

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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SEASPINE HOLDINGS CORPORATION

Petitioner,

v.

ROGER P. JACKSON, M.D.,

Patent Owner.

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IPR2025-00773

U.S. Patent No. 11,399,873

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**PETITION FOR *INTER PARTES* REVIEW  
UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104**

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**Petitioner's Exhibit List**

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|---------|------------------------------------------------------------------------------------|
| Ex.1001 | U.S. Patent No. 11,399,873 to Jackson <i>et al.</i> (“’873 patent”)                |
| Ex.1002 | Prosecution History of U.S. Patent No. 11,399,873 to Jackson (“’873 File History”) |
| Ex.1003 | Declaration of Troy D. Drewry under 37 C.F.R. § 1.68                               |
| Ex.1004 | Prosecution History of U.S. Patent No. 11,129,646 to Jackson (“’646 File History”) |
| Ex.1005 | U.S. Patent Publication No. 2011/0152947 to Kirschman (“Kirschman”)                |
| Ex.1006 | U.S. Patent No. 447,775 to Higbee (“Higbee”)                                       |
| Ex.1007 | U.S. Patent Publication No. 2007/0088357 to Johnson <i>et al.</i> (“Johnson”)      |
| Ex.1008 | U.S. Patent Publication No. 2005/0267477 to Jackson (“’477 Publication”)           |
| Ex.1009 | U.S. Patent No. 7,857,834 to Boschert (“Boschert”)                                 |
| Ex.1010 | ASME B1.7-2006 - Screw Threads- Nomenclature, Definitions, and Letter Symbols      |
| Ex.1011 | Handbook H28 (1969) - Screw-Thread Standards for Federal Services                  |
| Ex.1012 | U.S. Patent Publication No. 2005/0286984 to Weise <i>et al.</i> (“Weise”)          |
| Ex.1013 | U.S. Patent Publication No. 2011/0106179 to Prevost <i>et al.</i> (“Prevost”)      |
| Ex.1014 | U.S. Patent Publication No. 2010/0137918 to Wilcox <i>et al.</i> (“Wilcox”)        |
| Ex.1015 | Machinery’s Handbook, 3 <sup>rd</sup> Edition (1914)                               |

|         |                                                                                                                                                                           |
|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ex.1016 | Machinery's Handbook, 28 <sup>th</sup> Edition (2008)                                                                                                                     |
| Ex.1017 | U.S. Patent No. 4,707,001 to Johnson ("Johnson '001")                                                                                                                     |
| Ex.1018 | U.S. Patent No. 6,010,502 to Bagby ("Bagby")                                                                                                                              |
| Ex.1019 | American Heritage Dictionary, 5 <sup>th</sup> Edition                                                                                                                     |
| Ex.1020 | Third Amended Complaint, <i>Jackson v. SeaSpine Holdings Corporation</i> , C.A. No. 20-1784 (RGA), D.I. 165                                                               |
| Ex.1021 | Stipulation and Order to Amend Certain Case Deadlines, <i>Jackson v. SeaSpine Holdings Corporation</i> , C.A. No. 20-1784 (RGA), D.I. 194                                 |
| Ex.1022 | Scheduling Order, <i>Jackson v. SeaSpine Holdings Corporation</i> , C.A. No. 20-1784 (RGA), D.I. 42 (April 8, 2022) ("Original Scheduling Order")                         |
| Ex.1023 | Final Infringement Contentions, <i>Jackson v. SeaSpine Holdings Corporation</i> , C.A. No. 20-1784 (RGA), D.I. 190                                                        |
| Ex.1024 | Order to Amend Certain Case Deadlines, <i>Jackson v. SeaSpine Holdings Corporation</i> , C.A. No. 20-1784 (RGA), D.I. 201                                                 |
| Ex.1025 | Order Granting Stipulation to Amend Case Schedule and Set New Trial Date, <i>Jackson v. SeaSpine Holdings Corporation</i> , C.A. No. 20-1784 (RGA), D.I. 151              |
| Ex.1026 | Order Granting Plaintiff's Unopposed Motion for Leave to File Third Amended Complaint, <i>Jackson v. SeaSpine Holdings Corporation</i> , C.A. No. 20-1784 (RGA), D.I. 164 |
| Ex.1027 | Complaint, <i>Jackson v. SeaSpine Holdings Corporation</i> , C.A. No. 20-1784 (RGA), D.I. 1 ("Original Complaint")                                                        |
| Ex.1028 | Petition, <i>ZimVie, Inc. et al. v. Jackson</i> , IPR2023-01433, Paper 2                                                                                                  |
| Ex.1029 | U.S. Provisional Application No. 61/631,746 ("First Provisional Application")                                                                                             |

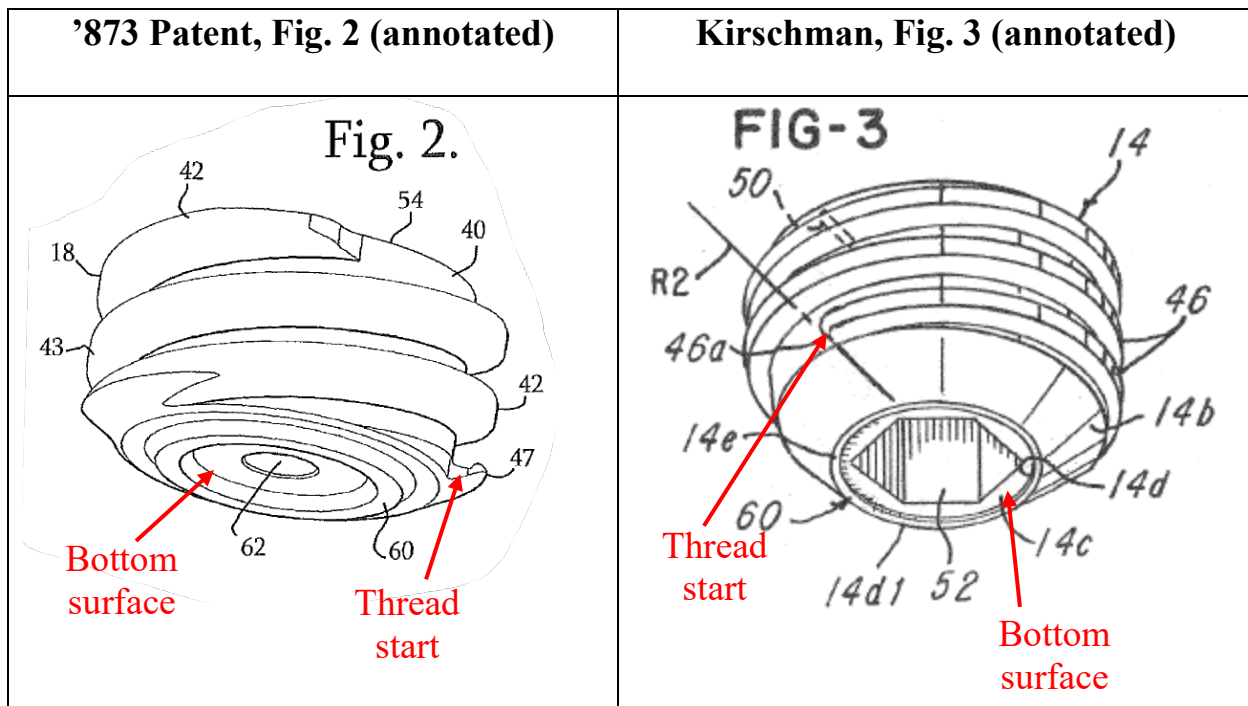
|         |                                                                                |
|---------|--------------------------------------------------------------------------------|
| Ex.1030 | U.S. Provisional Application No. 61/634,361 (“Second Provisional Application”) |
|---------|--------------------------------------------------------------------------------|

## **I. INTRODUCTION**

U.S. Patent No. 11,399,873 (“’873 Patent,” Ex.1001) claims a well-known threaded closure for bone anchor assemblies. The ’873 Patent describes a threaded closure in which the thread start has a blunt, partially curvate face that is spaced from the bottom surface of the closure.

This Petition, as supported by Mr. Drewry’s Declaration (Ex.1003), demonstrates that such closures were already known. Screws having blunt thread starts that were rounded and spaced above a bottom surface of the screw were first disclosed by Higbee in 1891 and have been routinely used since. In fact, Higbee’s blunt thread starts became so ubiquitous that they were commonly referred to as “Higbee cuts.” Kirschman then applied these well-known blunt thread starts to closures in bone anchor assemblies before the priority date of the ’873 Patent.

As shown below and further described herein, Kirschman discloses the same features described and claimed with respect to the ’873 Patent’s threaded closure:



Accordingly, pursuant to 35 U.S.C. §§ 311, 314(a), and 37 C.F.R. § 42.100, SeaSpine Holdings Corporation (“Petitioner”) respectfully requests that the Board review and cancel as unpatentable under 35 U.S.C. §103 claims 1-19 (hereinafter, the “Challenged Claims”) of the '873 Patent.

## II. GROUNDS FOR STANDING

Petitioner certifies that the '873 Patent is eligible for IPR and that Petitioner is not barred or estopped from requesting IPR challenging the patent claims. 37 C.F.R. § 42.104(a).

## III. NOTE

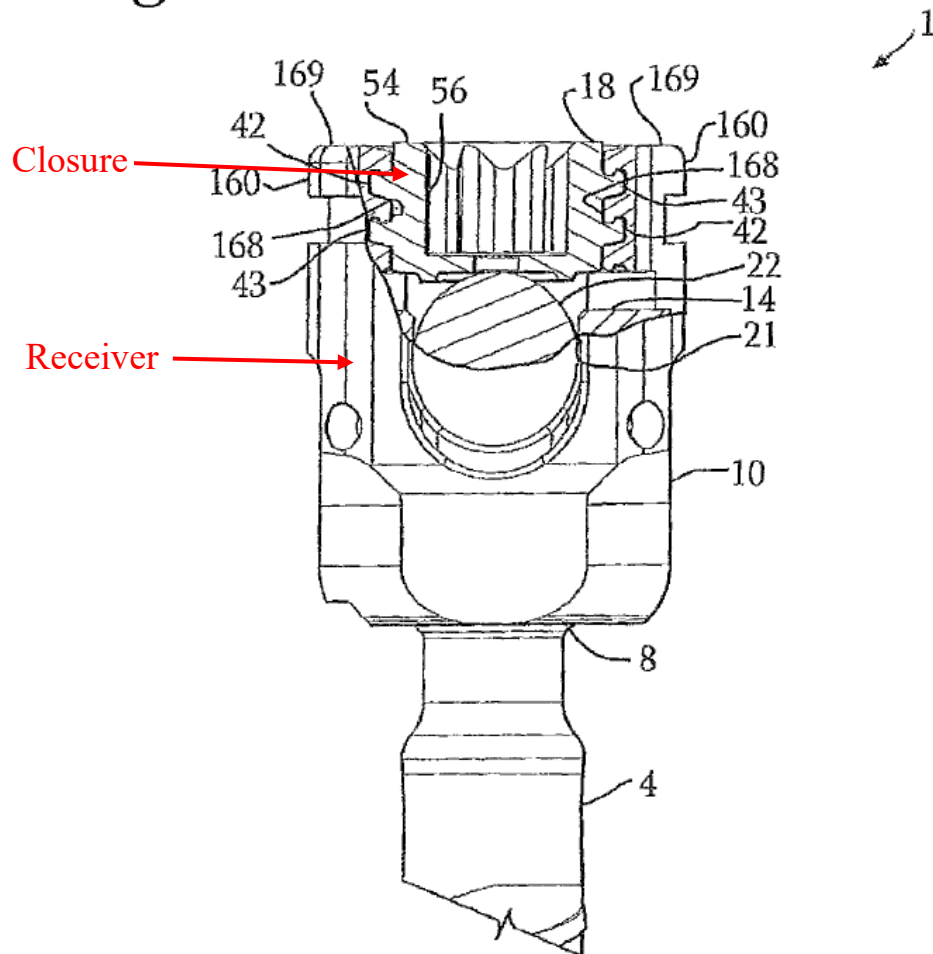
Petitioner cites to exhibits’ original page numbers. **Emphasis** in quoted material has been added. Claim terms are presented in *italics*.

#### **IV. SUMMARY OF THE '873 PATENT**

The '873 Patent “is directed to...closure mechanisms for use with open bone anchors in spinal surgery.” Ex.1001, 1:27-31. During assembly of bone anchors, it can be difficult to mate the closure threads with the corresponding threads on the receiver to secure the rod within the receiver. Ex.1001, 2:7-27. Accordingly, the '873 Patent describes threaded closures with blunt start structures that are spaced above the bottom surface to make it easier for the start structures of the closure threads to align with the receiver threads. Ex.1003, ¶32.

Specifically, the '873 Patent discloses “a polyaxial bone screw” that includes “a receiver” and a cylindrical closure. Ex.1001, 7:27-36. The “bottom surface 58 of the closure is planar and further includes a rim 60 for engagement and penetration into the surface 22 of the rod.” Ex.1001, 9:4-7. Fig. 8 illustrates an embodiment of the receiver and plug/closure:

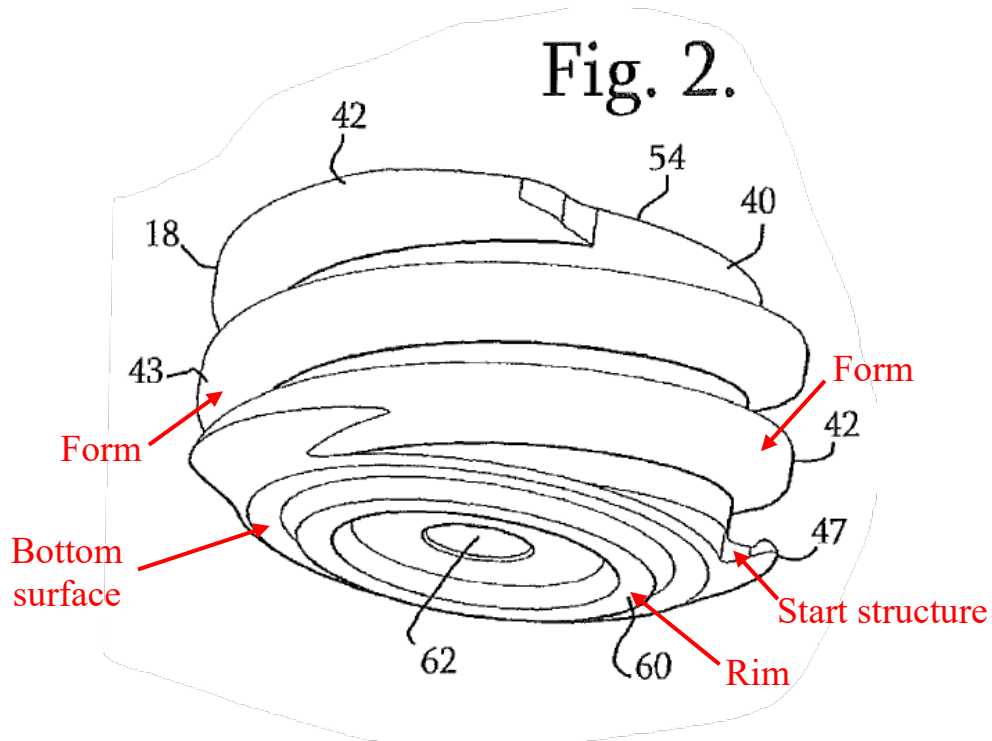
Fig. 8.



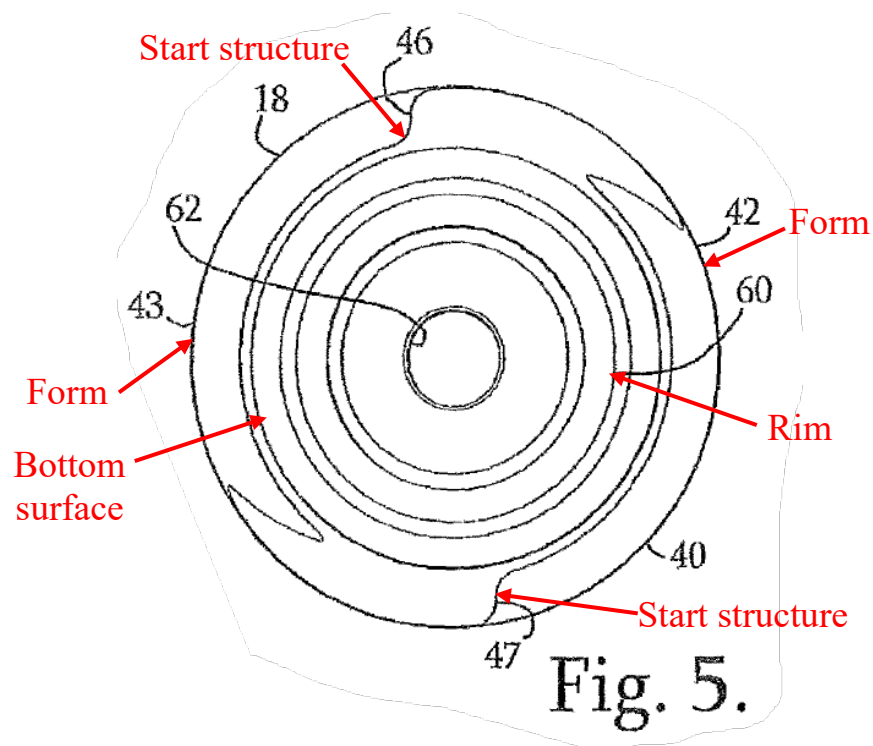
**Ex.1001, Fig. 8 (annotated)**

The plug includes “a pair of helically wound forms 42 and 43” that are configured to mate with corresponding thread forms on the receiver. Ex.1001, 8:22-30. The thread form includes “start structures 46 and 47” that “are both located adjacent the bottom surface 58.” Ex.1001, 9:15-19. These start structures each “include[] a leading face having at least one curvate surface” that may be

“both concave and convex” (Ex.1001, 9:38-42):



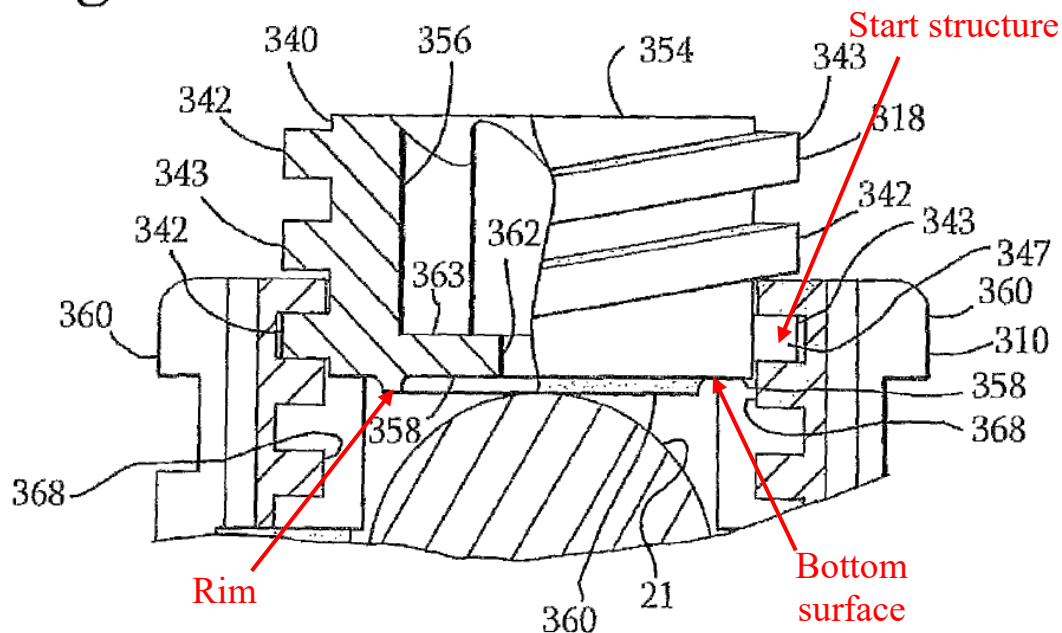
**Ex.1001, Fig. 2 (annotated)**



**Ex.1001, Fig. 5 (annotated)**

Fig. 11 below shows another embodiment of the receiver and closure in which the start structures of the threaded closure are not adjacent to the bottom surface, but instead are spaced above the bottom surface thereof (Ex.1001, 22:45-57; Ex.1003, ¶¶29-39):

Fig. 11.



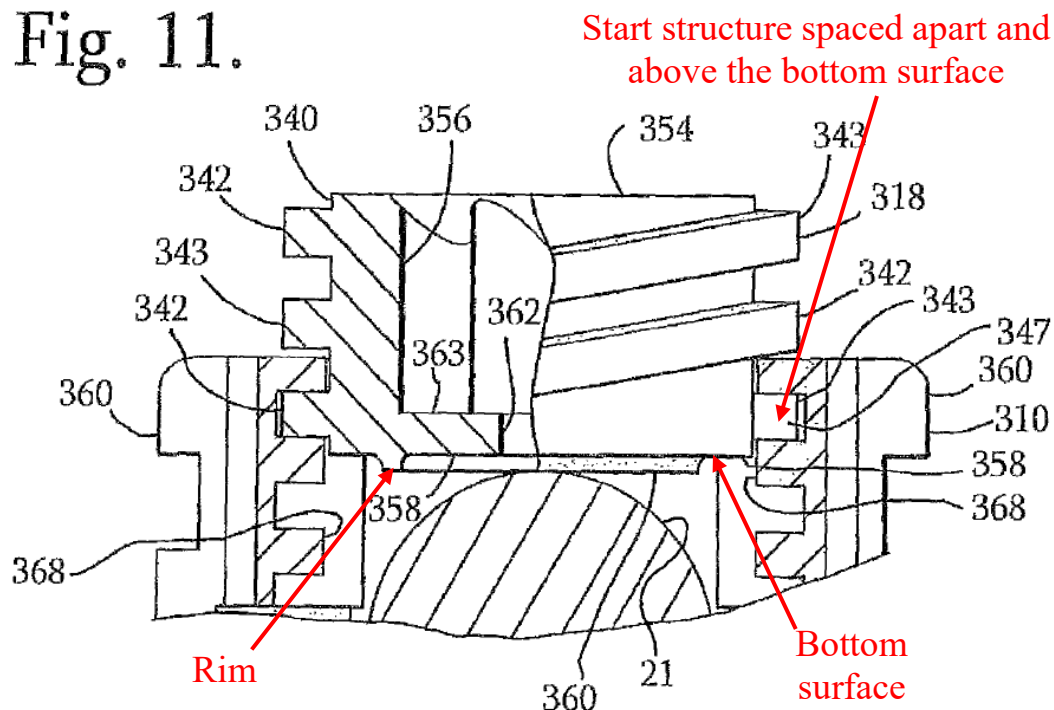
Ex.1001, Fig. 11 (annotated)

**A. Prosecution History of '873 Patent**

The '873 Patent was originally filed as U.S. Application No. 17/476,652 on September 16, 2021 as a continuation of U.S. Application No. 17/123,499 (“’499 Application”), now U.S. Patent No. 11,129,646 (“’646 Patent”). With respect to priority, Figs. 11-12 of the '873 Patent showing “*the lower surface of the start structure being spaced apart and above the annular outer edge of the bottom surface*” were first included in U.S. Provisional Application No. 61/634,361 (“Ex.1030), filed February 28, 2012. Ex.1003, ¶¶40-42 (citing Ex.1029, 28, 69-82; Ex.1030, 38-43).

The originally-filed claims of the '873 Patent were only rejected for

nonstatutory double patenting over the claims of the '646 Patent, which the Applicant overcame by filing a terminal disclaimer. Ex.1002, 38-39 (terminal disclaimer), 59-61 (office action); Ex.1003, ¶¶43-49.



**Ex.1001, Fig. 11 (annotated)**

## **V. LEVEL OF ORDINARY SKILL IN THE ART**

A POSITA as of the priority date would have had a working knowledge of bone screw assemblies for implantation into the spine relevant to the '873 Patent. A POSITA would have had a bachelor's degree in Mechanical Engineering, Biomedical Engineering, or an equivalent field, as well as at least 3-5 years of academic or industry experience related to the design of spinal fixation

implants. Lack of work experience can be remedied by additional education, and vice versa. Ex.1003, ¶¶18-22.

## **VI. CLAIM CONSTRUCTION**

In an IPR, claims “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b). The Board only construes the claims to the extent necessary to resolve the underlying controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Petitioner submits that, for the purposes of this proceeding, the terms of the Challenged Claims should be given their plain and ordinary meaning.<sup>1</sup> Ex.1003, ¶91.

## **VII. RELIEF REQUESTED**

Petitioner asks that the Board institute a trial for IPR and cancel the Challenged Claims in view of the analysis below.

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<sup>1</sup> Petitioner does not concede that any term in the challenged claims meets the statutory requirements of 35 U.S.C. § 112, or that the challenged claims recite patentable subject matter under 35 U.S.C. § 101.

## VIII. IDENTIFICATION OF HOW THE CLAIMS ARE UNPATENTABLE

### A. Statutory Grounds for Challenges

This Petition challenges the '873 Patent as being obvious in view of the teachings of the identified prior art references as well as the knowledge of a POSITA.

| Grounds | Claim(s)      | Basis                                                             |
|---------|---------------|-------------------------------------------------------------------|
| #1      | 1-2, 4, and 7 | 35 U.S.C. § 103 over Kirschman                                    |
| #2      | 5-6           | § 103 over Kirschman in view of Johnson                           |
| #3      | 8-11          | § 103 over Kirschman in view of the '477 Publication              |
| #4      | 3 and 12-16   | § 103 over Kirschman in view of Boschert                          |
| #5      | 17            | § 103 over Kirschman in view of Boschert and Johnson              |
| #6      | 18-19         | § 103 over Kirschman in view of Boschert and the '477 Publication |

U.S. Publication No. 2011/0152947 to Kirschman (“Kirschman,” Ex.1005) was filed on December 18, 2009 and published on June 23, 2011. Accordingly, Kirschman is prior art under at least 35 U.S.C. §§ 102(a), (e).

U.S. Publication No. 2007/0088357 to Johnson *et al.* (“Johnson,” Ex.1007) was filed on October 18, 2005 and published on April 19, 2007. Accordingly, Johnson is prior art under at least 35 U.S.C. §§ 102(a), (b), (e).

U.S. Publication No. 2005/0267477 to Jackson (“’477 Publication,” Ex.1008) was filed on July 22, 2005 and published on December 1, 2005. Accordingly, the ’477 Publication is under at least 35 U.S.C. § 102(b).

U.S. Patent No. 7,857,834 to Boschert (“Boschert,” Ex.1009) was filed on June 14, 2004 and issued on December 28, 2010. Accordingly, Boschert is prior art under at least 35 U.S.C. §§ 102(a), (b), (e).

**B. Ground 1: Claims 1-2, 4, and 7 are Obvious over Kirschman.**

**1. Summary of Kirschman**

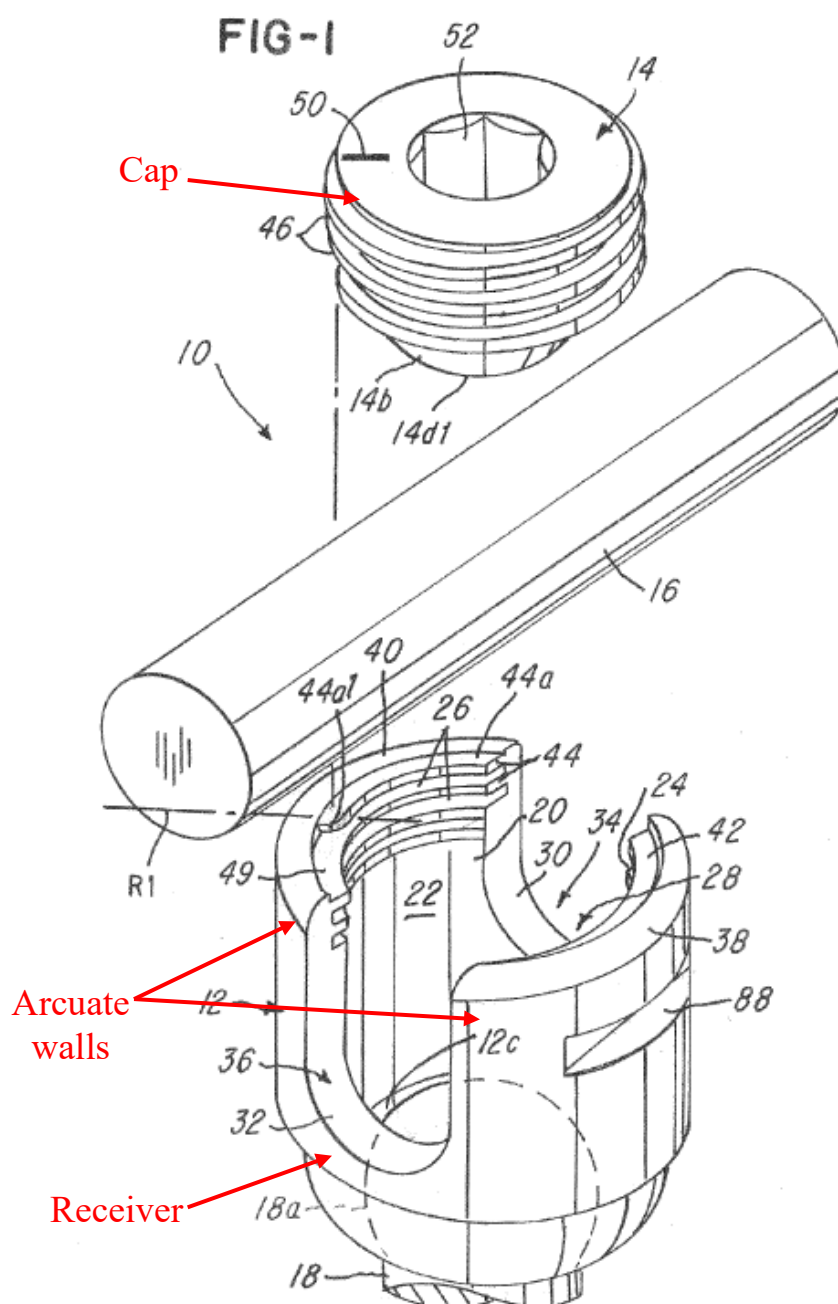
Kirschman is directed to “[a]n implant having a receiver that is adapted to receive a polyaxial screw in the bore and [] an internal...cap.” Ex.1005, Abstract.

As with the ’873 Patent, Kirschman recognized that, when securing a rod to the receiver, closures/caps must withstand “high torque loading which can result in cross-threading and/or thread failure,” making it “difficult to engage in the...receiver.” Ex.1005, [0005]-[0006]. Thus, Kirschman recognized that a cap thread was needed that “prevents cross threading” and “achieves high connection strength immediately after initial thread engagement.” Ex.1005, [0008]. For example, Kirschman explained that “blunt-tip threads” that were “first invented by Higbee in 1891 (U.S. Pat. No. 447,775)” (Ex.1006) prevented cross-threading. Ex.1005, [0009].

Kirschman discloses a “polyaxial screw” that “comprises a receiver 12 and a

cap 14 which is threadably mounted on the...receiver.” Ex.1005, [0034].

The receiver includes “a first arcuate wall 38 and a generally opposing second arcuate wall 40” with a “a first generally U-shaped wall 30 that defines a first rod-receiving opening 34 and a generally opposed second generally U-shaped wall 32 that defines a second rod-receiving opening 36” disposed between the arcuate walls. Ex.1005, [0035]. The rod-receiving openings “define the rod-receiving channel 28 for receiving the rod.” Ex.1005, [0035]. The arcuate walls include “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.” Ex.1005, [0036]. Fig. 1 illustrates the polyaxial screw:

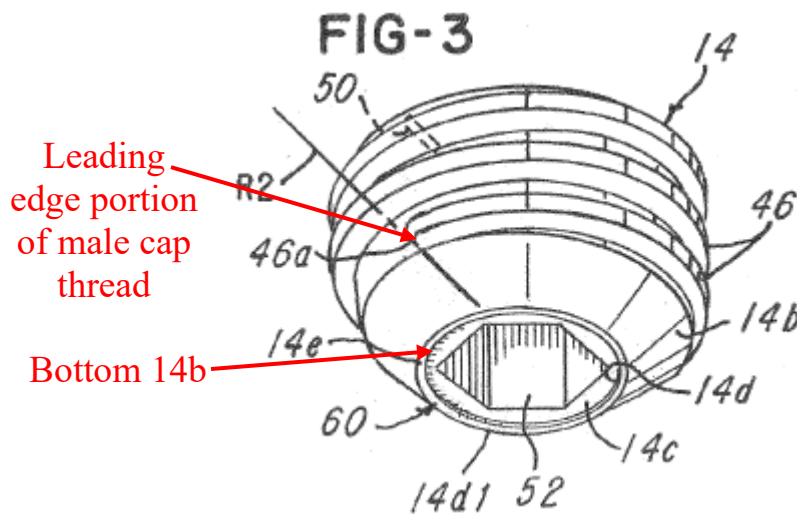


**Ex.1005, Fig. 1 (annotated)**

The cap includes a “leading edge portion 46a of the male cap thread 46 [that] is truncated” to cooperate with a complementary truncated “leading edge

portion 44a1 of the first thread 44a of the receiver 12.” Ex.1005, [0039]. This provides “tactile feedback” that allows “[t]he surgeon...[to] feel the cap 14 drop down into the receiver 12 when the leading edge portion 46a is aligned with the cut-out area 49” associated with the truncated thread of the receiver. Ex.1005, [0038].

