

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.: PGR2025-00001

U.S. Patent No. 12,023,254

PATENT OWNER'S PRELIMINARY RESPONSE

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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 Higgs, M.D.
2006	<i>Curriculum Vitae</i> of Geoffrey Higgs, M.D.
2007	European Patent EP 3 598 957 B1 (“Orphanos EP”)
2008	U.S. 10,357,373 (“Gargac CON”)
2009	<i>Shoulder Innovations, Inc. v. Catalyst OrthoScience Inc.</i> , No. 24-266-JPM, Dkt. No. 19 (Scheduling Order) (April 23, 2024)
2010	<i>Shoulder Innovations, Inc. v. Catalyst OrthoScience Inc.</i> , No. 24-266-JPM, Transcript of Nov. 22, 2024 Hearing (Excerpt)
2011	<i>Shoulder Innovations, Inc. v. Catalyst OrthoScience Inc.</i> , No. 24-266-JPM, Nov. 22, 2024 Minute Order Regarding Schedule
2012	<i>Shoulder Innovations, Inc. v. Catalyst OrthoScience Inc.</i> , No. 24-266-JPM, Dkt. No. 76 (Nov. 25, 2024 Order Regarding Schedule)

Petitioner, Catalyst OrthoScience Inc., has failed to demonstrate that any of the challenged claims of U.S. 12,023,254 (“’254 Patent”) “more likely than not” are unpatentable. Shoulder Innovations, Inc. (“Patent Owner”), respectfully requests that the Board deny the Petition (Paper 1).

I. INTRODUCTION

The ’254 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(1:10-13); Ex.1004 at 116; Ex.2001). Petitioner filed the present Petition after Patent Owner asserted the ’254 Patent in district court litigation (the “Litigation”). (Petition, 1; Paper 5). Petitioner previously requested post-grant review of related U.S. 11,771,561 (“’561 Patent”) based on the same references and arguments presented here. *See* PGR2024-00042, Paper 1. The Board denied post-grant review of the ’561 Patent, finding Petitioner’s obviousness and indefiniteness theories unconvincing. *See* PGR2024-00042, Paper 17.

Petitioner likewise fails to satisfy its burden here. As in PGR2024-00042, Petitioner’s obviousness grounds here (Grounds 1-4) are factually and legally deficient, based on non-prior-art disclosures and disclosures already considered during prosecution, and obviousness theories that the Board already considered and

found unconvincing.¹ (*Id.*). Petitioner's indefiniteness grounds (Grounds 5-6) are likewise legally deficient, and belied by its 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 while Fallin purports to have **known** and **worked with** persons of ordinary skill in the art for the '254 Patent ("POSITA"), he is not one himself. 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.²

¹ At least the "Orphanos," "Roche," and "Gargac" disclosures raised in Grounds 1-4 were cited during prosecution. (See Ex.1001 at 3 (identifying EP3598957 (Ex.2007) (European version of Orphanos (Ex.1006)), 2 (identifying U.S. 8,870,962 (Ex.2004) (divisional of Roche (Ex.1007)), 2 (identifying 10,357,373 (Ex.2008) (continuation of Gargac (Ex.1020))). The Gargac disclosure was specifically "cited by examiner" during prosecution. (See Ex.1001 at 2, 4; Ex.1004 at 120, 124).

² 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.

II. OVERVIEW OF THE '254 PATENT

A. Reverse Shoulder Replacement Systems

The '254 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(1:17-39)). 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 '254 Patent recite reverse shoulder implants comprising a unique combination of components used to replace the glenoid articulating surface. These components include a “baseplate,” “central post,” “locking nut,” “glenosphere,” and “glenosphere screw.” Figure 8 (reproduced and annotated

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

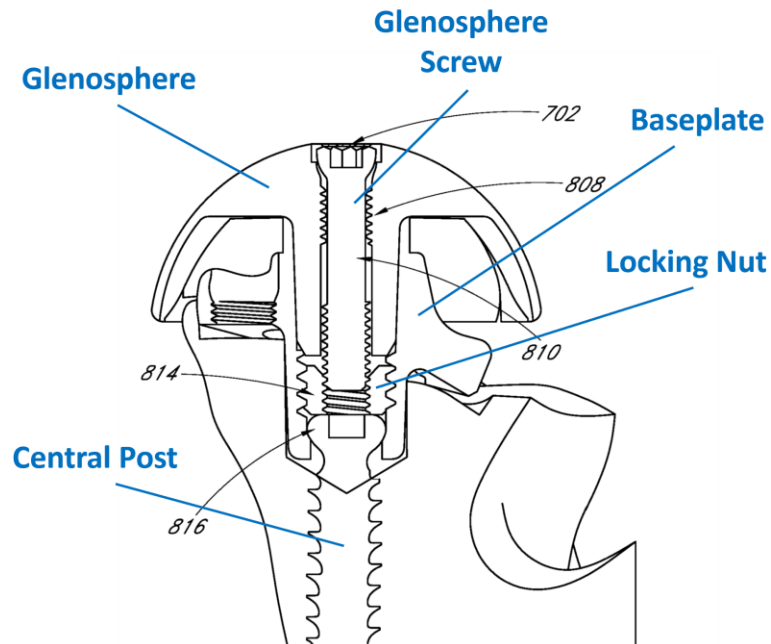


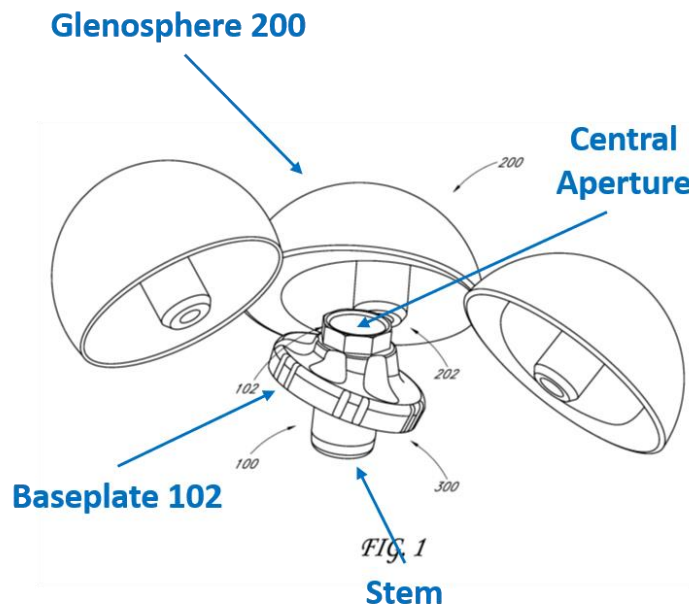
FIG. 8

'254 Patent, Figure 8 (Higgs-Annotated)

(*Id.* at 14-15(¶26); Ex.1001 at 12, 26(2:63-65), 30-31(claims 1-22)).

The Petition states that the challenged claims are “primarily directed toward the embodiment shown in Figure 8” of the '254 Patent, “which is described in column 6, lines 34-56.” (Petition, 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 5-25, 26-30(1:61-9:35); 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).



'254 Patent, Figure 1 (Higgs-Annotated)

(Higgs, 16(¶28); Ex.1001 at 5, 9, 11, 26-28(2:47-48, 3:39-57, 5:34-53, 6:1-33)).

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.”

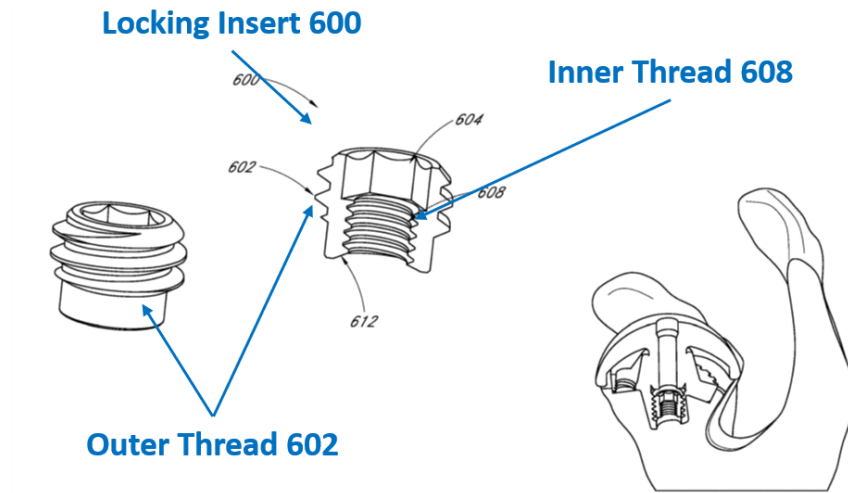


FIG. 6

'254 Patent, Figure 6 (Higgs-Annotated)

(Higgs, 16-17(¶29); Ex.1001 at 10, 28(5:54-67)).

B. Effective Filing Date Of The Claims

Contrary to Petitioner's argument (Petition, 9), **Petitioner** bears the burden of proving unpatentability (including that the identified references qualify as prior art), “and **this burden never shift[s]**.”³ See *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015). The '254 Patent and file history submitted with the Petition make clear the '254 Patent is entitled to an effective filing date earlier than March 2024.

³ Emphasis added, unless otherwise indicated.

The '254 Patent issued from Application No. 18/605,361, filed March 14, 2024 ("254 Application"). (Ex.1001 at 1; Ex.1004 at 2-6, 116-119). Petitioner concedes the challenged claims have an effective filing date at least by March 14, 2024, "the date that the patent application that issued as the '254 Patent was filed." (Petition, 9). There is no dispute that the claims are supported by the specification and figures of the '254 Application.

