UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARLA FOODS AMBA, x.

Petitioner

v.

LEPRINO FOODS COMPANY,

Patent Owner

IPR2025-01199
Patent 11,825,860

PATENT OWNER RESPONSE

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Statement of Material Facts in Dispute

Petitioner did not submit a statement of material facts in its Petition. Accordingly, no response is due pursuant to 37 C.F.R. § 42.23(a), and no facts are admitted.

I. Introduction

Leprino Foods Company ("Patent Owner") respectfully submits this Patent Owner 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"). The Declaration of Dr. Federico Harte is filed in support of this Response and is included as Ex. 2005. For the reasons addressed below, the Board should *affirm* the patentability of the challenged claims.

The Petition is legally deficient because ***each Ground fails to disclose one or more claim limitations***. Ground 1, which is based on anticipation, fails on this deficiency alone. For obviousness Grounds 2-4, Petitioner fails to properly cure the deficiencies of the prior art with secondary references or explain how the knowledge of a person of ordinary skill in the art ("POSITA") would remedy the missing claim limitations. Additionally, for Ground 4, the Petition fails to show that a POSITA would have combined the references with a reasonable expectation of success. As such, the Petition does not present legally viable anticipation and obviousness theories and each Ground fails.

Notably, this Response presents new arguments not considered at the Director's institution decision that are supported by an extensive evidentiary record, including the deposition testimony of Petitioner's expert, Dr. Etzel, and its

fact witness, Ms. Jaeger. In view of the foregoing, each of Petitioner's grounds should be rejected and the patentability of challenged claims 8-9, 11-13, and 15-20 of the '860 Patent should be affirmed.

II. Background

A. The '860 Patent

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; Ex. 2005, ¶¶ 12-28; Ex. 2005, ¶¶ 31-32. Whey, which includes milk-derived proteins such as beta-lactoglobulin (BLG), alpha-lactalbumin (ALA), and glycomacropeptide (GMP), may be used, for example, to make high protein compositions, e.g., whey protein powders, as described in the '860 Patent. Ex. 1001, 1:15-17, 4:36-43; Ex. 2005, ¶¶ 12-28.

As the '860 Patent explains, GMP is considered an inferior source of protein for muscle recovery, and protein powders containing a high native GMP content may provide undesirable flavor profiles in any ultimately formed whey protein products. Ex. 1001, 1:30- 39; Ex. 2005, ¶¶ 12-28. The '860 Patent describes a novel and inventive way of producing high protein whey compositions with reduced GMP content. *Id.*, 5:25-39.

The high protein whey compositions with reduced GMP content may include the components of Claim 15 and may be made according to the method of Claim 8. *Id.,* Claims 8, 15. Steps that can be used to make high protein whey compositions with reduced GMP content are also depicted in Figure 1:

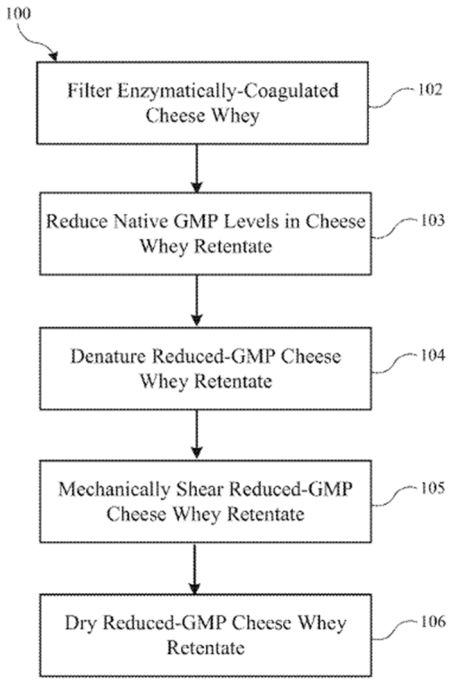


FIG. 1

Id., Figure 1. The inventors of the ’860 patent surprisingly and unexpectedly discovered that with their method, they could produce high protein whey compositions with reduced GMP content that possess desirable properties for downstream consumer uses. *Id.*, 1:28-40.

The many advantages and benefits of the claimed method for making high protein whey compositions with reduced GMP content and the resulting compositions themselves demonstrate that the USPTO’s decision to grant the ’860

Patent is consistent with the primary goal of the patent system: rewarding innovation for the benefit of society.

B. The Petitioned Prior Art

i. Nielsen785 (Ex. 1005)

The WO 2021/136785 patent application ("Nielsen785") describes the formation of whey protein nanogel compositions for food or beverage use with a "surprisingly high concentration of native [BLG]." Ex. 1005, 1:7-9, 34-35; Ex. 2005, ¶¶ 41-42. Nielsen785 describes that a BLG isolate powder may be mixed with water to form a solution, which is then heat treated to form the denatured nanogel. Ex. 1005, 89: 1-3, 11-16, 25-29; Ex. 2005, ¶¶ 41-42. As discussed below, Nielsen785 does not disclose a "reduced-GMP cheese whey retentate" as the term is used in the '860 Patent, let alone forming or heating the "reduced-GMP cheese whey retentate," as claimed.

ii. Bertelsen (Ex. 1006)

The WO 2018/115520 patent application ("Bertelsen") describes the formation of crystallized BLG powders and uses of its powders in food products. Ex. 1006, 1: 6-10; Ex. 2005, ¶¶ 43-45. In forming its crystalline BLG powders, Bertelsen describes that whey may be microfiltered to form a retentate and a permeate. Ex. 1006, 57:3-5; Ex. 2006, 120:17-19, 24; Ex. 2005, ¶¶ 43-45. The resulting cheese whey permeate—not the cheese whey retentate—is then directed

to an ultrafiltration step. Ex. 2006, 120:17-19, 24; Ex. 2005, ¶¶ 43-45. The ultrafiltration step forms an ultrafiltration retentate, which is seeded with a BLG crystal starter, cooled, and centrifuged to separate the BLG crystals. Ex. 1006, 57:17-18, 24-26, 29-30; Ex. 2005, ¶¶ 43-45. The BLG crystals are then freeze-dried and mixed with water to form a slurry, and then finally spray dried to form a powder. Id., 57: 31-32, 69:11-20; Ex. 2005, ¶¶ 43-45. As discussed below, because Bertelsen starts with a cheese whey ***permeate***, it does not disclose reducing GMP in a "cheese whey ***retentate,***" as claimed. Ex. 2005, ¶¶ 43-45. Additionally, Bertelsen fails to disclose denaturing its BLG powders. Ex. 2005, ¶¶ 43-45.

iii. Nielsen450 (Ex. 1007)

Like Nielsen785, the WO 2020/002450 patent application ("Nielsen450") describes the formation of BLG isolate powders and their use in beverages. Ex. 1007, 1:1-6; Ex. 2005, ¶¶ 46-47. Nielsen450 describes that the BLG isolate powder may be mixed with water to form a solution, which is then heat treated to form the denatured beverage. Ex. 1007, 97: 23-30; Ex. 2005, ¶¶ 46-47. As discussed below, Nielsen450 also does not disclose a "reduced-GMP cheese whey retentate" as the term is used in the '860 Patent, let alone forming or heating the "reduced-GMP cheese whey retentate composition" as claimed.

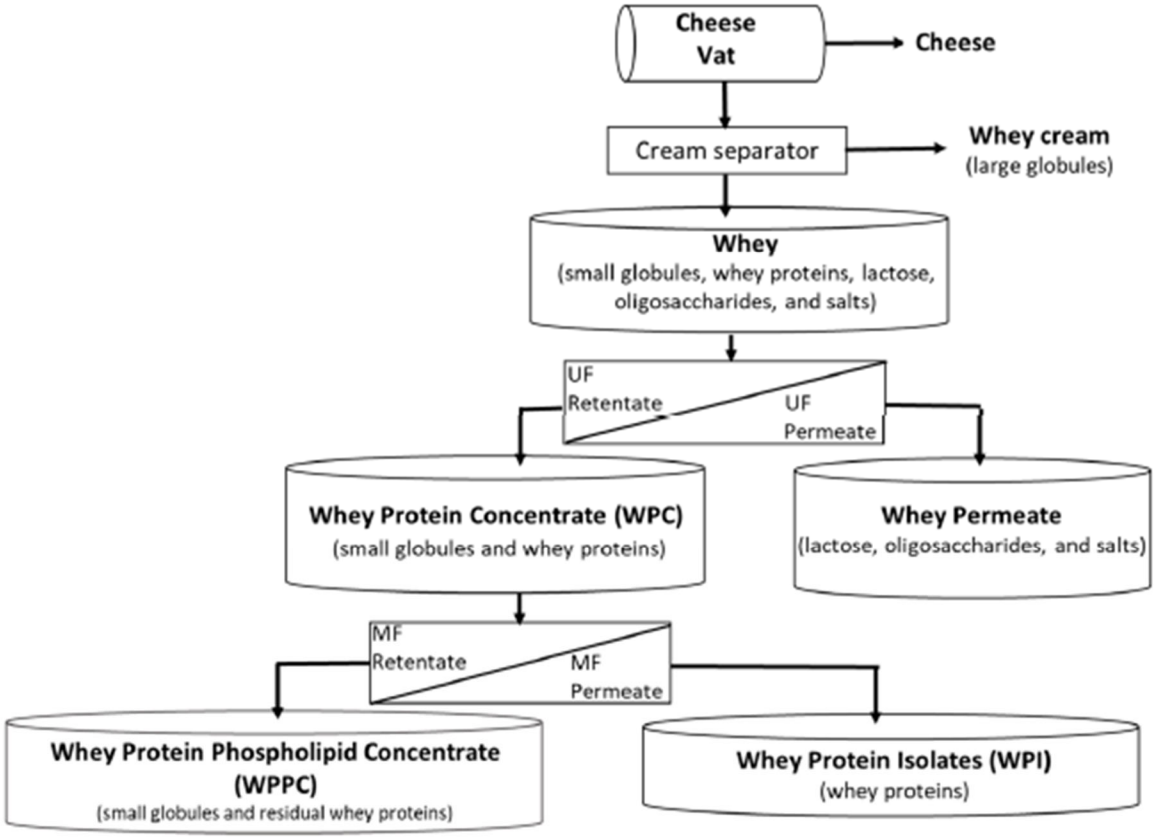
iv. Ozturk (Ex. 1008)

The article, "Glycoproteomic and Lipidomic Characterization of Industrially

Produced Whey Protein Phospholipid Concentrate with Emphasis on Antimicrobial Xanthine Oxidase, Oxylipins and Small Milk Fat Globules" ("Ozturk") was allegedly published in *Dairy* on April 20, 2022. Pet., 56. Ozturk describes high fat whey protein phospholipid concentrates ("WPPCs") that contain milk fat globule ("MFG") compounds useful for immune and gut health. Ozturk discusses that WPPC may be a source of valuable MFG byproducts. Ex. 1008, 1, 22; Ex. 2005, ¶¶ 48-50.[1]

In the Ozturk process, Whey from cheese making is subjected to ultrafiltration to produce a whey protein concentrate (WPC), which includes fat globules and whey proteins, and lacks lactose, oligosaccharides, and salts from the whey. *Id.*, 279. The WPC may then be microfiltered to produce a high protein, low fat whey protein isolate (WPI) and a lower protein high fat WPPC. *Id*. This process is shown in Figure 1 below:

[1] Petitioner did not include page numbering on any exhibit. Reference is made to the native document page number of Exhibit 1008 and to the native document page number of Exhibits 1009-1010 and 1021 hereafter.



Id., 3, Figure 1. Ozturk is completely silent concerning the GMP content/reduction of its whey, the WPC, and the WPPC. Additionally, Ozturk does not teach heating a "reduced-GMP cheese whey retentate composition" as claimed.

v. Kawasaki (Ex. 1009)

The article, "pH-dependent molecular weight changes of κ-casein glycomacropeptide and its preparation by ultrafiltration" ("Kawasaki") was allegedly published in *Milchwissenschaft* in 1993. Pet., 60. Kawasaki describes that GMP has numerous biological functions and, for this reason, should be isolated as an ingredient for food and pharmaceutical use. Ex. 1009, 191-192; Ex.

2005, ¶¶ 51-52. Kawasaki goes on to describe a filtration method for isolating GMP from a whey protein stream. Ex. 1009, 191-193; Ex. 2005, ¶¶ 51-52.

vi. LeanCreme (Ex. 1010)

The white paper, "APV LeanCreme" was allegedly published on the SPX Flow website by June 26, 2016. Pet., 63. As its name suggests, LeanCreme describes creating protein powders for use in "low fat content" food products. Ex. 1010, 23; Ex. 2005, ¶¶ 53-54. The LeanCreme powders are used to mimic the "viscosity of coffee cream" and provide a "mouth feel similar to fat." Ex. 1010, 4; Ex. 2005, ¶¶ 53-54. LeanCreme describes that its microparticulated whey protein is produced from WPC using "an innovative microparticulation process, in which whey protein concentrate is heated under controlled high-shear conditions, enabling the formation of fine particles with a specific particle size similar to fat globules." Ex. 1010, 4; Ex. 2005, ¶¶ 53-54. . LeanCreme teaches the desired microparticulated protein size to achieve the desired mouthfeel is between 1 and 10 μM. Ex. 1010, 5, 9; Ex. 2005, ¶¶ 53-54.

III. Person of Ordinary Skill in the Art

A person of ordinary skill in the art (POSITA) is a hypothetical person presumed to be aware of all pertinent art, to think along with conventional wisdom in the art, and to have ordinary creativity. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407-09, 420-21 (2007). Patent Owner does not dispute Petitioner's definition

of a POSITA as having 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. Pet., 5; Ex. 2005, ¶¶ 29-30.

IV. Claim Construction

A. Applicable Law

Claims are ordinarily given their "ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13, 1315 (Fed. Cir. 2005) (citation omitted). To construe a claim term, the Board should look to "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id., 1314 (citation omitted). "A patent's specification, together with its prosecution history, constitutes intrinsic evidence to which the PTAB gives priority when it construes claims." *Knowles Elecs. LLC v. Cirrus Logic, Inc.*, 883 F.3d 1358, 1361-62 (Fed. Cir. 2018) (footnote omitted). The Board need only construe claims to the extent necessary to resolve controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Claim terms not discussed herein have plain meanings on their face and should be construed to have their ordinary and customary meanings.

Petitioner proposes several defective claim constructions that do not represent the plain and ordinary meaning of the claims and improperly construes claim terms not requiring construction. The following discussion proposes constructions for certain terms in the challenged claims of the '860 patent.

