

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

U.S. Patent No. 11,825,860

**THIRD DECLARATION OF DR. MARK ETZEL, PH.D.
UNDER 37 C.F.R. § 1.68 IN SUPPORT OF PETITIONER'S OPPOSITION
TO PATENT OWNER'S MOTION TO AMEND**

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I, Mark Etzel, hereby declare as follows:

I. Introduction

1. I have been retained on behalf of Arla Foods AMBA (“Arla” or “Petitioner”) to provide technical opinions in support of Petitioner’s Opposition to Patent Owner’s Motion to Amend in this inter partes review of U.S. Patent No. 11,825,860. I understand that Patent Owner has proposed substitute claims 21-31, which correspond to originally challenged claims 8-9, 11-13, and 15-20.

2. I am being compensated for my time at my standard consulting rate. My compensation is not contingent on the substance of my opinions or on the outcome of this proceeding. I have no financial interest in the outcome of this matter.

3. I have reviewed Patent Owner’s Motion to Amend, the declaration of Dr. Federico Harte, relevant deposition testimony and exhibits cited by the parties, my first declaration (Ex1003), and the technical materials discussed below. My prior background, qualifications, understanding of the level of ordinary skill in the art, and prior technical background discussion from my first declaration continue to apply here unless I state otherwise.

II. Substitute claims 21-25 are indefinite

A. Independent claim 21 is indefinite

4. Patent Owner’s Motion to Amend adds a limitation to claim 21 requiring that reducing GMP in cheese whey retentate be completed in one of two

ways: “*either enzymatically treating with one or more enzymes that selectively hydrolyze GMP or by microfiltering the cheese whey retentate to form a reduced-GMP cheese whey retentate.*” The plain language of amended claim 21 thus recites two alternative means for reducing GMP—either enzymatic treatment or microfiltration—and under either alternative, the claim requires the same claimed result: the formation of a “*reduced-GMP cheese whey retentate.*”

5. Enzymatic treatment does not create a retentate. Enzymatic hydrolysis is a chemical process, not a filtration process. There is no membrane involved, no separation of a liquid into a retentate and permeate, and no portion of material “captured by a filter.” The ’860 patent’s own specification confirms this. When describing the enzymatic option, the ’860 patent describes “combining the cheese whey retentate with one or more enzymes that selectively hydrolyze GMP.” Ex1001, 2:36-39. It likewise states that the enzymes are “added to the whey protein feedstock” to hydrolyze GMP. *Id.*, 7:7-9. Neither “combining” nor “adding” processes involve any filtration step or produce any retentate. The ’860 patent specification does not explain or clarify what a “*reduced-GMP cheese whey retentate*” means in the context of the enzymatic hydrolysis option. The specification distinguishes between the starting “*cheese whey retentate*” (the product of the initial filtration step) and the “*reduced-GMP cheese whey retentate composition*” that results after GMP reduction. But the specification never explains how adding

enzymes to hydrolyze GMP would “*form*” a new filtration retentate. In fact, the specification confirms that the enzymatic process involves “combining” enzymes with the retentate and “adding” enzymes to the whey protein feedstock—language that describes modifying an existing material, not creating a new filtration product. *See id.*, 6:44-7:48.

6. In my opinion, this creates a fundamental technical inconsistency in amended claim 21. The claim requires that the enzymatic option must “*form a reduced-GMP cheese whey retentate*,” yet the enzymatic treatment described in the ’860 patent involves simply adding enzymes to hydrolyze GMP in the cheese whey retentate—it does not form a new retentate. The enzymes chemically break down the native GMP molecules into smaller peptide fragments, but this chemical transformation does not involve any filtration step that would create a new “*retentate*” in the technical sense of that term.

7. Accordingly, a POSITA would not have known what the claim requires when the enzymatic option itself must form a “*reduced-GMP cheese whey retentate*.” From a POSITA’s perspective, if the enzymatic treatment involves adding enzymes to a cheese whey retentate to hydrolyze GMP, the resulting product is not a retentate—it is an enzyme-treated solution that still contains the whey proteins, the hydrolyzed GMP fragments, and the enzymes. No filtration has occurred, and no new retentate has been formed.

8. Because the patent fails to explain what the “*reduced-GMP cheese whey retentate*” is or refers to in the context of enzymatic treatment, the claim fails to reasonably inform a POSITA of its scope. A POSITA reading the claim would be left to guess or speculate about what product the enzymatic alternative is supposed to produce when that process does not involve any filtration step that could create a retentate.

