

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ROGER P. JACKSON,
Patent Owner.

Case No. IPR2023-01432
Patent No. 10,898,233

**PATENT OWNER PRELIMINARY RESPONSE TO
POST-GRANT REVIEW PETITION**

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LIST OF EXHIBITS

Exhibit No.	Description
2001	U.S. Patent Publication 2005/0187549 (“the ’549 Publication”)

I. INTRODUCTION

Zimvie, Inc. and Zimmer Biomet Spine, Inc. (“Petitioner”) filed an *inter partes* review petition (the “Petition”) challenging claims 1-7 and 13-20 of U.S. Patent No. 10,898,233 (the ’233 Patent) on September 22, 2023.

The weakness of Petitioner’s challenge is apparent in its reliance on an unenumerated and undescribed line in a single figure of the ’477 Publication to teach the limitation of a “leading face with a concave surface portion and a convex surface portion” recited in the sole independent claim. Without analysis or supporting evidence, Petitioner concludes that the undescribed line teaches exactly what the independent claim recites. However, Petitioner’s conclusory assertion contradicts the other figures and disclosure in the prior art and cannot be the basis to support a rejection.

Therefore, the Board should find that Petitioner fails to demonstrate that it is more likely than not that at least one of the claims challenged in the Petition is unpatentable over the prior art in the Petition.

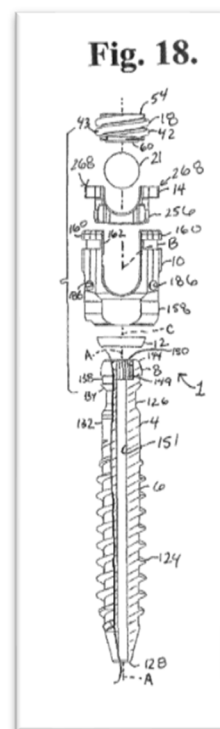
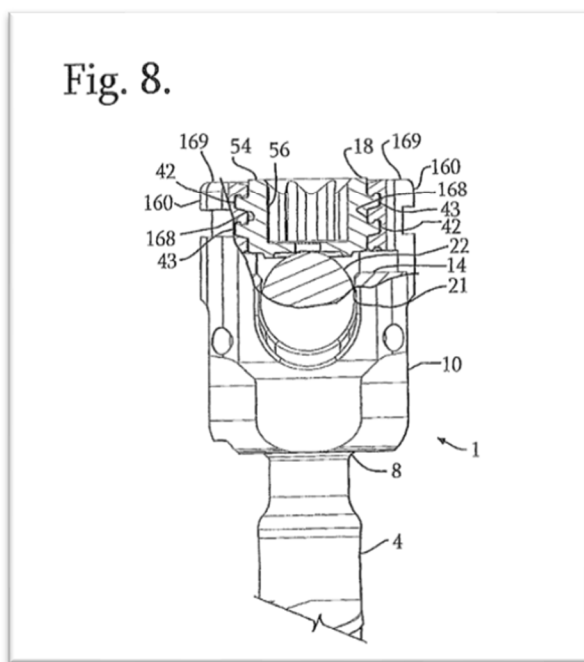
II. OVERVIEW OF THE ’233 PATENT

A. Specification

The invention of the ’233 patent is directed to closure mechanisms for use with open bone anchors in spinal surgery and mechanisms for use with spinal bone anchors such as polyaxial screws. Ex. 1001 at 1:26-30. “Bone anchors, such as bone

screws and hooks are utilized in many types of spinal surgery in order to secure various implants to vertebrae along the spinal column for the purpose of stabilizing and/or adjusting spinal alignment.” *Id.* at 31-34.

According to preferred embodiments of the invention, Figs. 1-8 and 18-58, and in particular to Figs. 8 and 18, depict an open implant in the form of a polyaxial bone screw apparatus or assembly that includes a shank having a body integral with an upwardly extending upper portion or capture structure, a receiver, a retaining structure or retainer, a compression or pressure insert, and a multi-start closure or plug. *Id.* at 7:27-35.