B. "cheese whey retentate" and "cheese whey retentate composition"

Claims 8.2 and 8.3 recite "cheese whey retentate" and "cheese whey retentate composition." These claim terms are entitled to their plain and ordinary meanings. *Phillips*, 415 F.3d at 1312-13, 1315.

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. Ex. 1001, 2:2-11, 18:18-24; Ex. 2005, ¶ 37. A cheese whey retentate is the opposite of a cheese whey permeate, which passes through the filter. Ex. 1001, 2:2-11, 18:18-24; Ex. 2005, ¶ 37.

The term "cheese whey retentate composition" is broader than the term "cheese whey retentate" and can include additional components, such as enzymes, so long as the cheese whey retentate composition also includes a cheese whey retentate. Ex. 1001, 2:3-9; Ex. 2005, ¶ 38. The '860 Patent specification is clear on this point: "The method includes . . . ***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***." Ex. 1001, 2:3-9.

(emphases added). This intrinsic evidence supports that the "cheese whey retentate" and the "cheese whey retentate composition" are different from one another in that the composition may contain the retentate plus additional components, such as one or more enzymes. *Id*. Thus, the plain and ordinary meaning of the term "cheese whey retentate" is the portion of cheese whey that is captured by the filter after initial filtration of the cheese whey. *Id.*, 2:2-11, 18:18-24; Ex. 2005, ¶ 38. The plain and ordinary meaning of the term "cheese whey retentate composition" is the portion of cheese whey that is captured by the filter after initial filtration of the cheese whey and optionally including one or more components added thereto. Ex. 1001, 2:3-9; Ex. 2005, ¶ 38.

Under the correct construction, Grounds 1-3 fail. The Bertelsen powder that was allegedly used in Nielsen785 and Nielsen450 was formed after processing a cheese whey permeate—not a cheese whey retentate. Ex. 2005, ¶ 39. For this reason, neither Nielsen785 nor Nielsen450 (nor Bertelsen) discloses forming or heating a "reduced-GMP ***cheese whey retentate*** composition." *Id.*

C. "beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00"

Claim 8.3 recites a "beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00." This limitation is entitled to its plain and ordinary meaning. *Phillips*, 415 F.3d at 1312-13, 1315.

The plain and ordinary meaning of a "beta-lactoglobulin [BLG] to alpha

lactalbumin [ALA] ratio of greater than 5.00" requires that some detectable amount of BLG and ALA must be present to meet the claim limitation. Ex. 2005, ¶ 40. As the Federal Circuit has recognized, a claimed ratio is the "result of dividing two values." *Zircon Corp. v. Stanley Black & Decker, Inc.*, 452 F. App'x 966, 978 (Fed. Cir. 2011). Basic math dictates that any ratio requires some amount in its denominator, otherwise it is undefined. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281*, n. 22 (Fed. Cir. 1985); Ex. 2005, ¶ 40 (citing Ex. 2030, 5). For example, in A:B, if B = 0, the ratio is undefined, not "greater than 5.00." *Ashland Oil*, *776 F.2d at* n. 22. The Board has reached the same conclusion in *Apple Inc. v. Masimo Corp.*, rejecting the petitioner's argument that a "ratio of operating time" can have a denominator of 0%. *Apple Inc. v. Masimo Corp.*, IPR2020-01524, Paper 29, 17 (PTAB 2022).

Thus, the plain and ordinary meaning of a "beta-lactoglobulin [BLG] to alpha lactalbumin [ALA] ratio of greater than 5.00" requires that some detectable amount of ALA must be present to meet the claim limitation. Ex. 2005, ¶ 40. This conclusion is also supported by the '860 Patent itself, which contemplates at least some detectable amount of BLG and ALA in its discussion of the claimed ratio. Ex. 1001, 8:17-23; Ex. 2005, ¶ 40.

The BLG:ALA ratio of the denatured nanogel in Nielsen785 is undefined because 0% ALA is present. Ex. 2005, ¶ 40. Thus, Grounds 1-2 cannot satisfy

claim limitation 8.6.

V. Overview of Arguments

For the reasons discussed below, Petitioner fails to show that the challenged claims should be cancelled. A summary of PO's arguments is provided below.

Ground	Brief Statement of Arguments
1: Anticipation by Nielsen785 (incorporating Bertelsen)	Nielsen785 fails to teach: • "reducing native [GMP] in the cheese whey retentate." • forming or heating the "reduced-GMP cheese whey retentate composition." • "a beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00."
2: Obvious over Nielsen785 and Bertelsen	Nielsen785 and Bertelsen fail to teach or suggest: • "reducing native [GMP] in the cheese whey retentate." • forming or heating the "reduced-GMP cheese whey retentate composition." • "a beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00."
3: Obvious over Nielsen450 (incorporating Bertelsen)	Nielsen450 fails to teach or suggest: • "greater than 50 wt. % denatured whey proteins relative to the total weight of the protein in the denatured whey protein composition." • "a beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00." • "reducing native [GMP] in the cheese whey retentate." • forming or heating the "reduced-GMP cheese whey retentate composition."
4: Obvious over Ozturk, Kawasaki, and LeanCreme	There is no motivation to combine Ozturk, Kawasaki, and LeanCreme. Ozturk, Kawasaki, and LeanCreme fail to teach or suggest: • "at least 60 wt. % whey protein on a dry weight basis" • "greater than 50 wt.% of the protein are denatured whey proteins."

VI. Petitioner fails to demonstrate the challenged claims are obvious over the cited references.

A. Ground 1: Nielsen785[2] fails to anticipate Claims 8-9, 11, and 13.

Claims 8-9, 11, and 13 are not anticipated by Nielsen785 (Ex. 1005) because Nielsen785 fails to teach three limitations of independent claim 8: (i) reducing native GMP in a cheese whey retentate (Cl. 8.2), (ii) forming and heating a reduced-GMP cheese whey retentate composition (Cls. 8.2-8.3), and (iii) a BLG:ALA ratio of greater than 5.00 as claimed (Cl. 8.6). Ex. 2005, ¶¶ 63-64.

A claim is anticipated only if a disclosure teaches every element of the claim, either expressly or inherently. *Verdegaal Bros., v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987). In other words, the claimed subject matter must be ***identically*** disclosed in the prior art. *In re Arkley*, 59 C.C.P.A. 804, 455 F.2d 586, 587 (1972).

Petitioner has failed to demonstrate that Nielsen785 anticipates claims 8-9, 11, and 13 because Nielsen785 fails to teach, expressly or inherently, several claim features. Independent claim 8 recites reducing (Cl. 8.2) native GMP in the cheese

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[2]Petitioner's arguments are based on Nielsen785 and Bertelsen and on the argument that Nielsen785 incorporates Bertelsen. Pet., 6. Reference herein to Nielsen785 also refers to Bertelsen to the extent the Petition argues Bertelsen is incorporated therein.

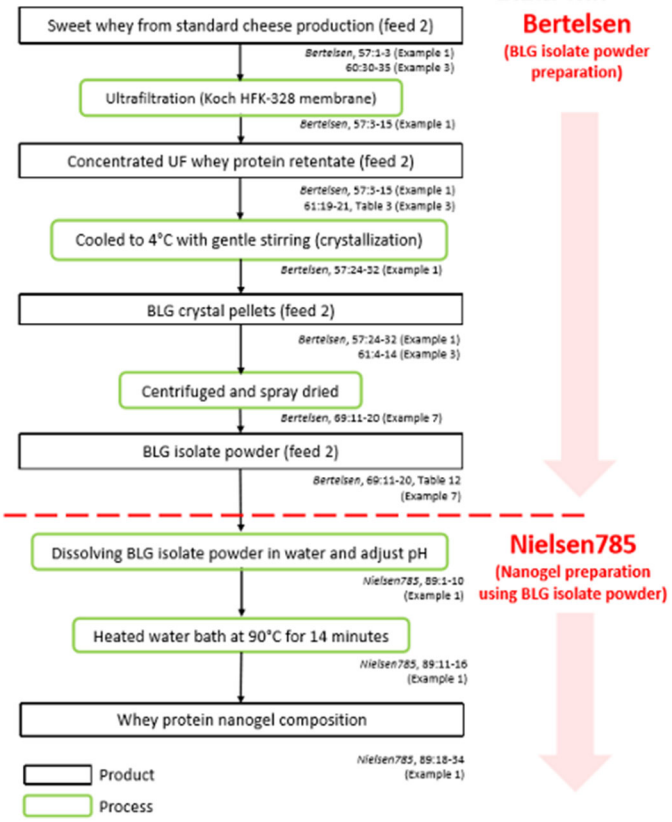
whey retentate "to form a reduced-GMP cheese whey retentate composition," and heating (Cl. 8.3) the resulting "***reduced-GMP cheese whey retentate composition***" to form a denatured whey protein composition. Ex. 1001, claim 8 (emphasis added). Nielsen785 fails to teach at least these claim elements. For these reasons, Ground 1 fails.

i. Nielsen785/Bertelsen does not disclose 8.2: "reducing native GMP in the cheese whey retentate."

a. Nielsen785*/Bertelsen describes reducing GMP in a cheese whey permeate—not in a cheese whey retentate.*

Petitioner alleges that Nielsen785 incorporates Bertelsen's Example 1, which Petitioner claims teaches filtering sweet whey from cheese production to obtain a cheese whey retentate for BLG crystallization. Pet., 5, 10-14. This interpretation of Bertelsen is incorrect. Ex. 2005, ¶ 65. In fact, the whey in Bertelsen is first subjected to a microfiltration step, which forms a cheese whey permeate and a cheese whey retentate. *Id.* Petitioner's expert confirmed in his deposition that Bertelsen's cheese whey "permeate" was then further processed to form its BLG isolate powder. Ex. 2006, 120:17-19, 24. Thus, the Bertelsen process for making BLG isolate powder starts from a ***cheese whey permeate—not from a cheese whey retentate.*** Ex. 2005, ¶¶ 65-81. For this reason, Nielsen785/Bertelsen fails to disclose reducing GMP "in a cheese whey retentate," as claimed. Ex. 2005, ¶¶ 65-81.

In alleging that Bertelsen discloses "reducing native glycomacropeptides (GMP) in the cheese whey retentate," the Petition includes the following flow chart that purportedly summarizes the Bertelsen process.



Pet., 8. This flow chart, however, omits several steps that Petitioner's own expert concedes are present in the Bertelsen process. Ex. 2006, 120: 21-122:6, 130:2-26:11. This distinction is not trivial, as the omitted steps in forming Bertelsen's BLG isolate powder demonstrate that the BLG isolate powder is actually made from a ***microfiltration permeate—which is the opposite of a cheese whey retentate.*** Ex. 2005, ¶¶ 65-81.

Although the above flow chart shows a single filtration step, the Bertelsen

process actually requires two filtration steps: a microfiltration step *and* an ultrafiltration step. Ex. 1006, 57:3-5; Ex. 2005, ¶¶ 65-81. Petitioner's flow chart omits the microfiltration step. Ex. 2005, ¶¶ 65-81. Example 1 of Bertelsen describes that:

> Lactose depleted UF retentate derived 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.

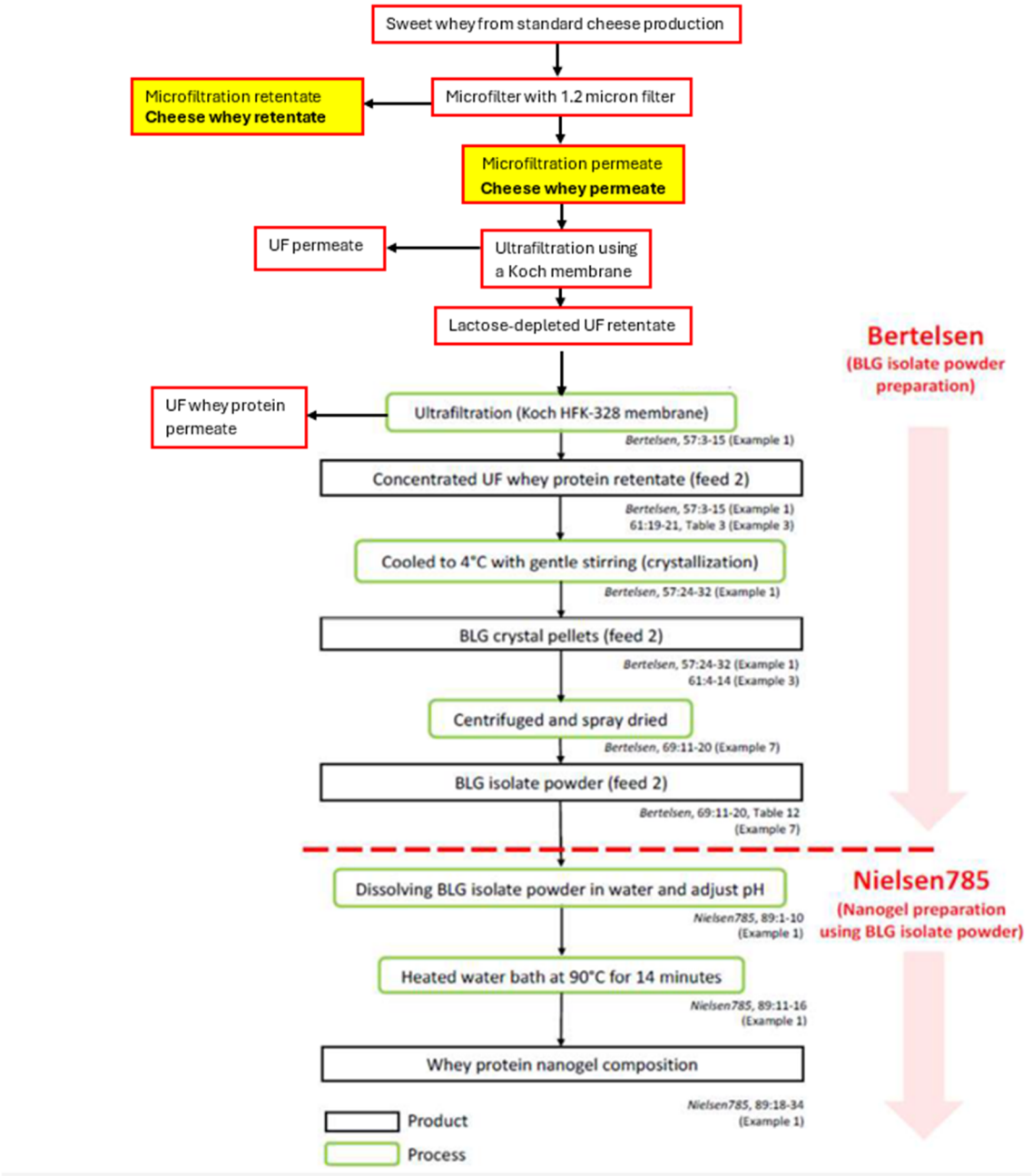
Ex. 1005, 57:3-5 (emphasis added). A POSITA would understand that filtration through a 1.2 micron filter is microfiltration. Ex. 2005, ¶¶ 65-81; Ex. 2004, 1, 8. And notably, microfiltration using a 1.2 micron filter results in protein removal. Ex. 2012, 8 (explaining 1.2 micron filter microfiltration removes 10% of proteins from skim milk). Moreover, a POSITA would understand that every microfiltration step creates a permeate and a retentate, and that these streams would be referred to as such. Multiple references support this view. Ex. 2027, 3, Fig. 1; Ex. 2019, 11; Ex. 2028, 8-9; Ex. 2029, 1-2. Thus, once cheese whey has been initially filtered, the resulting streams would be understood by those skilled in the art as being a cheese whey permeate and a cheese whey retentate. Ex. 2005, ¶¶ 65-81.

