

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. IPR2023-01433
Patent No. 11,129,646

**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 1-20 of U.S. Patent No. 11,129,646 (the ’646 Patent) on September 22, 2023.

The Petition is deficient in showing the prior art teaches a lower surface of a leading face that is apart and above the annular outer edge of the bottom surface of the closure. Petitioner wrongly relies on the annular outer edge of a rim instead of an annular outer edge of a bottom surface. In so doing, Petitioner ignores the disclosure in the ’646 Patent that differentiates the bottom surface of the closure from a rim. When the actual bottom surfaces of the prior art closures are considered (rather than just the rim surfaces) the prior art teaches no more than what was already distinguished during prosecution.

In addition, 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 limitations in the independent claims reciting a leading face with concave and convex surfaces that are defined by substantially equal radii of curvature. Without analysis or supporting evidence, Petitioner concludes that the undescribed line teaches exactly what the independent claims recite. However, Petitioner’s conclusory assertion contradicts the other figures and disclosure in the prior art and cannot be the basis to support a rejection.

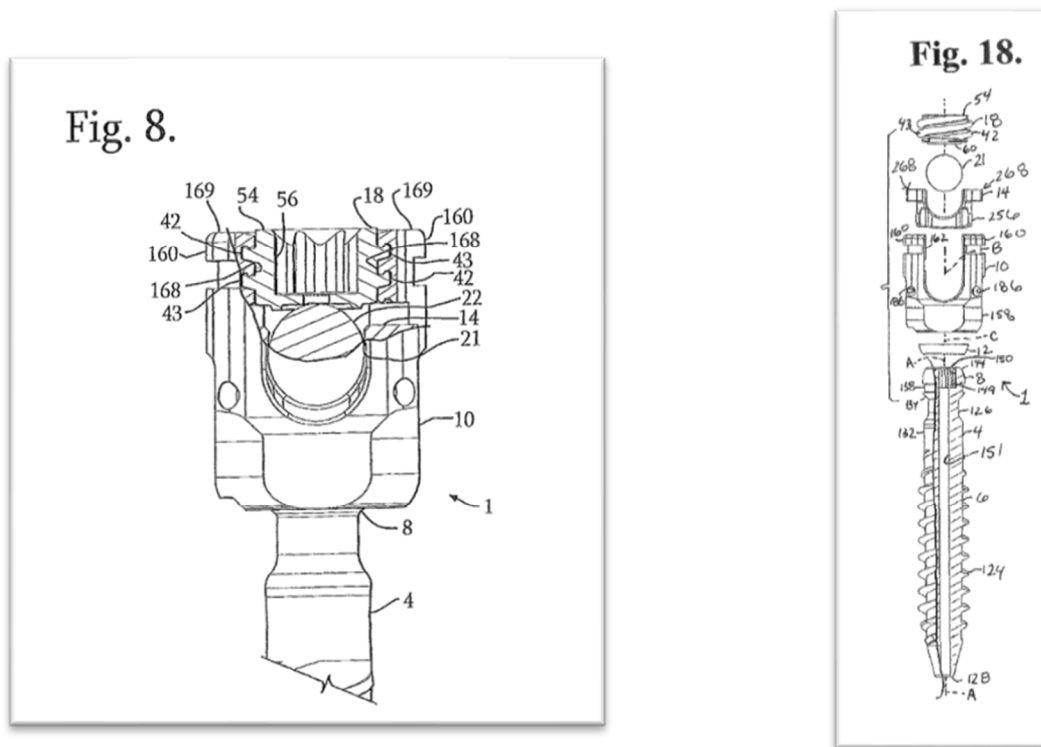
Therefore, the Board should find that Petitioner fails to demonstrate that it is more likely than not that at least one of the claims challenged in the Petition is unpatentable over the prior art in the Petition.

II. OVERVIEW OF THE '646 PATENT

A. Specification

The invention of the '646 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 1:27-31. “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 1:32-35.

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.

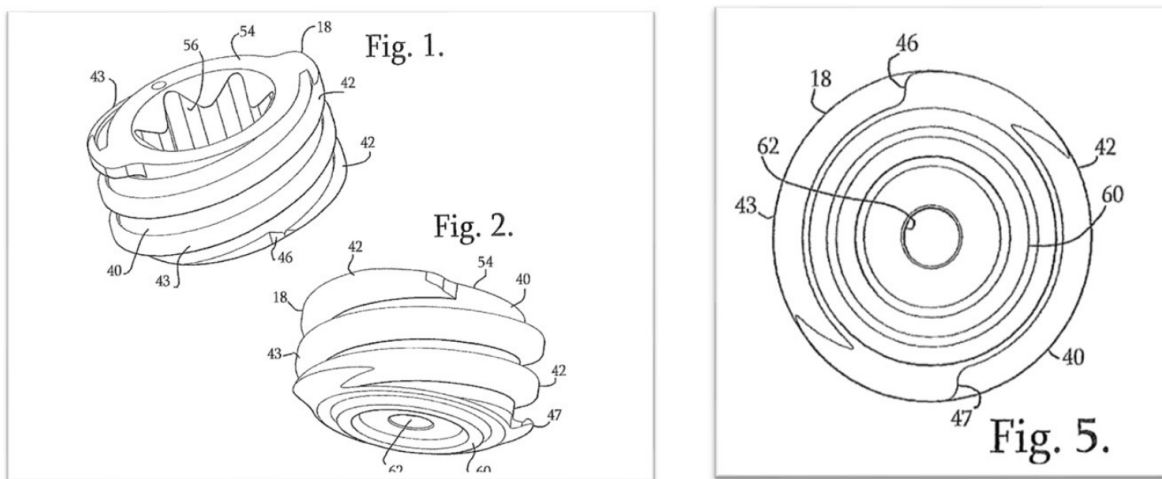


Ex. 1001 at Figs. 8 and 18

“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. The leading face can include “a partial concave surface adjacent the root and a partial convex surface adjacent the crest,” the “surfaces each defined by a radius of curvature that can be substantially equal with respect to each other.” *Id.* at Abstract; *see also* Figs. 1,2, and 5.



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

Furthermore, “[a] base or 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 21 in certain embodiments of the invention.” *Id.* at 9:4-7. The specification repeatedly differentiates the closure’s planar “base or bottom surface” from the “rim” with exemplary embodiments labeled as “base or bottom surface” 58, 58’, 358, 458, 558, or 658, while the “rim” is labeled as 60, 60’, 360’, 460’, 560’, or 660’ in the corresponding embodiments. *Id.* at 9:4-7; 22:25-33; 22:50-57; 23:4-11; 23:25-32; 23:45-52.

B. Prosecution History

The ’646 patent issued on September 28, 2021, with Roger Jackson and James Surber as the named inventors. The ’646 patent issued from Application No. 17/123,499, which was filed on December 16, 2020, and on its face claims priority to Provisional Application Nos. 61/634,361, filed on February 28, 2012, and 61/631,746, which was filed on January 10, 2012.

In the Office Action dated March 9, 2021, claims 1, 2, 4, 5, and 8-10 were rejected under pre-AIA 35 U.S.C. § 103(a) as being obvious over U.S. Patent Publication No. 2011/0106179 to Prevost (hereinafter “Prevost”). Ex. 1002 at 238.

