

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARLA FOODS AMBA,

Petitioner

v.

LEPRINO FOODS COMPANY,

Patent Owner

IPR2025-01199

Patent 11,825,860

**DECLARATION OF FEDERICO HARTE, PH.D.
IN SUPPORT OF PATENT OWNER'S PRELIMINARY RESPONSE**

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I. Introduction

1. I, Federico Harte, Ph.D. have been retained as an expert witness of behalf of Leprino Foods Company (“Patent Owner”) in connection its Preliminary Response in response to the Petition for *Inter Partes* Review (“Petition”) filed by Arla Foods AMBA (“Arla” or “Petitioner”) challenging Claims 8-9, 11-13, and 15-20 of U.S. Patent No. 11,825,860 (“the ’860 Patent”).
2. I have reviewed the ’860 Patent, the Petition, and the exhibits cited in the Petition to prepare this Declaration.
3. I am being compensated at my usual and customary rate. My compensation is in no way dependent on the outcome of this case. I have not previously served as an expert witness.

II. Education and Experience

4. I am an expert in the field of food engineering and the structure-function properties of milk proteins. Over the past two decades years, I have gathered significant experience investigating dairy processing. I currently serve as a Professor of Food Science at Pennsylvania State University, where I teach courses on dairy processing and oversee a research

laboratory investigating dairy proteins. Prior to this role, I held faculty positions at the University of Uruguay and the University of Tennessee.

5. I obtained a B.S. in Agricultural Engineering from the University of Uruguay in 1995 and graduated with an Ph.D. in Biosystems Engineering from Washington State University in 2002. I have been published in numerous journals influential in dairy food science, including *Journal of Dairy Science*, *International Journal of Food Microbiology*, *Innovative Food Science & Emerging Technologies*, *Journal of Food Protection*, and *Journal of Food Engineering*. I was a senior editor for the Dairy Foods Section of the *Journal of Dairy Science* from 2016 to 2022. I have also been invited to speak at numerous dairy and food science conferences.

III. Materials Considered

6. In forming the opinions in this declaration, I considered the materials cited in this declaration, in light of the general knowledge in the art before January 13, 2022.
7. I also relied on my education and knowledge, as well as my experience in academic and research, including those discussed in Section II.
8. I reserve the right to amend and supplement any of the opinions in this declaration as needed in response to new information and evidence made

available to me, additional analysis that leads me to conclude the supplementation is necessary, new issues that may arise, any discovery, arguments, evidence, or testimony presented in this inter partes review, and any Patent Trial and Appeal Board (“Board”) decisions or orders.

IV. Technology Background

9. Below I provide a brief background of the state of the art before the priority date to support my opinions on obviousness discussed in Sections VII-VIII. A person of ordinary skill in the art (“POSITA”) would also have been aware of the additional references related to whey protein compositions. Unless otherwise indicated, my below description of the relevant technology and my opinions contained herein are as of the state of the art before the priority date.
10. During cheese making, casein proteins from milk form curds, and whey is separated from the curds and diverted for further processing. Ex. 1001, 1:17-23. Whey may be used to make high protein compositions, e.g., whey protein powders, as described in the ’860 Patent. *Id.*, 1:15-17. Whey includes milk-derived proteins such as beta-lactoglobulin (BLG), alpha-lactalbumin (ALA), and glycomacropeptide (GMP). *Id.*, 4:36-43.

V. Person of ordinary skill in the art (“POSITA”)

11. I understand that a person of ordinary skill in the art is a hypothetical person who is presumed to be familiar with the relevant scientific field and its literature at the time when the patent application was filed.
12. In my opinion, for the '860 patent, a POSITA is a person with a relatively high level of skill, such as having at least a bachelor's degree in food science or a related field, and 2+ years of work experience or research related to processing dairy products or developing protein compositions for food products. A POSITA would have knowledge of the scientific literature pertaining to dairy processing and dairy proteins. A POSITA would also have knowledge of laboratory techniques related to dairy processing and dairy protein analysis.

VI. The '860 Patent

13. The '860 patent is directed to producing high protein whey compositions with reduced GMP content. Ex. 1001, 5:25-39. The '860 patent issued from U.S. Patent Application Number 18/097,003 and ultimately claims priority to U.S. Patent Application Number 18/503,535 filed on January 13, 2023. I understand that the “critical date” for prior art references is one year prior to the date for which a claim is entitled to priority, i.e., January 13, 2022.

