

Patent Owner's Notice of Appeal (PGR2023-00051)
U.S. Patent No. 11,617,795

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KINDERFARMS LLC,
Petitioner

v.

GENEXA, INC.,
Patent Owner

Case No. PGR2023-00051

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

PATENT OWNER'S NOTICE OF APPEAL

Pursuant to 35 U.S.C. §§ 141, 142 and 329 and 37 C.F.R. §§ 90.2(a), Patent Owner Genexa, Inc. ("Patent Owner") respectfully gives notice that it appeals to the United States Court of Appeals for the Federal Circuit from the Patent Trial and Appeal Board's ("Board") Final Written Decision entered March 24, 2025 (Paper 39), as well as from all other underlying orders, decisions, rulings, and opinions that are adverse to Patent Owner. A copy of the Final Written Decision is attached.

For the purpose of providing the Director with the information requested under 37 C.F.R. § 90.2(a)(3)(ii), the issues subject to Patent Owner's appeal include, but are not limited to:

(1) the Board's determination that claims 1-24 of U.S. Patent No. 11,617,795 ("the '795 patent") are unpatentable for obviousness under 35 U.S.C. § 103 based on the arguments and theories set forth in Ground 1 of the Petition under the combination of FR458 (Ex.1004), the '4666 patent (Ex.1005), and/or WO133 (Ex.1006);

(2) the Board's determination that claims 1-17 of U.S. Patent No. 11,617,795 ("the '795 patent") are unpatentable for obviousness under 35 U.S.C. § 103 based on the arguments and theories set forth in Ground 2 of the Petition under the combination of WO742 (Ex.1007), the '4666 patent (Ex.1005), and/or WO133 (Ex.1006); and

(3) any and all findings or determinations supporting or related to these
aforementioned determinations.

Pursuant to 37 C.F.R. § 90.3(a)(1), this Notice of Appeal is timely, having
been duly filed within sixty-three (63) days after the Board's March 24, 2025 Final
Written Decision. (*See* Paper 39.)

Simultaneous with this submission, a copy of the Notice of Appeal is being
filed electronically with the Patent Trial and Appeal Board. In addition, a copy of
this Notice of Appeal, along with the required docketing fees, is being electronically
filed with the Clerk's Office for the United States Court of Appeals for the Federal
Circuit.

Dated: April 8, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e)(4)(i) *et seq.*, a complete copy of the attached **NOTICE OF APPEAL**, are being served via email on April 8, 2025, upon Petitioner's appointed attorneys of record:

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I further hereby certify that, in addition to being filed electronically through the Board's electronic filing system, the original version of the foregoing Notice of Appeal was filed by email on April 8, 2025, with the Director of the United States Patent and Trademark Office, at the following address:

Director of the United States Patent and Trademark Office
c/o Office of the Solicitor
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I further hereby certify that on April 8, 2025, a true and correct copy of the foregoing Notice of Appeal, along with the attached copy of the Final Written Decision, was filed electronically via CM/ECF with the Clerk of Court for the United States Court of Appeals for the Federal Circuit, at the following address:

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DATED: April 8, 2025

/s/ Daniel J. Knauss
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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*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 328(a)

I. INTRODUCTION

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

We instituted trial on March 25, 2024. (Paper 8 (“Inst. Dec.”). During trial, Patent Owner filed a Patent Owner Response. (*See* Paper 20 (“PO Resp.”).) Petitioner filed a Reply (Paper 25 (“Pet. Reply”)) and Patent Owner filed a Sur-reply (Paper 29 (“PO Sur-reply”)). An oral hearing was held on December 12, 2024, and a transcript is of record. (Paper 38 (“Tr.”)).

We have jurisdiction under 35 U.S.C. § 6(b). After considering the full record developed through trial, we determine that Petitioner has proved by a preponderance of the evidence that the challenged claims are unpatentable. *See* 35 U.S.C. § 326(e). Our reasoning is explained below, and we issue this Final Written Decision under 35 U.S.C. § 328(a).

A. Real Parties-In-Interest

Petitioner identifies KinderFarms LLC as its real party-in-interest. (*See* Pet. 73.) Patent Owner identifies Genexa Inc. as its real party-in-interest. (*See* Paper 4, 1.)

B. Related Matters

The parties report related matters, including U.S. Application No. 17/817,637, filed on June 8, 2021, as well as U.S. Application Nos. 17/821,134 and 17/821,137, both filed on August 19, 2022, and the litigation, *Genexa, Inc. v. KinderFarms, LLC*, No. 2:23-cv-08378-GW-AGR

(C.D. Cal.), is a related matter. (*See* Pet. 72–73; Mandatory Notices, Paper 4, 1.)

C. The '795 Patent

The '795 patent discloses pharmaceutical syrup formulations for oral administration that address the problem of unnatural and artificial ingredients used to mask the taste of pharmaceutical agents. (*See* Ex. 1001, 1:12–35.) Agave syrup is provided as an alternate ingredient. (*See id.* at 1:31–34.)

Claim 1 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.

(*Id.*, at 5:34–41.) Claims 2–6 depend on claim 1. (*See id.* at 5:42–56.)

Independent claim 7 is similar to claim 1, 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 6:44–58.)

D. Evidence and Grounds of Challenge

Petitioner relies on the following patent evidence.

Name	Patent Document	Exhibit
FR458	FR 2,993,458 A1	1004
'4666 Patent	U.S. 4,684,666	1005
WO133	WO 95/00133 A1	1006
WO742	WO 2012/018742 A2	1007

Petitioner relies on the testimony of Michael Crowley, Ph.D. (*See* Ex. 1003 (“Crowley Decl.”)), and Patent Owner relies on the testimony of Cory J. Berkland, Ph.D. (*see* Ex. 2009 (“Berkland Decl.”).) Both Dr. Crowley and Dr. Berkland testify that they have extensive experience in the pharmaceutical field, including in drug formulations. (*See* Ex. 1003 ¶¶ 4–16; Ex. 2009 ¶¶ 4–15.) Neither party contests the qualifications of the other party’s witness. We find both Dr. Crowley and Dr. Berkland to be qualified to provide opinion testimony on subject matter relevant to the proceeding.

Petitioner asserts that claims 1–24 are unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–24	103	FR458, '4666 Patent, WO133
1–17	103	WO742, '4666 Patent, WO133
1–24	112(b)	Indefiniteness

As an initial matter, we note that Petitioner presents its indefiniteness ground “[i]n the alternative” and argues that the claims are indefinite “[t]o the extent” that Patent Owner makes certain arguments about the scope of the terms “palatable,” “stable,” and “consisting essentially of.” (Pet. 68–72.) In our decision to institute post-grant review, we indicated that we were not persuaded on the record before us at the time by Petitioner’s arguments that the limitations in claims 1–24 are indefinite under 35 U.S.C. § 112(b). (*See* Paper 8, 17–18.) In the Patent Owner Response, Patent Owner states that the indefiniteness ground was premised on positions that Patent Owner did not assert, and therefore, the ground is moot. (PO Resp. 68.) Petitioner does not dispute Patent Owner’s characterization of the alternative indefiniteness ground. (*See generally* Reply.) We agree that Petitioner’s indefiniteness challenge is an alternative to its obviousness challenges and is premised on positions not taken by Patent Owner, and, accordingly, we do not discuss this ground of challenge further as it is moot in view of our resolution of the obviousness challenges.

II. ANALYSIS

A. Legal Standards

In a post-grant review, Petitioner has the burden of proving unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 326(e). The burden never shifts from Petitioner. *Cf. Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (interpreting the corresponding and similarly worded statute for *inter partes* reviews, 35 U.S.C. § 316(e)).

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 Ordinary Skill in the Art

The parties’ positions about the level of ordinary skill in the art are similar. (*See* Pet., 13–14; *see* PO Resp., 10–12.) In light of the parties’ arguments and evidence, we determine that the ordinarily skilled artisan would have had a bachelor of science degree in a relevant life sciences field, such as chemistry, biochemistry, or pharmacy, with at least three to four years of work or laboratory experience in pharmaceutical formulations and would have had access to team members having experience in pharmaceutical formulation and pharmaceutical regulatory approvals. (*See* Pet. 13–14; *see* PO Resp. 10–12; *see* Dec. 6–7.) Both of the parties’ proposals as to the level of ordinary skill in the art are consistent with the disclosure of the ’795 patent and the asserted prior art. The distinction between the parties’ proposals is minimal and would not change the outcome of this Decision. Thus, we adopt and apply Patent Owner’s proposal.

