

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 MOTION TO AMEND

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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 Techniques,” Journal of Food Engineering, Vol. 67, Issues 1-2, March 2005, by Tolkach, et al.

No.	Exhibit
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.
New Exhibits	
Ex1024	Declaration of Dr. Mark Etzel, Ph.D. supporting Petitioner’s Reply
Ex1025	Declaration of Dr. Mark Etzel, Ph.D. supporting Petitioner’s Opposition to Amend

No.	Exhibit
Ex1026	“Technical Report: Whey Protein Heat Stability,” The U.S. Dairy Export Council (USDEC), 2012, by K.J. Burrington
Ex1027	“Caseinomacropeptide influences the functional properties of a whey protein concentrate,” International Dairy Journal, Vol. 60, pp. 14-23, Sept. 2016, by S. Svanborg et al.
Ex1028	“A proteomics approach to characterizing limited hydrolysis of whey protein concentrate,” Food Chemistry, Vol. 350, July 15, 2021, by C. Hinnenkamp et al.
Ex1029	Printout of Dr. Harte’s official web profile page at Pennsylvania State University https://foodscience.psu.edu/directory/fmh14
Ex1030	“Chromatographic Integration Methods,” Royal Society of Chemistry, 2nd ed., 1998, by N. Dyson
Ex1031	U.S. Pat. Appl. Pub. No. US2019/0274331 to Harte et al., published Sept. 12, 2019
Ex1032	Transcript of Dr. Harte’s Deposition
Ex1033	“Essentials of LC Troubleshooting, VI: How Wide Should Those Peaks Be?” LCGC North America, Vol. 40, Issue 12, Dec. 1, 2022, by D. Stoll
Ex1034	“Unit Operations of Chemical Engineering,” 5th ed., 1993, by W. McCabe
Ex1035	“Efficient removal of spores from skim milk using cold microfiltration: Spore size and surface property considerations,” Journal of Dairy Science, Nov. 2018, by E. Griep et al.
Ex1036	Printout of online product listing for “Ultrafree® Centrifugal Filter, 0.4 mL Sample Volume, pore size 0.45 µm,” MilliporeSigma, accessed Aug. 10, 2026 at: https://www.sigmaaldrich.com/US/en/product/mm/ufc30lh25?srsId=AfmBOopqLsCjJ-q2ZUfEsaL1yuWcpJNyrW3UYExWyMPJa7mAuzvsWITu

No.	Exhibit
Ex1037	“Dairy Technology Handbook,” SPX Flow, June 2017
Ex1038	U.S. Pat. Appl. Pub. No. US20210267238 to Lauridsen et al., published Sept. 2, 2021
Ex1039	“Differential Effects of Dry vs. Wet Heating of β -Lactoglobulin on Formation of sRAGE Binding Ligands and sIgE Epitope Recognition,” Nutrients, Vol. 11, Issue 6, June 25, 2019, by Zenker et al.
Ex1040	Printout of online product listing for “Centrifuge Filters 0.45 μ m CA, Micro 800ul Capacity with 2ml Receiver Tube, Non Sterile, pk100, MS CICA45(100),” MicroAnalytix, accessed Aug. 20, 2026 at: https://www.microanalytix.co.nz/centrifugal-filter-ca-2ml-045um
Ex1041	U.S. Pat. Appl. Pub. No. US2012/0114795, published May 10, 2012 to Havea et al.

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I. INTRODUCTION

Patent Owner's ("PO") Motion to Amend (at Paper 22) ("MTA") should be denied. PO proposes substitute claims 21-31 to replace challenged claims 8-9, 11-13, and 15-20. MTA, 2, Appx. A. The proposed amendments do not cure the deficiencies in the original claims but instead introduce new problems while failing to distinguish over the prior art. Substitute claims 21-25 fail the amendment requirements because the amendments create indefiniteness, lack written description and enablement, and, as to claim 25, fail to present a proper substitute claim. Substitute claims 26-31 remain unpatentable because they lack enablement and the combination of Nielsen⁴⁵⁰ and Nielsen⁷⁸⁵ teaches those claims.

II. THE CLAIM LISTING IS DEFICIENT

PO bears the burden to provide a clear claim listing that accurately reflects all proposed modifications. *See* 35 U.S.C. § 316(d); 37 C.F.R. § 42.121(b). PO fails to meet this requirement because the body of its motion directly conflicts with its claim listing. Specifically, the narrative text in the body of the motion purports to modify the claims differently than the actual text set forth in the claim listing section.

