

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ROGER P. JACKSON
Patent Owner

Patent No. 10,548,641
Filing Date: April 27, 2018
Issue Date: February 4, 2020
Title: MEDICAL IMPLANT RECEIVERS HAVING DUAL LEAD IN
CLOSURE MATING THREAD FORMS

Inter Partes Review No. IPR 2023-01431

DECLARATION OF DR. CARL MCMILLIN

TABLE OF CONTENTS

	Page
I. INTRODUCTION AND SUMMARY OF OPINIONS.....	1
II. RELEVANT EXPERIENCE.....	7
III. COMPENSATION	10
IV. DOCUMENTS AND INFORMATION CONSIDERED	11
V. APPLICABLE LEGAL STANDARDS.....	11
A. Invalidity	11
B. Claim Construction	19
VI. THE PERSON OF ORDINARY SKILL IN THE ART	19
A. Qualifications of a Person of Ordinary Skill in the Art	19
B. Knowledge of a Person of Ordinary Skill in the Art.....	22
1. Threaded Connectors	27
2. Other Aspects of Spinal Implant Design	58
VII. THE '641 PATENT.....	73
A. Overview	73
B. Prosecution History	79
C. The Challenged Claims	82
D. Opinions on Claim Construction.....	94
1. “a first start structure with a leading face surface extending below a first upper loading surface disposed between a root and a crest of the first continuously helically wound thread form” / “a second start structure with a leading face surface extending below a second upper loading surface disposed between a root and a crest of the second continuously helically wound thread form” (Claims 1 and 26) / “each of the first start structure and the second start structure having a leading face surface” (Claim 21).	95
2. “wherein the concave surface is adjacent the root and the convex surface is adjacent the crest” (Claims 11 and 27).	96

3.	“each of the first start structure and the second start structure includes a bottom beveled surface” (Claim 13).....	98
4.	“the first and second start structure leading face surfaces are at least partially planar surfaces parallel with respect to each other” (Claim 14) and “each of the leading face surfaces of the first start structure and the second start structure include at least a partial planar surface” (Claim 19).	101
5.	“the closure has a bottom surface that is closed” (Claim 22)	103
6.	“simultaneous mating” (Claim 26)	103
VIII.	SCOPE AND CONTENT OF THE PRIOR ART REFERENCES	105
A.	Overview of the '477 Publication	105
B.	Overview of Boschert.....	110
C.	Overview of the '391 Publication	118
D.	Overview of Johnson.....	122
IX.	MOTIVATION TO COMBINE.....	125
A.	Motivation to Combine the '477 Publication and Boschert.....	125
1.	Motivation to Use Known Dual Threads.....	127
2.	Motivation to Use a Flat Closure Top Bottom	129
B.	Motivation to Combine the '391 Publication with the '477 Publication and Boschert.....	132
C.	Motivation to Combine Johnson with the '477 Publication and Boschert.....	134
X.	SPECIFIC OPINIONS RELATING TO GROUNDS FOR UNPATENTABILITY.	137
A.	Ground 1: Claims 1, 3-19, and 21-28 Are Obvious in View of the '477 Publication and Boschert	137
1.	Claim 1	137
2.	Claim 3	165
3.	Claim 4.....	169
4.	Claim 5	172

5.	Claim 6	178
6.	Claim 7	180
7.	Claim 8	182
8.	Claim 9	183
9.	Claim 10	185
10.	Claim 11	188
11.	Claim 12	189
12.	Claim 13	191
13.	Claim 14	193
14.	Claim 15	195
15.	Claim 16	197
16.	Claim 17	199
17.	Claim 18	200
18.	Claim 19	203
19.	Claim 21	205
20.	Claim 22	212
21.	Claim 23	213
22.	Claim 24	216
23.	Claim 25	217
24.	Claim 26	217
25.	Claim 27	228
26.	Claim 28	229
B.	Ground 2: Claim 2 is Obvious Under 35 U.S.C. § 103 Based on the '477 Publication in View of Boschert and the '391 Publication.	229
1.	Claim 2	232
C.	Ground 3: Claim 20 is Obvious under 35 U.S.C. § 103 Based on the '477 Publication in View of Boschert and Johnson.	240
1.	Claim 20	243

XI.	DISCUSSION OF SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS.....	249
XII.	CONCLUSION.....	252

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

I. INTRODUCTION AND SUMMARY OF OPINIONS

1. I am submitting this declaration in connection with a Petition filed by ZimVie, Inc. and Zimmer Biomet Spine, Inc. (“Petitioners”) for an *inter partes* review of U.S. Patent No. 10,548,641 (“the ’641 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 ’641 Patent, (2) the general knowledge a person of ordinary skill in the part (“a POSA”) had at the effective filing date of the ’641 Patent (which I have been asked to assume is January 10, 2012), (3) the meaning a POSA would ascribe to the claims of the ’641 Patent, (4) the scope and content of the prior art references, and (5) whether Challenged Claims of the ’641 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, it is my opinion that the Challenged Claims of the '641 Patent are obvious. As explained further below, the '641 Patent relates to a closure top (also known as a 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 '641 Patent admits. The '641 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 closure top context of polyaxial pedicle screws. From my review of the prosecution history of the '641 Patent, the claims of the patent appear to have been allowed based on the use of truncated thread starts with curvate leading faces. But the benefits of truncating thread starts and curving the leading face to reduce sharp edges and facilitate thread alignment were well known in the prior art, including on prior art closure tops of polyaxial pedicle screws. The additional features claimed in the '641 Patent, including a detachable guide tool, various thread types (e.g., v-threads, square threads, reverse angle threads, and buttress threads), diametrically opposite start locations, and breakoff receiver arms, were all conventional features readily available to a POSA when designing a pedicle screw system. The '641 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 '641 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 closure tops that can be used with known U-shaped spinal bone screw receivers to capture a rod. The closure tops of the '477 Publication have many of the features claimed in the '641 patent, including various known thread types and a curvate leading face at the start of the thread. The '477 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). The '477 Publication was not cited or discussed during prosecution of the '641 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. *Id.*, 7:21-23 (“The threads 72 of the setscrew 70 can also be designed with a double lead to allow the

setscrew 70 to start more easily than with a single lead.”). Boschert also expressly invites modifications to its closure top, noting that “[t]he embodiments of the locking arrangements disclosed here (e.g., the set screw 70 []) are merely examples of the types of locking arrangements that can be used.” *Id.*, 7:58-60. Therefore, a POSA would naturally combine the teachings of Boschert regarding 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 prosecution of the ’641 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 dual-start thread claims, as is further discussed below.

6. Most polyaxial pedicle screws are designed with features to allow the screw to be held and manipulated while being implanted. For example, Boschert also teaches the inclusion on the receiver of “grasping features 119 on the outer surface 108 that would accommodate instrumentation to facilitate grasping, holding or manipulating of the receiver 30.” *Id.*, 6:15-19. Boschert does not disclose the details of the tools or instrumentation to be used with its receiver, thereby naturally leading a POSA to look to known tools, such as those disclosed in U.S. Patent Application Publication No. 2006/0069391 (“the ’391 Publication”)

(EX1030). The '391 Publication discloses the conventional feature of guide tools that (1) attach to the receiver head during implantation of the rod and (2) can then be detached and removed from the receiver after implantation. The '391 Publication was not cited or discussed during prosecution of the '641 Patent.

7. Finally, U.S. Patent Application Publication No. 2007/0088357 ("Johnson") (EX1008) is one of several prior art references that disclose the conventional feature of breakoff receiver arm extensions that can be added to any known receiver, such as the receivers disclosed in Boschert, to facilitate implantation of a rod and to accommodate severe spinal deformities. Johnson is cited on the face of the '641 Patent but was not discussed during prosecution of the '641 Patent, either alone or in combination with the other references discussed herein.

8. The '477 Publication, Boschert, the '391 Publication, and Johnson were never discussed in any rejection during the prosecution of the '641 Patent. Instead, the Challenged Claims were allowed on the basis of conventional prior art closure top features without the benefit of the full set of prior art, and combinations thereof, that are discussed herein. In my opinion, the '477 Publication with its curvate leading thread face, in combination with the dual-start threads taught by Boschert, rendered obvious Claims 1, 3-19, and 21-28 of the '641 Patent. Such a combination would have included every feature claimed in the '641 Patent with the

exception of the conventional guide tool described in Claim 2 and the conventional breakoff receiver arm extensions described in Claim 20. Claims 2 and 20 of the '641 Patent were also obvious because a guide tool and breakoff receiver arm extensions were conventional design options, as disclosed by the '391 Publication and Johnson.

9. Furthermore, nothing in the teaching of the '641 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 screw tops to assist in rod alignment; the particular type of thread used in the screw cap/set screw; the use of a single, double, or triple start for the set screw into the screw cap; the shape of the leading edge of the set screw; and the shape of the bottom of the set screw that interfaces with the rod. Therefore, in my opinion, each of the Challenged Claims of the '641 Patent are obvious.

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

II. RELEVANT EXPERIENCE

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

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

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

14. I helped develop rod bending systems used to bend stainless steel and titanium rods into the curvatures required for use in pedicle screw and rod systems intraoperatively and have scrubbed into operations where rods were bent and re-bent (sometimes to failure) in order to conform with patient’s anatomy. Both

polyaxial pedicle screws and pedicle screw extensions with appropriate instruments were developed to make this fitting easier.

15. I am currently an Independent Consultant and President of Synthetic Body Parts, Inc. in Brecksville, Ohio. I have held this position since 1997. In this time, I have conducted biomedical materials and device consulting for approximately 100 different companies from single person start-ups through small, medium, large, and multi-national corporations. This has included product development and evaluation, regulatory approval, patent infringement, product failure, and other related activities. Before AcroMed (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.

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

V. APPLICABLE LEGAL STANDARDS

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

A. Invalidity

22. I understand that the only grounds for invalidity that may be presented in a petition for *inter partes* review are those based on patents and/or printed publications.¹ I further understand that for *inter partes* review, invalidity must be

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

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

23. I understand that 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.

24. 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 ’641 Patent is January 10, 2012.

25. 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.

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

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

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

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

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

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

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

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

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

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

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

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

claimed invention would have been obvious to a POSA at the time of the alleged invention.

B. Claim Construction

35. I understand that to date no court has construed the claim terms of the '641 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 '641 Patent are based on the ordinary and customary meaning of the claim terms in the context of the entire '641 Patent, including its specification and prosecution history.

VI. THE PERSON OF ORDINARY SKILL IN THE ART

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

36. It is my opinion that the relevant field of the invention of the '641 Patent is spinal implants with threaded connections.

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

innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. I considered these factors in arriving at my opinion regarding the qualifications of a person of ordinary skill in the art.

38. I understand that Dr. Roger Jackson, the named inventor of the '641 Patent, received his bachelor's degree from the University of Kansas. I further understand that Dr. Jackson received his medical degree from School of Medicine at the University of Missouri, Columbia in 1973. I understand that, after receiving his medical degree from the University of Missouri, Columbia, Dr. Jackson attended graduate school at Kansas University Medical Center in 1978 and Toronto University in 1979. I understand that Dr. Jackson began practicing medicine in 1979 and is currently retired.

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

40. Based on my experience and my review of the relevant prior art, it is my opinion that technology for threaded connections for spinal implants, as of January 10, 2012, was not particularly complex. As I will discuss in more detail below (*see* Section VI.B), as of January 10, 2012, the basic framework of the device that the '641 Patent claims—i.e., an open-headed bone screw receiver and a closure top for locking a stabilization rod—was well-known. Within this framework, the technology for threaded connections for spinal implants in particular would have been relatively straightforward and simple. Indeed, as I discussed, the problems encountered in conceiving of and/or designing threaded connections for spinal implants were typically mechanical engineering problems with a defined set of known solutions. In my opinion, as long as a POSA possessed a baseline understanding of the basics in mechanical engineering, innovations and alterations related to spinal implants and threaded connections between various implant components were relatively straightforward.

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

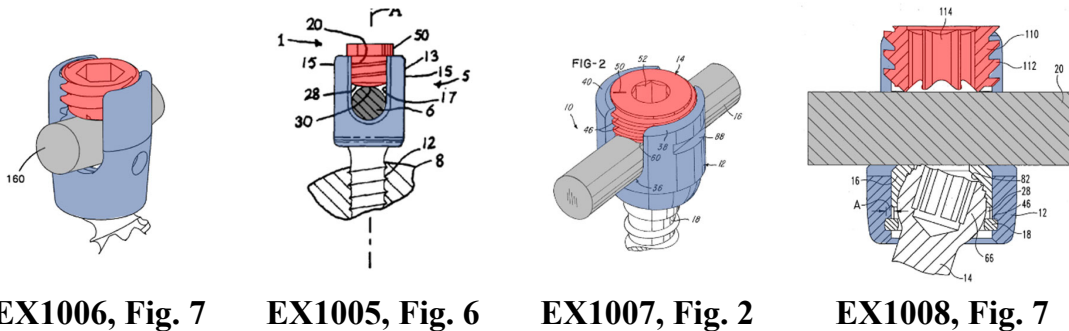
42. In view of the non-exhaustive list of factors discussed above, it is my opinion that a POSA would have had a bachelor's degree in mechanical engineering, or an equivalent discipline, and at least two years of experience designing or implanting spinal implants with threaded connections. More education could substitute for less experience, and vice versa. As of January 10, 2012, I met this definition of a POSA. All of the opinions expressed in this declaration are offered from the perspective of a POSA, as defined above, as of January 10, 2012.

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

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

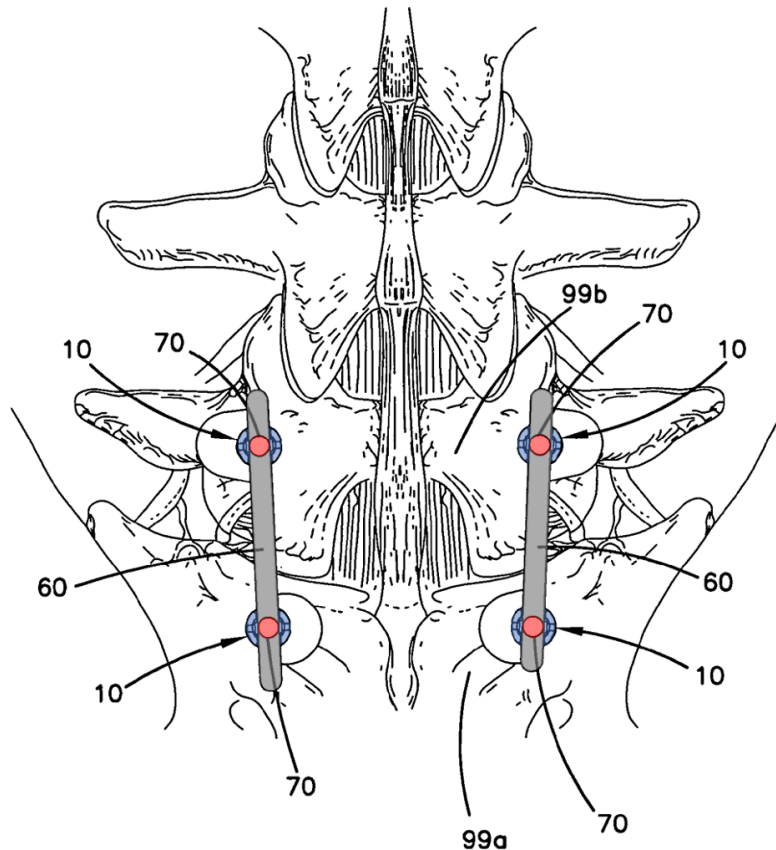
44. As the '641 Patent concedes, at least as of January 10, 2012, "[b]one anchors, such as bone screws and hooks," were well-known. EX1001, 1:28-31.

Known bone anchors included polyaxial bone screw assemblies. *Id.*, 1:46-50; *see also* EX1006, 4:44-47, 5:2-11, Figs. 4, 7, 9, 17; EX1005, ¶¶[0018], [0025]-[0027], [0039], Figs. 5-6; U.S. Patent Application Publication No. 2011/0152947 to Kirschman (“Kirschman”) (EX1007), 1:14-21, 1:52-62, 1:66-2:4, 2:15-32, 2:45-3:2, 3:45-4:6, 6:1-14, 6:20-36, cls. 1, 38, 58, 60-61, 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**):



45. In addition, at least as of January 10, 2012, using a rod with bone screws for “providing vertebral support” was a “common mechanism.” EX1001, 1:31-34. 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.*, 1:35-43. 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.

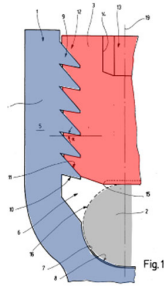


EX1006, Fig. 2.

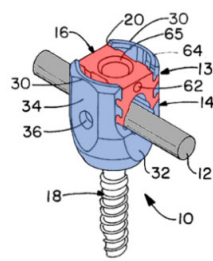
46. “Typical open-ended bone screws included a threaded shank with a head or receiver having a pair of parallel projecting branches or arms which form a yoke with a U-shaped slot or channel to receive a rod or other longitudinal

connecting member.” EX1001, 1:51-55; *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, 1:58-62. 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.*, 1:62-67; *see also* EX1005, Abstract, ¶¶[0005]-[0011], [0025]-[0046], Figs. 1-10; U.S. Patent No. 6,296,642 to Morrison (“Morrison”) (EX1016), Abstract, 1:6-10, 2:30-34, 3:49-51, 3:64-4:61, 5:14-28, Figs. 1, 3-6C; U.S. Patent No. 6,302,888 to Mellinger (EX1017), Abstract, 1:63-65, 2:10-22, 4:38-60, 5:53-57, Figs. 1-2, 5-7, 9-10. In addition to those shown above, sample depictions of representative prior art receiver (**blue**) and closure top (**red**) constructs with a longitudinal rod (**gray**) are shown below, along with their publication dates:

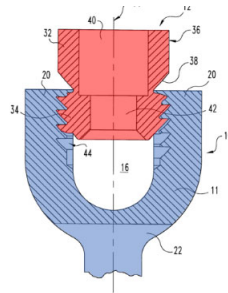
² Closure members have been referred to with a variety of terms in the prior art, including closure, closure top, closure plug, plug, set screw, and the like.



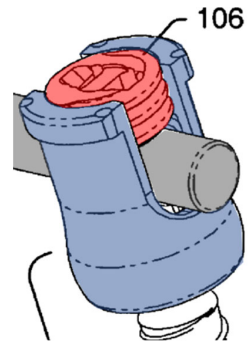
1999
EX1018, Fig. 1



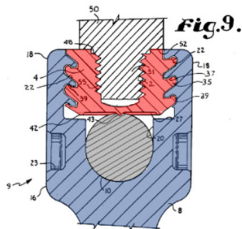
2001
EX1017, Fig. 1



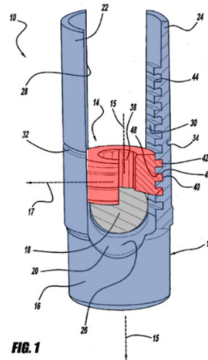
2001
EX1016, Fig. 1



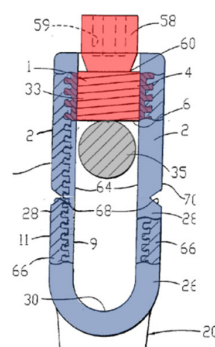
2004
EX1019, Fig. 1



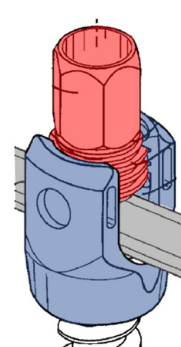
2004
EX1020, Fig. 9



2004
EX1021, Fig. 1



2006
EX1023, Fig. 1



2011
EX1022, Fig. 1

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

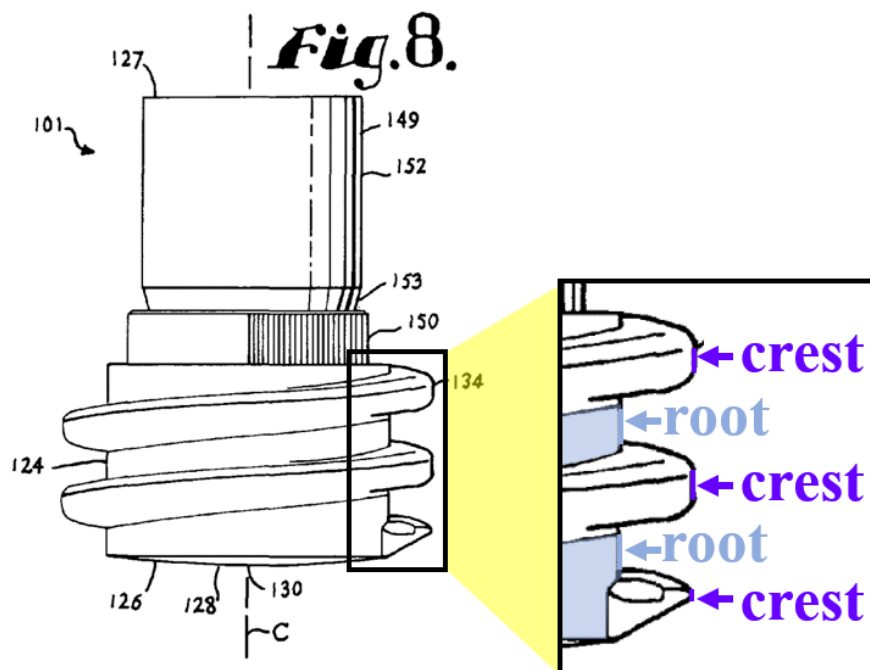
1. Threaded Connectors

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

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

50. 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

51. Before January 10, 2012, it was known that threaded connectors could use single, dual, or multiple helically wrapped threads as was desired for any given application. In particular, it was known that use of additional threads could present advantages in certain circumstances, including to facilitate easier thread engagement, balance threading forces, and increase the speed of insertion, which were important advantages in the field of spinal implants at least because they reduce surgical time and reduce the chance of implant failure.

52. A “start” of a thread is the beginning structure of the thread. Multi-start threads, and their advantages have long been known. For example, the

Ferguson Rifle used by Britain in the American Revolutionary War with British Patent Office No. 1139 filed in 1776 uses a multi-start thread to rapidly close the breach loading gun.³

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



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

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

54. Before January 10, 2012, well-known reference books had discussed multi-start threads as an available design choice. For example, the U.S. Department of Commerce's 1969 Handbook H28 ("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.

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

56. As another example, the 28th Edition of the Machinery's Handbook, which is a "REFERENCE BOOK FOR THE MECHANICAL ENGINEER, DESIGNER, MANUFACTURING ENGINEER, DRAFTSMAN, TOOLMAKER, AND MACHINIST," disclosed multi-start threads at least as early as 2008. Machinery's Handbook 28th Edition (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 degrees. In other words, the Machinery's Handbook teaches that the starts of a dual-start thread should be diametrically

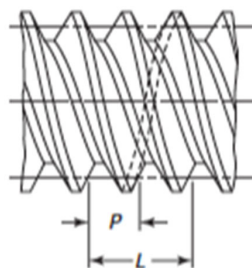
⁴ Emphases and text coloring added unless specified throughout.

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.

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.

57. Double lead threads were well known well before 2012, as evidenced by their description in 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

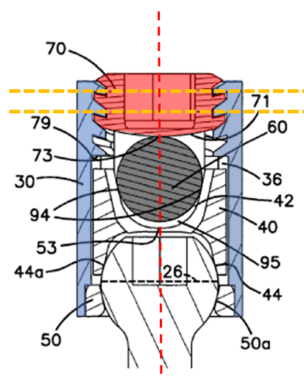
Id. at 9.

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

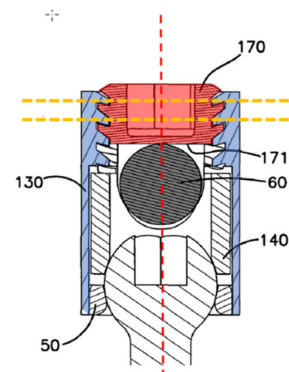
59. Moreover, before January 10, 2012, it was known that multi-start threads were beneficial, for the reasons discussed below, in the specific context of a set screw that needs to hold a rod in place in polyaxial spinal pedicle screw and rod spinal implants, the same as described by Jackson in the ’641 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.

60. A POSA would recognize that Boschert discloses diametrically opposed starts. Specifically, as shown below in annotated Figs. 3 and 15, (1) the reverse angle threads on either side of the receiver are symmetrically and diametrically opposed to each other across the longitudinal axis, and (2) the reverse angle threads on either side of the setscrew are also symmetrically and diametrically opposed to each other across the longitudinal axis, which therefore defines that the two threads leads are 180 apart (as illustrated by the yellow horizontal lines that are perpendicular to the red longitudinal line).

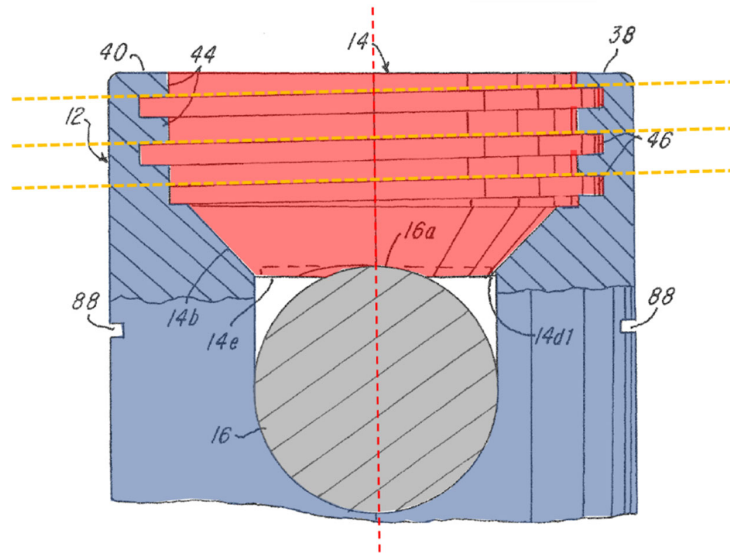


EX1006, Fig. 3



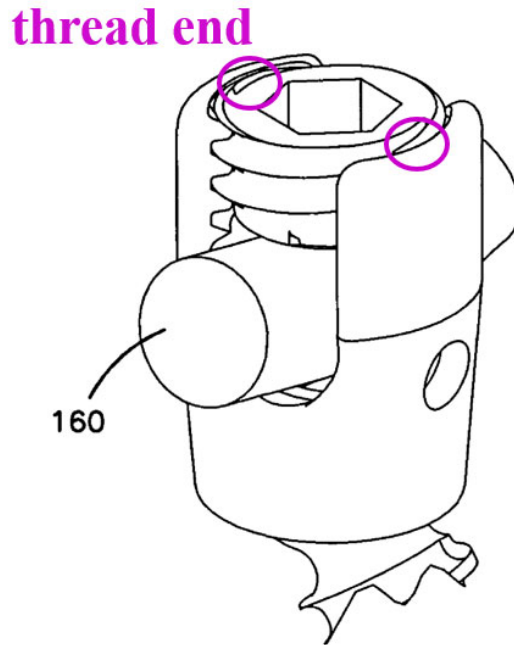
EX1006, Fig. 15

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

61. Finally, a POSA would recognize that Boschert discloses diametrically opposed starts because, as annotated Fig. 7 shows, at the top of the closure top, the trailing ends of Boschert's double lead thread are diametrically opposed. A POSA would have understood and expected that each of the double lead threads would have identical length, and therefore would have understood that diametrically opposed thread ends are the result of diametrically opposed thread starts.



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.

62. A POSA would have further understood that for double start threads on the setscrew to engage with the symmetrical, diametrically opposed receiver threads, (1) the receiver threads would necessarily have to mirror each other, and (2) the start and end structures would necessarily be spread equidistant around their respective ends. This understanding is further reinforced by the conventional manner of making dual start threads, which includes using diametrically opposed

thread starts and threads of equal lengths, as discussed above. *Supra* ¶¶ 54-61. Further, diametrically opposed thread starts would have been the obvious choice when threading a dual start closure under the threads of two symmetrical, diametrically opposed receiver arms. Specifically, a POSA would have understood that each of the thread starts on the closure top would be designed to simultaneously thread under the corresponding threads at the edge of each diametrically opposed receiver arm. This can only be accomplished by diametrically opposing the thread starts on the closure top.

63. Thus, before January 10, 2012, a POSA would have been aware of multi-start threads (including diametrically opposed dual-start threads) as an available and advantageous design choice when designing closure tops, as multi-start threads provided easier starting, balanced rotational forces, and faster closure top insertion, which were important advantages in the field of spinal implants because they reduce surgical time and reduce the chance of implant failure.

b. Truncated Threads and Leading Face Shapes

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



Tapered Start



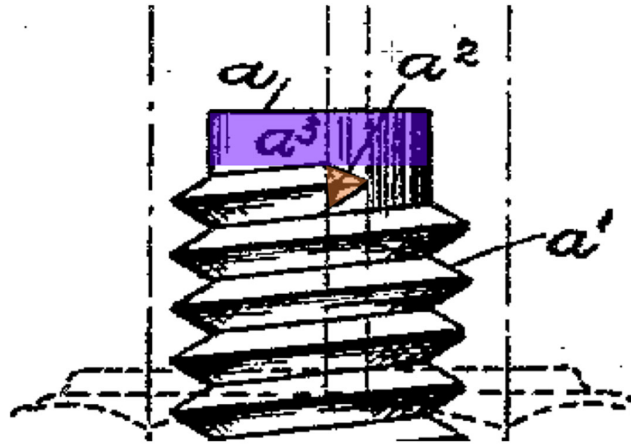
Truncated Start

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.

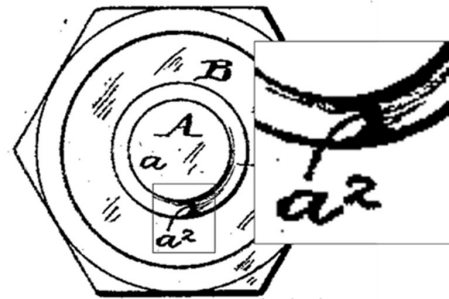
65. U.S. Patent No. 447,775 to Higbee ("Higbee") (EX1015) , entitled "Screw bolt and nut," issued in 1891 and disclosed a thread-start cut that is known today as the Higbee cut. Higbee noted that an issue in prior-art thread starts was that, "[i]n threaded couplings of the kind described the thread is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

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

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

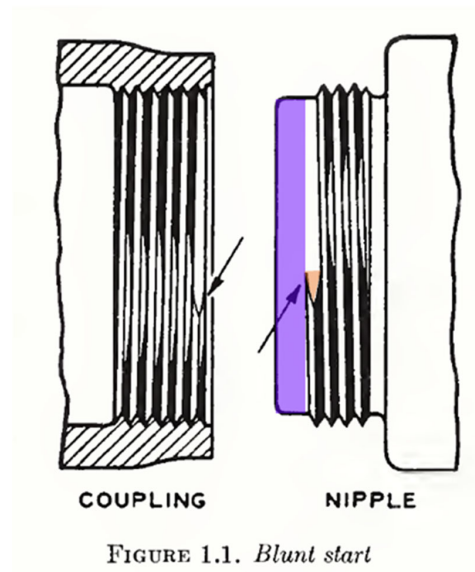


67. Further, Higbee disclosed that “[t]he exact form of the thread end is not very important so long as it is blunt and substantially symmetrical with respect to the center line of the thread” and “may be cut off on an oblique plane, as in Figs. 1, 2, 3, and 4, or cut off square, as in Fig. 5, or rounded,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



68. The Higbee cut, which is also known as a blunt start or blunt end thread, or a 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):

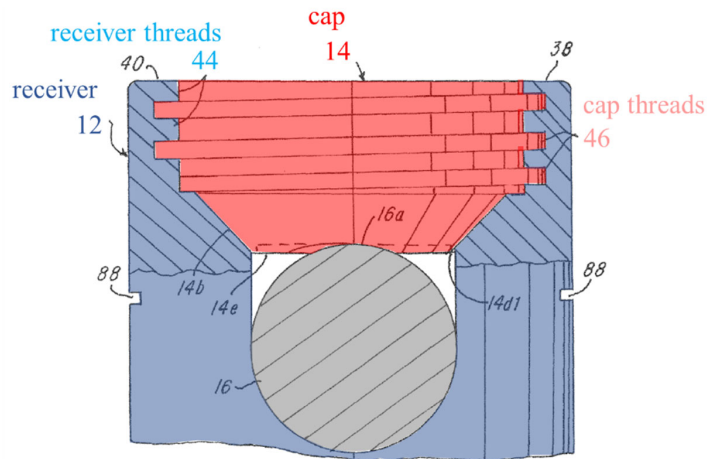


EX1204 at 13. This depiction also clearly shows the smooth extension of the nipple (shown in purple) extending below the thread start to facilitate alignment, as was taught by Higbee.

69. 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 '641 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], 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].

70. In response to this need, Kirschman disclosed truncated thread starts on the closure top. 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 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 end of the cap thread, highlighted in orange below.

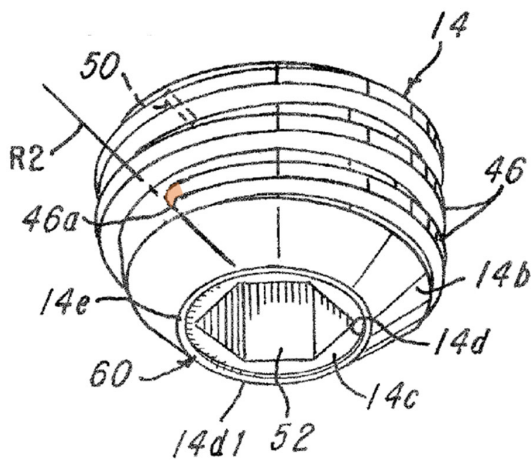


Fig. 3

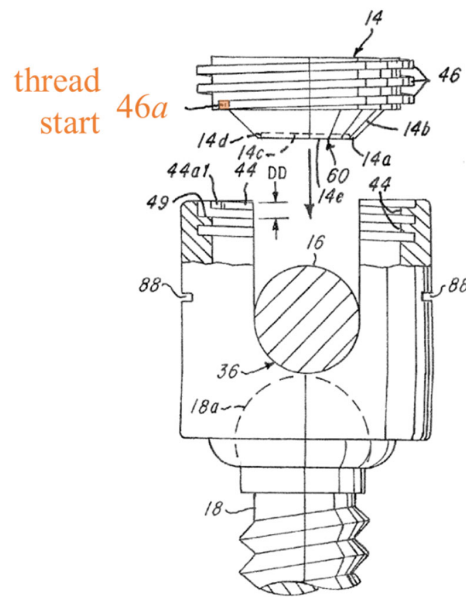
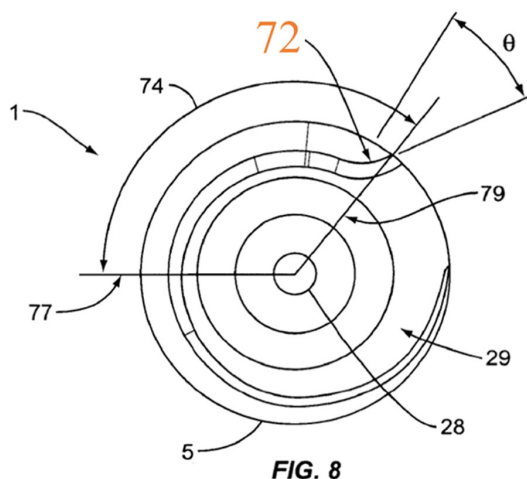


Fig. 4

As evidenced by Kirschman's identification of the 1891 patent to Higbee (U.S. Patent No. 447,775) (EX1015) as "first invent[ing]" "[u]tilizing blunt-tip threads for the prevention of cross threading," Kirschman acknowledges that truncated leads of threads was prior art. EX1007, ¶[0009].

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

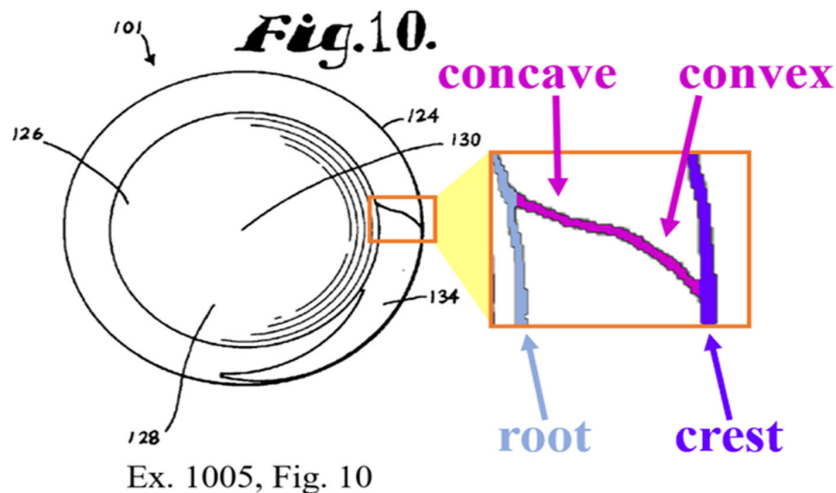
thread start 72. Referring to FIG. 8, the external thread 5 includes a thread start 72 at the bottom end 29 of the set screw 1. Thread start 72, as used herein, means the location at the bottom end 29 of the set screw 1 where the external thread 5 begins. The thread start 72 has a truncation cut 74 *so the threading begins smoothly and consistently at the same location.*” *Id.*, ¶[0031].



