

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CATALYST ORTHOSCIENCE INC.,

Petitioner,

v.

SHOULDER INNOVATIONS, INC.,

Patent Owner.

Case No.: PGR2024-00042

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

**DECLARATION OF T. WADE FALLIN, M.S., IN SUPPORT OF PETITION
FOR POST-GRANT REVIEW OF U.S. PATENT NO. 11,771,561**

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TABLE OF MATERIALS CONSIDERED

EX. NO.	DESCRIPTION
EX-1001	U.S. Patent No. 11,771,561 ("the '561 Patent")
EX-1004	Prosecution History of U.S. Patent No. 11,771,561 (Part I)
EX-1005	Prosecution History of U.S. Patent No. 11,771,561 (Part II)
EX-1006	U.S. Patent No. 10,813,769 ("Orphanos ")
EX-1007	U.S. Patent No. 9,233,003 ("Roche")
EX-1008	U.S. Pat. Pub. No. 2022/0125594 ("Frankle")
EX-1009	U.S. Patent No. 11,439,513 ("Lefebvre")
EX-1010	U.S. Patent No. 11,596,520 ("Perego")
EX-1011	U.S. Pat. Pub. No. 2018/0008350 ("Varadarajan")
EX-1012	U.S. Pat. Pub. No. 2020/0368032 ("Hodorek")
EX-1013	U.S. Patent No. 5,429,268 ("Hale")
EX-1014	Key of Limitations for Challenged Claims
EX-1017	Webster's Ninth New Collegiate Dictionary (1987)
EX-1018	Grainger Catalog No. 400, 2009-2010 ("Grainger")
	U.S. Patent No. 10,631,992 to Hopkins
	U.S. Patent No. 10,143,558 to Frankle

KEY OF LIMITATIONS FOR CHALLENGED CLAIMS

CLAIM	RECITED LIMITATIONS
[1]	[1-PRE] A reverse shoulder implant, comprising:
	[1-1] a baseplate configured to be secured to a glenoid of a scapular bone of [a] patient,
	[1-2] the baseplate having a lateral end, a medial end, and a central channel extending therethrough from the lateral end to the medial end;
	[1-3] a central screw sized to at least partially pass through the central channel and secure the baseplate to the glenoid of the patient;
	[1-4] locking nut having a cylindrical shape, an external thread on an outside surface of the locking nut and an internal thread on an internal surface of the locking nut,
	[1-5] the locking nut configured to engage the central screw when the central screw and baseplate are implanted within the medical patient,
	[1-6] wherein the external thread is configured to secure the locking nut to the central channel of the baseplate;
	[1-7] 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; and
	[1-8] a glenosphere screw, sized to pass at least partially within the glenosphere central channel and having external threads sized to secure the glenosphere screw to the internal thread on the internal surface of the locking nut to secure the glenosphere to the locking nut.

[2]	<p>[2-PRE] The reverse shoulder implant of claim 1,</p> <p>[2-1] wherein the glenosphere further comprises a stem configured to be positioned at least partially within the central channel of the baseplate.</p>
[3]	<p>[3-PRE] The reverse shoulder implant of claim 1,</p> <p>[3-1] wherein the glenosphere is configured to at least partially surround an external surface of the baseplate.</p>
[4]	<p>[4-PRE] The reverse shoulder implant of claim 1,</p> <p>[4-1] wherein the baseplate has a circular shape.</p>
[5]	<p>[5-PRE] The reverse shoulder implant of claim 1,</p> <p>[5-1] wherein the glenosphere is configured to surround the baseplate.</p>
[6]	<p>[6-PRE] The reverse shoulder implant of claim 1,</p> <p>[6-1] wherein the glenosphere is configured to be secured to the baseplate with a morse taper.</p>
[7]	<p>[7-PRE] The reverse shoulder implant of claim 1,</p> <p>[7-1] wherein a diameter of the locking nut is greater than a length of the locking nut.</p>
[8]	<p>[8-PRE] The reverse shoulder implant of claim 1,</p> <p>[8-1] wherein the locking nut comprises a rotational control feature configured to receive a tool to enable twisting of the locking nut to secure it to the central screw.</p>
[9]	<p>[9-PRE] A reverse shoulder implant, comprising:</p>

	[9-1] a baseplate configured to be secured to a glenoid of a scapular bone of patient,
	[9-2] the baseplate having a lateral end, a medial end, and a central channel extending therethrough from the lateral end to the medial end;
	[9-3] a central screw sized to at least partially pass through the central channel and secure the baseplate to the glenoid of the patient;
	[9-4] a locking nut having a cylindrical shape, an external thread on an outside surface of the locking nut and an internal thread on an internal surface of the locking nut,
	[9-5] the locking nut configured to engage the central screw when the central screw and baseplate are implanted within the medical patient,
	[9-6] wherein the external thread is configured to engage the central channel of the baseplate; and
	[9-7] 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; and
	[9-8] a glenosphere screw, sized to pass at least partially within the glenosphere central channel and having external threads sized to secure the glenosphere screw to the internal thread on the internal surface of the locking nut to secure the glenosphere to the locking nut.
[10]	<p>[10-PRE] The reverse shoulder implant of claim 9,</p> <p>[10-1] wherein the glenosphere further comprises a stem configured to be positioned at least partially within the central channel of the baseplate.</p>

[11]	<p>[11-PRE] The reverse shoulder implant of claim 9,</p> <p>[11-1] wherein the glenosphere is configured to at least partially surround an external surface of the baseplate.</p>
[12]	<p>[12-PRE] The reverse shoulder implant of claim 9,</p> <p>[12-1] wherein the baseplate has a circular shape.</p>
[13]	<p>[13-PRE] The reverse shoulder implant of claim 9,</p> <p>[13-1] wherein the glenosphere is configured to surround the baseplate.</p>
[14]	<p>[14-PRE] The reverse shoulder implant of claim 9,</p> <p>[14-1] wherein the glenosphere is configured to be secured to the baseplate with a morse taper.</p>
[15]	<p>[15-PRE] The reverse shoulder implant of claim 9,</p> <p>[15-1] wherein a diameter of the locking nut is greater than a length of the locking nut.</p>
[16]	<p>[16-PRE] The reverse shoulder implant of claim 9,</p> <p>[16-1] wherein the locking nut comprises a rotational control feature configured to receive a tool to enable twisting of the locking nut to secure it to the central screw.</p>

I. INTRODUCTION AND SUMMARY OF TESTIMONY

1. My name is T. Wade Fallin. I am at least 18 years of age and I reside in Hyde Park, Utah.

2. Catalyst OrthoScience Inc. ("Petitioner") has retained me to evaluate the patentability of claims 1-16 ("Challenged Claims") of United States Patent No. 11,771,561 ("the '561 Patent" or "Challenged Patent") in view of certain prior art references and in further view of the knowledge, skill, and perspective of a person of ordinary skill in the art ("POSITA") at the time of the alleged invention of the '561 Patent.

3. In connection with my evaluation, I have been asked to provide expert opinions in support of a petition for post-grant review ("PGR") of the '561 Patent that Petitioner is filing with the United States Patent and Trademark Office, Patent Trial and Appeal Board ("Board"). More particularly, I have been asked to provide opinions related to, among other things, the background and understanding of the state of the art pertaining to the '561 Patent, the knowledge, skill, and perspective of a POSITA at the time of the alleged invention of the '561 Patent, and the patentability of the Challenged Claims under U.S. patent law.

4. I am being compensated at my normal consulting rate of \$600/hour for my work on this matter. My compensation does not depend on the outcome of this or any other proceeding or matter either before the Board or in litigation in court

involving the '561 Patent.

5. As explained below, it is my opinion that each of the Challenged Claims is unpatentable as obvious in view of certain prior art references and the knowledge and skill of a POSITA at the time of the alleged invention. It is also my opinion that each of the Challenged Claims is unpatentable for failing to point out and distinctly claim with reasonable certainty the alleged invention from the perspective of a POSITA. I am prepared to testify about these and other subsidiary opinions expressed within this declaration.

A. Qualifications

6. In my opinion, I possess the requisite knowledge, skill, experience, training, and education to qualify as an expert in this proceeding, form an expert opinion on the technological subject matter at issue in this proceedings, and testify as an expert to aid the Board in reaching conclusions regarding the issues presented in this proceeding.

7. In 1984, I earned a B.M.E. in Mechanical Engineering from Georgia Institute of Technology. In 1995, I earned an M.S. in Mechanical Engineering from the University of Illinois at Champaign-Urbana.

8. Since February 2021, I have been a Research Professor in the Department of Orthopaedics at the University of Utah. I was an adjunct professor in the same department from October 2019 to February 2021. In addition, since January

2021, I have been a Special Content Editor of Foot and Ankle International and a Special Content Editor of Foot and Ankle Orthopaedics. Since February 2020, I have been a member of the Health Sciences Research Subcommittee on Innovation and Entrepreneurship at the University of Utah. Since October 2019, I have served as the Executive Director of the Orthopaedic Innovation Center at the University of Utah.

9. Throughout my professional career spanning four decades, I have spent 34 years engaged full time in the field of orthopaedics. In the first decade, I worked at increasing levels of responsibility in engineering at two of the largest orthopaedic companies, Zimmer and Smith and Nephew. Since then, I have founded and directed numerous organizations in the field of orthopaedics, including serving as the founder, director, and chief executive officer of Surgical Frontiers, LLC, Mortise Medical, LLC, Intrafuse, LLC, First Ray, LLC, KATOR, LLC, VentureMD, LLC, MTP Solutions, LLC, IMDS, Inc., Facet Solutions, Inc., and MedicineLodge, Inc., all of Logan Utah.

10. I have decades of experience working directly with joint replacement systems, including hip joint replacement systems, knee replacement systems, and facet joint replacement systems. My work on these joint replacement systems included my direct engagement or supervision of professionals in the inventing, designing, fabricating, testing, obtaining regulatory approvals, ensuring regulatory compliance, commercializing, and patenting of these systems.

11. My additional relevant experience, including listings of awards I have received, commercial products I have helped design, and patents for which I am a named inventor are included in my curriculum vitae, included as EX-1003 to the petition, which is incorporated-by-reference herein.

B. Materials Considered

12. In formulating my opinions expressed in this declaration, I reviewed the materials listed in the Table of Materials Considered above.

C. Additional Considerations

13. If asked to provide live testimony in this proceeding, I may use as exhibits or demonstratives various documents that refer or relate to the matters contained within this declaration or that are derived from the opinions and analyses discussed within this declaration. Additionally, I may create or supervise the creation of demonstratives to assist in understanding my testimony.

14. This declaration summarizes the entirety of the analysis I conducted and opinions I have reached in relation to the subject matter of this petition. I understand that Shoulder Innovations, LLC, ("SI") is the patent owner of the '561 Patent and may submit an opinion from another expert. If offered, I intend to respond to the opinion SI's expert provides and may, based on the opinions and analysis offered by SI's expert, modify, amend, or supplement my analysis and opinions explained in this declaration.

II. LEGAL PRINCIPLES

15. I am not a lawyer, but my opinions here necessarily involve understanding and following legal principles. Accordingly, I have been informed of certain legal principles and asked to apply them when forming my opinions and preparing this declaration.

16. I have been informed and understand that the Board construes patent claim terms during a post-grant proceeding under their plain and ordinary meaning as understood by a POSITA at the time of the invention claimed in the patent. The plain and ordinary meaning of a term is generally derived from how it is used in the patent, in accordance with the context of the claims in which the term is recited, the description of a claimed invention in the patent and its prosecution history, as well as other evidence, including evidence of the knowledge and understanding of a POSITA.

17. I have been informed and understand that, under 35 U.S.C. § 103, a claimed invention is unpatentable if the differences between the claimed invention and the prior art are such that the claimed invention, as a whole, would have been obvious to a POSITA before the effective filing date of the claimed invention.

18. I also understand that determining whether a claimed invention is obvious requires an understanding of the scope and content of the prior art, any differences between the claimed invention and the prior art, the level of skill of the

POSITA in the art to which the claimed invention is directed, and any objective indicia of non-obviousness that is present.

19. I have been informed and understand that a patent or printed publication constitutes prior art to a claimed invention if, among other things, it predates the effective filing date of the claimed invention or if the application that results in an issued patent or published patent application was effectively filed before the effective filing date of the claimed invention.

20. I have been informed and understand that prior art references considered for purpose of an obviousness determination must be analogous to the claimed invention, meaning that the prior art references must either come from the same field of endeavor as the claimed invention or be reasonably pertinent to the problem the inventor of the claimed invention was attempting to address.

21. I have been informed and understand that, when determining the appropriate level of skill of a POSITA at the effective filing date of the claimed invention, the following factors are often considered: (a) the types of problems encountered by those working in the field and prior art solutions to those problems; (b) the sophistication of the technology in question and the rapidity with which innovations occur in the field; (c) the education level of active workers in the field; and (d) the education level of the inventor.

22. I also have been informed and understand that objective indicia of non-

obviousness (also referred to as secondary considerations) may include: praise in the industry for the claimed invention; a long felt but unresolved need for the claimed invention; commercial success of products that practice the claimed invention; unexpected results of the claimed invention; and any copying of the claimed invention by others.

23. I further understand that the patent owner has the burden of coming forward with objective evidence of non-obviousness and that the patent owner has the additional burden of showing a nexus between the objective evidence of non-obviousness and the claimed invention.

24. I have been informed and understand that a claim can be obvious in light of a single prior art reference or multiple prior art references, where there is a reason or motivation to modify the single prior art reference or combine two or more references in order to achieve the claimed invention and that a POSITA would have had a reasonable expectation of success in doing so.

25. I have been informed and understand that a reason or motivation to modify a single prior art reference or combine multiple prior art references may come from common sense or the knowledge and skill of a POSITA. A POSITA may also have reason or be motivated to modify or combine references where: the modification or combination is made according to known methods that yield predictable results; the modification would have been made according to known and

predictable techniques or methods to improve similar devices to solve a known problem; the modification or combination is a substitution of one known element for another to obtain predictable results; the modification or combination would have been "obvious to try"—i.e., if would have involved a choice from a finite number of identifiable, predictable solutions, with a reasonable expectation of success; or known work in the field of endeavor would have prompted a modification or combination for use in the field based on design incentives and market forces with a reasonable expectation of success.

26. I have been informed and understand that under 35 U.S.C. § 112, a claimed invention is unpatentable unless it is particularly pointed out and distinctly claimed in a patent claim that, when read in light of the specification and prosecution history, informs a POSITA with reasonable certainty about the scope of the invention. I further understand that a patent should provide some objective guidance as to the scope of the invention and enable a POSITA to determine what falls within that scope.

27. I have been informed and understand that, under § 112, a claimed invention is unpatentable unless there is an adequate written description of the claimed invention such that a POSITA, reading the patent application directed to the claimed invention as originally filed, would recognize that the inventor in possession of the claimed invention as of the effective filing date. I further understand a claimed

invention that is not expressly described fails the written description requirement even if it is an obvious variant of a disclosed embodiment.

28. I have been informed and understand that, under § 112, a claimed invention is unpatentable unless it is described in a patent in such full, clear, concise, and exact terms as to enable a POSITA to make and use the full scope of the claimed invention without undue experimentation. I further understand whether the experimentation is undue is determined in light of the level of skill possesses by a POSITA in consideration of (1) the quantity of experimentation; (2) the amount of direction or guidance present; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.

29. I note other legal principles below where appropriate.

III. OVERVIEW OF OPINIONS

30. This declaration includes an explanation of opinions I have formed based on my independent analysis of the materials noted above. Based on my knowledge and experience—including my understanding of the knowledge, skills, experience, and perspective of a POSITA as of the effective filing date of the claimed invention—and my review of the materials listed above, it is my opinion that:

31. Claims 1, 3-9, and 11-16 are unpatentable under § 103 as obvious over

Orphanos in view of the knowledge and skill of a POSITA and Roche.

32. Claims 2 and 10 are unpatentable under § 103 as obvious over Orphanos in view of the knowledge and skill of a POSITA and Roche, and in further view of Frankle.

33. Claims 1, 3-9, and 11-16 are unpatentable under § 103 as obvious over Lefebvre in view of Orphanos and Roche.

34. Claims 2 and 10 are unpatentable under § 103 as obvious over Lefebvre in view of Orphanos and Roche, and in further view of Frankle.

35. Claims 1-16 are unpatentable under § 112 because the term "central channel" as used with respect to the baseplate is indefinite.

36. Claims 1-16 are unpatentable under § 112 because the term "Central channel ... configured to interface with the baseplate" is indefinite.

IV. BACKGROUND OF THE '561 PATENT AND APPLIED PRIOR ART

A. Background of the Art

37. The shoulder joint, or glenohumeral joint, is formed by a ball and socket relationship between the head of the humerus, or upper arm bone, and the glenoid cavity of the shoulder blade, or scapula. The head of the humerus is the "ball" of the "ball and socket," and the glenoid cavity is the "socket" of the "ball and socket."

38. The shoulder joint can deteriorate over time or be damaged due to injury. Problems associated with the shoulder joint include fractures, rotator cuff

injuries, rheumatoid arthritis, and osteoarthritis.

39. To alleviate prolonged pain associated with a damaged or deteriorated glenohumeral joint, a patient may undergo a total shoulder replacement surgery, where the glenohumeral joint is modified with implanted artificial parts.

40. There are two types of total shoulder replacement surgeries. First, there is what is called an "anatomic total shoulder replacement," where the head of the humerus is modified or reconstructed with a "ball" implant while the glenoid cavity is modified or reconstructed with a "socket" implant. This mimics the natural anatomic structure of the shoulder joint. Second, there is what is referred to as a "reverse total shoulder replacement," where the glenoid fossa is modified or reconstructed with the "ball" implant and the head of the humerus is modified with the "socket" implant. This provides a joint structure that is "reversed" from the natural anatomic structure of the shoulder joint. Prior to the 1970s, all shoulder replacement surgeries were of the first, anatomic, type; reverse total replacement surgeries began in the 1970s.

41. Many prior art reverse shoulder systems disclose a round baseplate and a glenosphere having a convex joint surface. *See, e.g.*, Hodorek, ¶ [0011], FIGS. 7-9; Lefebvre, FIGS. 18-23; Orphanos, Abstract, FIGS. 2B, 3, 7-8.

42. In such systems, the baseplate is fixed to the glenoid cavity of the scapula, while the glenosphere is fixed to the baseplate. *See, e.g.*, Hodorek, ¶ [0011].

43. Those skilled in the art appreciated at the time of the invention of the '561 Patent the possibility of using various structures to fasten the baseplate to the scapula, as well as using various structures to couple the glenosphere with the baseplate, e.g., threaded couplings and/or taper couplings (e.g., Morse taper). *Id.*

44. It was well known by a POSITA at the time of the invention of the '561 Patent that such prior art reverse shoulder systems may include a baseplate, a central channel, a central screw to be received through the central channel, a coupling member or reducing bushing to be received within the central channel, a convex glenosphere, and a glenosphere screw having threading to affix the glenosphere to the baseplate via those threads. *Id.*

45. Additionally, those skilled in the art recognized both the importance of keeping the baseplate fastened to the scapula, *see, e.g.,* Roche, 7:26-55, as well as the problem that, after implantation, the interface between the glenosphere and the baseplate may become loose, leading to misalignment between the glenosphere and the baseplate, *see, e.g.,* Hodorek, ¶ [0012].

46. Prior to the invention of the '561 Patent, compression screws and locking cap screws were used to fasten the baseplate to the scapula such that (i) the compression screw engages the scapula at a suitable angle, and (ii) the locking cap screw is screwed into the baseplate on top of the compression screw to lock the compression screw in a desired angular orientation and/or prevent the compression

screw from backing out of the scapula. *See, e.g., Roche*, 7:26-55, 10:57-59 ("The glenoid plate may allow for use of a locking cap screw which can be attached to any compression screw thereby making each screw a locking/compression screw.")

47. It was readily known at the time of the invention of the '561 Patent to provide a baseplate with through holes (e.g., central and peripheral channels) dimensioned to receive a compression screw, where the through holes also have internal threading to mate with a locking cap screw such that the locking cap screw may engage the compression screw. *See, e.g., Roche*, 7:33-38, 14:11-17.

48. Prior to the invention of the '561 Patent, adapters interposed between portions of the glenosphere and baseplate, in conjunction with fixing screws, had been used to fixedly couple the glenosphere relative to the baseplate. *See, e.g., Perego*, 12:37-63, FIGS. 7A-7D (adapter **24**, fixing screw **25**).

B. The '561 Patent

49. The '561 Patent, titled "Total Reverse Shoulder Systems and Methods," generally relates to a total reverse shoulder system including a glenoid baseplate (purple), a central screw (green), a threaded locking insert (red), a glenosphere (orange), and a secondary locking screw (blue). Ex.-1001, 3:25-28. The claimed subject matter of the '561 Patent is directed toward the embodiment shown in FIG. 8 of the '561 Patent, which is described in Column 6, lines 32-54.