B. Claims 22-25 are indefinite

1. Claims 22-25 are indefinite because they retained the term “composition”

9. Dependent claims 22-25 depend from amended claim 21 and are indefinite for the same reasons as I explained above in Section II.A. I also observed that dependent claims 22-24 retained the term “*composition*” in their recitation of “*reduced-GMP cheese whey retentate composition*,” while independent claim 21 deleted that term and now recites only “*reduced-GMP cheese whey retentate*.”

10. The fact that claims 22-24 still use the deleted term—while Patent Owner argues the term was unnecessary in claim 21—creates an internal contradiction that leaves a POSITA unable to ascertain the intended claim scope.

11. In my opinion, a POSITA would be unable to determine with reasonable certainty what claims 22-24 require. If the “*reduced-GMP cheese whey retentate composition*” in claims 22-24 is the same as the “*reduced-GMP cheese whey retentate*” in claim 21, then the use of different terminology is misleading and

creates unnecessary ambiguity. If, on the other hand, the “*reduced-GMP cheese whey retentate composition*” in claims 22-24 is something different from the “*reduced-GMP cheese whey retentate*” in claim 21, then a conflicting result would arise: the same GMP reduction process performed on the same starting material—“*cheese whey retentate*”—would yield two different products. Specifically, limitation 21.2 recites “*reducing native [GMP] in the cheese whey retentate...to form a reduced-GMP cheese whey retentate,*” whereas claim 22 recites “*the reduction of native GMP in the cheese whey retentate...[forms] the reduced-GMP cheese whey retentate composition.*” MTA, 7, 9. That is, the same process would yield “*reduced-GMP cheese whey retentate*” under claim 21 but “*reduced-GMP cheese whey retentate composition*” under claim 22.

12. Accordingly, claims 22-24 are indefinite because a POSITA cannot determine from the claim language whether the dependent claims require the narrowed “*reduced-GMP cheese whey retentate*” of claim 21 or the broader “*reduced-GMP cheese whey retentate composition*” that Patent Owner removed from claim 21.

2. Claim 24 reciting “high shear” is indefinite

13. Substitute claim 24 recites “*exposing the reduced-GMP cheese whey retentate composition to high shear conditions.*” MTA, 27. In my opinion, the term

“*high shear*” is indefinite because a POSITA cannot ascertain its scope with reasonable certainty.

14. First, the specification provides no clear definition of “*high shear conditions*.” The specification only 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. In my opinion, the word “generally” renders this definition merely illustrative rather than definitive, and the phrase “at least about” provides no clear lower boundary. More fundamentally, the specification’s enormous range—from $1,000\text{ s}^{-1}$ to $500,000\text{ s}^{-1}$ —spans more than two orders of magnitude, offering no meaningful guidance as to what constitutes “*high shear conditions*.”

15. Second, the prior art confirms this ambiguity. Havea (Ex1041) describes shear rates of “not greater than $2,000\text{ s}^{-1}$ ” as “essentially non-shearing conditions” for microparticulating whey protein. Ex1041, ¶[0010]. However, the $2,000\text{ s}^{-1}$ value falls squarely within the ’860 patent’s disclosed “*high shear*” range of $1,000\text{ s}^{-1}$ to $500,000\text{ s}^{-1}$. Thus, conditions the prior art considered “non-shearing” would qualify as “*high shear*” under the patent’s description. On the other hand, Singer (Ex1016) describes shear rates of “450,000 to 600,000 and usually about 500,000 reciprocal minutes” as “very high” shear. Ex1016, 17:7-11; Pet., 23-24;

Ex1003, ¶¶126-27. Converting these units, 500,000 reciprocal minutes equals approximately $8,333\text{ s}^{-1}$. This “very high” shear value falls near the bottom of the ’860 specification’s exemplary “*high shear conditions*” values ($1,000\text{ s}^{-1}$ to $500,000\text{ s}^{-1}$). *See* Ex1001, 8:66-9:4. 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.

C. Claims 21-25 lack written description

16. Patent Owner 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. In my opinion, this amended limitation lacks written description because the ’860 patent specification describes forming cheese whey retentate compositions after reducing GMP, not Patent Owner’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.

