

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KinderFarms LLC,
Petitioner

v.

Genexa Inc.,
Patent Owner

Case PGR2023-00051

U.S. Patent No. 11,617,795

**PETITION FOR POST-GRANT REVIEW OF U.S. PATENT NO. 11,617,795
UNDER 35 U.S.C. § 321 and 37 C.F.R. § 42.200 et seq.**

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EXHIBIT LIST

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1001	U.S. Patent No. 11,617,795 B2 Spielberg et al., “Pharmaceutical Syrup Formulation or Suspension” (filed as USSN 17/817,637 on Aug. 4, 2022; issued on Apr. 4, 2023)	‘795 Patent
1002	Prosecution History of U.S. Patent Application No. 17/817,637 (which issued as U.S. Patent No. 11,617,795 B2)	‘637 Appl. PH
1003	Declaration of Michael Crowley, Ph.D	Crowley Decl.
1004	French Patent Publication 2,993,458 and certified English translation of French Patent Publication 2,993,458	FR458
1005	U.S. Patent No. 4,684,666 Haas, R. T. “Stabilized Liquid Analgesic Compositions” (filed on Aug. 19, 1986; issued on Aug. 4, 1987)	‘666 Patent
1006	WO 95/00133	WO133
1007	WO2012/018742A2	WO742
1008	US2009/0148580A1	‘580 Publ.
1009	Prosecution History of U.S. Patent Application No. 16/827,529	the ‘529 Appl. PH
1010	Prosecution History of U.S. Patent Application No. 17/342,414	the ‘414 Appl. PH
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KinderFarms LLC (“KinderFarms” or “Petitioner”) requests post-grant review, under 35 U.S.C. §§ 321 *et seq.* and 37 C.F.R. §§42.1-42.80 and 42.200-42.207 *et seq.*, of claims 1-24 of U.S. Patent No. 11,617,795 (“the ’795 Patent”), issued on Apr. 4, 2023 to Spielberg, et al. A petition for post-grant review must demonstrate “that it is more likely than not that at least one claimed challenged in the petition is unpatentable.” 35 U.S.C. § 324(a). This Petition meets that threshold.

I. INTRODUCTION

After undergoing a cursory review that was unaided by the applicant’s decision to not provide any prior art, the Examiner issued United States Patent No. 11,617,795. The examination included a restriction requirement followed by an applicant’s interview, during which the Examiner and applicants’ attorney discussed a single prior art reference. Thereafter, the Examiner allowed the patent claims because the reference discussed did not show the acetaminophen included in an agave-syrup formulation. That justification for allowance cannot stand in view of prior art references presented by this petition. The prior art shows that, well before the filing of the patent at issue, others had turned to agave syrup to create a suspension of acetaminophen that masked its bitter taste. There is simply nothing in claims 1 through 24 of the ’795 Patent that was not known in the art. At bottom, these patent claims seek to remove from the public domain that which was well known and that others suggested years before. The Examiner imprudently granted

the '795 Patent, and the Board should rectify that error by cancelling all the claims of this patent.

II. REQUIREMENTS FOR POST-GRANT REVIEW UNDER 37 C.F.R. § 42.200 et seq.

A. Grounds for Standing (37 C.F.R. § 42.201)

KinderFarms certifies that the '795 patent is available for post-grant review and that KinderFarms is not barred or estopped from requesting a post-grant review challenging the patent claims on the grounds identified in this petition.

B. Eligibility for Post-Grant Review (37 C.F.R. § 42.202)

The '795 Patent issued on April 4, 2023. KinderFarms has filed its petition less than nine months from the issue date of the '795 Patent, so the patent is eligible to be challenged in a PGR.

C. Identification of Challenge (37 C.F.R. § 42.204)

KinderFarms respectfully requests that the Board cancel claims 1-24 of U.S. Patent No. 11,617,795 based on the following grounds of unpatentability:

Ground 1. Claims 1 to 24 are not patentable as obvious in view of FR458 combined with the '4666 Patent and/or WO133.

Ground 2. Claims 1 to 17 are not patentable as obvious in view of WO742 combined with the '4666 Patent and/or WO133.

Ground 3. In the alternative, Claims 1 to 24 are not patentable as indefinite under 35 U.S.C. § 112(b) through the use of the subjective terms “palatable” and

“stable” considering the specification’s lack of guidance concerning the meaning of these terms, and term “consisting essentially of” because the specification fails to provide guidance as to unlisted ingredients that would materially affect the basic and novel properties of the alleged invention.

Pursuant to 37 C.F.R. § 42.204, a detailed explanation of the precise relief requested for each challenged claim including where each element is found in the prior art, relevance of the prior art reference and exhibit numbers of the supporting evidence is provided in Section V below. The proposed construction of the challenged claims is in Section III.E. More detailed explanation and support for the grounds are in the Declaration of Michael Crowley, Ph.D. Ex. 1003.

III. RELEVANT INFORMATION REGARDING U.S. PATENT NO. 11,617,795

A. Concerns About Health Have Caused Many to Look for Healthier Options with Natural Ingredients.

Over the last several years, and well before the earliest date for which the claims of the ’795 Patent can find support in a patent application, others have discussed the desire to offer products with healthier alternatives to artificial ingredients, including sweeteners. U.S. Patent Publication No. 2009/0148580 provides an example of this trend. Ex. 1008. This publication proposed the use of agave syrup to replace high-calorie sugars and artificial sweeteners in food and

medicines. *Id.* at [0003-0005].¹ It explained how certain natural and artificial sweeteners caused a host of medical problems including obesity, diabetes, and poor eating habits. *Id.* at [0007]-[0009]. These medical problems can cause damage to the colon, heart, kidneys, and brain. *Id.* The use of agave syrup, as opposed to other natural and artificial sweeteners, can greatly reduce these problems because it results in substantially lower calorie intake and promotes gut health through improved digestion and a healthier colon. *Id.* at [0010]. The publication further details the benefits of using agave syrup in food and medicines by noting that for agave syrup: (a) 95% of its sugar is not absorbed; (b) unlike traditional sweeteners, agave syrup does not increase blood sugar levels; (c) the inulin content of agave syrup promotes growth of intestinal flora that improves digestion; (d) agave syrup is rich in vitamin B, C, D, E, calcium, iron, phosphorus, magnesium, potassium, zinc, selenium, and chromium while not including chemical substances like aspartame; and (e) agave syrup has been used medicinally as a blood purifier, to improve digestion and as an anti-inflammatory. *Id.* at [0012]-[0022]. Considering these benefits, the '580 Publ. discloses the use of agave syrup in medicines, pharmaceuticals, and other health food products. *Id.* at [0023]-[0026], [0036], [0046], claims 1, 2 and 5.

¹ Agave syrup can be processed as organic, natural or raw to a thicker or thinner consistency. *Id.* at [0005]. Thus, one can select the desired viscosity depending on the proposed use. Ex. 1003 at ¶52.

Years after the '580 Publ., the applicants of the '795 Patent filed their earliest application, U.S. Patent Application No. 15/912,785. This application published as US 2019/0125881 A1 on May 2, 2019.² The applicants discussed the use of agave or honey in a liquid formulation with undisclosed active pharmaceutical ingredients (“APIs”) and the desire to remove synthetic preservatives. Ex. 1041 at [0041]-[0044]. In the '881 Publ. and the '795 Patent, the applicants were embarking on a continuing trend that certain proportion of the population had long ascribed to – the avoidance of artificial ingredients in favor of “natural” ones. Ex. 1003 at ¶48. There is simply nothing inventive about what the applicants proposed with the '795 Patent, because many others had proposed using agave syrup in medicines much earlier. Ex. 1003 at ¶¶ 52-53; Ex. 1008 at [0008]-[0011], [0025], [0036]; Ex. 1004 at Example 1; Ex. 1042 at Example 1; Ex. 1007 at Example V; Ex. 1033; Ex. 1032.

B. Brief Description of the Challenged Patent

The '795 Patent identifies what it purports to be one problem in the art, i.e., chemists have turned to unnatural and artificial ingredients to mask the unpleasant taste of APIs. Ex. 1001 at col. 1, lns. 21-24. Ex. 1003 at ¶ 25. But, as shown in the background section above, others had disclosed the benefit of replacing artificial

² Section III.C explains how the applicants modified the specification when it submitted U.S. application No. 17/342,414 on June 8, 2021. As US 2019/0125881 published more than one year before applicants filed application No. 17/342,414, the publication qualifies as prior art to the '795 Patent

sweeteners in medicines with agave syrup. Ex. 1008 at Abstract, [0003]. Parroting the rationale for developing oral formulation expressed in several of the prior art references discussed below, the '795 Patent explains that children and the elderly have difficulty swallowing tablets so a liquid formulation is preferred. Ex. 1001 at col. 1, lns. 10-20; Ex. 1003 at ¶ 25; *see also*, Ex. 1042 at 2, lns. 36-42; *see also* Ex. 1004 at 2, lns. 39-45; Ex. 1006 at 1, ln.10 to 2, ln. 12 discussed in Sections IV.A and IV.D, respectively. The '795 Patent then reiterates another problem that persons of skill in the art have been discussing for decades—the unpleasant taste of some APIs. Ex. 1001 at col. 1, lns. 20-27; Ex. 1003 at ¶ 25, ¶¶ 46-47; *see also* Ex. 1004 at 2, lns. 39-45; Ex. 1005 at col. 2, lns. 19-21, at col. 3, lns. 19-54, Ex. 1006 at 1, ln.10 to 2, ln. 12 discussed in Sections IV.A, IV.C, and IV.D, respectively. The '795 Patent then lists several APIs disclosed in earlier-filed patents relating to agave syrup-based liquid oral pharmaceutical formulations, including acetaminophen, ibuprofen, dextromethorphan and guaifenesin. Ex. 1001 at col. 1, lns. 51-62; Ex. 1042 at p. 4, ln. 82 to 6, ln. 158; Ex. 1003 at ¶ 27; *see also* Ex. 1004 at 3, ln. 86 to 6, ln. 159; Ex. 1007, at 13, ln. 1 – 15, ln. 10 discussed in Sections IV.A and IV.B, respectively.

The '795 Patent includes some discussion of the properties of the agave syrup formulations that can be used to deliver the APIs mentioned therein. As with the prior art agave syrup-based formulations, the '795 Patent notes that its pharmaceutical suspensions or syrups can be formulated with one or more APIs,

acidic preservatives, sweetening agents, a diluent, and a flavoring or masking agent. Ex. 1001, at col. 1, ln. 65 – col. 2, ln. 6; Ex. 1003 at ¶¶ 24, 26 – 29, 31. It then suggests a proposed viscosity range for its formulations of between about 200 and 3500 centipoise, which overlaps with viscosity ranges of similar formulations disclosed in the prior art. Ex. 1001, col. 2, lns. 12-28; Ex. 1003 at ¶¶ 28, 58-59; *see also* Ex. 1005, at col. 4, lns. 9-14, at col. 6, lns. 61-68 (claims 9-11); Ex. 1006 at 7, ln. 27 – 8, ln. 4. The '795 Patent identifies a preference to use natural clean inactive ingredients that are gluten-free, non-GMO, and certified vegan, to mask the unpleasant taste of APIs. Ex. 1001 at col. 1, lns. 42-50; Ex. 1003 at ¶ 30. Suitable sweetening agents include sugars, such as monosaccharides, disaccharides and polysaccharides along with sugar alcohols such as sorbitol, xylitol, mannitol, glycerin and combinations thereof. Ex. 1001 at col. 3, lns. 44-64. Despite the purported preference for natural ingredients, the '795 Patent states that suitable flavoring agents include artificial flavors like artificial vanilla, artificial chocolate, and artificial fruit flavors. Ex. 1001 at col. 3, ln. 64-col. 4, ln. 10; Ex. 1003 at ¶ 98. The '795 patent concludes with an example of an agave syrup-based suspension that contains an API (e.g., acetaminophen), citrus acid extract, a blueberry-flavored masking agent, and water. Ex. 1001 at col. 5, lns. 5-22; Ex. 1003 at ¶ 31. It further explains that the suspension can be prepared by adding the API to heated agave and stirring. Ex. 1001 at col. 5, lns. 23-32; Ex. 1003 at ¶ 31. Water is also added to the

suspension to achieve the desired consistency. Ex. 1001 at col. 5, lns. 23-32; Ex. 1003 at ¶ 31. It is noted that other ingredients, such as a sweetening agent or a flavoring agent, can be added to the suspension. Ex. 1001 at col. 5, lns. 23-32; Ex. 1003 at ¶31. The patent does not provide information about the resulting viscosity of the formulation, the level of taste masking or the palatability, the stability of the formulation, or the ability of the formulation to deliver a therapeutic level of the API. Ex. 1003 at ¶ 31.

The '795 Patent includes 24 claims, three of which are independent. Ex. 1001; Ex. 1003 at ¶¶32-35. Claim 1 requires:

A pharmaceutical syrup formulation for oral administration comprising:
(a) acetaminophen,
(b) agave syrup, and
(c) a diluent,
wherein the syrup formulation has a viscosity of less than 1500 centipoise at about 22 degrees;
wherein the acetaminophen is suspended in the syrup; and
wherein the syrup is palatable.

Claims 2 through 6 depend from claim 1. These dependent claims narrow claim 1 by lowering the upper viscosity limit of the formulation or by defining the amount of acetaminophen in suspension. Ex. 1003 at ¶33.

Claim 7 is an independent claim similar to claim 1. It differs slightly in that its preamble describes the formulation as stable. It also differs because the body of the claim requires the presence of a flavoring agent, but does not require that the

syrup be palatable. Ex. 1003 at ¶ 34. Claims 8 through 17 depend from claim 7. These dependent claims add limitations that describe the percentage by weight of some of the formulation ingredients, require the addition of the preservative citric acid, modify the viscosity range, require that the flavoring agent added be a “bitter-taste-blocking ingredient,” and identify the formulation as useful for human and veterinary purposes. Ex. 1003 at ¶34.