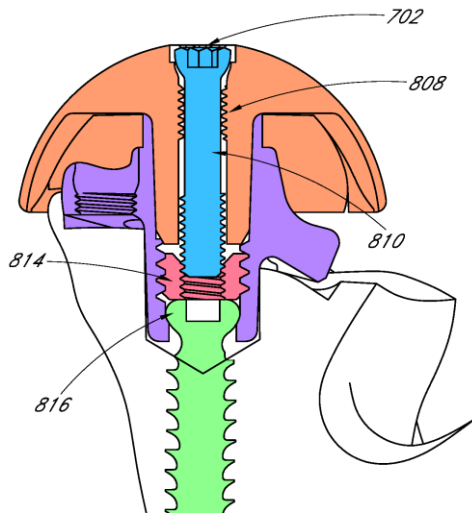
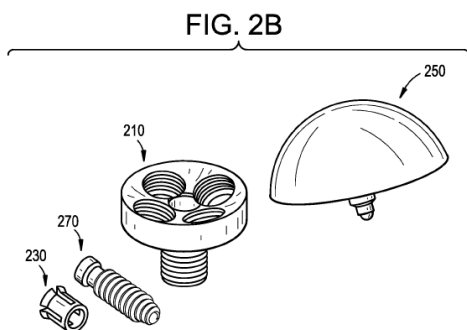
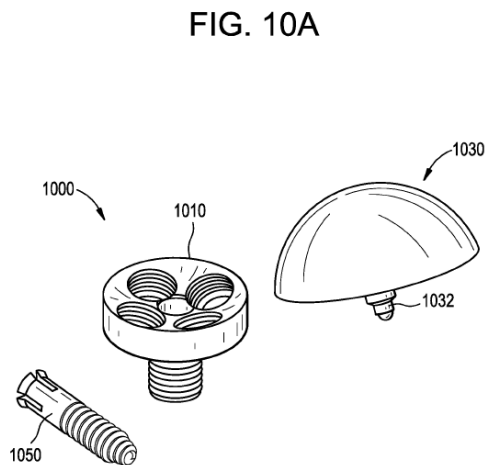
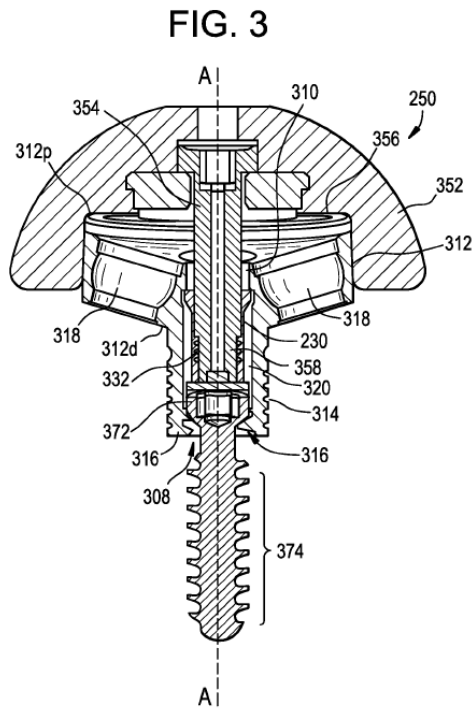
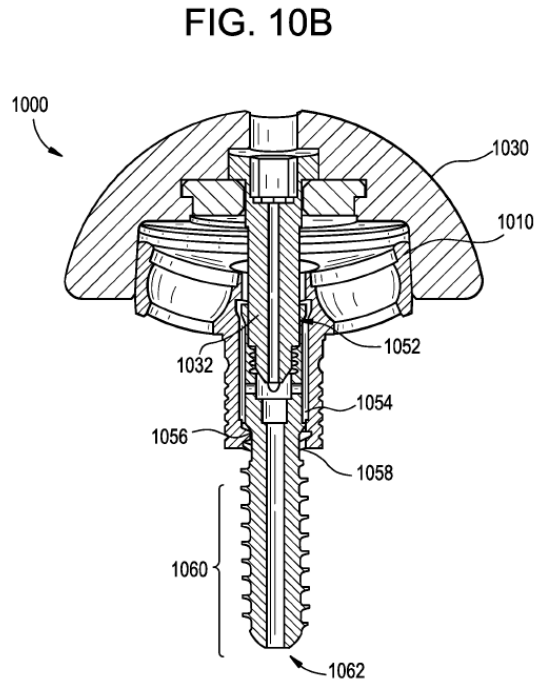
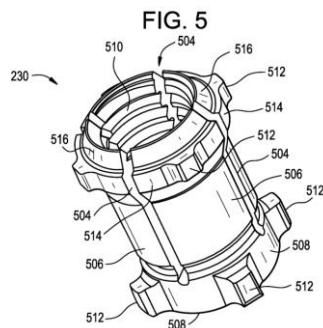
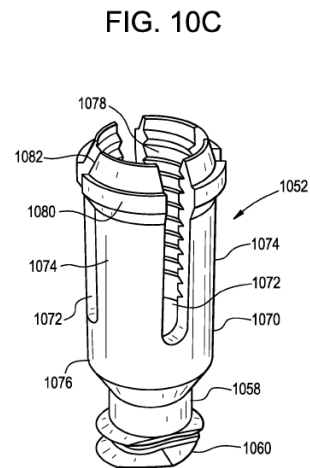


FIG. 8

C. Orphanos

50. Orphanos has a filing date of July 24, 2018, which is prior to the '561 Patent's effective filing date of November 22, 2022. I have been informed and understand that Orphanos is prior art at least under AIA 35 U.S.C. §102(a)(2). Moreover, it is my opinion that Orphanos arises from the same field of endeavor as the '561 Patent and is reasonably pertinent to the problem that the inventors of the '561 Patent sought to solve.





51. As generally shown in the figures taken from Orphanos above, Orphanos discloses two reverse shoulder implants 200, 1000, each of which may be used in a reverse shoulder procedure. See Orphanos, 2:20-24; 6:53-61. Each reverse shoulder implant 200, 1000 of Orphanos discloses a respective bone screw 270, 1050; baseplate 210, 1010; and glenosphere 250, 1030. See Orphanos, 2:23-28;

7:21-31; 17:17-38; FIGS. 2B-3, 6A, and 10A-10B. While Orphanos uses the terms baseplate, metaglene, and metaglene component interchangeably, I will use the term baseplate when referencing such components of Orphanos for sake of consistency. See Orphanos, 2:23-25, 6:53-61. The bone screw 270, 1050 is configured to fit within a central channel of the baseplate 210, 1010, driven into the glenoid bone of a patient, and thereby secure the baseplate 210, 1010 to the glenoid bone of the patient. Orphanos, 7:26-30; 16:39-26.

52. Further, for each reverse shoulder implant 200, 1000, Orphanos discloses a respective adapter, in the form of a collet 230, 1052. Each collet 230, 1052 is configured: (A) to be secured within the central channel of its respective baseplate 210, 1010, and (B) to threadably engage a respective locking screw 354, 1032 to secure the glenosphere 250, 1030 to its respective baseplate 210, 1010. See Orphanos, 10:30-56; 11:5-41. Use of the adapter 230, 1052 allows for a bone screw 270, 1050 to have a larger diameter compared to the locking screw 354, 1032; while also allowing central channel of baseplate 210, 1010 to operatively receive each of the locking screw 354, 1032 and the bone screw 270, 1050. Orphanos, 10:30-56. Orphanos teaches that the adapter 230, 1052 is a reducing bushing. Orphanos, 10:39-41.

D. Lefebvre

53. Lefebvre has a filing date of May 28, 2020, which is prior to the '561

Patent's effective filing date of November 22, 2022. I have been informed and understand that Lefebvre is prior art at least under AIA 35 U.S.C. §102(a)(2). Moreover, it is my opinion that Lefebvre arises from the same field of endeavor as the '561 Patent and is reasonably pertinent to the problem that the inventors of the '561 Patent sought to solve.

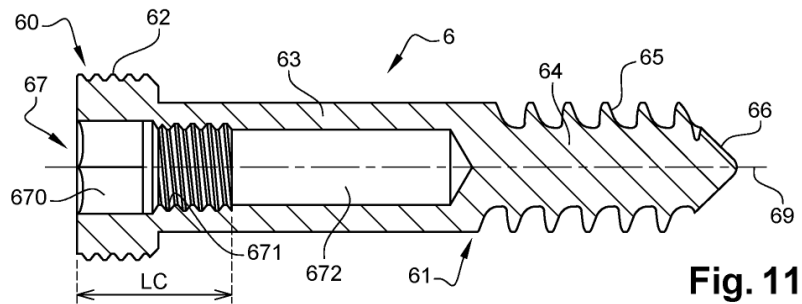


Fig. 11

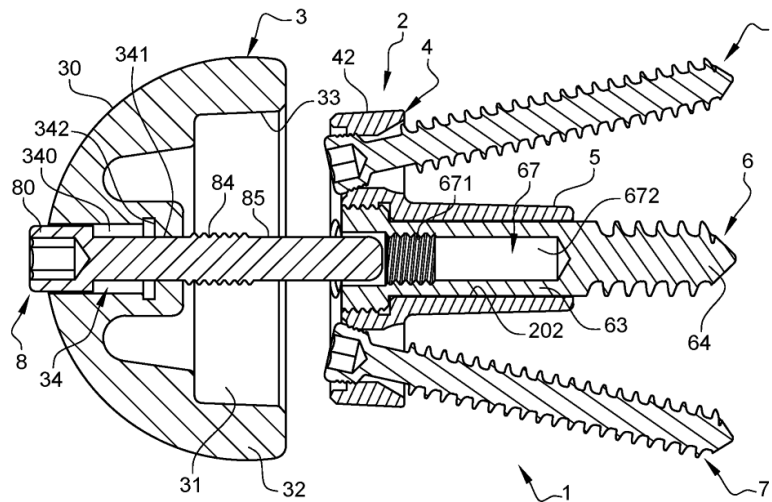


Fig. 21

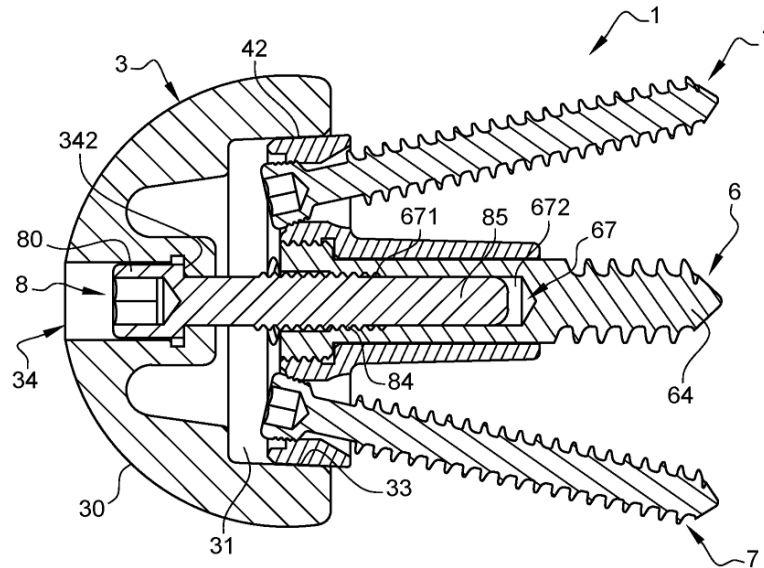


Fig. 23

54. Lefebvre discloses a glenoid implant 1 for an inverted shoulder prosthesis. Lefebvre, 6:20-22. The glenoid implant 1 includes a main anchoring screw 6 (i.e., a central screw), a base 2 (i.e., a baseplate), and a glenosphere 3. The anchoring screw 6 is inserted into a central channel defined by the base 2 and further implanted into the glenoid bone in order to anchor the base 2 to the scapula; while the glenosphere 3 is configured to be mounted onto base 2. Lefebvre, 6:23-24; 6:65-7:3; 8:32-34; 9:1-7.

55. Lefebvre also discloses the anchoring screw 6 having external tapping 62 and threading of intermediate portion 671. Together, these features of the anchoring screw are configured to: (A) be secured within the central through bore (i.e., central channel) of base 2, and (B) threadably engage a locking screw 8 to secure the glenosphere 3 to the base 2. Lefebvre, 7:4-12, 9:48-57. In other words,

these features of Lefebvre function as an adapter.

E. Roche

56. Roche has a filing date of March 23, 2007, which is prior to the '561 Patent's effective filing date of November 22, 2022. I have been informed and understand that Roche is prior art at least under AIA 35 U.S.C. §102(a)(2). Moreover, it is my opinion that Roche arises from the same field of endeavor as the '561 Patent and is reasonably pertinent to the problem that the inventors of the '561 Patent sought to solve.

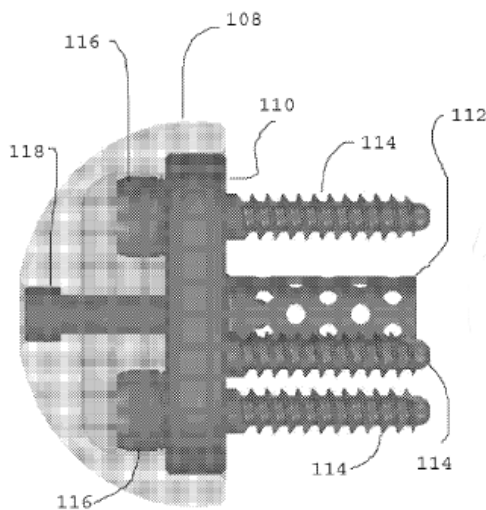


Fig. 8A

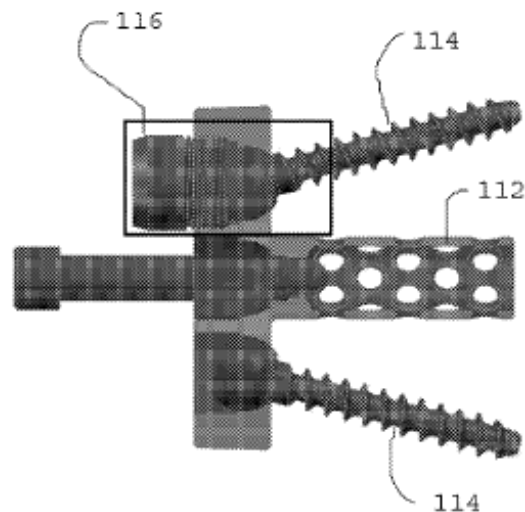
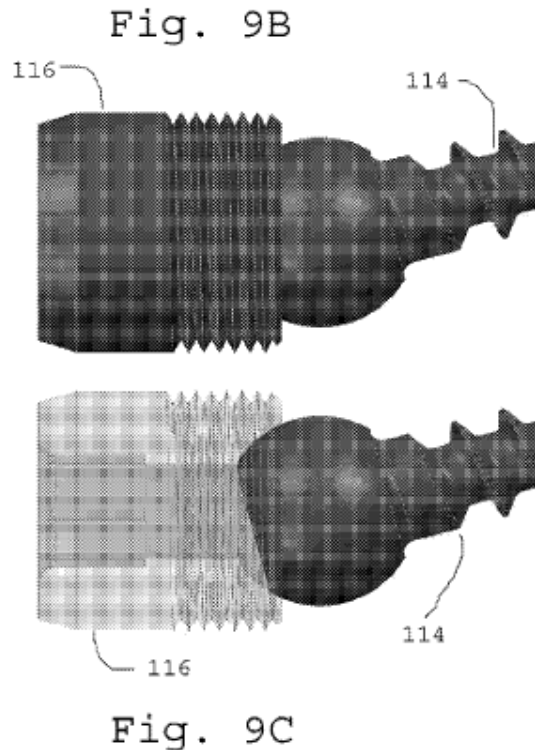


Fig. 9A



57. Roche discloses a reverse shoulder implant having a glenosphere 108, a glenoid plate 110 (i.e., a baseplate), compression screws 114, and locking cap screws 116 (i.e., locking nut). Roche describes the well-known problem of compressions screws 114 backing out of the bone after being implanted. Roche, 7:33-43. In order to stop such undesirable back out, Roche teaches the use of a locking cap screw 116 threadably inserted within screws holes of the glenoid plate 110, thereby enabling the locking cap screw 116 to engage the head of the compression screw 114 while threadably coupled to glenoid plate 110, thereby preventing the compression screw from backing out of the bone. Roche, 14:1-18.

F. Frankle

58. Frankle has a filing date of July 27, 2021, which is prior to the '561

Patent's effective filing date of November 22, 2022. I have been informed and understand that Frankle is prior art at least under AIA 35 U.S.C. §102(a)(2). Moreover, it is my opinion that Frankle arises from the same field of endeavor as the '561 Patent and is reasonably pertinent to the problem that the inventors of the '561 Patent sought to solve.

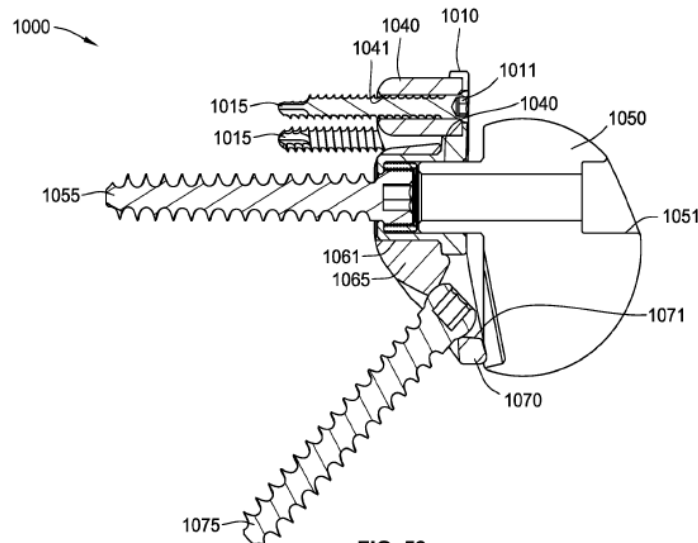


FIG. 58

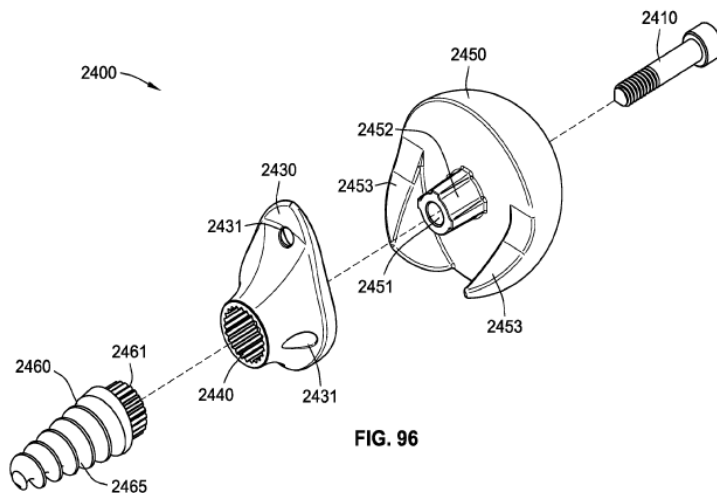


FIG. 96

59. As shown above, Frankle discloses various prior art reverse shoulder implants that are to be used in reverse shoulder procedures. See Frankle, Title, paras [0002], [0006-0008].

G. Hale

60. Hale has a filing date of March 5, 1993, which is prior to the '561 Patent's effective filing date of November 22, 2022. I have been informed and understand that Hale is prior art at least under AIA 35 U.S.C. §102(a)(2).