The '254 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; Ex.1004 at 102, 116-119). The '254 Application named the same inventors as the 2020 and 2021 Applications, and claimed priority to (and incorporated) each of those applications. (Ex.1001 at 1, 26(1:4-13); Ex.1004 at 8-10, 19(¶1), 116-119; Ex.2002 at 2-3; Ex.2003 at 3-4). The '254 Application included the same figures and substantially the same specification⁴ as the 2020 and 2021 Applications. (See Ex.1004 at 19-33, 70-90; Ex.2002 at 7-44; Ex.2003 at 17-54). Thus, the '254

⁴ The specifications differ with regard to the respective priority claims in paragraph 1 of each respective application. (*Compare* Ex.1004 at 19(¶1) *with* Ex.2003 at 17(¶1) *and* Ex.2002 at 7(¶1)).

Patent is entitled to an effective filing date at least as early as March 11, 2020—the date the priority PCT application was filed. *See* 35 U.S.C. § 120.⁵

Petitioner's obviousness theory in Grounds 3-4 assumes the "Lefebvre" reference is prior art based on its May 28, 2020 filing date. (Petition, 67). This date is **after** the March 11, 2020 effective filing date of the '254 Patent. Therefore, Lefebvre is not prior art.⁶

Petitioner states that it "may attempt to prove an earlier effective filing date" for the references cited in the Petition, but the time to do so has passed. (Petition, 9-10). The petition "guide[s] the life" and "define[s] the scope" of post-grant proceedings. *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 366-67 (2018). Petitions must identify "in writing and with particularity . . . the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim." 35 U.S.C. § 322(a)(3). Petitioner had an "obligation" to make its case "in [its] petition"—an obligation "of which [P]etitioner[] [was] aware."

⁵ The '254 Application also referenced and claimed priority to Provisional Application No. 62/816,708, filed March 11, 2019. (Ex. 1001 at 1, 26(1:4-10); Ex.1004 at 19(¶1), 116). 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.

⁶ Patent Owner reserves the right to rebut any future attempt by Petitioner to advance new prior art theories.

Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359, 1369-70 (Fed. Cir. 2016). The PTAB's Trial Practice Guide warned Petitioner of the consequences of failing to address foreseeable issues in their petitions—it “may not submit new evidence or argument in reply that it could have presented earlier, e.g. to make out a *prima facie* case of unpatentability.” PTAB Consolidated Trial Practice Guide (Nov. 2019) at 73.

The '254 Patent identifies on its face an effective filing date at least as early as March 11, 2020. (Ex.1001 at 1). If Petitioner wanted to “prove an earlier effective filing date for any reference that was obviated as prior art” under that filing date, then Petitioner could have (and should have) done so in the Petition. (Petition, 9-10). By choosing to assert a reference as prior art based on a priority date **after** March 11, 2020, Petitioner failed to make out a *prima facie* case for Grounds 3-4. Petitioner has failed to carry its burden regarding Grounds 3-4 for at least this reason. *See Intelligent Wellhead Sys., Inc. v. Downing Wellhead Equip., LLC*, IPR2024-00256, Papers 10-11 (refusing to consider post-petition evidence/argument regarding priority claim and denying institution for failure to satisfy burden regarding priority claim).

Petitioner's reliance on *Dynamic Drinkware* is misplaced, as that case concerned post-petition evidence regarding **actual reduction to practice**—an issue that was **not** foreseeable when the petition was filed (and not at issue here).

Dynamic Drinkware confirms that Petitioner bears the initial burden of production by making a *prima facie* case of unpatentability in the Petition. Petitioner flouted that burden by electing not to address foreseeable priority issues in the Petition. 800 F.3d at 1378-80.

C. 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, 13-16). 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 ’254 Patent. (Higgs, 18(¶31)). As Petitioner points out, the devices of the ’254 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, 15). Accordingly, a POSITA in the field of the ’254 Patent also includes a medical doctor with an engineering degree and at least 3

years of experience performing total joint arthroplasty in medical patients.⁷

(Higgs, 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. Dr. Higgs has decades of experience evaluating and implanting shoulder implant designs, and by 2024 had performed approximately 5,000 shoulder replacement surgeries in patients (including the types of systems described in the '254 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. (Higgs, 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 to provide opinions from the “perspective of a person of ordinary skill in the art.” (Ex.1002 at 9(¶¶2-3)). “To offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction,

⁷ See PGR2024-00042, Paper 17 at 18-20 (adopting level of skill “articulated by Petitioner [(in part)] and supplemented by Patent Owner”).

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 factfinder,” and “serve[] only to cause mischief and confuse the factfinder.” *Id.* at 1377 (citation and internal quotations omitted).

Petitioner failed to demonstrate that Fallin is qualified to render the opinions in his declaration. Fallin identifies **zero** personal experience designing joint replacement systems for medical patients. Fallin states he “work[ed] directly with and supervis[ed] professionals whose responsibilities included designing, developing, and commercializing joint replacement systems.” (Ex.1002 at 36-37 (¶73)). However, Fallin never once states that **he himself** has “at least three years’ of experience designing joint replacement systems for medical patients.” If Fallin had the experience necessary to qualify as a POSITA he surely would have said so in his October 11, 2024 declaration, particularly after Patent Owner previously pointed out his lack of qualifications in a related proceeding. *See* PGR2024-00042, Paper 7 at 10-11 (September 30, 2024 Patent Owner Preliminary Response). Fallin’s silence speaks volumes.

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, 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 as indefinite is belied by its decision in the Litigation not to “identif[y] any terms or phrases [of the ’254 Patent] for construction.” (Petition, 4).

V. THE BOARD SHOULD EXERCISE DISCRETIONARY 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.*, IPR2020-00019, Paper 11, at 5-6 (PTAB March 20, 2020).

In PGR2024-00042, the Board found that the *Fintiv* factors weighed in favor of denying post-grant review of the related '561 Patent. PGR2024-00042, Paper 17 at 11-53. The *Fintiv* factors weigh even more favorably in support of denial here.

With respect to Factor 1, Petitioner to date has not filed a motion to stay the Litigation in the event its Petition is granted, even though the parties and court have invested (and continue to invest) substantial resources towards an impending trial, as described below regarding Factors 2 and 3. Even if Petitioner had filed a stay motion, its evidence demonstrates that since 2009 the judge in the Litigation (Judge McCalla) denied 60% of the stay motions (9 denied versus 6 granted). (See Ex.1015). The 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 April 30, 2026. In the district court proceedings, trial was originally set for March 9, 2026 (Ex.2009 at 14, 17), however the judge has since indicated the trial will occur even earlier, in December 2025/January 2026 (Ex.2010 at 10(32:23-33:10, 34:22-25), 11(35:9-36:22); Ex.2011-2012). Factor 2 weighs in favor of denial.

With respect to Factor 3, the parties and the Delaware district court have invested and continue to invest substantial time and resources. By the time the

Board issues a decision whether to institute in April 2025, claim construction proceedings will be over, fact discovery and final infringement contentions will be completed, and the parties will be preparing for a trial just months later. (See Ex.2009 at 4, 16; Ex.2011-2012). 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, 105). 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 positions.⁸ Factors 4 and 5 weigh in favor of denial. See PGR2024-00042, Paper 17 at 16-17.

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

⁸ For example, Petitioner's argument in Grounds 5-6 (Petition, 95-102) that the claims should be construed as indefinite contradicts its litigation strategy not to engage in claim construction. (Petition, 4 (conceding Petitioner “identified [no] terms or phrases recited in the Challenged Claims for construction”)).

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).

Petitioner raises substantially the same obviousness and indefiniteness theories here that it previously raised in PGR2024-00042 regarding the related '561 Patent. *See* PGR2024-00042, Paper 1 at 4. As explained throughout this preliminary response, Petitioner's unpatentability grounds here are factually and legally deficient for at least the same reasons as in its prior petition. *See* PGR2024-00042, Paper 17 (finding unconvincing Petitioner's obviousness and indefiniteness theories raising same alleged prior art combinations and arguments presented here).⁹ 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. (Interim Procedure at 2).

⁹ Like here, for example, Petitioner's deficient obviousness theories in PGR2024-00042 were based on combining Orphanos and Roche (Grounds 1-2), and Lefebvre, Orphanos, and Roche (Grounds 3-4). PGR2024-00042, Paper 1 at 4. Petitioner's addition of Perego and Hopkins does not make up for the numerous factual and legal deficiencies highlighted by the Board in PGR2024-00042 regarding Petitioner's Orphanos, Roche, and Lefebvre arguments. *Id.*, Paper 17.

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 1-22 “more likely than not” would have been obvious (Grounds 1-4), or “more likely than not” are indefinite (Grounds 5-6).

A. Ground 1: Challenged Claims 1-7, 9-18, And 20-22 Would Not Have Been Obvious To A POSITA In View Of Orphanos, Hopkins, Perego, And Roche

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

As explained below, Ground 1 is deficient at least because Petitioner failed to address every limitation of the challenged claims. As a result, Petitioner failed to show that the proposed combinations (whatever they are) would satisfy each and every limitation of the challenged claims.