C. Claim Construction

Although Petitioner puts forth constructions for terms in the claims of the '795 patent, Patent Owner argues that we need not expressly construe any terms to resolve the controversy between the parties. (*See* Pet. 14–19; *see* PO Resp. 12.) Except as indicated below, we agree that express construction of the claim terms is not required because the parties do not materially dispute the meanings of the terms. *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))).

Limitation (c) of claim 1 recites “syrup formulation” once and then “syrup” by itself twice. The parties agree that two recitations of “syrup” by itself mean and are synonymous with “syrup formulation.” (*See* Tr. 15:16–19 (counsel for Petitioner: “[T]he term, syrup, by itself, means the formulation. And for that reason, we--it’s our position that it’s the syrup formulation that has the specific viscosity requirements as well as the other features that we discussed.”); 31:17–20 (counsel for Patent Owner: “But those wherein clauses, what it’s referring to, the syrup formulation and the syrup -- it was all to a complete to a final formulation, right, it’s not just the agave syrup. Everybody here recognizes and understands that from that perspective.”).) Thus, the parties agree that the “viscosity of less than 1500 centipoise at about 22 degrees” limits the final “pharmaceutical syrup formulation for oral administration,” not the “agave syrup” limitation in limitation (b) of claim 1.

D. Asserted Prior Art

1. FR458

FR458 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 exemplifies that drugs formulated with organic agave syrup include analgesics, such as “paracetamol” and ibuprofen. (*See* Ex. 1004, 3:86–90, 5:127–133; *see* Pet. 20.) Patent Owner does not dispute that “paracetamol” is an alternative name for acetaminophen commonly used outside of the U.S. (*See* Ex. 1003 ¶ 38.)

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

(Ex. 1004, 8:199–204; *see* Pet. 21; *see* PO Resp. 15–16.) The listed ingredients include paracetamol at 2.5g, certified agave syrup at 45g, xanthan gum at 0.4g, certified agar-agar at 0.2g, glycerin at 5g, sodium citrate at 0.5g, anhydrous citric acid at 0.4g, natural strawberry flavoring at 0.01g, and purified water “Up to 100 ml.” 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, 8:199–204¹; *see* Pet 21; *see* PO Resp. 16.)

¹ The “[sic]” appears in the source document (FR458, Ex. 1004, 8:199–204).

2. WO742

WO742 teaches 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 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),” although a specific viscosity or type of agave syrup is not disclosed. (Ex. 1007, 7:20–23; *see* Pet. 22; *see* PO Resp. 17–19 (citing Ex. 2009 ¶ 104.)

3. '4666 Patent

The '4666 patent teaches stabilized ibuprofen syrup suitable for liquid administration. (*See* Ex. 1005, abstract; *see* Pet. 24.) The '4666 patent teaches that orally administered moderately viscous syrups are 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 syrup of the '4666 patent can include a sweetening agent, although as Patent Owner argues, the '4666 patent does not mention agave syrup. (*See* PO Resp. 19 (citing Ex. 2009 ¶ 87).)

The '4666 patent teaches that the “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; *see* PO Resp. 20.) Claim 11 of the '4666 patent is drawn to a stabilized liquid ibuprofen syrup suitable for oral administration and states that “the viscosity is about 100 to 3000 centipoise at 20° C.” (Ex. 1005, 6:66–67.) There is disagreement between the parties as to whether the “100” is a typographical error and “1000” was intended to be recited instead.

We need not and do not reach this issue because even the range of 1000 to 3000 centipoise, which the '4666 patent clearly teaches, overlaps significantly with the range recited in the challenged claims (i.e., “less than 1500 centipoise”). Also, as explained below, we find that WO133 also teaches a range sufficient to support Petitioner’s patentability challenge.

4. WO133

WO133 teaches oral formulations of acetaminophen in suspension with sweetening agents to mask the taste, although WO133 does not teach using agave as a sweetener. (*See* Ex. 1006, abstract; *see* Pet. 25–26; *see* PO Resp. 21.) 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 the sweetening agent. (*See* Ex. 1006, 2:14–3:18, 5:11–6:6; *see* Pet. 16; *see* PO Resp. 21–22.) 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; *see* PO Resp. 22.) WO133 provides

examples of “viscous suspension[s]” of acetaminophen, including sweetening agents. (*See* Ex. 1006, 9:2–10:8, Examples 1 and 2; *see* Pet. 26.)

E. Ground 1

Petitioner argues that claims 1–24 of the ’795 patent would have been obvious over FR458 in combination with the ’4666 patent and/or WO133, under 35 U.S.C. § 103.² (*See* Pet. 27–33.)

1. Independent Claims 1, 7, 18

(a) Claim 1

Claim 1 is drawn to a pharmaceutical syrup formulation for oral administration that has three ingredients: acetaminophen, agave syrup, and a diluent. (*See* Ex. 1001, 5:34–41.) The syrup formulation of claim 1 must have a viscosity of less than 1500 centipoise at about 22 degrees. The acetaminophen must be suspended in the syrup, and the syrup must be palatable. (*See id.*)

As Petitioner argues, each of FR458, the ’4666 patent, and WO133 relates to “[a] pharmaceutical syrup formulation for oral administration,” as recited in the preamble to claim 1 of the ’795 patent. (*See* Pet. 29–30 (citing Ex. 1003 ¶ 107).) Specifically, FR458 teaches liquid pharmaceutical

² Petitioner asserts that the combination of FR458 and the ’4666 patent, the combination of FR458 and WO133, as well as the combination of all three references, teach each limitation of claim 1 and provide motivation to combine and a reasonable expectation of success, explaining the “and/or” provision in the grounds of challenge. (*See* Pet. 28 n.14.) Patent Owner argues that the “and/or” provision “renders Petitioner’s grounds more ambiguous and lacking sufficient particularity to support a finding of unpatentability” and that “Petitioner does not address each of these three proposed combinations with particularity in a reasonable discernable manner.” (PO Resp. 37–38.) We disagree and, as discussed below, explain why claim 1 would have been obvious as proposed by Petitioner.

preparations for oral administration that include certified organic agave syrup. (*See* Ex. 1004, 1:4–7, 3:58–68.) The ’4666 patent teaches stabilized liquid ibuprofen syrup formulations for oral administration. (*See* Ex. 1005, 1:6–15, 2:4–15.) And WO133 teaches liquid acetaminophen compositions for oral administration that include a sweetening agent, such as honey or corn syrup. (*See* Ex. 1006, 2:14–25, 6:7–25.) Patent Owner does not present argument or evidence to the contrary.

Petitioner argues that FR458, the ’4666 patent, and WO133 each teach formulations for oral administration of acetaminophen. (*See* Pet. 30 (citing Crowley Decl., Ex. 1003 ¶¶ 109–112).) We find that FR458 provides paracetamol (acetaminophen) as an example of an analgesic useful in pharmaceutical suspensions or syrups for oral administration. (*See* Ex. 1004, 5:127–133, Examples 1, 4 (providing ingredients including paracetamol).) We find that the ’4666 patent teaches that acetaminophen is “widely used as an analgesic” that can be formulated as a liquid. (*See* Ex. 1005, 1:18–35.) And we find that the disclosure of WO133 is “relate[d] to acetaminophen compositions in which acetaminophen is presented in taste-masked form.” (*See* Ex. 1006, 1:4–19.) Patent Owner does not present argument or evidence to the contrary.

Petitioner argues that FR458 teaches formulations for oral administration that include both acetaminophen and agave syrup. (*See* Pet. 30 (citing Crowley Decl., Ex. 1003 at ¶¶ 113–115).) We find that it does. (*See* Ex. 1004, pages 8–10 (Examples 1-4).) Patent Owner does not present argument or evidence to the contrary.

Petitioner argues that each of FR458 and the ’4666 patent teach including a diluent, specifically water, in the pharmaceutical formulation for

oral administration. (*See* Pet. 30 (citing Ex. 1003 ¶¶ 116–118).) We find that FR458 provides examples of formulations with active pharmaceutical ingredients (*e.g.*, paracetamol) and agave syrup that include “Purified water Up to 100 ml.” (Ex. 1004, 8–10, Examples 1–4.) We find further that the ’4666 patent provides examples of formulations with analgesics and “Deionized water, q.s.,” wherein the water makes up the remainder of the formulation. (Ex. 1005, 4:45–55 (Example 1).) Patent Owner does not present argument or evidence to the contrary.

