

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 IPR2025-00248

U.S. Patent No. 10,137,223

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 43 (“Decision”), finding claims 1-12 of U.S. Patent No. 10,137,223 (“the ’223 Patent”) unpatentable. 37 C.F.R. § 42.75. The Board’s decision includes several erroneous findings and conclusions, each a separate ground on which Director Review can be granted.

First, an erroneous conclusion of law: despite explicitly recognizing that the ’223 Patent’s specification included patentee’s lexicography with a clear definition of “major peaks” (Decision at 16), the Board concludes that “a person of ordinary skill in the art would consider ‘major peaks’ as used in the ’223 patent as referring to peaks that reflect the sole axis or primary axis of fiber alignment” and that “[t]his 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. Based on the totality of the evidence before us, we do not construe the claims to require non-major peaks.” Decision at 17. This conclusion is not only unsupported by the record but is also not one that either party proposed. The Board adopted it *sua sponte* while setting aside the parties’ offered constructions and the specification’s own definition. This is clear error.

There was also an erroneous finding of material fact: the Board reads the incorrect claim construction of “major peaks” onto Figure 8B resulting in

irreconcilable finding of fact in its Decision. And an abuse of discretion: Patent Owner's answer to that misinterpretation of Figure 8B was discounted for want of a citation after the Board denied it leave to answer with evidence. And another erroneous conclusion of law: despite evidence to the contrary, the Board held that a reference met the claim limitation of "less than about 8 wt % residual calcium." *See* '223 Patent, Claim 3. It did this by presuming a reference that was silent as to calcium, had zero calcium, and shifted the burden to Patent Owner to prove otherwise. This is improper under 35 U.S.C. § 316(e).

Finally, an erroneous finding of material fact: the Board found that Patent Owner did not rebut evidence in the Petitioner's Reply while citing the two Sur-Reply pages on which Patent Owner rebutted it three ways.

In light of these errors, Patent Owner requests that the Director grant review, vacate the determination that claims 1-12 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 reach the arguments the Board did not; in the alternative, that the Director vacate and remand in part. This request introduces no new evidence and asks the Director to reweigh nothing.

II. LEGAL STANDARD

Requests for Director Review of a final written decision are governed by 37 C.F.R. § 42.75 and the Director’s supervisory authority over the Board. 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 (Availability of Director Review: Proceedings under part 42 of 37 C.F.R.). 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.* at § 5.A.ii.c. Patent Owner’s request raises four bases for review that fall within the Director’s supervisory authority— an abuse of discretion, erroneous findings of material fact, and erroneous conclusions of law — and each independently warrants vacatur and remand.

III. THE BOARD HAS COMMITTED SEVERAL ERRORS

A. Erroneous Conclusion of Law: The Board Rests Its Decision on a Claim Construction Neither Party Proposed nor Was Heard On

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

The parties disputed one term — “major peaks.” Patent Owner argued that the specification defines “major peaks” as “peaks higher than the average of the peaks in the result,” (*see* Ex. 1001, 13:6-7), and that that definition governs. Paper 24 (Patent Owner Response), 6-9. Petitioner argued that the definition in the

specification is not clear enough to control and that the incorporated Ayres 2008 reference supplies a qualitative visual test. Paper 27 (Petitioner Reply), 3-12.

The Board agreed with Patent Owner that its construction “bears sufficient hallmarks of lexicography.” Decision at 16. Despite this, the Board then adopted its own construction, adding that “major peaks” “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.” *Id.* at 17. This is the antithesis of the claim language and the requirement that peaks be of different heights, *i.e.*, non-uniform, to demonstrate fiber alignment.

The Board created its own construction because, in its words, the specification “lacks any indication that so-called ‘minor peaks’ are a necessary component of the claimed invention,” and a specification cannot support a definition contrary to ordinary meaning absent “a deliberate and clear preference” for it. Decision at 17. Yet, there is a deliberate and clear preference for the specification’s definition. Major peaks requires peaks of different heights — otherwise, the term “major” becomes superfluous. Indeed, both parties agreed that “major” required a comparator. *See infra* at III.A.3.

Notably, the Board drew its lexicography criteria from *Alnylam Pharms., Inc. v. Moderna, Inc.*, 138 F.4th 1326, 1334 (Fed. Cir. 2025). Decision at 8-9. But the Board 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 16), 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 9, 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 incorrectly placed it on the patentee seeking to enforce its own definition.

