

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ARLA FOODS AMBA,

Petitioner

v.

LEPRINO FOODS COMPANY

Patent Owner

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Case IPR2025-01199

Patent No. 11,825,860

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**PATENT OWNER'S CONTINGENT MOTION TO AMEND**

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## **I. Introduction**

Patent Owner Leprino Food Company (“Patent Owner”) submits this Contingent Motion to Amend (“Motion”) under 37 C.F.R. § 42.121. Patent Owner respectfully requests that the Board substitute Challenged Claims 8-9, 11-13, and 15-20 with the respective Substitute Claims 21-31 as explained below. 37 C.F.R. § 42.22(a)(2); 35 U.S.C. § 316(d).

## **II. Statement of Relief Requested**

Patent Owner requests preliminary guidance from the Board on this Contingent Motion to Amend pursuant to 37 C.F.R. § 42.121(e). Patent Owner respectfully requests that the Board grant this contingent motion with respect to Substitute Claims 21-31, to replace Challenged Claims 8-9, 11-13, and 15-20, respectively. Patent Owner hereby moves to amend U.S. Patent No. 11,825,860 (the “860 patent”) contingent upon whether certain instituted claims are found unpatentable in the present trial. 37 C.F.R. § 42.121. The Substitute Claims are proposed on a contingent basis and should only be entered as to any corresponding original claims found to be unpatentable. The proposed amendments are detailed in the claim listing at Appendix A. 37 C.F.R. § 42.121(b); 37 C.F.R. § 42.22(a)(2); 35 U.S.C. § 316(d).

### III. Claim Construction

Claims 8.2 and 8.3 recite “cheese whey retentate” and “cheese whey retentate composition.” The plain and ordinary meaning of a “cheese whey retentate” is the portion of cheese whey that is captured by the filter after initial filtration of the cheese whey, as opposed to a cheese whey permeate, which passes through the filter. Ex. 1001, 2:2-11, 18:18-24; Ex. 2005, ¶ 37. The adjective “reduced-GMP” sufficiently modifies “cheese whey retentate composition” such that the term “composition” is redundant and has thus been deleted from Substitute Claim 21. Ex. 1001, 2:2-11, 18:18-24; Ex. 2005, ¶¶ 38-38; *See Am. Nat’l Mfg. Inc. v. Sleep No. Corp.*, 52 F.4<sup>th</sup> 1371, 1380 (Fed. Cir. 2022) (permitting clarifying amendments so long as the amendment also responds to a ground of unpatentability).

### IV. Legal Standard for Amending Claims

This Motion must be granted if the Board finds that: (1) Patent Owner has proposed a reasonable number of Substitute Claims; (2) the Substitute Claims do not enlarge the scope of the claims or introduce new matter; (3) the amendments are responsive to the grounds of unpatentability; and (4) the Substitute Claims are not shown by a preponderance of the evidence to be unpatentable. *Memorandum re: Guidance on Motions to Amend in view of Aqua Products* (Nov. 21, 2017) at 2. It is Petitioner’s burden to show that the proposed Substitute Claims are

unpatentable. *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 4 (PTAB Feb. 25, 2019) (precedential).

## V. Claim Listing and Number of Claims

Pursuant to 37 C.F.R. § 42.221(b), Appendix A includes a claim listing that indicates the changes made to the instituted claims of the '860 patent that would be replaced under this Motion. The listing of claims includes one Substitute Claim for each of Instituted Claims 8-9, 11-13, and 15-20 as listed below.

| Challenged Claim | Contingent Substitute Claim |
|------------------|-----------------------------|
| 8                | 21                          |
| 9                | 22                          |
| 11               | 23                          |
| 12               | 24                          |
| 13               | 25                          |
| 15               | 26                          |
| 16               | 27                          |
| 17               | 28                          |
| 18               | 29                          |
| 19               | 30                          |
| 20               | 31                          |

The number of proposed Substitute Claims is reasonable under 35 U.S.C. § 326(d)(1)(B) and 37 C.F.R. § 42.221(a)(3). There is a rebuttable presumption that one substitute claim per challenged claim is reasonable. 37 C.F.R. § 42.221(a)(3); *Western Digital Corp. v. SPEX Techs., Inc.*, IPR2018-00082, Paper 13, 4-5 (April 25, 2018).

## **VI. Scope of the Substitute Claims**

The Substitute Claims comply with 35 U.S.C. § 326(d)(3) and 37 C.F.R. § 42.221(a)(2)(ii) because no Substitute Claims enlarges the scope of the claim that it replaces. As explained below, the amendments to Challenged Claims 8-11, 13, 15, and 17 reflected in corresponding Substitute Claims 21-31 are all narrowing amendments.

### **a. Substitute Claims 21-25**

Independent Substitute Claim 21 is narrower than Challenged Claim 8 which did not recite a fat content of cheese whey from enzymatically coagulated milk, did not recite reducing GMP by enzymatic treatment or microfiltration, and did not recite the denatured whey protein composition comprises alpha lactalbumin. Substitute Claims 22-25 are narrowing amendments because they depend ultimately from narrowed Substitute Claim 21. Substitute Claim 23 also deletes the term “about” for clarity. *See Am. Nat’l*, 52 F.4<sup>th</sup> at 1380.

