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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ROGER P. JACKSON, Patent Owner.

IPR2023-01432 Patent 10,898,233 B2

Before ULRIKE W. JENKS, SHERIDAN K. SNEDDEN, and ZHENYU YANG, *Administrative Patent Judges*.

YANG, Administrative Patent Judge.

DECISION Denying Institution of *Inter Partes* Review 35 U.S.C. § 314

I. INTRODUCTION

ZimVie, Inc. and Zimmer Biomet Spine, Inc. (collectively, "Petitioner") filed a Petition (Paper 2, "Pet."), seeking *inter partes* review of claims 1–7 and 13–20 of U.S. Patent No. 10,898,233 B2 (Ex. 1001, "the '233 patent"). Roger P. Jackson ("Patent Owner") filed a Patent Owner Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a).

For the reasons provided below, we determine Petitioner has not demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition. Accordingly, we deny institution of *inter partes* review.

A. Related Matters

According to Petitioner, Patent Owner asserted the '233 patent against Petitioner in *Jackson v. ZimVie Inc.*, Case No. 1:22-cv-00891 (D. Del.). Pet. 1. Petitioner also filed IPR2023-01430,¹ IPR2023-01431, and IPR2023-01433, seeking *inter partes* review of three other patents related to the '233 patent. *Id*.

B. The '233 Patent and Related Background

The '233 patent relates to an open implant closure structure. Ex. 1001, Abstract; *see also id.* at 1:26–30 ("The present invention is directed to structure[s] for joining together parts of a medical implant, in particular to

¹ Patent Owner filed a statutory disclaimer disclaiming all claims of the patent challenged in IPR2023-01430.

closure mechanisms for use with open bone anchors in spinal surgery, and in some embodiments thereof, for use with spinal bone anchors such as polyaxial screws.").

The '233 patent explains that bone anchors, such as bone screws, were used in many types of spinal surgery to secure implants to vertebrae along the spinal column to stabilize and/or adjust spinal alignment. *Id.* at 1:31–37. Both open-ended or closed-ended bone anchors were known. *Id.* at 1:38–39. According to the '233 patent, open-ended bone screws typically "include a threaded shank with a head or receiver having a pair of parallel projecting branches or arms which form a yoke with a U-shaped slot or channel to receive a rod or other longitudinal connecting member." *Id.* at 1:53–57. "The open-ended head or rod receiver portion of such implants typically includes a pair of spaced arms forming a channel closed by a closure member after the rod or other longitudinal connecting member is placed in the channel." *Id.* at 1:60–64.

The '233 patent states that

spinal misalignments, irregularities and the placement of other surgical tools make it difficult to place the rod or other connector between the arms of the implant while a closure structure is mated with the open implant as well as used to push the rod or other connector downwardly into the implant. For example, when the closure is a cylindrical plug having a single start helically wound guide and advancement structure, such structure must be aligned with mating structure on one of the implant arms and then rotated until a portion of the structure is captured by mating guide and advancement structure on both arms of the implant, all the while the closure is being pressed down on the rod while other forces are pushing and pulling the rod back out of the implant.

Id. at 2:12–25.

The '233 patent discloses a closure structure with one or more helically wound guide and advancement features, each feature having a start structure located at or near a bottom surface of the closure, "each start structure simultaneously engaging and being captured by each of the spaced arms of the open implant upon initial rotation of the closure structure with respect to the open implant arms." *Id.* at 2:37–45. Specifically, the '233 patent discloses a double-start closure "having two helically wound forms thereon, each form having a start structure for simultaneously engaging a mating helical form on a respective open implant arm." *Id.* at 2:45–49.

C. Illustrative Claim

Among the challenged claims, claim 1 is independent. It is illustrative of the claimed subject matter and is reproduced below.