2. The “Materially Higher” Claim Requirement Appears for the First Time in the Decision

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). 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, 1079-82 (Fed. Cir. 2015) (quoting *Rodale Press, Inc. v. FTC*, 407 F.2d 1252, 1256-57 (D.C. Cir. 1968)). 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. The Board declined to construe any terms at institution. Paper 14 (Institution Decision), 8. The “materially” appears for the first time at page 17 of the Decision. The remedy in *SAS* was remand “for the Board to examine in the first instance after hearing from the parties on the new construction.” *SAS Inst.*, 825 F.3d at 1352. The same remedy is warranted here.

No party briefed what “materially higher” means or what quantum of difference satisfies it, nor did they have an opportunity to do so. It is not an answer that the phrase might be read as illustrative rather than limiting—that the construction is only “peaks that reflect the sole axis or primary axis of fiber alignment.” On that reading the error is the same, and more direct. Either “materially higher” is a threshold, in which case no party was heard on it and the Board never applies it to the one figure on which it would matter; or it is not, in which case the Board found lexicography and gave the definition no operative content at all. Either way the parties were entitled to notice and an opportunity to be heard on the construction that decided the case. 5 U.S.C. § 554(b)(3). This new and unvetted construction governs every unpatentability determination in the Decision.

3. Both Parties' Proposed Constructions Require Peak Comparisons

Both parties proposed constructions require a comparison of peak heights; they differed only over whether the comparison is arithmetic or visual. Patent Owner's expert explained "[a] POSITA would understand that the most prominent, or 'major,' peaks in a FFT result have heights higher than the heights of the other peaks present in the FFT." Ex. 2015 ¶ 57. And Petitioner's expert also defined "major peaks" by comparison: "the major peaks are higher than the other peaks that are present in ... the plot". Ex. 2017, 88:7-24. Petitioner's counsel said the same during the hearing: "if it's a visual average, you can say it stands out among the rest." Tr. 75:16-23; *see also* Tr. 20:7-10 ("it's a visual test, where you look to see whether you have two peaks or four peaks. ... And you don't do an average. That is our whole point."). Yet, the Board's construction removes the comparator altogether: it "would not be limited to situations involving peaks of different heights" (Decision at 17), 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 33. Every plot with a maximum satisfies that test if a peak is compared with "other data." What then makes a peak "material" is a question no party was asked or answered.

At the hearing, the Board seemingly recognized the need for a comparator and asked Petitioner: "Inherently though, if you had something major, wouldn't you also

have to have something minor? Otherwise the major, it becomes superfluous. That means that that term means nothing.” Tr. 74:3-8. The Board then holds the opposite: “[n]or are we persuaded that a person of ordinary skill in the art would readily understand the scope of the term ‘major peaks’ to require non-major peaks,” (Decision at 17) and it does not reconcile this holding with its own reading of Figure 8A, the patent’s aligned exemplar, as showing “major peaks at about 90° and 270° ... and smaller peaks at about 0° and 180°.” *Id.* at 5; *see also id.* at 12, 27.

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 not applying the specification’s definition to the claim term “major peaks” is that it found applying it would bring Figure 8B — the patent’s random-fiber control, within claim 1, “a clearly erroneous and nonsensical result.” *Id.* at 16. Under the specification’s definition, the Board found, Figure 8B’s FFT has “adjacent major peaks with about 180° apart from each other” because “two peaks are higher than the average of the total of the three peaks that are shown (or four peaks if including one at 0°).” *Id.* at 15. Figure 8 is shown below.

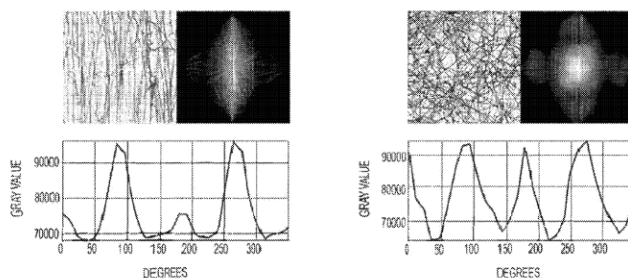


FIG. 8A

FIG. 8B

In doing so, the Board rendered the word “major” irrelevant, added its undefined “materially” requirement, and removed the one concept that both parties agreed upon: that identification of major peaks required comparison to other peaks.