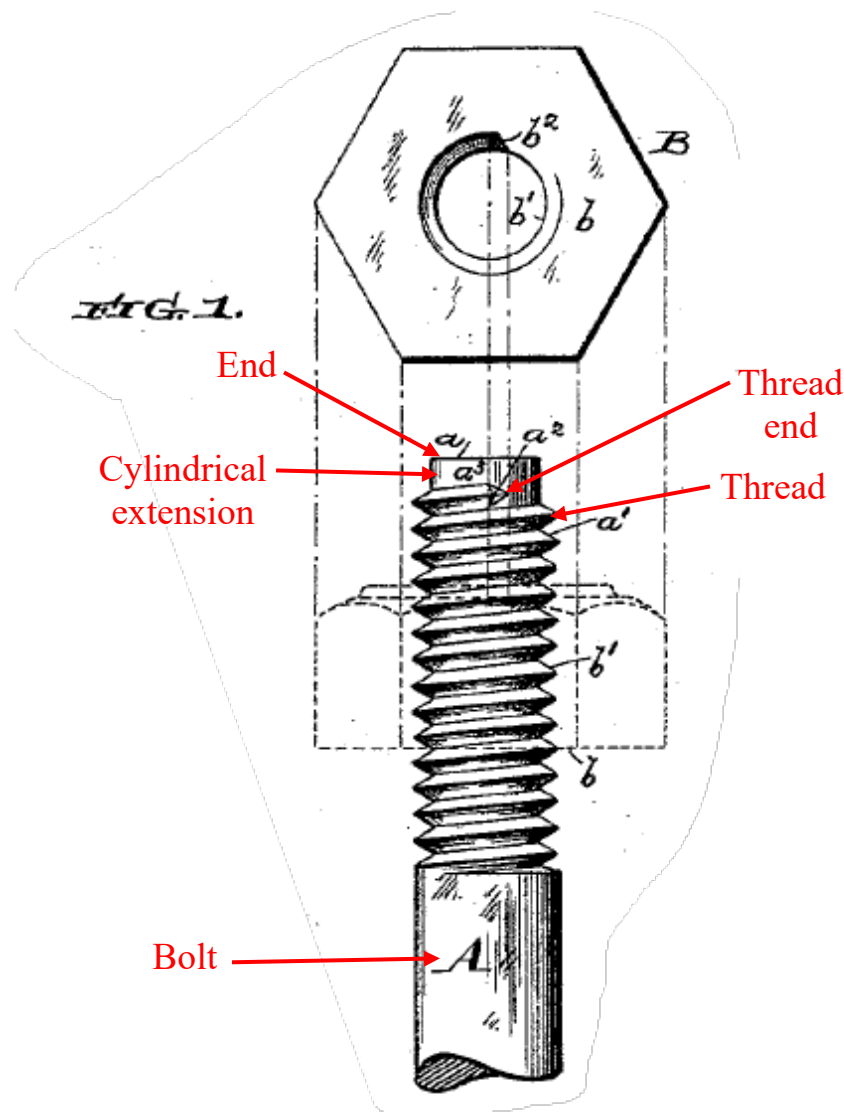
Additionally, the cap includes a “bottom 14b [] adapted to facilitate aligning and guiding the cap 14 onto the receiver 12 so that the cap 14 can be easily screwed onto the receiver.” Ex.1005, [0043]. The cap 14 is shown in Fig. 3 below (Ex.1003, ¶¶95-101):



**Ex.1005, Fig. 3 (annotated)**

Kirschman explicitly stated that Higbee is “incorporated herein by reference **and made a part hereof**” (Ex.1005, [0009]), making the disclosure of Higbee part of the disclosure of Kirschman. 37 C.F.R. § 1.57; *Paice LLC v. Ford Motor Co.*,

881 F.3d 894, 906 (Fed. Cir. 2018) (“Incorporation by reference provides ‘a method for integrating material from various documents into a host document[ ]...by citing such material in a manner that makes clear that **the material is effectively part of the host document as if it were explicitly contained therein.**’”) (citing *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000)). As Kirschman recognized, Higbee “first invented” the truncated or “blunt-tip threads for the prevention of cross threading” that are implemented in Kirschman’s cap. Ex.1005, [0009]. For example, Higbee discloses a truncated/blunt thread end that is spaced above the bottom end of the bolt/screw on which it is formed by a smooth, cylindrical extension (Ex.1003, ¶¶102-107):



Ex.1006, Fig. 1 (annotated)

## 2. Claim 1

1[pre] *A medical implant assembly comprising:*

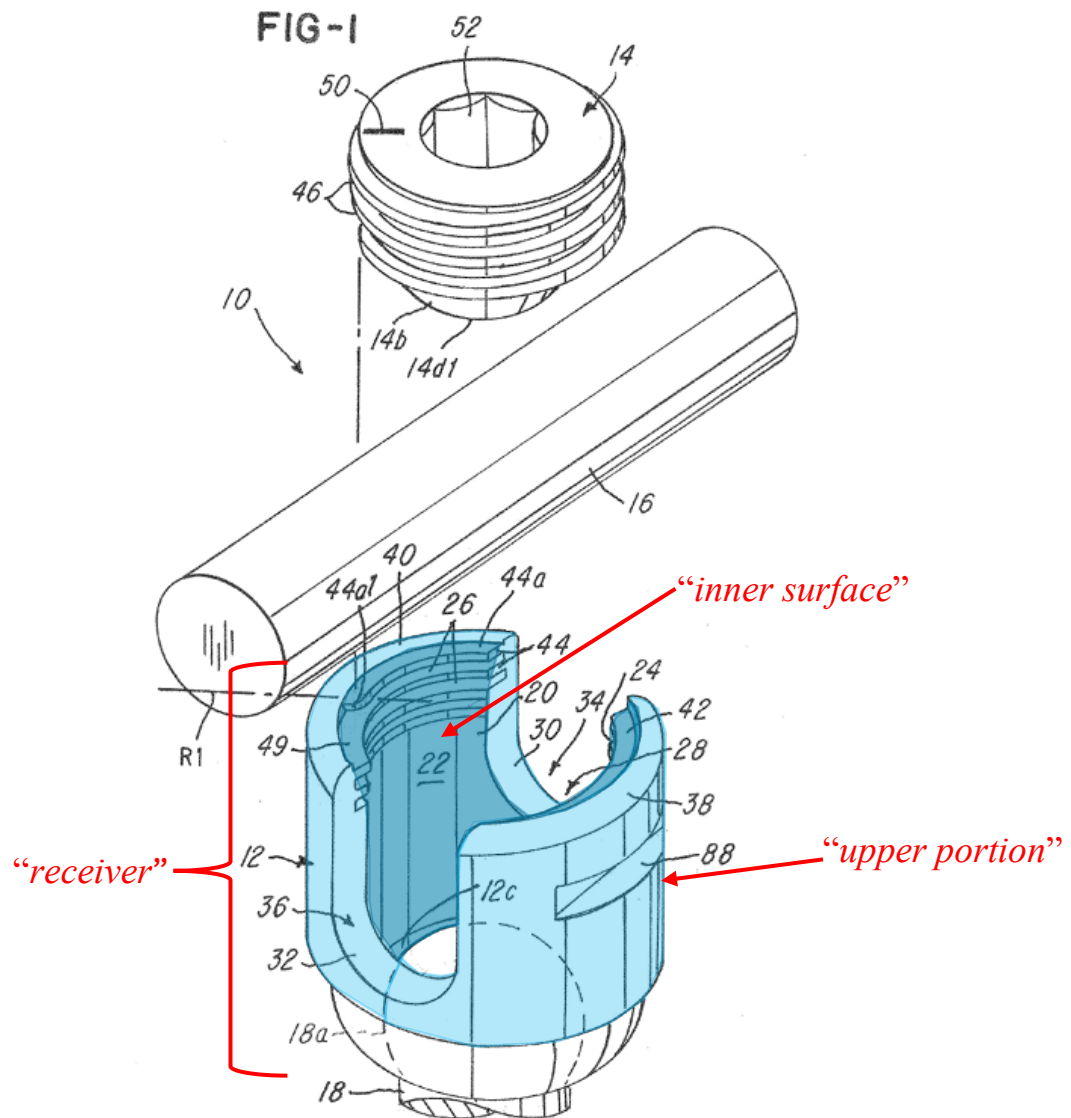
Petitioner does not believe the preamble is limiting, but to the extent it is, Kirschman's "invention relates to a spinal implant system" such as "an improved polyaxial screw." Ex.1005, [0002], [0012]; *see also* [0004] (explaining that spinal

implant screws are for implantation into the spine).

Therefore, because Kirschman teaches a polyaxial screw for implantation into the spine, Kirschman renders obvious limitation 1[pre]. Ex.1003, ¶¶108-111.

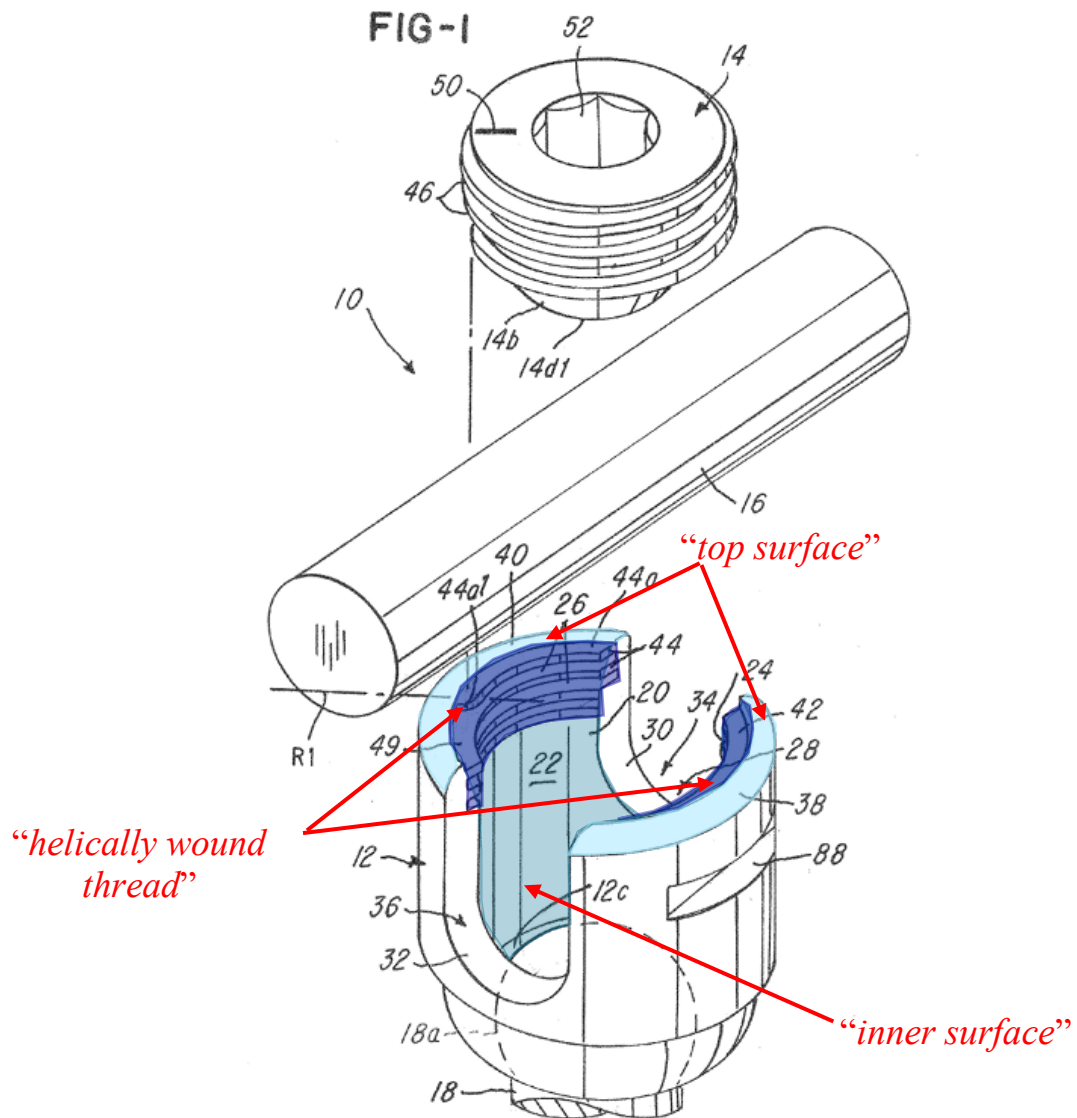
**1[a] a receiver having an upper portion with an inner surface at least partially configured as a helically wound thread extending up to a top surface of the receiver, and**

Kirschman's "polyaxial screw" includes "a receiver." Ex.1005, [0034]. The receiver includes "a first generally U-shaped wall 30 that defines a first rod-receiving opening 34 and a generally opposed second generally U-shaped wall 32 that defines a second rod-receiving opening 36" and "a first arcuate wall 38 and a generally opposing second arcuate wall 40 that lie between the first and second rod-receiving openings 34 and 36." Ex.1005, [0035]. The U-shaped and arcuate walls define an "*upper portion with an inner surface*" (Ex.1003, ¶113):



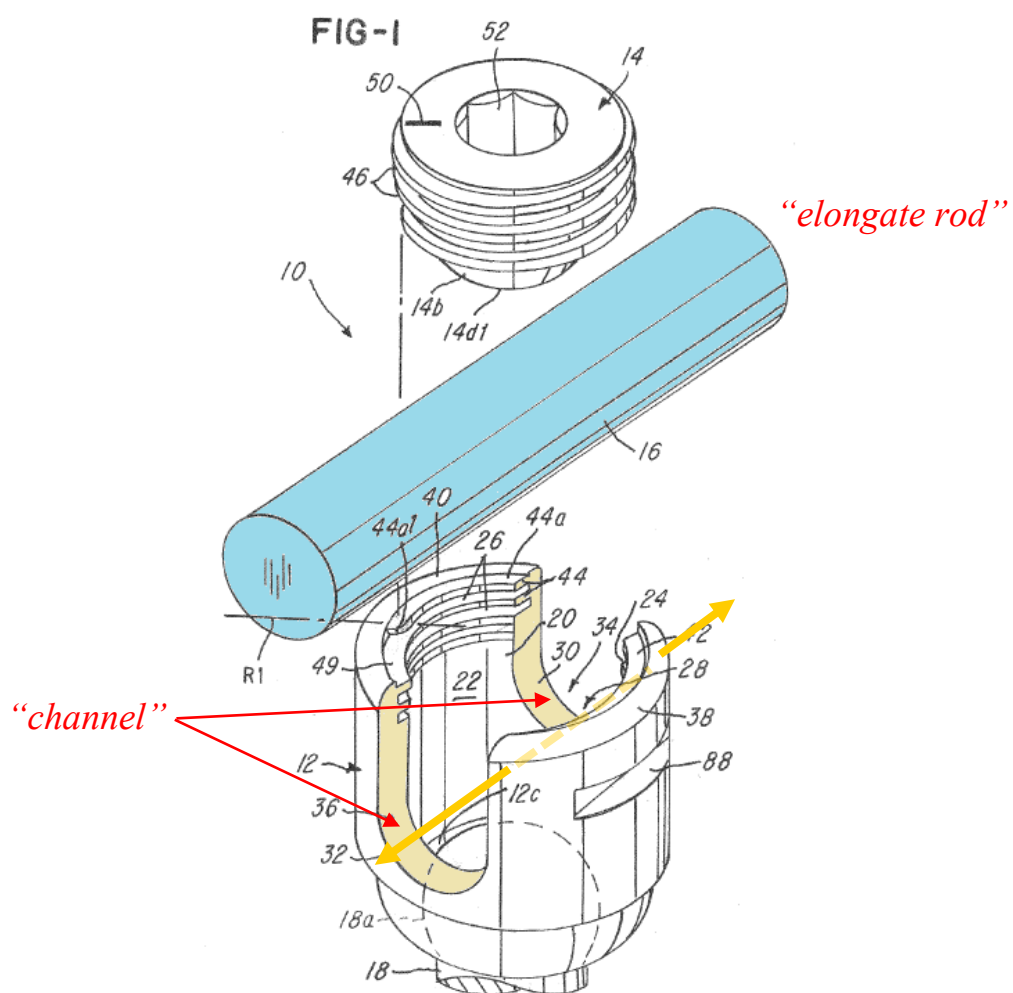
**Ex.1005, Fig. 1 (annotated)**

The “inner surface” of each arcuate wall has arcuate wall threads (“*helically wound thread*”). Ex.1005, [0036] (“The first arcuate wall 38 comprises first arcuate wall threads 42 and the second arcuate wall 40 comprises second arcuate wall threads 44.”). As shown in Figs. 1 and 7, these arcuate wall threads extend to a “top surface” of the receiver (Ex.1003, ¶115):

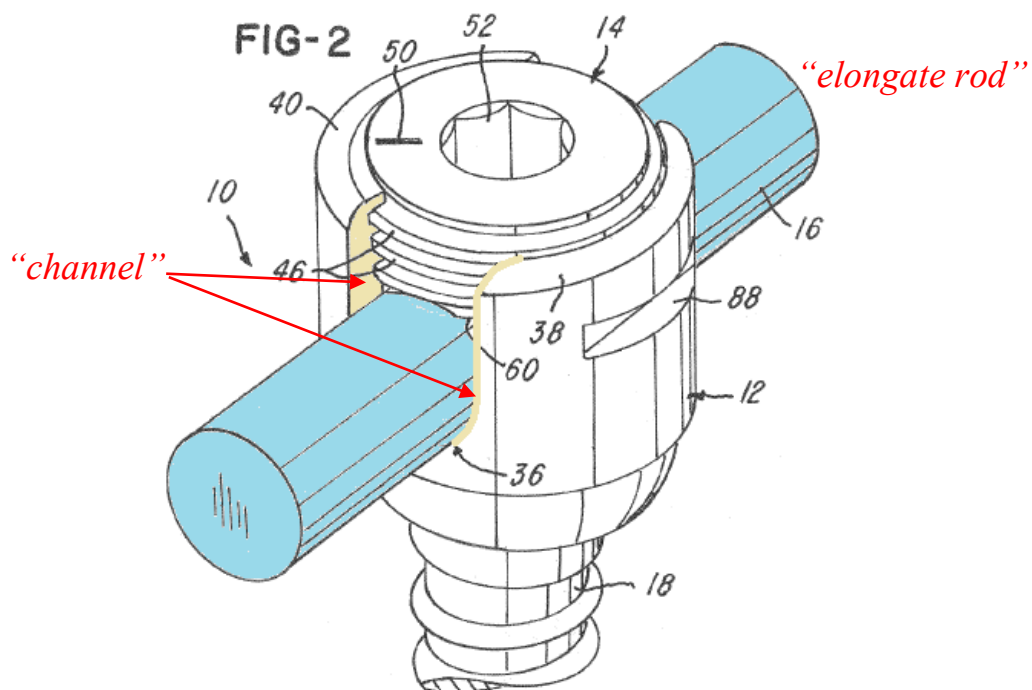


**Ex.1005, Fig. 1 (annotated)**

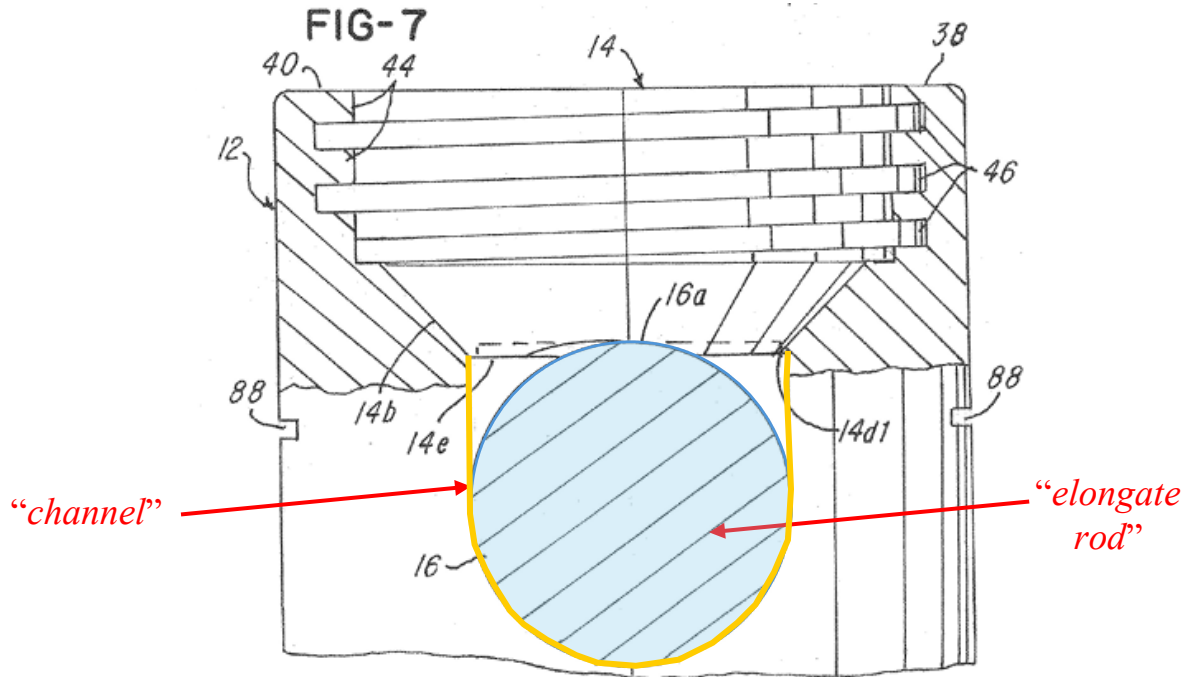




**Ex.1005, Fig. 1 (annotated)**



**Ex.1005, Fig. 2 (annotated)**



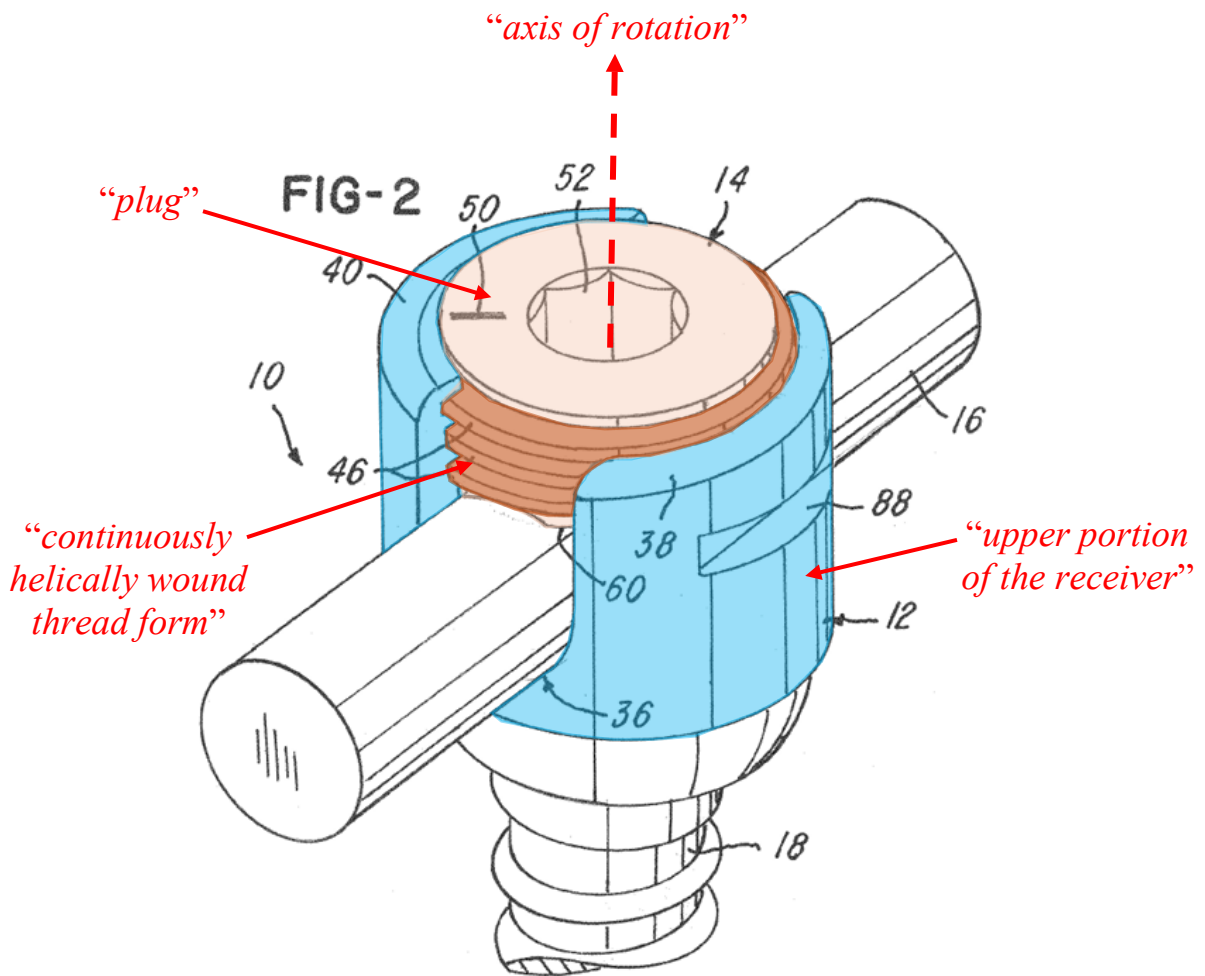
Ex.1005, Fig. 7 (annotated)

Therefore, because Kirschman's receiver includes a rod-receiving channel, Kirschman renders obvious limitation 1[b]. Ex.1003, ¶¶117-119.

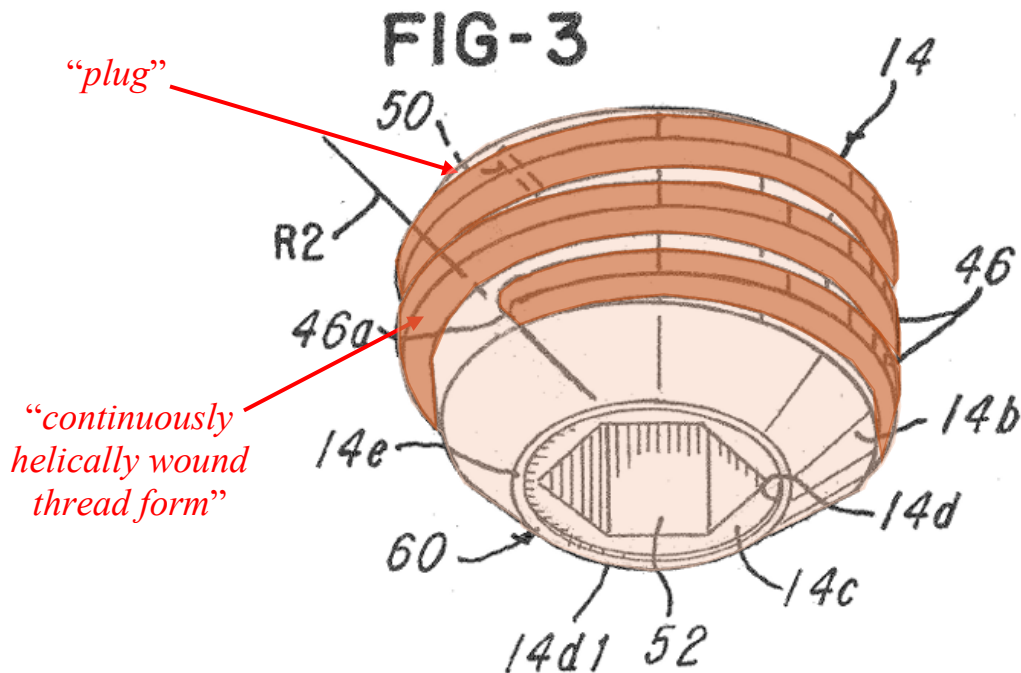
**1[c] a plug being threaded and configured to be positioned within the upper portion of the receiver, the plug having an axis of rotation, a continuously helically wound thread form, and**

Kirschman's polyaxial screw includes "a cap 14 which is threadably mounted on the...receiver." Ex.1005, [0034]. Specifically, the arcuate wall threads of the receiver "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." Ex.1005, [0036]. The cap thread form is "*continuously helically wound*" about the cap body. Ex.1003, ¶121. The cap is "rotatably driv[en]" into the receiver

via these threads. Ex.1005, [0044] (“[T]he cap 14 has a tool-receiving opening 52 (FIG. 2) for receiving a tool for rotatably driving the cap 14.”). Therefore, the cap (“*plug*”) is configured to rotate about an “*axis of rotation*” that extends through the center thereof (Ex.1003, ¶122):



Ex.1005, Fig. 2 (annotated)



Ex.1005, Fig. 3 (annotated)

Therefore, because Kirschman's cap has threads and is configured to be rotatably attached to the receiver between the arcuate walls, Kirschman renders obvious limitation 1[c]. Ex.1003, ¶¶120-125.

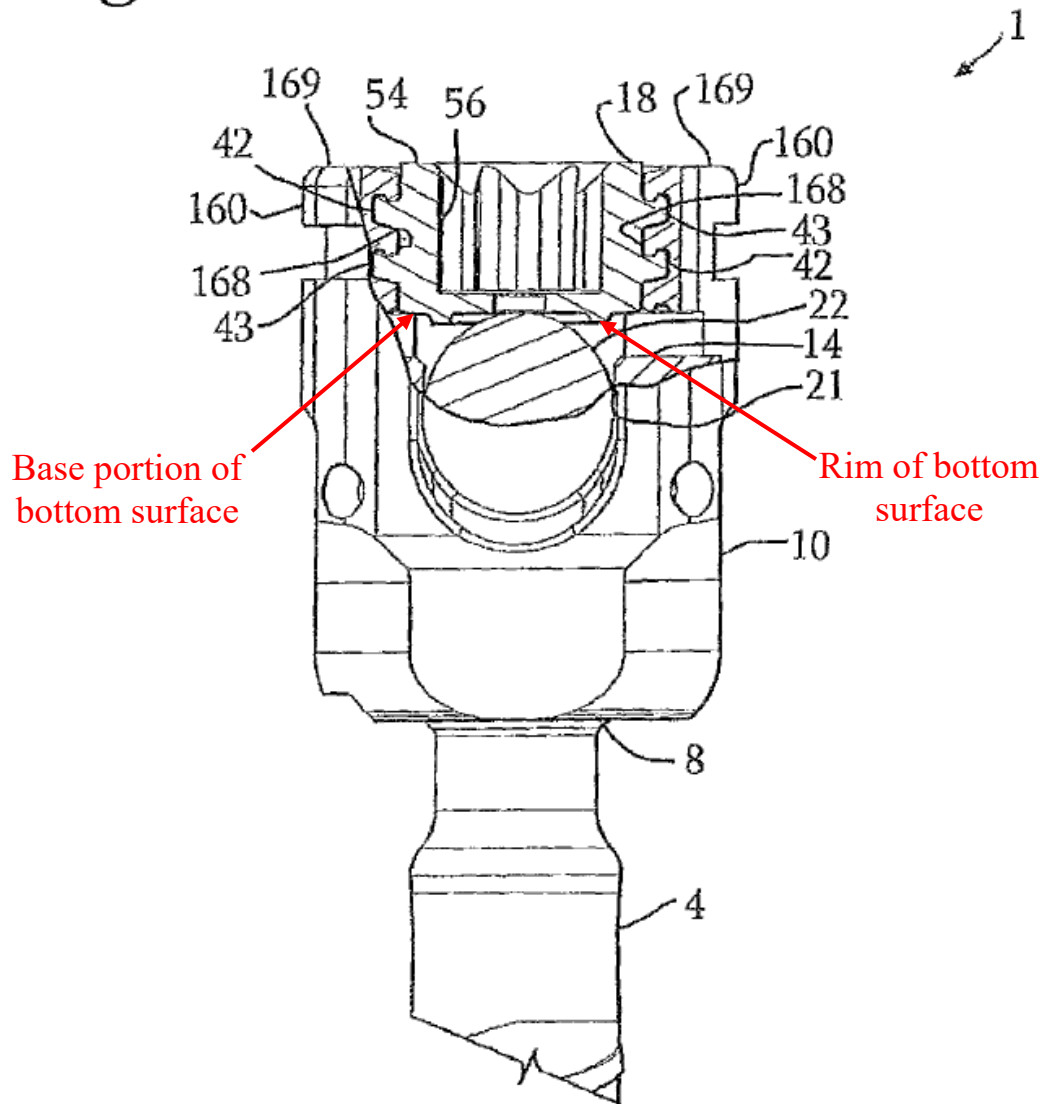
**1[d] a bottom surface with an annular outer edge,**

The '873 Patent does not describe an "*annular outer edge*" of a bottom surface. Ex.1003, ¶127. Based on the specification and figures, there are multiple ways to interpret the "*bottom surface*" and the "*annular outer edge*" thereof. Ex.1003, ¶127. With reference to the embodiment in Figs. 1-8, the '873 Patent states that the "base or bottom surface 58 of the closure [18] is planar and **further**

includes a rim 60 for engagement and penetration in the surface 22 of the rod 21”

(Ex.1001, 9:4-7):

Fig. 8.



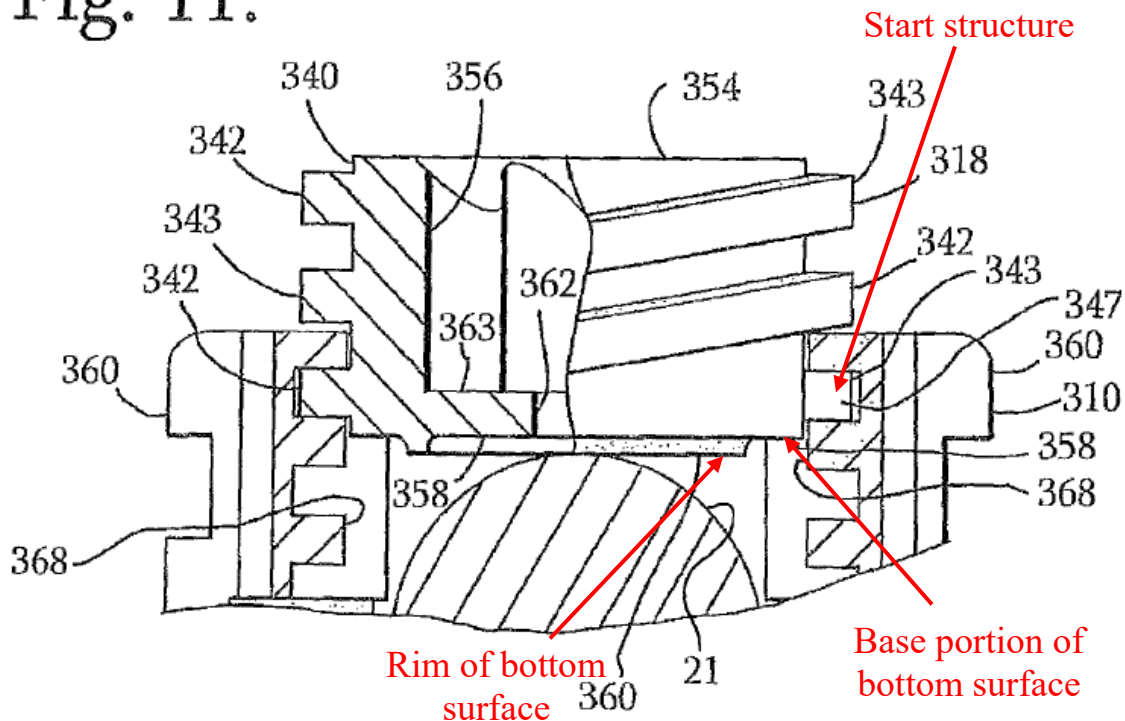
Ex.1001, Fig. 8 (annotated)

Because the rim is a part of the bottom surface, the claimed “*bottom surface*” appears to refer to the base portion of the bottom surface or to the lower

surface of the rim that contacts the rod and, thus, the “*annular outer edge*” appears to refer to an edge of the base portion or the rim. Ex.1003, ¶128.

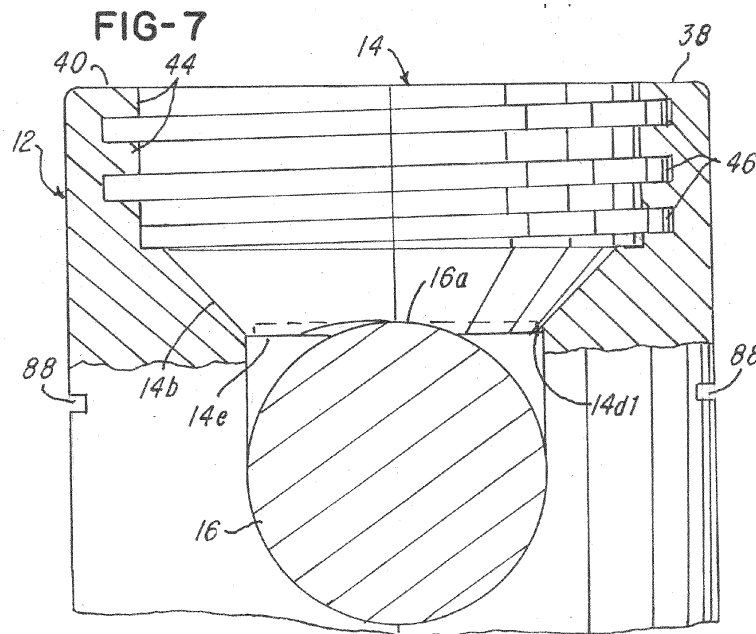
Similarly, the embodiment of Fig. 11, which shows the start structure 347 of the closure thread spaced above both parts of the bottom surface (*see* limitation 1[h] below), shows that the “closure top 318...is almost identical to the closure top 18” shown in Figs. 1-8, including “a base 358” and a “rim 360” that are “the same or substantially similar to the respective” “base 58” and “rim 60...previously described herein with respect to the closure top 18.” (Ex.1001, 22:45-57; Ex.1003, ¶129; *see also* Ex.1001, 22:66-23:19 (similar embodiment in Fig. 12); Ex.1003, ¶131):

Fig. 11.



Ex.1001, Fig. 11 (annotated)

Although there are various interpretations of this limitation, Kirschman discloses a closure having a bottom surface with a flat base member and a protruding rim that is substantially similar to the closure embodiments in the '873 Patent. Ex.1005, [0047]. Thus, obviousness of limitation 1[d] can be resolved by comparing the structures in Kirschman to the embodiments of the '873 Patent. Ex.1003, ¶131.

