

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MARINUS PHARMACEUTICALS, INC.,
Petitioner,

v.

OVID THERAPEUTICS, INC.,
Patent Owner.

PGR2023-00020
Patent 11,395,817 B2

Record of Oral Hearing
Held: May 22, 2024

Before JEFFREY N. FREDMAN, ZHENYU YANG, and TIMOTHY G.
MAJORS, *Administrative Patent Judges*.

APPEARANCES:

ON BEHALF OF THE PETITIONER:

MARTINA HUFNAL, ESQ.
Fish & Richardson P.C.
222 Delaware Avenue, 17th Floor
Wilmington, Delaware 19801
302-652-5070
hufnal@fr.com

ANITA L. MEIKLEJOHN, Ph.D.
KATIE E. HYMA, Ph.D.
Fish & Richardson P.C.
One Marina Park Drive
Boston, Massachusetts 02210
617-542-5070
meiklejohn@fr.com

ON BEHALF OF THE PATENT OWNER:

RYAN V. McDONNELL, ESQ.
ERIN M. SOMMERS, Ph.D.
KAITLYN S. PEHRSON, ESQ.
ANTHONY C. TRIDICO, ESQ.
Finnegan, LLP
901 New York Avenue, NW
Washington, DC 20001
202-408-4000
ryan.mcdonnell@finnegan.com

The above-entitled matter came on for hearing on Wednesday, May 22, 2024, commencing at 1:00 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P-R-O-C-E-E-D-I-N-G-S

1:00 p.m.

THE CLERK: All rise.

JUDGE FREDMAN: Good afternoon. This is the final hearing in PGR2023-00020 which is Patent Number 11,395,817. I believe the petitioner is Marinus Pharmaceuticals and the patent owner is Ovid Therapeutics. The hearing is open to the public, I think. And a full transcript of the hearing will be made part of the record in due course. I am Judge Fredman, I'm with Judge Yang, and Judge Majors. Counsel for the petitioner, would you kindly identify yourself and your colleagues?

MS. HUFNAL: Good afternoon, Your Honor. My name is Martina Hufnal from Fish & Richardson. With me today are Anita Meiklejohn, and Katie Hyma, also from Fish & Richardson, and Martha Manning, general counsel for Marinus.

JUDGE FREDMAN: Thank you, very much. Counsel for Patent Owner, would you identify yourself and your colleagues?

MR. MCDONNELL: Good afternoon, Your Honor. My name's Ryan McDonnell from Finnegan, Henderson. I will be arguing along with my colleague Erin Sommers, and with us as well is Kaitlyn Pehrson and Anthony Tridico.

JUDGE FREDMAN: And so you're our LEAP participant, right?

MR. MCDONNELL: Yes.

JUDGE FREDMAN: Thank you. So it sets forth in the April 15th, 2023, oral hearing order, you each have 60 minutes, you will get an additional 15 minutes as the LEAP practitioner. We'll try and keep track of

1 time, but I suggest you guys do the same. So Counsel for the petitioner, do
2 you want to reserve any time for rebuttal?

3 MS. HUFNAL: Yes, Your Honor, 15 minutes.

4 JUDGE FREDMAN: Okay. I guessed right. And then Counsel for
5 Patent Owner, how much would you like to reserve?

6 MR. MCDONNELL: We would also like to reserve 15 minutes.

7 JUDGE FREDMAN: Fifteen minutes. Okay, thanks. So looking
8 forward to your presentations, we're familiar with them. My colleagues are
9 probably going to not be able to see the demonstratives as easily as I can. So
10 you may want to just give the demonstratives numbers so that they can, you
11 know, have that, so they can look it up on their computer.

12 Also mute your microphone when you are not speaking, don't
13 interrupt the other party, save objections. Petitioner will go first as you bear
14 the patentability of showing the version of patentability. And you can begin
15 when you are ready.

16 MS. HUFNAL: Thank you, Your Honor, may it please the Board. As
17 I mentioned, my name is Martina Hufnal representing Petitioner Marinus.
18 I'm going to start, actually, and I'm going to jump around within our slides,
19 so I will absolutely make a point to call out the slide number. I would like to
20 start on Slide 7, just looking at the remaining challenged claims. There are 8
21 claims that remain, 23 were disclaimed.

22 JUDGE FREDMAN: Okay. Start here.

23 MS. HUFNAL: Excuse me, Your Honor?

24 JUDGE FREDMAN: No, just we had to push start, I'm sorry. No,
25 you can keep going, I'm sorry.

1 MS. HUFNAL: Okay. So I am -- all of the remaining claims depend
2 from Claim 21. I'm going to talk about the claim in two buckets, Claim 22 is
3 in one bucket and then the Claims 25 to 31 are in the other bucket. They
4 contribute that of the dosing mgs per day, whereas Claim 22 is the efficacy,
5 the result, the efficacy result.

6 So in terms of presentation, my 45 minutes for opening, I'm going to
7 start with claim construction, the two claim construction terms. And then
8 I'm going to go on Claim 22 and hit anticipation, focusing on the efficacy of
9 limitations, very briefly talk about obviousness.

10 Then I'll flip over to the other bucket, Claims 25 through 31, very
11 briefly talk about anticipation and obviousness. There I'm going to focus on
12 what I think is really the heart of the issue, which is the unexpected results.
13 That's where a lot of the briefing has been and I wanted to talk about some
14 statements in the Institution Decision.

15 And really just to, while these claims are up here, to underscore that
16 the fundamental issue, the Patent Owner's claims are directed to mgs per
17 day. That's what the claims are, and they're broad, they're not limited to a
18 bolus or no bolus, they are not limited to any particular infusion rate or time
19 or anything, just to give a total number of mgs per day.

20 The unexpected results, the work that Petitioner did and discovered,
21 was that you have a very specific plasma profile, so now we're talking
22 nanograms per milliliter. If you do bolus, get the plasma up very high, and
23 then you keep it up above 500 for eight hours, that was the unexpected result
24 that we see in the Houlihan Declaration, that resulted in the rapid and
25 persistent suppression of SE with that recurrence right after the taper.

1 So the claims are different, quite broad, and therefore fundamentally,
2 there's no nexus, the claimed unexpected results that the Patent Owners try
3 to point to.

4 So let me go inside claim construction. I'll start with patient, and let's
5 look at Slide 9, please. So in Slide 9, we put up the claim, Claim 21, the
6 term is "administering to a patient in need thereof" or just a patient.

7 I don't think it really matters how you, what the quote "term" is that
8 you are construing here, the key is the specification gives us guidance as to
9 what the term patient means, it specifically says human or non-human, and
10 limiting the claims to only human is just not --

11 JUDGE FREDMAN: So in their arguments, I think they're going to
12 talk about the term administration versus, you know, other terms. What do
13 you say about that?

14 MS. HUFNAL: It's interesting, because they try to stay with treating
15 and administration.

16 JUDGE FREDMAN: Right.

17 MS. HUFNAL: But both of those words are in the claim.

18 JUDGE FREDMAN: Right.

19 MS. HUFNAL: Right, so that's a very classic treating as far as
20 human, but administer, is this for a rat? But the claim itself says both
21 treating and administering. So I'm not really sure that, you know, gets them
22 to where they need to be. And there was actually a recent A-R-P decision,
23 actually Friday of last week, looking at a similar claim term, treating a
24 patient, that I think gives guidance as to this term as construed, especially
25 when in a specification it says human or non-human, it just needs to be
26 consistent with that.

1 JUDGE FREDMAN: Okay.

2 MS. HUFNAL: All right. So I'm going to move on to the next claim
3 term, unless Your Honors have any other questions.

4 So the next claim term is one that did not come up in the Institution
5 Decision. This term came up in the Patent Owner's response, and I think
6 the, I think it was like 13. The reason I think it came up is an argument
7 around the, when we talk about anticipation of Zhang, there's the dosing
8 every 2 hours. This claim construction I think is trying to get around that,
9 because they want the final dose in 8 hours after that.

10 JUDGE FREDMAN: Right.

11 MS. HUFNAL: But looking at the constructions that are being
12 proposed, the claim term itself says "Improvement -- to the patient after
13 administration for more than 8 hours." What the Patent Owner, and I put on
14 Slide 13, Patent Owner's proposal for us, since they brought this up, and
15 there's two sort of fundamentally wrong things here.

16 One is they switched the order, so they're re-writing a claim. So it
17 says "improvement to the patient after administration." In Patent Owner's
18 construction, they change it to "improvement to the patient more than 8
19 hours after the administration." And I, that is a difference with meaning
20 here.

21 And then the second problem, is they insert this phrase "full dose."
22 And putting aside the "full" for a moment, "dose" doesn't even appear on the
23 claim. So it's inserting this concept of dose, which is, it's different. Now
24 they're trying to re-write this claim as just something it didn't say before. So
25 as to --

1 JUDGE FREDMAN: So the terms that you're trying to make the
2 argument, that essentially after administration for more than 8 hours is after
3 a potentially disturbed administration, not succession of administration --

4 MS. HUFNAL: Correct, Your Honor.

5 JUDGE FREDMAN: -- after termination?

6 MS. HUFNAL: Correct. That's fundamentally the difference. Our
7 position is, and I can walk through the specification where it gives us some
8 guidance on that. But, you know, these are infusion treatments. It makes
9 logical sense that you are looking at the improvements, not after done all of
10 the administration. But I mean, can also look at that. But it does need to be
11 limited to that, you're looking for improvements immediately.

12 JUDGE FREDMAN: I mean, in Exhibit 2003, I think it is, they do
13 have, they do both, right, in Table 1?

14 MS. HUFNAL: Correct.

15 JUDGE FREDMAN: Right, they looked at it and after it, a
16 completion of infusion and Table 2, I was looking at the wrong one, I'm
17 sorry, Table 2, right. Table 2 shows sort of three lines, right. No escalation
18 during 24 hours following infusion initiation, status free during 24 hours
19 following infusion initiation, and then no escalation to IV or a third line IV
20 anesthetics during, you know, first of all, it's relapse during, you know,
21 compare as by infusion completion. So it distinguishes between them here.
22 It does both, it measures both.

23 MS. HUFNAL: Agreed, Your Honor. And that is, that last one, 24
24 hours after the infusion is complete, of course that infusion was multiple day
25 infusion. That's the unexpected result that we're going to get to, right.

26 JUDGE FREDMAN: Right.

1 MS. HUFNAL: The SE's going to come back, right, and so that --

2 JUDGE FREDMAN: Right.

3 MS. HUFNAL: But the claim here that we're talking about in the
4 patent, that concept is not discussed at all. So I would like to point the
5 Board to a few places where we get guidance in the patent.

6 So we have this definitional section in the -- in the patent, so it starts
7 at Column 29, that's where the patient, Slide 14, thank you. Yeah, where the
8 term patient we saw, there's also a definition of improvement.

9 And that is at Exhibit 1001, Column 29, Lines 57 through about 60,
10 "Improvement refers to the treatment of symptoms or conditions associated
11 with epileptic disorders, measured relative to at least one symptom or
12 condition of a metabolic disease." Right. So we're looking at improvement
13 of treatment versus what would you have had with the disease.

14 JUDGE FREDMAN: Okay.

15 MS. HUFNAL: There's a little bit more guidance. Well, what does it
16 mean by symptoms? We can look at Column 13, I'm sorry, Column 9. And
17 here it's talking about what an effective amount or therapeutically effective
18 amount of a dosage can be, this is around Lines 17 down through 26. But
19 it's instructive.

20 It says, "A dosage sufficient to treat, inhibit, or alleviate one or more
21 symptoms of an epileptic disorder, such as reducing the frequency or
22 severity of seizures, reducing the behavior of abnormalities, providing
23 desired pharmacologic and/or physiologic effect." In short, it's a very broad
24 understanding of what we're -- we're talking about symptoms. There could
25 be all kinds of symptoms. This patent is contemplating all of them.

1 Now have you measured these symptoms? The patent also gives us
2 some guidance on that. And that's at Column 9, Line -- and Slide 15, I think
3 we have the callout, Column 9, Lines 43 through 45. "In embodiments, the
4 symptom, pharmacologic, and/or physiologic indicator," that's what we just
5 talked about, "is measured in a subject prior to treatment," and that's what
6 we saw earlier, you want to see what it looks like in the disease, "and again,
7 one or more times after treatment is initiated."

8 And so that is the guidance that we have in the specification as to
9 what this term means, and the basis of our construction. So I will move on
10 to anticipation.

11 JUDGE FREDMAN: Please.

12 MS. HUFNAL: Okay. All right. So this is Slide 19. And on Slide
13 19, it's got the Claim 21 and 22. And very briefly, you know, Claim 22, it's
14 a method of treating SE, administering to a patient in need ganaxolone
15 intravenously, those are kind of the high level of Claim 21.

