

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CATALYST ORTHOSCIENCE INC.,

Petitioner,

v.

SHOULDER INNOVATIONS, INC.,

Patent Owner.

Case No.: PGR2025-00001

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

**PETITION FOR POST-GRANT REVIEW
OF U.S. PATENT NO. 12,023,254**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	MANDATORY NOTICES UNDER 37 C.F.R. § 42.8.....	1
	A. REAL PARTY-IN-INTEREST	1
	B. RELATED MATTERS	1
	C. LEAD AND BACK-UP COUNSEL.....	2
	D. SERVICE INFORMATION.....	3
III.	FEE AUTHORIZATION	3
IV.	REQUIREMENTS UNDER 37 C.F.R. § 42.204	3
	A. GROUNDS FOR STANDING	3
	B. UNPATENTABILITY GROUNDS AND RELIEF REQUESTED	3
	C. CLAIM CONSTRUCTION.....	4
V.	THE CHALLENGED PATENT.....	5
	A. BACKGROUND OF THE ART	5
	B. EFFECTIVE FILING DATE OF THE CHALLENGED CLAIMS.....	9
	C. ALLEGED INVENTION OF THE CHALLENGED PATENT	10
	D. CHALLENGED CLAIMS.....	11
	E. PROSECUTION HISTORY	13
VI.	THE CHALLENGED CLAIMS ARE UNPATENTABLE.....	16
	A. GROUND 1: CLAIMS 1-7, 9-18, AND 20-22 ARE OBVIOUS OVER ORPHANOS IN VIEW OF HOPKINS, PEREGO, ROCHE, AND KNOWLEDGE OF A PERSON HAVING ORDINARY SKILL IN THE ART	16
	1. Overview of Orphanos.....	16
	2. Overview of Hopkins.....	20
	3. Overview of Perego	21
	4. Overview of Roche	23
	5. Claim 1.....	26
	6. Claims 2-7 and 9-11	54
	7. Claim 12.....	57
	8. Claims 13-18 and 20-22.....	60
	B. GROUND 2: CLAIMS 8 AND 19 ARE OBVIOUS OVER ORPHANOS IN VIEW OF HOPKINS, PEREGO, ROCHE, KNOWLEDGE OF A PERSON HAVING ORDINARY SKILL IN THE ART, AND FURTHER IN VIEW OF GARGAC	63

1.	Overview of Gargac	63
2.	Claim 8.....	65
3.	Claim 19.....	67
C.	GROUND 3: CLAIMS 1-7, 9-18, and 20-22 ARE OBVIOUS OVER LEFEBVRE IN VIEW OF ORPHANOS, HOPKINS, PEREGO, AND ROCHE.....	67
4.	Overview of Lefebvre.....	67
5.	Claim 1:	70
6.	Claims 2-7, 9-11.....	88
7.	Claim 12.....	89
8.	Claims 13-18 and 20-21.....	91
D.	GROUND 4: CLAIMS 8 AND 19 ARE OBVIOUS OVER LEFEBVRE IN VIEW OF ORPHANOS, HOPKINS, PEREGO, AND ROCHE, AND IN FURTHER VIEW OF GARGAC	93
9.	Claim 8.....	93
10.	Claim 19.....	95
E.	GROUND 5: CLAIMS 1-22 ARE UNPATENTABLE BECAUSE THE TERM "BASEPLATE CENTRAL CHANNEL" RENDERS THE CLAIMS INDEFINITE.....	95
F.	GROUND 6: CLAIMS 1-22 ARE UNPATENTABLE BECAUSE THE TERM "CENTRAL CHANNEL ... CONFIGURED TO INTERFACE WITH THE BASEPLATE" RENDERS THE CLAIMS INDEFINITE.....	99
VII. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 314(A) AND 35 U.S.C. § 325(D) IS NOT WARRANTED		103
A.	THE <i>FINTIV</i> FACTORS WEIGH IN FAVOR OF INSTITUTION	103
B.	THE <i>ADVANCED BIONICS</i> FRAMEWORK WEIGHS IN FAVOR OF INSTITUTION	105
VIII. CONCLUSION		107

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH</i> , IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020).....	94
<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019, Paper 11 (PTAB March 20, 2020)	91, 92
<i>In re Bagnall</i> , Appeal 2009-013429, 2011 WL 1463378 (B.P.A.I. Apr. 14, 2011)	36
<i>In re Bigio</i> , 381 F.3d 1320 (Fed. Cir. 2004)	22, 55, 59
<i>In re Dulberg</i> , 289 F.2d 522 (CCPA 1961).....	70
<i>Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.</i> , 800 F.3d 1375 (Fed. Cir. 2015)	8, 9
<i>Energizer Holdings, Inc. v. International Trade Comm'n</i> , 435 F.3d 1366 (Fed. Cir. 2006)	3
<i>Environmental Designs, Ltd. v. Union Oil Co.</i> , 713 F.2d 693 (Fed. Cir. 1983)	15
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	22, 55, 59
<i>Nautilus, Inc. v. Biosign Instruments, Inc.</i> , 572 U.S. 898 (2014)	84
<i>Shoulder Innovations, Inc. v. Catalyst OrthoScience Inc.</i> , C.A. No. 24-00266-JPM (D. Del.)	1, 92
Statutes	
35 U.S.C. §102(a)(1).....	21
35 U.S.C. § 102(a)(2).....	18, 55, 58
35 U.S.C. § 103.....	3
35 U.S.C. § 112(b)	84
35 U.S.C. § 112(d)	85

35 U.S.C. § 314(A)	91
35 U.S.C. § 325(D)	91, 94, 95
35 U.S.C. § 325(e)(2).....	93

Other Authorities

37 C.F.R. § 42.8	1
37 C.F.R. § 42.15(a) and § 42.103(a)	2
37 C.F.R. § 42.204	2
MPEP § 2144.04(V)(C)	70
MPEP § 2159.01	9

TABLE OF EXHIBITS

EX. NO.	DESCRIPTION
EX-1001	U.S. Patent No. 12,023,254 ("the '254 Patent")
EX-1002	Declaration of T. Wade Fallin, M.S.
EX-1003	Curriculum Vitae for T. Wade Fallin, M.S.
EX-1004	Prosecution History of U.S. Patent No. 12,023,254 (Part I)
EX-1005	Prosecution History of U.S. Patent No. 12,023,254 (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-1015	Docket Navigator Report: Profile of Judge Jon P. McCalla decisions related to motions to stay, dated June 24, 2024
EX-1016	Shoulder Innovations, Inc. v. Catalyst OrthoScience Inc., C.A. No. 24-266-JMP (D. Del.), Scheduling Order, D.I. 51
EX-1017	Webster's Ninth New Collegiate Dictionary (1987)
EX-1018	Grainger Catalog No. 400, 2009-2010 ("Grainger")
EX-1019	U.S. Pat. Pub. No. 2018/0193074 ("Hopkins")
EX-1020	U.S. Pat. Pub. No. 2015/0305877 ("Gargac")

KEY OF LIMITATIONS FOR CHALLENGED CLAIMS¹

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 baseplate central channel extending through the baseplate from the lateral end to the medial end;
	[1-3] a central post configured to at least partially pass through the central channel;
	[1-4] 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,
	[1-5] the locking nut configured to engage the central post when the central post and baseplate are implanted within the medical patient,
	[1-6] wherein the external thread is configured to couple the locking nut with the baseplate central channel;
	[1-7] a glenosphere, having a lateral, convex articular side, a medial side, and a glenosphere central channel extending from the convex articular side to the medial side and configured to interface with the baseplate; 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.

¹ This key of claim limitations is also submitted as EX-1014.

CLAIM	RECITED LIMITATIONS
[2]	[2-PRE] The reverse shoulder implant of claim 1, [2-1] wherein the glenosphere is configured to at least partially surround an external surface of the baseplate.
[3]	[3-PRE] The reverse shoulder implant of claim 1, [3-1] wherein the baseplate has a circular shape.
[4]	[4-PRE] The reverse shoulder implant of claim 1, [4-1] wherein the glenosphere is configured to surround the baseplate.
[5]	[5-PRE] The reverse shoulder implant of claim 1, [5-1] wherein the glenosphere is configured to be secured to the baseplate with a Morse taper.
[6]	[6-PRE] The reverse shoulder implant of claim 1, [6-1] wherein a diameter of the locking nut is greater than a length of the locking nut.
[7]	[7-PRE] The reverse shoulder implant of claim 1, [7-1] 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.
[8]	[8-PRE] The reverse shoulder implant of claim 1, [8-1] wherein the central post has a length of about 5 mm, 5.5 mm, 6 mm, 6.5 mm, 7 mm, 7.5 mm, 8 mm, 8.5 mm, 9 mm, 9.5 mm, 10 mm, 10.5 mm, 11 mm, 11.5 mm, 12 mm, 12.5 mm, 13 mm, 13.5 mm, 14 mm, 14.5 mm, or 15 mm.
[9]	[9-PRE] The reverse shoulder implant of claim 1, [9-1] wherein the central channel defines a surface integral with the central post.

CLAIM	RECITED LIMITATIONS
[10]	[10-PRE] The reverse shoulder implant of claim 1, [10-1] wherein the central post includes a rotational control feature.
[11]	[11-PRE] The reverse shoulder implant of claim 1, [11-1] wherein the central post comprises a central channel configured to house a primary screw.
[12]	[12-PRE] A reverse shoulder implant, comprising:
	[12-1] a baseplate configured to be secured to a glenoid of a scapular bone of patient,
	[12-2] the baseplate having a lateral end, a medial end, and a baseplate central channel extending through the baseplate from the lateral end to the medial end;
	[12-3] a central post configured to at least partially pass through the central channel;
	[12-4] 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,
	[12-5] the locking nut configured to engage the central post when the central post and baseplate are implanted within the medical patient,
	[12-6] wherein the external thread is configured to engage the baseplate central channel; and
	[12-7] 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

CLAIM	RECITED LIMITATIONS
	[12-8] 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.
[13]	[13-PRE] The reverse shoulder implant of claim 12, [13-1] wherein the glenosphere is configured to at least partially surround an external surface of the baseplate.
[14]	[14-PRE] The reverse shoulder implant of claim 12, [14-1] wherein the baseplate has a circular shape.
[15]	[15-PRE] The reverse shoulder implant of claim 12, [15-1] wherein the glenosphere is configured to surround the baseplate.
[16]	[16-PRE] The reverse shoulder implant of claim 12, [16-1] wherein the glenosphere is configured to be secured to the baseplate with a Morse taper.
[17]	[17-PRE] The reverse shoulder implant of claim 12, [17-1] wherein a diameter of the locking nut is greater than a length of the locking nut.
[18]	[18-PRE] The reverse shoulder implant of claim 12, [18-1] 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.

CLAIM	RECITED LIMITATIONS
[19]	[19-PRE] The reverse shoulder implant of claim 12, [19-1] wherein the central post has a length of about 5 mm, 5.5 mm, 6 mm, 6.5 mm, 7 mm, 7.5 mm, 8 mm, 8.5 mm, 9 mm, 9.5 mm, 10 mm, 10.5 mm, 11 mm, 11.5 mm, 12 mm, 12.5 mm, 13 mm, 13.5 mm, 14 mm, 14.5 mm, or 15 mm.
[20]	[20-PRE] The reverse shoulder implant of claim 12, [20-1] wherein the central channel defines a surface integral with the central post.
[21]	[21-PRE] The reverse shoulder implant of claim 12, [21-1] wherein the central post includes a rotational control feature.
[22]	[22-PRE] The reverse shoulder implant of claim 12, [22-1] wherein the central post comprises a central channel configured to house a primary screw.

I. INTRODUCTION

Catalyst OrthoScience Inc. ("Petitioner") requests post-grant review ("PGR") of claims 1-22 ("Challenged Claims") of U.S. Patent No. 12,023,254 ("the '254 Patent" or "Challenged Patent") (EX-1001), which is assigned to Shoulder Innovations, Inc. ("Patent Owner").

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

A. REAL PARTY-IN-INTEREST

The real party-in-interest is Petitioner, Catalyst OrthoScience Inc.

B. RELATED MATTERS

Patent Owner has asserted the '254 Patent against Petitioner in *Shoulder Innovations, Inc. v. Catalyst OrthoScience Inc.*, C.A. No. 24-00266-JPM (D. Del.) ("the Lawsuit"). Petitioner filed counterclaims for non-infringement and invalidity of the '254 Patent in the Lawsuit. On July 3, 2024, Petitioner filed a PGR petition challenging the claims of U.S. Patent No. 11,771,561 ("the '561 Patent"), which Patent Owner has also asserted against Petitioner in the Lawsuit. *See Catalyst OrthoScience Inc. v. Shoulder Innovations, Inc.*, No. PGR2024-00042 (PTAB) ("the '561 Petition"). The '254 Patent and the '561 Patent both claim priority to application serial no. 17/435,333, filed as PCT/US2020/022094 on March 11, 2020, and to provisional application no. 62/816,708, filed on March 11, 2019. As of the filing of this petition, PTAB has not made an institution decision regarding the '561 Petition.

The Challenged Claims in this petition are nearly identical to those in the '561 Petition. The prior art relied on here significantly overlaps the prior art relied on in the '561 Petition. Petitioner is not aware of any other judicial or administrative matters that would affect, or be affected by, a decision in this proceeding.

C. LEAD AND BACK-UP COUNSEL

Petitioner designates the counsel below as its representatives for this proceeding and has filed a power of attorney to this effect:

LEAD COUNSEL	BACK-UP COUNSEL
Paul M. Ulrich (Reg. No. 46,404) FROST BROWN TODD LLP 301 East Fourth Street, Suite 3300 Cincinnati, Ohio 45202 Tel: (513) 651-6432 Fax: (513) 651-6981 Email: pulrich@fbtlaw.com	Paul J. Linden (Reg. No. 74,058) FROST BROWN TODD LLP 301 East Fourth Street, Suite 3300 Cincinnati, Ohio 45202 Tel: (513) 651-6135 Fax: (513) 651-6981 Email: plinden@fbtlaw.com Todd A. Spears (Reg. No. 76,887) FROST BROWN TODD LLP 301 East Fourth Street, Suite 3300 Cincinnati, Ohio 45202 Tel: (513) 651-6411 Fax: (513) 651-6981 Email: tspears@fbtlaw.com

D. SERVICE INFORMATION

Petitioner consents to electronic service by email of all documents and correspondence related to this proceeding. Any information related to this proceeding should be sent to Petitioner's lead and back-up counsel using the contact information above.

III. FEE AUTHORIZATION

Under 37 C.F.R. § 42.15(a) and § 42.103(a), Petitioner authorizes the USPTO to charge any and all fees for this petition to Deposit Account No. 06-2226.

IV. REQUIREMENTS UNDER 37 C.F.R. § 42.204

A. GROUNDS FOR STANDING

Petitioner certifies that the '254 Patent is eligible for PGR and Petitioner is not barred or estopped from requesting PGR on the grounds identified in this petition.

B. UNPATENTABILITY GROUNDS AND RELIEF REQUESTED

Petitioner requests cancellation of each of the Challenged Claims under AIA² 35 U.S.C. §§ 103 and 112, based on the following grounds, supported by the declaration of T. Wade Fallin, M.S., who has at least the qualifications of POSITA, and is qualified to be an expert in this matter. (Fallin Decl., EX-1002 at 10-12, ¶¶6-11("EX-1002").)

² The earliest possible priority date to which any of the Challenged Claims could be entitled is after March 16, 2013 and, thus, the Leahy-Smith America Invents Act ("AIA") applies to patentability determinations. MPEP § 2159.01.

SUMMARY OF GROUNDS	
1.	Claims 1-7, 9-18, and 20-22 are unpatentable under § 103 as obvious over Orphanos in view of Hopkins, Perego, Roche, and the knowledge and skill of a POSITA
2.	Claims 8 and 19 are unpatentable under § 103 as obvious over Orphanos in view of Hopkins, Perego, Roche, the knowledge and skill of a POSITA, and in further view of Gargac
3.	Claims 1-7, 9-18, and 20-22 are unpatentable under § 103 as obvious over Lefebvre in view of Hopkins, Perego, Orphanos, and Roche
4.	Claims 8 and 19 are unpatentable under § 103 as obvious over Lefebvre in view of Hopkins, Perego, Orphanos, and Roche, and in further view of Gargac
5.	Claims 1-22 are unpatentable under § 112 because the term "baseplate central channel" renders the claims indefinite
6.	Claims 1-22 are unpatentable under § 112 because the term "central channel... configured to interface with the baseplate" renders the claims indefinite

C. CLAIM CONSTRUCTION

Grounds five and six present arguments of unpatentability based on indefiniteness under § 112 and may require the Board to engage in claim construction analysis to resolve them. *Energizer Holdings, Inc. v. International Trade Comm'n*, 435 F.3d 1366, 1368 (Fed. Cir. 2006). That analysis is addressed below. Other than for those grounds, the Board need not construe the Challenged Claims to grant this petition. Petitioner may present proposed claim constructions later in this proceeding if necessary to respond to arguments presented by the Patent Owner or findings of the Board. In the Lawsuit noted above, neither Petitioner nor Patent Owner identified any terms or phrases recited in the Challenged Claims for construction.

V. THE CHALLENGED PATENT

A. BACKGROUND OF THE ART

The glenohumeral joint (i.e., shoulder joint) is formed by a ball and socket relationship between the head of the humerus (i.e., the upper arm bone), which represents the "ball," and the glenoid cavity of the scapula (i.e., shoulder blade), which represents the "socket." (EX-1002 at 18, ¶37.) Over time, a patient may experience damage to or deterioration of the glenohumeral joint, such as fractures, rotator cuff injuries, rheumatoid arthritis, osteoarthritis, cartilage loss, or bone loss. (*Id.* at 19, ¶38.) To alleviate prolonged pain associated with such damage or deterioration, a patient may undergo a total shoulder replacement surgery, where the glenohumeral joint is modified with implanted artificial parts. (*Id.*, ¶39.)

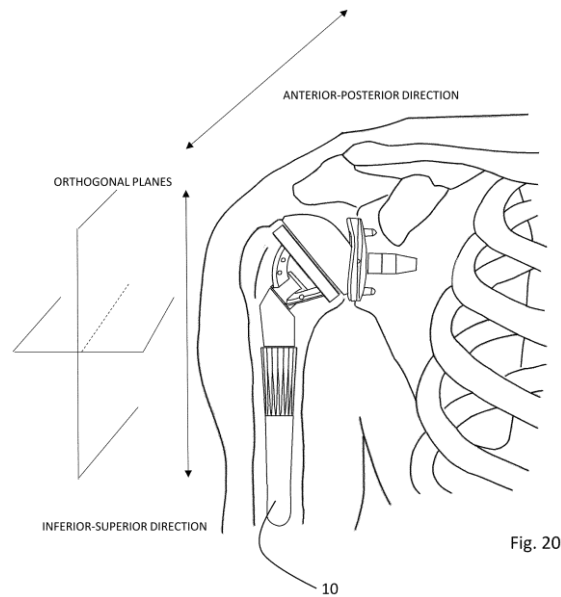
There are two types of total shoulder replacement surgeries: (i) an anatomic total shoulder replacement and (ii) a reverse total shoulder replacement. Anatomic shoulder replacement was the norm until the 1970s when reverse shoulder replacements were conceived. (*Id.*, ¶40; Roche, 1:32-63, EX-1007 at 66 ("EX-1007").)

An anatomic total shoulder replacement involves modifying: (i) the humeral head with a ball implant; and (ii) the glenoid cavity with a socket implant; thus, the implants reflect the natural shape of the bones. (EX-1002 at 19, ¶40.)

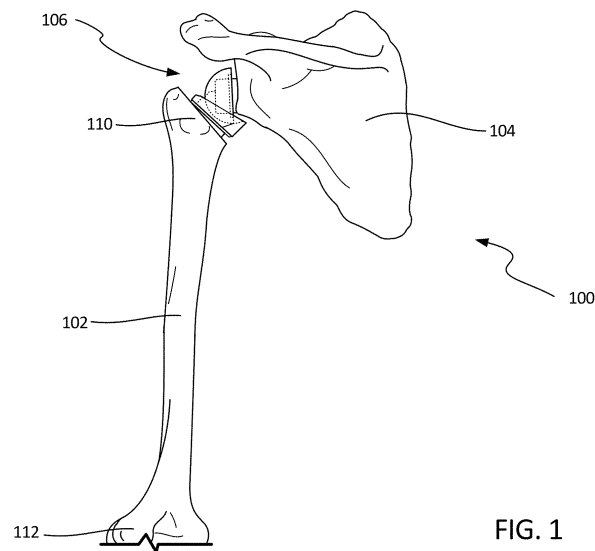
A reverse total shoulder replacement, by contrast, involves modifying: (i) the

glenoid fossa with a ball implant; and (ii) the humeral head with a socket implant; achieving the *reverse* of the natural configuration of the joint. (*Id.*)

Example of Anatomic Total Shoulder Replacement
Perego, Figure 20, EX-1010 at 17



Example of Reverse Total Shoulder Replacement
Varadarajan, Figure 1, EX-1011 at 12



Many prior art reverse shoulder systems disclose a round baseplate and a

glenosphere having a convex joint surface. (Hodorek, ¶[0011], FIGS. 7-9, EX-1012 at 5, 6, 27 ("EX-1012"); Lefebvre, FIGS. 18-23, EX-1009 at 10-12 ("EX-1009"); Orphanos, Abstract, FIGS. 2B, 3, 7-8, EX-1006 at 1, 4-5, 10-11 ("EX-1006"); EX-1002 at 19, ¶41.) In such systems, the baseplate is fixed to the glenoid cavity of the scapula, while the glenosphere is fixed to the baseplate. (EX-1012 at 27, ¶11; EX-1002 at 20, ¶42.) Those skilled in the art appreciated at the time of the invention of the '254 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). (EX-1002 at 20, ¶43.)

It was well known by a POSITA at the time of the invention of the '254 Patent that such prior art reverse shoulder systems may include a baseplate, a central channel, a central anchoring element (e.g., a compression screw, post, etc.) 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.*, ¶44.) Additionally, those skilled in the art recognized the importance of keeping the baseplate fastened to the scapula (*see, e.g.*, EX-1007 at 29, 7:26-55) and the problem that, after implantation, the interface between the glenosphere and baseplate may loosen, leading to misalignment between the glenosphere and baseplate (*see, e.g.*,

EX-1012 at 27, ¶[0012]). (EX-1002 at 20-21, ¶45.)

It also was well known by a POSITA at the time of the invention of the '254 Patent that various types of anchoring elements may be used to anchor the baseplate with the glenoid cavity of the scapular. (EX-1006 at 22, 25, 30, 1:43-2:8, 7:26-30, 8:4-30, 18:9-22; EX-1009 at 15-16, 6:65-7:35; Perego, 12:3-15, 12:52-56, EX-1010 at 23 ("EX-1010"); Hopkins, ¶¶[0037]-[0038],[0040]-[0041],[0051],[0068]-[0070], EX-1019 at 10-12, 14 ("EX-1019"); EX-1002 at 21, ¶46.) Further, it was well known by a POSITA at the time of the invention of the '254 Patent that the various types of anchoring elements may be used together, or as an alternative to one another (i.e., substitutes for one another), to anchor the baseplate with the glenoid cavity of the scapula. (EX-1006 at 22, 1:43-2:8; EX-1010 at 23, 12:3-15, 12:52-56; EX-1019 at 10, ¶[0039]; EX-1002 at 21, ¶46.)

Anchoring elements (e.g., compression screws, posts, etc.) and locking cap screws were, before the '254 Patent, used to fasten the baseplate to the scapula such that (i) the anchoring element engages the scapula at a suitable angle, and (ii) the locking cap screw is screwed into the baseplate on top of the anchoring element to lock the anchoring element at the desired angle or prevent the anchoring element from backing out of the scapula. (EX-1007 at 69-70, 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."); EX-

1002 at 21, ¶47.)

Therefore, it was known at the time of the '254 Patent to provide a baseplate with through-holes (e.g., central and peripheral channels) dimensioned to receive an anchoring element (e.g., a compression screw, post, etc.), where the through-holes also have internal threading to mate with a locking cap screw such that the locking cap screw may engage the anchoring element. (EX-1007 at 69, 72, 7:33-38, 14:11-17; EX-1002 at 22, ¶48.) And it was well known that adapters interposed between portions of the glenosphere and baseplate, in conjunction with fixing screws, had been used to fixedly couple the glenosphere to the baseplate. (EX-1010 at 8-9, 23, 12:37-63, FIGS. 7A-7D (adapter **24**, fixing screw **25**); EX-1002 at 22, ¶49.)

B. EFFECTIVE FILING DATE OF THE CHALLENGED CLAIMS

The effective filing date of the '254 Patent is March 14, 2024, the date that the patent application that issued as the '254 Patent was filed. (EX-1001 at 1.) If Patent Owner claims that the '254 Patent is entitled to an earlier effective filing date, it is Patent Owner's burden of proving said entitlement. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1379-80 (Fed. Cir. 2015) ("[B]ecause the PTO does not examine priority claims unless necessary, the Board has no basis to presume that a [] patent is necessarily entitled to the filing date of its provisional application"). If Patent Owner attempts to prove an earlier effective filing date, then Petitioner may attempt to prove an earlier effective filing date for any reference that was obviated

as prior art because of Patent Owner's establishing an earlier effective filing date than March 14, 2024. *Id.*³

C. ALLEGED INVENTION OF THE CHALLENGED PATENT

The '254 Patent, titled "Total Reverse Shoulder Systems and Methods," generally relates to a total reverse shoulder replacement system, which includes (as shown below in Figure 8) a glenoid baseplate (purple), a central post (e.g., light green or dark green), a threaded locking insert (red), a glenosphere (orange), and a locking screw (blue):

EX-1001 at 12, Figure 8

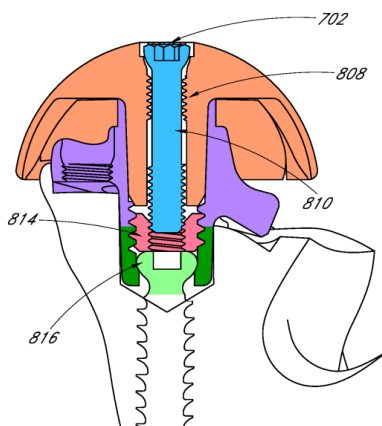


FIG. 8

(EX-1001 at 27, 3:25-28.) The claimed subject matter of the '254 Patent is primarily directed toward the embodiment shown in Figure 8 above, which is described in column 6, lines 34-56.