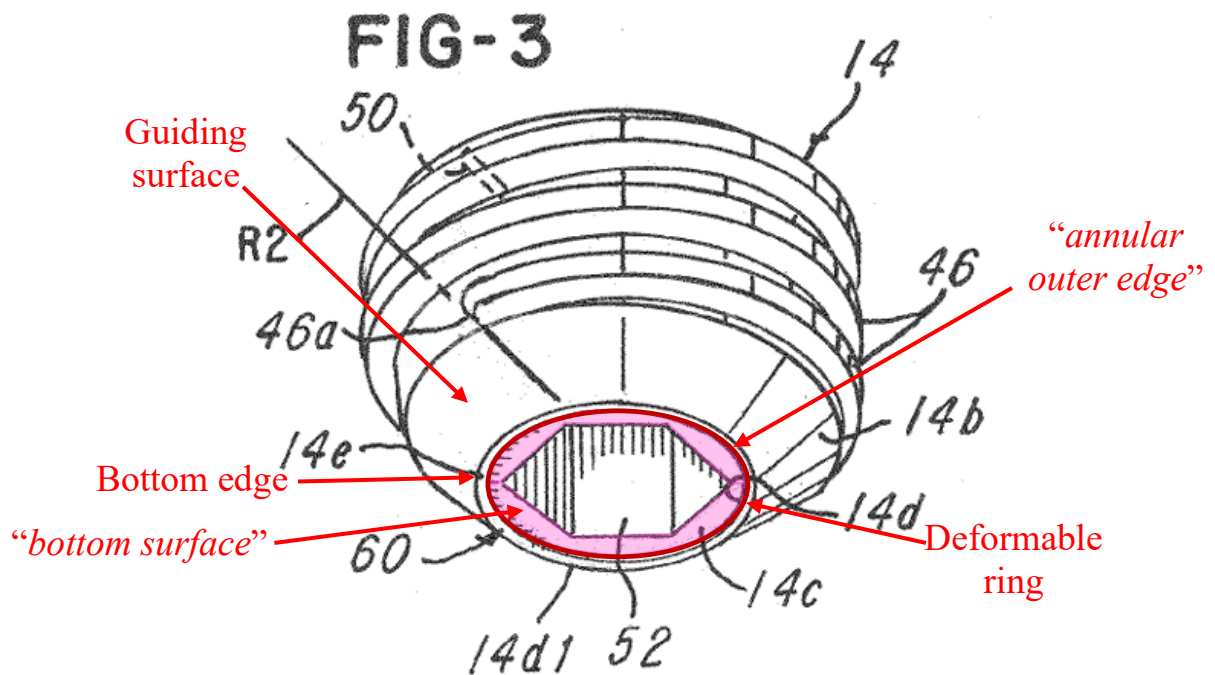


**Ex.1005, Fig. 7**

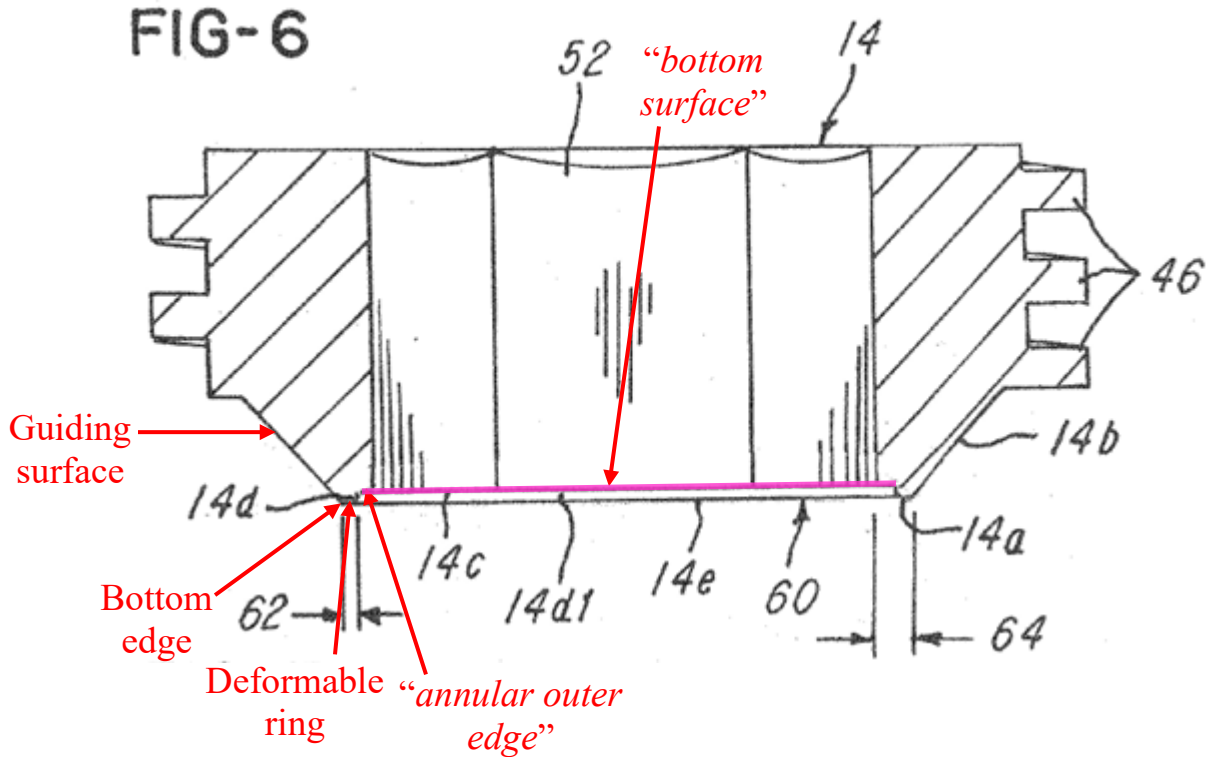
Specifically, Kirschman's cap includes a "bottom 14b [that] is adapted to facilitate aligning and guiding the cap 14 onto the receiver 12 so that the cap 14 can be easily screwed onto the receiver 12." Ex.1005, [0043]. The bottom includes a guiding "surface that is adapted to provide the lock aid by facilitating guiding the cap 14 on the receiver" to align the cap threads with the receiver threads. Ex.1005, [0043]. The "bottom 14b terminates at an end 14c." Ex.1005, [0044]. This end surface is surrounded by "a deformable ring 14d that is monolithically and integrally formed with the cap." Ex.1005, [0045]. The deformable ring includes "a bottom edge or surface 14e [that] engages the rod 16" just before deformation of the ring. Ex.1005, [0045]. The deformable ring allows "the end 14c [to] remain[]

undeformed.” Ex.1005, [0047].

In one interpretation, the end surface 14c is the “*bottom surface*” of the cap and the outer edge of the end surface adjacent to the deformable ring defines the “*annular outer edge*” thereof (Ex.1003, ¶136):

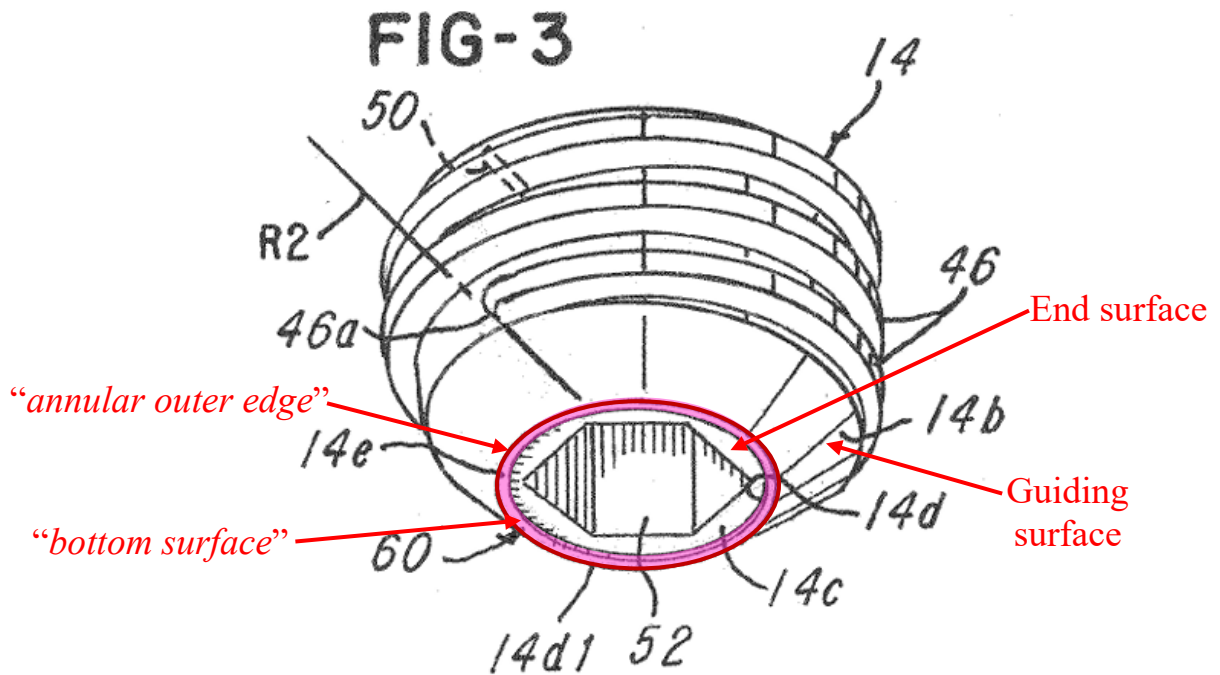


Ex.1005, Fig. 3 (annotated)

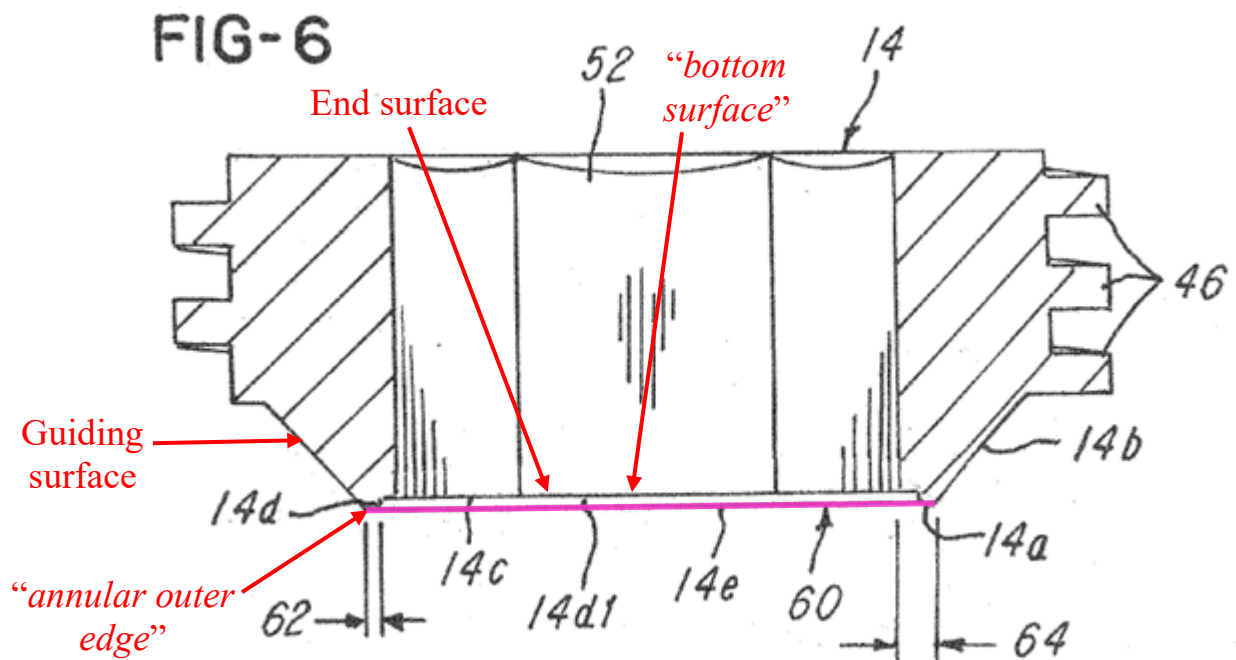


**Ex.1005, Fig. 6 (annotated)**

Alternatively, as the “*bottom surface*” includes a rim structure (e.g., the “rim 360” in Fig. 11 of the ’873 Patent), then the bottom surface of the deformable ring is also the “*bottom surface*” and the outer edge 14e thereof, which is the outermost structure at the bottom of the cap, is the “*annular outer edge*” (Ex.1003, ¶137):

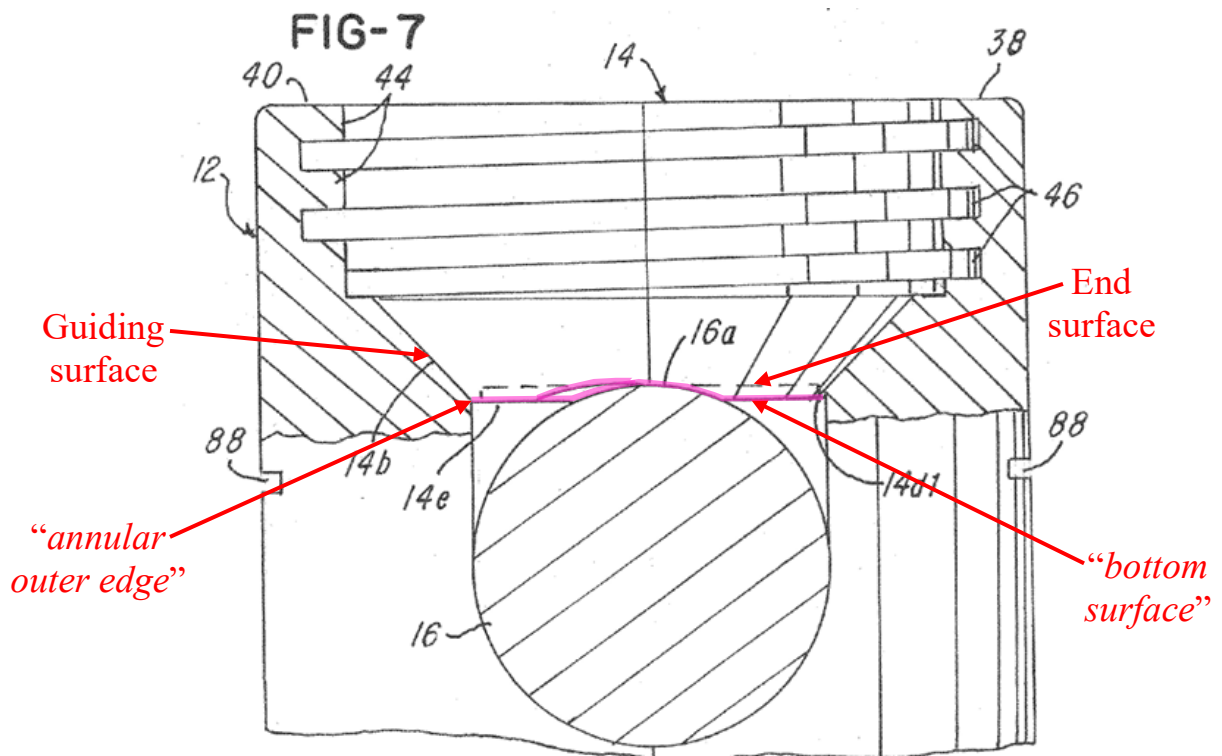


Ex.1005, Fig. 3 (annotated)



**Ex.1005, Fig. 6 (annotated)**

The cap 14 is “screwed into the receiver 12 until a bottom edge ...14e engages the rod.” Ex. 1005 [0045]. Fig. 7 below illustrates the cap after deformation of the deformable ring by the rod during rotation (Ex.1005, [0047]):



**Ex.1005, Fig. 7 (annotated)**

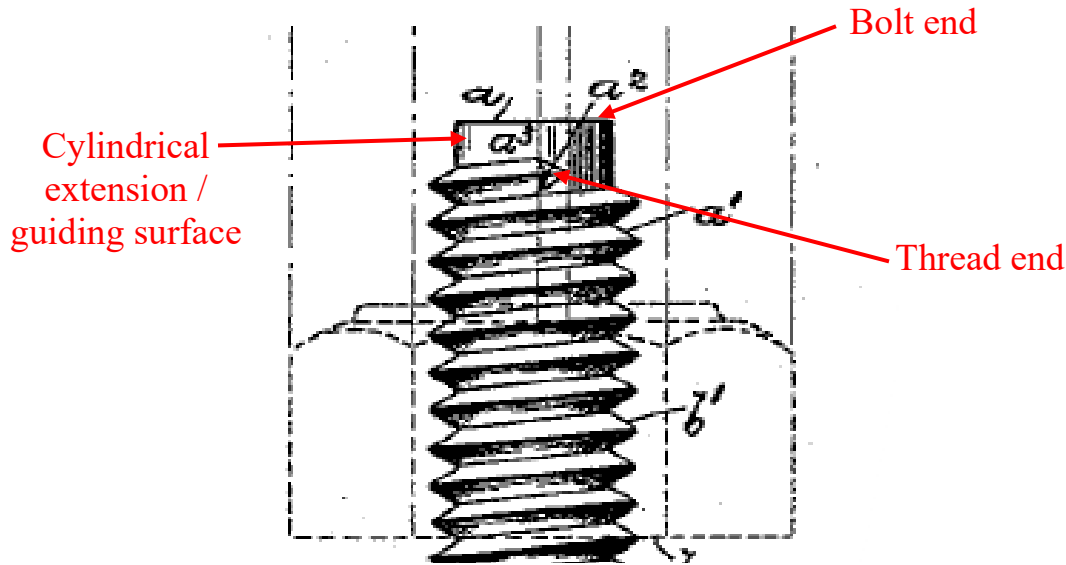
Thus, the embodiment shown in Figs. 1-7 of Kirschman discloses a “*bottom surface*” of a threaded closure having an “*outer annular edge*.” Ex.1003, ¶¶132-138.

**Kirschman as modified by Higbee**

To the extent the claimed “*bottom surface*” is understood to encompass a guiding surface, Kirschman also discloses a cylindrical guiding surface. Although

the guiding surface in Figs. 1-7 is shown as “frustoconical,” Kirschman explains that “it should be understood that the surface shape could be any suitable shape adapted to guide the cap.” Ex.1005, [0043]. Thus, a POSITA would have been motivated to consider alternative shapes for the guiding surface, including those disclosed in the patents incorporated by reference into Kirschman. Ex.1003, ¶139. Kirschman incorporates Higbee by reference, specifically pointing to Higbee as the “first invent[or]” of blunt start threads “for the prevention of cross threading.” Ex.1005, [0009]. Kirschman explains that a problem with previous polyaxial screws is that “the thread start-point of both the male and female threads are difficult to identify in a surgical environment” and “there is little, if any, tactile feedback that the thread is engaged.” Ex.1005, [0006]. Higbee solves these problems “[b]y leaving the smooth extension” (guiding surface) between the thread start and the bottom surface thereby ensuring that the screw and nut “are brought together and properly aligned before the thread ends engage, and thus an additional safeguard against misadjustment is provided.” Ex.1006, 1:83-88.

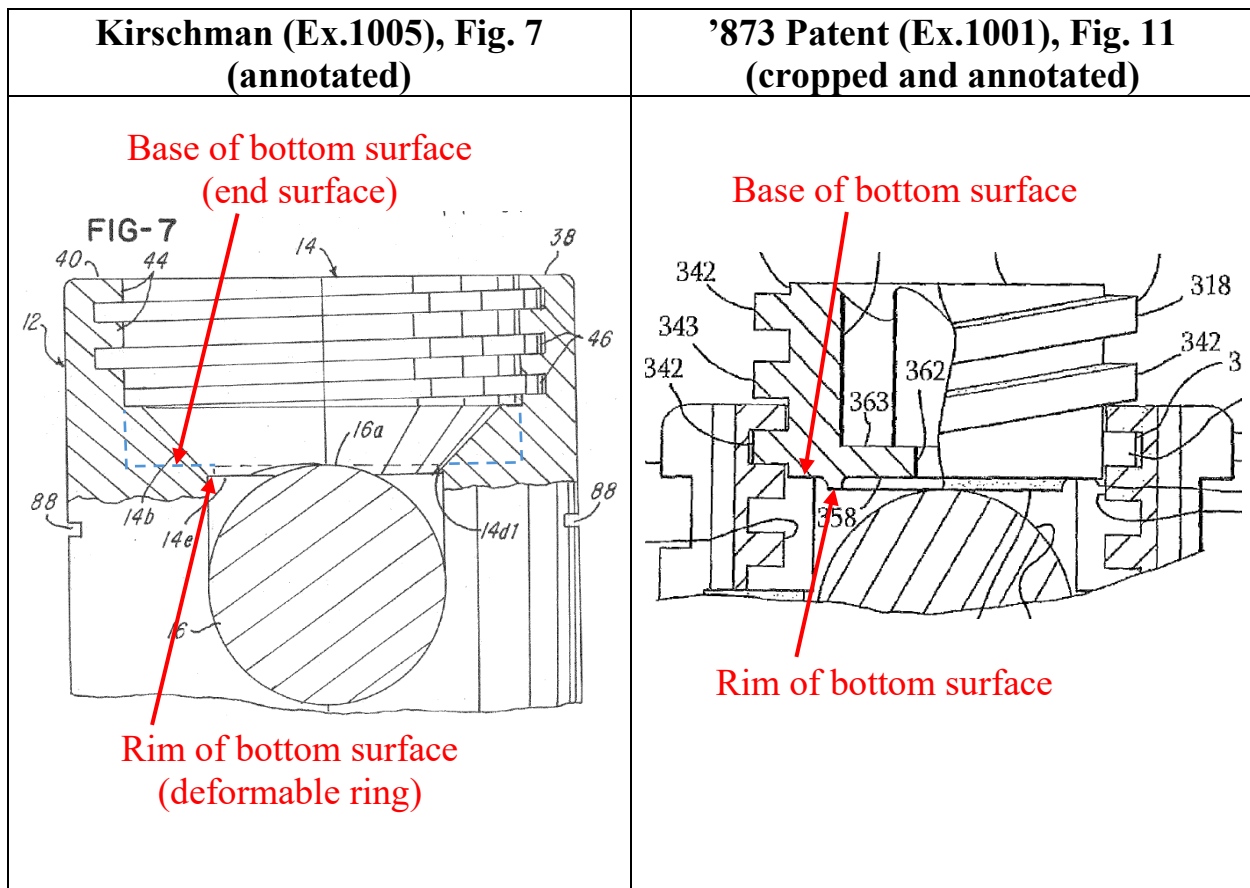
Specifically, Higbee describes a guiding surface in the form of a “cylindrical extension...between the thread end  $a^2$  and the bolt end  $a$ ” (Ex.1006, 1:69-71):



**Ex.1006, Fig. 1 (cropped and annotated)**

Accordingly, a POSITA would have been motivated to modify the frustoconical guiding surface of Kirschman's cap to be a cylindrical guiding surface as disclosed in Higbee along with a corresponding cylindrical cavity in receiver to provide an alternative guiding feature for proper alignment. Ex.1003, ¶141.

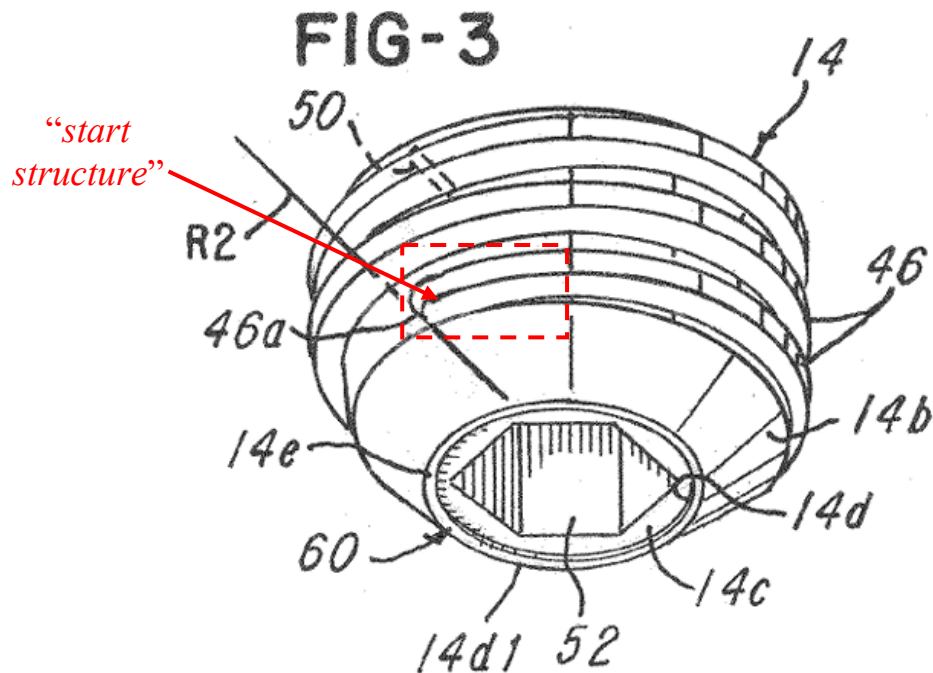
Thus, with Kirschman's guiding surface modified to be cylindrical as shown by the dashed blue lines, Kirschman's cap includes the same structure as the '873 Patent's closure (Ex.1003, ¶¶139-142):



Therefore, because Kirschman discloses a bottom end surrounded by a deformable ring, Kirschman renders obvious limitation 1[d]. Ex.1003, ¶¶126-143.

**1[e] the continuously helically wound thread form having a start structure with an upper surface extending between a root and a crest of the continuously helically wound thread form,**

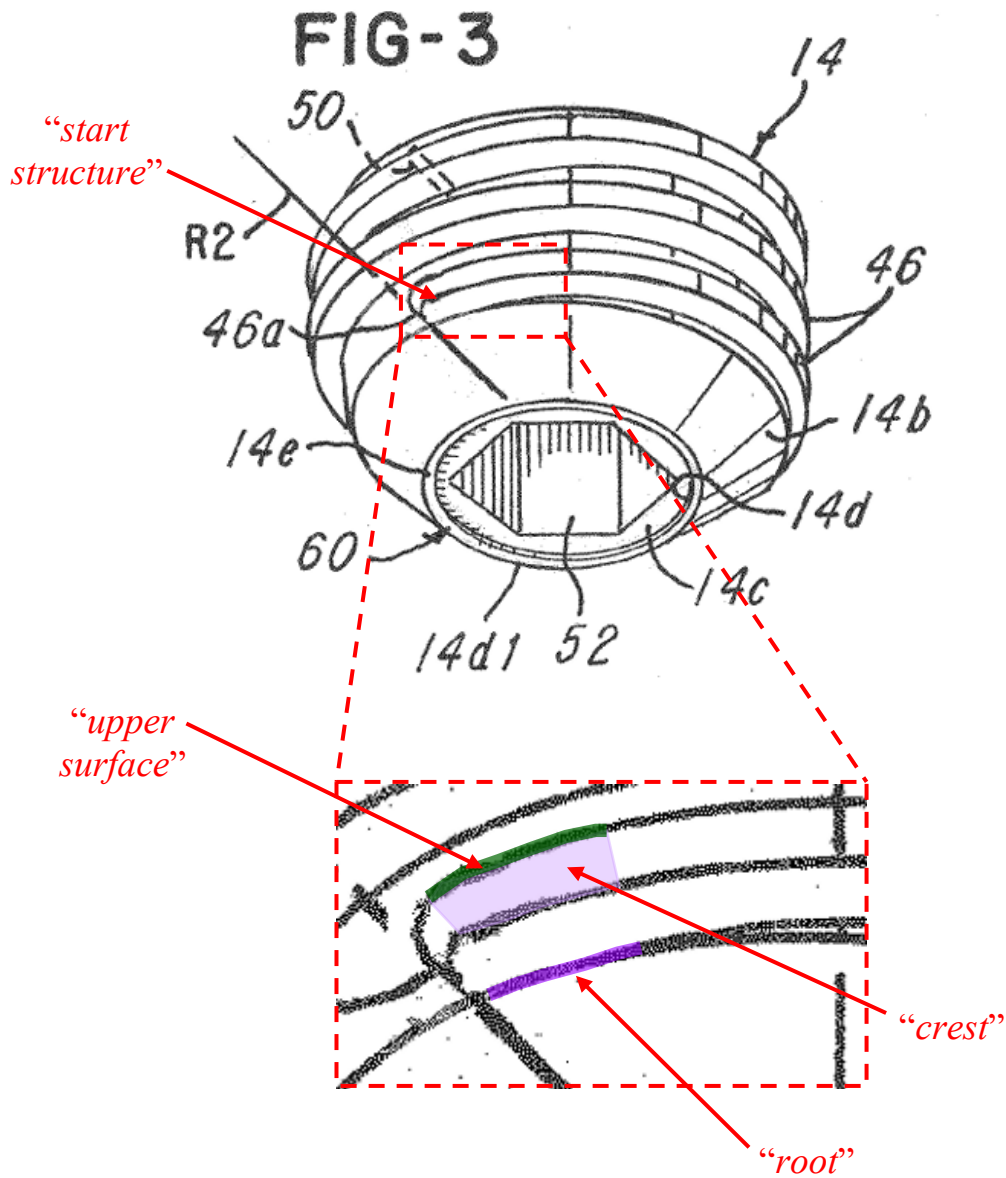
The thread on Kirschman's cap includes a leading edge portion that is truncated. Ex.1005, [0039]. This leading edge portion defines a "start structure" of the cap thread ("continuously helically wound thread") (Ex.1003, ¶147):



**Ex.1005, Fig. 3 (annotated)**

“Root” and “crest” are well-known terms in the art to describe the part of the thread disposed at the body of the screw and the outermost surface of the thread, respectively. Ex.1003, ¶148. Moreover, it was well-known that an upper surface extends between the root and crest facing the trailing/top end of the screw. Ex.1003, ¶¶149-150.

Thus, as shown in Fig. 3, a POSITA would have known that the leading edge portion (“start structure”) has a “root” disposed adjacent the body of the cap, a “crest” furthest from the body, and an “upper surface” extending between the “root” and “crest” facing the trailing end (Ex.1003, ¶151):



**Ex.1005, Fig. 3 (annotated)**

Because Fig. 3 above is bottom view of the thread, the “upper surface” (shown in green) extends into the page from the “crest” (in light purple) to the “root” (in dark purple). Ex.1003, ¶152.

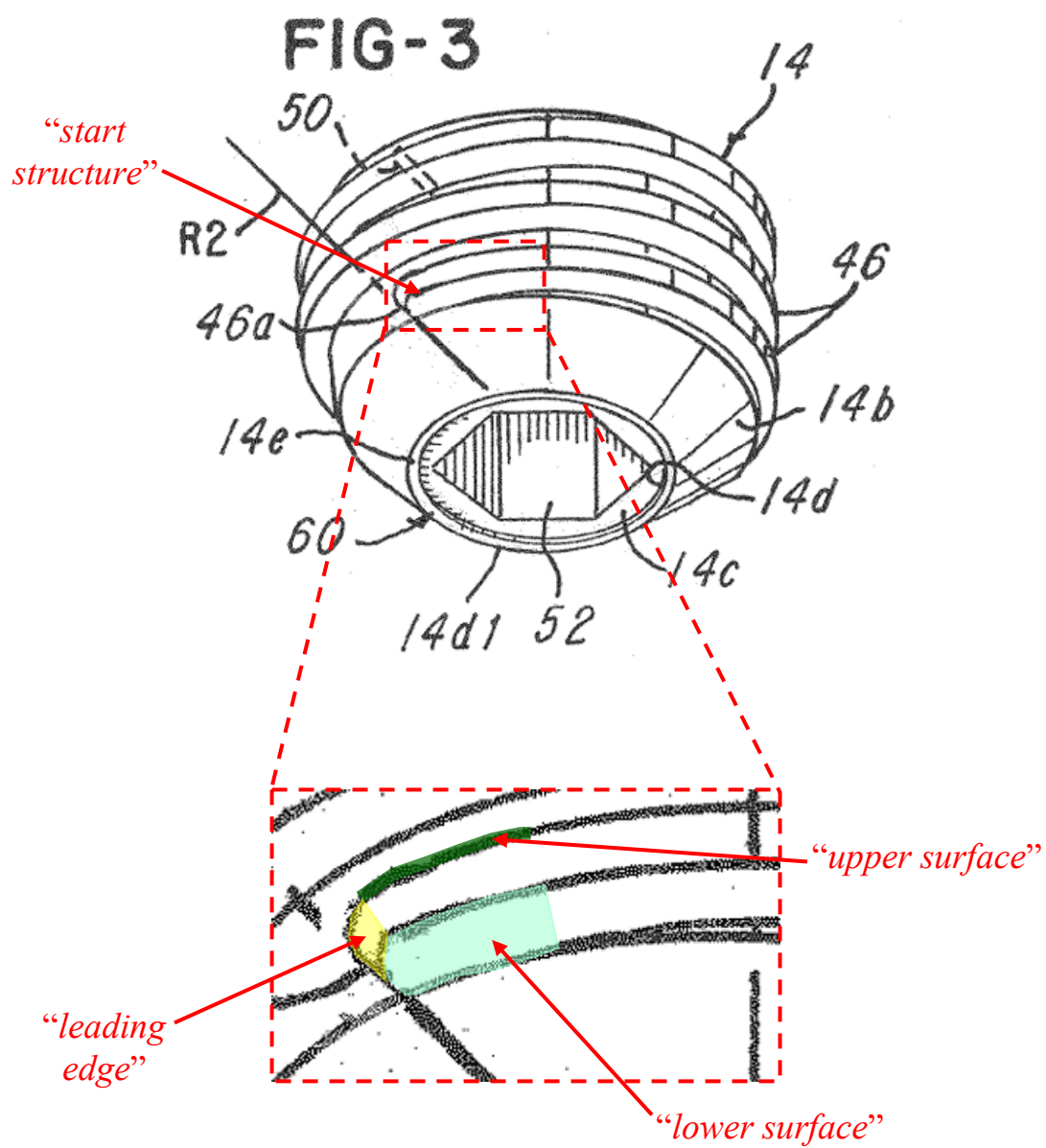
Therefore, because Kirschman discloses a truncated leading edge portion

having an upper surface that extends from the root to the crest, Kirschman renders obvious limitation 1[e]. Ex.1003, ¶¶144-153.

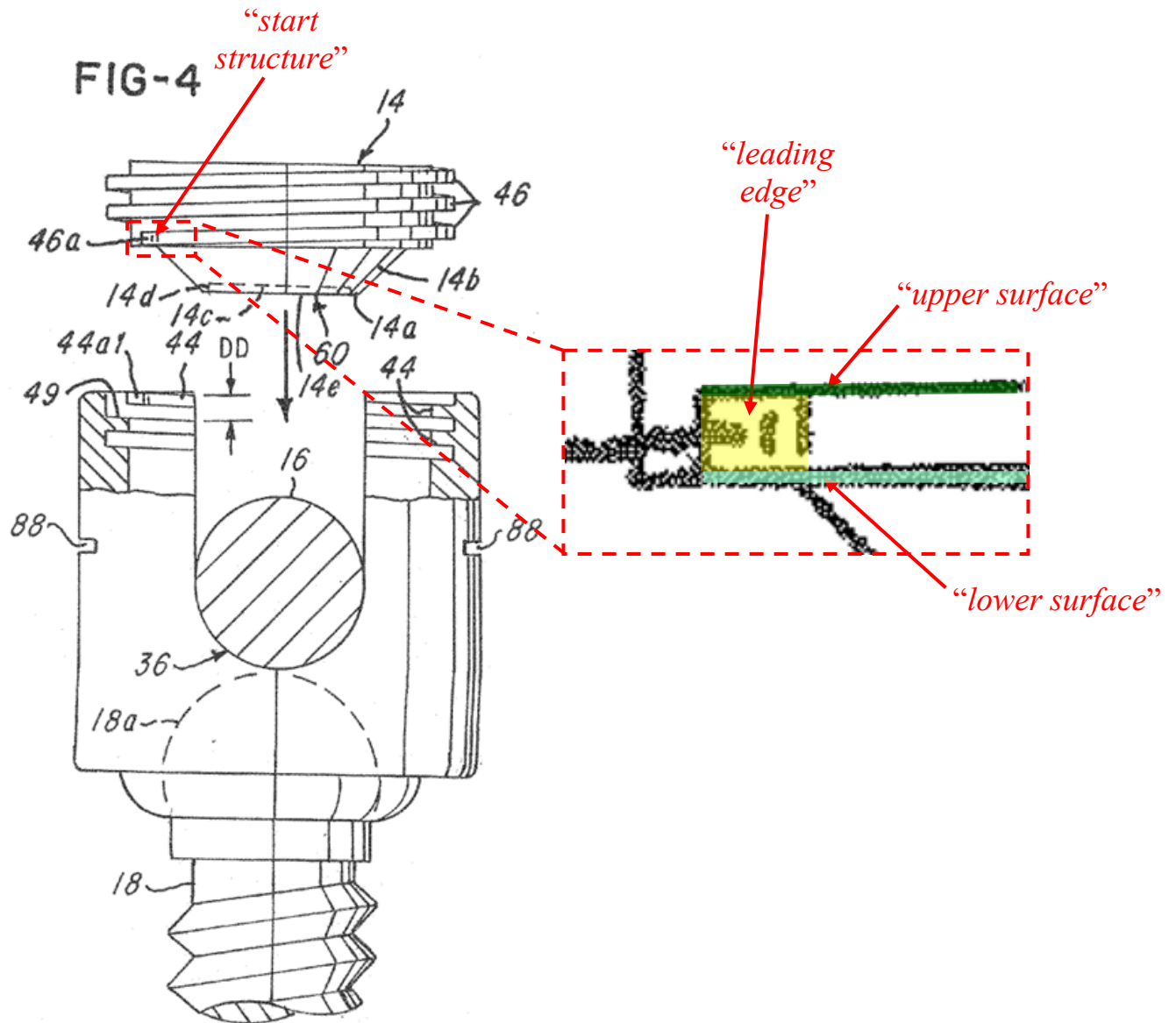
**1[f] *the start structure having a leading face extending below the upper surface to a lower surface of the start structure,***

As explained above in limitation 1[e], it was well-known that the upper surface of a thread extends between the root and crest facing the trailing end of the screw. Ex.1003, ¶¶149-150. Similarly, it was well known that a lower surface of the thread extends between the root and the crest facing the leading/bottom end of the screw opposite the upper surface. Ex.1003, ¶156.

