

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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Catalyst Orthoscience Inc.,

Petitioner

v.

Shoulder Innovations, Inc.,

Patent Owner

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Case No.: PGR2024-00042

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

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**DECLARATION OF GEOFFREY HIGGS, M.D.**

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## **I. INTRODUCTION**

1. My name is Geoffrey Bessom Higgs. I have been retained by Patent Owner, Shoulder Innovations, Inc., to investigate and opine on certain issues relating to U.S. Patent No. 11,771,561 (“the ’561 Patent”).

2. I understand that Petitioner, Catalyst Orthoscience Inc., has challenged the patentability of claims 1-16 of the ’561 Patent in the U.S. Patent Office by way of a petition seeking to institute a Post Grant Review (the “Petition”). I have been asked to review the Petition and supporting documents filed with the Petition. I have been asked to provide a response to certain technical issues raised in the Petition, from the perspective of a person of ordinary skill in the art of the ’561 Patent (“POSITA”).

## **II. QUALIFICATIONS AND EXPERIENCE**

### **A. Education and Work Experience**

3. I am a medical doctor and orthopaedic surgeon and have practiced medicine in the field of orthopedics for approximately 30 years. A copy of my curriculum vitae and a full list of publications authored or co-authored by me is provided in Exhibit 2006.

4. I received my undergraduate degree from the University of Virginia School of Engineering and Applied Science, a Bachelor of Science in Systems Engineering in 1983. I spent a year working as a systems engineer for the Mitre Corporation prior to attending medical school.

5. In 1984, I began work on my medical degree. I spent my first year of medical school at the University of Virginia School of Medicine. I then transferred to Columbia University College of Physicians and Surgeons. I received my Medical Doctorate from Columbia University in 1988.

6. After completing medical school, I was accepted into the six-year Academic track Orthopaedic Surgery Residency program at Columbia University Medical Center. The program was designed to train academically oriented orthopaedic surgeons. My medical training began at Columbia University Medical Center where I completed my General Surgery Internship in the Columbia University Department of General Surgery in 1989. I began my planned year of Fellowship in Orthopaedic Surgery Research at the Department of Orthopaedic Surgery at the University of California San Diego, which I completed in 1990.

7. I returned to Columbia University and completed my Orthopaedic Surgery Residency in 1994 in the Department of Orthopaedic Surgery at Columbia University. My final year of residency I was elected Chief Resident by the faculty. I received several awards while at Columbia University including: The Frank E. Stinchfield Award for Excellence in Orthopaedic Surgery awarded to the member of the resident staff who has demonstrated special qualities of research excellence in the treatment of musculoskeletal disease; The Orren D. Baab Award for Excellence in Orthopaedic Surgery, “Presented to the member of the senior

resident staff who best exemplifies those qualities of academic excellence, clinical proficiency and capacity for leadership throughout the residency training period”; Columbia University-Resident Clinical Research Award; Best Resident Research Award, Pediatric Orthopaedic Society of New York and Finalist, Best Resident Research, New York Academy of Medicine.

8. During my residency in the early 1990s I was also introduced to the subspecialty field of Orthopaedic Sports Medicine as I served as the Chief of Physicians for Yankee Stadium, home to the New York Yankees, and Madison Square Garden, home to the New York Knicks and the New York Rangers. I conducted multiple research projects during my orthopaedic residency and presented at multiple national medical specialty society meetings.

9. I served as a Major in the United States Army to fulfill an active duty service obligation for a full academic scholarship to Columbia University College of Physicians and Surgeons between the years 1985 and 1988. I served as Chief or Assistant Chief of Orthopaedic Surgery at the 121 General Hospital in Seoul, South Korea, the Heidelberg MEDDAC in Heidelberg, Germany, and the 67th Combat Support Hospital in Taszar, Hungary. I also served as the Head team physician for the All World Tae Kwon Do team. Also during this time period, I did a European traveling shoulder fellowship. I also received multiple awards while serving in the United States Army including the Meritorious Service Medal,

Army Commendation Medal, two Overseas Service Medals, Armed Forces Service Medal, Army Service Medal and the Military Service Medal.

10. In 1998 and 1999 I completed my Fellowship in Orthopaedic Sports Medicine & Shoulder Surgery at Harvard University. During my Fellowship I served as a team physician for the Harvard University athletic teams, the New England Patriots NFL team, the Boston Bruins NHL team, and the New England Revolution MLS team.

11. I joined Advanced Orthopaedic Centers in 2000 as the Co-Director for the Sports Medicine and Shoulder Centers. I left in June 2016, as the practice was dissolved and merged into a much larger practice. During that time, I built a busy Orthopaedic Sports Medicine practice including extensive work on shoulders and knees. I have also had a clinical appointment at the Medical College of Virginia/Virginia Commonwealth University throughout the 16 year period. During this time, I served as the team physician for several professional athletic teams including the Washington Redskins NFL team training camp, Richmond Raiders professional Arena Football team, Revolution professional Arena Football team, Richmond Speed professional Arena Football team, Richmond Bandits professional Arena Football team, and the Richmond Rhythm professional IBL basketball team.

12. For those 16 years, I volunteered several hundred hours per year as the Team Physician taking care of two underserved community high school athletic programs, Henrico High School and Highland Springs High School. Additionally, I volunteer my time as a Team Physician at Glenn Allen High School, The Steward School, the Richmond Lions Rugby Club, and the Men's and Women's James River Rugby Clubs.

13. I Co-Directed an International Sports Medicine and Arthroplasty Fellowship for 7 years training dozens of international Orthopaedic Surgeons per year in the field of Orthopaedic Sports Medicine, Shoulder Surgery, Knee Surgery and Orthopaedic Research. Throughout my 16 years in Richmond I was involved in many other professional activities and my CV provides more details. In 2017, I accepted a position as the Director of Orthopedic Surgery in Sports Medicine at Lumen Health in Plano, TX. After working for Lumen Health, I transitioned to working full time as a consultant orthopaedic surgeon for Optum Inc., Dand Street, and MES Solutions until August of 2023 at which time I returned to full time clinic medicine serving as a Sports Medicine and Shoulder Surgery specialist in Orthopaedic Surgery working for Prosser Memorial Hospital in Prosser, Washington.

14. In September of 2022, I returned to United States military service and accepted a commission in the United States Army Reserve as a Lieutenant Colonel serving in the capacity of an Orthopaedic Surgeon.

15. Throughout my career as an Orthopaedic Surgeon I have performed on average 700 shoulder and knee surgeries per year. By the 2000 timeframe, I had performed approximately 5,000 shoulder replacement surgeries in patients. I have had teaching appointments at Harvard University, Columbia University, University of California San Diego and Virginia Commonwealth University where I have been active in educating orthopaedic surgery residents and fellows in the art and science of Orthopaedic Surgery, Shoulder Surgery, and Sports Medicine. I have been intermittently active in basic science and clinical research. I have presented my research at multiple national and international medical professional society meetings within my field of expertise, orthopaedic surgery and orthopaedic sports medicine, shoulder and knee surgery. I continue to be active in both basic science research and clinical research with several ongoing current projects. I have consulted for several major orthopaedic device companies assisting in orthopaedic device design, testing and clinical application. I am a member and fellow of multiple national and international orthopaedic surgery and sports medicine specialty and subspecialty societies. I am American Board of Orthopaedic Surgery

Board Certified in Orthopaedic Surgery and Subspecialty American Board of Orthopaedic Surgery Board Certified in Orthopaedic Sports Medicine.

**B. Engagement**

16. I am being compensated \$700 per hour for services I provide in this case. This compensation is not contingent on the substance of my opinions or the outcome of any post grant review proceeding or any other proceeding.

**III. STATEMENT OF LEGAL PRINCIPLES**

17. I am a technical expert and do not offer any legal opinions. I applied the legal framework outlined below in rendering the opinions reflected in this declaration.

**A. Level Of Ordinary Skill in the Art**

18. I understand that a person of ordinary skill in the art (“POSITA”) is a hypothetical person who is presumed to know the relevant prior art. I have been advised that factors that guide the determination of the level of ordinary skill in the art may include: (1) types of problems encountered in the art; (2) prior art solutions to those problems; (3) sophistication of the technology; (4) rapidity with which innovations are made; and (5) educational level of active workers in the field.

**B. Claim Construction**

19. I understand that in a post grant review proceeding, the claims are to be given their ordinary meaning in the context of the specification and prosecution history, as understood by a person of ordinary skill in the art.

### **C. Obviousness**

20. I understand that a claim of a patent may be found unpatentable for a number of reasons, including, for example, if it recites subject matter that is not new or that would have been obvious to a POSITA.

21. I understand that a claim is not new if all of the elements of the claim are present in a single prior art printed publication or patent. In these cases, I understand that the claim is said to be “anticipated.” I understand that to anticipate a claim, the prior art does not have to use the same words as the claim, but all of the requirements of the claim must have been disclosed, either expressly or implied to a POSITA in the technology of the invention.

22. I also understand that, even though every element of a claim is not shown in a single piece of prior art, the claim may still be unpatentable if it would have been obvious to a POSITA at the time of the invention. In determining whether a claimed invention is obvious, I understand that a number of factors must be considered, including the level of ordinary skill in the art at the time the invention was made, the scope and content of the prior art, and any differences between the prior art and the claimed invention. I also understand that obviousness is not necessarily proved simply by showing the existence of each and every element of the claimed invention in the prior art. I understand that I should also consider whether there were reasons that would have prompted a POSITA to

combine the known elements in a way the claimed invention does, including:

- common sense;
- combining prior art elements according to known methods to yield predictable results;
- simple substitution of one element for another to obtain predictable results;
- use of a known technique to improve similar devices, methods, or products in the same way;
- applying a known technique to a known device, method, or product ready for improvement to yield predictable results;
- choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success, such that it is obvious to try;
- known work in one field of endeavor prompting variations for use in the same field or a different one based on design incentives or other market forces and the variations are predictable to one of ordinary skill in the art;
- some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

I am also advised that the prior art must provide a reasonable expectation of success. In addition, I understand that the use of hindsight is improper, and that only what was known at the time of the invention can be considered.

