

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Catalyst Orthoscience Inc.,

Petitioner

v.

Shoulder Innovations, Inc.,

Patent Owner

Case No.: PGR2024-00042

U.S. Patent No. 11,771,561

PATENT OWNER'S PRELIMINARY RESPONSE

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Exhibit	Description
2001	File History of priority U.S. Provisional Application No. 62/816,708
2002	File History of priority International Application PCT/US2020/022094
2003	File History of priority U.S. Nonprovisional Application No. 17/435,333
2004	U.S. 8,870,962 (“Roche ’962”)
2005	Declaration of Geoffrey B. Higgs, M.D.
2006	<i>Curriculum Vitae</i> of Geoffrey B. Higgs, M.D.
2007	August 30, 2024 Letter from Frost Brown Todd in <i>Shoulder Innovations, Inc. v. Catalyst OrthoScience Inc.</i> , C.A. No. 24-266-JPM (D. Del.) regarding claim construction.
2008	89 Fed. Reg. 28693 (proposed April 19, 2024) (Published Document: 2024-08362)
2009	Declaration of Andrew McElligott in Support of Patent Owner’s Motion to Admit <i>Pro Hac Vice</i>

Petitioner, Catalyst Orthoscience Inc., has failed to demonstrate that any of the challenged claims of U.S. 11,771,561 (“’561 Patent”) “more likely than not” are unpatentable. Shoulder Innovations, Inc. (“Patent Owner”), respectfully requests the Board deny the Petition (Paper 1).

I. INTRODUCTION

The ’561 Patent claims reverse shoulder implants developed by Patent Owner and first filed with the U.S. Patent Office in early 2019. (See Ex.1001 at 26(1:4-10); Ex.2001). Petitioner filed the Petition after Patent Owner filed a district court action asserting the ’561 Patent. (Petition, 1; Paper 6).

As explained below, the Petition fails to satisfy Petitioner’s burden. Petitioner raises factually and legally deficient obviousness grounds (Grounds 1-4), based on non-prior-art disclosures and disclosures already considered during prosecution. Petitioner’s indefiniteness grounds (Grounds 5-6) are likewise legally deficient, and belied by their position that the Board “need not construe” the claims. (Petition, 4). Petitioner attempts to support its arguments with testimony from Mr. Fallin (Ex.1002), but Fallin is not a person of ordinary skill in the art for the ’561 Patent (“POSITA”). Therefore, his opinions are entitled to ***no weight***.

Petitioner’s unsupported and legally-deficient grounds fall well short of meeting the statutory burden for obtaining post-grant review and, at the very least,

support discretionary denial.¹

II. OVERVIEW OF THE '561 PATENT

A. Reverse Shoulder Replacement Systems

The '561 Patent is directed to reverse ball-and-socket shoulder replacement systems. (Ex.2005 (“Higgs”), 14(¶25)). In contrast with “anatomic” shoulder replacement systems that attempt to recreate articulating surfaces “substantially the same shape as the natural anatomy,” reverse shoulder systems reverse the articular surfaces so that the ball is on the glenoid fossa (shoulder blade) and the socket is on the humeral bone of the arm. (*Id.*; Ex.1001 at 26(1:14-37)). Although both types of systems are used today, reverse shoulder replacement systems are preferred in certain clinical situations. (Higgs, 14(¶25)).

The claims of the '561 Patent recite reverse shoulder implants comprising a unique combination of components used to replace the glenoid articulating surface. These components include a “baseplate,” “central screw,” “locking nut,” “glenosphere,” and “glenosphere screw.” Figure 8 (reproduced and annotated

¹ This response is preliminary. Patent Owner reserves the right to identify additional and/or alternative arguments and evidence in the event the Petition is granted.

below) illustrates an example of a “fully assembled” implant including each of these claimed components combined.

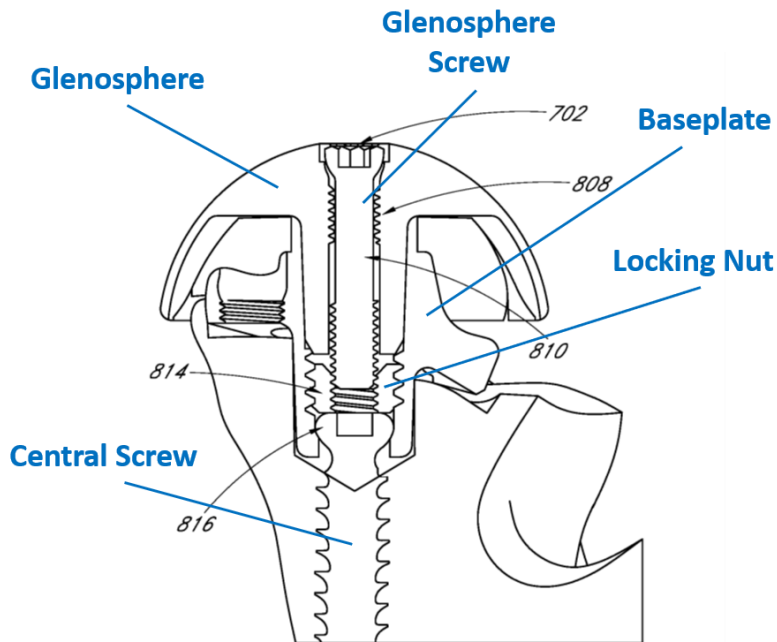


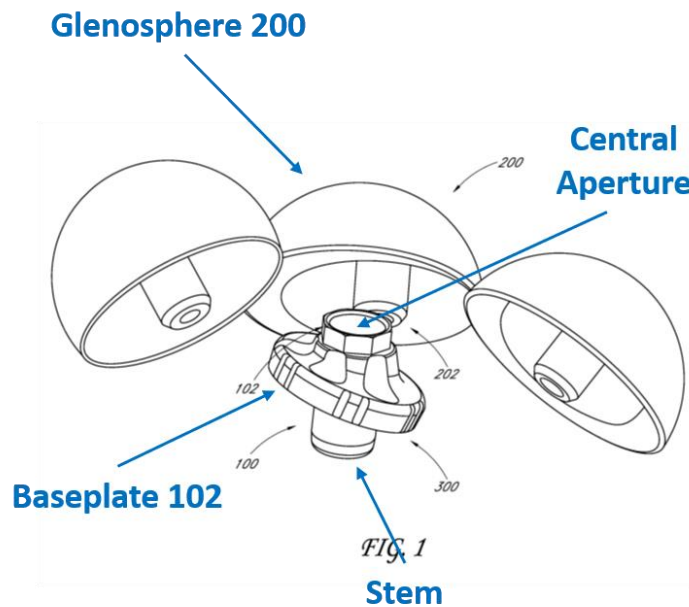
FIG. 8

'561 Patent, Figure 8 (Higgs-Annotated)

(Higgs, 14-15(¶26); Ex.1001 at 12, 26(2:61-63), 30(claims 1-16)).

The Petition states that the challenged claims are “primarily directed toward the embodiment shown in Figure 8 of the '561 Patent, which is described in column 6, lines 32-54.” (Petition, 9-10). However, the claims are not limited to Figure 8, and the claimed elements are illustrated and described throughout the figures and the supporting specification. (See, *e.g.*, Ex.1001 at 5-19, 26-30(1:59-9:33); Higgs, 15(¶27)).

For example, Figure 1 (reproduced and annotated below) illustrates “components of a total reverse shoulder system” including a glenosphere 200 and a baseplate 102 with “a generally disc-shaped structure” and a “central aperture defining a surface of . . . an elongate stem” (a central channel).



'561 Patent, Figure 1 (Higgs-Annotated)

(Higgs, 15-16(¶28); Ex.1001 at 5, 9, 11, 26-28(2:45-46, 3:37-55, 5:3-51, 5:66-6:31)).

Figure 6 (reproduced and annotated below) illustrates “a threaded locking insert 600” (locking nut) “configured to go into the central channel of a baseplate”

and including “outer male thread 602” and an inner “female thread 608 configured to receive a supplemental glenosphere locking screw.”

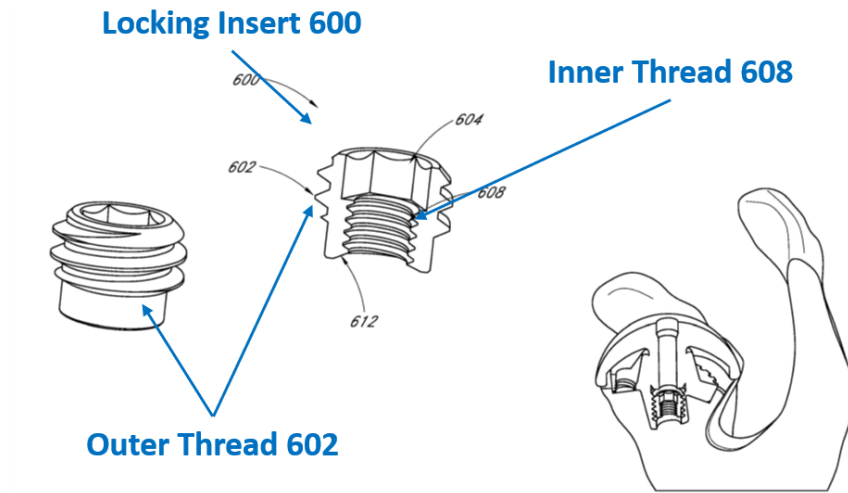


FIG. 6

'561 Patent, Figure 6 (Higgs-Annotated)

(Higgs, 16-17(¶29); Ex.1001 at 10, 28(5:52-65)).

B. Effective Filing Date Of The Claims

Contrary to Petitioner's argument (Petition, 8), **Petitioner** bears the burden of proving unpatentability (including that the identified references qualify as prior art), “and **this burden never shift[s]**.”² See *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015). The '561 Patent and file history submitted with the Petition make clear the '561 Patent is entitled to an effective filing date earlier than November 2022.

² Emphasis added, unless otherwise indicated.

The '561 Patent issued from Application No. 18/058,058, filed November 22, 2022 ("561 Application"). (Ex.1001 at 1; Ex.1004 at 1, 53-55, 59-62). Petitioner concedes the challenged claims have an effective filing date at least by November 22, 2022, "the date that the patent application that issued as the '561 Patent was filed." (Petition, 8). There is no dispute that the claims are supported by the specification and figures of the '561 Application.

The '561 Patent is a continuation of Application No. 17/435,333, filed August 31, 2021 ("2021 Application"), which in turn is the U.S. national phase of PCT/US2020/022094, filed March 11, 2020 ("2020 Application"). (Ex.1001 at 1, 26(1:4-10); Ex.1004 at 28-36, 59-62). The '561 Application named the same inventors as the 2020 and 2021 Applications, and claimed priority to (and incorporated) each of those applications. (Ex.1001 at 26(1:4-10); Ex.1004 at 28-36, 37(¶1), 59-62). The '561 Application included the same figures and substantially the same specification³ as the 2020 and 2021 Applications. (See Ex.1004 at 3-23, 37-52; Ex.2002 at 7-44; Ex.2003 at 17-54). Thus, the '561 Patent

³ The specifications differ with regard to the respective priority claims in paragraph 1 of each respective application. (*Compare* Ex.1004 at 37 *with* Ex.2003 at 17 *and* Ex.2002 at 7).

is entitled to an effective filing date at least as early as March 11, 2020—the date the priority PCT application was filed.⁴ *See* 35 U.S.C. § 120; MPEP 2152.01.

Petitioner's obviousness theory in Grounds 2-4 assumes the “Frankle” and “Lefebvre” references are prior art based on their July 27, 2021 and May 28, 2020 filing dates, respectively. (Petition, 53, 57). These dates are *after* the March 11, 2020 effective filing date of the '561 Patent. Therefore, Frankle and Lefebvre are not prior art.⁵

C. References Considered By The Patent Office During Prosecution

Petitioner incorrectly states the Examiner “neither identified nor described any particular prior art considered during examination in the [April 18, 2023] Notice of Allowability.” (*See* Petition, 13-14). In addition to a signed Information Disclosure Statement noting consideration of identified references, (Ex.1005 at 261, 274-285), the Examiner attached to the Notice of Allowance a “Notice of References Cited (PTO-892)” identifying additional references considered by the Examiner, as well as a “Continuation Sheet” identifying and attaching copies of

⁴ The '561 Application also referenced and claimed priority to Provisional Application No. 62/816,708, filed March 11, 2019. (Ex.1001 at 26(1:4-10); Ex.1004 at 28-36, 37(¶1), 59-62). While not necessary to dispose of Petitioner's arguments, Patent Owner contends the challenged claims have an effective filing date at least by March 11, 2019. *See* 35 U.S.C. § 119.

⁵ Patent Owner reserves the right to rebut any future attempt by Petitioner to advance new prior art theories.

eight specific references considered. (Ex.1005 at 261, 267-268, 286-593, 631-699).

Not only did the Examiner identify particular disclosures—they considered several disclosures that Petitioner relies on to argue unpatentability here. For example, the Examiner identified, considered, and distinguished EP 3598957 (“Orphanos EP”), which is the European version of the “Orphanos” reference cited in the Petition at Ex.1006 and raised in Grounds 1-4. (Ex.1005 at 262-264, 631-667(Orphanos EP); Ex.1006(Orphanos)). The Examiner also considered the disclosure of the “Roche” reference cited in the Petition at Ex.1007 and raised in Grounds 1-4. Patent Owner submitted a supplemental IDS in May 2023 identifying U.S. 8,870,962 (“Roche ’962”), among other references. (Ex.1005 at 754-758; Ex.2004). Roche ’962 is a divisional of Ex.1007. (Ex.1007 at 1 (“Appl. No. 11/690,516”); Ex.2004 at 1 (“Division of application No. 11/690,516”)). Like the Orphanos reference, the Examiner expressly considered the Roche disclosure during prosecution. (Ex.1005 at 797, 800, 806, 814).

