

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 REPLY

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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.

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	CLAIM CONSTRUCTION.....	2
A.	PO’s Construction of “ <i>Cheese Whey Retentate Composition</i> ” Is Not Supported by the Specification	2
B.	PO’s Construction of “BLG:ALA Ratio” as Requiring a Detectable Amount of ALA Should Be Rejected	4
III.	FOUNDATIONS 1-2.....	6
A.	Nielsen785-Bertelsen Describes Producing BLG Powder Using Cheese Whey Retentate.....	6
1.	Bertelsen Identifies Crystallization Feed as UF Retentate	6
2.	The Claims Do Not Require a Single Filtration Step	7
B.	Nielsen785-Bertelsen Discloses Reducing GMP in Cheese Whey Retentate	9
1.	The ’860 Patent Permits Processing Before GMP Reduction	10
2.	The Claim Requires a Cheese Whey Retentate Composition, Not an Unchanged Retentate.....	10
3.	Bertelsen Uses Microfiltration to Separate BLG Crystal Products.....	11
C.	Adjusting Water Content Before Heating Does Not Undermine Bertelsen/Nielsen785’s Disclosure of Limitation 8.3	12
D.	PO’s BLG:ALA Ratio Argument Misreads Nielsen785 and Imports Unsupported Detectability Requirements.....	13
1.	PO Misconstrues Rounding as Absolute Absence of ALA.....	13
2.	The Claims Do Not Require Native Proteins or Detectable ALA.....	14

3. POSITAs Would Have Understood Nielsen785's BLG or ALA Content Does Not Meaningfully Change During Nanogel Preparation.....15

IV. GROUND 3.....16

- A. Nielsen450 Teaches Greater Than 50% Denaturation.....16
 1. Nielsen450's Heating Conditions Cause Substantial Denaturation Exceeding the Claimed Threshold.....16
 2. Patent Owner's Own Evidence Confirms Substantial Denaturation Under Nielsen450's Heating Conditions 16
 3. PO's Arguments About Dr. Etzel's Experiments Do Not Undermine Petitioner's Showing as to Nielsen450.....18
 4. PO's Reliance on an Acidic Nielsen450 Embodiment Should Not Be Credited.....19
- B. The Petition Relies on a Consistent Embodiment in Nielsen450 to Meet the Claimed BLG:ALA Ratio 20
- C. Nielsen450 Incorporates Bertelsen and Discloses the Retentate-Based Limitations.....20

V. GROUND 4.....21

- A. The Petition Shows POSITAs Would Have Been Motivated to Combine the References.....22
 1. Ozturk's Microfiltration Reduces GMP in WPC.....22
 2. POSITAs Would Have Known Ozturk's WPC Contains GMP 22
 3. POSITAs Would Have Understood Ozturk's Microfiltration Reduces GMP in WPC to Form WPPC (the Microfiltration Retentate) 23
 4. Kawasaki Provides a Further GMP-Reduction Rationale 24
- B. POSITAs Would Have Been Motivated to Combine Ozturk and Kawasaki with LeanCreme 24

1.	LeanCreme Discloses Its Process Can Be Used with High Fat Feeds	24
2.	POSITAs Would Have Viewed Ozturk's WPPC As a Suitable LeanCreme Feed	25
C.	The Ozturk, Kawasaki, and LeanCreme Combination Teaches Denaturation Greater than 50%.....	26
1.	Applying LeanCreme to the Reduced-GMP WPPC Achieves Denaturation Greater Than 50%	26
2.	PO Ignores the Level of Ordinary Skill in Its Incorrect Arguments About Which Proteins Denature and At What Rate.	27
3.	PO's Reliance on Ozturk's Table 2 Is Misplaced.....	28
VI.	CONCLUSION	29

I. INTRODUCTION

Patent Owner's Response ("POR") does nothing to diminish the Petition's showing that claims 8-9, 11-13, and 15-20 are unpatentable under 35 U.S.C. §§102, 103. Rather than engage the prior-art disclosures and combinations as presented, Patent Owner ("PO") recasts the claims and references with requirements found nowhere in the intrinsic record. Its principal construction—that a "*cheese whey retentate composition*" must include the exact same retentate formed at an earlier step—would exclude the '860 patent's own enzymatic and microfiltration embodiments, which expressly contemplate processing, dilution, GMP hydrolysis, or GMP removal before heat treatment. PO's separate attempt to require a "detectable" amount of ALA would import an undefined, method-dependent threshold the '860 patent never supplies.

Further, PO misreads technical data to manufacture gaps in the prior art. PO treats Nielsen⁷⁸⁵ Table 13's rounded "0%" ALA as literal absence, ignores that Ozturk Table 2 reports proteomics relative abundance rather than gravimetric total protein, and dismisses milk fat globule membrane ("MFGM") protein denaturation despite contrary experimental evidence. In each instance, PO substitutes its misreading of data for what POSITAs would have actually understood. Dr. Harte's testimony and the record confirm PO's characterizations lack support. The POR

therefore does not rebut Petitioner's unpatentability showing, and the challenged claims should be cancelled.

II. CLAIM CONSTRUCTION

A. PO's Construction of "*Cheese Whey Retentate Composition*" Is Not Supported by the Specification

PO's construction of "*cheese whey retentate composition*" treats the claimed composition as requiring the original "*cheese whey retentate*" plus, at most, added components. That reading contradicts claim language. Claim 8 recites forming a "*cheese whey retentate composition*" by **reducing** GMP from "*cheese whey retentate*." Ex1001, Cl. 8. The term "*cheese whey retentate composition*" is used in conjunction with "*reduced-GMP*" throughout. *Id.*, Cls. 8-9 and 11-13. The '860 patent uses enzymatic hydrolysis and microfiltration to reduce GMP, thus removing components, not merely adding components as PO's construction requires. *See e.g., id.*, Cl. 9.