In response, Applicant amended claims 1, 3, 6, 8-12, and 16-17, canceled claims 4 and 14, and added new claims 18-22. Specifically, claim 1 was amended to recite as follows:

1. (Currently Amended) A medical implant assembly comprising:

~~a receiver having a first arm and a second arm spaced apart from each other by a channel, the first arm and the second arm each having a top surface and an upper portion with an inner surface, the first and second arms each having a discontinuously at least partially configured as a helically wound thread extending up to [[the]] a top surface of the receiver, and a [[the]] channel being formed in the upper portion of the receiver by the first arm and the second arm opening onto the top surfaces and configured to receive a rod; and~~

~~a closure plug being threaded and configured to be positioned within the upper portion close the channel, the closure plug having an axis of rotation, [[and]] a continuously helically wound thread form, and a substantially flat bottom surface with an annular outer edge, the substantially flat bottom surface configured to engage the rod, the continuously helically wound thread form having a start structure [[and]] with an upper leading surface extending between a root and a crest of the continuously helically wound thread form, the start structure having a leading face extending below the upper leading surface to a lower surface of the start structure, the leading face including a partial concave surface adjacent the root and a partial convex surface adjacent the crest, the partial concave and partial convex surfaces each defined by a radius of curvature that is substantially equal with respect to each other, the lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof.~~

Ex. 1002 at 283.

Relevant to this preliminary response, Applicant submitted Prevost, “does not describe the limitations of amended claim 1,” because, Claim 1 requires “the lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof.” *Id.* at 288-289. Applicant points out in Prevost, “the lower surface, as identified by the Examiner, is connected to the outer edge of the bottom end 29.” *Id.*

at 289. “For at least these reasons, Prevost does not disclose all the elements of independent claim 1...[a]nd therefore claim 1 is therefore allowable.” *Id.*

In response to Applicants amendments, the Office issued a Notice of Allowance on June 24, 2021 and the '646 patent issued on September 28, 2021.

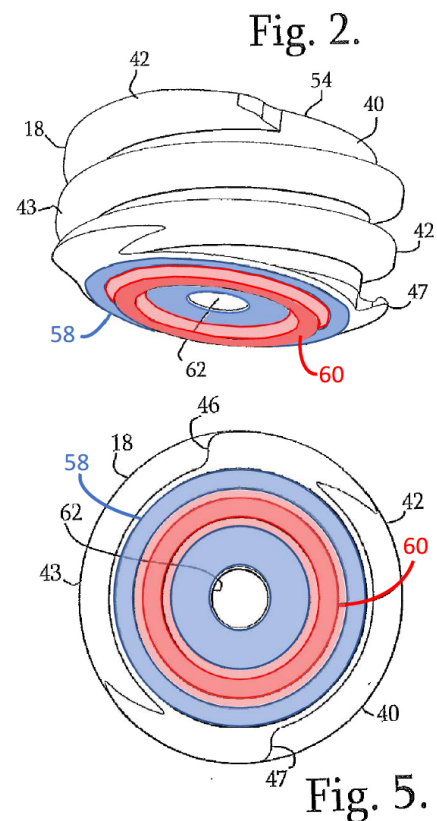
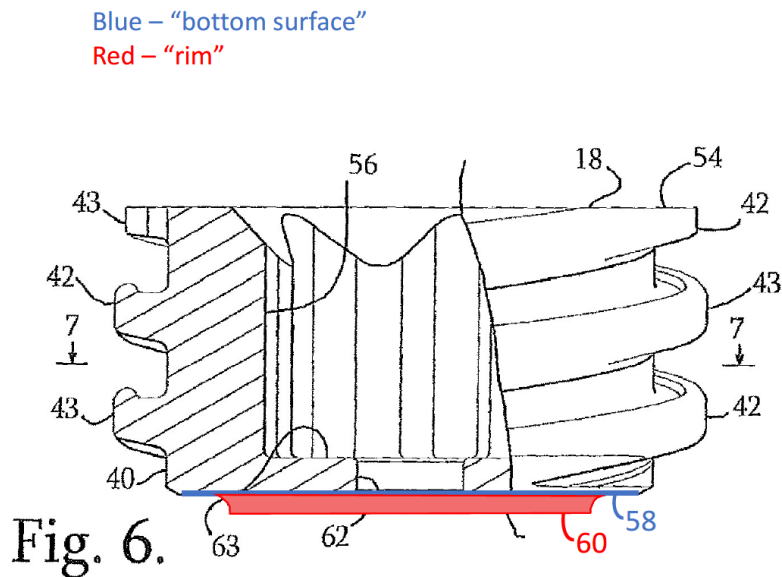
III. CLAIM CONSTRUCTION

Petitioner purports to construe certain claim limitations. Petition at 9-25. However, Petitioner doesn't provide any constructions, but rather alleges that the “plain meaning” of the limitations encompass certain embodiments in the '646 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.

Nonetheless, at least one of Petitioner's allegations in the claim construction section is relevant to the arguments in this preliminary response. Namely, Petitioner's allegation that the bottom surface of a rim alone can be the claimed “substantially flat bottom surface with an annular outer edge” contradicts the specification of the '646 Patent. Petition at 12. The '646 Patent repeatedly differentiates the closure's planar “base or bottom surface” from the “rim” throughout multiple embodiments. Ex. 1001 at 9:4-7; 22:25-33; 22:50-57; 23:4-11; 23:25-32; 23:45-52. These exemplary embodiments label the “base or bottom surface” as 58, 58', 358, 458, 558, or 658 while the “rim” is labeled as 60, 60', 360',

460', 560', or 660' in the corresponding embodiments. *Id.*

To help visualize the different surfaces of the “base or bottom surface” and the “rim,” Patent Owner provides the below annotations of Figures 2, 5 and 6 showing the “bottom surface 58 of the closure is planar” (shaded in blue) and the further included “rim 60” (shaded in red):



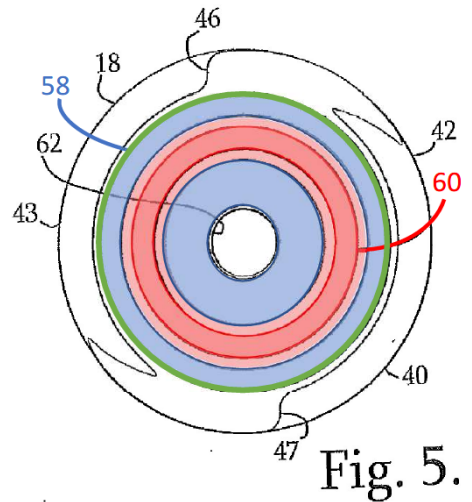
Ex. 1001 at Figs. 2, 5, and 6 (annotations by Patent Owner)

The claimed “substantially flat bottom surface with an annular outer edge” is a ring-shaped outer edge of the “bottom surface”, which is shown below as a green ring for the exemplary embodiment of Figure 5:

Blue – “bottom surface”

Red – “rim”

Green – “bottom surface with an annular outer edge”



Ex. 1001 at Fig. 5

As seen above, the position of the annular outer edge of the bottom surface is not influenced by the presence of the optional rim. *See* Ex. 1001 at 9:5-7 (rim 60 provides “penetration into the surface 22 of the rod 21 in certain embodiments of the invention) and 25:7-10. This is because the annular outer edge would remain the same if the bottom had no rim or if the bottom further includes a rim (with the latter embodiment being shown in Figure 5). As such, the inclusion of a rim on the bottom surface is irrelevant to the location of the annular outer edge of the bottom surface.