Thus, as shown in Figs. 3-4 of Kirschman, a POSITA would have known that the truncation at the leading edge portion (“*start structure*”) forms a “*leading face*” that “*extend[s] below*” the “*upper surface*” to the “*lower surface*” (Ex.1003, ¶157):



**Ex.1005, Fig. 3 (annotated)**



**Ex.1005, Fig. 4 (annotated)**

To the extent Kirschman does not explicitly disclose a “*leading face*,” this would have been obvious to a POSITA because it was well-known that truncated thread starts (such as leading edge portion 46a) include a leading face. Ex.1003, ¶158. For example, Higbee discloses a thread end (“*start structure*”) having a

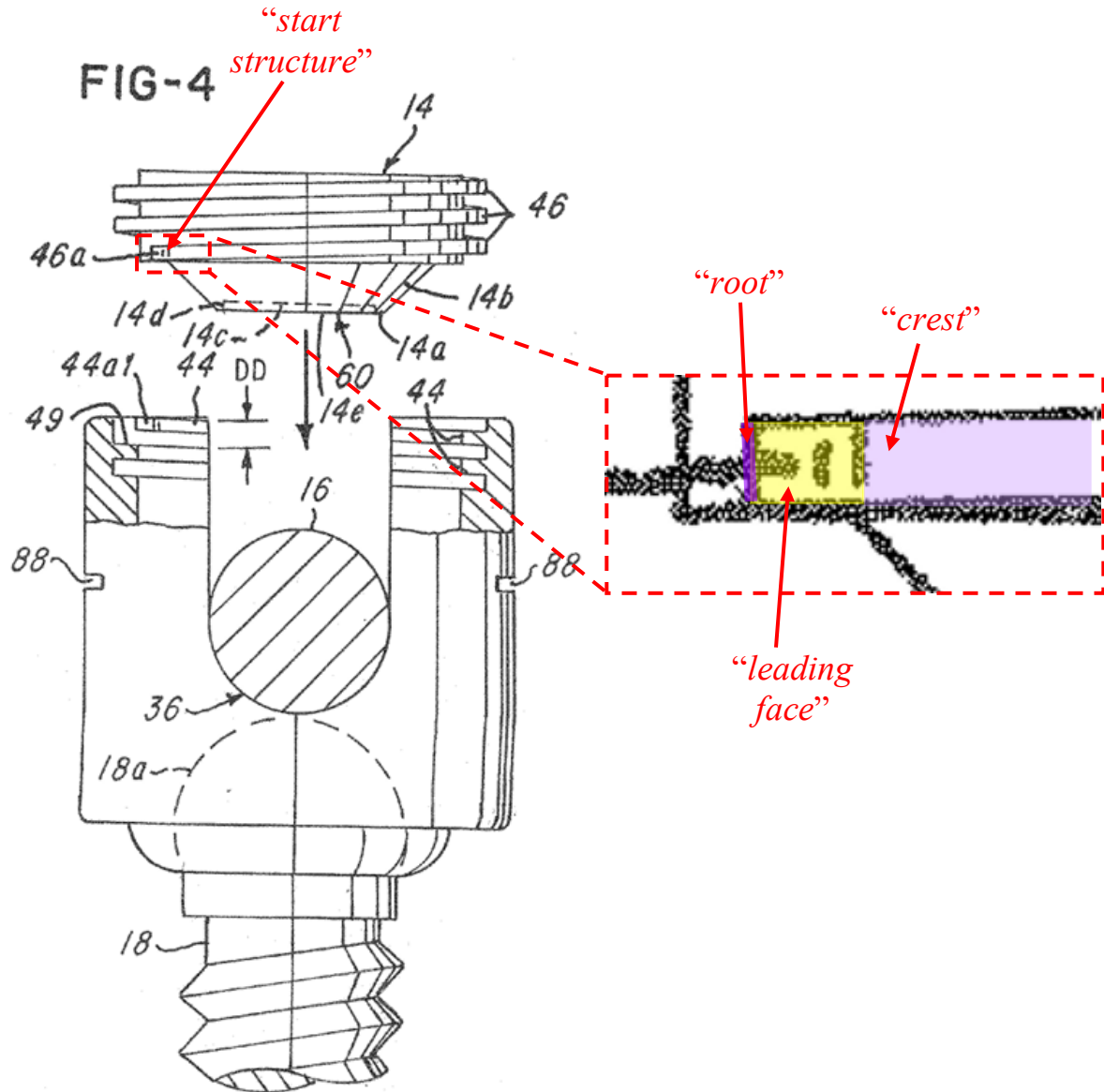
“broad blunt face” (“*leading face*”), as described in limitation 1[g] below. Ex.1006, 1:39-52, 67-68, Figs. 1, 6.

Therefore, because Kirschman discloses a truncated leading edge portion, Kirschman renders obvious limitation 1[f]. Ex.1003, ¶¶154-159.

**1[g] *the leading face including at least one partial curvate surface between the root and the crest,***

Kirschman’s “leading edge portion 46a of the male cap thread is truncated as shown.” Ex.1005, [0039]. A POSITA would have understood that Figs. 3-4 of Kirschman show the truncated face (“*leading face*”) of the leading edge portion (“*start structure*”) is curved (“*at least partially curvate*”) between the “*root*” and the “*crest*” (Ex.1003, ¶¶161-162):



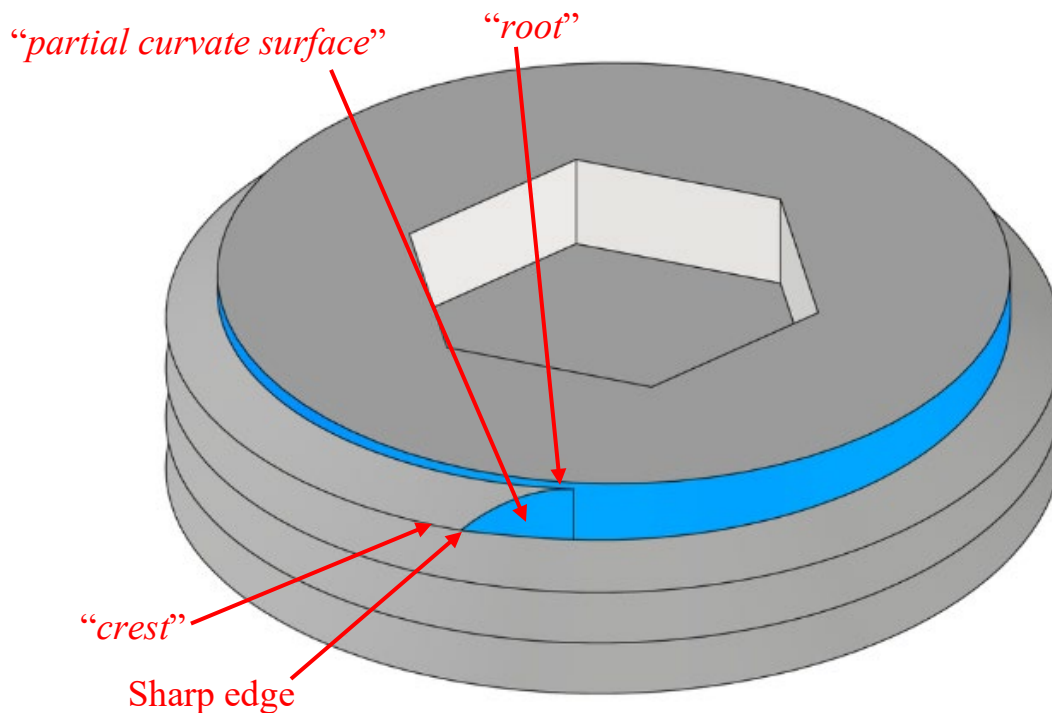


Ex.1005, Fig. 4 (annotated)

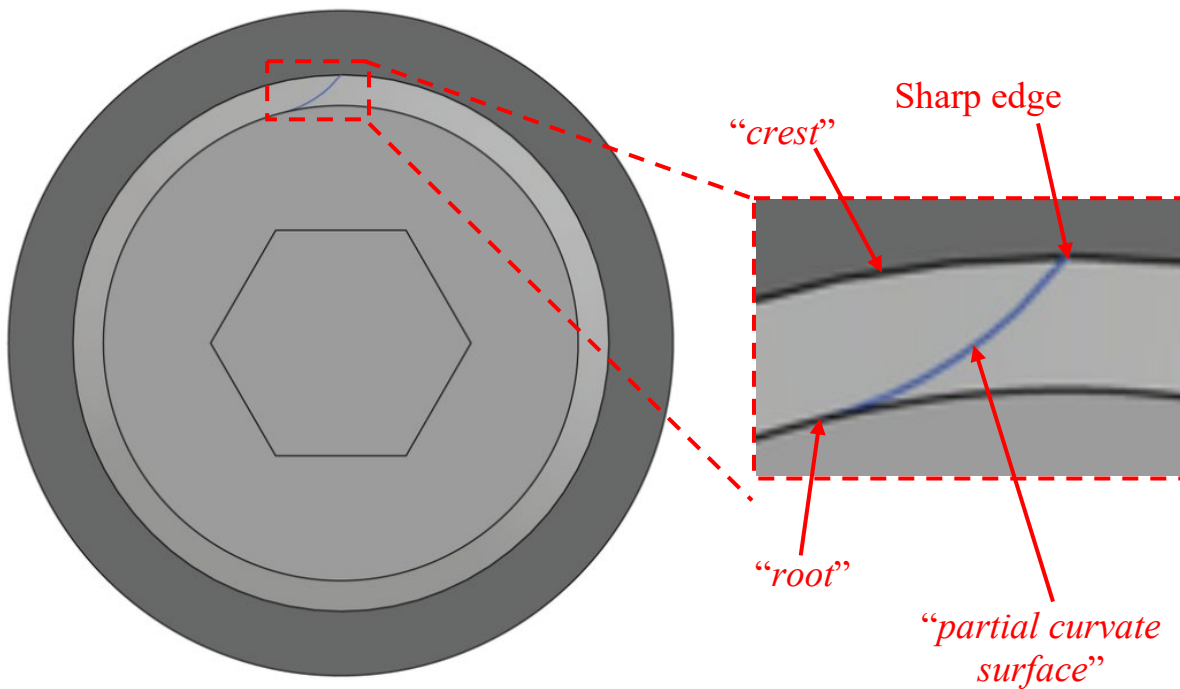
However, to the extent that Kirschman does not explicitly disclose that the leading face of the thread is “*at least partially curvate,*” this was well-known in the art. In particular, a POSITA would have understood that blunt thread starts are generally formed by removing the thin, incomplete thread at the end with a circular

tool. Ex.1003, ¶163. Because of the tool's circular shape, the face of the blunt thread start would have been formed with a concave surface between the root and the crest (Ex.1003, ¶163), as shown in the below graphics provided in Mr.

Drewry's Declaration:

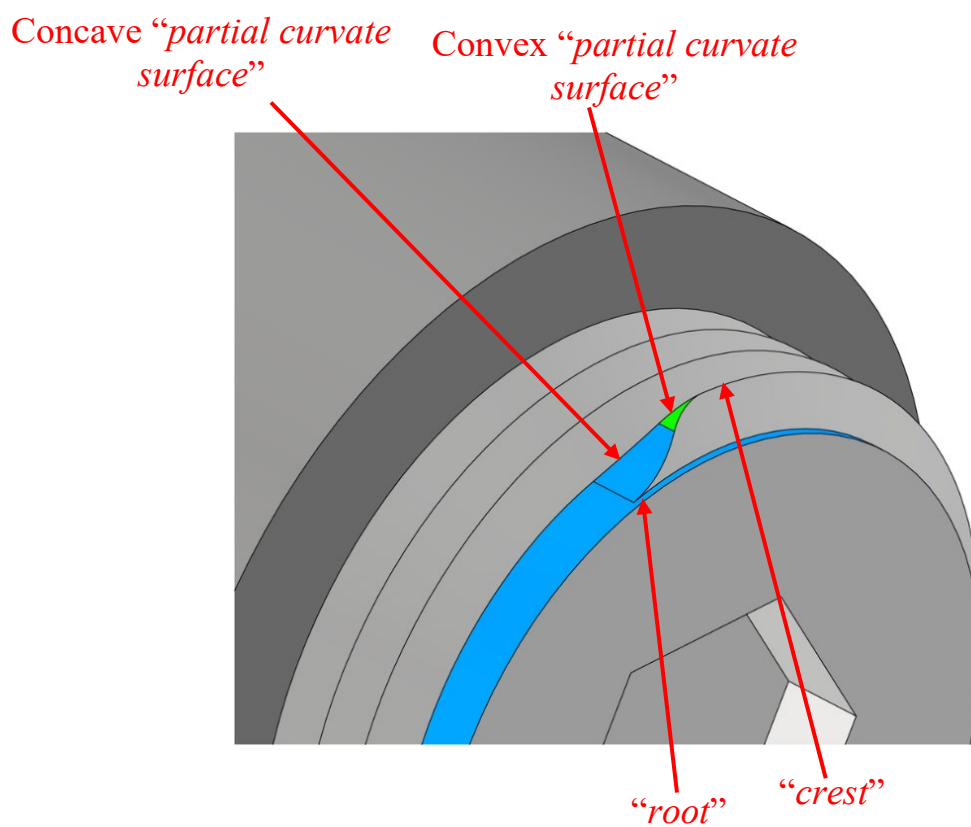


**Ex.1003, ¶163**

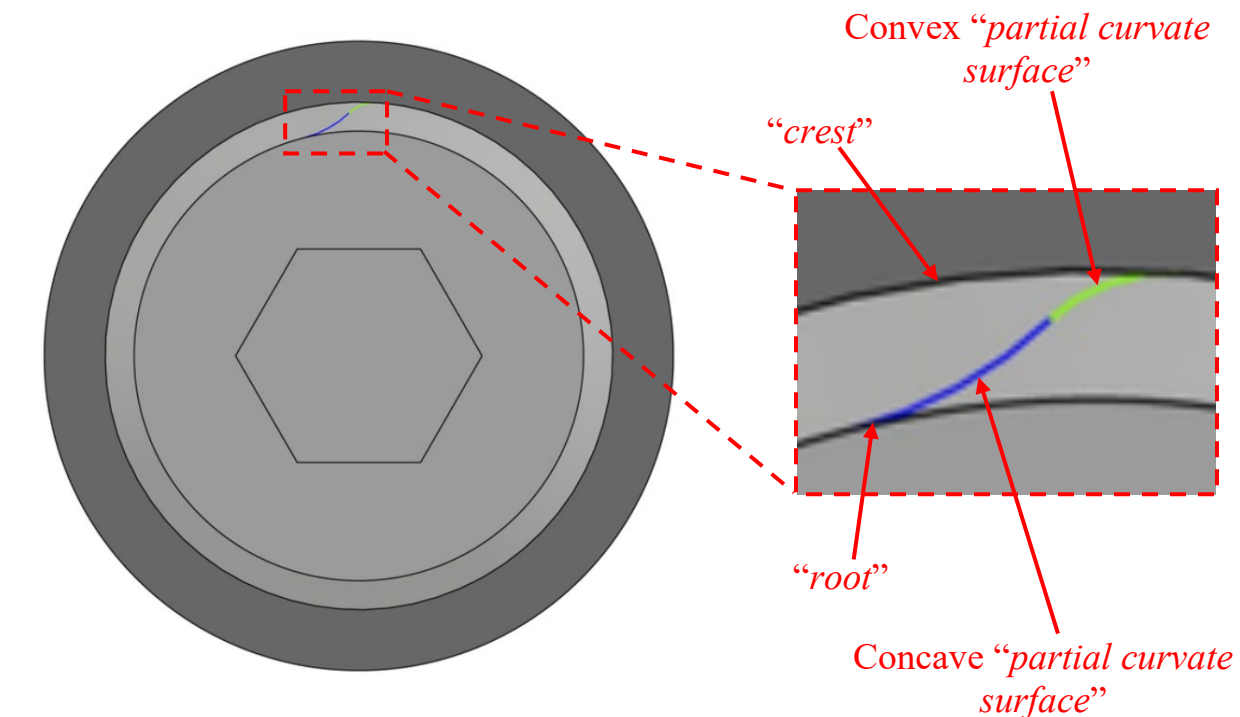


**Ex.1003, ¶163**

Moreover, particularly in medical device applications, the sharp edge at the crest would have been smoothed or rounded off using the circular tool to prevent the thread from cutting the surgeon's glove or irritating the patient. Ex.1003, ¶164. Smoothing/rounding of the blunt thread start would have resulted in a convex surface proximate the crest of the thread (Ex.1003, ¶¶164-165; *see also* ¶¶51-76), as shown in the below graphics provided in Mr. Drewry's Declaration:



**Ex.1003, ¶164**



**Ex.1003, ¶164**

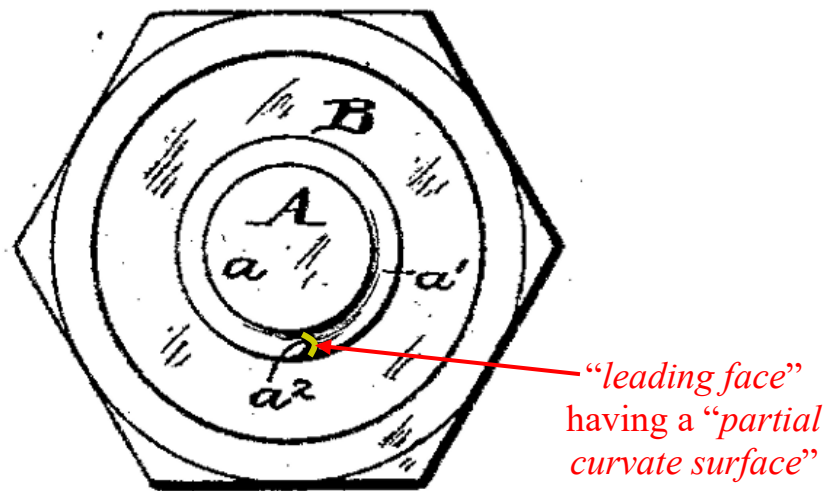
Additionally, a POSITA would have been motivated to combine the thread on Kirschman's cap with the rounded blunt thread start disclosed in Higbee.

Ex.1003, ¶166. As explained in limitation 1[d], Kirschman explicitly incorporates Higbee by reference and recognizes Higbee as the first disclosure of blunt thread starts. Kirschman explains that a problem with polyaxial screws is that "the threads of the locking cap and tulip must bear high torque loading which can result in cross-threading and/or thread failure upon initial thread engagement." Ex.1005, [0005]. Higbee's blunt thread start solves this problem by ensuring that "the ends

of the threads are made strong...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 the thread.” Ex.1006, 1:46-52. Thus, a POSITA would have looked to the embodiments in Higbee for a blunt thread start that could have been used in Kirschman’s cap. Ex.1003, ¶¶167-171.

Specifically, a POSITA would have used Higbee’s “rounded” blunt thread start shown in Fig. 6 below as Kirschman’s leading edge portion to avoid sharp edges that may irritate the patient or cut the surgeon’s glove (Ex.1006, 1:92-94; Ex.1003, ¶174):

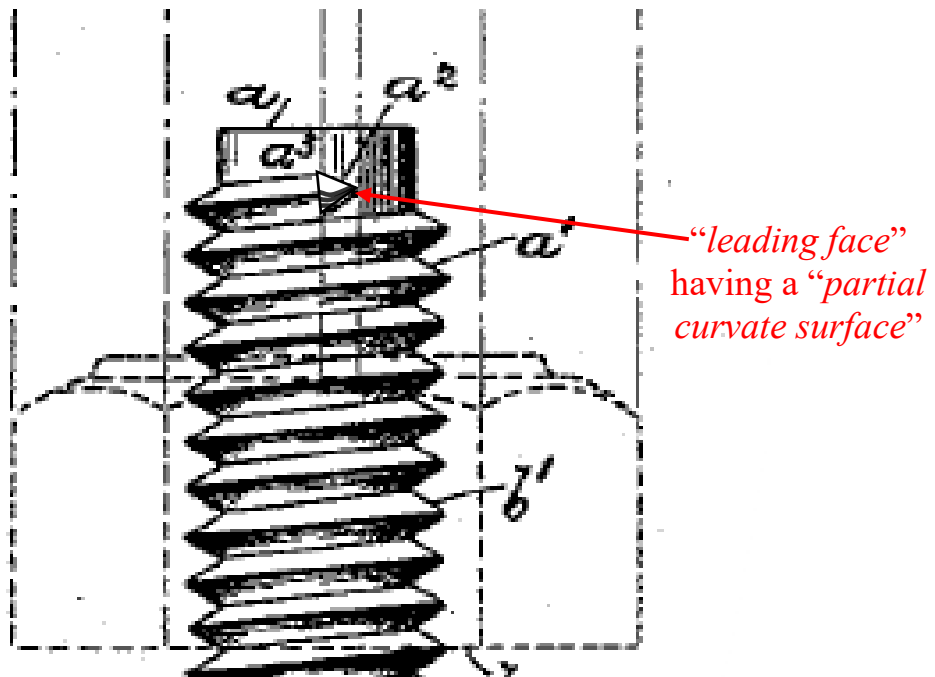
**FIG. 6.**



**Higbee (Ex.1006), Fig. 6 (annotated)**

Mr. Drewry modified Fig. 1 below to show Higbee’s thread with the rounded

thread start of Fig. 6:



**Ex.1003, ¶175**

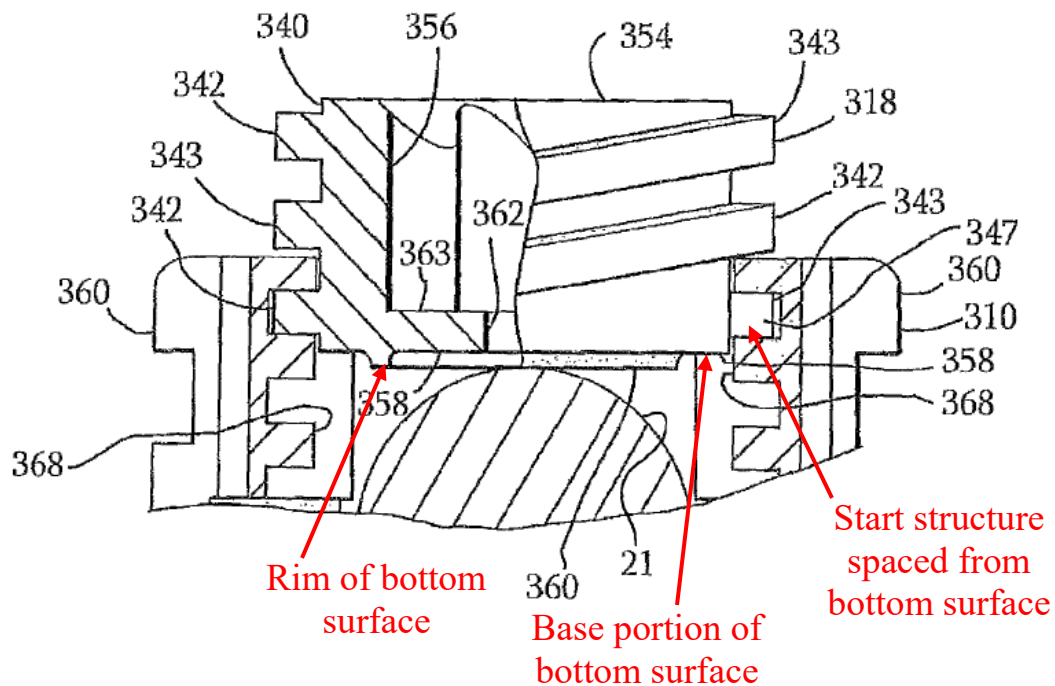
Therefore, because Kirschman discloses a truncated leading edge portion that is curved and, alternatively, Higbee discloses a rounded thread start, Kirschman renders obvious limitation 1[g]. Ex.1003, ¶¶160-177.

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

As explained above in limitation 1[d], the '873 Patent does not explain whether the “*annular outer edge*” refers to the edge of the base portion or the rim of the bottom surface. The '873 Patent also does not explain what it means for “*the lower surface of the start structure*” to be “*spaced apart and above the annular*

*outer edge...so as not to be connected therewith.*” Ex.1003, ¶179. The embodiment in Fig. 11 of the ’873 Patent shows both parts of the bottom surface are spaced apart from the start structure 347 (Ex.1003, ¶179):

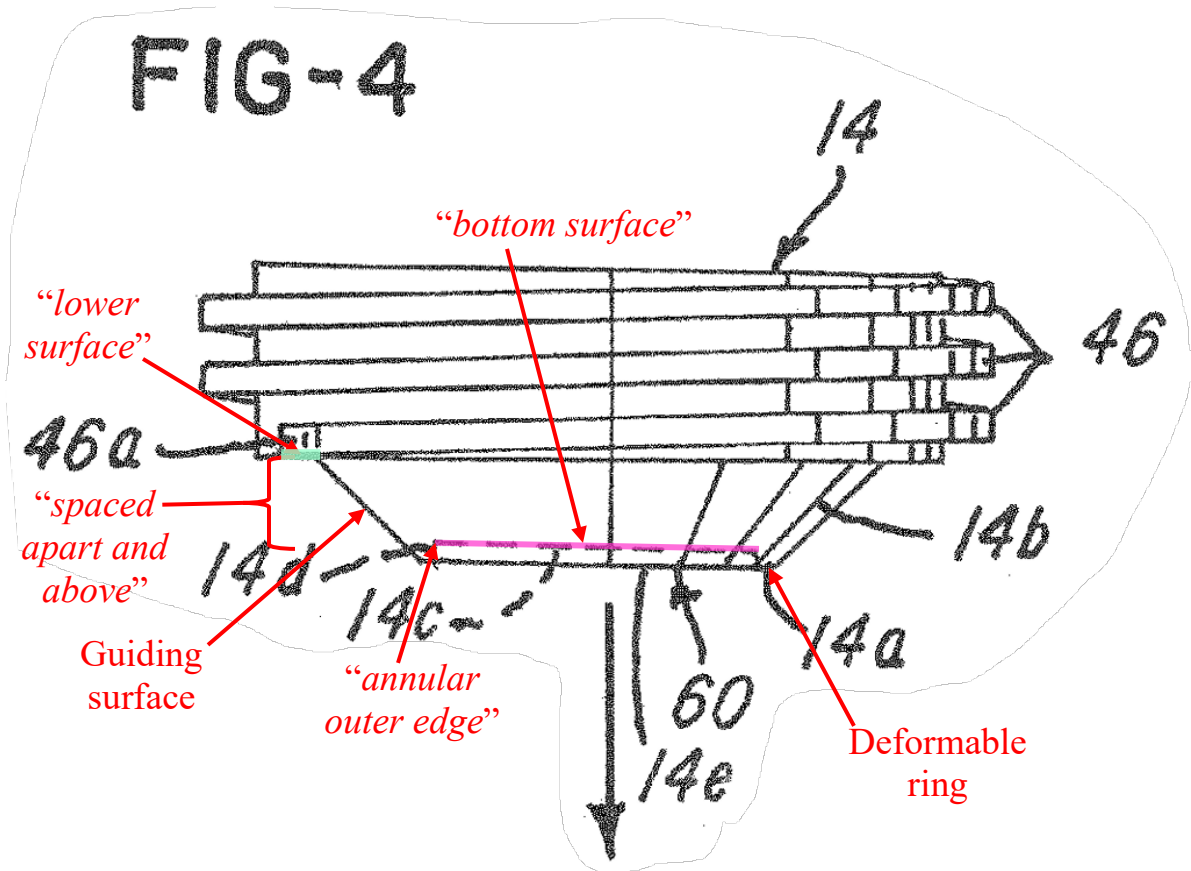
Fig. 11.



**Ex.1001, Fig. 11 (annotated)**

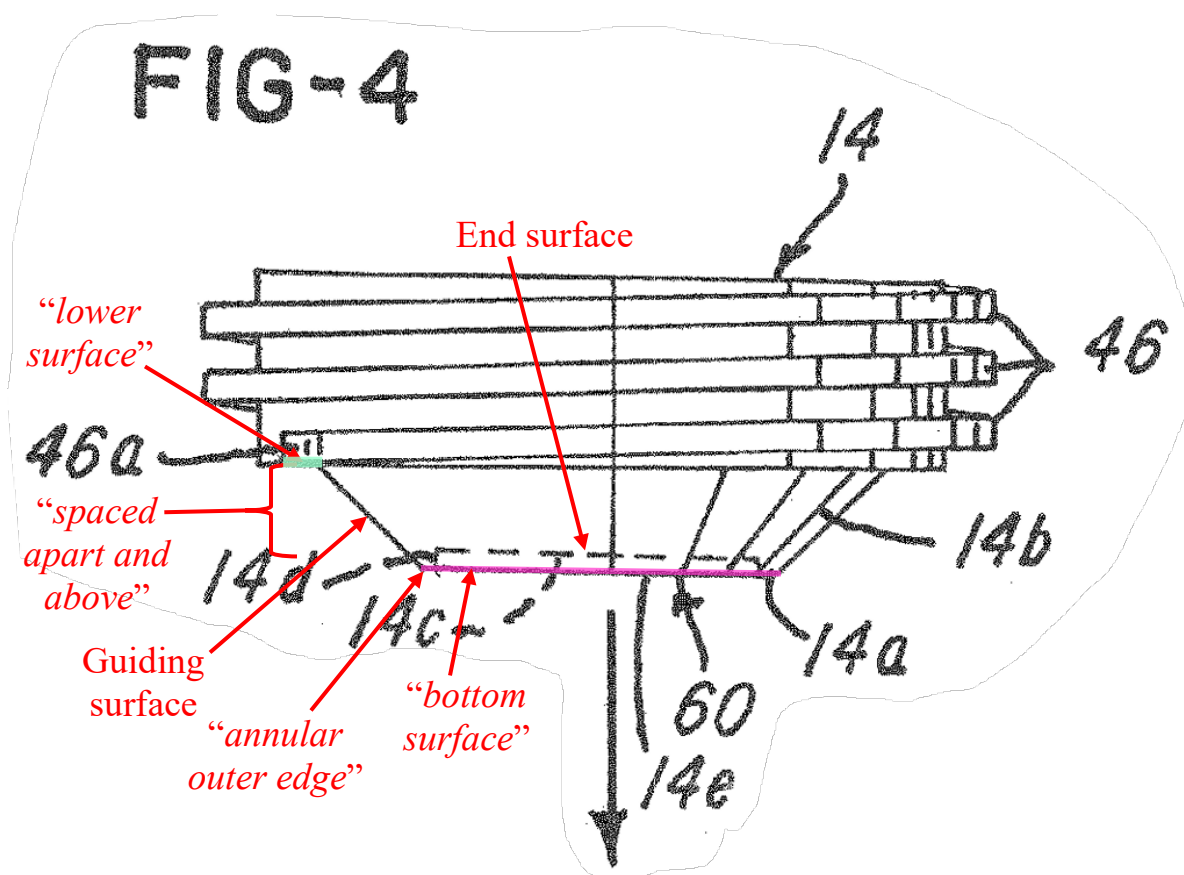
As explained above in limitation 1[d], Kirschman discloses a closure with a bottom surface that is substantially similar to the closure embodiments in the ’873 Patent. Kirschman discloses a bottom with an end surface further including a deformable ring. Ex.1005, [0043]-[0050]. A frustoconical guiding surface “*space[s]*” the “*lower surface*” of the leading edge portion (“*start structure*”)

“*apart and above*” both the end surface 14c and the bottom edge 14e of the deformable ring (Ex.1003, ¶¶183). Below this spacing is shown under the first interpretation in which the end surface 14c is the “*bottom surface*” and the edge thereof is the “*annular outer edge*”:



Ex.1005, Fig. 4 (cropped and annotated)

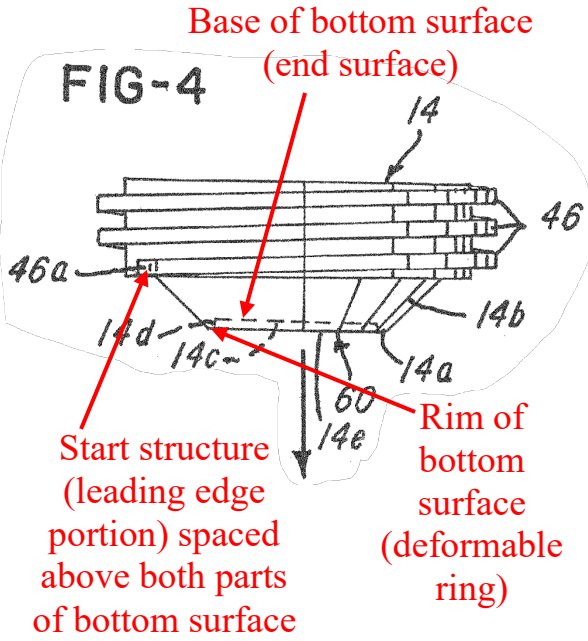
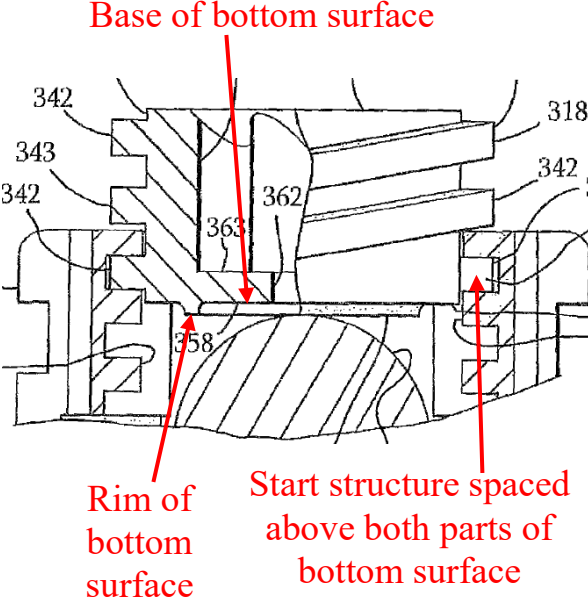
Below this spacing is shown under the second interpretation in which the bottom surface of the deformable ring is the “*bottom surface*” and the bottom edge 14e thereof is the “*annular outer edge*”:



Ex.1005, Fig. 4 (cropped and annotated)

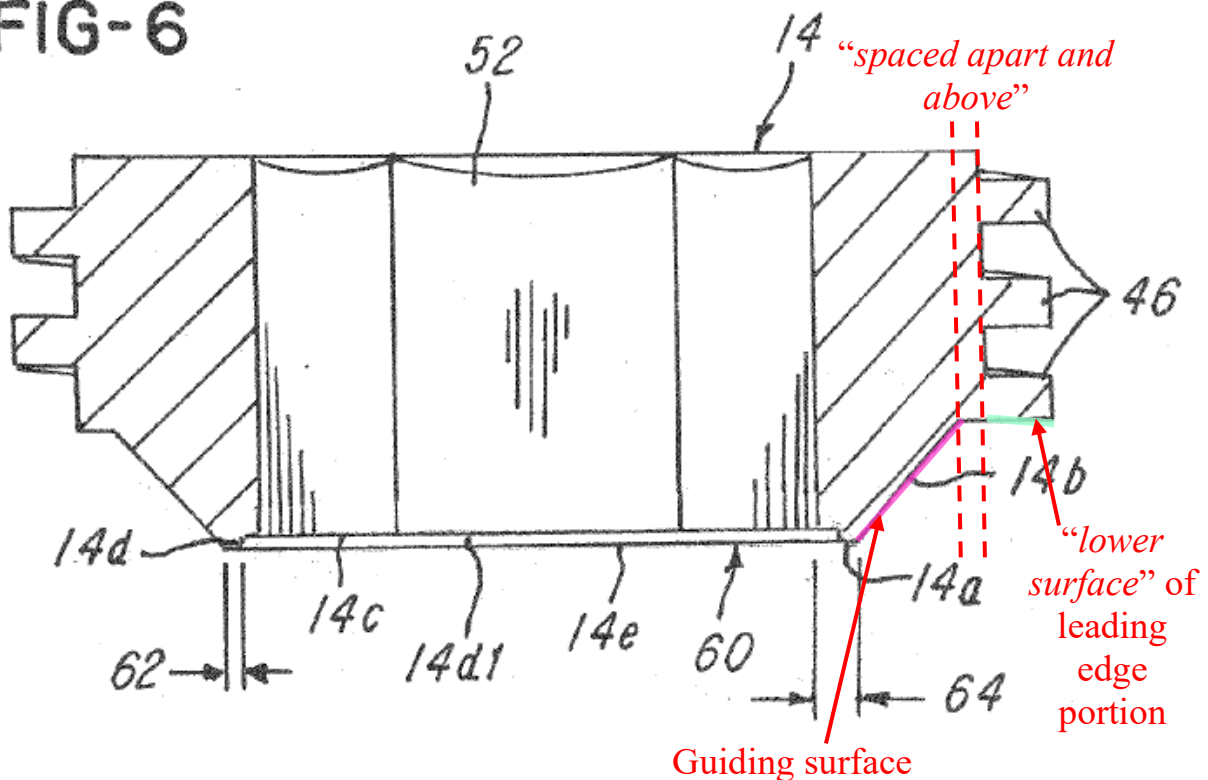
Accordingly, the “lower surface” of the leading edge portion is not “connected with” the end surface or the deformable ring surrounding it. Ex.1003, ¶185.