³ Petitioner respectfully reserves the right to rebut any attempt by Patent Owner to establish an effective filing date earlier than March 14, 2024.

D. CHALLENGED CLAIMS

Petitioner challenges the patentability of each Challenged Claim, which includes two independent claims (claims 1 and 12) and 20 dependent claims (claims 2-11 and claims 13-22), of which 10 claims depend directly from an independent claim. (*Id.* at 30, 9:35-10:63.)

Notably, the independent claims are nearly identical, differing in substance by just a few words in the recited language as shown in ***bold italics*** below:

Claim 1	Claim 12
1. A reverse shoulder implant, comprising:	12. A reverse shoulder implant, comprising:
a baseplate configured to be secured to a glenoid of a scapular bone of [a] patient, the baseplate having a lateral end, a medial end, and a baseplate central channel extending through the baseplate from the lateral end to the medial end;	a baseplate configured to be secured to a glenoid of a scapular bone of [a] patient, the baseplate having a lateral end, a medial end, and a baseplate central channel extending through the baseplate from the lateral end to the medial end;
a central post configured to at least partially pass through the central channel;	a central post configured to at least partially pass through the central channel;
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, the locking nut configured to engage the central post when the central post and baseplate are implanted within the medical patient, wherein the external thread is configured to <i>couple the locking nut with the baseplate central channel;</i>	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, the locking nut configured to engage the central post when the central post and baseplate are implanted within the medial patient, wherein the external thread is configured to <i>engage the baseplate central channel;</i> and

Claim 1	Claim 12
a glenosphere, having a lateral, convex articular side, a medial side, and a <i>glenosphere</i> central channel extending from the convex articular side to the medial side and configured to interface with the baseplate; and	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
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.	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. ⁴

Moreover, the claims that depend directly from claims 1 and 12, respectively, are identical (except for the independent claim for which they depend). (*Compare* EX-1001, claims 2-11 *with* claims 13-22.) To streamline the petition, Petitioner will take advantage of the nearly identical claim language recited in claims 1-11 and 12-22, respectively, by employing internal references to arguments and evidence made with respect to previously discussed claims or limitations. For example, to the extent Petitioner relies on prior art to disclose a particular limitation that is present in claims 2 and 13, Petitioner will make its arguments once with respect to claim 2 and refer back to that argument when discussing the same limitation in claim 13.

⁴ The language of claim 12 describes the glenosphere the glenosphere screw in the same paragraph. Petitioner has separated that claim language—making the claim language describing the glenosphere screw a separate paragraph—to aid in comparing the recited language of claim 12 with that of claim 1.

E. PROSECUTION HISTORY

The '254 Patent issued from application serial no. 18/605,361, ("the '361 Application"), which was filed on March 14, 2024. (EX-1001 at 1.) The '361 Application included an original set of claims 1-9 (Pros. Hist. of '254 Patent, EX-1004 at 23), which was cancelled in its entirety and, in a March 15, 2024 preliminary amendment, a new claim set was filed with claims 10-31. (*Id.* at 91-94)

On May 15, 2024, the examiner issued a Notice of Allowance and Fees Due without having issued any office actions. (*Id.* at 120-23.) The accompanying Notice of Allowability included Reasons for Allowance, which stated that the prior art did not disclose the recited limitations of the independent claims, listing all the recited limitations. (*Id.* at 121.) The examiner neither identified nor described any particular prior art considered during examination in the Notice of Allowability. (*Id.* at 120-23.)

On June 12, 2024, an Issue Notification was issued (Pros. Hist. of '254 Patent, EX-1005 at 13), and the '254 Patent ultimately was granted on July 2, 2024 (*id.* at 15-16). Nowhere in the file history of the '254 Patent does the examiner identify, discuss, or issue rejections based on the prior art of record.

F. LEVEL OF SKILL IN THE ART

Determining the level of skill of a POSITA at the effective filing date involves the following factors: (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. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696-97 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381-82 (Fed. Cir. 1983)). Not all these factors may be present in every case, and one or more of these or other factors may predominate. *Id.*

The level of skill of a POSITA in the art of the '254 Patent is at least a bachelor's degree in mechanical or biomedical engineering, or similar discipline, with at least 3 years of experience designing joint replacement systems for medical patients. (EX-1002 at 35-36, ¶70.) Additional experience in designing joint replacement systems may counterbalance a corresponding lack of education or vice versa—for example, an artisan with more than three years' experience designing joint replacement systems may have the requisite level of skill, even though they do not possess a bachelor's degree as stated above. (*Id.*)

The most relevant factors here are (a),(b), and (c).⁵ The problems encountered by those working in the field tend to involve those associated with the interaction and functionality of mechanical components. (*Id.* at 36, ¶71.) The mechanical

⁵ Petitioner is not aware of evidence related to factor(d).

components at issue in making and implementing a functional joint replacement system are relatively straightforward such that a bachelor's level mechanical or biomedical engineer would be able to understand and begin solving problems associated with such design. (*Id.*)

The technology of the '254 Patent, however, can present unique or more complex challenges than straightforward mechanical devices because the mechanical components are designed to be implemented in a medical context and interact inside a medical patient. Accordingly, a POSITA would have, in addition to the educational background above, years of experience working with mechanical devices and components whose purpose and function is to operate inside a medical patient. For the technology claimed in the '254 Patent, a POSITA should have at least three years' experience with joint replacement systems. (*Id.* at 36-37, ¶73.)

The experience of active workers in the field aligns with the above. During Petitioner's expert's 40-year career in the orthopedic industry designing joint replacement systems, he has worked with and supervised many professionals whose responsibilities included designing joint replacement systems. (*Id.*) Those he worked with and supervised had the above education and experience. (*Id.*)

Finally, the sophistication of the technology and rapidity of innovation in the technological field further supports the level of skill above. (*Id.* at 37, ¶75.) As noted previously, in addition to understanding mechanical devices, one skilled in the

art would also need to have an appreciation and understanding of the often unique challenges involved when implementing mechanical devices inside a medical patient and possess the technical education and experience necessary to address those challenges. (*Id.* at 36, ¶72.) Moreover, the technological field here tends to experience fast-paced innovation, as demonstrated by the disclosure of the '254 Patent itself, which shows a crowded field with many patents and patent applications arising in close temporal proximity to the purported invention. (*Id.*)

In sum, the record evidence supports the view that a POSITA in the field of the '254 Patent would have the level of skill asserted above.

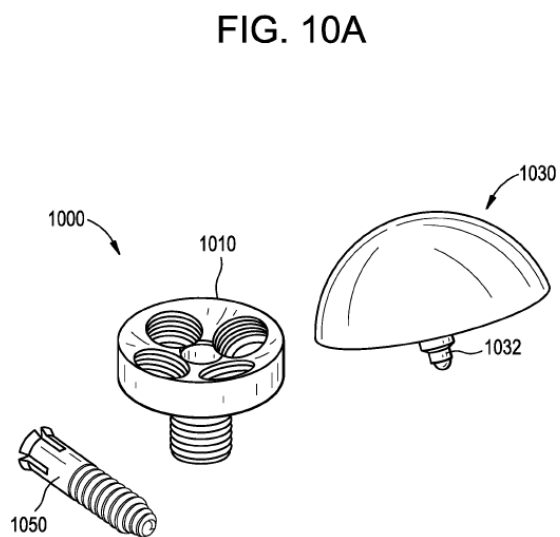
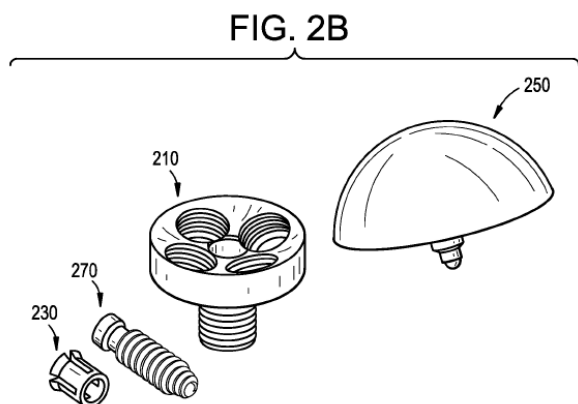
VI. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. GROUND 1: CLAIMS 1-7, 9-18, AND 20-22 ARE OBVIOUS OVER ORPHANOS IN VIEW OF HOPKINS, PEREGO, ROCHE, AND KNOWLEDGE OF A PERSON HAVING ORDINARY SKILL IN THE ART

1. Overview of Orphanos

Orphanos issued from an application filed on July 24, 2018, which is before the '254 Patent's effective filing date of March 14, 2024. (EX-1002 at 23, ¶51.) Therefore, Orphanos is prior art under AIA 35 U.S.C. § 102(a)(2). (*Id.*) Orphanos was not cited as a reference during prosecution. (EX-1001 at 1-4.)

EX-1006 at 4, 13, Figures 2B and 10A



EX-1006 at 5, 8, 14, 15, Figures 3, 5, and 10B-C

FIG. 3

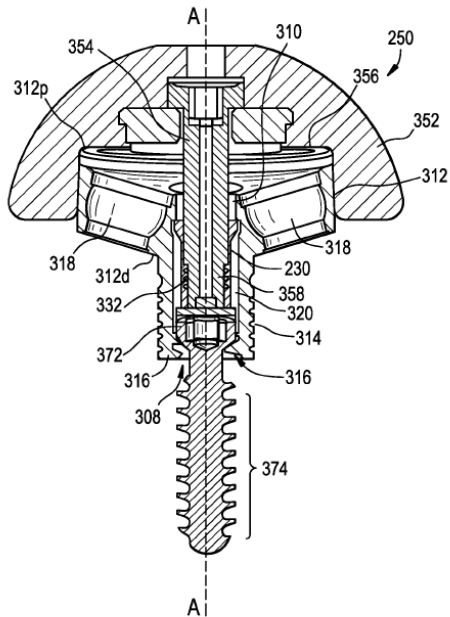


FIG. 10B

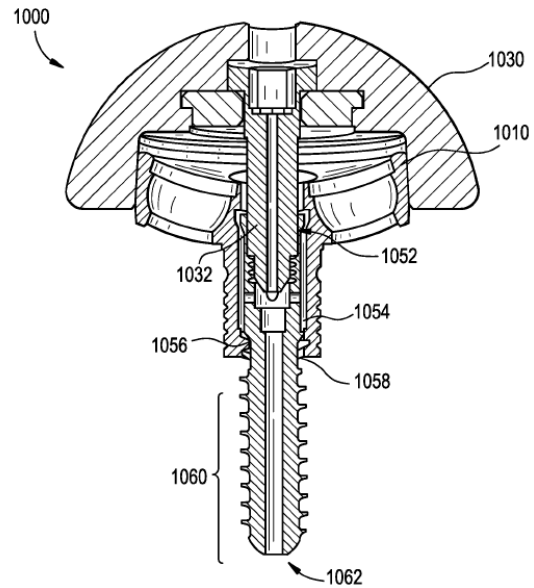


FIG. 10C

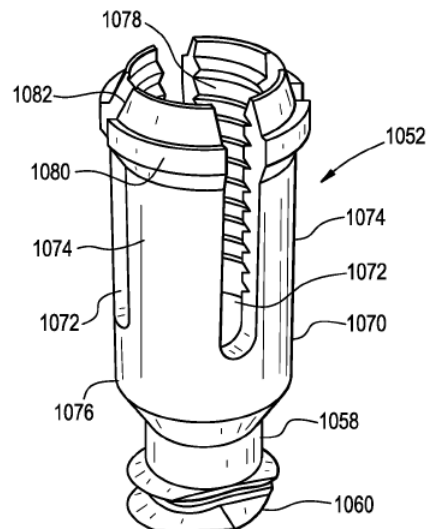
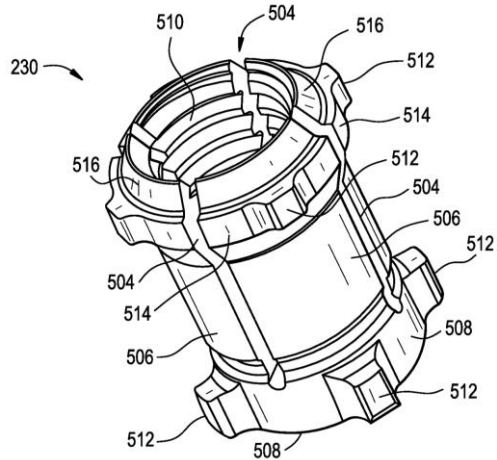


FIG. 5



Orphanos discloses at least two prior art reverse shoulder implants—a first reverse implant **200** and a second reverse implant **1000**—that are to be used in reverse shoulder procedures. (EX-1006 at 22, 24, 2:20-24, 6:53-61.) For each respective reverse shoulder implant **200**, **1000**, Orphanos discloses a respective bone screw **270**, **1050**; baseplate **210**, **1010**; and glenosphere **250**, **1030**. (*Id.* at 4-5, 8, 13-14, 22, 25, 30, 2:23-28, 7:21-31, 17:17-38, FIGS. 2B, 3, 6A, 10A-B.) The terms baseplate, metaglene, and/or metaglene component are used interchangeably within Orphanos. (*Id.* at 22, 24, 2:23-25, 6:53-61.)

Bone screw **270**, **1050** is disposed within a central throughbore (i.e., a central channel) of baseplate **210**, **1010** and driven into the glenoid bone of a patient to secure baseplate **210**, **1010** to such bone. (*Id.* at 25, 29, 7:26-30, 16:39-26.) Orphanos discloses that it was known to a POSITA that prior art baseplates **210** included a central post **314** designed to be press fit (i.e., fixed) into a void or hole drilled into glenoid **28** of the patient, thereby providing a *first* form of bone fixation. (*Id.* at 25, 8:4-30.) Further, Orphanos recognized that in some instances, it may be useful to drive a central bone screw **270** through throughbore **310** defined by central post **314** to further promote implantation of baseplate **210** onto the glenoid of the patient. (*Id.*)

Moreover, for each reverse shoulder implant, Orphanos discloses a respective adapter (i.e., a locking nut), in the form of a collet **230**, **1052**, that is configured:

(i) to be secured within the central throughbore of its respective baseplate **210, 1010**; and (ii) to threadably engage a respective locking screw **354, 1032** to secure glenosphere **250, 1030** to its respective baseplate **210, 1010**. (*Id.* at 26-27, 10:30-56, 11:5-41.)

2. Overview of Hopkins

Hopkins issued from an application filed on January 5, 2018, which is before the '254 Patent's effective filing date of March 14, 2024. Therefore, Hopkins is prior art under AIA 35 U.S.C. § 102(a)(2). Hopkins was not cited as a reference during prosecution. (EX-1001 at 1-4.).

EX-1019 at 2, 4, 7 Figures 1, 3A, and 6

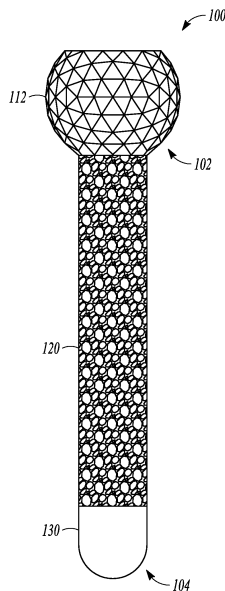


FIG. 1

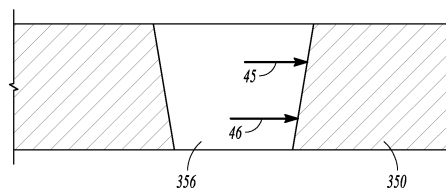


FIG. 3A

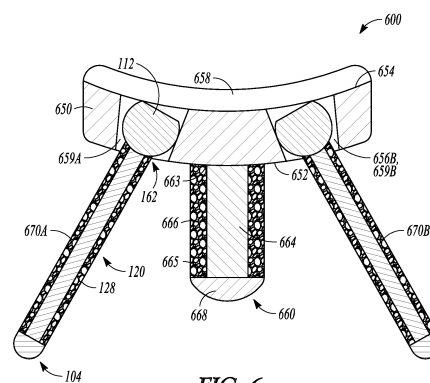


FIG. 6

Hopkins discloses a prior art orthopedic implant assembly, e.g., **600**, that may include fixation post(s) **100, 660, 670A, 670B** and a glenoid baseplate **350, 650**.

(EX-1019 at 10-12, 14, ¶¶[0037],[0040]-[0041],[0051],[0069]-[0072].) Hopkins recognizes the interchangeability between various fasteners that may be used to fix a baseplate **350, 650** onto the glenoid of a patient, such as posts, screws, and rods. (*Id.* at 10, ¶[0038].) Hopkins describes that such fasteners may be separate components of a baseplate **350, 650** such that the fasteners are inserted through a fastener bore **356, 656A** and into an surgically created post hole of the glenoid to selectively couple with baseplate **350, 650** and the glenoid. (*Id.* at 15, ¶[0082].)

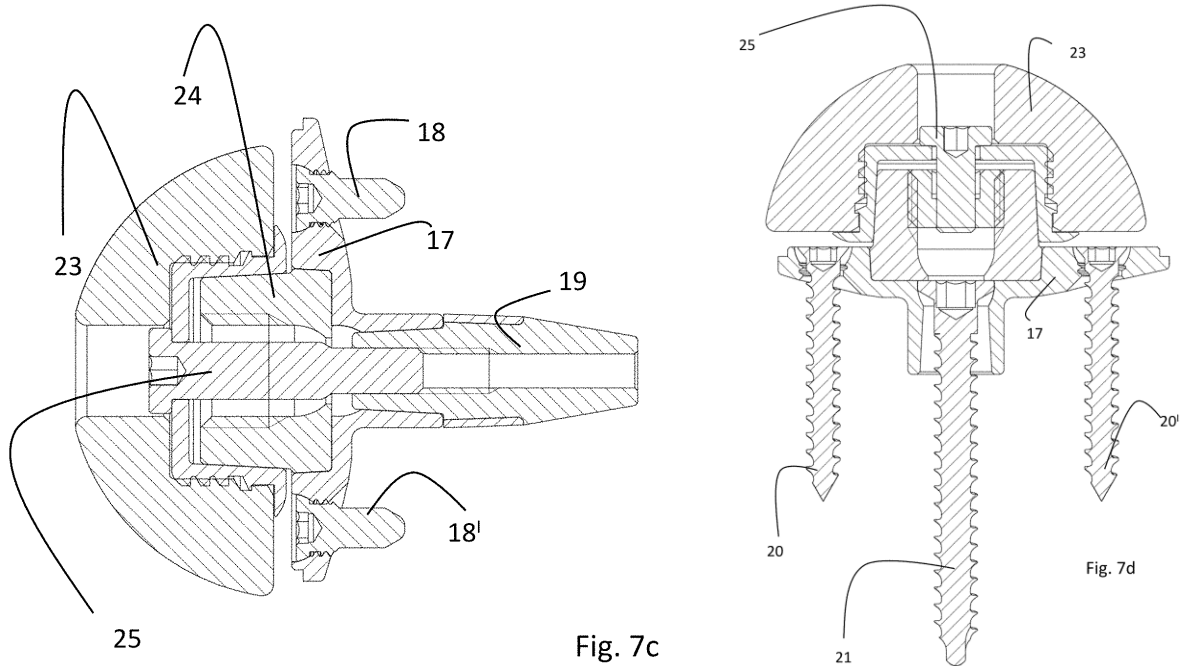
Further, Hopkins discloses a prior art method of inserting a fixation post **670A** through a fastener bore **656A** of a baseplate **650** such that a portion of the fixation post **670A** is inserted into an surgically created posthole within the glenoid of the patient, while another portion of the fixation post **670A** remains engaged with the baseplate **650**, thereby securing baseplate **650** with the glenoid of a patient. (*Id.* at 15-16, ¶¶[0078]-[0085].) Additionally, Hopkins discloses that a central post **660** can be inserted into a central fastener bore (not shown) such that a portion of central post **660** is inserted into an surgically created posthole within the glenoid of the patient to anchor base plate **650** into bone. (*Id.* at 14, ¶[0070].)

3. Overview of Perego

Perego issued from an application filed on February 20, 2020, which is before the '254 Patent's effective filing date of March 14, 2024. Therefore, Perego is prior

art under AIA 35 U.S.C. §102(a)(2). Perego was not cited as a reference during prosecution. (EX-1001 at 1-4.)

EX-1010 at 8, 9, Figures 7C and 7D



As shown above, Perego discloses various prior art reverse shoulder implants that are to be used in reverse shoulder procedures. (EX-1010 at 1, 23, Abstract, 12:16-18.) Perego discloses a prior art reverse shoulder implant having a glenosphere 23, a glenoid base-plate 17, an adapter 24 that is interposed between glenoid base-plate 17 and glenosphere 23, and a fixing screw 25 that is used to couple glenosphere 23 to the threaded grub screw inside adapter 24. (*Id.* at 23, 12:3-15, 12:37-56.) Perego also describes that it is readily known to a POSITA to use a central pin 19, a central compression screw 21, or both to fix glenoid base-plate 17 to the glenoid bone of a patient. (*Id.* at 23, 12:3-15.) Further, Perego describes that

central pin **19** is selectively attachable to base-plate **17** via a Morse taper. (*Id.* at 23, 12:9-11.)

4. Overview of Roche

Roche issued on January 12, 2016, which is before the '254 Patent's effective filing date of March 14, 2024. Therefore, Roche is prior art under AIA 35 U.S.C. §102(a)(1). Roche was not cited as a reference during prosecution. (EX-1001 at 1-4.)

EX-1007 at 14, Figures 8A and 9A

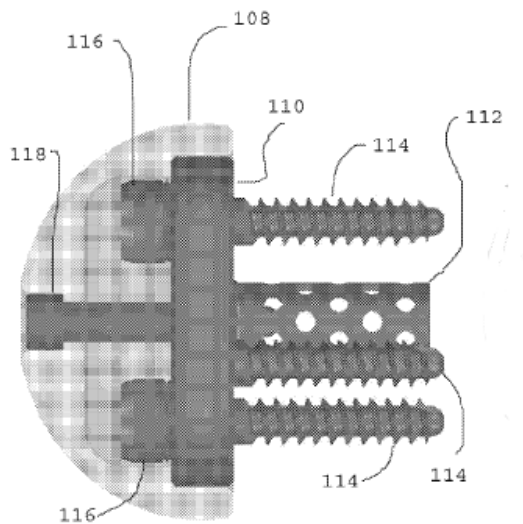


Fig. 8A

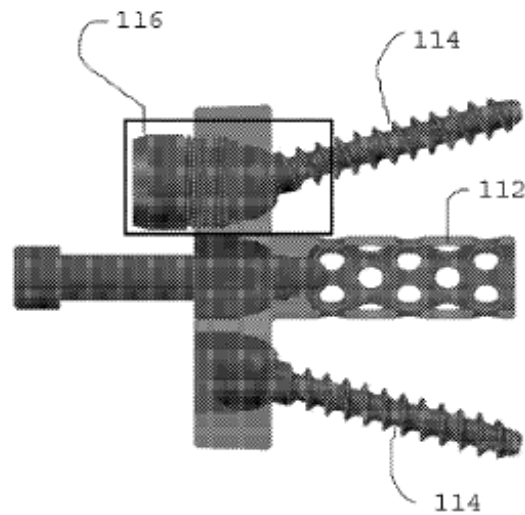
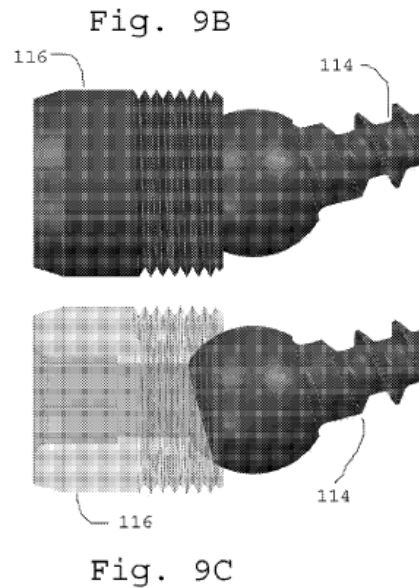


Fig. 9A

EX-1007 at 15, Figures 9B-C



Roche discloses a prior art reverse shoulder implant having a glenosphere **108**, a glenoid plate **110** (i.e., a baseplate), anchoring elements in the form of a central post **112** and compression screws **114**, and locking cap screws **116** (i.e., locking nuts). (EX-1007 at 70, 72, 10:53-55, 14:1-18.) Roche teaches inserting anchoring elements in the form of compression screws **114** through baseplate. (*Id.* at 70, 72, 10:53-55, 14:1-18.) Roche recognizes the long-known problem that compressions screws **114** tend to back out of the bone after being implanted. (*Id.* at 69, 72, 7:33-43, 14:1-18; EX-1002 at 32-33, ¶63.)

To solve this problem, Roche teaches incorporating a threaded feature in the screw holes of glenoid plate **110**, where such internal threading is configured to receive the external threading of locking cap screw **126**, thereby enabling locking cap screw **116** to engage and/or compress against the head of compression screw **114**

to lock the compression screw to glenoid plate **110** (i.e., preventing the compression screw from backing out of the bone). (*Id.* at 72, 14:1-18; EX-1002 at 32-33, ¶63.)