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

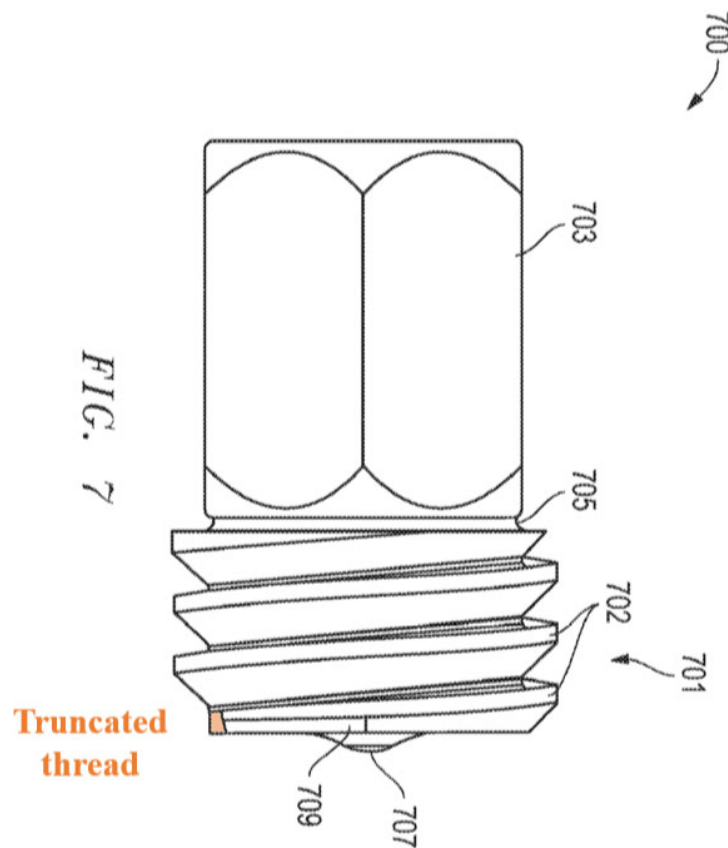
72. As another example, the '477 Publication, which published on December 1, 2005, discloses a “closure for use in conjunction with an open receiver of a medical implant for capturing and locking a rod member in the implant.” EX1005, Abstract. The '477 Publication disclosed two embodiments of its closure. For the first embodiment, the '477 Publication disclosed that the closure is cylindrical with a helically wound guide and advancement structure

along the outside surface. *Id.*, ¶¶[0029]-[0030]; *see also id.*, Fig. 1. For the second embodiment, the '477 Publication incorporated most of the features from the first embodiment. *Id.*, ¶[0039]. The primary difference between the embodiments is the shape of the closure break-off head. *Id.*, ¶¶[0033] (hexagonal), [0043] (cylindrical); *compare id.* Fig. 1, with *id.* Fig. 7. As shown in the annotated figure below, the '477 Publication disclosed a start structure with a leading face that is truncated and includes a concave segment near the thread root and a convex segment near the thread crest. *Id.*, Figs. 7, 10.



73. As a further example, U.S. Patent Application Publication No. 2010/0137918 to Wilcox et al. (“Wilcox”) (EX1035), 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.” Ex. 1035, ¶[0010]. As shown below in annotated Figure 7, Wilcox discloses that its set screw has a threaded portion 701 that “includes a Higby-style truncation 709 of the initial thread 702 which facilitates easier threading of the set screw 700 within the head portion 307. The Higby-style truncation 709 is manufactured such that the leading razor edge of the thread is removed.” *Id.*, ¶[0050].



74. Thus, before January 10, 2012, a POSA was aware of truncated threads with a curvate leading face and was further aware that such constructs

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

c. Thread Manufacturing

75. 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

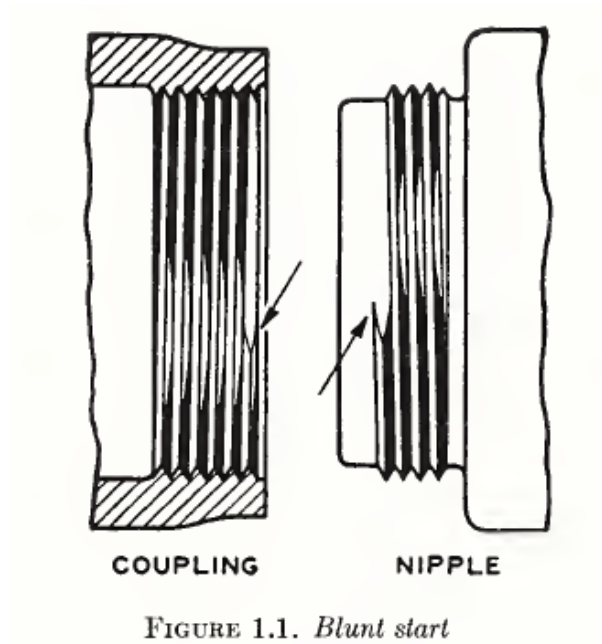
thread and is farthest from the cylinder or cone from which the thread projects,” and that the root of a thread is the “surface of the thread which joins the flanks of adjacent thread forms and is identical with or immediately adjacent to the cylinder or cone from which the thread projects.” *Id.* at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

76. 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 threading would be relatively thin and sharp.

77. 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.

78. To create such a blunt start thread, a POSA would have understood that an additional process would often need to be applied to the thread. *See* U.S. Patent Application Publication No. 2005/0286984 to Weise (EX1034), ¶¶[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.



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. EX1034, ¶[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

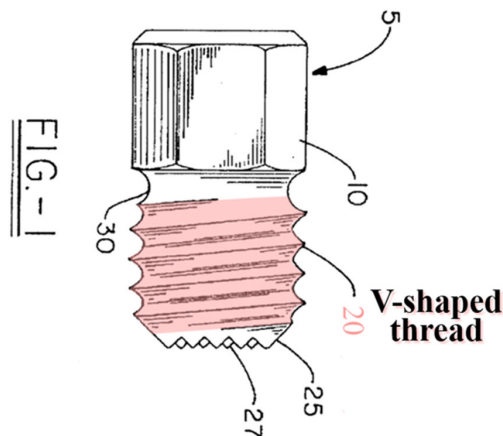
post-forming process could have been used, such as tumbling or electropolishing. In these circumstances, the use of standard manufacturing practices (as I described above) typically resulted in a leading face of the thread that is both concave near the root and convex near the crest.

79. 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

80. As the '641 Patent admits, before January 10, 2012, “***known closures include*** ... a variety of single start helically wound guide and advancement structures, including, for example, ***thread forms having v-thread, reverse-angle buttress or square thread forms***, to name a few, as well as other non-threadlike helically wound forms.” EX1001, 1:62-2:1.

81. 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.***” *Id.*, 2:60-61.



82. While V-shaped threads were the oldest thread configuration, a number of alternative thread designs were also well known well-before the '641 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 the 2001

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.

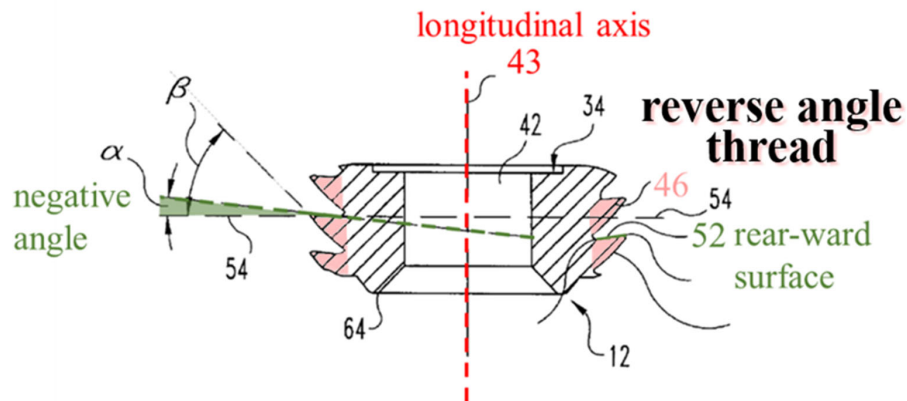
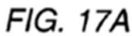


Fig. 3

EX1016, Fig. 3. Specifically, Morrison teaches that the “pressure angle is between -1 and -10 degrees. In a currently more-preferred embodiment, the pressure angle is -5 degrees.” *Id.*, 2:53-56. In such a configuration, “*splaying* of the medical device is *prevented*.” *Id.*, 2:60-62.

83. 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. *Id.*, 17:12-36. As shown in Figure 17A and annotated Figure 17 B below, these modified threads have “[r]aised portions 190 and recessed portions

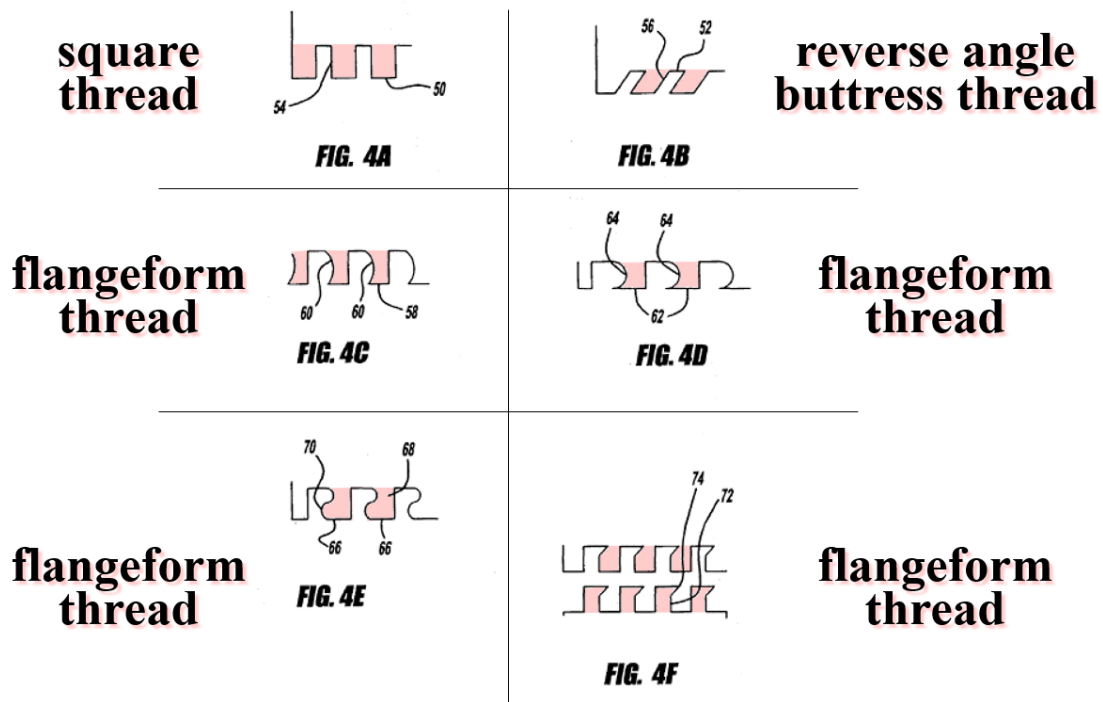
inhibit spreading of arms 142 away from each other.” Id. 17:43-47.



to the axis of the closure member.” *Id.*, 17:12-18.

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].)



85. Jackson himself acknowledged that all of these alternative thread types were well-known in the prior art in his own prior art publications. *See, e.g.*, U.S. Patent No. 6,726,687 to Jackson (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 (EX1036), ¶[0151] (“However, it is foreseen that the guide and advancement structure 162B could alternatively be *a buttress thread, a square thread, a reverse angle thread or thread like or non-thread like helically wound advancement structures* for operably guiding under rotation and advancing the closure 30B downward between the arms 152B[.]”). Thus, each of these known thread types had known advantages, and a POSA would have been readily able to choose between them for any given application.

2. Other Aspects of Spinal Implant Design

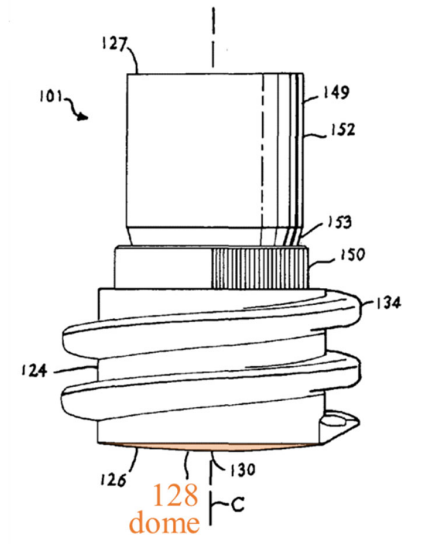
86. Before January 10, 2012, various design options for spinal implants were widely known and available in order to allow a POSA to design implants, taking into consideration the overall size of the implants and the needs of the procedure and the patient. In some instances, the development of minimally 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 the closure top bottoms, the use of break-off receiver arm extensions, and attachable/detachable guide tools.

a. Closure Bottoms

87. Before January 10, 2012, various design options for closure top bottom surfaces were well-known. It was known that different design options for the closure top bottom surface had certain advantages. Among the commonly known choices for closure top bottoms were domed bottoms and flat bottoms. Each of these options provided alternative ways for a POSA to facilitate engagement of the closure top's bottom surface with a stabilizing rod.

88. 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 C (downwardly in FIG. 8) and has an apex 130 where the dome 128 intersects the axis C" or "may be flat and may have a central point and a lateral rim." EX1005, ¶[0040]. As shown in annotated Figure 8 below, the '477 Publication illustrates the domed bottom surface but does not include a figure showing the disclosed rimmed alternative.



EX1005, Fig. 8

89. 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

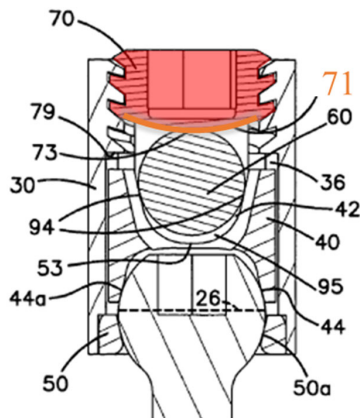


Fig. 3

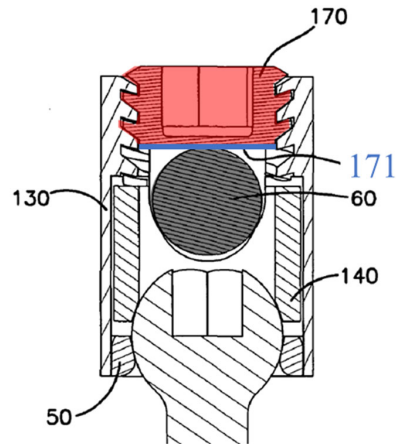
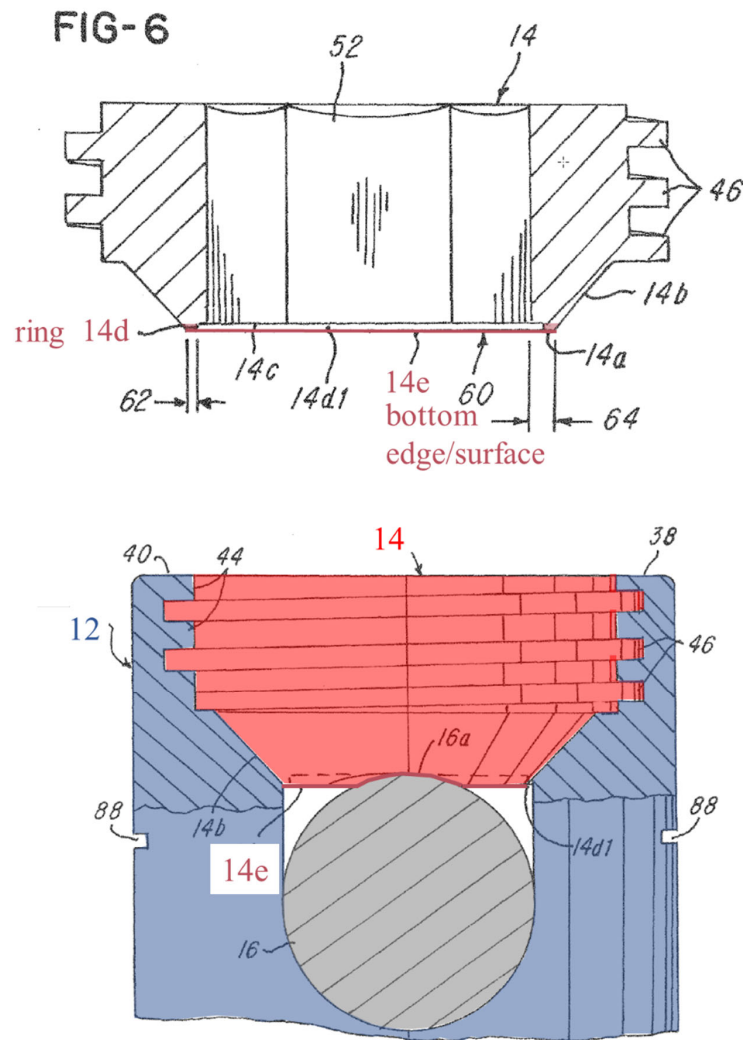


Fig. 15

As a further example and as shown in annotated Figures 6 and 7 below, Kirschman disclosed a closure top (cap 14) with a downwardly projecting ring that includes a flat “end 14c” and “comprises a deformable area 60 that is adapted to provide the lock aid. In the illustrating being describe, 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. 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].



Id., Figs. 6, 7.

90. 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. Designs for Facilitating Implantation of Spinal Implant Devices

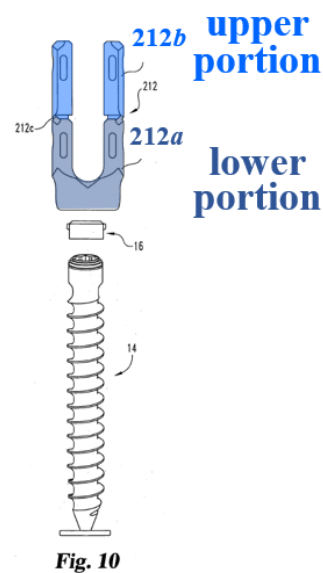
91. Surgeons generally use the smallest incision consistent with the desired access. Especially in certain patients, such as obese patients, attempting to place a small spinal implant by hand deep into the patient through a minimal incision would not be advisable. Accordingly, as discussed further below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

i. Break-Off Receiver Arm Extensions

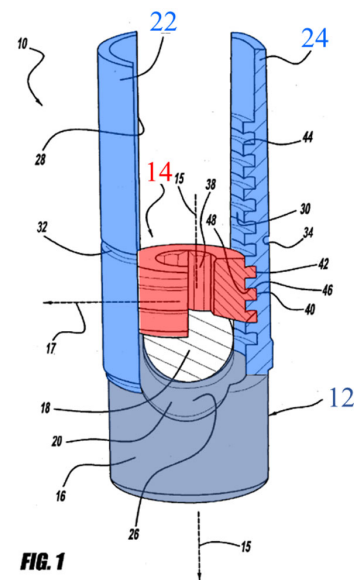
92. Before January 10, 2012, it was well-known that break-off extensions could be used in spinal implant devices, sometimes as an alternative to using a separate guide tool. As discussed above, during a spine surgery using the devices

at issue, a rod is placed into the U-shaped receiver of a spine screw, and by tightening a closure top into that receiver, the closure top forces the rod down until it is fully seated at the bottom of the U-shaped slot in the receiver. In many cases, the typical height of the receiver arms is sufficient to accomplish this function. But in cases of severe spinal deformity, longer U-shaped arms may be needed to capture the rod and allow for a longer tightening distance of the closure top or to allow the surgeon to implant the fixation devices and rods from outside the patient's body in minimally invasive operations. To address this issue, breakoff arm extensions were developed well before January 10, 2012. 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 break-off extensions in the prior art are discussed below.

93. For example, Johnson discloses break-off extension receiver arms. In particular, as shown in the annotated Figure 10, a receiver member 212 that “has a lower portion 212a and an upper portion

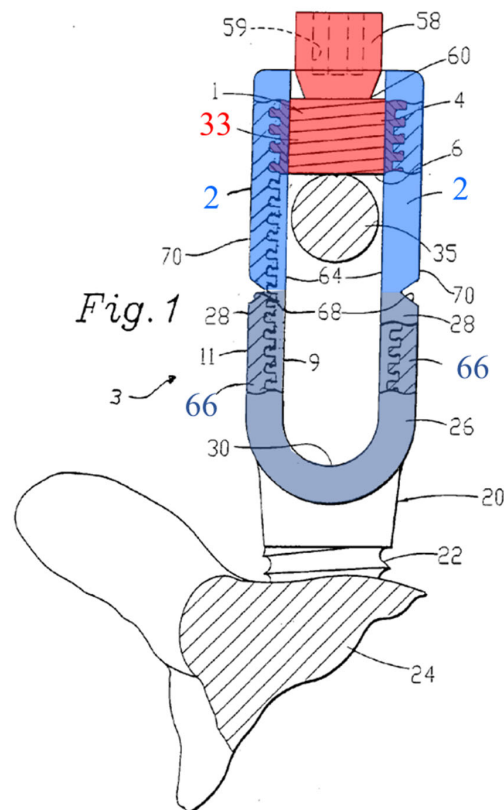


212b separated by a thinned section 212c.” EX1008, ¶[0051]. Johnson discloses that the “[t]hinned section 212c” “separates upper portion 212b and lower portion 212a.” *Id.*, ¶[0054]. The thinned section 212c “includes an external indentation or groove 260, which may include score lines or other fracture-inducing 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.*



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

95. As shown in annotated Figure 1 at right, 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 ’749 further disclosed that “[t]he



extensions 2 can be broken off or separated from the main portions 66 of the arms 28 by pivoting or bending the extensions 2 back and forth about the regions 68 while the main portions 66 are held in place, after the closure 33 has passed between the extensions 2,” “*resulting*” in a “*low-profile implanted structure.*” *Id.*; see also *id.* Abstract, ¶¶[0019]-[0020], [0027], [0040], Figs. 1-2, 6, cls. 1, 6, 10, 16.

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

97. 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.

ii. Attachable/Detachable Guide Tools

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

the guide tool can be removed from the receiver and from the patient's body. Some examples of these well-known attachable/detachable guide tools in the prior art are discussed below.

99. As early as 1985, U.S. Patent No. 4,545,374 to Jacobson ("Jacobson") (EX1032) described the use of a cannulated guide to "contact a predetermined position" in the spine and "conduct[] a surgical procedure on the spinal column by manipulating instruments through the cannula." EX1032 at Abstract, 2:24-30. Jacobson recognized the benefits of percutaneous methods of accessing the spine over long incisions from cutting a channel into a patient's back to access the spine. *See id.* 1:11-2:21.

100. U.S. Patent No. 7,862,595 to Foley ("Foley") (EX1033), which was filed in 2007 and issued in January 2011, similarly recognized that "[m]inimally invasive surgical techniques are particularly desirable in, for example, spinal . . . applications because of the need for access to locations deep within the body and the danger of damage to vital intervening tissues," and disclosed instruments to achieve the benefits of such minimally invasive techniques. EX1033, 1:20-2:2.

101. For example, as shown in annotated Figure 4, Foley disclosed attachable/detachable cannulated tools with bone screws to pass a set screw into the receiver of the bone screw from outside of the patient. In particular, Foley disclosed anchor extension 30 (i.e., the guide tool), mounted to anchor 60 (blue) to

insert set screw 76 (i.e., the closure). *Id.* Fig. 4. As disclosed in Foley, “yoke 68” of anchor 60 “is mountable to anchor extension 30.” *Id.*, 7:34-48. The anchor extension is “held firmly” against “upper surfaces 73” of anchor arms 71 “by set screw 76, which is releasably coupled to yoke 68” and anchor extension 30’s “inner sleeve 50.” *Id.*, 8:27-36.

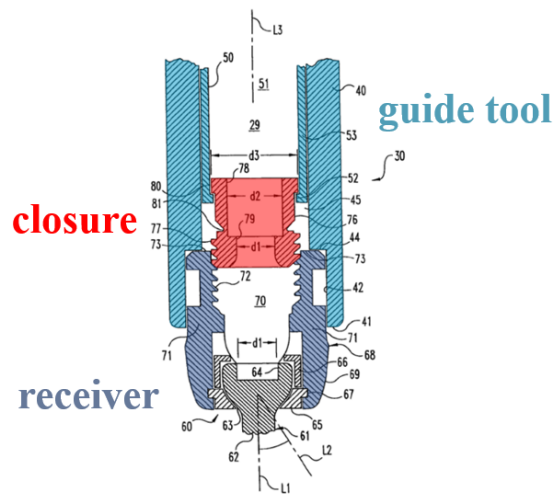


Fig. 4

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

102. In 2006, the '391 Publication disclosed an attachable/detachable guide tool as part of a system “for percutaneously implanting spinal screws and for implanting a rod for spinal support and alignment, using minimally invasive techniques.” EX1030, ¶[0002]. The guide tool disclosed in the '391 Publication

terminated in “bottom 112” with pins that mate with the bone screw receiver. *Id.*, ¶[0110].

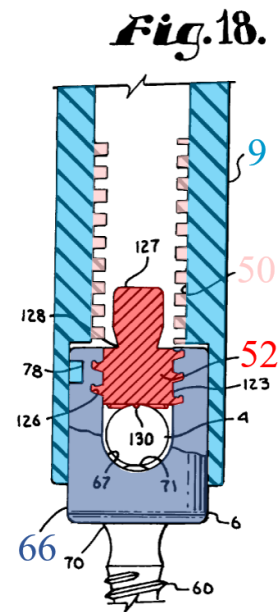
103. The '391 Publication also disclosed that bottom 112 also includes “implant engaging leg member 102 and 103,” each with “a helically wound but discontinuous square thread 114.” *Id.*, ¶[0103]. This thread “cooperates with the closure top 62.” *Id.* “[T]he closure top 62 engages the helically wound guide and advancement structure[] 114 of [] guide tool[] 10. The ... mated closure tops 62 are then rotated, mating the closure tops 62 with associated guide tool[] 10 so as to drive the closure top 62 downward against the rod 8 and to urge the rod 8 downward into the bone screw channel 153.” *Id.*, ¶[0171]; *see also id.* Fig. 42. “[A]t the bottom of the guide tool [] 10, the closure top mating structure 181 engages and begins to mate with the guide and advancement structure 183 on the respective bone screw 4” *Id.*, ¶[0172]; *see also id.* Fig. 43. Once the closure tops are finally seated, the guide tool 10 is “removed by rotating each guide tool[] 10 ninety degrees ... to disengage from the receiver portion 145 on the bone screw 4. The guide tool[] 10 is then pulled axially upward away from the bone screw 4, ... and then out of the incision 350.” *Id.*, ¶[0173].

104. As a further example and as shown in annotated Figure 18, in 2007, U.S. Patent No. 7,160,300 to Jackson (“Jackson '300”) (EX1012) disclosed apparatuses for “percutaneously implanting a rod for spinal support and alignment

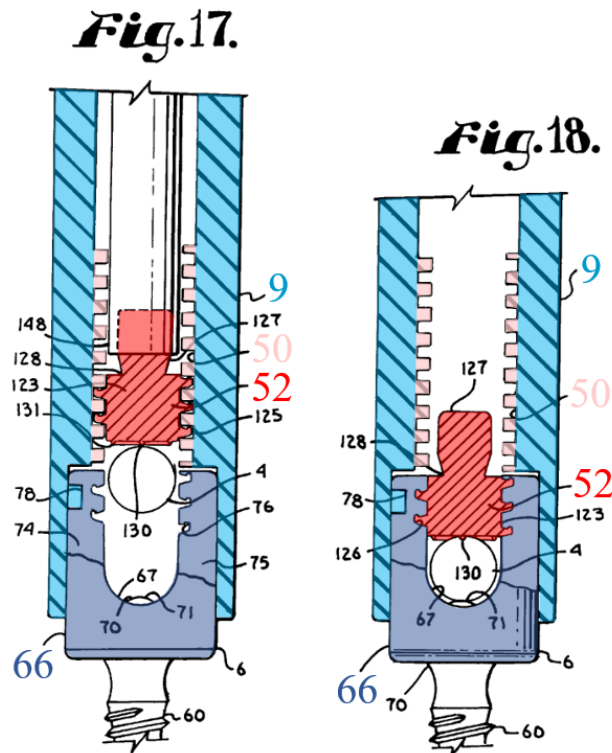
using minimally invasive techniques,” recognizing that was “desirable to develop apparatuses and techniques that allow for the insertion of bone screws . . . with significantly reduced invasion into the body of the patient and with minimal incision size in the skin over the operational site.”

EX1012 at 1:6-32. Jackson ’300 specifically disclosed a guide tool 9 with attachment structure 55 to be received on the outer surface of receiver 78 of the bone screw 6, “and locked therein.” *Id.*, 6:16-23; *see also id.*, Figs. 6-8.

105. As shown below in annotated Figures 17 and 18, Jackson ’300 disclosed using the attached guide tool to pass a set screw into the receiver, where the guide tool had a guide and advancement structure for rotatably advancing a closure top into corresponding guide and advancement structures on the receiver. Specifically, “[t]he helical wound guide 50 and advancement structure in the bottom 39 of each of the guide tools 9 and 10 is sized and shaped to receive the mating guide and advancement structure 125 of the closure top 52 and align with the second guide and advancement structure 76 of the bone screw 6 [i.e., receiver] to form a generally continuous helically wound pathway.” *Id.*, 8:5-11. In other words, the guide and advancement structure on the guide tool is “located and positioned to align” with that on the receiver “and pass the closure top 52



therebetween while allowing the closure top 52 to continue to rotate and to continuously apply force to rod 4, so as to seat the rod 4 in the bone screw head 66.” *Id.*, 8:23-30.



106. Jackson '300 further disclosed that the guide tool could then be detached from the receiver head. In particular, the guide tool is rotated “to allow the attachment structure 55 . . . to disengage from the receiver 78” and then the guide tool is pulled “upward away from the bone screw 6 and from the incision” in the patient. *Id.*, 11:7-15.

107. Thus, attachable/detachable guide tools and their benefits were well-known to POSA before January 10, 2012.

108. The decision to use or not use attachable/detachable guide tools was independent of other aspects of the pedicle screw and rod system such as whether a reverse angle thread is used or whether a single or double thread start is used.

VII. THE '641 PATENT

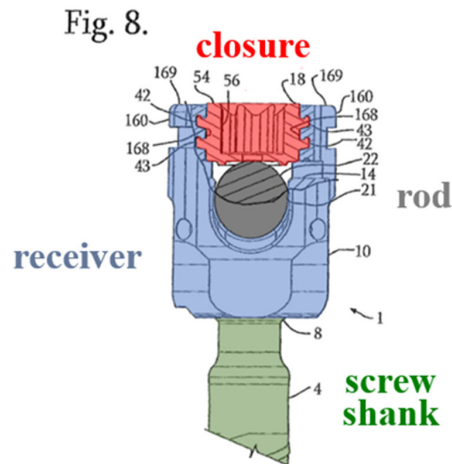
A. Overview

109. The '641 Patent is entitled “Medical Implant Receivers Having Dual Lead in Closure Mating Thread Forms.” EX1001 at 1. The '641 Patent issued on February 4, 2020. *Id.*

110. The '641 Patent claims priority to two provisional applications, the earliest of which was filed on January 10, 2012. *Id.*, 1:8-19. I therefore presume January 10, 2012 to be the effective filing date of the '641 Patent.

111. The '641 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.*, 1:28-31. The specification further states that “open-ended bone anchors are known,” *Id.*, 1:35-42, 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.*, 1:51-55. This U-shaped channel is “closed by a closure member after the rod or other longitudinal connecting member is placed in the channel.” *Id.*, 1:60-62. 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.*, 1:62-2:1. These known components are highlighted below in annotated Fig. 8.



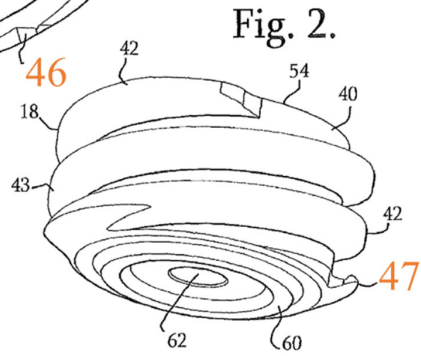
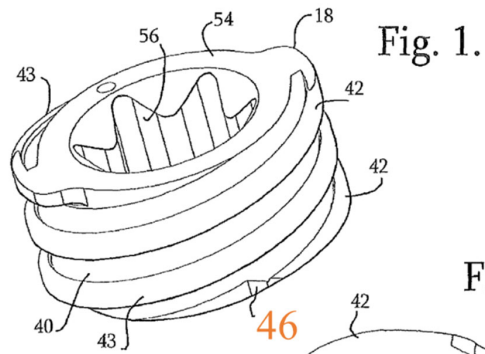
112. The patent then identifies the problem to be addressed as follows: “when the closure is a cylindrical plug having a single start helically wound guide and advancement structure, such structure must be aligned with mating structure on of the implant arms and the rotated until a portion of the structure 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.*, 2:15-23. 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.*, 2:44-47.

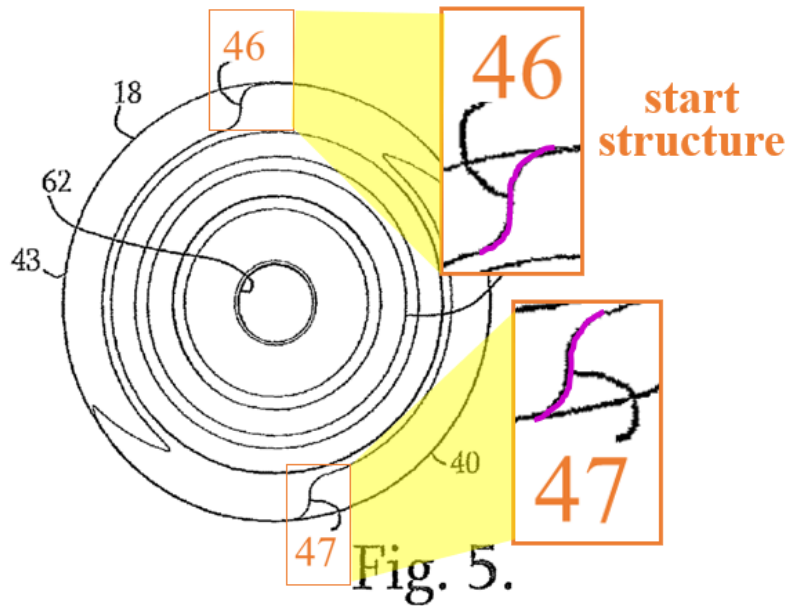
113. The '641 Patent does not describe any inventive significance to the leading face, let alone any particular shape of the leading face, of the closure top thread. Instead, the entirety of the textual description of the leading faces is as follows:

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.

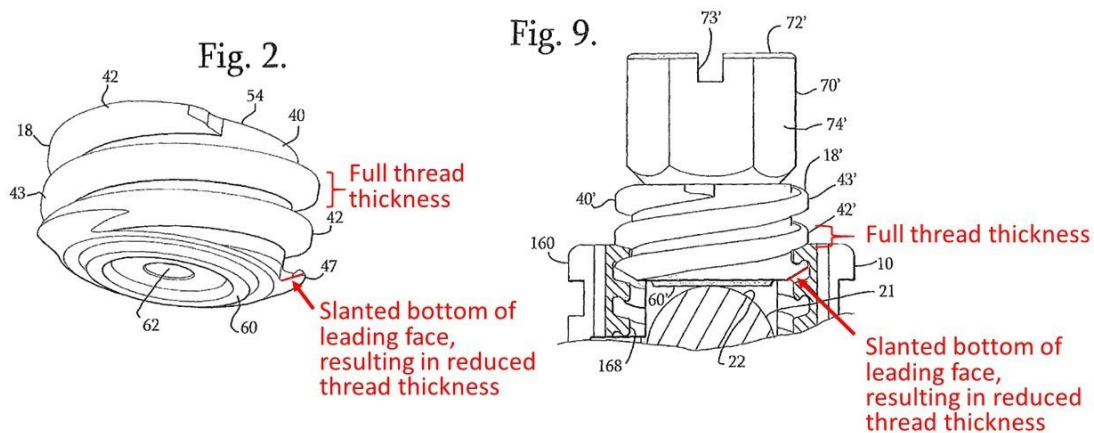
Id., 7:51-55. Nothing is taught of whether a leading curved surface or a double curved leading surface at the start of the thread face would be more advantageous than any other thread start configuration. There is no further discussion in the text of the disclosure. Figures 1 and 2 show these start structures 46 and 47, consisting of truncated thread starts as was well-known in the prior art, but the curvature of the leading faces cannot be observed and is not described in the corresponding text.



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



114. The '641 Patent never discusses any beveling at the bottom of the thread start structure and never describes any benefit achieved from the bevel or any particular shape, length, or angle of the bevel. In fact, the term “bevel” never appears in the '641 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.

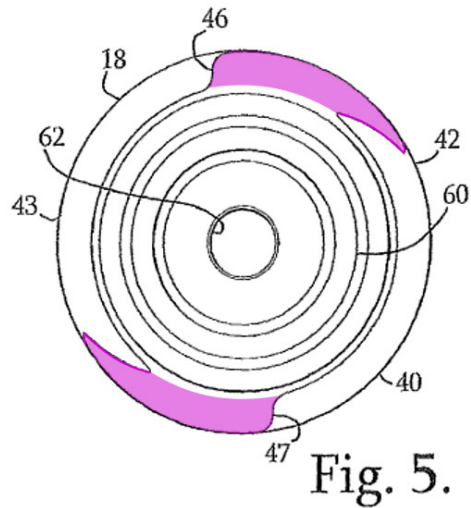
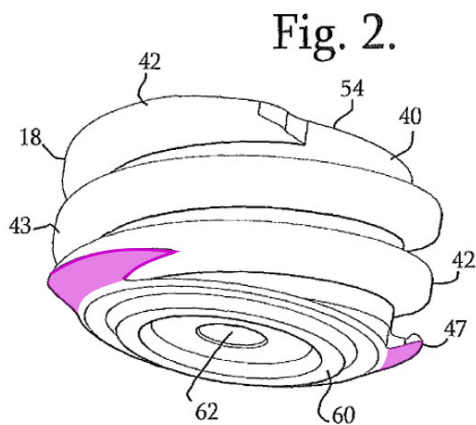
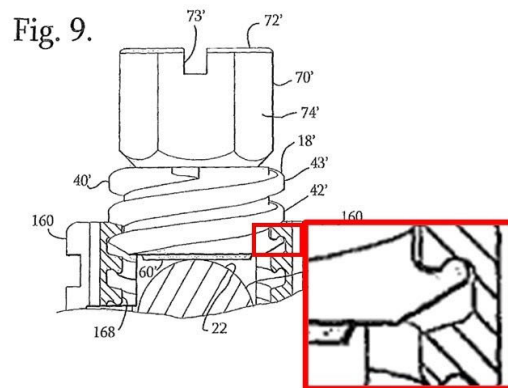
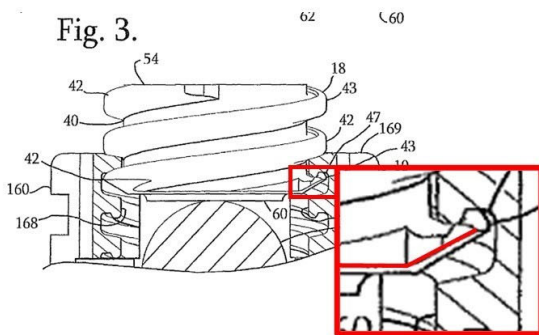


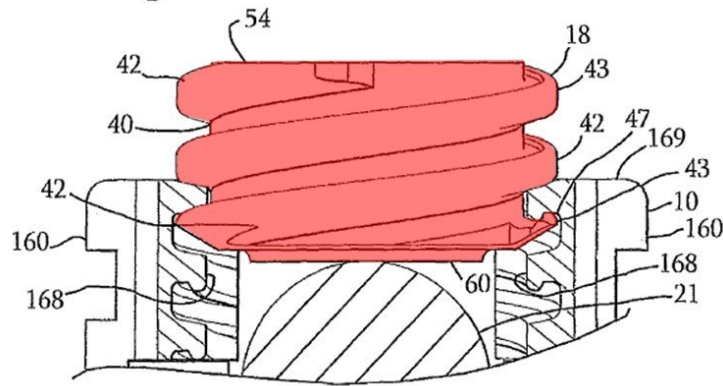
Fig. 3 shows an additional line on the leading face of the thread (highlighted in red below), which is not shown in Fig. 9, but the meaning of this additional line is not explained.