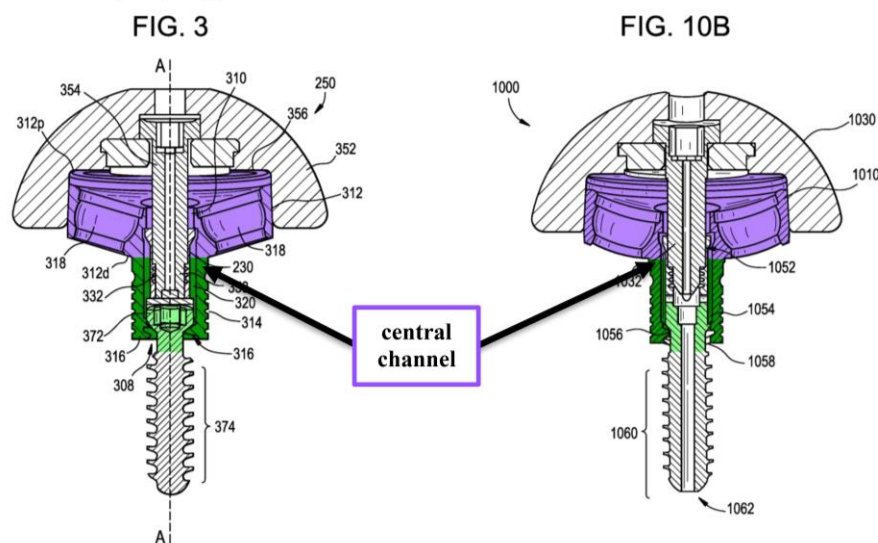
a. A Central Post “Configured To At Least Partially Pass Through The Central Channel”

Independent claims 1 and 12 (and the challenged dependent claims) each recite a “***baseplate having*** a lateral end, a medial end, and a ***baseplate central channel*** extending through the baseplate from the lateral end to the medial end” and separately a “***central post*** configured to at least ***partially pass through the [baseplate] central channel.***” The “baseplate” and “central post” are separate and distinct components, as confirmed by the requirement that the central post “at least partially pass ***through*** the central channel.” 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)). In the “Background of the Art” section of the Petition, Petitioner describes a “post” in the context of the claims as an “anchoring element” used “to anchor the baseplate with the glenoid cavity of the scapula.” (Petition, 7-9).

Petitioner alleges that Figures 3 and 10B of Orphanos each disclose structures that satisfy the “baseplate” and “central post” elements, as shown below in Petitioner’s annotated figures (alleged baseplates (with baseplate central channels) highlighted in purple and alleged central posts highlighted in light green and dark green).

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



Orphanos, Figures 3 and 10B (Petitioner-Annotated) (Petition at 31)

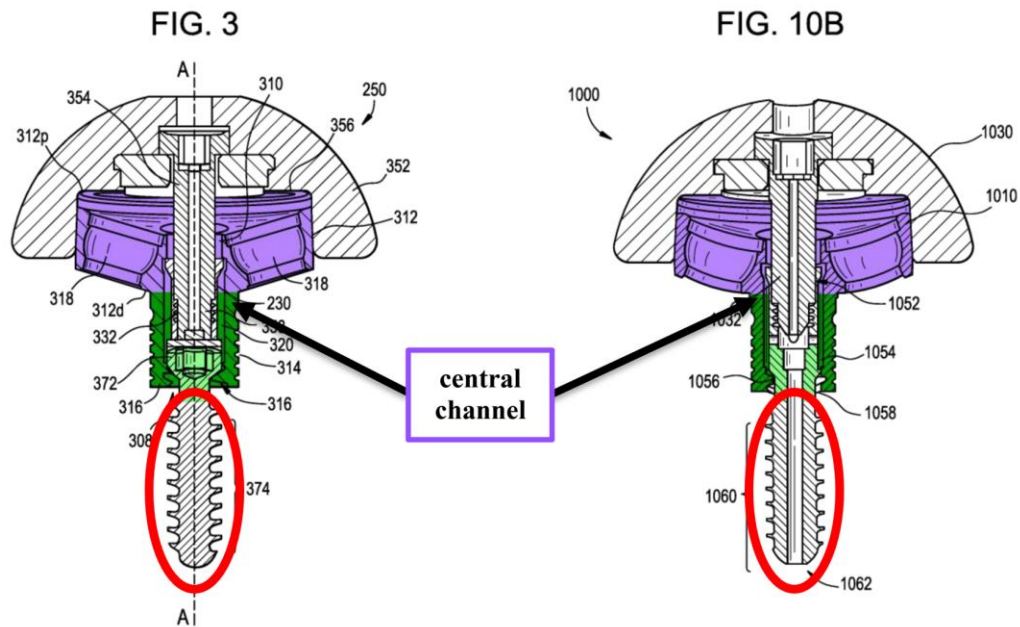
(Petition, 29-35). Petitioner failed to address all of the requirements of the “central post” as claimed.

Petitioner alleges that the “platform 312” portion (Figure 3, annotated purple) of Orphanos's metaglene 210 and corresponding portion (Figure 10B, annotated purple) of Orphanos's metaglene1010 discloses the claimed “baseplate.” (Petition, 29-30). Petitioner alleges that “post 314” portion (Figure 3, annotated dark green) of Orphanos's metaglene 210 and corresponding portion (Figure 10B, annotated dark green) of Orphanos's metaglene1010 “disclose a central post.” (Petition, 31-32). But Petitioner never addresses the claim requirement that the central post is “configured to at least partially pass through the [baseplate] central channel.” As shown above, the alleged posts (dark green) do not pass through any central channel of the alleged baseplate (purple), which Petitioner defines as extending between a “lateral end 312p” and “a medial end 312d” of “baseplate 210.” (Petition, 29-30). Rather, the alleged posts (dark green) extend “outwardly from [the] bottom or distal-facing surface 312d” of the alleged baseplates (purple). (Ex.1006 at 25(7:34-36); Higgs, 24-25(¶42)).

Petitioner also alleges that unthreaded portions (Figures 3 and 10B, annotated light green) of Orphanos's “bone screw 270” and “bone screw 1050” each “disclose a central post.” (Petition, 31-32). Again, Petitioner never addresses the claim requirement that the central post is “configured to at least partially pass

through the central channel.” Further, Petitioner failed to explain how the selectively-highlighted portions of Orphanos’s bone screws 270, 1050 qualify as a “central post” (which Petitioner describes as an “anchoring element”), when that highlighting (light green) **excludes** portions of Orphanos’s screws 270, 1050 that engage and anchor with the glenoid cavity (denoted below in red ovals added by Patent Owner).

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



**Orphanos, Figures 3 and 10B (Petitioner-Annotated) (Petition at 31)
(Further Annotated By Patent Owner)**

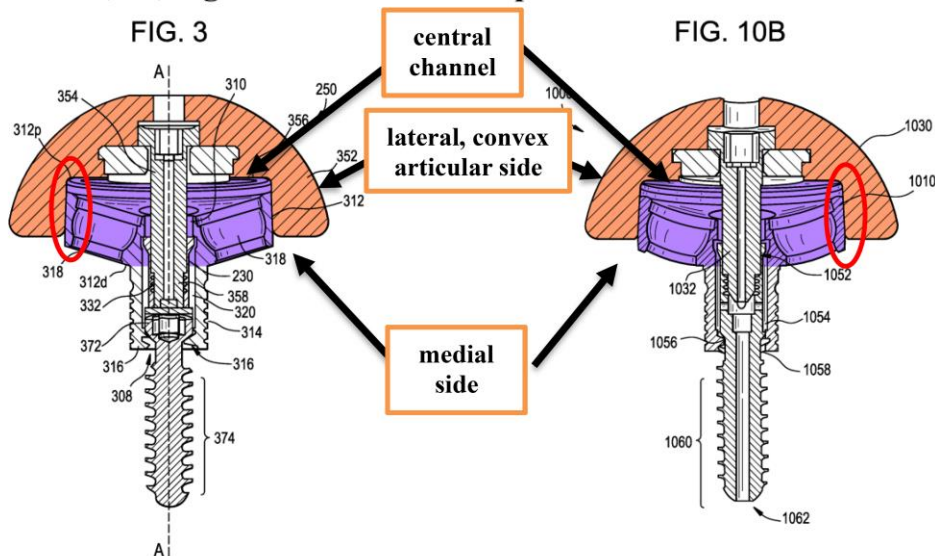
Petitioner’s assertion that the selectively-highlighted portions of Orphanos’s screws 270, 1050 that exclude anchoring structure qualify as a “central post” appears to contradict its position that a “post” is an “anchoring element” used “to anchor the baseplate with the glenoid cavity of the scapula.” (Petition, 7-9).

b. A Glenosphere Having A Glenosphere Central Channel “Extending From The Convex Articular Side To The Medial Side”

Independent claims 1 and 12 (and the challenged dependent claims) each recite a “glenosphere” having “a lateral, convex articular side, a medial side, and a glenosphere central channel extending from the convex articular side to the medial side.” Petitioner alleges Orphanos discloses a “glenosphere,” (Petition, 51-52), 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 51

(Petition, 51-52). While Petitioner summarily states that the annotated central channels extend “from the convex articular side to the medial side,” it provides no support for this assertion, and the annotated figures show otherwise. For example, while the red ovals in the annotated figures may indicate that the identified channels extend to the labeled “medial” sides, they do not show that the central channels extend “from the convex articular side.” See PGR2024-00042, Paper 17 at 37-39 (finding Petitioner’s annotated figures fail to “sufficiently show for purposes of compelling merits” that Orphanos discloses a glenosphere central channel “extending from the convex articular side to the medial side”).

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

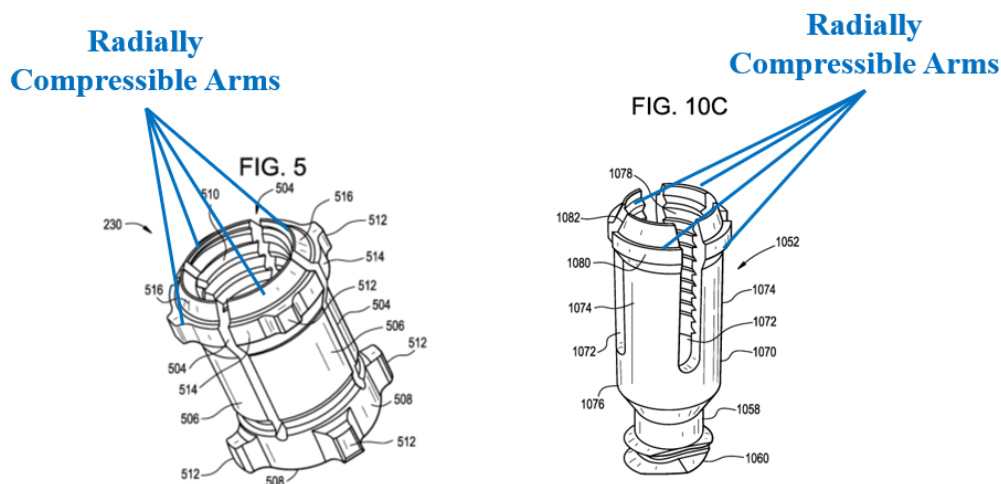
Independent claims 1 and 12 (and the challenged dependent claims) each require a “locking nut” having, among other things, “an external thread on an outside surface,” where the locking nut is “configured to engage the central post when the central post and baseplate are implanted within the medical patient,” wherein the “external thread” is “configured to couple the locking nut with the baseplate central channel” (claim 1) or “configured to engage the baseplate central channel” (claim 12). (Ex.1001 at 30(9:46-53, 10:34-40)). 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, 37).