Petitioner argues that each of FR458, the ’4666 patent, and WO133 teaches that the active pharmaceutical ingredient can be suspended in an oral formulation. (*See* Pet. 32–33 (citing Ex. 1003 ¶¶ 122–123).) We find that FR458 teaches “pharmaceutical suspensions or syrups for oral administration based on syrups with low glycemic indexes, consisting mainly of certified organic agave syrup alone or in combination with other syrups.” (Ex. 1004, 3:58–68; *see also* 7:187–198, 8:200–202 (Example 1, “The paracetamol is suspended . . . in the syrup to obtain Solution B. Solution A [including agave syrup] is added to Solution B and mixed well.”), 10:225–226 (Example 4, “The ibuprofen and the paracetamol are suspended in the agave syrup to make Solution B.”).) We find that the ’4666 patent teaches masking the unpleasant taste characteristics of ibuprofen when in suspension with sweetness. (*See* Ex. 1005, 3:50–53.) And we find that WO133 teaches that, “when the concentration of additive agent and suspension agent are properly adjusted, the taste of acetaminophen can be masked effectively.” (*See* Ex. 1006, 3:16–18; *see also*, 4:16–28 (“The acetaminophen compositions of the present invention contain a

suspension agent or mixtures of suspension agents.”), 8:17–24, 13:24–14:6.) Patent Owner does not present argument or evidence to the contrary.

Petitioner argues that each of FR458, the ’4666 Patent, and WO133 teaches a syrup that is palatable because each describes formulations that seek to mask the taste of the analgesic included in the oral formulation. (*See* Pet. 33 (citing Crowley Decl., Ex. 1003 ¶¶ 124–128.)) We find that FR458 teaches that some drugs are formulated in suspension to mask unpleasant taste. (*See* Ex. 1004, 2:43–45; *see also* pages 8–10, Examples 1–4 (providing formulations with analgesics and agave syrup).) We find that the ’4666 patent teaches it is desirable to mask the naturally bitter and unpleasant flavor of ibuprofen in a product with high sweetness. (*See* Ex. 1005, 2:19–21, 3:50–53.) And we find that WO133 teaches masking the unpalatable taste of acetaminophen with sweetening agents. (*See* Ex. 1006, 1:19–2:6, 3:8–18, 5:11–26, 9:3–4.) Patent Owner does not present argument or evidence to the contrary.

In summary, we find that all of the cited prior art references are focused on oral formulations that use sweeteners to mask the taste of analgesics. Whereas the ’4666 patent and WO133 provide for suspensions of acetaminophen and sweetening agents in general, FR458 specifically provides for suspensions of acetaminophen and agave syrup. (*See* Pet. Reply 2 (“FR458 discloses nearly all claim elements of claims 1-24 of the ’795 patent.”).) Patent Owner does not present argument or evidence to the contrary.

Furthermore, although Patent Owner disputes the contention that the ’4666 patent teaches oral formulations of analgesics with a viscosity of about 100 to 3000 centipoise at 20° C, Patent Owner does not dispute that

the '4666 patent teaches a range of 1000–3000 cP. Nor does Patent Owner dispute that WO133 teaches oral formulations of acetaminophen in suspension with sweetening agents to mask the taste and make the formulation more palatable, wherein the target viscosity of the resulting oral formulation of from 200 to 900 centipoise, preferably 300 to 700 centipoise. (*See* Ex. 1006, abstract, 7:27–8:3, 9:2–10:8, Examples 1 and 2; *see* Pet. 25–26; *see* PO Resp. 21–22.)

Patent Owner's argument is that Petitioner merely mixes and matches the prior art for individual claim elements, without assessing the obviousness of the claims as a whole. (*See* PO Resp. 23–24, 51–52.) Patent Owner argues that Petitioner fails to articulate a motivation for combining specific disclosures of FR458, the '4666 patent, and WO133. (*See* PO Resp. 40.) We disagree.

Petitioner's arguments persuade us that, although FR458 does not teach a viscosity and WO133 does not use agave syrup as a sweetening agent, one of ordinary skill in the art would have considered the claimed formulations to be obvious in view of their combined teachings. Both references are related to the same problem – making oral formulations of active pharmaceutical ingredients, specifically analgesics, palatable. We are persuaded that one of ordinary skill in the art would have considered it obvious to combine the teachings of each of these references to achieve a sweetened formulation of an analgesic, specifically a suspension of acetaminophen and agave syrup, that has a viscosity between 200 and 900 cP for oral administration.

Petitioner argues that because “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.” (Pet. 31.) Petitioner supports this argument by citing to the testimony of Dr. Crowley that each ingredient in the combination would be carrying out a function it was already known to perform in an oral analgesic formulation and, thus, the result of this combination would have been predictable to one of ordinary skill in the art. (See Ex. 1003 ¶ 102.) Dr. Crowley testifies further that one of ordinary skill would have been able to easily substitute the sweetening agents used in the analgesic formulations disclosed in the ‘4666 Patent and WO133 (e.g., sucrose, sorbitol, etc.) for agave syrup in an amount that would not change the overall sweetness/palatability of the formulation. (See Ex. 1003 ¶ 102.) Thus, Petitioner argues that one of ordinary skill in the art would have considered a palatable oral pharmaceutical syrup formulation including acetaminophen as a suspension, with a viscosity overlapping the range recited in claim 1, as taught in the ‘4666 patent and WO133, and also including agave syrup to mask the unpleasant taste of the acetaminophen, as taught in FR458, to be obvious.

Petitioner argues that “the fact that the viscosity ranges disclosed in WO133 and the ‘4666 patent overlap with [the viscosity range recited in claim 1] creates a presumption of obviousness.” (Pet. 32 n.17 (citing *UCB Inc. v. Actavis Laboratories*, 65 F.4th 679, 689-690 (Fed. Cir. 2023)).) Petitioner argues further that the ‘795 patent does not present any criticality to the viscosity range recited in the claims, but instead merely recites different viscosity ranges. (See Pet. 32 n.17 (citing Ex. 1001, 2:12–28).)

Petitioner also argues that this combination of elements is merely the combination of “old [ingredients] with each performing the same function it

had been known to perform” and that, thus, a person of ordinary skill in the art would be motivated to combine these teachings and would have had a reasonable expectation of success, as discussed in *KSR*, 550 U.S. at 417.³ (See Pet. 29 (citing Crowley Decl., Ex. 1003 ¶¶ 101–103).) Petitioner argues that “[t]he motivation-to-combine analysis is flexible, because ‘a person of ordinary skill in the art is not an automaton.’” (Pet 27 (quoting *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1379 (Fed. Cir. 2023)). *Intel* explains further that “[t]here is a motivation to combine when a known technique ‘has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way.’” *Id.* at 1380 (quoting *KSR*, 550 U.S. at 417).

Patent Owner responds that Petitioner’s argument fails because agave was not a “generally well-known excipient in the pharmaceutical formulations of oral syrups.” (PO Resp. 5, *see also id.* at 58; *see* PO Sur-Reply 21–23.) Patent Owner relies on Dr. Berkland’s testimony that agave syrup was not well-known because it did not have well-defined physical and chemical properties. (See *id.* (citing Ex. 2009 ¶ 46).) Dr. Berkland cites the absence of agave syrup in several pharmaceutical textbooks and the Food and Drug Administration’s “Generally Recognized as Safe” list of additives as evidence that it was not “generally well-known.” (See Ex. 2009 ¶ 46.)

³ Patent Owner argues that Petitioner never articulated a motivation to combine aspects of FR458 or WO742 (discussed below) to achieve the specific viscosities of WO133 or the ’4666 patent and that such arguments were improperly raised in Petitioner’s Reply. (Paper 27, 2–3.) We are not persuaded by Patent Owner’s argument because the Petition explains that the motivation to combine lies in the very similar focuses of the cited prior art references.

