

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KINDERFARMS LLC,
Petitioner,

v.

GENEXA INC.,
Patent Owner.

PGR2023-00051
Patent 11,617,795 B2

Before DEBORAH KATZ, MICHAEL J. FITZPATRICK, and
SUSAN L. C. MITCHELL, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

DECISION
Granting Institution of Post-Grant Review
35 U.S.C. § 324

I. INTRODUCTION

KinderFarms LLC (“KinderFarms” or “Petitioner”) filed a Petition requesting post-grant review of claims 1–24 of U.S. Patent No. 11,617,795 B2 (Ex. 1001, “the ’795 patent”). (Petition (“Pet.”), Paper 2.) Genexa, Inc. (“Genexa” or “Patent Owner”) filed a Preliminary Response identifying itself as the owner of the ’795 patent. (Preliminary Response (“Prelim. Resp.”), Paper 6.)

The Director may not authorize a post-grant review “unless the Director determines that the information presented in the petition filed under section 321, if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” 35 U.S.C. § 324(a). We determine whether to institute a post grant review on behalf of the Director. *See* 37 C.F.R. § 42.4(a).

The following findings of fact and conclusions of law are not final, but are made for the sole purpose of determining whether Petitioner meets the threshold for initiating review. Any final decision shall be based on the full trial record, including any response timely filed by Patent Owner.

Upon considering the Petition, the Preliminary Response, and the evidence of record, we determine that Petitioner has demonstrated it is more likely than not that at least one challenged claim will be held unpatentable. Accordingly, we institute a post-grant review of all challenged claims on all asserted grounds. *Cf. SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1354, 1359–60 (2018); 37 C.F.R. § 42.208(a).

A. Related Matters and Real Parties-in-Interest

Petitioner reports that application 17/817,637, filed on June 8, 2021, as well as applications 17/821,134 and application 17/821,137, both filed on August 19,

2022, are related to the challenged '795 patent. (Pet. 72–73.) Petitioner identifies KinderFarms LLC as its real party-in-interest. (*See id.* at 73.)

Patent Owner reports that the litigation *Genexa, Inc. v. KinderFarms, LLC*, No. 2:23-cv-08378-GW-AGR (C.D. Cal.), is a related matter. (Paper 4, 1.) Patent Owner identifies Genexa Inc. as its real party-in-interest. (*See id.*)

B. The '795 Patent

The '795 patent discloses pharmaceutical syrup formulations for oral administration that address the problem of unnatural and artificial ingredients being used to mask the taste of pharmaceutical agents. (*See* '795 patent, Ex. 1001, 1:12–35.) The formulations disclosed in the '795 patent include a pharmaceutically active ingredient, agave syrup, and a diluent. (*See id.*)

Petitioner argues that during examination of the application that became the '795 patent (application 17/817,637), the examiner cited a single reference (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)), but determined that the claims “are free of the prior art,” without issuing any rejection based on the prior art. (*See* Pet. 12 (quoting Notice of Allowability, Application 17/817,637, issued February 28, 2023, Ex. 1002, 17).) Petitioner argues that the applicant did not submit any information disclosure statements to identify relevant art. (*See* Pet. 12.) Patent Owner has not argued to the contrary.

C. The Challenged Claims

Petitioner challenges the patentability of claims 1–24 of the '795 Patent. (*See* Pet. 1.) Claim 1 of the '795 patent is illustrative of the subject matter claimed and recites:

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.

(’795 patent, 5:34–41.) Claims 2–6 of the ’795 patent depend on claim 1. (*See id.* at 5:42–56.) Independent claim 7 is similar, also reciting a pharmaceutical syrup formulation, but with the additional ingredients of an acidic preservative and a flavoring agent. (*See id.* at 5:57–6:5.) Claims 8–17 ultimately depend from claim 7. (*See id.* at 6:6–34.) Claim 18 is similar to claim 7 and recites:

- A stable, palatable pharmaceutical syrup formulation for oral administration consisting essentially of:
- (a) a therapeutically effective amount of acetaminophen;
 - (b) agave syrup;
 - (c) acidic preservative;
 - (d) a flavoring agent, and
 - (e) a diluent, wherein the syrup formulation has a viscosity of less than 1500 centipoise at about 22 degrees and the acetaminophen is suspended in the syrup.

(*Id.* at 6:35–43.) Claims 19–24 depend from claim 18. (*See id.* at 6:44–49.)

D. The Asserted Grounds of Unpatentability and Evidence

Petitioner asserts that claims 1–24 are unpatentable based on the following grounds (*see* Pet. 2):

Claims Challenged	Statutory Basis	References
1–24	35 U.S.C. § 103 ¹	FR458, ² the '4666 Patent, ³ WO133 ^{4,5}
1–17	35 U.S.C. § 103	WO742, ⁶ the '4666 Patent, WO133 ⁷
1–24	35 U.S.C. § 112(b)	

Petitioner asserts that each of the cited references is prior art and, at this point in the proceeding, we agree. (*See* Pet. 19, 22, 24, 25.) Patent Owner does not challenge this assertion in its Preliminary Response.

