

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 RESPONSE TO PETITION

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Exhibit No.	Description of Document
2001	<i>Genexa Launches First-to-Market Clean Over-the-Counter Medicine</i> , BusinessWire (Sept. 29, 2020)
2002	Patent Trial and Appeal Board Consolidated Trial Practice Guide (November 2019)
2003	Declaration of Adam M. Pivovar in Support of Motion to Appear <i>Pro Hac Vice</i>
2004	Biography of Adam Pivovar
2005	Declaration of Stephen Smith in Support of Motion to Appear <i>Pro Hac Vice</i>
2006	Biography of Stephen Smith
2007	Declaration of Brianna (Chamberlin) Patterson in Support of Motion to Appear <i>Pro Hac Vice</i>
2008	Biography of Brianna (Chamberlin) Patterson
2009	Declaration of Dr. Cory J. Berkland in Support of Patent Owner's Response to Petition
2010	Genexa Kids' Pain & Fever Blueberry Flavor, available at https://www.businesswire.com/news/home/20200929005330/en/
2011	September 2021 OTC Product News, Infants' Pain and Fever, <i>Pharmacy Times</i> , 87:9 (2021), available at https://www.pharmacytimes.com/view/september-2021-otc-product-news
2012	E. Mellado-Mojica and M. G. Lopez, Identification, classification, and discrimination of agave syrups from natural sweeteners by infrared

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	spectroscopy and HPAEC-PAD, <i>Food Chemistry</i> , 167, 349-357 (2015)
2013	B.I. Maldonado-Guevara et al., Production Process Effect on Mexican Agave Syrups Quality: A Preliminary Syrup, <i>J. Food Res.</i> , 7:3 (2018)
2014	E. Hill et al., Sweetener Content of Common Pediatric Oral Liquid Medications, <i>Am. J. Hosp. Pharm.</i> 45:135-42 (1988)
2015	SCOGS (Select Committee on GRAS Substances) Database, FDA available at: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=SCOGS
2016	Combined Index to USP 40 and NF 35, Volumes 1-4
2017	Search Results for “agave,” Combined Index to USP 40, available at: https://www.usp.org/search?search_api_fulltext=agave .
2018	Search results for “agave syrup,” Merck Index Online, available at: https://merckindex.rsc.org/search-results?q=agave+syrup
2019	L. Hernandez-Ramos et al., Nutritional value and antioxidant activity of the maguey syrup (<i>Agave salmiana</i> and <i>A. mapisaga</i>) obtained through three treatments, <i>Not. Bot. Horti. Agrobi.</i> , 48:3, 1306-1316 (2020)
2020	P. Subramaniam and N. Nandan, Cariogenic Potential of Pediatric Liquid Medicaments– An <i>in vitro</i> Study, <i>J. Clinical Pediatric Dentistry</i> , 36:4, 357-362 (2012)
2021	U.S. Patent No. 10,238,640
2022	J.F. Swindells et al., Viscosities of Sucrose Solutions at Various Temperatures: Tables of Recalculated Values, <i>Supplement to National Bureau of Standards Circular</i> , 440 (1958)

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Exhibit No.	Description of Document
2023	D. Reker et al., "Inactive" ingredients in oral medications, <i>Sci. Transl. Med.</i> , 11:483 (2019)

Patent Owner, Genexa, Inc. (“Genexa”) respectfully submits this Patent Owner Response to the Petition filed by KinderFarms, LLC (“Petitioner”) regarding U.S. Patent No. 11,617,795 (“the ’795 patent”).

I. INTRODUCTION

The Petition fails to prove the unpatentability of the claims of the ’795 patent because it relies on unsupported hindsight conclusions. Obviousness Grounds 1 and 2 in the Petition rest solely on the conclusory expert statement that “[t]he viscosity of agave syrup is reported to be about 212 centipoise. . . . Ex. 1031, at p. 1.” (Ex. 1003, ¶¶52, 119 (“As I previously noted at ¶52, a person of ordinary skill in the art would have known that agave syrup has a viscosity of around 212 centipoise.”); *see also* Petition for Post-Grant Review (“Pet.”), Paper 1 at 31, 57.) But Petitioner’s cited Ex. 1031 reports a viscosity for agave syrup of “2.56 Pa s”—i.e., 2,560 centipoise. This is over 10 times higher than the arbitrarily low value on which all of Petitioner’s obviousness grounds rely and falls well above and outside any recited viscosity in the claims of the ’795 patent. This single error is dispositive of the Petition’s failure.

The Petition’s clear and fundamental error regarding the purported viscosity of agave syrup also contradicts Petitioner’s additional conclusory assertion that agave syrup is simply a well-known “old” ingredient and performs the same function it had been known to perform. If this were true, which it is not, then certainly

Petitioner and Petitioner's expert would not have made so glaring of an error by identifying the viscosity as 212 cP instead of the cited 2,560 cP value in Exhibit 1031.

Petitioner presents no evidence to support a conclusion that agave syrup, with known variable viscosity, was well-established for use in oral pharmaceutical formulations. Nor could Petitioner have done so. Genexa's agave-based products were the first. Petitioner identifies no article, textbook, treatise, approved product, regulatory guidance, pharmaceutical index, or any other evidence that agave syrup was so well-established of an ingredient for oral pharmaceutical formulations that its use would be trivial.

To the contrary, it was well-known that there are a wide range of products sold under the name of agave syrup having wide variability of physicochemical quality parameters, including critically and indisputably different and variable viscosity. Petitioner expressly recognizes the variability of agave syrups, noting that agave syrup can be obtained from different species of agave and can be light or dark in color, with a thinner or thicker consistency. The Petition, however, is devoid of any reasoned articulation or evidence explaining how or why a POSA would allegedly deem agave syrup with known variability, particularly with respect to viscosity, simply a staple ingredient of oral pharmaceutical formulations.

Moreover, even if the Board were to accept Petitioner's conclusory and unsupported 212 cP viscosity for agave syrup, which the Board need not do to uphold the patentability of the claims based on the Petition's clear errors, Grounds 1 and 2 would still nevertheless fail. Specifically, none of the proposed combinations disclose viscosities that meet the claim limitations. Petitioner's conclusory statements regarding viscosity of any formulation in the Grounds are unsupported and fail as a result. The Grounds are further undercut by the variability of agave syrup as an ingredient, as well as the additional ingredients disclosed in the cited example formulation that dispel Petitioner's conclusory asserted combinations.

Finally, Petitioner's "alternative" Ground 3 is moot.

Petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable. Petitioner's blatant errors dooming the Petition cannot be cured. Genexa therefore respectfully requests that the Board find all claims of the '795 patent patentable.

II. BACKGROUND

A. Genexa and its Agave-Based Kids' and Infants' Pain & Fever Products

Genexa has redefined the over-the-counter ("OTC") pharmaceutical market by offering "clean" medicines. (*See* Ex. 2001.) These "clean" medicines offer the same therapeutic, active ingredients we have all known and used, but without any

artificial inactive ingredients. (*Id.*) Recognizing that these artificial ingredients found in OTC medicines are often the cause of negative side effects, such as allergic reactions, Genexa successfully developed a variety of OTC products eliminating the unnecessary ingredients and replacing them with safer, clean alternatives. (*Id.*) Genexa's Kids' and Infants' Pain & Fever Products is a natural, agave-syrup-based oral formulation that utilizes only 6 ingredients: acetaminophen, organic agave syrup, organic flavor, citrus extract, non-GMO flavor, and purified water. (Ex. 2010.)

B. The Characteristics of Agave Syrup

Agave syrup is a natural sweetener derived from agave plants. (Ex. 2009, ¶43.) There are several species of agave plants. (*Id.*, ¶44.) In addition to other naturally present components saponins and fructans such as inulin, agave syrup sweetening property is due to it containing a mixture of fructose and glucose dispersed in post-processing residual water. (*Id.*, ¶47 (citing Ex. 1003, ¶52 ("Agave syrup, which is predominantly composed of fructose and glucose, is a natural sweetener that is slightly sweeter than table sugar.")); Ex. 1007, 7:5-14).)

The composition and properties of agave syrup vary depending on the species of plant from which the syrup was derived and how it is processed—i.e., the relative amount of fructose, glucose, and residual water in the syrup. (Ex. 2009, ¶¶47-49.) Agave syrup "is generally considered a syrup-like product" and "[i]t can be light to

dark in color, thicker or thinner in consistency (viscosity), and even made into powder or crystals if dehydrated totally.” (Ex. 1007, 7:20-23.) Based on this variability, it was known that “[v]iscosity is one of the most significant physical chemical properties in determining the quality and acceptability of [agave] syrup.” (Ex. 1031.) It therefore comes as no surprise that the viscosity of agave syrup is variable depending upon its “quality and “acceptability,” and as shown by Petitioner’s own cited evidence (Ex. 1031) such agave syrup has been reported as having a viscosity of 2,560 cP. (Ex. 2009, ¶¶48-49 (citing Ex. 1031).)

While agave syrup may be well known as a natural sweetener, it is not a generally well-known excipient in the pharmaceutical formulations of oral syrups. (Ex. 2009, ¶46.) This largely derives from the fact that agave syrup is a natural product derived from different sources and different agave syrups are processed differently. (*See* Ex. 2009, ¶45.) Agave syrup is not a substance with singular characteristics, in contrast to other well-known pharmaceutical excipients like, for example, agar, glycerin, propylene glycol, sucrose, or xanthan gum, which are substances with well-known and understood physical chemical properties and regularly found in general pharmaceutical textbooks. (*See, e.g.*, Ex. 1029 (Handbook of Pharmaceutical Excipients), 13-14 (Agar), 283-85 (Glycerin), 592-94

(Propylene Glycol), 703-06 (Sucrose), 782-85 (Xanthan Gum); *see also* Ex. 1029, 14 (no entry for “Agave Syrup”).)

Additionally, whereas there are indexed United States Pharmacopeia (USP) monographs for essentially all of the standard components relied on in Petitioner's obviousness grounds—“acetaminophen,” “agar,” “aspartame,” “chlorpheniramine maleate,” “citric acid, anhydrous,” “citric acid and sodium citrate oral solution,” “dextromethorphan,” “glycerin,” “phenylephrine hydrochloride,” “propylene glycol,” “sodium citrate,” “sodium citrate and citric acid oral solution,” and “xanthan gum”—there is no such USP monograph for “agave syrup,” “agave nectar,” or simply “agave.” (*See* Ex. 2016.) Accordingly, it is unsurprising that the Petition identifies no example of a single, commercially available or regulatory approved prior art pharmaceutical product with agave syrup that was known in the art.

C. Acceptable Viscosities for Oral Liquid Pharmaceutical Formulations

Liquid pharmaceutical formulations for oral administration include “solutions, emulsions, suspensions, and extracts.” (Ex. 1012, 745; Ex. 1003, ¶42.) These oral formulations can have varying viscosities, for example, the liquid formulations may be rather thin solutions with a viscosity similar to water or be heavy syrups that “are concentrated, viscous aqueous solutions of sugar or a sugar substitute” (such as glycerin) which can be highly thick, but still pourable, up to, for

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example, 4,500 cP. (*See* Ex. 2009, ¶51; *see, e.g.*, Ex. 1012, 757 (“The main ingredients in elixirs are ethanol and water”); Ex. 2021, 8:20-21 (“about 1500 to about 4500 cPs”).)

