

KinderFarms LLC

Petitioner

v.

Genexa Inc.,

Patent Owner

PGR2023-00051

Patent 11,617,795

Patent Owner's Demonstratives

Oral Argument

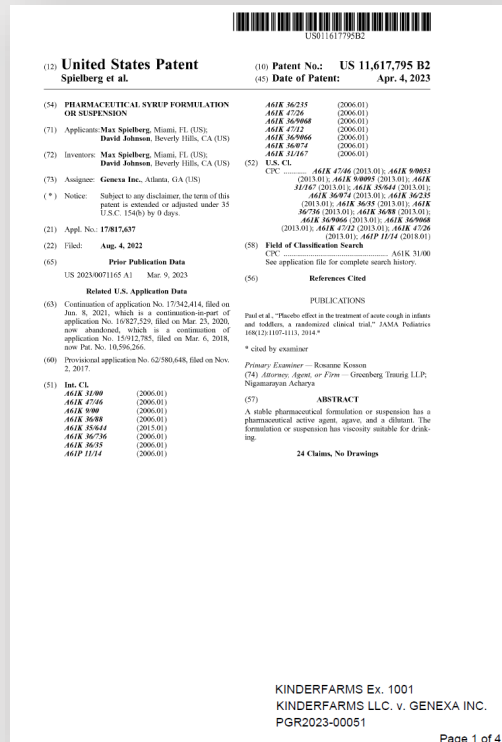
December 12, 2024

Overview of Patent Owner's Argument

- I. Introduction and Background
- II. Level of Skill
- III. Claim Construction
- IV. Legal Standards
- V. Material Errors in the Petition
- VI. Ground 1 Fails To Demonstrate Obviousness of Claims 1-24
- VII. Ground 2 Fails to Demonstrate Obviousness of Claims 1-17
- VIII. Ground 3 is moot

Introduction and Background

The '795 Patent



Ex.1001

SUMMARY

One aspect includes a stable, pharmaceutical syrup formulation or suspension for oral administration having one or more pharmaceutical active agents, agave syrup, and a dilutant. The syrup formulation can have a viscosity of less than 1500 centipoise at 22 degrees.

-Ex.1001, 1:30-35

The syrup can have a viscosity of the type used with pharmaceutical suspensions or syrup formulations. The syrup can have a viscosity of between about 200 and 3500 centipoise at about 2.5 rpm to about 30 rpm as determined by a Brookfield Viscometer at about 22 degrees. Further, the syrup can have a viscosity of between about 350 and about 1500 centipoise. For example, the syrup formulation can have a viscosity of about 1500 centipoise at about 22 degrees. For example, the syrup formulation has a viscosity of about 1000 centipoise at about 22 degrees. For example, the syrup formulation has a viscosity of about 600 centipoise at about 22 degrees. In many examples, 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.

-Ex.1001, 2:12-27

-POR, 8-10

Oral Pharmaceutical Suspensions: Viscosity 1,500-4,000 cP

For an exemplary embodiment of the pharmaceutical composition, the pH is about 3.5 to about 4.5 and the disturbed viscosity (e.g. viscosity measured after mixing under specified conditions) at 25° C. will be about 1500 to about 4500 cps.

-Ex.2021, 8:17-21; see also Ex.2009, ¶51; POR at 6-7

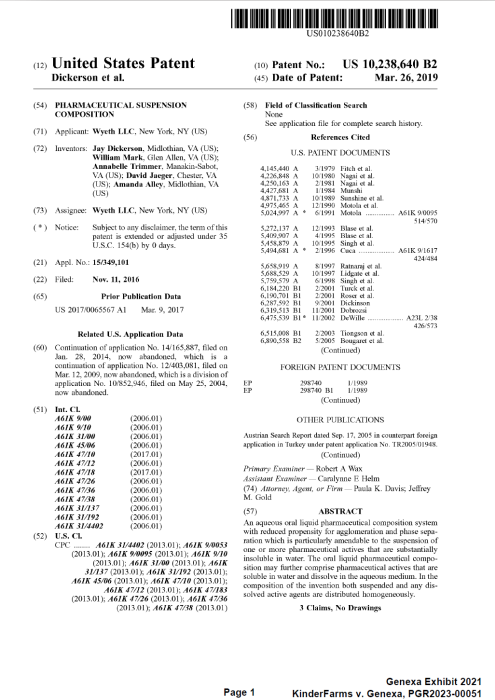
C. Acceptable Viscosities for Oral Liquid Pharmaceutical Formulations

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 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”).)

-POR at 6-7



Ex.2021

Commercially-Available Analgesic Oral Formulations: >1,500 cP

Cariogenic Potential of Pediatric Liquid Medicaments—An *in vitro* Study

Subramaniam P * / Nandan N **

Pediatric liquid medications (PLM) are popular and are easily accepted by both parents and children. They are widely prescribed and easily available. However the sugar content and properties of these preparations determines their cariogenic potential. **Aim and Objectives:** This study assessed the pH and viscosity of various PLM available in the market. **Methodology:** The study included all the most commonly prescribed analgesics, antibiotics, nutritional supplements, antiseptic and antiparasitic preparations. The endogenous pH was measured using a digital pH meter and the viscosity was measured using a viscometer. **Results:** Analysis of the results revealed that the majority of the preparations had High Performance Liquid Chromatography. The effect of PLM on Streptococcus mutans was done by a dilution plate method. **Results:** The pH of PLM ranged from 3.70 to 7.04 and viscosity varied from 307-365cP to 2408 cP respectively. Fifty percent of the preparations showed zones of inhibition against growth of streptococcus mutans. **Conclusions:** The physical properties of Pediatric Liquid Medicaments as well as the type and concentration of sugars present in them can be indicative of their cariogenic potential.

Keywords: pediatric liquid medications, pH, viscosity, sucrose, streptococcus mutans

J Clin Pediatr Dent 367: 357-362, 2012

INTRODUCTION

Systemic administration of drugs include oral, sublingual, rectal, cutaneous, inhalation, nasal and parenteral routes. Among these routes, the oral route is the oldest and the most common mode of drug administration. Pediatric liquid preparations are popular and are easily accepted by both parents and children. Syrups have a long history of use in pediatric medicine. They are widely prescribed, and are easily available. Their use is usually for a short duration, but for some children it may be a daily occurrence.

Although the active ingredients in these medicines are necessary for improvement or maintenance of health, some of the inactive ingredients pose a risk to dental health.³ The AAPD carries risk assessment tool (CAT) stipulates that children with chronic conditions and who are taking medicines may be at higher risk for dental diseases.⁴ Most of these liquid preparations are made palatable in order to gain patient compliance and are used extensively in children.⁵⁻⁸ The inclusion of sugars, in children's medicines is, primarily to mask the less pleasant taste of active ingredients.⁹ However, sugars added to medicines can be fermented by oral bacteria leading to acid formation and a drop in intra oral pH. Only few studies provide information about the concentration of free sugars present in liquid medicines and they are usually based on drug labels and on information from pharmaceutical

There is growing concern among pediatric dentists about the increased consumption of 'hidden sugars' by children, especially those who are chronically ill. It is important to assess the cariogenic potential of commonly used PLM. Hence the purpose of this study was to assess the endogenous pH and viscosity of pediatric liquid medicaments, type and concentration of sugars present in them and their effect on the growth of *Streptococcus mutans*.

Send all correspondence to: Dr. Priya Subramaniam, Department of Pedodontics and Preventive Dentistry, The Oxford Dental College, Hospital and Research Centre, Bommanahalli, Hosur Road, Bangalore-560068, Karnataka, India

Phone : + 91 9844225624
Fax : + 91 08025734656

E-mail: dpriyapedo@yahoo.com

MATERIALS AND METHOD

The study was conducted on ten pediatric liquid medications (PLM) of different pharmaceutical companies. These

The Journal of Clinical Pediatric Dentistry Volume 36, Number 4/2012

Page 1

357
Genexa Exhibit 2020
Genexa_PGR2023-00051

Page 1 KinderFarms v. Genexa, PGR2023-00051

Pediatric Liquid Medicaments

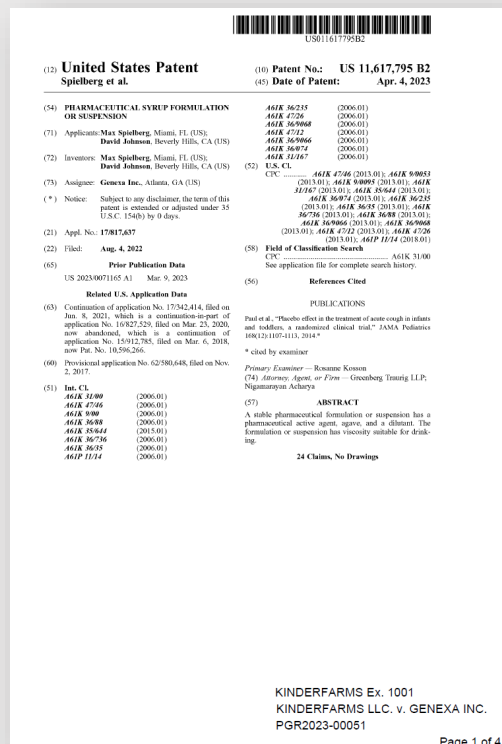
Table 1. Mean pH and Viscosity of Paediatric Liquid Medicaments

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	Dextromethorphan Hydrobromide, Chlorpheniramine maleate, Phenylephrine hydrochloride	Chericof	Sobrex Pharmaceuticals Company (for Ranbaxy Laboratories Limited)	4.66±0.01	1755.00±5.00

Ex.2020

-Ex.2020, 359; *see also* Ex.2009, ¶52; POR at 7

The '795 Patent: Claims Reciting Viscosity



Ex.1001

The invention claimed is:

1. A pharmaceutical syrup formulation for oral administration comprising:

- (a) acetaminophen,
- (b) agave syrup, and
- (c) a diluent, wherein the syrup formulation has a viscosity of less than 1500 centipoise at about 22 degrees; wherein the acetaminophen is suspended in the syrup; and wherein the syrup is palatable.

2. The pharmaceutical syrup formulation of claim 1, wherein the syrup formulation has a viscosity of less than 1000 centipoise at about 22 degrees.

3. The pharmaceutical syrup formulation of claim 1, wherein the syrup formulation has a viscosity of less than 750 centipoise at about 22 degrees.

4. The pharmaceutical syrup formulation of claim 1, wherein the syrup formulation has a viscosity of less than 600 centipoise at about 22 degrees.

7. A stable pharmaceutical syrup formulation for oral administration comprising:

- (a) acetaminophen;
- (b) agave syrup;
- (c) acidic preservative;
- (d) a flavoring agent, and
- (e) a diluent, wherein the syrup formulation has a viscosity of less than 1500 centipoise at about 22 degrees, and wherein the acetaminophen is suspended in the syrup.

15. The pharmaceutical syrup formulation of claim 7, wherein the composition is a medicinal preparation formulated as a syrup; and wherein the composition has a viscosity from about 1500 centipoise to about 400 centipoise at about 22 degrees.

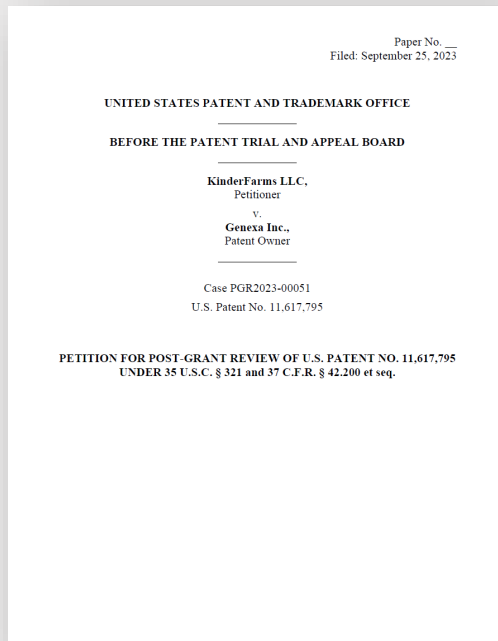
18. A stable, palatable pharmaceutical syrup formulation for oral administration consisting essentially of:

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

19. The formulation of claim 18, wherein the pharmaceutical syrup formulation has a viscosity of less than 1000 centipoise at about 22 degrees.

-Ex.1001, claims 1-4, 7, 15, 18-19; see also POR, 8-10

Petitioner's Grounds



Pet. (Paper 2)

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

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

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

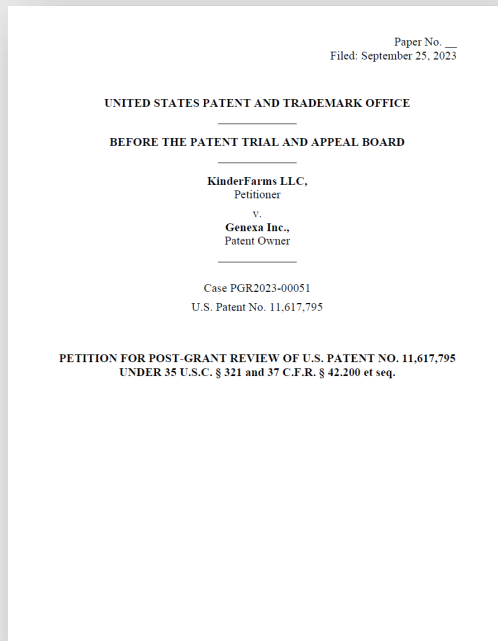
Ground 2. Claims 1 to 17 are not patentable as obvious in view of WO742 combined with the '4666 Patent and/or WO133.

Ground 3. In the alternative, Claims 1 to 24 are not patentable as indefinite

-Ex.1001, claims 1-4, 7, 15, 18-19

Level of Skill in the Art

Level of Skill



Institution Decision (Paper 8)

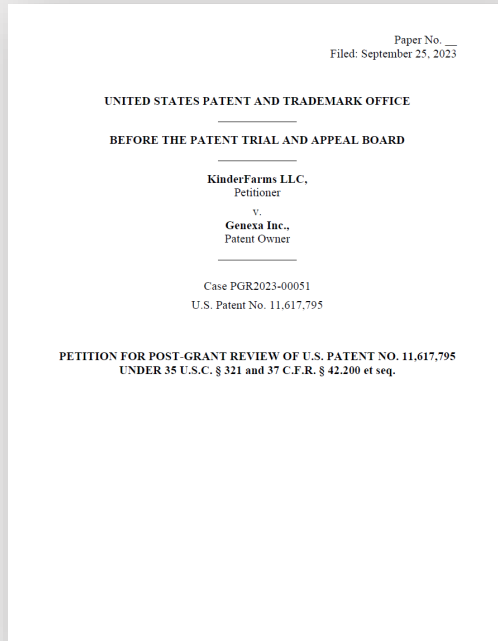
B. Level of Skill

Each party puts forth a characterization of the ordinarily skilled artisan in the field of the claims of the '795 patent. (See Pet. 13 (citing Crowley Decl., Ex. 1003, ¶¶ 90–91); see Prelim. Resp. 3–4.) The parties' proposed characterizations of the ordinarily skilled artisan are sufficiently similar that adoption of either would lead to the same result, institution. Thus, for the purposes of this Decision only, we adopt Patent Owner's characterization of the ordinarily skilled artisan as having a bachelor of science degree in a relevant life sciences field, such as, chemistry, biochemistry, or pharmacy, with at least two years of work or laboratory experience in pharmaceutical formulations, and access to one or more team members having experience in pharmaceutical formulation and pharmaceutical regulatory approvals, or, in the alternative, at least three to four years of work or laboratory experience in pharmaceutical formulations, and access to one or more team members having experience in pharmaceutical formulation and pharmaceutical regulatory approvals. (See Prelim. Resp. 3–4.) We also note that the level of skill of an ordinarily skilled artisan is revealed by the prior art. See *Okajima v. Bourdeau*, 261 F.3d 1350, 1354–55 (Fed. Cir. 2001) (holding that the absence of specific findings on the level of skill in the art does not give rise to reversible error "the prior art itself reflects an appropriate level and a need for testimony is not shown." (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163, 225 USPQ 34, 38 (Fed.Cir.1985))).

-ID, 6-7; see also POR at 10-12; Ex. 2009, 19-23

Claim Construction

The Board Construes Only Those Terms Necessary for Resolution



Institution Decision
(Paper 8)

C. Claim Construction

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

Patent Owner's Position Regarding Claim Construction

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.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KINDERFARMS, LLC,
Petitioner,

v.

