

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. 11,317,227 B2

AUTHORIZED RESPONSE TO DIRECTOR REVIEW REQUEST¹

Filed on behalf of Petitioners:

¹ By email dated September 4, 2026, the Office authorized Petitioner to file a response to Patent Owner's Request for Director Review.

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I. INTRODUCTION

Petitioners Embody, Inc., and Zimmer Biomet Holdings, Inc., respectfully submit this authorized response to Patent Owner LifeNet Health’s Request for Director Review (Paper 44, “Request”) of the Final Written Decision (Paper 41, “Decision”). The Request should be denied.

This *inter partes* review (“IPR”) concerns U.S. Patent No. 11,218,227 (“the ’227 patent”). Patent Owner’s Request repackages issues the Board considered and resolved after a full trial record. First, the Board did not disregard Patent Owner’s assertion that lexicography applies. It accepted that the specification’s statement that “major peaks” refer to peaks higher than the average bears the hallmarks of lexicography and applied that language in the context of the patent as a whole. (Decision 17–18.) What the Board rejected were Patent Owner’s added extra-textual requirements for minor peaks, statistically meaningful height differences, residual misalignment, and a “real-world scaffold” limitation. Indeed, the language Patent Owner argues was improper was introduced by Patent Owner itself.

The procedural history matters. Before institution, Patent Owner argued that Huang² reported only one peak because its plot stopped at 180°. (Paper 8, (“POPR”) 57–58; Paper 13, (“DI”) 22–28.) After institution, Patent Owner advanced a new lexicography theory and gave the average-height sentence a mechanical arithmetic meaning: identify all peaks in the fast Fourier transform

(“FFT”) result, assign their heights, calculate the arithmetic mean, and treat only peaks above the mean as “major.” (Paper 23, (“PO Resp.”) 7–9.) On that theory, Huang2’s two equal peaks over 360°, which demonstrated aligned collagen fibers, allegedly could not be “major” because there were no lower peaks to pull the average below them. (*Id.* 17.) Petitioners answered that theory directly in Reply, including by showing that the same arithmetic rule would identify two above-average peaks in Figure 8B, the patent’s random-fiber control. (Paper 26, (“Reply”) 4–9.) Patent Owner then changed its position again, arguing in Sur-reply that Figure 8B had no peaks above the average within “conventional bounds of experimental error.” (Paper 29, (“Sur-reply”) 4.) At oral argument, Patent Owner continued to insist that the claims require minor peaks and some residual misalignment but retreated from the formal mathematical procedure it had described in its Response. (Paper 40, (“Tr.”) 45:10–46:17, 47:6–50:16.) The Board rejected those added limitations, not the patent’s lexicography. Indeed, it was the Patent Owner itself that argued at oral argument that the claim is directed to a scaffold that has a “principal axis of alignment,” language that was ultimately adopted by the Board. (Tr. 45:16–19; Decision 18.) It was not a “third construction,” as now argued by Patent Owner.

That history also defeats the Request’s Administrative Procedure Act (“APA”) theory. The Board did not adopt a “third construction” without notice to

the parties. Instead, it considered the parties’ arguments, including those advanced by Petitioners and their expert, Dr. Simpson, and rejected Patent Owner’s arithmetic test based on that testimony. The parties did not litigate a single fixed construction that the Board later abandoned. Patent Owner’s own explanation of what the average-height sentence required shifted as Petitioners tested its consequences against Huang2 and Figure 8B: first a mechanical arithmetic rule that depended on lower peaks, then a statistical-significance qualification, and finally a non-mathematical requirement for minor peaks and residual misalignment that allegedly reflected “a real-world scaffold.” At oral argument, Patent Owner itself framed those minor peaks as corresponding to an “additional or secondary axis of alignment.” (Tr. 45:21–46:6.) The Board’s reference to a “sole axis or primary axis of fiber alignment” (Decision 18) therefore addressed a framework Patent Owner *itself* placed before the Board, *not* a new theory introduced for the first time in the Decision. The Board resolved that fully aired dispute and was not required to adopt verbatim any one of Patent Owner’s successive formulations, and Patent Owner doesn’t make clear even now which formulation that should be.

