

Filed: September 6, 2024

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**KinderFarms LLC,**  
Petitioner

v.

**Genexa Inc.,**  
Patent Owner

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Case PGR2023-00051

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

**PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE**

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| 1002       | Prosecution History of U.S. Patent Application No. 17/817,637 (which issued as U.S. Patent No. 11,617,795 B2)                                                              | '637 Appl. PH            |
| 1003       | Declaration of Michael Crowley, PhD                                                                                                                                        | Crowley Decl.            |
| 1004       | Corrected French Patent Publication 2,993,458 and certified English translation of French Patent Publication 2,993,458                                                     | FR458                    |
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**I. INTRODUCTION**

Faced with an irrefutable showing of unpatentability for every claim of U.S. Patent No. 11,617,795 (“the ’795 Patent”), Genexa Inc. (“Genexa”) resorts to theatrics – banging the table and loudly protesting so-called “glaring” and “dispositive” errors in the Petition. These exaggerated claims are mere distractions from the Petition’s substance and its undeniable conclusion: the challenged claims are obvious in view of the prior art combinations articulated in Grounds 1 and 2. The so-called dispositive “errors” – a miscitation in an expert declaration and an alleged typo in a prior art reference – are irrelevant to the obviousness analysis detailed in the Petition.

KinderFarms, LLC (“KinderFarms”) has clearly demonstrated, under the correct obviousness standard, that the cited prior art renders all the challenged claims obvious. The primary references, French Patent Publication 2,993,458 (“FR458”) and WO2012/018742A2 (“WO742”), cited in Grounds 1 and 2, respectively, teach agave-based acetaminophen formulations that meet nearly all the ’795 Patent claim limitations except for viscosity. U.S. Patent No. 4,684,666 (“the ’4666 Patent”) and WO 95/00133 (“WO133”), cited in both grounds, teach analgesic syrup formulations with the claimed viscosity ranges, which the ’795 Patent acknowledges are typical of syrup formulations. Moreover, the Petition has demonstrated that a person of ordinary skill in the art (“POSA”) would have

been motivated to combine the cited prior art, with a reasonable expectation of success.

The crux of Genexa's non-obviousness argument is a supposed lack of motivation and a reasonable expectation of success in combining the secondary references—WO133 and the '4666 Patent—due to their supposedly non-overlapping viscosity ranges. This argument is incorrect and irrelevant to the combinations of the FR458 with the '4666 Patent, FR458 with WO133, WO742 with the '4666 Patent, and WO742 with WO133. Genexa fails to meaningfully challenge the conclusion that a POSA would be motivated to combine the teachings of the cited prior art with a reasonable expectation of success. Accordingly, the Board should cancel every claim of the '795 Patent as unpatentable due to obviousness.

## **II. THE CHALLENGED CLAIMS ARE OBVIOUS**

### **A. A POSA Had Ample Reasons to Combine the Cited Prior Art and Reasonable Expectation of Success.**

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.

FR458, WO133, and the '4666 Patent are all analogous art in the field of oral liquid pharmaceutical formulations, each disclosing a liquid pharmaceutical formulation for orally administering an analgesic suspension to children and the elderly while masking the analgesic's bitter taste. Pet.,27-29; Ex.1003,¶101. FR458 and the '4666 Patent also disclose developing low sugar or no sugar oral liquid analgesic formulations for the benefit of diabetics and other persons with restricted sugar requirements. Pet.,28-29; Ex.1003,¶101. Given that all three references are in the same field of art, seek to address similar issues, and discuss the creation of oral analgesic formulations using "old [ingredients<sup>1</sup>] with each

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<sup>1</sup> Genexa's claim that agave syrup is not an "old ingredient" performing "the same function it has been known to perform" is contradicted by its own expert's testimony and the prior art. As Genexa's expert acknowledges, agave syrup is "***known as a natural sweetener***" and is "***used to replace*** other sweeteners like ***corn syrup and table sugar [sucrose]***," which are commonly found in oral liquid pharmaceutical formulations such as Children's Tylenol Elixir and Suspension Liquid. Ex.2009, ¶43, Ex.1008,[0007]; Ex.1003,¶52; Ex.1018,1537. To support this contention, Genexa and its expert emphasize the omission of "agave syrup" from the "FDA index of generally recognized safe (GRAS) ingredients" and other chemical, drug substance or ingredients indexes (USP 40, NF35, Merck Index). POR, 42. GRAS database is a non-exhaustive list of food additives or ingredients considered safe for their intended use in food assembled by scientific experts outside the FDA. Ex.2015. Honey is also not on the GRAS list. *Id.* While indexes like the FDA's Inactive Ingredient Database for NDA, USP40, NF35 and the Merck index may be useful references for pharmaceutical formulators (Ex.2009,¶144), they have no bearing on the obviousness of an agave syrup-based oral formulation with acetaminophen and a diluent. Moreover, during his deposition, Dr. Berkland acknowledged that most of his non-obviousness