16 In terms of Zhang, anticipating all of those limitations, it does. We
17 can go to Slide 20, and really we have some callouts in the papers, there's
18 callouts, but I think it's always helpful to just look at the title, to begin with.
19 The title of Exhibit 1009, the Zhang reference, is "Intravenous Ganaxolone
20 Formulations and Their Use in Treating Status Epilepticus and Other Seizure
21 Disorders."

22 The patent, because I say this, I believe we might hear that what's
23 unclear, what Zhang actually teaches or what disorders it teaches. And there
24 are multiple places, and I guess I will stand up on rebuttal if we hear some of
25 that, multiple places where Zhang leaves it quite clear that treating SE with

1 ganaxolone intravenously. So that's Claim 21. Oh, I'm sorry, let me just --
2 let me just finish.

3 So Paragraph 29 of Zhang talks about these injections being
4 intravenous. Claim, or Paragraph 69, which is under a methods of treatment
5 section in Zhang, says it's disclosure for treating status epilepticus using
6 ganaxolone to a patient suffering these disorders.

7 And what does Zang say about patient? Very similar, Paragraph 22 of
8 Zhang says a patient is a human or non-human animal in need of medical
9 treatment. And so Zhang teaches critically, I think, human dosing, a human
10 treatment of SE, in addition to what we're going to talk about Example A or
11 the rat. But I don't want it to get lost that Zhang itself is true teaching,
12 supposedly teaching a human.

13 All right. So what about the clinical results? And here in Claim 22,
14 we say the pharmaceutical composition provides improvement to the patient
15 after administration of more than 8 hours. And this is the natural result of
16 the administration.

17 JUDGE FREDMAN: So the concern, I think is, right, that there of
18 course, is efficacy in over 5 hours, right. So we don't even know what
19 happens in 8 hours if you left them alive in the context of Zhang itself. Now
20 the statements from your -- including, I think, Dr. Ragowski, where he says
21 and this is, I think, at Page 155 of his deposition, that "I think it's possible
22 there could be improvement, there might not be improvement. When one is
23 treating a medical condition, there is always a degree of variability and one
24 doesn't expect a certain outcome."

25 That says it's unpredictable, at least not perhaps necessarily the case,
26 right. And I think the Federal Circuit is pretty consistent in saying that from

1 here we have to have a necessarily standard, it's not enough to say that it
2 may be, or may even likely be, it has to necessarily be. And he's kind of not
3 agreeing with the position you just took.

4 MS. HUFNAL: So I, there's a few responses to that. I don't think he's
5 saying anything inconsistent with what I would submit is the correct
6 framework, which is in the Bristol-Meyers Squibb case, the natural result.
7 What is the natural result when you have a full treatment taught in the art,
8 the whole thing is taught in the art. The rat has SE, you are treating the rat
9 with the relevant dose, all of that's taught. If you have a natural result from
10 that, that is anticipated by such a reference.

11 And now as to, so I think that is the proper framework, the legal
12 framework to be analyzing this. The issue that necessarily must, you know,
13 occur, the cases that have been cited, one of them, the Allergan case. So that
14 was eyedrops, and the molecules but not across, and the prior art was it was
15 for glaucoma, you put it in your eyes to treat glaucoma. In the clinical
16 studies, they realized some people were growing eyelashes, like beautiful,
17 long eyelashes.

18 And the court there said, they're growing eyelashes when it's hitting
19 the skin, but when you're treating glaucoma, you are putting it in the eye.
20 And it doesn't always necessarily hit the skin, so you're not always going to
21 get the eyelash growth.

22 JUDGE FREDMAN: But there, like Perricone, for example, right, is,
23 you know, sunburn versus suntan, right. And where the treatment when you
24 treat sunburn, everyone has skin, right. So everyone has skin so they always
25 have suntan, not everyone has sunburn.

1 As far as because it wasn't necessarily the case, they didn't find that
2 medically they anticipated it for a sunburn I think, and they did find it for
3 suntan. And here is the same kind of distinction, right.

4 We have, well, I mean, there are people who may have, I mean,
5 patients who may, according to your expert, be treated intravenously with
6 ganaxolone, and it may work, you know for 6 or 8 or 20 hours or whatever,
7 and it may be that lower for some of them. I mean there's no dosing given
8 here, right, in the claim. So potentially low enough doses also would only
9 work for some limited time.

10 MS. HUFNAL: So and I think maybe there's two, two issues --

11 JUDGE FREDMAN: Zhang doses using 1 mg per kg, right. So we
12 don't know necessarily, right, that a milligram, you know, and a well, kg
13 goes too small, but in a five kilogram baby, if they have the disease, if they
14 would -- 5 mgs would be sufficient to actually talk to, it would give us an 8
15 hour result.

16 MS. HUFNAL: So what we know from Zhang is it, in Example 8,
17 there was an actual, you know, rat that has SE, it was dosed with 12 and 15
18 mgs per kg at 15 minutes after onset, okay. And all of those steps happened
19 up top. Yes, they were sacrificed at 5 hours. But we know what the natural
20 result is of that dosing at that time, we know what the result of that was at
21 some point after 8 hours.

22 JUDGE FREDMAN: How?

23 MS. HUFNAL: That's the Saporito paper --

24 JUDGE FREDMAN: But Saporito's not in the one, in the patient
25 reduction, right. I mean, the 103 yes, that's a separate question. You know,
26 Saporito does prove things that are not proven in Zhang. In Zhang itself, it

1 does not show that right, I mean, it's, we could -- we could say that, yes,
2 there is evidence in the record, I guess, but there's not evidence in Zhang.

3 MS. HUFNAL: So I think that the law is it doesn't have to be taught
4 in, and you're going to ask me what case is that?

5 JUDGE FREDMAN: No, not really because Zhang would often use
6 two references, I mean, to the case that went on appeal for me, I used three
7 references and any grounds to show evidence of a fact. But I never really
8 made that argument. Is that -- can you find that argument in the Petition?
9 Okay.

10 MS. HUFNAL: No, it's all right if that's a different question, I can
11 answer that question.

12 JUDGE FREDMAN: I know it's a different question.

13 MS. HUFNAL: Yeah. So this came up both really in the Institution
14 Decision and I read -- I read the Board's Institution Decision as inviting
15 additional evidence on a particular issue, a specific issue. And that's one of
16 the reasons, like with that Institution Decision at Page 28 saying that either
17 party could submit evidence showing a period of time for which the doses of
18 ganaxolone necessarily remain effective in more dose with the patients.

19 JUDGE FREDMAN: Yeah, okay.

20 MS. HUFNAL: Okay. And it also, additionally we, this came up
21 because of the claim construction argument that came up in the Patent
22 Owner's reply which is really addressed to the, you know, the 2-hour dosing.

23 JUDGE FREDMAN: Right.

24 MS. HUFNAL: So this was not a kind of hiding the ball, this was a
25 evolution of the discussion, I would say.

26 JUDGE FREDMAN: Okay.

1 MS. HUFNAL: All right. So did I answer all of the Board's
2 questions on, I guess I will just circle back on, well, let's look at the
3 Saporito, sorry, I always say that wrong, Saporito Poster. And I just want to
4 call out the, you know, have these two line up.

5 So we saw in Zhang, which is teaching the 12 mgs/kg at 30 minutes
6 after, 15 or 16 minutes after onset. And this is Slide 22, and then we can
7 look at Slide 23, and this is Exhibit 1013, the Saporito Poster 1, and you can
8 see 12 mgs is one of the exact doses that is also in Saporito, you can see the
9 60 minutes is at both 15 and 60 minutes, and this is on the righthand side of
10 Figure 3 of the Saporito Poster.

11 Those are, you know, the exact same time points of when the
12 ganaxolone was administered, they are both administered intravenously, and
13 as you can see, the vehicle, all the way over on the left of both of those
14 charts, is, you know, hovering around 40, less than 40 percent survival at 24
15 hours, and with the ganaxolone, the natural result of administering just that
16 one bolus dose, right, shows that there is significant increase in survival at
17 24 hours.

18 The same, similar type data, is the data that's in the '817 patent, which
19 the Board actually looked at for the Institution Decision. That the only
20 reason I start with Saporito is because the '817, the doses weren't exactly the
21 same, it's 10 and 20 with bracketed the doses in Zhang.

22 But if we look at Table 2 and this is Slide 24, Table 2 in the '817
23 patent has 10 mgs/kg and 20 mgs/kg and you see it, and just bolus dose,
24 right, one dose, and 24 hours later you see a 90 percent survival rate versus
25 the vehicle, which is 72. And that increase in survival rate, it's the natural
26 result of just administering this one bolus, which is completely taught in

1 Zhang, and that is, I don't think there's any dispute that that is an
2 improvement as contemplated in the claim.

3 JUDGE FREDMAN: What about Saporito in terms of the motion to
4 exclude at all, or?

5 MS. HUFNAL: I'm happy to do so. I think that Mr. Saporito set out
6 in his Declaration that the facts of this case are quite different than a lot of
7 the cases cited regarding, you know, indexing, and a library. The closest
8 case, that I've, we've seen in the briefing is In re Klopfenstein, and the
9 factors that you look at there are, you know, how many people were there.
10 And here the evidence is --

11 JUDGE FREDMAN: Yeah, I think the issue for this, the strongest
12 issue for Patent Owner, would be the question whether it's the same
13 document. So, I mean, do you want to address that?

14 MS. HUFNAL: I think that is just --

15 JUDGE FREDMAN: Because the ownership is slightly different, or
16 the authorship is slightly different it sounds like, and those sorts of things?

17 MS. HUFNAL: No, no. It was, I think the test, the first declaration,
18 the posters were made bigger so it spanned like four pages, and there were
19 some question, was that really the poster. And we submitted, to show,
20 submitted the supplemental declaration of Mr. Saporito said I was there,
21 these are the posters. I don't think that is materially refuted.

22 JUDGE FREDMAN: Okay.

23 MS. HUFNAL: Okay. So I would, because I kind of -- I would like
24 to talk about anticipation of the second group of claims briefly, and then I
25 will get to unexpected results.

26 JUDGE FREDMAN: Yes, go ahead.

1 MS. HUFNAL: Okay. So let's go to Slide 42, it's nice to skip
2 through, all right. Let's go to Slide 42, please.

3 And here, I just kind of for completeness, want to walk through what
4 we've submitted for evidence, and I don't know that it's really challenged
5 other than this construction that it has to be a human. But for, excuse me,
6 for Claims 25 through 31, which I have up on Slide 42, we see a mix per
7 day, so different ranges of mix per day.

8 If we look at Slide 43, which is Zhang, Exhibit 1009, and specifically
9 Paragraph 85 is what we've called out. This is where it says, you know,
10 quite clearly you can do multiple dosing, the 1 to 24 hours, and then each
11 full list dose can be 1 mg/kg to 20 mgs/kg.

12 So now we're in this world where Zhang is teaching mgs/kg and the
13 claim is in mgs/day. And so that is why Dr. Ragowski did the, which again,
14 I don't really think the process has challenged, the conversion. And if we
15 look at the next Slide 44, so what he did was convert the claimed ranges in
16 to mgs/kg using a standard 70 kilogram human.

17 JUDGE FREDMAN: Okay.

18 MS. HUFNAL: And then you can see that the mgs/kg in the claims,
19 they are all encompassed by the 1 to 20 teaching in Zhang, and that is --

20 JUDGE FREDMAN: So the question that I'm on now, is that you're
21 picking and choosing argument, right. I mean, is this too much picking and
22 choosing, do you want to talk about it?

23 MS. HUFNAL: Your Honor, I just actually --

24 JUDGE FREDMAN: For anticipation, I mean, is there any cases, you
25 know, I mean, we research those cases a lot, where we, the because the

1 CCPA case we often cite for an authority where it says well, picking and
2 choosing's okay when it's -- and obviousness, but not in one that you have.

3 MS. HUFNAL: My response to that is not we're not picking and
4 choosing, but unsurprisingly. So we are looking at this section, just because
5 it's in different paragraph numbers, I mean, that doesn't mean picking and
6 choosing.

7 There is a long section here that starts on Page 12 of Exhibit 1009 as
8 Zhang referenced, it's titled "Methods of Treatment." And if we go through
9 the paragraphs, it's not as if there's a bunch of paragraphs that are talking
10 about different dosing, there's only Paragraph 74.

11 It is, but I get the information in Paragraph 74, is what lays out the
12 dosing options. It's not, we are not going from different places. Yes, the
13 specification continues on, it talks about plasma levels, I mean, it does
14 elaborate. But everything that I just talked about, the range, and really it's
15 the one range, 1 mg/kg to 20 mg/kg, all we're doing is converting units.