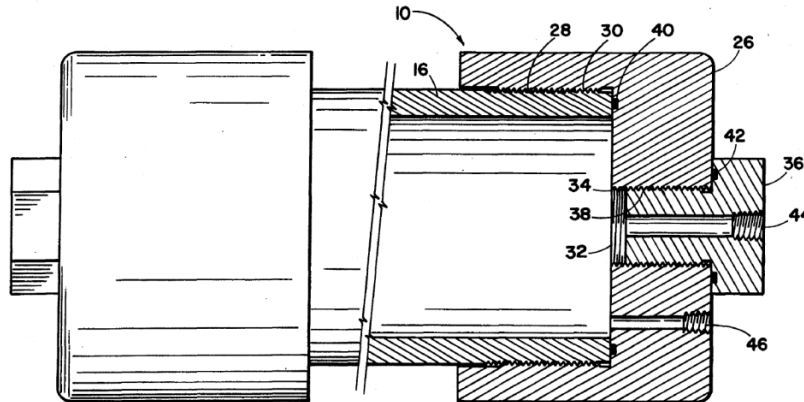


Fig. 2

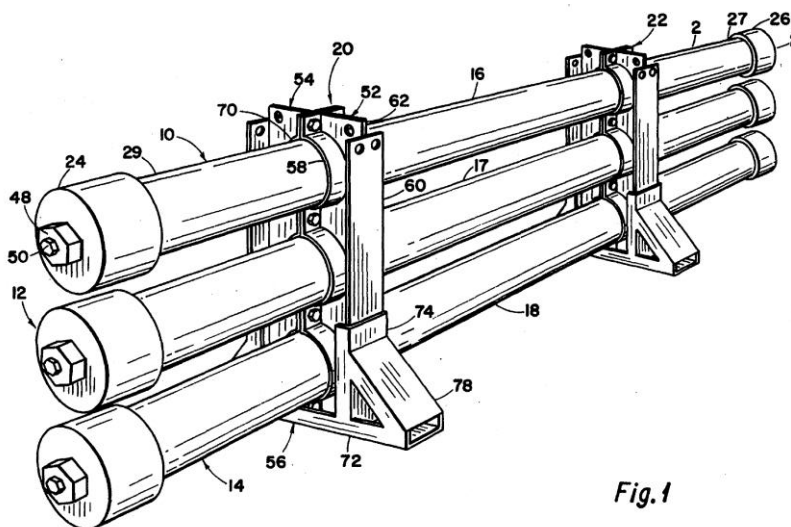


Fig. 1

61. As shown above in Fig. 2, Hale discloses a reducing bushing 36 having

outer threads that mate with threads 34 and has a central passage 44 that has inner threads that are smaller than the outer threads. Hale 5:7-17. Furthermore, Hale in Fig. 1 discloses a rotational control feature in reducing bushing 48 in the form of an external hex surface.

H. Grainger

62. Grainger discloses reducing bushings having a cylindrical body with external threads and internal threads with a smaller diameter than the external threads, and these reducing bushings have been readily available through publications since at least 2009. Grainger, pg. 3547.

63. Grainger discloses reducing bushings having a rotational control feature in the form of an external hex, and these reducing bushings have been readily available through publications since at least 2009. Grainger, pg. 3547.

I. Level of Skill of a POSITA

64. Based on the considerations set forth in the Legal Principles section, it is my opinion that the level of skill for a POSITA for the subject matter of the '561 Patent would be a bachelor's degree in mechanical or biomedical engineering, or similar discipline, with at least three years' of experience designing joint replacement systems for medical patients. In my opinion, for purposes of the level of skill, more education could make up for less practical experience and vice versa, such that a person with more than three years' experience designing joint replacement systems

could still possess the requisite skill level if they had not obtained a bachelor's degree. Conversely, a person with a more advanced degree in a relevant discipline could possess the requisite level of skill even if they had not yet reached three years of practical experience designing joint replacement systems.

65. In my experience, those working on designing joint replacement systems tend to encounter problems and challenges related to the interaction and functionality of mechanical devices and components. In this respect, the problem associated with joint replacement systems often involve straightforward mechanical issues and problems that those with mechanical or biomedical engineering, or similar disciplines would have the knowledge and education to begin solving.

66. Joint replacement systems are designed and intended to be used with medical patients, and, more particularly, designed and intended to be used inside the body of a medical patient for a prolonged period of time. Accordingly, it is my opinion that the relatively straightforward mechanical problems associated with designing the joint replacement systems can become unique or at least more complex by virtue of the medical application in which they will be used. The uniqueness and complexity primarily stem from the fact that the joint replacement system is required to interact and cooperate with the human body in which it is implanted.

67. Based on my experience, which includes working directly with and supervising professionals whose responsibilities included designing, developing,

and commercializing joint replacement systems and similar device, the experience level of active workers in this field includes those with three or more years of experience. That level of experience, coupled with the education attained by a person with at least a bachelor's degree in mechanical engineering, biomedical engineering, or similar discipline, provides the total knowledge and skill level of a person of ordinary skill in the art related to the claimed invention.

68. As noted above, in my opinion, the technology required to implement joint replacement systems tends to be fairly sophisticated inasmuch as it is required to work within the body of a medical patient.

69. Moreover, in my view, innovation in this field tends to evolve rather quickly, with new and improved joint replacement systems or their components being developed at a fast past. One can see that rapid innovation at play on the cover of the '561 Patent, which includes citations to numerous prior art references, many of which arose around the same time as the claimed invention. In other words, the high number of patents and patent applications filed and issued in this particular field in such a short amount of time indicates that innovation in the field is fast paced.

V. DETAILED EXPLANATION OF OPINIONS

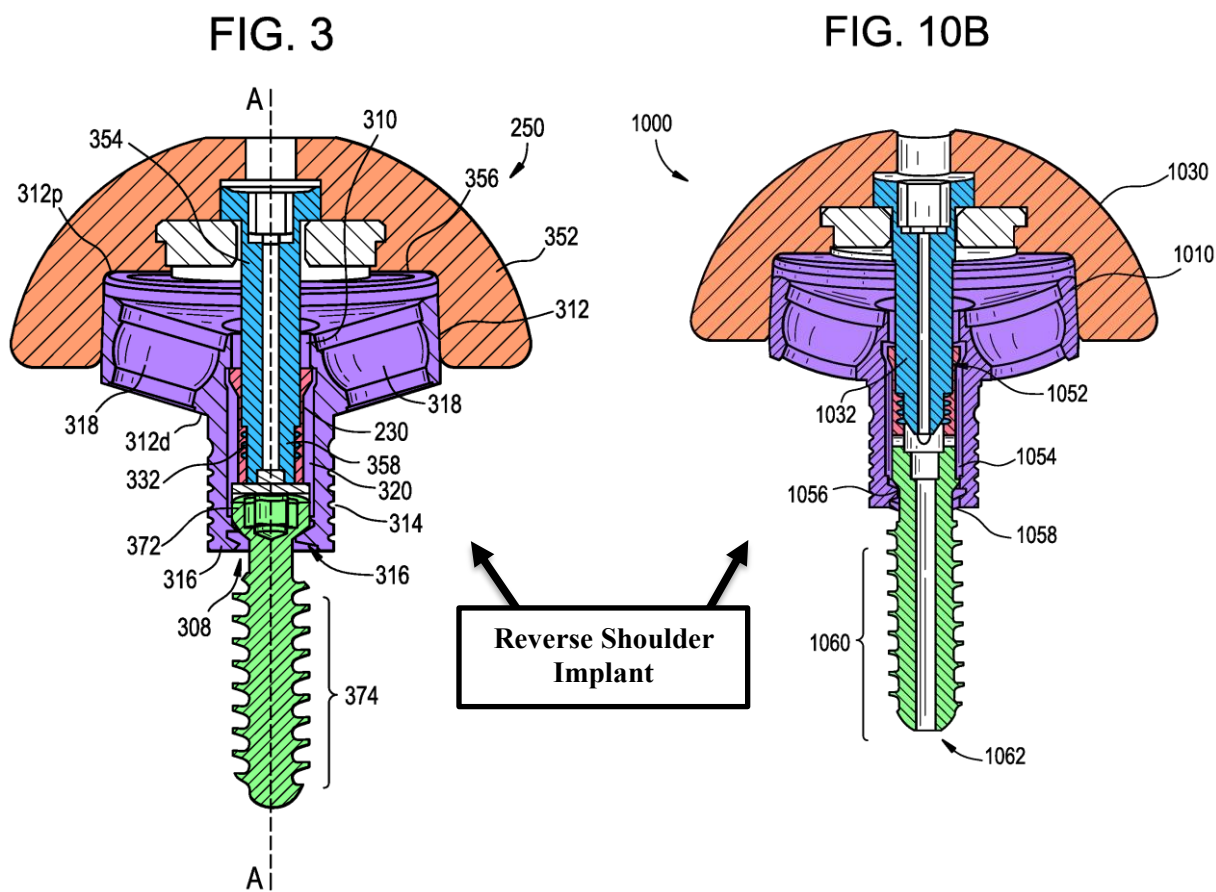
A. Ground 1: Claims 1, 3-9, and 11-16 are obvious over Orphanos in view of knowledge of a person having ordinary skill in the art and Roche

70. In my opinion, claims 1, 3-9, and 11-16 are obvious over Orphanos in

view of the knowledge and skill of a POSITA and Roche.

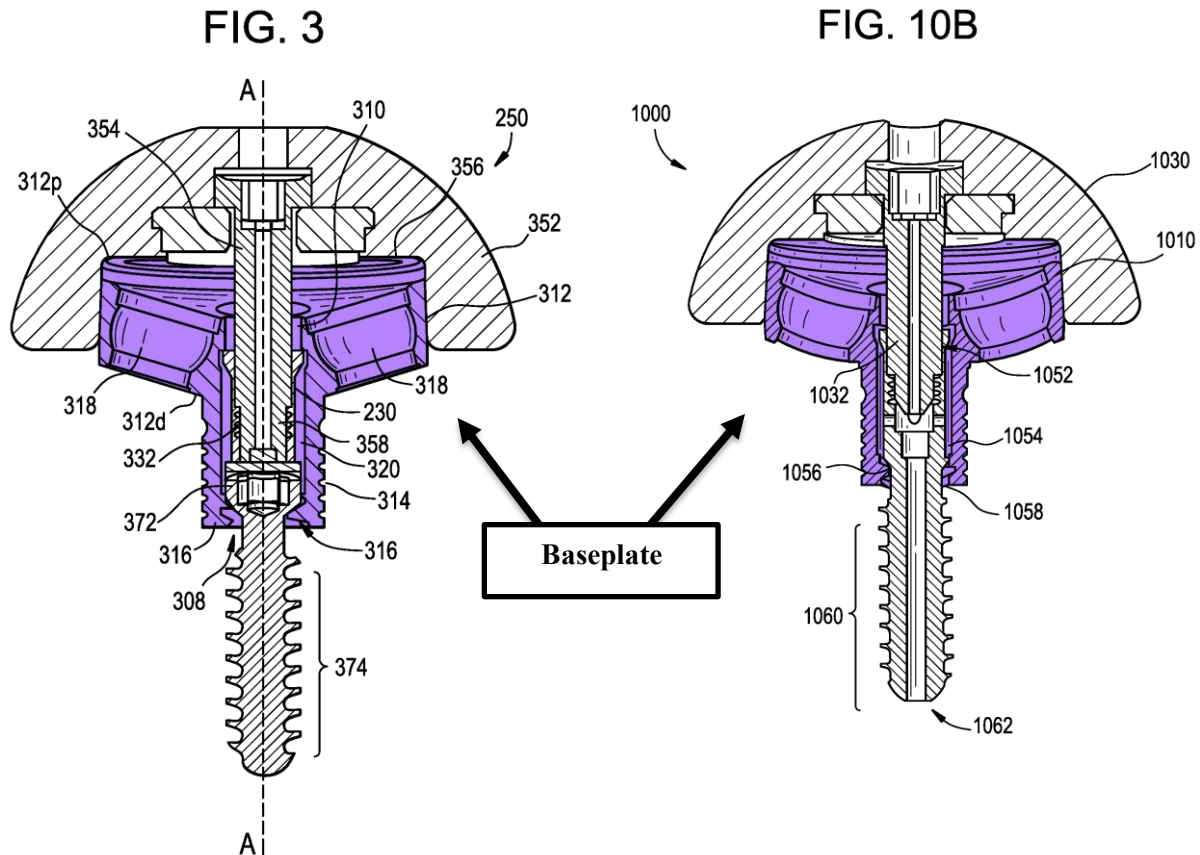
71. In my opinion, each of the limitations of claims 1, 3-9, and 11-16 are disclosed or provided by Orphanos, Roche, and/or the knowledge and skill of a POSITA for the reasons I explain below.

72. In my opinion, Orphanos discloses the preamble [1-PRE], which recites "A reverse shoulder implant, comprising," at least at column 2, lines 20-23 where Orphanos discloses "[t]he present disclosure is generally related to shoulder joint implants...These implants are often used in reverse shoulder procedures," and also FIGS. 3 and 10B, which depict the following:



73. It is my opinion, therefore, that a POSITA would understand Orphanos discloses limitation [1-PRE].

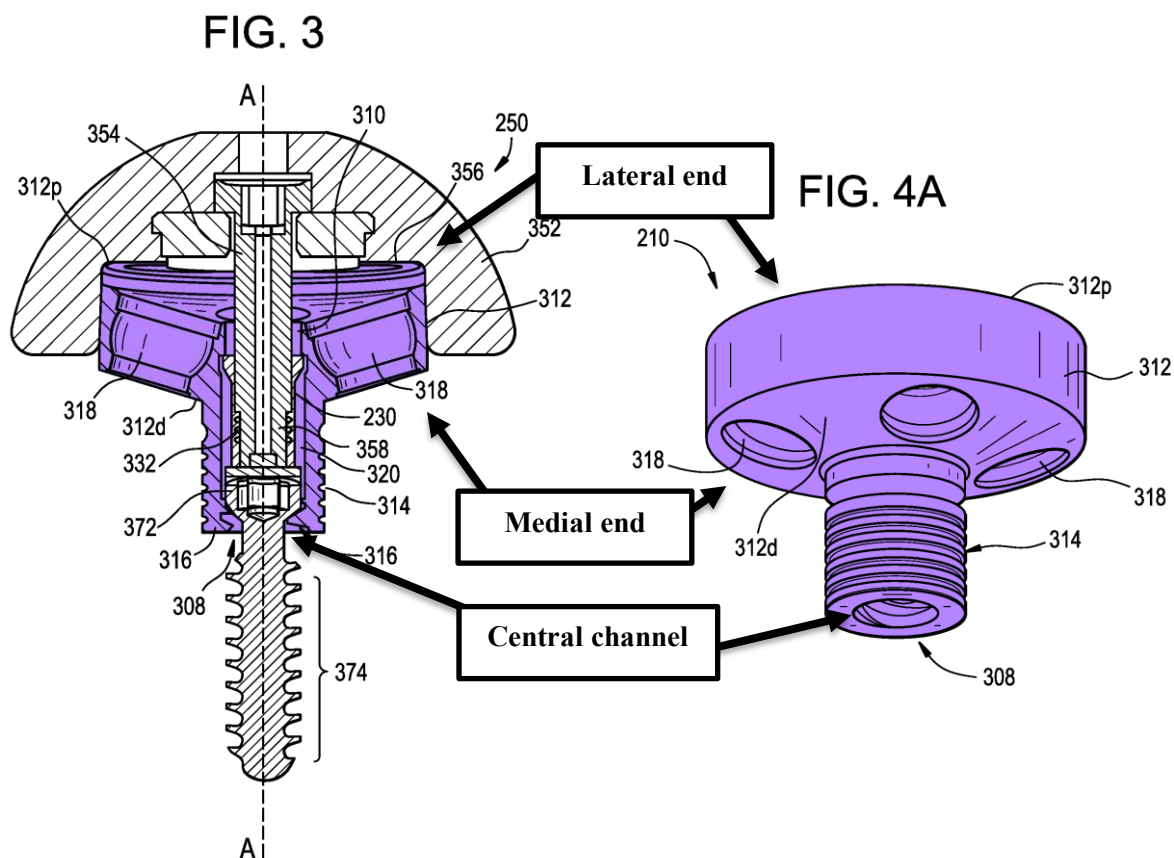
74. In my opinion, Orphanos discloses limitation [1-1], which recites "a baseplate configured to be secured to a glenoid of a scapular bone of a patient," for at least the following reasons, with reference below to FIGS. 3 and 10B of Orphanos. Column 6, lines 56-61 of Orphanos discloses "[t]ypically the shoulder joint implant includes a baseplate, sometimes referred to herein as a metaglene component (or metaglene). The baseplate 210, 1010 (purple) is configured to secure a glenosphere component (or glenosphere) (orange) to the bony anatomy of the glenoid to complete the repair." Column 7, lines 26-31 of Orphanos and Column 7, line 64 – Column 8, line 1 of Orphanos describes the baseplate 210 of the first disclosed implant 200 as being circular and configured to receive bone screws to be driven into the bony anatomy of the glenoid to help fix baseplate 210 in place. Column 17, lines 17-24 of Orphanos also describes baseplate 1010 of the second implant 1000 as being substantially similar to baseplate 210. Therefore, in my opinion, Orphanos discloses baseplate 210, 1010 (purple) of the second implant 1000 that may affix to the bony anatomy of the glenoid.



75. It is my opinion, therefore, that a POSITA would understand Orphanos discloses limitation [1-1].

76. In my opinion, Orphanos discloses limitation [1-2], which recites "the baseplate having a lateral end, a medial end, and a central channel extending therethrough from the lateral end to the medial end," for at least the following reasons, with FIGS. 3 and 4A of Orphanos provided below. Column 7, lines 36-44 of Orphanos describe a platform 312 of the baseplate 210, where "its bottom or distal-facing surface 312d engages in a complementary manner with a surface of the glenoid when implanted and a top or proximal-facing surface 312p engages in a complementary manner with the glenosphere 250 or other prosthetic component

when coupled together." Further, Column 7, lines 50-51 of Orphanos discloses "platform 312 can include a central throughbore 310 extending through a thickness of the platform 312." Column 17, lines 17-24 of Orphanos also describe that baseplate 1010 (purple) of the second implant 1000 is substantially similar to baseplate 210 (purple), such that baseplate 1010 also includes the same features as baseplate 210.

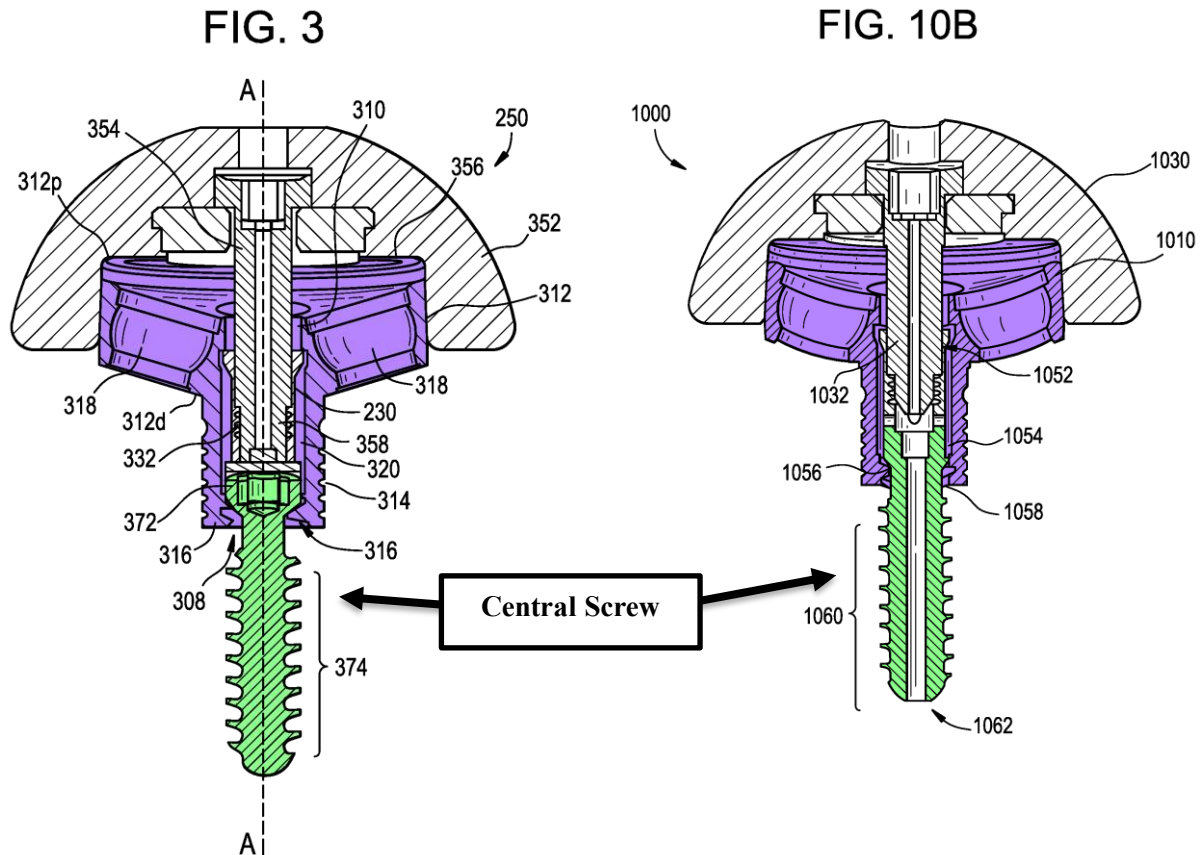


77. It is my opinion, therefore, that a POSITA would understand Orphanos discloses limitation [1-2].

78. In my opinion, Orphanos discloses limitation [1-3], which recites "a central screw sized to at least partially pass through the central channel and secure