We disagree with Patent Owner’s argument and Dr. Berkland’s testimony regarding the obviousness of including agave syrup in a pharmaceutical formulation for oral administration because FR458 clearly teaches the person of ordinary skill that agave syrup can be used as a sweetener in oral formulations with acetaminophen. (*See* Ex. 1004, abstract, 1:5–7, 3:58–68, 8–10 (Examples 1–4), Crowley Decl., Ex. 1003 ¶¶ 113–115.) *See In re Wood*, 599 F.2d 1032, 1036 (CCPA 1979) (“In resolving the question of obviousness under 35 U.S.C. § 103, we presume full knowledge by the inventor of all the prior art in the field of his endeavor.”); *KSR*, 550 U.S. at 416 (“The Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.”)

Patent Owner also argues that Petitioner’s grounds of challenge “rest solely” on unsupported testimony Dr. Crowley provides in paragraph 52 of his declaration regarding a viscosity of agave syrup of 212 cP. (PO Resp. 1; *see also id.* at 24–28; *see* PO Sur-Reply 10–15.) Patent Owner’s argument refers to Petitioner’s statement that

[t]he 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.

(Pet 31.) The cited paragraph 52 of Dr. Crowley’s declaration, in turn, provides “[t]he viscosity of agave syrup is reported to be around 212 mPa-S, or 212 cP, which is less than that of honey or sugar cane syrup. Ex. 1031, at p. 1.” (Ex. 1003 ¶ 52.) Patent Owner cites to other, similar testimony by Dr.

Crowley. (*See* Ex. 1003 ¶ 119 (“As I previously noted at ¶ 52, a person of ordinary skill would have known that agave syrup has a viscosity of 212 centipoise.”).)

Exhibit 1031 does not report a viscosity for agave syrup of 212 cP. (*See* Ex. 1031, 1 (reporting agave syrup viscosity of “2.56 Pa s”).) Patent Owner argues that “the Petition wrongly presumes that agave syrup simply has a viscosity of 212 cP, contrary to Petitioner’s own cited evidence,” and thus the Petitioner’s reliance on 212 cP “is plainly based on an impermissible hindsight-based reconstruction of the claims.” (PO Resp. 26–27.) According to Patent Owner, “[t]his single error is dispositive of the Petitioner’s failure.” (PO Resp. 1; *see also* Tr. 68:17–19 (“And this is the whole problem we have with the petition . . . is that they hinged it on 212.”).)

Petitioner replies that Dr. Crowley mistakenly cited Exhibit 1031 as opposed to Exhibit 1030. (Pet. Reply 10 n.4.) Indeed, Exhibit 1030 reports agave syrup viscosity of 212 +/- 3.5 Pa-s. (Ex. 1030, 5 (Table 4).) Accordingly, we are persuaded that Dr. Crowley’s testimony that the viscosity of agave syrup is reported to be around 212 mPa-S, or 212 cP, is adequately supported. (*Id.*)

Furthermore, even if Dr. Crowley’s testimony concerning the viscosity of agave syrup were completely unsupported, we would not be persuaded that it would be a fatal flaw to Petitioner’s grounds. Patent Owner places an inordinate amount of weight on one line of the Petition regarding an assertion of a viscosity of agave syrup.

Instead, Petitioner makes clear that the teaching regarding Example 1 in FR458 is to be considered with other references that disclose the claimed viscosity limitation. Petitioner argues:

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.*

(Pet. 31 (emphasis added).) Thus, Petitioner does not rely solely on the report of agave syrup having a viscosity of 212 centipoise as Patent Owner argues. Rather, Petitioner relies on the teachings in the '4666 patent and WO133 of viscosities of oral analgesic formulations.

Petitioner argues further that Patent Owner's arguments regarding the viscosity of agave syrup at 212 cP, or other specific values, are not relevant to the grounds of challenge because the relevant viscosity in the claims of the '795 patent is of the formulation, not the agave syrup component by itself. (See Pet. Reply 10.) As we have previously stated, we agree. Claim 1 of the '795 patent recites: "a pharmaceutical syrup formulation for oral administration . . . wherein the syrup formulation has a viscosity of less than 1500 centipoise at about 22 degrees" (Ex. 1001, 5:34–39.) Claim 1 does not require any particular viscosity for the "agave syrup," but does so for the "syrup formulation." Counsel for both parties agreed to this interpretation of the claim language. (See Tr. 15:17–19, 34:17–20.) Thus, even though Petitioner relies on Dr. Crowley's testimony about the report of the viscosity of agave syrup in Exhibit 1031, we find that the viscosity of agave syrup is not a dispositive factor of Petitioner's challenge. (*Contra* PO

Sur-Reply 5 (“But even if Petitioner’s erroneous citation theory is credited, that only demonstrates that the Petition was premised on the erroneous assertion that agave syrup *necessarily* has a viscosity of 212 cP—never acknowledging or addressing any other of the inherently variable viscosity values for agave syrup, including the 2,560 cP value reported in Dr. Crowley’s Exhibit 1031.”).) Because FR458 provides examples with agave syrup that include “Purified water Up to 100 ml,” we are persuaded that one of ordinary skill in the art would be able to achieve a desired viscosity. (Ex. 1004, 8–10, Examples 1–4.)

Rather than relying on the viscosity of agave syrup alone, we are persuaded that Petitioner’s argument relies on the viscosity of pharmaceutical formulations for oral administration as taught in WO133, as well as the ’4666 patent, which would have rendered the claimed pharmaceutical syrup formulation obvious.

Patent Owner argues that Petitioner’s obviousness challenges “are tacitly based on inherency,” with “Petitioner’s expert making the conclusory assertion that agave syrup simply *has* a viscosity of 212 cP,” while ignoring that Exhibit 1031 demonstrates that it was known that agave syrup can have viscosity up to at least 2,560 cP. (PO Resp. 29–30.) As explained above, Petitioner’s grounds of challenge do not rely exclusively on a reported viscosity of agave syrup of 212 cP. Instead, we are persuaded that the grounds of challenge are supported by teachings in the prior art, such as WO133, that show that oral formulations of analgesics preferably have viscosities that overlap with the ranges recited in the claims of the ’795 patent. *See In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981) (“The 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.”).

Patent Owner argues further that Dr. Crowley testifies that, “[g]enerally, suspensions having a viscosity in the range of 20 to 150 cP are considered readily pourable,” but that this range is well below the viscosity range of 200–900 cP taught in WO133 and the preferred viscosity range of 1000–3000 cP taught in the ’4666 patent. (*See* PO Resp. 45 (quoting Ex. 1003 ¶ 59).) Dr. Crowley testifies that “increasing the viscosity of a suspension formulation has been shown to impair the dissolution characteristics of immediate release acetaminophen” and that, “[w]ith respect to suspensions for oral administration, having a higher viscosity is generally not desirable.” (Ex. 1003 ¶ 59.) According to Patent Owner, this is a “teaching away” because

Petitioner’s own expert testimony demonstrates a motivation *not to combine* the acetaminophen formulation of FR458-Example 1 with the 1000-3000 cP range of the ’4666 patent and the 200-900 cP range of WO133 since by his own admission doing so would yield bad results (i.e., impairing the dissolution characteristics of the acetaminophen) and generally undesirable higher viscosity.

(PO Resp. 46 (citing Berkland Decl., Ex. 2009 ¶ 148).)

Dr. Crowley’s cited testimony, however, is about general characteristics of suspensions for oral administration, whereas the WO133 refers specifically to sweetened analgesic formulations. (*See* Ex. 1006, 8:1–3 (“The viscosity of the acetaminophen composition generally ranges from about 200–900 centipoise, preferably from about 300–700 centipoise.”); *see*

Pet. Reply 8–9.) As Petitioner notes, Dr. Crowley also testifies that the viscosity of 29 commercially available, pediatric liquid oral antibiotic formulations were measured and determined to range from 20 to 1,780 cP” and that “[t]he viscosity of Children’s Tylenol has been reported to be less than 1,000 centipoise at shear rates between 0.05 and 0.2 reciprocal seconds.” (Ex. 1005 ¶ 58.) Thus, we are not persuaded that Dr. Crowley’s testimony contradicts the teachings regarding viscosity of analgesic formulations in the cited prior art.

