

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PADAGIS US LLC,
Petitioner,

v.

NEURELIS, INC.,
Patent Owner

IPR2025-00464 (Patent 8,895,546 B2)
IPR2025-00465 (Patent 11,241,414 B2)
IPR2025-00466 (Patent 11,793,786 B2)

Held: June 16, 2026

Before GRACE KARAFFA OBERMANN, ANNETTE R.
REIMERS, and TIMOTHY G. MAJORS, *Administrative Patent
Judges*.

The above-entitled matter came on for hearing on June 16, 2026,
commencing at 9:01 a.m., via video teleconference.

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

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3 JUDGE MAJORS: Okay. If everyone's ready. This is
4 Judge Majors. Good morning. Everyone hear me? I just want to
5 confirm?

6 MR. LANDMON: Yes.

7 MR. TOBIN: Good morning.

8 MR. LANDMON: Good morning.

9 JUDGE MAJORS: Good. Okay. With me today are
10 Judges Grace Karaffa Obermann and Annette Reimers. This is a
11 final oral hearing in three proceedings, IPR2025-00464, which
12 concerns U.S. Patent Number 8,895,546. IPR2025-00465, which
13 relates to Patent Number 11,241,414. And lastly, IPR2025-00466,
14 and that is U.S. Patent 11,793,786.

15 Our Petitioner today is Padagis U.S. LLC. Hopefully I
16 pronounced that correctly. Patent Owner is Neurelis Inc. Our
17 Court Reporter is present. There will be a transcript of today's
18 hearing prepared, and it will be entered into the record when ready.
19 Counsel for Petitioner, would you please identify who is present
20 today on your side and who will be doing the presentations?

21 MR. LANDMON: Yes. Good morning, Your Honor.
22 Can you hear me?

23 JUDGE MAJORS: I can hear you great. Thank you.

24 MR. LANDMON: Great. My name's Chad Landmon

1 from Polsinelli. With me at Counsel table is Corey Casey. I'll be
2 doing the primary part of the argument, and my colleague
3 Christopher Jones, who's behind me to my left, will also be doing
4 part of it. We have James Murphy here as well, and Andrew
5 Spitzer, who's with our client Padagis.

6 JUDGE MAJORS: Great. Thank you everyone. And
7 Counsel for Patent Owner who is present today, and who's going
8 to be doing your presentations?

9 MR. TOBIN: Good morning, Your Honor. David Tobin
10 from the law firm of McDermott Will & Schulte from Patent
11 Owner. Can you hear me okay?

12 JUDGE MAJORS: I can hear you great. Thank you.

13 MR. TOBIN: Thank you, Your Honor. With me at the
14 table is Dr. Timothy Best, also from McDermott, and our LEAP
15 practitioner, Ms. Hannah Hurley from McDermott. We also have,
16 not at the table, but sitting behind us, we have Michael Sitzman,
17 our lead counsel from McDermott and other counsel of record.

18 We have Nicole Endejann and Ray Miller from the DLA
19 Piper Law Firm. And those presenting today, Your Honor, is
20 myself, David Tobin, our LEAP practitioner, Hannah Hurley, and
21 Timothy Best.

22 JUDGE MAJORS: Okay, great. And welcome to
23 everyone on Patent Owner's side. As we set forth in our May 21st,
24 2026 order, each side has 80 minutes to present its argument.
25 However, because each side has a LEAP practitioner, we're adding

1 15 minutes. So that means each side is going to get 95 minutes to
2 present its case today.

3 The panel is going to do our best to keep track of time.
4 And as you can see behind Judge Obermann, there will be a timer
5 there. But I would encourage Counsel to try to do the same and
6 just keep track of your time. Petitioner, you're going to go first as
7 you bear the burden of proof. Would you like to reserve any
8 rebuttal time?

9 MR. LANDMON: Yes, Your Honor. We'd like to
10 reserve 20 minutes.

11 JUDGE MAJORS: And Patent Owner, would you like
12 to reserve any rebuttal time?

13 MR. TOBIN: Yes, Your Honor. We'd also like to
14 reserve 20 minutes.

15 JUDGE MAJORS: Good.

16 JUDGE OBERMANN: I'm just going to set the clock
17 for 55 minutes.

18 MR. LANDMON: It should be 75 minutes.

19 JUDGE OBERMANN: Oh, 75. Sorry. You're right.

20 JUDGE MAJORS: You can of course go into your
21 rebuttal time if you so choose in your primary presentations and
22 we'll track that. I believe that there is some confidential
23 information that was submitted in this case. Although given the
24 demonstratives and what I understand the issues are at this point,
25 I'm not sure that we will need to get into that.

1 However, Counsel, please let us know if you anticipate
2 making any confidential information part of your presentations
3 today so we can take appropriate action. There's also a public
4 hearing line, which I understand is open. We have access to the
5 entire record, including the demonstratives.

6 So as you make your presentations today, if you would
7 just do your best to refer to the demonstrative by its page number,
8 we'll try to follow along with you. Our expectation is that the
9 parties will not interrupt each other unless it's absolutely necessary
10 during their presentations.

11 And if during today's presentation of argument, if you
12 notice that there's some technical issue, maybe one of the Judges
13 that is appearing remotely freezes up, just please let the staff there
14 know and we'll do our best to get everybody back online. And
15 with that, Petitioner, you have 75 minutes for your primary
16 presentation on the clock, and you can begin whenever you're
17 ready.

18 MR. LANDMON: Thank you, Your Honor. As I said
19 before, Chad Landmon for Padagis. So as you already mentioned,
20 this is a consolidated proceeding. The issues, however, largely
21 overlap. So our intent this morning is to address things by issue.
22 But we will identify any particular issues that relate to any specific
23 patent.

24 Why don't we turn to the next slide. So turning to Slide
25 2, just really wanted to quickly obviously set the stage in terms of

1 the prior art. Gwozdz and Meezan are the two primary references
2 that cut across all claims. We also have two other references, Cartt
3 and USP that go to certain claims.

4 And if we can go to Slide 3, I wanted to quickly
5 introduce to you our expert who has submitted two declarations.
6 As you know, it's Dr. Maureen Donovan, she's a professor of
7 pharmaceutical sciences and experimental therapeutics at the
8 University of Iowa College of Law.

9 She's got over 40 years of experience in education and
10 practical experience in formulation development, including a
11 particular nasal delivery formulation, which is important here.
12 And if we can turn to Slide 4. Turning to the merits, the Board's
13 going to hear an important theme throughout the discussion today.

14 There we go. There's Slide 4. Sorry about that. And
15 that's that a key obviousness dispute here is materially the same
16 dispute that was already resolved in the '451 IPR proceeding
17 involving the '876 Patent. Now, I'll discuss that in more detail as
18 we go along and discuss the contested issues.

19 But what you need to know is the '876 Patent was in the
20 same family, had nearly identical claim limitations, and involved
21 the same prior art of Gwozdz, Meezan, and Cartt. There the Board
22 determined that all claims were unpatentable, and the Federal
23 Circuit affirmed.

24 So we aren't plowing new ground here. And many of the
25 arguments, most of the arguments you're going to hear today have

1 already been resolved against Patent Owner. With all that in mind,
2 if we can turn to Slide 5, this is how we plan to address the issues.

3 Obviously, I'm open to answering your questions in any
4 order you choose, but generally this is how we plan to go through
5 the issues this morning. As I mentioned, I'll be splitting the
6 argument with my colleague, Chris Jones. I'll be taking essentially
7 from the start of the argument through where you see motivation to
8 combine and reasonable expectation of success.

9 There are a few different issues involved there. I'll
10 address the first couple, and then my colleague Chris Jones will get
11 up to address the rest of those along with the rest of the issues on
12 this slide. But if we can turn to the next slide, Slide 6.

13 Before getting into the actual contested issues, I just
14 wanted to set the stage by discussing what the state of the art was
15 prior to the priority date here. And just to clarify, in our slides,
16 you'll see mostly citations to the '786 Patent or the IPR proceeding
17 in record in the '786 Patent IPR.

18 You will see identical disclosures in the other patents and
19 the other IPR proceedings. But for sake of these, we cited the '786
20 Patent in our slide. But as we can see up on this slide here, one
21 thing that's important to keep in mind is benzodiazepines and
22 diazepam in particular had been used for many years to treat
23 emergency seizures.

24 But as we know, as was disclosed on the face of the
25 patents, there were certain solubility and other formulation issues

1 that would've led a POSA to look to improve the delivery of
2 diazepam. And if we can turn to the next slide, Slide 7, the prior
3 art didn't just recognize the problem, the prior art also began to
4 explore the problem.

5 We see up on the left, the EMS manual. What that
6 manual discloses is that in emergency settings, they were already
7 delivering diazepam intranasally to patients to address emergency
8 seizures. And that's important for two reasons. First, it shows that
9 the intranasal delivery of diazepam was not something new and
10 novel.

11 And second, as we see to the right there, the PDR
12 discloses Valium which was the solution that was being used in
13 emergency settings. It has two excipients that are important to the
14 dispute here, ethanol and benzyl alcohol. So again, the art was
15 already exploring solutions to the problem of delivering diazepam.

16 Now, if we can go to the next slide, Slide 8. Just really
17 quickly, Dr. Donovan explains how Gwozdz addresses the known
18 problem in the art to improve poorly soluble -- the delivery of
19 poorly soluble therapeutic agents, including diazepam.

20 And if we go to Slide 9. Meezan adds to the teaching of
21 Gwozdz by teaching alkyl glycoside absorption enhancer agents
22 that increase drug absorption through the nasal mucosa, and
23 increase bioavailability while avoiding toxicity and irritation.