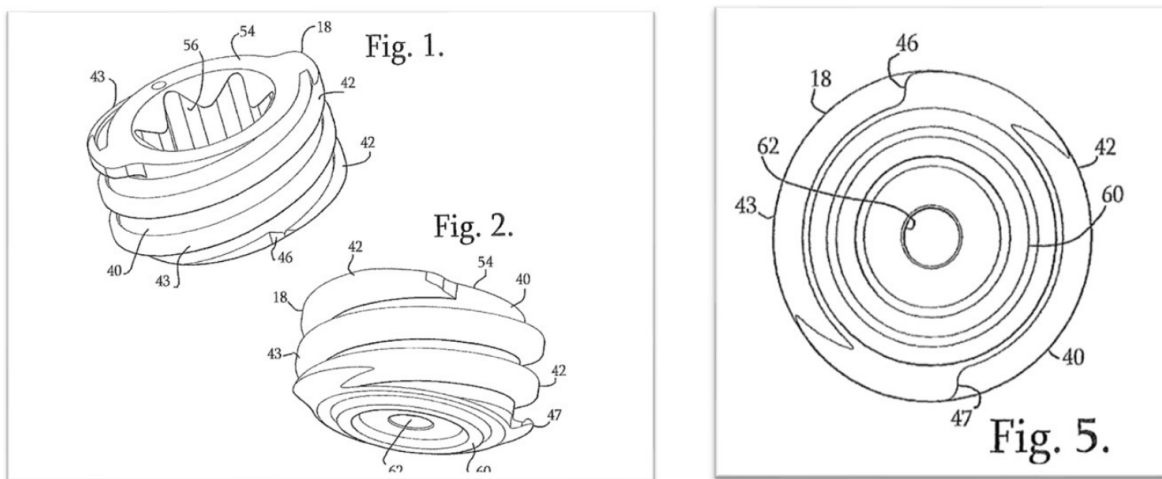


Ex. 1001 at Figs. 8 and 18

“It is noted that multi-start closure embodiments of the invention, such as the closure 18 may be used with a variety of open implants including, but not limited to

a wide variety of polyaxial screws, mono-axial or fixed screws, hooks and other types of open implants requiring a plug or closure mechanism to fix a rod or other implant member to a vertebra or other bone.” *Id.* at 7:36-42.

Perhaps most relevant to this preliminary response, in a preferred embodiment the “start structures 46 and 47...are located on opposite sides of the closure plug body 40 and are both located *adjacent* the bottom surface 58.” *Id.* at 9:16-19 (emphasis added). Moreover, “[e]ach of the start structures 46 and 47 includes a leading face having at least one curvate surface” with “at least one radius of curvature.” *Id.* at 9:38-41. “In one embodiment, the at least one curvate surface is both concave and convex.” *Id.* at 9:41-42; *see also* Figs. 1, 2, and 5.



Ex. 1001 at Figs. 1, 2, and 5

B. Prosecution History

The '233 patent issued on January 26, 2021, with Roger Jackson and James Surber as the named inventors. The '233 patent issued from Application No.

16/779,304, which was filed on January 31, 2020, and on its face claims priority to Provisional Application Nos. 61/631,746, filed on January 10, 2012, and 61/634,361, filed on February 28, 2012.

In the '304 application, the Examiner initially rejected all pending claims under pre-AIA 35 U.S.C. 103(a), and specifically claims 1-9, 13 and 14 as being unpatentable over Garamszegi (2008/0045953) in view of Boschert (2005/0277928). Ex. 1002 at 65. As part of the rejections, the Examiner contended that it would have been obvious to a POSITA, “to have provided the closure of Garamszegi with double-start (i.e., double lead) threads, in view of Boschert, in order to allow the closure (i.e., setscrew) to start more easily.” *Id.* at 67.

In response to the Office Action, Applicant amended claims 1-14, added new claims 15-20, submitted a replacement specification, and added new drawing sheets 1-12 all of which were supported by the originally filed disclosure and also by priority U.S. Provisional Patent App. No. 61/631,746. *Id.* at 321.

Relevant to this preliminary response, Patent Owner pointed out that there was no evidence at the time of invention to support combination of Garamszegi and Boschert with respect to “a closure having first and second continuous helically wound thread forms with their own starts.” *Id.* at 324. Specifically, the Office acknowledged “Garamszegi does not disclose a closure having first and second continuous helically wound thread forms with their own starts, such that rotation of

the closure causes simultaneous mating of the threads on each arm with the closure,” but “[i]nstead, it alleges that Boschert teaches these features.” *Id.*

Applicant submitted, “nowhere in Boschert does it show or describe a start structure of its threads...[t]herefore, Boschert does not teach or suggest a first and a second start structure each ‘having a leading face with a concave surface portion and a convex surface portion.’” *Id.* Additionally, “[b]ecause Boschert does not show or describe a first or second start structure,” it follows that it also does not teach or suggest these aspects of claim 1 and “the office does not assert otherwise.” *Id.* at 324-325. Applicant further amended claims 1, 10, 11, 13, and 20 on Sept. 4, 2020. In response to Applicants amendments, the Office issued a Notice of Allowance on Sept. 17, 2020, corrected Notice of Allowance on Nov. 5, 2020 and the ’233 patent issued on January 26, 2021.