Commercially-available oral formulations of the analgesics acetaminophen (“Paracetamol” *sic*) and ibuprofen are highly thick, with viscosities of 2,040 cP and 1,800 cP, respectively and antitussive (“Dexamethorphan” *sic*) of 1,755 cP:

Pediatric Liquid Medicaments

Table 1. Mean pH and Viscosity of Paediatric Liquid Medicaments

PLM	PRINCIPAL INGREDIENT	TRADE NAME	PHARMACEUTICAL COMPANY	pH Mean±SD	Viscosity(cP) Mean±SD
Analgesic	Paracetamol	Calpol	Glaxo Smithkline Pharmaceuticals Limited	6.08±0.04	2040.00±10.00
Analgesic	Ibuprofen	Ibugesic	CIPLA Ltd.	4.57±0.02	1800.00±20.00
Antitussive	Dexamethorphan Hydrobromide, Chlorpheniramine maleate, Phenylephrine hydrochloride	Chericof	Sobrex Pharmaceuticals Company (for Ranbaxy Laboratories Limited)	4.66±0.01	1755.00±5.00

(Ex. 2020, 359 (excerpted).)

D. Added Water Substantially Decreases Viscosities for Sugar and Polyol (e.g., Glycerin) Oral Liquid Pharmaceutical Formulations

Syrup-based liquid formulations for oral administration are typically based on sugar syrups, such as sucrose, or a sugar-like substitute, such as glycerin. (Ex. 2009, ¶55; Ex. 1012, 754 (“Syrups are concentrated, viscous, aqueous solutions of sugar or a sugar substitute . . . making a solution of sucrose In addition to sucrose, certain other polyols, such as glycerin or sorbitol, may be added”).) These

syrups are aqueous, meaning they contain water. The relative amount of water can profoundly impact the viscosity of the formulations. (*Id.*)

III. THE '795 PATENT

The '795 patent is directed to stable, pharmaceutical syrup formulations or suspensions for oral administration comprising pharmaceutical active agents, agave syrup, and a diluent. (*See* Ex. 1001, 1:31-41.) The impetus for the '795 patent's invention was to create pharmaceutical formulations that “includes the use of clean inactive ingredients that are gluten-free, non-GMO, and certified vegan,” excluding “unnatural ingredients such as aspartame, carbomer, EDTA, gelatin, milk, parabens, polyethylene glycol, titanium dioxide,” while taste masking unpalatable pharmaceutical active agents solely with “generally natural ingredients.” (*Id.*, 1:44-50.) The claims of the '795 patent all recite pharmaceutical syrup formulations with acetaminophen as the active pharmaceutical agent. (*See id.*, 5:33-6:59.)

The '795 patent teaches a broad scope for the possible viscosities of the disclosed agave-syrup/diluent-based pharmaceutical syrup formulations, including a formulation viscosity of up to 3500 centipoise. (*Id.*, 2:13-16.) The '795 patent, however, further teaches lowered viscosities for the agave-syrup/diluent-based pharmaceutical syrup formulations: “the viscosity of the syrup can be less than 2000 centipoise, less than 1750 centipoise, less than 1500 centipoise, less than 1000 centipoise, less than 750 centipoise, less than 600 centipoise, or less than 500

centipoise.” (*Id.*, 2:23-27.) In recognition that agave syrup can have varied viscosity, the independent claims of the '795 patent expressly require a “diluent” such that the recited “syrup formulation has a viscosity of less than 1500 centipoise at about 22 degrees.” (Ex. 1001, 5:33-6:59 (cls. 1, 7, and 18).)

The dependent claims recite further viscosity limitations for the claimed agave-syrup/diluent-based pharmaceutical syrup formulations, as summarized in the table below:

<u>Claim No.</u>	<u>Viscosity Limitation</u>
Independent Claims 1, 7, & 18	“a diluent, wherein the syrup formulation has a viscosity of less than 1500 centipoise at about 22 degrees”
Dependent Claims 5-6, 14, 16-17, & 20-24	“wherein the syrup formulation has a viscosity of less than 1500 centipoise at about 22 degrees”
Dependent Claims 2 & 19	“wherein the syrup formulation has a viscosity of less than 1000 centipoise at about 22 degrees”
Dependent Claim 3	“wherein the syrup formulation has a viscosity of less than 750 centipoise at about 22 degrees”
Dependent Claim 4	“wherein the syrup formulation has a viscosity of less than 600 centipoise at about 22 degrees”

Dependent Claim 15	“wherein the composition has a viscosity from about 1500 centipoise to about 400 centipoise at about 22 degrees”
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(Ex. 1001, 5:33-6:60.)

The remaining dependent claims of the '795 patent recite a variety of further limitations relating to the dosage of acetaminophen, the relative amount of diluent, and the relative amount of agave syrup, among others. (*Id.*)

IV. A PERSON OF ORDINARY SKILL IN THE ART

Factors pertinent to a determination of the level of ordinary skill in the art include “(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.” *Env’t Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 696 (Fed. Cir. 1983). “Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case.” *Id.* at 696-97.

Here, a POSA would encompass persons with:

- (a) a bachelor of science (B.S.) degree in a relevant life sciences field, such as, chemistry, biochemistry, or pharmacy, with at least 2

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,

(b) at least 3-4 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.

(Ex. 2009, ¶21.)

The '795 patent supports a definition that requires some amount of laboratory experience in pharmaceutical formulations. For example, the '795 patent refers to “pharmaceutical chemists” suggesting it is someone investigating and developing the pharmaceutical formulation. (*See* Ex. 1001, 1:23.) This is also supported by the prior art asserted by Petitioner. (Institution Decision (“Inst. Dec.”), Paper 8 at 7 (“[not]ing that the level of skill of an ordinarily skilled artisan is revealed by the prior art”).) For example, WO742 supports this definition as it states “all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention pertains” (Ex. 1007, 10:14-16), describing the invention as pertaining to the formulation of particular pharmaceutical

compositions without specific inactive ingredients and methods of administering the same. (Ex. 1007, 1:9-11.) And all prior art references relied on in Petitioner's combinations recognize that the field of invention pertains to the development of oral pharmaceutical formulations. (Ex. 1004, 1:4-7; Ex. 1005, 1:6-15; Ex. 1006, 1:4-2:12; Ex. 1007, 1:4-6.)

The Board's Institution Decision adopted Patent Owner's proposed description of a POSA. (Inst. Dec. at 6-7.) To the extent any issues arise where the similarity in Patent Owner's and Petitioner's proposal regarding the level of skill of a POSA differ or where the board concludes that the level of skill is not revealed by the prior art, Patent Owner's characterization should be adopted.

V. CLAIM CONSTRUCTION

The Board "need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). Significantly, based upon Petitioner's arguments here, Genexa does not believe the Board need construe any terms to resolve the present controversy and sustain the patentability of all claims of the '795 patent. However, Patent Owner provides the following regarding the scope of "agave syrup" as understood by a POSA.

A. “Agave Syrup”

The '795 patent refers to the term “agave syrup” as “a processed juice obtained from the agave sp. Plant (e.g. also referred to as processed sap or processed aguamiel).” (Ex. 1001, 2:7-9.) The '795 patent does not limit “agave syrup” to any particular type of agave syrup. Petitioner agrees and acknowledges that a POSA would understand there are various types of agave syrup with different properties, including critically different viscosities. (*See* Pet. at 14-15 (“The '795 patent does not limit the definition to a specific type of agave syrup.”).)

The Petition contends that “agave syrup” should be construed to “encompass all liquid materials derived from any agave plant that is free flowing, irrespective of its other properties.” (Pet. at 15.) The Petition further admits that “[a] person of ordinary skill in the art would understand that agave syrup can be obtained from different species of agave and can be light or dark in color, *with a thinner or thicker consistency.*” (*Id.* (emphasis added).)

Patent Owner agrees with Petitioner that a person of ordinary skill in the art would understand that “agave syrup” is “free flowing” and can have variable viscosity—i.e., “thinner or thicker consistency”—including at least up to 2,560 cP as in Petitioner’s cited Exhibit 1031. (Ex. 2009, ¶108.) Indeed, the '795 patent itself recognizes that a “‘syrup’ means a formulation that has a flow without applied pressures” and can have viscosity up to 3,500 cP while remaining “free flowing.”

(Ex. 1001, 2:9-16; Ex. 2009, ¶106.) Petitioner's recognition that "agave syrup" should be construed to include any type of agave, "irrespective of its other properties" demonstrates that Petitioner understood that "agave syrup" can have variable viscosity despite its obviousness arguments failing to ever address such variability viscosity, including its own cited Exhibit 1031 showing agave syrup with viscosity of 2,560 cP, which is well-above any of the recited viscosity values cited within the claims of the '795 patent. (Ex. 2009, ¶108.)

VI. THE PRIOR ART OF PETITIONER'S OBVIOUSNESS GROUNDS 1 AND 2

A. FR458

"FR458" is French-language patent publication no. 2,993,458. (Ex. 1004.) The Petition attaches a translation of FR458. (*Id.*, Pages¹ 17-32 of 33.) As translated by Petitioner, FR458 is entitled "Liquid Pharmaceutical Preparation for Oral Administration Based on Organic Agave Syrup with a Low Glycemic Index." (*Id.*, Page 17.) Although FR458 discloses the use of "agave syrup" within a pharmaceutical formulation, FR458 does not specify the type of agave syrup that

¹ Citations to "Page(s)" from within Petitioner's exhibits refer to the page numbering applied by Petitioner to such exhibit in the form of "Page [N] of [N]" in the footer of the exhibit. All other citations refer to the page numbering and/or lines within the original document.

was used or should be used, nor does it disclose a viscosity for agave syrup or the viscosity of the agave syrup used in any of the Examples therein. (Ex. 2009, ¶80.) Further, FR458 provides no information relating to the viscosity for any syrup formulations disclosed, including no discussion of the viscosity of the example formulations. (*Id.*)

FR458 acknowledges that “[f]ormulations based on natural syrups are not easy to obtain and must be heated to obtain homogenized suspensions.” (Ex. 1004, Page 19, ln. 52-53 (emphasis added).) To overcome this, FR458 provides “a general method for the preparation of suspensions/solutions at room temperature” in conjunction with the use of “xanthan gum and agar-agar in the formulation.” (*Id.*, Page 24, ln. 188-197.) FR458 explains that “Agar-agar and xanthan gum are mixed with glycerin in a separate container and mixed with a spatula to provide Solution A” and the “active pharmaceutical ingredient(s) is (are) dispersed or dissolved in agave syrup to make Solution B.” (*Id.*) “Solution A is added to Solution B” and “[w]ater and then the rest of the ingredients are added and mixed and the preparation is placed in vials.” (*Id.*)

1. FR458-Example 1

Example 1 in FR458, including the identity and amount of the constituent ingredients, is reproduced in its entirety as follows:

Example 1

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

(Ex. 1004, Page 25, ln. 185-198.)

FR458-Example 1 is formed by combining “Solution A” (xanthan gum, agar-agar, and glycerin) and “Solution B” (paracetamol suspended in agave syrup), and then “the water is topped up to 100 mL and everything is mixed together.” (Ex. 1004, Page 25, ln. 185-200; Ex. 2009, ¶82.) A POSA would understand that “[t]he collective mass of each ingredient (other than water) within FR458-Example 1 is 54.01 g.” (Ex. 2009, ¶82.) A POSA would further recognize that these ingredients would generally have a density higher than water (i.e., above 1 g/cm³), such that FR458-Example 1 is at least ~50% water by volume (and almost certainly closer to ~60% water by volume). (*Id.*)

FR458 discloses no details related to the type or viscosity of the “[c]ertified

agave syrup” used in FR458-Example 1. Nor does FR458 disclose the viscosity value of the Example 1 formulation, which has a substantial amount of added water. (Ex. 2009, ¶83.)