24 So keeping in mind here, this combination is not
25 hindsight, it's a straightforward use of two references that solve

1 complementary problems in the same formulation space. And if
2 we go to the next slide, Slide 10, I mentioned before in the '451
3 IPR, the Board found that a POSA would've been motivated to
4 combine Gwozdz and Meezan, and would've had a reasonable
5 expectation of success in doing so to arrive at the claimed
6 invention.

7 Now, that finding matters here because Neurelis tries to
8 repackage its arguments, but the technical story has not changed.
9 Gwozdz addressed diazepam solubility, Meezan addressed
10 absorption and bioavailability, and a POSA would've reasoned to
11 do both.

12 Now, just on the next slide, Slide 11, we mentioned the
13 Cartt and USP references that, as I mentioned, will be relevant to
14 certain claim limitations. But I do want to turn to Slide 12, back to
15 the contested issues. And I wanted to begin with collateral
16 estoppel.

17 Now, Your Honors, collateral estoppel applies across all
18 three IPRs, but in slightly different ways. And we can see that on
19 the next slide, on Slide 13. So first, with respect to the '546 Patent,
20 collateral estoppel applies to the finding of obviousness because
21 dodecyl maltoside, as I'll try and say shorthand DDM for sake of
22 making it easier on myself.

23 DDM was recited in the claims of the previous '876
24 Patent, it was argued in the '451 IPR, and was found unpatentable.
25 Now, with respect to the '414 and '786 Patent, patent IPR is

1 collateral estoppel is somewhat different. What the issue relates to
2 is the claim requirement of n-dodecyl- β -D-maltoside, or as I'll
3 refer to it as NDDM.

4 And collateral estoppel applies here because that claim
5 limitation and those patents do not present a materially different
6 question of patentability over what was previously decided. And
7 --

8 JUDGE OBERMANN: Can I ask you a question,
9 please?

10 MR. LANDMON: Mm-hm.

11 JUDGE OBERMANN: Are you saying that they're the
12 exact same scope, DDM and NDDM?

13 MR. LANDMON: Well, so not necessarily the additions
14 of the β -D-maltoside. So there are kind of two issues going on
15 here. One of the disputes relates to whether the disclosure of
16 dodecyl- β -D-maltoside is the same as n-dodecyl- β -D-maltoside or
17 NDDM. It is our position, and I'm happy to jump in and talk about
18 that if you'd like to, right now.

19 It is our position that a POSA would understand those to
20 be the same ingredient. Dodecyl maltoside itself, if it's just the
21 disclosure of dodecyl maltoside, that's slightly different because it
22 doesn't have the beta and D isomer and anomer notes.

23 JUDGE OBERMANN: Well, my question is really
24 pretty simple, it's a claim construction issue. And what I'm asking
25 you is, in Petitioner's view, DDM as you call it, is

1 indistinguishable from NDDM. So in other words, they're the
2 same scope?

3 MR. LANDMON: So it's our position that dodecyl- β -D-
4 maltoside is the same as n-dodecyl- β -D-maltoside.

5 JUDGE OBERMANN: So that's a, yes?

6 MR. LANDMON: Yes. But there is a disclosure, the
7 '546 Patent, and sorry if I'm making this confusing, the '546 Patent
8 just says dodecyl maltoside. And that's what was decided in the
9 '451 IPR, just the dodecyl maltoside.

10 JUDGE OBERMANN: I understand that, but I'm trying
11 to get at your claim construction.

12 MR. LANDMON: Mm-hm.

13 JUDGE OBERMANN: So under your claim
14 construction, the little n and the B have no meaning?

15 MR. LANDMON: No, the beta and the D definitely
16 have a meaning. And it's not our position even that this needs to
17 be construed. But in our position, the n designator, which is the
18 normal designator, every POSA would understand that if they saw
19 the disclosure of dodecyl- β -D-maltoside, they don't need the n
20 disclosure. In other words --

21 JUDGE OBERMANN: So let me ask it a different way.
22 When I look at the '451 Patent, dodecyl maltoside, you're telling
23 me that that is construed as n and beta?

24 MR. LANDMON: The n part, yes, not the beta part.

25 JUDGE OBERMANN: So they're not the same?

1 MR. LANDMON: So sorry if I'm being unclear here.
2 Dodecyl- β -D-maltoside, which is what is disclosed in the Meezan
3 prior art reference, also the prior art reference in the '451, that is
4 the same as n-dodecyl- β -D-maltoside. Because the beta and the
5 delta are the anomer and stereo isomer designations. I don't know
6 if I made that clear or just made it more confusing.

7 JUDGE OBERMANN: I'm just trying to get your
8 understanding of these terms, and whether or not they're identical.

9 MR. LANDMON: Right.

10 JUDGE OBERMANN: I think I heard you say yes once,
11 and then you qualified it just now.

12 MR. LANDMON: So dodecyl- β -D-maltoside is
13 identical to n-dodecyl- β -D-maltoside because the n prefix, a POSA
14 would not need the n prefix.

15 JUDGE OBERMANN: Okay. So the beta is included in
16 the dodecyl maltoside as well?

17 MR. LANDMON: No, the beta is a designation showing
18 what the isomer or the anomer is.

19 JUDGE MAJORS: Okay.

20 MR. LANDMON: Okay. Hopefully I didn't make that
21 more confusing.

22 JUDGE MAJORS: Mr. Landmon, if I could jump in for
23 a moment. In the '451 IPR, did Patent Owner contest the teaching
24 of any of the limitations in those claims?

25 MR. LANDMON: Yes. Yes. No, the Patent Owner

1 very much challenged the teachings of the claims, in particular
2 addressed the dodecyl maltoside claim limitation. And if we want,
3 we can skip ahead to Slide 15, Your Honor. So a couple things
4 that are important here.

5 Obviously, you're getting at Patent Owner's argument
6 that they didn't actually litigate the dodecyl maltoside limitation.
7 And what they like to do is they like to focus on Claim 1 of the
8 '876 Patent. Claim 1 is broadly directed to alkyl glycoside. Claim
9 26, and we have this up on the screen, is directed to dodecyl
10 maltoside itself.

11 That claim was found unpatentable in the final written
12 decision, and it was upheld by the Federal Circuit. So clearly it
13 was decided. But if we look on the next slide, Slide 16, this really
14 gets at the heart of the issue. So Patent Owner is here before you
15 saying, no, no, we didn't contest dodecyl maltoside.

16 Well, here's their Federal Circuit briefing. We've gone to
17 the left of the screen, their opening brief. Right in the statement of
18 the issues, they address dodecyl maltoside, and the statement of the
19 issues to be decided by the Federal Circuit. Down below they then
20 talk about the priority date, and again mentioned dodecyl
21 maltoside.

22 Now, there was some dispute before the Federal Circuit.
23 You're going to hear them reference Judge Moore's comment
24 asking about whether it was waived because -- whether they had
25 actually raised it before the Board. Well, their own position before

1 the Board, and we can see this to the right on the screen.

2 To the right on the screen, is their reply brief. And they
3 have a whole section dedicated to how they argue dodecyl
4 maltoside below before. So I don't think they can be before the
5 Federal Circuit and say, yes, DDM was litigated, we argued about
6 DDM, we didn't waive our argument on DDM. And then come
7 before this panel and say, no, it wasn't litigated.

8 JUDGE MAJORS: So I have a follow-up question.
9 Aren't these arguments that you're showing me here, aren't these
10 related to the priority issue, whether there's sufficient priority
11 support? And my question was a little bit different, I was arguing
12 -- or I was raising the issue of whether Patent Owner argued to the
13 Board that either the Gwozdz or Meezan reference did not teach
14 dodecyl maltoside.

15 MR. LANDMON: Yes. So they did before the Board.
16 Obviously Claim 26, as I pointed to earlier, related to DDM. And
17 they said the claims weren't unpatentable as obvious. Now they
18 did it in a broader brush. Certainly, they focused on the alkyl
19 glycoside limitation, but the claim was squarely at issue, and they
20 were squarely arguing that the claim wasn't obvious.

21 Whether they did it with this full force or gusto, maybe
22 not because they focus on the alkyl glycoside. But certainly, it was
23 an issue and certainly it was an issue they argued about. I think
24 they can't argue about it there both for priority. And these are the
25 things we're citing to right here do relate to the priority date issue.

1 But clearly DDM was at issue, and clearly, they argued
2 that that claim shouldn't have been rendered unpatentable both
3 before the Federal Circuit and before the Board itself.

4 JUDGE MAJORS: Maybe I'm mistaken on this, but my
5 reading of the arguments that were raised to the '451 IPR Board
6 panel, obviously there was the priority issue. But on the
7 obviousness piece, it seemed that the argument was focused on a
8 lack of reasonable expectation and a lack of motivation, not on the
9 absence of any teaching of any particular limitation. Am I wrong
10 in reading the prior record that way?

11 MR. LANDMON: I don't think you're wrong in reading
12 the record that way, but that's how they chose to argue that DDM,
13 that a claim involving DDM was not obvious and not unpatentable.
14 Just because they chose to argue it this way, I don't think they can
15 come here and say, well, no, we didn't argue about DDM at all.

16 It wasn't that they just said it's a non-issue, they clearly
17 and squarely addressed that claim. They did it through different
18 means, arguing reasonable expectation of success. I mean, they
19 chose to argue the case the way they chose to argue the case.

20 It doesn't mean the collateral estoppel doesn't apply
21 because the patentability of the claim to DDM was squarely at
22 issue and they squarely took issue with it being unpatentable and
23 said it was valid. It was their opinion that it was valid. So just a
24 couple other points on collateral estoppel.