Thus, Kirschman’s cap includes the same claimed structure as the ’873 Patent’s closures (Ex.1003, ¶¶180-189):

| Kirschman (Ex.1005), Fig. 4<br>(annotated)                                                                                                                                                                                                                                                                                       | '873 Patent (Ex.1001), Fig. 11<br>(cropped and annotated)                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p><b>FIG-4</b></p> <p>Base of bottom surface (end surface)</p> <p>Start structure (leading edge portion) spaced above both parts of bottom surface</p> <p>Rim of bottom surface (deformable ring)</p> <p>14, 46a, 14d, 14c, 14a, 14b, 60</p> |  <p>Base of bottom surface</p> <p>Rim of bottom surface</p> <p>Start structure spaced above both parts of bottom surface</p> <p>342, 343, 362, 363, 318, 3, 358, 60</p> |

Moreover, to the extent PO asserts Kirschman’s guiding surface is the only surface that can be the claimed “*bottom surface*,” as set forth below, the leading edge portion is still “*spaced apart and above*” the top of the guiding surface “*so as to not be connected*” thereto. Ex.1003, ¶190. As shown in Fig. 6 below, the diameter of the cap at the top of the guiding surface is smaller than the diameter of the cap at the root of the threads (Ex.1003, ¶190):

FIG-6

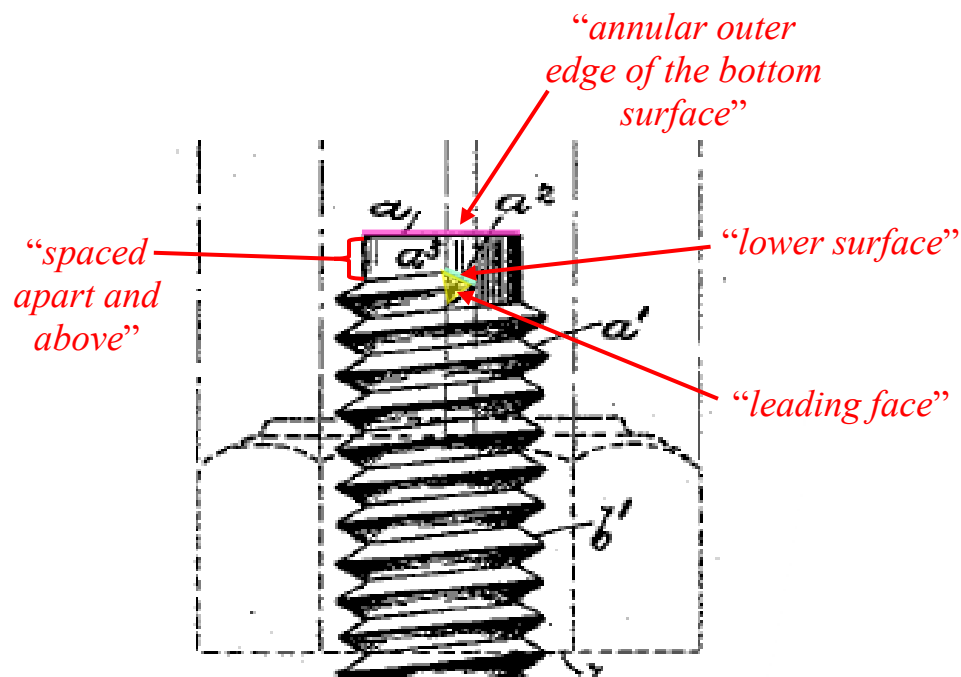


Ex.1005, Fig. 6 (annotated)

Thus, the lower surface of the leading edge portion is “spaced apart and above” the guiding surface such that it is not “connected” thereto. Ex.1003, ¶191.

To the extent PO argues that the embodiment in Figs. 1-7 of Kirschman does not explicitly teach that “the lower surface of the start structure [is] spaced apart and above the annular outer edge of the bottom surface,” it was well-known in the art that a cylindrical guiding surface would have been formed when removing the incomplete thread upward from the bottom surface during formation of a Higbee blunt thread start. Ex.1003, ¶192; see ¶¶51-76 (citing, e.g., Ex.1010, Ex.1011, Ex.1012).

For example, Higbee describes “terminating the thread below the face-level of the cylinder or annulus on which it is formed” such that there is a “cylindrical extension...between the thread end  $a^2$  and the bolt end  $a$ .” Ex.1006, 1:40-42, 1:69-71; *see* limitation 1[d]. Accordingly, “the thread end begins at some little distance below the face  $a$ ” (“*spaced apart and above*”) (Ex.1006, 1:81-83):



**Ex.1006, Fig. 1 (cropped and annotated)**

As explained above in limitation 1[d], a POSITA would have been motivated to modify Kirschman’s guiding surface to be cylindrical as described in Higbee, thereby spacing Kirschman’s leading edge portion above the bottom surface. Ex.1003, ¶195. This would have included spacing the leading edge portion

above the deformable ring and the end surface (as already described) or spacing the leading edge portion above the guiding surface. Ex.1003, ¶195.

Therefore, because Kirschman discloses a guiding surface, which can be modified to be cylindrical as disclosed in Higbee, that separates the deformable ring and end surface from the leading edge portion of the cap threads, Kirschman renders obvious limitation 1[h]. Ex.1003, ¶¶178-196.

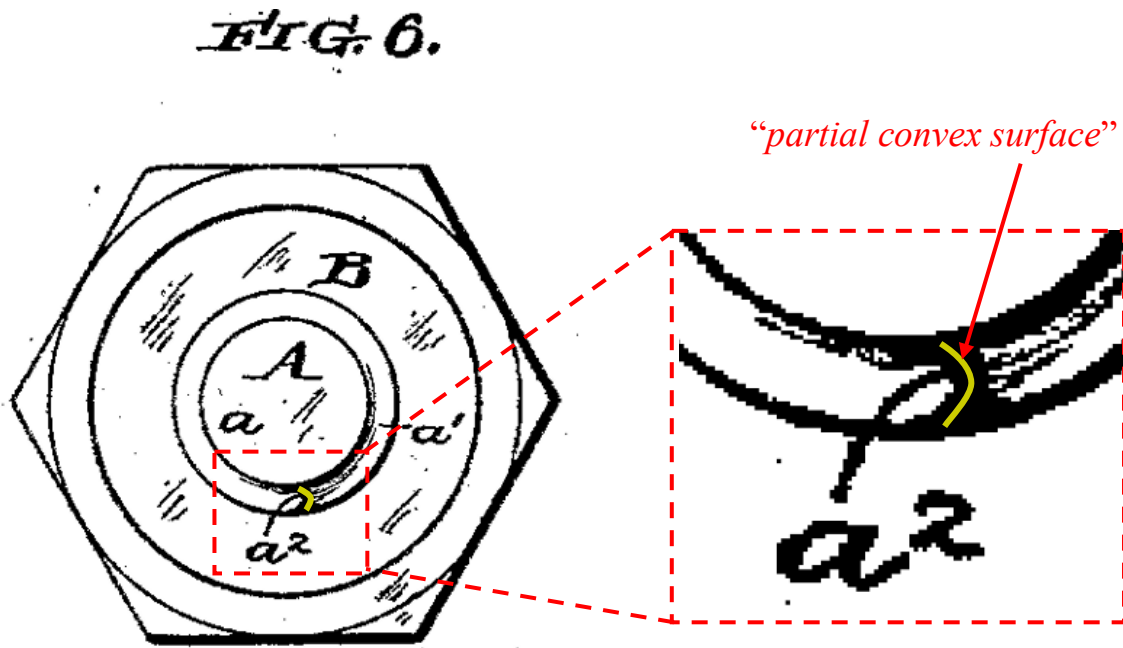
### **3. Claim 2**

**2[a] *The medical implant assembly of claim 1, wherein the at least one partial curvate surface is one of a partial concave surface or a partial convex surface.***

A POSITA would have known that Fig. 3 of Kirschman illustrates the face (“*leading face*”) of the leading edge portion curves outward to form a “*partial convex surface*” (Ex.1003, ¶199):



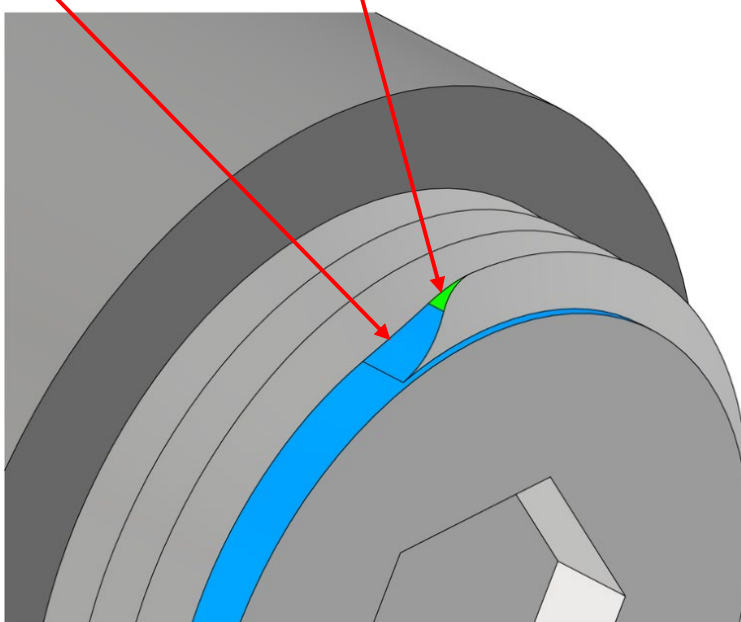
“partial convex surface” (Ex.1006, 1:93-94; Ex.1003, ¶201):



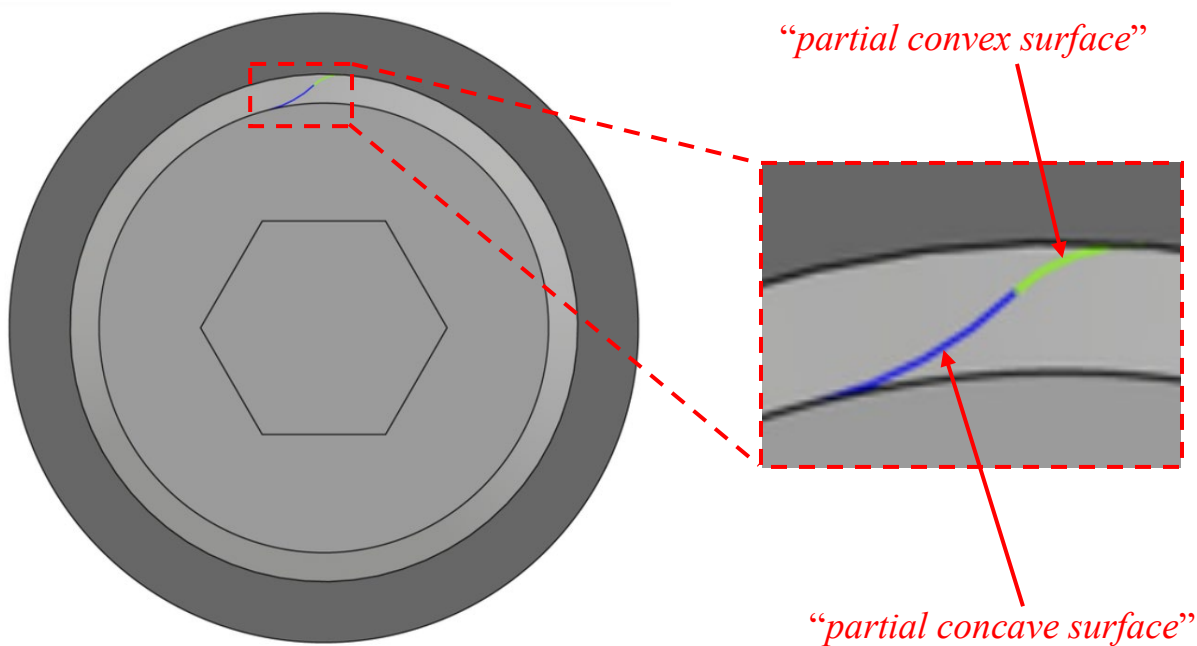
**Ex.1006, Fig. 6 (annotated)**

Additionally, a POSITA would have understood how to form a blunt thread start with a convex and concave surface. Ex.1003, ¶202; *see* limitation 1[g]. A POSITA would have known that blunt thread starts are generally formed by removing the incomplete portion of the thread with a circular tool such that a concave surface is formed. Ex.1003, ¶202. Because a fully-concave leading face would have formed a sharp edge at the crest, it was also well-known to round off the edge along the crest using the same circular tool such that a convex surface is formed at the crest (Ex.1003, ¶203), as shown in the below graphics provided in Mr. Drewry’s Declaration:

*“partial concave surface”*   *“partial convex surface”*



**Ex.1003, ¶203**



**Ex.1003, ¶203**

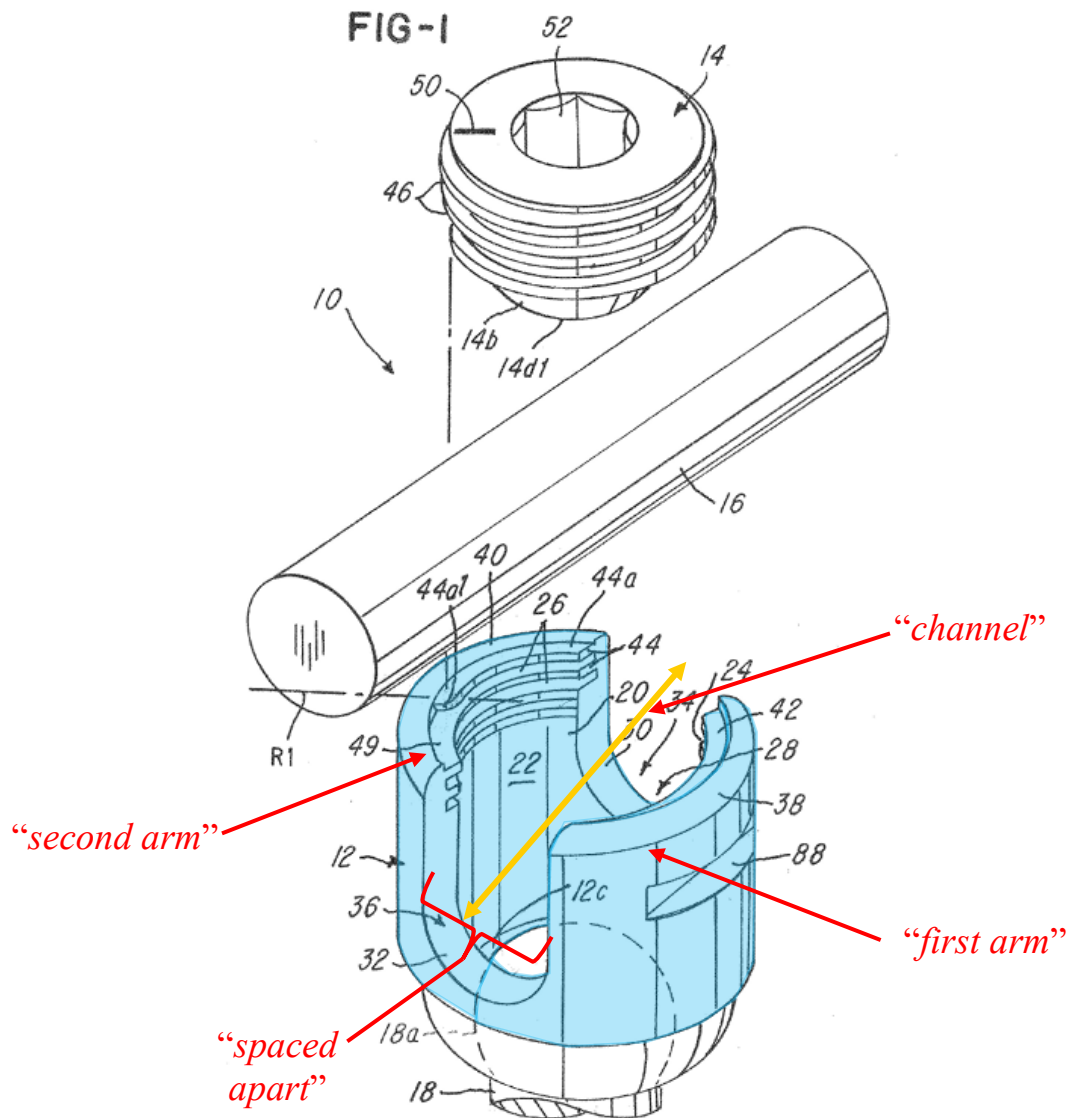
This would have smoothed out the leading face, thereby preventing the threads from cutting the surgeon's glove or irritating the patient. Ex.1003, ¶203. Accordingly, a POSITA would have known that the leading face would have had both a concave surface proximate the root and a convex surface proximate the crest. Ex.1003, ¶203; *see* ¶¶51-76.

Therefore, because Kirschman teaches a truncated leading edge portion with a convex face, Higbee teaches a convex rounded thread end, and a POSITA would have known how to form a blunt thread start with a concave and convex surface, Kirschman renders obvious limitation 2[a]. Ex.1003, ¶¶197-204.

#### 4. Claim 4

**4[a] *The medical implant assembly of claim 1, wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm.***

Kirschman's receiver includes a first arcuate wall ("*first arm*") and a second arcuate wall ("*second arm*") disposed between the U-shaped walls that define the rod-receiving channel ("*channel*") (Ex.1005, [0035]):

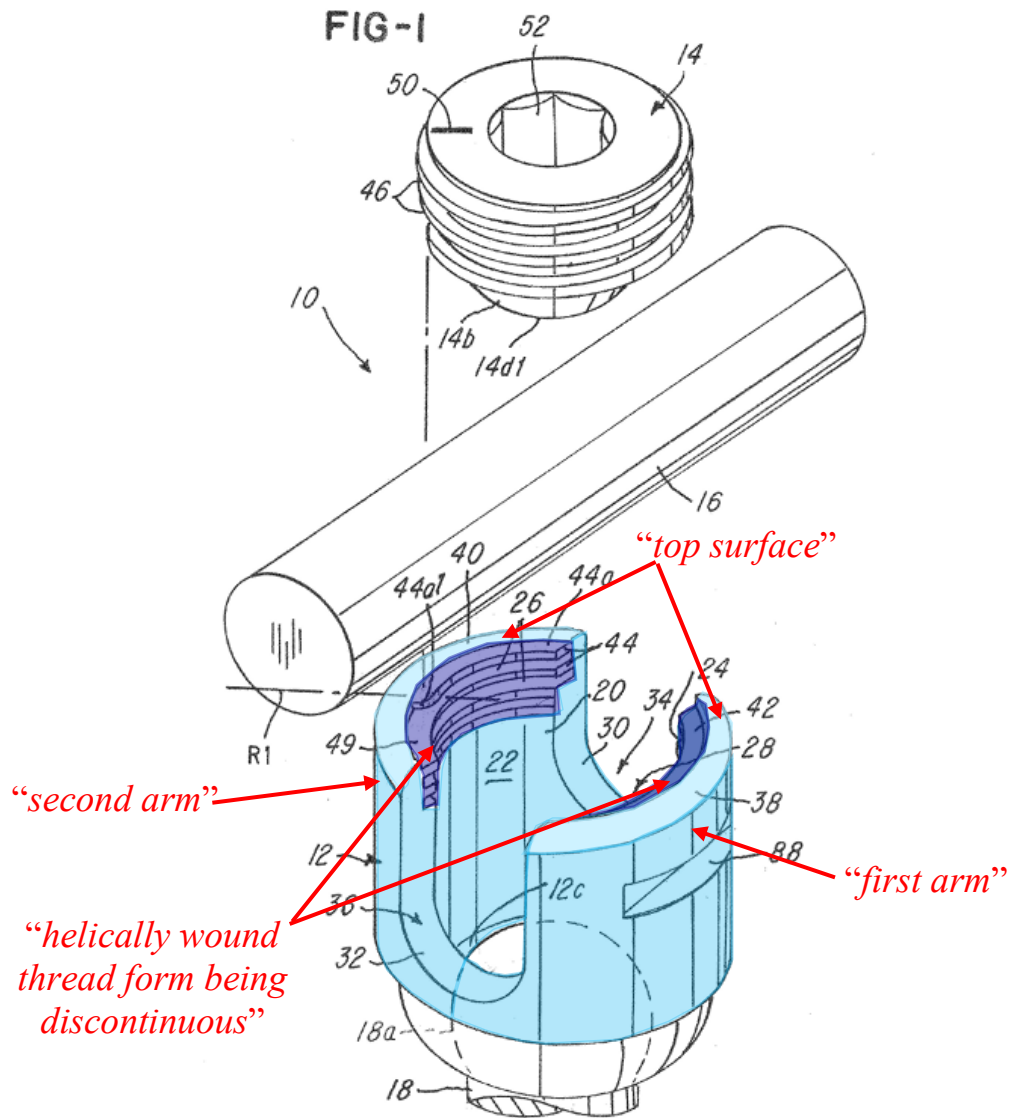


Ex.1005, Fig. 1 (annotated)

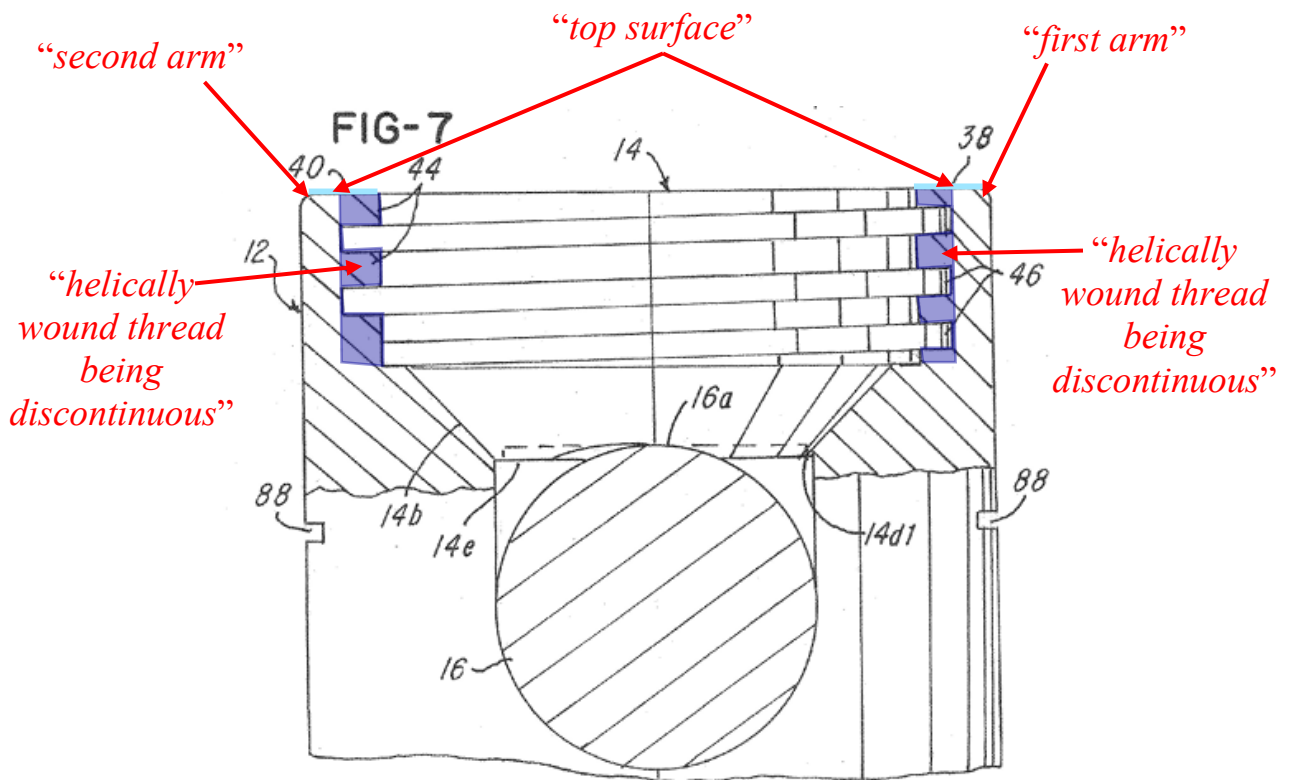
Kirschman’s “first arcuate wall 38 comprises first arcuate wall threads 42 and the second arcuate wall 40 comprises second arcuate wall threads 44” that “cooperate to define the receiver threads” (“*helically wound thread*”). Ex.1005, [0036]. Because the arcuate wall threads are split between the arcuate walls, the receiver threads are “*discontinuous*.” Ex.1003, ¶209. Moreover, the “*top surface*”

of the receiver is disposed on the tops of the arcuate walls (“[first]/[second] arm”)

(Ex.1003, ¶210):



Ex.1005, Fig. 1 (annotated)



**Ex.1005, FIG. 7 (annotated)**

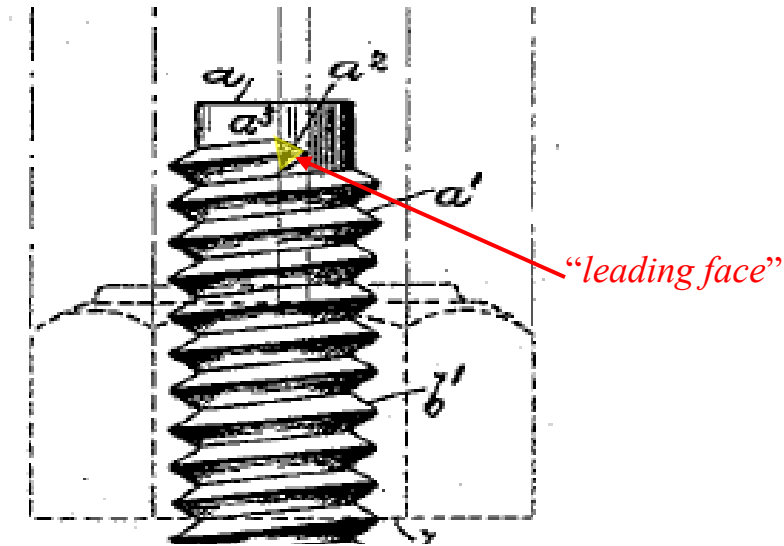
Therefore, because Kirschman discloses a first arcuate wall with first arcuate wall threads and second arcuate wall with second arcuate wall threads spaced by a channel, Kirschman renders obvious limitation 4[a]. Ex.1003, ¶¶205-211.

## 5. Claim 7

**7[a] *The medical implant assembly of claim 1, wherein the leading face of the start structure includes at least a partial planar surface.***

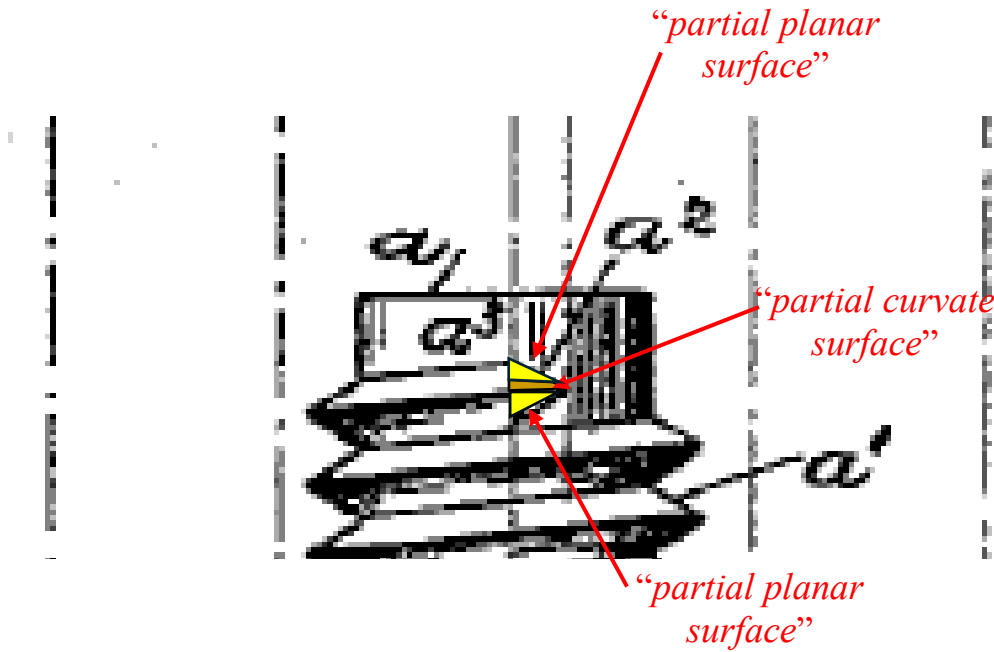
It would have been obvious to a POSITA that the leading face of a start structure would have included a partial planar surface. Ex.1003, ¶214. For example, Higbee explains that "[t]he exact form of the thread end is not very

important so long as it is blunt” and “may be cut off on an oblique plane” as shown in Fig. 1 (Ex.1006, 1:89-94):



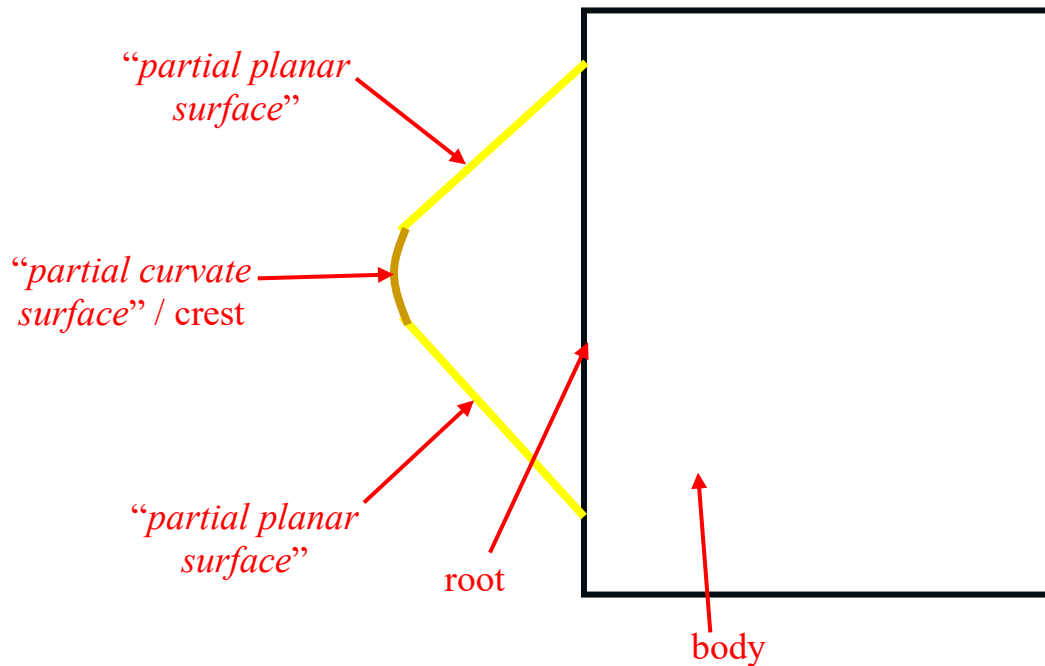
**Ex.1006, Fig. 1 (cropped and annotated)**

A POSITA would have known that sharp edges in medical devices could have cut the hand/glove of the surgeon or irritate the patient. Ex.1003, ¶215. Thus, a POSITA would have removed these sharp edges in multiple ways. Ex.1003, ¶215. For example, a POSITA would have used a circular tool to round/smooth the sharp edges of the thread or deburred the screw to remove all sharp edges, including those on the thread. Ex.1003, ¶215. Mr. Drewry modified Fig. 1 of Higbee below to illustrate the leading face with a curved surface between the oblique planar surfaces after the sharp edge therebetween is removed:



**Ex.1003, ¶216**

Moreover, Mr. Drewry prepared the below illustration showing a side view of the above leading face:



**Ex.1003, ¶216**

Thus, instead of using the rounded blunt thread start described in Higbee (Fig. 6), a POSITA would have alternatively combined the threads of Kirschman's cap with the blunt thread start having the oblique planes as shown in Fig. 1 of Higbee modified to round the sharp edge because "[t]he exact form of the thread end is not very important so long as it is blunt." Ex.1006, 1:89-92; Ex.1003, ¶217; *see* Ex.1003, ¶¶51-76.

Therefore, because Higbee discloses a blunt thread start with oblique planes and a POSITA would have known that the sharp edges would have been rounded, Kirschman renders obvious limitation 7[a]. Ex.1003, ¶¶212-218.

**C. Ground 2: Claims 5-6 are Obvious over Kirschman in view of Johnson.**

**1. Summary of Johnson**

Johnson describes a “[r]eceiver member 212 ha[ving] a lower portion 212a and an upper portion 212b separated by a thinned section 212c” and divided into two “[b]ranches 250, 252 [that] further define a substantially U-shaped channel 254.” Ex.1007, [0051]-[0052]. The “upper portion 212b may be cut or sheared off or otherwise removed from lower portion 212a” by breaking the thinned portion therebetween. Ex.1007, [0056]. The “internal threads 256 are formed in branches 250, 252 through substantially the entire length of upper portion 212b and into lower portion 212a” for cooperating with a closure. Ex.1007, [0052]; Ex.1003, ¶¶219-225.

Johnson’s receiver is shown below in Figs. 11-12:

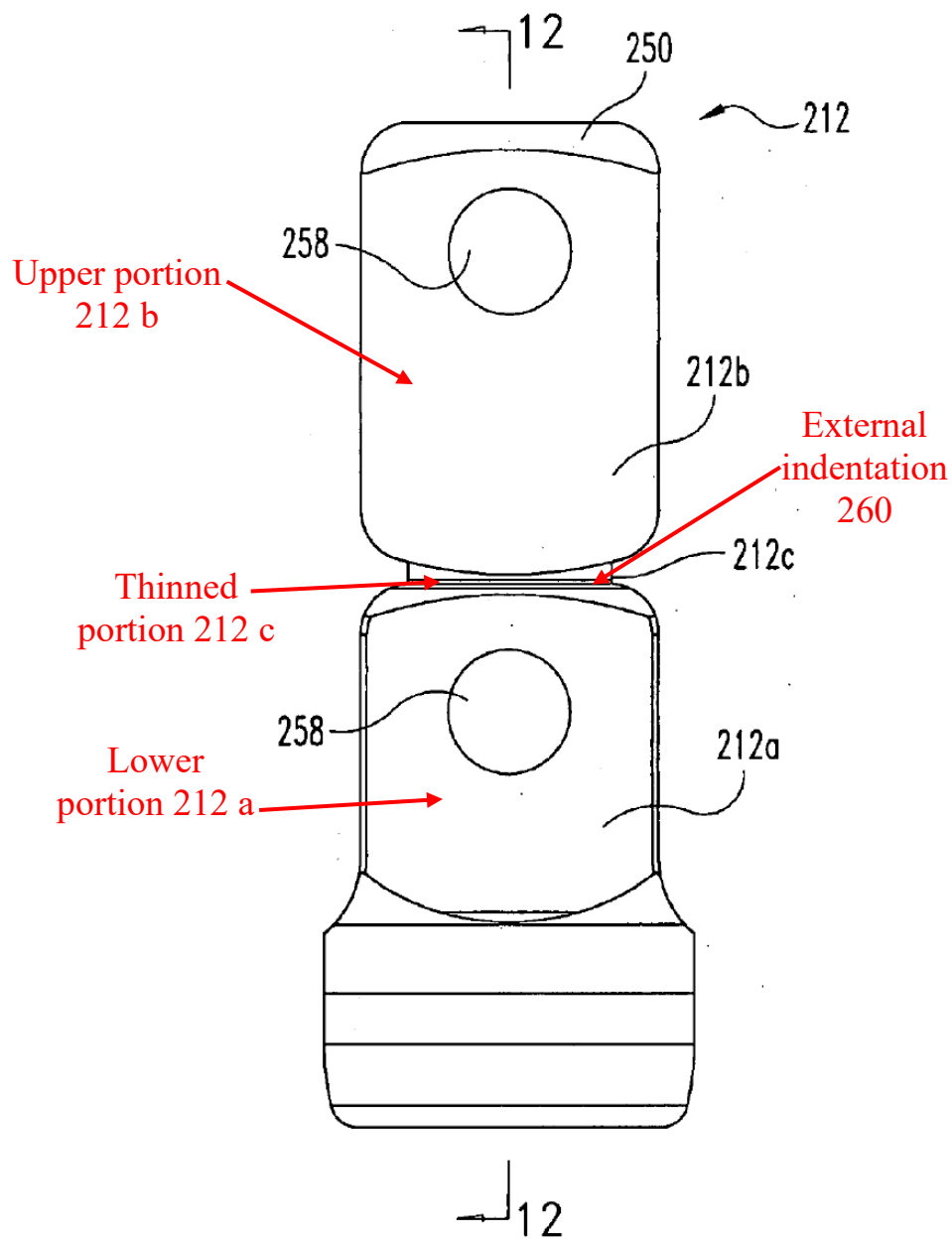
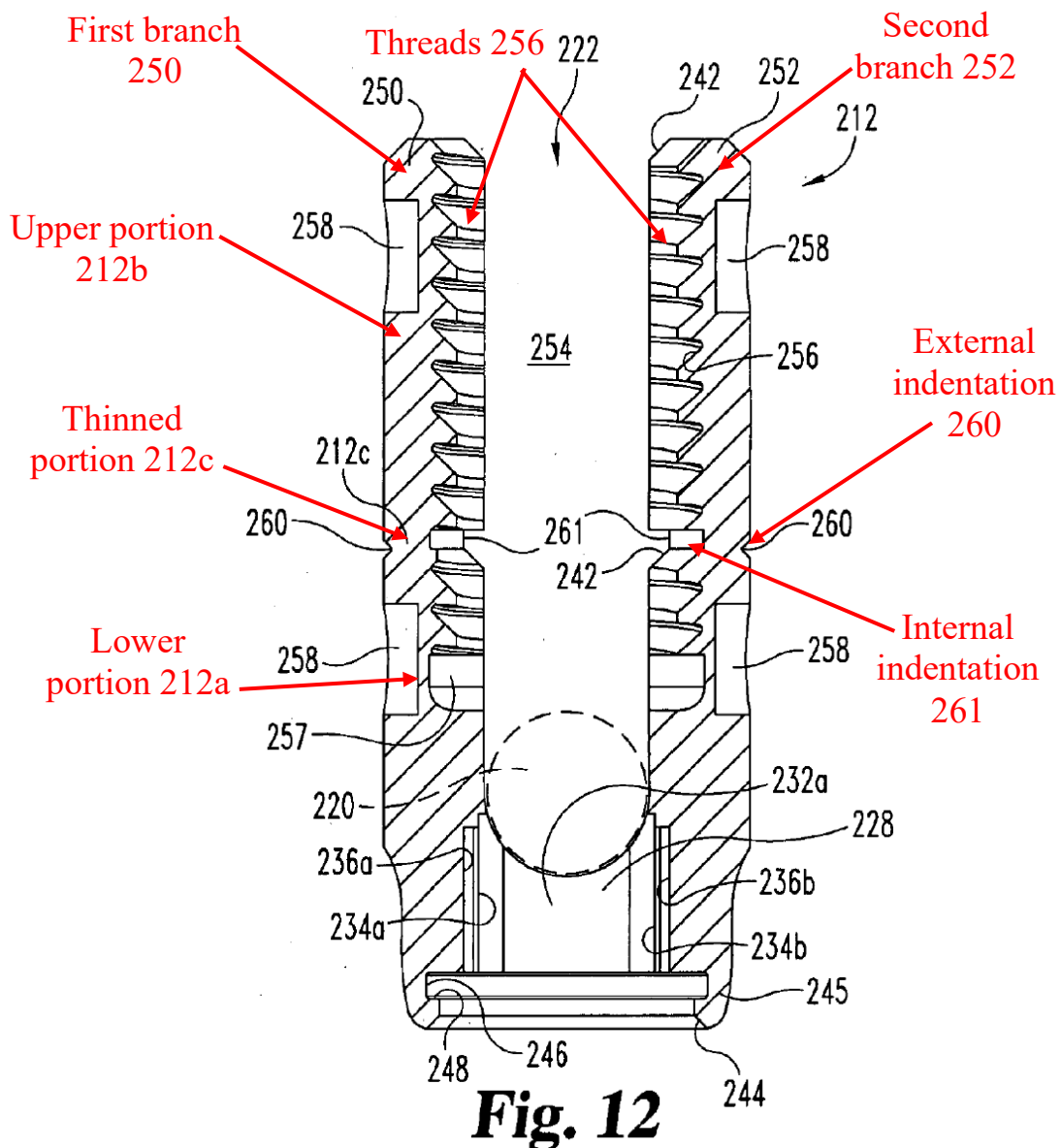


**Fig. 11**

Ex.1007, Fig. 11 (annotated)



**Ex.1007, Fig. 12 (annotated)**

## 2. Reasons to Combine Kirschman and Johnson

As an initial matter, Kirschman and Johnson are analogous art to the '873 Patent because they are in the same field of endeavor as the '873 Patent. The '873

Patent “is directed to...closure mechanisms for use with open bone anchors in spinal surgery.” Ex.1001, 1:27-31. Similarly, Kirschman “relates to a spinal implant system...having [] a lock aid that provides...enhanced fixation and locking of a cap in a receiver of the implant.” Ex.1005, [0002]. Moreover, Johnson “relates to anchors and other implants for use in tissue, to be placed during orthopedic surgery,” specifically “for correcting and stabilizing damage or malformation of...the vertebrae of the spine.” Ex.1007, [0001]-[0002]. Thus, like the ’873 Patent, Kirschman and Johnson are related to the field of bone anchors for use in spinal surgery. Ex.1003, ¶226.