1. A medical implant assembly comprising:

a receiver having a longitudinal axis, a first arm, and a second arm, the first and the second arms each extending in the same direction as the longitudinal axis and having a top side surface and an outer side face surface;

a channel formed by the first arm and the second arm and opening between a front outer face surface adjacent the channel and a back outer face surface adjacent the channel opposite the front outer face surface of the receiver, the channel adapted to receive a longitudinal connecting member, the channel configured to be closed with a closure having an axis of rotation;

a first interior surface of the first arm opposite the outer side face surface thereof;

a second interior surface of the second arm opposite the outer side face surface thereof;

a first discontinuously helically wound structure on the first interior surface of the first arm, the first discontinuously

helically wound structure configured to engage a first start structure of a first continuously helically wound thread form disposed on the closure, the first start structure having a leading face with a concave surface portion and a convex surface portion;

a second discontinuously helically wound structure on the second interior surface of the second arm, the second discontinuously helically wound structure configured to engage a second start structure of a second continuously helically wound thread form disposed on the closure, the second start structure having a leading face with a concave surface portion and a convex surface portion, a rotation of the closure about the axis of rotation between the first arm and the second arm configured to cause a simultaneous mating of the first start structure under the first discontinuously helically wound structure and the second start structure with the second discontinuously helically wound structure due to a diametrically timed positioning of the first and second start structures on the closure, the closure configured to be rotationally advanced within the channel until the bottom surface engages and locks the longitudinal connecting member within the channel; and

the first and second arm outer side face surfaces each having a curvate extending groove configured to be engaged by an instrument, each groove extending horizontally to at least one of the front or back outer face surface of each arm and being located adjacent the top side surface on each arm, wherein an entirety of each groove is configured to be located above a top surface of the longitudinal connecting member when the longitudinal connecting member is received and locked in the channel by the closure.

Ex. 1001, 25:12-26:2.

D. Asserted Challenges to Patentability

Petitioner asserts the following challenges to patentability:

Claim(s) Challenged	35 U.S.C. § ²	References
1-7, 13, 15-20	103	The '477 publication, ³
		the '287 publication, ⁴ Boschert ⁵
14	103	The '477 publication,
		the '287 publication, Boschert,
		Johnson ⁶

To support its Petition, Petitioner relies on the declaration of Carl McMillin, Ph.D. Ex. 1003.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, we construe a claim term "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)." 37 C.F.R. § 42.100(b). Under this standard, we construe the claim term "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in

² The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29,

¹²⁵ Stat. 284, 287-88 (2011), amended 35 U.S.C. § 103, effective

March 16, 2013. Because the '233 patent has an effective filing date before March 16, 2013, the pre-AIA version of § 103 applies.

³ U.S. Patent Appl. Pub. No. 2005/0267477 A1, published December 1, 2005 (Ex. 1005, "the '477 publication").

⁴ U.S. Patent Appl. Pub. No. 2010/0312287 A1, published December 9, 2010 (Ex. 1007, "the '287 publication").

⁵ U.S. Patent No. 7,857,834 B2, issued December 28, 2010 (Ex. 1006, "Boschert").

⁶ U.S. Patent Appl. Pub. No. 2007/0088357 A1, published April 19, 2007 (Ex. 1008, "Johnson").

the art and the prosecution history pertaining to the patent." *Id.*; *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (holding that the words of a claim "are generally given their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application").

Claim 1 recites "start structure having a leading face with a concave surface portion and a convex surface portion." Petitioner argues that based on the disclosure of the '233 patent, "and consistent with the plain meaning, a POSA would have understood that a 'start structure' is the beginning of a thread and the 'leading face' is the forward most surface of the thread in the direction the thread is to be rotated." Pet. 13 (citing Ex. 1001, 9:38–42, Fig. 5; Ex. 1003 ¶¶ 151, 152). Petitioner further asserts that the concave portion is "inwardly curving," and the convex portion is "outwardly curving." *Id.* at 14 (citing Ex. 1003 ¶ 154).

Patent Owner does not propose any claim construction. *See* Prelim. Resp. 5. Instead, Patent Owner asserts that "there are no express constructions for the Board to consider or the Patent Owner to address." *Id.* We disagree with Patent Owner's allegation because Petitioner sufficiently explains the plain meaning of the terms "start structure," "leading face," "concave surface portion," and "convex surface portion." Pet. 13–14. On this record, and for purposes of this Decision, we adopt Petitioner's proposed constructions of these terms.

Claim terms need only be construed to the extent necessary to resolve the controversy. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361

(Fed. Cir. 2011). On this record, and for purposes of this Decision, we see no need to address the construction of any other claim term.