### **b. Substitute Claims 26-31**

Independent Substitute Claim 26 narrows the scope of Challenged Claim 15 by narrowing both the range of wt.% fat on a dry basis from greater than 7% to greater than 11% and the range of wt.% denatured proteins from greater than 50% to greater than 75% and requiring alpha lactalbumin. Substitute Claims 27-31 now include the limitations of narrower Substitute Claim 26. Claims 28-31 also delete the term “about” for clarity.

## VII. Written Description Support

As explained below, the proposed Substitute Claims are fully supported by U.S. Patent Application No. 18/097,003 (“the ’003 Application”) and thus comply with the written description requirement.<sup>1</sup> Ex. 1002, 366-395.

| Cl.    | Limitation                                                                                                                                                                                                                                                | Support from the ’003 Application (Ex. 1002)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 21.pre | A method of making a denatured whey protein composition, the method comprising:                                                                                                                                                                           | Original Claim 8. Ex. 1002, 356-357.<br><br>“Embodiments of the present technology also include a method of making a denatured whey protein composition.” Ex. 1002, 368.<br><br>“A method of making a denatured whey protein composition, the method comprising:...” Ex. 1002, 356.                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 21.1   | filtering cheese whey from enzymatically coagulated milk into a cheese whey retentate and a permeate, <u>wherein the cheese whey from enzymatically coagulated milk has a fat content of about 16 wt.% or greater based upon a dry basis weight</u> ; and | Original Claim 8. Ex. 1002, 356-357.<br><br>“[F]iltering cheese whey from enzymatically coagulated milk into a cheese whey retentate and a permeate...” Ex. 1002, 356.<br><br>“The <i>whey composition feedstock utilized herein may be obtained from a cheesemaking process</i> , a whey protein concentrate, a whey protein isolate, <i>such as derived from cow's milk</i> , or a combination thereof. In some embodiments, the whey feedstock may be generated from the cheesemaking process and may be referred to as <i>"sweet whey" when the cheesemaking process uses rennet enzymes like chymosin . . .</i> ” Ex. 1002, 374.<br><br>“[I]n some embodiments of the present technology, <i>a high fat content feedstock can be utilized having a fat</i> |

<sup>1</sup> The ’003 Application and corresponding ’860 Patent have identical specifications.

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|      |                                                                                                                                                                                                                                                                                   | <i>content of about 7% or greater, based upon the dry basis weight of the whey protein feedstock, . . . such as about 16% or greater . . .</i> ” Ex. 1002, 376 (emphases added).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 21.2 | reducing native glycomacropeptides (GMP) in the cheese whey retentate <u>by either enzymatically treating with one or more enzymes that selectively hydrolyze GMP or by microfiltering the cheese whey retentate</u> to form a reduced-GMP cheese whey retentate composition; and | <p>Original Claim 8. Ex. 1002, 356-357.</p> <p>“[R]educing native glycomacropeptides in the cheese whey retentate to form a reduced-GMP cheese whey retentate composition;...” Ex. 1002, 357.</p> <p>“The method includes filtering cheese whey from enzymatically coagulated milk, creating a retentate and a permeate, <i>combining the cheese whey retentate with one or more enzymes that selectively hydrolyze GMP in the cheese whey retentate to form a reduced-GMP cheese whey retentate composition. . . .</i>” Ex. 1002, 368 (emphasis added)</p> <p>“In embodiments, the <i>reduction of GMP includes combining the cheese whey retentate with one or more enzymes that selectively hydrolyze GMP in the cheese whey retentate or the reduction of GMP occurs through the microfiltration of the cheese whey retentate.</i>” <i>Id.</i>, 369 (emphasis added).</p> |
| 21.3 | heating the reduced-GMP cheese whey retentate <del>composition</del> to form the denatured whey protein composition,                                                                                                                                                              | <p>Original Claim 8. Ex. 1002, 356-357.</p> <p>“[H]eating the reduced-GMP cheese whey retentate composition to form the denatured whey protein composition;...” Ex. 1002, 357.</p> <p>Figure 1 shows native GMP is reduced in the cheese whey retentate and the reduced-GMP cheese whey retentate is denatured.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 21.4 | <u>wherein the denatured whey protein composition comprises alpha lactalbumin;</u>                                                                                                                                                                                                | <p>Original Claim 8. Ex. 1002, 356-357.</p> <p>Figure 3B shows the capillary electrophoresis profile of a denatured whey protein composition and specifically shows the denatured whey protein composition comprises alpha lactalbumin. Ex. 1002, 183, 371.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