Electing to process cheese whey retentate by enzymatic hydrolysis does not preclude removing other components. The specification confirms that water can be **removed** from the retentate through concentration, and retentate may also be diluted before processing. Ex1001, 6:34-43. That contradicts PO's construction of "*cheese whey retentate composition*," which allows only the original cheese whey retentate plus optional additives.

The same flaw applies to the microfiltration embodiment, which removes GMP and also allows “some or all native proteins” to pass through and thus be removed from retentate. Ex1001, 8:8-12. Specifically, microfiltration causes “a higher proportion of the α -lactalbumin [to] pass[] through with the permeate,” resulting in higher BLG:ALA ratios compared to before filtration. *Id.*, 8:20-23. Retentates formed by microfiltration have therefore lost GMP and other native proteins (e.g., ALA) relative to the starting retentate. *Id.* This too conflicts with PO’s proposed construction because it is not simply the original cheese whey retentate plus an added component. Ex1024, ¶¶4-7.

Dr. Harte’s testimony confirms the flaws in PO’s construction. He admitted that Example 1 adds enzyme to a “diluted whey protein solution” not a “*cheese whey retentate*,” and could not confirm Example 1 meets claim 8. Ex1032, 117:1-118:1. He further conceded that “removing the word ‘composition’” from the claim “should not change what this is saying.” *Id.*, 125:15-126:4. This further shows PO’s proposed construction is inconsistent with the intrinsic record and should be rejected. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

In contrast, Petitioner’s construction comports with the intrinsic record. “*Cheese whey retentate composition*” is a composition formed to include cheese whey retentate and allows for additional processing. *See* Ex1001, 17:18-33; Ex1024, ¶¶8-9. Petitioner’s construction aligns with the term’s plain meaning, gives meaning

to the term “*composition*,” and is consistent with embodiments of the ’860 patent. *See id.* Accordingly, the Board should adopt Petitioner’s construction and reject PO’s contrary construction.

B. PO’s Construction of “BLG:ALA Ratio” as Requiring a Detectable Amount of ALA Should Be Rejected

PO argues the plain meaning of BLG:ALA ratio “requires that some detectable amount of BLG and ALA must be present.” POR 15-16. But PO’s “detectable amount” requirement should be rejected because it appears nowhere in the ’860 patent. Importantly, PO never defines “detectable,” identifies a qualifying threshold, or points to intrinsic evidence establishing any ALA detection limit. *See id.*; Ex1024, ¶¶10-11.

The challenged independent claims recite a ratio, not a detectability requirement. *See* Ex1001, Cls. 8, 15. The specification discusses BLG:ALA ratios and quantities but never defines the claimed ratio by reference to a “detectable” amount of ALA, much less any minimum detectable threshold. Ex1001, 8:17-39, 17:1-18:14. Nor does the specification’s analytical disclosure supply the missing standard needed for PO’s construction. As Dr. Etzel explains, the ’860 patent describes peak-area quantification of GMP, ALA, and BLG but provides no objective standard for determining when they are “detectable,” and chromatographic peak detection depends on method-specific and operator-specific factors for which the patent supplies no governing standard. Ex1001, 12:10-49; Ex1024, ¶¶12-14.

PO's construction would thus make claim scope depend on undefined variables like instrument sensitivity, laboratory protocol, reporting convention, or operator judgment. *Id.*

That is not permissible. Claim construction must be anchored in the intrinsic record and reflect how POSITAs would have understood the term in view of the claims and specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-17 (Fed. Cir. 2005). Claim scope must inform POSITAs, with reasonable certainty, of the scope of invention; constructions turning on undefined degrees or thresholds are improper where the patent provides no objective boundaries. *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370-74 (Fed. Cir. 2014).

Additionally, PO seeks to use its detectable amount requirement to restrict the claims to an exact BLG:ALA ratio, but that is not what the claims require. Instead, the claims require only that the ratio be greater than 5.00. The Petition explains why POSITAs would have understood a ratio exceeding 5.00 was taught in the prior art, even where ALA exists but below a detectable amount. Pet., 36-37; Ex1003, ¶¶162-63. Put another way, the claims encompass all ratios greater than 5.00, and do not exclude ratios greater than 5.00 but that cannot be exactly calculated because ALA is below a detection limit. Accordingly, the Board should reject PO's unsupported construction.

III. GROUNDS 1-2

A. Nielsen⁷⁸⁵-Bertelsen Describes Producing BLG Powder Using Cheese Whey Retentate

Bertelsen's BLG powder is made from an ultrafiltration ("UF") retentate (Ex1006, 57:3-5), and PO's argument that the powder is made from permeate is incorrect.

1. Bertelsen Identifies Crystallization Feed as UF Retentate

Bertelsen's BLG crystallization feed is a UF retentate derived from sweet whey "conditioned on an ultrafiltration setup," and the "retentate was then concentrated" and seeded for BLG crystallization. Ex1006, 57:3-18. PO and Dr. Harte both acknowledge that Bertelsen uses a UF retentate. POR, 20-21; Ex1032, 136:20-137:9.

PO argues that is insufficient because Bertelsen also teaches a microfiltration ("MF") step. In particular, both experts agree Bertelsen is unclear whether its MF step occurs before or after UF. Ex2006, 118:14-18; Ex1032, 134:16-21, 135:1-6. As explained below, Bertelsen teaches "*cheese whey retentate*" under either reading.

PO argues the MF step occurs first, with MF permeate as UF input. But Bertelsen's MF step is a routine clarification that removes cheese fines and bacteria—a physical separation, not protein separation. Ex2006, 118:6-12; Ex1024, ¶¶15-21; Ex1032, 53:9-17; 54:3-9; 100:24-101:11. Dr. Harte agreed, admitting "clarification is something that I don't see as changing the cheese whey" and that without

clarification, fines and bacteria would remain in the retentate. Ex1032, 53:9-17; 176:6-11; 100:11-101:14.

