

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARLA FOODS AMBA,

Petitioner

v.

LEPRINO FOODS COMPANY,

Patent Owner

IPR2025-01199

Patent 11,825,860

PATENT OWNER PRELIMINARY 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.

Patent Owner's Exhibit List

2001	Declaration of Dr. Federico Harte
2002	Sithole, R., et al., 2005. Rate of Maillard browning in sweet whey powder. Journal of dairy science, 88(5), pp.1636-1645.
2003	Nishanthi, M. et al., 2018. Impact of storage conditions on solubility, heat stability and emulsifying properties of selected spray dried whey protein concentrates. LWT – Food and Science Technology, 92, pp.16-21.
2004	Khatkar, S. et al., 2023, An Overview of Membrane Technology in Dairy & Food Industry. Novel Technologies in Food Science, pp. 65-108.

I. Introduction

Leprino Foods Company (“Patent Owner”) respectfully submits this Preliminary Response in response to the Petition for *Inter Partes* Review (“Petition”) filed by Arla Foods AMBA (“Arla” or “Petitioner”) challenging Claims 8-9, 11-13, and 15-20 of U.S. Patent No. 11,825,860 (“the ’860 Patent”). Institution should be denied for the following reasons.

As explained in the Patent Owner’s Brief in Support of Discretionary Denial (Paper 7), the Petition improperly relies on expert testimony to fill gaps in the prior art and presents highly fact-specific issues that significantly burden the Board’s resources. As explained below, the Petition suffers from even more issues that warrant denying institution.

The Petition is legally deficient because *each Ground fails to disclose one or more claim limitations*. Ground 1, based on anticipation, fails on this deficiency alone. For Grounds 2-4, based on obviousness, 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.

In view of the foregoing, the Petition fails to demonstrate a reasonable likelihood of prevailing in showing any one of claims 8-9, 11-13, and 15-20 of the '860 Patent is unpatentable. Institution should be denied.

II. Background

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. 2001, ¶ 10. Whey may be used to make high protein compositions, e.g., whey protein powders, as described in the '860 Patent. Ex. 1001, 1:15-17; Ex. 2001, ¶ 10. Whey includes milk-derived proteins such as beta-lactoglobulin (BLG), alpha-lactalbumin (ALA), and glycomacropeptide (GMP). Ex. 1001, 4:36-43; Ex. 2001, ¶ 10.

As the '860 Patent explains, GMP is considered an inferior source of protein for muscle recovery, and a high native GMP content may result in undesirable flavors in whey protein products. Ex. 1001, 1:30- 39. The '860 Patent describes a novel and nonobvious 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:

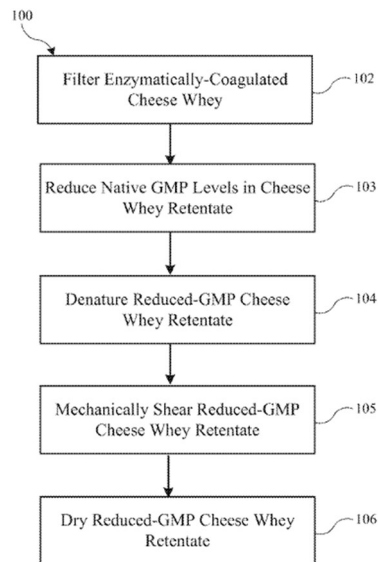


FIG. 1

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 with 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.

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). For the limited purpose of this Preliminary Response, 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.

IV. Claim Construction

A. Institution should be denied because Petitioner failed to construe disputed claim terms.

As an initial matter, institution should be denied because as discussed in Sections VII.A.i.-VII.A.ii, Petitioner failed to construe several additional claim terms that are necessary for understanding the scope of the claims, including limitations Petitioner alleges are met by the references. The Petition has thus failed to satisfy its obligation to construe those limitations relevant to its challenges. 37 C.F.R. § 42.104(b)(3) (Petition “*must* identify ... [h]ow the challenged claim is to be construed.”) (emphasis added). In *Inter Partes* Reviews, the petitioner always bears the burden of persuasion to prove unpatentability. *FanDuel, Inc. v.*

Interactive Games LLC, 966 F.3d 1334, 1341 (Fed. Cir. 2020) (citing 35 U.S.C. § 316(e)). As an initial matter, Petitioner’s failure to construe disputed claim terms means its burden of persuasion is not met, and institution should be denied. *Jiawei Tech. (HK) Ltd. v. Richmond*, IPR2014-00937, Paper 22 at 8 (PTAB 2014) (denying institution because petitioner failed to construe a critical term, stating “[i]t is *Petitioner’s burden to explain how the challenged claims are to be construed and how they read on the prior art.* 37 C.F.R. § 42.104(b)(3)–(5).”) (emphasis added)).

In addition, Dr. Etzel’s declaration (Ex. 1003) should be afforded little or no weight because the lack of claim construction renders it unclear how Dr. Etzel is applying the art to the claims. At a minimum, given the lack of claim construction in the Petition and expert declaration, Petitioner should be precluded from arguing any claim construction other than the plain and ordinary meaning given the lack of notice to Patent Owner for any other construction. *Dropbox, Inc. v. Synchronoss Tech. Inc.*, IPR2016-00850, Paper 41 at 9-12 (agreeing with patent owner that a claim term petitioner failed to construe is entitled to its plain and ordinary meaning).

B. 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.* at 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.

C. “native glycomacropeptide”

Petitioner offers only a single claim construction. Claims 8, 9, 13, and 15 recite “native glycomacropeptide” or “native GMP.” For the limited purpose of this Preliminary Response, Patent Owner does not dispute Petitioner’s definition of “native GMP” as “non-hydrolyzed GMP.” *Pet.*, 4.

D. “cheese whey retentate” and “cheese whey retentate composition”

Petitioner does not offer a construction of “cheese whey retentate” or “cheese whey retentate composition” as recited in claims 8.2-8.3. The term is entitled to its plain and ordinary meaning. *Phillips*, 415 F.3d at 1312-13, 1315. A “cheese whey retentate” is the portion of cheese whey that is captured by the filter, as opposed to a cheese whey permeate, which passes through the filter. Ex. 1001, 2:2-11, 18:18-24; Ex. 2001, ¶ 15. A “cheese whey retentate composition” is the portion of cheese whey that is captured by the filter and optionally may comprise additional components.¹ Thus, the plain and ordinary meaning of the terms “cheese whey retentate” and “cheese whey retentate composition” is the portion of cheese whey that is captured by the filter. Ex. 1001, 2:2-11, 18:18-24; Ex. 2001, ¶ 15.

¹ According to the challenged patent, the “cheese whey retentate composition” must comprise the cheese whey retentate, but it optionally may include additional components, such as enzymes. *See, e.g.*, Ex. 1001, 2: 3-9 (“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.”).

E. “beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00”

Petitioner does not offer a construction of a “beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00” as recited in claim 8.3. Accordingly, the term is entitled to its plain and ordinary meaning. *Phillips*, 415 F.3d at 1312-13, 1315. As a basic mathematic principle, 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) (“*[W]hen n is equal to zero, i.e., no methylene bridges, the ratio of m to n is undefined.* But, whenever methylene bridges are present, i.e., n is a real number unequal to zero, the ratio of m to n is a finite real number.”). The plain and ordinary meaning of a “beta-lactoglobulin [BLG] to alpha lactalbumin [ALA] ratio of greater than 5.00” thus requires that *some non-zero* amount of each BLG and ALA be present to meet the claim limitation.