Orphanos, Hopkins, Perego, and Roche are analogous art for §103 purposes because all arise from the same field of endeavor as the '254 Patent and all are reasonably pertinent to the problem that the inventors of the '254 Patent sought to solve (EX-1002 at 23, 28, 29-30, 31, ¶¶51, 58, 60, 62). *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). A POSITA would be motivated to combine Orphanos, Hopkins, Perego, and Roche with a reasonable expectation of succeeding in doing so for reasons set forth below. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007) ("[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.").

5. Claim 1

a. [1-PRE]: "A reverse shoulder implant, comprising"⁶

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

FIG. 3

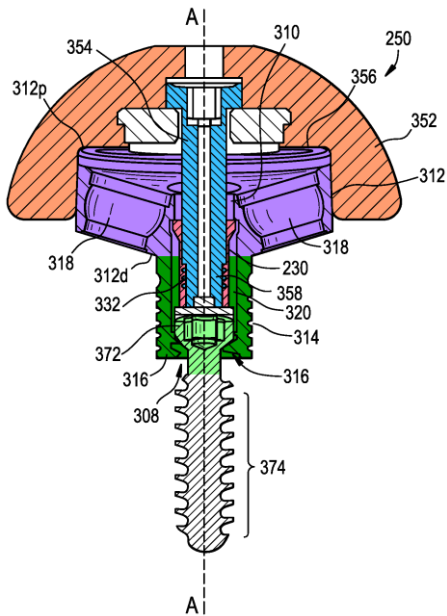
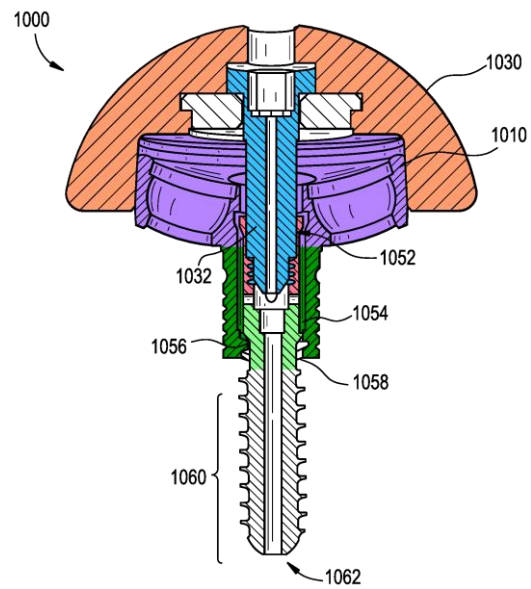


FIG. 10B



EX-1001 at 12, Figure 8 of '254 Patent

Color Key:
 glenosphere
 glenosphere screw
 baseplate
 central post (1)
 central post (2)
 locking nut

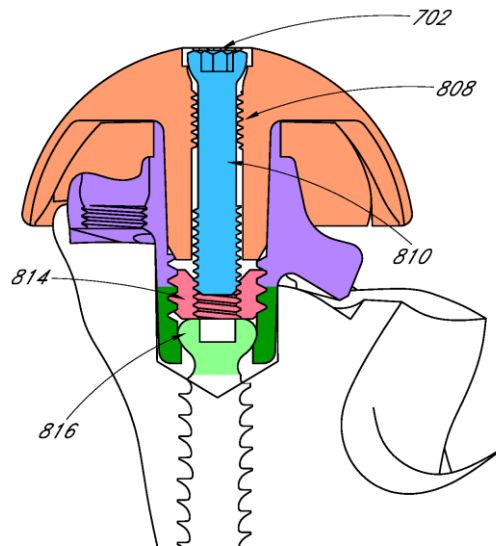
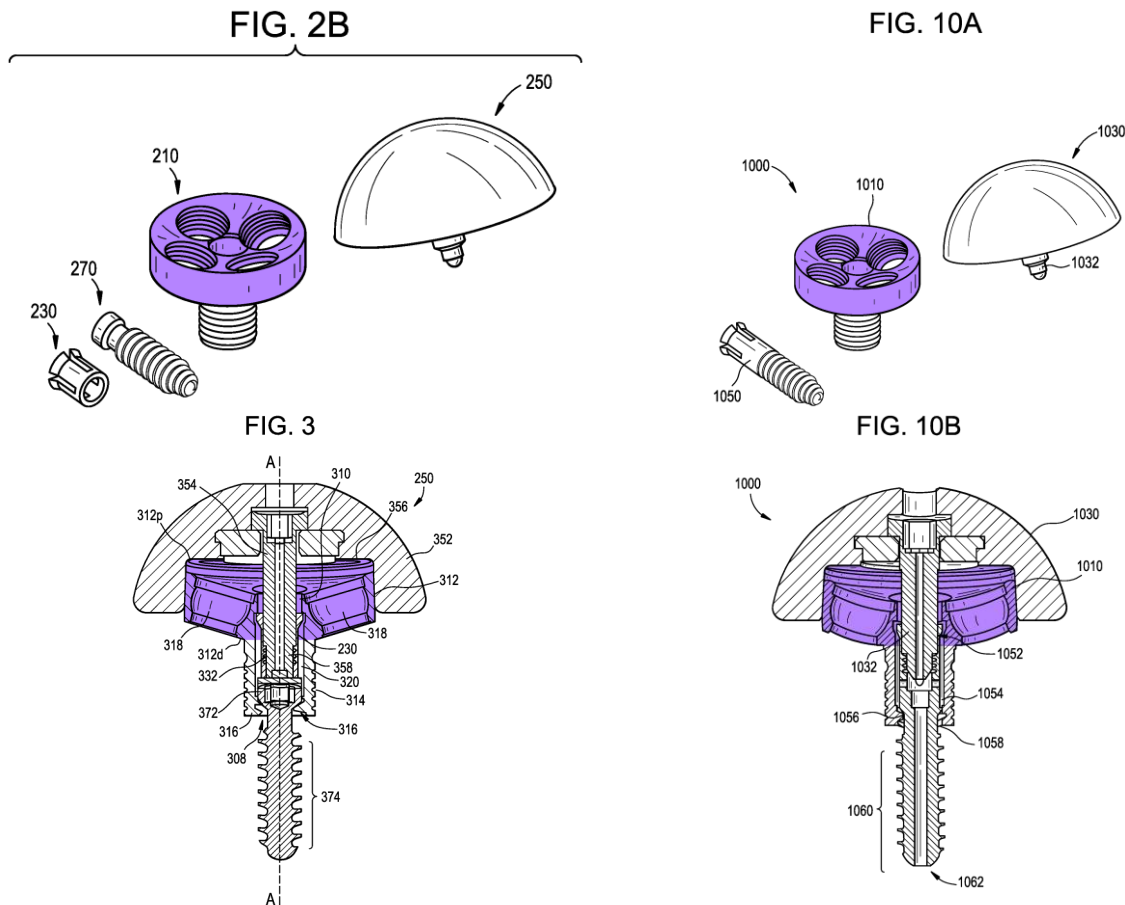


FIG. 8

Orphanos discloses this preamble, stating "[t]he present disclosure is generally related to shoulder joint implants.... These implants are often used in reverse shoulder procedures." (EX-1006 at 22, 2:20-23.) Orphanos discloses a first implant **200** and a second implant **1000**, each teaching the reverse shoulder implant of claim 1. (EX-1002 at 38, ¶78.)

b. [1-1]: "a baseplate configured to be secured to a glenoid of a scapular bone of [a] patient"

EX-1006 at 4, 5, 13, 14, Figures 2B, 3, and 10A-B



⁶ Insofar as the preamble of any Challenged Claim is limiting, Petitioner includes teachings for such preamble without conceding it is limiting.

EX-1001 at 12, Figure 8 of '254 Patent

Color Key:
baseplate

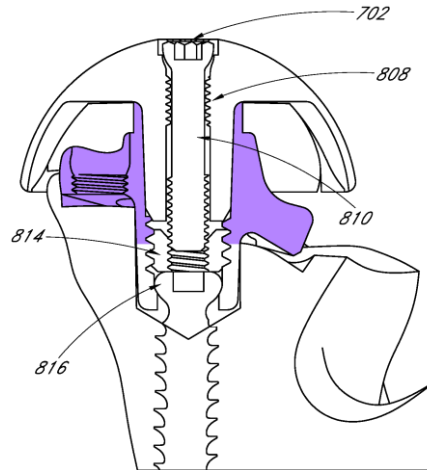
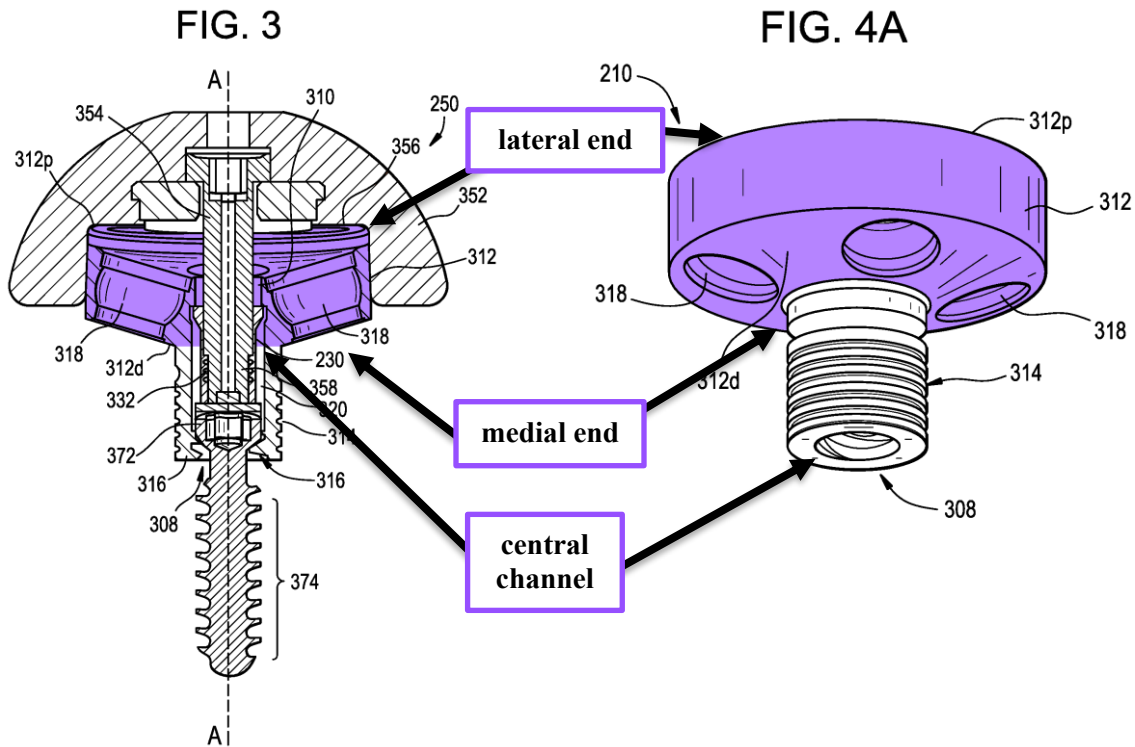


FIG. 8

Orphanos discloses this limitation, describing "Typically the shoulder joint implant includes a baseplate, sometimes referred to herein as a metaglene component (or metaglene). The baseplate is configured to secure a glenosphere component (or glenosphere) to the bony anatomy of the glenoid to complete the repair." (EX-1006 at 24, 6:53-61.) Baseplate **210** of first implant **200** is circular and configured to receive one or more bone screws and/or posts that can be driven into the glenoid to help affix baseplate **210**. (*Id.* at 25, 7:26-31, 7:64-8:1; EX-1002 at 38-39, ¶80.) Further, baseplate **1010** of second implant **1000** is substantially similar to baseplate **210**, such that baseplate **1010** may affix to the glenoid in a substantially similar manner as baseplate **210**. (EX-1006 at 30, 17:17-24; EX-1002 at 38-39, ¶80.)

- c. [1-2]: "the baseplate having a lateral end, a medial end, and a baseplate central channel extending through the baseplate from the lateral end to the medial end"**

EX-1006 at 5, 6, Figures 3 and 4A



EX-1001 at 12, Figure 8 of '254 Patent

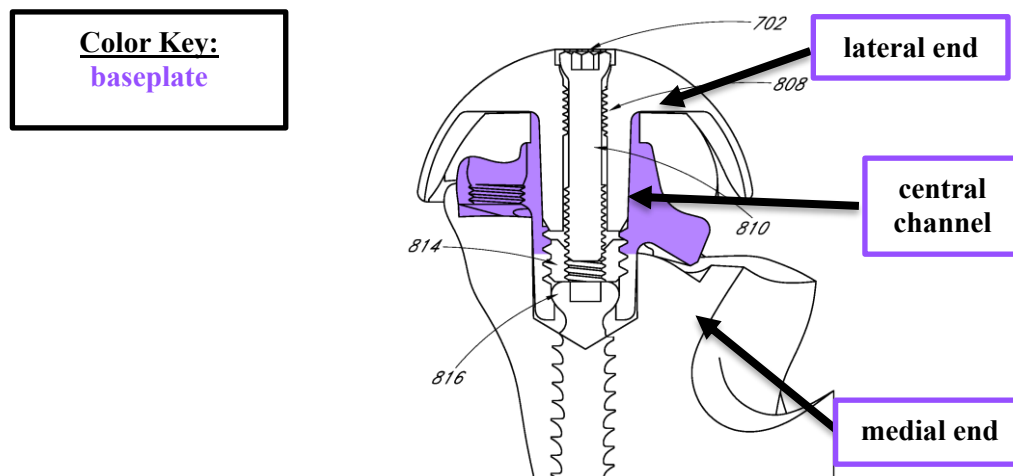


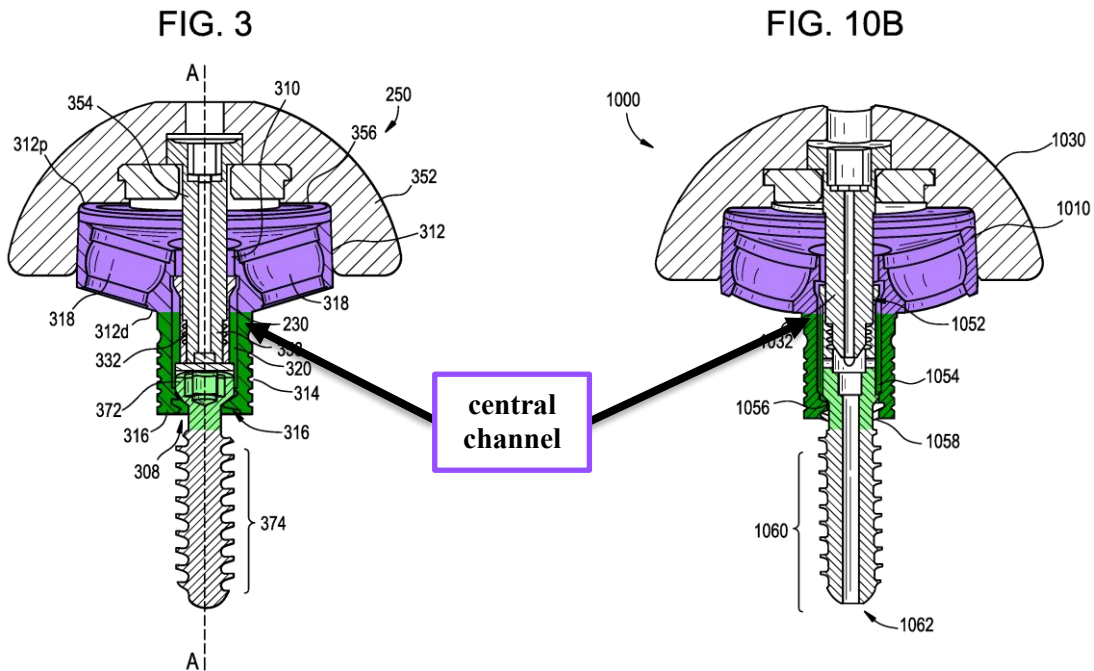
FIG. 8

Each implant **200**, **1000** of Orphanos discloses this limitation. First implant **200** discloses a baseplate **210** having a platform **312** configured such that "its bottom or distal-facing surface **312d** (i.e., medial end) engages in a complementary manner with a surface of the glenoid when implanted and a top or proximal-facing surface **312p** (i.e., lateral end) engages in a complementary manner with glenosphere **250** or other prosthetic component when coupled together." (EX-1006 at 25, 7:36-44; EX-1002 at 40-41, ¶82.)

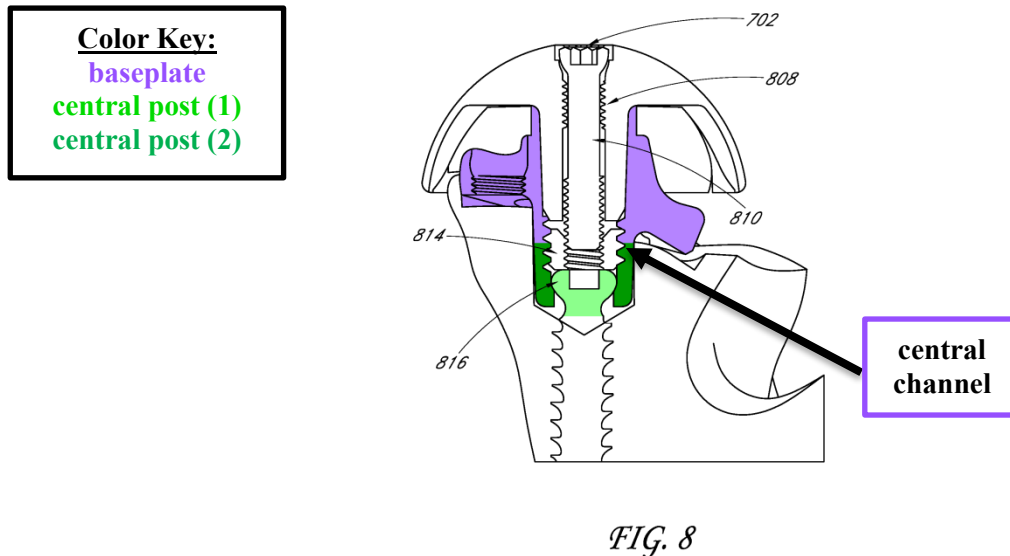
Moreover, first implant **200** discloses that "platform **312** can include a central throughbore **310** (i.e., a central channel) extending through a thickness of platform **312**." (EX-1006 at 25, 7:50-51.) Therefore, first implant **200** discloses baseplate **210** having a lateral end **312p**, a medial end **312d**, and a central channel **310** extending therethrough from the lateral end to the medial end. (EX-1002 at 40-41, ¶82.) Further, baseplate **1010** of second implant **1000** is substantially similar to baseplate **210**, such that baseplate **1010** also discloses this limitation—a baseplate **1010** having a lateral end, a medial end, and a central channel extending therethrough from the lateral end to the medial end. (*Id.*; EX-1006 at 30, 17:17-24.)

- d. [1-3]: "a central post configured to at least partially pass through the central channel"

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



EX-1001 at 12, Figure 8 of '254 Patent



Each implant **200**, **1000** of Orphanos discloses this limitation. Regarding implant **200**, as shown above in FIG. 3, portions of central bone screw **270** (unthreaded portions highlighted in light green), as well as central post **314** of baseplate **210** (highlighted in dark green), **each** disclose a central post as recited in claim 1. (EX-1002 at 42-43, ¶¶85-86) Regarding implant **1000**, as shown above in FIG. 10B, portions of integrated collet/bone screw **1050** (highlighted in light green, hereinafter "integrated collet/bone screw **1050**"), as well as central post of baseplate **1010** (highlighted in dark green), each disclose a central post as recited in claim 1. (*Id.*, ¶¶87-88.)

Further, it would be obvious to a POSITA, at the time of invention of the '254 Patent, to substitute bone screw **270** and integrated collet/bone screw **1050** of each respective implant **200**, **1000**, with a central post. Bone screw **270** and integrated collet/bone screw **1050** of Orphanos are each configured to at least partially pass through central throughbore **310** (i.e., a central channel) of baseplate **210**, **1010** such that the bone screw can be driven into the glenoid of a patient. (EX-1006 at 5, 10-11, 25, 7:26-30, 8:16-23.) As also discussed above, both Hopkins and Perego teach that it was well known to a POSITA at the time of the invention that screws and posts are readily interchangeable for fastening a baseplate to the glenoid. (EX-1010 at 23, 12:9-11; EX-1019 at 10, ¶[0038].) Therefore, it would have been obvious to simply modify the central bone screw **270** of Orphanos's first implant **200** and the integrated

collet and central bone screw **1050** of Orphanos's second implant **1000** to replace the threaded screw sections of each with a post, as such a modification is a simple substitution of one known element for another (i.e., substitute a known post for a known screw) to obtain very predictable results (i.e., both posts and screws are well known to be successful for anchoring a baseplate with the glenoid). (EX-1002 at 44-45, ¶90.) Accordingly, a POSITA would have had a reasonable expectation of success in substituting a central post for a central screw.

Further, Hopkins teaches an enabling use of such posts to anchor a baseplate with the glenoid, where a post is inserted through a central channel defined by a baseplate. Hopkins teaches that posts may be configured to at least partially pass through a baseplate central channel. (EX-1019 at 10-12, 14, ¶¶[0037],[0040]-[0041],[0051],[0069]-[0072].) Additionally, Hopkins discloses that a central post **660** can be inserted into a central fastener bore (not shown) such that a portion of central post **660** is inserted into a surgically created posthole within the glenoid to anchor baseplate **650** into bone. (*Id.* at 14, ¶[0070].) Hopkins discloses a prior art method of inserting a fixation post **670A** through a fastener bore **656A** of a baseplate **650** such that a portion of fixation post **670A** is inserted into a surgically created posthole within the glenoid, thereby securing baseplate **650** with the glenoid. (*Id.* at 15-16, ¶¶[0078]-[0085].)

Hopkins's and Perego's teachings would have made this modification of Orphanos's screw anchoring element to a post anchoring element obvious to try because it would have involved choosing from the finite number of known and predictable fixation elements at the time of the invention of the '254 Patent, which would have included fixation posts and the corresponding surgically created post holes. (EX-1002 at 45, ¶91.) Such a well-known substitution with very predictable results would provide a POSITA a reasonable expectation of success. (*Id.*)

The use of screws and posts are readily recognized by a POSITA as being interchangeable for fastening a baseplate to the glenoid. (*Id.* at 44, ¶89; EX-1010 at 23, 12:9-11; EX-1019 at 10, ¶[0038].) Therefore, the post as recited in claim 1 would have also been obvious to a POSITA as a matter of design choice at the time of the invention. (EX-1002 at 45-46, ¶92.) "Design choice applies when old elements in the prior art perform the same function as the now claimed structures." *In re Bagnall*, Appeal 2009-013429, 2011 WL 1463378, at *6 (B.P.A.I. Apr. 14, 2011) (citing *In re Kuhle*, 526 F.2d 553, 555 (CCPA 1975) (use of claimed feature solves no stated problem and presents no unexpected result and "would be an obvious matter of design choice within the skill of the art"))).

Specifically, the '254 Patent fails to describe any advantages provided by incorporating a central post configured to at least partially pass through the central channel. (EX-1002 at 45-46, ¶92.) Besides the background, which briefly describes the functionality of a post being "adapted to be rigidly fixed within the glenoid fossa of a scapula," the other disclosed functionalities (which are not solving any stated problem nor providing unexpected results) of the claimed post described in the specification includes a description that such a post may include a rotational control feature (recited in claim 10), may include a Morse taper configured to mate with a glenosphere, or may house a primary screw (recited in claim 11). (EX-1001 at 26, 28, 1:29-32, 5:34-53.) Therefore, the '254 Patent is silent—other than what is described above and shown in Figures 1, 4, 5, and 8—as to any advantages or unexpected results of having a central post that "is configured to at least partially pass through the central channel."

Without providing any explanation on the advantages or unexpected results of using such a central post over a central screw, the use of a post in replacement of distal threaded portions **608, 1060** of Orphanos's screws **270, 1050** would have been obvious as a matter of design choice.

