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September 17, 2025

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Via USPS Express Mail

RE: Protest to Reissue Application 17/992,647 (Reissue of U.S. Pat No. 10,888,100)

Commissioner:

If you do not receive all of the pages described below, please contact the undersigned by telephone us at 303-607-3289 or by email at ajhunter@ktslaw.com.

1. Letter to Attorney for Applicant with Certificate of Service (1 pg);
2. Protest to Reissue Application Under 37 C.F.R. 1.291 (25 pgs);
3. U.S. Publication No. 2011/0046048 to Minor et al. (18 pgs);
4. U.S. Publication No. 2009/0298767 to Rowney et al. (18 pgs);
5. U.S. Publication No. 2006/0204643 to Merril et al. (10 pgs);
6. Copy of Dairy Processing Handbook (DPH), pages 361-374, published in 1995 by Tetra Pack Processing Systems AB, S-221, 86 Lund, Sweden (14 pgs);
7. Applicant's Response to USPTO Final Office Action filed November 26, 2019, in U.S. Application No. 16/214,548 (subsequently U.S. Patent No. 10,888,100) (14 pgs);
8. Applicant's Response to USPTO Final Office Action filed October 24, 2016, in U.S. Application No. 13/264,564 (11 pgs).

Total pages including cover letter: 117 pgs.

By: _____

Alexa J. Hunter
Reg. No.: 74,538

Enclosures: 8

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OPAP
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September 17, 2025

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Via First Class Mail and Facsimile

RE: Protest to Reissue Application 17/992,647 (Reissue of U.S. Pat No. 10,888,100)

Dear Mr. O'Connor:

If you do not receive all of the pages described below, please telephone us at 303-607-3289 or email at ajhunter@ktslaw.com.

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Total pages including cover letter: 116 pgs.

By: _____

Alexa J. Hunter

Enclosures: 7

CERTIFICATE OF SERVICE

I hereby certify that this paper and all attachments are being sent via First Class Mail, to the address identified above, and by facsimile to (312) 980-0868, on the date shown below.

_____ Sept. 17, 2025

Signature Date of Mailing/Facsimile

Alexa Hunter

Printed Name

OPAP
SEP 17 2025

9-19-25

PATENT
Attorney Docket No.: 088835-1521849

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

OK to Enter 553 9/19/25

In re Reissue Application of:	Confirmation No.: 1845
U.S. Patent No. 10,888,100	Examiner: Elizabeth L. McKane
Reissue Serial No.: 17/992,647	Technology Center/Art Unit: 3991
Filed: November 22, 2022	
Inventors: Palatasa Havea, et al.	**PROTEST UNDER 37 C.F.R. §1.291**
For: DAIRY PRODUCT AND PROCESSES	
Applicant: Fonterra Co-Operative Group Limited	

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In accordance with 37 C.F.R. § 1.291, the following Protest is submitted for consideration with regard to the examination of the above-referenced reissue application. This is the first Protest submitted in the application by the real party in interest (hereinafter "Protestor"). This Protest has been served on the Applicant in accordance with 37 C.F.R. § 1.248, as indicated by the attached proof of service.

REMARKS

The Protestor notes that the Applicant's Reissue Application proposes to add new claims 21-47 that were not presented for examination in the original prosecution of U.S. Patent No. 10,888,100 (hereinafter "the '100 Patent").

For the reasons discussed below, the Protestor respectfully requests that the Office reject new claims 21, 27, 40, 46, and 47 under 35 U.S.C. §112 as not being supported by the originally filed specification.

Additionally, the Protestor respectfully requests that the Office reject proposed new claims 21-47 under 35 U.S.C. §103 as being obvious over the references discussed below.

The Protestor also respectfully requests that the Office reconsider the issuance of claim 1 of the '100 Patent under 35 U.S.C. §112 since the Applicant has requested the reopening of prosecution by filing this reissue.

Prosecution History

U.S. Patent No. 10,888,100, or the '100 Patent, issued on January 12, 2021. The '100 Patent was filed on December 10, 2018 and received U.S. Application No. 16/214,548 (hereinafter "the '548 Application") which was published on April 25, 2019, as Publication No. 2019/0116827. The '100 Patent is entitled to a priority date of April 15, 2009, rendering it examinable under pre-AIA law.

The '548 Application was filed with 35 claims, and the '100 Patent issued with 20 claims. The claims as originally filed in the '548 Application are attached as Exhibit A.

A preliminary amendment was filed on December 10, 2018. In the amendment, claims 1-35 were cancelled and new claims 36-55 were added.

Claims 36-55 were identical to claims 36-55 in abandoned parent U.S. Application No. 15/362,216 (hereinafter "the '216 application"). Further, the '216 application was based on highly similar claims to abandoned parent application U.S. Application No. 13/264,564 (hereinafter "the '564 application". Claims 36-55 in the '216 application were rejected in a Non-Final Office Action mailed June 20, 2018. No response was filed, resulting in

abandonment of the application. As the claims were identical to the '216 application, a Final Rejection was received as a first action in the '100 Patent.

May 30, 2019 Final Office Action

A Final Office Action was mailed in the '548 Application (which issued as the '100 Patent) on May 30, 2019.

The May 30, 2019 Final Office Action rejected claims 36-55 under pre-AIA 35 U.S.C. § 103(a), as detailed below:

> Claims 36-45 and 51-55 were rejected as being unpatentable over *Havea* (WO 2007/108709 A1) in view of *Borgwardt et al.* (DD 236 449) (hereinafter "*Borgwardt*"). Specifically, the Office alleged it would have been obvious to modify *Havea's* method of preparing a liquid WPC to perform heat treatment using a turbulent flow with a Reynold's number of at least 500 taught by *Borgwardt*.