For example, the motion's body states that substitute claim 26 requires "*greater than 77.5 wt.%*" denatured whey proteins, but the claim listing recites "*greater than 75%.*" MTA, 13, 20-23, 27. PO also argues that removing "*composition*" from claim 21 was a clarifying amendment, yet dependent claims 22-

24 in both the rest of the motion’s body and the claim listing retained “*composition*”—creating an internal inconsistency that PO never reconciles. *Id.*, 3, 7, 9-10, 26-27. Additionally, the motion’s summary table for claim 23 omits the deletion of “*or about*” from “*less than or about 11 wt. % GMP*,” yet the claim listing in Appendix A shows “*or about*” being deleted. *Id.*, 10, 27.

Without a claim listing that is consistent with the MTA and makes clear what the proposed claim amendments actually are, the MTA is deficient, and the Board should deny it.

III. THE MTA DOES NOT MEET THE STATUTORY AND REGULATORY REQUIREMENTS

PO bears the ultimate burden to show that its motion to amend complies with the requirements of 35 U.S.C. § 316(d)(1), (3) and 37 C.F.R. § 42.121(a)(2), (a)(3), (b)(1), (b)(2), and (d)(1). For the reasons discussed below, PO has not met that burden.

A. The MTA does not propose a reasonable number of substitute claims.

Although PO proposes the same number of substitute claims, PO actually proposes more than one substitute claim for an original claim. Because PO provides no reason why it needs more than one substitute claim for an original claim, its MTA should be denied.

Specifically, PO identified claim 25 as a proposed substitute for original claim 13 (MTA, 4), but it is not. Original claim 13 recited that the denatured whey protein composition is characterized by “*a weight ratio of native GMP to total whey protein of less than or about 0.15*” or by “*less than or about 11 wt.% GMP.*” Ex1001, 24:14-20. Substitute claim 25 deletes those limitations completely and adds *entirely new* and unrelated limitations, including microfiltering through a membrane “*having a pore size of 0.4 micrometers or less*” and that the reduced-GMP retentate have “*at least 5 wt.% denatured protein*” before heating. MTA, 27.

A motion to amend must propose a reasonable number of substitute claims, and the amendment must be responsive to a ground involved in the trial. 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121(a)(2)(i), (a)(3). The Board has required substitute claims to replace, not recast, the challenged claim. *See* 37 C.F.R. § 42.121(a)(2)(i); *Idle Free Sys., Inc. v. Bergstrom, Inc.*, IPR2012-00027, Paper 26 at 5 (PTAB June 11, 2013) (“a proposed substitute claim is not responsive to an alleged ground of unpatentability of a challenged claim if it does not either include or narrow each feature of the challenged claim being replaced”). Claim 25 is effectively a new claim, not a narrowing substitute for claim 13. And to the extent PO meant to propose this as a substitute for a different original claim, PO has not provided any explanation for why it needs two substitute claims for one original claim.

B. The MTA improperly seeks to add new matter to the original claims.

A proposed amendment may not “introduce new subject matter.” 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii). New matter exists when an amendment lacks written description support in the original specification. See *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001).

Substitute claim 21 introduces new matter by claiming a “*reduced-GMP cheese whey retentate*” that the specification does not describe. PO seeks to amend original claim 8 by deleting “*composition*” from “*reduced-GMP cheese whey retentate composition*.” MTA, 3, 7, 25. But the ’860 patent specification describes only retentate *compositions*—not a “*reduced-GMP cheese whey retentate*.” See e.g., Ex1001, 2:7-10, 2:23-25, 2:45-53. Every disclosed embodiment on reducing GMP involves adding materials to, or removing materials from, the retentate before heating—which yields a composition, not a retentate. Dr. Harte admitted that adding an enzyme transforms the material into “*a cheese whey retentate composition*” rather than a “*cheese whey retentate*,” and that dilution or concentration would change the character of the retentate. Ex1032, 118:18-120:6, 123:21-124:3, 85:8-86:3, 88:13-89:2. The ’860 patent itself confirms that microfiltration removes “some or all native proteins,” thus changing the BLG:ALA ratio. Ex1001, 8:8-23. PO’s position is also internally inconsistent: in the PO’s Response (“POR”), PO argued that

“*composition*” is broader and includes additional components (POR, 14-15), yet in the MTA, PO calls the deletion merely “clarifying” (MTA, 3). Dr. Harte’s own testimony undermines PO’s MTA position: he conceded that “removing the word ‘composition’” from the claim “should not change what this is saying” because “a cheese whey retentate is part of a cheese whey retentate composition.” Ex1032, 125:15-126:4. But under PO’s own claim construction, that explanation confirms “composition” is the broader term, and its deletion narrows the claim scope. Because the specification lacks support for a “*reduced-GMP cheese whey retentate*,” the amendment introduces new matter and should be denied.

