

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 IPR2025-00248
U.S. Patent No. 10,137,223 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 of the Final Written Decision. (Paper 45, "Request.") The Request should be denied.

This *inter partes* review ("IPR") concerns U.S. Patent No. 10,137,223 ("the '223 patent"). Patent Owner's Request repackages issues the Board considered and resolved on a full trial record. First, contrary to Patent Owner's assertions, the Board did not disregard the '223 patent's statement that "major peaks" refer to peaks higher than the average of the peaks in the result. Rather, the Board recognized that language, read it in the context of the specification's repeated focus on fiber alignment, and rejected Patent Owner's progressively narrowing gloss on the meaning. Patent Owner now characterizes that analysis as the Board's "own construction," but that misstates the Final Written Decision (Paper 43, "Decision"16–17.) The Decision applied the patent's definitional language in context and declined to import limitations Patent Owner proposed but the definition simply does not recite. That is proper claim construction, not a refusal to apply lexicography or a *sua sponte* departure from it. Indeed, the language Patent Owner argues was improper was introduced by Patent Owner itself.

The procedural history is important. Patent Owner repeatedly changed its

theory concerning the claimed FFT peaks. (See Paper 42, (“Tr.”) 48:21–49:2.) Before institution, it argued that Huang² disclosed only one peak because its plot ended at 180°. (Paper 9 “POPR” 14.) The Board correctly rejected that argument because FFT analysis is symmetrical. (Paper 14, 16.) After institution, Patent Owner argued that “major” peaks must exceed a calculated average height, then abandoned that theory after Petitioners showed it would produce “major” peaks in the patent’s random-fiber control, Figure 8B. (PO Resp. 6–9; Sur-reply 4–5.) Patent Owner next argued that measurement error should be disregarded and that the FFT must reflect a “real-world scaffold.” (Sur-reply 4–7.) At oral argument, it abandoned the average-height requirement, instead asserting that the claims require “some minor peaks” reflecting an “*additional or secondary axis of alignment.*” (Tr. 43:4–6; 45:10–46:17; 75:1–5 (emphasis added).) The Board correctly rejected these shifting constructions not imposed by the patent claims or specification.

That history defeats Patent Owner’s APA theory. The Board’s construction was not announced for the first time in the Decision, thereby depriving the parties of notice. Patent Owner made claim construction a central trial issue, Petitioners disputed Patent Owner’s construction, including with expert evidence, and the parties fully litigated peak height, minor peaks, Figure 8B, measurement error, and whether a perfectly aligned scaffold falls within the claims. And, Patent Owner itself argued at the hearing 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 17.) The Board therefore did not unexpectedly introduce a new construction, depriving the parties of notice; it based its claim construction on the arguments set forth by the parties.

Second, Patent Owner’s remaining challenges likewise do not warrant Director Review. For claim 3, the Board expressly applied Petitioners’ burden of proof and found it satisfied, while Patent Owner identified no evidence that hypothetical residual calcium from undisclosed processing or later culture media would exceed about 8 weight percent. (Decision 36–37.) For claim 2, the Board relied on evidence that electrospun collagen exposed to HFIP retained its native structure. (Decision 34–35.) Patent Owner’s disagreement with the Board’s assessment of that evidence presents no Director-level error.

Director Review should therefore be denied, and the Decision determining claims 1–12 unpatentable should remain undisturbed.

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 the '223 patent's definitional language and properly rejected the Patent Owner's added limitations

Patent Owner's principal argument rests on a false dichotomy: because the Board recognized that the sentence "[t]he 'major peaks' herein refers to peaks higher than the average of the peaks in the result" bears hallmarks of lexicography, Patent Owner says the Board had to adopt its interpretation. (Request 3–9.) But recognizing definitional language did not answer how that language applies in context, and the Board was not required to adopt Patent Owner's litigation-derived arguments as to how the definition applies. *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.* Thus, the Board still had to decide what qualifies as a "peak," what makes it "major," and whether the definition requires separate "minor peaks" in every qualifying FFT result, as Patent Owner urged.

The Board resolved those questions using the intrinsic record. The '223

patent repeatedly ties FFT analysis to measuring fiber alignment. (Decision 12–17.) The Board found no claim or specification language requiring “minor peaks,” a secondary alignment axis, or a minimum amount of alignment. (*Id.*) Patent Owner’s construction would exclude a perfectly aligned scaffold solely because it lacked minor peaks, an implication Patent Owner confirmed at oral argument. (Tr. 45:10–46:17.) The Board reasonably declined to import an unrecited misalignment requirement into a patent directed to aligned fibers. (Decision 12–13.)