performing the same function it had been known to perform,” namely, acetaminophen (analgesic), agave syrup (sweetener in which the active is suspended), water (diluent), a POSA would be motivated to combine these teachings with a reasonable expectation of success. *KSR Int'l Co., v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

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.

WO742, WO133, and the '4666 Patent are all analogous art in the field of oral liquid pharmaceutical formulations, each disclosing an orally administered

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opinions did not require a POSA to have pharmaceutical regulatory approval knowledge. Ex.1051,21:8-20. The notion that agave syrup is not an “old ingredient” is also undermined by the FDA's Global Substance Registration System (GRSR) listing “agave tequilana juice” and providing it with a unique ingredient identifier number to track its presence in FDA-regulated-products. Ex.1047. A quick review of the GRSR index confirmed that agave syrup was used in food products (Ex.1053) and in commercially available liquid health products that are orally administered to infants prior to the relevant date for obviousness, June 8, 2021. Ex.1048, Ex.1052.

liquid analgesic pharmaceutical formulation. Pet.,54-55; Ex.1003,¶¶195-198. WO742 teaches a safer oral liquid dextromethorphan pharmaceutical formulation, which may further comprise acetaminophen, that omits harmful ingredients common to over-the-counter antitussives. Pet.,54-55; Ex.1003,¶196. Since dextromethorphan is often combined with analgesics like acetaminophen and ibuprofen in liquid over-the-counter cough and cold medications, a POSA would have been motivated to combine WO742's safer dextromethorphan and acetaminophen formulation with the viscosity ranges for oral analgesics taught by either or both of the '4666 Patent and WO133. Pet.,54-55; Ex.1003,¶196. Since all three references disclose formulations that comprise old ingredients (i.e., dextromethorphan, acetaminophen, agave syrup, and water) performing well-known functions, a POSA would have had a reasonable expectation of success in combining these references. *KSR*, 550 U.S. at 417.

**B. Genexa's Lack of Motivation to Combine and Reasonable Expectation of Success Arguments Are Fundamentally Flawed**

Genexa's arguments against a motivation to combine and a reasonable expectation of success in combining the prior art references cited in Grounds 1 and 2 are a scattershot of factually and legally flawed assertions which are contradicted by the Petition, the prior art references, and the knowledge and skills

of a POSA as of the relevant date.<sup>2</sup> Genexa's approach is largely preoccupied with matters having no bearing on the Petition's obviousness analysis. Tellingly, Genexa's motivation to combine arguments either mainly focus on the three-reference combinations cited in Grounds 1 and 2 of the Petition or argue generally against any combination of the primary references with any of the secondary references based on purported "teaching away" and the "erroneous 212 cP agave syrup."

1. *The Petition clearly articulates three distinct combinations of the prior art cited in Grounds 1 and 2*

Genexa's contention, that the Petition is ambiguous due to the use of "and/or" in describing the prior art combinations cited in the grounds, and thereby lacking the specificity required to support a finding of unpatentability, is disingenuous. POR, 37-38. Not only is the use of "and/or" confined to title or subtitles in the Petition, the Petition consistently and explicitly outlines all the three prior art combinations asserted for each ground, including in relation to the motivation to combine arguments. Pet.,28fn14, 29, 39, 41, 47, 54fn26, 61.

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<sup>2</sup> Notably, one of the references that Genexa's expert cites in his declaration reports that oral liquid pediatric formulations with high viscosity and high sucrose content have increased cariogenic potential (i.e., the risk of causing tooth decay). Ex.2020, 360. Thus, this reference identifies yet another problem in the art that can be solved by combining FR458 and WO742's oral liquid formulations made with healthier agave syrup, rather than sucrose syrup, and the '4666 Patent and WO133's teaching of appropriate viscosities for oral liquid analgesic formulations (particularly the lower end of the ranges they teach.)