November 26, 2019 Final Office Action Response

A response to the May 30, 2019 Final Office Action was filed on November 26, 2019. No claim amendments were made. The Applicant argued the cited references did not disclose all the features of independent claims 1, 47, and 52. Specifically, the Applicant argued particle size, amount other features, stating in regards to particle size:

> the references did not disclose "the volume weighted mean particle size D[4,3] of the whey protein particles in the pressurized solution is less than about 10μM" because *Havea* only disclosed the median particle size of the reconstituted denatured WPC, ***not the size of the whey particles in the pressurized solution***. (emphasis added)

December 16, 2019 Non-Final Office Action

A Non-Final Office Action was mailed December 16, 2019, in which the Office maintained the rejections to claims 36-55 under pre-AIA 35 U.S.C. § 103(a). In response to the Applicant's arguments, amount other rejections, the Office alleged the particle size of the whey particles in the pressurized solution in *Havea* as being is less than about 10μM would have been obvious to a person of ordinary skill in the art because the stated the particle size could be adjusted and could be the same size as the reconstituted denatured WPC product.

Applicant-Initiated Examiner Interview

The Applicant initiated an interview with the Examiner on May 4, 2020, and a follow-up interview on June 2, 2020. According to the interview summary filed June 12, 2020, Applicants discussed the cited art and presented arguments regarding the lack of instruction in the cited art with respect to the claimed particle size.

June 12, 2020 Non-Final Office Action Response

The Applicant maintained its nonobviousness arguments from the previous response. In addition, independent claims 36 and 52 were amended as follows:

> (c) heat treating the pressurized solution to more than 50°C and not more than 150°C, for a time that allows protein denaturation to occur, wherein at least 50% of denaturable proteins are denatured, said time being less than about 120 s; the heat treating comprising heating the solution while under conditions of turbulent flow with a Reynold's number of at least 500 and wherein the volume weighted mean particle size D[4,3] of the whey protein particles in the pressurized solution is less than about 10 μm and the pressurized solution is not subjected to a mechanical shear process to break up particles within the solution; . . .

The Applicant argued the cited references did not disclose a WPC or WPC solution wherein at least 50% of denaturable proteins are denatured, and heat treated for less than 120 seconds at a temperature above 50°C but not more than 150°C.

Notice of Allowance

A Notice of Allowance was mailed on August 21, 2020. The examiner stated:

> Applicant's arguments were determined to be persuasive in overcoming the obviousness rejections. Specifically, Applicant's assertion that Example 13 of Havea is effectively of no instructional value as related to omitting homogenization due to the particle size being substantially higher than the claimed range, even though the reference states that fine particles can be manufactured in absence of homogenization (Applicant's Remarks, p. 8, ¶2 - p. 9, ¶2), was found to be persuasive. Considered in the context of the claimed processes overall, including limitations drawn to the degree of denaturation, the particle size at different stages of the process, and the parameters and effects related to the application of turbulent

> flow, the claimed processes are considered novel and non-obvious. The claims are thus allowed.

The Applicant did not respond to the Notice of Allowance. The Issue Fee was paid on November 20, 2020, and the '538 application issued as the '100 Patent on January 12, 2021.

Claim 1 and Proposed New Claims 21, 27, 46, and 47 Are Not Supported by the Originally Filed Specification

The Applicant's claim 1 and proposed new claims 21, 27, 46, and 47 should be rejected under 35 U.S.C. § 112.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Original claim 1 and proposed new claims 21, 27, 40, 46, and 47 contain subject matter which were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time of the application was filed, had possession of the claimed invention.

Protestor has also attached the original claims from the priority application hereto as "Exhibit A" to illustrate that the claim limitations discussed in this section were not present in the originally filed specification or contained in the originally filed claims. Therefore, Protestor submits that at least claims 1, 21, 27, 46, and 47 should be rejected for failing to provide a written description of the invention.

Claims 1 and 21

Both claim 1 and claim 21 recite that the volume weighted mean particle size D[4,3] of the whey protein particles is less than about 10 μm. However, nowhere in the original specification or originally filed claims discloses this limitation. Therefore, the Patent Owner must be relying upon FIGs. 4 and 10 for asserted support for this feature.

This appears to be admitted by the Applicant in the response to the '564 application. Namely, in the response dated October 24, 2016, the Applicant introduced the following amendment "wherein the volume weighted mean particle size D[4,3] of the whey protein particles in the treated WPC stream from the heat treatment arrangement (c) is less than about 10 μm and the particles are not subject to a particle size reduction procedure prior to drying." From Protestor's review of this family, this is the first mention of the limitation of the volume weighted mean particle size D[4,3] of the whey protein particles being less than about 10 μm. In the response dated October 24, 2016 in the '564 application, the Patent Owner stated:

> Support for the amendment regarding the whey protein particle size can be found, for example, in the discussion of Figures 2 and 3 on pages 18 and 19 of the specification, and with reference to Figures 2,3 and 10. Figure 2 discusses and presents the size of the 'wet' denatured whey protein particles in the pressurized whey protein solution (i.e., prior to drying), while Figure 3 presents the size of the powder particles in the final dried product. As can be seen in Figures 2 and 3, in the presented example these two different populations of particles differ in size by approximately an order of magnitude or more. Figure 10 shows the 'wet' denatured protein particle size distribution, being below an average particle size D[4,3] of 10 um.

Initially, Protestor believes that Patent Owner must be referencing FIGs. 3 and 4, as FIG. 2 concerns process viscosity. Nonetheless the only discussion of particle size on pages 18 and 19 is that the dry products of FIG. 3 had particle sizes of greater than 100 μm. No written support is present regarding a particle size distribution having an average particle size D[4,3] of below 10 μm.