Petitioner’s representations that the Orphanos and Roche disclosures “w[ere] not cited” or considered during prosecution are false or, at the very least, misleading. (Petition, 18, 21).

D. Level Of Skill In The Art

For purposes of this preliminary response, Patent Owner does not dispute a POSITA includes a person with “at least a bachelor’s degree in mechanical or biomedical engineering, or similar discipline, with at least 3 years of experience designing joint replacement systems for medical patients.” (Petition, 15-17). Petitioner’s proposed level is incomplete, however, to the extent it excludes other persons of ordinary skill, in particular those who had qualifying technical and medical clinical experience with respect to the subject matter of the ’561 Patent. (Higgs, 17-18(¶31)). As Petitioner points out, the devices of the ’561 Patent “are designed to be implemented *in a medical context* and interact *inside a medical patient*,” and as such a POSITA should have “experience working with mechanical devices and components whose purpose and function is *to operate inside a medical patient*.” (Petition, 16). Accordingly, a POSITA in the field of the ’561 Patent also includes a medical doctor with an engineering degree and at least 3 years of experience performing total joint arthroplasty in medical patients. (Higgs, 17-18(¶31)).

Patent Owner submits the Declaration of Dr. Geoffrey Higgs (Ex.2005), a medical doctor and orthopaedic surgeon who has been practicing approximately 30 years. Dr. Higgs received a Bachelor of Science in Engineering in 1983, and a Doctorate of Medicine in 1988. By the 2019-2020 timeframe, Dr. Higgs had

decades of experience evaluating and implanting shoulder implant designs, and had performed approximately 5,000 shoulder replacement surgeries in patients (including the types of systems described in the '561 Patent background).

Dr. Higgs qualified as a person having at least ordinary skill in the art in the 2019-2020 timeframe. His declaration provides his opinions from the perspective of POSITA at that time. (Ex.2005 at 4-10(¶¶3-15), 17-19(¶¶30-32); Ex.2006).

III. PETITIONER'S FALLIN DECLARATION IS ENTITLED TO NO WEIGHT

Exhibit 1002 to the Petition is a Declaration of T. Wade Fallin. Fallin states he was retained by Petitioner to provide opinions from the “perspective of a person of ordinary skill in the art.” (Ex.1002, 8(¶¶2-3)). “To offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art.” *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1376-77 (Fed. Cir. 2022). Opinions from witnesses who lack that qualification “are neither relevant nor reliable,” are not “based on any specialized knowledge, training, or experience that would be helpful to the fact-finder,” and “serve[] only to cause mischief and confuse the factfinder.” *Id.* at 1377 (citation omitted).

Petitioner fails to demonstrate (or even allege) that Fallin is qualified to render the opinions in his declaration. Fallin identifies **zero** personal experience designing joint replacement systems for medical patients. The Petition states

Fallin “worked with and supervised” individuals responsible for designing joint replacement systems, and that “[t]hose he worked with and supervised tended to have” qualifications of a POSITA. (Petition, 17). However, the Petition never states that Fallin himself has qualifying design experience. Fallin’s declaration offers no help. Despite his opinion that a POSITA had “at least three years’ of experience designing joint replacement systems for medical patients” (Ex.1002, 30-31(¶64)), Fallin never once states he has such experience, or otherwise qualifies as a POSITA.

The Board should ignore Exhibit 1002 and afford it ***no weight***. See *Kyocera*, 22 F.4th at 1377-78 (ALJ abused discretion by admitting expert testimony of witness lacking POSITA qualification).

IV. CLAIM CONSTRUCTION

Petitioner states the Board “need not construe” the challenged claims. (Petition, 3-4). Accordingly, the claims are entitled to their plain and ordinary meaning. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005).

Petitioner’s position in Grounds 5-6 that the claims should be construed indefinite is belied by its decision in the related litigation “not [to] seek construction of any claim terms or phrases” of the ’561 Patent. (Petition, 83-89; Ex.2007).

V. THE BOARD SHOULD EXERCISE DISCRETIONARY DENIAL

A. The *Advanced Bionics* Framework Demands Denial

Petitioner's assertion that 35 U.S.C. § 325(d) and *Advanced Bionics* supports institution is based on the incorrect assertion that none of the disclosures in Grounds 1-4 were before the Office during prosecution. (Petition, 93-94). As explained above in Section II.C., at least the Orphanos and Roche disclosures raised in Grounds 1-4 were considered by the Office during prosecution. Thus, every petitioned obviousness ground raises disclosures previously presented to (or cited by) the Patent Office. The first part of *Advanced Bionics* is satisfied. See IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential).

The second part of *Advanced Bionics* is also satisfied. Petitioner does not argue that the Office "erred" with regard to the considered references "in a manner material to the patentability of challenged claims." *Id.* Nor does Petitioner allege that the Examiner erred in any material manner by not rejecting the challenged claims under § 112. Accordingly, the Director should exercise its discretion not to institute post-grant review. *Id.* at 9.

Petitioner's argument that references were not "meaningfully considered" during prosecution is misplaced. (Petition, 93-94). This argument is based on comments in the April 19, 2024 Notice of Proposed Rulemaking, not the proposed

rules themselves.⁶ And the proposed rules are just that—***proposed, not adopted***.

The statute and prevailing standard in this case permit discretionary denial where, like here, the same disclosures that Petitioner raises in obviousness grounds were previously “presented” to the Office.

B. The *Fintiv* Factors Further Weigh In Favor Of Denial

Under 35 U.S.C. § 324(a), the Director is authorized to institute a post-grant review only when the petition demonstrates at least one challenged claim “more likely than not” is unpatentable.” *See also* PTO Interim Procedure for Discretionary Denials, dated June 21, 2022 (“Interim Procedure”) at 4 n.5. Where, as here, there is parallel district court litigation, the PTAB considers the so-called *Fintiv* factors to determine whether to discretionarily deny a petition, even if the petition is determined to satisfy the “more likely than not” statutory threshold. (*See id.* at 1-2); *Apple Inc. v. Fintiv, Inc.*, IPR2020-0019, Paper 11, at 7-8 (PTAB March 20, 2020).

The *Fintiv* factors weigh in favor of denial. Petitioner’s evidence demonstrates that since 2009 the judge in the related litigation (Judge McCalla) denied 60% of the stay motions (9 denied versus 6 granted). (*See* Ex.1015). The

⁶ The proposed rules would permit discretionary denial where, like here, the same art was “meaningfully ***addressed***” during prosecution. (Ex.2008 at 14; Section II.C., above).

denial rate has increased to over 71% in the last five years (5 denied versus 2 granted). Factor 1 weighs in favor of denial.

With respect to Factor 2, a PGR, if instituted and held to the statutory schedule, would conclude on or around January 3, 2026, whereas trial is currently scheduled to begin in the district court proceedings just weeks later, on March 9, 2026 (or earlier).⁷ (Petition, 92; Ex.1016). Factor 2 is neutral.

With respect to Factor 3, and contrary to the Petition, the parties and the Delaware district court have invested substantial time and resources. The parties have served infringement and invalidity contentions, and are currently in the middle of fact discovery. Factor 3 weighs in favor of denial.

With respect to Factors 4 and 5, Petitioner concedes both an “identity of parties” and “significant overlap” between the issues raised here and in the related litigation. (Petition, 92). While Petitioner states it “*will* be subject” to statutory estoppel provisions (*id.*), those only apply in a post-grant review “that results in a final written decision under section 328(a).” See 35 U.S.C. § 325(e)(2). In the meantime, Petitioner intends to litigate the same issues before both the Patent Office and the district court, and already is taking apparently contradictory

⁷ The district court judge has expressed interest in compressing the current schedule and moving the trial date earlier.

positions.⁸ Factors 4 and 5 weigh in favor of denial.

Finally, Factor 6 weighs in favor of denial. Pursuant to the Patent Office's Interim Procedure, the PTAB "will not rely on the *Fintiv* factors to discretionarily deny institution . . . where a petition presents compelling evidence of unpatentability." (Interim Procedure, 2-5, 9). "Compelling evidence" is evidence that, "if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence." (*Id.* at 3-5). As explained throughout this preliminary response, Petitioner's unpatentability grounds are factually and legally deficient for numerous reasons. The Petition fails to satisfy the statutory "more likely than not" threshold for institution, let alone the greater "compelling evidence" threshold required to avoid denial based on the *Fintiv* factors. (*Id.* at 2).

VI. PETITIONER FAILED TO DEMONSTRATE THAT ANY CLAIM "MORE LIKELY THAN NOT" IS UNPATENTABLE

As explained below, Petitioner has not carried its burden of demonstrating that claims 1-16 "more likely than not" would have been obvious (Grounds 1-4), or "more likely than not" are indefinite (Grounds 5-6).

⁸ For example, Petitioner's argument in Grounds 5-6 (Petition, 83-90) that the claims should be construed indefinite contradicts its litigation strategy not to engage in claim construction. (Ex.2007).

A. Ground 1: Challenged Claims 1, 3-9, And 11-16 Would Not Have Been Obvious To A POSITA In View Of Orphanos And Roche

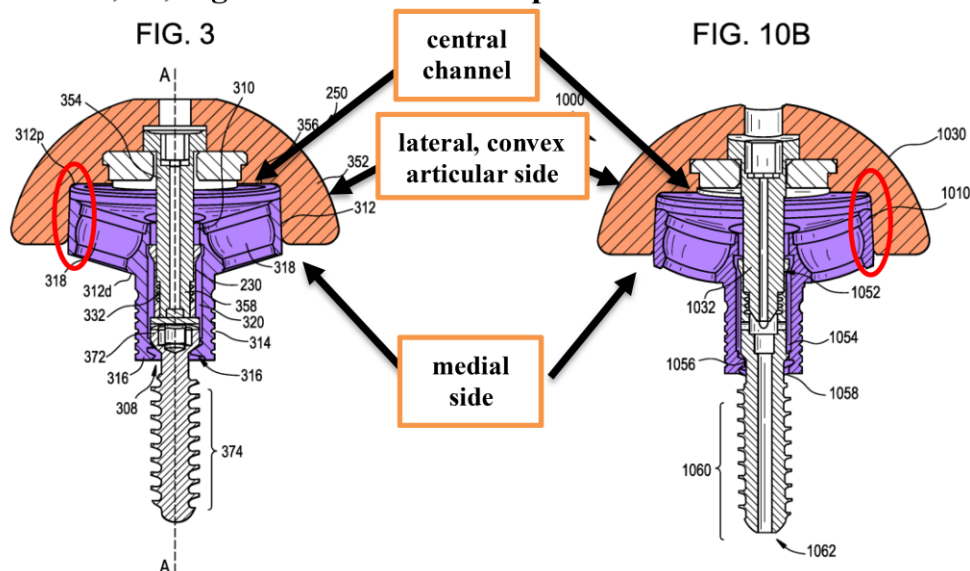
1. All Challenged Claims: Petitioner Fails To Address All The Limitations Of The Challenged Claims

Independent claims 1 and 9 (and dependent claims 3-8 and 11-16) each recite a “glenosphere” having “a lateral, convex articular side, a medial side, and a central channel extending from the convex articular side to the medial side.”

Petitioner alleges Orphanos discloses a “glenosphere,” (Petition, 42-44), but fails to address all of the requirements of the “glenosphere” as claimed.

As shown below, the Petition includes annotated versions of Orphanos’s Figures 3 and 10B (reproduced below) annotating alleged central channels in Orphanos’s glenospheres 250, 1030.

EX-1006 at 5, 14, Figures 3 and 10B of Orphanos



Annotated Figures from Petition at 42

(Petition, 42-44). Petitioner explains how the identified channels allegedly are “configured to interface” with a baseplate, but never addresses the separate claim requirement that the central channel “extend[s] from the convex articular side to the medial side” of the glenosphere. Ground 1 is deficient at least because Petitioner fails to address every limitation of the challenged claims.

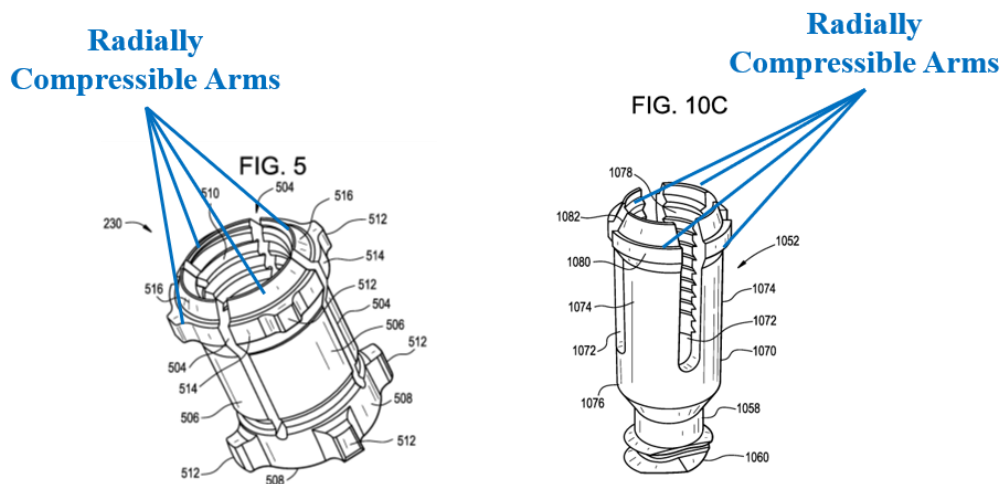
2. All Challenged Claims: Orphanos Does Not Disclose A “Locking Nut” As Claimed

Independent claims 1 and 9 (and dependent claims 3-8 and 11-16) each require a “locking nut” having, among other things, “an external thread on an outside surface,” where the locking nut is “configured to engage the central screw when the central screw and baseplate are implanted within the medical patient,” wherein the “external thread” is “configured to secure the locking nut to the central channel of the baseplate” (claim 1) or “configured to engage the central channel of the baseplate” (claim 9). (Ex.1001 at 30(9:43-51, 10:25-32)). The Petition identifies two alleged locking nut embodiments in Orphanos: collet 230 (**Embodiment 1**) and collet portion 1052 of bone screw 1050 (**Embodiment 2**). (Petition, 31). Neither of these embodiments includes a “locking nut” as claimed. (Higgs, 20-28(¶¶36-49)).

a. “an external thread on an outside surface”

Petitioner concedes Orphanos's collet embodiments do not include “an external thread on an outside surface,” at least “in the drawings.” (Petition, 32). Petitioner identifies **no** disclosure in Orphanos of a collet having “an external thread on an outside surface of the locking nut,” let alone one “configured to secure the locking nut to the central channel of the baseplate” or “configured to engage the central channel of the baseplate.”