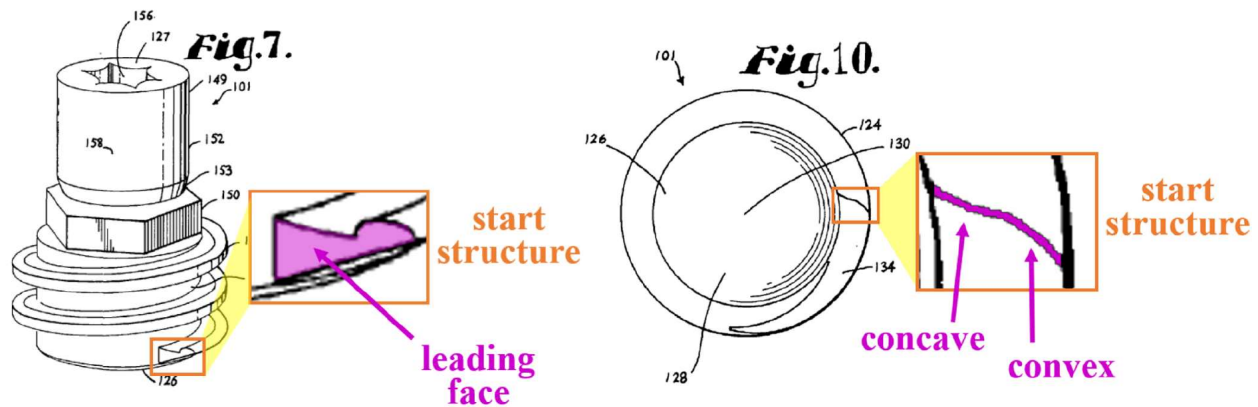
III. CLAIM CONSTRUCTION

Petitioner purports to construe certain claim limitations. Petition at 12-18. However, Petitioner doesn’t provide any constructions, but rather alleges that the “plain meaning” of the limitations encompass certain embodiments in the ’233 Patent or are taught by certain features of the asserted prior art. *Id.* As such, there are no express constructions for the Board to consider or the Patent Owner to address. Petitioner has not shown how the prior art renders the claims obvious even under Petitioner’s understanding of the plain meaning of certain limitations.

IV. PROPOSED GROUNDS OF REJECTION ARE NOT LIKELY TO PREVAIL

A. Prior art does not teach “the first start structure having a leading face with a concave surface portion and a convex surface portion” (Claim 1)

Petitioner’s argument for this limitation is based entirely on an undescribed line in Figure 10 of the ’477 Publication, shown with no elevation, structure, or identifiable related surface, that Petitioner alleges is a leading face with concave and convex surface portions. Petition at 53-54. Since the ’477 Publication does not describe the identified line in Figure 10, Petitioner assumes, without basis, that it is “the same leading face as shown in Fig. 7.” *Id.* These features of Figures 7 and 10 are identified in the Petition as shown below:



Petition at 53-54 (annotations by Petitioner)¹

¹ Patent Owner does not concede the unidentified line in Figure 10 discloses both a concave curve and a convex curve. However, Patent Owner’s arguments in this preliminary response demonstrates why the claims are not obvious assuming *arguendo* the line has concave and convex curves as Petitioner alleges.

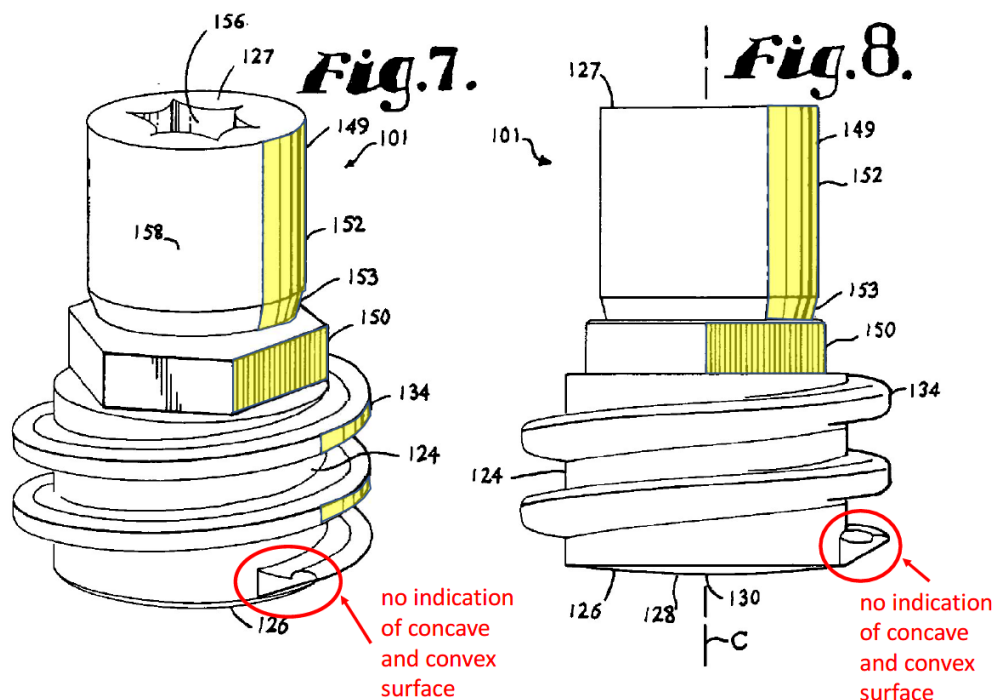
Yet, Petitioner's argument is undercut by the fact that Figure 7 does not show a concave and convex leading face surface as seen above – a fact that Petitioner never addresses in its argument. In addition, Petitioner's reliance on the undescribed line in Figure 10 as a concave and convex leading face surface is inconsistent with the figures of other closures in the '477 Publication and its parent application. Finally, Petition's expert declaration is entitled to no weight on this issue since it repeats verbatim the conclusory assertions in the Petition.