B. WO742

“WO742” is PCT patent publication no. WO 2012/018742. (Ex. 1007.) WO742 is entitled “Dextromethorphan Antitussive Compositions.” (*Id.*) As self-described, WO742 is directed to oral pharmaceutical compositions containing the active ingredient dextromethorphan hydrochloride, which is highly soluble, for treating the symptoms of coughs and colds. (*See id.*, Abstract, 3:9-10 (“The field of the invention relates generally to antitussive compositions containing dextromethorphan....”); *see generally* Ex. 1007, 1:17-3:13.)

WO742 discloses that “agave syrup is similar to honey in color and texture, but it is not as viscous and flows more easily.” (Ex. 1007, 5:9-10; *see also* Ex. 1031.) WO742 further notes that “it is generally considered a syrup-like product” and that “[i]t can be light to dark in color, thicker or thinner in consistency (viscosity), and even made into powder or crystals if dehydrated totally.” (Ex. 1007, 7:20-23.)

Although WO742 expressly recognizes that agave syrups have variable viscosity (i.e., “thicker or thinner in consistency (viscosity),” WO742 does not disclose a specific type of agave syrup that must be used or otherwise was used to practice the “invention” disclosed therein, does not disclose a viscosity value for

agave syrup or the viscosity value of the agave syrup used in any of the Examples therein, and never mentions anything relating to the viscosity of the Example formulations disclosed therein. (Ex. 2009, ¶¶95-96; Ex. 1003, ¶216 (“WO742 does not expressly disclose the viscosity (or range of viscosities) of liquid formulations of the invention.”).)

1. WO742-Example IX

Example IX in WO742, which is relied on by Petitioner, including the identity and amount of the constituent ingredients, is reproduced in its entirety as follows:

EXAMPLE IX. Liquid Cough Composition Ingredients Amount/15 ml Dose:	
Acetaminophen	160.0
Dextromethorphan Hydrochloride monohydrate	9.0 mg
Chlorpheniramine maleate	1.0 mg
Phenylephrine Hydrochloride	2.5 mg
Agave nectar	11.0 ml
Propylene Glycol	1.74 g
Ethanol (95%)	1.5 ml
Flavorants	0.05 ml
F, D & C Red #40	5.1 mg
Glycerin	750.0 mg
Aspartame	23.2 mg
Water, Purified q.s.	

(Ex. 1007, 23:17-29.)

WO742 does not identify the type of agave nectar that is used, the viscosity of the agave nectar that is used, the ultimate amount of water used, or the resulting

viscosity of the formulation in WO742-Example IX. (Ex. 2009, ¶104.)

C. The '4666 Patent

The nearly 40-year-old U.S. Patent No. 4,684,666 (“the '4666 patent”) that issued in 1987 is entitled “Stabilized Liquid Analgesic Compositions.” (Ex. 1005.) The '4666 Patent does not mention agave syrup, let alone disclosing its use in an oral pharmaceutical formulation. (Ex. 2009, ¶87.)

The '4666 Patent discloses *alkaline* ibuprofen syrup formulations comprising more than 50% by weight of a water compatible bodying agent that “yields a water-clear aqueous suspension or solution of increased viscosity” and the formulations must have pH from 7.0 to 7.7. (See Ex. 1005, Abstract, 2:4-14, 2:22-25, 3:37-45, cl. 1.) The '4666 Patent further teaches the “water compatible bodying agents” require “[s]uitable materials [that] must be capable of being freely incorporated into water without affecting clarity of the resultant suspension or solution.” (*Id.*, 2:44-48.) The '4666 patent explains that the preferred bodying agents are “polyhydric alcohols,” such as glycerol, sorbitol, mannitol, and propylene glycols. (*Id.*, 2:44-54.) The '4666 patent acknowledges that it is only “permissible to use other materials such as sucrose as an incidental part of the bodying agent component” and “should not constitute a major part thereof because of the general metabolic undesirability of including larger amounts of sugar and the visual haze that develops in the syrup from its use unless special precautions are taken.” (*Id.*, 2:59-65.)

A critical aspect of achieving the “stabilized liquid ibuprofen syrup” disclosed in the '4666 patent is the formulations having “a PH of higher than 7.0 and below 7.7.” (*Id.*, Abstract.) As taught in the '4666 patent, “[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.*” (*Id.*, 3:37-45 (emphasis added).)

The '4666 patent further explains that “[a]n important aspect of this invention is the inclusion of a major portion of water compatible material or materials that contribute to *a rather heavy and uniform viscosity* in the final composition. (Ex. 1005, 2:41-44 (emphasis added).) Characterizing such compositions as being “moderately viscous syrups” (*id.*, 1:11-12), the '4666 patent teaches that: “Viscosity of the product should be controlled for optimum stability. A viscosity of *about 1000 to 3000 centipoise* at 20° C., as measured by the Brookfield Synchro-Lectric viscometer, *is the preferred range.*” (*Id.*, 4:9-17 (emphasis added).)

There are three independent claims in the '4666 patent, claims 1, 6, and 7. (*Id.*, 6:19-67.) Dependent claims 9 and 10, which are dependent on claims 1 and 6, respectively, recite verbatim the preferred viscosity range expressly taught within the specification: “9/10. The syrup of claim 1/6 wherein the viscosity is *about 1000 to 3000 centipoise* at 20° C.” (*Id.*, 6:62-65 (emphasis added).) Dependent claim

11—in what Patent Owner argues below in this Response is an obvious typographical error—recites: “The syrup of claim 7 wherein the viscosity is ***about 100 to 3000*** at 20° C.” (*Id.*, 6:66-67 (emphasis added).)

D. WO133

“WO133,” which published in 1995, is PCT Publ. No. WO 95/00133. (Ex. 1006.) WO133 is entitled “Taste-masked Acetaminophen Suspensions and Methods of Making the Same.” (Ex. 1006.) WO133 does not mention or teach the use of agave within a pharmaceutical formulation.

WO133 is directed to taste-masking acetaminophen by reducing its solubility: “the taste of the acetaminophen is effectively masked by suspending the drug in a suspension medium containing suspension agent and additive agents that decrease the solubility of the acetaminophen in aqueous solution.” (*Id.*, Abstract.) To accomplish this, WO133 teaches acetaminophen formulations in which the “acetaminophen solubility is limited by the presence of additive agents, such as sweetening agents.” (*Id.*, 1:6-9.) WO133 teaches that “[t]he pH of the acetaminophen composition is held below about 6, and most preferably between about 3.5 and 5.” (*Id.*, 7:20-21.)

WO133 teaches that “[s]weetening agents which can be used in the present invention to limit the solubility of the acetaminophen in aqueous solution are those of the polyol type, particularly those which are highly soluble in water.” (*Id.*, 3:3-6.)

“Sweetening agents of this type include the sugars such as sucrose ($C_{12}H_{22}O_{11}$), glucose ($C_6H_{12}O_6$), fructose ($C_6H_{12}O_6$), lactose ($C_{12}H_{22}O_{11}$), and maltose ($C_{12}H_{22}O_{11}$),” “[n]atural and semi-refined sweetening agents such as honey and corn syrups, which are mixtures of sugars with other related compounds, can be used, as well as polymers of sugars such as maltodextrin[,]” and “can also include polyhydric alcohols such as sorbitol ($C_6H_{14}O_6$), mannitol ($C_6H_{14}O_6$), and maltitol ($C_6H_{11}O_5$ [$C_6H_{10}O_5$] $_n$ $C_6H_{13}O_6$), $n=1-20$, - otherwise known as hydrogenated glucose and hydrogenated starch hydrolysate[.]” (*Id.*, 6:7-24.)

WO133 discloses that “[t]he viscosity of the acetaminophen composition generally ranges from about 200-900 centipoise, preferably from about 300-700 centipoise.” (Ex. 1006, 8:1-3.) Other than this single sentence, WO133 provides no disclosure regarding the specific viscosity values for any of the example formulations disclosed therein, instead merely stating that they are “a viscous suspension.” (*See id.*, 9:16-17 (“[t]he acetaminophen composition obtained was a viscous suspension with a pH=4.3”), 10:4-5 (“[t]he acetaminophen composition obtained was a viscous suspension with a pH=4.4”).)

VII. ARGUMENT

“[P]etitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). The petitioner continues to bear the burden of proving

unpatentability after institution. *See In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1376–77 (Fed. Cir. 2016). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). Here, the Petition relies on dispositive errors and conclusory statements, resulting in it being both factually and legally deficient. *See Magnum Oil Tools*, 829 F.3d at 1380 (Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements”).

The Petition includes three grounds. Petitioner's Ground 1 alleges that claims 1-24 are invalid for obviousness over the combination of FR458 with the '4666 Patent and/or WO133. (Pet. at 2.) Petitioner's Ground 2 alleges that claims 1-17 are invalid for obviousness over the combination of WO742 with the '4666 Patent and/or WO133. (*Id.*) Petitioner's Ground 3 conditionally alleges indefiniteness of three claim terms “in the alternative,” and is moot (as described below). (*Id.* at 2-3, 68-72.)

The Petition fails to establish obviousness as to any claims under Grounds 1 and 2. “The determination of obviousness is made with respect to the subject matter as a whole, not separate pieces of the claim.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1086 (Fed. Cir. 2008). In addition to its reliance on dispositive errors, the Petition also fails because an obviousness challenge must address the claimed

combination of elements as a whole—it cannot merely mix-and-match the prior art to individual claim elements as Petitioner has done here in Grounds 1 and 2:

The “as a whole” instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. . . . Section 103 precludes this hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole.

Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1275 (Fed. Cir. 2004).

A. The Petition Relies on Facial and Unaddressed Errors that Cannot Support a Finding of Obviousness

1. The Petition’s conclusory and dispositive error regarding the asserted viscosity of agave syrup

The Petition is fundamentally flawed because of its reliance on an unsupported as well as incorrectly presumed viscosity for agave syrup. Obviousness Grounds 1 and 2 in the Petition are entirely premised on the conclusory expert statements that “[t]he viscosity of agave syrup *is reported to be about 212 centipoise*. . . . Ex. 1031, at p. 1” (Ex. 1003, ¶52 (emphasis added)) and “[a]s I previously noted at ¶ 52, a person of ordinary skill in the art would have known that agave syrup *has a viscosity of around 212 centipoise*” (Ex. 1003, ¶119 (emphasis

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added)). (See also Pet. at 31, 57; Ex. 1003, ¶216 (agave syrup has “a viscosity around 200 centipoise”).)

