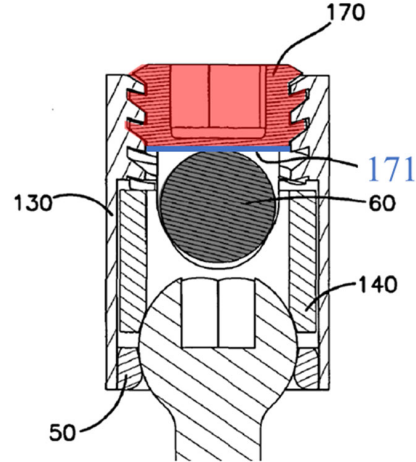
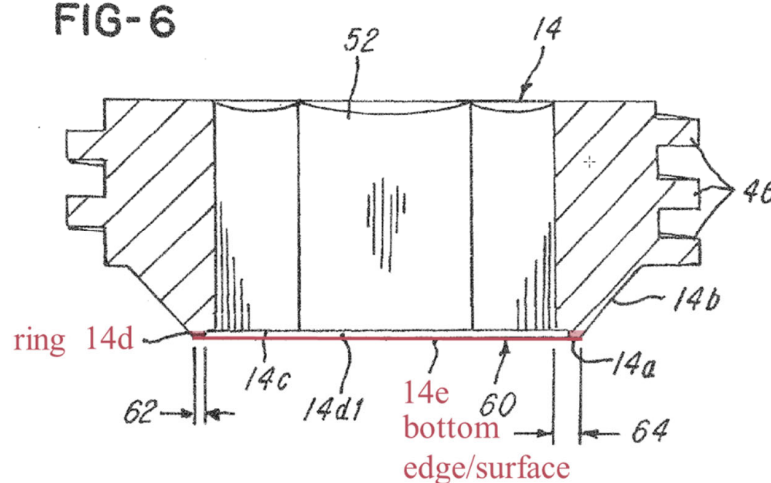


Fig. 15

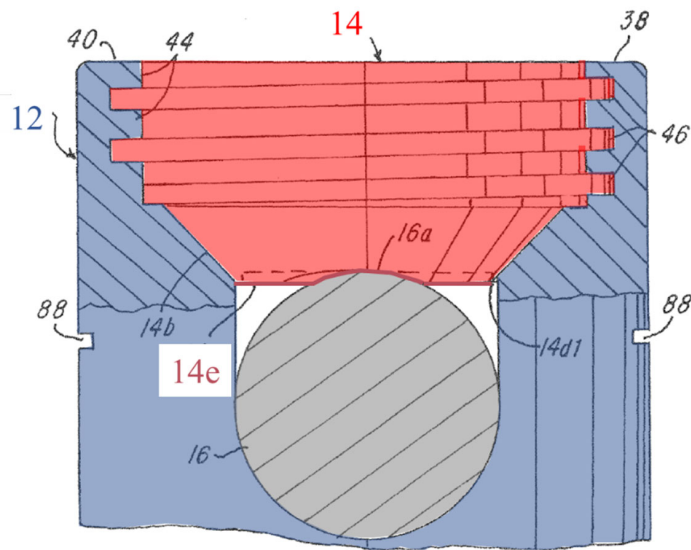
92. As an additional example, Kirschman disclosed a closure top (cap 14) with a downwardly projecting ring. As shown in annotated Figure 6 below, Kirschman disclosed a cap 14 that includes a flat “end 14c” and “comprises a deformable area 60 that is adapted to provide the lock aid. In the illustration being described, the deformable area 60 comprises a deformable ring 14d that is monolithically and integrally formed with the cap 14, as best illustrated in FIG. 6.”

EX1007, ¶¶[0044], [0045], Fig. 6.

FIG-6

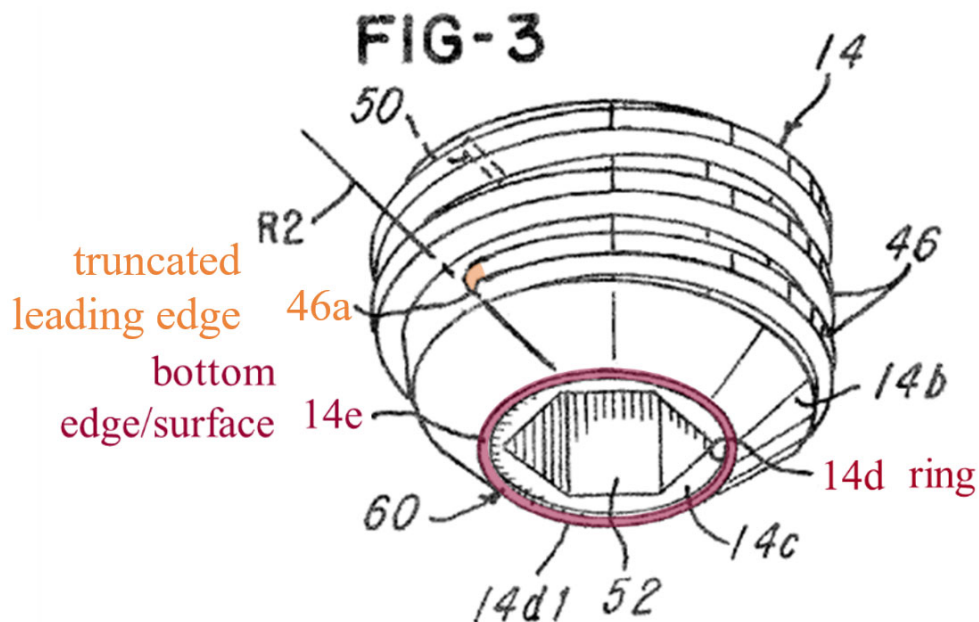


Kirschman further disclosed that “the cap 14 is received on the receiver 12 and screwed into the receiver 12 until a bottom edge or surface 14e engages the rod 16.” *Id.*, ¶[0045]. As shown in annotated Figure 7 below, “[t]he deformable ring 14d and the deformable area 60 deforms about the rod 16 as the cap 14 is screwed into the receiver 12 and as it compresses against the rod 16 as illustrated in FIGS. 2 and 7.” *Id.*, Fig. 7. This “provides a friction engagement and causes the surfaces to become cold-welded in the illustration.” *Id.*, ¶[0045], Figs. 2, 7.



Id., Fig. 7.

93. As further seen above and in annotated Figure 3, below, Kirschman discloses that the thread of the cap 14 starts at 46a, above the bottom surface/edge 14e and above the disclosed ring 4d. *Id.*, Fig. 3.



94. As yet another example, U.S. Patent Pub. No. 2004/0167526 to Jackson (“the ’526 Publication”) (EX1020) similarly discloses a downwardly

projecting ring with a flat bottom surface. As shown in annotated

Figure 9 (right), the ’526 Publication states that “to more positively secure

the rod 10 within the head 16 of the bone screw 8, the closure 4 is

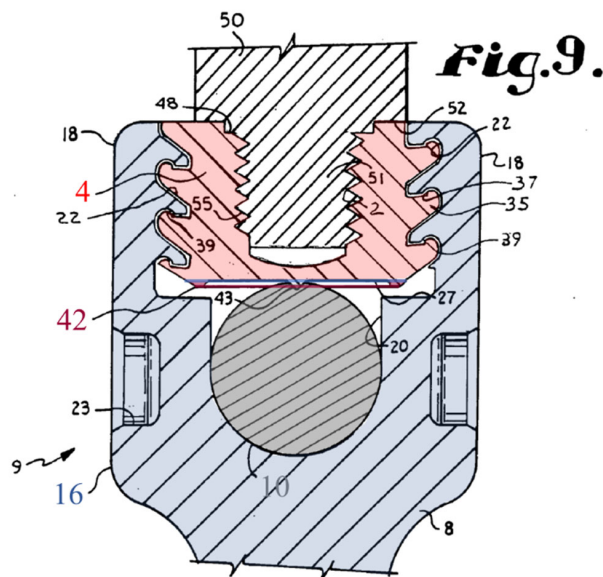
provided with a penetrating structure such as a V-ring 42 and an axially

aligned point 43 on the inner or forward end 27 thereof. The V-ring 42 cuts into

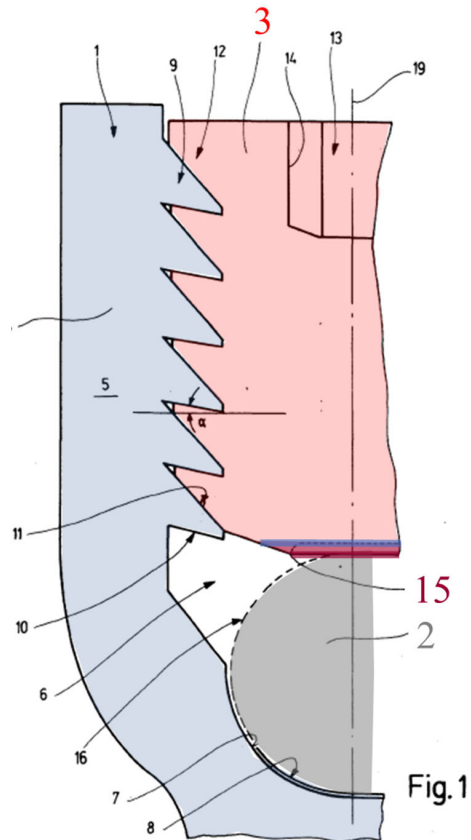
the surface of the rod 10 when the body 4 is tightly torqued into the head 16. The

V-ring 42 extends about a periphery of the inner end 17 of the body 4 and, thus, provides two possible areas of engagement between the body 4 and the rod 10.”

EX1020 ¶[0057]; *id.* Fig. 9. The disclosed V-ring 42 extends from the flat bottom surface and also has a flat surface as its lowermost surface.



95. As still another example, German Patent No. 29810798 to Schafer (EX1018) (“Schafer”), was filed on June 17, 1998, and published on October 28, 1999. Schafer is directed to a closure top used to secure a rod within the U-shaped channel located between the spaced arms on the head of a bone screw. EX1018, Fig. 1. As shown in annotated Fig. 1 (right), Schafer’s setscrew 3 includes “an annular cutting edge 15 which digs into the surface of the support rod 2 when tightening the setscrew 3 and thus additionally secures the support rod 2.” *Id.*, 9:9-12.



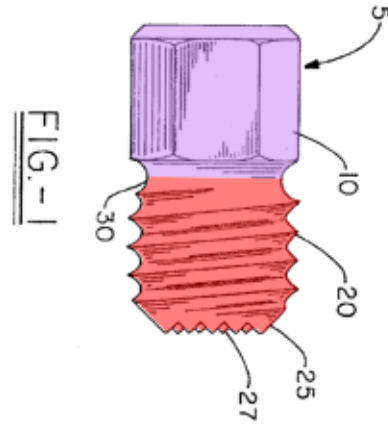
96. Thus, before January 10, 2012, a POSA was aware of closure top bottoms that were flat and included downwardly projecting rims with flat bottom surfaces for engaging with the rod. Moreover, the known rims and rim bottom surfaces were generally located below the thread starts, as shown in the exemplary figures above.

b. Breakoff Closure Tops

97. Before January 10, 2012, multiple structures for engaging and torquing a closure top were well known. Of course, inset recesses were known for engaging screwdriver heads of various shapes and sizes, but it was also a well-known option to have an external driving structure equivalent to the head of a bolt. One known advantage of an external drive structure is that such a structure could be built to breakoff at a predetermined torque, thereby ensuring that the closure top would be tightened to the desired level, but not over torqued, when it was installed. *See* EX1027, 2:34-39; EX1016, 4:4-17. Another known advantage of a breakoff head in a spinal implant was that it allowed the use of a low profile device that would increase patient safety. EX1027, 1:36-40 (“[I]t is also an object to provide a design which is as small as possible to provide *minimal disruption* to the biological environment.”); *see also id.*, 3:15-19 (“[T]he necked area 30 is intended to shear evenly, i.e., in a way which will prevent an uneven break which could inhibit the insertion of a removal tool into the set screw or leave a jagged surface which could cause irritation to the patient.”).

98. Mellinger '929 is one example of a known breakoff top. See EX1027.

As shown in annotated Figure 1 (right), Mellinger '929 disclosed a “set screw” that included a “necked area 30” that “joins the external torque head to the threaded screw portion of the set screw.” *Id.*, Abstract; *id.*, Fig.



1. Mellinger '929 further disclosed that the “necked portion has a cross-sectional thickness

and strength to provide for shearing at a predetermined load limit, such as from about 54 to about 64 pounds per inch.” *Id.*; see also *id.*, 1:5-8 (“The invention relates generally to set screws for use with spinal implant systems, and more particularly to a set screw having a head for the external application of torque which will shear at a predetermined load”); *id.*, 2:19-22 (“A set screw 5 in accordance with the invention is shown in FIG. 1 having a first externally threaded screw portion 20 and an axially aligned external torque or tightening head 10 joined to the screw portion 20 by a neck shearing area 30.”); *id.*, 2:34-39 (“The external torque head or tightening head 10 is dimensioned so as to transmit a predetermined torque level, i.e., more than about 45 or 50 inch-pounds and preferably 55 to 65 inch-pounds. The amount of torque which can be applied to the head prior to shearing will depend on the material as well as the cross-sectional

area of the neck.”); *id.*, 3:6-15 (“In accordance with the invention, a torque-limiting area 30 is provided to limit the application of tightening torque in order to protect the threaded area 20. More specifically, the torque-limiting area 30 comprises a necked portion having a longitudinal length of about 0.03 to about 0.05 inch and having a groove or radiused area which is designed to cause the torque applicator head 10 to shear at a predetermined load which is between 50 and 70 inch-pounds, preferably from 54 to 64 inch-pounds, in order to eliminate the need for a torque wrench to measure the tightening.”); *id.*, Figs.1, 4-5, cls. 1-2, 9-10, 12, 15-18.

99. Morrison issued on October 2, 2001, and also disclosed a closure member 12 that “includes a break-off section 32 and a screw section 34.” EX1016, 3:64-67, Fig. 4. As shown in annotated Figure 4 below, Morrison disclosed that “closure member 12 is threadedly engaged with receiving member 11 to a point at which further threaded progression is impeded, as for example when the screw section 34 contacts an object within the channel 16, such as rod R seated against wall 24. As further torque is applied to break-off screw closure member 12, as with an [sic] hexagonal driving tool inserted into hole 40, eventually the stress on the neck portion 38 is great enough to cause the upper section 36 *to break off from* screw section 34 at neck portion 38.” *Id.*, 4:4-17; *see also id.*, 4:18-22, Figs. 1, 3-4, 5-6C, cls. 10, 14, 31.

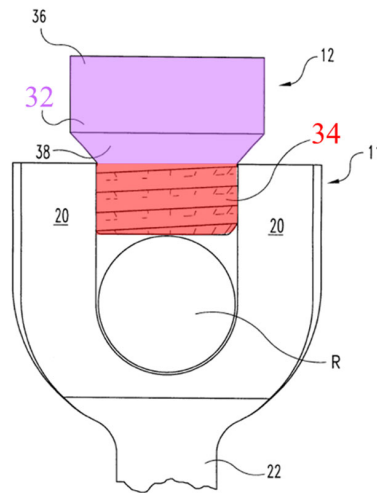
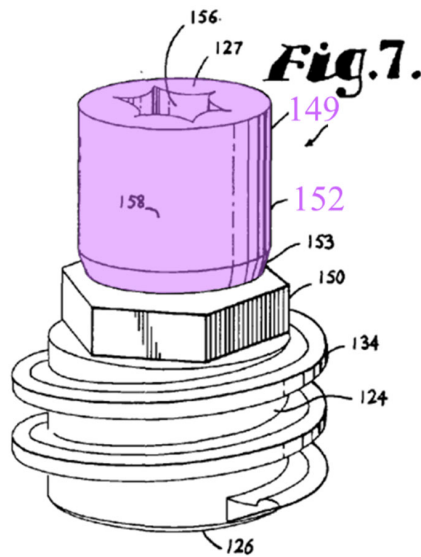


Fig. 4

100. The '477 Publication provides yet another example of a known breakoff top. Specifically, as shown below in annotated Figure 7, the '477 Publication states that “closure 101 also includes a driving or installation break-off head 149 and a removal head 150 that are coaxially attached to the body 124.” EX1005 ¶[0042]; *id.* Fig. 7. In addition, the “driving head 149 is disposed on a break-off portion 152 that is secured to the body 124 at a breakaway region 153 adjacent the removal head 150 and is designed to break away from the remainder of the closure 101 subsequent to a predetermined torque being applied to the driving head.” *Id.*



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

102. The choice to use breakoff heads on set screws or to use non-breakoff heads was independent of whether breakoff receiver arm extensions are used on the pedicle screws, whether a dual start or single start thread is used, what type of thread is used, or what shape of closure top bottom is used.

c. Break-Off Receiver Arm Extensions

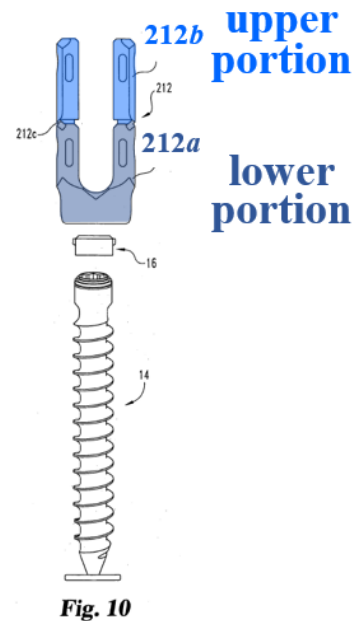
103. Surgeons generally use the smallest incision consistent with the desired access. Especially in certain patients, such as obese patients, attempting to place a small spinal implant by hand deep into the patient through a minimal incision would not be advisable. Accordingly, as discussed further below, before

January 10, 2012, there were well-known designs for facilitating the implantation of spinal implant devices from outside the patient's body through a small incision in the patient.

104. Before January 10, 2012, it was well-known that breakoff extensions could be used in spinal implant devices to facilitate the implantation of spinal implant devices from outside the patient's body through a small incision in the patient. 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. 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

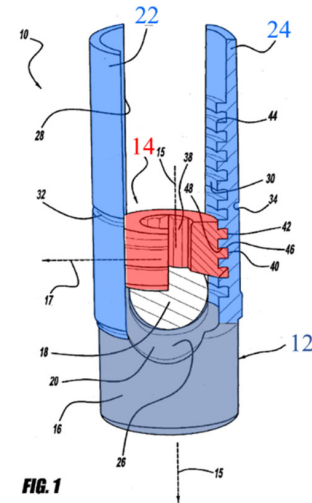
rod and the closure top, to remain in the patient's body. Some examples of these well-known breakoff extensions in the prior art are discussed below.

105. For example, Johnson discloses breakoff extension receiver arms. In particular, as shown in the annotated Figure 10, a receiver member 212 “has a lower portion 212a and an upper portion 212b separated by a thinned section 212c.” EX1008, ¶[0051]. Johnson discloses that the “[t]hinned section 212c” “separates upper portion 212b and

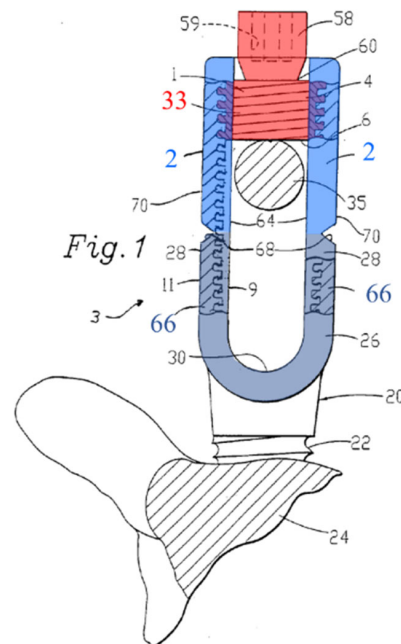


lower portion 212a.” *Id.*, ¶[0054]. The thinned section 212c “includes an external indentation or groove 260, which may include score lines or other fracture-inducing or fracture-enabling features.” *Id.* Johnson discloses that “[a]n interior indentation 261 is also provided.” *Id.* Johnson discloses 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.*

106. Raynor similarly discloses 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].



107. As shown in the annotated Figure 1 at right, in 2006 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.

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

109. 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, the shape of the bottom of the set screw, whether the leading edge of the thread is truncated, or whether a single or double thread start is used.

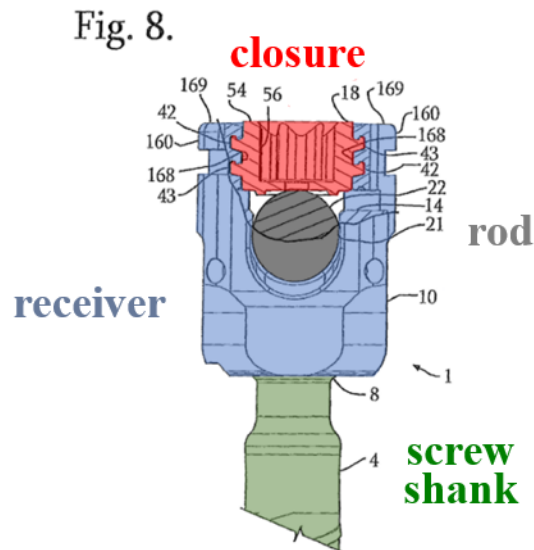
VII. THE '646 PATENT

A. Overview

110. The '646 Patent is entitled “Medical Implant Threaded Plug Having A Start Structure With Symmetrically Shaped Concave and Convex Leading Surfaces” and names Roger P. Jackson as the inventor. EX1001 at 1. The '646 Patent issued on September 28, 2021. *Id.*

111. The '646 Patent claims priority to two provisional applications, the earliest of which was filed on January 10, 2012. *Id.*, 1:9-23. I therefore presume January 10, 2012, to be the effective filing date of the '646 Patent.

112. The '646 Patent appears to have been drafted under the mistaken assumption that using dual-start threads on a closure top was a new idea. The patent acknowledges that bone screws and closure tops were well known in the prior art, stating that “[b]one anchors, such as bone screws ... are utilized in many types of spinal surgery in order to secure various implants to vertebrae along the spinal column of the purpose of stabilizing and/or adjusting spinal alignment.” *Id.*, 1:32-35. The specification further states that “open-ended bone anchors are known,” *id.*, 1:39-40, 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.*, 1:54-58. This U-shaped channel is “closed by a closure member after the rod or other longitudinal connecting member is placed in the channel.” *Id.*, 1:61-65. The specification 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.*, 1:64-2:4. These known components are highlighted below in annotated Fig. 8.



113. The patent then identifies the problem to be addressed as follows: “when the closure is a cylindrical plug having a single start helically wound guide and advancement structure, such structure must be aligned with mating structure on of the implant arms and the rotated until a portion of the structure is captured by mating guide and advancement structure on both arms of the implant, all the while the closure is being pressed down on the rod while other forces are pushing and pulling the rod back out of the implant.” *Id.*, 2:17-27. The specification then 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 and mating helical form on a respective open implant arm.” *Id.*, 2:47-51.

114. The '646 Patent does not describe any inventive significance to the leading face of the closure top 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. The '646 Patent also does not discuss the start of the thread face of closures or set screws in any prior art. 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.

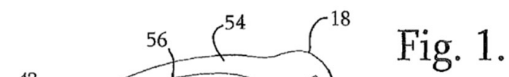


Fig. 1.

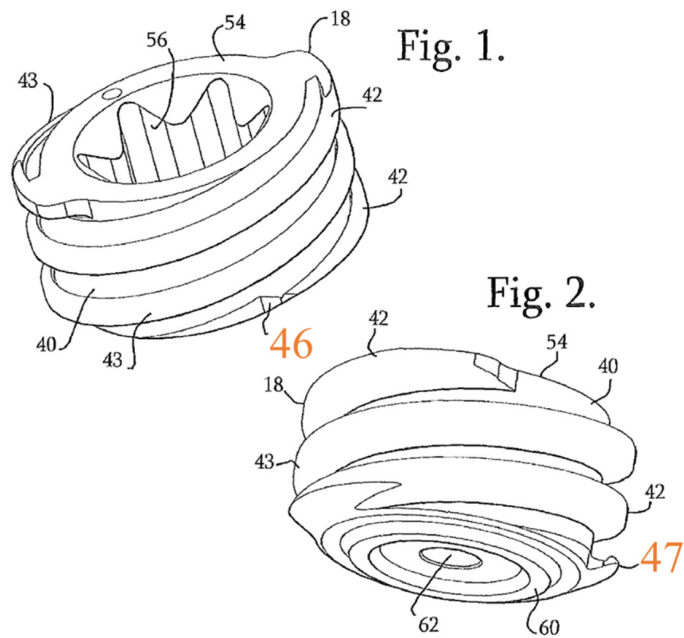


Fig. 2.

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

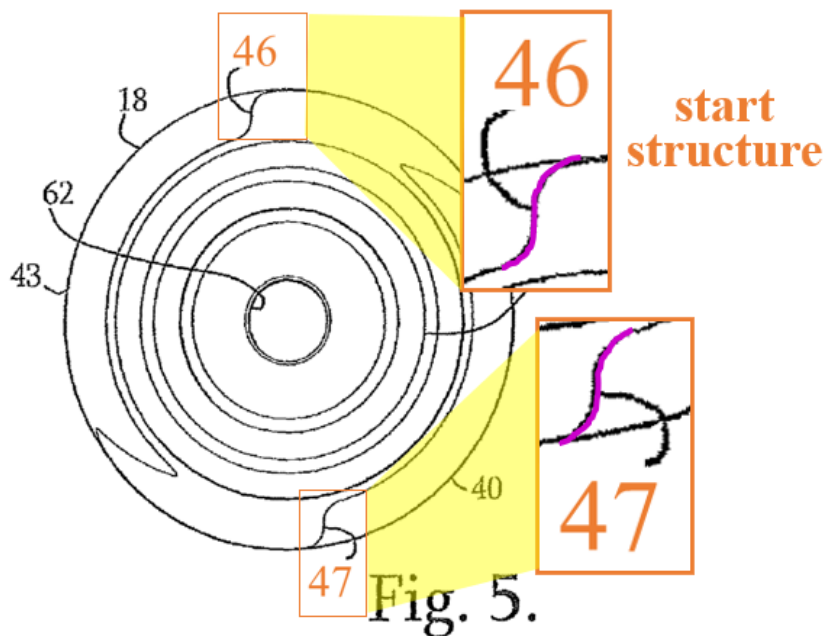
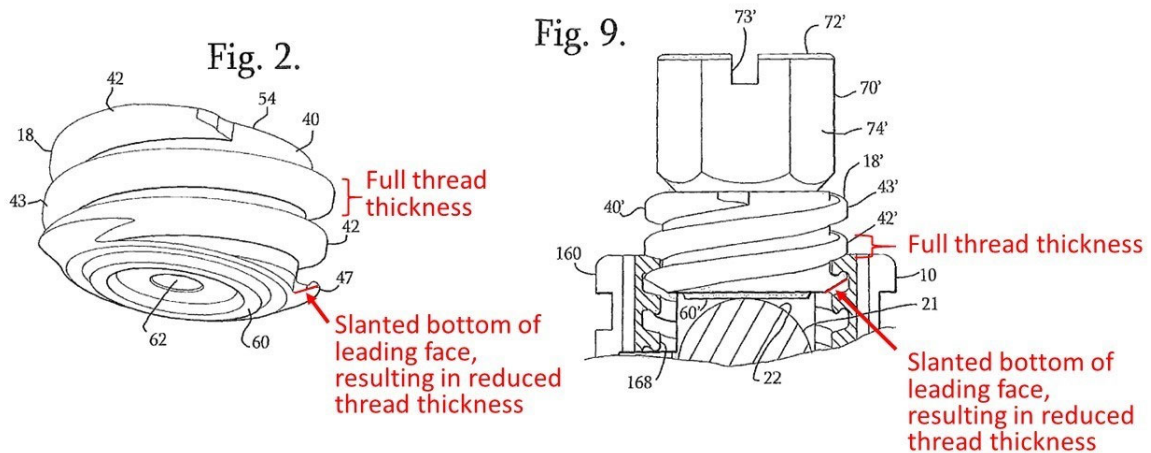
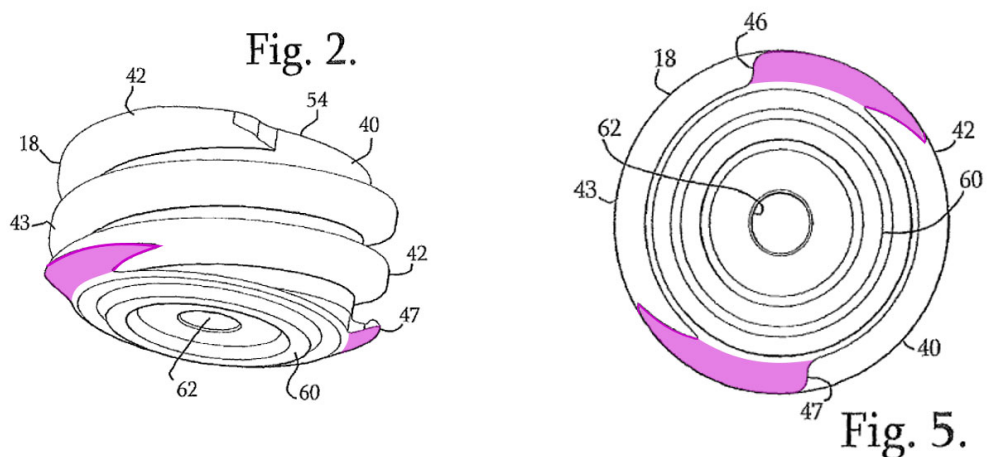


Fig. 5.

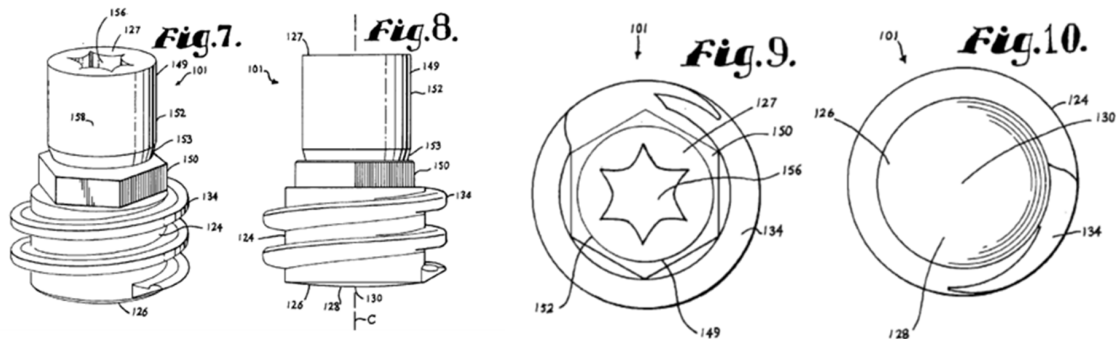
115. The '646 Patent never discusses any beveling at the bottom of the thread start structure. In fact, the term “bevel” never appears in the '646 Patent's specification. The figures offer little guidance. The figures show that the thickness of the thread at the start structure is less than the full thickness of the thread, at least because the bottom outside corner of the thread has been cut off at a slanted angle, as shown in Figs. 2 and 9.



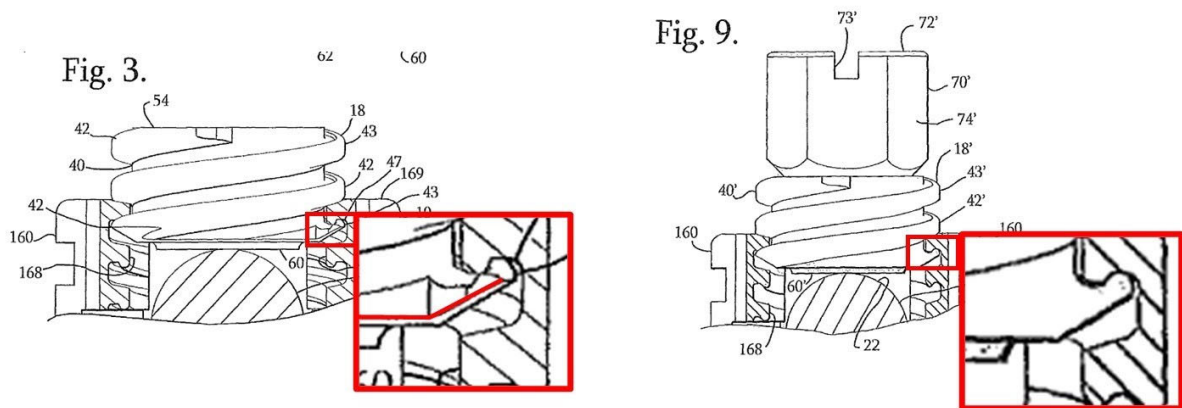
Figs. 2 and 5 also show the point at which the thread reaches its full thickness, shown below and highlighted in magenta.



Very similar drawings of the bottom of set screws showing truncated and curved leading faces from Jackson's '477 Publication in 2005 are shown below. There is nothing in the '646 Patent to describe any differences in the leading face of the thread as compared to the '477 Publication or any other prior art or why one would be superior to the other.

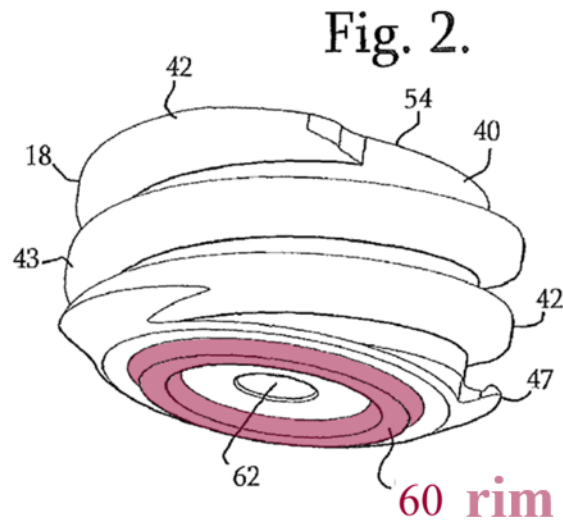


EX1005, Figs. 7-10. Moreover, in the '646 Patent, Fig. 3 shows an additional line on the leading face of the thread (highlighted in red below), which is not shown in Fig. 9, but the meaning of this additional line is not explained. EX1001, Figs. 3, 9.



116. The specification does not prescribe any particular significance to the closure top bottom. It describes two possible bottom arrangements, both of which

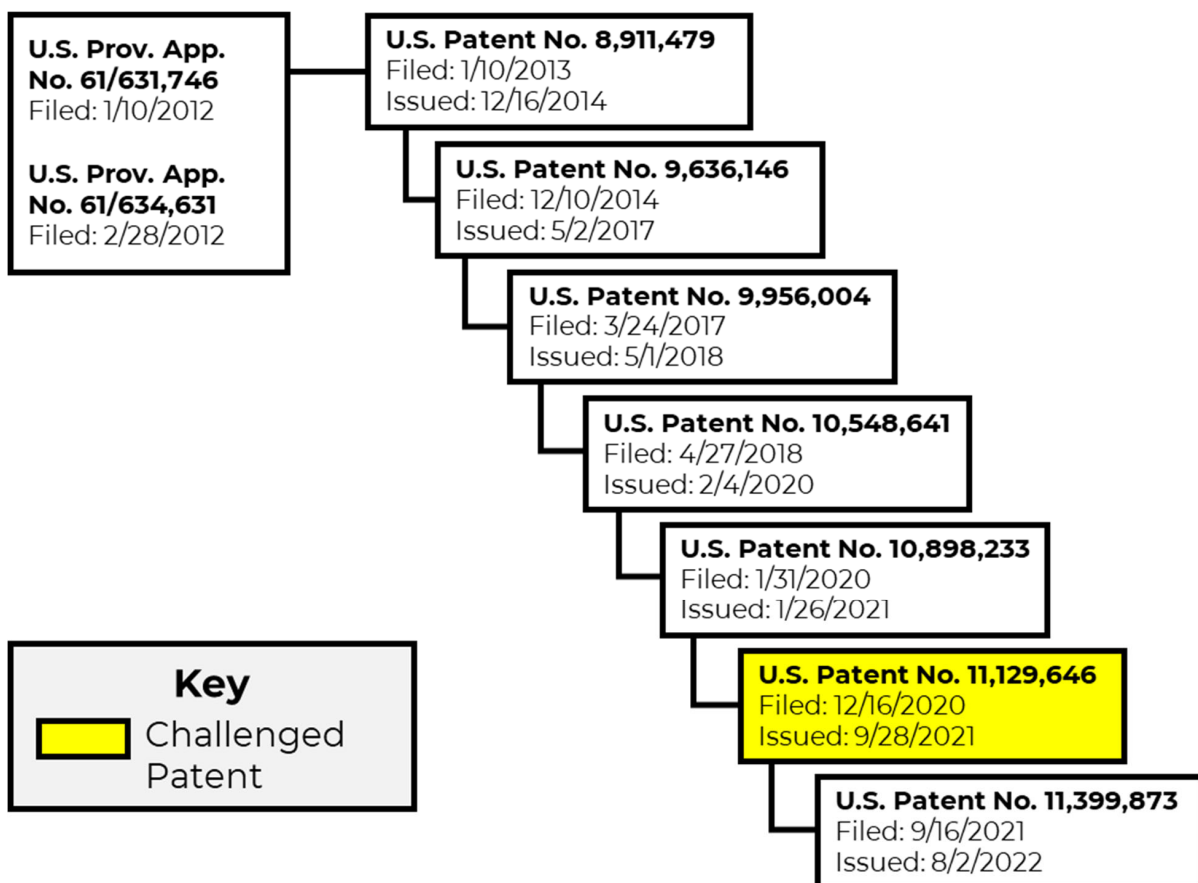
were well-known in the prior art: one with a domed shape, *id.*, 9:58-62, Fig. 50, and the other that is “planar and further includes a rim 60 for engagement and penetration into the surface 22 of the rod 21, *id.*, 9:4-7. The latter embodiment is illustrated in Figs. 1-8, including annotated Fig. 2 set forth below.