- e. [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"

EX-1006 at 10, Figure 5, 7, and 10C of Orphanos

FIG. 7

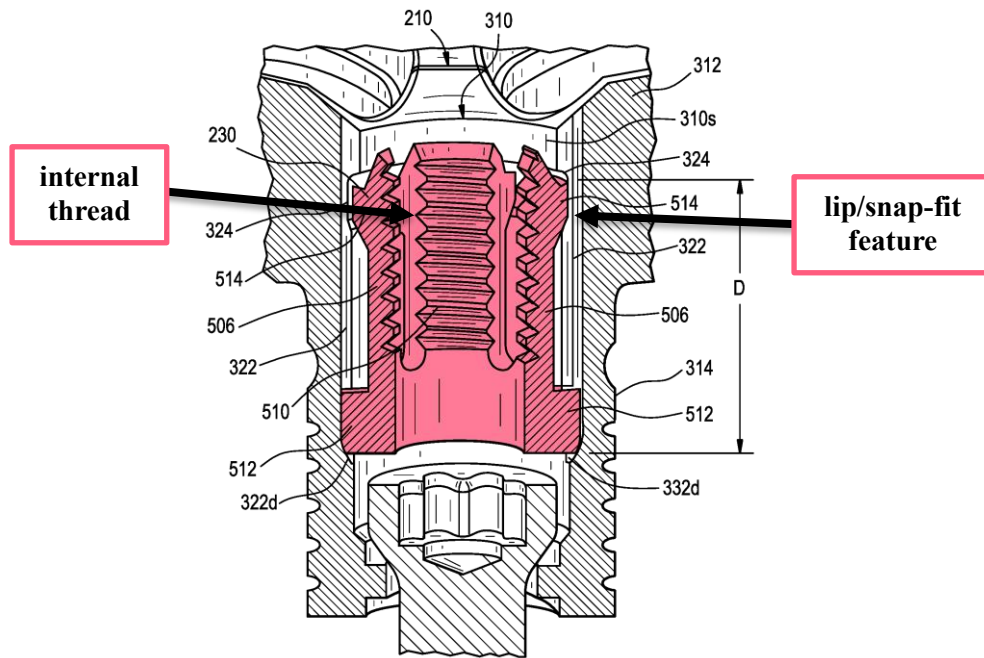


FIG. 5

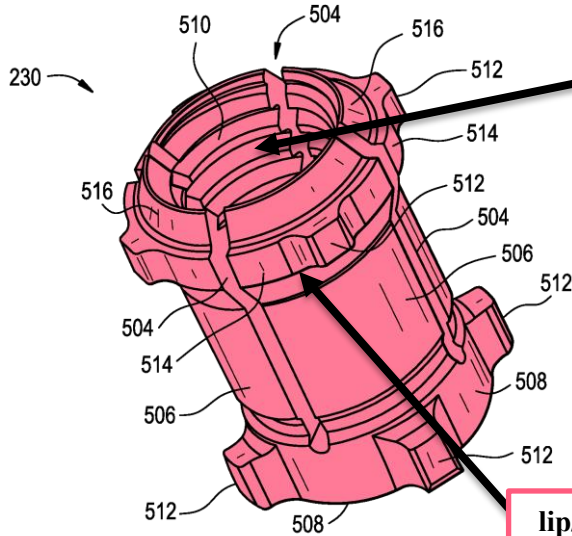
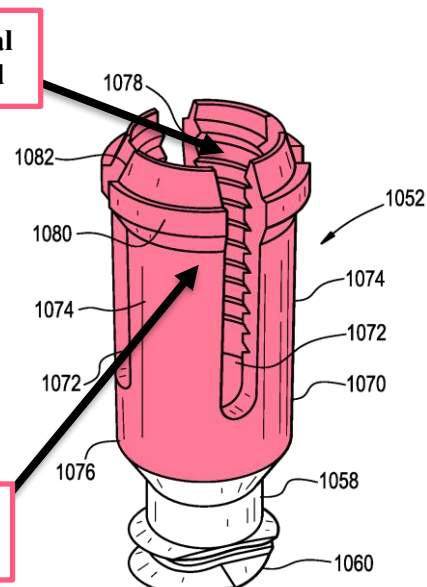


FIG. 10C



EX-1001 at 10, 12, Figures 6 and 8 of the '254 Patent

Color Key:
locking nut

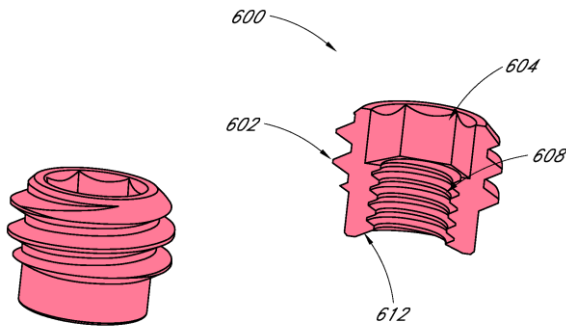


FIG. 6

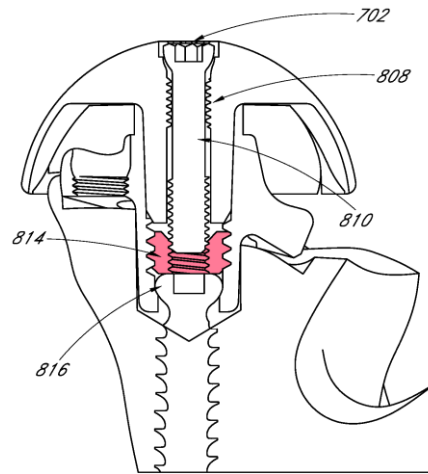


FIG. 8

First implant **200** discloses a locking nut in the form of a collet **230** having a cylindrical shape in the form of hollow cylinder body **502**. (EX-1006 at 26, 10:42-43; EX-1002 at 48, ¶95.) Further, collet **230** includes an internal thread on an internal surface in the form of inner threaded portion **510**. (EX-1006 at 26, 10:52-56; EX-1002 at 48, ¶95.)

Second implant **1000** discloses a locking nut in the form of a collet portion **1052** having a cylindrical shape in the form of hollow cylindrical body **1070**. (EX-1006 at 30, 17:39-58; EX-1002 at 48, ¶96.) Further, collet portion **1052** includes an internal thread on an internal surface in the form of inner threaded portion **1078**. (EX-1006 at 30, 17:59-63.)

Collet **230** of first implant **200** and collet portion **1052** of second implant **1000** do not explicitly show an external thread on an outside surface of the locking nut in the drawings. Orphanos, however, does disclose that both collet **230** of first implant **200** and collet portion **1052** of second implant **1000** include respective radially compressible arms **506**, **1074** each having a respective lip **514**, **1080** that is configured to secure collet **230** and collet portion **1052**, respectively, within central throughbore **310** of baseplate **312** to form a snap-fitting engagement with inner sidewall **310s** defining central throughbore **310**. (EX-1006 at 28, 30 14:14-30, 18:34-45; EX-1002 at 49, ¶97.) Orphanos further discloses that rather than the snap-fitting coupling with the inner sidewall **310s**, collet/collet portion **230**, **1052** can include *alternative features to "otherwise mate"* with inner sidewall **310s** of central throughbore **310**. (EX-1006 at 28, 30, 14:14-30, 18-34-45; EX-1002 at 49, ¶97.)

Orphanos also teaches that it is readily known to a POSITA 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." (EX-1006 at 26, 10:11-15; EX-1002 at 49-50, ¶98.) Not only does Orphanos emphasize that collet **230** may "otherwise mate" with the inner sidewall **310s** of central throughbore **310**, but Orphanos also discloses that collet **230** may be referred to as a *reducing bushing*. (EX-1002 at 49-50, ¶98.)

One embodiment of a reducing bushing readily known to a POSITA at the time of the invention of the '254 Patent includes a cylindrical body having external threading for coupling and internal threading for coupling to solve a problem addressed by Orphanos (i.e., reducing the diameter of central throughbore of the baseplate to accommodate a smaller diameter locking screw after receiving a larger diameter bone screw). (*Id.*;EX-1006 at 26, 10:30-41.) Examples of the general knowledge of a POSITA regarding known reducing bushings are provided in Figure 2 of Hale and page 3547 of Grainger. Figure 2 of Hale discloses a reducing bushing **36** having a threaded outer diameter **32** and a threaded central passage **44** that functions as an adapter to receive portions of various diameters. (EX-1013 at 9, 5:7-18;EX-1002 at 50-51, ¶99.) Additionally, page 3547 of Grainger discloses reducing bushings with an external thread to reduce the diameter of a passage, and an internal thread having a smaller diameter than the external thread, and these reducing bushings have been readily available through publication since at least 2009. (EX-1018 at 2, p.3547.)

Therefore, not only does Orphanos recognize the known interchangeability between snap-fitting coupling techniques (such as those provided by lip **514**, **1080** and inner sidewall **310s**) and threaded coupling techniques, Orphanos describes that collet **230** may otherwise mate with inner sidewall **310s** of central throughbore **310**, and that collet **230** can be a reducing bushing (which is known for having a

cylindrical body with external and internal threading for coupling). (EX-1002 at 51, ¶100.)

It would also have been well known and obvious to a POSITA, at the time of the invention of the '254 Patent, that an externally threaded reducing bushing to engage to inner sidewall **310s**, inner sidewall **310s** would also need simply to be modified to include a known internal thread to correspond to the external thread of the reducing bushing. (*Id.* at 51-52, ¶101.)

Thus, it would have been obvious to a POSITA at the time of the invention of the '254 Patent to simply replace/modify the snap-fitting coupling of collet/collet portion **230, 1052** (i.e., radially compressible arms **506, 1074** with a respective lip **514, 1080** and inner sidewall **310s**) with a threaded coupling (i.e., a reducing bushing having external threading and internal threading on inner sidewall **310s** of central throughbore **310**) to couple and/or engage the substituted externally-threaded reducing bushing to baseplate **312** within its central throughbore **310** in view of Orphanos's teachings and general knowledge of a POSITA. (*Id.* at 52, ¶102.)

And it would have been obvious to a POSITA that this threaded coupling would still secure the glenoid to baseplate **210, 1010** and permit the reduced diameter of the glenoid screw. (*Id.*) In short, 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. (*Id.*; EX-1006 at 26, 10:11-15.)

The use of snap-fitting coupling features and thread-fitting coupling features are readily recognized by a POSITA as being interchangeable. (EX-1006 at 26, 10:11-15.) Therefore, the use of an external thread on the recited locking nut of claim 1 should also be obvious as a matter of design choice. "Design choice applies when old elements in the prior art perform the same function as the now claimed structures." *In re Bagnall*, Appeal 2009-013429, 2011 WL 1463378, at *6 (B.P.A.I. Apr. 14, 2011) (citing *In re Kuhle*, 526 F.2d 553, 555 (CCPA 1975) (use of claimed feature solves no stated problem and presents no unexpected result and "would be an obvious matter of design choice within the skill of the art"))).

Significantly, the '254 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. (EX-1002 at 52-53, ¶103.) In fact, locking nut **814** shown in Figure 8 of the '254 Patent is only *shown* with "external threading," with no description in the text of the specification. Further, the text of the '254 Patent describes that locking nut **812** is "connected to" the base plate without mentioning what structure achieves such connection. (*Id.*) The only description within the '254

Patent of an outer male thread is directed toward locking insert **600** of Figure 6, which states "insert **600** can include an outer male thread **602** and configured to go into the central channel of a baseplate." (*Id.*) Therefore, the '254 Patent is silent, other than what is shown in Figure 8, as to a locking nut having an 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 internally-threaded baseplate central channel) to replace Orphanos's snap-fitting coupling is obvious as a matter of design choice. (*Id.*)

Further, modifying Orphanos to include a threaded coupling instead of the snap-fitting coupling would not render the device of Orphanos inoperable for its intended purposes. Although one embodiment of Orphanos teaches the use of keys **512** to provide resistance to torsional rotation, such a feature is merely optional, because other embodiments of Orphanos (e.g., implant **1000**) have a collet **1052** that does not include keys **512** or resists torsional rotation. (*Id.* at 55, ¶107.) 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. (*Id.*)

- f. [1-5]: "the locking nut configured to engage the central post when the central post and baseplate are implanted within the medical patient"**

EX-1006 at 10, 14, 15, Figures 7, 10B, and 10C of Orphanos

FIG. 7

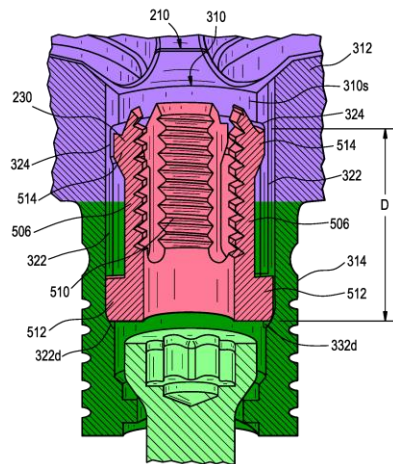


FIG. 10C

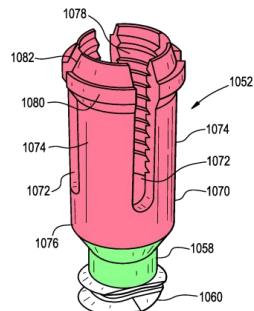
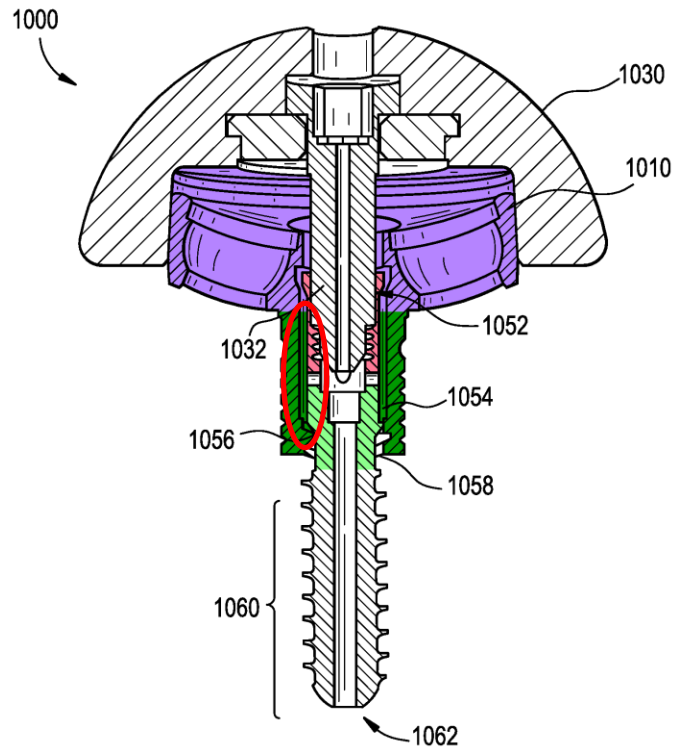


FIG. 10B



EX-1001 at 12, Figure 8 of '254 Patent

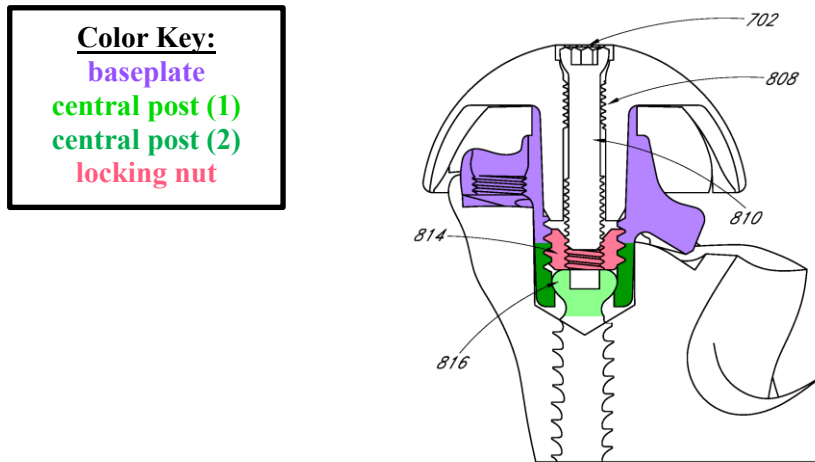


FIG. 8

Each implant **200**, **1000** of Orphanos discloses this limitation. As shown above in FIG. 7 of Orphanos, first implant **200** teaches a locking nut in the form of collet **230** and that locking nut **230** is configured to engage the central post when the central post and baseplate are implanted within the medical patient.

First, the first implant **200** teaches a locking nut in the form of collet **230** being directly adjacent to screw head **602** of central post (e.g., screw head **602**, shoulder portion **604**, and cylindrical unthreaded neck portion **606**) when the central post and baseplate **312** are implanted within the medical patient, as shown in Figure 7 of Orphanos. (EX-1006 at 28, 13:36-52.) As discussed above in section VI(A)(5)(d), portions of central bone screw **270** include all the limitations of the central post of claim 1. As also discussed above in section [1-3], it would also have been obvious

to a POSITA to modify the threaded screw section **608** of Orphanos's central bone screw **270** with a post.

As discussed above and as appreciated by Roche, it was known to a POSITA that back driving occurs to an implanted anchoring feature, such as a compression screw or post. (EX-1007 at 69, 72, 7:33-43, 14:1-18.) Because collet **230** (i.e., locking nut) of Orphanos is adjacent and above screw head **602** of central post (e.g., screw head **602**, shoulder portion **604**, and cylindrical unthreaded neck portion **606** of bone screw **270**), a POSITA would have readily appreciated locking nut **230** is configured to engage screw head **602** of central post when the central post and baseplate **312** are implanted within the medical patient. (EX-1002 at 57, ¶110.) In particular, collet **230** (i.e., locking nut) is configured for such engagement when the central anchoring feature (e.g., central bone screw **270**) back drives toward collet **230**. (*Id.*)

Alternatively, as shown in FIGS. 3 and 7, first implant **200** includes a central post **314**, and as shown, locking nut **230** engages an inner surface of throughbore **320** of that central post **314**—thus engaging central post **314**. Therefore, locking nut **230** is configured to engage central post **314** when locking nut **230** and baseplate **312** are implanted into a medical patient. (*Id.* at 56-57, ¶109.)

Accordingly, first implant **200** discloses locking nut **230** configured to engage both central post **314** and the central post (e.g., screw head **602**, shoulder portion

604, and cylindrical unthreaded neck portion **606** of central screw **270**) when the central post and baseplate are implanted within the medical patient.

Further, as set forth above, Roche teaches using locking cap screws **116** having external threads meshed within glenoid plate **110** to engage anchoring features (e.g., compression screws **114**) after being implanted to prevent compression screws **114** from backing out. (EX-1007 at 72, 14:1-18.) As described above, a POSITA would have readily appreciated the use of a threaded coupling (e.g., an external thread on Orphanos's reducing bushing and corresponding internally-threaded central channel of the baseplate) as a simple substitution of Orphanos's snap-fit coupling to secure the glenoid to the baseplate **210**, **1010** and permit the reduced diameter of the glenoid screw. (EX-1002 at 51-55, ¶¶101-06.)

A POSITA would have been motivated to modify the location of an externally threaded reducing bushing to engage the anchoring feature (e.g., a central post), prior to this central post backing out, after being implanted as taught by Roche, as such a modification would provide the well-known benefit of inhibiting central post from backing out. (*Id.* at 58, ¶112.) Such a modification would provide immediate contact between the externally threaded reducing bushing and central post (e.g., screw head **602**, shoulder portion **604**, and cylindrical unthreaded neck portion **606**), which would provide enhanced resistance to back out by this central post. (*Id.*)

Regarding second implant **1000** of Orphanos, second implant **1000** also teaches a locking nut in the form of collet portion **1052** engaged with the central post of baseplate **1010** (as highlighted by the red oval in Figure 10B above). As discussed in section VI(A)(5)(d), the central post of baseplate **1010** discloses the central post of claim 1. As shown in FIG. 10B above, collet portion **1052** engages an inner surface of the central post (highlighted dark green) of baseplate **1010** defining throughbore (not labeled but highlighted)—thus engaging the central post (highlighted dark green). (*Id.* at 59, ¶115.) Therefore, collet portion **1052** of Orphanos is configured to engage the central post (highlighted dark green) when the central post and baseplate are implanted within the medical patient. (*Id.*)

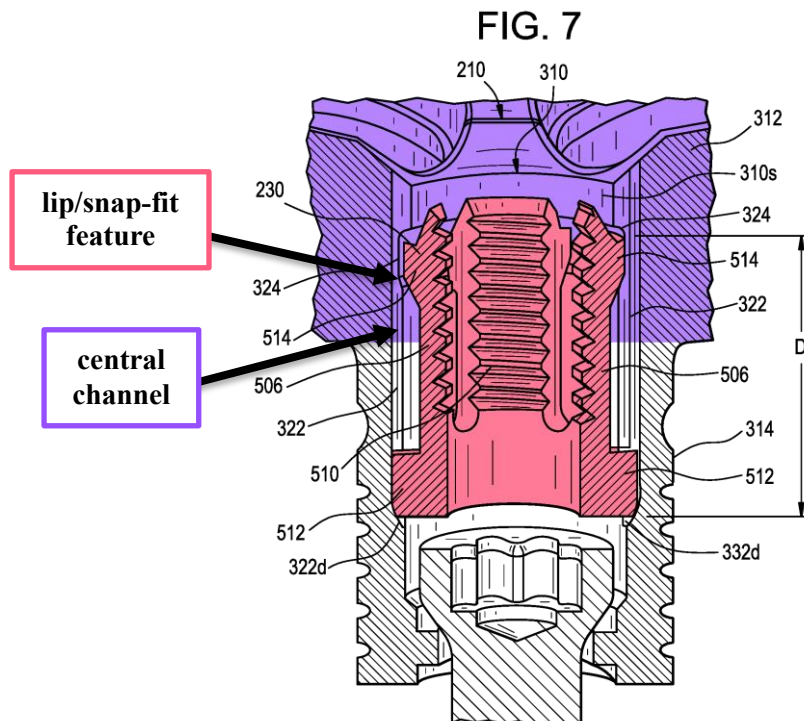
Alternatively, second implant **1000** teaches a locking nut in the form of collet portion **1052**. Collet portion **1052** is fixedly coupled to proximal head **1054** of screw. (*Id.*, ¶114; EX-1006 at 30, 17:39-47.) As discussed above in section [1-3], the central post (e.g., shoulder portion **1056** and unthreaded neck portion **1058**—highlighted in light green) includes all the limitations of the central post of claim 1. As also discussed in section VI(A)(5)(d), it would have been obvious to a POSITA to also replace the distal threaded portion **1060** of Orphanos's central bone screw **1010** with a post.

Therefore, collet portion **1052** is configured to engage the central post (e.g., shoulder portion **1056** and unthreaded neck portion **1058** of bone screw **1050**) when

the central post and baseplate are implanted within the medical patient. Although collet portion **1052** may be fixedly attached to the anchoring feature (e.g., central post (including shoulder portion **1056** and unthreaded neck portion **1058**), claim 1 does not require a locking nut that is separate or removable from central screw. Claim 1 only requires that such a locking nut be "configured to engage the central post when the central post and baseplate are implanted within the medical patient," which is taught by integrated collet/bone screw **1050**.

- g. [1-6]: "wherein the external thread is configured to couple the locking nut with the baseplate central channel"

EX-1006 at 10, Figure 7 of Orphanos



EX-1001 at 12, Figure 8 of '254 Patent

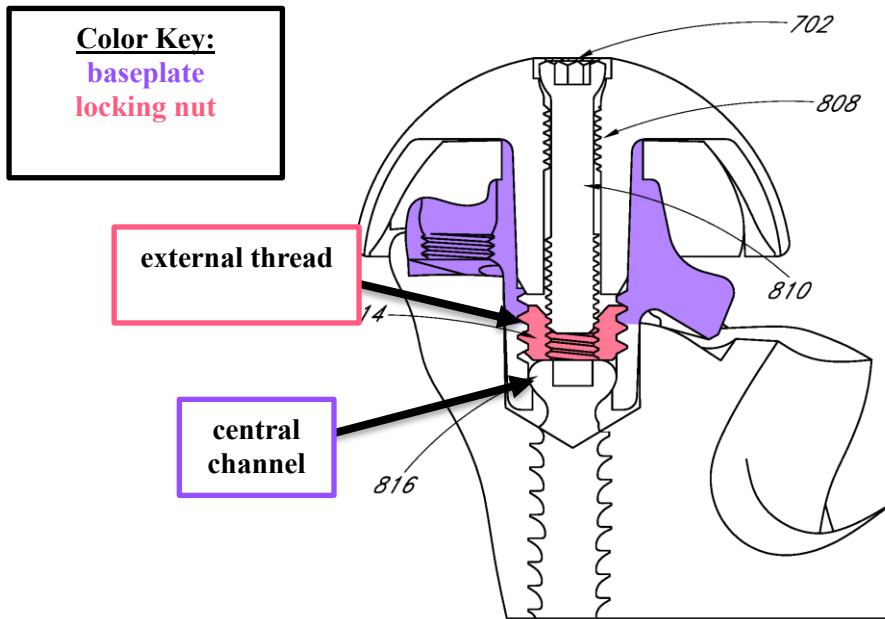


FIG. 8

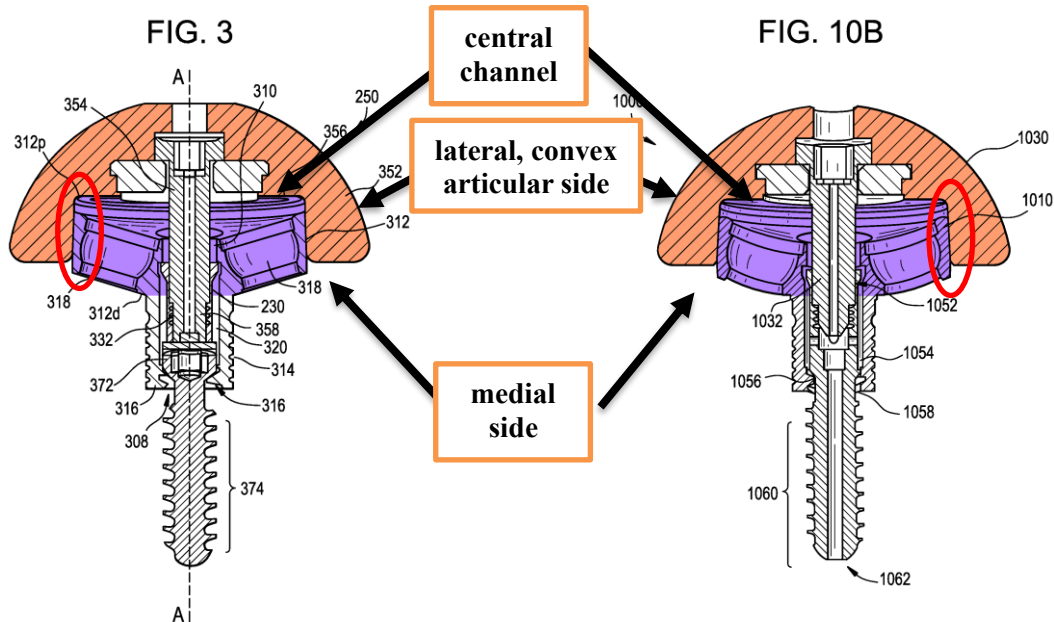
Each implant **200**, **1000** of Orphanos discloses this limitation. As discussed in Section VI(A)(1)(e), Orphanos teaches that collet **230** of first implant **200** and collet portion **1052** of second implant **1000** each include a coupling feature on its outer surface in the form of lip **514**, **1080**, respectively, which is configured to secure collet **230** and collet portion **1052**, respectively, within central throughbore **310** of baseplate **312** via a snap-fitting or *an alternative way to "otherwise mate"* with inner sidewall **310s** of central throughbore **310**. (EX-1006 at 28, 30, 14:14-30, 18:34-45.)

