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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KINDERFARMS LLC,
Petitioner

v.

GENEXA INC.,
Patent Owner.

PGR2023-00051
Patent 11,617,795 B2

Record of Oral Hearing
Held: December 12, 2024

Before DEBORAH KATZ, MICHAEL J. FITZPATRICK, and SUSAN L. C. MITCHELL, *Administrative Patent Judges.*

APPEARANCES:

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The above-entitled matter came on for hearing on Thursday, December 12, 2024, commencing at 1:00 p.m. EST, at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia/via video-conference.

P R O C E E D I N G S

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1:00 p.m.

JUDGE KATZ: Just going to get set up here. Okay, so good afternoon. We are here for oral arguments in post-grant review PGR2023-00051 which pertains to patentability challenges for U.S. Patent 11,617,795.

So I'm Judge Katz. This is Judge Mitchell, and Judge Fitzpatrick is on the screens. All right. Let me first ask who will be appearing for Petitioner?

MR. NOLAN: Good afternoon, Your Honor. Brian Nolan of Mayer Brown on behalf of KinderFarms with my colleague.

MS. LAFAYETTE: Shantelle Lafayette, also for Mayer Brown for KinderFarms.

JUDGE KATZ: Okay, thank you. And do you have anybody else? I don't see anybody else with you.

JUDGE FITZPATRICK: I'm sorry. I need to interrupt, Judge Katz. I can tell that you must have asked somebody to introduce themselves. So I heard them, but I didn't hear you. Is --

JUDGE KATZ: I think it's my mic. Can you hear me now?

JUDGE FITZPATRICK: Okay, there we go. Yes, thank you.

JUDGE KATZ: Okay. Hope it'll stay on, my mic. Okay. All right, so is there any -- there's nobody else in the room, but is there anybody else who you want to introduce who is online or isn't in?

MR. NOLAN: Yes, we have the current CEO of KinderFarms, I believe, is online and one of the co-founders of KinderFarms is also online.

JUDGE KATZ: Can you give us their names?

MS. LAFAYETTE: Kristin Recchiuti. I'm probably not saying her last name properly, Recchiuti, and Jeremy Adams.

JUDGE KATZ: Okay, we may, the court reporter may ask you for spellings of those afterwards.

MS. LAFAYETTE: I can get that to you.

MR. NOLAN: Thank you, Your Honor.

JUDGE KATZ: Okay, thank you. And for patent owner?

MR. PIVOVAR: Good afternoon, Your Honor, Adam Pivovar of Cooley LLP on behalf of patent owner. And with me today is my colleague, Dan Knauss --

MR. KNAUSS: Good afternoon.

MR. PIVOVAR: -- also of Cooley and lead counsel in this proceeding, and Steve Smith, another one of our colleagues from Cooley. We're all attorneys of record. No one else is here with us today besides those people, in person.

Online, I believe, people intending to join was going to be Janet Spielberg, who is in-house counsel for patent owner, as well as Brianna Patterson, who is counsel of record on behalf of patent owner but is listening in remotely. Thank you, Your Honor.

JUDGE KATZ: Okay, thank you. All right, so just a few housekeeping things to begin. Recording of PTAB hearings is prohibited. We do have a court reporter with us today who will provide a transcript of the hearing that will become part of the record.

To ensure that the transcript is clear, please speak directly into the microphone, as I just demonstrated you shouldn't, and identify specific slide

numbers, numbers in figures and other pertinent identifying information as you make your arguments so that the record is complete.

I think that this proceeding is being streamed since we have people in attendance, so if the parties wish to discuss anything that's confidential, you need to let us know before so we can make arrangements. I don't think there is anything. There haven't been any requests or anything confidential, either party. Okay, thank you.

So each of you requested 45 minutes to argue their case, and Petitioner has a LEAP Practitioner. So Petitioner will receive an extra 15 minutes of argument time, so that's 60 minutes for Petitioner, 45 minutes for patent owner.

The LEAP Practitioner must provide us with something meaningful and substantive during the hearing today. So I will try to use the clock here to give you an idea of how the time is going. We'll see if that -- if I am capable of doing that. If not, I will try to five you a 5-minute warning when we're coming to the end of your time.

Okay, so the Panel, we have reviewed the record. Judge Mitchell and Judge Fitzpatrick and I have reviewed the record. We also see that both parties have filed demonstratives and we see that you've also filed objections to each other's demonstratives.

We want to remind you that demonstratives are not evidence. They're just a means for making new arguments. Oh, and they are not -- they are not a means for making new arguments, which I think has been your objections. We will address the arguments that you have to each other's demonstratives in our final written decision when the time comes, if necessary.

When referring to the demonstratives, please make sure, again, to indicate the slide number for the record so that the record is complete.

Okay, so I think we're about ready to begin. Judge Mitchell or Judge Fitzpatrick, do you have anything else to add to the preliminary --

JUDGE FITZPATRICK: Just one thing I would just, for those objections to the demonstratives, whether it's in demonstratives or otherwise, if counsel or opposing counsel makes an argument that's not in the record, you can use your time to point that out, but whether or not it's tied to a demonstrative or not. Thanks.

JUDGE KATZ: Thank you. Okay, so we will begin today with Petitioner followed by Patent Owner. Petitioner will then get a chance for rebuttal and patent owner will get a chance for surrebuttal. So, Petitioner, how much time would you like to reserve for that rebuttal?

MR. NOLAN: Brian Nolan, Your Honor, on behalf of Patent Owner -- Petitioner. We would like to reserve 15 minutes, Your Honor.

JUDGE KATZ: Okay, so that will be 45 minutes for the argument and 15 minutes for rebuttal. Okay, Ms. Layfayette, if you would like to, whenever you're ready.

MS. LAFAYETTE: Okay.

JUDGE KATZ: Go ahead, when you're ready.

MS. LAFAYETTE: Good afternoon, Your Honors. So I will be starting us off by providing an overview of the 795' patent, its prosecution history and some claim construction issues.

We're all familiar with the 795' patent, and if it's all right with Your Honors, I will refer to the patent by its last three digits as well as the

applications that are in our petition and described by their last three digits, unless you would like me to say the full numbers, which can be a mouthful.

So the 795' patent was issued to Genexa on April 4th, 2023 and it compromises 24 claims, three of which are independent. All of the claims have been challenged in this proceeding, as you're aware.

The 795' patent issued from the 637 application, which was filed on August 4th, 2022, so just eight short months later it issued. The 637 application is a continuation of Application 414, which was filed on June 8th 2021. And that application, the 414 application is itself a continuation, in part, of the 529 application.

So I'll stop there. There are other applications in the patent family, but those are the main ones that we'll be discussing. And --

JUDGE FITZPATRICK: Counsel, whenever you -- I'm sorry to interrupt. Whenever you think it's helpful that we're also visually looking at a demonstrative, let us know the number, please.

MS. LAFAYETTE: Oh, sorry, that was Slide 4. Thank you for pointing that out.

JUDGE FITZPATRICK: Thank you.

MS. LAFAYETTE: And I just advanced to Slide 5. And as we note in the petition the 529 application is -- or the 795 patent, its specification is a wholesale rewriting of the specification of the 529 application which reflects the original application Genexa filed in this patent family.

As such, the challenged claims in the PGR are completely untethered from the disclosure of the original patent application that Genexa filed. Of particular relevance is the fact that the 529 application does not mention any specific APIs including acetaminophen nor does it disclose any particular

formulation viscosity ranges including those that are claimed in the challenged claims of the 795 patent.

So in essence, the elements that were added to the specification of the 414 patent, which is a continuation and part of the 529, are the acetaminophen API as well as the viscosity ranges and some other matter.

Since the claims of the 795 patent require acetaminophen and viscosity at a minimum, particular viscosity ranges, it's our position that the earliest possible priority date for the challenged claims is June 8th, 2021. And it's our understanding that Genexa does not contest this, so that would be the earliest possible priority date for the purposes of our state of the art review and other discussions in this proceeding.

I'm now advancing to Slide 6, or at least I'm trying to. So going back to the 637 application, which is the one that issued as the 795 patent, this application underwent a very cursory review by the patent examiner. As I mentioned, the review took all of eight months before the patent issued, and it was completely unaided by the Patent Owner who did not file any IDS's identifying relevant prior art references.

The examiner, for their part, did conduct five searches for prior art references using a combination of different key words. They used acetaminophen syrup, Agave syrup -- sorry, Agave, water and diluent -- and managed to identify a single prior art reference which is shown here on Slide 6.

And critically, the examiner did not include in their search terms the word, Paracetamol, which is a common pseudonym used to describe the same molecule that is acetaminophen. However that term is more commonly used outside the U.S.

The single prior art reference that the examiner identified in -- with respect to the 637 application is shown here. It's a 2014 research article published in the *Journal of American Medical Association of Pediatrics*. It disclosed a composition that is for treating nighttime cough in babies and toddlers that is comprised of Agave syrup, a flavoring agent and an acetic preservative.

Additionally, this publication discloses, if we look at the paragraph on the right, the second highlighted sentence, it also discloses the co-administration of acetaminophen along with this Agave syrup-based cough remedy.

The -- just going back to the, how quickly the patent application progresses through the patent examination, we also want to point out that, not only was this examination very quick, didn't identify a lot of prior art, it also led to the examiner missing the fact that Claims 20 and 21 in the 795 application are identical.

These are dependent claims. They both depend on the same independent claim, 18. And, in fact, neither of these claims add any new limitations because they claim the same viscosity range that is already called for by Claim 18.

I'm now advancing to Slide 7. In the examiner's reasons for allowance, she indicated that the claims of the 795 patent were free of the art, so this one prior art reference we just discussed, for the simple fact that, while it disclosed acetaminophen, Agave syrup, acetic preservative, a diluent, it did not disclose the acetaminophen mixed inside of or included in the Agave syrup formulation.

However, this justification for allowing the 795 patent claims cannot stand in view of the prior art that we have raised in our petition. And in particular, if you look at the right of this slide, you can see the two primary references cited in Grounds 1 and 2 of the petition, FR458 and W0742, which is how we refer to them in the petition.

Both disclose formulations that include agave syrup, acetaminophen, or Paracetamol, however you would like to call it, as well as other ingredients that are called out in the 795 patent claims.

So unless Your Honors have any questions for me on the file history or anything that I've said in the last few slides, I'll move on to claim construction.

Okay, so the petition only offered a construction for a single claim term, and that's agave syrup. And in particular, what the petition says, at Page 15, is that the Board should construe agave syrup to encompass all liquid materials derived from an Agave plant that is free-flowing, irrespective of its other properties.

In reaching this construction, the petition noted that a POSITA would understand that agave syrup can be obtained from different species of Agave, can be light or darker in color and with a thicker or thinner consistency which we have said in both Dr. Crowley's report and the petition, is essentially referring to its viscosity. And this is also at Page 15 of the petition.

Patent Owner has not disputed our construction of agave syrup and agrees that the 795 patent does not limit the agave syrup to any particular type or any particular properties.

I've moved on to Slide 9 of the Petitioner's demonstratives. The Petitioner's construction of agave syrup is also informed by the specification of the 795 patent, as it should be, and notably, the 795 patent defines agave syrup on -- in Column 2 -- sorry. And the 795 patent is Exhibit 1001 at Column 2 from Line 6 to 9.

