

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CATALYST ORTHOSCIENCE INC.,
Petitioner,

v.

SHOULDER INNOVATIONS, INC.,
Patent Owner.

Case PGR2024-00042
Patent 11,771,561

**PETITIONER'S REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE¹**

¹ The Board authorized this reply by email on October 22, 2024 (EX-1021).

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TABLE OF EXHIBITS

EX. NO.	DESCRIPTION
EX-1001	U.S. Patent No. 11,771,561 ("the '561 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. 11,771,561 (Part I)
EX-1005	Prosecution History of U.S. Patent No. 11,771,561 (Part II)
EX-1006	U.S. Patent No. 10,813,769 ("Orphanos")
EX-1007	U.S. Patent No. 9,233,003 ("Roche")
EX-1008	U.S. Pat. Pub. No. 2022/0125594 ("Frankle")
EX-1009	U.S. Patent No. 11,439,513 ("Lefebvre")
EX-1010	U.S. Patent No. 11,596,520 ("Perego")
EX-1011	U.S. Pat. Pub. No. 2018/0008350 ("Varadarajan")
EX-1012	U.S. Pat. Pub. No. 2020/0368032 ("Hodorek")
EX-1013	U.S. Patent No. 5,429,268 ("Hale")
EX-1014	Key of Limitations for Challenged Claims
EX-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. 19
EX-1017	Webster's Ninth New Collegiate Dictionary (1987)
EX-1018	Grainger Catalog
EX-1019	-
EX-1020	-
EX-1021	Email from the Board, dated October 22, 2024, authorizing Petitioner to file a reply to Patent Owner's preliminary response
EX-1022	PCT/FR/2018/052996 ("the '996 PCT"), as filed November 27, 2018, in French
EX-1023	Certified English Translation of PCT/FR/2018/052996

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Reply to Patent Owner's Preliminary Response

EX. NO.	DESCRIPTION
EX-1024	PCT/US2020/015199 ("the '199 PCT"), filed January 27, 2020
EX-1025	U.S. Provisional Application No. 62/797,866 ("the '866 Provisional"), filed January 28, 2019
EX-1026	Shoulder Innovations, Inc. v. Catalyst OrthoScience Inc., C.A. No. 24-266-JMP (D. Del.), [Proposed] Amended Scheduling Order, D.I. 49, filed August 10, 2024
EX-1027	Shoulder Innovations, Inc. v. Catalyst OrthoScience Inc., C.A. No. 24-266-JMP (D. Del.), Scheduling Order, D.I. 51, entered August 14, 2024

KEY OF LIMITATIONS FOR CHALLENGED CLAIMS²

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

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

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

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

The Board authorized this reply to address: "(1) the trial date in the parallel district court litigation; and (2) the effective filing dates of the Lefebvre and Frankle references." (EX-1021.) Petitioner addresses the second issue first below.

I. LEFEBVRE AND FRANKLE ARE PRIOR ART

Patent Owner alleges that Lefebvre (EX-1009) and Frankle (EX-1008) are not prior art to the Challenged Claims of the '561 Patent because, according to Patent Owner, the Challenged Claims are entitled either to the March 11, 2020 filing date of PCT/US2020/022094 (Paper 7 at 5-7) or the March 11, 2019 filing date of provisional application No. 62/816,708 ("the '708 Provisional") (*id.* at 7, n.4). Patent Owner fails to demonstrate that the '708 Provisional contains written description support for the limitations of the Challenged Claims, neither introducing the '708 Provisional on the record nor matching the limitations of the Challenged Claims to the disclosure of the '708 Provisional to show § 112 support. *Penumbra, Inc. v. RapidPulse, Inc.*, IPR2021-01466, Paper 34, at 18 (PTAB March 10, 2023) ("[F]or a patent's claims to be entitled to an earlier priority date, the patentee must demonstrate that the claims meet the requirements of 35 U.S.C. § 120,' which include fulfilling the requirements of § 112.") (citing, among others, *In re NTP, Inc.*, 654 F.3d 1268, 1276-77 (Fed. Cir. 2011)); *see also id.* (citing *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378-80 (Fed. Cir. 2015) (discussing the parties' shifting burdens for showing priority)).

Regardless, the earliest effective filing dates to which both Lefebvre and Frankle are entitled, respectively, predate the March 11, 2019 filing date of the '708 Provisional. For prior art priority determinations under AIA § 102, "there is no need to evaluate whether any claim of [a reference] patent document is *actually entitled to priority* or benefit under 35 U.S.C. 119, 120 ... [r]ather, under the AIA, a reference patent document need only meet the 'ministerial requirements' of §§ 119 and 120, and the provisional or other earlier application(s) to which the reference patent document claims a right of priority must 'describe[] the subject matter' relied upon in the reference patent document as prior art. 35 U.S.C. § 102(d)(2)." *Penumbra, supra*, at 32 (emphasis in original) (citations omitted) (Section II.E.3, precedential).