IV. PROPOSED SUBSTITUTE CLAIMS 21-25 ARE INVALID UNDER SECTION 112.

Proposed substitute claims 21-25 are invalid under Section 112 on three bases:

(1) indefiniteness, (2) lack of written description, and (3) lack of enablement.

A. Claims 21-25 are indefinite.

1. Proposed independent claim 21’s deletion of “composition” renders claims 21-25 indefinite.

A claim is indefinite if, in view of the specification and prosecution history, it fails to inform, with reasonable certainty, a POSITA about the scope of the invention. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). Petitioner may challenge proposed substitute claims under § 112, including for indefiniteness. *Uniloc 2017 LLC v. Hulu, LLC*, 966 F.3d 1295, 1306 (Fed. Cir. 2020). PO’s

substitute claim 21 seeks to amend claim 8 to add a limitation requiring that a further retentate—“*reduced-GMP cheese whey retentate*”—to be formed in one of two ways: “*either enzymatically treating [the cheese whey retentate] with one or more enzymes that selectively hydrolyze GMP or by microfiltering the cheese whey retentate to form a reduced-GMP cheese whey retentate.*” MTA, 7, 25. Accordingly, the plain language of amended claim 21 recites two alternative means for reducing GMP—either enzymatic treatment or microfiltration, and under either alternative, the claim requires the same claimed result of the formation of a “*reduced-GMP cheese whey retentate.*”

Yet PO’s proposed construction of a “*cheese whey retentate*” is “the portion of cheese whey that is captured by the filter after initial filtration of the cheese whey.” MTA, 3. Enzymatic treatment itself does not create a retentate captured by the filter. Ex1025, ¶¶4-6. The ’860 patent describes the enzymatic option as “combining the cheese whey retentate with one or more enzymes that selectively hydrolyze GMP.” Ex1001, 2: 3-11. It likewise states that the enzymes are “added to the whey protein feedstock” to hydrolyze GMP. *Id.*, 6:36-39. Neither “combining” nor “adding” processes produce a retentate, let alone a “*reduced-GMP cheese whey retentate.*”

A POSITA therefore would not have known what the claim requires when the enzymatic option must form a “*reduced-GMP cheese whey retentate.*” Ex1025, ¶¶7-

8. Because the patent fails to explain what the “*reduced-GMP cheese whey retentate*” is or refers to, it fails to reasonably inform a POSITA of the scope of proposed claim 21 (and its proposed dependent claims 22-25).

2. Dependent claims 22-24 have further indefiniteness issues.

The amendments to substitute claims 22-24 create additional indefiniteness issues. In particular, claims 22-24 depend from claim 21 but retain “composition” in “reduced-GMP cheese whey retentate composition.” MTA, 9-10, 26-27. That term no longer has antecedent basis because claim 21 recites only a “reduced-GMP cheese whey retentate.” *Id.* The inconsistency is material. PO’s MTA characterizes deleting “composition” from claim 21 as a clarifying amendment, yet claims 22-24 still use the deleted term. *Id.* The Board should find these claims are invalid as indefinite because it is unclear whether the dependent claims require the narrowed retentate of claim 21 or the broader composition that PO removed. The Board addressed an analogous situation in *Unified Patents Inc. v. KCG Technologies LLC*, IPR2019-01536, Paper 28 (PTAB Feb. 10, 2021). There, the patent owner amended the independent claim to replace “handheld device” with “smartphone” but initially failed to make the same amendment in several dependent claims. The Board’s preliminary guidance found that those dependent claims were indefinite for lacking antecedent basis. *Id.* at 38 (citing Paper 19, Prelim. Guidance (Mar. 15, 2019), at 7-8. The Board held in its final written decision that the dependent claims were indefinite and therefore

unpatentable because they “fail[ed] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Id.* at 40-41. The same situation exists here. PO deleted “*composition*” from claim 21 but left it in claims 22-24. MTA, 9-10, 26-27. A POSITA would not have understood what “*composition*” means in those dependent claims when the independent claim no longer forms a “*composition*,” rendering these claims indefinite. Ex1025, ¶¶9-12.

