

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

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Patent Owner's Exhibit List

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

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

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Exhibit No.	Description of Document
2022	J.F. Swindells et al., Viscosities of Sucrose Solutions at Various Temperatures: Tables of Recalculated Values, <i>Supplement to National Bureau of Standards Circular</i> , 440 (1958)
2023	D. Reker et al., “Inactive” ingredients in oral medications, <i>Sci. Transl. Med.</i> , 11:483 (2019)

I. INTRODUCTION

Petitioner's Reply only confirms the dispositive failures of the Petition to demonstrate obviousness of any claims of the '795 patent under Grounds 1 and 2.¹ The Petition and Dr. Crowley's supporting declaration wrongly premised its theory of obviousness on the erroneous and conclusory assertion that agave syrup has a viscosity of 212 centipoise, despite the cited Exhibit 1031 showing agave syrup with a viscosity of 2,560 cP. (Ex. 1003, ¶¶52, 119 ("As I previously noted at ¶52, *a person of ordinary skill in the art would have known that agave syrup has a viscosity of around 212 centipoise.*");² Ex. 1031; POR, 31, 57.)

Rather than defend the Grounds presented in the Petition and for which this Review was instituted, Petitioner's Reply tacitly acknowledges the fundamental failure of the Petition by abandoning those theories and improperly attempting to assert new ones based solely on attorney argument that is unsupported by any evidence. Indeed, Petitioner failed to provide any new Reply expert declaration. Ultimately, Petitioner's new Reply arguments contradict the Petition and only further demonstrate that the Petition as instituted failed to satisfy Petitioner's burden to prove obviousness.

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

² All emphasis in this brief has been added, unless noted otherwise.

Accordingly, the Board should uphold all claims of the '795 patent as non-obvious and patentable over the failed arguments and evidence presented by Petitioner.

II. PETITIONER'S REPLY FAILS TO ADDRESS THE UNDISPUTED AND DISPOSITIVE ERRORS IN THE PETITION AND IMPROPERLY RAISES NEW ARGUMENTS

Unable to respond directly to the undeniable and dispositive errors in the Petition exposed by Patent Owner's Response ("POR"), Petitioner's Reply wrongly seeks to have the Board ignore the theories and evidence presented in the Petition in lieu of improper new arguments that were never previously presented. It is a statutory requirement that the initial Petition must identify *with particularity* the evidence that supports the grounds for the challenge to each claim. *E.g.*, *DynaEnergetics Europe GmbH et al v. QinetiQ Ltd.*, PGR2023-00003, Paper 19 at 49 (P.T.A.B. Apr. 11, 2024) ("Petitioner shoulders the burden to point out evidence supporting its position with 'particularity.'") (quoting 35 U.S.C. § 322(a)(3) and citing *cf. Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359 (Fed. Cir. 2016) ("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.'" (citing the analogous 35 U.S.C. § 312(a)(3))).

It is neither fair nor necessary for the Board or Patent Owner to address obviousness arguments that were not raised with particularity by the Petition. *See, e.g., Apple Inc. v. MemoryWeb, LLC*, PGR2022-00006, Paper 41 at 85 (P.T.A.B. June 7, 2023) (“[A]n IPR petitioner may not raise in reply ‘an entirely new rationale’ for why a claim would have been obvious.”) (quoting *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1331-32 (Fed. Cir. 2019)); *Apple Inc. v. MemoryWeb, LLC*, PGR2022-00006, Paper 43 at 5-6 (P.T.A.B. June 7, 2023) (upon denial of rehearing, the Board recognizing that “***Petitioner was required to make its case in the Petition, not the Reply***”). As explained in Patent Owner’s notice submitted with the approval of this Board, the Reply contains several improper new arguments that should be disregarded. (Paper 27.)

The arguments raised in Petitioner’s Reply also fail because they are not supported by any expert testimony, relying instead solely on unsubstantiated attorney argument. But “argument of counsel is not evidence.” *See Icon Health & Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017).