Claim 18 is an independent claim similar to claim 1. It differs slightly in that its preamble describes the formulation as stable and palatable and consisting essentially of (a) a therapeutically effective amount of acetaminophen; (b) agave syrup; (c) acidic preservative; (d) a flavoring agent, and (e) a diluent. Ex. 1003 at ¶ 35. This claims also requires that the viscosity of the formulation is less than 1500 centipoise and that the acetaminophen in the formulation is in suspension. Claims 19-24 depend from claim 18 and add limitations similar to those described for the other abovementioned dependent claims.³ Ex. 1003 at ¶35.

C. Discussion of the File History

United States Patent No. 11,617,795 issued from United States Patent Application No. 17/817,637. The application was filed on August 4, 2022 as a

³ The '795 Patent claims include several errors because claims 20 and 21 (1) are identical to one another and (2) depend from claim 18, but the limitation that they purport to add already appears in claim 18. Ex. 1001 at col. 6, lns. 35-53; Ex. 1003 at ¶ 35.

continuation of U.S Patent Application No. 17/342,414, which was filed on June 8, 2021. Ex. 1010. The '414 Application is a continuation-in-part of U.S. Patent Application No. 16/827,529, which was filed on March 23, 2020. Ex. 1009; Ex. 1003 at ¶¶ 36, 40. A comparison of the specifications filed with the '414 Application and the '529 Application shows that the two are drastically different. Ex. 1011; Ex. 1003 at ¶¶ 40-41. In fact, the '414 Application is a wholesale rewriting of the '529 Application specification as shown by the redline comparing the two specifications submitted with these applications. Ex. 1011. Relevant to the claims of the '795 Patent, the specification submitted with the '529 Application does not mention specific APIs, such as acetaminophen, ibuprofen, dextromethorphan, and guaifenesin, which were all added to the specification submitted with the '414 Application. Ex. 1011; Ex. 1003 at ¶ 41. The '529 Application does not discuss the viscosity of the formulations disclosed, let alone a preferred viscosity range. Compare Ex. 1010 at [0011] with Ex. 1009; *see also* Ex. 1011; Ex. 1003 at ¶ 41. Each claim of the '795 Patent includes limitations that require the presence of acetaminophen in the formulation and a formulation viscosity that falls within a described range. As the '529 Application does not support either of these

limitations, the earliest filing date that the claims of the '795 Patent can look to for support is June 8, 2021.⁴ Ex. 1003 at ¶ 41.

Applicants submitted U.S. Patent Application No. 17/817,637 on August 4, 2022 and requested prioritized examination. Ex. 1002 at 123-127; Ex. 1003 at ¶ 37. The USPTO granted priority review on November 21, 2022 and issued an Office Action on December 1, 2022, respectively. Ex. 1002 at 62-63, 51-56; Ex. 1003 at ¶ 37. This Office Action found that the twenty-five claims were subject to a restriction requirement. Ex. 1002 at 52; Ex. 1003 at ¶ 37. The Examiner identified three distinct species: (a) claims that recite the viscosity (or range of viscosity) of the pharmaceutical syrup product; (b) claims that recite the amount of acetaminophen in the pharmaceutical syrup product; and (c) claims that recite the amount of agave syrup in the pharmaceutical syrup product. Ex. 1002 at 53; Ex. 1003 at ¶ 37. Applicants responded on December 14, 2022. *Id.* at 45-49. The Examiner restated the restriction requirement on January 3, 2023, noting that the Applicants had not fully understood it. Ex. 1002 at 36-41; Ex. 1003 at ¶ 37. The Examiner conducted a prior art search but did not include the term “paracetamol,” which is a commonly used alternative name for acetaminophen, in the search. Ex. 1002 at 25; Ex. 1003 at

⁴ While the claims of the '795 Patent are not entitled to the filing date of provisional application No. 62/580,648—November 2, 2017, the prior art relied upon in this petition is also prior art to the provisional application.

¶ 38. The examiner only cited a single reference during prosecution, Paul *et al.*, “Placebo effect in treatment of acute cough in infants and toddlers, a randomized clinical trial,” *JAMA Pediatrics* 168(12): 1107-1113, 2014. (Paul *et al.*).⁵ Ex. 1002 at 20; Ex. 1003 at ¶ 38; Ex. 1043. Applicants did not submit any information disclosure statements to identify relevant art. The Examiner conducted an interview on February 17, 2023 and stated that “the claims are free of art” but needed to be rewritten. Ex. 1002 at 19. In the reasons for allowance, the Examiner stated that the claims are free of the prior art because, even though Paul *et al.* discloses a composition for treating night-time coughing in babies and toddlers comprising agave syrup, a flavoring agent and an acidic preservative, this reference did not teach including acetaminophen in this composition. Ex. 1002 at 17; Ex. 1003 at 39. According to the examiner, Paul *et al.* only taught the potential to co-administer a separate acetaminophen composition with the agave-syrup-containing composition. Ex. 1002 at 19; Ex. 1003 at 39; *see also* Ex. 1043 at 1108-1110 (administering agave

⁵ It appears that during the prosecution neither the applicants nor the Examiner undertook a detailed assessment of the claims. For example, three of the issued claims appear identical, in violation of 35 U.S.C. § 101. Ex. 1001, see claims 18 and its dependent claims 20 and 21; Ex. 1003 at ¶35. Both dependent claims recite “wherein the pharmaceutical syrup formulation has a viscosity of less than 1500 centipoise at about 22 degrees,” which is a limitation included in claim 18. Ex. 1003 at ¶ 35.

nectar, grape flavoring, citric acid, and potassium sorbate and explaining acetaminophen can be administered as needed for comfort).

D. Person of Ordinary Skill in the Art (POSITA)

The '795 Patent describes oral pharmaceutical formulations and discusses the practices of pharmaceutical chemists in developing these formulations. Ex. 1001 at col. 1, lns. 11-41; Ex. 1003, at ¶¶ 24-25. As the patent focuses on pharmaceutical formulations, a person of ordinary skill in the art would have an educational background or equivalent work experience that would allow them to function as a pharmaceutical scientist.^{6, 7} Ex. 1003 at ¶¶ 90-91. The educational background of a pharmaceutical scientist would include a bachelor of science (B.S.) degree in a relevant life sciences field, such as, chemistry, biochemistry, pharmacy, or

⁶ It appears that the persons listed as named inventors on the face of the '795 Patent do not have educational backgrounds of a person of ordinary skill in the art, and it is unclear whether they have the relevant work or laboratory experience of a person of ordinary skill in the art. Ex. 1003 at 57, fn. 14. This does not affect the definition of a person of ordinary skill in the art for this patent, because persons listed on the patent need not meet the definition of a person of ordinary skill in the art. *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 448).

⁷ The specification of the '795 Patent describes oral pharmaceutical formulations and discusses the practices of pharmaceutical chemists in developing these formulations. *See, e.g.*, Ex. 1001, at 1:21-26. However, a pharmaceutical scientist with an academic background or practical experience relating to any relevant life sciences disciplines (i.e. chemistry, biochemistry, biology or pharmacy) would have been capable of developing a drug formulation as simple as the one disclosed in the '795 Patent. Ex. 1003, 56, fn. 13.

molecular biology. *Id.* A person of ordinary skill in the art with a B.S. degree would likely have some relevant work experience and/or other laboratory experience. *Id.* A person of ordinary skill in the art may include a person without a B.S. degree, provided that this person has several years of experience in the pharmaceutical industry and/or working in a laboratory. *Id.* A person of ordinary skill in the art could include a person with advanced degrees, but this person would require less experience outside of the educational setting to be considered a person of ordinary skill in the art. *Id.*

E. Claim Construction

The Board applies the ordinary and customary meaning that the term would have to a POSITA as of the effective filing date of the patent. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1313 (Fed. Cir. 2005) (*en banc*); 37 C.F.R. § 42.100(b) (2019); *Volkswagen Group of America, Inc. v. Michigan Motor Technologies LLC*, IPR2020-00068, 2020 WL 2026678 *3 (PTAB Apr. 27, 2020). The meaning is viewed in light of the claim language, the specification, and prosecution history of the patent. *Phillips*, 415 F.3d at 1313.

1. “agave syrup” – claims 1 through 24

The patent explains that “agave syrup” is processed juice from the agave plant and that it is a sticky substance that will flow without applied pressure. Ex. 1001 at col. 2, lns. 6-11. The ’795 Patent does not limit the definition to a specific type of

agave syrup. Ex. 1003 at ¶ 93. A person of ordinary skill in the art would understand that agave syrup can be obtained from different species of agave and can be light or dark in color, with a thinner or thicker consistency. Ex. 1003 at ¶¶ 93, 51-52; Ex. 1008 at [0005]. Agave syrup may also be referred to as agave extract or agave nectar. The Board should construe “agave syrup” to encompass all liquid materials derived from any agave plant that is free flowing, irrespective of its other properties. Ex. 1003 at ¶ 93.

2. “a viscosity of less than [] centipoise at about 22 degrees” – claims 1 through 24

The '795 Patent states that the “syrup can have a viscosity of between about 200 and 3500 centipoise at about 2.5 rpm to about 30 rpm as determined by a Brookfield Viscometer at about 22 degrees.”⁸ Ex. 1001 at col. 2, lns. 12-16; Ex. 1003 at ¶94. While the specification provides a minimal description of the viscosity measurement conditions, those same conditions are not included in the claims. *Id.* Thus, the Board should not import any limitations concerning the viscosity

⁸ Measurement of the viscosity of certain liquids (i.e. non-Newtonian liquids) using a Brookfield Viscometer can be unreliable unless certain methodologies are utilized. Ex. 1003, at ¶¶ 56-57. The specification of the '795 Patent provides minimal information about how to carry out the viscosity measurement of compositions using a Brookfield Viscometer. Ex. 1003 at 13, fn. 3. It provides a broad definition of the rpms to apply without identifying other details, e.g., spindle size. *Id.* A person of ordinary skill in the art would have to make their own selections, and this would likely result in variable results. *Id.* Moreover, the '795 Patent fails to disclose the viscosity of the formulation described in Examples 1 and 2.

determining method into the claims. The claims do state acceptable viscosity ranges for the formulations of the invention at “about 22 degrees”.⁹ The claims use the term “about,” so the claims should not be limited to 22 degrees. A person of ordinary skill in the art would understand that the term includes flexibility. Ex. 1003 at ¶ 94. For example, room temperature is often described as about 20-25° C. *Id.* As a person of ordinary skill in the art often measures viscosity at room temperature, such a person would understand “about 22 degrees” to include measuring viscosity at room temperature. *Id.* The Board should construe the term to encompass this range.

3. “palatable” – claims 1 through 6 and 18 through 24

While palatable is a subjective term, at least one court has construed “palatable” as requiring the oral formulation to have an acceptable and not an unpleasant taste. *Naturals v JR Carlson*, 2008 WL 2357312 *10-*11 (N.D. Cal June 6, 2008). That construction is consistent with the plain and ordinary meaning as understood by a person of ordinary skill in the art. Ex. 1003 at ¶ 95.

4. “stable” – claims 7 through 18

The patent provides no disclosure of what is required for a stable formulation. It merely recites in five places that it discloses stable pharmaceutical formulations.

⁹ Neither the specification nor the claims define whether the measurement should be taken at about 22 degrees Celsius or Fahrenheit. Viscosity is often measured around room temperature, e.g., 20-25° C. Ex. 1003 at ¶ 94. A person of ordinary skill in the art would likely assume that the disclosure references Celsius. *Id.*

Ex. 1001 at abstract, col. 1, lns. 31-39, claim 7, claim 18. A person of ordinary skill in the art reading this specification would understand the term in its ordinary meaning in this field of art, i.e., that the formulation must be suitable for administration to patients for the duration of its shelf life. Ex. 1003 at ¶ 96.

5. “consisting essentially of” - claims 18 through 24

Claim 18 and its dependent claims use the transitional phrase “consisting essentially of.” This phrase straddles the middle ground between the open transitional phrase “comprising” and the closed transitional phrase “consisting of.” *PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998); *AVX Corp. v. Greatbatch LTD*, IPR2014-01361, 2015 WL 782026, *3-*4 (PTAB Feb. 19, 2015). This phrase includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. *Id.* Thus, claim 18 and its dependent claims require the inclusion of (a) a therapeutically effective amount of acetaminophen, (b) agave syrup, (c) acidic preservative, (d) a flavoring agent, and (e) a diluent. Additional materials may be included in the formulation provided that the patent disclosure does not indicate that they will materially affect the basic and novel properties of the invention. *AVX Corp.*, IPR2014-01361, 2015 WL 782026, *3-*4.

The '795 Patent description is rather thin and provides a person of ordinary skill in the art with little information as to what additional materials will materially

affect the basic and novel properties of the invention. Ex. 1003 at ¶¶ 97-98. The specification does make the unsupported statement that “one problem is that liquids containing . . . pharmaceutical agents taste terrible and pharmaceutical chemists have turned to unnatural and artificial ingredients to mask the taste.”¹⁰ *Id.*, at col. 1, lns. 20-24. Additional language included in the specification suggests the potential exclusion—although only conditionally—of unnatural ingredients—“embodiments may exclude unnatural ingredients such as aspartame, carbomer, EDTA, gelatin, milk, parabens, polyethylene glycol, titanium dioxide, and other unnatural ingredients.”¹¹ Considering the conditional nature of the statement “may exclude unnatural ingredients, such as,” the specification does not make clear that these ingredients materially affect the basic and novel aspect of the invention.¹² To the

¹⁰ As discussed in section III.A, others had suggested replacing artificial sweeteners with agave syrup in medicines to avoid the negative health issues with those sweeteners. Ex. 1008 at [0007]-[0020].

¹¹ The specification’s inclusion of “gelatin” and “milk” is odd because they are both natural ingredients derived from animals. Ex. 1003 at ¶ 98. It is unclear whether the patentees are seeking to act as their own lexicographers by defining these materials as “unnatural.” Considering that the specification expressed a preference for vegan ingredients in the preceding sentence, a person of ordinary skill in the art would read the inclusion of these materials as “unnatural ingredients” as evidencing a desire to avoid animal products. Ex. 1001; Ex. 1003 at ¶ 98.

