

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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

v.

LIFENET HEALTH,  
Patent Owner.

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

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**PATENT OWNER'S DISCRETIONARY DENIAL REPLY**  
**37 C.F.R. § 42.20(d)**

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## **I. INTRODUCTION**

Patent Owner submits this authorized Reply in support of its Request for Discretionary Denial (Paper 8, “Req.”). Ex. 3101. Because the asserted prior art is cumulative and Petitioner does not address material error, 35 U.S.C. § 325(d) supports denial. Denial is additionally appropriate in view of the Petition’s weak merits, where Petitioner inappropriately relies on extensive expert testimony to gap-fill a claim limitation *missing* from the prior art.

## **II. DENIAL IS WARRANTED BY 35 U.S.C. § 325(d)**

### **A. The Petition’s Prior Art is Cumulative**

The Petition’s prior art, Huang2 (Ex. 1005) and Lee (Ex. 1011), is cumulative to the art applied during prosecution, Huang1 (Ex. 1008) and Simpson (Ex. 1009), because they present *substantially* the same structure, purpose, and manner of reliance. Req. 16–17, 23–24. Petitioner’s sole point of dispute is that Huang1 and Simpson lack the combination of collagen fibers—added to the claims by amendment—with a FFT analysis result having “adjacent major peaks with about 180° apart from each other.” Paper 10 (“Opp.”) at 20. Petitioner contends that Huang2 and Lee specifically disclose this combination of features and, therefore, the prior art is “substantially different.” *Id.* at 1–2, 17, 22.

Not so. First, the claims recite several elements including, *inter alia*, collagen fibers and a FFT analysis result having “adjacent major peaks with about 180° apart from each other.” The Examiner concluded that Huang1 and Simpson failed to show

these claim elements in combination. Req. 6–9. Similarly, Huang2 and Lee also fail to disclose these claim elements in combination. *Id.* at 11–13 (disclosing collagen but not FFT analysis results with major adjacent peaks 180° apart); *contra* Opp. 20. Indeed, Huang2 discloses a FFT analysis result with only a *single* major peak and Lee does not employ FFT *at all*. *See infra* III; POPR 15–30, 41–49.

Second, the Office considers both *similarities* and differences in determining whether prior art is “substantially the same.” Petitioner identifies no precedent suggesting that *any* difference between references dictates they are non-cumulative when the references are otherwise substantially similar. To the contrary, the Office evaluates relative similarities and differences to determine if art is cumulative. Here, by focusing solely on amendments regarding collagen, the Opposition entirely ignores the extensive similarity in structure, purpose, and manner of reliance set forth in the Request. *See, e.g.*, Req. 13–28.

**B. Denial is Appropriate Because the Art is Cumulative and Petitioner Does Not Allege Material Error**

There is no dispute that § 325(d) dictates a two-part framework where the second part is invoked after the first part is satisfied. Req. 14. If the first part is satisfied, denial is appropriate if “petitioner fails to make a showing of material error” under the second part. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8–9 (PTAB Feb. 13, 2020) (precedential). To make this showing, Petitioner *must address* material error

specifically; it may not rely on its merits arguments to “imply that an error occurred.” *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 5–6 (Stewart May 19, 2025) (precedential § A).

Petitioner did not address material error. Opp. 24–26. Because the art is cumulative, *supra*, and Petitioner did not argue material error, denial is appropriate.

### **III. EXPERT GAP-FILLING IS FATAL TO THE MERITS**

Petitioner’s failure on the merits also warrants denial and begins with its misreading of the claims. According to Petitioner, “[t]he claims hinge on aligned collagen comprising fibers with specified FFT peaks.” Opp. 25. Not so. The claims do not recite “aligned” fibers; they recite a FFT analysis result having “adjacent major peaks with about 180° apart from each other.” Despite arguing anticipation,<sup>1</sup> this limitation is entirely absent from Petitioner’s references: Huang<sup>2</sup> discloses a *single* peak (Ex. 1005, Fig. 1) and Lee does not employ FFT *at all* (Ex. 1011).