And it's defined as a processed juice obtained from the Agave species of plant. That's it. It's a very broad definition. It's also worth noting that just below that, the specification defines syrup separately, to mean, a formulation that has flow without applied pressures and is sticky or tacky to the touch.

It also notes, right in the next sentence, that the syrup, formulation syrup, can have a viscosity of the type used with pharmaceutical suspensions or syrup formulations. So in other words, the specification of the 795 patent is telling us that agave syrup and syrup or the formulation are different things.

And the syrup formulation is required to have a particular viscosity range, and those viscosity ranges are those of the type found in pharmaceutical suspensions and syrups.

Dr. Crowley testified that, in his experience, at Paragraph 28 of his report, which is Exhibit 1003, that formulations that fall in the viscosity range taught by the specification of the 795 patent are typical for orally administered liquids that are pourable and drinkable.

I'm advancing to Slide 10. The 795 patent says almost nothing about the agave syrup that is included in the formulation. It doesn't describe its properties anywhere. Here we're showing a number of different excerpts

from the 795 patent specification, and the only information we're really given about the agave syrup is the amount to include in the formulation.

JUDGE KATZ: So Ms. Lafayette --

MS. LAFAYETTE: Yes.

JUDGE KATZ: -- if can take you back to the -- what you were just discussing about the word syrup --

MS. LAFAYETTE: Right.

JUDGE KATZ: -- if we go to the claim, say, Claim 1 --

MS. LAFAYETTE: Is it okay if I pull up a slide that has it?

JUDGE KATZ: Yes, please.

MS. LAFAYETTE: Okay. Yes.

JUDGE KATZ: Okay, and that's Slide ---

MS. LAFAYETTE: I'm on Slide 12.

JUDGE KATZ: -- 12. Okay. So can you take us through that word, syrup, in the claim? What is the, specifically, Element E in Claim 1? What is the viscosity? Is it referring to --

MS. LAFAYETTE: Right.

JUDGE KATZ: -- the word, syrup, which occurs twice in the claims, or 3 times, but.

MS. LAFAYETTE: Absolutely. So it's Petitioner's position that if you look at Claim 1 -- if it's okay with you, I'll just explain the claim and then I'll answer your question.

JUDGE KATZ: Mm-hmm.

MS. LAFAYETTE: So the claim starts with a preamble that says, a pharmaceutical syrup formulation for oral administration compromising -- so it's a comprising claim that then goes on to list at A, B and C the

components that are required at a minimum, so acetaminophen, agave syrup and a diluent.

Then after the comma in C, it describes the properties of the syrup formulation. And given that the preamble says "a" pharmaceutical syrup formulation, and this is Claim Construction 101 which I'm still learning, but we believe the syrup formulation refers back to the pharmaceutical formulation that is described in the preamble.

And this is also consistent with that portion of the specification I showed you. If I can go back to Slide 9, where it's defined agave syrup separately, and then the term syrup to mean a formulation, and then it goes on to describe the viscosity of that syrup.

And, but while we've cut off at the top of the second paragraph, in the second column of Exhibit 1001, if you continue reading down, it then describes all of the different viscosity ranges that are disclosed for this syrup. At no point is the word, agave, mentioned in that paragraph.

So to answer your question, our position is that the viscosity is only referring to the pharmaceutical syrup formulation, which does include agave syrup, but it includes other things. And because it's a comprising claim, it can include other things beyond what is listed here.

JUDGE KATZ: Thank you.

MS. LAFAYETTE: Thank you. Actually, you pretty much took my last point and --

JUDGE KATZ: I'm sorry.

MS. LAFAYETTE: -- made it a -- no, no, that's great. So if it's

all right with you, and if you, unless you have any other questions for me, I'll turn the reigns over to Brian who will walk you through our invalidity arguments.

JUDGE FITZPATRICK: One quick question.

MS. LAFAYETTE: Of course.

JUDGE FITZPATRICK: I tried to get it out but I was on mute. In Claim 1, for example --

MS. LAFAYETTE: Yeah.

JUDGE FITZPATRICK: -- in Subsection C or Element C, it's the one in where there's a couple hearing clauses, or three maybe.

MS. LAFAYETTE: Yeah.

JUDGE FITZPATRICK: The first one, types of syrup formulation, refers back to the preamble, as you just said. And that's what has the viscosity limitation, talks about the whole, in your view, the whole plan, the whole intention.

The next two mentions the syrup. That -- what's your view? Is that referring back to Element -- just Element B or is that referring back to the preamble?

MS. LAFAYETTE: Yes. It's referring to the preamble. So our view is, after the diluent, that comma, that's when the claim is describing the properties of the formulation. And that makes sense because once you mix these three things together or however many components, depending on what else you add, you'll have a formulation that will have a viscosity. So that's the first part.

It'll be the formulation that the acetaminophen is suspended in. The acetaminophen's not going to selectively go to the agave in a formulation

that also includes water and potentially other ingredients. And then you'll also have the final syrup that will be palatable or not.

So that's over view, that all of those components after the comma following diluent, refer back to the properties of the pharmaceutical syrup formulation that is mentioned in the preamble of the claim.

JUDGE FITZPATRICK: Okay, and I don't know that it would even matter, but I'm hung up on the fact that it just says syrup twice. Or, in C, it says, syrup formulation. And that says, syrup, by itself, and then it says, syrup, by itself. And it probably doesn't mean anything here, but would it matter to your case, I guess, is if the mentions of syrup -- the last two mentions of syrup in Claim 1, if those refer back to Element B only?

MS. LAFAYETTE: It would matter. However, it's our position that they don't. And I think -- it is a good point you're raising and one that Patent Owner has attempted to raise as well.

However, if we go back to the definitions that are given to the specification of the 795 patent, they make it clear that the term, syrup, by itself, means the formulation. And for that reason, we -- it's our position that it's the syrup formulation that has the specific viscosity requirements as well as the other features that we discussed.

JUDGE FITZPATRICK: Thank you.

MS. LAFAYETTE: Thank you.

MR. NOLAN: Thank you, Your Honors. Brian Nolan on behalf of KinderFarms. At this point I would like to discuss the obviousness arguments and the other arguments that KinderFarms has presented against the patent, the 795 patent.

We believe that everything that's disclosed in these claims -- that are claimed in this patent, the Claims 1 through 24, was known in the art and is shown in the collection of references that we have presented.

We have presented, as our main references, two base references in separate grounds. One is Exhibit 1004. We refer to that as e is Exhibit 1004. We refer to that as FR458. And then with that we have articulating combinations for the secondary references. The secondary references go to identifying the specific viscosity of the formulation that Ms. Lafayette was just discussing.

In fact, as Ms. Lafayette has explained, those viscosity levels or ranges in those formulations, as the 795 admits at Column 4, are those that are typically used in -- for oral liquid pharmaceutical formulations.

And so you will see the viscosity range in Patent 4666. It has a viscosity range, as far as we're concerned, of 100 to 3000 CP. And CP refers to Centipoise. Patent Owner objects or disagrees with that position and suggests that, at most, it discloses a viscosity range -- and if you look in the specification, the preferred embodiment talks of about 1000 CP to 3500 CP.

But as Your Honors can understand and see by looking at these claims, even at about 1000, would encompass and teach most of the claim limitations. There are just a few, I think one that's 750 CP and one that's 600 CP, that if the about 1000 is the appropriate reading of the 4666 patent, then it would be a question on whether that's disclosed.

But that is, in our view, irrelevant because, if you look at W01666, that's Exhibit 1006, we talk about combining that with FR458. That has has a viscosity range of 200 Centipoise to 900 Centipoise. And all of -- that

would encompass all of the range, and that is W0133, if I misspoke on that one.

And so that's the first grounds, so we have in that W, we have FR458 combined with the 4666 patent. And then separately, we have FR458 combined with W0133. And then we also have just, we added in additionally, that you could combine all three of those references.

And these are in our petition and they are in our, I think it was Footnote 14 in the petition and it is in our Expert Declaration as well. But I can -- I point to you more specifically of that later.

The second ground is based on W0742. And again, that discloses an agave syrup acetaminophen formulation with the diluent. So that this does discuss most of the limitations in the claim. These are oral liquid formulations so they will have a viscosity.

While W0742 does talk about agave having thicker or thinner consistency, it doesn't talk about the specific viscosity of the final formulation. But again, those secondary references that we just discussed clearly show that.

So with that introduction, I would like to start off and talk about what is the problems purportedly identified in the 795 patent. And if we can go to Petitioner's Slide 14, on Petitioner's Slide 14 you will see that the 795 patent identifies what it purports to be problems.

The problems would be that two patient populations, pediatric patient populations and elderly patient populations, have difficulties taking solid dosage forms, have difficulty taking pills or capsules. And so a liquid formulation would be preferrable for those two patient populations.

They also note that when you make a liquid formulation, again, we're looking at the patent on Petitioner's Slide 14, that those may have -- the API may make those formulations taste bitter or sour. And so you're going to want to have a masking agent in there.

And second -- and finally, although it's a little inconsistent, it talks about the desire to avoid artificial and unnatural masking agents. But if you look at the patent, it talks specifically allowing the flavoring agents to be artificial vanilla, artificial chocolate and artificial fruit flavors as well.

But, so this is the purported problem that the 795 patent lays out. But these problems are just recitations of the problems that the prior art that we have identified -- all of them -- W0742, FR458, 4666 patent and W0742 have shown.

So we look at Slide 15, Petitioner's Slide 15, we're talking about the first aspect. And so these are the primary references. On the left of Slide 15, we have a citation from FR458 explaining that solid dosage form are problematic for pediatric and elderly patient populations. And thus, a liquid dosage form is preferred. And you can see the same thing on the right.

So both the W0133 and FR458 are identifying the same problems -- or same issue that the patent sought to identify. If we go to Slide 16, Slide 16 talks about the need to taste mask because when you put these in oral formulations the API may be bitter and cause taste issues.

So again, FR458 talks about the needing to cover that unpleasant taste. And the same thing with W0133. And then finally, if we go to our Slide 17, we'll see this is, again, in the prior art. Now, FR458 is one of the primary references. It talks about the desire to minimize artificial ingredients.

And then additionally, in our background section, well then we don't rely on Heyer 2009. It's Exhibit 1008. It provides a very detailed summary of what was known in the art. And again, it's talking about avoiding artificial sweeteners and, specifically, using -- it talks about using agave syrup and the like in medicines and health products to do this.

So the problems that the 795 patent purports to address were known in the art and were identified in our prior art references. And not only were the problems identified, but the purported solutions that the 795 patent offers was also identified.

So if we can go to Slide 19, you'll see the abstract of the 795 talks about the desire to make a pharmaceutical formulation with agave, with some API, an active pharmaceutical ingredient and a diluent. And this is a drinkable oral formulation, so any drinkable formulation will have some -- any liquid has some sort of viscosity. And they suggested here the viscosity has to be one that is drinkable, which is -- makes sense, because if it's not drinkable, it's not an oral liquid formulation that you could administer to pediatric or elderly patient populations.

And, but this, again, if we go to our prior art references and we go to Exhibit -- the next slide, please, which would be Slide 20, we have included the primary references on the left. You can see, we have the 458. It has Paracetamol, as my colleague, Ms. Lafayette, has already explained, that's acetaminophen. It has certified Agave syrup and water. And then, on the right, W0742 has acetaminophen, agave nectar and purified water.