1. Figures 7 and 8 do not disclose a concave and convex leading face surface

It is undisputed that Figures 7, 8 and 10 all depict the same closure embodiment. Ex. 1005 at [0039-0043] (discussing “the embodiment shown in FIGS. 7-10.”); Petition at 20-22 (noting Figures 7, 8 and 10 all describe “closure 101”). The difference is that each figure illustrates the closure from a different viewpoint. Figure 7 shows a “perspective view” of the closure, Figure 8 shows a “front elevation view of the closure of FIG. 7,” and Figure 10 shows a “bottom plan view of the closure of FIG. 7.” Ex. 1005 at [0020-0023].

Thus, if there is no concave and convex surface portions on the leading face of Figures 7 and 8, shown below, that fact cannot be changed by Figure 10 since the figures are different viewpoints of the exact same closure. Petitioner never tries to explain how Figures 7 or 8 would be understood to disclose a concave and convex surface. There is no indication of any curved surface let alone *two* curved surfaces

in Figures 7 or 8, such as by a vertical line, shading, or other technical drawing representation. *See e.g.*, Ex. 1001 at Figs. 1 and 2 (vertical line indicating inflection between concave and convex surfaces on leading face).

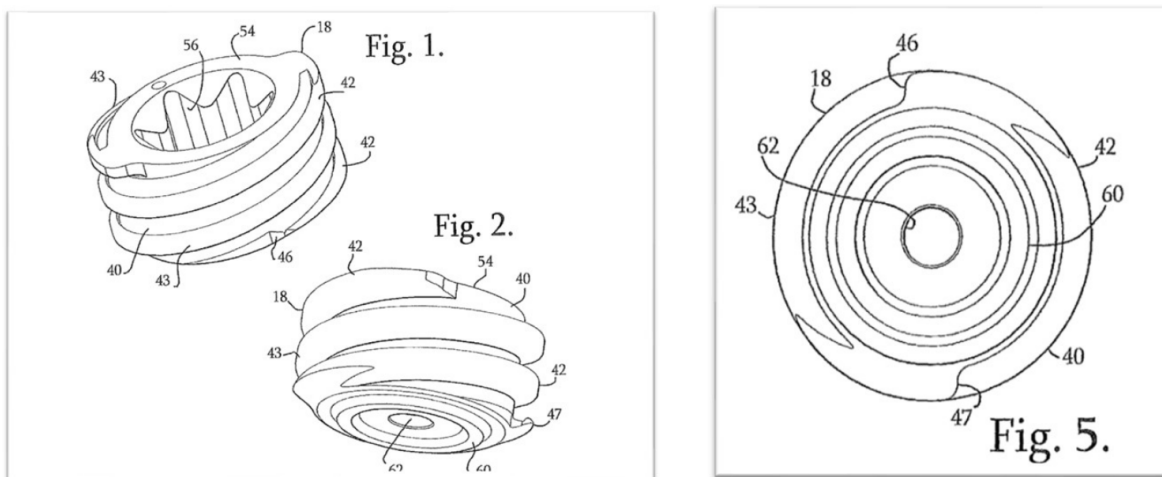


Ex. 1005 at Figures 7 and 8 (annotated by Patent Owner)

As seen above, rather than a concave and convex surface, Figures 7 and 8 depict a flat continuous surface for the leading face. As Dr. McMillin acknowledges, a flat continuous leading face surface was well-known at the time of the '477 Publication. Ex. 1003 at ¶¶ 64-67 (describing truncated threads including “[t]he Higbee cut, which is also known as a blunt start, blunt end thread, or truncated thread start” based on a 1891 patent). Given the conventional nature of flat leading face

surfaces, it is unsurprising that the leading face surface of the '477 Publication is never discussed in the specification or identified by number in the figures.

Comparing Figures 7, 8, and 10 of the '477 Publication with Figures 1, 2, and 5 of the '233 patent make clear that the concave and convex structure are visible across all views. *See* Ex. 1001, at Fig. 1 and Fig. 2 (showing a technical drawing transition line traversing the concave and convex surface portions on leading faces 46 and 47); *see also id.*, at Fig. 5 (showing a bottom view of the concave and convex leading faces surfaces 46 and 47).



Ex. 1001 at Figs. 1, 2, and 5

Rather than explain how Figures 7 and 8 illustrate something other than this conventional flat leading face surface, Petitioner simply posits that the line it identifies in Figure 10 “is the only feature shown that matches the shape of the” leading face shown in Figure 7. Petition at 53. This conclusory argument makes little sense. Assuming *arguendo* that the line in Figure 10 is a concave and convex line as

Petitioner alleges, then it does not match the shape of the leading face surface of Figure 7 (or Figure 8), as discussed above. Furthermore, there is no indication the unidentified line represents any surface rather than representing some other undisclosed feature.