PO tries to contradict its own expert by arguing that microfiltration would cause protein loss (POR, 21 (citing Ex2012, 8)), but the cited evidence concerns skim milk, not cheese whey—skim milk contains casein micelles absent after cheesemaking, so the reported protein loss is inapplicable. Ex2012, 97; Ex1024, ¶¶26-27; Ex1032, 12:1-6, 17:22-20:8. In Bertelsen, whey proteins pass through the clarification membrane and are subsequently ultrafiltered to form UF retentate. Ex2006, 127:4-21. That UF retentate is a “*cheese whey retentate*” because it results from filtering cheese whey and retaining the whey proteins. Ex1006, 57:3-18.

And if Bertelsen’s UF precedes MF, there is no dispute that a “*cheese whey retentate*” is disclosed. Dr. Harte confirmed that Bertelsen’s process would begin with a cheese whey retentate and that Bertelsen expressly identifies UF retentate as the crystallization feed. Ex1032, 136:12-137:9. Accordingly, under either filtration sequence, Bertelsen discloses using UF retentate as the feed for BLG crystallization. Ex1006, 57:3-5; Ex1024, ¶25.

2. The Claims Do Not Require a Single Filtration Step

Claim 8 recites “*the method compris[es] filtering cheese whey from enzymatically coagulated milk into a cheese whey retentate and a permeate.*” Ex1001, 23:34-37 (emphasis added). PO appears to limit claim 8 to one and only one filtration

process performed on cheese whey before GMP reduction. *See* POR, 19-20. The claim language, however, does not limit filtration process to a single filtration step, nor does it specify a filtration type. The open-ended term “*comprising*,” as recited here, permits additional, unrecited steps. *E.g.*, *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003) (“*comprising*” in a method patent claim indicates that the claim is open-ended and allows for additional steps); *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007) (“‘*comprising*’...is inclusive or open-ended and does not exclude additional, unrecited elements or method steps”).

The specification itself confirms that PO’s “first filtration only” theory is wrong. The ’860 patent describes whey composition feedstock obtained from whey protein concentrate (e.g., WPC80). *See* Ex1001, 6:14-19, 15:44-56. Indeed, Dr. Harte conceded that enzyme is added not to cheese whey retentate but to a “diluted whey protein solution” that has undergone concentration to WPC80 and then diluted. Ex1032, 116:16-117:24, 119:8-13. As Dr. Etzel explains, WPC80 production involves serial processing steps, including microfiltration clarification performed before UF to filter out microscopic fat globules and residual casein fines. Ex1024, ¶¶22-24. PO’s attempt to exclude this type of upstream processing should be rejected.

Dr. Harte's testimony defeats PO's attempt to import a "first filtration only" requirement. He admitted that clarification followed by filtration can still satisfy claim 8, and also confirmed there is no single typical route from sweet whey to WPC80 because the process uses multiple filtration steps with different pore sizes. *Id.*, 77:6-78:25, 31:17-32:2. Thus, Bertelsen's 1.2-micron filtration is part of a routine preparatory process, and POSITAs would have recognized Bertelsen's UF retentate as the claimed "*cheese whey retentate*." Ex1024, ¶¶22-24.

In sum, PO disregards Bertelsen's express disclosure that the BLG crystallization feed was a UF "*cheese whey retentate*."

B. Nielsen785-Bertelsen Discloses Reducing GMP in Cheese Whey Retentate

Bertelsen discloses GMP levels during BLG powder production and GMP reduction in UF retentate. Ex1006, 57:17-32, 60:30-35, 61:11-20, 69:9-20, 70:1-5; Pet., 11-14; Ex1003, ¶¶71-72, 81-85. Bertelsen's BLG crystals remain a composition formed from UF cheese whey retentate, with GMP reduced as BLG crystallizes and separates from non-BLG components. *Id.* PO argues Bertelsen reduces GMP only from a "downstream heterogenous crystallized mixture," not from cheese whey retentate, because limitation 8.2 allegedly requires GMP reduction in the "*exact same* 'cheese whey retentate'" formed in limitation 8.1. POR, 25-32 (emphasis in original). This argument contradicts the specification and imports a restriction the claim does not contain, as explained below.

1. The '860 Patent Permits Processing Before GMP Reduction

The '860 patent states that whey protein retentate “may be concentrated” or “diluted prior to processing,” including by “mixing with water.” Ex1001, 6:34-43. In Example 1, WPC80 retentate is transferred to a holding tank, kept cold at about 45°F (7°C) or less, diluted, and *only then* are enzymes added to hydrolyze and reduce GMP. Ex1001, 15:44-16:11; Ex1024, ¶¶28-29. Thus, PO’s “exact same retentate” theory would exclude '860 Example 1.

Bertelsen’s process is analogous to the '860 patent. In Bertelsen, UF retentate is transferred to a crystallization tank, kept cold at 4°C, and held overnight before using microfiltration to separate BLG crystals. Ex1006, 57:3-32; Ex1024, ¶29. Accordingly, those intervening steps do not remove the process from limitation 8.2.

2. The Claim Requires a Cheese Whey Retentate Composition, Not an Unchanged Retentate

PO’s assertion that BLG isolate powder cannot satisfy the claim because it is “not a retentate” also misconstrues the claim. POR, 30. Limitation 8.2 recites forming a “*reduced-GMP cheese whey retentate composition*.” Ex1001, 23:36-40. Bertelsen’s BLG isolate powder satisfies that language because it is formed using concentrated UF retentate derived from sweet whey and has reduced GMP content. Ex1006, 57:3-32, 69:11-20, 70:1-15; Pet., 10-14; Ex1003, ¶¶71-72, 83-85; Ex1024, ¶¶30-32.

