

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ARLA FOODS AMBA,

Petitioner

v.

LEPRINO FOODS COMPANY,

Patent Owner

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IPR2025-01199

Patent 11,825,860

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**PATENT OWNER'S BRIEF IN SUPPORT OF DISCRETIONARY DENIAL**

## Table of Contents

|                                                                                                                                                                |    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| I. Introduction .....                                                                                                                                          | 2  |
| II. The Director should exercise his discretion and deny institution under 35<br>U.S.C. § 314(a).....                                                          | 3  |
| A. Background of the Invention .....                                                                                                                           | 4  |
| B. The Petition’s gap-filling with Dr. Etzel’s testimony warrants denial.....                                                                                  | 4  |
| i. Grounds 1 and 2: Petitioner relies entirely on Dr. Etzel’s testimony in<br>an attempt to supply the claimed BLG to ALA ratio absent from<br>Nielsen785..... | 7  |
| ii. Ground 3: Dr. Etzel’s testimony supplies the amount of denatured<br>whey proteins absent from Nielsen450.....                                              | 9  |
| iii. Dr. Etzel’s testimony is repetitive of the petition and conclusory.....                                                                                   | 10 |
| C. Reliance on Dr. Etzel’s testimony to circumvent the Board’s word limits<br>is improper .....                                                                | 15 |
| D. Institution would be unduly burdensome on the Board’s finite resources....                                                                                  | 16 |
| III. Conclusion .....                                                                                                                                          | 18 |

## **I. Introduction**

Pursuant to the “Interim Processes for PTAB Workload Management” Memorandum dated March 26, 2025 (“Interim Processes Memo”), Patent Owner submits this brief in support of discretionary denial. The Petition’s overreliance on complicated and highly fact-specific expert testimony renders it unsuitable for this forum. Institution should be denied.

First, Petitioner improperly relies on its expert’s declaration (Ex. 1003)—citing the Etzel declaration *at least 250 times* in nearly every sentence of its Grounds and attempting to “fill gaps” in its unpatentability arguments. Moreover, when it is not gap-filling with complex experimental details, Dr. Etzel’s testimony is highly conclusory, simply parroting language from the petition. In short, the Petition is not based on “prior art patents and printed publications,” but on conclusory expert testimony, weighing heavily against institution.

Second, the declaration’s extreme length and multiple factual issues weigh heavily in favor of discretionary denial. Dr. Etzel’s declaration alone is *over 27,000 words—nearly double the 14,000 word limit of the Petition*<sup>1</sup>. What is

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<sup>1</sup> Dr. Etzel’s declaration includes additional background discussion and experimental records compared to the Petition but otherwise largely replicates text from the Grounds in the Petition. Ex. 1003, ¶¶74-314; Pet., 9-93.

more, *the Petition includes numerous factual issues and highly technical experimentation*. Such highly fact-specific issues present a significant burden on the Board's limited resources and are much better suited for an Article III court. For these reasons, the Director should exercise his discretion and deny institution.

**II. The Director should exercise his discretion and deny institution under 35 U.S.C. § 314(a).**

The Director has discretion to institute an *inter partes* review under 35 U.S.C. §§ 314(a). *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.”); 35 U.S.C. § 314(a) (stating “[t]he Director *may not* authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition” (emphasis added)). Institution of review is ultimately entrusted to the Director's discretion. *See* 37 C.F.R. § 42.108(a), § 42.4(a); *Cuozzo Speed Techs., LLC v. Lee*, 136 579 U.S. 261, 273 (2016).

Here, 35 U.S.C. § 314(a) supports discretionary denial. As described below, the Petition relies on conclusory expert testimony and presents complicated factual issues more suitable for evaluation by an Article III court. Institution would be unduly burdensome on the Board and should be denied.

**A. Background of the Invention**

During cheese making, casein proteins from milk form curds, and whey is separated from the curds and diverted for further processing. Ex. 1001, 1:17-23. Whey may be used to make high protein compositions, e.g., whey protein powders, as described in the '860 Patent. *Id.*, 1:15-17. Whey includes milk-derived proteins such as beta-lactoglobulin (BLG), alpha-lactalbumin (ALA), and glycomacropeptide (GMP). *Id.*, 4:36-43. As the '860 Patent explains, GMP is considered an inferior source of protein for muscle recovery, and a high native GMP content may result in undesirable flavors in whey protein products. *Id.*, 1:30-39. The '860 Patent describes a novel and nonobvious way of producing high-protein whey compositions with reduced GMP content. *Id.*, 5:25-39.