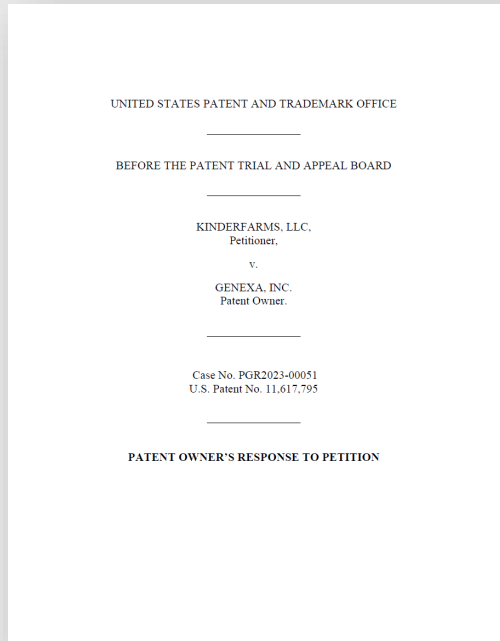
GENEXA, INC.,
Patent Owner.

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

PATENT OWNER'S RESPONSE TO PETITION

POR (Paper 20)

“Agave Syrup”



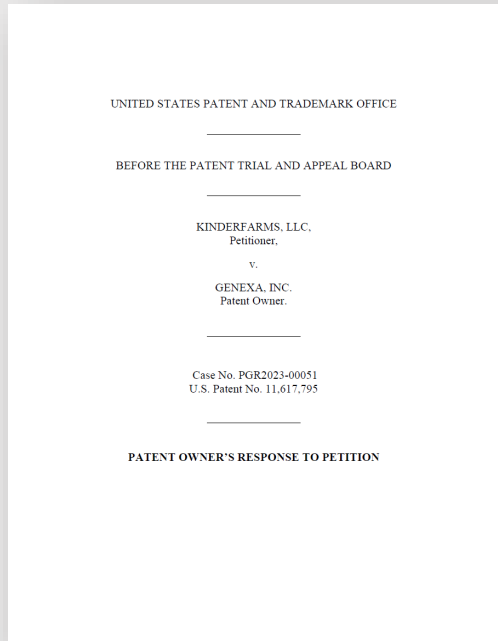
POR (Paper 20)

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.”

-POR, 13; see also Ex.2009, ¶¶106-108

The Board Need Not Construe “palatable,” “stable,” or “consisting essentially of”



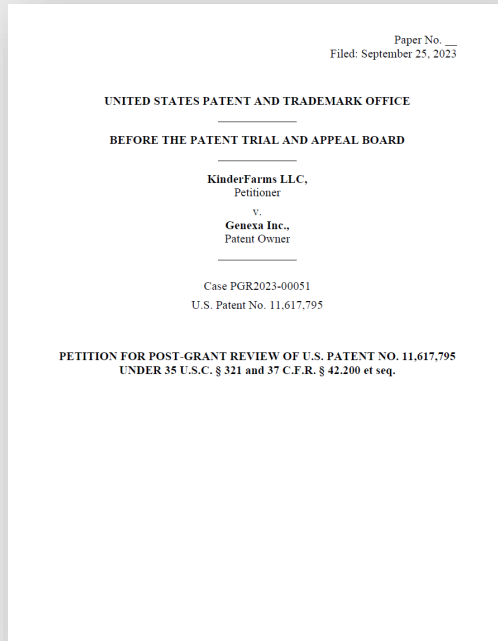
POR (Paper 20)

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.

-POR, 68; see also see also Ex.2009, ¶¶180-182

The Board Construes Only Those Terms Necessary for Resolution



Institution Decision
(Paper 8)

F. Ground 3 – Indefiniteness

Petitioner asserts a third ground of challenge, arguing that the claims of the '795 patent are indefinite under 35 U.S.C. § 112(b). (*See* Pet. 68–72.) Specifically, Petitioner argues that one of ordinary skill in the art would not have understood the scope of the terms “palatable,” “stable,” and “consisting essentially of.” (*See id.* (citing Crowley Decl., Ex. 1003, ¶¶ 268–273).) Petitioner explains that this ground of challenge is presented “[i]n the alternative,” because although Petitioner asserts that a person of ordinary skill in the art can apply the plain meanings to these terms, which are proposed in the construction section of the Petition, Patent Owner may argue that the cited prior art references do not teach one or more of these limitations. (*See* Pet. 68; *see also id.* at 69 (“To the extent that patentees assert that the prior art references discussed in section V.A.2(a)7 do not disclose the ‘palatable’ limitation, a person of ordinary skill in the art would not understand the meaning of the term.”). Essentially, Petitioner argues that if the prior art fails to teach the limitations in question, then they would necessarily be indefinite as “a person of ordinary skill in the art would not understand” their meaning. (*See id.* at 69.)

Legal Standards

Petitioner's Burden for Unpatentability and Particularity



- “[T]he petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable. See 35 U.S.C. § 312(a)(3) (requiring IPR petitions to identify ‘with particularity... the evidence that supports the grounds for the challenge to each claim’).”

—*Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016);
see also 35 U.S.C. § 322(a)(3) (Petitions in post-grant review)
- “It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify ‘with particularity’ the ‘evidence that supports the grounds for the challenge to each claim.’ 35 U.S.C. § 312(a)(3). . . [T]he expedited nature of IPRs bring with it an obligation for petitioners to make their case in their petition to institute. While the Board’s requirements are strict ones, they are requirements of which petitioners are aware when they seek to institute an IPR.”

—*Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016)
- “[T]he petitioner’s petition, not the Director’s discretion, is supposed to guide the life of the litigation.”

—*SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018)

Petitioner Cannot Carry Burden with Conclusory Statements



- “In an inter partes review, the burden of persuasion is on the petitioner to prove ‘unpatentability by a preponderance of the evidence,’ 35 U.S.C. § 316(e), and that **burden never shifts to the patentee.**”
—*Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015);
see also 35 U.S.C. § 326(e) (Conduct of post-grant review)
- Petitioner **cannot satisfy its burden of proving obviousness by “mere conclusory statements,”** but “must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.”
—*In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016)

Obviousness must address the claims “as a whole”



- “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)

- “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)

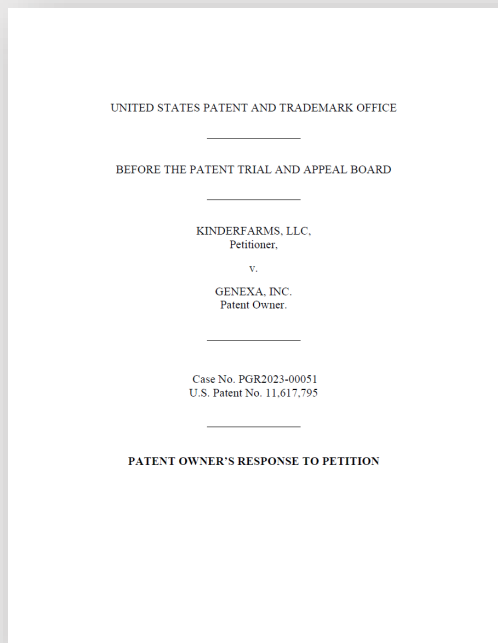
Material Errors in the Petition

Agave Syrup Does Not Have an Inherent Viscosity of 212 cP

The Petition Fails Because It Relied on an Unsubstantiated and Incorrect Viscosity Value for Agave Syrup

- Petitioner's cited Ex.1031 shows a mean viscosity of 2,560 cP for agave syrup
- Dr. Berkland could not identify any evidence from within Dr. Crowley's Declaration or exhibits to support agave syrup viscosity of 212 cP (Ex.1051, 24:3-17, 47:5-49:18)
- Petitioner presents to evidence to rebut that agave syrup with a mean viscosity of 2,560 cP cannot support obviousness within FR458-Example 1 and WO742-Example IX because a POSA would understand the resulting formulations would have viscosities >1,500 cP (Ex.2009, ¶¶118-119; see POR 47, 48, 30)
- A POSA would not have been motivated to select an agave syrup of low 212 cP viscosity (low quality) over a higher 2,560 cP viscosity (higher quality) agave syrup (Ex.2009, ¶¶120-121)
- Dr. Crowley did not submit a reply declaration
- Petitioner's attorney arguments in reply cannot rebut Dr. Berkland's declaration

The Petition Relies on an Incorrect Viscosity Value for Agave Syrup



POR (Paper 20)

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

-POR, 25; see also Ex.2009, ¶¶111-113

Petitioner’s Ex.1031: Agave Syrup Has Mean Viscosity Value of 2,560 cP

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

POR (Paper 20)

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

KINDERFARMS LLC. v. GENEXA INC.

PGR2023-00051

Page 1 of 1

UnitConverters.net

Home / About Us / Privacy Policy / Contact Us / 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: 2.56 pascal second

To: 2560 centipoise

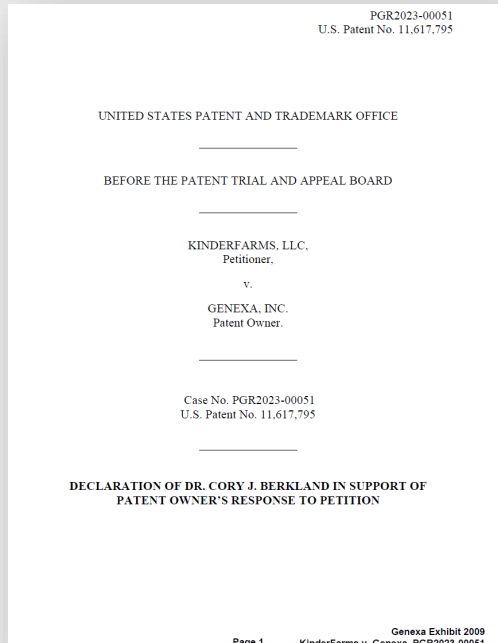
Convert Clear

Result: 2.56 pascal second = 2560 centipoise

(See Ex. 2009, ¶¶114-15; Ex. 1031.)

-POR, 25; see also Ex.2009, ¶¶114-115

Ex.1031 Shows Agave Syrup with a Viscosity Over 10 times more than 212 cP



Ex.2009
(Berkland Decl.)

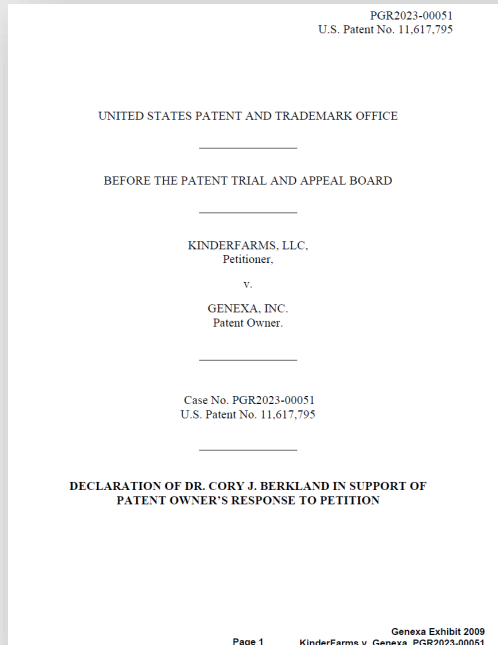
115. It is well known and understood that 1 Pascal second (Pa s) is equivalent to 1000 centipoise (cP), this is simply a trivial unit conversion. (*See, e.g.,* <https://www.unitconverters.net/viscosity-dynamic/pascal-second-to-centipoise.htm>.) Thus, in my opinion, a person of ordinary skill in the art would have immediately understood that the viscosity value of agave syrup reported in Dr. Crowley's Ex. 1031 as 2.56 Pa s is a centipoise-scale viscosity of 2,560 cP. There is no value in Exhibit 1031 that corresponds to a viscosity of 212 cP.

116. This reported viscosity in cited Exhibit 1031 is over 10 times higher than the value of 212 cP Dr. Crowley relies on throughout his declaration (Ex. 1003 at ¶¶52, 119, 216) and Petitioner relies on in its Petition (Pet. at 31, 57).

117. As Exhibit 1031 notes, "[v]iscosity is one of the most significant physical chemical properties in determining the quality and acceptability of syrup." (Ex. 1031 at 1.) Yet Dr. Crowley does not provide any reasoning as to why he chose to rely on a 212 cP value for the viscosity of agave syrup instead of the 2,560 cP value *actually* reported in Exhibit 1031. Nor does Dr. Crowley or Petitioner ever purport to explain why or how a POSA would have done so.

-Ex.2009, ¶¶115-117; *see also* POR, 25-26; Ex.1051 (Berkland Tr.), 24:3-17, 47:5-49:18

It Is Undisputed that Agave Syrup with the Reported Viscosity of 2,560 cP in Petitioner's Ex.1031 Could Not Support a Finding of Obviousness

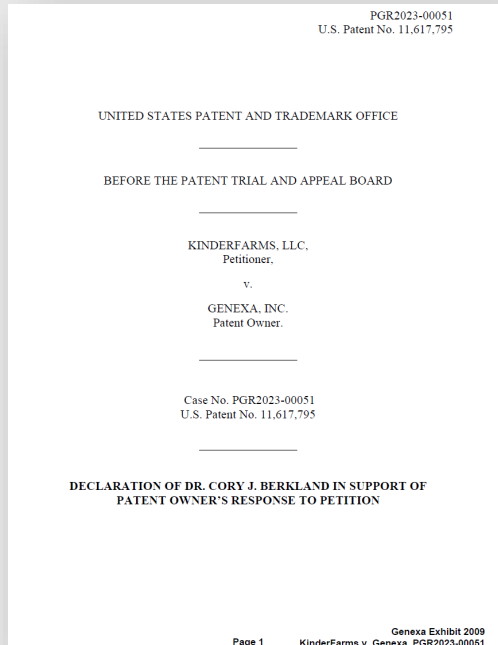


Ex.2009
(Berkland Decl.)

118. Although Petitioner does acknowledge that agave syrup can have varying consistencies and be “thinner or thicker” (Pet. at 15), again no reasoning is provided for the reliance on the viscosity of agave syrup being at or about 212 cP instead of any other viscosity for agave syrup, such as the 2,560 cP viscosity value reported in Ex. 1031. It is further unclear to me why Dr. Crowley and Petitioner did not address the vast differences of viscosity agave syrup may have in light of the evidence they have relied upon. In my opinion, this single error in Dr. Crowley’s opinions and the Petition, disproves any basis for obviousness because Dr. Crowley and Petitioner’s own submitted evidence disproves the sole rationale underlying the obviousness theories presented—i.e., agave syrup does not necessarily have a viscosity of 212 cP. The 2,560 cP viscosity value actually reported in Petitioner’s Exhibit 1031 is well-above and far outside the recited viscosity of the claims and, in my opinion, could not support obviousness under Petitioner’s theories (even if such assertions had been made).

-Ex.2009, ¶118; see also POR, 26-28

It Is Undisputed that Agave Syrup with the Reported Viscosity of 2,560 cP in Petitioner's Ex.1031 Could Not Support a Finding of Obviousness

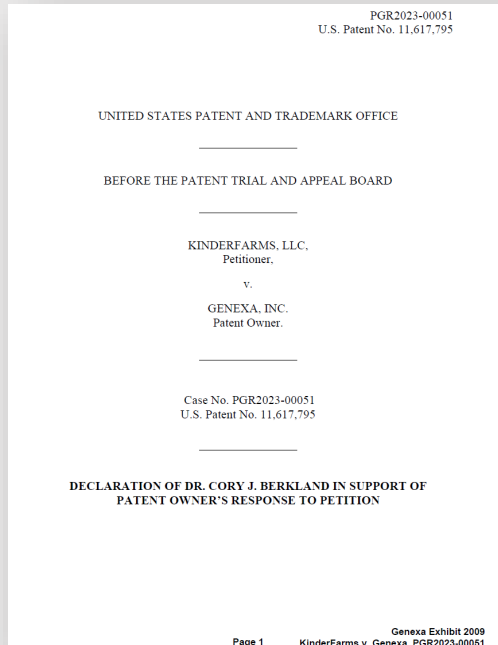


Ex.2009
(Berkland Decl.)

119. That being said, I also note that Dr. Crowley and Petitioner never purport to identify the viscosity of any formulation it relies on within the Prior Art references or what viscosity a person of ordinary skill in the art would have believed FR458-Example 1 or WO742-Example IX would have.⁴ To the contrary, the Petition is ambiguous and non-committal on the actual or expected viscosity value for either of these examples. The Petition only asserts that “*Example 1 of FR458*, which is largely made up of agave syrup, *may have* a viscosity less than 1500 centipoise” and “*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.” (Pet. at 31, 57 (emphasis added).) Of course, the viscosity of these example formulations that Petitioner contends are “largely” or “consists mainly of” agave syrup, will be heavily influenced by the viscosity of the agave syrup itself and a viscosity of 2,560 cP as identified in Ex. 1031 is well above 1500 cP. As such, use of that agave syrup within the examples would result in formulations that a POSA would have expected to have a viscosity of *more than* 1500 cP.