In contrast, Petitioner’s alternative theory that the rim alone can be the claimed “substantially flat bottom surface with an annular outer edge” ignores the specification of the ’646 Patent. Petition at 12. As illustrated below, the annular edge

of the rim (shown in orange) is not the annular “outer edge” of the bottom surface but rather is internal to the annular outer edge of the bottom surface.

Blue – “bottom surface”

Red – “rim”

Orange – Petitioner’s alleged “bottom surface with annular outer edge”

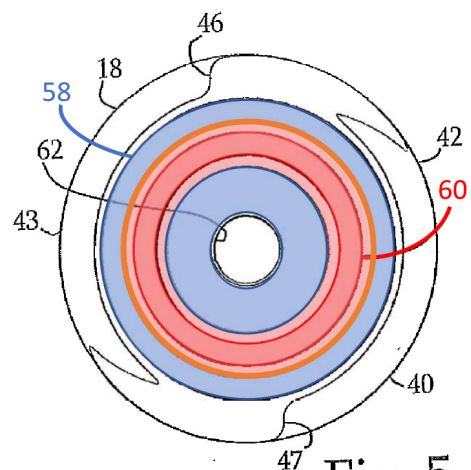


Fig. 5.

Ex. 1001 at Fig. 5

The only way Petitioner’s theory could be correct is if one ignored the teachings in the specification that the “base or bottom surface” includes the surfaces shaded in blue above. However, it is axiomatic that claims are interpreted in light of the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315-16 (Fed. Cir. 2005); *Vitronics Corporation v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (“the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.”). Indeed, Petitioner’s assertion that a rim alone can be the claimed “bottom surface” would improperly exclude the preferred embodiment’s “base or bottom 58” as the claimed bottom surface. *Vitronics Corporation v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (construction that excludes a preferred embodiment “is

rarely, if ever, correct”).

As one analogous example, the Federal Circuit admonished the Board for construing a claim limitation to “body” as any generic body rather than the body identified in the specification:

We conclude that the Board’s construction of “body” was unreasonably broad...It is true that some of the claims at issue recite a broad term “body” without further elaboration on what the term “body” encompasses. J.A. 15, 17 (claims 28 and 43). However, the remainder of the specification does not use the term as a generic body. There is no dispute that the ’817 patent specification consistently describes and refers to the body as a component distinct from others, such as the mandrel, piston, and drive ring.

In re Smith Int’l, Inc., 871 F.3d 1375, 1382 (Fed. Cir. 2017).¹ Likewise, Petitioners seek to construe a “substantially flat bottom” as a generic flat surface that is not consistent with the distinctly described planar “base or bottom surface” in the specification.

As discussed herein, all of Petitioner’s arguments allege the edge of a rim is the “annular outer edge” of the bottom surface. This is inconsistent with the specification as just discussed. For example, claim 1 of the ’646 Patent recites “the

¹ Notably, this decision was decided under the more permissive broadest reasonable interpretation standard and would be even more pertinent under the *Phillips* standard applicable to the instant IPR.

plug having...a substantially flat bottom surface with an annular outer edge configured to engage the rod” rather than a rim having a substantially flat bottom surface with an annular outer edge configured to engage the rod. *See* Ex. 1001 at claim 1.

As such, the Board should find that none of the proposed grounds of rejection render the claims obvious.

IV. PROPOSED GROUNDS OF REJECTION ARE NOT LIKELY TO SUCCEED

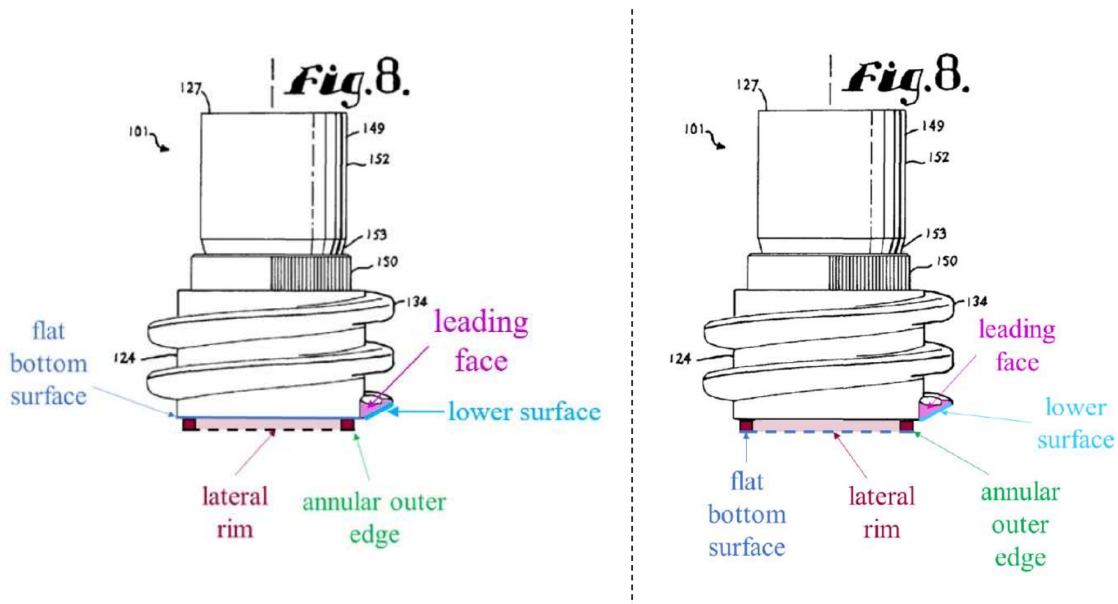
A. Prior art does not teach “a substantially flat bottom surface with an annular outer edge... the lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof” (Claim 1)

As previously discussed in the claim construction section, the “substantially flat bottom surface with an annular edge” cannot be the edge of the bottom surface of a rim. *See* Section II. When the bottom surface of the prior art is viewed in the same context as described in the ’646 Patent, it is clear that the alleged start structures of the ’477 Patent and the Kirschman reference are not “spaced apart and above the annular outer edge of the substantially flat bottom surface.”

1. Ground 1 – ’477 Publication

Petitioner presents two arguments for this limitation, purportedly to address “this limitation under either [of Petitioner’s] constructions.” Petition at 32. However, Petitioner does not present two different claim constructions, only two alternative

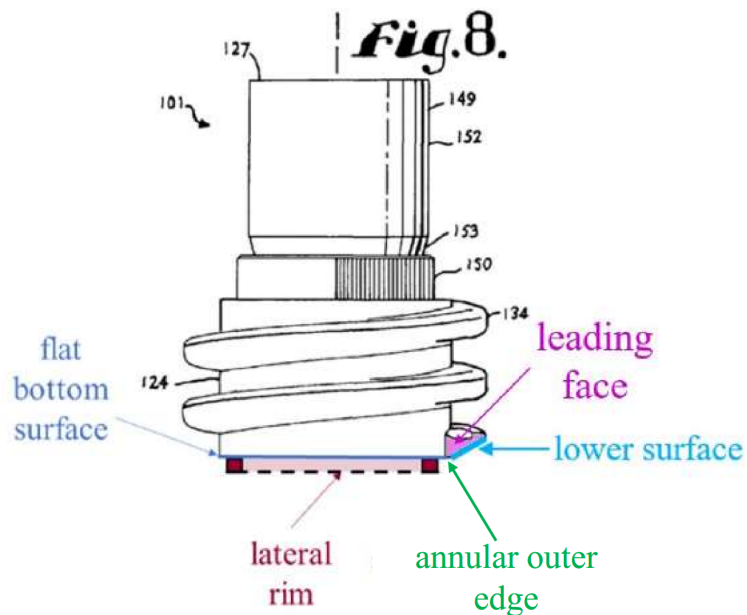
theories describing the flat bottom surface with an annular outer edge. Both theories suffer from the same flaw in that both rely on an annular outer edge of the *rim* rather than an annular outer edge of the *bottom surface*. Petitioner’s two alternative theories are shown below.