As the Federal Circuit has held, 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). A defined ratio necessarily compares two quantities. 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 at 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 non-zero* amount of ALA must be present to meet the claim limitation. This conclusion is also supported by the ’860 Patent itself, which contemplates at least some non-zero amount of each BLG and ALA in its discussion of the claimed ratio. Ex. 1001, 8: 17-23.

V. The Prior Art

A. Nielsen785 (Ex. 1005)

The WO 2021/136785 patent application entitled “[m]ethod of producing dense whey protein nanogels, the resulting whey protein nanogels or nanogel compositions, and food products containing such whey protein nanogels or nanogel compositions” 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. Nielsen785 starts with a BLG isolate powder mixed with water to form a solution, which is then heat treated to form the denatured nanogel. *Id.*, 89: 1-3, 11-16, 25-29. 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.

B. Bertelsen (Ex. 1006)

The WO 2018/115520 patent application entitled “[p]roduction of novel beta-lactoglobulin preparations and related methods, uses, and food products” describes the formation of isolated crystallized BLG powder compositions and uses of such powders in food products. Ex. 1006, 1: 6-10. Bertelsen begins from a retentate derived from cheese production. *Id.*, 57:1-5. The retentate is then seeded with a BLG crystal starter, cooled, and centrifuged to separate the BLG crystals. *Id.*, 57:17-18, 24-26, 29-30. 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. As discussed below, Bertelsen at least does not disclose heating the “reduced-GMP cheese whey retentate” as claimed.

C. Nielsen450 (Ex. 1007)

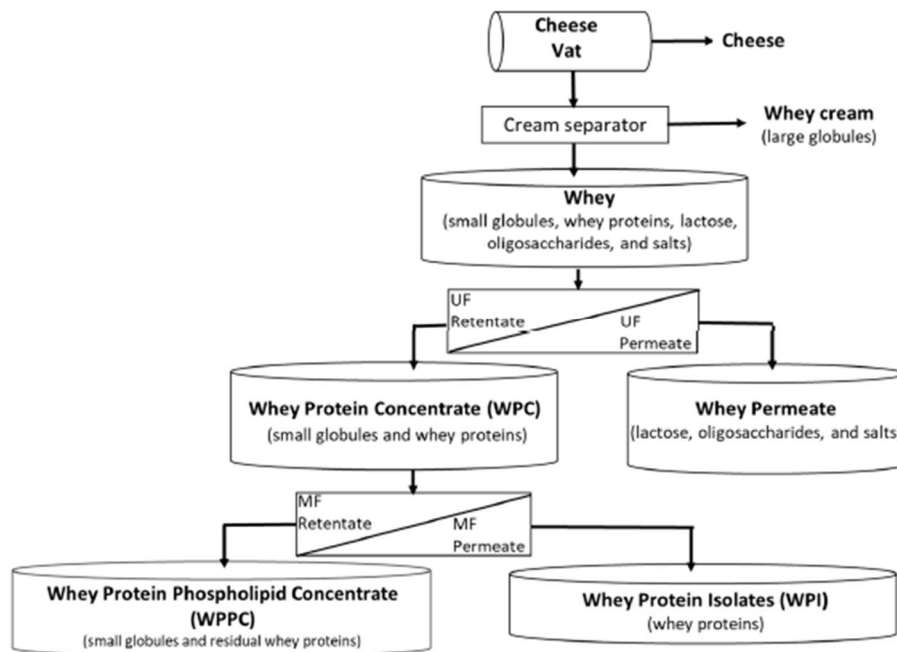
The WO 2020/002450 patent application entitled “[p]H neutral beta-lactoglobulin beverage preparation” describes the formation of BLG isolate powders and their use in beverages.” Ex. 1007, 1:1-6. Similar to Nielsen785, Nielsen450 starts from a BLG isolate powder mixed with water to form a solution, which is then heat treated to form the denatured beverage. *Id.*, 97: 23-30. 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” as claimed.

D. 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” was allegedly published in *Dairy* on April 20, 2022. Pet., 56. Ozturk describes whey protein phospholipid concentrates (“WPPCs”) that contain milk fat globule (“MFG”) compounds that are useful for immune and gut health and discusses that WPPC may be a source of valuable MFG byproducts. Ex. 1008, 277, 298.²

Whey from cheese making is filtered 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 can be filtered again 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:

² 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., Figure 1. Ozturk does not teach heating a “reduced-GMP cheese whey retentate” as claimed.

E. Kawasaki (Ex. 1009)

The article, “pH-dependent molecular weight changes of κ -casein glycomacropeptide and its preparation by ultrafiltration” 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. Kawasaki goes on to describe a filtration method for isolating GMP from a whey protein stream. *Id.*, 191-193.

F. LeanCreme (Ex. 1010)

The white paper, “APV LeanCreme” was allegedly published on the SPX Flow website by June 26, 2016. Pet., 63. LeanCreme describes “microparticulated whey protein . . . with a viscosity like coffee cream and a mouth feel similar to fat.” Ex. 1010, 4. LeanCreme describes that 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.” *Id.*, 4. LeanCreme teaches the desired microparticulated protein size is between 1 and 10 μM to achieve the desired mouthfeel. *Id.*, 5, 9.

VI. Overview of Arguments

The Board may institute an *Inter Partes* Review (IPR) proceeding only if Petitioner demonstrates that there is “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314. For the reasons discussed below, Petitioner failed to meet that burden and institution should be denied. A summary of Patent Owner’s arguments is provided below.

Ground	Brief Statement of Arguments
1: Anticipation by Nielsen785 (incorporating Bertelsen)	Nielsen785 fails to teach: <ul style="list-style-type: none"> forming or heating the “reduced-GMP cheese whey retentate.” “reducing native [GMP] in the cheese whey retentate.” “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: <ul style="list-style-type: none"> forming or heating the “reduced-GMP cheese whey retentate.” “reducing native [GMP] in the cheese whey retentate.” “a beta-lactoglobulin to alpha lactalbumin ratio of greater than 5.00.”
3: Obvious over Nielsen450 (incorporating Bertelsen)	Nielsen450 fails to teach or suggest: <ul style="list-style-type: none"> “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.” forming or heating the “reduced-GMP cheese whey retentate.” “reducing native [GMP] in the cheese whey retentate.”
4: Obvious over Ozturk, Kawasaki, and LeanCreme	<p>There is no motivation to combine Ozturk, Kawasaki, and LeanCreme has been provided.</p> <p>Ozturk, Kawasaki, and LeanCreme fail to teach or suggest:</p> <ul style="list-style-type: none"> “at least 60 wt. % whey protein on a dry weight basis” “greater than 50 wt.% of the protein are denatured whey proteins.”

VII. Petitioner has not demonstrated that it has a reasonable likelihood of prevailing with respect to at least one of the challenged claims.

A. Ground 1 is unlikely to prevail because Nielsen785³ fails to teach (i) forming and heating a reduced-GMP cheese whey retentate composition, (ii) reducing native GMP in a cheese whey retentate, and (iii) a BLG:ALA ratio of greater than 5.00.