-Ex.2009, ¶119; see also POR, 26-28

It Is Undisputed that a POSA Would Select a High Quality Agave Syrup with the Reported Viscosity of 2,560 cP in Petitioner's Ex.1031 over one with 212 cP

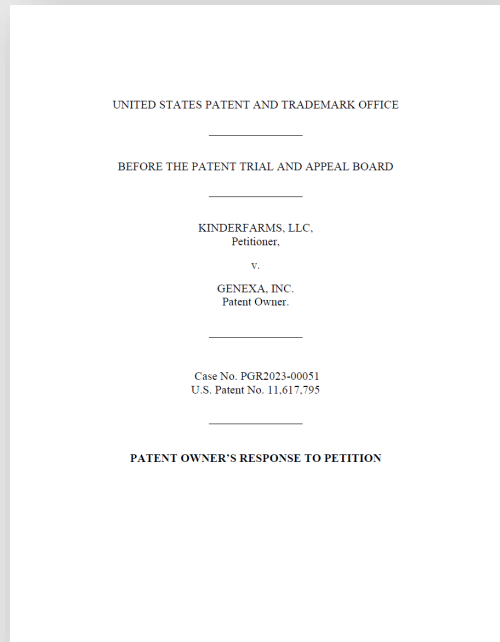


Ex.2009
(Berkland Decl.)

121. Further, I note that it would seem unusual to me for a POSA to choose an agave syrup of such low viscosity, such as 212 cP, if there was one available of higher viscosity, at least when preparing pharmaceutical formulations. A viscosity of 212 cP indicates to me that the agave syrup has a lower quality. (*See* Ex. 1031.) In my opinion, a POSA would plainly use a high-quality agave syrup such as an agave syrup like that reported in Ex. 1031 having a viscosity of 2,560 cP instead of an apparently watered-down low quality agave syrup with a viscosity of 212 cP. Moreover, employing a high-quality, high-viscosity agave syrup would provide a POSA with more control over the formulation process. The overall water content of

-Ex.2009, ¶121; *see also* Ex.2009, ¶120; POR, 25-28

The Claims Should Be Upheld as Patentable Because the Petition Relied on an Incorrect Viscosity Value for Agave Syrup



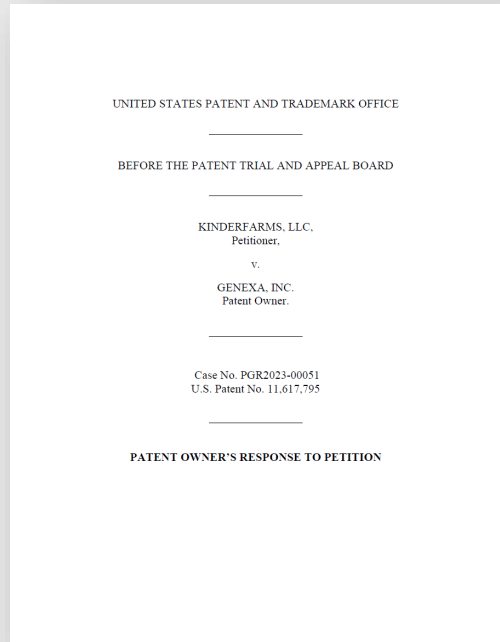
POR (Paper 20)

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.”).

-POR, 28; Ex.2009, ¶114 (citing Ex.1031); *see also* Reply, 10, n.4 (“Exhibit 1031, which describes samples of agave syrup with a mean viscosity of 2,560 cP”)

Agave Syrup Is Not an “Old” Ingredient for Performing Viscosity-Control in Oral Pharmaceutical Syrup Formulations

Agave Syrup Was Not Well-Known in the Art for Performing a Viscosity-Control Function

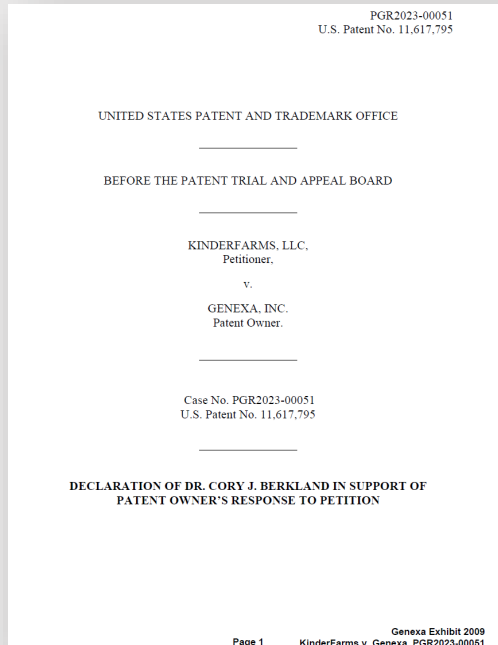


POR (Paper 20)

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

-POR, 41; Ex.2009, ¶¶142-146

Agave Syrup Was Not Well-Known in the Art for Performing a Viscosity-Control Function

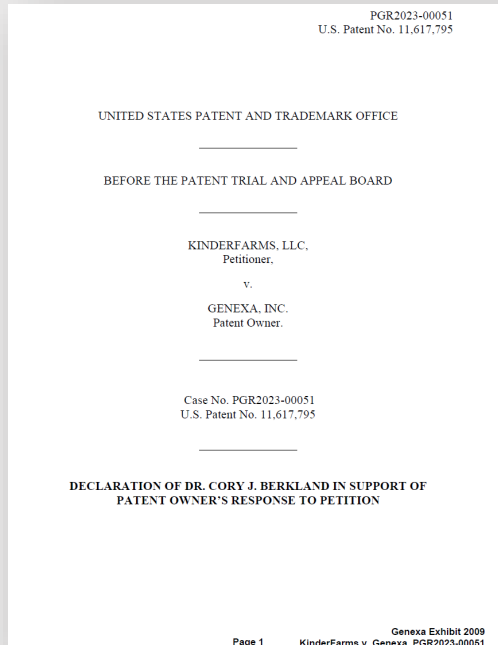


Ex.2009
(Berkland Decl.)

146. Thus, in my opinion, it is abundantly clear that agave syrup is not merely an “old ingredient” that was well-known and performing the same well-known function that it performs in the formulations claimed in the ’795 patent. Again, if agave syrup was a clearly established and well-known ingredient, then Dr. Crowley should have recognized his erroneous citation to the viscosity of agave syrup in Ex. 1031 and would not have wrongly asserted that “a person of ordinary skill in the art would have known that agave syrup has a viscosity of around 212 centipoise” when his own cited Exhibit 1031 reports a viscosity of 2,560 cP. (Ex. 1003 at ¶119.)

-Ex.2009, ¶142; see also POR, 41

Agave Syrup is Not a Well-Known Staple Component of Pharmaceutical Formulations

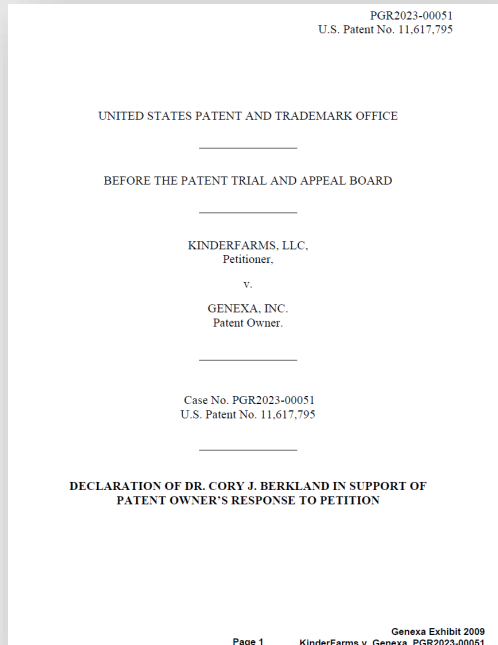


Ex.2009
(Berkland Decl.)

144. While other standard components of pharmaceutical formulations can be found in textbooks and standard pharmaceutical references, Dr. Crowley has not identified “agave syrup” within any such references. For instance, Dr. Crowley’s cited “Handbook of Pharmaceutical Excipients” has no entry for agave syrup. (See Ex. 1029 at 14 (no entry for agave syrup).) Similarly, there is no United States Pharmacopeia (USP) monograph for agave, let alone agave syrup. (See Ex. 2016.) Agave syrup is also nowhere disclosed in the FDA index of generally recognized as safe (GRAS) ingredients. (See Ex. 2015.) Indeed, in my experience, agave syrup is not a typical inactive ingredient that was used in pharmaceuticals as of 2021, including in over-the-counter pharmaceutical products.

-Ex.2009, ¶144; see also POR, 42

Agave Syrup has Widely Variable Physicochemical Quality Properties



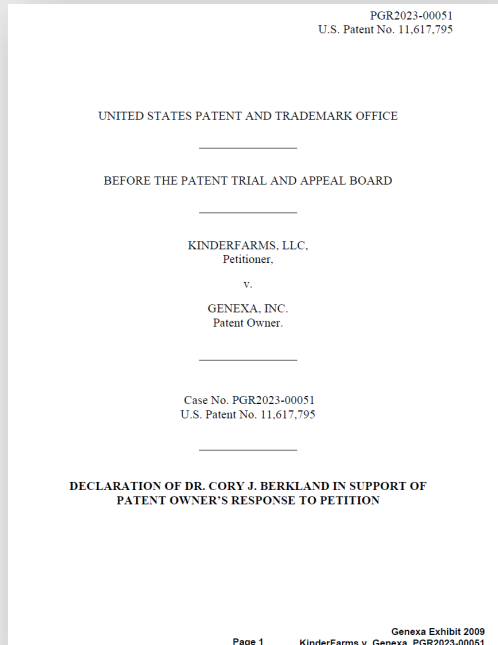
Ex.2009
(Berkland Decl.)

44. As Dr. Crowley states in his Declaration, agave syrup, also known as agave nectar, can be obtained from various species of agave. (Ex. 1003 at ¶51; Ex. 1027 at 22; Ex. 1023 at 55.) As a naturally-derived product from various agave species grown in different habitats and manufactured in a variety of different processing steps and conditions, agave syrups are diverse in their quality and compositions: “*The variability of production methods, kind of agave, growing agave’s region, and part of the plant used in the production process (sap, leaves or pine), generates a wide range of products sold under the name of agave syrup.*” (Ex. 2013 at 50-51 (Maldonado-Guevara, Production Process Effect on Mexican Agave Syrups Quality: A Preliminary Study, *J. Food Res.*, Vol. 7, No. 3 (2018)); *see also id.* at 50 and Fig. 1 (describing different processes for producing agave syrup).)

45. Arising from this diversity, analyses performed on a variety of different agave syrups have shown them to have “[a] wide variability of physicochemical quality parameters.” (*Id.* at 56.) It was also recognized in the art that agave syrups are not well known, but rather that “[f]urther analysis of a wide range of syrups . . . are needed to get more information for a deeper characterization of agave syrups.” (*Id.* at 50.)

-Ex.2009, ¶¶44-45; *see also* POR, 4-6

Agave Syrup is Widely Variable

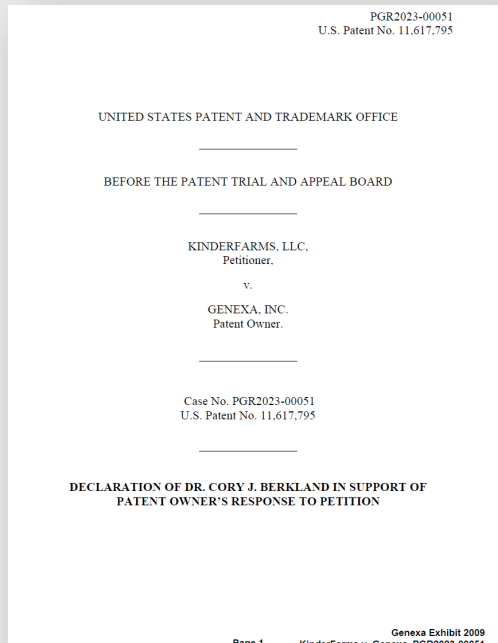


Ex.2009
(Berkland Decl.)

48. “Viscosity is one of the most significant physical chemical properties in determining the quality and acceptability of an [agave] syrup.” (Ex. 1031.) For example, a comparison of agave syrup¹ obtained from two different agave plants (*A. salmiana* and *A. mapisaga*) and three different processing treatments (artisanal evaporation, evaporation under reduced pressure, and lyophilization), the viscosities ranged from 2.05 Pa-s to 15.98 Pa-s, or 2,050 cP to 15,980 cP, respectively. (Ex. 2019 (L. Hernandez-Ramos et al., Nutritional value and antioxidant activity of the maguey syrup (*Agave salmiana* and *A. mapisaga*) obtained through three treatments, *Not. Bot. Horti. Agrobi.* 48(3):1306-1316) at 1311.)

-Ex.2009, ¶48; see also POR, 4-6

Agave Syrup is Widely Variable



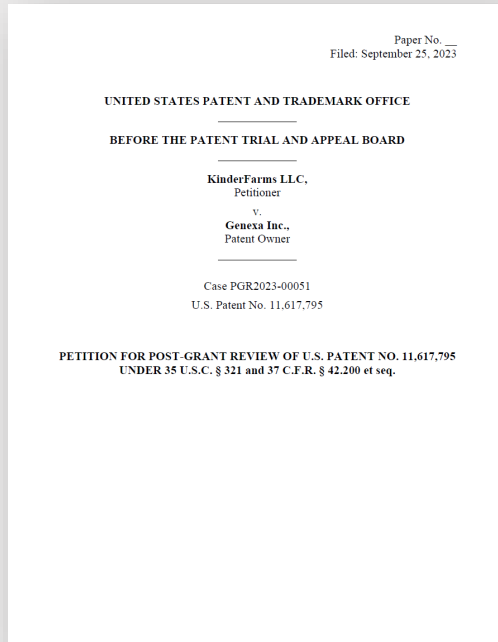
Ex.2009
(Berkland Decl.)

acceptability of [agave] syrup.” (Ex. 1031.) Dr. Crowley also recognized that “agave syrup is obtained from the agave plant by extracting its juice and processing it into a syrup, and this syrup can be light or dark in color, thicker or thinner in consistency (viscosity).” (Ex. 1003 at ¶68.) Consistent with this, it was known that “[t]he variability of production methods, kind of agave, growing agave’s region, and part of the plant used in the production process (sap, leaves or pine), generates a wide range of products sold under the name of agave syrup.” (Ex. 2013 at 50-51.) Accordingly, it was also known that different agave syrups have “[a] *wide variability of physicochemical quality parameters*.” (*Id.* at 56.) It was also recognized in “[f]urther analysis of a wide range of [agave] syrups . . . *are needed* to get more information for a deeper characterization of agave syrups.” (*Id.* at 50.) In my opinion, the broad variability of agave syrup, particularly coupled with Petitioner’s and Dr. Crowley’s erroneously cited viscosity from Exhibit 1031, further demonstrates that agave syrups are not the same sort of a singular uniform ingredient that is well-known for use in oral formulations.

-Ex.2009, ¶143; see also POR, 41

The Petition Improperly Relies on an Obvious Typographical Error in the '4666 Patent

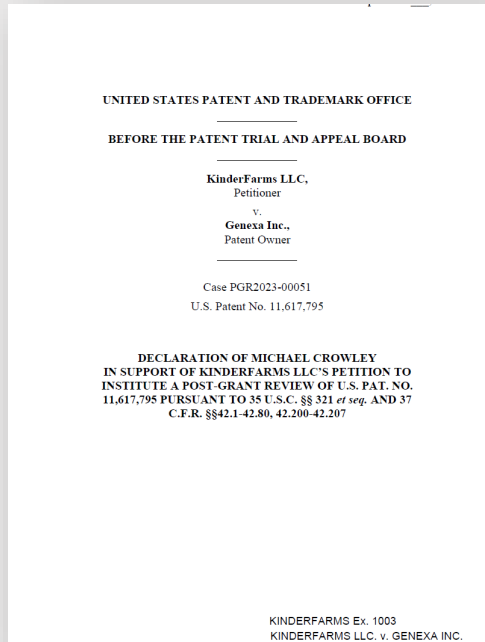
Petitioner Relied on an Obvious Error in Claim 11 of the '4666 Patent



Pet. (Paper 2)

conclude that Example 1 of the FR458 meets this limitation. The '4666 patent discloses a viscosity range measured at 20° by a Brookfield Synchro-Lectric viscometer of 1000 to 3000 centipoise.¹⁵ Ex. 1005 at col. 4, lns. 9-17. Claim 11 lowers the lower viscosity limit from 1000 to 100 centipoise. *Id.*, at col. 6, lns. 66-67. WO133 teaches a tighter viscosity range of 200 to 900 centipoise for its oral analgesic formulation.¹⁶ Ex. 1006 at [8, lns. 1-3]. A person of ordinary skill in the art would conclude that the viscosity ranges disclosed in the '4666 Patent and WO133 teach the viscosity limitation of the '795 Patent.¹⁷ Ex. 1003 at ¶¶ 119-121.