But the sole exhibit cited by Petitioner's expert for this conclusory assertion—
“Ex. 1031, at p. 1” (Ex. 1003, ¶52)—entitled “Rheology of Agave syrup” *actually*
reports a viscosity for agave syrup of 2,560 centipoise (i.e., “2.56 Pa s”):

174 - Rheology of Agave syrup
Araceli M. Vera-Guzmán MS, Laura V. Aquino-Gonzalez, Professor Mercedes G. López Ph.D.. Unidad Oaxaca, CIIDIR-IPN, Oaxaca, Oaxaca, Mexico; Biotechnology and Biochemistry, Centro de Investigación y de Estudios Avanzados, Irapuato, Guanajuato, Mexico
Agave syrup, a natural product with high sweetener capacity, is obtained from cooking and concentrating the juice of Agave plants. Viscosity is one of the most significant physical chemical properties in determining the quality and acceptability of syrup. Knowledge of the rheology of Agave syrup is therefore necessary in its production, processing, and storage. The aim of the present study was to evaluate the viscosity of Agave syrup, over five temperatures. The viscosity of 10 Agave syrup samples as well as 2 honeybee and 2 sugar cane syrup were used as references. Samples were analyzed over a range of shear rates (1.0 - 100 s⁻¹) with five temperatures (10, 20, 40, 60, and 80°C) in an Anton Park rheometer MR301. In general, the viscosity curves of all samples exhibited a Newtonian behavior. The mean **viscosity values of Agave syrup**, sugar cane, and honeybee were **2.56 Pa s**, 6.06 Pa s, and 10.47 Pa s, respectively, at 20°C and 10 s⁻¹. The viscosity value of Agave syrup was less than the values of the references. The viscosity of Agave Syrup (8.94 - 0.16 Pa s), sugar cane syrup (74.45 - 0.23 Pa s) and honeybee (109 - 0.09 Pa s) decreased with an increase in temperature (10 - 80°C). The viscosity of samples depended on the type of syrup and the temperature of the measurement.
Wednesday, March 30, 2011 01:30 PM
[Bioactives in Natural Sweeteners \(01:30 PM - 04:50 PM\)](#)
Location: Anaheim Marriott
Room: Orange County III

KINDERFARMS **Ex. 1031**
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UnitConverters.net
Home / Viscosity - Dynamic Conversion / Convert Pascal Second to Centipoise

Convert Pascal Second to Centipoise
Please provide values below to convert pascal second [Pa*s] to centipoise [cP], or [vice versa](#)

From: pascal second

To: centipoise

Result: 2.56 pascal second = 2560 centipoise

(See Ex. 2009, ¶¶114-15; Ex. 1031.)

The reported value of agave syrup viscosity in Petitioner's Exhibit 1031
(2,560 cP) is more than **10 times higher** than the arbitrarily low value of 212 cP on

which Petitioner's obviousness grounds rely. Indeed, that same exhibit explains the critical importance of the viscosity of agave syrup: "*Viscosity is one of the most significant physical chemical properties in determining the quality and acceptability of [agave] syrup.*" (Ex. 1031 (emphasis added); *see also* Ex. 1031 ("Agave syrup . . . is obtained from cooking and concentrating the juice of agave plants.")) Petitioner never explains why a person of ordinary skill in the art would have been motivated to develop a pharmaceutical formulation by selecting a low quality and less acceptable agave syrup with its erroneously cited 212 cP value, particularly as opposed to the higher quality and more acceptable agave syrup with the viscosity of 2,560 cP that is actual value reported in Petitioner's Exhibit 1031. (Ex. 2009, ¶112.)

The Petition never addresses or justifies propounding obviousness arguments based on the indisputable facial error for the viscosity of agave syrup as reported in Petitioner's Exhibit 1031. Nor does the Petition provide any justification for disregarding the 2,560 cP viscosity value as Petitioner has nevertheless done. Instead, the Petition wrongly presumes that agave syrup simply *has* a viscosity of 212 cP, contrary to Petitioner's own cited evidence. This single indisputable and unaddressed error, evidencing Petitioner's flagrant and unexplained conclusory cherry-picking, is dispositive because Petitioner's own submitted evidence

disproves the sole rationale underlying the Petition's obviousness theories—agave syrup does not necessarily have a viscosity of 212 cP. (Ex. 2009, ¶¶118-19.)

In the absence of any reasoned articulation, the Petition's erroneous and conclusory reliance on the 212 cP viscosity value for agave syrup is plainly based on an impermissible hindsight-based reconstruction of the claims. Nearly all of the claims of the '795 patent recite agave-syrup-based acetaminophen formulations with a viscosity of "less than 1500 centipoise," "less than 1000 centipoise," "less than 750 centipoise," or "less than 600 centipoise." (Ex. 1001, cls. 1-4, 7, 15, 18-21.) The 2,560 cP viscosity value *actually* reported in Petitioner's Exhibit 1031, the only reference cited by Petitioner's expert for this point, is well-above and far outside any of the claims and therefore could not support Petitioner's obviousness theories.

Petitioner has instead incorrectly cited 212 cP for agave syrup, apparently because it falls within the recited viscosities of these claims. Indeed, the Petitioner fails to justify or cite any evidence for the Petition's asserted reliance of 212 cP in the obviousness grounds. No viscosity for agave syrup other than the unsupported value of 212 cP is ever addressed in the Petition's obviousness grounds despite the Petition's express recognition that "[a] person of ordinary skill in the art would understand that agave syrup can [have] . . . a thinner or thicker consistency." (Pet. at 15.)

Nor does Petitioner ever acknowledge or even seek to justify ignoring its own cited exhibit's face value of 2,560 cP as part of the known variable viscosity reported for agave syrup. The Petition is bereft of any reasoned or plausible basis to explain why a person of ordinary skill in the art (POSA) would simply ignore the 2,560 cP teaching in Ex. 1031 in lieu of Petitioner's conclusory asserted value. Petitioner's error and conclusory assertion cannot support a finding of obviousness. *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.").

Petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable. The Petition has not done so here because it relies on the single erroneous 212 cP value for the presumed viscosity of agave syrup despite Petitioner's own cited evidence showing a materially higher viscosity of 2,560 cP. The Petition's reliance on this undisputable and dispositive error in asserting obviousness cannot be cured and the claims should be upheld as patentable on this basis alone. *See* 35 U.S.C. § 322(a)(3); *Magnum Oil Tools*, 829 F.3d at 1381 ("[T]he Board must base its decision on arguments that were advanced by a party, and to which the opposing party was given a chance to respond.").

2. The Petition's tacit reliance on erroneous inherency-based obviousness theories

Petitioner's obviousness Grounds are tacitly based on inherency, with Petitioner's expert making the conclusory assertion that agave syrup simply *has* a viscosity of 212 cP. The Petition compounds this error by presuming (without any rationale or explanation) that if such an erroneously identified viscosity of 212 is used within FR458-Example 1 (Ground 1) or WO742-Example IX (Ground 2), the necessary result would be formulations that meet the viscosity ranges of the secondary references (i.e., the '4666 patent and WO133). (Ex. 1003, ¶¶ 52, 119, 216; Pet. at 31, 57.) Not only is this not true, as explained in more detail below, Petitioner nevertheless fails to acknowledge its reliance on inherency regarding the asserted 212 cP viscosity of agave syrup, which is undeniably disproven by Petitioner's own evidence demonstrating agave syrup with a viscosity of 2,560 cP that is over 10 times higher than the viscosity identified in the Petition.

Moreover, the Petition fails to satisfy the high standard for any reliance on inherency. “[I]n order to rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis – the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art.” *Par Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1195-96 (Fed. Cir. 2014). Under this standard, “[i]nherency . . . may not

be established by probabilities or possibilities.” *Id.* at 1195 (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981)). Petitioner has not, and cannot, meet that standard here.

The Petition inexplicably ignores the fact that agave syrup can have viscosity up to at least 2,560 cP as shown in Exhibit 1031. The Petition never presents any argument that would support a conclusion that the use of such an agave syrup with a viscosity of 2,560 cP would necessarily result in FR458-Example 1 or WO742-Example IX having viscosities that fall within the viscosity ranges of the proposed combinations with the '4666 patent and/or WO133 in Petitioner's Grounds 1 and 2. Indeed “[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient” to render the result inherent.” *Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1367 (Fed. Cir. 2017) (quoting *Oelrich*, 666 F.2d at 581). Thus, even if the Board were to look past Petitioner's dispositive error regarding the viscosity of agave syrup, the Petition's tacit inherency-based obviousness Grounds nevertheless also fail.

3. Grounds 1 and 2 of the Petition rely on an obvious error in the '4666 patent that a POSA would disregard

a. Claim 11 of the '4666 patent recites an obvious typographical error

The Petition relies on the '4666 Patent as purportedly teaching a POSA a viscosity range of 100-3000 centipoise even though such recitation is an obvious

error. (Ex. 2009, ¶¶122-33.) It has long been held that “where a prior art reference includes an obvious error of typographical or similar nature that would be apparent to one of ordinary skill in the art who would mentally disregard the errant information as a misprint or mentally substitute it for the correct information, the errant information cannot be said to disclose subject matter.” *LG Elecs. Inc. v. ImmerVision, Inc.*, 39 F.4th 1364, 1372 (Fed. Cir. 2022) (citing *In re Yale*, 434 F.2d 666, 667–69 (C.C.P.A. 1970)). This is the case here, as a POSA would readily recognize that the overbroadly recited viscosity range in claim 11 is an error that plainly contradicts the express teachings in the '4666 Patent's specification and in light of the other similarly recited dependent claim language.

As described above, the '4666 Patent's specification expressly discloses that “viscosity of the product should be controlled for optimum stability” and provides a preferred “viscosity of about 1000 to 3000 centipoise at 20° C” to accomplish this. (Ex. 2009, ¶¶125-29; Ex. 1005, 4:9-12.) Although the '4666 Patent mentions that a “[f]inished product with *somewhat less* thickness” may be used, it further counsel's against doing so because viscosities less than 1000 cP “are less able to withstand adverse conditions which may be encountered in storage and shipment.” (Ex. 2009, ¶126; Ex. 1005, 4:13-17.) A POSA would therefore have recognized that the '4666 patent teaches the importance of “[a] viscosity of about 1000 to 3000 centipoise at

20° C” and cautions against those with even “*somewhat less* thickness” than the preferred range. (Ex. 2009, ¶129; Ex. 1005, 4:9-17.)

There are only three independent claims in the '4666 patent (claims 1, 6 and 7) and only three corresponding sequential dependent claims (claims 9, 10, and 11) that recite viscosity with dependency back to each independent claim, respectively. (See Ex. 1005, 6:19-65.) The dependent claims 9, 10, and 11 have the same format, use the same language, and are each directed to one of the independent claims:

- 9. The syrup of claim 1 wherein the viscosity is about 1000 to 3000 centipoise at 20° C.**
10. The syrup of claim 6 wherein the viscosity is about 1000 to 3000 centipoise at 20° C.
11. The syrup of claim 7 wherein the viscosity is about 100 to 3000 centipoise at 20° C.

(Ex. 1005, 6:62-65.)

As is readily apparent, the specification's expressly disclosed and preferred range for the “viscosity of about 1000 to 3000 centipoise at 20° C” is recited in dependent claims 9 and 10 verbatim. (*Compare* Ex. 1005, 4:10-11 *with id.*, 6:62-65.) Claim 11, however, contains an obvious typographical error, reciting instead “the viscosity of about 100 to 3000 centipoise at 20° C.” (Ex. 1005, 6:62-65 (underline added).) Not only is a viscosity of 100 cP inconsistent with any disclosure in the '4666 patent's specification, it is also plainly inconsistent with the patentee's attempt

to consistently recite the same language in claims 9, 10, and 11 in reference to their dependency on independent claims 1, 6, and 7. (Ex. 2009, ¶131.)

Indeed, there seems to be little question that if claim 11 were accepted as broadly as the typographical error recites, it would not be supported by the disclosures within the '4666 patent's specification, which merely refers to "somewhat less thickness" than 1000 cP and not *drastically less* thickness (i.e., 1/10th the thickness). (Ex. 2009, ¶¶129-130.) This further demonstrates that the recitation of "100" in claim 11 was actually meant to recite "1000," same as disclosed in the specification and as recited in claims 9 and 10. (*Id.*, ¶131.)