A POSITA would have found it obvious to combine Kirschman and Johnson to add Johnson’s well-known break-off extensions to the arcuate walls of Kirschman’s receiver to further improve seating of the rod. Ex.1003, ¶227.

Kirschman explains that “[d]uring the surgical procedure the surgeon must forcefully seat the rod into the tulip via rotation of the locking cap,” which “affects the desired correction of the spine.” Ex.1005, [0005]. Accordingly, Kirschman proposes a variety of “locking aid[s]” that, for example, provide “enhanced locking,” “facilitat[e] guiding and mounting the cap on the receiver,” and “facilitat[e] locking the cap on the receiver and thereby locking a rod to a screw.” Ex.1005, [0012]-[0017]. Kirschman contemplates that, “[a]lthough not shown, it should be appreciated that other conventional components may be used with the

receiver.” Ex.1005, [0051]. Therefore, a POSITA would have been motivated to look elsewhere in the art for other well-known components that would further improve seating of the rod in the tulip/receiver. Ex.1003, ¶228.

Johnson describes one of these well-known components: break-off extensions. Ex.1003, ¶229. Johnson’s receiver member “includes a pair of upright branches” with a channel therebetween, “a portion of each branch form[ing] at least a part of upper portion 212b of receiver member.” Ex.1007, [0052]. The “upper portion 212b may be cut or sheared off or otherwise removed from lower portion” of the receiver after locking the rod in the channel via a compression member. Ex.1007, [0056]. The upper portion (*i.e.* breakoff extensions) of the receiver branches/walls allow the surgeon to insert the rod without “bend[ing]...or us[ing] a special reducing tool to insert it into the lower end of a receiving channel,” thereby improving seating of the rod in the receiver. Ex.1007, [0055].

Thus, it would have been obvious to a POSITA to modify the arcuate walls of Kirschman’s receiver to include Johnson’s well-known breakoff extensions to further improve seating/locking of the rod in the receiver. Ex.1003, ¶230.

Johnson explains how these breakoff extensions may be formed on the branches. The upper portion can be “integrally formed with lower portion,” “separately made and joined together, or otherwise formed.” Ex.1007, [0053]. A POSITA would have reasonably expected that Kirschman’s receiver could have

been formed with breakoff extensions as described in Johnson. Ex.1003, ¶231. As one example, a POSITA would have formed Kirschman's receiver with two extended arcuate walls and material could have been removed on the inner/outer part of the walls to form a groove, thereby defining an upper portion/breakoff extension on each wall. Ex.1003, ¶231 (alternatively, breakoff extensions would be attached to the arcuate walls via a thinned portion). A POSITA would have known that threads could have been formed on the inner surface of the walls according to well-known techniques before or after forming the breakoff extensions so that Kirschman's cap could have been continuously threaded from the breakoff extensions to the walls. Ex.1003, ¶¶231-232.

### 3. Claim 5

**5[a] *The medical implant assembly of claim 4, wherein the first arm includes a first breakoff extension coupled to the top surface of the first arm, and the second arm includes a second breakoff extension coupled to the top surface of the second arm,***

Johnson discloses a “[r]eceiver member 212 ha[ving] a lower portion 212a and an upper portion 212b separated by a thinned section 212c” divided between two branches (Ex.1007, [0051]-[0052] (“A portion of each branch 250, 252 forms at least a part of lower portion 212a” and “at least a part of upper portion 212b of receiver member 212.”)):

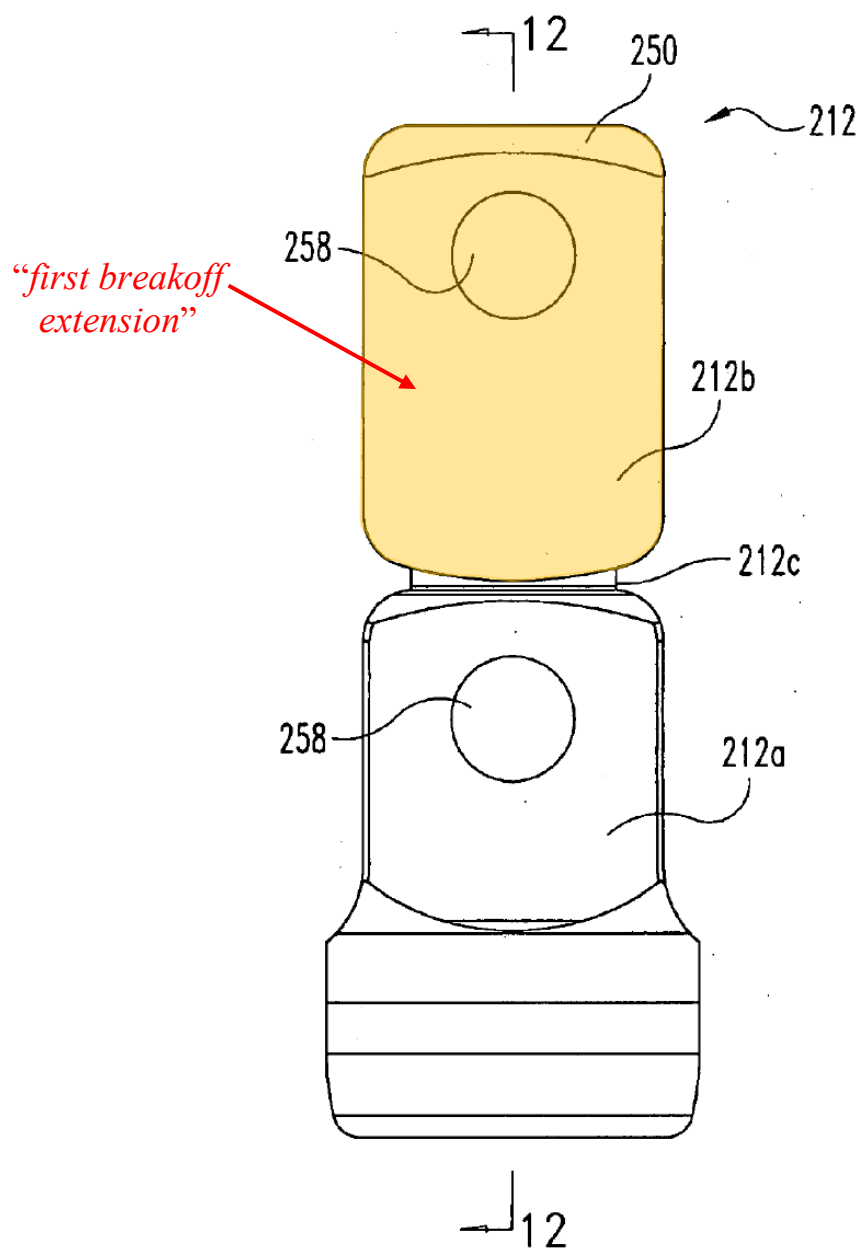


**Fig. 11**

Ex.1007, Fig. 11 (annotated)

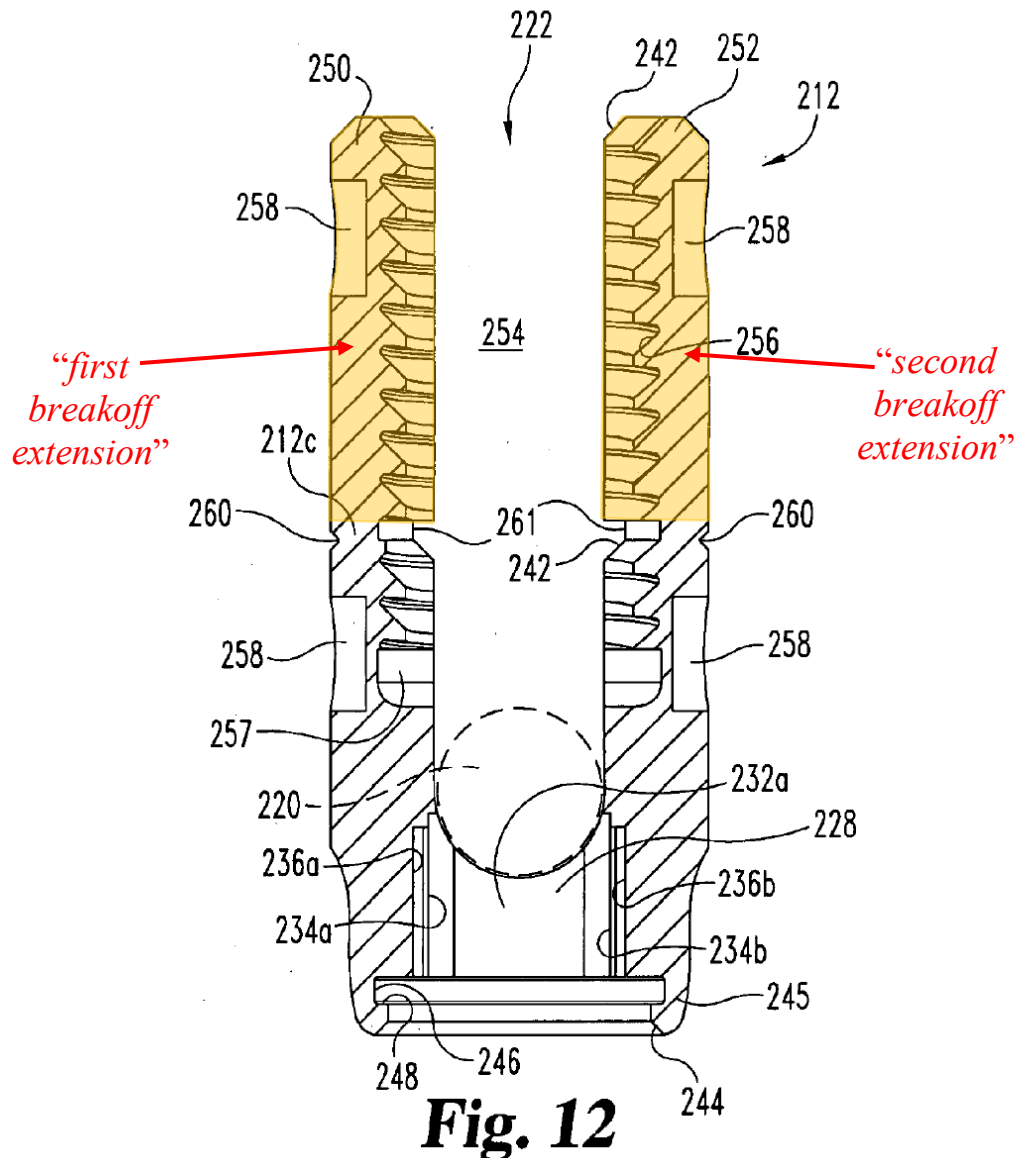


**Fig. 12**  
**Ex.1007, Fig. 12 (annotated)**

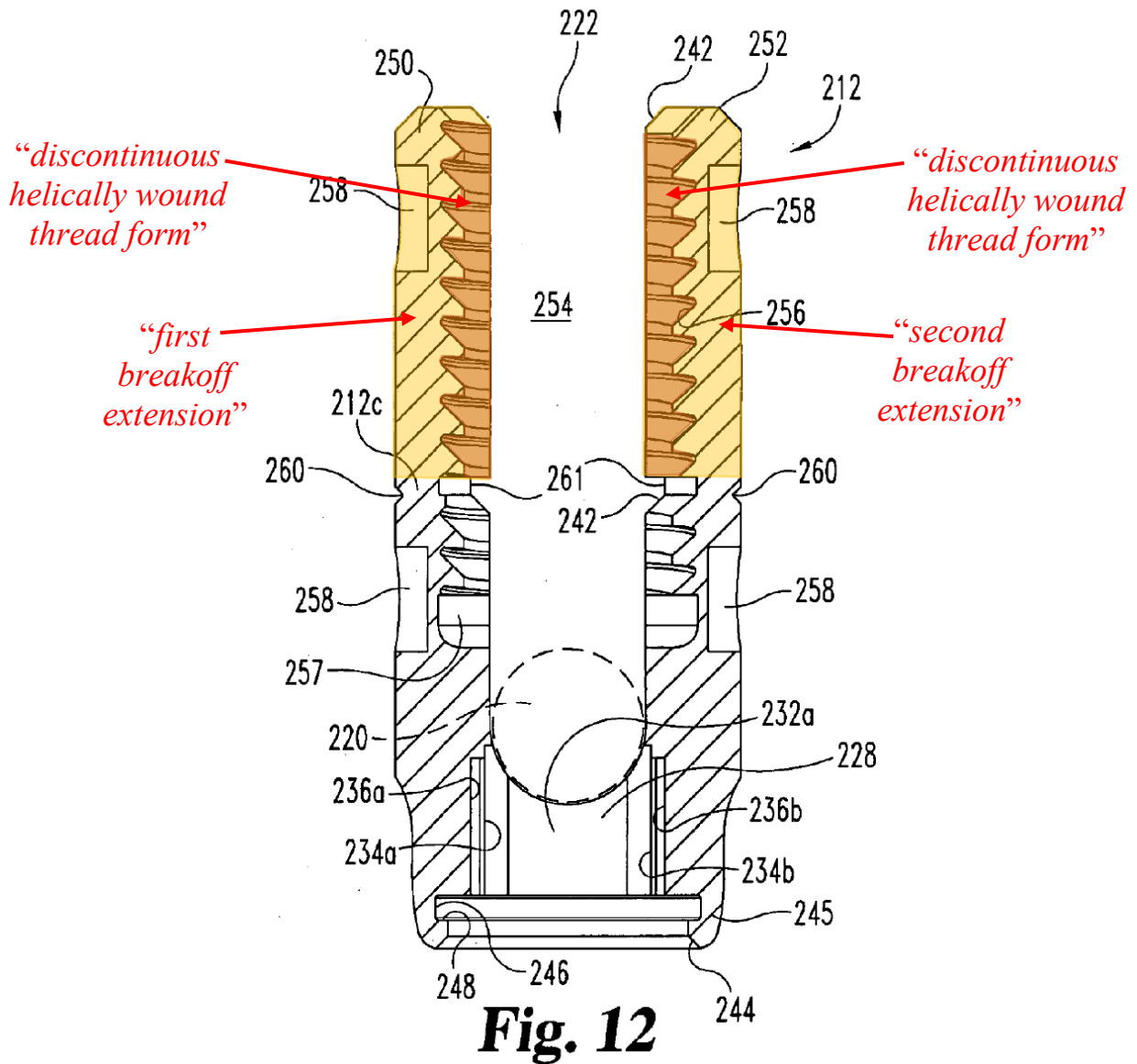
The upper portion (“*first*” and “*second breakoff extension*”) “may be cut or sheared off or otherwise removed from lower portion.” Ex.1007, [0056].

As described above in Section VIII.C.2., a POSITA would have been motivated to form Kirschman’s arcuate walls with Johnson’s upper portion.

Therefore, because Johnson teaches a removable upper portion, Kirschman and Johnson render obvious limitation 5[a]. Ex.1003, ¶¶233-240.

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

Johnson's receiver includes "internal threads" that are "essentially continuous from upper portion 212b to lower portion 212a" so that "a set screw threaded into upper portion 212b can be threaded along opening 222 into lower portion 212a" (Ex.1007, [0053]):



Ex.1007, Fig. 12 (annotated)

As described above in Section VIII.C.2., a POSITA would have been motivated to form threads that continuously extend from Johnson's upper portion to Kirschman's arcuate wall so that the cap ("plug") can be "rotatably

*transfer[red]” “therebetween.”*

Therefore, because Johnson discloses internal threads that extend continuously from the upper portion into the lower portion so that a set screw can be threaded therebetween, Kirschman and Johnson render obvious limitation 5[b]. Ex.1003, ¶¶241-245.

#### 4. Claim 6

**6[a] *The medical implant assembly of claim 5, wherein a first outer radiused notch is located at a convergence of the first breakoff extension and the first arm at the top surface thereof, and a second outer radiused notch is located at a convergence of the second breakoff extension and the second arm at the top surface thereof, the first outer radiused notch being located opposite a first inner radiused recess, and the second outer radiused notch being located opposite a second inner radiused recess.***

The thinned portion that “separates upper portion 212b and lower portion 212a” of Johnson’s receiver “includes an external indentation” and “an interior indentation” on each branch. Ex.1007, [0054]. As shown in Figs. 11-12, the external indentations (“*[first]/[second] outer radiused notch*”) are “*located opposite*” the internal indentations (“*[first]/[second] inner radiused recess*”):

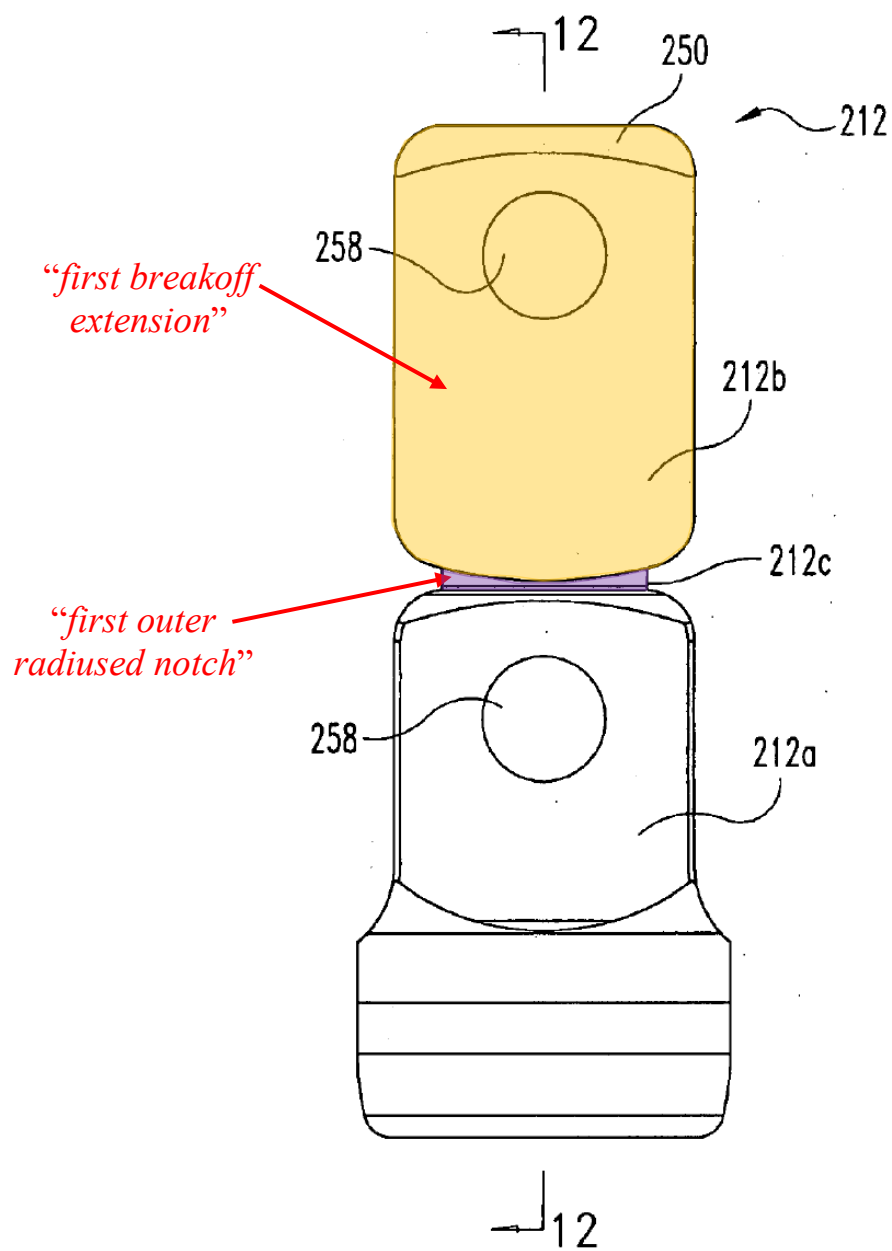
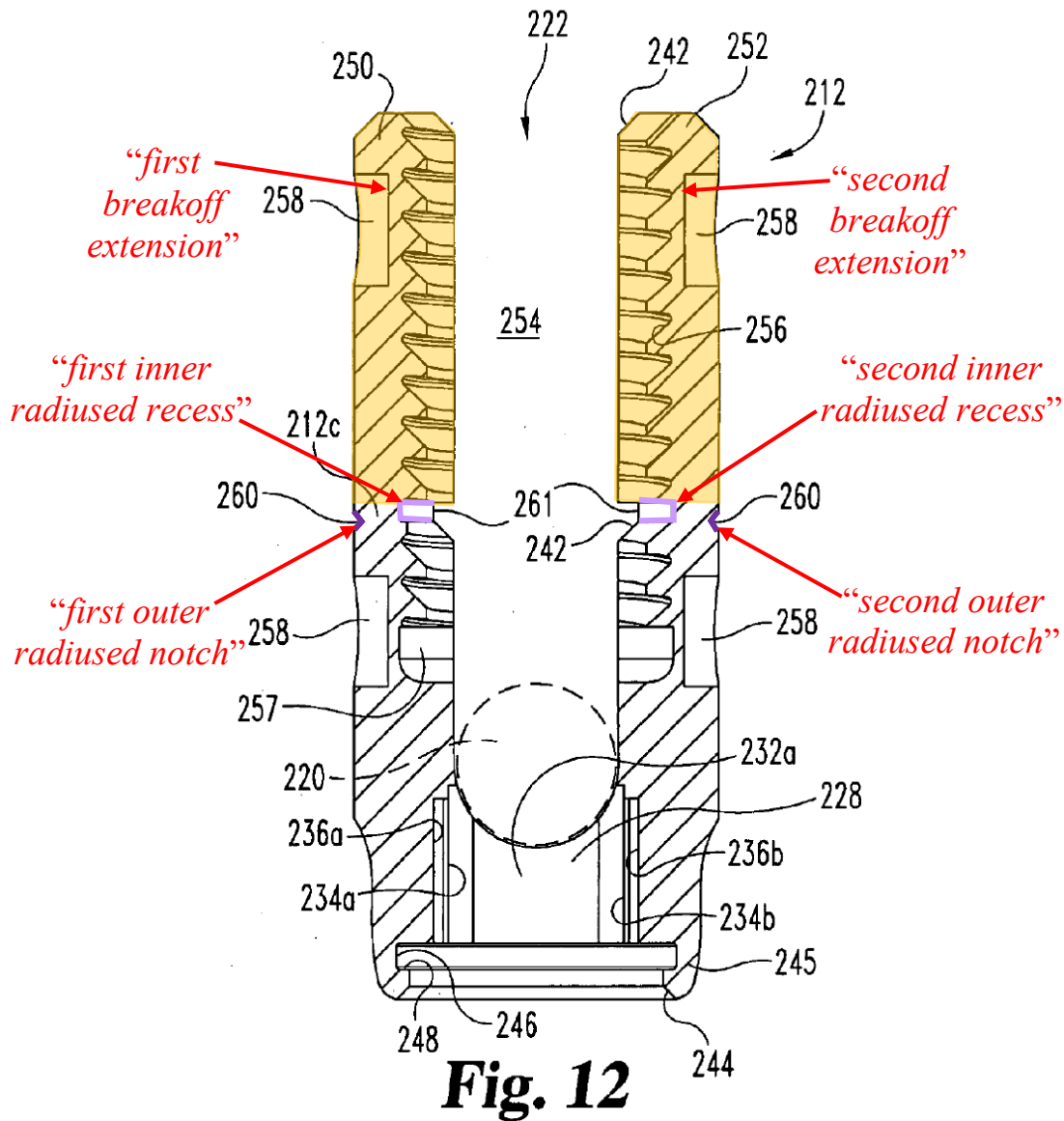


**Fig. 11**

Ex.1007, Fig. 11 (annotated)



**Ex.1007, Fig. 12 (annotated)**

As described above in Section VIII.C.2., a POSITA would have been motivated to form Johnson's thinned portion between Kirschman's arcuate walls and Johnson's removable upper portion.

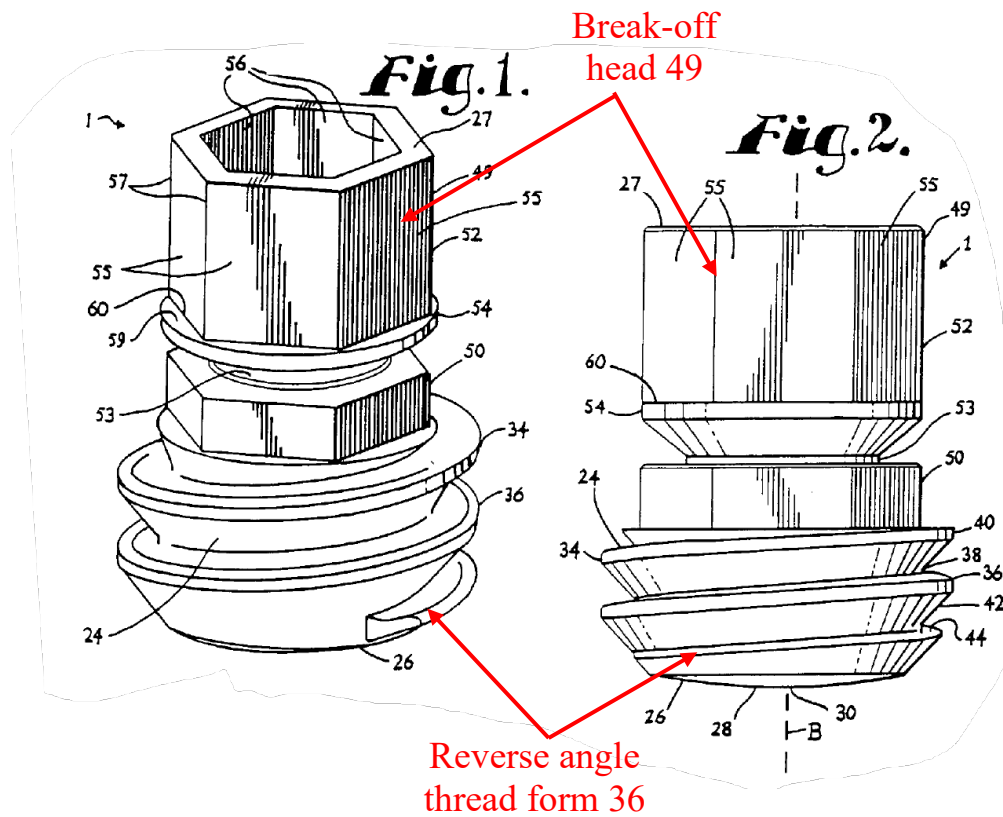
Therefore, because Johnson discloses a thinned section with outer indentations opposite inner indentations, Kirschman and Johnson render obvious limitation 6[a]. Ex.1003, ¶¶246-251.

**D. Ground 3: Claims 8-11 are Obvious over Kirschman in view of the '477 Publication.**

**1. Summary of the '477 Publication**

The '477 Publication is directed to “[a] closure for use in conjunction with an open receiver of a medical implant for capturing and locking a rod member in the implant.” Ex.1008, Abstract. The '477 Publication discloses two closure embodiments. Both embodiments include a “break-off head” that “is designed to break away from the remainder of the closure 1 subsequent to a predetermined torque being applied to the driving head.” Ex.1008, [0032] (first embodiment); *see* [0042] (second embodiment).

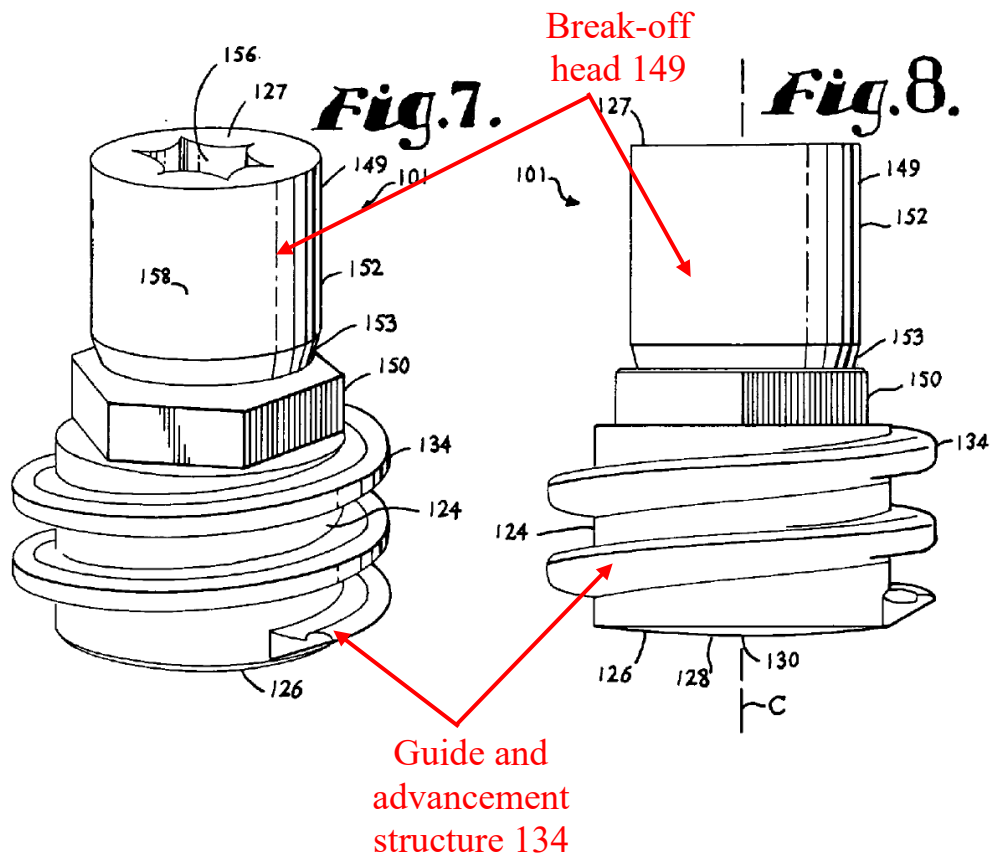
The first embodiment shown in Figs. 1-4 includes “a helically wound reverse angle thread form” that “resists splaying in the bone screw receiver” (Ex.1008, [0030]):



**Ex.1008, Figs. 1-2 (annotated)**

The second embodiment shown in Figs. 7-10 is similar to the first embodiment, but includes a different thread form having a bevel at the thread start.

(Ex.1008, [0039]-[0041]; Ex.1003, ¶¶252-261):



**Ex.1008, Figs. 7-8 (annotated)**

## **2. Reasons to Combine Kirschman and the '477 Publication**

As an initial matter, the '477 Publication is analogous art to the '873 Patent because both are in the same field of endeavor. The '873 Patent “is directed to...closure mechanisms for use with open bone anchors in spinal surgery.”

Ex.1001, 1:27-31. Similarly, the '477 Publication is directed to “[a] closure for use in conjunction with an open receiver of a medical implant for capturing and locking a rod member in the implant,” specifically for “spinal surgery.” Ex.1008, Abstract, [0003]. Thus, like the '873 Patent, the '477 Publication is related to the

field of bone anchors for use in spinal surgery. Ex.1003, ¶262.

A POSITA would have found it obvious to combine Kirschman and the '477 Publication to add the '477 Publication's well-known closure features (beveled thread start, reverse angle thread, and/or break-off extension) to Kirschman's cap. Ex.1003, ¶263.

Kirschman explains that “[d]uring the surgical procedure the surgeon must forcefully seat the rod into the tulip via rotation of the locking cap” which “affects the desired correction of the spine.” Ex.1005, [0005]. Accordingly, Kirschman proposes a variety of “locking aid[s]” that, for example, provide “enhanced locking,” “facilitat[e] guiding and mounting the cap on the receiver,” and “facilitat[e] locking the cap on the receiver and thereby locking a rod to a screw.” Ex.1005, [0012]-[0017]. Kirschman contemplates that “[a]lthough not shown, it should be appreciated that other conventional components may be used with the receiver.” Ex.1005, [0051]. Therefore, a POSITA would have been motivated to look elsewhere in the art for other well-known components that would further improve locking of the cap on the receiver. Ex.1003, ¶264.

The '477 Publication describes some of these well-known components: beveled thread starts, reverse angle threads, and break-off heads. First, a POSITA would have recognized that the '477 Publication's beveled thread start would have improved engagement of the closure's threads with the threads of the receiver.

Ex.1003, ¶265. Moreover, the '477 Publication's reverse angle thread "resists 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."

Ex.1008, [0030]. Thus, these threads improve locking of the closure on the receiver. *See* Ex.1008, [0005] ("[M]any of the prior art devices cannot be sufficiently tightened or torqued against the rod member so as to lock the rod from both axial and rotational movement relative to the implant.").

Additionally, "[t]he breaking away" of the '477 Publication's break-off head "provides for a low profile" of the closure, thereby preventing the closure from extending substantially above the receiver. Ex.1008, [0008], [0005].

Thus, it would have been obvious to a POSITA to modify Kirschman's cap to include one or more of the '477 Publication's components to further improve locking of the cap on the receiver. Ex.1003, ¶¶265-266.

A POSITA would have had a reasonable expectation of success in forming a bevel on the leading edge portion of Kirschman's cap threads because this was well-known in the art. Ex.1003, ¶267 (citing Ex.1015, 864 ("In making a thread roll, the ends are beveled at an angle of 45 degrees.")).