Additionally, substitute claim 24 recites “exposing the reduced-GMP cheese whey retentate composition to high shear conditions.” MTA, 27. “*High shear*” is indefinite. The specification states that “[m]echanical shear conditions as used herein generally refer to high shear conditions in which at least about $1,000\text{s}^{-1}$ of shear is applied,” and further states that “up to about $500,000\text{s}^{-1}$ of shear is applied.” Ex1001, 8:66-9:4. While “generally” renders this definition merely illustrative and “at least about” provides no clear lower boundary, the more fundamental problem is the specification’s enormous range—from $1,000\text{s}^{-1}$ to $500,000\text{s}^{-1}$ —spanning more than two orders of magnitude. The prior art confirms the ambiguity. Havea (Ex1041) describes shearing rates “not greater than $2,000\text{s}^{-1}$ ” for microparticulating whey protein as “essentially non-shearing conditions.” Ex1041, ¶[0010]. However, this $2,000\text{s}^{-1}$ shear rate—considered non-shearing in the prior art—falls squarely within the “high shear” range disclosed by the ’860 patent. On the other hand, Singer (Ex1016) describes “very high” shear rates of “450,000 to 600,000 and usually about

500,000 reciprocal minutes,” which equals approximately $8,333\text{s}^{-1}$. Ex1016, 17:7-11; Pet., 23-24; Ex1003, ¶¶126-27. Yet $8,333\text{s}^{-1}$ falls near the bottom of the specification’s claimed range and well below the specification’s examples of 10,000-1 to 500,000-1 values. Because shear rates that the prior art considered “essentially non-shearing conditions” ($2,000\text{ s}^{-1}$) and “very high” shear ($8,333\text{ s}^{-1}$) both fall within the “*high shear conditions*” recited in claim 24, a POSITA cannot ascertain the scope of “*high shear conditions*” with reasonable certainty. Ex1025, ¶¶13-15.

B. Claims 21-25 lack written description.

A claim lacks adequate written description where the specification fails to show, with reasonable clarity, that the inventor possessed the claimed invention as of the application’s filing date. *Centrak, Inc. v. Sonitor Techs., Inc.*, 915 F.3d 1360, 1365 (Fed. Cir. 2019).

PO seeks to amend original claim 8 in substitute claim 21 by changing “*reduced-GMP cheese whey retentate composition*” to “*reduced-GMP cheese whey retentate*.” MTA, 7, 25. This amended limitation lacks written description because the ’860 patent specification describes forming cheese whey retentate compositions after reducing GMP, not PO’s newly claimed “*reduced-GMP cheese whey retentate*.” The specification does not disclose how to form a reduced-GMP cheese whey retentate without it being a composition—every disclosed embodiment involves adding materials, removing materials, or performing additional processing steps. Because

the specification lacks support for a “*reduced-GMP cheese whey retentate*” in isolation, rather than as part of a composition, the amendment lacks written description.

In Example 1 of the '860 patent, filtration performed on sweet whey forms WPC80, which is transferred to a holding tank and “mixed with water to make a 14% protein solution.” All of these processes are performed before heating is applied. Ex1001, 15:44-16:24; Ex1025, ¶¶16-18. Similarly in Example 2, feed material is taken from “the retentate side of the microfiltration process,” then is “adjusted to 14% protein” by *adding water* before denaturation. Ex1001, 17:19-25. Those disclosures support, at most, the formation of retentate compositions. They do not describe a “*reduced-GMP cheese whey retentate*” when “*composition*” is omitted. Accordingly, substitute claim 21 (and its proposed dependent claims 22-25) lack written description. Ex1025, ¶¶16-18.

C. Claims 21-25 are not enabled.

A claim is enabled only if a POSITA could make and use the claimed invention without undue experimentation, and the specification itself must disclose the novel aspects of the invention. *Automotive Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1281-83 (Fed. Cir. 2007).

Claim 21 lacks enablement. PO's amendment to claim 21 eliminated “*composition*” and now requires forming a “*reduced-GMP cheese whey retentate*.” But the specification provides no direction or guidance on how to form a “retentate” apart