Neither of these embodiments includes a “locking nut” as claimed. (Higgs, 20-30(¶¶36-50)).

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, 38). 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 couple the locking nut with the baseplate central channel” or “configured to engage the baseplate central channel.”

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, 18:23-45)). 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, 38). 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, 22-23(¶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, 38; 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, 38). 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.”

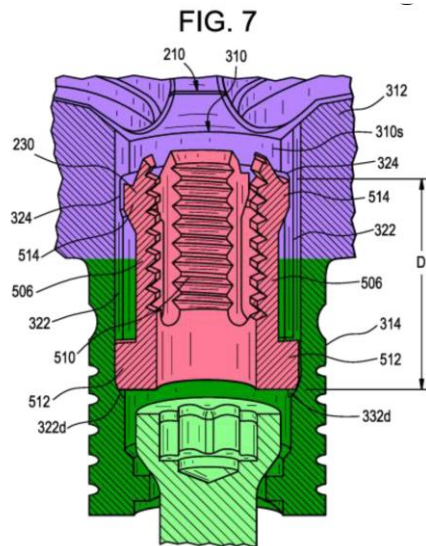
b. “configured to engage the central post when the central post and baseplate are implanted within the medical patient”

(1) Orphanos, First Embodiment

In addition to lacking an external thread, neither of Orphanos's embodiments includes a collet “configured to engage the central post¹⁰ when the central post 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 post (portion of screw 270 highlighted by Petitioner in light green).¹¹

¹⁰ Petitioner failed to address all of the requirements of the claimed “central post,” for the reasons in Section VI.A.1.a., above.

¹¹ While collet 230 appears to contact the post 314 (structure highlighted dark green by Petitioner in Figure 7), post 314 is not a central post “configured to at least partially pass through the central channel” of the alleged baseplate as claimed. (See Section VI.A.1.a., above; Higgs, 24-25, 28-29(¶¶42, 48)).



Orphanos, Figure 7 (Petitioner-Annotated) (Petition at 43)

(Higgs, 24-25(¶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 (or a portion of a bone screw) that is not there. (Higgs, 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, 26(¶44)).

Petitioner's "back driving" theory fails. (Petition, 45-46). The claimed "locking nut" is "configured to engage the central post **when** the central post 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 collet 230 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 post 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 back driving necessarily would be sufficient to result in

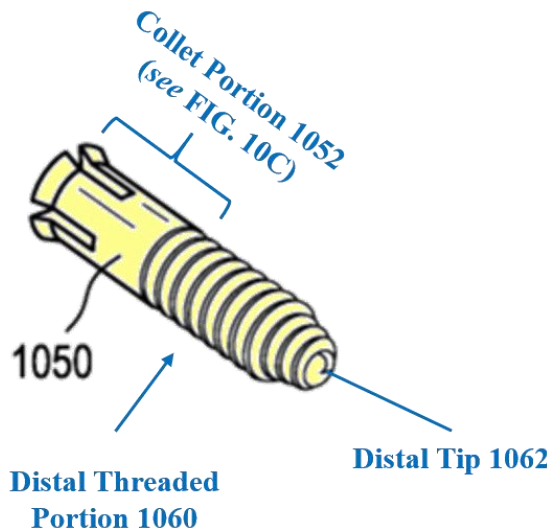
engagement with collet 230. (Petition, 45-46; Higgs, 26(¶45)). Petitioner's reliance on Fallin is misplaced as: (1) Fallin likewise identifies nothing in Orphanos to support Petitioner's allegations; and (2) Fallin's POSITA testimony is irrelevant (*see* Section III., above).

Petitioner's reliance on Roche is likewise misplaced. (Petition, 45-46). Roche does not disclose any general knowledge that compression screws in reverse shoulder implants are necessarily susceptible to back driving. Nor does Roche disclose that compression screws in *Orphanos's implants* are necessarily susceptible to back driving. 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, 26-27(¶46)).

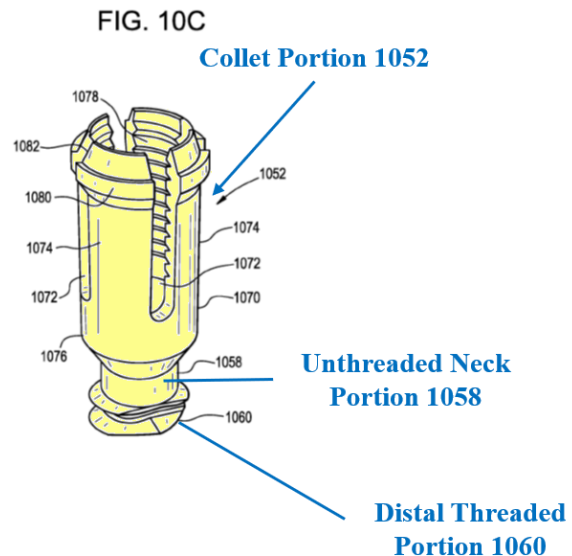
Thus, collet 230 is not a locking nut "configured to engage [a] central post when the central post and baseplate are implanted within the medical patient."

(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, 47-48). 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, 27-28(¶47)). As illustrated above, the unitary bone screw 1050 includes a "collet

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, 29(¶49)).

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, 48). Petitioner's interpretation misreads the claims as reciting a central post **comprising** a locking nut, which is not what the claims say. (Higgs, 29-30(¶50)). Independent claims 1 and 12 recite the “central post” and “locking nut” separately, which creates a “clear implication” that the elements are separate and distinct components. *See Becton*, 616 F.3d at 1262 (“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)); *see also* PGR2024-00042, Paper 17 at 43. This understanding is confirmed by the claim language requiring that the locking nut “engage the central post when the central post and baseplate are implanted within the medical patient,” as well as the specification, which describes the locking nut and central post as separate and distinct structures. (Ex.1001 at 28(6:46-56); *see also id.* at 29(7:1-

13)). Logically, in order to have a collet that engages a central post, the structures that make up the collet must be separate and distinct from the structures that make up the central post. However, the alleged “collet” in Orphanos’s second embodiment is part of the bone screw 1050 itself, including the portions of the screw 1050 that allegedly make up a “central post.” Petitioner’s argument that the collet portion of the unitary screw satisfies the “configured to engage the central post” element of claims 1 and 12 is illogical, as a structure cannot engage itself. (Higgs, 29-30(¶50)).

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

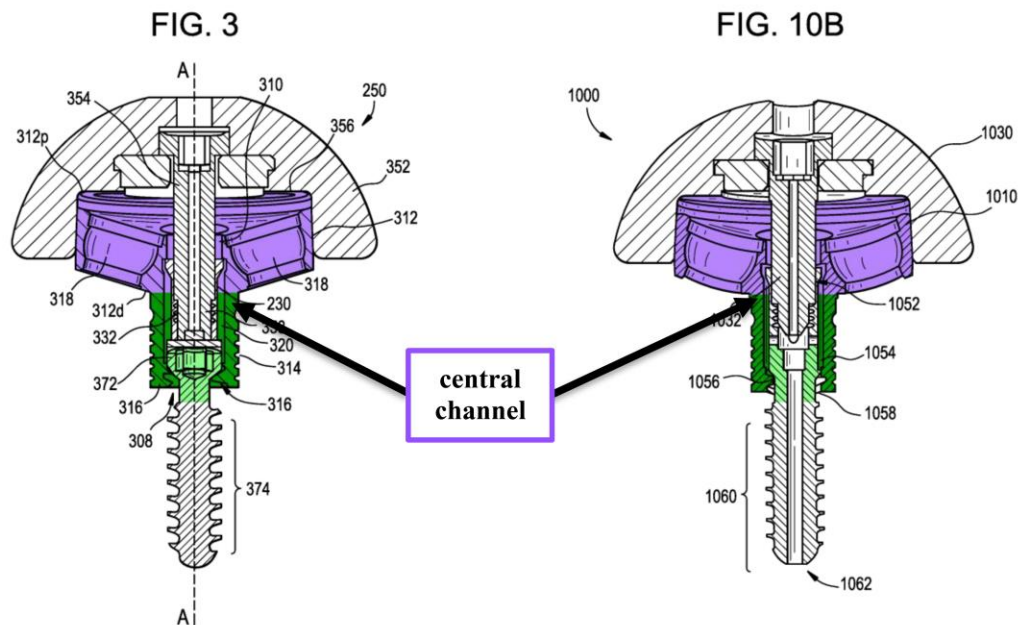
3. **All Challenged Claims: Petitioner Failed To Demonstrate The Challenged Claims Were Obvious**
 - a. **Petitioner Failed To Demonstrate The Proposed Combinations Would Include All The Limitations Of The Challenged Claims**

As explained above in Section VI.A.1., Petitioner failed to address all of the limitations of the challenged claims, including a central post “configured to at least partially pass through the [baseplate] central channel” and a “glenosphere” having “a lateral, convex articular side, a medial side, and a glenosphere 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 these limitations alone and/or in combination with the other limitations.

For example, Petitioner proposes no modifications to Orphanos's "post 314" or the portion of Orphanos's "metaglene 1010" that Petitioner contends is a "central post" (both highlighted by Petitioner below in dark green), even though the identified structures clearly do not pass through any central channel of the alleged baseplate (highlighted by Petitioner below in purple). (See Section VI.A.1.a., above).