115. The specification does not prescribe any particular significance to the closure top bottom. It describes one possible bottom arrangement that is “planar and further includes a rim 60 for engagement and penetration into the surface 22 of

the rod 21.” *Id.*, 7:19-21. This embodiment is illustrated in Figs. 1-8, including Fig. 3 set forth below.

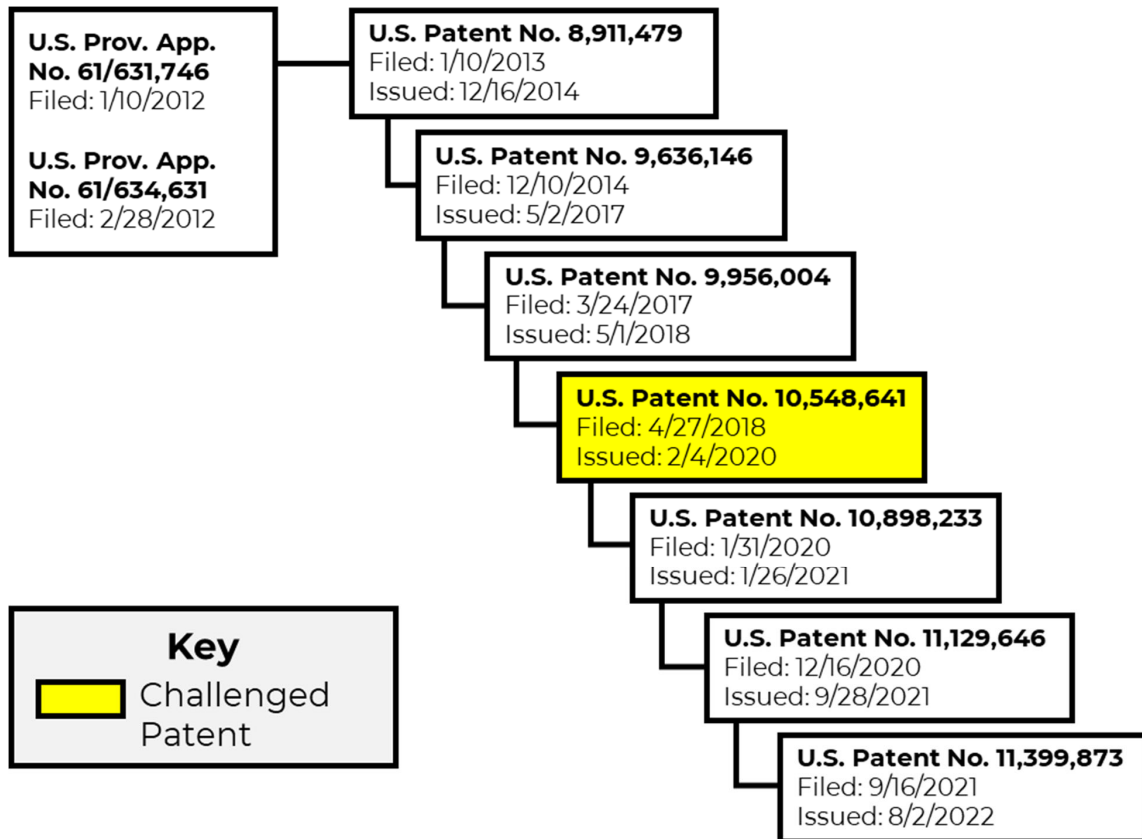
Fig. 3.



Figs. 9-14 show additional closure tops using various well-known thread types, 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 form type. *Id.*, 8:58, 9:17, 9:39, 9:61, 10:15. All of these alternative closure tops include the same rim 60 as shown above. *Id.*, Figs. 9-14.

B. Prosecution History

116. The '641 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:



117. During prosecution of the '641 Patent, the Examiner rejected the proposed claims over Jackson (U.S. Pub. No. 2005/0182410), which disclosed a conventional polyaxial bone screw and a closure top with a bottom surface that is closed and flat, in view of Bagby's (U.S. Patent No. 6,010,502 (EX1026)) dual start threads. EX1002 at 51-54 (6.4.18 Rejection). In response, Applicant amended the claims to require that each thread have "a leading face including at least one curvate surface." Applicant argued that a curvate leading face was not shown in either of the references cited by the Examiner. *Id.* at 74-76 (11.27.18

Amendment). The Examiner responded with another rejection, *id.* at 238-43 (1.9.19 Rejection), but this rejection was based on confusing the loading flank of the thread (the top surface) with the leading face (the front surface), *id.* at 270-274 (4.9.19 Amendment). Once Applicant pointed out this confusion, the claims were allowed. *Id.* at 276 (allowing pending claims 1-11, 15-25, 31-36); *id.* at 310 (9.25.19 Allowance).

118. While the claims of the '641 Patent appear to have been allowed based on the amendment to require “a leading face with at least one curvate surface,” in the examination of subsequent family members the Examiner concluded that this feature was not patentable. Specifically, during prosecution of U.S. Patent No. 11,129,646 (“the '646 Patent”) Applicant’s claims included substantially the same limitation. There, the examiner found curvate leading faces obvious based on Prevost (U.S. Pub. No. 2011/0106179) (EX1022), which disclosed a curvate leading face on a closure top thread. EX1043 at 237-246. In response to the rejection over Prevost, Applicant amended the claims of the '646 Patent to require additional features relating to the closure top bottom. *Id.* at 281-86. The additional features added to obtain allowance of the '646 Patent are not included in the claims of the '641 Patent.

119. While Boschert was cited during prosecution of the '641 Patent in an Information Disclosure Statement along with hundreds of other references,

EX1002 at 106-08, the Examiner appears not to have discovered Boschert's teaching regarding dual-start threads until prosecution of subsequent family members, including U.S. Patent No. 10,898,233 ("the '233 Patent") and the '646 Patent. In both cases the Examiner rejected the pending claims in view of Boschert in combination with other art, and in response Applicant amended his claims to add additional features. EX1042 at 61-69 (6.12.20 Rejection), 311-330 (9.1.2020 Amendment); EX1043 at 235-251 (3.9.21 Rejection), 283-93 (6.9.21 Amendment).

120. Neither the '477 Publication, the '391 Publication, nor Johnson were cited during the prosecution of the '641 Patent.

C. The Challenged Claims

121. The Challenged Claims of the '641 Patent are Claims 1-28. The '641 Patent includes three independent claims—1, 21, and 26.

122. Claim 1⁶ in its entirety, states as follows:

⁶ I have attached as an appendix to my declaration a claim listing of all Challenged Claims. Because many limitations of claims 1, 21, and 26, 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, group [C] relates to the interaction between the receiver and the closure top, group [D] relates to guide tools, and group [E] relates to

A medical implant assembly comprising:

[A] a receiver having a first arm and a second arm spaced apart from each other by a channel, the first arm and the second arm each having a top surface and an inner surface having a first thread on the first arm and a second thread on the second arm comprising discontinuously helically wound threads being symmetrically and diametrically opposed to each other and extending up to the top surface on each arm, the opposed discontinuously helically wound threads forming a dual lead in closure starting arrangement for the receiver;

[B] a closure having a longitudinal axis with an outer surface having a first continuously helically wound thread form and a second continuously helically wound thread form, the first continuously helically wound thread form having a first start structure with a leading face surface extending below a first upper loading surface disposed between a root and a crest of the first continuously helically wound thread form, the second continuously helically wound thread form having a second start structure with a leading face surface extending below a second upper loading surface disposed between a root and a crest of the second continuously helically wound thread form,

breakoff arm extensions). This claim listing, and my assignment of a unique identifier for each limitation, are intended solely for ease of reference. My opinions herein address each and every limitation of the Challenged Claims.

[B1] the leading face surface on each of the first start structure and the second start structure including at least one curvate surface;

[A1] the channel positioned between the first arm and the second arm and opening onto the top surface, the channel adapted to receive a longitudinal connecting member, the channel closeable with the closure having an axis of rotation;

[A2] the first discontinuously helically wound thread form on the inner surface of the first arm having a first lower loading surface, the first start structure being rotatably advanceable under the first discontinuously helically wound thread form and the first lower loading surface being mateable with the first upper loading surface; and

[A3] the second discontinuously helically wound thread form on the inner surface of the second arm having a second lower loading surface, the second start structure being rotatably advanceable under the second discontinuously helically wound thread form and the second lower loading surface being mateable with the second upper loading surface,

[B2] a rotation of the closure about the axis of rotation between the first arm and the second arm causing a simultaneous advancement of the first start structure under the first discontinuously helically wound thread form and the second start structure under the second discontinuously helically wound thread form and a

mating of the first and second lower loading surface with the first and second upper loading surface, respectively,

[C] the closure rotationally advanceable within the channel until the closure locks the longitudinal connecting member within the channel.

123. Claim 2 depends from Claim 1 and adds the limitation: [D] a guide tool having a first guide arm and a second guide arm detachably attached to the receiver; [D1] a third discontinuously helically wound thread form on the first guide arm; and a fourth discontinuously helically wound thread form on the second guide arm, [D2] the first start structure threadably engageable with the third discontinuously helically wound thread form simultaneously with the second start structure threadably engageable with the fourth discontinuously helically wound thread form when the closure is rotated between the first guide arm and the second guide arm, the third discontinuously helically wound thread form and the fourth discontinuously helically wound thread form adapted to transfer the closure between the guide tool and the receiver.

124. Claim 3 depends from Claim 1 and adds the limitation [B3]: wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each flange forms.

125. Claim 4 depends from Claim 1 and adds the limitation [B4]: wherein the first continuously helically wound thread form and the second continuously

helically wound thread form are each one of: v-threads, square threads, reverse angle threads, or buttress threads.

126. Claim 5 depends from Claim 1 and adds the limitation **[B5]**: wherein the first start structure is disposed at a diametrically opposite location on the closure from the second start structure.

127. Claim 6 depends from Claim 1 and adds the limitation: **[B6]** wherein each of the continuously first and the second helically wound thread form is disposed at a top of the closure, the first helically wound thread form and the second helically wound thread form each extending along the outer surface of the closure to a bottom of the closure and ending at the first and the second start structure, respectively.

128. Claim 7 depends from Claim 1 and adds the limitation: **[B7]** wherein the at least one curvate surface of both the first start structure and the second start structure is defined by at least one radius of curvature, the at least one radius of curvature being less than a radius of curvature for an outer surface on the crest of the first continuously helically wound thread form.

129. Claim 8 depends from Claim 1 and adds the limitation: **[B8]** wherein the at least one curvate surface of both the first start structure and the second start structure is defined by at least one radius of curvature, the at least one radius of

curvature being less than a radius of curvature for an outer surface on the crest of the second continuously helically wound thread form.

130. Claim 9 depends from Claim 1 and adds the limitation: **[B9]** wherein the at least one curvate surface includes both a convex surface and concave surface.

131. Claim 10 depends from Claim 9 and adds the limitation: **[B10]** wherein both of the concave surface and the convex surface of the first start structure are positioned between the root and the crest of the first continuously helically wound thread form, and wherein both of the concave surface and the convex surface of the second start structure are positioned between the root and the crest of the second continuously helically wound thread form.

132. Claim 11 depends from Claim 10 and adds the limitation: **[B11]** wherein the concave surface is adjacent the root and the convex surface is adjacent the crest of the first and second start structures for the first and second continuously helically wound thread form, respectively.

133. Claim 12 depends from Claim 9 and adds the limitation: **[B12]** wherein a radius of curvature of the convex surface is substantially equal to a radius of curvature of the concave surface.

134. Claim 13 depends from Claim 9 and adds the limitation: **[B13]** wherein each of the first start structure and the second start structure includes a bottom beveled surface.

135. Claim 14 depends from Claim 1 and adds the limitation: **[B14]** wherein the first and second start structure leading face surfaces are at least partially planar surfaces parallel with respect to each other.

136. Claim 15 depends from Claim 1 and adds the limitation: **[B15]** wherein each of the at least one curvate surfaces is substantially parallel to the closure longitudinal axis.

137. Claim 16 depends from Claim 1 and adds the limitation: **[B9]** wherein each of the at least one curvate surface includes both a convex surface and concave surface.

138. Claim 17 depends from Claim 1 and adds the limitation: **[B9]** wherein each of the at least one curvate surfaces is a concave surface.

139. Claim 18 depends from Claim 1 and adds the limitation: **[B16]** wherein the closure first continuously helically wound thread form includes a first lower surface disposed between the root and the crest and the closure second continuously helically wound thread form includes a second lower surface disposed between the root and the crest, and wherein the leading face surface of the first start structure extends between the first upper surface and the first lower

surface and the leading face surface of the second start structure extends between the second upper surface and the second lower surface.

140. Claim 19 depends from Claim 18 and adds the limitation: **[B14]** wherein each of the leading face surfaces of the first start structure and the second start structure include at least a partial planar surface.

141. Claim 20 depends from Claim 1 and adds the limitation: **[E]** wherein the receiver first arm and the second arm top surface each include a breakoff extension with an inner surface having a discontinuously helically wound thread form, the first arm breakoff extension thread form being continuous with the first discontinuously helically wound thread form on the inner surface of the first arm and the second arm breakoff extension thread form being continuous with the second discontinuously helically wound thread form on the inner surface of the second arm.

142. Claim 21 is an independent claim and recites many of the same limitations as Claim 1, but also expressly requires “first and second” discontinuously helically wound threads. Claim 21, in its entirety, states as follows:

A medical implant assembly comprising:

[A] a receiver having a first arm and a second arm spaced apart from each other by a rod-receiving channel, the first arm and the second arm each having a

top surface and an inner surface having a first thread on the first arm and a second thread on the second arm comprising first and second discontinuously helically wound threads, respectively, being symmetrically and diametrically opposed to each other and extending up to the top surface on each arm, the opposed discontinuously helically wound threads forming a dual lead in closure starting arrangement for the receiver;

[B] a closure having a first continuously helically wound thread form and a second continuously helically wound thread form, the first continuously helically wound thread form having a first start structure and a first loading surface extending between a root and a crest of the first continuously helically wound thread form, the second continuously helically wound thread form having a second start structure and a second loading surface extending between a root and a crest of the second continuously helically wound thread form,

[C] each of the first start structure and the second start structure having a leading face surface extending below each closure loading surface and including at least a partial concave surface;

[A1] the channel being formed by the first arm and the second arm, the channel closeable with the closure having an axis of rotation;

[A2] the first discontinuously helically wound thread form on the inner surface of the first arm having a first discontinuous loading surface, the first start

structure rotatable under the first discontinuously helically wound thread form and the first discontinuous loading surface mateable with the closure first loading surface; and

[A3] the second discontinuously helically wound thread form on the inner surface of the second arm having a second discontinuous loading surface, the second start structure rotatable under the second discontinuously helically wound thread form and the second discontinuous loading surface mateable with the closure second loading surface,

[B2] a rotation of the closure about the axis of rotation between the first arm and the second arm causing the first start and the second start structures to simultaneously rotatably advance under the first discontinuously helically wound thread form and the second discontinuously helically wound thread form, respectively, the closure rotationally advanceable within the channel until a rod positioned within the channel is locked therein.

143. Claim 22 depends from Claim 21 and adds the limitation: [B17] wherein the closure has a bottom surface that is closed.

144. Claim 23 depends from Claim 22 and adds the limitation: [B18] wherein the bottom surface is flat.

145. Claim 24 depends from Claim 21 and adds the limitation: [B4] wherein the first continuously helically wound thread form and the second

continuously helically wound thread form are each one of: v-threads, square threads, reverse angle threads, or buttress threads.

146. Claim 25 depends from Claim 21 and adds the limitation: **[B3]** wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each flange forms.

147. Claim 26 is an independent claim and recites many of the same limitations as Claims 1 and 21, but also requires that each leading face include “at least a partial concave surface and a partial convex surface.” Claim 26, in its entirety, states as follows:

A medical implant assembly comprising:

[A] a receiver having a first arm and a second arm spaced apart from each other by a rod-receiving channel, the first arm and the second arm each having a top surface and an inner surface having a first thread on the first arm and a second thread on the second arm comprising first and second discontinuously helically wound threads, respectively, being symmetrically and diametrically opposed to each other and extending up to the top surface on each arm, the opposed discontinuously helically wound threads forming a dual lead in closure starting arrangement for the receiver;

[B] a closure having a first continuously helically wound thread form and a second continuously helically wound thread form, each of the first continuously

helically wound thread form and the second continuously helically wound thread form being a reverse angle thread, the first continuously helically wound thread form having a first start structure and a first upper loading surface extending between a root and a crest of the first continuously helically wound thread form, the second continuously helically wound thread form having a second start structure and a second upper loading surface extending between a root and a crest of the second continuously helically wound thread form,

[C] each of the first start structure and the second start structure having a leading face extending below their respective upper loading surfaces, each leading face including at least a partial concave surface and a partial convex surface;

[A1] the channel being formed by the first arm and the second arm opening onto the top surface, the channel adapted to receive a rod, the channel closeable with the closure having an axis of rotation;

[A2] the first discontinuously helically wound thread form on the inner surface of the first arm being a reverse angle thread having a first lower loading surface, the first start structure rotatable under the first discontinuously helically wound thread form and the first lower loading surface threadably engageable to the first upper loading surface; and

[A3] the second discontinuously helically wound thread form on the inner surface of the second arm being a reverse angle thread having a second lower

loading surface, the second start structure rotatable under the second discontinuously helically wound thread form and the second lower loading surface threadably engageable to the second upper loading surface,

[B2] a rotation of the closure about the axis of rotation between the first arm and the second arm causing a simultaneous mating of the first continuously helically wound thread form with the first discontinuously helically wound thread form and the second continuously helically wound thread form with the second discontinuously helically wound thread form, the closure rotationally advanceable within the channel until the closure locks the rod received within the channel.

148. Claim 27 depends from Claim 26 and adds the limitation: [B11] wherein the concave surface is adjacent the root and the convex surface is adjacent the crest for each of the first and second continuously helically wound thread forms.

149. Claim 28 depends from Claims 26 and adds the limitation: [B5] wherein the first start structure is disposed at a diametrically opposite location on the closure from the second start structure.

D. Opinions on Claim Construction

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

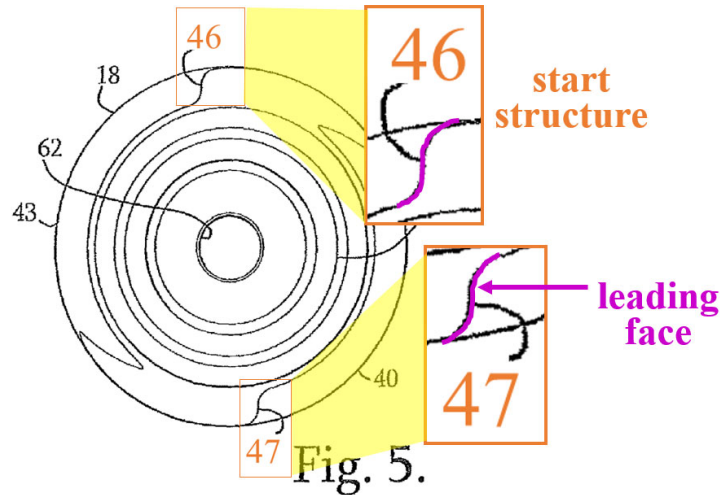
view of the '641 Patent specification and prosecution history. In the paragraphs that follow, I opine on the ordinary and customary meaning of select terms that are not used or explained in the specification and relate those terms to the disclosed embodiments of the '641 Patent.

1. **“a first start structure with a leading face surface extending below a first upper loading surface disposed between a root and a crest of the first continuously helically wound thread form” / “a second start structure with a leading face surface extending below a second upper loading surface disposed between a root and a crest of the second continuously helically wound thread form” (Claims 1 and 26) / “each of the first start structure and the second start structure having a leading face surface” (Claim 21).**

151. The claimed “leading face” is never specifically identified by reference number in the '641 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, 7:51-55. Start structures 46 and 47 are shown in Figure 5, enlarged and annotated below, which is the only figure that shows the described concave and convex surfaces on the leading face.



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

2. “wherein the concave surface is adjacent the root and the convex surface is adjacent the crest” (Claims 11 and 27).

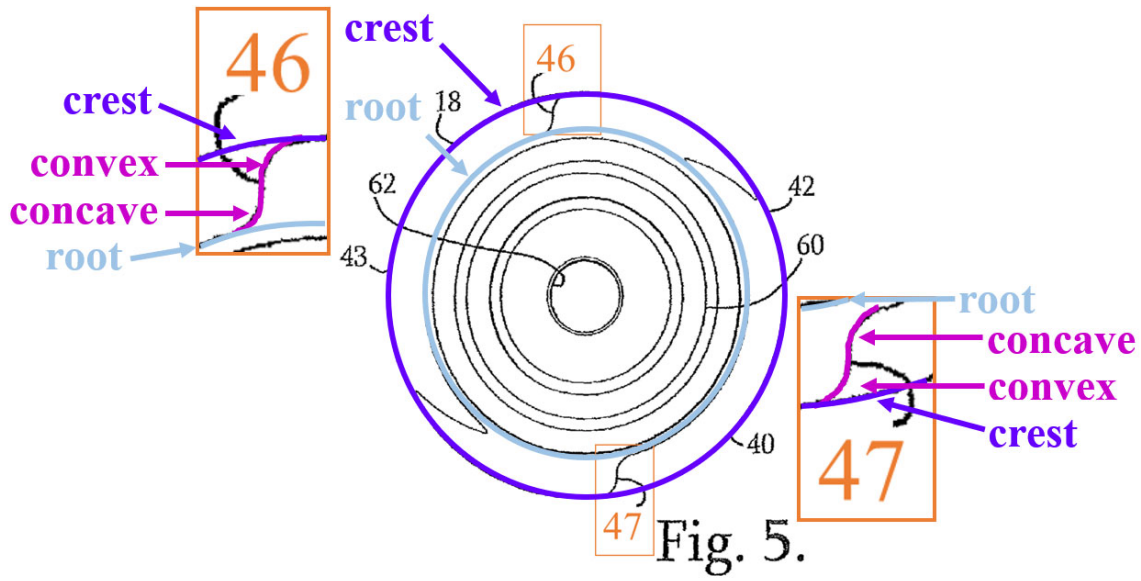
153. The claimed “concave surface” that is “adjacent the root” and “convex surface” that is “adjacent the crest” is never specifically identified by reference number in the ’641 Patent. The entirety of the written description on this feature states:

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, 7:51-55. Figure 5 is the only figure that shows the described concave and convex surfaces on the leading face.

154. 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 forms and is immediately adjacent to the cylindrical body from which the thread projects. *Id.* at 5.

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



EX1001, Fig. 5

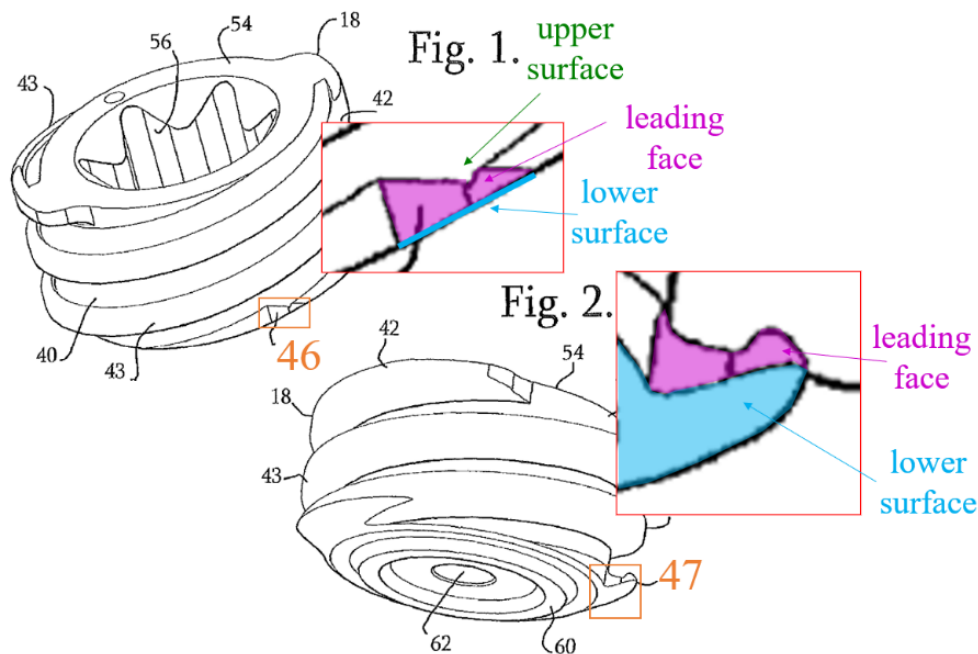
I've also labeled the concave and convex portions of the leading face, showing that they are adjacent to the root and the crest, respectively.

3. “each of the first start structure and the second start structure includes a bottom beveled surface” (Claim 13).

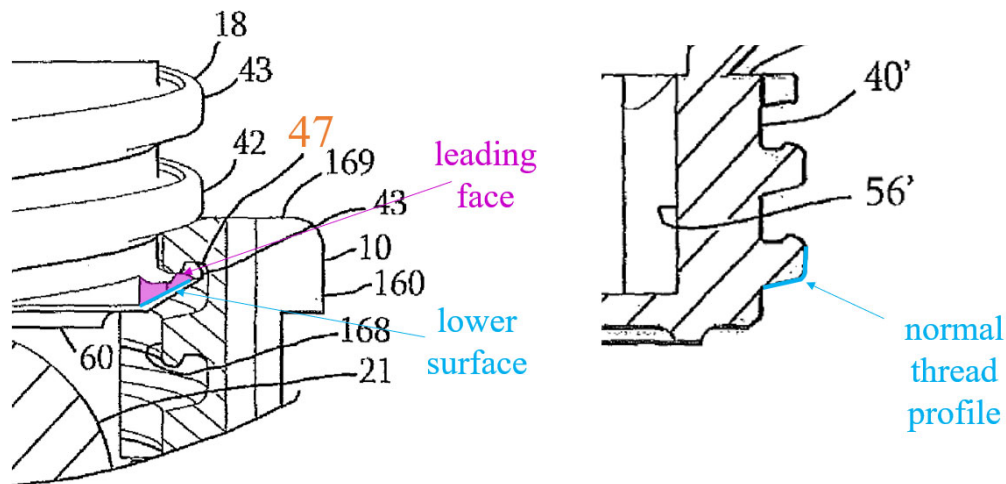
156. The specification of the '641 Patent does not contain any textual description of a bottom beveled surface of a start structure. Nevertheless, in my opinion a POSA would have understood these phrases according to their plain and ordinary meaning.

157. “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 3. I have seen nothing in the specification or prosecution history of the '641 Patent that requires any departure from this plain and ordinary meaning.

158. The claim language identifies the “bottom beveled surface” as part of the start structure: “each of the first start structure and the second start structure includes a bottom beveled surface.” EX1001, cl. 13. Claim 13 depends from Claim 9, which depends from Claim 1. Claim 1 identifies a “first start structure with a leading face surface extending below a first upper loading surface disposed between a root and a crest of the first continuously helically wound thread form” and a “second start structure with a leading face surface extending below a second upper loading surface disposed between a root and a crest of the second continuously helically wound thread form.” *Id.*, cl. 1. This is shown below in annotated and enlarged Figures 1 and 2.



159. A POSA would have understood that the figures of the '641 Patent are consistent with the plain meaning of this phrase and show the sloped angle of the bottom surface of the start structure. Unlike the normal thread profile, as shown in Fig. 10 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).



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.

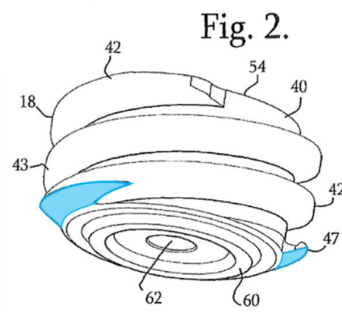


Fig. 2.

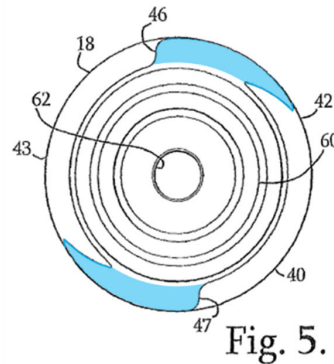


Fig. 5.

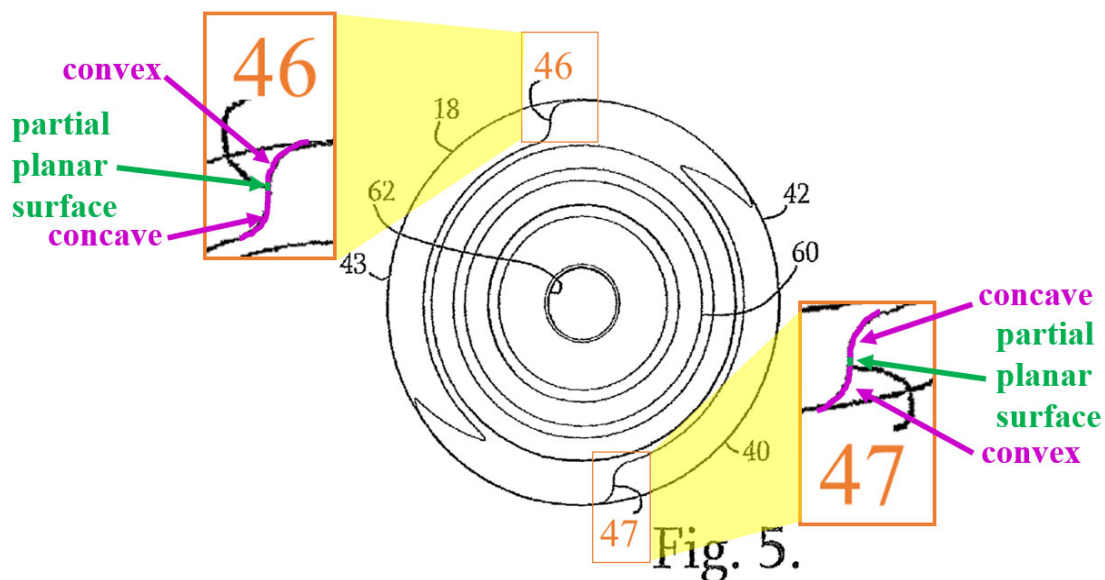
4. **“the first and second start structure leading face surfaces are at least partially planar surfaces parallel with respect to each other” (Claim 14) and “each of the leading face surfaces of the first start structure and the second start structure include at least a partial planar surface” (Claim 19).**

160. The specification of the '641 Patent never identifies a “partially planar surface” or 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.

161. “Partial” is defined as relating to a part rather than the whole. EX1029 at 6. “Planar” is defined as having a flat surface. *Id.* at 7. I have seen nothing in the specification or prosecution history of the '641 Patent that requires any departure from these plain and ordinary meanings.

162. Claims 14 and 19 expressly refer to the leading faces of the start structure, as illustrated in reference to Figure 5. The “partially planar surfaces” and “partial planar surface” limitations were added for the first time in the

applicant's April 9, 2019 Amendment. EX1002 at 266-67, 269. The applicant stated that “[s]upport for these amendments may be found through the specification, figures and claims as originally filed, e.g., FIGS. 1-3, 5-6, and 15.” *Id.* at 270. 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.



5. “the closure has a bottom surface that is closed” (Claim 22)

163. The specification of the '641 Patent never identifies a “bottom surface that is closed.” Nevertheless, in my opinion, a POSA would have understood these phrases according to their plain and ordinary meaning.

164. “Bottom” is generally defined as either the underside of something or lowermost. EX1029 at 4. “Closed” is generally defined as enclosed. *Id.* at 5. I have seen nothing in the specification or prosecution history of the '641 Patent that requires any departure from these plain and ordinary meanings.

165. As discussed above, the '641 Patent describes a closure top bottom surface that is “planar and further includes a rim 60 for engagement and penetration into the surface 22 of the rod 21.” EX1001, 7:19-21, Figs. 1-14. While the '641 Patent only discloses closure embodiments that are cannulated (i.e., open), in my opinion, a POSA would have nevertheless understood that a closure bottom that was “closed” was a closure bottom that was not cannulated.

6. “simultaneous mating” (Claim 26)

166. The term “simultaneous mating” is never used in the '641 Patent's specification. Nevertheless, in my opinion a POSA would have understood this phrase to have its plain and ordinary meaning.

167. The '641 Patent discloses a closure top that includes one or more helically wound guide and advancement features that each have a start surface,

wherein “each start structure simultaneously engaging and being captured” by the spaced arms of the open implant upon initial rotation of the closure top. EX1001, 2:35-43; *see also id.*, 3:7-12 (describing a multi-start closure embodiment with a pair of opposed arms each “having guide and advancement structure for simultaneous mating engagement with a start of the helically wound multi-start closure”). The ’641 Patent further discloses that, “when the closure structure 18 is rotated into the receiver 10 between receiver arms 160, each having a guide and advancement structure 168, the start 46 engages mating guide and advancement structure 168 on one arm 160 and the start 47 simultaneously engages guide and advancement structure 168 on the opposing arm 160, both forms 42 and 43 being simultaneously captured by the mating forms 168 on the opposed arms 160.” *Id.*, 8:33-40.

168. Claim 26 recites “a rotation of the closure about the axis of rotation between the first arm and the second arm causing a simultaneous mating of the first continuously helically wound thread form with the first discontinuously helically wound thread form and the second continuously helically wound thread form with the second discontinuously helically wound thread form, the closure rotationally advanceable within the channel until the closure locks the rod received within the channel.” *Id.*, cl. 26. In my opinion, a POSA, having read the specification of the ’641 Patent, would have understood that “simultaneous

ming” meant that the first and second continuously helically wound thread forms engaged the first and second discontinuously helically wound thread forms at the same time. This understanding is also confirmed by the ’641 Patent itself, which shows the same symmetrical threads on the receiver. *E.g., id.* Figs. 3, 8, 9, 11-15, 17.

VIII. SCOPE AND CONTENT OF THE PRIOR ART REFERENCES

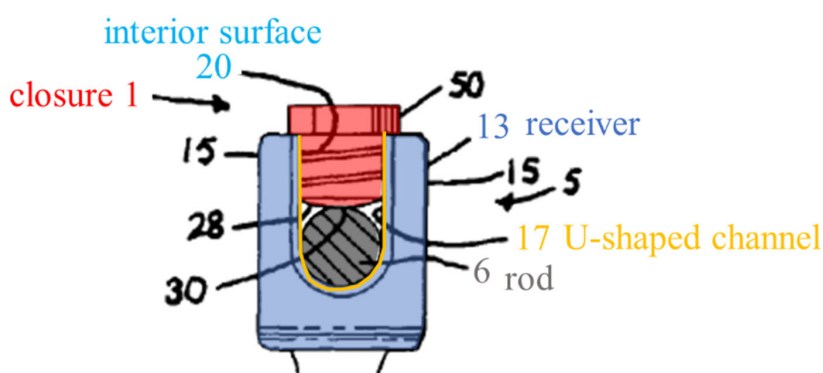
A. Overview of the ’477 Publication

169. The ’477 Publication, EX1005, was published on December 1, 2005, more than 6 years before the earliest effective filing date of the ’641 Patent. I understand the ’477 Publication is therefore prior art to the ’641 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 the 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 ’641 Patent. *Compare id.* ¶[0007] (“A closure and locking member is provided for a medical implant . . . used in a spinal implant system for providing support or reconstruction to the spine, such as a transverse connector. A typical implant for use with a closure of the invention includes a receiver having a pair of spaced arms with an open channel located therebetween.”), *with* EX1001, 1:23-27 (“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].

170. 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



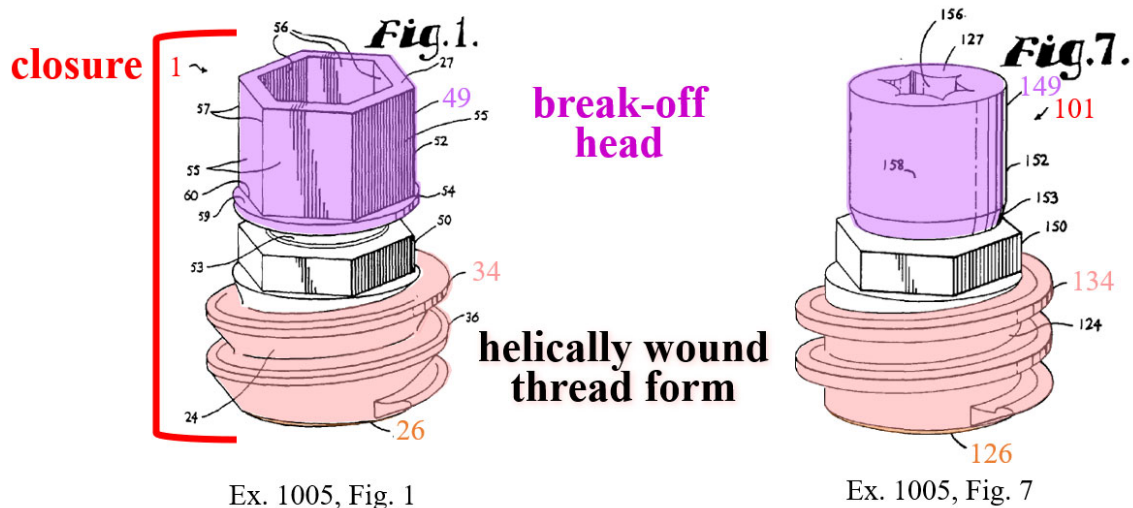
Ex. 1005, Fig. 6

structure that

mates with a similar structure on a closure 1 when the closure is rotated. *Id.*, ¶¶[0007], [0029], Fig. 5.