23. In addition, I also understand that objective evidence, or “secondary considerations,” that existed at the time of the invention and afterwards may shed light on the non-obviousness or obviousness of the claimed invention, and should

be taken into account. These considerations include, for example:

- whether products incorporating the claimed invention have been commercially successful and, if so, whether the commercial success can be attributed to the claimed invention;
- whether the invention satisfied a long-felt, unmet need;
- whether others had tried and failed to make the invention;
- whether others copied the invention;
- whether the invention achieved unexpected results;
- whether others in the field praised the invention;
- whether persons having ordinary skill in the art in the technology of the invention expressed surprise or disbelief regarding the invention; and
- whether the inventor proceeded contrary to the accepted wisdom in the field.

I also understand that, in order to be relevant to the issue of obviousness, any such secondary consideration must have some connection (or nexus) to the claimed invention.

#### **D. Indefiniteness**

24. I understand that a claim is indefinite if it fails to inform those skilled in the art about the scope of the invention with reasonable certainty. I understand that a claim term is not indefinite merely because it may be susceptible to different interpretations. I understand that indefiniteness is a matter of claim construction.

#### **IV. OVERVIEW OF THE '561 PATENT**

##### **A. Reverse Shoulder Replacement Systems**

25. The '561 Patent is directed to reverse ball-and-socket shoulder replacement systems. In contrast with “anatomic” shoulder replacement systems that attempt to recreate articulating surfaces “substantially the same shape as the natural anatomy,” (*i.e.*, with a ball on the humeral bone of the arm and the socket on the glenoid fossa of the scapula (shoulder blade)), reverse shoulder systems reverse the articular surfaces so that the ball is on the glenoid fossa and the socket is on the humeral bone. (Ex.1001 at 26 (1:14-37)). Although both types of systems are used today, reverse shoulder replacement systems are sometimes preferred in certain clinical situations, for example in rotator cuff arthropathy (a procedure for which reverse shoulder procedures were originally developed). (*Id.* (1:38-55)).

26. The claims of the '561 Patent recite reverse shoulder implants comprising a combination of components used to replace the glenoid articulating surface. These components include a “baseplate,” “central screw,” “locking nut,” “glenosphere,” and “glenosphere screw.” Figure 8 (reproduced and annotated below) illustrates an example of a “fully assembled” implant including each of these claimed components combined.

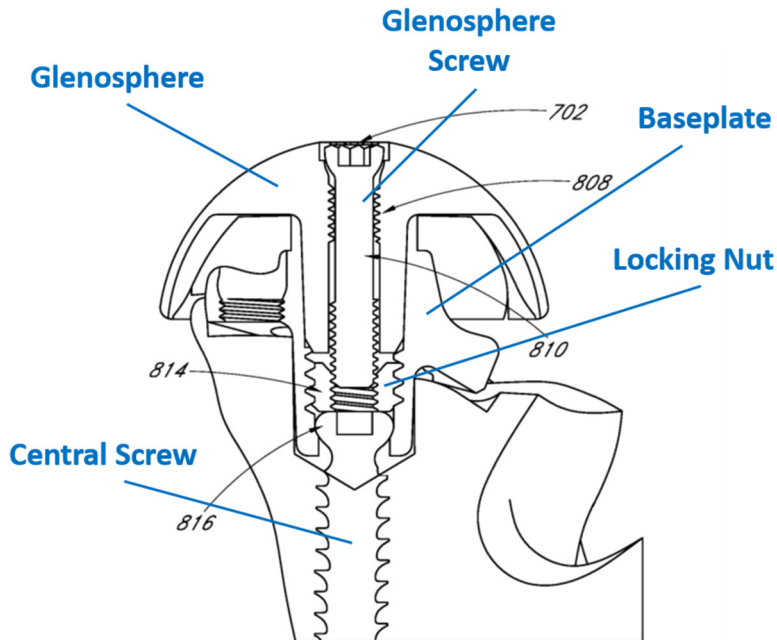


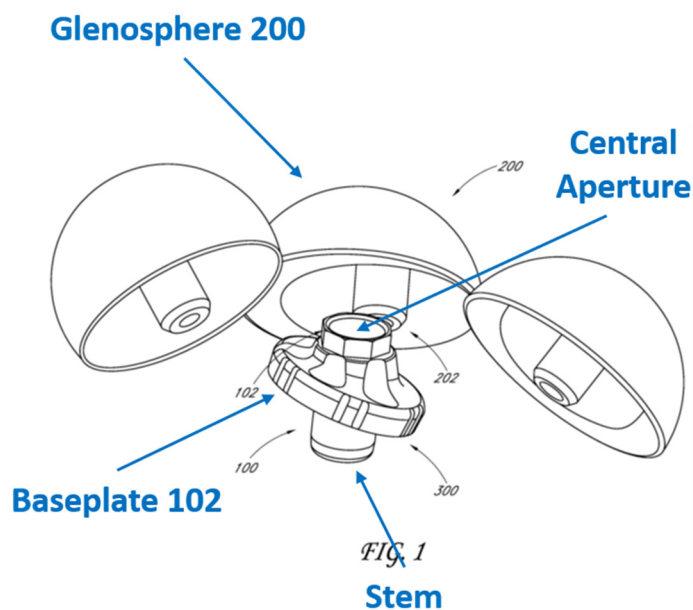
*FIG. 8*  
**'561 Patent, Figure 8 (Annotated)**

(Ex.1001 at 12, 26 (2:61-63), 30 (claims 1-16)).

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

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

defining a surface of . . . an elongate stem” (a central channel).



### '561 Patent, Figure 1 (Annotated)

(*Id.* at 5, 26-27 (2:45-46, 3:37-55); *see also id.* at 9, 28 (5:3-51) (describing a “glenoid baseplate” with a “central channel” extending therethrough); *id.* at 11, 28 (5:66-6:31) (describing glenospheres)).

29. Figure 6 (reproduced and annotated below) illustrates “a threaded locking insert 600” (locking nut) “configured to go into the central channel of a baseplate” and including “outer male thread 602” and an inner “female thread 608 configured to receive a supplemental glenosphere locking screw.”

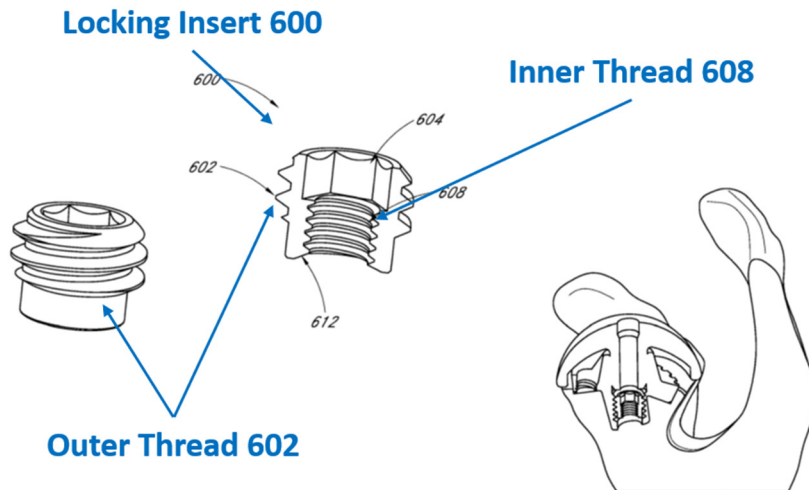


FIG. 6

### '561 Patent, Figure 6 (Annotated)

(*Id.* at 10, 28 (5:52-65)).

#### B. Level Of Skill In The Art

30. I understand that the Petitioner contends that the level of skill of a POSITA in the context of the '561 Patent 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 at 15-16; Ex.1002 at 30-31 (¶ 64)).

31. In my opinion, Petitioner’s definition excludes (or at least fails to recognize) other persons having ordinary skill in the art and, in particular, those who had qualifying technical and medical clinical experience with respect to the types of devices described in the '561 Patent. In my opinion, a POSITA in the context of the '561 Patent would include a medical doctor with an engineering

degree and at least 3 years of experience performing total joint arthroplasty in medical patients. My opinion is consistent with Petitioner's observation that the '561 Patent presents "unique or more complex challenges" due to the fact that the claimed devices "are designed to be implemented in a *medical context* and interact inside a *medical patient*," that a POSITA must have "an appreciation and understanding of the often unique or more complex challenges involved when implementing mechanical devices *inside a medical patient*," and that this person must "possess the technical education and experience necessary to address those challenges." (Petition at 16-17 (emphases added)).

32. Unless otherwise noted, my opinions in this Declaration are made from the perspective of a POSITA in the 2019-2020 timeframe. I qualified as a person having at least ordinary skill in the art in that timeframe. As summarized above and in my CV (Exhibit 2006), I received a Bachelor of Science in Engineering in 1983, and a Doctorate of Medicine from Columbia University College of Physicians and Surgeons in 1988. By the 2009-2020 I had consulted for several major orthopaedic device companies assisting in orthopaedic device design, testing, and clinical application. I had approximately 30 years experience with joint replacement system designs, including hands-on experience evaluating and implanting numerous shoulder implant designs. By that time, I had performed approximately 5,000 shoulder replacement surgeries in patients, including

implanting anatomical and reverse shoulder replacement systems, such as the types described in the background of the '561 Patent.