Petitioner has not established that it has a reasonable likelihood of prevailing on its position that Claims 8-9, 11, and 13 are anticipated by Nielsen785 (Ex. 1005) because Nielsen785 fails to teach three limitation of independent claim 8: (i) forming and heating a reduced-GMP cheese whey retentate (Cls. 8.2-8.3), (ii) reducing native GMP in a cheese whey retentate (Cl. 8.2), and (iii) a BLG:ALA ratio of greater than 5.00 as claimed (Cl. 8.6).

A claim is anticipated only if a disclosure teaches every element of the claim, either expressly or inherently. Petitioner has failed to demonstrate that it is reasonably likely to prevail on its position that Nielsen785 anticipates claims 8-9, 11, and 13 because Nielsen785 fails to teach, expressly or inherently, several claim

³ 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.

elements. As Nielsen785 fails to teach each element of the claims and thus cannot anticipate the claims, Petitioner is unlikely to prevail on Ground 1.

- i. **Nielsen785 fails to disclose forming and heating a “reduced-GMP cheese whey retentate composition” (Cls. 8.2-8.3) and “reducing native GMP in the cheese whey retentate” (Cl. 8.2).**

The Board should exercise its discretion under 35 U.S.C. § 325(d) and reject Ground 1 because Nielsen785 fails to disclose each claim element. Independent claim 8 recites reducing (Cl. 8.2) native GMP in the cheese 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 and cannot meet the high burden of anticipating the challenged claims.

a. 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 unfounded and flies in the face of the meaning of the term “cheese whey retentate composition.” As described above, properly construed, the term “cheese whey

retentate composition” refers to the portion of cheese whey that is captured by the filter. Ex. 1001, 2:2-11, 18:18-24; Ex. 2001, ¶ 15.

Petitioner alleges Nielsen⁷⁸⁵ incorporated Bertelsen’s Example 1, which describes lactose-depleted ultrafiltered 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. The lactose-depleted ultrafiltered retentate was seeded with a BLG crystal starter, cooled, and centrifuged to separate the BLG crystals. *Id.*, 57:17-18, 24-26, 29-30. The BLG crystals were then spray dried to form a powder. *Id.*, 57:31-32, 69:11-20.

In an attempt to satisfy limitation 8.2, Petitioner 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 show the alleged GMP⁴ reduction between the feed before BLG crystallization (Table 3) and the BLG crystal powder (Table 12). Pet., 12-13.

⁴ As Petitioner explains, GMP is the same protein as caseinomacropeptide (CMP), which is discussed in Nielsen⁷⁸⁵. Pet., 11.

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)

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)

CMP
Reduction

Pet., 12-13 (citing Ex. 1006, Tables 3, 12 (annotated)). In so doing, Petitioner overlooks a key distinction: ***GMP is reduced in the BLG isolate powder, which is not a retentate at all*** (let alone a cheese whey retentate as claimed and as described below). 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 BLG isolate powder are distinct compositions.

Additionally, Petitioner glosses over the numerous steps between the lactose-depleted ultrafiltered retentate at the start of Bertelsen, and the BLG isolate powder formed by crystallization. Instead, Petitioner conflates “cheese whey retentate” with BLG isolate powder, in turn giving the term a meaning completely contrary to the ’860 Patent and to those skilled in the art. Ex. 1001, 2:2-11, 18:18-24; Ex. 2001, ¶ 15. As discussed above, according to the ’860 Patent, the cheese whey retentate is *the portion of the cheese whey captured by the filter*. Ex. 1001, 2:2-11, 18:18-24; Ex. 2001, ¶ 15.

The terminology in Bertelsen is also 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 not cheese whey retentate compositions. Bertelsen repeatedly describes that the BLG crystals were isolated *from the lactose-depleted ultrafiltered retentate*. Ex. 1006, 80:5-7. (“At this point the amount of diafiltration water was adjusted so that the retentate was around 30% [total solids]. The amount of [total solids] in the [mother liquor] decreases *when BLG is removed as crystals*” (emphasis added)).

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 separated by multiple processing steps (seeding,

cooling, centrifugation, BLG crystal separation, freeze drying, reconstitution, and spray drying). Ex. 1006, 57:17-18, 24-26, 29-30.

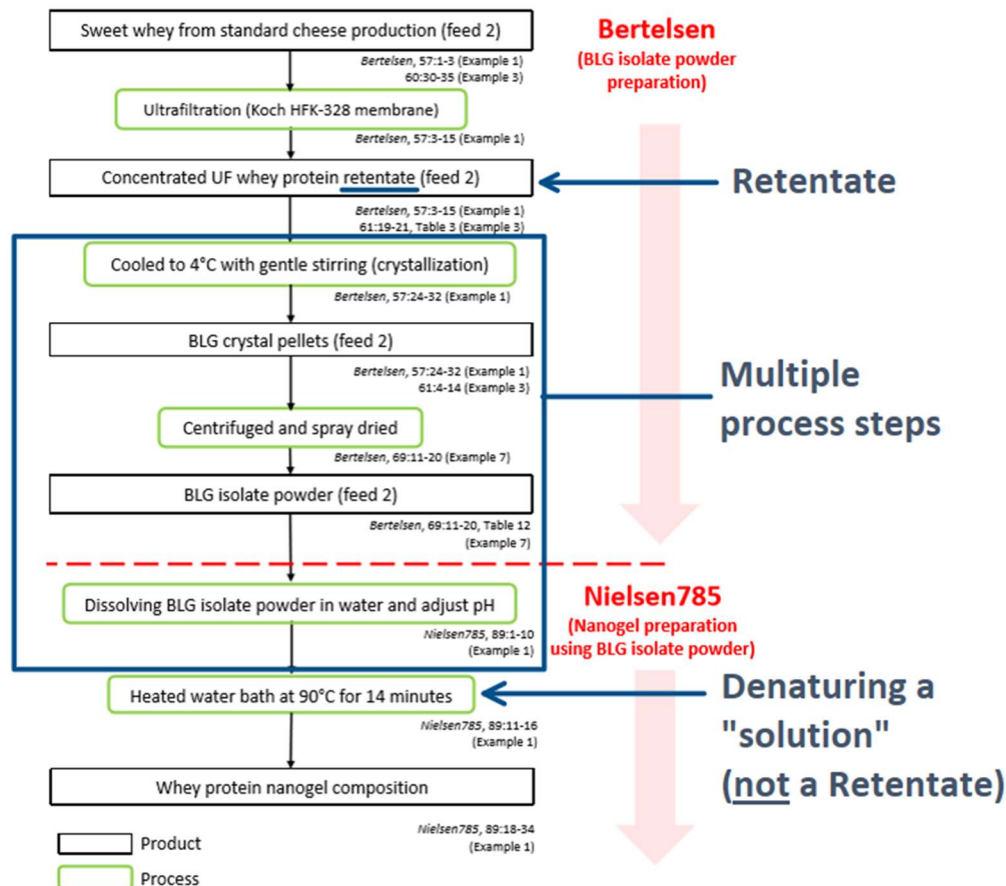
In view of the foregoing, Nielsen785 fails to anticipate independent claim 8 and institution should be denied.

b. Nielsen785/Bertelsen does not disclose 8.3: heating a “reduced-GMP cheese whey retentate composition”