25 One, I just wanted to address, if we can turn to Slide 17.

1 There's a lot of argument here about the identity of claim language.
2 And again, that's not the issue. We know under Ohio Willow
3 Wood and Soverain, both of those cases dealt with later claims that
4 were narrower in scope than the adjudicated claims.

5 And both of those cases stand for the relevant, that the
6 legal inquiry is not whether there's a difference in claim language,
7 but whether there's any difference that materially alter the question
8 of invalidity. And Neurelis clearly hasn't established that here.

9 And if we turn to the next slide, Slide 18. And I
10 apologize, the slide is a little busy, but we were trying to get a lot
11 on the slide. This shows the heart of the issue. The '876 Patent,
12 yes, it was a method claim. So yes, it has different language and
13 some of the language is different.

14 But if you go across the claims of all the three patents at
15 issue, you'll see '876 is a method of delivering a composition. And
16 it's the composition that's now claimed in the '546, '414 and '786
17 Patents with nearly identical claim limitations.

18 And that's why collateral estoppel should apply from the
19 '451 final written decision, Federal Circuit decision to the patents
20 at issue here. So I did want to switch gears a little. If we can go to
21 Slide 19 and discuss first the priority date issue. So as you know,
22 Your Honors mentioned there was a priority date issue in the '451
23 Patent.

24 And Neurelis again here argues that the patented issue
25 can reach back to the March 28th, 2008 filing date of the '558

1 provisional. And they do that based on a disclosure and alleged
2 incorporation of reference of the SIGMA Catalog that's mentioned
3 in the '558 provisional.

4 Now, they're doing that with an attempt to disqualify the
5 Gwozdz and Cartt as prior art references. But these arguments as
6 noted, were already dismissed by the Board in the '451 final
7 written decision. But let's talk about the heart of the issue here.

8 If we go to the next slide, Slide 20. What we have up on
9 the screen here is we have the '558 provisional application that's on
10 the left. We've got Dr. Donovan's declaration on the right. This is
11 Slide 20. And what we see here is Neurelis focuses on the fact that
12 the first paragraph in the '558 that's up on the screen, it's paragraph
13 150 of the '558 provisional.

14 Second line, it mentions the term enhancer and says that
15 it can include an enhancer material compound. It then goes
16 through, and near the bottom of this call out in paragraph 152, we
17 see it lists biological detergents listed in the SIGMA Catalog.

18 But this slide really shows the issue for why it doesn't
19 obtain the priority date. And that's that there are 15 categories of
20 compounds that are listed as enhancers. They don't just list
21 biological detergents, they list 15 categories. Dr. Donovan
22 explains that the provisional provides no meaningful guidance for
23 the compounds in those classes.

24 And for example, a POSA is not told to choose biological
25 detergents over things like acyl carnitines, chelating agents,

1 surface active agents, fatty acids, bile salts, or other listed
2 categories. They mischaracterize the issue by focusing solely on
3 the SIGMA Catalog disclosure.

4 And in fact, the biological detergent appears is only one
5 item in this much longer list. It certainly doesn't indicate that the
6 inventors had DDM or NDDM in mind amongst the merely
7 limitless number of enhancers. And if we go to the next slide,
8 Slide 21, Neurelis' position is also inconsistent with the case law,
9 and it's inconsistent with how a POSA would've read and
10 interpreted the disclosures of the '558 provisional.

11 Now, the SIGMA Catalog itself says that there is a wide
12 range of detergents. Dr. Donovan, and we've got that up on the
13 screen here, she explains that the catalog pages include over 150
14 biological detergents. Only a small subset of those is alkyl
15 glycosides.

16 In the '558 Patent, it doesn't tell a POSA to select alkyl
17 glycosides. It doesn't tell a POSA to select DDM. Under the
18 standards of Advanced Display Systems that we have up on the
19 screen here, the host document is required to identify the specific
20 material with detailed particularity.

21 But here's the key here, the reference -- the host on
22 SIGMA Catalog, the reference to biological detergent is where the
23 claim compound is found amongst the many options. And if we
24 turn to the next slide, Slide 22, this really shows the heart of the
25 issue. This is up on the screen here to the right. We've got the

1 '439 application.

2 This is the first non-provisional application filed after the
3 '558 provisional. It was filed on March 27th, 2009, it's Exhibit
4 1039 in the proceedings here. And here's what we see. When they
5 submitted the non-provisional application, the '439 application,
6 they added specific details and a detailed discussion of alkyl
7 glycosides in DDM.

8 Now, at the same time we see, and it's up on the screens,
9 they kept in the biological detergents discussion in the SIGMA
10 Catalog. But this is significant. Why add material that calls out
11 alkyl glycosides and DDM in particular, if you already thought
12 you had support in the '558 provisional?

13 Now, if we go to the next slide, Slide 23, I mentioned the
14 law before. Neurelis argues that blaze marks are not required here,
15 and that the SIGMA Catalog is apparently enough because NDDM
16 is listed verbatim. But that position fails because the issue is not
17 whether a catalog somewhere contains disclosure of one
18 compound in one of the limitations of the claim.

19 The question is whether the priority document reasonably
20 conveys possession. And under Regents, a laundry list disclosure
21 does not provide written description when it fails to reasonably
22 lead a POSA to the particular species. And that's what happened
23 here, that's what Dr. Donovan explains here.

24 And we can see that on the next slide, on Slide 24,
25 applying Regents. Dr. Donovan explains that the '558 provisional

1 gives a broad enhancer definition. As I said before, it could
2 encompass seemingly an endless amount of compounds within 15
3 different categories of compounds.

4 Dr. Donovan explains the provisional application, the
5 '558 provisional gives no reason to pick biological detergents
6 amongst the many enhancers, and certainly gives no reason to
7 cherry pick NDDM or DDM from the list of over 150 options in
8 the SIGMA Catalog.

9 There simply are not adequate blaze marks to
10 demonstrate that the provisional application possessed and enabled
11 the claimed NDDM and DDM. The '558 provisional put very
12 simply discloses a forest, more than 15 enhancer classes, a broad
13 biological detergent classes and more than 150 Sigma detergent
14 options. But there are no blaze marks to NDDM. And finally, on
15 this --

16 JUDGE MAJORS: Mr. Landmon, can I interrupt you?
17 I'm sorry.

18 MR. LANDMON: No, please.

19 JUDGE MAJORS: Does Petitioner's argument change at
20 all if let's say we were to find that the SIGMA Catalog in its
21 entirety is at least in the specified pages, if those are incorporated
22 as though they were set forth in the specification itself?

23 MR. LANDMON: So obviously it's our position that
24 they weren't. But even if they were, no, the position doesn't
25 change. There are still no blaze marks, there are no indications as

1 to why a POSA should go within the list of 150 different detergent
2 -- I mean, first go within the 15 categories.

3 In those 15 categories, as I mentioned, there's a limitless
4 amount of compounds, then go down and choose biological
5 detergents, then go through the list of 150 and then say, yes,
6 NDDM. And the important thing is here, the claim is not just to
7 NDDM, the claim is to the diazepam with tocopherol, with certain
8 alcohols in certain percentages.

9 There is nothing in the patent specification that provides
10 the blaze marks to use NDDM in connection with the other claim
11 elements. And that's really the key here. And the key here under
12 the law is that you need to look at all the different claim
13 limitations, and whether there's demonstration of possession with
14 respect to that combination and all the different claim limitations.

15 JUDGE MAJORS: Well, I would add, I suppose this
16 isn't a question, but you can address it if you'd like. There's been a
17 lot of argument in this case around the use of the consisting of
18 transitional phrase.

19 MR. LANDMON: Mm-hm.

20 JUDGE MAJORS: And so, it seems to me if you read
21 the claim, it's diazepam, the alcohol, the tocopherol. And then for
22 the '466 proceeding, n-dodecyl- β -D-maltoside and that -- that
23 detergent alone. So it would require the skilled person to go and
24 look, even if SIGMA is included, to go and pick that particular one
25 and nothing else for the composition.

1 MR. LANDMON: That's exactly right, Your Honor.
2 Certainly, consisting of further limits and further demonstrates
3 why the '558 provisional doesn't demonstrate written description
4 support.

5 JUDGE MAJORS: One final point just to clarify, is
6 Petitioner still arguing that under rule § 1.57(b), that Patent Owner
7 is not able to incorporate the contents of the SIGMA Catalog?

8 MR. LANDMON: So it is still our position, Your
9 Honor, but frankly we don't think the Board needs to go there
10 because even to your point in your question, even if it was
11 incorporated, there's not sufficient written description support. But
12 it is still our position.

13 So why don't we switch gears and talk about the
14 consisting of limitation that you just asked about in a different
15 context, obviously. And we could jump ahead to Slide 26 here.
16 So this is an argument again that cuts across all three IPR
17 proceedings.

18 Neurelis attempts to use the District Court, co-pending
19 District Court litigation, basically to argue two things. First, they
20 try to argue that Petitioner has taken inconsistent claim
21 construction positions. And second, they argue that in light of that,
22 the claim term consisting of, requires nothing -- requires absolutely
23 no additional water or other impurities.

24 And they say, because of that, the Gwozdz and Meezan
25 references do not render the claims unpatentable. Both of these

1 positions, however, fall short. The '451 IPR proceeding already
2 found that Gwozdz and Meezan meet this claim limitation. But I
3 do want to address their argument here.

4 And if we turn to the next slide, Slide 27. I need to make
5 one thing clear from the start. There was never any inconsistency
6 between the claim construction positions Petitioner took before the
7 Board, and took in District Court.

8 However, to remove any shadow of a doubt, to remove
9 anything that would render this unclear, we see up on the screen
10 here in Exhibit 1083 that we submitted, Petitioner has withdrawn
11 any claim construction position that was before the District Court
12 relating to consisting of.