As shown below in annotated Figures 5 and 10C (annotated by Dr. Higgs), Orphanos's collet 230 and collet portion 1052 do not include any external thread on an outside surface.



Orphanos, Figures 5 and 10C (Higgs-Annotated)

(Ex.1006 at 8, 15; Higgs, 21-22(¶38)). Rather, Orphanos's collet and collet portion include “radially compressible arms” configured to “flex[] in response to changes in the diameter of the throughbore 310 of the [baseplate].” (Ex.1006 at 22-23, 26,

30(2:63-3:6, 10:39-56, 17:48-58)). The flexible arms “flex inward” during insertion of the collet into a smaller-diameter throughbore, and thereafter “flex outward” to “engage an annular recessed portion of an inner sidewall of the throughbore,” fixing the collet in place “at a predetermined depth in the throughbore of the baseplate.” (*Id.* at 22-23, 26, 28, 30(2:63-3:6, 10:39-56, 14:4-30, 18:34-45)). As the flexible arms move outward they snap into place, creating “an audible and/or tactile cue (e.g., a ‘click’) to notify the surgeon that the collet has reached the desired depth.” (*Id.* at 28, 30(14:14-30, 18:34-45; Higgs, 21-22(¶38))).

Petitioner’s reliance on Orphanos’s statement that the collet “flex[es] outward such that the lip snaps into or otherwise mates within [a] catch” is misplaced. (*See* Petition, 32). Orphanos never discloses a collet with an external thread. (*See* Ex.1006 at 28, 30(14:14-30, 18:34-45)). Nor does Orphanos disclose a collet that couples in any way other than via arms that flex outward to snap into (or otherwise mate within) a catch. Orphanos’s statement that the collet “flex[es] outward” reinforces that Orphanos is referring to a snap-fitting type coupling, as does Orphanos’s statement the coupling must “otherwise mate[] ***within the catch.***” A POSITA would understand that “otherwise mates” does not describe or suggest any alternative to a flexible snap-fitting type collet, but instead describes a flexible

snap-fitting type collet with a lip that snaps “**into** . . . [a] catch,” or that “**otherwise mates within** [a] catch. (Higgs, 22(¶39)).

Petitioner's assertion that Orphanos's collet 230 “may be referred to as a reducing bushing” does not help Petitioner, since calling collet 230 a “reducing bushing” (or any other name) cannot change the fact that collet 230 does not include an “external thread” as claimed. (Petition, 32-33; Higgs, 23(¶40)).

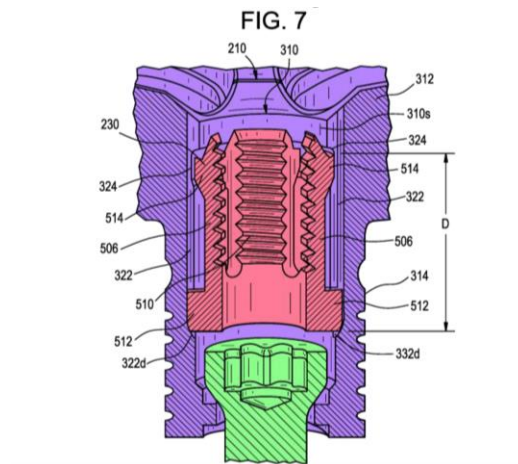
Petitioner's statement that Orphanos teaches a general proposition that “snap-fitting coupling techniques and threaded coupling techniques are readily interchangeable” misrepresents Orphanos's disclosure. (Petition, 32). Orphanos never makes such a broad (and technically dubious) statement. A POSITA would not consider snap-fitting coupling techniques and threaded coupling techniques to be readily interchangeable in the context of Orphanos's flexible collet. (Higgs, 23-24(¶41)). Nor does the cited portion of Orphanos refer to the collet, or how the collet is secured to Orphanos's baseplate. Rather, Orphanos describes a specific “thread fit” between the glenosphere 250 and the baseplate 210, and states that the ***glenosphere/baseplate fit*** could, in some embodiments, be “a snap fit or any other coupling technique known to those skilled in the art for coupling two mechanical components.” (Ex.1006 at 26(10:4-15)). This statement has nothing to do with the collet. (Higgs, 23-24(¶41)).

Thus, Orphanos's embodiments do not include a locking nut as claimed, including "an external thread on an outside surface."

b. "configured to engage the central screw when the central screw and baseplate are implanted within the medical patient"

(1) Orphanos, First Embodiment

In addition to lacking an external thread, neither of Orphanos's embodiments includes a collet "configured to engage the central screw when the central screw and baseplate are implanted within the medical patient." Petitioner's assertion that collet 230 in the first embodiment satisfies this limitation is belied by Petitioner's annotations of Orphanos's Figure 7, which clearly illustrate a spacing and lack of engagement between the collet (highlighted by Petitioner in red) and the alleged central screw (screw 270) (highlighted by Petitioner in green).



Orphanos, Figure 7 (Petitioner-Annotated) (Petition at 37)

(Higgs, 24(¶42)).

The lack of engagement illustrated in Figure 7 is no accident, as Orphanos discloses that the collet 230 and central screw 270 are never intended to engage when they are implanted. Orphanos explains, for example, that “insertion of the bone screw [is] optional.” (Ex.1006 at 1(Abstract); *see also, e.g., id.* at 22-23, 25 (2:38-43(“a collet can allow a bone screw to be omitted from the implant”), 3:50-62(“In some embodiments, the implant can be devoid of a central bone screw.”), 7:4-9, 7:22-26)). The collet cannot engage a bone screw that is not there. (Higgs, 24-25(¶43)).

When the collet and screw are both used in an implant, Orphanos explains “the collet is disposed within the throughbore of the baseplate, ***proximal to the proximal head of the central bone screw***” (*i.e.*, spaced apart from the proximal head as shown above in Figure 7). (Ex.1006 at 23(3:50-62); *see also id.* at 28(13:46-49)). To ensure this collet is spaced apart from any screw (if used), Orphanos’s throughbore includes a distal “mechanical stop 322d” (illustrated above in Figure 7), which “seat[s] the collet 230” at a “predetermined depth” and defines “a distal most depth, or the key depth, at which the distal end of the collet 230 is capable of bottoming out within the throughbore 310 of the baseplate 210.” (*Id.* at 25, 28(8:41-43, 14:22-35); Higgs, 25(¶44)).

Petitioner’s “backdriving” theory fails. (Petition, 38-39). The claimed “locking nut” is “configured to engage the central screw ***when*** the central screw

and baseplate are implanted within the medical patient.” Petitioner’s theory, on the other hand, is that even though collet 230 is specifically described as **not** engaging a central screw, a central screw might somehow back out and into engagement with the central screw at some indeterminate time **after** the central screw and baseplate are implanted within the body. Petitioner’s theory improperly ignores the claim language “when the central screw and baseplate are implanted within the medical patient,” rendering it meaningless.

Even if it was proper to ignore a claim limitation (it is not), Petitioner identifies nothing in Orphanos to support its allegation that Orphanos’s “central bone screw 270” necessarily “back drives toward collet 230” after implantation, or that any alleged backdriving necessarily would be sufficient to result in engagement with collet 230. (Petition, 38-39; Higgs, 25-26(¶45)). Petitioner’s reliance on Fallin is misplaced as: (1) Fallin likewise identifies nothing in Orphanos to support Petitioner’s allegations; and (2) Fallin’s POSITA testimony is irrelevant (*see* Section III., above).

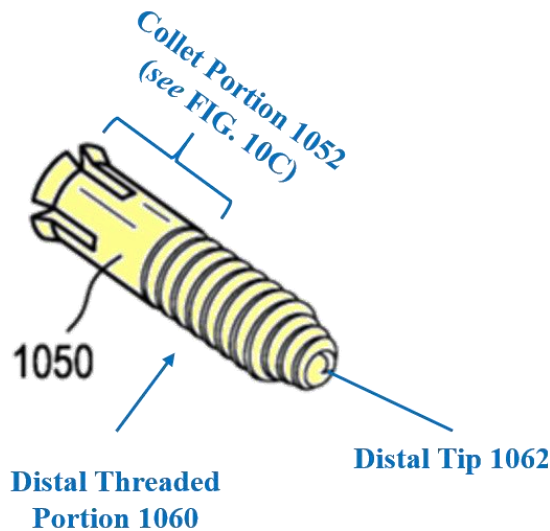
Petitioner’s reliance on Roche is likewise misplaced. (Petition, 38-39). Roche does not disclose any general knowledge that compression screws in reverse shoulder implants are necessarily susceptible to backdriving. Nor does Roche disclose that compression screws in ***Orphanos’s implants*** are necessarily susceptible to backdriving. Roche describes ***Roche’s devices***, and explains that ***in***

Roche's devices a locking cap screw “may [be] screwed into the glenoid plate on top of a compression screw to prevent the compression screw from backing out.” (Ex.1007 at 69(7:33-43); *see also id.* at 72(14:1-18)). The fact that a locking cap screw “may” be used in Roche’s device is hardly a disclosure that backdriving necessarily occurs or is a problem in Roche’s device. Roche says nothing about central screws and how they are used or perform in *Orphanos’s* device. (Higgs, 26(¶46)).

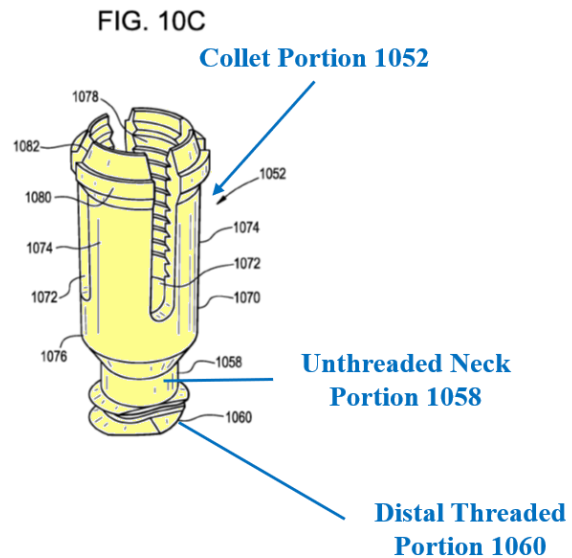
Thus, collet 230 is not a locking nut “configured to engage [a] central screw when the central screw and baseplate are implanted within the medical patient.”

(2) Orphanos, Second Embodiment

Petitioner’s assertion that “collet portion 1052” of Orphanos’s “integrated collet and bone screw 1050” satisfies the claimed “locking nut” limitation is wrong. (Petition, 39-40). As described in Orphanos and illustrated below in annotated Figures 10A (excerpt) and 10C (annotated by Dr. Higgs), the second embodiment includes an “integrated collet and bone screw 1050,” to “allow surgeons to add a bone screw down the center axis of the [baseplate] component as a single unitary component in one step.”



**Orphanos, Figure 10A
(Excerpt, Higgs-Annotated)**



**Orphanos, Figure 10C
(Higgs-Annotated)**

(Ex.1006 at 13, 15, 24(5:40-48), 30(17:8-16, 18:9-22, 18:55-67); Higgs, 26-27(¶47)). As illustrated above, the unitary bone screw 1050 includes a “collet portion 1052,” an “unthreaded neck portion 1058,” a “distal threaded portion 1060,” and “distal tip 1062.” (Ex.1006 at 30(17:25-38)).

The collet portion 1052 of Orphanos’s “bone screw 1050” structure is not “configured to engage the central screw when the central screw and baseplate are implanted within the medical patient.” Rather, the collet portion 1052 is part of the disclosed screw, itself. In operation, the collet portion 1052 is “coupled to the distal head of a delivery tool,” which is “operated by the surgeon” both to “push” the screw 1050 into the central throughbore, and to “rotate” the screw until it is “secured to the glenoid.” (Ex.1006, 30(18:60-67)). Without the collet

portion 1052, the remaining structure would not be a screw 1050, and would not operate as a screw 1050, as disclosed in Orphanos. (Higgs, 27-28(¶48)).