Yet, Petitioner extensively relies on this typographical error found only in dependent claim 11 in an effort to unjustifiably expand that viscosity range that a POSA would recognize as being taught by the '4666 patent from "1000 to 3000 centipoise at 20° C" (and arguably expanded to include "*somewhat less* thickness") to "100 to 3000 centipoise." (*See, e.g.*, Pet. at 34 ("Claim 11 of the '4666 patent discloses a viscosity range from 100 to 3000 centipoise."); Ex. 2009, ¶¶124, 132-33.) Petitioner, however, provides no explanation as to why a POSA would not immediately recognize the inconsistency in claim 11 with the 1000 to 3000 centipoise range otherwise recited in claims 9 and 10 and expressly identified as the preferred range in the '4666 patent's specification. *See Yale*, 434 F.2d at 667

(recognizing that an internal inconsistency within a reference is a signal that a POSA “would readily recognize” as an error).

Because a POSA would readily recognize the nature of the error within the '4666 Patent, as well as the internal inconsistency, the Board should disregard Petitioner's assertion that the '4666 patent discloses a viscosity of 100-3000 centipoise since such a typographical error would have been disregarded. *See LG Elecs*, 39 F.4th at 1365 (“Because substantial evidence supports the Board's finding that prior art disclosure critical to both of LG's petitions for *inter partes* review was an apparent error that would have been disregarded or corrected by a person of ordinary skill in the art, we affirm.”).

b. The obvious error in the '4666 patent that a POSA would disregard negates any motivation to combine the distinct viscosity ranges taught by the '4666 patent and WO133

The Petition relies extensively on the obvious typographical error in claim 11 of the '4666 Patent as purportedly teaching an oral formulation viscosity range of 100-3000 centipoise that, as explained above, a POSA would disregard. (*See* Pet. at 25, 31, 34, 44, 58, 60, 66.) A POSA would not have been motivated to combine the 1000-3000 cP range of the '4666 patent with the 200-900 cP range of WO133 or have reasonably expected success in doing so because they are wholly distinct and non-overlapping ranges. (Ex. 2009, ¶¶147-50.) Why would a POSA combine two

different and non-overlapping viscosity ranges in these references? The answer is simple. A POSA would not make any such combination. (*Id.*) Indeed, Petitioner makes no attempt to address the obvious disconnect between the viscosity ranges in the '4666 patent (1000-3000 cP) and WO133 (200-900 cP) asserted in the Petition.

Moreover, a POSA would implicitly recognize that any assertion of a reasonable expectation of success in achieving one of the ranges would necessarily mean that there would not be a reasonable expectation of success in achieving the other since they are each directed to *different* viscosity values. (Ex. 2009, ¶¶149-50.)

This failure in logic is further amplified considering that the Petition's Grounds 1 and 2 are presented in an ambiguous "and/or" manner. In doing so, the Petition asserts in conclusory fashion regarding the claims' viscosity limitation that either FR458-Example 1 (Ground 1) or WO742-Example IX (Ground 2) would allegedly satisfy the 1000-3000 cP range of the '4666 patent *and/or* the 200-900 cP range of WO133. (*See* Pet. at 31-32, 57-58.)

The Petition never purports to identify any viscosity value for the formulations of either FR458-Example 1 or WO742-Example IX to show that either would fall

within the range of the '4666 patent or the range of the WO133.² Regardless, a POSA would understand that FR458-Example 1 and WO742-Example IX are each specifically identified, complete single formulations and each would have a distinct viscosity value. (*See* Ex. 2009, ¶¶119 n.4, 165; *see also* Ex. 2009, ¶¶147-50, 170-71.) A distinct (and single) viscosity FR458-Example 1 and WO742-Example IX, regardless of the actual viscosity value, cannot satisfy both the 1000-3000 cP range of the '4666 patent *and* the 200-900 cP range of WO133 at the same time.³ As a matter of logic, any combination must therefore, at best, be *one or the other* of Petitioner's cited viscosity ranges—it cannot be *both*.⁴

² Nor does the Petition advance any theory, argument, or evidence in which these formulations would be modified in any way to achieve a particular viscosity value.

³ Notably, the Board's Institution Decision only addressed Grounds 1 and 2 based on the “and” permutation of the proposed combinations—i.e., FR458/WO742 in combination with the '4666 Patent *and* WO133. (Inst. Dec. at 11 (“over FR458 in combination with the '4666 patent *and* WO133”), 15 (“over WO742 in combination with the '4666 patent *and* WO133”) (emphases added).)

⁴ As set forth in more detail below, Petitioner's theory relying on a viscosity of agave syrup of 212 cP within FR458-Example 1 and WO742-Example IX would result in

Thus, Petitioner's "and/or" obviousness Grounds are internally inconsistent and self-defeating. The Petition never identifies *whether* a POSA would have had a reasonable expectation of success that FR458-Example 1 or WO742-Example IX would have a viscosity falling within the relatively higher 1000-3000 cP range of the '4666 patent *or* the relatively lower 200-900 cP range of WO133. Since the example formulations cannot satisfy *both*, the Petition lacks the particularity required to discern any plausible arguments that do not improperly rely on the obvious typographical error in claim 11 that permeates Petitioner's obviousness grounds. The Petition's ambiguous "and/or" combinations only further renders Petitioner's grounds more ambiguous and lacking sufficient particularity to support a finding of unpatentability of any claim because the Board should not "have to decode a petition to locate additional arguments beyond the ones clearly made." *See Netflix, Inc. v. DIVX, LLC*, 84 F. 4th 1371, 1377 (Fed. Cir. 2023) ("A petitioner may not rely on a vague, generic, and/or meandering petition and later fault the Board for failing to understand what the petition really meant. Ultimately, it is the petitioner's

formulations with viscosities well below 200 cP and thus would not satisfy either the 1000-3000 cP range of the '4666 patent or the 200-900 cP range of WO133. (*See* Sections VII.B.1 and VIII.C.2.)

burden to present a clear argument.”).

B. Ground 1 Fails to Demonstrate Obviousness of Any Claim

1. Ground 1 relies on errors and conclusory assertions riddled with impermissible hindsight

Petitioner identifies three “and/or” permutations under Ground 1 against claims 1-24 of the '795 patent: (i) FR458 in combination with the '4666 patent; (ii) FR458 in combination with WO133; and (iii) FR458 in combination with the '4666 patent and WO133.⁵ (*See* Pet. at 28 n.14.) Petitioner does not address each of these three proposed combinations with particularity in a reasonable discernable manner. Instead, Petitioner presents Ground 1 without drawing any clear distinctions between the three references and simply cites (or drops) them on an *ad hoc* basis throughout the Petition.

With respect to a motivation to combine and reasonable expectation of success, the Petition's allegations under Ground 1 are confined to a single paragraph. (*See* Pet. at 27-29.) With respect to a motivation to combine, the Petition generically alleges that (apparently the entirety of) FR458, the '4666 patent, and WO133 can be combined in any arbitrary manner simply because “FR458 is seeking to develop an

⁵ Notably, in its Institution Decision the Board only addressed FR458 in combination with the '4666 Patent and WO133. (Inst. Dec. at 5 n.5.)

oral formulation for children or the elderly that masks the unpleasant taste of the API” and that “[t]he ‘4666 patent and WO133 identify similar rationales for developing their oral formulations that contain analgesics.” (*Id.* at 28.) Notwithstanding that the ‘4666 patent teaches that “[w]hile acetaminophen is a widely used analgesic . . . it lacks anti-inflammatory activity and is not as an effective pain reliever as ibuprofen” (Ex. 1005, 1:32-36), the Petition further alleges motivation because “each of these references discuss acetaminophen as an analgesic that is used in oral formulations” and “shows a preference for having the analgesic suspended in the oral formulation.” (Pet. at 28.)

Without mentioning WO133, the Petition further alleges that “FR458 and the ‘4666 patent seek to develop formulations with a lower sugar content to benefit diabetics and other persons with restricted sugar requirements.” (*Id.* at 28-29.) In this regard, the ‘4666 patent discloses that “[t]he stabilized liquid *ibuprofen* formulations of this invention include both sucrose sweetened and *sugar free* formulations suitable for administration to diabetics and other patients whose sugar intake should be restricted.” (Ex. 1005, 2:15-19 (emphases added).) To accomplish this, the ‘4666 patent advocates replacing sugars with “polyhydric alcohols,” such as the particularly preferred glycerol and sorbitol. (*Id.*, 2:48-3:6 (sugars “should not constitute a major part thereof because of the general metabolic undesirability of

including larger amounts of sugar and the visual haze that develops in the syrup from its use”).)

Beyond its mere assertion that the three references are directed to the same field of taste-masking oral formulations of analgesics and *only* with respect to the combination of FR458 and the '4666 patent that there is a general desire for low-sugar content for diabetic patients, there is no articulated motivation for combining with particularity of any specific disclosures within FR458, the '4666 patent, and/or WO133. *See William Wesley Carnes, Sr., Inc. v. Seaboard Int'l, Inc.*, IPR2019-00133, Paper 10 at 18 (P.T.A.B. May 8, 2019) (A mere “statement of similarity, however, does not constitute an articulated reasoning with rational underpinning as to why a POSITA would combine elements of one reference with another, and why a POSITA would modify the teachings of the references to arrive at the claimed invention.”).

Instead of presenting any specific motivation for combining any specific features of the three references of Ground 1, Petitioner instead essentially restates the conclusory legal conclusion articulated in *KSR* without any specific facts to support it, particularly with respect to the use of agave syrup:

Considering that each prior art reference is in the same field of art, seeks to address similar issues, and discusses the creation of oral analgesic formulations using “old [ingredients] with each performing the same

function it had been known to perform,” a person of ordinary skill in the art would be motivated to combine these teachings and would have a reasonable expectation of success in combining these teachings. *KSR Int’l Co.*, at 417; Ex. 1003 at ¶¶101-103.

(Pet. at 29.)

As described throughout this response, Petitioner’s conclusory assertion that agave syrup is simply a well-known old ingredient merely performing the same function it has known to perform is demonstrably false. (Ex. 2009, ¶146.) Petitioner’s undeniably clear error regarding the viscosity of agave syrup, which is identified in the exhibit cited by Petitioner as 2,560 cP (Ex. 1031), demonstrates that agave syrup was not so well-established in the art and merely “performing the same function it had known to perform” as it relates to developing an oral pharmaceutical formulation with a specified and desired viscosity to support Petitioner’s conclusory assertion of obviousness. (Ex. 2009, ¶¶142-46.) If agave syrup was so well-known within the art, certainly Petitioner and Petitioner’s expert would not have made such a glaring error as to mistakenly assert a viscosity for agave syrup that is ***10 times less*** than the value actually reported in Exhibit 1031. This error alone belies any assertion that agave syrup is just an old, well-known ingredient. Petitioner’s conclusory assertions and lack of any reasoned articulation relating to the use of

agave syrup is nothing more than routine skill is demonstrably false by its own erroneous assertions. (*Id.*)

To the contrary, Petitioner's Exhibit 1031 demonstrates that agave syrups have different "quality and acceptability" and that "viscosity is one of the most significant physical chemical properties in determining the quality and acceptability of [agave] syrup." (Ex. 1031.) Petitioner has cited to no textbooks or articles in standard pharmaceutical journals disclosing an agave-syrup based oral pharmaceutical formulation. Agave syrup is not included within Petitioner's cited "Handbook of Pharmaceutical Excipients." (*See* Ex. 1029, 14 (no entry for agave syrup).) There is no USP monograph for agave, let alone agave syrup. (Ex. 2009, ¶144; *see* Ex. 2016.) Likewise, agave syrup is also not found in the FDA index of generally recognized as safe (GRAS) ingredients. Agave syrup's absence from within these types of general resources within the art further proves that agave syrup is not merely an "old ingredient" performing the same function it was known to perform. Indeed, there is no reference cited by Petitioner that mentions the use of agave syrup to make oral formulations *with specifically desirable viscosity*, as recited in the claims. Plus, again, Petitioner's own cited exhibit demonstrates that variable viscosity of agave syrup impacts their quality and acceptability, which is a known variable never acknowledged or explained in the Petition.