16 Okay. But so the ranges in the prior art, it does kind of segue into this
17 argument, is there something special about, and really, this is what they're
18 arguing on the unexpected results, right. Is there something special about
19 what the Patent Owner claimed those mgs/kg?

20 And that is where they have set it out as obviousness, the unexpected
21 results can overcome any arguments biasness. And I would very much like
22 to take a minute to walk through the data. So let's go to Slide 50. So and
23 then this is just reiterating again, this is Petitioner's clinical studies and data
24 and what Petitioner discovered. And specifically --

25 JUDGE FREDMAN: That doesn't really matter that Petitioner did it,
26 I mean the results could be unexpected, whoever did it right?

1 MS. HUFNAL: It could be, but it's important because, I mean, I
2 think, it might be easier to believe Patent Owner drafted their claims to go
3 with their own work type of thing.

4 But the work that we did and the claims that Petitioner has drafted,
5 they're quite different. They're related to the dosing regimen, bolus dosing,
6 the plasma level concentrations, that's the only reason I call it out.

7 JUDGE FREDMAN: Okay.

8 MS. HUFNAL: Because they're, it's kind of evidence that they're
9 coming from two different places.

10 All right. So I showed you several times the claim mix per days.
11 Let's look at what happened in that Exhibit 2003, the Phase 2 Clinical Study
12 Report. And Slide 54, so Slide 54 is Exhibit 1055, Your Honors may have
13 seen this in the briefing. So Exhibit 2003, is the, I believe CF paper, it says
14 use the bolus and an infusion, specifics are in S1, this is S1. Okay. Excuse
15 me.

16 So the table in Exhibit 1055 sets out the three cohorts as they are
17 called that are being tested, high, medium, and low. These cohorts all have
18 an initial bolus. The amount of the initial bolus is different, so the low
19 cohort actually has a higher initial bolus.

20 All three cohorts all have on day one, a different set of infusion
21 amounts and rates, okay. And then they all have on days two to four, this
22 kind of set infusion rate, they vary. But it is not as simple as saying a certain
23 amount of ganaxolone per day. And that's what the Patent Owner wants to
24 latch onto is just those numbers underneath the high, medium, and low mgs
25 per day, and they're saying because that's covered by the claims these
26 unexpected results apply. And that is just, it is wrong.

1 JUDGE FREDMAN: So the numbers are the same for every day? I
2 mean, it seems like all sides, and I should do the math, but it seemed like the
3 numbers for day 2, 29 times 24, is that 713, is that where that 713's coming
4 from or is it the day 1?

5 MS. HUFNAL: I -- pardon?

6 JUDGE FREDMAN: I'm just going to do that really quickly.

7 MS. HUFNAL: Right, I think you're, Your Honor's welcome to talk
8 about day two to four, but yes, so on day one--

9 JUDGE FREDMAN: That would only be 696, so actually it's a little
10 bit lower on day two to four. Yeah, I know, I'm just curious.

11 MS. HUFNAL: Okay.

12 JUDGE FREDMAN: Perfect.

13 MS. HUFNAL: Okay. So this is the kind of dosing regimen, and I
14 use that term, I don't know if that's really the right term, it's a cohort, it's the
15 definition of a cohort, right?

16 JUDGE FREDMAN: Right.

17 MS. HUFNAL: Now I'm going to leave, and I know, for the Judges
18 who can't see the slides, but I think it's helpful to leave Slide 54 up for it to
19 have that next to, and then look at Exhibit 2003, the actual paper and the
20 results. Because it really illustrates the discovery that Petitioner had. And
21 so specifically Figure 2 of Exhibit 2003, is the, it's a model pharmacokinetic
22 curve for these three different cohorts.

23 JUDGE FREDMAN: I mean it highlights, though, just so you all
24 know, it's actually on page 1231 of the Post-Institution document that we
25 have.

1 MS. HUFNAL: Okay. All right. So looking at Figure 2 which is the
2 little figure on the bottom left. And I'm not sure if Your Honors are color
3 versions?

4 JUDGE FREDMAN: I think it might be, yeah.

5 MS. HUFNAL: Okay.

6 JUDGE FREDMAN: So I'm, the page is 1229, but --

7 MS. HUFNAL: All right. So you can see all three lines, dotted lines,
8 are times zero there, spike up to 900, right, that's the bolus. And then if we
9 look at the light blue, which is the medium, if we're looking at the dosing
10 regimen, you see the medium for the first 12 hours only have 35 milligrams
11 per hour. And that, you can see that, it drops down in terms of this profile.
12 And then it goes back up, because you are adding, you know, more infusion
13 as you go on.

14 If you look at the low, that drop, shot up for the bolus, it stays pretty
15 high because the low cohort had 85 mgs/hour for the first two hours. But
16 then it drops down and it gets progressively lower, and you see that the low
17 drops down under, you know, it's close to 200 by our sticks.

18 And it's really the high that they realized you have the initial bolus
19 shoots up your plasma level concentrations, you're maintaining pretty high
20 infusion rates, and it stays above 500 for 8 hours. And that is what, Mr.
21 Houlihan, you know, in his declaration, was talking about.

22 And if you look now at Figure 3 of Exhibit 2003, which sets out what
23 you saw, the effect of SE, and it, you know, I guess, it lines up so at time
24 point zero, you're SE drops, shoots down, negative 100. The low stays down
25 there for a pretty long time.

1 But then at a little bit around hour 6 it starts going up because our
2 infusions had dropped. The medium, which was the triangles, it goes down
3 but kind of immediately starts going up again. And the high, the high is the
4 one that it is staying low, you know, for a long period of time. And that is,
5 that high cohort, that is the unexpected result that was in the Houlihan
6 declaration that the Petitioners kind of claims are directed to that we were
7 advocating for.

8 And, just fundamentally, there can be no nexus for purposes of
9 unexpected or secondary considerations if the claims are not commensurate
10 in scope with the unexpected results.

11 And, you know, we submitted this, a Baughman modeling as well.
12 And that really was just to underscore the point that without the bolus, right,
13 if you don't have a bolus, you may not even get up to 500. And there are
14 just, I can't even, I don't even know how many iterations of regimens you
15 could put together with just your mgs per day, and that there's no evidence to
16 support they would meet the unexpected results.

17 I will just walk through, since I have about ten more minutes, not that
18 I need to use all my time, but I will walk through Slides 57, 58, and 59 just
19 for completeness here.

20 And this is our, we're asking Dr. Sankar, the Patent Owner's expert,
21 about some of these unexpected results. And you may have seen in our
22 papers we've created this table, we tried to collect all of the different
23 unexpected results. And what it -- let's start with 57, to do, yes, 57.

24 So the first unexpected result, this is rapid seizure cessation and
25 reduction. And Dr. Sankar, when we asked him that seizure, reductions in
26 seizure burden rapidly, you see that all three dose cohorts -- dose cohorts,

1 yes, that's a function of the bolus, yes. Any claims are not, you could do
2 bolus or not.

3 Slide 58, we asked him about the, and this is specific to the high dose
4 cohort, the rapid and sustained effect observed for the high cohort. And it's
5 the same, there's some back and forth and we asked, that's a function of the
6 bolus, and then the continuous infusions, yes, because you maintain that
7 high dose level, yes.

8 And just finally the same thing for the last, kind of unexpected result,
9 the lack of treatment escalation, which is the one Your Honor pointed out in
10 Table 2. And Dr. Sankar, you know we asked could you have done that
11 without the bolus, could you have achieved that endpoint? He says, my
12 suspicion is they would not have been controlled as rapidly. Would they
13 have been controlled at all, potentially. So changing a dosing regimen could
14 change the results, yes.

15 And just taking one step back, those endpoints, that's not the -- that's
16 not the unexpected result that Petitioner has ever claimed. Of course, I
17 mean, that's just a successful case to a clinical study. It was the high dose
18 cohort that observed these unexpected results that the Petitioner has pointed
19 to.

20 So, Your Honor, with that, I have covered all the topics that I had to
21 cover. If there are no questions, I will sit down.

22 JUDGE FREDMAN: Any other questions? Okay, no further
23 questions, I guess we'll move to Patent Owner. Whenever you are ready.

24 MR. MCDONNELL: Thank you. Good afternoon, and may it please
25 the Board. My name is Ryan McDonnell, as I mentioned previously, I'm

1 joined by colleague Erin Sommers and together we will present Patent
2 Owner's presentation for this proceeding. If we go to Slide 2.

3 As a brief overview of how we will cover the issues and divide our
4 presentation, I will first begin by addressing anticipation and obviousness for
5 Claims 25 through 31, which are patentable regardless of how the Board
6 construes those claims.

7 Ms. Sommers will then cover the two claim construction issues, and I
8 will discuss anticipation and obviousness for Claim 22. If the Board
9 agrees with Patent Owner's constructions for both disputed claim terms, we
10 believe this would essentially preclude finding that Claim 22 is unpatentable.

11 Starting first with Petitioner's anticipation grounds for Claims 25
12 through 31. As I previously mentioned, regardless of how the Board
13 construes the treating a patient need throughout the claim time, these claims
14 are legally anticipated by Zhang for two reasons: first, it's undisputed that
15 no C1 embodiment in Zhang discloses a method for treating SE and a patient
16 need thereof by intravenously administering any of the specific dose ranges
17 that are cited in those claims. Nor does Petitioner argue that any such
18 embodiment in Zhang exists. And while Petitioner focuses on Zhang's
19 disclosure of treating as --

20 JUDGE FREDMAN: Is this anticipation area? I'm just --

21 MR. MCDONNELL: This is anticipation, yes, Your Honor.

22 And while Petitioner focuses on Zhang's disclosure of treating SE,
23 Zhang is ultimately a publication about various formulations of ganaxolone.
24 If we could go to Slide 45.

25 That means the Petitioner must resort to picking and choosing among
26 discreet, unrelated disclosures in Zhang, to allege that Zhang anticipates the

1 claims, which as the federal circuit has found, is an improper anticipation
2 analysis, it is instead, more appropriate for obviousness.

3 That is why here Petitioner, recognizing the shaky ground that it's
4 anticipation analysis on Zhang stands on, also included an obviousness
5 ground based on Zhang alone. But for that obviousness ground, the Board
6 recognized in its Institution Decision, the inventiveness of these claims
7 through Patent Owner's offered unexpected results.

8 The extent of Petitioner's picking and choosing is best exemplified by
9 the Board's summary of Petitioner's anticipation position in the Institution
10 Decision on Pages 26, and 28 through 30, as well as Petitioner's
11 demonstratives that they presented today.

12 To give patient in need thereof, Petitioner pointed to Paragraph 22 of
13 Zhang. To give method of treating status epilepticus, Petitioner jumps
14 nearly 50 paragraphs, skipping over 30 other diseases or disorders,
15 formulations that amounts of ganaxolone, those formulations that Zhang
16 discloses, to Paragraph 70 of Zhang. To get intravenous administration,
17 Petitioner moves an additional six paragraphs, skipping over the 30 diseases
18 and disorders again to Paragraph 76.

19 And with respect to the specific daily dose amounts recited in the
20 claims, Petitioner points to three portions of Paragraph 85 as shown on Slide
21 46, that discuss administering multiple bolus doses of ganaxolone, that in
22 certain embodiments, multiple bolus doses are given over 1 to 10 days at
23 intervals of 1 to 24 hours and that in certain embodiments, each bolus dose
24 comprises about 1 milligram per kilogram to about 20 milligrams per
25 kilogram ganaxolone.

1 Now earlier Petitioner mentioned that all of the dosing discussion in
2 Zhang resides in Paragraph 74 of Zhang, but that's not even the paragraph
3 that Petitioner relies on to get the dosing amounts. So that just shows the
4 amount of picking and choosing that's required. And Paragraph 74 through
5 85 of Zhang actually applied to dosing, all of those paragraphs.

6 Once they settled on this Paragraph 85 disclosure, Petitioner then had
7 its expert, Dr. Ragowski, choose a 70 kilogram average weight for a human
8 to show that all -- that all of the daily dose ranges recited in Claims 25
9 through 31 fell within the broad 1 to 20 milligram per kilogram --

10 JUDGE FREDMAN: Would it have mattered what weight had been
11 picked within reason, really?

12 MR. MCDONNELL: I'm sorry?

13 JUDGE FREDMAN: Would it have mattered what weight for the
14 patient they picked within reason? I mean, 70 kgs is a fairly normal size,
15 what 150-something pounds, right, from what I read, but I wish I'd had it
16 while it last. But I mean, it's not an unreasonable number, and certainly if
17 you picked a bit lower or a bit higher, you still would have been within the
18 range. Right?

19 MR. MCDONNELL: Sure. And I don't think we dispute the exact
20 number that they picked, more it just highlights the picking and choosing
21 required to get from this broad range of 1 to 20 milligrams per kilogram, to
22 the exact specific and precise doses that are recited in the claims.