Given the '477 Publication never discusses or even identifies the line Petitioner relies on in Figure 10, the only evidence of its meaning would need to be provided by Petitioner's expert declaration. Yet, Dr. McMillin's declaration parrots the conclusory analysis from the Petition as shown below:

<u>Petition</u>	<u>Dr. McMillin Declaration</u>
<u>Also, as shown in the annotated Figure 10 below, the leading face of the start structure includes a partial concave surface portion and a convex surface portion. Ex. 1005, Fig. 10; Ex. 1003, ¶238. A POSA would recognize this feature depicted in Fig. 10 to be the same leading face as shown in Fig. 7, at least because it is the only feature shown that matches the shape of the structure.</u>	<u>In addition, as shown in the annotated Figure 10 below, the leading face of the start structure disclosed in the '477 Publication includes a partial concave surface portion and a convex surface portion. <i>Id.</i>, Fig. 10. A POSA would recognize this feature of Fig. 10 as the leading face of the thread, at least because it is the only feature shown that matches with leading face shown in Fig. 7.</u>

Compare Petition at 53 *with* Ex. 1003 at ¶238.

Importantly, the declaration provides no explanation of why Dr. McMillin concludes the line in Figure 10 matches the shape of the leading face surface in Figures 7 or 8, when a reasonable inspection of Figures 7 and 8 indicates they do not depict a leading face with a concave and convex surface. The above conclusory and unsupported sentence is the totality of Dr. McMillin’s analysis for why the ’477 Publication teaches a “start structure having a leading face with a concave surface portion and a convex surface portion.” Ex. 1003 at ¶238. Such conclusory and unsupported expert testimony is afforded little or no weight. *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (PTAB Aug. 24, 2022) (precedential) (“[T]he cited declaration testimony is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight.”) (collecting cases).

Here, just as in *Xerox*, Dr. McMillin’s declaration on this issue “merely repeats, verbatim, the conclusory assertion for which it is offered to support. Dr. [McMillin] does not cite to any additional supporting evidence or provide any technical reasoning to support his statement.” *Id.* (internal citation omitted); *see also Xerox v. Bytemark*, Director’s Review Decision, Paper 12 at 3 (PTAB Feb. 10, 2023) (“The declaration sets forth Petitioner’s conclusory assertions as though they are facts, rather than setting forth facts and evidence in support of Petitioner’s

assertions.”). As such, the Board should afford the testimony of Dr. McMillin little to no weight on this issue.

A surface or face, unlike a line on a page, has structure including dimensions, elevations, and depth, which require some description or analysis in Dr. McMillin’s declaration to explain. Absent any supporting evidence or technical reasoning provided by Dr. McMillin’s declaration to support the conclusions in the Petition, Petitioner has no evidence that the unidentified line in Figure 10 of the ’477 Publication suggests the flat leading face surface of Figure 7 should be considered to have concave and convex surfaces. *TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1358 (Fed. Cir. 2019) (“Conclusory expert testimony does not qualify as substantial evidence.”); *Icon Health & Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017) (“Attorney argument is not evidence.”).

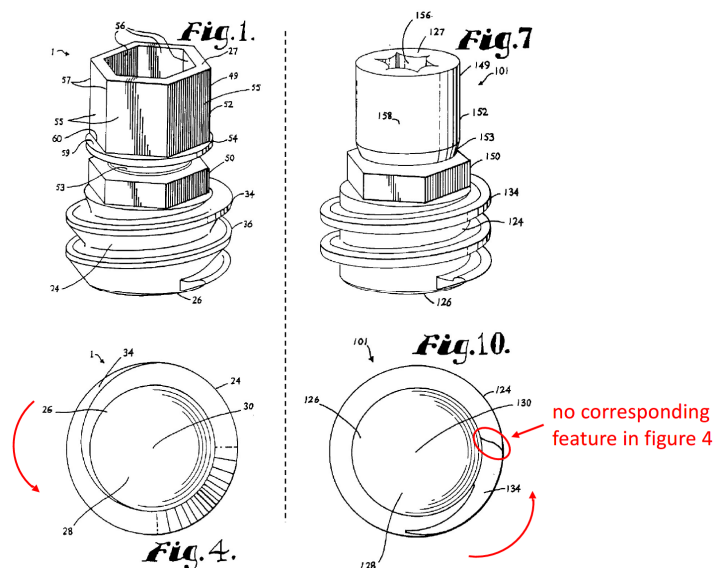
2. Petitioner’s theory contradicts disclosure of related embodiments

Petitioner’s theory about the unidentified line in Figure 10 also contradicts the disclosure provided for the other embodiments in the ’477 Publication and its parent application.

Starting with the embodiment for “closure 1” in the ’477 Publication, shown in Figures 1-4, this closure has substantially the same leading face as the “closure 101” embodiment in Figures 7-10. *Compare* Ex. 1005 at Figs. 1-4 *with* Figs. 7-10; *see also* [0014-0017], [0020-0023] and [0038-0045]. As acknowledged by Dr.