17. The specification's examples confirm this lack of support. In Example 1 of the '860 patent, sweet whey was filtered to form WPC80, which is transferred to a holding tank and "mixed with water to make a 14% protein solution." Ex1001, 15:44-16:24. All of these processes are performed before heating is applied. Similarly, in Example 2, feed material is taken from "the retentate side of the microfiltration process" and "adjusted to 14% protein" by adding water before denaturation. Ex1001, 17:15-24. These disclosures support, at most, the formation of retentate compositions—not a "*reduced-GMP cheese whey retentate*" when the word "*composition*" is omitted.

18. Accordingly, in my opinion, substitute claim 21 and its proposed dependent claims 22-25 lack written description.

D. Claims 21-25 lack enablement

19. In my opinion, claim 21 does not teach a POSITA how to make and use the claimed subject matter without undue experimentation. Patent Owner's amendment to claim 21 eliminated the word "*composition*" and now requires forming a "*reduced-GMP cheese whey retentate*." But the specification provides no direction or guidance on how to form a new "retentate" apart from changing the composition by adding materials, removing materials, or performing additional processing steps. The specification's enzymatic treatment disclosure describes only "combining" or "adding" enzymes to form a mixture—not forming a new retentate.

Ex1001, 2:21-37, 6:44-7:39. Moreover, the specification contains no working examples and provides no guidance on how enzymatic treatment alone could yield a “*reduced-GMP cheese whey retentate*” that is “captured by the filter” under Patent Owner’s own construction. Paper 22, 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.

20. 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. However, the examples in the specification 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 and benefits could be obtained.

21. Accordingly, in my opinion, a POSITA could not have practiced the full scope of claim 21 without undue experimentation. Dependent claims 22-25 inherit claim 21's limitations and therefore also lack enablement.

III. Substitute claims 26-31 are unpatentable

22. Substitute claims 26-31 are amended claims based on originally challenged claims 15-20, which I addressed in my first declaration regarding Ground 3. The Petition demonstrated that claims 15-20 are unpatentable based on Nielsen450. I address below the new claim amendments in substitute claims 26-31 and explain why those claims remain unpatentable.

A. Substitute claim 26 lacks enablement

23. In my opinion, claim 26 lacks enablement because the “*composition...comprises alpha lactalbumin*” limitation provides no guidance on the quantity of ALA required to satisfy the claim and fails to enable the full scope of the claim. The specification provides no standard or minimum quantity of ALA sufficient to meet the claim limitation. Protein filtration is not a perfect method, and whey protein compositions obtained through filtration will always contain traces of ALA. A POSITA would have understood that no filtration separation process achieves perfect removal. For example, distillation requires an infinite number of plates for perfect removal of the heavy component from a feed stream flowing into the distillate. Ex1034, 545-47. Likewise, filtration and crystallization processes

cannot selectively remove every last molecule of a protein such as ALA from the feed stream, and achieving 100% rejection is scientifically unrealistic. To illustrate, 14 grams of the whey protein ALA contains approximately 6.023×10^{20} molecules—on the order of one hundred quintillion. For at least these reasons, a POSITA would have understood that trace amounts of ALA would remain even after BLG crystallization or membrane filtration, because complete molecular removal of ALA would require an infinite separation factor that no real-world process can achieve.

24. Additionally, 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. ALA may be measured by chromatographic peak integration, as evidenced by the '860 patent itself. Ex1001, 12:39-43 (“Quantity of each protein component is determined by comparing the peak area of each component peak to the total peak areas.”). Whether a small peak is reported may depend on the analytical method, software settings, peak-integration parameters, baseline selection, reporting precision, and operator judgment. In chromatographic analysis, peaks are located where the signal’s first derivative departs from zero by more than a prescribed threshold known as “slope sensitivity”—“the smallest shift in baseline position which the integrator sees as a positive or negative slope.” Ex1030, at 159, 162. The expected range of slope sensitivity values varies because “different columns,

detectors and sample types all contribute to the range.” *Id.* at 162. Moreover, the analyst retains discretion to “over-rule the integrator and enter an alternative value for slope sensitivity, for example, to allow more micro-peaks to be seen if these are important.” *Id.* Even the initial values for peak width and slope sensitivity “require revision and updating” as analyses progress, and “may be programmed to increase on a timed basis via a time program.” *Id.* at 163. Additionally, whether small peaks are detected depends on the integrator’s and user’s adjustment of bunch width, which “varies the qualifying time, allowing selective filtration of small peaks.” *Id.* at 165.