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

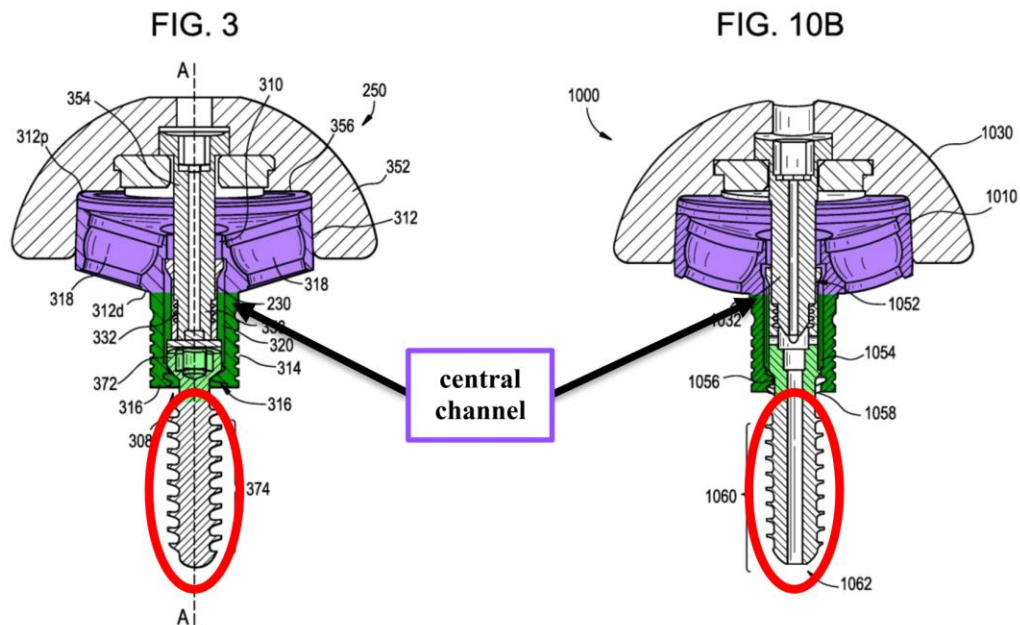


Orphanos, Figures 3 and 10B (Petitioner-Annotated) (Petition at 31)

Nor does Petitioner propose modifying Orphanos's glenosphere to have a central channel "extending from the convex articular side to the medial side." (*Id.*).

Further, Petitioner fails to sufficiently explain what its proposed modifications to Orphanos's screws 270, 1050 **are**, let alone how those modifications would result in a "central post" as claimed. As presently understood, it appears Petitioner is proposing somehow modifying Orphanos's screws 270 and 1050 "**to replace** threaded screw sections of each with a[n] [unthreaded] post," (threaded portions denoted below with red ovals by Patent Owner), while **keeping** the light green highlighted portions. (Petition, 32-33).

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



**Orphanos, Figures 3 and 10B (Petitioner-Annotated) (Petition at 31)
(Further Annotated By Patent Owner)**

Even if such a modification was feasible and a POSITA was motivated to make such a modification (which Petitioner failed to substantiate and Patent Owner does not concede), Petitioner failed to explain how substituting an unthreaded “post” for the threaded portions of Orphanos’ screws 270, 1050 would satisfy the challenged claims. As shown above in annotated Figures 3 and 10B, for example, the alleged “locking nuts” (collets 230, 1052) are positioned **above** the light green-highlighted portions of Orphanos’s screws 270, 1050, whereas the alleged “post” that Petitioner proposes adding would be positioned **below** the light green-highlighted portions of Orphanos’s screws. As a result, in the modified device the collets 230, 1052 would be **spaced apart** from the substituted unthreaded post by the light green-highlighted portions, and would not be “**configured to engage**” the substituted post.

Petitioner has failed to carry its burden in Ground 1 regarding the challenged claims for at least these reasons.

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

Petitioner argues that it would have been obvious to modify Orphanos to include a locking nut and central post 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, 40). The Board previously considered and rejected this same theory in PGR2024-00042. *See* PGR2024-00042, Paper 17 at 32-37.

As in PGR2024-00042, Petitioner argues here that 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 '254 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 inner sidewall 310s) ***with a threaded coupling*** (i.e., a reducing bushing having external threading and internal threading on inner sidewall 310s of central throughbore 310) to couple and/or engage the substituted externally-threaded reducing bushing to baseplate 312 within its central throughbore 310

(Petition, 40); PGR2024-00042, Paper 1 at 40. There are numerous problems with Petitioner’s theory. (Higgs, 30-34(¶¶51-57)).

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 post" **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, 31(¶52)). 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, 39). 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, 31-32(¶53)); *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, 40). 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 42). 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 and internal quotations omitted).

Petitioner's proposal to “include a threaded coupling instead of the snap-fitting coupling” (Petition, 42) is further problematic as it would require substantial redesign and change the principles of operation of the collet/collet portion. (Higgs, 32(¶54)); *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 and internal quotations 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.* at 26(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.* at 26(10:39-56); Higgs, 32(¶54)).

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 32-33(¶55)).

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.¹⁴ (Higgs, 33-34(¶56)).

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

¹⁴ Petitioner's argument that the proposed modification "would not render the device of Orphanos inoperable" does not address the reasons presented here. (Petition, 40).

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.A.2.a., above. (Petition, 38-40). 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.¹⁵ (Petition, 38-41; Section VI.A.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.

At bottom, Petitioner's obviousness theory boils down to "snap-fitting coupling" and "threaded coupling" were both known, which is legally insufficient

¹⁵ Petitioner's assertion that the '254 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, 41-42).

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, 33-34(¶¶56-57)); *see also* PGR2024-00042, Paper 17 at 34-37 (finding Petitioner failed to satisfy burden of showing a POSITA would have been motivated to modify Orphanos to include an external thread)).

(2) A POSITA Would Not Have Been Motivated To Modify Orphanos So That Collet 230 Is “Configured To Engage The Central Post”

Petitioner does not propose any modifications to Orphanos's **second embodiment** to address the lack of both a “central post” and “locking nut” as claimed. (See Section VI.A.2.b., above; Higgs, 38(¶65)). 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 have been motivated to modify the location of an externally threaded reducing bushing to engage the anchoring feature (e.g., a central post), prior to this central post backing out, after being implanted as taught by Roche, as such a modification would provide the well-known benefit of inhibiting central post from backing out. Such a modification would provide immediate contact between the externally threaded reducing bushing and central post (e.g., screw head 602, shoulder portion 604, and cylindrical unthreaded neck portion 606), which would provide enhanced resistance to back out by this central post.

(Petition, 46 (internal citations omitted)). There are numerous problems with this theory. (Higgs, 35-38(¶¶58-64)).

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, 35(¶60)).

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, 46). 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, 35-36(¶61)).

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, 36-37(¶62)). 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, 36-37(¶62)).

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 back driving to be a concern in Orphanos's embodiments. (Higgs, 26, 37(¶¶45, 63)). Even assuming a POSITA was concerned about a central compression screw “backing out” in the first embodiment (they would not be), Petitioner failed 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 back driving. (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, 37-38(¶64)). 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 back driving necessarily occurs (or is capable of occurring) in Roche’s device, let alone in Orphanos’s device.

(3) A POSITA Would Not Have Been Motivated To Modify Orphanos’s Screws To Replace The Threaded Sections With “A Post”

Petitioner argues that it would have been obvious in view of Hopkins and Perego to modify Orphanos’s screws 270, 1050 “to replace the threaded screw sections of each with a post.” (Petition, 32-35). There are numerous problems with Petitioner’s theory.

Petitioner’s theory 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.*, 848 F.3d at 993-94. Petitioner summarily concludes that a POSITA could replace “the threaded sections” of Orphanos’s screws with “a post,” but never actually describes the

structure of the “post” that it believes a POSITA would use, or explains how a POSITA would have modified Orphanos’s screws to include the “post” (whatever Petitioner thinks that structure is). As a result, Patent Owner and the Board are left guessing what specifically Petitioner alleges would have been obvious. *See Trend Micro*, IPR2023-00692, Paper 8 at 28-29.

Petitioner also failed to explain why a POSITA allegedly would have modified Orphanos’s screws 270, 1050 to add a “post” to the unthreaded portions of the screws, particularly when Petitioner alleges the unthreaded portions already qualify as posts. Petitioner provides no support in the Petition for its “hat on a hat” theory—a theory that makes no sense. Even if Petitioner was correct that Perego and Hopkins demonstrate that “screws and posts are readily interchangeable” (which Patent Owner does not concede),¹⁶ that still would not explain Petitioner’s proposal to combine **part** (but not all) of a screw with a generic (but undescribed in the Petition) “post.”¹⁷ Further, Petitioner identifies no benefits or advantages, and

¹⁶ Contrary to the Petition, Hopkins and Perego do not disclose that “posts” and “screws” are “interchangeable,” either generally or in the context of Orphanos’s screws 270, 1050. (Petition, 21, 32).

¹⁷ Petitioner’s assertion that the ’254 Patent “is silent” regarding “advantages provided by incorporating a central post configured to at least partially pass through the central channel” is irrelevant, and does not make up for Petitioner’s failure to identify a motivation to combine. (Petition, 35).

no design needs or market pressures that might provide a requisite motivation. See *Virtek*, 97 F.4th at 886-88. And Petitioner provides no evidence that the proposed modification of eliminating threads from a compression screw would provide the same (or even similar) functionality and advantages that Orphanos's compression screws 270, 1050 provide, or would yield a device operable for Orphanos's intended purpose.

Petitioner's reliance on Fallin is misplaced, as he is not a POSITA. Further, Fallin's declaration merely parrots Petitioner's unsupported and conclusory arguments that fail to satisfy Petitioner's burden. (See Ex.1002 at 44-46 (¶¶90-92)).