Moreover, each obviousness argument in the Petition distinctly identifies the prior art references relevant to it, making it evident what is being argued with respect to each specific prior art combination. Ex.1051, 209:2-210:19. At bottom, there is no ambiguity.

2. *The Petition articulates specific motivations to combine the prior art references cited in the grounds*

Genexa's argument that the Petition fails to provide a specific motivation to combine with regard to the Ground 1 prior art references and merely reiterates "the conclusory legal conclusion" from *KSR* without any specific facts to support it is simply incorrect. (POR, 40). As shown in the Petition and reiterated above, all three references belong to the same field of art as the '795 Patent and aim to address the same problem identified by the '795 Patent, developing an oral liquid analgesic formulation for children and the elderly that masks the unpleasant taste of the API. Pet., 28-29; *supra* at 3. Moreover, the prior art teaches using the claimed formulation components for the same purpose as recited in the claims. *See* fn.1 above. The same is true for Ground 2, because the three prior art references cited are all in the same field, and all three references discuss the creation of oral liquid analgesic formulations. POR, pp. 54-55; *supra*, 5.

Thus, the Petition establishes a sufficient motivation to combine the prior art references cited in both Grounds 1 and 2 since "***any need or problem known in the field of endeavor*** at the time of the invention ***and addressed by the patent***

*can provide a reason for combining* the elements in the manner claimed.” *Intel Corp. v PACT XPP Schweiz AG*, 61 F.4th 1373, 1379 (Fed. Cir. 2023) (citing *KSR*, 550 U.S. at 420-421) (emphasis added).

3. *There is no “teaching away” that would discourage a POSA from combining the cited prior art references*

Genexa’s argument that a supposed “teaching away” exists, based on a benign statement in the background section of Dr. Crowley’s declaration, is not supported by fact or law. Genexa contends that Dr. Crowley’s observation that suspensions with a viscosity ranging from 20-150cP are “[generally] considered readily pourable” would discourage a POSA from combining the prior art cited in both grounds. POR, 45-46, 49-50, 62-63. However, this statement from an expert declaration cannot constitute a “teaching away” for a POSA reviewing the cited prior art at the relevant time. Moreover, Genexa and its expert implying that formulations with viscosities greater than 150cP are less desirable because they are not “readily pourable” is unfounded, as a POSA would be well aware that formulations with viscosities higher than 150 cP are both pourable and drinkable. Ex.1003, ¶¶28, 58, 216 and 227; Ex.2020, table 1; Ex.1046, table 4; Ex.1051, 106:7-22.<sup>3</sup> From the outset, the claims are not limited to a “readily pourable”

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<sup>3</sup> Genexa grossly misrepresents paragraph 59 of Dr. Crowley’s declaration, accusing him of arguing against any viscosity higher than those considered “readily pourable” formulations with “*a viscosity in the range of 20 to 150 cP*” (POR, p. 45). This is patently false. Dr. Crowley repeatedly asserts that formulations with viscosities higher than 150cP are pourable and drinkable.

formulation. Further, Genexa's focus on the impact of a formulation's pourability overlooks other key formulation characteristics (e.g., palatability, suspending properties) equally influenced by viscosity. Ex.1003, ¶59; Ex.1012, 745, 768; Ex.1051, 107:6-112:6. A single statement in Dr. Crowley's report cannot erase extensive prior art disclosures of syrup formulations with viscosities that overlap with the claimed ranges, and Genexa provides no evidence that a POSA would find these formulations not pourable.

Genexa's attempt at "teaching away" based on the supposed non-overlapping viscosity ranges taught by WO133 and the '4666 Patent is similarly flawed. This argument hinges on Genexa's unproven assertion that the 100-3000cP viscosity range disclosed in claim 11 is an obvious typo that a POSA would have readily disregarded. Even assuming that the '4666 Patent only discloses its preferred viscosity range of 1000-3000cP, the lack of overlap between this range and that disclosed by WO133 would have no bearing on the two-reference combinations asserted in Grounds 1 and 2, as they only include one of WO133 or the '4666 Patent, not both. Furthermore, the close proximity of these

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Ex.1003, ¶¶28, 58, 216, and 227. Likewise, despite Genexa implying otherwise, Dr. Crowley never asserted that the dissolution of immediate release acetaminophen would be impaired in formulations with a viscosity above 150cP. POR, 45. Rather, he cited a study that reports the impaired dissolution of *immediate release acetaminophen* in formulations with viscosities of 3650cP and 4380cP, which had a thickener added to increase their viscosity. Ex.1003, ¶59, Ex.1013, 1542 and table 3.

viscosity ranges, coupled with the '4666 Patent's explicit endorsement of formulations with "somewhat less thickness [than 1000cP]," makes it unlikely that a POSA would be discouraged from combining all three-reference combinations cited in Grounds 1 and 2.