Figs. 9-14 show additional closure tops using various well-known thread alternatives, but the specification repeatedly states that these closure tops are “almost identical” to the closure top shown in Fig. 3 with the exception of change of thread type. *Id.*, 22:19-23:59. All of these alternative closure tops include the same rim 60 as shown above. *Id.* The specification never identifies any “annular outer edge” or “outward facing surface encircling the substantially flat bottom surface” with respect to any disclosed embodiment.

B. Prosecution History

117. The '646 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:



118. The as-filed claims of the application for the '646 Patent required a curvate leading face on the closure top threads. These claims were rejected over Prevost (EX1022), which disclosed a curvate leading face on a closure top thread,

in view of Boschert's (EX1006) dual start closure top. EX1002 at 235-351. In response, Applicant amended the claims to require that the closure top bottom have "a substantially flat bottom surface with an annular outer edge" and that the thread start structure be "spaced apart and above the annular outer edge of the substantially flat bottom surface." *Id.* at 283. Applicant did not identify any particular specification support for these amendments. Applicant distinguished Prevost on the basis of this amendment, *id.* at 287-89, and the amended claims were allowed, *id.* at 305-11.

119. While Kirschman (EX1007) was cited in an Information Disclosure Statement along with hundreds of other references, EX1002 at 84-91, the Examiner did not rely on Kirschman in any rejection during the prosecution of the '646 Patent. In the Examiner's March 9, 2021 Non-Final Rejection, the Examiner identified Kirschman as "prior art made of record" that was "not relied upon" but "considered pertinent to applicant's disclosure" and "particularly relevant to the thread start structure." *Id.* at 250. The Examiner stated that Kirschman "teaches a bone anchor with a cap (set screw) starting thread having a cut-out area to provide tactile feedback to the surgeon as the cap drops into the receiver." *Id.*

120. While the '477 Publication (EX1005) was identified in the Examiner's March 9, 2021 "Notice of References Cited," *id.* at 252, and appears in a search query conducted on February 26, 2021, *id.* at 273, the Examiner did not

cite to or rely on the '477 Publication in the March 9, 2021 Non-Final Rejection, *see id.* at 236-252, or any office action during the prosecution of the '646 Patent.

121. Johnson (EX1008) was not cited or relied on during the prosecution of the '646 Patent. Johnson was cited on the face of the '479 Patent, a parent patent to the '646 Patent, but Johnson's teachings regarding breakoff arm extensions were not discussed by the Examiner, either alone or in combination with Boschert, the '477 Publication, and/or Kirschman, during the prosecution of the '479 Patent. *See* EX1035.

C. The Challenged Claims

122. The Challenged Claims of the '646 Patent are Claims 1-20. The '646 Patent includes two independent claims—1 and 12.

123. Claim 1 in its entirety, is reproduced below.⁶

⁶ I have attached as an appendix to my declaration a claim listing of all Challenged Claims. Because many limitations of claims 1 and 12, and their respective dependent claims, are common, I have assigned a unique identifier to each limitation found in the claims and I have attempted to group limitations based on the feature the limitation is directed at (group [A] relates to the receiver, group [B] relates to the closure top, and group [C] relates to breakoff arm extensions). This claim listing, and my assignment of a unique identifier for each limitation, are

A medical implant assembly comprising:

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

[B] a plug being threaded and configured to be positioned within the upper portion, the plug having an axis of rotation,

[B1] a continuously helically wound thread form,

[B2] and a substantially flat bottom surface with an annular outer edge, the substantially flat bottom surface configured to engage the rod,

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

intended solely for ease of reference. My opinions herein address each and every limitation of the Challenged Claims.

[B4] the partial concave and partial convex surfaces each defined by a radius of curvature that is substantially equal with respect to each other,

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

124. Claim 12 recites many of the same limitations as Claim 1, but also expressly requires “a first thread and a second thread” each having the claimed start structure. Claim 12 in its entirety, states as follows:

A medical implant assembly comprising:

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

[B] a plug configured for positioning within the upper portion of the receiver, the plug having an axis of rotation,

[B1] a continuously helically wound thread form comprising a first thread and a second thread,

[B2] a substantially flat bottom surface with an annular outer edge, and

[B13] an outward facing surface encircling the substantially flat bottom surface,

[B3] the first thread comprising a first start structure and a first upper surface extending between a first root and a first crest of the first thread, the first start structure including a first leading face extending below the first upper surface to a first lower surface, the second thread comprising a second start structure and a second upper surface extending between a second root and a second crest of the second thread, the second start structure including a second leading face extending below the second upper surface to a second lower surface, the first and second leading faces each including a partial concave surface adjacent the first and second root, respectively, and a partial convex surface adjacent the first and second crest, respectively, the partial concave and partial convex surfaces of the first and second leading faces each defined by a radius of curvature,

[B5] the first lower surface of the first thread and from the second lower surface of the second thread are spaced above and apart from the annular outer edge of the substantially flat bottom surface of the plug.

125. Claim 2 depends from Claim 1 and adds the limitation: **[B6]** wherein the partial concave surface tangentially blends with the partial convex surface.

126. Claim 3 depends from Claim 1 and adds the limitation: **[B7]** wherein the start structure is a first start structure disposed at a diametrically opposite location on the plug from a second start structure.

127. Claim 4 depends from Claim 1 and adds the limitation: **[B8]** wherein the leading face of the start structure includes at least a partial planar surface.

128. Claim 5 depends from Claim 1 and adds the limitation: **[B9]** wherein the lower surface of the start structure includes a bottom beveled surface.

129. Claim 6 depends from Claim 1 and adds the limitation: **[B10]** wherein the upper surface of the continuously helically wound thread form of the threaded plug slopes rearward from the root towards the crest.

130. Claim 7 depends from Claim 6 and adds the limitation: **[B11]** wherein a slope of the upper surface is at an angle greater than five degrees measured between a line drawn perpendicular to the axis of rotation of the plug and a tangent line drawn tangent along the upper surface.

131. Claim 8 depends from Claim 1 and adds the limitation: **[B12]** wherein the plug is a breakoff plug.

132. Claim 9 depends from Claim 1 and adds the limitation: **[A1]** wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm.

133. Claim 10 depends from Claim 9 and adds the limitation: **[C]** wherein the first arm includes a first breakoff extension coupled to the top surface of the

first arm, and the second arm includes a second breakoff extension coupled to the top surface of the second arm, each of the first and second breakoff extensions including an inner surface having a discontinuously helically wound thread form, the discontinuously helically wound thread form of the first breakoff extension configured to cooperate with the discontinuously helically wound thread of the first arm, and the discontinuously helically wound thread form of the second breakoff extension configured to cooperate with the discontinuously helically wound thread of the second arm to rotatably transfer the plug therebetween prior to the first and second breakoff extensions being separated from the first and second arms, respectively.

134. Claim 11 depends from Claim 10 and adds the limitation: **[C1]** wherein a first outer radiused notch is located at a convergence of the first breakoff extension and the first arm at the top surface thereof, and a second outer radiused notch is located at a convergence of the second breakoff extension and the second arm at the top surface thereof, the first outer radiused notch being located opposite a first inner radiused recess, and the second outer radiused notch being located opposite a second inner radiused recess.

135. Claim 13 depends from Claim 12 and adds the limitation: **[B7]** wherein the first start structure and the second start structure are disposed at diametrically opposite locations from each other on the plug.

136. Claim 14 depends from Claim 12 and adds the limitation: **[B14]** wherein the first leading face includes a first inflection point between the partial concave surface and the partial convex surface of the first leading face, and the second leading face includes a second inflection point between the partial concave surface and the partial convex surface of the second leading face.

137. Claim 15 depends from Claim 12 and adds the limitation: **[B8]** wherein the first and second leading faces each includes at least a partial planar surface.

138. Claim 16 depends from Claim 12 and adds the limitation: **[B9]** wherein the first lower surface includes a first bottom beveled surface and the second lower surface includes a second bottom beveled surface.

139. Claim 17 depends from Claim 12 and adds the limitation: **[B12]** wherein the plug is a breakoff plug.

140. Claim 18 depends from Claim 12 and adds the limitation: **[A1]** wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm.

141. Claim 19 depends from Claim 18 and adds the limitation: **[C]** wherein the top surfaces of the first and second arms each include a breakoff extension with

an inner surface having a discontinuously helically wound thread form, the first and second arm breakoff extension thread forms being continuous with the respective discontinuous helically wound thread form on the inner surface of the first and second arms.

142. Claim 20 depends from Claim 12 and adds the limitation: **[B4]** wherein the radius of curvature for the partial concave and partial convex surfaces of the first and second leading faces are substantially equal with respect to each other.

D. Opinions on Claim Construction

143. 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 '646 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 '646 Patent.

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

144. The specification of the '646 Patent never identifies an “annular outer edge” on any “substantially flat bottom surface.” Nevertheless, in my opinion, a

POSA would have understood these phrases according to their plain and ordinary meaning.

145. “Substantially” is generally defined as for the most part (or essentially). EX1030 at 4. “Bottom” is generally defined as either the underside of something or lowermost. EX1029 at 6. “Annular” is generally defined as shaped like or forming a ring. *Id.* at 3. An “annulus” is generally defined as a ring like area bounded by and containing the area between two concentric circles. *Id.* “Outer” is generally defined as farther from the center. *Id.* at 9. “Edge” is generally defined as either (a) a thin, sharpened side or (b) the line of intersection of two surfaces. *Id.* at 8. I have seen nothing in the specification or prosecution history of the ’646 Patent that requires any departure from these plain and ordinary meanings.

146. As discussed above, the ’646 Patent describes only two alternative closure top bottom surfaces, one that is “planar and further includes a rim 60 for engagement and penetration into the surface 22 of the rod 21,” EX1001, 9:4-7, Figs. 1-14, and another “that has a domed portion 66’ with a central nub 68’ in lieu of the flat and rimmed surfaces,” *id.*, 9:58-62, Fig. 50. A POSA would have understood the claims to be directed to the first set of embodiments (planar with rim), but not the second (domed).

147. With reference to Fig. 6, annotated below, the specification identifies “bottom surface 58 of the closure” as “planar” (i.e., flat). *Id.*, 9:4-7. This surface “further includes a rim 60 for engagement and penetration into the surface 22 of the rod 21.” *Id.* In my opinion, a POSA would have understood that, despite the presence of the rim, bottom surface 58 is substantially flat, because it is mostly planar. Moreover, a POSA would have understood that “rim 60” is the claimed “annular outer edge.” This rim is ring shaped (i.e., annular), located near the periphery of the closure top bottom (i.e., outer), and it is a narrow shape (i.e., an edge).

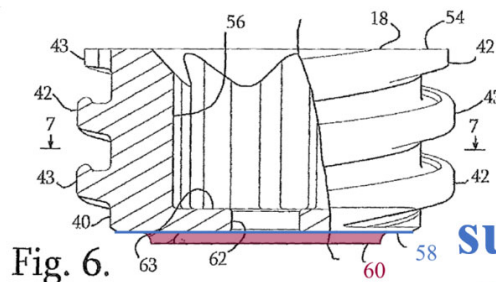
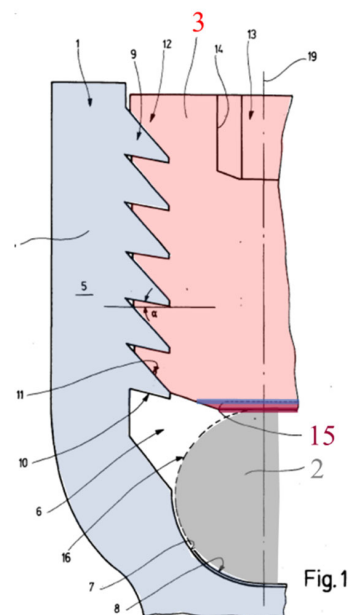


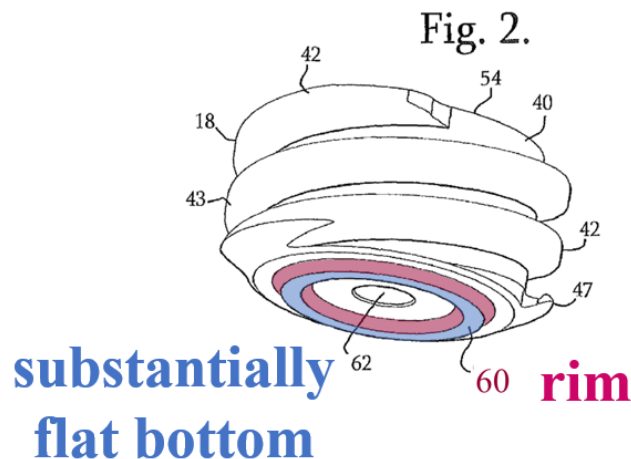
Fig. 6. **substantially flat**
rim **bottom surface**

148. Further, in the prior art, downwardly projecting rims were referred to as annular edges. For example, Schafer describes setscrew 3 that includes “an annular cutting edge 15 which digs into the surface of the support rod 2 when tightening the setscrew 3 and thus additionally secures the support rod 2.” EX1018, 9:9-12. Therefore, in my opinion, a POSA reading the

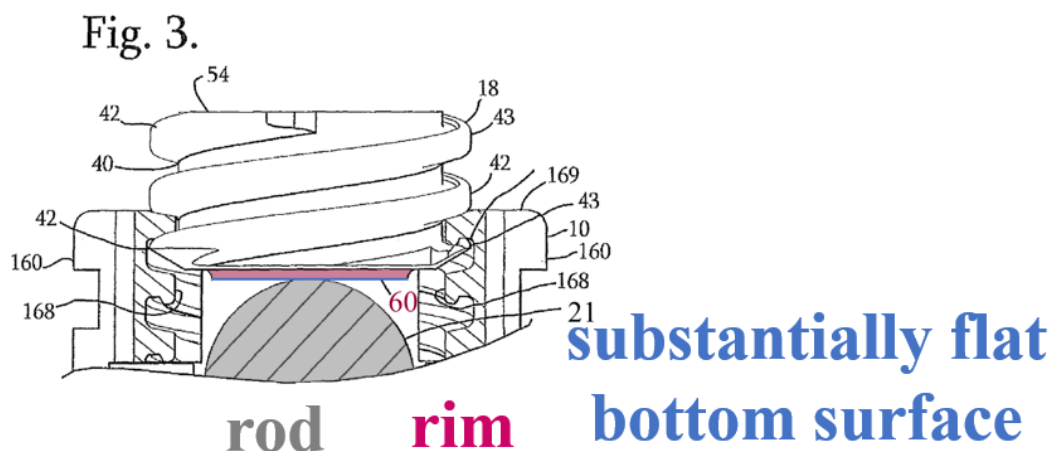


claims of the '646 Patent in view of the specification would have understood the claim language “a substantially flat bottom surface with an annular outer edge, the substantially flat bottom surface configured to engage the rod” (Claim 1) and “a substantially flat bottom surface with an annular outer edge” (Claim 12) to refer to a essentially flat bottom surface of the closure top that includes a downwardly projecting rim configured to engage the rod.

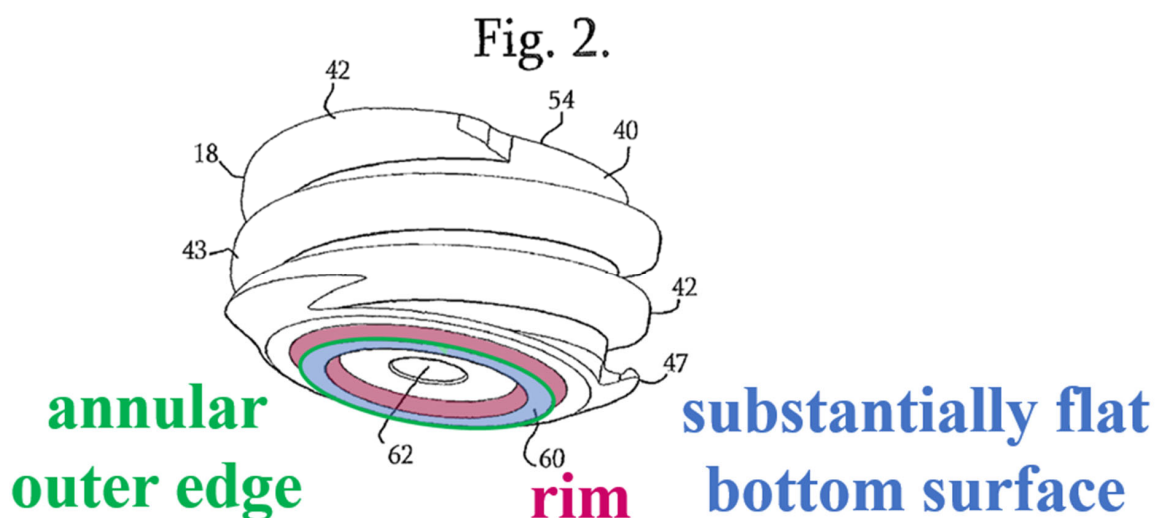
149. While a less preferred construction, I note that an alternative construction of this language is also possible. Specifically, while not described in text of the '646 Patent specification as a bottom surface, the disclosed rim of the preferred embodiments appears to have a lowermost surface that is flat. EX1001, Figs. 2, 3. This flat lowermost surface of the rim could alternatively be understood as the claimed “substantially flat bottom surface.” Fig. 2 provides a visual representation of rim 60 and shows that the rim includes generally vertical side walls as well as a flat lowermost surface.



This flat bottom surface of rim 60 is the lowermost surface of the disclosed closure top. This bottom surface of the rim also engages the rod, as depicted, for example, in Fig. 3 below.



150. If the bottom surface of the rim is considered the “substantially flat bottom surface,” then the claimed “annular outer edge” could be understood to refer to the ring-shaped edge of rim 60 located farthest from the center of the rim, shown in green in annotated Figure 2 below.



EX1001, Fig. 2. This edge is a line that is the intersection of the plane face of the flat lowermost surface and the outward facing rim side surface.

151. Therefore, a POSA could alternatively understand the claim language “a substantially flat bottom surface with an annular outer edge, the substantially flat bottom surface configured to engage the rod,” *id.*, 25:18-37 (Claim 1), and “a substantially flat bottom surface with an annular outer edge,” *id.*, 26:26-57 (Claim 12), to refer to a flat lowermost surface of the closure top, e.g., the flat bottom of a downwardly projecting rim, with an annular outer edge being the line at the periphery where that flat bottom surface meets a more vertically oriented surface, e.g., the side surface of a downwardly projecting rim.

152. As set forth further below, in my opinion, the claims of the ’646 Patent are all anticipated or obvious in view of the prior art under either my preferred or alternative constructions of these limitations.

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

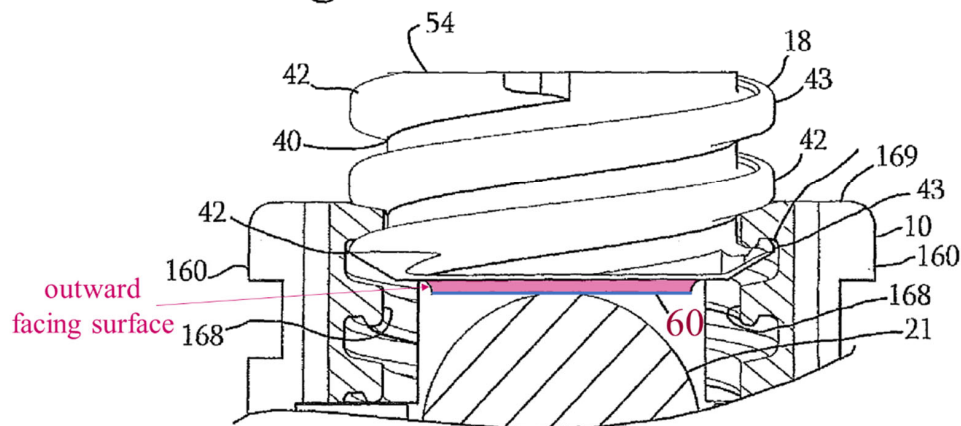
153. The specification of the ’646 Patent never identifies an outward facing surface encircling the substantially flat bottom surface. Nevertheless, in my opinion a POSA would have understood this phrase to have its plain and ordinary meaning.

154. “Outward” is generally defined as toward the outside (or away from a central point) of the closure top. EX1029 at 10. “Encircling” is generally defined

as forming a circle around and surrounding. EX1029 at 7. I have seen nothing in the specification or prosecution history of the '646 Patent that requires any departure from these plain and ordinary meanings. Therefore, in my opinion, a POSA would have understood this phrase to refer to any surface that faces away from the center of the closure top and forms a circle around the bottom surface of the closure.

155. Applying this plain and ordinary meanings to the preferred embodiments, there are at least two surfaces that could be understood as “an outward facing surface encircling the substantially flat bottom surface.” First, the “cylindrical closure plug body 40” comprises a surface that faces away from the center of the closure top (i.e., outward facing) and forms a circle around (i.e., encircles) the “substantially flat bottom surface” under my preferred construction of that phrase. EX1001, 8:22-30. Because closure plug body 40 is cylindrical, its side surface is necessarily in the shape of a circle. And this circle formed by the closure plug body 40 surrounds bottom surface 58, as shown, for example, in annotated Fig. 6 below.

Fig. 3.



This surface faces away from the center of rim 60 and surrounds and forms a circle around the lowermost flat surface of rim 60.

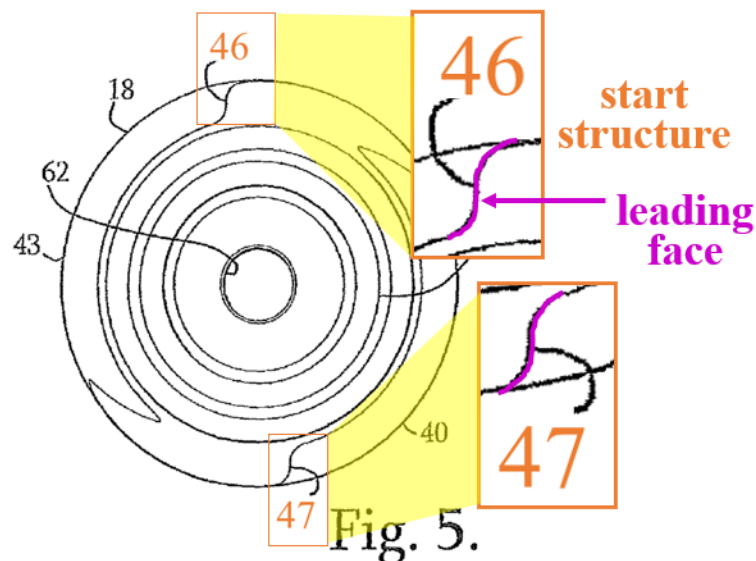
157. As set forth further below, in my opinion, the claims of the '646 Patent are all anticipated or obvious in view of the prior art because the prior discloses multiple outward facing surfaces encircling the flat bottom surface (under any construction), including both closure body surfaces and rim side surfaces.

3. **“a start structure with an upper surface extending between a root and a crest . . . having a leading face extending below the upper surface to a lower surface of the start structure, the leading face including a partial concave surface adjacent the root and a partial convex surface adjacent the crest” (Claims 1 and 12 (modified to claim “first” and “second” start structures)).**

158. The claimed “leading face” is never specifically identified by reference number in the '646 Patent. The entirety of the written description on this feature states:

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

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

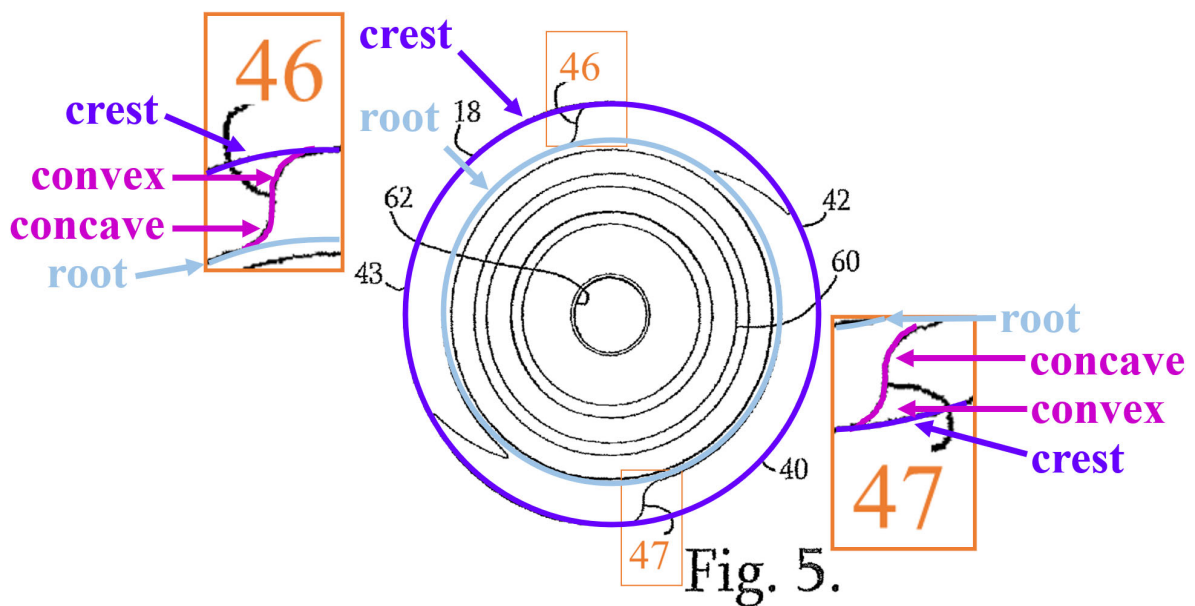


159. From this disclosure, and consistent with the plain meaning, in my opinion a POSA would have understood that a “start structure” is the beginning of a thread and the “leading face” is the forward most surface of the thread in the direction the thread is to be rotated.

160. 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 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 the “surface of the thread which joins the flanks of the adjacent thread ... and is ... immediately adjacent to the [cylindrical body] from which the thread projects. *Id.* at 5.

161. 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.



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.

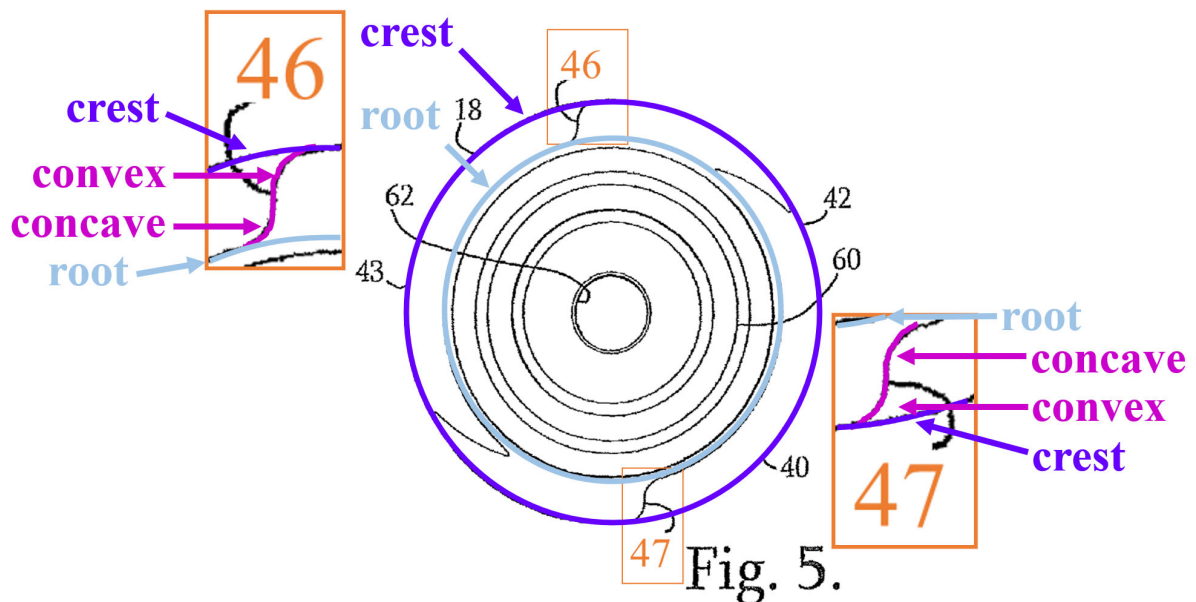
4. “the partial concave surface tangentially blends with the partial convex surface” (Claim 2).

162. The specification of the '646 Patent never describes or identifies a partial concave surface that tangentially blends with a partial convex surface. Nevertheless, in my opinion a POSA would have understood this phrase according to its plain and ordinary meaning.

163. “Tangent” is generally defined as a line that touches a curve or curved surface at a point, but if extended does not cross it at that point. EX1029 at 13. To “blend” is to combine or mix so that constituent parts of indistinguishable from one another. *Id.* at 5. Together, I understand this phrase to describe a concave surface that touches a convex surface at a point such that the two curved surfaces are merged together at that point. I have seen nothing in the specification or prosecution history of the '646 Patent that requires any departure from this plain and ordinary meanings.

164. A POSA would have understood this phrase to relate to the “leading face” of the thread start structures. Claim 2 refers to “the partial concave surface” and “the partial convex surface.” I understand that “the” indicates a reference to the same structure earlier in the claims (i.e., antecedent basis). The antecedent basis for these phrases is provided in claim 1, which requires a “start structure

having a leading face ... the leading face including a partial concave surface adjacent the root and a partial convex surface adjacent the crest.” Figure 5 illustrates the start structures 46 and 47 of the preferred embodiment and shows a partially concave surface near the root of the thread and a partially convex surface near the crest of the thread, as annotated below.



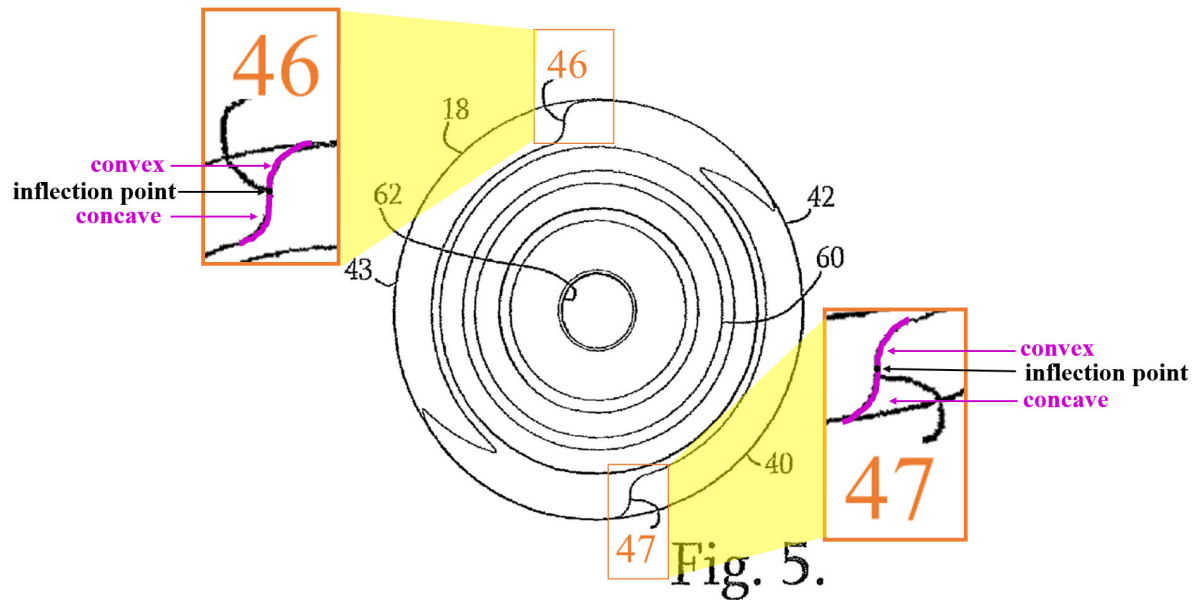
165. As Figure 5 shows, these convex and concave surfaces touch each other at a single point and are smoothly blended (i.e., merged) together. Therefore, a POSA would have understood this phrase to refer to the area near the center of the leading face where the curvate surface transitions from concave to convex.

5. **“the first leading face includes a first inflection point between the partial concave surface and the partial convex surface of the first leading face, and the second leading face includes a second inflection point between the partial concave surface and the partial convex surface of the second leading face” (Claim 14).**

166. The specification of the '646 Patent never identifies an “inflection point” on any leading face of a thread. Nevertheless, a POSA would have understood this phrase according to its plain and ordinary meaning.

167. An “inflection point” is mathematically defined as a point of a curve at which a change in the direction of curvature occurs. EX1030 at 3. I have seen nothing in the specification or prosecution history of the '646 Patent that requires any departure from this plain and ordinary meaning.

168. Claim 14 expressly refers to the leading faces of the start structure, as illustrated in reference to Figure 5. In the annotated version of Figure 5, I have marked the approximate point where the curve changes from convex to concave. A POSA would have understood this transition point to be the inflection point in the disclosed embodiment.



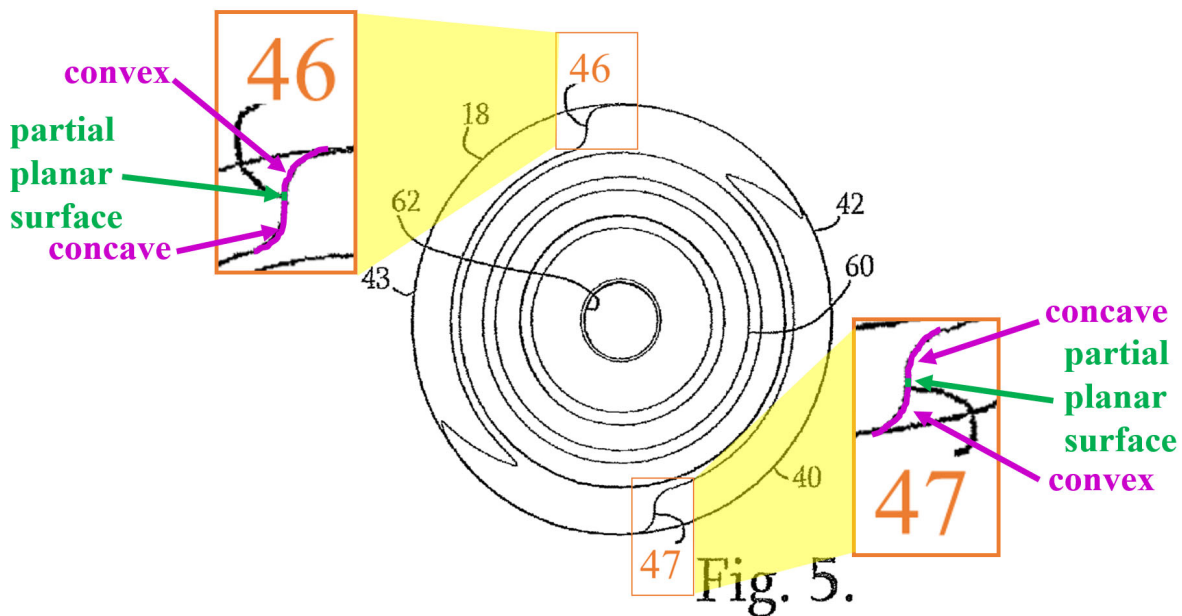
6. “the leading face of the start structure includes at least a partial planar surface” (Claims 4 and 15).

169. The specification of the '646 Patent never identifies a “partial planar surface” that is part of the leading face of a thread. Nevertheless, in my opinion a POSA would have understood that this phrase according to its plain and ordinary meaning.

170. “Partial” is defined as relating to a part rather than the whole. EX1029 at 11. “Planar” is defined as having a flat surface. *Id.* at 12. I have seen nothing in the specification or prosecution history of the '646 Patent that requires any departure from this plain and ordinary meanings.

171. Claims 4 and 15 expressly refer to the leading faces of the start structure, as illustrated in reference to Figure 5. In the annotated version of Figure 5 I have marked as a “partial planar surface” the approximate point where the

curve changes from convex to concave. At this location, the surface of the leading face is approximately flat in all directions. At all other locations along the leading face, the surface of the leading face is curved in at least one direction. Therefore, POSA would have understood the area around the inflection point to be a partial planar surface.