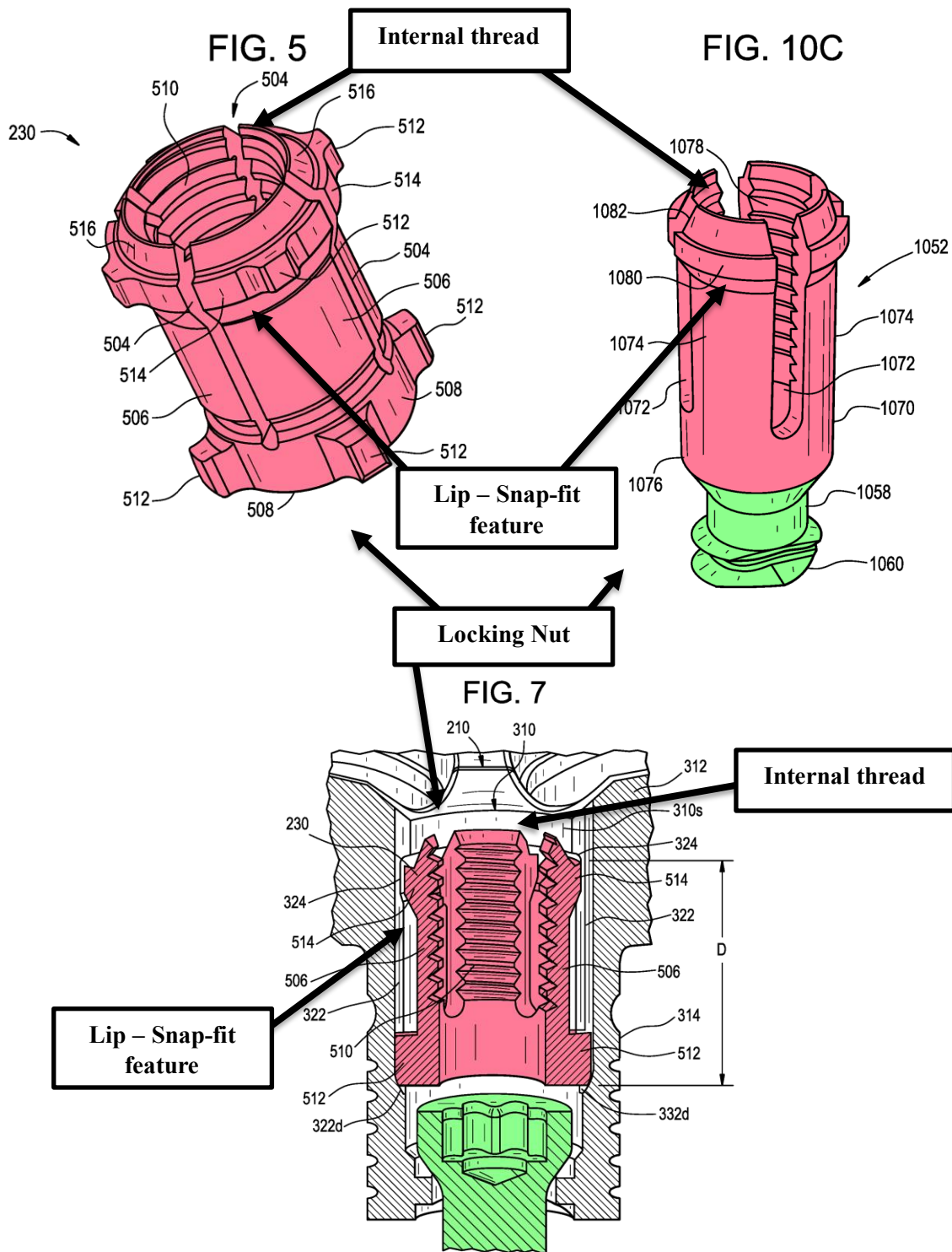
the baseplate to the glenoid of the patient," for at least the following reasons and FIGS. 3 and 10B of Orphanos provided below.

79. As described in Column 6, lines 26-30; Column 8, lines 16-23; and Column 12, lines 30-35, the first implant 200 of Orphanos discloses a central bone screw 270 (green) that can be disposed within the central throughbore 310 (i.e., a central throughbore) of the baseplate 210 such that the bone screw can be driven into the glenoid of a patient, while screwhead 372 remains engaged with baseplate 210 to secure baseplate 210 to the glenoid. As described in Column 17, lines 25-38 of Orphanos, the second implant 1000 of Orphanos discloses an integrated collet and bone screw 1050 (green) having a shoulder portion 1056, distal threaded portion 1060, and distal tip 1062 that are substantially similar to shoulder portion 604, distal threaded portion 608, and distal tip 610 of central bone screw 270.



80. It is my opinion, therefore, that a POSITA would understand Orphanos to disclose limitation [1-3].

81. In my opinion, Orphanos in view of the knowledge and skill of a POSITA renders limitation [1-4] obvious, which recites "a locking nut having a cylindrical shape, an external thread on an outside of the locking nut and an internal thread on an internal surface of the locking nut," for at least the following reasons, with FIGS. 5, 7 and 10C of Orphanos provided below.



82. As described in Column 10, lines 42-43 of Orphanos, the first implant 200 of Orphanos discloses a locking nut in the form of a collet 230 (red) having a

hollow cylinder body 502 which forms a cylindrical shape. Further, as described in Column 10, lines 52-56, collet 230 includes an internal thread on an internal surface in the form of inner threaded portion 510.

83. As described in Column 17, lines 39-58 of Orphanos, the second implant 1000 of Orphanos discloses a locking nut in the form of a collet portion 1052 (red) having a hollow cylindrical body 1070 which forms a cylindrical shape. Further, as described in Column 17, lines 59-63, collet portion 1052 includes an internal thread on an internal surface in the form of inner threaded portion 1078.

84. The collet 230 of first implant 200 and the collet portion 1052 of second implant 1000 are not shown in the drawings as having an external thread on an outside surface. However, both collet 230 and collet portion 1052 include respective radially compressible arms 506, 1074 each having a respective lip 514, 1080. As described in Column 14, lines 14-30 and Column 18, lines 34-45, Orphanos teaches radially compressible arms 506, 1074 and lips 514, 1080 are configured to secure collet 230 and collet portion 1052, respectively, within central channel throughbore 310 of baseplate 312 to form a snap-fitting engagement with the inner sidewall 310s defining central throughbore 310. The same sections of Orphanos further disclose that rather than the snap-fitting coupling with the inner sidewall 310s, the collet/collet portion 230, 1052 can include alternative features to "otherwise mate" with the inner sidewall 310s of central throughbore 310. Therefore, collets 230 (red)

and collet portion 1052 (red) include a snap-fit feature on an outer surface to engage inner sidewall 310s of the central channel throughbore 310 to secure collet 230 and collet portion 1052 within central channel throughbore 310 of baseplate 312.

85. Column 10, lines 11-15 of Orphanos teaches that snap-fitting coupling techniques and threaded coupling techniques are readily interchangeable and "known to those skilled in the art for coupling two mechanical components." Not only does Orphanos emphasize that collet 230 may "otherwise mate" (as an alternative to the snap-fitting engagement via radially compressible arms 506, 1074 and lips 514, 1080) with the inner sidewall 310s of central throughbore 310, Column 10, lines 39-41 of Orphanos discloses that collet 230 may be referred to as a reducing bushing. Reducing bushings, at the time of the invention of the '561 Patent, were well known to a POSITA to include a cylindrical body having external threads and internal threads that are smaller in diameter than the external threads. At the time of the invention of the '561 Patent and for many decades before, reducing bushings have been used as adapters to effectively reduce the diameter of an internal thread.

86. As an example of the widespread knowledge of reducing bushings in the mechanical arts at the time and before of the invention of the '561 Patent, Hale discloses a reducing bushing used in an invention in the gas storage field. As depicted in Fig. 2, Hale discloses a reducing bushing 36 having outer threads that mate with threads 34 and has a central passage 44 that has inner threads that are

smaller than the outer threads. Hale 5:7-17. Additionally, page 3547 of Grainger discloses reducing bushings having a cylindrical body with external threads and internal threads with a smaller diameter than the external threads, and these reducing bushings have been readily available through publications since at least 2009. Grainger, pg. 3547.

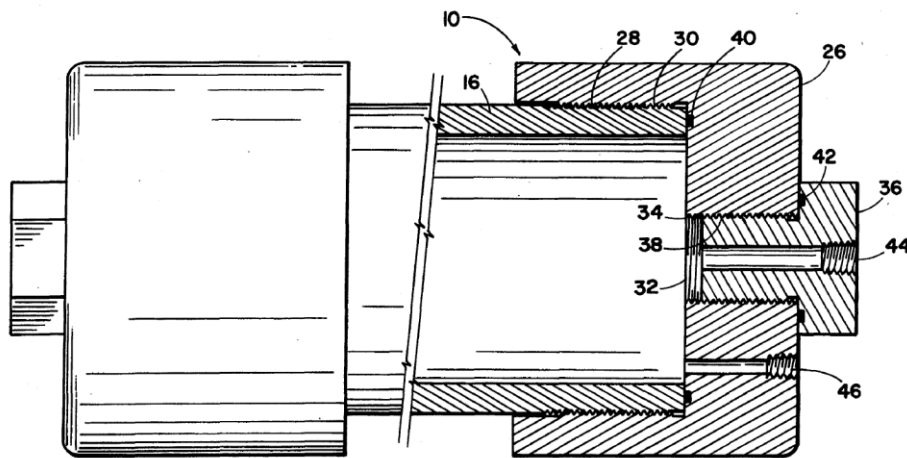


Fig. 2

87. Therefore, not only does Orphanos recognize the interchangeability between snap-fitting coupling techniques (such as those provided by lip 514, 1080 and the inner sidewall 310s) and threaded coupling techniques (e.g., an externally threaded reducing bushing and corresponding internal threaded baseplate central channel), Orphanos describes that collet 230 may otherwise mate with the inner sidewall 310s of central throughbore 310, and that collet 230 may be referred to as a reducing bushing (which is known for having a cylindrical body with external threads that engage internal threads to effectively reduce its diameter).

88. In my opinion, in view of Orphanos' teachings and general knowledge of a POSITA, a POSITA would have found it obvious to simply replace/modify the snap-fitting coupling of the collet/collet portion 230, 1052 (i.e., radially compressible arms 506, 1074 and 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) as an alternative way to secure ("otherwise mate") the substituted externally-threaded reducing bushing to baseplate 312 within its central throughbore 310. Additionally, in my opinion, it would have been well-known and obvious to a POSITA at the time of the invention of the '561 Patent to modify the inner sidewall 310s of baseplate 312 to include a known internal thread to suitably receive the external threading of the reducing bushing in order to provide suitable engagement between the inner sidewall 310s and the external threading on the collet (reducing bushing).

89. In my opinion, it would have been obvious to a POSITA that this threaded coupling would still secure the glenoid to the baseplate 210, 1010 and still permit the reduced diameter of the glenoid screw. In my opinion, Orphanos makes obvious the substitution of a known threaded reducing bushing for the snap-fitting collet/collet portion 230, 1052 because it is a substitution of a known part for a known problem—i.e., threaded couplings were a known replacement/substitution for snap-fit couplings to couple two mechanical components—with predictable

results—i.e., threaded couplings were known to successfully connect externally-threaded reducing bushings to corresponding internally-threaded channels. Orphanos, 10:11-15.

90. Also, the '561 Patent fails to describe any advantages provided by incorporating an external thread on a locking nut to engage internal threads of the central channel of the baseplate. The locking nut 814 shown in FIG. 8 of the '561 Patent is only shown with "external threads," with no descriptive text. Additionally, Column 6, lines 32-54 of the '561 Patent describe the locking nut 812 as being "connected to" the base plate without mentioning what structure achieves such connection. The only description within the '561 Patent of an outer male thread is directed toward the locking insert 600 of FIG. 6, which discloses "insert 600 can include an outer male thread 602 and configured to go into the central channel of a baseplate." Therefore, the '561 Patent is entirely silent, other than what is shown in FIG. 8, as to a locking nut having external thread that "is configured to secure the locking nut to the central channel of the baseplate." Without providing any explanation on the advantages of using an external thread on the locking nut to "secure the locking nut to [internal threads of] the central channel of the baseplate," the use of a threaded coupling (e.g., an externally-threaded reducing bushing and internal thread on the baseplate central channel) in replacement of Orphanos' snap-fitting coupling (i.e., engagement of lip 514, 1080 and the inner sidewall 310s)

between the collet /collet portion 230, 1052 and baseplate central channel is obvious as a matter of design choice.

91. Therefore, it is my opinion, that a POSITA would view limitation [1-4] as being obvious in view of Orphanos' teachings and general knowledge of a POSITA. In particular, it is my opinion that a POSITA would find it obvious to replace the snap-fitting coupling (i.e., radially compressible arms 506, 1074 with a respective lip 514, 1080 configured to engage the inner sidewall 310s) of collet/collet portion 230, 1052 with a threaded coupling (e.g., an externally threaded reducing bushing and corresponding internal threaded baseplate central channel) in order to secure collet/collet portion 230, 1052 to baseplate 312 within its central throughbore 310. Additionally, a substitution of threaded couplings (e.g., an externally threaded reducing bushing and corresponding internal threaded baseplate central channel) in replacement of snap-fitting couplings (i.e., radially compressible arms 506, 1074 with a respective lip 514, 1080 configured to engage the inner sidewall 310s) is merely a design choice well within the knowledge of a POSITA, as snap-fitting coupling features and thread-fitting coupling features are readily recognized by a POSITA as being interchangeable.

92. This replacement of Orphanos' snap-fitting coupling (i.e., engagement of lip 514, 1080 and the inner sidewall 310s) with a threaded coupling (e.g., an externally-threaded reducing bushing and internal thread on the baseplate central

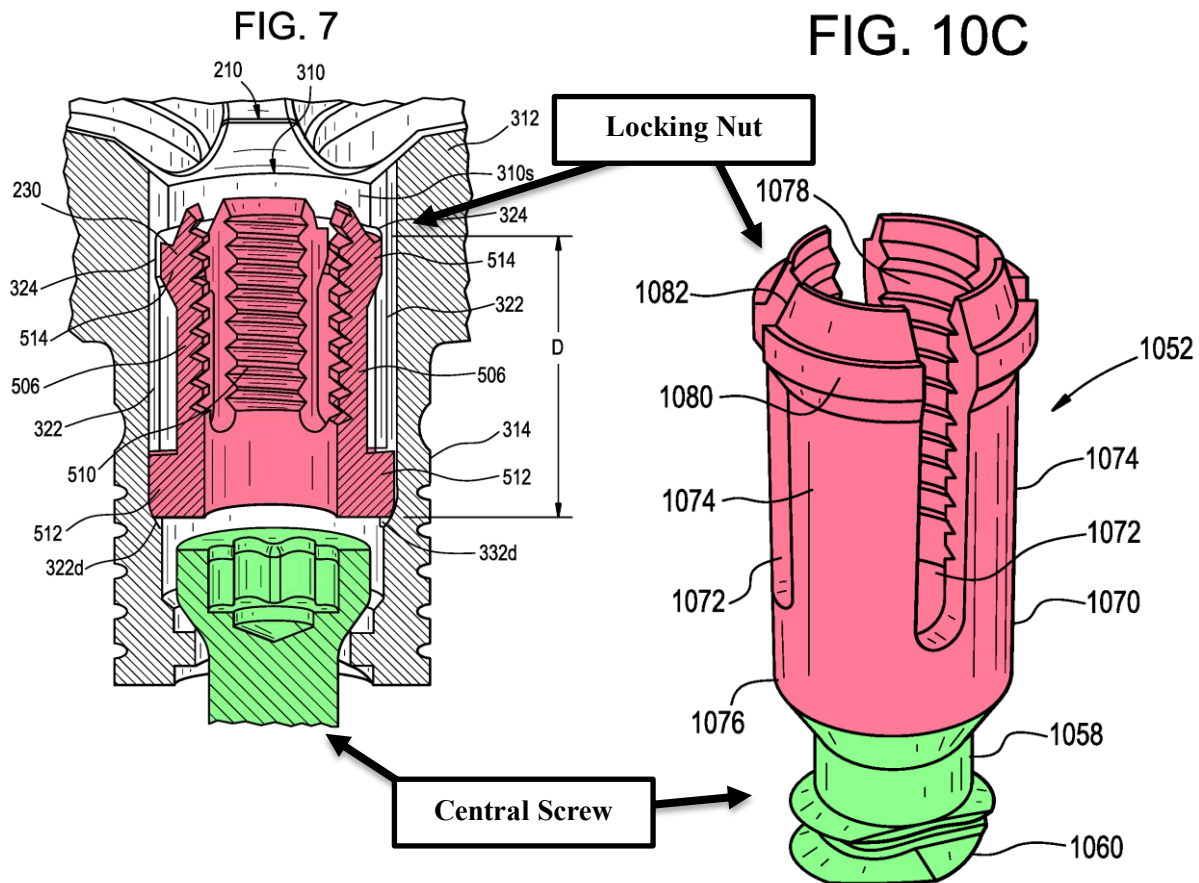
channel) would have been a mere substitution of one known element for another known element to obtain very predictable results as demonstrated by Orphanos itself and well known to a POSITA at the time of the invention of the '561 Patent.

93. Orphanos' teachings would have made this modification of Orphanos' snap-fitting coupling to a threaded coupling obvious to try because it would have involved choosing from the finite number of known and predictable reducing bushings at the time of the invention of the '561 Patent which would have included an externally threaded reducing bushing and the corresponding internally threaded central channel with a reasonable expectation of success.

94. Further, modifying Orphanos to include threaded coupling (e.g., an externally threaded reducing bushing and internal threads on the baseplate central channel) would not render the device of Orphanos inoperable for its intended purposes. While one embodiment of Orphanos teaches the use of keys 512 to provide resistance to torsional rotation, such a feature is merely optional, since other embodiments of Orphanos (e.g., implant 1000) have a collet 1052 that does not include keys 512, nor resists torsional rotation. Further, adding keys to resist rotation in implant 1000 would render collet portion 1052 non-functional, since it would prevent threaded distal portion 1060 from being insertable (by threaded rotation) into the bone.

95. In my opinion, Orphanos discloses limitation [1-5], which recites "the

locking nut configured to engage the central screw when the central screw and baseplate are implanted within the medical patient," for at least the following reasons, with FIGS. 7 and 10C of Orphanos provided below.



96. As shown in FIG. 10C of Orphanos, the second implant 1000 of Orphanos teaches a locking nut in the form of collet portion 1052. As described in Column 17, lines 39-47 of Orphanos, collet portion 1052 is fixedly coupled to proximal head 1054 of the screw. Therefore, collet portion 1052 is configured to engage the central screw when the central screw and baseplate are implanted within the medical patient.

97. As shown in FIG. 7 of Orphanos, and as described in Column 13, lines 36-52 of Orphanos, the first implant 200 of Orphanos teaches a locking nut in the form of collet 230 being directly adjacent to central bone screw 270 when the central bone screw 270 and baseplate 312 are implanted within the medical patient. As exemplified by the teachings of Roche at Column 7, lines 33-43 and Column 14, lines 1-18, a POSITA readily appreciates that back driving occurs to an implanted compression screw. Since the collet 230 of Orphanos is directly adjacent and above central bone screw 270, a POSITA would readily appreciate that the collet 230 is configured to engage the central bone screw 270 when the central bone screw 270 and baseplate 312 are implanted within the medical patient. In particular, collet 230 is configured for such engagement when central bone screw 270 back drives toward collet 230.

98. Further, as mentioned above, Column 14, lines 1-18 of Roche teaches utilizing locking cap screws 116 having external threads meshed within glenoid plate 110 in order to engage compression screws 114 after being implanted to prevent compression screws 114 from backing out. As also described above in paragraphs 83-92 above, a POSITA would readily appreciate the use of a threaded coupling (e.g., an external thread on Orphanos' reducing bushing and corresponding internal threads on Orphanos' baseplate central channel) as a simple substitution of Orphanos' snap-fit coupling to secure the glenoid to the baseplate 210/1010 and

permit the reduced diameter of the glenoid screw.