And so they're providing the same solutions that the 795 patent purports to provide. And they also -- the prior art also provides the solution of the need for it to be drinkable. And if we can just turn to the next slide,

that shows that the 795 patent admits it is using the viscosities of the type that are used in pharmaceutical suspensions or syrup formulations.

They're telling you they're pulling this right out of prior art. And then they list the types of viscosity formulations, and on the right, we have a chart. And so the 4666 patent is one of our secondary references. Again, we've already discussed that viscosity range, 100 to 3000. The W0133 is 200 to 900 CP. And there are other references that show, that are consistent with and actually support the admission in the patent that all they're using is the viscosity ranges for oral liquid formulations that are already know.

JUDGE KATZ: So Mr. Nolan, if we can sort of focus in on that range in the 4666 patent, because that seems to be something that's at issue. You are listing it there on Slide 21 at 100 to 3000 Centipoise, I guess is the right way to say it.

And I know that Patent Owner is going to dispute that. So you are taking that 100 to 3000 range from the claims. Is that right?

MR. NOLAN: Yeah. So, well in two places because the specification talks about a preferred embodiment. And it says that preferred embodiment is about 1000 to 3000, so it doesn't say 1000. It says it's about.

It then goes on, after it talks about that, and it says, the final formulation can be somewhat less thick. So even 1000 is not the range. It doesn't put a specific number on what is meant by somewhat less thick. But it does put that in the specification as below that.

Now if you look at the claims, the claims take about the 100. Now, they've said that this is an obvious error. The one thing I would note, I think that the seminal case on this is the application of Yale, and that's 434 F.2d 666 and 668 to 69. And that talks about that it's an obvious error.

Now in that Yale case, it was talking about a scientific article. And this scientific article was talking about a structural formula that, you know, appeared nowhere else. We think that this is what we're talking about in the 4666. This is a patent. This is in the claim. The examiner reviewed this.

If that was in error, it could've been corrected by a certificate of correction. Also, they're saying it's an obvious error. They never went back and pulled the file history on this. If that 1000 to 3000 was in the claim when the application was filed, that's a disclosure. I mean, that is supported by the specifications.

So their argument that it's not supported by the specification, it's a questionable whether this is an obvious error. But I think, at bottom, it really doesn't matter because even the about 1000 knocks out most of their claims. And the about 1000 is consistent with, you know, what we have in W0133 which talks about 200 to 900.

And finally, I mean, at bottom, all these ranges, you can just look at the admission in the patent, and this is the 795 patent, again, on Slide 21 that says, all we're using is those formulations that are typically used, the viscosities that are typically used in these formulations.

So have I sufficiently responded to your question, Your Honor?

JUDGE KATZ: So are you saying that your lowest range, I guess, is about 1000?

MR. NOLAN: No, we think --

JUDGE KATZ: Or that 100, their Claim 11 is supported by the "about"? You're hanging a lot on the "about".

MR. NOLAN: Well, I'm not hanging a lot on the about. I mean, I think the 100 is a disclosure. They're saying that disclosure's wrong. And I

don't think they've shown it as an obvious error. And so, but I'm just saying, even if it's wrong, it's not at 1000 because there's an about 1000 that says it could be somewhat less thick.

One of the arguments that Patent Owner proffers is that there's no overlap in the range when the -- and this only goes to our three reference combinations. So this would only be if we said a FR458 plus W0133, which is the 200 to 900, and then the 4666 patent which, if we accept their position, they say it's 1000 to 3000.

But again, they say -- and because there's no overlap, you wouldn't combine them. To be clear, that doesn't touch the two reference combinations, FR458 alone with 4666 or FR458 alone with W133. But even in that, we're saying about a 900. It very -- the overlap very well may still be there anywhere so their argument that you wouldn't combine those because their ranges don't overlap, we think, also fails.

And, you know, I think, at bottom, what they talked about -- so did I address your question on that one, Your Honor?

JUDGE KATZ: I think so.

MR. NOLAN: Okay, thank you.

JUDGE KATZ: Plus, saying it doesn't matter.

MR. NOLAN: Well, hopefully. Valinoti --

JUDGE MITCHELL: Can I follow up for a minute? Because you were talking about, say we buy what Patent Owner is saying, and so we think the disclosure really is the "about" 1000 and up. You were talking about, are there any claims that then would not be obvious, would not have been obvious in light of the combination when you're looking at the 4666?

Or are you still arguing, no, even if we're at 1000, because it's "about", you're going to get some overlap; it's still going to cover all the claims?

MR. NOLAN: If this tribunal comes to the conclusion that about 1000 doesn't teach, I think it was 750 CP for one claim and 600 CP for the other claim, then there would be a factual issue to whether or not that -- there's not an overlap now with that range, so the question would be, would there be an obviousness issue there?

We think you don't have to come to that conclusion because what it comes down to is we always can go back and say, we can look at FR458, the primary reference which talks about agave, a diluent, acetaminophen suspened therein and just look at W0133, that combination by itself. That is 200 CP to 900 CP.

So 200 CP would encompass the less than 600 CP. It obviously would encompass the less than 750 CP. It would encompass, overlap the range of one claim that is 1500 CP to about 400 CP, and obviously it would encompass anything that says less than 1000 CP and less than 1500 CP. So even --

JUDGE MITCHELL: Your other combinations would --

MR. NOLAN: The other combinations could do that. So I think, you know, there's -- there could be an argument that the admission here that we're using those typically in the art, that may be about -- a POSITA would consider 750 and 600 obvious in light of a disclosure that says about 1000.

But I don't think this tribunal needs to reach that because of the fact that we have these other disclosures.

JUDGE KATZ: If we could also, just to make sure that we get it in, there was also another sort of assertion of viscosity through the witness, Dr. Crowley citing an exhibit with a viscosity of agave syrup of 212 CP.

MR. NOLAN: Yes, Your Honor. So --

JUDGE KATZ: Can we make sure that we address that?

MR. NOLAN: Yeah, and so Dr. Crowley -- in our petition, we recognize that the agave syrup could have thicker or thinner consistencies. And then in Dr. Crowley's declaration, he also explains that the agave syrup could have thicker or thinner consistencies.

He did cite one of the examples, and if you look at Exhibit 1030, which was with our initial petition, and unfortunately, when he cited the 212 Centipoise for that, he mistakenly pointed to Exhibit 1031. Exhibit 1031 is an abstract. It also talks about agave syrup, and it compares it to honey and, I think, another syrup. That's in there.

And it talks at the beginning that, it just says, generically, viscosity of syrups, all the syrups here, is an important property. It doesn't say whether, you know, lower or higher is better. It just says it's an important property.

And there, when they measured the viscosity of that agave syrup that they had taken from that plant, whatever it may be, the agave syrup viscosity was measured as 2560 CP. So again, consistent with what we've said in the petition, that agave syrup can have a thicker or thinner consistency.

Now, at the end of the day, we don't think the agave syrup consistency is really what matters because it's the consistency of the formulation. It's the consistency of the formulation that would go to it. And I think I could point us to -- and if we can pull up Slide 51 -- so we had the opportunity to -- and

maybe if we can, if I can just focus your attention on the left side of this slide.

So on Exhibit 51, we're talking -- we have on the left side we offer Exhibit 0151. And Exhibit 0151 is the deposition transcript of Dr. Berkland, which is expert declaration that was put in on behalf of Patent Owner.

And so when he is asked on this slide, it says, we were asking about what a person of skill in the art would know after reading the 795 patent. And he acknowledges that a POSITA would know that agave has a range of viscosities. And, but he then suggests what the teaching of the 795 patent would tell you is that you would then try to make a formulation that falls within -- the highest in the claims is less than 1500 Centipoise.

But as we've spoken on numerous occasions, if you look at Column 4 of the 795 patent, it is telling you they're using the viscosities that are known in the art. They're using -- there's no new disclosure. So when he says, yes, a POSITA -- consistent with Dr. Crowley -- would know there's different types of viscosity levels for agave syrup, and they would know that whatever viscosity level they
took, they would know how to manipulate that and get it down to the formulation.

Their argument is -- becomes a red herring. The issue is not about the agave syrup's viscosity. And as this Court has recognized, in the -- I think if you look at your initial determination at Page 24 to 25, you talk about the fact that it's clear, at the bottom of that page, it clears that the petition discloses the 4666 patent and W0133 for the viscosity ranges, for the viscosity of the formulation.

So, yes, there was an error. I think that --

JUDGE KATZ: Can I take you back to that error for just a moment?

MR. NOLAN: Sure.

JUDGE KATZ: Sorry, not to interrupt, but, so the error was in using the wrong exhibit number. Is that correct?

MR. NOLAN: Correct, Your Honor.

JUDGE KATZ: There's also -- I think the citation was to Exhibit 1031, Page 1, I believe, is in the declaration, Paragraph 52.

MR. NOLAN: I can pull up the declaration, Your Honor, Paragraph 52 of that.

JUDGE KATZ: Yeah. I think that would -- Exhibit 1003 Paragraph 52. It says, the viscosity of agave syrup is reported to be around 212 millipascal-second or 212 Centipoise, which is less than that of honey or other syrup -- Exhibit 1031, at Page 1.

MR. NOLAN: Well, 1031 is just an abstract. It's a single page exhibit.

JUDGE KATZ: Right.

MR. NOLAN: So I think it just --

JUDGE KATZ: But my point is, though, that if you're that the error is in the exhibit number, then if we go to Exhibit 1030, which is what you say it should be, that value, that viscosity value is actually on Page 5, I believe, not on Page 1.

MR. NOLAN: Yeah, and I think the whole citation is just wrong. So, I mean, I think that -- I don't know how this was missed, and I apologize how it was missed when we went through, but we did put in those two references that show that range of viscosity can be talking about from 212 CP, you know, to 2560 CP and the like.

JUDGE KATZ: Okay. And Dr Crowley wasn't questioned on that.

MR. NOLAN: Oh, and I think that the issue, too -- and my colleague, Ms. Lafayette -- it's always good to have the more intelligent people around to help you -- is that when it says, less than honey or sugar cane, I think that the cite to one was for honey on that. And then, Ms. Lafayette is explaining to me, that the cite for agave would have been later on. So I think that's how we realized it was missed.

We probably should have had two citations in there. But that's -- but anyway, we made Dr. Crowley available for deposition. They filed the notice of deposition and they withdrew the notice of deposition, and they chose not to take his deposition.

JUDGE KATZ: Oh, so he was not -- okay.

MR. NOLAN: So I see that we're kind of running down on time. But one thing that I just -- and I think if I could point you to it, and I think the Intel v. Pact, the case 61 F.4th 1373, 1379-1380 is instructive here because I think, at bottom, what they get to is they say there's a lack of motivation to combine on much of this.

And what the Intel case says, if there's these known problems, these recognized problems and these solutions -- and this is, you know, this is basically, in our view, this is kind of the poster child for KSR in the sense that, when you look at this, you have FR458 and you have W0742, those two primary references.

They both say we want to make an agave syrup with analgesics, acetaminophen, in them with a diluent. We want to do this because we have solid dosage forms that are problematic to swallow for two patient populations, elderly and pediatrics.