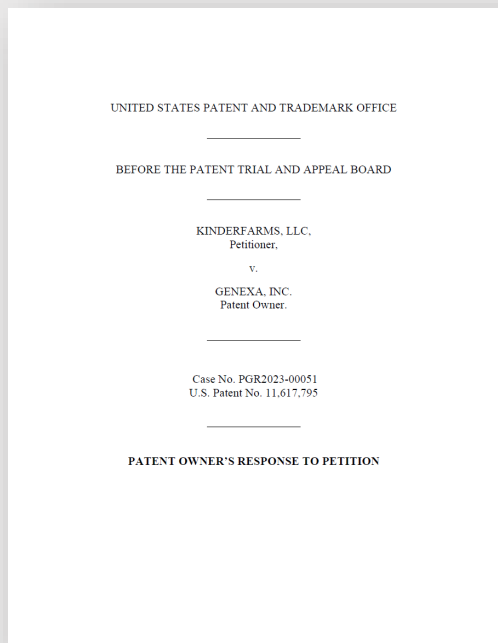
Dr. Crowley Relied on the Obvious Error in Claim 11 of the '4666 Patent



Ex.1003
(Crowley Decl.)

than 1500 centipoise” viscosity limitation. The '4666 Patent teaches controlling the viscosity of an oral liquid analgesic formulation to ensure its stability and discloses formulations with a broad range of viscosities from 100 to 3000 cP, as measured by the Brookfield Synchro-Lectric viscometer. *Id.*, at 4:9-12 [“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.”], at p. 6, lns. 66-67 (claim 11) [“The syrup of claim 7 wherein the viscosity is about 100 to 3000 centipoise at 20°C”]. While the '795 Patent and

Claim 11 of the '4666 Patent Recites an Obvious Typographical Error

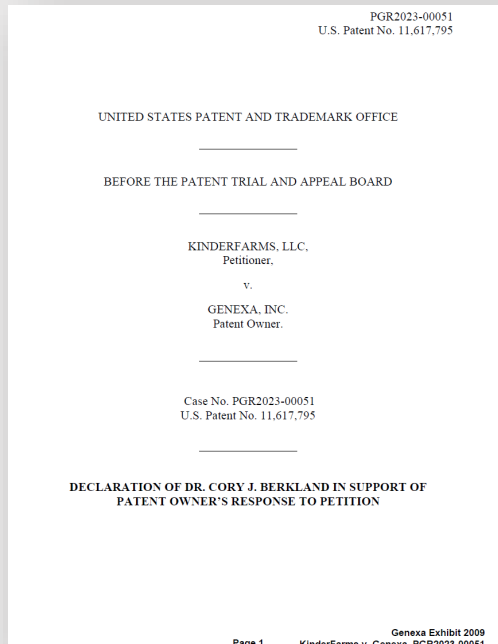


POR (Paper 20)

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.

-POR, 30-31; Ex.2009, ¶¶125-133

Dr. Berkland's Testimony Demonstrating the Obvious Error in Claim 11 of the '4666 Patent is Unaddressed and Unrebutted by Petitioner



Ex.2009
(Berkland Decl.)

125. I disagree with Dr. Crowley that a POSA would understand that the '4666 patent teaches a viscosity range from 100 to 3000 cP.

126. The '4666 patent's specification provides only the following statements relating to viscosity values:

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. Finished product of somewhat less thickness are capable of being stored for commercially acceptable time periods, but these are less able to withstand adverse conditions which may be encountered in storage and shipment.

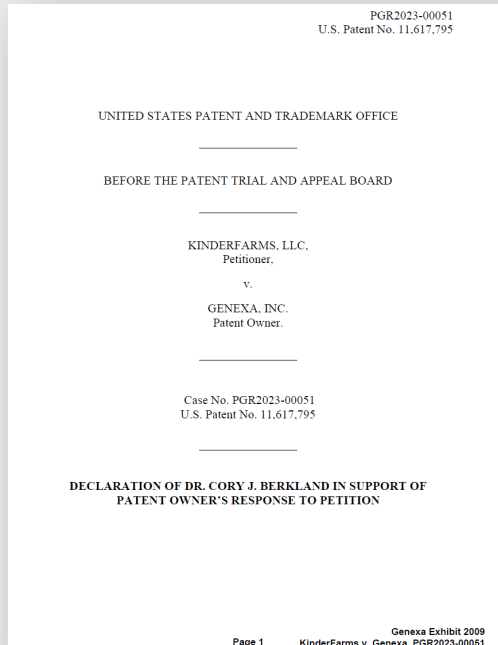
(Ex. 1005 at 4:9-17.)

127. The '4666 patent also has three dependent claims related to viscosity, each modifying the three independent claims (Claims 1, 6 and 7). The dependent claims are reproduced below:

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.2009, ¶¶125-128; see also POR, 31-34

Dr. Berkland's Testimony Demonstrating the Obvious Error in Claim 11 of the '4666 Patent is Unaddressed and Unrebutted by Petitioner

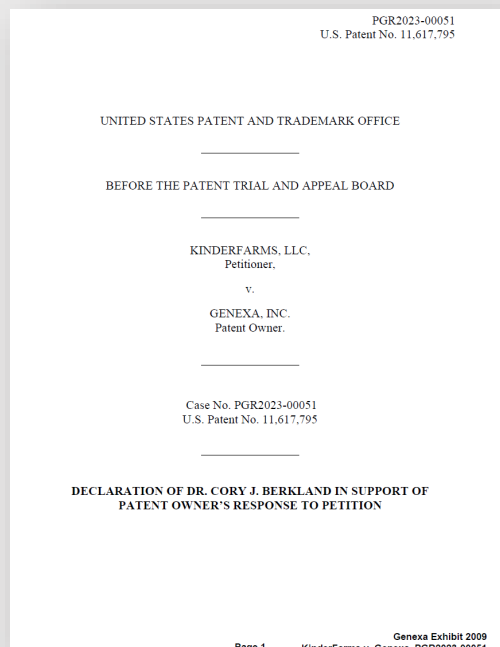


Ex.2009
(Berkland Decl.)

129. I do not see any support for a viscosity range of “about 100 to 3000 centipoise” in the specification of the '4666 patent. Indeed, a range of 100 to 3000 centipoise would be inconsistent with the specification which states that “[a] viscosity of about 1000 to 3000 centipoise at 20°C, as measured by the Brookfield Synchro-Lectric viscometer, is the preferred range.” (*Id.* at 4:9-17.) Although the specification states that “[f]inished product of somewhat less thickness are being capable of being stored for commercially acceptable time periods,” in my opinion a POSA would not understand “somewhat less” to mean that the preferred 1000-3000 cP range that must be “controlled for optimal stability” would extend to a product that is 90% lower in viscosity (100 cP) than the identified minimum viscosity of the preferred range (1000 cP).

-Ex.2009, ¶¶129-133; see also POR, 31-34

Dr. Berkland's Declaration Demonstrating the Obvious Error in Claim 11 of the '4666 Patent is Unaddressed and Unrebutted by Petitioner



Ex.2009
(Berkland Decl.)

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.

131. In my further opinion, the similarity in the language of recited claims 9, 10, and 11 further demonstrate that a POSA would have immediately recognized that the “100” in claim 11 was an obvious typographical error. In my opinion, a POSA would have seen each of these three claims and, in the context of the teaching of the specification, have understood that they were each meant to recite the same consistent viscosity of “about 1000 to 3000 centipoise” (as in claims 9 and 10, and the preferred range of the specification).

-Ex.2009, ¶¶129-133; see also POR, 31-34

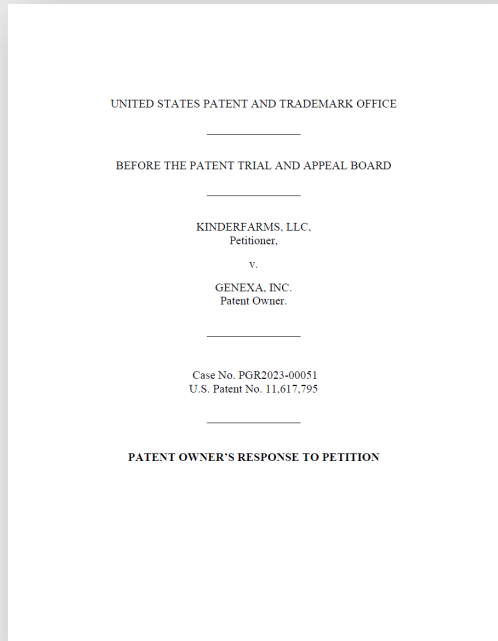
Ground 1 Fails to Demonstrate Obviousness of any Challenged Claims 1-24

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

Ground 1 Fails to Demonstrate Obviousness

- The Petition failed to articulate with particularity any motivation to combine FR458 with the viscosity ranges of the '4666 patent or WO133 (e.g., POR, 38-40; Ex.2009, ¶140)
- The Petition failed to articulate with particularity any reasonable expectation of success in achieving the viscosity ranges of the '4666 patent or WO133 (e.g., POR, 38-40; Ex.2009, ¶140)
 - The Petition does not identify or suggest any modifications to the example formulations in FR458 (e.g., POR, 35-36 (n.2), 48; Ex.2009, ¶150)
 - The Petition relies on the conclusory and incorrect assertion that agave syrup as a viscosity of 212 cP (e.g., POR, 43-44; Ex.2009, ¶147)
 - The Petition failed to address the claims “as a whole” (e.g., POR, 51-52; Surreply, 14-15)
 - There would be no motivation or expectation of success in using agave syrup with 212 cP in FR458-Example 1 (e.g., Ex.2009, ¶150; POR)

FR458 Does Not Disclose Any Viscosity Values for Agave Syrup or Its Formulations



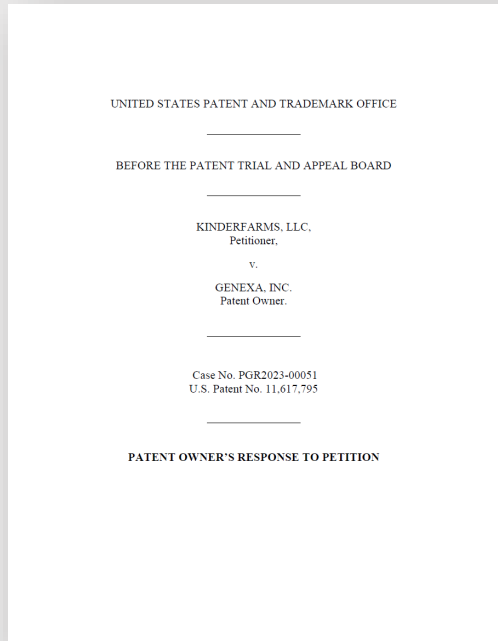
POR (Paper 20)

“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 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.*)

-POR, 14-15; Ex.2009, ¶80

FR458 Uses Additional Ingredients Because Formulations Based on Natural Syrups are Not Easy to Obtain

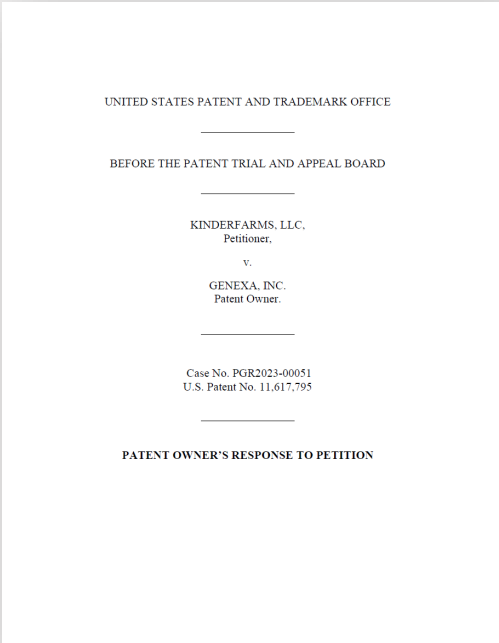


POR (Paper 20)

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.*)

-POR, 15; Ex.2009, ¶79; ID, 9; Ex.1003 (Crowley Decl., ¶64)

FR458-Example 1: 100 mL formulation with substantial water



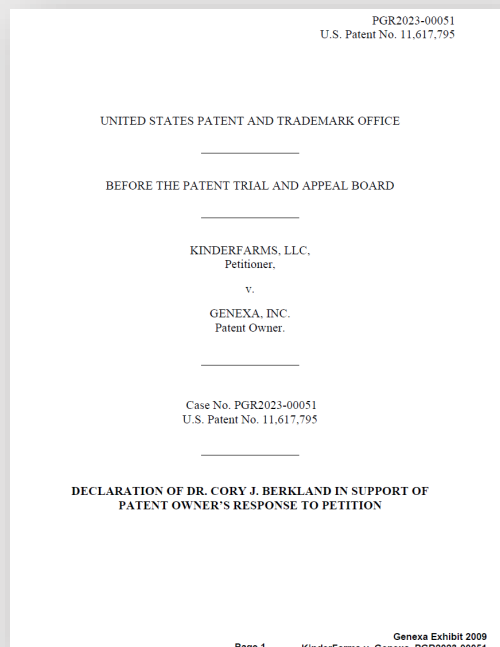
POR (Paper 20)

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

-POR, 15-16; Ex.2009, ¶¶ 81-82

FR458-Example 1: No Disclosure re Viscosity of Agave or Final Formulation

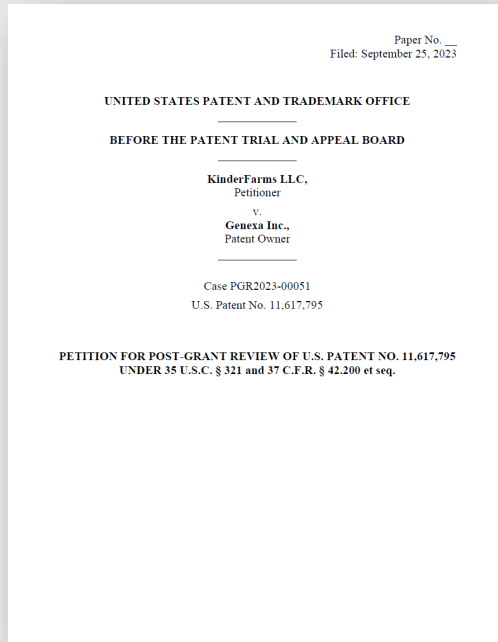


Ex.2009
(Berkland Decl.)

83. Notably, Example 1 of FR458 does not disclose the identity or viscosity of the agave syrup used in Example 1 or the viscosity of the formulation itself upon addition of the substantial amount of water to create the 100 mL dose.

-Ex.2009, ¶¶82-83; *see also* POR, 16-17

The '4666 Patent: No Agave Syrup; Viscosity Range of 1000-3000 cP

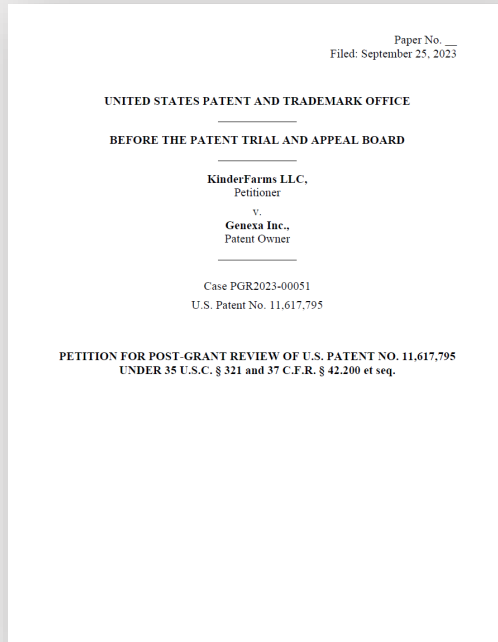


Institution Decision
(Paper 8)

3. *The '4666 patent*

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

WO133: No Agave Syrup; Viscosity Range of 200-900 cP

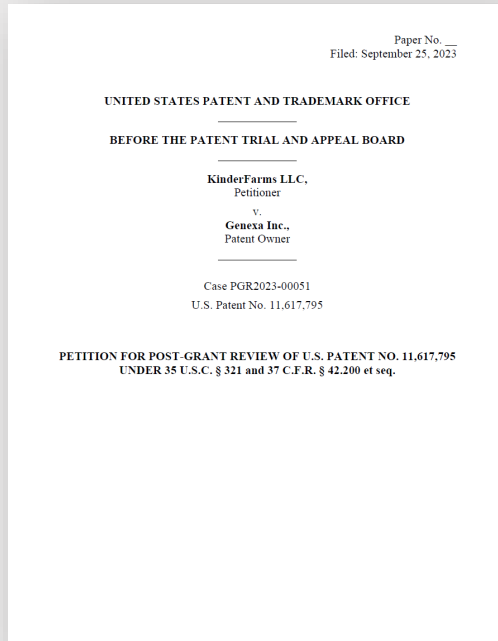


Institution Decision
(Paper 8)

4. WO133

WO133, also cited by Petitioner in both Ground 1 and Ground 2, teaches oral formulations of acetaminophen in suspension that mask the taste with sweetening agents. (*See* Ex. 1006, abstract; *see* Pet. 25–26.) WO133 teaches including a suspension agent for dispersing the acetaminophen in the aqueous medium and an additive agent for decreasing the solubility of acetaminophen in the aqueous medium, along with a sweetening agent. (*See* Ex. 1006, 2:14–3:18, 5:11–6:6; *see* Pet. 16.) WO133 teaches a target viscosity of the resulting oral formulation of from 200 to 900 centipoise, preferably 300 to 700 centipoise. (*See* Ex. 1006, 7:27–8:3; *see* Pet. 26.) WO133 provides examples of viscous suspensions of acetaminophen, including sweetening agents. (*See* Ex. 1006, 9:2–10:8, Examples 1 and 2; *see* Pet. 26.)