Genexa's argument that Petitioner's alleged "erroneous identification of the purported viscosity of agave syrup [as 212 cP]" negates any motivation to combine the references cited in Grounds 1 and 2 is also baseless. POR, 47. This argument is premised entirely on a miscitation in Dr. Crowley's declaration, which incorrectly attributed a statement regarding the viscosity of agave syrup being reported as 212cP to the wrong exhibit.<sup>4</sup> Genexa's overemphasis of this miscitation, citing to *In re Magnum Oil Tools International*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) as support, is misguided (POR, 28). Unlike in *Magnum Oil Tools*, this miscitation did not deprive Genexa of the opportunity to respond to the substantive obviousness arguments clearly articulated in the Petition. Moreover, none of these 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. Genexa chose to focus on strawman arguments based on the

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<sup>4</sup> Dr. Crowley's declaration incorrectly cited to Exhibit 1031, which describes samples of agave syrup with a mean viscosity of 2,560cP. The reference intended to be cited was Exhibit 1030, which reports agave syrup with a viscosity of 212 cP.

“erroneous 212cP [viscosity] value,” neglecting to adequately address the Petition’s substantive obviousness arguments.

Genexa’s contention that a POSA would not have been motivated or had a reasonable expectation of success in combining FR458-Example 1 or WO742-Example IX, prepared using the “erroneous 212 cP value for the viscosity of agave syrup” with the viscosity ranges disclosed by ’4666 Patent (1000-3000cP) or WO133 (200-900cP) is fundamentally flawed, as is Genexa’s criticism of Petitioner for not performing this same analysis using the “correct” agave syrup 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.<sup>5</sup> 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.<sup>6</sup>

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<sup>5</sup> While Dr. Berkland was willing to speculate as to the final formulation viscosity of Example 1-FR458 and Example IX-WO742 in his report, he was unwilling to do so during his deposition. Ex.2009, ¶¶150, 171. Ex.1051, 168:15-169:7.

<sup>6</sup> Dr. Berkland cites to Ex.1031 for support for his assertion that agave syrup with a viscosity of 212cP would be “low quality,” however, this references does not indicate whether higher or lower viscosity correlates with better quality.

In sum, none of these arguments are sufficient to rebut the Petition's showing of motivation to combine the prior art references cited in each ground and a reasonable expectation of success in so doing.

**C. All of the Limitations of the Challenged Claims Are Taught by the Cited Prior Art**

Genexa does not dispute that the prior art cited in Grounds 1 and 2<sup>7</sup> expressly teaches the majority of the limitations of the challenged claims – nor could it, as both the Petition and Dr. Crowley's testimony clearly demonstrate this.<sup>8</sup> Pet., 29-54, 56-68; Ex.1003, ¶¶104-194, 199-265. Unable to deny that the '795 Patent claim limitations are taught by the cited prior art, Genexa asserts a lack of motivation to combine the cited prior art's teachings of viscosity ranges that overlap with the claimed viscosity limitations and challenges the disclosure of a few dependent claim limitations. POR, 3, 53-56, 63-67.

1. *Genexa's claim of a lack of disclosure of the viscosity limitations by the cited prior art is wrong*

The Board should appreciate from the above discussion in II.B that Genexa has not meaningfully challenged the Petition's showing that a POSA would have

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<sup>7</sup> Ground 1 of the Petition alleges that claims 1-24 are invalid for obviousness over the combination of FR458, the '4666 Patent, and WO133. Ground 2 of the Petition alleges that claims 1-17 are invalid for obviousness over the combination of WO742, the '4666 Patent, and WO133.

