

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARLA FOODS AMBA,

Petitioner

v.

LEPRINO FOODS COMPANY,

Patent Owner

IPR2025-01199

Patent 11,825,860

**PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST
FOR DISCRETIONARY DENIAL**

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<i>Valneva Austria GMBH v. Takeda Vaccines, Inc.</i> , IPR2025-00776, Paper No. 11 (Director August 11, 2025)	3

EXHIBIT LIST

No.	Exhibit
Ex1001	U.S. Patent No. 11,825,860 (“’860 patent”)
Ex1002	File History of the ’860 patent
Ex1003	Declaration of Dr. Mark Etzel, Ph.D.
Ex1004	Curriculum Vitae of Dr. Mark Etzel, Ph.D.
Ex1005	PCT Application Publication No. WO2021/136785 (“Nielsen785”)
Ex1006	PCT Application Publication No. WO2018/115520 (“Bertelsen”)
Ex1007	PCT Application Publication No. WO2020/002450 (“Nielsen450”)
Ex1008	“Glycoproteomic and Lipidomic Characterization of Industrially Produced Whey Protein Phospholipid Concentrate with Emphasis on Antimicrobial Xanthine Oxidase, Oxylipins and Small Milk Fat Globules,” Dairy, Vol. 3, Issue 2, April 20, 2022, by Ozturk, et al. (“Ozturk”)
Ex1009	“pH-Dependent Molecular Weight Changes of κ -casein Glycomacropeptide and Its Preparation by Ultrafiltration,” Milchwissenschaft, Vol. 48, Issue 4, April 1993, by Kawasaki, et al. (“Kawasaki”)
Ex1010	“APV LeanCreme™ Microparticulation of Whey Protein with SPX Flow Technology, White Paper,” November 2012, (“LeanCreme”), Wayback Machine Capture, June 24, 2016, at https://web.archive.org/web/20160624161613/https://www.spxflow.com/en/assets/pdf/LeanCreme_22008_04_11_2012_GB_tcm11-7662.pdf
Ex1011	Affidavit of Tanya Zeif
Ex1012	“Fractionation of Whey Proteins and Caseinomacropeptide by Means of Enzymatic Crosslinking and Membrane Separation

No.	Exhibit
	Techniques,” Journal of Food Engineering, Vol. 67, Issues 1-2, March 2005, by Tolkach, et al.
Ex1013	“Cheese Whey Tangential Filtration Using Tubular Mineral Membranes,” Chemical Papers, Vol. 70, pp. 325-32, December 28, 2016, by Hinkova et al.
Ex1014	“A Study of Various Chemical Pretreatments to Fractionate Lipids from Whey Protein Phospholipid Concentrate,” Journal of Dairy Science, Vol. 104, Issue 12, December 2021, by Swaminathan et al.
Ex1015	U.S. Pat. No. 5,280,107 to Kawasaki et al., issued January 18, 1994
Ex1016	U.S. Pat. No. 4,734,287 to Singer et al., issued March 29, 1988
Ex1017	PCT Application Publication No. WO2015059245
Ex1018	“Cheese pH—What’s Behind the Rise and Fall?” Dairy Pipeline, Vol. 14, No. 4, December 2002, by Mark Johnson
Ex1019	U.S. Pat. Appl. Pub. No. US2011/0003975, published January 6, 2011 to Arase et al.
Ex1020	U.S. Pat. Appl. Pub. No. US2016/0058025, published March 3, 2016 to Christensen et al.
Ex1021	Declaration of Tanja Christine Jæger
Ex1022	Declaration of June Ann Munford
Ex1023	“A Differential Scanning Calorimetric Study of the Thermal Denaturation of Bovine β -lactoglobulin Thermal Behaviour at Temperatures Up to 100°C,” Biochimica et Biophysica Acta, Vol. 624, pp. 40-50, July 24, 1980, by de Wit et al.

I. INTRODUCTION

Petitioner Arla Foods amba (“Petitioner”) requests that the Director deny Leprino Foods Co.’s (“Patent Owner”) request for discretionary denial (Paper 7, “DD Request”), and institute this IPR challenging U.S. Patent No. 11,825,860 (“the ’860 Patent,” or Ex1001).