We are going to have a taste, a bitterness taste issue because of the fact that we have now this API is in a liquid form as opposed to in a solid dosage form. And so they're giving you those solutions. They're identifying these problems. They're giving you those solutions.

A person in the skill of the art reading that would understand these are liquid formulations. They have to have a viscosity because if they're a liquid formulation and they -- they will have a viscosity, and that viscosity has to be one where it can be administered.

Now, admittedly, FR458 doesn't expressly state what the viscosity of the formulation is. And W0742, the other primary reference, doesn't state what the viscosity of the formulation is. But as you talked about in your institution decision, and this was at Page 22, considering the commonality of these prior art references, they're in the field of oral analgesics.

And if you look at the 4666, the secondary reference that discussed the viscosity, and if you look at the W0133, the other secondary reference, that discusses the viscosity, they are talking about, again, wanting to make a liquid formulation for these pediatric and elderly populations.

And so when a person skilled in the art is looking at FR458 or is looking at W0742 and they note it's got to be drinkable because it's a liquid oral formulation, but it doesn't specifically tell me the viscosity, clearly, they could go to the other art and say, this is telling you what the appropriate viscosity is.

And I think what you'll hear from my colleague, when he gets up on behalf of Patent Owner, he's going to talk about issues of, well, would you have been able to put that into the formulation? They say, look, if you had 212 Centipoise as the viscosity of agave syrup, their expert acknowledges

that, in his view, when he read that, he said, well, I think the viscosity of this formulation of FR458, Example No. 1 would be below 200. It would be close to water.

Well, that's within all the ranges. And they're saying, well, because you have that, this specific formulation, you wouldn't have combined this. But remember, this is not -- and you often say this in re Keller and other cases that it's the combination of the teachings. And I would note, the teachings of FR458 is not limited to Example 1. Very early on, up front, in the summary of the invention, it says that you can use the agave with the acetaminophen alone or in combination with other excipients.

And so I think you're going to hear discussions that 212 is a fatal error. 212 is not a fatal error in any sense or imagination because of the fact that, first of all, it doesn't go to the specific claim limitation, the syrup formulation, the viscosity of that.

And it's -- they're going to try to, I think, limit it to just what is Example 1 of FR458 or, I believe, it's Example 6 of -- Example 5 of W07 -- Example 9 of W0742. Now I see that I only have a --

JUDGE KATZ: Yes, one minute.

MR. NOLAN: -- or a half left, but if there's any questions that you would have that you would like me to address now, I can address them now because I'd like to make sure that I maintain the time that I've held in reservation.

JUDGE MITCHELL: Is there anything in the record that tells us, like, why a particular viscosity -- is it for mouth feel or, like why would it matter whether it's as thin as water or is, you know, really, really thick.

Just -- I mean, is it just so a child or an older adult can swallow it? It's not too thick?

MR. NOLAN: Yeah. I think if you look at the abstract of the 795 patent, it's just purely for drinkability.

JUDGE MITCHELL: Okay.

MR. NOLAN: It's just purely that. You don't want to be sitting there, turning the bottle upside down and nothing coming out because it's too viscous. And so what the 795 patent tells you on that is we know what those -- those are typically used. Again, Column 4 is saying, this is what's typically used.

They're not saying -- they put nothing that says novel or inventive about this viscosity range. They're just doing that, that's typically used. And they are correct. It is what's typically used, as we've shown in the 4666 patent, the W0133 patent. And I think, even when you look at some of their -- they're going to pull up -- I think maybe they'll pull up Exhibit 2021 which talks about a greater range.

But even if you look at that, that says about 1500 to about maybe 4000 —and they say, see -- this would be much higher. This is a much higher acceptable range. But again, that about 1500 is overlapping with the claim language, so that's actually another disclosure under then Genentech case.

If you look at the Genentech case that we've cited for overlap, and that would be Genentech v. Hospira 946 F3d. 133, App 1341, again, it says that if there's any -- the overlap, unless they can show criticality or something to the patentability or novelty about that, that range, that's a teaching, and that makes it prima facie obviousness.

Thank you for your time, and I cede to my colleague for Patent Owner.

JUDGE KATZ: Okay. All right, thank you. Counsel, all right, are you ready for Patent Owner's argument, Mr. Pivovar?

MR. PIVOVAR: Thank you. That's well done.

JUDGE KATZ: How much time would you like to reserve for rebuttal?

MR. PIVOVAR: Could I get five minutes, please?

JUDGE KATZ: Five minutes?

MR. PIVOVAR: I'm not going to need more than that.

JUDGE KATZ: Okay.

MR. PIVOVAR: So just to address a couple of things that were raised and how I'd like to be, and Judge Fitzpatrick raised a question about the interpretation of the claims.

I think everybody understands that the wherein clauses that are -- although it looks like it's in Element C, it really should have been like a return instead of over, so it's really not part of Element C. But those wherein clauses, what it's referring to, the syrup formulation and the syrup -- it was all to a complete to a final formulation, right, it's not just the agave syrup. Everybody here recognizes and understands that from that perspective.

I think we heard a lot about attorney argument here and obviously in our briefing, especially on surreply, our notice that we filed and our objections. And we heard today a lot of arguments that are predicated solely on attorney argument.

There was no expert declaration submitted with the reply, no opportunity to depose anyone on reply. So all the arguments that have been

made here today about what the error was and what Dr. Cowley did or didn't do, it's unsubstantiated. They could have put in a declaration from him. He could have tried to justify what he did, and we could have had a chance to depose him then.

But his direct testimony is in his declaration. We have no obligation to cross-examine him. What his declaration says, a person of ordinary skill in the art knew that agave syrup has a viscosity of 212 CP, right, and thats in Paragraph 119 of Dr. Crowley's declaration.

He refers specifically back there to what's said in Paragraph 52. So under his declaration testimony, the only value for the viscosity of agave syrup anywhere -- in the petition or in his declaration -- is 212 Centipoise, and that's one, right.

And when we talked about a little bit, so all the explanations there are attorney argument. The idea that --

JUDGE KATZ: So, Mr. Pivovar, what difference does it make if W0133, if the reference gives a viscosity range of the formulation, what do we care what the viscosity of agave syrup is?

MR. PIVOVAR: Oh, you have to treat the claim as a whole, Your Honor. What formulation are we making, what agave syrup are we putting into it, and whats the final formulation viscosity of that for a motivation to combine, and a reasonable expectation of success, right.

You can't just conclusory say agave syrup has a viscosity of 212 because, when you look at the formulations that are here -- any formulation, right -- it will have a viscosity. And that viscosity will be dependent on the types and nature of the components that are put into it and the relative amount, right.

So you have to have a formulation that achieves a viscosity under the proposed combination and there would be a motivation to combine and do all of those things, which we believe is lacking. So it's important because the viscosity of the agave syrup contributes to the viscosity of the final formulation.

And if you look at how Dr. Crowley and Petitioner argued what the prior art example formulations include, they say consist mainly or largely of agave syrup. So this is FR458 Example 1, W0742 Example 9. They say it's largely agave syrup.

And if you have largely agave syrup in that formulation, the viscosity of the agave syrup is going to have an impact on the final formulation. If I select an agave syrup that is 212, that formulation will have a different viscosity than if I select an agave syrup that has a viscosity of 2560 because these are the constituent components that are put in.

JUDGE KATZ: So Mr. Pivovar, I think you said in the, I believe it's the Patent Owner's response to the petition on Page 49, that FR458 Example 1 is primarily made up of water, at least 50 percent. And as such, the viscosity of the example, with its substantial additional water, would be much less than the viscosity of the agave syrup.

MR. PIVOVAR: Yes, we did, and that was in -- so Dr. Crowley says -- Dr. Crowley from Petitioner's side -- said it's largely made up of agave syrup. And we said, well, you know, if you actually look at this, it's more water than it is agave syrup. But the point remains that they're both substantial components, right.

Agave syrup is, I believe, 40 percent in one and 70 percent in the other. That's a large fraction of the amount of the formulation. And the

overall formulation will then be impacted by the viscosity of those components. That's the point we were trying to make.

And we point out that the water is there specifically in that portion of the petition and in Dr. Berkland's supporting declaration because, if you actually use -- and maybe I should just dial this back. Think about the ranges that are in their prior art. Now, you guys talked about, a little bit, the error, and I can come back to that on the 4666 patent for the range.

But let's, you know, come back to you have a range of, in our view, 200 to 900 in W0133 that they're pointing to and a range of 1000 to 3000 in the 4666 patent if you correct for the error. And again, the error -- they could put it in a declaration and they could have responded. They never did. This is all attorney argument.

They mentioned, you could have gotten the file history, and they could have gotten the file history, right, like the evidence is what it is. But anyhow, so you have a range of 200 to 900 and a range of 1000 to 3000. Why would you select a viscosity that's 212?

Or, you know, Dr. Crowley says this later. I believe it's in Paragraph 251 along with 200. So if my desire is, again, accepting there is no motivation to combine, no reasonable expectations to have success for this, those are the ranges I want to achieve, right. And if my expert is saying it's largely made up of agave syrup, why would I select something that's right on the edge when there is additional water in there that will thin it out and push it below 200?

So the reasoning of why we put that in, and to Your Honor's question is, if you were to unjustifiably conclusory select 212 for the agave syrup, if you put that into either FR458 Example 1, there's too much water, and it's

going to come down. It's going to come down and it's going to be below any of the viscosity ranges they have.

So, and Dr. Berkland says this in the citations that he says, a person of ordinary skill in the art would immediately recognize that there's water in there. If you put 212 in, it would be less than 200. There's no motivation to try to get it to 200 for the range in the W0133 and no reasonable expectation of success because you know it would be less.

JUDGE KATZ: So your argument is relying on Dr. Crowley's testimony as the prior art, and I'm sort of confused by it. The prior art that we're presented with provides a formulation of acetaminophen and agave syrup.

And then prior art, which says that if you want a pharmaceutical syrup for oral administration would likely have -- should have a viscosity between a range that's less than 1500 -- 200 to 900. So where does the 212 come into that? I'm confused where the 212 comes into that challenge.

MR. PIVOVAR: Well, there's not really a well articulated theory of motivation to combine, but you need to have an oral pharmaceutical formulation, right, that's what the claims require. And that pharmaceutical formulation has to include acetaminophen, agave syrup and a diluent .

And then that overall formulation has to have the claimed viscosity of less than 1500, less than 1000 and all that, right.

JUDGE KATZ: Okay.

MR. PIVOVAR: So when it comes to the patent claims and the prior art, and in particular, the prior art -- and I'm showing this. This is on Slide 50. This is Example 1 of FR458. Now we pointed this out in our reply that

there's nothing in the petition that talks about modifying any of these references.

They never set forth any formulations, any combinations. The only thing is they make a conclusory reference to Example 1 of FR458. So there is the formulation that they're saying for their obviousness ground.

And what's important here Your Honor, is that that formulation does not say in the example, or in the patent anywhere what the viscosity is of the agave syrup or the final viscosity of the formulation.

So if we follow what they say, and this is their formulation and this is what they're saying in their obviousness ground, if we put 212 agave syrup -- or agave syrup with 212 Centipoise at 45 grand in that particular formulation, that formulation would not be expected to and would not have a reasonable expectation of success in achieving a viscosity in the ranges of their secondary references.