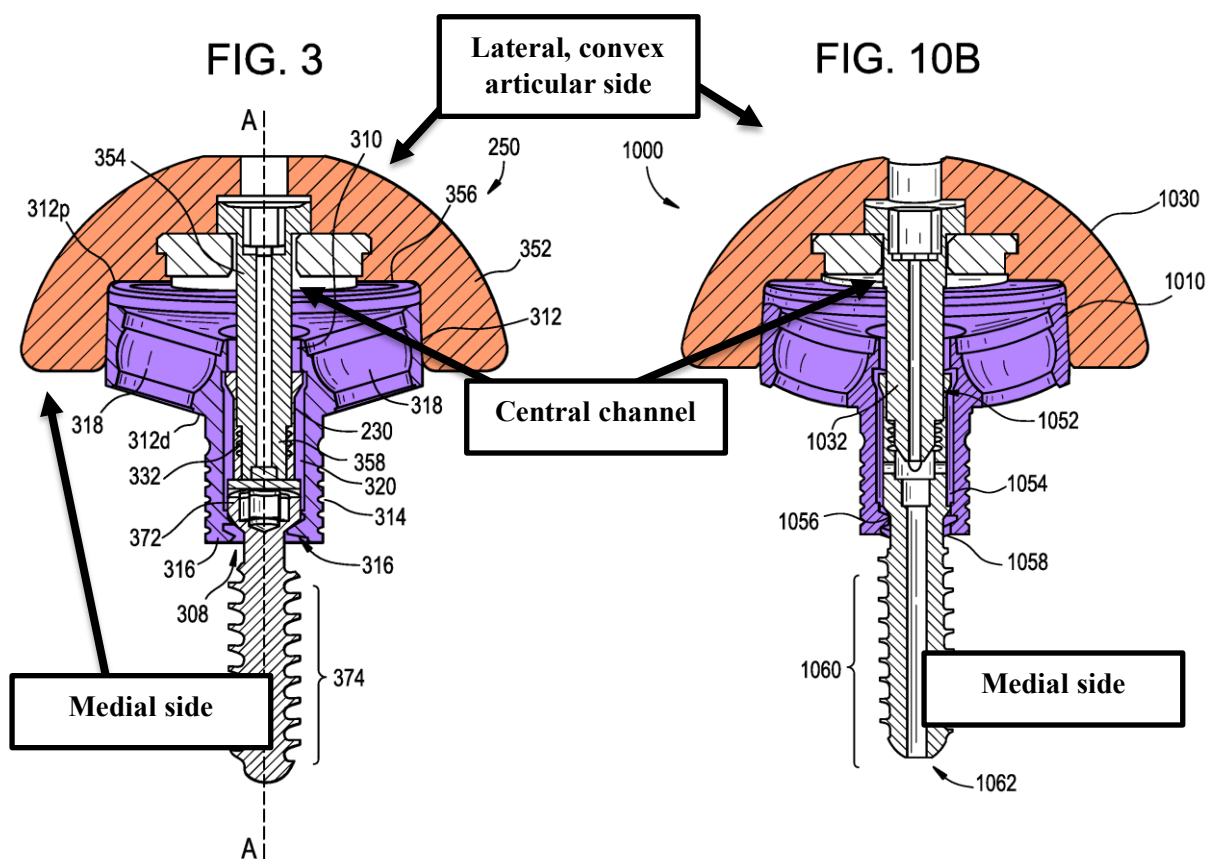
99. In my opinion, it would have been obvious to a POSITA to incorporate the teachings of Roche to modify the location of an externally threaded reducing bushing to engage in central bone screw 270 prior to bone screw 270 initially backing out. Such a modification would provide immediate contact between the externally threaded reducing bushing and central bone screw 270, which would provide enhanced resistance to back out by central bone screw 270.

100. Therefore, in my opinion, a POSITA would understand Orphanos discloses limitation [1-5], as well as render limitation [1-5] obvious in light of the knowledge and skill of a POSITA and the teachings of Roche.

101. In my opinion, Orphanos in view of the knowledge and skill of a POSITA renders limitation [1-6] obvious, which recites: "wherein the external thread is configured to secure the locking nut to the central channel of the baseplate," for at least the reasons described above and following reasons with reference to FIG. 7 of Orphanos provided below.

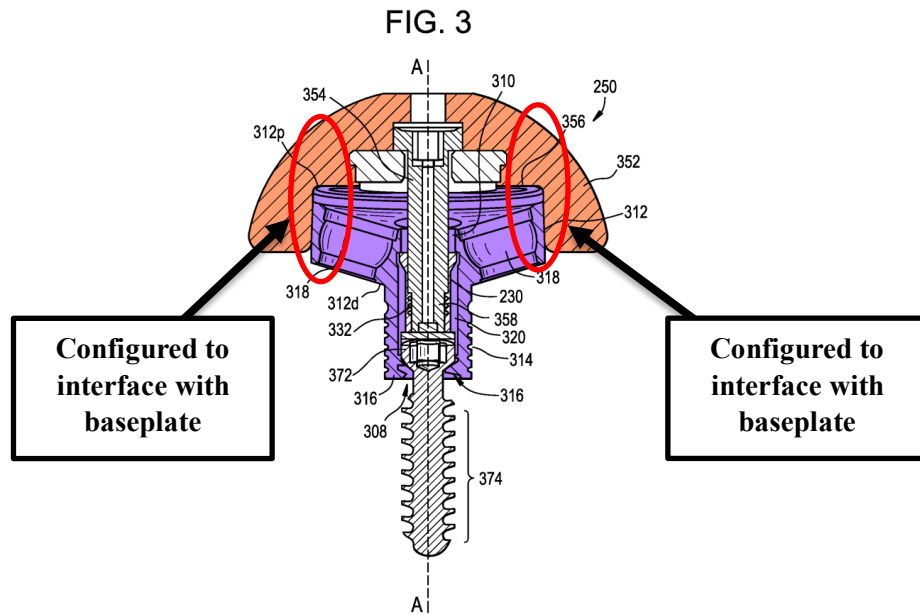
view of the knowledge and skill of a POSITA renders limitation [1-6] obvious.

104. In my opinion, Orphanos discloses limitation [1-7], which recites "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," for at least the following reasons, with reference to FIGS. 3 and 10B provided below.



105. As shown in FIGS. 3 and 10B of Orphanos, each implant 200, 1000 of Orphanos includes a respective glenosphere 250, 1030 (orange) having a lateral, convex articular side; a medial side, and a central channel. As described in Column 8, lines 44-62 and Column 15, lines 1-6, each glenosphere 250, 1030 is configured

to surround and to interface with baseplate 312, 1010 via a taper lock of the distal facing surface of the glenosphere 250, 1030 and the proximal facing surface of the baseplate 210 (highlighted by the red ovals).

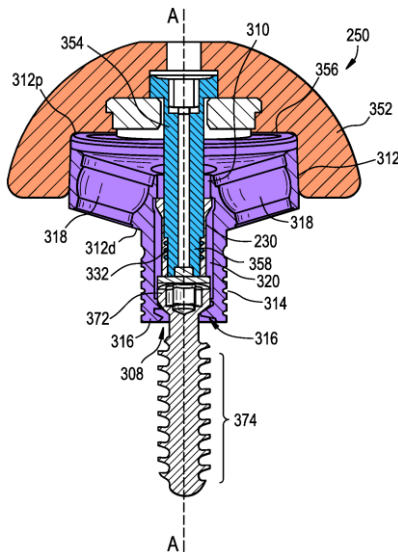


106. As demonstrated above in annotated FIG. 3, the inner surfaces of the glenosphere 250 (orange) define a central channel. Thus, the central channel of glenosphere 250 is configured to interface with its respective baseplate 210 via at least the interfacing surfaces of the inner surfaces of these inner surfaces of glenosphere 210 and the exterior surfaces of the baseplate (as highlighted with red ovals above in FIG. 3; the same interfacing surfaces are also found in reverse glenoid implant of FIG. 10).

107. Further, as described in Column 10, lines 4-29; Column 15, lines 11-31; and column 17, lines 17-24 and demonstrated below in annotated FIGS. 3 and 10, each central channel of glenosphere 250, 1030 is configured to interface with

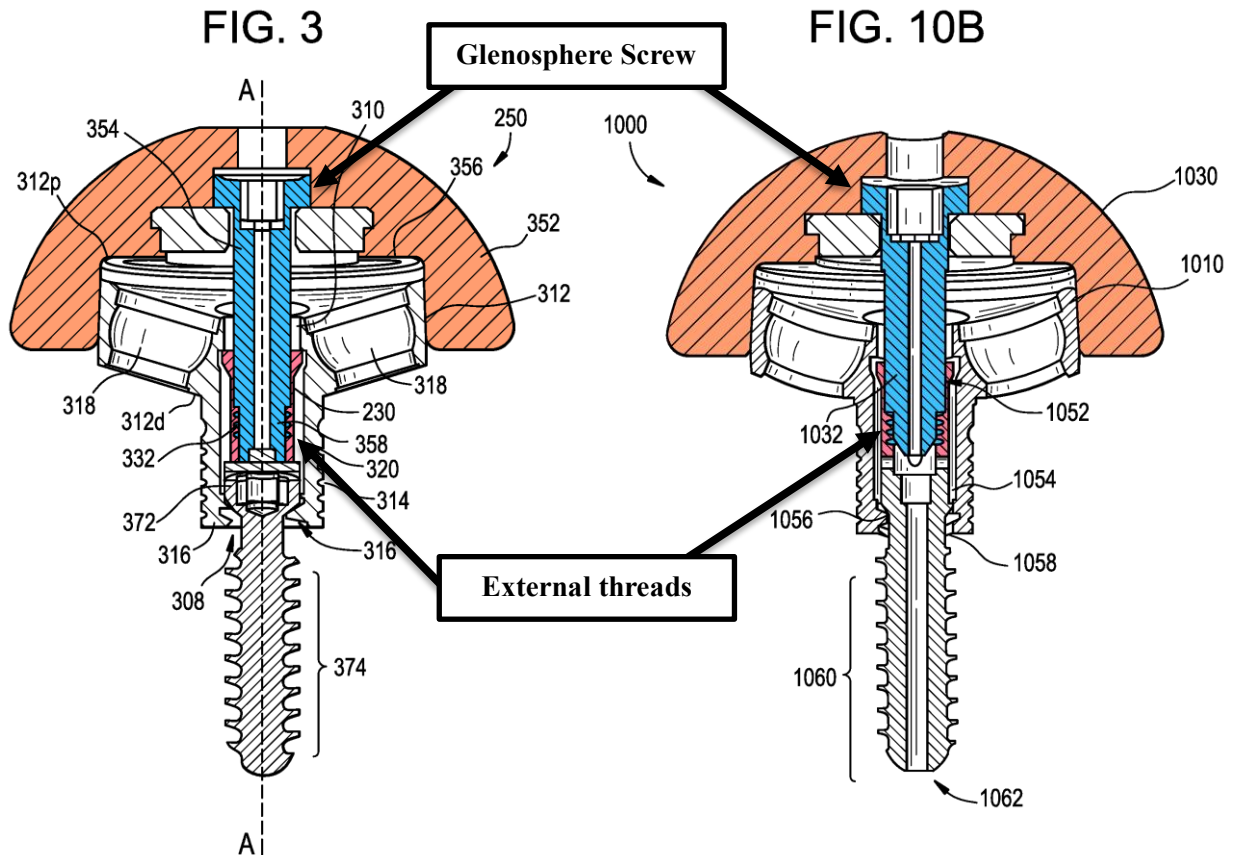
their respective baseplate 210, 1010 via at least an interfacing element in the form of a glenosphere locking screw 354, 1032 (blue).

FIG. 3



108. It is my opinion, therefore, that a POSITA would understand Orphanos to disclose limitation [1-7].

109. In my opinion, Orphanos discloses limitation [1-8], which recites "a glenosphere screw, sized to pass at least partially within the glenosphere central channel and having external threads sized to secure the glenosphere screw to the internal thread on the internal surface of the locking nut to secure the glenosphere to the locking nut," for at least the following reasons, with reference to FIGS. 3 and 10B of Orphanos provided below.



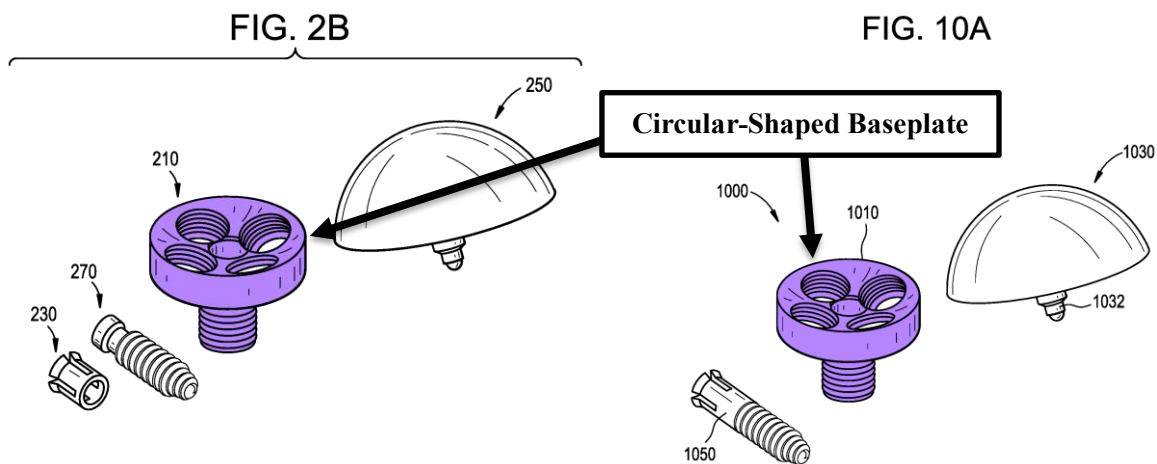
110. Column 10, lines 39-26 and Column 11, lines 19-27 of Orphanos describe the first implant 200 of Orphanos having a glenosphere locking screw 354 (blue) that is configured to threadably engage inner threaded portion 332 of collet 230, which secures the glenosphere locking screw 354 to the collet 230 (i.e., locking nut). Similarly, Column 18, lines 59-63 of Orphanos describes the second implant 1000 of Orphanos having glenosphere locking screw 1032 (blue) having external threads that are configured to threadably engage an inner threaded portion 1078 of collet portion 1052, which secures the glenosphere locking screw 1032 to the collet portion 1052 (i.e., locking nut).

111. It is my opinion, therefore, that a POSITA would understand Orphanos

to disclose limitation [1-8].

112. In my opinion, Orphanos discloses limitation [3-1], which recites "The reverse shoulder implant of claim 1, wherein the glenosphere is configured to at least partially surround an external surface of the baseplate," at least as described regarding limitation [1-7] and as shown in Orphanos, FIGS. 3 and 10B. As described in Column 8, lines 44-62 and Column 15, lines 1-6, each glenosphere 250, 1030 is configured to surround and to interface with baseplate 312, 1010 via a taper lock of the distal facing surface of the glenosphere 250, 1030 and the proximal facing surface of the baseplate 210. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Orphanos.

113. In my opinion, Orphanos discloses limitation [4-1], which recites "The reverse shoulder implant of claim 1, wherein the baseplate has a circular shape," at least as described regarding limitation [1-1] and as shown in Orphanos, FIGS. 2B and 10A.



114. Therefore, in my opinion, a POSITA would understand limitation [4-1] to be disclosed by Orphanos.

115. In my opinion, Orphanos discloses limitation [5-1], which recites "The reverse shoulder implant of claim 1, wherein the glenosphere is configured to surround the baseplate," at least as described regarding limitation [1-7] and as shown in Orphanos, FIGS. 3 and 10B. As described in Column 8, lines 44-62 and Column 15, lines 1-6, each glenosphere 250, 1030 is configured to surround and to interface with baseplate 312, 1010 via a taper lock of the distal facing surface of the glenosphere 250, 1030 and the proximal facing surface of the baseplate 210. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Orphanos.

116. In my opinion, Orphanos discloses limitation [6-1], which recites "The reverse shoulder implant of claim 1, wherein the glenosphere is configured to be secured to the baseplate with a morse taper," at least as described regarding limitation [1-7] and as shown in Orphanos, FIGS. 3 and 10B. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Orphanos.

117. In my opinion, Roche discloses limitation [7-1], which recites "The reverse shoulder implant of claim 1, wherein a diameter of the locking nut is greater than a length of the locking nut," is shown in FIG. 53 of Roche. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Orphanos in

view of Roche.

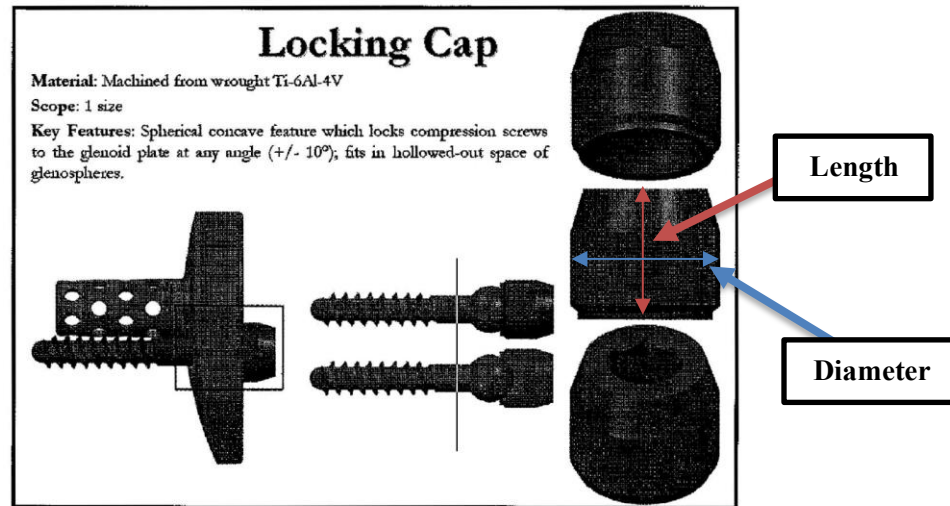


Fig. 53

118. In addition, the '561 Patent does not provide any disclosure as to how the diameter of the locking nut being greater than its length has any operational or functional benefit. As such, the modification of Orphanos' known locking nut (i.e., collet) to meet this limitation would have been obvious as a mere design choice.

119. Moreover, such a modification would have been obvious to a person skill in the art as a POSITA would be motivated to keep the length less than the diameter to provide a low profile to the locking nut.

120. In my opinion, Orphanos in view of the knowledge and skill of a POSITA renders limitation [8-1] obvious, which recites "The reverse shoulder implant of claim 1, wherein the locking nut comprises a rotational control feature configured to receive a tool to enable twisting of the locking nut to secure it to the

central screw." As noted above with regards to limitation [1-4], Orphanos discloses the substitution of the collet with other mating connections (e.g., other types of reducing bushings). As also noted above, Orphanos in view of the knowledge in the art at the time of the invention made obvious that such reducing bushings could include externally threaded reducing bushings. It would be obvious to a POSITA for the locking nut to also include the rotational control feature of claim 8, as any threaded device must have this rotational control feature to facilitate threaded engagement.

121. Furthermore, Roche in Fig. 7A discloses a rotational control feature in locking cap 116 in the form of an internal hex surface as shown. Additionally, Hale in Fig. 1 discloses a rotational control feature in reducing bushing 48 in the form of an external hex surface. Moreover, page 3547 of Grainger discloses reducing bushings having a rotational control feature in the form of an external hex, and these reducing bushings have been readily available through publications since at least 2009. Grainger, pg. 3547. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Orphanos in view of Roche, Hale, or the knowledge and skill of a POSITA.

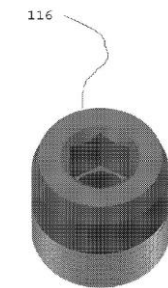


Fig. 7A

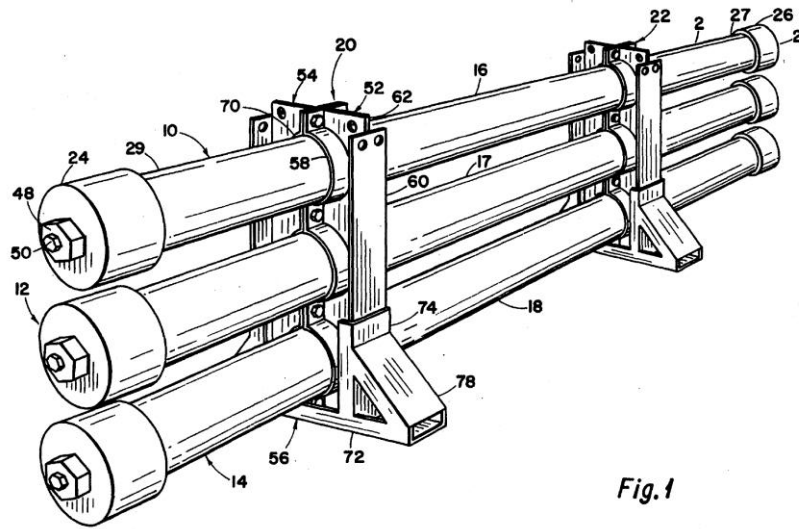


Fig. 1

122. In my opinion, Orphanos in view of the knowledge and skill of a POSITA and Roche discloses and makes obvious all the limitations of claim 9, which recites language that can be found in other claims already discussed above. By way of illustration, the following language of claim 9 on the left is materially indistinct from the language of other claims on the right as set forth below in the table. My opinion that Orphanos, the knowledge and skill of a POSITA, and Roche disclose all limitations of claim 9 on the left is based on my discussion regarding the limitations from other claims indicated on the right.

