

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 IPR2025-00249

U.S. Patent No. 11,318,227

PATENT OWNER'S REQUEST FOR DIRECTOR REVIEW

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Patent Trial and Appeal Board
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I. INTRODUCTION

Patent Owner LifeNet Health respectfully requests Director Review of the Final Written Decision entered August 4, 2026, Paper 41 (“Decision”), finding Claims 1 and 4-8 of U.S. Patent No. 11,318,227 unpatentable. 37 C.F.R. § 42.75. Patent Owner does not ask the Director to disturb the determination that Claims 2 and 3 are not unpatentable. That said, Petitioner has asked the Board to rehear that determination. Paper 43. Claims 2 and 3 depend from Claim 1, and the construction error addressed below is therefore antecedent to the relief Petitioner seeks: on the construction the specification supplies, no claim of the ’227 Patent is unpatentable on this record. Patent Owner respectfully submits that the Director resolves the questions presented here before or together with those presented in Petitioner’s Request.

As described herein, the record reflects an abuse of discretion, two erroneous findings of material fact, and an erroneous conclusion of law—each a separate ground on which Director Review can be granted. The request also presents an important issue of law and policy: whether a final written decision may rest on a claim construction that neither party proposed and on which neither party was heard.

In effect, the Board found the Specification's definition of “major peaks” to be lexicography, declined to apply it, and substituted a new construction for the first time in the Decision—“peaks that reflect the sole axis or primary axis of fiber

alignment,” including peaks “materially higher” than an average. Every claim held unpatentable in the Decision turns on this. This is also an erroneous conclusion of law: the Board agreed that the specification’s definition of “major peaks” bears “sufficient hallmarks of lexicography” (Decision at 17) and then declined to give that definition effect. This is surprising given that the Board took its lexicography criteria from the Federal Circuit decision in *Alnylam* which holds that, once lexicography is established, a high threshold must be met before departing from the controlling definition and then the Board applied no threshold at all.

Second, an erroneous finding of material fact: the reason the Board gave for setting the definition aside was that applying it would bring Figure 8B — the ’227 Patent’s own random-fiber control — within claim 1. That conflict does not survive the Board’s own findings. In footnote 11, the Board finds that Figure 8B contains no major peaks because none of its peaks reflect fiber alignment; this finding removes the conflict entirely. And its findings about Ayres 2008, the reference the specification incorporates, establish the very thing the Board said the specification nowhere indicates.

Third, an abuse of discretion: the Board denied Patent Owner leave to move to strike or to submit sur-reply evidence, authorized instead only a non-argumentative identification of the improper material, and then sustained claim 1 on

that same Reply material. It acknowledged the parties' papers on the issue and ruled on none of them.

Fourth, a second erroneous finding of material fact: on the elastic modulus of Huang2's scaffold, the Board found that "Patent Owner does not dispute this point" and cited the two Sur-Reply pages on which Patent Owner disputed it three ways. Decision 41. The Board's contrary finding rests on no citation at all.

In light of these errors, Patent Owner requests that the Director grant review, vacate the determination that claims 1 and 4-8 are unpatentable, and remand to decide the issues based on Patent Owner's construction; in the alternative, that the Director vacate and remand to permit the parties to be heard on the construction the Board adopted and to decide the matters the Board left undecided; in the alternative, that the Director vacate and remand in part. This request introduces no new evidence and asks the Director to reweigh nothing. 37 C.F.R. § 42.75(c)(3).

II. LEGAL STANDARD

Requests for Director Review of a final written decision are governed by 37 C.F.R. § 42.75. Such requests "shall be limited to decisions presenting (a) an abuse of discretion, (b) important issues of law or policy, (c) erroneous findings of material fact, or (d) erroneous conclusions of law." USPTO, Director Review Process § 2.B. Decisions of the Board under Director Review are reviewed de novo, and the Director may "make any findings or conclusions that the Director deems proper

based on the record.” Id. § 5.A.ii.c. Patent Owner raises all four, and each independently warrants vacatur and remand.

