

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 IPR2025-00249
U.S. Patent No. 11,318,227

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

Filed on behalf of Petitioners:

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35 U.S.C. § 325(d)	1, 2, 5
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Petitioners submit this authorized Sur-Reply in response to Patent Owner's request for discretionary denial under 35 U.S.C. § 325(d). Because neither the prior art cited, nor the arguments raised, in the Petition are cumulative of what was considered during prosecution, discretionary denial is not warranted.

I. *ECTO WORLD DOES NOT APPLY*

Patent Owner cites *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13, (P.T.A.B. May, 19, 2025) to argue it is irrelevant that the Examiner didn't explicitly consider Simpson or Patel as to the issued claims of the '227 patent. (Reply, 1.) But *Ecto* is inapposite as it involved art cited in an IDS, where the Board assumed the Examiner considered the references despite no discussion. *Ecto World*, Paper 13, at 3. That is not the case here.

Here, the Examiner explicitly relied on Simpson and Patel *only* in rejecting canceled claim 26, which required "anisotropic" fibers. (*See Opp.*, 15-19). This limitation was not recited in claim 25, which issued as claim 1. (*Id.*, 18.) Claim 1 instead recites FFT peaks 180° apart, an element disclosed by the Petition's new art. (*Id.*, 15, 18.) Patent Owner even acknowledged that the rejection based on Simpson and Patel was "moot" upon cancellation of claim 26. (*Id.*, 18-19.)

Thus, this case is governed by decisions like *Bowtech, Inc. v. MCP IP, LLC*, IPR2019-00383, 2019 WL 3714347, at *2 (P.T.A.B. Aug. 6, 2019), where

§ 325(d) did not apply because the art was applied to only canceled claims. Patent Owner fails to address why *Bowtech* does not control.

II. THE PETITION CITES NEW, NON-CUMULATIVE ART NOT CONSIDERED DURING PROSECUTION

Patent Owner claims Simpson and Patel are cumulative of Huang² and Lee (Reply, 2), even though the former merely list collagen as a possible material and did not make collagen fibers—unlike Huang² and Lee, which actually produced collagen fibers with the claimed FFT peaks. (See Opp., 19-26.) Patent Owner also notes in a footnote that Petitioner didn't argue Simpson or Patel lack enablement. (*Id.*, 2 n.1.) But this misses the point entirely.

It was Patent Owner who argued during prosecution that a POSA would not have expected to achieve collagen fibers with the claimed FFT peaks without a specialized collector (e.g., rotating rod-shaped electrodes). (See Opp., 33–34.) Simpson and Patel disclosed no such collector, and Patent Owner does not claim otherwise. These arguments, however, are contradicted by Huang² and Lee, references that prepared collagen fibers with the claimed peaks that did not use the special collector. The references thus specifically contradict the arguments Patent Owner made during prosecution, making them non-cumulative. (See Opp., 34); *Azurity Pharms., Inc. v. Alkem Labs. Ltd.*, 133 F.4th 1359, 1368 (Fed. Cir. 2025); *Regeneron Pharms., Inc. v. Merus N.V.*, 864 F.3d 1343, 1355–56 (Fed. Cir. 2017).)

Patent Owner also argues, without citation, that differences in references

related to claim elements—even those critical to patentability—don’t matter for cumulateness. (Reply, 2.) This defies logic. *See PLR Worldwide Sales Ltd. v. Flip Phone Games, Inc.*, IPR2024-00209, 2024 WL 2106683, at *7 (P.T.A.B. May 10, 2024) (art disclosing an element that was added during prosecution to overcome prior art is not cumulative). Patent Owner also does not dispute that Simpson and Patel disclose neither crosslinking nor the actual preparation of collagen fibers, both of which are required by certain claims.