Petitioner incorrectly asserts, without explanation, that the BLG isolate powder produced using Bertelsen’s methods is a “reduced-GMP cheese whey retentate composition.” Pet., 14. Petitioner further asserts 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, again without any explanation, that heating the BLG solution 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 as claimed. It is multiple steps separated from a lactose-depleted ultrafiltered retentate (e.g., seeding, cooling, centrifugation, BLG crystal separation, freeze drying, reconstitution, and spray drying). Ex. 1006, 57:17-18, 24-26, 29-30. They are not the same compositions. Here, Petitioner’s own proposed flow chart is instructive. Namely, Petitioner’s proposed flow chart

concedes that the only retentate in the entire process set forth by Petitioner, cobbled together from Examples 1 and 3 of Bertelsen, 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),⁵ there is no mention of a

⁵ As discussed below and as shown in the corrected Bertelsen flowchart below, the actual “cheese whey retentate” is formed several steps before Bertelsen’s “concentrated UF whey protein retentate.”

retentate again after the third step. Rather, the retentate is seeded, cooled, crystallized, centrifuged, slurried, and spray dried into a powder. 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:

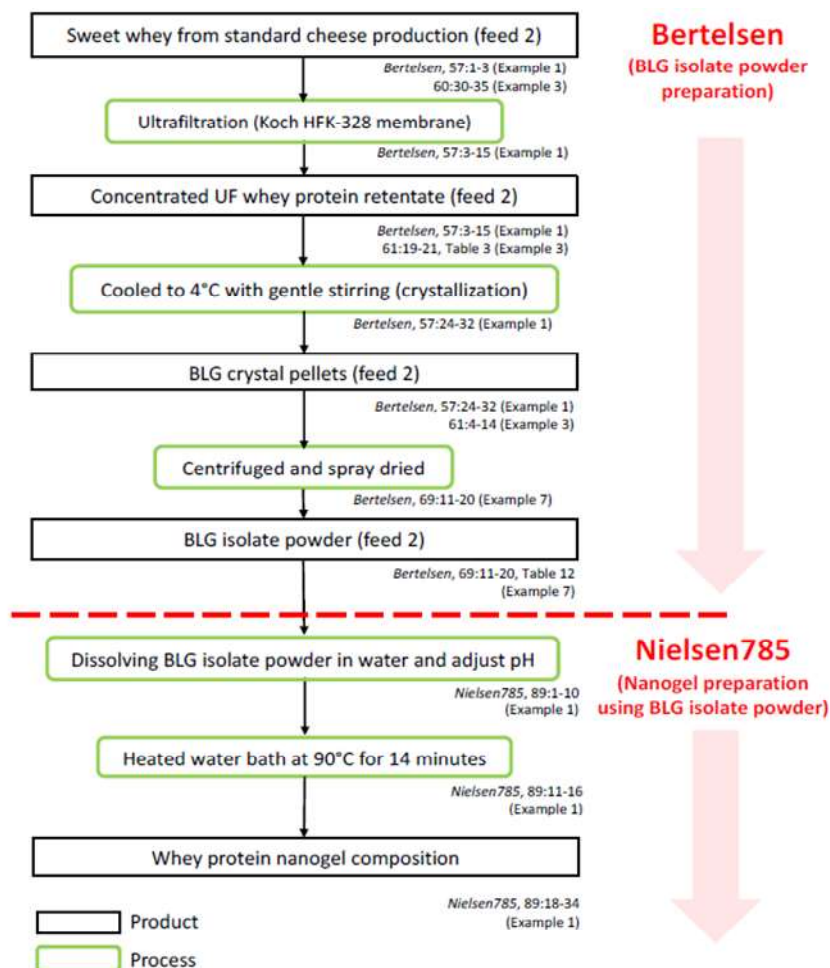
“Nielsen785 described dissolving that BLG powder from Bertelsen’s Example 7 to form whey protein solutions . . . *Those solutions were heated* at 90°C for 14 minutes in a water bath.” *Id.*, 14 (internal citations omitted) (emphasis added).

Simply put, these “solutions” 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*, as indicated by the intrinsic evidence. Ex. 1001, 2:2-11, 18:18-24.

In sum, even if Petitioner’s flow chart is taken as true, which is not conceded for the reasons set forth below, Nielsen785 incorporating Bertelsen discloses heating a solution of BLG isolate powder in water—not heating a “reduced-GMP cheese whey retentate” as required by limitation 8.3. As Nielsen785 incorporating Bertelsen does not teach each element of independent claim 8, Nielsen787 fails to anticipate independent claim 8 and institution should be denied.

c. Nielsen785/Bertelsen does not disclose “reducing native GMP in the cheese whey retentate.”

Petitioner alleges that Nielsen785 incorporates Bertelsen’s Example 1, which teaches filtering sweet whey from cheese production to obtain a cheese whey retentate for BLG crystallization. Pet., 5, 11-14. Petitioner created the below flow chart, which purportedly summarizes the Bertelsen process, in alleging that Bertelsen discloses “reducing native glycomacropeptides (GMP) in the cheese whey retentate to form a reduced-GMP cheese whey retentate composition.” Pet., 12.



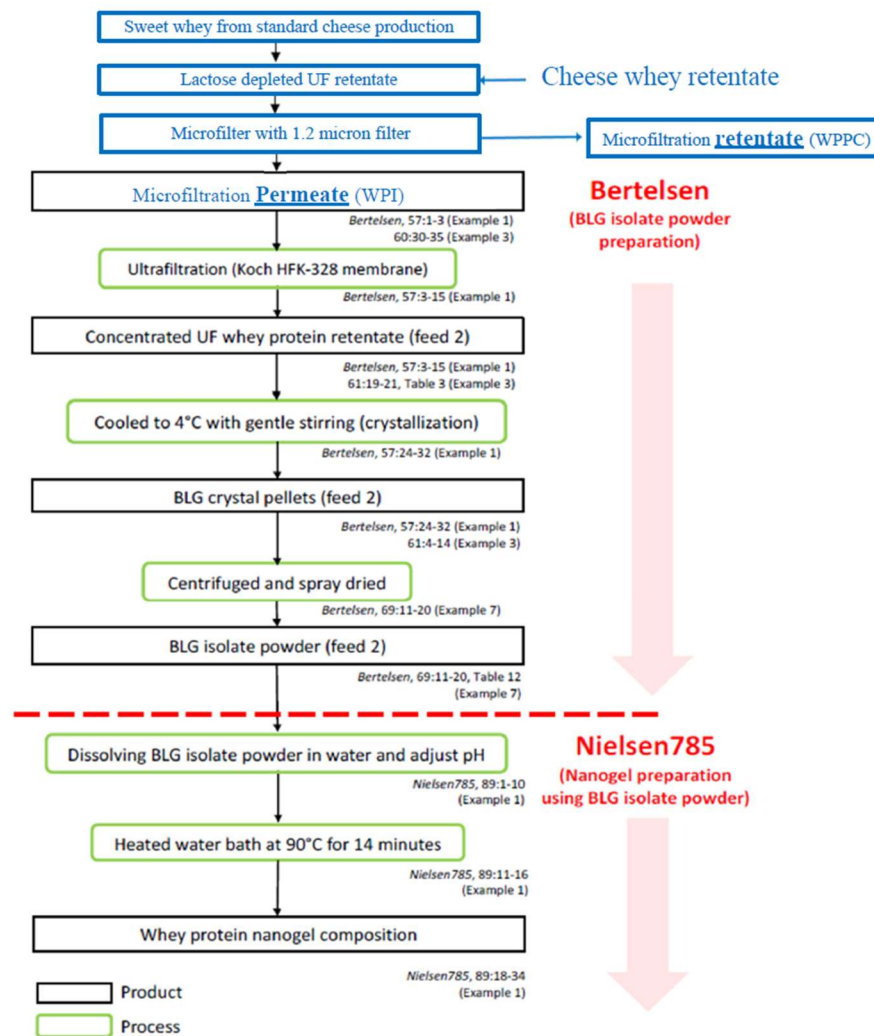
Pet., 8. The Bertelsen process, however, is much more complicated than shown in Petitioner's flow chart, which omits several critical process steps. This distinction is not trivial, as the omitted steps in forming Bertelsen's BLG isolate powder demonstrate that the GMP is not reduced "in the cheese whey retentate."