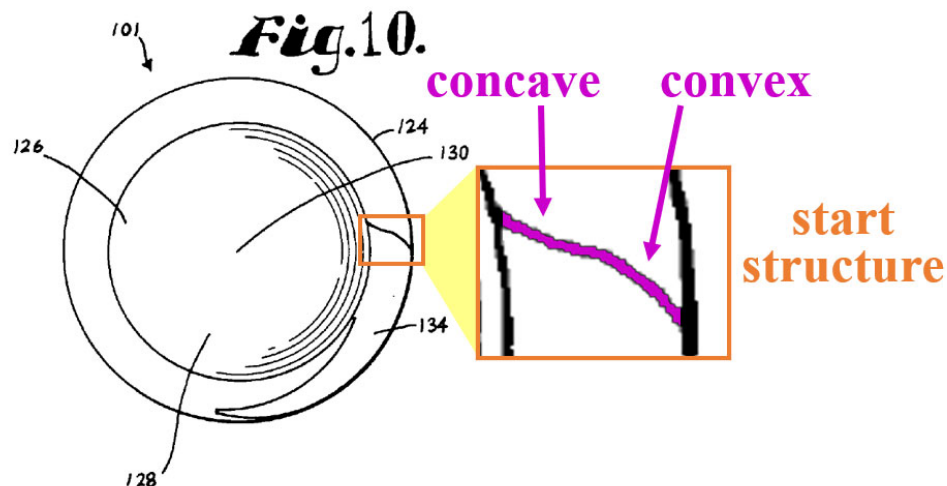
171. The ’477 Publication discloses that the guide and advancement structure could be any one of a variety of different thread types, including a reverse angle thread. *Id.*, ¶[0030].

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



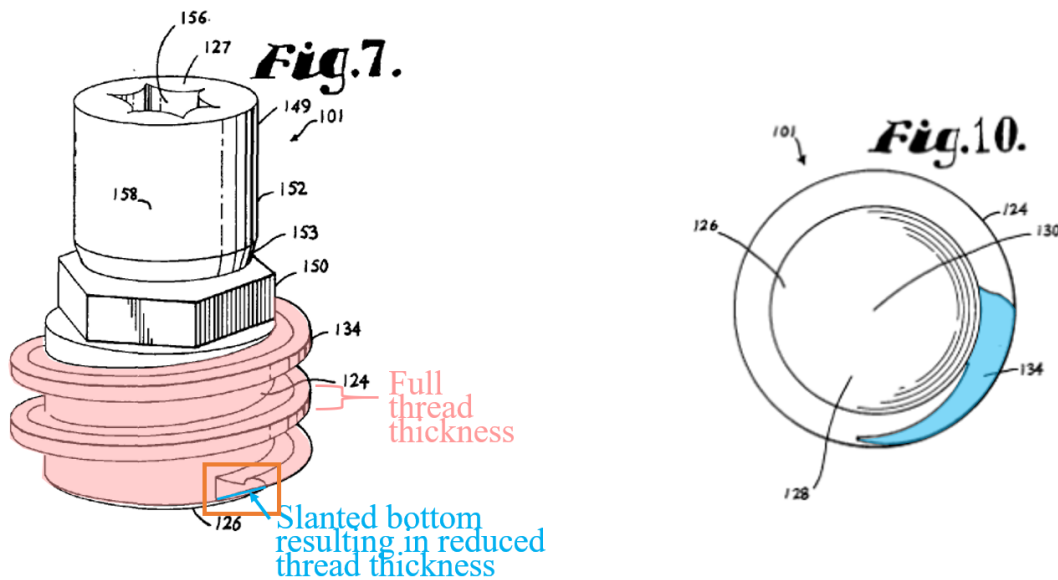
173. In the first embodiment, the '477 Publication discloses that the closure 1 is cylindrical and has a central axis of rotation. *Id.*, ¶[0029], Fig. 1. The closure has a single helically wound guide and advancement structure 34 along the outside, which could be one of a variety of thread types, including a reverse angle thread or a flange form. *Id.*, ¶[0030]; *see also, e.g., id.*, Fig. 1. In Fig. 1, the '477 patent 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]. Both closure bottoms disclosed by the '477 Publication are closed. *Id.*, Figs. 2, 4, 8, 10. Finally, the '477 Publication discloses that the closure top may include a break-off portion 49 designed to break away from the closure “subsequent to a predetermined torque being applied.” *Id.*, ¶[0032].

174. 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]. Specifically, the '477 Publication teaches that the closure 101 is cylindrical and has a central axis of rotation. *Id.*, ¶[0040], Figs. 7, 8. The closure has a single helically wound guide and advancement structure 134 along the outside, which could be one of a variety of thread types, including a reverse angle thread or a flange form. *Id.*, ¶[0041]; *see also, e.g., id.*, Fig. 7, 8. In addition, the second embodiment teaches that the leading face of the start structure is formed in an s-curve, with both concave and convex curves. *Id.*, Fig. 10 (bottom plan view).



Ex. 1005, Fig. 10

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 shows the second embodiment as having a domed bottom, but also 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]. Finally, the '477 Publication discloses that the closure may include a break-off portion 149 designed to break away from the closure “subsequent to a predetermined torque being applied.” *Id.*, ¶[0042].

175. 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* ¶[0007] (“A closure and locking member is provided for a medical implant. The implant may be a bone screw, hook, or other open or closed element used in a spinal implant system for providing support or reconstruction to the spine, such as a transverse connector.” A typical implant for use with a closure of the invention includes a receiver having a pair of spaced arms with an open channel located therebetween.”); Abstract (“A closure for use in conjunction with an open receiver of a medical implant...”); ¶[0025] (“[T]he closure 1 is shown utilized to close a top of a polyaxial medical implant bone screw, generally 5”).

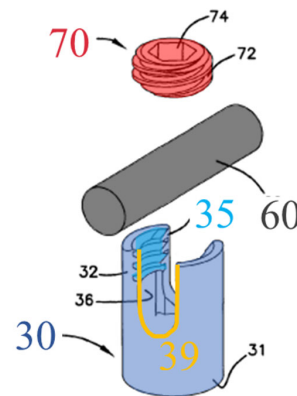
B. Overview of Boschert

176. Boschert, EX1006, published on December 15, 2005, more than 6 years before the earliest effective filing date of the ’641 Patent. I understand Boschert therefore is prior art to the ’641 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 ’641 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, 1:23-27 (“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...”).

177. 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.

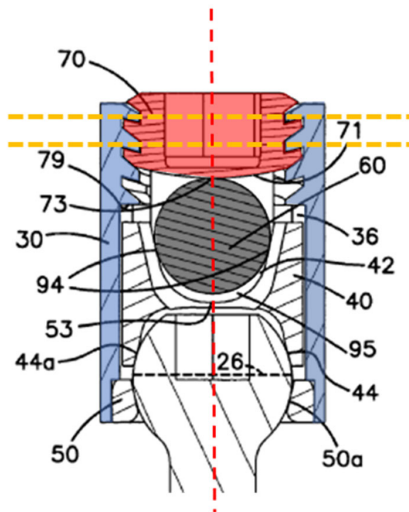
178. Boschert discloses a receiver 30 (blue) with two upwardly extending legs defining the saddle 39 (yellow) (i.e., the channel) which is U-shaped for receiving the rod 60 (gray). *Id.*, 6:20-24, Fig. 1. The legs have interior threads (light blue) that mate with corresponding exterior threads on the set screw 70



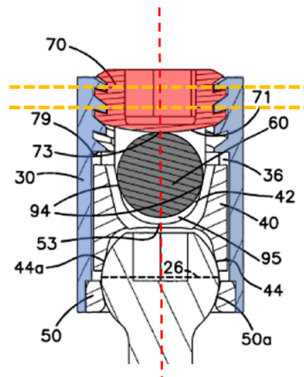
Ex. 1006, Fig. 1

(red) (i.e., the closure), such that the set screw can be threaded into the saddle to lock the rod in place. *Id.*, 6:24-48; *see also id.*, 7:12-15. Boschert further discloses that the threads of the set screw can be designed to have a “double lead to allow the

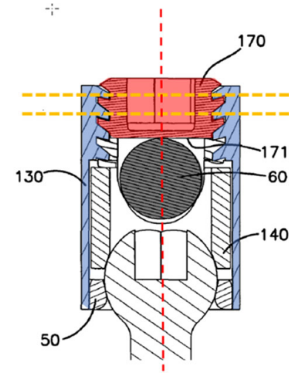
setscrew 70 to start more easily than with a single lead.” *Id.*, 7:21-23. Relatedly, as shown below in annotated Figure 3, Boschert discloses that interior threads on the receiver are mirrored along the longitudinal axis (**red**), thereby providing for simultaneously receiving the double leads of the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



179. 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**).



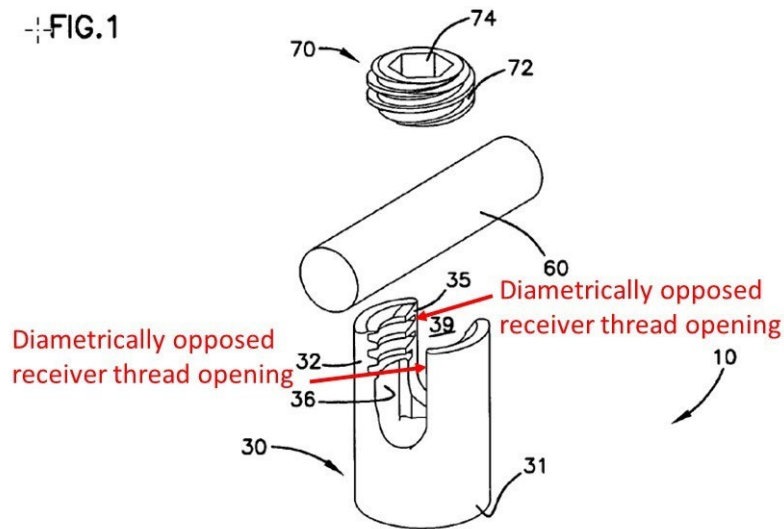
EX1006, Fig. 3



EX1006, Fig. 15

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

FIG. 1

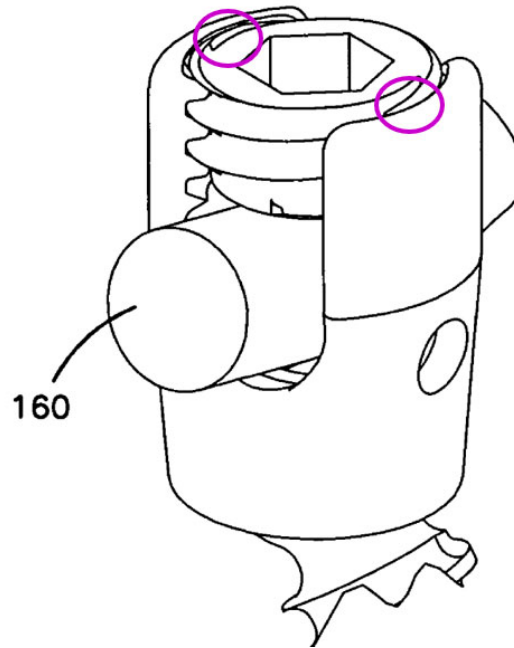


EX1006, Fig. 1

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

181. 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.

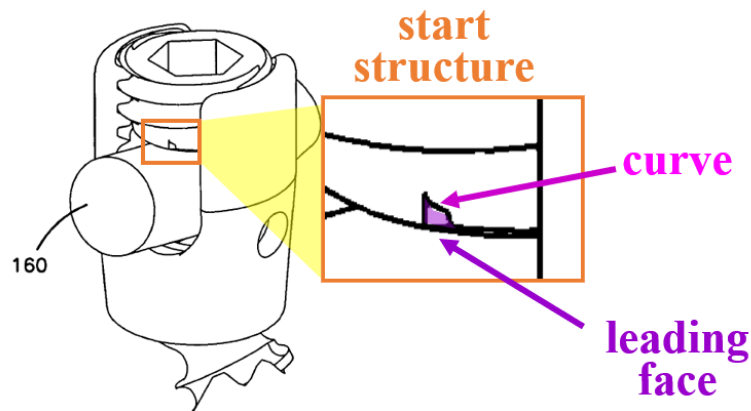
thread end



EX1006, Fig. 7

182. 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.

183. Boschert also suggest 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.



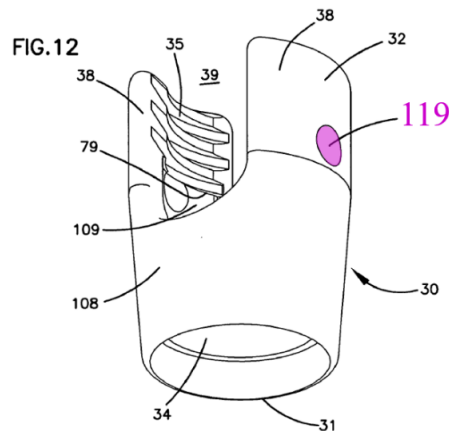
EX1006, Fig. 7

184. 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. Both the curved and flat bottom surfaces disclosed by Boschert are closed.

185. Boschert expressly contemplates potential modifications to its closure top, stating that “[t]he embodiments of the locking arrangements disclosed herein (e.g., the set screw 70[]) are merely examples of types of locking arrangements that can be used. The locking arrangements can include any mechanism adapted to provide an axial locking force on the rod 60.” *Id.*, 7:58-62. Therefore, in my opinion, a POSA would naturally look to other prior art that discloses known

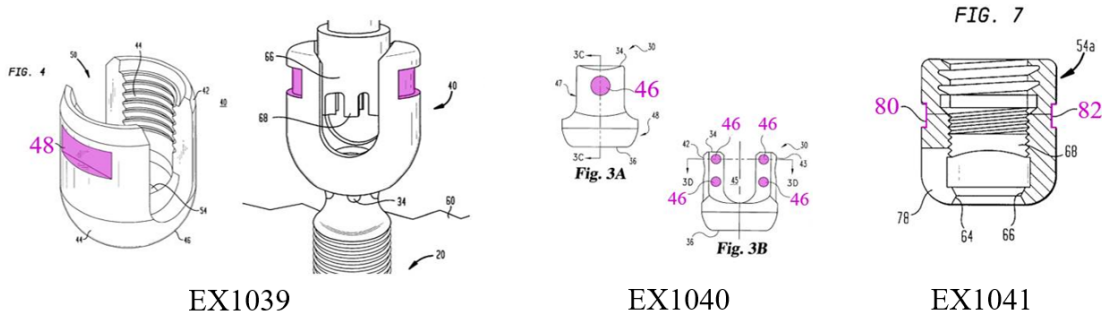
closure tops for use with the receiver of Boschert, such as the closure tops of the '477 Publication.

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



EX1006, Fig. 12

Boschert does not describe these “grasping features” in any more detail, but does incorporate by reference several patents disclosing exemplary grasping features, including U.S. Patent Nos. 6,488,681 (EX1039) (grooves 48, Figs 4 & 8 at left); 6,280,442 (EX1040) (indentations or holes 46, Figs. 3A & 3B at middle), and 6,074,391 (EX1041) (slots 80 and 82, Fig. 7 at right) pictured below. EX1006, 1:55-60.

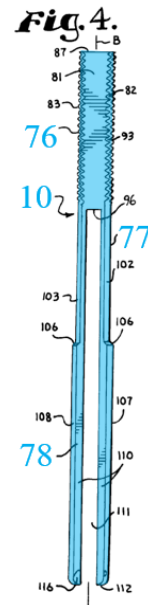


187. From these disclosures, a POSA would have understood that the type of grasping feature was not material to Boschert and that any known grasping feature could be used.

C. Overview of the '391 Publication

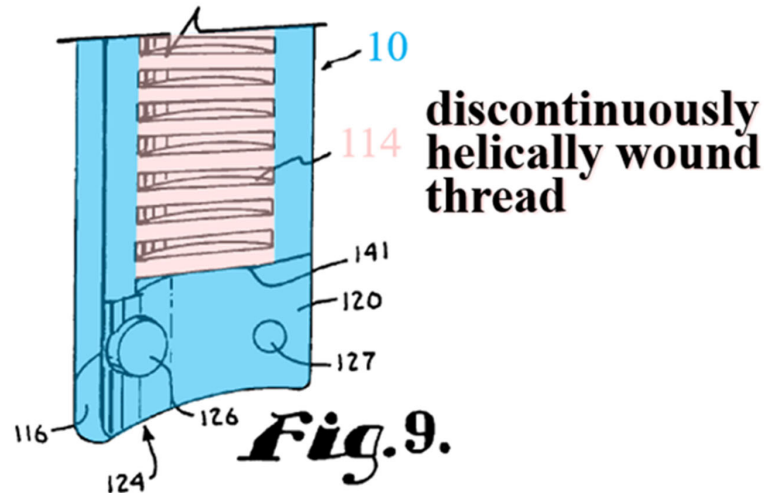
188. The '391 Publication, EX1030, was published on March 30, 2006, which is almost six years before the earliest effect filing date of the '641 Patent. I understand the '391 Publication is therefore prior art to the '641 Patent under 35 U.S.C. § 102(b). The '391 Publication discloses a “tool set for implanting bone screws in a human spine, followed by the implantation of a rod into the bone screws includes end guide tools having flexible back wall flaps that receive opposite ends of the rod and intermediate guide tools that hold the rod in intermediate locations between the end guide tools.” EX1030, Abstract. Therefore, and as described further below, in my opinion, the '391 Publication is in the same field of endeavor as, and is analogous art to, the '641 Patent. *Compare Id.*, ¶[0002] (“The present invention relates to apparatuses and methods for use in performing spinal surgery and, in particular, to tools and methods of using such

tools, especially for percutaneously implanting spinal screws and for implanting a rod for spinal support and alignment, using minimally invasive techniques.”) *with* EX1001, 1:23-27 (“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...”).

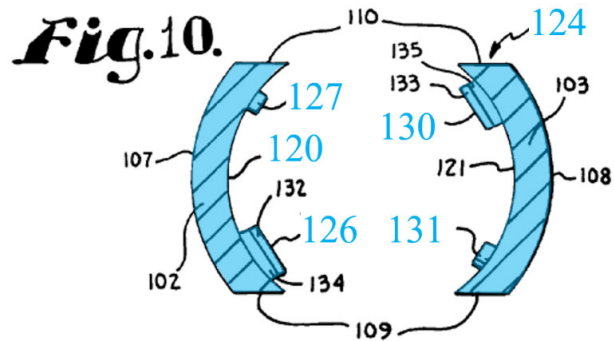


189. As shown in Figure 4 to the right, the '391 Publication discloses a “tool embodiment assembly 1” that “includes an intermediate guide tool 10.” EX1030, ¶[0082]. The intermediate guide tool 10 has “an overall elongate body 74 with an upper handle portion 76, and intermediate portion 77 and a lower implant engaging portion 78 which includes opposed implant engaging members for securing one of the implants there between.” *Id.*, ¶[0096].

190. As shown in Figure 9, below, at the bottom 112 of the intermediate tool guide 10, the '391 Publication discloses “a helically wound but discontinuous square thread 114” that “cooperates with the closure top 62,” although “other type of guide and advancement structure may be utilized such as helically wound flange forms, reverse angle threads, buttress threads, etc.” *Id.*, ¶[0103].



191. As shown in Figure 10 (right), the bottom 112 of the intermediate guide tool 10 also includes a “radially inward facing attachment structure, generally 124.”



Id., ¶[0104]. The attachment structure 124 has “a first projection, stop or pin 126 in a spaced relation with a second smaller projection, stop or pin 127, both pins being disposed on the surface 120.” *Id.*, ¶[0105]. A “cooperating third projection, stop or pin 130” and “a fourth smaller projection, stop or pin 131” are disposed on the opposite leg of the intermediate tool guide 10. *Id.* The larger pins 126 and 130 are “substantially rounded, radially inward projecting nodules, each having a ridge or lip 132 and 133, respectively, projecting upwardly toward the guide and advancement structure 114 and that preferably follows the curvature of

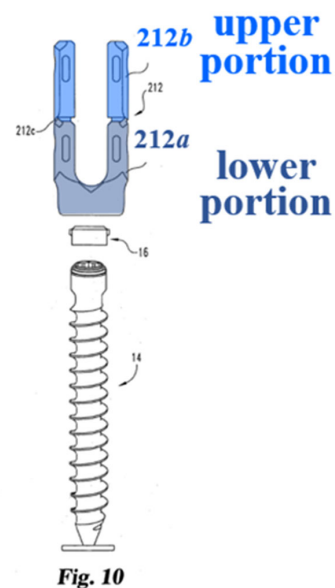
the respective leg inner surface 120 and 121.” *Id.*, ¶[0106]. “The pins 126, 127, 130 and 131 cooperate and mate with the bone screw 4, at a receiver portion, generally identified by reference numeral 145, of a head 146 thereof.” *Id.*, ¶[0110]. “[T]o attach the bone screw head 146 to the guide tool 10, the guide tool 10 is rotated about its axis B such that the legs 102 and 103 are lowered into place,” *id.* ¶[0114], and, to “disengage” the guide tool 10 from the bone screw 4, the guide tool 10 is “rotated counterclockwise from an attaching configuration,” *id.*, ¶[0115]. *See also id.*, ¶[0017] (“The attachment structure secures the guide tool to the bone screw during insertion of the screw into bone, but allows the tool to release from the bone screw for removal of the tool at the end of the procedure by rotation of the tool about a central axis thereof or by some other mechanism, as described herein.”).

192. The ’391 Publication discloses that the benefit of this attachable/detachable guide tool is that they “allow for the insertion of bone screws, the insertion and reduction of a rod into the bone screws and the securing of the rod to the bone screws with significantly less invasion into the body of the patient and with minimal surgical incision of the skin over the operational site.” *Id.*, ¶[0006].

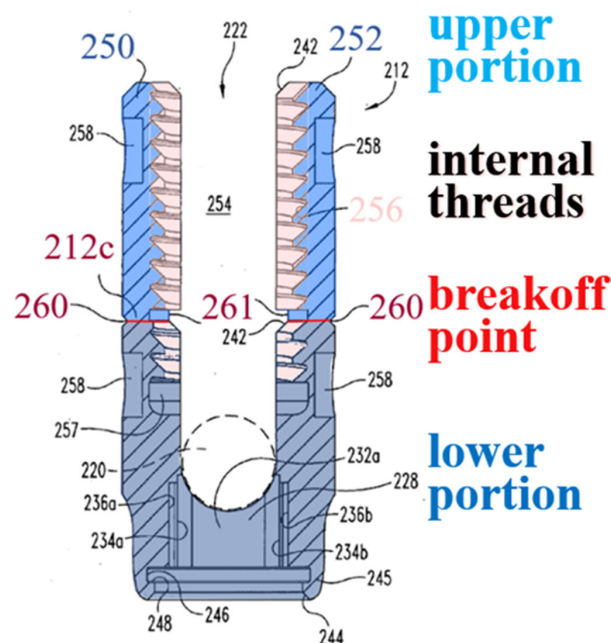
D. Overview of Johnson

193. Johnson, EX1008, was published on April 19, 2007, which is more than three years before the earliest effective filing date of the '641 Patent. I understand Johnson is therefore prior art to the '641 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 field of endeavor as, and is analogous art to, the '641 Patent. *Compare* 1008, ¶[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, 1:23-27 (“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...”).

194. 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 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].



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

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

into lower portion 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 and Boschert

197. In my opinion, it would have been obvious to a POSA to combine the closure top of the ’477 Publication and the receiver of Boschert before the priority date of the ’641 Patent.

198. The ’477 Publication is in the exact same field as the ’641 Patent, as set forth above. *Supra* Section VIII.A. The ’477 Publication teaches closure tops that could be used with any conventional bone screw receivers, stating “A closure and locking member is provided for a medical implant. The implant may be a bone screw, hook, or other open or closed element used in a spinal implant system for providing support or reconstruction to the spine, such as a transverse connector. A typical implant for use with a closure of the invention includes a receiver having a pair of spaced arms with an open channel located therebetween.” EX1005, ¶[0007]; *see also id.*, Abstract (“A closure for use in conjunction with an open receiver of a medical implant...”), ¶[0025] (“the closure 1 is shown utilized to close a top of a polyaxial medical implant bone screw, generally 5.”), ¶[0027] (“[I]t is foreseen that the closure 1 may be used in conjunction with any type of medical implant having an open or closed head.”). The generic “medical implant”

shown for use with the claimed closure top of the '477 Publication, as in Boschert, is a polyaxial bone screw with a U-shaped receiver. *Id.*, ¶[0025], Figs. 5 and 6; *see also supra* Sections VIII.A-B. Therefore, in my opinion, a POSA would have been motivated to use the closure of the '477 Publication in conjunction with known medical implants, such as the polyaxial bone screw disclosed in Boschert. The closure of the '477 Publication includes threading of various disclosed types with a curvate leading face for mating with the arms of the receiver.

199. Boschert is also in the exact same field as the '641 Patent—the design of polyaxial pedicle screw and rod implant systems to treat spinal column disorders. *See supra* Section VIII.B. Boschert, like the '477 Publication, teaches a polyaxial pedicle screw including a U-shaped receiver for capturing a rod once its opening has been closed with a setscrew. *See supra* Sections VIII.A-B.

200. 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 closures with a double lead in order “to start more easily than with a single lead,” EX1006, 7:21-23, and discloses symmetrical threads on the receiver to mate simultaneously with the double-lead threads on the setscrew, *id.* Figs. 3 & 15. Boschert also expressly contemplates potential modifications to its disclosed closure top, stating that “[t]he embodiments of the locking arrangements disclosed herein (e.g., the set screw

70[] are merely examples of types of locking arrangements that can be used. The locking arrangements can include any mechanism adapted to provide an axial locking force on the rod 60.” *Id.*,7:58-62.

201. As explained further below, based on the express teachings of the references and their complimentary disclosures, a POSA would have been motivated to combine the closure of the '477 Publication and the receiver of Boschert. In particular, a POSA implementing the polyaxial pedicle screw of the '477 Publication would have looked to Boschert's teachings of the advantages of double-start leads and symmetrical threads disposed on the receiver. A POSA would have been motivated to use the dual-start threads of Boschert in combination with the thread types discussed in the '477 Publication, each with a curvate leading face. Further, in making this combination, it would have been obvious to a POSA that the closure bottom surface could be designed to have any known shape, as there were a limited number of known bottom shape options all of which could be used with a reasonable expectation of success.

1. Motivation to Use Known Dual Threads

202. As set forth above, the '477 Publication teaches that closure tops should include a breakoff top for tightening the closure top to a desire torque, threading (of various disclosed types) for mating with the arms of the receiver, a leading thread face that includes a concave surface near the root and a convex

surface near the crest, a bottom beveled surface at the thread start, and a bottom surface of the closure top that is closed. *See supra* Section VIII.A. As also set forth above, a POSA would have been familiar with these various thread types and their known advantages, including reducing outwardly directed forces that could cause splaying of the receiver arms. *Supra* Section VI.B.1.d. Also as set forth above, a POSA would have been familiar with truncated thread starts, such as the curvate leading face of the '477 Publication, and their advantages for easing thread insertion, reducing thread deformation, and eliminating sharp edges. *Supra* Section VI.B.1.b.

203. Boschert teaches that it would be advantageous to design a closure—including a closure with a closed and flat bottom surface—with a double lead. EX1006, 7:21-23, 7:40-43; Fig. 15. Boschert teaches that a double lead allows a closure “to start more easily than with a single lead” when loaded into the top of an open receiver. *Id.*, 7:21-23. Thus, a POSA would have been motivated to modify the closure of the '477 Publication with the double lead thread disclosed in Boschert, given, at the very least, the POSA’s understanding that such a change would result in more reliable threading of the fastener into the receiver, as was expressly taught by Boschert. A POSA would also have been motivated to so modify the '477 Publication to take advantage of known benefits of double-lead threads, including balancing insertion forces (*see* U.S. Patent No. 6,010,502 to

Bagby (EX1026), 13:35-41), and increasing insertion speed, *see* Machinery's Handbook (EX1014), at 6). *See supra* Section VI.B.1.a. In making this combination, a POSA would also have retained the truncated thread starts of the '477 Publication with their curvate leading faces, in order to obtain their known advantages for further easing thread insertion, reducing thread deformation, and reducing sharp edges. *Supra* Section VII.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.

204. 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 '641 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 and readily available and already in use in multi-axial pedicle screws. *Supra* Section VI.B.1.a.

2. Motivation to Use a Flat Closure Top Bottom

205. In combining the disclosures of the '477 Publication and Boschert it also would have been obvious to a POSA to use any of the closure bottom surface shapes taught in either the '477 Publication or Boschert, all of which are disclosed

as successfully engaging and locking the rod into the receiver. In other words, closure bottom shape was a design choice from among a limited number of options (e.g., domed, flat, rimmed) each with a reasonable expectation of success.

206. As discussed above, the preferred embodiments of the '477 Publication show closed domed bottoms. EX1005, ¶¶[0029], [0040] Figs. 2, 4, 8, 10. The '477 Publication states that a domed bottom is not material to its functionality, and “it is foreseen that a bottom surface of the closure body may be substantially flat and include a small dome having a central point for gripping or penetrating a rod surface.” *Id.*, ¶¶[0029], [0040]. The '477 Publication also states that, [i]n addition, the bottom surface may be flat and may have a central point and lateral rim.” *Id.* From these teachings, a POSA would have understood that the type of bottom surface used with the closure of the '477 Publication is not critical so long as it engages and “lock[s] the rod member relative to the implant with the closure.” *Id.*, ¶[0006]; *see also id.*, ¶¶[0007], [0011], [0028]-[0029].

207. Boschert discloses in one embodiment that the bottom surface is a curved surface (i.e., domed). EX1006, 7:15-16, Fig. 4. In a second embodiment 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.

208. As the '477 Publication and Boschert reflect, 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 shape of the bottom surface, including a domed surface, a flat surface, and a rimmed surface. *Supra* Section VI.B.2.a. Each of these bottom surface shapes had been successfully used to engage and lock a rod into a receiver. *Id.* Therefore, a POSA designing a pedicle screw system would have known that closure bottom shape 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 flat bottom surface to engage the rod when combining the disclosures of the '477 Publication and Boschert.

209. Using a flat bottom closure surface would yield predictable results, as it was well known to a POSA before the priority date of the '641 Patent that a closure top with a closed flat bottom provided these advantages, including locking a stabilization rod in place, and could be successfully used in closure tops. *Supra* Section VI.B.2.a. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for machining a closed flat bottom were well known and readily available and already in use in multi-axial pedicle screws. *Supra* Section VI.B.2.a.

B. Motivation to Combine the '391 Publication with the '477 Publication and Boschert

210. In my opinion, a POSA implementing the closure and receiver taught by the '477 Publication and Boschert before the priority date further would have looked to the '391 Publication's teachings of the advantages of providing guide tools with pedicle screws. In particular, a POSA would have been motivated to add a guide tool with discontinuously helically wound threads to an existing system at least based on the benefits of such a guide tool as taught by the '391 Publication.

211. Like the '477 Publication and Boschert, the '391 Publication is in the exact same field as the '641 Patent, as set forth above. *Supra* Section VIII.C. The '391 Publication discloses that the benefit of its attachable/detachable guide tool is that it “allow[s] for the insertion of bone screws, the insertion and reduction of a rod into the bone screws and the securing of the rod to the bone screws with significantly less invasion into the body of the patient and with minimal surgical incision of the skin over the operational site.” EX1030, ¶[0006]. Moreover, the '391 Publication discloses that the guide and advancement structures on the guide tool “allow the closure top 62 to be rotated and the surgeon to develop mechanical advantage to urge or drive the rod 8, while still outside or partially outside the bone screw 4, toward and into the bone screw 146. This is especially helpful where the rod 8 is bent relative to the location of the vertebra 16 (which is sometimes the

case) to which the rod 8 is to attach and is not easily placed in the bone screw head 146 without force and the mechanical advantage provided by the guides 64 and 114.” *Id.*, ¶[0120]. The ’391 Publication further discloses that alignment of the guide tool’s guide and advancement structures with the receiver arms’ guide and advancement structures “allow[s] the closure top 62 to continue to rotate and to continuously apply force to the rod 8, so as to aid in seating the rod 8 in the bone screw head 146.” *Id.*

212. Boschert already contemplates the use of various tools and instruments with its disclosed receiver, and therefore discloses “grasping features” that could “accommodate instrumentation to facilitate grasping, holding or manipulating of the receiver 30” during implantation. EX1006, 6:15-19. But Boschert does not disclose the details of the tools and instruments to be used with its receiver, and thereby invites a POSA to look to tools and instruments already known in the art. A POSA implementing the combination of the ’477 Publication and Boschert would have naturally looked to the ’391 Publication because the ’391 Publication also discloses a closure and receiver and expressly teaches the advantages of using its guide tool with a closure and receiver. *See supra* Section VIII.C. Therefore, in my opinion, a POSA would have been motivated to use an attachable/detachable guide tool as disclosed in the ’391 Publication with the receiver of Boschert at least to obtain the recognized benefits of guide tools as

taught by the '391 Publication and otherwise known in the art as discussed above.

Supra Section VI.B.2.b.ii.

213. A POSA would have expected success with this combination because it merely involves the combination of familiar elements using known methods to yield predictable results, as it was well-known to a POSA before the priority date of the '641 Patent that guide tools provided these advantages and could be successfully used in medical implant devices. *Supra* Section VI.B.2.b.ii. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for machining guide tools were well known and readily available. *Supra* Section VI.B.2.b.ii.

214. Moreover, a POSA would have been motivated to combine the teachings of the '391 Publication with the '477 Publication and Boschert based on the demands known to the medical device design community for medical devices that allow minimal surgical incision of the skin and less invasion into the body of the patient. *Supra* Section VI.B.2.b.ii.

C. Motivation to Combine Johnson with the '477 Publication and Boschert

215. In my opinion, it would also have been obvious to a POSA to combine the breakoff arm extensions disclosed in Johnson with the closure top of the '477 Publication and the receiver of Boschert before the priority date of the '641 Patent.

216. Like the '477 Publication and Boschert, Johnson is in the exact same field as the '641 Patent, as set forth above. *Supra* Section VIII.D. In my opinion, a POSA would have been motivated to add break-off extension arms to an existing system at least based on the benefits of break-off extensions in multi-axial pedicle screws as taught by Johnson. *Supra* Section VIII.D.

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

218. 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 '641 Patent that break-off extension arms provided these advantages and could be successfully used in medical implant devices (and were indeed being used in scoliosis surgeries at the time). *Supra* Section VI.B.2.b.i. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for machining break-off extension arms were well known and readily available. *Supra* Section VI.B.2.b.i.

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

X. SPECIFIC OPINIONS RELATING TO GROUNDS FOR UNPATENTABILITY.

A. Ground 1: Claims 1, 3-19, and 21-28 Are Obvious in View of the '477 Publication and Boschert

1. Claim 1

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

220. To the extent the preamble of Claim 1 is considered limiting, in my opinion the '477 Publication in view of Boschert 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]. Similarly, Boschert is titled "Spinal Fixation Implant Assembly," and discloses a spinal fixation technique "whereby surgical implants are used for fusing together and/or mechanically immobilizing vertebrae of the spine." EX1006, 1:34-37.

- b. **1[A]: a receiver having a first arm and a second arm spaced apart from each other by a channel, the first arm and the second arm each having a top surface and an inner surface having a first thread on the first arm and a second thread on the second arm comprising discontinuously helically wound threads being symmetrically and diametrically opposed to each other and extending up to the top surface on each arm, the opposed discontinuously helically wound threads forming a dual lead in closure starting arrangement for the receiver**

221. In my opinion, the '477 Publication in view of Boschert discloses this limitation. In particular, Boschert discloses “a receiver 30 having a top portion 32 defining a saddle 39 (i.e., a pocket) for receiving a rod 60.” EX1006, 4:16-18. The receiver “includes two upwardly extending legs 38 [i.e., arms] between which the saddle 39 of the receiver 30 is defined. The saddle 39 of the receiver 30 provides an open region or pocket for receiving the rod 60. The legs 38 also preferably include fastening structure for interconnecting with the setscrew 70. For example, the legs 38 are shown defining interior threads 35 that mate with corresponding exterior threads 72 of the setscrew 70 to allow the setscrew 70 to be threaded into the saddle 39 to lock the rod 60 and screw in place.” *Id.*, 6:20-28. The threads are helically wound and extend to the top surface of the receiver. *See, e.g., id.*, Figs. 1 and 3. Moreover, as shown in the excerpted and annotated Figure 1 below, because the threads on the receiver are interrupted by a channel, Boschert discloses discontinuously helically wound threads.

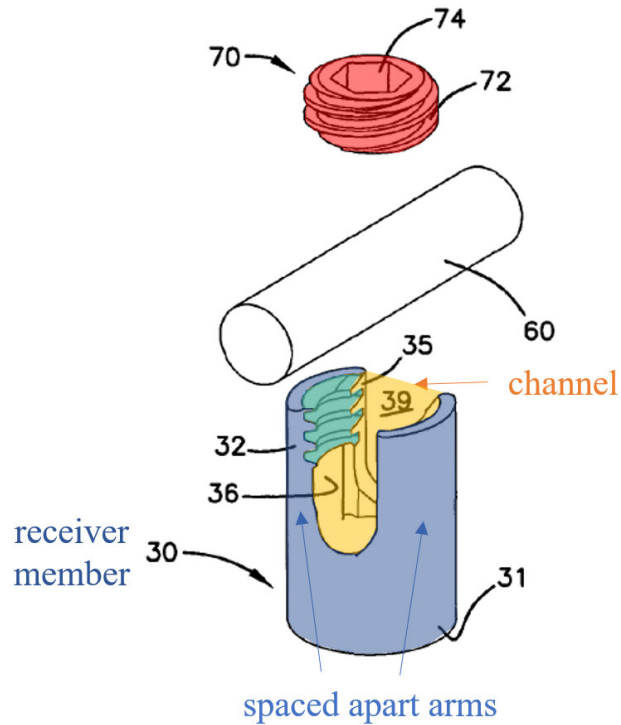
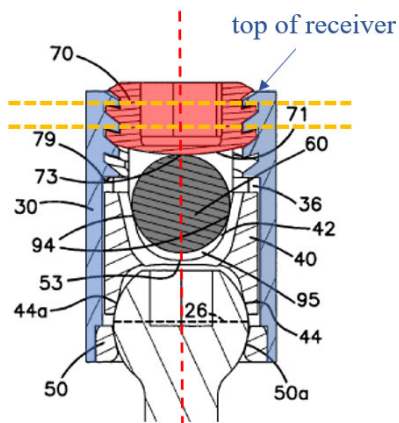
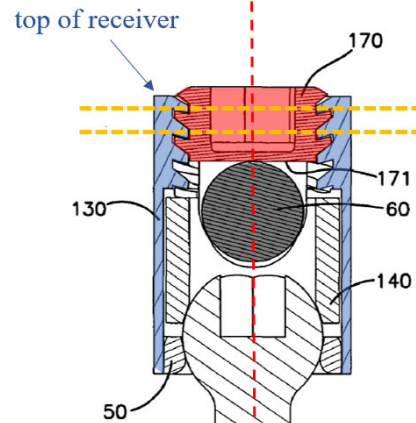


Fig. 1 (excerpt)

222. Moreover, Figures 3 and 15 of Boschert shows that the threads on either side of the receiver extend to the top of the receiver and are symmetrically and diametrically opposed to one another across the longitudinal axis (shown in **red**), as illustrated by the lines perpendicular to the longitudinal axis (**yellow**). *Id.*, Figs. 3, 15; *see also id.*, Fig. 14.