**B. The Petitioner's gap-filling with Dr. Etzel's testimony warrants denial.**

Petitioner's excessive reliance on Dr. Etzel's 27,000+ word declaration alone warrants denial. PTAB Rule 104(b)(4) requires that an IPR petition "specify where each element of the claim is found *in the prior art patents or printed publications* relied upon." 37 C.F.R. § 104(b)(4) (emphasis added). As the Office has made clear, "extensive reliance on expert testimony" indicates that the issues are "better resolved in an Article III court." *See* FAQs for Interim Processes for PTAB Workload Management, FAQ 21. IPR proceedings must be based on patents

and printed publications—not expert opinion. The role of an expert is to provide focused support (e.g., explaining terms of art or relevant context), ***not to supply elements absent from the prior art or substitute petitioner’s obviousness rationale***. *Id.* Extensive reliance on expert argument and inferences to ***fill gaps*** of the prior art weighs in favor of denial. *iRhythm Technologies, Inc. v. Welch Allyn, Inc.*, IPR2025-00363, Paper 10, 2–3 (June 6, 2025). In her July 31, 2025

Memorandum, then Acting Director Stewart formalized this policy stating:

As a practical matter, enforcement of Rule 104(b)(4) means . . . expert testimony . . . may not be used to supply a missing claim limitation.

Per 35 U.S.C. § 312(a)(4), ***the Board shall deny an IPR petition that fails to comply with Rule 104(b)(4)***.

Enforcement and Non-Waiver of 37 C.F.R. § 42.104(B)(4) and Permissible Uses of General Knowledge in Inter Partes Reviews (“Rule 104(B)(4) Memo”), dated July 31, 2025, 1-2 (emphasis added).<sup>2</sup>

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<sup>2</sup> Although the Memorandum applies to Petitions filed on or after September 1, 2025, excessive reliance on Expert testimony also is a basis for discretionary denial under the original Interim Processes Memo. *See* Interim Process Memo at 2; Rule 102(B)(4) Memo at 3.

The Petition exemplifies overreliance on expert testimony in precisely the manner the Interim Processes Memo, Rule 104(b)(4), and Acting Director Stewart have cautioned against. *The Petition cites the Etzel declaration at least 250 times—in nearly every sentence of the Grounds. See generally* Pet., 5-93.

Notably, although portions of the Petition do cite to the prior art, the Petition repeatedly *cites solely to Dr. Etzel’s declaration (not the ’860 Patent claims or the cited references) for numerous conclusions without citation to the alleged prior art, for example:*

- “POSITAs would have understood that at least 95% of the protein in the solutions of BLG powder was denatured after heat treatment. *Etzel*, ¶90.” *Id.*, 15.
- “Heat-denaturation processes would not effect the BLG/ALA ratio because Cl.8.6 does not differentiate between denatured and undenatured BLG.” *Id.*, 16-17 (citing *Eztel*, ¶94-95).
- “Dr. Etzel confirmed—through replicating Nielsen<sup>450</sup>’s examples 11-12—that denaturation in heat-treated beverages prepared as described would have exceeded 5% (e.g., 77-85%). *Etzel*, ¶141.” *Id.*, 30.
- “At minimum, disclosures related to making BLG powders were expressly incorporated<sup>3</sup> with particularly. *Etzel*, ¶138.” *Id.*, 29.

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<sup>3</sup> Notably, Petitioner cites *solely* to Dr. Etzel’s declaration to support its *legal conclusion* that Nielsen<sup>450</sup> expressly incorporated Bertelsen. Pet., 29.

- “Claim 15 recites a composition with limitations mirroring 8.4-8.7. *Etzel*, ¶196.” *Id.*, 50.
- “Both references were directed toward the same field of endeavor concerning preparation of protein compositions for food products. *Etzel*, ¶¶232-33.” *Id.*, 65.