¹ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), included revisions to 35 U.S.C. §§ 102 and 103 that became effective on March 16, 2013, before the filing of the applications to which the '795 patent claims priority. Therefore, we apply the AIA versions of Sections 102 and 103.

² French Patent Application Publication No. 2 993 458, published January 24, 2014 (English translation, Ex. 1004).

³ U.S. Patent 4,684,666, issued August 4, 1987 (Ex. 1005).

⁴ International Patent Application Publication WO 95/00133, published January 5, 1995 (Ex. 1006).

⁵ Petitioner presents these references in one ground of challenge with the conjunction “and/or.” (Pet. 2.) We review the challenge as including both the '4666 patent and WO133 contributing together to the obviousness of the claims of the '975 patent in order to encompass all of Petitioner’s arguments. (*See id.*, at 28, n.14.)

⁶ International Patent Application publication WP 2012/018742 A2, published February 9, 2012 (Ex. 1007).

⁷ Petitioner presents these references in one ground of challenge with the conjunction “and/or.” (Pet. 2.) We review the challenge as including both the '4666 patent and WO133 contributing together to the obviousness of the claims of the '975 patent in order to encompass all of Petitioner’s arguments. (*See id.*, at 54, n.26.)

In support of these grounds for unpatentability, Petitioner submits, *inter alia*, the Declaration of Michael Crowley (Ex. 1003 (“Crowley Decl.”)). Patent Owner has not submitted testimonial evidence at this stage of the proceeding.

II. ANALYSIS

A. Legal Standards

In a post-grant review, Petitioner bears the burden of demonstrating “it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” *See* 35 U.S.C. § 324(a).

A claim is unpatentable “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C. § 103. “[W]hen a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)).

B. Level of Skill

Each party puts forth a characterization of the ordinarily skilled artisan in the field of the claims of the ’795 patent. (*See* Pet. 13 (citing Crowley Decl., Ex. 1003, ¶¶ 90–91); *see* Prelim. Resp. 3–4.) The parties’ proposed characterizations of the ordinarily skilled artisan are sufficiently similar that adoption of either would lead to the same result, institution. Thus, for the purposes of this Decision only, we adopt Patent Owner’s characterization of the ordinarily skilled artisan as having a bachelor of science degree in a relevant life sciences field, such as, chemistry, biochemistry, or pharmacy, with at least two years of work or laboratory

experience in pharmaceutical formulations, and access to one or more team members having experience in pharmaceutical formulation and pharmaceutical regulatory approvals, or, in the alternative, at least three to four years of work or laboratory experience in pharmaceutical formulations, and access to one or more team members having experience in pharmaceutical formulation and pharmaceutical regulatory approvals. (See Prelim. Resp. 3–4.) We also note that the level of skill of an ordinarily skilled artisan is revealed by the prior art. See *Okajima v. Bourdeau*, 261 F.3d 1350, 1354–55 (Fed. Cir. 2001) (holding that the absence of specific findings on the level of skill in the art does not give rise to reversible error “the prior art itself reflects an appropriate level and a need for testimony is not shown.” (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163, 225 USPQ 34, 38 (Fed.Cir.1985))).

C. Claim Construction

Petitioner puts forth constructions of certain terms used in the claims of the ’795 patent. (See Pet. 14–19.) Patent Owner does not dispute any of these constructions specifically, but at this point, argues that we need not construe any terms “to resolve the present controversy.” (Prelim. Resp. 2.) We agree that an express construction is not required at this point in the proceeding. See *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

D. The Asserted Prior Art

I. FR458

FR458, cited by Petitioner in its Ground 1, addresses the “growing interest in organic products and low-calorie products, especially for liquid pharmaceutical compositions” and recognizes a need to mask the unpleasant taste of some drugs. (Ex. 1004, abstract, 2:43–45; *see* Pet. 19–20.) To satisfy this need, FR458 teaches “(certified) organic agave syrup as a vehicle for liquid dosage forms, active pharmaceutical ingredients . . . alone or in combination, suspending agents and natural flavorings.” (Ex. 1004, abstract; *see* Pet. 19–20.) FR458 teaches further that drugs formulated with organic agave syrup include analgesics, such as paracetamol (another name for acetaminophen⁸) and ibuprofen. (*See* Ex. 1004, 3:86–90, 5:127–133; *see* Pet. 20.)

FR458 provides a formulation in Example 1 containing the following ingredients:

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

⁸ Dr. Crowley testifies that paracetamol is an “alternative name for acetaminophen that is commonly used outside of the U.S.” (Ex. 1002 ¶ 38.)

(Ex. 1004, 8:199–204; *see* Pet. 21.) FR458 teaches that these ingredients are combined, wherein

[t]he 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.

(FR458, Ex. 1004, 199–204; *see* Pet 21.)

At this point in the proceeding, we understand FR458 to teach a pharmaceutical syrup formulation for oral administration comprising acetaminophen and agave syrup and a diluent (Solution A and water).