In fact, Dr. Etzel admitted exactly this:

> Q: Okay. So you're saying it is the output of that first microfiltration step that is the sweet whey feed. Is that what you're saying? . . .

> A: That's how I read this. . . .
>
> A: ***Permeate*** . . . ***[f]rom the 1.2 micron filter is the feed*** . . . to the UF membrane process.

Ex. 2006, 125:13-15, 20, 126:23-24. As shown in the below ***corrected*** Bertelsen flow chart, the feed to the BLG crystallization process of Example 1 is formed by first microfiltering cheese whey and then further processing the ***microfiltration permeate***, i.e., a cheese whey permeate. Ex. 2005, ¶¶ 65-81.



Pet., 8, (red boxes and red text added); Ex. 1006, 57:3-5.

Thus, Nielsen785/Bertelsen does not satisfy Claim 8.2 because, as shown in the corrected Bertelsen flow chart, the BLG isolate powder is actually made from a

cheese whey ***permeate***—not from a "cheese whey retentate" as claimed.[3] Ex. 2005, ¶¶ 65-81. For this reason the Petition's interpretation of Bertelsen is incorrect, and Ground 1 fails.

Additionally, in its discussion of limitation 8.2, the Petitioner goes to lengths in arguing that the BLG isolate powder has reduced GMP content, but there is ***not a single mention*** in this section of reducing GMP "***in the cheese whey retentate***" as claimed. Pet. 11-14. That is because the BLG isolate powder is formed from a completely different composition than a cheese whey retentate. Ex. 2005, ¶¶ 65-81. Specifically, the BLG isolate powder is instead formed, after many additional process steps, from a "microfiltration permeate." Ex. 2005, ¶¶ 65-81. As shown in the corrected Bertelsen flowchart, above, under Dr. Etzel's interpretation of Bertelsen, the "concentrated UF whey protein retentate" is decidedly **not** a "cheese whey retentate." *Id.* For this reason, Petitioner's suggestion in Ground 1 that formation of the BLG isolate powder satisfies the "reducing GMP in the cheese whey retentate" lacks merit. *Id.*

[3] In fact, Dr. Etzel admits the microfiltration cheese whey retentate in Bertelsen is used in a separate cheesemaking process, *not* to make the BLG isolate powder. Ex. 2006, 128:5-9.

b. Nielsen785/Bertelsen at most reduces GMP from a downstream heterogenous crystallized mixture, but not from a "cheese whey retentate".

Setting aside Bertelsen's microfiltration step, Bertelsen also describes ultrafiltering the microfiltered cheese whey permeate to form a UF retentate, which is then processed through multiple steps to form a heterogenous mixture comprising BLG crystals and a supernatant solution. Ex. 1006, 57:1-31. According to Bertelsen, the crystals are then isolated through centrifugation. Petitioner's position in Grounds 1-3 appears to be that this centrifugation step reduces GMP by separating the supernatant solution, which contains GMP, from the BLG crystals. Pet., 11-14.

Claim limitation 8.2, however, requires "reducing native GMP ***in the cheese whey retentate***"**—**not from a different downstream composition *derived from* a retentate. As explained above, the plain and ordinary meaning of the term "cheese whey retentate" is the portion of cheese whey that is ***captured by the filter after initial filtration of the cheese whey***. Ex. 1001, 2:2-11, 18:18-24; *supra*, IV.B.. Simply put, the heterogenous mixture, from which GMP is arguably removed, was ***formed through a crystallization step***—not from filtering the cheese whey. Ex. 2005, ¶¶ 74-75. Thus, the heterogenous mixture cannot reasonably be characterized as a "retentate"—let alone as a "cheese whey retentate." *Id.* As a result, centrifuging of the heterogeneous mixture is different from reducing GMP "in the

cheese whey retentate" as claimed. *Id.* For this reason also, Nielsen785/Bertelsen fails to disclose "reducing native GMP in the cheese whey retentate," as claimed. *Id.*

Thus, even assuming *arguendo* that the feed for BLG crystallization is a cheese whey retentate (it is not), Nielsen785/Bertelsen discloses, at most, reducing GMP in a heterogenous crystalized mixture rather than reducing GMP ***in the cheese whey retentate*** as claim 8.2 requires. Ex. 2005, ¶ 76. As explained above, Bertelsen's Example 1 teaches that a lactose-depleted UF retentate (formed by ultrafiltering the microfiltered permeate feed) was transferred to a crystallization tank, seeded with a BLG crystal starter, cooled, and centrifuged to separate the BLG crystals. Ex. 1006, 57:17-18, 24-25, 29-30; Ex. 2006, 130:2-132:4. As Dr. Etzel explains, the GMP is only reduced when the BLG crystals are separated from the "protein solution," i.e., the supernatant solution. Ex. 1003, ¶¶ 71-72; Ex. 2006, 149:16-21.

In view of the foregoing, Bertelsen describes that several process steps are required between the formation of the alleged cheese whey retentate (the lactose-depleted UF retentate) and the centrifugation step that separates the GMP crystals from the supernatant solution. Ex. 1006, 57:17-18, 24-25, 29-30; Ex. 2006, 130:2-132:4. That is, Nielsen785/Bertelsen describes (i) forming a UF retentate (the lactose-depleted UF retentate as Petitioner argues) and then, after (ii) seeding and

(iii) cooling the UF retentate, arguably reducing GMP by (iv) centrifuging the resulting heterogenous mixture to isolate the BLG crystals. Ex. 1006, 57:17-18, 24-25, 29-30; Ex. 2006, 130:2-132:4. Thus, the Bertelsen process at most describes separating GMP from BLG in a downstream heterogenous mixture, but it does not describe reducing GMP *in the cheese whey retentate*, as claimed. Ex. 2005, ¶ 77.

Moreover, reading limitation 8.2 in context with limitation 8.1 supports that the process in Nielsen785/Bertelsen falls squarely outside scope of the challenged claims.

Limitations 8.1-8.2 state:

> 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;

Ex. 1001, Claim 8. Limitation 8.2 clearly refers back to the cheese whey retentate formed in limitation 8.1—it does not permit unlimited processing or changes to the composition or structure of the cheese whey retentate before GMP is reduced. Ex. 2005, ¶¶ 78-81. Federal Circuit precedent on this point is clear—Petitioner cannot ignore that limitation 8.2 refers to ***the same cheese whey retentate*** recited in limitation 8.1. *Summit 6 LLC v. Samsung Elecs. Co.,* 802 F.3d, 1283, 1291 (Fed. Cir. 2015) ("[t]he use of the term 'said' indicates that this portion of the claim limitation is a reference back to the previously claimed [limitation]"); *Baldwin*

Graphic Sys., Inc. v. Siebert, Inc., 512 F.3d 1338, 1343 (Fed. Cir. 2008) (holding that "the" and "said" are anaphoric phrases referring to the initial antecedent phrase).

Petitioner's mapping ignores the antecedent basis of "***the*** cheese whey retentate" and appears to permit unlimited processing of the cheese whey retentate until it is a completely different composition so long as GMP is reduced at some point downstream of the cheese whey retentate. Ex. 2005, ¶¶ 78-81. But this interpretation is inconsistent with the claim language itself. *Id.* Interpreting the claims to permit unlimited processing is nonsensical in that the claim language *requires* in Claim 8.2 the reduction of GMP from the ***exact same*** "cheese whey retentate" that was formed in the preceding filtering step of Claim 8.1—not from some derivative composition that may have been formed from the cheese whey retentate. *Id.*

For this reason, Nielsen785/Bertelsen fails to anticipate the challenged claims and Ground 1 cannot support cancellation of Claims 8-9, 11, and 13.

ii. Nielsen785/Bertelsen does not disclose 8.2: forming a "reduced-GMP cheese whey retentate composition"

Limitation 8.2 requires the formation of a "reduced-GMP cheese whey retentate composition." Petitioner's argument that Bertelsen's BLG isolate powder is somehow a "reduced GMP cheese whey retentate composition" is inconsistent with the plain meaning of the term "cheese whey retentate composition." Ex.

2005, ¶¶ 82-89. As described above, properly construed, a "cheese whey retentate composition" includes the cheese whey retentate (the portion of cheese whey that is captured by the filter after initial filtration of the cheese whey).[4] Ex. 1001, 2:2-11, 18:18-24; *supra*, Section IV.B.

The Petition alleges that Nielsen785 incorporated Bertelsen's Example 1, which describes "[l]actose depleted UF retentate derived 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, 57:1-5; Pet., 5, 11-14. As discussed above, the lactose-depleted ultrafiltered retentate was transferred to a crystallization tank, seeded with a BLG crystal starter, cooled, and centrifuged to separate the BLG crystals. Ex. 1006, 57:17-18, 24-25, 29-30; Ex. 2006, 130:2-132:4. The BLG crystals were then spray dried to form a powder. Ex. 1006, 57:31-32, 69:11-20.

In an attempt to satisfy limitation 8.2, the Petition describes how GMP content is reduced through the crystallization process in Bertelsen. Pet., 11-14. Specifically, as shown below, Petitioner cites Bertelsen's Tables 3 and 12 to

[4] As explained above, a "cheese whey retentate composition" can include additional components, such as enzymes, so long as the cheese whey retentate composition includes the cheese whey retentate. *Supra*, Section IV.B.

show the alleged GMP[5] reduction between the feed before BLG crystallization (Table 3) and the BLG crystal powder (Table 12). Pet., 12-13.

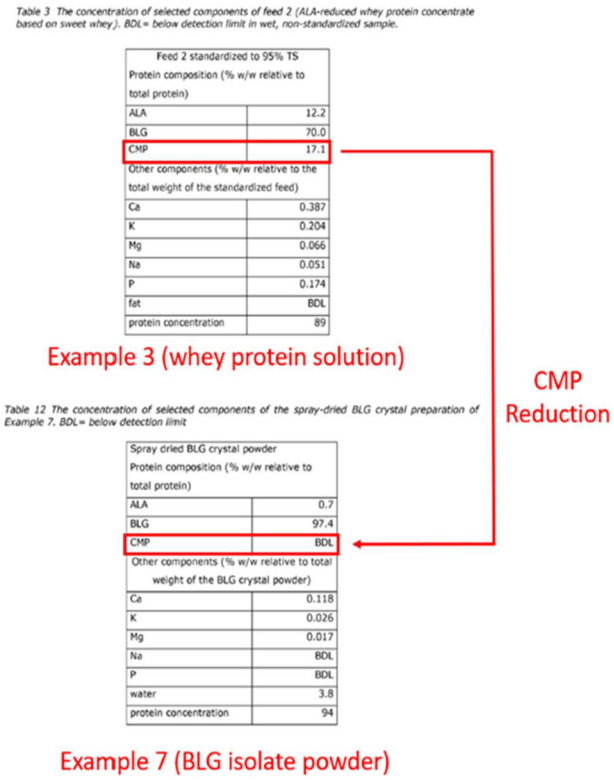


Table 3 The concentration of selected components of feed 2 (ALA-reduced whey protein concentrate based on sweet whey). BDL= below detection limit in wet, non-standardized sample.

Feed 2 standardized to 95% TS	
Protein composition (% w/w relative to total protein)	
ALA	12.2
BLG	70.0
CMP	17.1
Other components (% w/w relative to the total weight of the standardized feed)	
Ca	0.387
K	0.204
Mg	0.066
Na	0.051
P	0.174
fat	BDL
protein concentration	89

Example 3 (whey protein solution)

CMP Reduction

Table 12 The concentration of selected components of the spray-dried BLG crystal preparation of Example 7. BDL= below detection limit

Spray dried BLG crystal powder	
Protein composition (% w/w relative to total protein)	
ALA	0.7
BLG	97.4
CMP	BDL
Other components (% w/w relative to total weight of the BLG crystal powder)	
Ca	0.118
K	0.026
Mg	0.017
Na	BDL
P	BDL
water	3.8
protein concentration	94

Example 7 (BLG isolate powder)

Pet., 12-13 (citing Ex. 1006, Tables 3, 12 (annotated)). In so doing, Petitioner overlooks a key distinction: ***the BLG isolate powder is not a retentate at all*** (let alone a cheese whey retentate as claimed and as described below). Ex. 2005, ¶¶ 82-85. Petitioner does not attempt to equate the BLG isolate powder with any cheese whey retentate composition to satisfy claim 8.2. As discussed above, Petitioner cannot equate the two: the cheese whey retentate composition and the

[5] As Petitioner explains, GMP is the same protein as caseinomacropeptide (CMP), which is discussed in Nielsen785. Pet., 11.

BLG isolate powder are distinct compositions. Ex. 2005, ¶¶ 82-89.

For one, the Petition disregards numerous process steps between the lactose-depleted ultrafiltered retentate in Bertelsen, and the BLG isolate powder formed after crystallization, centrifugation, and spray drying. Ex. 2005, ¶¶ 82-89. Instead, Petitioner conflates "cheese whey retentate" with BLG isolate powder, in turn giving the term a meaning completely contrary to the meaning provided in the '860 Patent and to those skilled in the art. Ex. 1001, 2:2-11, 18:18-24. As discussed above, according to the '860 Patent, the cheese whey retentate is ***the portion of cheese whey that is captured by the filter after initial filtration of the cheese whey***. Ex. 1001, 2:2-11, 18:18-24. A "cheese whey retentate composition" is broader than a "cheese whey retentate" and can include additional components, so long as the cheese whey retentate composition includes the cheese whey retentate. Ex. 1001, 2:3-9.