Here, the Board should disregard and reject Petitioner’s new Reply arguments. The Reply fails to address with any evidence the unrebutted testimony from Dr. Berkland that a POSA would have had no motivation nor any reasonable expectation of success under the Petition’s arguments and evidence in Grounds 1

and 2. Petitioner simply failed to carry its burden in the initial petition, and cannot assert new arguments on Reply. *See* 35 U.S.C. § 322(a)(3); *Intelligent Bio-Systems*, 821 F.3d at 1369.

A. The Petition's Assertion that Agave Syrup Has a Viscosity of 212 cP Is Indisputably Wrong and Dispositive of Non-Obviousness

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.)

On Reply, Petitioner seeks to cast this dispositive error as merely "a miscitation in Dr. Crowley's declaration"—but never submitted a reply declaration from Dr. Crowley to substantiate this claim. (*See* Reply, 10.) Petitioner asserts that "[t]he reference intended to be cited was Exhibit 1030, which reports agave syrup

with a viscosity of 212 cP.” (Reply, 10 n.4) But even if Petitioner’s erroneous citation theory is credited, that only demonstrates that the Petition was premised on the erroneous assertion that agave syrup *necessarily* has a viscosity of 212 cP—never acknowledging or addressing any other of the inherently variable viscosity values for agave syrup, including the 2,560 cP value reported in Dr. Crowley’s Exhibit 1031. (*See, e.g.*, POR, 25-27, 30 (“The Petition inexplicably ignores the fact that agave syrup can have viscosity up to at least 2,560 cP as shown in Exhibit 1031” and “never presents any argument” regarding any such viscosity); Ex. 2009, ¶118 (“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 Dr. Crowley and Petitioner did not address the vast differences in viscosity agave syrup may have in light of the evidence they have relied on”).)

Confronted with this fatal flaw, Petitioner’s Reply attempts to pivot by asserting, without evidence, that “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.” (Reply, 11; *see also* Reply at 19 (same), 20 (same).)

But Petitioner cannot advance an entirely new theory on Reply simply because its initial Petition failed to present a viable theory of obviousness. “The ‘newness’ restriction prohibits the petitioner from raising, in reply, ‘an entirely new theory of *prima facie* obviousness absent from the petition,’ even if the new theory is responsive to the patent owner’s response or the Board’s institution decision.” *Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1008 (Fed. Cir. 2023) (quoting *Wasica Fin. GmbH v. Cont’l Auto. Sys., Inc.*, 853 F.3d 1272, 1286 (Fed. Cir. 2017). “Shifting arguments in this fashion is foreclosed by statute, [Federal Circuit] precedent, and Board guidelines.” *Wasica*, 853 F.3d at 1286.

Petitioner’s new attorney arguments on Reply are flawed in various ways and should be rejected.

1. The Petition never once mentioned “selecting an agave syrup of appropriate viscosity” but instead wrongly presumed that agave syrup “has a viscosity of around 212 centipoise”

As noted, the only viscosity value for agave syrup presented in the Petition was about 212 cP. (*See* Pet., 31, 57.) The only viscosity value for agave syrup in Dr. Crowley’s declaration was about 212 cP (or around 200 cP). (*See* Ex.1003, ¶¶52, 119, 216.) Thus, the Petition and Dr. Crowley undeniably relied on the incorrect assertion that a POSA would have known there was only one value—i.e., around 212 cP—for the viscosity of agave syrup. (*See, e.g.*, Ex.1003, ¶119 (“*a person of*

ordinary skill in the art would have known that agave syrup has a viscosity of around 212 centipoise”).)

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.)

Additionally, Dr. Berkland’s testimony that a POSA would not have been motivated to select a low quality 212 cP agave syrup within Grounds 1 and 2 proposed in the Petition remains unrebutted. (Ex. 2009, ¶121.) As Dr. Berkland’s declaration states, “[a] viscosity of 212 cP indicates to me that the agave syrup has a lower quality” because it is “an apparently watered-down low quality agave syrup.” (Ex. 2009, ¶121; *see also* Ex.1031; Ex.1051, 130:7-134:19, 136:15-22.)