1. The Board Never Defined Its “Materially” Standard

The construction the Board crafted requires “peaks *materially* higher than the average of the peaks in the result.” Decision at 17 (emphasis added). The Board never says how much higher that is, and it never applies the requirement to Figure 8B — not where it describes the figure (*id.* at 5), not where it announces there is a conflict (*id.* at 15-16), and nowhere in between. In its use of Figure 8B, the Board finds that Figure 8B “shows at least three large, but *not* uniform peaks.” *Id.* (emphasis added). This finding is clearly erroneous. *See* Figure 8B.

The three peaks in Figure 8B are uniform as shown by each peak being nearly the same height. Petitioner’s own expert agreed. In the declaration filed with the Petition, he wrote that Figure 8B’s peaks “are all the same height,” and that “[s]eeing that the peaks are uniform in height and shape instantly communicates there is no preferential orientation to the data in the image.”¹ Taking this reading, along with

¹ The Board focused on a single paragraph the Reply declaration, where he measured Figure 8B’s peaks as differing and claimed Patent Owner’s expert “essentially agrees with these numbers.” Ex. 1219 ¶ 19. But the Patent Owner’s

Ayres 2008’s teaching that “[p]eaks of nearly uniform height are a hallmark of a scaffold composed of random elements,” (incorporated by reference into the ’223 Patent and acknowledged by the Board in the Decision at 16) is entirely consistent with the specifications teaching that Figure 8B does not have *major* peaks. It is not, as the Board holds “further evidence that Figure 8B shows results obtained from ‘a scaffold composed of random elements’” yet also one with “major peaks” under the specification’s definition. Decision at 16 (quoting Ex. 1010, 609).

2. The Board Contradicts Its Ultimate Finding

Footnote 9 of the Decision, attached to the sentence on which the conflict rests, states that Figure 8B “does not contain ‘major peaks’”—even though the figure “clearly depict[s] 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 16 n.9. Two things follow. If none of Figure 8B’s peaks reflects fiber alignment, then Figure 8B does not come within claim 1 on the specification’s definition, and the conflict the Board gives as its reason for declining to enforce the

expert said the opposite: “I cannot tell because it’s — the reproduction does not allow me to do so.” Ex. 1220, 69:15-19. A tribunal “must disregard the testimony of an expert that is plainly inconsistent with the record.” *Homeland Housewares, LLC v. Whirlpool Corp.*, 865 F.3d 1372, 1378 (Fed. Cir. 2017).

specification’s definition does not exist. The Board itself does not know whether the figure has three peaks or four—the count any average has to begin with. The Board does not reconcile the footnote with the text it annotates.

C. Abuse of Discretion: Patent Owner’s Answer Was Improperly Discounted

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), and must “articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made,” *In re NuVasive, Inc.*, 842 F.3d 1376, 1382 (Fed. Cir. 2016) (“*NuVasive II*”) (quoting *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). 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, 973 (Fed. Cir. 2016) (“*NuVasive I*”)(holding the Board violated the APA where it refused the patent owner leave to file a surreply and permitted only tightly circumscribed “observations.”). That entitlement does not turn on whether the Reply complied with 37 C.F.R. § 42.23(b). *NuVasive I*, 841 F.3d at 973 n.2 (“satisfying that rule does not mean that the pre-Response notice was sufficient”).

The Board rejected Patent Owner's answer to the Figure 8B conflict as "unpersuasive attorney argument" because "no citation is provided." Decision 15-16. But Patent Owner made that argument at the oral hearing, with a citation, across four transcript pages, in answer to questions from the presiding judge. Tr. 47:6-50:16. The four citations to the hearing transcript all fall within a single colloquy, Tr. 45:10-46:17. Decision at 11, 12, 14, 33. It does not cite Tr. 47-50, or any part of the questioning by the presiding judge — who raised the materiality question himself, calculating the deviation from the record numbers and asking whether it was "really a smaller peak, or ... just measurement error." Tr. 19:14-17; *see* Tr. 19:22-20:5.