III. THE BOARD COMMITTED SEVERAL ERRORS WARRANTING DIRECTOR REVIEW

A. Erroneous Conclusion of Law: The Board Rests Its Decision on a Claim Construction Neither Party Proposed

1. The Board Held the Specification’s Definition to Be Lexicography and Then Declined to Apply It

The Petition proposed no construction (Paper 2), and the Board “did not construe expressly any claim term in [its] institution decision.” Decision at 8. Patent Owner argued that the specification defines the term—“The ‘major peaks’ herein refer to peaks higher than the average of the peaks in the result,” Ex. 1001, 13:28-29—and that the definition governs. Paper 23 (Patent Owner Response), 7. Petitioner “dispute[d] this lexicography-based construction,” Decision at 8, arguing in Reply that Ayres 2008’s “visual assessment of the relative sizes and shape of the peaks” “is the correct claim construction.” Paper 26 (Petitioner Reply), 5.

The Board agreed with Patent Owner that the sentence “bears sufficient hallmarks of lexicography.” Decision at 17. It nonetheless adopted a third construction:

We conclude that a person of ordinary skill in the art would consider “major peaks” as used in the ’227 patent as referring to peaks that reflect the sole axis or primary axis of fiber alignment. ... This would certainly include peaks materially higher than the

average of the peaks in the result, but it would not be limited to situations involving peaks of different heights or require so-called minor peaks.

Decision at 18.

The reason given is that the specification “lacks any indication that so-called ‘minor peaks’ are a necessary component of the claimed invention.” Decision at 17. That does not reach the objection. Patent Owner does not ask that “minor peaks” be written into the claims; it asks that the sentence the Board found to be lexicography be given operative content. Under the Board’s construction it has none: whether a peak is “major” turns on whether the fibers are aligned, not on the height of the peaks the claim requires the FFT result to have.

2. The Board Improperly Rejected the Patent’s Definition

The Board drew its lexicography criteria from *Alnylam Pharms., Inc. v. Moderna, Inc.*, 138 F.4th 1326, 1333 (Fed. Cir. 2025). Decision at 9. But it did not apply *Alnylam*’s holding, which is that “as a general matter, once the high threshold for lexicography is met in a patent, it makes sense that a high threshold would have to be met before finding a departure from that controlling definition,” because “when a definition is expressly stated, the public is generally entitled to expect clear notice of exceptions.” *Alnylam*, 138 F.4th at 1334. The Board found that threshold met with “sufficient hallmarks” (Decision at 17), and then inexplicably departed from that finding stating that (1) there was “some ambiguity,” (2) the specification “lack[ed]

any indication,” and (3) “[t]here is no indication.” *Id.* at 10, 17. The Board nowhere identifies a clear statement of exception or applies any threshold to the departure. *Alnylam* places the burden of clarity on the departure; the Board placed it on the patentee seeking to enforce its own definition.

Alnylam also refutes the ground on which the Board distinguished the only other lexicography decision it discusses. It distinguished the majority in *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363 (Fed. Cir. 2009), on the ground that it “enforced lexicography that resulted in a broader, not narrower, claim scope than that being proposed by the adversary” Decision at 15 n.9. But *Alnylam* is itself a narrowing case: the parties stipulated to noninfringement of every asserted claim under the definition the court enforced, and it was affirmed. *Alnylam*, 138 F.4th at 1332, 1338. That a definition narrows is not a reason to disregard it.

The Board also restated *Alnylam*’s fourth characteristic as its opposite. *Alnylam* listed, among the characteristics *supporting* lexicography, that “elsewhere in the Definitions section, *Alnylam* used non-limiting terms that *contrast with* the ‘refer to’ language at issue here.” *Alnylam*, 138 F.4th at 1333. The Board restated it as “(d) whether there are other non-limiting terms (e.g., ‘for example,’ or ‘include’) that *contradict* a definitional intent.” Decision at 9. Under *Alnylam* such language sharpens the definitional character of a “refer to” sentence; under the Board’s restatement it undercuts it. The Board then found “at least two of the criteria”

satisfied and treated that count as leaving the question open. Decision at 9-10. Alnylam asked whether “the foregoing characteristics, at least taken together, confirm that the . . . language at issue is definitional.” *Alnylam*, 138 F.4th at 1333. It did not treat the characteristics as a tally to be counted.