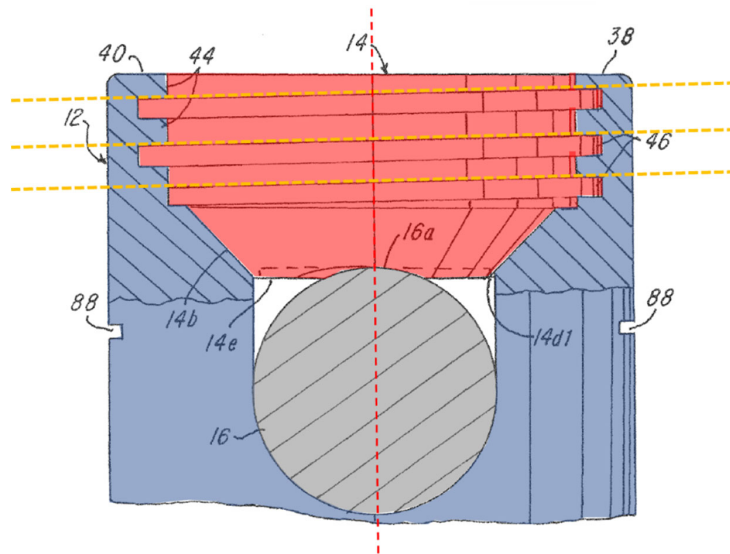


Ex. 1006, Fig. 3



Ex. 1006, 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

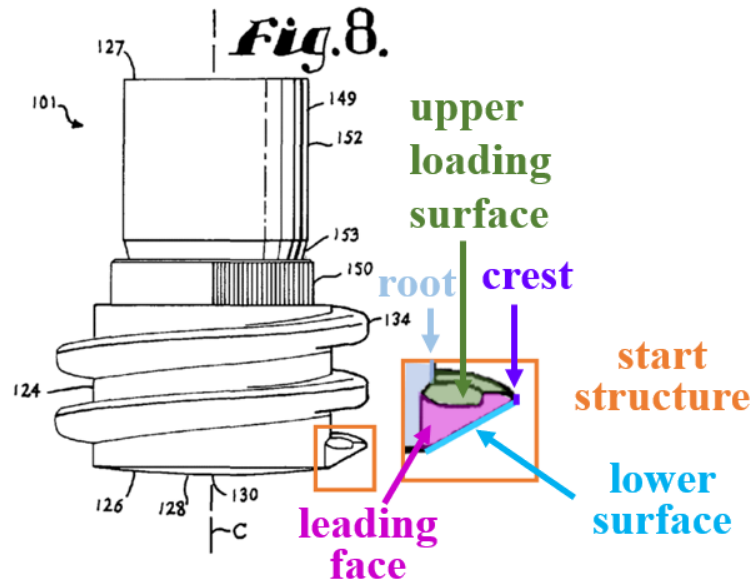
223. Boschert also discloses that “[t]he threads 72 of the setscrew 70 can also be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead.” EX1006, 7:21-23. Therefore, the threads of the receiver of Boschert form a dual lead in closure starting arrangement for the receiver.

- c. **1[B]: a closure having a longitudinal axis with an outer surface having a first continuously helically wound thread form and a second continuously helically wound thread form, the first continuously helically wound thread form having a first start structure with a leading face surface extending below a first upper loading surface disposed between a root and a crest of the first continuously helically wound thread form, the second continuously helically wound thread form having a second start structure with a leading face surface extending below a second upper loading surface disposed between a root and a crest of the second continuously helically wound thread form**

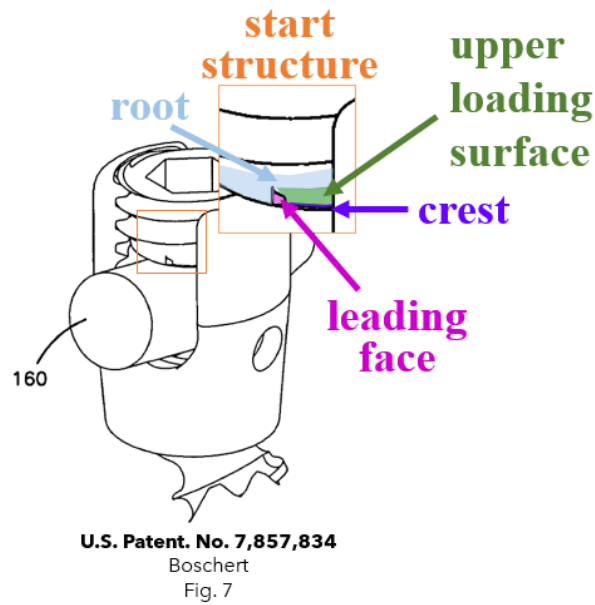
224. In my opinion, the '477 Publication in view of Boschert discloses this limitation. The '477 Publication discloses a “closure for use in conjunction with an open receiver of a medical implant for capturing and locking a rod in the implant.” EX1005, Abstract; *see also id.*, ¶[0002]. The '477 Publication discloses that the “closure 101 . . . has . . . a central axis of rotation C.” *Id.*, ¶[0040]; *see also id.*, ¶[0029] (“[T]he closure 1 . . . has . . . a central axis of rotation B.”). The '477 Publication also states that “closures are externally threaded and are screwed into mating threads on the interior surfaces of the implant arms.” *Id.*, ¶[0005]. The '477 Publication discloses that “[l]ocated on the cylindrical closure body 124” of

the closure 101 “is a guide and advancement structure 134 mateable with a guide and advancement structure on the inner surfaces of the arms of the” receiver. *Id.*, ¶[0041]; *see also id.*, ¶¶[0007], [0030], Figs. 1-2 and 5-6.

225. The ’477 Publication discloses that its “guide and advancement structure 134 is a helical interlocking form.” *Id.*, ¶[0041]. The ’477 Publication discloses that its 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 continuously helically wound closure thread with an upper loading 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 loading surface to a lower surface of the start structure. *Id.*, Figs. 7 & 8.



226. While the '477 Publication discloses a single continuously helically wound thread form, start, and leading face, as discussed above, Boschert teaches that a double-start design “allow[s] the setscrew 70 to start more easily than with a single lead.” EX1006, 7:21-23. Moreover, as shown in the annotated Figure 7 below, Boschert discloses a continuously helically wound thread form that has a start structure with a leading face surface extending below an upper loading surface disposed between a root and a crest of the continuously helically wound thread form.



EX1006, Fig. 7.

227. As discussed above (*see* Section IX.A.1), a POSA would have been motivated to combine the closure top of the '477 Publication with the receiver of Boschert, and in making this combination, would have modified the closure top of the '477 Publication to include two continuously helically wound thread forms with two start structures. A POSA would have been motivated to use dual start threads on the closure at least to match the closure threads to the dual start receiver threads of Boschert, because Boschert teaches that double leads “start more easily than with a single lead,” EX1006, 7:21-23, and because of the known benefits of double-lead threads of balancing insertion forces, U.S. Patent No. 6,010,502 to Bagby (EX1026), 13:35-41, and increasing insertion speed, EX1014 at 6. Moreover, as discussed above (*see* Section IX.A.1), when combining the '477

Publication with the teachings of Boschert, a POSA would have also been motivated to retain the start structure and leading face surface disclosed in the '477 Publication on both continuously helically wound thread forms, at least due to the known benefits of truncated thread starts for easing thread insertion, avoiding sharp edges, and reducing thread deformation.

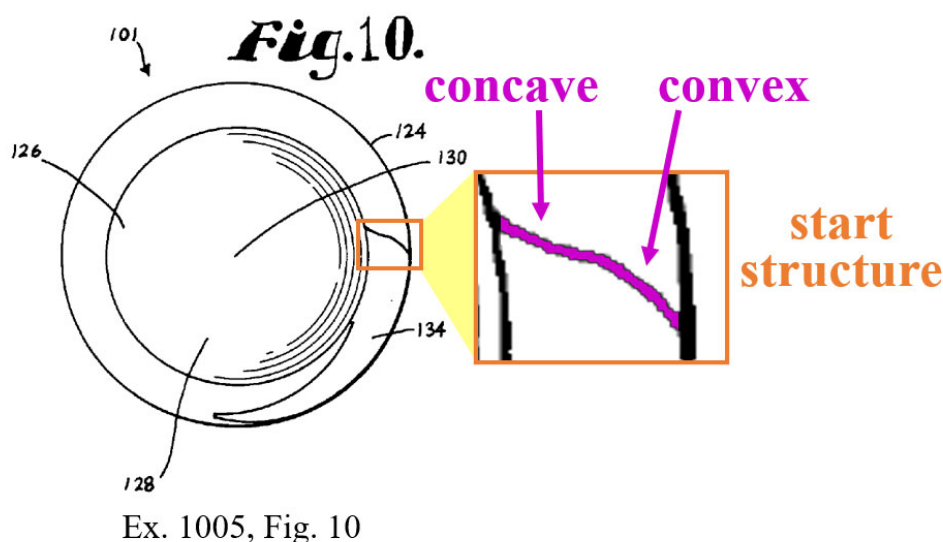
228. Finally, a POSA would have had an expectation of success with this combination, at least because multi-start threads and curvate leading faces, and techniques for manufacturing them, were well known in the art. *See supra* Section VI.B.1.a-c.

229. In my opinion, the closure top resulting from the combination of the disclosures of the '477 Publication and Boschert would have two continuously helically wound thread forms. Thus, the resulting closure would have a longitudinal axis with an outer surface having a first continuously helically wound thread form and a second continuously helically wound thread form, the first continuously helically wound thread form having a first start structure with a leading face surface extending below a first upper loading surface disposed between a root and a crest of the first continuously helically wound thread form, the second continuously helically wound thread form having a second start structure with a leading face surface extending below a second upper loading

surface disposed between a root and a crest of the second continuously helically wound thread form.

- d. **1[B1]: the leading face surface on each of the first start structure and the second start structure including at least one curvate surface**

230. In my opinion, the '477 Publication in view of Boschert discloses this limitation. As shown in annotated Figure 10 below, the '477 Publication discloses a leading face of the start structure that includes at least one curvate surface (i.e., the concave surface or the convex surface).



231. When the closure top of the '477 Publication is combined with dual-start receiver of Boschert, a POSA would have kept the same leading face structure with at least one curvate surface from the '477 Publication on each of the dual lead threads taught by Boschert. A POSA would have been motivated to keep the

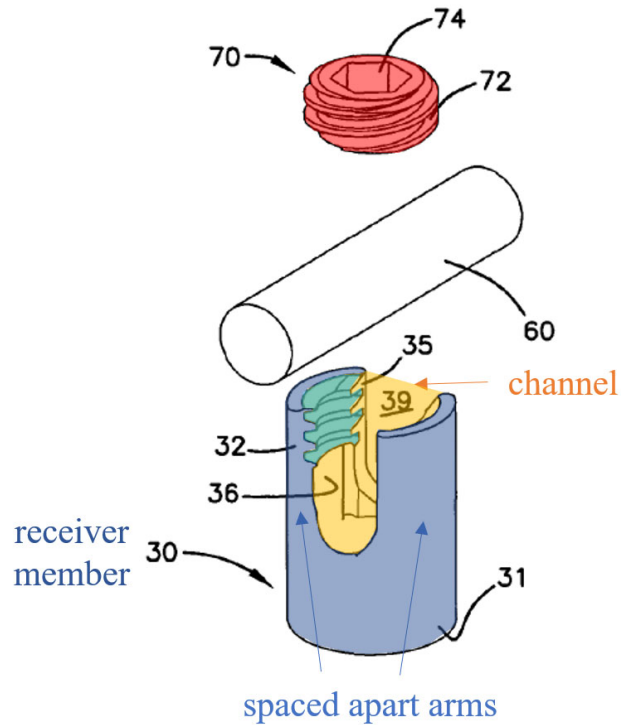
curvate leading thread faces of the '477 Publication at least based on their known advantages of facilitating thread alignment and starting, eliminating sharp surfaces, and reducing thread deformation, *supra* Section VI.B.1.b, and based on Boschert's own suggestion, in Fig. 7, to use truncated thread starts with curvate leading faces.

232. Finally, a POSA would have had an expectation of success with this combination, at least because multi-start threads and curvate leading faces, and techniques for manufacturing them, were well known in the art. *See supra* Section VI.B.1.a-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 dual start threads taught by Boschert.

233. 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 closure would have a leading face surface on each of the first start structure and the second start structure that includes at least one curvate surface.

- e. **1[A1]: the channel positioned between the first arm and the second arm and opening onto the top surface, the channel adapted to receive a longitudinal connecting member, the channel closeable with the closure having an axis of rotation;**

234. In my opinion, the '477 Publication in view of Boschert discloses this limitation. In particular, Boschert discloses “a receiver 30 having a top portion 32 defining a saddle 39 (i.e., a pocket) for receiving a rod 60.” EX1006, 4:16-18. A POSA would have understood that the rod 60 was a longitudinal connecting member. The receiver “includes two upwardly extending legs 38 [i.e., arms] between which the saddle 39 of the receiver 30 is defined. The saddle 39 of the receiver 30 provides an open region or pocket for receiving the rod 60. The legs 38 also preferably include fastening structure for interconnecting with the setscrew 70. For example, the legs 38 are shown defining interior threads 35 that mate with corresponding exterior threads 72 of the setscrew 70 to allow the setscrew 70 to be threaded into the saddle 39 to lock the rod 60 and screw in place.” *Id.*, 6:20-28. The threads are helically wound and extend to the top surface of the receiver. *See, e.g., id.*, Figs. 1 and 3.

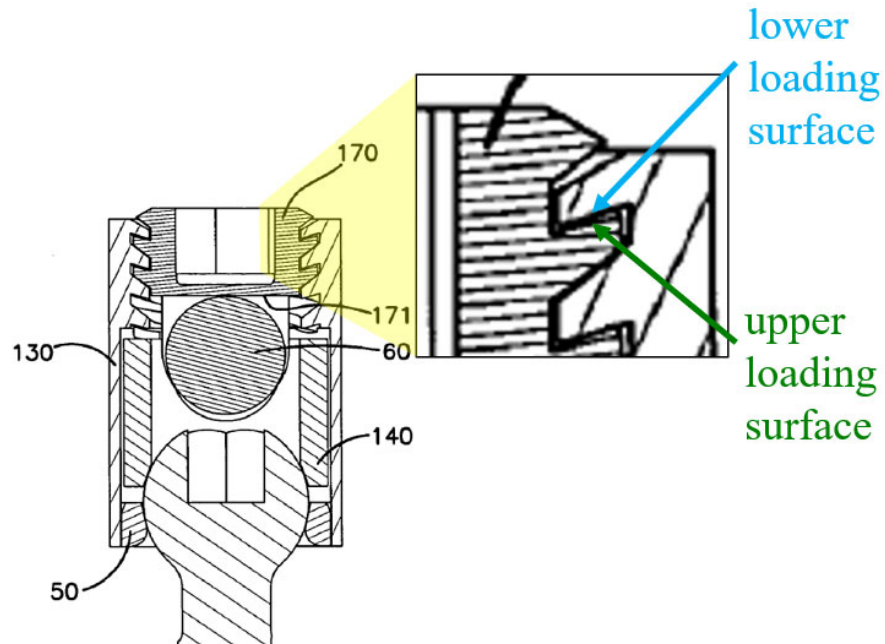


235. As Fig. 1 above shows, the receiver of Boschert therefore includes a channel positioned between the first arm and the second arm and opening onto the top surface, the channel adapted to receive a longitudinal connecting member (i.e., rod 60), the channel closeable with the closure having an axis of rotation.

- f. **1[A2]: the first discontinuously helically wound thread form on the inner surface of the first arm having a first lower loading surface, the first start structure being rotatably advanceable under the first discontinuously helically wound thread form and the first lower loading surface being mateable with the first upper loading surface; and**

236. In my opinion, the '477 Publication in view of Boschert discloses this limitation. In particular, Boschert discloses a receiver 30 that “includes two upwardly extending legs 38” with “interior threads 35 that mate with corresponding exterior threads 72 of the setscrew 70 to allow the setscrew 70 to be threaded into the saddle 39 to lock the rod 60 and screw in place.” EX1006, 6:20-28. As shown in the annotated Figure 15 below, Boschert discloses a first discontinuously helically wound thread form on the inner surface of the first arm having a first lower loading surface and the first lower loading surface is mateable with the first upper loading surface of the closure.

FIG.15



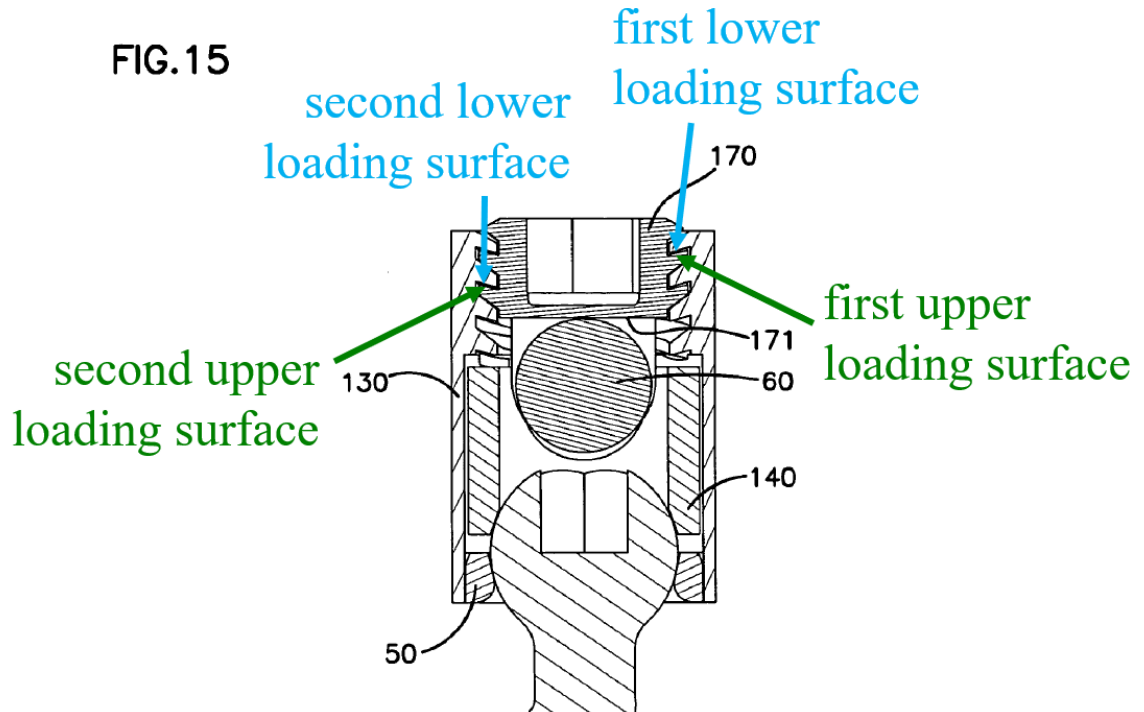
EX1006, Fig. 15.

237. In my opinion, when combining the closure of the '477 Publication and the receiver of Boschert, a POSA would have understood that the threads on the receiver must mate with the thread forms on the closure top, at least based on the express disclosures in the '477 Publication and Boschert on mating thread forms, EX1005, ¶¶[0011], [0026], [0030], [0041]; EX1006, 6:20-28, and based on a POSA's knowledge of threaded connectors, *see supra* Section VI.B.1. Thus, the '477 Publication in view of Boschert would have resulted in a first discontinuously helically wound thread form on the inner surface of the first arm having a first lower loading surface, the first start structure being rotatably advanceable under

the first discontinuously helically wound thread form and the first lower loading surface being mateable with the first upper loading surface.

- g. 1[A3]: the second discontinuously helically wound thread form on the inner surface of the second arm having a second lower loading surface, the second start structure being rotatably advanceable under the second discontinuously helically wound thread form and the second lower loading surface being mateable with the second upper loading surface,**

238. In my opinion, the '477 Publication in view of Boschert discloses this limitation. In particular, Boschert discloses two discontinuously helically wound thread forms on the inside surface of its receiver arms. In particular, Boschert discloses that “[t]he threads 72 of the setscrew 70 can also be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead.” EX1006, 7:21-23. As shown in the annotated Figure 15, when the setscrew 70 includes a double lead, Boschert discloses a second discontinuously helically wound thread form on the inner surface of the first arm having a second lower loading surface and the second loading surface being mateable with the second upper loading surface.



239. In my opinion, when combining the closure of the '477 Publication and the receiver of Boschert, a POSA would have understood that the thread forms on the receiver must mate with the thread forms on the closure top, at least based on the express disclosures in the '477 Publication and Boschert on mating thread forms, EX1005, ¶¶[0011], [0026], [0030], [0041]; EX1006, 6:20-28, and based on a POSA's knowledge of threaded connectors, *see supra* Section VI.B.1. Thus, the '477 Publication in view of Boschert would have resulted in a second discontinuously helically wound thread form on the inner surface of the second arm having a second lower loading surface, the second start structure being rotatably advanceable under the second discontinuously helically wound thread

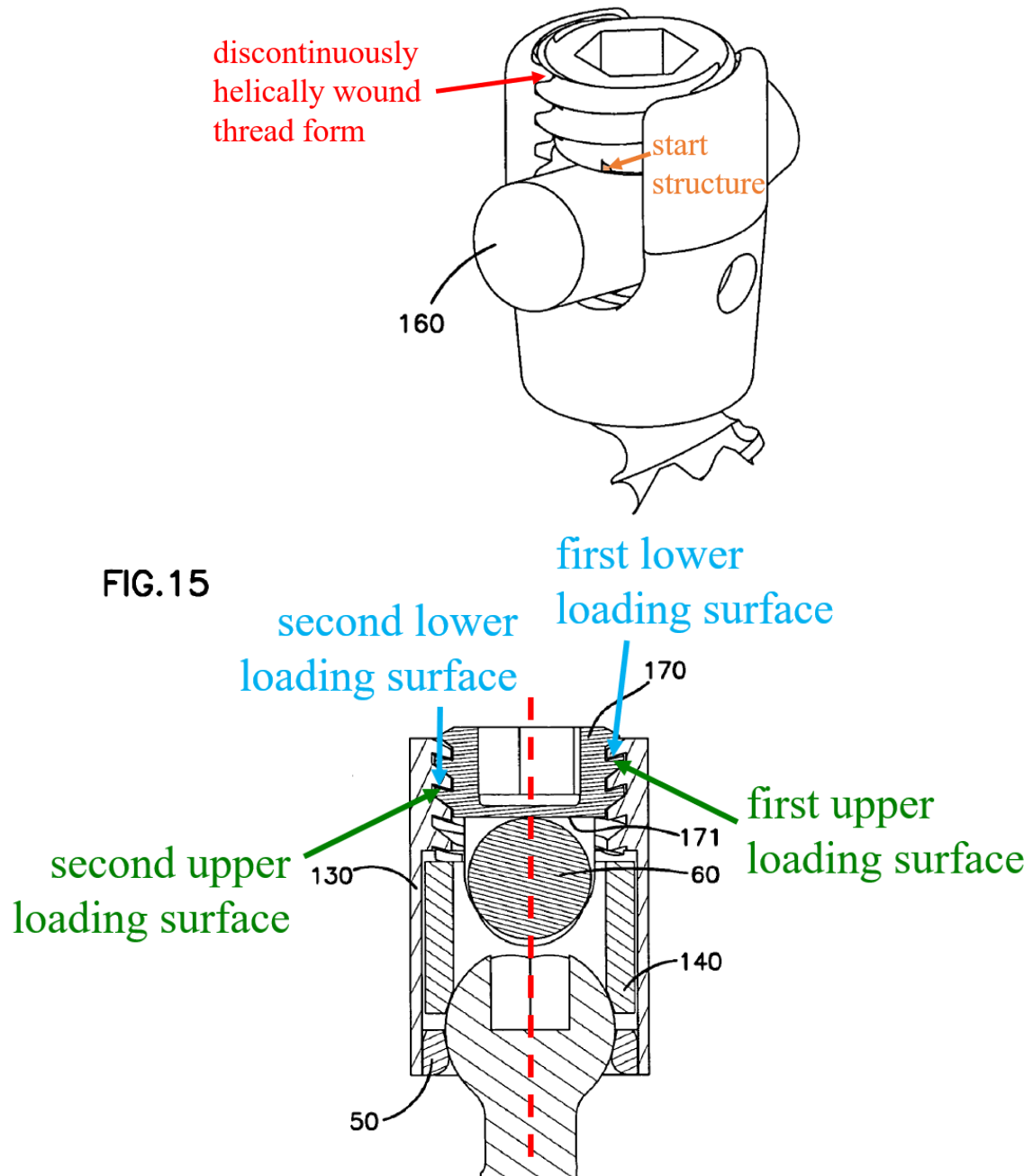
form and the second lower loading surface being mateable with the second upper loading surface.

- h. **1[B2]: a rotation of the closure about the axis of rotation between the first arm and the second arm causing a simultaneous advancement of the first start structure under the first discontinuously helically wound thread form and the second start structure under the second discontinuously helically wound thread form and a mating of the first and second lower loading surface with the first and second upper loading surface, respectively,**

240. In my opinion, the '477 Publication in view of Boschert discloses this limitation. The '477 Publication discloses a closure 101 with a “central axis of rotation C.” EX1005, ¶[0040]; *see also id.*, ¶[0030]. The '477 Publication further discloses that its guide and advancement structure “acts cooperatively” to “allow the closure” to be “inserted into and rotated relative to the bone screw receiver” and to “guide and advance the closure” along the axis of rotation as the closure is “rotated clockwise.” *Id.*, ¶[0030].

241. While the '477 Publication only discloses a single start on the closure, Boschert discloses a receiver with two discontinuously helically wound thread forms for receiving a double start closure. For example, Boschert discloses that the threads 72 can “be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead.” EX1006, 7:21-23. Boschert further discloses that the closure is “threaded into the saddles 39 [of the receiver] thereby forcing

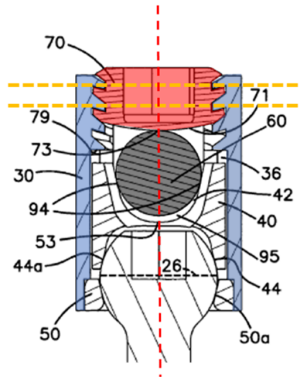
the rods 60 to seat against the top sides of the seat structures 40.” *Id.*, 4:47-50; *see also id.*, 6:20-28, Figs. 1, 3-4, 7, and 15. As discussed above (*see* Section X.A.1.f-g) and shown in the annotated Figures 7 and 15 below, Boschert discloses that a rotation of the closure about the axis of rotation between the first arm and the second arm causes advancement of the first start structure under the first discontinuously helically wound thread form and the second start structure under the second discontinuously helically wound thread form and a mating of the first and second lower loading surface with the first and second upper loading surface.



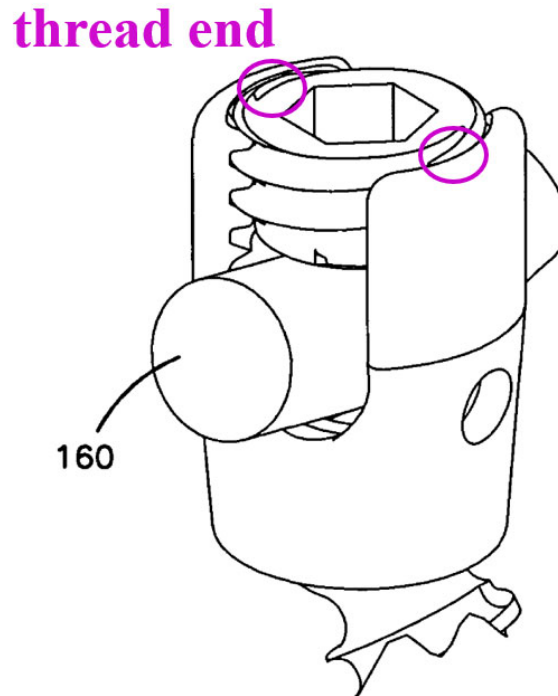
EX1006, Figs. 7, 15. As I discussed above (*see* Section X.A.1.f-g), a POSA would have understood that the thread forms on the receiver must mate with the thread forms on the closure top, at least based on the express disclosures in the '477

Publication and Boschert on mating thread forms, EX1005, ¶¶[0011], [0026], [0030], [0041]; EX1006, 6:20-28, and based on a POSA's knowledge of threaded connectors, *see supra* Section VI.B.1. Thus, in my opinion, based on the above disclosures, a POSA would have understood that the combination of the closure top of the '477 Publication and receiver of Boschert would have resulted in a combined structure where a rotation of the closure about the axis of rotation causes mating of the first and second lower loading surface with the first and second upper loading surface, respectively.

242. Boschert also discloses to a POSA that rotation of the closure about the axis of rotation between the first arm and the second arm causes simultaneous advancement of the first start structure under the first discontinuously helically wound thread form and the second start structure under the second discontinuously helically wound thread form. 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 Figure 3, below, Boschert shows that the threads on either side of the receiver 30 are symmetrically and diametrically opposed to other across the longitudinal axis (shown in red), as demonstrated by the horizontally parallel threads (shown in yellow) on each side of the receiver. EX1006, Fig. 3; *id.* Fig. 15.



243. 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 would have understood that diametrically opposed thread ends are the result of diametrically opposed thread starts.



EX1006, Fig. 7.

244. 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 thread starts. *See supra* ¶¶ 54-63; 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

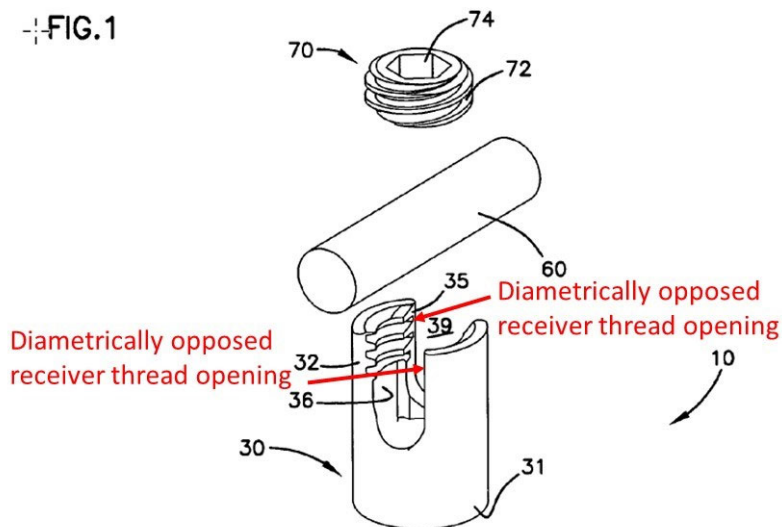
the second start structure. This understanding is also confirmed by the '641 Patent itself, which shows the same symmetrical threads on the receiver. *E.g.*, EX1001 Figs. 3, 8, 9, 11-15.

245. Based on Boschert's disclosures and the knowledge of a POSA before the priority date of the '641 Patent, a POSA would have understood that Boschert expressly discloses that rotation of the closure about the axis of rotation between the first arm and the second arm causes a simultaneous advancement of the first start structure under the first discontinuously helically wound thread form and the second start structure under the second discontinuously helically wound thread form and a mating of the first and second lower loading surface with the first and second upper loading surface. 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. Thus, in view of Boschert's

disclosure of both receiver threads and closure top thread starts that are symmetrically and diametrically opposed, a POSA would have understood that rotation of a closure about the axis of rotation between the first and second arm causes a simultaneous advancement of the first start structure under the first discontinuously helically wound thread form and the second start structure under the second discontinuously helically wound thread form and a mating of the first and second lower loading surface with the first and second upper loading surface.

246. To the extent that Boschert does not expressly disclose simultaneous advancement of the first and second start structure, based on Boschert's disclosures and the knowledge of a POSA before the priority date of the '641 Patent, a POSA would have understood that Boschert necessarily discloses simultaneous advancement of the first and 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, 13:35-41; *supra* ¶¶ 54-63.

247. To the extent that Boschert does not expressly or inherently disclose simultaneous advancement of the first and second start structure, in my opinion, it would have been obvious to a POSA before the priority date of the '641 Patent to use simultaneous advancement of the first and second start structure 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.



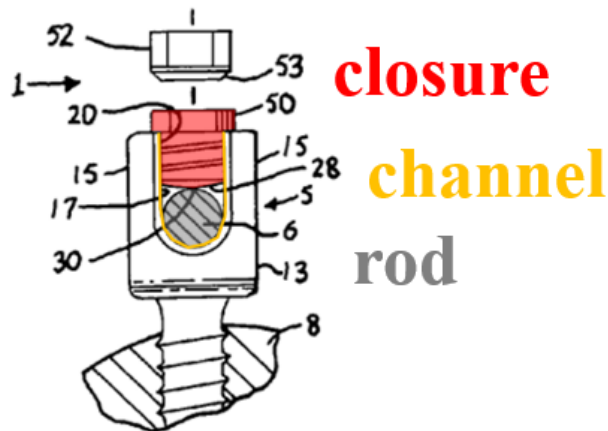
Ex.1006, Fig. 1. This can only be accomplished by diametrically opposing the thread starts on the closure top. Furthermore, of all of the examples that I have seen of double started threads in a wide variety of applications, I have never seen an example where the two thread starts do not simultaneously advance upon

rotation of the closure. *Supra* ¶¶ 51-63. Indeed, diametrically opposed starts, and thus, simultaneous advancement of these starts, is the standard way to manufacture dual start threads. *Supra* ¶¶ 54-63. For all of these reasons, in my opinion, Boschert discloses and renders obvious rotation of the closure about the axis of rotation between the first arm and the second arm that causes a simultaneous advancement of the first start structure under the first discontinuously helically wound thread form and the second start structure under the second discontinuously helically wound thread form and a mating of the first and second lower loading surface with the first and second upper loading surface. Therefore, when the closure top of '477 Publication is modified to incorporate the double lead threads of Boschert, a POSA would have understood that those double lead threads necessarily lead to a rotation of closure about the axis of rotation between the first arm and the second arm that causes a simultaneous advancement of the first start structure under the first discontinuously helically wound thread form and the second start structure under the second discontinuously helically wound thread form.

i. **1[C]: the closure rotationally advanceable within the channel until the closure locks the longitudinal connecting member within the channel**

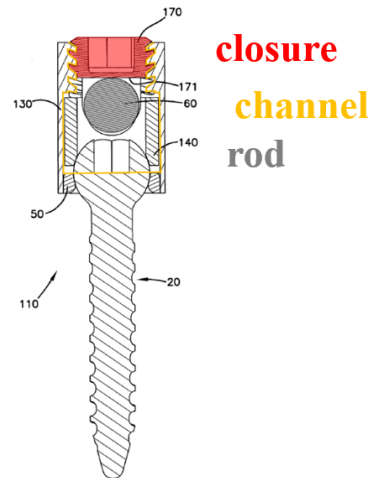
248. In my opinion, the '477 Publication in view of Boschert discloses this limitation. The '477 Publication expressly discloses a “*closure*” for use in

conjunction *with an open receiver* of a medical implant for capturing and **locking a rod in the implant.** EX1005, Abstract; *see also id.*, ¶¶[0002]. The '477 Publication further discloses that its guide and advancement structure “allow[s] the closure 1 to be inserted into and rotated relative to the bone screw receiver 13” to “guide and advance the closure 1 along the axis B as the closure 1 is rotated clockwise.” *Id.*, ¶[0030]. As shown in the excerpted, annotated Figure 5 below, after closure 1 is driven (i.e., rotatably advanced), closure 1 “**lock[s] the rod 6** in position relative to the bone screw” and within the channel. *Id.*, ¶[0037], Fig. 5; *see also id.*, ¶¶[0018]-[0019], Fig. 6.



249. Boschert discloses that the legs 38 of its receiver include “interior threads 35 that mate with corresponding exterior threads 72 of the setscrew 70 to allow the setscrew 70 [i.e., closure] to be threaded into the saddle 39 to **lock the rod 60** and screw in place” and within the channel. EX1006, 6:25-28. As shown in annotated Figure 15, Boschert discloses that its setscrew 170 (i.e., closure)

includes a “flat bottom surface 171” that “contact[s] the rod 60 when the rod is clamped within the device 110.” *Id.*, 7:40-43, Fig. 15.



250. Thus, based on the above disclosures, the closure top of the '477 Publication, as modified to mate with the receiver of Boschert, would have included a closure rotationally advanceable within the channel until the closure locks the longitudinal connecting member within the channel.

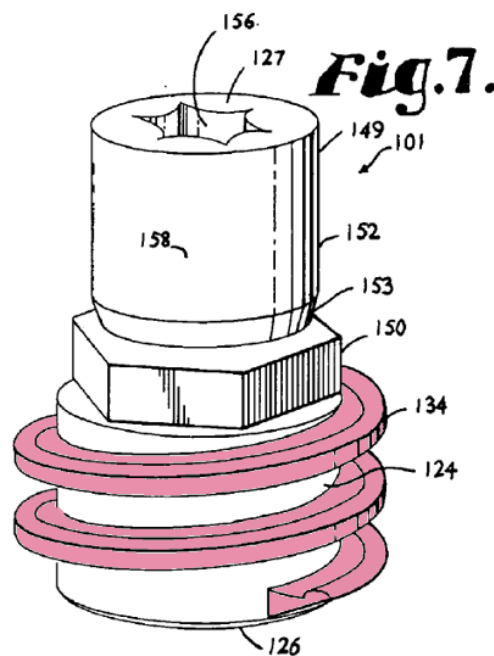
251. Accordingly, in my opinion the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 1.