Patent Owner also argues that Petitioner fails to explain how the resulting viscosity of the formulation in Example 1 of FR458 would meet both the preferred 1000–3000 cP range of the ’4666 patent and the 200–900 cP range of WO133, if agave syrup with a viscosity of 212 cP were used. (*See* PO Resp. 48–51.) Patent Owner relies on Dr. Berkland’s testimony that one of ordinary skill in the art would have understood that using an agave syrup of 212 cP in Example 1 of FR458 would result in a viscosity of the overall formulation that is “certainly well below 200 cP and more likely than not below 100 cP.” (Ex. 2009 ¶ 150.) This argument is not persuasive because, as explained above, we are not persuaded that the grounds of challenge are based on the agave syrup in Example 1 of FR458 necessarily having a viscosity of 212 cP.

In the Sur-reply, Patent Owner argues that the Petitioner’s Reply improperly asserts new theories of obviousness that are based only on attorney argument. (*See* PO Sur-Reply 1.) Patent Owner argues that instead of addressing what Patent Owner asserts are flaws in the Petition,

Petitioner’s Reply attempts to pivot by asserting, without evidence, that “a POSA [person of ordinary skill in the art] would be capable of selecting an agave syrup with appropriate

viscosity and, if necessary, adjusting the water content and/or other components to achieve the desired final viscosity.”
(Reply, 11; *see also* Reply at 19 (same), 20 (same).)

(PO Sur-Reply 5, 15–20.) Specifically, Patent Owner argues that the Petition never mentioned selecting a viscosity for agave syrup, but instead relied on Dr. Crowley’s incorrect assertion that one of ordinary skill in the art would have known there was only one viscosity of agave syrup – 212 cP. (*See* Sur-Reply 6–10 (citing Crowley Decl., Ex. 1003 ¶ 119).) Patent Owner argues that the Petition did not propose a reason to combine the teachings of FR458 with the ’4666 patent and/or WO133 if agave syrup had the viscosity reported in Exhibit 1031 of 2,560 cP. (*See* Sur-Reply 7.)

Similarly, Patent Owner identifies passages on page 11, 19, 20, and 21 of Petitioner’s Reply, which refer to the ability of one of ordinary skill in the art to select an agave syrup with an appropriate viscosity or adjust the viscosity, as being improper. (*See* Paper 27, 1–2.) As discussed above and below, we are persuaded by the grounds of challenge articulated in the Petition. Because we rely on Petitioner’s arguments in the Petition, we need not reach Patent Owner’s arguments about certain of Petitioner’s Reply being improper.

After considering the arguments and evidence Petitioner presents in the Petition, in light of Patent Owner’s arguments and evidence, we are persuaded that the pharmaceutical syrup formulation recited in claim 1 would have been considered to be obvious by one of ordinary skill in the art over the prior art.

(b) Claim 7

Independent claim 7 is similar to claim 1, requiring an acidic preservative and a flavoring agent. (Ex. 1001, 5:57–6:5.) Claim 7 recites:

A stable pharmaceutical syrup formulation for oral administration comprising:
(a) 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 wherein the acetaminophen is suspended in the syrup.

(*Id.*) Petitioner puts forth the same arguments for the obviousness of the limitations of claim 7 that are also present in claim 1 (i.e., acetaminophen in suspension, agave syrup, diluent, and viscosity less than 1500 centipoise). (*See* Pet. 39.) For the reasons discussed above, we are persuaded by Petitioner's arguments regarding the obviousness of claim 7.

In regard to the limitation (c) of an acidic preservative, Petitioner argues that both FR458 and WO133 teach acidic preservatives in the orally administered formulations of analgesics. (*See* Pet. 40 (citing Ex. 1004, 6:172–181 (Example 1); Ex. 1006, 7:11–26).) Petitioner argues further that FR458, WO133, and the '4666 patent teach flavorings in oral analgesic formulations. (*See* Pet. 40–41 (citing Ex. 1004, 7:182–184 (natural flavoring), 8 (Example 1, natural strawberry flavoring and Example 2, natural lemon flavoring); Ex. 1006, 7:5–10, 8:15–16; Ex. 1005, 4:18–20).) Patent Owner does not dispute Petitioner's arguments regarding the teachings of the prior art.

We are persuaded by Petitioner's arguments because we find that the prior art teaches these elements. We agree with Petitioner that because the prior art is very closely related, each being drawn to sweetened oral analgesic formulations, one of ordinary skill in the art would have had

reason to combine their teachings to arrive at claim 7 with a reasonable expectation of success. (*See* Pet. 41.)

(c) *Claim 18*

Independent claim 18 is similar to independent claims 1 and 7, but uses the transition phrase “consisting essentially,” instead of “comprising,” reciting:

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.

(Ex. 1001, 6:36–43.) Petitioner puts forth the same arguments for the obviousness of the limitations of claim 18 that are also present in claim 1 (i.e., acetaminophen in suspension, agave syrup, diluent, and viscosity less than 1500 centipoise). (*See* Pet. 47.) For the reasons discussed above, we are persuaded by Petitioner’s arguments regarding the obviousness of these limitations.

Petitioner argues that the transition phrase “consisting essentially of” requires the presence of each of the listed items and other items that do not materially affect the basic and novel properties of the invention. (*See* Pet. 48.) Petitioner argues that Example 1 of FR458 includes a therapeutically effective amount of acetaminophen (paracetamol), agave syrup, the acidic preservatives anhydrous citric acid and sodium citrate, a flavoring agent, and water as a diluent. (Pet. 48 (citing Ex. 1004, page 8 (Example 1).) Example 1 of FR458 includes additional ingredients, specifically xanthan

gum, certified agar-agar, and glycerin, which Petitioner argues would not materially affect the basic and novel properties of the invention described in the '795 patent. (*See* Pet. 49–50 (citing Crowley Decl., Ex. 1003 ¶¶ 179–182).) Petitioner argues that the '795 patent suggests optional exclusion of unnatural and artificial ingredients from the disclosed pharmaceutical formulations, but does not indicate whether these items would materially affect the basic and novel properties of the invention. (*See* Pet. 49 (citing Ex. 1003 ¶¶ 179–180).) We note that claim 18 does not include a limitation excluding nonnatural or artificial ingredients. (Ex. 1001, 6:36–43.)

Petitioner relies on the testimony of Dr. Crowley and the specification of the '795 patent to argue that xanthan gum, certified agar-agar, and glycerin are natural ingredients found in other formulations and would not materially affect the basic and novel properties of the claimed formulation. (*See* Pet. 50 (citing Ex. 1003 ¶ 181.) Patent Owner does not argue to the contrary.

We are persuaded by Petitioner's arguments and cited evidence in the Petition that one of ordinary skill in the art would have considered the formulation recited in claim 18 to have been obvious in light of Dr. Crowley's testimony that the basic and novel properties of the claimed formulation would not have been materially changed with the additional ingredients. *See PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998) ("By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.").

2. Dependent claims 2–4, 15, and 19

Dependent claims 2–4, 15, and 19 further limit the scope of independent claims 1, 7, and 18 by reciting the viscosity range as “less than 1000 centipoise,” “less than 750 centipoise,” “less than 600 centipoise,” or “from about 1500 centipoise to about 400 centipoise,” each at about 22 degrees. (Ex. 1001, 5:42–6:47.) Petitioner argues that each of these ranges is disclosed in or overlaps with the ranges taught in the prior art references. (See Pet. 34.) Petitioner cites, for example, WO133, which teaches the range of viscosity of 200 to 900 centipoise. (See *id.* (citing Ex. 1006, 7:27–8:4; Crowley Decl., Ex. 1003 ¶¶ 132–133).)

Patent Owner argues that Petitioner “merely alleges in conclusory fashion” that the ranges recited in the dependent claims would have been obvious by relying on the “obvious error” in claim 11 of the ’4666 patent. (PO Resp. 53–54.) Although Patent Owner also acknowledges the teaching in WO133 of a viscosity range of 200 to 900 centipoise, Patent Owner focuses on the disclosure of the ’4666 patent and on Petitioner’s statement regarding the viscosity of agave syrup at 212 cP. (See *id.*) As explained above, we are not persuaded by Patent Owner’s assertions that either of these facts is fatal to Petitioner’s challenges of the claims as being obvious at least because, even if we disregard the teachings of the ’4666 patent and the assertion of the viscosity of agave syrup, the combination of the teachings of FR458 and WO133 would have rendered the claimed formulations obvious.

We are persuaded that one of ordinary skill in the art would have considered dependent claims 2–4, 15, and 19 to have been obvious.