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|      |                                                                                                                              | <p>Example 1 lists BLG:ALA ratios of 3.37 and 3.31. Example 2 lists a BLG:ALA ratio of 7.65. Ex. 1002, 389, 391. A non-zero BLG:ALA ratio requires the composition to comprise ALA.</p>                                                                                                                                                                                                                                                                                                                                                                                                  |
| 21.5 | and wherein the denatured whey protein composition is characterized by at least 60 wt. % whey protein on a dry weight basis; | <p>Original Claim 8. Ex. 1002, 356-357.</p> <p>“[W]herein the denatured whey protein composition is characterized by at least 60 wt.% protein on a dry weight basis;...” Ex. 1002, 357.</p> <p>“[T]he final protein contains about 45 wt.% or more denatured whey proteins...such as about 60 wt.% or more...” Ex. 1002, 378.</p> <p>“Embodiments of the present technology also include a denatured whey protein composition. The composition includes at least 60 wt.% protein on a dry weight basis.” Ex. 1002, 369.</p>                                                              |
| 21.6 | less than 11 wt. % native GMP relative to a total weight of protein in the denatured whey protein composition;               | <p>Original Claim 8. Ex. 1002, 356-357.</p> <p>“[L]ess than 11 wt.% native GMP relative to the total weight of the protein;...” Ex. 1002, 357.</p> <p>“[A] denatured whey protein composition according to the present technology can include less than 12 wt.% native GMP based on the total weight of protein in the denatured whey protein composition, such as about 11 wt.% or less...” Ex. 1002, 379.</p> <p>“The denatured whey protein composition may be characterized by containing...less than 11 wt.% GMP relative to the total weight of the protein...” Ex. 1002, 368.</p> |
| 21.7 | a proteolysis index of at least 8.0 wt. % or a beta-lactoglobulin to alpha lactalbumin ratio of greater than                 | <p>Original Claim 8. Ex. 1002, 356-357.</p> <p>“[A] proteolysis index of at least 8.0 wt.% or a beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00; and...” Ex. 1002, 357.</p>                                                                                                                                                                                                                                                                                                                                                                                           |

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|      | 5.00; and                                                                                                                                                                                                                                                                                                                                    | "The denatured whey protein composition may be characterized by containing . . . a proteolysis index of at least 8.0 wt.% or a beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00..." Ex. 1002, 368.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 21.8 | greater than 50 wt.% denatured whey proteins relative to the total weight of the protein in the denatured whey protein composition.                                                                                                                                                                                                          | <p>Original Claim 8. Ex. 1002, 356-357.</p> <p>"[G]reater than 50 wt.% denatured whey proteins relative to the total weight of the protein." Ex. 1002, 357.</p> <p>"[T]he final protein contains about 45 wt.% or more denatured whey proteins relative to the total weight of the proteins in the whey protein composition...such as about 60 wt.% or more..." Ex. 1002, 378.</p> <p>"Embodiments of the present technology also include a denatured whey protein composition. The composition includes . . . greater than 50 wt.% denatured whey proteins relative to the total weight of the protein." Ex. 1002, 369.</p>                                                                                                                                                                                                                                                                                                            |
| 22   | The method of claim [[8]] <b>21</b> , wherein the reduction of native GMP in the cheese whey retentate includes combining the cheese whey retentate with one or more enzymes that selectively hydrolyze GMP in the cheese whey retentate to form the reduced-GMP cheese whey retentate composition, the one or more enzymes that selectively | <p>Original Claim 9. Ex. 1002, 357.</p> <p>"The method of claim 8, wherein the reduction of GMP includes combining the cheese whey retentate with one or more enzymes that selectively hydrolyze GMP in the cheese whey retentate to form the reduced-GMP cheese whey retentate composition, the one or more enzymes that selectively hydrolyze GMP in the cheese whey retentate comprises at least one alkaline serine protease enzyme and at least one neutral protease enzyme..." Ex. 1002, 357.</p> <p>"[R]educing native glycomacropeptides in the cheese whey retentate to form a reduced-GMP cheese whey retentate composition;..." Ex. 1002, 357.</p> <p>"In embodiments, the reduction of GMP includes combining the cheese whey retentate with one or more enzymes that selectively hydrolyze GMP in the cheese whey retentate . . . . In more embodiments, the one or more enzymes that selectively hydrolyze GMP in the</p> |

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|    | hydrolyze GMP in the cheese whey retentate comprises at least one alkaline serine protease enzyme and at least one neutral protease enzyme, <del>or wherein the reduction of GMP occurs through the microfiltration of the cheese whey retentate.</del> | cheese whey retentate includes at least one alkaline serine protease enzyme and at least one neutral protease enzyme. Ex. 1002, 369.                                                                                                                                                                                                                                                                                                                                                 |
| 23 | The method of claim [[8]] <u>21</u> , wherein the reduced-GMP cheese whey retentate composition is heated to a temperature of greater than or about 160°F.                                                                                              | Original Claim 11. Ex. 1002, 357.<br><br>“The method of claim 8, wherein the reduced-GMP cheese whey retentate composition is heated to a temperature of greater than or about 160°F.” Ex. 1002, 357.<br><br>“In still additional embodiments the reduced-GMP cheese whey retentate composition is heated to a temperature of greater than or about 160°F.” Ex. 1002, 369.                                                                                                           |
| 24 | The method of claim [[8]] <u>21</u> , wherein the heating of the reduced-GMP cheese whey retentate composition further comprises exposing the reduced-GMP cheese whey retentate composition to high shear conditions.                                   | Original Claim 12. Ex. 1002, 357.<br><br>“The method of claim 8, wherein the heating of the reduced-GMP cheese whey retentate composition further comprises exposing the reduced-GMP cheese whey retentate composition to high shear conditions.” Ex. 1002, 357.<br><br>“In more embodiments, the heating of the reduced-GMP cheese whey retentate composition further includes exposing the reduced-GMP cheese whey retentate composition to high shear conditions.” Ex. 1002, 378. |
| 25 | The method of claim [[8]] <u>21</u> ,                                                                                                                                                                                                                   | “In some embodiments, <i>the low native GMP and high fat levels discussed above in the high fat feedstock can</i>                                                                                                                                                                                                                                                                                                                                                                    |