3. Both Parties Proposed Constructions with Comparisons

IPR proceedings are “formal administrative adjudications subject to the procedural requirements of the Administrative Procedure Act,” and 5 U.S.C. § 554(b)(3) entitles the parties to be “timely informed of ... the matters of fact and law asserted.” *SAS Inst., Inc. v. ComplementSoft, LLC*, 825 F.3d 1341, 1351 (Fed. Cir. 2016), *rev’d on other grounds sub nom; SAS Inst. Inc. v. Iancu*, 584 U.S. 357 (2018); *see Dell Inc. v. Accelaron, LLC*, 818 F.3d 1293, 1300-01 (Fed. Cir. 2016). An agency “may not change theories in midstream without giving respondents reasonable notice of the change” and “the opportunity to present argument under the new theory.” *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1080 (Fed. Cir. 2015) (quoting *Rodale Press, Inc. v. FTC*, 407 F.2d 1252, 1256-57 (D.C. Cir. 1968)). That is what happened here. The Board “change[d] theories in midstream,” and it is “unreasonable to expect that [the parties] would have briefed or argued, in the alternative, hypothetical constructions not asserted by their opponent.” *SAS Inst.*, 825 F.3d at 1351-52. SAS remanded “for the Board to examine in the first instance after hearing from the parties on the new construction.” *Id.* at 1352.

The words “materially higher” appear nowhere in the parties’ written submissions, or the record of the oral hearing. It appears for the first time at page 18 of the Decision. Both parties’ proposed constructions required a comparison of peak heights, differing only over whether the comparison is arithmetic or visual; Petitioner’s Reply quoted Ayres 2008 for the proposition that aligned scaffolds “exhibit asymmetrical peaks, two larger peaks at 90 and 270° and two smaller peaks at 0 and 360°.” Paper 26, 5 (quoting Ex. 1010 at 610). The Board’s construction removes the comparator: it “would not be limited to situations involving peaks of different heights,” (Decision at 18), and its operative test is that “the asserted major peak in the Aniso plot shown in Huang2’s Figure 1C is higher than any other data point on the plot,” (Decision at 36). Every plot with a maximum satisfies that test.

Reading “materially higher” as illustrative rather than limiting does not avoid the error. Either it is a threshold, in which case no party was heard on it and the Board applies it to no figure in the patent; or it is not, in which case the definition the Board found controlling does nothing. Either way the parties were entitled to be heard on the construction that decided the case. 5 U.S.C. § 554(b)(3). It governs the anticipation determination on claims 7 and 8 as well. Decision at 52.

B. Erroneous Finding of Material Fact: The Intrinsic Evidence Is Not in Conflict with the Patent’s Definition of “Major Peaks”

The reason the Board gives for the not using the specification’s definition is that applying it would bring Figure 8B, the patent’s random-fiber control, within

claim 1, “a clearly erroneous and nonsensical result.” Decision at 17; *see also* Decision at 15-16. That “nonsensical result” is the factual predicate for the legal error above, and the Board’s own findings in the Decision defeat it. But, we only get to the “nonsensical result” if the Board (a) ignores the teaching of the incorporated Ayres 2008 reference, i.e., that uniform peaks are indicative of nonalignment, (b) ignores the testimony of both parties’ experts, and (c) ignores both parties’ offered constructions requiring a comparison.

In a footnote in the Decision, the Board acknowledges that Figure 8B “does not contain ‘major peaks’ despite clearly depicting two ‘peaks higher than the average of the [three or possibly four] peaks in the result’ because none of the peaks is a reflection of fiber alignment.” Decision at 17 n.11. And yet the Board does not reconcile this footnote with the text it annotates, and it also does not reconcile it with its reliance on Ayres 2008’s teaching that “[p]eaks of nearly uniform height are a hallmark of a scaffold composed of random elements” as “further evidence that Figure 8B shows results obtained from ‘a scaffold composed of random elements.’” Decision at 16-17 (quoting Ex. 1010, 609).

Ayres 2008 is incorporated by reference into the ’227 patent. Decision at 16 (citing Ex. 1001, 13:39-46). The Board relies on it as intrinsic evidence against the specification’s definition, reasoning that Ayres 2008’s statement that “[p]eaks of nearly uniform height are a hallmark of a scaffold composed of random elements”

is “further evidence that Figure 8B shows results obtained from ‘a scaffold composed of random elements.’” Decision at 16-17 (quoting Ex. 1010, 609). That reading is incorrect. Ayres’s teachings when applied to the specification’s definition proffered by Patent Owner, are, as suggested by the experts and parties, illuminating as to when and how uniformity of peaks signals nonalignment.