That's why it's important, right, because if they're not going to treat the claim as a whole, right, as a whole -- you have to have a formulation. That's their formulation. 212 in that does not satisfy any of the ranges in their secondary references. And that evidence is unrebutted on that point.

JUDGE KATZ: Which evidence is unrebutted?

MR. PIVOVAR: The evidence that Dr. Berkland submitted stating specifically that, if a person of ordinary -- you know, if you put 212 Centipoise agave syrup into the formulation example, it would be below 100. So that could --

JUDGE KATZ: Wouldn't that still meet the claim limitation of being below 1500 or 700 or over 600 or 400?

MR. PIVOVAR: Well, the claim limitation, but you can't do obviousness from the claim limitation. Their combinations is what we're pointing to. And this is, I think, another thing where you hear Petitioner saying, well, the typical range is the typical ranges.

They're not relying on anything other than the ranges in the secondary references, right. Their combination is 200 to 900 Centipoise. So the need that they have to do is say there's a motivation and reasonable expectation to a person of ordinary skill in the art to make their proposed combination, right.

So instead -- like, the patent can't be looked at, so I'm disagreeing that 100 falls within the range of the patent claims except for Claim 15, and that has a bottom end range that wouldn't meet it. But they have to be able to show that their combination works. And their petition and their combination says 200 to 900, from 100 -- or W0133 and 1000 to 3000 from the 4666 patent.

If we're going to just ignore what their combination is and what the prior art references says there, that's a different argument. And that wasn't the argument that we could even discern from the petition. So our point is, even though it would, at 100 Centipoise, meet the claim, it doesn't satisfy the obviousness burden that they have because it wouldn't meet the combination that they've proposed in their argument.

So I hope that helps to explain the difference because I'm concerned that there's a lot of hindsight going on here when you can't use the patent claim to understand what their motivation would be or the resulting formulations. They have to construct that from what's in the prior art and according to the theories that they presented in their petition.

So I hope that you just at least understand our argument. And if you have no further questions, I'll move on.

JUDGE KATZ: Go ahead.

MR. PIVOVAR: Thank you, Your Honor. So I think that you have a lot on the background of what's already been talked about here. I think the main thing is, and, you know, counsel for Petitioner flagged this a little bit, is that typical viscosity, so liquid solutions will have viscosities.

But they do not have inherent viscosities within the ranges of the claims and they do not have inherent viscosities that meet the ranges that Petitioners proposed in their secondary references of 200 to 900 or 1000 to 3000, right. They're not inherent.

They're not necessarily present in every oral formulation because of the range of viscosities. It can be from, you know, low, all they way up to, you know, 4500, what we've put in and all these different things. So it's a broad range.

And when you look at the claim, so we talked about this -- it can't just be any formulation that has acetaminophen, agave syrup and a diluent in it. If that formulation has a viscosity outside the range, it doesn't meet the claim, right.

So there is a viscosity functional limitation as well as the stability and palatability, but those aren't in dispute here, that has to be satisfied by whatever the formulation is, right, by whatever that formulation is.

And of course, if you had a formulation that, hypothetically, met all the -- agave syrup, acetaminophen and diluent, had that in it and it had a viscosity of 1200, it would meet Claim 1 but not Claim 2 or Claim 3 or Claim 4 because those are beneath that.

So there is a narrowing that -- or a, now we say change in scope that happens with respect to the types of agave syrup, the types of diluent, the formulation of the acetaminophen and the final viscosity that you would get from whatever formulation you have, including other ingredients.

And I think that's the important thing, is like, there are other ingredients that we see in both the examples that Petitioner relies on from FR458 and W0742. It's not just, I have agave syrup, acetaminophen and water, right. They have more.

And FR48 says you have to have agar-agar and Xanthan Gum. You got to cure it. It's really hard to make these into natural syrups. So it has more components. And all of those components contribute to the viscosity and if the viscosity's above the claims, doesn't meet it. And if it's below what the claim range is, then it does.

So I'm just going to skip ahead. I don't think there's any issues for claim construction.

JUDGE KATZ: So let's go back to the issue with the Claim 11 of the, what is it, this 4666 patent because I just want to make sure that we hit on that.

MR. PIVOVAR: Sure thing, Your Honor. This --

JUDGE KATZ: So you're saying that that's an obvious error?

MR. PIVOVAR: Yes.

JUDGE KATZ: It is a claim. It's a legal definition. For us to say that that legal definition is an obvious error is kind of a big deal. What evidence do you have that that's an obvious error?

MR. PIVOVAR: Yeah, so Your Honor, we went through this. And what Dr. Berkland said was a few different things. And the first thing he

says is, well, you know, there's the ranges. There's no 100 to 3000 taught anywhere in the specification.

The specification emphasizes 1000 to 3000 or, you know, slightly less or whatever the language is, a little bit less than that. But those are important for the stability.

JUDGE KATZ: So do claims -- they're kind of self-supporting, right. That's the original claim that was put in, 100 to 3000. It doesn't have to have supported elsewhere in the specification, does it?

MR. PIVOVAR: Well, we don't know whether it was or not. I don't know if there's amendments.

JUDGE KATZ: Do you --

MR. PIVOVAR: Huh?

JUDGE KATZ: Do you know if it was the original claim?

MR. PIVOVAR: I do not. I do not.

JUDGE KATZ: You don't? Okay.

MR. PIVOVAR: Yeah, we tried to look it up on PEAR, and then I don't that we were able to use it since it's such an old patent, like it's not on -- or not PEAR, whatever the new, yeah, patents --

JUDGE KATZ: Right, but it probably does exist somewhere in the prosecution, Mr. --

MR. PIVOVAR: Presumably.

JUDGE KATZ: Okay.

MR. PIVOVAR: Presumably.

JUDGE KATZ: But you didn't get it?

MR. PIVOVAR: I didn't get that. But also, Your Honor, it's like, you can see here, this is Dr. Berkland saying, I don't see any support for a

viscosity of about 1000 to 3000 Centipoise. And I just want to kind of highlight this. What if it said 1000 to 30000, right. Is that not an obvious error, and if it was in the original claims, it's still fully supported and everything would be in there?

I think you have to kind of --

JUDGE KATZ: Do you know, Mr. Pivovar, if that claim was enforced ever at the range that it recites?

MR. PIVOVAR: I do not know if that --

JUDGE KATZ: Okay.

MR. PIVOVAR: --- was ever enforced.

JUDGE KATZ: Okay, thank you.

MR. PIVOVAR: And I don't even know if it embodied a commercial product or anything like that, so I'm sorry. I don't actually know that. But, I mean, the way you would show -- not to get into this, but Dr. Berkland says, I don't see any support for that viscosity range or whatever, right. It says 1000 to 3000. If you line up each of the patent claims, 9, 10 and 11, you see, like it's meant to be 1000, it's meant to be 1000, it's meant to be 1000 and just 100, right.

So from our perspective, it's an obvious error. People would just count it in. And then, yeah, that's in our brief, and I think you asked about it, so like it's like -- I do want to emphasize this point though. I don't know whose burden it would be to show that it's an error, right, at this point.

It's like it's in there and it's not -- so I don't know that. But all I will say is this. They could have put in expert declaration testimony to respond to say the things they're saying through their attorney argument, but they

didn't, right. So I would say, like attorney argument is in evidence. You have Dr. Berkland's evidence.

I don't know if it's our burden or their burden but a strange issue to be this -- their burden to prove unpatentability, but what's the presumption of what a patent says when it looks like there's an obvious error and who has the burden, that I do not know. There's not a lot of case law on this.

But I would say, again, no evidence from their side refuting Dr. Berkland's opinions, pure attorney argument. So that's the first part. And then I do want to come back to this error. That was pretty plain in Dr. Crowley's identification of the viscosity, right.

And you need to know not just that it has a viscosity. You need to know what the value of the viscosity is. If you are going to put that into a formulation, like they have -- and again, lots of agave syrup there. What's the value of the viscosity that you're putting into that? Is that the thickness, and the quantifiable thickness of the agave syrup? Is it going to impact what the final formulation's viscosity is, right.

And this is where, you know, we really couldn't make heads or tails of this, right. And, Your Honor, you asked, you know, was Table 4 of Exhibit 1030 ever cited? It was never cited anywhere in their papers, not even in their reply, right.

JUDGE KATZ: So let's say that, I mean, there might be two different errors here, right. There could be an error either in the 212 Centipoise statement or there could be an error in the citation. If the error is in, let's just say that the citation is correct and it should have read 2000-what is it, 500 Centipoise? Is that --

MR. PIVOVAR: 2560, Your Honor.

JUDGE KATZ: 560, okay. Then would your statement, in your response -- I don't know if I can pull it up again. That FR458 Example 1 is primarily made up of water, at least 50 percent, is such that viscosity of the example, with its substantial additional water, would be much less than the viscosity of the agave syrup.

If water is 50 percent, then wouldn't that be the correct -- I'm sorry, I'm not speaking clearly. The viscosity from Exhibit 1031 would then sort of refute your statement. You're sort of admitting that Example 1 FR458 is 50 percent. So that 50 percent of 2560 or whatever it is would come to be within the claim range, right?

MR. PIVOVAR: I understand what you're saying, and that's just incorrect.

JUDGE KATZ: Thank you, because I wasn't very clear with that.

MR. PIVOVAR: Yeah, what you're saying is, what if we put in 2560? Then, does it work? And the answer is no.

JUDGE KATZ: Okay.

MR. PIVOVAR: Because viscosity doesn't just scale in the way that I think you're contemplating. Oh, well, it comes down by 50 percent if you use 212, so won't it come down by 50 percent if you use something higher? It does not.

And even though, like there's nothing in the record, but before we get to anything that is kind of hypothetical, and I'll try to address your question from an attorney perspective based on the record, but if you look at our Slide 28, you can see the only evidence in the record here about -- so they never mentioned 2560, right. That's not in their petition. There's nothing there. They can't carry their burden. I understand this is a different question.

But if you look at it, and on Slide 28 is Dr. Berkland's declaration at Paragraph 119 and he says, if you were to use 2560, it's well above the 1500 Centipoise recited in the claims and the agave syrup examples would result in formulations that a person would expect to have a viscosity of more than 1500 Centipoise.

Now, that's his opinion testimony and that's what's there, if you were to use that it wouldn't work. It wouldn't achieve the claims, right. And Dr. Berkland talks about this up front. And this was never briefed so I'll try to make it so that it's, like I can explain to you the basis for this from what I know that's there.

But Dr. Berkland explains the amount of residual water that's in agave syrup, right, so agave syrup is fructans, you know, it's got fructose, sucrose, it's got things in it, and it has water. And then, so it has residual water in it. So when you have an agave syrup that's a viscosity of 212, there's a lot of water there, so it's pretty low, right.

And we all know this. If you take honey or agave syrup and you put it in your coffee, right, it comes out squeezable. Once you get in the water, it's just like water, right, the viscosity goes down.

So the viscosity of the agave syrup, and this is mentioned in Dr. Berkland's report and in Exhibit 1031 is that viscosity is a measure of the quality of the agave syrup. And when they mentioned that, and Dr. Berkland testifies to this, it's really like, how much water is there?

If you think about it, if I'm going to buy agave syrup, you want to buy something that's 80 percent water and 20 percent this? Or do I want something that's 80 percent kind of all dissolved and 20 percent water? So it's watered down.