The ’860 Patent has never been asserted in litigation. Moreover, the present IPR is the first post-issuance challenge to the ’860 Patent. The Board’s institution of IPR under these circumstances advances a fundamental purpose of IPR proceedings, namely, to provide an efficient and non-duplicative alternative to litigation. In other words, the Office is not only the most efficient for this challenge, but indeed the only forum that can address invalidity now, early in the ’860 Patent’s life.

Further, the ’860 Patent was issued on Nov. 28, 2023—less than two years ago, and Patent Owner does not have settled expectations arising from the short duration the ’860 Patent has been in force. Instead, where Petitioner has brought an early challenge, as here, the Director has repeatedly found such challenges favor robust, predictable patent rights and weigh against discretionary denial.

Patent Owner’s Request contains a scattershot of merits arguments cloaked as discretionary ones. Regardless, those arguments do not show that denial is warranted because they rest on mischaracterizations of the Petition and Dr. Etzel’s declaration. When Patent Owner’s arguments are examined critically, it is clear that the Petition

maps each claim limitation to the cited prior art and properly relies on expert testimony to support how a person of ordinary skill in the art (POSITA) would have understood the prior art references' disclosures. The Director has recognized that reliance on such testimony in IPR is proper. 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"), 1-2 (July 31, 2025) (citing *Unification Techs. LLC v. Micron Tech. Inc.*, No. 2023-1348, 2024 WL 3738401, at *7 (Fed. Cir. Aug. 9, 2024)).

II. THE CHALLENGED PATENT IS NOT INVOLVED IN CO-PENDING LITIGATION AND HAS NOT PREVIOUSLY BEEN CHALLENGED

The '860 Patent has never been asserted in litigation, and there is no co-pending litigation now. In addition, the '860 Patent has never been subject to any post-grant proceeding. This factor weighs strongly against discretionary denial. *See CSPC Pharm. Grp. Ltd. v. Ipsen Biopharm Ltd.*, IPR2025-00505, Paper 11, at 2 (Director July 16, 2025) (denying request for discretionary denial where the parties "are not engaged in a parallel litigation"); *Ajinomoto Co. v. AbTis Co.*, IPR2025-00283, Paper 13, at 2 (Director July 2, 2025) (denying request for discretionary denial where "[i]n particular, Patent Owner and Petitioner are not engaged in a parallel litigation").

III. PATENT OWNER DOES NOT HAVE SETTLED EXPECTATIONS AS TO THE '860 PATENT, WHICH ISSUED LESS THAN TWO YEARS AGO

The '860 Patent issued on November 28, 2023. *See* Ex1001, Cover; Ex1002, 186. Petitioner diligently filed this IPR on July 15, 2025—well under two years after the '860 Patent issued.

Patent Owner does not have strong settled expectations based on the short length of time of the '860 Patent has been in force. *See Valneva Austria GMBH v. Takeda Vaccines, Inc.*, IPR2025-00776, Paper No. 11, at 2 (Director August 11, 2025) (referring petition to a merits panel because a 2023-issued patent “has not been in force for a significant period of time”). This weighs against discretionary denial.

IV. PATENT OWNER HAS NOT SHOWN DISCRETIONARY DENIAL IS WARRANTED

Patent Owner attempts to support discretionary denial by arguing that (1) the Petition's reliance on expert testimony is improper, (2) the Petition improperly circumvents the word limit, and (3) the PTAB is not the correct forum for this challenge. As discussed in detail below, none of these arguments supports discretionary denial of institution. *See* DD Request.

A. The Petition Does Not Improperly Rely on Expert Testimony

Patent Owner's contention that the Petition relied on Dr. Etzel's testimony to "fill gaps of the prior art" (DD Request 4-5) is incorrect. Instead, the Petition properly relies on Dr. Etzel's expert testimony to explain and provide context about how a POSITA would have understood the prior art disclosures to teach the claim limitations. Rule 104(B)(4) Memo, 1-2 (noting expert testimony can be used to demonstrate the knowledge of a POSITA). Dr. Etzel further cites the facts and data on which his opinion is based, including where each claim element is found in the prior art patents and printed publications (with specific citations to them), as required by 37 C.F.R. §§42.65(a) and 42.104(b)(4).