B. Alleged Obviousness of Claims 1–7, 13, and 15–20

Petitioner asserts that claims 1–7, 13, 15–20 of the '233 patent would have been obvious over the combination of the '477 publication, the '287 publication, and Boschert. Pet. 19–89. Based on this record, and for

at least the following reasons, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

1. <u>Prior Art Disclosures</u>

a. The '477 Publication

The '477 publication relates 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. 1005, Abstract. The implant may be an open or closed element used in a spinal implant system, such as a bone screw. *Id.* ¶ 7.

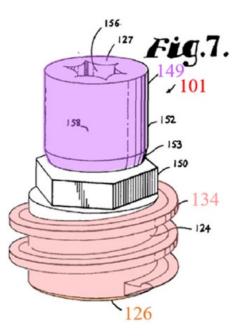
Specifically, the '477 publication teaches that

[a] typical implant for use with a closure of the invention includes a receiver having a pair of spaced arms with an open channel located therebetween. The channel receives a rod or other elongate structure. A closure of the invention is used to capture and fix the rod in the receiver subsequent to the receiver receiving the rod. In particular, internal surfaces of the arms of the receiver include a discontinuous guide and advancement structure, and the closure includes cooperating external guide and advancement structure so as to be rotated and driven into the receiver. Once the closure is matingly received in the receiver, the closure acts to capture the rod member.

Id.

The '477 publication depicts an embodiment of the disclosed closure in Figure 7, reproduced below.

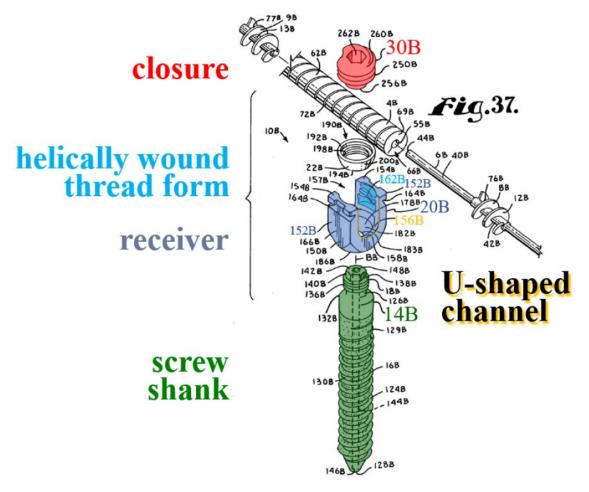
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Reproduced above is Figure 7 of the '477 publication, as annotated by Petitioner. Pet. 21. It is an enlarged and perspective view of a bone screw closure, showing the closure 101 having a cylindrical closure body 124 with a guide and advancement structure 134. Ex. 1005 ¶¶ 20, 41. The closure 101 also includes a break-off head 149 and a removal head 150 that are coaxially attached to the body 124. *Id.* ¶ 42.

b. The '287 Publication

The '287 publication is directed to "dynamic fixation assemblies for use in bone surgery, particularly spinal surgery, and in particular to longitudinal connecting members and cooperating bone anchors or fasteners for such assemblies, the connecting members being attached to at least two bone fasteners." Ex. 1007 ¶ 2. It depicts an embodiment of the disclosed assembly in Figure 37, reproduced below.

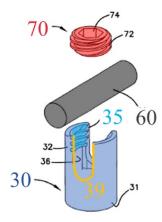


Reproduced above is Figure 37 of the '287 publication, as annotated by Petitioner. Pet. 28. It is a partial and exploded perspective view of a dynamic fixation bone screw assembly with a bone screw shank 14B, a receiver 20B, a retaining structure 22B, a dynamic fixation connecting member assembly 1B, and a closure member 30B. Ex. 1007 ¶¶ 53, 133–135.

The receiver 20B includes a pair of opposed upstanding arms 152B that form a U-shaped cradle and define a U-shaped channel 156B between the arms 152B. *Id.* ¶ 150. Each of the arms 152B has an interior surface that includes a partial helically wound guide and advancement structure 162B. *Id.* ¶ 151. In the illustrated embodiment, the guide and advancement structure 162B is a partial helically wound flange form configured to mate under rotation with a similar structure on the closure member 30B. *Id.*

c. Boschert

Boschert describes an orthopedic fixation device for securing a rod to a bone, and specifically, an intervertebral connection system suited for stabilization of the spine. Ex. 1006, Abstract, 1:5–7. It depicts an embodiment of the disclosed device in Figure 1, the relevant portion of which is reproduced below.