The Request recasts that merits disagreement as a refusal to apply lexicography and says the Board adopted its “own construction.” (Request 4–5.) Not so. The Decision did not discard the specification’s definition; it applied the definitional sentence in the patent’s FFT-alignment context and declined to convert it into a categorical “minor peaks” requirement. (Decision 16–17.) The Board gave the definition effect while rejecting Patent Owner’s added limitations.

1. *Alnylam* does not make the Patent Owner’s interpretation of the definition binding

Patent Owner’s reliance on *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc.*, 138 F.4th 1326 (Fed. Cir. 2025), does not change the analysis. *Alnylam* requires courts and the Board to respect controlling lexicography once an express definition is established; it does not hold that a party’s progressively changing litigation gloss on a definitional sentence for litigation purposes must be adopted as well. The Board here did not ignore the specification’s definition. It interpreted the definition

and rejected implications, including mandatory minor peaks and required misalignment, that are not stated in the definition itself.

Patent Owner's theory conflates the definition with Patent Owner's asserted consequences of that definition. If accepted, every limitation Patent Owner inferred from arithmetic averaging would become mandatory once the sentence was deemed lexicographic. *Alnylam* does not require that result.

2. The phrase “materially higher” did not impose a new, outcome-determinative claim requirement

The Request next isolates the Decision's construction that peaks reflecting a “sole or primary axis of alignment” “would certainly include peaks materially higher than the average” and argues that this amounted to a construction neither party advanced. (Request 5–6.) That is incorrect.

The Board explained that the phrase “major peaks herein refer to peaks higher than the average of the peaks in the result” teaches a POSA how to distinguish peaks reflecting “a principal axis of alignment” from any non-major peaks “caused by something else.” (Decision 17.) It then explained that “major peaks” are “peaks that reflect the sole axis or primary axis of fiber alignment.” (*Id.*) This is the language Patent Owner used to describe major peaks. (Tr. 45:16–18 (“a principal axis of alignment that's represented by major peaks”), 62:1–11 (“primary axis of alignment . . . result as major peaks”); Sur-reply 26 (major peaks “indicates a primary axis of alignment”).) This was thus not a new construction.

Further, the Board’s later statement that its construction “would certainly include peaks materially higher than the average of the peaks in the result” merely illustrated the construction; it did not limit it. The statement 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.) Rejecting that argument, the Board explained that major peaks *may* be significantly or “materially” higher, but the claim is not confined to that circumstance. (Decision 17.) Instead, the Board held that its construction “would not be limited to situations involving peaks of different heights or require so-called minor peaks.” (*Id.*.) The Board thus rejected 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.) This was all the Board needed to do as the Board need only construe terms “*to the extent necessary* to resolve the controversy.” *Nichia Corp. v. DSS, Inc.*, 2023 WL 7211097, at *2 (Fed. Cir. 2023)(emphasis in original). The Decision did not impose a percentage, statistical test, or minimum numerical deviation from an average, as Patent Owner incorrectly contends.

The Board’s references to a “sole axis or primary axis for fiber alignment” and “would certainly include peaks materially higher than the average,” therefore,

addressed a framework/argument Patent Owner itself placed before the Board—using Patent Owner’s own language—not a theory newly introduced in the Decision. These issues were discussed by the parties and resolved by the Board. Patent Owner’s lack-of-notice argument fails.

Patent Owner’s reliance on *SAS Institute, Inc. v. ComplementSoft, LLC*, 825 F.3d 1341 (Fed. Cir. 2016), is misplaced. There, the parties agreed to a claim construction and litigated on that basis. *Id.* 1351–52. Here, no such agreement existed. And even if the Board’s articulation is deemed a “new” construction, 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); *TQ Delta*, 929 F.3d at 1354–56; *Hamilton Beach*, 908 F.3d at 1338–39. Here, Patent Owner put “major peaks” at issue, and the parties litigated that issue extensively. (See PO Resp. 7; Reply 3–12; Sur-reply 1–12.)

3. Figure 8B confirms why Patent Owner’s literal arithmetic rule was not the whole construction

Figure 8B was not an issue the Board invented. Petitioners cited it in Reply to show the flaw in Patent Owner’s literal arithmetic interpretation. (Paper 27, “Reply” 8–9.) Under that interpretation, numerical differences among the random-control peaks would produce two above-average peaks and bring Figure 8B within

the claim, even though the patent identifies Figure 8B as an unclaimed random-control sample. (*Id.*; Decision 15–16.) Patent Owner responded that no peak in Figure 8B exceeds the average within “conventional bounds of experimental error” or under a “statistical significance” analysis. (Sur-reply 4–5.) In so doing, Patent Owner added a gloss requiring “major peaks” to exceed average peak height after accounting for measurement error and statistics—requirements found nowhere in the ’223 patent. The Board properly rejected those arguments.