The Reply does not contest Dr. Berkland’s opinion that a POSA would have known that the use of such a low-quality, low-viscosity 212 cP agave syrup within FR458-Example 1 (Ground 1) or WO742-Example IX (Ground 2) would result in

formulations that are “readily pourable”—i.e., having low viscosity within the range of 20-150 cP—well below and outside the viscosity values of the ’4666 patent and WO133 in Grounds 1 and 2. (See Ex. 2009, ¶¶147-150 (Ground 1), ¶¶167-171 (Ground 2).) Dr. Berkland’s further opinion that a POSA’s understanding of the expected low viscosity of these example formulations using an agave syrup with 212 cP viscosity negates any motivation to combine or any reasonable expectation of success in achieving the viscosity ranges in the ’4666 patent or WO133 likewise remains unrebutted:

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.*

(Ex. 2009, ¶150 (Ground 1).)

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). . . . *a POSA would 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 combine WO742-Example IX with the viscosity ranges of the '4666 patent or WO133, any such motivation *would necessarily indicate to a POSA not to use an agave syrup with about 200 cP, contrary to what Petitioner and Dr. Crowley have relied on.*

(Ex. 2009, ¶171 (Ground 2).)

The Petition failed to present any viable theory of obviousness with particularity based on the incorrect assertion that agave syrup has a viscosity of 212 cP, as demonstrated by the POR and Dr. Berkland's unrebutted testimony. (*See* POR, 43-51 (Ground 1), 58-63 (Ground 2).) Instead, Petitioner pivots to its new and unsubstantiated Reply argument that a POSA would somehow know to "select[] an agave syrup of appropriate viscosity." (*See* Reply, 11, 19, 21.) But, as noted, this new argument must be rejected. *See* 35 U.S.C. § 312(a)(3); *see Henny Penny*, 938 F.3d at 1330 ("Board did not abuse its discretion in holding [Petitioner] to its word and disregarding its new theory first raised in reply.") Contrary to Petitioner's apparent belief, a Reply in this proceeding is not an opportunity to make new

arguments simply because the initial petition failed. *See Corephotonics*, 84 F.4th at 1008.

2. Petitioner's Reply cannot salvage the Petition's failure to prove obviousness under Grounds 1 and 2

Petitioner's failure to present any defense of the Petition's theories based on agave syrup having 212 cP and instead abandoning them in lieu of its new and improper Reply arguments only underscores that Petitioner failed to carry its burden to prove obviousness, especially since it cannot overcome the nonobviousness evidence presented by Patent Owner in the POR. Petitioner's new attorney arguments on Reply with respect to Grounds 1 and 2 now mischaracterize its own Petition, wrongly asserting that "*none of [the Petition's] arguments even relied on a specific viscosity of agave syrup* because the relevant viscosity is that of the formulation—not the agave syrup component only." (Reply, 10.) The Reply further contradicts the Petition by asserting that it also did not rely on any example formulations from FR458 and WO742: "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*. Pet., 31-32, 57-58." (Reply, 11.)

But these new attorney arguments, which are not evidence, are undeniably contrary to the Petition. (*See* POR, 43-45 (quoting Pet., 31-32), *id.* at 58-60 (quoting

Pet., 57-58).) The Petition expressly relied on the supposed prior art teaching that “the viscosity of agave syrup is reported to be 212 centipoise”; it also expressly pointed to “the formulation disclosed in Example 1 of FR458” (Ground 1) and “the formulation disclosed in Example IX of WO742” (Ground 2). (See Pet., 31, 57.) The Petition also relied on evidence from Dr. Crowley’s declaration under Ground 1 (Pet., 31 (citing Ex. 1003, ¶119)) and Ground 2 (Pet., 57 (citing Ex. 1003, ¶216)) with respect to the claimed viscosity limitation in the ’795 patent. These citations also make clear Dr. Crowley’s reliance on FR458-Example 1 and WO742-Example IX utilizing an agave syrup with viscosity of 212 cP (or around 200 cP):

The formulations in *Examples 1-4 of FR458 are largely made up of agave syrup*. Ex. 1004, pp. 8-10. As I previously noted at ¶ 52, *a person of ordinary skill would have known that agave syrup has a viscosity of around 212 centipoise. Therefore*, such a person would have known that it was possible for *the viscosity of the formulations in Example 1-4* to be less than 1500 centipoise . . .