Ground 1: No Articulated Motivation or Reasonable Expectation of Success in Combining FR458 with The Viscosity Ranges of the '4666 Patent or WO133

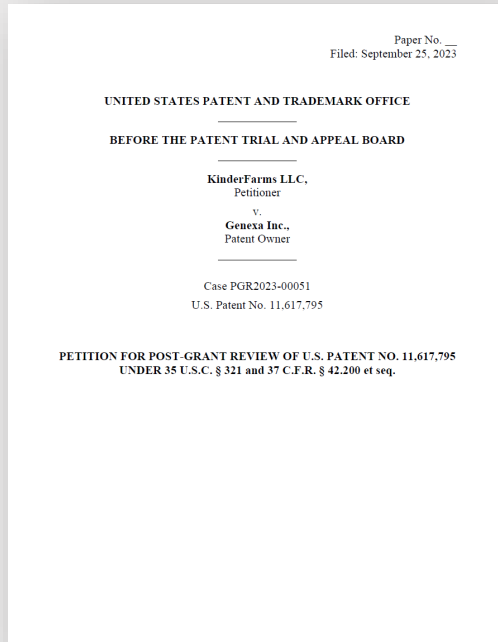


Pet. (Paper 2)

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

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

Ground 1: No Articulated Motivation or Reasonable Expectation of Success in Combining FR458 with The Viscosity Ranges of the '4666 Patent or WO133



Pet. (Paper 2)

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

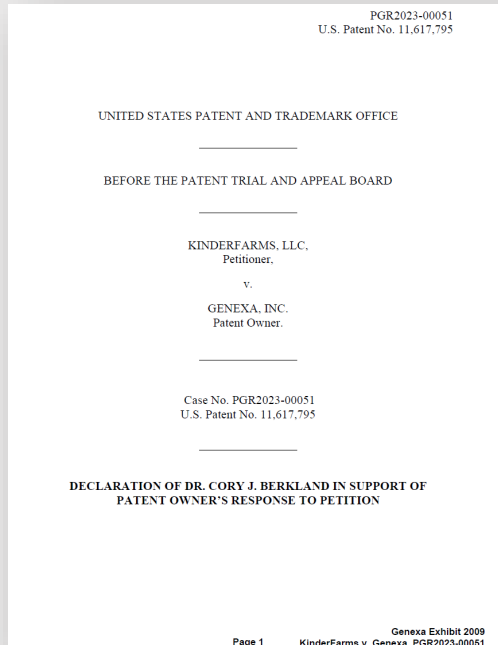
a lower sugar content to benefit diabetics and other persons with restricted sugar requirements. Ex. 1005 at 2 :15-21; Ex. 1004 at 1, lns. 14-16, 3, lns. 70-74; Ex. 1003 at ¶102. Considering that each prior art reference is in the same field of art, seeks to address similar issues, and discusses the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

The Petition did not assert with particularity any motivation or reasonable expectation of success with respect to combining FR458 with the specific viscosity ranges of the '4666 patent or WO133

-see POR, 38-40, 43-45, 47-50, 62-63; Surreply, 20-21.

-Pet. 28-29

Ground 1: Petitioner's Motivation to Combine Never Mentions Viscosity and Does Not Propose Any Modifications to FR458 to Achieve a Particular Viscosity

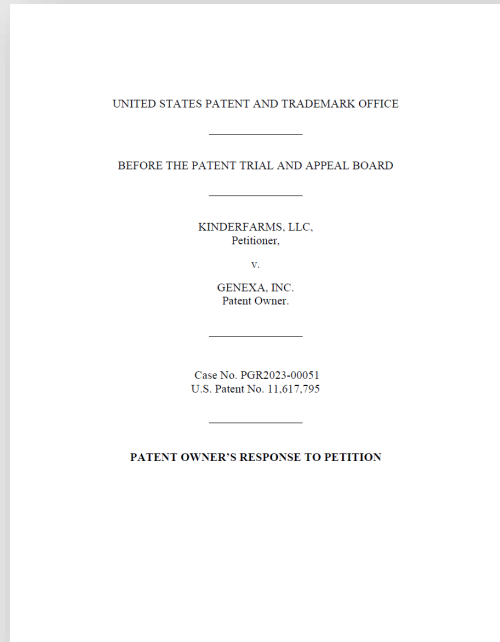


Ex.2009
(Berkland Decl.)

140. Petitioner and Dr. Crowley's only motivation for combining the references is generic—i.e., that all three references are in the field of liquid pharmaceutical formulations for oral administration, contain analgesics, and seek to provide low glycemic index formulations that still mask the bitter taste of the active ingredient(s). (Pet. at 28-29; Ex. 1003 at ¶101.) However, this does not speak to how a POSA would be motivated to combine the three references to arrive at an agave-based suspension with the claimed viscosity as disclosed in claims 1-24 of the '795 patent.

-Ex.2009, ¶140; see also POR, 40

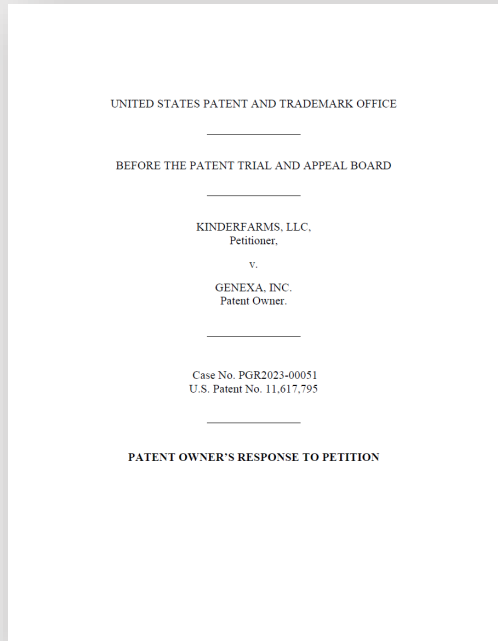
Ground 1: Petitioner's Motivation to Combine Never Mentions Viscosity and Does Not Propose Any Modifications to FR458 to Achieve a Particular Viscosity



POR (Paper 20)

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.").

Ground 1: The Petition Does Present Any Proposed Modifications to the Example Formulations of FR458 or WO133 to Achieve a Particular Viscosity Value



POR (Paper 20)

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

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.

(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.)

-POR, 35-36 (n.2), 48; see also Ex.2009, ¶¶150, 167

Petitioner's Improper New Attorney Arguments on Reply Further Show the Petition's Failures re Motivation to Combine and Reasonable Expectation of Success

Trials@uspto.gov
571-272-7822

Filed: September 6, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KinderFarms LLC,
Petitioner

v.

Genexa Inc.,
Patent Owner

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

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

Reply (Paper 25)

FR458 discloses nearly all claim elements of claims 1-24 of the '795 Patent. Pet. 29-54; Ex.1003, ¶¶104-194. A POSA would have been motivated to combine FR458's low glycemic index agave syrup-based liquid oral acetaminophen formulation with the viscosity ranges for liquid oral analgesic formulations taught by WO133, the '4666 Patent, or both, to predictably arrive at the claimed invention. Pet. 27-29; Ex.1003, ¶¶100-103. A POSA also would have had a reasonable expectation of success in combining these teachings. Pet. 27-29; Ex.1003, ¶102.

-Reply, 2; see also POR, 38-40,43; Ex.2009, ¶¶140, 147; Surreply (Paper 29), 20-21; Notice (Paper 27), 2-3

Petitioner's Improper New Attorney Arguments on Reply Further Show the Petition's Failures re Motivation to Combine and Reasonable Expectation of Success

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

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KINDERFARMS, LLC,
Petitioner,

v.

GENEXA, INC.,
Patent Owner.

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

PATENT OWNER'S SURREPLY

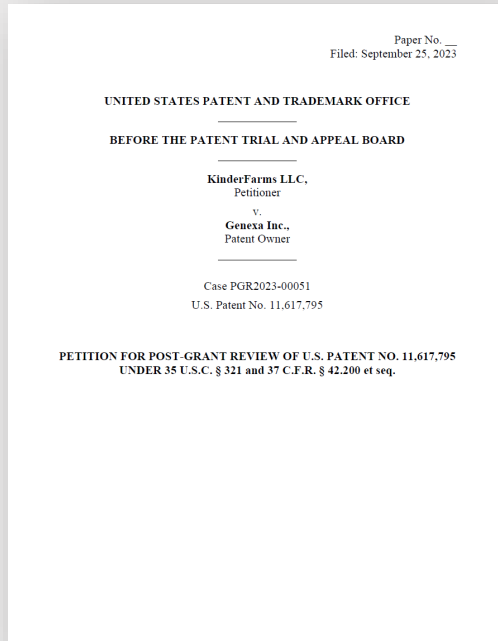
Surreply (Paper 29)

Nevertheless, Petitioner now contends for the first time that a POSA would have been motivated to combine (unidentified) formulations of either FR458 (Ground 1) or WO742 (Ground 2) specifically “with the viscosity ranges for liquid oral analgesic formulations taught by WO133, the ’4666 patent, or both[.]” (Reply, 2, 4.) But the Petition never once mentioned “viscosity” in connection with the asserted motivation to combine. (*See* Pet., 27-29, 54-55.) Similarly, the Petition never indicated any motivation to combine FR458 or WO742 with the specific “viscosity ranges” of WO133 or the ’4666 patent. (*See id.*) These new Reply arguments are foreclosed by statute, Federal Circuit precedent, and Board guidelines. *See Wasica*, 853 F.3d at 1286.

-Surreply, 20-21; Notice (Paper 27), 2-3

Ground 1: The Viscosity Limitation

The Petition's Assertions re the Viscosity Limitation of Claim 1 Fail to Address the Claims "as a whole"



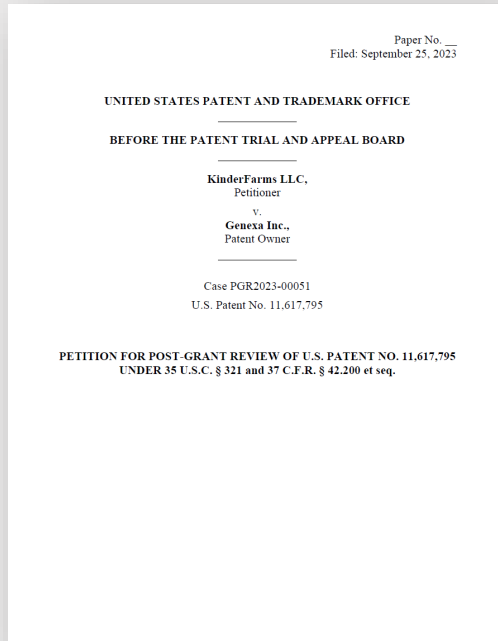
Pet. (Paper 2)

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

A person of ordinary skill in the art would understand that an oral liquid formulation needs a viscosity low enough for it to be pourable and drinkable. Ex. 1003 at ¶¶ 28, 58-59, 216. The viscosity of agave syrup has been reported to be about 212 centipoise. Ex. 1003 at ¶ 52. Thus, a person of ordinary skill in the art would understand that the formulation disclosed in Example 1 of FR458, which is largely made up of agave syrup, may have a viscosity less than 1500 centipoise. Ex. 1003 at ¶ 119. As both the ’4666 Patent and WO133 disclose appropriate viscosity ranges for an oral formulation with an analgesic, it is unnecessary for the Board to conclude that Example 1 of the FR458 meets this limitation. The ’4666 patent

-Pet. 31-32; see also POR, 43-44; Ex.2009, ¶147

The Petition's Assertions re the Viscosity Limitation of Claim 1 Fail to Address the Claims "as a whole"

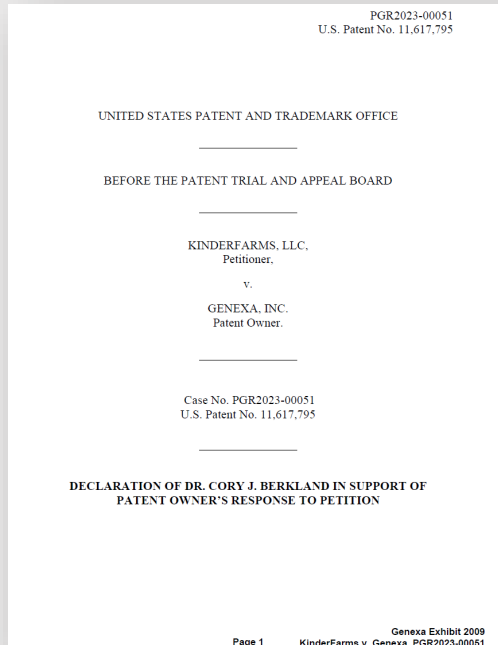


Pet. (Paper 2)

conclude that Example 1 of the FR458 meets this limitation. The '4666 patent discloses a viscosity range measured at 20° by a Brookfield Synchro-Lectric viscometer of 1000 to 3000 centipoise.¹⁵ Ex. 1005 at col. 4, lns. 9-17. Claim 11 lowers the lower viscosity limit from 1000 to 100 centipoise. *Id.*, at col. 6, lns. 66-67. WO133 teaches a tighter viscosity range of 200 to 900 centipoise for its oral analgesic formulation.¹⁶ Ex. 1006 at [8, lns. 1-3]. A person of ordinary skill in the art would conclude that the viscosity ranges disclosed in the '4666 Patent and WO133 teach the viscosity limitation of the '795 Patent.¹⁷ Ex. 1003 at ¶¶ 119-121.

-Pet. 31-32; see also POR, 43-44; Ex.2009, ¶147

It is Undisputed that a POSA Would Have Known That Using Agave Syrup with Viscosity of 212 cP in FR458-Example 1 Would Yield a “readily pourable” Formulation

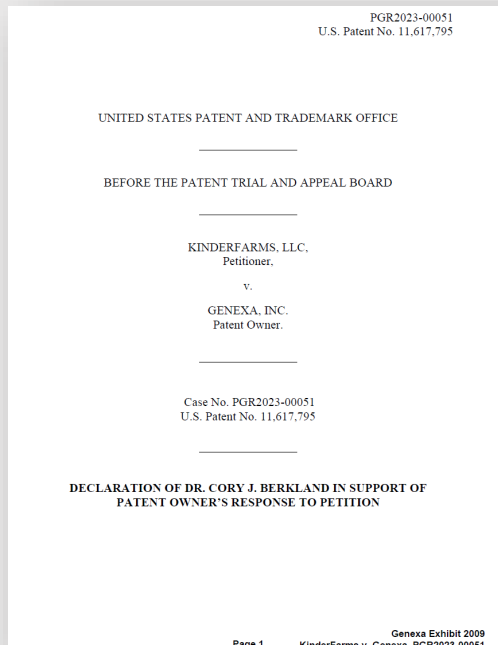


Ex.2009
(Berkland Decl.)