<sup>8</sup> Genexa has not argued that the Petitioner's prior art references fail to teach any of the limitations of the challenged claims not expressly discussed *infra* at 9-16. Thus, Genexa has waived any such argument. See Paper 9, p. 9.

combined the primary references FR458 and WO742 with either or both of the secondary references WO133 and the '4666 Patent. Genexa argues that a POSA would not have combined WO133 and the '4666 patent because their viscosity ranges supposedly do not overlap. POR, 34-35; Ex.2009, ¶¶134-138. Yet each of these references, cited in both Grounds 1 and 2, undoubtedly teach all the viscosity limitations of the challenged claims. WO133 describes a taste-masked oral liquid acetaminophen formulation with a target viscosity of 200-900 cP, and preferably 300-700 cP. Ex.1003, ¶119; Ex.1006, 8:1-3. The '4666 Patent discusses controlling the viscosity of a stabilized liquid analgesic formulation “for optimum stability,” with a disclosed range of 100-3000 cP and a preferred range of 1000-3000 cP. Ex.1003, ¶119; Ex.1005, claim 11, 4:9-17. Genexa, however, argues that the disclosed 100-3000 cP range is a typo.<sup>9</sup> Regardless, the overlap between all

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<sup>9</sup> Genexa argues that the viscosity range of 100-3000cP at 20°C in claim 11 of the '4666 Patent is not disclosed because the lower end—100cP—is an obvious typographical error that a POSA would recognize and correct to 1000cP. POR, 30-34. To support its argument, Genexa points to the '4666 Patent's description of the formulations as “moderately viscous syrups” having “a rather heavy and uniform viscosity” and notes the '4666 Patent's preferred viscosity range of 1000-3000cP for *optimum* stability. POR, 30-34; Ex.1005, 1:11-15; 2:41-44, 4:9-17. Genexa overlooks, however, that the '4666 Patent teaches formulations with viscosities below 1000cP. First, it explicitly states that “[f]inished product of somewhat less thickness [than 1000cP] are capable of being stored for commercially acceptable time periods.” Second, none of the independent claims require a viscosity between 1000-3000cP. Finally, claim 7 (on which claim 11 depends) recites a very simple stabilized formulation that could consist minimally of components like 10-80mg/mL of ibuprofen suspended in an aqueous solution of 51% propylene glycol and 10% sucrose. Each of these components has a reported viscosity well below 1000 centipoise. Ex.1051, 245:10-246:20, 248:12-

of these viscosity ranges taught by these references and the claimed viscosity ranges creates a presumption of obviousness.<sup>10</sup> *Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1341 (Fed. Cir. 2020); *UCB, Inc. v. Actavis Laboratories UT, Inc.*, 65 F.4th 679, 689 (Fed. Cir. 2023). This presumption shifted the burden of production to Genexa to establish “teaching away, unexpected results or criticality, or other pertinent objective indicia indicating that the overlapping range would not have been obvious in light of the prior art.” *UCB*, 65 F.4th at 689-690; *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1008 (Fed. Cir. 2018) (collecting cases). Genexa has not met its burden.

Genexa has not attempted to show – nor could it – that “there is something special or critical about the claimed [viscosity] range.” The ’795 Patent specification explains that the claimed viscosity ranges are those “***of the type used with pharmaceutical suspensions or syrup formulations***... between about ***200-3500 centipoise***.” Ex.1001, 2:12-27, emphasis added. Evidence from both parties shows that the claimed viscosity ranges are typical of pourable and drinkable oral

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249:25; 253:16-24; 256:4-25; Ex.2009, ¶169; POR, 61, Ex.1049, Table 2; Ex.1050, Fig.8. When taken together, it is clear that the 100-3000cP range is not an obvious “error” or “internal inconsistency” that a POSA “would readily recognize as an error” as in *Application of Yale*, 434 F.2d 666, 668-669 (C.C.P.A. 1970).

<sup>10</sup> Independent claims 1, 7, and 18 require that the syrup formulation has a viscosity of “less than 1500 centipoise at about 22 degrees.” Dependent claims 2-6 and 15 further narrow the claimed viscosity range to “less than [1000, 750 or 600] centipoise,” or “from about 1500 centipoise to about 400 centipoise,” respectively.

liquid pharmaceutical formulations and, therefore, nothing “special”.  
Ex.1003, ¶¶28, 58-59, 216, 227; Ex.1036, 420; Ex.1039, 81; Ex.1014, 1489-1490;  
Ex.2009, ¶52; Ex.2020, 359 (Table 1), Ex.1046, 49 (Table 4); Ex.1051, 43:6-46:3.