Moreover, a POSITA would have reasonably expected that Kirschman's cap threads could have been formed as the '477 Publication's reverse angle thread

because forming closures with reverse angle threads had successfully been accomplished in the art (as recognized by the '873 Patent itself). Ex.1003, ¶268 (citing Ex.1001, 1:65-2:6 (“Known closures include...a variety of single start helically wound guide and advancement structures including, for example, thread forms having...reverse-angle...thread forms....”); Ex.1007, [0047] (“thread 112 [of the set screw] is a reverse angle thread as disclosed in U.S. Pat. No. 6,296,642 to Morrison et al., incorporated herein by reference in its entirety...”); Ex.1013, [0030] (“[T]he external thread 5 [of the set screw] illustrated preferably has about 45° reverse angle buttress thread form.”)). Thus, forming a reverse angle thread would have involved well-known techniques within the skill of a POSITA.

Ex.1003, ¶268.

Moreover, a POSITA would have had a reasonable expectation of success in adding the '477 Publication's break-off head to Kirschman's cap because forming caps with break-off heads had been successfully accomplished in the art. Ex.1003, ¶269 (citing Ex.1013, [0026]-[0027] (“A frangible portion 32 connects the upper portion 40 and the lower portion 42 of the set screw1. The frangible portion 32 is easily or readily ruptured, separated or broken when a pre-selected torque or force is applied.”); Ex.1014, [0051] (“The set screw 700 can further include a break off region 705 located between the cap 703 and threaded portion 701. As will be appreciated, the break off region 705 facilitates separation of the cap 703 from the

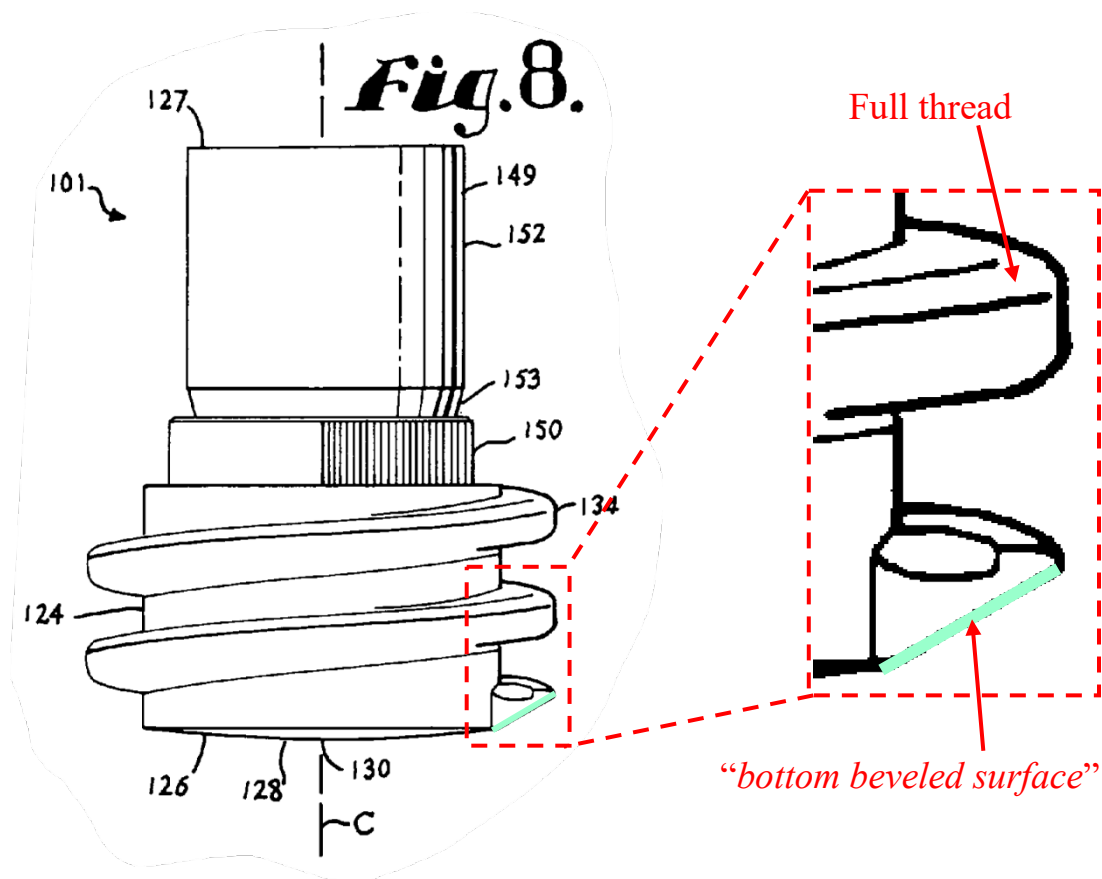
threaded portion 701 upon engaging the set screw 700 at a specified torque within the head portion 307.”)). Thus, forming the cap with a break-off head would have involved well-known techniques within the skill of a POSITA. Ex.1003, ¶¶269-270.

### 3. Claim 8

**8[a] *The medical implant assembly of claim 1, wherein the lower surface of the start structure includes a bottom beveled surface.***

It was well-known that a “*beveled*” surface is a surface that meets another at an angle other than 90°. *See* Ex.1003, ¶273 (citing Ex.1019, 174 (“bevel” “The angle or inclination of a line or surface that meets another at any angle but 90°....To cut an inclination that forms an angle other than a right angle.”)).

A POSITA would have understood that Fig. 8 of the ’477 Publication shows the lower surface of the thread start cut at an angle other than 90° relative to the other portions of the thread, *i.e.*, “*beveled*” (Ex.1003, ¶274):



**Ex.1008, Fig. 8 (annotated)**

As described above in Section VIII.D.2., a POSITA would have been motivated to form the lower surface of Kirschman's leading edge portion as a "beveled surface" as disclosed in the '477 Publication.

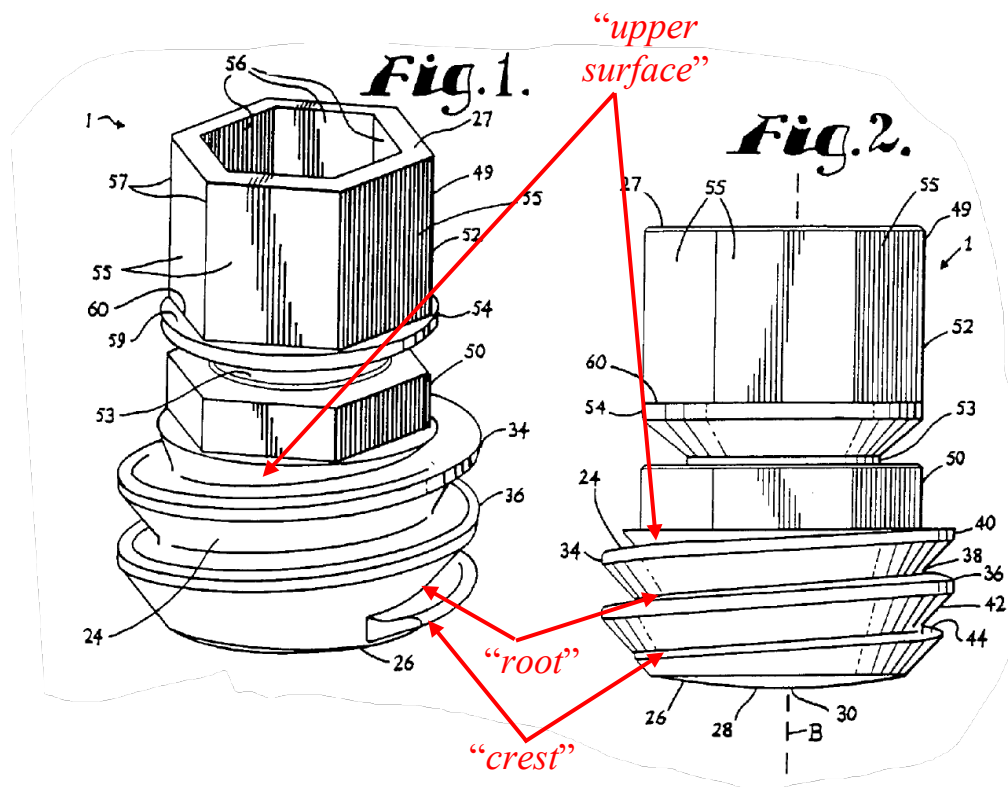
Therefore, because the '477 Publication discloses a beveled start structure, Kirschman and the '477 Publication render obvious limitation 8[a]. Ex.1003, ¶¶271-276.

#### **4. Claim 9**

**9[a] The medical implant assembly of claim 1, wherein the upper surface of the**

*continuously helically wound thread form of the plug slopes rearward from the root towards the crest.*

The '477 Publication's closure includes "a helically wound reverse angle thread form." Ex.1008, [0030]. The '477 Publication explains that, "[i]n a reverse angle thread, the trailing surface 44 from the root 38 to the crest 40 extends at an angle rearwardly from a perpendicular line relative to the axis B" (Ex.1008, [0031]):



**Ex.1008, Figs. 1-2 (annotated)**

As described above in Section VIII.D.2., a POSITA would have been motivated to form the threads on Kirschman's cap as the '477 Publication's reverse

angle thread.

Therefore, because the '477 Publication discloses a reverse angle thread, Kirschman and the '477 Publication render obvious limitation 9[a]. Ex.1003, ¶¶277-281.

## 5. Claim 10

**10[a] *The medical implant assembly of claim 9, wherein a slope of the upper surface is at an angle greater than five degrees measured between a line drawn perpendicular to the axis of rotation of the plug and a tangent line drawn along the upper surface.***

The '477 Publication's closure includes "a helically wound reverse angle thread form" in which "the trailing surface 44 is at an angle between 1 and 20 degrees relative to" a line perpendicular to the axis of rotation of the closure. Ex.1008, [0030]-[0031].

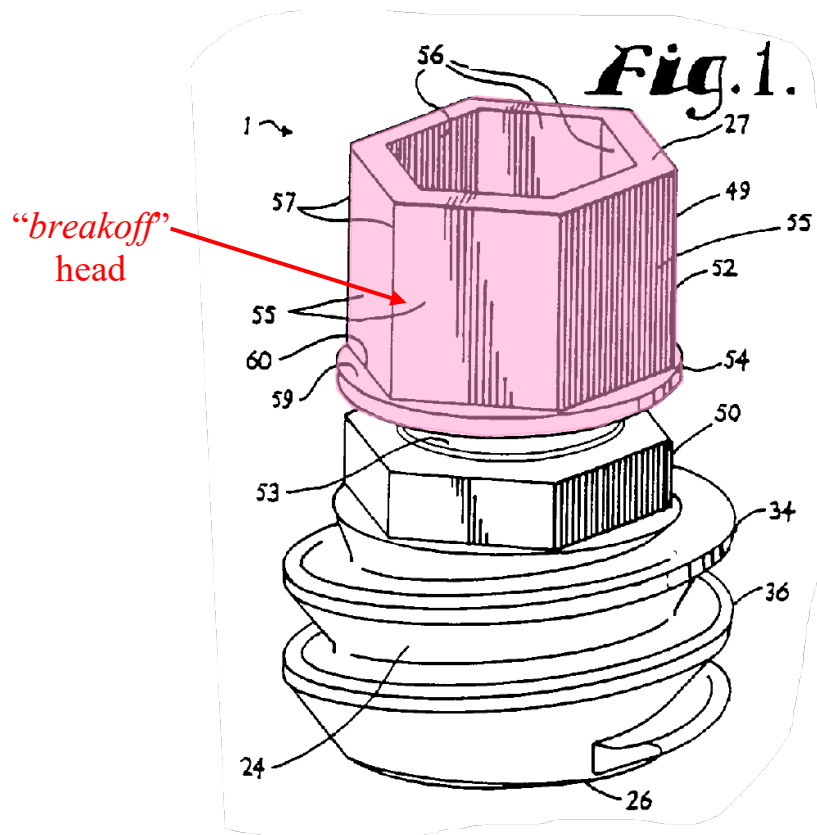
As described above in Section VIII.D.2., a POSITA would have been motivated to form the threads on Kirschman's cap as the '477 Publication's reverse angle thread.

Therefore, because the '477 Publication discloses a reverse angle thread with a trailing surface that is angled at 6-20 degrees, Kirschman and the '477 Publication render obvious limitation 10[a]. Ex.1003, ¶¶282-285.

## 6. Claim 11

**11[a] *The medical implant assembly of claim 1, wherein the plug is a breakoff plug.***

The '477 Publication's "closure 1 also includes a driving or installation break-off head... designed to break away from the remainder of the closure 1 subsequent to a predetermined torque being applied to the driving head 49" (Ex.1008, [0032]):



**Ex.1008, Fig. 1 (annotated)**

As described above in Section VIII.D.2., a POSITA would have been motivated to add the '477 Publication's break-off head to Kirschman's cap.

Therefore, because the '477 Publication discloses a closure having a break-off head, Kirschman and the '477 Publication render obvious limitation 11[a].

Ex.1003, ¶¶286-290.

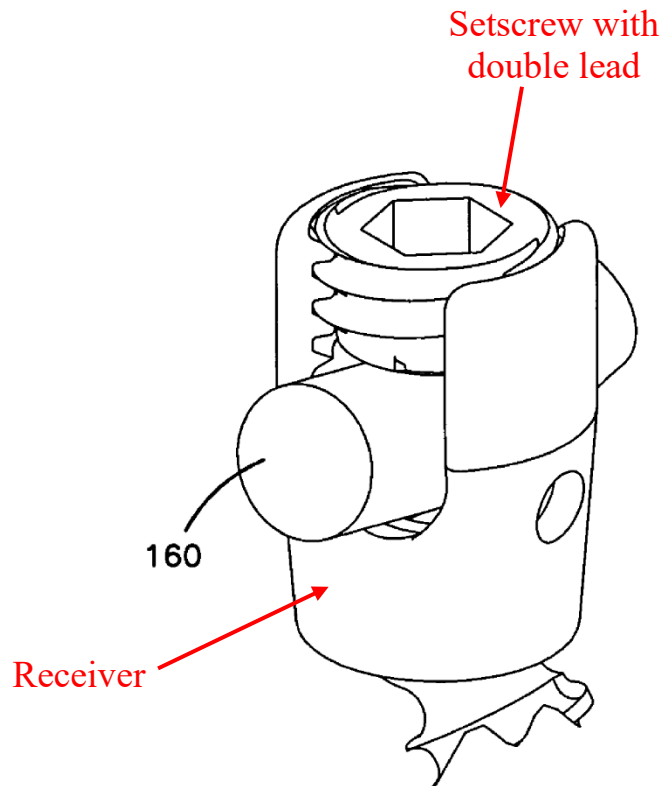
**E. Ground 4: Claims 3 and 12-16 are Obvious over Kirschman in view of Boschert.**

**1. Summary of Boschert**

Boschert “provides intervertebral connection systems suited for stabilization of the spine.” Ex.1009, 1:5-7.

Specifically, Boschert discloses a fixation device that “includes a fastener such as a setscrew 70 for clamping the rod 60 within the saddle 39 of the receiver.” Ex.1009, 4:26-28. Boschert explains 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” (Ex.1009, 7:21-23; Ex.1003, ¶¶291-295):

**FIG.7**



**Ex.1009, Fig. 7 (annotated)**

## **2. Reasons to Combine Kirschman and Boschert**

As an initial matter, Boschert is analogous art to the '873 Patent because both are in the same field of endeavor. The '873 Patent “is directed to...closure mechanisms for use with open bone anchors in spinal surgery.” Ex.1001, 1:27-31. Similarly, Boschert “provides intervertebral connection systems suited for stabilization of the spine.” Ex.1009, 1:5-7. Thus, like the '873 Patent, Boschert is also related to the field of bone anchors for use in spinal surgery. Ex.1003, ¶296.

A POSITA would have found it obvious to combine Kirschman and Boschert to form Kirschman's cap with Boschert's two threads as was well-known in the art. Ex.1003, ¶297.

Kirschman explains that “[d]uring the surgical procedure the surgeon must forcefully seat the rod into the tulip via rotation of the locking cap” which “affects the desired correction of the spine.” Ex.1005, [0005]. To improve seating of the rod in the channel, Kirschman discloses a polyaxial screw that “incorporat[es] 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.” Ex.1005, [0008]. Kirschman contemplates that “[a]lthough not shown, it should be appreciated that other conventional components may be used with the receiver.” Ex.1005, [0051]. Therefore, a POSITA would have been motivated to look elsewhere in the art for other well-known components that would further improve locking of the cap on the receiver. Ex.1003, ¶298.

Boschert describes one of these well-known components: two threads. Ex.1003, ¶¶299-300. In particular, Boschert explains 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.” Ex.1009, 7:21-23; *see also* 2:17-35 (“There is a need for a screw head securing mechanism or device that provides a

strong, effective, and secure lock of the screw head in its desired position” and “a screw head securing mechanism or device that is minimal in size and has a reduced amount of components to provide for a simpler, more effective, and less cumbersome device for fixing screws.”). A POSITA would have understood that “double lead” refers to screws that include two leads/threads. Ex.1003, ¶300.

Thus, it would have been obvious to a POSITA to modify Kirschman’s cap to include two threads as taught by Boschert, thereby allowing the cap to start more easily and reduce the number of rotations needed to secure the cap in the receiver. Ex.1003, ¶301.

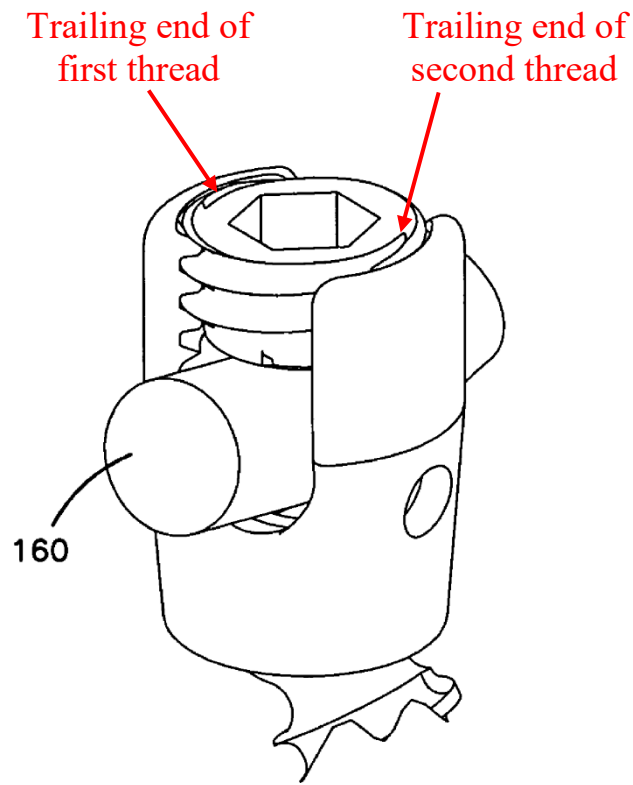
Multi-threaded screws and the manufacturing thereof were well-known in the art. Ex.1003, ¶302 (citing Ex.1010, 13 (“multiple start thread: a screw thread with two or more threads”) (emphasis removed); Ex.1011, 1.35 (“A multiple-start thread is one in which the lead is an integral multiple...of the pitch”)); Ex.1015, 1028 (describing design of multi-start threads); Ex.1017, 2:36-65 (“[B]y introducing two separate thread helixes that start and finish 180° apart, the load the connection will carry has found to increase....This increase in strength is made possible by balancing the two areas of greatest train, that is at the thread discontinuities at opposing sides.”); Ex.1018, 13:35-41 (“With such a dual thread construction, the threads start 180 degrees apart, such that cutting forces produced by self-tapping will substantially offset one another. Hence a self-tapping implant

will tend to rotate into a pilot hole in a balanced manner.”)); see ¶¶77-89. Thus, forming a double-threaded closure would have involved well-known techniques within the skill of a POSITA. Ex.1003, ¶¶302-303.

### 3. Claim 3

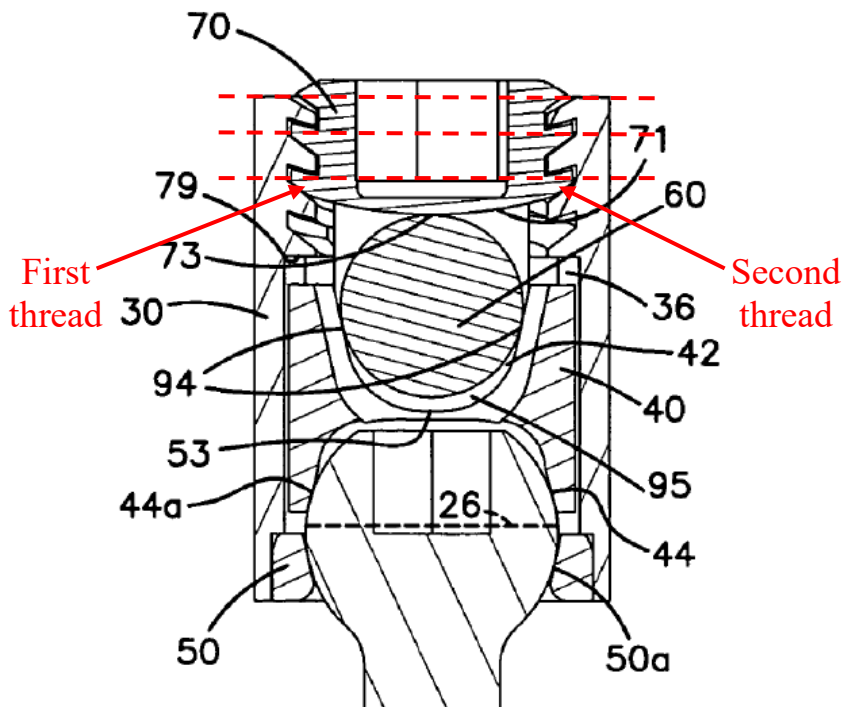
**3[a] *The medical implant assembly of claim 1, wherein the start structure is a first start structure disposed at a diametrically opposite location on the plug from a second start structure.***

Boschert’s setscrew has “a double lead to allow the setscrew 70 to start more easily than with a single lead.” Ex.1009, 7:21-23. It would have been obvious to a POSITA that Fig. 7 shows the trailing ends of the threads located opposite each other (approximately 180° from each other) on the top of the setscrew, indicating the “*first*” and “*second start structure*” would be disposed at “*diametrically opposite location[s]*” from each other (Ex.1003, ¶307):



**Ex.1009, Fig. 7 (cropped and annotated)**

Moreover, a POSITA would have understood that Fig. 3 shows the threads as symmetrical and diametrically opposed about the length of the setscrew and as being vertically aligned, indicating that the “*first*” and “*second start structure*” are symmetric and diametrically opposed (Ex.1003, ¶¶308-309):



**Ex.1009, Fig. 3 (cropped and annotated)**

It was well-known in the art that, “to achieve proper distribution of each start around the cylinder, each thread has to start at an equal angle.” Ex.1003, ¶310 (quoting Ex.1016, 1250, citing Ex.1015, 1028; Ex.1017, 2:18-65; Ex.1018, 13:35-41); see ¶¶77-89. Accordingly, a POSITA would have understood that a double-threaded setscrew, as disclosed in Boschert, would have been spaced at an angle of 180°. Thus, the “*first start structure*” would be disposed 180° from the “*second start structure*” at a “*diametrically opposite location.*” Ex.1003, ¶310.

As described above in Section VIII.E.2., a POSITA would have formed Kirschman’s cap with a second thread, as taught by Boschert.

Therefore, because Boschert discloses a setscrew with dual lead threads that

are symmetric and diametrically opposed, Kirschman and Boschert render obvious limitation 3[a]. Ex.1003, ¶¶304-312.

#### **4. Claim 12**

##### **12[pre] *A medical implant assembly comprising:***

This limitation is substantially similar to limitation 1[pre], and for the same reasons as discussed above, the prior art renders this limitation obvious. Ex.1003, ¶313.

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

This limitation is substantially similar to limitations 1[a] and 1[b], and for the same reasons as discussed above, the prior art renders this limitation obvious. Ex.1003, ¶314.

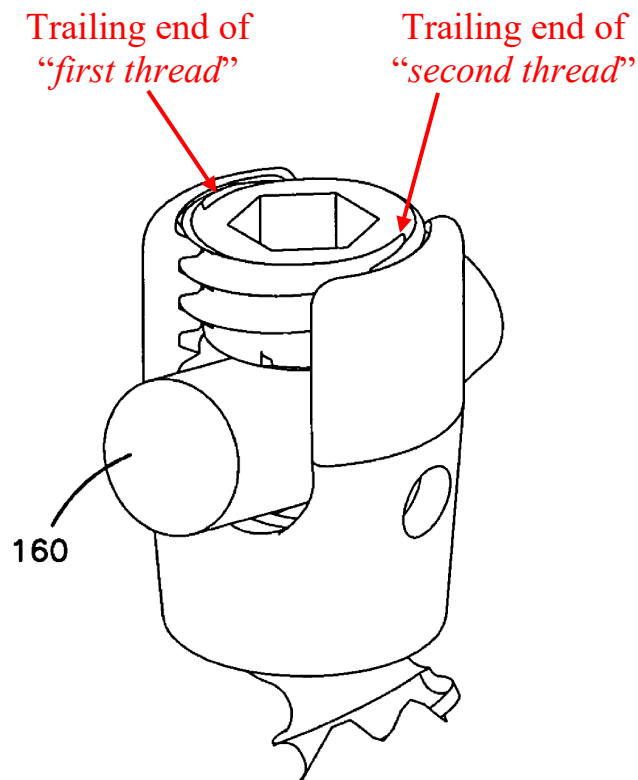
##### **12[b] *a plug configured for positioning within the upper portion of the receiver, the plug having an axis of rotation,***

This limitation is substantially similar to limitation 1[c], and for the same reasons as discussed above, the prior art renders this limitation obvious. Ex.1003, ¶315.

##### **12[c] *a continuously helically wound thread form comprising a first thread and a second thread,***

As explained above in limitation 1[c], Kirschman's cap includes a male cap thread ("*continuously helically wound thread form*").

However, to the extent Kirschman does not disclose multiple cap threads, this was well-known in the art. For example, Boschert's setscrew has "a double lead to allow the setscrew 70 to start more easily than with a single lead" (Ex.1009, 7:21-23; Ex.1003, ¶317):



**Ex.1009, Fig. 7 (cropped and annotated)**

As described above in Section VIII.E.2., a POSITA would have formed Kirschman's cap with a second thread, as taught by Boschert.

Therefore, because Boschert discloses a dual lead setscrew, Kirschman and Boschert render obvious limitation 12[c]. Ex.1003, ¶¶316-319.

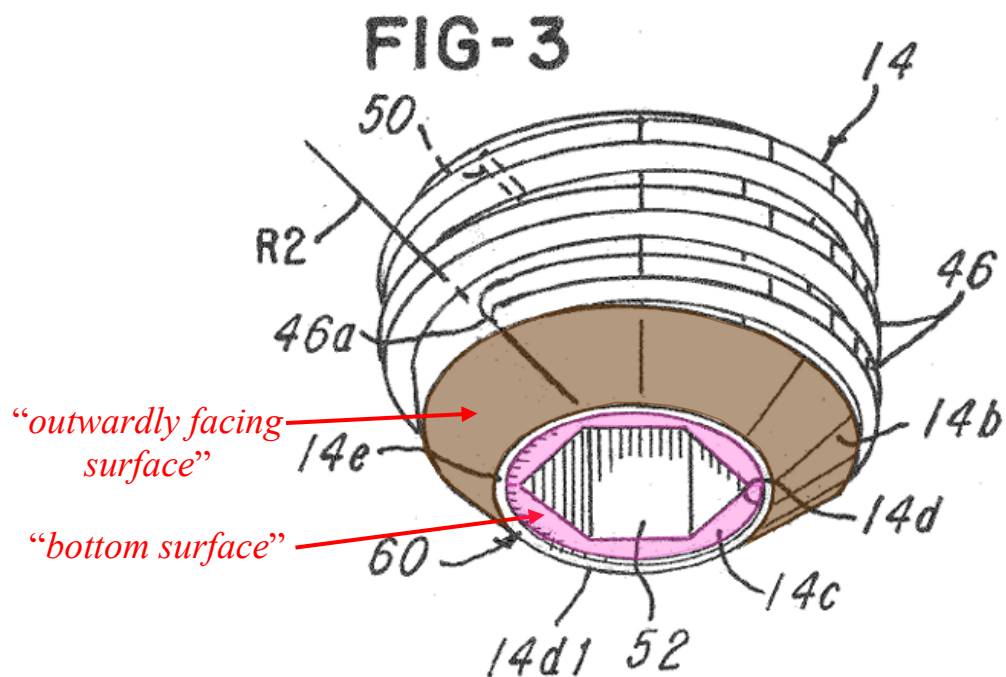
**12[d] *a bottom surface with an annular outer edge,***

This limitation is substantially similar to limitation 1[d], and for the same reasons as discussed above, the prior art renders this limitation obvious. Ex.1003, ¶320.

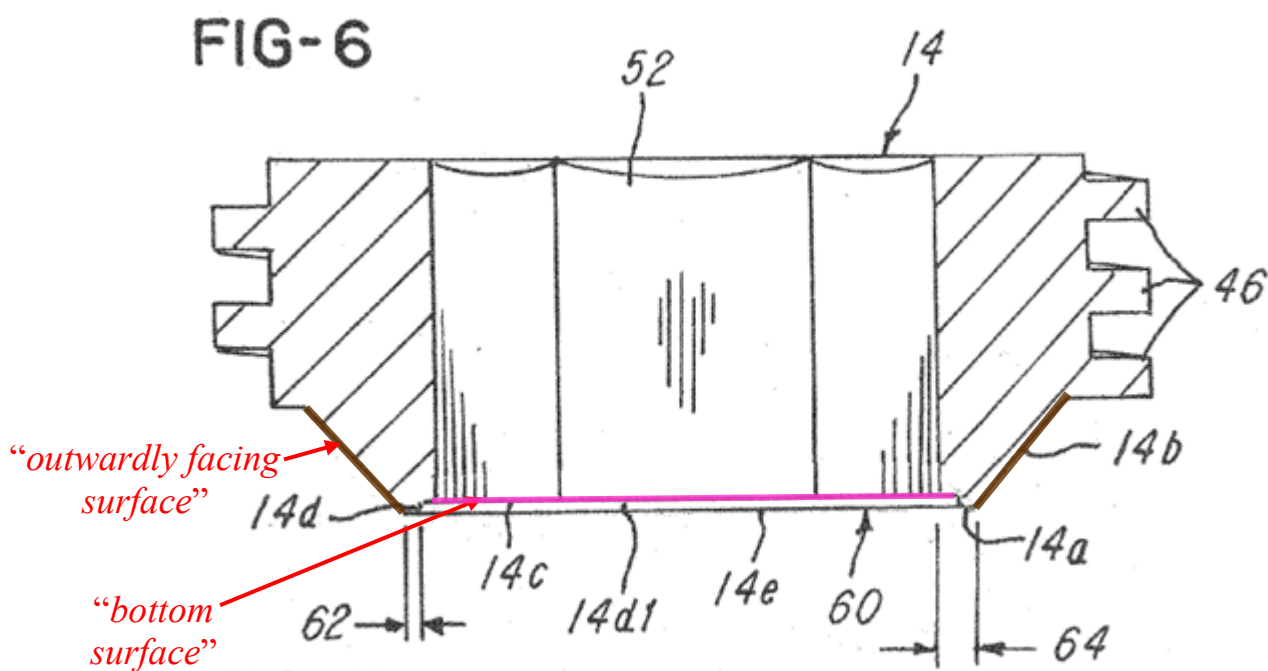
**12[e] *and an outward facing surface encircling the bottom surface,***

As explained above in limitations 1[d] and [h], Kirschman's cap includes a bottom having a guiding surface (*e.g.* a “frustoconical” surface) that is “adapted to guide the cap 14 into the bore 22 and onto the receiver 12” so that the cap threads and receiver threads can be aligned. Ex.1005, [0043], [0049]. This guiding surface of the “the bottom 14b terminates at an end 14c” (“*bottom surface*”). Ex.1005, [0044]; *see* limitation 1[d], 1[h]. The guiding surface (“*outwardly facing surface*”) is “*outwardly facing*” and “*encircles*” both the end surface (first interpretation of “*bottom surface*”) and the deformable ring (second interpretation of “*bottom surface*”) (Ex.1003, ¶¶324).

**First interpretation:**

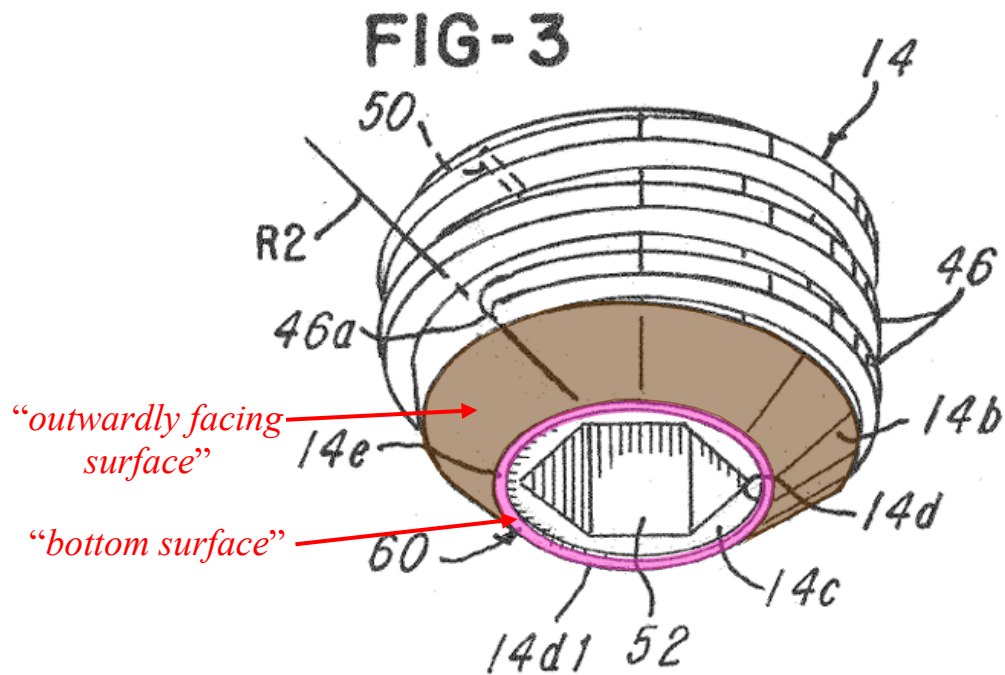


Ex.1005, Fig. 3 (annotated)

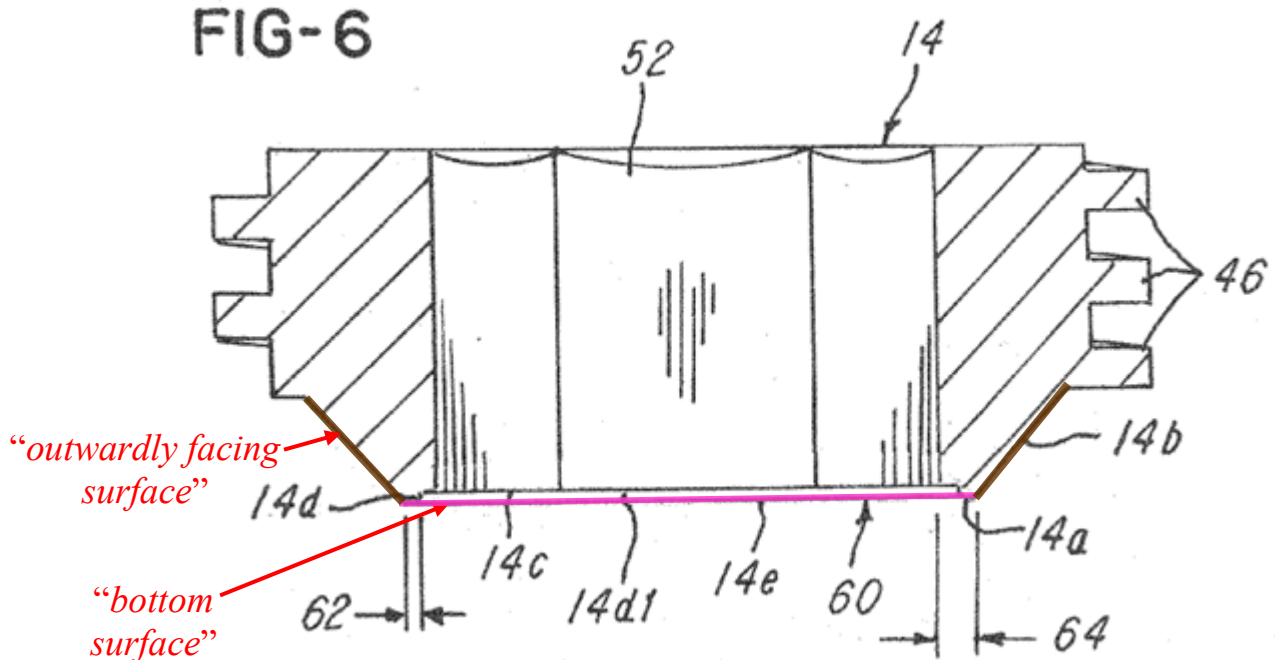


Ex.1005, Fig. 6 (annotated)

Second interpretation:

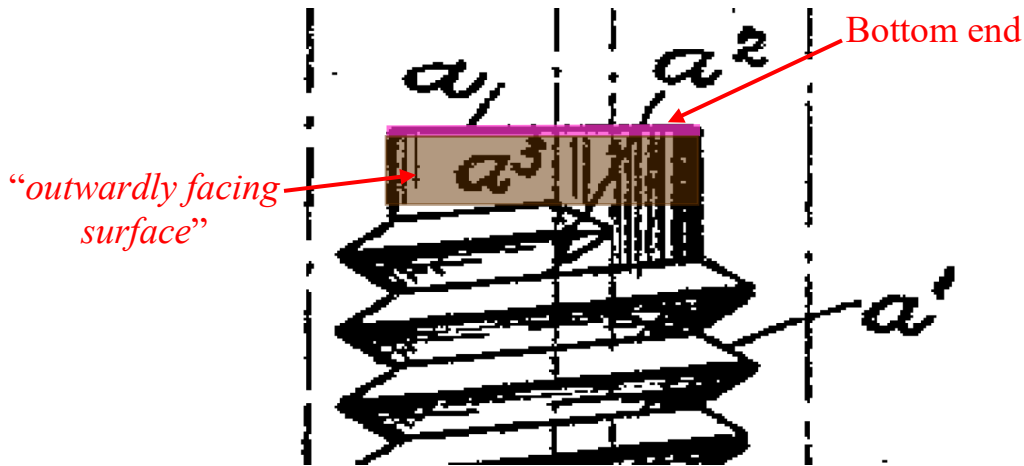


Ex.1005, Fig. 3 (annotated)



**Ex.1005, Fig. 6 (annotated)**

To the extent Kirschman does not explicitly disclose an “*outwardly facing surface*,” this was well-known in the art. For example, Higbee’s bolt/screw includes “a cylindrical extension...between the thread end  $a^2$  and the bolt end  $a$ ” (Ex.1006, 1:69-71):



Ex.1006, Fig. 1 (cropped and annotated)

Thus, to the extent that Kirschman's guiding surface is not considered an *"outwardly facing surface"* of the cap, as described in limitations 1[d] and 1[h], a POSITA would have been motivated to form Kirschman's guiding surface to be cylindrical as described in Higbee. Ex.1003, ¶326. Thus, the cylindrical guiding surface (*"outwardly facing surface"*) would surround both the end surface and the deformable ring (*"encircl[e] the bottom surface"*). Ex.1003, ¶326.