As described under Section VI(A)(1)(e), a POSITA would have readily appreciated Orphanos as making obvious a locking nut having an external thread (e.g., reducing bushing) configured to couple and engage the locking nut to the baseplate central channel. (EX-1002 at 60-61, ¶118.)

As also described under Section VI(A)(1)(e), the use of a threaded coupling (e.g., an externally-threaded reducing bushing and internal threads on the baseplate central channel) in replacement of Orphanos's snap-fitting coupling (i.e., engagement of lip **514, 1080** and inner sidewall **310s**) between collet/collet portion **230, 1052** and baseplate central channel is obvious as a matter of design choice. Therefore, Orphanos makes obvious the substitution of Orphanos's snap-fitting collet with an externally-threaded locking nut configured to couple the locking nut with internal threads of the central channel of the baseplate. (*Id.*, ¶¶118-19.)

- h. [1-7]: "a glenosphere, having a lateral, convex articular side, a medial side, and a glenosphere central channel extending from the convex articular side to the medial side and configured to interface with the baseplate"

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



EX-1001 at 12, Figure 8 of '254 Patent

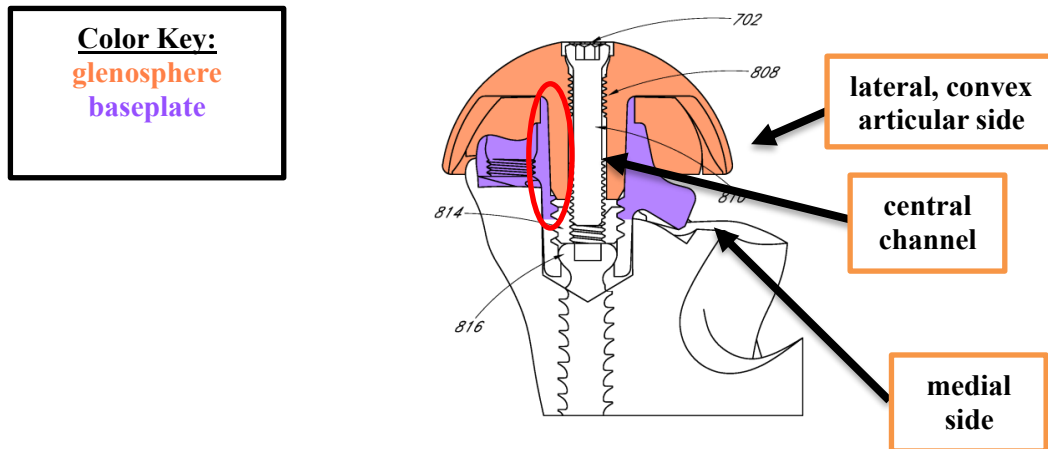


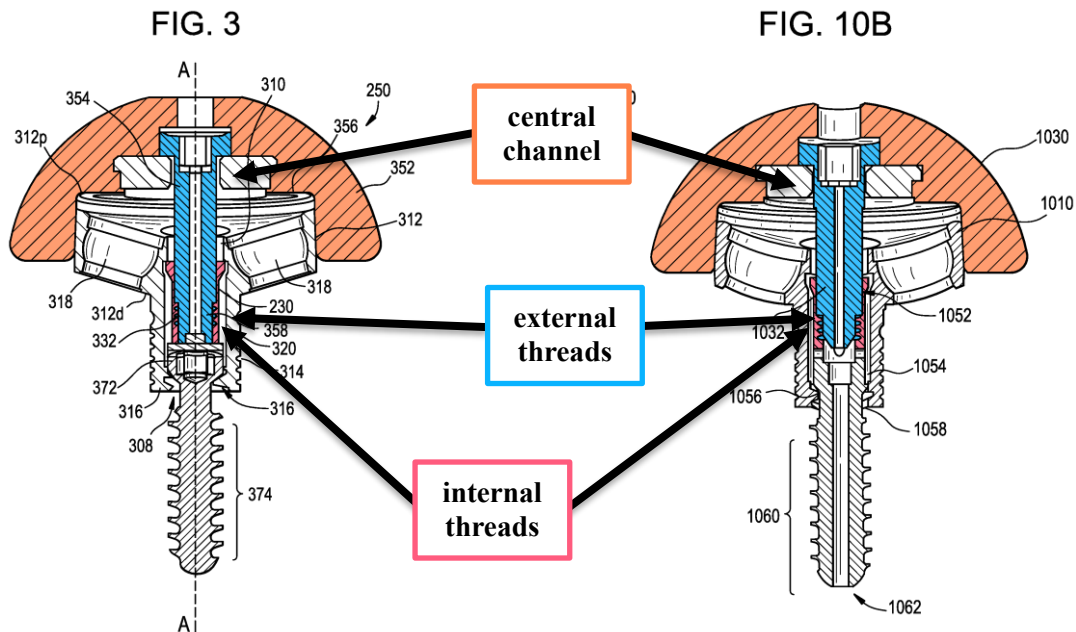
FIG. 8

Each implant **200**, **1000** of Orphanos discloses this limitation. As shown in Figures 3 and 10B of Orphanos, each implant **200**, **1000** includes a respective glenosphere **250**, **1030** having a lateral, convex articular side; a medial side, and a central channel extending from the convex articular side to the medial side and configured to interface with the baseplate. (EX-1002 at 62, ¶121.) Each glenosphere **250**, **1030** is configured to surround and interface with baseplate **312**, **1010** via a taper lock of the distal facing surface of glenosphere **250**, **1030** and the proximal facing surface of baseplate **210** (as highlighted by the red ovals in Figures 3 and 10B above). (EX-1006 at 25, 29, 8:44-62, 15:1-6.)

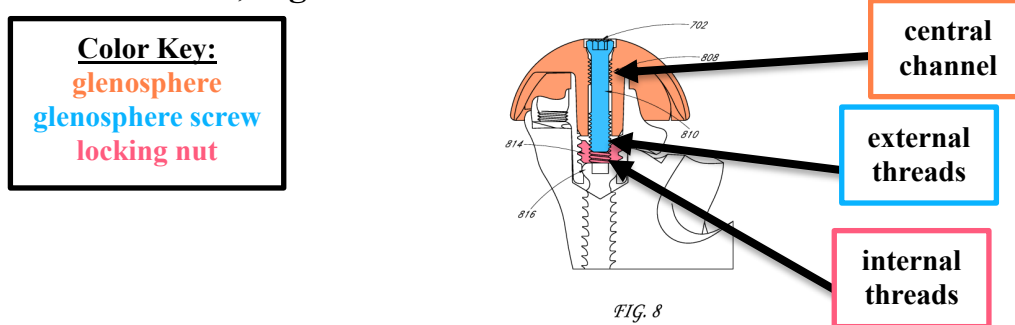
As demonstrated above in annotated FIG. 3, the inner surfaces of glenosphere **250** define a central channel extending from the convex articular side to the medial side. Thus, the central channel of glenosphere **250** is configured to interface with its respective baseplate **210** via at least the interfacing surfaces of the inner surfaces of glenosphere **250** and the exterior surfaces of baseplate (as highlighted with red ovals above in FIG. 3; the same interfacing surfaces are also found in the implant **1000** of FIG. 10). Further, each central channel of glenosphere **250**, **1030** is configured to interface with their respective baseplate **210**, **1010** via an interfacing element in the form of a glenosphere locking screw **354**, **1032**. (*Id.* at 26, 29, 30, 10:4-29, 15:11-31, 17:17-24; EX-1002 at 63, ¶123.)

- i. [1-8]: "a glenosphere screw,⁷ sized to pass at least partially within the glenosphere central channel and having external threads⁸ 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"

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



EX-1001 at 12, Figure 8 of '254 Patent



⁷ The term "glenosphere screw" never appears in the specification or the prosecution history of the '254 Patent, leaving Petitioner and the public at large to guess that the secondary locking screw **810** shown in Figure 8 is the claimed glenosphere screw.

⁸ The term "external threads" never appears in the specification or the prosecution history of the '254 Patent, leaving Petitioner and the public at large to guess what "external threads" are intended to include.

Each implant **200**, **1000** of Orphanos discloses this limitation. Each implant **200**, **1000** includes a respective glenosphere screw in the form of glenosphere locking screw **354**, **1032** that is sized to pass at least partially within the glenosphere central channel. (EX-1002 at 64-65, ¶¶125-26.) First implant **200** teaches a glenosphere locking screw **354** that is configured to threadably engage inner threaded portion **332** of collet **230**, which secures glenosphere locking screw **354** to collet **230** (i.e., locking nut). (EX-1006 at 26-27, 10:39-56, 11:19-27.) Similarly, second implant **1000** teaches glenosphere locking screw **1032** having external threads that are configured to threadably engage an inner threaded portion **1078** of collet portion **1052**, which secures glenosphere locking screw **1032** to collet portion **1052** (i.e., locking nut). (*Id.* at 30, 17:59-63.)

6. Claims 2-7 and 9-11

For the following reasons, claims 2-7 and 9-11 are likewise obvious and therefore unpatentable:

Claims 2-7 and 9-11	Disclosure
[2-1]The reverse shoulder implant of claim 1, wherein the glenosphere is configured to at least partially surround an external surface of the baseplate.	As noted at [1-7], Orphanos discloses this limitation. (EX-1006 at 25, 26, 29, 8:44-62, 10:4-29, 15:1-6;EX-1002 at 66, ¶128.)
[3-1]The reverse shoulder implant of claim 1, wherein the baseplate has a circular shape.	As noted at [1-1], Orphanos discloses this limitation. (EX-1002 at 66, ¶129.)

Claims 2-7 and 9-11	Disclosure
[4-1]The reverse shoulder implant of claim 1, wherein the glenosphere is configured to surround the baseplate.	As noted at [1-7], Orphanos discloses this limitation. (<i>Id.</i> at 67, ¶131;EX-1006 at 25, 29, 8:44-62, 15:1-6.)
[5-1]The reverse shoulder implant of claim 1, wherein the glenosphere is configured to be secured to the baseplate with a morse taper.	As noted at [1-7], Orphanos discloses this limitation. (EX-1006 at 25, 29, 8:44-62, 15:1-6; EX-1002 at 67, ¶132.)
[6-1]The reverse shoulder implant of claim 1, wherein a diameter of the locking nut is greater than a length of the locking nut.	Roche teaches this limitation. The specification of the '254 Patent provides no description of any type of benefit to having a diameter that is greater than the length of the locking nut. Therefore, it would have been obvious to make such a modification of Orphanos based on design choice as taught by Roche. Such a modification would have also been obvious to a POSITA, as a POSITA would have been motivated to keep the length less than the diameter to provide a low profile to the locking nut. Locking Cap Material: Machined from wrought Ti-6Al-4V Scale: 1 size Key Features: Spherical concave feature which locks compression screws to the glenoid plate at any angle ($\pm 10^\circ$), fits in hollowed-out space of glenospheres. The diagram shows a side view of the Locking Cap with a red arrow indicating its Length and a blue arrow indicating its Diameter. It also shows a cross-section view of the cap and a perspective view of the cap being inserted into a hole in a plate. Fig. 53 (EX-1002 at 67-68, ¶133.)

Claims 2-7 and 9-11	Disclosure
[7-1]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 in [1-4], Orphanos discloses the substitution of the collet with a reducing bushing. It would have been 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 thread engagement. Furthermore, Roche in Figure 7A discloses a rotational control feature in locking cap 116 in the form of an internal hex surface. Furthermore, Hale discloses a rotational control feature in reducing bushing 48 in the form of an external hex surface. Furthermore, page 3547 of Grainger discloses reducing bushing having a reducing bushing in the form of an external hex. (<i>Id.</i> at 68-69, ¶¶136-37.)
[9-1]The reverse shoulder implant of claim 1, wherein the central channel defines a surface integral with the central post.	As noted in [1-3],the first implant 200 of Orphanos discloses a central post 314 of baseplate 210 that defines a throughbore 320 in communication with throughbore 310 defined by platform 312 of baseplate 210. (Orphanos, 8:4-30). Further, FIG. 3 shows throughbores 310, 320 as being integral with each other such that the surface of baseplate 210 defining throughbore 310 is integral with central post 314. (<i>Id.</i> at 70, ¶138.)

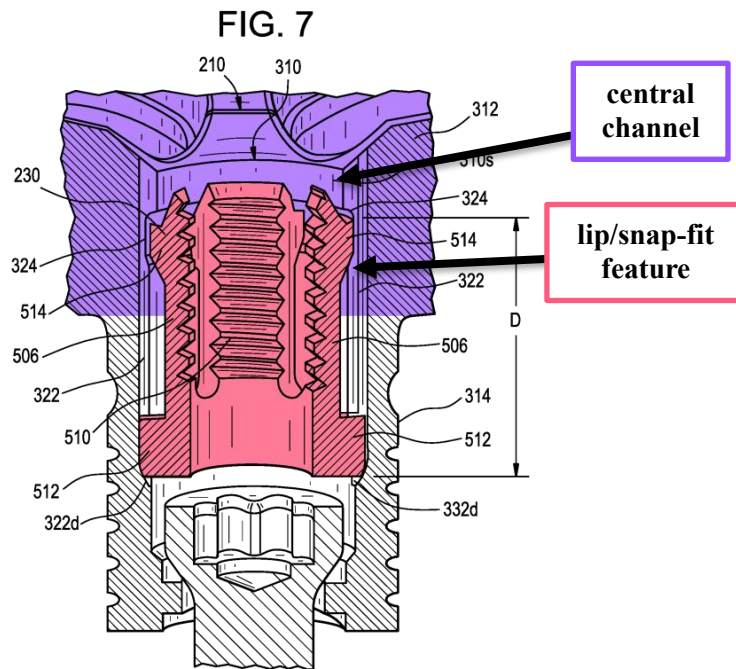
Claims 2-7 and 9-11	Disclosure
[10-1]The reverse shoulder implant of claim 1, wherein the central post includes a rotational control feature.	As noted in [1-3], Orphanos discloses a central bone screw 270 includes a screw head 602 (having a rotational control feature) coupled to a cylindrical unthreaded neck portion 606 (which discloses a cylindrical post configured to at least partially pass through the [baseplate] central channel. <i>(Id. at 71, ¶139.)</i>
[11-1]The reverse shoulder implant of claim 1, wherein the central post comprises a central channel configured to house a primary screw.	As noted in [1-3], Orphanos discloses the central post 314 of baseplate 210 defines a throughbore 320 that is configured to house a bone screw 270 . <i>(Id., ¶140; Orphanos, 8:16-23.)</i>

7. Claim 12

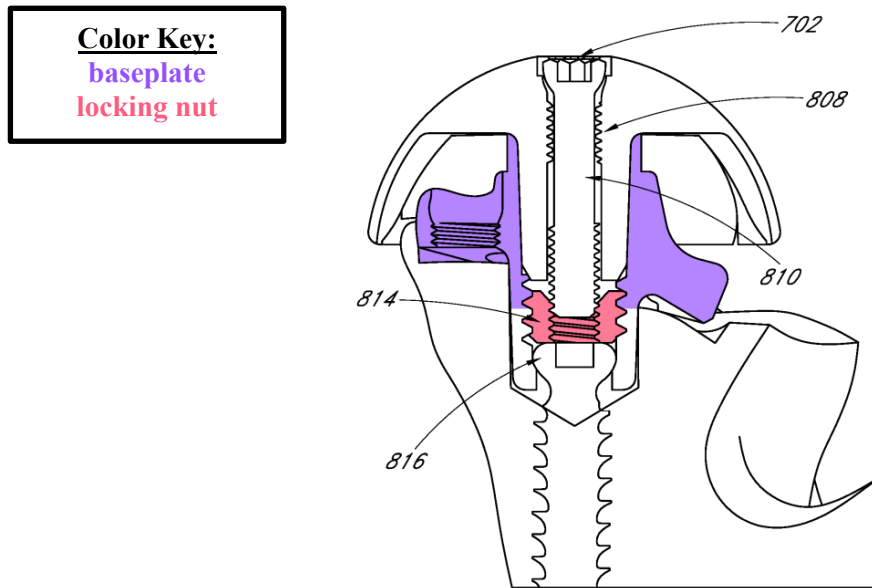
For the reasons discussed, Orphanos and Roche disclose limitations [12-PRE]-[12-5] and [12-7]-[12-8]. (*See* Sections VI(A)(1)(a)-(f),(h)-(i).) The remaining limitation of claim 12 (i.e., limitation[12-6]) is discussed below.

- j. [12-6]: "wherein the external thread is configured to engage the baseplate central channel"

EX-1006 at 10, Figure 7 of Orphanos



EX-1001 at 12, Figure 8 of '254 Patent



Each implant **200**, **1000** of Orphanos discloses this limitation. As discussed in Section VI(A)(1)(e), collet **230** of first implant **200** and collet portion **1052** of second implant **1000** each includes a coupling feature its outer surface in the form of lip **514**, **1080**, respectively, which is configured to secure collet **230** and collet portion **1052**, respectively, within central throughbore **310** of baseplate **312** via a snap-fitting engagement or an *alternative way to "otherwise mate"* with the inner sidewall **310s** of central throughbore **310**. (EX-1006 at 28, 30, 14:14-30, 18:34-45.)

As described above under Section VI(A)(1)(e), a POSITA would have readily appreciated Orphanos as making obvious a locking nut having an external thread configured to couple and engage the locking nut to the central channel of the baseplate. (EX-1002 at 49-55, ¶¶97-106.) As also described under Section VI(A)(1)(e), the use of a threaded coupling (e.g., an externally-threaded reducing bushing and internal threads on the baseplate central channel) to replace Orphanos's snap-fitting coupling (i.e., engagement of lip **514**, **1080** and the inner sidewall **310s**) between collet/collet portion **230**, **1052** and baseplate central channel is obvious as a matter of design choice. (*Id.* at 52-54, ¶¶103-04.) Therefore, Orphanos makes obvious the substitution of Orphanos's snap-fitting collet with an externally-threaded locking nut configured to engage the internal threads of the baseplate central channel.

8. Claims 13-18 and 20-22

For the following reasons, claims 13-18 and 20-22 are likewise obvious and therefore unpatentable:

Claims 13-18 and 20-22	Disclosure
[13-1]The reverse shoulder implant of claim 12, wherein the glenosphere is configured to at least partially surround an external surface of the baseplate.	As noted at [1-7], Orphanos discloses this limitation. (EX-1006 at 25, 26, 29, 8:44-62, 10:4-29, 15:1-6;EX-1002 at 73-74, ¶143.)
[14-1]The reverse shoulder implant of claim 12, wherein the baseplate has a circular shape.	As noted at [1-1], Orphanos discloses this limitation. (EX-1002 at 74, ¶144.)
[15-1]The reverse shoulder implant of claim 12, wherein the glenosphere is configured to surround the baseplate.	As noted at [1-7], Orphanos discloses this limitation. (<i>Id.</i> , ¶145;EX-1006 at 25, 29, 8:44-62, 15:1-6.)
[16-1]The reverse shoulder implant of claim 12, wherein the glenosphere is configured to be secured to the baseplate with a morse taper.	This limitation is taught by Orphanos at 8:44-62, 15:1-6, EX-1006 at 25, 29. (EX-1002 at 75, ¶146.)

Claims 13-18 and 20-22	Disclosure
[17-1]The reverse shoulder implant of claim 12, wherein a diameter of the locking nut is greater than a length of the locking nut.	Roche teaches this limitation. The specification of the '254 Patent provides no description of any type of benefit to having a diameter that is greater than the length of the locking nut. Therefore, it would have been obvious to make such a modification of Orphanos based on design choice as taught by Roche. Such a modification would have also been obvious to a POSITA, as a POSITA would have been motivated to keep the length less than the diameter to provide a low profile to the locking nut. Fig. 53 (<i>Id.</i> at 75, ¶147.)

Claims 13-18 and 20-22	Disclosure
[18-1]The reverse shoulder implant of claim 12, 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 in [1-4], Orphanos discloses the substitution of the collet with a reducing bushing. It would have been obvious to a POSITA for the locking nut to also include the rotational control feature of claim 16, as any threaded device must have this rotational control feature to facilitate thread engagement. Furthermore, Roche in Figure 7A discloses a rotational control feature in locking cap 116 in the form of an internal hex surface. Furthermore, Hale discloses a rotational control feature in reducing bushing 48 in the form of an external hex surface. Furthermore, page 3547 of Grainger discloses reducing bushing having a reducing bushing in the form of an external hex. (<i>Id.</i> at 75-76, ¶148.)
[20-1]The reverse shoulder implant of claim 12, wherein the central channel defines a surface integral with the central post.	As noted in [1-3],the first implant 200 of Orphanos discloses a central post 314 of baseplate 210 that defines a throughbore 320 in communication with throughbore 310 defined by platform 312 of baseplate 210. (Orphanos, 8:4-30). Further, FIG. 3 shows throughbores 310, 320 as being integral with each other such that that the surface of baseplate 210 defining throughbore 310 is integral with central post 314. (<i>Id.</i> at 76, ¶149.)

Claims 13-18 and 20-22	Disclosure
[21-1]The reverse shoulder implant of claim 12, wherein the central post includes a rotational control feature.	As noted in [1-3], Orphanos discloses a central bone screw 270 includes a screw head 602 (having a rotational control feature) coupled to a cylindrical unthreaded neck portion 606 (which discloses a cylindrical post configured to at least partially pass through the [baseplate] central channel. (<i>Id.</i> , ¶150.)
[22-1]The reverse shoulder implant of claim 12, wherein the central post comprises a central channel configured to house a primary screw.	As noted in [1-3], Orphanos discloses the central post 314 of baseplate 210 defines a throughbore 320 that is configured to house a bone screw 270 . (<i>Id.</i> at 76-77, ¶151; Orphanos, 8:16-23.)

B. GROUND 2: CLAIMS 8 AND 19 ARE OBVIOUS OVER ORPHANOS IN VIEW OF HOPKINS, PEREGO, ROCHE, KNOWLEDGE OF A PERSON HAVING ORDINARY SKILL IN THE ART, AND FURTHER IN VIEW OF GARGAC

For the following reasons, claims 8 and 19 are also obvious and therefore unpatentable, based in part on another reference, Gargac.

1. Overview of Gargac

Gargac published on October 29, 2015, which is before the '254 Patent's effective filing date of March 14, 2024. Therefore, Gargac is prior art under AIA 35 U.S.C. §102(a)(1). Gargac was not cited as a reference during prosecution. (EX-1001 at 1-4.)

EX-1020 at 5, Figure 4 of Gargac

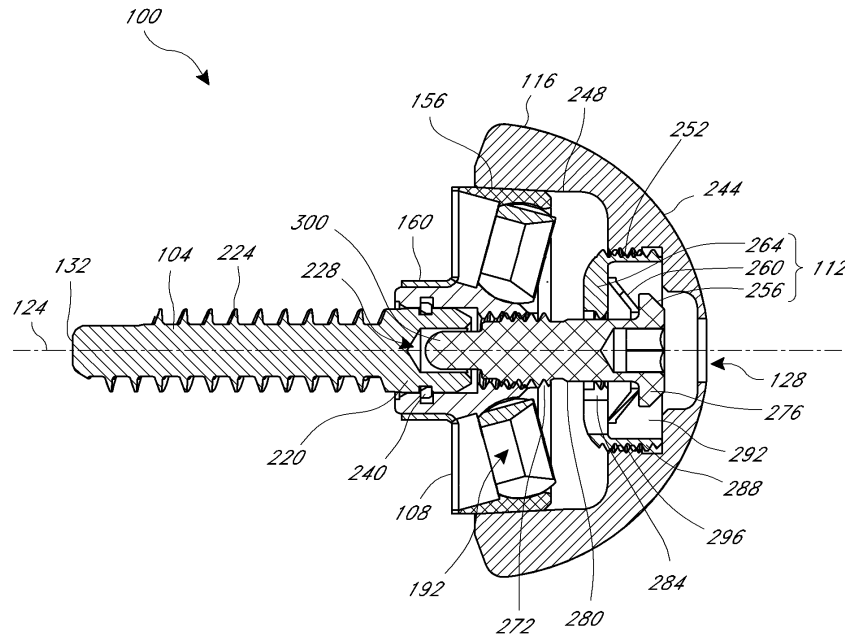


FIG. 4

Gargac discloses various prior art reverse shoulder implants for use in reverse shoulder procedures. (EX-1020 at 1, 39, Title, ¶[0047]; EX-1002 at 34, ¶65.) Gargac is analogous art for §103 purposes because Gargac arises from the same field of endeavor as the '254 Patent and is reasonably pertinent to the problem that the inventors of the '254 Patent sought to solve (EX-1002 at 33, ¶64). *In re Bigio*, 381 F.3d at 1325. A POSITA would have been motivated to combine Orphanos, Hopkins, Perego, and Roche with Gargac with a reasonable expectation of success in doing so for reasons set forth below. *KSR*, 550 U.S. at 420 ("[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.").

2. Claim 8

For the reasons discussed, Orphanos, Hopkins, Perego, and Roche disclose limitations [1-PRE]-[1-8]. (*See* Sections VI(A)(1)(a)-(i).) The remaining limitation of claim 8 (i.e., limitation[8-1]) is discussed below.