In addition, while Patent Owner asserts this limitation may also be located in FIGs. 4 and 10, no such disclosure is present. FIG. 4 discloses a maximum particle size of approximately 2.5 μm and a minimum of approximately 0.4 μm. Further, FIG. 10 contains no graduations between 0 μm and 10 μm. However, the largest heat treated sample (noting that the value at 40 appears to have been untreated as the legend indicates "0" seconds) would appear to be approximately 6 μm with no indication of the bottom limit, as the particles clearly cannot have a D[4,3] of 0 μm. Protestor also notes that there is no disclosure in the original specification of the conditions or composition of the sample tested in FIG. 10, as the only mention states "FIG. 10 shows that very fine particle dispersions can be prepared ex the tubular reactor of this

invention." ('100 Patent at Col. 27, Lines 63-64). Therefore, Protestor submits that reliance upon FIG. 10 would also run afoul of the enablement requirement, as no indication is present of what composition was tested and under what conditions.

Therefore, Protestor submits that the specification as originally filed fails to provide support for a range of "less than about 10 microns". As this limitation is also not contained in the figures or the originally filed claims, Protestor submits that claims 1 and 21 are not supported by the originally filed written description, and should be rejected under 35 U.S.C. § 112.

Further, regarding claim 21, it is noted that FIGs. 4 and 10 are specific to "Wet stream particle size". However, claim 21 does not disclose if the particles are part of the wet stream or otherwise. Therefore, as FIGs. 4 and 10 only supports particles in a wet stream, Protestor submits that claim 21 is further unsupported by the original specification. This interpretation is also admitted by the Patent Owner.

Namely, as discussed above, during prosecution of the '564 application, Applicant argued:

> Figure 2 discusses and presents the size of the 'wet' denatured whey protein particles in the pressurized whey protein solution (i.e., prior to drying), while Figure 3 presents the size of the powder particles in the final dried product. As can be seen in Figures 2 and 3, in the presented example these two different populations of particles differ in size by approximately an order of magnitude or more. Figure 10 shows the 'wet' denatured protein particle size distribution, being below an average particle size D[4,3] of 10 μm.

Protestor believes that Applicant must be referencing FIGs. 3 and 4, as FIG. 2 concerns process viscosity. Nonetheless, Protestor submits that the Patent Owner admits and argues on the record that the particle size would not be consistent between the dry powder and the protein solution prior to drying by an order of magnitude. Thus, Protestor submits that claim 21 must fail to be supported by the specification as written, and should be rejected under 35 U.S.C. § 112.

Claims 27 and 46

Regarding claims 27 and 46, the Applicant appears to rely on FIG. 3 for claiming a volume weighted mean particle size D(4,3) of ***a dry powder*** in claim 27 and for claiming a hardness of ***a nutrition bar*** in claim 46, as there is no written support in the originally filed specification for either limitation.

Nonetheless, regarding claim 46, Protestor notes that FIG. 3 reports hardness values of approximately 500 g (noting that no graduations are located between 400 g and 800 g) up to a value far greater than 1200 g (noting that no graduations are located between 1200 g and 1600 g). Therefore, the endpoints of the claimed range of 400 g to 1100 g are not present nor supported by FIG. 3. Therefore, as the originally filed specification and claims contain no written description of a hardness value of 400 g to 1100 g, and as no other support is present in the originally filed specification or original claims, Protestor submits that claim 46 is not supported by the written description of the specification and should be rejected under 35 U.S.C. § 112.

Similarly, claim 27 recites "wherein said dry powder has a volume weighted mean particle size D(4,3) up to 130 microns". However, FIG. 3 only provides particle sizes ranging from approximately 75 microns to approximately 125 microns. Thus, the endpoints of the claimed range are not present in FIG. 3. Further, there is no other support in the originally filed specification or claims. Therefore, Protestor submits that claim 27 and claim 46 must fail to be supported by the specification as written, and should be rejected under 35 U.S.C. § 112.

Claim 47

Regarding claim 47, the specification does not provide support for a nutrition bar comprising less than 37.3 (w/w) or greater than 37.3 (w/w) of the heat-denatured whey protein composition. Namely, Col. 11, lines 19-21 of the '100 Patent contains the only disclosure of the protein content in a nutritional bar, stating that the recipe contained 37.3% heat treated WPC. As such, the specification does not provide support for a nutrition bar comprising 30-45% (w/w) of the heat-denatured whey protein composition. As there is also no disclosure of this feature in the figures or originally filed claims, Protestor submits that claim 47 must fail to be supported by the specification as written, and should be rejected under 35 U.S.C. § 112.

Proposed New Independent Claim 22-47 Should Be Rejected Under 35 U.S.C. §103

The Applicant's proposed new independent claim 21 should be rejected as obvious under 35 U.S.C. §103 over U.S. Publication No. 2011/0046048 to *Minor et al.* (hereinafter "*Minor*") alone or in view of common knowledge in the art (e.g., *Dairy Processing Handbook*, published in 1995 by Tetra Pack Processing Systems AB, S-221, 86 Lund, Sweden (hereinafter "*Dairy*")). *Minor* has an earlier filing date and was filed by a different patent owner than Applicant. For instance, *Minor* was filed by Nutricia NV as a PCT on March 12, 2009, claiming earliest priority to a foreign application filed on March 12, 2008, whereas the '100 Patent has an earliest filing date of April 15, 2009. Thus, *Minor* has a priority date earlier than the priority date of the present Reissue Application. As such, *Minor* is proper prior art over Applicant's Reissue Application.

Minor is directed to the formation of shelf-stable liquid enteral compositions with a high content of denatured but non-hydrolyzed globular proteins, particularly whey proteins. (¶ [0007] and [0039]). *Minor* discloses that previously, forming high protein liquid compositions was challenging, as increased protein content caused sedimentation or high viscosity. (¶¶ [0009]-[0014]). *Minor* states that it is "believed that raising the temperature quickly to a temperature **well above the denaturation temperature** of whey protein" results in the formation of small, compact whey protein particles which are largely inert to any further heat treatment. (¶ [0039]). This would indicate that all or largely all of the denaturable proteins have been denatured during the heat treatment of *Minor* (noting that *Minor* likens its process to traditional denaturation methods in ¶ [0039], except that the process of *Minor* results in small compact particles instead of large voluminous aggregates). *Minor* states that this treatment provides for formation of pasteurized or sterilized liquid enteral composition having a long shelf life and good sensory properties. (¶¶ [0038] and [0039]). *Minor* discloses that large particle diameters lead to a sandy taste, and recommends particle diameter of less than 30 um, preferably less than 10 um. (¶ [0067], noting that the examples indicate that "average particle diameter" refers to d[4,3] at ¶ [0131]). *Minor* discloses that suitable non-hydrolyzed globular proteins include whey protein concentrates and isolates, and that the heat treatment is conducted on an aqueous composition of the non-hydrolyzed globular proteins. (¶¶ [0029] and [0042]-[0044]).