¹² The ambiguous nature of the specification is evidenced by later statements that suggest using artificial sweeteners. Ex. 1001 at col. 3, ln. 64-col. 4, ln. 10; Ex. 1003 at ¶ 98. The patent states that suitable flavoring agents include artificial flavors such as artificial vanilla, artificial chocolate and artificial fruit flavors. Ex. 1001 at col. 1, lns. 20-23, col. 3, ln. 64-col. 4, ln. 10; Ex. 1003 at ¶ 98.

extent that the Board is to exclude these ingredients from the scope of “consisting essentially of,” it should not go further, because the specification does not support such breadth.

IV. OVERVIEW OF THE APPLIED PRIOR ART

A. French Patent Publication 2,993,458

French Patent Publication 2,993,458 (“FR458”) published on January 24, 2014. FR458 qualifies as prior art as a printed publication under 35 U.S.C. § 102(a)(1).¹³ This publication is entitled “Liquid Pharmaceutical Preparation for Oral Administration Based on Organic Agave Syrup with a Low Glycemic Index.” The abstract explains that “[t]here is a growing interest in organic products . . . , especially for liquid pharmaceutical compositions.” Ex. 1004 at Abstract. The disclosed orally-administrable liquid pharmaceutical compositions are “based on (certified)

¹³ Exhibit 1004 comprises a certified English translation of FR458, a certificate of translation, and a copy of the original French version of FR458. The original French version of FR458 is publicly available on the French Patent Office website. A search for “FR2993458” on the French Patent Office’s patent database provided a link to the file history of FR458, which included a copy of the original French version of FR458 that published on January 23, 2014 to Francoise Dumas. Ex. 1003 at 39, fn. 9. The Board has relied upon an English translation of French patent publication to invalidate patent claims in another post-grant proceeding. *See Yita LLC v. MacNeil IP LLC*, IPR2020-01139, Paper 82 at 13 (PTAB April 15, 2022) (Rabbe Exhibit 1005 – certified translation of French Patent Publication No. 2,547,252), affirmed-in-part and revised-in-part, *Yita LLC v. MacNeil IP LLC*, 2023 WL 3829624 **7 (Fed. Cir. June 6, 2023) (reverse determination that evidence did not show certain claims were obvious).

organic agave syrup as a vehicle for liquid dosage forms, active pharmaceutical ingredients.” Ex. 1004, at Abstract; Ex. 1003 at ¶¶ 61-62. Generating the composition as a single dose can avoid the needs for preservatives. Ex. 1004 at 3, lns. 58-68, at 6, lns.171-178; Ex. 1003 at ¶ 63.

Solid dosage forms are not always suitable for children and the elderly, so FR458 describes liquid dosage forms, either in a clear syrup or suspension. Ex. 1004 at 2, lns. 39-45; Ex. 1003 at ¶ 62. It further explains the need to mask the unpleasant taste of some drugs. Ex. 1004 at 2, lns. 43-45; Ex. 1003 at ¶ 62. The potential drugs to include in the syrups and suspensions are antitussives like dextromethorphan, expectorants like guaifenesin, and analgesics like paracetamol (a.k.a. acetaminophen) and ibuprofen. Ex. 1004 at 3, ln. 86 – 4, ln. 94, at 4, ln. 111 – 6, ln. 159; Ex. 1003 at ¶ 63. The formulations are based upon agave syrup and can include natural organic and naturally-occurring suspending agents, such as xanthan gum, pH regulating agents, such as citric acid, and natural flavorings. Ex. 1004 at 6, ln. 160 –7, ln. 187; Ex. 1003 at ¶ 63. FR458 provides four examples of liquid pharmaceutical formulations that include different drugs. Example 1 describes a formulation with paracetamol, along with natural ingredients including agave syrup, xanthan gum, agar-agar, glycerin, sodium citrate, citric acid, natural strawberry flavoring, and purified water. Ex. 1004 at 8; Ex. 1003 at ¶ 65. Example 1 is reproduced below:

Example 1

Ingredients	Quantity
Paracetamol	2.5 g
Certified agave syrup	45 g
Xanthan gum	0.4 g
Certified agar-agar	0.2 g
Glycerin	5 g
Sodium citrate	0.5 g
Anhydrous citric acid	0.4 g
Natural strawberry flavoring	0.01 g
Purified water	Up to 100 ml

FR458 explains that the “active pharmaceutical ingredient(s) is (are) dispersed or dissolved in the agave syrup to make Solution B.” Ex. 1004 at 7, lns. 193-198; Ex. 1003 at ¶ 64. For Example 1, the xanthan gum and the agar-agar are mixed with the glycerin to obtain Solution A. Ex. 1004 at 8, lns. 199-205. The paracetamol (a.k.a. acetaminophen) is suspended in syrup to obtain Solution B. Ex. 1004 at 8, lns. 200-201; Ex. 1003 at ¶ 65. Solution A is added to Solution B and mixed well, and then water is added. Ex. 1004 at 8, lns. 201-204. See also Ex. 1004 at 3, lns. 58-85 (noting that the API is suspended in agave syrup and identifying potential amounts for the API.).

B. WO2012/018742 A2

International Patent Publication Number WO 2012/018742 A2 published on February 9, 2012. Ex. 1007. As this is more than one year before the earliest application date for the '795 Patent and several years before June 8, 2021, the earliest date for which the '795 Patent claims may find support in the specification, WO742 qualifies as prior art to the '795 Patent. The publication discloses compositions with various APIs suspended in agave syrup. Ex. 1007 at 9, lns. 1-25, 13, ln. 4 – 18, ln. 6. The APIs that can be suspended in the agave syrup include dextromethorphan hydrochloride monohydrate, acetaminophen, and guaifenesin. Ex. 1007 at 13, ln. 21- 15, ln. 10, at 16, ln. 7- 18, ln. 32; Ex. 1003 at ¶¶ 67 and 69.

The background of the invention section provides a long discussion of the use of agave syrup and its benefits. Ex. 1007 at 7, ln. 5 – 8, ln. 27. It explains that agave syrup began appearing in health food stores in the early 2000s. *Id.* at 7, lns. 5-7. While similar to honey in color and texture, agave syrup is less viscous and flows more easily. Ex. 1007 at 7, lns. 9-10; Ex. 1003 at ¶ 68. Agave also includes several components that have various health benefits. Ex. 1007 at 7, lns. 10-15. Agave syrup or nectar is obtained by extracting agave juice and processing into a syrup. Ex. 1007 at 7, lns. 15-23. The product can be processed in an organic, natural, or raw state and can be of thicker or thinner consistency (viscosity). Ex. 1007 at 7, lns. 20-23. As discussed in the background section above, other prior art publications,

including the '580 Publ., had disclosed “using natural agave extract as a sweetener to replace all of part of the high calorie sugars and/or artificial sweeteners added in foods and medicines, thereby promoting an important reduction of calories and the elimination of artificial sweeteners by using natural agave extract as the main sweetening ingredient.” Ex. 1007 at 8, lns. 8-20; see above III.A; Ex. 1003 at ¶ 70.

The compositions disclosed in WO742 are intended for oral administration and include compositions in the form of syrups and suspensions. Ex. 1007 at 13, lns. 7-10. Agave nectar is the preferred carrier in which one or more APIs, such as antihistamines, bronchodilators, decongestants, expectorants, anti-inflammatory/analgesics, can be suspended. Ex. 1007 at 13, lns. 16-20; Ex. 1003 at ¶ 70. Specific examples of APIs included in the specification are expectorants such as guaifenesin, anti-inflammatory/analgesic, such as acetaminophen and ibuprofen, and cough suppressants, such as dextromethorphan. Ex. 1007 at 12, lns. 3-25; at 13, ln. 21-15, ln. 10. The patent describes compositions including several that include acetaminophen and agave nectar. *Id.* at 16, lns. 7-25; at 21, ln. 15-23, ln. 31 (Examples V and VI). The patent states that Examples V and VI are “made by adding the active ingredients to the propylene glycol, polyethylene glycol, alcohol, flavorants, and glycerin with stirring. The solution is added to agave nectar with stirring and then the dye is added to the solution with stirring. Purified water is added to volume with stirring.” *Id.* at 23, ln. 30-24, ln. 2.

WO742 provides several other examples of APIs suspended in agave nectar. These disclosures include specific examples teaching the combination of dextromethorphan hydrochloride monohydrate, guaifenesin and agave nectar. Ex. 1007 at 18, lns. 1-16; 22, ln. 24-23, ln. 15 (Examples VII and VIII). These liquid compositions are made in the same manner as Examples V and VI, discussed above. *Id.* at 23, ln. 30-24, ln. 3. The disclosure of a whole host of examples of agave syrup-based formulations with various combinations of APIs and excipients shows that these applicants understood that agave syrup could be used in many types of oral liquid medicines. Ex. 1003 at 136, fn. 30.

C. U.S. Patent No. 4,684,666

U.S. Patent No. 4,684,666 (“the ’4666 Patent”) issued on August 4, 1987 and qualifies as prior art to the ’795 Patent. The ’4666 Patent discloses a stabilized liquid ibuprofen syrup suitable for oral administration. Ex. 1005 at Abstract; Ex. 1003 at ¶ 72. The described composition forms a moderately viscous syrup that is useful in treating various medical conditions. Ex. 1005 at col. 1, lns. 5-15. The ’4666 patent explains that pediatric and geriatric patients often have difficulty swallowing tablets, so an oral formulation is required. *Id.*, at col. 1, lns 29-32. The patent notes that while good liquid formulations of acetaminophen exist for pain relief, the same was not true for ibuprofen. *Id.* at col. 1, lns. 15-35. Liquid ibuprofen oral formulations pose a challenge because of this API has low water solubility, lacks stability in

aqueous solutions and has an unpleasant bitter taste. Ex. 1005 at col. 1, lns. 15-35, col. 2, lns. 4-21; Ex. 1003 at 73. The '4666 patent explains that when ibuprofen is placed in suspension it increases its unpleasant taste characteristics. *Id.* at col. 3, lns. 50-54. For this reason, masking the flavor of ibuprofen with sweetening agents is important. *Id.*

An important aspect of the formulations of the invention is controlling the viscosity for optimum stability. Ex. 1005, at col. 4, lns. 9-17; col. 2, lns. 41-48; Ex. 1003 at ¶ 74. The '4666 Patent disclosing formulations with a viscosity of about 100 to 3000 centipoise at 20° C, as measured by the Brookfield Synchro-Lectric viscometer. Ex. 1005 at col. 4, lns. 9-17, claims 9-11; at ¶ 74.

The '4666 patent describes other components included in the composition, such as stabilizers, alkalinizing agents, sweetening agents, antioxidants, and flavoring agents. Ex. 1005 at col. 2, lns. 22-40, 4, lns. 18-31.

D. PCT/US94/07037

PCT/US94/07037 has an international filing date of June 21, 1994 and claims priority back to a U.S. Patent Application No. 08/083,651 filed on June 25, 1993. This patent application published January 5, 1995 as International Publication No. WO 95/00133. Ex. 1006. WO133 qualifies as prior art to the '795 Patent. This patent publication discloses oral formulations with acetaminophen in suspension that effectively mask the unpleasant taste of acetaminophen. Ex. 1006 at Abstract; Ex.

1003 at ¶ 76. Similar to the rationale provided by the '4666 Patent, WO133 explains that the tablet form of acetaminophen is hard to administer to elderly and young patients, so a liquid formulation is needed for these patient populations. Ex. 1006 at 1, lns. 14-17. However, as previously noted, dissolving acetaminophen in a liquid formulation unleashes its strongly unpalatable taste. Ex. 1006 at Abstract, 1, ln. 17-2, ln. 13; Ex. 1003 at ¶ 76. Thus, WO133 provides taste-masked oral formulations that contain a suspension agent and an additive agent (preferably a sweetening agent) to decrease the solubility of acetaminophen in suspension. Ex. 1006 at 2, ln. 14-3, ln. 18; 5, ln. 11-6, ln. 6; Ex. 1003 at ¶¶ 78-79. The specification notes that acetaminophen should be present in the formulation in a therapeutically effective amount. Ex. 1006 at 4, lns. 8-15; 8, lns. 4-10; Ex. 1003 at ¶ 77. The formulation may include natural sweeteners such as honey, ideally present in the composition in an amount of at least 25% by weight, flavoring and pH-controlling agents, like citric acid. Ex. 1006 at 6, lns. 7-28; 7, lns. 5-26; Ex. 1003 at ¶ 78. WO133 discloses a target viscosity of the resulting oral formulation of from 200 to 900 centipoise and preferably 300 to 700 centipoise. Ex. 1006 at 7, ln. 27 – 8, ln. 3; Ex. 1003 at ¶ 80. WO133 provides several examples of a viscous suspension of acetaminophen. Ex. 1006 at 9-10, Examples 1 and 2.

E. US 2009/0148580

U.S. Patent Publication No. 2009/014580 (“ the’580 Publ.”) is a prior art publication cited in WO742 that provides insight into the thoughts of persons of ordinary skill in the art seeking natural, healthy sweetening agents to use in food products and medicines. See III.A above; Ex. 1003 at ¶ 53. The ’580 Publ. lists a host of benefits of agave syrup, including reduce caloric update, limited increase of blood sugar levels, improved gut health, and inclusion of several important vitamins. Ex. 1008 at [0012]-[0021]; Ex. 1003 at ¶ 70. The publication explains that agave nectar can make up anywhere from 2% to 98% of the medicine. Ex. 1008 at [0023]-[0036]; Ex. 1003 at ¶ 52.