2. WO742

WO742, cited by Petitioner in Ground 2, provides similar teachings as FR458, including that it was known to use “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, 8:8–12 (citing U.S. Pat. Application Publication No. US 2009/0148580); *see* Pet. 22–23.) WO742 discloses an aspect of the invention as a pharmaceutical composition of dextromethorphan and a carrier comprising agave nectar, water, and ethanol. (*See* Ex. 1007, 9:18–23.) WO742 teaches further that the pharmaceutical composition can include other active drug agents, such as analgesics, including acetaminophen. (*See* Ex. 1007, 13:21–29, 15:4–5; *see* Pet. 23.) WO742 also teaches that agave was known to be a “syrup-like product,” which can be “thinner or thicker in consistency (viscosity)” (Ex. 1007, 7:20–23; *see* Pet. 22.)

At this point in the proceeding, we understand WO742 to teach an oral pharmaceutical formulation comprising acetaminophen, agave syrup, and a diluent, as well as dextromethorphan and that viscosity is a consideration in making such a formulation.

3. *The '4666 patent*

The '4666 patent, cited by Petitioner in both Ground 1 and Ground 2, teaches stabilized ibuprofen syrup suitable for liquid administration. (*See* Ex. 1005, abstract; *see* Pet. 24.) The syrup of the '4666 patent can include a sweetening agent. (*See id.*) The '4666 patent teaches that moderately viscous syrup is useful for treating various medical conditions, including pain, and that liquid acetaminophen products are known. (*See* Ex. 1005, 1:11–15, 29–32; *see* Pet. 24.) The '4666 patent teaches that “viscosity of the product should be controlled for optimum stability.” (*See* Ex. 1005, 4:9–10; *see* Pet. 25.) Specifically, the '4666 patent teaches that a “viscosity of about 1000 to 3000 centipoise at 20° C, as measured by the Brookfield Synchro-Lectric viscometer, is the preferred range.” (*See* Ex. 1005, 4:10–12; *see* Pet. 25.)

At this point in the proceeding, we understand the '4666 patent to teach that viscosity is a factor to be considered in formulating a liquid analgesic solution and to teach a viscosity range overlapping the range recited in the claims of the '795 patent (less than 1500 centipoise at about 22 degrees), wherein the acetaminophen is suspended in the syrup.

4. *WO133*

WO133, also cited by Petitioner in both Ground 1 and Ground 2, teaches oral formulations of acetaminophen in suspension that mask the taste with sweetening agents. (*See* Ex. 1006, abstract; *see* Pet. 25–26.) WO133 teaches including a suspension agent for dispersing the acetaminophen in the aqueous

medium and an additive agent for decreasing the solubility of acetaminophen in the aqueous medium, along with a sweetening agent. (*See* Ex. 1006, 2:14–3:18, 5:11–6:6; *see* Pet. 16.) WO133 teaches a target viscosity of the resulting oral formulation of from 200 to 900 centipoise, preferably 300 to 700 centipoise. (*See* Ex. 1006, 7:27–8:3; *see* Pet. 26.) WO133 provides examples of viscous suspensions of acetaminophen, including sweetening agents. (*See* Ex. 1006, 9:2–10:8, Examples 1 and 2; *see* Pet. 26.)

At this point in the proceeding, we understand WO133 to teach oral pharmaceutical compositions that include acetaminophen and sweetening agents, preferably with a viscosity in a range overlapping that recited in the claims of the '795 patent.

E. Ground 1 – Obviousness Based on FR458, the '4666 Patent and/or WO133

Petitioner argues that claim 1 would have been obvious over FR458 in combination with the '4666 patent “and/or” WO133, under 35 U.S.C. § 103. (*See* Pet. 27–33.) Petitioner argues that each and every element of claim 1 is taught or suggested in these references. (*See id.*) After considering Petitioner’s and Patent Owner’s arguments, as indicated below, we are persuaded that it is more likely than not that claim 1 is unpatentable under 35 U.S.C. § 103 over FR458 in combination with the '4666 patent and WO133.

In regard to the preamble, Petitioner argues that each of the prior art references teaches a “[a] pharmaceutical syrup formulation for oral administration comprising” other ingredients. (*See* Pet. 29–30 (citing FR458, Ex. 1004, 1:4–7, 3:58–68, claim 1; '4666 patent, Ex. 1005, abstract, 1:6–15, 2:4–15; WO133, Ex. 1006, 2:14–25, 6:7–18; Crowley Dec., Ex. 1003, ¶¶ 106–108).) Dr. Crowley supports Petitioner’s argument, testifying that FR458 teaches liquid pharmaceutical

preparations for oral administration that include certified organic agave syrup. (See Ex. 1003 ¶ 107 (citing FR458, Ex. 1004, 3:58–68).) Dr. Crowley testifies further that the ’4666 patent teaches stabilized liquid ibuprofen syrup formulations for oral administration, which are moderately viscous. (See Ex. 1003 ¶ 107 (citing ’4666 patent, Ex. 1005, 1:6–15).) Dr. Crowley continues by testifying that WO1333 teaches liquid acetaminophen compositions for oral administration that include a sweetening agent, such as honey or corn syrup. (See Ex. 1003 ¶ 107 (citing WO133, Ex. 1006, 2:14–25, 6:7–25).)