2. Claim 3

252. All of the limitations of Claim 3 are recited in Claim 1, except Claim 3 recites: **[B3]** “wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each flange forms.” EX1001, cl. 3. In my opinion, the '477 Publication in combination with Boschert discloses this limitation.

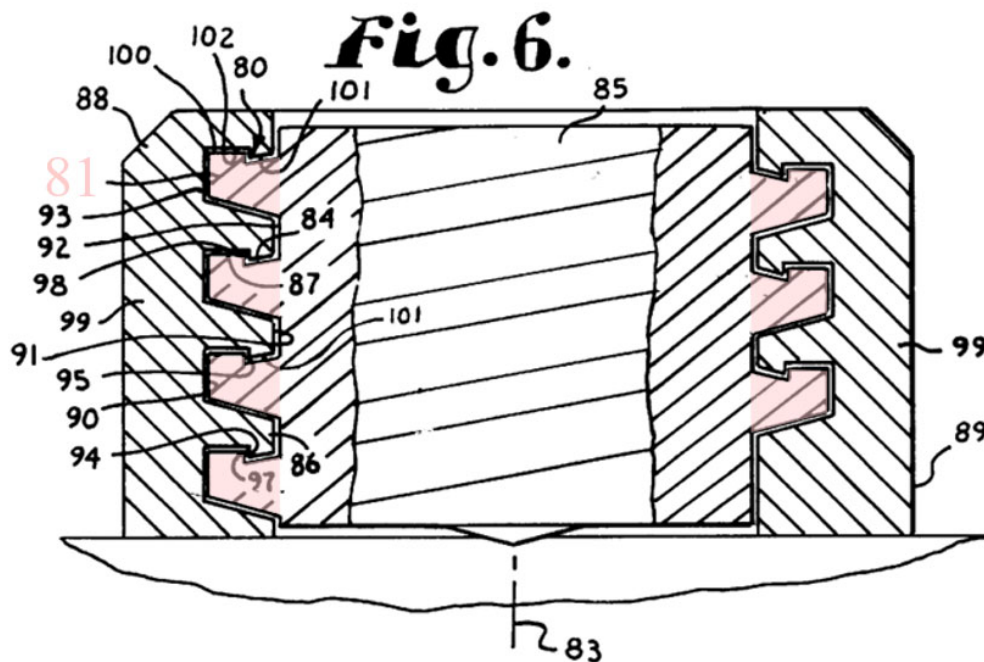
253. The '477 Publication discloses that “[l]ocated on the cylindrical closure body 124 is a guide and advancement structure 134 mateable with a guide and advancement structure on inner surfaces of the arms of the bone screw

receiver.” EX1005, ¶[0041]. In particular, the ’477 Publication discloses a guide and advancement structure 134 that “is a helical interlocking form, such as that described in U.S. Pat. No. 6,726,689 [(Jackson ’689, EX1013)], incorporated by reference herein.” *Id.* Jackson ’689 is the same patent that the ’641 Patent incorporates to disclose “interlocking flange forms.” EX1001, 6:27-30. As shown below in annotated Figure 7, the ’477 Publication discloses a continuously helically wound thread form that is a flange form. EX1005, Fig. 7.



254. Jackson ’689, which is incorporated by reference into the ’477 Publication, confirms that the helical interlocking form of the ’477 Publication is a flange form. As shown below in annotated Figure 6, Jackson ’689 discloses that a guide and advancement structure 80 that “includes the external interlocking form

81 having an *axially aligned shoulder or flange-like shaped configuration* when view[ed] in cross section in a plane passing through an axis of rotation 83.”
EX1013, 13:12-16.



EX1013, Fig. 6.

255. While the '477 Publication only discloses a single continuously helically wound thread form that is a flange form, as discussed above, a POSA would have been motivated to modify the closure top of the '477 Publication to made with Boschert's dual lead receiver. When making this combination, a POSA would have been motivated to use the flange form taught by the '477 Publication

on each of the first continuously helically wound thread form and the second continuously helically wound thread form. The '477 Publication teaches that the purpose of its guide and advancement structure is to “resist[] splaying in the bone screw receiver 13 as forces applied to the closure” “during application of clockwise rotational torque into a downward axial force and inwardly directed radial force.” EX1005, ¶[0030]. The '477 Publication teaches that there are a finite number of guide and advancement structures that could be used, including a reverse angle thread form, a buttress thread form, a square thread form, or a flange form. *Id.*, ¶[0030]; *see also id.*, ¶[0041]. In view of the design need for a guide and advancement structure to resist splaying and the finite number of predictable solutions (*i.e.*, thread form configurations), a POSA would have had good reason to pursue the known options, including a flange form. Moreover, as evidenced by the '477 Publication's discussion of thread forms and the prior arts' discussion of thread forms (*see supra* Section VI.B.1.d), each of these thread form configurations, including a flange form, were well within the technical capabilities of a POSA as of the priority date of the '641 Patent and a POSA would have anticipated success in using each of these thread form configurations, including a flange form.

256. Moreover, a POSA would have been motivated to use the '477 Publication's teaching of a flange form in the combination of the '477 Publication

and Boschert based on the explicit disclosures of Jackson '689, which is incorporated by reference into the '477 Publication. Jackson '689 teaches that an interlocking form 81 that has a “flange-like shaped configuration” resists splaying. EX1013, 13:12-24; *see also id.*, 13:28-31, 13:41-46.

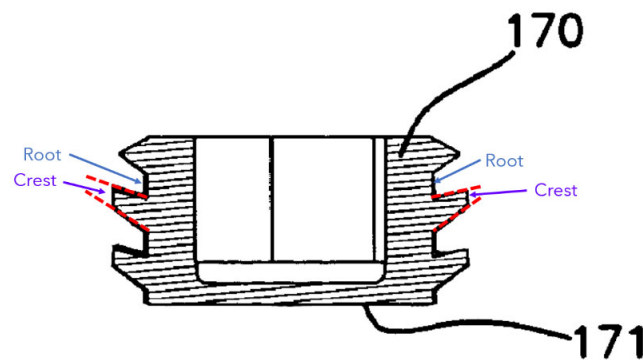
257. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 3.

3. Claim 4

258. All of the limitations of Claim 4 are recited in Claims 1, respectively, except Claim 4 recites: **[B4]** “wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each one of: v-threads, square threads, reverse angle threads, or buttress threads.” EX1001, cl. 4. In my opinion, the '477 Publication in combination with Boschert discloses this limitation.

259. 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]. In particular, the '477 Publication discloses a guide and advancement structure 34 that “is a helically wound reverse angle thread form 36.” *Id.*

260. Boschert also discloses that its first and second continuously helically wound thread forms are a reverse angle thread. As shown in excerpted, annotated Figure 15 below, Boschert discloses a first and second continuously helically wound thread forms that each include flank surfaces that are negatively sloped (shown in red) from the crest of the thread to the root of the thread, which, as I explained above, a POSA would have understood to be a reverse angle thread.



EX1006, Fig. 15; *see also id.*, Figs. 3-4, 9-10 (single reverse angle thread on closure).

261. While the '477 Publication only discloses a single continuously helically wound thread that is a reverse angle thread, as discussed above, a POSA would have been motivated to modify the closure top of the '477 Publication to mate with Boschert's dual lead receiver. When combining the teachings of the '477 Publication and Boschert, a POSA would have been motivated to use the reverse angle thread taught by the '477 Publication and Boschert on each of the

first continuously helically wound thread form and the second continuously helically wound thread form. The '477 Publication teaches that the purpose of its guide and advancement structure is to “resist[] splaying in the bone screw receiver 13 as forces applied to the closure 1 are conveyed by the reverse angle thread form 36 during application of clockwise rotational torque into a downward axial force and inwardly directed radial force.” EX1005, ¶[0030]. The '477 Publication teaches that there are a finite number of guide and advancement structures that could be used, including a reverse angle thread, a buttress thread, a square thread, or a flange form. *Id.*, ¶[0030]; *see also id.*, ¶[0041]. In view of the design need for a guide and advancement structure to resist splaying and the finite number of predictable solutions (*i.e.*, thread form configurations), a POSA would have had good reason to pursue the known options, including a reverse angle thread. Moreover, as evidenced by the '477 Publication's discussion of thread types and the prior arts' discussion of thread types (*see supra* Section VI.B.1.d), each of these thread configurations, including a reverse angle thread, were well within the technical capabilities of a POSA as of the priority date of the '641 Patent and a POSA would have anticipated success in using each of these thread configurations, including a reverse angle thread.

262. Moreover, a POSA implementing the '477 Publication in view of Boschert would have been motivated to use a reverse angle thread as taught by the

'477 Publication and Boschert at least because doing so would have been nothing more than the simple substitution of one known element (the flange form disclosed in the alternative bone screw closure depicted in the '477 Publication's Figure 7) for another (the reverse angle thread form disclosed in the bone screw closure depicted in Figure 1). The '477 Publication's teaching that various thread types, including a reverse angle thread and a flange form, are interchangeable, *see* EX1005, ¶¶[0030], [0041], confirms that a POSA would have considered the use of a reverse angle thread to be nothing more than a simple substitution of one known element for another.

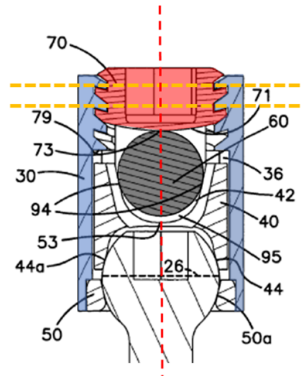
263. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claims 4.

4. Claim 5

264. All of the limitations of Claim 5 are recited in Claim 1, except Claim 5 recites: **[B5]** "wherein the first start structure is disposed at a diametrically opposite location on the closure from the second start structure." EX1001, cl. 5. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

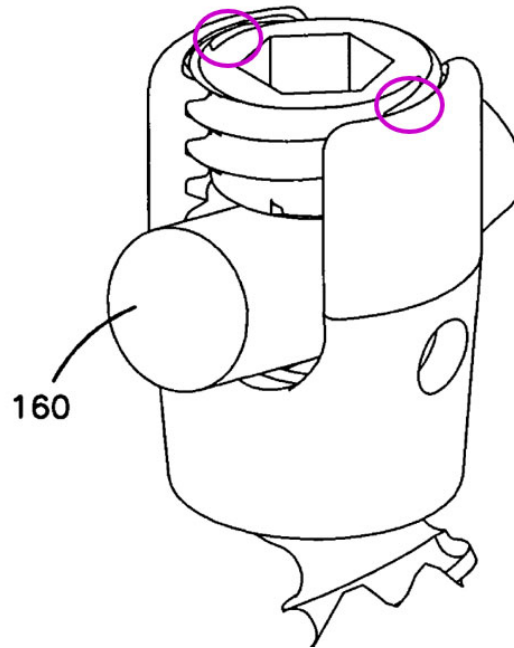
265. As set forth above, in my opinion, the '477 Publication in view of Boschert discloses each and every limitation of Claim 1, including a first continuously helically wound thread form having a first start structure and a second continuously helically wound thread form having a second start structure.

266. In my opinion, Boschert also discloses to a POSA that the start structures of the disclosed double lead would be symmetrically and diametrically opposed to one another. Specifically, as seen in Figure 3, below, Boschert shows that the threads on either side of the receiver 30 are symmetrically and diametrically opposed to each other, as illustrated below by the use of horizontally parallel threads on each side of the receiver (as shown by the yellow horizontal lines that are perpendicular to the red longitudinal line). EX1006, Fig. 3; *id.* Fig. 15.



267. 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 would have understood that diametrically opposed thread ends are the result of diametrically opposed thread starts. *Id.*, Fig. 7.

thread end



268. 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 thread starts. *See supra* ¶¶ 54-63; Specifically, a POSA would know that “[i]n order to achieve proper distribution” for a multi-start thread, “each thread ***has to start at an equal angle***, determined by the following calculation: “Thread cylindrical spacing angle = $360 / \text{Number of starts}$.” EX1014 at 3. Accordingly, a POSA would have understood Boschert’s disclosure of a setscrew with dual lead as teaching two starts 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 ‘641 Patent

itself, which shows the same symmetrical threads on the receiver. *E.g.*, EX1001 Figs. 3, 8, 9, 11-15.

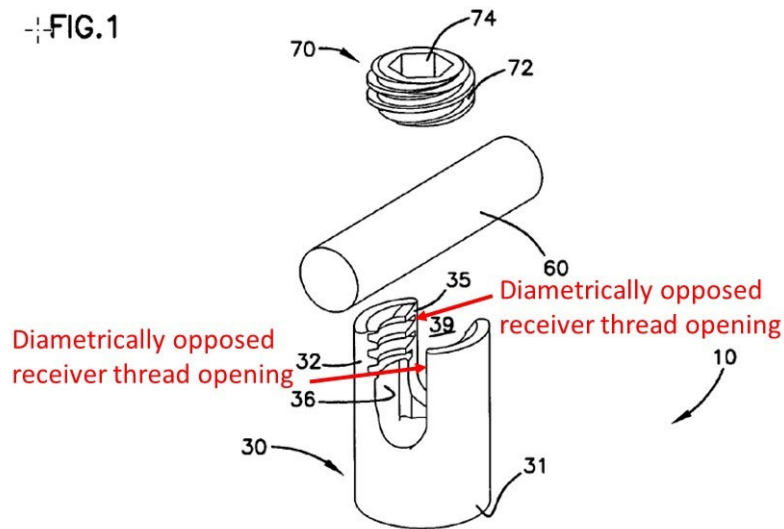
269. Based on Boschert's disclosures and the knowledge of a POSA before the priority date of the '641 Patent, a POSA would have understood that Boschert expressly discloses a first start structure that is disposed at a diametrically opposite location on the closure from the second start structure. Boschert's 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 ends on the top of the closure in Figure 7 also teaches a POSA that the first and second thread starts 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, which terminate the threads at the bottom of the closure.

270. 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 '641 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 tread starts as discussed above. EX1014 at 3; EX1026, 13:35-41; *supra* ¶¶ 54-63.

271. 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 '641 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.

FIG. 1



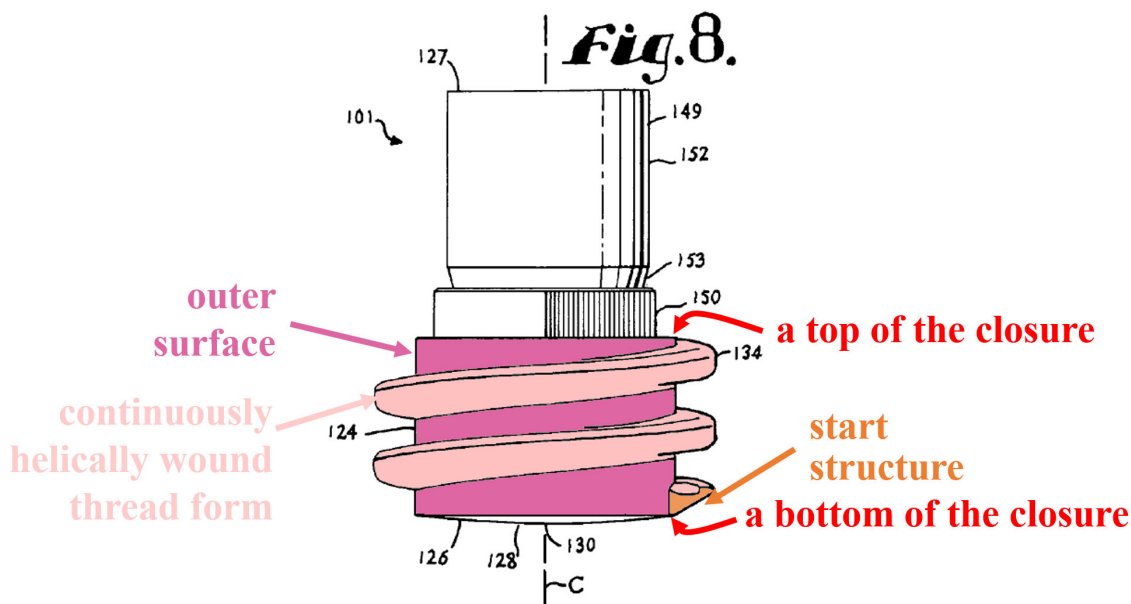
EX1006, Fig. 1. This can only be accomplished by diametrically opposing the thread starts on the closure top. Furthermore, of all of the examples that I have seen of double start threads in a wide variety of applications, I have never seen an example where the two thread starts are not located diametrically opposite each other. *Supra* ¶¶ 51-63. 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 closure top of '477 Publication is modified to mate with the double lead receiver of Boschert, a POSA would have understood that the double lead closure threads necessarily have a first start structure and a second start structure that are disposed at diametrically opposite locations from each other.

272. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 5.

5. Claim 6

273. All of the limitations of Claim 6 are recited in Claim 1, except Claim 6 recites: **[B6]** “wherein each of the continuously first and the second helically wound thread form is disposed at a top of the closure, the first helically wound thread form and the second helically wound thread form each extending along the outer surface of the closure to a bottom of the closure and ending at the first and the second start structure, respectively.” EX1001, cl. 6. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

274. The '477 Publication discloses a guide and advancement structure 134 that is “[l]ocated on the cylindrical closure body 124.” EX1005, ¶[0041]. As shown below in annotated Figure 8, the '477 Publication discloses a continuously helically wound thread form that is disposed at a top of the closure, extends along the outer surface of the closure surface to a bottom of the closure, and ends at a start structure. *See id.*, Fig. 8; *see also id.*, Figs. 7, 9-10.



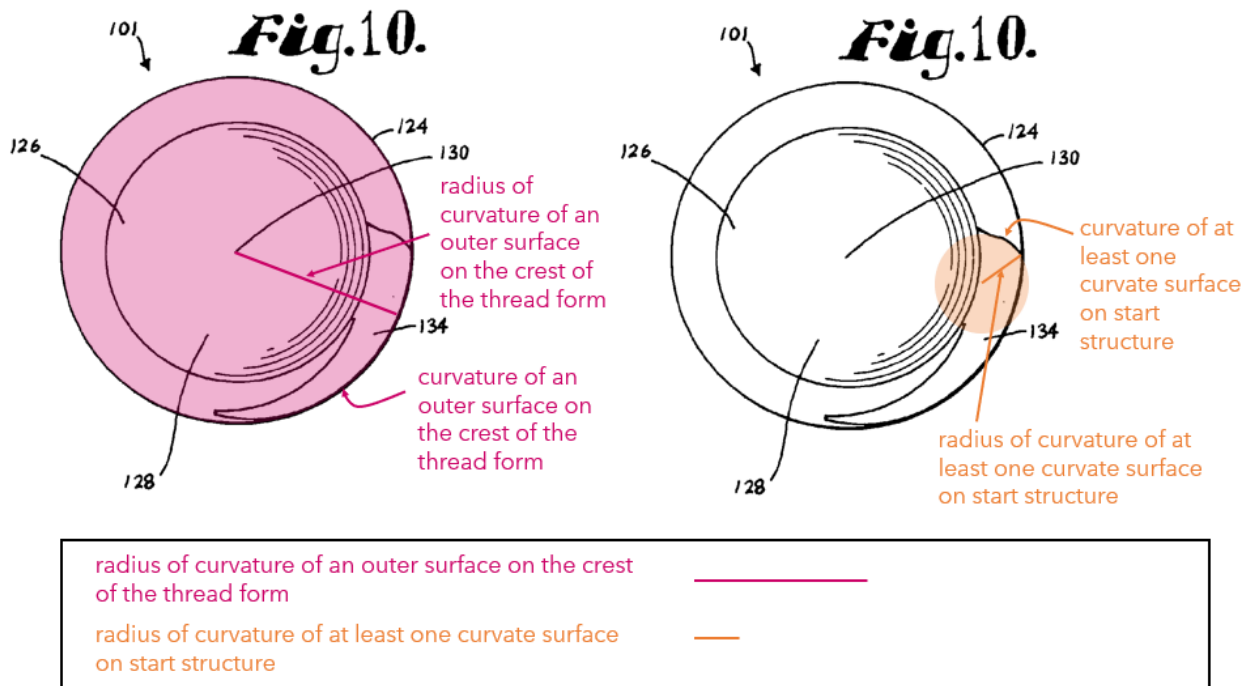
275. As discussed above (*see* Section IX.A.1), a POSA would have been motivated to combine the '477 Publication and the teachings of Boschert to include a closure top with two continuously helically wound thread forms with two start structures. In my opinion, the closure top resulting from the combination of the disclosures of the '477 Publication and Boschert would have two continuously helically wound thread forms. Moreover, the resulting closure would include each of the continuously first and the second helically wound thread form that is disposed at a top of the closure, the first helically wound thread form and the second helically wound thread form each extending along the outer surface of the closure to a bottom of the closure and ending at the first and the second start structure, respectively.

276. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 6.

6. Claim 7

277. All of the limitations of Claim 7 are recited in Claim 1, except Claim 7 further recites: **[B7]** “wherein the at least one curvate surface of both the first start structure and the second start structure is defined by at least one radius of curvature, the at least one radius of curvature being less than a radius of curvature for an outer surface on the crest of the first continuously helically wound thread form.” EX1001, cl. 7. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

278. In particular, as shown in the annotated Figure 10 below, the '477 Publication discloses a start structure wherein at least one curvate surface of the start structure is defined by a radius of curvature that is less than a radius of curvature for an outer surface on the crest of the continuously helically wound thread form.



Notably, while this limitation is observed solely in Fig. 10 of the '477 Publication, this is the same level of disclosure found in the '641 Patent itself, which never describes the radius of curvature of the start structure's curvate surface with respect to the radius of curvature of an outer surface on the crest of the thread form as part of the textual description in the specification. 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, and because in this start structure the curvate surface is defined by at least one radius of curvature that is less than a radius of curvature for an outer surface on the crest of the first continuously helically wound thread form, this combination renders obvious every element of Claim 7.

279. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 7.

7. Claim 8

280. All of the limitations of Claim 8 are recited in Claim 1, except Claim 8 further recites: **[B8]** “wherein the at least one curvate surface of both the first start structure and the second start structure is defined by at least one radius of curvature, the at least one radius of curvature being less than a radius of curvature for an outer surface on the crest of the second continuously helically wound thread form.” EX1001, cl. 8. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

281. In particular, as discussed above (*see* Section X.A.6), the '477 Publication discloses a start structure wherein at least one curvate surface of the start structure is defined by a radius of curvature that is less than a radius of curvature for an outer surface on the crest of the continuously helically wound thread form. As also discussed above (*see* Section IX.A.1), a POSA would have been motivated to use Boschert’s teaching of double lead threads on the closure of the '477 Publication, resulting in two continuously helically wound thread forms on the closure. Thus, the resulting closure would have at least one curvate surface of both the first start structure and the second start structure that is defined by at least one radius of curvature, the at least one radius of curvature being less than a

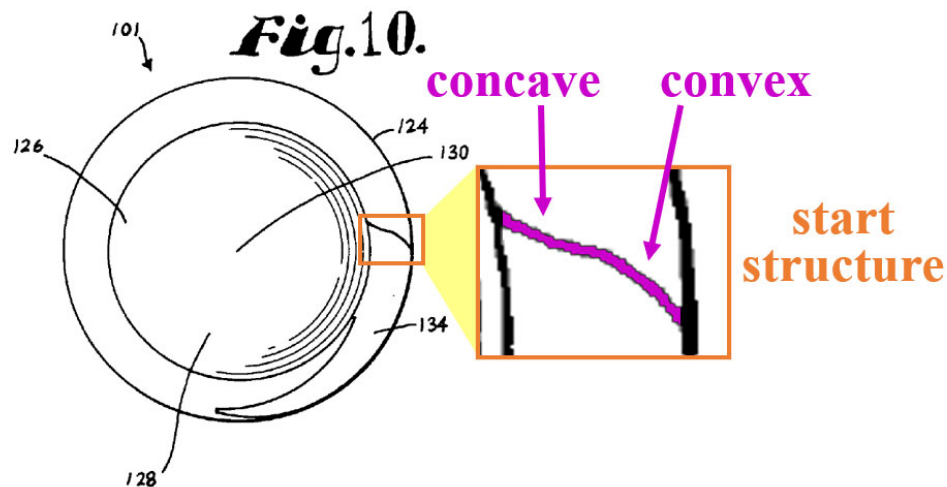
radius of curvature for an outer surface on the crest of the second continuously helically wound thread form.

282. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 8.

8. Claim 9

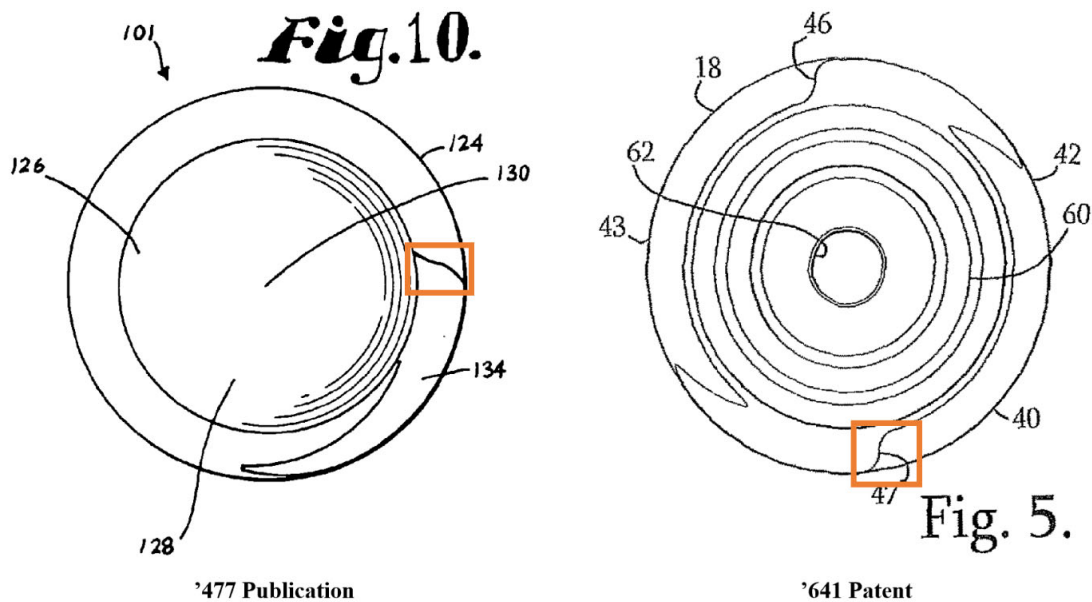
283. All of the limitations of Claim 9 are recited in Claim 1, except Claim 9 further recites: [B9] “wherein the at least one curvate surface includes both a convex surface and concave surface.” EX1001, cl. 9. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

284. In particular, as shown in the annotated Figure 10 below, the '477 Publication discloses a start structure wherein the curvate surface includes both a convex surface and a concave surface.



Ex. 1005, Fig. 10

Notably, while this limitation is observed solely in Figure 10 of the '477 Publication, the start structure disclosed in Figure 10 of the '477 Publication is similar to the start structures disclosed in the '641 Patent, which is observed solely in Figure 5, as shown below.



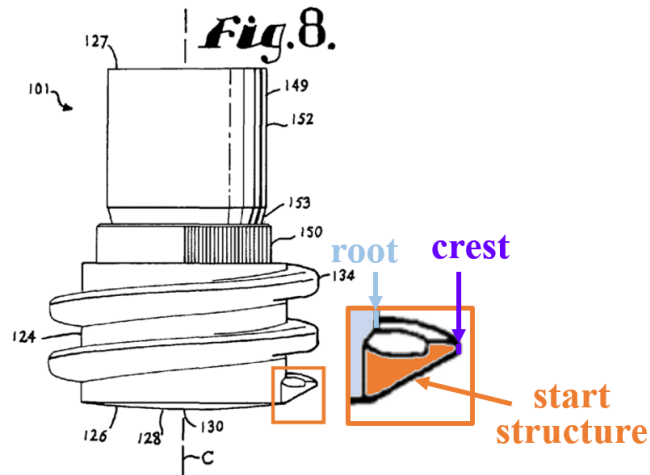
Accordingly, because a POSA implementing the '477 Publication in view of Boschert would have used the start structure of the '477 Publication on each of the dual lead threads disclosed by Boschert, and because in this start structure the curvate surface includes both a convex surface and concave surface, this combination renders obvious every element of Claim 9.

285. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 9.

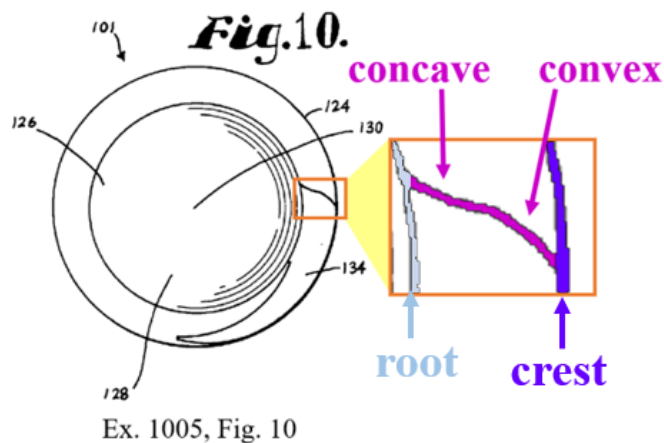
9. Claim 10

286. All of the limitations of Claim 10 are recited in Claim 9, except Claim 10 further recites: **[B10]** “wherein both of the concave surface and the convex surface of the first start structure are positioned between the root and the crest of the first continuously helically wound thread form, and wherein both of the concave surface and the convex surface of the second start structure are positioned between the root and the crest of the second continuously helically wound thread form.” EX1001, cl. 10. In my opinion, the ’477 Publication in view of Boschert discloses this limitation.

287. 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.” *Id.*, ¶[0031]. As shown in annotated and enlarged Figure 8 below, the ’477 Publication discloses a start structure on the closure thread that is positioned between a root and a crest of the continuously helically wound thread form. *Id.*, Figs. 7 & 8.



288. In addition, as shown in Figure 10 below, the start structure disclosed in the '477 Publication includes both a concave surface and a convex surface between the root and the crest of the continuously helically wound thread form. *Id.*, Fig. 10.



289. While the '477 Publication discloses the above start structure 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. 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.” EX1005, 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, ¶ 203. 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.

290. 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* Section VI.B.1.a. Therefore, the closure top resulting from the combination of the disclosures of the '477 Publication and Boschert would have used the start structure of the '477 Publication as the start structure on each of the two dual start threads taught by Boschert.

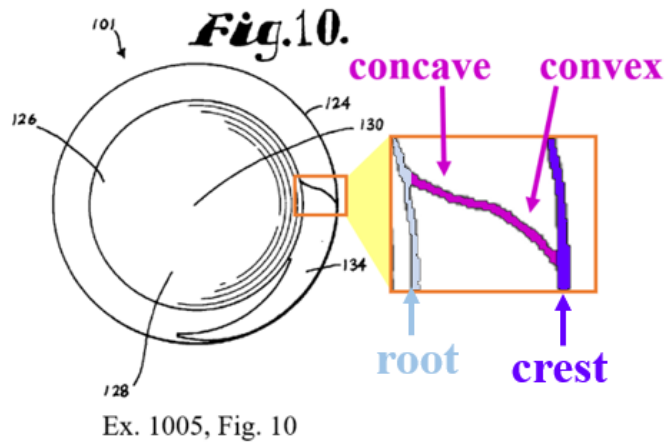
291. In my opinion, the closure top resulting from the combination of the disclosures of the '477 Publication and Boschert would have resulted in a concave surface and a convex surface of the first start structure that are positioned between the root and the crest of the first continuously helically wound thread form, and wherein both of the concave surface and the convex surface of the second start structure are positioned between the root and the crest of the second continuously helically wound thread form.

292. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 10.

10. Claim 11

293. All of the limitations of Claim 11 are recited in Claim 10, except Claim 11 further recites: **B[11]**“wherein the concave surface is adjacent the root and the convex surface is adjacent the crest of the first and second start structures for the first and second continuously helically wound thread form, respectively.” EX1001, cl. 11. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

294. In particular, as shown in the annotated Figure 10 below, the '477 Publication discloses a start structure with a concave surface that is adjacent the root and a convex surface that is adjacent the crest of the continuously helically wound thread form.



295. Because, as discussed above, 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, the '477 Publication in view of Boschert would have resulted in a concave surface that is adjacent the root and a convex surface that is adjacent the crest of the first and second start structures for the first and second continuously helically wound thread form, respectively.

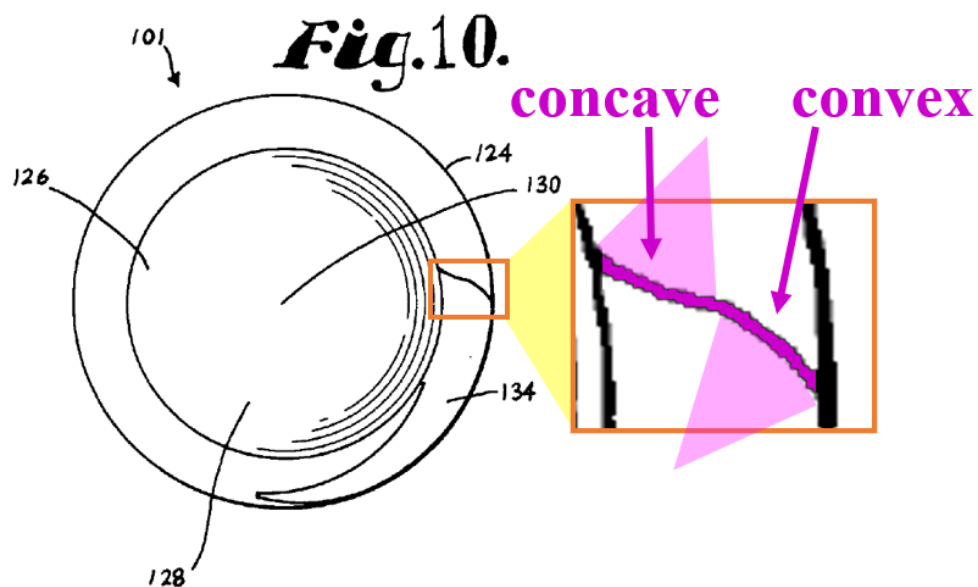
296. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 11.

11. Claim 12

297. All of the limitations of Claim 12 are recited in Claim 9, except Claim 12 further recites: [B12] “wherein a radius of curvature of the convex surface is substantially equal to a radius of curvature of the concave surface.” EX1001, cl.

12. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

298. Specifically, as shown in annotated Figure 10 below, the '477 Publication discloses that the partial concave and convex surfaces of the start structure have a radius of curvature that are substantially equal with respect to each other. EX1005, Fig. 10.



Ex. 1005, Fig. 10

Notably, while the numeric radii of curvature are not disclosed in the '477 Publication, the claims of the '641 Patent do not require any numeric radii of curvature. Moreover, in view of the manufacturing processes 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 would have been consistent with

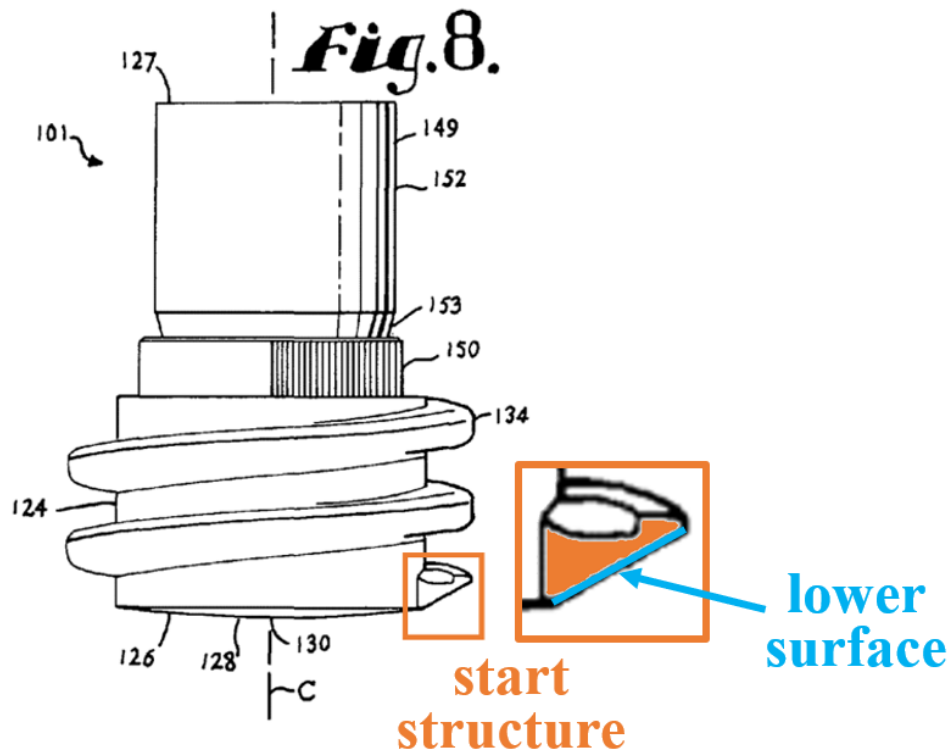
the easiest manufacturing processes for the lead face of a thread start structure. Finally, while the comparison of the radii of curvature of the concave surface to the convex surface is possible only via Figure 10 of the '477 Publication, I note that this is the same level of disclosure available in the '641 Patent itself, which never compares the radius of curvature of the concave surface to the radius of curvature of the convex surface in the textual description of the specification. Instead, the '641 Patent only shows this limitation in Figure 5.

299. In my opinion, based on the above disclosures, when combining the disclosures of the '477 Publication and Boschert, a POSA would have included 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 are substantially equal with respect to each other. *Supra* Section IX.A. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 12.

12. Claim 13

300. All of the limitations of Claim 13 are recited in Claim 9, except Claim 13 further recites: **[B13]** “wherein each of the first start structure and the second start structure includes a bottom beveled surface.” EX1001, cl. 13. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

301. 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, that is the same level of disclosure available in the '641 Patent itself with respect to a bottom beveled surface. *See* EX1001, Fig. 3.