V. STATEMENT OF PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. § 42.204)

A. Explanation of Ground 1

1. Motivation to Combine FR458 with the ’4666 Patent and/or WO133

The motivation-to-combine analysis is flexible, because “a person of ordinary skill in the art is not an automaton.” *Intel Corp. v PACT XPP Schweiz AG*, 61 F.4th 1373, 1379 (Fed. Cir. 2023) citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 420-421 (2007). “So, ‘in many cases[,] a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *Id.* at 1379-1380. “Any need or problem known in the field of endeavor at the time of the invention

and addressed by the patent can provide a reason for combining the elements in the manner claim.” *Id.* at 1379. Here the ‘795 Patent states that it was seeking to develop an oral formulation for children and the elderly that masks the taste of the APIs. Ex. 1001 at col. 1, lns. 10-28. The prior art relied upon here had the same goals.¹⁴ FR458 is seeking to develop an oral formulation for children and the elderly that masks the unpleasant taste of the API. Ex. 1004 at 2, lns. 39-4. The ‘4666 Patent and WO133 identify similar rationales for developing their oral formulations that contain analgesics. Ex. 1005 at col. 1, lns. 18-29, at col. 2, lns. 3-22; Ex. 1006 at 1, ln. 4- 2, ln. 12. Moreover, each of these references discusses acetaminophen as an analgesic that is used in oral formulations. Ex. 1004 at 5, lns. 127-132; Ex. 1005 at col. 1, lns. 28-35; Ex. 1006 at 1, ln. 16- 2, ln. 12. Each also shows a preference for having the analgesic suspended in the oral formulation. Ex. 1004 at 2, lns. 39-45, 8, lns. 199-205; Ex. 1005 at col. 2, lns. 41-58, at col. 3, 50-53; Ex. 1006 at 3, lns. 7-18. Additionally, FR458 and the ‘4666 patent seek to develop formulations with

¹⁴ Petitioner submits that FR458 and the ‘4666 Patent teach each limitation and a motivation to combine with a reasonable expectation of success for these patents. Petitioner also asserts the same for FR458 and WO133. Finally, Petitioner and its declarant have provided evidence that a person of ordinary skill in the art would have a motivation to combine FR458, the ‘4666 Patent and WO133 with a reasonable expectation of success. Therefore, Petitioner asserts that FR458 in combination with the ‘4666 Patent, FR458 in combination with WO133, and FR458 in combination with the ‘4666 Patent and WO133 each render the claims of the ‘795 Patent not patentable as obvious.

a lower sugar content to benefit diabetics and other persons with restricted sugar requirements. Ex. 1005 at 2 :15-21; Ex. 1004 at 1, lns. 14-16, 3, lns. 70-74; Ex. 1003 at ¶102. Considering that each prior art reference is in the same field of art, seeks to address similar issues, and discusses the creation of oral analgesic formulations using “old [ingredients] with each performing the same function it had been known to perform,” a person of ordinary skill in the art would be motivated to combine these teachings and would have a reasonable expectation of success in combining these teachings. *KSR Int’l Co.*, at 417; Ex. 1003 at ¶¶101-103.

2. Claim 1 and its Dependent Claims are Obvious over FR458 when Combined the ’4666 Patent and/or WO133

(a) Claim 1

A person of ordinary skill in the art would conclude that the following combinations, FR458 in combination with the ’4666 Patent, FR458 in combination with WO133, and FR458 in combination with the ’4666 Patent and WO133 each disclose all the limitations of claim 1 as shown below.

1. “A pharmaceutical syrup formulation for oral administration comprising”

While the preamble is normally not considered a limitation, to the extent that the Board concludes the preamble is a limitation, each of the prior art references teach a pharmaceutical syrup formulation for oral administration. Ex. 1004 at 1, lns.

4-7, 3, lns. 58-68, 12, claim 1; Ex. 1005 at abstract, at col. 1, lns. 6-15, at col. 2, lns. 4-15; Ex. 1006 at 2, lns. 14-25, 6, lns. 7-18; Ex. 1003 at ¶¶106-108.

2. “acetaminophen”

Similarly, each of the prior art references discloses acetaminophen as an analgesic in an oral formulation. Ex. 1004 at 5, lns. 127-133, at 8, Example 1, at 10, Example 4; Ex. 1005 at col. 1, lns. 18-35; Ex. 1006 at 1, lns. 4-19, at abstract, at 2, lns. 14-25, 3, lns. 8-18, 4, lns. 8-15; Ex. 1003 at ¶¶ 109-112.

3. “agave syrup, and”

FR458 discusses using agave syrup as the base of a formulation that contains acetaminophen. FR458 states that “[t]he present invention provides pharmaceutical suspensions or syrups for oral administration based upon syrups with low glycemic indexes, consisting mainly of certified agave syrup alone or in combination with other syrups and of an active ingredient.” Ex. 1004 at 3, lns. 58-68. *See also* Ex. 1004 at abstract, at 1, lns. 5-7, 12, claim 1, 8-10, Examples 1-4; Ex. 1003 at ¶¶ 113-115.

4. “a diluent,”

Like the '795 Patent, FR458 and the '4666 Patent teach the inclusion of water in the formulation as a diluent to bring the formulation to the desired final volume. Compare Ex. 1001, Example 1; Ex. 1004, Examples 1-4, Ex. 1005, Example 1; Ex. 1003 at ¶¶ 116-118.

5. “wherein the syrup formulation has a viscosity of less than 1500 centipoise at about 22 degrees”

A person of ordinary skill in the art would understand that an oral liquid formulation needs a viscosity low enough for it to be pourable and drinkable. Ex. 1003 at ¶¶ 28, 58-59, 216. The viscosity of agave syrup has been reported to be about 212 centipoise. Ex. 1003 at ¶ 52. Thus, a person of ordinary skill in the art would understand that the formulation disclosed in Example 1 of FR458, which is largely made up of agave syrup, may have a viscosity less than 1500 centipoise. Ex. 1003 at ¶ 119. As both the ’4666 Patent and WO133 disclose appropriate viscosity ranges for an oral formulation with an analgesic, it is unnecessary for the Board to conclude that Example 1 of the FR458 meets this limitation. The ’4666 patent discloses a viscosity range measured at 20° by a Brookfield Synchro-Lectric viscometer of 1000 to 3000 centipoise.¹⁵ Ex. 1005 at col. 4, lns. 9-17. Claim 11 lowers the lower viscosity limit from 1000 to 100 centipoise. *Id.*, at col. 6, lns. 66-67. WO133 teaches a tighter viscosity range of 200 to 900 centipoise for its oral analgesic formulation.¹⁶ Ex. 1006 at [8, lns. 1-3]. A person of ordinary skill in the

¹⁵ As discussed in the claim construction section, a person of ordinary skill in the art would understand “about 22 degrees” as likely referring to room temperature, because viscosity is often measured at room temperature. Ex. 1003 at ¶ 94. Thus, a person of ordinary skill in the art would understand the disclosure of the ’4666 patent to teach this limitation.

¹⁶ A formulation should have a specific viscosity when measured using a given method under specific set of conditions (e.g. temperature, rpm, spindle size, etc.).

art would conclude that the viscosity ranges disclosed in the '4666 Patent and WO133 teach the viscosity limitation of the '795 Patent.¹⁷ Ex. 1003 at ¶¶ 119-121.

6. “wherein the acetaminophen is suspended in the syrup; and”

FR458, the '4666 patent, and WO133 each teach that the API can be suspended in an oral formulation. Ex. 1004, at 2, lns. 39-55, at 3, lns. 58-68; 7, lns. 187-198, 8, lns. 199-204 (including Example 1), 10, ln. 221- 11, ln. 245 (including Example 4); Ex. 1005 at col. 2, lns. 41-48, col. 3, 50-53; Ex. 1006; at abstract; at 2, ln. 13-3, ln. 3, 3, lns. 7-18 (“The composition is a liquid formulation in which

Ex. 1003, at ¶¶ 56-57, 13, fn. 3. Ideally, each viscosity measurement determined under the same method should produce the same result. *Id.* In practice, different methods will lead to different results due to the accuracy of the method, the precision of the device and the skill of the person conducting the testing. *Id.* The fact that neither claim 1 of the '795 Patent nor the specification of WO133 define the method to measure the viscosity is immaterial to this obviousness analysis because the key is that both direct the person of skill in the art to the desired viscosity range of the oral formulation. Moreover, considering that viscosity is often measured at room temperature, a person of ordinary skill in the art would read the viscosity range of 200-900 centipoise to teach measuring the viscosity at room temperature—about 20° to about 22° C. Ex. 1003, at ¶94.

¹⁷ To the extent that the Board treats this limitation as a range, e.g., 0 to 1500 centipoise, the fact that the viscosity ranges disclosed in WO133 and the '4666 patent overlap with this range creates a presumption of obviousness. *UCB Inc. v. Actavis Laboratories*, 65 F.4th 679, 689-690 (Fed. Cir. 2023). Moreover, the patent provides no evidence as to the importance of the viscosity range. Ex. 1003 at ¶ 28. It merely recites different viscosity ranges. Ex. 1001 at col. 2, lns. 12-28. The viscosity appears so trivial that the '795 patent even fails to report the viscosity of the single example in the patent. Ex. 1001 at col. 5, lns. 5-22; Ex. 1003 at ¶ 28.

acetaminophen is suspended. . .”), 4, lns. 16-28, 8, lns. 17-24, 13, ln. 24 – 14, ln. 6.

A person of ordinary skill in the art would understand that each of these references teaches this limitation. Ex. 1003 at ¶¶ 122-123.

7. “wherein the syrup is palatable.”

FR458, the '4666 Patent, and WO133 describe formulations that seek to mask the taste of the analgesic included in the oral formulation. Ex. 1004, at 2, lns. 43-45, at 7, lns. 182-184, 8-10, Examples 1 - 4; Ex. 1005 at col. 2, lns. 15-21, col. 3, lns. 50-53; Ex. 1006, at 1, lns. 4-6, 2, lns. 2-25, 3, lns. 8-18, 5, lns. 11-26, 9, 3-4. Based upon these disclosures, a person of ordinary skill in the art would understand these formulations to be “palatable,” i.e., have an acceptable and not an unpleasant taste. Ex. 1003 at ¶¶ 124-128. If the patentees assert otherwise, then as explained in Ground 3 below at Section C.1(a), claims 1 to 6 and 18 to 24 fail to comply with the requirements of 35 U.S.C. § 112(b).

As shown by the sections above, a person of ordinary skill in the art would have a motivation to combine these references with a reasonable expectation of success and would understand that these references, when combined, teach each limitation. Therefore, these prior art references render claim 1 unpatentable. Ex. 1003 at ¶ 129.

(b) Dependent Claims 2 through 6 are Obvious over FR458 when Combined the '4666 Patent and/or WO133

A person of ordinary skill in the art would conclude that the following combinations, FR458 in combination with the '4666 patent, FR458 in combination with WO133, and FR458 in combination with the '4666 patent and WO133, each disclose all the limitations of claims 2-6 as shown below.

Claim 2 narrows the viscosity range to less than 1000 centipoise. Claim 3 narrows the range further to less than 750 centipoise, while claim 4 narrows further to less than 600 centipoise. Each of these ranges is disclosed in the references relied upon here. Claim 11 of the '4666 patent discloses a viscosity range from 100 to 3000 centipoise. Ex. 1005 at col. 6, lns. 66-67. WO133 teaches a tighter viscosity range of 200 to 900 centipoise for its oral analgesic formulation. Ex. 1006 at 7, ln. 27-8, ln. 4. As both teach viscosity below the upper limit required by claims 2, 3, and 4, a person of ordinary skill in the art would conclude that the presence of these limitations do not save the claims from an obviousness conclusion. Ex. 1003 at ¶¶ 114-116, 132-133.

Claim 5 provides a wide concentration range of 0.01 to 2 grams of suspended acetaminophen per 100mL of the syrup, while claim 6 narrows the range to 0.01 to 1 gram per 100 mL. Since WO133 sets an upper concentration limit for acetaminophen in the compositions disclosed of “up to about 10% by weight”, and

not a lower limit, a person of ordinary skill in the art would have understood that would include compositions with less than 2g/100mL and/or 1g/100mL of acetaminophen. Ex. 1003 at ¶ 136. Similarly, a person of ordinary skill in the art would have understood that the broad API concentration ranges of 0.01% to 90% disclosed in FR458 would necessarily include formulations that contain less than 2g/100mL or 1g/100mL of acetaminophen. Ex. 1003 at ¶ 136. Additionally, as of the 2017, a person of ordinary skill in the art would have been familiar with various oral liquid formulations that included analgesics like acetaminophen and ibuprofen and the preferred dosage. Ex. 1003 at ¶ 134. The Physician Desk Reference (PDR) from 1966 explained that a dose of Elixir Tylenol included 120 mg per teaspoon—5 mL or 5 cc. Ex. 1017 at 742; Ex. 1003 at ¶ 134. The PDR from 1998 showed that the suggested dosing for Children's Tylenol suspension was 160 mg per 5 mL. Ex. 1018 at 1537; Ex. 1003 at ¶ 134. A person of ordinary skill in the art would understand that the key is to administer an effective amount of API, e.g., 120 mg or 160 mg of acetaminophen, and that the skilled artisan has flexibility in selecting the concentration by which to administer the effective dose. Ex. 1003 at ¶ 134. By changing the concentration, a person would have more ability to control the amount of API administered to a particular patient. Ex. 1003 at ¶¶ 134-135. A person of ordinary skill in the art would also appreciate that a practical limit exists for concentration—if it is so low patient compliance would be a concern because the

patient would need to ingest a large volume to get a sufficient amount of the API. Ex. 1003 at ¶¶ 134-135, 81, table 2 and fn. 16. The table below illustrates this point using the suggested therapeutic doses the two previously described liquid oral Tylenol products. Ex. 1017 at 742; Ex. 1018 at 1537; Ex. 1003 at ¶ 134. This table shows the relationship between the final concentration of an API in a drug formulation, the desired therapeutic dose and the volume that needs to be administered to achieve said dose. Ex. 1003 at ¶ 134.

Desired Therapeutic Dose of API (mg)	Concentration of API in the Formulation (g/100 mL)	Volume Required to Achieve the API Therapeutic Dose (teaspoons=mL)
120 mg	2.4 g/100 mL ¹⁸	1 teaspoon = 5 mL
120 mg	1.2 g/100 mL	2 teaspoons = 10 mL
120 mg	0.8 g/100 mL	3 teaspoons = 15 mL
120 mg	0.01 g/100 mL	240 teaspoons = 1,200 mL or 1.2 Liters
120 mg	2 g/100 mL	1.2 teaspoons = 6 mL
60 mg	0.01 g/100 mL	120 teaspoons = 600 mL
60 mg	2 g/100 mL	0.6 teaspoons = 3 mL

¹⁸ The concentration at g/100 mL was calculated as follows: ((120 mg/1,000 mg/g) * (100 mL/5 mL)). Ex. 1003 at 81, fn. 17.