Second, Patent Owner’s remaining arguments fare no better. Petitioners’ Reply responded directly to Patent Owner’s Huang2/Kuo arguments without changing the instituted ground or the arguments advanced in the petition. And the elastic-modulus argument isolates one sentence from an analysis in which the

Board considered the competing positions and found that a skilled artisan could tailor scaffold properties to the intended tissue application.

Patent Owner's request to coordinate Director Review with Petitioners' separate rehearing request concerning claims 2 and 3 adds no additional basis for review. The Request challenges different determinations with no overlap of issues for which Petitioner requested rehearing, and the dependency of claims 2 and 3 from claim 1 does not establish error in the Board's findings as to claims 1 and 4-8.

Director review should, therefore, be denied, and the Decision left undisturbed as to claims 1 and 4-8.

II. LEGAL STANDARD

Director Review is limited to an abuse of discretion, an important issue of law or policy, an erroneous finding of material fact, or an erroneous conclusion of law. 37 C.F.R. § 42.75(c); U.S. Patent and Trademark Office, Director Review Process § 2B. Disagreeing with the resolution of a disputed claim construction and evidence does not establish such an error. *See Hamilton Beach Brands Inc. v. f'real Foods LLC*, 908 F.3d 1328, 1338-39 (Fed. Cir. 2018); *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378-80 (Fed. Cir. 2015); *TQ Delta, LLC v. DISH Network LLC*, 929 F.3d 1350, 1354-56 (Fed. Cir. 2019).

III. PATENT OWNER IDENTIFIES NO ERROR WARRANTING DIRECTOR REVIEW

A. The Board applied lexicography but rejected the Patent Owner's additional interpretations

Patent Owner's principal argument rests on a false premise: that the Board found lexicography but refused to apply it and instead adopted a "third construction" without notice to the parties (Request 4). It did not. The Decision instead recognized that the average-height sentence bears hallmarks of lexicography, construed it in the context of FFT analysis for fiber alignment, and rejected only Patent Owner's extra-textual limitations (Decision 15–18).

The record shows why. Patent Owner's theory shifted: first, Huang² fails to anticipate because its 0–180° plot showed only one peak (POPR 57–58; DI 22–28); next, the average-height sentence controlled (PO Resp. 7–9); then, the claims required minor peaks, statistical significance, and differences beyond experimental error to reflect "real-world scaffolds" (Sur-reply 4–8).

Oral argument confirmed the shift. Patent Owner said the claim covers a "real-world manufactured scaffold" that includes major peaks and requires "[s]ome minor peaks," which reflect an "*additional or secondary axis of alignment.*" (Tr. 45:10–46:6 (emphasis added).) When asked where the specification required misalignment, it returned to the inference that an average requires minor peaks. (Tr. 46:7–17.) The Board rejected that inference because neither the claims nor the specification requires minor peaks, and the theory conflicts with the patent's focus on aligned fibers. (Decision 13–18.)

Nor did the Board adopt a “third construction.” (Request 4, 7–8.) It accepted the definitional sentence, addressed Patent Owner’s asserted consequences, and rejected mandatory minor peaks, a minimum number of peaks, statistical significance, and residual misalignment. (Decision 13, 15–18.) That is claim construction, not mischaracterization.

1. *Alnylam* does not bind Patent Owner’s gloss.

Patent Owner’s reliance on *Alnylam Pharms., Inc. v. Moderna, Inc.*, 138 F.4th 1326 (Fed. Cir. 2025), does not change the analysis. There, the specification expressly defined “branched alkyl” to require a carbon atom bound to at least three other carbons, “[u]nless otherwise specified.” *Id.* at 1332–34. The Federal Circuit enforced that express requirement and held that a high threshold applies before finding an exception to controlling lexicography. *Id.* at 1334.

The Board here did not create an exception to an express requirement. It applied the “higher than the average” language and rejected Patent Owner’s added implication that minor peaks must appear in every FFT result. That is an ordinary application of the definition in light of the intrinsic record, not a departure from lexicography. Patent Owner’s approach would make its interpretation binding whenever a sentence is deemed definitional. *Alnylam* says no such thing: the definition controls, not a party’s extra-textual gloss. Indeed, the Federal Circuit has accepted a specification’s express definition as lexicography while rejecting the

patent owner’s proposed interpretation of language within that definition. *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1376–78 (Fed. Cir. 2006). There, the court agreed that the patentees “acted as their own lexicographers,” but nevertheless rejected the patentee’s proposed interpretation of the term “derivatives” within the express definition. *Id.* The same principle applies here: accepting the specification’s definition of “major peaks” did not require the Board to accept Patent Owner’s asserted requirement for separate minor peaks.