B. Ground 2: Challenged Claims 8 And 19 Would Not Have Been Obvious To A POSITA In View Of Orphanos, Hopkins, Perego, Roche, And Gargac

Claims 8 and 19 depend from claims 1 and 12, respectively. (Ex.1001 at 30-31(10:13-17, 11:1-5)). Petitioner failed to demonstrate these claims are obvious, for at least the reasons in Sections VI.A.1.-3., above.

C. Ground 3: Challenged Claims 1-7, 9-18, And 20-22 Would Not Have Been Obvious To A POSITA In View Of Lefebvre, Orphanos, Hopkins, Perego, And Roche

1. All Challenged Claims: Lefebvre Is Not Prior Art

Petitioner's obviousness theory 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 failed 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 Post” And “Locking Nut” As Claimed

Independent claims 1 and 12 (and the challenged dependent claims) each recite a “central post” and, separately, a “locking nut” “configured to engage the central post when the central post and baseplate are implanted within the medical patient” (among other things). (Ex.1001 at 30(9:44-53, 10:32-40)). Lefebvre does not disclose a “central post” and “locking nut” as claimed. (Higgs, 38-45(¶¶67-74)).

Petitioner argues that the “central stud 5” portion of Lefebvre’s “base 2” (illustrated below in Petitioner’s annotated Figure 21 in dark green) is a “central post,” (Petition, 73-74), but fails to explain how stud 5 is “configured to at least partially pass through the [baseplate] central channel” as claimed. As shown below, central stud 5 portion (highlighted by Petition in dark green) of base 2 does not pass through any central channel of the alleged baseplate (“subplate 4” portion (purple) of base 2).

EX-1009 at 11, Figure 21 of Lefebvre

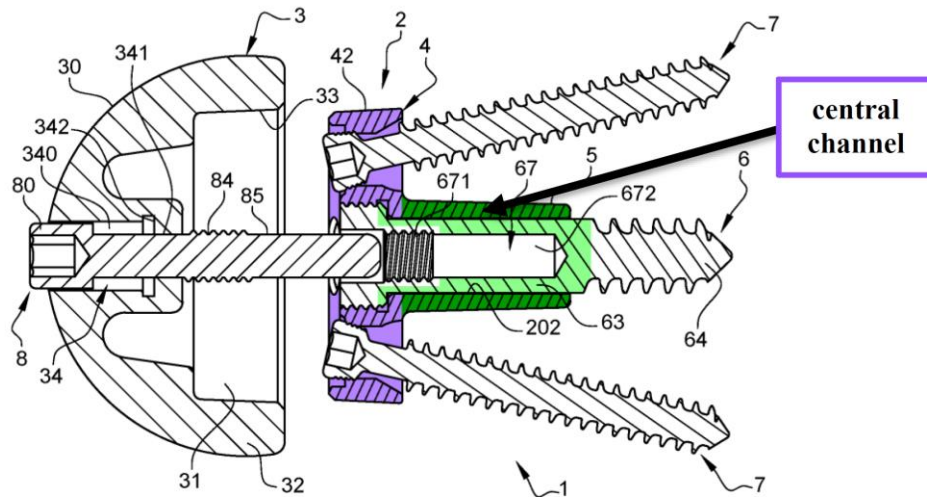
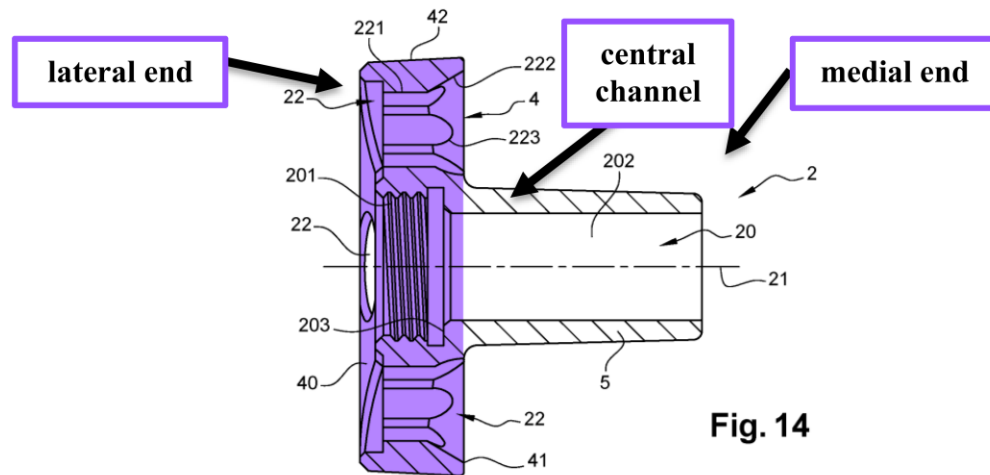


Fig. 21

Lefebvre, Figure 21 (Petitioner-Annotated) (Petition, 73)

Rather, the stud 5 portion (dark green) of base 2 extends outwardly and away from the subplate 4 portion (purple) of base 2. (See Ex.1009 at 15(6:25-26 (“This base 2 is an integral part made of a metallic material . . . [and] comprises a subplate 4 and a central stud 5.”)). As illustrated below in Petitioner’s annotated Figure 14, the alleged “central channel” runs through the stud 5 (and not *vice versa* as claimed).

EX-1009 at 7, 8, Figure 14 of Lefebvre

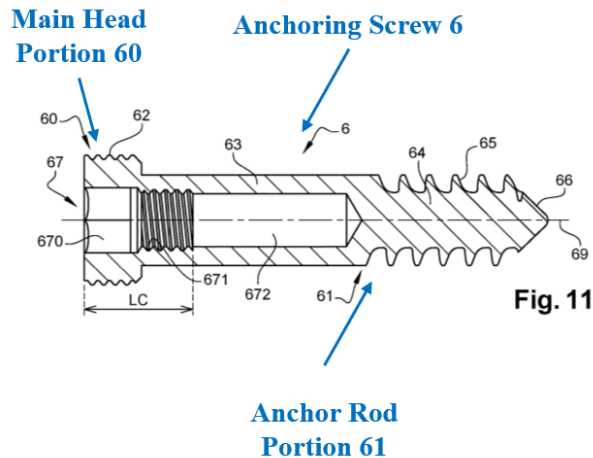


Lefebvre, Figure 14 (Petitioner-Annotated) (Petition, 72)

(See Higgs, 39-40(¶68)).

Petitioner separately argues that “portions of anchor rod 61 of main anchoring screw 6” correspond with the “central post,” and that “main head” portion 60 of anchoring screw 6 corresponds with the “locking nut” element. (Petition, 74, 76-81). 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 monolithic anchoring screw 6 (indicated by uniform cross-hatching in the main and anchor rod portions).¹⁸

¹⁸ 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, 79-80; Higgs, 39-40(¶68)). Petitioner’s argument that “claim 1 does not require a locking nut that is removable or separate from the central post” (Petition, 80) misses the point. (See Section VI.A.2.b.).



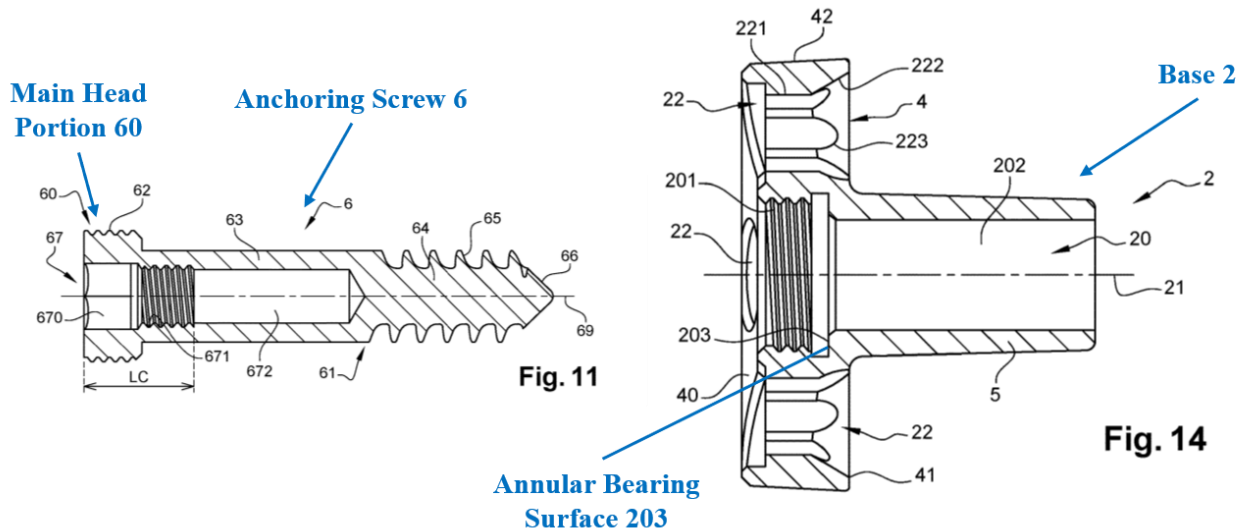
Lefebvre, Figure 11 (Higgs-Annotated)

(See Ex.1009 at 1, 6, 13-14, 16(Abstract, 2:50-54, 2:61-3:13, 7:4-12); Higgs, 39-40(¶68)).