The terminology in Bertelsen is clear: at no point does Bertelsen refer to the BLG crystals or the BLG isolate powder as a "cheese whey retentate composition"—precisely because they are <u>not</u> cheese whey retentate compositions. In fact, ***Petitioner's entire argument regarding limitation 8.2 does not mention the word "retentate" once.*** Pet., 11-14. That is because the BLG isolate powder is not a retentate (or a cheese whey retentate composition as claimed)—the two are distinct compositions formed by entirely different

processing steps, i.e., filtering vs. seeding, cooling, centrifugation, BLG crystal separation, freeze drying, reconstitution, and spray drying. Ex. 1006, 57:17-18, 24-25, 29-30, 69:11-20; Ex. 2006, 130:2-132:4.

Additionally, the BLG crystals cannot be considered a cheese whey retentate composition because they are formed through centrifugation—not from an initial filtration of cheese whey.[6] Ex. 2005, ¶¶ 82-89. Simply put, crystallization followed by centrifugation does not result in the formation of a retentate. *Id.*, Ex. 2031, 1-2. A cheese whey retentate composition must include at least a cheese whey retentate, the portion of cheese whey that is ***captured by the filter after initial filtration of the cheese whey.*** *Supra,* Section IV.B. The BLG crystals cannot be classified as a "reduced-GMP cheese whey retentate composition" as claimed because they are not formed through filtration of cheese whey. Ex. 2005, ¶¶ 82-89.

For this reason, Nielsen785/Bertelsen fails to anticipate the challenged claims.

[6] Centrifugation separates compositions based on density, not based on particle size. As a result, a POSITA would understand that centrifugation is not a filtration or membrane process and does not form a retentate as that term is used in the '860 patent. Ex. 2005, ¶¶ 85-87; Ex. 2031, 1-2; Ex, 2032, 5.

iii. Nielsen785/Bertelsen does not disclose 8.3: heating a "reduced-GMP cheese whey retentate composition."

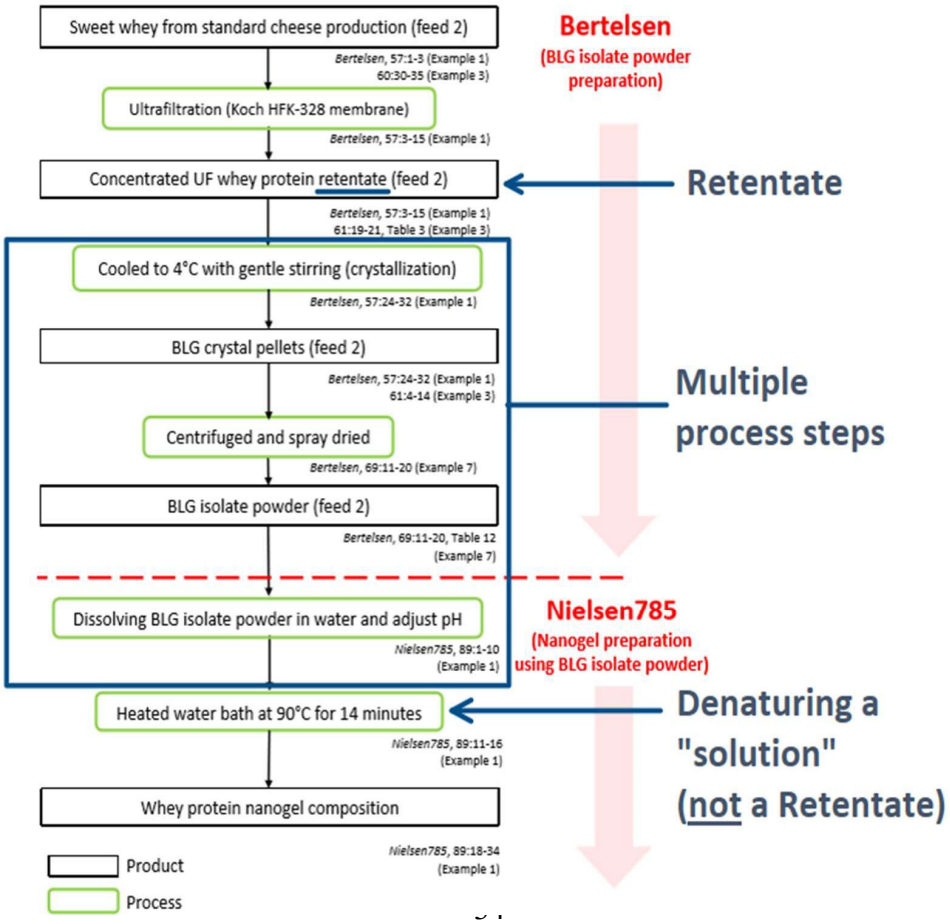
The Petition asserts that the BLG isolate powder produced using Bertelsen's methods is a "reduced-GMP cheese whey retentate composition." Pet., 14. The Petition then relies on Nielsen 785 for disclosing the claimed heating step, asserting that Nielsen785 teaches dissolving the BLG isolate powder (formed according to Bertelsen) in water to form a BLG solution and ***heating the BLG solution***. Pet., 14; Ex. 1005, 89:1-10. Petitioner incorrectly concludes, however, that heating the BLG solution formed from the BLG isolate powder somehow satisfies heating a "reduced-GMP cheese whey retentate composition" as required by claim limitation 8.3. As described above, however, the BLG isolate powder is not a cheese whey retentate composition as claimed. Ex. 2005, ¶¶ 89-94. Instead, it is multiple steps[7] removed from the lactose-depleted ultrafiltered retentate, which Petitioner incorrectly[8] alleges constitutes a cheese whey retentate. *Id.*; Ex. 1006, 57:17-18, 24-25, 29-30; Ex. 2006,

[7] The multiple steps include at least seeding, cooling, centrifugation, BLG crystal separation, freeze drying, reconstitution, and spray drying. Ex. 1006, 57:17-18, 24-25, 29-30, 69:11-20; Ex. 2006, 130:2-132:4.

[8] As discussed above, the UF retentate is not a cheese whey retentate because it was derived from a cheese whey *permeate*. *Supra*, Sections VI.A.i-ii.

130:2-132:4.

A POSITA simply would not consider a solution formed from a BLG isolate powder to be the same as a cheese whey retentate composition because the solution does not include a cheese whey retentate at all. Ex. 2005, ¶¶ 89-94. The powder, which is formed through spray drying, is completely different from a retentate that is formed through filtration; they are not similar compositions. *Id.* Here, Petitioner's own proposed flow chart is instructive in that it shows that the only retentate in the entire process occurs ***six steps before*** the asserted denaturation in Nielsen785:



Pet., 8 (blue text added). Even taking Petitioner's asserted "concentrated UF whey protein retentate" as a "cheese whey retentate" (it is not),[9] there is no mention of a retentate again after the third step. Ex. 2005, ¶¶ 89-94. Rather, the UF retentate is seeded, cooled, crystallized, centrifuged, slurried, and spray dried into a powder. *Id.* That powder is then dissolved to form a BLG solution, which is finally heated (denatured). Petitioner even agrees that the BLG "solution" (not a retentate) is heated, stating: "Nielsen785 described dissolving that BLG powder from Bertelsen's Example 7 to form whey protein solutions . . . ***Those solutions were heated*** at 90°C for 14 minutes in a water bath." *Id.*, 14 (internal citations omitted) (emphasis added).

Simply put, BLG "solutions" formed from BLG powders cannot reasonably be characterized as "cheese whey retentates," as claimed, which anyone skilled in the art would appreciate refers to the portion of cheese whey that is captured by the filter after initial filtration of the cheese whey, as indicated by the intrinsic evidence. Ex. 2005, ¶¶ 89-94; Ex. 1001, 2:2-11, 18:18-24. Moreover, as explained above, the BLG isolate powder is actually formed from a microfiltration ***permeate***, reinforcing that the BLG solution is

[9] As discussed and as shown in the above corrected Bertelsen flowchart, the only actual "cheese whey retentate" is formed in a microfiltration step before the UF step.

not a "cheese whey retentate" as claimed. *Supra,* Section VI.A.i-ii.

In sum, even if Petitioner's flow chart is taken as accurate, Nielsen785 incorporating Bertelsen discloses heating a solution of BLG isolate powder formed from a permeate in water—not heating a "reduced-GMP cheese whey ***retentate composition***" as required by limitation 8.3. Ex. 2005, ¶ 94. For this reason, Nielsen785/Bertelsen fails to anticipate the challenged claims and Ground 1 cannot support cancellation of Claims 8-9, 11, and 13.

iv. Nielsen785/Bertelsen does not disclose 8.6: a BLG:ALA ratio of greater than 5.00.

Claim feature 8.6 recites "a proteolysis index of at least 8.0 wt. % or a beta-lactoglobulin [BLG] to alpha lactalbumin [ALA] ratio of greater than 5.00." Ex. 1001. The Petition fails to show that Nielsen785 discloses this claim element. For this reason also, Ground 1 does not support cancellation of Claims 8-9, 11, and 13.

a. Petitioner's reliance on disparate compositions is improper.

First, the Petition cites two disparate compositions in attempting to satisfy this limitation. For example, Petitioner argues that Nielsen785's BLG isolate powder formed according to Bertelsen satisfies the BLG:ALA ratio of greater than 5.00. Pet., 16-17. In so doing, Petitioner relies on Table 1 of Nielsen785:

Table 1 Characteristics of exemplary whey protein powder used for preparation of whey protein nano-gels.

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

Pet., 16; Ex. 1005, 88, Table 1. As the title of the table indicates, this table shows the composition of the BLG isolate powder that is used to prepare the nanogel product of Nielsen785. Ex. 1005, 88, Table 1. As discussed above in Section VI.A.iii., the BLG isolate powder made according to Bertelsen is dissolved in water to form a BLG solution, which is then heated to denature the proteins and form a nanogel composition. *Id.*, 89:1-3, 11-16, 25-29. Thus, the ALA and BLG content shown in Table 1 is undenatured (native) and does *not* reflect a "denatured whey protein composition," as required by claim 8. *Id.*, 88, Table 1; Ex. 2005, ¶¶ 95-102.

In contrast, for claim elements 8.5 (less than 11 wt. % native GMP) and

8.7 (greater than 50 wt. % denatured whey proteins), Petitioner relies on Nielsen785's nanogel compositions, which clearly *are* denatured. Ex. 2005, ¶¶ 95-10; Pet., 15-16 ("GMP weight percentages remained approximately the same . . . in the denatured whey protein nanogel"); 17 ("[A]t least 95-97% of whey protein in Nielsen's whey protein nanogel preparations was denatured after heating.").

Thus, Petitioner improperly relies on two disparate compositions (the BLG isolate powder and Nielsen785's nanogel) in attempting to satisfy multiple claim limitations in an anticipation analysis. It is improper to "mix and match" features of different compositions from a reference without ***any*** explanation of how those features would be present in a single composition. *Abiomed, Inc. v. Maquet Cardiovascular, LLC*, IPR2017-01204, Paper 9 at 11 (PTAB 2017) (denying institution in part because when petitioner failed to show various embodiments were interchangeable or that a POSITA would have combined the embodiments in the manner proposed).

i. The denatured product fails to disclose the protein content.

Perhaps sensing this deficiency, Petitioner attempts to explain its reliance on both the undenatured BLG isolate powder and denatured nanogel by arguing "[h]eat-denaturation processes would not affect the BLG/ALA ratio because Cl.8.6 does not differentiate between denatured and undenatured BLG." Pet.,

16. This attempt suffers two defects.

First, Petitioner does not offer any support for this statement. The Petition cites Dr. Etzel's declaration (Ex. 1003), which offers an equally unsupported and conclusory assertion:

> The disclosed heat-denaturation process would not affect the BLG-to-ALA ratio because claim limitation 8.6 does not differentiate between denatured and undenatured BLG, therefore, a POSITA would have understood that both denatured and undenatured BLG contents are considered in the calculation of the BLG-to-ALA ratio.

Ex. 1003, ¶ 95.

Second, this assertion is factually incorrect and is undermined by Petitioner's own prior art. Ex. 2005, ¶¶ 95-102. Although Nielsen785 indicates that the BLG isolate powder contains 0.2 wt. % ALA (see above Table 1), the sole example of a denatured nanogel composition in Nielsen785 that measures ALA content without added whey protein isolate (WPI) ***shows an ALA content of 0 wt.%***.[10] Ex. 2005, ¶¶ 95-102.

[10] It is curious that the Petition relies on the BLG:ALA ratio of the *undenatured* BLG protein isolate powder, instead of relying on the *actual* values that were reported for the denatured nanogel preparations, and which notably fail to satisfy the claimed BLG:ALA ratio.

Table 13 Whey protein nanogel preparations prepared from BLG and WPI

Protein	12%	12%	12%	12%	12%	12%
BLG fraction	100%	80%	75%	66.7%	66.7%	50%
WPI fraction	0%	20%	25%	33.3%	33.3%	50%
aLA, final	0%	2%	2%	3%	3%	5%
BLG, final	97%	88%	86%	83%	83%	76%
CMP, final	1%	4%	5%	6%	6%	9%
pH	6.0	6.0	6.0	6.0	6.2	6.0
Ca in g/g BLG	0.0016	0.0028	0.0032	0.0037	0.0037	0.0048
Na+K	12.2	14.4	15.0	15.9	20.9	17.7
State	Liquid	Liquid	Liquid	Liquid with lumps	liquid	Gel
Soluble aggre-gates and non-de-natured protein	20.8%	10%	11.6%	-	22.5%	-
Nanogels	79.2%	90%	88.4%	-	77.5%	-

Ex. 1005, 106-107, Table 13 (annotated). The nanogel shown in Table 13 was prepared by dissolving the BLG isolate powder formed in Example 1 (relied on by Petitioner) in water. Ex. 1005, 105:11-12.

Third, any argument that a POSITA would have recognized "0%" as a below-detection limits or a rounding convention is inconsistent with the Nielsen785 disclosure. Ex. 2005, ¶¶ 95-102. Nielsen785 uses "below detectable limits" (BDL) elsewhere in its disclosure. Ex. 1005, 109, Table 15. If "0%" ALA was a below-detection convention, a POSITA would have expected Nielsen785 to say as much, as it did elsewhere in its specification. Ex. 2005, ¶¶ 95-102. Nielsen785 also expressed many data values as fractions to the tenth place (e.g., 0.1), but it did not do so for ALA. Id., Tables 9-15. Thus, if the composition in Table 13 contained 0.2% ALA, it would have so indicated. Ex. 2005, ¶¶ 95-102. A POSITA would thus have understood Table 13 for what it states: that "0%" ALA was present in the nanogels. Ex. 2005, ¶¶ 95-102.