Therefore, as will be shown in the following claim chart, it is believed that *Minor* explicitly discloses all of the features of new claim 21. Namely, as discussed above, *Minor* discloses that the whey proteins are largely inert to further heat treatment. It is common knowledge that native whey proteins are sensitive to aggregation and quickly denature above the denaturation temperature. (*Minor* at ¶ [0033], *Dairy* at p. 363, "Heat treatment denatures whey proteins", "the spray-cooking step appears to have stabilized the protein aggregates against further aggregation..." ¶ [0131]). Therefore, *Minor* discloses that the denaturable whey proteins are denatured or largely denatured if the whey proteins are largely inert to further heat treatment.

Nonetheless, while Protester believes that all of the limitations of claim 21 are disclosed by *Minor*, in case it is argued that *Minor* does not disclose "wherein at least 50% (w/w) of denaturable proteins in the composition are denatured", Protestor notes that Table 17.2 of *Dairy* discloses that it is common knowledge that a degree of denaturation of whey proteins is obtained by increasing intensity of heat treatment. (*Dairy* at p. 363). *Dairy* discloses that a degree of denaturation of the whey proteins of greater than 94% is obtained even at 85 °C. (5-6 mg of undenatured whey in 1 g of powder). Therefore, as *Minor* discloses a heat treatment of 100 °C to 190 °C, it would be understood based upon Table 17.2 of *Dairy* that greater than 95% of the whey proteins are denatured.

The Protester provides the claim chart below to show precisely where *Minor* and common knowledge in the art describe the limitations of proposed new independent claim 21:

Proposed New Independent Claim 21 of Reissue Application	**Prior Art Reference Discussion**
21. A heat-denatured whey protein composition containing:	Surprisingly, the inventors have now found that it is possible to prepare a pasteurized or sterilized liquid enteral nutritional composition having a long shelf life by means of a method wherein a composition that comprises mainly globular proteins as a protein source, in particular whey proteins, is subjected to a specific heat-treatment... (*Minor* at ¶ [0038]). Without being bound (or restricted) to any theory, it is believed that raising the temperature quickly to a temperature well

	above the denaturation temperature of the whey protein, **leads to denaturation of whey protein**. (*Minor* at ¶ [0039], *emphasis added*).
whey protein comprising insoluble whey protein particles having a volume weighted mean particle size D(4,3) of less than 10 micron;	The average particle diameter as obtained from static light scattering (Malvern Mastersizer 2000), d[4,3], after homogenisation (a), spray-cooking (b) and UHT pasteurization (c) were 7.7 μm, 6.0 μm and 5.4 μm, respectively. (*Minor* at ¶ [0131]). The average particle diameter as obtained from static light scattering (Malvern Mastersizer 2000), d[4,3], after homogenisation (a), spray-cooking (b) and UHT pasteurization (c) or retorting (d) were 4.7 μm, 3.7 μm, 3.9 μm or 3.8, respectively. (*Minor* at ¶ [0133]). The average particle diameter as obtained from static light scattering (Malvern Mastersizer 2000), d[4,3], after homogenisation (a), spray-cooking (b) were 0.48 μm and 0.29 respectively. (*Minor* at ¶ [0135]).
wherein at least 50% (w/w) of denaturable proteins in the composition are denatured, and	Without being bound (or restricted) to any theory, it is believed that raising the temperature quickly to a temperature well above the denaturation temperature of the whey protein, leads to denaturation of whey protein. (*Minor* at ¶ [0039]). The non-hydrolysed globular proteins, in particular whey proteins, are subjected to a heat-treatment, comprising the consecutive steps of:... c) subjecting the aerosol obtained in step b) to a temperature of 100 to 190° C. during a time of about 30 to 300 milliseconds; d) flash-cooling the heat-treated aerosol obtained in step c) to a temperature below 85° C. to obtain an aqueous solution comprising heat-treated globular proteins. (*Minor* at ¶¶ [0041] and [0044]-[0045]). According to the method of the present invention a longer duration of heating time is

	necessary. Apparently, sufficient time is required to allow the formation of small, compact whey proteins to take place, making it possible to produce sterilized or pasteurized liquid enteral nutritional compositions containing high concentrations of whey proteins. (*Minor* at ¶ [0059]). The *Dairy Processing Handbook* at Table 17.2 shows that it is well known to vary temperature to obtain various degrees of denaturation. (*Dairy* at pg. 363 "Skim Milk Powder" providing "the percentage denaturated increasing with the intensity of heat treatment"). A temperature of 95° C resulted in 4-5mg of undenatured whey protein per gram of powder, which correlates to 95-96% denaturation, while noting that even temperatures of 70° C - 85° C resulted in denaturation levels of 94-95%. (*Dairy* at pg. 363).
wherein at least 65% of total solids in the composition are whey protein.	It is generally understood that a whey protein isolate refers to a mixture in which at least 90 weight % of the solids are whey proteins. (*Minor* at ¶ [0030]). The non-hydrolysed globular proteins, in particular whey proteins, are subjected to a heat-treatment, comprising the consecutive steps of: a) adjusting the pH of **an aqueous composition comprising non-hydrolysed globular proteins** to a value of between about 2 and 8; b) converting the composition comprising nonhydrolyzed globular proteins obtained in step a) into an aerosol; c) subjecting the aerosol obtained in step b) to a temperature of 100 to 190° C. during a time of about 30 to 300 milliseconds… (*Minor* at ¶¶ [0041]-[0044], *emphasis added*).