25. Additional literature confirms that peak detection is influenced by method-specific parameters. “Peak width in any chromatogram is dependent on many factors, including the size and other physicochemical characteristics of the analyte; the mobile phase flow rate, temperature, and viscosity; and the particle size, pore structure, and chemistry associated with the stationary phase.” Ex1033, at 562. Furthermore, “the more time the analyte spends in the column, the wider its peak is at the detector.” *Id.* at 563. Because the claim recites only that the composition “*comprises*” ALA without specifying any minimum quantity or measurement method, 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. Accordingly, a

POSITA could not have practiced the full scope of claim 26 without undue experimentation.

B. Substitute claims 26-31 are unpatentable over Nielsen450 in combination with Nielsen785

1. Nielsen450 teaches the fat limitation

26. Proposed claim limitation 26.3 requires a denatured whey protein composition to comprise “*greater than 11 wt.% fat on a dry basis.*” Paper 22, Appx. A, 27. Nielsen450’s Example 12 discloses a composition that satisfies this limitation.

27. Example 12 of Nielsen450 describes “high protein beverages at neutral pH with a lipid content of 25% and 50% of the total energy content.” Ex1007, 111:1-2. The reference states that “lipids were added” to beverages prepared from BLG powder A to evaluate the products “in the presence of fat.” Ex1007, 111:1-6.

28. As explained in my first declaration for original limitation 15.3, the 3% protein, pH 7.0 composition in Example 12 contained about 3.04 wt.% dry matter from the BLG powder plus 0.45 wt.% lipid, resulting in about 12.9 wt.% fat on a dry basis. Pet., 50-51; Ex1003, ¶201. This fat value exceeds both the original 7 wt.% threshold in claim 15 and the amended 11 wt.% threshold in claim 26. 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 during the spray drying process while dry matter is retained in the dried product. This is a fundamental principle of food science: spray drying removes moisture but does not remove or destroy the dry matter. The resulting powder would thus have the same fat content as the starting beverage, well exceeding claim 26's 11 wt.% threshold.

29. Moreover, Nielsen785 independently confirms that denatured whey protein powder compositions can include fat. Nielsen785 teaches that its whey protein nanogel composition can be provided as a powder (Ex1005, 36:21-24), and that this powder composition is not limited to protein alone—it may also include other macronutrients (Ex1005, 40:20-24). Nielsen785 specifically identifies lipids as one such macronutrient and teaches that lipid content can constitute up to 50% of total energy (Ex1005, 64:15-16). Because lipids are macronutrients, Nielsen785 expressly teaches a POSITA that denatured whey protein powders can contain significant fat content. This teaching reinforces that a POSITA would have had no difficulty achieving the fat limitation in claim 26 when combining Nielsen450 with Nielsen785.

2. Nielsen450 teaches or renders obvious the denaturation limitation

30. As a threshold matter, Patent Owner's Motion is internally inconsistent on the denaturation degree limitation, reciting either 77.5 wt.% or 75 wt.% denatured whey proteins in different sections. Regardless of whether Patent Owner intended to amend 50 wt.% to 75 wt.% or 77.5 wt.%, it is my opinion that Nielsen450 teaches or renders either limitation obvious.

31. Nielsen450 states that the beverages in Examples 11 and 12 are produced by dissolving BLG isolate powder in water and heating the resulting solution in a water bath at 90°C for 5 minutes. Ex1007, 109:32-110:1, 111:11-13. Nielsen450 teaches that when protein solutions are heat-treated at "85-95 degrees C" for "5-20 minutes," the resulting degree of denaturation is "most preferably at least 80%." Ex1007, 72:14-32.

32. A POSITA would have understood that the beverages prepared in Examples 11 and 12 achieved high denaturation levels, including levels of 90% or greater, through the heat treatment step. My replication experiments confirmed 85% denaturation for Example 11 and 77% denaturation for Example 12 after the water bath heating. Pet., 41-42, 46-47; Ex1003, ¶¶177, 185. A POSITA would have understood that heating at 90°C for 5 minutes would result in significant denaturation of the whey proteins.