Petition at 37 (left) and 38 (right)

The only difference in these two alternatives is what feature of the '477 Publication the Petitioner alleges is the “flat bottom surface.” Despite changing the location of the bottom surface between the two alternatives, Petitioner inexplicably leaves the location of the bottom surface’s “annular outer edge” unchanged. Petitioner’s second modified Figure 8, shown on the right, is clearly incorrect since it identifies the rim surface by itself as the bottom surface. This contradicts the specification’s description of the bottom surface of the closure in the '646 Patent. *See supra* Section III.

Petitioner's first modified Figure 8, shown on the left above, more accurately identifies the surface corresponding to the bottom surface of the closure. However, the annular outer edge Petitioner points to is the outer edge of the rim, not the outer edge of the bottom surface it identified. The proper identification of the annular outer edge of the bottom surface in Petitioner's modified Figure 8 is shown below:

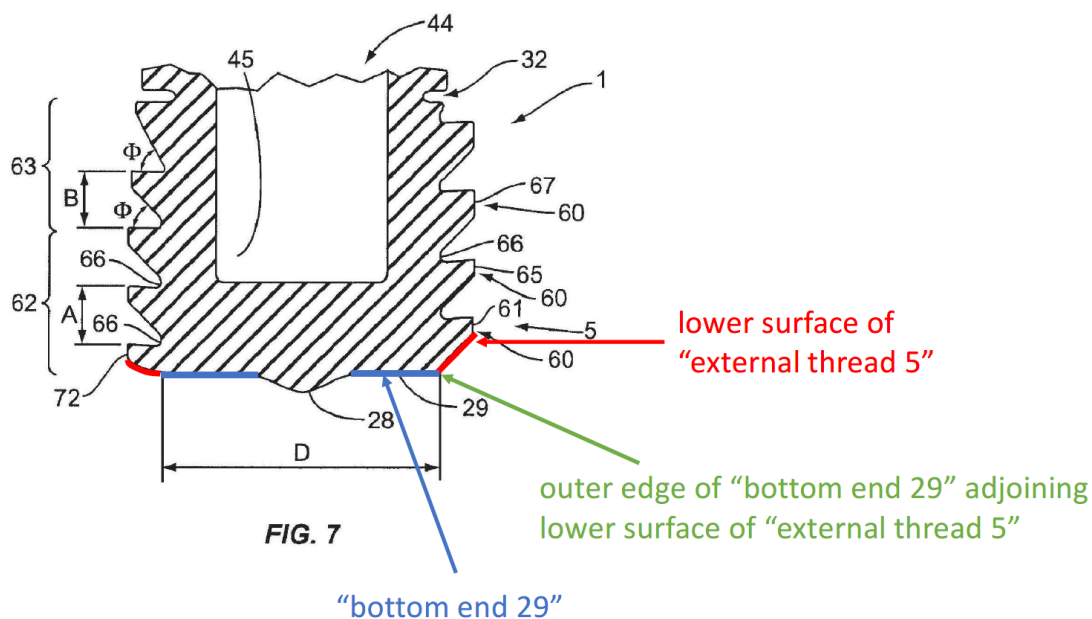


Petition at 37 (annular outer edge arrow modified by Patent Owner)²

When the annular outer edge of the bottom surface is correctly identified, it is clear that the '477 Patent fails to teach “the lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof.” Rather, the alleged

² Patent Owner does not necessarily agree with all of Petitioner's annotations. This modified figure is intended to show how Petitioner's argument fails in view of its assertion of the location of the flat bottom surface.

Indeed, the closure of the '477 Patent is no different in this respect than the Provost reference distinguished during prosecution that also disclosed a thread connected to the bottom surface. Ex. 1002 at 288 (“The [lower] surface identified by the Examiner is contiguous with the bottom end 29 of the set screw 1. That is the [lower] surface of the external thread 5 and the bottom end 29 adjoin each other.”); *see* Ex. 1022 at Figs. 5-8. For example, Figure 7 of Provost is provided below showing the distinguished Provost closure:



Ex. 1022 at Fig. 7 (Provost reference distinguished during prosecution)

Therefore the Board should determine that the '477 Publication does not teach “the lower surface of the start structure being spaced apart and above the annular

outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof.”

2. Ground 2 – ’477 Publication in view of Kirschman

Petitioner asserts that, “[i]f this limitation requires a lateral rim positioned near the periphery of the closure and the ’477 Publication is insufficient to anticipate or render obvious this limitation, then it would have been obvious to a POSA to modify the ’477 Publication’s closure to add such a lateral rim, as disclosed by Kirschman.” Petition at 49. However, as discussed above, the outer edge of the rim is not the outer edge of the bottom surface. As such, the presence or location of the lateral rim is irrelevant. Accordingly, Petitioner’s combination with Kirschman does not cure the deficiencies in the ’477 Publication with regard to this limitation.

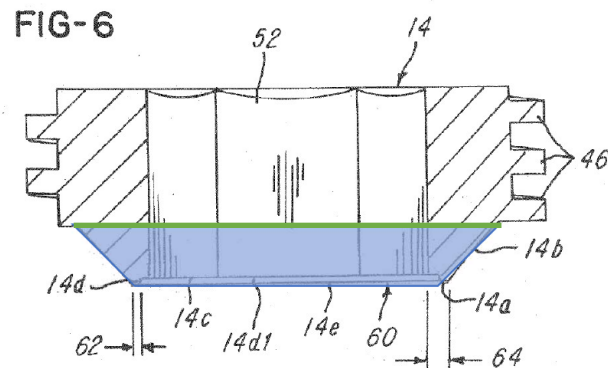
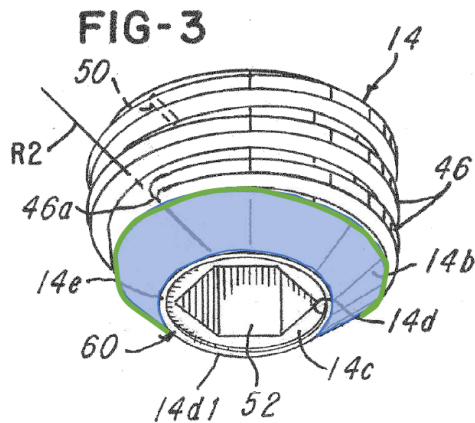
In fact, Kirschman is even less relevant to the claim limitation than the ’477 Publication since Kirschman discloses “the bottom 14b is frusto-conical” instead of a substantially flat bottom.³ Ex. 1007 at [0043]. As shown in the annotations of Kirschman’s figures below, the bottom surface includes at least frusto-conical

³ While Kirschman mentions the bottom 14b can be other shapes to guide the cap into the bore, Petitioner does not rely on any other shape. *See* Ex. 1007 at [0044]. Instead, Petitioner expressly relies on the “frusto-conical surface” to make its argument. Petition at 52-53. Moreover, the other shapes contemplated by Kirschman would not change the outcome of the obviousness analysis.

