

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.

IPR2025-00248 (Patent 10,137,223 B2)
IPR2025-00249 (Patent 11,318,227 B2)

**PETITIONERS' RESPONSE TO PATENT-OWNER'S
IDENTIFICATION OF ALLEGED NEW EVIDENCE**

Filed on behalf of Petitioners

I. INTRODUCTION

Patent-Owner claims that Petitioners' Reply introduces "new" evidence beyond "the proper scope of reply" and thus should not be considered. Petitioners disagree and, as directed by the Board's February 12, 2026 email, identify which arguments and evidence in Patent-Owner's Response are directly addressed by the alleged new material in their Reply. *See Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1008-10 (Fed. Cir. 2023) ("[Petitioner] may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner") (citation omitted).

II. RESPONSE

A. Allegations of "New" Evidence in IPR2025-00248

1. FFT Testing: EX1219, ¶¶32, 35, 39, 64

In the Patent-Owner Response ("POR"), Patent-Owner, and its expert (Dr. Mikos), raised questions regarding Dr. Simpson's FFT analysis related to Huang² and Lee, addressing issues such as image format and compression, noting that "the image compression used in .JPG format will degrade image integrity." (POR, 28; *see also* EX2015 ¶96.) Patent-Owner further discussed the impact of "optical and electronic noise" on FFT analysis (POR, 28; *see also id.*, 16-18, 44-46; EX2015 ¶¶98, 150-152), and disputed using a mask, asserting that "[i]nclusion or exclusion of a mask *directly* impacts the resulting FFT plot" (POR, 19-21 (emphasis in

original); POR, 47-48; *see also* EX2015, ¶¶81-84, 102, 154-156, 158).

Dr. Simpson responded to these points in ¶¶32, 35, 39, and 64 of his reply declaration (EX1219) through additional testing. For instance, in ¶32, Dr. Simpson responded that his testing “show[s] that JPEG files do not meaningfully degrade an image for FFT testing if opened and closed a reasonable number of times.” In ¶35, Dr. Simpson responded his testing shows that “noise, even large amounts, does not impact whether the FFT can detect alignment.” In ¶39, Dr. Simpson responded that “Huang2 with and without a mask . . . both show the requisite peaks.” In ¶64, Dr. Simpson responded that the image “which has the most noise, still demonstrates two major peaks.” The pages in the Reply cited by Patent-Owner (14-15, 23) rely on this testing and are responsive to Patent-Owner’s arguments as well.

2. Porosity of Aligned Scaffolds: EX1219, ¶55, EX1211-1213

In the POR, Patent-Owner, citing Dr. Mikos, argued that a POSA would not have reasonably expected success in modifying Huang2 with Kumbar’s porosity because Huang2’s porosity would be lower due to several factors, including “due to the aligned fibers present in Huang2’s scaffold.” (POR, 38-39; *see also id.*, 36-39; EX2015, ¶¶130-131, 135, 140.) Dr. Simpson’s reply declaration, at ¶55, and EX1211-1213 respond to these arguments, stating that “the prior art plainly taught aligned scaffolds that have the claimed porosity.” (EX2019, ¶55 (citing EX1211-1213).) Page 19 of the Reply cites to this evidence and is responsive as well.

3. Adjustment of Porosity: EX1219, ¶54, EX1214-1215

In the POR, Patent-Owner, citing Dr. Mikos, argued “A POSITA would not expect to achieve Kumbar’s high porosity levels in Huang2’s scaffold given the notably different electrospinning parameters used in each reference.” (POR, 36; *see also id.*, 36-39; EX2015, ¶¶130-131, 135, 140.) Dr. Simpson’s reply declaration, at ¶54, and EX1214-1215, respond to that argument: “A POSA would have known that routine electrospinning parameters could be changed to alter porosity.” (EX2019, ¶54 (citing EX1214-1215).) Page 19 of the Reply cites to this evidence and is responsive as well.