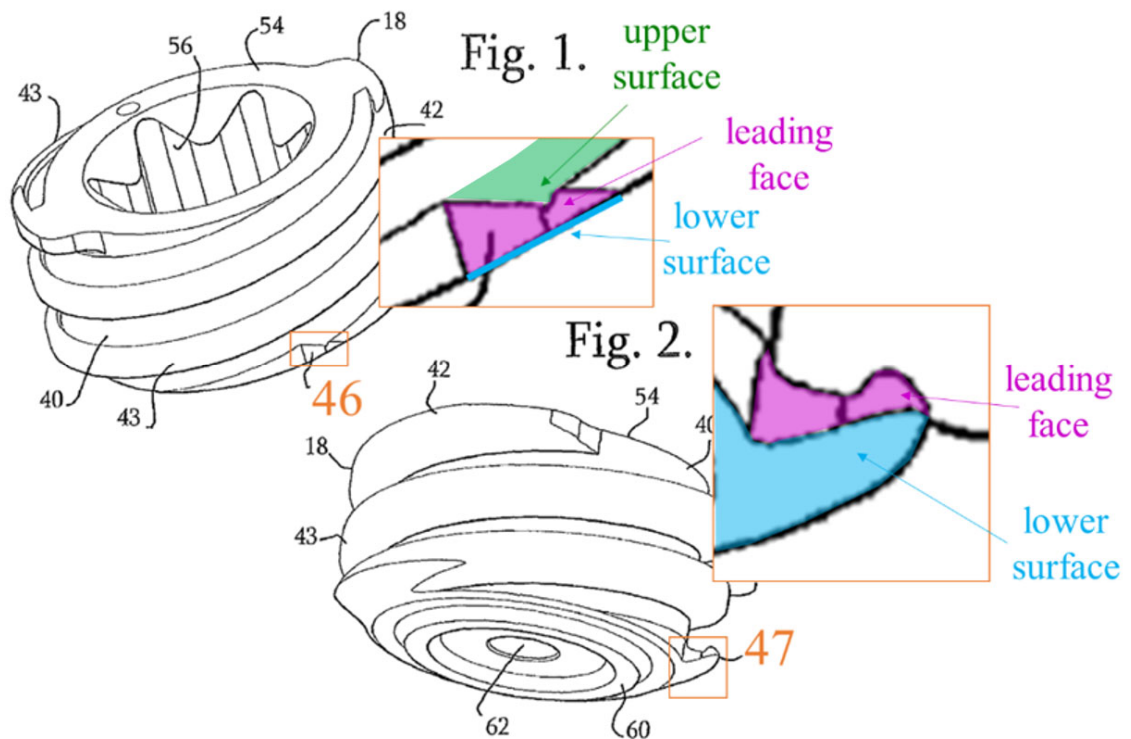


7. “the lower surface of the start structure includes a bottom beveled surface” (Claim 5) and “the first lower surface includes a first bottom beveled surface and the second lower surface includes a second bottom beveled surface” (Claim 16).

172. The specification of the '646 Patent does not contain any textual description of a bottom beveled surface of a lower surface of the thread start structure. Nevertheless, in my opinion a POSA would have understood these phrases according to their plain and ordinary meaning.

173. “Beveled” is defined as a line or surface that meets another line or surface with an angle or inclination other than 90 degrees. EX1029 at 4. I have seen nothing in the specification or prosecution history of the ’646 Patent that requires any departure from this plain and ordinary meanings.

174. The claim language identifies the “lower surface” as part of the start structure: “the continuously helically wound thread form having a start structure with an upper surface extending between a root and a crest of the [thread form], the start structure having a leading face extending below the upper surface to a lower surface of the start structure” EX1001, cls. 1, 12. This is shown below in annotated and enlarged Figures 1 and 2.



175. A POSA would have understood that the figures of the '646 Patent are consistent with the plain meaning of this phrase and show the sloped angle of the lower surface of the start structure. Unlike the normal thread profile, as shown in Fig. 3 below, at the leading face the lower outside corner of the thread has been removed, resulting in a beveled (i.e., sloping) lower surface of the leading face, as seen in the front elevational view of the closure shown in Figures 1 and 2 above. A cropped and annotated Figure 3 (below left) also shows the beveled lower surface of the leading face in comparison to the normal thread profile shown in Figure 10 (below right).

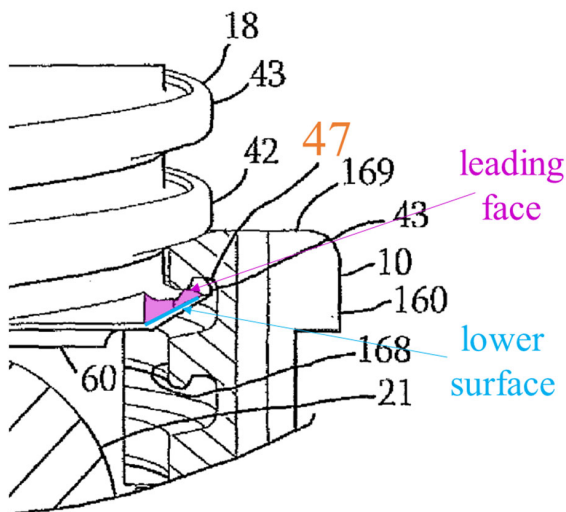


Figure 3

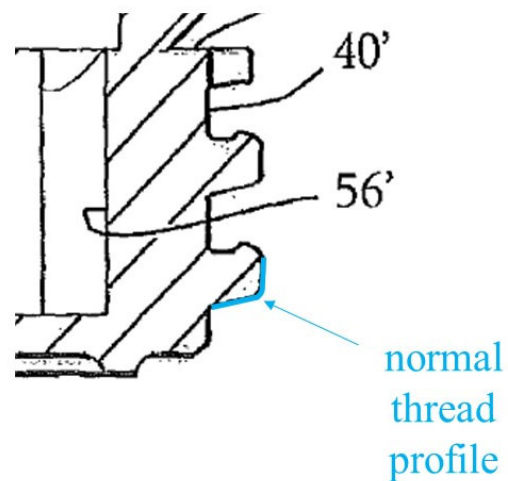
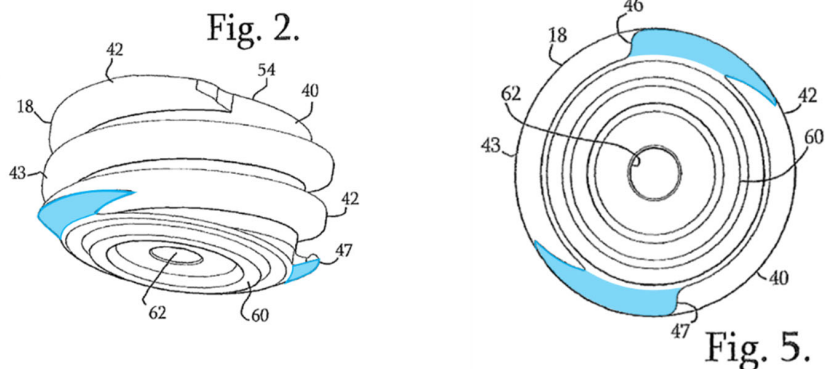


Figure 10

EX1001, Figs. 3 and 10. Figs. 2 and 5 also show the distance over which the thread is less than its full thickness, shown below and highlighted in blue.



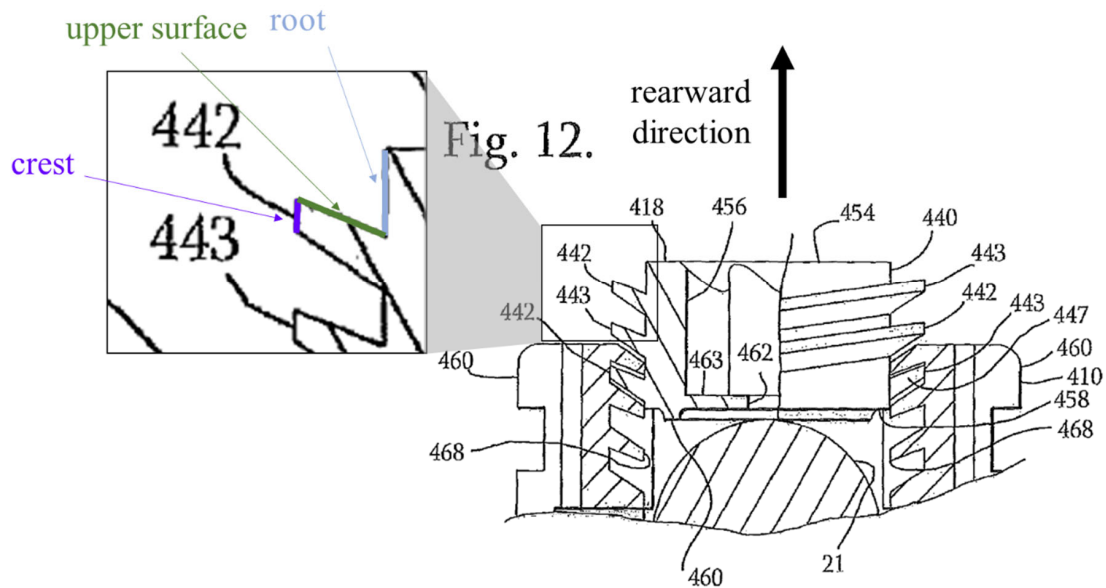
8. **“the upper surface of the continuously helically wound thread form of the threaded plug slopes rearward from the root toward the crest.” (Claim 6).**

176. The specification of the '646 Patent never identifies an “upper surface of the continuously helically wound thread form” or explains what it means for such a surface to “slope[] rearward from the root toward the crest.” Nevertheless, in my opinion a POSA would have understood this language according to its plain and ordinary meaning.

177. 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 as the “surface of the thread which joins the flanks of the thread and is farthest from the [cylindrical body] from which the thread projects.” EX1014 at 4. The “root” is defined as the “surface of a thread which joins the flanks of the adjacent thread... and is... immediately adjacent to the [cylindrical

body] from which the thread projects. *Id.* at 5. The “upward surface” of the thread is the thread flank extending between the crest and the root located closest to the top of the closure top. And because the thread advances into the receiver when it is turned, the “rearward” direction is up toward the top of the closure top. I have seen nothing in the specification or prosecution history of the ’646 Patent that requires any departure from these plain and ordinary meanings.

178. With this understanding of the plain and ordinary meaning, a POSA would have understood this phrase to describe a reverse angle thread of the type illustrated in Fig. 12, enlarged and annotated below. EX1001, 22:66-23:4. The upward surface of this reverse angle thread “slopes rearward from the root toward the crest” because it is inclined outwardly and upwardly away from the direction that the closure top advances as you move along the upper surface from the root to the crest.



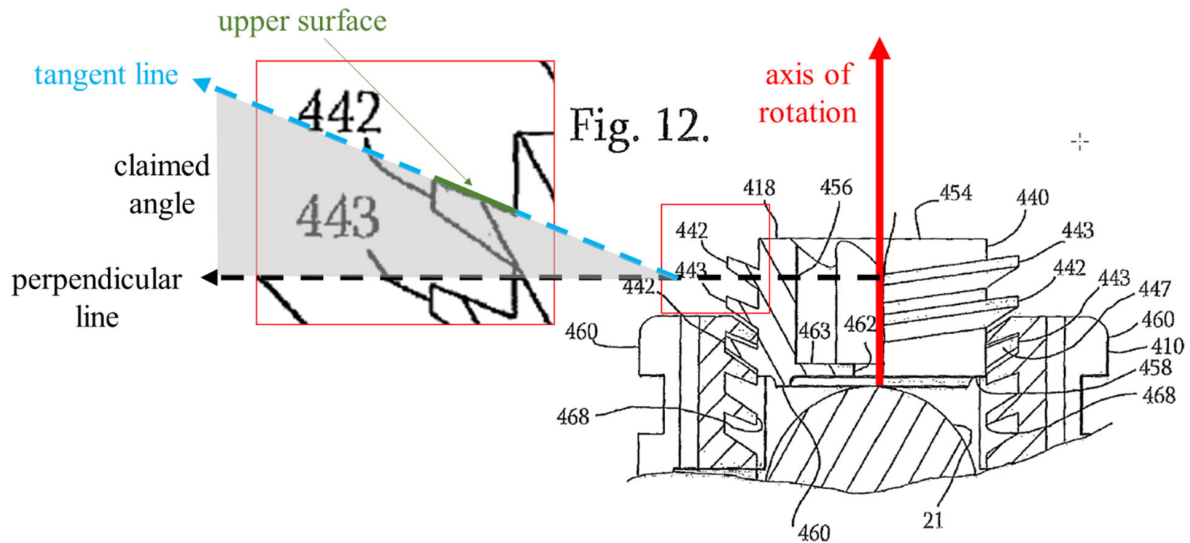
9. **“a slope of the upper surface is at an angle greater than five degrees measured between a line drawn perpendicular to the axis of rotation of the plug and a tangent line drawn tangent along the upper surface.” (Claim 7).**

179. The specification of the '646 Patent never identifies the claimed angle. Nevertheless, in my opinion a POSA would have understood this language according to its plain and ordinary meaning.

180. The plain and ordinary meaning of the phrases “upper surface” and “tangent” are discussed above. I have seen nothing in the specification or prosecution history of the '646 Patent that requires any departure from this plain and ordinary meanings.

181. With this understanding of the plain and ordinary meaning, a POSA would have understood this phrase to describe the angle of inclination of the upper

surface of a reverse angle thread of the type illustrated in Fig. 12, enlarged and annotated below. EX1001, 22:66-23:4.



VIII. SCOPE AND CONTENT OF THE PRIOR ART REFERENCES

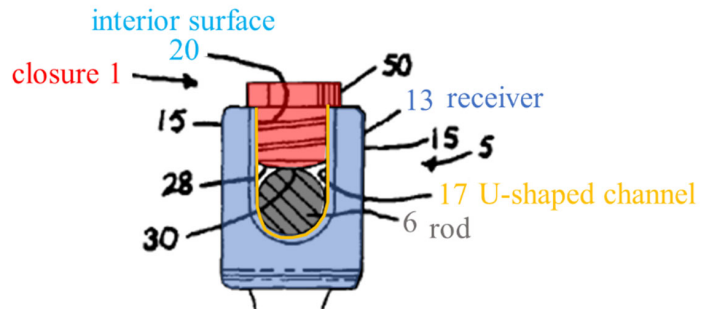
A. Overview of the '477 Publication

182. The '477 Publication, EX1005, was published on December 1, 2005, more than 6 years before the earliest effective filing date of the '646 Patent. I understand the '477 Publication is therefore prior art to the '646 Patent under 35 U.S.C. § 102(b). The '477 Publication discloses a closure top for use with a generic medical implant assembly to capture and lock a rod in a spinal implant. EX1005, ¶¶[0007], [0026]-[0029], [0039]-[0041]. Therefore, and as described further below, in my opinion the '477 Publication is in the same field of endeavor as, and is analogous art to, the '646 Patent. *Compare Id.* ¶¶[0007] (“A closure and

locking member is provided for a medical implant . . . used in a spinal implant system for providing support or reconstruction to the spine, such as a transverse connector. A typical implant for use with a closure of the invention includes a receiver having a pair of spaced arms with an open channel located therebetween.”), *with* EX1001 at 1:27-31 (“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].

183. 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

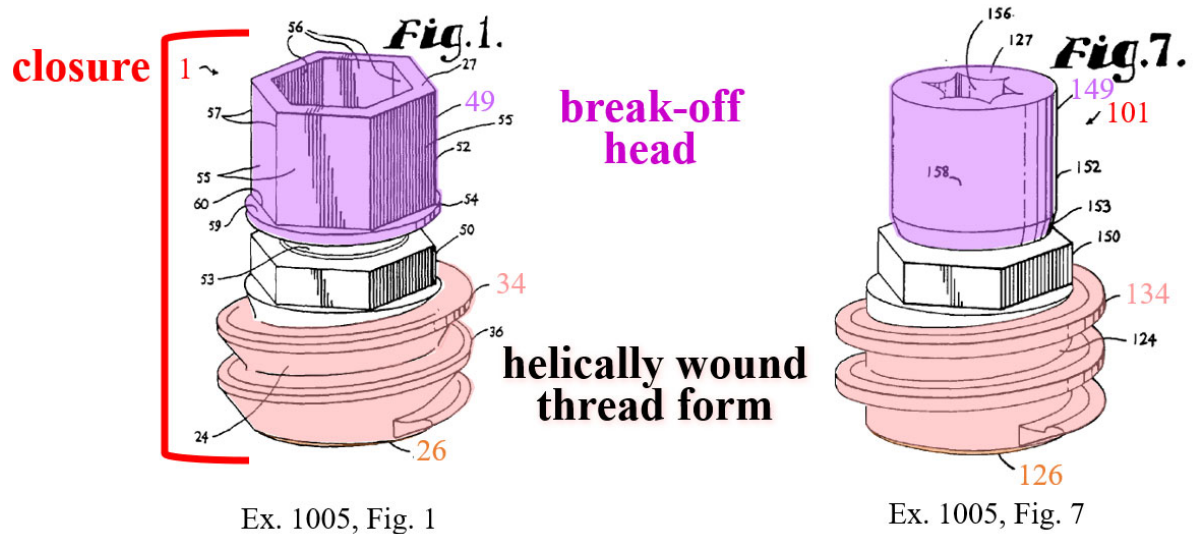
surface 20 of each arm has a partial helically wound guide and advancement structure that mates with a similar structure on a closure 1 when the



Ex. 1005, Fig. 6

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 threads, including a reverse angle thread. *Id.*, ¶[0030].

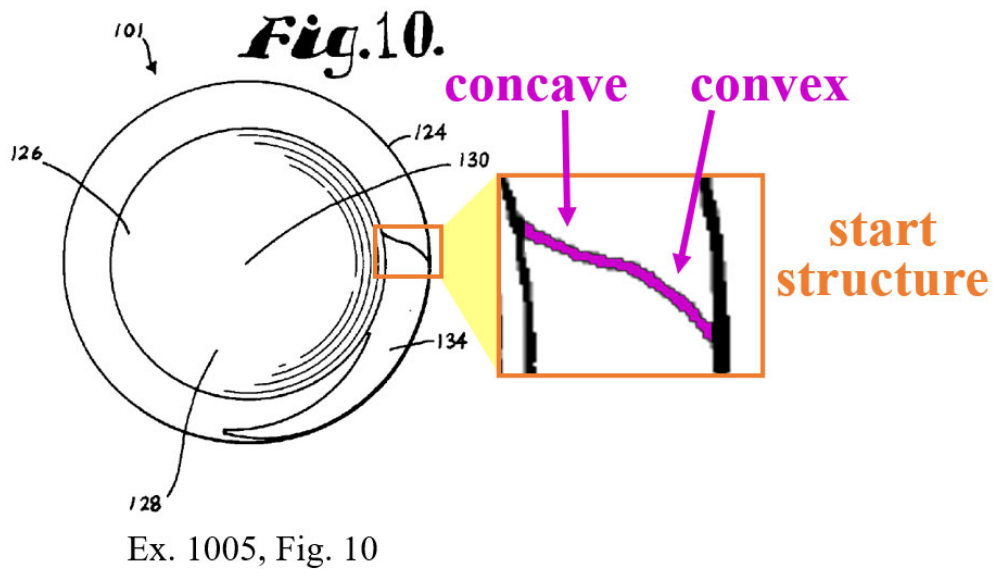
184. The '477 Publication discloses two preferred embodiments of the closure as shown and annotated below.



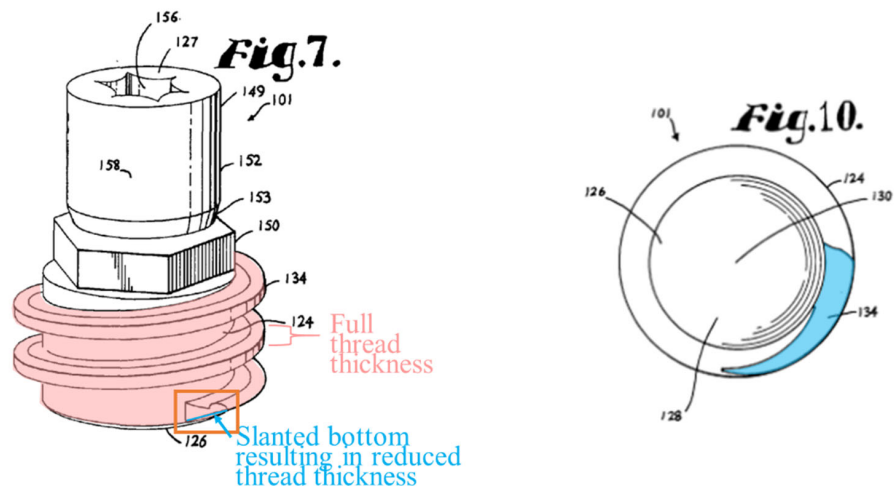
185. In the first embodiment, the '477 Publication discloses that the closure 1 is cylindrical and has a central axis of rotation. *Id.*, ¶[0029], Fig. 1. The closure has a single helically wound guide and advancement structure 34 along the outside, which could be one of a variety of threads, including a reverse angle thread. *Id.*, ¶[0030]; *see also, e.g., id.*, Fig. 1. In Fig. 1, the '477 Publication shows a preferred embodiment with a domed bottom 26, but the '477 Publication also discloses that the bottom surface of the closure top may be substantially flat and may have a central point and a lateral rim. *Id.*, ¶[0029]. The lateral rim is not pictured, but a POSA would have understood that it projects below the start structure of the threads. Finally, the '477 Publication discloses that the closure top may include a

breakoff portion 49 designed to break away from the closure “subsequent to a predetermined torque being applied.” *Id.*, ¶[0032].

186. 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 breakoff 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 threads, 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, 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).



Further, Figs. 7 and 10 of the '477 Publication show that the start structure has a sloped bottom surface that reduces the thickness of the thread near the start structure, and therefore teaches a bottom beveled surface at the thread start. *Id.*, Figs. 7, 10.



As with the first embodiment, the '477 Publication discloses that the bottom surface of the closure in the second embodiment may be substantially flat and may have a central point and a lateral rim. *Id.*, ¶[0040]. Again, though the lateral rim is not pictured, the lateral rim would project below the disclosed start structure. Finally, the '477 Publication discloses that the closure may include a breakoff portion 149 designed to break away from the closure “subsequent to a predetermined torque being applied.” *Id.*, ¶[0042], Fig. 7.

187. 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.” *Id.*, ¶[0027]; *see also id.*, ¶[0007] (“A closure and locking member is provided for a medical implant. The implant may be a bone screw, hook, or other open or closed element used in a spinal implant system for providing support or reconstruction to the spine, such as a transverse connector. A typical implant for use with a closure of the invention includes a receiver having a pair of spaced arms with an open channel located therebetween.”); 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”). The '477 Publication also expressly contemplates that the bottom of the described closure would be modified in

numerous ways, including a closure top where the bottom surface is “flat” and that includes a “lateral rim.” EX1005, ¶[0029]; *see also id.*, ¶[0040].

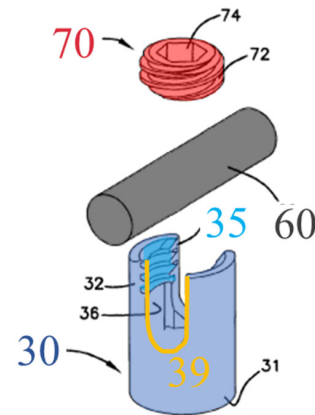
B. Overview of Boschert

188. Boschert, EX1006, published on December 15, 2005, more than 6 years before the earliest effective filing date of the ’646 Patent. I understand Boschert therefore is prior art to the ’646 Patent under 35 U.S.C. § 102(b). Boschert discloses an orthopedic fixation device for securing a rod to a bone for stabilization of the spine. EX1006, Abstract, 1:5-7. Therefore, and as described further below, in my opinion Boschert is in the same field of endeavor as, and is analogous art to, the ’646 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, 1:27-31 (“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...”).

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

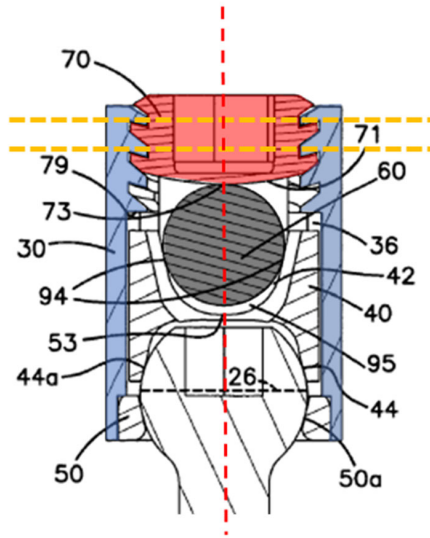
rod to seat against the top of the seat structure. *Id.*, 4:26-28, 48-50. The bone screws have a polyaxial configuration. *Id.*, 4:44-47, 5:5-11.

190. Boschert discloses a receiver 30 (**blue**) with two upwardly extending legs defining the saddle 39 (**yellow**) (i.e., the channel) which is U-shaped for receiving the rod 60 (**gray**). *Id.*, 6:20-24, Fig. 1. The legs have interior threads (**light blue**) that mate with corresponding exterior threads on the set screw 70 (**red**) (i.e., the closure), such that the set screw can be threaded into the saddle to lock the rod in place. *Id.*, 6:24-48; *see*

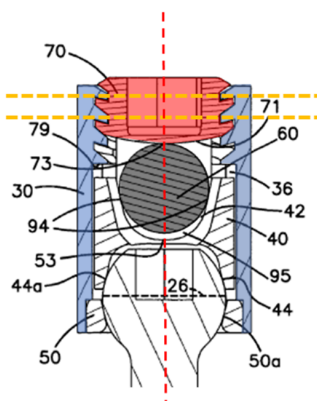


Ex. 1006, Fig. 1

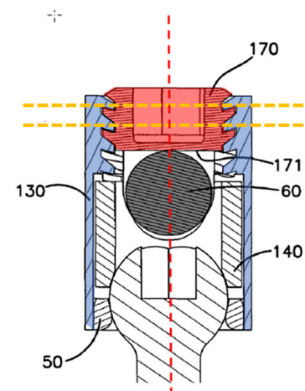
also id., 7:12-15. Boschert further discloses that the threads of the set screw can be designed to have a “double lead to allow the setscrew 70 to start more easily than with a single lead.” *Id.*, 7:21-23. Relatedly, as shown below in annotated Figure 3, Boschert discloses that interior threads on the receiver are mirrored along the longitudinal axis (**red**), thereby providing for simultaneously receiving the double leads of the closure top. *Id.*, Fig. 3.



191. 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**).



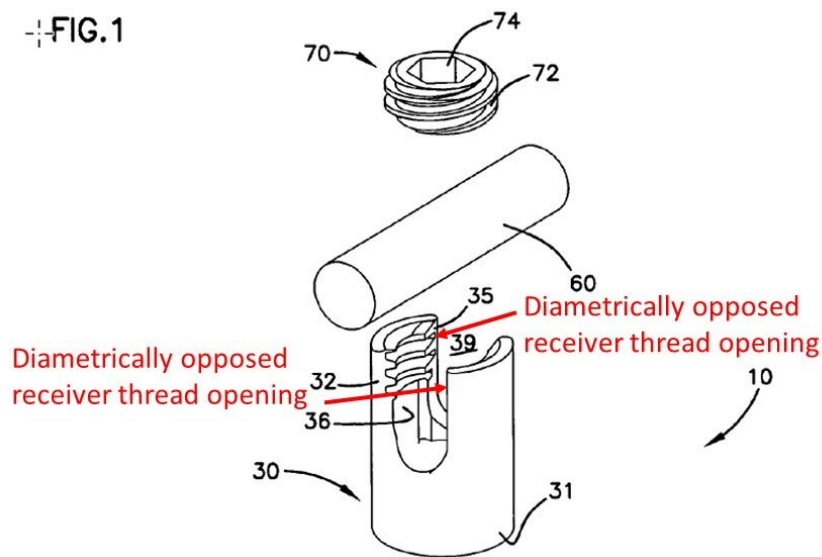
EX1006, Fig. 3



EX1006, Fig. 15

192. A POSA would have understood that for double start threads on the setscrew to engage with these receiver threads, (1) the receiver threads would

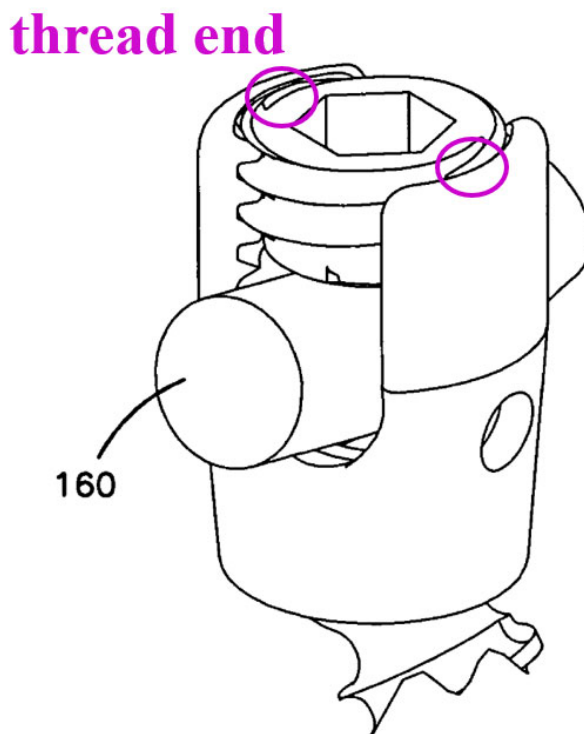
necessarily have to mirror each other, and (2) the start structures would necessarily be spread equidistant around the starting end. This understanding is further reinforced by the conventional manner of making dual start threads, which includes using diametrically opposed thread starts as discussed 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 of Boschert below.



EX1006, Fig. 1

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

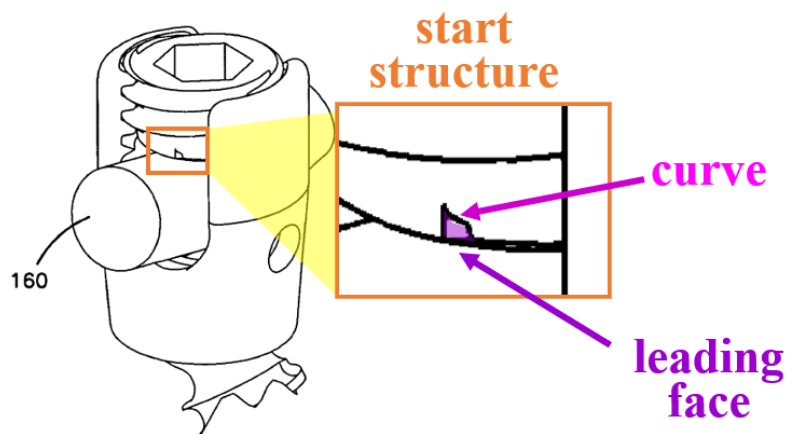
193. My opinion that Boschert discloses diametrically opposed thread starts is also supported by Fig. 7. As annotated below, Fig. 7 shows, at the top of the closure top, that the trailing ends of the double lead thread are diametrically opposed. A POSA would have understood and expected that each of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



EX1006, Fig. 7

194. 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.

195. 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

196. Boschert also discloses various possible bottom surfaces of the closure top. In one embodiment, the bottom surface is a curved surface. *Id.*, 7:15-16, Fig. 4. The set screw contacts the rod and “provides axial locking force on the

rod.” *Id.*, 7:7-8. Boschert also discloses a second embodiment in which the bottom of the set screw is flat. *Id.*, 7:40-42, Fig. 15. As in the first embodiment, the flat bottom contacts the rod when clamped within the device. *Id.*, 7:40-43, Fig. 15.

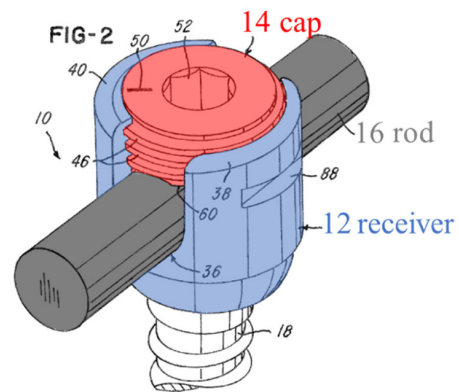
C. Overview of Kirschman

197. Kirschman, EX1007, was filed on December 18, 2009, which is more than two years before the ’646 Patent’s earliest effective filing date. I understand Kirschman is therefore prior art to the ’646 Patent under 35 U.S.C. § 102(e). Kirschman also published on June 23, 2011, which is approximately six months before the ’646 Patent’s earliest effective filing date. I understand Kirschman is therefore also prior art to the ’646 Patent under 35 U.S.C. § 102(a). Moreover, regardless of whether Kirschman itself is prior art to the ’646 Patent, its disclosures reflect the knowledge of a POSA at or before the earliest effective filing date of the ’646 Patent, and therefore are relevant to understanding how a POSA would implement the teachings of the ’477 Publication and Boschert.

198. Kirschman discloses an improved polyaxial screw, including various locking aids to facilitate mating a closure top to the polyaxial screw to capture a rod. EX1007, Abstract, ¶¶[0012]-[0016]. Therefore, and as described further below, in my opinion Kirschman is in the same filed of endeavor as, and is analogous art to, the ’646 Patent. *Compare id.*, ¶[0002] (“This invention relates to

a spinal implant system ... having [] a lock aid that provides at least one of improved guidance, tactile or visual feedback or enhanced fixation and locking of a cap in a receiver of the implant.”), *with* EX1001 at 1:27-31 (“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...”).

199. Kirschman discloses various improvements to the prior art spinal bone screw with “three main components: a screw shaft, a polyaxial tulip head or receiver incorporating a female thread, and a locking cap incorporating a male thread.



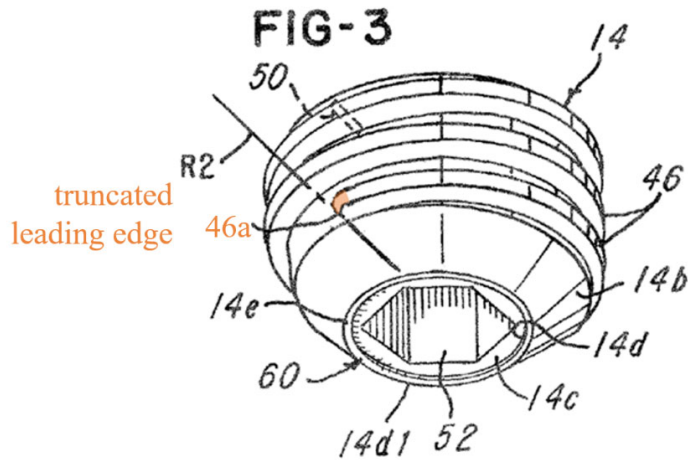
Ex. 1007, Fig. 2

The purpose of the threaded locking cap is to affix a spinal stabilizing element, typically a cylindrical rod, to the screw assembly.” EX1007, ¶[0004]; *id.* Fig. 2. Kirschman discloses several “locking aids” that can be optionally used in this context to provide “improved guidance, tactile or visual feedback or enhanced fixation and locking of a cap in a receiver of the implant.” *Id.*, Abstract, ¶[0002]. This declaration focuses on three of Kirschman’s disclosed “locking aids.”

200. First, Kirschman discloses that “[u]tilizing blunt-tip threads for the prevention of cross threading was first invented by Higbee in 1891 (U.S. Pat. No.

447,775)” and that such a blunt-tip thread has advantages for “prevent[ing] cross threading of the small-pitch threads of the locking cap/tulip pair” and “achiev[ing] high connection strength immediately after initial thread engagement.” *Id.*, ¶¶[0008]-[0009]. In

Kirschman’s preferred embodiment, “the leading edge portion 46a of the male cap thread 46 is truncated as shown” in Fig. 3 at right. *Id.*, ¶[0039]. Therefore,



Kirschman discloses that truncated threads with a curvate leading thread face are advantageous for preventing cross threading and achieving high connection strengths upon engagement. In my opinion, Kirschman’s disclosure is consistent with Higbee’s disclosure in 1891 of a rounded leading thread face. EX1015, 1:88-94, Fig. 6.

201. Second, Kirschman discloses a substantially flat bottom surface with an annular outer edge. Specifically, “end 14c” includes a “deformable ring 14d that is monolithically and integrally formed with the cap 14.” EX1007, ¶¶[0044]-[0045]. This ring (shown in cross-section below) includes “a bottom edge or surface 14e [that] engages the rod 16,” *id.*, ¶[0045], and “provides an enhanced

fixation or even a cold-weld between the cap 14 and the rod 16 when the cap 14 is received on the receiver 12,” *id.*, ¶[0047]. Fig. 6 shows that both end 14c and the bottom surface 14e of ring 14d are flat.