The above citations to Dr. Etzel’s declaration are provided not merely to explain the background knowledge of a POSA—contrary to *iRhythm*—but to improperly fill gaps in the prior art as applied to claim limitations. *iRhythm*, IPR2025-00363, Paper 10, 2. Two specific examples of gap-filling, discussed below, are demonstrative.

**i. Grounds 1 and 2: Petitioner relies entirely on Dr. Etzel’s testimony in an attempt to supply the claimed BLG to ALA ratio absent from Nielsen785.**

In Grounds 1 and 2, Petitioner improperly relies on Expert testimony to supply the requisite BLG:ALA ratio in claim limitation 8.6. Pet., 16-17, 22.

Specifically, in its invalidity theory, Petitioner appears to cite properties of completely different compositions in Nielsen785 and Bertelsen and attempts to cobble them together through expert testimony. As background, Bertelsen disclosed that a ***BLG powder*** may be formed by filtering whey to obtain a concentrated BLG formulation, which is centrifuged and crystalized to make the powder. Ex. 1006, 57:1-33, 3:25-39; Ex. 1005, 89:1-2. Nielsen785, on the other hand, discloses the formation of ***whey protein nanogels by dissolving BLG***

***powders*** in water and heating the solution to purportedly denature the proteins therein. Ex. 1005, 89:1-2, 25-34. The Petition alleges that claim limitation 8.7 (greater than 50 wt.% denatured whey proteins) is described in Nielsen<sup>785</sup>'s nanogel products. Pet., 17. But the Petition switches<sup>4</sup> to Bertelsen's BLG powder as allegedly disclosing the features of claim limitations 8.4 (at least 60% whey protein) and 8.6 (BLG:ALA ratio greater than 5). *Id.*, 15-17.

Appreciating the impropriety of relying on disparate compositions to satisfy the claim limitations of the claimed denatured whey protein composition, ***Petitioner relies on Dr. Etzel's testimony to fill the gaps.*** For example, for claim limitation 8.4, Dr. Etzel parrots the language in the Petition asserting—without any support—that “a POSITA would have understood that at least 95% of the protein in the solutions of crystallized BLG powder was denatured after heat treatment.” Pet., 15; Ex. 1003, ¶ 90. Similarly, for claim limitation 8.6, Dr. Etzel (conclusorily) testified:

The disclosed heat-denaturation process would not affect the BLG-to-ALA ratio because claim limitation 8.6 does not differentiate between denatured and undenatured BLG, therefore, a POSITA would have

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<sup>4</sup> Petitioner must rely on the nanogel product for claim limitations 8.7 because the BLG powder is not denatured. Ex. 1005, Table 1 (stating the BLG isolate contains 96.5% native (undenatured) BLG and 0.2% native ALA).

understood that both denatured and undenatured BLG contents are considered in the calculation of the BLG-to-ALA ratio.<sup>5</sup>

Ex. 1003, ¶95; Pet., 16-17.

Thus, because Petitioner could not point to all limitations in the actual denatured product of Nielsen785 (nor in Bertelson, for Ground 2), it instead relies upon Dr. Etzel's testimony to supply the missing features. Further, as will be discussed more fully in the POPR, had Petitioner looked to the reference instead of Dr. Etzel's testimony, it would have found the heat denaturation process *does* indeed affect the BLG:ALA ratio: the first column of Table 13 of Nielsen785 shows a nanogel product composition ***containing 0% ALA*** without the addition of exogenous whey protein isolate (0% WPI). Ex. 1005, 106.

**ii. Ground 3: Dr. Etzel's testimony supplies the amount of denatured whey proteins absent from Nielsen450.**

Petitioner again uses Dr. Etzel's testimony to supply a missing claim limitation in Ground 3. As Petitioner acknowledges, ***Nielsen450 fails to teach specific degrees of whey protein denaturation***, e.g., claim limitation 8.7. Pet., 30.

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<sup>5</sup> The Petition does not formally construe the claimed BLG:ALA ratio in its claim construction section, instead appearing to rely on Dr. Etzel's proposed construction, which also weighs in favor of discretionary denial. *iRhythm*, IPR2025-00363, Paper 10, 2–3.