B. Allegations of “New” Evidence in IPR2025-00249

1. FFT Testing: EX1219, ¶¶32, 35, 39, 75

This is the same evidence cited by Patent-Owner in §II.A.1, *supra*. As set forth above, this evidence directly responds to the corresponding paragraphs of at least EX2015, ¶¶91-94, 105, 107, 112, 164-165, 167-169, 171, (*see generally id.*, ¶¶84-115); and pages of POR, 20-24, 29-30, 49-53. Petitioners’ Reply, at 12 and 25, also cites to this evidence and is responsive.

2. Obviousness in view of Huang2 (or Lee) and Kuo: EX1219, ¶¶44-50, 78-80

In the POR, Patent-Owner argues that differences between Huang2 and Kuo “counsel against their combination,” noting that “Huang2’s scaffold is designed only for skin tissue repair and is seeded with normal human dermal fibroblasts.”

(POR, 32, 36, 37-39; EX2015, ¶¶116 (bullet three), 134-135, 137, 141.) Dr. Simpson responds in ¶¶44-50. For example, in ¶49, Dr. Simpson stated: “Dr. Mikos asserts that one would **only** seed the scaffold made by the techniques of Huang2 with dermal fibroblasts to treat, for example, a tendon injury.” (EX1219, ¶49 (emphasis in original).) Dr. Simpson responded: “I disagree. A POSA combining Huang2 and Kuo would take the flat sheet made by the techniques of Huang2 and, according to Kuo, seed it with the appropriate cells that *correspond* to the tissue injury one would like to treat. Kuo unambiguously teaches that ‘any cells may be employed that are found in the natural tissue to which the *construct is intended to correspond.*’” (*Id.* (emphasis in original) (citing Ex1018, [0058])).

Patent-Owner advanced similar arguments regarding Lee (*see* POR, 60-62; *see also* EX2015, ¶¶183-199), to which Dr. Simpson responded in ¶¶76-81 of EX1219. For example, at ¶78, Dr. Simpson responded that “a POSA would have been motivated to use the scaffold made by Lee of aligned collagen fibers as the first step in the figure 1 schematic of Kuo. Lee’s scaffolds are made without cells (EX1011, [0063]) and cells ‘may’ be added (*id.*, Abstract).” (EX1219, ¶78.) Petitioners’ Reply, at 14-17 (Huang2) and 26 (Lee), also cites to this evidence and is responsive.

The Patent Owner also claims that these paragraphs present “new evidence directed to the alleged obviousness of performing Kuo’s method to create a

scaffold for tendon or ligament repair by using the scaffold of Huang2 or Lee as a starting point in that process.” (PO Ident., 3.) Petitioners thus identify citations from the Petition, and the supporting declaration of Dr. Simpson, where it was argued it was obvious to use Huang2 aligned fibers in the method taught by Kuo for tendon or ligament repair. For example, the Petition states that “a POSA would have been motivated and able to use a scaffold comprising Huang2’s aligned fibers—as shown by FFT analysis—containing collagen, which may be cross-linked, to treat a tendon, ligament, or nerve defect as taught by Kuo.” (Pet., 30; *see also id.*, 32-33 (citing, e.g., EX1018, Abstract & [0022])).) “A POSA would have been motivated to use Huang2’s aligned fibers . . . to fabricate a scaffold to treat a tendon, ligament, or a nerve defect as taught by Kuo.” (*Id.*, 39-40.) “And a POSA would have been able to make and use a scaffold comprising Huang2’s aligned fibers and seeded with various cell types using well-known established methods described in both Huang2 and Kuo” (EX1003, ¶102); *see also id.*, ¶¶97, 130 (citing, e.g., EX1018, Abstract & [0022])).)

III. CONCLUSION

Petitioners oppose Patent-Owner request for leave to file a reply to this paper and further oppose Patent-Owner request to dispute additional evidence in its sur-reply that is not identified in this paper.

Respectfully submitted,

Dated: February 27, 2026

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

CERTIFICATE OF SERVICE

I hereby certify that on February 27, 2026, I caused a true and correct copy of the forgoing Petitioners' Response To Patent-Owner's Identification Of Alleged New Evidence to be served via electronic upon to the Patent-Owner's counsel of record at the following addresses:

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