(Ex. 1003, ¶119 (Ground 1).)

Such a [POSA] would also know that *agave syrup can have a viscosity of around 200 centipoise* – which is well under 1,500 centipoise. *Considering that the bulk of the formulation disclosed in Example IX*

of WO742 is agave syrup, none of the added ingredients would be expected to increase the viscosity of the composition above 1,500 centipoise. . . . *Therefore*, a person of ordinary skill in the art would have understood that the viscosity of *the final formulation disclosed* is likely to be less than 1,500 centipoise.

(Ex. 1003, ¶216 (Ground 2).)

Dr. Crowley expressly identified “Examples 1-4 of FR458” and “Example IX of WO742,” noting they are “largely made up of agave syrup” or “the bulk of the formulation” is agave syrup, respectively. (See Ex. 1003, ¶¶119, 216.) He also coupled these assertions with his identification of agave syrup having a viscosity of “around 212 centipoise” (or “around 200 centipoise”) to reach his asserted conclusion that “it is possible” or “likely” that the viscosity of the final formulations of Examples 1-4 of FR458 or the final formulation (singular) of “Example IX of WO742” allegedly could be less than 1,500 centipoise, as recited in the independent challenged claims. (*Id.*) Accordingly, there can be no reasonable debate that Dr. Crowley’s (incorrect) opinions in his declaration were entirely premised on both “a specific viscosity of agave syrup” (i.e., “around 212 cP”), and the example formulations of FR458 and WO742-Example IX.

Petitioner's Reply fails to provide any justification for why Dr. Crowley's clear testimony should now simply be disregarded, leaving the initial Petition's theories under Grounds 1 and 2 completely devoid of *any* evidentiary support. Indeed, Petitioner's assertion that its Grounds 1 and 2 did not rely on FR458-Example 1 and WO742-Example IX are refuted by the Reply's continued reliance on those examples as allegedly satisfying limitations within the challenged dependent claims.³ (*See, e.g.*, Reply, 16-17 (relying on "Example IX of WO742 (Ground 2)" and "Example 1 of FR458" with respect to dependent claims 5 and 6).)

The POR also expressly noted the lack of any particularity in the Petition regarding a motivation to combine and the mere "conclusory identification of: (1) a clearly erroneous viscosity of agave syrup, (2) FR458-Example 1 (unmodified)/WO742-Example IX (unmodified), and (3) viscosity ranges from the '4666 patent and WO133." (POR, 43-44, 58-59; Ex. 2009, ¶147 ("I understand that Petitioner and Dr. Crowley identify: (1) the erroneous assertion that agave syrup has a viscosity of 212 cP; (2) FR458-Example 1; and (3) the viscosity ranges of the

³ Petitioner's attorney arguments on Reply cannot salvage the failure to prove obviousness of those claims, as shown by the POR. (*See* POR, 53-56, 63-68; Reply, 12-22.)

'4666 patent (1000-3000 cP) and WO1333 (200-900 cP) (*See* Pet., 31-32; Ex. 1003, ¶119.)"); *see also* Ex. 2009, ¶¶166-168.)

Petitioner cannot reasonably deny that Ground 1 and Ground 2 of its Petition and supporting expert declaration from Dr. Crowley expressly relied on an agave syrup with 212 cP (or around 200 cP) within either FR458-Example 1 or WO742-Example IX, respectively, as purportedly being the "formulation" meant to be combined with the viscosity ranges of the '4666 patent and WO133. (*See* Ex. 1003, ¶¶119, 216; POR, 1, 24-28; Ex. 2009, ¶¶117-121.) No other theory or evidence was ever set forth with particularity. *See DynaEnergetics*, PGR2023-00003, Paper 19 at 59 (it is not proper "to augment[] the Petition with factual findings that are not, in the first instance, pointed out with 'particularity' in the Petition").