CLAIM 9	OTHER CLAIMS
[9-PRE] A reverse shoulder implant, comprising:	See previous discussion at [1-PRE]: "A reverse shoulder implant, comprising,"
[9-1] a baseplate configured to be secured to a glenoid of a scapular bone of patient,	See previous discussion at [1-1]: "a baseplate configured to be secured to a glenoid of a scapular bone of a patient,"

CLAIM 9	OTHER CLAIMS
[9-2] the baseplate having a lateral end, a medial end, and a central channel extending therethrough from the lateral end to the medial end;	See previous discussion at [1-2]: "the baseplate having a lateral end, a medial end, and a central channel extending therethrough from the lateral end to the medial end,"
[9-3] a central screw sized to at least partially pass through the central channel and secure the baseplate to the glenoid of the patient;	See previous discussion at [1-3]: "a central screw sized to at least partially pass through the central channel and secure the baseplate to the glenoid of the patient,"
[9-4] a locking nut having a cylindrical shape, an external thread on an outside surface of the locking nut and an internal thread on an internal surface of the locking nut,	See previous discussion at [1-4]: "a locking nut having a cylindrical shape, an external thread on an outside of the locking nut and an internal thread on an internal surface of the locking nut"
[9-5] the locking nut configured to engage the central screw when the central screw and baseplate are implanted within the medical patient,	See previous discussion at [1-5]: "the locking nut configured to engage the central screw when the central screw and baseplate are implanted within the medical patient"
[9-6] wherein the external thread is configured to engage the central channel of the baseplate; and	See previous discussion at [1-6]: "wherein the external thread is configured to secure the locking nut to the central channel of the baseplate." It is noted that the external thread secures the locking nut to the central channel of the baseplate (as recited in claim 1) by engaging the central channel of the baseplate (as recited in claim 9).

CLAIM 9	OTHER CLAIMS
[9-7] 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; and	See previous discussion at [1-7]: "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"
[9-8] a glenosphere screw, sized to pass at least partially within the glenosphere central channel and having external threads sized to secure the glenosphere screw to the internal thread on the internal surface of the locking nut to secure the glenosphere to the locking nut.	See previous discussion at [1-8]: "a glenosphere screw, sized to pass at least partially within the glenosphere central channel and having external threads sized to secure the glenosphere screw to the internal thread on the internal surface of the locking nut to secure the glenosphere to the locking nut"

123. Thus, in my opinion, a POSITA would understand that Orphanos in view of the knowledge and skill of a POSITA and Roche and Hale disclose all the limitations of claim 9.

124. In my opinion, Orphanos discloses limitation [11-1], which recites "The reverse shoulder implant of claim 9, wherein the glenosphere is configured to at least partially surround an external surface of the baseplate," at least as described regarding limitation [1-7] and as shown in Orphanos, FIGS. 3 and 10B. As described in Column 8, lines 44-62 and Column 15, lines 1-6, each glenosphere 250, 1030 is configured to surround and to interface with baseplate 312, 1010 via a taper lock of the distal facing surface of the glenosphere 250, 1030 and the proximal facing surface of the baseplate 210. Therefore, in my opinion, a POSITA would understand

this limitation to be disclosed by Orphanos.

125. In my opinion, Orphanos discloses limitation [12-1], which recites "The reverse shoulder implant of claim 9, wherein the baseplate has a circular shape," at least as described regarding limitation [1-1] and as shown in Orphanos, FIGS. 2B and 10A. Therefore, in my opinion, a POSITA would understand limitation [4-1] to be disclosed by Orphanos.

126. In my opinion, Orphanos discloses limitation [13-1], which recites "The reverse shoulder implant of claim 9, wherein the glenosphere is configured to surround the baseplate," at least as described regarding limitation [1-7] and as shown in Orphanos, FIGS. 3 and 10B. As described in Column 8, lines 44-62 and Column 15, lines 1-6, each glenosphere 250, 1030 is configured to surround and to interface with baseplate 312, 1010 via a taper lock of the distal facing surface of the glenosphere 250, 1030 and the proximal facing surface of the baseplate 210. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Orphanos.

127. In my opinion, Orphanos discloses limitation [14-1], which recites "The reverse shoulder implant of claim 9, wherein the glenosphere is configured to be secured to the baseplate with a morse taper," at least as described regarding limitation [1-7] and as shown in Orphanos, FIGS. 3 and 10B. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Orphanos.

128. In my opinion, Roche discloses limitation [15-1], which recites "The reverse shoulder implant of claim 9, wherein a diameter of the locking nut is greater than a length of the locking nut," at least as described regarding limitation [7-1] and as shown in FIG. 53 of Roche. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Orphanos in view of Roche.

129. In my opinion, Orphanos in view of the knowledge and skill of a POSITA renders limitation [16-1] obvious, which recites "The reverse shoulder implant of claim 9, wherein the locking nut comprises a rotational control feature configured to receive a tool to enable twisting of the locking nut to secure it to the central screw," at least as described regarding limitation [8-1]. As noted above with regards to limitation [1-4], Orphanos discloses the substitution of the collet with other mating connections (e.g., other types of reducing bushings). As also noted above, Orphanos in view of the knowledge in the art at the time of the invention made obvious that such reducing bushings could include externally threaded reducing bushings. Furthermore, Roche in Fig. 7A discloses a rotational control feature in locking cap 116 in the form of an internal hex surface as shown. Moreover, page 3547 of Grainger discloses reducing bushings having a rotational control feature in the form of an external hex, and these reducing bushings have been readily available through publications since at least 2009. Grainger, pg. 3547. Additionally, Hale in Fig. 1 discloses a rotational control feature in reducing bushing 48 in the

form of an external hex surface. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Orphanos in view of Roche, Hale, or the knowledge and skill of a POSITA.

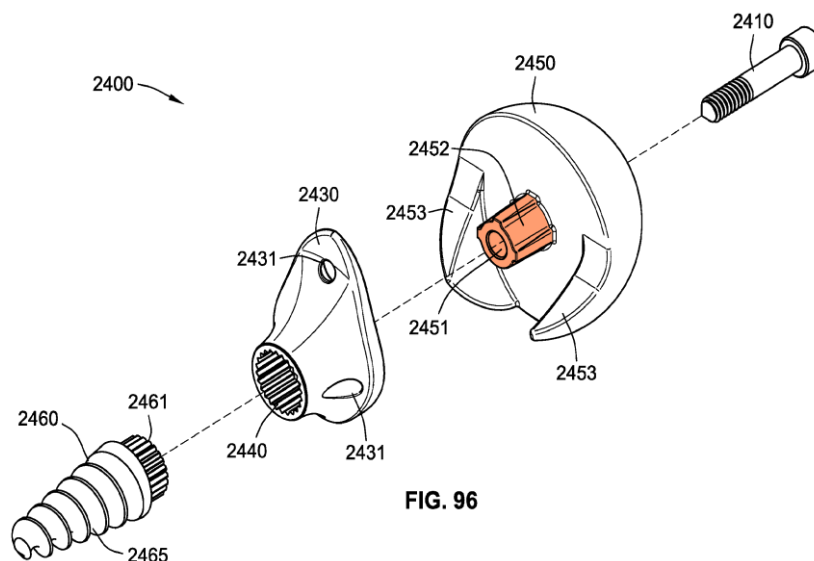
B. Ground 2: Claims 2 and 10 are obvious over Orphanos in view of knowledge of a person having ordinary skill in the art, Roche, and further in view of Frankle

130. In my opinion, claims 2 and 10 are obvious over Orphanos in view of knowledge and skill of a POSITA, Roche, and further in view of Frankle for the reasons I explain below. Claim 2 depends from claim 1, while claim 10 depends from claim 9. As I described above, it is my opinion that Orphanos in view of knowledge and skill of a POSITA and Roche teach all the limitations of claims 1 and 9. Therefore, I will limit my discussion of claims 2 and 10 below to the limitation [2-1] and [10-1], respectively.

131. In my opinion, Orphanos in view of knowledge and skill of a POSITA, Roche, and Frankle renders limitation [2-1] obvious, which recites "wherein the glenosphere further comprises a stem configured to be positioned at least partially within the central channel of the baseplate," for at least the following, while FIG. 96 of Frankle is provided below.

132. Paragraph [0244] of Frankle discloses a glenoid implant 2400 that includes a face plate 2430 (i.e., a baseplate) defining a receiving element 2440 (i.e., a central channel), and a glenosphere 2450 having a protrusion element 2452 (i.e., a

stem) configured to be received within the receiving element 2440 (i.e., central channel) of face plate 2430 (i.e., baseplate). A POSITA would be motivated to incorporate the protrusion element 2452 (i.e., stem) (orange) of Frankle into the glenosphere 250, 1030 of Orphanos such that the incorporated protrusion element is configured to be positioned at least partially within the central channel of the baseplate, as doing so would further promote guidance, maintain alignment of glenosphere and baseplate, and provide further structural rigidity in the connection of the glenosphere to the baseplate while the two are coupled together. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Orphanos in view of knowledge of a Person Having Ordinary Skill in the Art, Roche, and further in view of Frankle.



133. In my opinion, Orphanos in view of knowledge and skill of a POSITA, Roche, and Frankle renders limitation [10-1] obvious, which recites "wherein the

glenosphere further comprises a stem configured to be positioned at least partially within the central channel of the baseplate," as least as described regarding limitation [2-1] and as shown in Frankle, FIG. 96.

C. Ground 3: Claims 1, 3-9, and 11-6 are obvious over Lefebvre in view of Orphanos and Roche

134. In my opinion, claims 1, 3-9, and 11-16 are obvious over Lefebvre in view of Orphanos and Roche.

135. In my opinion, each of the limitations of claims 1, 3-9, and 11-16 are disclosed or provided by Lefebvre, Orphanos, and Roche for the reasons I explain below.

136. In my opinion, Lefebvre discloses the preamble [1-PRE], which recites "A reverse shoulder implant, comprising," at least in the Abstract of Lefebvre, where Lefebvre discloses "A glenoid implant for an inverted shoulder prosthesis," and also FIG. 23, which depicts the following:

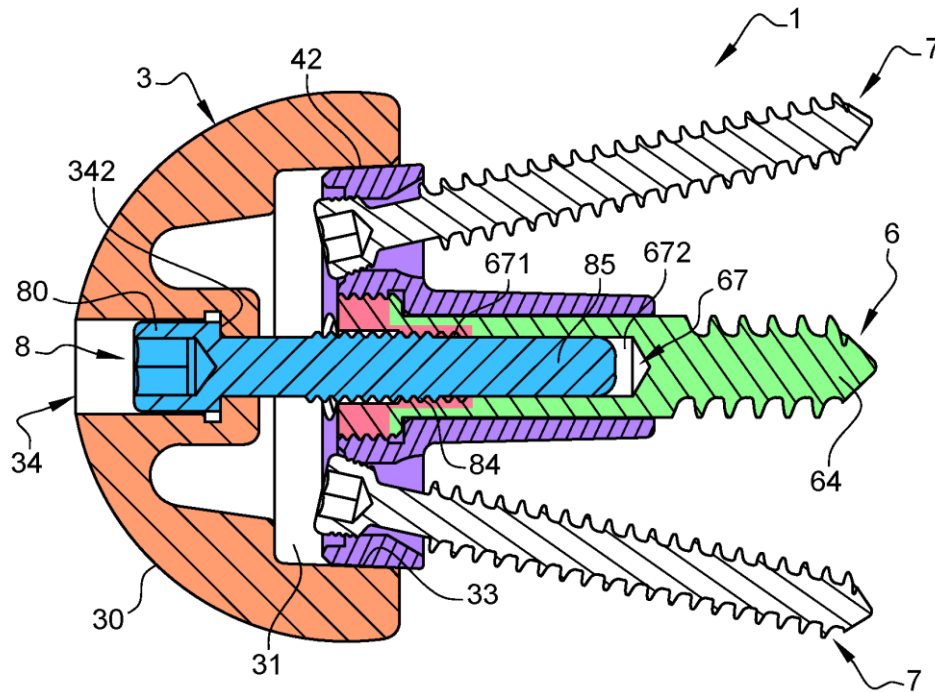
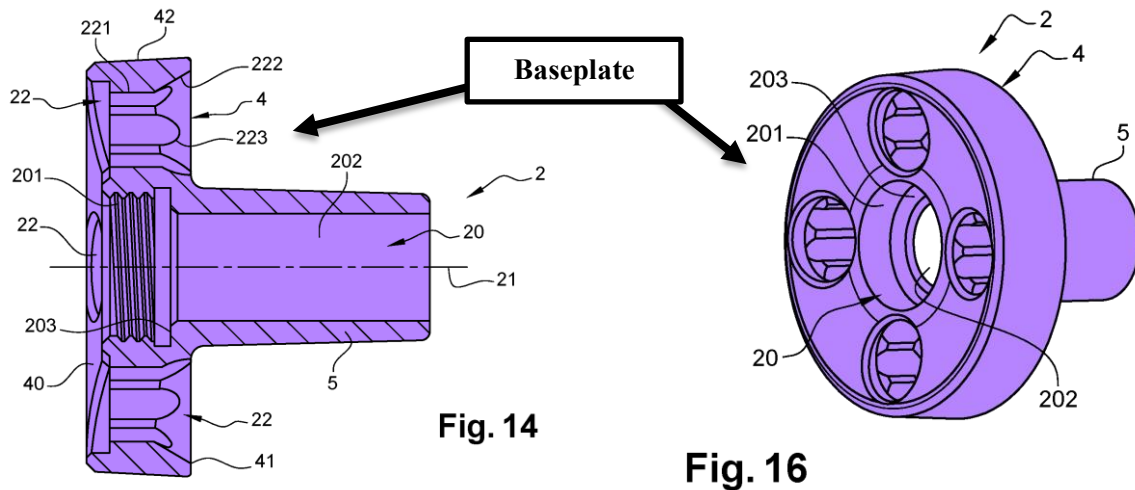


Fig. 23

137. It is my opinion, therefore, that a POSITA would understand Lefebvre to disclose limitation [1-PRE].

138. In my opinion, Lefebvre discloses limitation [1-1], which recites "a baseplate configured to be secured to a glenoid of a scapular bone of a patient," for at least the following reasons, with FIGS. 4 and 16 shown below.

139. Column 6, lines 20-24 of Lefebvre describe "a glenoid implant 1...intended for an inverted shoulder prostheses, comprises a base 2...the base 2 is intended to be anchored on a glenoid cavity of a scapula." Further, Column 6, line 65 – Column 7, line 3 and Column 8, lines 15-21 describe the base 2 (i.e., baseplate shown in purple) is circular and configured to receive anchoring screws 6, 7 in order to secure base 2 to the glenoid cavity of the scapula.



140. It is my opinion, therefore, that a POSITA would understand Lefebvre to disclose limitation [1-1].

141. In my opinion, Lefebvre discloses limitation [1-2], which recites "the baseplate having a lateral end, a medial end, and a central channel extending therethrough from the lateral end to the medial end," for at least the following reasons, with FIGS. 12 and 14 shown below for reference.

142. Column 6, lines 26-31 of Lefebvre describe base 2 (purple) as including a subplate 4 having an outer face 40 (i.e., lateral end) and inner face 41 (i.e., medial end) facing opposite directions from each other, where the inner face is intended to bear on the glenoid cavity. Further, Column 6, lines 44-48 of Lefebvre describe base 2 having a main orifice 20 (i.e., central channel) that extends through base 2 along a central axis 21.

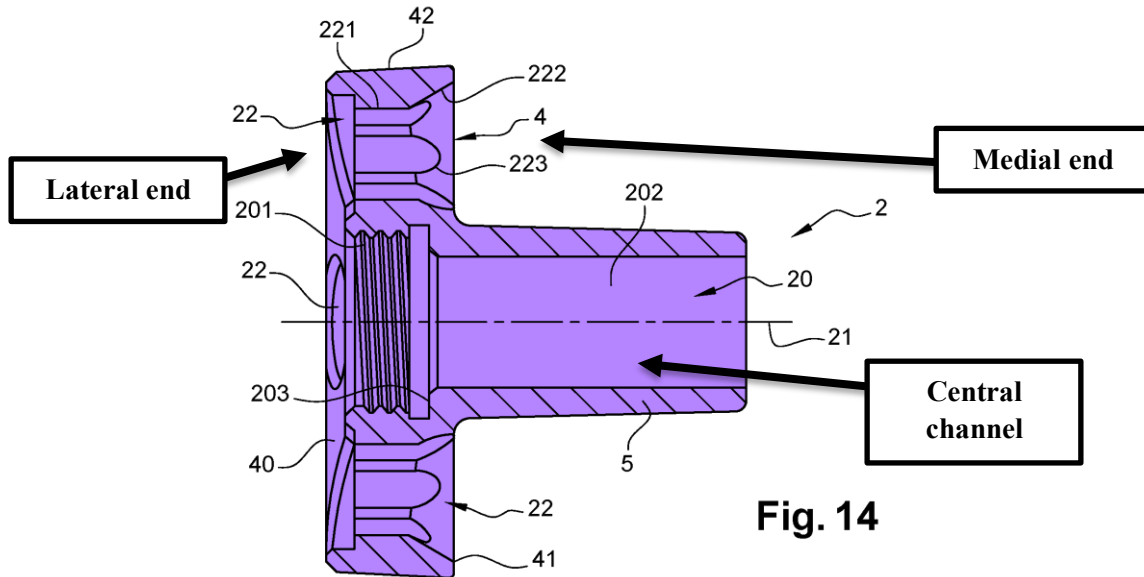
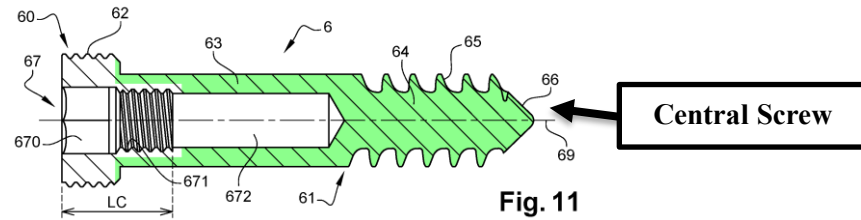
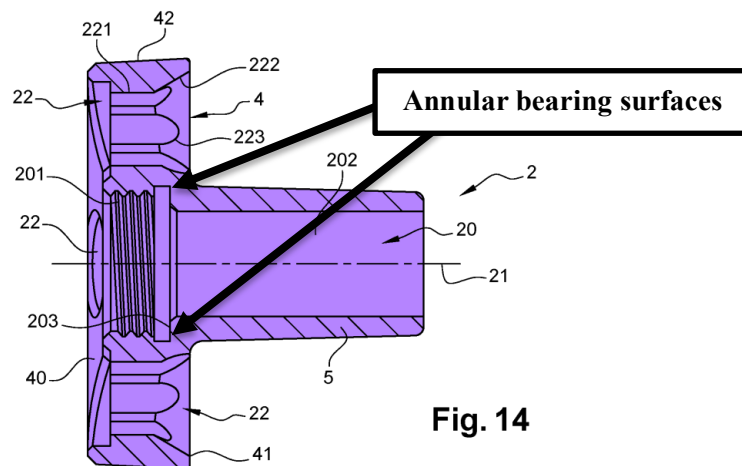
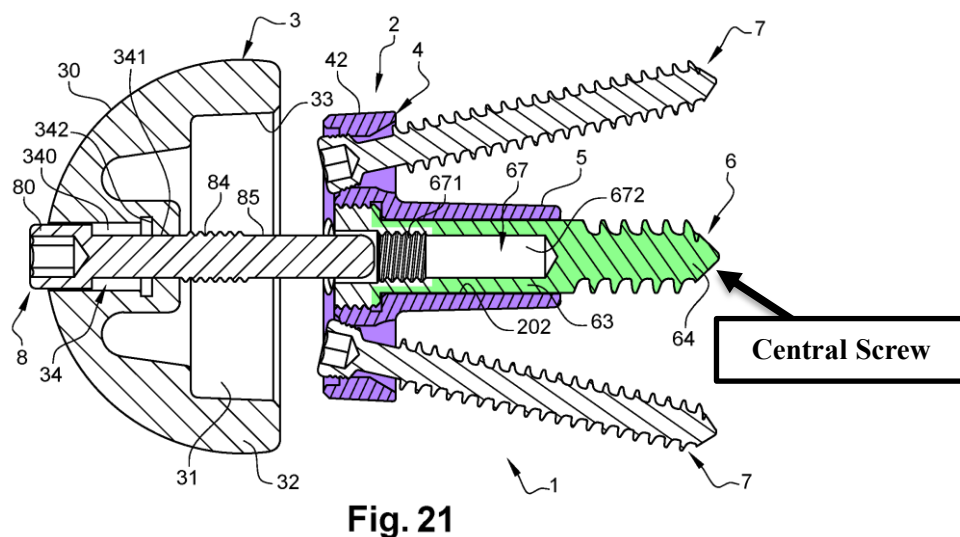


Fig. 14

143. It is my opinion, therefore, that a POSITA would understand Lefebvre to disclose limitation [1-2].

144. In my opinion, Lefebvre discloses limitation [1-3], which recites "a central screw sized to at least partially pass through the central channel and secure the baseplate to the glenoid of the patient," for at least the following reasons, with FIGS. 11, 14, and 21 shown below for reference.