“bottom 14” (shaded in blue) that has an annular outer edge (shaded in green) adjoining the lower surface of the external threads.

Blue – “bottom 14b is frusto-conical”

Green – bottom surface annular outer edge



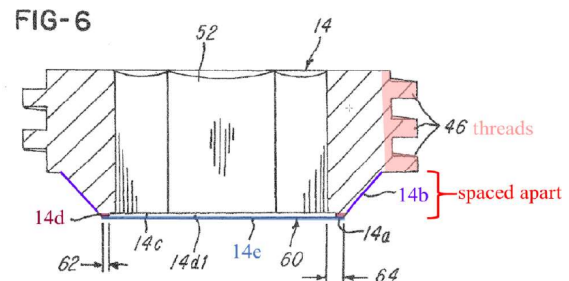
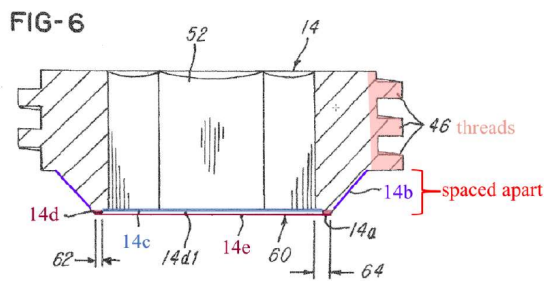
Ex. 1007 at Figure 3 and Figure 6

Petitioner simply ignores surface 14b that Kirschman expressly describes as “the bottom” to assert that either surface 14c or 14e alone read on the claimed “substantially flat bottom surface.” Petition at 49-50. Petitioner’s approach is wrong on multiple fronts. First, Petitioner ignores the meaning of “substantially flat bottom surface” as described in the ’646 Patent. As previously discussed, the bottom surface of the ’646 Patent is not a rim alone or a flat surface inside the rim. *See supra* Section III. The bottom surface of Kirschman that corresponds to the bottom surface of the ’646 Patent includes at least the surface for frusto-conical “bottom 14b.” As such, Kirschman’s bottom surface is not substantially flat given it is frusto-conical.

Second, Petitioner cannot ignore Kirschman's express disclosure that the frusto-conical surface 14b is "the bottom" surface of the closure. Petition ignores Kirschman's express teachings of his bottom surface by using hindsight to find some other surface in Kirschman to be the claimed "substantially flat bottom surface." However, Petitioner cannot pick and choose isolated elements in the prior art to read on the claims while ignoring the teachings of the prior art as a whole. *In re Enhanced Security Research, LLC*, 739 F.3d at 1355 (cannot "stitch together an obviousness finding from discrete portions of prior art references without considering the references as a whole."); *ATD v. Lydall*, 159 F.3d at 546 ("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.").

Finally, Petitioner's argument that the threads of Kirschman are spaced apart and above the closure's bottom surface is based on Petitioner's faulty analysis that frusto-conical bottom 14b is not in fact the bottom surface. Indeed, Petitioner brazenly relies on the surface for "bottom 14b" to show the separation between the thread and its alleged bottom surface. Petition at 52-53 ("the lower surface of the thread is spaced above and apart from the annular outer edge of the substantially flat bottom surface of the plug at least by a distance of the surface 14b").

Patent Owner provides Petitioner's figures illustrating this point below, which highlights the surface for "bottom 14b" in purple:



Petition at 53 (left) and 54 (right)

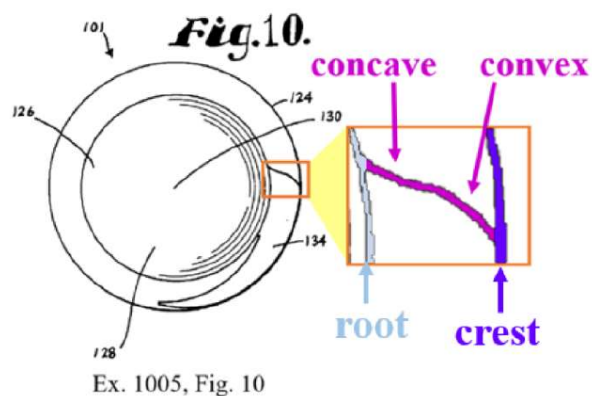
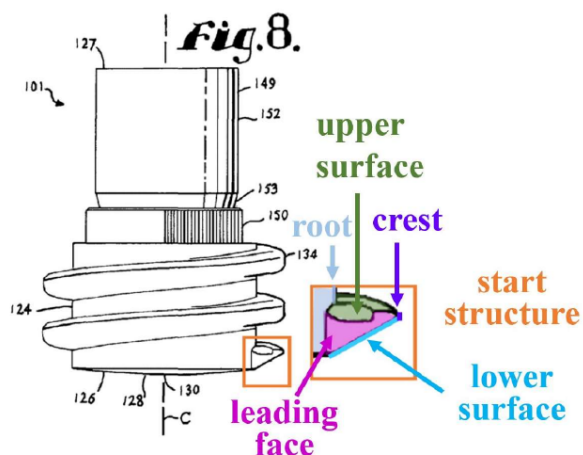
The irony of Petitioner's arguments on this point is apparent when one considers that Petitioner is relying on the surface for "bottom 14b" as a surface allegedly separating the bottom surface from the threads. However, Petitioner's figure shows the exact opposite. They illustrate that the lower surface of the thread is adjoined to "bottom 14b" rather than being spaced apart and above Kirschman's frusto-conical bottom surface.

Therefore, the Board should determine that the '477 Publication in view of Kirschman does not teach "the lower surface of the start structure being spaced apart and above the annular outer edge of the substantially flat bottom surface so as to not be connected with the annular outer edge thereof."

B. Prior art does not teach “the leading face including a partial concave surface adjacent the root and a partial convex surface adjacent the crest” (Claim 1)

Petitioner makes the same argument for this limitation for both Grounds 1 and 2. *See* Petition at 54 (Ground 2 relies on the '477 Publication for limitations not discussed for Ground 2).

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 34-36. Since the '477 Publication does not describe the unidentified line in Figure 10, Petitioner assumes, without basis, that the '477 Publication “discloses a partial concave surface adjacent the root and a partial convex surface adjacent the crest.” *Id.* Petitioner incorrectly assumes the unidentified line in Figure 10 is the same leading face surface as shown in Figures 7 and 8. *Id.* These features of Figures 8 and 10 are identified in the Petition as shown below:



Petition at 35-36 (annotations by Petitioner)⁴

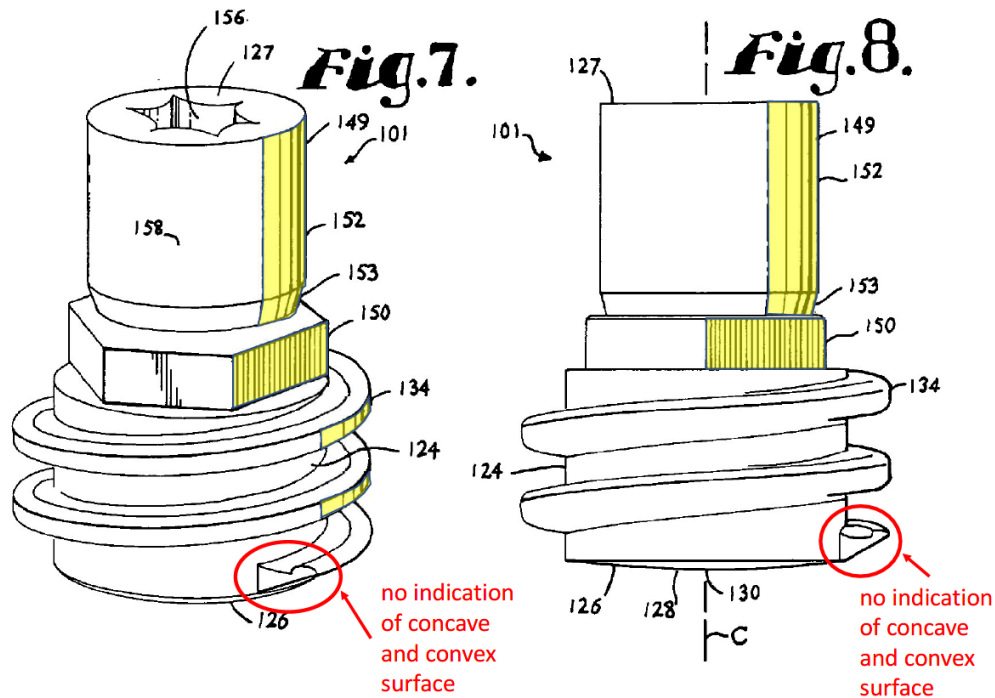
Yet, Petitioner's argument is undercut by the fact that Figures 7 and 8 do not show a concave and convex leading face surface as seen above – a fact that Petitioner never addresses in its argument. In addition, Petitioner's reliance on the undescribed line in Figure 10 as a concave and convex leading 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.

⁴ 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.

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 27-28 (noting Figures 7, 8 and 10 disclose a “second embodiment”). 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).

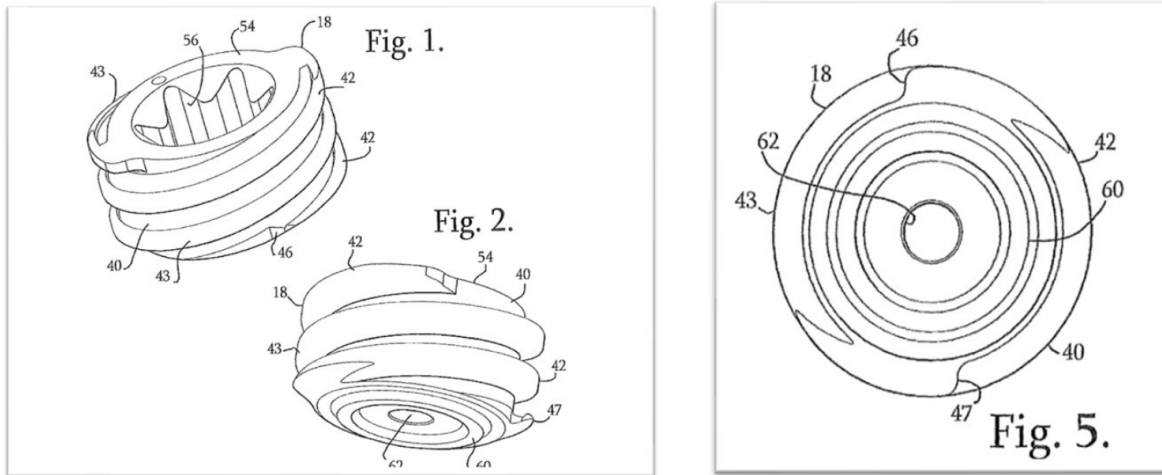


Ex. 1005 at Figures 7 and 8 (annotated by Patent Owner)

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 ¶¶ 65-68 (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 '646 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 “discloses a partial concave surface adjacent the root and a partial convex surface adjacent the crest.” Petition at 36. This conclusory argument makes little sense. Assuming arguendo 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 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 entire testimony on this issue is as equally conclusory as the Petition:

<u>Petition</u>	<u>Dr. McMillin Declaration</u>
As shown in Figure 10 below, the leading face of the start structure is formed in an s-curve, with both concave and convex curves. In particular, the '477 Publication discloses a partial concave surface adjacent the root and a partial convex surface adjacent the crest. EX1005, Fig. 10; EX1003, ¶234.	In addition, as shown in Figure 10, the leading face of the start structure disclosed in the '477 Publication includes a partial concave surface adjacent the root and a partial convex surface adjacent the crest. <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. 8 and extends continuously from the root to the crest.

Petition at 35-36; Ex. 1003 at ¶234.

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 ¶158. 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 Figures 7 and 8 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.”).

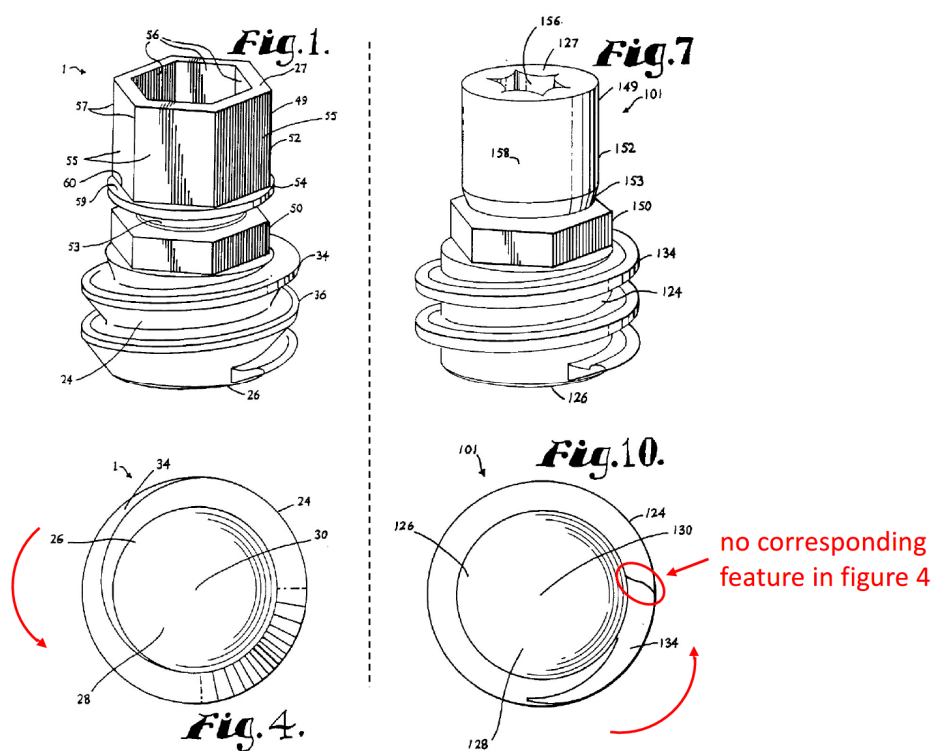
2. Petitioner’s theory contradicts disclosure of related embodiments

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 ¶186. 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 10⁵