3. Bertelsen Uses Microfiltration to Separate BLG Crystal Products

PO next argues that BLG crystals cannot be a “*cheese whey retentate composition*” because they are separated by centrifugation rather than filtration. POR, 31-32. This argument, however, misunderstands claim 8, which requires reducing GMP without specifying reduction methods, much less requiring that reduction happen only through filtration. Ex1001, 23:36-40. Nonetheless, Bertelsen uses microfiltration to separate BLG crystal products, including a Maxi-Spin filter with a 0.45 μ m CA membrane, which Dr. Etzel explained is known as microfiltration and has a pore size within the microfiltration range. Ex1006, 61:4-10; Ex1003, ¶¶99-102; Ex1024, ¶¶33-34.

Dr. Harte’s testimony confirms that spin filters use a membrane through which liquid passes, and that microfiltration uses filters between 0.1 μ m and 2 μ m. Ex1032, 37:9-14, 32:22-33:1. Bertelsen’s filter size of 0.45 μ m falls squarely within that admitted microfiltration range. Ex1006, 61:4-10; Ex1024, ¶35. Moreover, POSITAs would have known that microfiltration can be performed using both tangential flow and centrifugation methods. Ex1024, ¶¶34-35. Whether its driving force is centrifugal force or hydraulic pressure, the separation mechanism remains passage of liquid through a membrane with a defined pore size. *Id.* Indeed, centrifuge-driven 0.45 μ m CA membranes are commercially listed as microfiltration filters. *Id.* PO’s categorical framing of “centrifugation, not filtration” is not accurate.

C. Adjusting Water Content Before Heating Does Not Undermine Bertelsen/Nielsen785's Disclosure of Limitation 8.3

Bertelsen/Nielsen785 discloses heating a reduced-GMP cheese whey retentate composition. Specifically, Bertelsen forms BLG crystal compositions from UF retentate and dries it into BLG crystal powder. Ex1006, 57:17-32, 69:11-20, 70:1-15. Nielsen785 then uses that BLG powder to prepare whey protein solutions and heats those solutions at 90°C for 14 minutes. Ex1005, 89:1-16; Ex1024, ¶¶36-39.

PO argues that drying and dissolving Bertelsen's reduced-GMP BLG crystal composition means the BLG solution cannot be "*reduced-GMP cheese whey retentate composition*." POR, 33-35. Claim 8 does not require, however, heating the composition immediately after GMP reduction or preclude water from being added before heating. Notably, PO's argument again contradicts the '860 patent specification: Example 2 describes a high-fat WPC feedstock obtained from microfiltration retentate that was "adjusted to 14% protein...*by adding water*" before denaturation. Ex1001, 17:15-29 (emphasis added); Ex1024, ¶¶36-39.

Dr. Harte also confirmed this understanding. He testified that when WPC80 "is mixed with water" the resulting composition remains a "cheese whey retentate" because "only water is changing" and "the ratio of whatever we have in there is not changing." Ex1032, 175:11-16, 176:1-16, 176:24-177:3. Dr. Harte further confirmed that a cheese whey retentate "would still be a cheese whey retentate" if only water is removed. *Id.*, 180:15-22. In sum, both '860 specification and PO's

expert confirm that claim 8 does not preclude adjusting water content after GMP reduction and before denaturation.

D. PO's BLG:ALA Ratio Argument Misreads Nielsen785 and Imports Unsupported Detectability Requirements

1. PO Misconstrues Rounding as Absolute Absence of ALA

PO's BLG:ALA ratio argument fails because it treats Nielsen785's reported "0%" ALA as literal absence rather than the result of rounding or analytical reporting. But POSITAs would have recognized that Table 13 reports ALA and CMP with one significant digit and BLG with two. Ex1024, ¶40. When Table 1 values are rounded to Table 13's precision, they match: ALA 0.2→0, CMP 0.7→1, BLG 96.5→97. Ex1005, Tables 1, 13. As Dr. Etzel explained, this rounding procedure conforms to standard analytical metrology where fractional components of 0.5 or greater are rounded up and values below 0.5 are rounded down, both to the nearest integer. Ex1024, ¶¶41-42.

Table 1 Characteristics of exemplary whey protein powder used for preparation of whey protein nanogels.

Protein source	BLG isolate
pH	5.67
Total solids%	95.2
Protein/total solids %	98.7
Ash %	0.51
Fat %	0.11
Lactose %	<0.09
Pho % of TS	<0.025
Na % of TS	0.025
K % of TS	0.051
Ca % of TS	0.146
Mg % of TS	0.022
Native ALA %	0.2
Native BLG %	96.5
CMP %	0.7
Ca:BLG w/w ratio	0.0016

Table 13 Whey protein nanogel preparations prepared from BLG and WPI

Protein	12%	12%	12%	12%	12%	12%
BLG fraction	100%	80%	75%	66.7%	66.7%	50%
WPI fraction	0%	20%	25%	33.3%	33.3%	50%
aLA, final	0%	2%	2%	3%	3%	5%
BLG, final	97%	88%	86%	83%	83%	76%
CMP, final	1%	4%	5%	6%	6%	9%
pH	6.0	6.0	6.0	6.0	6.2	6.0
Ca in g/g BLG	0.0016	0.0028	0.0032	0.0037	0.0037	0.0048
Na+K	12.2	14.4	15.0	15.9	20.9	17.7
State	Liquid	Liquid	Liquid	Liquid with lumps	liquid	Gel

Annotated Tables 1 and 13 of Nielsen785

PO treats Table 13's rounded "0%" as though ALA completely disappeared. POR, 39-41. But POSITAs would have known that perfect removal is scientifically unrealistic. Ex1024, ¶¶43-47. Nielsen⁷⁸⁵ used the BLG powder of Table 1 to prepare nanogel compositions of Table 13; therefore, Table 13 reflects rounded values, not absolute absence of ALA. Ex1005, 88:8-20, 89:1-16, 106-107, Tables 1, 13; Ex1024, ¶¶43-47.