Based on the foregoing, Petitioner's assertion that "[h]eat-denaturation processes would not affect the BLG/ALA ratio" is incorrect for the nanogel of Nielsen785. Ex. 2005, ¶¶ 95-102. For this reason also, Nielsen785/Bertelsen fails to anticipate the challenged claims and Ground 1 cannot support cancellation of Claims 8-9, 11, and 13.

ii. The denatured nanogel of Nielsen785 has an undefined BLG:ALA ratio.

As shown in Table 13 above, the undenatured nanogel preparation disclosed in Nielsen785 has an ALA content of 0 wt. % and a BLG content of 97 wt. %. Ex. 1005, 106-107, Table 13. As described in IV.C., correctly construed, the term "beta-lactoglobulin [BLG] to alpha lactalbumin [ALA] ratio of greater than 5.00" requires at least some detectable amount of ALA in the composition. This is because, as the Federal Circuit acknowledges, ***a ratio with a zero denominator is undefined and cannot be greater than 5***. *Ashland Oil, Inc.*, 776 F.2d at n.22. As explained above, whether the methylene bridges at issue in *Ashland Oil* could be expressed as fractions does not matter because Table 13 shows "0%" ALA—not a fraction. Ex. 1005, 106-107, Table 13; *supra,* IV.C. The BLG:ALA ratio of the denatured nanogel in Nielsen785 is thus undefined and cannot satisfy claim limitation 8.6. Ex. 2005, ¶ 102. In view of the foregoing, Petitioner has not shown that independent claim 8 is anticipated by Nielsen785 incorporating Bertelsen.

B. Ground 2: Nielsen785 and Bertelsen fail to render Claims 8-9 and 11-13 obvious.

Claims 8-9 and 11-13 are not invalid as obvious over Nielsen785 (Ex. 1005) and Bertelsen (Ex. 1006) because Nielsen785 and Bertelsen fail to teach or suggest (i) reducing native GMP in a cheese whey retentate, (ii) forming and heating a reduced-GMP cheese whey retentate composition, and (iii) a BLG:ALA ratio of greater than 5.00, as claimed. Ex. 2005, ¶ 103. Ground 2 repeats the errors of Ground 1 and compounds them by failing to offer a proper *KSR* rationale for combining these references.

Petitioner bears the burden of demonstrating that subject matter was obvious in view of (i) the scope and content of the prior art, (ii) ***the differences between the claimed invention and the prior art***, and (iii) the level of ordinary skill in the art. *See KSR*, 550 U.S. at 418 (quoting *Graham*, 383 U.S. at 17-18 (emphasis added)). The obviousness analysis articulated in *Graham* and *KSR* is not optional—a finding of obviousness cannot be sustained without providing the requisite analysis. *Apple Inc. v. Samsung Elecs*., 839 F.3d 1034, 1048 (Fed. Cir. 2016).

Petitioner relies on Nielsen785 and Bertelsen's disclosures of BLG isolate powders and nanogels in asserting (incorrectly) that the references disclose all features of the challenged claims. Pet., 19-24. In so doing, Petitioner fails to offer any explanation or *KSR* rationale for how the knowledge of a POSITA would remedy Nielsen785 and Bertelsen's failure to teach or suggest (i) reducing native

GMP in the cheese whey retentate, (ii) forming and heating a reduced-GMP cheese whey retentate composition, and (iii) a BLG:ALA ratio of greater than 5.00.

As explained above in VI.A., the Petition fails to sufficiently address how several claim elements are present in the prior art. In an obviousness analysis, failing to map every claim limitation and dismissing differences in the references with conclusory and unsupported statements is fatal. *In re NuVasive, Inc.*, 842 F.3d 1376, 1382 (Fed. Cir. 2016) ("conclusory statements alone are insufficient and, instead, the finding must be supported by a reasoned explanation") (internal quotations omitted); *PersonalWeb Techs., LLC v. Apple Inc.*, 848 F.3d 987, 993 (Fed. Cir. 2017) (holding an obviousness finding must explicitly map each claim limitation to the art).

In view of these deficiencies, Petitioner has failed to present a legally sound argument that the challenged claims are obvious over Nielsen785 and Bertelsen.

i. Nielsen785 and Bertelsen do not disclose 8.2: "reducing native GMP in the cheese whey retentate" or 8.2-8.3: forming and heating a "reduced-GMP cheese whey retentate composition."

Nielsen785 and Bertelsen do not teach or suggest "reducing native GMP ***in the cheese whey retentate***" (Cl. 8.2) or forming and heating a "***reduced-GMP cheese whey retentate composition***" (Cls. 8.2-8.3). Ex. 1001, Claim 8 (emphases added); Ex. 2005, ¶¶ 104-105. For the reasons discussed above in Section IV.A.i-iii., Petitioner improperly conflates the BLG isolate powder with the claimed "reduced-GMP cheese whey retentate composition."

First, as discussed in Section IV.A.i., the Bertelsen process begins, according to Petitioner's expert, with a cheese whey microfiltration step which forms a cheese whey permeate. This cheese whey permeate is then processed through several steps to ultimately form the BLG isolate powder used in Nielsen785. Ex. 2005, ¶¶ 73-77. Since the BLG isolate powder is made from a cheese whey *permeate*, it cannot reasonably be characterized as a cheese whey *retentate*. *Id.*

Second, as discussed in Section IV.A.i-ii., the heterogenous mixture that is centrifuged in Bertelsen to isolate the BLG and allegedly reduce GMP content cannot reasonably be characterized as a "cheese whey retentate," as claimed. Ex. 2005, ¶¶ 78-82.

Third, as discussed in Section IV.A.iii., the combination of Nielsen785 and Bertelsen also fails to disclose forming or heating a "reduced-GMP cheese whey retentate composition" as required by Claims 8.2 and 8.3. Ex. 2005, ¶¶ 82-94. Ex. 1001, Claim 8. Petitioner has supplied no explanation of how the knowledge of a POSITA may remedy Nielsen785 and Bertelsen's failure to disclose these claim limitations. As explained above, the Petition also does not set forth a proper obviousness rationale for combining the prior art. Simply because Ground 2 relies on obviousness does not excuse conclusory statements. *In re NuVasive, Inc.*, 842 F.3d at 1382. For at least these reasons, Ground 2 fails and cannot support cancellation of

ii. Nielsen785/Bertelsen does not disclose 8.6: a BLG:ALA ratio of greater than 5.00.

Nielsen785 and Bertelsen also do not teach or suggest a BLG:ALA ratio of greater than 5.00. Ex. 2005, ¶ 106. As explained above in Section IV.A.iv., Petitioner improperly jumps between disparate compositions, relying on Nielsen785's denatured nanogel product for limitations 8.5 and 8.7 but switching to the undenatured BLG isolate powder for the BLG:ALA ratio. The Petition does not explain why the undenatured BLG isolate powder is interchangeable with the denatured nanogel product instead concluding, *without any supporting evidence,* that the BLG:ALA ratio would not change upon denaturation. Pet., 16-17; Ex. 1003, ¶ 95. Nielsen785 itself proves this conclusion is incorrect: 0% ALA was reported in the denatured nanogel composition. Ex. 1005, 106-107, Table 13. There cannot be a BLG:ALA ratio of at least 5.00 if no ALA is present. Ex. 2005, ¶¶ 102. For this reason also, Ground 2 fails and cannot support cancellation of Claims 8-9 and 11-13.

C. Ground 3: Nielsen450[11] fails to render Claims 8-9 and 11-13 obvious.

Claims 8-9, 11-13, and 15-17 are patentable over Nielsen450 (Ex. 1007) because Nielsen450 fails to teach or suggest: (i) greater than 50 wt. % denatured whey proteins, (ii) a BLG:ALA ratio of greater than 5.00, (iii) "reducing native GMP in the cheese whey retentate," and (iv) forming and heating a "reduced-GMP cheese whey retentate composition." Ex. 2005, ¶ 107.

The Petition fails to offer a legally cognizable basis for how the knowledge of a POSITA would remedy Nielsen450's failure to teach or suggest the absent claim features. Like in Ground 1-2, Petitioner appears to conflate various compositions disclosed in Nielsen 450 with various claim elements. Petitioner also ***fails to provide any motivation for combining*** Nielsen450 and Bertelsen. This failure alone is dispositive—an obviousness showing must include a reason or *KSR* rationale for combining the prior art. *Virtek Vision Int'l ULC, v. Assembly Guidance Sys.,* 97 F.4th 882, 887 (Fed. Cir. 2024). In view of these and the below deficiencies,

[11] Petitioner's arguments are based on Nielsen450 and Bertelsen and on the argument that Nielsen450 incorporates Bertelsen. Pet., 29. Reference herein to Nielsen450 also refers to Bertelsen to the extent the Petition argues Bertelsen is incorporated therein.

Ground 3 fails.

i. Nielsen450 fails to teach or suggest greater than 50 wt. % denatured whey proteins, and Dr. Etzel's attempt to fill this gap is flawed (Cls. 8.7 and 15.5)."

At the outset, Nielsen450 fails to teach or suggest (as Petitioner concedes) greater than 50 wt. % denatured whey proteins, and the Petition's attempt to fill this gap with Dr. Etzel's "replicated" experiments is inconclusive since it starts with an extremely old sample that had a *different composition* than what was reported in the Nielsen450 examples. Ex. 2005, ¶ 109.

***a.* The BLG isolate powder Dr. Etzel use would have denatured more readily after the 7+ year storage rendering the Etzel experiments inconclusive.**

Claims 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. The Petition concedes that ***"Nielsen450 did not teach specific degrees of denaturation*** . . ." and thus does not teach or suggest "greater than 50 wt. % denatured whey proteins." Pet., 30; Ex. 1001, Claims 8, 15. Petitioner attempts to dismiss this deficiency by arguing that Nielsen450 discloses heating protein solutions,[12] and that it would have been obvious to a POSITA that the heating would result in "significant denaturation." Pet., 30.

[12] As discussed above, a protein solution formed from a GMP powder is *not* a retentate since it is not formed in a filtration step.

Attempting to show just how "significant" the denaturation in Nielsen450 would have been, Petitioner enlists Dr. Etzel to purportedly "replicate" experiments from Nielsen450 in an attempt to show that the denaturation in Nielsen450 would have exceeded 50%. Pet., 30. However, Dr. Etzel's experiments were flawed: ***the BLG isolate powder used as Dr. Etzel's starting material was stored for at least 7 years*** and would have undergone numerous changes during storage. Ex. 2005, ¶ 109; Ex. 1021, 2; Ex. 1003, ¶ 145, 166-167.

Petitioner touts Dr. Etzel's experiments as replicating Nielsen450, alleging that Dr. Etzel used a BLG isolate powder from the same batch that was used in Nielsen450's experiments. Pet., 31; Ex. 1003, ¶ 145. Petitioner fails to recognize, however, that at least 7 years[13] had passed from when the BLG isolate powder was first made. Ex. 1021, 2; Ex. 1003, ¶ 145, 166-167. As Arla employee Tanja Jæger recounted, the sample was stored at room temperature (approximately 22°C) between 30-50% humidity for 7+ years until Dr. Etzel used it. Ex. 2007, 98:15-16; Ex. 1021, 2.

Dr. Etzel fails to account for ***any*** expected changes to the sample after it was stored for 7+ years. Ex. 2005, ¶¶ 108-123. Instead, Dr. Etzel imports denaturation levels taken after the extensive storage into Nielsen450 retroactively, assuming the

[13] BLG isolate powder A was made on November 28, 2017. Ex. 2007, 84:2-4. Dr. Etzel performed the experiments in 2025. *Id.*, 98:9-14.

sample did not undergo *any* expected changes after 7+ years of storage. *Id.*, Ex. 1003, ¶ 186. Not only is this assumption implausible, but it also fatally flaws Dr. Etzel's denaturation measurements. Ex. 2005, ¶¶ 108-123.

In fact, ***Petitioner's own European Food Safety Authority (EFSA) filing proposes a shelf-life of only 1.5 years for BLG isolate powder because of anticipated protein loss.*** Ex. 2011, 10. As the EFSA decision explained, Arla "proposes an 18-month shelf-life under ambient conditions for the [novel food] produced under acidic and neutral conditions." *Id.*, 5. The novel food is defined in Ex. 2011 as a spray dried powder containing primarily BLG that is "produced from bovine whey by crystallisation under acidic or neutral conditions."[14] *Id.*, 4. Table 2 in Ex. 2011 shows that the novel food is comparable to BLG isolate powder A used by Dr. Etzel in protein, BLG, lactose, fat, ash, mineral, and moisture content. *Id.*, 7, Table 2; Ex. 1007, 104, Table 8, 108, Table 9. Ex. 2011 goes on to say that the novel food is intended to be used exactly as described in Nielsen450: "as an ingredient in isotonic and sport drinks, whey powder and milk-based drinks and similar products." Ex. 2011, 12; Ex. 1007, 108:14, 109:28, 111:1 (Examples 10-12 describe "high protein beverages"); Ex. 1003, ¶¶ 40, 130-132, 134-135, 137, 139. The novel food describes exactly the "BLG isolate powder" from Nielsen450 that

[14] The BLG isolate powder A sample from Nielsen450 was produced under acidic conditions, at 5.7 pH. Ex. 1007, 108, Table 9; Ex. 1003, ¶ 137.

Dr. Etzel purportedly tested. Ex. 2005, ¶¶ 108-123; Ex. 1003, ¶ 142.

Ex. 2011 also describes that Arla's data showed after only 18 months of storage at room temperature and 40-50% relative humidity, "***a total loss of BLG of 7.9%*** (on average) and ***increase in moisture content*** (from 3.6 to 6.6%, on average) were observed in the [novel food] produced under acidic conditions." Ex. 2011, 10 (emphases added). Because of this protein loss and moisture content, ***Arla proposed an 18-month shelf-life*** under ambient conditions for the BLG isolate powder. *Id.* Dr. Etzel testified that he was unaware of and hence did not consider the shelf life of BLG isolate powders:

> Q: . . . Are you aware of a -- a shelf life for BLG isolate powder formed through crystallization?
> A: No.

Ex. 2006, 227:11-14. Dr. Etzel's failure to consider this important factor significantly impacts the credibility of his analysis. Ex. 2005, ¶¶ 108-123.