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

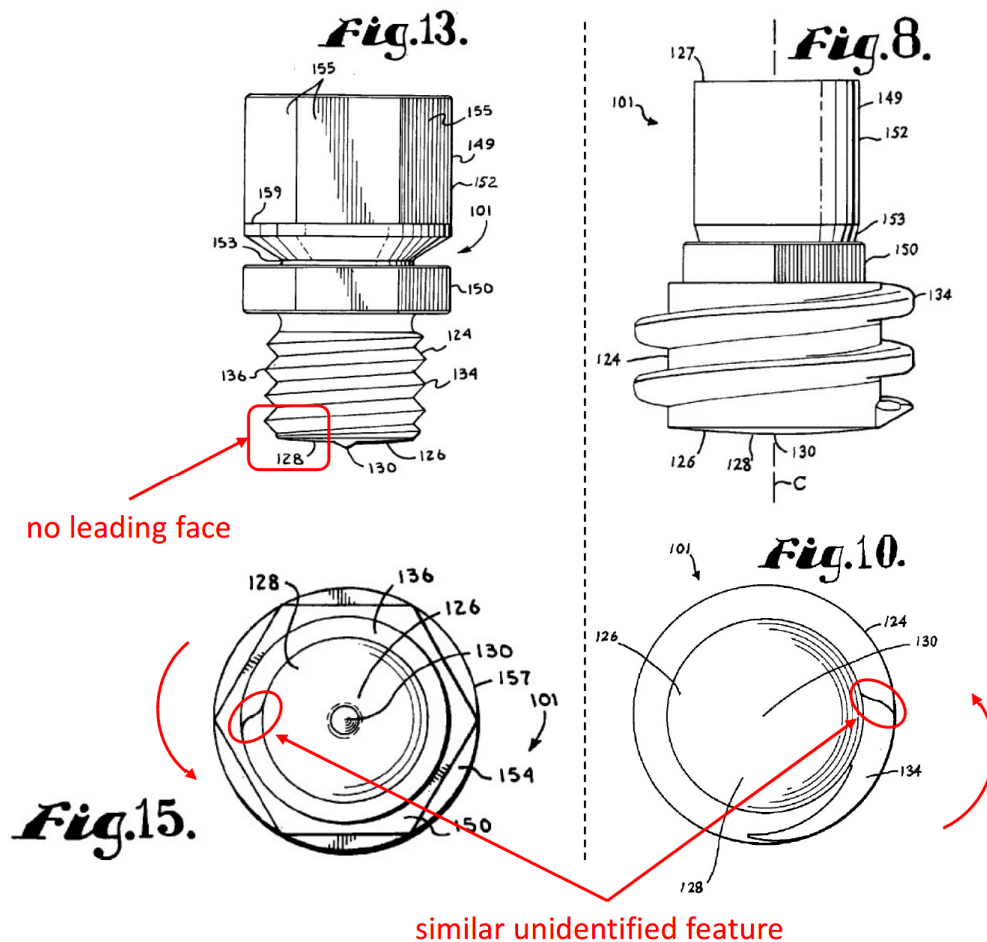
⁵ Red semi-circular arrows in bottom view of these embodiments indicates the direction of rotation according to Petitioner when inserting closure into a receiver.

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 ¶186.

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.

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 ¶65 (“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 '646 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 so, 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 ’646 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.

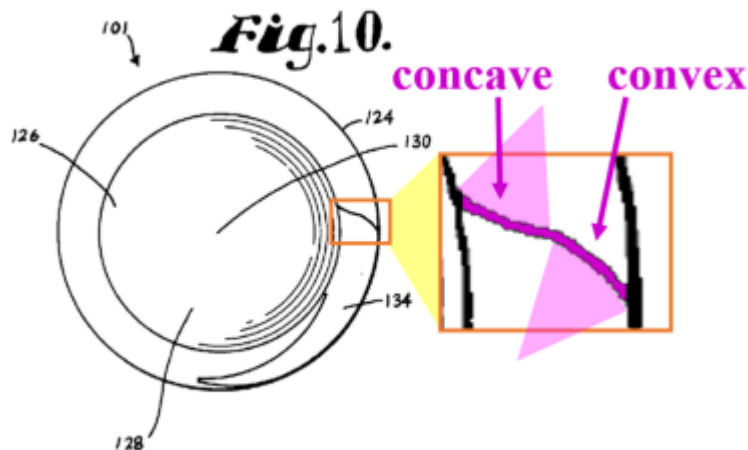
Therefore, the Board should find that there is no reasonable likelihood that the Petition would prevail with respect to claim 1.

C. Prior art does not teach “the partial concave and partial convex surfaces each defined by a radius of curvature that is substantially equal with respect to each other” (Claim 1)

Petitioner makes the same argument for this limitation for both Grounds 1 and 2. *See* Petition at 54 (Ground 2 relies on the '477 Publication for limitations not discussed for Ground 2).

1. The '477 Publication does not teach the above limitation

Petitioner’s argument that the allegedly concave and convex line in Figure 10 is defined by substantially equal radius of curvature is again conclusory and unsupported by evidence. Petition at 36. Petitioner relies on an annotated Figure 10 to conclude the limitation is taught. *Id.* Still, Petitioner provides no explanation for why the pink triangles in the annotations represent a substantially equal radius of curvature.



Petition at 36 (annotated Figure 10 by Petitioner)

As before, Dr. McMillin provides no additional explanation about this figure other than the conclusory statement from the Petition, so his testimony about the figure should be given little weight. *Xerox*, IPR2022-00624, Paper 9 at 15. 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 represents "partial concave and partial convex surfaces each defined by a radius of curvature that is substantially equal with respect to each other." *TQ Delta*, 942 F.3d at 1358.

For example, Dr. McMillin's conclusory analysis apparently assumes (without explanation) that each of the convex and concave lines in its annotated Figure 10 have a single radius of curvature shown by the pink triangles. However, only curves that lie on a perimeter of a circle have a single radius of curvature. Other common curves have different radius of curvature at different points on their curve, which is easily shown by the curved lines forming the perimeter of an ellipse. As illustrated below, the radius of curvature of the perimeter is smaller near the ends of the ellipse than the center of the ellipse where the perimeter curve flattens.

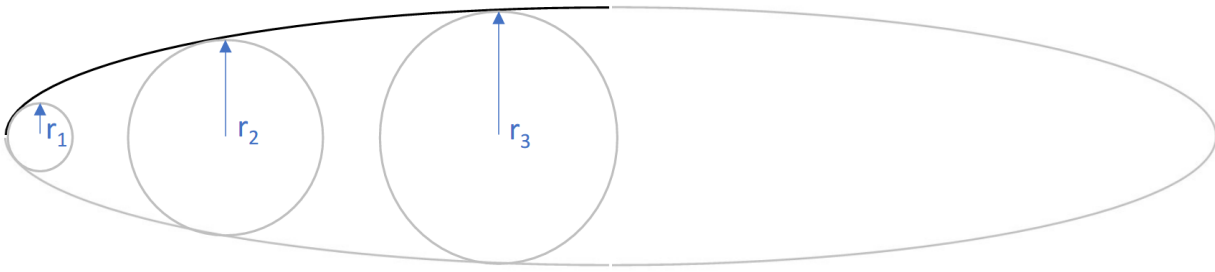


Illustration of different radius of curvature along a curved line⁶

Dr. McMillin fails to address how he was able to determine the alleged concave and convex curves in Figure 10 have a single radius of curvature (e.g., are circular). Conversely, assuming the curves identified by Dr. McMillin have multiple radius of curvature then Dr. McMillin failed to explain how those curves disclose substantially equal radii of curvature.