The same reference states the converse proposition, and the Board found it as a fact: “The 2D FFT alignment plots generated from sample scaffolds containing aligned elements exhibit asymmetrical peaks, two larger peaks at 90 and 270° and two smaller peaks at 0 and 360°,” while “[t]he 2D FFT alignment plot of a random matrix will exhibit 4 peaks that occur every 90°.” Decision at 28 (quoting Ex. 1010, 609-610); *see* Paper 26, 5. That is intrinsic evidence, in the reference the specification incorporates, that an aligned scaffold’s FFT result has larger (major) peaks and smaller (minor) ones. The findings that the specification “lacks any indication” and that “[t]here is no indication” that non-major peaks accompany major peaks (Decision at 17), cannot be reconciled with the Board’s own finding at page 28.

The one place the Board addressed Patent Owner’s answer on Figure 8B, it declined to weigh it. Patent Owner argued that Figure 8B “depicts a ‘control’ sample of random fibers, *where no peaks exceed the average height (within conventional bounds of experimental error).*” Sur-Reply at 4 (italics added). The Board found that

“no citation is provided to support the italicized portion of the argument, which thus constitutes unpersuasive attorney argument.” Decision at 16. This is incorrect. The relevant citations appear on that page and the next: Ayres 2008 and the cross-examination of Petitioner’s expert, Ex. 1010, 609; Ex. 2017, 88:7-15; the testimony that the reproduction of the figure “is not very clear” and that peak height can only be “guesstimate[d],” Ex. 1220, 69:25-70:7; and Petitioner’s own measurement, which places the two above-average peaks 820 and 1,790 units above a mean of 92,810 — under two percent — with no assertion of statistical significance. Ex. 1219, ¶ 19; Paper 29, 4-5.

The cross-examination testimony of Petitioner’s expert is similarly telling. Asked how he would describe “major peaks” in a 2D FFT alignment plot, he pointed to a peak at about 90° in one of Ayres 2008’s own plots he said: “I would not refer to that as a major peak because all the peaks in that particular plot look like they’re essentially very similar in height.” Ex. 2017, 88:12-15 (discussing Ex. 1010, 608, Fig. 1-C). He identified a major peak in another plot of the same figure by the very comparison the Board’s construction disclaims: adjacent peaks “on the order of two and a half times taller.” *Id.* at 88:19-21. That testimony was of record and was cited, and it cannot be reconciled with a construction that “would not be limited to situations involving peaks of different heights.” Decision at 18. The Board neither weighed it nor mentioned it.

**C. Abuse of Discretion: The Board Invalidated Claim 1 on Reply
Material Patent Owner Was Refused Leave to Answer**

The Board must “base its decision on arguments that were advanced by a party, and to which the opposing party was given a chance to respond,” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016). Where the Board relies on material first presented in a reply after refusing the patent owner leave to answer it fully, the Administrative Procedure Act is violated, and a vehicle short of a full response does not cure the defect. *In re NuVasive, Inc.*, 841 F.3d 966, 972 (Fed. Cir. 2016) (“We cannot view ‘observations’ as a substitute for the opportunity to present arguments and evidence.”). A reply may fall within the rule and the patent owner may still be entitled under the Administrative Procedure Act to an opportunity to respond. *Id.* at 975 n.2 (“satisfying that rule does not mean that the pre-Response notice was sufficient”).

On February 13, 2026, by email, the Board denied Patent Owner’s request for authorization to file a motion to strike or to submit sur-reply evidence, and authorized instead a paper “identifying the alleged improper arguments and evidence,” directing that Patent Owner “should only identify” that material. Paper 27, 1. Patent Owner filed that paper and identified Exhibit 1219, ¶¶ 44-50, and Reply pages 14-17 as new evidence and argument directed to the obviousness of using Huang2’s scaffold as the starting point of Kuo’s rolling method. Paper 27, 3. It asked for the opportunity to supply context and for leave to reply. Paper 27, 4.