Similarly, the Applicant's proposed new claims 22, 23, and 26-40 should also be rejected as obvious under 35 U.S.C. §103 over *Minor* alone or in view of common knowledge in the art.

In regards to claims 22 and 23, it is noted that the viscosity of *Minor* disclosed in ¶ [0100] relates to the viscosity of the liquid enteral composition. *Minor* discloses that the liquid enteral composition can have 9 to 20 grams of the non-hydrolyzed globular protein per 100 mL and that the liquid enteral composition can undergo UHT sterilization. (¶¶ [0073], [0076], and [0107]). While the liquid enteral composition can contain other components such as fat, carbohydrate, or vitamins and minerals, the liquid enteral composition of paragraph [0100] does not require anything other than a liquid, such as water (¶ [0105]), and the non-hydrolyzed globular protein. (*see*, "Nutritional Composition, ¶¶ [0071]-[0086], where fats and other ingredients are cited as other embodiments at ¶¶ [0087], [0091], [0095]). Therefore, it is believed that the gelling and viscosity of *Minor* corresponds to the features of claims 22 and 23.

In regards to claim 27, Protestor initially notes that this claim is invalid for failing to limit claim 21 as discussed in greater detail above, as claim 21 requires a volume weighted mean particle size D(4,3) of less than 10 micron.

Nonetheless, *Minor* discusses that its product can be provided in the form of a powder that can be reconstituted in water to produce the "composition according to the invention". (¶ [0105]). In addition, *Minor* discloses that spray cooking stabilizes the aggregates against further aggregation and that the particle size after UHT is nearly unchanged compared to the spray cooked intermediate product. (¶ [0131]). Therefore, *Minor* indicates that the particle size of a D[4,3] is less than 10 after homogenization (in liquid form "The oil was blended into the product and the pre-emulsion was homogenised at 40° C. in a 2-stage homogenizer at a pressure of 550/50 bar"), after spray cooking and after UHT pasteurization. (*Minor* at [0131]).

The Protester provides the claim chart below to show precisely where *Minor* and common knowledge in the art describe the limitations of proposed new claim 22 and 26-40:

Proposed New Claims 22, 23, and 26-40 of Reissue Application	**Prior Art Reference Discussion**
22. The heat-denatured whey protein composition of claim 21, wherein a formulation comprising water and about 12% (w/w) of the heat-denatured whey protein composition does not gel after heating at 121 ° C for 10 minutes.	Hence, in an embodiment of the invention, a liquid enteral nutritional composition comprising 10 to 20 g of non-hydrolysed globular proteins per 100 ml of the composition is provided. (*Minor* at ¶ [0073]). [A] composition may be provided to a person in need thereof in powder form, suitable for reconstitution using an aqueous solution or water ***such that the composition according to the invention is produced***. (*Minor* at ¶ [0105], emphasis added]). As a result, small, compact whey protein particles are formed which are largely inert in any further heat-treatment. (*Minor* at ¶ [0039]). Denatured whey proteins are reactive molecules capable of aggregate formation. In the experiments we have observed that the same formulation can form a gel or a liquid product depending on the heating conditions. For example, **slow heating in a rheometer, tube heat exchanger, or during gentle mixing in the retort results in a gelled product**. However, ***when the product is heated under high shear in the surface scraped heat exchanger or heated instantaneously to above the denaturation temperature (as in the spray-cooking technique),*** **a liquid products result**. (*Minor* at ¶ [0136], *emphasis added*).
23. The heat-denatured whey protein composition of claim 22, wherein the formulation has a viscosity at 100 s-1 of less than 90 cP after heating at 121 ° C for 10 minutes.	[T]he viscosity of the liquid enteral nutritional composition is lower than 500 mPa·s, measured at 20° C. (i.e. room temperature) at a shear rate of 100 s^{-1}, preferably between 10 and 200 mPa·s, more preferably between 10 and 100 mPa·s, most preferably below 50 mPa·s. (*Minor* at ¶ [0100]).
26. The heat-denatured whey protein composition of claim 21, wherein at least	A temperature of 95° C resulted in 4-5mg of undenatured whey protein per gram of powder, which correlates to 95-96%

70% of denaturable proteins in the composition are denatured.	denaturation, while noting that even temperatures of 70° C - 85° C resulted in denaturation levels of 94-95%. (*Dairy* at pg. 363).
27. The heat-denatured whey protein composition of claim 21, wherein the composition is in the form of a dry powder and wherein said dry powder has a volume weighted mean particle size D(4,3) up to 130 microns.	In a further aspect, the present invention relates to the non-hydrolysed heat-treated globular protein per se obtainable by the process according to the invention… in any form, such as a … powder, in any concentration conceivable. (*Minor* at ¶ [0109]). The average particle diameter as obtained from static light scattering (Malvern Mastersizer 2000), d[4,3], ***after homogenisation (a), spray-cooking (b) and UHT pasteurization (c) were 7.7 µm, 6.0 µm and 5.4 µm, respectively***. (*Minor* at ¶ [0131], *emphasis added*).
28. A high protein drinking yoghurt comprising the heat-denatured whey protein composition of claim 21.	In a specific embodiment of the composition according to the invention, the composition is acidic (yoghurt-like or juice-like) with a pH of about 4. (*Minor* at ¶ [0078]).
29. The high protein drinking yoghurt of claim 28, wherein 30-90% of the protein in the yoghurt is whey protein.	[T]he amount of whey proteins in the liquid nutritional composition according to the invention is at least 85 weight %, more preferably at least 90 weight %, more preferably at least 95 weight % of the total protein present in the liquid nutritional composition. (*Minor* at ¶ [0083]).
30. The high protein drinking yoghurt of claim 28, wherein the yoghurt comprises at least 7% (w/v) total protein.	Preferably, the globular proteins are whey proteins. In another embodiment, the amount of non-hydrolysed globular proteins is 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19 or 20 gram per 100 ml of the composition, or any value in between the aforementioned values. (*Minor* at ¶ [0076]).
31. The high protein drinking yoghurt of claim 28, wherein the yoghurt comprises 10-15% (w/v) total protein.	Preferably, the globular proteins are whey proteins. In another embodiment, the amount of non-hydrolysed globular proteins is 9, 10,