Patent Owner’s criticisms of the Board’s discussion of *Alnylam* and *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363 (Fed. Cir. 2009), do not change the result. Because the Board agreed the specification bears sufficient hallmarks of lexicography (Decision 17), any alleged error in describing *Alnylam* or distinguishing *Martek* is immaterial. The dispute concerned Patent Owner’s added requirements, not whether the statement was definitional.

2. The Board did not adopt a “Third Construction.”

In further support of its “third construction” argument, Patent Owner argues that the Board’s construction was improper because it included words not selected by either party when the Board explained that a person of ordinary skill would understand “major peaks” as peaks reflecting the “sole axis or primary axis of fiber alignment” and that this would “certainly include peaks materially higher than the average of the peaks in the result.” (Decision at 18.) It was not.

The Board explained that “major peaks” distinguish peaks reflecting “a principal axis of alignment” from nonmajor peaks “caused by something else,” and therefore reflect the sole or primary axis of fiber alignment. (*Id.*) This was not a new theory. This is the exact language Patent Owner used to describe major peaks. (Tr. 45:10–20 (“a principal axis of alignment that’s represented by major peaks”), 62:1–11 (“primary axis of alignment . . . result as major peaks”); Sur-reply 27 (major peaks “indicate a primary axis of alignment”).)

Further, the Board’s later “materially higher” statement illustrated that construction; it did not narrow it. It responded to Patent Owner’s argument that “major peaks” require the presence of “minor peaks” and that the major peaks must be statistically significantly higher than the average peaks and exceed experimental error. (Decision 8, 13–15; Sur-Reply 4–5, 7.) In rejecting that argument, the Board explained that major peaks *may* be significantly or materially higher, but the claim does *not require* different peak heights or minor peaks. (Decision 18.) Nor did the Board hold that any numerical maximum is a major peak. It held that major peaks reflect the sole or primary axis of fiber alignment. (Decision 18.) Ultimately, the Board concluded that “we do not construe the claims to require non-major peaks,” which is an issue clearly raised by the parties’ papers. (Decision. 18.)

In other words, the Board rejected the Patent Owner’s argument that the claims required “[s]ome minor peaks,” which the Patent Owner expressly referred

to as “an additional or secondary axis of alignment” during oral argument. (Tr. 45:21–46:6.) Patent Owner therefore placed the relationship between major peaks and axes of fiber alignment squarely before the Board. The Decision’s conclusion that major peaks reflect the “sole axis or primary axis of fiber alignment” resolved the very issue—using the Patent Owner’s own language—by correctly finding that the claims do not require separate peaks corresponding to a “secondary axis.” (Decision 18.) This was all the Board needed to do as the Board “is required to construe “only those terms . . . that are in controversy, and *only to the extent necessary* to resolve the controversy.” *Nichia Corp. v. DSS, Inc.*, 2023 WL 7211097, at *2 (Fed. Cir. 2023)(emphasis in original); *see also Nidec Motor Corporation v. Zhongshan Board Ocean Motor Co., Ltd.*, 863 F.3d 1013, 1017 (Fed. Cir. 2017).

Further, the Board’s refusal to require minor peaks was plainly supported by the intrinsic evidence. The ’227 patent is directed to aligned fibers (Decision 18), and requiring separate minor peaks would mean that a more perfectly aligned scaffold could fall outside the claims simply because the lower peaks disappear. The Board reasonably declined to read the definition to require such misalignment peaks, as the Patent Owner contended was necessary.

Even if the Board’s articulation is deemed a construction proposed by neither party, which it was not, no APA violation occurred. The Board may adopt

its own construction when claim construction was disputed, the parties had notice and an opportunity to be heard, and the Board is not bound to adopt either party's wording. *WesternGeco LLC v. ION Geophysical Corp.*, 889 F.3d 1308, 1328 (Fed. Cir. 2018); *Axonics, Inc. v. Medtronic, Inc.*, 75 F.4th 1374, 1381 & n.7 (Fed. Cir. 2023); *TQ Delta*, 929 F.3d at 1354–56; *Hamilton Beach*, 908 F.3d at 1338–39; *see also Praxair Dist., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, 890 F.3d 1024, 1034 (Fed. Cir. 2018). That rule defeats Patent Owner's APA theory. Patent Owner put “major peaks” at issue, and the parties extensively litigated that issue. (See PO Resp. 7; Reply 3–12; Ex. 1219 ¶¶ 4–7, 19–23, 40–41, 69–72; Sur-reply 1–12; Tr. 45:10–46:17.) Patent Owner thus received the opportunity to be heard that the APA requires.