3. Dependent claims 5, 6, and 8

Dependent claims 5, 6, and 8 recite different concentrations of acetaminophen – “0.01 to 2 grams of acetaminophen” per 100 mL of syrup in claim 5, “0.01 to 1 grams of acetaminophen” per 100mL of syrup in claim 6, and “between 0.01 to 2% of the formulation by weight” in claim 8. (Ex. 1001, 4:51–6:8.) Petitioner cites Dr. Crowley’s testimony that WO133 teaches that acetaminophen can be present at “up to about 10% by weight,” which one of ordinary skill would have known includes acetaminophen concentrations that are less than 1 g/100 mL of formulation. (*See* Pet. 34–35 (citing Ex. 1006, 2:16–19; Ex. 1003 ¶ 136).)⁴ The record supports Petitioner’s argument.

Patent Owner argues that the ranges of acetaminophen taught in FR458 and WO133 are so broad that obviousness due to overlap with the claimed ranges does not apply. (*See* PO Resp. 54–55.) Patent Owner argues further that Petitioner fails to address the claims as a whole and fails to address how the broad ranges of acetaminophen taught in FR458 and WO133 could be added without impacting the viscosity. (*See* PO Resp. 55.)

These arguments are unpersuasive. First, the ranges recited in the claims are not much narrower than the ranges taught in the prior art. Thus, we are not persuaded that the breadth of ranges in the prior art would not indicate obviousness. *Cf. In re Baird*, 16 F.3d 380, 383 (Fed. Cir. 1994) (“A disclosure of millions of compounds does not render obvious a claim to three compounds, particularly when that disclosure indicates a preference

⁴ Patent Owner argues that Petitioner improperly relies on ranges of acetaminophen in FR458 for the first time in the Reply. (*See* Paper 27, 3.) Because we do not rely on Petitioner’s Reply, this argument is moot.

leading away from the claimed compounds.”). Because the ranges of acetaminophen recited in the claims are encompassed by or overlap with the ranges taught in the prior art, there is a presumption that the claimed ranges would have been obvious. *See Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004) (“[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness.”); *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (“In cases involving overlapping ranges, we and our predecessor court have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness.”). Patent Owner does not direct us to evidence rebutting the *prima facie* case presented by Petitioner, for example that the claimed range achieves unexpected results.

Furthermore, because WO133 teaches that acetaminophen can be present at up to 10% in formulations for oral administration and also teaches that the preferable viscosity range is 200 to 900 cP, we are persuaded that one of ordinary skill in the art would have understood a therapeutically effective amount of acetaminophen would be achievable with the viscosity range. (*See* Ex. 1006, 2:16–19, 7:27–8:3.)

4. Dependent claim 9–13 and 22–24

Dependent claims 9–13 and 22–24 limit the diluent and agave syrup in the pharmaceutical syrup formulations of the independent claims. (*See* Ex. 1001, 6:9–22, 6:55–58.) Dependent claim 9 limits the diluent in the pharmaceutical formulation of claim 7 to “about 5% of the formulation by weight,” and dependent claim 12 limits the diluent in the pharmaceutical formulation of claim 7 to water. (*Id.* at 6:9–11, 6:17–18.)

Petitioner argues that FR458 teaches water is added to the formulation as required to bring the volume up to the total desired amount, thus rendering the amount of diluent recited in claim 9 obvious because one of ordinary skill in the art would have understood that the amount of water could be modified “within reason without altering the effectiveness of the formulation.” (Pet. 42 (citing Ex. 1003 ¶ 155; Ex. 1004, 8:199–204 (“the water is topped up to 100 mL and everything is mixed together”).))

Dr. Crowley testifies that one of ordinary skill in the art would have understood from at least FR458 and WO133 that limiting the amount of diluent can help reduce the dissolution of the active pharmaceutical ingredient in the composition, which is advantageous if the ingredient is bitter or unpleasant-tasting when dissolved. (*See* Ex. 1003 ¶ 155 (citing Ex. 1006, 3:8–18 (“It has surprisingly been found that when the concentration of the additive agent and suspension agent are properly adjusted, the taste of the acetaminophen can be masked effectively.”))).)

Patent Owner relies on Dr. Berkland’s testimony to argue that Example 1 of FR458 is at least about 45% water and that a change in the formulation of Example 1 from 45% to 5% diluent, as recited in claim 9, is “far greater” and would not be “within reason.” (PO Resp. 55 (citing Ex. 2009 ¶¶ 160–161).) Patent Owner argues that Petitioner fails to identify anything lacking in Example 1 of FR458 that would justify changing it. (*See* PO Resp. 55–56.) Patent Owner argues further that Petitioner fails to address the claims as a whole by failing to address the expected significant viscosity changes of any purported modification of FR458 when so much of its water is removed. (*See* PO Resp. 56.)

We are persuaded by Petitioner’s arguments that the cited prior art encompasses the amount of diluent (water) recited in claim 9 and would have rendered the amount of diluent obvious because WO133 teaches that adjusting the concentration of the diluent is helpful in masking the taste of acetaminophen and FR458 teaches that the amount of water as a diluent is variable. (*See* Ex. 1006, 3:8–18; Ex. 1004, 8:199–204.) Patent Owner does not dispute Dr. Crowley’s testimony in support. (*See* Ex. 1003 ¶ 155.) Because, as Dr. Crowley notes and Patent Owner does not dispute, the ’795 patent does not explain why “about 5% diluent” is critical in a formulation as claimed, we are persuaded that the teachings of the prior art to adjust water as needed render the claimed formulation obvious. (*See id.*)

Accordingly, we are persuaded that the pharmaceutical syrup formulations of claims 9 and 12 would have been obvious over the teachings of the prior art.

Dependent claims 10, 11, and 13, which depend on claim 7, limit the agave syrup in the pharmaceutical formulation of claim 7 to “less than 98%,” “less than 95%,” and “about 95%,” respectively. (Ex. 1001, 6:12–22.) Dependent claims 22, 23, and 24 limit the agave syrup in the pharmaceutical formulation of claim 18 to “less than 98%,” “less than 95%,” and “about 95%,” respectively. (*See* Ex. 1001, 6:54–59.) Petitioner argues, relying on Dr. Crowley’s testimony, that FR458 describes formulations with agave syrup at concentrations of less than 98% and 95%. (*See* Pet. 43 (citing Ex. 1004, 8–10, Examples 1–4; Ex. 1003 ¶¶ 157, 161–162).) Petitioner also relies on Dr. Crowley’s testimony that one of ordinary skill in the art would have understood the amount of agave syrup in a formulation to

be a design choice using skills that the ordinarily skilled artisan would have. (*See* Pet. 43 (citing Ex. 1003 ¶¶ 161–164).)

Patent Owner argues, relying on Dr. Berkland’s testimony, that the agave syrup in Example 1 of FR458 is less than 45% of the formulation by weight and that Petitioner puts forth a conclusory argument that this amount is merely a design choice. (*See* PO Resp. 56 (citing Ex. 2009 ¶ 163).)

Patent Owner argues that Petitioner fails to address the claims as a whole, failing to show how a modification to the amount agave syrup would impact the viscosity of Example 1 of FR458. (*See id.*)

Petitioner’s arguments are supported by the teachings of FR458 and Dr. Crowley’s testimony that it would have been within the skill of one of ordinary skill in the art to make the design choices necessary for the percentages recited in the challenged claims. (*See* Ex. 1003 ¶¶ 161–163.) We are persuaded that the percentages recited in claims 10, 11, 13, 22, 23, and 24 are taught by, and would have been obvious over, the prior art. (*See* Ex. 1003 ¶¶ 161–163; *see* Pet. 43.).

Accordingly, we are persuaded that claims 10, 11, 13, 22, 23, and 24 would have been obvious over the teachings of the prior art.

5. Dependent claims 14, 16 and 17

Petitioner argues that claims 14, 16, and 17 would have been obvious by citing to the teachings of the prior art. (*See* Pet. 44–46.) Patent Owner does not cite to contradictory evidence.

Specifically, dependent claim 14 recites the pharmaceutical syrup formulation of claim 13, “wherein the acidic preservative comprises citric acid.” (Ex. 1001, 6:23–24.) Petitioner argues that FR458 and WO133 teach using citric acid in the oral formulations disclosed and, thus, claim 14 would

have been obvious. (*See* Pet. 44 (citing Ex. 1004, page 8 (Example 1); Ex. 1006, 7:24–26).) Patent Owner does not argue to the contrary.