302. Accordingly, because, as discussed above, 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, the '477

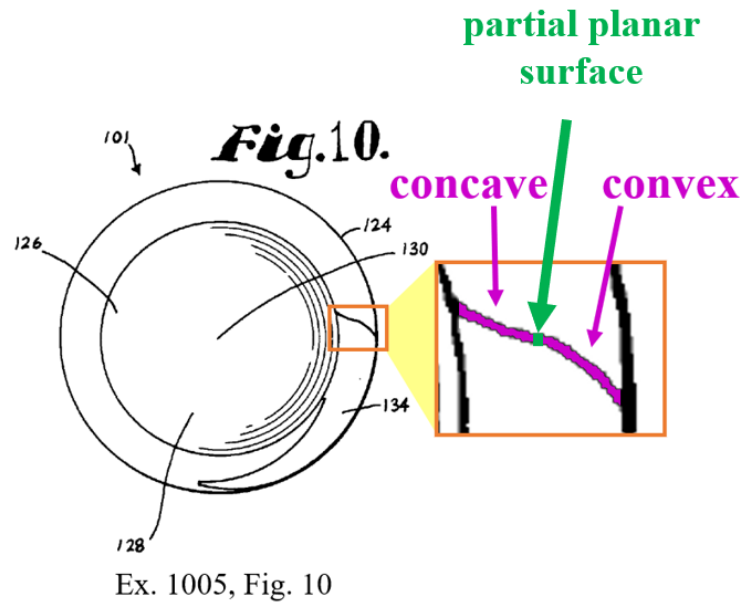
Publication in view of Boschert would have resulted in each of the first start structure and the second start structure including a bottom beveled surface.

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

13. Claim 14

304. All of the limitations of Claim 14 are recited in Claim 1, except Claim 14 further recites: **[B14]** “wherein the first and second start structure leading face surfaces are at least partially planar surfaces parallel with respect to each other.” EX1001, cl. 14. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

305. 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.

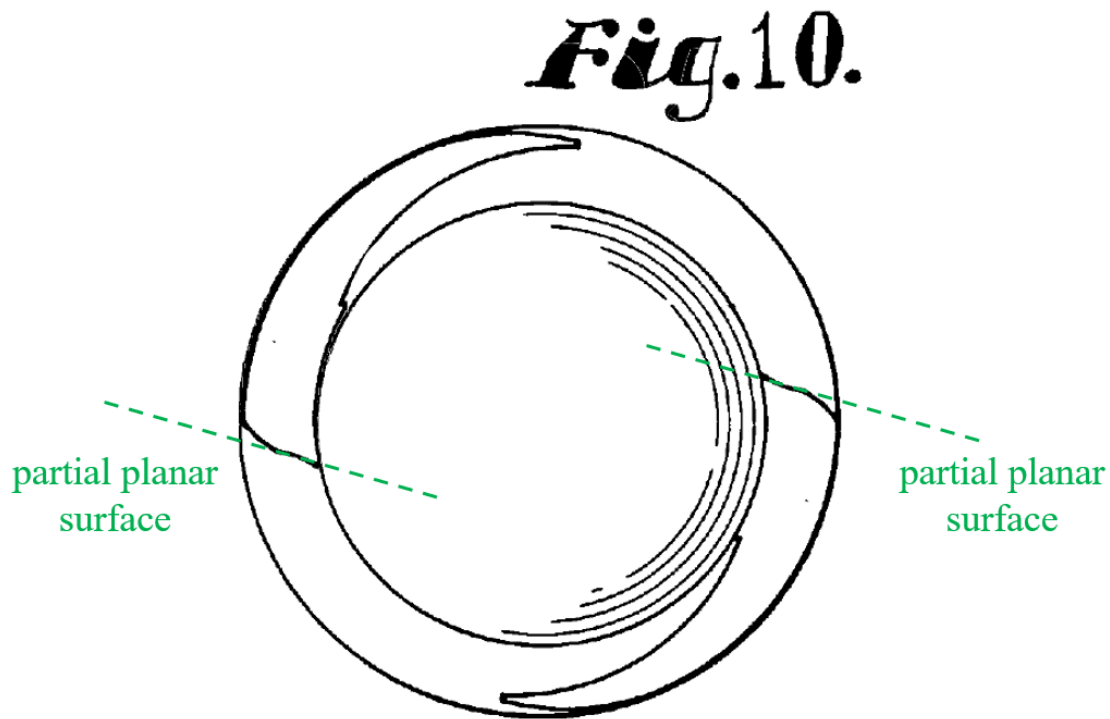


EX1005, Fig. 10. Notably, this is the same level of disclosure available in the '641 Patent itself with respect to a partial planar surface. *See* EX1001, Fig. 5.

306. Accordingly, because, as discussed above, 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, the '477 Publication in view of Boschert would have resulted in first and second start structure leading face surfaces that are at least partially planar surfaces parallel with respect to each other.

307. Moreover, because the start structures themselves would be diametrically opposed around the closure bottom and mirror images of each other, *supra* Section X.A.4, a POSA would have understood that the partial planar surface of the leading face of each start structure would be parallel to each other.

Below I have provided a modified version of Figure 10 of the '477 Publication, with a dual start arrangement, that depicts the partial planar surfaces of the leading face of each start structure that are parallel to each other.

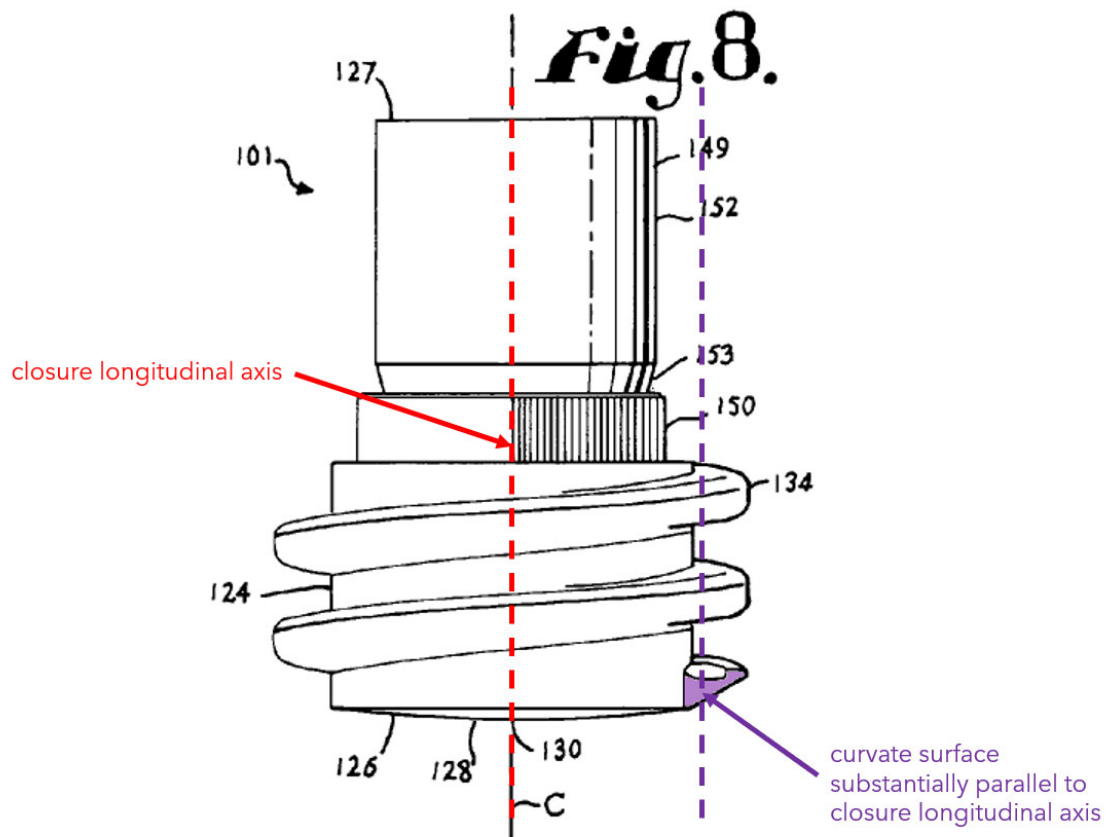


308. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 14.

14. Claim 15

309. All of the limitations of Claim 15 are recited in Claim 1, except Claim 15 further recites: **[B15]** “wherein each of the at least one curvate surfaces is substantially parallel to the closure longitudinal axis.” EX1001, cl. 15. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

310. In particular, as shown below in annotated Figure 8, the '477 Publication discloses a curvate surface of the start surface that is substantially parallel to the closure longitudinal axis. For clarity, the **purple line** in the annotated Figure 8 below extends along the surface of the curvate surface of the start surface.



EX1005, Fig. 8; *see also id.*, Fig. 7. Notably, this is the same level of disclosure available in the '641 Patent itself with respect to a partial planar surface. *See* EX1001, Figs. 1-2. Because, as discussed above, a POSA implementing the '477

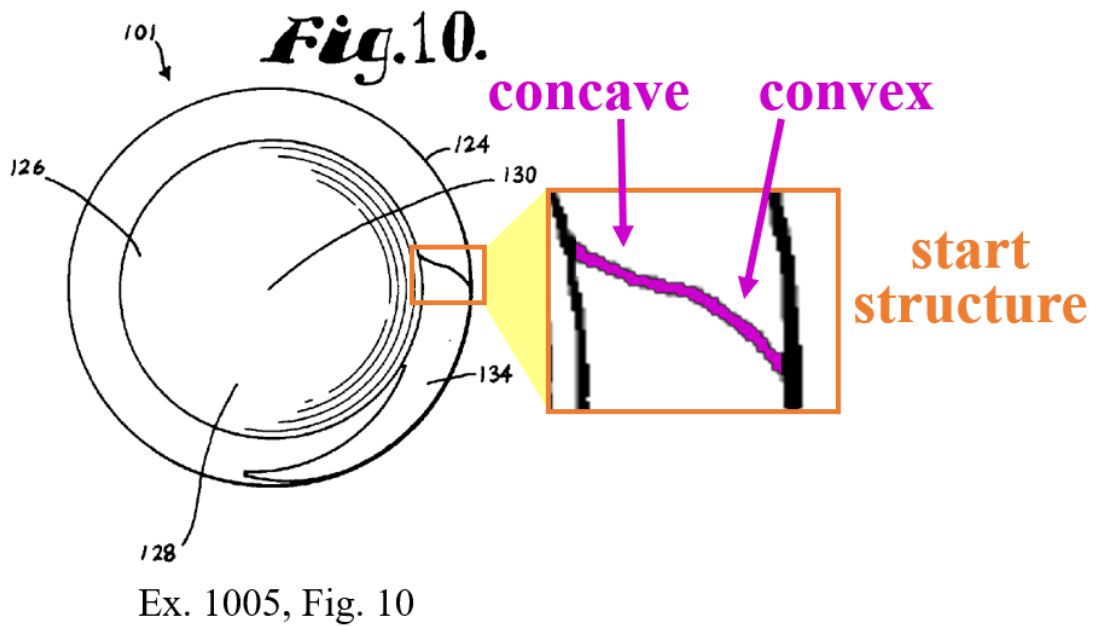
Publication in view of Boschert would have used the start structure of the '477 Publication on each of the dual lead threads disclosed by Boschert, the '477 Publication in view of Boschert would have resulted in each of the at least one curvate surfaces being substantially parallel to the closure longitudinal axis.

311. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 15.

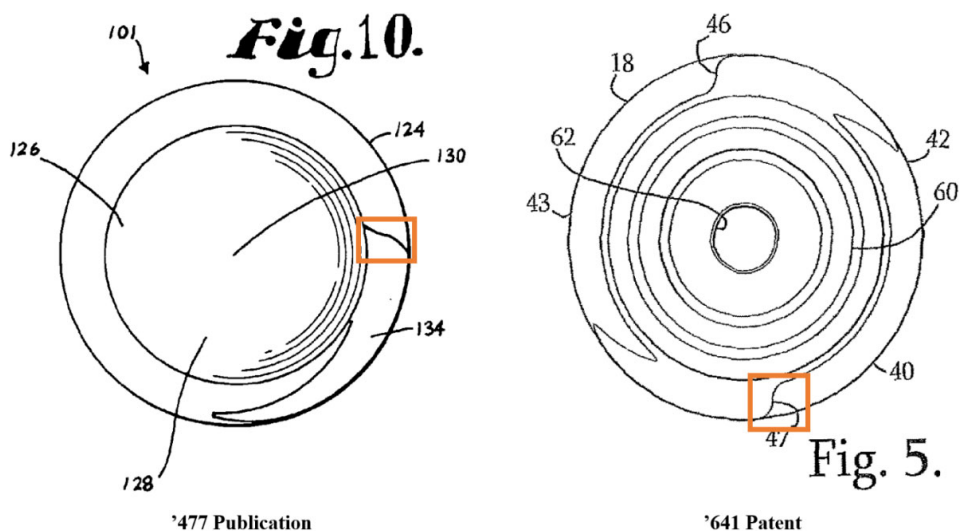
15. Claim 16

312. All of the limitations of Claim 16 are recited in Claim 1, except Claim 16 further recites: **[B9]** “wherein each of the at least one curvate surface includes both a convex surface and concave surface.” EX1001, cl. 16. This limitation recites the same requirement as Claim 9, but with the requirement that *each* of the curvate surfaces include the convex surface and concave surface. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

313. In particular, as shown in the annotated Figure 10 below, the '477 Publication discloses a start structure wherein the curvate surface includes both a convex surface and a concave surface.



Notably, while this limitation is observed solely in Figure 10 of the '477 Publication, the start structure disclosed in Figure 10 of the '477 Publication is similar to the start structures disclosed in Figure 5 of the '641 Patent, as shown below.



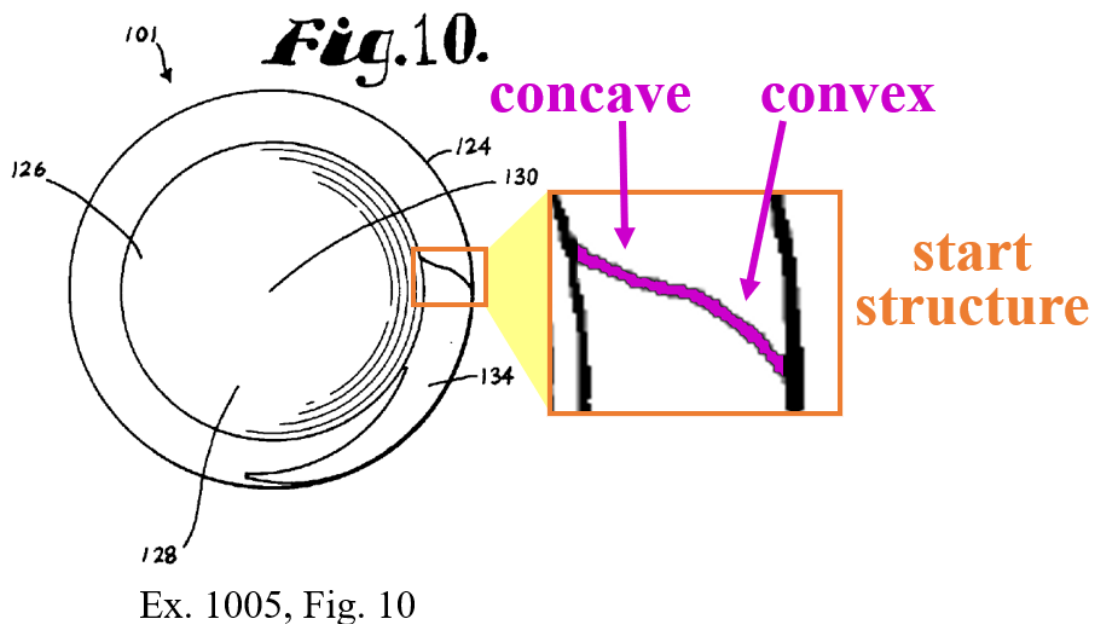
314. Accordingly, because a POSA implementing the '477 Publication in view of Boschert would have used the start structure of the '477 Publication on each of the dual lead threads disclosed by Boschert, and because in this start structure the curvate surface includes both a convex surface and concave surface, this combination renders obvious every element of Claim 16.

315. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 16.

16. Claim 17

316. All of the limitations of Claim 17 are recited in Claim 1, except Claim 17 further recites: **[B9]** “wherein each of the at least one curvate surfaces is a concave surface.” EX1001, cl. 17. This limitation is similar to Claim 16, but with the requirement that each of the curvate surfaces is a concave surface. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

317. In particular, as shown in the annotated Figure 10 below, the '477 Publication discloses a curvate surface that is a concave surface.



318. Because, as discussed above, 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, the '477 Publication in view of Boschert would have resulted in each of the at least one curvate surfaces being a concave surface.

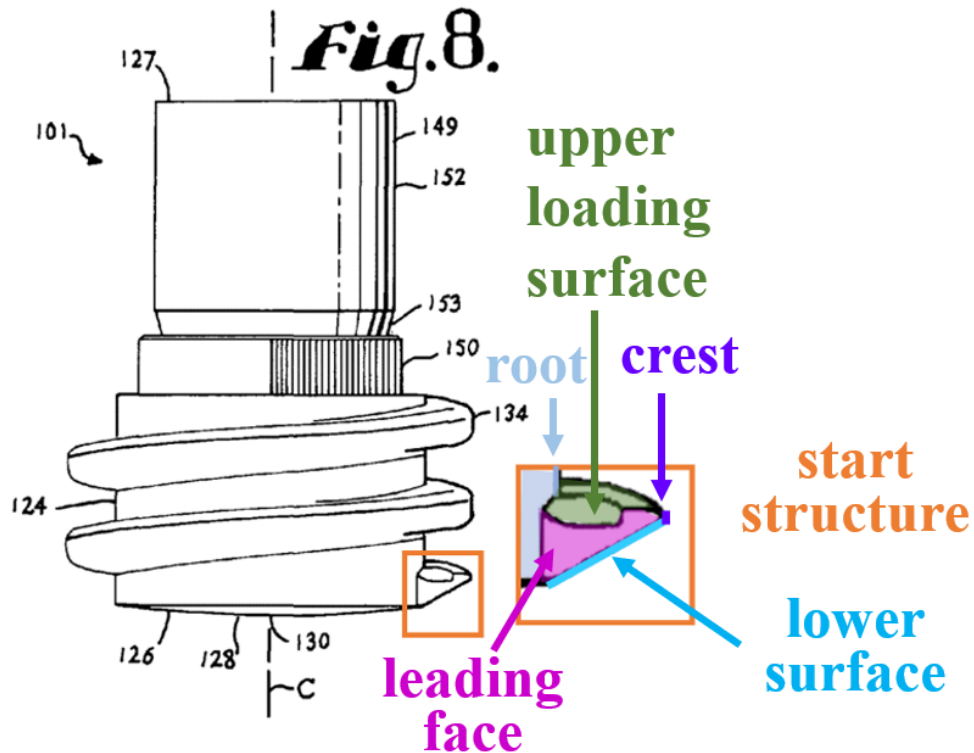
319. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 17.

17. Claim 18

320. All of the limitations of Claim 18 are recited in Claim 1, except Claim 18 further recites: **[B16]** “wherein the closure first continuously helically wound thread form includes a first lower surface disposed between the root and the crest

and the closure second continuously helically wound thread form includes a second lower surface disposed between the root and the crest, and wherein the leading face surface of the first start structure extends between the first upper surface and the first lower surface and the leading face surface of the second start structure extends between the second upper surface and the second lower surface.” EX1001, cl. 18. In my opinion, the ’477 Publication in view of Boschert discloses this limitation.

321. 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 lower surface disposed between the root and a crest of the continuously helically wound thread form and a leading face that extends between the upper surface and lower surface of the start structure. *Id.*, Figs. 7 & 8.



EX1005, Fig. 8.

322. Because, as discussed above, 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, the '477 Publication in view of Boschert would have resulted in a closure first continuously helically wound thread form that includes a first lower surface disposed between the root and the crest and a closure second continuously helically wound thread form that includes a second lower surface disposed between the root and the crest, and wherein the leading face surface of the first start structure extends between the first upper surface and the first lower surface and the leading face surface of the

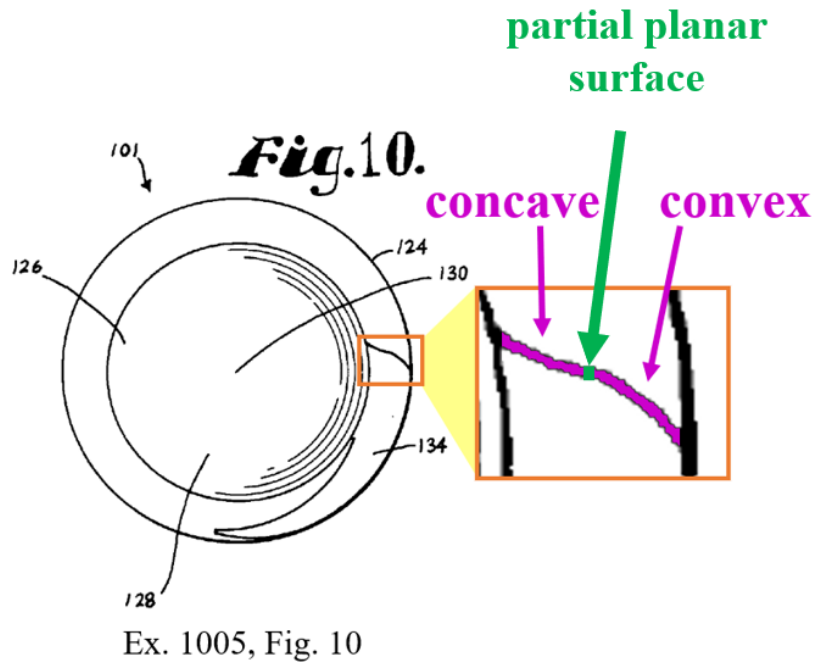
second start structure extends between the second upper surface and the second lower surface.

323. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 18.

18. Claim 19

324. All of the limitations of Claim 19 are recited in Claim 18, except Claim 19 further recites: **[B14]** “wherein each of the leading face surfaces of the first start structure and the second start structure include at least a partial planar surface.” EX1001, cl. 19. This limitation is similar to Claim 14, except that Claim 19 does not require that the leading face structures are parallel. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

325. 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. Around 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 '641 Patent itself with respect to a partial planar surface. *See* EX1001, Fig. 5.

326. Because, as discussed above, 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, the '477 Publication in view of Boschert would have resulted in each of the leading face surfaces of the first start structure and the second start structure including at least a partial planar surface.

327. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 19.

19. Claim 21

a. 21[Preamble]: A medical implant assembly comprising:

328. To the extent the preamble of Claim 21 is considered limiting, in my opinion the '477 Publication in view of Boschert discloses this limitation. The preamble to Claim 21 recites the same requirements as the preamble to Claim 1. *Compare* EX1001, cl. 1 *with id.*, cl. 21. 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]. Similarly, Boschert is titled "Spinal Fixation Implant Assembly," and discloses a spinal fixation technique "whereby surgical implants are used for fusing together and/or mechanically immobilizing vertebrae of the spine." EX1006, 1:34-37.

b. 21[A]: a receiver having a first arm and a second arm spaced apart from each other by a rod-receiving channel, the first arm and the second arm each having a top surface and an inner surface having a first thread on the first arm and a second thread on the second arm comprising first and second discontinuously helically wound threads, respectively, being symmetrically and diametrically opposed to each other and extending up to the top surface on each arm, the opposed discontinuously helically wound threads forming a dual lead in closure starting arrangement for the receiver;

329. In my opinion, the '477 Publication in view of Boschert discloses this limitation. Limitation 21[A], while worded a little differently regarding the channel, includes the same requirements as Limitation 1[A], and the combination

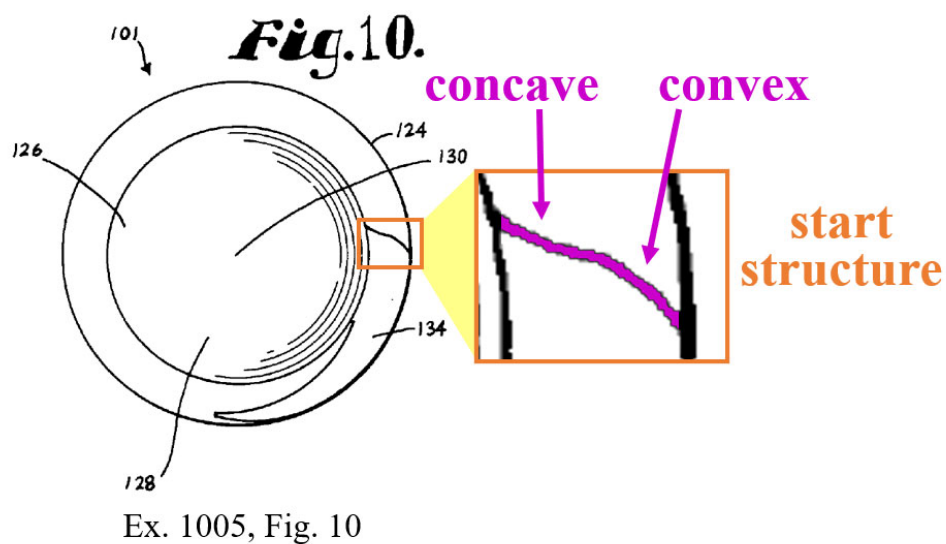
of the '477 Patent and Boschert meets the requirements of Limitation 21[A] for the same reasons. *See supra* Section X.A.1.b.

- c. **21[B]: a closure having a first continuously helically wound thread form and a second continuously helically wound thread form, the first continuously helically wound thread form having a first start structure and a first loading surface extending between a root and a crest of the first continuously helically wound thread form, the second continuously helically wound thread form having a second start structure and a second loading surface extending between a root and a crest of the second continuously helically wound thread form,**

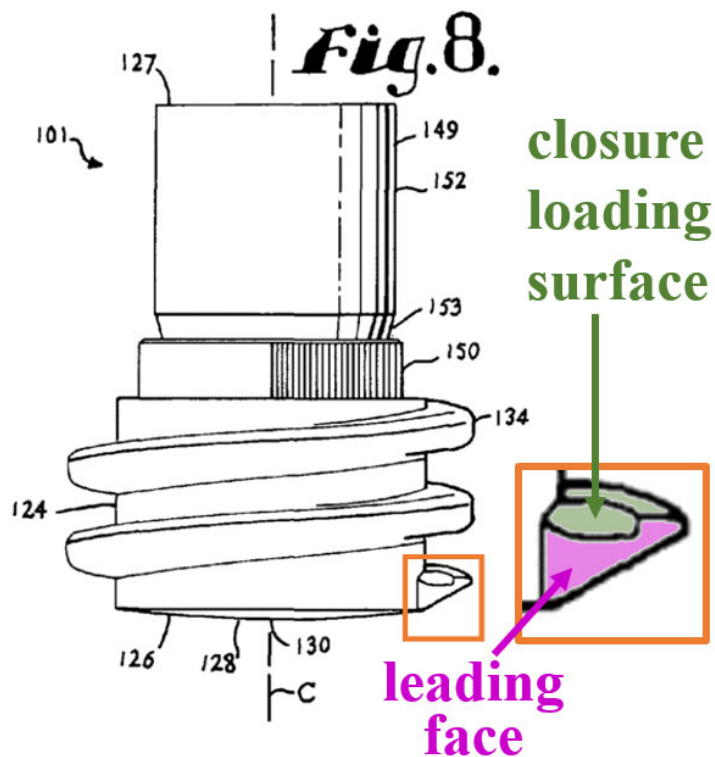
330. In my opinion, the '477 Publication in view of Boschert discloses this limitation. Limitation 21[B], while worded a little differently because it does not discuss a longitudinal axis or an outer surface, includes the same requirements as Limitation 1[B], except that Limitation 21[B] does not require that the closure include a longitudinal axis or that the start structures include leading faces. The '477 Publication in view of Boschert meets the requirements of Limitation 21[B] for the same reasons as Limitation 1[B]. *See supra* Section X.A.1.c.

- d. **21[C]: each of the first start structure and the second start structure having a leading face surface extending below each closure loading surface and including at least a partial concave surface;**

331. In my opinion, the '477 Publication in view of Boschert discloses this limitation. As shown in annotated Figure 10 below, the '477 Publication discloses a leading face that includes at least a partial concave surface.



332. Moreover, as shown in the annotated Figure 8 below, the '477 Publication discloses a leading face surface extending below the closure loading surface. *Id.*, Figs. 7 & 8.



333. Boschert discloses that “[t]he threads 72 of the setscrew 70 can also be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead.” EX1006, 7:21-23.

334. When the closure top of the ’477 Publication is modified to mate with the dual start receiver of Boschert, a POSA would have kept the same leading face structure with at least a partial concave surface from the ’477 Publication on each of the dual lead threads taught by Boschert. A POSA would have been motivated to keep the leading face structure from the ’477 Publication because, from their knowledge of truncated threads generally, a POSA would have understood that a

truncated thread, such as the one disclosed in the '477 Publication, avoids thin, sharp portions of the thread that could cut a surgeon's glove, be damaged, or lead to cross threading. *See* EX1024 at 13. A POSA, from their knowledge of truncated threads generally, would have understood that a truncated thread facilitates alignment and starting of threading. *See* EX1007 ¶¶[0006], [0008], [0043], [00049]; EX1022, ¶[0031]. A POSA also would have understood that a truncated thread provides structural stability during assembly. *See* EX1015, 1:40-52, 2:88-94.

335. 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 closure would have a leading face surface on each of the first start structure and the second start structure having a leading face surface extending below each closure loading surface and including at least a partial concave surface.

- e. **21[A1]: the channel being formed by the first arm and the second arm, the channel closeable with the closure having an axis of rotation;**

336. In my opinion, the '477 Publication in view of Boschert discloses this limitation. Limitation 21[A1], while worded a little differently regarding the channel, includes the same requirements as Limitation 1[A1], except that

Limitation 21[A1] does not require that the channel be configured to receive a longitudinal connecting member. *Compare* EX1001, cl. 1 *with id.*, cl. 21. The '477 Publication in view of Boschert meets the requirements of Limitation 21[A1] for the same reasons as Limitation 1[A1]. *See supra* Section X.A.1.e.

- f. **21[A2]: the first discontinuously helically wound thread form on the inner surface of the first arm having a first discontinuous loading surface, the first start structure rotatable under the first discontinuously helically wound thread form and the first discontinuous loading surface mateable with the closure first loading surface; and;**

337. In my opinion, the '477 Publication in view of Boschert discloses this limitation. Limitation 21[A2], while worded a little differently regarding the thread form surface, includes the same requirements as Limitation 1[A2], except that Limitation 21[A2] does not require “upper” or “lower” loading surfaces. *Compare* EX1001, cl. 1 *with id.*, cl. 21. The '477 Publication in view of Boschert meets the requirements of Limitation 21[A2] for the same reasons as Limitation 1[A2]. *See supra* Section X.A.1.f.

- g. 21[A3]: the second discontinuously helically wound thread form on the inner surface of the second arm having a second discontinuous loading surface, the second start structure rotatable under the second discontinuously helically wound thread form and the second discontinuous loading surface mateable with the closure second loading surface,**

338. In my opinion, the '477 Publication in view of Boschert discloses this limitation. Limitation 21[A3], while worded a little differently regarding the thread form surface, includes the same requirements as Limitation 1[A3], except that Limitation 21[A3] does not require “upper” or “lower” loading surfaces. *Compare* EX1001, cl. 1 *with id.*, cl. 21. The '477 Publication in view of Boschert meets the requirements of Limitation 21[A3] for the same reasons as Limitation 1[A3]. *See supra* Section X.A.1.g.

- h. 21[B2]: a rotation of the closure about the axis of rotation between the first arm and the second arm causing the first start and the second start structures to simultaneously rotatably advance under the first discontinuously helically wound thread form and the second discontinuously helically wound thread form, respectively, the closure rotationally advanceable within the channel until a rod positioned within the channel is locked therein.**

339. In my opinion, the '477 Publication in view of Boschert discloses this limitation. Limitation 21[B2], while worded a little differently regarding simultaneous advancement, includes the same requirements as Limitation 1[A3] and Limitation 1[B2] and simply describes the top of all polyaxial pedicle screws

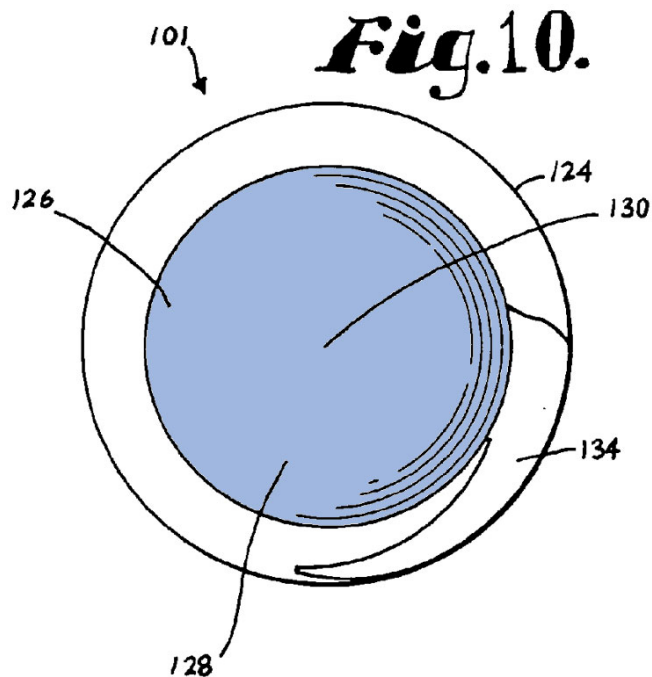
designed to be used with rods. *Compare* EX1001, cl. 1 *with id.*, cl. 21. The '477 Publication in view of Boschert meets the requirements of Limitation 21[B2] for the same reasons as Limitation 1[B2]. *See supra* Section X.A.1.h.

340. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 21.

20. Claim 22

341. All of the limitations of Claim 22 are recited in Claim 21, except Claim 22 further recites: [B17] “wherein the closure has a bottom surface that is closed.” E x. 1001, cl. 22. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

342. In particular, as shown in the annotated Figure 10 below, the '477 Publication discloses a closure that has a **bottom surface** that is closed.



EX1005, Fig. 10; *see also id.*, Fig. 4.

343. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 22.

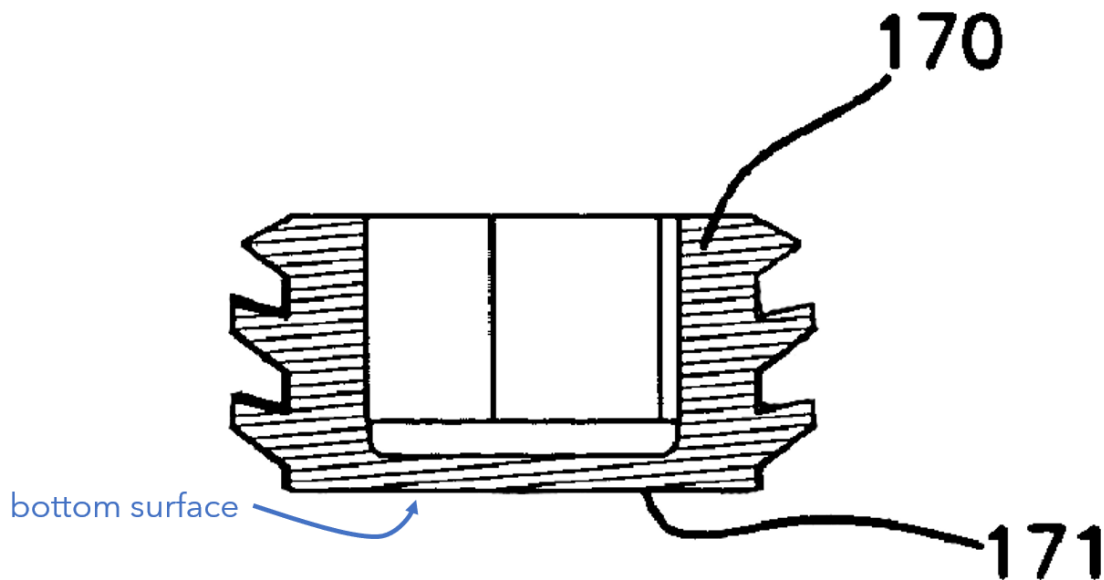
21. Claim 23

344. All of the limitations of Claim 23 are recited in Claim 22, except Claim 23 further recites: **[B18]** “wherein the bottom surface is flat.” EX1001, cl.

23. In my opinion, the '477 Publication in view of Boschert discloses this limitation.

345. While the '477 Publication discloses a preferred embodiment of the described closure that has a bottom surface that is domed, the '477 Publication also discloses a number of alternative bottom surfaces that could be used

interchangeably, including a bottom that is “substantially flat and include[s] a small dome having a central point” or “flat and may have a central point and a lateral rim.” EX1005, ¶¶[0029], [0040]. Boschert similarly discloses interchangeable closure bottom surfaces including a domed bottom surface, EX1006, 7:16-17, and a “setscrew 170 having a flat bottom surface 171 for contacting the rod 60 when the rod is clamped within the device 110.” EX1006, 7:41-43. As shown in excerpted, annotated Figure 15 below, Boschert discloses a closure that has a bottom surface that is flat.



346. As discussed above, a POSA would have understood that there were a limited number of bottom surface shapes each of which had been successfully used to engage the rod and lock the rod into the receiver of a bone screw. Therefore, it would have been obvious to try any of these shapes, including a flat closed bottom,

with a reasonable likelihood of success. For example, Boschert expressly teaches that such a “flat bottom surface” has the benefit of “contacting the rod 60 when the rod is clamped within the device 110.” EX1006, 7:41-43. Further, from their knowledge of closures generally, a POSA would have been further motivated to use a flat bottom surface of the closure to engage a rod. Finally, a POSA would have had an expectation of success with this combination, at least because a flat bottom surface of a closure, and techniques for manufacturing such a surface, were well known in the art.

347. Moreover, the '477 Publication and Boschert teach that there are a finite number of surfaces of a closure that are meant to engage with a rod, including a domed bottom surface, a flat bottom surface, and a rimmed bottom surface. In view of the design need for a closure bottom that engages a rod and the finite number of predictable solutions, a POSA would have had good reason to pursue the known options, including a flat bottom surface of the closure. As evidenced by Boschert, each of the known closure bottom configurations were well within the technical capabilities of a POSA as of the priority date of the '641 Patent and a POSA would have anticipated success in using each of these closure bottom configurations, including a flat bottom surface.