The sequence matters. The Figure 8B conflict was built from evidence Petitioner filed with its Reply. Paper 27, 8-9; Ex. 1219 ¶¶ 8-19; Decision at 15. 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). An objection to reply evidence of this kind is ordinarily resolved on a motion to strike, and Patent Owner was denied that vehicle. 37 C.F.R. § 42.75(a). 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.” Paper 28, 1. Patent Owner could therefore answer Exhibit 1219 with argument alone—and the Board then discounted that argument because it carried no citation. Decision at 15-16. At the hearing, after Patent Owner explained that it had not been permitted new rebuttal evidence, the response was that Patent Owner “could’ve asked.” Tr. 81:16-20. Patent Owner had asked and had been refused.

D. Erroneous Conclusion of Law: The Board Held a Reference’s Silence Discharges Petitioner’s Burden of Proving Anticipation

The flaw in the Board’s Claim 3 analysis stands on its own. It does not depend on the construction of “major peaks,” and it is dispositive of Claim 3. Decision at 54. On that claim the Board held that Petitioner carried its burden of proving anticipation by showing only what the prior art does not say — a conclusion of law that inverts 35 U.S.C. § 316(e).

Claim 3 recites “less than about 8 wt % residual calcium.” Ex. 1001, 23:12–13. Petitioner’s entire showing on that limitation was that Huang2 says nothing about calcium: the Petition “points out that Huang2 does not indicate that any calcium was used when describing the materials used to prepare the nanofibers.” Decision 36 (citing Paper 2, 34). Petitioner offered no measurement, no calculation, and no testimony as to how much residual calcium Huang2’s fibers contain. That a reference is silent as to a property is not evidence of the quantity of that property.

Treating that absence as an affirmative demonstration and then faulting Patent Owner for not quantifying the property assigns to the patent owner the burden the statute assigns to the petitioner. Section 316(e) places the burden of proving unpatentability on the petitioner, and “that burden never shifts to the patentee.” *Magnum Oil*, 829 F.3d at 1375 (quoting *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015)).

Patent Owner preserved the point, arguing “it is Petitioner’s burden to demonstrate that the residual calcium would not exceed the limit recited in claim 3,” Decision at 36 (citing PO Resp. 33), and “[t]he burden is Petitioner’s alone, and Petitioner failed,” Sur-Reply at 19. It also highlighted the rule that an undisclosed limitation is anticipated only if necessarily present: “[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Par Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1195 (Fed. Cir. 2014) (quoting *In re Oelrich*, 666 F.2d 578 (C.C.P.A. 1981)); Paper 30, 16–17. The Board’s analysis addresses neither. Decision at 36–37.

E. Erroneous Finding of Material Fact: On Claim 2 the Board Found No Rebuttal at the Pages Containing the Rebuttal

Claim 2 requires fibers comprising “type I collagen in its native triple helical structure.” Ex. 1001, 23:10-11. Patent Owner argued that type I collagen denatures in HFIP, the solvent Huang² uses. Decision at 34 (citing Paper 24, 30). The Board resolved that dispute on one piece of Reply evidence—that Patent Owner’s own

expert had published that electrospun collagen “possessed the typical 67 nm banding pattern observed in native collagen”—and found: “Patent Owner does not directly address or otherwise rebut this evidence. Decision at 35 (citing Paper 30, 17-18).

The cited pages, however, do rebut this evidence. Patent Owner argued that Petitioner “simply argues that other, different fibers maintained native triple-helical structure after dissolution in HFIP,” which “is irrelevant to Huang2’s fibers,” because “specific biomolecules in other fibers protected against denaturation” and “Petitioner presents no evidence that Huang2’s fibers are similarly protected.” Paper 30, 18 (citing Ex. 1220, 124:14-19, 127:17-128:1). It turned Petitioner’s own exhibit against it: “electrospinning of biological materials [e.g., collagen] is less versatile because a suitable solvent that does not compromise its integrity has to be used.” *Id.* (quoting Ex. 1209, 1205). And it objected that Exhibit 1209 is a review article whose underlying publications Petitioner never submitted, so that “applicable differences cannot be examined.” Paper 30, 18 n.11. The Board did not rule on that objection. Claim 2 was held unpatentable on this evidence alone. Decision at 35. The Board did not find the rebuttal unpersuasive; it erroneously thought that none existed.

IV. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that the Director grant review, vacate the determination that Claims 1-12 of the ‘223 patent 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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