Dependent claim 16 recites the pharmaceutical syrup formulation of claim 7 “wherein the formulation is orally administered for veterinary and human use.” (Ex. 1001, 6:30–32.) Petitioner relies on Dr. Crowley’s testimony that it would have been known that the oral pharmaceutical formulations of FR458, the ’4666 patent, and WO133 would likely be administered to humans and other mammals and, thus, the further limitation of claim 16 would have been obvious. (*See* Pet. 45 (citing Ex. 1003 ¶¶ 170–172).) Patent Owner does not argue to the contrary.

Dependent claim 17 limits the pharmaceutical syrup formulation of claim 7, “wherein the flavoring agent is a bitter-taste-blocking ingredient.” (Ex. 1001, 6:32–34.) Petitioner argues FR458, the ’4666 patent, and WO133 are all directed to masking the bitter taste of analgesics in oral formulations and, thus, claim 17 would have been obvious. (*See* Pet. 46 (citing Ex. 1004, 2:39–45; Ex. 1005, 2:3–21; Ex. 1006, 1:4–2).) Patent Owner does not argue to the contrary.

We are persuaded that claims 14, 16, and 17 would have been obvious because the evidence Petitioner cites supports the arguments presented.

6. Dependent claims 20 and 21

Dependent claims 20 and 21 both recite: “The formulation of claim 18, wherein the pharmaceutical syrup formulation has a viscosity of less than 1500 centipoise at about 22 degrees.” (Ex. 1001, 6:47–52.) As Petitioner argues, and Patent Owner does not dispute, claims 20 and 21 are identical and neither limits the scope of claim 18, on which they both depend, because claim 18 recites the limitation “wherein the syrup

formulation has a viscosity of less than 1500 centipoise at about 22 degrees.” (Ex. 1001, 6:41–43; *see* Pet. 53.) Thus, we are persuaded that they are unpatentable for the reasons discussed above in regard to claim 18.

7. Conclusion

We are persuaded by the arguments and evidence that Petitioner cites that Ground 1 renders all of the claims of the ’795 patent obvious. Patent Owner’s arguments and evidence do not persuade us to the contrary.⁵

F. Ground 2

Petitioner argues that claims 1–17 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.) We are persuaded that one of ordinary skill in the art would have considered the formulation recited in claim 1 to be obvious in light of the teachings of WO742 in combination with either WO133 or the ’4666 patent or with both references together, we are persuaded that the grounds of challenge articulated in the Petition are sufficient for a finding of unpatentability. Patent Owner opposes. (PO Resp. 57.)

1. Independent Claims

Petitioner argues that WO742 teaches agave-based formulations that include dextromethorphan and other active pharmaceutical ingredients, including acetaminophen, as safer forms of oral pharmaceutical formulations. (*See* Pet. 54, 56–57 (citing Ex. 1007, 16:7–25, 13:21–27, 13:27–15:57.) WO742 provides embodiments, wherein “the liquid

⁵ Petitioner and Patent Owner each filed objections to the other’s demonstratives. (*See* Papers 36, 37.) Because we do not rely on the information in either party’s demonstratives in reaching our decision, the parties’ arguments are moot.

composition is administered at a dose of about 15 ml and comprises about 18 mg of dextromethorphan hydrochloride, monohydrate, about 325 mg acetaminophen, about 6.25 mg doxylamine succinate, and about 11 ml of agave nectar.” (Ex. 1007, 16:17–20.) Petitioner cites to Examples V and IX of WO742, which both include 11 ml of agave nectar and acetaminophen at 325 mg and 160 mg, respectively, along with other ingredients. (See Pet. 56–57 (citing Ex. 1007, 21:30–22:10, 23:17–29).) The total volume of the formulations in Examples V and IX of WO742 is made up with “Water, Purified q.s.” (See Ex. 1007, 21:30–22:10, 23:17–29; see Pet. 57.) WO742 also teaches that the acetaminophen can be provided in a suspension. (See Ex. 1007, 13:7–10; see Pet. 58.)

Accordingly, WO742 teaches a pharmaceutical syrup formulation for oral administration comprising (a) acetaminophen, (b) agave syrup, and (c) a diluent, wherein the acetaminophen is suspended in the syrup and the syrup is palatable, even though WO742 does not expressly teach the viscosity of this formulation. Patent Owner does not argue to the contrary regarding these elements of claim 1 of the ’795 patent.

In addition to restating that “[t]he viscosity of agave syrup is reported to be about 212 centipoise. Ex. 1003 at ¶ 52,” Petitioner states:

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. . . . 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. Ex. 1003 at ¶¶ 215-218.

(Pet. 57–58 (footnote omitted).) Thus, as in Ground 1, Petitioner relies on the viscosity ranges for an oral formulation of analgesic taught in the ’4666

patent and WO133 to show that the viscosity limitation of claim 1 would have been obvious to one of ordinary skill in the art.

Petitioner argues that WO742, the '4666 patent, and WO133 are in the same field, each discussing the creation of oral formulations with an analgesic. (*See* Pet. 55 (citing Ex. 1003 ¶ 196).) Petitioner argues further that, because each of the cited references discusses acetaminophen, one of ordinary skill in the art would have had a reason to combine their teachings and would have had a reasonable expectation of success doing so. (*See id.*) As in Ground 1, Petitioner argues, citing *KSR*, that one of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of WO742, the '4666 patent, and WO133 because each discloses formulations comprising known ingredients performing known functions. (*See* Pet. 55 (citing Ex. 1003 ¶¶ 195–198).)

In regard to independent claim 7, Petitioner argues that WO133 teaches including acidic preservatives, such as citric acid, and flavorants in the formulations it discloses. (*See* Pet. 61–63, 66 (citing Ex. 1006, 7:11–26; Ex. 1007, 20:18–23:29 (Examples I–IX)).)

Patent Owner presents many of the same arguments against Petitioner's second ground of challenge based on WO742 as presented against the first ground of challenge based on FR458 in regard to claim 1. (*See* PO Resp. 57–63.) For example, Patent Owner argues that agave syrup was not a well-known ingredient. (*See id.* at 57–58.) We are not persuaded by this argument for the reasons discussed above in regard to Ground 1. We are persuaded that agave syrup was known because at least WO742 teaches using it in pharmaceutical formulations including acetaminophen for oral

administration in order to mask the unpleasant taste. (*See* Ex. 1007, 9:18–21.)

Patent Owner also argues that Petitioner does not provide a reason to combine the disclosures or teachings of WO742, the '4666 patent, or WO133 with a reasonable expectation of success, relying on the “clearly erroneous” viscosity of agave syrup (212 cP), rather than the viscosity of the formulations provided in Example IX of WO742. (*See* PO Resp. 58–60.) As in regard to Ground 1, Patent Owner argues that one of ordinary skill in the art would have known that Example IX of WO742 would have a viscosity of at most approximately 100 cP if agave syrup with a viscosity of 212 cP was used due to the other ingredients present, referring to Dr. Crowley’s statement of a reported viscosity of agave syrup. (*See* PO Resp. 61–62 (citing Berkland Decl., Ex. 2009 ¶¶ 168–170).) Patent Owner argues that one of ordinary skill in the art would have no reason to combine and no reasonable expectation of success in using an agave syrup with a viscosity of 212 cP with the formulation taught in Example IX of WO742 to achieve the viscosities taught in the '4666 patent and WO133 for orally administered formulations. (*See* PO Resp. 62–63 (citing Ex. 2009 ¶ 171).)

We are not persuaded by Patent Owner’s arguments, for reasons similar to those discussed regarding Ground 1 and FR458. More specifically, Ground 2 is not based on the agave syrup in the examples of WO742 necessarily having a viscosity of 212 cP. Petitioner clearly states that, because “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.” (Pet. 57–58.) We are persuaded that

Petitioner's grounds of challenge are based on the obviousness of the viscosity of the formulation as a whole, as taught in the prior art, for example WO133. Patent Owner again places undue emphasis on the statements in the Petition that "[t]he viscosity of agave syrup has been reported to be about 212 centipoise." (Pet. 57.)

After considering the arguments and evidence presented by both parties, we are persuaded that one of ordinary skill in the art would have considered the formulation recited in claims 1 and 7 to have been obvious.