145. Column 7, lines 21-36 of Lefebvre disclose an anchor rod 61 (i.e., central screw shown in green) of main anchoring screw 6 having an end segment 64 with external tapping 65 configured to be anchored into the glenoid cavity. Additionally, Column 7, lines 4-12 of Lefebvre disclose a portion of main head 60 of anchoring screw 6 that is configured to abut against annular bearing surface 203 (see FIGS. 14-15 of Lefebvre) to simultaneously secure main anchoring screw 6 to base 2.



146. It is my opinion, therefore, that a POSITA would understand Lefebvre to disclose limitation [1-3].

147. In my opinion, Lefebvre discloses limitation [1-4], which recites "a locking nut having a cylindrical shape, an external thread on an outside of the locking nut and an internal thread on an internal surface of the locking nut," for at least the

following, with reference to FIGS. 11 and 16 provided below.

148. Column 7, lines 4-19 and 45-56 of Lefebvre teaches a locking nut (red) in the form of the enlarged head of main head 60 and the internal threading 671 (i.e., internal threads) of intermediate portion 671. Further, the same sections of Lefebvre teach main head 60 having a cylindrical shape and an external tapping 62 (i.e., external threads) which is complementary to the threading of the inlet portion 201 of main orifice 20 of base 2. Additionally, the same sections of Lefebvre teach main head 60 having an inner blind hole 67 defined by an inner surface that includes a threading at intermediate portion 671.

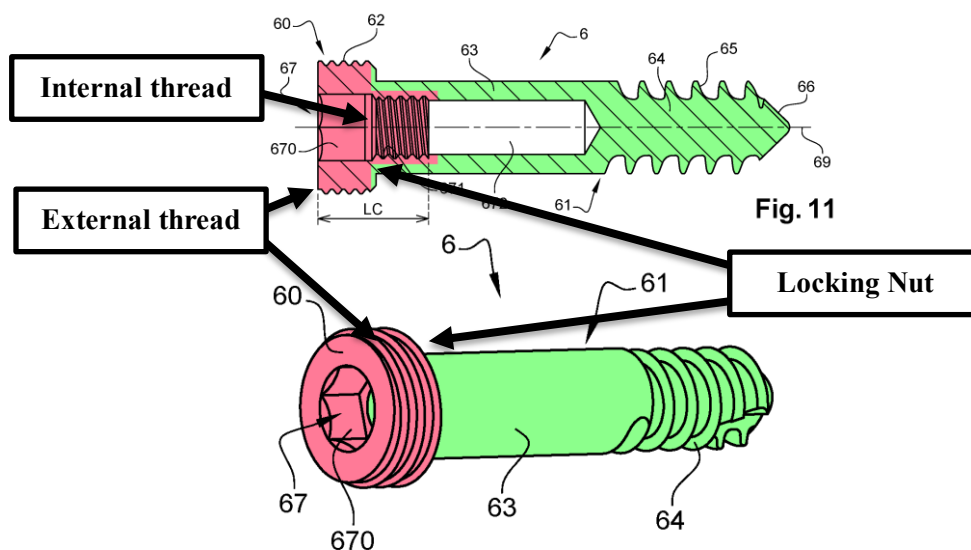


Fig. 16

149. It is my opinion, therefore, that a POSITA would understand Lefebvre to disclose limitation [1-4].

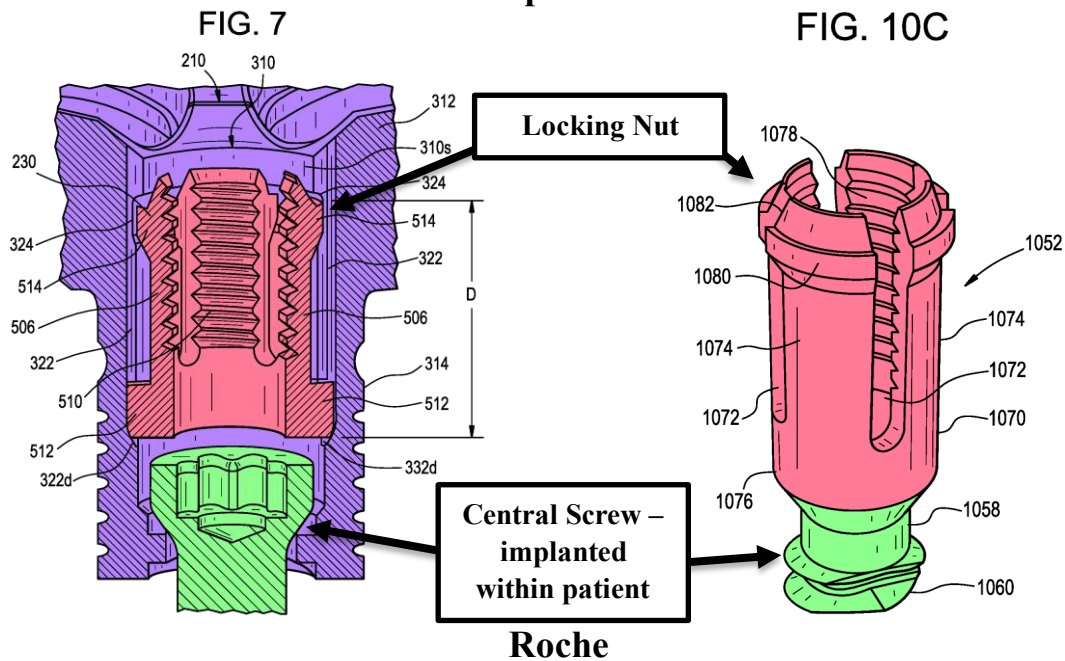
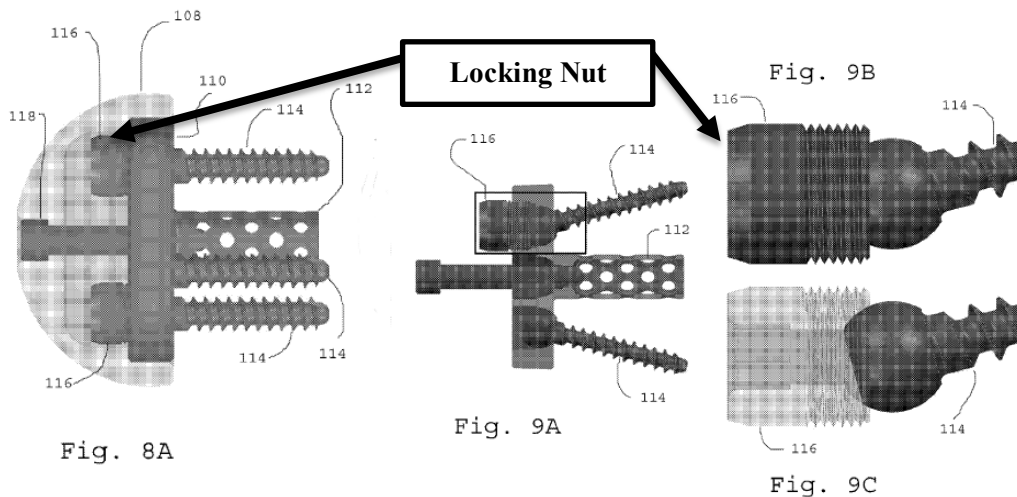
150. In my opinion, Lefebvre discloses limitation [1-5], which recites "the

locking nut configured to engage the central screw when the central screw and baseplate are implanted within the medical patient," for at least the following reasons, with reference to FIGS. 11 and 21 below.

151. As mentioned above, Column 7, lines 4-29 and 45-56 of Lefebvre teach a locking nut in the form of the enlarged head of main head 60 and the threading 671 of intermediate portion 671. Additionally, as also mentioned above, Column 7, lines 4-12 and 21-36 of Lefebvre teach a central screw in the form of an anchor rod 61 and a portion of main head 60 of anchoring screw 6 configured to abut against annular bearing surface 203 (see FIGS. 14-15 of Lefebvre). Main head 60 of main anchoring screw 6 is attached to anchor rod 61 as a single piece. Since claim 1 only requires a locking nut that is "configured to engage the central screw when the central screw and baseplate are implanted within the medical patient," and not a locking nut that is ever configured to be separate, decoupled, or disengaged from the central screw, it is my opinion that a POSITA would understand Lefebvre to disclose limitation [1-5].

152. However, if claim 1 was somehow interpreted to include a locking nut that is somehow separated, decoupled, or disengaged from the central screw, it is my opinion that a POSITA would view this modification as obvious in view of Lefebvre, Orphanos, and Roche for the following reasons, with reference to FIGS. 7 and 10C of Orphanos, and FIGS. 8A, 9A, and 9C of Roche below.

Orphanos



153. As mentioned above, Orphanos discloses an implant 200 that includes a central bone screw 270 and a locking nut in the form of collet 230. Column 12, lines 49-61 of Orphanos discusses the desire to make central bone screw 270 a "free spinning screw" design within baseplate 210 in order to allow bone screw 270 to "act like any other socket head cap screw that is assembled into a counter-bored hole

to provide compression." Further, that same section of Orphanos teaches that providing a "spree spinning screw" design between central bone screw 270 and baseplate 210 allows bone screw 270 to turn within bone to provide additional compression between the bone and the distal facing surface 312d of baseplate 270 while preventing bone screw 270 from binding up within baseplate 210.

154. Therefore, a POSITA would consider it desirable 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, as separation of such components would allow Lefebvre's central screw to have a "free spinning screw" design as taught by Orphanos to provide additional compression between the bone and Lefebvre's base 2. Separating the components of Lefebvre's main anchoring screw 6 forming the central screw from the external tapping 62 and internal threading of intermediate portion 671 (i.e. the components of Lefebvre that interface between the base 2 and glenosphere screw 8) provide a "free spinning screw" design by allowing end segment 64 to anchor into the glenoid cavity of a medical patient without having threaded engagement between external tapping 62 and inlet portion 201 of base 2 inhibit such free spinning of end segment 64.

155. Not only does Orphanos provide motivation to separate the components of Lefebvre's main anchoring screw 6, Orphanos teaches how to modify the implant

1 of Lefebvre to separate the above referenced components of main anchoring screw 6 while enabling the implant 1 of Lefebvre suitable for its intended purposes. As mentioned above, Orphanos discloses two implants 200, 1000. The first implant 200 includes a locking nut in the form of collet 230 that is separated from the compression screw 270, while the second implant 1000 teaches a locking nut in the form of a collet portion 1052 that is integral with the compression screw 1050. Therefore, Orphanos teaches a POSITA how to incorporate a locking nut that may be either (A) separated from the compression screw, or (B) integral with the compression screw; all while still allowing compression screw to anchor baseplate to the glenoid of the patient.

156. A POSITA would utilize the teachings of Orphanos to (A) separate the components of Lefebvre's main anchoring screw 6 forming the central screw from the components of Lefebvre's main anchoring screw 6 forming the locking nut, (B) enable Lefebvre's separated central screw to compress base 2 against the glenoid cavity of the medical patient when suitably implanted, as well as (C) enable Lefebvre's separated locking nut to suitably interface between base 2 and locking screw 8.

157. After separating the components of Lefebvre's main anchoring screw 6 forming the locking nut from the components of Lefebvre's main anchoring screw 6 forming central screw in order to allow for a "free spinning screw" design as taught

by Orphanos, Lefebvre's locking nut would still be configured to engage the central screw when the central screw and baseplate are implanted within the medical patient as recited in the claim.

158. Additionally, as mentioned above, Column 14, lines 1-18 of Roche teach utilizing locking cap screws 116 within glenoid plate 110 in order to engage compression screws 114 after being implanted to prevent compression screws 114 from backing out. A POSITA would be motivated to ensure the location of Lefebvre's separated locking nut is engaged with Lefebvre's separated central screw after being implanted, as taught by Roche, as such engagement would provide the well-known benefit of inhibiting Lefebvre's separated central screw from backing out.

159. In my opinion, it would have been obvious to try, particularly in light of the teachings of Orphanos and Roche, to separate the components of Lefebvre's main anchoring screw 6 forming the central screw from the components of Lefebvre's main anchoring screw 6 forming the locking nut because it would have involved a choice from a finite number of identifiable, predictable solutions, with a reasonable expectation of success. A POSITA would have a reasonable expectation that such modification would be successful because it simply is a known successful solution—separating compression screw from locking nut—to solve a known problem—not allowing free spinning.

160. It is my opinion, therefore, that a POSITA would understand Lefebvre

in view of Orphanos and Roche as teaching limitation [1-5], as well as the additional, unclaimed feature of a locking nut that is separable from the central screw.

162. Column, 7, lines 7-12 of Lefebvre teach the main head 60 of main anchoring screw 6 to include external tapping 62 (i.e., external threading) that is complementary to the threading of the inlet portion 201 of the main orifice 20, thereby allowing external tapping 62 of main head 60 (red) to be screwed into the inlet portion 301 of main orifice 20 of base 20.

Fig. 21

to disclose limitation [1-6].

164. In my opinion, Lefebvre discloses limitation [1-7], which recites "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," for at least the following reasons, with reference to FIGS. 6 and 23 of Lefebvre provided below.

165. Column 8, lines 22-26 and lines 41-44 of Lefebvre disclose a glenosphere 3 (orange) having a convex articulation surface 30, a medial side (i.e., the side of glenosphere 3 opposite the convex articulation surfaces 30), and a central orifice 34 (i.e., a central channel) that extends from the convex articulation surface 30 into a main cavity 31 and thus the medial side. Further, Column 8, lines 27-40 of Lefebvre disclose the central orifice 34 and main cavity 31 of glenosphere 3 being configured to interface with base 2 via a Morse taper via peripheral faces 33, 42; while the glenosphere 3 also surrounds the base 2 (highlighted by the red ovals).

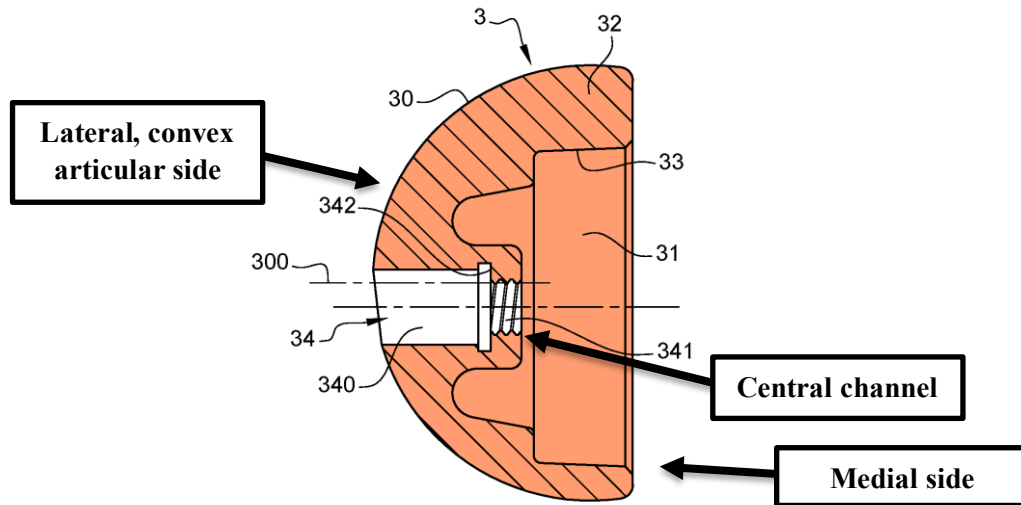


Fig. 6

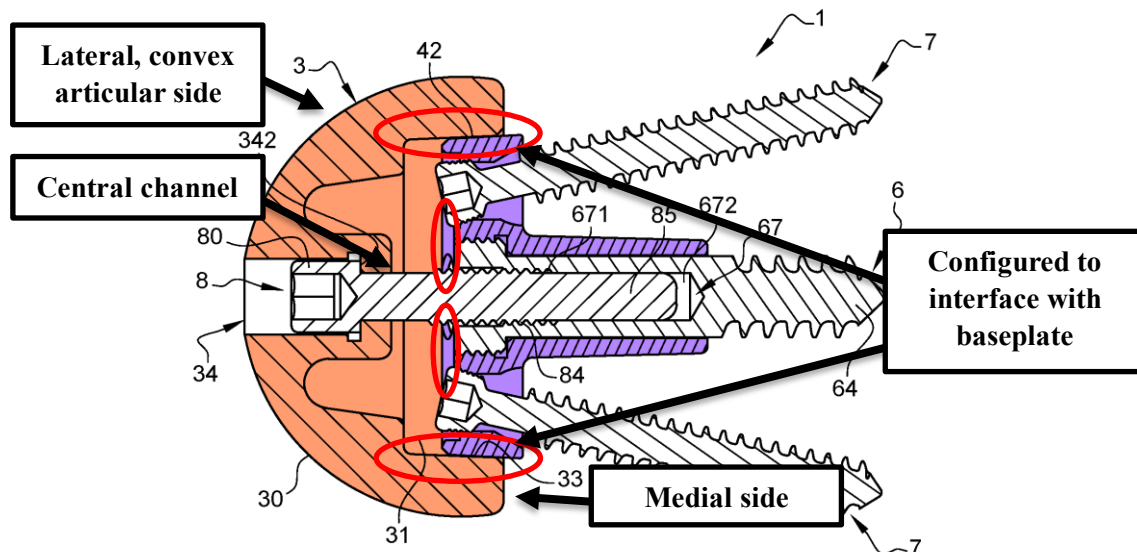


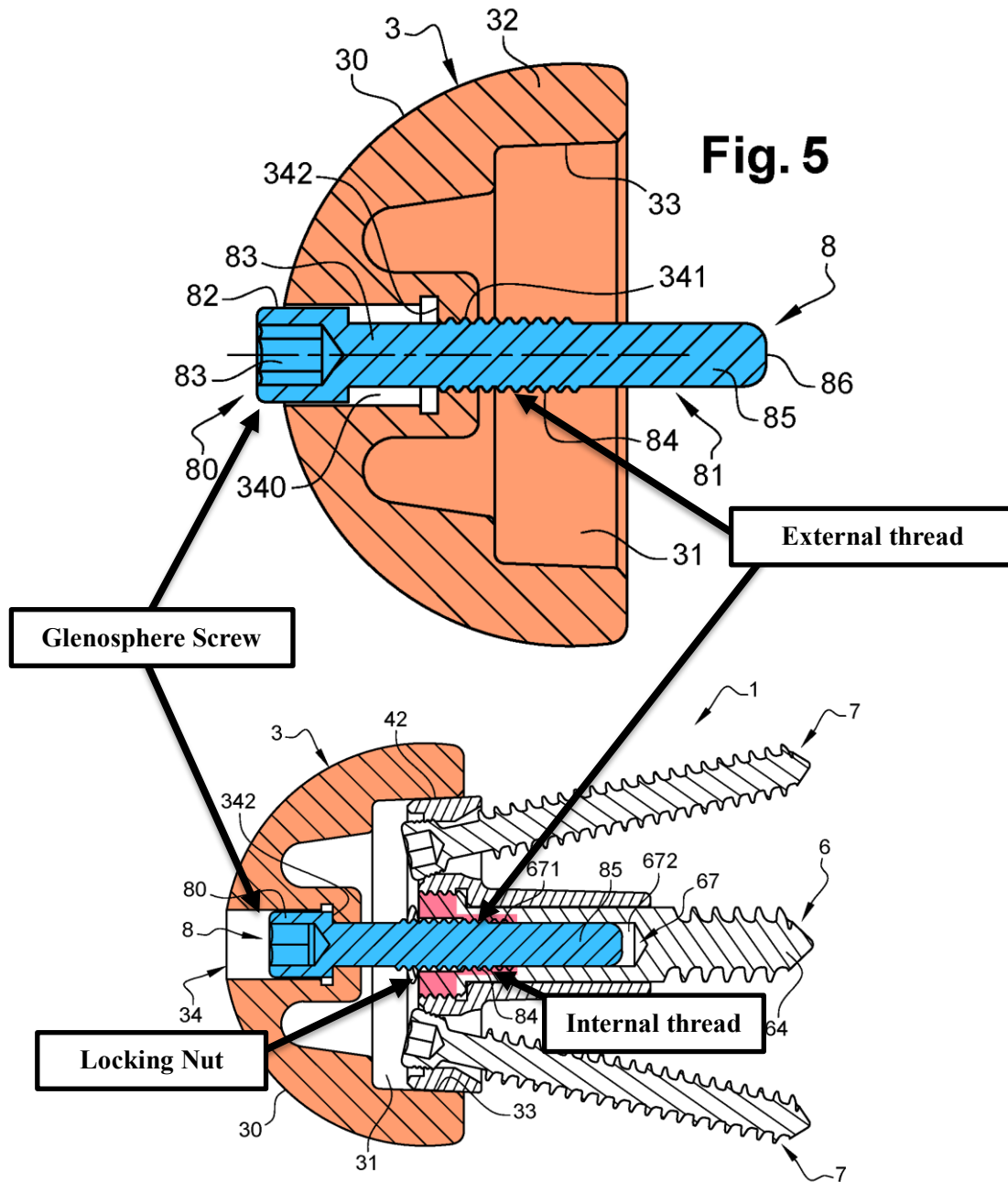
Fig. 23

166. It is my opinion, therefore, that a POSITA would understand Lefebvre to disclose limitation [1-7].

167. In my opinion, Lefebvre discloses limitation [1-8], which recites "a glenosphere screw, sized to pass at least partially within the glenosphere central channel and having external threads sized to secure the glenosphere screw to the internal thread on the internal surface of the locking nut to secure the glenosphere to

the locking nut," for at least the following reasons, with reference to FIGS. 5 and 23 provided below.