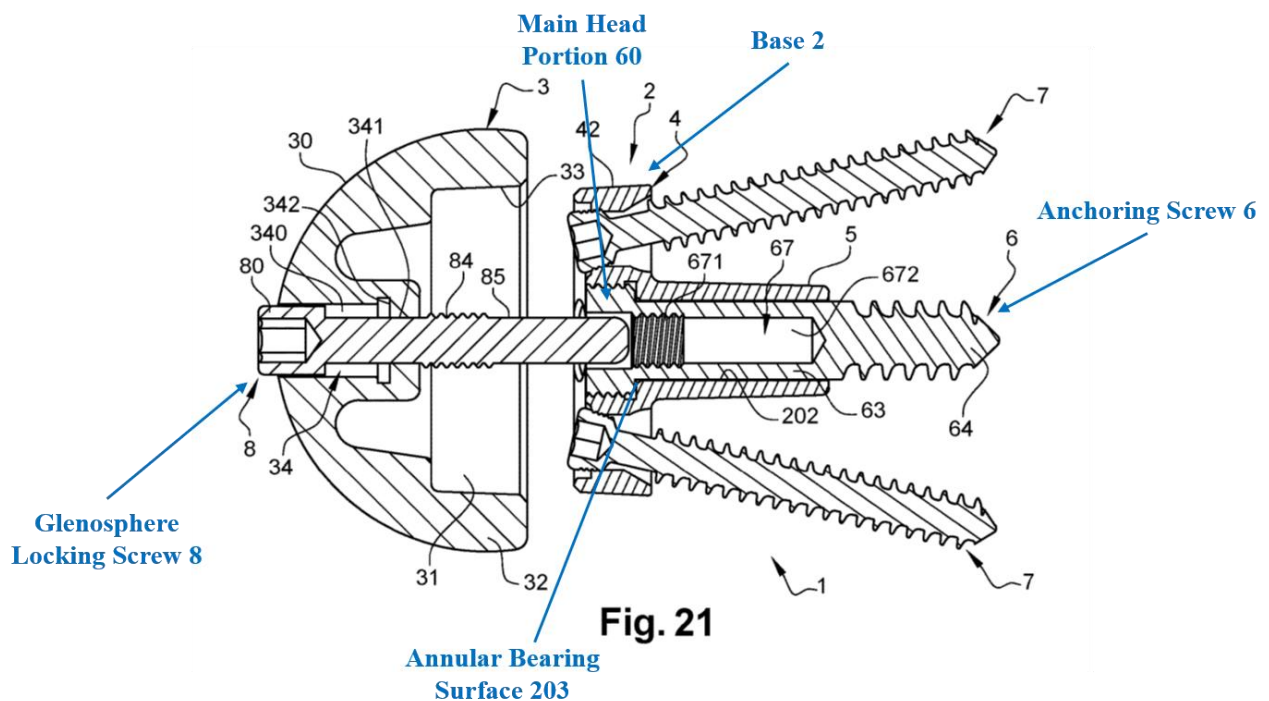
A POSITA would recognize the monolithic nature of the anchoring screw structure as an important aspect of Lefebvre's device. (Higgs, 40-42(¶69)).

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 62” (threading) of the main head 60 and “external tapping 65” of the anchor rod 61 work in tandem, which “improv[es] the anchorage of the external tapping [65] 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, 40-42(¶69)). 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 (including the external tapping 65 of the anchor rod 61 configured to anchor in bone) was essential to the structural integrity of Lefebvre's implant for long-term function of the device in a patient. (Higgs, 44(¶73)).

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, 43(¶71)). 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, 44(¶73)).

Further, the challenged claims recite the "central post" and "locking nut" as separate and distinct elements, including requiring the locking nut "engage the central post when the central post and baseplate are implanted within the medical patient." (See Section VI.A.2.b.); *see also* PGR2024-00042, Paper 17 at 43. Petitioner's theory that the monolithic anchoring screw 6 is both the claimed

“central post” **and** “locking nut” is nonsensical, as a structure cannot engage itself. (Higgs, 43-44(¶72)).

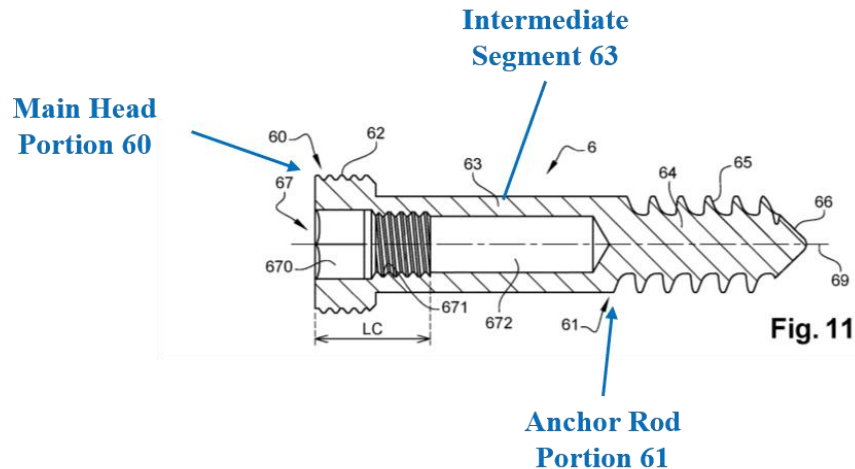
Thus, Lefebvre does not disclose both a “central post” **and** a “locking nut” as claimed. (Higgs, 44-45(¶74)).

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

a. A POSITA Would Not Have Been Motivated To Modify Lefebvre To Have A Central Post And A Locking Nut

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 post.” (Petition, 81-83). There are numerous problems with Petitioner’s theory. (Higgs, 45-51(¶¶75-83)).

Lefebvre’s anchoring screw 6 does not have “components” to separate. Anchoring screw 6 is a monolithic structure, with main head, anchor rod with external tapping 65, and intermediate segment portions 60, 61, 63 that collectively form a screw.



Lefebvre, Fig. 11 (Higgs-Annotated)

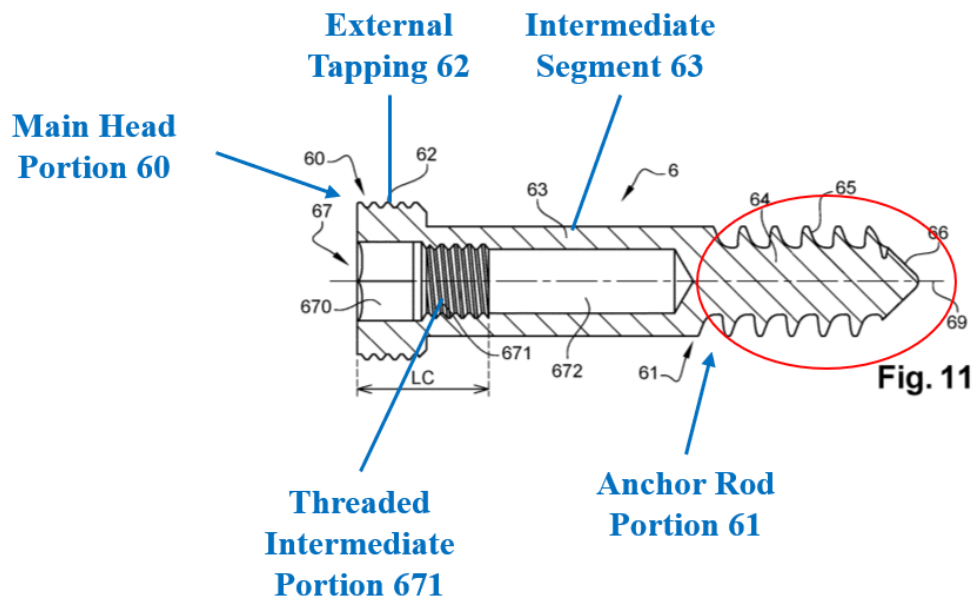
(Ex.1009 at 6; Higgs, 45-46(¶76)). Petitioner's argument that a POSITA would separate portions of the anchoring screw from components "forming the central post" of the anchoring screw makes no sense. Petitioner describes a "post" as an "anchoring element" used "to anchor the baseplate with the glenoid cavity of the scapula." (Petition, 7-9). Without the main head 60 (with external tapping 62) to abut the base 2, there is no anchoring element (and no screw). Similarly, without the anchor rod portion 61 with external tapping 65 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 anchoring element (and no screw). (See Section VI.C.2.; Higgs, 46-47(¶77)).

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, 47(¶78)). 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 (“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 and internal quotations omitted)); *see also* PGR2024-00042, Paper 17 at 46 (finding Petitioner’s argument that it would have been obvious to modify Lefebvre’s anchoring screw “appear[s] to amount to a hindsight manufacturing of Lefebvre to achieve the central screw and locking nut recited in the claims”).

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 with external tapping 65 (illustrated in the red oval).



Lefebvre, Fig. 11 (Higgs-Annotated)

(Ex.1009 at 6; Higgs, 47-48(¶79)). 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, 48-49(¶80)). 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. 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, 48-49(¶80)); 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 have allowed Lefebvre's central post to have a 'free spinning' design." (Petition, 81). 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 Petitioner theorizes a modification could "provide additional compression between the bone and Lefebvre's base 2," (Petition, 81), 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, 49-50(¶81); 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, 49-50(¶81) (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.¹⁹ (Petition, 80-81). 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**,” and

¹⁹ Petitioner’s assertion that “Orphanos teaches how to modify implant 1 of Lefebvre to separate the above referenced components” (Petition, 81) is unsupported and wrong. Petitioner provides no detail of what any of the alleged modifications taught by Orphanos are, how a POSITA would modify the monolithic anchoring screw 6 of Lefebvre into separate components, how such separated components would work in a modified device (assuming they even could), or how the modifications would result in a “locking nut” and “central post,” with the locking nut “configured to engage the central post,” as claimed.

explains it may “**be omitted** from the implant” (see Section VI.A.3.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.” (Ex.1006 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.²⁰ (Higgs, 51(¶83)).

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

²⁰ Petitioner’s reliance on MPEP 2144.04(V)(C) and *In re Dulberg*, 289 F.2d 522 (C.C.P.A. 1961) 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; see also PGR2024-00042, Paper 17 at 47 n.14 (describing as “misplaced” Petitioner’s reliance on *In re Dulberg* to “modify[] Lefebvre’s single screw into two distinct parts”).

first embodiment and optional spinning screw. Petitioner's suggestion that a POSITA would instead attempt to redesign and reconstruct Lefebvre, just so it 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. *See GCE Gas*, IPR2023-00326, Paper 27 at 53.