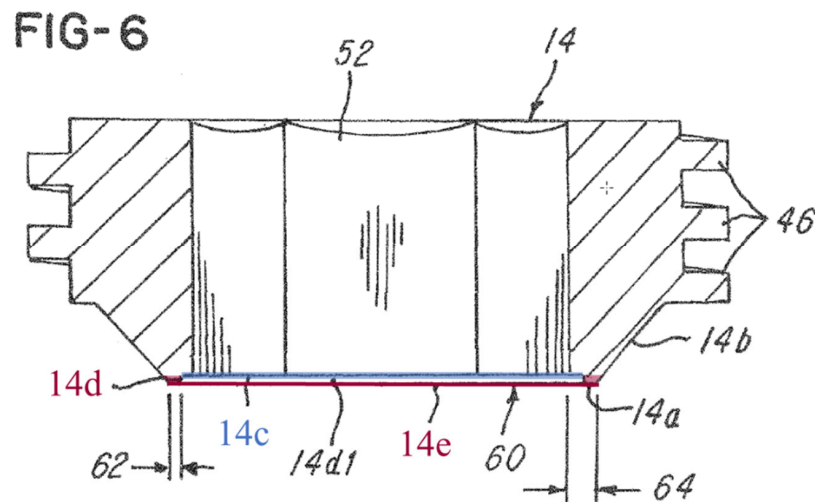
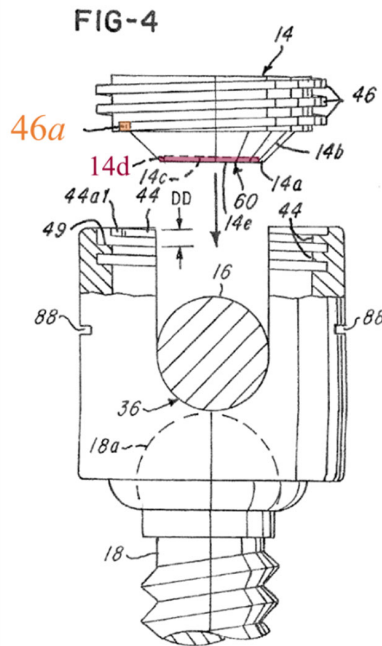


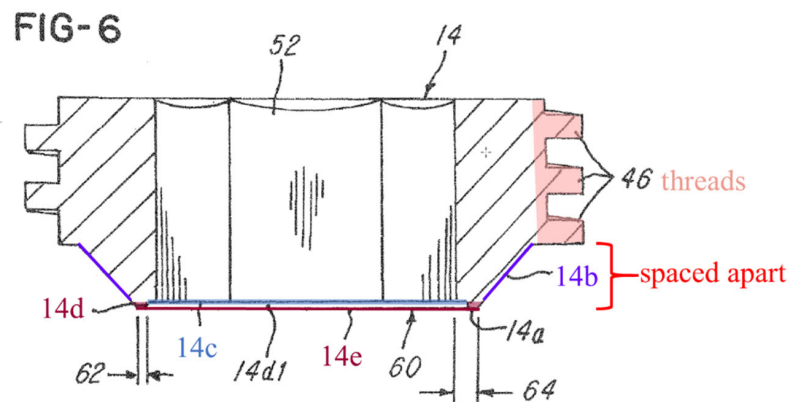
Figure 4 also shows the truncated thread start 46a spaced above the downwardly projecting ring 14d at the bottom of the closure top.



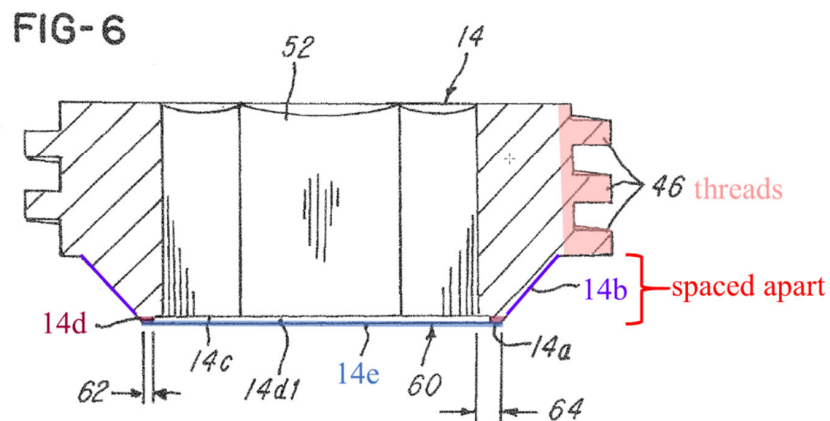
Therefore, under either my preferred or alternative construction of “substantially flat bottom surface with an annular outer edge,” Kirschman discloses this limitation, and further discloses that is advantageous to space the annular outer edge below the closure top threads.

134

(1)



(2)

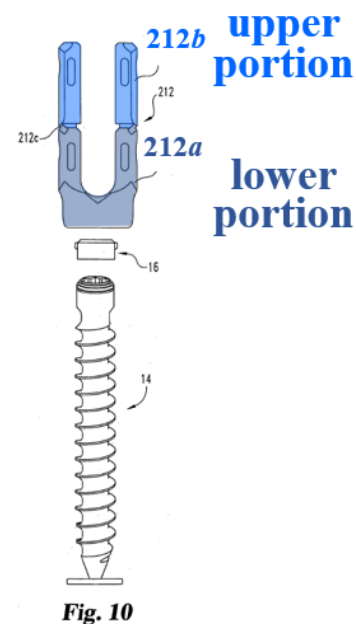


D. Overview of Johnson

203. Johnson, EX1008, was published on April 19, 2007, which is more than three years before the earliest effective filing date of the '646 Patent. I understand Johnson is therefore prior art to the '646 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, and as described further below, in my opinion Johnson is in the same filed of endeavor as, and is analogous

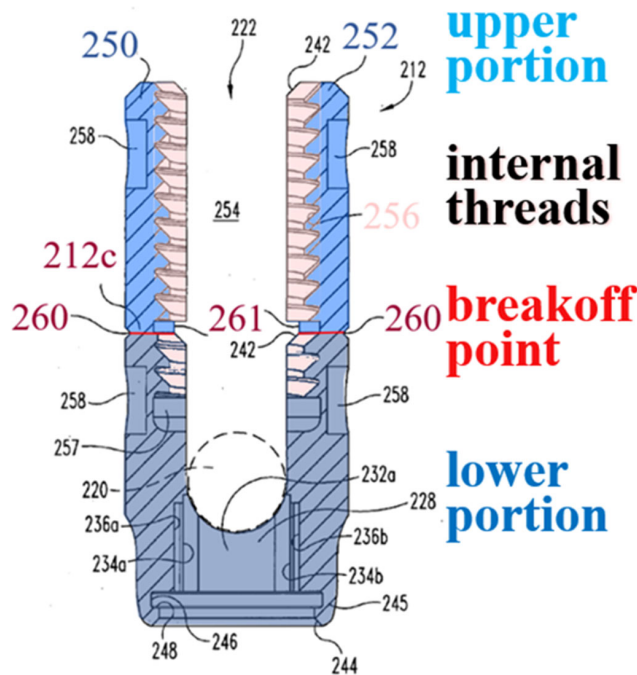
art to, the '646 Patent. *Compare* EX1008, ¶[0001] (“The present disclosure relates to devices and methods useful in surgery, such as orthopedic surgery. In particular, it relates to anchors and other implants for use in tissue, to be placed during orthopedic surgery.”), *with* EX1001 at 1:27-31 (“The 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...”).

204. 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



portion of lower portion 212a of receiver member 212, and a portion of each branch 250, 252 forms at least a part of upper portion 212b of receiver member 212.” *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 212*b* to lower portion 212*a*” so that a compression member “can be inserted into upper portion 212*b* and moved down to lower portion 212*a*.” *Id.*, ¶[0053].



205. As further shown in the annotated Figure 12 above, Johnson discloses a “[t]hinned section 212*c*” that “separates upper portion 212*b* and lower portion 212*a*.” *Id.*, ¶[0054]. The thinned section 212*c* “includes an external indentation or groove 260, which may include score lines or other fracture-inducing or fracture-enabling features.” *Id.* Johnson discloses that “[a]n interior indentation 261 is also provided.” *Id.* 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 212*b* 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.*

206. Johnson discloses that the benefit of these extended arms is that, “[w]hen the surgeon wishes to insert an elongated member 220 into receiver member 212, he or she need not bend it or use a special reducing tool to insert it into the lower end of a receiving channel. Rather, he or she places a portion of the elongated member 220 into channel 254 in upper portion 212b of receiver member 212.” *Id.*, ¶[0055]. Johnson discloses that a compression member is then “thread into threads 256, forcing elongated member 220 further down in channel 254” so that the “elongated member 220 is forced all the way through upper portion 212b, into lower portion 212a, and against a crown member and/or anchor member in chamber 228.” *Id.*

IX. MOTIVATION TO COMBINE

A. Motivation to Combine the '477 Publication with Kirschman (with or without Boschert)

207. In my opinion, it would have been obvious to a POSA to combine the teachings of the '477 Publication (with or without modifications in view of Boschert, as discussed further below) with a flat closure bottom surface having a downward projecting ring and unthreaded surface between the thread(s) and the

closure bottom surface, as described in Kirschman, before the priority date of the '646 Patent.

208. The '477 Publication is in the exact same field as the '646 Patent, as set forth above. *See supra* Section VIII.A. The '477 Publication teaches closure tops that could be used with any conventional bone screw receiver, 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], 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 top of the '477 Publication, as in Kirschman, is a polyaxial bone screw with a U-shaped receiver. *Id.*, ¶[0025], Figs. 5 and 6. Moreover, the '477 Publication expressly teaches that “it is foreseen” that its closure tops may be modified in numerous ways, including a closure top where the bottom surface is “flat” and that includes a “lateral rim.” *Id.*, ¶[0029]; *see also*

id., ¶[0040]. Because the '477 Publication does not actually depict such a lateral rim, a POSA would naturally have looked to other prior art references that did teach a lateral rim on the bottom of a closure top, such as the closure top disclosed by Kirschman. Therefore, in my opinion, a POSA would have been motivated to modify the closure of the '477 Publication in view of known closure configurations, such as the closure disclosed in Kirschman.

209. Kirschman is also in the exact same field as the '646 Patent—the design of polyaxial pedicle screw and rod implant systems to treat spinal column disorders. *See supra* Section VIII.C; EX1007, ¶[0004], Fig. 2. Kirschman discloses an improved polyaxial screw, including various locking aids to facilitate mating a closure top to the polyaxial screw to capture a rod. EX1007, Abstract, ¶¶[0002], [0012]-[0016]. Kirschman discloses that these “locking aids” that can be used to provide “improved guidance, tactile or visual feedback or enhanced fixation and locking of a cap in a receiver of the implant.” *Id.*, Abstract, ¶[0002]. Kirschman recognizes that conventional bone screws are well known in the prior art and proposes that its improved “locking aids” could be used to modify a conventional system. *Id.*, Abstract (teaching a cap that “has at least one locking aid in the form of at least one of a tactile feedback, a visual feedback or an enhanced fixation between the cap and a rod that is received in the receiver), ¶¶[0002]-[0013].

210. Kirschman teaches advantages provided by certain closure configurations. In particular, Kirschman discloses that using a “locking aid” with a flat bottom surface with a downwardly projecting ring (that also has a flat bottom surface and an annular outer edge under my alternative construction) provides advantages for engaging the rod and providing “enhanced fixation” between the cap and the rod. *Id.*, ¶¶[0045], [0047]; *see also supra* Section VIII.C. Kirschman further teaches that an unthreaded segment of the closure top located between the thread starts and the bottom of the closure had benefits for “guiding the cap 14 on the receiver 12 to facilitate aligning the cap 14 and the male cap threads 46” and the corresponding threads of the receiver. EX1007, ¶[0043]. These teachings, along with a POSA’s knowledge relating to closure top bottoms discussed above, *supra* Section VI.B.2.a, would have motivated a POSA to incorporate a flat bottom with an annular outer edge (under either construction) on the closure of the ’477 Publication with an unthreaded surface between the closure thread and the closure bottom. *See* EX1007, ¶¶[0043], [0049]; *supra* Section VI.B.2.a.

211. 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 (with or without modifications in view of Boschert) and the closure of Kirschman. In making this combination, it would have been obvious to POSA to add any of the disclosed locking aids to the closure

of the '477 Publication, at least based on the benefits of each locking aid as taught by Kirschman. In particular, a POSA implementing the combination of the closure of the '477 Publication and the closure of Kirschman would have been motivated to modify the closure disclosed by the '477 Publication by retaining the various thread types discussed in the '477 Publication, each with a curvate leading face, and adding the closure locking aids disclosed by Kirschman, including Kirschman's unthreaded segment between the thread start(s) and the closure bottom (i.e., Kirschman's frusto-conical surface) and flat bottom surface with a downwardly projecting ring (that also has a flat bottom surface and an annular outer edge under my alternative construction).

212. 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 '646 Patent that a closure that includes a flat bottom surface with a downwardly projecting ring provided advantages for engaging a rod and providing enhanced fixation between a closure and a rod and could be successfully used in closure tops. Indeed, the '477 Publication itself indicates that the closure top could have a flat bottom with a ring projecting below the thread starts. *Supra* ¶186. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for machining Kirschman's

flat-bottom closure with a downwardly projecting ring were well known and readily available and already in use in multi-axial pedicle screws.

B. Motivation to Combine the '477 Publication with Johnson (with or without Kirschman and/or Boschert)

213. In my opinion, a POSA implementing the closure top and receiver taught by the '477 Publication, with or without the modification of the closure in view of Kirschman and/or Boschert, before the priority date would have looked to Johnson's teachings of the advantages of providing breakoff arm extensions for use with pedicle screws. In particular, a POSA would have been motivated to add breakoff arm extensions to an existing system at least based on the benefits of such breakoff arm extensions as taught by Johnson.

214. Like the '477 Publication, Kirschman, and Boschert, Johnson is directed to a medical implant device that receives a longitudinal connecting member, such as a rod. EX1008, Abstract. As in the '477 Publication, the bone screw of Johnson has a U-shaped open receiver that captures a rod when a closure top is threaded into it. *See supra* Section VIII.D. In my opinion, a POSA would have been motivated to add breakoff extension arms to an existing system at least based on the benefits of breakoff extensions in multi-axial pedicle screws as taught by Johnson, *id.*, and as was otherwise known in the art, *supra* Section VI.B.2.c.

215. For example, Johnson teaches that breakoff extension arms provide the benefit of simplifying the introduction of an elongate member or rod. Johnson

discloses that, “[w]hen the surgeon wishes to insert an elongated member 220 into receiver member 212, he or she need not bend it or use a special reducing tool to insert it into the lower end of a receiving channel. Rather, he or she places a portion of the elongated member 220 into channel 254 in upper portion 212*b* of receiver member 212.” EX1008, ¶[0055]. Johnson discloses that a compression member is then “thread into threads 256, forcing elongated member 220 further down in channel 254” so that the “elongated member 220 is forced all the way through upper portion 212*b*, into lower portion 212*a*, and against a crown member and/or anchor member in chamber 228.” *Id.* Johnson also discloses that “[o]nce separate, upper portion 212*b* may be removed from the surgical site and discarded.” *Id.*, ¶[0056]. Thus, based on these teachings, a POSA would have recognized the benefits of including breakoff extension arms in an existing device, including easier delivery of a rod while maintaining a low-profile device, and would have been motivated to use this feature with the ’477 Publication or the combination of the ’477 Publication and Kirschman and/or Boschert. *See also, supra* Section VI.B.2.c.

216. 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 ’646 Patent that breakoff 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.c. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for machining breakoff extension arms were well known and readily available. *See id.*

217. Moreover, a POSA would have been motivated to combine the '477 Publication, with or without the modification of the closure in view of Kirschman and/or Boschert, with Johnson 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.c.

C. Motivation to Combine the '477 Publication with Boschert (with or without Kirschman and/or Johnson)

218. In my opinion, it would have been obvious to a POSA to combine the teachings of the '477 Publication, with or without modifications in view of Kirschman or Johnson, with the double lead thread of Boschert before the priority date of the '646 Patent.

219. Like the '477 Publication, Boschert is in the exact same field as the '646 Patent—the design of polyaxial pedicle screw and rod implant systems to treat spinal column disorders. *See supra* Section VIII.B. 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.” EX1005, ¶[0007]; *see also id.*, Abstract, ¶[0025], ¶[0027]. The generic “medical implant” shown for use with the claimed closure is a polyaxial bone screw with a U-shaped receiver. *Id.*, ¶[0025], Figs. 5, 6. Boschert teaches a polyaxial pedicle screw including a U-shaped receiver for capturing a rod once its opening has been closed with a setscrew. EX1006, 6:20-24, Fig. 1. Boschert further teaches advantages provided by certain features of closure tops (setscrews) used with polyaxial pedicle screws. In particular, Boschert discloses that it would be advantageous to design closure tops with a double lead in order “to start more easily than with a single lead,” *Id.*, 7:21-23, and discloses symmetrical threads on the receiver to mate simultaneously with the double-lead threads on the setscrew, *id.*, Figs. 3, 15. Thus, based on these teachings, a POSA would have recognized the benefits of including a dual lead on an existing closure (such as the closure disclosed by the ’477 Publication, with or without modifications in view of Kirschman), including starting more easily, as disclosed in Boschert, as well as balancing rotation forces and speeding insertion, as was well-known in the art, *supra*, Section VI.B.1.a.

220. Boschert also expressly contemplates potential modifications to its disclosed closure, stating that “[t]he embodiments of the locking arrangements disclosed herein (e.g., the set screw 70[]) are merely examples of types of locking arrangements that can be used. The locking arrangements can include any

mechanism adapted to provide an axial locking force on the rod 60.” EX1006,7:58-62. Thus, based on these teachings, a POSA would have recognized the benefits of using dual-start threads of Boschert in combination with any of the various thread types discussed in the ’477 Publication, including the curvate leading face taught by the ’477 Publication, including easing thread insertion, reducing thread deformation, and eliminating sharp edges. *Supra* Section VI.B.1.b.

221. 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 Boschert’s disclosure of a closure with double lead threads and symmetrical threads on the receiver. In particular, a POSA implementing the closure of the ’477 Publication, with or without modifications in view of Kirschman, would have looked to the teachings of Boschert regarding the advantages of a closure top with a double lead and symmetrical threads on the receiver to mate simultaneously with double-lead threads on a setscrew. In making this combination, a POSA would have been motivated to use the dual-start threads of Boschert in combination with any of the various thread types discussed in the ’477 Publication, in order to obtain the known advantages of dual start threads for further easing thread alignment, balancing rotational forces, and speeding insertion time. *Supra* Section VI.B.1.a. Further, in making this combination, a POSA

would have maintained the curvate leading faces of the '477 Publication on each of the dual start threads in order to obtain their known advantages for further easing insertion, reduce thread deformation, and reducing sharp edges. *Supra* Section VI.B.1.b. The resulting closure top would thus have dual-lead threads, each with a curvate leading face, that simultaneously mate with matching threads on the receiver.

222. 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 '646 Patent that double lead threads provided these advantages and could be successfully used in closure tops. *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, readily available, discussed in thread standards, and manufacturing techniques were described in machining handbooks. *Id.*

X. SPECIFIC OPINIONS RELATING TO GROUNDS FOR UNPATENTABILITY.

A. Ground 1: Claims 1-2, and 4-9 Are Anticipated or Obvious in View of the '477 Publication.

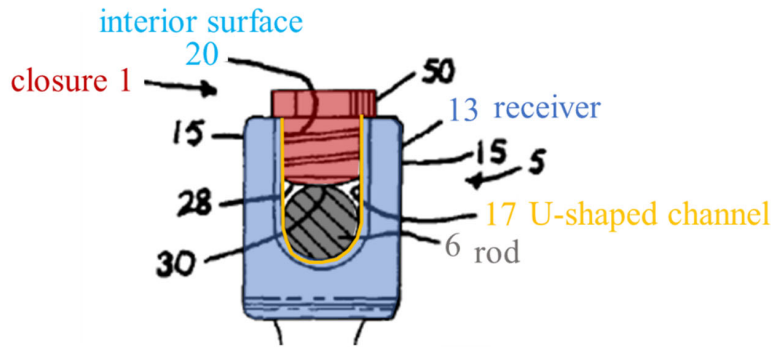
1. Claim 1

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

223. To the extent the preamble is limiting, in my opinion the '477 Publication discloses 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].

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

224. In my opinion, the '477 Publication discloses this limitation. The '477 Publication discloses that “receiver 13 has a pair of



Ex. 1005, Fig. 6

spaced and generally parallel arms 15 that form an open generally U-shaped channel 17 therebetween that is open at distal ends of the arms 15.” *Id.*, ¶¶[0026], [0039]. Further, the '477 Publication discloses that the arms of the receiver “each include radially inward or interior surfaces 20 that have a discontinuous guide and advancement structure mateable with cooperating structure on the closure 1.” *Id.*, ¶¶[0026], [0039]; Figs. 5, 6. A POSA would have understood that the guide and advancement structure was discontinuous because it was interrupted by a channel.

225. In my opinion, a POSA would have understood that the interior surfaces of the receiver arms with the guide and advancement structures are located in the upper portion of the receiver, as least because the closure top is threaded into the receiver from the top (upper portion) of the receiver and does not advance past the mid-point of the receiver, as shown in Fig. 6 above. In addition, a POSA would have understood that the threads on interior surfaces 20 extend to the top surface of the “distal ends of the arms 15,” such that the corresponding closure

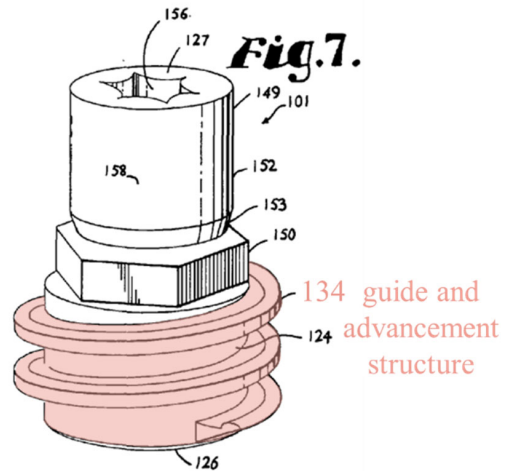
top threads can enter into these threads at the top surface of the arms as the closure is threaded down into the top of the receiver. *See, e.g., id.*, Fig. 6. A rod 6 is captured in the U-shaped channel of the receiver by the closure top, as shown above in Fig. 6. *Id.*, ¶¶[0025], [0039].

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

226. In my opinion, the '477 Publication discloses 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.” *Id.*, Abstract, ¶[0002], Fig. 6. A POSA would have understood that “closure” and “plug” are interchangeable terms, as those terms were commonly used in the art to refer to the same structure. 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]. Thus, a POSA would have understood that the closure is positioned within the upper portion of the receiver, as further explained above. *Id.*, Fig. 6. The '477 Publication also discloses “*closure* 101 . . . has . . . a central *axis of rotation* C.” *Id.*, ¶¶[0040], [0029].

d. **1[B1]: a continuously helically wound thread form, and**

227. In my opinion, the '477 Publication discloses this limitation. The '477 Publication discloses that “[l]ocated on the cylindrical closure body 124 is a guide and advancement structure 134 mateable with the guide and advancement structure on the inner surfaces of the arms of the bone screw receiver.” *Id.*, ¶[0041]. A POSA would have understood that the disclosed guide and advancement structure of the '477



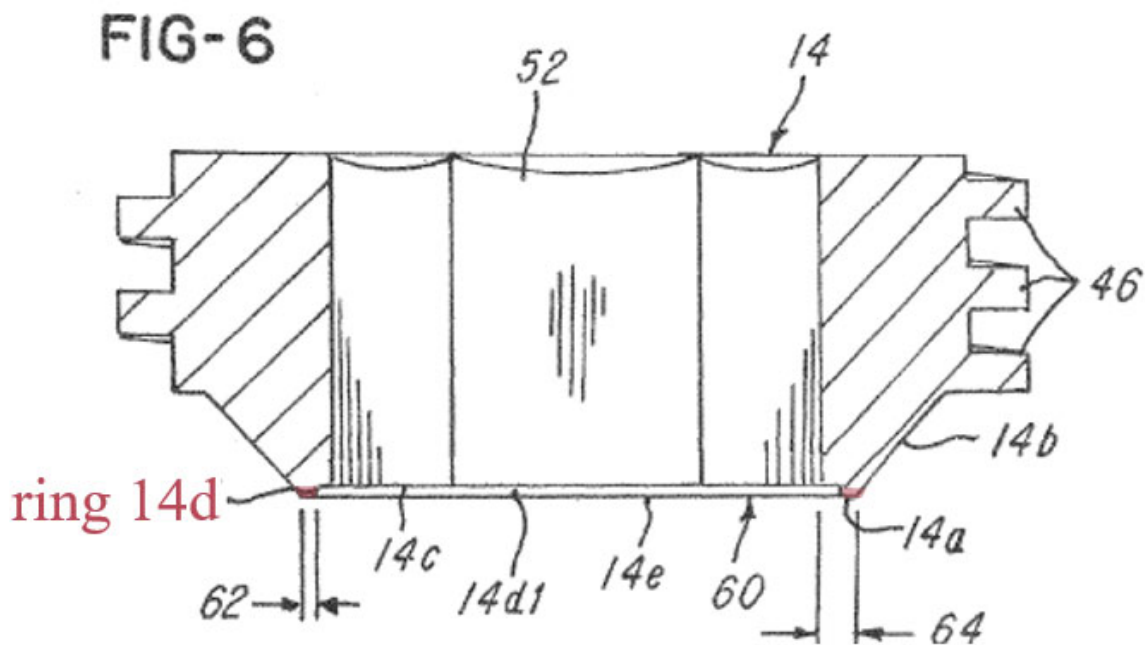
Ex. 1005, Fig. 7

Publication is a continuously helically wound thread, as shown for example in Figs. 7-8. Indeed, at least as of January 10, 2012, “guide and advancement structure” was a commonly known synonym for a helically wound thread form, and Figs. 7-8 show that the helically wound thread is unbroken (i.e., continuous).

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

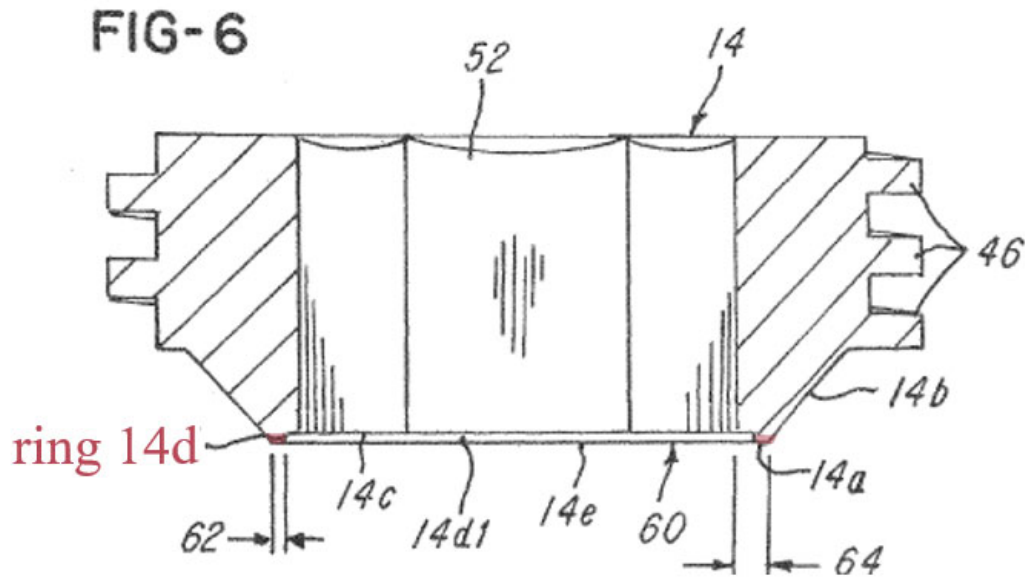
228. In my opinion, the '477 Publication discloses or renders obvious this limitation under any construction. The '477 Publication discloses that, for the first disclosed embodiment, “the *bottom surface may be flat* and may have a central point and a lateral rim.” *Id.*, ¶[0029]. The '477 Publication also makes these same disclosures for its second embodiment. *Id.*, ¶[0040]. The disclosed “lateral rim” is

not pictured, but a POSA would have immediately recognize this feature as a downwardly projecting rim near the periphery of the closure top bottom configured to engage the rod. *See Supra* ¶186. In my opinion, a POSA would have also immediately recognized that the downwardly projecting rim would have been inset from the outer surface of the closure's cylindrical body. For example, as shown in the annotated Figure 6 below, Kirschman discloses a downwardly projecting rim 14d that is inset from the outer surface of the closure's cylindrical body and that "facilitate[es] guiding the cap 14 on the receiver 12 to facilitate aligning the cap 14 and the male cap threads 46 and the leading edge portion 46a" with the threads of the receiver." EX1007, ¶¶[0043], [0049], Fig. 6.

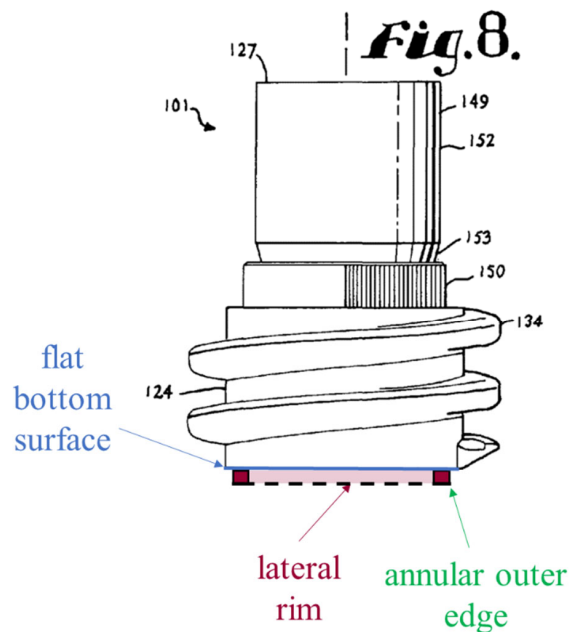


My opinion is reinforced by the '477 Publication's teaching that the lateral rim is an alternative to the domed bottom with a central point "for gripping or penetrating the rod surface." EX1005, ¶¶[0029], [0040]. Therefore, a POSA would have known that the disclosed alternative "lateral rim" would have performed these same functions of gripping or penetrating the rod surface.

229. A POSA reading the '477 Publication would also have been familiar with lateral rims as a common feature included on the bottom of closure tops to grip or penetrate the rod. *See supra* Section VI.B.2.a. For example, as set forth above, Kirschman, *supra* ¶¶92-93, and the '526 Publication, *supra* ¶94, both disclose such a feature. A POSA would further understand that such rims are "lateral" because they are positioned away from the midline of the closure, generally near the periphery of the closure top. *Supra* Section VI.B.2.a. Moreover, a POSA would have understood that a rim that is somewhat inset from the outer surface of the cylindrical body provides an advantage for guiding the closure top into the receiver arms and facilitating thread alignment. *Supra* ¶¶92-93, 201-02. For example, as shown below in annotated Figure 6, Kirschman discloses a rim that is inset from the outer surface of the closure's cylindrical body that "facilitate[es] guiding the cap 14 on the receiver 12 to facilitate aligning the cap 14 and the male cap threads 46 and the leading edge portion 46a" with the threads of the receiver." EX1007, ¶¶[0043], [0049], Fig. 6.



Therefore, the '477 Publication's disclosure of a lateral rim would have immediately brought to mind for the POSA a downwardly projecting ring-like rim near the periphery of the closure top bottom, as depicted below in modified Fig. 8 of the '477 Publication (with the rim shown in cross-section) as a substitution for the domed bottom surface.



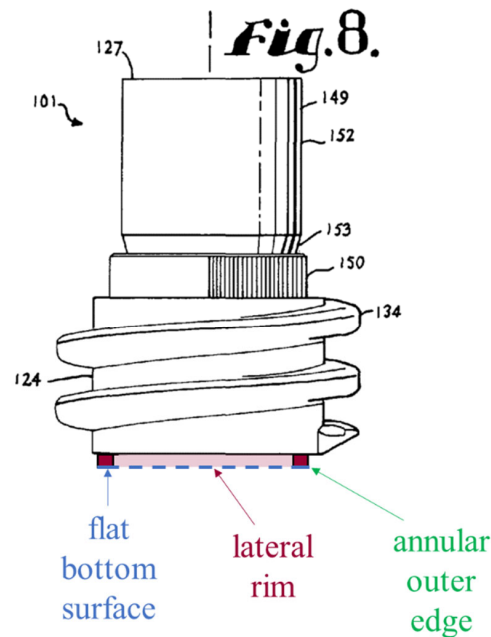
230. If this limitation is construed as an essentially flat bottom surface of the closure top that includes a downwardly projecting rim configured to engage the rod (i.e., my preferred construction), the '477 Publication discloses this feature. The '477 Publication expressly states that the “the bottom surface may be flat” and further states that this surface may include a “lateral rim,” which a POSA would recognize as a downwardly projecting rim configured to engage the rod. EX1005, ¶[0029]. That this disclosed bottom surface may also include a central point is immaterial, as the bottom surface would still be essentially (i.e., substantially) flat.

231. If this limitation is alternatively construed as requiring a flat lowermost surface of the closure top, e.g., the flat bottom of a downwardly projecting rim, with an annular outer edge being the line at the periphery where

that flat bottom surface meets a more vertically oriented surface, e.g., the side surface of a downwardly projecting rim, such a feature is also disclosed or rendered obvious by the '477 Publication, in my opinion.

232. Any lateral rim would necessarily have a thickness, and thus, would necessarily have a bottom surface. A POSA would have been aware that conventional lateral rims for engaging with the rod, such as those described in Kirschman, *supra* ¶¶92-93, and the '526 Publication, *supra* ¶94, have flat bottom surfaces. Indeed, flat bottom surfaces maximize the area of contact between the rim and the rod, and thereby aid the gripping function of a lateral rim. A POSA would also have been aware that some known lateral rims have a pointed bottom surface for penetrating into the rod. *E.g.*, EX1018. Because the '477 Publication does not specify any further details of the disclosed lateral rim, in my opinion a POSA would have known that either a flat or pointed bottom surface of the rim were available options, and therefore would have considered both options to be within the disclosure of the '477 Publication. This opinion is further reinforced by the '477 Publication's recognition that the bottom structures on a closure top can be used to either grip or penetrate the rod. This would have obviously suggested to a POSA a choice of either a flat bottom rim on the set screw for gripping the rod or a pointed bottom rim on the set screw for penetrating the rod. As illustrated below with reference to Fig. 8, the known option of a rim with a flat lowermost surface

includes an annular outer edge (under my alternative construction) at the intersection of the lowermost surface and the side surface of the rim. EX1005, Fig. 8.

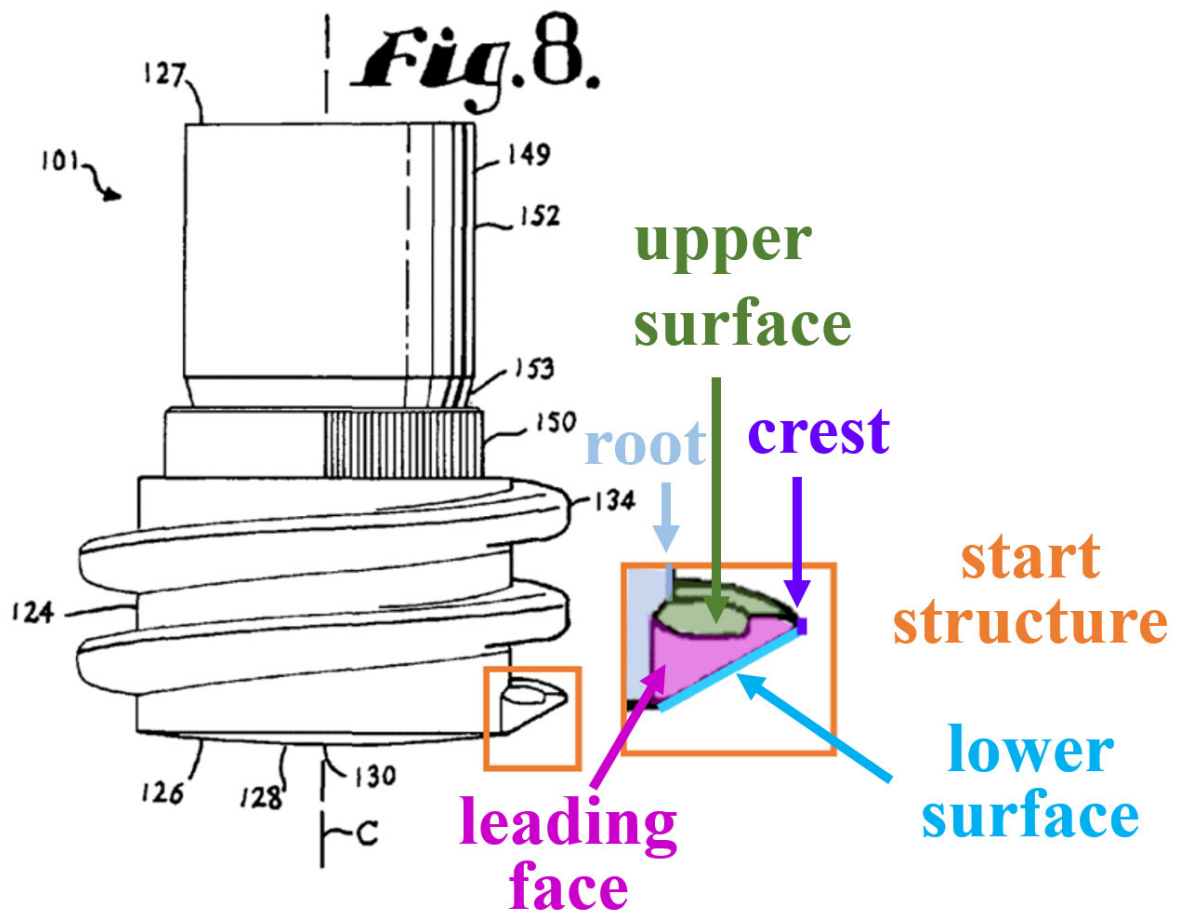


EX1005, Fig. 8.