14. Below is claim 8 of the '860 patent :

8. 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; and

reducing native glycomacropeptides (GMP) in 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 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.

VII. Grounds 1-3: Nielsen785 and Nielsen450 do not teach reducing native GMP in a cheese whey retentate (Cl. 8.2).

15. Claim 8, challenged in Grounds 1-3, recites “reducing native [GMP] in the cheese whey retentate” (8.2). Ex. 1001. A POSITA would understand a retentate is the portion of a solution or feed captured by the filter, i.e.,

not able to pass through the pores of the filter and obtained in the filter.

Ex. 2004, 5. Language in the the '860 patent also supports this meaning:

the “cheese whey retentate” is the portion of cheese whey that is captured

by the filter. Ex. 1001, 2:2-11. The portion of the cheese whey which

passes through the filter is referred to as the “cheese whey permeate.” Ex.

1001, 18:18-24.

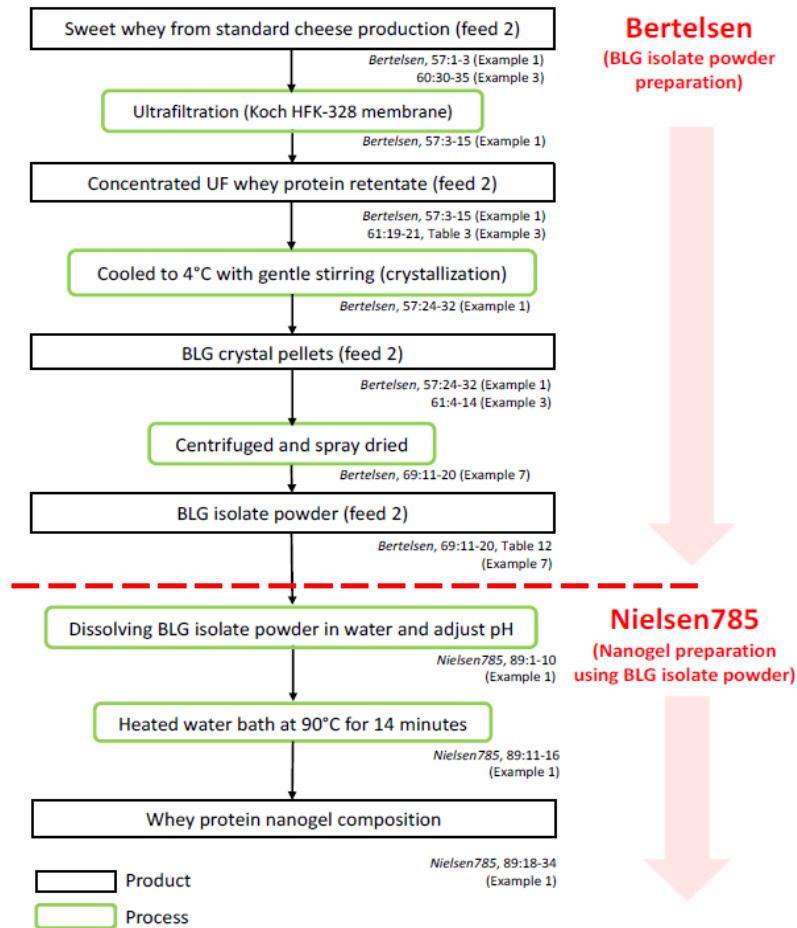
16. Petitioner argues that Nielsen⁷⁸⁵ (Grounds 1-2) and Nielsen⁴⁵⁰

(Ground 3) incorporate Bertelsen’s Example 1, which teaches “reducing

native glycomacropeptides (GMP) in the cheese whey retentate to form a

reduced-GMP cheese whey retentate composition.” Pet., 11-14.

Petitioner created a flow chart, allegedly showing this process:



Pet., 8.