McMillin, “[t]he primary difference between the embodiments is the shape of the closure break-off heads 49 and 149” – not the leading face. Ex. 1003 at ¶167. Indeed, Dr. McMillin observed that the ’477 Publication discloses “incorporating by reference the description of the first embodiment [of closure 1] into the second embodiment [for closure 101].” *Id.* Thus, a POSITA would understand the leading face between the two embodiments is substantially the same.

Given the similarity in their leading faces, one would expect the same depiction of the leading faces across all embodiments. However, the bottom view of Figure 1 (as shown in Figure 4) does not contain the same line depicted in the bottom view of Figure 7 (as shown in Figure 10) that Petitioner relies on, shown below.



Ex. 1005 at Figs. 1, 4, 7 and 10²

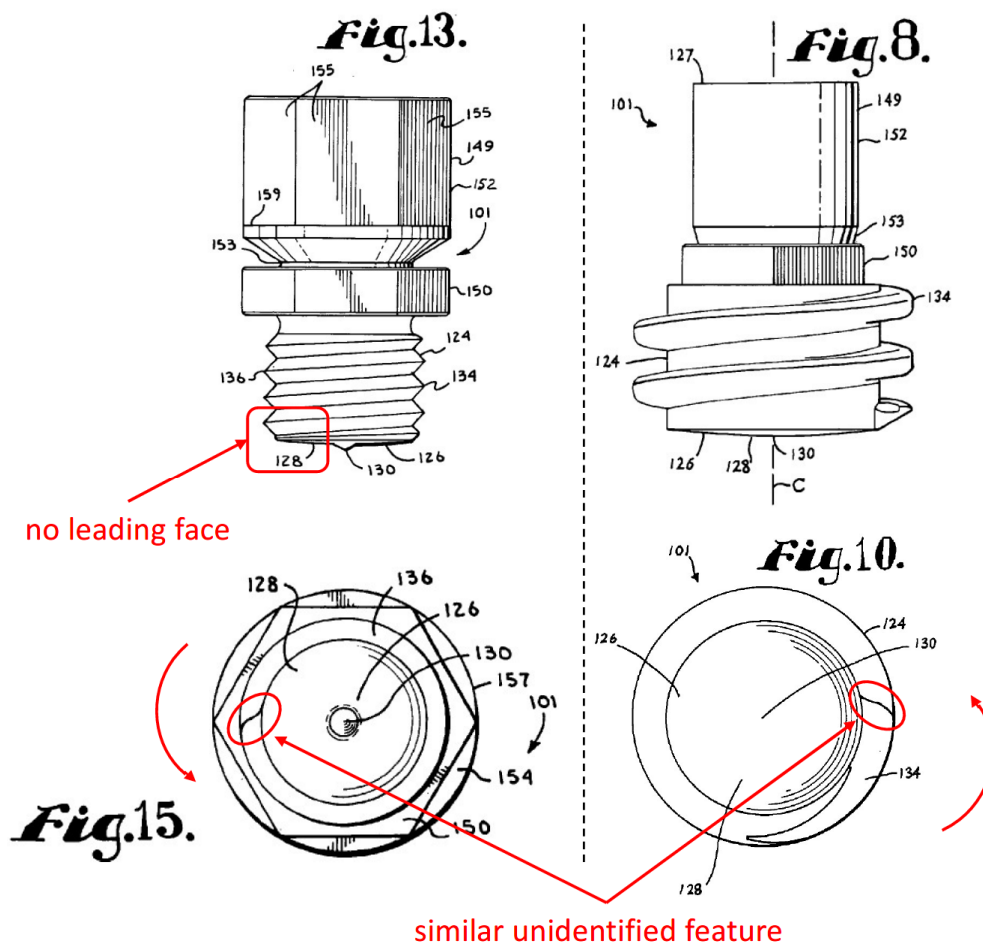
² Red semi-circular arrows in bottom view of these embodiments indicates the direction of rotation according to Petitioner when inserting closure into a receiver.

Despite acknowledging the relatedness of the embodiment for “closure 1” (shown in Figures 1-4) with “closure 101” (shown in Figures 7-10), Petitioner is silent as to how its conclusory analysis would be consistent with the “closure 1” embodiment. Rather, Petitioner’s interpretation results in an unexplainable discrepancy since the line relied on as the alleged leading face surface (shown in Figure 10), appears nowhere in Figure 4. Indeed, there is no line that is arguably concave and convex in all of Figure 4. Thus, if Petitioner’s allegations were accepted, it leads to the untenable result that “closure 1” and “closure 101” would be interpreted to have substantially different leading faces despite the fact the specification and Figures 1 and 7 indicate their leading faces are substantially the same. Ex. 1005 at Figs. 1, 7, [0014-0017], [0020-0023] and [0038-0045]; Ex. 1003 at ¶167.