Reproduced above is a portion of Figure 1 of Boschert, as annotated by Petitioner. Pet. 24. It is an exploded perspective view of an orthopedic fixation device, including a receiver 30 having a top portion 32 defining a saddle 39 (i.e., a pocket) for receiving a rod 60. Ex. 1006, 2:58–61, 4:16–18. The fixation device also includes a setscrew 70 for clamping the rod 60 within the saddle 39 of the receiver 30. *Id.* at 4:26–38.

Boschert teaches that the threads 72 of the setscrew 70 can "be designed with a double lead to allow the setscrew 70 to start more easily than with a single lead." *Id.* at 7:21–23.

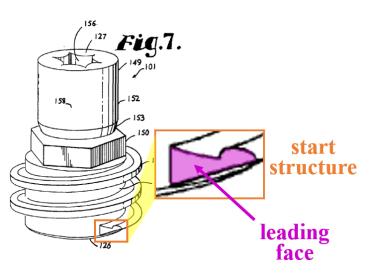
2. <u>Analysis</u>

We focus our analysis on the sole independent claim, claim 1. Petitioner contends that the combination of the '477 publication, the '287 publication, and Boschert teaches each limitation of claim 1. Pet. 41–67. Petitioner also argues that an ordinarily skilled artisan would

have been motivated to use the closure of the '477 publication with the receiver and inserts of the '287 publication and to modify the closure and receiver to have the double lead thread of Boschert. *Id.* at 34–41.

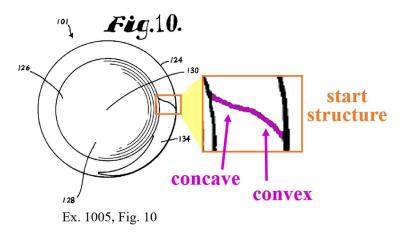
Patent Owner counters that Petitioner fails to show the prior art teaches the "start structure having a leading face with a concave surface portion and a convex surface portion" ("disputed limitation"). Prelim. Resp. 6–19. Based on this record, and as explained below, we find Patent Owner's argument more persuasive.

Petitioner relies on the '477 publication for teachings the disputed limitation. Pet. 52–54 (citing Ex. 1003 ¶ 238; Ex. 1005, Figs. 7, 8, 10). Petitioner argues that the '477 publication teaches "a start structure on the closure thread, the start structure having a leading face." Pet. 52–53 (citing Ex. 1003 ¶ 238; Ex. 1005, Figs. 7, 8). Petitioner annotates Figure 7 as follows:



The figure above is a reproduction of Petitioner's annotated Figure 7 of the '477 publication. Pet. 53. According to Petitioner, this figure shows a start structure having a leading face. *Id.* We find this assertion sufficiently supported, and Patent Owner does not disagree.

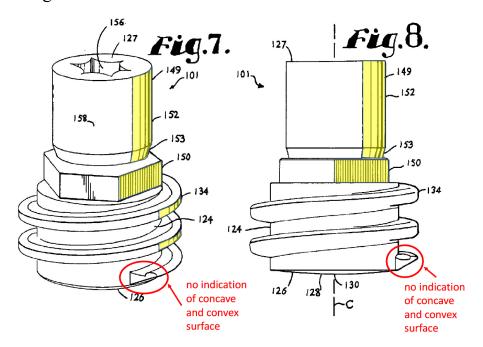
Petitioner next refers to an annotated Figure 10, reproduced below:



The figure above is a reproduction of Petitioner's annotated Figure 10 of the '477 publication. *Id.* at 54. Petitioner asserts that an ordinarily skilled artisan would recognize the line in the orange box in annotated Figure 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." *Id.* at 53 (citing Ex. 1003 ¶ 238). We are not persuaded.

First, we find Dr. McMillin's testimony insufficient to support Petitioner's argument on this point. As Patent Owner correctly points out, the '477 publication does not describe, or even identify, the line in Figure 10 that Petitioner relies on as the leading face. Prelim. Resp. 6, 7, 10. Thus, the only evidence purportedly supports Petitioner's argument that the unidentified and undescribed line is the leading surface is Dr. McMillin's testimony. *See* Ex. 1003 ¶ 238. Dr. McMillin's testimony, however, merely repeats, nearly verbatim, Petitioner's argument, without any explanation or other evidentiary support. *See id.* As a result, we accord limited weight to Dr. McMillin's testimony on this issue. *See Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (PTAB Aug. 24, 2022) (precedential).

