UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EMBODY, INC. AND ZIMMER BIOMET HOLDINGS, INC.,
Petitioners

v.

LIFENET HEALTH,
Patent Owner.

Case IPR2025-00248
U.S. Patent No. 10,137,223

SUR-REPLY TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

Filed on behalf of Petitioners:

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Petitioners herein submit this authorized Sur-Reply in response to Patent Owner's request for discretionary denial under 35 U.S.C. § 325(d). Because the prior art cited in the Petition is *not* cumulative of the art considered during prosecution, discretionary denial under § 325(d) is not warranted.

I. PATENT OWNER'S NEW MERIT BASED ARGUMENT IS IMPROPER AND DOES NOT JUSTIFY DISCRETIONARY DENIAL

Patent Owner's argument in support of discretionary denial under § 325(d) is both procedurally improper and substantively flawed. For the first time—in its Reply—Patent Owner asserts that the prior art cited in the Petition is cumulative because it purportedly fails to disclose collagen fibers with the FFT peaks recited in the claims and is therefore similar to the art considered during prosecution. (Reply, 1–2.) This new argument was *not* raised in Patent Owner's opening brief and should be disregarded as untimely. Even if considered, however, the argument fails on its face because it assumes the correctness of Patent Owner's position without any substantive analysis. Whether the newly cited prior art discloses the claimed features is a merits-based determination that can only be resolved through institution and trial. Until such evaluation occurs, the art cannot properly be deemed cumulative. In fact, Patent Owner's argument underscores why institution is appropriate as it confirms that a substantive review is necessary. At a minimum, it shows that discretionary denial under § 325(d) is premature and unsupported.

II. THE PETITION'S PRIOR ART SHOWS COLLAGEN FIBERS WITH THE CLAIMED FFT PEAKS

Contrary to Patent Owner's assertions (Reply, 3), newly cited references Huang2 and Lee, disclose collagen fibers meeting all the elements of the '223 patent claims. (*See* Opp., 11-17.) During prosecution, Patent Owner argued the prior art lacked aligned collagen fibers with FFT peaks 180° apart and that there was no reasonable expectation of success in achieving such alignment. (EX1002, 238–39.) But the claims only require demonstration of alignment via FFT—i.e. two adjacent major peaks that are 180° apart—and does not call for specific peak positions. Huang2 shows this—it shows FFT results indicating that the collagen fibers are aligned and have the requisite two peaks 180° apart. (Pet., §§ IX.A, X.A.3; EX1003, §§ V.A, VI.A.1.c.) Lee discloses equivalent analytical methods confirming similar alignment. (Pet., §§ IX.C, XII.A.3; EX1003, §§ V.C, VI.C.1.c.) This non-cumulative art was not before the Examiner and discloses aligned collagen fibers with the claimed FFT peaks—rendering the claims unpatentable.

Patent Owner's new assertion (Reply, 2) that Huang2 lacks the claimed two peaks is incorrect. As shown in the Petition (Pet., §§ IX.A, X.A.3; EX1003, §§ V.A, VI.A.1.c), a POSA clearly would have understood that Huang2's FFT image of aligned collagen fibers exhibits the required two peaks. It was well-established that FFTs produce symmetrical peaks; a peak at X implies a second peak at X + 180°, as confirmed by the Ayres paper (EX1010), which is incorporated by

reference “in its entirety” in the ’223 patent (EX1001, 13:16–26; EX1010, 609). Patent Owner cannot contradict the admissions in its own patent. *See PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007).

Dr. Simpson’s analysis of Huang2 Fig. 1.B independently confirms the presence of two FFT peaks. (EX1003, § VI.A.1.c; EX1005, 1793.) His expert assessment reflects how a POSA would have interpreted the data—he is not supplying “missing” claim elements, as Patent Owner incorrectly asserts in its Reply at 3-5. In fact, the Federal Circuit in *Sage Prods. v. Stewart*, 133 F.4th 1376, 1384-85 (Fed. Cir. 2025), recently reaffirmed that it is proper to use expert testimony to show how a POSA would have understood an anticipatory reference. Contrary to Patent Owner’s assertion (Reply, 4), *Sage* is not an “inherency” case.