|        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | <p>wherein <b><u>reducing the native GMP comprises microfiltering the cheese whey retentate through a microfiltration membrane having a pore size of 0.4 micrometers or less and wherein the reduced-GMP cheese whey retentate, prior to the heating, includes at least 5 wt. % denatured protein.</u></b> 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, and/or wherein the denatured whey protein composition is characterized by less than or about 11 wt.% GMP relative to the total weight of the protein in the denatured whey protein composition.</p> | <p><i>be obtained</i> or improved by utilizing a microfiltration membrane (<i>such as a microfiltration membrane having a pore size of</i> about 0.5 micrometers or less, <i>such as about 0.4 micrometers or less</i>, such as about 0.3 micrometers or less, or such as about 0.08 micrometers or greater, or any ranges therebetween) filtration process.” Ex. 1002, 376-77 (emphasis added).</p> <p>“However, it should be understood that, in some embodiments, <i>at least a portion of the proteins in the whey protein composition are denatured prior to heating</i>. For instance, in some embodiments, <i>the whey protein feedstock may have about 5 wt.% or more denatured protein</i> based upon the total weight of the protein in the whey protein feedstock, such as about 20 wt.% or more, such as about 25 wt.% or more, such as about 30 wt.% or more, such as about 35 wt.% or more, such as about 40 wt.% or more, or any ranges or values therebetween.” Ex. 1002, 387 (emphases added).</p> |
| 26.pre | A denatured whey protein composition                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Original Claim 14 (issued as Claim 15). Ex. 1002, 358.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

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|      | comprising:                                                                               | <p>“A denatured whey protein composition comprising:...” Ex. 1002, 358.</p> <p>“The present technology overcomes these issues by providing denatured whey protein compositions, such as powdered or denatured whey protein compositions” Ex. 1002, 373.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 26.1 | at least 60 wt.% protein on a dry weight basis;                                           | <p>Original Claim 14 (issued as Claim 15). Ex. 1002, 358.</p> <p>“[A]t least 60 wt.% protein on a dry weight basis;...” Ex. 1002, 358.</p> <p>See analysis for Substitute Claim Limitation 21.5 above, which recites the same limitation.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 26.2 | less than 11 wt.% native glycomacropeptide (GMP) relative to total weight of the protein; | <p>Original Claim 14 (issued as Claim 15). Ex. 1002, 358.</p> <p>“[L]ess than 11 wt.% native GMP relative to total weight of the protein;...” Ex. 1002, 358.</p> <p>“[T]he denatured whey protein composition is characterized by less than or about 11 wt.% GMP relative to the total weight of the protein.” Ex. 1002, 369.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 26.3 | greater than <u>[[7]]</u> <b>11</b> wt.% fat on a dry basis                               | <p>Original Claim 14 (issued as Claim 15). Ex. 1002, 358.</p> <p>“[G]reater than 7 wt.% fat on a dry basis;...” Ex. 1002, 358.</p> <p><b><i>“In some embodiments as discussed above, the denatured whey protein composition may be considered to be “high fat” and have a fat content of about 7% or greater, based upon the dry basis weight of the whey protein feedstock, such as about 8% or greater, such as about 9% or greater, such as about 10% or greater, <b>such as about 11% or greater</b>, such as about 12% or greater, such as about 13% or greater, such as about 14% or greater, such as about 15% or greater, such as about 16% or greater, such as about 17% or greater, such as about 18% or greater, such as about 19% or greater, such as about 20% or greater, such as about 20.5% or greater, or any ranges or values therebetween.” Ex. 1002, 380</i></b></p> |

|      |                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
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|      |                                                                                                                                    | (emphases added).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 26.4 | a beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00; and                                                          | Original Claim 14 (issued as Claim 15). Ex. 1002, 358.<br><br>“a beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00; and...” Ex. 1002, 358.<br><br>See analysis for Substitute Claim limitation 21.7 above, which recites the same limitation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 26.5 | greater than [[50]] <b><u>77.5</u></b> wt.% denatured whey proteins relative to the total weight of the protein; <b><u>and</u></b> | Original Claim 14 (issued as Claim 15). Ex. 1002, 358.<br><br>“greater than 50 wt.% denatured whey proteins relative to the total weight of the protein.” Ex. 1002, 358.<br><br><i>Nonetheless, after heating, or in the denatured whey protein composition of the present technology, the final protein contains</i> about 45 wt. % or more denatured whey proteins relative to the total weight of the protein in the whey protein composition, such as about 50 wt. % or more, such as about 55 wt. % or more, such as about 60 wt. % or more, such as about 65 wt. % or more, such as about 70 wt. % or more, such as about 75 wt. % or more, <b><i>such as about 77.5 wt. % or more</i></b> , such as about 80 wt. % or more, such as about 85 wt. % or more, such as about 90 wt. % or more, or any ranges or values therebetween.” Ex. 1002, 378 (emphases added). |
| 26.6 | <b><u>wherein the denatured whey protein composition is a powder and comprises alpha lactalbumin.</u></b>                          | Ratio in Original Claim 14 (issued as Claim 15). Ex. 1002, 358.<br><br>“Notwithstanding the final composition of proteins, the denatured whey protein composition may be optionally cooled and concentrated after heating and shearing, following by drying 106 <b><i>to produce a powdered or denatured whey protein composition.</i></b> ” Ex. 1002, 379 (emphasis added).<br><br>“Following heating and mechanical shearing, the resulting denatured whey protein mixture is subjected to optional cooling (e.g., 50°F) and concentration (e.g., by evaporation or nanofiltration), followed by spray drying to <b><i>produce a powdered reduced-GMP denatured whey</i></b>                                                                                                                                                                                            |