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

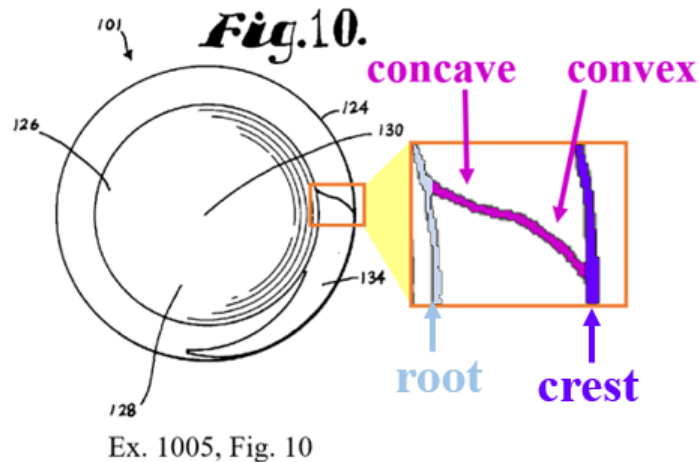
233. In my opinion, the '477 Publication discloses this limitation. The '477 Publication discloses a helically wound thread form on the closure top. That thread, like every thread, has a root and a crest. *See also* EX1005 ¶[0031]; *supra*

¶51. As shown in annotated and enlarged Figure 8 below, the '477 Publication discloses a start structure on the closure thread with an upper surface extending between a root and a crest of the continuously helically wound thread form, the start structure having a leading face extending below the upper surface to a lower surface of the start structure. EX1005, Figs. 7, 8.



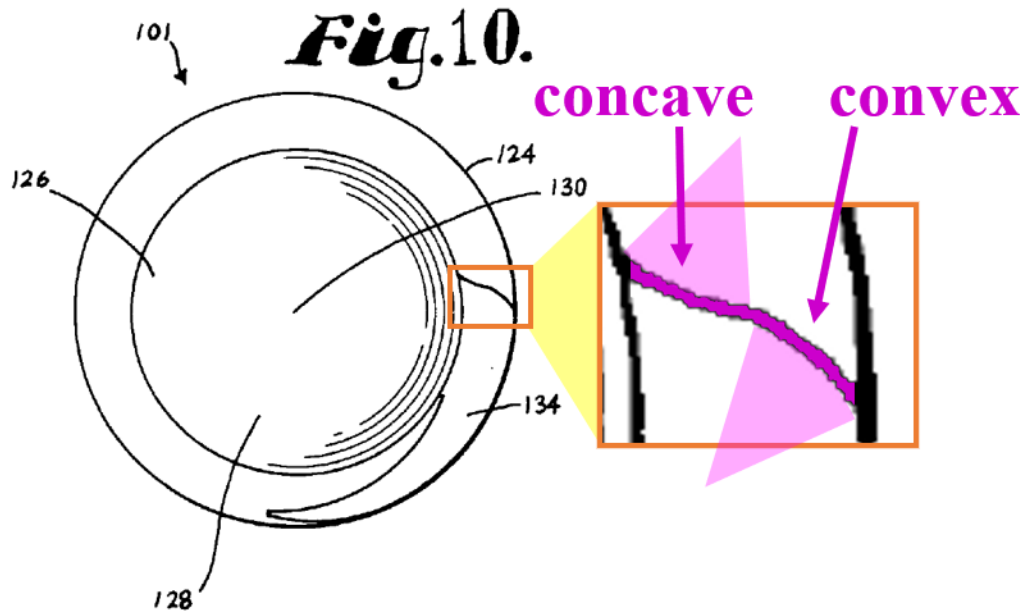
234. In addition, as shown in Figure 10, the leading face of the start structure disclosed in the '477 Publication includes a partial concave surface adjacent the root and a partial convex surface adjacent the crest. *Id.*, Fig. 10. A

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.



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

235. In my opinion, the '477 Publication discloses this limitation. Specifically, as shown in annotated and enlarged Figure 10 below, the partial concave surface adjacent the root and a partial convex surface adjacent the crest are each defined by a radius of curvature that is substantially equal with respect to each other. EX1005, Fig. 10.

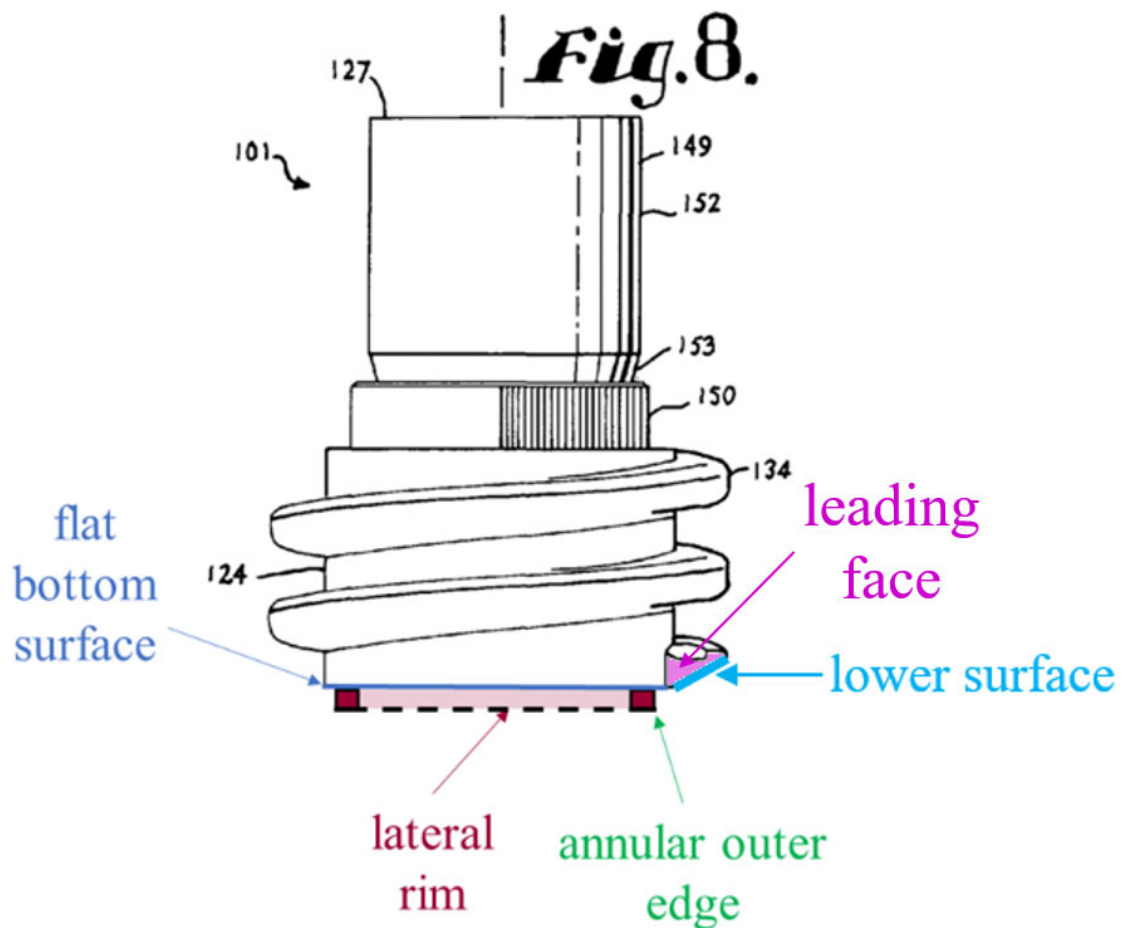


Ex. 1005, Fig. 10

EX1005, Fig. 10. While the numeric radii of curvature are not disclosed in the '477 Publication, the claims of the '646 Patent do not require any numeric radii of curvature. Moreover, in view of the manufacturing process described above (*supra* Section VI.B.1.c), in my opinion, radii of curvature that are substantially equal for each of the concave and convex curves is consistent with the easiest manufacturing processes for the lead face of a thread start structure. Finally, while the comparison of the radii of curvature of the concave surface to the convex surface is possible only via Figure 10 of the '477 Publication, I note that this is the same level of disclosure available in the '646 Patent itself. EX1001, Fig. 5.

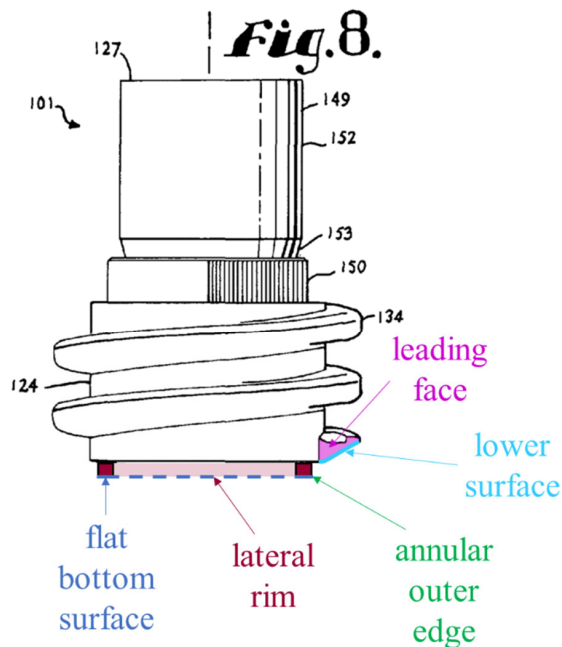
- h. 1[B5]: the lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof.**

236. In my opinion, the '477 Publication discloses or renders obvious this limitation under any construction of the “annular outer edge of the substantially flat bottom surface.” The preferred embodiment pictured in Figs. 7-10 includes a domed bottom, but the '477 Publication discloses that a substantially flat bottom surface with a lateral rim could be used instead. EX1005, ¶[0040]; *supra* ¶ 186. Under my preferred construction, the lateral rim is the annular outer edge. As discussed above, a POSA would have understood that a rim that is somewhat inset from the outer surface of the cylindrical body provides an advantage for guiding the closure top into the receiver arms and facilitating thread alignment. *Supra* ¶¶92-93, 201-02. The lateral rim is thus below, spaced apart from, and not connected to the lower surface of the leading face of the start structure, as illustrated below in a modified version of Figure 8, where such a lateral rim has been added.



EX1005, Fig. 8.

237. Under my alternative construction, the annular outer edge is the outer periphery of the lowermost surface of the lateral rim. Under this alternative construction as well, the annular outer edge remains below, spaced apart from, and not connected to, the lower surface of the leading face of the start structure, as illustrated below in a modified version of Figure 8, where such a lateral rim with a flat lowermost surface has been added.



EX1005, Fig. 8.

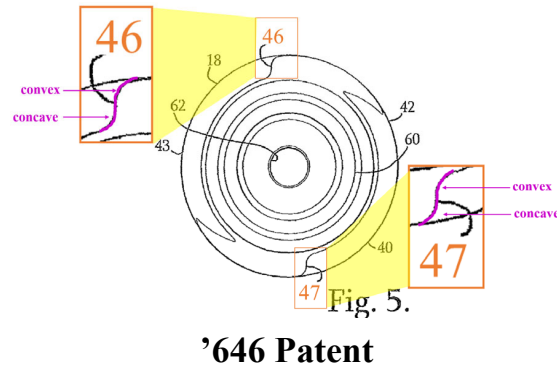
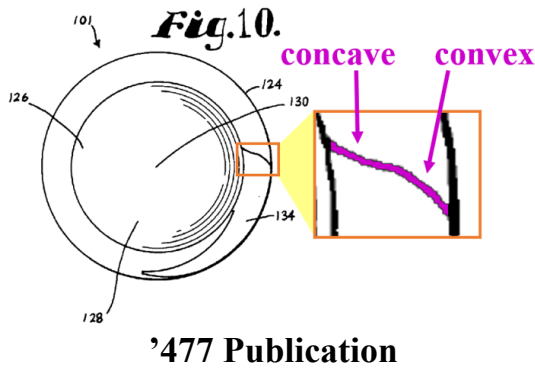
238. Finally, as discussed above, a POSA would know that when using truncated thread starts, the thread start is by definition spaced apart from the bottom of the closure leaving an unthreaded segment of any desired length to guide the closure into the receiver and help align the threads. *Supra* ¶¶92-93, 201-02. A POSA would have understood that when designing a closure top for use in an open receiver of a bone screw, there were a limited number of options for the spacing of the thread starts relative to the closure top's bottom surface, including having the threads flush with the closure top's bottom surface and having the threads spaced apart from the closure top's bottom surface, or truncated. *Id.* Each of these limited, known design options for the spacing of the threads on a closure top had

been successfully used with a closure top. *See id.* Therefore, a POSA designing a pedicle screw system would have known that closure threads that were spaced apart from the closure top's bottom was a design choice from among a limited number of options each with a reasonable expectation of success, and thus it would have been obvious to try a closure with threads spaced apart from the closure top's bottom.

239. Accordingly, in my opinion the '477 Publication anticipates or renders obvious every element of Claim 1.

2. Claim 2

240. All of the limitations of Claim 2 are recited in Claim 1, except Claim 2 further recites: **[B6]** “wherein the partial concave surface tangentially blends with the partial convex surface.” In my opinion the '477 Publication discloses this limitation. As discussed above, the '477 Publication discloses partial concave and convex surfaces of the leading face in Figure 10. Figure 10 also shows that the convex curve and the concave curve of the leading face touch each other at a single point and are smoothly merged together at that point that is the tangent of the two curves. Therefore, a POSA would have recognized that these two curves are tangentially blended.



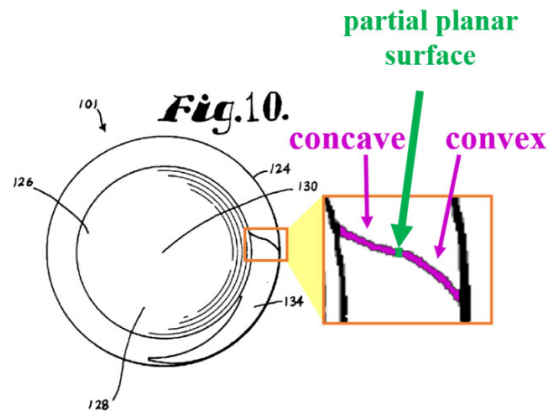
EX1005, Fig. 10; EX1001, Fig. 5. Notably, this is the same level of disclosure available in the '646 Patent itself with respect to tangential blending. *See* EX1001, Fig. 5.

241. Accordingly, in my opinion the '477 Publication anticipates or renders obvious every element of Claim 2.

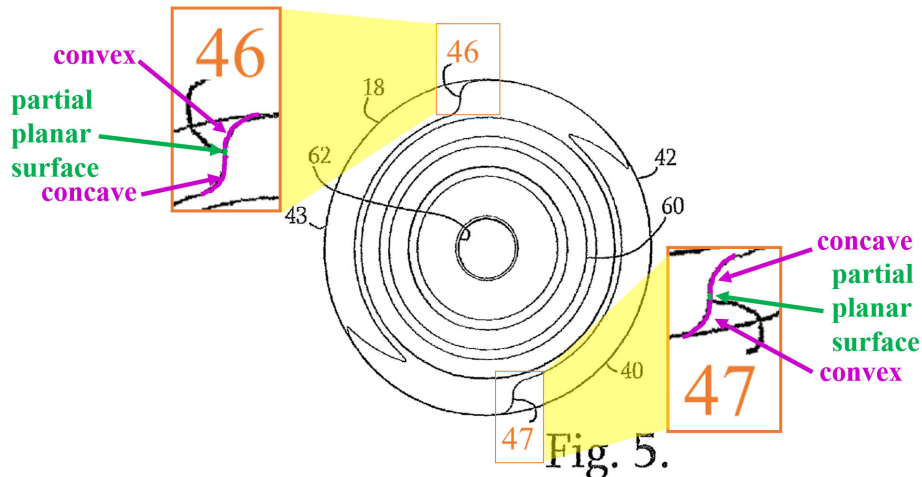
3. Claim 4

242. All of the limitations of Claim 4 are recited in Claim 1, except Claim 4 further recites: [B8] “wherein the leading face of the start structure includes at least a partial planar surface.” In my opinion the '477 Publication discloses or renders obvious a leading face that includes a partial planar surface, at least at the point of inflection between the partial concave and partial convex surfaces, as shown below with reference to Figure 10. At this location the convergence of the concave curve and the convex curve result in a length of the leading face without any substantial curvature. Thus, at this location, a POSA would have recognized a portion of the leading face that is approximately flat in all directions.

'477 Publication



'646 Patent



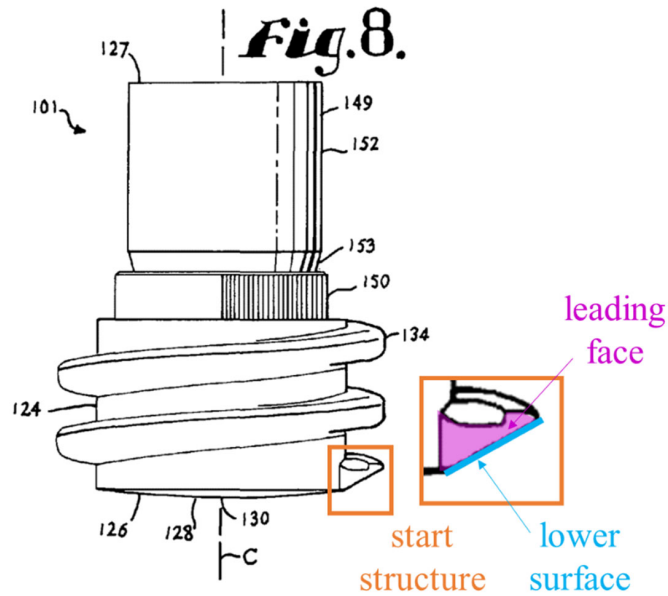
EX1005, Fig. 10; EX1001, Fig. 5. Notably, this is the same level of disclosure available in the '646 Patent itself with respect to a partial planar surface. See EX1001, Fig. 5. Moreover, from the standard manufacturing techniques for a truncated thread cut, *see supra* Section VI.B.1.b, it would have been obvious to a POSA to use any tool path that transitions from one curve to the opposite curve, including paths that transition immediately and paths that include an elongated straight segment between curves. In my opinion, a POSA would have understood that there was no particular advantage to any of these tool path choices, so long as

a concave curve is used near the root and a convex curve is used near the crest. Moreover, a POSA would have understood that, as Higbee disclosed, a truncated thread end “may be cut off on an oblique plane . . . or cut off square . . . or rounded[.]” EX1015, 1:92-94.

243. Accordingly, in my opinion the ’477 Publication anticipates or renders obvious every element of Claim 4.

4. Claim 5

244. All of the limitations of Claim 5 are recited in Claim 1, except Claim 5 further recites: **[B9]** “wherein the lower surface of the start structure includes a bottom beveled surface.” In my opinion, the ’477 Publication discloses this feature. In particular, the ’477 Publication discloses that the lower surface of the start structure is a beveled (i.e., sloped) surface, rather than a squared one, as shown in enlarged and annotated Figure 8 below such that the lower outside corner of the normal thread profile has been removed.



EX1005, Fig. 8. Notably, this is the same level of disclosure available in the '646 Patent itself with respect to a bottom beveled surface. See EX1001, Fig. 3.

245. Accordingly, in my opinion the '477 Publication anticipates or renders obvious every element of Claim 5.

5. Claim 6

246. All of the limitations of Claim 6 are recited in Claim 1, except Claim 6 further recites: **[B10]** “wherein the upper surface of the continuously helically wound thread form of the threaded plug slopes rearward from the root towards the crest.” In my opinion, this limitation refers to a reverse angle thread form. In my opinion, the '477 Publication discloses this limitation. In particular, the '477 Publication discloses that the thread form of the plug can be a reverse angle thread. EX1005 ¶[0041]. As described in the '477 Publication: “In a *reverse angle thread*,

the trailing surface 44 from the root 38 to the crest 40 *extends at an angle rearwardly* from a perpendicular line relative to the axis B. Typically, the trailing surface 44 is at an angle between 1 and 20 degrees relative to such a perpendicular.” *Id.* ¶[0031]. In my opinion, a POSA would have understood that “trailing surface 44” is the upper surface of the continuously helically wound thread form, because it is trailing in the sense that it faces away from the direction of advancement of the closure top (i.e., upward toward the top of the closure top). Because trailing surface 44 is part of a reverse angle thread, a POSA would have understood that this surface slopes rearwardly (i.e., outwardly and upwardly) from the root toward the crest.

247. Accordingly, in my opinion the ’477 Publication anticipates or renders obvious every element of Claim 6.

6. Claim 7

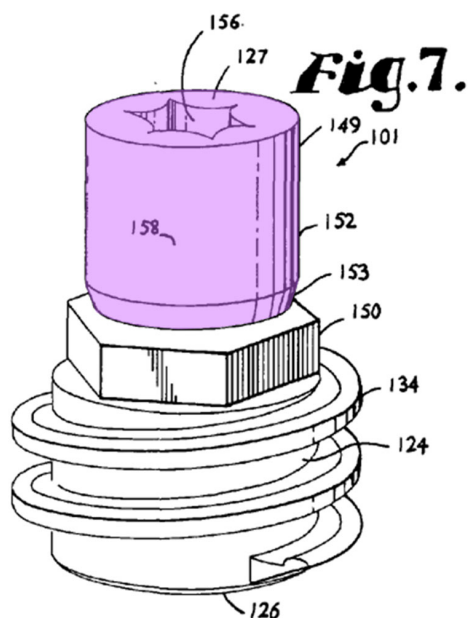
248. All of the limitations of Claim 7 are recited in Claims 1 and 6, except Claim 7 further recites: **[B11]** “wherein a slope of the upper surface is at an angle greater than five degrees measured between a line drawn perpendicular to the axis of rotation of the plug and a tangent line drawn tangent along the upper surface.” In my opinion the ’477 Publication discloses this limitation. In particular, the ’477 Publication discloses a reverse angle “*between 1 and 20 degrees*,” which includes an angle greater than five degrees. EX1005, ¶[0031]. In my opinion, a POSA

would have understood this description of the trailing surface of a reverse angle thread as being between 1 and 20 degrees to describe the slope of the upper surface measured between a line drawn perpendicular to the axis of rotation of the plug and a tangent line drawn tangent along the upper surface. In addition, the disclosure of angles between 1 and 20 degrees, includes numerous angles greater than five degrees.

249. Accordingly, in my opinion the '477 Publication anticipates or renders obvious every element of Claim 7.

7. Claim 8

250. All of the limitations of Claim 8 are recited in Claim 1, except Claim 8 further recites: **[B12]** “wherein the plug is a breakoff plug.” In my opinion the '477 Publication discloses this limitation. In particular, the '477 Publication discloses that the closure may include a breakoff portion designed to break away from the closure “subsequent to a predetermined torque being applied.” EX1005 ¶[0042]; *id.* Figs. 5-8. As shown below, Figure 7 illustrates the breakoff portion of the closure top. *Id.*, Fig. 7.



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

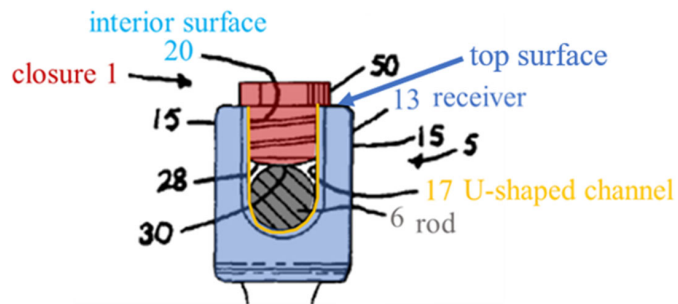
251. Accordingly, in my opinion the '477 Publication anticipates or renders obvious every element of Claim 8.

8. Claim 9

252. All of the limitations of Claim 9 are recited in Claim 1, except Claim 9 further recites: [A1] “wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top

surface of the receiver being formed on the first arm and the second arm.” In my opinion, the ’477 Publication discloses this limitation.

253. 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



Ex. 1005, Fig. 6

receiving a rod 6. EX1005, ¶¶[0007], [0026]-[0038], Figs. 1-6. As seen in Figure 6, the upper half of each arm of the receiver is separated by the channel and the arms 15 “each . . . have a discontinuous guide and advancement structure” on interior surfaces 20. *Id.* ¶[0026]. The guide and advancement structures on the receiver arms mate with a similar structure on closure 1/101 when the closure is rotated. *Id.*, ¶¶[0007], [0029], [0039], 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]. Moreover, Figure 6, above, shows that the top surface of the receiver is formed on both arms.

254. Accordingly, in my opinion the ’477 Publication anticipates or renders obvious every element of Claim 9.

B. Ground 2: Claims 1-2 and 4-9 Are Obvious Based on the '477 Publication in View of Kirschman.

255. As set forth above, it also would have been obvious to a POSA to combine the teachings of Kirschman with the '477 Publication before the priority date of the '646 Patent. *Supra* Section IX.A. Like the '477 Publication, Kirschman is directed to a bone screw with an open U-shaped receiver that receives a rod member and discloses various locking aids to facilitate mating a closure top to the polyaxial screw to capture a rod. EX1007, Abstract, ¶¶[0012]-[0016]. Kirschman recognizes that conventional bone screws are well known in the prior art and proposes several optional “locking aids” that could be added to a conventional system. EX1007, Abstract (teaching a cap that “has at least one locking aid in the form of at least one of a tactile feedback, a visual feedback or an enhanced fixation between the cap and a rod that is received in the receiver), ¶¶[0002]-[0013]. A POSA would have been motivated to add each of the disclosed locking aids to an existing system at least based on the benefits of each locking aid as taught by Kirschman.

256. For example, Kirschman's discloses that a ring with a flat lowermost surface and an annular outer edge (under my alternative construction) had advantages for engaging the rod and providing “enhanced fixation” between the cap and the rod would have motivated a POSA to use these features in conjunction with the '477 Publication. *Id.*, ¶¶[0045], [0047].

257. As a further example, Kirschman teaches that an unthreaded segment of the closure top located between the thread starts and the bottom of the closure had benefits for “guiding the cap 14 on the receiver 12 for facilitate aligning the cap 14 and the male cap threads 46,” and the corresponding threads of the receiver would have motivated a POSA to incorporate such a surface between the thread starts and the bottom of the closure top when implementing the teachings of the ’477 Publication. *Id.*, ¶¶[0043], [0049].

258. A POSA would have expected success with each of these combinations because they are all combinations of familiar elements using known methods to yield predictable results, as it was well known to a POSA before the priority date of the ’646 Patent that rings with a flat bottom surface and unthreaded bottom segments provided these advantages and could be successfully used in closure tops. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for manufacturing these features were well known and readily available.

259. As set forth above, *supra* Section X.A, the ’477 Publication already anticipates or renders obvious all limitations of Challenged Claims 1-2 and 4-9. Kirschman’s additional teachings relating to a bottom ring with a flat lowermost surface and an unthreaded segment above the bottom surface of the closure top merely reinforce the benefits of these locking aids, thereby confirming the

obviousness of Challenged Claims 1-2 and 4-9 as set forth below. In my opinion, all limitations of Challenged Claims 1-2 and 4-9 are obvious in view the '477 Publication in view of Kirschman. Below I address the limitations for which Kirschman's disclosures are additive. For all other limitations, my opinions expressed above (that these features were already anticipated or rendered obvious by the disclosures of the '477 Publication) remain and are unaffected by the additional disclosures of Kirschman.

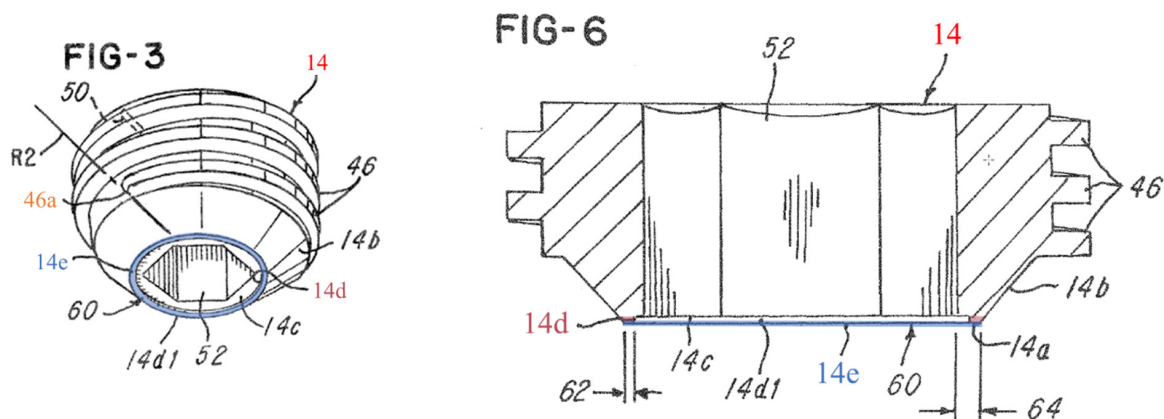
1. Claim 1

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

260. As set forth above, the '477 Publication discloses or renders obvious this limitation under any construction. *Supra* Section X.A.1.e. If, for any reason, this limitation requires a lateral rim positioned near the periphery of the closure top and the disclosure of the '477 Publication were insufficient to anticipate or render obvious a lateral rim positioned near the periphery, then, in my opinion, it would have been obvious to a POSA to modify the '477 Publication's closure top to add a lateral rim positioned near the periphery of the closure top, as disclosed by Kirschman.

261. As discussed above, *supra* ¶¶185-86, 208, the '477 Publication expressly teaches that "it is foreseen" that its closure tops may be modified in

insufficient to render obvious a flat lowermost surface of a ring with an annular outer edge under my alternative construction, it would have been obvious to a POSA to modify the '477 Publication's closure top to add such a feature in view of the disclosures of Kirschman. Kirschman discloses a closure top with a "deformable ring 14d that is monolithically and integrally formed with the cap 14," and that includes a flat bottom surface 14e, as shown in Figures 3 and 6 below. EX1007, ¶¶[0044], [0045]. Kirschman discloses that in "one illustrative embodiment, the monolithic ring comprises a width of between 0.120-0.280 inches." *Id.*, ¶[0045].



263. Further, the edge where the flat bottom surface of the ring meets surface 14d1 is an annular outer edge under my alternative construction, because it is a ring-shaped line where the two planar surfaces join, shown below. *Id.*, Figs. 3, 6.

obvious this limitation because a POSA would not have already known of a lateral rim near the periphery of the closure top or of a lateral rim with a flat lowermost surface and an annular outer edge, a POSA would have looked to Kirschman as an example of such a lateral rim, and would have learned from Kirschman that such a ring with a flat lowermost and an annular outer edge positioned near the periphery of the closure top was advantageous for engaging the rod. In view of Kirschman's disclosures, in my opinion, it would have been obvious to modify the closure top disclosed by the '477 Publication to add a flat bottom surface with a downwardly projecting ring (that also has a flat bottom surface and an annular outer edge under my alternative construction), as taught by Kirschman, at least because the '477 Publication expressly invites modifications to its closure top, including a flat surface and a lateral rim on the closure top's bottom surface, and because Kirschman teaches that its closure top's bottom provides the benefit of enhanced fixation. *See supra* Section IX.A. In my opinion, the '477 Publication in view of Kirschman renders obvious a closure top having substantially flat bottom surface with an annular outer edge, the substantially flat bottom surface configured to engage a rod under any possible construction.

266. Moreover, to the extent the '477 Publication does not anticipate or render obvious this limitation, in my opinion, based on the above disclosures and in view of a POSA's knowledge of various closure top bottoms and the design

need for a closure to securely lock a rod, a POSA would have been motivated to modify the '477 Publication's closure top with the lateral rim and flat closure bottom disclosed by Kirschman at least because (1) it would have been nothing more than the simple substitution of one known element (such as the domed closure bottom in the '477 Publication) for another (a lateral rim and flat closure bottom as disclosed by Kirschman) to obtain a predictable result (securely locking a rod); (2) it would have been the mere application of a known technique (use of a lateral rim and flat closure bottom as disclosed by Kirschman) to a known device (the closure top of the '477 Publication) to yield a predictable result (securely locking a rod); and (3) there was a known design need for a closure to securely lock a rod and a finite number of identified, predictable solutions (a flat closure bottom, a domed closure bottom, a central point on the closure bottom, and a lateral rim with a flat closure bottom) that were known to a POSA and within their technical grasp. Accordingly, the '477 Publication and Kirschman render obvious this limitation.

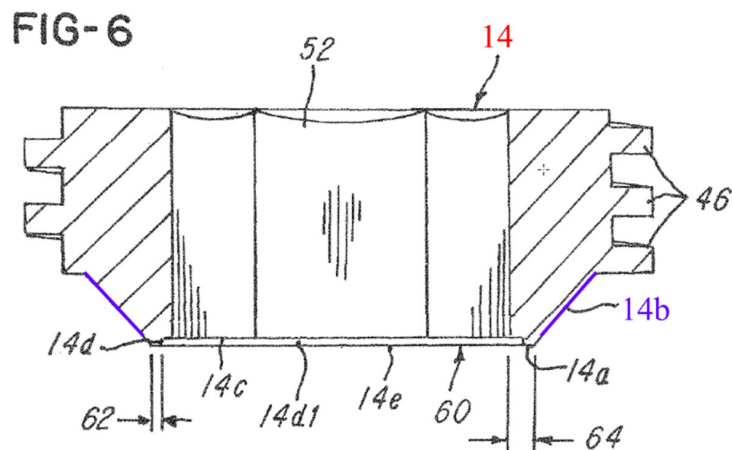
- b. 1[B5]: the lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof.**

267. As set forth above, in my opinion, the '477 Publication discloses and renders obvious this limitation under any construction of “annular outer edge of the substantially flat bottom surface.” *See* Section X.A.1.h. If, for any reason, the

'477 Publication is insufficient to anticipate or render obvious this limitation, then, in my opinion, it would have been obvious to a POSA to modify the '477 Publication's closure top to add a lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge, as discussed by Kirschman.

268. As discussed above, *supra* ¶¶185-86, 208, the '477 Publication expressly teaches that “it is foreseen” that its closure tops may be modified in numerous ways, including a closure top where the bottom surface is “flat” and that includes a “lateral rim.” EX1005, ¶¶[0029], [0040]. Because the '477 Publication

does not actually depict such a lateral rim, a POSA would naturally have looked to other prior art references that did teach a lateral rim on the bottom of

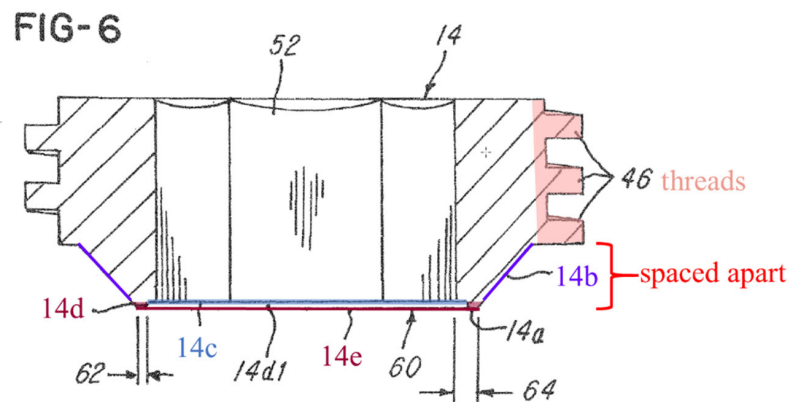


a closure top. Kirschman discloses one such lateral rim and further substantiates the obviousness of spacing the thread start structures above the annular outer edge of the substantially flat bottom surface. Kirschman discloses a frusto-conical surface 14b below the closure top threads and above the substantially flat bottom surface at the bottom of the closure top. EX1007, Fig. 6. Kirschman discloses that

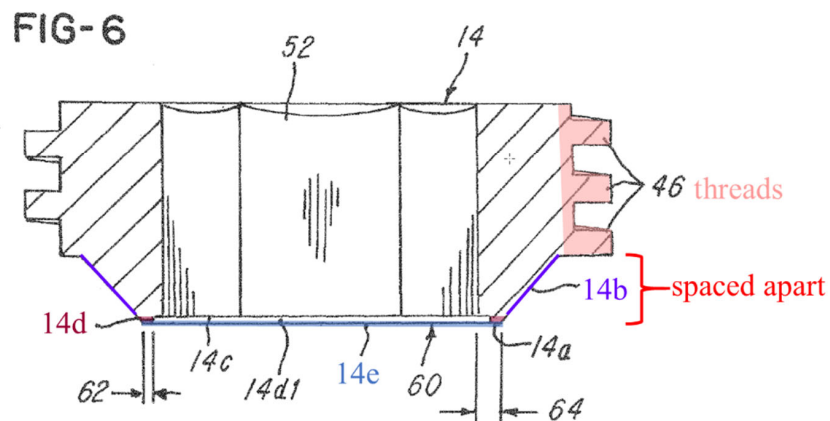
this unthreaded surface “14*b* of the cap 14 has a surface that is adapted to provide the lock aid by facilitating guiding the cap 14 on the receiver 12 to facilitate aligning the cap 14 and the male cap threads 46 and the leading edge portion 46*a*” with the threads of the receiver. *Id.*, ¶¶[0043], [0049]; *see, e.g., id.*, ¶[0038] (describing the benefits of providing “tactile feedback” so that a “surgeon or user can feel the cap 14 drop down into the receiver 12 when the leading edge portion 46*a* is aligned with the cut-out area 49”). Therefore, Kirschman specifically teaches that it is advantageous to space the start structures apart from and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof.