- k. [8-1]"The reverse shoulder implant of claim 1, wherein the central post has a length of about 5mm, 5.5mm, 6mm, 6.5mm, 7mm, 7.5mm, 8mm, 8.5mm, 9mm, 9.5mm, 10mm, 10.5mm, 11mm, 11.5mm, 12mm, 12.5mm, 13mm, 13.5mm, 14mm, 14.5mm, or 15mm."

EX-1020 at 3, 5, Figures 2 and 4 of Gargac

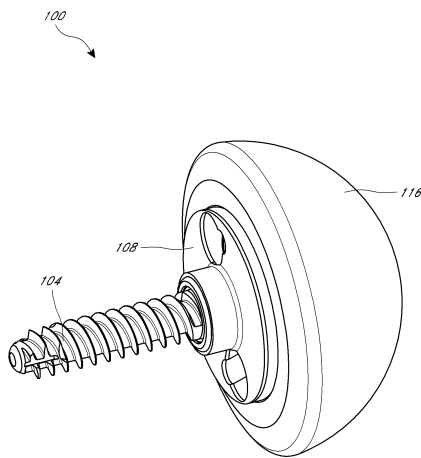


FIG. 2

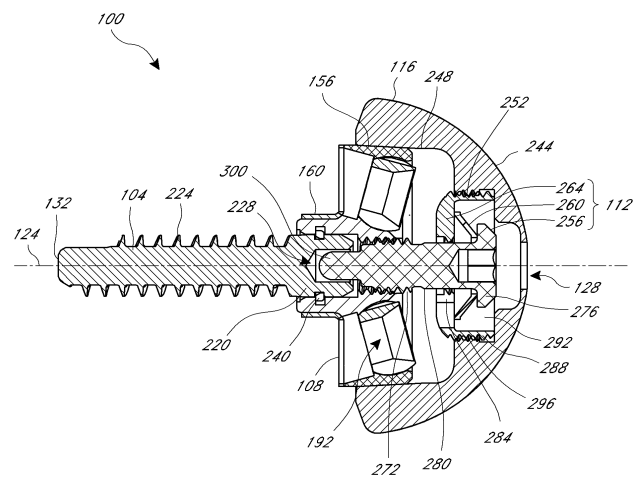


FIG. 4

Gargac discloses the above recited limitation. Gargac discloses a variety of anchor members **104A-104C** that are inserted through a central aperture **168** of baseplate **108** to anchor baseplate **108** to the glenoid. (EX-1020 at 38, ¶¶[0055]-[0058]). Gargac also teaches that such anchor members **104A-104C** may include various lengths, including 15mm-40mm, thus disclosing the limitation recited in

claim 8. As discussed above, Perego and Hopkins teach that various suitable anchor members may be used to fix a baseplate to a glenoid, including a screw, post, pin, etc. Therefore, it would have been obvious to a POSITA to incorporate an anchoring member in the form of a post to be 15mm in length, as such a length would have simply been combining prior art elements according to known methods to yield a predictable result. (EX-1002 at 78, ¶156.)

Further, it would have been obvious to make the central post of Orphanos and/or Orphanos as modified by Hopkins and Perego, to include any of the lengths of limitation[8-1] as a matter of design choice and mere optimization. "Design choice applies when old elements in the prior art perform the same function as the now claimed structures." *In re Bagnall*, Appeal 2009-013429, 2011 WL 1463378, at *6 (B.P.A.I. Apr. 14, 2011) (citing *In re Kuhle*, 526 F.2d 553, 555 (CCPA 1975) (use of claimed feature solves no stated problem and presents no unexpected result and "would be an obvious matter of design choice within the skill of the art")). The '254 Patent fails to describe any advantages of incorporating a central post having any of the lengths recited in claim 8. Without providing any explanation on the advantages of using such a central post, the use of a central post having any of the lengths recited in claim 8 is obvious as a matter of design choice. (EX-1002 at 78-79, ¶157.)

Further, Orphanos teaches that a central post **314** can have a length approximately within the range of about 5mm-30mm. (EX-1006 at 26, 9:56-59). Therefore, Orphanos also discloses the limitation of claim 8. (EX-1002 at 78, ¶154.)

3. Claim 19

For the reasons discussed, Orphanos, Hopkins, Perego, and Roche disclose limitations [19-PRE]-[19-8]. (*See* Sections VI(A)(1)(a)-(f),(h)-(i),VI(A)(3)(a).) Additionally, for reasons discussed, Orphanos in view of Hopkins, Perego, Roche, and further in view of Gargac discloses limitation[19-1]. (*See* Section VI(B)(1)(a).)

C. GROUND 3: CLAIMS 1-7, 9-18, and 20-22 ARE OBVIOUS OVER LEFEBVRE IN VIEW OF ORPHANOS, HOPKINS, PEREGO, AND ROCHE

In addition to the reasons provided above with respect to ground 1, claims 1-7, 9-18, and 20-22 are obvious and therefore unpatentable over Lefebvre in view of Orphanos, Hopkins, Perego, and Roche.

4. Overview of Lefebvre

Lefebvre issued from an application that was filed on May 28, 2020, which is before the '254 Patent's filing date of March 14, 2024. (EX-1002 at 23-24, ¶53.) Therefore, Lefebvre is prior art under AIA 35 U.S.C. §102(a)(2). (*Id.*) Lefebvre was not cited as a reference during prosecution. (EX-1001 at 1-4.)

Further, Lefebvre discloses an adapter (i.e., a locking nut), in the form of external tapping **62** and threading of intermediate portion **671**, which is configured to: (i) be secured within the central through bore (i.e., a central channel) of base **2**, and (ii) threadably engage a locking screw **8** to secure glenosphere **3** to base **2**. (EX-1009 at 16, 17, 7:4-12, 9:48-57; EX-1002 at 27-28, ¶57.)

Lefebvre discloses that it was readily known to a POSTIA that prior art baseplates **2** includes a central stud **5** (i.e., a central post) that anchors into the glenoid cavity. (EX-1009 at 15, 6:38-43).

Lefebvre is analogous art for § 103 purposes because Lefebvre arises from the same field of endeavor as the '254 Patent and is reasonably pertinent to the problem that the inventors of the '254 Patent sought to solve (EX-1002 at 26, ¶55). *In re Bigio*, 381 F.3d at 1325. A POSITA would have been motivated to combine Lefebvre with Orphanos and Roche for reasons set forth below. *KSR*, 550 U.S. at 420 ("[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.").

5. Claim 1:

a. [1-PRE]: "A reverse shoulder implant, comprising"

EX-1009 at 12, Figure 23 of Lefebvre

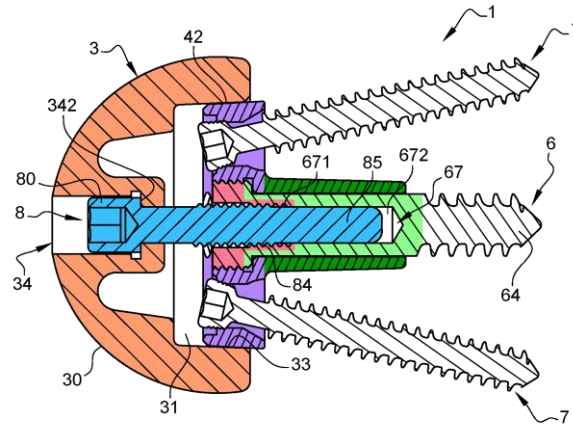


Fig. 23

EX-1001 at 12, Figure 8 of '254 Patent

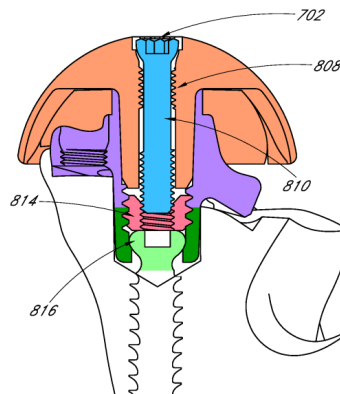


FIG. 8

Lefebvre discloses this preamble, as Lefebvre is directed toward "A glenoid implant for an inverted shoulder prosthesis." (EX-1009 at 1, Abstract; EX-1002 at 79-80, ¶161.)

- b. [1-1]: "a baseplate configured to be secured to a glenoid of a scapular bone of a patient"

EX-1009 at 8, 9, Figures 14 and 16 of Lefebvre

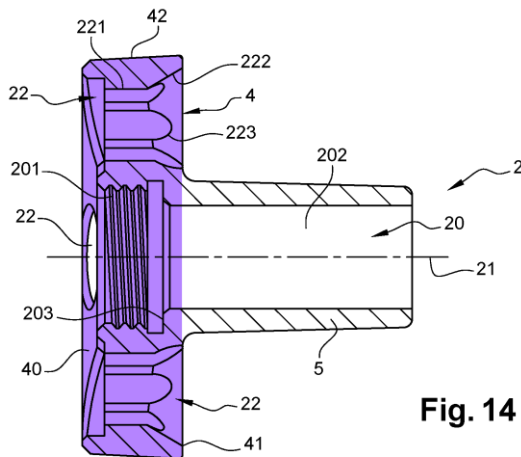


Fig. 14

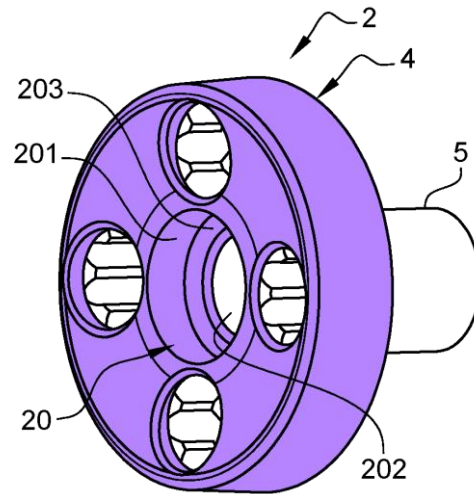


Fig. 16

EX-1001 at 12, Figure 8 of '254 Patent

Color Key:
baseplate

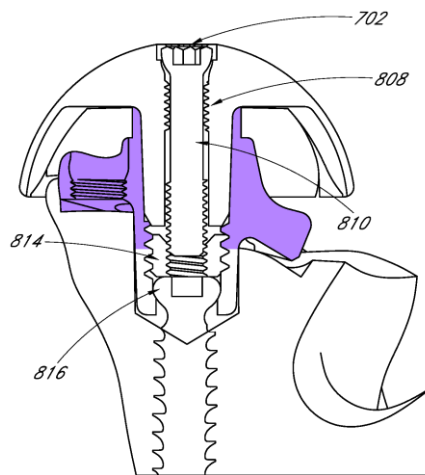


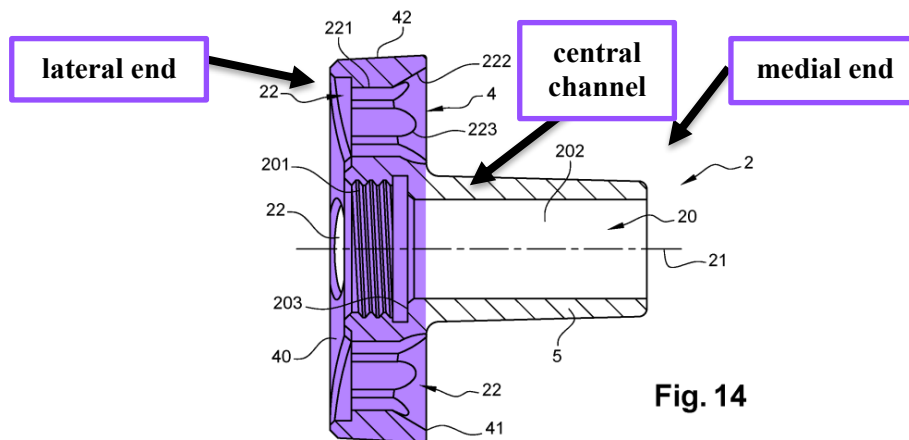
FIG. 8

Lefebvre discloses this limitation, describing "a glenoid implant 1...intended for an inverted shoulder prosthesis, comprises a base 2...the base 2 is intended to be anchored on a glenoid cavity of a scapula." (EX-1009 at 15, 6:20-24.) Base 2 is

circular and configured to receive anchoring screws **6**, **7** to secure base **2** to the glenoid cavity of the scapula. (EX-1009 at 15, 16, 6:65-7:3, 8:15-21; EX-1002 at 80, ¶164.) Therefore, Lefebvre teaches a baseplate configured to be secured to a glenoid of a scapular bone of a patient.

- c. [1-2]: "the baseplate having a lateral end, a medial end, and a baseplate central channel extending through the baseplate from the lateral end to the medial end"**

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



EX-1001 at 12, Figure 8 of '254 Patent

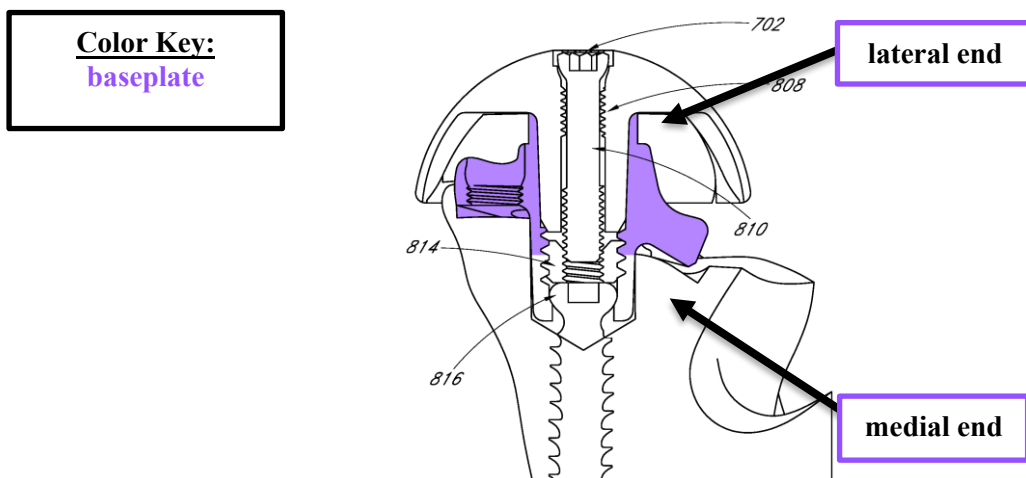
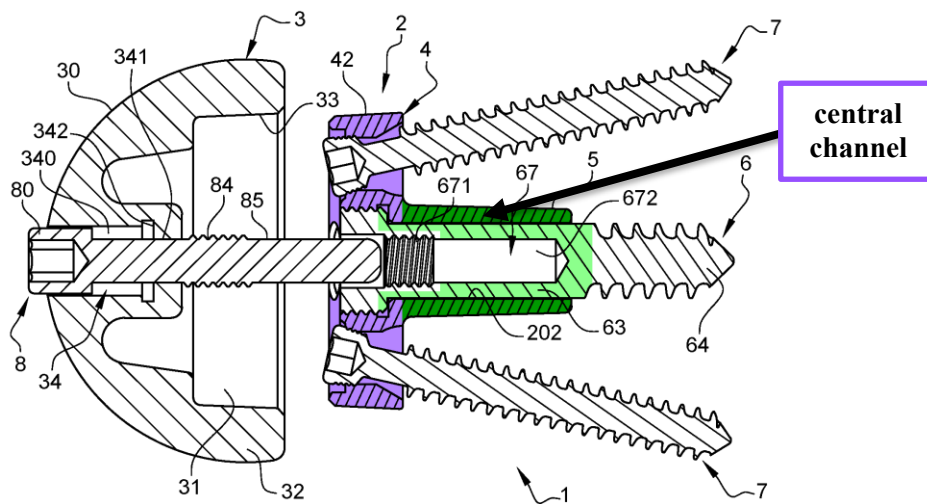


FIG. 8

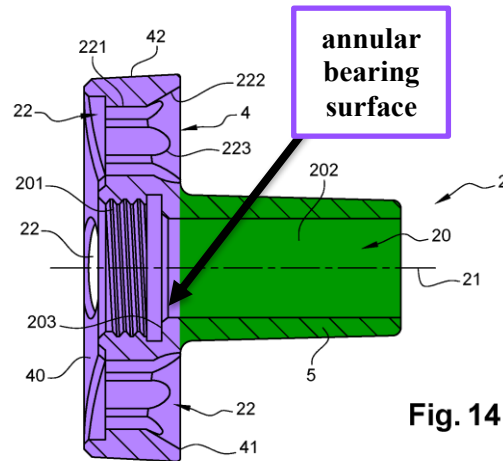
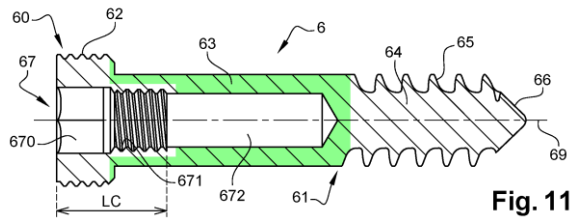
Lefebvre discloses this limitation. Base **2** of Lefebvre includes a subplate **4** having an outer face **40** (i.e., lateral end) and inner face **41** (i.e., medial end) facing opposite directions from each other, where the inner face is intended to bear on the glenoid cavity. (EX-1009 at 15, 6:26-31.) Further, base **2** has a main orifice **20** (i.e., central channel) that extends through base **2** along a central axis **21** from the lateral end to the medial end. (EX-1009 at 15, 6:44-48.) Therefore, Lefebvre teaches the baseplate having a lateral end, a medial end, and a central channel extending therethrough from the lateral end to the medial end. (EX-1002 at 81, ¶167)

d. [1-3]: "a central post configured to at least partially pass through the central channel"

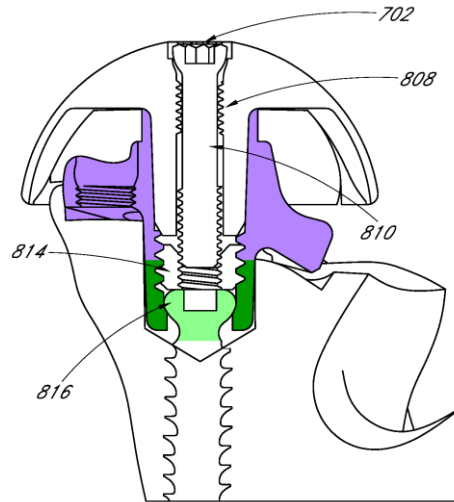
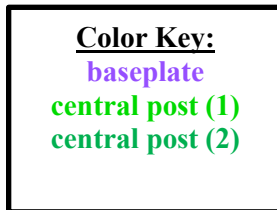
EX-1009 at 11, Figure 21 of Lefebvre



EX-1009 at 6, 8, Figures 11 and 14 of Lefebvre



EX-1001 at 12, Figure 8 of '254 Patent



Lefebvre discloses this limitation. As shown in FIG. 11, 14, and 21, portions of anchor rod **61** of main anchoring screw **6** (highlighted in light green), as well as central stud **5** of baseplate **2** (highlighted in dark green) **each** disclose a central post as recited in claim 1 (EX 1002 at 82-83, ¶¶170-171.)

Further, for at least the reasons provided below, it would have been obvious to a POSITA, at the time of invention of the '254 Patent, to substitute main anchoring screw **6** with a central post. Anchoring screw **6** is inserted into a central channel defined by base **2** to anchor base **2** to the glenoid cavity. (EX-1009 at 15, 6:65-7:13.) Lefebvre describes anchor rod **61** of anchoring screw **6** as having external tapping **65** that has a different pitch compared to external tapping **62** of main head **60**, where such external tapping **65** is driven into bone (e.g., the glenoid). (EX-1009 at 16, 7:35-44) As also discussed above, both Hopkins and Perego teach that screws and posts are readily interchangeable for fastening a baseplate to the glenoid. (EX-1010 at 23, 12:9-11; EX-1019 at 10, ¶[0038]; EX-1002 at 83-84, ¶172). Therefore, it would have been obvious to modify anchoring screw **6** to replace external tapping **65** with a post (i.e., no external tapping **65**), as such a modification was a simple substitution of one known element for another (i.e., screws and posts) to obtain predictable results (i.e., anchoring the baseplate to the glenoid) and as such a POSITA would have had a reasonable expectation of success that replacing the bone screw with a known bone post would work. (EX-1002 at 84, ¶173-174).

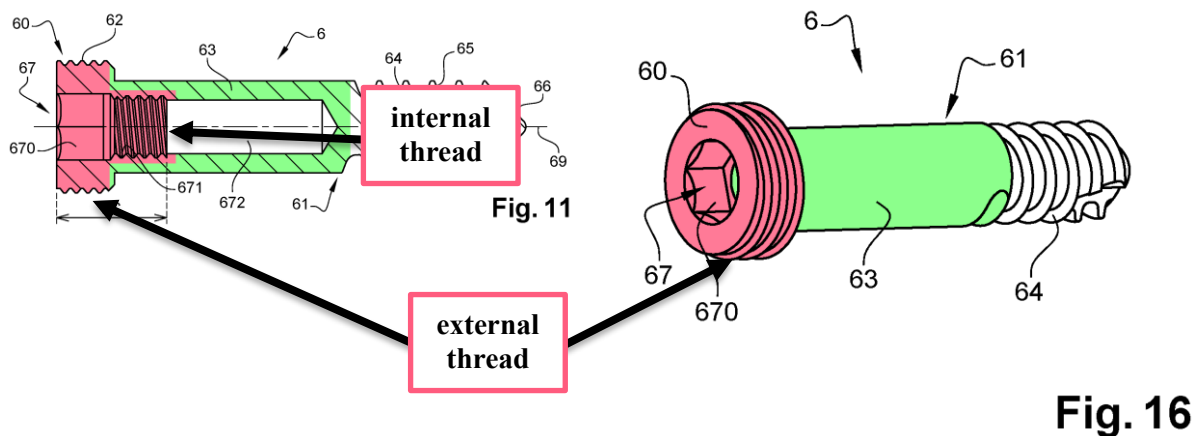
Further, as discussed in section (VI)(A)(5)(d), Hopkins teaches an enabling use of such posts to anchor a baseplate to the glenoid, where a post is inserted through a central channel defined by a baseplate. Hopkins's and Perego's teachings would have made this modification of Lefebvre's screw anchoring element to a post

anchoring element obvious to try because it would have involved choosing from the finite number of known and predictable fixation elements at the time of the invention of the '254 Patent which would have included fixation posts and the corresponding surgically created post holes within the glenoid with a reasonable expectation of success. (EX-1002 at 84-85, ¶175.)

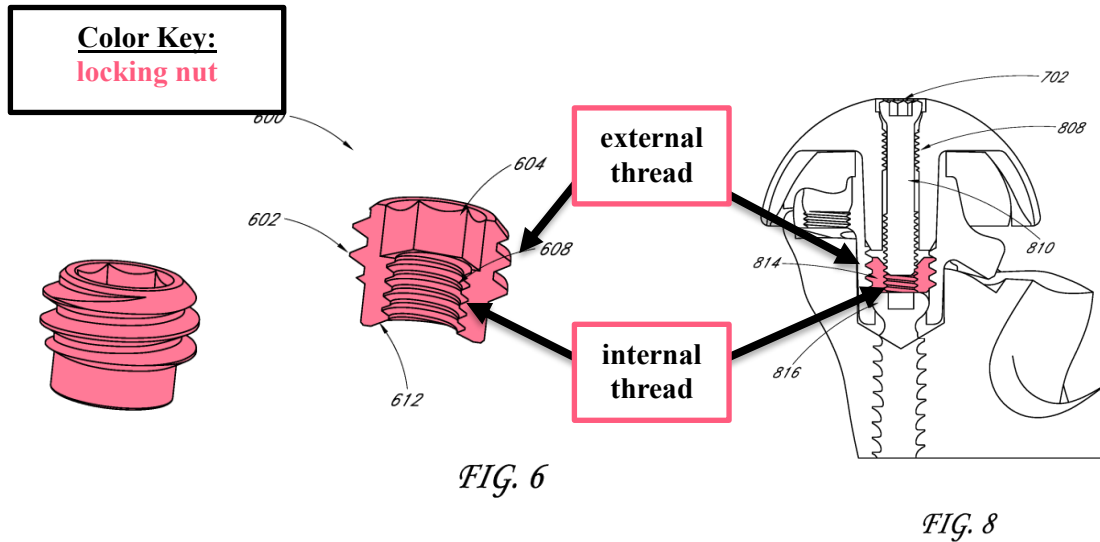
The use of screws and posts are readily recognized by a POSITA as being interchangeable for fastening a baseplate to the glenoid. (EX-1010 at 23, 12:9-11; EX-1019 at 10, ¶[0038]). Therefore, for reasons similar to those described in Section (VI)(A)(5)(d), the post as recited in claim 1 is obvious as a matter of design choice.

- e. [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"

EX-1009 at 6, 9, Figures 11 and 16 of Lefebvre



EX-1001 at 12, Figures 6 and 8 of the '254 Patent



Lefebvre discloses this limitation. Lefebvre teaches a locking nut in the form of the enlarged head of main head **60** and internal threading **671** of intermediate portion **671**. (EX-1009 at 16, 7:4-19, 7:45-56; EX-1002 at 86-87, ¶179.) Main head **60** has a cylindrical shape and an external tapping **62** which is complementary to the threading of inlet portion **201** of main orifice **20** of base **2**. (EX-1009 at 16, 7:4-19.) Further, main head **60** defines an inner blind hole **67** defined by an inner surface that includes internal threading at intermediate portion **671**. (EX-1009 at 16, 7:45-56.) Therefore, Lefebvre teaches 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. (EX-1002 at 86-87, ¶¶178-79.)