Petitioner's argument that "claim 1 does not require a locking nut that is separate or removable from [the] central screw" misses the point. (Petition, 40). Petitioner's interpretation misreads the claims as reciting a central screw **comprising** a locking nut, which is not what the claims say. (Higgs, 28(¶49)). Independent claims 1 and 9 recite the "central screw" and "locking nut" separately, which creates a "clear implication" that the elements are separate and distinct components. *See Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1262 (Fed. Cir. 2010) ("Where a claim lists elements separately, 'the clear implication of the claim language' is that those elements are 'distinct component[s]' of the patented invention." (alteration in original) (citation omitted)). This understanding is confirmed by the claim language requiring that the locking nut "engage the central screw when the central screw and baseplate are implanted within the medical patient," as well as the specification, which describes the locking nut and central screw as separate and distinct structures. (Ex.1001 at 28(6:44-54); *see also id.* at 28-29(6:66-7:11)). Logically, in order to have a collet that engages a central screw, the structures that make up the collet must be separate and distinct from the structures that make up the central screw. However, the alleged "collet" in Orphanos's second embodiment is part of the alleged "central

screw,” itself. Petitioner’s argument that the collet portion of the unitary screw satisfies the “configured to engage the central screw” element of claims 1 and 9 is illogical, as a structure cannot engage itself. (Higgs, 28(¶49)).

Thus, collet portion of 1052 is not a locking nut “configured to engage [a] central screw when the central screw and baseplate are implanted within the medical patient.”

3. All Challenged Claims: Petitioner Fails To Demonstrate The Challenged Claims Were Obvious

a. Petitioner Fails To Demonstrate The Proposed Combination Would Include A “Glenosphere” As Claimed

As explained above in Section VI.A.1., Petitioner failed to address all of the limitations of the challenged claims, including a “glenosphere” having “a lateral, convex articular side, a medial side, and a central channel extending from the convex articular side to the medial side.” While Petitioner argues that it would have been obvious to modify Orphanos, it does not propose any modifications to address this limitation. Petitioner has failed to carry its burden in Ground 1 regarding the challenged claims for at least this reason.

b. A POSITA Would Not Have Been Motivated To Modify Orphanos

Orphanos’s embodiments do not include a locking nut (1) having “an external thread on an outside surface” (see Section VI.A.2.a.), or (2) “configured to

engage the central screw when the central screw and baseplate are implanted within the medical patient” (see Section VI.A.2.b.). Petitioner argues that it would have been obvious to modify Orphanos to use a locking nut as claimed. As explained below, Petitioner has failed to demonstrate a POSITA would have been motivated to make the proposed modifications.

(1) A POSITA Would Not Have Been Motivated To Modify Orphanos To Include A Locking Nut With An “External Thread On An Outside Surface”

Petitioner argues that it would have been obvious to modify Orphanos to include a locking nut as claimed, “in view of Orphanos’s teachings and general knowledge of a POSITA.” (Petition, 34). Petitioner argues it would have been obvious to “replace/modify” the “snap-fitting coupling” of Orphanos’s collet/collet portion with “a threaded coupling,” as follows:

[I]t would have been obvious to a POSITA at the time of the invention of the ’561 Patent ***to simply replace/modify the snap-fitting coupling*** of the collet/collet portion 230, 1052 (i.e., radially compressible arms 506, 1074 with a respective lip 514, 1080 and the inner sidewall 310s) ***with a threaded coupling*** (i.e., a reducing bushing having external threading and internal threading on the inner sidewall 310s of the central throughbore 310) in order to secure the substituted externally-threaded reducing bushing to baseplate 312 within its central throughbore 310

(*Id.*). There are numerous problems with Petitioner's theory. (Higgs, 28-32(¶¶50-56)).

To start, Petitioner's proposed modification of Orphanos's second embodiment does not address the issue, described above in Section VI.A.2.b., that Orphanos's integrated bone screw 1050 does not include a "central screw" **and** a "locking nut" as claimed. Thus, Petitioner's obviousness theory regarding the second embodiment, even if credited, would not result in a device satisfying the requirements of the challenged claims.

Petitioner's theory also lacks sufficient detail to support a conclusion that a POSITA would have been motivated to modify Orphanos, and had a reasonable expectation of success in doing so. *See Pers. Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017). Petitioner argues it would have been obvious to "replace/modify" Orphanos's flexible, snap-fit coupling, but provides no detail regarding how it believes a POSITA would have done this, even though a POSITA would understand Petitioner's proposal (if even possible) would require substantial reconstruction and redesign. (Higgs, 29(¶51)). Petitioner's reliance on Fallin is misplaced for the reasons in Section VI.A.2.b., including he is not a POSITA and he identifies nothing in Orphanos (or anywhere else) that supports Petitioner's conclusory arguments.

Petitioner argues a POSITA would have known about so-called “reducing bushings” described in the “Hale” (Ex.1013) and “Grainger” (Ex.1018) references, but Petitioner does not allege that a POSITA would have been motivated to modify or replace Orphanos’s collet/collet portion with a reducing bushing disclosed in those references. (Petition, 33). Further, Hale and Grainger are not related to medical devices or problems in the medical device field, and would not have been pertinent to a POSITA. (Higgs, 29-30(¶52)); *In re Clay*, 966 F.2d 656, 658-660 (Fed. Cir. 1992) (reversing obviousness finding based on nonanalogous art).

Petitioner also argues that it would have been “well known and obvious” that Orphanos’s “inner sidewall 310s would also need simply to be modified to include a known internal thread to correspond to the external thread of the reducing bushing,” but provides no detail how a POSITA allegedly would have modified the sidewall. (Petition, 34). Nor does Petitioner detail how a POSITA allegedly would have modified the collet/collet portion to include an external thread “instead of [a] snap-fitting.” (*Id.* at 37). Petitioner’s vague obviousness theory leaves Patent Owner and the Board guessing what, specifically, Petitioner alleges would have been obvious, and why a POSITA would have been motivated to do whatever Petitioner believes (but never says) was obvious. *See Trend Micro, Inc. v. Open Text Inc.*, IPR2023-00692, Paper 8 at 28-29 (PTAB Nov. 6, 2023) (denying institution where the petitioner “does not provide a clear explanation of its

combinations” and “it would be difficult for the Board or Patent Owner to analyze or respond to Petitioner’s case”). Petitioner’s proposed modifications would require substantial reconstruction and redesign in a manner not detailed in the Petition. This reflects “a hindsight desire to recreate the claimed invention, as opposed to a known need in the art for such a device.” *Medtronic, Inc. v. Teleflex Innovations S.A.R.L.*, 70 F.4th 1331, 1347 (Fed. Cir. 2023) (citation omitted).

Petitioner’s proposal to “include a threaded coupling instead of the snap-fitting coupling” (Petition, 37) is further problematic as it would require substantial redesign and change the principles of operation of the collet/collet portion. (Higgs, 30-31(¶53)); *see also Medtronic*, 70 F.4th at 1347 (affirming Board’s rejection of obviousness theory requiring “extensive need to modify [prior art] in a way not suggested in the Petition” (citation omitted)); *In re Ratti*, 270 F.2d 810, 813 (C.C.P.A. 1959) (modification “requir[ing] a substantial reconstruction and redesign . . . as well as a change in the basic principles under which the [prior art] was designed to operate” not obvious). Orphanos explains that “[i]n previous iterations of shoulder joint implants, a glenosphere locking screw was screwed directly into a central throughbore of a [baseplate] to secure the glenosphere to the [baseplate].” (Ex.1006 at 26(10:30-33)). The diameter of the central throughbore could vary, however, and sometimes “exceed the diameter or width of a glenosphere locking screw such that the locking screw cannot be screwed directly

to the [baseplate].” (*Id.* (10:33-38)). “To address this problem,” Orphanos discloses a collet 230 (and collet portion of bone screw 1050) having “radially compressible arms 506” that are “configured to facilitate insertion and/or removal of the collet by flexing in response to changes in the diameter of the throughbore 310 of the [baseplate] 210.” (*Id.* (10:39-56); Higgs, 30-31(¶53)).

As explained above in Section VI.A.2.a., Orphanos’s flexible arm structure is what provides the snap-fit functionality of the collet/collet portion 230, 1052 (among other things). To the extent Petitioner proposes eliminating the flexible arm structure and replacing it with an inflexible “threaded coupling,” the collet/collet portion would no longer “address th[e] problem” that Orphanos was attempting to solve via one with arms that “flex[] in response to changes in the diameter” of the baseplate throughbore. It would also change the principles of operation of the collet/collet portion from a flexible structure to an inflexible structure and, in the process, destroy important functions of Orphanos’s collet/collet portion including at least the ability to “flex[] in response to changes in the diameter,” to “flex outward” to “engage an annular recessed portion of an inner sidewall of the throughbore” and fix the collet in place “at a predetermined depth in the throughbore of the baseplate,” and to provide “an audible and/or tactile cue . . . to notify the surgeon that the collet has reached the desired depth.” (See Section VI.A.2.a.; Higgs 31(¶54)).

Eliminating Orphanos's flexible arm structure would render Orphanos "inoperable for its intended purpose." *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). Orphanos's flexible arms are configured to flex outward and lock into place "at a predetermined depth in the throughbore of the baseplate," and more particularly within a "**recessed portion** of [the] inner sidewall of the [baseplate] throughbore." (Ex.1006 at 22-23, 26, 28(2:63-3:6, 10:39-56, 14:4-30)). By replacing the flexible arm structure with an inflexible "threaded coupling," the collet/collet portion would need to be designed with an outer diameter smaller than the diameter of the recessed portion in order to fit within the non-recessed portion of the throughbore, rendering it incapable of engaging and locking into place within the recessed portion. Alternatively, if the diameter of the inflexible collet/collet portion was large enough to engage the recessed portion, it would be too large to fit within the non-recessed portion of the throughbore. Either way, the modification would render the collet/collet portion inoperable for its intended purpose.⁹ (Higgs, 31-32(¶55)).

Petitioner provides no rationale for why a POSITA allegedly would have made the proposed modification/replacement (whatever it is). Petitioner identifies

⁹ Petitioner's argument that the proposed modification "would not render the device of Orphanos inoperable" does not address the reasons presented here. (Petition, 37).

no benefits or advantages, and no design needs or market pressures that would have provided requisite motivation. *See Virtek Vision Int'l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 886-88 (Fed. Cir. 2024) (reversing Board's obviousness finding where no "reason for combining" was presented, noting it "does not suffice [for two things] to simply be known"). Petitioner's reliance on Orphanos's statements that the collet "flex[es] outward such that the lip snaps into **or otherwise mates** within [a] catch," and that the collet can be called a "reducing bushing" are misplaced for the reasons in Section VI.2.a., above. (Petition, 32). Petitioner's assertion that a POSITA would recognize "snap-fitting" and "threaded" coupling techniques as "interchangeable" or a "matter of design choice" is unsupported and wrong, particularly in the context of Orphanos's collet/collet portion.¹⁰ (Petition, 32-35; Section VI.2.a., above). As explained above, Orphanos's flexible snap-fit design was provided to address problems Orphanos identified in the prior art, and performs different functions than an inflexible threaded design, which, if used instead, would potentially render Orphanos inoperable.

¹⁰ Petitioner's assertion that the '561 Patent "is silent" regarding "advantages provided by incorporating an external thread on a locking nut" is irrelevant, and does not make up for Petitioner's failure to identify a motivation to combine. (Petition at 36).

At bottom, Petitioner's obviousness theory boils down to "snap-fitting coupling" and "threaded coupling" were both known, which is legally insufficient to demonstrate obviousness. *See Virtek*, 97 F.4th at 886 ("It does not suffice to meet the motivation to combine requirement to recognize that two alternative arrangements . . . were both known in the art."); *see also GCE Gas Control Equip. Inc. v. VBox, Inc.*, IPR2023-00326, Paper 27 at 53-54 (PTAB June 18, 2024) (argument that two alternatives were known "does not provide a sufficient rationale" for modifying prior art).

Contrary to the Petition, a POSITA would not have been motivated to modify/replace Orphanos's collet/collet portion as proposed, which would amount to a substantial redesign and reconstruction with no identified benefits or advantages, and no reasonable expectation of success. (Higgs, 32(¶56)).

**(2) A POSITA Would Not Have Been Motivated To
Modify Orphanos So That Collet 230 Is
"Configured To Engage The Central Screw"**

Petitioner does not propose any modifications to Orphanos's **second embodiment** to address the lack of both a "central screw" and "locking nut" as claimed. (*See* Petition, 39-40; Section VI.A.2.b., above; Higgs, 36(¶64)).

Petitioner has failed to meet its burden of demonstrating the challenged claims would have been obvious in view of Orphanos's second embodiment.

For the **first embodiment**, Petitioner's obviousness theory in total is as follows:

A POSITA would be motivated to modify the location of an externally threaded reducing bushing to engage [Orphanos's] central bone screw 270 (prior to central bone screw 270 backing out) after being implanted as taught by Roche, as such a modification would provide the well-known benefit of inhibiting central bone screw 270 from backing out. (*Id.*, ¶ 99, EX-1002 [(Fallin Declaration)] at 49.) Such a modification would provide immediate contact between the externally threaded reducing bushing and central bone screw 270, which would provide enhanced resistance to back out by central bone screw 270. (*Id.*)

(Petition, 39). There are numerous problems with this theory. (Higgs, 33-36(¶¶57-63)).

To start, Petitioner's argument that a POSITA would have modified the location "of an externally threaded reducing bushing" is problematic since Orphanos does not disclose any "externally threaded reducing bushing," (see Section VI.A.2.a.), and a POSITA would not have been motivated to modify Orphanos's embodiments to include a collet with an "external thread" as claimed (see Section VI.A.3.b.1.). (Higgs, 33(¶59)).

Petitioner's theory also lacks sufficient detail to support a conclusion that a POSITA would have been motivated to modify Orphanos, and had a reasonable

expectation of success in doing so. *Pers. Web Techs.*, 848 F.3d at 993-94.