150. A POSA would have understood that the use an agave syrup with a viscosity 212 cP with FR458-Example 1 (and the other ingredients therein) would be watered-down by such a large amount of added water that the POSA would expect the overall formulation to have a viscosity closer to water than the starting viscosity of the agave syrup—i.e., certainly well below 200 cP and more likely than not below 100 cP.⁵ Such a formulation would be a formulation that Dr. Crowley has recognized as being “readily pourable” (Ex. 1003 at ¶52 (“a viscosity in the range of 20 to 150 cP are considered readily pourable”).) Thus, in my opinion, a POSA would not have had any motivation or reasonable expectation of success in combining an agave syrup with viscosity of 212 cP in FR458-Example 1 with the viscosity ranges 1000-3000 cP of the ’4666 patent or 200-900 cP of WO133 because the expected viscosity of such a formulation would fall well below and outside either of these ranges. I note that Dr. Crowley proposed no modifications to FR458-Example 1 and

--Ex.2009, ¶150; see also POR, 47-48

The Petition Proposed No Modifications to FR458

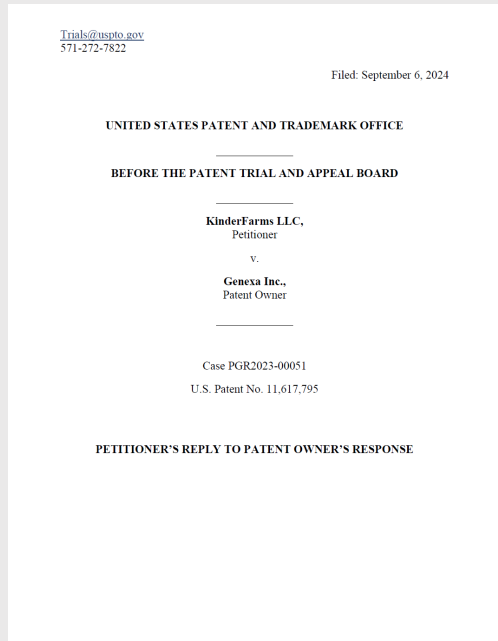


Ex.2009
(Berkland Decl.)

ranges. I note that Dr. Crowley proposed no modifications to FR458-Example 1 and never addresses why there would be any motivation to combine FR458 with the '4666 patent and/or WO133 if agave syrup has the viscosity reported in Ex. 1031 of 2,560 cP.

--Ex.2009, ¶150.

Petitioner's Improper New Attorney Arguments on Reply Further Show the Petition's Failures re Motivation to Combine and Reasonable Expectation of Success



Reply (Paper 25)

viscosity value of 2,560cP. POR, 46-49, 58-63. The Petition makes clear that it relies on the formulation viscosity ranges expressly taught by the '4666 Patent and WO133, not on any hypothetical viscosity teachings from the examples in FR458 and WO742.⁵ Pet., 31-32, 57-58. Furthermore, a POSA would be capable of selecting an agave syrup with appropriate viscosity and, if necessary, adjusting the water content and/or other components to achieve the desired final viscosity. Ex.1051, 117:4-23; 128:16-20, 138:7-139:17, 147:16-149:23, 150:16-151:9; Ex.2009, ¶121.⁶

-Reply, 11; see also POR, 35-36 (n.2), 48; Ex.2009, ¶¶150; Surreply (Paper 29), 5-10; Notice (Paper 27), 1-2

Petitioner's Improper New Attorney Arguments on Reply Further Show the Petition's Failures re Motivation to Combine and Reasonable Expectation of Success

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

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KINDERFARMS, LLC,
Petitioner,

v.

GENEXA, INC.,
Patent Owner.

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

PATENT OWNER'S SURREPLY

Surreply (Paper 29)

It is undisputed that the Petition relied on Dr. Crowley's (incorrect) opinion that "[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.*" (See Ex. 1003 ¶119; Pet., 31 ("The viscosity of agave syrup has been reported to be about 212 centipoise. Ex. 1003 at ¶52."), 57 ("The viscosity of agave syrup is reported to be about 212 centipoise. Ex. 1003 at ¶52").) As detailed in the POR, despite citing to Exhibit 1031 that reports agave syrup having a viscosity of 2,560 cP, neither Petitioner nor Petitioner's expert ever acknowledged or posited any other viscosity value for agave syrup with the Petition other than the incorrect, unsupported, and conclusory assertion that a POSA "would have known that agave syrup has a viscosity of around 212 centipoise." (See POR, 24-28; Ex.2009, ¶¶111-121.)

-Surreply, 4; Notice (Paper 27), 1-2

Petitioner's Improper New Attorney Arguments on Reply Further Show the Petition's Failures re Motivation to Combine and Reasonable Expectation of Success

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

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KINDERFARMS, LLC,
Petitioner,

v.

GENEXA, INC.,
Patent Owner.

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

PATENT OWNER'S SURREPLY

Surreply (Paper 29)

As noted by Dr. Berkland regarding Ground 1, “Dr. Crowley proposed no modifications to FR458-Example 1 and never addresses why there would be any motivation to combine FR458 with the ’4666 patent and/or WO133 if agave syrup has the viscosity reported in Ex. 1031 of 2,560 cP.” (Ex. 2009, ¶150.) Dr. Berkland’s testimony regarding Ground 2 was similar: “I note that neither Petitioner nor Dr. Crowley have addressed how the references in Ground 2 would satisfy the independent claims if utilizing a high-quality agave syrup with a viscosity of 2,560 cP found in Ex. 1031.” (Ex. 2009, ¶167.)

-Surreply, 7; Notice (Paper 27), 1-2

The Petition Relied on Added Water to Achieve a Final Volume—Not a Final Desired Viscosity

3. The Petition never mentions adjusting the water content to achieve a final desired viscosity

Neither Ground 1 nor Ground 2 of the Petition ever mentioned Petitioner’s additional new Reply theory of “adjusting the water content and/or other components to achieve the desired final viscosity.” (*See* Reply, 11.) To the contrary, Dr. Crowley’s declaration states that the examples of FR458 under Ground 1 “contain water and the water is provided in quantity sufficient (q.s.) for the formulation to achieve a particular final volume” and the examples of WO742 under Ground 2 “contain water and the water is provided in quantity sufficient (q.s.) for the formulation to achieve a final volume.” (Ex. 1003, ¶¶117, 212; *see also* Ex. 1003, ¶¶ 155 (“the exact amount of water added will depend on the desired final volume”), 213 (“water is being added to a formulation in a quantity sufficient (q.s.) to bring it to desired final volume”).)

Patent Owner’s Surreply
PGR2023-00051
U.S. Patent No. 11,617,795

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KINDERFARMS, LLC,
Petitioner,

v.

GENEXA, INC.,
Patent Owner.

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

PATENT OWNER’S SURREPLY

Surreply (Paper 29)

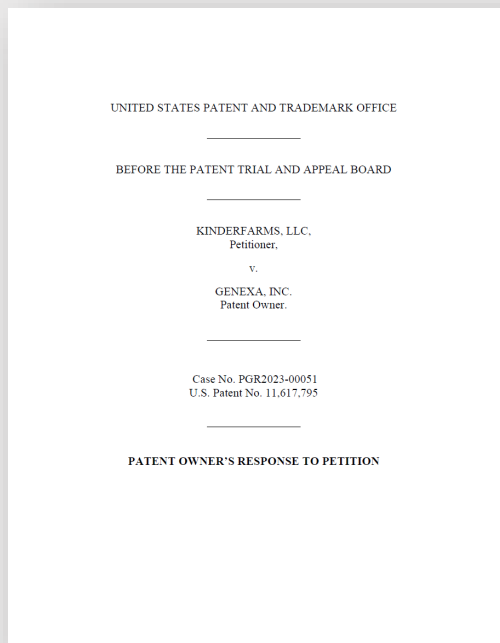
-Surreply, 15-16; Notice (Paper 27), 1-2

Ground 1: Dependent Claims

Ground 1 Fails to Demonstrate Obviousness of Dependent Claims

- The Petition fails to articulate any reasoned motivation to combine or reasonable expectation of success with respect to the dependent claims as a whole (e.g., POR, 53-56; Ex.2009, ¶¶ 154-164)

Ground 1: Exemplary Failure to Address Dependent Claims as a Whole (Claim 9)



POR (Paper 20)

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.*)

-POR, 55-56; see also Ex.2009, ¶¶160-161

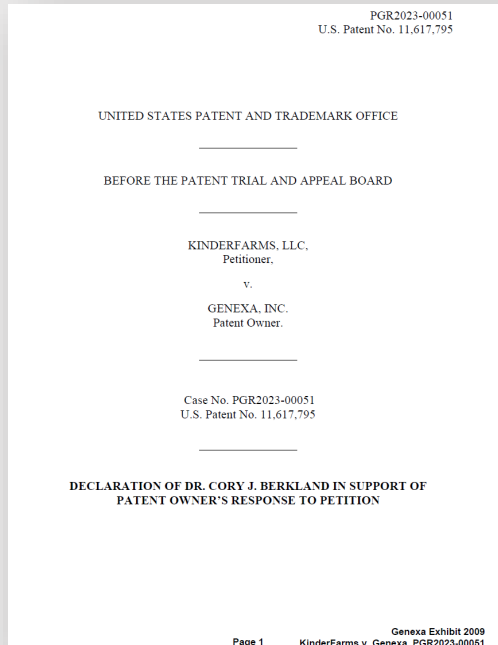
Ground 2 Fails to Demonstrate Obviousness of Challenged Claims 1-17

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

Ground 2 Fails to Demonstrate Obviousness

- The Petition failed to articulate with particularity any motivation to combine WO742 with the viscosity ranges of the '4666 patent or WO133 (*e.g.*, POR, 57-58; Ex.2009, ¶167)
- The Petition failed to articulate with particularity any reasonable expectation of success in achieving the viscosity ranges of the '4666 patent or WO133 (*e.g.*, POR, 58-63; Ex.2009, ¶¶ 168-171)
 - The Petition does not identify or suggest any modifications to the example formulations in FR458 (*e.g.*, POR, 35-36 (n.2), 48; Ex.2009, ¶167)
 - The Petition relies on the conclusory and incorrect assertion that agave syrup as a viscosity of 212 cP (*e.g.*, POR, 43-44; Ex.2009, ¶¶166-168)
 - The Petition failed to address the claims “as a whole” (*e.g.*, Surreply, 14-15)
 - There would be no motivation or expectation of success in using agave syrup with 212 cP in FR458-Example 1 (*e.g.*, Ex.2009, ¶¶ 168-171; POR 58-63; Surreply, 7-9)

WO742 Does Not Disclose Any Viscosity Values for Agave Syrup or Its Formulations

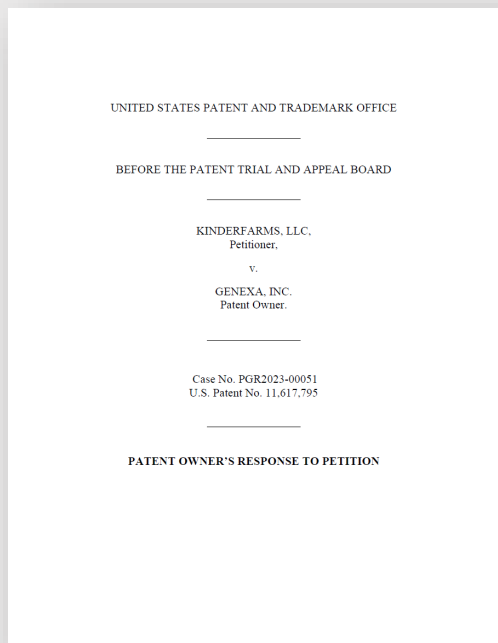


Ex.2009
(Berkland Decl.)

104. 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. (See also Ex. 1003 at ¶216 (“WO742 does not expressly disclose the viscosity (or range of viscosities) of liquid formulations of the invention”).)

--Ex.2009, ¶104; see also POR, 18-19

WO742-Example IX: 15 mL formulation with various constituent ingredients



POR (Paper 20)

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:

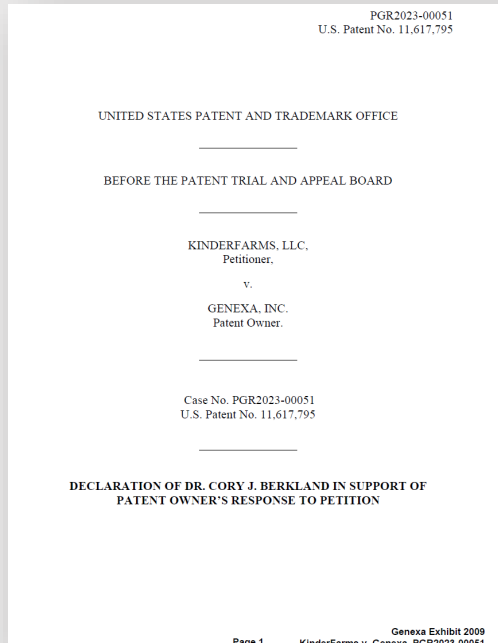
EXAMPLE IX. Liquid Cough Composition Ingredients Amount/15 ml Dose:

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.)

-POR, 18; see *a/so* POR, 62; Ex.2009, ¶102; Ex.1003, ¶¶64-65; Pet., 57-58 (“Example IX of WO742, which consists mainly of agave syrup and **other ingredients**”)

Ground 2 Fails for the Same Reasons as Ground 1



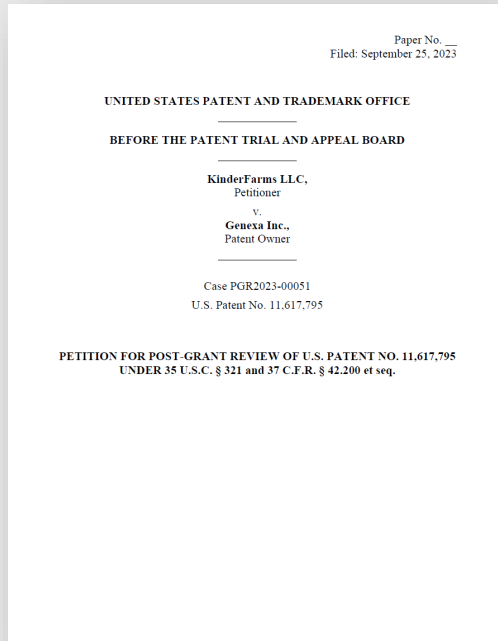
Ex.2009
(Berkland Decl.)

166. I incorporate all of my reasonings for Ground 1 here as to why agave syrup is not simply a well-known ingredient that is being used in a manner for which it is well established, contrary to Petitioner and Dr. Crowley's statements and why Petitioner's errors regarding the viscosity of agave and the teachings of the '4666 patent weigh against a finding of obviousness. (*See generally above*, ¶¶111-138.)

167. For the sake of clarity, as with Ground 1, I note that neither Petitioner nor Dr. Crowley have addressed how the references in Ground 2 would satisfy the independent claims if utilizing a high-quality agave syrup with a viscosity of 2,560 cP found in Ex. 1031. Nor does either make any argument regarding the motivation to combine such references with a reasonable success under such circumstances.

--Ex.2009, ¶¶ 166-167; *see also* POR, 57-58

Ground 2: No Articulated Motivation or Reasonable Expectation of Success in Combining WO742 with The Viscosity Ranges of the '4666 Patent or WO133



Pet. (Paper 2)

B. Explanation for Ground 2

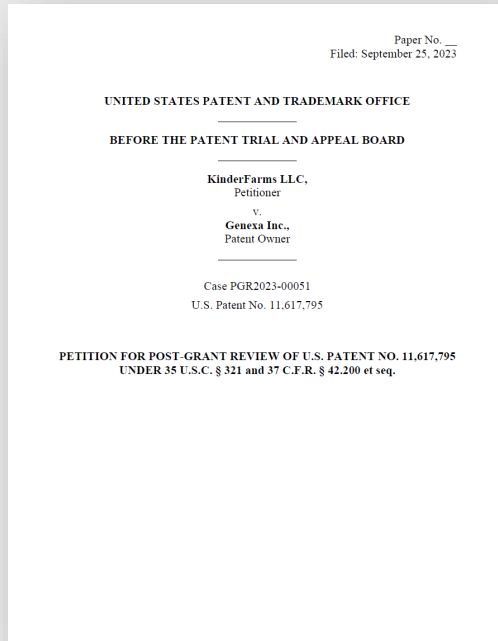
1. Motivation to Combine WO742 with the '4666 Patent and/or WO133²⁶

WO742 describes various agave-based formulations that include dextromethorphan and other APIs including acetaminophen. Ex. 1007 at 16, lns. 7-25, 13, lns. 21-27, 13, ln. 27 – 15, ln. 57 WO742 seeks to provide a safer form of an oral pharmaceutical formulation. Ex. 1007 at 9, lns. 1-25. Like WO742, the '4666 Patent and WO133 identify pharmaceutical oral formulations that include acetaminophen as an analgesic. Ex. 1005 at col. 1, lns. 28-35; Ex. 1066 at 1, lns. 3-9. A person of ordinary skill in the art would look to the disclosure of a formulation that seeks to provide a safe oral formulation for patients and combine that with existing prior art references that also discuss oral formulations of APIs. Ex. 1003 at ¶ 197. These references are in the same field and each discuss the creation of oral formulations with an analgesic. Ex. 1003 at ¶ 196. The fact that each of the references discuss acetaminophen would provide an additional rationale for a person of ordinary skill in the art to combine the references. Ex. 1003 at ¶ 196. Moreover,

a person of ordinary skill in the art would have been motivated to combine these references because such a person would have known that antitussives like dextromethorphan are often combined with analgesics like acetaminophen and ibuprofen in over-the-counter liquid cough and cold formulations. Ex. 1003 at ¶ 197. A person of ordinary skill in the art would have had a reasonable expectation of success in combining these references because they all disclose formulations comprising well known ingredients performing well known functions. *KSR Int'l Co.*, at 417. Therefore, a person of ordinary skill in the art would be motivated to combine these teachings and would have a reasonable expectation of success in so doing. Ex. 1003 at ¶¶ 195-198.