13 There Petitioner confirmed that consisting of should have
14 its conventional meaning as recognized by this Board's institution
15 decision, that the claim solutions contain only the compositions
16 recited in the claims. Now, you're going to hear Neurelis or Patent
17 Owner argue that Padagis' withdrawal of the claim construction
18 position is somehow gamesmanship.

19 They try to come before the Board and they're going to
20 argue that other defendants are pushing a claim construction of
21 consisting of, or are arguing that consisting of is indefinite in the
22 District Court. But here's the issue with that. It is pure sleight of
23 hand.

24 What they're doing is they're referring to earlier Papers
25 that were filed in the District Court proceeding. We submitted to

1 the Board on June 10th, 2026, Exhibits 1105 and 1106. Both of
2 those exhibits show that no defendant in the District Court case is
3 pushing a claim construction of consisting of, and no defendant is
4 pushing an indefiniteness argument relating to consisting of.

5 So their improper tactics argument is simply a
6 distraction. What we have here in the proceedings here and before
7 the District Court, is the same claim construction of consisting of.
8 And if we go to the next slide, Neurelis argues that Petitioner has
9 shifted theories here.

10 But here's what needs to be clear, we haven't. We have
11 up on the screen here, both the petition and Dr. Donovan's original
12 declaration. Both of those address the consisting of limitation, and
13 we see both on the top left, which is the petition in the top right is
14 Dr Donovan's definition -- I'm sorry, declaration.

15 Both of those say that consisting of, paren, i.e.,
16 containing only the claim compounds and then whatever's left in
17 the claim. So from day one, we have taken the same position
18 before the Board on what consisting of means. And it's our
19 position and Dr. Donovan's position, that the prior art renders the
20 claim limitations with the consisting of language obvious,
21 unpatentable is obvious.

22 The Board recognized our position as we see in the
23 bottom right in a footnote of the institution decision. They
24 recognized our position with respect to the consisting of phrase.
25 And even in the '451 final written decision, the panel decided that

1 no terms including consisting of required any construction because
2 there is an established legal meaning of what consisting of means.

3 So Neurelis is wrong to characterize this as any sort of
4 new construction or anything that's a dispute or discrepancy
5 between here and the District Court. But then let's turn to the
6 merits. So they try and turn the consisting of construction then to
7 the merits. And we've got up on the screen Slide 29.

8 And they start by saying, well, then Gwozdz doesn't meet
9 the ethanol determination under a limited extreme view of
10 consisting of. We need to get that out of the way right away. We
11 see up on the screen a quote from Gwozdz. Gwozdz expressly
12 disclosed as ethanol. We see in the second line there.

13 In the '451 final written decision, again, we have that to
14 the right of the screen on Slide 29. Again, found that Gwozdz
15 teaches the use of ethanol, benzyl alcohol and combinations
16 thereof. So that has already been determined.

17 And that's really important because what Neurelis is
18 trying to do, is recast its argument about Gwozdz's disclosure into
19 some sort of consisting of argument. But really that's already been
20 dealt with in the '451 final written decision.

21 But if we turn to the next slide, Slide 30, they also have
22 an extreme argument that under a limited view of consisting of,
23 there can be no water, no impurities, and anything that follows the
24 consisting of language. And then they say, because of that,
25 Gwozdz doesn't render the claim -- it doesn't disclose the claim

1 limitation.

2 But here's the issue with that. We have Gwozdz up on
3 the screen. At the bottom left, you'll see Gwozdz discloses the use
4 of 100 percent ethanol. And what does 100 percent ethanol mean?
5 It means 100 percent ethanol without any additional components.

6 So that ends even Neurelis' extreme argument about
7 consisting of. And if we turn to the next slide, Slide 31, they also
8 argue that Gwozdz discloses and only discloses formulations that
9 contain water. And what they focus on is on the top left here or
10 the left-hand side of the screen here on Slide 31.

11 They focus on a disclosure in Gwozdz relating to the
12 pharmaceutical composition for injection. Well, what does that
13 disclose? It discloses a formulation for injection, combining into a
14 solution. And then it says with e.g., that is with, for example,
15 saline solution or water.

16 What they are saying, what this is saying is not a
17 requirement that Gwozdz has water, but that Gwozdz can include
18 water. And Gwozdz makes this abundantly clear. If we look to
19 the right-hand side of the screen, Gwozdz says that the formulation
20 suitable for parenteral administration, that is for injection, can be
21 aqueous or non-aqueous injection solutions.

22 So Gwozdz makes this very clear in its face that it can
23 have non-aqueous solutions without water. Now, what you're
24 going to hear Patent Owner argue, you're going to hear them argue,
25 well, Petitioner is relying on a different embodiment when they

1 cite that passage to the right in Gwozdz in the reply brief. But
2 that's not true.

3 What the passage to the right does, all it does is explain
4 what the passage to the left is already setting forth. It provides
5 more detail. It says, just for clarity's sake, it can be non-aqueous.
6 So we're not relying on a different embodiment in Gwozdz in the
7 reply brief, all we're doing is citing further explanation to respond
8 to Patent Owner's arguments.

9 And if we turn to the next slide, Slide 32, they make a
10 very similar argument with respect to Meezan. They argue that
11 Meezan has examples. Some of the examples are -- or the
12 examples have water in them. So Meezan is only an aqueous
13 solution and it doesn't render obvious then the claim or disclose the
14 claims.

15 But here's the problem with that. Dr. Donovan explains,
16 we see to the left here, she quotes Meezan. And Meezan explicitly
17 says, a pharmaceutical carrier is an aqueous or non-aqueous agent.
18 It's very clear here. Beyond that in the '451 final written decision,
19 we see that to the right.

20 They already found that Meezan discloses non-aqueous.
21 They already rejected the same argument that Patent Owner is
22 putting forth. And in doing that, they cite the same passage that
23 Dr. Donovan cites here. Basically, Patent Owner is trying to
24 convert optional components and some embodiments in these
25 disclosures to mandatory components. And that's not required.

1 So if we could turn forward now to Slide 33. I wanted to
2 get at, and this gets at Your Honor's earlier question or at least part
3 of Your Honor's earlier question about NDDM. And this is the
4 NDDM issue. Now, Neurelis basically tries to do a word game
5 here. Meezan expressly discloses dodecyl- β -D-maltoside and
6 dodecyl maltoside.

7 And Neurelis says though, but that's not enough because
8 Meezan doesn't say n-dodecyl- β -D-maltoside with the n prefix.
9 But what that argument doesn't account for is how a POSA would
10 understand Meezan's disclosure of dodecyl- β -D-maltoside to be
11 the claimed n-dodecyl- β -D-maltoside.

12 But let me explain that. If we turn to the next slide, Slide
13 34, this slide summarizes our argument from the beginning. And
14 as we can see to the left here, this is the disclosure in Meezan.
15 Right up top we have highlighted the disclosure of dodecyl- β -D-
16 maltoside. Then Meezan says see, Table 1.

17 And here, and Your Honor, I apologize if this is part of
18 what your question was earlier, here Meezan is referring to
19 dodecyl- β -D-maltoside also as dodecyl maltoside. So Meezan is
20 using those two terms interchangeably. And if that was your
21 question, I apologize for creating any confusion here.

22 But Meezan in Table 1 we see says dodecyl maltoside.
23 Meezan is using that to be consistent with dodecyl- β -D-maltoside.
24 Importantly here, Dr. Donovan relies on this disclosure. We've
25 seen her original declaration to the top right. She says that a

1 POSA would select n-dodecyl- β -D-maltoside based on Meezan
2 -- based on the disclosure of Meezan, and add that to the Gwozdz
3 formulation.

4 Now, in her reply, she then has to address basically
5 nomenclature confusion that Patent Owner has tried to assert here.
6 But it doesn't change the combination. She's not relying on a
7 different compound, she's not relying on different prior art, she's
8 not relying on different disclosures. All she's doing is explaining
9 the nomenclature issues in her reply declaration, which is proper to
10 respond to what Patent Owner said in response.

11 JUDGE OBERMANN: I have a question about that.
12 She had no idea about this in her cross-examination. So how can
13 this possibly be something that was so well known that your own
14 expert who's supposed to understand this is a critical part of your
15 case, how is it that she couldn't come up with this during her
16 deposition?

17 MR. LANDMON: So I don't think it's true that she had
18 no idea what it was. When you look at her testimony, she was
19 asked about it. And what she says is, at the moment I can't recall
20 -- at the moment to testify to, I can't recall what the n stands for.
21 What she says at the moment, she then says -- in the next line, she
22 says, well, I did consider it, but I can't recall as I sit here today
23 during my deposition. But --

24 JUDGE OBERMANN: Isn't that a problem though,
25 because you put this in your reply declaration and they didn't have

1 a chance to cross her on this testimony that is now for the first time
2 clear in the reply.

3 MR. LANDMON: Well, there I think is the rub. They
4 had every chance to cross-examine her. They could have taken her
5 deposition. It is common in these --

6 JUDGE OBERMANN: After the reply?

7 MR. LANDMON: Yes, no, it is common in these cases
8 that after you have -- if you do have a reply declaration, which
9 obviously doesn't happen in every case, but if you do, it's common
10 that you then depose the expert again. Frankly, we fully expected
11 that to happen.

12 So Dr. Donovan, if there was any confusion, because
13 basically they're trying to take this deposition testimony and hang
14 their hat on this deposition testimony, which we submit is anything
15 but clear. And they try to take that instead of then deposing her
16 after her reply declaration.

17 If they depose her after a reply declaration, she would've
18 explained both the issue with any confusion she had or memory
19 loss she had at that time. And she would've explained it in
20 conjunction with her reply declarations. They chose not to take
21 her deposition. I can't explain that except they didn't want to get
22 bad deposition testimony that would've then removed any doubting
23 -- sorry, Your Honor.