Petitioner argues it would be obvious “to modify the location of an externally threaded reducing bushing,” but never actually explains in any detail what that modification would be or how it would be accomplished. (Petition, 39). For example, Petitioner never explains how it believes a POSITA would have modified Orphanos’s collet 230 to include an “outer thread” as claimed (*see* Section VI.A.3.b.1.), or what additional modifications would have been made to the collet 230 and/or Orphanos’s other components in order to “modify the location of an externally threaded reducing bushing.” (Higgs, 33-34(¶60)).

Petitioner’s vague obviousness theory leaves Patent Owner and the Board guessing what specifically Petitioner alleges would have been obvious, and why a POSITA would have been motivated to do whatever Petitioner believes (but never says) was obvious. *See Trend Micro*, IPR2023-00692, Paper 8 at 28-29.

To the extent Petitioner is suggesting moving the location of collet 230 more distally within the throughbore 310 of baseplate 210, such a proposal would be inconsistent with Orphanos’s provision of a “mechanical stop 322d” in the throughbore to prevent the collet 230 from moving distally beyond the “key depth” for the collet (*i.e.*, spaced apart from the screw, as shown in Orphanos’s Figure 7). (*See* Section VI.A.2.b., above; Higgs, 34-35(¶61)). A POSITA would not have been motivated to make such a modification in view of Orphanos’s teaching away.

See Tec Air, Inc. v. Denso Mfg. Mich. Inc., 192 F.3d 1353, 1360 (Fed. Cir. 1999)

(“There is no suggestion to combine . . . if a reference teaches away from its combination with another source.”). A POSITA would have recognized that Orphanos specifically designed this embodiment so that the collet 230 is spaced apart from the screw (if one is even used). (Higgs, 34-35(¶¶61)).

Petitioner also identifies nothing in Orphanos to support its conclusory allegation that a POSITA would have been concerned about Orphanos's central bone screw 270 (if used) “backing out.” (See Section VI.A.2.b., above). A POSITA would not have considered backdriving to be a concern in Orphanos's embodiments. (Higgs, 25-26, 35(¶¶45, 62)). Even assuming a POSITA was concerned about a central compression screw “backing out” in the first embodiment (they would not be), Petitioner fails to explain why a POSITA would have considered going through the trouble of attempting to redesign Orphanos when Orphanos already discloses two simple solutions: (1) omit the central screw altogether because it is “optional”; or (2) use the “integrated collet and bone screw 1050” of Orphanos's **embodiment 2**, which Petitioner does not allege is susceptible to backdriving. (See Section VI.A.2.b., above; Ex.1006 at 1, 22-23, 25(Abstract, 2:38-43, 3:50-62, 7:4-9, 7:22-26)). A POSITA would have considered the latter option particularly desirable as Orphanos teaches it “reduce[s] the number of steps performed during a procedure, thereby simplifying the

procedure.” (Ex.1006 at 22(2:38-43); Higgs, 35-36(¶63)). Petitioner’s argument that a POSITA instead would have been motivated to redesign Orphanos to solve a problem that does not exist in the first place makes no sense.

Petitioner’s reliance on Fallin is misplaced, for the reasons in Section VI.A.2.b., including he is not a POSITA and he identifies nothing in Orphanos to support Petitioner’s allegations. Petitioner’s reliance on Roche is likewise misplaced for the reasons in Section VI.A.2.b., including Roche does not disclose that backdriving necessarily occurs (or is capable of occurring) in Roche’s device, let alone in Orphanos’s device.

4. Petitioner Fails To Demonstrate Claims 7 and 15 Were Obvious

Claims 7 and 15 depend from claims 1 and 9, respectively, and further recite “a diameter of the locking nut is greater than a length of the locking nut.” (Ex.1001 at 30(10:11-13, 10:56-58)). Petitioner failed to demonstrate these claims are obvious, for at least the reasons in Sections VI.A.1.–3., above.

Petitioner fails to demonstrate that a POSITA would have been motivated to modify the modified Orphanos devices to include the “diameter” and “length” requirements of claims 7 and 15. Petitioner does not allege that Orphanos’s collet/collet portion satisfies this limitation, either as disclosed in Orphanos or as modified in Petitioner’s obviousness theory for claims 1 or 9. Petitioner argues

that “Roche teaches this limitation” (Petition at 47, 52), but Petitioner never suggested using any alleged “locking nut” from Roche in Orphanos, let alone provided an alleged motivation to do so. (Higgs, 36-37(¶66)).

Petitioner's argument that Roche satisfies the “diameter” and “length” requirements is based solely on Petitioner's measurement of Roche's figures, without any evidence the figures are to scale, or the specification otherwise describes the dimensions. This is improper. *See Hockerson-Halberstadt, Inc. v. Avia Group Int'l Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000) (“[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.”). A POSITA would understand the figures Petitioner measured are not engineering drawings and are not intended to convey specific dimensions. (Higgs, 37(¶67)).

Petitioner's argument that a POSITA “would be motivated to keep the length less than the diameter to provide a low profile to the locking nut” (Petition, 47, 52) is unsupported, and makes no sense. Petitioner fails to explain how “provid[ing] a low profile to the locking nut” in the context of the proposed modification would be desirable, or confer any technical or medical advantages to Orphanos's collet/collet portion. (Higgs, 37(¶68)); *see Virtek*, 97 F.4th at 886-88. A POSITA would understand that reducing the length relative to the diameter of Orphanos's

collet/collet portion would create potential disadvantages, including shortening the coupling between the locking screw and baseplate resulting in a potentially **weaker structure**. (Higgs, 37-38(¶69)). A POSITA would not have been motivated to make such a modification. (*Id.*).

Petitioner's reliance on Fallin is misplaced, for the reasons in Section VI.A.2.b.

5. Petitioner Fails To Demonstrate Claims 8 and 16 Were Obvious

Claims 8 and 16 depend from claims 1 and 9, respectively, and further recite “the locking nut comprises a rotational control feature configured to receive a tool to enable twisting of the locking nut to secure it to the central screw.” (Ex.1001 at 30(10:13-16, 10:59-62)). Petitioner failed to demonstrate these claims are obvious, for at least the reasons in Sections VI.A.1.–3., above.

Petitioner fails to demonstrate that a POSITA would have been motivated to modify the modified Orphanos devices to include the claimed “rotational control feature.” Petitioner's argument is based on a misrepresentation that “Orphanos discloses the substitution of the collet with a reducing bushing.” (Petition, 48, 53). Orphanos states that the collet may be “referred to” as a reducing bushing. (See Section VI.A.2.a., above; Higgs, 23(¶40)).

Petitioner's suggestion that "any threaded device must have [a] rotational control feature to facilitate thread engagement" (Petition, 48, 53) is unsupported, and readily belied by Orphanos, which discloses a threaded collet/collet portion (albeit with internal, rather than external threads) **without** a rotational control feature. (Ex.1006 at 25-27(8:44-67, 10:39-56, 11:19-27)).

Petitioner argues that Roche, Hale, and Grainger each disclose "a rotational control feature" (Petition, 48, 53), but Petitioner never suggests using any alleged "locking nut" from Roche, Hale, or Grainger in Orphanos, let alone provided an alleged motivation to do so. Petitioner's reliance on Fallin is misplaced, for the reasons in Section VI.A.2.b.

B. Ground 2: Challenged Claims 2 And 10 Would Not Have Been Obvious To A POSITA In View Of Orphanos, Roche, And Frankle

1. Frankle Is Not Prior Art

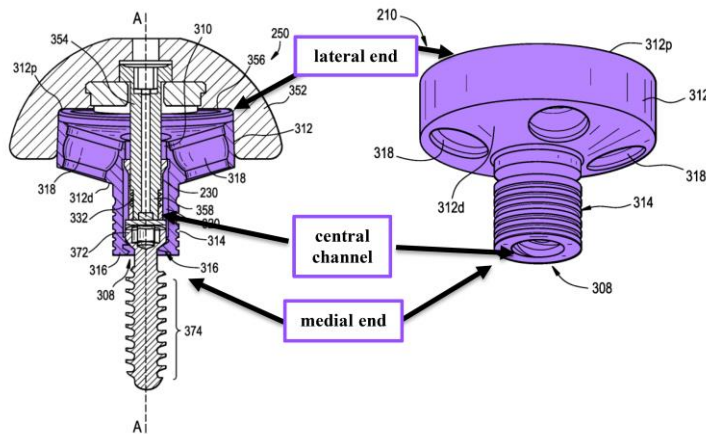
Claims 2 and 10 depend from claims 1 and 9, respectively, and further recite "the glenosphere further comprises a stem configured to be positioned at least partially within the central channel of the baseplate." (Ex.1001 at 30(9:61-64, 10:42-45)). Petitioner failed to demonstrate these claims are obvious, for at least the reasons in Sections VI.A.1.–3., above.

Petitioner's obviousness theory in Ground 2 relies on its arguments in Ground 1 for all of the limitations of claims 2 and 10 found in independent

claims 1 and 9. (Petition, 55-56). Petitioner does not allege that Orphanos, either alone or as modified in Ground 1, has a glenosphere comprising “a stem configured to be positioned at least partially within the central channel of the baseplate.” Instead, Petitioner states that “Frankle” provides this limitation. (*Id.*). As explained above in Section II.B., however, Frankle is not prior art. Accordingly, Petitioner has failed to demonstrate claims 2 and 10 would have been obvious in view of the prior art. Ground 2 should be dismissed for at least this reason.

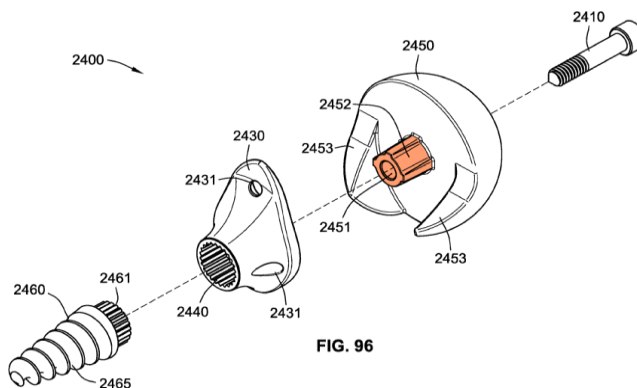
2. A POSITA Would Not Have Been Motivated To Modify Orphanos To Incorporate Frankle's Protrusion Element

Even if Frankle was prior art, Petitioner's theory lacks sufficient detail to support a conclusion that a POSITA would have been motivated to modify Orphanos in view of Frankle and had a reasonable expectation of success in doing so. *See Pers. Web Techs.*, 848 F.3d at 993-94. Petitioner proposes modifying Orphanos “to incorporate [Frankle's] protrusion element 2452 . . . into [Orphanos's] glenosphere 250, 1030” so that Frankle's protrusion element “is configured to be positioned at least partially within the central channel of the baseplate.” As shown below in annotated Figures 3 and 4A (annotations by Petitioner), however, the alleged “central channel” of Orphanos's baseplate (highlighted in purple) is occupied by the glenosphere locking screw 354.



Orphanos, Figures 3 and 4A (Petitioner-Annotated) (Petition at 26)

Petitioner provides no explanation how a POSITA would have modified Orphanos's glenosphere to include Frankle's "protrusion element 2452" (shown below in Petitioner's annotated Figure 96, highlighted in orange) and position it "at least partially within the central channel of [Orphanos's] baseplate," particularly when there is no space in the alleged central channel for any "protrusion element" to fit.



Frankle, Figure 96 (Petitioner-Annotated) (Petition at 55)

Petitioner's vague obviousness theory leaves Patent Owner and the Board guessing what specifically Petitioner alleges would have been obvious, and why a POSITA

would have been motivated to do whatever Petitioner believes (but never says) was obvious. *Trend Micro*, IPR2023-00692, Paper 8 at 28-29. The proposed modification would not have been obvious to a POSITA. (Higgs, 38-40(¶¶70-72)).

Petitioner provides no evidence that a POSITA would have been motivated to modify Orphanos to “promote guidance,” “maintain alignment,” or “provide further structural rigidity.” (Petition, 56). Petitioner identifies no evidence that a POSITA would have considered Orphanos’s device as deficient in any of these respects. Nor does Petitioner explain how “protrusion 2452” allegedly promotes guidance, maintains alignment, or provides structural rigidity in *Frankle’s* device, let alone how the proposed modification would provide any benefit in guiding, aligning, or providing structural rigidity in *Orphanos’s* device. A POSITA would not have considered Orphanos’s devices as deficient, and would not have been motivated to make the proposed modifications. (Higgs, 40(¶72)). Petitioner’s reliance on Fallin is misplaced, for the reasons in Section VI.A.2.b.

C. Ground 3: Challenged Claims 1, 3-9, And 11-16 Would Not Have Been Obvious To A POSITA In View Of Lefebvre, Orphanos, And Roche

1. All Challenged Claims: Lefebvre Is Not Prior Art

Petitioner’s obviousness theory in Ground 3 relies on Lefebvre as a primary reference. As explained above in Section II.B., however, Lefebvre is not prior art. Accordingly, even if Petitioner was correct in all of its assertions in Ground 3 (it is

not), Petitioner still would fail to demonstrate that the challenged claims would have been obvious in view of the prior art. Ground 3 should be dismissed for at least this reason.