Patent Owner provides six bullet points with statements from the Petition that Patent Owner contends improperly rely on expert testimony, as well as arguments for two claim limitations with alleged gap-filling. As discussed below, none of these arguments withstands scrutiny.

1. Patent Owner's six cherry-picked sentences from the Petition properly rely on expert testimony, the challenged patent, and the prior art references.

Patent Owner plucks six sentences out of the Petition without their surrounding context to argue that "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.” DD Request 6-7. Patent Owner’s six examples do not support its argument, as discussed below.

First, Patent Owner cites the Petition’s statement that “POSITAs would have understood that at least 95% of the protein in the solutions of BLG powder was denatured after heat treatment. Etzel, ¶90.” DD Request 6 (citing Pet. 15). But Patent Owner ignores the remainder of this paragraph which cites portions of Nielsen⁷⁸⁵ (with those same citations also in Dr. Etzel’s cited testimony) to support this statement.

Second, Patent Owner points to this statement: “Heat-denaturation processes would not effect [*sic*] the BLG/ALA ratio because Cl.8.6 does not differentiate between denatured and undenatured BLG.” *Id.* (citing Pet. 16-17 (citing Etzel, ¶¶94-95)). Again, Patent Owner ignores the context of this statement. In addressing limitation 8.6, which recites, in relevant part, “a beta-lactoglobulin [BLG] to alpha lactalbumin [ALA] ratio of greater than 5.00,” the Petition points to Nielsen⁷⁸⁵’s Table 1 and explains that composition has a ratio greater than 5 (~482.5), as a matter of arithmetic. Pet. 16-17. The sentence Patent Owner cites merely explains the plain language of the claim limitation, which encompasses both denatured and undenatured BLG, such that subsequent heat-denaturation processes do not affect whether Nielsen⁷⁸⁵’s Table 1 composition meets the limitation. Dr. Ezel’s cited testimony explains this based on Nielsen⁷⁸⁵’s Table 1, including that a POSITA

would have understood limitation 8.6 as considering both denatured and undenatured BLG contents in the calculation of the BLG-to-ALA ratio. EX1003, ¶95.

Third, Patent Owner cites this statement: “Dr. Etzel confirmed—through replicating Nielsen450’s examples 11-12—that denaturation in heat-treated beverages prepared as descri[b]ed would have exceeded 5[0]% (e.g., 77-85%). Etzel, ¶141.” DD Request 6 (citing Pet. 30). This statement is from a section of the Petition explaining Nielsen450’s disclosures regarding denaturing exemplary high-protein beverages; the Petition’s explanation of how those disclosures meet specific claim limitations comes in subsequent sections of the Petition. *See* Pet. 25-32 (explaining Nielsen450’s disclosures and Dr. Etzel’s replication of Nielsen450’s Examples 11-12), 32-56 (mapping the claim limitations to Nielsen450’s teachings).

Fourth, Patent Owner points to the statement: “At minimum, disclosures related to making BLG powders were expressly incorporated with particularly. Etzel, ¶138.” DD Request 6 (citing Pet. 29). Here, Patent Owner goes so far as to state that “Petitioner cites solely to Dr. Etzel’s declaration to support its legal conclusion that Nielsen450 expressly incorporated Bertelsen.” *Id.* 6 n.3 (citing Pet. 29). This is clearly incorrect. Instead, the Petition explains how Nielsen450 incorporates Bertelsen expressly as well as when Nielsen450 teaches its BLG powder was preferably prepared using Bertelsen’s methods. Pet. 6, 28-29. Dr. Etzel

likewise points to Nielsen⁴⁵⁰'s disclosure for his opinion on Bertelsen's incorporation into it. EX1003, ¶138.

Fifth, Patent Owner faults the Petition's statement that: "Claim 15 recites a composition with limitations mirroring 8.4-8.7. Etzel, ¶196." DD Request 7 (citing Pet. 50). Other than the citation to Dr. Etzel's declaration, PO's objection is unclear because the Petition simply provides an accurate comparison between two challenged claims.

Finally, Patent Owner points to the statement: "Both references were directed toward the same field of endeavor concerning preparation of protein compositions for food products. Etzel, ¶¶232-33." DD Request 7 (citing Pet. 65). Dr. Etzel's testimony, however, cites disclosure from both Ozturk and Kawasaki to support his opinion that the references are from the same field of endeavor. EX1003, ¶¶232-33 (citing EX1008, Abstract; EX1009, 191).