from a composition. The specification's enzymatic treatment disclosure describes only "combining" or "adding" enzymes to form a mixture—not a retentate. Ex1001, 2:3-11, 6:36-39. Moreover, the specification contains no working examples nor provides any guidance on how enzymatic treatment alone could yield a "*reduced-GMP cheese whey retentate*" that is "captured by the filter" under PO's own construction. MTA, 3. Every example in the specification describes forming a "*composition*," not a standalone "*retentate*." See Ex1001, Examples 1-5. Accordingly, a POSITA would be left to undue experimentation to practice that alternative. Ex1025, ¶19; see *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Claim 21 also lacks enablement because the specification fails to enable the full scope of the claim. Claim 21 requires a BLG:ALA ratio greater than 5.00 but fails to require any minimum amount of these proteins relative to total protein. The claim thus covers an entire spectrum—from trace amounts of BLG and ALA (where other whey proteins dominate) to BLG and ALA-abundant compositions, and everything in between. The specification, however, only discloses examples at the abundant end of this spectrum. Ex1001, 3:10-15, 4:55-65, 8:32-43. The specification's examples rely on BLG's specific denaturation behavior to achieve the claimed benefits of high protein denatured whey protein composition. *Id.*, 5:30-37. When BLG and ALA are present only in trace amounts, the composition's heat treatment behavior would be dominated by other whey proteins, and a POSITA would have no basis

to predict whether the claimed results could be obtained. The specification provides no guidance on achieving the claimed invention when BLG is not the dominant protein. Accordingly, a POSITA could not have practiced the full scope of claim 21 without undue experimentation. Ex1025, ¶¶20-21; *see In re Wands*, 858 F.2d at 737 (identifying “the breadth of the claims” as a factor for undue experimentation).

V. Proposed Substitute Claims 26-31 are unpatentable as lacking enablement and obvious.

Substitute claims 26-31 correspond to original claims 15-20. MTA, 4, 20, 23. Ground 3 of the Petition already showed original claims 15-20 are unpatentable over Nielsen450, including the composition limitations that remain unamended in substitute claim 26 and substitute dependent claims 27-31. Pet., 25-53; Section V.A-V.D, below; Ex1025, ¶22. That analysis applies equally to the unamended limitations of the proposed substitute claims.

PO proposes four amendments to original claim 15: (1) amending the fat content of the recited denatured whey protein composition from greater than 7 wt.% to greater than 11 wt.% on a dry basis; (2) amending the denaturation percentage from greater than 50 wt.% denatured whey proteins to greater than 75 wt.% denatured whey proteins relative to the total weight of the protein; (3) adding a requirement that the recited composition comprise ALA; and (4) adding a requirement that the recited composition be a powder. Claim 26 lacks enablement because the specification provides no guidance on how much ALA is needed to meet

the “*composition...comprises alpha lactalbumin*” requirement, and fails to enable the full scope of the claim. Additionally, the specification also fails to enable the full scope of the recited BLG:ALA ratio limitation for the same reasons discussed above for claim 21. Further, the first three amendments are all taught by Nielsen450, and the fourth (that the composition be a powder) would have been obvious in light of Nielsen450 in combination with Nielsen785. Because proposed substitute claim 26 would have been obvious over Nielsen450 in combination with Nielsen785, claims 27-31 are also unpatentable at least based on their dependency to claim 26.

A. Claim 26 lacks enablement.

Claim 26 lacks enablement because the specification provides no guidance on the quantity of ALA required to enable the full scope of the “*composition...comprises alpha lactalbumin*” limitation . Specifically, the specification provides no standard or minimum quantity of ALA sufficient to meet the claim limitation. As Dr. Etzel explained, protein filtration is not a perfect method, and whey protein compositions obtained through filtration will contain traces of ALA. Ex1025, ¶23. Measuring ALA quantity at low concentrations is particularly challenging because measurement accuracy varies with equipment calibration and user methodology, yet the specification provides no guidance on either. *Id.*, ¶24. Because the claim recites only that the composition “*comprises*” ALA without specifying any minimum quantity, the claim covers an entire spectrum—from trace

amounts of ALA to ALA-abundant compositions—but the specification only discloses examples at the abundant end of this spectrum. *See* Ex1001, 3:10-15, 4:55-65. A POSITA could not have practiced the full scope of claim 26 without undue experimentation. *See In re Wands*, 858 F.2d at 737; Ex1025, ¶25.

B. Nielsen450 teaches the amended fat limitation.

Substitute claim 26 recites a denatured whey protein composition to comprise “*greater than 11 wt.% fat on a dry basis*,” amended from 7% in original claim 15. MTA, 12-13. Nielsen450’s Example 12 discloses “high protein beverages at neutral pH with a lipid content of 25% and 50% of the total energy content.” Ex1007, 109:26-30. It states that “lipids were added” to beverages prepared from BLG powder A to evaluate beverages “in the presence of fat.” Ex1007, 111:1-6. As the Petition and Dr. Etzel’s Declaration supporting the Petition explained for original limitation 15.3, the 3% protein, pH 7.0 composition contained about 3.04 wt.% dry matter from the BLG powder plus 0.45 wt.% lipid. Pet., 50-51; Ex1003, ¶201. That results in about 12.9 wt.% fat on a dry basis. *Id.* Accordingly, Nielsen450 discloses a fat value that exceeds both the original 7 wt.% threshold and claim 26’s amended 11 wt.% threshold. Ex1025, ¶¶26-28.