With respect to the viscosity limitation of claim 1 of the '795 patent, the Petition fails to carry its burden by identifying with particularity *any* basis for combining specific aspects of FR458 with either the '4666 patent and/or WO133 patent. (Ex. 2009, ¶¶139-53, 165-172.) *See Simpson Strong-Tie Co. v. Columbia Ins. Co.*, PGR2021-00109, Paper 73 at 11 (P.T.A.B. March 15, 2013) (citing 35 U.S.C. § 322(a)(3) as requiring post-grant review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”); *cf. Harmonic Inc.*, 815 F.3d at 1363 (“[I]t was [Petitioner’s] burden to explain to the Board how [the combination of prior art] rendered the challenged claims unpatentable.”). Additionally, although “[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,” *In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981); *see also In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012) (citing *Keller*, 642 F.2d at 425), the Petitioner must address whether “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention,” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007).

Without any argument regarding a specific motivation to combine them, the entirety of the Petition’s arguments regarding the viscosity limitation are improperly framed from the perspective of the recited claim language and make a conclusory

identification of: (1) a clearly erroneous viscosity of agave syrup, (2) FR458-Example 1 (unmodified), and (3) viscosity ranges disclosed in the '4666 patent and WO133:

A person of ordinary skill in the art would understand that an oral liquid formulation needs a viscosity low enough for it to be pourable and drinkable. Ex. 1003 at ¶¶ 28, 58-59, 216. ***The viscosity of agave syrup has been reported to be about 212 centipoise.*** Ex. 1003 at ¶ 52. Thus, a person of ordinary skill in the art would understand that the formulation disclosed in ***Example 1 of FR458***, which is largely made up of agave syrup, ***may have a viscosity less than 1500 centipoise.*** Ex. 1003 at ¶ 119. As both the '4666 Patent and WO133 disclose appropriate viscosity ranges for an oral formulation with an analgesic, ***it is unnecessary for the Board to conclude that Example 1 of the FR458 meets this limitation.*** The '4666 patent discloses a viscosity range measured at 20° by a Brookfield Synchro-Lectric viscometer of 1000 to 3000 centipoise. Ex. 1005 at col. 4, lns. 9-17. Claim 11 lowers the lower viscosity limit from 1000 to 100 centipoise. *Id.*, at col. 6, lns. 66-67. WO133 teaches a tighter viscosity range of 200 to 900 centipoise for its oral analgesic formulation. Ex. 1006 at [8, lns. 1-3]. A person of ordinary skill in the art would conclude that the viscosity ranges disclosed in the '4666 Patent and WO133 teach the viscosity limitation of the '795 Patent. Ex. 1003 at ¶¶ 119-121.

(Pet. at 31-32 (emphasis added and footnotes omitted); *see also id.* at 34, 45-45, 52-53 (discussing dependent claims related to viscosity).) With respect to

independent claims 7 and 18, Ground 1 merely asserts that the viscosity limitation in those claims is disclosed for the same reasons as set forth for claim 1. (*See id.* at 39, 47.)

Petitioner's own expert, Dr. Crowley, states that "[g]enerally, suspensions ***having a viscosity in the range of 20 to 150 cP are considered readily pourable.***" (Ex. 1003, ¶59 (emphasis added).) This shows that the Petition's assertion that "[a] person of ordinary skill in the art would understand that an oral liquid formulation needs a viscosity low enough for it to be pourable and drinkable" can and does apply to oral formulations with viscosities of from 20-150 cP, which is well below and outside the preferred 1000-3000 cP range of the '4666 patent and the 200-900 cP range of WO133 in Petitioner's conclusory assertion under this claim element. (Ex. 2009, ¶148.) *See Magnum Oil Tools*, 829 F.3d at 1380 (holding petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements.").

Petitioner's expert further argued against any viscosity higher than those that are considered "readily pourable with ***“a viscosity in the range of 20 to 150 cP”*** for acetaminophen formulations because "increasing the viscosity of a suspension formulation has been show to impair the dissolution characteristics of immediate release acetaminophen." (Ex. 1003, ¶59 (emphasis added).) Petitioner's expert also

argued that “[w]ith respect to suspensions for oral administration, having a higher viscosity is generally not desirable.” (*Id.*) Thus, 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. (Ex. 2009, ¶148.)

Such teaching away—even beyond the lack of any particular motivation articulated in the Petition to carry Petitioner’s burden in combining any specific features of FR458, the ’4666 patent, and WO133 in anything other than in an omnibus fashion—further proves that a POSA would not have been motivated to combine FR458-Example 1 with the 1000-3000 cP range of the ’4666 patent and the 200-900 cP range of WO133. (Ex. 2009, ¶¶148-50.) A reference that “teaches away” negates motivation to combine. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (Fed. Cir. 2007) (“[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious”); *Chemours Co. FC, LLC v. Daikin Ind., Ltd.*, 4 F.4th 1370, 1376–77 (Fed. Cir. 2021) (reversing the PTAB’s finding of obviousness because the prior art reference relied on taught away from the claim limitation broadening

molecular weight distribution and there was no substantial evidence as to why a POSA would alter the prior art's teaching).

Further underscoring the failure in any motivation to combine is the plain error in Petitioner's assertion for the viscosity of agave syrup, which in the Petition's cited exhibit 1031 is 2,560 cP—not 212 cP. (Ex. 2009, ¶¶111-21.) Ground 1 is wholly reliant on Dr. Crowley's conclusory error, which cannot sustain a finding of obviousness. *See Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001) (holding that conclusory statements offered by experts are not evidence).

Additionally, Petitioner articulates no motivation or any reasonable expectation of success under Ground 1 when the correct cited value of 2,560 cP is used. (Ex. 2009, ¶¶119-20.) Of course, such a value for the viscosity of agave syrup is well-outside the viscosity limitation of all claims of the '795 patent and the absence of any explanation of this error or any discussion for how using the *correct* cited viscosity value for agave syrup of 2,560 cP would yield any legally-plausible and particularized theory of obviousness simply dooms the petition. *See Dynamic Drinkware*, 800 F.3d at 1378 (stating the "burden never shifts to patentee").

Nevertheless, Petitioner's erroneous identification of the purported viscosity of agave syrup and related arguments further negate any motivation to combine

FR458-Example 1 with the preferred 1000-3000 cP range of the '4666 patent and the 200-900 cP range of WO133 or any reasonable expectation of success in doing so. (Ex. 2009, ¶¶148-50.) First, Petitioner fails to carry its burden since there is simply nothing other than a conclusory assertion of a reasonable expectation of success. Even accepting Petitioner's erroneous 212 cP value for the viscosity of agave syrup, which the Board should not do, Petitioner never asserts or demonstrates that the resulting viscosity of the formulation in FR458-Example 1 using agave syrup with a viscosity of 212 cP would simply meet both the preferred 1000-3000 cP range of the '4666 patent and the 200-900 cP range of WO133 as viable combinations. (Ex. 2009, ¶¶150-52.) Notably, there is no argument in the Petition regarding modifying FR458-Example 1 as part of the combination under Ground 1. The Petition just presumes FR458-Example 1 without modification using an agave syrup with a viscosity of 212 cP would somehow result in a successful combination with the preferred 1000-3000 cP range of the '4666 patent and the 200-900 cP range of WO133. But this presumption is indisputably wrong. (*See* Ex. 2009, ¶¶139-53.)

While it is not Patent Owner's burden to disprove arguments that have not been raised in a Petition, a POSA would not have been motivated or had a reasonable expectation of success in combining FR458-Example 1 using an agave syrup with 212 cP in combination with either the preferred 1000-3000 cP range of the '4666

patent and the 200-900 cP range of WO133, as demonstrated by Petitioner's own arguments and evidence. (Ex. 2009, ¶150.) The Petition never asserts a viscosity of FR458-Example 1 if an agave syrup with viscosity of 212 cP is used to show it would have been reasonably expected to fall within either the preferred 1000-3000 cP range of the '4666 patent and the 200-900 cP range of WO133. In this regard, however, Petitioner's expert's declaration testimony proves otherwise.

Dr. Crowley cites to the erroneous viscosity value of 212 cP for agave syrup and then admits, as he must, that "[a] person of ordinary skill in the art would have known that the viscosity of agave syrup can be further reduced by adding additional water to the syrup." (Ex. 1003, ¶52.) The Petition never addresses the fact that FR458-Example 1 is primarily made up of water (at least ~50%) and, as such, that the viscosity of the example with its substantial additional water would be much less than the viscosity of the agave syrup. (Ex. 2009, ¶¶149-50.)

Indeed, a POSA would have expected, using the erroneous viscosity of the undiluted agave syrup that Petitioner wrongly contends is 212 cP, that the viscosity of FR458-Example 1 with all of its additional water would be closer to the viscosity of water (i.e., below 100 cP) than Petitioner's undiluted agave syrup with 212 cP value. (Ex. 2009, ¶150.) FR458-Example 1 would be just the sort of formulation that Dr. Crowley has recognized as being "readily pourable" (Ex. 1003, ¶52 ("a

viscosity in the range of 20 to 150 cP are considered readily pourable”), such that a POSA would have had neither a motivation or a reasonable expectation of success in using FR458-Example 1 in combination with either the preferred 1000-3000 cP range of the ’4666 patent and the 200-900 cP range of WO133 because FR458-Example 1 would have been expected to have a viscosity well below and outside either of those ranges.⁶ (*Id.*)

The Petition never explains why it ignores Petitioner’s own expert’s assertions teaching away from any combination of FR458-Example 1 and the 1000-3000 cP range of the ’4666 patent and the 200-900 cP range of WO133. (Ex. 2009, ¶152.) Instead, the Petition merely selects an unjustifiable and erroneous viscosity of agave syrup (212 cP) that falls within the claims, never accounts for the final viscosity of the FR458-Example 1 simply assuming it falls within the claims, never provides any articulation of how FR458-Example 1 could or should be modified *at all* let alone in

⁶ A POSA also would have had no motivation or reasonable expectation of success in combining FR458 with the obviously erroneous 100-3000 cP viscosity range cited by Petitioner in the ’4666 patent since a POSA would have expected the viscosity of FR458 with its substantial addition of water to the agave syrup to result in a viscosity that is more likely than not below 100 cP. (Ex. 2009, ¶150.)

support of any articulated obviousness theory, and never demonstrates any plausible motivation or reasonable expectation of success that FR458-Example 1 would achieve the viscosity ranges in either the '4666 patent or WO133 based. (*See* Pet. at 31-32.) Petitioner's failures and reliance on hindsight cannot demonstrate obviousness of any independent claims, and hence all claims, of the '795 patent.

2. The Petition's conclusory and hindsight assertions under Ground 1 fail to address the independent claims *as a whole*

In using the claim as a hindsight-based template and devoid of any articulated justification, Petitioner merely contends that “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 of less than 1500 centipoise.*” (Pet. at 31 (emphasis added).) The Petition then avers that “[a]s 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 FR458 meets this [viscosity] limitation.*” (*Id.* (emphasis added).) Petitioner's reference to the limitations of the claims—less than 1500 centipoise—evinces the Petition's reliance on hindsight.