The Board invalidated claim 1 on that material. It relied on Petitioner’s “step-by-step description of how a person of ordinary skill in the art would go about it. *See* Pet. Reply 14-17.” Decision at 38-39. It quoted the Reply at 16: “[T]here was motivation to use the flat sheet aligned scaffold of Huang2 as the first step of the Kuo schematic;” and the Reply at 17, that a person of ordinary skill “would have been motivated to take the electrospun flat scaffold made by the techniques of Huang2, seed it with the desired cells, and roll it to treat a tendon and ligament.” Decision at 39, 42. Those are the sentences Patent Owner identified as improper. Paper 27, 3 (quoting Ex. 1219 ¶¶ 48, 50).

The Board acknowledges Papers 27, 28, 34 and 35 and rules on none of them, and does not mention 37 C.F.R. § 42.23(b) or the objection anywhere. Section 42.23(b) confines a reply to responding to arguments raised in the patent owner response, and “the expedited nature of IPRs bring with it an obligation for petitioners to make their case in their petition to institute.” *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016). The Director may reach both the omission and the underlying denial. 37 C.F.R. § 42.75(a). The omission was not harmless: in the same discussion the Board announced that the institution decision’s contrary finding — “Petitioner does not address Kuo’s teaching regarding this rolled structure at all, let alone present any rationale” — “is incorrect.” Decision at 39-40 (quoting Inst. Dec. 33-34). Whether the rationale came

from the Petition or first from the Reply was therefore squarely presented, and was resolved on the challenged pages after Patent Owner was refused the vehicle in which to brief it.

D. Erroneous Finding of Material Fact: On the Elastic Modulus the Board Found No Dispute at the Pages Containing It

Claim 1 requires “applying the scaffold to the tissue defect to repair a tendon, a ligament or a nerve defect.” Ex. 1001, 23:36-37. Patent Owner argued that Huang2’s scaffold, with an elastic modulus of 8.98 MPa, cannot do that. Decision 40 (citing PO Resp. 36). Petitioner replied that the ’227 patent is “entirely silent” about elastic modulus, “suggesting that a person of ordinary skill in the art was more than capable of” optimizing it. Decision at 40-41 (quoting Pet. Reply 19). The Board found: “Patent Owner does not dispute this point. PO Sur-Reply 23-24.” *Id.* at 41.

Those cited pages dispute it. Patent Owner argued there that Huang2’s scaffold “would remain inapplicable to tendon/ligament/nerve repair” because elastic modulus, stiffness and degradation rate “differ from that required for those tissues”; that “tendon/ligament repair requires 73.5 and 49.78 times more stiffness, and nerve repair requires 472 times less stiffness, than Huang2’s scaffold imparts”; and that modifying them “requires tailoring of factors that are not accounted for in the Petition.” Sur-Reply at 23 (citing Ex. 2015 ¶¶ 133, 138-142). Footnote 15 on the same page answers the Reply directly: “Elastic modulus is a measurement of

scaffold stiffness and must match the target tissue.” Sur-Reply at 23 n.15. The scope objection the Board does describe was an additional argument, not the only one.

The contrary finding rests on no citation: “the record supports that the person of ordinary skill knew how to modify the elastic modulus of a scaffold of aligned fibers and tailor it to the tissue application.” Decision at 41. No exhibit, paragraph, or page is identified, and no reason is given for setting aside Exhibit 2015 ¶¶ 125-142. A finding stated that way is not “a rational connection between the facts found and the choice made,” *In re NuVasive, Inc.*, 842 F.3d 1376, 1382 (Fed. Cir. 2016) (quoting *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)), and it relieves Petitioner of the burden 35 U.S.C. § 316(e) assigns it. *See Magnum Oil*, 829 F.3d at 1375 (confirming that the burden “never shifts to the patentee”). The Board did not weigh Patent Owner’s dispute and reject it; it recorded that there was none.

IV. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that the Director grant review, vacate the determination that claims 1 and 4-8 are unpatentable, and remand.

Respectfully submitted,

Dated: September 3, 2026

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on September 3, 2026 a complete copy of the foregoing Patent Owner's Request for Director Review of the Final Written Decision was served by electronic mail, pursuant to the parties' agreement to electronic service, upon the following counsel of record for Petitioner:

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