24 JUDGE REIMERS: And I have a follow-up question
25 also. If this was so well known, what the n is, and that the n

1 supposedly according to my understanding of what you are saying
2 to us, is equivalent to dodecyl- β -D-maltoside, wouldn't she, or
3 shouldn't she have known that?

4 I mean, if a POSA is supposed to know that, wouldn't she
5 have said, this is what it stands for and it's the equivalent of -- n-
6 dodecyl- β -D-maltoside is equivalent to dodecyl- β -D-maltoside?
7 Wouldn't she have said that if a POSA is saying that they're
8 equivalent?

9 MR. LANDMON: So I guess I --

10 JUDGE REIMERS: Are the same?

11 MR. LANDMON: Yes. I guess I'd say two things. I
12 mean, one, obviously depositions are high stress environments
13 where you are asked for hours and hours on the record or asked
14 about all different things, and put in a lot of different directions.
15 They do ask whether n stands for normal. And she says, yes, I
16 think that makes sense that n does stand for normal.

17 I mean they quote that in the slide that you're going to
18 see them put up. So I don't think that she sat there and said, me
19 and no other POSA would ever know what n meant. What I think
20 is she had a moment of confusion that she clarified in her reply
21 declarations. And I think it's very telling that they didn't depose
22 her to find out and clarify any confusion she might have had.

23 JUDGE OBERMANN: Well, there's also a problem
24 because they couldn't counter that testimony in their surreply with
25 counter testimony. I mean, doesn't this go to your case in chief,

1 because n is in the claim and I don't see anything in your petition
2 or her original declaration that makes clear that your position is
3 that DDM would've just been generally known absolutely to mean
4 NDDM.

5 And we have counter testimony from Dr. Brown. I think
6 there's 355 isomers of DDM. So how do we deal with that?
7 Because they did not have an opportunity because of the logistics
8 here to come forward with counter testimony. Even if they had
9 deposed her, that's not the same as having an ability to come
10 forward with counter testimony. And it seems like our process is
11 set up so that you've got to put all that in your petition.

12 MR. LANDMON: So a couple things. They had every
13 opportunity to come forward with counter testimony. Dr. Brown
14 could have submitted a declaration on surreply.

15 JUDGE OBERMANN: No.

16 MR. LANDMON: Frankly we --

17 JUDGE OBERMANN: No, we don't do that here. You
18 can't have new declaration testimony with a surreply.

19 MR. LANDMON: Well, to respond to our experts on
20 reply, we think they could have. I mean, we --

21 JUDGE OBERMANN: Oh, I've been doing this for 14
22 years. We don't allow that because then it goes on and on and on.
23 Because then you can say, you have a right to depose that surreply
24 declarant without having a brief, then you want a surreply. We do
25 not do that.

1 MR. LANDMON: I would've expected them to come
2 forward if there was any confusion, if there was any doubt in what
3 she was saying. I would've expected them to come forward with a
4 declaration, even if it was seeking leave to do that. So I
5 understand --

6 JUDGE OBERMANN: Okay. Have you been doing this
7 for 14 years? Because we don't do that.

8 MR. LANDMON: No, I --

9 JUDGE MAJORS: Sorry, Mr. Landmon, this is Judge
10 Majors. Yes, our trial practice guide is quite clear on no additional
11 testimony from Patent Owner on a surreply. They could have
12 asked, but --

13 MR. LANDMON: So --

14 JUDGE MAJORS: -- the general course is that's denied.
15 But hold on one second.

16 MR. LANDMON: Mm-hm.

17 JUDGE MAJORS: Let's go back to first principles, and
18 the fact that it has to be set -- your case in chief has to be set forth
19 in the petition. We're looking at right here in this slide, paragraph
20 151 of the Donovan declaration. What is her support for the
21 notion that Meezan discloses the n isomer of DDM?

22 MR. LANDMON: Yes. So just to be clear, the n is not
23 the isomer. The beta and the D are reflecting the anomer and
24 isomer issues. The n is just saying it is normal. In other words,
25 i.e., it is a straight chain, there is no chains coming off of it. Her

1 support there is exactly what she says.

2 That the disclosure of dodecyl- β -D-maltoside, every
3 POSA would've understand that to be the straight chain. And you
4 don't need then. And she explains in her reply declaration why
5 you don't need the n. She relies on the IUPAC guidance which
6 sets forth IUPAC nomenclature is whatever your organic chemist
7 follows. IUPAC says --

8 JUDGE OBERMANN: Can we back up for a second?

9 MR. LANDMON: Yes.

10 JUDGE OBERMANN: Because I think you just said
11 that in paragraph 151, she says n is the same as -- it's the straight
12 -- that DDM is the straight chain. I'm not seeing her say that at all.
13 I'm seeing her say that the POSA would select the NDDM based
14 on the disclosure of DDM. Is that what she's saying?

15 MR. LANDMON: And I apologize if I misspoke. What
16 she's saying is a POSA looks at the disclosure of dodecyl- β -D-
17 maltoside or dodecyl maltoside in Meezan, which Meezan uses
18 interchangeably. And a POSA knows that that is the n-dodecyl- β -
19 D-maltoside. She didn't go and take that separate step because
20 frankly, no one would think to take that separate step because the n
21 is meaningless unless you have a chain.

22 JUDGE OBERMANN: It's hard for us to read that into
23 paragraph 151 when under cross-examination, she couldn't put this
24 into words at all.

25 MR. LANDMON: It wasn't that she couldn't put it into

1 words, it's that she said, well, I can't as I'm sitting here right now
2 explain to you -- I can't remember basically what I did in terms of
3 putting it. I mean, she even goes and says, well, I looked at the
4 description and noted it, but it didn't stick. So in other words,
5 there's nothing enlightening or different about it. But she clearly
6 understood it, and she clearly --

7 JUDGE REIMERS: Well, I mean, Counsel, that's the
8 point that I'm trying to make here for us, is that if it is so well
9 known to a POSA, that these are the same, that should
10 automatically come like out of her mouth automatically, yes,
11 they're the same or something like that. And with the fact that
12 there was confusion here, that leads me to believe, I'm not going to
13 speak for my panel members, but that leads me to believe that
14 they're not the same.

15 MR. LANDMON: So I can't --

16 JUDGE REIMERS: From a POSA's perspective.

17 MR. LANDMON: I can't explain why she had a memory
18 loss in the heat of a deposition. What I can explain is what she
19 said in her reply declarations. And they had every opportunity to
20 ask her about it and they didn't. But what I also want to say is
21 there's further evidence about this. It's not just what she said.

22 Obviously, we've got some slides on this. She cites the
23 Streitwieser reference that they rely on. Streitwieser clearly shows
24 that you don't need a prefix when you have a straight chain. But
25 let's look at the patents themselves. If we turn to Slide 41 --

1 JUDGE MAJORS: Mr. Landmon, let me interrupt you
2 before you get onto that. Does Petitioner agree that if we're just
3 looking at the phrase dodecyl maltoside, that there's 355 different
4 permutations of that chemical?

5 MR. LANDMON: No. No, we don't. And if I turn us to
6 Slide 38. So what's really interesting, right? Dr. Brown takes this
7 position in his declaration that there are these 355 different things
8 that fall under the disclosure of DDM or NDDM. But we address
9 that in our reply, Dr. Donovan addresses in the reply.

10 So of the top left of the screen here, is we have a call out
11 from Dr. Brown's declaration. He says that only-- he says that all
12 of these compounds can be DDM. And Dr. Donovan comes back
13 and says, well, no, only the top one can, it's the only one that has
14 the straight chain with 12 carbons.

15 Now, in their brief, in their Patent Owner response, they
16 spend pages on this 355-compound explanation. Dr. Brown has
17 more than 15 pages in support, but there is little to no substantive
18 response in their surreply when we say that that's wrong.

19 When Dr. Donovan calls this out and says, no, that's
20 wrong, they don't respond to that. And I think that's telling
21 because I think it is wrong. We showed it was wrong, and they
22 don't come back and take issue with that.

23 JUDGE OBERMANN: I just want to follow up on this
24 slide. So are you telling us that no one of ordinary skill in the art,
25 looking at the box that's in the upper left, no one would call those

1 other six compounds DDM?

2 MR. LANDMON: Correct, Your Honor.

3 JUDGE OBERMANN: What would they be called?

4 MR. LANDMON: So if, for example, and we can
5 actually see this on the next slide, Slide 39, not to jump back and
6 forth. But on Slide 39 to the right there, that is -- sorry to make
7 you jump back and forth, but that's -- the compound there to the
8 bottom right is the same compound as the second compound on the
9 prior slide.

10 Or if you just want to get -- yes, if you see that on the
11 prior slide. And if we can then go forward to this slide, Dr.
12 Donovan explains that under the IUPAC rules, which again, is
13 what governs nomenclature. And they don't disagree that IUPAC
14 nomenclature is what governs.

15 Dr. Donovan explains that, that -- at the right side it has
16 an 11-carbon backbone, which corresponds to undecane. And then
17 it has this methyl branch at the 2 position. And she says, under the
18 IUPAC rules, this structure would be named 2-methylundecane.
19 Not dodecane. So they would all get different names based on the
20 branches that are coming off of them.

21 JUDGE MAJORS: So Mr. Landmon, then how do we
22 explain -- if we read Meezan as it is, how do we explain that they
23 describe a quote, highly branched DDM? That would suggest to
24 me that Meezan is not following IUPAC rules.