Patent Owner now relies heavily on footnote 9, where the Board explained that Figure 8B does not contain “major peaks” because the peaks do not reflect fiber alignment. (Request 10.) But that is not a contradiction in the Board’s reasoning; it is the point. The footnote demonstrates why the bare arithmetic fact that two plotted values may sit above average cannot constitute the claim construction. The claim uses FFT “major peaks” in a patent where FFT measures fiber alignment. The Board therefore read the definitional sentence in that technological context rather than allowing variations above a calculated numerical average in a random control to dictate claim scope.

Patent Owner’s contrary argument effectively asks the Director to detach “peaks higher than the average” from what the peaks represent. But the specification itself ties FFT analysis to fiber alignment. The Board’s treatment of Figure 8B thus reconciles the definitional sentence with the patent’s own

identification of Figure 8B as a random control; it does not negate the definition.

B. The Board did not abuse its discretion in addressing Patent Owner's Figure 8B argument

Patent Owner also characterizes the Board's treatment of its Figure 8B response as an abuse of discretion because the Board declined to authorize a motion to strike or additional sur-reply evidence. (Request 11–13.) The docket shows otherwise. Patent Owner filed a full Sur-reply, submitted an authorized paper identifying allegedly improper Reply material, participated in responsive briefing on those objections, and addressed Figure 8B and experimental error at oral argument. (Papers 28, 29, 30, 35, 36; Tr. 19:14–20:5, 47:6–50:16, 81:16–20.)

The Board's observation that one Sur-reply assertion lacked evidentiary support did not create a due-process violation. Patent Owner chose to add "conventional bounds of experimental error" as a reason to disregard numerical differences in Figure 8B. (Sur-reply 3–5.) The Board was entitled to ask whether that new factual proposition had evidentiary support. Its conclusion that the assertion was attorney argument was an evidentiary assessment, not evidence that Patent Owner lacked notice. Indeed, Patent Owner raised a new claim-construction theory in its Sur-Reply by requiring peaks to exceed conventional measurement error and be statistically significant. Patent Owner did not advance that construction in its Preliminary Response or Response, and Petitioners identified those arguments to the Board as improper Sur-reply material. (Paper 35.)

And unlike *In re NuVasive, Inc.*, 841 F.3d 966 (Fed. Cir. 2016), on which Patent Owner relies (Request 11), Patent Owner here was not confronted with a new prior-art basis after the evidentiary record closed and without an opportunity to respond. Figure 8B is intrinsic evidence from Patent Owner’s own patent, and Petitioners used it responsively to test the construction Patent Owner advanced after institution. (Reply 8–9.) Patent Owner addressed that issue in its Sur-reply and again at the hearing. (Sur-reply 4; Tr. 47:7–20.) The Federal Circuit cautions against parsing reply arguments “with too fine a filter” and permits reply evidence and argument that refute, rebut, explain, or discredit a patent owner’s position while remaining within the same legal ground. *Rembrandt Diagnostics, LP v. Alere, Inc.*, 76 F.4th 1376, 1384–86 (Fed. Cir. 2023); *see also Apple Inc. v. Andrea Electronics Corp.*, 949 F.3d 697, 706 (Fed. Cir. 2020). Petitioners’ use of Figure 8B did exactly that: it answered Patent Owner’s new construction; it did not substitute a new ground for unpatentability.

C. The Board did not shift Petitioner’s burden on Claim 3’s “less than about 8 weight percent residual calcium” limitation

Claim 3 requires “less than about 8 wt % residual calcium.” (Decision 35.) Patent Owner argues that the Board legally erred by finding Huang2 satisfies this limitation and shifting the burden to Patent Owner. It did not. The Board expressly stated that “Petitioner bears the burden to prove (by a preponderance of the evidence) that Huang2 anticipates claim 3.” (Decision 36–37.) The Board then

found that burden satisfied on the record. That is not burden shifting.

The record basis for that finding was straightforward. Patent Owner argues that “Petitioner offered no measurement . . . as to how much *residual calcium* Huang2 fibers contain” (Request 13), but that assumes Huang2’s fibers contained calcium in the first place. The record showed otherwise. The Petition identified Huang2’s disclosed materials for preparing the electrospun fibers and noted that Huang2 does not identify calcium as a component of those fiber-forming materials. (Paper 2, “Pet.” 34; Decision 36; Ex. 1003 ¶ 121.) Nor does the standard collagen-obtaining process use calcium. (Ex. 1219 ¶ 50.) Because “less than about 8 weight percent” includes zero, Huang2’s disclosed calcium-free preparation supported the Board’s finding under a preponderance standard. Petitioners were not required to prove a laboratory measurement of absolute zero merely because Patent Owner hypothesized an undisclosed contamination source. The Board nevertheless considered Patent Owner’s calcium theory, but correctly found no showing that any residual calcium would exceed 8 weight percent. (Decision 36.)