33. My replication experiments confirmed this understanding. The replication confirmed 85% denaturation for Example 11 and 77% denaturation for the homogenized Example 12 sample. Pet., 41-48; Ex1003, ¶141. Nielsen⁴⁵⁰ therefore meets the 75% wording in Appendix A. The reference also renders the 77.5% limitation obvious because a POSITA could predictably increase time or temperature to reach a higher denaturation level, as suggested by Nielsen⁷⁸⁵ and well-known teachings including those discussed in Patent Owner's own exhibit Ex2017 (Qian).

34. Nielsen⁷⁸⁵ expressly teaches that “a high level of BLG denaturation gives a better heat-stability of the resulting whey protein nanogels composition” and that heating should be performed “for a duration sufficient to denature at least 50% w/w of the native BLG, more preferably at least 80% w/w of the native BLG, even more preferably at least 90% of the native BLG and most preferably at least 95% w/w of the native BLG.” Ex1005, 20:16-26. A POSITA would thus have understood that higher denaturation levels were expressly preferred and would have been motivated to increase the time or temperature of Nielsen⁴⁵⁰'s heating step to achieve such higher denaturation if necessary.

35. Patent Owner's own exhibit Ex2017 (Qian) further confirms that whey protein denaturation increases with both temperature and heating time. Qian reports that whey proteins completely denatured when heated at 85°C for 10 minutes or at

95°C for 5 minutes, and shows that denaturation increased from 27.31% to 46.50% at 75°C and from 65.30% to 100% at 85°C as heating time extended. Ex2017, 47-48. Qian’s quadratic regression models confirm the well-known relationship between heat treatment conditions and denaturation, providing a POSITA with clear guidance on how to predictably increase denaturation levels by increasing temperature or time. Ex2017, 48-49. A POSITA seeking to meet any higher denaturation threshold would have found it obvious to simply extend the heating duration and/or increase the temperature of Nielsen450’s heat treatment.

3. Nielsen450 teaches its powder comprises ALA

36. Nielsen450 teaches that its composition comprises ALA. Table 8 of Nielsen450 reports that BLG powder A contains ALA at “<0.5%,” and Table 9 identifies BLG powder A as the starting material used in Examples 11 and 12. Ex1007, 104:20-34, 108:20-32, 109:29-110:4, 111:1-13. The “<0.5%” designation indicates that ALA is present in the powder—albeit below a certain reporting threshold—rather than completely absent. Because heat treatment does not remove ALA from the composition (Ex1007, 41:10-15; Pet., 36-37; Pet. Reply, 25), the ALA present in the starting BLG powder remains in the final denatured composition.

4. The combination of Nielsen450 and Nielsen785 teaches or renders obvious limitation 26.6

37. Claim 26 newly requires that the denatured whey protein composition is “*a powder*” and “*comprises alpha lactalbumin.*” Paper 22, Appx. A, 28. As I

explain below, the Nielsen450-Nielsen785 combination teaches or suggests both of these limitations.

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

(a) It was well known to perform denaturation on a liquid whey protein solution

38. It was well known to perform denaturation on liquid whey protein solutions, not dry powders. A POSITA would have understood that Nielsen450's process—dissolving BLG isolate powder in water and then heating to denature—is needed to achieve controlled denaturation, rather than directly heating the dry BLG isolate powder from Bertelsen. This understanding is rooted in well-established principles of whey protein chemistry that demonstrate why denaturation should preferably occur in aqueous solution rather than in dry powder form, and that denaturing BLG powder by direct dry heating can be inefficient, unpredictable, and destructive.

39. First, controlled denaturation of whey proteins is favored in an aqueous environment because water enables the molecular mobility needed for protein unfolding, intermolecular contact, and aggregation. Wet heating of BLG produces more aggregation and polymer formation than dry heating. Ex1039, 2 (“[w]et heating of β -lactoglobulin (BLG) results in relatively more aggregation and the formation of polymers with a molecular weight (MW) > 10 kDa compared to dry