Additionally, the Petition does nothing more than make a conclusory identification FR458-Example 1 and the viscosity ranges in the '4666 patent or WO144. (Pet. at 29.) The Petition, however, fails to address the claims *as a whole*

since there is no articulation that FR458-Example 1 (as posited by Petitioner without any modifications) would have a viscosity that fell within either the 1000-3000 cP range of the '4666 patent and the 200-900 cP range of WO133, let alone in the context of Petitioner's erroneous identification of agave syrup with viscosity of 212 cP. To the contrary, the Petition ambiguously alleges that FR458-Example 1 "may have a viscosity of less than 1500 centipoise," tacitly admitting that FR458-Example 1 may equally have a viscosity of greater than 1500 centipoise.

Petitioner's hypothetical conjecture that FR458-Example 1 *may* or *may not* satisfy the claims viscosity limitation, particularly in the absence of any showing that a POSA would expect FR458-Example 1 to have a viscosity that meets the viscosity ranges in either the '4666 patent or WO133, cannot carry the Petition's burden for obviousness. Ground 1 does not address the claims *as a whole* and therefore cannot support a plausible basis for a finding of obviousness. *See Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108 (Fed. Cir. 1987) (In determining obviousness, "the inquiry is not whether each element existed in the prior art, but whether the prior art made obvious ***the invention as a whole*** for which patentability is claimed.") (emphasis added)).

3. Ground 1 further fails with respect to the obviousness of the dependent claims

Petitioner's reliance on hindsight and its failure to address the claims as a whole is further demonstrated by the Petition's conclusory assertions regarding the dependent claims.

a. Dependent claims reciting narrowed viscosity ranges (claims 2-4, 15, 19)

Claims 2-4 and 19 of the '795 patent further narrow the recited viscosity range of independent claims 1 and 18 to "less than 1000 centipoise," "less than 750 centipoise," or "less than 600 centipoise." (Ex. 1001, 5:42-50.) Here, Petitioner merely alleges in conclusory fashion that these dependent claims are satisfied under Ground 1 by relying on the obvious error in "Claim 11 of the '4666 patent [that] discloses a viscosity range from 100 to 3000 centipoise" and WO133 teaches a viscosity range of 200 to 900 centipoise." (Pet. at 34 (cls. 2-4), 52 (cl. 19).)

As noted above, a POSA would have disregarded the obvious typographical error in claim 11 of the '4666 patent. Also, again, Petitioner fails to demonstrate or acknowledge that a POSA would have understood that FR458-Example 1, being composed of substantial amounts of additional water, would have a viscosity well below 200 cP if an agave syrup with 212 cP was used within it such that there would be neither a motivation nor a reasonable expectation of success in any such combination with the 200-900 cP range of WO133. (Ex. 2009, ¶¶150-52.) The

Petition's mere conclusory statement that "both teach viscosity below the upper level required" by claims 2-4 and 19 fails to address the claims as a whole. (*See* Pet. at 34 (cls. 2-4), 52 (cl. 19).)

Claim 15 further narrows the viscosity range of independent claim 7 to "a viscosity from about 1500 centipoise to about 400 centipoise." (Ex. 1001, 6:24-29.) Again, here, Petitioner merely points to the obvious error range of the '4666 patent and the range of WO133 without addressing the claims as a whole and the fact that highly watered-down FR458-Example 1 does not satisfy any of the viscosity ranges in the '4666 patent or WO133. (Ex. 2009, ¶¶150-52.)

b. Dependent claims reciting acetaminophen concentrations (claims 5, 6, 8)

Claims 5, 6, and 8 recite concentrations of the acetaminophen in the claimed formulations as being "0.01 to 2 grams . . . per 100 mL," "0.01 to 1 grams...per 100 mL," and "between 0.01% to 2% of the formulation by weight." (Ex. 1001, 5:51-56, 6:6-8.) Petitioner contends that the proposed combination of Ground 1 allegedly satisfies these dependent concentration limitations based on FR458 teaching that "the API can be between 0.01 to about 90% of the formulation" and WO133 teaching a concentration of "up to about 10% by weight." (Pet. at 42; *see also id.* at 34-35.) Where, as here the disclosed range is "so broad as to encompass a very large number of possible distinct compositions," overlapping ranges do not apply. *Genetics Inst.*,

LLC v. Novartis Vaccines & Diagnostics, Inc., 655 F.3d 1291, 1306 (Fed. Cir. 2011) (citing *In re Peterson*, 315 F.3d 1325, 1330 n.1 (Fed. Cir. 2003)). Second, Petitioner again fails to address the claims as a whole and never accounts for how the addition of substantial amounts of insoluble acetaminophen particles—i.e., up to 90% or up to 10%—would impact the overall viscosity of any such formulations or how FR458-Example 1 would otherwise have been modified to address the expected impacts of any such highly concentrated formulations. (Ex. 2009, ¶¶158-59.)

c. Dependent claim 9 reciting “about 5%” diluent

Claim 9 recites a further limitation to independent claim 7, “wherein the diluent is about 5% of the formulation by weight.” (Ex. 1001, 6:9-11.) FR458-Example 1 is at least about 45% of the formulation by weight. (Ex. 2009, ¶160.) Petitioner makes the conclusory assertion that “[a] person of ordinary skill in the art would understand that the amount of water serves to bring the formulation to a desired volume and can be modified *within reason* without altering the effectiveness of the formulation” and that “this would include formulations where the water is about 5% by weight.” (Pet. at 42-43.) But a change in FR458-Example 1 from over 45% water to 5% water would not be “within reason.” (See Ex. 2009, ¶161.) FR458 already provides a final volume of 100 mL for FR458-Example 1 to achieve, at least in part, the desired concentration of acetaminophen. (See *id.*, ¶¶82-83.) Petitioner fails to address why a POSA would find anything lacking in FR458-Example 1 to

justify changing FR458 and further fails to address the claim 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. (*Id.*)

a. Dependent claims 13 and 24 reciting “about 95%” agave syrup

Claims 13 and 24 recites the further limitation that the claimed formulations, “wherein the agave syrup is about 95% of the formulation by weight.” (Ex. 1001, 6:19-21, 57-58.) The agave syrup in FR458-Example 1 is less than 45% of the formulation by weight. (Ex. 2009, ¶163.) Petitioner makes the conclusory assertion that “the amount of agave syrup to use in the formulation is a design choice within the general knowledge of the skilled artisan” and that the claim is allegedly satisfied because a prior art reference teaches that “sweeteners” can be added to “food products and medicines” in a “range from 2% to 98% of their total content.” (Pet. at 43.) This range is so broad it cannot support obviousness. *See Genetics Inst.*, 655 F.3d at 1306. Likewise, Petitioner’s conclusory assertion of a “design choice” cannot support obviousness. *See Magnum Oil Tools*, 829 F.3d at 1380. Finally, Petition again fails to address the claims as a whole by failing to provide any discussion regarding a motivation or reasonable expectation of success to make a “design choice” to modify FR458-Example 1 or how such a modification would also impact the viscosity of FR458-Example 1. (*See* Ex. 2009, ¶164.)

C. Ground 2 Fails to Demonstrate Obviousness of Any Claim

Petitioner identifies three “and/or” permutations under Ground 2 against claims 1-17 of the '795 patent that merely substitutes FR458 of Ground 1 with WO742, and combines it with the '4666 patent and/or WO133. (*See* Pet. at 54 n.26.) Petitioner does not address each of these proposed combinations individually or with particularity, instead merely conflating the permutations within the Petition.

1. Agave syrup is not a “well known ingredient” for use in oral pharmaceutical formulations

The Petition's assertions of a motivation to combine and reasonable expectation of success under Ground 1 are generic as to the entirety of the references and asserted in a single paragraph. (*See* Pet. at 54-55.) With respect to a motivation to combine, the Petition generically alleges that WO742, the '4666 patent, and/or WO133 can be combined allegedly because “WO742 seeks to provide a safer form of an oral formulation” and that because all three references are in the same filed and include acetaminophen as an analgesic a POSA would generically combine them together. (*Id.* at 55.) The Petition provides no motivation for combining any of the specific teachings within the three references with any specific teachings of the other references.

The Petition asserts only the following conclusory statements regarding a purported reasonable expectation of success:

A person of ordinary skill in the art would have had a reasonable expectation of success in combining these references because they all disclose formulations comprising well known ingredients performing well known functions. *KSR Int'l Co.*, at 417. Therefore, a person of ordinary skill in the art would be motivated to combine these teachings and would have a reasonable expectation of success in so doing. Ex. 1003 at ¶¶ 195-198.

(*Id.*)

Patent Owner has already addressed Petitioner's incorrect and conclusory assertion that agave syrup is simply a "well known ingredient performing well known functions" with respect to Ground 1 and incorporates those same arguments and cited evidence herein. (*See* Section II.B.) As noted, however, if agave syrup was indeed a "well known ingredient" as Petitioner contends, then Petitioner presumably would not have made so glaring of an error regarding the cited viscosity of agave syrup as reported in Petitioner's cited Exhibit 1031.

2. There is no reasoned articulation of a motivation to combine or reasonable expectation of success regarding the viscosity of WO742-Example IX

Petitioner makes no motivation to combine arguments for any specific disclosures or teachings within WO742, the '4666 patent, or WO133 with a reasonable expectation of success under Ground 2. Rather, with respect to the viscosity limitation of independent claim 1 of the '795 patent, the Petition makes a

conclusory identification of: (1) a clearly erroneous viscosity of agave syrup, (2) WO742-Example IX (unmodified), and (3) viscosity ranges from the '4666 patent and WO133:

A person of ordinary skill in the art would understand that an oral formulation needs a viscosity that allows it to be pourable and drinkable. Ex. 1003 at ¶¶ 216. ***The viscosity of agave syrup is reported to be about 212 centipoise.*** Ex. 1003 at ¶ 52. Thus, a person of ordinary skill in the art would understand that the formulation disclosed in ***Example IX of WO742***, which consists mainly of agave syrup and other ingredients with relatively low viscosities, ***may have a viscosity of less than 1500 centipoise.*** Ex. 1003 at ¶ 216, p. 121, fn. 25. As both the '4666 Patent and WO133 disclose viscosity ranges for an oral formulation with an analgesic that overlap with this claim limitation, ***it is unnecessary for the Board to conclude that Example V [sic] of the WO742 meets this limitation.*** The '4666 patent discloses a viscosity range measured at 20° C. by a Brookfield Synchro-Lectric viscometer of 1000 to 3000 centipoise. Ex. 1005 at col. 4, lns. 9-19. Claim 11 of the '4666 Patent further lowers the lower limit of this range from 1000 to 100. *Id.*, col. 6, lns. 66-67. WO133 teaches a tighter viscosity range of 200 to 900 centipoise for its oral analgesic formulation. Ex. 1006 at 8, lns. 1-3. A person of ordinary skill in the art would conclude that the viscosity ranges disclosed in the '4666 Patent and WO133 teach the viscosity limitation of the '795 Patent. Ex. 1003 at ¶¶ 215-218.

(Pet. at 57-58 (emphasis added and footnotes omitted); *see also id.* at 60, 66-67 (discussing dependent claims related to viscosity).) With respect to independent claims 7, Ground 2 merely asserts that the viscosity limitation in that claim is disclosed for the same reasons as set forth for claim 1. (*See id.* at 61-62.)