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|    |                                                                                                                                                                                                                                                                                                                                                      | <p><i><b>protein composition.</b></i>” (emphasis added).</p> <p>See analysis for Substitute Claim Limitation 21.4 above, which recites the same limitation.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 27 | <p>The denatured whey protein composition of claim [[15]] <u>26</u>, wherein the denatured whey protein composition contains at least 60 wt.% beta lactoglobulin relative to a total weight of protein and/or wherein the denatured whey protein composition contains at most 12 wt.% alpha lactalbumin relative to the total weight of protein.</p> | <p>Original Claim 16. Ex. 1002, 358.</p> <p>“The denatured whey protein composition of claim 14, wherein the whey protein contains at least 60 wt.% beta lactoglobulin relative to the total weight of protein and/or wherein the whey protein contains at most 12 wt.% alpha lactalbumin relative to the total weight of protein.” Ex. 1002, 358.</p> <p>“In additional embodiments, the whey protein contains at least 60 wt.% beta lactoglobulin relative to the total weight of protein. Additionally or alternatively, in embodiments, the whey protein contains at most 12 wt.% alpha lactalbumin relative to the total weight of protein.” Ex. 1002, 369-370.</p> |
| 28 | <p>The denatured whey protein composition of claim [[15]] <u>26</u>, wherein the denatured whey protein composition comprises a weight ratio of beta lactoglobulin to alpha lactalbumin of greater than or about 5.</p>                                                                                                                              | <p>Original Claim 17. Ex. 1002, 358.</p> <p>“The denatured whey protein composition of claim 14, wherein the whey protein comprises a weight ratio of beta lactoglobulin to alpha lactalbumin of greater than or about 5.” Ex. 1002, 358.</p> <p>“The denatured whey protein composition may be characterized by containing . . . a beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00 . . . .” Ex. 1002, 368. See also Ex. 1002 at 370, 372, 377.</p>                                                                                                                                                                                                   |
| 29 | <p>The denatured whey protein composition of</p>                                                                                                                                                                                                                                                                                                     | <p>Original Claim 18. Ex. 1002, 358.</p> <p>“The denatured whey protein composition of claim 14,</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

|    |                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | claim [[15]] <u>26</u> , wherein the denatured whey proteins are characterized by a D50 particle size distribution value of less than <del>or about</del> <u>0.3 <math>\mu</math>m.</u>                                                   | wherein the denatured whey proteins are characterized by a D50 particle size distribution value of less than or about 0.3 $\mu$ m.” Ex. 1002, 358.<br><br>“In further embodiments, the denatured whey proteins are characterized by a D50 particle size distribution value of less than or about 0.3 $\mu$ m.” Ex. 1002, 370.                                                                                                                  |
| 30 | The denatured whey protein composition of claim [[15]] <u>26</u> , wherein the denatured whey proteins are further characterized by a D10 particle size distribution value of less than <del>or about</del> <u>0.1 <math>\mu</math>m.</u> | Original Claim 19. Ex. 1002, 358.<br><br>“The denatured whey protein composition of claim 14, wherein the denatured whey proteins are further characterized by a D10 particle size distribution value of less than or about 0.1 $\mu$ m.” Ex. 1002, 358.<br><br>“In yet more embodiments, the denatured whey proteins are further characterized by a D10 particle size distribution value of less than or about 0.1 $\mu$ m.” Ex. 1002, 370.   |
| 31 | The denatured whey protein composition of claim [[15]] <u>26</u> , wherein the denatured whey proteins are further characterized by a D90 particle size distribution value of less than <del>or about</del> <u>1.0 <math>\mu</math>m.</u> | Original Claim 20. Ex. 1002, 358.<br><br>“The denatured whey protein composition of claim 14, wherein the denatured whey proteins are further characterized by a D90 particle size distribution value of less than or about 1.0 $\mu$ m.” Ex. 1002, 358.<br><br>“In additional embodiments, the denatured whey proteins are further characterized by a D90 particle size distribution value of less than or about 1.0 $\mu$ m.” Ex. 1002, 370. |

### **VIII. The Amendments are Responsive to the Grounds of Unpatentability and the Substitute Claims are Patentable Over the Prior Art**

The Substitute Claims are responsive to the four Grounds of unpatentability at issue in this proceeding because the Substitute Claims narrow the Challenged