SAS Institute, Inc. v. ComplementSoft, LLC, 825 F.3d 1341 (Fed. Cir. 2016), relied on by Patent Owner, is distinguishable because there, the parties proceeded under the Board's institution-stage construction, both parties relied on it, and the Board changed the construction in the final decision. *Id.* at 1351–52. The issue was *not* that the Board used wording proposed by neither side. Here, the institution decision did not construe “major peaks” because Patent Owner did not raise its claim construction until *after* institution—in its PO Response, 4, 6–9. After Petitioner challenged it, Patent Owner refined it in the Sur-reply and defended it at oral argument. The Decision resolved that fully developed controversy.

3. Patent Owner’s construction conflicts with aligned fibers and misreads Figure 8B.

Patent Owner argues that Figure 8B proves the Board contradicted itself. (Request 9.) The Board noted in Footnote 11 that Figure 8B does not contain “major peaks” despite having two peaks higher than the average based on Patent Owner’s arithmetic approach. Figure 8B is the patent’s example of randomly oriented fibers. The Board explained that Figure 8B does not contain “major peaks” because its peaks do not reflect a primary axis of fiber alignment. (Decision 17 n.11.)

That does not undermine the Board’s construction but instead shows why Patent Owner’s rigid arithmetic test for identifying “major peaks” is wrong. Under the Patent Owner’s approach, one first identifies peaks, calculates their average height, and then treats peaks above average as “major.” But applying that rule mechanically to Figure 8B would identify above-average peaks even though Figure 8B represents random fibers and has no primary direction of alignment. The Board reasonably concluded that the claim term must be understood in the context of the FFT analysis the patent is using to measure fiber alignment. (Decision 14.) In that context, as mentioned above, the Board explained that a person of ordinary skill would understand “major peaks” as peaks reflecting the sole axis or primary axis of fiber alignment and does not require “minor peaks” with a “secondary axis of alignment.” (*Id.* 18; *see also* Tr. 46:4–6.)

Patent Owner's reliance on *Ayres 2008* does not change the point. *Ayres* explains that random-fiber plots tend to have peaks of relatively uniform height, while aligned-fiber plots show more prominent peaks. (Ex. 1010, 609.) That supports using relative peak height as evidence of alignment. It does not establish that every qualifying FFT result must contain separate minor peaks or that a mathematical averaging procedure determines whether a peak is "major."

Nor does Petitioners' expert testimony establish Patent Owner's construction. (Request 11.) Testimony that relative peak height can help identify a major peak does not mean that every qualifying FFT result must contain both major and minor peaks. The Board therefore did not contradict itself by concluding that Figure 8B lacks claim-relevant major peaks while rejecting Patent Owner's additional minor-peak requirement.

B. The Board properly considered Petitioners' Reply material

Patent Owner argues that the Board improperly relied on contested Reply material. (Request 12–14.) That overstates the record. The Petition challenged claim 1 as obvious over Huang2 and Kuo, explaining that a skilled artisan would roll Huang2's flat scaffold sheet in Kuo's process and add the appropriate cells as Kuo taught. (See, e.g., Pet. 22, 30, 39–40; Ex. 1003 ¶¶ 102, 130.) Patent Owner attacked that combination, arguing there was no motivation to use Huang2's aligned scaffold in Kuo's method and that the resulting scaffold could not be used

for tendon, ligament, or nerve repair. (PO Resp. 31–38.) Petitioners’ Reply answered those attacks within the same Huang2/Kuo ground (Reply 14–18); it did not raise a new one. The Decision confirms this. The Board expressly found that Petitioners had raised the challenged arguments in the Petition, citing Petition pages 22 and 39, and Kuo’s supporting disclosures. (Decision 40.)