	11, 12, 13, 14, 15, 16, 17, 18, 19 or 20 gram per 100 ml of the composition, or any value in between the aforementioned values. (*Minor* at ¶ [0076]).
32. The high protein drinking yoghurt of claim 31, wherein the yoghurt has an apparent viscosity at 50 s-1 of less than 600 mPa·s.	In one embodiment of the present invention, the viscosity of the liquid enteral nutritional composition is lower than 500 mPa·s, measured at 20° C. (i.e. room temperature) at a shear rate of 100 s^{-1}, preferably between 10 and 200 mPa·s, more preferably between 10 and 100 mPa·s, most preferably below 50 mPa·s. (*Minor* at ¶ [0100]). In the context of the current application, enteral means any form of administration that involves any part of the gastrointestinal tract, i.e. by mouth (orally)… (*Minor* at ¶ [0008]). In a specific embodiment of the composition according to the invention, the composition is acidic (yoghurt-like or juice-like) with a pH of about 4. (*Minor* at ¶ [0078]).
33. A nutritional product comprising the heat-denatured whey protein composition of claim 21, wherein the nutritional product is a beverage or a medical liquid or nonliquid food.	Therefore, the problem underlying the present invention is to provide a shelf-stable liquid enteral composition for providing nutrition, either as a supplement, or as a complete nutrition, with a high content of non-hydrolysed globular protein as major protein source, in particular whey proteins, in the smallest volume of liquid, and which supports nutrition and well-being in the different patient groups mentioned above. (*Minor* at ¶ [0007]).
34. A beverage comprising the heat-denatured whey protein composition of claim 21.	Therefore, the problem underlying the present invention is to provide a shelf-stable liquid enteral composition for providing nutrition, either as a supplement, or as a complete nutrition, with a high content of non-hydrolysed globular protein as major protein source, in particular whey proteins, in the smallest volume of liquid, and which supports nutrition and well-being in the different

	patient groups mentioned above. (*Minor* at ¶ [0007]). In the context of the current application, enteral means any form of administration that involves any part of the gastrointestinal tract, i.e. by mouth (orally)… (*Minor* at ¶ [0008]).
35. The beverage of claim 34, wherein at least 40% of the protein in the beverage is whey protein.	[T]he amount of whey proteins in the liquid nutritional composition according to the invention is at least 85 weight %, more preferably at least 90 weight %, more preferably at least 95 weight % of the total protein present in the liquid nutritional composition. (*Minor* at ¶ [0083]).
36. The beverage of claim 34, wherein the beverage comprises at least 4.5% (w/v) of the heat-denatured whey protein composition.	Preferably, the globular proteins are whey proteins. In another embodiment, the amount of non-hydrolysed globular proteins is 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19 or 20 gram per 100 ml of the composition, or any value in between the aforementioned values. (*Minor* at ¶ [0076]).
37. The beverage of claim 34, wherein the beverage comprises at least 9% (w/v) total protein.	Preferably, the globular proteins are whey proteins. In another embodiment, the amount of non-hydrolysed globular proteins is 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19 or 20 gram per 100 ml of the composition, or any value in between the aforementioned values. (*Minor* at ¶ [0076]).
38. The beverage of claim 34, further comprising water and a soluble carbohydrate.	[A] composition may be provided to a person in need thereof in powder form, suitable for reconstitution using an aqueous solution or water such that the composition according to the invention is produced. Thus in one embodiment of the present invention, the present composition is in the form of a powder, accompanied with instructions to dissolve or reconstitute in an aqueous composition or water to arrive at the liquid nutritional enteral composition according to the present invention. (*Minor* at ¶ [0105]).

	Hence, the composition according to the invention may further comprise at least fat and/or carbohydrate and/or a source of vitamins and minerals and/or a source of prebiotics. (*Minor* at ¶ [0086]).
39. The beverage of claim 34, further comprising oil or fat.	In one embodiment of the present invention, the liquid nutritional composition according to the invention further comprises fat... (*Minor* at ¶ [0087]). The fat may include medium chain triglycerides (MCT, mainly 8 to 10 carbon atoms long), long chain triglycerides (LCT) or any combination of the two types. LCT sources, such as canola oil, rapeseed oil, or corn oil are preferred because they can reduce immune suppression associated with certain types of fatty acids concentrated in the body. (*Minor* at ¶ [0088]).
40. The beverage of claim 34, wherein the beverage has a calorific value from 0.5 kcal/mL to 3 kcal/mL.	The liquid enteral nutritional composition according to the invention may have the form of a complete food, i.e. it can meet all nutritional needs of the user. As such, it preferably contains 1200 to 2500 kcal per daily dosage. The daily dosage amounts are given with respect to a daily energy supply of 2000 kcal to a healthy adult having a body weight of 70 kg. For persons of different condition and different body weight, the levels should be adapted accordingly. It is understood that the average daily energy intake preferably is about 2000 kcal. The complete food can be in the form of multiple dosage units, e.g. from 4 (250 ml/unit) to 20 units (50 ml/unit) per day for an energy supply of 2000 kcal/day using a liquid enteral nutritional composition according to the invention of 2.0 kcal/ml. (*Minor* at ¶ [0102]). In one embodiment of the present invention, the composition has an energy density of at least 0.36 kcal/ml, preferably at least 1.0 kcal/ml, preferably at least 1.5 kcal/ml, preferably at least 2.0 kcal/ml, more

	preferably at least 2.4 kcal/ml. . (*Minor* at ¶ [0082]).