So an agave syrup that's 212 has a lot more water than agave syrup that's 2560. And then that's the difference. If you have residual water in the agave syrup, you mix that with the 50 percent water in the FR458 Example 1, it's going to come down, right. And it's not linear, but it comes down and it's below 100, right.

If you take agave syrup that's 50 -- 2560, you put that into the formulation of FR458 Example 1, there's not enough residual water in that to cause the viscosity to come down as far as it would if you had a more watered down 212 version of the agave syrup.

So if I were to look at Formulation 1 of FR458 on Slide 50, Example 1, so if were to look at that and say, how much water is there? Well, we know it's up to 100 milliliters, so let's say, I don't remember the numbers, like 50 or 45 milliliters of water -- for the water.

JUDGE KATZ: You say at least 50 percent?

MR. PIVOVAR: At least 50 percent, right, so 50 percent. If we were to look at, like, how much water is actually there, there's more, right, because within the agave syrup, there is water as well. Sorry, right, because agave syrup has water in it. Now, the amount of water is important when you're dealing with multi-component formulations like this because these other components, xantham gum and agar-agar are viscosity increasing agents or thickening agents or gelling agents, right.

So if you've ever made Jello and you put in too much water, it still stays kind of syrupy, right. So if you put in a lot of water to your Jello, if you're making it, it'll just be runny because you haven't put enough in -- or you put too much water in. Now, you have to have a low enough amount of water for everything to gel in Jello, right.

These, xanthan gum and agar-agar, work just like that. If you have a lot of water they, they thin out and they don't gel.

JUDGE KATZ: Their viscosity is less than 1500?

MR. PIVOVAR: I can't say the number, Your Honor. But certainly, yes. Like they're --

JUDGE KATZ: Okay.

MR. PIVOVAR: So if you think about it, it's these things can be in a solution and you could put them in there and they could just be like water. If I just put a little bit in, they don't change anything. But they hit a gel point, right. At one percent of, I believe, xantham gum, it's a gel, right, so those things are viscosity raising agents.

Whether you hit the gel point, which again is non-linear, and you just add more, add more, add more and all of a sudden, it gels because you have enough of this in there to gel, the viscosity's going to skyrocket. So the point is, and this is, you know, going into some of the things that Dr. Berkland said in his report about what all of these components do, is if you add in an agave syrup with 2560, there's less water.

The contributions from the xantham gum and the agar-agar to the viscosity increase are going to go way up. And that's why this formulation, according to Dr. Berkland, has a viscosity that wouldn't fall within the range if you use agave syrup 2560 with less residual water.

JUDGE KATZ: Okay.

MR. PIVOVAR: Does that help or no?

JUDGE KATZ: So let me ask you another question ==

MR. PIVOVAR: Mm-hmm.

JUDGE KATZ: -- Mr. Pivovar. This is not in anticipation challenge, so actually the FR458 Example 1, that formulation, doesn't actually have to have the viscosity, right? So we're all talking about what the viscosity of Example 1 would be, but this is an obviousness challenge. It has to be obvious to have a viscosity within the claimed range, right?

MR. PIVOVAR: Let me see if I can parse that. Are you saying -- because there's nothing in the petition that talks about any modifications to any of the example formulations of any of the primary references in FR458.

JUDGE KATZ: Well, isn't their challenge, doesn't their challenge recite what typical formulations of oral administered syrup formulations are, orally administered? Isn't that what W0133 tells us?

MR. PIVOVAR: W0133 says viscosity of 200 to 900, that's correct, Example.

JUDGE KATZ: Right, so what do we do with that?

MR. PIVOVAR: Well, you put that into what their alleged combination is, right?

JUDGE KATZ: Yeah.

MR. PIVOVAR: So if you're going to treat the claims as a whole, you need to have a formulation that achieves the 200 to 900 range somehow, right. One formulation is going to have a viscosity value, right. A specific formulation, like that's laid out there, if you select a specific agave syrup that will have viscosity. You select a different agave syrup, it'll have a different viscosity.

But each one of those two different formulations I just articulated, one at 212 CP and one at 2560, they will have individual viscosity values, right, within experimental error -- not ranges. There's no proposal anywhere in the

petition of any modification to any of these exemplary formulations that we've seen, right.

So when we talk about, like what we need to have, you know, we need to something that connects, right, and treats the claim as a whole. The FR458, what is the formulation that they're saying they would be motivated to modify or change to achieve the viscosity value of W0133? It's not there. There's nothing there.

All we could glean, Your Honor, from the kind of abstract, you know, how they argued this was what they said, right. So this is in their petition. This is for the viscosity limitation. You can see this. This is the entirety of their argument. And on the next slide, I have the rest of it, but it says, the viscosity of agave syrup --

JUDGE FITZPATRICK: I'm sorry to interrupt. Can you identify the slide, please?

MR. PIVOVAR: Oh, I'm sorry. I'm at Slide 62, Your Honor.

JUDGE FITZPATRICK: Thank you.

MR. PIVOVAR: Thank you, sorry. This is where they say, they're dealing with the viscosity limitations. So when you read this, it says, you know, a person of ordinary skill in the art would understand viscosity low enough to be pourable and drinkable. The viscosity of agave syrup has reported to be about 212 Centipoise. Person of ordinary skill in the art would understand that the formulations disclosed in Example 1 of FR458 which is largely made up of agave syrup may have a viscosity of less than 1500 Centipoise.

Then they say, as both the 4666 patent and W0133 disclose appropriate viscosity ranges for an oral formulation with an analgesic, it is

unnecessary for the Board to conclude that Example 1 of FR458 meets this limitation. So that's what they say.

So what we did is we said, okay, I don't understand what it means on that last statement. They're basically saying, you don't have to consider any formulations. You can just mix and match without considering the claims as a whole and find viscosity limitations in the other references which is, you know, obviously, a legal error. But what we did is we looked at this and we said, okay, at best, here's what we can make out.

They're saying you would take viscosity, like an agave syrup of 212 Centipoise, put it into Example 1 of FR458. Now, they're not saying what that would be. They're saying, oh, maybe it's more or less. But our expert said definitely what it is. It'd be less than 100 if you did that. They deposed him. It's unimpeached.

That's why -- so from the perspective of what's actually in the petition, Your Honor, this is what we have. And if you take this away, and if you don't have anything related to an actual formulation and all you're looking at is the 4666 patent and W0133 in isolation, you're not treating the claims as a whole and you're just using hindsight to say, hey, these are references that I can pull from that overlap with your viscosity range.

Without identifying any formulation within the primary references, that would achieve the viscosity ranges of the secondary references, right. And this is the fundamental problem with the petition. It's Petitioner's burden to point out with particularity what its grounds are. And they just haven't done that, right.

And you need to know what the viscosity is of the agave syrup because that's going to impact the final viscosity. And then you need to

have a formulation, like our best was, okay, they're pointing to these examples. You can see in their slides today, they're pointing to the examples.

Otherwise, this is all just mixing and matching from disparate pieces of art without any particular articulated motivation to combine. And that's really, I think, the next thing I'd like to get to, Your Honors, is --

JUDGE FITZPATRICK: Let me --

MR. PIVOVAR: Yes, Your Honor.

JUDGE FITZPATRICK: Sorry to interrupt to you. I have a question. There's been a lot of talk about what the person of ordinary skill. What have -- what is Petitioner referred person of ordinary skill to have modified, or, in your opinion, there is no modification, you know, about what they would have been motivated to do and what to not do?

What about -- I just want to set the scene and separate out the issue of level of skill. Is there anything -- did -- would -- is it your position as to whether or not it would have been beyond the level skill for a person of ordinary skill in the art at the time, at the critical date, to have made any of the claimed inventions if he or she had these prior references in front of them?

MR. PIVOVAR: Okay, so you're saying, without any of the teachings of the actual 795 patent, just on its own?

JUDGE FITZPATRICK: Well, let me put it another way. Let's say, hey, here are the claims. Let's go with hindsight. Here are the challenged claims and you hand it to this hypothetical person with these prior art references and say, is this beyond the level of skill? Can you make these things based on these references -- if you're motivated to. And now you are,

because you have the claims. There's no dispute about that in my hypothetical. You have the claims. Is it beyond the level of skill?

And the reason I'm asking this is because you mentioned a lot of things that are -- you know, I understand exactly why you had, you know, you mentioned things like the xantham, you know, and you add water and, you know, take out water and all these things have an effect on the overall viscosity when you get to tinker with it.

Is there anything about that process, you know, that precludes a person from making these inventions, if they wanted to?

MR. PIVOVAR: Yeah, I think that this kind of comes down to the standard kind of difference between what a person of ordinary skill in the art could do and what a person of ordinary skill in the art would do, right.

And if you look through the Berkland declaration -- or deposition, on cross-examination, there were numerous questions that were asked of him, and I can get a citation to this but it's also in our surreply brief where he was asked about, you know, how would a person understand the 795 patent, how would a person understand Claim 1.

And what Dr. Berkland said is here on our Slide -- or I should say on Petitioner's Slide 51, Judge Fitzpatrick. You can see what our response was to that in our surreply, because they put that in. And what Dr. Berkland testified to is a POSA would have been able to, based on the teachings that are in the 795 patent to do that.

And I really want to focus you down on that last sentence there because I think it really addresses --

JUDGE FITZPATRICK: Can you help me? I'm on the slide. I see the depositions.

MR. PIVOVAR: Absolutely. On the right-hand side box, the last sentence begins, yet -- 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, I have not seen evidence that would lead me to believe that.

And that's because the Petitioner has never put in that evidence, right. There is no evidence anywhere of anyone knowing how to select an agave syrup the way that they're purporting to. And again, reiterating this, their expert said agave syrup has a viscosity of 212 Centipoise, like a person of ordinary skill in the art would understand agave syrup has a viscosity of 212 Centipoise.

That's at Paragraph 52 and Paragraph 119 of Dr. Crowley's declaration at Exhibit 1003. Why am I selecting anything, if there is only one value of agave syrup, according to Dr. Crowley's analysis, right? They talk about thicker and thinner. And we briefed -- and so, it's like they should have acknowledged there was more than one. Where is that one value coming from?

It's conclusory. We point out the error. Of course, we were prejudiced. We had no idea where it came from. Dr. Berkland testified on this very topic. Sorry, I have to get back to my slides, and I'll give you the slide number, Judge Fitzpatrick, in a second.

JUDGE FITZPATRICK: We're on 62. And so I have one more question about that before we go --

MR. PIVOVAR: Yeah, so just to flesh out the last point, and I'll get to your next question, Your Honor, if that's okay. On Slide 23 of our slides, the second bullet point says Dr. Berkland could identify any evidence from

within Dr. Crowley's declaration or exhibits to support the agave syrup of 212 Centipoise, right.

Dr. Berkland looked to try to find it. There is no pincitation anywhere in their briefing to that 212 value. We had no notice of that beforehand. We couldn't do any analysis. And they're saying, oh, just a mistake. It's inconsequential. Ignore it. It's not. It's, from our view, it's material and likely dispositive.

Sorry, Judge Fitzpatrick. You had a question about Slide 62?

JUDGE FITZPATRICK: Yeah, the last sentence there. I mean, you know, you might say this -- you'll probably disagree with this interpretation. I'm not saying it's my final or anything, but one way to look at the last sentence is to say that the prior art, in this case, the 4-Triple-6 patent and the W0133 disclosed they -- it says they disclosed appropriate viscosity range for an oral formulation of analgesic.