To satisfy claim limitation 8.7, *Petitioner attempts to fill the whey protein denaturation gap left by Nielsen450 using testimony of experiments purportedly “replicated” by Dr. Etzel. Id.*, 30-32, 37-48. As the forthcoming POPR will confirm, Petitioner’s new “evidence” does not match the alleged prior art examples, instead beginning with a *different* starting composition than Nielsen450 and using an *altered* process to measure protein denaturation levels. Not surprisingly, the results did not even match those reported in Nielsen450. *Id.*, 31. This is classic gap filling—*Petitioner enlisted Dr. Etzel to coax out protein denaturation levels not disclosed, expressly or inherently, by Nielsen450.*

Thus, as Petitioner concedes, Nielsen450 fails to disclose the degree of denaturation achieved through heating. *Id.*, 30. Instead, the Petition fills this gap in the prior art entirely by its expert’s testimony. Such over-reliance on expert testimony is improper under the Director’s guidance and warrants discretionary denial.

**iii. Dr. Etzel’s testimony is repetitive of the petition and conclusory.**

Discretionary denial is further supported by the conclusory and repetitive nature of Dr. Etzel’s declaration. For example, Dr. Etzel’s “opinions” on the Grounds in the Petition are largely verbatim or near-verbatim assertions parroted from the Petition without any independent analysis or supporting evidence.

Compare Ex. 1003, ¶¶74-314 with Pet., 9-93. The quote below regarding Nielsen785's alleged disclosure of claim limitation 8.7 is exemplary.

| Pet., 17                                                                                                                                                                                                                                                                                    | Ex. 1003, ¶ 98                                                                                                                                                                                                                                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Denaturing at least 95% of whey protein in the BLG powder composition relative to total protein weight—corresponded to a denatured whey protein composition having well over 50wt.% denatured whey proteins relative to the total weight of protein in the composition. <i>Etzel</i> , ¶98. | Denaturing at least 95% of the whey protein in the BLG powder composition relative to the total weight of protein corresponded to a denatured whey protein composition having well over 50 wt.% denatured whey proteins relative to the total weight of protein in the composition. |

The only difference between the Petition and Dr. Etzel's "opinion" is a dash (which appears to be misplaced) and a semantic difference in the phrase "total protein weight" instead of "total weight of protein" in the Petition. Again, it is telling the Petition only cites to Dr. Etzel's declaration—it cannot cite to Nielsen785; it instead gap fills with conclusory expert testimony. Numerous other sections of Dr. Etzel's declaration are similarly deficient and parrot the Petition as shown below:

| Petition Section | Petition Pages | Substantially mirrored paragraphs in Etzel Decl. (Ex. 1003) |
|------------------|----------------|-------------------------------------------------------------|
| VII.A.2          | 6-7            | 70-72                                                       |

| Petition Section             | Petition Pages | Substantially mirrored paragraphs in Etzel Decl. (Ex. 1003) |
|------------------------------|----------------|-------------------------------------------------------------|
| VII.A.2.b                    | 9-10           | 76-80                                                       |
| VII.A.2.c                    | 11             | 84                                                          |
| VII.A.2.d                    | 14             | 87                                                          |
| VII.A.2.h                    | 17             | 97-98                                                       |
| VII.A.5-VII.A.6              | 18-19          | 103-104                                                     |
| VII.B.1                      | 19-20          | 108-109                                                     |
| VII.B.5                      | 23             | 125                                                         |
| VII.B.5                      | 24             | 127                                                         |
| VII.C.1                      | 25-27          | 130-134                                                     |
| VII.C.3                      | 29-30          | 139-140                                                     |
| VII.C.3                      | 31-32          | 144-148                                                     |
| VII.C.4.a                    | 32-33          | 150                                                         |
| VII.C.4.b                    | 33             | 152                                                         |
| VII.C.4.c                    | 33-34          | 154                                                         |
| VII.C.4.d                    | 34-36          | 158-159                                                     |
| VII.C.4.g.i                  | 41             | 174                                                         |
| VII.C.4.g.i-<br>VII.C.4.g.ii | 41-43          | 176-178                                                     |
| VII.C.4.g.ii                 | 45-47          | 182-183                                                     |
| VII.C.4.g.ii                 | 47-48          | 185-186                                                     |
| VII.C.6                      | 49             | 188-189                                                     |
| VII.C.9.b                    | 50-52          | 200-201                                                     |