23 JUDGE FREDMAN: Right. I mean it's only anticipation, right, so
24 we're not looking at obviousness?

25 MR. MCDONNELL: Anticipation, yes, that's correct.

26 JUDGE FREDMAN: Okay. Wait for obviousness, okay.

1 MR. MCDONNELL: And it's also important to note that the broad
2 bolus dose range that's described in Paragraph 85 of Zhang, is not directly
3 related or in any way tied to the rest of Zhang's disclosure or any of the
4 individual statements that has to be cobbled together to reach the full, entire
5 claim as set out in Claims 25 through 31.

6 Moreover, the sentence in Paragraph 85 of Zhang does not tie that
7 bolus dose range to any particular disease or disorder. And it's shown on
8 Slide 49, Petitioner's expert, Dr. Ragowski, admitted as much, testifying that
9 the phrase "method of treatment" is not mentioned in Paragraph 85, and that
10 the broad dose range is not tied to any specific disease or disorder.

11 And this is particularly relevant, given that it's shown on Slide 47, that
12 Paragraphs 70 to 74 of Zhang describe over 30 different diseases or
13 disorders that the ganaxolone formulations that are described may treat.

14 To kind of sum all this up, the relevant question for anticipation is not
15 whether Zhang teaches each limitation of the claims individually, such that
16 they can be combined together to reach the ultimate claim language, that's
17 obviousness.

18 The correct question is whether Zhang teaches all elements of the
19 claimed invention as they are arranged in the claim. And here, Zhang does
20 not anticipate these claims because as the federal circuit says in
21 NetMoneyIN, Zhang does not describe the thing that is claimed. Based on
22 its correct legal standard, Zhang cannot anticipate Claims 25 through 31.

23 There's also a second separate reason that the Board can find that
24 Zhang does not anticipate those claims. And that's because the broad bolus
25 dose range that's described in Paragraph 85 in Zhang, does not anticipate the

1 specific and narrowly defined daily dose ranges that are recited in those
2 claims.

3 Petitioner and the Board in its Institution Decision at Pages 29
4 through 30 cite to INEOS against Berry Plastics, a federal circuit decision, to
5 support the finding that based on the record institution, that Zhang teaches a
6 range of doses of about 1 milligram per kilogram to about 20 milligrams per
7 kilogram ganaxolone, that overlap with the recitation of ganaxolone ranges
8 recited in Claims 25 through 31.

9 But INEOS actually only demonstrates why the broad range in
10 Paragraph 85 of Zhang does not anticipate the specific daily dose ranges. In
11 INEOS, the court stated that if the prior art discloses its own range rather
12 than a specific point, the prior art is only anticipatory if it describes the
13 claimed range with sufficient specificity such that a reasonable factfinder
14 could conclude that there's no reasonable difference in how the invention
15 operates over the ranges. The court then noted that the patent owners --

16 JUDGE FREDMAN: So your contention that they have -- the range
17 matters, that different doses give different results?

18 MR. MCDONNELL: Yes. And I think that's proven by the Board
19 finding that the specific, in its Institution Decision, that the specific dose
20 ranges claimed in Claims 25 through 31, have unexpected results.

21 And there's actually un rebutted testimony from Dr. Sanker that there's
22 many ranges outside of those that are claimed, that would not operate to treat
23 SE. And Petitioner did nothing to contradict or rebut that in either its papers
24 or through their expert's supplemental declaration.

25 JUDGE FREDMAN: So the exact -- the exact framer is a dosing
26 matter, is that what you are saying?

1 MR. MCDONNELL: I'm sorry?

2 JUDGE FREDMAN: The exact framer is a dosing matter?

3 MR. MCDONNELL: I would say the range of the amount of dosing
4 matters.

5 JUDGE FREDMAN: Just the amount or does it matter how it's
6 delivered?

7 MR. MCDONNELL: I would say based on the record before the
8 Board, it's the amount of dosing.

9 JUDGE FREDMAN: Just the amount, nothing else?

10 MR. MCDONNELL: Yes, just the amount.

11 JUDGE FREDMAN: Okay.

12 MR. MCDONNELL: But there's sort of a little bit further as
13 explained on Patent Owner's response at Page 38, and by Dr. Sanker at
14 Paragraphs 83 through 85 of his declaration, the broad range bolus dose is
15 described in Zhang of 1 to 20 milligrams, refers only to a single
16 administration of ganaxolone. Meanwhile Claims 25 through 31 recites
17 daily doses of ganaxolone.

18 Directly after providing this 1 to 20 milligram per kilogram bolus
19 dose range, same states of this dose could be administered from every 1 to
20 24 hours, which equates to doses of 1 milligram per kilogram per day to 480
21 milligrams per kilogram per day.

22 And if you would assume a 70 kilogram adult human as Petitioner's
23 expert have done, this dose range in Zhang actually amounts to ranging from
24 70 to 33,000 milligrams per day.

25 And as I previously mentioned, Dr. Sankar has un rebutted testimony
26 showing that doses outside of what's actually claimed within that very broad

1 range would not operate to treat SE and that the unexpected results further
2 demonstrated the criticality of these claims as the federal circuit found that
3 INEOS can show that a broad bolus dose range does not anticipate.

4 So now that the record is fully developed, it should be clear to the
5 Board that Zhang does not anticipate Claims 25 through 31 because of
6 Petitioner's heavy reliance on picking and choosing, that the broad bolus
7 dose range disclosed in Zhang's Paragraph 85 does not anticipate the narrow
8 and critical range disclosed in the claims.

9 If there's no additional questions regarding anticipation for Claims 25
10 to 31, I will now turn to obviousness.

11 JUDGE FREDMAN: Are there any other questions from you guys,
12 I'm guessing no. Okay.

13 MR. MCDONNELL: Thank you. So Petitioner's addressed three
14 obviousness grounds with respect to at least Claims 25 through 31. The
15 Board's Institution Decision found that these claims were not obvious for
16 any of those grounds because of the specific daily dose ranges recited have
17 unexpected results of non-obviousness.

18 Since Institution, Petitioners failed to rebut these unexpected results
19 and has put forth no relevant evidence demonstrating that the claimed dose
20 ranges are not what's responsible for those unexpected results. I will first
21 walk through the unexpected results themselves, and then discuss
22 Petitioner's only basis for contesting them, that the unexpected results are
23 not commensurate in scope with the claims.

24 JUDGE FREDMAN: But first are you -- so we're doing obviousness
25 now, right?

26 MR. MCDONNELL: We are talking about obviousness now.

1 JUDGE FREDMAN: Right. So are you not challenging that it would
2 have been obvious to select the dose ranges?

3 MR. MCDONNELL: No --

4 JUDGE FREDMAN: That the overlapping ranges would have
5 rendered your range obvious, your claimed ranges, obvious? Like Peterson
6 or Pfizer that just came out, or Sanofi.

7 MR. MCDONNELL: I think you still have to look to the criticality of
8 the actual dose ranges claimed.

9 JUDGE FREDMAN: Right. But that's evidence of secondary
10 considerations of objective indicia. I'm talking about the prima facie case as
11 it were?

12 MR. MCDONNELL: I don't think we would concede that, it's not, I
13 wouldn't say it's prima facie obvious, I'm not sure that there would be --

14 JUDGE FREDMAN: So you don't think though the case law that
15 says overlapping ranges are obvious in the absence of secondary
16 considerations is correct?

17 MR. MCDONNELL: No, I think that, I would say that is correct.

18 JUDGE FREDMAN: And here we have overlapping ranges, do you
19 dispute that?

20 MR. MCDONNELL: I would agree that the range of 1 to 20
21 milligrams per kilogram, if you apply Dr. Ragowski's 70 kilogram thing,
22 would overlap.

23 JUDGE FREDMAN: Or honestly, any amount would actually, or
24 virtually any weight would?

25 MR. MCDONNELL: Okay, sure.

1 JUDGE FREDMAN: Okay. So now we're going to the secondary
2 considerations to argue that nonetheless, we don't have a prima facie case,
3 because we have objective indicia?

4 MR. MCDONNELL: Yes, that's correct.

5 JUDGE FREDMAN: Okay, sure.

6 MR. MCDONNELL: So we can turn to Slide 52. The clinical trial
7 data from Petitioner's own study published in Epilepsia, provides unexpected
8 results over Petitioner's scientist's expectation that a high ganaxolone
9 exposure for a long treatment period would be required to break SE.

10 In particular, as shown on Slide 53, the Epilepsia results show that all
11 three dose cohorts tested, and that's a high set of 113 milligram per day dose,
12 a medium 650 milligram per day dose, and a low 500 milligram per day
13 dose, met the study's primary endpoints.

14 JUDGE FREDMAN: As Petitioner points out, the doses were not
15 given simply in daily doses, they were given in particular arrangements.
16 Okay. There's a bolus dose followed by a series of infusion rates for the
17 intravenous administration. Your claim, actually, I think, is solely
18 intravenous? Right?

19 MR. MCDONNELL: Yes.

20 JUDGE FREDMAN: And so you don't even include the bolus dose,
21 is that true?

22 MR. MCDONNELL: I would not say it does not include a bolus
23 dose, a bolus dose can --

24 JUDGE FREDMAN: But does your claim cite a bolus dose?

25 MR. MCDONNELL: Not expressly.

26 JUDGE FREDMAN: So you're stuck without a bolus dose?

1 MR. MCDONNELL: There is, I believe, support for a bolus dose --

2 JUDGE FREDMAN: And does it give particular amounts for the
3 bolus dose?

4 MR. MCDONNELL: I'm sorry?

5 JUDGE FREDMAN: Does it give particular amounts for the bolus
6 dose?

7 MR. MCDONNELL: I would have to check, but I believe that it
8 does. But I do just want to note that Petitioner did not rely in its papers on
9 these specific dose amounts and how the bolus Institution --

10 JUDGE FREDMAN: The question though, the question that
11 confronts us nonetheless is, is it mentioned in scope?

12 MR. MCDONNELL: Right.

13 JUDGE FREDMAN: I mean when we have this variation with it's a
14 very different dosing profile in the paperwork with particular details, and
15 those details don't appear to be in the specification unless I am mistaken.
16 And if they are, I'd love to hear that, we need to know that. That's quite
17 relevant for objective indicia commensurate in scope. Right? That's a
18 central element to show that you have unexpected results, is that they're
19 actually commensurate in scope, not that you've done something. Right?

20 MR. MCDONNELL: Correct.

21 JUDGE FREDMAN: I'm not saying that you're not showing results,
22 but they're not commensurate in scope until we find that those results are not
23 precise on obviousness. I mean, but I'm ex parte judge as well, so that's not
24 a conflict of offering on that issue, one way or the other.

25 MR. MCDONNELL: Sure, and I agree with you that INEOS results
26 need to be transferring stuff to claims, but if we go to Slide 57, Petitioner's

1 own statements to the public in corporate presentations, talk only about the
2 dose itself being what provides the unexpected results. So look on the left, it
3 says the high dose achieved target range, greater than or equal to 500 --

4 JUDGE FREDMAN: The high dose, it's showing, right, the blood
5 levels, which is based on the infusion. Right? It's not, they may say that is
6 where the shorthand, but what they're really saying is that this particular
7 protocol that was used, resulted in this, and it's not, that's with any protocol.

8 MR. MCDONNELL: And I just want to point that the unexpected
9 results aren't solely tied to the plasma concentrations that Petitioner relied on
10 its declaration. Sure, for the purposes of their own claims, that's what they
11 relied on.

12 But if you actually look at what the epilepsy cite shows, it's that
13 regardless of the plasma concentration, you still had rapid reduction in
14 seizures and cessation of seizures, of SE, across all three of the dose ranges
15 that were -- that were tested, so --

16 JUDGE FREDMAN: It does look though, if you look at the data,
17 especially the one on the right of your figure there, that it would -- it didn't
18 go all the way back up, but it does go significantly back up for one of them
19 before the 8-hour time point that you claim in 22. Is that where this is?

20 MR. MCDONNELL: I'm sorry?

21 JUDGE FREDMAN: They -- go ahead.

22 MR. MCDONNELL: Oh, I was just going to point out that if you
23 look at Exhibit 2003 on Page --

24 JUDGE FREDMAN: 2003, okay.

25 MR. MCDONNELL: -- 2386. It states that "sustained clinical
26 response was associated with maintaining the ganaxolone plasma

1 concentrations greater than or equal to 500 nanograms per milliliter.