## **V. CLAIM CONSTRUCTION**

33. I understand that Petitioners do not propose any special constructions for the claims. (Petition at 3-4). In arriving at my opinions, I have given the claim terms their plain and ordinary meaning as a POSITA would have understood those terms.

## **VI. REFERENCES COMBINED IN ASSERTED GROUNDS 1-4**

34. I understand that Petitioner alleges in Grounds 1-4 that claims 1-16 of the '561 Patent would have been obvious in view of the following combinations of references:

- **Ground 1**: Claims 1, 3-9, and 11-16 in view of U.S. 10,813,769 ("Orphanos," Ex.1006) and U.S. 9,233,003 ("Roche," Ex.1007)
- **Ground 2**: Claims 2 and 10 in view of Orphanos, Roche, and U.S. 2022/0125594 ("Frankle," Ex.1008)
- **Ground 3**: Claims 1, 3-9, 11-16 in view of U.S. 11,439,513 ("Lefebvre," Ex.1009), Orphanos, and Roche
- **Ground 4**: Claims 2 and 10 in view of Lefebvre, Orphanos, Roche, and Frankle

35. Orphanos, Roche, Frankle, and Lefebvre are described below in the analysis of the grounds.

## VII. ANALYSIS OF THE GROUNDS OF THE PETITION

### A. Ground 1: Claims 1, 3-9, And 11-16 In View Of Orphanos And Roche

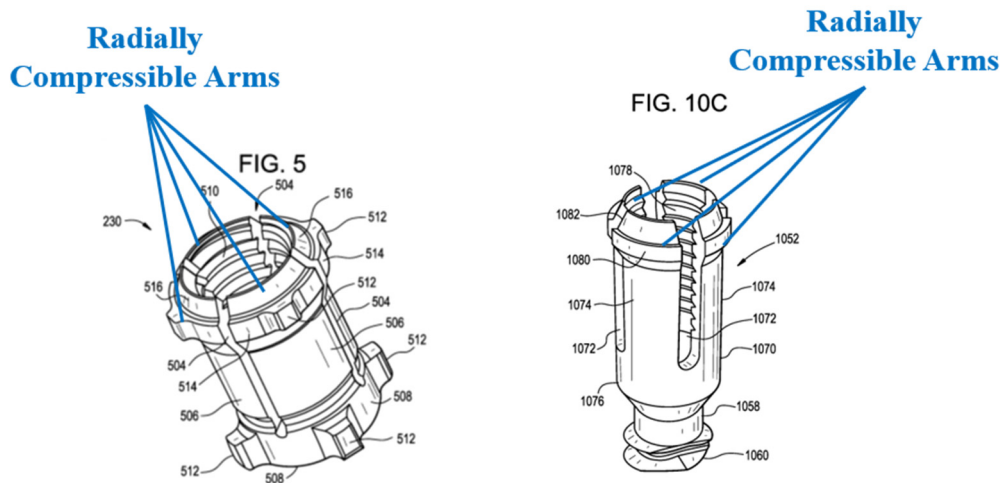
#### 1. Orphanos Does Not Disclose A “Locking Nut” As Claimed

36. Independent claims 1 and 9 both require a “locking nut” having, among other things, “an external thread on an outside surface.” Independent claim 1 requires the locking nut be “configured to engage the central screw when the central screw and baseplate are implanted within the medical patient, wherein the external thread is configured to secure the locking nut to the central channel of the baseplate,” (Ex.1001 at 30 (9:43-51)), and independent claim 9 requires the locking nut be “configured to engage the central screw when the central screw and baseplate are implanted within the medical patient, wherein the external thread is configured to engage the central channel of the baseplate,” (*id.* (10:26-32)). Claims 3-8 depend from claim 1, and recite all of the elements of claim 1 (and more). Claims 11-16 depend from claim 9, and recite all of the elements of claim 9 (and more). Therefore, claims 3-8 and 11-16 require a “locking nut” as recited in claims 1 and 9.

37. 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 at 31).

- a. “an external thread on an outside surface . . . the external thread is configured to secure the locking nut to the central channel of the baseplate”

38. Neither of the embodiments identified in the Petition includes a locking nut having “an external thread on an outside surface . . . the external thread is configured to secure the locking nut to the central channel of the baseplate.” As shown below in annotated Figures 5 and 10C, Orphanos’s collet 230 and collet portion 1052 do not include any external thread on an outside surface.



**Orphanos, Figures 5 and 10C (Annotated)**

(Ex.1006 at 8, 15). 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].” (*Id.* 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 “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)).

39. Petitioner references Orphanos’s statement that the collet “flex[es] outward such that the lip snaps into or otherwise mates within [a] catch,” and suggests that this somehow discloses something other than Orphanos’s flexible, snap-fit type coupling. (*See* Petition at 32). In my opinion, Petitioner is misreading Orphanos. Orphanos never discloses a collet with an external thread, let alone one that “flex[es] outward” as described. (*See* Petition at 32 (citing Ex.1006 at 28, 30 (14:14-30, 18:34-45))). Orphanos never discloses a collet that couples in any way other than via arms that flex outward and 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.” In this context, a POSITA would understand that the words “otherwise mates” do not describe or suggest any alternative to a flexible snap-fitting type collet, but instead to a flexible snap-fitting type collet with a lip that snaps “*into* . . . [a] catch,” or that “*otherwise mates within* [a] catch.”

40. Petitioner also relies on Orphanos's statement that collet 230 "may be referred to as a reducing bushing." (Petition at 32-33 (relying on Ex.1006 at 26 (10:30-41))). But calling collet 230 a "reducing bushing" (or any other name) does not change the fact that collet 230 as described in Orphanos does not include an "external thread." A POSITA would not interpret Orphanos's statement that collet 230 could be "sometimes referred to" as a reducing bushing as a teaching or suggestion that collet 230 or its snap-fitting design could be substituted with anything else in the art that might also be referred to as a "reducing bushing."

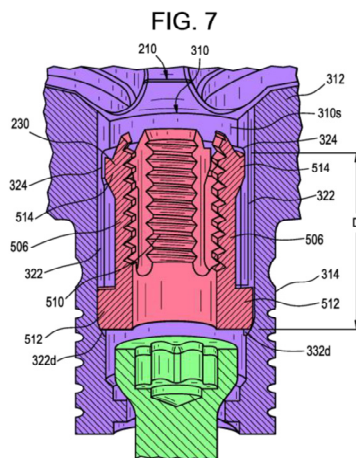
41. Petitioner's statement that Orphanos teaches a general proposition that "snap-fitting coupling techniques and threaded coupling techniques are readily interchangeable" is wrong. (Petition at 32). Orphanos never makes such a broad (and technically dubious) statement. A POSITA would not consider snap-fitting coupling techniques and threaded coupling techniques to be readily and necessarily interchangeable, particularly in the context of Orphanos's flexible collet. Further, the portion of Orphanos that Petitioner relies on (column 10, lines 11-15) does not even refer to the collet, or describe how the collet is secured to Orphanos's baseplate. The cited portion 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.

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

**(1) Orphanos, First Embodiment**

42. Orphanos’s embodiments also lack a locking nut “configured to engage the central screw when the central screw and baseplate are implanted within the medical patient.” As shown below in annotated Figure 7 (annotated by Petitioner), Orphanos clearly discloses a spacing and lack of engagement between the collet (highlighted by Petitioner in red) and the alleged central screw (screw 270) (highlighted by Petitioner in green).



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

43. A POSITA would understand from Orphanos’s description that the collet 230 and central screw 270 are never intended to engage when they are implanted. Orphanos explains that “insertion of the bone screw [is] optional.” (Ex.1006 at 1 (Abstract); *see also, e.g., id.* at 22-23, 25 (2:38-43 (“a collet can

allow a bone screw to be omitted from the implant”), 3:50-62 (“In some embodiments, the implant can be devoid of a central bone screw.”), 7:4-9, 7:22-26)). The collet cannot engage a bone screw that is not there.

44. 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). (*Id.* at 23 (3:50-62); *see also id.* at 28 (13:46-49)). To ensure this collet is spaced apart from any screw (if a screw is 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)).

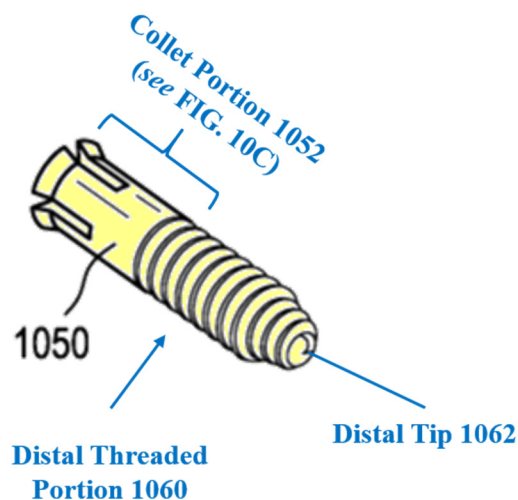
45. Petitioner appears to suggest that the collet and screw *might* somehow engage *if* the screw were to back out after implantation. (Petition at 38-39). But Petitioner identifies no evidence suggesting that central bone screw 270, if used, would necessarily back out towards collet after implantation – let alone that it would back out enough to result in engagement between the collet and screw. In my opinion, there is nothing in Orphanos that would suggest to a POSITA that backdriving of the central bone screw (itself optional) was a concern in Orphanos’s

embodiments.