-Pet. 54-55

Ground 2: No Articulated Motivation or Reasonable Expectation of Success in Combining WO742 with The Viscosity Ranges of the '4666 Patent or WO133



Pet. (Paper 2)

B. Explanation for Ground 2

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

WO742 describes various agave-based formulations that include dextromethorphan and other APIs including acetaminophen. Ex. 1007 at 16, lns. 7-25, 13, lns. 21-27, 13, ln. 27 – 15, ln. 57 WO742 seeks to provide a safer form of an oral pharmaceutical formulation. Ex. 1007 at 9, lns. 1-25. Like WO742, the '4666 Patent and WO133 identify pharmaceutical oral formulations that include acetaminophen as an analgesic. Ex. 1005 at col. 1, lns. 28-35; Ex. 1066 at 1, lns. 3-9. A person of ordinary skill in the art would look to the disclosure of a formulation that seeks to provide a safe oral formulation for patients and combine that with existing prior art references that also discuss oral formulations of APIs. Ex. 1003 at ¶ 197. These references are in the same field and each discuss the creation of oral formulations with an analgesic. Ex. 1003 at ¶ 196. The fact that each of the references discuss acetaminophen would provide an additional rationale for a person of ordinary skill in the art to combine the references. Ex. 1003 at ¶ 196. Moreover,

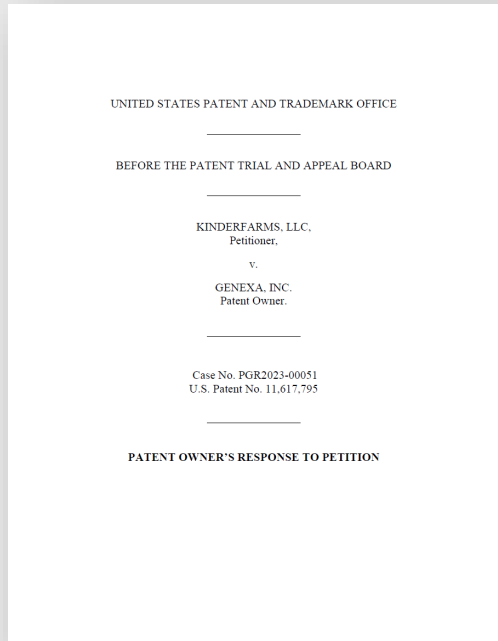
a person of ordinary skill in the art would have been motivated to combine these references because such a person would have known that antitussives like dextromethorphan are often combined with analgesics like acetaminophen and ibuprofen in over-the-counter liquid cough and cold formulations. Ex. 1003 at ¶ 197. A person of ordinary skill in the art would have had a reasonable expectation of success in combining these references because they all disclose formulations comprising well known ingredients performing well known functions. *KSR Int'l Co.*, at 417. Therefore, a person of ordinary skill in the art would be motivated to combine these teachings and would have a reasonable expectation of success in so doing. Ex. 1003 at ¶¶ 195-198.

The Petition did not assert with particularity any motivation or reasonable expectation of success with respect to combining WO742 with the specific viscosity ranges of the '4666 patent or WO133

-see POR, 58.

-Pet. 54-55

Ground 2: Petitioner's Motivation to Combine Never Mentions Viscosity and Does Not Propose Any Modifications to FR458 to Achieve a Particular Viscosity

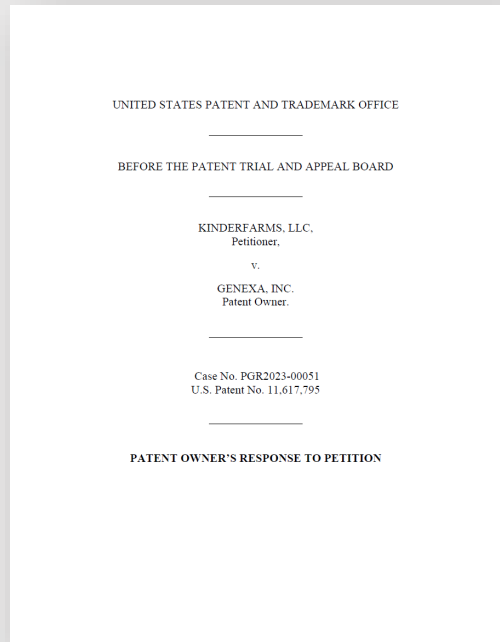


POR (Paper 20)

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

Ground 2: The Petition Does Present Any Proposed Modifications to the Example Formulations of FR458 or WO133 to Achieve a Particular Viscosity Value



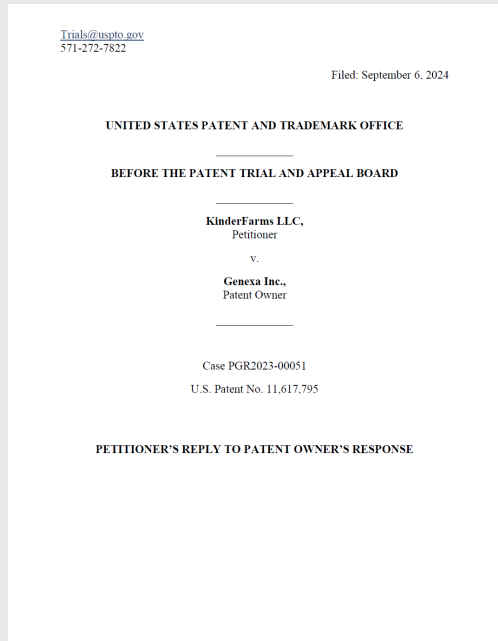
POR (Paper 20)

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

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.

-POR, 35-36, n.2

Petitioner's Improper New Attorney Arguments on Reply Further Show the Petition's Failures re Motivation to Combine and Reasonable Expectation of Success



Reply (Paper 25)

WO742 discloses nearly all the claim limitations of claims 1-17 of the '795 Patent. Pet. 56-68; Ex.1003, ¶¶195,199-265. A POSA would have been motivated to combine WO742's agave syrup-based liquid dextromethorphan and acetaminophen formulations for oral administration with the viscosity ranges for oral analgesic formulations taught by either WO133, the '4666 Patent, or both, to predictably arrive at the claimed invention. Pet.,54-55; Ex.1003, ¶¶195-198. A POSA also would have had a reasonable expectation of success in combining these teachings. Pet.,54-55; Ex.1003, ¶197.

--Reply, 4; see also POR, 57-58; Ex.2009, ¶¶165-168; Surreply (Paper 29), 20-21; Notice (Paper 27), 2-3

Petitioner's Improper New Attorney Arguments on Reply Further Show the Petition's Failures re Motivation to Combine and Reasonable Expectation of Success

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

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KINDERFARMS, LLC,
Petitioner,

v.

GENEXA, INC.,
Patent Owner.

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

PATENT OWNER'S SURREPLY

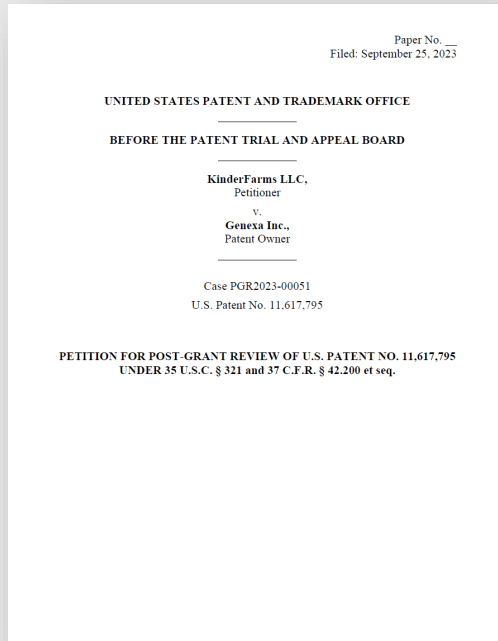
Surreply (Paper 29)

Nevertheless, Petitioner now contends for the first time that a POSA would have been motivated to combine (unidentified) formulations of either FR458 (Ground 1) or WO742 (Ground 2) specifically “with the viscosity ranges for liquid oral analgesic formulations taught by WO133, the ’4666 patent, or both[.]” (Reply, 2, 4.) But the Petition never once mentioned “viscosity” in connection with the asserted motivation to combine. (*See* Pet., 27-29, 54-55.) Similarly, the Petition never indicated any motivation to combine FR458 or WO742 with the specific “viscosity ranges” of WO133 or the ’4666 patent. (*See id.*) These new Reply arguments are foreclosed by statute, Federal Circuit precedent, and Board guidelines. *See Wasica*, 853 F.3d at 1286.

-Surreply, 20-21; Notice (Paper 27), 2-3

Ground 2: The Viscosity Limitation

The Petition's Assertions re the Viscosity Limitation of Claim 1 Fail to Address the Claims "as a whole" (same as Ground 1)



Pet. (Paper 2)

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

A person of ordinary skill in the art would understand that an oral formulation needs a viscosity that allows it to be pourable and drinkable. Ex. 1003 at ¶¶ 216.

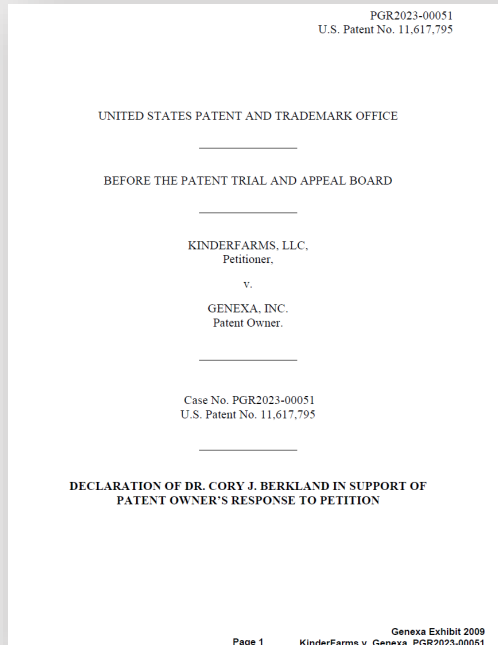
The viscosity of agave syrup is reported to be about 212 centipoise. Ex.1003 at ¶ 52.

Thus, a person of ordinary skill in the art would understand that the formulation disclosed in Example IX of WO742, which consists mainly of agave syrup and other ingredients with relatively low viscosities, may have a viscosity of less than 1500 centipoise. Ex. 1003 at ¶ 216, p. 121, fn. 25. As both the ’4666 Patent and WO133

disclose viscosity ranges for an oral formulation with an analgesic that overlap with this claim limitation, it is unnecessary for the Board to conclude that Example V of the WO742 meets this limitation. The ’4666 patent discloses a viscosity range

-Pet. 57-58; see also POR, 58-60; Ex.2009, ¶¶ 168-171

It is Undisputed that a POSA Would Have Known That Using Agave Syrup with Viscosity of 212 cP in WO742-Example IX Would Be a “readily pourable” Formulation

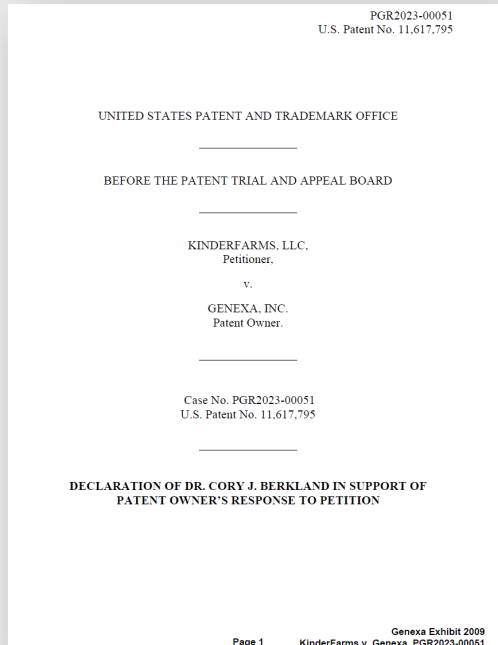


Ex.2009
(Berkland Decl.)

168. The Petitioner and its expert also do not provide any evidence as to what a POSA would have understood the viscosity of WO742-Example IX to be. To the extent that one relied on Petitioner’s asserted viscosity of agave syrup of 212 cP or Dr. Crowley’s assertion under this Ground that a POSA would “know that agave syrup can have a viscosity of around 200 centipoise,” a POSA would have understood and immediately recognized that such a formulation of WO742-Example IX would result in formulation with a much lower viscosity than the initial viscosity of the agave syrup—i.e., it would be less than 200 cP and at most around ~100 cP.

--Ex.2009, ¶168; see also POR, 61-63

It is Undisputed that a POSA Would Have Known That Using Agave Syrup with Viscosity of 212 cP in WO742-Example IX Would Be a “readily pourable” Formulation



Ex.2009
(Berkland Decl.)

171. A POSA therefore would have had no motivation, nor a reasonable expectation of success, of combining an agave syrup with a viscosity of 212 cP or about 200 cP with the remaining ingredients as taught by WO742-Example IX to achieve a formulation with a viscosity in the range of either the '4666 patent (1000-3000 cP) or WO133 (200-900 cP). Because of the known and expected thinning caused by the other ingredients—e.g., the ethanol and added water—a POSA to understand the viscosity of WO742-Example IX using an agave syrup of 200 cP would not satisfy these ranges. Moreover, even if there was any motivation to

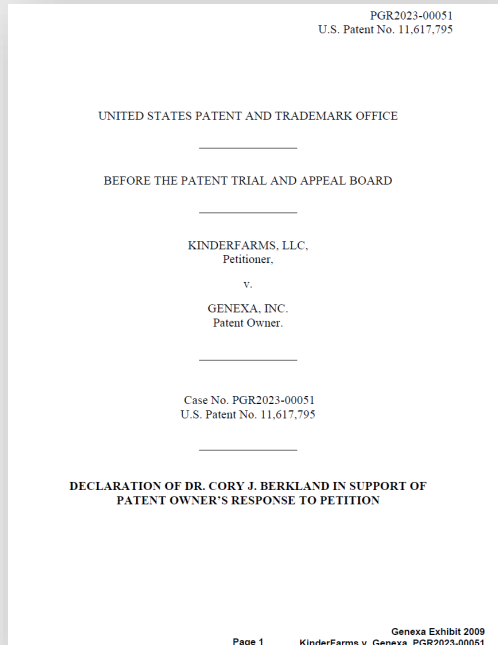
--Ex.2009, ¶171; see also POR, 61-63

Ground 2: Dependent Claims

Ground 2 Fails to Demonstrate Obviousness of Dependent Claims

- The Petition fails to articulate any reasoned motivation to combine or reasonable expectation of success with respect to the dependent claims as a whole (e.g., POR, 63-68; Ex.2009, ¶¶173-179)

Ground 2: Exemplary Failure to Address Dependent Claims as a Whole (Claim 9)



Ex.2009
(Berkland Decl.)

4. Dependent Claim 9

178. Claim 9 requires that the amount of diluent is “about 5%” of the formulation by weight. (Ex. 1001 at 6:9-11.) WO742-Example IX has a final volume of 15 mL. (Ex. 1007 at 23:17-24:2.) I note that the Petition and Dr. Crowley do not explain how WO742-Example IX would need to be altered to ensure it contains about 5% diluent (or water). Indeed, there is no reasoning provided as to why one would be motivated to alter the amount of diluent in WO742-Example IX when the formulation volume is already identified. I also note there is no explanation provided by Petitioner or Dr. Crowley for how the change in the amount of diluent would affect the viscosity of Example IX of WO742 or if the resulting formulation would meet the claimed viscosity limitation. Based on this, I believe there is no motivation or expectation of success in combining these references to achieve the claimed diluent concentration while maintaining the claimed viscosity based on the references of Ground 2.