- f. [1-5]: "the locking nut configured to engage the central post when the central post and baseplate are implanted within the medical patient"**

EX-1009 at 6, 11, Figures 11 and 21 of Lefebvre

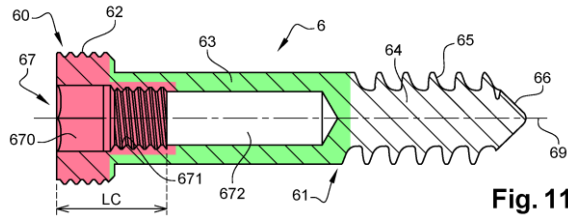


Fig. 11

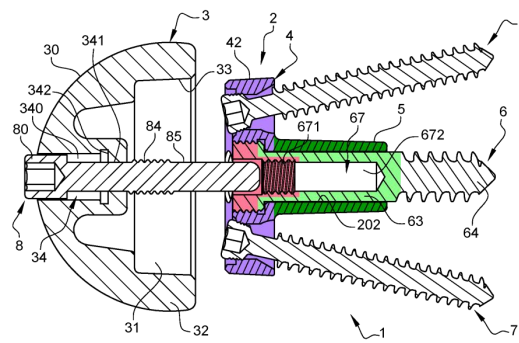


Fig. 21

EX-1006 at 10, 15, Figures 7 and 10C of Orphanos

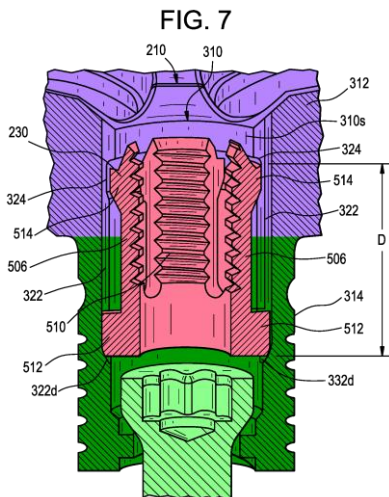


FIG. 7

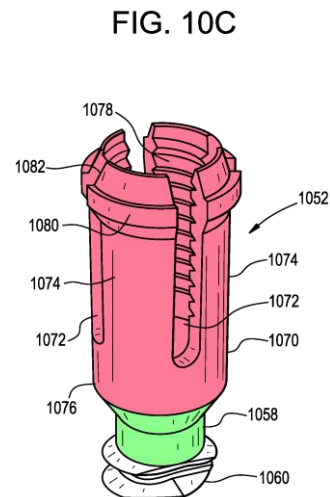


FIG. 10C

EX-1007 at 14, 15, Figures 8A and 9A-C of Roche

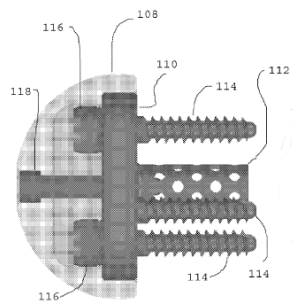


Fig. 8A

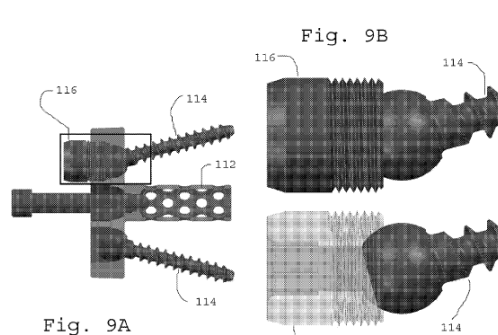


Fig. 9A

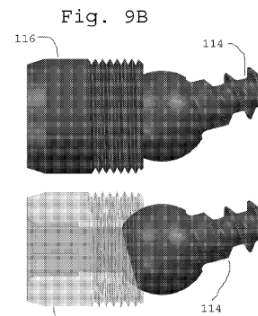


Fig. 9C

EX-1001 at 12, Figure 8 of '254 Patent

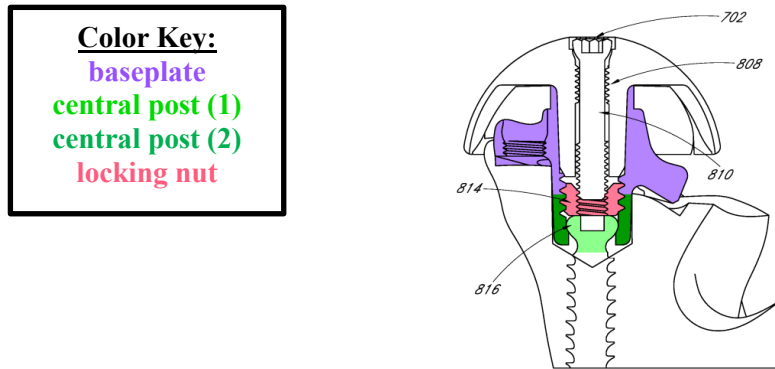


FIG. 8

Lefebvre discloses this limitation. As discussed above, Lefebvre teaches a locking nut in the form of the enlarged head of main head **60** and threading **671** of intermediate portion **671**. (EX-1009 at 16, 7:4-19, 7:45-56.) Additionally, Lefebvre teaches at least two different central posts in the form of cylindrical and non-threaded intermediate segment **63** of anchor rod **61** and a central stud **5** of base **2**. (EX-1009 at 8, FIGS. 14-15.)

Main head **60** is shown and described as being threadably engaged with inlet portion **201** of main orifice **20**, so that main head **60** is screwed into inlet portion **201**. (EX-1009 at 16, 7:7-12). Therefore, main head **60** is configured to engage central stud **5** via such a threaded connection when base **2** and central stud **5** are implanted within the medical patient.

Additionally, main head **60** of main anchoring screw **6** is attached to cylindrical non-threaded intermediate segment **62** of anchor rod **61** as a single piece.

(EX-1002 at 87-88, ¶182.) Although main head **60** is shown fixedly attached to cylindrical non-threaded intermediate segment **62** of anchor rod **61**, claim 1 does not require a locking nut that is removable or separate from the central post. Claim 1 requires only that such a locking nut be "configured to engage the central post when the central post and baseplate are implanted within the medical patient," which is taught by Lefebvre.

If Patent Owner, however, were to argue that claim 1 recites a locking nut that is somehow separate from the central post (although such amendment/interpretation would lack §112 support), such a concept would have been obvious over Lefebvre in view of Orphanos and Roche.

MPEP § 2144.04(V)(C) provides that separating two parts is considered obvious "if it were considered desirable for any reason." *In re Dulberg*, 289 F.2d 522, 523 (CCPA 1961). As discussed above, Orphanos discloses an implant 200 that includes a central bone screw **270** and a locking nut in the form of collet **230**. Orphanos discusses the desire to make central bone screw **270** a "free spinning" design to allow bone screw **270** to anchor against bone to provide additional compression between the bone and distal facing surface **312d** of baseplate **270** while preventing bone screw **270** from binding up within baseplate **210**. (EX-1006 at 27, 12:49-61; EX-1002 at 89, ¶184.)

Therefore, a POSITA would have considered 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 post, as separation of such components would have allowed Lefebvre's central post to have a "free spinning" design to provide additional compression between the bone and Lefebvre's base **2**. (EX-1002 at 89-90 ¶185.) Separating the components of Lefebvre's main anchoring screw **6** forming the central post from external tapping **62** and internal threading of intermediate portion **671** (i.e., the components of Lefebvre that interface between base **2** and glenosphere screw **8**) provide a "free spinning" design by allowing end segment **64** to anchor into the glenoid cavity of a medical patient without having external tapping **62** inhibit such free spinning via threaded engagement with inlet portion **201** of base **2**. (*Id.*)

Further, Orphanos teaches how to modify implant **1** of Lefebvre to separate the above referenced components of main anchoring screw **6** while enabling implant **1** suitable for its intended purposes. As discussed above, Orphanos discloses two implants **200**, **1000**. First implant **200** includes a locking nut in the form of collet **230** that is separated from compression screw **270**, while second implant **1000** teaches a locking nut in the form of a collet portion **1052** that is integral with compression screw **1050**. Therefore, Orphanos teaches a POSITA how to

incorporate a locking nut that may be either (i) separated from the compression screw, or (ii) integral with the compression screw. (*Id.* at 90, ¶186.)

A POSITA would use the teachings of Orphanos to (i) separate the components of Lefebvre's main anchoring screw **6** forming the central post and the components of Lefebvre's main anchoring screw **6** forming the locking nut, (ii) enable Lefebvre's separated central post to compress base **2** against the glenoid cavity of the patient when suitably implanted, as well as (iii) enable Lefebvre's separated locking nut to suitably interface between base **2** and locking screw **8**. (*Id.* at 91, ¶187.)

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 the central post to allow for a "free spinning" design as taught by Orphanos, Lefebvre's locking nut would still be configured to engage the central post when the central post and baseplate are implanted within the medical patient as recited in the claim. (*Id.*, ¶188.)

Additionally, as discussed above, Roche teaches using locking cap screws **116** within glenoid plate **110** to engage compression screws **114** after being implanted to prevent compression screws **114** from backing out. (EX-1007 at 72, 14:1-18.) A POSITA would have been motivated to ensure the location of Lefebvre's separated locking nut is engaged with Lefebvre's separated central post after being implanted,

as taught by Roche, as such engagement would have provided the well-known benefit of inhibiting Lefebvre's separated central post from backing out. (EX-1002 at 91, ¶189.)

A POSITA would have had a reasonable expectation that such modification would have been successful because it simply is a known successful solution—separating compression screw from locking nut—to solve a known problem—not allowing free spinning. (*Id.* at 92, ¶190)

- g. [1-6]: "wherein the external thread is configured to couple the locking nut with the baseplate central channel"

EX-1009 at 11, Figure 21 of Lefebvre

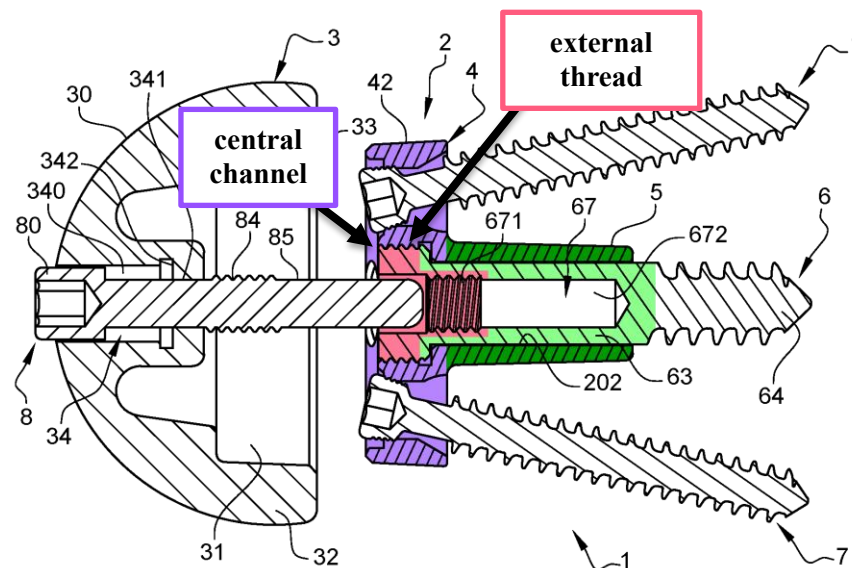


Fig. 21

EX-1001 at 12, Figure 8 of '254 Patent

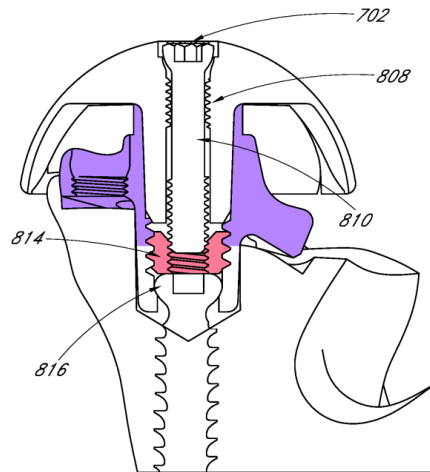
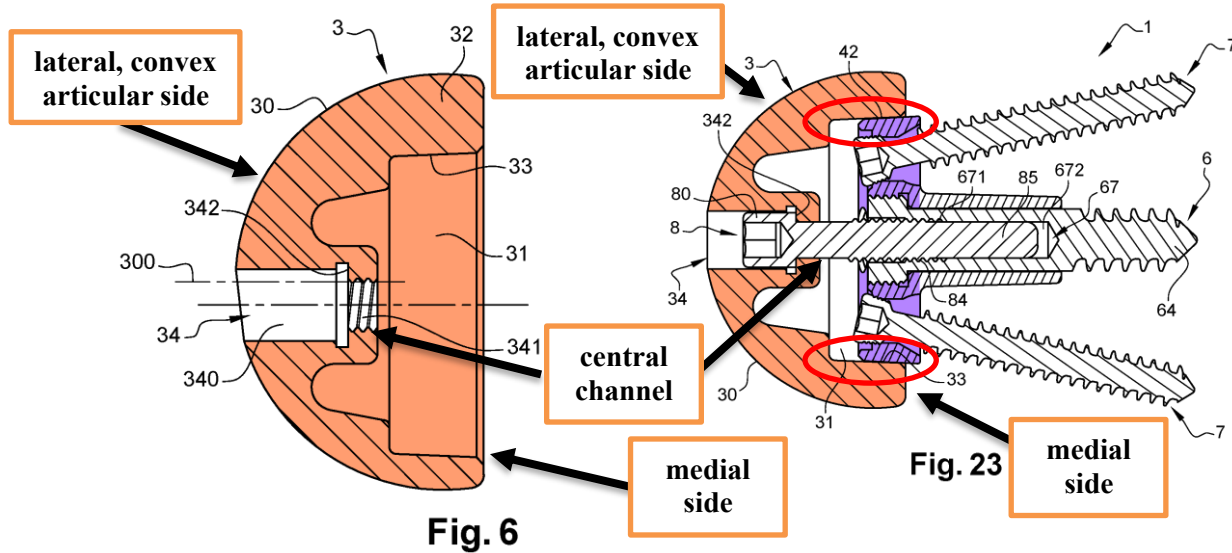


FIG. 8

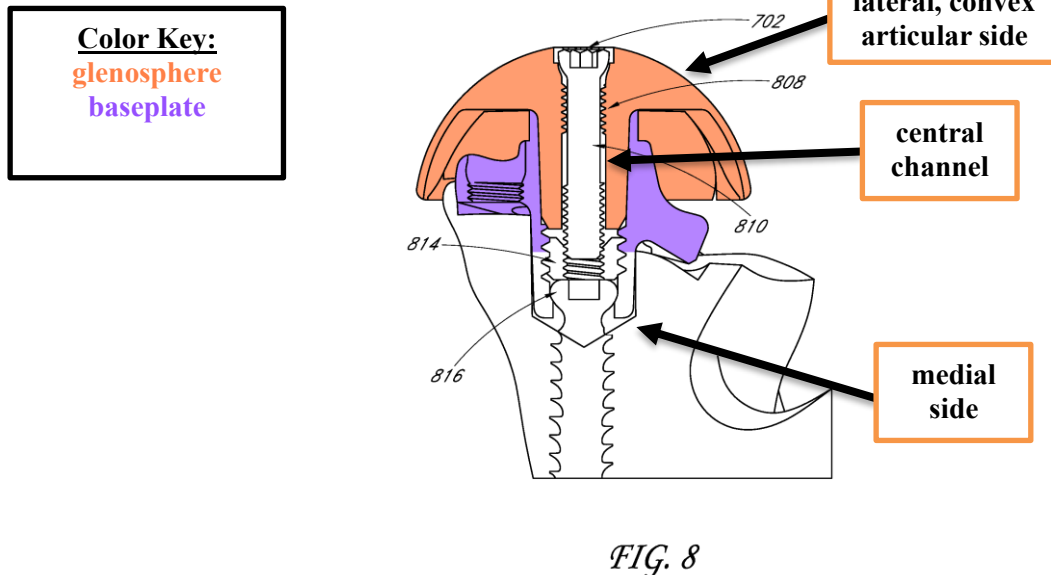
Lefebvre discloses this limitation. Main head **60** of main anchoring screw **6** includes external tapping **62** that is complementary to the threading of inlet portion **201** of main orifice **20**, thereby allowing external tapping **62** of main head **60** to be screwed into inlet portion **301** of main orifice **20** of base **2**. (EX-1009 at 16, 7:7-12; EX-1002 at 92-93, ¶193.) Therefore, Lefebvre teaches an external thread of the locking nut being configured to couple the locking nut to the baseplate central channel.

- h. [1-7]: "a glenosphere, having a lateral, convex articular side, a medial side, and a glenosphere central channel extending from the convex articular side to the medial side and configured to interface with the baseplate"

EX-1009 at 5, 12, Figures 6 and 23 of Lefebvre



EX-1001 at 12, Figure 8 of '254 Patent

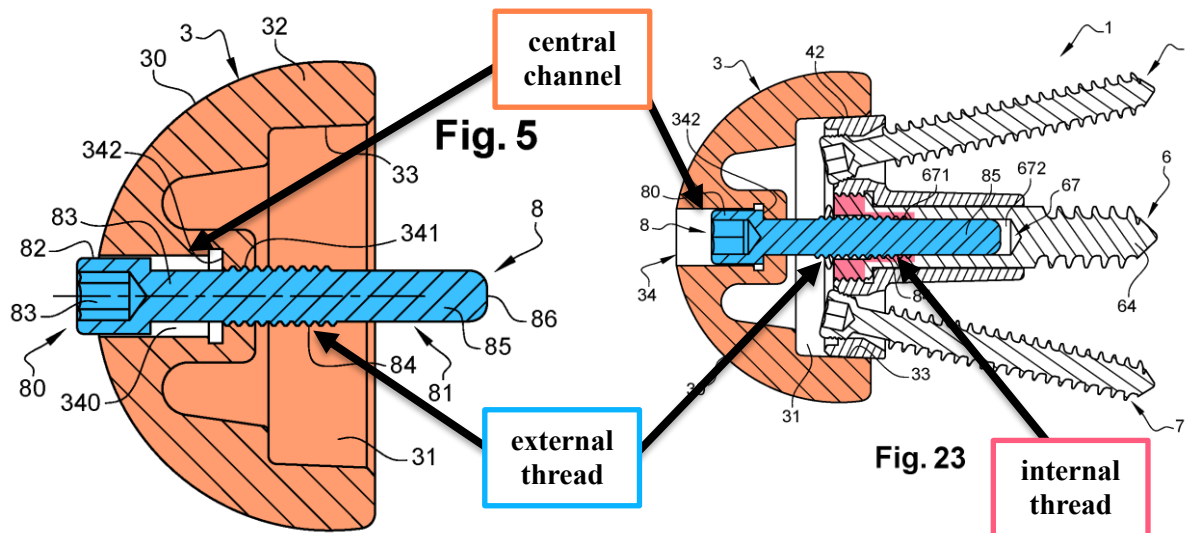


Lefebvre discloses this limitation. Lefebvre discloses a glenosphere 3 having a convex articulation surface 30, a medial side (i.e., the side of glenosphere 3 opposite the convex articulation surfaces 30), and a central orifice 34 that extends from convex articulation surface 30 into a main cavity 31 and thus the medial side.

(EX-1009 at 16, 8:22-26, 8:41-44; EX-1002 at 93-94, ¶196.) Further, Lefebvre discloses 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 glenosphere **3** also surrounds base **2** (as highlighted by the red ovals in Figure 23 above). (EX-1009 at 16, 8:27-40; EX-1002 at 93-94, ¶196.) Therefore, Lefebvre teaches a glenosphere, having a lateral, convex articular side, a medial side, and a glenosphere central channel extending from the convex articular side to the medial side and configured to interface with the baseplate.

- i. [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"

EX-1009 at 5, 12, Figures 5 and 23 of Lefebvre



EX-1001 at 12, Figure 8 of '254 Patent

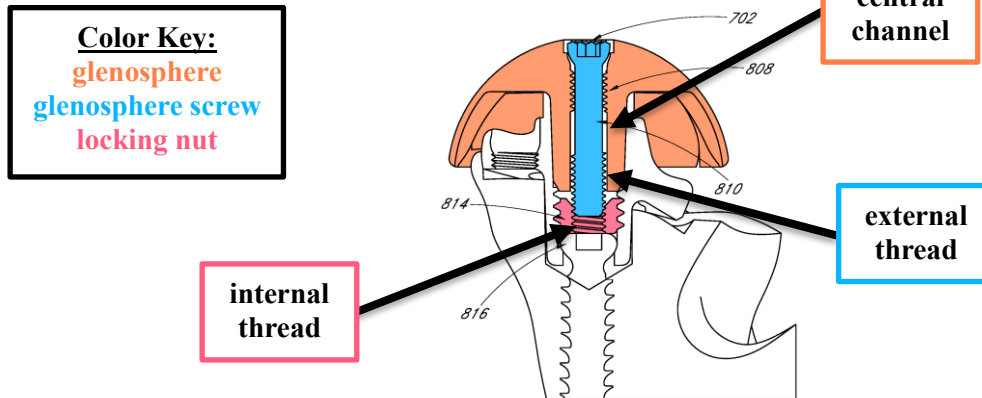
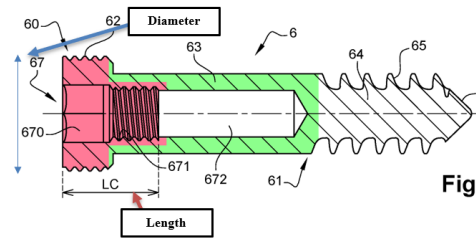


FIG. 8

Lefebvre discloses this limitation. Lefebvre teaches a locking screw **8** inserted into central orifice **34** of glenosphere **3** to lock glenosphere **3** on base **2**. (EX-1009 at 17, 9:1-7; EX-1002 at 95, ¶199.) Further, locking screw **8** includes a locking rod **81** provided with external tapping that is complementary to the threading of intermediate portion **671** of main anchoring screw **6**. (EX-1009 at 17, 9:8-10, 9:27-35.) External tapping of locking rod **81** is screwed into internal threading of intermediate portion **671** until proximal head **80** of locking screw **8** abuts on annular bearing surface **342** of glenosphere **3**. (EX-1009 at 17, 9:51-57; EX-1002 at 95, ¶199.) Therefore, Lefebvre teaches 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.

6. Claims 2-7, 9-11

For the following reasons, claims 2-7 and 9-11 are likewise obvious and therefore unpatentable:

Claims 2-7 and 9-11	Disclosure
[2-1]The reverse shoulder implant of claim 1, wherein the glenosphere is configured to at least partially surround an external surface of the baseplate.	As noted at [1-7], Lefebvre discloses this limitation. (EX-1009 at 16, 8:27-40; EX-1002 at 96-97, ¶¶201.)
[3-1]The reverse shoulder implant of claim 1, wherein the baseplate has a circular shape.	As noted at [1-1], Lefebvre discloses this limitation. (EX-1002 at 97, ¶¶202.)
[4-1]The reverse shoulder implant of claim 1, wherein the glenosphere is configured to surround the baseplate.	As noted at [1-7], Lefebvre discloses this limitation. (<i>Id.</i> , ¶¶203; EX-1009 at 16, 8:27-40.)
[5-1]The reverse shoulder implant of claim 1, wherein the glenosphere is configured to be secured to the baseplate with a morse taper.	This limitation is taught by Lefebvre at 8:32-34 (EX-1009 at 16). (EX-1002 at 97-98, ¶¶204.)
[6-1]The reverse shoulder implant of claim 1, wherein a diameter of the locking nut is greater than a length of the locking nut.	Lefebvre discloses this limitation. Moreover, such a modification would have been obvious to a POSITA, as a POSITA would have been motivated to keep the length less than the diameter to provide a low profile to the locking nut.  Fig. 11

(*Id.* at 98-99, ¶¶205-07.)

Claims 2-7 and 9-11	Disclosure
[7-1]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.	Lefebvre discloses main head 60 having an inlet portion 670 shaped to cooperate with a screwing tool. (<i>Id.</i> at 99, ¶208;EX-1009 at 16, 7:51-54)
[9-1]The reverse shoulder implant of claim 1, wherein the central channel defines a surface integral with the central post.	As noted in [1-3], central stud 5 of Lefebvre is integral with subplate 4 of baseplate 2 (which also includes a surface that defines a portion of central orifice 20) such that the surface of subplate 4 defining main orifice 20 is integral with the central stud 5. (EX-1002 at 99, ¶209.)
[10-1]The reverse shoulder implant of claim 1, wherein the central post includes a rotational control feature.	Lefebvre discloses main head 60 having an inlet portion 670 shaped to cooperate with a screwing tool. (<i>Id.</i> at 99-100, ¶210;EX-1009 at 16, 7:51-54.)
[11-1]The reverse shoulder implant of claim 1, wherein the central post comprises a central channel configured to house a primary screw.	Lefebvre discloses central stud 5 defines a portion of main orifice 20, while a primary screw 6 is housed within the central stud 5. (EX-1009 at 15, 6:38-7:3;EX-1002 at 100, ¶211.)

7. Claim 12

For the reasons discussed, Lefebvre in view of Orphanos, Hopkins, Perego, and Roche discloses limitations [12-PRE]-[12-5] and [12-7]-[12-8]. (*See* Sections VI(C)(1)(a)-(f),(h)-(i).) The remaining limitation of claim 12 (i.e., limitation[12-6]) is discussed below.