In sum, none of Patent Owner's six cited sentences shows improper reliance on expert testimony.

2. Petitioner's grounds do not rely on expert testimony for gap filling.

Patent Owner next describes in detail two purported examples of gap-filing. Those examples fare no better.

a. Grounds 1 and 2: Petitioner Relies on Nielsen785's Teachings for the Recited BLG to ALA Ratio.

For Grounds 1 and 2, Patent Owner argues “Petitioner improperly relies on [e]xpert testimony to supply the requisite BLG:ALA ratio in claim limitation 8.6.” DD Request 7-9 (citing Pet. 16-17, 22). This is incorrect because Nielsen785 (Ex1005) expressly discloses the percentages of BLG and ALA. Pet. 16-17 (citing Ex. 1005, Table 1 (showing ALA percentage of 0.2 and BLG percentage of 96.5)). In addressing limitation 8.6, the Petition points to Nielsen785's Table 1 and explains that composition has a ratio of BLG to ALA greater than 5 (~482.5), as a matter of arithmetic. Pet. 16-17. The Petition also explains this ratio does not change with heating (i.e., the ratio does not change in Nielsen785 from the “reduced-GMP cheese whey retentate composition” (i.e., BLG powder) to the “denatured whey protein composition” after heating) because the plain language of the claim limitation encompasses both denatured and undenatured BLG in calculating the ratio.

Patent Owner does not seriously dispute that this showing is supported by Nielsen785's teachings. Instead, Patent Owner tries to sow confusion about limitation 8.6 by mischaracterizing both the teachings of Nielsen785 (and Bertelsen as incorporated) and the way the Petition maps those teachings. But there is nothing improper about the Petition's mappings either.

Specifically, Patent Owner argues Petitioner relies on Nielsen's nanogel product to teach 8.7, but relies on Bertelsen's BLG powder to teach 8.4 and 8.6. DD Request 8 (citing Pet. 15-17). This is incorrect. Rather, the Petition explains Nielsen785 (incorporating Bertelsen (Ex1006)) describes a complete manufacturing process that produces a single composition—BLG nanogel, with the BLG powder serving as the product of an intermediate process step. Pet. 7-8 (showing Bertelsen's BLG isolate power preparation and Nielsen785's nanogel preparation using Bertelsen's BLG isolate powder). It is this combined method that teaches the method limitations of claim 8.

Limitation 8.3 recites the “denatured whey protein composition,” and then limitations 8.4 to 8.7 recite properties of that composition. The Petition clearly maps Nielsen785's BLG powder as the “reduced-GMP cheese whey retentate composition” in 8.2 that is heated in 8.3 to form the “denatured whey protein composition.” Pet. 15. As to 8.3, the Petition explains Nielsen785 taught such heating to denature the native BLG and form a “denatured whey protein composition.” *Id.*

The Petition then explains why that heated, denatured composition has the properties recited in 8.4-8.7. *See* Pet. 15 (for 8.4, explaining why Nielsen785's heating denatures at least 95% of the protein in the BLG powder and thus, as a matter of arithmetic, why the resulting “denatured whey protein composition” would have

“over 60 wt. % whey protein on a dry-weight basis”); *id.* at 15-16 (for 8.5, explaining the total protein weight does not change with heat treatment because no protein is added or removed during that step, so BLG powder with “less than 11 wt. % native GMP relative to a total weight of protein in the denatured whey protein composition” would not alter this property); *id.* at 16-17 (for 8.6, explaining that the BLG powder had “a beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00” and that heating would not change the ratio); *id.* at 17 (for 8.7, explaining that the denaturation taught in Nielsen785 results in “greater than 50 wt. % denatured whey proteins relative to the total weight of the protein in the denatured whey protein composition”). The Petition does not rely on disparate compositions to satisfy limitations or Dr. Etzel’s testimony to fill gaps. Rather, it relies on the properties of the “denatured whey protein composition” (i.e., the composition after heating) taught in Nielsen785, including the properties present in that composition based on the reference’s teachings. Patent Owner seems to demand an in haec verba disclosure for anticipation (Ground 1) or obviousness (Ground 2). This is not required. *See Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1341 (Fed. Cir. 2016) (quoting *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015)) (“a reference can anticipate a claim even if it ‘d[oes] not expressly spell out’ all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would ‘at once envisage’ the claimed arrangement or

combination”); *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984) (holding that in an obviousness context “the teaching in the prior reference need not be *ipsissimis verbis*” but rather “a teaching with respect to the entirety of the claimed invention”).