| Petition Section      | Petition Pages | Substantially mirrored paragraphs in Etzel Decl. (Ex. 1003) |
|-----------------------|----------------|-------------------------------------------------------------|
| VII.C.10              | 52-53          | 204-205                                                     |
| VII.C.12              | 54-56          | 215-216                                                     |
| VII.D.2               | 60-63          | 223-226                                                     |
| VII.D.3               | 63-65          | 228-231                                                     |
| VII.D.4.a             | 66-68          | 236-237                                                     |
| VII.D.5.b             | 71-72          | 250-251                                                     |
| VII.D.5.c             | 75-78          | 262-264                                                     |
| VII.D.5.d             | 78-79          | 266-269                                                     |
| VII.D.5.e             | 81-82          | 275-277                                                     |
| VII.D.5.f             | 82-83          | 279-280                                                     |
| VII.D.5.g             | 84             | 282-283                                                     |
| VII.D.5.h             | 85             | 286-287                                                     |
| VII.D.7               | 86             | 291                                                         |
| VII.D.8               | 86-87          | 294                                                         |
| VII.D.9.d             | 88-89          | 302                                                         |
| VII.D.11              | 89-90          | 306                                                         |
| VII.D.12-<br>VII.D.13 | 90-92          | 308-313                                                     |

Such conclusory testimony that simply parrots the Petition without additional support should be accorded little to no weight. *cxLoyalty, Inc. v. Martitz Holdings Inc.*, 986 F.3d 1367, 1378 (Fed. Cir. 2021) (noting “[w]e do not accord

weight to conclusory expert testimony.”) (citation omitted); 37 C.F.R. §42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”); *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (PTAB Aug. 24, 2022) (noting testimony which is “conclusory and unsupported, [and] adds little to the conclusory assertion for which it is offered to support . . . is entitled to little weight.”) (precedential).

In short, the Petition is not based entirely on “prior art patents and printed publications,” as the statute and regulations require. 35 U.S.C. § 312(a)(4); Rule 104(b)(4). Instead, the petition is based on portions of the prior art coupled with gap-filling by a sprawling, 27,000+ word expert declaration. This is precisely what Rule 104(b)(4) warns against: a petition that motions toward a theory but uses expert testimony to provide missing details. Unlike in *iRhythm*, where the Director found no such overreliance, the Petition here defers extensively to expert narrative for supplying missing claim limitations in place of prior art analysis. *iRhythm*, IPR2025-00363, Paper 10, 2.

Petitioner’s extensive reliance on expert testimony would not have been necessary if the references relied on by Petitioner indeed disclosed the purportedly anticipated and obvious aspects alleged by Petitioner. Instead, the Petition’s overreliance on expert testimony to supplant missing claim limitations demonstrates fatal defects in the prior art and Petitioner’s arguments. Accordingly,

the credibility of the Petition and its overreliance on expert testimony to fill gaps in the prior art weighs strongly against institution.

**C. Reliance on Dr. Etzel’s testimony to circumvent the Board’s word limits is improper**

The form of expert testimony further supports discretionary denial. The Etzel Declaration is 164-pages and 314-paragraphs long, totaling over 27,000 words—almost two times the 14,000-word limit available for petitions.<sup>6</sup> That disparity, coupled with the extreme length of the Petition itself—including figures and images, *it exceeds the 14,000 word limit by more than 1,000 words*<sup>7</sup>—reflects an improper avoidance of the Board’s word limits and conflicts with the Office’s bar on incorporating by reference.

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<sup>6</sup> As a practical matter, it is not even clear how Patent Owner can respond to 27,000+<sup>6</sup> words of expert testimony within its 14,000 word limit. Thus, the extreme length of the Etzel declaration also will result in unfair prejudice to Patent Owner.

<sup>7</sup> Although parties are permitted to rely on a word processing system word count, they are not permitted to abuse the process with words in figures or images. 37

C.F.R. § 42.24(d); Trial Practice Guide, 40.