Moreover, by asking the Board to disregard the only viscosity for agave syrup identified anywhere in the Petition's Grounds and the only "final formulation(s)" identified from within FR458 and WO742, Petitioner's Reply further demonstrates that the Petition fails to address the claims as a whole and reveals Petitioner's reliance on impermissible hindsight. *See Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1085 (Fed. Cir. 2008) ("The determination of obviousness is made with respect to the subject matter as a whole, not separate pieces of the claim."); *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998) (a "[d]etermination of

obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention”).

Petitioner's attorney argument that “[t]he 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” transparently rejects any consideration of the challenged claims as a whole. (Reply, 11.) Instead, it impermissibly seeks to view the claim limitations in isolation, rather than requiring all elements of the claim to be satisfied by the proposed combination—i.e., presenting a complete “final formulation” with all of the claimed components and formulated in a manner that allegedly achieves the viscosity values of the '4666 patent and WO133. Since Petitioner's Reply argument is based on mere hindsight that wrongly attempts to break apart the claims and find the individual limitations within the cited references without consideration of the combination as a whole, it is legally deficient and cannot support obviousness. *See Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004).

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*").)

The use of water to achieve a desired final volume is indisputably distinct from the use of water to achieve a desired final viscosity. But the Petition undeniably referred *only* to adding water to bring the example formulations to a final volume—it never once mentioned "adjusting the water content . . . to achieve the desired final viscosity." As explained by Dr. Berkland, the Petition thus failed to properly address the viscosity limitation of the challenged claims. (*See* Ex. 2009, ¶161 ("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 1 of FR458 or if the resulting formulation would meet the claimed viscosity limitation."), ¶178 ("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”).) There is nothing in the Petition to support any adjustments to the amount of added water since changing the amount of added water would necessarily lead to a “final volume” different from the alleged “desired final volume,” directly contrary to the Petition’s Grounds 1 and 2.

Furthermore, as noted in the POR, the Petition does not advance “any theory, argument, or evidence in which these [FR458-Example 1 or WO742-Example IX] formulations would be modified in any way to achieve a particular viscosity value.” (POR, 36 n.2; *see also* Ex. 2009, ¶150 (“I note that Dr. Crowley proposed no modifications to FR458-Example 1”).) There is simply nothing in the Petition to support Petitioner’s new Reply argument that a POSA would simply know to “adjust” any of the components within FR458-Example 1 or WO742-Example IX “to achieve the desired final viscosity.” (*See* Ex. 2009, ¶¶159 (“Dr. Crowley does not address how the variability of acetaminophen concentration would impact the viscosity of any formulation, let alone that of FR458 Example 1.”), 177 (same regarding WO742-Example IX); *see* 2009, ¶¶164 (“Petitioner and its expert provide no reasoning or motivation within the references of Ground 1 as to why one would increase the concentration of agave by over two-fold, nor does it discuss how this would affect the viscosity of the formulation”), 179 (similar regarding WO742-Example IX).)

4. Dr. Berkland's deposition testimony rejects the Reply's new theory and further demonstrates Petitioner's reliance on impermissible hindsight

During his deposition, Petitioner's counsel questioned Dr. Berkland about the teachings disclosed in the '795 patent and a POSA's understanding of them. With respect to Example 1 of the '795 patent, Dr. Berkland testified as to how a POSA would have been able, based on the teachings of the '795 patent, to select an appropriate agave syrup in order to achieve the claimed "pharmaceutical syrup formulation having a resulting viscosity of less than 1500," which "as a POSA, it tells me that I need to be using [an] agave syrup that can get me to that claimed result." (Ex. 2009, 116:11-23.) Yet, when asked whether "[a] POSA would have known how to do that [select an appropriate agave syrup] before the '795 patent was filed," he unequivocally testified that "*I have not seen any evidence that would lead me to believe that.*" (Ex. 2009, 116:24-117:5.)

Dr. Berkland then further testified that "I can tell you that just looking at [Dr. Crowley's] exhibits and *knowing that agave syrups can come in viscosities of at least 2560 centipoise, that then in hindsight the '795 patent is achievable[.]*" (Ex. 2009, 120:7-14.) Dr. Berkland's testimony was clear: when following the teachings of the patent, the appropriate selection of an agave syrup is achievable, but he did not see "any evidence" that making such a selection would have been within the

knowledge of a POSA prior to the '795 patent, including based on the evidence provided by Dr. Crowley.