Therefore, because Kirschman discloses a guiding surface, which may be cylindrical as described in Higbee, that surrounds the deformable ring and the bottom surface, Kirschman renders obvious limitation 12[e]. Ex.1003, ¶¶321-327.

**12[f] the first thread comprising a first start structure and a first upper surface extending between a first root and a first crest of the first thread,**

This limitation is substantially similar to limitations 1[e], and for the same

reasons as discussed above, the prior art renders this limitation obvious. Ex.1003, ¶328.

**12[g] *the first start structure including a first leading face extending below the first upper surface to a first lower surface,***

This limitation is substantially similar to limitation 1[f], and for the same reasons as discussed above, the prior art renders this limitation obvious. Ex.1003, ¶329.

**12[h] *the second thread comprising a second start structure and a second upper surface extending between a second root and a second crest of the second thread,***

As explained above in limitation 12[c], Boschert discloses a “double lead” setscrew that has a “*first thread*” and a “*second thread*.” A POSITA would have known that the “*second thread*” would be identical to the “*first thread*” and axially spaced therefrom because it would have been the simplest way to manufacture the threads and would have ensured easy insertion of the closure into the receiver. Ex.1003, ¶332; see ¶¶77-89.

Therefore, for the same reasons as explained above for limitation 12[f], Kirschman and Boschert render obvious limitation 12[h]. Ex.1003, ¶¶330-333.

**12[i] *the second start structure including a second leading face extending below the second upper surface to a second lower surface,***

As explained above in limitation 12[h], a POSITA would have understood that the “*second thread*” would have been the same as the “*first thread*,” but

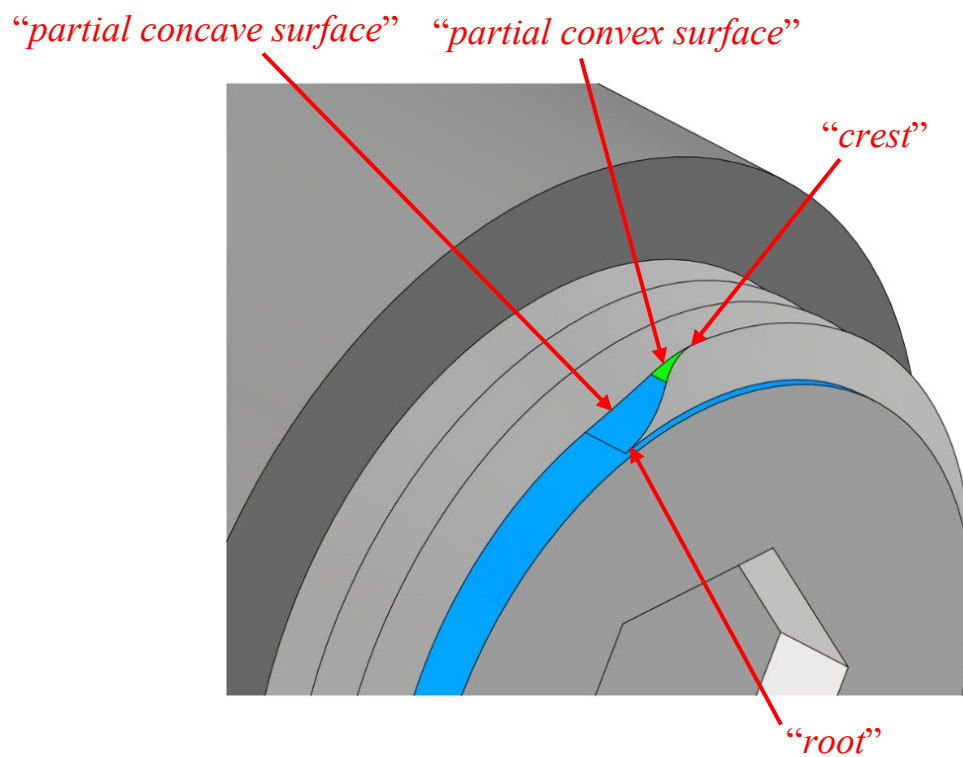
axially spaced therefrom.

Thus, for the same reasons as explained above for limitation 12[g], Kirschman and Boschert render obvious limitation 12[i]. Ex.1003, ¶¶334-336.

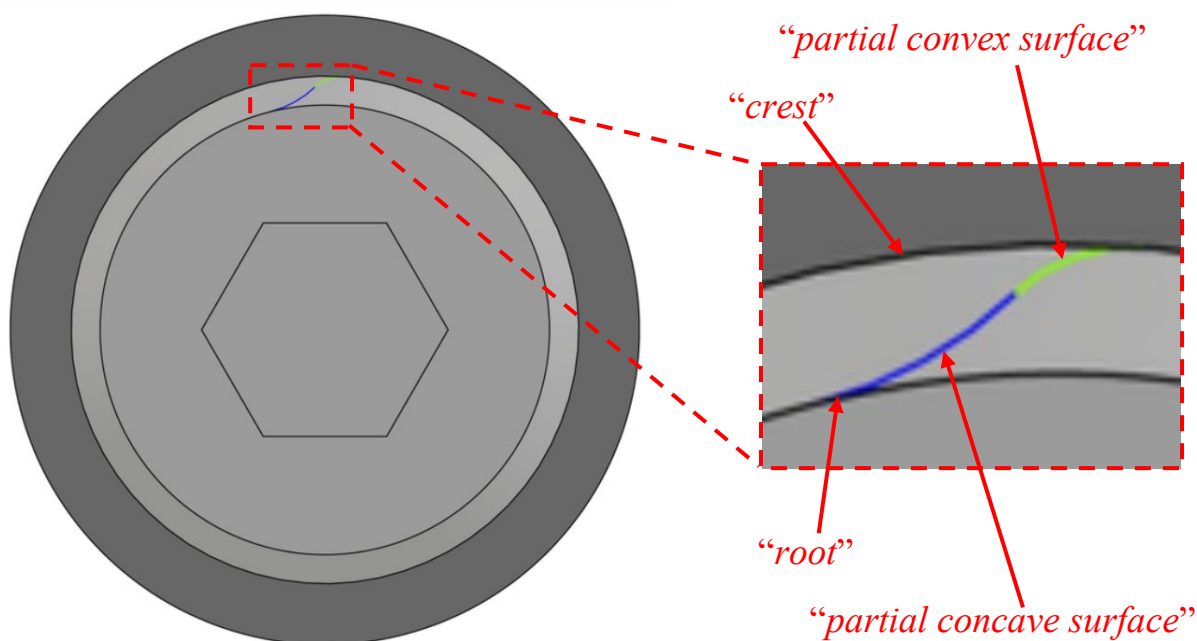
**12[j] *the first and second leading faces each including a partial concave surface adjacent the first and second root, respectively, and a partial convex surface adjacent the first and second crest, respectively,***

As explained in limitation 2[a] above, Kirschman discloses that the leading edge portion has a convex surface (*see* Ex.1005, Fig. 3) and Higbee discloses that the thread end is a rounded, convex surface (*see* Ex.1006, Fig. 6). To the extent that Kirschman and Higbee do not explicitly disclose both a “*partial convex surface adjacent the...crest*” and “*a partial concave surface adjacent the...root,*” this was well-known in the art. Ex.1003, ¶338.

A POSITA would have understood how to form a blunt thread start with a convex surface proximate the crest and a concave surface proximate the root. *See* limitation 2[a]. A POSITA would have known that blunt thread starts are generally formed by removing the incomplete portion of the thread with a circular tool such that a concave surface is formed. Ex.1003, ¶339. Because a fully-concave leading face would have formed a sharp edge at the crest, it was also well-known to round the edge along the crest using the same circular tool such that a convex surface is formed at the crest (Ex.1003, ¶339), as illustrated in the below graphics provided in Mr. Drewry’s Declaration:



**Ex.1003, ¶339**



**Ex.1003, ¶339**

This would have smoothed the leading face, thereby preventing the threads from cutting the surgeon's glove or irritating the patient. Ex.1003, ¶340; see ¶¶77-89. Accordingly, a POSITA would have understood that the blunt face would have had a *"partial concave surface adjacent...the root"* and a *"partial convex surface adjacent the...crest."* Ex.1003, ¶340.

As explained above in limitation 12[h], a POSITA would have understood that the *"second thread"* would have been the same as the *"first thread,"* but axially spaced therefrom.

Therefore, because forming a thread having a blunt face with a concave surface proximate the root and a convex surface proximate the crest was well-known to POSITAs, Kirschman and Boschert render obvious limitation 12[j]. Ex.1003, ¶¶337-342.

**12[k] *the first lower surface of the first thread and the second lower surface of the second thread are spaced above and apart from the annular outer edge of the bottom surface of the plug.***

As explained above in limitation 12[h], a POSITA would have understood that the “*second thread*” would have been the same as the “*first thread*,” but axially spaced therefrom.

Limitation 12[k] is substantially similar to limitation 1[f]. Therefore, for the same reasons as discussed above, Kirschman and Boschert render obvious limitation 12[k]. Ex.1003, ¶¶343-345.

## **5. Claim 13**

**13[a] *The medical implant assembly of claim 12, wherein the first start structure and the second start structure are disposed at diametrically opposite locations from each other on the plug.***

This limitation is substantially similar to limitation 3[a], and for the same reasons as discussed above, the prior art renders this limitation obvious. Ex.1003, ¶346.

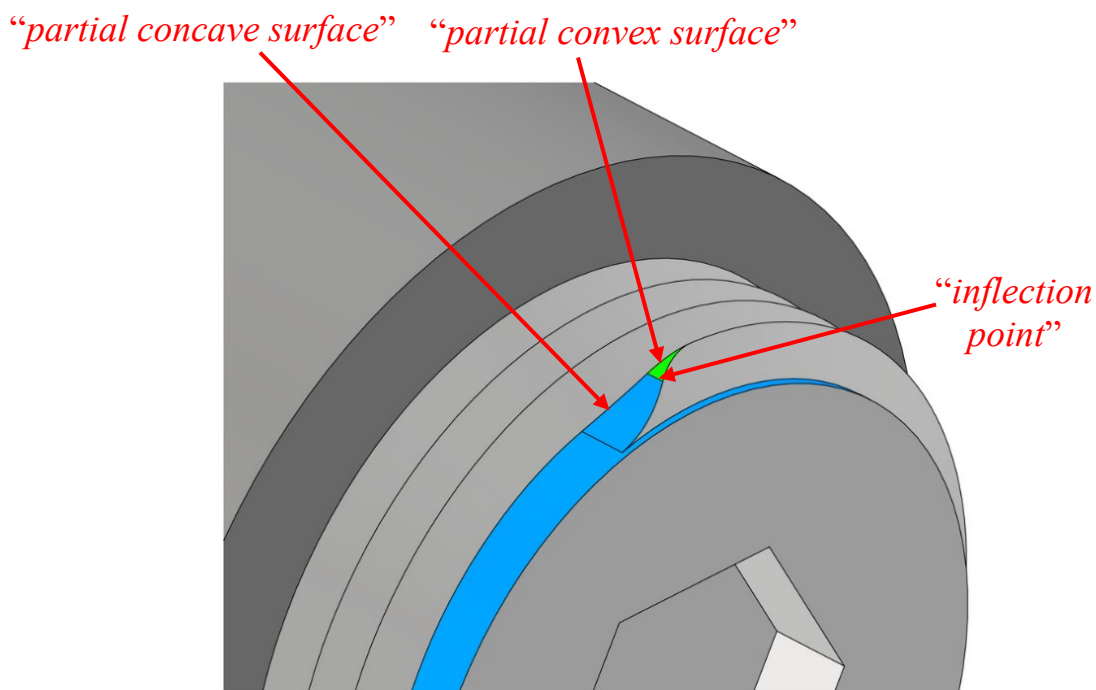
## **6. Claim 14**

**14[a] *The medical implant assembly of claim 12, wherein the first leading face***

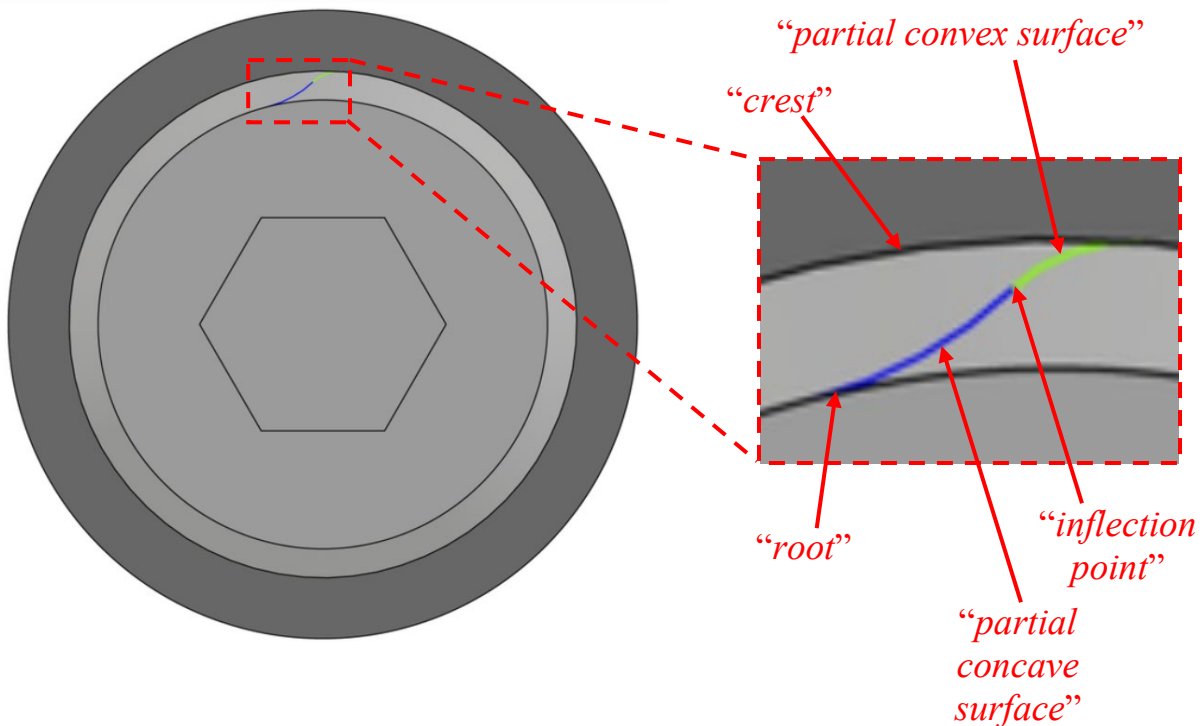
*includes a first inflection point between the partial concave surface and the partial convex surface of the first leading face, and the second leading face includes a second inflection point between the partial concave surface and the partial convex surface of the second leading face.*

As explained above in limitation 12[j], a POSITA would have known that a blunt face of a blunt start thread would have been formed with a concave surface proximate the root and a convex surface proximate the crest to remove sharp portions of the blunt face after cutting.

A POSITA would have understood that an “*inflection point*” would have been formed where the concave surface transitions to the convex surface (Ex.1003, ¶348), as shown in the below graphic prepared by Mr. Drewry:



**Ex.1003, ¶348**



**Ex.1003, ¶348**

As explained above in limitation 12[h], a POSITA would have understood that the *“first thread”* and the *“second thread”* would have been the same, but axially spaced from each other.

Therefore, because a POSITA would have known that an inflection point would have been formed where the concave surface transitions to the convex surface, Kirschman and Boschert render obvious limitation 14[a]. Ex.1003, ¶¶347-350.

**7. Claim 15**

**15[a] *The medical implant assembly of claim 12, wherein the first and second leading faces each includes at least a partial planar surface.***

As explained above in limitation 12[h], a POSITA would have understood that the “*first thread*” and the “*second thread*” would have been the same, but axially spaced from each other.

Limitation 15[a] is substantially similar to limitation 7[a]. Therefore, for the same reasons as discussed above, Kirschman and Boschert render obvious limitation 15[a]. Ex.1003, ¶¶351-353.

**8. Claim 16**

**16[a] *The medical implant assembly of claim 12, wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm.***

This limitation is substantially similar to limitation 4[a], and for the same reasons as discussed above, the prior art renders this limitation obvious. Ex.1003, ¶354.

**F. Ground 5: Claim 17 is Obvious over Kirschman in view of Boschert and Johnson.**

**1. Reasons to Combine Kirschman, Boschert, and Johnson**

A POSITA would have been motivated to combine Kirschman and Boschert with Johnson for at least the same reasons described above in Section VIII.C.2.

Ex.1003, ¶355.

**2. Claim 17**

**17[a]** *The medical implant assembly of claim 16, wherein the top surfaces of the first and second arms each include a breakoff extension with an inner surface having a discontinuously helically wound thread form, the first and second arm breakoff extension thread forms being continuous with the respective discontinuous helically wound thread form on the inner surface of the first and second arms.*

This limitation is substantially similar to limitation 5[a], and for the same reasons as discussed above, the prior art renders this limitation obvious. Ex.1003, ¶356.

**G. Ground 6: Claims 18-19 are Obvious over Kirschman in view of Boschert and the '477 Publication.**

**1. Reasons to Combine Kirschman, Boschert, and the '477 Publication**

A POSITA would have been motivated to combine Kirschman and Boschert with the '477 Publication for at least the same reasons described above in Section VIII.D.2. Ex.1003, ¶357.

**2. Claim 18**

**18[a]** *The medical implant assembly of claim 12, wherein the first lower surface includes a first bottom beveled surface and the second lower surface includes a second bottom beveled surface.*

This limitation is substantially similar to limitation 8[a], and for the same reasons as discussed above, the prior art renders this limitation obvious. Ex.1003, ¶358.

### 3. Claim 19

**19[a] *The medical implant assembly of claim 12, wherein the plug is a breakoff plug.***

This limitation is substantially similar to limitation 11[a], and for the same reasons as discussed above, the prior art renders this limitation obvious. Ex.1003, ¶359.

## IX. DISCRETIONARY DENIAL WOULD BE INAPPROPRIATE

### A. 35 U.S.C. § 325(d)

Although Kirschman and Higbee were two of hundreds of prior art references considered (Ex.1002, 98, 104), the examiner erred in not relying on the full disclosure of Kirschman (including Higbee) to reject the claims of the '873 Patent. Ex.1002, 57-62 (office action); *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential) (Part 2: The Board should consider “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of [the] challenged claims.”). Despite Kirschman and Higbee teaching every limitation of claim 1 (and almost every limitation of claim 12), the claims of the '873 Patent were only rejected for nonstatutory double patenting over the claims of the '646 Patent (parent to the '873 Patent)—no prior art rejections were presented. Ex.1002, 59-61 (office action), 38-39 (terminal disclaimer overcoming this

rejection). Because the examiner failed to appreciate and sufficiently evaluate the teachings of a blunt thread start of Kirschman and, still further, the foundational blunt thread start teachings in Higbee, the examiner materially erred during prosecution of the '873 Patent. *Becton-Dickinson and Company v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (PTAB December 15, 2017) (precedential as to Section III.C.5, first paragraph) (The Board should consider “(c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection... (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art.”); *Advanced Bionics*, 10 (factors (c) and (e) are relevant to Part 2).

Moreover, Mr. Drewry provides additional evidence regarding the knowledge of a POSITA, including the ubiquity of blunt thread starts such as those described in the '873 Patent. Because Mr. Drewry's testimony demonstrates that the technology covered by the Challenged Claims was well-known, reconsideration of Kirschman and Higbee in view of Mr. Drewry's declaration is warranted. *Becton-Dickinson*, 18 (The Board should consider “(f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments”); *Advanced Bionics*, 10 (factor (f) is relevant to Part 2).

The '873 Patent is a continuation of the '499 Application (now the '646 Patent). Thus, the Office's review of the '499 Application may be relevant to the § 325(d) analysis of the '873 Patent.

During prosecution of the '499 Application, the examiner rejected the pending claims over Prevost alone and in view of other references (*e.g.*, Boschert, discussed below). Ex.1004, 88-98. Neither Kirschman nor Higbee were relied on by the Examiner to reject any of the pending claims. Ex.1004, 86-102. The examiner merely listed Kirschman as being pertinent to the application, but did not indicate that he substantively analyzed Kirschman or Higbee against each limitation of the pending claims of the '499 Application. Ex.1004, 101.

As explained above and in Mr. Drewry's declaration, Kirschman and Higbee include disclosure of specific features that a POSITA would have found relevant to the claim limitations and arguments for patentability advanced by the Applicant. The disclosures in Kirschman and Higbee provide technical details of a thread start configuration that was not disclosed in the references relied on to reject the pending claims of the '499 Application. Particularly, Prevost failed to show the curved start structure spaced apart and above the outer annular edge, as disclosed in both Kirschman and Higbee. Thus, during prosecution of the '499 Application, the Examiner erred in not identifying the disclosures in Kirschman and Higbee, erred in not appreciating how the claim limitations were already disclosed by the

prior art, and erred in failing to reject the claims based on the disclosure in these references. *Advanced Bionics*, 8 (Part 2).

For similar reasons, the Examiner's reliance on Boschert during prosecution of the '499 Application does not warrant denial of institution. The Examiner cited Prevost in combination with Boschert to reject a pending claim of the '499 Application. Ex.1004, 92. However, this Petition cites Kirschman as the primary reference with Boschert as the secondary reference, demonstrating that Kirschman teaches limitations purportedly missing from Prevost, namely that the lower surface of the start structure is spaced apart and above the annular outer edge of the bottom surface. Ex.1004, 66-78 (Applicant arguing that Prevost does not disclose this limitation), 39-45 (notice of allowance issued after Applicant's arguments). Accordingly, this Petition presents substantially different arguments than the Examiner considered. *Compare* claims 1 and 12 above *to* Ex.1004, 88-98.

For these reasons, the Board should grant institution of this IPR in view of the new arguments presented in this Petition.

**B. The Fintiv Factors.**

The Board should not discretionarily deny institution based on the co-pending district court litigation involving PO and Petitioner (*Jackson v. SeaSpine Holdings Corporation*, C.A. No. 20-1784 (RGA) (D. Del.)) because the '873

Patent was recently added to the litigation and the trial date, after being moved multiple times, is not currently set.

Specifically, the Board balances six factors in considering denial under § 314. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 5-6 (Mar. 20, 2020) (precedential). These factors favor institution.

**1. *No evidence regarding a stay***

No motion to stay has been filed, so the Board should not infer the outcome of such a motion. *Sand Revolution II, LLC v. Continental Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24 at 7 (June 16, 2020) (informative). Thus, this factor is neutral.

**2. *Parallel proceeding trial date***

The Original Scheduling Order (Ex.1022) in the co-pending litigation set the trial date for June 10, 2024. Ex.1022, 12. However, since the Original Scheduling Order was filed, the Court has pushed the trial date back multiple times at the request of the parties and PO has dropped seven asserted patents. First, the Court moved the trial date to December 2, 2024 (Ex.1025, 3), then further pushed the trial date to September 29, 2025 to accommodate adding three new patents and dropping two previously asserted patents. Ex.1026, 2. The Court again granted an extension of case deadlines (Ex.1021, 2) and noted in an associated oral order that “[s]hould the case reach [the dispositive motion] point, the Court may push the

trial back.” Co-pending litigation, D.I. 195. Recently on March 17, 2025, the Court granted another extension of case deadlines and removed the trial date from the calendar, indicating that a new trial date will be set by the Court at some point in the future. Ex.1024, 2. Thus, as of the filing of this Petition, there is no trial date set.

The expected date for a Final Written Decision in this case is Q1 2026. Because the date for trial has moved many times and is not currently set, this factor weighs against discretionary denial. *Fintiv*, Paper 11 at 11–12; *see Sand Revolution*, Paper 24 at 8-10, 14 (panel granting institution on rehearing based on finding that **uncertainty over district court’s trial date weighed against discretionary denial**).

### 3. *Investment in the parallel proceeding*

The ’873 Patent was first asserted in PO’s **Third** Amended Complaint in the co-pending litigation—over four years after filing the Original Complaint. *Compare* Ex.1027 (Original Complaint, filed December 30, 2020) *to* Ex.1020 (Third Amended Complaint, filed April 2, 2024). The district court has not construed any claims of the ’873 Patent. PO recently narrowed the claims asserted in the co-pending litigation on November 8, 2024, including dropping assertion of the ’646 Patent, along with previously dropping five other patents. PO is set to further narrow the claims asserted by June 20, 2025 (Ex.1024, 2), which may

include dropping the assertion of claim 1 of the '873 Patent (the only claim of this patent asserted in the co-pending litigation). *See* Ex.1020 (newly asserting three additional patents, including the '873 and '646 Patents); Ex.1023 (dropping two of the newly-asserted patents).

Therefore, because Petitioner filed this Petition expeditiously after becoming aware of the claims being asserted, this factor weighs against discretionary denial. *Fintiv*, Paper 11 at 11-12 (“**[I]t is often reasonable for a petitioner to wait to file its petition until it learns which claims are being asserted against it in the parallel proceeding...**If the evidence shows that the petitioner filed the petition expeditiously, such as promptly after becoming aware of the claims being asserted, this fact has weighed against exercising the authority to deny institution.”).

#### **4. *Overlapping issues with the parallel proceeding***

This factor weighs against discretionary denial. To reduce overlap between the two proceedings, if the Board institutes an IPR trial on this Petition, Petitioner hereby stipulates that it will not pursue in the co-pending litigation the specific grounds asserted in this Petition, or any other ground that could have been reasonably raised in an IPR (i.e., grounds that could have been raised under §§102 or 103 on the basis of prior art patent or printed publications). *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12, 18-19 (Dec. 1, 2020) (precedential as to Section II.A).

**5. *Petitioner is a defendant***

Petitioner is a defendant in the co-pending litigation. That is true of most Petitioners in IPR proceedings, making this factor neutral. *See HP Inc. v. Slingshot Printing LLC*, IPR2020-01084, Paper 13 at 9 (Jan. 14, 2021).

**6. *Other circumstances***

The Petition—along with Mr. Drewry’s testimony—plainly shows that the ’873 Patent claims no more than well-known subject matter. The compelling merits of unpatentability weigh against discretionary denial.

**C. No basis for *General Plastic* denial**

The ’873 Patent has not been challenged in any prior IPR, so none of the *General Plastic* discretionary institution factors apply to this Petition. *See General Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 16 (PTAB Sept. 6, 2016) (precedential as to Section II.B.4.i.).

**X. CONCLUSION**

Petitioner has established a reasonable likelihood that the Challenged Claims are unpatentable.

Respectfully submitted,

Dated: March 26, 2025  
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## XI. MANDATORY NOTICES

### A. Real Party-in-Interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner certifies that the real party-in-interest is Orthofix Medical, Inc.

### B. Related Matters

Pursuant to 37 C.F.R. § 42.8(b)(2), to the best knowledge of the Petitioner, the '873 Patent is or was involved in the following cases:

| Case Heading                                    | Number               | Court | Filed             |
|-------------------------------------------------|----------------------|-------|-------------------|
| <i>Jackson v. SeaSpine Holdings Corporation</i> | <i>1-20-cv-01784</i> | Del.  | December 30, 2020 |

To the best knowledge of the Petitioner, patents in the family of the '873 Patent are or were involved in the following cases:

| Case Heading                                      | Number               | Court | Filed              | U.S. Patents                                        |
|---------------------------------------------------|----------------------|-------|--------------------|-----------------------------------------------------|
| <i>Jackson v. SeaSpine Holdings Corporation</i>   | <i>1-20-cv-01784</i> | Del.  | December 30, 2020  | 11,129,646                                          |
| <i>Jackson v. ZimVie Inc.</i>                     | <i>1-22-cv-00891</i> | Del.  | June 30, 2022      | 11,129,646<br>10,898,233<br>10,548,641<br>8,911,479 |
| <i>Zimmer Biomet Spine, LLC et al. v. Jackson</i> | <i>IPR2023-01433</i> | PTAB  | September 22, 2023 | 11,129,646                                          |
| <i>Zimmer Biomet Spine, LLC et al. v. Jackson</i> | <i>IPR2023-01432</i> | PTAB  | September 22, 2023 | 10,898,233                                          |

| Case Heading                                      | Number               | Court | Filed              | U.S. Patents |
|---------------------------------------------------|----------------------|-------|--------------------|--------------|
| <i>Zimmer Biomet Spine, LLC et al. v. Jackson</i> | <i>IPR2023-01431</i> | PTAB  | September 22, 2023 | 10,548,641   |
| <i>Zimmer Biomet Spine, LLC et al. v. Jackson</i> | <i>IPR2023-01430</i> | PTAB  | September 22, 2023 | 8,911,479    |

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Please address all correspondence in this proceeding to lead and back-up counsel. Petitioner consents to service in this proceeding by email at the addresses above.

## **XII. CLAIM APPENDIX**

### **Claim 1**

**1[pre]** A medical implant assembly comprising:

**1[a]** a receiver having an upper portion with an inner surface at least partially configured as a helically wound thread extending up to a top surface of the receiver, and

**1[b]** a channel configured to be attached to an elongate member; and

**1[c]** a plug being threaded and configured to be positioned within the upper portion of the receiver, the plug having an axis of rotation, a continuously helically wound thread form, and

**1[d]** a bottom surface with an annular outer edge,

**1[e]** the continuously helically wound thread form having a start structure with an upper surface extending between a root and a crest of the continuously helically wound thread form,

**1[f]** the start structure having a leading face extending below the upper surface to a lower surface of the start structure,

**1[g]** the leading face including at least one partial curvate surface between the root and the crest,

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

**Claim 2**

**2[a]** The medical implant assembly of claim 1, wherein the at least one partial curvate surface is one of a partial concave surface or a partial convex surface.

**Claim 3**

**3[a]** The medical implant assembly of claim 1, wherein the start structure is a first start structure disposed at a diametrically opposite location on the plug from a second start structure.

**Claim 4**

**4[a]** The medical implant assembly of claim 1, wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm.

**Claim 5**

**5[a]** The medical implant assembly of claim 4, wherein the first arm includes a first breakoff extension coupled to the top surface of the first arm, and the second arm includes a second breakoff extension coupled to the top surface of the second arm,

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

**Claim 6**

**6[a]** The medical implant assembly of claim 5, wherein a first outer radiused notch is located at a convergence of the first breakoff extension and the first arm at the top surface thereof, and a second outer radiused notch is located at a convergence of the second breakoff extension and the second arm at the top surface thereof, the first outer radiused notch being located opposite a first inner radiused recess, and

the second outer radiused notch being located opposite a second inner radiused recess.

**Claim 7**

7[a] The medical implant assembly of claim 1, wherein the leading face of the start structure includes at least a partial planar surface.

**Claim 8**

8[a] The medical implant assembly of claim 1, wherein the lower surface of the start structure includes a bottom beveled surface.

**Claim 9**

9[a] The medical implant assembly of claim 1, wherein the upper surface of the continuously helically wound thread form of the plug slopes rearward from the root towards the crest.

**Claim 10**

10[a] The medical implant assembly of claim 9, wherein a slope of the upper surface is at an angle greater than five degrees measured between a line drawn perpendicular to the axis of rotation of the plug and a tangent line drawn along the upper surface.

**Claim 11**

**11[a]** The medical implant assembly of claim 1, wherein the plug is a breakoff plug.

**Claim 12**

**12[pre]** A medical implant assembly comprising:

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

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

**12[c]** a continuously helically wound thread form comprising a first thread and a second thread,

**12[d]** a bottom surface with an annular outer edge, and

**12[e]** an outward facing surface encircling the bottom surface,

**12[f]** the first thread comprising a first start structure and a first upper surface extending between a first root and a first crest of the first thread,

**12[g]** the first start structure including a first leading face extending below the first upper surface to a first lower surface,

**12[h]** the second thread comprising a second start structure and a second upper surface extending between a second root and a second crest of the second thread,

**12[i]** the second start structure including a second leading face extending below the second upper surface to a second lower surface,

**12[j]** the first and second leading faces each including a partial concave surface adjacent the first and second root, respectively, and a partial convex surface adjacent the first and second crest, respectively,

**12[k]** the first lower surface of the first thread and the second lower surface of the second thread are spaced above and apart from the annular outer edge of the bottom surface of the plug.

### **Claim 13**

**13[a]** The medical implant assembly of claim 12, wherein the first start structure and the second start structure are disposed at diametrically opposite locations from each other on the plug.

### **Claim 14**

**14[a]** The medical implant assembly of claim 12, wherein the first leading face includes a first inflection point between the partial concave surface and the partial convex surface of the first leading face, and the second leading face includes a

second inflection point between the partial concave surface and the partial convex surface of the second leading face.

**Claim 15**

**15[a]** The medical implant assembly of claim 12, wherein the first and second leading faces each includes at least a partial planar surface.

**Claim 16**

**16[a]** The medical implant assembly of claim 12, wherein the upper portion of the receiver includes a first arm and a second arm spaced apart from each other by the channel, the helically wound thread being discontinuous and formed on the first and second arms, the top surface of the receiver being formed on the first arm and the second arm.

**Claim 17**

**17[a]** The medical implant assembly of claim 16, wherein the top surfaces of the first and second arms each include a breakoff extension with an inner surface having a discontinuously helically wound thread form, the first and second arm breakoff extension thread forms being continuous with the respective discontinuous helically wound thread form on the inner surface of the first and second arms.

**Claim 18**

**18[a]** The medical implant assembly of claim 12, wherein the first lower surface includes a first bottom beveled surface and the second lower surface includes a second bottom beveled surface.

**Claim 19**

**19[a]** The medical implant assembly of claim 12, wherein the plug is a breakoff plug.

**CERTIFICATE OF WORD COUNT**

Pursuant to 37 C.F.R. §42.24(d), Petitioner hereby certifies, in accordance with and reliance on the word count provided by the word-processing system used to prepare this Petition, that the number of words in this paper is 13,997. Pursuant to 37 C.F.R. §42.24(d), this word count excludes the table of contents, table of authorities, mandatory notices under §42.8, certificate of service, certificate of word count, appendix of exhibits, and any claim listing.

Dated: March 26, 2024

/J. Andrew Lowes/  
J. Andrew Lowes  
Lead Counsel for Petitioner  
Registration No. 40,706

**CERTIFICATE OF SERVICE**

The undersigned certifies that, in accordance with 37 C.F.R. §42.6(e) and 37 C.F.R. §42.105, service was made on Patent Owner as detailed below.

*Date of service* March 26, 2025

*Manner of service* Priority Mail Express

*Documents served* Petition for *Inter Partes* Review Under 35 U.S.C. §312 and 37 C.F.R. §42.104 of U.S. 11,399,873;  
Petitioner's Power of Attorney; Petitioner's Exhibit List;  
Exhibits Ex.1001-Ex.1030

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The undersigned also certifies that a courtesy copy was served on litigation counsel for Patent Owner as detailed below:

*Date of service* March 26, 2025

*Manner of service* Fed Ex

*Documents served* Petition for *Inter Partes* Review Under 35 U.S.C. §312 and 37 C.F.R. §42.104 of U.S. 11,399,873;  
Petitioner's Power of Attorney; Petitioner's Exhibit List;  
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