The chart shows that the selection of the concentration is a design choice. Ex. 1003 at ¶ 135. A lower concentration may provide flexibility in administration. Ex. 1003 at ¶ 135. While a full 120 mg dose of acetaminophen may be administered to an adult patient, less than a full dose (e.g. 60mg) may be administered to an infant or a child. Ex. 1003 at ¶ 135. A formulation with a lower acetaminophen concentration would allow a caregiver to easily titrate the amount of drug administered to each type of patient.¹⁹ Ex. 1003 at ¶ 135. In practice, there are some lower concentrations that are unrealistic. If a person of ordinary skill in the art focused on the lower claimed range of 0.01 g per 100 mL, the patient would need to take 240 teaspoons (i.e. 1.2 liters) to ingest 120 mg of acetaminophen. Ex. 1003 at 81, fn. 16.

Based upon the general knowledge available regarding the concentration of acetaminophen in commercial liquid oral drug products captured, a person of ordinary skill in the art would understand the concentration ranges of, i.e., below 2 g /100 mL and below 1 g/100 mL are obvious and thus, claims 5 and 6 are obvious.²⁰

¹⁹ A caregiver could achieve the same result by providing a half of a third of a teaspoon to the patient, but there may be inaccuracies in attempting to administer that small a dose. Ex. 1003 at ¶ 134.

²⁰ The Board should be able to rely upon the 12th edition of the PDR to show the general understanding in the art. *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015) (“Art can legitimately serve to document the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness.”). To the extent that the Board concludes that Petitioner must provide support for the combination of the PDR 1966 and PDR 1998 with FR458, the ’4666 Patent, and WO133, Petitioner submits that the PDR is a well-

Ex. 1003 at ¶¶ 45, 134-137. This conclusion is further bolstered by the fact that other references discussed in this petition teach concentration ranges similar to those claimed here. For example, the '4666 patent discloses a range of 1 g to 20 g of ibuprofen per 100 mL. Ex. 1005 at col. 2, lns. 4-14. Ex. 1003 at ¶ 136. A person of ordinary skill in the art would have also understood FR458 and WO133 as disclosing formulations liquid acetaminophen formulations that comprise less than 2 g/100mL or 1 g/100mL. Ex. 1003 at ¶¶ 137-137.

3. Claim 7 and its Dependent Claims are Obvious over FR458 when Combined the '4666 Patent and/or WO133

(a) Claim 7

Claim 7 is similar to claim 1 with a few additions. Ex. 1003 at ¶ 138. The preamble of claim 7 states that it is a stable pharmaceutical syrup formulation. Ex. 1001 at col. 5, lns. 57-58. The formulation also requires an acidic preservative. Finally, the formulation of claim 7 requires a flavoring agent instead of requiring

known reference that it used as a trusted resources for information about available medicines, including oral formulations of analgesics. Ex. 1003 at 79, fn. 15. As FR458, the '4666 Patent, and WO133, each discuss oral formulations of analgesics, a person of ordinary skill in the art would look to the PDR to understand the amount of an API used in commercial formulations that have received regulatory approval, which would be a safe and effective amount. Ex. 1003 at 79, fn. 15. If the Board concludes that Petitioner must offer this combination as a formal ground, Petitioner submits that combining the teachings of FR458, PDR1966 and PDR1998, along those of the '4666 Patent and/or WO133 renders claims 5 and 6 unpatentable as obvious. Ex. 1003 at ¶¶ 134-137.

that the formulation be palatable. For the same reasons and evidence provided with respect to claim 1, a person of ordinary skill in the art would conclude that the following combinations, FR458 in combination with the '4666 Patent, FR458 in combination with WO133, and FR458 in combination with the '4666 Patent and WO133, each disclose all the limitations of claim 1 as shown below. Ex. 1003 at ¶ 139.

1. The Overlapping Limitations between Claims 1 and 7 are Taught for the Reasons Described Above

The formulations described in claim 1 and claim 7 both require acetaminophen, agave syrup, a diluent, a viscosity less than 1500 centipoise and the acetaminophen in suspension. Ex. 1001 at col. 5, lns. 33-43, col. 5, ln. 57 – col. 6, ln. 5; Ex. 1003 at ¶ 138. As shown above, and incorporated here by reference, FR458, the '4666 Patent, and WO133 teach these limitations. See V.A.2(a)2, V.A.2(a)3, V.A.2(a)4, V.A.2(a)5, and V.A.2(a)6.

2. “A stable pharmaceutical syrup formulation for oral administration comprising”

While the preamble is normally not considered a limitation, to the extent that the Board concludes the preamble is a limitation, each of the prior art references teaches a stable pharmaceutical syrup formulation for oral administration. Ex. 1004 at 1, lns. 4-5, 3, lns. 58-68, 12, lns. 4-6 (claim 1); Ex. 1005 at abstract, at col. 1, lns.

6-15, col. 2, lns. 15-21; Ex. 1006 at 1, ln. 11 - 2, ln. 12, 2, lns. 14-25. A person of ordinary skill in the art would understand that each of the oral formulations in FR458, the '4666 Patent, and WO133 was meant for administration to patients. Ex. 1003 at ¶¶ 140-143. Therefore a person of ordinary skill in the art would understand that each discloses a stable formulation, because if they were unstable they would not be suitable to administer to patients.²¹ Ex. 1003 at ¶ 142.

3. “acidic preservative”

FR458 and WO133 each teach inclusion of an acidic preservative in the formulation. Ex. 1004 at 6, lns. 172-181, 8, Example 1; Ex. 1006 at 7, lns. 11-26. A person of ordinary skill in the art would understand that each of these references teaches this limitation. Ex. 1003 at ¶¶ 144-147.

4. “flavoring agent”

Instead of requiring a syrup that is palatable like claim 1, claim 7 requires the inclusion of a flavoring agent. Ex. 1001 at col. 5, lns. 33-43, at col. 5, ln. 57 – col. 6, ln. 5. While the claims use different language, a person of ordinary skill in the art

²¹ The '795 Patent does not provide any description of what is required to be considered a stable formulation. Ex. 1003 at ¶¶ 142, 271. But if the oral formulations of FR458, the '4666 Patent, and WO133 are not deemed to meet the claim limitation “stable,” then a person of ordinary skill in the art would not understand the scope of the claims of the '795 Patent that use the term “stable.” Ex. 1003 at ¶ 271. It would be proper for the Board to hold them invalid as indefinite under 35 U.S.C. § 112(b) as asserted in Ground 3 below. See Section V.C.1(b).

would understand that they cover similar, if not the same, concepts. Ex. 1003 at ¶¶ 148-149. FR458 teaches the use of flavoring agents in its formulation. Ex. 1004 at Abstract, at 3, lns. 58-79 (discloses use of natural flavorings and advises avoiding the use of artificial sweeteners), at 7, lns. 182-184, 8-10, Examples 1, 3 and 4 (discloses using natural strawberry flavoring), Example 2 (discloses using natural lemon flavoring). WO133 teaches that the aqueous solutions of the invention, in which acetaminophen is suspended, may contain flavoring agents. Ex. 1006 at 7, lns. 5-10, 8, lns. 10-16, 9-10, Examples 1 and 2. The '4666 Patent discloses that flavoring is a desirable ingredient which may be optionally added to the compositions of the invention. Ex. 1005 at col. 4, lns. 18-31. As a person of ordinary skill in the art would be motivated to combine FR458 and the '4666 Patent, FR458 and WO133, and FR458, the '4666 Patent, and WO133 with a reasonable expectation of success and these combinations teach each limitation of claim 7, a person of ordinary skill in the art would conclude that claim 7 is obvious. Ex. 1003 at ¶ 150.

(b) Dependent Claims 8 through 17 are Obvious over FR458 when Combined with the '4666 Patent and/or WO133

A person of ordinary skill in the art would conclude that the following combinations, FR458 in combination with the '4666 Patent, FR458 in combination

with WO133, and FR458 in combination with the '4666 Patent and WO133, each disclose all the limitations of claims 8-17 as shown below.

Claim 8 requires that the acetaminophen is between 0.01 to 2% of the formulation by weight. FR458 teaches that the API can be between 0.1 to about 90% of the formulation. Ex. 1004 at 3, lns. 78-85. Similarly, WO133 teaches suspensions that contain acetaminophen in an amount of up to about 10% by weight and, most preferably, from about 2% to 5% by weight in the final composition. Ex. 1006 at 4, lns. 8-15, 2, lns. 16-19. Therefore, the prior art references teach the additional limitation of claim 8 and thus render the claim unpatentable as obvious. Ex. 1003 at ¶¶ 153-154.

Claim 9 requires that the diluent is about 5% of the formulation by weight. Claim 12 requires that the diluent is water. FR458 teaches that water is added to the formulation as required to bring it to the desired total amount. Ex. 1004, Example 1 (purified water is added “up to” 100 mL), 8, lns. 199- 204 (explaining that “the water is topped up to 100 ml and everything is mixed together.”). Similarly, the '4666 Patent teaches adding water to the formulation in Example 1 to achieved the final desired volume of 1000 gal. Ex. 1005 at col. 4, ll. 40-56 (Example 1). A person of ordinary skill in the art would understand that amount of water serves to bring the formulation to the desired volume and can be modified within reason without altering the effectiveness of the formulation. Ex. 1003 at ¶ 155. That disclosure

would include formulations where the water is about 5% by weight. Ex. 1003 at ¶ 155. Therefore, the prior art reference teaches the additional limitations of claims 9 and 12. Thus, the prior art references render the claims unpatentable as obvious. Ex. 1003 at , ¶¶ 155-156, 159-160.

Claims 10 and 11 require that the agave syrup is less than 98% and 95% of the formulation by weight, respectively. FR458 discloses formulations with concentrations of agave syrup below both of these thresholds. Ex. 1004, Examples 1-4; Ex. 1003 at ¶ 157. FR458 teaches the additional limitations of claims 10 and 11 and renders the claims unpatentable as obvious. Ex. 1003 at ¶ 158.

Claim 13 requires that the agave syrup make up about 95% of the formulation. A person of ordinary skill in the art would understand the amount of agave syrup to use in the formulation is a design choice within the general knowledge of the skilled artisan. Ex. 1003 at ¶¶ 161-162. Moreover, the '580 Publ. evidences the general knowledge of a person skilled in the art with regard to agave syrup concentrations by noting that “[t]raditional natural and artificial sweeteners are added to most food products and medicines. These sweeteners can range from 2% to 98% of their total content.”²² Ex. 1003 at [0023]; Ex. 1003 at ¶ 163. Thus, a person of ordinary skill

²² The Board should be able to rely upon the '580 Publ. to show the general understanding in the art. *Ariosa Diagnostics*, 805 F.3d at 1365. To the extent that the Board concludes that Petitioner must provide support for the combination of the '580 Publ. with FR458, the '4666 Patent, and WO133, Petitioner submits that the

in the art would conclude that this claim is unpatentable as obvious. Ex. 1003 at ¶ 164.

Claim 14 limits the acidic preservative to citric acid. FR485 and WO133 disclose using citric acid in oral formulations. Ex. 1004 at 8, Example 1; Ex. 1006 at 7, lns. 24-26. These disclosures render claim 14 unpatentable. Ex. 1003 at ¶¶ 165-166.

Claim 15 limits the viscosity of the oral formulation to between about 1500 centipoise to about 400 centipoise. WO133 teaches a tighter viscosity range of 200 to 900 centipoise for its oral analgesic formulation. Ex. 1006 at 7, ln. 27-8, ln. 4. The WO133 range falls within the claimed range. The '4666 patent discloses a viscosity range of 100 to 3000 centipoise, which overlaps the claimed range. Ex. 1005 at col. 6, lns. 66-67 (claims 10 and 11). Either of these disclosures suffices to

'580 Publ. teaches the benefit of using agave syrup with medicines, which aligns with the disclosure of FR458 that describes using agave syrup as the base for an acetaminophen formulation. Ex. 1003 at ¶ 163. The '580 Publ. explains the health benefits of using agave syrup in oral formulations like those described in FR458. Ex. 1003 at ¶ 70; Ex. 1008 at [0003], [0010]-[0021]. Considering that the '580 Publ. and FR458 address the benefits of using agave syrup in oral formulations, a person of ordinary skill in the art would have a motivation to combine with a reasonable expectation of success. Ex. 1003 at ¶ 163, at 97, fn. 18. Moreover, for the reasons expressed above in section V.A.1, a skill artisan would have the same motivation and expectation of success to add the teachings of the '4666 patent and WO133 with those of the '580 Publ. and FR458. If the Board concludes that Petitioner must offer this combination as a formal ground, Petitioner submits that combining the teachings of FR458 and the '580 Publ. along with the '4666 Patent and/or WO133 renders claim 13 unpatentable as obvious. Ex. 1003 at ¶ 164.

render the claimed range obvious to a person of ordinary skill in the art. Ex. 1003 at ¶¶ 167-169.

Claim 16 adds the limitation where in the formulation is orally administered for veterinary and human use.²³ The additional limitation is confusing because it is unclear whether claim 16 seeks to claim a formulation or a method of using the formulation. Ex. 1007 at ¶ 170. Irrespective of this issue, the additional limitation identifies all of the subjects for which an oral formulation may be administered, i.e., humans or animals. Ex. 1003 at ¶ 170. Considering that a person of ordinary skill in the art would understand these two subject types to be the normal recipients of oral pharmaceutical formulation, the additional limitation would be obvious to a person of ordinary skill in the art. Ex. 1003 at ¶ 170. Moreover, WO133 and the ‘4666 Patent both disclose formulations that are administered to patients (i.e. humans). Ex. 1005 at col. 1, lns. 6-15; Ex. 1006 at 1, ln. 16- 2, ln. 1; Ex.1003 at ¶ 171. These disclosures, coupled with the person of ordinary skill in the art’s knowledge at the relevant time, render this claim unpatentable. Ex. 1003 at ¶ 172.