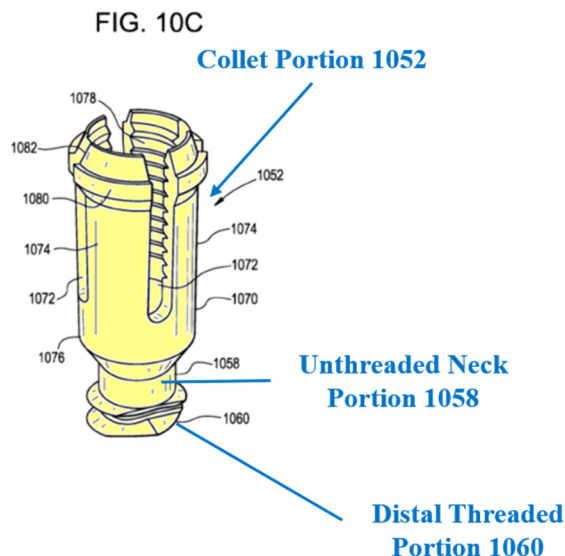
46. Petitioner cites Roche, but Roche does not disclose any general knowledge that compression screws in reverse shoulder implants are necessarily susceptible to backdriving. (Petition at 38-39). Nor does Roche disclose that compression screws in *Orphanos's implants* are necessarily susceptible to backdriving. Roche describes *Roche's devices*, and explains that *in Roche's devices* a locking cap screw “may [be] screwed into the glenoid plate on top of a compression screw to prevent the compression screw from backing out.” (Ex.1007 at 69 (7:33-43); *see also id.* at 72 (14:1-18)). The fact that a locking cap screw “may” be used in Roche’s device is hardly a disclosure to a POSITA 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.

## **(2) Orphanos, Second Embodiment**

47. As illustrated below in annotated Figures 10A (excerpt) and 10C, Orphanos’s 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  
(Annotated Excerpt)**



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

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

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

remaining structure would not operate as a screw 1050, as disclosed in Orphanos.

49. Petitioner’s analysis of Orphanos appears to misread the claims as reciting a central screw *comprising* a locking nut, but that is not how a POSITA would understand the claims. Claims 1 and 9 each recite a “central screw” *and* a “locking nut” separately, and state that the locking nut “engage[s] the central screw when the central screw and baseplate are implanted within the medical patient.” (Ex.1001 at 30 (9:43-49, 10:25-30)). In addition, the specification describes the locking nut and central screw as separate and distinct structures. (*Id.* at 28 (6:44-54); *see also id.* at 28-29 (6:66-7:11)). Logically, in order to have a collet that engages a central screw, the structures that make up the collet must be separate and distinct from the structures that make up the central screw. However, the alleged “collet” in Orphanos’s second embodiment is part of the alleged “central screw,” itself. Petitioner’s argument that the collet portion of the unitary screw satisfies the “configured to engage the central screw” element of claims 1 and 9 is illogical, as a structure cannot engage itself.

**2. A POSITA Would Not Have Been Motivated To Modify Orphanos To Include A “Locking Nut” With An “External Thread”**

50. Petitioner argues that it would have been obvious to modify Orphanos to include a “locking nut” with an “external thread” as claimed, “in view of Orphanos’s teachings and general knowledge of a POSITA.” (Petition at 34).

According to Petitioner, it would have been obvious to “replace/modify” the “snap-fitting coupling” of Orphanos’s collet/collet portion with “a threaded coupling,” as follows:

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

(Petition at 34 (emphases added)). I disagree.

51. Petitioner argues that it would have been obvious simply to “replace/modify” Orphanos’s snap-fitting coupling, but provides no detail regarding how it believes a POSITA actually would have done this. In my opinion, Petitioner’s proposal is not a “simple” replacement/modification, but instead would reflect a substantial reconstruction and redesign of Orphanos’s device (assuming the proposed replacement/modification was even possible in the first place and a POSITA was motivated to attempt it), with no reasonable expectation of success.

52. Petitioner points to so-called “reducing bushings” described in the “Hale” and “Grainger” references (Ex.1013 and Ex.1018), but fails to explain how the devices in those references would have been relevant to a POSITA interested in modifying or replacing Orphanos’s collet/collet portion. (Petition at 33). Hale and

Grainger are not directed to medical devices or problems in the medical device field, but instead relate to pressure vessels for above-ground compressed natural gas storage (Ex.1013 at 7 (1:7-10)) and industrial stainless steel pipe fittings (Ex.1018 at 2)), respectively. Hale and Grainger relate to entirely different fields of endeavor from Orphanos and the '561 Patent. In my opinion, a POSITA would not have considered the devices and structures in Hale or Grainger to be pertinent to the problems associated with modifying or replacing Orphanos's flexible collet/collet portion.

53. Petitioner's proposal to "include a threaded coupling instead of the snap-fitting coupling" (Petition at 37) would require substantial redesign and change the principles of operation of the collet/collet portion. Orphanos explains that "[i]n previous iterations of shoulder joint implants, a glenosphere locking screw was screwed directly into a central throughbore of a [baseplate] to secure the glenosphere to the [baseplate]." (Ex.1006 at 26 (10:30-33)). The diameter of the central throughbore could vary, however, and sometimes "exceed the diameter or width of a glenosphere locking screw such that the locking screw cannot be screwed directly to the [baseplate]." (*Id.* (10:33-38)). "To address this problem," Orphanos discloses a collet 230 (and collet portion of bone screw 1050) having "radially compressible arms 506" that are "configured to facilitate insertion and/or removal of the collet by flexing in response to changes in the diameter of the

throughbore 310 of the [baseplate] 210.” (*Id.* (10:39-56)).

54. As explained above in Section VII.A.1.a., Orphanos’s flexible arm structure is what provides the snap-fit functionality of the collet/collet portion 230, 1052 (among other functions). 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 with arms that “flex[] in response to changes in the diameter” of the baseplate throughbore. *Id.* 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 VII.A.1.a. (citing Ex.1006 at 22-23, 26, 28, 30 (2:63-3:6, 10:39-56, 14:4-30, 17:48-58, 18:23-45))).

55. Eliminating Orphanos’s flexible arm structure would also render Orphanos inoperable for its intended purpose. 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. With an outer diameter smaller than the diameter of the recessed portion, and without a flexible arm structure to flex outward, the resulting structure would be 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.

56. In my opinion, a POSITA would not have been motivated to modify/replace Orphanos’s collet/collet portion. Petitioner identifies no benefits or advantages associated with the proposed modification/replacement, which would change the principles of operation of Orphanos’s device and render it inoperable. In my opinion, a POSITA would not have been motivated to entertain what would amount to a substantial redesign and reconstruction of Orphanos, with no identified benefits or advantages, and no reasonable expectation of success.

**3. A POSITA Would Not Have Been Motivated To Modify Orphanos To Include A “Locking Nut” “Configured To Engage The Central Screw”**

**a. Orphanos, First Embodiment**

57. As explained above in Section VII.A.1.b.(1)., Orphanos’s first embodiment does not include a “locking nut” “configured to engage the central screw.” A POSITA would understand that Orphanos’s collet 230 (the alleged “locking nut”) was designed *not* to engage the central bone screw 270 (the alleged “central screw”). (*See* Section VII.A.1.b.(1).).

58. Petitioner alleges the following:

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

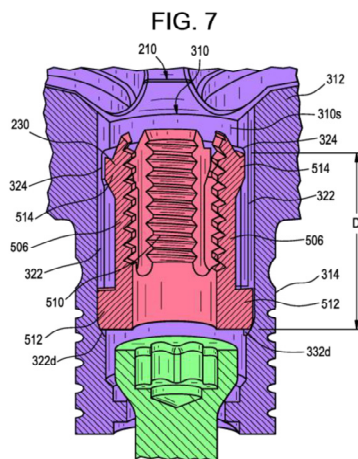
(Petition at 39). I disagree.

59. Orphanos does not disclose any “externally threaded reducing bushing.” Therefore, Petitioner’s argument that a POSITA would have modified the location of Orphanos’s “externally threaded reducing bushing” makes no sense.

60. Petitioner argues that it would have been 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. Petitioner never explains how it believes a POSITA would have modified Orphanos's collet 230 to include an "outer thread" as claimed, 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."

61. 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 at odds 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 below in Petitioner's annotated Figure 7 ).



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

A POSITA would not have been motivated to make such a modification. As explained above in Section VII.A.1.b.(1)., a POSITA would recognize that Orphanos specifically designed this embodiment so that the collet 230 is spaced apart from the screw (if one is even used). A POSITA would have understood this, in connection with Orphanos's disclosure of a mechanical stop 322d to prevent movement of the collet distally towards the bone screw beyond a "key depth," to teach away from Petitioner's proposed modification.

62. Petitioner also identifies no evidence that a POSITA would have been concerned about Orphanos's central bone screw 270 (if used) "backing out." As explained above in Section VII.A.1.b.(1)., a POSITA would not have considered backdriving to be a concern in Orphanos's embodiments.

63. Even assuming, despite the lack of evidence, that a POSITA was concerned about Orphanos's screw "backing out" in the first embodiment, the skilled artisan would not have been motivated to go through the trouble of attempting to redesign Orphanos's first embodiment, particularly when Orphanos already discloses two simple solutions. First, if a POSITA was truly concerned about backdriving in the first embodiment (in my opinion they would not have been), Orphanos discloses omitting the central screw altogether because it is "optional." (Ex.1006 at 1 (Abstract); *see also, e.g., id.* at 22-23, 25 (2:38-43, 3:50-62, 7:4-9, 7:22-26)). Alternatively, a POSITA could use the "integrated collet and

bone screw 1050” of Orphanos’s embodiment 2. Unlike the bone screw 270 in the first embodiment, Petitioner does not allege that the integrated bone screw 1050 in the second embodiment is susceptible to backing out. In my opinion, the second option would have been particularly desirable to a POSITA as Orphanos teaches the integrated bone screw 1050 “reduce[s] the number of steps performed during a procedure, thereby simplifying the procedure.” (*Id.* at 22 (2:38-43)).