348. In addition, a POSA implementing the '477 Publication would have been motivated to use a flat bottom surface as taught by Boschert at least because

doing so would have been nothing more than the simple substitution of one known element (the domed bottom surface of the closure disclosed in the '477 Publication) for another (the flat bottom surface of the closure disclosed in Boschert). Boschert teaches that various closure bottom configurations, including a flat bottom surface, are interchangeable, *see* EX1006, 7:16-43, confirms that a POSA would have considered the use of a flat bottom surface of a closure to be nothing more than a simple substitution of one known element for another.

349. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 23.

22. Claim 24

350. All of the limitations of Claim 24 are recited in Claim 21, except Claim 24 further recites: **[B4]** “wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each one of: v-threads, square threads, reverse angle threads, or buttress threads.” EX1001, cl. 24. This additional limitation is identical to the additional limitation in Claim 4. *Compare* EX1001, cl. 4 *with id.*, cl. 24. In my opinion, the '477 Publication in view of Boschert discloses this limitation for the same reasons provided above. *See supra* Section X.A.3.

351. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 24.

23. Claim 25

352. All of the limitations of Claim 25 are recited in Claim 21, except Claim 25 recites: **[B3]** “wherein the first continuously helically wound thread form and the second continuously helically wound thread form are each flange forms.” EX1001, cl. 25. This additional limitation is identical to the identical limitation in Claim 3. *Compare* EX1001, cl. 3 *with id.*, cl. 25. In my opinion, the ’477 Publication in view of Boschert discloses this limitation for the same reasons provided above. *See supra* Section X.A.2.

353. Accordingly, in my opinion, the ’477 Publication in view of Boschert discloses or renders obvious every element of Claim 25.

24. Claim 26

a. **26[Preamble]: A medical implant assembly comprising:**

354. To the extent the preamble of Claim 21 is considered limiting, in my opinion the ’477 Publication in view of Boschert discloses this limitation. The preamble to Claim 26 recites the same requirements as the preamble to Claim 1. *Compare* EX1001, cl. 1 *with id.*, cl. 26. 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]. Similarly, Boschert is titled “Spinal Fixation Implant Assembly,” and discloses a

spinal fixation technique “whereby surgical implants are used for fusing together and/or mechanically immobilizing vertebrae of the spine.” EX1006, 1:34-37.

- b. **26[A]: a receiver having a first arm and a second arm spaced apart from each other by a rod-receiving channel, the first arm and the second arm each having a top surface and an inner surface having a first thread on the first arm and a second thread on the second arm comprising first and second discontinuously helically wound threads, respectively, being symmetrically and diametrically opposed to each other and extending up to the top surface on each arm, the opposed discontinuously helically wound threads forming a dual lead in closure starting arrangement for the receiver;**

355. In my opinion, the '477 Publication in view of Boschert discloses this limitation. Limitation 26[A], while worded a little differently regarding the channel, includes the same requirements as Limitation 1[A], and the '477 Publication in view of Boschert meets the requirements of Limitation 26[A] for the same reasons. *See supra* Section X.A.1.b.

- c. **26[B]: a closure having a first continuously helically wound thread form and a second continuously helically wound thread form, each of the first continuously helically wound thread form and the second continuously helically wound thread form being a reverse angle thread, the first continuously helically wound thread form having a first start structure and a first upper loading surface extending between a root and a crest of the first continuously helically wound thread form, the second continuously helically wound thread form having a second start structure and a second upper loading surface**

**extending between a root and a crest of the second
continuously helically wound thread form,**

356. In my opinion, the '477 Publication in view of Boschert discloses this limitation. Limitation 26[B], while worded a little differently regarding the thread form, includes the same requirements as Limitation 1[B], except that Limitation 26[B] requires reverse angle thread forms. *Compare* EX1001, cl. 1 *with id.*, cl. 26. The '477 Publication in view of Boschert meets the requirements of Limitation 26[B] for the same reasons as Limitation 1[B]. *See supra* Section X.A.1.c. In addition, the '477 Publication and Boschert both expressly disclose reverse angle threads on a closure top.

357. In particular, the '477 Publication discloses that its 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).” EX1005, ¶[0031]. The '477 Publication also discloses its guide and advancement structure 34 “is a helically wound reverse angle thread form 36.” *Id.*, ¶[0030].

358. Boschert also discloses that its first and second continuously helically wound thread forms are a reverse angle thread. EX1006, Fig. 15; *see also id.*, Figs. 3-4, 9-10 (single reverse angle thread on closure).

359. When combining the closure top of the '477 Publication and the dual start receiver of Boschert, a POSA would have been motivated to use the reverse

angle thread form taught by the '477 Publication and Boschert on each of the first continuously helically wound thread form and the second continuously helically wound thread form of the closure. The '477 Publication teaches that the purpose of its guide and advancement structure is to “resist[] splaying in the bone screw receiver 13 as forces applied to the closure 1 are conveyed by the reverse angle thread form 36 during application of clockwise rotational torque into a downward axial force and inwardly directed radial force.” EX1005, ¶[0030]. The '477 Publication teaches that there are a finite number of guide and advancement structures that could be used, including a reverse angle thread form, a buttress thread form, a square thread form, or a flange form. *Id.*, ¶[0030]; *see also id.*, ¶[0041]. In view of the design need for a guide and advancement structure to resist splaying and the finite number of predictable solutions (*i.e.*, thread form configurations), a POSA would have had good reason to pursue the known options, including a reverse angle thread form. Moreover, as evidenced by the '477 Publication's discussion of thread forms and the prior arts' discussion of thread forms, *see supra* Section VI.B.1.d, each of these thread form configurations, including a reverse angle thread form, were well within the technical capabilities of a POSA as of the priority date of the '641 Patent and a POSA would have anticipated success in using each of these thread form configurations, including a reverse angle thread form.

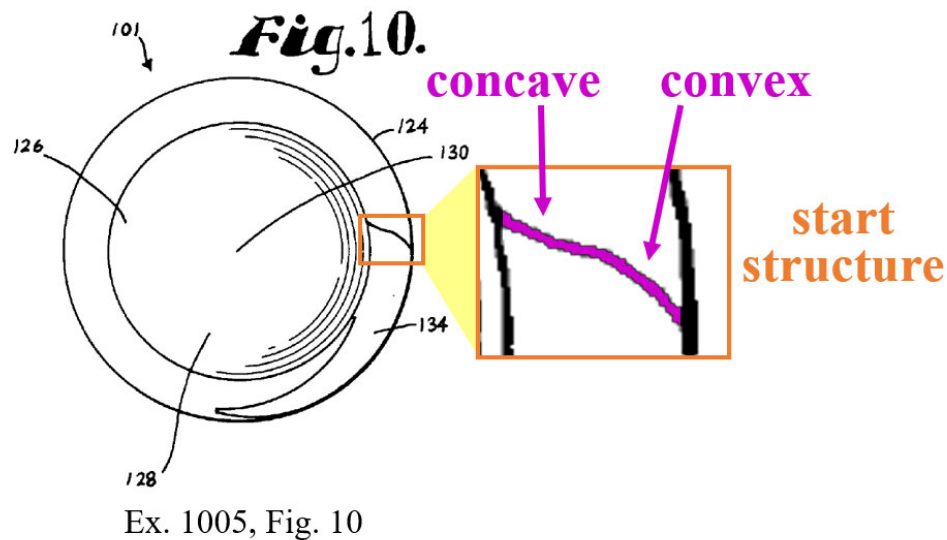
360. Moreover, a POSA implementing the '477 Publication would have been motivated to use a reverse angle thread form as taught by the '477 Publication and Boschert at least because doing so would have been nothing more than the simple substitution of one known element (the flange form disclosed in the alternative bone screw closure depicted in Figure 7) for another (the reverse angle thread form disclosed in the bone screw closure depicted in Figure 1). The '477 Publication's teaching that various thread forms, including a reverse angle thread form and a flange form, are interchangeable, *see* EX1005, ¶¶[0030], [0041], confirms that a POSA would have considered the use of a reverse angle thread form to be nothing more than a simple substitution of one known element for another.

361. In my opinion, the closure top resulting from the combination of the disclosures of the '477 Publication and Boschert would have two continuously helically wound thread forms. Thus, the resulting closure would have a closure having a first continuously helically wound thread form and a second continuously helically wound thread form, each of the first continuously helically wound thread form and the second continuously helically wound thread form being a reverse angle thread, the first continuously helically wound thread form having a first start structure and a first upper loading surface extending between a root and a crest of the first continuously helically wound thread form, the second continuously

helically wound thread form having a second start structure and a second upper loading surface extending between a root and a crest of the second continuously helically wound thread form.

- d. 26[C]: each of the first start structure and the second start structure having a leading face extending below their respective upper loading surfaces, each leading face including at least a partial concave surface and a partial convex surface;**

362. In my opinion, the '477 Publication in view of Boschert discloses this limitation. Limitation 26[C], while worded a little differently regarding the leading face, includes the same requirements as Limitation 21[C], except that Limitation 26[C] requires a leading face with both a partial concave surface and a partial convex surface. *Compare* EX1001, cl. 1 *with id.*, cl. 26. The '477 Publication in view of Boschert meets the requirements of Limitation 26[C] for the same reasons as Limitation 21[C]. *See supra* Section X.A.19.d. In addition, the '477 Publication discloses in Figure 10 a leading face that includes at least a partial concave surface and a partial convex surface.



363. When the closure top of the '477 Publication is modified to mate with the dual start receiver of Boschert, a POSA would have kept the same leading face structure with at least a partial concave surface from the '477 Publication in the dual lead threads taught by Boschert. A POSA would have been motivated to keep the leading face structure from the '477 Publication because, from their knowledge of truncated threads generally, a POSA would have understood that a truncated thread, such as the one disclosed in the '477 Publication, avoids thin, sharp portions of the thread that could cut a surgeon's glove, be damaged, or lead to cross threading. See EX1024 at 13. A POSA, from their knowledge of truncated threads generally, would have understood that a truncated thread facilitates alignment and starting of threading. See EX1007, ¶¶[0006], [0008], [0043],

[00049]; EX1022, ¶[0031]. A POSA also would have understood that a truncated thread provides structural stability. *See* EX1015, 1:40-52, 2:88-94.

364. 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 closure would have each of the first start structure and the second start structure having a leading face extending below their respective upper loading surfaces, each leading face including at least a partial concave surface and a partial convex surface.

- e. **26[A1]: the channel being formed by the first arm and the second arm opening onto the top surface, the channel adapted to receive a rod, the channel closeable with the closure having an axis of rotation;**

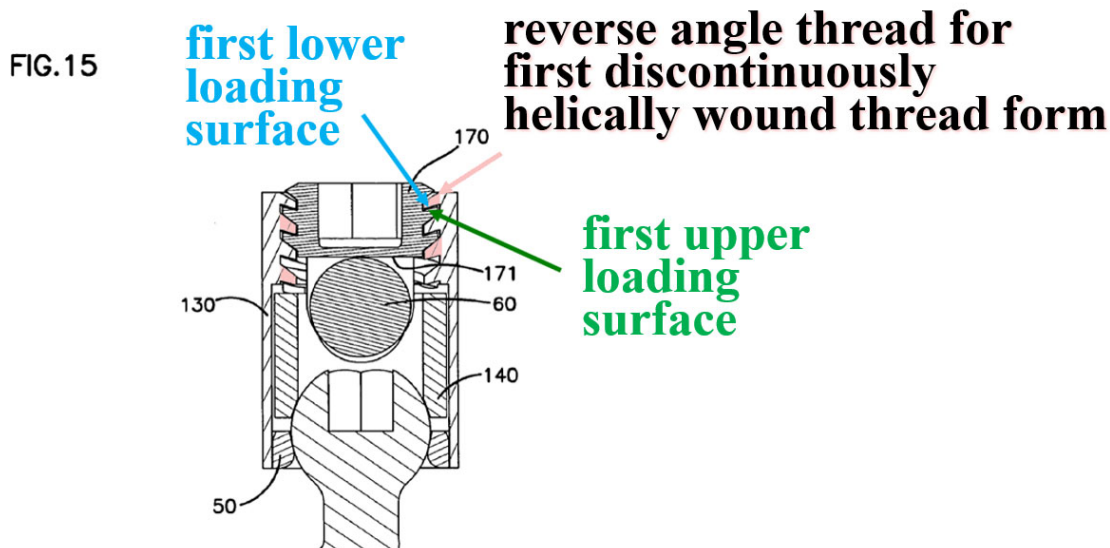
365. In my opinion, the '477 Publication in view of Boschert discloses this limitation. Limitation 26[A1], while worded a little differently regarding the channel, includes the same requirements as Limitation 1[A1]. *Compare* EX1001, cl. 1 *with id.*, cl. 26. The '477 Publication in view of Boschert meets the requirements of Limitation 26[A1] for the same reasons as Limitation 1[A1]. *See supra* Section X.A.1.e.

- f. **26[A2]: the first discontinuously helically wound thread form on the inner surface of the first arm being a reverse angle thread having a first lower loading surface, the first start structure rotatable under the first discontinuously helically wound thread**

form and the first lower loading surface threadably engageable to the first upper loading surface; and

366. In my opinion, the '477 Publication in view of Boschert discloses this limitation. Limitation 26[A2], while worded a little differently regarding the thread form, includes the same requirements as Limitation 1[A2], except that Limitation 26[A2] requires the threads on the receiver arms to be reverse angle threads. *Compare* EX1001, cl. 1 *with id.*, cl. 26. The '477 Publication in view of Boschert meets the requirements of Limitation 26[A2] for the same reasons as Limitation 1[A2]. *See supra* Section X.A.1.f. In addition, both the '477 Publication and Boschert both expressly disclose reverse angle threads on the receiver.

367. As shown in annotated Figure 15 below, Boschert discloses the use of reverse angle threads on the receiver arms. EX1006, Fig. 15.



368. The '477 Publication similarly discloses the use of a “reverse angle thread form” on the closure. EX1005, ¶[0030]. Further, the '477 Publication teaches that the closure threads should be mateable with the threads of the receiver. *Id.*, ¶[0030] (“Located 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.”); *id.*, ¶[0041] (“Located on the cylindrical closure body 124 is a guide and advancement structure 134 mateable with a guide and advancement structure on inner surfaces of the arms of the bone screw receiver (not shown) or other implant.”). Based on these disclosures, a POSA would have understood that '477 Publication discloses a first discontinuously helically wound thread form on the inner surface of the first arm and a first start structure rotatable under the first discontinuously helically wound thread form.

369. As I discussed above, *see* Section X.A.24.c, when combining the closure top of the '477 Publication and dual start receiver of Boschert, a POSA would have been motivated to use reverse angle threads, as taught by the '477 Publication and Boschert, on the closure. In view of the '477 Publication and Boschert's express teachings that the threads on the closure must mate with threads on the receiver arms, *see* EX1005, ¶[0030], [0041], Figs. 5-6; EX1006, 6:25-28, and based on a POSA's background knowledge that the threads on a receiver arm

must be shaped to mate with the threads on a closure, a POSA would have also been motivated to use reverse angle threads on the receiver arms. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses this limitation.

- g. 26[A3]: the second discontinuously helically wound thread form on the inner surface of the second arm being a reverse angle thread having a second lower loading surface, the second start structure rotatable under the second discontinuously helically wound thread form and the second lower loading surface threadably engageable to the second upper loading surface,**

370. In my opinion, the '477 Publication in view of Boschert discloses this limitation. Limitation 26[A3], while worded a little differently regarding the thread form, includes the same requirements as Limitation 1[A3], except that Limitation 26[A3] requires the threads on the receiver arms to be reverse angle threads. *Compare* EX1001, cl. 1 *with id.*, cl. 26. The '477 Publication in view of Boschert meets the requirements of Limitation 26[A3] for the same reasons as Limitations 1[A3] and 26[A2], which also requires receiver arms with reverse angle threads. *See supra* Section X.A.1.g.

371. In my opinion, the resulting closure and receiver from the '477 Publication in view of Boschert would include a second discontinuously helically wound thread form on the inner surface of the second arm being a reverse angle thread having a second lower loading surface, the second start structure rotatable

under the second discontinuously helically wound thread form and the second lower loading surface threadably engageable to the second upper loading surface.

- h. 26[B2]: a rotation of the closure about the axis of rotation between the first arm and the second arm causing a simultaneous mating of the first continuously helically wound thread form with the first discontinuously helically wound thread form and the second continuously helically wound thread form with the second discontinuously helically wound thread form, the closure rotationally advanceable within the channel until the closure locks the rod received within the channel.**

372. In my opinion, the '477 Publication in view of Boschert discloses this limitation. Limitation 26[B2], while worded a little differently regarding the advancement of the closure, includes the same requirements as Limitation 1[B2]. *Compare* EX1001, cl. 1 *with id.*, cl. 26. The '477 Publication in view of Boschert meets the requirements of Limitation 26[B2] for the same reasons as Limitation 1[B2]. *See supra* Section X.A.1.h.

373. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 26.

25. Claim 27

374. All of the limitations of Claim 27 are recited in Claim 26, except Claim 27 further recites: **[B11]** “wherein the concave surface is adjacent the root and the convex surface is adjacent the crest for each of the first and second continuously helically wound thread forms.” EX1001, cl. 27. This additional

limitation is identical to the additional limitation in Claim 11. *Compare* EX1001, cl. 11 *with id.*, cl. 27. In my opinion, the '477 Publication in view of Boschert discloses this limitation for the same reasons. *See supra* Section X.A.10. The convex surface adjacent to the crest yields a smooth and rounded surface.

375. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 27.

26. Claim 28

376. All of the limitations of Claim 28 are recited in Claim 26, except Claim 28 recites: **[B5]** “wherein the first start structure is disposed at a diametrically opposite location on the closure from the second start structure.” EX1001, cl. 28. This additional limitation is identical to the additional limitation in Claim 5. *Compare* EX1001, cl. 5 *with id.*, cl. 28. In my opinion, the '477 Publication in view of Boschert discloses this limitation for the same reasons. *See supra* Section X.A.4.

377. Accordingly, in my opinion, the '477 Publication in view of Boschert discloses or renders obvious every element of Claim 28.

B. Ground 2: Claim 2 is Obvious Under 35 U.S.C. § 103 Based on the '477 Publication in View of Boschert and the '391 Publication.

378. As set forth above, it also would have been obvious to a POSA to further combine the teachings of the '391 Publication with the combination of '477 Publication and Boschert before the priority date of the '641 Patent. *Supra* Section

IX.B. Like the '477 Publication and Boschert, the '391 Publication is directed to a bone screw with an open U-shaped receiver that receives a rod member. EX1030, Abstract, ¶[0002]. In my opinion, a POSA would have been motivated to add a guide tool with discontinuously helically wound thread forms to an existing system at least based on the benefits of such a guide tool as taught by the '391 Publication.

379. For example, the '391 Publication discloses that the benefit of its attachable/detachable guide tool is that it “allow[s] for the insertion of bone screws, the insertion and reduction of a rod into the bone screws and the securing of the rod to the bone screws with significantly less invasion into the body of the patient and with minimal surgical incision of the skin over the operational site.” EX1030, ¶[0006]. Moreover, the '391 Publication discloses that the guide and advancement structures on the guide tool “allow the closure top 62 to be rotated and the surgeon to develop mechanical advantage to urge or drive the rod 8, while still outside or partially outside the bone screw 4, toward and into the bone screw head 146. This is especially helpful where the rod 8 is bent relative to the location of the vertebra 16 (which is sometimes the case) to which the rod 8 is to attach and is not easily placed in the bone screw head 146 without force and the mechanical advantage provided by the guides 64 and 114.” *Id.*, ¶[0120]. The '391 Publication further discloses that alignment of the tool guide’s guide and advancement structures with the receiver arms’ guide and advancement structures “allow[s] the

closure top 62 to continue to rotate and to continuously apply force to the rod 8, so as to aid in seating the rod 8 in the bone screw head 146.” *Id.*

380. Boschert already contemplates the use of various tools and instruments with its disclose receiver, and therefore discloses “grasping features” that could “accommodate instrumentation to facilitate grasping, holding or manipulating of the receiver 30” during implantation. EX1006, 6:15-19. But Boschert does not disclose the details of the tools and instruments to be used with its receiver, and thereby invites a POSA to look to tools and instruments already known in the art. Therefore, in my opinion, a POSA would have been motivated to use an attachable/detachable guide tool as disclosed in the ’391 Publication with the receiver of Boschert at least to obtain the recognized benefits of guide tools as taught by the ’391 Publication and otherwise known in the art as discussed above.

381. 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 ’641 Patent that guide tools 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 guide tools were well known and readily available.

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

383. As set forth above, the '477 Publication in view of Boschert renders obvious every limitation of challenged Claims 1, 3-19, and 21-28. Claim 2 adds the additional element of a guide tool with discontinuously helically wound thread forms, but this additional element was well known in the prior art, including as taught by the '391 Publication. Therefore, below I address why the additional elements of Claim 2 are rendered obvious by the '391 Publication. For all other limitations, my opinions expressed above (that these features were already rendered obvious by the combination of the '477 Publication and Boschert) remain and are unaffected by the additional disclosures of the '391 Publication.

1. Claim 2

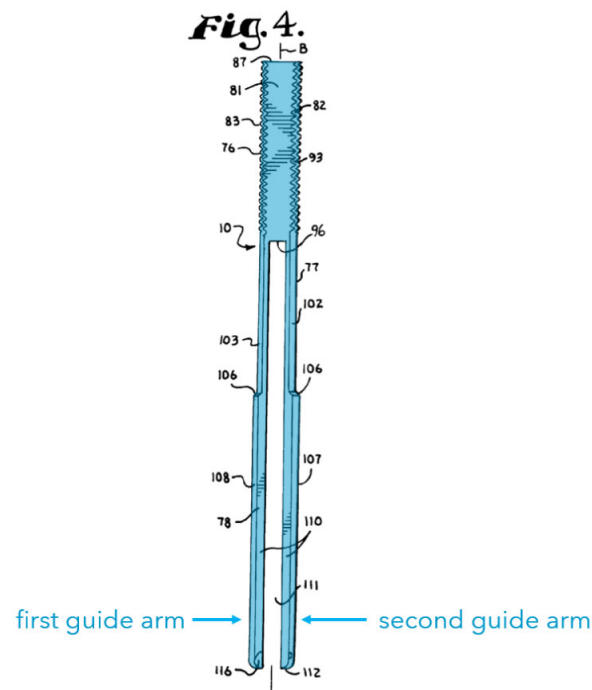
384. All of the limitations of Claim 2 are recited in Claim 1, except Claim 2 further recites: “a guide tool having a first guide arm and a second guide arm detachably attached to the receiver; a third discontinuously helically wound thread form on the first guide arm; and a fourth discontinuously helically wound thread form on the second guide arm, the first start structure threadably engageable with

the third discontinuously helically wound thread form simultaneously with the second start structure threadably engageable with the fourth discontinuously helically wound thread form when the closure is rotated between the first guide arm and the second guide arm, the third discontinuously helically wound thread form and the fourth discontinuously helically wound thread form adapted to transfer the closure between the guide tool and the receiver.” EX1001, cl. 2. In my opinion, the ’391 Publication renders this additional limitation obvious when its disclosures are considered in view of the ’477 Publication in combination with Boschert.

a. **2[D]: a guide tool having a first guide arm and a second guide arm detachably attached to the receiver;**

385. In my opinion, the ’477 Publication in view of Boschert in further combination with the ’391 Publication discloses this limitation. The ’391 Publication discloses a “tool embodiment assembly 1” that “includes an intermediate guide tool 10.” EX1030, ¶[0082]. The ’391 Publication further discloses that, “to **attach** the bone screw head 146 to the guide tool 10, the guide tool 10 is rotated about its axis B such that legs 102 and 103 are lowered into place,” *id.*, ¶[0114], and, to “**disengage**” the guide tool 10 from the bone screw 4, the guide tool 10 is “rotated counterclockwise from an attaching configuration,” *id.*, ¶[0115]. *See also id.*, ¶[0017] (“The **attachment structure** secures the guide tool to the bone screw during insertion of the screw into bone, but allows the tool

to *release* from the bone screw for removal of the tool at the end of the procedure by rotation of the tool about a central axis thereof or by some other mechanism, as described herein.”). As shown in the annotated Figure 4 below, the ’391 Publication discloses a **guide tool** having a first guide arm and a second guide arm detachably attached to the receiver (not pictured).



386. In my opinion, a POSA implementing the ’477 Publication in view of Boschert would have been motivated to further modify the combination of the ’477 Publication and Boschert (as discussed above, *see* Section IX.B) to add a detachably attached guide tool as disclosed by the ’391 Publication. As previously noted, Boschert already contemplates the use of various tools and instruments with its disclosed receiver, and therefore discloses “grasping features” that could

“accommodate instrumentation to facilitate grasping, holding or manipulating of the receiver 30” during implantation. EX1006, 6:15-19. But Boschert does not disclose the details of the tools and instruments to be used with its receiver, and thereby invites a POSA to look to tools and instruments already known in the art. Therefore, in my opinion, a POSA would have been motivated to use an attachable/detachable guide tool as disclosed in the ’391 Publication with the receiver of Boschert at least to obtain the recognized benefits of guide tools as taught by the ’391 Publication and otherwise known in the art as discussed above. In my opinion, when combining the disclosures of the ’477 Publication, Boschert, and the ’391 Publication a POSA would have included a guide tool having a first guide arm and a second guide arm detachably attached to the receiver.

387. In addition, because the ’477 Publication, Boschert, and the ’391 Publication are each directed to spinal implants with threaded connections, a POSA would have understood that the technique of using a detachably attached guide tool, as taught by the ’391 Publication, 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 a detachably attached guide tool in a spinal implant was within the skill of a POSA.

388. Moreover, a POSA implementing the '477 Publication in view of Boschert would have been motivated to modify the combination of the '477 Publication and Boschert to add a detachably attached guide tool, as taught by the '391 Publication, because it would have been nothing more than a combination of familiar elements (a spinal implant receiver and a detachably attached guide tool) using known methods that would yield predictable results. In addition, the modification of the '477 Publication to add a detachably attached guide tool, as taught by the '391 Publication, would not have changed the respective functions of either the '477 Publication's device or the detachably attached guide tool taught by the '391 Publication.

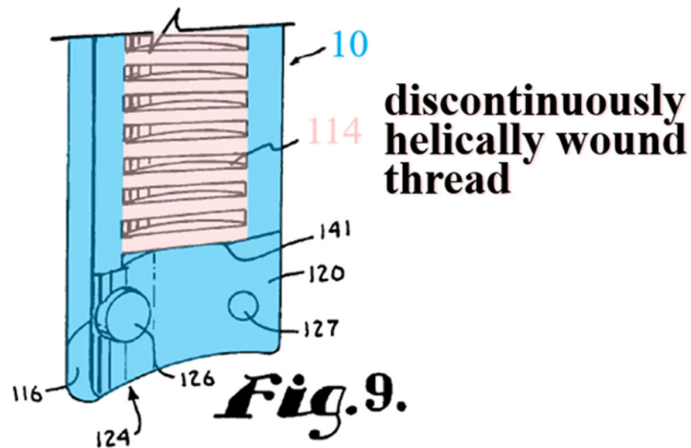
389. A POSA implementing the '477 Publication in view of Boschert would have been motivated to modify the combination of the '477 Publication and Boschert to add a detachably attached guide tool, as taught by the '391 Publication, because it would have been nothing more than the simple substitution of one known element (a spinal implant receiver) for another (a spinal implant receiver with a detachably attached guide tool). In my opinion, a POSA would have been motivated to pursue this combination 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.

390. In addition, a POSA would have had a reasonable expectation of success in making such a combination, at least because the techniques for machining a detachably attached guide tool 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 Boschert on the one hand and the '391 Publication on the other hand.

391. Accordingly, in my opinion, the '477 Publication in view of Boschert in further view of the '391 Publication discloses or renders obvious this limitation.

- b. **2[D1]: a third discontinuously helically wound thread form on the first guide arm; and a fourth discontinuously helically wound thread form on the second guide arm,**

392. In my opinion, the '477 Publication in view of Boschert in further combination with the '391 Publication discloses this limitation. The '391 Publication discloses “a *helically wound* but *discontinuous* square *thread* 114” at the bottom 112 of the intermediate tool guide 10 that “cooperates with the closure top 62,” although “other type of guide and advancement structure may be utilized such as helically wound flange forms, reverse angle threads, buttress threads, etc.” EX1030, ¶[0103]. As shown in the annotated Figure 9 below, each of the guide arms disclosed in the '391 Publication includes a discontinuously helically wound thread form on the guide arm.



393. Accordingly, in my opinion, the '477 Publication in view of Boschert in further view of the '391 Publication discloses or renders obvious this limitation.

- c. **2[D2]: the first start structure threadably engageable with the third discontinuously helically wound thread form simultaneously with the second start structure threadably engageable with the fourth discontinuously helically wound thread form when the closure is rotated between the first guide arm and the second guide arm, the third discontinuously helically wound thread form and the fourth discontinuously helically wound thread form adapted to transfer the closure between the guide tool and the receiver.**

394. In my opinion, the '477 Publication in view of Boschert in further combination with the '391 Publication discloses this limitation. As discussed above, *see* Section X.A.1, the '477 Publication in view of Boschert includes a closure with a first start structure and a second start structure and wherein rotation of the closure about the axis of rotation between the first arm and the second arm of the receiver causes a simultaneous advancement of the first start structure and

second start structure under the first discontinuously helically wound thread form and the second discontinuously helically wound thread form, respectively.

395. The '391 Publication discloses “a helically wound but discontinuous square thread 114” at the bottom 112 of the intermediate tool guide 10 that “cooperates with the closure top 62,” although “other type of guide and advancement structure may be utilized such as helically wound flange forms, reverse angle threads, buttress threads, etc.” EX1030, ¶[0103]. The '391 Publication further discloses that the guide and advancement structure 114 is “located and positioned to align” with a guide and advancement structure on the “insides of the bone screw arms 150 and 151” and “pass the closure top 62 therebetween while allowing the closure top 62 to continue to rotate and to continually apply force to the rod 8, so as to aid in seating the rod 8 in the bone screw head 146.” *Id.*, ¶[0120].

396. As discussed above, *see* Section X.A.1.h, the '477 Publication in view of Boschert would include a closure wherein the first start structure and the second start structure simultaneously rotatably advance under the first discontinuously helically wound thread form and the second discontinuously helically wound thread form. In view of the teaching in the '391 Publication that the guide and advancement structure on the arms of the guide tool align with the guide and advancement structure on the arms of the receiver, a POSA would have understood

that the '391 Publication discloses that the helically wound thread forms on the closure top threadably engage the discontinuously helically wound thread forms on the arms of the guide tool in the same way that they engage the discontinuously helically wound thread forms on the receiver arms—otherwise, the alignment described by the '391 Publication would not be possible. As a result, the '477 Publication in view of Boschert in further view of the '391 Publication would have resulted in the first start structure threadably engageable with the third discontinuously helically wound thread form simultaneously with the second start structure threadably engageable with the fourth discontinuously helically wound thread form when the closure is rotated between the first guide arm and the second guide arm, the third discontinuously helically wound thread form and the fourth discontinuously helically wound thread form adapted to transfer the closure between the guide tool and the receiver.

397. Accordingly, in my opinion, the '477 Publication in view of Boschert in further view of the '391 Publication discloses or renders obvious this limitation.

398. Accordingly, the '477 Publication in view of Boschert and the '391 Publication renders obvious every element of Claim 2.

C. Ground 3: Claim 20 is Obvious under 35 U.S.C. § 103 Based on the '477 Publication in View of Boschert and Johnson.

399. As set forth above, it also would have been obvious to a POSA to further combine the teachings of Johnson with the combination of the '477

Publication and Boschert before the priority date of the '641 Patent. *Supra* Section IX.C. Like the '477 Publication and Boschert, Johnson is directed to a polyaxial pedicle screw implant that receives a rod member. EX1008, Abstract. In my opinion, a POSA would have been motivated to add break-off extension arms to an existing system at least based on the benefits of break-off extensions as taught by Johnson.

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

401. 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 '641 Patent that break-off 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 break-off extension arms were well known and readily available.

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

403. As set forth above, the '477 Publication in combination with Boschert render obvious every limitation of challenged Claims 1, 3-19, and 21-28. Claim 20 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 elements of Claim 20 is rendered obvious by Johnson.

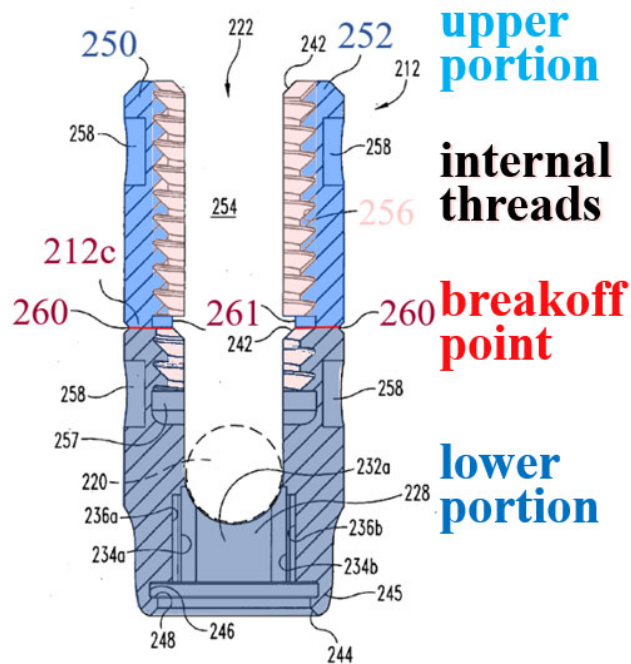
For all other limitations, my opinions expressed above (that these features were already rendered obvious by the disclosures of the '477 Publication and Boschert) remain and are unaffected by the additional disclosures of Johnson.

1. Claim 20

404. All of the limitations of Claim 20 are recited in Claim 1, except Claim 20 further recites: [E] “wherein the receiver first arm and the second arm top surface each include a breakoff extension with an inner surface having a discontinuously helically wound thread form, the first arm breakoff extension thread form being continuous with the first discontinuously helically wound thread form on the inner surface of the first arm and the second arm breakoff extension thread form being continuous with the second discontinuously helically wound thread form on the inner surface of the second arm.” EX1001, cl. 20. In my opinion, Johnson renders this additional limitation obvious when its disclosures are considered in view of the '477 Publication in combination with Boschert.

405. Johnson discloses a receiver member with breakoff extensions. In particular, Johnson discloses receiver member 212 that “has a lower portion 212a and an upper portion 212b separated by a thinned section 212c.” EX1008, ¶[0051], Fig. 10. 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 212b and into lower portion 212a.” *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.” EX1008, ¶[0055]; Fig. 12.



406. As also shown in the annotated Figure 12 above, Johnson discloses a first breakoff extension coupled to the top surface (i.e., reference numeral 260 on

left) of the first arm 250 and a second breakoff extension coupled to the top surface (i.e., reference numeral 260 on right) of the second arm 252. Each of the breakoff extensions include an inner surface having a discontinuously helically wound thread form 256 that cooperates 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. Thus, Johnson discloses a first breakoff extension thread form being continuous with the first discontinuously helically wound thread form on the inner surface of the first arm and a second arm breakoff extension thread form being continuous with the second discontinuously helically wound thread form on the inner surface of the second arm.

407. In my opinion, a POSA implementing the '477 Publication in view of Boschert would have been motivated to further modify the combination of the '477 Publication and Boschert (as discussed above, *see* Section IX.C) to add break off arm extensions as disclosed by Johnson. In my opinion, when combining the disclosures of the '477 Publication, Boschert, and Johnson a POSA would have included a first arm that includes a receiver first arm and a second arm top surface that each include a breakoff extension with an inner surface having a discontinuously helically wound thread form, the first arm breakoff extension thread form being continuous with the first discontinuously helically wound thread

form on the inner surface of the first arm and the second arm breakoff extension thread form being continuous with the second discontinuously helically wound thread form on the inner surface of the second arm.

408. A POSA implementing the '477 Publication in view of Boschert would have been motivated to further modify the combination of the '477 Publication and Boschert (as discussed above) with the 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 and Boschert combination.

409. In addition, because the '477 Publication, Boschert, 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.

410. Moreover, a POSA implementing the '477 Publication in view of Boschert would have been motivated to modify the combination of the '477 Publication and Boschert to add 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.

411. A POSA implementing the '477 Publication in view of Boschert would have been motivated to modify the combination of the '477 Publication and Boschert to add break off arm extensions, as taught by Johnson, because it would have been nothing more than the simple substitution of one known element (a spinal implant receiver) for another (a spinal implant receiver with break off arm extensions). In my opinion, a POSA would have been motivated to pursue this combination 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.

412. 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 Boschert on the one hand and Johnson on the other hand.

413. Accordingly, the '477 Publication in view of Boschert and Johnson renders obvious every element of Claim 20.

XI. DISCUSSION OF SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

414. I am not aware of any evidence of secondary considerations that supports the non-obviousness of the Challenged Claims of the '641 Patent.

415. I am, however, aware of evidence of secondary considerations that rebuts the non-obviousness of the Challenged Claims of the '233 Patent. For example, on January 4, 2017, Zimmer Spine filed U.S. Patent Application No. 15/397,959 ("the '959 Application"), entitled "Bone screw including a dual thread closure member." EX1044 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.

416. 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.

417. The examiner for the '959 Application rejected pending Claim 2 as being unpatentable over U.S. 6,726,689 to Jackson (Jackson '689, EX1013) 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. EX1044 at 57-63 (11.5.2018 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.

418. 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 (EX1044 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’s 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’s 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.*

419. In my opinion, the prosecution of the '959 Application, and its subsequent express abandonment, supports the *obviousness* of the Challenged Claims of the '641 Patent that recite simultaneous mating of the dual start features. This evidence has a clear nexus to the claimed inventions of the Challenged Claims because it relates to medical implants, specifically pedicle bone screws, and in particular ones with dual thread closures. This evidence demonstrates that the claimed invention was the product only of ordinary mechanical or engineering

skill. This evidence also undercuts any suggestion that there was praise by others for the claimed invention because Zimmer abandoned the technology after discovering prior art relating to routine machining skills and techniques.

420. 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

421. 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.

422. 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.

423. 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.

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

Dated: September 19, 2023

Carl McMillin
Carl McMillin, PhD