269. As shown below in the annotated versions of Figure 6 below, regardless of whether the substantially flat bottom surface is (1) the end 14*c* of the cap 14 (with rim 14*d* and its bottom surface 14*e* comprising the annular outer edge), or (2) surface 14*e* of the lateral rim 14*d*, Kirschman’s lower surface of the thread is spaced above and apart from the annular outer edge of the substantially flat bottom surface of the plug at least by a distance of the surface 14*b*. *Id.*, Fig. 6.

(1)



(2)



270. Regardless of the construction, it would have been obvious to a POSA to modify the closure top of the '477 Publication to include starts of the closure threads that are spaced above the annular edge of the substantially flat bottom surface of the closure top, as disclosed by Kirschman, at least because the '477 Publication expressly invites modifications to its closure top and because Kirschman teaches that its closure top's bottom provides the benefit of enhanced fixation and facilitating alignment of its cap and cap threads with the threads of a receiver.

271. 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 '646 Patent that a closure that includes a flat bottom surface with a downwardly projecting ring provided advantages for engaging a rod and providing enhanced fixation between a closure and a rod and could be successfully used in closure tops. Indeed, the '477 Publication itself indicates that the closure top could have a flat bottom with a ring and teaches providing space between the bottom surface and the thread starts. *Supra* ¶¶185-86, 208. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for machining Kirschman's flat-bottom closure with a downwardly projecting ring were well known and readily available and already in use in multi-axial pedicle screws.

C. Ground 3: Claims 10 and 11 Are Obvious Based on the '477 Publication (Alone or in Combination with Kirschman) in View of Johnson.

272. As set forth above, it also would have been obvious to a POSA to combine the teachings of Johnson with the '477 Publication either alone or in further combination with Kirschman before the priority date of the '646 Patent. *Supra* Section IX.C. Like the '477 Publication and Kirschman, Johnson is directed to a polyaxial bone screw with a U-shaped receiver that receives a rod member. EX1008, Abstract; *supra* Section VIII.D. In my opinion, a POSA would have been

motivated to add breakoff extension arms to an existing system at least based on the benefits of breakoff extensions as taught by Johnson.

273. For example, Johnson teaches that breakoff extension arms provide the benefit of simplifying the introduction of an elongate member or rod. Johnson discloses that, “[w]hen the surgeon wishes to insert an elongated member 220 into receiver member 212, he or she need not bend it or use a special reducing tool to insert it into the lower end of a receiving channel. Rather, he or she places a portion of the elongated member 220 into channel 254 in upper portion 212*b* of receiver member 212.” EX1008, ¶[0055]. Johnson discloses that a compression member is then “thread into threads 256, forcing elongated member 220 further down in channel 254” so that the “elongated member 220 is forced all the way through upper portion 212*b*, into lower portion 212*a*, and against a crown member and/or anchor member in chamber 228.” *Id.* Johnson also discloses that “[o]nce separate, upper portion 212*b* may be removed from the surgical site and discarded.” *Id.*, ¶[0056]. Thus, based on these teachings, a POSA would have recognized the benefits of including breakoff extension arms in an existing device, including easier delivery of a rod while maintaining a low profile device, and would have been motivated to use this feature in the receiver of the ’477 Publication, either alone or in combination with Kirschman.

274. 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 '646 Patent that breakoff extension arms provided these advantages and could be (and had been) successfully used in medical implant devices. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for machining breakoff extension arms were well known and readily available. Moreover, a POSA would have been motivated to combine the teachings of Johnson with the '477 Publication, Boschert, and Kirschman 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 VI.B.2.c.

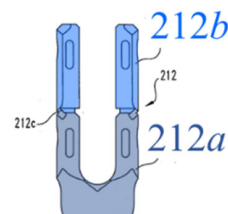
275. As set forth above, the '477 Publication, either alone or in combination Kirschman, anticipates or render obvious every limitation of challenged Claims 1-2, and 4-9. Claims 10 and 11 add the additional element of breakoff arm extensions, but this additional element was well known in the prior art, including as taught by Johnson. Therefore, below I address why the additional elements of Claims 10 and 11 are rendered obvious by Johnson. For all other limitations, my opinions expressed above (that these features were already disclosed or rendered obvious by the disclosures of the '477 Publication, either

alone or in combination with Kirschman) remain and are unaffected by the additional disclosures of Johnson.

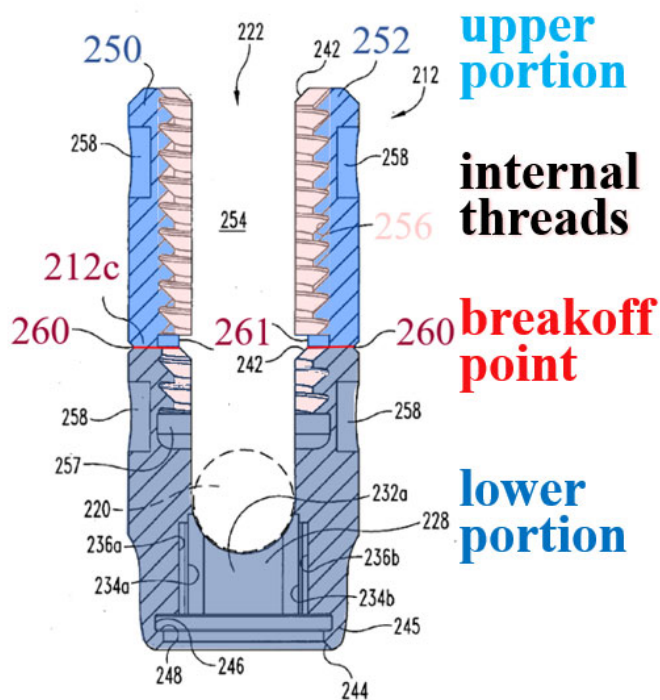
1. Claim 10

276. All of the limitations of Claim 10 are recited in Claims 1 and 9, except Claim 10 further recites: [C] “wherein the first arm includes a first breakoff extension coupled to the top surface of the first arm, and the second arm includes a second breakoff extension coupled to the top surface of the second arm, each of the first and second breakoff extensions including an inner surface having a discontinuously helically wound thread form, the discontinuously helically wound thread form of the first breakoff extension configured to cooperate with the discontinuously helically wound thread of the first arm, and the discontinuously helically wound thread form of the second breakoff extension configured to cooperate with the discontinuously helically wound thread of the second arm to rotatably transfer the plug therebetween prior to the first and second breakoff extensions being separated from the first and second arms, respectively.” In my opinion, Johnson renders this additional limitation obvious when its disclosures are considered in view of the ’477 Publication, either alone or in combination with Kirschman.

277. Johnson discloses a receiver member with breakoff extensions. In particular, Johnson discloses receiver



member 212 that “has a lower portion 212*a* and an upper portion 212*b* separated by a thinned section 212*c*.” EX1008, ¶[0051], Fig. 10. As seen in Figure 12 below, Johnson discloses that “internal threads 256 are formed in branches 250, 252 through substantially the entire length of upper portion 212*b* and into lower portion 212*a*.” *Id.* ¶[0052]; Fig. 12. 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 212*b* to lower portion 212*a*” so that a compression member “can be inserted into upper portion 212*b* and moved down to lower portion 212*a*.” *Id.*, ¶[0053]. Johnson also discloses that a compression member is “threaded into threads 256, forcing elongated member 220 further down in channel 254” so that the “elongated member 220 is forced all the way through upper portion 212*b*, into lower portion 212*a*, and against a crown member and/or anchor member in chamber 228.” *Id.*, ¶[0055]; Fig. 12.



278. As also shown in the annotated Figure 12 above, Johnson discloses a first breakoff extension coupled to the top surface of the first arm 250 and a second breakoff extension coupled to the top surface of the second arm 252. Each of the breakoff extensions include an inner surface having a discontinuously helically wound thread form 256 that cooperate with the discontinuously helically wound thread form of the respective arm to rotatably transfer the plug prior to the first and second breakoff extensions being separated from the first and second arms.

279. In my opinion (as discussed above, *see* Section IX.B), based on the above disclosures, when implementing the '477 Publication (either alone or in further combination with Kirschman), a POSA would have been motivated to use a first arm that includes a first breakoff extension coupled to the top surface of the

first arm, and a second arm that includes a second breakoff extension coupled to the top surface of the second arm, each of the first and second breakoff extensions including an inner surface having a discontinuously helically wound thread form, the discontinuously helically wound thread form of the first breakoff extension configured to cooperate with the discontinuously helically wound thread of the first arm, and the discontinuously helically wound thread form of the second breakoff extension configured to cooperate with the discontinuously helically wound thread of the second arm to rotatably transfer the plug therebetween prior to the first and second breakoff extensions being separated from the first and second arms, respectively, as taught by Johnson.

280. A POSA implementing the '477 Publication (either alone or in view of Kirschman) would have been motivated to use break off arm extensions as taught by Johnson at least because of the known benefits explicitly disclosed by Johnson. 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 separate, upper portion 212*b* may be removed from the surgical site and discarded.” *Id.*, ¶[0056]. Thus, based on these teachings, a POSA would have recognized the benefits of including break-off extension arms in an existing device, including easier delivery of a rod while maintaining a low profile device, and would have been motivated to use this feature in the ’477 Publication, either alone or in further combination with Kirschman.

281. In addition, because the ’477 Publication, Kirschman, and Johnson are each directed to spinal implants with threaded connections, a POSA would have understood that the technique of using break off arm extensions, as taught by Johnson, was a technique that had been used to improve spinal implants with threaded connections and would have recognized that it would improve other spinal implants with threaded connections in the same way. Moreover, as I discussed above, using break off extensions in a spinal implant was within the skill of a POSA.

282. Moreover, a POSA implementing the ’477 Publication (either alone or in view of Kirschman) would have been motivated to use break off arm extensions,

as taught by Johnson, because it would have been nothing more than a combination of familiar elements (a spinal implant receiver and break off arm extensions) using known methods that would yield predictable results. In addition, the modification of the '477 Publication to add break off arm extensions, as taught by Johnson, would not have changed the respective functions of either the '477 Publication's device or the break off arm extensions taught by Johnson.

283. A POSA would have been motivated to modify the '477 Publication (either alone or in further combination with Kirschman) due to the demands known to the spinal implant design community at the time, including the demands for devices that facilitated surgeries while maintaining a low profile for the final implant.

284. 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. Moreover, a POSA also would have had a reasonable expectation of success with this combination in view of the significant overlap in subject matter between the '477 Publication and Kirschman on the one hand and Johnson on the other hand.

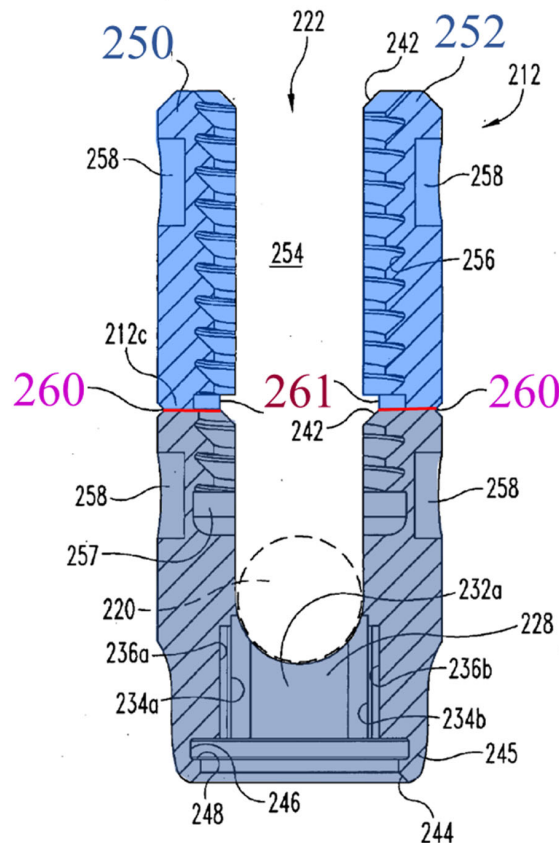
285. Accordingly, the '477 Publication (either alone or in view of Kirschman) and Johnson renders obvious every element of Claim 10.

2. Claim 11

286. All of the limitations of Claim 11 are recited in Claims 1 and 10, except Claim 11 further recites: [C1] “wherein a first outer radiused notch is located at a convergence of the first breakoff extension and the first arm at the top surface thereof, and a second outer radiused notch is located at a convergence of the second breakoff extension and the second arm at the top surface thereof, the first outer radiused notch being located opposite a first inner radiused recess, and the second outer radiused notch being located opposite a second inner radiused recess.” In my opinion, the ’477 Publication (either alone or in view of Kirschman) in view of Johnson discloses this limitation.

287. In particular, as previously discussed, Johnson discloses a rod receiving member with breakoff extensions. *Supra* Section VIII.D. Johnson discloses “thinned section 212c” with an “external indentation or groove 260” and “[a]n interior indentation 261.” EX1008, ¶[0054], Fig. 12. I understand, and a POSA as of the priority date of the ’646 Patent would have understood, that these indentations or grooves are radiused, because Johnson describes section 212c in relation to the diameter and thickness of the helical threads, which are necessarily radiused. *See id.* ¶[0054]. Thus, as shown in the annotated Figure 12 below, Johnson discloses a first outer radiused notch that is located at a convergence of the first breakoff extension and the first arm at the top surface thereof and a second

outer radiused notch that is located at a convergence of the second breakoff extension and the second arm at the top surface thereof, the first outer radiused notch being located opposite a first inner radiused recess, and the second outer radiused notch being located opposite a second inner radiused recess.



288. As discussed above, *see supra* ¶¶ 279-84; *see also supra* Section IX.B, a POSA would have been motivated to combine the disclosure of the '477 Publication (either alone or in combination with Kirschman) and Johnson's teachings of breakoff arm extensions. In my opinion, based on the above disclosures, a POSA implementing the '477 Publication (either alone or in

combination with Kirschman) would have been motivated to use a first outer radiused notch located at a convergence of the first breakoff extension and the first arm at the top surface thereof, and a second outer radiused notch located at a convergence of the second breakoff extension and the second arm at the top surface thereof, the first outer radiused notch being located opposite a first inner radiused recess, and the second outer radiused notch being located opposite a second inner radiused recess, as taught by Johnson.

289. Accordingly, the '477 Publication (either alone or in view Kirschman) and Johnson renders obvious every element of Claim 10.

D. Ground 4: Claims 3, 12-18, and 20 Are Obvious Based on the '477 Publication in View of Boschert.

290. As set forth above, it would have been obvious to a POSA to combine the teachings of Boschert with the '477 Publication before the priority date of the '646 Patent. *Supra* Section IX.C.

291. As set forth above, in my opinion the '477 Publication discloses all of the features of Claim 1, including the claimed leading face with a partial concave surface and a partial convex surface, but does so only on a single thread. In my opinion, when the disclosures of the '477 Publication are combined with Boschert, a POSA would have kept the same leading face structure from the '477 Publication for use with the dual lead threads taught by Boschert. A POSA would have been motivated to use the dual lead structure taught by Boschert in the closure top of the

'477 Publication at least because Boschert teaches that a “double lead [] allow[s] the set screw 70 to start more easily than with a single lead.” EX1006, 7:21-23. Further, from their knowledge of multi-start threads generally, a POSA would have been further motivated to use a double lead thread to balance rotational forces and to speed the insertion process. *Supra* Section VI.B.1.a.

292. A POSA would have maintained the curvate leading thread faces of the '477 Publication at least based on their known advantages of facilitating thread alignment and starting, eliminating sharp surfaces, and reducing thread deformation, *supra* Section VI.B.1.b, and based on Boschert's own suggestion, in Fig. 7, to use truncated thread starts with curvate leading faces. In addition, both the '477 Publication, EX1005, ¶[0047] and Boschert, EX1006, 7:58-8:2, 8:44-49, expressly invite modifications to the disclosed embodiments of polyaxial pedicle screw and rod systems.

293. A POSA would have had an expectation of success with this combination, at least because multi-start threads, and techniques for manufacturing them, were well known in the art. 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 '646 Patent that double lead threads provided these advantages and could be successfully used in closure tops. *Supra* Sections VI.B.1.a, Section VI.B.1.d. Therefore, the closure top resulting from the

combination of the disclosures of the '477 Publication and Boschert would have used the curvate leading face of the '477 Publication as the start structure on each of the two dual start threads taught by Boschert.

294. All other features of the resulting closure top and receiver would have been selected by a POSA from among the known, available options, including those taught in the '477 Publication and Boschert. For example, it would have been obvious for a POSA to use either a breakoff top, as taught by the '477 Publication, EX1005, ¶[0042], or non-breakoff top, as taught by Boschert, EX1006, 7:23-26, based on their known advantages. *Supra* Section VI.B.2.b. It would have been obvious to select any of the many well-known thread types, including helical interlocking forms, buttress threads, reverse angle threads, or square threads as taught by the '477 Publication, EX1005, ¶[0041], based on their known advantages. *Supra* Section VI.B.1.c. It would have been obvious to select any of the known closure top bottoms, including flat bottoms as taught by Boschert, EX1006, Fig. 15, or essentially flat bottoms with a lateral rim as taught by the '477 Publication, EX1005, ¶[0040], in order to engage the rod. *Supra* Section VI.B.2.a. And it would have been obvious to space the closure top bottom below the start of the threads as taught by both the '477 Publication, EX1005, ¶[0040], and Boschert, EX1006, Fig. 15, in order to achieve the known benefits of

facilitating closure top insertion and thread alignment. *Supra* Section VI.B.2.a, ¶¶ 89-96, 201-02.

295. As set forth above, in my opinion the '477 Publication anticipates or renders obvious every limitation of challenged Claim 1. Claim 3 depends from Claim 1 and adds the additional requirement for dual lead threads. Claim 12 and its dependent claims state many of the same requirements as Claim 1, but do so in the context of a dual lead closure top. Therefore, below I address why the additional elements of Claim 3 and Claim 12 and its dependent claims are rendered obvious by the Boschert/'477 Publication combination. For all other limitations of Claim 3, my opinions expressed above (that these features were already disclosed or rendered obvious by the disclosures of the '477 Publication) remain and are unaffected by the additional disclosures of Boschert.

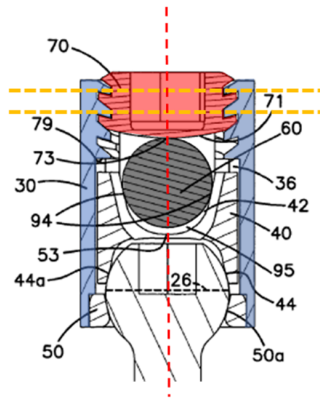
1. Claim 3

296. All of the limitations of Claim 3 are recited in Claim 1, except Claim 3 further recites: [B7] “wherein the start structure is a first start structure disposed at a diametrically opposite location on the plug from a second start structure.” In my opinion, the '477 Publication in view of Boschert discloses this limitation.

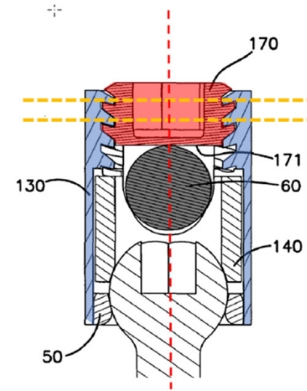
297. As set forth above, in my opinion the '477 Publication discloses all of the features of Claim 1, including the claimed leading face with a partial concave surface and a partial convex surface, but does so only on a single thread.

298. 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. In my opinion, when the disclosures of the ’477 Publication are combined with Boschert, a POSA would have kept the same leading face structure from the ’477 Publication for use with the dual lead threads taught by Boschert. *Supra* Section IX.C. Therefore, the closure top resulting from the combination of the disclosures of the ’477 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.

299. In my opinion, Boschert also discloses to a POSA that the start structures of the disclosed double starts would be symmetrically and diametrically opposed to one another. Specifically, as Figures 3 and 15 both show, Boschert discloses that the threads on either side of the receiver 30 are symmetrically and diametrically opposed to each other (as illustrated by the yellow horizontal lines that are perpendicular to the red longitudinal lines). EX1006, Figs. 3,15.



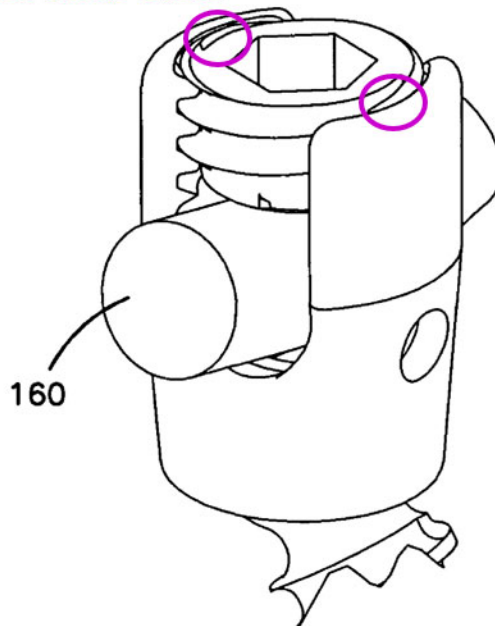
EX1006, Fig. 3



EX1006, Fig. 15

300. A POSA would recognize that Boschert discloses diametrically opposed starts because, as annotated Figure 7 shows, at the top of the closure top, 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. EX1006, Fig. 7.

thread end



EX1006, Fig. 7. Therefore, in my opinion, Boschert discloses a first start structure disposed at a diametrically opposite location on the plug from a second start structure

301. Further, based on the knowledge of a POSA of the conventional manner of making double start threads before January 10, 2012, a POSA would have understood Boschert to disclose diametrically opposed starts. *See supra* ¶¶ 52-64. Specifically, a POSA would have known that “[i]n order to achieve proper distribution” for a multi-start thread, “each thread ***has to start at an equal angle***, determined by the following calculation: Thread cylindrical spacing angle = $360 / \text{Number of starts}$.” EX1014 at 3. Accordingly, a POSA would have understood Boschert’s disclosure of a setscrew with dual lead as teaching two

starts having a cylindrical spacing angle 180° (*i.e.*, $360^\circ / 2$) and, thus, a first start structure that is disposed at a diametrically opposite location on the closure from the second start structure. This understanding is also confirmed by the '646 Patent itself, which shows the same symmetrical threads on the receiver. *E.g.*, EX1001 Figs. 3, 8, 9, 11-15.

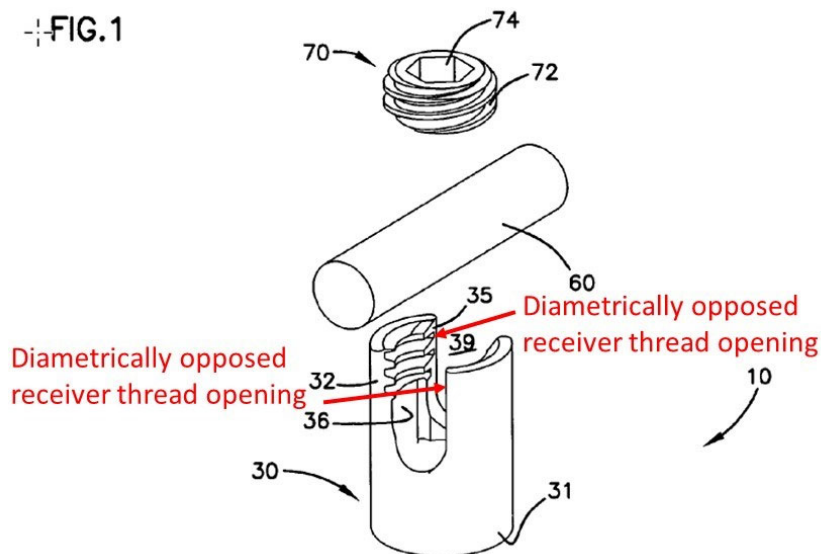
302. Based on Boschert's disclosures and the knowledge of a POSA before the priority date of the '646 Patent, a POSA would have understood that Boschert expressly discloses a first start structure that is disposed at a diametrically opposite location on the closure from the second start structure. Boschert's disclosure of symmetrically and diametrically opposed receiver threads in Figures 3 and 15 teaches a POSA that the first and second threads of the closure top, which threadably mate with the receiver threads, EX1006, 6:25-28, are also symmetrically and diametrically opposed. Boschert's disclosure of symmetrically and diametrically opposed threads on the top of the closure in Figure 7 also teaches a POSA that the first and second threads of the closure top are symmetrically and diametrically opposed. In view of Boschert's disclosures, a POSA would have understood that the symmetrically and diametrically opposed nature of Boschert's first and second threads also applies to the thread starts at the bottom of the closure.

303. To the extent that Boschert does not expressly disclose symmetrically and diametrically opposed start structures, based on Boschert's disclosures and the knowledge of a POSA before the priority date of the '646 Patent, a POSA would have understood that Boschert necessarily discloses a first start structure that is disposed at a diametrically opposite location on the closure from the second start structure. 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, 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 at 13:35-41; *supra* Section VI.B.1.a.

304. To the extent that Boschert does not expressly or inherently disclose a first start structure that is disposed at a diametrically opposite location on the closure from the second start structure, in my opinion, it would have been obvious to a POSA before the priority date of the '646 Patent to use diametrically opposed thread starts in the combination of the '477 Publication and Boschert. 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.

EX1006, Fig. 1.



This can only be accomplished by diametrically opposing the thread starts on the closure top. Furthermore, of all of the examples that I have seen of double started 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. *Id.* For all of these reasons, 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. Therefore, when the double start threads of Boschert are incorporated into the closure top of '477 Publication, a POSA would have understood that those double start threads necessarily have a

first start structure and a second start structure that are disposed at diametrically opposite locations from each other on the plug.

305. When Boschert's disclosures of diametrically opposed double-start threads are combined with the disclosures of the '477 Publication, the resulting closure top would have two start structures each with a curvate leading face, and the two start structures would be disposed at a diametrically opposite location on the plug from each other.

306. Accordingly, in my opinion, the '477 Publication in view of Boschert renders obvious every element of Claim 3.

2. Claim 12

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

307. To the extent the preamble is considered limiting, in my opinion the '477 Publication in view of Boschert discloses this limitation. The preamble of Claim 12 recites the same requirements of the receiver as Limitation 1[Preamble] and the same teachings apply. *See supra* § X.A.1.a. The medical implant assembly addressed in the '477 Publication is a polyaxial spinal pedicle screw and rod system. The '477 Publication is titled "Removeable Medical Implant Closure" and discloses "a closure and/or locking member for use in conjunction with medical implants." EX1005, ¶[0002].

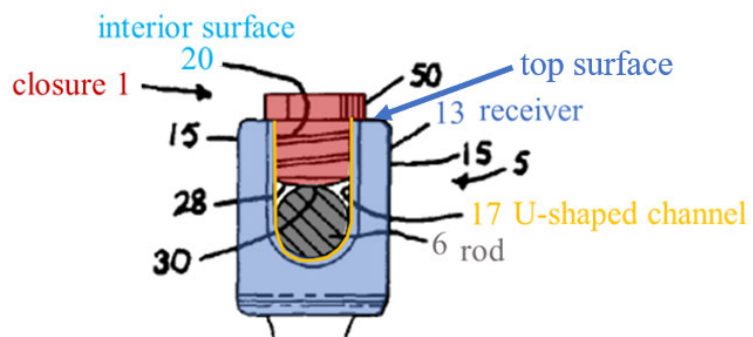
- b. 12[A]: “a receiver having an upper portion with an inner surface, a top surface, and a channel, the inner surface having a helically wound thread extending up to the top surface, the channel configured to receive a rod; and”

308. In my opinion, the '477 Publication in view of Boschert discloses this limitation. While worded slightly differently than Limitation 1[A] regarding the receiver, this limitation recites the same requirements. *Supra* § X.A.1.b. The '477 Publication describes a polyaxial spinal pedicle screw and rod system where the top of the pedicle screw is configured to capture a rod in a portion called a receiver and hold it in place with a set screw. The '477 Publication expressly discloses “a receiver having a pair of spaced arms with an open channel located therebetween. The channel receives a rod or other elongate structure In particular, internal surfaces of the arms of

the receiver include a discontinuous guide and advancement structure” EX1005, ¶[0007].

The '477 Publication further states that the

“receiver 13 has a pair of spaced and generally parallel arms 15 that form an open generally U-shaped channel 17 therebetween that is open at distal ends of the arms



Ex. 1005, Fig. 6

15.” *Id.*, ¶[0026], Fig. 6. Further, the ’477 Publication discloses that the upper portion of the arms of the receiver “each include radially inward or interior surfaces 20 that have a discontinuous guide and advancement structure mateable with cooperating structure on the closure 1.” *Id.*, ¶[0026], Figs. 5-6. The thread extends to the top surface of the receiver. *See, e.g., id.*, Figs. 5-6. A rod 6 is captured in the U-shaped channel. *Id.*, ¶[0025], Figs. 5-6.

309. In my opinion, based on the above disclosures, a POSA implementing the ’477 Publication in view of Boschert would have included a receiver having an upper portion with an inner surface, a top surface, and a channel, the inner surface having a helically wound thread extending up to the top surface, the channel configured to receive a rod. *See supra* Section IX.C.

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

310. This limitation recites the same requirements of the plug as Limitation 1[B], but without the requirement that the plug be threaded. *See supra* Section X.A.1.c. In my opinion, the ’477 Publication in view of Boschert discloses this limitation for the reasons set forth above. *Id.* In particular, 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, ¶[0002]. Specifically, 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]. Thus, a continuously helically wound, threaded closure—or plug—is configured to be positioned within the upper portion of the receiver: “located 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” receiver.” EX1005, ¶¶[0041], [0007], [0030], Figs. 1-2 and 5-6. The ’477 Publication also discloses “*closure* 101 . . . has . . . a central *axis of rotation* C.” *Id.*, ¶¶[0040], [0029]. Moreover, by their nature, all set screws have a central axis of rotation because they have external threads and are rotated or screwed into position, as is their function.

311. In my opinion, based on the above disclosures, a POSA implementing the ’477 Publication in view of Boschert would have included a plug configured for positioning within the upper portion of the receiver, the plug having an axis of rotation. *See supra* Section IX.C.

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

312. This limitation recites the same requirements as Limitation 1[B1], but with the requirement of a second thread. *See supra* § X.A.1.d. In my opinion, the ’477 Publication in view of Boschert discloses this limitation. 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], [0040]. 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.

313. While the ’477 Publication discloses only a single continuously wound thread, Boschert teaches that a “double lead [] allow[s] the set screw 70 to start more easily than with a single lead.” EX1006, 7:21-23.

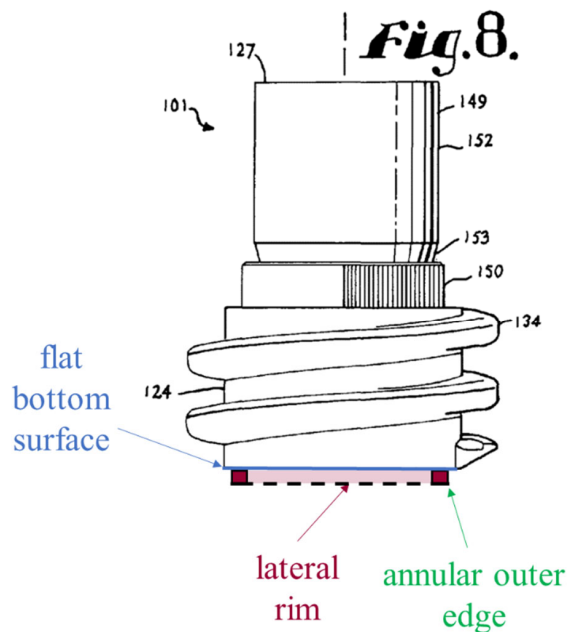
314. Based on the express teachings of the references, a POSA would have been motivated to use the double start threads of Boschert on the closure of the ’477 Publication. *See supra* Section IX.C. Further, in addition to starting more easily, from their knowledge of multi-start threads generally, a POSA would have been further motivated to use a double lead thread to balance rotational forces, speed the insertion process, and reduce cross threading. *Supra* Section VI.B.1.a. In addition, both the ’477 Publication, EX1005, ¶[0047] and Boschert, EX1006, 7:58-8:2, 8:44-49, expressly invite modifications to the disclosed embodiments. Finally, a POSA would have had an expectation of success with this combination, at least because multi-start threads, and techniques for manufacturing them, were well known in the art. *Supra* Sections VI.B.1.a, VI.B.1.d.

315. Accordingly, in my opinion, a POSA implementing the '477 Publication in view of Boschert would have included a continuously helically wound thread form comprising a first thread and a second thread.

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

316. This limitation recites the same requirements as Limitation 1[B2], but without the requirement that the substantially flat bottom surface is “configured to engage the rod.” In my opinion, the '477 Publication in view of Boschert includes or renders obvious this limitation under any construction. *See supra* Section X.A.1.e. The '477 Publication discloses that, for the first disclosed embodiment, “the *bottom surface may be flat and may have* a central point and *a lateral rim.*” *Id.*, ¶[0029]. The '477 Publication also makes these same disclosures for its second embodiment. *Id.*, ¶[0040]. The disclosed “lateral rim” is not pictured, but a POSA would have immediately recognize this feature as a downwardly projecting rim near the periphery of the closure top bottom configured to engage the rod. *See supra* ¶186. My opinion is reinforced by the '477 Publication’s teaching that the lateral rim is an alternative to the domed bottom with a central point “for gripping or penetrating the rod surface.” EX1005, ¶¶[0029], [0040]. Therefore, a POSA would have known that the disclosed alternative “lateral rim” would have performed these same functions of gripping or penetrating the rod surface.

317. A POSA reading the '477 Publication would also have been familiar with lateral rims as a common feature included on the bottom of closure tops to grip or penetrate the rod. *See supra* Section VI.B.2.a. For example, as set forth above, Kirschman, *supra* ¶¶92-93, and the '526 Publication, *supra* ¶94, both disclose such a feature. A POSA would have further understood that such rims are “lateral” because they are positioned away from the midline of the closure, generally near the periphery of the closure top. *Supra* Section VI.B.2.a. Moreover, a POSA would have understood that a rim that is somewhat inset from the outer surface of the cylindrical body provides an advantage for guiding the closure top into the receiver arms and facilitating thread alignment. *Supra* ¶¶92-93, 201-02. Therefore, the '477 Publication’s disclosure of a lateral rim would have immediately brought to mind for the POSA a downwardly projecting ring-like rim near the periphery of the closure top bottom, as depicted below in modified Fig. 8 of the '477 Publication (with the rim shown in cross-section) as a substitution for the domed bottom surface.



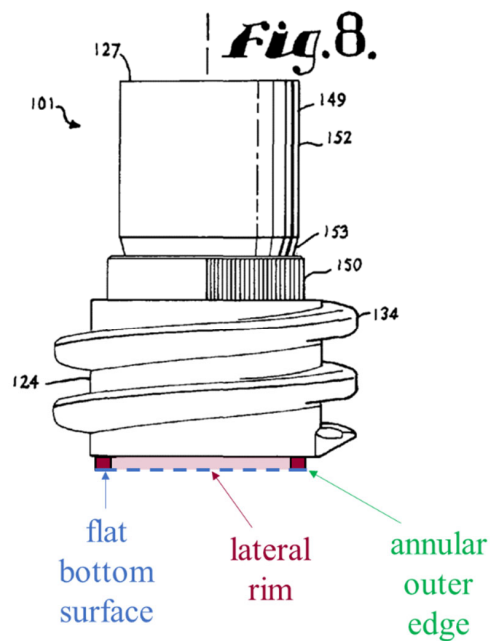
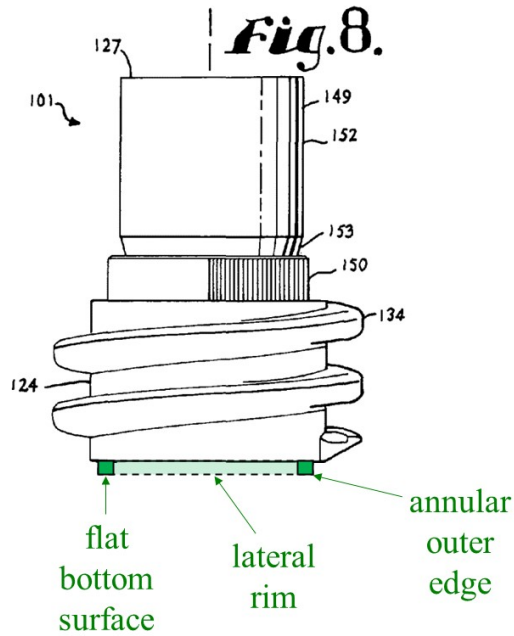
318. If this limitation is construed as a essentially flat bottom surface of the closure top that includes a downwardly projecting rim configured to engage the rod, the '477 Publication discloses this feature. The '477 Publication expressly states that the “the bottom surface may be flat” and further states that this surface may include “lateral rim,” which a POSA would recognize as a downwardly projecting rim configured to engage the rod. EX1005, ¶[0029]. That this disclosed bottom surface may also include a central point is immaterial, as the bottom surface would still be mostly (i.e., substantially) flat.

319. If this limitation is alternatively construed as requiring a flat lowermost surface of the closure top, e.g., the flat bottom of a downwardly projecting rim, with an annular outer edge being the line at the periphery where

that flat bottom surface meets a more vertically oriented surface, e.g., the side surface of a downwardly projecting rim, such a feature is also disclosed or rendered obvious by the '477 Publication, in my opinion.