2. The Claims Do Not Require Native Proteins or Detectable ALA

PO's "detectable ALA" argument is also inconsistent with the plain claim language. Claim 8 requires a BLG:ALA ratio; it does not require a specific amount of ALA or that ALA be "detectable." PO never defines "detectable," and PO's expert-created construction requiring "some detectable amount" of ALA has no basis in the intrinsic record. POR, 15-16; Ex2005, ¶40. As Dr. Etzel explained, requiring "some detectable amount" of ALA without specifying detection methods is scientifically meaningless because ALA is measured by chromatographic peak integration, which depends on software settings, baseline choices, reporting precision, and operator judgment. Ex1024, ¶¶48-49.

Dr. Harte's testimony supports this point. He confirmed that detection limits for whey proteins vary by analytical method, and that it is "very difficult to talk about absolutes" regarding filtration and protein rejection. Ex1032, 146:12-22, 152:2-10, 153:1-6. When asked whether any pore size would give 100% rejection of

ALA, Dr. Harte testified: “I don’t know.” *Id.*, 153:3-6. These admissions undermine PO’s position that “0%” ALA reflects literal absence rather than below-detection-limit or rounded reporting. Ex1024, ¶¶50-51.

PO’s reliance on *Ashland Oil* and *Masimo* is misplaced. *Ashland Oil* concerned integer counts that cannot exist in fractional amounts and *Masimo* addressed duty cycles where 0% meant inactive light sources—neither case is analogous to Nielsen785’s compositional measurements subject to rounding or below-reporting-limit values, and neither supports importing a “detectable amount” requirement where the patent provides no detectability standard. *See* POR, 16, 41; Paper 10, 3; *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, [297] n.22 (Fed. Cir. 1985); *Apple Inc. v. Masimo Corp.*, IPR2020-01524, Paper 29 at 17-18 (PTAB 2022).

3. POSITAs Would Have Understood Nielsen785’s BLG or ALA Content Does Not Meaningfully Change During Nanogel Preparation.

Nielsen785’s nanogel preparation involved dissolving BLG isolate powder in water and heating without adding or removing any protein; PO identifies no separation step that would selectively remove all ALA. Ex1005, 89:1-16. Dr. Harte confirmed that denaturation does not add or remove BLG or ALA, testifying that “denaturization means changes in secondary and tertiary structure” and “is not changes in the primary structure.” Ex1032, 41:21-25, 42:5-6. There is no dispute

that Nielsen785 meets the recited BLG:ALA ratio in Table 1 before heating, and the evidence supports that it continues to meet the cited ratio after heating. Ex1024, ¶52.

IV. GROUND 3

A. Nielsen450 Teaches Greater Than 50% Denaturation

1. Nielsen450's Heating Conditions Cause Substantial Denaturation Exceeding the Claimed Threshold

Nielsen450 plainly teaches heating BLG compositions at high temperature under conditions that POSITAs would have understood cause substantial denaturation, well above the claimed 50% threshold. Specifically, Nielsen450's Examples 11-12 used BLG powder containing 95.9% BLG and heated the resulting beverage compositions at 90°C for 5 minutes. Ex1007, 108:20-32, 109:29-110:4, 111:1-13; Pet., 29-30. When protein solutions are heat-treated at “85-95 degrees C” for “5-20 minutes,” the degree of denaturation is “most preferably at least 80%.” Ex1007, 72:14-32; Ex1003, ¶140; Ex1024, ¶¶53-55. That disclosure alone shows Nielsen450 teaches denaturation above 50%.

2. Patent Owner's Own Evidence Confirms Substantial Denaturation Under Nielsen450's Heating Conditions

Dr. Harte confirmed that a patent publication on which he is a named inventor states that denaturation of “BLG has been reported at temperatures above 77°C” with “complete whey protein denaturation” at 85-92°C. Ex1031, ¶¶[0082], [0091], Figs. 9A-9B; Ex1032, 63:17-24, 64:1-65:11; Ex1024, ¶56.

Qian (PO's exhibit) confirms complete BLG denaturation at 85°C for 10 minutes or 95°C for 5 minutes, illustrating that denaturation increased with both temperature and time. Ex2017, 44-49. Applying Qian's regression model, even 85°C for 1 minute exceeds 50% denaturation (53.5%), and Dr. Etzel's replication of Nielsen450 Examples 11-12 at 90°C for 5 minutes produced 77-85% denaturation, consistent with Qian. Ex2017, 48; Ex1003, ¶¶177, 185-186; Ex1024, ¶57. Accordingly, POSITAs seeking higher denaturation would have simply increased temperature or duration, as Nielsen450 teaches. Ex1007, 72:14-32; Ex2017, 47-50.

Additionally, Dr. Etzel explained that heating Nielsen450 Examples 11-12 at 90°C for 5 minutes would cause *rapid, significant denaturation*. Ex1003, ¶¶139-141, 164-166; Ex1024, ¶58. Dr. Etzel's opinion is supported by other objective evidence of record: Nielsen785 reports that heating BLG at 90°C for 10 minutes produced “*95-97% denaturation*” (Ex1005, 89:29-31; Ex1003, ¶165), and Tolkach similarly states that heating whey at 90°C for 1 hour leads to “*complete denaturation*.” Ex1012, 14; Ex1024, ¶58.