²³ The specification does not describe any formulations as “orally administered for veterinary and human use.” Ex. 1003. These terms only appear in claim 16. Ex. 1003. To the extent that the patentees rely upon the knowledge of a person of skill in the art to support the additional limitation of claim 16, that knowledge renders the additional limitation of claim 16 obvious. Ex. 1003.

Claim 17 requires that the flavoring agent is a bitter-taste-blocking ingredient. A person of ordinary skill in the art would understand that acetaminophen and ibuprofen are bitter tasting. Ex. 1003 at ¶ 173; Ex. 1006 at 5, ln. 21-6, ln. 6; Ex. 1005 at col. 1, lns. 24-28. FR458, the '4666 Patent, and WO133 each seek to mask the taste of analgesics in oral formulations. FR458 at 2, lns. 39-46, 8-10, Examples 1-4; Ex. 1005 at col. 2, lns. 3-21; Ex. 1006 at 1, ln. 4- 2, ln.12. WO133 notes that the “additive agent is preferably comprised of a sweetening agent or mixtures of sweetening agents so that not only is the bitter taste of acetaminophen in solution limited, but it is replaced by a pleasant tasting sweetener.” Ex. 1006 at 5, lns. 21-24. As the prior art teaches formulation for masking the bitter taste of acetaminophen, claim 17 is unpatentable as obvious. Ex. 1003 at ¶¶173-174

4. Claim 18 and its Dependent Claims are Obvious over FR458 when Combined with the '4666 Patent and/or WO133

(a) Claim 18

Claim 18 is similar to claims 1 and 7 with some minor differences. Ex. 1001 at col. 5, lns. 34-41, ln. 56-col. 6, ln. 5, lns. 36-44. Compared to claim 7, the preamble of claim 18 describes the syrup formulation as “palatable” and replaces “comprising” with “consisting essentially of.” The latter change is the most material from the perspective of claim scope. Claim 18 also requires a “therapeutically effective amount of acetaminophen” as opposed to just “acetaminophen” as recited

in claim 7. For the same reasons and evidence provided with respect to claims 1 and 7, a person of ordinary skill in the art would conclude that the following combinations, FR458 in combination with the '4666 Patent, FR458 in combination with WO133, and FR458 in combination with the '4666 Patent and WO133 each disclose all the limitations of claim 1 as shown below.

1. The Overlapping Limitations of claims 1 and 7 as compared to claim 18

As with claims 1 and/or 7, claim 18 requires a stable formulation, agave syrup, a diluent, an acidic preservative, a flavoring agent, a viscosity of less than 1500 centipoise at about 22 degrees, and acetaminophen is suspended in the syrup. Ex. 1001 at col. 5, lns. 33-42, ln. 57 – col. 6, ln. 5, lns. 35-44. As shown above, and incorporated here by reference, FR458, the '4666 Patent, and WO133 teach these limitations. See V.A.3(a)2 V.A.2(a)3; V.A.2(a)4V.A.2(a)5; V.A.2(a)6; Ex. 1; Ex. 1003 at ¶¶ 175-176.

2. The Preamble – “Palatable” and “Consisting Essentially of”

While the preamble is normally not considered a limitation, to the extent that the Board concludes the preamble is a limitation, FR458, the '4666 Patent, and WO133 describe formulations that seek to mask the taste of the analgesic included in the oral formulation. Ex. 1004 at 2, lns. 39-45, 3, lns. 58-73, 7, lns. 182-184; Ex. 1005 at col. 2, lns. 15-21; Ex. 1006 at 2, lns. 2-25. Based upon these disclosures, a

person of ordinary skill in the art would understand these formulations to have a “palatable,” i.e, an acceptable and not an unpleasant test. Ex. 1004 at 3, lns. 58-68; Ex. 1005 at col. 2, lns. 4-21; Ex. 1006 at 1, ln. 10 - 2, ln. 12; Ex. 1003 at ¶¶ 177-178.

As described in Section III.E.5 above, “consisting essentially of” requires the presence of each of the listed items and allows the presence of other items that do not materially affect the basic and novel properties of the invention. *PPG Industries*, 156 F.3d at 1354; *AVX Corp.*, IPR2014-01361, 2015 WL 782026, *3-*4. Example 1 of FR458 (reproduced below) includes a therapeutically effective amount of acetaminophen (a.k.a. paracetamol), agave syrup, anhydrous citric acid and sodium citrate —acidic preservatives, natural strawberry flavoring—a flavoring agent, and purified water—a diluent. Ex. 1004 at 8, Example 1; Ex. 1003 at ¶ 180.

Example 1

Ingredients	Quantity
Paracetamol	2.5 g
Certified agave syrup	45 g
Xanthan gum	0.4 g
Certified agar-agar	0.2 g
Glycerin	5 g
Sodium citrate	0.5 g
Anhydrous citric acid	0.4 g
Natural strawberry flavoring	0.01 g
Purified water	Up to 100 ml

The xanthan gum and the agar-agar are mixed with the glycerin to obtain Solution A. The paracetamol is suspended 225 [sic] in the syrup to obtain Solution B. Solution A is added to Solution B and mixed well. The water is topped up to 100 ml and everything is mixed together. The preparation is placed in vials.

Thus, the FR458 meets the requirement of the “consisting essentially of” language because it discloses each of the listed items. Ex. 1003 [Crowley Decl], at ¶ 180. Next, we consider whether the presence of xanthan gum, certified agar-agar, and glycerin materially affects the basic and novel properties of the invention. This task is hampered by the scant disclosure in the ’795 patent. Ex. 1003 at ¶ 179. As discussed in section III.E.5 above, the specification alleges that a problem existed with pharmaceutical chemists using unnatural and artificial ingredients to mask taste. Ex. 1001 at col. 1, lns. 20-24. It then states that, for one embodiment of the invention, a preference for the use of inactive ingredients that are gluten free, non-GMO, and certified vegan exists. Ex. 1001 at col. 1, lns. 44-46; Ex. 1003 at ¶ 179. In another embodiment, certain ingredients such as aspartame, carbomer, EDTA, gelatin, milk, parabens, polyethylene glycol, titanium dioxide, and other unnatural ingredients, can, optionally, be omitted from formulations of the invention. Ex. 1001 at col. 1, lns. 46-50. As the ’795 Patent only suggests the optional exclusion of these items, and only expresses a general desire to avoid unnatural and artificial sweeteners, it is unclear whether these items would materially affect the basic and novel properties of the invention. Ex. 1003 at ¶¶ 179-180. The patent does not provide further insight into the items that should be excluded from the formulation. Ex. 1003 at ¶ 179.

The additional items included in Example 1 of FR458 are not items that fall into the categories described above. Ex. 1003 at ¶¶ 180-181. Xanthan gum is a naturally occurring polysaccharide that is a common thickening agent. Ex. 1003 at ¶ 181; Ex. 1029 at 782. The specification mentions the use of polysaccharides in the formulation, so a person of ordinary skill in the art would not consider the inclusion of xanthan gum as materially affecting the basic and novel properties of the claimed formulation. Ex. 1001 at col. 3, lns. 51-53; Ex. 1003 at ¶ 181. Certified agar-agar is a vegan substitute for gelatin that is obtained from red algae like seaweed.²⁴ Ex. 1003 at ¶ 181; Ex. 1029 at 13. The specification discloses a preference for vegan ingredients, so a person of ordinary skill in the art would not consider the inclusion of certified agar-agar as materially affecting the basic and novel properties of the claimed formulation. Ex. 1001 at col. 1, lns. 44-46; Ex. 1003 at ¶ 181. The '795 patent states that the formulation may include sugar alcohols such as glycerin as sweetening agents, so a person of ordinary skill in the art would not consider the inclusion of glycerin as materially affecting the basic and novel properties of the claimed formulation. Ex. 1001 at col. 3, lns. 51-56; Ex. 1003 at ¶ 181. Based upon the specification of the '795 Patent, a person of ordinary skill in the art would not consider any of the additional items of Example 1 of FR458 as excluded from the

²⁴ Gelatin is a protein made from animal collagen, such as cows and pigs. Ex. 1029, at p. 280.

“consisting essentially of” limitation of claim 18. Ex. 1003 at ¶ 181. A person of ordinary skill in the art would conclude that Example 1 of FR458 discloses the “consisting essentially of” limitation. Ex. 1003 at ¶ 182.

3. “a therapeutically effective amount of acetaminophen”

Considering that acetaminophen was included in pharmaceutical formulations well before the earliest filing date of the '795 Patent, a person of ordinary skill in the art would understand the amount of acetaminophen required to be therapeutically effective. Ex. 1003 at ¶ 183. The '795 Patent supplements this knowledge by mentioning a lower limit of 0.01 w/w % of an API in the formulations of the patent. Ex. 1001 at col. 2, lns. 40-49. Based on this disclosure, a person of ordinary skill in the art would understand an amount of API above 0.01 w/w % would constitute a therapeutically effective amount of the API. Moreover, Example 4 of FR485 disclose a formulation with acetaminophen in an amount of about 35mg/mL and WO133 discloses oral formulations that contain acetaminophen in an amount of about 32mg/mL. Ex. 1004; Ex. 1006 at 9, Example 1; Ex. 1003 at ¶ 184. These amounts of acetaminophen are on par with the amounts in marketed acetaminophen formulations for infants and children sold in the U.S. Ex. 1018, at p. 2; Ex. 1003 at ¶ 184. A person of ordinary skill in the art would understand that FR458 and WO133 disclose therapeutically effective amounts of acetaminophen. Ex. 1003 at ¶¶ 183-

186. As a person of ordinary skill in the art would be motivated to combine FR458 and the '4666 Patent, FR458 and WO133, and FR458, the '4666 Patent, and WO133 with a reasonable expectation of success and these combinations teach each limitation of claim 18, a person of ordinary skill in the art would conclude that claim 18 is obvious and unpatentable. Ex. 1003 at ¶ 187

(b) Dependent Claims 19 through 24 are Obvious over FR458 when Combined the '4666 Patent and/or WO133

A person of ordinary skill in the art would conclude that the following combinations, FR458 in combination with the '4666 Patent, FR458 in combination with WO133, and FR458 in combination with the '4666 Patent and WO133, each disclose all the limitations of claims 19-24 as shown below.

Claim 19 reduces the viscosity range to less than 1000 centipoise. Ex. 1001 at col. 6, lns. 44-46. Both the '4666 Patent and WO133 disclose viscosity below 1000 centipoise. Claim 11 of the '4666 patent discloses a viscosity range from 100 to 3000. Ex. 1005 at col. 6, lns. 66-67. WO133 teaches a tighter viscosity range of 200 to 900 centipoise for its oral analgesic formulation. Ex. 1006 at 7, ln. 27-8, ln. 4. As both teach viscosity below the upper level required by claim 19, a person of ordinary skill in the art would conclude that the presence of this limitation does not save the claim from an obviousness conclusion. Ex. 1003 at ¶¶ 190-192.

Claim 18 requires a viscosity of less than 1500 centipoise at about 22 degrees. Claims 20 and 21 are identified as dependent claims, but they do not appear to limit claim 18 because they both state that the “syrup formulation has a viscosity of less than 1500 centipoise at 22 degrees.” Ex. 1001 at col. 6, lns. 36-54. The fact that the claims do not further limit claim 18 renders them unpatentable under 35 U.S.C. § 101 for statutory double patenting. Irrespective of the issue under § 101, Claim 11 of the ’4666 patent discloses a viscosity range from 100 to 3000 centipoise. Ex. 1003 at col. 6, lns. 66-67. WO133 teaches a tighter viscosity range of 200 to 900 centipoise for its oral analgesic formulation. Ex. 1006 at 7, ln. 27-8, ln. 4. As both ranges are below the upper viscosity limit required by claims 20 and 21, a person of ordinary skill in the art would conclude that the presence of this limitation does not save the claims from an obviousness conclusion. Ex. 1003 at ¶¶ 190-192.

Claims 22, 23 and 24 add the limitation that the agave syrup is less than 98%, less than 95% or about 95% of the formulation by weight, respectively. Ex. 1001 at col. 6, lns. 55-60. A person of ordinary skill in the art would understand that the amount of agave syrup to use in the formulation is a design choice within the general knowledge of the skilled artisan. Ex. 1003 at ¶¶ 190-194. Example 1 of FR458 shows agave syrup less than 95%. Ex. 1003 at 8, Example 1. The ’580 Publ. evidences the general knowledge of the art when it states that “[t]raditional natural and artificial sweeteners are added to most food products and medicines. These

sweeteners can range from 2% to 98% of their total content.”²⁵ Ex. 1008 at 2, [0023].

Thus, for all of the reasons provided above, a person of ordinary skill in the art would conclude that claims 1-24 are unpatentable as obvious in view of the skilled artisan’s knowledge and the disclosure of the prior art referenced in relation to this ground. Ex. 1003 at ¶¶ 99-194.

B. Explanation for Ground 2

1. Motivation to Combine WO742 with the ’4666 Patent and/or WO133²⁶

WO742 describes various agave-based formulations that include dextromethorphan and other APIs including acetaminophen. Ex. 1007 at 16, lns. 7-25, 13, lns. 21-27, 13, ln. 27 – 15, ln. 57 WO742 seeks to provide a safer form of an

²⁵ The Board should be able to rely upon the ’580 Publ. to show the general knowledge of a person of ordinary skill in the art. *Ariosa Diagnostics*, 805 F.3d at 1365. As described in footnote 22 above, a person of ordinary skill in the art would be motivated to combine the ’580 Publ. with FR458, the ’4666 Patent, and WO133. If the Board concludes that Petitioner must offer this combination as a formal ground, Petitioner submits that combining the teachings of FR458 and the ’580 Publ. along with the ’4666 Patent and/or WO133 renders claims 23 and 24 unpatentable as obvious. Ex. 1003 at ¶194.