That reasoning did not shift the ultimate burden of persuasion. Section 316(e) keeps that burden on Petitioners throughout. But Federal Circuit precedent distinguishes the ultimate burden of persuasion from the burden of production that may arise after a challenger makes a sufficient evidentiary showing. *Dynamic Drinkware, LLC*, 800 F.3d at 1378–80; *see also E.I. du Pont de Nemours & Co. v.*

Synvina C.V., 904 F.3d 996, 1007–09 (Fed. Cir. 2018) (explaining that *Magnum Oil* does not foreclose burden-of-production principles in IPR while the ultimate burden remains with petitioner). Here, the Board recognized Petitioners’ burden, evaluated Huang2’s disclosed fiber composition and process, and considered whether Patent Owner’s contrary theory was supported. It properly found Patent Owner’s hypothetical calcium sources insufficient to overcome Petitioners’ evidentiary showing without shifting the ultimate burden.

As such, the Request overstates the record by framing the issue as “silence.” (Request 13.) This is not a case where the reference was silent about the composition, and the Board presumed an undisclosed property. Huang2 disclosed the materials and process it used, and Patent Owner’s theory depended on adding theoretical calcium from steps or sources Huang2 did not disclose. The Board was entitled to weigh Huang2’s disclosed recipe against that speculation.

Finally, *Par Pharm.* does not require a different result. Patent Owner cites the rule that inherency cannot rest on what merely may occur. (Request 14.) But the Board did not presume away an undisclosed high-calcium condition. It found, based on Huang2’s disclosed fiber preparation and the record evidence, that Petitioners proved the “less than about 8 weight percent” limitation by a preponderance. Patent Owner’s speculative calcium theory did not show otherwise.

D. The Board Considered Patent Owner’s Claim 2 Rebuttal and Properly Weighed the Native-Collagen Evidence

Claim 2 requires type I collagen in its native triple-helical structure.

(Decision 34.) Patent Owner argues the Board erred in finding the claim unpatentable because Huang²’s HFIP solvent allegedly denatures collagen.

(Request 14; PO Resp. 30–31.) Petitioners presented contrary evidence that HFIP preserves collagen. (Ex. 1003 ¶ 117; Decision 34.) The Board therefore had an expert conflict to resolve. (*Id.* 35.) The Board correctly resolved that conflict by relying on Dr. Mikos’s pre-litigation review article, which stated that collagen electrospun with HFIP “possessed the typical 67 nm banding pattern observed in *native collagen*.” (Ex. 1220, 141:4–142:2 (emphasis added); Ex. 1209, 1205; Ex. 1219 ¶ 45; Decision 35). The article cited Dr. Simpson’s work, showing that both experts’ pre-litigation work supported the same point: HFIP does not destabilize collagen. The Board therefore properly credited Petitioners’ evidence. And despite Patent Owner’s “one piece of Reply evidence” assertion (Request 14), the Board relied on “the evidence cited above,” including Dr. Simpson’s testimony that HFIP “was known to stabilize collagen’s triple helix structure.” (Decision 35–36.)

The Board also correctly found that Patent Owner failed to rebut Dr. Mikos’s review article. (Decision 35.) Patent Owner offered no authority for disregarding it as a “review article,” and its theory that unspecified “biomolecules” protected the fibers was speculation. (Sur-reply 18 n.11.) In any event, the Board

need not discuss every argument or piece of evidence to show it was considered. *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1327–28 (Fed. Cir. 2017); *see also Synopsys, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309, 1322 (Fed. Cir. 2016). As the Board cited the Sur-reply pages allegedly overlooked, Patent Owner seeks a reweighing, not a correction of a material factual omission.

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

Although the Request says it asks the Director to “reweigh nothing,” its arguments do exactly that. It asks the Director to adopt Patent Owner’s “major peaks” construction, revisit Figure 8B and *Ayres 2008*, recast routine evidentiary management as an APA violation despite full Sur-reply and hearing opportunities, reject the residual-calcium findings, and credit Patent Owner’s native-collagen distinctions over the evidence the Board found persuasive. Director Review is not another merits appeal whenever a losing party recasts adverse claim-construction or evidentiary rulings as Director-level error. The Board considered the parties’ competing positions and explained its rulings; that is ordinary adjudication on a full trial record.

V. CONCLUSION

For these reasons, Petitioners respectfully request that the Director deny Patent Owner’s Request and leave the Final Written Decision determining claims 1–12 of U.S. Patent No. 10,137,223 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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Respectfully submitted,

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