Dr. Berkland's deposition testimony thus does not support Petitioner's new Reply argument that "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" prior to the '795 patent. (*See* Reply, 11.) Rather, this only shows that Petitioner is improperly using hindsight by trying to use the teachings of the patent itself to show obviousness. Dr. Berkland's deposition testimony cited in Petitioner's Reply was not related to obviousness, but instead were directed to answering questions in the context of the sufficiency of the disclosures of the '795 patent. (*See* Ex. 1051, 117:4-23 (testimony related to "Example 1 of the '795 patent", *see* Ex.1051, 116:11-117:19), 128:16-20 (testimony related to "a POSA would know how to select an agave syrup to be used with the '795 patent"), 138:7-139:17 (testimony related to "a person of skill in the art reading the '795 patent"), 147:16-149:23 (testimony related to "Example 1" of the '795 patent), 150:16-151:9 (testimony related to "Example 1 of the '795 patent").)

Accordingly, these portions of Dr. Berkland's testimony do not and cannot support Petitioner's new theory of obviousness. It is improper to base a conclusion of obviousness upon facts and evidence gleaned only through hindsight reference to

the challenged patent. *See, e.g., Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570 (Fed. Cir. 1996) (“The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made.”); *In re Rouffet*, 9 F.3d 1350, 1358 (Fed. Cir. 1998) (“Impermissible hindsight is inferred when the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one (with no knowledge of the claimed invention) to make the proposed combination has not been explained.”).

B. Petitioner's Improper New Motivation to Combine Arguments on Reply Are Prohibited

On Reply, Petitioner also makes improper new arguments regarding a motivation to combine. *See Corephotonics*, 84 F.4th at 1008. The POR demonstrated the Petition's absence of any argument for a motivation to combine with particularity “any specific disclosures” within FR458/WO742, the '4666 patent, and/or WO133. (*See* POR, 40, 58; Ex. 2009, ¶¶140 (“Petitioner and Dr. Crowley's only motivation for combining the references is generic” and “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.”), 147 (“With respect to the viscosity limitation of claim 1, neither the Petitioner nor Dr. Crowley ever identify any motivation to combine any specific

aspects of FR458 with any of the specific aspects of either the '4666 patent and/or WO133").)

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.

C. Agave Syrup Was Not Well-Known to a POSA for Performing the Function of Achieving a Desired Viscosity in an Oral Formulation

Even if Petitioner's improper new arguments are considered, they still fail. Patent Owner provided ample evidence demonstrating that agave syrup is not simply a well-known "old ingredient" performing a function it was known to perform in the context of an oral pharmaceutical formulation with a specified and desired viscosity. (POR, 40-42; Ex. 2009, ¶¶142-146.) As Dr. Berkland stated, "if agave syrup was so well-established in the field, Petitioner and Dr. Crowley would not have made so

glaring of an error of agave syrup having a viscosity (212 cP) that is an order of magnitude less than the actual reported value in the cited Exhibit 1031 (2,560 cP)” and “if agave syrup was such a well-known ingredient for liquid pharmaceutical formulations certainly Dr. Crowley would have recognized that he was relying on a viscosity that is not even what is reported in his own cited Exhibit 1031.” (Ex. 2009, ¶142.) Petitioner’s Reply never addresses Dr. Berkland’s opinions that Dr. Crowley’s undisputed erroneous assertion that “a person of ordinary skill in the art would have known that agave syrup has a viscosity of around 212 centipoise” (Ex.1003, ¶119) proves that agave syrup was not simply a well-known pharmaceutical formulation component for use in achieving a specified and desired oral formulation viscosity. (See Ex. 2009, ¶¶140-146.)