Lefebvre claims benefit to PCT/FR/2018/052996, which was filed November 27, 2018, before the March 11, 2019 filing date of the '708 Provisional. (EX-1009 at 1.) The '996 PCT was filed in French (EX-1022). Because Lefebvre was co-pending with the '996 PCT and shares at least one common inventor with the '996 PCT (*compare* EX-1009 with EX-1022), it meets the ministerial requirements of 35 U.S.C. § 120. And as demonstrated by a translation (EX-1023), the '996 PCT describes the subject matter Petitioner relies on from Lefebvre in the Petition. Table 1 below provides where in the Petition reliance on Lefebvre may be found, the portions of Lefebvre on which Petitioner relies, and the corresponding portions of the '996 PCT that describe the subject matter relied on from Lefebvre.

Table 1

Where Petition Cites Lefebvre (Paper 1)	Portions of Lefebvre relied on (EX-1009)	Corresponding Portions of '996 PCT (EX-1023)
6, 58, 60, 61, 62, 63, 64, 65, 66, 73, 74, 76, 78, 79, 82	FIGS 6, 11, 14-16, 18-23	19, 20, 22, 23, 24, 25, 26
60	Abstract	16:3-13
57, 84	2:34-36	2:18-20
58, 59, 61	6:20-24	6:32-34
63	6:26-31	6:35-7:4
63	6:44-48	7:13-15
59, 62	6:65-7:3	7:29-32
59, 64, 65, 66, 68, 74, 80	7:4-36	7:33-8:19
66, 68, 79, 82	7:45-56	8:25-32
59, 62, 75, 78, 81	8:15-44	9:16-10:3
59, 77	9:1-10	10:20-26
77	9:27-35	11:2-7
59, 77	9:48-57	11:17-23

Because the ministerial requirements of § 120 are satisfied and the '996 PCT describes the subject matter of Lefebvre that Petitioner relied on, Lefebvre is entitled to a November 27, 2018 effective filing date.

Frankle claims benefit to PCT/US2020/015199 (EX-1024), filed on January 27, 2020, which claims benefit to provisional application 62/797,866 (EX-1025), filed on January 28, 2019, before the March 11, 2019 filing date of the '708 Provisional. (EX-1008.) Frankle was co-pending with the '199 PCT, which

was previously co-pending with the '866 Provisional. Frankle also shares at least one common inventor with the '199 PCT and the '866 Provisional. (*Compare* EX-1008 *with* EX-1024 *and* EX-1025.) Therefore, Frankle meets the ministerial requirements of 35 U.S.C. §§ 119 and 120. And, as shown in Table 2 below, the portions of Frankle relied on in the Petition are described in both the '199 PCT and the '866 Provisional.

Table 2

Where Petition Cites Frankle (Paper 1)	Portions of Frankle relied on (EX-1008)	Corresponding Portions of '199 PCT (EX-1024)	Corresponding Portions of '866 Provisional (EX-1025)
55	Title	Title	Title
55, 56, 83	FIGS 58 and 96	FIGS 58 and 96	FIGS 55 and 96
55	¶ [0002]	¶ [0002]	¶ [0001]
57, 83	¶ [0244]	¶ [0244]	¶ [0199]

Because Frankle satisfies the ministerial requirements of §§ 119 and 120—and both the '199 PCT and the '866 Provisional describe the subject matter of Frankle relied upon by Petitioner—Frankle is entitled to an effective filing date of January 28, 2019.

Thus, both the Lefebvre reference (EX-1009) and the Frankle reference (EX-1008) are prior art to the alleged invention of the '561 Patent.

II. THE TRIAL DATE IS UNCERTAIN

When Petitioner filed its petition on July 3, 2024, the district court presiding over the co-pending litigation had already entered a scheduling order wherein the

trial was scheduled to begin on March 9, 2026 (EX-1016 at 17), *after* the statutory deadline for an expected final written decision to issue for this post-grant review. Subsequently, the district court held a conference during which, among other things, adjusting dates in the schedule was discussed. Patent Owner stated in its preliminary response that the "district court judge has expressed interest in compressing the current schedule and moving the trial date earlier." (Paper 7 at 14, n.7.)

The parties, however, addressed the practicalities and implications of moving the trial date earlier in a joint submission to the district court on August 10, 2024 (EX-1026). Although Patent Owner baldly alleged its support for an earlier trial date, Petitioner demonstrated with documentary evidence of the pretrial schedule from another patent infringement case that moving the trial date earlier was impractical and only supported by Patent Owner as a tactic to avoid post-grant review. On August 14, 2024, the district court entered an amended scheduling order (that Petitioner did not include with its September 30, 2024 preliminary response) (EX-1027) that vacated the schedule post-*Markman* and contemplates adjusting the trial date after the *Markman* order is issued, which would include, based on Petitioner's portion of the joint submission, moving the trial date later than originally scheduled.

III. CONCLUSION

Based on the petition and this reply, Petitioner respectfully requests the Board grant the petition and institute post-grant review of the '561 Patent.

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Dated: October 30, 2024

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

Pursuant to 37 C.F.R. § 42.6(e)(4), the undersigned certifies that a copy of the foregoing PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE and its accompanying exhibits have been served via electronic mail upon the following counsel of record for Patent Owner:

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