2 Ganaxolone plasma levels were achieved only briefly during the initial bolus
3 for patients in the medium dose cohort. Whereas the doses of low and high
4 dose cohorts maintained such levels for 4 and 8 hours respectively. So this
5 doesn't just limit the unexpected results --

6 JUDGE FREDMAN: Wait, where are you reading again, give me the
7 page number one more time?

8 MR. MCDONNELL: This is on Page 2386.

9 JUDGE FREDMAN: 2386, okay.

10 MR. MCDONNELL: So this is two paragraphs right above Section
11 3.3 on Page 2386. So this is --

12 JUDGE FREDMAN: Is 1238 one of our entries, okay.

13 MR. MCDONNELL: So this is about halfway down that, the
14 paragraph that starts, that column.

15 JUDGE FREDMAN: Mm-hmm.

16 MR. MCDONNELL: It essentially shows that ganaxolone levels
17 were achieved only briefly during the initial bolus for patients in a medium
18 dose cohort, whereas those in low and high dose cohorts maintained such
19 levels for 4 and 8 hours respectively. And then it states that the greatest
20 decrease in seizure burden was seen when ganaxolone concentrations were
21 maintained by greater than or equal to 500 for at least 8 hours.

22 This shows that while the plasma concentration dipped, even though it
23 dipped, the patient, if you look at the primary endpoints and the table at the
24 top of this page, in the low and medium-dose cohorts still met the primary
25 endpoints of rapid reduction seizure burden and cessation of SE for at least
26 24 hours.

1 And if you look at, based on what Petitioner's expectations were in its
2 declaration, they would have expected to reach those two sort of endpoints,
3 you would have to have a much longer and higher duration of ganaxolone
4 exposure. So I would say that the unexpected results aren't just limited to
5 maintaining a plasma concentration above 500 for 8 hours.

6 JUDGE FREDMAN: But it does matter how they were given, right?
7 I think that's what this data really is showing, and that's what you're having
8 trouble with, I think. Because you can also give 713 mgs in a single bolus
9 dose, right? You could divide it evenly and give it to patients. It seems like
10 those would not necessarily give the same results, it's even showing that.
11 Co-counsel can speak, if she wants, go ahead.

12 MS. SOMMERS: Well, Your Honor, just respectfully. I think
13 Petitioner said that she gave the table with the different doses, the different
14 rate, the different boluses in each of those groups, and I think what that
15 shows, is it doesn't actually matter, the bolus and the infusion, and the
16 different dosing rates, the different times. Because there were multiple
17 different dosing regimens as she said, in those different cohorts. And every
18 single one of them across the board met all of the endpoints that they were
19 testing.

20 JUDGE FREDMAN: Okay. I see the point you're making. But this
21 isn't every possible dosing within the scope of your claim?

22 MR. MCDONNELL: I don't think we're, I wouldn't say we're
23 required to show that every single possible dosing within the scope of the
24 claim.

25 JUDGE FREDMAN: I'm not sure what the scope of the claim, the
26 claim is the full scope of the claim.

1 MR. MCDONNELL: When we showed it for each of the doses that
2 are recited in the claim, that there would be unexpected results.

3 JUDGE FREDMAN: Right.

4 MR. MCDONNELL: You don't have to have absolute identity of
5 scope between the unexpected results and the claim language to show
6 unexpected results. The contrary has to be plainly disproportionate to the
7 scope of the claims. And that just hasn't been proven by Petitioner here.

8 JUDGE FREDMAN: Your claims did tell me about a bolus, but
9 didn't tell me how much to give in the first hour, the second hour, and the
10 third hour. It's not the same at all, honestly. But I hear -- I hear what you
11 are arguing.

12 MR. MCDONNELL: And I guess to that point, the bolus plus
13 continuous infusion, that is something that, when you administer SE
14 intravenously, that that's how you would administer it, you would administer
15 a drug intravenously to treat SE by bolus and --

16 JUDGE FREDMAN: I think there are other choices, right. You're
17 patent gives other choices, doesn't it? I mean, intravenous isn't the only
18 option, is it?

19 MR. MCDONNELL: Well, intravenous is what is claimed, that's
20 what they're citing to --

21 JUDGE FREDMAN: It's claimed but, are you saying there is another
22 option, there are other options, you claim that.

23 MR. MCDONNELL: I would say within intravenous administration,
24 the way that a person of ordinary skill in the art would recognize that you
25 treat SE, is through bolus plus continuous infusion. And that was agreed to
26 by both parties' experts. If you go to Slide 63 --

1 JUDGE FREDMAN: Okay.

2 MR. MCDONNELL: Patent Owner's expert, Dr. Sankar, testified that
3 it is important to use a bolus dose when treating SE to constantly achieve a
4 therapeutic level and gain control of SE. And then if you go to Slide 64,
5 Petitioner's expert, Dr. Rogawski, acknowledged that it's common to use a
6 bolus dose to rapidly administer medication and control SE.

7 JUDGE FREDMAN: But it's not in the claim, I mean honestly, that is
8 still, it's not part of the claim.

9 MR. MCDONNELL: It's not expressly in the claim language.

10 JUDGE FREDMAN: Yeah. I mean, there was that loading dose
11 case recently that was written description case, I think, where the federal
12 circuit found that there was a good description for loading dose and that was
13 at, I think, the flipped one where they had initially came out one way and
14 then flipped the decision to the other way.

15 And initially there was no description and then I understood they
16 found a description that will adapt into what loading dose would be okay.
17 And then they added that that limitation was not described. Do you know
18 which case I'm talking about? I will look for it, I think I can find it.

19 MR. MCDONNELL: So I'd like to next talk about, a little bit about
20 Dr. Baughman's declaration that was put in. And apart from her declaration
21 being excludable for failing to provide the data that was underlying her
22 analysis --

23 JUDGE FREDMAN: Novartis, in Novartis, right, we have an original
24 decision where there was an invalid for failure to test for the written
25 description requirement, which decided, it kind of also could be related to
26 commensurate in scope.

1 And the claim was silent about an immediately preceding loading
2 dose regimen, right, that no loading dose regimen was added during
3 prosecution. And initially the court was okay with that and then, in the
4 second opinion, on re-hearing, the majority found that it was not acceptable.

5 MR. MCDONNELL: I would just like to point out that a written
6 description --

7 JUDGE FREDMAN: So I understand this, that there is kind of
8 relationships here between the different statutes.

9 MR. MCDONNELL: So discussing Dr. Baughman's declaration a
10 little bit, there's kind of two points I would like to make there, why the data
11 that she provides or the charts she provides in analysis is irrelevant to the
12 unexpected results here.

13 JUDGE FREDMAN: Mm-hmm.

14 MR. MCDONNELL: First as shown on Slide 66, the output for Dr.
15 Baughman's analysis is in plasma concentration, which is not any measure of
16 treatment efficacy, which is required for the claims and is sort of the basis
17 for the unexpected results the Patent Owner is relying on.

18 And then as a second matter, on Slide 68, the sort of entire crux of
19 Petitioner's commensurate in scope argument is based on the unexpected
20 results being tied to the particular bolus plus continuous infusion dosing
21 regimen used in the epilepsy study. But the two dosing scenarios and the
22 only two dosing scenarios that Dr. Baughman modeled, use only continuous
23 intravenous infusion and neither included a bolus dose of ganaxolone.

24 JUDGE FREDMAN: Their claim doesn't require a bolus dose, so
25 now why is that a problem?

1 MR. MCDONNELL: But you would have expected if she were trying
2 to show that there would be a difference between using a bolus dose and
3 only continuous intravenous infusion, that you would compare the two.

4 Instead, she only compared continuous to continuous, and also only
5 did it in plasma concentration, which doesn't sort of belies the actual study
6 results that show that there was clinical efficacy across all the all the dose
7 cohorts tested.

8 Then I would like to make just a few points about a motivation to
9 combine reasonable expectation success. Petitioner has also failed to
10 demonstrate that a POSA would have combined or have had a reasonable
11 expectation of success with any of these secondary references that they rely
12 on for the specific daily dose claims that are recited in Claims 25 through 31.

13 None of the secondary references disclose any of the specific dose amounts
14 were cited in the claims or otherwise speak to ganaxolone's ability to treat
15 SE.

16 JUDGE FREDMAN: They could have already admitted and stated
17 that picking the dose, knowing, once you know a dose, you can optimize that
18 the way you want to, if you want to use a bolus or not. It seemed to be
19 inconsistent as they allowed, but we can do it for boluses, but you can't do it
20 for the amount. That the physician will not know, given an overlapping
21 range, we could, the optimization ranges for those amounts. That's an
22 inconsistent argument to me.

23 MR. MCDONNELL: And I would say that the overlapping range
24 here which is 70 to 33,000 --

1 JUDGE FREDMAN: There are other references getting us closer,
2 right, I mean, they are not all that far apart. That's the broadest range in
3 Zhang, right?

4 MR. MCDONNELL: I think, I mean I would say that that's the only
5 dose range the Petitioner has relied on is the dose range provided in Zhang
6 of 1 milligram per day or 1 milligram per kilogram of 20.

7 JUDGE FREDMAN: Even with that, it's still, the physician knows
8 the amounts that they have been giving, right, I mean, they did, during the
9 epilepsy study, they could, the dose was appropriate for a 70 kilogram
10 patient, right?

11 MR. MCDONNELL: Sure, but the epilepsy study isn't prior art here,
12 it came --

13 JUDGE FREDMAN: I understand that, but when they picked for the
14 mice, the rat interpreting studies, right. They still picked amounts that didn't
15 kill the rats and headed back. So I think to argue that you can't optimize this
16 is inconsistent with a lot of long list of case law, from Allergan to Pfizer to
17 many more, you know, Antonie.

18 MR. MCDONNELL: I mean, and I still think that doesn't, the fact
19 that you could -- you could optimize those, that wasn't argued here, by the
20 Petitioner, they argued --

21 JUDGE FREDMAN: I think it was. And I think that honestly,
22 reaching optimization is a pretty standard position to take, I mean, you
23 know. There are a lot of cases where that comes up in general, it's argued
24 that reaching opposition is obviously an absence for secondary
25 consideration, right? That's what your secondary consideration is for, your
26 objective indicia.

1 MR. MCDONNELL: Right.

2 JUDGE FREDMAN: I mean it's not, not to say that you wouldn't
3 have been motivated to pick the bolus that works, because honestly, you
4 always are going to go ahead and pick the bolus that works, that's true for
5 any drug, any pharmaceutical and honestly, in almost any case we see.
6 Somewhere there's a reason people pick the things that work, they don't pick
7 things that don't.

8 MR. MCDONNELL: And I guess the point I'm trying to make is that
9 none of the additional references that Petitioner provides really say anything
10 beyond what Zhang says. So there's really no need to really dive into those
11 references because they don't, they don't provide any additional data beyond
12 essentially Example 8 in Zhang in the rat model. So unless the Board has
13 any further questions on the amount obviousness of Claims 25 to 31, I'll turn
14 it over to my colleague, Ms. Sommers, to discuss the two claim construction
15 issues.

16 JUDGE FREDMAN: Thank you.

17 MS. SOMMERS: Good afternoon, Your Honors. Before I turn to
18 claim construction, I would just like to address a few of those points on
19 routine optimization. Here I think we are distinguishable from those cases
20 because we don't have a range where any dose was shown to be effective in
21 the prior art for a human patient. The only doses --

22 JUDGE FREDMAN: Isn't it routine in the medical arts, to look at
23 animal models when it's like this, and based on those animal models,
24 selecting the patient. Is that not ordinarily done by doctors?

25 MS. SOMMERS: I don't think it is done in every case and
26 specifically in this case.

1 JUDGE FREDMAN: So when they do these animal models before
2 they did clinical trials, before they did a phase one trial, they don't use that
3 information to help guide selection of the doses?

4 MS. SOMMERS: They may internally, but that may not be known in
5 the public art, public -- prior art, which is important in this case.

6 JUDGE FREDMAN: I mean the thing is, is we are talking about, this
7 is to be a person of ordinary skill in the art, not -- this is not, which is going
8 to be a physician who is doing clinical trials. It's not, you know, even me,
9 it's just a Ph.D., right? The physicians who do clinical trials know how to do
10 these things, I mean, this is something they routinely do.

11 MS. SOMMERS: Again, with data that may be internal to a company
12 and is not in the prior art.

13 JUDGE FREDMAN: The data for the rat data in Klopfenstein was in
14 public art.

15 MS. SOMMERS: That was, and that dose is significantly lower than
16 the only dose range that Petitioner is pointing to.

17 JUDGE FREDMAN: So it's according dose that could be used,
18 though. I mean your claims start off with Claim 21 doesn't have a dose at
19 all. Right. So you're talking about Claims 26 to 31.