-Ex.2009, ¶178; see also POR, 66-67

Ground 3 is Moot

Conditional Ground 3 Has Not Been Triggered and It is Moot

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.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KINDERFARMS, LLC,
Petitioner,

v.

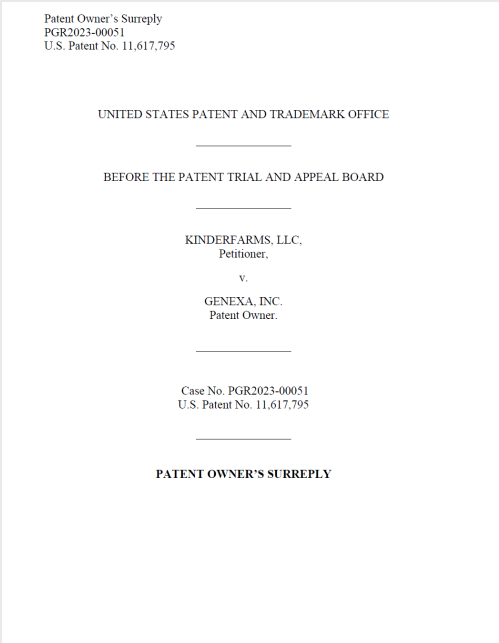
GENEXA, INC.,
Patent Owner.

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

PATENT OWNER'S RESPONSE TO PETITION

POR (Paper 20)

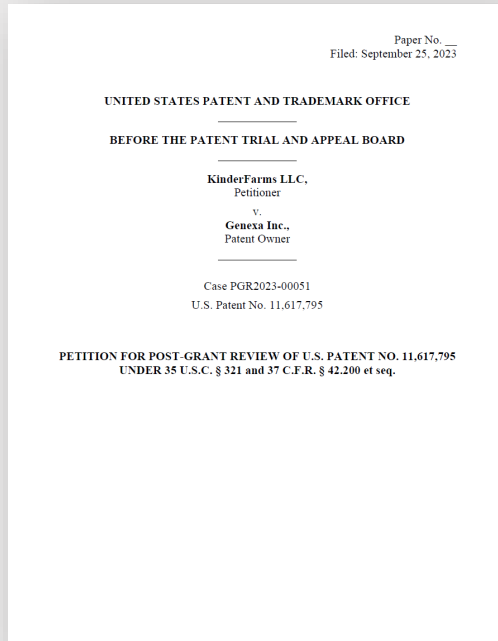
Conditional Ground 3 Has Not Been Triggered and It is Moot



Surreply (Paper 29)

¹ Petitioner’s Reply does not dispute that Ground 3 is moot. (*See* POR, 68.)

The Institution Decision re Ground 3



Institution Decision
(Paper 8)

F. Ground 3 – Indefiniteness

Petitioner asserts a third ground of challenge, arguing that the claims of the '795 patent are indefinite under 35 U.S.C. § 112(b). (*See* Pet. 68–72.) Specifically, Petitioner argues that one of ordinary skill in the art would not have understood the scope of the terms “palatable,” “stable,” and “consisting essentially of.” (*See id.* (citing Crowley Decl., Ex. 1003, ¶¶ 268–273).) Petitioner explains that this ground of challenge is presented “[i]n the alternative,” because although Petitioner asserts that a person of ordinary skill in the art can apply the plain meanings to these terms, which are proposed in the construction section of the Petition, Patent Owner may argue that the cited prior art references do not teach one or more of these limitations. (*See* Pet. 68; *see also id.* at 69 (“To the extent that patentees assert that the prior art references discussed in section V.A.2(a)7 do not disclose the ‘palatable’ limitation, a person of ordinary skill in the art would not understand the meaning of the term.”). Essentially, Petitioner argues that if the prior art fails to teach the limitations in question, then they would necessarily be indefinite as “a person of ordinary skill in the art would not understand” their meaning. (*See id.* at 69.)

All Challenged Claims Should Be Found
Patentable

Backup Slides



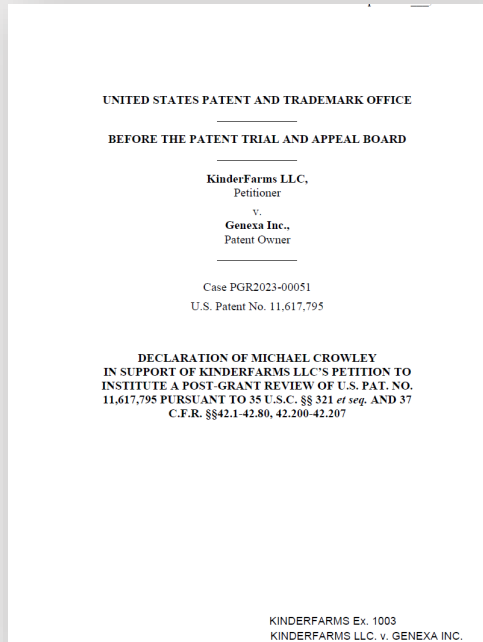
- “[T]he decision to institute and the final written decision are ‘two very different analyses,’ and each applies a ‘qualitatively different standard.’”

—*In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1376 (Fed. Cir. 2016)
(quoting *TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016))

- “This court has provided further assurance of an ‘as a whole’ assessment of the invention under § 103 by requiring a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner.”

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

Dr. Crowley's Declaration Teaches Away from "higher viscosity" and States a Desire for "readily pourable" formulations with 20-150 cP

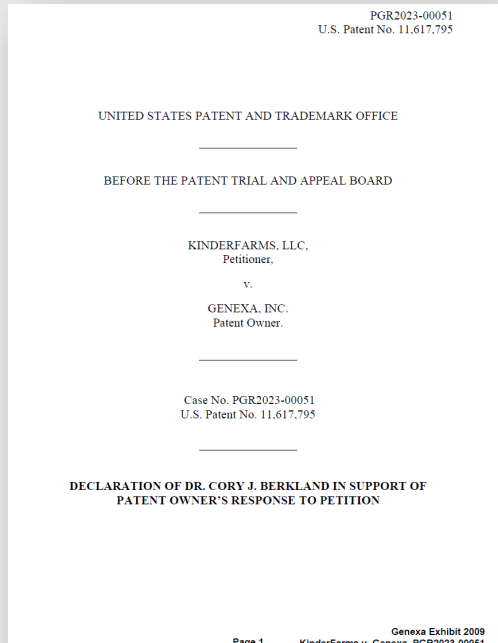


Ex.1003
(Crowley Decl.)

59. With respect to suspensions for oral administration, however, having a higher viscosity is generally not desirable. One drawback of having too high a viscosity in a suspension formulation is that it can make the formulation difficult to pour. Ex. 1012, at p. 768. Generally, suspensions having a viscosity in the range of 20 to 150 cP are considered readily pourable. Ex. 1014, at pp. 1489-1490. Additionally, increasing the viscosity of a suspension formulation has been shown to impair the dissolution characteristics of immediate release acetaminophen. Ex. 1013, at p. 1537.

- Ex.1003, ¶59; see also Ex.2009, ¶55

Excipients in FR458 includes Agar-Agar and Xanthan Gum

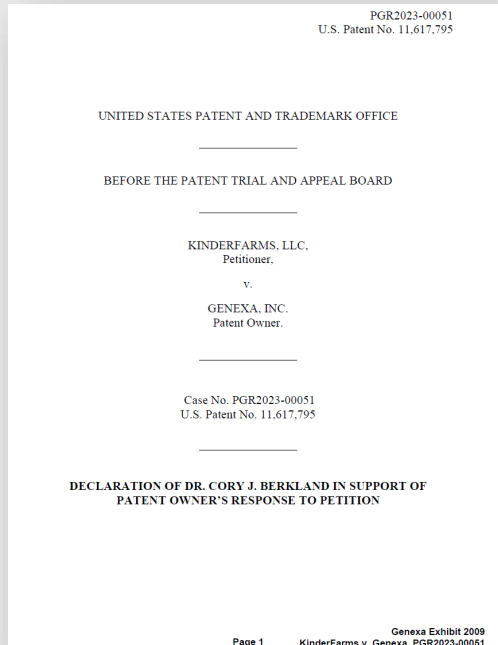


Ex.2009
(Berkland Decl.)

82. FR458 explains that Example 1 is formed by combining “Solution A” (xanthan gum, agar-agar, and glycerin) and “Solution B” (paracetamol suspended in agave syrup) together and then “the water is topped up to 100 mL and everything is mixed together.” (Ex. 1004 at pp.24-25, lns.185-200.) The collective mass of each ingredient (other than water) within FR458-Example 1 is 54.01 g (i.e., 2.5 g (paracetamol) + 45 g (agave syrup) + 0.4 g (xanthan gum) + 0.2 g (agar-agar) + 5 g (glycerin) + 0.5 g (sodium citrate) + 0.4 g (anhydrous citric acid) + 0.01 g (flavoring)). Because these ingredients would all be generally expected to have a density higher than water (i.e., above 1 g/cm³), FR458-Example 1 would be at least ~50% water by volume (and almost certainly closer to ~60% water by volume).

--Ex.2009, ¶82; POR, 15-16.

Excipients in FR458 includes Agar-Agar and Xanthan Gum

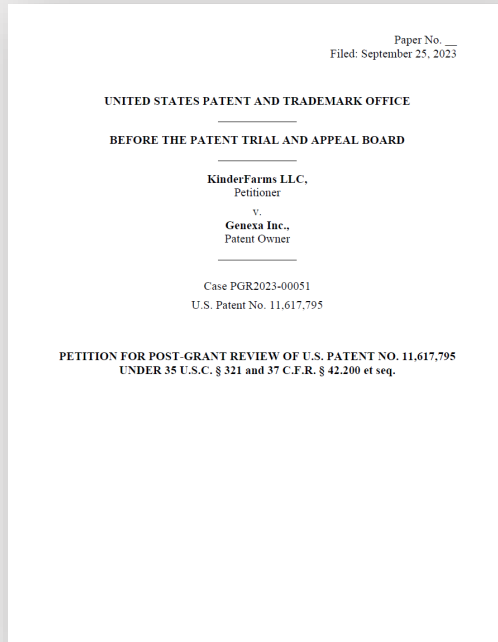


Ex.2009
(Berkland Decl.)

65% sucrose: 146 cP; 55% sucrose: 28.4 cP).) Hence, the amount of water in a formulation can have a profound impact on the formulation's viscosity—i.e., decreasing the viscosity (when water is added) or increasing the viscosity (when water is removed)—and these changes can be highly sensitive to the viscosity and resulting concentration in the amount of the excipients. That is, the amount of water in a formulation needed to achieve “a viscosity in the range of 20 to 150 cP” and therefore be “readily pourable,” according to Dr. Crowley, would be low when the other components of the formulation generally have overall lower viscosities and higher when the other components of the formulation generally have overall higher viscosities.

--Ex.2009, ¶155; see also POR, 7-8

Dr. Berkland's Testimony Is More Credible than Dr. Crowley's



Institution Decision
(Paper 8)

F. Ground 3 – Indefiniteness

Petitioner asserts a third ground of challenge, arguing that the claims of the '795 patent are indefinite under 35 U.S.C. § 112(b). (*See* Pet. 68–72.) Specifically, Petitioner argues that one of ordinary skill in the art would not have understood the scope of the terms “palatable,” “stable,” and “consisting essentially of.” (*See id.* (citing Crowley Decl., Ex. 1003, ¶¶ 268–273).) Petitioner explains that this ground of challenge is presented “[i]n the alternative,” because although Petitioner asserts that a person of ordinary skill in the art can apply the plain meanings to these terms, which are proposed in the construction section of the Petition, Patent Owner may argue that the cited prior art references do not teach one or more of these limitations. (*See* Pet. 68; *see also id.* at 69 (“To the extent that patentees assert that the prior art references discussed in section V.A.2(a)7 do not disclose the ‘palatable’ limitation, a person of ordinary skill in the art would not understand the meaning of the term.”). Essentially, Petitioner argues that if the prior art fails to teach the limitations in question, then they would necessarily be indefinite as “a person of ordinary skill in the art would not understand” their meaning. (*See id.* at 69.)

Dr. Berkland's Testimony is More Reliable than Dr. Crowley's

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

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KINDERFARMS, LLC,
Petitioner,

v.

GENEXA, INC.,
Patent Owner.

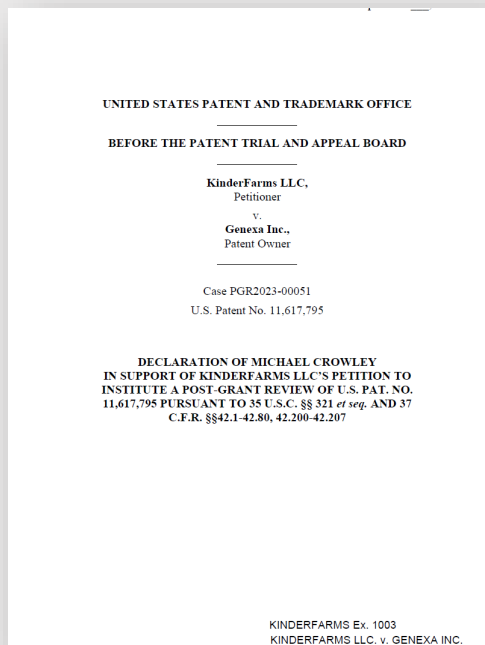
Case No. PGR2023-00051
U.S. Patent No. 11,617,795

PATENT OWNER'S SURREPLY

Surreply (Paper 29)

In contrast, Dr. Crowley has provided no Reply declaration, despite having the opportunity to do so, leaving in the record his indefensibly wrong assertion that agave syrup has a viscosity of 212 cP while erroneously citing to Exhibit 1031 that reports a viscosity of 2,560 cP. Dr. Crowley provides no explanation for why he cited to (and presumably read) Exhibit 1031, but then ignored what it says in rendering his opinions. This critical mistake renders Dr. Crowley's testimony unreliable. As such, the Board should give no weight to the error-riddled and conclusory opinions of Dr. Crowley and credit the testimony of Dr. Berkland over Dr. Crowley.

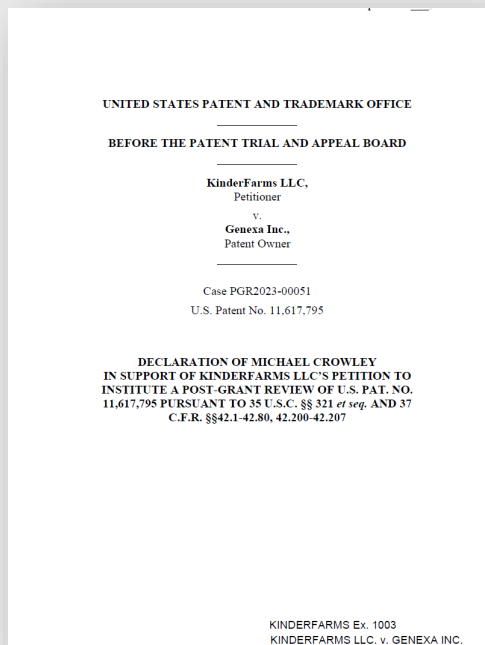
Dr. Crowley's Error Regarding the Viscosity of Agave Syrup



Ex.1003
(Crowley Decl.)

52. Agave syrup, which is predominantly composed of fructose and glucose, is a natural sweetener that is slightly sweeter than table sugar. Ex. 1027, at p. 22; Ex. 1008, at p. 2, ¶ 0043. There are several grades of agave syrup available that vary in flavor, color and intensity. Ex. 1027, at p. 22. When included in food products or medicines to replace other sweeteners, like corn syrup, agave syrup can be added in amounts ranging from 2% to 98% of the total weight of the product. Ex. 1008, at p. 2, [0039]-[0042]. The viscosity of agave syrup is reported to be around 212 mPa-S, or 212 cP, which is less than that of honey or sugar cane syrup. Ex. 1031, at p. 1. 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. Therefore, agave syrup is relatively thinner in consistency and more pourable than other common naturally sourced sweeteners.

Dr. Crowley's Assertion of Water to Achieve a Final Formulation Volume



Ex.1003
(Crowley Decl.)

4. “a diluent,”

116. In my opinion, FR458 and the '4666 Patent both disclose this limitation.

117. Both FR458 and the '4666 Patent provide examples of liquid pharmaceutical formulations that contain water and the water is provided in quantity sufficient (q.s.) for the formulation to achieve a particular final volume. Ex. 1004, p. 8, lns. 202-203 [“The water is topped up to 100mL and everything is mixed together.”], pp. 8-10, Examples 1-4; Ex. 1005, col. 4, Example 1. A person of ordinary skill in the art would know that, if water is being added to a formulation in a quantity sufficient to bring it to desired final volume, it is playing the role of a diluent.

- Ex.1003, ¶117