Moreover, it is well known in the art that an increase in moisture content causes numerous chemical modifications that can increase the denaturation rate of BLG. Ex. 2005, ¶¶ 108-123; Ex. 2013, 2, 3 ("Residual moisture can be responsible for protein instability in the solid state"); Ex. 2014, 5-6. Even modest water uptake can accelerate chemical degradation, including deamidation, oxidation of methionine or cysteine residues, or hydrolysis. Ex. 2005, ¶¶ 108-123; Ex. 2013, 2-3; Ex, 2014, 5-6; Ex. 2015, 1. These reactions act as "pre-conditioning" events that

weaken stabilizing interactions in the protein (and lead to increased denaturation) without immediate unfolding. Ex. 2005, ¶¶ 108-123; Ex. 2013, 2-3; Ex, 2014, 5-6. Notably, even after these chemical changes, the protein would appear structurally intact,[15] even though denaturation rate is increased. Ex. 2005, ¶¶ 108-123; Ex. 2013, 2-3. The earlier chemical modifications lower both the thermodynamic and kinetic barriers to unfolding, making the protein more prone to denaturation. Ex. 2005, ¶¶ 108-123; Ex. 2016, 9. The practical consequence is that, once BLG is later exposed to heat, denaturation occurs more readily and at lower stress thresholds than it would for BLG that has not undergone chemical modifications due to increased moisture content. Ex. 2005, ¶¶ 108-123; Ex. 2013, 2-3; Ex. 2014, 5-6. The increased ease of denaturation of the aged BLG samples demonstrates that Dr. Etzel's percent denaturation experiments lack credibility in that they necessarily ***cannot align*** with the compositions in the Examples of Nielsen450. Ex. 2005, ¶¶ 108-123.

Dr. Etzel's use of a 7+ year old sample, which was ***more than 4.5 times beyond its shelf-life***, to allegedly "replicate" experiments from Nielsen450 without considering the significate changes Arla itself identified as impacting BLG isolate powders renders his experiments unreliable and inconclusive. Ex. 2005, ¶¶ 108-

[15] Dr. Etzel's purported test of denaturation after storage but before heat treatment is immaterial for this reason. Ex. 1003, ¶ 177.

123. For this reason, Petitioner has not met its burden of showing that the BLG isolate powder sample used in the experiments would not have undergone changes that affect protein denaturation rate. *Id.* As such, Dr. Etzel's denaturation measurements are fatally flawed and cannot be used to fill the gaps from Nielsen450. *Id.*

In view of the foregoing, a POSITA would understand that Dr. Etzel's experiments are unreliable and inconclusive and do not remedy Nielsen450's failure to disclose or suggest a denatured whey protein composition comprising at least 50 wt.% denatured whey proteins. Ex. 2005, ¶ 123. In fact, even Dr. Etzel's experiments show that the batch Dr. Etzel used in fact underwent compositional changes. Pet., 31; Ex. 1003, ¶ 72; Ex. 1021, ¶ 9. As shown below, the BLG, total protein, and dry matter were each reduced after storage.

% w/w	Measured 2018/2019	Measured 2025
A-LA	BDL	BDL
B-LG	95.9	92.03
CMP	BDL	BDL
Total protein	93.97	89.25
Dry matter	95.19	92.18

*BDL = below detection limit

Ex. 1021, ¶ 9. Petitioner dismisses these compositional changes, ***without any supporting evidence***,[16] as allegedly being caused by moisture absorption during

[16] Petitioner cites to Dr. Etzel's declaration, which states, ***without any citation***,

storage. Ex. 1003, ¶ 146; Pet., 31. Even considering the alleged moisture absorption during storage, there is an unexplained reduction in protein on a dry basis (total protein/dry matter) after storage. Ex. 2005, ¶¶ 120-121; Ex. 1021, ¶ 9. The protein on a dry basis was originally 98.72 (93.97 total protein/95.19 dry matter) but after the extended storage, reduced to 96.82 (89.25 total protein/92.18 dry matter). Ex. 1021, ¶ 9.. In view of the foregoing, Dr. Etzel's experiments are not representative of the compositions actually disclosed in Nielsen450. Ex. 2005, ¶¶ 120-121.

To the extent Petitioner is arguing that greater than 50 wt. % denatured whey proteins are inherently present in the heat-treated protein solutions of Nielsen450, Petitioner cannot establish from Dr. Etzel's experiments that the claim element is ***necessarily*** present. Ex. 2005, ¶ 122; Pet., 30. Nielsen450 itself shows that Petitioner's assertion that heating protein solutions above 70°C would result in "rapid, significant denaturation" is untrue—the solution in Nielsen450 is largely undenatured after heating at 75°C. Ex. 1007, 97:25-30 ("[T]he heat-treatment did not cause any protein denaturation"); Ex. 2005, ¶ 122. Ground 3 cannot succeed for

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"the slight (~3%) decrease in dry matter content compared to the earlier value reported in Nielsen450's Table 9 most likely reflects limited moisture adsorption by the powder during storage." Ex. 1003, ¶ 145.

this reason. *PAR Pharm., Inc.v. TWi Pharms., Inc.*, 773 F.3d 1186, 1195-96 (Fed. Cir. 2014); *Care Brands, LLC*, IPR2017-00693, Paper 11, 9–10 (July 17, 2017).

b. **Petitioner cannot show the BLG isolate powder sample Dr. Etzel used was the same used in Nielsen450.**

Petitioner alleges that Dr. Etzel used the same sample from Examples 11-12 of Nielsen450 without showing any chain of custody. Numerous discrepancies make it doubtful Dr. Etzel used the same sample from Nielsen450.

Dr. Etzel obtained the sample from Ms. Jaeger at Arla Laboratories. Ex. 1021, ¶ 9. Ms. Jaeger's testimony makes clear, however, that she provided Dr. Etzel a sample that had ***a different composition than BLG isolate powder A*** used in Examples 11-12 of Nielsen450. Specifically, Ms. Jaeger alleged that she[17] "used methods disclosed by Nielsen450 to perform testing on the identified BLG powder to determine its current composition." Ex. 1021, ¶ 9; Ex. 2007, 75:1-10.

[17] Contrary to her declaration testimony, Ms. Jaeger did not perform the composition testing. Instead, a "production lab" at Arla performed the 2018/2019 and 2025 testing. Ex. 2007, 94:6-17.

Results shown in table below:

% w/w	Measured 2018/2019	Measured 2025
A-LA	BDL	BDL
B-LG	95.9	92.03
CMP	BDL	BDL
Total protein	93.97	89.25
Dry matter	95.19	92.18

*BDL = below detection limit

Ex. 1021, ¶ 9. The 2018/2019 measurements, shown above, purport to reflect the BLG isolate powder A used in Examples 11-12 of Nielsen450, but numerous values were altered. For example, the ***CMP in Nielsen450 is "1.08," but in Ms. Jaeger's table, it is modified to BDL***. Ex. 1007, 104, Table 8; Ex. 1021, ¶ 9. The ***ALA content also changed from "<0.5" to BDL***. Ex. 1007, 104, Table 8; Ex. 1021, ¶ 9. Ms. Jaeger initially claimed the 2018/2019 values were from Tables 8-9 in Nielsen450, ***but when asked why the CMP and ALA values were different, she could not answer***. Ex. 2007, 7:12-83:23, 89:13-20.

On cross-examination, Ms. Jaeger testified:

> Q.· · You listed in your declaration that CMP was below detection limit; is that correct?
>
> A.· · Yes.
>
> Q.· · Why did you write below detection limit if Table 8 states 1.08?
>
> A.· · Yeah, I can't remember the detection limit . . . of CMP.
>
> ***Q.· · Table 8 states that BLG powder B has a CMP concentration of 1.08.·This means that CMP was detected; correct?***
>
> ***A.· · Yeah.· Yes.***
>
> Q.· · So CMP was not below the detection limit; right?

A.· · Yeah.· I think so.· It seems like.

Q.· · Your declaration is incorrect?

A.· · Yeah.·It must be.· I don't know.·I can't remember why.· If it's because we used Table 9 to put in the results. I think we used Table 9.

Q.· · But CMP is not listed in Table 9; right?

A.· · Yeah.·Yeah.

Q.· · So your declaration's incorrect?

A.· · Yeah.·But the CMP is very – it's very close to the detection limit. . . .

Q.· · You don't know the actual detection limits, though, right?

A.· · I don't know the correct -- correct value. Yeah.

Ex. 2007, 89:21-90:15, 91:17-20. Ms. Jaeger's testimony makes clear that the sample she provided to Dr. Etzel was different than the one used in Examples 11-12 of Nielsen450. Petitioner did not provide any explanation for these discrepancies, and its own fact witness was unable to explain them, thereby further undermining the credibility and reliability the data. Petitioner cannot fill the denaturation rate gaps in Nielsen450 using Dr. Etzel's experiments because Petitioner has not shown Dr. Etzel used the same sample from Nielsen450 Examples 11-12. For this reason also, Ground 3 fails.

ii. Nielsen450 fails to teach or suggest a BLG:ALA ratio of greater than 5.00 (Cls 8.6 and 15.4).

Nielsen450 also fails to disclose the feature of Claims 8.6 and 15.4, i.e., "a beta-lactoglobulin [BLG] to alpha lactalbumin [ALA] ratio of greater than 5.00."

Ex. 1001; Ex. 2005, ¶¶ 124-126.

Similar to its argument for Nielsen785 in Grounds 1 and 2, Petitioner asserts that Nielsen450's BLG isolate powder formed according to the methods of Bertelsen satisfies the BLG:ALA ratio of greater than 5.00. Pet., 36, 52. Petitioner also relies on Table 9 of Nielsen450, which describes select components of the undenatured BLG isolate powder:

Table 9: Chemical composition of BLG isolate powder A

Description	A - Dry BLG (w/w%)
BLG	95.9
Ash	0.51
Ca	0.1455
Cl	0.04
Lipid	0.11
K	0.0512
Mg	0.022
Na	0.025
NO_3	2
NO_2	0.07
PHO	0.025
Protein	93.97
Dry matter	95.19
pH	5.7

Ex. 1007, 108, Table 9. Table 9 does not disclose an ALA measurement. *Id;* Ex. 2005, ¶¶ 124-126. Petitioner seems to appreciate this deficiency and argues that since BLG makes up 95.9 wt. % of the BLG isolate powder, ALA must make up at most the other 4.1 wt. %. Pet., 36-37. Based upon this calculation, Petitioner argues that Nielsen450 discloses a ratio of at least 23.4. This argument, however, fails to

account for the situation where no amount of ALA is present in the denatured product, as discussed above and supported by Nielsen785.[18] Petitioner also relies on Nielsen450's Table 8 to argue that the same BLG isolate powder shown in Table 9 has less than 0.5% ALA. Pet., 36-37; Ex. 2005, ¶¶ 124-126. Petitioner argues that using either its imagined "up to 4.1% ALA" from Table 9, or the less than 0.5% ALA from Table 8, the BLG:ALA ratio would be above 5.00. Pet., 36-37.

Just as in its arguments for Nielsen785 in Grounds 1 and 2, however, Petitioner switches between the denatured BLG beverage for certain claim limitations (8.3, 8.4, 8.7, 15.1, 15.3, and 15.5) and the undenatured BLG isolate powder to satisfy the BLG:ALA ratio in claims 8.6 and 15.4. Pet., 33-37, 50-52. Once again, the Petition fails to explain why a POSITA would combine these two disparate compositions in Nielsen450. As explained above, Petitioner mixes and matches disparate teachings from a reference without ***explaining why*** a POSITA would combine such teachings. Ground 3 fails for this reason alone. *Abiomed*, IPR2017-01204, -01205, Paper 8, 11.

What is more, the Petition fails to recognize that the BLG:ALA ratio from the BLG isolate powder would (and does) change after denaturation in the

[18] Notably, the Petition fails to address that Ex. 1021 discloses that the BLG isolate powder allegedly used in Nielsen450 ***had an ALA amount below detection limits*** while still having a BLG content of 95.9%. Ex. 1021, ¶ 9.

beverage of Nielsen785. Ex. 2005, ¶¶ 124-126. As Petitioner acknowledges, the BLG isolate powders in both Nielsen450 and Nielsen785 are made according to the methods of Bertelsen. Pet., 5, 27-28. As explained above in Section VI.A.iv., Nielsen785 shows that ***there is 0% ALA present in the denatured nanogel product.*** Ex. 1005, 106-107, Table 13. It follows that the denatured beverage in Nielsen450, which starts from the same BLG isolate powder as in Nielsen785, and assertedly denatured under the same conditions, would contain 0% ALA after denaturation. Ex. 2005, ¶¶ 124-126. Because a BLG:ALA ratio requires some detectable amount of ALA, there cannot be a BLG:ALA ratio of greater than 5.00 when there is 0% ALA, and Petitioner does not argue otherwise. *Supra,* Section IV.C.

For these reasons, a POSITA would not understand that Nielsen450's denatured beverage product necessarily had a BLG:ALA ratio of greater than 5.00. Ex. 2005, ¶¶ 124-126. As Petitioner does not explain how the knowledge of a POSITA would remedy Nielsen450 and Bertelsen's failure to teach or suggest the absent claim feature, Ground 3 fails and cannot support cancellation of Claims 8-9, 11-13, and 15-20.

iii. Nielsen450 fails to teach or suggest "reducing native GMP in the cheese whey retentate" (Cl. 8.2) and forming and heating a "reduced-GMP cheese whey retentate composition" (Cls. 8.2-8.3).

Nielsen450 does not teach or suggest reducing native GMP ***in the cheese***

whey retentate" (8.2) or forming and heating a "***reduced-GMP cheese whey retentate composition***" (8.2-8.3). Ex. 1001, Claim 8 (emphasis added); Ex. 2005, ¶¶ 127-128. As discussed above in Section VI.A.i.-iii., Petitioner improperly conflates the BLG isolate powder with the claimed "reduced-GMP cheese whey retentate composition." For the reasons discussed above, Nielsen450 fails to disclose the "reduced-GMP cheese whey retentate composition" recited in claims 8.2 and 8.3. Ex. 1001, Claim 8; Ex. 2005, ¶¶ 127-128. As with Nielsen785, the BLG isolate powder of Nielsen450 (made according to the methods of Bertelsen) is not a reduced-GMP cheese whey retentate composition. Ex. 1007, 97: 23-30; s*upra,* Section VI.A.i.-iii.