Because Nielsen450's Examples 11-12 heat BLG at 90°C for 5 minutes—squarely within temperature ranges the record associates with significant to complete denaturation—POSITAs would have understood that corresponded to denaturation greater than 50%. Ex1007, 72:14-32, 109:29-110:4, 111:1-13; Ex1024, ¶59.

3. PO's Arguments About Dr. Etzel's Experiments Do Not Undermine Petitioner's Showing as to Nielsen450

PO's remaining arguments about Ground 3 attack experiments that Dr. Etzel performed to provide further evidence of denaturation levels in Nielsen450 Examples 11-12. As discussed above, the record contains other evidence showing POSITAs would have understood Nielsen450 meets that limitation. Ex1024, ¶¶60-62.

Regardless, PO's arguments attacking those experiments are baseless. Ms. Jæger confirmed that Nielsen450's Examples 11-12 used Batch N11 BLG powder A, which she located triple-wrapped with multiple identifying labels. Ex1021, ¶¶4-5, 8; Ex2007, 57:12-24, 63:10-17, 66:2-12. Dr. Etzel inspected and used that batch, finding records consistent with Nielsen450's data and no evidence of substitution or contamination. Ex1003, ¶¶141-148, 177, 185-86; Ex1024, ¶¶63-64. His experiments confirmed Examples 11-12 would have resulted in denaturation exceeding 50%. *Id.*

PO nitpicks those experiments, but its arguments fail. The alleged ALA "discrepancies" (" $<0.5\%$ " in Table 8 vs. "BDL" in Ms. Jæger's declaration) both reflect amounts too small to quantify reliably. POR, 55. The alleged CMP difference likewise reflects near-threshold uncertainty: Table 8 reports CMP for BLG powder A as " $<1\%$," and Ms. Jæger testified the 1.08% value was "very, very close to the detection limit." Ex1007, 104:20-34; Ex2007, 90:17-91:5; Ex1024, ¶¶65-68.

PO also argues storage-related moisture absorption made Dr. Etzel's sample more prone to denaturation. POR, 47-54. But PO provides no objective evidence that the reported dry-matter change (95.19% to 92.18%) made Nielsen450's original composition fail to exceed 50% denaturation under 90°C heat treatment. Even if PO were correct that Nielsen450's original sample denatured slightly more slowly, Nielsen450 teaches 90°C heating and broader 85-95°C, 5-20 minute heat treatments, and POSITAs would have understood how to adjust time and/or temperature to achieve desired denaturation. Ex1007, 72:14-32, 109:29-110:4, 111:1-13; Ex2017, 47-50; Ex1024, ¶¶69-70.

PO's reliance on EFSA is also problematic: EFSA evaluated the safety of BLG as a novel food, not denaturation behaviors, and nothing in EFSA addresses whether a neutral-pH beverage heated at 90°C would exceed 50% denaturation. Ex2011, 1, 4, 17; Ex1024, ¶¶71-72.

4. PO's Reliance on an Acidic Nielsen450 Embodiment Should Not Be Credited

PO also relies on Nielsen450 Example 2, where a 75°C treatment allegedly did not denature BLG. POR, 53. That example is irrelevant. Example 2 concerns production of an *acidic* BLG isolate powder, not neutral-pH beverage compositions of Examples 11 and 12. Ex1007, 97:23-30; Pet., 29-30. POSITAs would have understood that *acidic* nature of Example 2 made BLG more heat-stable and inhibits denaturation. Ex1026, 2. Dr. Harte's testimony also confirmed that pH will affect

protein denaturation. Ex1032, 40:13-17. By contrast, Examples 11-12 are *neutral-pH* compositions where BLG would denature, and POSITAs would not have viewed Example 2 as instructive for Examples 11-12. Ex1007, 109:29-110:4, 111:7-13; Ex1024, ¶¶73-74.

B. The Petition Relies on a Consistent Embodiment in Nielsen450 to Meet the Claimed BLG:ALA Ratio

PO argues Petitioner relied on different compositions. POR, 56-59. That mischaracterizes the Petition, which relied on the same protein source through different stages of processing. Nielsen450 does not add another protein source that would alter BLG:ALA ratio during processing. Ex1007, 109:29-110:4, 111:1-13; Ex1003, ¶¶132-139, 162-163. Additionally, PO argues that Nielsen450's Table 9 (composition of BLG Powder A in Examples 11-12) does not show any ALA. POR, 57-58. However, as Petitioner explained, Table 8 reports *the same powder* (Powder A) as having less than 0.5% ALA, yielding a BLG:ALA ratio of at least 191.8, far exceeding 5.00. Ex1007, 104:20-34, 108:20-32; Pet., 36-37; Ex1003, ¶¶162-163, 207; Ex1024, ¶¶75-77. As explained in Section III.D, "<0.5" reflects a value below detection threshold, not literal absence. Ex1024, ¶77.

C. Nielsen450 Incorporates Bertelsen and Discloses the Retentate-Based Limitations

PO's final Ground 3 argument—that Nielsen450 does not teach reducing GMP in a cheese whey retentate or forming/heating a reduced-GMP cheese whey

retentate composition—depends entirely on PO’s flawed Bertelsen arguments. POR, 59-60. Nielsen⁴⁵⁰’s Examples 11-12 use BLG powders preferably obtained according to Bertelsen (incorporated by reference) to prepare high-protein beverages. Ex1007, 62:7-9, 74:22-24, 79:19-20, 109:29-110:4, 111:1-13; Pet., 27-29; Ex1003, ¶¶135-141, 150-154; Ex1024, ¶78.