Genexa's “teaching away” arguments fail to rebut the presumption of obviousness created by the overlapping viscosity ranges claimed in the '795 Patent and disclosed by WO133 and the '4666 Patent. *E.I. DuPont*, 904 F.3d at 1006. As previously discussed, Dr. Crowley's statement that “[g]enerally, suspensions having a viscosity in the range of 20 to 150 are considered readily pourable,” is not a “teaching away” that would discourage a POSA from employing the claimed range. *Supra* at 8. Likewise, Genexa's “teaching away” based on the non-overlapping viscosity ranges of the '4666 Patent and WO133 fails for at least three reasons. First, it is a moot argument with regard to the two-reference prior art combinations cited in each ground. *Supra* at 9-10. Second, it is based on the unproven assertion that the 100-3000cP viscosity range disclosure in the '4666 Patent is a “typo.” *Supra* at 10 fn 13. Third, it disregards that a POSA would understand that the 1000-3000cP and 200-900cP ranges disclosed by these two references are combinable given that, as acknowledged by the '795 Patent, a POSA would understand at the time of filing the '795 patent that viscosities of ~200-3000cP are “of the type used with pharmaceutical suspensions or syrup formulations.” Ex.1001,2:12-27; Ex.2020, table 1; Ex.1046, table 4.

Taken together, Genexa has failed to rebut Petition's clear demonstration that each of WO133 and the '4666 Patent disclose all of the viscosity limitations of the challenged patent.

2. *All of the Acetaminophen Limitations are Taught or Suggested by WO742, WO133 and FR458*

The acetaminophen limitations of dependent claims 5, 6 and 8 are all taught or suggested by the prior art cited in both grounds. Claims 5 and 6 specify acetaminophen concentration ranges of "0.01 to 2 grams . . . per 100 mL" and "0.01 to 1 gram . . . per 100mL," respectively. Example IX of WO742 (Ground 2) discloses a formulation containing 160 mg (0.16g) in 15mL, equivalent to roughly 1 gram per 100 mL. Pet., 60-61, Ex.1003, ¶231, Appendix D; Ex.1007, 23:16-29.<sup>11</sup> The overlap between this disclosed acetaminophen concentration and the claimed ranges of claims 5 and 6 renders them presumptively obvious. *UCB*, 65 F.4th at 687. A POSA would have also recognized that FR458 (Ground 1) and WO133 (Grounds 1 and 2) disclose the acetaminophen concentration ranges in claims 5 and 6. Pet., 34-35, 60-61, Ex.1003, ¶231, Appendix D. FR458 teaches API concentrations, including acetaminophen, of about 0.01% to about 90%, with

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<sup>11</sup> Genexa attempts to exploit a typo in the Petition and Dr. Crowley's declaration which reported the final concentration of acetaminophen in Example IX of WO742 as 1mg per 100mL, rather than 1g per 100mL. POR, 65, Pet, p. 61, Ex.1003, ¶231, Appendix D. However, a POSA would have understood that Example IX of WO742 discloses a formulation with a final concentration of acetaminophen of 1g per 100mL (160mg=0.16 g, 0.16g/15mL = 0.01066g/mL \* 100mL= 1.06g/mL).

a preferred range of 1.0% to about 25%. Ex.1003, ¶136; Ex.1004, 3:78-85. Notably the concentration of acetaminophen in Example 1 of FR458, 2.5 g per 100mL, is very close to the range in claim 5. WO133 discloses acetaminophen concentration of up to about 10% in weight, with a preferred range of 2 to 5%. Ex.1006, 2:16-19. A POSA would have understood that the broad acetaminophen concentration ranges in claims 5 and 6 overlap those disclosed by both prior art references. Pet., 34-35, 60-61; Ex.1003, ¶¶137-138, 231-232.

In relation to both grounds, claim 8's acetaminophen range of "0.01 to 2% of the formulation by weight" overlaps with and is rendered obvious by WO133's disclosed acetaminophen ranges of "up to about 10% by weight" and of "2 to 5%." (Ex.1006, 2:16-19). It is also rendered obvious by FR458's disclosure of API concentrations from about 0.01% to about 90%. Ex.1004, 3:78-85.