III. THE PETITION CITED ART THAT DISCLOSES COLLAGEN FIBERS WITH THE CLAIMED FFT PEAKS

Patent Owner improperly first argued in the Reply that Huang2 and Lee lack the claimed FFT peaks. (Reply, 3-4.) As demonstrated above and confirmed by Dr. Simpson’s analysis, this is incorrect. If these references had been before the Examiner, allowing the claims would have been a clear material error, especially given Patent Owner’s earlier prosecution arguments.

Contrary to Patent Owner’s assertions (Reply, 3), Huang2 discloses aligned collagen fibers that have the two FFT peaks recited in the claims. As shown in the Petition (Pet., §§ IX.C, X.A.3; EX1003, §§ V.C, VI.A.1.c; Opp. § III.D.1), a POSA readily would have recognized that Huang2’s FFT image demonstrates two peaks, consistent with established FFT symmetry, i.e., a peak at X implies a second peak at $X + 180^\circ$, as confirmed by the Ayres reference incorporated “in its entirety” into the ’227 patent. (EX1001, 13:38–48; EX1010, 609.) Patent Owner cannot now

contradict the admissions set forth in its own patent. *See PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007).

Dr. Simpson independently confirms these two peaks in Huang² Fig. 1.B. (EX1003, § VI.A.1.c; EX1005, 1793.) His expert interpretation reflects how a POSA would have understood the reference, not a substitution of “missing” elements as Patent Owner wrongly suggests (*see* Reply, 3, 5). 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. And, contrary to Patent Owner’s assertion (Reply, 4), *Sage* is not an “inherency” case.

Further, in contrast to Patent Owner’s attorney argument, which is not evidence, the Petition provides robust analysis and support, including expert analysis, to meet Petitioner’s burden for institution. *See Elbit Sys. of Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1359 (Fed. Cir. 2018) (rejecting attorney argument); *see also KEYnetik, Inc. v. Samsung Elecs. Co., Ltd.*, No. 2022-1127, 2023 WL 2003932, *2 (Fed. Cir. Feb. 15, 2023) (same).

Lee also made collagen fibers and verified alignment by multiple known methods, as Patent Owner admits. (*See* POPR, 43–44.) While Lee did not perform FFT, applying it was routine for a POSA. (Pet., 49–51; EX1003, ¶¶ 181–87.) Dr. Simpson confirmed that Lee’s fiber images, if analyzed by FFT, exhibit the

claimed peaks. (EX1003, ¶¶ 183–85.) Patent Owner fails to show any flaw in this analysis that would affect the result. Alternatively, applying FFT to Lee would have been obvious, as FFT was a standard method published years before the '227 patent. (Pet., § XI.A.3; EX1003, ¶ 187; EX1010.) A POSA would have been motivated to apply FFT to assess fiber alignment, and doing so—as shown by Dr. Simpson—yields the claimed peaks, supporting a reasonable expectation of success. (Opp., 25-26.)

Further, the March 26th memorandum, which was issued prior to the Patent Owner filing its opening brief, stated that strength of the merits is a factor that must be taken into consideration. However, the Patent Owner did not address this factor in its opening brief and instead reserved this argument for its reply brief.

Accordingly, Huang² and Lee are not cumulative of the prior art cited during prosecution. Unlike Simpson and Patel, they disclose actual collagen fibers with the claimed FFT peaks. (*See* Opp., 19-26.) This is precisely the feature Patent Owner argued was missing, which is the epitome of non-cumulative art. (Opp., § III.C.1, 33–35); *Belcher Pharms., LLC v. Hospira, Inc.*, 11 F.4th 1345, 1352–53 (Fed. Cir. 2021). The Petition demonstrates strong merits, relies on non-cumulative new prior art, and shows the Examiner did not substantively consider these references. These factors favor institution, and Patent Owner's request for discretionary denial under § 325(d) should be denied. Institution is warranted.

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 1198 words, as measured by the word-processing system used to prepare this paper.

Dated: June 13, 2025

By: /Howard Levine/
Howard W. 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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