MR. PIVOVAR: I'm sorry, Judge. I hate to interrupt you, but I think I'm -- our slide, Patent Owner Slide 61, are you on? I'm sorry -- or Petitioner's?

JUDGE FITZPATRICK: Hold on. I must have misspoke -- 62.

MR. PIVOVAR: Patent Owner's or Petitioner's?

JUDGE FITZPATRICK: Patent Owner's.

MR. PIVOVAR: All right.

JUDGE FITZPATRICK: Sorry.

MR. PIVOVAR: Give me one second, thank you. I'm sorry. Okay, Slide 62.

JUDGE FITZPATRICK: So that last sentence, and I'll just read the whole thing because --

MR. PIVOVAR: Mm-hmm.

JUDGE FITZPATRICK: -- we'll get that out of the way. Quote, as both the 4666 patent and W0133 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, unquote -- or end quote.

To me, that is at least suggesting modification. And I assume you disagree with that, and now I want to know why.

MR. PIVOVAR: Well, I mean, it would be nice to know what that hypothetical modification would be, but that's not anywhere in the --

JUDGE FITZPATRICK: Well, well me at least put -- yeah, I'll put the spin that I think the Petitioner would put on, and that is that you would do what you need to to get to the viscosity ranges that are taught in either of the first two references mentioned in that sentence.

MR. PIVOVAR: Yeah, I mean, that kind of comes back to could somebody do it, not would they do it and why, right. And these are all things that are lacking in the petition and not spelled out at all. And --

JUDGE KATZ: So --

MR. PIVOVAR: Sorry.

ADMIN. JUDGE GARCIA: Mr. Pivovar, what about the petition on Page 4 at Footnote 1 does say that one can select the desired viscosity depending on the proposed use and it cites to Dr. Crowley's testimony?

MR. PIVOVAR: Right. I'm glad you that one up because that's part of our objection.

JUDGE KATZ: And I think that's what -- well, I think that Petitioner cited to that as being in their petition.

MR. PIVOVAR: Okay. So, I mean, one, it's in a footnote. It's nowhere -- discussed anywhere in any of their grounds, right, and the Board has a presumption against relying on statements in footnotes that aren't spelled out anywhere else, okay.

What is the other value of -- and I'm going to pose a hypothetical and get into this more. What's the other value of viscosity for agave syrup that Dr. Crowley is positing is there? There's none. He says it's 212, 212 Centipoise.

Now, I think the other thing I'd like to, Your Honor, really quickly, is to go to Petitioner's Slide 50, because this is one in which we have an objection. As you see this, this is them. And they say, agave syrup can be processed as organic, natural or raw to a thicker or thinner consistency. This is on the top of Slide 50 of Petitioner's slides.

And it says, thus, one can select the desired viscosity depending on the proposed use, Example 1003 at Paragraph 52. Now, that is the sentence from the footnote that you're referring to, right, Judge Katz?

JUDGE KATZ: It's what I read here.

MR. PIVOVAR: Right?

JUDGE KATZ: Yep.

MR. PIVOVAR: Paragraph 52 of Dr. Crowley's declaration never says that. It never says that. You see below that, it says, Dr. Crowley's declaration, and it has a truncated excerpt of Paragraph 52.

When we met and conferred on our objections, we said, at a minimum -- at a minimum, you should put in the entirety of Paragraph 52 so the Board can see that Paragraph 52 does not support that attorney assertion -- anywhere -- but they didn't, which is why we've objected to this slide.

Now, if you look at Paragraph --

JUDGE KATZ: Wait, can you explain to me why the highlighted part doesn't -- you can select the desired viscosity depending on the proposed use. One of --

MR. PIVOVAR: That's --

JUDGE KATZ: -- ordinary skill would have known that the viscosity can be further reduced by adding additional water to the syrup. That, I mean, it's about the same thing. It's about changing viscosity by -- it's about what one of ordinary in the art can do.

MR. PIVOVAR: Well, Your Honor, so first of all, one can select the desired viscosity based on the proposed use. That's talking about selecting an agave syrup with a given viscosity. It doesn't say anything there, it's not referring there to watering it down or adding additional water. That's a different reply argument that they raised.

And they raised this in conjunction -- they say, first -- and this is part of our notice, and I wish I had the pin cite available to us. It's not -- it's -- here right now, but they say first, right, in their reply, their new argument is, a person of ordinary skill in the art would know how to select am agave syrup and would know how to add water to the formulation as well.

That's a new argument. Those are two separate things. Footnote 1 here, at best -- at best -- is talking about the selection of the agave syrup. What that sentence is saying below that is, if I have a formulation I can add water, more water to it to get there, not the initial selection of the agave syrup.

So this comes down to the selecting, do I select 212 Centipoise or do I select 2560 Centipoise. That's what, as I read it, this -- but, of course, this is not there, and if we look at Paragraph 52 --

JUDGE KATZ: So just to step back, we're talking about a formulation of acetaminophen and agave syrup at a certain viscosity. And to change viscosity, what can you do?

MR. PIVOVAR: What can you do hypothetically?

JUDGE KATZ: No, in reality.

MR. PIVOVAR: In reality?

JUDGE KATZ: You were talking about Jello a minute ago.

MR. PIVOVAR: Yeah, anything. Anything, right? You can add things in it to thicken it. You can add things in it to thin it. You put stabilizing agents that might help to direct it toward something in-between. You could change the pH. That might change the viscosity. You could change the temperature and how it's processed and maybe that is going to change things.

You can do anything that's going to adjust that, right. I mean, the bottom line in all of this is, I have a formulation. What is it and what is its viscosity -- from the perspective of where we're at right now, right? That's kind of what the claims say.

JUDGE KATZ: Well the bottom line is sort of, we have -- we know we can use agave syrup to sweeten a formulation of acetaminophen and we have prior art that says if you want to administer it orally you should have a viscosity in this range.

MR. PIVOVAR: In what range?

JUDGE KATZ: 200 to 900.

MR. PIVOVAR: Exactly. So where's the formulation to have that, achieves that?

JUDGE KATZ: Well, but you just said, you can do a whole bunch of things to get to the 200 and 900.

MR. PIVOVAR: What somebody could --

JUDGE KATZ: You say, very easily.

MR. PIVOVAR: Could do, right, what they could do. What would they do? What is there in the petition that they're saying --

JUDGE KATZ: But this is not a method of making it, right. This is just a formulation claim.

MR. PIVOVAR: Why would someone make a formulation that would meet the 200 to 900 Centipoise viscosity under the articulations that the Plaintiff is -- or Petitioner is before here?

JUDGE KATZ: Because it wanted to administer it orally, because that was in the prior art, that there's reasons that we want to administer it orally.

MR. PIVOVAR: Absolutely, and oral administration of pharmaceuticals does not inherently fall within 200 to 900 Centipoise or 1000 to 3000. It could be 20.

JUDGE KATZ: Isn't that --

MR. PIVOVAR: It could be 4000. It's not necessarily going to fall into that range. That's the point.

JUDGE KATZ: Okay. Okay.

MR. PIVOVAR: That's the point. All right.

JUDGE KATZ: All right, I think you're -- are there anymore questions? I've sent you over all of these. All right, so 15 more minutes for --

MR. NOLAN: Your Honor's Brian Nolan, Mayer Brown on behalf of Petitioner again. Just a few points to address the counsel's address. First, you kept on hearing it's not necessarily present. That is the case law for inherent art to -- inherent anticipation.

You have hit it right on the head, Judge Katz, is there is a specific teaching of the viscosity ranges that they are -- that are claimed. These are viscosity ranges that the 795 patent admits are typically used with oral formulations.

He keeps on asking, why we would somebody do this? Well, you have, you know that a liquid formulation needs a viscosity, and it has to be pourable and drinkable. All of these references, they talk about all liquid formulations for a specific patient population, pediatrics and elderly. They talk about taste masking. All of them do, even the ones without agave do.

They're all addressing the same problem. The viscosity ranges in this 4666 patent and the viscosity ranges in W0133, they're in there for the function of being able to be pourable. That's exactly the function that they would be serving in this combination.

And so it's known solutions, known ingredients being used for precisely the functions that they were used in the prior art. This is absolutely what KSR tells you. That is the motivation and that is the expectation of success.

So when he asked you, why would they do it? They would do it because this is what the prior art is telling them. When you want to make

oral formulations and you want to address these patient populations, and you want to use natural ingredients, FR458, W0742 tells you acetaminophen, agave syrup in suspension with a diluent. The secondary references give you the viscosity ranges.

Again, I would like to just point out we heard a whole listing, and if we could just pull up our Slide 85, we heard a whole listing of what agave -- I mean, what agar-agar would do and what these other excipients would do. And I would just to you, Your Honor, that that's just all attorney argument.

Their expert couldn't answer those questions at the deposition. And I point to you, Petitioner's Slide 85, on the right side here, when I asked him about, to tell us how the excipients would impact this. And I said, if you knew the agave syrup you had in there, would you expect the formulation to be below a certain viscosity? And he said, no, because he didn't know what the agar-agar would do or the gums would do.

So everything that you heard from my opposing counsel here, that's not what Dr. Berkland testified to. Those are new arguments, that they're trying to say, oh, for, somehow, because you have the other viscosity altering agents in there, that this somehow makes this non-obvious.

It's wrong because it's a comprising claim. It's wrong because we're not offering an inherent anticipation argument. We expressly said we don't need to do that. And it's also wrong because this is, again, the folly of he's trying to limit it specifically to only the Example 1.

And if we could go to -- and I believe, if we can pull up Slide 34 of Petitioner's arguments, you can see here, this is the summary of the invention of FR458. It says that you have an oral administration based on syrups with low glycemic indexes. It can be agave syrup alone or in

combination with other syrups. It talks about, throughout this, that the claim itself -- and we cite this all in our petition.

Now, they said we didn't make this combination. And if, I believe if you look at -- sorry, if you look at the petition, on 29 through 30, in that section of petition, this is where we're dealing with the claim. And we're dealing with the claim term, a pharmaceutical syrup formulation for oral administration, talking about Claim 1 in our combination of FR458.

And we talk -- we specifically point to these disclosures. So we didn't just limit ourselves to Example 1. For the oral formulation, we pointed specifically to these disclosures of Lines, you know, one, Lines 4 through 7, three lines, 58 to 68 and Claim 1. So it's not just whether or not you can put in the viscosity ranges of the secondary reference into that sole and specific reference.

Again, this is the case law that is in Re: Keller which says it's a combination of teachings. It's not physically pushing this all together. And that is, again, at 642 F.2d 413, 425 (CCPA 1981).

Another point, when they talk about agave syrup and they say that Dr. Crowley stated that this is it -- it is only 212 -- again, that is wrong. As, if you look at Exhibit 103 at Paragraph 68 and 93, you'll see that he, again, he acknowledges, talks about agave syrup can have thicker or thinner consistencies.

That testimony of thicker or thinner consistencies is saying it has a range of viscosities, so we're not limiting it to 212. And even if you read -- and I apologize to Ms. Lafayette, if you can go back to, because you were just on Paragraph 52 -- if we look at what Paragraph 52 says, it says the

viscosity of agave is reported to be around 212. It didn't say the viscosity of agave syrup is 212. It said, it is reported to be. And that's absolutely true.