**D. Institution would be unduly burdensome on the Board's finite resources.**

The discretionary denial process explicitly aims to “improve PTAB efficiency” and “maintain PTAB capacity to conduct AIA proceedings.” Interim Processes Memo, 3. Instituting the present *inter partes* review would contradict these goals. The excessive overreliance on expert testimony and number of factual issues contained in the Etzel declaration weigh strongly in favor of discretionary denial. *Id.*, 2-3 (the parties may address “any other [unlisted] considerations bearing on the Director’s discretion.”).

As discussed above, the Petition is laden with factual issues<sup>8</sup> much better suited for the comprehensive discovery and fact investigation permitted by Article III courts. Specifically, since they are not laid out in the prior art, numerous complicated factual issues will need to be fully assessed by the Board, including: (i) the BLG:ALA protein ratio, (ii) the denatured protein percentage discussed above in Nielsen785 and Nielsen450 (Grounds 1-3), (iii) the reduced GMP content

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<sup>8</sup> As will be shown in the forthcoming POPR, the Petition fails to show a reasonable likelihood of prevailing with respect to at least one claim.

in Ozturk (Ground 4); and (iv) several factual issues concerning Dr. Etzel's experiments.<sup>9</sup> Pet., 16-17, 30-48, 74, 81.

Each factual issue will require prolific expert testimony from both Petitioner and Patent Owner, assessment of which will push the limits of the Board's finite resources. The Board should not be made to wade through and evaluate countless pages of fact-intensive expert laboratory reconstruction on top of prior art references which themselves amount to hundreds of pages. Additionally, the credibility of witnesses, including Petitioner's fact and expert witnesses, can be much better evaluated through trial testimony in district court than in the current forum. These issues would similarly benefit from third party discovery, e.g., of the other inventors of Bertelsen, Nielsen785, and Nielsen450, and of employees of the parties, which is largely unavailable in IPR proceedings.

The PTAB, with limited opportunity for evaluating complex expert testimony, is simply much less equipped to handle detailed fact discovery—especially when Petitioner's expert testimony spans hundreds of pages and nearly

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<sup>9</sup> For example, Dr. Etzel's experiments began with a *different* starting composition than Nielsen450 and used an *altered* process to measure protein denaturation levels. Pet., 30-32, 37-48. Petitioner claims, without evidence, that its different results can be attributed to "water adsorption [sic] during storage." *Id.*, 31.

*exceeds the word limit for briefing two times over.* Accordingly, institution would be unduly burdensome on the Board and its resources. In view of the foregoing, the Director should grant discretionary denial.

### **III. Conclusion**

Petitioner's excessive reliance on the Etzel declaration in an attempt to fill the gaps in the prior art render it improper. Moreover, the "copy and paste" parroting of text from the Grounds of the Petition into the Etzel declaration—without supplementation—entitle it to be given little weight. Lastly, the complicated nature of Dr. Etzel's experiments and the extreme length of the declaration will unduly burden the Board and its limited resources. Because complex fact investigation is better suited for district court rather than the PTAB, and in view of the importance of balancing PTAB workload, Rule 104(B)(4) and 35 U.S.C. § 312(a)(4) warrant denying institution.

Dated: September 26, 2025

Respectfully submitted,

/Justin Krieger/

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*Lead Attorney for Patent Owner*

**CERTIFICATE OF COMPLIANCE**

The undersigned certifies that this brief complies with the page limitations of 37 CFR § 42.24(a)(1)(i). This brief contains 17 pages as measured by the word processing software used to prepare the document, exclusive of table of contents, mandatory notices, certificates of service and compliance and appendix of exhibits.

The undersigned further certifies that this brief complies with the typeface requirements of 37 CFR § 42.6(a)(2)(ii) and typestyle requirements of 37 CFR § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in Times New Roman 14 point font.

Dated: September 26, 2025

Respectfully submitted,

/Justin Krieger/

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**CERTIFICATE OF SERVICE**

The undersigned certifies that on September 26, 2025, Patent Owner's Brief in Support of Discretionary Denial (Paper 7) has been served via email on Counsel for Petitioner at the email address as indicated in their Mandatory Notices Under 37 C.F.R. § 42.8:

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