The Applicant's proposed new claims 24 and 25 should also be rejected as obvious under 35 U.S.C. §103 over *Minor* in view of U.S. Publication No. 2009/0298767 to *Rowney et al.,* (hereinafter "*Rowney*"). *Rowney* has an earlier filing date and was filed by a different patent owner than Applicant. For instance, *Rowney* was filed by the inventors on June 15, 2007 (and later assigned to Murray Goulburn Co-operative Co., Limited). Thus, *Rowney* has a priority date earlier than the priority date of the present Reissue Application. As such, *Rowney* is proper prior art over Applicant's Reissue Application.

In regards to claims 24 and 25, Protestor notes that while *Minor* discloses that the composition is non-hydrolyzed, paragraph [0072] allows for up to 20 wt.% of the composition to include hydrolyzed whey proteins. Further, claims 24 and 25 do not require all of the composition to be hydrolyzed.

The Protester provides the claim chart below to show precisely where *Minor* and common knowledge in the art describe the limitations of proposed new claim 23-25:

Proposed New Claims 24 and 25 of Reissue Application	**Prior Art Reference Discussion**
24. The heat-denatured whey protein composition of claim 21, wherein a hydrolysate prepared by treating the heat-denatured whey protein composition with a protease at 65 °C, pH 7.5 for 5 hours has less than 1 % of material greater than 20 kDa.	In the context of this application, "non-hydrolysed" proteins is equivalent to "intact" proteins, meaning that the proteins have not been subjected to an hydrolysis process. However, minor amounts of hydrolysed proteins may be present in the source of non-hydrolysed proteins, or may be added to the formulation, such as additional amino acids, such as, for example leucine, isoleucine, and the like. In this context, "minor" should be understood as an amount of about 20 weight % or less, for example of about 10 weight % or less. The term "about" should be interpreted as a deviation of plus or minus 10% of the given value. (*Minor* at ¶ [0072]). It may be advantageous to utilise proteinases which possess proteinase activity at close to

	neutral pH, in particular from pH 5.3 to 8.5. (*Rowney* at ¶ [0044]). Whey protein hydrolysates having a degree of hydrolysis of about 0.5% to about 20% contain less than about 5% of free amino acids, about 15% to about 55% of peptides having a molecular weight of less than 1000 Da, about 20% to about 55% of peptides having a molecular weight of 1000 Da to 5000 Da, and about 15% to about 35% of peptides having a molecular weight of greater than 5000 Da. (*Rowney* at ¶ [0053]).
25. The heat-denatured whey protein composition of claim 24, wherein the protease comprises a combination of Alcalase and Thermoase.	In the context of this application, "non-hydrolysed" proteins is equivalent to "intact" proteins, meaning that the proteins have not been subjected to an hydrolysis process. However, minor amounts of hydrolysed proteins may be present in the source of non-hydrolysed proteins, or may be added to the formulation, such as additional amino acids, such as, for example leucine, isoleucine, and the like. In this context, "minor" should be understood as an amount of about 20 weight % or less, for example of about 10 weight % or less. The term "about" should be interpreted as a deviation of plus or minus 10% of the given value. (*Minor* at ¶ [0072]). Similarly, enzymes from the IUBMB Enzyme Nomenclature class EC 3.4.21.62 (also known as subtilisin, Alcalase®; alcalase 0.6L; alcalase 2.5L; colorase N, ALK-enzyme; bacillopeptidase A; bacillopeptidase B; Bacillus subtilis alkaline proteinase bioprase; bioprase AL 15; bioprase APL 30; colistinase; subtilisin J; subtilisin S41; subtilisin Sendai; subtilisin GX; subtilisin E; subtilisin BL; subtilisin A (Type VIII); genenase I; esperase; maxatase; thermoase PC 10; protease XXVII; thermoase; superase; subtilisin DY; subtilopeptidase; SP 266; savinase 8.0L; savinase 4.0T; kazusase; protease VIII; optimase; opticlean; Bacillus subtilis alkaline proteinase; protin A 3L; savinase; savinase 16.0L; savinase 32.0L EX; orientase 10B;

	protease S and similar serine endopeptidases are candidate enzymes which are potentially suitable for hydrolysis. (*Rowney* at ¶ [0048]).

The Applicant's proposed new claims 41-45 should also be rejected as obvious under 35 U.S.C. §103 over U.S. Publication No. 2006/0204643 to *Merrill et al.* (hereinafter "*Merrill*") in view of *Minor*. *Merrill* has an earlier filing date and was filed by a different patent owner than Applicant. For instance, *Merrill* was filed by Leprino Foods Company on March 13, 2006. Thus, *Merrill* has a priority date earlier than the priority date of the present Reissue Application. As such, *Merrill* is proper prior art over Applicant's Reissue Application.

Merrill discloses that there is increased interest in the development of whey proteins for the replacement of fats and sugars in foods. (*Merrill* at ¶¶ [0002] and [0003]). *Merrill* discloses methods of producing whey proteins with reduced particle sizes with good mouthfeel that do not clog machinery due to gelling of native proteins. (*Merrill* at ¶¶ [0002]-[0006]). *Minor* discloses denatured whey particles with good mouthfeel and in the form of small compact whey protein particles that are inert to further heat treatment. (*Minor* at [0039]).