20 MS. SOMMERS: I know.

21 JUDGE FREDMAN: Twenty-two doesn't have a dose either, it has a
22 certain point to resolve.

23 MS. SOMMERS: That's right.

24 JUDGE FREDMAN: Right? Which, Saporito shows. So I'm not
25 sure I see the point here.

26 MS. SOMMERS: Well, I --

1 JUDGE FREDMAN: And this is where -- this is where we just need
2 to study this, once you have that, then you optimize to what the dose is going
3 to be the best dose. And that's what these cases all say, once we get
4 something, we narrow it to start, we optimize to the dose that works the best.

5 MS. SOMMERS: So without seeming impertinent, I would like to
6 understand what you think is the starting dose that we're starting with?

7 JUDGE FREDMAN: The starting dose would be the dose that the
8 range requirement gives you plus the examples. Those would be the dose
9 ranges.

10 MS. SOMMERS: And when would I try to articulate is that starting
11 dose, that range is significantly higher in a human patient than the rat data
12 that we have. And so there is no tie in the prior art here and it's not just a
13 matter of routinely optimizing a dose --

14 JUDGE FREDMAN: The evidence, that's not stating the evidence
15 that supports that position.

16 MS. SOMMERS: We do have evidence to support that position.

17 JUDGE FREDMAN: Can you state that, please?

18 MS. SOMMERS: It's an absence of the evidence.

19 JUDGE FREDMAN: An absence of evidence isn't evidence. Do you
20 have evidence from an expert who says we could not routinely optimize
21 this?

22 MS. SOMMERS: I think that would -- with all due respect, be an
23 opinion, I think the absence of --

24 JUDGE FREDMAN: You could say that, but you don't have an
25 expert saying that, do we? We have you saying that, you're an attorney
26 making an attorney argument, do you have an expert saying that?

1 MS. SOMMERS: I do not have a testimony from Dr. Sankar saying it
2 would not have been routine to optimize a dose and issue in patient. What
3 I'm trying to articulate here, is there is no clinical evidence --

4 JUDGE FREDMAN: I hear your argument. Okay, thank you.

5 MS. SOMMERS: I just wanted to make that clear, because I think
6 we are distinguishable from the cases we're discussing.

7 With respect to claim construction, Petitioner believes that, excuse
8 me, let me get my paper, actually, sorry. Petitioner's anticipation challenge
9 of Claim 22 hinges on its reading of the claims. And the developed record
10 now before the Board, I think, makes clear that the claims should be given
11 their plain and ordinary meaning through the Petitioner's anticipation
12 challenge of Claim 22.

13 So I'd like to start with the improvement claim, and we can look just
14 at the claim language there, which is Slide 19. Looking just at the claim
15 language, we don't even need to look at how it's construed, it says that "The
16 method provides improvement to the patient after administration for more
17 than 8 hours." It doesn't say after initiating, it doesn't say during the
18 administration, it says after administration.

19 JUDGE FREDMAN: So the question though is really, is it the end of
20 administration or the beginning of administration, right. In the reference, the
21 Epilepsia reference, which is the only evidence that really addresses this sort
22 of in any real way. They are both after the completion and after the
23 initiation, right.

24 When we think about this from, going back to sort of ordinary life,
25 right, take your Advil, right, and then you take your Tylenol, you know, 4
26 hours later, right, then you want to have, you know, pain reduction, and you

1 want it to last say 8 hours. You have the situation there again where you
2 would be taking, you often take doses in the middle, right. You measure the
3 pain reduction at 8 hours from the whole dosing, not just the end of the
4 dosing?

5 MS. SOMMERS: I'm not -- I'm not sure that's an apt analogy,
6 because we're talking about a situation where the claim language itself
7 explains what after administration means. And maybe we need to take a
8 step back --

9 JUDGE FREDMAN: I don't know that it's absolutely clear, that's, I
10 think there's some ambiguity here. I hear your point of view.

11 MS. SOMMERS: Well, I'd like to share, if we go back to Claim 21,
12 that's the predicate claim, and that says administering to a patient in need
13 thereof. And what is administered, a pharmaceutical composition. And the
14 pharmaceutical composition is after the full dosage of ganaxolone.

15 JUDGE FREDMAN: Where does it say about full dosage, in the, I
16 mean, in their claim?

17 MS. SOMMERS: The claim does not say that, but we do have expert
18 testimony from Dr. Sankar that a person of ordinary skill in the art would
19 understand that administering the pharmaceutical composition is giving that
20 after the full dosage --

21 JUDGE FREDMAN: He says that, he doesn't point to a reference
22 supporting that statement, right, he just says that in his declaration?

23 MS. SOMMERS: He's giving a perspective --

24 JUDGE FREDMAN: I understand that, and again that's better than
25 nothing. He's an expert to be given, you know, credit that with some weight.

1 I think Dr. Rogawski responded with pointing to the epilepsy paper which
2 shows that it could be either.

3 MS. SOMMERS: Well, I think -- I think the patent -- I think what he
4 points to is a time period for measuring. And I'd like to say that this is not a
5 litigation inspired construction, it's taken directly, the clean language is
6 taken directly from our specification. And that is at Slide 20.

7 JUDGE FREDMAN: Okay.

8 MS. SOMMERS: And this is at, for example, one of them is Column
9 14, Line 21 through 41. And right here, we're talking about the
10 improvement, that's what's claimed, improving at least one symptom. And
11 here it's saying that that improvement can be established after administration
12 of the pharmaceutical composition and that can be done at various points in
13 time. We've claimed Point 8. So here we're talking about the improvement
14 that's claimed after administration of pharmaceutical composition --

15 JUDGE FREDMAN: Does it say completion though of the
16 administration, if it were an infusion, it doesn't really tell us.

17 MS. SOMMERS: It says after administration of the pharmaceutical
18 composition. And the pharmaceutical composition is a dosage of the
19 ganaxolone. So rather than address that, which Dr. Rogawski on Petitioner's
20 side doesn't even talk about, he skips back in the patent to talking about
21 measuring.

22 And that reading is not -- that passage itself, if we can pull up the next
23 slide maybe, nope one more -- is not inconsistent with the claim as it would
24 be properly construed under a plain and ordinary meaning. At Column 9,
25 Lines 43 through 46, which Petitioner explained earlier, talks about a time
26 period for measuring and that can happen starting right after initiation.

1 But key here, and as we have highlighted, is it can be, you measure
2 before administration, which makes sense, we need to know what the patient
3 looks like before, and you can do it again one or more times after
4 administration.

5 JUDGE FREDMAN: After treatment is initiated?

6 MS. SOMMERS: That, excuse me, after treatment is --

7 JUDGE FREDMAN: No it's not --

8 MS. SOMMERS: I don't mean to mislead the Board. No, it does say
9 after treatment. But the point is you can measure it at multiple time points,
10 including 8 hours after the complete administration, which is exactly what
11 one of the time points was in the epilepsy article.

12 JUDGE FREDMAN: So when it's ambiguous like this, and I think,
13 we can't honestly be able to doubt, it's in this context, when there is two
14 possible interpretations, how should we construe this, in favor of the drafter
15 or opposed to the drafter?

16 MS. SOMMERS: Respectfully, I don't think it's ambiguous --

17 JUDGE FREDMAN: You don't think it's ambiguous --

18 MS. SOMMERS: Because it says after administration. It doesn't say
19 after initiating treatment, it doesn't say during administration, it says after
20 administration. And after administration of what? The full dosage of
21 pharmaceutical composition --

22 JUDGE FREDMAN: It doesn't say the full dosage though. You are
23 interpolating that, you're assuming that, it doesn't say that.

24 MS. SOMMERS: The pharmaceutical composition is what's
25 administered and it's, using the epilepsy article as an example, that's a bolus
26 and continuous infusion that is after the full dosage.

1 JUDGE FREDMAN: You can't measure a full, but yes.

2 MS. SOMMERS: Right, that's measuring. That, just to be very clear,
3 the evidence that Petitioner is relying on is about measuring and we are
4 clearly --

5 JUDGE FREDMAN: And this would imply, I mean the issue that's
6 within 22, which would be working within 8 hours. That affects the Zhang
7 reference by the way, pretty strongly as does the Rogawski statement in his
8 declaration. It doesn't really affect Saporito as much, because that was 24
9 hours which is significantly more than 8 hours after infusion had been
10 completed by taking those routes.

11 MS. SOMMERS: Well, I think it's important to note that the only
12 information provided there is that the rats were alive. It doesn't say what
13 their condition was.

14 JUDGE FREDMAN: I would say that's improvement because --

15 MS. SOMMERS: Well, you know, we --

16 JUDGE FREDMAN: That to me is an improvement if it's me who is
17 being treated and on that route.

18 MS. SOMMERS: Well, it might be to say they're seizure free. So we
19 don't know what --

20 JUDGE FREDMAN: Again, it doesn't, a lot of it still, alive and with
21 seizures would still be better than dead with no seizures, right?

22 MS. SOMMERS: I'm not sure we can be so cavalier.

23 JUDGE FREDMAN: Really.

24 MS. SOMMERS: I think it's pretty awful what these patients are
25 going through.

26 JUDGE FREDMAN: Okay. We were talking about the rat patient.

1 MS. SOMMERS: So with respect to that, just to be clear, that it's
2 measuring versus improvement, and we relate it to improvement.

3 So with respect that the Board found in Institution that the only data in
4 Zhang showing improvement goes up to 5 hours in a rat, and Petitioner's
5 reliance on Zhang's multiple dosing is basically mooted, if the Board were to
6 adopt this plain and ordinary meaning.

7 So if you have further questions on that term, I think there is a
8 separate and independent reason why anticipation is mooted by the claim
9 construction if the Board were to adopt the plain and ordinary meaning.
10 And that goes to the claim term "treating status epileptic as comprising
11 administering to a patient in need thereof." That claim term, as Dr. Sankar
12 has presented his evidence, means treating a human patient suffering from
13 SE and that entire term needs to be construed.

14 JUDGE FREDMAN: And we're supposed to ignore your
15 specification which says a subject, that a subject could be human or animal?

16 MS. SOMMERS: Well, I think you ignore it in the context of the
17 claims and here's why, and that is federal circuit precedent, so Jansen case
18 that we rely on, as well as its predecessor case, Rappaport, that's discussed in
19 Jansen, tells us that when we have a method of treatment preamble and the
20 phrase "in need thereof," those need to be considered together in tandem and
21 not picking and choosing among the different terms.

22 JUDGE FREDMAN: In this case does it matter, because the mice are
23 in need thereof. After they've been treated with the pilocarpine, they're in
24 need.

25 MS. SOMMERS: Well, I think it does matter here because what
26 Jansen further instructs for us is that to do the proper construction, we have

1 to look at what the claim means. So according to Jansen, the preamble
2 provides the statement of intended purpose for which the method must be
3 performed. And here that's treatment of SE.

4 And so in our case, we need to look at what the intrinsic record says
5 about treatment in this case. And at Slide 10, we can put up, the '817 patent
6 tells us exactly what it means by treatment and treating. Here at Column 29,
7 Lines 30 through 50, it talks about treating in the context of a clinical or
8 subclinical response. And it also talks about how a physician, not a
9 veterinarian, not a research, would recognize whether that treatment
10 occurred or not.

11 So in the context of this claim, and looking at a method for treatment,
12 which is what Jansen tells us we have to look at, this is directed to clinical
13 treatment by a physician.

14 JUDGE FREDMAN: So you want us to come to a decision where we
15 ignore the definition of the Specification, go to the federal circuit and tell
16 them that we're going to read treatment as more important than the word
17 case subject, right, we're going to ignore that word, we're going to focus on
18 this other word?

19 MS. SOMMERS: Well, I don't think you're ignoring either of the
20 words, Your Honor.

21 JUDGE FREDMAN: You're ignoring an express definition in the
22 specification to get to your result.

23 MS. SOMMERS: It is -- it is a definition that includes certain things.
24 And that doesn't mean that in every context it will include all of those
25 things, and it's important to consider the claims, consider the terms in the
26 claims as they are, in the context with which -- with where they sit.

1 JUDGE FREDMAN: And then we even have the discussion at
2 Column 30 of your specification about pharmaceutically acceptable, it's not
3 like you're treating, well, if you treat it, it's got to be pharmaceutically
4 acceptable, right, that's a reasonable statement there.

5 And it says "Entities that are regarded as safe" and it does talk about
6 entities approved by regulatory agencies or another generally, and this is at
7 the end of Lines 22 to 23, "or another generally recognized pharmacopeia
8 (phonetic) for use in animals and more particularly use in humans," well it
9 didn't say use, "particularly in humans." So we here again, have animals
10 expressly talked about in the context of pharmaceutically acceptable.

11 MS. SOMMERS: Sure.

12 JUDGE FREDMAN: So it's pretty clear that this specification is
13 encompassing animals, they're not trying to exclude it in any way. I don't
14 think you have any positive exclusion that I've seen of that.