heating”). This difference is not merely a matter of temperature; it reflects the different physical environment in which the protein molecules move and react. In wet systems, molecular mobility is higher, which increases the rate of protein aggregation. *Id.*, 14 (“reactant mobility during the wet heating also affects the aggregation rate of proteins, where higher inter-molecular mobility results in higher protein aggregation”). The greater translational motion in wet systems also favors formation of covalent cross-links between protein molecules, leading to more extensive aggregation. *Id.*, 15 (“[d]ue to the higher translational motion in the wet system compared to the dry system the formation of these covalent linkages is favored in the wet system leading to higher extend of aggregation”). Thus, without the aqueous-phase mechanism that permits unfolding, collision, and aggregation, dry heating is not expected to achieve the same controlled structural changes. Accordingly, a POSITA would have understood that water is needed to provide the molecular mobility required for whey protein denaturation to proceed in a controlled manner. Specifically, convection heating a stirred liquid solution ensures a uniform temperature distribution that is impossible to achieve with large-scale conduction heating of dry powder. A liquid beverage composition can be heated with stirring in a tank or other controlled environment where convection heat transfer created by stirring the liquid is much more efficient and uniform throughout the composition than the slower conduction heat transfer through a solid such as a powder. This is

especially true at manufacturing scale where powders are stored in silos or holding tanks 10 feet in diameter. Heat transfer through a stagnant 10-foot distance of powder would take many days compared to a few seconds for stirring of a liquid during heating in the same tank. Indeed, Nielsen⁷⁸⁵ confirms that heating whey protein solutions under controlled conditions produces predictable, quantifiable denaturation, stating that the insoluble whey protein particles are typically produced by heating a solution of whey protein having an appropriate pH while subjecting the solution to a high degree of internal shear. Ex1005, 24:31-34.

40. Second, dry proteins lack the molecular mobility of wet systems, making controlled denaturation more difficult. Dry protein powders resist structural change precisely because they lack sufficient free water to facilitate unfolding and molecular rearrangement. In food-science terms, dry protein powders have low water content and low water activity, which makes them inherently more stable to further protein denaturation than wet protein solutions. Chemical transformations, including protein denaturation and aggregation, occur much more readily in wet liquid foods with high water activity because the reactants have greater molecular mobility. By contrast, in dry foods with low water activity, the same transformations proceed very slowly because the available water is limited and the protein molecules have less freedom to move, unfold, and react with one another.

41. Third, attempting to overcome this dry-state stability by applying higher temperatures can lead to charring, uneven heating, and chemical degradation rather than controlled denaturation. Attempting to heat dry whey protein concentrates is problematic because air trapped between the dry particles has poor heat transfer, becoming a barrier to uniform heating, resulting in poor protein denaturation uniformity spatially within the dry powder product. Ex1016, 16:1-18. In practical terms, localized hot spots may develop before the entire powder mass reaches conditions sufficient for controlled protein unfolding. This means that heating dry BLG powder to temperatures sufficient to attain a target protein denaturation at the coldest spot may trigger excessive protein denaturation at the hottest spot and make it impossible to attain uniform protein denaturation spatially throughout the material. Accordingly, a POSITA would have performed controlled denaturation of BLG in an aqueous environment, where mixing of the protein solution solves the problem of spatial variation of temperature during the protein denaturation step. On the other hand, the liquid-based heating approach followed by spray drying preserves protein functionality and the denatured structure. Spray drying rapidly removes water from the denatured protein solution, producing a stable dry powder that retains the denaturation level achieved by heating the liquid. This is consistent with industry practice where spray drying is used to stabilize dairy protein compositions for long-term storage and transport.

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

42. As Nielsen785 teaches, whey protein products are more stable and easier to transport in powder form. A POSITA would have recognized these advantages and turned to Nielsen785, which discloses detailed processes for drying liquid BLG-products into powder.

43. 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. Nielsen785 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.” Ex1005, 24:5-13. The reference further states that nanogel powder can be “rehydrated and homogenized to facilitate its use in a beverage composition.” Ex1005, 108:24-30.

44. The dairy industry well understood the advantages of dehydration into a powder, as confirmed throughout the scientific literature. Transporting water at the price of protein is financially unattractive. Bertelsen explains that high density dry protein powders allow for more compact packaging because less packaging material is required per kg dry powder and more powder mass can be transported in a given container or truck without also transporting the water. Ex1006, 70:18-23. US 2021/0267238 to Lauridsen et al. similarly teaches that high density variants take up

less space during transportation, thereby increasing the weight of BLG isolate powder that can be transported in one volume unit, and that the storage stability of instant beverage powder may increase when lowering the water content of the wet protein solution. Ex1038, ¶¶0167, 0434.