Petitioner continues by arguing that the prior art references teach the ingredients recited in the formulation of claim 1 of the ’795 patent. Specifically, Petitioner argues that FR458 and W0133 teach acetaminophen as an analgesic in a medicine formulation. (See Pet. 30.) Petitioner also argues that FR458 teaches using agave syrup as a base formulation with acetaminophen to provide a low glycemic index formulation. (See *id.*) Dr. Crowley supports this argument with testimony citing to the prior art. (See Ex. 1003 ¶¶ 109–115 (citing FR458, Ex. 1004, 1:5–7, 3:58–68, 3:70–73, 5:127–133 (“paracetamol”), 8:199–204 (Example 1), claim 1; WO133, Ex. 1006, 1:4–9).)

In addition, Petitioner argues that the prior art, specifically FR458 and the ’4666 patent, teach inclusion of a diluent in analgesic formulations to bring the formulations to the desired final volume. (See Pet. 30.) In support, Petitioner cites to Dr. Crowley’s testimony that Example 1 of FR458 and Example 1 of the ’4666 patent both use water to achieve a final volume. (See Ex. 1003 ¶¶ 116–118 (citing FR358, Ex. 1004, 8:202–23; ’4666 patent, Ex. 1005, 4:55, Example 1).)

In regard to the limitation of claim 1 of the ’795 patent “wherein the syrup formulation has a viscosity of less than 1500 centipoise at about 22 degrees,” Petitioner cites to Dr. Crowley’s testimony that the ’4666 patent discloses a

viscosity range measured at 20° of 1000 to 3000 centipoise and that WO133 teaches a viscosity range of 200 to 900 centipoise for its oral analgesic formulation. (See Ex. 1003 ¶¶ 119–121 (citing ’4666 patent, Ex. 1005, 4:9–17, 6:66–67 (claim 11); WO133, Ex. 1006, 8:1–3).) Dr. Crowley testifies that the ’4666 patent teaches, in general, that “viscosity of the product should be controlled for optimum stability.” (’4666 patent, Ex. 1005, 4:9–12; see Crowley Decl., Ex. 1003 ¶ 119.)

Petitioner argues that the prior art teaches that acetaminophen can be suspended in syrup, as required in claim 1 of the ’795 patent, citing to Dr. Crowley’s testimony that FR458, the ’4666 patent, and WO133 each teaches that the active pharmaceutical agent can be suspended in an oral formulation. (See Pet. 32 (citing Ex. 1003, ¶¶ 122–123).) Dr. Crowley cites, for example, to FR458, which teaches that syrups and suspensions are suitable for children and the elderly and that “[p]harmaceutical suspensions and syrups consist of water, sugar, suspending agents, wetting agents, co-solvents, solubilizers, preservatives, flavorings, acid pH modifiers and salts thereof or bases and salts thereof, sweetening agents, colorants.” (Ex. 1004, 2:46–50, *see also id.* at 3:58–68, 7:187–198, 8:199–204 (Example 1), 10:221–11:245.) Similarly, WO133 teaches that “acetaminophen compositions of the present invention contain a suspension agent or mixtures of suspension agents.” (Ex. 1006, abstract, 4:16–28, *see also id.* at 8:17–24, 13:24–14:6; *see also* ’4666 patent, Ex. 1005, 2:41–48, 3:50–53; *see* Crowley Decl., Ex. 1003 ¶¶ 122–123.)

Petitioner argues further that the cited prior art references teach formulations to mask the taste of an analgesic and, thus, are palatable. (See Pet. 33 (citing Crowley Decl., Ex. 1003 ¶¶ 124–128).) For example, Petitioner cites to the examples of FR458, which include agave syrup and natural flavorings in

formulations of active pharmaceutical ingredients, including paracetamol. (*See* FR458, Ex. 1004, 1:8–10, Examples 1–4.) Similarly, the '4666 patent teaches: “Because of the bitter and unpleasant flavor of ibuprofen, it is desirable to have a product of high sweetness,” noting that sugar intake should be restricted for some patients. ('4666 patent, Ex. 1005, 2:15–20.)

Petitioner argues that FR458, the '4666 patent, and WO133 identify a need for developing oral formulations of analgesics that can be more suitable for children and the elderly and that mask the unpleasant taste. (*See* Pet. 28 (citing FR458, Ex. 1004, lines 39–40; '4666 patent, Ex. 1005, 1:18–29, 2:3–22; WO133, Ex. 1006, 1:4–2:12).) Petitioner argues further that each of these references teaches acetaminophen as an analgesic in oral formulation and teaches a preference for suspending the analgesic in the oral formulation. (*See* Pet. 28 (citing FR458, Ex. 1004, lines 39–45, 127–132, 199–205; '4666 patent, Ex. 1005, 1:28–35, 2:41–58, 3:50–53; WO133, Ex. 1006, 1:16–2:12, 3:7–18).) Petitioner argues that, in addition, FR458 and the '4666 patent are concerned with the development of formulations with a lower sugar content to benefit diabetics and other persons with restricted sugar requirements. (*See* Pet. 28–29 (citing FR458, Ex. 1004, 1:14–16, 3:70–74; '4666 patent Ex. 1005 at 2:15–21).)