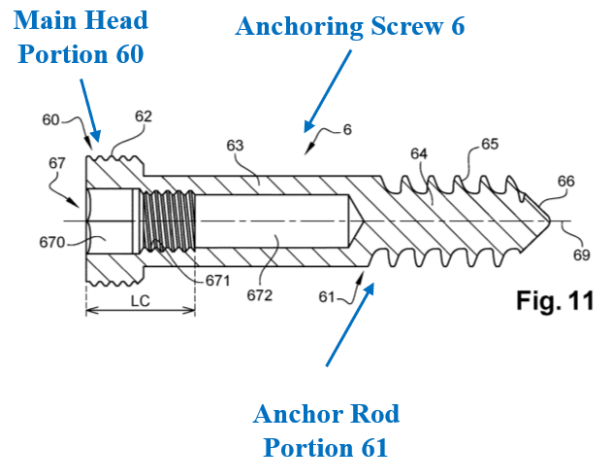
2. All Challenged Claims: Lefebvre Does Not Disclose A “Central Screw” And “Locking Nut” As Claimed

Independent claims 1 and 9 (and dependent claims 3-8 and 11-16) each recite a “central screw” and, separately, a “locking nut” “configured to engage the central screw when the central screw and baseplate are implanted within the medical patient” (among other things). (Ex.1001 at 30(9:43-49, 10:25-30)).

Lefebvre does not disclose a “central screw” and “locking nut” as claimed. (Higgs, 41-46(¶¶73-80)).

Petitioner argues that “anchor rod” portion 61 of Lefebvre’s “anchoring screw 6” corresponds with the “central screw” element of the challenged claims, and “main head” portion 60 of anchoring screw 6 corresponds with the “locking nut” element. (Petition, 62-67). As shown below in annotated Figure 11 (annotations provided by Dr. Higgs), main head 60 and anchor rod 61 portions are not distinct components with distinct functions, but rather parts of a single

anchor rod portions).¹¹



Lefebvre, Figure 11 (Higgs-Annotated)

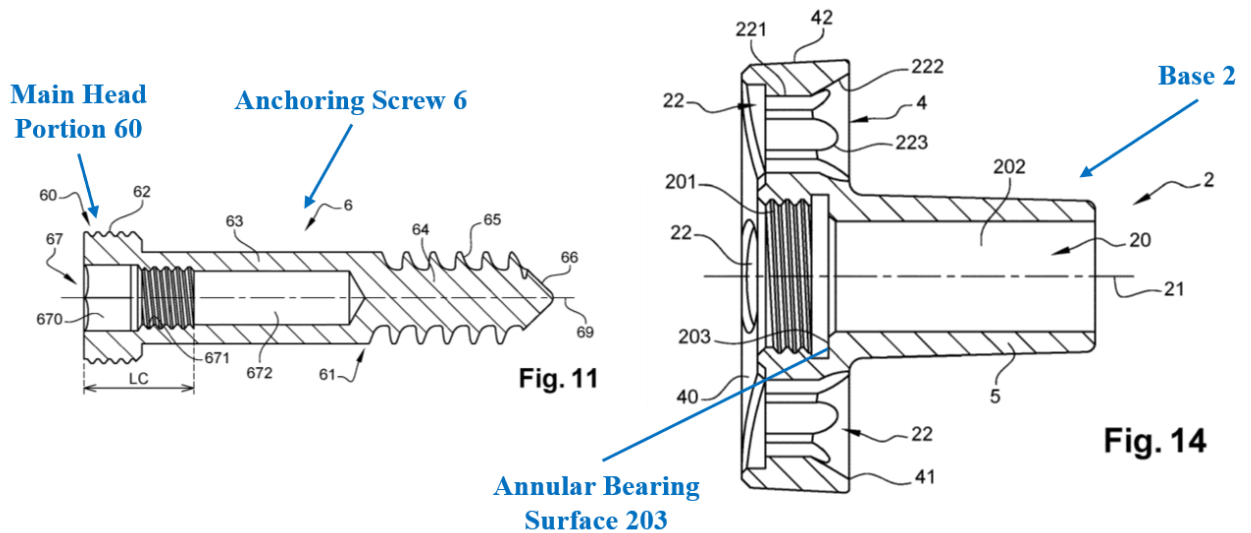
(See Ex.1009 at 1, 6, 13-14, 16(Abstract, 2:50-54, 2:61-3:13, 7:4-12); Higgs, 41-42(¶74)).

A POSITA would recognize the monolithic nature of the anchoring screw structure as an important aspect of Lefebvre's device. (Higgs, 42-44(¶75)).

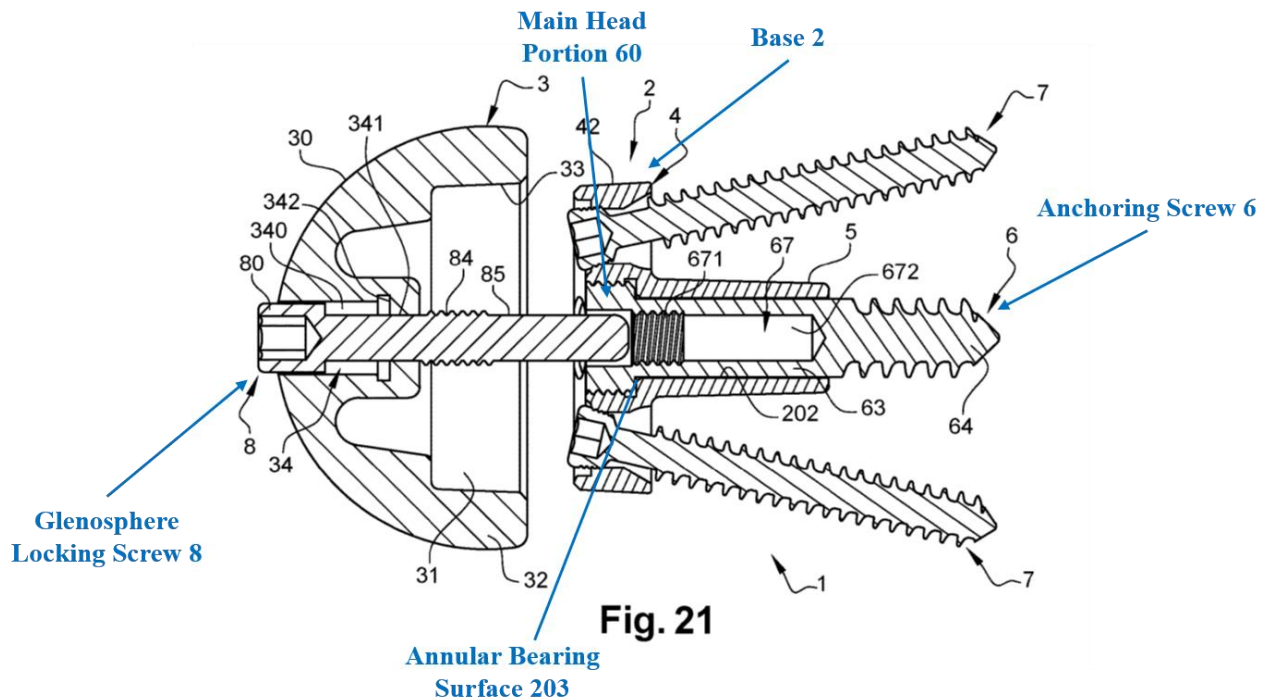
Lefebvre describes the monolithic design as a “**remarkable**” aspect of the design. (Ex.1009 at 13-14(2:61-3:13)). The screw 6 includes at the main head 60 an “inlet portion [670] shaped so as to cooperate with a screwing tool.” (*Id.* at 13-14, 16(2:61-3:13, 7:45-54)). During implantation, the “external tapping” (threading)

¹¹ This uniform cross-hatching demonstrates the anchoring screw 6 is a monolith, and belies Petitioner’s description of main head 60 as “attached” to anchor rod 61. (Petition, 67; Higgs, 41-42(¶74)). Petitioner’s argument that “claim 1 does not require a locking nut that is removable or separate from central screw” misses the point. (See Section VI.A.2.b.).

of the main head 60 and anchor rod 61 work in tandem, which “improv[es] the anchorage of the external tapping of the end segment of the anchor rod by screwing into the glenoid cavity.” (*Id.* at 14(4:14-27); *see also id.* at 16(7:37-44)). Implanted, the main head 60 “abut[s] on the annular bearing surface 203 [of base 2] in a locked position,” as illustrated below in annotated Figures 11 and 14 (prior to abutting) and 21 (abutting). (*Id.* at 16(7:7-12)).



Lefebvre, Figure 11 and 14 (Higgs-Annotated)



Lefebvre, Figure 21 (Higgs-Annotated)

(Higgs, 42-44(¶75)). Abutting of the main head portion 60 “promot[es] a transmission of the compressed forces in the main anchoring screw via th[e] annular bearing surface.” (Ex.1009 at 14(4:1-5)). Locking the glenosphere locking screw 8 with the monolithic anchoring screw 6 provides “transmission of the compressive forces which pass through the central anchoring screw and also through the locking screw and through the annular bearing surface provided inside the central orifice of the glenosphere *thereby providing enhanced mechanical strength in comparison with the prior art.*” (Id. at 14(3:14-23)).

A POSITA would understand that the monolithic nature of the anchoring screw structure is a key part of what Lefebvre considered to be remarkable and

inventive. They would recognize that improved strength of the construct and its joined components is part of what Lefebvre considered remarkable and inventive, and that this improved strength is provided by the monolithic anchoring screw design and the rigidity in the construct that it creates by interfacing with a locking mechanism to the base 2. A POSITA would have understood that this locking mechanism provided by the monolithic screw design was essential to the structural integrity of Lefebvre's implant for long-term function of the device in a patient. (Higgs, 44(¶76)).

Petitioner's attempt to arbitrarily divide unitary anchoring screw 6 into separate and distinct components with allegedly separate and distinct functions is improper. A POSITA would understand that Lefebvre's main and anchoring rod portions 60, 61 are not separate and distinct structures or components, capable of being divided into discrete subcomponents with separate and distinct functions. Without the main head portion 60 to abut the base 2 and transmit forces (among other things), the remaining portion of the monolithic structure would not be an anchoring screw 6. The main head 60 works collectively with the rest of the anchoring screw 6 to perform the function of a screw, and is therefore necessary to have a "screw" in the first place. (Higgs, 44-45(¶77)). A POSITA would understand that attempting to break up Lefebvre's screw into pieces as proposed would defeat Lefebvre's disclosed purposes (including functioning as a screw),

eliminate the anchoring screw's locking function, and reduce the mechanical integrity of the device. (Higgs, 45-46(¶79)).

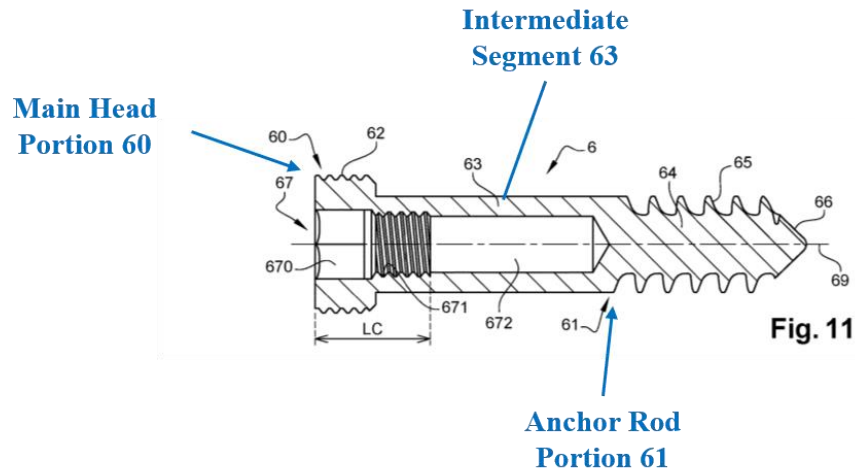
Further, the challenged claims recite the “central screw” and “locking nut” as separate and distinct elements, including requiring the locking nut “engage the central screw when the central screw and baseplate are implanted within the medical patient.” (See Section VI.A.2.b.). Plaintiffs’ theory that the monolithic anchoring screw 6 is both the claimed “central screw” **and** “locking nut” is nonsensical, as a structure cannot engage itself. (Higgs, 45(¶78)).

Thus, Lefebvre does not disclose both a “central screw” **and** a “locking nut” as claimed. (Higgs, 46(¶80)).

3. All Challenged Claims: Petitioner Fails To Demonstrate The Challenged Claims Were Obvious

Petitioner argues a POSITA would “separate the components of Lefebvre’s main anchoring screw 6 forming the locking nut (which includes external tapping 62 and internal thread of intermediate portion 671) from the components of Lefebvre’s main anchoring screw 6 forming the central screw.” (Petition, 67-69). There are numerous problems with Petitioner’s theory. (Higgs, 46-52(¶¶81-89)).

Lefebvre’s anchoring screw 6 does not have “components” to separate. Anchoring screw 6 is a monolithic structure, with main head, anchor rod, and intermediate segment portions 60, 61, 63 that collectively form a screw.