25 MR. LANDMON: So I think there are two things in

1 response to that. Dr. Donovan obviously could explain how, in her
2 view, how a POSA would read that. But if we go to Slide 44, in
3 our reply, we submitted Exhibit 1078. This is in Meezan, in the
4 Meezan application. They came forward to amend the application
5 to change the words, highly branched.

6 And you see that they changed the branching to length
7 and highly branched to long. So what Meezan was doing in that
8 application, was fixing it to be consistent with how a person of
9 ordinary skill in the art would've read the science. Dr. Donovan
10 talks about that in her reply declaration.

11 They take issue with this saying, well, it's new evidence
12 and it's something new. And more importantly they say, well, it
13 wasn't admitted in the file -- it wasn't actually amended because
14 the application was abandoned. That's really beside the point. I
15 think what this shows is this is how a POSA would've always read
16 Meezan. And Meezan came forward to fix the issue. But --

17 JUDGE OBERMANN: So in other words, you're saying
18 that an ordinarily skilled artist in reading Meezan saying highly
19 chained DDM would go back and look at this abandoned
20 application that was never entered and say, oh, that's what Meezan
21 meant here?

22 MR. LANDMON: No, that's not what I'm saying. I
23 think a POSA would've seen the disclosure of dodecyl- β -D-
24 maltoside in the other passage we looked at in Meezan, and seen
25 and realized that that is an unbranched chain because there is

1 nothing indicating a branch. And they would've seen that that
2 compound is unbranched.

3 And then in the general disclosures, yes, Meezan has an
4 amendment showing that what they intended all along was to have
5 long chains, not branch chains. But it's really the disclosure of the
6 dodecyl- β -D-maltoside that indicates to POSA that it's a straight
7 unbranched chain of carbons. I think there are two --

8 JUDGE MAJORS: Mr. Landmon, this is Judge Majors
9 again. So then how do we square that with -- again, if we go back
10 to the original cross-examination of Dr. Donovan, she was asked
11 specifically about Meezan's disclosure of highly branched DDM.
12 And she didn't say that seems wrong, that's not right, it should be
13 straight chain.

14 MR. LANDMON: But she did testify both in her
15 deposition and in both declarations that dodecyl- β -D-maltoside is a
16 straight chain, and that dodecyl- β -D-maltoside in Meezan is the
17 NDDM. And I think that's --

18 JUDGE OBERMANN: I have to take issue with that.
19 She did not testify to that in her original declaration.

20 MR. LANDMON: Well, in the part we had up on the
21 screen, she says, Meezan discloses DDM, and that meets the claim
22 limitation of NDDM.

23 JUDGE OBERMANN: No, she says that someone
24 would've selected the straight chain from that. She could have
25 meant that of the 355 DDMs, someone would've selected n, but

1 that would be a conclusory statement.

2 MR. LANDMON: Yes, I mean obviously we take issue
3 with the 355.

4 JUDGE OBERMANN: It was your burden to come
5 forward with clear evidence in the petition. So what do we do with
6 that? That's kind of hard. You want us to read a lot into paragraph
7 151, especially where she wasn't able to articulate it in her cross.

8 MR. LANDMON: So there were other disclosures and
9 obviously the petition itself, aside from the declaration, the petition
10 itself cites the disclosures of the dodecyl- β -D-maltoside. But
11 there's really two important things to view here of why their
12 position that NDDM is something different than the DDM.

13 And if we can turn to their specification in the file
14 history, they use the same nomenclature that Dr. Donovan uses.
15 They don't use NDDM. And let me just make this clear here. On
16 the screen, on the '786 file history, this is where they added
17 NDDM as a claim limitation.

18 What they say at the bottom here is they say all claims
19 submitted herewith are fully supported as a specification in the
20 file. Well, let's look at the specification. Look throughout the
21 specification, you will never see a reference to NDDM. That
22 never shows up. N is not used in any context.

23 What we do have to the right here in the specification, is
24 a disclosure of exemplary alkyl glycosides that may be used. In
25 the second highlighted row, we see dodecyl, and later it attaches it

1 to the β -D-maltoside. So they went to the patent office, they said
2 that the disclosure of dodecyl- β -D-maltoside, no n prefix, supports
3 our claim to NDDM.

4 But now they're coming before you and saying, Meezan's
5 disclosure of dodecyl- β -D-maltoside, no prefix, does not support
6 or disclose NDDM. And I think that shows the problem with their
7 position, and that their nomenclature position isn't correct. And I'll
8 point you to one other thing as well, if we could turn to Slide 45.

9 This is a sworn declaration of Dr. Maggio. Dr. Maggio
10 is an inventor in the patent at issue here. He was an inventor in
11 Meezan. And this is a declaration he submitted, again, sworn to
12 the PTO Exhibit 1076. In this declaration, he says, n-dodecyl- β -D-
13 maltoside.

14 So here we have an inventor of the patents at issue, in
15 this case, an inventor of Meezan saying the exact same thing that
16 Dr. Donovan said.

17 JUDGE OBERMANN: Why isn't that hearsay?

18 MR. LANDMON: Because it's a sworn -- it was -- a
19 couple reasons. It was a sworn declaration that was submitted to
20 the patent office. We think it's also not hearsay because we're not
21 necessarily relying it for the truth of the matter asserted, it's really
22 showing the problems.

23 We are not relying -- in other words, we're not relying on
24 this as a prior art reference, but it shows the problems with the
25 position they're trying to argue about what the prior art reference

1 says. We're relying obviously on Dr. Donovan's statements about
2 what Meezan discloses, we're relying on the disclosures of Meezan
3 itself.

4 This is something showing what every POSA would've
5 understood. Dr. Maggio understands it, Dr. Donovan understands
6 it. That's how someone would've read Meezan. Let's see, I have a
7 few minutes left. I just want to address a couple other issues.

8 If we turn to Slide 47. As I mentioned before, we have a
9 few issues on motivation to combine and reasonable expectation of
10 success. I'm going to address a couple of them, but my colleague
11 Mr. Jones is going to come up and I'm going to finish in four and a
12 half minutes, so I don't take away any of his time, subject to any of
13 your questions, of course.

14 So first, I wanted to address Neurelis' argument relating
15 to motivation to combine the art and modify Gwozdz. And if we
16 turn to the next slide, Slide 48. What we have here is Neurelis
17 tries to argue that we are somehow using hindsight because we and
18 Dr. Donovan rely on the face of the patents for what was disclosed
19 in the prior art.

20 Just need to be clear about this, the law in PharmaStem
21 says that whatever the Patent Owner admits on the specification
22 regarding the prior art is binding on the patent holder. And we
23 have here on the face of the slide what the Patent Owner says
24 regarding the deficiencies in the prior art.

25 Now, if we turn to the next slide, Slide 49, Neurelis also

1 argues that Gwozdz had already solved the solubility problem. So
2 they said there would be no reason to modify Gwozdz with
3 Meezan. Again, that's wrong. It recycles another argument they
4 said in the '451.

5 As we explained in our petition, as Dr. Donovan
6 explains, Gwozdz may have improved solubility, but that's not the
7 end of the story, and we see that up here on the screen. Gwozdz
8 teaches, and we see that on the top left, that formulations may have
9 additionally pharmaceutically acceptable excipients.

10 Dr. Donovan explains in her declaration on the right, that
11 a POSA would've used that disclosure to have additional
12 pharmaceutically acceptable excipients, and looked for other ways
13 to improve the formulation, including by using the penetration
14 enhancers that are disclosed in Meezan.

15 And again, the Board in the '451 IPR decision already
16 found that. I did want to just quickly address -- why don't we skip
17 to the third issue, which relates to the penetration enhancer
18 language in Gwozdz. And what they argue here, Neurelis disputes
19 a motivation to combine Gwozdz and Meezan because the specific
20 words penetration enhancer do not appear in the Gwozdz
21 provisional cited by Petitioner.

22 But this really is just a misguided attempt to distract from
23 the full record. The Board in the '451 final written decision found
24 ample motivation to combine. And we turn to Slide 57. We're
25 going to see the motivation to combine doesn't come from the

1 words penetration enhancer.

2 The motivation was really threefold. Dr. Donovan
3 explained in her original declaration that there were no insolubility
4 issues that limited diazepam formulations. That Meezan taught
5 that alkyl glycosides increased bioavailability, and that Meezan's
6 alkyl glycosides are compatible with non-aqueous carriers,
7 including those -- including alcohol.

8 And the Board already credited this, and we can see this
9 on the next slide, the broader rationale, broader motivation to
10 combine. The panel found that in the '451 final written decision as
11 well. And Neurelis just seeks to re-litigate this issue. In my final
12 minute, we'll quickly address one last issue on excipient
13 interactions.

14 So if we want to back up to Slide 51. Neurelis also
15 argues that nonionic surfactants were known to potentially
16 decrease antimicrobial efficacy or preservatives such as ethanol
17 and benzyl alcohol. And they argue, because of that, a POSA
18 would apparently be dissuaded from using these alkyl glycosides
19 in the Gwozdz formulation that had the alcohol.

20 But Dr. Donovan explained why that logic was flawed.
21 We have the call out on the slide. She explains why these nasal
22 formulations, while they needed to be virtually no bacteria present
23 when they were made, they're designed to be single use. And once
24 they're used, they're discarded because they're used in these
25 emergency seizure settings.

1 So any bacterial contamination after the package is open,
2 simply doesn't matter. And more importantly, if we turn to the
3 next page, even if it was credited as a multi-use product, Dr.
4 Donovan explains that a POSA wouldn't expect the very low
5 concentrations of DDM disclosed by Meezan to inactivate the anti-
6 microbial properties of the relatively high concentrations of
7 alcohol.

8 Notably, they don't respond to this argument. So unless
9 the panel has any other questions, I will turn the remainder of my
10 time over to my colleague, Mr. Jones.