According to Petitioner, because each prior art reference is in the same field of art, seeks to address similar issues, and discusses the creation of oral analgesic formulations, a person of ordinary skill in the art would be motivated to combine their teachings as doing so is merely using old ingredients performing the same function they were known to perform. (*See* Pet. 29 (citing *KSR*, 550 U.S. at 417).) Petitioner cites to the testimony of Dr. Crowley that a skilled person would have had a reasonable expectation of success in combining the teachings of the cited references and that all of the ingredients were known, could be combined by

routine methods, and were carrying out known functions. (*See* Crowley Decl., Ex. 1003, ¶¶ 101–103; *see* Pet. 29.)

Petitioner argues that the limitations of claims 2–24 of the ’795 patent are also taught in the prior art and that these claims are rendered obvious by the prior art. (*See* Pet. 34–38.) Because, after considering Petitioner’s and Patent Owner’s arguments, as indicated below, we are persuaded that Petitioner’s challenge under Ground 1 is more likely than not to demonstrate that claim 1 is unpatentable, we need not assess the challenges to claims 2–6 at this point in the proceeding. *Cf.* *SAS Inst., Inc.*, 138 S. Ct. at 1356 (holding that the somewhat analogous “Threshold” statute for *inter partes* reviews, i.e., 35 U.S.C. § 314(a), “simply requires . . . whether the petitioner is likely to succeed on ‘at least 1’ claim”).

F. Ground 2 – Obviousness Based on WO742, the ’4666 Patent and/or WO133

Petitioner argues that claim 1 of the ’795 patent would have been obvious over WO742 in combination with the ’4666 patent “and/or” WO133, under 35 U.S.C. § 103. (*See* Pet. 54–59.) Petitioner argues that each element of the claims of the ’795 patent is taught or suggested in these references. (*See id.*) After considering Petitioner’s and Patent Owner’s arguments, as indicated below, we are persuaded that it is more likely than not that claim 1 is unpatentable under 35 U.S.C. § 103 over WO742 in combination with the ’4666 patent and WO133.

Petitioner argues that WO742 teaches agave-based liquid formulations that include dextromethorphan and other active pharmaceutical ingredients, such as acetaminophen. (*See* Pet. 28 (citing WO742, Ex. 1007, 9:18–25, 16:7–25, 13:21–15:57).) Thus, according to Petitioner, WO742 teaches a pharmaceutical syrup for oral administration, as recited in the preamble of claim 1 of the ’795 patent, and teaches the ingredients, acetaminophen and agave, recited in claim 1. (*See* Pet. 56–57 (citing WO742, Ex. 1007, 8:8–14, 16:7–25, 13:21–15:57).) In addition,

Petitioner argues that WO742 teaches using water as a diluent in a formulation that includes acetaminophen and agave syrup. (*See* Pet. 57 (citing Ex. 1007, 21:30–22:10, 23:17–29, Examples V and IX).) Petitioner cites to Dr. Crowley’s testimony in support of these findings. (*See* Pet. 56–57 (citing Ex. 1003 ¶¶ 201–214).)

Petitioner argues that the ’4666 patent and WO133 teach viscosity ranges for an oral formulation with an analgesic that overlap with viscosity limitations of claim 1 of the ’795 patent, citing the same portions of these references as cited and discussed above in regard to Ground 1. (*See* Pet. 57–58 (citing ’4666 patent, Ex. 1005 at 4:9–19, 6:66–67 (claim 11); WO133, Ex. 1006, 8:1–3; Crowley Decl., Ex. 1003, ¶¶ 215–218).) Petitioner argues further that WO133, as well as WO742, teach oral formulations of acetaminophen as suspensions. (*See* Pet. 58 (citing WO133, Ex. 1006, abstract, 2:13–3:6, 3:7–18; WO742, Ex. 1007, 13:7–10; Crowley Decl., Ex. 1003, ¶¶ 219–220).) Petitioner cites to Dr. Crowley’s testimony to argue that the sweetening agent, agave, taught in WO742 would mask the taste of the analgesic taught in the ’4666 patent and WO133 and that one of ordinary skill in the art would understand the resulting formulation to be palatable as required in claim 1 of the ’795 patent. (*See* Pet. 59 (citing Ex. 1003, ¶¶ 221–223).)