45. Patent Owner's own evidence confirms this understanding. Because proteins have limited physical and chemical stability in the presence of water, they often have to be dehydrated to achieve an acceptable shelf life. Ex2013, at 7. Spray drying is the preferred method for this dehydration because it is relatively economical compared to freeze drying and has considerably higher throughput. Ex2023, at 4-5. Patent Owner's own exhibit, the Dried Dairy Ingredients Handbook, further acknowledges that dried dairy powders produced by these methods—with less than 5% water content—can be stored at temperatures below 25°C with less than 65% relative humidity for 6-24 months. Ex2025, at 13, 52, 68.

46. The combined Nielsen450 and Nielsen785 process dissolves the BLG isolate powder from Nielsen450 (incorporating Bertelsen) in water and heats it to achieve substantial denaturation. Ex1007, 109:29-110:4, 111:1-13. The denatured composition is then converted into powder according to the methods described in Nielsen785. Ex1005, 24:5-13, 27:35-28:6. The resulting denatured powder can be added as a powder into other food products or rehydrated for use in beverage compositions.

47. A POSITA would have been motivated to modify Nielsen450's beverage products in Examples 11 and 12 to include the drying process disclosed by Nielsen785. This modification applies a known technique—Nielsen785's drying to convert liquid BLG products into a dry powder—to improve similar products such as Nielsen450's milky beverage in the same way, namely by making them easier to transport and improving storage stability.

b. A POSITA would have had a reasonable expectation of success

48. A POSITA would also have combined these teachings with a reasonable expectation of success because Nielsen450 produces a beverage that can be made using the same type of BLG powders as those used in Nielsen785. Ex1005, 88:1-89:20; Ex1007, 109:28-112:12.

49. Nielsen450 and Nielsen785 are both assigned to Arla Foods AMBA and are in the same field of endeavor: dairy protein processing. Ex1005, Cover; Ex1007, Cover. Both references use BLG powder to make protein products, and both produce neutral pH products using the same type of BLG powder. Nielsen785 discloses that its spray drying method uses a liquid as a feed, which is exactly what Nielsen450's Example 12 makes: a liquid beverage. Ex1005, 27:35-28:6; Ex1007, 111:1-13.

50. Spray drying of dairy protein compositions was a well-established technique at the time of the invention. Spray drying is widely used in the food and pharmaceutical industry and has been the most frequently used milk drying technique for more than thirty years. A POSITA would have had a reasonable expectation that applying Nielsen785's spray drying process of a denatured whey protein to Nielsen450's denatured whey protein beverage made using a spray dried denatured whey protein powder would produce a stable, transportable protein powder while retaining the protein denaturation level achieved during the solution-phase wet heating step.

C. Dependent claims 27-31 fall with independent claim 26

51. Substitute dependent claims 27-31 depend directly or indirectly from claim 26 and do not add any limitations that change my analysis. Claims 27-31 are unpatentable for the same reasons discussed above for claim 26 because each claim incorporates all the limitations of claim 26 and is therefore taught or rendered obvious by the combination of Nielsen450 and Nielsen785. Additionally, the experimental data I generated in replicating Nielsen450's experiments, as described in my first declaration, are incorporated herein and are equally applicable to claims 27-31.

52. Patent Owner amended claims 28-31 to remove the phrase "or about" from before the numerical limitations. It is my understanding that this amendment

narrows the scope of those claims. Because my first declaration demonstrated that the prior art disclosed or suggested the broader numerical ranges (i.e., “greater than or about” the specified values), the prior art necessarily also discloses or suggests the narrower ranges now recited in the amended claims.

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 in my first declaration (Ex1003):

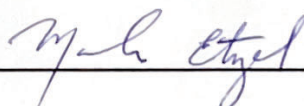
MTA Claim No.	Original Claim No.	Petition	First Declaration (Ex1003)
27	16	52-53	¶¶204-05
28	17	53	¶¶206-07
29-31	18-20	53-56	¶¶208-16

IV. Conclusion

54. For the reasons set forth above, and based on the full evidentiary record I have reviewed, the proposed substitute claims 21-31 are unpatentable. My opinions are based on my education, research, consulting experience, review of the record, and technical understanding of dairy protein processing, membrane separations, GMP reduction, BLG/ALA analytical measurements, and whey protein denaturation.

55. This declaration and my opinions herein are made to the best of my knowledge and understanding, and based on the material available to me at the time of signing this declaration. I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Date: 23 August 2026



Mark Etzel