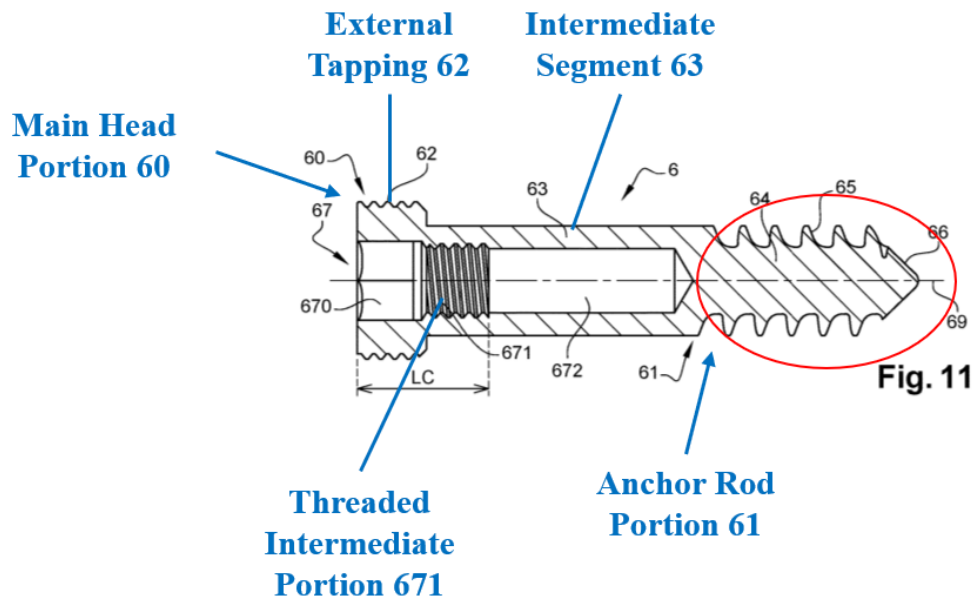
Lefebvre, Fig. 11 (Higgs-Annotated)

(Ex.1009 at 6; Higgs, 47(¶82)). Petitioner's argument that a POSITA would separate portions of the anchoring screw from components forming the screw is circular. Without the main head 60 (with external tapping 62) to abut the base 2, there is no screw. Similarly, without the anchor rod 61 to engage the patient, or the intermediate segment 63 (with intermediate threaded portion 671) to bridge the main head and anchor rod portions, there is no screw. (See Section VI.C.2.; Higgs, 47-48(¶83)).

Petitioner's theory also lacks sufficient detail to support a conclusion that a POSITA would have been motivated to modify Lefebvre and had a reasonable expectation of success in doing so. See *Pers. Web Techs.*, 848 F.3d at 993-94. Petitioner provides no explanation how a POSITA allegedly would "separate the components," let alone how to do so and still have a functional device, even though a POSITA would understand Petitioner's proposal (if even possible) would

require substantial reconstruction and redesign. (Higgs, 48(¶84)). Petitioner's vague obviousness theory leaves Patent Owner and the Board guessing what specifically Petitioner alleges would have been obvious, and why a POSITA would have been motivated to do whatever Petitioner believes (but never says) was obvious. *Trend Micro*, IPR2023-00692, Paper 8 at 28-29. Petitioner's proposal to redesign and reconstruct Lefebvre without detailing how it would be done reeks of improper hindsight. *See Medtronic*, 70 F.4th at 1347 (Fed. Cir. 2023) ("extensive need to modify [prior art] in a way not suggested in the Petition" reflects "a hindsight desire to recreate the claimed invention, as opposed to a known need in the art for such a device" (citation omitted)).

Petitioner's proposal to subdivide Lefebvre's anchoring screw 6 is further problematic, because it would render the anchoring screw 6 inoperable for its intended purposes. As illustrated below, if the main head 60 comprising external tapping 62 and the intermediate segment 62 comprising internal threaded portion 671 were separated as proposed, all that would be left would be the anchor rod portion 61 (illustrated in the red oval).



Lefebvre, Fig. 11 (Higgs-Annotated)

(Ex.1009 at 6; Higgs, 49-50(¶85)). But the anchor rod 61, by itself, is not a screw, and lacks the “remarkable” structure and function of Lefebvre’s anchoring screw 61, including portions “shaped so as to cooperate with a screwing tool” and designed “to abut[] on the annular bearing surface 203” of base 2 and transmit compressive forces passing “through the central anchoring screw,” “through the locking screw,” and “through the annular bearing surface provided inside the central orifice of the glenosphere” (among other things). (See Section VI.C.2., above; Higgs, 48-50(¶¶85-86)). Thus, the proposed modification would render Lefebvre’s anchoring screw 6 no longer a screw, let alone one with Lefebvre’s

“remarkable” structure and functions.¹² Indeed, by separating the anchor rod portion 61 from the main head portion 60 with structure “shaped so as to cooperate with a screwing tool,” there would be no way for a surgeon to screw the remaining anchoring rod portion 61 into the body. (Higgs, 49-50(¶86)); see *Tec Air*, 192 F.3d at 1360 (affirming nonobviousness where proposed screw redesign would render device “inoperable for its intended purpose—no screw driver would be able to turn the smooth-headed screws from the cavity-side of the mold”).

Petitioner also provides no evidence a POSITA would have been motivated to make the proposed modifications (whatever they are). Petitioner's reliance on Fallin is misplaced, for the reasons in Section III. Petitioner argues that carving up Lefebvre's anchoring screw 6 would be “desirable” because it “would allow Lefebvre's central screw to have a ‘free spinning screw’ design.” (Petition at 69). But Petitioner provides no evidence that replacing Lefebvre's design with a so-called “free spinning” design would be desirable, or provide any benefits or advantages. Nor does Petitioner identify any design needs or market pressures for replacing non-free-spinning screw designs with free-spinning designs. While

¹² Ground 3 should be rejected for this reason, alone, as the proposed modification would no longer include at least the alleged “central screw sized to at least partially pass through the central channel and secure the baseplate to the glenoid of the patient.”

Petitioner theorizes a modification could “provide additional compression between the bone and Lefebvre’s base 2,” it provides no description of a functional modification, or how such a modification, if even feasible, would provide “additional compression” in comparison with Lefebvre’s “remarkable” dual-threading design. (See Higgs, 50-51(¶87); Ex.1009 at 13-14, 16(2:61-3:13, 4:14-27, 7:37-44)). As Dr. Higgs explains, Petitioner’s proposed modification would destroy aspects of Lefebvre’s screw that provide improved anchorage, and replace it with an undescribed design “without any evidence or explanation how the new design (whatever it is) would provide compression and anchorage *at least as good* as Lefebvre’s monolithic screw already provides.” (Higgs, 50-51(¶87) (emphasis in original)).

Petitioner’s reliance on Orphanos’s discussion of bone screw 270 as allegedly teaching the “desirability” of utilizing free spinning screws is misplaced.¹³ (Petition, 68-69). Unlike Lefebvre’s screw design, which Lefebvre describes as “remarkable” and is designed with features to improve anchorage and transmit compressive forces with the glenosphere and glenosphere locking screw (see Section VI.C.2., above), Orphanos describes bone screw 270 as “*optional*,”

¹³ Petitioner’s assertion that “Orphanos teaches how to modify the implant 1 of Lefebvre to separate the above referenced components” (Petition, 69) is unsupported and wrong. (See, e.g., Section VI.C.3., above).

and explains it may “**be omitted** from the implant” (see Section VI.A.2.b., above; see also, e.g., Ex.1006 at 27(11:63-67)). And even when bone screw 270 is used, Orphanos explains that the threaded neck portion (the feature that purportedly “allow[s] a ‘free spinning screw’ design”) is **optional** and “**can be omitted**” permitting the screw to “function as intended with less contact area.” (*Id.* at 27-28(12:49-61, 13:1-3)). Further, while Orphanos explains that the first embodiment can include a “free spinning” screw, it makes no similar disclosure regarding the integrated collet/bone screw 1050 of the second embodiment. Thus, not only does Orphanos fail to motivate using free spinning screws in Lefebvre’s device—it discloses that this design is **optional** and **may be omitted** in Orphanos’s devices.¹⁴ (Higgs, 51(¶88)).

Petitioner’s motivation argument makes no sense. If a free spinning screw truly was a motivating factor to a POSITA knowledgeable of Lefebvre and Orphanos, then that person simply could have (and would have) used Orphanos’s first embodiment and optional spinning screw. Petitioner’s suggestion that a POSITA would instead attempt to redesign and reconstruct Lefebvre, just so it

¹⁴ Petitioner’s reliance on MPEP 2144.04(V)(C) and *In re Dulberg* as supporting obviousness “for any reason” does not excuse Petitioner’s failure to evidence a motivation to combine. As the Federal Circuit made clear, “KSR did not do away with the requirement that there must exist a motivation to combine various prior art references.” *Virtek*, 97 F.4th at 887.

could have an “optional” free spinning screw, without any explanation of how the reconstruction/redesign would be accomplished, and no evidence that doing so would necessarily provide benefit or advantage, bears the “unmistakable taint” of impermissible hindsight. *GCE Gas*, IPR2023-00326, Paper 27 at 53. Petitioner’s theory is not based on any knowledge or motivation of a POSITA. (Higgs, 52(¶89)).

Petitioner also fails to provide a clear, evidence-supported account sufficient to support a conclusion that a POSITA would have been motivated to make any of the additional modifications proposed in the Petition, or to demonstrate that the modifications would result in a device that not only was operable, but satisfied all of the requirements of the challenged claims. For example, Petitioner states in conclusory fashion that “Orphanos teaches how to modify” Lefebvre’s implant, that a POSITA would “separate [Lefebvre’s] components,” and that the modified device would include a “locking nut . . . configured to engage [a] central screw.” (Petition, 69-71). But Petitioner provides no detailed explanation of what those modifications are, how a POSITA allegedly would divide into components Lefebvre’s monolithic anchoring screw 6, how the separated pieces would work together in the modified device (assuming they could), or how the modifications

would result in a “locking nut” and “central screw,” let alone a locking nut “configured to engage the central screw” as claimed.¹⁵ (*Id.*).

At bottom, Petitioner's obviousness theory boils down to free spinning screws were known, which is legally insufficient to demonstrate obviousness. *See Virtek*, 97 F.4th at 886-88; *GCE Gas*, IPR2023-00326, Paper 27 at 53-54.

4. Petitioner Fails To Demonstrate Claims 7 and 15 Were Obvious

Petitioner fails to demonstrate claims 7 and 15 are obvious, for at least the reasons in Sections VI.C.1.–3., above.

Petitioner fails to demonstrate that a POSITA would have been motivated to modify the modified Lefebvre devices to include the “diameter” and “length” requirements of claims 7 and 15. Petitioner's argument that Lefebvre satisfies these requirements is based solely on its measurement of arbitrary portions of Lefebvre's anchoring screw 6, without any evidence the figures are to scale, or the specification otherwise describes the dimensions. This is improper.

See Hockerson-Halberstadt, 222 F.3d at 956. A POSITA would understand the figures Petitioner measured are not engineering drawings and are not intended to convey specific dimensions. (Higgs, 52-53(¶91)).

¹⁵ Petitioner's characterization of Roche (Petition, 71) is incorrect, for the reasons in Section VI.A.2.b., above.

Petitioner's argument that a POSITA "would be motivated to keep the length less than the diameter to provide a low profile to the locking nut" (Petition, 77, 81) is unsupported, and makes no sense. (See Section VI.A.4., above; Higgs, 53(¶92)). A POSITA would understand that reducing the length relative to the diameter of the portion of Lefebvre's anchoring screw 6 that includes the inner and outer threading would create potential disadvantages, including shortening the coupling between the glenosphere locking screw 8 and the anchoring screw 6, and between the anchoring screw 6 and the base, resulting in a potentially **weaker structure**. A POSITA would not have been motivated to make such a modification. (Higgs, 53-54(¶93)). Petitioner's reliance on Fallin is misplaced, for the reasons in Section III.

D. Ground 4: Challenged Claims 2 And 10 Would Not Have Been Obvious To A POSITA In View Of Lefebvre, Orphanos, Roche, And Frankle

1. Frankle Is Not Prior Art

Petitioner fails to demonstrate claims 2 and 10 are obvious, for at least the reasons in Sections VI.C.1.–3., above.

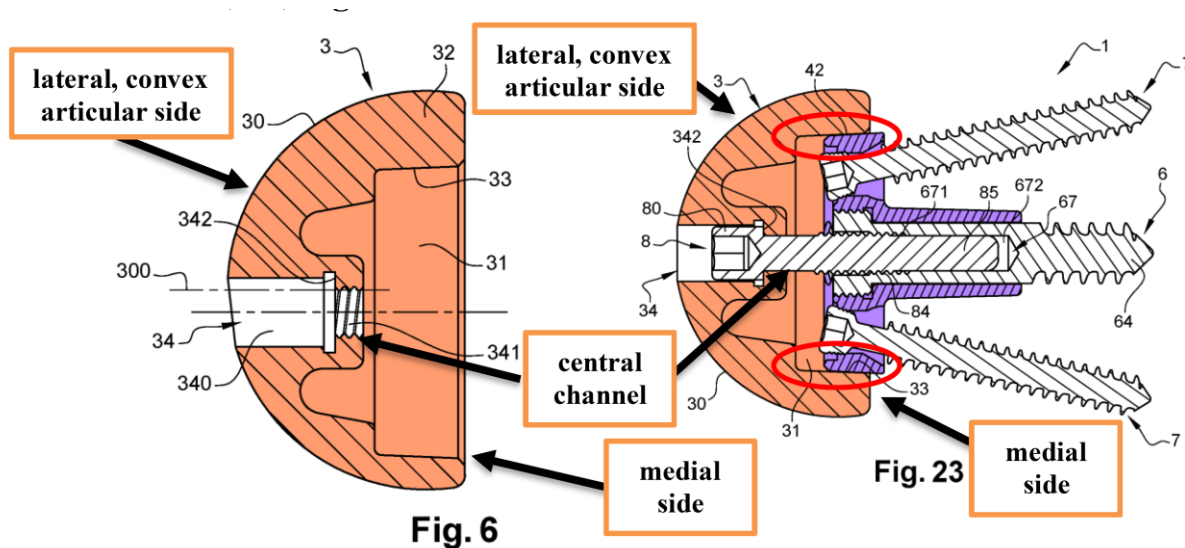
Petitioner's obviousness theory in Ground 4 relies on its arguments in Ground 3 for all of the limitations of claims 2 and 10 found in independent claims 1 and 9. (Petition, 81). Petitioner does not allege that Lefebvre, either alone or as modified in Ground 1, has a glenosphere comprising "a stem

configured to be positioned at least partially within the central channel of the baseplate.” Instead, Petitioner states that “Frankle” provides this limitation. (Petition, 82). As explained above in Section II.B., however, Frankle is not prior art. Accordingly, Petitioner has failed to demonstrate claims 2 and 10 would have been obvious in view of the prior art. Ground 4 should be dismissed for at least this reason.