Relying on similar reasoning as Ground 1, Petitioner argues that the formulation of claim 1 of the ’795 patent would have been obvious because WO742 describes various agave-based formulations that include acetaminophen along with other active pharmaceutical agents. (*See* Pet. 54–55 (citing WO742, Ex. 1007, 16:7–25, 13:21–15:57).) Petitioner notes that each of WO742, the ’4666 patent, and WO133 teach oral pharmaceutical formulations including acetaminophen as an analgesic and that a person of ordinary skill in the art would

look to the disclosure of a safe oral formulation for patients and combine it with existing prior art references that also discuss oral formulations of active pharmaceutical ingredients. (*See* Pet. 55 (citing '4666 patent, Ex. 1005, 1:28–35; WO133, Ex. 1066, 1:3–9; Crowley Decl., Ex. 1003 ¶¶ 196–197).) Moreover, Petitioner argues that one 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. (*See* Pet. 55 (citing Crowley Decl., Ex. 1003 ¶ 197).) Petitioner argues further that one 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. (*See* Pet. 55 (citing Crowley Decl., Ex. 1003 ¶¶ 195–198).)

F. Ground 3 – Indefiniteness

Petitioner asserts a third ground of challenge, arguing that the claims of the '795 patent are indefinite under 35 U.S.C. § 112(b). (*See* Pet. 68–72.) Specifically, Petitioner argues that one of ordinary skill in the art would not have understood the scope of the terms “palatable,” “stable,” and “consisting essentially of.” (*See id.* (citing Crowley Decl., Ex. 1003, ¶¶ 268–273).) Petitioner explains that this ground of challenge is presented “[i]n the alternative,” because although Petitioner asserts that a person of ordinary skill in the art can apply the plain meanings to these terms, which are proposed in the construction section of the Petition, Patent Owner may argue that the cited prior art references do not teach one or more of these limitations. (*See* Pet. 68; *see also id.* at 69 (“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.”). Essentially, Petitioner argues that if the prior art fails to teach the limitations in question, then they would necessarily be indefinite as “a person of ordinary skill in the art would not understand” their meaning. (*See id.* at 69.)

Patent Owner does not directly address Ground 3, arguing only that “Petitioner has already recognized that all claim terms it alleges are indefinite had meanings to a skilled artisan at the time of invention” and reserves the right to propose other constructions. (Prelim. Resp. 17, n.2; *see also id.* at 2.)

As explained below, at this point in the proceeding we consider the prior art asserted in Grounds 1 and 2 to teach or suggest the limitations of claim 1 of the ’795 patent and, thus, we do not find the identified limitations to be indefinite. Thus, we are not persuaded by Petitioner’s arguments that the identified limitations are indefinite.

G. Patent Owner’s Arguments

In its Preliminary Response, Patent Owner argues that Petitioner does not clearly state why one of ordinary skill in the art would have had a reason to combine the prior art cited by Petitioner under either Ground 1 or Ground 2 to achieve the formulation recited in claim 1. (*See* Prelim. Resp. 4–5.) Patent Owner correctly notes that Petitioner relies on the ’4666 Patent and WO133 for teaching the viscosity limitations. (*See* Prelim. Resp. 6.) According to Patent Owner, however, Petitioner fails to provide a reason why a person of ordinary skill in the art would have modified either FR458 or WO742 in view of such teachings because they “are based on substantially different oral compositions.” (*Id.*)

This argument does not persuade us that Petitioner fails to meet its burden in regard to at least claim 1. As Petitioner argues, each of the cited prior art references focuses on oral formulations that include analgesics and each discusses

acetaminophen. At this point in the proceeding, we are persuaded that one of ordinary skill in the art would have been aware that acetaminophen could be combined with sweeteners to mask its taste and that agave syrup was a known sweetener that could be used, as recited in claim 1. (See FR458, Ex. 1004, abstract, 8:199–204; WO742, Ex. 1007, 9:18–23, 13:21–29, 15:4–5.) Furthermore, at this point, we are persuaded that one of ordinary skill in the art would have known that the viscosity of such a combination would be a factor in the formulation. See *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448 (Fed. Cir. 1986) (“The issue of obviousness is determined entirely with reference to a *hypothetical* ‘person having ordinary skill in the art.’ It is only that hypothetical person who is presumed to be aware of all the pertinent art.” (quoting *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985))).

Patent Owner argues further that Petitioner fails to “account for various inconsistencies between the ’4666 Patent and WO133 that would preclude them from being combined as Petitioner proposed in Grounds 1 and 2.” (Prelim. Resp. 7.) Patent Owner cites to the teaching in the ’4666 patent that “[i]t is essential to the optimum stability of the final product that the pH be maintained in the alkaline range at all times. An acceptable range is above 7.0 and below 7.7, although best results are achieved at a pH of 7.3 to 7.5.” (US4666, Ex. 1005, 3:37–41; see Prelim Resp. 7.) Patent Owner argues that this teaching contrasts with the formulations in the examples of WO133 having pH values between 4.2 and 4.4, which Patent Owner asserts are “well below those of the ‘essential’ range of the ’4666 Patent.” (Prelim. Resp. 7 (citing WO133, Ex. 1006, 9:16–17, 10:17, 10:4–5, 13:5–6).) According to Patent Owner, Petitioner does not address these inconsistencies, which are a “plain teaching away between the ’4666 Patent and WO133.” (Prelim. Resp. 7.)