Genexa relies on *Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc.*, 655 F.3d 1291 (Fed. Cir. 2011), to argue that the presumption of obviousness due to "overlapping ranges [does] not apply" because the acetaminophen ranges disclosed by the prior art are "so broad as to encompass a very large number of possible distinct compositions." POR, 54. This argument fails for at least three reasons. First, it ignores the narrower preferred acetaminophen ranges disclosed by FR458 (1.0% to about 25%) and WO133 (2 to 5%). Ex.1004, 3:78-85; Ex.1006, 2:16-19. Second, *Genetics Institute, LLC* is distinguishable because the court in that case found no *prima facie* case of

obviousness due to the unusually broad ranges in the prior art, which encompassed many distinct compositions requiring nonobvious invention.<sup>12</sup> *Genetics Institute*, 655 F.3d at 1306. Here, the ranges in WO133 and FR458, particularly the narrower preferred ranges, are not as broad and only encompass varying amounts of acetaminophen, not distinct compositions that require nonobvious invention. *Id.* Thus, the present case is more akin to *In re Peterson*, 315 F.3d 1325 (Fed.Cir.2003), where the court held the presumption of obviousness applied because “[prior art] ranges that are not especially broad invite routine experimentation to discover optimum values, rather than require nonobvious invention.” *Id.* fn 1. Lastly, the claimed ranges themselves are extremely broad, with their lower limits being impractically low. Ex.1003 at 121 fn 27.

The acetaminophen concentrations in claims 5, 6 and 8 overlap with those disclosed in WO133 (Grounds 1 and 2), WO742 (Ground 2) and/or FR458 (Ground 1). Thus, these claimed ranges are presumed *prima facie* obvious, a presumption Genexa has failed to rebut.

3. *The “about 5%” diluent limitation is disclosed by FR458, the '4666 Patent, and WO742*

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<sup>12</sup> In *Genetics Institute*, the disclosed prior art range included 68,000 truncated protein variants made up of 2,332 amino acids, which differed in terms of the size of the permitted amino acid deletions, the location of those deletions, and the degree of allowable amino acid substitutions.

Claim 9 requires that “the diluent is about 5% of the formulation by weight.” Notably, the '795 Patent specification does not specify the significance of 5% diluent. The only two examples in this patent reference adding a non-specific amount of diluent (described as “remaining”) to an acetaminophen suspension (Example 1), or a non-specific amount of water “to achieve a desired consistency” during the preparation of another drug suspension (Example 2). (Ex.1001,5:5-32). Genexa criticizes KinderFarms' assertion that this limitation is disclosed by FR458 (Ground 1), the '4666 Patent (Grounds 1 and 2), and WO742 (Ground 2), which describe formulations including water in a quantity sufficient (q.s.) to achieve a desired final volume, potentially including about 5% by weight. POR, 55-56, 66-67; Pet., 42-43, 64-65; Ex.1003,¶¶116-117, 155-156, 211-214, 247-248.

Regarding Ground 1, Genexa argues that reducing the water in Example 1 of FR458 from ~45% to 5% is unreasonable and criticizes KinderFarms for failing to address the “significant viscosity changes” that would result. POR, 55. This criticism fails to recognize that a POSA would know how to select agave syrup with an appropriate viscosity and adjust the relative amounts of the formulation components as needed to achieve the desired final viscosity, and would also know that this adjustment may involve adding water or another diluent in an amount as low as 5%. Ex.1051, 138:7-139:3. Genexa's argument that KinderFarms failed to justify *why* a POSA would alter FR458's Example 1

overlooks testimony and prior art teachings that limiting the dissolution of API/acetaminophen (one way of doing this is by reducing the amount of solvent/diluent) is advantageous for bitter or unpleasant-tasting APIs like acetaminophen. POR, 55; Ex.1003,¶155; Ex.1006, 3:8-18. Thus, the Petition explains why a POSA would want to reduce the diluent to 5% of the formulation weight.

Regarding Ground 2, Genexa argues that KinderFarms' statement that "the amount of water is not critical" fails to address the claim as a whole, particularly its impact on viscosity. POR, 66. However, a POSA would understand how to adjust the amount and/or type of agave syrup (which itself includes water), as well as the amounts of other components, to achieve an effective formulation with a desired viscosity and minimal water added as a diluent. Ex.1003,¶52; Ex.2009,¶55. Example 2 of the '795 Patent supports this very point, by teaching the addition of a nondescript amount of water to a drug suspension to achieve a desired consistency, also without specifying the type or viscosity of the agave syrup.