2. Dependent Claims

Petitioner presents similar arguments for the unpatentability of the challenged dependent claims in regard to the challenges under Ground 2 as for the challenges of the same claims under Ground 1. (*See* Pet. 59–61, 64–68.) For example, Petitioner argues that the '4666 patent and WO133 each disclose viscosity ranges that overlap with the viscosity ranges recited in claims 2, 3, 4, and 15. (*See* Pet. 60, 66 (citing Ex. 1005, 6:66–67; Ex. 1006, 7:27–8:4; Crowley Decl., Ex. 1003 ¶¶ 227–228, 258–260).) Patent Owner raises similar arguments against these challenges as raised against the challenges to claim 1, for example that the viscosity range recited in claim 11 of the '4666 patent is an error and that the formulation of Example X of WO742 would have a viscosity well below 200 cP if an agave syrup with 212 cP was used. (*See* PO Resp. 64.)

Petitioner argues further that WO133 and WO742 disclose different concentrations of acetaminophen, which overlap with the concentrations recited in claims 5, 6, and 8. (*See* Pet. 60–61, 64.) Claim 5 recites 0.01 to 2g of acetaminophen per 100 mL, claim 6 recites 0.01 to 1g of acetaminophen per 100 mL, and claim 8 recites 0.01 to 2% of

acetaminophen by weight. (*See* Ex. 1001, 5:51–56, 6:6–8.) Petitioner argues that WO133 teaches amounts of acetaminophen including up to 10% by weight, which would be understood to be less than 1 g/100mL, and that WO742 teaches formulations with different amounts of acetaminophen.⁶ (*See* Pet. 60–61, 64 (citing Ex. 1006, 2:16–19, 4:8–15; Ex. 1007, 21:30–22:10, 23:17–28 (Examples V and IX); Crowley Decl., Ex. 1003 ¶¶ 230–231, 245–246.) Petitioner argues that one of ordinary skill in the art would have been familiar with various oral formulations that include analgesics like acetaminophen and that Dr. Crowley testifies that “the concentration of acetaminophen in the liquid formulation must be carefully chosen to avoid having to administer very large volumes or very minute volumes of the formulation to get a therapeutically effective dose.” (Ex. 1003 ¶ 230; *see* Pet. 60.)

Patent Owner argues that Petitioner fails to address the claims as a whole and fails to address how the broad ranges of acetaminophen taught in WO742 and WO133 could be achieved without impacting the viscosity. (*See* PO Resp. 65.) As discussed above, in regard to the challenge under Ground 1, these arguments are unpersuasive because of the teachings of WO133 regarding the ranges of acetaminophen that overlap with the

⁶ Patent Owner argues that Petitioner’s argument that WO133 teaches a narrower range of 2% to 5% is a new argument in the Petitioner’s Reply. (*See* Paper 27, 3.) Because we do not rely on this teaching, being persuaded by the Petition’s argument that one of ordinary skill in the art would have considered the ranges of acetaminophen recited in claims 5 and 6 to be obvious in light of the teaching in WO133 that acetaminophen can be present up to 10% of the formulation and that those of ordinary skill in the art would have known that concentrations must be carefully chosen, Patent Owner’s argument is moot. (*See* Pet. 60–61, 64.)

claimed ranges and of the preferable viscosity range being 200 to 900 cP. (*See* Ex. 1006, 2:16–19, 7:27–8:3.) Patent Owner argues further that “1 mg per 100 mL,” which is taught in Example IX of WO742 and equals 0.001 g per 100 mL, is below the lower limit of the claimed range of 0.01 g per 100 mL recited in claims 5 and 6. (PO Resp. 65.) Nevertheless, WO133 teaches a range that overlaps with the claimed ranges. (*See* Crowley Decl., Ex. 1003 ¶ 230.) Accordingly, we are persuaded that the formulations recited in claims 5, 6, and 8 would have been obvious over the references of Ground 2.

In regard to claims 9 and 12, Petitioner argues that WO742 discloses “Water, Purified q.s.” in the exemplified formulations, indicating a sufficient amount of water to achieve the desired volume and that the amount of water is variable. (*See* Pet. 64–65 (citing Ex. 1007, 21:30–22:10 (Example V); Ex. 1003 ¶¶ 247–248, 251–252).)

Patent Owner argues that Petitioner does not discuss the amount of added water in Example 1 of WO742 and does not explain whether water would have to be added or removed to achieve 5% of the formulation. (*See* PO Resp. 66.) Patent Owner argues that Petitioner fails to address why a POSA would find anything lacking in Example IX of WO742 to justify changing it. (*See id.*) Patent Owner relies on Dr. Berkland’s testimony to argue that changes in the amount of water in a formulation can have significant impacts on the viscosity of the formulation. (*See* PO Resp. 67 (citing Ex. 2009 ¶ 55).)

We are persuaded by Petitioner’s arguments because the challenge is based on obviousness, not anticipation, and, therefore WO742 need not teach each and every specific element of the claimed formulations. Rather, we are persuaded that one of ordinary skill in the art would have understood

from the notation “q.s.” that different amounts of water could be chosen for different formulations because the amount is not critical. Even if the amount impacts viscosity as Dr. Berkland testifies, we are persuaded that one of ordinary skill in the art would have understood that an amount of water could be used that would achieve the claimed limitations. (*See* Crowley Decl., Ex. 1003 ¶ 247.) Patent Owner fails to direct us to any evidence that the amount of water is critical. (*See* Crowley Decl., Ex. 1003 ¶ 247.) The arguments and evidence cited by Petitioner persuade us that claims 9 and 12 would have been obvious.

Petitioner argues further that WO742 teaches agave syrup at concentrations that render the concentrations recited in claims 10 (less than 98%), 11 (less than 95%), and 13 (about 95%) obvious and that the amount of agave syrup in a formulation would have been a design choice within the general knowledge of one of ordinary skill in the art. (*See* Pet. 65–66 (citing Ex. 1007, 21:30–22:10, 23:16–29; Ex. 1003 ¶¶ 249–257).)

As in response to Petitioner’s challenges under Ground 1, Patent Owner argues that Petitioner’s conclusory assertion of a “design choice” cannot support obviousness. (*See* PO Resp. 67.) *See In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 364, 1380 (Fed. Cir. 2016). Patent Owner does not cite to evidence contradicting Dr. Crowley’s testimony. We are persuaded by Petitioner’s challenge in light of Dr. Crowley’s testimony about the knowledge, skill, and design choices of one of ordinary skill in the art. (*See* Ex. 1003 ¶¶ 249–257.)

Petitioner relies on Dr. Crowley’s testimony that it would have been known that the oral pharmaceutical formulation of WO742, the ’4666 patent, and WO133 would likely be administered to humans and other mammals

and that, thus, the further limitation of claim 16 would have been obvious. (*See* Pet. 67 (citing Ex. 1003 ¶¶ 261–263).) Patent Owner does not argue to the contrary. We are persuaded by Petitioner’s challenge.

Petitioner argues WO742, the ’4666 patent, and WO133 are all directed to masking the bitter taste of analgesics in oral formulations and that, thus, claim 17 would have been obvious. (*See* Pet. 67–68 (citing Ex. 1007, 21:30–22:10 (Example V); Ex. 1005, 2:3–22; Ex. 1006, 1:4–17; Ex. 1003 ¶¶ 264–265).) Patent Owner does not argue to the contrary. Again, we are persuaded by Petitioner’s challenge.

3. Conclusion

We are persuaded by the arguments and evidence that Petitioner cites that Ground 2 renders claims 1–17 of the ’795 patent obvious.

III. CONCLUSION⁷

For the reasons given, based on the arguments and evidence of record, Petitioner has met the burden to prove by a preponderance of the evidence that claims 1–24 of the '795 patent are unpatentable under 35 U.S.C. § 103 as obvious. As discussed above, the grounds of challenge under 35 U.S.C. § 112(b) is moot.

In summary:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–24	103	FR458, the '4666 patent, WO133	1–24	
1–17	103	WO742, the '4666 patent, WO133	1–17	
1–24	112(b) ⁸	Indefiniteness		
Overall Outcome			1–24	

IV. ORDER

In consideration of the foregoing, it is hereby:

⁷ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

⁸ We do not reach this ground because, as explained in Section I.D, we determine it is moot.

ORDERED that, Petitioner has proved by a preponderance of the evidence that claims 1–24 of the '795 patent are unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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Patent 11,617,795 B2

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