Dr. Berkland also further provided evidence expressly demonstrating the lack of a well-known understanding of agave syrup: “further analysis of a wide range of [agave] syrups . . . are needed to get more information for a deeper characterization” of them. (Ex. 2009, ¶143 (quoting Ex. 2013, 50).) Accordingly, “agave syrups are not the same sort of singular uniform ingredient that is well-known for use in oral formulations,” in contrast to other standard components that can be found in pharmaceutical textbooks and regularly used references, and none of these sources include reference to “agave syrup” as a standard component of pharmaceutical

formulations. (Ex. 2009, ¶144.) Petitioner's attorney argument on Reply, which is not evidence, cannot rebut Dr. Berkland's opinions, and the Petition's conclusory assertions that agave syrup is performing a well-known function should be rejected by the Board. *See Icon Health*, 849 F.3d at 1043; *In re Van Os*, 844 F.3d 1359, 1361 (Fed. Cir. 2017).

D. Dr. Berkland's Testimony that a POSA Would Disregard the Clear Error in the '4666 Patent Is Unrebutted

Supported by Dr. Berkland's testimony, which remains unrebutted, the POR thoroughly demonstrated that the '4666 patent's claim 11 recitation of a viscosity range of "about 100-3000 centipoise" is an obvious typographical error that a POSA would disregard in favor of the clearly correct reading of "1000-3000 centipoise." (POR, 30-34; Ex. 2009, ¶¶122-133.) Petitioner provided no evidence in response to Dr. Berkland's testimony, which demonstrated the clear error and is unrebutted. Petitioner's unexplained reliance on the clearly erroneous viscosity range from claim 11 of the '4666 patent further underscores that the Petition's factually inaccurate and hindsight-based theories cannot carry Petitioner's burden of demonstrating obviousness with particularity. (POR, 34-38; Ex. 2009, ¶¶134-138.)

E. The Petition Failed to Establish a Presumption of Obviousness

"[T]o establish a prima facie case of obviousness based on a combination of elements in the prior art, the law requires a motivation to select the references and

to combine them in the particular claimed manner to reach the claimed invention.”

Eli Lilly & Co. v. Zenith Goldline Pharms., 471 F.3d 1369, 1379 (Fed. Cir. 2006).

Petitioner's obviousness arguments under Grounds 1 and 2 rest entirely on the false presumption that agave syrup has an inherent viscosity of around 212 cP. (POR, 29-30.) As described above and in the POR, Petitioner failed to state any prima facie case of obviousness and therefore failed to create any presumption of obviousness. *See id.* (affirming finding of nonobviousness over an allegation of a presumption of obviousness upon concluding that the prior art compound would not have been chosen as a lead compound).

III. DR. BERKLAND'S CREDIBLE TESTIMONY SHOULD BE GIVEN MORE WEIGHT THAN DR. CROWLEY'S CONCLUSORY AND ERRONEOUS OPINIONS

Petitioner's Reply asserts that Dr. Berkland's opinions are somehow unreliable and should be given little weight. (Reply, 22.) Petitioner seems to believe that Dr. Berkland was required to answer any-and-all of Petitioner's ill-formed, and incomplete hypotheticals with off-the-cuff testimony even though the questions had no relation to the opinions set forth in his declaration. For example, Dr. Berkland's testimony that "I haven't conducted that analysis," "[m]y analysis was restricted to responding to Dr. Crowley," or "I haven't formed an opinion on that" was in response to questions from Petitioner's that went far beyond the scope any opinions in his declaration; this testimony has no bearing on Dr. Berkland's credibility. (*See*,

e.g., Ex. 1051, 119:11-13, 120:2-3, 161:8-9.)

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.

IV. CONCLUSION

Genexa respectfully requests that the Board confirm the patentability of Claims 1-24.

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

Dated: October 11, 2024

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CERTIFICATE OF COMPLIANCE WITH WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), I certify that this surreply complies with the type-volume limits of 37 C.F.R. § 42.24(b)(2) because it contains 5,598 words, according to the word-processing system used to prepare this surreply, excluding the parts of this surreply that are exempted by 37 C.F.R. § 42.24(a) (including the table of contents, a table of authorities, mandatory notices, a certificate of service or this certificate word count, appendix of exhibits, and claim listings).

Dated: October 11, 2024

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Patent Owner's Surreply
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4), the undersigned certifies that on October 11, 2024, a complete and entire copy of PATENT OWNER'S SURREPLY served via electronic mail on the Petitioner by serving Petitioner's counsel of record as follows:

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