Even assuming a POSITA could determine the allegedly concave and convex curves identified by Dr. McMillin had a defined radius of curvature, Figure 10 alone does not provide evidence the radii of curvature of the alleged curves would be substantially equal. Petitioner's reliance on Figure 10 alone to demonstrate a substantially equal radius of curvature is analogous to the argument rejected by the Federal Circuit in *Nystrom. Nystrom v. Trex Co.*, 424 F.3d 1136, 1148 (Fed. Cir. 2005) (reciting "a radius of curvature..., defining a difference in thickness between the longitudinal centerline and the opposite side edges, with the ratio of said

⁶ The radii r_1 , r_2 and r_3 are illustrative only to show an increasing radius of curvature along points of a curved line. The actual radius of curvature for points on the curve near r_2 and r_3 would be significantly larger than as shown in the above illustration.

difference in thickness to the width of the board being about 1:40”). While the ratio in *Nystrom* was about 1:40, that is not a material distinction to the present claims which have a ratio of about 1:1 (e.g., substantially equal). The Federal Circuit admonished against “reading precise proportions into patent drawings which do not expressly provide such proportions” when the specification is completely silent on the issue. *Id.* at 1149 (citing *Hockerson-Halberstadt, Inc. v. Avia Group International, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000)). Petitioner commits the same error here that the Federal Circuit found and cautioned against in *Nystrom*.

In sum, neither Petitioner nor its expert attempt to explain why its interpretation of substantially equal radii curves is what Figure 10 would reasonably convey to a POSITA given the lack of details in Figure 10 or the specification of the ’477 Patent. This is unlike the ’646 patent where the leading face surfaces are expressly described:

The leading face including a partial concave surface adjacent the root and a partial convex surface adjacent the crest. The partial concave and partial convex surfaces each defined by a radius of curvature that can be substantially equal with respect to each other.

Ex. 1001 at Abstract; *see also id.* at Fig. 5 and 9:38-42.

As before, Petitioner improperly relies on hindsight from the ’646 Patent to guide its interpretation on what Figure 10 of the ’477 Publication reasonably discloses. *ActiveVideo v. Verizon*, 694 F.3d at 1327; *ATD v. Lydall*, 159 F.3d at 546.

2. Dr. McMillin's alternative argument not persuasive

Although not relied on in the Petition, Dr. McMillin also relies on alternative theory that “in [his] opinion, radii of curvature that are substantially equal for each of the concave and convex curves is consistent with the easiest manufacturing processes for the lead face of a thread start structure.” Ex. 1003 at ¶235. Unlike the theory that alleges Figure 10 of the '477 Publication discloses this limitation, this argument is premised on the idea that the limitation would have been obvious over the background knowledge of a POSITA. This argument fails for a number of reasons.

First, portions of expert declaration not explained or relied on in a Petition should not be considered by the Board. *See Cisco Sys., Inc. v. C-Cation Techs., LLC*, Case IPR2014-00454, Paper 12, [at] 11 (PTAB Aug. 29, 2014) (informative) (“we will not consider arguments that are not made in the Petition, but are instead incorporated by reference to the cited paragraphs” of the expert declaration); *see also DeSilva v. DiLeonardi*, 181 F.3d 865, 866-67 (7th Cir. 1999) (“A brief must make all arguments accessible to the judges, rather than ask them to play archeologist with the record.”). As such, the Board should not consider this alternative theory that is presented only in Dr. McMillin's declaration and not explained by Petitioner how it renders the claims obvious.

Second, Dr. McMillin's alternative theory lacks any details on what manufacturing processes he believes are the "easiest manufacturing processes" that would in turn produce a leading face with radii of curvature that are substantially equal for each of the concave and convex curves. Ex. 1003 at ¶235. Rather than specify any manufacturing processes, Dr. McMillin cites to "Section VI.B.1.c" of his declaration which is a reference to about five pages of allegedly background knowledge a POSITA would have about thread manufacturing. *See* Ex. 1003 at ¶¶77-81. A review of this section reveals that Dr. McMillin's believes a POSITA would have known to how to make concave and convex surfaces with known manufacturing processes, yet nothing in the section discusses why a leading face would have concave and convex surfaces with substantially equal radii of curvature or how such leading face surfaces would be manufactured. *Id.*

This kind of high-level vague expert analysis has been discredited by the Federal Circuit as insufficient to show obviousness. *Activevideo*, 694 F.3d at 1327 ("expert's testimony on obviousness was essentially a conclusory statement that a person of ordinary skill in the art would have known, based on the 'modular' nature of the claimed components, how to combine any of a number of references to achieve the claimed inventions. This is not sufficient and is fraught with hindsight bias.").

At best, this is evidence a POSITA *could* have manufactured a thread leading face with some type of curved surface, but it is not evidence why a POSITA *would*

manufacture a thread leading face with concave and convex surfaces having substantially equal radii of curvature. *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (“[O]bviousness concerns whether a skilled artisan not only could have made but would have been motivated to make the...modifications of prior art to arrive at the claimed invention.”).

D. Prior art does not teach independent claim 12 for same reasons as claim 1

Petitioner addresses independent claim 12 in Grounds 4 and 5. However, independent Claim 12 recites similar limitations as the above limitations distinguished from the prior art with respect for claim 1, which are identified in the Petition as limitations 12[B2], 12[B3] and 12[B5]. *See* Petition, Appendix at 2-3.

In particular the prior art asserted for Grounds 4 and 5 do not teach the following limitations of claim 12 for the reasons previously discussed:

- “a substantially flat bottom surface with an annular outer edge,...the first lower surface of the first thread and from the second lower surface of the second thread are spaced above and apart from the annular outer edge of the substantially flat bottom surface of the plug”

See supra at Section IV(A).

- “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”

See supra at Section IV(B).

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

See supra at Section IV(C).

While Petitioner adds in Boschert to address other limitations of claim 12, it does not rely on Boschert to cure any of the deficiencies of the '477 Publication or Kirschman with respect to these limitations discussed above in Grounds 1 and 2.

For instance, Petitioner relies on the same arguments about the '477 Publication for claim 12 in Ground 4 that it does for claim 1 of Ground 1. *See* Petition at 68 (limitation 12[B2]), 71 (limitation 12[B3]), and 72 (limitation 12[B5]). Additionally, Petitioner relies on the same arguments about the '477 Publication in view of Kirschman for claim 12 in Ground 5 that it does for claim 1 of Ground 2. *See* Petition at 79-81.

E. Dependent Claims 2-11 and 13-20

Dependent claims 2-11 and 13-20 are patentable at least due to their dependence on independent claims 1 or 12, which are 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

The prior art does not show a leading face surface spaced apart and above an annular outer edge of the bottom surface. In both the '477 Publication and Kirschman, the threads adjoin the annular outer edge of the bottom surface which is precisely what was distinguished during the prosecution of the '646 Patent. To argue otherwise, Petitioner relies on the annular outer edge of a rim instead of an annular outer edge of a bottom surface. Yet, the '646 Patent makes clear that a rim alone is not the claimed bottom surface. Thus, the outer edge of a rim is not the same as the claimed outer edge of the bottom surface.

In addition, Petitioner's case to show a leading face with concave and convex surfaces having substantially equal radii of curvature hinges on hindsight driven interpretations of Figures 7-10 of the '477 Publication. Moreover, accepting Petitioner's interpretations 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 interpretations are conclusory statement from Petitioner's expert lacking any technical reasoning or additional supporting evidence.

The Board cannot sustain a finding of obviousness based on 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:

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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 7,740 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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