

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

LIFENET HEALTH,
Patent Owner.

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

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 7, “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 because Petitioner relies upon 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. Petitioner Misstates the Cumulativeness Inquiry

Section 325(d) concerns whether the same or substantially the same prior art or arguments “previously were presented to the Office.” Such prior art need not have been *applied* in a rejection at all, let alone against the challenged claims or claim language. *Contra* Paper 9 (“Opp.”) 28–31; *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 4 (Stewart May 19, 2025) (precedential § A) (inclusion of a reference in an Information Disclosure Statement is sufficient). The inquiry is simply whether it “previously w[as] presented.” Clearly, Simpson (Ex. 2001) and Patel (Ex. 2002) were. Req. 7–9. It is of no moment that rejected claim 26 was later cancelled or that pending claim 25 was not rejected. Opp. 30–31.

B. The Petition’s Prior Art is Cumulative

The Petition’s prior art, Huang2 (Ex. 1005) and Lee (Ex. 1011), is cumulative to Simpson and Patel because they present *substantially* the same structure, purpose, and manner of reliance. Req. 19–24, 26–31. Petitioner argues that Huang2 and Lee

“show the *actual* preparation of fibers comprising *collagen*,” as compared to Simpson and Patel. Opp. 32–35. Although Petitioner acknowledges that Simpson and Patel disclose collagen, *id.* at 33, Petitioner discounts these disclosures as mere “prophetic disclosure[s] [that] cannot be ... cumulative.” *Id.*

Not so. A reference is prior art for all that it teaches. *Beckman Instr. v. LKB Produkter AB*, 892 F.2d 1547, 1550–51 (Fed. Cir. 1989).¹ And Simpson and Patel provide substantial disclosure of using collagen to create electrospun scaffolds. *See, e.g.*, Ex. 2001 ¶¶ 49 (“[C]ollagens ... may also be used.”), 61–62, 67, 76, 86, 127; Ex. 2002 ¶¶ 17, 24, 86–91, 114, 116, 117, 131 (“[C]ollagen is used ... to provide structural integrity and because it biodegrades quickly.”), 135, 189.

Petitioner also argues that Simpson and Patel are not cumulative because they do not disclose cross-linking. Opp. 35–37. Again, not so. 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. *See also* Opp. 36 n.12 (alleging cross-linking was well known). Petitioner ignores the extensive similarity in structure, purpose, and manner

¹ Petitioner does not allege that Simpson and Patel are non-enabling.

of reliance set forth in the Request, which establish the substantial similarity of these references. Req. 16–31.

C. 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 is satisfied. Req. 15. 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* at 5–6.

Petitioner did not address material error. Opp. 27–28. 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, “the claims of the ’227 patent require scaffolds of aligned fibers that have major peaks 180° apart as analyzed by FFT.” Opp. 37. Not so. The claims do not recite “aligned” fibers; they recite a FFT analysis result that “demonstrates that the fibers have major adjacent peaks that are about 180° apart from each other.” However, this limitation is entirely absent from Petitioner’s references: Huang2 discloses a FFT analysis result with only a *single*

peak (Ex. 1005, Fig. 1C) and Lee does not employ FFT *at all* (Ex. 1011).

To address this deficiency, Petitioner relies on Dr. Simpson. Pet. 35–39, 47–51. 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 (“[E]xpert testimony may explain ‘patents and printed publications,’ but is not a substitute for disclosure in a prior art reference itself.”); POPR 17–18 (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. 39. 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 inherency. Pet. 35–39 (no inherency claim regarding Huang2), 47–51 (nor Lee); POPR 15–19, 41–45. 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. POPR 15–30, 41–49.

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 ¶ 47; POPR 19–20. 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 21–23. Similarly, his testimony regarding post-hac testing violates § 42.65(b) by failing to explain how it “was performed and the data was generated.” *Id.* at 23–30, 45–49.

Petitioner criticizes the POPR for offering “attorney argument” to attack its grounds, Opp. 39, 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 1252 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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