15 MS. SOMMERS: Well, I think --

16 JUDGE FREDMAN: But again, Novartis wouldn't support that
17 either, by the way.

18 MS. SOMMERS: Okay. There's one example of why it should be
19 excluded that I'd like to provide with you, but I would like to respond. I
20 think as you said, the specification considers multiple things. It could be
21 treating, it could be for research purposes. And those are not definitions
22 where it's changed the ordinary meaning and we backed it as our own
23 lexicographer, but what we need to do is consider --

24 JUDGE FREDMAN: You don't think when you say patient and
25 subject, quote, unquote for both are used interchangeably here that we can
26 include but not limit it to "primates such as humans, canines, porcine,

1 ungulates, rodents, poultry, and avian," that that's serving as a
2 lexicographer?

3 MS. SOMMERS: I think --

4 JUDGE FREDMAN: You would argue that that's not a lexicography,
5 a statement of express definition?

6 MS. SOMMERS: I think, it doesn't say as defined, and I think subject
7 could be a rat, for example, under a person of ordinary skills understanding,
8 it's not taking the person of ordinary skill --

9 JUDGE FREDMAN: They are used interchangeably it says, so if you
10 add a patient or a subject, and it defines as any of these species, you're
11 saying that's not lexicography?

12 MS. SOMMERS: I --

13 JUDGE FREDMAN: You can say that, if you want to say that, go for
14 it.

15 MS. SOMMERS: I think that's what I'm saying.

16 JUDGE FREDMAN: Okay.

17 MS. SOMMERS: I think it doesn't say that it's providing a definition.

18 JUDGE FREDMAN: That's fine.

19 MS. SOMMERS: And that it's saying includes, not that it's required
20 that each and every time it be that. And you have to look at it in the context
21 of the claims. With respect to why it makes sense --

22 JUDGE MAJORS: Ms. Sommers, this is Judge Majors, if I could just
23 interject for a moment, we want to understand this position. What part, what
24 language in the claim is it that you're latching onto that purports a narrow
25 definition of patient as set forth in the specification?

1 Because if I understand what you're saying, you're not taking the
2 position that patient as defined in the specification doesn't list rats and other
3 animals, but you are saying some other context in the claim, limits the
4 claims to humans, and that of humans alone?

5 MS. SOMMERS: That's right, Your Honor. And the basis for that is
6 our reliance on how those types of claims that have that "in need thereof"
7 language have been interpreted by the federal circuit and the precedent that
8 Jansen and Rappaport provide. That you have to consider both what is the
9 preamble on method of treating, and what is the intended purpose of that
10 method that's in the preamble, tied to what has the recognized need. And
11 here we have a method of treating SC and -- I'm sorry.

12 JUDGE MAJORS: Why is it the case that animals for veterinary
13 purposes, why is it that animals would not need treatment?

14 MS. SOMMERS: Well, one, they may, but again we need to look at
15 the context of our intrinsic record and the only -- the only reference to
16 treating is to clinical and subclinical responses that are specifically tied to
17 how a physician would understand those.

18 JUDGE MAJORS: But I don't know, I'm sorry to interrupt you. I
19 don't know that that's true, I mean, I was just skimming through a portion of
20 this decking, in fact with respect, I think it's Figure 2, which is of the rats
21 data in your specification, I think it describes them as being parts of a
22 treatment group.

23 So I can -- what got me thinking of this was your latching onto the
24 language about treating and treatment and specification, but I just don't even
25 see that portion of the claim language or the specification language as
26 limited to humans only.

1 MS. SOMMERS: So I think there's more than just the treating. And
2 with respect to treatment in Figure 2, I think that's a little bit like treating,
3 applying, you know, thinking about --

4 JUDGE FREDMAN: You keep referring to Jansen, in Jansen, wasn't
5 Jansen limited, the claim itself in Jansen was limited to humans, is that not
6 true?

7 MS. SOMMERS: Yes. It had human in the -- in the language "in
8 need thereof." But that, so we're not relying on it to say patient equals
9 human, that's not the point. It's that you have to consider the phrases
10 together.

11 JUDGE FREDMAN: But it's a different fact pattern, I don't think it's
12 quite the same as here.

13 MS. SOMMERS: Well, if you look at the Rappaport decision, that
14 had patient in the language. So it's not the specific language that we're
15 latching onto in that case, it is the --

16 JUDGE FREDMAN: Does Rappaport need to exclude animals?

17 MS. SOMMERS: That wasn't an issue before the --

18 JUDGE FREDMAN: So that's -- in either case, then there's this
19 situation with an express definition of the patient population, and we have an
20 express statement that these are the patients being treated. In both those
21 cases, that was not an issue, so it's not really a problem, they're not really
22 relevant, they're not on course with this, is what you're telling me.

23 MS. SOMMERS: That isn't actually what I'm telling you.

24 JUDGE FREDMAN: That's how I'm interpreting it.

25 MS. SOMMERS: That's fine. I believe Jansen is relevant to how we
26 need to construe the entire term and not just take the definition in the

1 specification for plaintiff, sorry, not plaintiff, patient, and plop it in to Claim
2 1.

3 And we have additional context and that's from Claims 25 through 31
4 that have doses that Petitioner has acknowledged are not appropriate for rats.

5 So we know that these doses are human doses and a person of ordinary skill
6 in the art, which we have reading the claims would understand the claims in
7 this way.

8 And I think it's notable, and of course, Dr. Sankar's opinions were
9 given in the perspective of a person of ordinary skill in the art, is that the
10 Petitioner's own definition of a person of ordinary skill in the art, expressly
11 does not include a veterinary medical, veterinary doctor.

12 It does expressly include a practicing neurologist for somebody who is
13 practicing seizure disorders. This definition is undisputed, it was adopted by
14 the Board. Petitioner has made no effort why somebody with that level of
15 ordinary skill in the art would have thought these claims are directed to
16 veterinary or rat research purposes.

17 And so for that additional reason, if the Board were to find that the
18 plain and ordinary meaning should control as Patent Owner believes it does,
19 that would be a separate reason that the anticipation argument from
20 Petitioner on Claim 22 would not be moot.

21 If there's further questions on that? Would you like to continue?

22 MR. MCDONNELL: Sure. So I just have two points I would like to
23 make on anticipation and obviousness for Claim 22. I think as Your Honor
24 recognized during Petitioner's presentation that based on Zhang alone, you
25 don't necessarily inevitably get improvement to the patient after
26 administration --

1 JUDGE FREDMAN: Dr. Rogawski seems to imply that, yes.

2 MR. MCDONNELL: Yes. So then Petitioner relies on extrinsic
3 evidence to Saporito P1, 24-hour survival, and then similar data in Table 2
4 of the '817 patent. But if you look at those -- that specific data, that also
5 does not demonstrate that you would necessarily and inevitably have
6 improvement to the patient after --

7 JUDGE FREDMAN: It is that rats, more rats live long-term, right?

8 MR. MCDONNELL: I'm sorry?

9 JUDGE FREDMAN: It's more rats live longer, that is more rats have
10 24-hour survival?

11 MR. MCDONNELL: Sure. It shows more rats, but doesn't show that
12 every rat lived longer, so it doesn't show that they necessarily are living
13 longer, all this tells you is that there's a certain number of a rats surviving
14 after 24 hours. It doesn't tell you how many of those rats are still seizing.

15 JUDGE FREDMAN: So let's assume that there isn't any anticipation
16 for it right now. For obviousness, does that really matter, right. Once we
17 know that it makes it better, it's obvious to try. There is a reasonable
18 expectation, because we've got this evidence showing that it works.

19 MR. MCDONNELL: I respectfully disagree. If you would go to
20 Slide 96. In terms of obviousness for this point, Petitioner relies merely on
21 attorney argument without any evidentiary support, not from the reference
22 itself and not from Dr. Rogawski.

23 They simply state "In addition, Saporito P1 shows that ganaxolone
24 promoted survival in the rats, measured 24 hours after the onset of CSE,
25 suggesting improvement after 8 hours." And the only cite they have there is
26 to Figure 3 in Saporito P1 itself.

1 So there's really no, which based on looking at that and what evidence
2 Petitioners put forward, just shows that a certain number of rats survived.
3 So I don't think that necessarily demonstrates that the claims would have
4 been obvious based on the evidence the Petitioner put in with its petition.

5 JUDGE FREDMAN: I mean, they measure the number of rats, and
6 the number of rats was higher, is that not evidence that it survived -- that
7 they did better?

8 MR. MCDONNELL: Based on what --

9 JUDGE FREDMAN: They expressly said, the very last conclusion on
10 Saporito, the 2016 Exhibit 1013 says "The maximum IV promoted survival
11 rates similar to those observed with the administration of Allepregnanolone,
12 those measured at 24 hours after CSC onset." And so they're saying that you
13 basically get better than control levels, which is what they have. Right?

14 MR. MCDONNELL: But that's not something that Petitioner relied
15 on in its petition, that specific language, all they say was they'd measured
16 rats 24 --

17 JUDGE FREDMAN: But that's what their expert said it, and that's
18 what's relying on the testimony of Dr. Saporito, right?

19 MR. MCDONNELL: I'm sorry?

20 JUDGE FREDMAN: Dr. Rogawski said that, I think.

21 MR. MCDONNELL: He didn't -- there's no citation in the petition to
22 this, he doesn't say it in this petition to this effect, either. So it's just part of
23 the failure of proof and their attorney argument on the Petitioner's part.

24 If there's no further questions on Claim 22, then I will sit down.

25 JUDGE FREDMAN: Sure. Okay. Oh, are you guys done?

26 MR. MCDONNELL: Yes. I'm sorry.

1 JUDGE FREDMAN: I thought co-counsel was going to join us.
2 Okay. You have 15 minutes. Are you ready?

3 MS. HUFNAL: Yes, Your Honor. I'm just going to pick up on that
4 very, I don't -- Your Honor I can do it just with slides. Do you want me to
5 put the slides up as well?

6 JUDGE FREDMAN: You don't need to, I mean you can point to
7 them, we can see them.

8 MS. HUFNAL: Yeah, all right. Just on the very last point about there
9 being no citation, just the attorney argument about the Saporito poster and
10 the 24-hour survival rate, I would just direct the Court to Dr. Rogawski's
11 supplemental declaration, Exhibit 1041 where he discusses this at Paragraph
12 49, he even has, copies and pastes a picture of that. So small point, but I
13 figured I would make it.

14 So on the patient, and I'm sorry, I'm just going to do this a bit staccato,
15 but I'm happy to go anywhere Your Honor --

16 JUDGE FREDMAN: No, no, you're in charge.

17 MS. HUFNAL: All right. On the patient, taking a kind of big step
18 back, the Patent Owner could clearly have claimed human patient if that's
19 what they intended, and in fact, they are getting patents to human patients
20 now.

21 The argument that the doses are for humans in the claims that are at
22 issue, that is not, I think, the way that one does that claim construction under
23 Phillips. So the fact that certain patients, those doses may be more
24 appropriate for certain patients than others, that doesn't limit the term
25 patient, does not change the construction or the understanding of the word
26 patient. And --

1 JUDGE FREDMAN: I sort of will ask you, so in context of the
2 dosing claims, not so much 21 or 22 but 25 through 31, I mean, you do have
3 a statement, I think by Dr. Rogawski or he mentioned that it could be dogs,
4 right. So I mean I think patients were, while we, and dogs are expressly
5 listed in the specification, so.

6 MS. HUFNAL: That's exactly the point I was going to make. So, that
7 there is evidence and he cites extrinsic evidence, you know, dogs could be
8 within those dose ranges, those weight ranges, I think, pigs, you know, some
9 mention of pigs. And then I'm kind of going to the flip side, I mean, you
10 could have --

11 JUDGE FREDMAN: And the dogs also have this disease, can they --

12 MS. HUFNAL: Absolutely, absolutely. And he did testify that, that I
13 want to talk about this concept that a person skilled in the art would be
14 thinking about that narrow. As Dr. Rogawski, is a person of skill in the art,
15 and he did set out in 1041, Exhibit 1041, his discussion about veterinary use
16 and how that is something that it's contemplated. And actually, I could pull
17 the site, but he was asked about this at his deposition as well, Dr. Rogawski
18 consults for several universities for veterinary purposes. Treating SE is not
19 limited to humans even for, you know, people of person skilled in the art.

20 Oh, and just by, the kind of flip side of this whole those doses are only
21 appropriate for humans, of course there could be little humans, where those
22 doses are not appropriate, so it is an arbitrary construction that they are
23 proposing here.