Additionally, as discussed above in Section IV.A.i., the BLG isolate powder of Nielsen450 (made according to the methods of Bertelsen) is made from a microfiltration permeate, not a cheese whey retentate. Petitioner has supplied no explanation of how the knowledge of a POSITA may remedy Nielsen450's failure to disclose the claim limitation. For at least these reasons, Ground 3 as it relates to claims 8.2 and 8.3 fails.

D. Ground 4: Ozturk, Kawasaki, and LeanCreme fail to render Claims 8-9, 11-13, 15-17, and 20 obvious.

Claims 8-9, 11-13, 15-17, and 20 are patentable over Ozturk (Ex. 1008), Kawasaki (Ex. 1009), and LeanCreme (Ex. 1010) because (i) a POSITA would not have been motivated to combine the references, and (ii) the references in

combination do not teach or suggest greater than 50 wt. % denatured whey proteins relative to the total weight of the protein. Ex. 2005, ¶ 129. In view of these deficiencies, the Petition fails to present a legally sound argument that the challenged claims are obvious over Ozturk, Kawasaki, and LeanCreme.

i. A POSITA would not have been motivated to combine Ozturk, Kawasaki, and LeanCreme.

The Petition fails to demonstrate that a POSITA would have been motivated to combine Ozturk, Kawasaki, and LeanCreme. In addition to the requirement that Petitioner articulate the three *Graham* factors, discussed above, the Supreme Court explained in *KSR* that "obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

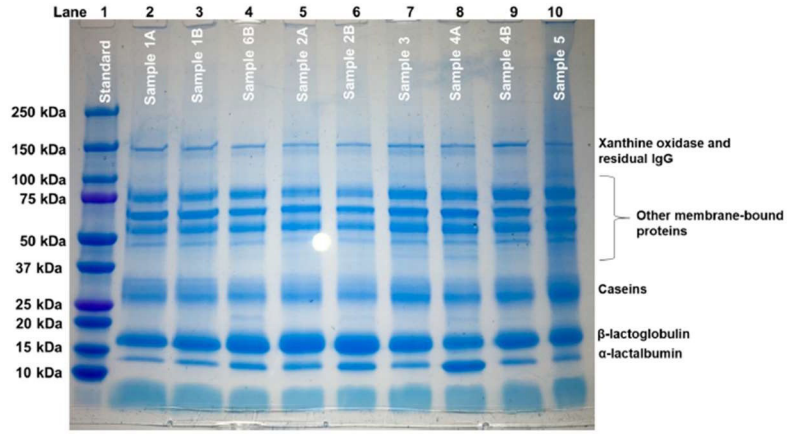
The recent Federal Circuit decision *Virtek Vision Int'l ULC, v. Assembly Guidance Systems* is instructive. 97 F.4th 882 (Fed. Cir. 2024). The *Virtek* court held that "*KSR* did not do away with the requirement that there must exist a motivation to combine" *Id*. at 887. On the contrary, "[i]t does not suffice to simply be known. ***A reason for combining must exist***." *Id.* at 888 (emphasis added).

a. A POSITA would not use Kawasaki's methods to remove GMP from the composition in Ozturk because the composition in Ozturk does not report GMP.

Petitioner conflates three references starting from different compositions

with entirely different aims without showing how or why a POSITA would successfully combine the references. Ex. 2005, ¶¶ 130-131. Petitioner first argues that a POSITA would combine Kawasaki with Ozturk to remove GMP from the whey protein phospholipid concentrate (WPPC) compositions of Ozturk using the methods taught in Kawasaki. Pet., 66-67. In so doing, Petitioner attempts to explain away a colossal gap: ***Ozturk is completely silent concerning GMP content.*** Ex. 1008, 11, Figure 2, 13, Figure 3; Ex. 2005, ¶¶ 131-138. A POSITA would not use the methods allegedly taught in Kawasaki to remove a component from Ozturk which is not reported. Ex. 1008, 11, Figure 2, 13, Figure 3; Ex. 2005, ¶¶ 131-138.

As Petitioner acknowledges, the sole and stated aim of Ozturk is to characterize WPPC. Ex. 1008, 1-3; Pet., 56-57; Ex. 2005, ¶¶ 131-138. Ozturk conducts protein analysis studies on WPPC to determine its protein composition. Ex. 1008, 11, Figure 2, 13, Figure 3; Pet., 58-59. Some BLG and ALA are present in WPPC, with BLG being the predominant whey protein. Ex. 1008, Figures 2-3. Although Ozturk does report dozens of proteins, however, ***no GMP was reported***:



Id., 11, Figure 2.

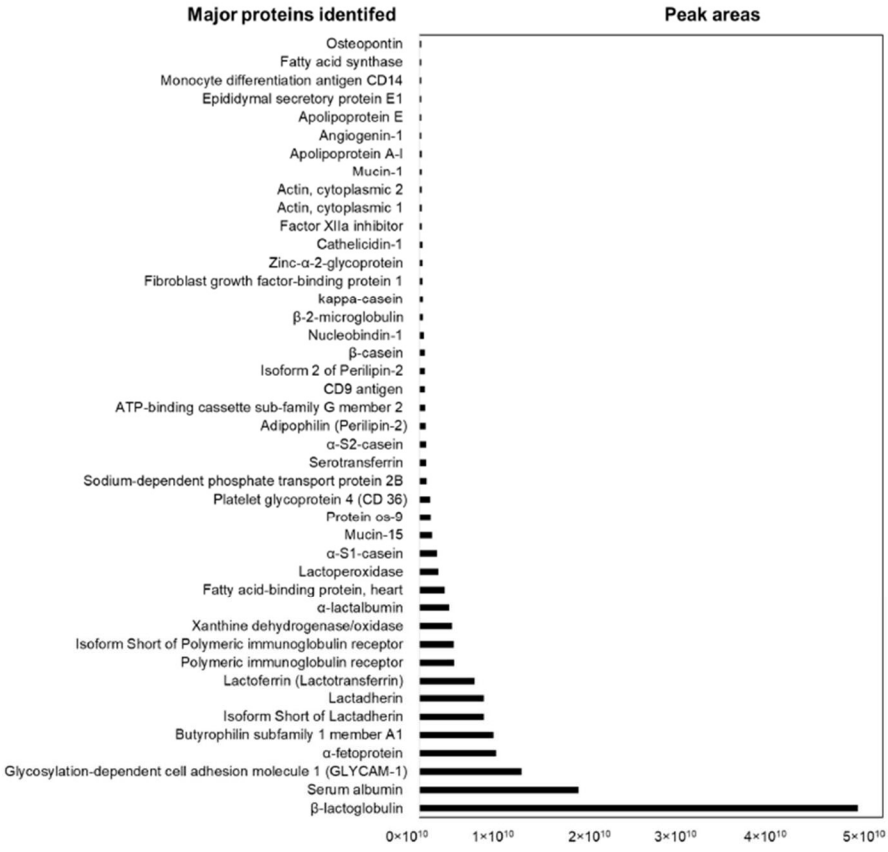


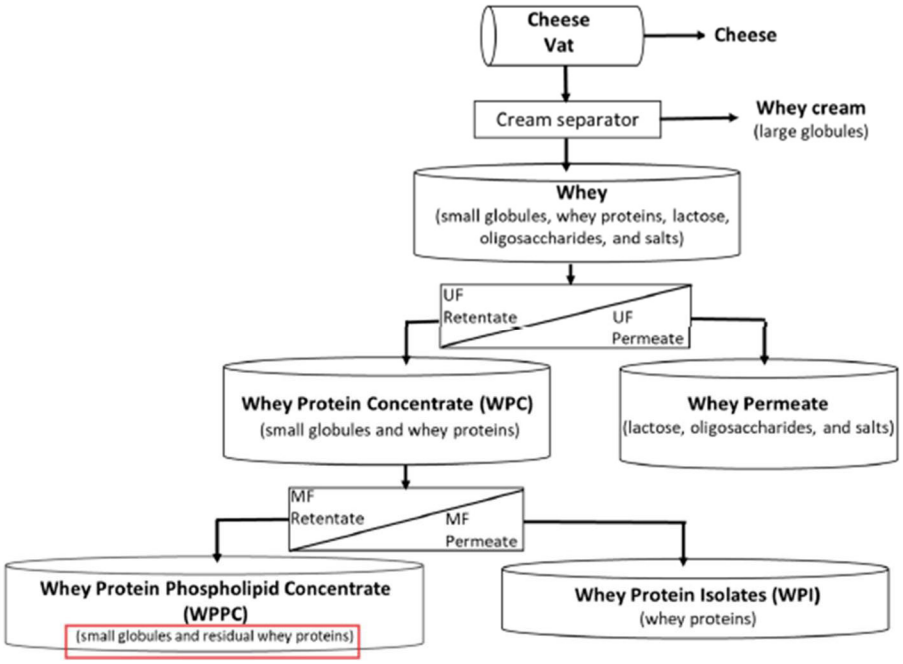
Figure 3. Relative abundance of major proteins identified in WPPC by proteomics.

Id., 13, Figure 3. Although Figures 2 and 3 are pasted into the Petition, Petitioner fails to note that they conclusively demonstrate that ***GMP is not shown in the WPPC of Ozturk***. *Id.*, 11, Figure 2, 13 Figure 3; Ex. 2005, ¶¶ 133-138.

Kawasaki, as described above in Section II.B.v., touts GMP as having numerous biologic functions and describes a filtration method to isolate GMP from a WPC stream. Ex. 1009, 191-192. Petitioner argues that a POSITA would combine Kawasaki with Ozturk to remove GMP from the WPPC compositions of Ozturk, using the filtration methods taught in Kawasaki. Pet., 66-67. Petitioner cannot, however, point to any statement in Ozturk supporting this point because, as explained above, Ozturk's protein analysis is ***completely silent concerning GMP content in the WPPC.*** Ex. 1008, 11, Figure 2, 13 Figure 3. Since there is no GMP reported in the WPPC of Ozturk, ***it is illogical to conclude that a POSITA would be motivated to modify Ozturk by further filtering its WPPC to remove unreported GMP.*** Ex. 2005, ¶¶ 131-138.

The Petition appears to argue that GMP was inherently present in the WPPC of Ozturk. Pet., 67, 81. For this, Petitioner points to multiple references describing that GMP is present in cheese whey. *Id.*, 67. As shown below, however, the Petition's proposal to modify Ozturk with Kawasaki does not start from cheese whey, but from the downstream WPPC product in Ozturk. Ex. 1008, 11, Figure 2, 13 Figure 3. As discussed above, Ozturk is silent concerning GMP content in its WPPC. Ex. 2005, ¶¶ 131-138.

As shown in the red box, below, Ozturk's WPPC contains ***residual*** whey proteins. Ex. 1008, Figure 1 (annotated).



Id. This is because the majority of proteins are filtered into the high protein, low fat WPI composition (bottom right of the above flow diagram). *Id;* Ex. 2005, ¶¶ 131-138. Petitioner argues, citing Ex. 1013, that GMP would have accounted for 10% of proteins present in a whey composition, with the remaining 90% comprising whey proteins (e.g., BLG and ALA). Pet., 67. But Ozturk starts from WPPC, which results after proteins have already been twice filtered from the initial whey input. Ex. 1008, 3, Figure 1. As Ozturk shows, there are numerous processing steps and compositional differences between whey and WPPC. *Id*; Ex. 2005, ¶¶ 131-138. As such, Petitioner's inherency argument fails because Petitioner cannot point to a reference which shows that the relevant composition—specifically WPPC—

necessarily contains GMP, let alone GMP in an amount sufficient to support that a POSITA would be motivated to further remove GMP from the WPPC according to Kawasaki. *PAR Pharm.* 773 F.3d at 1195-96; *Care Brands*, IPR2017-00693, Paper 11 at 9–10; Ex. 2005, ¶¶ 131-138. For these reasons, the Petition fails to provide a logical rationale as to why a POSITA would modify Ozturk based on Kawasaki to recover GMP from the Ozturk WPPC.

b. A POSITA would not use LeanCreme methods on the modified composition from Ozturk/Kawasaki because the references have different aims.

Petitioner additionally relies upon LeanCreme and argues that a POSITA would be motivated to modify the reduced-GMP version of WPPC from Ozturk/Kawasaki by further processing it to produce denatured microparticulates as taught by LeanCreme. Ex. 2005, ¶¶ 139-145. Assuming *arguendo* that Ozturk and Kawasaki are combinable without the benefit of hindsight (they are not), a POSITA would not have applied LeanCreme, which focuses on powders for "low fat content" food products (Ex. 1010, 23), to the high-fat low GMP WPPC purportedly made by Ozturk and Kawasaki because the references have wholly different aims. Ex. 2005, ¶¶ 139-145.

As discussed above, LeanCreme seeks to satisfy demand for low fat food products by providing a fat replacer by producing a "microparticulated whey protein . . . with a viscosity like coffee cream and a mouth feel similar to fat." Ex.

1010, 4. LeanCreme describes that the whey protein is produced from WPC using "an innovative microparticulation process, in which whey protein concentrate is heated under controlled high-shear conditions, enabling the formation of fine particles with a ***specific particle size similar to fat globules***." Ex. 1010, 4. LeanCreme teaches that the desired microparticulated protein size is "between 1 and 10 μM" to achieve the desired mouthfeel. Ex. 1010, 5, 9.

A POSITA would not start from the *high-fat* WPPC product allegedly produced by Ozturk and Kawasaki and apply LeanCreme, which teaches *reducing* fat by replicating the mouthfeel of fat using microparticulated protein in low-fat products. Ex. 1010, 4-5; Ex. 2005, ¶¶ 139-145.

True to its aim at providing "low fat content" food products, the LeanCreme process starts with WPC, which has much less fat than WPPC. Ex. 1010, 8; Ex. 1008, 3; Ex. 2006, 309:13-16. Nowhere does LeanCreme suggest staring its process with WPPC. Ex. 2005, ¶¶ 139-145. Although LeanCreme mentions that for certain downstream products such as low-fat cheese or ice cream, WPC can be mixed with cream prior to the LeanCreme process, that disclosure does not support applying LeanCreme to a completely different, high fat, WPPC product. Ex. 1010, 8, Table 2; Ex. 2005, ¶¶ 139-145. The Petition makes no showing that WPPC and WPC with added cream are comparable in any way, and they are not. Ex. 2005, ¶¶ 139-145.