320. Any lateral rim would necessarily have a thickness, and thus, would necessarily have a bottom surface. A POSA would have been aware that conventional lateral rims for engaging with the rod, such as those described in Kirschman, *supra* ¶¶92-93, and the '526 Publication, *supra* ¶94, have flat bottom surfaces. Indeed, flat bottom surfaces maximize the area of contact between the rim and the rod, and thereby aid the gripping function of a lateral rim. A POSA would also have been aware that some known lateral rims have a pointed bottom surface for penetrating into the rod. *E.g.*, EX1018. Because the '477 Publication does not specify any further details of the disclosed lateral rim, in my opinion a POSA would have known that either a flat or pointed bottom surface of the rim were available options, and therefore would have considered both options to be within the disclosure of the '477 Publication. This opinion is further reinforced by the '477 Publication's recognition that the bottom structures on a closure top can be used to either grip or penetrate the rod. This would have obviously suggested to a POSA a choice of either a flat bottom rim on the set screw for gripping the rod or a pointed bottom rim on the set screw for penetrating the rod. As illustrated below with reference to Fig. 8, the known option of a rim with a flat lowermost surface

includes an annular outer edge (under my alternative construction) at the intersection of the lowermost surface and the side surface of the rim.



EX1005, Fig. 8.

321. In my opinion, based on the above disclosures, it would have been obvious to a POSA implementing the '477 Publication in view of Boschert to use a flat bottom surface of the closure with a downwardly projecting lateral rim (as disclosed the '477 Publication), and to further use a lateral rim with a flat lowermost surface. *See supra* Section IX.C. Therefore, in my opinion, the '477 Publication in view of Boschert renders this limitation obvious under any construction.

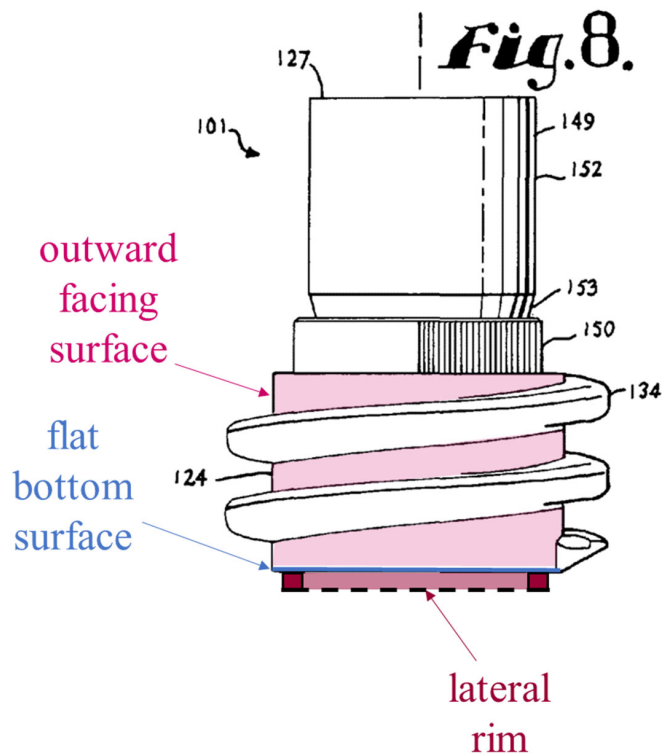
f. 12[B13]: “an outward facing surface encircling the substantially flat bottom surface,”

322. In my opinion, the '477 Publication in view of Boschert discloses this limitation. As discussed above, the '477 Publication discloses that “the *bottom surface may be flat and may have* a central point and *a lateral rim.*” EX1005, ¶[0040]. And as discussed above, under either construction, the '477 Publication discloses or renders obvious a “substantially flat bottom surface.” *Supra* Section X.D.2.e. In addition, under either construction, the '477 Publication discloses or renders obvious an outward facing surface encircling the substantially flat bottom surface.

323. As to my preferred construction where the flat bottom surface is the bottom surface of the plug body, the '477 Publication discloses that “closure 101 includes a body 124 that has a generally cylindrical or plug shape with a

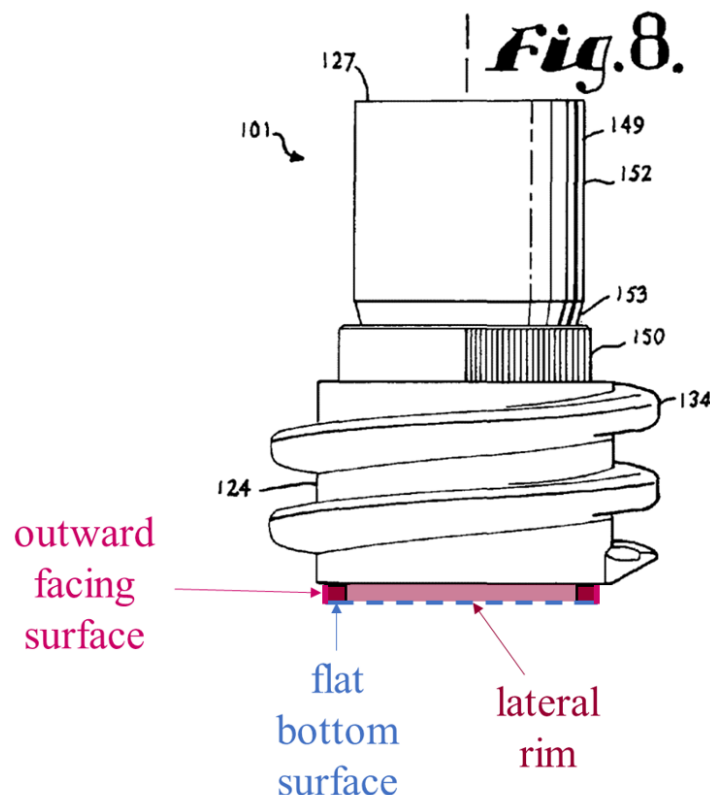
substantially circular horizontal cross section.” EX1005, ¶[0040]. Thus, the disclosed body includes a surface that faces away from the center of the plug and that surrounds the bottom surface (which can be substantially flat) in a circular fashion. This outward facing surface is identified below with reference to Fig. 8.

Id. Fig. 8.



324. In my opinion, based on the above disclosures, it would have been obvious to a POSA implementing the '477 Publication in view of Boschert to use a closure top with a cylindrical body with an outward facing surface that surrounds the closure top bottom (which can be substantially flat) in a circular fashion. See *supra* Section IX.C.

325. If this limitation is alternatively construed as requiring a flat lowermost surface of the closure top, e.g., the flat bottom of a downwardly projecting rim, with an outward facing surface being the side surface of the downwardly projecting rim, such a feature is also disclosed or rendered obvious by the '477 Publication, in my opinion. In particular, as illustrated below with reference to Fig. 8, the known option of a rim with a flat lowermost surface (under my alternative construction) includes an outward facing surface (i.e., the side surface of the rim facing away from the center of the rim) encircling the flat bottom surface. *Id.* Fig. 8.

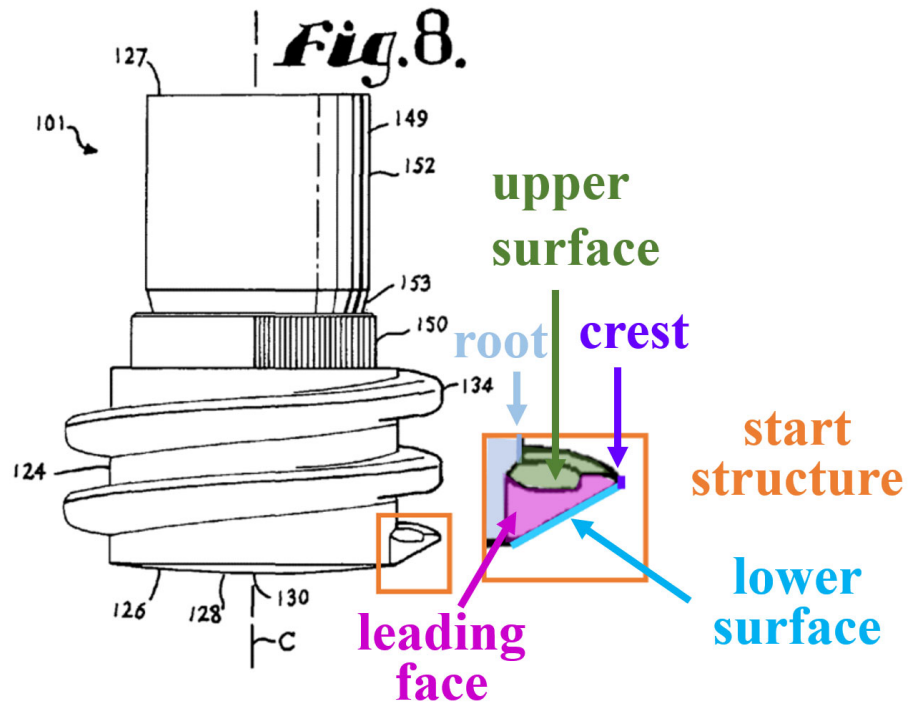


326. In my opinion, based on the above disclosures, it also would have been obvious to a POSA implementing the '477 Publication in view of Boschert to include a downwardly projecting lateral rim with a flat lowermost surface and an outward facing side surface of the rim encircling the flat lowermost surface of the rim. *See supra* Section IX.C.

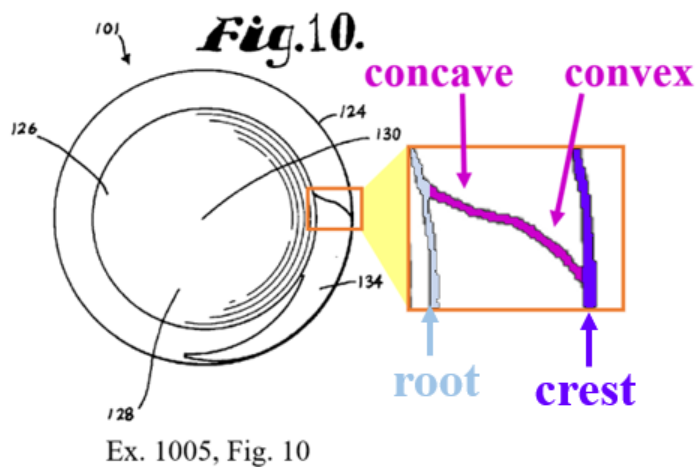
- g. **12[B3]: “the first thread comprising a first start structure and a first upper surface extending between a first root and a first crest of the first thread, the first start structure including a first leading face extending below the first upper surface to a first lower surface, the second thread comprising a second start structure and a second upper surface extending between a second root and a second crest of the second thread, the second start structure including a second leading face extending below the second upper surface to a second lower surface, the first and second leading faces each including a partial concave surface adjacent the first and second root, respectively, and a partial convex surface adjacent the first and second crest, respectively, the partial concave and partial convex surfaces of the first and second leading faces each defined by a radius of curvature,”**

327. This limitation recites the same start structure requirements as Limitations 1[B3] and 1[B4] for the single start structure, but in addition requires those start structure elements for a second start structure on a double-start thread. In my opinion, the '477 Publication in view of Boschert discloses this limitation. *See supra* Sections X.A.1.f-g, X.D.1.

328. 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], [0040]. The disclosed threads have “a *root* 38 and a *crest* 40. Further, the thread form 36 has a lead [lower] surface 42 and a trailing [upper] surface 44 (described relative to the position thereof during insertion of the closure 1 into the bone screw receiver 13.)” *Id.*, ¶[0031]. As shown in annotated and enlarged Figure 8 below, the '477 Publication discloses a start structure on the closure thread with an upper surface extending between a root and a crest of the continuously helically wound thread form, the start structure having a leading face extending below the upper surface to a lower surface of the start structure. *Id.*, Figs. 7, 8.

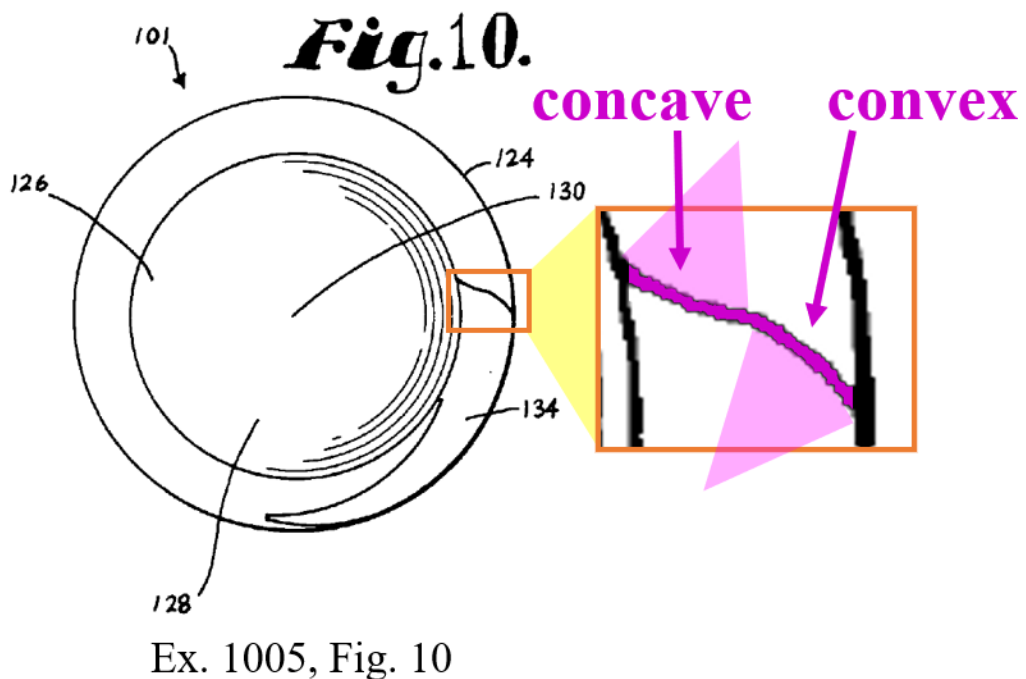


329. In addition, as shown in Figure 10 below, the leading face of the start structure disclosed in the '477 Publication includes a partial concave surface adjacent the root and a partial convex surface adjacent the crest. *Id.*, Fig. 10. A POSA would recognize this feature of Fig. 10 as the leading 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.



330. Figure 10 also discloses that each of the partial concave and partial convex surfaces of the leading face of the start structure has a radius of curvature.

EX1005, Fig. 10.



While the numeric radii of curvature are not disclosed in the '477 Publication, the claims of the '646 Patent do not require any numeric radii of curvature

331. While the '477 Publication discloses the above leading face on only a single thread, when the disclosures of the '477 Publication are combined with Boschert, a POSA would have kept the same leading face structure from the '477 Publication in the dual lead threads taught by Boschert. *See supra* Section IX.C. A POSA would have been motivated to use the double-start structure taught by Boschert in the closure top of the '477 Publication at least because Boschert teaches that a “double lead [] allow[s] the set screw 70 to start more easily than with a single lead.” EX1006, 7:21-23. Further, from their knowledge of multi-start threads generally, a POSA would have been further motivated to use a double lead thread to balance rotational forces and to speed the insertion process. *Supra* Section VI.B.1.a. Still further, a POSA would have maintained the curvate leading thread faces of the '477 Publication at least based on their known advantages of facilitating thread alignment and starting, eliminating sharp surfaces, and reducing thread deformation, *supra* Section VI.B.1.b, and based on Boschert's own suggestion, in Fig. 7, to use truncated thread starts with curvate leading faces. In addition, both the '477 Publication, EX1005, ¶[0047] and Boschert, EX1006, 7:58-8:2, 8:44-49, expressly invite modifications to the disclosed embodiments.

332. Finally, a POSA would have had an expectation of success with this combination, at least because multi-start threads, and techniques for manufacturing them, were well known in the art. *Supra* Sections VI.B.1.a, VI.B.1.d. Therefore, the closure top resulting from the combination of the disclosures of the '477 Publication and Boschert would have used the curvate leading face of the '477 Publication as the start structure on each of the two dual start threads taught by Boschert.

333. In my opinion, the closure top resulting from the combination of the disclosures of the '477 Publication and Boschert would have used the curvate leading face of the '477 Publication as the start structure on each of the two dual start threads taught by Boschert. Thus, the resulting plug would have a first thread comprising a first start structure and a first upper surface extending between a first root and a first crest of the first thread, the first start structure including a first leading face extending below the first upper surface to a first lower surface, the second thread comprising a second start structure and a second upper surface extending between a second root and a second crest of the second thread, the second start structure including a second leading face extending below the second upper surface to a second lower surface, the first and second leading faces each including a partial concave surface adjacent the first and second root, respectively, and a partial convex surface adjacent the first and second crest, respectively, the

partial concave and partial convex surfaces of the first and second leading faces each defined by a radius of curvature.

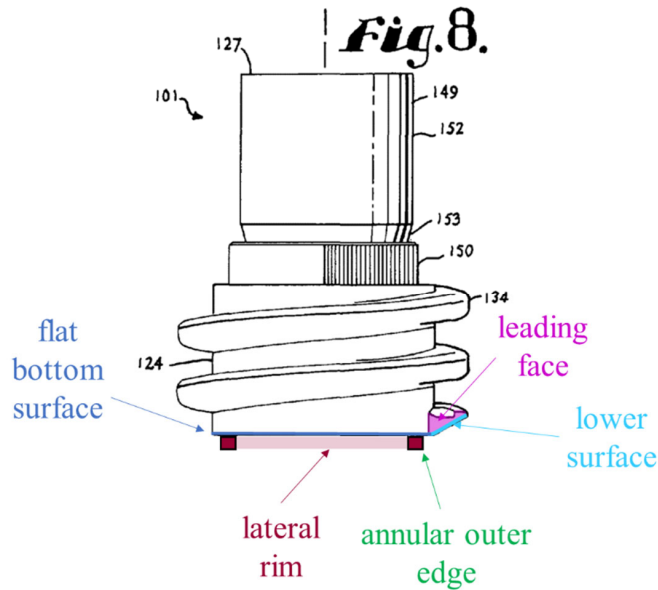
- h. 12[B5]: “the first lower surface of the first thread and from⁷ the second lower surface of the second thread are spaced above and apart from the annular outer edge of the substantially flat bottom surface of the plug.”**

334. This limitation recites the same leading face requirements as Limitation 1[B5], but does so in the context of a double-start thread, rather than a single-start thread as required by claim 1. *See supra* Section X.A.1.h. In my opinion, the ’477 Publication in view of Boschert includes or renders obvious this limitation. The preferred embodiment pictured in Figs. 7-10 of the ’477 Publication includes a domed bottom, but the ’477 Publication discloses that a substantially flat bottom surface with a lateral rim could be used instead. EX1005, ¶[0040].

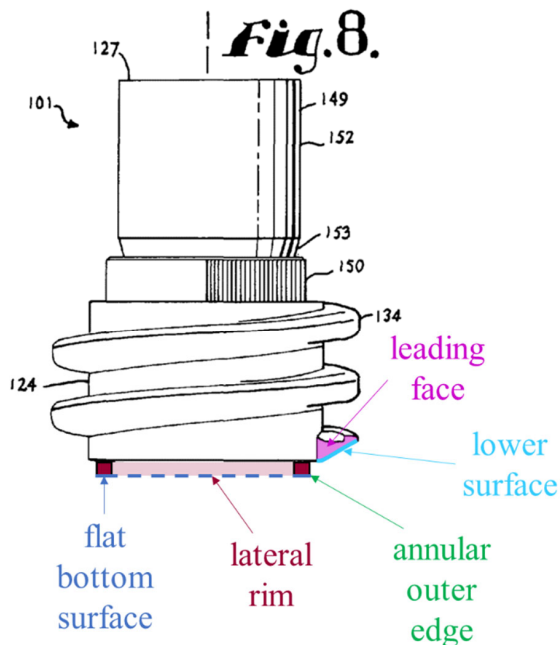
335. Under my preferred construction, the lateral rim is the annular outer edge. A POSA would have understood that a rim that is somewhat inset from the outer surface of the cylindrical body provides an advantage for guiding the closure top into the receiver arms and facilitating thread alignment. *Supra* ¶¶92-93, 201-02. Thus, the lateral rim is below and spaced apart from the lower surface of the

⁷ “From” appears to have been included in this limitation in error.

threads, as illustrated below in a modified version of Figure 8, where such a lateral rim has been added. EX1005, Fig. 8.



336. Under my alternative construction, the annular outer edge is the outer periphery of the lowermost surface of the lateral rim. Under this alternative construction, the annular outer edge remains below and spaced apart from the lower surface of the threads, as illustrated below in a modified version of Figure 8, where such a lateral rim with a flat lowermost surface has been added. EX1005, Fig. 8.



337. In my opinion, based on the above disclosures, it would have been obvious to a POSA implementing the '477 Publication in view of Boschert to position the lower surfaces of the threads spaced above and apart from the annular outer edge of either an entirely flat bottom surface or lateral rim with a flat lowermost surface. *See supra* Section IX.C. Further, as discussed above, a POSA would know that when using truncated thread starts, it is well known that the thread start can be spaced apart from the bottom of the closure leaving an unthreaded segment of any desired length to guide the closure into the receiver and help align the threads. *Supra* ¶¶92-93, 201-02. A POSA would have understood that when designing a closure top for use in an open receiver of a bone screw, there were a limited number of options for the spacing of the thread starts relative to the

closure top's bottom surface, including having the threads flush with the closure top's bottom surface and having the threads spaced apart from the closure top's bottom surface and therefore truncated. *Id.* Each of these limited, known design options for the spacing of the threads on a closure top had been successfully used with a closure top. *See id.* Therefore, a POSA designing a pedicle screw system would have known that closure threads that were spaced apart from the closure top's bottom was a design choice from among a limited number of options each with a reasonable expectation of success, and thus it would have been obvious to try a closure with threads spaced apart from the closure top's bottom.

338. As set forth above, in my opinion, the '477 Publication in view of Boschert renders obvious every element of Claim 12.

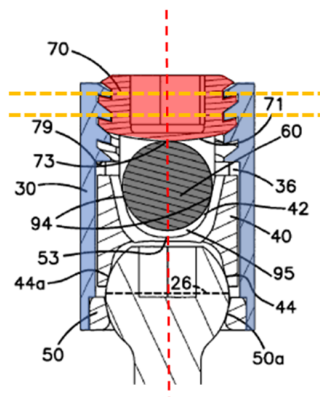
3. Claim 13

339. All of the limitations of Claim 13 are recited in Claim 12, except Claim 13 further recites: [B7] "wherein the first start structure and the second start structure are disposed at diametrically opposite locations from each other on the plug." In my opinion, the '477 Publication in view of Boschert discloses this limitation. *See supra* Section X.D.1.

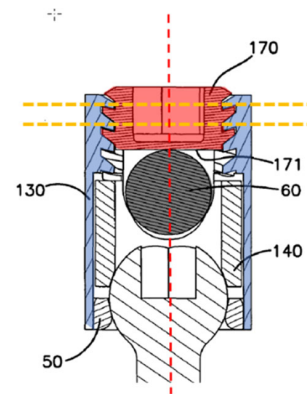
340. Boschert expressly teaches double threads on the closure top, or set screw, and specifically that a "double lead [] allow[s] the set screw 70 to start more easily than with a single lead." EX1006, 7:21-23. In my opinion, when the

disclosures of the '477 Publication are combined with Boschert, a POSA would have kept the same leading face structure from the '477 Publication for use with the dual lead threads taught by Boschert. *See supra* Section IX.C. Therefore, the closure top resulting from the combination of the disclosures of the '477 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.

341. In my opinion, Boschert discloses to a POSA that the start structures of the disclosed double starts would be symmetrically and diametrically opposed to one another. Specifically, as seen in Figures 3 and 15, below, Boschert shows that the threads on either side of the receiver 30 are symmetrically and diametrically opposed to each other (as illustrated by the yellow horizontal lines that are perpendicular to the red longitudinal lines). EX1006, Figs. 3,15.

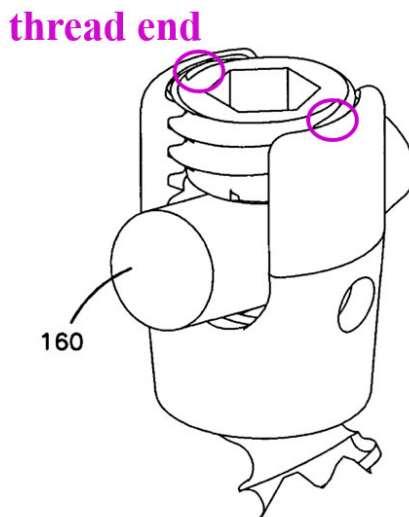


EX1006, Fig. 3



EX1006, Fig. 15

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



343. Further, based on the knowledge of a POSA of the conventional manner of making double start threads before January 10, 2012, a POSA would have understood Boschert to disclose diametrically opposed starts. *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 / 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 having a cylindrical spacing angle 180° (*i.e.*, $360^\circ / 2$) and, thus, a first start structure that is disposed at a diametrically opposite location on the closure from the second start structure. This understanding is also confirmed by the ‘646 Patent itself, which shows the same symmetrical threads on the receiver. *E.g.*, EX1001 Figs. 3, 8, 9, 11-15.

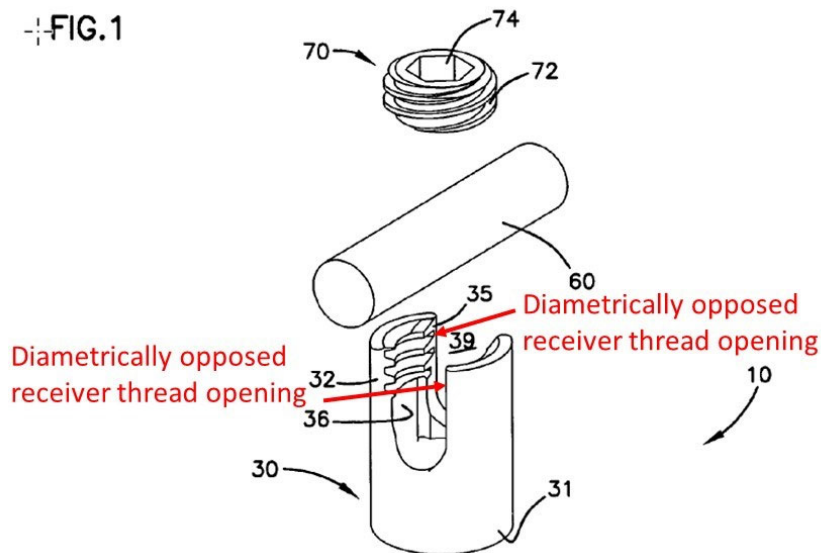
344. Based on Boschert’s disclosures and the knowledge of a POSA before the priority date of the ‘646 Patent, a POSA would have understood that Boschert expressly discloses a first start structure that is disposed at a diametrically opposite location on the closure from the second start structure. Boschert’s disclosure of symmetrically and diametrically opposed receiver threads in Figures 3 and 15 teaches a POSA that the first and second threads of the closure top, which threadably mate with the receiver threads, EX1006, 6:25-28, are also symmetrically and diametrically opposed. Boschert’s disclosure of symmetrically and diametrically opposed thread forms on the top of the closure in Figure 7 also teaches a POSA that the first and second threads of the closure top are symmetrically and diametrically opposed. In view of Boschert’s disclosures, a POSA would have understood that the symmetrically and diametrically opposed

nature of Boschert's first and second threads also applies to the thread starts at the bottom of the closure.

345. To the extent that Boschert does not expressly disclose symmetrically and diametrically opposed start structures, based on Boschert's disclosures and the knowledge of a POSA before the priority date of the '646 Patent, a POSA would have understood that Boschert necessarily discloses a first start structure that is disposed at a diametrically opposite location on the closure from the second start structure. 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, 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 at 13:35-41; *supra* Section VI.B.1.a.

346. To the extent that Boschert does not expressly or inherently disclose a first start structure that is disposed at a diametrically opposite location on the closure from the second start structure, in my opinion, it would have been obvious to a POSA before the priority date of the '646 Patent to use diametrically opposed thread starts in the combination of the '477 Publication and Boschert. 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. EX1006, Fig. 1.



This can only be accomplished by diametrically opposing the thread starts on the closure top. Furthermore, of all of the examples that I have seen of double started 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. *Id.* For all of these reasons, 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. Therefore, when the double

start threads of Boschert are incorporated into the closure top of the '477 Publication, a POSA would have understood that those double start threads necessarily have a first start structure and a second start structure that are disposed at diametrically opposite locations from each other on the plug.

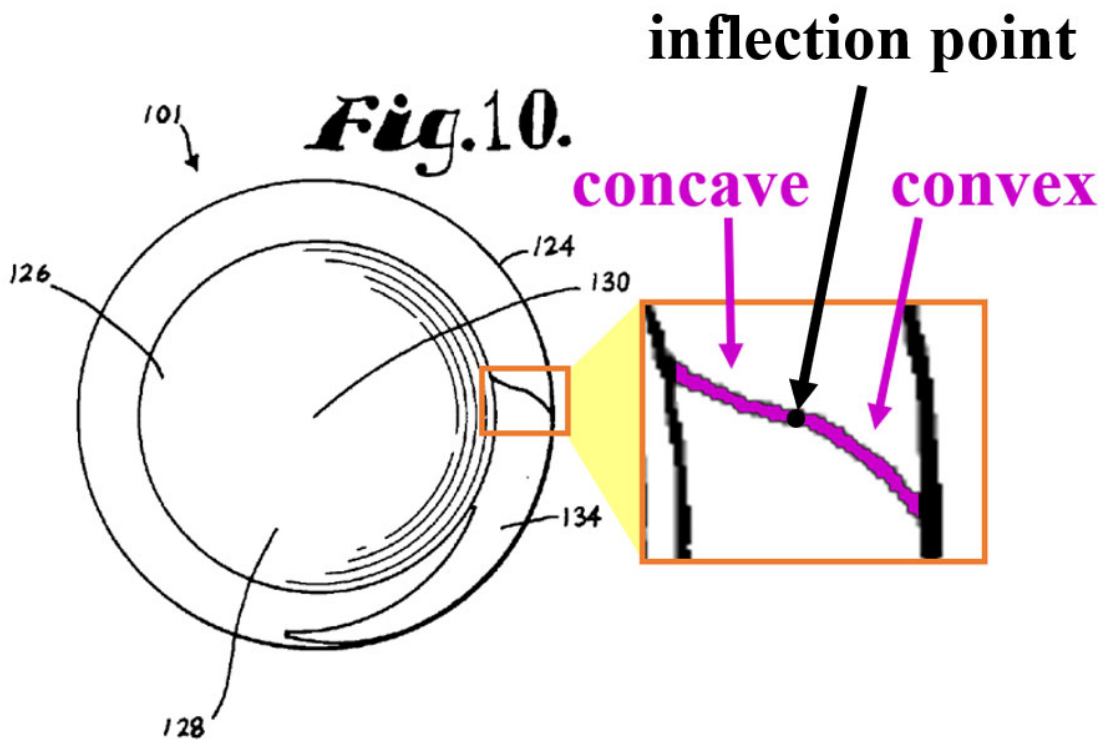
347. When Boschert's disclosures of diametrically opposed double-start threads are combined with the disclosures of the '477 Publication, the resulting closure top would have two start structures each with a curvate leading face, and the two start structures would be disposed at a diametrically opposite location on the plug from each other.

348. Accordingly, in my opinion, the '477 Publication in view of Boschert renders obvious every element of Claim 13.

4. Claim 14

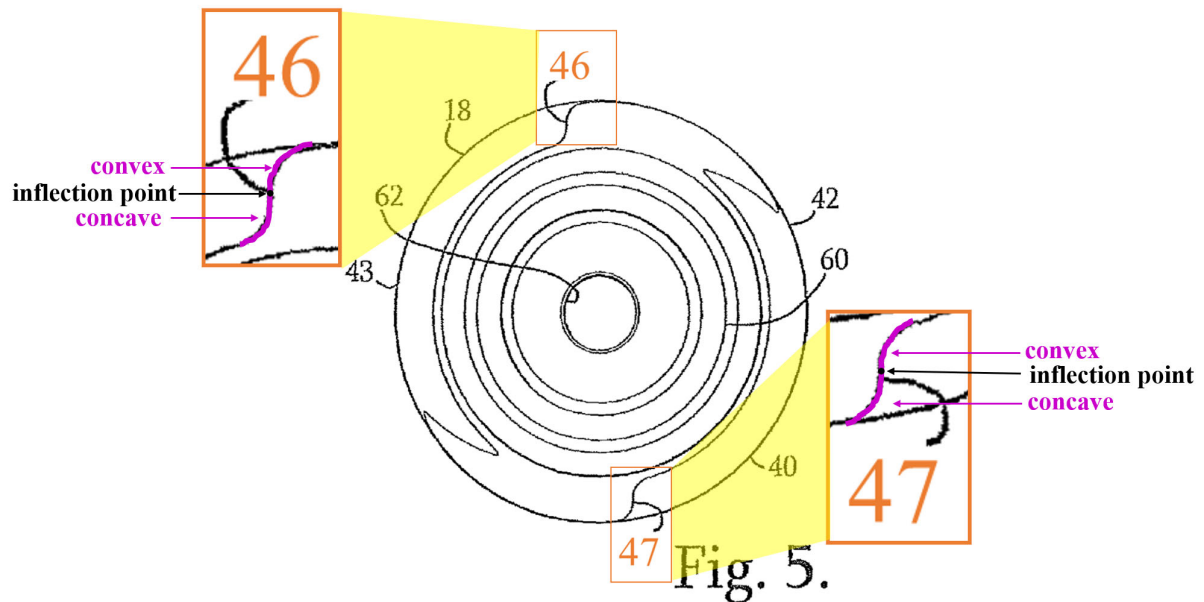
349. All of the limitations of Claim 14 are recited in Claim 12, except Claim 14 further recites: **[B14]** "wherein the first leading face includes a first inflection point between the partial concave surface and the partial convex surface of the first leading face, and the second leading face includes a second inflection point between the partial concave surface and the partial convex surface of the second leading face." In my opinion, the '477 Publication in view of Boschert discloses this limitation.

350. The '477 Publication discloses an inflection point between the partial concave and the partial convex surface of the leading face of the start structure, as seen below in annotated Figure 10. EX1005, Fig. 10. Figure 10 also shows that the convex curve and the concave curve of the leading face touch each other at a single point and that the curve changes direction at that point. Therefore, a POSA would recognize this location as an inflection point.



Ex. 1005, Fig. 10

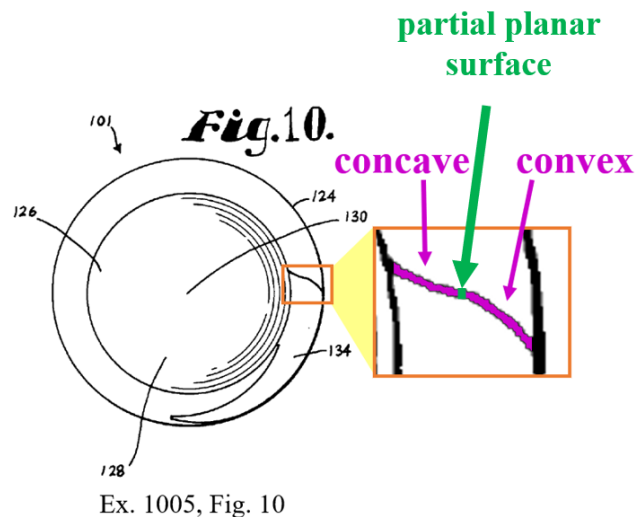
EX1005, Fig. 10. Notably, this is the same level of disclosure available in the '646 Patent itself with respect to an inflection point, shown below. See EX1001, Fig. 5.



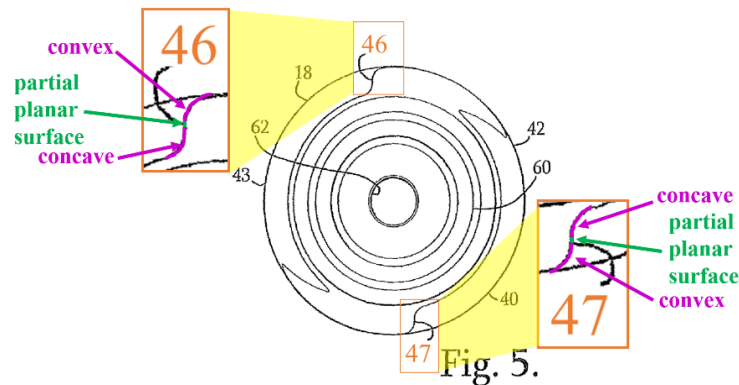
351. As set forth above, when a POSA combines the disclosures of the '477 Publication with Boschert, they would use the start structure from the '477 Publication on each of the two threads disclosed by Boschert. *Supra* Section IX.C. A POSA would have made this modification of the '477 Publication based on the expressed benefit of using dual starts, as set forth in Boschert, that dual-start threads “start more easily than with a single lead.” EX1006, 7:21-23. Therefore, the resulting combination of the '477 Publication and Boschert would have two thread starts, each with an inflection point between the partial concave and the partial convex surface of the leading face. Accordingly, in my opinion, the '477 Publication in view Boschert renders obvious every element of Claim 14.