In addition to being inconsistent with the “closure 1” embodiment, Petitioner’s conclusory assertion is also inconsistent with an embodiment in the parent application of the ’477 Publication. The ’477 Publication is a continuation-in-part of application No. 11/110,405 which published as U.S. Patent Publication 2005/0187549 (“the ’549 Publication”). *See* Exhibit 2001.

The ’549 Publication has a similar “closure 1” embodiment as the ’477 Publication. *Compare* Ex. 2001 at Figs. 1-4 *with* Ex. 1005 at Figs. 1-4. However, the “101” closure embodiment of the ’549 Publication is substantially different than that

of the '477 Publication in that the '549 Publication has a tapered thread initiation instead of the flat leading face of the '477 Publication. *Compare* Ex. 2001 at Figs. 12-15 *with* Ex. 1005 at Figs. 7-10. Despite disclosing a tapered thread initiation, the bottom view of the closure contains essentially the same unidentified line that Petition alleges is a concave and convex leading face surface. *Compare* Ex. 2001 at Fig. 15 *with* Ex. 1005 at Fig. 10.



Ex. 2001 at Figs. 13 and 15 (left) and Ex. 1005 at Figs. 8 and 10 (right)

The difference in the tapered thread initiation of the '549 Publication and the flat leading face of the '477 Patent are illustrated by Dr. McMillian, as shown below:



Tapered Start

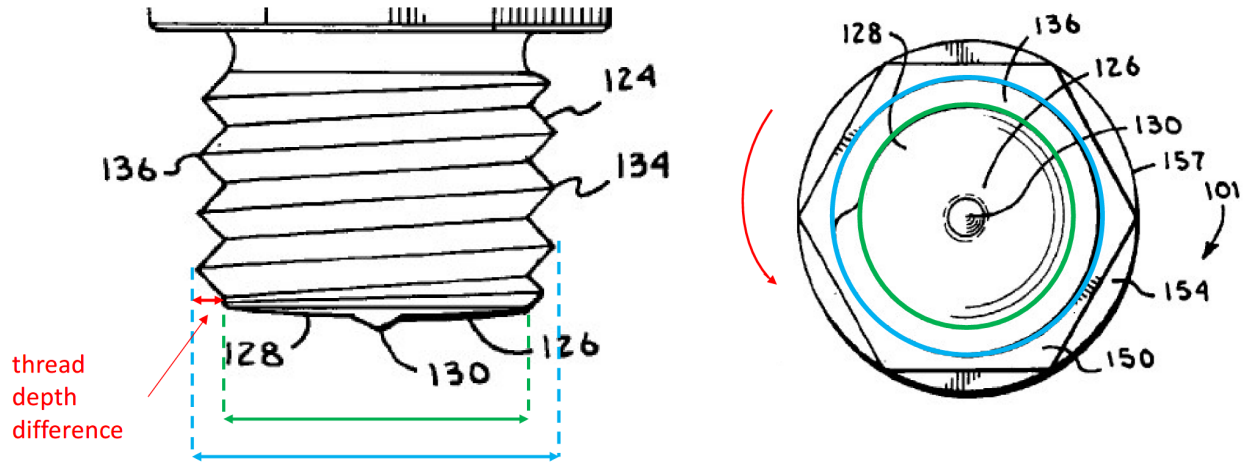


Truncated Start

Dr. McMillin's Illustration (Ex. 1003 at ¶64)

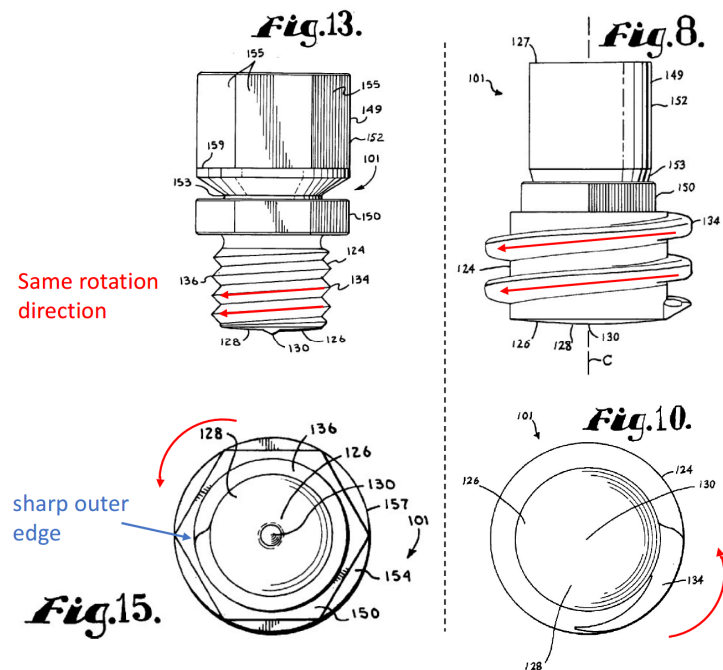
The tapered thread of Figure 13 of the '549 Publication does not disclose any leading face and certainly not a leading face with a concave and convex surface. However, under Petitioner's misguided theory, the unidentified line in Figure 15 of the '549 Publication should be interpreted to mean Figure 13 has a concave and convex leading face surface. Since Petitioner's theory results in a clearly erroneous outcome, it cannot be correct.