To address this deficiency, Petitioner relies on Dr. Simpson. Pet. 29–33, 49–

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<sup>1</sup> Petitioner also fails to show that a person of ordinary skill in the art (“POSITA”) would have modified Lee to confirm alignment with FFT, as Lee already confirms alignment by three distinct mechanisms, and Petitioner identifies no reason to add a *fourth* confirmation mechanism. Paper 9 (“POPR”) at 43–46.

53. But Petitioner may not rely on an expert to supply a missing claim limitation. “The statute and our reviewing court require that petitions be based on prior art patents and printed publications,” not expert testimony attempting to fill gaps in references. FAQs for Interim Processes for PTAB Workload Management, <https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management> at #21; PTAB Consolidated Trial Practice Guide (Nov. 2019) 36 (“[A] petitioner asserting anticipation cannot rely on its expert to supply disclosure of a claim element that is not expressly or inherently present.”); POPR 18–19 (citing case law).

Petitioner cites *Sage Products, LLC v. Stewart*, 133 F.4th 1376, 1385 (Fed. Cir. 2025) to argue that an expert may shed light on what an allegedly anticipatory reference would have meant to a POSITA. Opp. 25–26. But *Sage* concerns inherency and how a POSITA would have understood the term “sterile” in a prior art reference. Here, Petitioner does not clearly allege that this missing limitation is inherent. Pet. 29–33 (no inherency claim regarding Huang2), 49–53 (or Lee); POPR 16–18, 36–37. Moreover, Petitioner’s reliance on expert testimony to supply a claim limitation that is *entirely missing* from the prior art is a far cry from *Sage*’s expert testimony regarding the meaning of “sterile” in a reference. See POPR 16–32, 36–42.

Even *if* Dr. Simpson’s testimony is not determined to be improper gap-filling, (it is), that testimony is insufficient because it is conclusory, unsupported, and

entitled to little weight. 37 C.F.R. § 42.65(a). For example, Dr. Simpson testifies:

the 2D FFT output image is symmetric about the horizontal axis, so a pixel summation to 360° is unnecessary. As a way of further explanation, the fact that the 2D FFT output image is symmetric about the horizontal axis, ensures that the peaks in the 2D FFT alignment plot repeat between 0°–180° and 180°–360°.

Ex. 1003 ¶ 46; POPR 21–23. But far from providing “further explanation” of the purported symmetry upon which his testimony hinges to supply the missing claim limitation, Dr. Simpson simply offers a circular conclusion that points back to itself for support. The evidence cited by Dr. Simpson (his own past papers) likewise simply states that FFT analyses are symmetric, but again without support or explanation. POPR 23–26. Similarly, his testimony regarding post-hac testing violates § 42.65(b) by failing to sufficiently explain how it “was performed and the data was generated.” *Id.* at 26–33 (“I conducted my own analysis ... using the FFT analysis described in Huang<sup>2</sup> and the ’223 patent.”), 38–42.

Petitioner criticizes the POPR for offering “attorney argument” to attack its grounds, Opp. 26, but Petitioner is wrong. It is indisputably *Petitioner’s burden* to present a reasonable likelihood of prevailing to warrant institution. When Petitioner falls short, Patent Owner may identify those shortcomings, with no obligation to offer evidence of its own, and institution may be denied on that basis.

#### **IV. CONCLUSION**

For these reasons, Patent Owner respectfully requests denial of institution.

Dated: June 9, 2025

Respectfully submitted,

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**Certification under 37 C.F.R. § 42.24(d)**

I hereby certify that this Reply, excluding its table of contents, table of authorities, certification under 37 C.F.R. § 42.24(d), and certificate of service, has 1199 words as counted by Microsoft Word, the word-processing system used to prepare this Reply.

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**Certification of Service**

Pursuant to 37 C.F.R. § 42.6, the undersigned certifies that on June 9, 2025, a copy of the foregoing document was served by electronic mail upon the following counsel of record for Petitioner:

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