²⁶ Petitioner submits that WO742 and the ’4666 Patent teach each limitation and a motivation to combine with a reasonable expectation of success for these patents. Petitioner also asserts the same for WO742 and WO133. Finally, Petitioner and its declarant have provided evidence that a person of ordinary skill in the art would have a motivation to combine WO742, the ’4666 Patent and WO133 with a reasonable expectation of success. Therefore, Petitioner asserts that WO742 in combination with the ’4666 Patent, WO742 in combination with WO133, and WO742 in combination with the ’4666 patent and WO133 each renders the claims of the ’795 patent not patentable as obvious.

oral pharmaceutical formulation. Ex. 1007 at 9, lns. 1-25. Like WO742, the '4666 Patent and WO133 identify pharmaceutical oral formulations that include acetaminophen as an analgesic. Ex. 1005 at col. 1, lns. 28-35; Ex. 1066 at 1, lns. 3-9. A person of ordinary skill in the art would look to the disclosure of a formulation that seeks to provide a safe oral formulation for patients and combine that with existing prior art references that also discuss oral formulations of APIs. Ex. 1003 at ¶ 197. These references are in the same field and each discuss the creation of oral formulations with an analgesic. Ex. 1003 at ¶ 196. The fact that each of the references discuss acetaminophen would provide an additional rationale for a person of ordinary skill in the art to combine the references. Ex. 1003 at ¶ 196. Moreover, a person of ordinary skill in the art would have been motivated to combine these references because such a person would have known that antitussives like dextromethorphan are often combined with analgesics like acetaminophen and ibuprofen in over-the-counter liquid cough and cold formulations. Ex. 1003 at ¶ 197. A person of ordinary skill in the art would have had a reasonable expectation of success in combining these references because they all disclose formulations comprising well known ingredients performing well known functions. *KSR Int'l Co.*, at 417. Therefore, a person of ordinary skill in the art would be motivated to combine these teachings and would have a reasonable expectation of success in so doing. Ex. 1003 at ¶¶ 195-198.

2. Claims 1 through 17 are Obvious over WO742 when Combined the '4666 Patent and/or WO133

(a) Claim 1

A person of ordinary skill in the art would conclude that the following combinations, WO742 in combination with the '4666 Patent, WO133 in combination with WO133, and WO742 in combination with the '4666 Patent and WO133 each disclose all the limitations of claim 1 as shown below.

1. “A pharmaceutical syrup formulation for oral administration comprising”

While the preamble is normally not considered a limitation, to the extent that the Board concludes that the preamble is a limitation, each of the prior art references teaches a pharmaceutical syrup formulation for oral administration. Ex. 1007 at 9, lns. 18-25, 13, lns. 7-20; Ex. 1005 at col. 2, lns. 4-21; Ex. 1006 at 1, ln. 10 - 2, ln. 12; Ex. 1003 at ¶¶ 201-203

2. “acetaminophen”

Similarly, each of the prior art references discloses acetaminophen as an analgesic in an oral formulation. Ex. 1007 at 13, ln. 21-15, ln. 7, 16, lns. 7-25, 21, ln. 30-22, ln. 10 (Example V), 23, lns. 17-29 (Example IX); Ex. 1005 at col. 1, lns. 18-35; Ex. 1006 at 1, lns. 4-19; Ex. 1003 at ¶¶ 204-207.

3. “agave syrup, and”

WO742 teaches the benefits of using agave syrup as the base formulation that contains different API, including acetaminophen. Ex. 1007 at 8, lns. 8-14 (citing to the ‘580 Publ.), 13, lns. 4-20, 21, ln. 30-22, ln. 10 (Example V), 23, lns. 17-29 (Example IX); Ex. 1003 at ¶¶ 208-210.

4. “a diluent”

WO742 and the ‘4666 Patent teach using water as a diluent in a formulation that includes acetaminophen and agave syrup. Ex. 1007 at 21, ln. 30-22, ln. 10 (Example V), 23, lns. 17-29 (Example IX); Ex. 1005 at 4:39-57 (Example 1); Ex. 1003 at ¶¶ 211-214.

5. “wherein the syrup formulation has a viscosity of less than 1500 centipoise at about 22 degrees”

A person of ordinary skill in the art would understand that an oral formulation needs a viscosity that allows it to be pourable and drinkable. Ex. 1003 at ¶¶ 216. The viscosity of agave syrup is reported to be about 212 centipoise. Ex.1003 at ¶ 52. Thus, a person of ordinary skill in the art would understand that the formulation disclosed in Example IX of WO742, which consists mainly of agave syrup and other ingredients with relatively low viscosities, may have a viscosity of less than 1500 centipoise. Ex. 1003 at ¶ 216, p. 121, fn. 25. As both the ‘4666 Patent and WO133 disclose viscosity ranges for an oral formulation with an analgesic that overlap with this claim limitation, it is unnecessary for the Board to conclude that Example V of

the WO742 meets this limitation. The '4666 patent discloses a viscosity range measured at 20° C. by a Brookfield Synchro-Lectric viscometer of 1000 to 3000 centipoise.²⁷ Ex. 1005 at col. 4, lns. 9-19. Claim 11 of the '4666 Patent further lowers the lower limit of this range from 1000 to 100. *Id.*, col. 6, lns. 66-67. WO133 teaches a tighter viscosity range of 200 to 900 centipoise for its oral analgesic formulation.²⁸ Ex. 1006 at 8, lns. 1-3. A person of ordinary skill in the art would conclude that the viscosity ranges disclosed in the '4666 Patent and WO133 teach the viscosity limitation of the '795 Patent.²⁹ Ex. 1003 at ¶¶ 215-218.

6. “wherein the acetaminophen is suspended in the syrup; and”

WO133 teaches oral formulations with acetaminophen in suspensions.; Ex. 1006; abstract; at 2, ln. 13-3, ln. 6, 3, lns. 7-18 (“The composition is a liquid formulation in which acetaminophen is suspended. . . .”). WO742 states that the compositions disclosed include suspensions. Ex. 1007 at 13, lns. 7-10. A person of ordinary skill in the art would understand that these references teach this limitation. Ex. 1003 at ¶¶ 219-220.

7. “wherein the syrup is palatable.”

²⁷ See footnote 15.

²⁸ See footnote 16.

²⁹ See footnote 17

The '4666 Patent and WO133 describe formulations that seek to mask the taste of the analgesic included in the oral formulation by adding sweetening agents, flavoring agents and/or by limiting the solubility of the analgesic (e.g. placing it in suspension). Ex. 1005 at col. 2, lns. 15-21, col. 3, lns. 50-53; Ex. 1006 at 1, lns. 4-6, 2, lns. 2-25, 3, lns. 8-18, 9, lns. 3-4; Ex. 1003 at ¶¶ 221-222. WO742 discloses including sweetening agents (i.e. agave and aspartame) and flavorants in the formulations. Ex. 1007 at 21, ln. 30-22, ln. 10. Based upon these disclosures, a person of ordinary skill in the art would understand these formulations to be “palatable,” i.e., have an acceptable and not an unpleasant taste. Ex. 1003 at ¶ 223

As shown by the sections above, a person of ordinary skill in the art would have a motivation to combine these references with a reasonable expectation of success and would understand that these references teach each limitation of claim 1. Therefore, these prior art references render claim 1 unpatentable. Ex. 1003 at ¶ 224.

(b) Dependent Claims 2 through 6 are Obvious over WO742 when Combined with the '4666 Patent and/or WO133

A person of ordinary skill in the art would conclude that the following combinations, FR458 in combination with the '4666 Patent, FR458 in combination with WO133, and FR458 in combination with the '4666 Patent and WO133 each disclose all the limitations of claims 2-6 as shown below.

Claim 2 narrows the viscosity range to less than 1000 centipoise. Claim 3 narrows the range further to less than 750 centipoise, while claim 4 narrows it further to less than 600 centipoise. Each of these ranges is disclosed in the reference relied upon here. Claim 11 of the '4666 patent discloses a viscosity range from 100 to 3000. Ex. 1005 at col. 6, lns. 66-67. WO133 teaches a tighter viscosity range of 200 to 900 centipoise for its oral analgesic formulation. Ex. 1006 at 7, ln. 27-8, ln. 4. As both teach viscosity below the upper level required by claims 2, 3, and 4, a person of ordinary skill in the art would conclude that the presence of these limitations does not save the claims from an obviousness conclusion. Ex. 1003 at ¶¶ 227-228.

Claim 5 states that 0.01 to 2 grams of acetaminophen is suspended per 100mL of the syrup, while claim 6 lowers the upper limit to 1 gram per 100 mL. As of the 2017, a person of ordinary skill in the art would have been familiar with various oral formulations that included analgesics like acetaminophen and ibuprofen. Ex. 1003 at ¶ 230; Ex. 1017 at 742; Ex. 1018 at 1537. WO133 teaches formulations with less than 10% by weight of acetaminophen and a person of ordinary skill in the art would have understood that such formulations would include formulations that contain 0.01-2g/mL or 0.01 -1g/mL of acetaminophen. Ex. 1006 at p. 2, lns. 16-19; Ex. 1003 at ¶ 231. WO742 identifies different amounts of acetaminophen in its examples. Ex. 1003 at ¶ 231; Ex. 1007, compare Examples V and IX. The concentration of

acetaminophen in Example IX is 1 mg per 100 mL. Ex. 1003 at ¶ 231. Thus, a person of ordinary skill in the art would have understood that WO742 and WO133 both teach acetaminophen concentrations that fall within the ranges required by claims 5 and 6 and, therefore, these claims are unpatentable as obvious. Ex. 1003 at ¶¶ 229-232.

3. Claim 7 and its Dependent Claims are Obvious over WO742 when Combined the '4666 Patent and/or WO133

(a) Claim 7

Claim 7 is similar to claim 1 with a few additions. Ex. 1003 at ¶ 233. The preamble of claim 7 states that it is a stable pharmaceutical syrup formulation. Ex. 1001 at col. 8, ln. 57 – col. 9, ln. 5. The formulation also requires an acidic preservative. Finally, the formulation of claim 7 requires a flavoring agent instead of requiring that the formulation be palatable. For the same reasons and evidence provided with respect to claim 1, a person of ordinary skill in the art would conclude that WO742 in combination with the '4666 Patent, WO742 in combination with WO133, and WO742 in combination with the '4666 Patent and WO133, each disclose all the limitations of claim 1 as shown below. Ex. 1003 at ¶ 234.

1. The Overlapping Limitations between Claims 1 and 7 are Taught for the Reasons Described Above

The formulations described in claim 1 and claim 7 both require acetaminophen, agave syrup, a diluent, a viscosity less than 1500 centipoise, and the

acetaminophen in suspension. Ex. 1001 at col. 5, lns. 33-43, col. 5, ln. 57 – col. 6, ln. 5. As shown above, and incorporated here by reference, WO742, the '4666 Patent, and WO133 teach these limitations. See V.B.2(a)2, V.B.2(a)3, V.B.2(a)4, V.B.2(a)5, and V.B.2(a)6; Ex. 1003 at ¶¶233, 242.

2. “A stable pharmaceutical syrup formulation for oral administration comprising”

While the preamble is normally not considered a limitation, to the extent that the Board concludes that the preamble is a limitation, each of the prior art references teaches a stable pharmaceutical syrup formulation for oral administration. Ex. 1007 at lns. 1-10 (discussing inclusion of acidic buffering to keep API in solution); Ex. 1005 at abstract, col. 1, lns. 6-15, at col. 2, lns. 15-21, col. 6, lns. 19-29; Ex. 1006 at 1, ln. 10 - 2, ln. 25. A person of ordinary skill in the art would understand that each of the oral formulations in WO742, the '4666 Patent, and WO133 were meant for administration to patients. Ex. 1003 at ¶ 236. Therefore a person of ordinary skill in the art would understand that each discloses a stable formulation, because if they were unstable they would not be suitable to administer to patients.³⁰ Ex. 1003 at ¶ 237.

³⁰ The '795 Patent does not provide any description of what is required to be considered a stable formulation. Ex. 1003 at ¶ 141. But if the oral formulations of WO742, the '4666 Patent, and WO133 do not meet the “stable” limitation of claim 7 of the '795 Patent, then a person of ordinary skill in the art would not understand the scope of the this claim and its dependent claims. Ex. 1003 at ¶¶ 271-273. It

3. “acidic preservative”

WO133 teaches the inclusion of common food preservatives in the formulation, such as sorbic acid, and acidic pH regulating agents that can also act as preservatives, like citric acid. Ex. 1006 at 7, lns. 11-26. A person of ordinary skill in the art would understand that this disclosure meets this limitation. Ex. 1003 at ¶¶ 238-239.

4. “flavoring agent”

Instead of requiring a syrup that is palatable such as in claim 1, claim 7 requires the inclusion of a flavoring agent. Ex. 1001 at col. 5, lns. 33-43, col. 5, ln. 57 – col. 6, ln. 5. While the claims use different language, a person of ordinary skill in the art would understand that formulations are made palatable through the inclusion of flavoring agents. Ex. 1003 at ¶ 240. WO742 discloses the use of flavoring agents in its formulation. Ex. 1007 at 20-23 (Examples I-IX). WO133 and the ‘4666 Patent also disclose the use of flavoring agents to achieve a palatable formulation. Ex. 1005 at col. 4, lns. 29-31, at col. 4, ln. 40- col. 6, ln. 12 (Examples 1-4); Ex. 1006, at 8, lns. 10-16, 9-10 (Examples 1-2); Ex. 1003 at ¶¶ 240-241.

would be proper for the Board to hold them invalid as indefinite under 35 U.S.C. § 112(b) as asserted in Ground 3 below. See Section V.C.1(b).

(b) Dependent Claims 8 through 17 are Obvious over WO742 when Combined the '4666 Patent and/or WO133

A person of ordinary skill in the art would conclude that the following combinations, WO742 in combination with the '4666 Patent, WO742 in combination with WO133, and WO742 in combination with the '4666 Patent and WO133, each disclose all the limitations of claims 8-17 as shown below.

Claim 8 requires that the acetaminophen is between 0.01 to 2% of the formulation by weight. WO133 teaches an acetaminophen content from about 2% to 5%. Ex. 1006 at 4, lns. 8-15, 2, lns. 16-19. Therefore, the prior art reference teaches the additional limitation of claim 8 and thus renders the claim unpatentable as obvious. Ex. 1003 at ¶¶ 245-246.