168. Column 9, lines 1-7 of Lefebvre teach a locking screw 8 intended to be inserted into the central orifice 34 of the glenosphere 3 in order to lock the glenosphere 3 on the base 2 in a locked position. Further, Column 9, lines 8-10 and lines 27-35 teach that the locking screw 8 includes a locking rod 81 having an intermediate segment 84 provided with an external tapping that is complementary to the threading of intermediate portion 671 of the main anchoring screw 6. Further, Column 9 lines 51-47 of Lefebvre teach external tapping of intermediate segment 84 being configured to screw into internal threading of intermediate portion 671 until the proximal head 80 of locking screw 8 abuts on the annular bearing surface 342 of glenosphere 3.



169. It is my opinion, therefore, that a POSITA would understand Lefebvre to disclose limitation [1-8].

170. In my opinion, Lefebvre discloses limitation [3-1], which recites "The reverse shoulder implant of claim 1, wherein the glenosphere is configured to at least

partially surround an external surface of the baseplate," at least as described regarding limitation [1-7] and as shown in Lefebvre, FIG. 23. Lefebvre discloses this limitation because as shown in FIG. 23, the glenosphere includes a distal inner surface that surrounds the proximal peripheral surface of the baseplate (i.e., the Morse taper engagement via peripheral faces 33, 42 between the glenosphere 3 and base 2). Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Lefebvre.

171. In my opinion, Lefebvre discloses limitation [4-1], which recites "The reverse shoulder implant of claim 1, wherein the baseplate has a circular shape," at least as described regarding limitation [1-1] and as shown in Lefebvre, FIG. 16. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Lefebvre.

172. In my opinion, Lefebvre discloses limitation [5-1], which recites "The reverse shoulder implant of claim 1, wherein the glenosphere is configured to surround the baseplate," at least as described regarding limitation [1-7] and as shown in Lefebvre, FIG. 23. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Lefebvre.

173. In my opinion, Lefebvre discloses limitation [6-1], which recites "The reverse shoulder implant of claim 1, wherein the glenosphere is configured to be secured to the baseplate with a morse taper," at least as described regarding

174. In my opinion, Lefebvre discloses limitation [7-1], which recites "The reverse shoulder implant of claim 1, wherein a diameter of the locking nut is greater than a length of the locking nut," is shown in Lefebvre, FIG. 11. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Lefebvre.



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176. Moreover, such a modification would have been obvious to a person skill in the art as a POSITA would be motivated to keep the length less than the diameter to provide a low profile to the locking nut.

177. In my opinion, Lefebvre discloses limitation [8-1], which recites "The reverse shoulder implant of claim 1, wherein the locking nut comprises a rotational control feature configured to receive a tool to enable twisting of the locking nut to secure it to the central screw," at Column 7, lines 51-54 of Lefebvre. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Lefebvre.

178. In my opinion, Lefebvre in view of Orphanos and Roche discloses all the limitations of claim 9, which recites language that can be found in other claims already discussed above. By way of illustration, the following language of claim 9 on the left is materially indistinct from the language of other claims on the right. My opinion that Orphanos in view of the knowledge and skill of a POSITA and Roche discloses all limitations of claim 9 on the left is based on my discussion regarding the limitations from other claims indicated on the right.

CLAIM 9	OTHER CLAIMS
[9-PRE] A reverse shoulder implant, comprising:	See previous discussion at [1-PRE]: "A reverse shoulder implant, comprising,"
[9-1] a baseplate configured to be secured to a glenoid of a scapular bone of patient,	See previous discussion at [1-1]: "a baseplate configured to be secured to a glenoid of a scapular bone of a patient,"

CLAIM 9	OTHER CLAIMS
[9-2] the baseplate having a lateral end, a medial end, and a central channel extending therethrough from the lateral end to the medial end;	See previous discussion at [1-2]: "the baseplate having a lateral end, a medial end, and a central channel extending therethrough from the lateral end to the medial end,"
[9-3] a central screw sized to at least partially pass through the central channel and secure the baseplate to the glenoid of the patient;	See previous discussion at [1-3]: "a central screw sized to at least partially pass through the central channel and secure the baseplate to the glenoid of the patient,"
[9-4] a locking nut having a cylindrical shape, an external thread on an outside surface of the locking nut and an internal thread on an internal surface of the locking nut,	See previous discussion at [1-4]: "a locking nut having a cylindrical shape, an external thread on an outside of the locking nut and an internal thread on an internal surface of the locking nut"
[9-5] the locking nut configured to engage the central screw when the central screw and baseplate are implanted within the medical patient,	See previous discussion at [1-5]: "the locking nut configured to engage the central screw when the central screw and baseplate are implanted within the medical patient"
[9-6] wherein the external thread is configured to engage the central channel of the baseplate; and	See previous discussion at [1-6]: "wherein the external thread is configured to secure the locking nut to the central channel of the baseplate." It is noted that the external thread secures the locking nut to the central channel of the baseplate (as recited in claim 1) by engaging the central channel of the baseplate (as recited in claim 9).

CLAIM 9	OTHER CLAIMS
[9-7] 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; and	See previous discussion at [1-7]: "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"
[9-8] a glenosphere screw, sized to pass at least partially within the glenosphere central channel and having external threads sized to secure the glenosphere screw to the internal thread on the internal surface of the locking nut to secure the glenosphere to the locking nut.	See previous discussion at [1-8]: "a glenosphere screw, sized to pass at least partially within the glenosphere central channel and having external threads sized to secure the glenosphere screw to the internal thread on the internal surface of the locking nut to secure the glenosphere to the locking nut"

179. Thus, in my opinion, a POSITA would understand that Lefebvre in view of Orphanos and Roche disclose all the limitations of claim 9.

180. In my opinion, Lefebvre discloses limitation [11-1], which recites "The reverse shoulder implant of claim 9, wherein the glenosphere is configured to at least partially surround an external surface of the baseplate," at least as described regarding limitation [1-7] and as shown in Lefebvre, FIG. 23. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Lefebvre.

181. In my opinion, Lefebvre discloses limitation [12-1], which recites "The reverse shoulder implant of claim 9, wherein the baseplate has a circular shape," at least as described regarding limitation [1-1] and as shown in Lefebvre, FIG. 16.

Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Lefebvre.

182. In my opinion, Lefebvre discloses limitation [13-1], which recites "The reverse shoulder implant of claim 9, wherein the glenosphere is configured to surround the baseplate," at least as described regarding limitation [1-7] and as shown in Lefebvre, FIG. 23. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Lefebvre.

183. In my opinion, Lefebvre discloses limitation [14-1], which recites "The reverse shoulder implant of claim 9, wherein the glenosphere is configured to be secured to the baseplate with a morse taper," at least as described regarding limitation [1-7] and as shown in Lefebvre, FIG. 23. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Lefebvre.

184. In my opinion, Lefebvre discloses limitation [15-1], which recites "The reverse shoulder implant of claim 9, wherein a diameter of the locking nut is greater than a length of the locking nut," at least as described regarding limitation [7-1] and as shown in Lefebvre, FIG. 11. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Lefebvre.

185. In my opinion, Lefebvre discloses limitation [16-1], which recites "The reverse shoulder implant of claim 9, wherein the locking nut comprises a rotational control feature configured to receive a tool to enable twisting of the locking nut to

secure it to the central screw," at Column 7, lines 51-54 of Lefebvre. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Lefebvre.

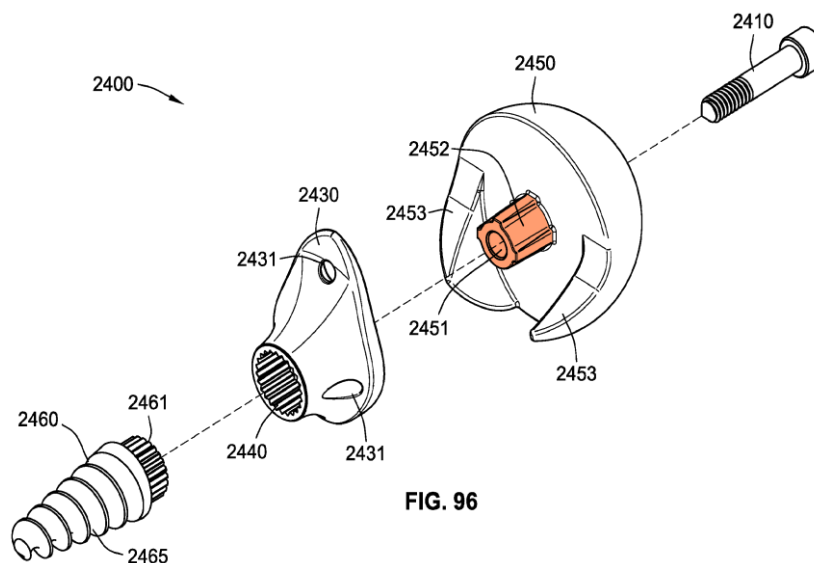
D. Ground 4: Claims 2 and 10 are obvious over Lefebvre in view of Orphanos and Roche, and in further view of Frankle

186. In my opinion, claims 2 and 10 are obvious over Lefebvre in view of Orphanos, Roche, and further in view of Frankle for the reasons I explain below. Claim 2 depends from claim 1, while claim 10 depends from claim 9. As I described above, it is my opinion that Lefebvre in view of Orphanos and Roche teach all the limitations of claims 1 and 9. Therefore, I will limit my discussion of claims 2 and 10 below to the limitation [2-1] and [10-1], respectively.

187. In my opinion, Lefebvre in view of Orphanos, Roche, and Frankle renders limitation [2-1] obvious, which recites "wherein the glenosphere further comprises a stem configured to be positioned at least partially within the central channel of the baseplate," for at least the following, while FIG. 96 of Frankle is provided below.

188. Paragraph [0244] of Frankle discloses a glenoid implant 2400 that includes a face plate 2430 (i.e., a baseplate) defining a receiving element 2440 (i.e., a central channel), and a glenosphere 2450 having a protrusion element 2452 (i.e., a stem) (orange) configured to be received within the receiving element 2440 (i.e., central channel) of face plate 2430 (i.e., baseplate. A POSITA would be motivated to incorporate the protrusion element 2452 (i.e., the stem) of Frankle into the

glenosphere 3 of Lefebvre such that the incorporated protrusion element is configured to be positioned at least partially within the central channel of the baseplate, as doing so would further promote guidance, maintain alignment of glenosphere and baseplate, and provide further structure rigidity in the connection of the glenosphere to the baseplate while the two are coupled together, as taught by Lefebvre at Column 2, lines 34-36. Therefore, in my opinion, a POSITA would understand this limitation to be disclosed by Lefebvre in view of Orphanos, Roche, and Frankle.



189. In my opinion, Lefebvre in view of Orphanos, Roche, and Frankle renders limitation [10-1] obvious, which recites "wherein the glenosphere further comprises a stem configured to be positioned at least partially within the central channel of the baseplate," at least as described regarding limitation [2-1] and as shown in Frankle, FIG. 96.

E. Ground 5: Claims 1-16 are unpatentable because the term "central channel" as used with respect to the baseplate is indefinite

190. Based on the standard set forth in the Legal Principles section above, it is my opinion that the term "central channel" as used with respect to the baseplate in each of claims 1-16 is indefinite and renders those claims unpatentable under § 112.

191. More particularly, "central channel" of the baseplate, read in light of the specification and prosecution history, is indefinite because, in my opinion, it fails to inform a POSITA of the scope of the claim with reasonable certainty.

192. I have been informed and understand that claims 1 and 9 are independent claims in the '561 Patent and that claims 2-8 and 10-16 are dependent claims.

193. Claims 1 and 9 both recite as a limitation of the baseplate "a central channel extending therethrough from the lateral end to the medial end." '561 Patent, 9:38-40, 10:20-22.

194. I have been informed and understand that because the "central channel" of the baseplate is recited in both independent claims of the '561 Patent, the term is understood to be present in each of the dependent claims as well.

195. Claims 1 and 9 also both recite that "a central screw sized to at least partially pass through the central channel." '561 Patent, 9:40-42, 10:23-25.

196. Claim 1 also recites, with respect to the "locking nut" limitation, that "a locking nut [has] . . . an external thread on an outside surface of the locking nut . . .

wherein the external thread is configured to secure the locking nut to the central channel of the baseplate." '561 Patent, 9:44-51.

197. Claim 9 also recites, with respect to the "locking nut" limitation, that "a locking nut [has] . . . an external thread on an outside surface of the locking nut . . . wherein the external thread is configured to engage the central channel of the baseplate." '561 Patent, 10:25-32.

198. Claims 2 and 10 recite "wherein the glenosphere further comprises a stem configured to be positioned at least partially within the central channel of the baseplate." '561 Patent, 9:60-64, 10:43-47.

199. In the context of Figure 8, which depicts the embodiment recited in claims 1-16, the specification provides that a "post of the glenosphere can be placed at least partially within a central channel of the baseplate as illustrated." '561 Patent, 6:42-44.

200. The specification also state that a "central set screw/locking nut 814 can be connected to, and in some cases removably attachable to a central channel, e.g., of the glenoid baseplate[,]" which, again, seems to infer that the central channel is physical structure that can be connected with or removably attached to rather than empty space. '561 Patent, 6:44-47.

201. During the original prosecution of the '561 Patent, the examiner did not issue any office actions prior to allowance. *See* EX-1004, EX-1005.

202. It is my opinion that the scope of the limitation recited as a "central channel" of the baseplate in claims 1-16 cannot be ascertained by a POSITA with reasonable certainty because, per the claim language and the description in the specification, the "central channel" is impermissibly both an empty space allowing passage of the central screw or glenosphere stem and a physical structure to which the locking nut can be connected or attached.

203. Claims 1 and 9 recite that the "a central screw sized to at least partially pass through the central channel," '561 Patent, 9:40-42, 10:23-25, which, in my opinion, creates an understanding to a POSITA that the "central channel" is empty space or passageway through which the central screw may at least partially pass.

204. In my view, claims 2 and 10 further inform a POSITA that the "central channel" is an empty space or passageway by reciting "wherein the glenosphere further comprises a stem configured to be positioned at least partially within the central channel of the baseplate." '561 Patent, 9:60-64, 10:43-47.

205. The recitation of the "locking nut" of claim 1 as being secured to the central channel and "locking nut" of claim 9 as being engaged with the central channel would both be understood by a POSITA as presenting the "central channel" with some physical structure.

206. In my opinion, rather than clarifying, the specification further complicates matters. When, in the context of Figure 8, the specification states that a

"post of the glenosphere can be placed *at least partially within a central channel of the baseplate* as illustrated," it suggests to a POSITA that the "central channel" is an empty space or passageway. *Id.*, 6:42-44.

207. However, it is my opinion, that where the specification states that a "central set screw/locking nut 814 can be connected to, and in some cases removably attachable to a central channel, e.g., of the glenoid baseplate[.]" a POSITA would infer that the central channel has physical structure that can be connected with or removably attached to rather than empty space. '561 Patent, 6:44-47.

208. In my opinion, the '561 Patent fails to describe the "central channel" is a manner that a POSITA would be able to determine the boundaries of the scope of the "central channel" of the baseplate with reasonable certainty.

F. Ground 6: Claims 1-16 are unpatentable because the term "central channel . . . configured to interface with the baseplate" is indefinite

209. Based on the standard set forth in the Legal Principles section above, it is my opinion that the term "central channel . . . configured to interface with the baseplate" as recited in claims 1-16 is indefinite and renders those claims unpatentable under § 112.

210. More particularly, "central channel . . . configured to interface with the baseplate," read in light of the specification and prosecution history, is indefinite because, in my opinion, it fails to inform a POSITA of the scope of the claim with reasonable certainty.

211. I have been informed and understand that claims 1 and 9 are independent claims in the '561 Patent and that claims 2-8 and 10-16 are dependent claims.

212. Claims 1 and 9 both recite as a limitation of the baseplate "a central channel . . . configured to interface with the baseplate." '561 Patent, 9:52-55, 10:33-37.

213. I have been informed and understand that because the "central channel . . . configured to interface with the baseplate" is recited in both independent claims of the '561 Patent, the term is understood to be present in each of the dependent claims as well.

214. In addition to the reciting "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," '561 Patent, 9:52-55, 10:33-37, both claims 1 and 9 also recite "a glenosphere screw, sized to pass at least partially within the glenosphere central channel." *Id.*, 9:56-57, 10:37-39.

215. In my view, unlike the "central channel" of the baseplate discussed above in ground 5, the "central channel . . . configured to interface with the baseplate" refers to the "central channel" of the glenosphere and is claimed only as empty space or a passageway, and not a physical structure.

216. It is my opinion that a POSITA would not be able to determine with reasonable certainty the scope of the claim language "a central channel [of the glenosphere] . . . [to be] . . . configured to interface with the baseplate" because the term "to interface" is ambiguous on its face."

217. "Interface" can have several meanings as evidenced by the dictionary definition submitted as EX-1017. According to the dictionary entry in EX-1017, "interface" could mean a variety of things, including "to connect by means of an interface," "serving as an interface," and "interacting or coordinating harmoniously." But each of those possible meanings would, if adopted, provide a different scope of the claims.

218. Based on reviewing FIG. 8 in context of the entire patent's disclosure, a POSITA would understand that FIG. 8 provides merely an example of how a "central channel" can be "configured to interface with the baseplate." Accordingly, although FIG. 8 may depict an example of a configuration the inventor intended to satisfy the limitation but does nothing to provide reasonable certainty to the POSITA as to the full scope of the recited language of a "central channel . . . configured to interface with the baseplate."

219. The specification does not help determine the scope of this limitation. The only two references to "interface" in the specification are:

1. "As shown in the right illustration of FIG. 4, the baseplate can be configured to pivot around the stem/taper at arrow 495 for version correction and to allow for a direct bone-implant interface without requiring augmentation." '561 Patent, 4:55-58.
2. "The baseplate can advantageously pivot around the central stem with a Morse taper for version correction and allows for a direct bone-implant interface." *Id.*, 4:67-5:2.

220. In my opinion, neither of these instances are references to the embodiment claimed in claims 1-16 nor does either instance discuss the relationship between the "central channel" of the glenosphere and the. In fact, both instances include the modifiers "direct" and "bone-implant" with respect to "interface." A POSITA would not look to the description of a "direct bone-implant interface"—which is a noun—for guidance about what the inventor meant to convey in reciting a "central channel" of the glenosphere—which, recall, is claimed as an empty space or passageway in the Challenged Claims—to be "configured to interface"—which is a verb—with the baseplate.

221. During the original prosecution of the '561 Patent, the examiner did not issue any office actions prior to allowance. *See* EX-1004, EX-1005.

222. For the reasons above, it is my opinion that a POSITA would not be able to determine the scope of claims 1-16 regarding the limitation "central channel . . . configured to interface the baseplate" with reasonable certainty, when read in light of the specification and prosecution history.

VI. CONCLUSION

Based on the information I reviewed and for the reasons explained above, it is my opinion that each of the Challenged Claims is unpatentable.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on July 3, 2024.



T. Wade Fallin, M.S.