Example 1 of Bertelsen describes that the sweet whey from standard cheese production is subjected to ultrafiltration to form a lactose depleted ultrafiltration (UF) retentate. Ex. 1006, 57:3-5 That lactose depleted UF retentate is then subjected to microfiltration, and the resulting *permeate*⁶ is used as a feed for the BLG crystallization process. Ex. 1006, 57, 1-3; Ex. 2001, ¶ 17. As shown in the below *corrected* Bertelsen flow chart, the Petition conveniently ignores the fact that the feed for the BLG crystallization process of Example 1 of Bertelsen begins

⁶ Bertelsen describes a "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. A POSITA would understand that filtration through a 1.2 micron filter is microfiltration. Ex. 2001, ¶ 17 Ex. 2004, 1, 8. As described in Ozturk (Ex. 1008), microfiltration creates a whey protein isolate (WPI) permeate. Ex. 2001, ¶ 18-19; Ex. 1008, Figure 1. Bertelsen states WPI is a preferred feed source. Ex. 1006, 19; Pet., 72.

with a *permeate* obtained from microfiltration of the UF retentate. Ex. 1006, 19; Pet., 72; Ex. 2001, ¶ 18.

Corrected Bertelsen Flow Chart



Ex. 1006, 57:1-3 (blue text added). Thus, as is clear from the above **corrected** Bertelsen flow chart, the BLG isolate powder is actually made from a microfiltration *permeate*—not from a “cheese whey retentate” as claimed. Ex. 2001, ¶ 20-21. Although Petitioner did not construe “cheese whey retentate” or

“cheese whey retentate composition,” to the extent Petitioner is asserting that “reducing GMP in the cheese whey retentate” refers to reducing GMP in a composition that is somehow derived from a “cheese whey retentate,” Petitioner’s argument fails because Bertelsen reduces GMP from a *permeate*—which is the opposite of a retentate. *Supra*, Section IV.D. For this reason, Petitioner’s Ground 1 lacks merit and is unlikely to prevail.

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. Specifically, the BLG isolate powder is instead formed, through many additional process steps, from a “microfiltration permeate.” As shown in the corrected Bertelsen flowchart, above, the “concentrated UF whey protein retentate” is an entirely different composition from the “cheese whey retentate.” For this reason, even under Petitioner’s apparent construction of “cheese whey retentate” and “cheese whey retentate composition,” Petitioner’s suggestion in Ground 1 that formation of the BLG isolate powder satisfies the “reducing GMP in the cheese whey retentate” lacks merit and is unlikely to prevail.

ii. Nielsen785 fails to teach or suggest a BLG:ALA ratio of greater than 5.00 (Cl. 8.6).

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, institution should be denied.

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

First, Petitioner 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, Table 1. As the title of the table makes clear, the table shows the content of the BLG isolate powder that is used to prepare the nanogel product of Nielsen785. Ex. 1005, Table 1. As discussed above in Section V.A., 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.*, Table 1.

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. 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).

b. 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 fatal flaws.

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 undermined by Petitioner’s own prior art. Although Neilsen⁷⁸⁵ 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.%*.⁷

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 aggregates and non-denatured protein	20.8%	10%	11.6%	-	22.5%	-
Nanogels	79.2%	90%	88.4%	-	77.5%	-

Ex. 1005, 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.

Based on the foregoing, it is clear that Petitioner's statement that "[h]eat-denaturation processes would not affect the BLG/ALA ratio" is incorrect for the

⁷ 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.

nanogel of Nielsen785. For this reason also, Nielsen785 fails to teach the ratio of limitation 8.6 and institution should be denied.

c. 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. %. As described in Section IV.D., correctly construed, the term “beta-lactoglobulin [BLG] to alpha lactalbumin [ALA] ratio of greater than 5.00” requires at least some non-zero 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. Therefore, as Nielsen785 shows that 0% ALA remains in the denatured product, Nielsen 785 fails to disclose at least this feature of claim 8. In view of the foregoing, Petitioner is unlikely to prevail in showing that independent claim 8 is anticipated by Nielsen785 incorporating Bertelsen.

B. Ground 2 is unlikely to prevail because Nielsen785 and Bertelsen fail to teach or suggest (i) forming and heating a reduced-GMP cheese whey retentate composition, (ii) reducing native GMP in the cheese whey retentate, and (iii) a BLG:ALA ratio of greater than 5.00.

Petitioner does not have a reasonable likelihood of prevailing in its argument that any of Claims 8-9 and 11-13 are invalid as obvious over Nielsen785 (Ex. 1005) and Bertelsen (Ex. 1006) because Nielsen785 and Bertelsen fail to teach or

suggest (i) forming and heating a reduced-GMP cheese whey retentate, (ii) reducing native GMP in the cheese whey retentate, and (iii) a BLG:ALA ratio of greater than 5.00, as claimed. Ground 2 repeats the errors of Ground 1 and compounds them by failing to offer any proper *KSR* analysis.

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) (“A determination of whether a patent claim is invalid as obvious under § 103 requires consideration of all four *Graham* factors, and it is error to reach a conclusion of obviousness until all those factors are considered.”) (internal citations omitted)); *In re Magnum Oil Tools International, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) (reversing the PTAB’s determination of obvious in part because petitioner failed to articulate how the prior art differed from the claims).

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) forming and heating a reduced-GMP cheese whey retentate, (ii) reducing native GMP in the cheese whey retentate, and (iii) a BLG:ALA ratio of greater than 5.00 (limitation 8.6). 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 fail to teach or suggest forming and heating a “reduced-GMP cheese whey retentate composition” (Cls. 8.2-8.3) and “reducing native GMP in the cheese whey retentate” (Cl. 8.2).

Nielsen785 and Bertelsen do not teach or suggest forming and heating a “*reduced-GMP cheese whey retentate composition*” (Cls. 8.2-8.3) and “reducing native GMP *in the cheese whey retentate*” (Cl. 8.2). Ex. 1001, claim 8 (emphasis added). As discussed above in Section VII.A.i.a, Petitioner improperly conflates the BLG isolate powder with the claimed “reduced-GMP cheese whey retentate composition.” Additionally, the BLG isolate powder of Nielsen785 (made according to the methods of Bertelsen) is made from a microfiltration permeate, not a cheese whey retentate.

In combination, Nielsen785 and Bertelsen fail to disclose the “reduced-GMP cheese whey retentate composition” claim limitation recited in claims 8.2 and 8.3. 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 the claim limitation. For at least these reasons, Petitioner is unlikely to prevail on Ground 2.

ii. Nielsen785 and Bertelsen fail to teach or suggest a BLG:ALA ratio of greater than 5.00 (Cl. 8.6).