WO742 does not disclose the viscosity of WO742-Example IX. Nor does it disclose the type or viscosity of the agave syrup used within the example. (Ex. 2009, ¶¶104, 165.) Neither Petitioner nor Petitioner's expert identifies what a person of ordinary skill in the art would understand to be the viscosity of WO742-Example IX. (*Id.*, ¶¶167-68.) To the contrary, the Petition contends only that WO742-Example IX "may have a viscosity of less than 1500 centipoise," which presumably means Petitioner believes that WO742-Example IX is may have a viscosity of more than 1500 centipoise. (*Id.*, ¶¶119-20.) Petitioner's failure to identify any plausible viscosity for WO742-Example IX without reference to the viscosity limit recited in claim 1 is transparently based on impermissible hindsight.

As with Ground 1, Petitioner provides no identification, let alone a reasoned argument, as to how claim 1 would be satisfied by a high-quality agave syrup with a viscosity of 2,560 cP as disclosed in Petitioner's own cited Ex. 1031. (Ex. 2009, ¶167.) This error alone should be dispositive of Ground 2.

Nevertheless, a POSA would immediately recognize that WO742-Example IX would have a viscosity of at most around ~100 cP if Petitioner's erroneously identified agave syrup with a viscosity of 212 cP was used within the formula. (Ex. 2009, ¶¶168-69.) A POSA would recognize that the ethanol in WO742-Example IX would cause the overall formulation to be substantially thinner than the viscosity of the agave syrup and this thinning would be further increased by the addition of water up to the desired 15 mL dose volume—reducing the overall viscosity of the formulation well below that of the pure and undiluted agave syrup. (*Id.*; *see also* Ex. 1003, ¶52 (“A person of ordinary skill in the art would have known that the viscosity of agave syrup can be further reduced by adding additional water to the syrup.”).)

The presence of large amounts of propylene glycol with a low viscosity of 58.1 cP would further cause the overall formulation's viscosity to go down further because it is thinner than the agave syrup (and the propylene glycol's contribution to viscosity would also be further thinned by the ethanol and added water that is present). (Ex. 2009, ¶169.) Petitioner's expert further states that “[a]n 83% w/w solution of glycerin has a viscosity of 111.0 cP” to support his contention that “none of the added ingredients would be expected to increase the viscosity” of the

formulation, and this lower viscosity material would further impart a lower viscosity in the overall formulation of WO742-Example IX. (*See* Ex. 1003, ¶216.)

A POSA would further know that the viscosity of sugars and polyols like sucrose and glycerin have non-linear changes in viscosity with the addition of solvents such as ethanol and water. (Ex. 2009, ¶170.) A POSA would therefore have expected there to be a substantial lowering of the viscosity in WO742-Example IX in view of the amount of ethanol and added water within the milieu of the other ingredients. (*Id.* (citing Ex. 1029, 592 (Table V); Ex. 2022).) That is, a POSA would have reasonably expected that using an agave syrup with viscosity of 212 cP in WO742-Example IX would result in a formulation with a viscosity below 200 cP (and most likely around ~100 cP). (Ex. 2009, ¶¶168-70.)

In view of the foregoing, a POSA would have neither a motivation to nor a reasonable expectation of success in combining an agave syrup with viscosity of 212 cP within WO742-Example IX to achieve either the 1000-3000 cP range of the '4666 patent or the 200-900 cP range of WO133. (Ex. 2009, ¶171.) A POSA would not find an agave syrup with 212 cP that is thinned by ethanol and water as in WO742-Example 1 to be remotely suitable in combination with the 1000-3000 cP range of the '4666 patent. (*Id.*) Likewise, a POSA would understand that Petitioner's proposed use of an agave syrup of 212 cP would result in a viscosity of WO742-

Example 1 well below the 200-900 cP range of WO133, negating any motivation to combine or reasonable expectation of success in that 200-900 cP viscosity range. Rather, use of the low quality/low viscosity 212 cP agave syrup in WO742-Example IX merely results in a low viscosity and readily pourable oral formulation. (Ex. 1003, ¶59 (“Generally, suspensions having *a viscosity in the range of 20 to 150 cP* are considered readily pourable.”) (emphasis added).)

Accordingly, beyond the dispositive errors regarding the cherry-picked viscosity for agave syrup that is not the 2,560 cP in Petitioner's cited exhibit, even Petitioner's conclusory assertion regarding obviousness with an agave syrup of 212 cP still fail.

3. Ground 2 further fails with respect to the obviousness of the dependent claims

Petitioner's reliance on hindsight and its failure to address the claims as a whole is further demonstrated by the Petition's conclusory assertions regarding the dependent claims.

a. Dependent claims reciting narrowed viscosity ranges (claims 2-4, 15)

Here, Petitioner merely alleges in conclusory fashion that the narrowed viscosity limitations in dependent claims 2-4 are satisfied under Ground 2 by relying on the obvious error in “Claim 11 of the '4666 patent [that] discloses a viscosity

range from 100 to 3000 centipoise” and WO133 teaches a viscosity range of 200 to 900 centipoise.” (Pet. at 60.)

As noted above, a POSA would have disregarded the obvious typographical error in claim 11 of the '4666 patent. Also, again, Petitioner fails to demonstrate or acknowledge that a POSA would have understood that WO742-Example IX, which includes ethanol and added water, would have a viscosity well below 200 cP if an agave syrup with 212 cP was used within it such that there would be neither a motivation nor a reasonable expectation of success in any such combination with the 200-900 cP range of WO133. (Ex. 2009, ¶¶169-71.) The Petition's mere conclusory statement that “both [the '4666 patent and WO133] teach viscosity below the upper level required” by claims 2-4 fails to address the claims as a whole. (See Pet. at 34 (cls. 2-4), 52 (cl. 19).)

Claim 15 further narrows the viscosity range of independent claim 7 to “a viscosity from about 1500 centipoise to about 400 centipoise.” (Ex. 1001, 6:24-29.) Again, here, Petitioner merely points to the obvious error range of the '4666 patent and the range of WO133 without addressing the claims as a whole and that a POSA would not have had a motivation or reasonable expectation that WO742-Example IX (even using the erroneous agave syrup viscosity of 212 cP) would satisfy the viscosity ranges in the '4666 patent or WO133. (See Ex. 2009, ¶174.)

b. Dependent claims reciting acetaminophen concentrations (claims 5, 6)

Claims 5 and 6 recite concentrations of the acetaminophen in the claimed formulations as being “0.01 to 2 grams . . . per 100 mL,” “0.01 to 1 grams . . . per 100 mL,” (Ex. 1001, 5:51-56, 6:6-8.) Petitioner contends that the proposed combination of Ground 1 allegedly satisfies these dependent concentration limitations based on WO133 teaching a concentration of “up to about 10% by weight.” (Pet. at 60-61.) Where, as here the disclosed range is “so broad as to encompass a very large number of possible distinct compositions,” overlapping ranges do not apply. *Genetics Inst.*, 655 F.3d at 1306. Additionally, Petitioner again fails to address claims as a whole and never accounts for how the addition of substantial amounts of insoluble acetaminophen particles—i.e., up to 10%—would impact the overall viscosity of any such formulations or how WO742-Example IX could or would otherwise have been modified to address the expected impacts of any such highly concentrated formulations. (Ex. 2009, ¶177.)

Petitioner further contends that the concentration of acetaminophen in WO742-Example IX is “1 mg per 100 mL.” (Pet. at 61.) But this assertion does not satisfy either claims 5 or 6 since “1 mg per 100 mL” is 0.001 g per 100 mL, which is below the lower “0.01 g” per 100 mL limit recited in claims 5 and 6. (Ex. 2009, ¶¶175-77.)

c. Dependent claim 9 reciting “about 5%” diluent

Claim 9 recites a further limitation to independent claim 7, “wherein the diluent is about 5% of the formulation by weight.” (Ex. 1001, 6:9-11.) Petitioner asserts that “[t]he examples of WO742 and the '4666 patent include ‘Water, Purified q.s.’ in this context ‘q.s.’ means to add the quantity of water sufficient to achieve the desired final volume.” (Pet. at 64.) Petitioner then makes the conclusory assertion that “[a] person of ordinary skill in the art would understand that [the] amount of water is not critical, but merely serves to bring the formulation to a desired volume” and “[t]hat disclosure would include formulations where the water is about 5% by weight.” (*Id.*)

But WO742-Example IX already provides a final volume of 15 mL for the final volume to achieve the desired concentration of acetaminophen. (Ex. 2009, ¶178.) Petitioner does not contend or assert the amount of added water that is present in WO742-Example 1 and, as such, does not explain whether the example would need to have water removed or added in order for the water to be 5% of the formulation. (*Id.*) Petitioner also fails to address why a POSA would find anything lacking in WO742-Example IX to justify changing it.

Moreover, Petitioner's statement that “the amount of water is not critical” further demonstrates its failure to address the claim as a whole. A POSA would both understand and expect that changes in the amount of water in a formulation could

impart significant viscosity changes. (Ex. 2009, ¶55.) The Petition fails to square its assertion that the “amount of water is not critical” when more water is added to WO742-Example IX such that its viscosity would be further reduced away from the viscosity ranges of Petitioner's asserted combination. (*See id.*, ¶¶55, 169-70.)

d. Dependent claim 13

Claim 13 recites “wherein the agave syrup is about 95% of the formulation by weight.” (Ex. 1001, 6:19-21, 57-58.) The agave syrup in WO742-Example IX constitutes 11 mL of the 15 mL formulation—i.e., ~73% by volume—and this is much less than the “about 95% of the formulation by weight” recited in the claims. (Ex. 1007, 23:16-29.) Petitioner makes the conclusory assertion that “the amount of agave syrup to use in the formulation is a design choice within the general knowledge of the skilled artisan” and that the claim is allegedly satisfied because a prior art reference teaches that “sweeteners” can be added to “food products and medicines” in a “range from 2% to 98% of their total content.” (Pet. at 43.) This range is so broad it cannot support obviousness. *See Genetics Inst.*, 655 F.3d at 1306. Likewise, Petitioner's conclusory assertion of a “design choice” cannot support obviousness. *See Magnum Oil Tools*, 829 F.3d at 1380. Finally, Petition again fails to address claim 15 as a whole by failing to provide any discussion regarding a motivation or reasonable expectation of success to make a “design

choice” to modify WO742-Example IX or how such a modification would also impact viscosity. (*See* Ex. 2009, ¶174.)

D. Ground 3

Petitioner's Ground 3 is presented as merely an “alternative” ground, which alleges indefiniteness but only “[t]o the extent that patentees assert” that FR458, the '4666 Patent, and WO133 under Ground 1 do not satisfy the “palatable,” “stable,” and “consisting essentially of” limitation of certain challenged claims. (*See* Pet. at 68-72.) In this Response, Patent Owner has not made any arguments relating to the terms “palatable,” “stable,” or “consisting essentially of.” Hence, the conditions of Petitioner's alternative Ground 3 have not been met. Petitioner's alternative Ground 3 is moot, and the Board need not reach it.

VIII. CONCLUSION

For the foregoing reasons, Genexa respectfully requests that the Board confirm the patentability of Claims 1-24.

Patent Owner's Response
PGR2023-00051
U.S. Patent No. 11,617,795

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CERTIFICATE OF COMPLIANCE WITH WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), I certify that this petition complies with the type-volume limits of 37 C.F.R. § 42.24(b)(2) because it contains 14,642 words, according to the word-processing system used to prepare this response, excluding the parts of this response that are exempted by 37 C.F.R. § 42.24(a) (including the table of contents, a table of authorities, mandatory notices, a certificate of service or this certificate word count, appendix of exhibits, and claim listings).

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4), the undersigned certifies that on June 14, 2024, a complete and entire copy of PATENT OWNER'S RESPONSE TO PETITION and EXHIBITS 2009-2023 were served via electronic mail on the Petitioner by serving Petitioner's counsel of record as follows:

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