5. Claim 15

352. All of the limitations of Claim 15 are recited in Claim 12, except Claim 15 further recites: [B8] “wherein the first and second leading faces each includes at least a partial planar surface.” This limitation recites the same requirements as Claim 4, but with the requirement of a second thread and, in my opinion, the ’477 Publication in view of Boschert discloses this limitation. *See supra* Section X.A.3; *see also supra* Section IX.C. In particular, the ’477 Publication discloses the leading face that includes a partial planar surface, at least at the point of inflection between the partial concave and partial convex surfaces, as shown below. EX1005, Fig. 10. At this location, a POSA would recognize that the leading face is approximately flat in all directions, and is therefore partially planar.



EX1005, Fig. 10. Notably, this is the same level of disclosure available in the '646 Patent itself with respect to a partial planar surface, as shown below. *See EX1001, Fig. 5.*



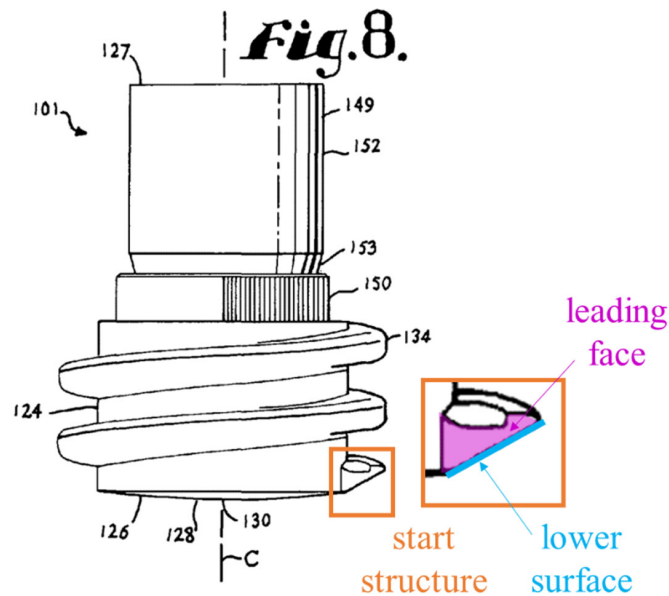
Moreover, a POSA would have understood from the standard manufacturing techniques for a truncated thread cut, *see supra* Section VI.B.1.b, that any tool path could be used to transition from one curve to the opposite curve, including paths that transition immediately and paths that include an elongated straight segment between curves. In my opinion, a POSA would have understood that there was no particular advantage to any of these tool path choices, so long as a concave curve is used near the root and a convex curve is used near the crest.

353. Accordingly, the '477 Publication in view Boschert renders obvious every element of Claim 15.

6. Claim 16

354. All of the limitations of Claim 16 are recited in Claim 12, except Claim 16 further recites: **[B9]** “wherein the first lower surface includes a first

bottom beveled surface and the second lower surface includes a second bottom beveled surface.” In my opinion, the ’477 Publication in view of Boschert discloses this limitation. In particular, as discussed above, the ’477 Publication discloses that the lower surface of the start structure is a beveled (i.e., sloped) surface, rather than a squared one. *Supra* Section X.A.4. This is again shown in enlarged and annotated Figure 8 below. EX1005, Fig. 8.



In particular, the front-elevational view of Figure 7 shown in Figure 8, above, shows that the lower surface of the start structure is slanted and that the lower outside corner of the normal thread profile has been removed. Notably, this is the same level of disclosure available in the ’646 Patent itself with respect to a bottom beveled surface. *See* EX1001, Fig. 3.

355. Accordingly, because a POSA implementing the '477 Publication in view of Boschert would have used the start structure of the '477 Publication on each of the dual lead threads disclosed by Boschert, *see supra* Section IX.C, and because this start structure includes a bottom beveled surface in the same manner as that phrase is used in the '646 Patent, the '477 Publication in view of Boschert renders obvious every element of Claim 16.

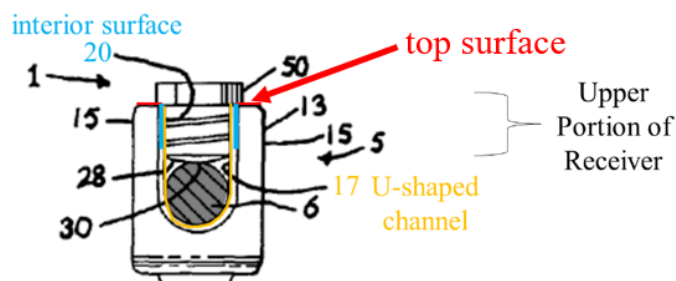
7. Claim 17

356. All of the limitations of Claim 17 are recited in Claim 12, except Claim 17 further recites: **[B12]** “wherein the plug is a breakoff plug.” In my opinion, the '477 Publication in view of Boschert discloses this limitation. As discussed above, the '477 Publication discloses that the closure may include a breakoff portion designed to break away from the closure “subsequent to a predetermined torque being applied.” EX1005, ¶[0042]; *supra* Section X.A.7. Moreover, before January 10, 2012, a POSA would have been well aware of breakoff tops as an available drive structure that could be used to torque closure tops to a desired level. *Supra* Section VI.B.2.b. Therefore, it would have been obvious to POSA implementing the '477 Publication in view of Boschert to include a breakoff portion as disclosed in the '477 Publication. *See supra* Section IX.C. Accordingly, the '477 Publication in view Boschert renders obvious every element of Claim 17.

8. Claim 18

357. All of the limitations of Claim 18 are recited in Claim 12, except Claim 18 further recites: [A1] “wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm.” In my opinion, the ’477 Publication in view of Boschert discloses this limitation.

358. As discussed above, the ’477 Publication discloses this limitation. *Supra* Section X.A.8. In particular, as shown in annotated Figure 6 below, the upper portion of receiver has first and second arms spaced apart from each other by channel 17, and the top surface of the receiver is shown on the first and second arms of the receiver.



The ’477 Publication discloses that the “internal surfaces of the arms of the receiver include a *discontinuous* guide and advancement structure...” EX1005, ¶[0007]. The ’477 Publication further states that the “receiver 13 has a pair of

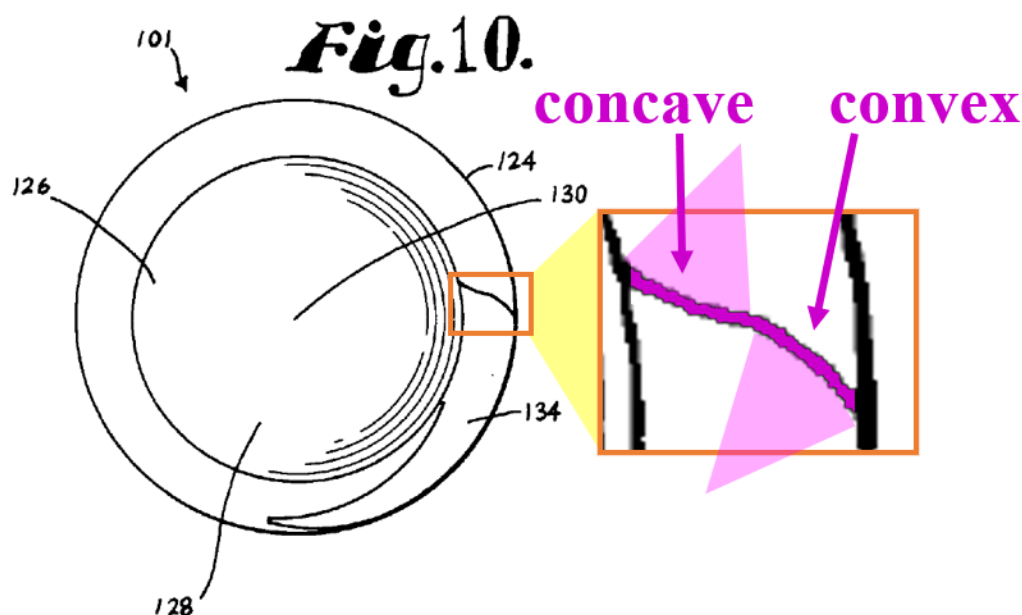
spaced and *generally parallel arms* 15 that form an open generally *U-shaped channel 17 therebetween* that is open at distal ends of the arms 15.” *Id.*, ¶[0026]. Further, the ’477 Publication discloses that the arms of the receiver “each include radially inward or interior surfaces 20 that have a discontinuous guide and advancement structure mateable with cooperating structure on the closure 1.” *Id.*, ¶[0026]; *see also* Figs. 5-6. The thread extends to the top surface of the receiver. *See, e.g., id.*, Figs. 5-6.

359. In my opinion, based on the above disclosures, a POSA implementing the ’477 Publication in view of Boschert would have been motivated to include a receiver having an upper portion that includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm. *Supra* Section IX.C. Accordingly, the ’477 Publication in view Boschert renders obvious every element of Claim 18.

9. Claim 20

360. All of the limitations of Claim 20 are recited in Claim 12, except Claim 20 further recites: [B4] “wherein the radius of curvature for the partial concave and partial convex surfaces of the first and second leading faces are substantially equal with respect to each other.” In my opinion, the ’477

Publication in view of Boschert discloses this limitation. This limitation recites the same requirements as Claim 1[B4] which are met by the '477 Publication, but with the requirement of a second thread start. As discussed above and as shown in annotated Figure 10 below, the '477 Publication discloses that the partial concave and convex surfaces of the leading face have a radius of curvature that is substantially equal with respect to each other. *See supra* Section X.A.1.g. Specifically, the '477 Publication discloses that the partial concave and convex surfaces of the leading face have a radius of curvature that is substantially equal with respect to each other, as seen below in annotated Figure 10.



Ex. 1005, Fig. 10

Notably, while the numeric radii of curvature are not disclosed in the '477 Publication, the claims of the '646 Patent do not require any numeric radii of

curvature. Moreover, radii of curvature that are substantially equal for each of the concave and convex curves is consistent with the easiest manufacturing processes for the lead face of a thread start structure. *Supra* Section VI.B.1.c. Finally, while the comparison of the radii of curvature of the concave surface to the convex surface is possible only via Figure 10 of the '477 Publication, I note that this is the same level of disclosure available in the '646 Patent itself. EX1001, Fig. 5.

361. In my opinion, based on the above disclosures, a POSA implementing the '477 Publication in view of Boschert would have been motivated to use the start structure of the '477 Publication on each of the dual lead threads disclosed by Boschert, and in this start structure the radius of curvature for the partial concave and partial convex surfaces of the leading face are substantially equal with respect to each other. *Supra* Section IX.C. Accordingly, this combination renders obvious every element of Claim 20.

E. Ground 5: Claims 3, 12-18, and 20 Are Obvious Based on the '477 Publication and Boschert in View of Kirschman.

362. As set forth above, it also would have been obvious to a POSA to combine the teachings of Kirschman with the '477 Publication and Boschert before the priority date of the '646 Patent. *Supra* Section IX.A. Kirschman recognizes that conventional bone screws are well known in the prior art and proposes several optional “locking aids” that could be added to a conventional system. EX1007, Abstract (teaching a cap that “has at least one locking aid in the form of at least

one of a tactile feedback, a visual feedback or an enhanced fixation between the cap and a rod that is received in the receiver), ¶¶[0002]-[0013]. Notably, Kirschman does not present these locking aids in an all-or-nothing manner, but rather recognizes that a POSA may optionally choose to use one or more of the disclosed locking aids as they see fit based on the disclosed benefits of each locking aid. *Id.* A POSA would have been motivated to add each of the disclosed locking aids to an existing system at least based on the benefits of each locking aid as taught by Kirschman.

363. For example, Kirschman’s disclosure that a ring with a flat lowermost surface and an annular outer edge (under my alternative construction) had advantages for engaging the rod and providing “enhanced fixation” between the cap and the rod would have motivated a POSA to use these features in conjunction with the ’477 Publication and/or the ’477 Publication/Boschert combination. *Id.*, ¶¶[0045], [0047].

364. As a further example, Kirschman teaches that an unthreaded segment of the closure top located between the threads and the bottom of the closure had benefits for “guiding the cap 14 on the receiver 12 to facilitate aligning the cap 14 and the male cap threads 46” and the corresponding threads of the receiver would have motivated a POSA to incorporate such a surface between the thread starts and the bottom of the closure top when implementing the teachings of the ’477

Publication either alone or in further combination with Boschert. *Id.*, ¶¶[0043]; [0049].

365. A POSA would have expected success with each of these combinations because they are all combinations of familiar elements using known methods to yield predictable results, as it was well known to a POSA before the priority date of the '646 Patent that rings with a flat bottom surface and unthreaded bottom segments provided these advantages and could be successfully used in closure tops. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for manufacturing these features were well known and readily available.

366. As set forth above, the '477 Publication in combination with Boschert already renders obvious all limitations of challenged Claims 3, 12-18, and 20. Kirschman's additional teachings relating to a bottom ring with a flat lowermost surface and an unthreaded segment above the closure top bottom merely reinforce the benefits of these locking aids, thereby confirming the obviousness of challenged Claims 3, 12-18, and 20 as set forth below. In my opinion, all limitations of challenged Claims 3, 12-18, and 20 are obvious in view of Kirschman, the '477 Publication, and Boschert. Below I address the limitations for which Kirschman's disclosures are additive. For all other limitations, my opinions expressed above (that these features were already rendered obvious by the

disclosures of the '477 Publication and Boschert, *supra* Section X.D) remain and are unaffected by the additional disclosures of Kirschman.

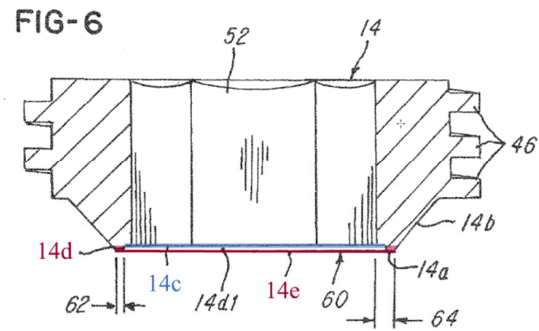
1. Claim 3 (which depends from Claim 1)

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

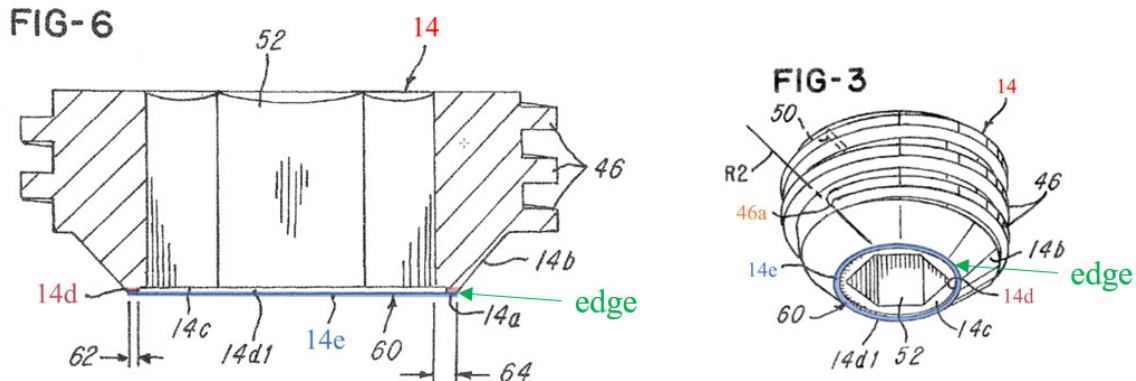
367. As set forth above, the '477 Publication discloses that a closure top “*bottom surface may be flat* and may have a central point and a *lateral rim*.” EX1005, ¶¶[0029], [0040]. The '477 Publication identifies these features as an alternative to the domed bottom with a central point “*for gripping or penetrating the rod surface*.” *Id.*, ¶¶[0029], [0040]. A POSA would have known that the disclosed alternative “lateral rim” would have performed these same functions of gripping or penetrating the rod surface. Moreover, a POSA reading the '477 Publication would have been familiar with lateral rims as a common feature included on the bottom of closure tops to grip or penetrate the rod. *Supra* Section VI.B.2.a. Therefore, the '477 Publication's disclosure of a lateral rim would have immediately brought to mind for the POSA a downwardly projecting ring-like rim near the periphery of the closure top bottom. *Supra* ¶¶185-86, 208. Any such lateral rim would necessarily have a thickness, and thus, would necessarily have a bottom surface. A POSA would have been aware of conventional lateral rims for engaging with the rod that have flat bottom surfaces. *Supra* Section VI.B.2.a.

Indeed, flat bottom surfaces maximize the area of contact between the rim and the rod, and thereby aid the gripping function of a lateral rim. Consequently, in my opinion, the '477 Publication disclosed or rendered obvious a lateral rim with a flat bottom surface and an annular outer edge (i.e., lateral rim), under my preferred construction, and either disclosed or rendered obvious a lateral rim with a flat lowermost surface and an annular outer edge (under my alternative construction).

368. If, for any reason, the disclosures of the '477 Publication were insufficient to anticipate or render obvious a lateral rim positioned near the periphery of the closure top, Kirschman reinforces the teachings of the '477 Publication by disclosing a closure top with a substantially flat bottom surface that includes a downward projecting ring (i.e., a lateral rim) positioned near the periphery of the closure top. In particular, Kirschman discloses a flat “end 14c” that includes “deformable **ring 14d** that is monolithically and integrally formed with the cap 14.” EX1007, ¶¶[0044], [0045], Fig. 3. This ring is shown in Figures 3 and 6 below, and is disclosed to “**engage[] the rod 16.**” *Id.*, ¶¶[0045], [0047], [0051], Figs. 3, 6. Under my preferred construction, a POSA would recognize end 14c as the “substantially flat bottom surface” and the ring 14d as the “annular outer edge.”



Further, the edge where the flat bottom surface of the ring meets surface 14b is an annular outer edge under my alternative construction because it is a ring-shaped line where the two planar surfaces join, shown below. *Id.*, Figs. 3, 6.



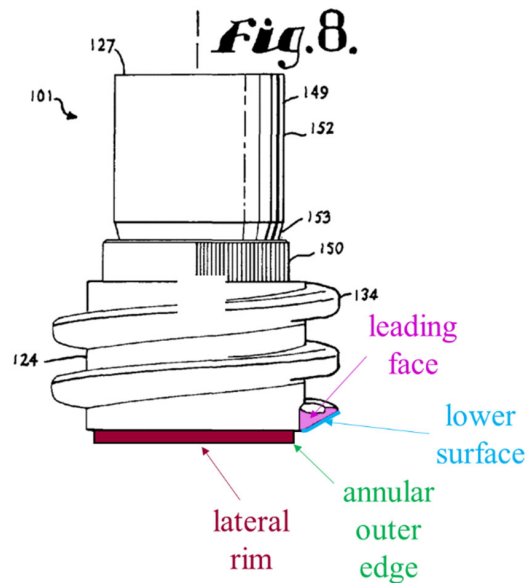
Ring 14d “provides an enhanced fixation or even a cold-weld between the cap 14 and the rod 16 when the cap 14 is received on the receiver 12.” *Id.*, ¶[0047]. In particular, “the cap 14 is received on the receiver 12 and screwed into the receiver 12 until a bottom edge or surface 14e engages the rod 16.” *Id.*, ¶¶[0045], [0051].

369. Therefore, under either construction, Kirschman discloses a “substantially flat bottom surface with an annular outer edge.” To the extent a POSA would not already know of a lateral rim positioned near the periphery of the closure top or a lateral rim with a flat lowermost surface and an annular outer edge, they would look to Kirschman as an example of a lateral rim, and would learn from Kirschman that such a ring with a flat lowermost surface and an annular outer edge was advantageous for engaging the rod. *Supra* Section IX.A. Therefore, in my

opinion, adding the disclosures of Kirschman to those of the '477 Publication in further combination with Boschert, renders obvious a plug having substantially flat bottom surface with an annular outer edge, the substantially flat bottom surface configured to engage a rod under any possible construction.

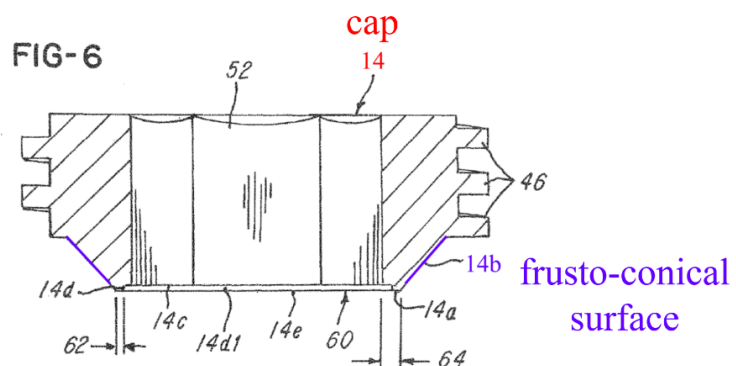
- b. 1[B5]: the lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof.**

370. As set forth above, in my opinion, the '477 Publication in combination with Boschert discloses this limitation under any construction of “annular outer edge of the substantially flat bottom surface.” The preferred embodiment of the '477 Publication pictured in Figs. 7-10 includes a domed bottom, but the '477 Publication discloses that a substantially flat bottom surface with a lateral rim could be used instead. EX1005, ¶[0040]. In such an embodiment, the lateral rim would either be the “annular edge” (my preferred construction), or would include an “annular outer edge” at the periphery of the flat lowermost surface of the lateral rim (my alternative construction). In either case, the annular outer edge would be below and spaced apart from the lower surface of the leading face of the start structure, as illustrated below in a modified version of Figure 8, where such a lateral rim has been added.



371. If, for any reason, the disclosures of the '477 Publication were insufficient to render obvious spacing the thread start structures above the annular outer edge of the substantially flat bottom surface, adding the disclosure of Kirschman substantiates the obviousness of such a feature. *Supra* Section IX.A. Kirschman discloses a frusto-conical surface 14b below the closure top threads and above the substantially flat bottom surface at the bottom of the closure top.

EX1007, Fig. 6. Kirschman discloses that this unthreaded surface “14b of the cap 14 has a surface that is adapted to provide the lock aid by facilitating



guiding the cap 14 on the receiver 12 to facilitate aligning the cap 14 and the male cap threads 46 and the leading edge portion 46a” with the threads of the receiver. *Id.*, ¶¶[0043], [0049]. Therefore, Kirschman specifically teaches that it is advantageous to space the start structures apart from and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof. *See supra* Section VI.B.2.a, ¶¶201-02. Adding the disclosures of Kirschman to those of the ’477 Publication and Boschert, would only reinforce to POSA the obviousness of spacing the start of the threads above annular outer edge of the substantially flat bottom surface (under any construction).

2. Claim 12

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

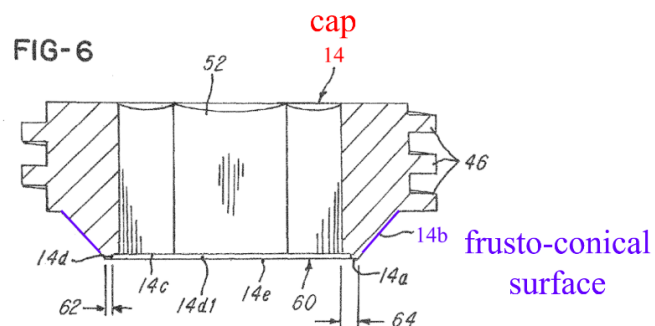
372. This element of Claim 12 is the same as Limitation B2 of Claim 1 except that Claim 12 does not require “the substantially flat bottom surface configured to engage the rod.” Therefore, Kirschman, in combination with the ’477 Publication, either alone or in further combination with Boschert, renders this limitation obvious for the reasons explained above. *Supra* Section X.A.1.e.

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

373. As set forth above, in my opinion, the '477 Publication in view of Boschert discloses this limitation, with the outward facing surface being either the outward facing surface of the cylindrical closure top body or the outward facing side surface of a downwardly projecting lateral rim with a flat lowermost surface. *Supra* Section X.D.2.f.

374. If, for any reason, the disclosures of the '477 Publication were insufficient to render obvious an outward facing surface encircling the substantially flat bottom surface, adding the disclosure of Kirschman substantiates the obviousness of such a feature. Kirschman discloses a frusto-conical surface below the closure top threads and above the substantially flat bottom surface at the bottom of the closure top.

Kirschman discloses that this unthreaded surface “14b of the cap 14 has a surface that is adapted to provide the lock aid by facilitating guiding the cap 14 on



the receiver 12 to facilitate aligning the cap 14 and the male cap threads 46 and the leading edge portion 46a” with the threads of the receiver. *Id.*, ¶¶[0043], [0049]. In the preferred embodiment, this unthreaded surface is frusto-conical (as shown

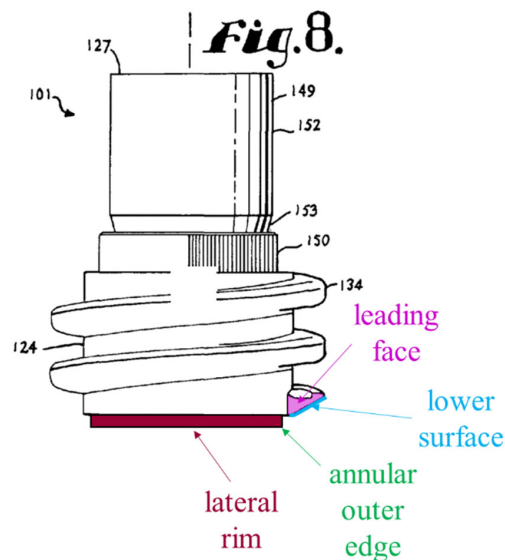
above and highlighted in purple), but Kirschman discloses that “it should be understood that the surface shape could be any suitable shape adapted to guide the cap 14 into the bore 22 and onto the receiver 12.” *Id.* As Figure 6 shows, this surface 14b is faces way from the center of the rim (i.e., outward) and surrounds in a circular fashion (i.e., encircles) both the substantially flat bottom surface 14c and the flat lowermost surface of the lateral rim 14e. Therefore, Kirschman specifically teaches that it is advantageous to have an outward facing surface that encircles the substantially flat bottom surface (under any construction) in order to help guide the cap onto the receiver and facilitate aligning of the cap threads into the receiver threads. *See also supra* Section VI.B.2.a, ¶¶201-02.

- c. **12[B5]: “the first lower surface of the first thread and from⁸ the second lower surface of the second thread are spaced above and apart from the annular outer edge of the substantially flat bottom surface of the plug.”**

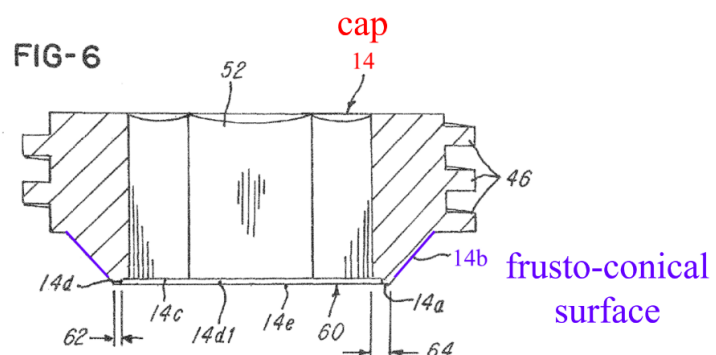
375. As set forth above, in my opinion, the combination of the '477 Publication discloses and renders obvious this limitation under any construction of “annular outer edge of the substantially flat bottom surface.” *Supra* Section X.D.2.h. The preferred embodiment pictured in Figs. 7-10 includes a domed bottom, but the '477 Publication discloses that a substantially flat bottom surface

⁸ “From” appears to be included in this limitation in error.

with a lateral rim could be used instead. *Id.*, ¶[0040], Figs. 7-10. In such an embodiment, the lateral rim would either be the “annular outer edge” (my preferred construction), or would include an “annular outer edge” at the periphery of the flat lowermost surface of the lateral rim (my alternative construction). In either case, the annular outer edge would be below and spaced apart from the lower surface of the leading face of the start structure, as illustrated below in a modified version of Figure 8, where such a lateral rim has been added.



376. If, for any reason, the disclosures of the '477 Publication were insufficient to render obvious spacing the thread start structures above the



annular outer edge of the substantially flat bottom surface, adding the disclosure of Kirschman substantiates the obviousness of such a feature. Kirschman discloses a frusto-conical surface 14b below the closure top threads and above the substantially flat bottom surface at the bottom of the closure top. Kirschman discloses that this unthreaded surface “14b of the cap 14 has a surface that is adapted to provide the lock aid by facilitating guiding the cap 14 on the receiver 12 to facilitate aligning the cap 14 and the male cap threads 46 and the leading edge portion 46a” with the threads of the receiver. *Id.*, ¶¶[0043], [0049]. Therefore, Kirschman specifically teaches that it is advantageous to space the start structures apart from and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof. Adding the disclosures of Kirschman to those of the ’477 Publication and Boschert would only reinforce to POSA the obviousness of spacing the start of the threads above annular edge of the substantially flat bottom surface (under any construction). *See supra* Section IX.A.

377. Therefore, adding the disclosures of Kirschman to those of the ’477 Publication and Boschert would only have reinforce to POSA the advantage of including an outward facing surface encircling the substantially flat bottom surface of the plug (under any construction).

F. Ground 6: Claim 19 is Obvious Based on the '477 Publication in View Boschert (Alone or in Further Combination with Kirschman), and Johnson.

378. As set forth above, it also would have been obvious to a POSA to combine the teachings of Johnson with the '477 Publication and Boschert (either alone or in further combination with Kirschman) before the priority date of the '646 Patent. *Supra* Section IX.B. Like the '477 Publication, Boschert, and Kirschman, Johnson is directed to a polyaxial bone screw with a U-Shaped receiver that receives a rod member. EX1008, Abstract. In my opinion, a POSA would have been motivated to add breakoff extension arms to an existing system at least based on the benefits of breakoff extensions as taught by Johnson. *See also supra* Section VI.B.2.c, ¶¶204-06.

379. For example, Johnson teaches that breakoff extension arms provide the benefit of simplifying the introduction of an elongate member or rod. Johnson discloses that, “[w]hen the surgeon wishes to insert an elongated member 220 into receiver member 212, he or she need not bend it or use a special reducing tool to insert it into the lower end of a receiving channel. Rather, he or she places a portion of the elongated member 220 into channel 254 in upper portion 212*b* of receiver member 212.” EX1008, ¶[0055]. Johnson discloses that a compression member is then “thread into threads 256, forcing elongated member 220 further down in channel 254” so that the “elongated member 220 is forced all the way

through upper portion 212*b*, into lower portion 212*a*, and against a crown member and/or anchor member in chamber 228.” *Id.* Johnson also discloses that “[o]nce separate, upper portion 212*b* may be removed from the surgical site and discarded.” *Id.*, ¶[0056]. Thus, based on these teachings, a POSA would have recognized the benefits of including breakoff extension arms in an existing device, including easier delivery of a rod while maintaining a low profile device, and would have been motivated to use this feature in the ’477 Publication and Boschert (either alone or in further combination with Kirschman) combination.

380. 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 ’646 Patent that breakoff extension arms provided these advantages and could be successfully used in medical implant devices. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for machining breakoff extension arms were well known and readily available. *Supra* Section VI.B.2.c, ¶¶204-06.

381. Moreover, a POSA would have been motivated to combine the teachings of Johnson with the ’477 Publication, Boschert, and Kirschman based on the demands known to the medical device design community for medical devices with low profiles and that minimize the difficulty of use.

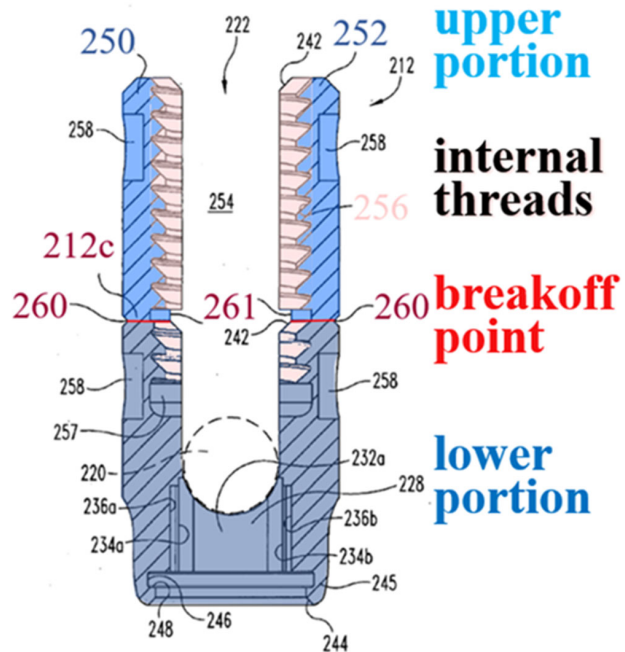
382. As set forth above, the '477 Publication and Boschert (either alone or in further combination with Kirschman), render obvious every limitation of challenged Claim 3, 12-18, and 20. Claim 19 adds the additional element of breakoff arm extensions, but this additional element was well known in the prior art, including as taught by Johnson. Therefore, below I address why the additional element of Claim 19 is rendered obvious by Johnson. For all other limitations, my opinions expressed above (that these features were already rendered obvious by the disclosures of the '477 Publication, either alone or in view of Kirschman, in further view of Boschert) remain and are unaffected by the additional disclosures of Johnson.

1. Claim 19

383. All of the limitations of Claim 19 are recited in Claims 12 and 18, except Claim 19 further recites: [C] “wherein the top surfaces of the first and second arms each include a breakoff extension with an inner surface having a discontinuously helically wound thread form, the first and second arm breakoff extension thread forms being continuous with the respective discontinuous helically wound thread form on the inner surface of the first and second arms.” Claim 19 requires many of the same elements as Claim 10, and this combination meets the limitations of Claim 19 for the same reasons. *See supra* Section X.C.1.

In my opinion, the '477 Publication (either alone or in view of Kirschman) in further view of Boschert and Johnson discloses this limitation.

384. In particular, as discussed above, as seen in Figure 12 to the right, Johnson discloses a first breakoff extension coupled to the top surface of the first arm 250 (i.e., at breakoff point 260 on arm 250) and a second breakoff extension coupled to the top surface of the second arm 252 (i.e., at breakoff point 260 on arm 252). EX1008, Fig. 12. Johnson further 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.* ¶[0052]; Fig. 12. Johnson further discloses that the “[t]hreads 256 may [be] configured so that they *are essentially continuous* from upper portion 212b to lower portion 212a” so that a compression member “can be inserted into upper portion 212b and moved down to lower portion 212a.” *Id.*, ¶[0053]. Johnson also discloses that a compression member is rotatably advanced because it is “threaded into threads 256, forcing elongated member 220 further

down in channel 254” so that the “elongated member 220 is forced all the way through upper portion 212*b*, into lower portion 212*a*, and against a crown member and/or anchor member in chamber 228.” *Id.*, ¶[0055]; Fig. 12.

385. In my opinion, based on the above disclosures, a POSA implementing the implementing the ’477 Publication (either alone or in view of Kirschman) in view of Boschert would have been motivated to use top surfaces of the first and second arms each include a breakoff extension with an inner surface having a discontinuously helically wound thread form, the first and second arm breakoff extension thread forms being continuous with the respective discontinuous helically wound thread form on the inner surface of the first and second arms as taught by Johnson. *See supra* Section IX.B.

386. Accordingly, the ’477 Publication (either alone or in view of Kirschman) in view of Boschert in further view of Johnson renders obvious every element of Claim 19.

XI. DISCUSSION OF SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

387. I am not aware of any evidence of secondary considerations that supports the non-obviousness of the Challenged Claims of the ’646 Patent.

388. I am, however, aware of evidence of secondary considerations that rebuts the non-obviousness of the Challenged Claims of the ’646 Patent, in particular, the non-obviousness of a closure with a first thread and a second thread

and a first start structure disposed at a diametrically opposite location on the closure from a second start structure. For example, on January 4, 2017, Zimmer Spine filed U.S. Patent Application No. 15/397,959 (“the ’959 Application”), entitled “Bone screw including a dual thread closure member.” EX1036 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.

389. 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.

390. The examiner for the '959 Application rejected pending claim 2 as being unpatentable over U.S. 6,726,689 to Jackson ("Jackson '689") 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. EX1036 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.

391. 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 (EX1036 at 70). In particular, Zimmer Spine stated that it had become "aware of Oberg's Machinery Handbook, 28th Edition, which is a reference book that discusses conventional

thread forms for use in a variety of applications” and that the Machinery Handbook “includes disclosure explaining how to produce a screw with multi-start threads on a CNC machine.” *Id.* at 71. Zimmer Spine stated that, in view of the Machinery Handbook’s disclosure that “[i]n order to achieve proper distribution of each start around the cylinder each thread has to start at an equal angle, determined by the following calculation: Thread cylindrical spacing = $360 / \text{Number of starts}$,” Zimmer Spine’s “previous arguments regarding simultaneous engagement can no longer be supported.” *Id.*

392. In my opinion, the prosecution of the ’959 Application, and its subsequent express abandonment, supports the *obviousness* of the Challenged Claims of the ’646 Patent that recite a closure with a first thread and a second thread or a first start structure disposed at a diametrically opposite location on the closure from a second start structure. This evidence has a clear nexus to these claimed features of 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 of these claimed features of the claimed invention because Zimmer abandoned the technology after discovering prior art relating to routine machining skills and techniques.

393. 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

394. 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.

395. 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.

396. 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.

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

Dated: September 21, 2023

Carl McMillin
Carl McMillin, PhD