Nielsen785 and Bertelsen do not teach or suggest a BLG:ALA ratio of greater than 5.00. As explained above in Section VII.A.ii., 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. Petitioner makes no effort to explain why the undenatured BLG isolate powder is interchangeable with the denatured nanogel product. Instead, Petitioner concludes, *without any supporting evidence*, that the BLG:ALA ratio would not change upon denaturation. Pet., 16-17; Ex. 1003, § 95. Nielsen785 itself proves Petitioner wrong: 0% ALA was reported in the denatured nanogel composition. Ex. 1005, Table 13. There cannot be a BLG:ALA ratio of at least 5.00 if no ALA is present.

In combination, Nielsen785 and Bertelsen fail to disclose the "reduced-GMP cheese whey retentate composition" claim limitation recited in claims 8.2 and 8.3. Ex. 1001, Claim 8. Petitioner has provided no explanation of how the knowledge of a POSITA may remedy the failure of Nielsen785 and Bertelsen to disclose these

claim limitations. For at least these reasons, Petitioner is unlikely to prevail on Ground 2.

C. Ground 3 is unlikely to prevail because Nielsen450⁸ fails to teach or suggest (i) greater than 50 wt. % denatured whey proteins, and (ii) a BLG:ALA ratio of greater than 5.00, and (iii) forming and heating a reduced-GMP cheese whey retentate composition and reducing native GMP in the cheese whey retentate.

Petitioner has not established that it has a reasonable likelihood of prevailing on its position that any of Claims 8-9, 11-13, and 15-17 are invalid as obvious 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, and (iii) forming and heating a “reduced-GMP cheese whey retentate composition” (Cls. 8.2-8.3) and “reducing native GMP in the cheese whey retentate” (Cl. 8.2). Petitioner 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. In view of these deficiencies, Petitioner is unlikely to prevail on Ground 3.

⁸ 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.

- 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, the Board should exercise its discretion under 35 U.S.C. § 325(d) and reject Ground 3 since Nielsen450 fails to teach or suggest (as Petitioner concedes) greater than 50 wt. % denatured whey proteins, and Petitioner’s attempt to fill this gap with Dr. Etzel’s “replicated” experiments is fatally defective.

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. *As Petitioner admits, “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 Nielsen450 discloses heating protein solutions,⁹ and that it would have been obvious to a POSITA that the heating would result in “significant denaturation.” Pet., 30.

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

⁹ As discussed above, a protein solution is *not* a retentate as the protein solution of Nielsen450 also begins with Example 1 of Bertelsen.

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 at room temperature for at least 7 years* and would have undergone changes in protein denaturation during storage. Ex. 1021, 2; Ex. 1003, ¶ 145, 166-167.

Petitioner touts Dr. Etzel's experiments as replicating Nielsen⁴⁵⁰, alleging Dr. Etzel used a BLG isolate powder from the same batch that used in Nielsen⁴⁵⁰'s experiments. Pet., 31; Ex. 1003, ¶ 145. Petitioner fails to recognize, however, that at least 7 years¹⁰ had passed from when the BLG isolate powder was first made. Ex. 1021, 2; Ex. 1003, ¶ 145, 166-167. As Arla employee Tanja Jæger recounts, the sample was stored at room temperature (approximately 22°C) between 30-50% humidity after it was made in 2017 until Dr. Etzel used it. Ex. 1021, 2.

¹⁰ Assuming Dr. Etzel conducted his experiments in 2025, the sample from the batch made November 28, 2017, would be at least 7 years old. Ex. 1021, 2. It is unclear when exactly Dr. Etzel conducted his experiments. Arla employee Tanja Jæger described a sample from the batch Dr. Etzel used was assessed in 2025. *Id.*, 3.

Numerous studies discuss the changes which whey protein powders undergo during storage, and the resultant limited shelf life for whey protein powders. Ex. 2001, ¶ 24. For example, Exhibits 2002 and 2003 discuss these changes in detail. Ex. 2002, 1-2; Ex. 2003, 1. Notably, storage decreases heat coagulation time (the time it takes for proteins to form visible aggregates following denaturation), signaling faster denaturation rates. Ex. 2003, 2 (stating heat coagulation time decreased throughout the storage); Ex. 2001, ¶ 27-28. One study, described in Exhibit 2003, found that in whey protein concentrate samples stored at 25 °C and 22% relative humidity, heat coagulation time dropped from 53 seconds at day 0 of storage, to 28 seconds at 90 days of storage. Ex. 2003, Table 1; Ex. 2001, ¶ 27-28. Notably, the batch Dr. Etzel used *was stored for 28 times as long* (7+ years versus 90 days), and *at higher humidity* (30-50% versus 22% relative humidity), suggesting the sample Dr. Etzel used would have denatured much more readily than those in Exhibit 2003. Ex. 2001, ¶ 28.

Dr. Etzel fails to account for *any* expected changes to protein denaturation rate after the sample used was stored for 7+ years. Instead, Dr. Etzel imports denaturation levels taken after the extensive storage into Nielsen450 retroactively, assuming the sample did not undergo *any* expected protein denaturation rate changes after a 7+ year storage. Ex. 1003, ¶ 186. Not only is this assumption implausible, but it also fatally flaws Dr. Etzel's denaturation measurements.

Accordingly, 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. 2001, ¶ 26, 28.

In fact, even Dr. Etzel's experiments show that the batch Dr. Etzel used had undergone compositional changes. Pet., 31; Ex. 1003, ¶ 72; Ex. 1021, 3. 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, 3. Petitioner dismisses these compositional changes, *without any supporting evidence*,¹¹ as caused by moisture absorption during storage. Ex. 1003, ¶ 146; Pet., 31. Even considering the alleged moisture absorption during storage,

¹¹ Petitioner cites to Dr. Etzel's declaration, which conclusorily states "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. Dr. Etzel does not cite to any evidence to support this statement.

there is an unexplained reduction in protein on a dry basis (total protein/dry matter) after storage. Ex. 1021, 3. 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, 3. Additionally, as explained above, a POSITA would expect the stored sample to denature faster after 7+ years of storage. Ex. 2003, 2; Ex. 2004, ¶ 27-28. Thus, Dr. Etzel's experiments are not representative of the compositions actually disclosed in Nielsen450, which would be expected to have slower denaturation rates. Ex. 2004, ¶ 27-28. Petitioner does not account for this fact and cannot show that a POSITA would have expected Nielsen450's heat treated protein solutions to contain greater than 50 wt. % denatured whey proteins based on measurements taken 7 years later, when denaturation rates would have increased.

To the extent Petition is arguing greater than 50 wt. % denatured whey proteins are inherently present in the heat treated protein solutions of Nielsen450, Petitioner cannot establish with Dr. Etzel's experiments that the claim element is *necessarily* present. Pet., 30. Nielsen450 itself shows 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"). Ground 3 cannot succeed for 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 at 9–10 (July 17, 2017).

In view of the foregoing, Petitioner is unlikely to prevail on Ground 3.

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

The Board also should exercise its discretion under 35 U.S.C. § 325(d) and reject Ground 3 since Petitioner cannot show that Nielsen450 discloses each claim element. Claims 8.6 and 15.4 recite “a beta-lactoglobulin [BLG] to alpha lactalbumin [ALA] ratio of greater than 5.00.” Ex. 1001.