As shown in Ozturk, WPPC and WPC are completely different compositions: WPC is once-filtered from whey and contains much more protein than twice-filtered WPPC. Ex. 1008, Figure 1; Ex. 2005, ¶¶ 139-145. WPC has a protein content up to 80% while WPPC can have only 50% protein. Ex. 1008, 2-3. WPPC is formed during processing, not by adding cream to WPC. Ex. 1008, Figure 1; Ex. 2005, ¶¶ 139-145. Further, although LeanCreme discloses that WPC with added cream may be used, LeanCreme states, true to its aim, that ***the product has "low fat content."*** Ex. 1010, 23. Adding some undefined amount of cream to WPC simply would not provide sufficient rationale for a POSITA to modify the high fat Ozturk WPPC with the LeanCreme microparticulation process. Ex. 2005, ¶¶ 139-145.

LeanCreme is directed to forming low or reduced-fat products. Ex.1010, 4. The WPPC used in Ozturk is high-fat and, as stated above, Ozturk teaches the numerous benefits of the milk fats present in WPPC. Ex. 1008, 1-2. Based on this teaching in Ozturk, a POSITA would be motivated to retain milk fats—not manipulate a protein to replace fats as taught by LeanCreme. Ex. 1008, 1-2.

What is more, the method taught by LeanCreme aims to achieve a desired protein size between 1 and 10 μm to replicate the mouthfeel of fat. Ex. 1010, 5, 9. Ozturk discloses that the milk fats in WPPC already had mean sizes within this range (2.09 ± 0.10, 1.75 ± 0.02, and 2.64 ± 0.01 μm). Ex 1008, 17. For this reason

also, A POSITA would not be motivated to use the methods of LeanCreme to reduce particle size using microparticulation on the WPPC in Ozturk because the WPPC already contained particles with the desired size taught by LeanCreme. *Id*; Ex. 2005, ¶¶ 145.. For at least these reasons, a POSITA would not denature and powder the WPPC of Ozturk using the methods of LeanCreme. Ex. 2005, ¶¶ 139-145.

In view of the foregoing, the Petition fails to show that a POSITA would have been motivated to combine Ozturk, Kawasaki, and LeanCreme.

ii. A POSITA would not have been motivated to combine Ozturk and LeanCreme.

Although Petitioner's Ground IV relies on the combination of Ozturk, Kawasaki, and LeanCreme, to the extent Petitioner also asserts—without Kawasaki—that GMP would somehow inherently be reduced by the filtration steps in Ozturk, as an initial matter, this argument has not properly been presented as a separate Ground in the Petition and is thus improper. Pet., 73. As shown below, the Petitions grounds do not include an obviousness position based on Ozturk and LeanCreme alone. Ex. 2005, ¶¶ 146-150.

Ground		Claims	Prior Art
1	§102	8-9, 11, 13	Nielsen785
2	§103	8-9, 11-13	Bertelsen, Nielsen785
3	§103	8-9, 11-13, 15-20	Nielsen450
4	§103	8-9, 11-13, 15-17, 20	Ozturk, Kawasaki, LeanCreme

Pet., 2. Petitioner's heading for Ground 4 also does not mention an Ozturk and LeanCreme combination, without Kawasaki. Pet., 56. In every instance, Petitioner defines Ground 4 as obviousness over Ozturk, Kawasaki, and LeanCreme.

Rule 42.104(b) makes clear that petitioners must identify, on a claim-by-claim basis, the specific statutory grounds and references relied upon for each ground. The rule is designed to ensure patent owners have fair notice and an opportunity to respond to the specific challenges raised. Here, Petitioner's absence of notice as to which references are raised in Ground 4 raises serious due process concerns under the Administrative Procedure Act, which requires "adequate notice and an opportunity to respond." 5 U.S.C. § 554(b)(3); *see also Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1080 (Fed. Cir. 2015) ("the rules and practices of the Board generally protect against loss of patent rights without the required notice and opportunity to respond.").

Nevertheless, assuming *arguendo* that Petitioner's alternative argument for Ground IV is deemed proper, Petitioner cannot show that Ozturk ***necessarily*** reduces GMP. Ex. 2005, ¶¶ 146-150. Specifically, Petitioner cannot show that

either of the two filtration steps in Ozturk reduces GMP because Ozturk does not show protein concentration after microfiltration or after ultrafiltration. *Id.* Citing Hinkova (Ex. 1013) as evidence that filtration would allow "substantial GMP removal," the Petition alleges that the microfiltration step would inherently reduce GMP from cheese whey. Pet., 86. Hinkova, however, does not support that GMP would have been removed from cheese whey using a 0.1 micron filter because Hinkova ***did not analyze whey protein separation***. Ex. 2005, ¶¶ 146-150. This conclusion is evident from Hinkova Table 7.

Table 7. Average protein rejection on ceramic membranes

Rejection factor ± SD/%				
Protein	Protein size[a]/kDa	Membrane cut-off		
		5 kDa	100 nm	500 nm
CMP	7	94.6 ± 7.6	70.2 ± 7.6	16.3 ± 2.3
α−La	14.2	96.7 ± 5.7	69.7 ± 1.5	16.3 ± 2.8
β−Lg B	18.4	97.5 ± 4.3	81.8 ± 2.7	17.8 ± 2.1
β−Lg A	18.4	96.3 ± 6.5	87.2 ± 3.1	26.3 ± 0.9

a) Maubois and Ollivier (1997); R_{CMP} – rejection of casein macropeptide, $R_{\alpha-La}$ – rejection of α-lactalbumin, $R_{\beta-Lg\ A}$ – rejection of β-lactoglobulin B, $R_{\beta-Lg\ A}$ – rejection of β-lactoglobulin A, SD – standard deviation.

Ex. 1013, 6, Table 7. The rejection factors of GMP (62.6%-77.8%), ALA (68.2%-71.2%), and BLG (79.1%-84.5% for BLG-β) at 0.1 microns (100 nm) overlap when considering the listed standard deviations. *Id*; Ex. 2005, ¶¶ 146-150. The GMP rejection factors are not significantly different than ALA or BLG. Ex. 2005, ¶¶ 146-150. Additionally, the high standard deviation for GMP suggests variability in experimental results, suggesting that GMP rejection by the membrane would not be statistically significant if the experiment is repeated. *Id.* Accordingly, Hinkova

does not demonstrate that GMP would be removed from cheese whey over other proteins using a 0.1 micron filter as Petitioner proposes. *Id*. Petitioner cannot show Ozturk ***necessarily*** reduces GMP in either filtration step. *Id.*

iii. Ozturk, Kawasaki, and LeanCreme[19] do not teach of suggest that greater than 50 wt.% of denatured whey proteins.

Petitioner has not met its burden to show Ozturk, Kawasaki, and LeanCreme disclose "greater than 50 wt. % denatured whey proteins relative to the total weight of the protein" recited in claims 8.7 and 15.5. Ex. 1001; Ex. 2005, ¶¶ 151-159. Ozturk and Kawasaki are silent as to the denaturation rate of the protein compositions therein, and Petitioner does not argue otherwise.As Petitioner explains, and as its expert, Dr. Etzel, agrees, LeanCreme teaches ***up to***[20] 75 wt. % of the protein can be microparticulated[21] for the composition shown in Figure 2. Petition, 85; Ex. 2006, 258:12-19; Ex. 1003, ¶286; Ex 1010,, 7, 20, Figure 2. More

[19] The same argument applies to Petitioner's covert argument relying on Ozturk and LeanCreme, discussed below in Section VI.D.ii.

[20] Dr. Etzel acknowledged that LeanCreme teaches denaturing "75 % or less" proteins in Figure 2 and that his prior statement that LeanCreme teaches denaturing "at least" 75% of proteins in Figure 2 was an error. Ex. 2006, 258:12-20.

[21] LeanCreme explains microparticulation is simultaneous heat denaturation and mechanical shear. Ex. 1010, 5-6.

importantly, the "up to 75% denaturation" estimate from LeanCreme is ***specific only to the composition of sweet whey shown in Figure 2***. Ex. 1010, 6-7, Figure 2; Ex. 2006, 259:9-20.

Petitioner has not shown that the denatured GMP-reduced WPPC prepared from Ozturk, Kawasaki, and LeanCreme would have the same composition as sweet whey. Ex. 2005, ¶¶ 151-159. Ozturk contains numerous proteins beyond those shown in Figure 2 of LeanCreme. Ex. 1008, 15, Table 2, 13, Figure 3. This deficiency is fatal because, as Dr. Etzel acknowledges, protein denaturation differs based on whey protein concentration because certain proteins do not fully denature. Ex. 2006, 267:6-13; 268:4-9; Ex. 2005, ¶¶ 151-159. For example, Ozturk contains 22.81% "MFGM proteins" and 31.32% "other proteins." Ex. 1008, 15, Table 2. Together these proteins make up ***over 50%*** of WPPC and ***Petitioner has not made any showing that these proteins would denature***. 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.

As shown in Figure 2 of LeanCreme, 48% of the protein in WPPC is formed from BLG, with the remainder being formed from ALA, BSA, Ig, GMP, and NPN. *Id*, Figure 2. Conversely, referring to Table 2 of Ozturk, shown below, only 45.42% of the total proteins in WPPC are from milk proteins similar to the proteins

in Figure 2 of LeanCreme. Ex. 1008, 15, Ex. 1010, 6.

	This Study	Brink et al. (2020)							
	Whey Based		Formula		Cream Based				
	WPPC	MFGM-10	PF	SF	PL-20	BPC-50	BSP2	PLC1	SM2
MFGM proteins	22.81	10.71	5.06	2.85	24	25.73	23.33	23.93	26.39
Butyrophilin	5.11	1.65	1.14	0.1	4.99	5.7	5.42	5.44	5.2
Fatty acid-binding protein	1.75	2.35	1.35	1.03	2.60	4.26	4	4.54	3.18
GLYCAM-1	7.00	3.94	2.17	1.32	7.16	3.88	3.64	4.52	7.74
Lactadherin	4.45	1.36	0.1	0.1	5.42	4.93	4.21	4.24	4.26
Adipophilin (Perilipin-2)	0.44	0.1	0.1	0.1	2.3	3.63	2.94	3.11	3.13
Platelet glycoprotein 4 (CD36)	0.74	1.21	0.1	0.1	0.1	1.05	1.15	0.1	1.09
Xanthine oxidase	2.25	0.1	0.1	0.1	1.43	2.28	1.97	1.98	1.79
Mucin-15	0.90	-	-	-	-	-	-	-	-
Mucin-1	0.18	-	-	-	-	-	-	-	-
Milk proteins	45.42	55.64	61.64	68.5	56.5	50.58	51.39	52.4	52.34
α-lactalbumin	2.07	0.1	1.4	2.65	1.05	1.12	1.2	0.1	1.4
α-S1-casein	1.22	0.1	8.20	12.23	9.80	9.45	9.90	10.45	9.07
α-S2-casein	0.48	0.1	8.24	11.92	11.60	10.64	11.24	14.5	10.22
β-lactoglobulin	30.11	46.29	13.62	14.14	15.30	10.07	13.64	10.69	10.91
Serum albumin	10.95	7.10	4.58	4.17	1.97	1.70	2.23	1.51	2.03
β-casein	0.36	0.1	15.05	24.27	16.58	17.5	12.98	13.79	18.51
Kappa-casein	0.24	0.1	0.1	0.1	0.1	0.1	0.1	1.26	0.1
Lactoferrin (Lactotransferrin)	3.80	1.75	10.45	1.81	0.1	0.1	1.1	0.1	0.1
Other proteins	31.32	33.65	33.3	28.65	19.5	76.31	25.28	23.67	21.27

Ex. 1008, 15, Table 2 (annotated). Petitioner has failed to provide any evidence that the MFGM proteins or the "other proteins" of Ozturk would be denatured according to the process of LeanCreme.

Beyond protein composition, WPPC contains other components which do not denature. Ex. 2005, ¶¶ 151-159. WPPC contains up to 10% lactose, which protects BLG from denaturation. Ex. 1008, 10; Ex. 2005, ¶¶ 151-159. Garrett *et al.* found that ***lactose in whey protected BLG against denaturation*** after heat treatment. Ex. 2009, 2, Table 2; Ex. 2005, ¶¶ 151-159. Anema *et al.* likewise found that ***lactose in skim milk protected BLG against denaturation***. Ex. 2010, 7, Table 5; Ex. 2005, ¶¶ 151-159. Caseins, also present in the denatured GMP-reduced WPPC prepared from Ozturk and Kawasaki, are also

known ***not to denature***. Ex. 2017, 1; Ex. 2034, 10; Ex. 2005, ¶¶ 151-159.

In view of the multiple components in WPPC that would not denature, and Petitioner's failure to make any showing as to which of the other half of the proteins in Ozturk's WPPC would denature, Petitioner cannot meet claim limitations 8.7 and 15.5. Ex. 2005, ¶¶ 151-159. For this reason, Ozturk, Kawasaki, and LeanCreme fail to render the challenged claims obvious, and Ground 4 cannot support cancellation of Claims 8-9, 11-13, 15-17, and 20.

VII. Conclusion

For the foregoing reasons, Petitioner has not demonstrated the instituted claims are unpatentable. Patent Owner respectfully requests that the Board affirm patentability of the instituted claims.

Dated: April 21, 2026

Respectfully submitted,

/Justin Krieger/
Reg. No. 47,719
Lead Attorney for Patent Owner

CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the page limitations of 37 C.F.R. § 42.24(a)(1)(i). This brief contains 13,986 words as measured by the word processing software used to prepare the document, exclusive of table of contents, mandatory notices, certificates of service and compliance and appendix of exhibits.

The undersigned further certifies that this brief complies with the typeface requirements of 37 C.F.R. § 42.6(a)(2)(ii) and typestyle requirements of 37 C.F.R. § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in Times New Roman 14 point font.

Dated: April 21, 2026

Respectfully submitted,

/Justin Krieger/
Reg. No. 47,719
Lead Attorney for Patent Owner

Kilpatrick Townsend & Stockton LLP
1400 Wewatta Street, Suite 600
Denver, CO USA 80202
303.405.1486 (telephone)
202.380.0913 (facsimile)

CERTIFICATE OF SERVICE

The undersigned certifies that on April 21, 2026, this Patent Owner Response (Paper 21), Motion to Amend (Paper 22), Patent Owner's Updated Exhibit List (Paper 23), and Exhibits 2005-2038, have been served via email on Counsel for Petitioner at the email address as indicated in their Mandatory Notices Under 37 C.F.R. § 42.8:

Jessica Kaiser kaiser-ptab@perkinscoie.com
Andrew Dufresne dufresne-ptab@perkinscoie.com
Yuanfeng Gao gao-ptab@perkinscoie.com
arla-leprinoipr@perkinscoie.com

Respectfully submitted,

/Justin Krieger/
Justin Krieger
Reg. No. 47,719