11 MR. JONES: Good morning, Your Honors. My name is
12 Chris Jones, and I'll be addressing a few remaining issues on
13 behalf of Petitioner. So the first issue I'm going to address today is
14 related to Neurelis' argument that Meezan was directed to large
15 macromolecules rather than small molecules like diazepam.

16 And relatedly, I'll address Neurelis' argument that a
17 POSA would not have been motivated to use DDM in a non-
18 aqueous formulation in view of Meezan. And as with many of the
19 other issues we've already discussed today, both of these points
20 were already addressed by the Board in the '451 IPR.

21 We go to Slide 62. So first, Neurelis is again arguing
22 that Meezan only disclosed large macro molecules, and that POSA
23 would not have been motivated to use DDM in small molecule
24 formulations like those disclosed in Gwozdz.

25 In the '451 IPR, the Board considered these issues, and

1 determined that the compositions of Meezan can be used with
2 small molecule, organic drug molecules, including anti-seizure
3 agents like diazepam, and can be delivered nasally.

4 And the Board was correct in the '451 IPR. Because as
5 we see on this slide, Meezan expressly states that the alkyl
6 glycoside enhancers can be used with small molecules including
7 anti-seizure agents, which we see, for example, in paragraphs 52
8 and 130, and which Dr. Donovan also explained in her
9 declarations.

10 Go to Slide 63. The second point I mentioned, Neurelis
11 also repeats many of its '451 IPR arguments with respect to
12 whether a POSA would've been motivated by Meezan to use DDM
13 in a non-aqueous formulation like the tocopherol-based systems
14 disclosed in Gwozdz.

15 But as I mentioned, this argument was also raised by
16 Neurelis and rejected by the Board in the '451 IPR. As we see on
17 the slide here, specifically, the Board determined that Meezan is
18 not limited to water soluble therapeutic drugs, and discloses using
19 alkyl glycosides in aqueous or non-aqueous systems.

20 And again, the Board's determination on this already
21 litigated issue was correct. Meezan expressly stated that DDM
22 could be used in aqueous or non-aqueous systems, which would
23 include the tocopherol-based systems disclosed in Gwozdz. And
24 again, which Dr. Donovan explained in her declaration.

25 So there's no reason to deviate from the Board's prior

1 determinations on these issues, which are expressly disclosed by
2 Meezan and supported by Dr. Donovan's testimony. We go to
3 Slide 64. The other point I want to address on motivation is
4 related to Meezan as well.

5 And specifically, whether a POSA would've been
6 motivated to use DDM with a reasonable expectation of success in
7 view of Meezan. Neurelis argues that a POSA would've been
8 motivated to select tetradecyl maltoside or TDM for short, from
9 Meezan rather than DDM.

10 And Neurelis' argument is premised on Meezan's
11 description of TDM as having, quote, the greatest effect among the
12 alkyl glycosides that it discusses. And while Patent Owner
13 certainly has failed to show that Meezan actually supports that
14 TDM is better than DDM, that issue is really irrelevant here
15 because the standard for obviousness does not limit a POSA's
16 motivation to the best or most preferred options in the prior art.

17 JUDGE OBERMANN: What's your best case for that,
18 Counsel?

19 MR. JONES: So if we look at Slide 66, actually, this is a
20 case that we cited in, sorry, one of our Papers in re Fulton, which
21 plainly supports this position. Which is that which the prior art
22 discloses a handful of effective or preferred options, a POSA is not
23 limited to one that may be slightly better than the other, or one that
24 might be preferred as well.

25 So that's exactly what we had in this case with Meezan.

1 It describes DDM as preferred, and for that reason a POSA
2 would've been motivated to use DDM. If we jump back to Slide
3 65, just to quickly show what I mean. So as we see here in
4 paragraph 157, Meezan expressly identifies DDM as a preferred
5 alkyl glycosides and describes it as more effective than other alkyl
6 glycosides.

7 And again, Dr. Donovan supported this in her
8 declarations as well, explaining that based on Meezan, a POSA
9 would've understood that DDM had an absorption enhancing and
10 bioavailability increasing effect on the drug compound. And while
11 I mentioned in re Fulton, there certainly are other Federal Circuit
12 cases that support this point.

13 That is one that we cited in our Papers. And if we go to
14 Slide 67, just to continue on this point, Neurelis also argues that a
15 POSA would lack a motivation to use DDM in view of Meezan,
16 because DDM was, quote, ineffective in one test.

17 And because other alkyl glycosides allegedly performed
18 better than DDM. But as we see in Table 1 here, on the left side of
19 the slide, DDM was unquestionably effective at the 0.25, 0.375
20 and 0.5 percent concentrations. And Dr. Donovan, again, also
21 explains that those concentrations all achieved a dramatic
22 improvement in absorption and efficacy.

23 And neither Neurelis nor Dr. Brown actually dispute the
24 fact that DDM was effective at those concentrations. And so for
25 those reasons, there's really no question that a POSA would've

1 been motivated to use DDM in view of Meezan. And that they
2 would've had a reasonable expectation of success.

3 If we go to Slide 66 -- 68, I'm sorry. I'm going to quickly
4 address one additional point related to obviousness, which is the
5 prior art status of Cartt and USP 23. So as you recall, Petitioner is
6 relying on Cartt and USP 23 for a couple dependent claims in the
7 '786 Patent only.

8 And in Patent Owner's response, they argued that Cartt
9 and USP 23 do not qualify as prior art for reasons unrelated to the
10 joint research agreement and the priority date issues. In our reply,
11 Petitioner and Dr. Donovan in support responded to Patent Owner
12 on these points.

13 And for those reasons, Petitioner has established the
14 Cartt and USP 23 are prior art against the '786 Patent. And
15 importantly, Patent Owner did not contest those points in its
16 surreply. So for the reasons explained in Petitioner's reply, Cartt
17 and USP 23 are prior art against the '786 Patent.

18 JUDGE MAJORS: Mr. Jones, I have a question.

19 MR. JONES: Yes, Your Honor.

20 JUDGE MAJORS: So just picking up on what you just
21 talked about. I think as I understood Patent Owner's argument,
22 they say that Cartt is not a § 102(e) reference because there's some
23 overlap in the listed inventors and the references. Why are they
24 wrong on that?

25 MR. JONES: Yes. So I think there's one main point.

1 And if we look at Slide 72, so it's true that Cartt is § 102(e) prior
2 art, and that's what the Board determined in the '451 IPR. But as
3 we see here, Cartt is also prior art under § 102(a). And so Patent
4 Owner's arguments that Cartt should be disqualified under §
5 103(c)(1) really are not relevant here.

6 Because that can only be used to disqualify art under
7 subsections E, F, and G. And again, that's a point that Patent
8 Owner has not contested in these proceedings. All right. Unless
9 Your Honors have any other questions, I'm going to hit one last
10 point.

11 So if we go to Slide 80, I'm going to quickly address
12 Petitioner's motions to strike. And if we look at Slide 82, you may
13 recall that Petitioner moved to strike the declarations of -- certain
14 inventor declarations that Patent Owner filed in support of its
15 response.

16 Specifically, the declarations of Steve Cartt, Mark
17 Mitchnick, and David Hale. And I'm not going to go through
18 every detail raised in the briefing, which I think speaks for itself on
19 these issues. But the bottom line here is that Patent Owner refused
20 to make these three declarants available for a deposition in these
21 proceedings.

22 And not only does that violate the Board's rules regarding
23 routine discovery, but it's also prejudicial to Petitioner here. If we
24 go to Slide 83. So this is a messy slide as well, apologies. But it's
25 essentially showing the timeline of the parties back and forth about

1 these depositions, which Your Honors asked us to brief in our
2 motion to strike.

3 And again, I'm not going to rehash all of that, which I
4 think is explained in the briefs, but after all the back and forth on
5 this, what ended up happening was that in late March after the
6 Board denied Patent Owner's rehearing request on the certificate of
7 correction, Patent Owner offered deposition dates in late April and
8 early May, which were well past the deadline for our reply, which
9 was on March 31st.

10 And we tried to compromise with them as we did
11 throughout this process by requesting that these declarants be
12 available for a deposition by April 10th, so that we could cross
13 examine them and rely on their testimony in our reply. But again,
14 Patent Owner just refused to compromise and said, these are the
15 earliest dates that the declarants can be available.

16 JUDGE MAJORS: Mr. Jones, this is Judge Majors
17 again. I suppose my question with this motion is, why would we
18 strike these depositions -- these declarations, though? As I
19 understand Patent Owner's position, they say that the certificate of
20 correction issue is now moot given the current record.

21 And that they're not going to be relying on these
22 declarations for purposes of the issues that remain in the case. So
23 I'm just a little I guess concerned, like why would we throw these
24 declarations out in their entirety if in all likelihood they're not
25 going to be a factor in the final written decision?

1 MR. JONES: Right. And if we look at Slide 85, we've
2 sort of explained the prejudice here, which is sort of a two-pronged
3 issue, I think. But the first point is you're absolutely correct. And
4 we agree that under one -- because they did not get the certificate
5 of correction to amend the specification, under § 103(c)(2)(C),
6 Gwozdz can't be disqualified.

7 But the issue is that Petitioners still contends that under §
8 103(c)(2)(A) and (B), the Board should independently find that
9 Gwozdz cannot be disqualified for the reasons we explained in our
10 reply. And having been deprived of the opportunity to cross-
11 examine these declarants on these issues, which we could have
12 relied on, is prejudicial to us here.

13 And at this point, the record is what it is, and these
14 declarations are part of the record that could be used on appeal or
15 potentially on remand, when all of these issues could have just
16 been very easily dealt with now instead of a more inefficient
17 process like that.