**b. Orphanos, Second Embodiment**

64. As explained above in Section VII.A.1.b.(2)., Orphanos’s second embodiment does not include a “locking nut” “configured to engage the central screw. I understand that Petitioner has not proposed any modifications to address this deficiency.

**4. A POSITA Would Not Have Been Motivated To Modify Orphanos To Include “A Diameter Of The Locking Nut Is Greater Than A Length Of The Locking Nut” (Claims 7 and 15)**

65. Claims 7 and 15 depend from claims 1 and 9, respectively, and further recite “a diameter of the locking nut is greater than a length of the locking nut.” (Ex.1001 at 30 (10:11-13, 10:56-58)).

66. I understand that Petitioner does not allege that Orphanos, either by itself or as modified to address claims 1 or 9, discloses a locking nut where “a diameter of the locking nut is greater than a length of the locking nut.” Petitioner argues that “Roche teaches this limitation” (Petition at 47, 52), but Petitioner has

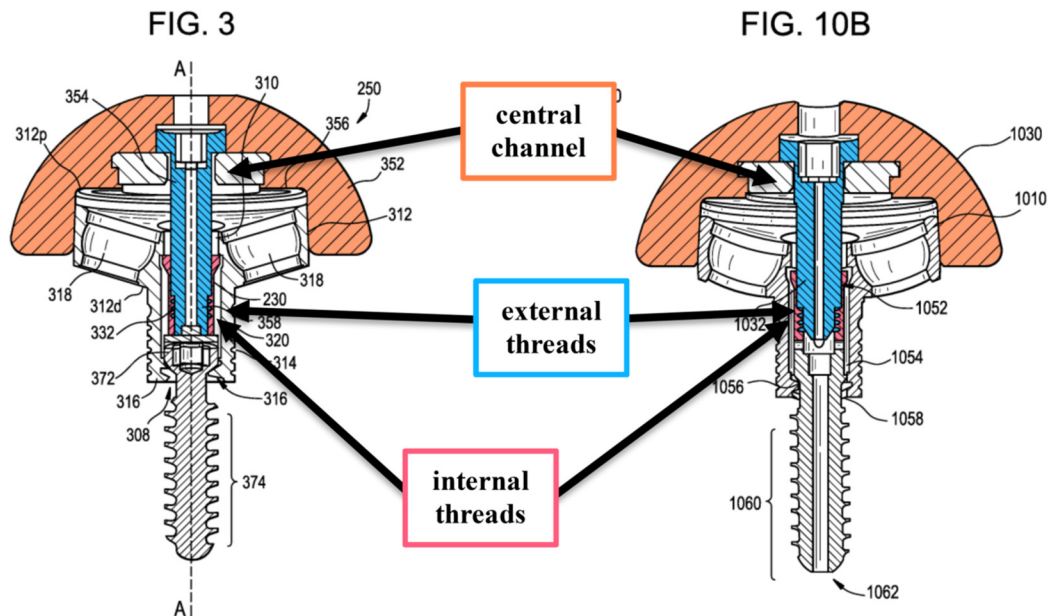
never suggested using any alleged “locking nut” from Roche in Orphanos, or suggested a POSITA would be motivated to do so.

67. I understand that Petitioner’s argument that Roche satisfies the “diameter” and “length” requirements is based solely on Petitioner’s measurement of Roche’s figures. However, Roche does not disclose that the figures that Petitioner measured are to scale. Further, the specification does not describe the dimensions of the figures or the structures that the figures purport to depict. In my opinion, a POSITA would understand that the figures that Petitioner is relying on are not engineering drawings and are not intended to convey specific dimensions.

68. Petitioner argues that a POSITA “would be motivated to keep the length [of Orphanos’s collet] less than the diameter to provide a low profile to the locking nut.” (Petition at 47, 52). Petitioner identifies no support for this alleged motivation, either in Orphanos or Roche (or any other reference). Nor does Petitioner explain what it means “to provide a low profile” in the context of Orphanos’s device, what technical or medical benefits or advantages an alleged “low profile” would provide (if any), or any disadvantages of not having a “low profile.”

69. On the other hand, a POSITA would understand that reducing the length relative to the diameter of Orphanos’s collet/collet portion would create potential disadvantages that the skilled artisan would want to avoid. As shown

below in annotated Figures 3 and 10B (annotated by Petitioner), for example, collet 232 (highlighted in red) couples the locking screw 354, 1032 (highlighted in blue) to the baseplate 210, 1010 (not highlighted).



### Orphanos, Figures 3 and 10B (Petitioner-Annotated) (Petition at 44)

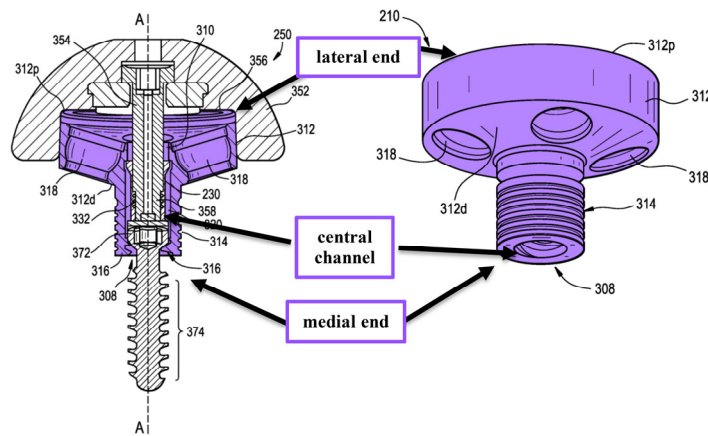
Reducing the length relative to the diameter of the collet/collet portion would tend to shorten the coupling between the locking screw and baseplate, which in turn would result in a potentially weaker structure. In my opinion, a POSITA would not have been motivated to make such a modification.

### B. Ground 2: Claims 2 And 10 In View Of Orphanos, Roche, And Frankle

70. I understand that Petitioner contends it would have been obvious to modify Orphanos “to incorporate [Frankle’s] protrusion element 2452 . . . into [Orphanos’s] glenosphere 250, 1030” so that Frankle’s protrusion element “is

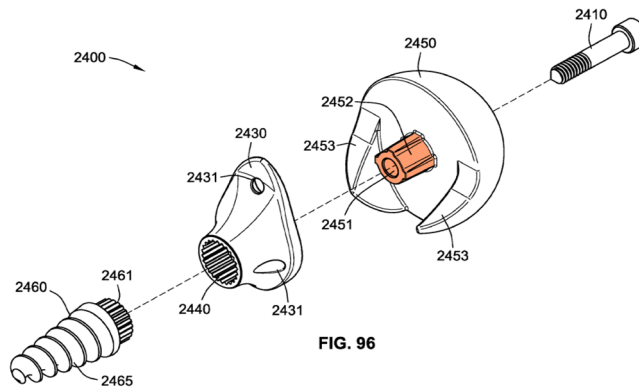
configured to be positioned at least partially within the central channel of the baseplate.” (Petition at 53-55). I disagree.

71. Figures 3 and 4A of Orphanos are illustrated below, with annotations and coloring provided by Petitioner. As shown below, the alleged “central channel” of Orphanos’s baseplate (highlighted in purple) is occupied by the glenosphere locking screw 354.



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

Petitioner proposes modifying Orphanos to include Frankle’s “protrusion element 2452” (shown below in Petitioner’s annotated Figure 96, highlighted in orange) and position it “at least partially within the central channel of [Orphanos’s] baseplate,” but provides no explanation how a POSITA would have done that when there is no space in the alleged central channel for any “protrusion element” to fit. In my opinion, this would not have been an obvious modification.



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

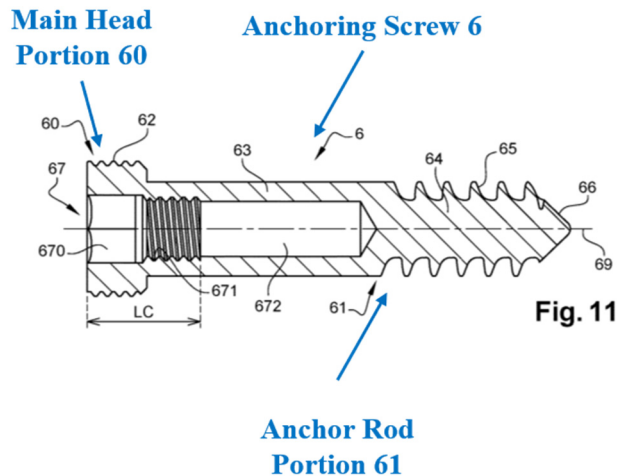
72. Petitioner argues that a POSITA would have been motivated to modify Orphanos to “promote guidance,” “maintain alignment,” or “provide further structural rigidity” for Orphanos’s device. (Petition at 56). But Petitioner fails to explain how “protrusion 2452” allegedly promotes guidance, maintains alignment, or provides structural rigidity in *Frankle*’s device, let alone how the proposed modification would provide any benefit in guiding, aligning, or providing structural rigidity in *Orphanos*’s device. Petitioner also identifies no evidence that a POSITA would have considered Orphanos’s device as deficient in any of these respects. In my opinion, a POSITA would not have considered Orphanos’s device as deficient, and would not have been motivated to make the proposed modifications. The POSITA would have recognized that Orphanos’s locking screw 354 already occupies the central channel and would perform the above functions.