2. A POSITA Would Not Have Been Motivated To Modify Lefebvre To Incorporate Frankle's Protrusion Element

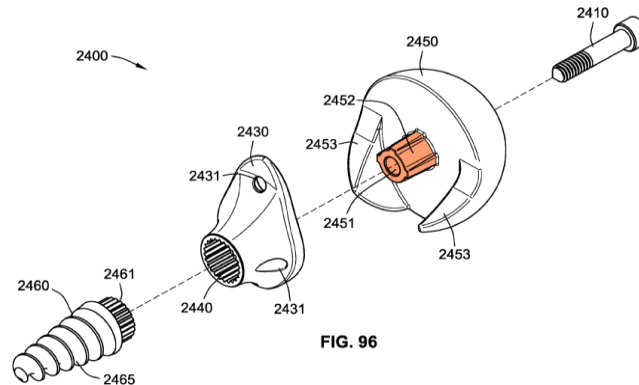
Even if Frankle was prior art, Petitioner's theory lacks sufficient detail to support a conclusion that a POSITA would have been motivated to modify Lefebvre in view of Frankle and had a reasonable expectation of success in doing so. *See Pers. Web Techs.*, 848 F.3d at 993-94. Petitioner proposes modifying Orphanos “to incorporate [Frankle's] protrusion element 2452 . . . into [Lefebvre's] glenosphere 3” so that Frankle's protrusion element “is configured to be positioned at least partially within the central channel of the baseplate.” (Petition at 82). As shown below in annotated Figures 6 and 23 (annotations by

Petitioner), however, the alleged “central channel” of Lefebvre’s base (highlighted in purple) is occupied by the anchor screw 6 and locking screw 8.



Lefebvre, Figures 6 and 23 (Petitioner-Annotated) (Petition at 73)

Petitioner provides no explanation how a POSITA would have modified Lefebvre’s glenosphere to include Frankle’s “protrusion element 2452” (shown below in Petitioner’s annotated Figure 96, highlighted in orange) and position it “at least partially within the central channel” of Lefebvre’s base, particularly when there is no space in the alleged central channel for any “protrusion element” to fit.



Frankle, Figure 96 (Petitioner-Annotated) (Petition at 82)

Petitioner's vague obviousness theory leaves Patent Owner and the Board guessing what specifically Petitioner alleges would have been obvious, and why a POSITA would have been motivated to do whatever Petitioner believes (but never says) was obvious. *Trend Micro*, IPR2023-00692, Paper 8 at 28-29. The proposed modification would not have been obvious to a POSITA. (Higgs, 54-55(¶¶94-95)).

Petitioner provides no evidence that a POSITA would have been motivated to modify Lefebvre to “promote guidance,” “maintain alignment,” or “provide further structural rigidity.” (Petition, 82). Petitioner identifies no evidence that a POSITA would have considered Lefebvre's device as deficient in any of these respects. It is not. (See Ex.1009 at 13(2:34-36 (explaining Lefevre's design “enable[s] guidance and locking of the glenosphere on the base, while providing an improved mechanical strength”))). Nor does Petitioner explain how “protrusion 2452” allegedly promotes guidance, maintains alignment, or provides structural rigidity in *Frankle's* device, let alone how the proposed modification

would provide any benefit in *Lefebvre's* device. A POSITA would not have considered Lefebvre's devices as deficient, and would not have been motivated to make the proposed modifications. (Higgs, 55-56(¶¶96)). Petitioner's reliance on Fallin is misplaced, for the reasons in Section III.

E. Ground 5: Challenged Claims 1-16 Are Not Indefinite (Baseplate "Central Channel")

"Definiteness is a matter of claim construction." *ClearOne Inc. v. Shure Acquisition Holdings, Inc.*, 35 F.4th 1345, 1348 (Fed. Cir. 2022). Claim terms are given their "ordinary and customary meaning," absent compelling reason to deviate. *See Weber, Inc. v. Provisur Techs., Inc.*, 92 F.4th 1059, 1070 (Fed. Cir. 2024) (citing *Phillips*, 415 F.3d at 1312-13).

The test for indefiniteness is whether the claims, "viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instr., Inc.*, 572 U.S. 898, 910 (2014). This standard "recogniz[es] that absolute precision is unattainable." *Id.* A claim is not indefinite merely because it may be "susceptible to differing interpretations." *Nevro Corp. v. Boston Sci. Corp.*, 955 F.3d 35, 41 (Fed. Cir. 2020); *see also ClearOne*, 35 F.4th at 1351).

Contrary to the Petition, a POSITA would understand the scope of the challenged claims with reasonable certainty. (Higgs, 56-57(¶¶97-100)). Petitioner

concedes that, consistent with its ordinary meaning, the challenged claims describe “channel” both in terms of structure, as well as space formed by that structure. (Petition, 84-85; Higgs, 56-57(¶98)). Petitioner further acknowledges that the specification supports this ordinary meaning. (Petition, 85-86 (explaining the specification describes channel as connoting both “passageway” and “physical structure”); *see also* Ex.1001, *e.g.*, at 27-28(4:38-40, 5:14-17, 6:34-38)). Nothing in the claims or specification would indicate to a POSITA that the inventors intended “central channel” to deviate from its plain and ordinary meaning. (Higgs, 57(¶¶99-100)). Thus, the ordinary meaning of “channel” (and “central channel”) in the context of the claims and specification connotes both structure, as well as a space formed by that structure.

Petitioner's argument that the scope of the claimed baseplate “central channel” is “not reasonably certain” is incredible. Petitioner had no problem interpreting and applying “central channel” in Grounds 1-4, and never once expressed uncertainty about its meaning. Further, Petitioner had no problem identifying alleged central channels in the cited references, both by structure and space. *See ClearOne*, 35 F.4th at 1350 (Petitioner's “ability to determine” existence of claim term in prior art undermines indefiniteness). For example, Petitioner states that Orphanos's “throughbore 310” is a “central channel” having structure (Petition, 41-42 (proposing securing a locking nut “to” Orphanos's

throughbore) as well as space (Petition, 29 (explaining central screw 270 passes “through” throughbore)). Orphanos, itself, describes the “throughbore” both with respect to its physical structure, as well as space formed by that structure. (See, e.g., Ex.1006, 25(8:31-43) (describing “inner sidewall” of the throughbore (structural) **and** a collet “within” the throughbore (spatial))).

Petitioner's attempt to manufacture a controversy with Fallin is misplaced. To start, Fallin's opinions are irrelevant because he is not a POSITA. (See Section III., above). Further, Fallin (like Petitioner) had no problem interpreting and applying “central channel” with respect to Grounds 1-4, and never once expressed uncertainty regarding its meaning in those grounds. (See, e.g., Ex.1002, 40-41(¶84)). Fallon (like Petitioner) concedes that central channel connotes “both an empty space . . . and a physical structure.” (*Id.* at ¶202). His opinion that this, by itself, renders the claims indefinite is factually and legally unsupported.¹⁶ (*Id.* (asserting the claims are “impermissible” and indefinite “because” they claim both structure and space)).

Petitioner's argument that the challenged claims are unpatentable under § 112 lacks merit. Ground 5 should be rejected.

¹⁶ Fallin's opinions are premised on a legally erroneous presumption that the challenged claims are “unpatentable **unless**” Patent Owner demonstrates otherwise. (Ex.1002, 15(¶26)).

**F. Ground 6: Challenged Claims 1-16 Are Not Indefinite
(Glenosphere “Central Channel”)**

Petitioner's argument that the glenosphere “central channel” renders the challenged claims indefinite likewise lacks merit. Contrary to the Petition, a POSITA would understand the scope of the challenged claims with reasonable certainty. (Higgs, 58-59(¶¶101-104)).

As explained above in Section VI.E., the ordinary meaning of “channel” connotes both structure as well as space formed by that structure. There is nothing in the claims or specification that would indicate to a POSITA that the inventors intended “central channel” to deviate from its plain and ordinary meaning. (Higgs, 59(¶¶103-104)).

Petitioner's indefiniteness argument incorrectly assumes the claims recite a ***central channel*** “configured to interface with the baseplate.” (Petition, 88). The challenged claims recite “***a glenosphere***, having a lateral, convex articular side, a medial side, and a central channel extending from the convex articular side to the medial side and ***configured to interface with the baseplate.***” (Ex.1001 at 30(9:52-55, 10:33-36)). It is the “glenosphere”—and not necessarily the “central channel” of the glenosphere—that is “configured to interface” as claimed. (Higgs, 58-59(¶102)). This is consistent with Petitioner's application of the claim in the obviousness grounds. (See, e.g., Petition, 43 (alleging Orphanos discloses the

claimed glenosphere because “[e]ach ***glenosphere*** 250, 1030 is ***configured to*** surround and ***interface with baseplate***”). Petitioner does not allege that the glenosphere “central channel” is indefinite under this proper interpretation of the claim. Nor does Petitioner allege that a ***glenosphere*** “configured to interface with the baseplate” renders the claim indefinite. Ground 6 should be rejected for at least this reason.

Ground 6 should be rejected for the additional reason that it is premised on an incorrect legal standard. According to Petitioner, the term “to interface” is “problematic” because it allegedly is “ambiguous on its face,” and may be interpreted “in a variety of ways.” (Petition, 88-90). But a claim is not indefinite merely because it includes an alleged ambiguity, or may be susceptible to different interpretations. The Supreme Court declined to adopt such a test in *Nautilus*, that would have found indefiniteness merely “when a claim is ‘ambiguous, such that readers could reasonably interpret the claim’s scope differently.’” *Nautilus*, 572 U.S. at 908-10; *see also ClearOne*, 35 F.4th at 1351 (affirming Board’s finding claim not indefinite despite argument claim term can be interpreted in different ways); *Nevro*, 955 F.3d at 42 (holding court erred by applying legally erroneous “susceptible to different constructions” indefiniteness standard). Petitioner fails to explain how any alleged ambiguity or alternative interpretation of “to interface” actually would render the claim indefinite. Petitioner does not contend, for

example, that the claims are valid under one interpretation of “to interface,” but invalid under another.

Petitioner's indefiniteness arguments also fail because they are based on the incorrect premise that the glenosphere “central channel” is claimed “only as an empty space or passageway” and not as physical structure. (Petition, 87-90). The word “channel” ordinarily connotes both space and structure, and there is nothing in the claims or specification to the contrary. (Higgs, 56-57, 59(¶¶98-100, 103-104)). Further, Petitioner concedes the specification describes certain “physical features” of a glenosphere central channel. (Petition, 88). Petitioner's suggestion that the claimed central channel somehow excludes these physical features is unsupported, and improperly excludes preferred embodiments of the '561 Patent.¹⁷ *Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (claim construction that excludes preferred embodiment “is rarely, if ever, correct and would require highly persuasive evidentiary support, which is wholly absent in this case”).

¹⁷ Such an interpretation also ignores the challenged claims' use of the transitional term “comprising,” which means recited elements “are essential, but other elements may be added and still form a construct within the scope of the claim.” *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997).

Petitioner's argument that the specification's description of Figure 8 "does nothing to provide reasonable certainty . . . as to the full scope" of the glenosphere "central channel" limitation is misplaced. (Petition, 89). That the claimed glenosphere "central channel" is broader than the example of Figure 8 "does not make the term indefinite." *ClearOne*, 35 F.4th at 1350; *see also BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1367 (Fed. Cir. 2017) (noting "breadth is not indefiniteness" and holding "the inference of indefiniteness simply from [a broad scope] is legally incorrect" (citation and internal quotations omitted)).

Petitioner's indefiniteness arguments are belied by its actions in Grounds 1-4. Petitioner had no problem interpreting and applying "central channel" and "configured to interface" to the cited references, without expressing uncertainty about their meanings. *See ClearOne*, 35 F.4th at 1350. While Petitioner argues in Ground 6 that the glenosphere "central channel" is claimed "**only as an empty space** or passageway" and **not structure**, when it came time to apply the claims to Orphanos (Petition, 87), Petitioner relied on **structure**, stating for example that "**inner surfaces** of [Orphanos's] glenosphere 250 **define a central channel**." (*Id.* at 43-44). Petitioner's reliance on Fallin is misplaced, for the reasons explained above regarding Ground 5. (See Sections III., VI.E.). In addition to his lack of qualifications, Fallin (like Petitioner) had no problem interpreting and applying the glenosphere "central channel" and "configured to interface" terms with respect to

Grounds 1-4, and never once expressed uncertainty regarding their meaning in those grounds. (*See, e.g.*, Ex.1002, 51-52(¶105)).

Petitioner's argument that the challenged claims are unpatentable under § 112 lacks merit. Ground 6 should be rejected.

VII. CONCLUSION

Patent Owner respectfully requests that the Board deny institution of post-grant review.

Dated: September 30, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the type-volume limitations of 37 CFR § 42.24(a)(1)(ii) and (b)(1). This brief, excluding a table of contents, a table of authorities, and a certificate of service or word count, or appendix of exhibits or claim listing contains 13,740 words as calculated by the “Word Count” feature of Microsoft Word, the word processing program used to create it.

The undersigned further certifies that this brief complies with the typeface requirements of 37 CFR § 42.6(a)(2)(ii) and typestyle requirements of 37 CFR § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, 14 point font.

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing PATENT OWNER'S
PRELIMINARY RESPONSE has been served in its entirety on September 30,
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