In sum, FR458, WO742, and the '4666 Patent's disclosures of adding a quantity of water to an oral analgesic formulation sufficient to bring it to a desired final volume, coupled with a POSA's knowledge and skills, teaches "the diluent is about 5% of the formulation by weight" limitation renders it obvious. Ex.1003,¶¶155-156, 247-248; Ex.1051, 147:16-149:23, 150:16-151:9.

4. *“About 95%” agave syrup limitation is disclosed by FR458 and WO742*

Claims 13 and 24 require that “agave syrup is about 95% of the formulation by weight.” Genexa challenges KinderFarms’ argument that this amount of agave syrup is a design choice rendered obvious by FR458 and WO742. POR, 56, 67-68. Genexa also criticizes KinderFarms for not addressing how the selection of agave syrup would affect the formulation’s viscosity. *Id.* However, the Petition explicitly addresses the fact that agave syrups can have different viscosities (i.e., thinner or thicker consistency) and one can select the desired viscosity depending on the proposed use. Pet., 4 fn 1. Furthermore, Genexa’s own expert acknowledges that a POSA would know how to select the appropriate agave syrup to achieve the desired final properties of the formulation, including viscosity. Ex.1051, 138:7-139:3.

Genexa’s assertion that the Petition only offers a conclusory argument that “agave syrup is about 95% of the formulation weight” is a “design choice” that cannot support obviousness is incorrect factually and legally. POR, 56. Dr. Crowley explained that selecting about 95% agave syrup per formulation weight was within the knowledge of a POSA and discussed background art that confirms that agave syrup can constitute 2% to 98% of a medicinal formulation. Pet, 43-44; Ex.1003, ¶¶ 161-164; Ex.1008 at [0023]. This shows that the “about 95%” agave syrup limitation is “an obvious matter of design choice within the skill of

the art.” *Application of Kuhle*, 526 F.2d 553, 555 (C.C.P.A. 1975). This limitation represents a design change over the prior art, such as the “less than 45% agave syrup” or “~73% agave syrup” that Genexa’s expert estimates would be included in the exemplary formulations disclosed in FR458 and WO742,<sup>13</sup> because it offers “no *novel* or *unexpected* result.” *Id.* (citing *Graham v. John Deere Co.*, 383 U.S. 1 (1966)) (emphasis added). Additionally, it is unclear how Genexa can claim that the “about 95%” agave syrup limitation provides a novel or unexpected result given that the ’795 Patent does not specify the properties of the agave syrup used in its formulations, including its water content and viscosity.

**D. Dr. Berkland’s Opinions Are Not Reliable and Should Be Given Very Little Weight**

Dr. Berkland’s opinions should be given very little weight due to their unreliability. During his deposition, Dr. Berkland admitted to not having analyzed the scope of the claims-at-issue and appeared unfamiliar with the specification of the ’795 Patent, despite it only being four pages long. Ex.1051, 33:4-21, 38:7-22; 119:8-120:23, 160:11-162:16. Having failed to consider the scope of claims 1-24 of the ’795 Patent, Dr. Berkland’s opinion on the non-obviousness of said claims is not reliable. Consequently, the influence of Dr. Berkland’s testimony on the outcome of this proceeding should be minimal and, to the extent that his opinions

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<sup>13</sup> FR458 and WO742 would have taught a POSA that the disclosed analgesic formulations can differ in the amount of agave syrup that they include. Ex.1003, ¶¶162, 253.

conflict with those of Dr. Crowley, the latter opinions should be given more weight.

### **III. CONCLUSION**

KinderFarms has met its burden of establishing in its Petition that each of the challenged claims is unpatentable as obvious. For the foregoing reasons, Genexa has failed to rebut this showing of obviousness in its Patent Owner's Response. As such, KinderFarms respectfully asks the Board to cancel claims 1-24 of the '795 patent as unpatentable for obviousness.

**CERTIFICATE OF WORD COUNT**

Pursuant to 37 C.F.R. § 42.24, the undersigned attorneys for the Petitioner declare that the argument section of this PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE (Sections I-III) has a total of 5,577/5,600 words, according to the word count tool in Microsoft Word™.

Dated: September 6, 2024

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 6th day of September, 2024, a copy of the attached PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE was served by electronic mail to the attorneys of record, at the following addresses:

| <b>LEAD COUNSEL</b>                                                                                                                                                                                      | <b>BACK-UP COUNSEL</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
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Case PGR2023-00051  
U.S. Patent No. 11,617,795  
Petitioner's Reply

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Dated: September 6, 2024

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