Claim 9 requires that the diluent is about 5% of the formulation by weight. Claim 12 requires that the diluent is water. The examples of WO742 and the '4666 Patent include "Water, Purified q.s," in this context "q.s." means to add the quantity of water sufficient to achieve the desired final volume. Ex.1007 at 21, ln. 30-22, ln. 10 (Example V), 23, lns. 17-29 (Example IX); Ex. 1005 at col. 4, lns. 40-56 (Example 1); Ex. 1003 at ¶¶ 247-248, 251-252. A person of ordinary skill in the art would understand that amount of water is not critical, but merely serves to bring the formulation to the desired volume. Ex. 1003 at ¶ 247. That disclosure would include formulations where the water is about 5% by weight. Ex. 1003 at ¶ 247. Therefore,

the prior art reference teaches the additional limitations of claims 9 and 12. Thus, the prior art references render the claims unpatentable as obvious. Ex. 1003 at ¶¶ 247-248, 251-252.

Claims 10 and 11 require that the agave syrup be less than 98% and 95% of the formulation by weight, respectively. WO742 discloses formulations with an agave syrup concentration below both of these thresholds. Ex. 1007 at 21, ln. 30-22, ln. 10, Example V, 23, lns. 16-29; Ex. 1003 at ¶ 249. WO742 teaches the additional limitations of claims 10 and 11, which claims are unpatentable as obvious. Ex. 1003 at ¶¶ 249-250.

Claim 13 requires that the agave syrup make up about 95% of the formulation. A person of ordinary skill in the art would understand that the amount of agave syrup to use in the formulation is a design choice within the general knowledge of the skilled artisan. Ex. 1003 at ¶ 253. The '580 Publ. evidences the general knowledge of the art when it states that “[t]raditional natural and artificial sweeteners are added to most food products and medicines. These sweeteners can range from 2% to 98% of their total content.”³¹ Ex. 1008 at [0023]. Thus, a person of ordinary skill in the

³¹ The Board should be able to rely upon the '580 Publ. to show the general understanding in the art. *Ariosa Diagnostics*, 805 F.3d at 1365. To the extent that the Board concludes that Petitioner must provide support for the combination of the '580 Publ. with WO742, the '4666 Patent, and WO133, then Petitioner provides that evidence here. A person of ordinary skill in the art would have a motivation to combine the '580 Publ. with these references. WO742 actually references the '580

art would conclude that this claim is unpatentable as obvious. Ex. 1003 at ¶¶ 253-255, 137, fn. 29.

Claim 14 limits the acidic preservative to citric acid. WO133 discloses using citric acid in oral formulations. Ex. 1006 at 7, lns. 24-26. This disclosure render claim 14 unpatentable. Ex. 1003 at ¶¶ 256-257.

Claim 15 limits the viscosity of the oral formulation to between about 1500 centipoise to about 400 centipoise. WO133 teaches a viscosity range of 200 to 900 centipoise for its oral analgesic formulation. Ex. 1006 at 7, ln. 27-8, ln. 4. This range includes viscosities that fall within the claim range. Similarly, the '4666 patent discloses a viscosity range of 100 to 3000 centipoise, which includes

Publ. when it states that “U.S. Pat. Application Publication No. US2009/0148580 of Heyer discloses using natural agave extract as a sweetener to replace all or part of the high-calorie sugars and/or artificial sweeteners added in foods and medicines, thereby promoting an important reduction of calories and the elimination of artificial sweeteners by using natural agave extract as the main sweetening ingredient.” Ex. 1007 at 8, lns. 8-14. Thus, the Board need not speculate whether people in the field would have combined these references, because the applicants of WO742 actually did. Ex. 1003 at ¶ 70. The '580 Publ. explains that it is providing improvements to oral medicinal formulations by providing a healthier sweetener option - agave syrup. Ex. 1008 at [0003]-[0021]; Ex. 1003 at ¶70. A person of ordinary skill in the art would be motivated to combine these improvements with publications such as the '4666 Patent and WO133, which disclose oral medicinal formulations that feature unpleasant, bitter tasting APIs that require sweeteners to render them palatable. Ex. 1005 at col. 1, lns. 28-35, at col. 2, lns. 15-22; Ex. 1006 at 1, lns. 3-9; Ex. 1003 at ¶ 254. If the Board concludes that Petitioner must offer this combination as a formal ground, then Petitioner submits that combining the teachings of WO742 and the '580 Publ. along with the '466 Patent and/or WO133 renders claim 13 unpatentable as obvious. Ex. 1003 at ¶¶ 253-255.

viscosities that overlap with the claimed range. Ex. 1005 at col. 6, lns. 66-67. Either of these disclosures suffices to render the claimed range obvious to a person of ordinary skill in the art. Ex. 1003 at ¶¶ 258-260.

Claim 16 adds the limitation where in the formulation is orally administered for veterinary and human use. The additional limitation is confusing because it is unclear whether claim 16 seeks to claim a formulation or a method of using the formulation. Irrespective of this issue, the additional limitation identifies all of the subjects for which an oral formulation may be administered, i.e., humans or animals. Ex. 1003 at ¶ 261. WO742, WO133 and the '4666 Patent all disclose formulations that are administered to human subjects, therefore a person of ordinary skill in the art would have understood that they disclose this claim limitation. Ex. 1007 at 9, lns. 26-28, 28 (claim 12); Ex. 1006 at 1, ln. 16- 2, ln.1; Ex1005 at 1:6-15; Ex. 1003 at ¶¶ 261-263.

Claim 17 requires that the flavoring agent be a bitter-taste-blocking ingredient. A person of ordinary skill in the art would understand that acetaminophen is bitter tasting. Ex. 1003 at ¶ 264; Ex. 1006 at 5, lns. 20-6, 6. The '4666 Patent and WO133 each seek to mask the taste of analgesics in oral formulations. Ex. 1005 at col. 2, lns. 3-22; Ex. 1006 at 1, lns. 4-17. WO742 teaches a formulation with acetaminophen—a bitter-tasting API—and flavorants. Ex. 1007 at 21, ln. 30-22, ln. 10, Example V; Ex. 1003 at ¶ 264. WO133 notes that the

“additive agent is preferably comprised of a sweetening agent or mixtures of sweetening agents so that not only is the bitter taste of acetaminophen in solution limited, but it is replaced by a pleasant tasting sweetener.” Ex. 1006 at 5, ln. 21-6, ln. 6. As the prior art teaches a formulation for masking the bitter taste of acetaminophen, claim 17 is unpatentable as obvious. Ex. 1003 at ¶¶ 264-265.

C. Explanation of Ground 3

- 1. In the alternative, Claims 1 through 24 are Indefinite based upon the use of the subjective terms “palatable” and “stable” and the use of “consisting essentially of” without providing direction on ingredients that materially affect the basic and novel aspect of the invention**
 - (a) To the extent that patentees assert that the taste-masked formulations of FR458, the ’4666 Patent, and WO133 do not meet the “palatable” limitation, then claims 1 through 6 and 18 through 24 are invalid as indefinite**

When a patentee uses a subjective term like “palatable” to delineate the invention, a tribunal must review the specification to discern whether it provides some standard for identifying the scope of the claim. *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) (holding the term “unobtrusive manner” indefinite because of lack of sufficient guidance in the specification.). A review of the patent provides no insight into the scope of the term “palatable.” The specification states that some aspects of the invention include “taste masking of unpalatable pharmaceutical active agents with generally natural ingredients,” and

“flavoring agents are generally provided as a minor component . . . to provide a palatable flavor.” Ex. 1001 at col. 1, lns. 42-44, at col. 4, lns. 4-7. The specification’s lack of definition leaves the term subjective, because what is unpleasant tasting to one may not be to another. Ex. 1003 at ¶ 268.

As explained in sections III.E.3 and V.A.2(a)7 above, Petitioner asserts that a person of ordinary skill in the art can apply the plain meaning and would conclude that any formulation that is meant to mask the taste of the API or includes flavoring would meet the “palatable” limitation. To the extent that patentees assert that the prior art references discussed in section V.A.2(a)7 do not disclose the “palatable” limitation, a person of ordinary skill in the art would not understand the meaning of the term. Ex. 1003 at ¶ 268. The failure of the specification to provide context to the meaning of “palatable” is fatal, and the claims are unpatentable under 35 U.S.C. § 112(b), because a person of ordinary skill in the art would not understand what is required by this claim limitation. Ex. 1003 at ¶¶ 268-269.

(b) To the extent that patentees assert that the oral formulations of FR458, the ’4666 Patent, and WO133 do not meet the “stable” limitation, then claims 7 through 24 are invalid as indefinite

Petitioner offers a similar argument as that in the preceding section with respect to the term “stable.” The term appears three times in the disclosure. Ex. 1001 at Abstract, at col. 1, lns. 30-37. Each time, it merely recites a “stable

pharmaceutical formulation” or “stable, pharmaceutical syrup formulation” without providing insight into determining whether a formulation is stable. Ex. 1001 at Abstract, col. 1, lns. 30-37; Ex. 1003. In sections III.E.4 and V.A.3(a)2 above, Petitioner asserts that a person of ordinary skill in the art would conclude that the oral formulations taught in the prior art discussed in section V.A.3(a)2 would be understood to disclose a stable formulation. Ex. 1003 at ¶ 271. To the extent that the patentees assert otherwise, they would be applying a bespoke definition of “stable.” Ex. 1003 at ¶ 271. The failure of the specification to provide the boundaries of that definition would then become problematic, because a person of ordinary skill in the art would not understand the claim scope. Ex. 1003 at ¶ 271. Thus, the claim would fail to meet the requirements of 35 U.S.C. § 112(b). Ex. 1003 at ¶¶ 270-272. The Board should hold unpatentable each of the claims using the term “stable.”

(c) To the extent that patentees assert that “consisting essentially of” excludes ingredients other than non-natural or artificial sweeteners, then claims 18 through 24 are invalid as indefinite

While the courts agree upon how to construe the term “consisting essentially of,” the term can run afoul of 35 U.S.C. § 112(b) if it is unclear what ingredients would materially affect the basic and novel properties of the invention. *Horizon Pharma Ireland Limited v. Actavis Laboratories UT, Inc.*, 14-7992, 2016 WL

4408990 *7-*9 (D. N.J. Aug. 17, 2016). When undertaking this analysis, the Board should apply the Supreme Court’s standard articulated in *Nautilus* that asks whether the claim read in light of the specification and prosecution history fails to inform, with reasonable certainty, the claim scope to a skilled artisan. *Horizon Pharma*, 2016 WL 4408990 *8 citing *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 2030 (2014). As explained in section III.C above, the prosecution history of this patent is virtually non-existent and does not provide any insight into the basic and novel properties of the invention. Ex. 1003 at ¶¶ 97-98, 179. The specification is only slightly better. It asserts that a problem existed with pharmaceutical chemists using unnatural and artificial ingredients to masks taste and then includes a list of ingredients the embodiments “**may exclude**” as unnatural. Ex. 1001 at col. 1, lns. 12-54 (emphasis added). Despite what the patentees may assert is a teaching to avoid unnatural or artificial products, the patent then states that the suitable flavoring agents include artificial flavors including artificial vanilla, artificial chocolate, and artificial fruit flavors. Ex. 1001 at col. 3, ln. 63-col. 4, ln. 10.

The disclosure that artificial flavor agents are suitable for the formulation in contradiction of the earlier statements would leave a person of ordinary skill in the art perplexed as to what ingredients would materially affect the basic and novel aspect of the invention. Ex. 1003 at ¶ 273. Thus, claims 18 to 24 fail to comply with 35 U.S.C. § 112(b), because a person of ordinary skill in the art would not

understand the ingredients that would material affect the basic and novel properties of the invention. Ex. 1003 at ¶ 273; *Horizon Pharma*, 2016 WL 4408990 *10 (holding “consisting essentially of” indefinite due to the inability of the skilled artisan to have “reasonable certainty” about the basic and novel properties of the invention).

VI. CONCLUSION

Based upon the evidence and arguments provided with respect to Grounds 1-3 above, there is a reasonable likelihood that Petitioner will prevail as to each of the challenged claims. Petitioner requests that the Board Institute a Post Grant Review of Grounds 1-3, find claims 1-24 of the '795 patent unpatentable under 35 U.S.C. § 103 and/or 35 U.S.C. § 112(b), and cancel those claims under 35 U.S.C. § 328(b).

VII. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

As set forth below and pursuant to 37 C.F.R. § 42.8(a)(1), the following mandatory notices are provided as part of this Petition:

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

KinderFarms LLC, a limited liability company incorporated in the State of Delaware, is the real party-in-interest in this PGR.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

United States Patent No. 11,617,795 is related to several pending patent applications including Application No. 17/817,637 filed on June 8, 2021,

Application No. 17/821,134 filed on August 19, 2022, and Application No. 17/821,137 also filed on August 19, 2022. Other than these related applications, Petitioner is unaware of other related patent matters.

C. Lead and Back-up Counsel Under 37 C.F.R. § 42.8(b)(3) and Deposit Account Information

Pursuant to 37 C.F.R. § 42.8(b)(3) and § 42.104(a), KinderFarms provides the following designation of counsel:

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Please charge any fees or credit overpayment to Deposit Account 130019.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Please address all correspondence to the lead counsel at the address shown above. KinderFarms also consents to electronic service to the e-mail addresses provided above for Lead Counsel and Back-Up Counsel.

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24, the undersigned attorney for the Petitioner declares that the argument section of this Petition (Sections I-VI) has a total of 18,655 words, according to the word count tool in Microsoft Word™.

Dated: September 25, 2023

Respectfully submitted,

By: /Brian W. Nolan/

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Case PGR2023-00051
U.S. Patent No. 11,617,795

CERTIFICATE OF SERVICE

Pursuant to 35 CFR §§ 42.6(e) and 42.105, I hereby certify that true and correct copies of the foregoing Petition for Post-Grant Review of U.S. Pat. No. 11,617,795 and Exhibits 1001-1043 were served on September 25, 2023 via UPS Next Day Air to the correspondence address for the attorneys of record for U.S. Pat. No. 11,617,795, as evidenced on the USPTO's Patent Center's Address & Attorney/Agent Information page on September 25, 2023:

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