At this point in the proceeding, we are not persuaded that these “inconsistencies” indicate Petitioner has failed to meet its burden in regard to at least one claim of the ’795 patent is unpatentable. Petitioner does not rely on the teachings regarding pH in any of the references and the challenged claims do not require a particular pH or pH range. Nor does Patent Owner present persuasive evidence or reasoned analysis showing that the differing pH ranges taught in the references would somehow prevent or discourage one of ordinary skill in the art from combining their teachings as to ingredients.

Patent Owner’s argument assumes that one of ordinary skill in the art would require every feature of the formulations in the prior art references cited to be combined, but

[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

In re Keller, 642 F.2d 413, 425 (CCPA 1981). Thus, at this point in the proceeding, Patent Owner’s argument is not persuasive because it does not address the teachings in the prior art that Petitioner asserts would render the formulations claimed in the ’795 patent obvious.

Patent Owner argues that Petitioner’s use of “and/or” in the citation of references is ambiguous and puts a burden on Patent Owner and the Board to discern the arguments. (*See* Prelim Resp. 6–8.) In general, Patent Owner argues that Petitioner fails to provide clarity about the combination of prior art references. (*See* Prelim. Resp. 6 (citing 35 U.S.C. § 322(a)(3) (“A petition filed under section 321 may be considered only if . . . the petition identifies, in writing and with particularity, each claim challenged, the grounds on which the challenge to each

claim is based, and the evidence that supports the grounds for the challenge to each claim”)).)

At this point in the proceeding, we are not persuaded by Patent Owner’s argument because Petitioner has identified teachings in the cited prior art and has articulated a reason why one of ordinary skill in the art would have combined them to render the formulations claimed in the ’795 patent obvious, with sufficient rational underpinning, and with a reasonable expectation of success. At this point in the proceeding, we are persuaded the prior art demonstrates there was a desire to develop oral formulations of acetaminophen to mask the unpleasant taste and that agave syrup was a known natural sweetener for medicines, including acetaminophen, which would preferably be formulated with a viscosity overlapping with the claimed range.

Patent Owner argues further that Petitioner relies on hindsight because Petitioner does not provide an adequate reason to support its argument that a combination of FR458 or WO742 with the ’4666 Patent and/or WO133 would have been obvious to a skilled artisan at the time of invention. (*See* Prelim Resp. 8–11.) Patent Owner argues that Petitioner’s reasoning that the prior art references are in the same field of art is insufficient. (*See* Prelim. Resp. 10–12.) Patent Owner argues further that the fact that the art seeks to address similar issues is inadequate, where each reference allegedly solved the issue at hand. (*See* Prelim. Resp. 11.) According to Patent Owner, there is nothing in the prior art references that would have suggested combining them, other than a “generic interrelatedness that all of the cited prior art references happen to be in the same field” (Prelim. Resp. 10–11.)

We are not persuaded by Patent Owner’s arguments because, on the record before us, as identified by Petitioner, FR458 teaches a formulation with

acetaminophen, agave syrup, and diluent. (*See, e.g.*, FR458, Ex. 1004, abstract, lines 43–45, 86–90, 127–133, page 8.) Similarly, as identified by Petitioner, WO742 teaches that agave syrup and a diluent can be included in formulations for analgesics, that also include acetaminophen. (*See, e.g.*, WO742, Ex. 1007, 8:8–12, 9:18–23, 13:21–29, 15:4–5.) From Petitioner’s identification of these teachings in each of the prior art references, which are not contested by Patent Owner at this point in the proceeding, we are persuaded that one of ordinary skill in the art would have considered it obvious to combine acetaminophen and agave syrup with a diluent. Furthermore, the teachings of the ’4666 patent and WO133 identified by Petitioner, which are uncontested by Patent Owner at this point in the proceeding, teach that it was known that oral formulations of analgesics, such as acetaminophen, need a degree of viscosity to be pourable and drinkable. (*See* WO133, Ex. 1006, 7:27–8:3 (teaching a target viscosity); *see* ’4666 patent, Ex. 1005, 4:9–10 (“viscosity of the product should be controlled for optimum stability”); *see* Pet. 25, 26, 31, 57.) Thus, at this point in the proceeding and on the record before us, we are persuaded by Petitioner’s arguments that one of ordinary skill in the art would have had a reason to combine the teachings of the prior art. At this point, we are persuaded that the commonality of the prior art being all in the field of oral analgesic formulations indicates that the hypothetical person of ordinary skill in the art would have considered the use of acetaminophen, agave syrup, and diluent, at a specific viscosity to be merely the combination of known ingredients combined in a known way. (*See* Pet. 29, 55.) “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

Patent Owner also argues that Petitioner has impermissibly relied on the same problem addressed by the challenged '795 patent to provide a rationale to combine the teachings of the prior art. (*See* Prelim. Resp. 9–10.) We are not persuaded that merely because Petitioner notes the prior art indicates the same goals as the '795 patent, Petitioner fails to meet its burden. Instead, at this point in the proceeding, because Petitioner has identified teachings from the prior art of masking the bad taste of analgesics in oral formulations, i.e., independent of the disclosure of the '795 patent, Petitioner has provided a proper rationale for combining the prior art. That the rationale independently suggested by prior art teachings is the same as that of the inventors of the '795 patent contributes to, rather than detracts from, persuading us of the likelihood that at least one claim of the '795 patent is unpatentable at this point in the proceeding because it appears to have been a well-known rationale in the art at the time.