The Protester provides the claim chart below to show precisely where *Merrill* and *Minor* describe the limitations of proposed new claim 41-45:

Proposed New Claims 41-45 of Reissue Application	**Prior Art Reference Discussion**
41. A food product comprising the heat-denatured whey protein composition of claim 21.	Native whey proteins, for example whey proteins separated from dairy milk following a cheesemaking process, do not have the consistency, mouthfeel, and low water absorption characteristics of an ideal food ingredient to be used in nutrition bars and other confectionary products. Thus, the native whey protein is denatured by, for example, heating at temperatures of about 140° F. to about 300° F., to produce more hydrophobic compositions with lower water absorption properties and smoother, thicker consistencies that have desirable organoleptic qualities as a food ingredient. (*Merrill* at ¶ [0015]). The dried whey protein powder may then be packaged or added directly to other

	ingredients for making a foodstuff. (*Merrill* at ¶ [0023]). [A] composition may be provided to a person in need thereof in powder form... (*Minor* at ¶ [0105]).
42. The food product of claim 41, wherein the food product is a nutrition bar.	One with skill in the art will recognize that the method outlined in FIG. 2 can be used to make foodstuffs other than confectionaries. The foodstuffs made can broadly illustrate any type of food to which one can substitute at least a portion of an ingredient with whey protein. Examples of suitable types of foods into which the provided whey protein can be added, include, but are not limited to: pastries, candies, salty-crunchy snacks (such as potato chips), confectionaries, candy bars, ***nutrition bars***, protein bars, meal replacement foods, jellies, jams, dressings, ice creams, cheeses, and meats, among other foods. (*Merrill* at ¶ [0029], *emphasis added*).
43. The food product of claim 42, further comprising a carbohydrate source.	Embodiments of the invention may further include a method of making protein enhanced caramel or nutrition bars. … The method may also include drying the slurry to form a whey protein powder, and ***adding the whey protein powder to other ingredients*** such as butter, **sugar**, and condensed milk to form the protein enhanced caramel. (*Merrill* at ¶ [0009], *emphasis added*). It is emphasized that the aqueous composition comprising non-hydrolysed globular proteins may contain, next to non-hydrolysed globular proteins, in particular whey, any other nutritional ingredients, such as other proteins, amino acids, fat, ***carbohydrates***, fibers, minerals, vitamins, and the like... (*Minor* at ¶ [0046], *emphasis added*).
44. A nutrition bar comprising the heat-denatured whey protein composition of claim 21.	One of the most superior classes of food protein is whey protein. It is known for its excellent amino acid profile, high cystein content, rapid digestion, and interesting bioactive proteins (lactoglobulins, immunoglobulins, and lactoferrins). Nutritionally speaking, whey protein is

	known as a naturally complete protein because it contains all of the essential amino acids required in the daily diet. It is also one of the richest sources of branched chain amino acids (BCAAs, in particular leucine) which play an important role in muscle protein synthesis. Moreover, some of the individual components of whey protein have been shown to prevent viral and bacterial infection and modulate immunity in animals. Whey protein is the preferred choice of proteins to treat persons suffering from sarcopenia, but is also suitable for healthy persons, such as sportsmen and active elderly. (*Minor* at ¶ [0029]). Embodiments of the invention may further include a method of making protein enhanced caramel or nutrition bars. (*Merril* at ¶ [0009]).
45. The nutrition bar of claim 44, further comprising a carbohydrate source and fat.	Embodiments of the invention may further include a method of making protein enhanced caramel or nutrition bars. … The method may also include drying the slurry to form a whey protein powder, and ***adding the whey protein powder to other ingredients*** such as butter, **sugar**, and condensed milk to form the protein enhanced caramel. (*Merrill* at ¶ [0009], *emphasis added*). It is emphasized that the aqueous composition comprising non-hydrolysed globular proteins may contain, next to non-hydrolysed globular proteins, in particular whey, any other nutritional ingredients, such as other proteins, amino acids, fat, ***carbohydrates***, fibers, minerals, vitamins, and the like... (*Minor* at ¶ [0046], *emphasis added*).
46. The nutrition bar of claim 45, wherein the nutrition bar, after storage for one week at 20° C, has a hardness from 400 to 1100 g as measured at room temperature by penetration force using a 5 mm stainless steel cylindrical probe pushed into the bar at a constant rate of 1 mm/s to a compression depth of 12 mm.	

47. The nutrition bar of claim 44, wherein the nutrition comprises 30-45% (w/w) of the heat-denatured whey protein composition.	

REAL PARTY IN INTEREST

The real party in interest is Leprino Foods Company of Denver, Colorado.

REQUIREMENTS UNDER 37 C.F.R. §1.291

As required by 37 C.F.R. § 1.291, the Protestor hereby provides the following list of information relied upon in the Protest, and a statement of relevance of the information.

The Protestor identifies the following U.S. Patents and U.S. Published Applications as being relevant for the Protest:

- U.S. Publication No. 2011/0046048 to *Minor et al* (*Minor*) filed 3/12/2009 and published 2/24/2011
- U.S. Publication No. 2009/0298767 to *Rowney et al* (*Rowney*) filed 6/15/2007 and published 12/3/2009
- U.S. Publication No. 2006/0204643 to *Merril et al* (*Merril*) filed 3/13/2006 and published 9/14/2006

In accordance with 37 C.F.R. 1.291(c)(3), the Protestor is not providing paper copies of the above-identified U.S. patents and published patent applications.

The Protestor also identifies and provides the following non-patent literature as being relevant for the Protest:

- *Dairy Processing Handbook*, Ch. 17, pages 361-374, published in 1995 by Tetra Pack Processing Systems AB, S-221, 86 Lund, Sweden
- Applicant's Response to USPTO Final Office Action filed November 26, 2019, in U.S. Application No. 16/214,548 (subsequently U.S. Patent No. 10,888,100)
- Applicant's Response to USPTO Final Office Action filed October 24, 2016, in U.S. Application No. 13/264,564

All the above identified documents are relevant because they show how the Applicant's proposed new claims 21-47 are obvious in view of the above-identified documents.

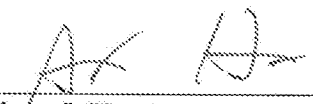
The undersigned certifies that on this day, the undersigned has caused to be served copies of this Protest by facsimile and first-class mail on:

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CONCLUSION

In view of the foregoing, the Protestor respectfully asserts that claims 1 to 47 of the above-captioned reissue application should not be allowed. Protestor respectfully requests the Office carefully consider the arguments presented herein before taking action regarding this reissue application.

Respectfully submitted,



Alexa J. Hunter
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