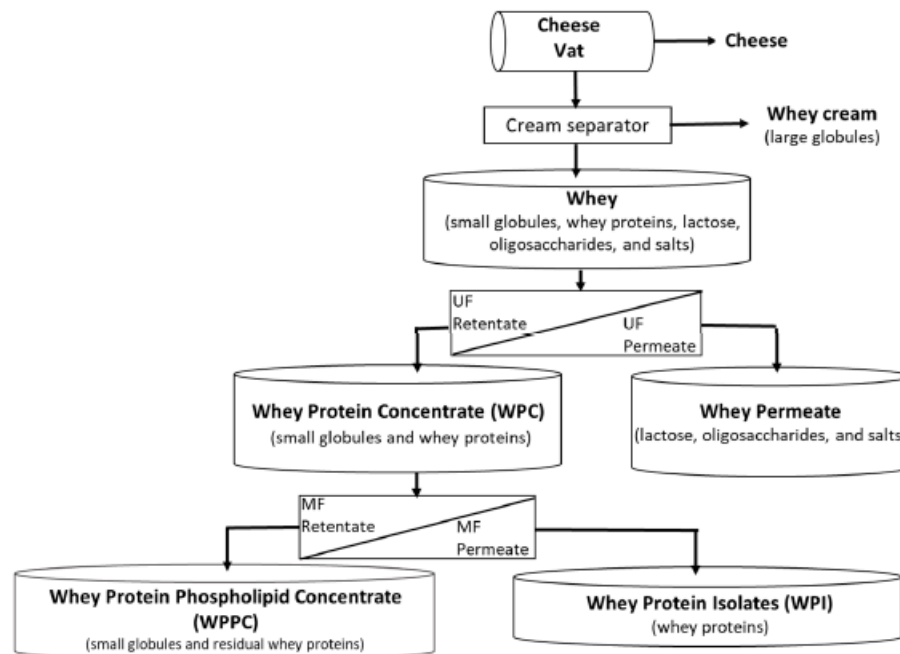
17. Petitioner’s flow chart does not accurately depict Bertelsen’s method.

Example 1 of Bertelsen describes “lactose depleted [ultrafiltered] retentate from sweet whey from a standard cheese production process and filtered through a 1.2 micron filter was used as feed for the BLG crystallization process.” Ex. 1006, 57:3-5. This sentence requires two steps which Petitioner does not explain. First, sweet whey from cheese production is ultrafiltered to reduce lactose and form the “lactose depleted [ultrafiltered retentate].” Ex. 1006, 57:3-5. Second, the “lactose

depleted [ultrafiltered retentate]” is filtered through a 1.2 micron filter.

Ex. 1006, 57:3-5. A POSITA would know that filtering through a 1.2 micron filter is microfiltration. Ex. 2004, 1, 8.

18. A POSITA would also know that microfiltering an ultrafiltered retentate, as described in Bertelsen, creates a permeate. Ex. 1008, Figure 1. Petitioner’s own reference, Ozturk (Ex. 1008), clearly shows this:

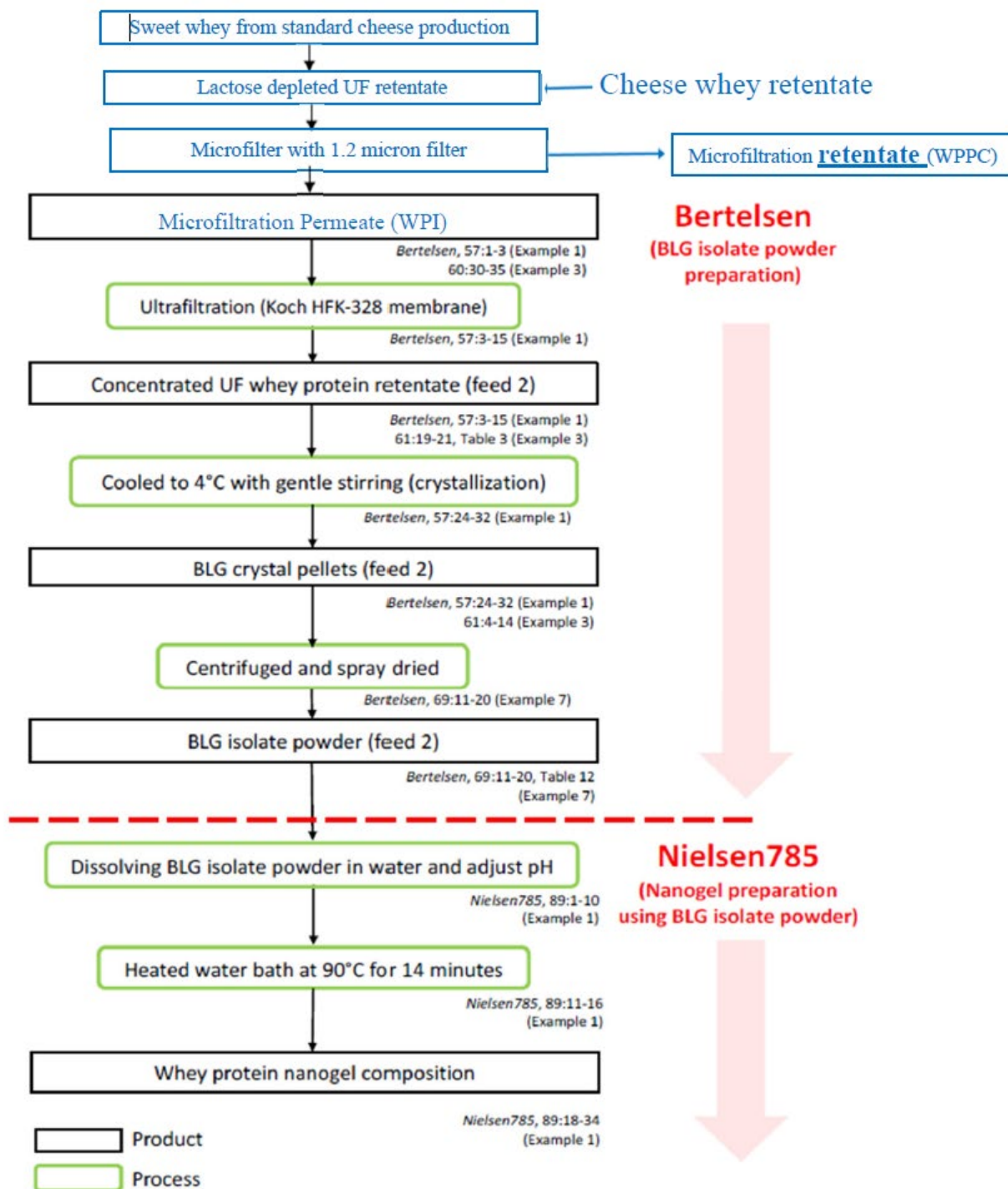


Ex. 1008, Figure 1.

19. As shown above, microfiltering the “lactose depleted [ultrafiltered retentate]” (called a WPC in the chart above) would create two compositions: a whey protein phospholipid concentrate (WPPC) and a whey protein isolate (WPI). Ex. 1008, Figure 1. WPI has a higher whey

protein concentration than WPPC, which is higher fat. Ex. 1008, Figure 1. Bertelsen describes that the composition of the microfiltered “lactose depleted [ultrafiltered retentate]” has 79 wt. % protein and 5.6 wt. % fat. Ex. 1006, Table 1. A POSITA would understand the microfiltered “lactose depleted [ultrafiltered retentate]” is thus a whey protein isolate (WPI), which, as shown in the chart above, is a permeate—not a retentate. Ex. 1006, Table 1; Ex. 1008, Figure 1.

20. Although Petitioner relies on Bertelsen’s “concentrated retentate” from Example 1, it would be clear to a POSITA that this “retentate” is not a “cheese whey retentate” because it is formed from a permeate microfiltered from the cheese whey retentate. Ex. 1006, Table 1; Ex. 1008, Figure 1. While the “concentrated retentate” of Example 1 of Bertelsen may be a retentate of the sweet whey feed, after further processing, it is no longer a “cheese whey retentate.” Ex. 1006, Table 1; Ex. 1008, Figure 1. Properly showing the method of Bertelsen, Petitioner’s flow chart should be modified as follows:



Pet., 8 (blue text and boxes added).

21. As shown in the above corrected flow chart, the sweet whey feed of

Bertelsen is not a cheese whey retentate, it is a permeate because it passes

through the microfiltration filter. Ex. 1006, Table 1; Ex. 1008, Figure 1; Ex. 2004, 5; Ex. 1001: 2:2-11, 18:18-24. Thus, a POSITA would not understand that Nielsen785 or Nielsen450 (starting from a BLG isolate powder produced according to Bertelsen) discloses a reduced native GMP in the cheese whey retentate. For at least these reasons, it is my opinion that Nielsen785 incorporating Bertelsen and Nielsen450 incorporating Berterlsen do not teach claim element 8.2 and does not anticipate or render obvious claim 8.

VIII. Ground 3: Nielsen450 fails to teach or suggest greater than 50 wt. % denatured whey proteins, and Dr. Etzel's experiments are faulty (Cls. 8.7 and 15.5).

22. Claim limitations 8.7 and 15.5 recite “greater than 50 wt. % denatured whey proteins relative to the total weight of the protein.” Ex. 1001, claims 8, 15. Petitioner admits Nielsen450 does not teach degrees of protein denaturation, and thus does not disclose “greater than 50 wt. % denatured whey proteins relative to the total weight of the protein.” Pet., 30; Ex. 1001, claims 8, 15. Instead, Petitioner argues that Nielsen450 discloses heating protein solutions, and that it would have been obvious to a POSITA that the heating would result in “significant denaturation.” Pet., 30.