Patent Owner is also incorrect that Petitioner somehow failed to propose a construction of the ratio recited in 8.6. DD Request 9 n.5. Instead, the Petition tracks the plain language of that limitation, and Patent Owner does not argue for any contrary construction. This issue is a red herring in any event because considering only denatured BLG after heating, as disclosed in Nielsen785, would alter the ratio only slightly. As explained by the Petition, Nielsen785 teaches BLG powder containing native BLG and ALA of 96.5% and 0.2%, respectively, corresponding to a BLG:ALA ratio of about 482.5. Pet. 16 (citing Nielsen785, 88:8-20, Table 1). Nielsen785 teaches a high BLG denaturation level of “at least 99% w/w of the native BLG” (Pet. 5, 14 (citing Nielsen785 at 20:10-30); Ex1003, ¶87), which would reduce the ratio from 482.5 to 477.7 after heating if only denatured BLG were considered. That still far exceeds the recited BLG:ALA ratio of 5.0. Therefore, regardless of whether all BLG or only denatured BLG is used to calculate the BLG:ALA ratio, Nielsen785 teaches this limitation.

Finally, Patent Owner argues that Table 13 of Example 7 in Nielsen785 shows that heat denaturation affects the BLG:ALA ratio. DD Request 9. That argument is flawed for multiple reasons.

First, Patent Owner's argument relies on a different embodiment than the Petition. Nielsen785 teaches several distinct embodiments (Examples 1 through 11) with differing properties and preparation methods. The Petition relies on Example 1 of Nielsen785, which is directed to the preparation of dense whey protein nanogel solutions, and *not* on Example 7, which addresses the use of WPI and BLG mixtures to prepare whey protein nanogels. *See, e.g.*, Pet. 15-17 (citing Nielsen785, 88:15-89:3); Ex1003, ¶¶88-95.

Second, even using the values reported in Table 13, the BLG:ALA ratio exceeds the recited value of 5.0. The first column of Table 13, highlighted by Patent Owner, reports a BLG level of 97% and an ALA level of 0%. DD Request 9; Nielsen785, 106 (Table 13). Dividing 97% by a near-zero denominator yields a ratio that approaches infinity. In other words, the BLG:ALA ratio reflected by compositions disclosed in Table 13 is greater than the recited 5.0 BLG:ALA ratio.

b. Ground 3: The Petition shows the heating process of Nielsen450 far exceeded BLG's known denaturation temperature, satisfying limitation 8.7.

Limitation 8.7 recites that the “denatured whey protein composition” has “greater than 50 wt. % denatured whey proteins relative to the total weight of the

protein in the denatured whey protein composition.” The Petition explains that a POSITA would have understood Nielsen450’s disclosed heating results in a “denatured whey protein composition” having the recited property. Specifically, Nielsen450 teaches a heat treatment temperature of 90°C, and the Petition cites Dr. Etzel’s testimony explaining that a POSITA would have known that temperature far exceeds the known denaturization temperature of BLG (70°C). Pet. 37; Ex1003, ¶165 (citing Ex1005, 89:29-31; Ex1023, 40 as support). The Petition also explains that Nielsen450 teaches a substantial heating duration of five minutes, and points to Dr. Etzel’s testimony explaining that a POSITA would have understood and expected that Nielsen450’s disclosed heating of its compositions at 90°C for 5 minutes would have resulted in greater than 50 wt. % denatured whey proteins relative to the total weight of the protein in the denatured whey protein composition. Pet. 37 (citing Ex1003, ¶¶164-165); *see also id.* 30 (citing Nielsen450 at 72:14-32 (the heat treatment “provide[s] a degree of protein denaturation of at least 40%...and more preferably at least 95%”); Ex1003, ¶140 (citing Ex1019, [0003] (“it is known that whey protein is poor in heat stability and is therefore rapidly denatured by heating at 70°C to 90°C”))).