**C. Ground 3: Claims 1, 3-9, And 11-16 In View Of Lefebvre, Orphanos, And Roche**

**1. Lefebvre Does Not Disclose A “Central Screw” And “Locking Nut” As Claimed**

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

74. Petitioner argues that the “anchor rod” portion 61 of Lefebvre’s “anchoring screw 6” corresponds with the “central screw” element of the challenged claims, and the “main head” portion 60 of the anchoring screw 6 corresponds with the “locking nut” element. (Petition at 62-67). I disagree. As shown below in annotated Figure 11 of Lefebvre, the 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).

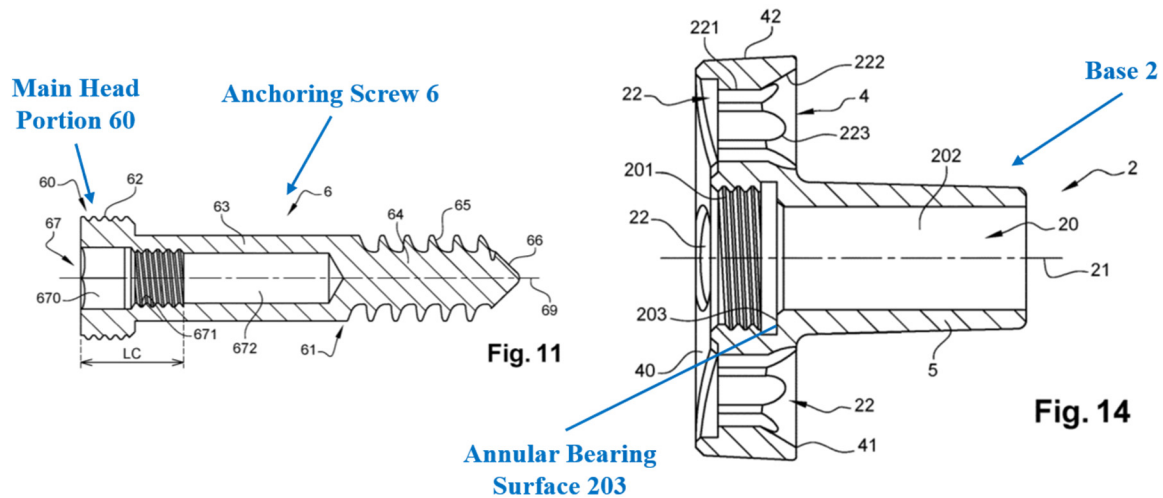


**Lefebvre, Figure 11 (Annotated)**

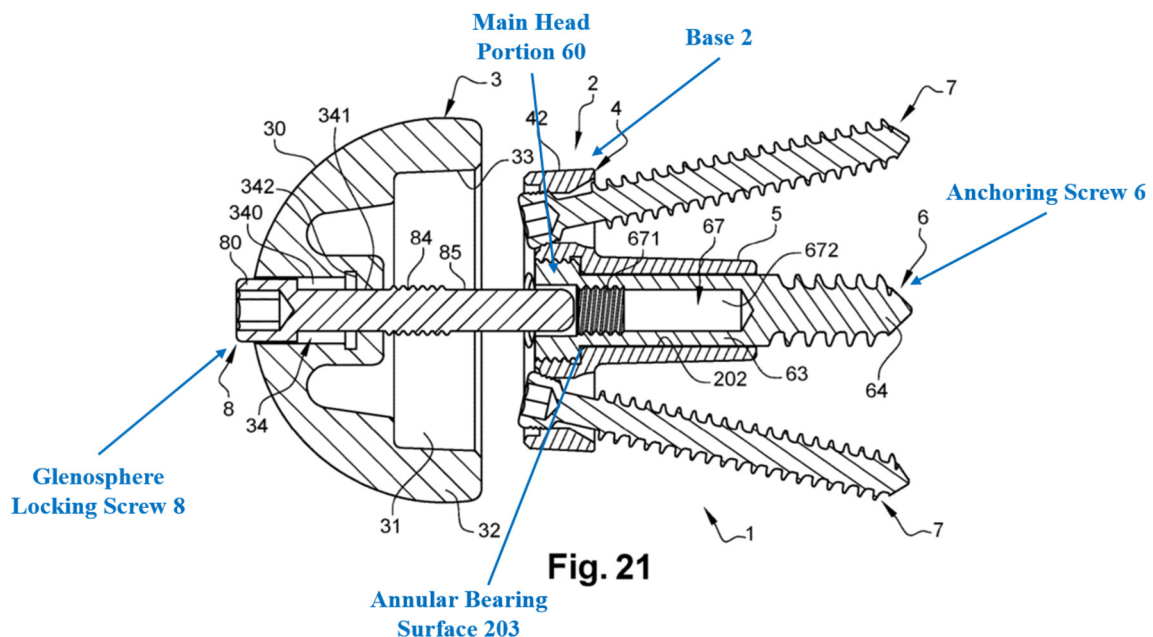
(See Ex.1009, 1, 6, 13-14, 16 (Abstract, 2:50-54, 2:61-3:13, 7:4-12)). The uniform cross-hatching in combination with the description in the specification demonstrates the anchoring screw 6 is a monolith, and that the main head 60 is not “attached” to anchor rod portion 61, as Petitioner wrongly states. (Petition at 67).

75. A POSITA would recognize that the monolithic nature of the anchoring screw structure was an important feature of Lefebvre’s device. Lefebvre describes the monolithic design as a “remarkable” aspect of the disclosed glenoid implant. (*Id.* at 13-14 (2:61-3:13)). The screw 6 includes at the main head 60 an “inlet portion [670] shaped so as to cooperate with a screwing tool.” (*Id.* at 13-14, 16 (2:61-3:13, 7:45-54)). During implantation, the “external tapping” (threading) of the main head 60 and anchor rod 61 work in tandem, which “improv[es] the anchorage of the external tapping of the end segment of the anchor rod by screwing into the glenoid cavity.” (*Id.* at 14 (4:14-27) (“the external tapping of the

main head . . . has a tapping pitch smaller than that of the external tapping of the end segment of the anchor rod”); *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, Figures 11 and 14 (Annotated)**



**Lefebvre, Figure 21 (Annotated)**

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.” (*Id.* 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)).

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

77. A POSITA would understand that the main and anchoring rod portions 60, 61 of Lefebvre’s anchoring screw 6 are not separate and distinct

structures or components, capable of being divided into discrete subcomponents with separate and distinct functions. The main head and anchoring rod portions 60, 61 are portions of a unitary whole anchoring screw 6, with interrelated structures and functions that cannot be arbitrarily and discretely subdivided. For example, without the main head portion 60 to abut the base 2 and transmit forces (among other things), a POSITA would not consider the remaining portion of the monolithic structure to 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.

78. In addition, the challenged claims recite the “central screw” and “locking nut” as separate and distinct elements, including requiring the locking nut “engage the central screw when the central screw and baseplate are implanted within the medical patient.” (Ex.1001 at 30 (9:43-49, 10:25-30)). Because the main head portion 60 is part of the alleged “central screw,” itself (*i.e.*, the anchoring screw 6), Petitioner’s argument that the main body portion satisfies the “configured to engage the central screw” element of claims 1 and 9 is illogical, as a structure cannot engage itself.

79. A POSITA would also understand that attempting to break up Lefebvre’s monolithic anchoring screw into pieces would defeat Lefebvre’s purpose of providing a rigid construct with improved strength. Separating the

main head portion 60 would eliminate the anchoring screw's locking function, and reduce the mechanical integrity of the device. A POSITA would recognize that one of the main advantages of Lefebvre's monolithic screw design is the rigid construct that it creates by interfacing with a locking mechanism to the base 2. Separating the monolithic screw into pieces would not only disrupt the screw's ability to function as a screw, but also reduce or destroy the rigidity it otherwise would impart to the entire construct of the combination of the base 2 and screw (as well as the glenosphere). The locking mechanism provided by the monolithic screw structure would have been considered essential to Lefebvre for providing structural integrity for long-term function of the device in a patient.

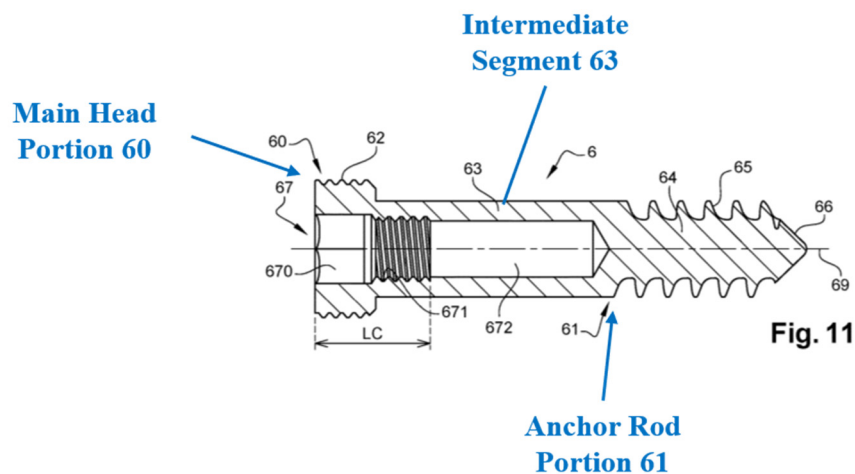
80. To the extent Petitioner contends anchoring screw 6 corresponds with the claimed "central screw," Lefebvre fails to disclose a "locking nut" as claimed, including one "configured to engage the central screw when the central screw and baseplate are implanted within the medical patient." Alternatively, to the extent Petitioner contends the main head portion 60 of anchoring screw 6 corresponds with the claimed "locking nut," Lefebvre fails to disclose a "central screw" as claimed, or a "locking nut" "configured to engage the central screw when the central screw and baseplate are implanted within the medical patient."