Patent Owner argues further that Petitioner's arguments about the benefits of a low sugar formulation that masks the taste of an active ingredient should not be considered without comparison to FR458. (*See* Prelim. Resp. 12–13.) Patent Owner acknowledges the teachings in FR458, the '4666 patent, and WO133 of the need to mask active ingredient tastes, but argues that these teachings do not explain why a person of skill in the art would have modified FR458, which already teaches the use of agave, a lower-sugar alternative, for this purpose. (*See id.*) At this point in the proceeding, this argument is unpersuasive because, as Petitioner explains, the '4666 patent and WO133 indicate that other elements of claim 1 of the '795 patent would have been obvious, including the viscosity limitation of claim 1. (*See, e.g.,* Pet. 31–32, 57–58.) Accordingly, at this point we are persuaded that it is more likely than not that claim 1 would have been obvious.

Patent Owner argues that Petitioner focuses on why the teachings in the cited references “could be combined” instead of providing a reason why one of ordinary skill in the art *would* have been motivated to modify FR458 and WO742 with the teachings of the ’4666 patent and/or WO133 to arrive at the claimed formulations. (*See* Prelim. Resp. 13–14.) This argument is unpersuasive because Petitioner explains that the claimed formulations merely combine old ingredients to provide the same function in the same field of art. (*See* Pet. 29, 55.) At this point in the proceeding, we agree that combining acetaminophen with agave syrup and diluent, to mask the taste of the acetaminophen, at a viscosity taught in the prior art to be preferable for oral analgesic formulations, would have been obvious to the ordinarily skilled artisan.

Patent Owner argues that Petitioner fails to specifically explain how the recited prior art references differ from the challenged claims. (*See* Prelim. Resp. 14–16.) According to Patent Owner, Petitioner’s “choice to not address this required *Graham* Factor,” renders the grounds of obviousness unclear. (*See id.*) Patent Owner argues that FR458 and WO742 do not disclose the viscosity element recited in the claims of the ’795 patent and that Petitioner fails to acknowledge this and, thus, fails to explain why one of ordinary skill in the art would have modified the teachings of FR458 and WO742 by the teachings of the other references (the ’4666 patent and WO133) cited in Grounds 1 and 2. (*See id.* at 15.)

This argument does not persuade us that Petitioner fails to meet the standard of showing it is “more likely than not” that at least one claim of the ’795 patent is unpatentable. 35 U.S.C. § 324(a). Although the Petition does not indicate whether FR458 or WO742 teaches the viscosity element recited in the claims (*see* Pet. 19–24), it clearly relies on the ’4666 patent and WO133 for their teachings regarding viscosity. (*See* Pet. 24–26.) At this point in the proceeding, we have no difficulty

understanding Petitioner’s presentation of the relevant teachings of the prior art, the differences between these teachings and the limitations of the challenged claims, and the reason why one of ordinary skill in the art would have looked to combine the references recited in Ground 1 and Ground 2.

We note that Patent Owner argues that we should disregard the claim charts provided in Dr. Crowley’s declaration at Appendix D (*see* Ex. 1003, 162–242) because they were improperly incorporated by reference into the Petition. (*See* Prelim. Resp. 17–19.) For purposes of this Decision, we have not relied on Appendix D to Dr. Crowley’s Declaration, as we do not rely on any arguments presented therein unless they are also presented in the Petition. At this point in the proceeding, we are persuaded by Petitioner’s arguments expressly stated in the Petition and the evidence it cites.

III. CONCLUSION

Having reviewed the preliminary record and the parties’ arguments, we are persuaded that Petitioner has met the standard for instituting a trial on the basis of Ground 1 and Ground 2 in regard to claim 1 of the ’795 patent.

Having made the determination regarding claim 1, we decline to further address the other claims of the ’795 patent. We have not made a final determination as to the patentability of any challenged claim or as to the construction of any claim term. Any final determination will be based on the record developed during trial.

Despite that Petitioner’s Ground 3 challenge fails to meet the threshold for institution, we proceed to trial on all three Grounds in light of our determination that each of Grounds 1 and 2 meets the threshold with respect to claim 1. *See* 37 C.F.R. § 42.208(a) (“When instituting post-grant review, the

Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.”).

IV. ORDER

It is hereby

ORDERED that, pursuant to 35 U.S.C. § 324(a), a post-grant review of claims 1–24 of U.S. Patent 11,617,795 B2 is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 324(c) and 37 C.F.R. § 42.4(b), we give notice of the commencement of post-grant review of the '795 patent on the date of this Order.

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Patent 11,617,795 B2

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