- j. [12-6]: "wherein the external thread is configured to engage the baseplate central channel"

EX-1009 at 11, Figure 21 of Lefebvre

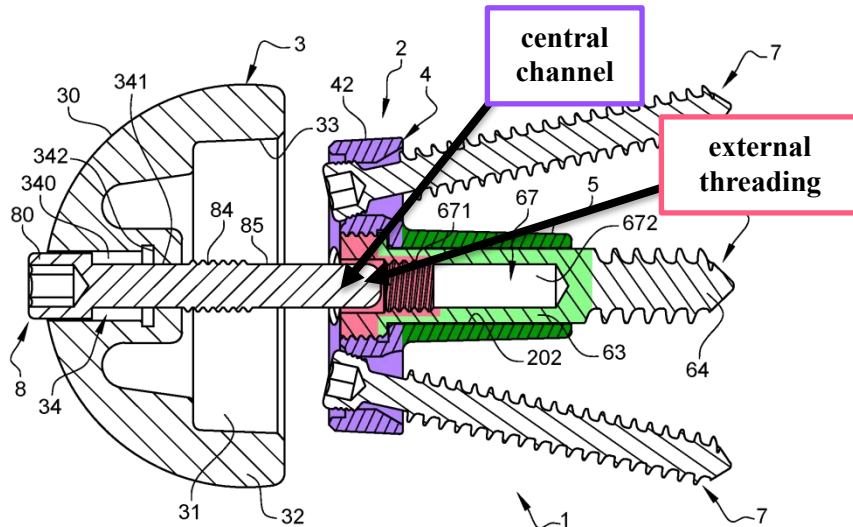


Fig. 21

EX-1001 at 12, Figure 8 of '254 Patent

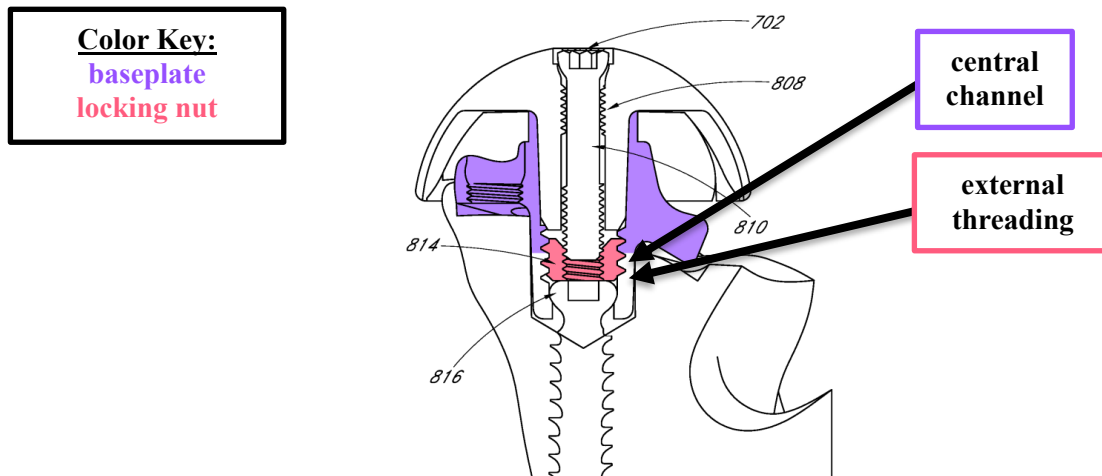


FIG. 8

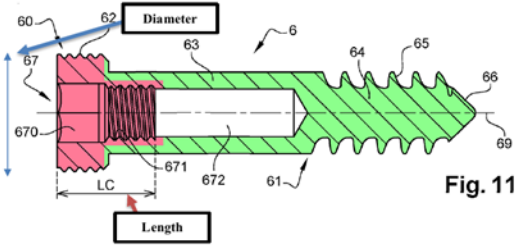
Lefebvre discloses this limitation. Main head **60** of main anchoring screw **6** includes external tapping **62** that is complementary to the threading of inlet portion **201** of main orifice **20**, thereby allowing external tapping **62** of main head **60** to

engage inlet portion **301** of main orifice **20** of base **2**. (EX-1009 at 16, 7:7-12;EX-1002 at 100-02, ¶¶212-13.) Therefore, Lefebvre teaches an external thread of the locking nut being configured to engage the baseplate central channel.

8. Claims 13-18 and 20-21

For the following reasons, claims 13-18 and 20-21 are likewise obvious and therefore unpatentable:

Claims 13-18 and 20-21	Disclosure
[13-1]The reverse shoulder implant of claim 12, wherein the glenosphere is configured to at least partially surround an external surface of the baseplate.	As noted at [1-7], Lefebvre discloses this limitation. (EX-1009 at 16, 8:27-40;EX-1002 at 102-03, ¶214.)
[14-1]The reverse shoulder implant of claim 12, wherein the baseplate has a circular shape.	As noted at [1-1], Lefebvre discloses this limitation. (EX-1002 at 103, ¶215.)
[15-1]The reverse shoulder implant of claim 12, wherein the glenosphere is configured to surround the baseplate.	As noted at [1-7], Lefebvre discloses this limitation. (<i>Id.</i> , ¶216;EX-1009 at 16, 8:27-40.)
[16-1]The reverse shoulder implant of claim 12, wherein the glenosphere is configured to be secured to the baseplate with a morse taper.	This limitation is taught by Lefebvre at 8:32-34 (EX-1009 at 16). (EX-1002 at 103, ¶217.)

Claims 13-18 and 20-21	Disclosure
[17-1]The reverse shoulder implant of claim 12, wherein a diameter of the locking nut is greater than a length of the locking nut.	Lefebvre discloses this limitation. Moreover, such a modification would have been obvious to a POSITA, as a POSITA would have been motivated to keep the length less than the diameter to provide a low profile to the locking nut.  Fig. 11 (<i>Id.</i> at 103-04, ¶218.)
[18-1]The reverse shoulder implant of claim 12, 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.	Lefebvre discloses main head 60 having an inlet portion 670 shaped to cooperate with a screwing tool. (<i>Id.</i> at 104, ¶219; EX-1009 at 16, 7:51-54.)
[20-1]The reverse shoulder implant of claim 12, wherein the central channel defines a surface integral with the central post.	As noted in [1-3], central stud 5 of Lefebvre is integral with subplate 4 of baseplate 2 (which also includes a surface that defines a portion of central orifice 20) such that the surface of subplate 4 defining main orifice 20 is integral with the central stud 5. (EX-1002 at 104, ¶220.)

Claims 13-18 and 20-21	Disclosure
[21-1]The reverse shoulder implant of claim 12, wherein the central post includes a rotational control feature.	Lefebvre discloses main head 60 having an inlet portion 670 shaped to cooperate with a screwing tool. (<i>Id.</i> , ¶221;EX-1009 at 16, 7:51-54.)
[22-1]The reverse shoulder implant of claim 12, wherein the central post comprises a central channel configured to house a primary screw.	Lefebvre discloses central stud 5 defines a portion of main orifice 20, while a primary screw 6 is housed within the central stud 5. (EX-1009 at 15, 6:38-7:3;EX-1002 at 104-05, ¶222).

D. GROUND 4: CLAIMS 8 AND 19 ARE OBVIOUS OVER LEFEBVRE IN VIEW OF ORPHANOS, HOPKINS, PEREGO, AND ROCHE, AND IN FURTHER VIEW OF GARGAC

For the following reasons, claims 8 and 19 are also obvious and therefore unpatentable, based in part on another reference, Gargac.

9. Claim 8

For the reasons discussed, Lefebvre, Orphanos, Hopkins, Perego, and Roche discloses limitations [1-PRE]-[1-8]. (*See* Sections VI(C)(1)(a)-(i).) The remaining limitation of claim 8 (i.e., limitation[8-1]) is discussed below.

- k. [8-1]: "The reverse shoulder implant of claim 1, wherein the central post has a length of about 5mm, 5.5mm, 6mm, 6.5mm, 7mm, 7.5mm, 8mm, 8.5mm, 9mm, 9.5mm, 10mm, 10.5mm, 11mm, 11.5mm, 12mm, 12.5mm, 13mm, 13.5mm, 14mm, 14.5mm, or 15mm."

EX-1020 at 5, Figure 4 of Gargac

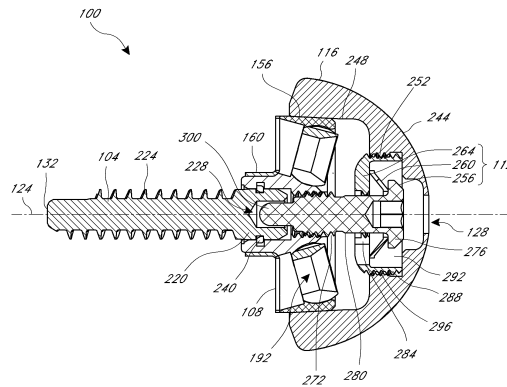


FIG. 4

Gargac discloses the above recited limitation. Gargac discloses a variety of anchor members **104A-104C** that are inserted through a central aperture **168** of baseplate **108** to anchor baseplate **108** to the glenoid. (EX-1020 at 38, ¶¶[0055]-[0058].) Gargac also teaches that such anchor members **104A-104C** may include various lengths, including 15mm-40mm. (EX-1002 at 105, ¶226.) As discussed above, Perego and Hopkins teach that various suitable anchor members may be used to fix a baseplate to a glenoid, including a screw, post, pin, etc. Therefore, it would have been obvious to a POSITA to incorporate an anchoring member in the form of a post to be 15mm in length, as such a length would have simply been combining prior art elements according to known methods to yield predictable result. (*Id.* at 106, ¶227.)

Further, for reasons similar to those described above in Section (VI)(B)(2)(k), it would have been obvious to make the central post of Lefebvre and/or Lefebvre as

modified by Hopkins and Perego, to include a lengths of limitation[8-1] as a matter of design choice.

Further, Orphanos teaches that a central post **314** can have a length approximately within the range of about 5mm-30mm. (EX-1006 at 26, 9:56-59). Therefore, Orphanos also discloses the limitation of claim 8. It would have been obvious to modify the central post of Lefebvre to include the central post length(s) disclosed in Orphanos, as such a modification would have been a simple substitution of one known element for another to obtain predictable results. (EX-1002 at 105-06, ¶225.)

10. Claim 19

For the reasons discussed, Lefebvre, Orphanos, Hopkins, Perego, and Roche disclose limitations [12-PRE]-[12-8]. (*See* Sections VI(C)(1)(a)-(f),(h)-(i),VI(C)(3)(a).) Additionally, for reasons discussed, Lefebvre, Orphanos, Hopkins, Perego, and Roche in view of Gargac discloses limitation[19-1]. (*See* Section VI(D)(1)(a).)

E. GROUND 5: CLAIMS 1-22 ARE UNPATENTABLE BECAUSE THE TERM "BASEPLATE CENTRAL CHANNEL" RENDERS THE CLAIMS INDEFINITE

Patents are required to "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). This is known as the

definiteness requirement, and a claim that does not satisfy this requirement is invalid for being indefinite. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 902 (2014) ("A lack of definiteness renders invalid 'the patent or any claim in suit.'" (citing 35 U.S.C. § 282)). "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id.* at 901.

Each of the Challenged Claims is indefinite because both independent claims, i.e., claims 1 and 12, include claim terms that fail the definiteness requirement of § 112 with respect to the "baseplate central channel" limitation.⁹ (EX-1001 at 30, 9:38-43, 10:27-31; EX-1002 at 109, ¶241.) Moreover, because each of the dependent claims is understood to incorporate all the limitations of the claims from which they depend (*see* 35 U.S.C. § 112(d)), the dependent claims also contain the offending "baseplate central channel" limitation. (EX-1002 at 108, ¶234.)

⁹ The "baseplate central channel" claim term to which this ground is directed is distinguishable from the "central channel" of the glenosphere. *Compare* "a base plate configured to be secured to a glenoid of a scapular bone of [a] patient, the baseplate having a lateral end, a medial end, and a baseplate central channel extending therethrough," *with* "a glenosphere, having a lateral, convex articular side, a medial side, and a glenosphere central channel extending from the convex articular side to the medial side," as recited in claim 1, or "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," as recited in claim 12. ('254 Patent, 9:37-64, 10:27-50, EX-1001 at 30.)

Claims 1 and 12 both recite as a limitation of the baseplate "a baseplate central channel extending therethrough from the lateral end to the medial end." (EX-1001 at 30, 9:38-43, 10:27-31; EX-1002 at 108, ¶233.) Both claims also recite that "a central post sized to at least partially pass through the central channel" (EX-1001 at 30, 9:44-45, 10:32-33). These limitations create an understanding to a POSITA that the "baseplate central channel" is an empty space or passageway through which the central post may at least partially pass. (EX-1002 at 109, ¶242.)

When describing the "locking nut" limitation, however, both claims 1 and 12 refer to the "baseplate central channel" limitation in terms of having physical structure. (*Id.* at 109-10, ¶243; EX-1001 at 30, 9:50-53, 10:39-41.) For instance, as recited in Claim 1, "a locking nut [has]...an external thread on an outside surface of the locking nut...wherein the external thread is configured ***to couple the locking nut with the baseplate central channel.***" (EX-1001 at 30, 9:46-53.) Although claim 12 recites the relationship between the locking nut and baseplate central channel slightly differently, it still describes the central channel in a way that suggests it has physical structure, by reciting 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 baseplate central channel.***" (*Id.*, 10:34-41.) A POSITA would understand that, to "couple" and "engage" with the baseplate central channel, the channel must have some physical structure with which to couple or engage. (EX-

1002 at 109-10, ¶243.)

Rather than clarify, the specification further complicates matters. In the context of Figure 8, which depicts an embodiment recited in claims 1-22, the specification states that a "post of the glenosphere can be placed *at least partially within a central channel of the baseplate* as illustrated," which, again, suggests that the "baseplate central channel" is an empty space or passageway. (*Id.* at 108-09, ¶238; EX-1001 at 28, 6:44-46.) Immediately thereafter, however, 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[.]" which, again, implies that the central channel is a physical structure, rather than empty space, that can be connected with or removably attached to. (6:46-49, EX-1001 at 28, 6:46-49; EX-1002 at 109, ¶239.)¹⁰

The scope of the "baseplate central channel" is not reasonably certain to a POSITA. (EX-1002 at 109, ¶241.) The claimed "central channel" cannot at once be both an empty space allowing passage of the central post or glenosphere stem, on one hand, and a physical structure to which the locking nut can be coupled or engaged with, on the other hand. (*Id.*) Even if such duality were possible, the '254 Patent fails to describe the "baseplate central channel" in terms that clearly delineate

¹⁰ The prosecution history provides no guidance here. As noted above, the examiner did not issue any office actions prior to allowance. (EX-1004, EX-1005.)

its boundaries and describe its scope in a manner that is reasonably clear. (*Id.* at 110, ¶246.)

In sum, the use of "baseplate central channel" with respect to the purported invention claimed in the '254 Patent is indefinite because a POSITA, reading the claims in light of the specification, could not determine the scope of the "baseplate central channel" with reasonable certainty. (EX-1002 at 110, ¶246.) Each of the Challenged Claims, therefore, is unpatentable as indefinite. (*Id.*)

F. GROUND 6: CLAIMS 1-22 ARE UNPATENTABLE BECAUSE THE TERM "CENTRAL CHANNEL...CONFIGURED TO INTERFACE WITH THE BASEPLATE" RENDERS THE CLAIMS INDEFINITE

Unlike the "baseplate central channel," the "central channel" of the glenosphere is claimed only as an empty space or passageway. (EX-1002 at 112, ¶253.) Claim 1 recites a "glenosphere, having a lateral, convex articular side, a medial side, and a glenosphere central channel extending from the convex articular side to the medial side and configured to interface with the baseplate." (EX-1001 at 30, 9:54-57.) Claim 12 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." (EX-1001 at 30, 9:42-45.) In addition, both independent claims recite "a glenosphere screw, sized to pass at least partially within the glenosphere central channel." (EX-1001 at 30, 9:58-

59, 10:45-47.) Based on the claims, a POSITA would understand the "central channel" of the glenosphere to be a passageway through which the glenosphere screw can at least partially pass. (EX-1002 at 111-12, ¶¶252-53.)

To be sure, the specification describes physical features of the glenosphere "central channel." (EX-1001 at 28, 6:36-44.) According to the specification, for example, the glenosphere "central channel" can include a rotational control feature and threaded surfaces. (*Id.*) But a POSITA would understand that those physical features are not recited in claims 1-22. (EX-1002 at 112, ¶253.)¹¹

In this respect, a POSITA would not be able to determine with reasonable certainty the scope of the claim language that calls for "a glenosphere central channel," as recited in claim 1, or the "central channel" of the glenosphere, as recited in claim 12, to be "***configured to interface with the baseplate.***" (*Id.*, ¶254.) Here, the problematic language is "to interface," which is ambiguous on its face. Based on the understanding of the term "interface" (*see, e.g.,* EX-1017) applied in the context of the patent, a POSITA may interpret "to interface" in a variety of ways, ranging from, for example, "to connect by means of an interface" to "serving as an interface" to "interacting or coordinating harmoniously." (EX-1002 at 112, ¶255.)

But each, if adopted, would provide a different understanding of the scope of

¹¹ Again, the prosecution history provides no guidance here—the examiner did not issue any office actions prior to allowance. (EX-1004;EX-1005)

the claim to a POSITA. (*Id.*)

Figure 8 and the description of the purported invention relative to Figure 8 fail to resolve the ambiguity of the claim language. (EX-1002 at 112-113, ¶256.) Although Figure 8 purports to depict the embodiment for claims 1-22, the specification also makes clear that Figure 8 is just an example. (EX-1001 at 30, 6:34-36("FIG 8 illustrates a schematic cross-section of a fully assembled glenosphere with a locking bolt, according to some embodiments[.]"); *id.* at 26, 2:63-65 (same).) In this respect, Figure 8 may depict an example of a configuration the inventor intended to illustrate the "configured to interface" 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." (EX-1002 at 112-13, ¶256.)

Moreover, the term "to interface" as used in the phrase a "glenosphere central channel...configured to interface with the baseplate" is undefined within the specification or prosecution history. (*Id.* at 113, ¶¶257-59.) There are only two instances of the term "interface" in the specification:

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." (EX-1001 at 27, 4:56-59.)

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.* at 28, 5:1-2.)

Neither of these instances, however, is a reference to the embodiment for claims 1-22. Nor does either instance discuss the relationship between the "central channel" of the glenosphere and the baseplate. (EX-1002 at 113, ¶258.) 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, again, is claimed as an empty space or passageway in the Challenged Claims—to be "configured to interface"—which is an adjective—with the baseplate. (*Id.*)

Finally, the prosecution history provides no guidance, and "interface" is not a term of art with a widely understood meaning in the technical field of the purported invention. (*Id.*, ¶259.)

For these reasons, a POSITA, reading the claim language "glenosphere central channel...configured to interface with the baseplate" in light of the specification and prosecution history, could not determine the scope of the claim with reasonable certainty. (*Id.* at 113-14, ¶260.) Each of the Challenged Claims, therefore, is unpatentable as indefinite.

VII. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 314(A) AND 35 U.S.C. § 325(D) IS NOT WARRANTED

A. THE *FINTIV* FACTORS WEIGH IN FAVOR OF INSTITUTION

Discretionary denial under § 314(a) may be determined upon consideration of the following factors related to events in a co-pending district court litigation concerning the same patent challenged in a petition for PGR: (1) whether the court granted a stay or evidence exists to suggest that a stay may be granted if a proceeding is instituted; (2) the proximity of the trial court's trial date to the Board's projected statutory deadline for a final written decision; (3) investment in the parallel proceeding by the court and the parties; (4) overlap between issues raised in the petition and in the parallel proceeding; (5) whether the petitioner and the defendant in the parallel proceeding are the same party; and (6) other circumstances that impact the Board's exercise of discretion, including the merits. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, at 7-8 (PTAB March 20, 2020) (precedential) (citing *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper, at 20 (PTAB Sept. 12, 2018) (precedential)).

Here, the factors above weigh against discretionary denial. For example, although no definitive evidence exists regarding whether the presiding judge in the Lawsuit would grant a stay, evidence collected from Docket Navigator indicates that Judge McCalla has been willing to stay cases pending resolution of PTAB

proceedings in the past. (EX-1015.)¹²

Also, based on an amended scheduling order entered by the Court in the Lawsuit, no trial date is set. The Court may adjust the schedule after the *Markman* hearing upon issuance of the Court's claim construction order. (EX-1016.) In other words, at this time, there is no way to determine whether this proceeding, if instituted, would conclude before or after trial in the co-pending Lawsuit.¹³

Moreover, at this time, neither the parties nor the Court in the co-pending Lawsuit have invested considerable time and resources as discovery has just begun, and the Court has yet to issue any rulings on the merits. Even at the expected time of institution, the Court will not have conducted a *Markman* hearing (scheduled for February 2025) or held a hearing on dispositive motions (scheduled for November 2025), and the parties will likely still be engaged in fact discovery while expert discovery will still be months away.

¹² EX-1015 shows decisions issued by Judge McCalla on motions for stay pending completion of USPTO proceedings such as reexaminations, covered business method, and *inter partes* review since 2009, as reported by Docket Navigator when searched by counsel for the Petitioner on June 24, 2024.

¹³ The claim construction proceedings in the co-pending Lawsuit involve a patent Petitioner has asserted against Patent Owner and, therefore, are not relevant to this proceeding in substance.

In the co-pending Lawsuit, Patent Owner alleges that Petitioner infringes claims 1-6, 10, 12-17, and 21 of the '254 Patent and Petitioner alleges that each of those claims is invalid. Here, Petitioner has challenged every claim of the '254 Patent in this petition and Petitioner will be subject to the estoppel provision of 35 U.S.C. § 325(e)(2), which bars Petitioner from raising in the co-pending Lawsuit any invalidity argument it did or could have raised in this proceeding. Accordingly, there exists both an identity of parties and a significant overlap in issues between this proceeding, if instituted, and the co-pending Lawsuit.

All told, the factors above weigh against discretionary denial under § 314(a) and in favor of institution.

B. THE *ADVANCED BIONICS* FRAMEWORK WEIGHS IN FAVOR OF INSTITUTION

With respect to its discretion under 35 U.S.C. § 325(d), "the Board uses the following two-part framework: (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims." *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential).

None of the specific prior art references or arguments presented in this petition were before the examiner during the original examination of the application that issued as the '254 Patent. EP 3598957, which is on the list of references cited for the '254 Patent, appears to be related to Orphanos and U.S. Pat. 8,870,962, which is also on the list of references cited for the '254 Patent, appears to be related to Roche. But "mere prior citation of prior art in an IDS will not automatically satisfy the first prong of the analytical framework set for in *Advanced Bionics*." *JUUL, Inc. v. NJOY, LLC*, IPR2024-00160, Paper 10, at 10-11 (PTAB May 24, 2024). Patent Owner cannot argue that either the EP 359857 or the '962 Patent was materially addressed during the original examination where the examiner neither issued any office actions applying prior art to the pending claims nor otherwise articulated any consideration of the prior art of the record of the application. (EX-1004;EX-1005.)¹⁴

In sum, discretionary denial under § 325(d) is not warranted and, therefore, institution is favored.

¹⁴ A proposed rule documented in an April 19, 2024 Notice of Proposed Rulemaking, if adopted, would provide that § 325(d) is not applicable to prior art references that were not "meaningfully addressed" during examination, which is defined as situations "where the Office has evaluated the art or arguments and articulated its consideration of the art or arguments in the record of the application...." 89 Fed. Reg. 28693, 28700, 28705, 28706 (Apr. 19, 2024); *see JUUL, supra*, at 10-11.

VIII. CONCLUSION

For the foregoing reasons, Petitioner requests that the Board institute post-grant review and find the Challenged Claims unpatentable.

Dated: October, 11, 2024

/ Paul M. Ulrich/

Paul M. Ulrich (Reg. No. 46,404)
Frost Brown Todd LLP
Attorney for Petitioner

CERTIFICATE OF WORD COUNT (37 C.F.R. §§ 42.24(D))

The undersigned hereby certifies that, according to the word-processing system used to prepare the foregoing document, this document has **TK** words, exclusive of the table of contents, table of authorities, mandatory notices under § 42.8, certificates of service and word count, or appendix of exhibits or claim listing, and thus complies with the applicable word limit.

Dated: October 11, 2024

/ Paul M. Ulrich/

Paul M. Ulrich (Reg. No. 46,404)
Frost Brown Todd LLP
Attorney for Petitioner

CERTIFICATE OF SERVICE (37 C.F.R. §§ 42.6(E), 42.105(A))

The undersigned certifies that a true and complete copy of this petition for post-grant review (including exhibits) was provided via Federal Express to the Patent Owner by serving the following correspondence address of record for the '254 Patent:

Knobbe Martens Olson & Bear LLP
2040 Main Street, Fourteenth Floor
Irvine, CA 92614

A courtesy copy of this petition for post-grant review (including exhibits) was also sent to Patent Owner's below counsel of record for *Shoulder Innovations, Inc. v. Catalyst OrthoScience Inc.*, C.A. No. 24-00266-JPM (D. Del.) via electronic mail:

Karen Elizabeth Keller, Esq.
Nathan R. Hoeschen, Esq.
Emily DiBenedetto, Esq.
Lindsey M. Gellar, Esq.
Shaw Keller LLP
1105 North Market Street, 12th Floor
Wilmington, DE 19801
Email: kkeller@shawkeller.com
nhoeschen@shawkeller.com
edibenedetto@shawkeller.com
lgellar@shawkeller.com

Jon W. Gurka, Esq.
Crowell & Moring LLP
3 Park Plaza, Suite 20
Irvine, Ca 92614
jgurka@crowell.com

Andrew McElligott, Esq.
Ryan Fitzgerald, Esq.
Crowell & Moring LLP
455 N. Cityfront Plaza Drive
Chicago, IL 60611
amcelligott@crowell.com
rfitzgerald@crowell.com

Dated: October 11, 2024

/ Paul M. Ulrich/

Paul M. Ulrich (Reg. No. 46,404)
Frost Brown Todd LLP
Attorney for Petitioner