Claims by incorporating additional limitations supported by the original disclosure of the '003 Application that are not disclosed in the petitioned prior art. Paper 1 (“Petition”), 2. The Grounds at issue in this proceeding are listed below.

| Ground | 35 U.S.C. | Reference(s)                | Claims                                              |
|--------|-----------|-----------------------------|-----------------------------------------------------|
| I      | § 102     | Nielsen ‘785                | 8-9, 11, 13 (Substitute Claims 21-23, 25)           |
| II     | § 103     | Nielsen ‘785, Bertelsen     | 8-9, 11-13 (Substitute Claims 21-25)                |
| III    | § 103     | Nielsen ‘450                | 8-9, 11-13, 15-20 (Substitute Claims 21-31)         |
| IV     | § 103     | Ozturk, Kawasaki, LeanCreme | 8-9, 11-13, 15-17, 20 (Substitute Claims 21-28, 31) |

Substitute Claims 21-31 are patentable over the references relied upon by the Board for institution of this proceeding, and all other prior art within the knowledge of Patent Owner. Although Patent Owner does not bear the burden regarding the patentability of the Substitute Claims, Patent Owner nevertheless summarizes below why the petitioned references do not teach or suggest the amended subject matter. *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1296 (Fed. Cir. 2017) (en banc) (holding that the burden of persuasion regarding the patentability of proposed amended claims does not rest with the patent owner); *Lectrosonics* at 4 (citing *Aqua Prods., Inc.*, 872 F.3d at 1296).

#### **a. Substitute Claim 21**

Substitute Claim 21 corresponds to Challenged Claim 8, which was challenged in Grounds I-IV.

- i. “[W]herein the cheese whey from enzymatically coagulated milk comprises greater than or 16 wt.% fat on a dry weight basis.”*

The references in Grounds I-IV fail to disclose or suggest using a cheese whey from enzymatically coagulated milk comprising greater than 16 wt.% fat on a dry weight basis as recited in Substitute Claim 21. Nielsen 785 discloses that the cheese whey feedstock contains at most 8 wt. % fat on a dry weight basis. Ex. 1005, 18:4-7. Nielsen 450 appears to be silent as to fat in the cheese whey feedstock. Bertelsen discloses a cheese whey feedstock containing up to 15 wt. % fat on a dry weight basis and most preferably, at most 0.5 wt. % on a dry weight basis. Ex. 1006, 18:34-19:1. Petitioner’s proposed combination for Ground IV begins with Ozturk, which does not disclose starting with a high fat feedstock in its process. Ex. 1008. The WPPC in Ozturk is twice-filtered from the cheese whey. The standard cheese whey used as the feedstock in Ozturk only contains 1.5 wt.% fat on a dry weight basis. Ex. 2018, 1. Accordingly, Petitioner’s references in Ground IV do not disclose cheese whey from enzymatically coagulated milk comprising greater than or 16 wt.% fat on a dry weight basis as recited in Substitute Claim 21.

- ii. “[R]educing native glycomacropeptides (GMP) in the cheese whey retentate by 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.”*

Nielsen785, Bertelsen, and Nielsen450 do not reduce GMP in a cheese whey retentate through enzymatic treatment or microfiltration. The references are silent regarding enzymatic treatment and Petitioner's expert explicitly testified that the 1.2-micron microfiltration step described in Bertelsen<sup>2</sup> and Nielsen450 would not reduce GMP content. Ex. 2006, 122:14-21; Ex. 2005, ¶ 69.

Instead, as Petitioner's expert explains, the GMP is allegedly reduced through crystallization of BLG crystals and subsequent centrifugation—not by enzymatic treatment or microfiltration. Ex. 1006, 61:4-10. Ex. 2006, 131:12-24. Neither Nielsen785, Bertelsen, nor Nielsen450 disclose or suggest reducing GMP in the cheese whey retentate *through enzymatic treatment or microfiltration*. Accordingly, Substitute Claim 21 is not anticipated or rendered obvious under Grounds I-III.

Ozturk, Kawasaki, and LeanCreme also fail to teach or suggest the method of Substitute Claim 21. Specifically, neither Ozturk, Kawasaki, nor LeanCreme disclose or suggest reducing GMP in a cheese whey retentate by enzymatic treatment or microfiltration. Ozturk is silent concerning GMP content and on reducing GMP in a cheese whey retentate by enzymatic treatment or

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<sup>2</sup> Petitioner argues Nielsen785 used BLG isolate powder produced using Bertelsen's methods. Pet., 5; Ex. 1005, 89:1-3, 18:27-31.

microfiltration. Pet., 56-59, 72. For this reason, a POSITA would have no motivation to remove GMP from the Ozturk WPPC. Ex. 2005, ¶¶ 131-135.

Also, Petitioner cannot show Ozturk inherently (i.e., *necessarily*) reduces GMP by microfiltration, in particular because Petitioner cannot show which of the two filtration steps in Ozturk allegedly reduces GMP, and because Ozturk is silent concerning GMP content and concerning protein concentration after microfiltration or after ultrafiltration. Ex. 2005, ¶¶ 136-138; 146-150.