In this case, Dr. Etzel went even further by faithfully replicating Nielsen450’s Examples 11–12 to confirm denaturation levels exceeding the claim limitation. Specifically, Dr. Etzel utilized BLG powder sourced from the same batch employed

in Nielsen450's original experiments; conducted the replication studies in the same facility using the same equipment; and followed the step-by-step sample preparation procedures set forth in the prior art. *See e.g.*, Pet. 30-32; Ex1003, ¶¶139-48. Taken together, these controls render Dr. Etzel's work, for all practical purposes, the best achievable replication of Examples 11-12. Minor discrepancies such as moisture absorption by the powder during storage are within the expected range of experimental variability and do not negate the experimental results showing properties of the heat-treated composition as a POSITA would have understood. *See* Ex1003, ¶145.

3. Dr. Etzel's Testimony is Not Conclusory

Patent Owner contends Petitioner's expert parrots the Petition and this is grounds for discretionary denial. DD Request 10-15. First, Patent Owner substantively discusses just one example of parroting from a declaration spanning over 160 pages. DD Request 11 (comparing Ex1003, ¶98 with Pet. 17). As with the Patent Owner's six cherry-picked snippets discussed in Section IV.A.1, Patent Owner discusses Paragraph 98 in isolation here without acknowledging that Petition also cites the prior paragraph, which provides objective support for the opinion in Paragraph 98. *See* Pet. 17 (citing Ex1003, ¶¶97-98).

Patent Owner then provides, without discussion or explanation, a table of alleged parroting examples spanning two pages of its brief. Petitioner could not

possibly address every table entry in this page-limited brief, but even review of the first one addressing the claim mapping shows Patent Owner's parroting argument is incorrect. Specifically, Patent Owner argues the analysis at Petition pages 9-10 (discussing limitation 8.1) is "substantially mirrored" in Paragraphs 76-80 of Dr. Etzel's declaration. But in those paragraphs, Dr. Etzel cites additional evidence to support his opinions. *E.g.*, Ex1003, ¶76 (citing Ex1012), ¶77 (citing Ex1006, Fig. 26F). And in Paragraphs 76-80, Dr. Etzel cites the portions of Bertelsen supporting his testimony. The same pattern repeats throughout Patent Owner's undeveloped list.

Dr. Etzel's testimony contains detailed technical analysis, data interpretation, and scientific explanation—precisely what is required for a robust and credible record. Importantly, Dr. Etzel's testimony is supported not only by corroborating evidence in the references relied upon in the unpatentability grounds, but also numerous references to support his opinions about a POSITA's knowledge. *See generally*, Ex1003-1010, Ex1012-1020, Ex1023. Dr. Etzel's testimony is lengthy (and longer than the petition) precisely because it does not parrot it. In sum, Dr. Etzel's testimony offered independent technical analysis, interpretation of experimental data, relevant calculations, and explanation of motivations to combine, among other things, and corroborated his testimony with supporting scientific literature. *See generally*, Ex1003.

B. The Petition Complies with the Word-limit Requirements

Patent Owner's arguments criticizing the length of Dr. Etzel's declaration and alleged word-limit circumvention are meritless. There is no rule that limits the length of supporting declarations, and the Petition itself contains 13,472 words—few than the 14,000-word limit set by PTAB rules. The Petition's use of annotations in reproduced figures and tables have been deliberately limited to the minimum necessary, often including only limited highlights or brief notations. *See generally*, Pet. A few examples are provided below:

Table 3 The concentration of selected components of feed 2 (ALA-reduced whey protein concentrate based on sweet whey). BDL= below detection limit in wet, non-standardized sample.