Indeed, Federal Circuit precedent allows a petitioner to elaborate on a theory in the petition and respond to patent-owner arguments, so long as the reply does not assert a new ground. *Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1008–10 (Fed. Cir. 2023); *Rembrandt Diagnostics, LP v. Alere, Inc.*, 76 F.4th 1376, 1384–86 (Fed. Cir. 2023); *Apple Inc. v. Andrea Electronics Corp.*, 949 F.3d 697, 706–07 (Fed. Cir. 2020); *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1078–82 (Fed. Cir. 2015). The Reply did just that: it answered Patent Owner’s implementation and motivation-to-combine attacks using the same Huang2/Kuo combination.

And unlike *In re NuVasive, Inc.*, 841 F.3d 966 (Fed. Cir. 2016), relied on by Patent Owner, the challenged material introduced no new ground or reference after Patent Owner’s last opportunity to respond. Patent Owner attacked the Huang2/Kuo combination, Petitioners replied, Patent Owner filed a Sur-reply, and the Board found the challenged points were already in the Petition. (Decision 40.)

The Institution Decision does not change that result. Institution findings are preliminary, and after the full briefing, expert testimony, and Reply, the Board

concluded that its initial observation was incorrect. (Decision 39–40.) Revisiting a preliminary assessment on the full trial record is not an abuse of discretion; it is the purpose of trial. And, the Board need not address every filing, argument, or item of evidence to show the issue was considered. *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1327–28 (Fed. Cir. 2017); *Synopsys, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309, 1322 (Fed. Cir. 2016). The Reply responded to Patent Owner’s arguments, and the Board resolved the merits on the full record.

C. Patent Owner’s elastic-modulus argument shows no material error requiring vacatur

Patent Owner focuses on the Board’s statement that it “does not dispute” Petitioners’ point that the ’227 patent is silent on elastic modulus and that a skilled artisan therefore could optimize that property. (Decision 41; Reply 14–15.) Patent Owner responds that its Sur-reply did dispute whether Huang2’s modulus was appropriate for tendon repair. (Request 14.) But that misses the point.

The Board cited *Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1339 (Fed. Cir. 2020), for the settled principle that a patent owner cannot demand more detail from the prior art than the challenged patent itself provides. (Decision 41.) The Board then relied on Petitioners’ Reply in noting that the ’227 patent says nothing about elastic modulus, showing that a POSA was “more than capable” of adjusting that parameter. (*Id.*; Reply 14–15.) Patent Owner did not dispute the patent’s silence on that point, which was sufficient to reject its modulus argument.

The '227 patent itself and the additional evidence cited in Petitioners' Reply further showed that a POSA could adjust elastic modulus. (Reply 19–20; Ex. 1205 786; Ex. 1219 ¶¶ 58–59.) That evidence was more than sufficient to satisfy Petitioners' burden by a preponderance of the evidence. Patent Owner's disagreement with the Board's weighing of the evidence does not justify vacating the determinations for claims 1 and 4–6, nor does it alter Petitioners' burden under 35 U.S.C. § 316(e). And, as discussed above, the Board was not required to list every item of evidence it considered. Finally, the modulus issue does not affect the Board's separate anticipation findings for claims 7–8. Patent Owner's request to vacate claims 1 and 4–8 therefore exceeds the asserted error it raises.

IV. THE REQUEST SEEKS TO RELITIGATE THE MERITS, NOT CORRECT A DIRECTOR-LEVEL ERROR

The Request simply relitigates issues resolved on a full record: Patent Owner's shifting "major peaks" theory, Figure 8B and *Ayres 2008*, the responsive reply material, and the elastic-modulus evidence. Director Review is not a second merits appeal. The Board considered Patent Owner's evolving theories and adopted a construction faithful to the patent as a whole.

V. CONCLUSION

For these reasons, Petitioners respectfully request that the Director deny Patent Owner's request and leave the Final Written Decision determining claims 1, 4–8 of U.S. Patent No. 11,318,227 B2 unpatentable undisturbed.

Respectfully submitted,

Dated: September 14, 2026

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

CERTIFICATE OF SERVICE

I hereby certify that on September 14, 2026, I caused a true and correct copy of the foregoing Petitioner's Authorized Response to Patent Owner's Request for Director Review to be served via electronic means upon the Patent Owner's counsel of record at the following addresses:

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