Similar to its argument for Nielsen785 in Grounds 1 and 2, Petitioner argues 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, Table 9. Table 9 does not disclose an ALA measurement. *Id.* Petitioner seems to appreciate this deficiency and argues 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 Nielsen785.¹² Petitioner also relies on Nielsen450's Table 8 to argue

¹² 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, 3.

that the same BLG isolate powder shown in Table 9 has less than 0.5% ALA. Pet., 36-37. 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, Petitioner 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. Institution should be denied on this failure alone. *Abiomed*, IPR2017-01204, -01205, Paper 8 at 11.

What is more, Petitioner fails to recognize that the BLG:ALA ratio from the BLG isolate powder would (and does) change after denaturation in the beverage of Nielsen785. 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 VII.A.ii, Nielsen785 shows that denaturation would change the BLG:ALA ratio in Nielsen785’s nanogel because *there is 0% ALA present in the denatured nanogel product*. Ex. 1005, 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. 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 VII.A.ii.

For these reasons, a POSITA would not understand that Nielsen450's denatured beverage product had a BLG:ALA ratio of greater than 5.00. 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, Petitioner is unlikely to prevail on Ground 3.

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

Nielsen450 does not teach or suggest forming and heating a “*reduced-GMP cheese whey retentate composition*” (8.2-8.3) and “reducing native GMP *in the cheese whey retentate*” (8.2). Ex. 1001, claim 8 (emphasis added). As discussed above in Section VII.A.i.a, Petitioner improperly conflates the BLG isolate powder with the claimed “reduced-GMP cheese whey retentate composition.” Nielsen450 fails to disclose the “reduced-GMP cheese whey retentate composition” claim limitation recited in claims 8.2 and 8.3. Ex. 1001, Claim 8. Similar to 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; *supra*, Section VII.A.ia. Additionally, as discussed above, 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, Petitioner is unlikely to prevail on Ground 3 as it relates to claims 8.2 and 8.3.

D. Ground 4 is unlikely to prevail because (i) a POSITA would not have combined Ozturk, Kawasaki, and LeanCreme with a reasonable expectation of success, 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.

Petitioner has not established that it has a reasonable likelihood of prevailing on its position that any of Claims 8-9, 11-13, 15-17, and 20 is invalid as obvious 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. In view of these deficiencies, Petitioner has failed 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 Board should exercise its discretion under 35 U.S.C. § 325(d) and reject Ground 4 since Petitioner has failed to show 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 has explained 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)).

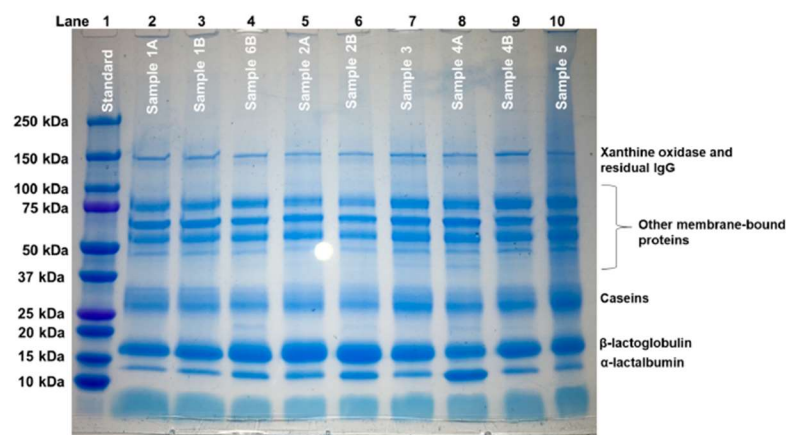
The recent Federal Circuit decision *Virtek Vision Int’l ULC, v. Assembly Guidance Systems* is instructive. 97 F.4th 882 (Fed. Cir. 2024). The *Virtek* court held that “*KSR* did not do away with the requirement that there must exist a motivation to combine” *Id.* at 887. On the contrary, “[i]t does 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 why or how a POSITA would successfully combine the references. Petitioner first argues 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: *there is no GMP reported in the WPPC of Ozturk*. Ex. 1008, Figures 2-3. A POSITA would not use the methods allegedly taught in Kawasaki to remove a component from Ozturk which is not reported. Ex. 1008, Figures 2-3.

As Petitioner acknowledges, the sole and stated aim of Ozturk is to characterize WPPC. Ex. 1008, 277-279; Pet., 56-57. Ozturk conducts protein analysis studies on WPPC to determine its protein composition. Ex. 1008, Figures 2-3; Pet., 58-59. Some BLG and ALA are present in WPPC, with BLG being the predominant whey protein. Ex. 1008, Figures 2-3. However, as shown below, no GMP is reported:



Id., Figure 2.

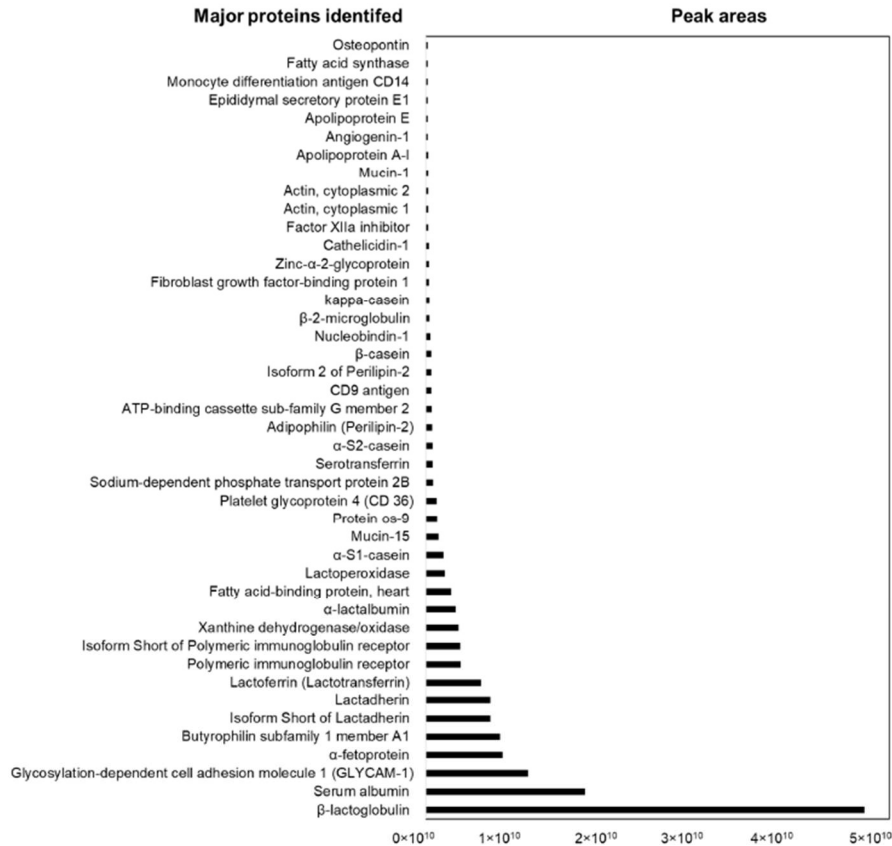


Figure 3. Relative abundance of major proteins identified in WPPC by proteomics.