As explained above for Grounds 1-2, Bertelsen forms a UF cheese whey retentate, reduces GMP/CMP through BLG crystallization and separation, and forms a reduced-GMP cheese whey retentate composition. Ex1006, 57:3-32, 69:11-20, 70:1-15; Pet., 10-14; Ex1003, ¶¶71-72, 83-85. Nielsen⁴⁵⁰ dissolves that same Bertelsen BLG powder and heats the resulting composition. Ex1007, 109:29-110:4, 111:1-13; Ex1024, ¶79. PO’s contrary argument rests on the same overly narrow “retentate” and “composition” constructions already addressed and should be rejected for the same reasons.

V. GROUND 4

As to Ground 4, PO raises two arguments (1) no motivation to combine and (2) the references do not sufficiently teach greater than 50 wt.% denatured whey proteins relative to total weight of protein. Both are incorrect.

A. The Petition Shows POSITAs Would Have Been Motivated to Combine the References.

1. Ozturk's Microfiltration Reduces GMP in WPC

PO argues that POSITAs would not have been motivated to apply Kawasaki to remove GMP from Ozturk's composition because Ozturk's composition does not report GMP. POR, 61-66. But as discussed below, this argument ignores POSITAs' knowledge of the art.

2. POSITAs Would Have Known Ozturk's WPC Contains GMP

Ozturk undisputedly teaches WPC, and POSITAs would have known that GMP is the third most abundant protein in WPC, after BLG and ALA.

Table 1. Whey Protein Composition²

Whey Protein	WPC %	WPI %
α -lactalbumin	12 to 16	14 to 15
β -lactoglobulin	50 to 60	44 to 69
Glycomacropeptide (GMP)	15 to 21	2 to 20
Serum albumin	3 to 5	1 to 3
Immunoglobulins	5 to 8	2 to 3
Lactoferrin	<1	Not reported

Ex1026, 1, Table 1 (annotated); *see also*, Ex1012, 13-14; Ex1027, 2; Ex1028, 5. PO's argument that Ozturk does not report GMP and therefore cannot motivate GMP reduction (POR, 60-66, 70-71) ignores this well-established background knowledge. Ex1024, ¶80.

Dr. Etzel explains why Ozturk does not explicitly disclose GMP, even though POSITAs would have understood GMP was present. Specifically, Ozturk focuses on characterizing WPPC with an emphasis on MFGM, so its SDS-PAGE/proteomic workflow (which yielded Ozturk's composition reporting) was not a GMP-specific assay. Ex1008, 277-81, 287-91; Ex1024, ¶81. Moreover, Dr. Harte confirmed that "most gels that...we use in the lab to separate proteins in milk are outside the [molecular weight] range of GMP." Ex1032, 141:14-22.

3. POSITAs Would Have Understood Ozturk's Microfiltration Reduces GMP in WPC to Form WPPC (the Microfiltration Retentate)

Ozturk microfilters WPC using 0.1µm membrane to produce WPPC as the MF retentate. Ex1008, 278-79, 293, Fig. 1; Pet., 70-73; Ex1003, ¶¶250-257. POSITAs would have understood this microfiltration reduces GMP. *See e.g.*, Ex1012, 16, 18 (most CMP remained in permeate after 0.1µm microfiltration); Ex1013, 330-31, Table 7; Ex1001, 8:1-14; Ex1024, ¶¶82-83. The Petition relied on, among other evidence, Hinkova (Ex1013) as support for this understanding, which the POR tries to undermine. That attempt fails.

Hinkova reports 70.2% CMP rejection for a 100 nm membrane, meaning ~30% CMP passed into permeate. Ex1013, 330-31, Table 7; Ex1024, ¶83. This confirms that a 100 nm membrane permits GMP permeation and reduces GMP in retentate—consistent with the '860 patent's recognition that 0.08-0.5µm membranes

reduce GMP by allowing native GMP to pass to permeate. Ex1001, 8:1-14; Ex1024, ¶83. Accordingly, Ozturk alone discloses reducing GMP in cheese whey retentate through microfiltration, satisfying limitation 8.2. Pet., 72-73; Ex1003, ¶¶254-257; Ex1024, ¶83.

4. Kawasaki Provides a Further GMP-Reduction Rationale

PO argues POSITAs would not have been motivated to apply Kawasaki to Ozturk's WPPC because Ozturk does not report GMP content. POR, 61-66. This fails because POSITAs knew WPC and WPPC contain GMP (discussed above), and Kawasaki provides a well-known method for further reducing and recovering GMP as a valuable ingredient. Kawasaki teaches GMP permeates during filtration while the majority of whey proteins are retained, and additional filtration steps may further recover GMP. Ex1009, 192-94; Pet., 60-62; Ex1003, ¶¶225-226. As the Petition explained, POSITAs would have been motivated to apply Kawasaki to Ozturk's WPPC to further reduce and recover GMP as a valuable ingredient. Pet., 67-77; Ex1003, ¶¶235-264; Ex1024, ¶¶84-87.

B. POSITAs Would Have Been Motivated to Combine Ozturk and Kawasaki with LeanCreme

1. LeanCreme Discloses Its Process Can Be Used with High Fat Feeds

POSITAs would have been motivated to combine Ozturk and Kawasaki with LeanCreme. Pet., 69-70; Ex1003, ¶¶242-244; Ex1024, ¶¶88-89. PO's contrary

argument rests on the incorrect premise that LeanCreme is limited to low-fat products. POR, 66-70. LeanCreme expressly teaches otherwise: “WPC can be mixed with cream prior to the APV LeanCreme™ process.” Ex1010, 8. Additionally, LeanCreme further states that the dairy product’s creaminess increases with higher fat levels. *Id.*, 19, Table 9. LeanCreme therefore expressly discloses use of its process on whey-protein compositions with added dairy fat. Ex1024, ¶¶88-89.

2. POSITAs Would Have Viewed Ozturk’s WPPC As a Suitable LeanCreme Feed

Ozturk’s WPPC is a whey-derived protein-and-fat composition. Ozturk describes WPPC as a co-product containing protein and fat and identifies it as a source of valuable functional compounds. Ex1008, 279, 298.