PO contends that the BLG powders contain only 0.11% fat (MTA, 20-21), but that figure reflects the fat content of the BLG isolate powder alone—not the final product. Specifically, the combination relies on Example 12 of Nielsen450, which

discloses a beverage prepared with lipid and BLG powder. Ex1007, 111:1-112:12. PO's further argument that fat is added to the beverage rather than the powder (MTA, 20-21) is also irrelevant: in the Nielsen450-Nielsen785 combination (which takes Nielsen450's composition and processes it into powder form as discussed in Section V.E below), the final powder contains all the components of the beverage, including fat. Specifically, a POSITA would have taken the heat-treated beverages from Nielsen450's Example 12, which had fat contents of 25% and 50% of total energy, and converted them to powder using Nielsen785's drying process. A POSITA would have understood that fat content relative to total energy remains unchanged during drying because only water is removed and dry matter is retained. Ex1025, ¶28. The resulting powder would thus have the same fat content as the starting beverage, well exceeding claim 26's 11 wt.% threshold.

Moreover, Nielsen785 independently confirms that denatured whey protein powder compositions can include fat. Nielsen785 teaches that its whey protein nanogel composition can be a powder (Ex1005, 36:21-24) and may include macronutrients beyond proteins (*id.*, 40:20-24). Nielsen785 further teaches that the lipid content can be up to 50% of total energy (*id.*, 64:15-16). Because lipids are macronutrients, Nielsen785 teaches a POSITA that denatured whey protein powders can contain significant fat content. Ex1025, ¶29.

C. Nielsen450 teaches or renders obvious the amended denaturation limitation.

As discussed in Section II, the MTA is internally inconsistent on the denaturation degree limitation and fails to conform to 37 C.F.R. § 42.121(b). The MTA's Sections VII-VIII describe claim 26 as requiring "**77.5 wt.%** denatured whey proteins" (MTA, 13, 20-21, emphasis added) while the claim listing in Appendix A recites "greater than [[50]] **75 wt.%** denatured whey proteins" (*id.*, 27, emphasis added).

Regardless of whether PO intended to amend 50 wt.% to 75 wt.% or 77.5 wt.%, Nielsen450 teaches or renders the limitation obvious because a POSITA would have understood that Nielsen450's heating temperature and duration would have resulted in substantial denaturation exceeding either threshold. Ex1025, ¶30.

Nielsen450 stated that the beverages in Examples 11 and 12 are produced by dissolving BLG isolate powder in water and heat treating the resulting solutions in a water bath at 90°C for 5 minutes. Ex1007, 109:28-112:12. Nielsen450 also discloses that BLG isolate powder can have a significant level of protein denaturation in some embodiments, such as when an opaque beverage is desired, with denaturation levels "preferably at least 75%, and most preferably at least 90%." *Id.*, 57:9-13; Pet., 29-30; Ex1003, ¶¶139-41; Ex1025, ¶31. Accordingly, whether the denaturation is achieved through the starting powder or through heat treatment of the aqueous

solution, Nielsen450 teaches or suggests a denaturation level greater than 75% or 77.5%.

A POSITA would have understood that Nielsen450's heating conditions (e.g., 90°C for 5 minutes) resulted in high degrees of denaturation, including complete denaturation, because it was well known that heating at high temperatures (e.g., above 85°C) for the duration used in Nielsen450 results in high degrees of denaturation, including complete denaturation. As explained in the Petitioner's Reply, it was well known that whey protein—and especially BLG—starts denaturing around 77°C and achieves high degrees of denaturation at high temperature (e.g., 85°C-95°C). Pet. Reply, 16-17 (citing Ex1031, ¶¶82, 91; Ex2017, 44-49); Ex1025, ¶¶31-32.