The Petition provides detailed expert analysis and evidence, meeting Petitioner’s burden to institute the IPR. In contrast, Patent Owner relies solely on unsupported attorney argument, which is not evidence and should be disregarded. *See Elbit Sys. of Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1359 (Fed. Cir. 2018); *KEYnetik, Inc. v. Samsung Elecs. Co., Ltd.*, No. 2022-1127, 2023 WL 2003932, at *2 (Fed. Cir. Feb. 15, 2023).

Lee also prepared aligned collagen fibers and verified their alignment using three different methods, which Patent Owner admits. (Reply, 3 n.1; POPR, 11, 43–44.). Although Lee did not perform an FFT, applying that test was well within a

POSA's routine skill. (Pet., 65–66; EX1003, ¶ 243.) Dr. Simpson confirmed that the image of the fibers in Lee (Fig. 1D) exhibits the same FFT peaks recited in the claims. (Pet., 49–53, 65–66; EX1003, ¶¶ 188–190, 244–245.) Patent Owner has not shown—and cannot show—that any alleged issues with Dr. Simpson's method would alter the result, which demonstrates two FFT peaks.

Alternatively, the Petition argues that applying FFT to Lee would have been obvious, as FFT was a well-established, straightforward method at the time. (Pet., § XIII; EX1003, ¶¶ 241–43.) Ayres (EX1010), published years before the '223 patent, confirms that FFT was within a POSA's skill set. (EX1003, ¶ 243.) A POSA would have been motivated to use FFT to confirm alignment, and Dr. Simpson showed that doing so yields the claimed peaks, supporting a reasonable expectation of success. (Pet., § XIII; EX1003, ¶¶ 244–45.) Patent Owner responds with unsupported attorney argument, which cannot rebut such expert analysis for the reasons set forth above.

Accordingly, Huang2 and Lee are not cumulative of the art before the Examiner. Unlike Huang1 and Simpson, they disclose actual collagen fibers with the claimed FFT peaks—the very feature Patent Owner argued was missing to distinguish those references. (*See* Opp., 8-11, 20–23.) This is the epitome of art that is not cumulative. *See Belcher Pharms., LLC v. Hospira, Inc.*, 11 F.4th 1345, 1352–53 (Fed. Cir. 2021) (rejecting "argument that the withheld art . . . is

'cumulative'" because the patent owner's current "argument is directly at odds with its argument during prosecution"); (Opp., § III.A.)

III. MATERIAL ERROR ANALYSIS IS UNNECESSARY

Because the references are not cumulative, no material error analysis is required—as admitted by Patent Owner. (Reply, 2–3); *see* A*dvanced Bionics, LLC v. MED-EL*, IPR2019-01469, Paper 6, at 8–9 (P.T.A.B. Feb. 13, 2020) (precedential). Further, Patent Owner's reliance on *Ecto World, LLC v. RAI Strategic Holdings*, Inc., IPR2024-01280, Paper 13 (P.T.A.B. May, 19, 2025), is misplaced. That case addressed art cited in an IDS during prosecution (*Ecto World*, Paper 13, at 5)—a fact not present here, as neither Huang2 nor Lee was before the Examiner. *Ecto World* is thus irrelevant.

Further, as mentioned above, Patent Owner has improperly argued for the first time in its Reply that neither Huang2 nor Lee have the claimed FFT peaks. As set forth above, this is not the case, as confirmed by Dr. Simpson's analysis. In sum, the Petition has strong merits, relies on non-cumulative, new art, and the Examiner did not substantively consider the newly cited references. These factors strongly favor institution. Patent Owner's request for discretionary denial under § 325(d) should be denied and institution granted.

Dated: June 13, 2025

Respectfully submitted,

By: /Howard Levine/
Howard Levine (Reg. No. 41,453)

CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that the foregoing **Sur-Reply to Patent Owner's Request for Discretionary Denial** contains 1181 words, as measured by the word-processing system used to prepare this paper.

Dated: June 13, 2026

By: /Howard Levine/
Howard Levine (Reg. No. 41,453)

CERTIFICATE OF SERVICE

I hereby certify that on June 13, 2025, I caused a true and correct copy of the forgoing Sur-Reply to Patent Owner's Request for Discretionary Denial to be served via electronic upon to the Patent Owner's counsel of record at the following addresses:

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