## **2. A POSITA Would Not Have Been Motivated To Modify Lefebvre As Described In The Petition**

81. Petitioner argues that a POSITA would have found it obvious to

“separate the components of Lefebvre’s main anchoring screw 6 forming the locking nut (which includes external tapping 62 and internal thread of intermediate portion 671) from the components of Lefebvre’s main anchoring screw 6 forming the central screw.” (Petition at 67-69). I disagree.

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



**Lefebvre, Fig. 11 (Annotated)**

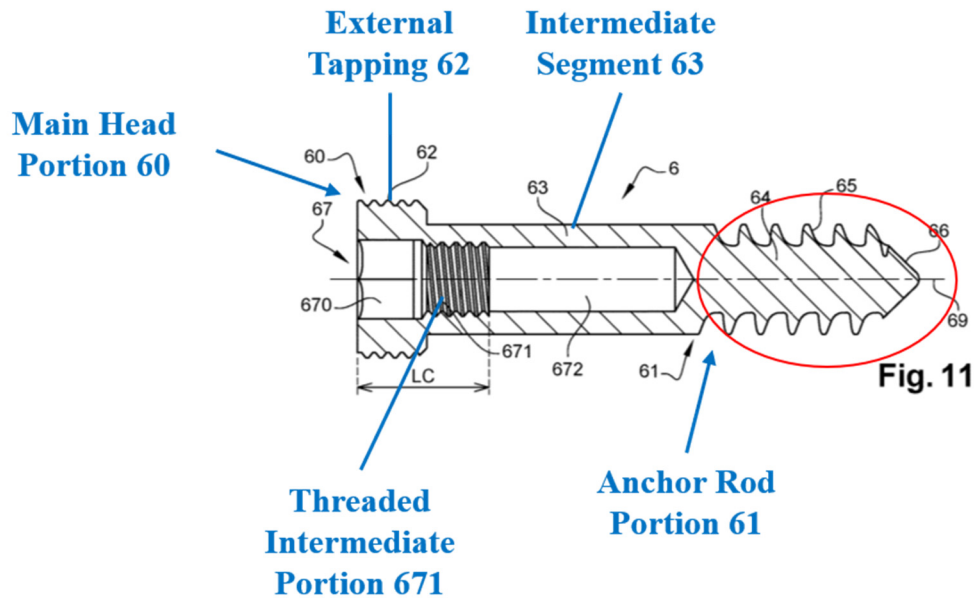
(Ex.1009 at 6; *see also* Section VII.C.1., above).

83. Petitioner’s argument that a POSITA would separate portions of the anchoring screw from components forming the screw is circular. Without the main head 60 (with external tapping 62) to abut the base 2, a POSITA would recognize that there is no screw. Similarly, without the anchor rod 61 to engage the patient,

or the intermediate segment 63 (with intermediate threaded portion 671) to bridge the main head and anchor rod portions, a POSITA would recognize there is no screw.

84. Notably, while Petitioner argues that it would be obvious to “separate the components of Lefebvre’s main anchoring screw 6,” (Petition at 67, 69) it provides no detail regarding how it believes a POSITA actually would have done this, let alone how to do so and still have a functional device. In my opinion, Petitioner’s proposal would reflect a substantial reconstruction and redesign of Lefebvre’s device (assuming the proposed modification was even possible in the first place and a POSITA was motivated to attempt it), with no reasonable expectation of success.

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



**Lefebvre, Fig. 11 (Annotated)**

(Ex.1009 at 6). But a POSITA would understand that the anchor rod 61, by itself, is not a screw.

86. Further, the anchoring rod 61, by itself, 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 VII.C.1., above (citing Ex.1009 at 13-14, 16 (2:61-3:13, 4:1-5, 7:7-12, 7:45-54))). The proposed modification would render Lefebvre’s anchoring screw 6 no longer a screw, let alone one with Lefebvre’s “remarkable” structure and functions. (*Id.*). A POSITA would recognize that 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.

87. Petitioner argues that carving up Lefebvre’s anchoring screw 6 would be “desirable” because it “would allow Lefebvre’s central screw to have a ‘free spinning screw’ design.” (Petitioner at 67, 69). I disagree. To start, Petitioner identifies no reason (and I am aware of no reason) why replacing Lefebvre’s design with a so-called “free spinning” design as described in the Petition would be desirable, or provide any benefits or advantages over Lefebvre’s “remarkable” monolithic screw design. Petitioner theorizes that a modification could “provide additional compression between the bone and Lefebvre’s base 2,” (*id.*) but provides no description of a functional modification of Lefebvre’s device, or how such a modification, if even feasible, would provide “additional compression” in comparison with Lefebvre’s design. For example, Lefebvre discloses different external tapping of the main head and end segments of the monolithic anchoring screw 6, which Lefebvre explains “allows improving the anchorage of the external tapping of the end segment of the anchor rod by screwing into the glenoid cavity.” (See Ex.1009 at 13-14, 16 (2:61-3:13, 4:14-27, 7:37-44)). Petitioner’s proposed modification would apparently destroy this aspect of Lefebvre by separating the main head and end segments into separate pieces, and replace it with an

undescribed “free-spinning screw” 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.

88. Petitioner suggests that Orphanos’s statement that bone screw 270 may be a free spinning screw would have motivated a POSITA to modify Lefebvre. (Petition at 68-69). I disagree. Orphanos describes bone screw 270 as an “optional” component of Orphanos’s first embodiment, and states that it may “be omitted from the implant.” (*See, e.g.*, Ex.1006 at 27 (11:63-67 (“central bone screw 270 is an optional component that can be omitted while still allowing the rest of the shoulder implant 200 to be successfully used for a repair procedure.”))). And even when bone screw 270 is used, Orphanos explains that the threaded neck portion (the feature that purportedly “allow[s] a ‘free spinning screw’ design”) is optional and “can be omitted” permitting the screw to “function as intended with less contact area.” (*Id.* at 27-28 (12:49-61, 13:1-3)). While Orphanos explains that the first embodiment can include a “free spinning” screw, it makes no similar disclosure regarding the integrated bone screw 1050 of the second embodiment. In view of this, Orphanos’s statements regarding the optional use of a “free spinning” screw hardly would have motivated a POSITA to use a free spinning screw *in Orphanos’s* devices. In my opinion, these statements would not have motivated a POSITA to modify *Lefebvre’s* device.

89. Petitioner’s motivation argument makes no sense. If a free spinning screw truly was a motivating factor to a POSITA knowledgeable of Lefebvre and Orphanos, then that person simply could have (and would have) used Orphanos’s first embodiment and optional spinning screw. In my opinion, Petitioner’s “free-spinning screw” theory is not based on any knowledge or motivation of a POSITA in the 2019-2020 timeframe, but instead based on a hindsight attempt to try to turn Lefebvre’s device into one that satisfies the elements of the claims of the ’561 Patent.

**3. A POSITA Would Not Have Been Motivated To Modify Lefebvre To Include “A Diameter Of The Locking Nut Is Greater Than A Length Of The Locking Nut” (Claims 7 and 15)**

90. Claims 7 and 15 depend from claims 1 and 9, respectively, and further recite “a diameter of the locking nut is greater than a length of the locking nut.” (Ex.1001 at 30 (9:11-13, 9:56-58)).

91. Petitioner argues that the main head portion 60 of Lefebvre’s anchoring screw 6 has “a diameter of the locking nut is greater than a length of the locking nut.” (Petition at 77, 81). I disagree. As explained above, Lefebvre’s anchoring screw 6 is not a “locking nut” as claimed. (See Section VII.C.1.). Further, Petitioner’s argument that Lefebvre satisfies the “diameter” and “length” requirements is based solely on Petitioner’s measurement of arbitrary portions of Lefebvre’s anchoring screw 6. Lefebvre does not disclose that the figures that

Petitioner measured are to scale. Further, the specification does not describe the dimensions of the figures or the structures that the figures purport to depict. In my opinion, a POSITA would understand that the figures that Petitioner is relying on are not engineering drawings and are not intended to convey specific dimensions.

92. Petitioner argues that a POSITA “would be motivated to keep the length less than the diameter to provide a low profile to the locking nut.” (Petition at 77, 81). Petitioner identifies no support for this alleged motivation, either in Lefebvre, Orphanos, or Roche (or any other reference). Nor does Petitioner explain what it means “to provide a low profile” in the context of Lefebvre’s device, what technical or medical benefits or advantages an alleged “low profile” would provide (if any), or any disadvantages of not having a “low profile.”