Nielsen450's heating conditions meet and exceed heating conditions described in the prior art. Ex1025, ¶31. For example, Nielsen450 states that Example 11 beverages were "heat treated as described in example 5 in a water bath at 90°C for 5 min." Ex1007, 107:14-20. Example 12 likewise states that the solutions were "heat treated in a water bath at 90°C for 5 min." *Id.*, 111:7-13. Nielsen450's Figure 7 also describes "liquid beverages at 10-16w/w% protein after heat treatment at 90°C for 5 minutes." *Id.*, 4:28-29. Dr. Etzel's replication experiments additionally confirmed 85% denaturation for Example 11 and 77% denaturation for the homogenized Example 12 sample. Pet., 41-48; Ex1003, ¶141; Ex1025, ¶¶32-33. Thus, Nielsen450 explicitly teaches the 75% recited in the MTA's claim appendix. MTA, 25-27. To

the extent PO seeks to revise its claim appendix to 77.5%, Nielsen450 teaches that limitation as well because a POSITA would have understood that Example 11 exceeds that threshold and Example 12 would be around that threshold as well. In addition, it would have been well within the skill in the art to make minor increases to time or temperature to reach a higher denaturation level as suggested by well-known teachings including those discussed in PO's own exhibit Ex2017 (Qian). Ex1025, ¶¶34-35.

D. Nielsen450 teaches its composition comprises ALA.

Nielsen450 teaches its composition comprises ALA because Table 8 reports BLG powder A with ALA "<0.5%" and Table 9 identifies BLG powder A as the powder used in Examples 11 and 12. Ex1007, 104:20-34, 108:20-32, 109:29-110:4, 111:1-13. Heat treatment does not remove ALA from the composition. *Id.*, 41:11-15; Pet., 36-37; Pet. Reply, 25; Ex1025, ¶36.

E. The Nielsen450-Nielsen785 combination renders obvious the recited composition is a powder.

1. A POSITA would have been motivated to perform denaturation on a whey protein solution and then process that solution into a powder.

As discussed in detail below, POSITAs would have been motivated to heat solutions made from Bertelsen's powder for controlled denaturation, as taught in both Nielsen785 and Nielsen450 (and as was widely known in the art), and then

spray-dry that composition into a powder as taught in Nielsen785 for well-known stability and transportation benefits.

- a) **It was well known (and taught by both Nielsen785 and Nielsen450) to perform denaturation on a liquid whey protein solution.**

At the relevant time, it was well known to perform denaturation on liquid whey protein solutions, not dry powders. As Dr. Etzel explains, a POSITA would have understood that such a process (as described in both Nielsen785 and Nielsen450)—dissolving BLG isolate powder in water and then heating to denature—is needed to achieve the desired degree of controlled denaturation, rather than directly heating the dry BLG isolate powder from Bertelsen. Ex1025, ¶¶37-38. This understanding is rooted in well-established principles of whey protein chemistry that demonstrate why denaturation should occur in aqueous solution rather than in dry powder form. As Dr. Etzel explained, the scientific literature confirms that dry heating is inefficient and unpredictable compared to aqueous-phase denaturation because dry heating lacks the molecular mobility needed for controlled protein unfolding. *Id.*, ¶¶39-41 (citing Ex1039, 2, 14, 15; Ex1016, 16; Ex1005, 24:31-34). Accordingly and consistent with Nielsen785's and Nielsen450's disclosures, a POSITA would have understood that water is needed to enable the molecular mobility required for protein unfolding for denaturation to proceed in a controlled manner. *Id.*

b) POSITAs would have been motivated to follow solution-based denaturation with spray drying for stability and transportation benefits.

A POSITA would have known that whey protein products are more stable and easier to transport in powder form, as taught by Nielsen⁷⁸⁵, and would have turned to Nielsen⁷⁸⁵, which discloses detailed processes for drying liquid BLG-products into powder. Ex1025, ¶¶42-43. Specifically, Nielsen⁷⁸⁵ teaches “spray-drying” using a dryer in which the dryer feed comprises a liquid-mixture form of whey protein nanogels. Ex1005, 27:35-28:6. It also states that drying is “*particularly preferred*” because it provides the composition “in the form of a powder” that is “easy to transport” and has “better storage stability.” *Id.*, 24:5-13. Nielsen⁷⁸⁵ further states that nanogel powder can be “rehydrated and homogenized to facilitate its use in a beverage composition.” *Id.*, 107:24-30.

These advantages were well known in the dairy industry and are confirmed throughout the scientific literature. Ex1025, ¶44. “[H]igh density powders [allow] for more cost-effective packaging and logistics of the powder as less packaging material is required per kg powder and more powder (mass) can be transported by a given container or truck.” Ex1006, 70:21-23. Similarly, “high density variants...take up less space during transportation and thereby increase weight of BLG isolate powder that can be transported in one volume unit,” and “[t]he storage stability of the

instant beverage powder may increase when lowering the water content of the powder.” Ex1038, ¶¶[0167], [0434].