Second, Petitioner's argument that the unidentified and undescribed line in Figure 10 shows a curved leading face is inconsistent with the disclosures in Figures 7 and 8, showing a flat leading face for the same embodiment. Indeed, Figures 7, 8, and 10 show the same bone screw closure from different viewpoints. Ex. 1005 ¶¶ 20, 21, 23 (stating Figure 7 shows the "perspective view," Figure 8 shows the "front elevational view of the closure of FIG. 7," and Figure 10 shows the "bottom plan view of the closure of FIG. 7"). Patent Owner contends that Figures 7 and 8 do not show any curved surface in the leading face. Prelim. Resp. 7–8. Patent Owner annotates Figures 7 and 8 as follows:



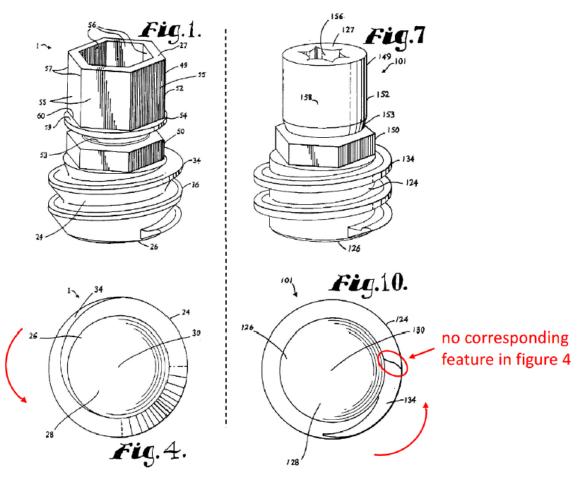
The figures above are the reproduction of Patent Owner's annotated Figures 7 and 8 of the '477 publication. *Id.* at 8. We agree with Patent Owner that Figures 7 and 8 appear to depict a flat surface for the leading face, rather than a partially concave and partially convex surface, as required in claim 1. *Id.* at 7–8.

We are also persuaded by Patent Owner's showing that, in the challenged '233 patent, the partially concave and partially convex surface is "visible across all views." *Id.* at 9 (citing Ex. 1001, Figs. 1, 2, 5); *see also* Ex. 1001, 3:40–43 (explaining each of Figures 1 and 2 is a perspective view of the same closure), 3:53–54 (explaining Figure 5 is a bottom plan view of the same closure). In other words, if the '477 publication taught the disputed limitation, the partially concave and partially convex leading face would have been visible not only in Figure 10 (the bottom plan view), but also in Figure 7 (the perspective view). Yet, the leading face shown in Figure 10, appears flat. This contradicts Petitioner's argument that the unidentified line in Figure 10 is a leading surface because it "matches the shape" of the leading face shown in Figure 7. *See* Pet. 53.

Third, Petitioner's argument that the unidentified and undescribed line in Figure 10 shows a leading face is also inconsistent with the disclosure for another embodiment in the '477 publication. The '477 publication teaches two embodiments of bone screw closure, one shown in Figures 1–4, the other in Figures 7–10. Ex. 1005 ¶¶ 14–17, 20–23. According to Dr. McMillin, "[t]he primary difference between the embodiments is the shape of the closure break-off heads 49 and 149." Ex. 1003 ¶ 167 (citing Ex. 1005 ¶¶ 33, 43, Figs. 1, 7); *id*. (citing Ex. 1005 ¶ 39, observing the '477 publication "incorporating by reference the description of the first embodiment into the second embodiment"). Thus, we agree with Patent Owner that an ordinarily skilled artisan "would understand the leading face between the two embodiments is substantially the same." Prelim. Resp. 13.

Patent Owner annotates Figures 1, 4, 7 and 10, which we reproduce

below:



The figures above are the reproduction of Patent Owner's annotated Figures 1, 4, 7, and 10 of the '477 publication. Prelim. Resp. 13. Figures 1 and 4 depict the same first embodiment of a closure from the perspective view and bottom plan view, respectively. Ex. 1005 ¶¶ 14, 17. Similarly, Figures 7 and 10 depict the same second embodiment of a closure from the perspective view and bottom plan view, respectively. Ex. 1005 ¶¶ 20, 23.