Furthermore, to moot any argument about the unseen backside of Figure 13 of the '549 Publication, there is no possibility the backside of Figure 13 could portray a concave and convex surface that matches the unidentified line in Figure 15. This is because the unidentified line in Figure 15 extends to the outermost crest. Yet, Figure 13 shows that the depth of the thread is already much less than outermost crest (assuming the thread continued at all to the backside). Thus, even if one were to speculate the backside of Figure 13 might have a truncated end with a leading face, any depiction of that leading face in the bottom view would not extend to the largest diameter crest like the unidentified line does.



Ex. 2001 at Figs. 13 (partial) and 15

Finally, it is important to note the unidentified line in Figure 15 of the '549 Publication has the *reverse orientation* as the unidentified line in Figure 10 of the '477 Publication even though their direction of thread rotation is the same, which leads to a sharp outer edge of the leading face under Petitioner's theory.



Ex. 2001 at Figs. 13 and 15 (left) and Ex. 1005 at Figs. 8 and 10 (right)

This is further evidence that the unidentified line shown in Figure 10 of the '477 Publication is not a leading face surface since Dr. McMillin testified the purpose to truncate a thread is to provide a leading face without sharp outer edges. Ex. 1003 at ¶64 (“By truncating a thread start a POSA was able to avoid very thin portions of the tapered thread, which are sharp and could cut a surgeon’s glove, could be easily damaged, and could lead to cross threading.”). As such, Petitioner’s interpretation of the unidentified line results in an embodiment in the parent of the '477 Publication with the sharp edge leading face that Dr. McMillin testified a POSITA would avoid.

Therefore, the disclosure and context provided by the '477 Publication and its parent contradicts Petitioner’s conclusory assessment that a POSITA would understand the unidentified line in Figure 10 of the '477 Publication to mean the leading face of Figures 7 and 8 has a concave surface portion and a convex surface portion.

3. Petitioner’s assertions are based on hindsight, not evidence

Blinded by its pursuit to invalidate the claims of the '233 Patent, Petitioner wrongly ignored portions of the '477 Publication and its parent that contradicted its theory that the unidentified line in Figure 10 would be understood by a POSITA as a concave and convex leading face surface. In doing do, the Petitioner improperly tries to “stitch together an obviousness finding from discrete portions of prior art

references without considering the references as a whole.” *In re Enhanced Security Research, LLC*, 739 F.3d 1347, 1355 (Fed. Cir. 2014).

Petitioner’s conclusory analysis is nothing more than a hindsight driven approach that reads the teachings of a concave and convex leading face surface from the ’233 Patent into the ’477 Publication. *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) (warning against a “temptation to read into the prior art the teachings of the invention in issue”); *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) (“[T]he expert’s testimony on obviousness was essentially a conclusory statement...This is not sufficient and is fraught with hindsight bias.”); *ATD Corp. v. Lydall , Inc.*, 159 F.3d 534,546 (Fed. Cir. 1998) (“Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.”).

As such, Petitioner’s allegation that the ’477 Publication discloses a “leading face with a concave surface portion and a convex surface portion” is not based on competent evidence and is not persuasive. Petitioner does not rely on any other art or argument for to teach this limitation in independent claim 1.

Therefore, the Board should find that there is no reasonable likelihood that the Petition would prevail with respect to claim 1.

B. Dependent Claims 2-7 and 13-20

Dependent claims 2-7 and 13-20 are patentable at least due to their dependence on independent claim 1, which is patentable for the reasons discussed above. Should the Board institute this IPR proceeding, Patent Owner may address additional reasons why these dependent claims are separately patentable.

V. CONCLUSION

Petitioner's case hinges on a hindsight driven interpretation of Figures 7-10 of the '477 Publication. Moreover, accepting Petitioner's interpretation of Figures 7-10 would result in unjustified contradictions with the disclosure of other embodiments in the '477 Patent and its parent application. Compounding the problems is that the only purported evidence of Petitioner's interpretation is a conclusory statement from Petitioner's expert lacking any technical reasoning or additional supporting evidence.

The Board cannot sustain a finding of obviousness based on such conclusory allegations, especially those that contradict the record as here. Therefore, the Board should deny the instant IPR Petition.

Dated: January 3, 2024

Respectfully submitted:

/James P. Murphy/

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CERTIFICATE OF WORD COUNT

Under the provisions of 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the Microsoft Office word count for the foregoing Patent Owner's Preliminary Response Under 35 U.S.C. § 313 and 37 C.F.R. § 42.107, excluding the table of contents, table of authorities, certificate of word count, and certificate of service, totals 3,826 words, which is less than the 14,000 words allowed under 37 C.F.R. § 42.24(b)(1).

Dated: January 3, 2024

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the Patent Owner's Preliminary Response and all exhibits were served on January 3, 2024, via email directed to the following email addresses of record:

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