LeanCreme teaches using its process on fat-added WPC and heating the WPC products under shear to form creamy microparticulated whey proteins that improve texture, creaminess, stability, and sensory properties. Ex1010, 3-5, 8, 19, 21, 23. Accordingly, in the combined process, LeanCreme’s heating-under-shear process results in protein denaturation in Ozturk’s WPPC product, which otherwise would have remained undenatured. Ex1024, ¶¶88-89. Accordingly, POSITAs would have been motivated to apply LeanCreme’s heat-and-shear process to Ozturk’s WPPC, achieving predictable results including enhanced flavor and mouthfeel as well as improved product stability. Pet., 68-70; Ex1003, ¶¶242-244; Ex1024, ¶¶88-89.

C. The Ozturk, Kawasaki, and LeanCreme Combination Teaches Denaturation Greater than 50%

1. Applying LeanCreme to the Reduced-GMP WPPC Achieves Denaturation Greater Than 50%

PO argues LeanCreme's statement that "up to 75% of the protein can be microparticulated" means only up to 75% denaturation is achievable. POR, 73. But that 75% figure is specific to the sweet whey composition in Figure 2 of LeanCreme. Ex1010, 7, Fig. 2. The Dairy Technology Handbook confirms that LeanCreme recovery verified in actual plants is "approx. 75-82%," explaining that recovery "is limited by the content of NPN and GMP," which "are not affected by heat and can therefore not be transformed into LeanCreme™ particles." Ex1037, 56. The recovery value reflects the denaturation level because small undenatured proteins are lost in the whey, meaning denatured, microparticulated proteins are recovered. Ex1010, 19-20. POSITAs would therefore have understood that applying LeanCreme's microparticulation process to Ozturk's WPPC would achieve denaturation of at least 75-82% of total protein. Pet., 84-85; Ex1003, ¶¶285-287; Ex1024, ¶¶90-91.

Ozturk's WPPC contains less GMP and NPN than sweet whey because microfiltration removes these small proteins. Ex1008, 278-79, Fig. 1. POSITAs would therefore have expected reduced-GMP WPPC to achieve denaturation at least in the 75-82% range, and likely higher. Ex1024, ¶92.

LeanCreme's particle size data further support high denaturation. WPC materials undergo microparticulation when heated to 60-85°C under controlled shear, producing mean particle sizes of 3.98-4.855µm. Ex1010, 6-11, 13, 15-16, Figs. 6-8. Undenatured proteins are an order of magnitude smaller and could not form particles in this range without first denaturing and aggregating. Ex1010, 20; Ex1024, ¶93.

2. PO Ignores the Level of Ordinary Skill in Its Incorrect Arguments About Which Proteins Denature and At What Rate.

Contrary to PO's argument (POR, 73-74), MFGM proteins and "other proteins" in Ozturk's WPPC would in fact denature in LeanCreme's process. Swaminathan demonstrated that MFGM proteins, BLG, and ALA underwent denaturation at 50-80°C, with 79% of total protein sedimenting at 80°C. Ex1014, 12253-55, Table 3; Ex1024, ¶94.

PO also argues that lactose in WPPC protects BLG from denaturation. POR, 74-75. This fails. POSITAs would have known to overcome any slowing effect by adjusting LeanCreme's process parameters (e.g., increasing heating time and/or temperature) to achieve denaturations taught in LeanCreme. Ex1010, 6, 20; Ex1024, ¶95. PO also argues caseins in WPPC would not denature. POR, 74-75. This also fails. Caseins are present only in low abundance (approximately 2.3% of total protein), and moreover, under the '860 patent's TKN-based denaturation test,

caseins are counted as denatured protein because they precipitate at pH 4.6 just like heat-denatured whey proteins. Ex1008, 290, Table 2, Fig. 4c; Ex1001, 14:16-40; Ex1024, ¶95.

3. PO's Reliance on Ozturk's Table 2 Is Misplaced

PO relies on Table 2's categorical breakdown showing 45.42% "milk proteins" to argue that Ozturk's WPPC cannot achieve greater than 50% denaturation. POR, 73-74. But Table 2 reports relative protein abundances from a proteomics analysis, not the gravimetric "total weight of protein" that Claim 8 uses as the denominator. Ex1008, 287-91, Table 2; Ex1024, ¶96.

The '860 patent's TKN-based denaturation method measures all nitrogenous protein without differentiating between BLG, ALA, MFGM, or other proteins. Ex1001, 13:56-15:10; Ex1024, ¶97. Under this method, all proteins in Ozturk's WPPC listed in Table 2's proteomics breakdown are likewise counted in the denominator. LeanCreme achieves 75-82% recovery of microparticulated protein from sweet whey, with recovery limited by NPN and GMP contents. Ex1037, 56; Ex1024, ¶¶97-99. Because Ozturk's WPPC contains less GMP and NPN than sweet whey, POSITAs would have expected WPPC achieving at least 75-82% denaturation using LeanCreme's method. Ex1008, 278-79, Fig. 1; Ex1024, ¶¶97-99.

VI. CONCLUSION

Petitioner requests the Board find claims 8-9, 11-13, and 15-20 unpatentable as obvious over the prior art.

Dated: August 25, 2026

Respectfully submitted,

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CERTIFICATE OF WORD COUNT

I hereby certify that the foregoing PETITIONER’S REPLY includes 5,594 words (as calculated by Microsoft Word), excluding those in a table of contents; a table of authorities; a listing of facts that are admitted, denied, or cannot be admitted or denied; a certificate of service or word count; or an appendix of exhibits. Accordingly, this Reply is under the word count limit of 5,600 words.

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