Patent Owner argues that

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[.] Prelim. Resp. 13.

We find Patent Owner's argument persuasive. Indeed, from the perspective view, closure 1shown in Figure 1 and closure 101 shown in Figure 7 appear to have substantially the same leading faces. Yet, from the bottom plan view, Figure 4 (closure 1) does not appear to have a curved line similar to the one shown in Figure 10 (closure 101), which Petitioner alleges as representing a leading face with a concave surface portion and a convex surface portion. *See* Pet. 53–54. Petitioner does not explain this discrepancy.

For the foregoing reasons, Petitioner does not persuade us that the unidentified and undescribed line in Figure 10 of the '477 patent represents a leading surface as required in the disputed limitation.⁷ Petitioner does not rely on any other prior art teaching or knowledge of an ordinarily skilled artisan for the disputed limitation. *See* Pet. 53–54. In other words, Petitioner does not show the combination of the '477 publication, the '287 publication, and Boschert teaches or suggests "start structure having a leading face with a concave surface portion and a convex surface portion." As a result, on this record, Petitioner has not established a reasonable likelihood that it would prevail in its obviousness challenge of claim 1 over the asserted prior art.

⁷ We also express doubt on whether Petitioner adequately shows the line in Figure 10 is partially concave and partially convex, as required in the disputed limitation. Petitioner's argument on this point is predicated on an enlarged section of a small drawing, showing a single unidentified and undescribed line that was not apparently intended to demonstrate the direction of any curvature. *See* Pet. 53–54. Ultimately, we do not need to address this issue, because Petitioner does not sufficiently persuade us that the line depicts the leading face recited in the disputed limitation.

Each of claims 2–7, 13, 15–20 depends from claim 1. Petitioner does not advance additional argument regarding the disputed limitation. Thus, for the same reasons as explained above, Petitioner has not established a reasonable likelihood that it would prevail in its obviousness challenge of these claims either.

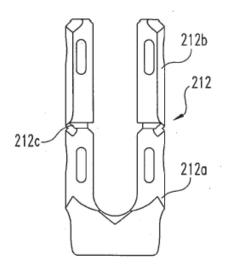
C. Alleged Obviousness of Claim 14

Petitioner asserts that claim 14 of the '233 patent would have been obvious over the combination of the '477 publication, the '287 publication, Boschert, and Johnson. Pet. 89–95. Based on this record, and for at least the following reasons, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

1. Johnson

Johnson "relates to devices and methods useful in surgery, such as orthopedic surgery. In particular, it relates to anchors and other implants for use in tissue, to be placed during orthopedic surgery." Ex. 1008 ¶ 1.

Specifically, Johnson teaches an adjustable bone anchor assembly that includes a receiver. *Id.* ¶ 31. An embodiment of the assembly is illustrated in Figure 10, the receiver portion of which is reproduced below.



The figure above is a portion of Johnson's Figure 10, showing the receiver 212 of an adjustable bone anchor assembly. Ex. 1008 ¶¶ 22–23, 50. Receiver 212 has a lower portion 212a and an upper portion 212b separated by a thinned section 212c. *Id.* ¶ 51. According to Johnson, after the receiver receives an elongated member, a compression member is inserted to force the elongated member through the upper portion 212b to the bottom of the lower portion 212a. *Id.* ¶ 55. Once the assembly is locked, upper portion 212*b* may be but or sheared off or otherwise removed from lower portion 212*a*. *Id.* ¶ 56.

2. <u>Analysis</u>

Claim 14 recites "[t]he medical implant assembly of claim l, wherein the first and second arm each has a breakoff extension." Petitioner advances the same argument for the other limitations recited in claim 1, including the disputed limitation. *See* Pet. 94. It relies on Johnson only for teaching the additional limitation recited in claim 14. *Id.* at 94–95. As explained above, Petitioner does not show the combination of the '477 publication, the '287 publication, and Boschert teaches or suggests "start structure having a leading face with a concave surface portion and a convex surface portion." For that same reason, Petitioner has not established a reasonable likelihood that it would prevail in its obviousness challenge of claim 14.

III. CONCLUSION

Based on the current record, and for the reasons explained above, we find Petitioner has not demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition. Thus, decline to institute *inter partes* review.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied, and no trial is instituted.

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