Petitioner has not and cannot demonstrate that the references necessarily teach reducing GMP in a cheese whey retentate by enzymatic treatment or microfiltration. Instead, Kawasaki teaches isolating GMP from whey protein concentrates (WPC) through a multi-stage *ultrafiltration* process that includes acidifying WPC and passing the acidified WPC through a first ultrafiltration membrane stage, followed by ultrafiltering the permeate and retentate again to further isolate GMP. Pet., 61-63, 72; Ex. 1009, 192-93, Figure 3. Kawasaki does not disclose or suggest reducing GMP in a cheese whey retentate by enzymatic treatment or microfiltration. Pet., 61-63, 72; Ex. 1009, 192-93, Figure 3.

LeanCreme is silent on reducing GMP in a cheese whey retentate by enzymatic treatment or microfiltration and Petitioner does not argue otherwise. Pet., 63-64, 72. As such, Substitute Claim 21 is patentable over Ozturk, Kawasaki, and LeanCreme.

**iii. “[W]herein the denatured whey protein composition comprises alpha lactalbumin.**

Nielsen785, Bertelsen, and Nielsen450 do not disclose a denatured whey protein composition comprising alpha lactalbumin. Bertelsen does not disclose denatured whey protein compositions and Nielsen450 is silent as to whether the denatured BLG beverages contain any ALA. Nielsen785 shows there is 0% ALA present in the denatured nanogel product. Ex. 1005, Table 13; Ex. 2005, ¶¶ 98-100.

**b. Substitute Claims 22-25**

Substitute Claims 22-25, corresponding to Challenged Claims 9 and 11-13, respectively, depend from Substitute Claim 21 and recite further claim limitations making them narrower than Claim 21. Substitute Claims 22-25 incorporate the limitations of independent Substitute Claim 21 and are thus patentable over the references in each of Grounds I-IV for at least the same reasons as Substitute Claim 21, as explained above.

**c. Substitute Claim 26**

Substitute Claim 26 corresponds to Challenged Claim 15 which was challenged in Grounds III-IV.

As Petitioner has acknowledged, the denatured whey protein compositions in Nielsen450 are beverages, not powders as claimed. Pet. 22, 25. Additionally, the BLG isolate powder of Bertelsen is not denatured. Thus, Bertelsen fails to disclose the claimed greater than 77.5% denaturation limitation. Further, the BLG isolate

powders of Bertelsen and Nielsen450 have 0.11 wt.% fat/lipid (much less than the claimed 11 wt.% fat), further distinguishing these references from Substitute Claim 26. Ex. 1005, 88, Table 1; Ex. 1007, 108, Table 9. Additionally, Nielsen450 and Nielsen785 disclose adding fat *to the denatured beverages* and do not describe powders having the claimed fat content. Pet., 34; Ex. 1007, 111-112, Table 11. For these reasons, Nielsen450, Nielsen 785, and Bertelsen fail to teach or suggest the features of Substitute Claim 25.

Further, Nielsen785, Bertelsen, and Nielsen450 do not disclose a denatured whey protein composition comprising alpha lactalbumin. Accordingly, Substitute Claim 26 is patentable over these references for this reason also.

Ozturk, Kawasaki, and LeanCreme also fail to teach or suggest the method of Substitute Claim 26 because the references fail to disclose or suggest that the denatured whey protein composition comprises ***greater than*** 77.5 wt.% denatured whey proteins relative to the total weight of the protein as recited in Substitute Claim 26. Ozturk and Kawasaki are silent as to the denaturation rate of the protein compositions therein. LeanCreme teaches ***up to*** 75 wt. % of the protein can be microparticulated for the composition shown in Figure 2. Pet., 85; Ex. 2006, 258:2-17; Ex. 1003, ¶286; Ex 1010, 7, 20, Figure 2. More importantly, the “up to 75% denaturation” estimate from LeanCreme is specific only to the composition of sweet whey shown in Figure 2—not for *all* of the proteins described in the Ozturk

WPPC composition. Ex. 1010, 6-7, Figure 2; Ex. 2006, 259:9-; Ex. 1008, 291, Table 2, 289, Figure 3.

Protein denaturation differs based on whey protein concentration because certain proteins do not fully denature. Ex. 2006, 267:6-13; 268:4-9. Petitioner has not shown that the denatured GMP-reduced WPPC prepared from Ozturk, Kawasaki, and LeanCreme has the same composition as sweet whey. Ozturk contains numerous proteins beyond those shown in Figure 2 of LeanCreme. Ex. 1008, 291, Table 2, 289, Figure 3. For example, Ozturk contains 22.81% “MFGM proteins” and 31.32% “other proteins.” Ex. 1008, Table 2. Together these proteins make up *over 50%* of WPPC and ***Petitioner has not made any showing these proteins would denature.*** Ex. 2005, ¶¶ 153-159. In fact, certain proteins present in Ozturk are known not to denature at all. For example, LeanCreme itself states GMP does not denature at all and ALA only denatures 40-60%. Ex. 1010, 11.

Beyond protein composition, WPPC contains other components which would not denature. WPPC contains up to 10% lactose, which protects BLG from denaturation. Ex. 1008, 10. Garrett *et al.* found that ***lactose in whey protected BLG against denaturation*** after heat treatment. Ex. 2009, Table 7. Anema *et al.* likewise found that ***lactose in skim milk protected BLG against denaturation.*** Ex. 2010, Table 5. Caseins, also present in the denatured GMP-

reduced WPPC prepared from Ozturk and Kawasaki, are also known *not to denature*. Ex. 2034, p. 10; Ex. 2017, 1; Ex. 2005, ¶¶ 156-158.