Feed 2 standardized to 95% TS	
Protein composition (% w/w relative to total protein)	
ALA	12.2
BLG	70.0
CMP	17.1
Other components (% w/w relative to the total weight of the standardized feed)	
Ca	0.387
K	0.204
Hg	0.066
Na	0.051
P	0.174
fat	BDL
protein concentration	89

Example 3 (whey protein solution)

Table 12 The concentration of selected components of the spray-dried BLG crystal preparation of Example 7. BDL= below detection limit

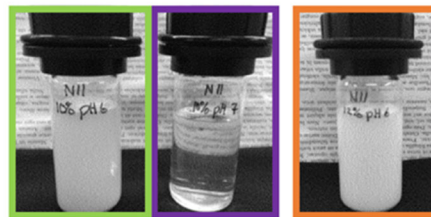
Spray dried BLG crystal powder	
Protein composition (% w/w relative to total protein)	
ALA	0.7
BLG	97.4
CMP	BDL
Other components (% w/w relative to total weight of the BLG crystal powder)	
Ca	0.118
K	0.026
Hg	0.017
Na	BDL
P	BDL
water	3.8
protein concentration	94

Example 7 (BLG isolate powder)

Table 10. Properties of high protein BLG beverages at pH 6.0 and pH 7.0. Grey cells = not determined due to sample gelation.

Powder	Protein w/w%	pH	Viscosity cP	Turbidity NTU	Description	L*	a*	b*	Δb*	Insoluble protein matter %
A	6	6.0								
			1.9	-	Milky	90.73	-1.96	1.76	-1.54	0
	7.0	4.1	14.6		Clear	39.87	-0.11	0.04	0.26	0
		2.8	>11000		Milky	90.47	-2.54	-2.4	-2.18	0
	12	6.0	57.7	11.1	Clear	39.74	-0.11	0.04	0.26	0
		4.5	-		Milky	90.38	-2.24	1.92	-1.70	0
		7.0	Gel							

Figure 10



Pet. 13 (citing Ex1006, Tables 3 and 12), 39 (citing Ex1007, Table 10, Figure 10).

The flow chart presented on page 8 of the Petition constitutes the only illustration created based on prior art teachings. *See* Pet. 8; Ex1003, ¶73. This flow chart shows

the combined manufacturing process of Bertelsen/Nielsen⁷⁸⁵, but importantly for word-count purposes, even including the textual content within the illustration (128 words) the Petition's word count (13,600 words) remains under the threshold.

Patent Owner speculates that the Petition improperly circumvented the word count limitation through the use of figures or images, allegedly exceeding the permissible word limit by more than 1,000 words (DD Request 15). However, Patent Owner fails to identify any specific illustration or provide evidentiary support substantiating this allegation. The Director should reject it.

C. The PTAB Is the Proper Forum for This Early Challenge.

Patent Owner's reliance on the Interim Processes Memo as a basis for discretionary denial is misplaced. Discretionary considerations are not a substitute for an evaluation of the merits and should not be used to deny institution where the Petition demonstrates a reasonable likelihood of success. *See* Interim Processes for PTAB Workload Management Memorandum (USPTO, Mar. 26, 2025).

The factual issues presented in the Petition are squarely within the Board's technical expertise. The Federal Circuit has repeatedly highlighted the Board's intended role as an administrative tribunal designed to handle technical issues, often highlighting the Board's ability to assess and weigh expert testimony. *See e.g., Synopsys, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309, 1328 (Fed. Cir. 2016), *overruled on other grounds by Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir.

2017) (Newman, J., dissenting) (“The [AIA] vests the PTAB with authority to adjudicate post-grant validity under sections 102 (anticipation) and 103 (obviousness)...These grounds are well suited to resolution by the PTAB whose adjudicators are experienced in technology, for the determination is required to be made from the viewpoint of ‘a person having ordinary skill in the art to which said subject matter pertains,’ the words of section 103.”). This expertise shows that the Board is ideally suited to evaluate patents and technical publications presented here. Additionally, none of the prior art references asserted in the Petition were before the Examiner during prosecution of the ’860 patent. *See* Pet. 1; Ex1003, ¶¶35-64.

Patent Owner suggests that the factual issues in the Petition are “much better suited for” an Article III court. DD Request 16. ***But there is no proceeding before an Article III court.*** This IPR is the first and remains the only proceeding before any tribunal involving the ’860 Patent. Waiting for a dispute to arise in an Article III court would be contrary to the Director’s policy of encouraging early challenges.

V. CONCLUSION

The Director should deny Patent Owner’s request for discretionary denial and institute this IPR on the merits.

Respectfully submitted,

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Dated: October 28, 2025

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CERTIFICATE OF SERVICE

The undersigned certifies that a true copy of the foregoing PETITIONER'S
OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY
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