Yes, were erred in the citation, but there's no dispute that in 1030 it reports viscosity of agave syrup at 212, and in 1031 it reports it at a different rate. But again, this comes back to the formulation. The formulation here is what is the formulation of -- the viscosity of the syrup formulation.

And the secondary references teach that. And you've identified, and as we pointed to, a POSITA would know how to modify those references. And I believe if we can pull up -- and I'd like to just take, just go to our Slide 52 quickly because we also heard about a whole host, about the importance of selecting the specific viscosity of the agave syrup.

Well if that's very important, there's not a single mention of it in the patent, what type of viscosity you need for agave syrup. The only mention of viscosity in the patent is the statement, "To use viscosities for the syrup formulations that are typically used for those formulations."

So if the selecting the agave viscosity was so paramount to this invention, it has been lost in the specification. It is no -- it doesn't exist anywhere in there. And again, I appreciate my opposing counsel's arguments here. He has a difficult row to hoe here. You have nailed it.

We have the prior art teaching this formulation. And we have the prior art showing you precisely what level of viscosity you want. And so, and then finally, and I think you talked about this -- and if we go back, if we just walk through 52, this paragraph again.

So not only does it say, "it's been reported to" if you go further up in that paragraph, it talks about there are several grades of agave. So it's not saying there's one type of agave syrup.

Again, he notes what it's been reported to, and then he states -- and I think if you go down to the next page on this, he says that a person skilled in the art would have known that the viscosity of agave syrup can be further reduced by adding additional water, that you can control this.

And I think this is actually consistent with what Dr. Berkland has said. And we both point to that slide, and it's our Slide 51, I believe. But if you read what he's saying, he's saying, yes, if a POSITA was given an agave syrup with a certain viscosity, they would know how to make the formulation.

Now, he did posit, he said, they would know how to make the formulation because the 795 patent gave you a target range of viscosity you want to fulfill the formulation. But again, I will leave you with this, that target range that I gave was the range that it admitted was typically used for oral formulations.

It's the range that -- and if we could just go to Slide 21. The patent is right. These viscosity limitations are those that are typically used. You see it in the chart over there. There's nothing new, novel or anything about these viscosity limitations for the formulations. There's nothing in this patent about the importance of selecting the agave syrup viscosity.

And their expert acknowledges and our expert also testified that a person skilled in the art would know how to modify the viscosity to get to the desired viscosity of the final formulation.

I don't want to take up, go over my time, but if you have any other questions or if there's anything that counsel has raised that you think that we have not properly addressed, I certainly could respond to those few right now, Your Honor.

JUDGE MITCHELL: One quick question. Are you really arguing an obvious to try, that like there's just limited amounts, limited choices, you know what's in the prior art, it'd be obvious to try this particular formulation?

MR. NOLAN: I don't think we are really arguing obvious to try because I think that this is exactly -- what we're arguing is, you know, you have the same problem that's in the art. These patents -- the prior art -- and it just so happens that the 795 kind of talks about the same problem.

But on prior art, and why you would combine them, why a person of skill in the art would know they're coming from the same field of endeavor is our prior art references all talk about these problems.

They talk about the problem with solid dosage forms. They talk about the problem for patients of -- the elderly and for pediatrics. They talk about the problem with bitterness and tasting. So all prior art are all talking about the same issues. And so that's why you would combine them.

This is not obvious to try. These are the problems. And they're coming up with the same solutions. And so FR458 give you the solution of agave syrup-acetaminophen suspended therein, a diluent, the benefit of these natural products. And it'll be a sweetener and it will overcome the taste masking.

And then, again, although not agave syrup, W0133 talks about, I think that talks about acetaminophen again in a suspension, having the need to taste mask. And the reason you're doing this is for pediatric patients and elderly patients.

I believe that 4666 is an analgesic. In this instance, it's more ibuprofen than it is acetaminophen. But again, suspending that and the need to taste mask because you have the patient population.

So this is, again, I would just point the court, this is on all squares, I think, with *Intel Corp. v. Pact*, 61 F.4th 1373 at 1379 (Fed. Cir. 2023) where the Federal Circuit talked about you're dealing with the same problems.

These prior art references are addressing the same problems. They're coming up with solutions. This is, you know, again, the picture child for KSR of why you would combine them with that reasonable expectation of success. This is not just willy nilly could you do it, the question of would you do it.

Under the appropriate federal case law, this meets the standard of this is why there would be the motivation to combine and the expectation of success and why all of these claims should go down as obvious in view of KinderFarm, Petitioner's perspective.

If there's anything else, I can respond to that. If not, I'll give back the last two minutes of my time.

JUDGE FITZPATRICK: I have one question. I see all the references to agave syrup being not limited to a specific viscosity. I also see, obviously, you've talked Petitioner's focus in the petition on 212. Why did Petitioner focus on 212?

MR. NOLAN: Your Honor, we asked the expert to put his declaration together. He put his declaration together. That's one of the references that he cited. He did recognize thicker or thinner. I think he just under -- that's something that he saw.

It was in an article that he thought was appropriate. Unfortunately, it was mis-cited. He didn't -- and he cited to the abstract that has a different level. I don't think he meant to kind of focus on it.

What he was just trying to, and I think gets the point across, is when we had asked him would Example 1 have the viscosity and the range and he said, you know, it very well could because agave has been reported to be 212.

But again, we said, that's fine. But we don't need to get to that point because we have the other references that tell you what the formulation would be. So I think it was just more, he had selected it. And I can tell you right now, I wish he had just said agave syrup has a range consistent with how he said in those other ones as opposed to pulling out.

But when the expert gave us his declaration, it was his declaration, and that's where we went and unfortunately, there was that one error in it, so we apologize for that one issue.

JUDGE FITZPATRICK: Thank you.

MR. NOLAN: Thank you, Your Honors, and thank you for your time. We appreciate your thoughtful consideration on behalf of our client, KinderFarms.

JUDGE KATZ: Okay, rebuttal for Patent Owner?

MR. PIVOVAR: Thank you, Your Honor.

JUDGE FITZPATRICK: And while you're getting set up, if I could start off with a relating question. What would be the problem or what would be your case, if Petitioner had left it vague and did not add those references to 212 in the petition?

MR. PIVOVAR: That -- so, I'm sorry, can I ask a clarifying --

JUDGE FITZPATRICK: So Petitioner's pointed to teachings in the prior art, basically final viscosities that are advantageous or known in the use for oral formulations, you know, medicine, analgesic medicines. And the Petitioner does point to that stuff.

But Petitioner also points to 212 as a starting point. What if they did not -- what if the Petitioner just omitted that sentence or did that?

MR. PIVOVAR: Yeah, I understand what you're saying, Your Honor. So here, there's clearly no reasonable expectation of success under 212, right. Our expert has said 2560, no reason why -- and this is in the context of Example 1 or whatever they have. That's obviously not the petition we have here.

They would have had to have shown that a person would have been able to construct a formulation. There's a lot of discussion of this formulation. I don't know what's being discussed under than this formulation. When I think about the petition it's the examples of the two prior art references.

But they would have had to have shown that there would be an agave syrup you could put into that that would work, right. And there is going to be, probably -- and I don't know this for sure, but I'm thinking of something like the Goldilocks Zone, right. Two low, it's not going to meet your combination. Too high, it's not going to meet your combination. Where does that play out?

And I think this comes a little bit back to Judge Mitchell's question of obvious to try. And we don't have any information here about result effective parameters and how you're going to do this optimization. They never said that.

We never had to get there because they just said -- and I want to be clear here, Your Honor, agave syrup has this viscosity of 212, just like you said. And if you look at -- I don't know if you can see my screen, Your Honor, but if you look at Exhibit 1003 at Paragraph 119, you heard --

JUDGE FITZPATRICK: Give me one second. I had it open. Let me just scroll to it.

MR. PIVOVAR: Yeah, it's on Page 71 of 242.

JUDGE FITZPATRICK: Yep, yep. I'm there.

MR. PIVOVAR: Right, so you just heard Petitioner's counsel get up there and, like, oh, I don't know, you know, where -- and all he said is it's been cited to have a viscosity of 212.

And this is why I point out not just Paragraph 52 but Paragraph 119 where he says, as I previously noted in Paragraph 52, a person of ordinary skill in the art would have known that agave syrup has a viscosity of around 212, right, that's his direct testimony.

You just take that at face value. All this attorney explanation trying to say, no, we didn't really do that is just wrong, right. And this is the whole problem we have with the petition, Judge Fitzpatrick, is that they hinged it on 212.

And if they have to say, well, if they didn't do that, then what's the viscosity value that you would select that would give you a motivation to combine for a reasonable expectation of success with the specific viscosity ranges in the secondary references.

You heard a lot about typical viscosity of these formulations. Let me just come back to our slides, Your Honors, at Slide 99. And this is a quotation from Dr. Crowley's report, right. And he's saying that suspensions

having a viscosity range of 20 to 150 are considered readily pourable. He explains that higher viscosities are generally not desirable, and that you don't want to have a high viscosity because it could impair the dissolution characteristics of immediate release of acetaminophen, right.

So this is saying, like, okay, well maybe you would want a typically readily pourable viscosity of 50 -- or 20 to 150 Centipoise or a really thin one, right. That could be one that you could look to have. That would not satisfy their proposed combination, if you did that, right. That's the whole point. It's not inherent that you would get the viscosity ranges that are in the references they're proposing.

We're not saying that 20 to 150 here wouldn't be a viscosity that you could have for an oral formulation, just that it doesn't work in the grounds as they proposed it.

And then I would like to just lastly go back to Judge Fitzpatrick's last question to opposing counsel. And Judge Fitzpatrick, if you'll please go to and, of course, all Your Honors go -- you'll see it on the screen. Go to Exhibit 1003, Paragraph 216 on Page 119.

JUDGE FITZPATRICK: Okay, I'm there.

MR. PIVOVAR: All right, and if you scroll down, in about the middle of that, it's -- and again, this is Petitioner's expert. And it says, "Such a person" -- do you see that kind of around the middle of where it starts?

It says, "Such a person would also know that agave syrup can have a viscosity of around 200 Centipoise which is well under 1500 Centipoise." Right, where is the 1500 Centipoise coming from? It's coming from the claim, right. They're using hindsight saying, we're going to select 212 because it falls within the claim, and we're going to start there.

We're going to ignore agave syrups that could be higher, that might not get us there because we believe if we start in the claim, we'll stay in the claim. And you can see that in all their assertions under Paragraph 119 and in their motivation to combine for the viscosity limitations.

And I see I'm over my limit, but if there are any further questions on that, I'd be happy to address them. Other?

JUDGE KATZ: Judge Mitchell?

JUDGE FITZPATRICK: No further questions, thank you.

MR. PIVOVAR: On behalf of Patent Owner and myself, thank you very much.

JUDGE KATZ: All right, okay, thank you to everybody. I think we are aware of your positions and we also want to thank Ms. Lafayette for your participation. That was great. And we will take the case under advisement and issue a decision in due course. All right, thank you all.

MR. NOLAN: Thank you, Your Honors.

JUDGE KATZ: Thank you.

MR. NOLAN: Have a good day.

JUDGE KATZ: You too.

(Whereupon, the above-entitled matter went off the record at 3:00 p.m.)

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