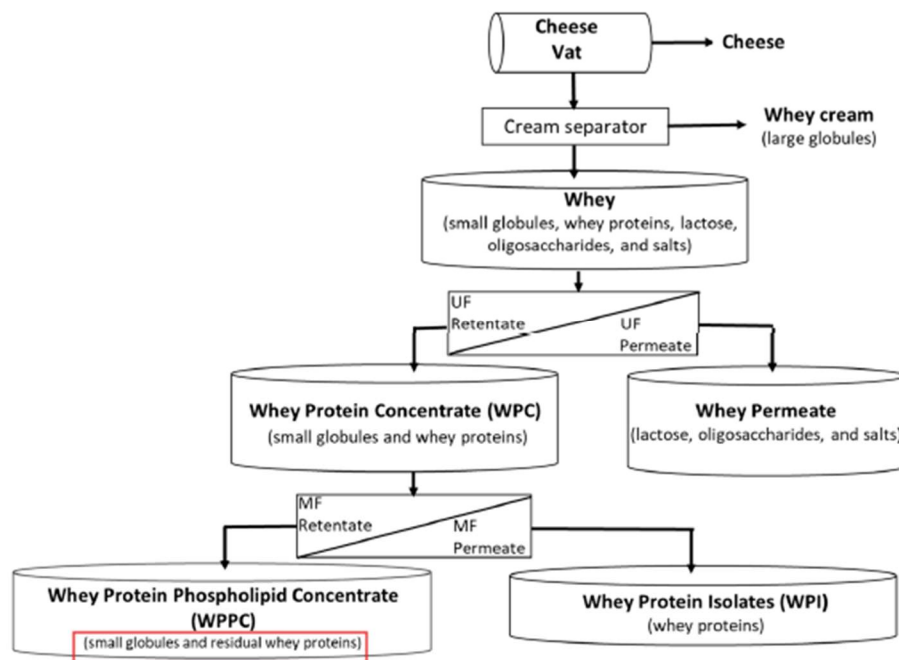
Id., Figure 3. Though Figures 2 and 3 are pasted into the Petition, Petitioner fails to note that they conclusively show that ***GMP is not shown in the WPPC in Ozturk.*** *Id.*, Figures 2-3.

Kawasaki, as described above in Section V.E., 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 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 point to any statement in Ozturk supporting this point because, as explained above,

Ozturk's protein analysis conclusively shows **GMP is not reported in the WPPC**.

Ex. 1008, Figures 2-3. Since there is no GMP reported in the WPPC in Ozturk, **a POSITA would not be motivated to further filter the WPPC to remove a GMP**.

Petitioner appears to argue GMP was inherently present in the WPPC of Ozturk. Pet., 67, 81. For this, Petitioner points to multiple references describing 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 that does not contain GMP. Ex. 1008, Figures 2-3.



Ex. 1008, Figure 1 (annotated). As shown in the red box above, WPPC contains **residual** whey proteins. *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.* 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, Figure 1. As Ozturk shows, there are numerous processing steps and compositional differences between whey and WPPC. *Id.* As such, Petitioner's inherency argument fails because Petitioner cannot point to a reference which shows that the relevant composition, WPPC, ***necessarily*** contains GMP—let alone 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.

b. A POSITA would not use LeanCreme's 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. Assuming *arguendo* that Ozturk and Kawasaki are combinable (they are not), without the benefit of hindsight, a POSITA would not

have applied LeanCreme to the high-fat reduced-GMP WPPC purportedly made by Ozturk and Kawasaki because the references have wholly different aims.

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.*” *Id.* LeanCreme teaches the desired microparticulated protein size is between 1 and 10 μM ” to achieve the desired mouthfeel. *Id.*, 5, 9.

A POSITA would not start from the high-fat reduced-GMP 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. *Id.*, 4-5. First, LeanCreme is directed to forming low or reduced-fat products. *Id.*, 4. Whereas 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, 277-278. Based on Ozturk, a POSITA would be motivated to retain milk fats—not manipulate a protein to replace fats as taught in LeanCreme.

Lastly, 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 the milk fats in liquid WPPC samples already had mean sizes within this range (2.09 ± 0.10 , 1.75 ± 0.02 , and $2.64 \pm 0.01 \mu\text{m}$). Ex 1008, 293. A POSITA would not be motivated to use the methods of LeanCreme to reduce particle size using microparticulation on the WPPC in Ozturk because Ozturk already contained particles with the desired size taught by LeanCreme. *Id.*

In view of the foregoing, Petitioner has failed to show a POSITA would have been motivated to combine Ozturk, Kawasaki, and LeanCreme.

ii. Ozturk, Kawasaki, and LeanCreme do not teach or suggest that greater than 50 wt.% of the protein are denatured whey proteins.

Second, the Board should exercise its discretion under 35 U.S.C. § 325(d) and reject Ground 4 since Petitioner has failed to prove Ozturk, Kawasaki, and LeanCreme disclose each claim element. Claims 8.7 and 15.5 recite “greater than 50 wt. % denatured whey proteins relative to the total weight of the protein.” Ex. 1001.

Petitioner again improperly equates Ozturk’s WPPC with WPC in LeanCreme for features 8.7 and 15.5. Petitioner argues that up to 75% of the protein is denatured during LeanCreme’s microparticulation methods. Pet., 85; Ex 1010, 7, 20, Figure. 2. Petitioner concludes that “[POSITAs] would have found it

obvious to apply LeanCreme's denaturation step to GMP-depleted WPPC to achieve at least 75wt.% denatured whey proteins relative to the total weight of the protein in the denatured whey protein composition." Pet., 85.

This statement is factually incorrect, however, and takes LeanCreme out of context. LeanCreme specifies that the "up to 75%" microparticulation is based upon the *case shown in FIG. 2.*" Ex. 1010, 7 (emphasis added) Thus, the 75% value of LeanCreme is limited to the proteins shown in Figure 2. However, Figure 2 of LeanCreme is specific to "*whey proteins in sweet whey.*" *Id.*, 6 (emphasis added). As shown in Figure 2, 48% of the protein is formed from BLG, with the remainder being formed from ALA, BSA, Ig, GMP, and NPN. *Id.* Conversely, referring to Table 2 of Ozturk, only 45.42% of the total proteins in WPPC are from

milk proteins similar to the proteins in Figure 2 of LeanCreme. Ex. 1008, 291, 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, Fig. 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. Instead, based upon the evidence set forth from LeanCreme, only about 34% of the total protein of Ozturk (0.75 x 45.42) would be denatured based upon the portion of LeanCreme cited in the Petition, which fails to disclose the feature of claims 8.7 and 15.5. Ex. 1010, 7, FIG. 2.

Combining Ozturk, Kawasaki, and LeanCreme would not produce a denatured whey protein composition comprising “greater than 50 wt. % denatured whey proteins relative to the total weight of the protein.” Petitioner has supplied no explanation of how the knowledge of a POSITA may remedy Ozturk, Kawasaki,

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and LeanCreme's failure to disclose the claim limitation. For at least these reasons, Petitioner is unlikely to prevail on Ground 4.

VIII. Conclusion

For the foregoing reasons, Petitioner is unlikely to prevail on any ground with respect to any of the challenged claims. Patent Owner respectfully requests that the Board institution of this Petition for *inter partes* review.

Dated: October 28, 2025

Respectfully submitted,

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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 10,261 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: October 28, 2025

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CERTIFICATE OF SERVICE

The undersigned certifies that on October 28,, 2025, this Patent Owner Preliminary Response (Paper 9) has 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:

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