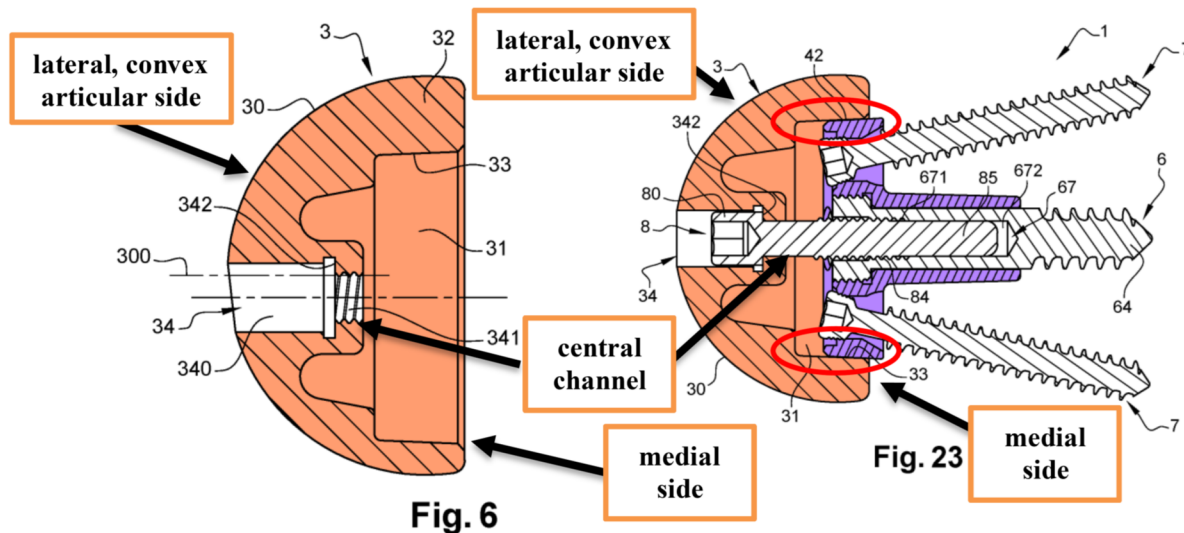
93. In my opinion, a POSITA would understand that reducing the length relative to the diameter of the portion of Lefebvre’s anchoring screw 6 that includes the inner and outer threading (external tapping 62 and internal threaded intermediate portion 671) would create potential disadvantages that the skilled artisan would want to avoid. For example, the external tapping 62 couples and locks the anchoring screw 6 to Lefebvre’s base 2, and the internal threaded intermediate portion 671 couples and locks the locking rod 81 of the glenosphere locking screw 8 to the anchoring screw 6. (Ex.1009 at 16-17 (7:7-12, 7:45-58, 9:8-57, 10:41-52)). Reducing the length relative to the diameter of the these portions

of the anchoring screw 6 would tend to shorten the coupling between the glenosphere locking screw 8 and the anchoring screw 6, and between the anchoring screw 6 and the base 2, which in turn would result in a potentially weaker structure. In my opinion, a POSITA would not have been motivated to make such a modification.

**D. Ground 4: Claims 2 And 10 In View Of Lefebvre, Orphanos, Roche, And Frankle**

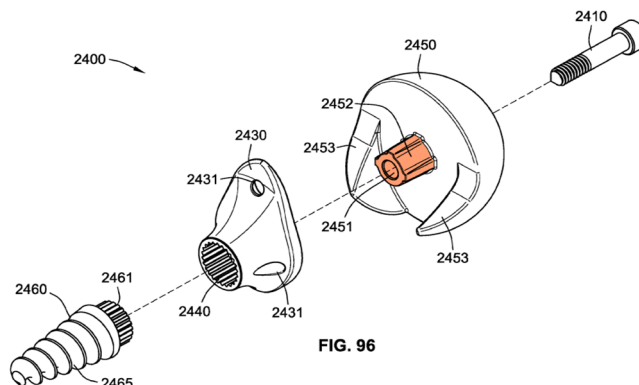
94. I understand that Petitioner contends it would have been obvious to modify Lefebvre “to incorporate [Frankle’s] protrusion element 2452 . . . into [Lefebvre’s] glenosphere 3” so that the protrusion element “is configured to be positioned at least partially within the central channel of the baseplate.” (Petition at 82). I disagree.

95. Figures 6 and 23 of Lefebvre are illustrated below, with annotations and coloring provided by Petitioner. As shown below, the alleged “central channel” of Lefebvre’s base (highlighted in purple) is occupied by the anchor screw 6 and locking screw 8.



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

Petitioner proposes modifying Lefebvre to include Frankle’s “protrusion element 2452” (shown below in Petitioner’s annotated Figure 96, highlighted in orange) and position it “at least partially within the central channel” of Lefebvre’s base, but provides no explanation how a POSITA would have done that when there is no space in the alleged central channel for any “protrusion element” to fit. In my opinion, this would not have been an obvious modification.



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

96. Petitioner argues that a POSITA would have been motivated to

modify Lefebvre to “promote guidance,” “maintain alignment,” or “provide further structural rigidity” for Lefebvre’s device. (Petition at 82-83). But Petitioner fails to explain how “protrusion 2452” allegedly promotes guidance, maintains alignment, or provides structural rigidity in *Frankle*’s device, let alone how the proposed modification would provide any benefit in guiding, aligning, or providing structural rigidity in *Lefebvre*’s device. Petitioner also identifies no evidence that a POSITA would have considered Lefebvre’s device as deficient in any of these respects. On the other hand, Lefebvre expressly states that its implant “enable[s] guidance and locking of the glenosphere on the base, while providing an improved mechanical strength.” (Ex.1009 at 13 (2:34-36)). In my opinion, a POSITA would not have considered Lefebvre’s device as deficient, and would not have been motivated to make the proposed modifications.

**E. Ground 5: Claims 1-16 Are Not Indefinite (Baseplate “Central Channel”)**

97. I understand Petitioner alleges that “the use of the term ‘central channel’ with respect to the baseplate” in the claims of the ’561 Patent is indefinite. (Petition at 83-87). I disagree. In my opinion, a POSITA would understand the scope of the challenged claims with reasonable certainty.

98. The word “channel” is a common word, and ordinarily connotes both structure as well as space formed by that structure. Consistent with this ordinary meaning, the claims of the ’561 Patent describe channels both in terms of structure,

as well as space formed by that structure. For example, the claims recite a channel “extending *therethrough*” a baseplate (space) and a locking nut with an external thread “configured to secure the locking nut *to the central channel*” (structure) or “configured to engage *the central channel*”). (Ex.1001 at 30 (9:37-40, 9:43-51, 10:18-21, 10:25-32) (emphases added)). Likewise, the specification describes channels both in terms of structure, as well as space formed by that structure. (*See, e.g., id.* at 27-28 (4:38-40 (explaining “the glenoid baseplate includes a central channel *therethrough defining a surface*”) (space and structure), 5:14-17 (explaining a “central channel can *extend through the baseplate 500, as well as include a superiorly-extending sidewall or lip 511*”) (space and structure), 6:34-38 (explaining the glenosphere can include “a central channel *therethrough*” including “*threaded surface*”) (space and structure) (emphases added))).

99. I disagree with Petitioner’s argument that a central channel “cannot be at once both an empty space . . . and a physical structure,” (Petition at 86) as this argument is inconsistent with the ordinary meaning of “channel,” as well as the claims and specification that describe channels both respect to their structure and their space.

100. In my opinion, there is nothing in the claims or specification of the ’561 Patent that would indicate to a POSITA that the inventors intended the term “central channel” to deviate from its plain and ordinary meaning.

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

101. I understand Petitioner also alleges that the claims of the '561 Patent are indefinite because “a POSITA, reading the claim language ‘central channel . . . configured to interface with the baseplate’ in light of the specification and prosecution history, would not be able to determine the scope of the claim with reasonable certainty.” (Petition at 87-90). I disagree. In my opinion, a POSITA would understand the scope of the challenged claims with reasonable certainty.

102. I understand that Petitioner’s position is premised on a POSITA reading claim language reciting a central channel “configured to interface with the baseplate.” But that is not what the claims of the '561 Patent say. The relevant portion of the challenged claims states in full “*a glenosphere, having a lateral, convex articular side, a medial side, and a central channel extending from the convex articular side to the medial side and configured to interface with the baseplate.*” (Ex.1001 at 30 (9:52-55, 10:33-36) (emphases added)). It is the “glenosphere”—and not necessarily the “central channel” of the glenosphere—that is “configured to interface” as claimed. Petitioner appears to acknowledge that the structure that is “configured to interface” is the glenosphere (and not necessarily the “central channel” of the glenosphere) in its obviousness grounds. For example, Petitioner alleges at page 43 of the Petition that Orphanos discloses the claimed glenosphere because “[e]ach *glenosphere 250, 1030 is configured to* surround and

*interface with baseplate . . . .*” (Petition at 43).

103. In any event, as explained above in Section VII.E., the ordinary meaning of “channel” connotes both structure as well as space formed by that structure. By its ordinary meaning the claimed glenosphere “central channel” necessarily connotes structure. Petitioner’s suggestion that the claimed central channel somehow excludes physical structure is inconsistent with the ordinary meaning of “channel,” as used in the claims and specification.

104. In my opinion, there is nothing in the claims or specification of the ’561 Patent that would indicate to a POSITA that the inventors intended the term “central channel” to deviate from its plain and ordinary meaning.

#### **VIII. OTHER TESTIMONY**

105. I reserve the right to provide additional opinions and testimony that is responsive to, or in rebuttal to, any position taken by or on behalf of Petitioner at a later date in connection with this PGR2024-00042. I also reserve the right to revise or supplement this declaration in consideration of any further materials or arguments that Petitioners may provide, or other additional relevant information in any form.

## **IX. MATERIALS CONSIDERED**

106. In addition to the materials identified in this declaration, I have considered the Petition and Exhibits 1001-1018 filed by Petitioner in support of Post Grant Review.

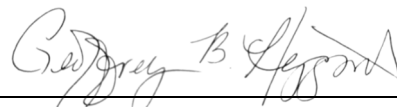
## **X. PRIOR TESTIMONY**

107. During the previous four years, I have not testified as an expert at trial or by deposition.

This declaration and my opinions herein are made to the best of my knowledge and understanding, and based on the material available to me, at the time of signing this declaration. I declare under penalty of perjury under the laws of the United States of America that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I understand that willful false statements and the like are punishable by fine or imprisonment, or both under § 1001 of Title 18 of the United States Code.

Dated: September 29, 2024

By:

  
\_\_\_\_\_  
Geoffrey Higgs, M.D.