23. To show specific degrees of protein denaturation, Dr. Etzel claims to have replicated experiments from Nielsen⁴⁵⁰. Pet., 30. However, the BLG isolate powder used as Dr. Etzel's starting material was stored at room temperature (approximately 22°C) between 30-50% humidity for at least 7 years. Ex. 1021, 2; Ex. 1003, ¶ 145, 166-167. During this extended storage, the BLG isolate powder would have undergone significant changes in protein denaturation. Ex. 2002, 1-2; Ex. 2003, 1.
24. It is well known in the art that whey protein powders undergo numerous changes during storage, which is why consumer whey protein powders have a very limited shelf-life. Ex. 2002, 1-2; Ex. 2003, 1. Two studies, in particular, discuss these changes in detail. Ex. 2002; Ex. 2003.
25. Sithole et al. (Ex. 2002) evaluated Maillard browning in stored commercial sweet whey powders. Ex. 2002, 1. Maillard browning is non-enzymatic browning of lactose and protein in whey protein powders and can lead to protein loss, among other effects. Ex. 2002, 1. The powders in Sithole et al. were stored under normal storage conditions (closed containers at 21° C, 35% residual humidity) or accelerated shelf-life testing conditions (open containers at 21° C, 35% residual humidity). Ex. 2002, 1.-2. Samples were withdrawn for analysis after storage for 1, 5, 9, 12, and 19 months. Ex. 2002, 2.

26. Sithole et al. found Maillard browning increased as storage duration and temperature increased in both normal storage conditions and accelerated shelf-life testing conditions. Ex. 2002, 5. The samples in Sithole et al. were stored at similar temperature and humidity (21° C, 35% residual humidity) as the sample used by Dr. Etzel (approximately 22°C, 30-50% residual humidity). Ex. 2002, 1-2. However, the samples in Sithole et al. were stored for much less time (19 months at most) than the sample used by Dr. Etzel (7+ years). Ex. 2002, 1-2; Ex. 1021, 2; Ex. 1003, ¶ 145, 166-167. From these data, a POSITA would understand that Dr. Etzel's sample stored for 7+ years would have undergone significant Maillard browning, since the sample was stored at similar conditions for much more time than the samples in Sithole et al.
27. Further, Nishanthi et al. discuss the impact of storage conditions for whey protein powders. Ex. 2003, 1-2. Nishanthi et al. assessed heat stability of the whey protein powders samples stored at 25 °C and either 22% or 33% relative humidity for 90 days. Ex. 2003, 1-2. Heat stability was assessed using heat coagulation time, which is the time it takes for proteins to form visible aggregates following heat denaturation. Ex. 2003, 3. Lower heat coagulation time signals faster denaturation rates. Ex. 2003, 3.

28. Nishanthi et al. found that heat coagulation time dropped from 53 seconds at day 0 of storage, to 28 seconds at 90 days of storage in whey protein concentrate samples stored at 25 °C and 22% relative humidity. Ex. 2003, Table 1. The whey protein powder sample Dr. Etzel used was stored for 28 times as long (7+ years versus 90 days), and at higher humidity (30-50% versus 22% relative humidity). Ex. 2003, 1-2; Ex. 1021, 2; Ex. 1003, ¶ 145, 166-167. From these results, a POSITA would understand the sample Dr. Etzel used would have reduced heat coagulation time, and thus would have denatured much more readily than those in Nishanthi et al.

IX. Conclusion

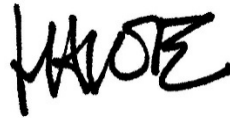
29. For at least the reasons I discussed above, it is my opinion that Claims 8-9, 11-13, and 15-20 of the '860 Patent are not anticipated or obvious over Petitioner's references.

I hereby declare that statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. Should further information become available to me as this matter proceeds, I may revise my opinions accordingly as necessary. I declare under penalty of perjury that the foregoing Declaration is true and correct and understand that willful false statements and the like are punishable by fine or imprisonment, or both, pursuant to 18 U.S.C. § 1001.

Respectfully Submitted,

10/28/2025

Date

A handwritten signature in black ink, appearing to read 'HARTE', written over a horizontal line.

Federico Harte, Ph.D.