24 JUDGE FREDMAN: What's the age range, do children get status
25 epilepticus?

26 MS. HUFNAL: Yes.

1 JUDGE FREDMAN: At any age, even babies?

2 MS. HUFNAL: Yes. Okay. So next, I was going to talk about the
3 unexpected results and a benchmark of the argument that Patent Owner is
4 making comes from Exhibit 2008, there's two of them, but the Houlihan
5 declaration, I'm pulling Exhibit 2008, because that's what I pulled out of my
6 binder.

7 But the language is the same, and this is Page 26 of Exhibit 2008, it's
8 Paragraph 7 of the Houlihan declaration, and it's language that I'm sure the
9 Board heard where Marinus, Petitioner, said we initially believed that a high
10 ganaxolone exposure for a long treatment period of at least four days --

11 JUDGE FREDMAN: 2008, is that right?

12 MS. HUFNAL: I was looking at Exhibit 2008. Did I mess that up?

13 JUDGE FREDMAN: I don't know, maybe.

14 MS. HUFNAL: Oh, yeah. It's the excerpts from a file.

15 JUDGE FREDMAN: Okay. Yes. What page, do you know what
16 page of that exhibit it's on?

17 MS. HUFNAL: 26 of 60.

18 JUDGE FREDMAN: 26, okay, thank you.

19 MS. HUFNAL: It's Paragraph 7.

20 JUDGE FREDMAN: This was submitted as an example, okay.

21 MS. HUFNAL: Yes. This is the fundamental point that I think they
22 need to prove to even be talking about unexpected results, the fact that there
23 was something expected, right. And so what they point to is Paragraph 7.

24 And this is Dr. Houlihan saying, I apologize, I called him Mr. earlier,
25 Dr. Houlihan saying "We initially believed," of course this is Marinus, not
26 some understanding of the art but we'll put that aside, "that you would need

1 some long exposure, long treatment period for at least 4 days in order to
2 break SC, i.e. stop seizures and prevent seizures from rapidly returning when
3 ganaxolone was discontinued." That's that Line 3 that Your Honor pointed
4 to me in Table 2 at the outset of this.

5 JUDGE FREDMAN: Yes.

6 MS. HUFNAL: Looking at 24 hours afterwards, making sure it
7 doesn't come back, that's the high cohort that we're saying. That's what we
8 have said was unexpected, not what Patent Owner's trying to say is just the
9 fact that we had successful clinical trials that was unexpected. I mean, we
10 expected to have success in our clinical trials, right. That cannot be the
11 basis, and I don't think they've established that that is a proper basis for
12 unexpected results.

13 Okay. So then on the concept that we, Petitioner, just refers to the,
14 and I think Your Honor got this, but we are somehow walking away from
15 things we've said in public statements and the slide put up was an excerpt
16 from Exhibit 2002, which was a intellectual property presentation by
17 Marinus. And the slide that you're, the Board was pointing to was Page 27,
18 which was the figures and it just shorthanded, you know, the high dose.

19 And just the slide before that, Slide 26, lays out the entire dosing
20 cohort profile, so I do not think that the record suggests that we have any
21 way said that it's just the amount of ganaxolone per day that leads to these
22 results.

23 Okay. So on that point, talk about Dr. Rogawski, there was some
24 suggestion that the experts agree that you would always use a bolus in
25 dosing. And we are turning the analysis like completely on its head now,
26 because they are talking about how would a person skilled in the art read

1 their claims, and that person skilled would understand you would need a
2 bolus, I mean now that sounds like a new claim construction argument. But
3 fundamentally, Dr. Rogawski did not say that. In his deposition he was
4 asked, this is Exhibit 2015. He said --

5 JUDGE FREDMAN: Can you tell me what page?

6 MS. HUFNAL: I'm sorry, yes. Exhibit 2015, so I'm looking at Page
7 29 of his depo, it goes from 29 into 30.

8 JUDGE FREDMAN: Mm-hmm.

9 MS. HUFNAL: And he's saying, yes, status SC is a serious, life-
10 threatening neurological emergency, you want to get medication quickly.
11 And he was asked, that's accomplished through an intravenous
12 administration, this is the top of Page 30, not always, but most commonly,
13 he will agree with that.

14 And then he says it's, or he was asked, is intravenous administration
15 the fastest way? And he's like look, and he says, answers, sorry, there are
16 multiple ways of administering medications to patients, the speed of onset
17 depends, basically he goes on and on and then goes on to talk about other
18 routes of administration. The point here is, we cannot be all of a sudden
19 construing the claims to require a bolus, I do not think that is supported in
20 the record by any admission certainly from Dr. Rogawski.

21 And then on, yeah, this point of do you need a bolus, the claim that, I
22 think we are all in agreement the claims are silent on whether or not a bolus
23 is administered. We submitted evidence, you know, in addition to Exhibit
24 2003, which shows even two of the regimens that have bolus didn't meet
25 these unexpected results.

1 But then just to back end that, the modeling from Dr. Baughman,
2 that's Exhibit 1058 where she showed she just took 720 milligrams
3 ganaxolone, dosed it, just for infusion, dosing a constant infusion, dosing at
4 a rate and length that would, you know, total up to 720, and doesn't even get
5 close to 500.

6 And of course, I already walked through Dr. Sankar's admissions
7 where he said you'd need a bolus for this. And then I think, oh, you know
8 what, I will close on our Slide 25.

9 And our Slide 25, there was back and forth between the Board just
10 now about whether or not being alive is an improvement. And Dr. Sankar,
11 this is from his deposition, Exhibit 1042, we excerpted it on Page 25, with
12 the citation, it's Page 37, Lines 12 through 21. Dr. Sankar says "It's pretty
13 common that we want to know how many rats survived. We know lithium
14 pilocarpine has significant mortality associated with it, so in a study
15 pertaining to treatment, if you increase survival, that will be a beneficial
16 outcome to treatment." And with that, unless the Board has any questions, I
17 have nothing further.

18 JUDGE FREDMAN: Are there any questions, Judge Yang? Judge
19 Majors?

20 JUDGE MAJORS: No.

21 MS. HUFNAL: Thank you, Your Honors.

22 JUDGE FREDMAN: Okay. Thank you very much.

23 MR. MCDONNELL: Just have a few quick points I would like to
24 make.

25 JUDGE FREDMAN: Wait for your time, sir.

26 MR. MCDONNELL: Oh, sorry.

1 JUDGE FREDMAN: You have 15 minutes.

2 MR. MCDONNELL: Thank you.

3 JUDGE FREDMAN: Here we go, go.

4 MR. MCDONNELL: I just want to say the even if the Board
5 determines that Claims 25 through 31 do have doses that could be
6 appropriate or are appropriate for other animals besides humans, they're
7 definitely not appropriate for rats. And we put in testimony from Dr.
8 Sankar, extrinsic evidence, showing that at the doses that are recited in those
9 claims, you're doing harm to rats, you're not treating SE.

10 JUDGE FREDMAN: Right, so the example in, for example Saporito,
11 or in Zhang doesn't anticipate, that's what they're argument is.

12 MR. MCDONNELL: Yes, it --

13 JUDGE FREDMAN: It just doesn't really apply to obviousness
14 where it would be obvious to treat dogs that have SE and then you keep
15 doses appropriate for those dogs, it's a different question. But that argument
16 does apply for anticipation.

17 MR. MCDONNELL: Yes, it applies to anticipation, but I think it also
18 applies to obviousness because the only data that Petitioner relies on is for
19 rats, there's no argument in their petition or in their reply that any of this
20 information would give you a reasonable expectation of success for any of
21 these --

22 JUDGE FREDMAN: Well, actually Zhang does mention that it could
23 be used for animals as well, doesn't it?

24 MR. MCDONNELL: I think that is included in the definition of
25 patients, but again, you can't just directly translate these animal models
26 necessarily from one animal to another, there's no evidence --

1 JUDGE FREDMAN: The discussion of optimization, but yes, okay.

2 MR. MCDONNELL: Yeah, but there's no evidence in the record
3 demonstrating that the information that you get from example in Zhang is
4 applicable to any other species. Besides, the only arguments they've made
5 are about humans besides rats.

6 Moving on to unexpected results, Petitioner has gone to great lengths
7 to try to reframe what the unexpected results are. And I think showing
8 Paragraph 7 of the Houlihan declaration, Exhibit 2007, shows that the two
9 unexpected results were based on that you would, sorry, that you would
10 expect either a higher and long exposure of ganaxolone to have rapid
11 reduction in seizure burden, and cessation of seizures for 24 hours.

12 And if you look at Exhibit 2003, and the table on Page 2036, it shows
13 that not just the high dose cohort met those two end points, the unexpected
14 results of rapid reduction seizures and cessation of seizures for 24 hours, but
15 it met it in the low and medium-dose cohort, too. So while Petitioner --

16 JUDGE FREDMAN: But the question here is what is expected, right?
17 I mean, it sounds like what's expected could be, for example, that it takes
18 four days, at least of the prior art prior to this administration to reduce
19 seizures to a manageable level. And so the results here, I guess you are
20 arguing, are showing that it's only, they only took one day. And the problem
21 with that again, is still that it's the way it's being administered and so you,
22 you don't really have any time frame for this, you know, how many days it
23 has to be administered, right? Yours could be administered for weeks
24 potentially, there was no exclusion of that.

25 MR. MCDONNELL: I --

26 JUDGE FREDMAN: -- per day --

1 MR. MCDONNELL: -- milligrams per day.

2 JUDGE FREDMAN: Correct. The results are that it's a one-day
3 thing. And your claims don't really aren't limited that way either, right. I
4 mean, you're not limited in any of the parameters that the results provide.
5 You have a number and that's it, you don't have any of the other parameters
6 around it in terms of time, in terms of how it's being administered, other than
7 that it's intravenous, in terms of the infusion rates, any of that stuff.

8 MR. MCDONNELL: Respectfully, all the Petitioner relied in its
9 reply is the continuous, the bolus and continuous infusion. It didn't go into
10 the nitty gritty of --

11 JUDGE FREDMAN: They made an argument here, otherwise, but
12 yeah, okay.

13 MR. MCDONNELL: Yeah, but that was not something that they had
14 made before. And I would also like to just point out that they had talked, the
15 Petitioner had mentioned how oh, it's not limited to, look there's many
16 different ways you can administer ganaxolone, but the claims recite
17 intravenous. And there's two ways you can administer ganaxolone
18 intravenously and that's with a bolus dose or a continuous infusion. And
19 there's not --

20 JUDGE FREDMAN: Could you not do a pulsatile?

21 MR. MCDONNELL: I'm sorry?

22 JUDGE FREDMAN: You couldn't administer a pulsatile, up and
23 down, like they've been administered that way sometimes. I mean, there are
24 other ways to administer drugs, it's not only continuous or bolus, you could
25 do any patterns or lots of, in fact, the example is, right, an 80 mg, and a 40
26 mg, not a 20 mg in the epilepsy paper, they're not -- they're not sort of

1 continuous infusion of one dose, it's a gradual change in doses over a
2 different timeframes.

3 MR. MCDONNELL: Sure. I would say the changes in the dose are
4 still continuous, you might be increasing the amount that you are
5 administering continuously.

6 JUDGE FREDMAN: All right. But then you could say anything, a
7 bolus is continuous for the ten seconds that it's administered, I mean, that's
8 not a, that's sounds reasonable, I guess. I mean, that's trying to say that
9 continuous is therefore anything, that eliminates the meaning of the word.

10 MR. MCDONNELL: Right. But those are the two ways, those are
11 the only ways, that Petitioner argued from a high level that you would have
12 bolus and continuous infusion, not the specifics of how each of those bolus.

13 JUDGE FREDMAN: Did you point to the other one, okay.

14 MR. MCDONNELL: So based on everything we've discussed today,
15 and the unexpected results in Claims 25 through 31, and Claim 22 are not
16 anticipated and obvious so from Zhang or any of the other references that
17 Petitioner cites. And I will yield back the rest of the time.

18 JUDGE FREDMAN: Okay. Thank you very much. Are there any
19 further questions before you go? Judge Majors? Judge Yang?

20 JUDGE MAJORS: Not from me, thank you.

21 JUDGE FREDMAN: Okay. Thank you. I guess we will go off the
22 record, this proceeding is concluded. Was there anything else? So thank
23 you, and have a great day.

24 (Whereupon, the above-entitled matter went off the record at 2:50
25 p.m.)

PETITIONER:

Martina Tyreus Hufnal
Anita L. Meiklejohn
Katie E. Hyma
Michael Kane
FISH & RICHARDSON P.C.
hufnal@fr.com
meiklejohn@fr.com
hyma@fr.com
kane@fr.com

PATENT OWNER:

Anthony C. Tridico
Erin M. Sommers
Ryan V. McDonnell
Kaitlyn S. Pehrson
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
anthony.tridico@finnegan.com
erin.sommers@finnegan.com
ryan.mcdonnell@finnegan.com
kaitlyn.pehrson@finnegan.com