PO’s own evidence confirms this understanding: “proteins often have to be made into solid forms to achieve an acceptable shelf life as pharmaceutical products” because of “the limited physical and chemical stability of proteins” in liquid form, and “[s]pray drying is widely used technique in food and pharmaceutical industry as it is relatively economical compared to freeze drying and also it has considerably high throughput.” Ex2013, at 7; Ex2023, at 4-5. Consistent with this, dried dairy powders with less than 5% water content can be stored at temperatures below 27°C with less than 65% relative humidity for 6-24 months. Ex2025, 13, 52, 68; Ex1025, ¶45.

In the combined Nielsen450 and Nielsen785 process, the BLG isolate powder from Nielsen450 (incorporating Bertelsen) is dissolved in water and heated to achieve substantial denaturation, *see* Ex1007, 109:29-110:4, 111:1-13 (describing preparation of high-protein beverages by dissolving BLG powder and heat treating “in a water bath at 90°C for 5 min”), and converted into powder according to the methods described in Nielsen785, *see* Ex1005, 24:5-13, 27:35-28:6 (teaching spray-drying of liquid whey protein nanogel feed to produce powder that is “easy to transport” and has “better storage stability”), so the denatured powder can be added

as a powder into other food products or rehydrated for use in beverage compositions. Ex1025, ¶46.

A POSITA would have been motivated to modify Nielsen450's beverage products in Examples 11 and 12 to apply the drying process disclosed by Nielsen785. Doing so would have amounted to no more than using a known technique (e.g., Nielsen785's drying to convert liquid BLG products into powder) to improve similar products (e.g., Nielsen450's milky beverage) in the same way (e.g., making them easier to transport and improving storage stability). *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007); Ex1025, ¶47.

2. A POSITA would have had a reasonable expectation of success in making the combination.

Nielsen785 denatures a liquid whey protein solution, and then spray dries it into a powder. A POSITA would have understood Nielsen785's spray drying process applies in the same way to Nielsen450's denatured whey protein solution, and would have had a reasonable expectation of success in combining these teachings. Specifically, Nielsen450 produces a beverage that can be made using the same type of BLG powders as those used in Nielsen785. *See* Ex1005, 88:1-89:20; Ex1007, 109:28-112:12. Nielsen450 produces a liquid beverage and Nielsen785's dryer feed "pertains to the *liquid feed* that is fed to a dryer in order to convert the feed to a powder." Ex1005, 24:11-13 (emphasis added); Ex1025, ¶¶48-50.

Additionally, Nielsen450 and Nielsen785 are in the same field of endeavor, further supporting the motivation to combine and reasonable expectation of success. Ex1025, ¶¶48-49. For example, Nielsen450 states that its invention concerns a “packaged, heat-treated beverage preparation” containing BLG (Ex1007, 1:1-5), and Nielsen785 similarly states that its invention concerns “whey protein nanogels” and their use “in food products, such as beverages” (Ex1005, 1:5-11). Additionally, both references identify the same applicant Arla Foods amba. *Compare* Ex1007, Cover with Ex1005, Cover. Accordingly, converting Nielsen450’s denatured BLG composition into powder would have been the predictable use of Nielsen785’s spray-drying technique to obtain transport, storage, and later beverage-use benefits. *KSR Int’l Co.*, 550 U.S. at 417.

F. Claims 27-31 fall with claim 26.

Substitute claims 27-31 depend from claim 26 and correspond to original claims 16-20. MTA, 14-15, 28. PO seeks to amend claims 27-31, only to change their dependency to claim 26 and for claims 28-31 to remove “or about” from numerical thresholds. PO makes no arguments particular to those amendments or dependent claims, either in the MTA (MTA, 23) or in the POR (POR, 46-75). And Petitioner already explained why the additional limitations of these dependent claims were taught by Nielsen450. Pet., 52-56; Ex1003, ¶¶204-76. Removing “or about” from certain limitations does not affect that showing because the Petition did not

rely on that language. Ex1025, ¶¶51-53. The following table summarizes the correspondence between the substitute claims in the MTA and the originally challenged claims, and identifies where each original claim was addressed in the Petition and Dr. Etzel's first declaration:

MTA Claim No.	Original Claim No.	Petition	First Declaration (Ex1003)
27	16	52-53	¶¶204-05
28	17	53	¶¶206-07
29-31	18-20	53-56	¶¶208-16

VI. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that the Board deny PO's Motion to Amend.

Dated: August 25, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 25, 2026 true and correct copies of the foregoing PETITIONER'S OPPOSITION TO MOTION TO AMEND was served via electronic mail upon the following counsel of record for PO:

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