In view of the foregoing, neither Ozturk, Kawasaki, nor LeanCreme disclose or suggest denatured whey protein composition comprises *greater than* 77.5 wt.% denatured whey proteins relative to the total weight of the protein as recited in Substitute Claim 26. In view of the foregoing, Substitute Claim 26 is not anticipated or rendered obvious under Grounds III-IV.

**d. Substitute Claims 27-31**

Substitute Claims 27-31, corresponding to Challenged Claims 16-20, respectively, depend from Substitute Claim 26 and recite further claim limitations making them narrower than Claim 26. Substitute Claims 27-31 incorporate the limitations of independent Substitute Claim 26 and are thus patentable over the references in each of Grounds I-IV for at least the same reasons as Substitute Claim 26, as explained above.

## **IX. Conclusion**

For at least the foregoing reasons, Patent Owner asserts that the proposed amended claims meet all statutory requirements and respectfully requests that the Board allow Substitute Claims 21-31 in the event that it finds any of the corresponding Challenged Claims to be unpatentable.

Respectfully submitted,

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**PATENT OWNER'S CONTINGENT MOTION TO AMEND  
APPENDIX A – CLAIM LISTING**

21. A method of making a denatured whey protein composition, the method comprising:

filtering cheese whey from enzymatically coagulated milk into a cheese whey retentate and a permeate, wherein the cheese whey from enzymatically coagulated milk has a fat content of 16 wt.% or greater based upon a dry basis weight; and

reducing native glycomacropeptides (GMP) in the cheese whey retentate by 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 ~~composition~~; and

heating the reduced-GMP cheese whey retentate ~~composition~~ to form the denatured whey protein composition,

wherein the denatured whey protein composition comprises alpha lactalbumin;

and wherein the denatured whey protein composition is characterized by at least 60 wt. % whey protein on a dry weight basis;

less than 11 wt. % native GMP relative to a total weight of protein in the denatured whey protein composition;

a proteolysis index of at least 8.0 wt. % or a beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00;

and

greater than 50 wt. % denatured whey proteins relative to the total weight of the protein in the denatured whey protein composition.

22. The method of claim [[8]] **21**, wherein the reduction of native GMP in the cheese whey retentate includes combining the cheese whey retentate with **the** one or more enzymes that selectively hydrolyze GMP in the cheese whey retentate to form the reduced-GMP cheese whey retentate composition, **and** **wherein** the one or more enzymes that selectively hydrolyze GMP in the cheese whey retentate comprises at least one alkaline serine protease enzyme and at least one neutral protease enzyme, ~~or wherein the reduction of GMP occurs through the microfiltration of the cheese whey retentate.~~

23. The method of claim [[8]] **21**, wherein the reduced-GMP cheese whey retentate composition is heated to a temperature of greater than ~~or about~~ 160°F.

24. The method of claim [[8]] **21**, wherein the heating of the reduced-GMP cheese whey retentate composition further comprises exposing the reduced-GMP cheese whey retentate composition to high shear conditions.

25. The method of claim [[8]] **21**, wherein **reducing the native GMP comprises microfiltering the cheese whey retentate through a microfiltration membrane having a pore size of 0.4 micrometers or less and wherein the reduced-GMP cheese whey retentate, prior to the heating, includes at least 5 wt. % denatured protein.** ~~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, and/or wherein the denatured whey protein composition is characterized by less than or about 11 wt.% GMP relative to the total weight of the protein in the denatured whey protein composition.~~

26. A denatured whey protein composition comprising:  
at least 60 wt.% protein on a dry weight basis;  
less than 11 wt.% native glycomacropeptide (GMP) relative to total weight of the protein;  
greater than [[7]] **11** wt.% fat on a dry basis;  
a beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00; and  
greater than [[50]] **75** wt.% denatured whey proteins relative to the total weight of the protein; **and**

**wherein the denatured whey protein composition is a powder and comprises alpha lactalbumin.**

27. The denatured whey protein composition of claim [[15]] **26**, wherein the denatured whey protein composition contains at least 60 wt.% beta lactoglobulin relative to a total weight of protein and/or wherein the denatured whey protein composition contains at most 12 wt.% alpha lactalbumin relative to the total weight of protein.

28. The denatured whey protein composition of claim [[15]] **26**, wherein the denatured whey protein composition comprises a weight ratio of beta lactoglobulin to alpha lactalbumin of greater than ~~or about~~ 5.

29. The denatured whey protein composition of claim [[15]] **26**, wherein the denatured whey proteins are characterized by a D50 particle size distribution value of less than ~~or about~~ 0.3  $\mu\text{m}$ .

30. The denatured whey protein composition of claim [[15]] **26**, wherein the denatured whey proteins are further characterized by a D10 particle size distribution value of less than ~~or about~~ 0.1  $\mu\text{m}$ .

31. The denatured whey protein composition of claim [[15]] **26**, wherein the denatured whey proteins are further characterized by a D90 particle size distribution value of less than ~~or about~~ 1.0  $\mu\text{m}$ .