Petitioner's theory is not based on any knowledge or motivation of a POSITA. (Higgs, 51(¶84)).

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 post." (Petition, 81-83). 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 post,” let alone a locking nut “configured to engage the central post” as claimed.²¹ (*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.

b. A POSITA Would Not Have Been Motivated To Modify Lefebvre's Anchoring Screw To Replace External Tapping 65 With “A Post”

Petitioner separately argues that it would have been obvious in view of Hopkins and Perego to modify Lefebvre's anchoring screw 6 “to replace external tapping 65 with a post (i.e., no external tapping 65).” (Petition, 75). There are numerous problems with Petitioner's theory.

Petitioner's theory 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 summarily concludes that a POSITA could replace external tapping 65 of Lefebvre's anchoring screw 6 with a post having “no external tapping 65,” but never actually describes the structure of the “post” that it believes a POSITA

²¹ Petitioner's characterization of Roche (Petition, 71) is incorrect, for the reasons in Section VI.A.2.b., above.

would use, or explains how a POSITA would have modified Orphanos's screws to include the "post" (whatever Petitioner thinks that structure is). As a result, Patent Owner and the Board are left guessing what specifically Petitioner alleges would have been obvious. *See Trend Micro*, IPR2023-00692, Paper 8 at 28-29.

Petitioner also failed to explain why a POSITA allegedly would have modified Lefebvre's monolithic screw 6 to replace external tapping 65 with a "post," particularly when Petitioner alleges the unthreaded portions of screw 6 already qualify as a post. Petitioner provides no support in the Petition for its "hat on a hat" theory – a theory that makes no sense. Even if Petitioner was correct that Perego and Hopkins demonstrate that "screws and posts are readily interchangeable" (which Patent Owner does not concede),²² that still would not explain Petitioner's proposal to combine *part* (but not all) of a screw with a generic (but undescribed in the Petition) "post."

Further, Petitioner identifies no benefits or advantages, and no design needs or market pressures that might provide a requisite motivation. *See Virtek*, 97 F.4th at 886-88. And Petitioner provides no evidence that the proposed modification would provide the same (or even similar) functionality and advantages that

²² Contrary to the Petition, Hopkins and Perego do not disclose that "posts" and "screws" are "interchangeable," either generally or in the context of Orphanos's screws 270, 1050. (Petition, 21-22, 32, 75).

Lefebvre's screw 6 already provides, or would yield a device operable for Lefebvre's intended purpose. To the contrary, Lefebvre describes the disclosed screw 6 as a "remarkable" aspect of the design. (See Section VI.C.2., above; Higgs, 52-53(¶86)). Lefebvre explains that the external tapping 65 of the anchor rod portion 61 is "adapted for hooking in cancellous bone," and works in tandem with other portions of the screw to "provide[] enhanced mechanical strength in comparison with the prior art." (Ex.1009 at 14, 16(4:14-23, 7:39-44)). Petitioner's proposal to remove the external tapping 65 would destroy these aspects of Lefebvre's "remarkable" design, rendering the modified screw 6 inoperable for its intended purposes. (Higgs, 52-53(¶86)).

Petitioner's proposal also undermines its rationale described above in Section VI.C.3.a. for "separat[ing] the components of Lefebvre's main anchoring screw 6" into pieces. (See Petition, 80-83). Petitioner argues a POSITA would have been motivated to separate components of Lefebvre's anchoring screw 6 based on an alleged desire to make a "bone screw" a "free spinning design," and to "provide additional compression between the bone and . . . [the] baseplate." (Petition, 80). Petitioner then argues that this same person would have been motivated to modify anchoring screw 6 to remove the external tapping 65 that spins and hooks into bone, **rendering it no longer a bone screw**. A POSITA would recognize that removing the external tapping 65 would **reduce if not**

eliminate the ability of the modified screw 6 to provide compression between the bone and the baseplate. (Higgs, 53(¶87)). Petitioner's rationales are contradictory, and further confirm that Petitioner's obviousness theory is based on a hindsight desire to invalidate the challenged claims, rather than any knowledge or motivation of a POSITA.

Petitioner's reliance on Fallin is misplaced, as he is not a POSITA. (See Section III., above). Further, Fallin's declaration merely parrots Petitioner's unsupported and conclusory arguments that fail to satisfy Petitioner's burden. (See Ex.1002 at 83-85 (¶¶172-175)).

D. Ground 4: Challenged Claims 8 And 19 Would Not Have Been Obvious To A POSITA In View Of Lefebvre, Orphanos, Hopkins, Perego, Roche, And Gargac

Petitioner failed to demonstrate claims 8 and 19 are obvious, for at least the reasons in Sections VI.C.1.-3., above.

E. Ground 5: Challenged Claims 1-22 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 Instruments, 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.

Petitioner's argument that the “baseplate central channel” renders the challenged claims indefinite lacks merit. *See* PGR2024-00042, Paper 17 at 49-51. Contrary to the Petition, a POSITA would understand the scope of the challenged claims with reasonable certainty. (Higgs, 53-54(¶¶89-91)). 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, 97; Higgs, 54(¶90)). Petitioner further acknowledges that the specification supports this ordinary meaning. (Petition, 98 (explaining the specification describes channel as connoting both “passageway” and “physical structure”); *see also* Ex.1001, *e.g.*, at 27-28(4:39-40, 5:15-18, 6:36-44)). 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, 54(¶91)). 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 1350-51 (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 (*e.g.*, Petition, 38-39 (describing "**sidewall** 310s of central throughbore 310"), 45 ("locking nut 230 engages an **inner surface** of throughbore 320")) as well as space (*e.g.*, *id.* at 32 (explaining central screw 270 passes "**through**" throughbore 310)). (*See also id.* at 9 (describing "through-holes" to "receive an anchoring element" (space) and having "internal threading" (physical structure))). 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 at 49, 52(¶¶97, 101)). Fallin (like Petitioner) concedes that central channel connotes "both an empty space . . . and a physical structure," and has no trouble describing channels or "through holes" both in terms of space ("dimensioned to receive an anchoring element") and structure ("have internal threading"). (*Id.* at 22, 110(¶¶48, 241)). His opinion that this, by itself, renders the claims indefinite is factually and legally unsupported.²³ (*Id.* (asserting the claims are "impermissible" and indefinite "because" they claim both structure and space)).

At bottom, Petitioner "refutes" its own argument that a POSITA would have been unable to discern the scope of "central channel" with reasonable certainty, and otherwise fails to explain why a skilled artisan "could not have reasonably discerned the claimed 'central channel' of the baseplate to encompass" both space and physical structure. See PGR2024-00042, Paper 17 at 51. Petitioner's

²³ Fallin's opinions are premised on a legally erroneous presumption that the challenged claims are "unpatentable **unless**" Patent Owner demonstrates otherwise. (Ex.1002 at 16(¶26)).

argument that the challenged claims are unpatentable under § 112 lacks merit. *Id.* at 49-51 (finding Petitioner's argument that a "central channel" cannot connote both space and structure "conclusory," "[un]compelling," and "[non]meritorious"). Ground 5 should be rejected.

F. Ground 6: Challenged Claims 1-22 Are Not Indefinite ("Central Channel . . . Configured To Interface With The Baseplate")

Petitioner's argument that the phrase "central channel . . . configured to interface with the baseplate" renders the challenged claims indefinite likewise lacks merit. *See* PGR2024-00042, Paper 17 at 51-53. Contrary to the Petition, a POSITA would understand the scope of the challenged claims with reasonable certainty. (Higgs, 54-56(¶¶92-95)).

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, 55-56(¶¶94-95)).

Petitioner's indefiniteness argument incorrectly assumes the claims recite a ***central channel*** "configured to interface with the baseplate." (Petition, 100). The challenged claims recite "***a glenosphere***, having a lateral, convex articular side, a medial side, and a glenosphere central channel extending from the convex articular

side to the medial side and ***configured to interface with the baseplate.***” (Ex.1001 at 30(9:54-57, 10:42-45)). It is the “glenosphere”—and not necessarily the “central channel” of the glenosphere—that is “configured to interface” as claimed. (Higgs, 55(¶93)). This is consistent with Petitioner’s application of the claim in the obviousness grounds. (See, e.g., Petition, 52 (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, 100-102). But a claim is not indefinite merely because it includes an alleged ambiguity, or may be susceptible to different interpretations. See PGR2024-00042, Paper 17 at 52-53 (“That ‘to interface’ may have multiple definitions providing varying claim scope raises an issue of breadth and interpretation of the claim, rather than indefiniteness.”). 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 differing constructions” indefiniteness standard). Petitioner failed 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, 99-102). The word “channel” ordinarily connotes both space and structure, and there is nothing in the claims or specification to the contrary. (Higgs, 53-56(¶¶89-91, 93-95)). Further, Petitioner concedes the specification describes certain “physical features” of a glenosphere central channel. (Petition, 100). Petitioner’s suggestion that the claimed central channel somehow excludes these physical features is unsupported,

and improperly excludes preferred embodiments of the '254 Patent.²⁴ *Vitronics Corp. v. Conceptronic, Inc.*, 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”).

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, 101). 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

²⁴ 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).

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** (Petition, 99), when it came time to apply the claims to Orphanos Petitioner relied on **structure**, stating for example that “**inner surfaces** of [Orphanos’s] glenosphere 250 **define a central channel**.” (*Id.* at 52). Petitioner’s reliance on Fallin is misplaced, for the reasons explained above. (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 at 62-63(¶¶121-122)).

Petitioner’s argument that the challenged claims are unpatentable under § 112 lacks merit. *See* PGR2024-00042, Paper 17 at 51-53 (finding Petitioner’s indefiniteness challenge regarding glenosphere central channel “[un]compelling” and “[non]meritorious”). Ground 6 should be rejected.

VII. CONCLUSION

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

Dated: January 30, 2025

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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 14,918 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 January 30, 2025
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