18 JUDGE MAJORS: Okay. And now maybe Patent
19 Owner will say something different, but I think even Patent Owner
20 would agree that if this issue bounced back to the panel through
21 appeal or otherwise, I think they would even agree that we'd have
22 to come back and likely address what we do with these
23 declarations, and possible depositions, and further briefing if that's
24 how the record goes. So I guess I'm just not seeing the prejudice
25 point for Petitioner here.

1 MR. JONES: Sure. And I think one additional point on
2 that is that if we get to that point, at that point, the arguments have
3 been made, and Patent Owner is going to have the benefit of
4 knowing what our positions are. They can prepare these witnesses
5 for deposition or potentially submit new declarations to address
6 other issues.

7 And so, our opportunity to depose these witnesses on a
8 clean slate before we've advanced our positions or before these
9 issues have gone on appeal is gone forever. That's not going to
10 come back.

11 JUDGE OBERMANN: Sometimes what we do -- we
12 don't like to strike the -- expunge and strike because that corrupts
13 the record in a way. And sometimes what we'll do is we'll say, if
14 we haven't had an opportunity to cross a witness, we'll give it due
15 weight and which is very little weight. Why can't we do that here?

16 MR. JONES: Certainly, yes, Your Honor, if that's the
17 view of the Board here. I think, I would just reiterate our position
18 though that the prejudice here is related to not being able to cross-
19 examine them with sort of a clean slate of our arguments not being
20 out there already. And like I said, we still believe that these are
21 independent issues that are live issues in the case, even though
22 under § 103(c)(2)(C), in a sense that has been decided already.

23 JUDGE MAJORS: Mr. Jones, I have I think one final
24 question on this if you could address. The slide that you have up
25 here where you're pointing to elements A and elements B. And as

1 I understand Petitioner's argument, Petitioner says that the Gwozdz
2 reference and the challenged patent were not owned by the same
3 person, in fact.

4 But doesn't the statute, the safe harbor provision that
5 they're trying to invoke here, doesn't that have a provision of
6 where the ownership is deemed to be part of the same company,
7 even if in fact it's not? So whether they're one's owned by Particle
8 Sciences and another was owned by -- I forget the other party's
9 name at the time, but why doesn't the safe harbor apply through
10 this deeming mechanism?

11 MR. JONES: So without getting into I guess
12 confidential information, we contest that that is correct here. And
13 we believe that the testimony we would've gotten from these
14 inventor declarants would've established that point for us as well.

15 JUDGE MAJORS: Okay. Thank you.

16 MR. JONES: Thank you, Your Honors. Unless the
17 Board has any other questions at this time, we'll reserve our
18 remaining time for rebuttal. Thank you

19 JUDGE OBERMANN: Thank you, Mr. Jones.

20 MR. TOBIN: Your Honors, can I have just a two-minute
21 break to switch that up and get ready?

22 JUDGE MAJORS: Sure.

23 MR. TOBIN: Thank you for your indulgence, Your
24 Honor.

25 JUDGE OBERMANN: Would Counsel and our guests

1 like to just take a five- or 10-minute break?

2 MR. TOBIN: That sounds good, Your Honor. We're
3 struggling with the password --

4 JUDGE OBERMANN: Yes.

5 MR. TOBIN: -- of the laptop to switch it open.

6 JUDGE OBERMANN: Okay. It's 10:25. Should we
7 come back at 10:35? Okay.

8 MR. TOBIN: Yes. For Patent Owner.

9 (Whereupon, the above-entitled matter went off the
10 record at 10:25 a.m. and resumed at 10:35 a.m.)

11 JUDGE OBERMANN: I think we're ready in the
12 Courtroom. We may begin.

13 MR. TOBIN: May it please the Board. Good morning,
14 Your Honors. David Tobin here on behalf of Patent Owner. Your
15 Honors, we will also be dividing the topics among us, although of
16 course we'll answer whatever questions the Board wishes. I'll
17 present on collateral estoppel and certain issues of priority date,
18 the first two bullets.

19 My colleague, Dr. Best, will also present on priority date
20 and nonobviousness. We'll split claim construction. And then our
21 colleague, Ms. Hurley, will present on the last five bullets on the
22 agenda slide. Your Honors, first I'd like to start with collateral
23 estoppel.

24 So the three patents across these proceedings, the '786,
25 the '414 and the '546. They're shown here on Slide 4. They're on

1 different legs of the family tree. Shown on Slide 5, is this
2 decision, Paper 44, the final written decision from the '451
3 proceedings.

4 And Petitioner is using this final written decision as their
5 important theme across this case, trying to apply collateral estoppel
6 to the patents rather than litigating the actual claims of what's in
7 these patents. As both sides have pointed out in their briefing, and
8 we're on Slide 6, the Google versus Hammond case, in order for
9 collateral estoppel to apply, Petitioner has the burden of showing
10 that four elements are met.

11 First, Petitioner has to show that the issue is identical to
12 one decided in the first action. And that hits directly on Judge
13 Obermann's question about dodecyl maltoside versus n-dodecyl- β -
14 D-maltoside, which I'll cover shortly. Two, the issue was actually
15 litigated in the first action.

16 Three, resolution of the issue was essential to a final
17 judgment in the first action. And four, which isn't at issue. So
18 moving on to Slide 7, again, the three patents that are at issue in
19 these three proceedings were not litigated in the previous IPR, the
20 '451 proceedings.

21 And as we cite in the Comair versus Nippon case,
22 separate patents describe separate and distinct inventions. And it
23 cannot be presumed that related patents rise and fall together. But
24 that's exactly what Petitioner is trying to do with their petition and
25 their presentation.

1 They're focusing everything on the patent at issue, and
2 the '451 proceedings, and then saying, never mind the differences
3 in these patents, never mind what was actually litigated. But the
4 fact that the '876 Patent fell in the '451 proceeding, Petitioner is
5 now trying to say that the three patents here should also fall.

6 So I'd like to turn now to Judge Obermann's question.
7 And in the context, I'd ask my colleague please to put up
8 Petitioner's demonstrative Slide 18. And I'd like to focus the Court
9 on several pieces of Petitioner's highlighted example. First, in
10 Claim 1 of the '876 Patent, they highlight in gray an alkyl
11 glycoside.

12 And that last case, as I'll demonstrate shortly, was all
13 about alkyl glycosides. That was the focus of the priority date
14 argument, that was the focus of the obviousness arguments. That
15 case was all about alkyl glycosides. True, there was a dependent
16 claim or several dependent claims that were cited dodecyl
17 maltoside.

18 That's one of the chemical categories Judge Obermann
19 asked about. Two of our patents here in this case recite n-dodecyl-
20 β -D-maltoside, that's the '414 Patent. Every claim in the '414
21 Patent has n-dodecyl- β -D-maltoside. No claims of the '876 Patent
22 had n-dodecyl- β -D-maltoside. Every claim of the '786 Patent here
23 has n-dodecyl- β -D-maltoside. No claims of the '876 Patent have
24 that chemical species.

25 JUDGE OBERMANN: If we accept your friend's view

1 that -- I'm sorry, DDM is the same as NDDM, does your collateral
2 estoppel argument fall apart, or is there some other aspect to it?

3 MR. TOBIN: There is some other aspect to it, including
4 what was actually litigated. And I'm going to turn to that, Your
5 Honor. But just to give Your Honor a very clear, straightforward
6 answer to what was a clear, straightforward question about the
7 difference between dodecyl maltoside and n-dodecyl- β -D-
8 maltoside, which Judge Majors asked about.

9 It has over 300 isomers within that sub genus. That's 300
10 distinct chemicals. And Dr. Brown discusses all of this in his
11 opening declaration, his only declaration. Alkyl glycosides, which
12 was really the issue in the last case is a large genus. And when
13 you have alkyl glycosides, there's two pieces of that. There's
14 alcohol and glycoside.

15 The glycoside refers to the sugar portion of the chemical,
16 and there's many types of sugars that are glycosides. The alkyl
17 refers to the carbon chain. And there's many types of carbon
18 chains varying in number, arrangement, branch linear, it's a large
19 genus, alkyl glycosides.

20 Within that, Your Honor asked about dodecyl maltosides.
21 Dodecyl maltoside is less broad than the genus, alkyl glycoside,
22 but it still has sub genus with over 300 isomers. Those isomers
23 can include the arrangement of the carbon atoms in the dodecyl
24 piece.

25 The dodecyl means 12 carbons, but they can be

1 branched, as in Meezan, or they can be linear, the n variety, as in
2 the '414 and the '786 claim. So again, alkyl glycoside, broad
3 genus, dodecyl maltoside, less broad, but a sub genus of 300 some
4 isomers --

5 JUDGE OBERMANN: I didn't mean to sidetrack you, I
6 was just saying if we were to accept that say the IUPAC naming
7 system applies, and that we read dodecyl maltoside in for example
8 the '546 Patent as being limited to the straight chain, does that
9 change your argument about estoppel?

10 MR. TOBIN: No, it doesn't, Your Honor. And let me go
11 back to the -- can you please turn back to our deck, please? Thank
12 you, Ms. Hurley. I'm on Slide 6 now. So Your Honor seems to be
13 asking if the Board were to presume, which we disagree with, that
14 the issue is identical in terms of the chemicals being identical, does
15 collateral estoppel apply?

16 And the answer is no, Your Honor. Because as the party
17 seeking to invoke collateral estoppel, Petitioner, they have to show
18 that all four elements are met in this Google versus Hammond
19 case. And the key elements that they cannot show were met is,
20 one, the issue was actually litigated in the first action. And two,
21 that resolution of the issue was essential to a final judgment.

22 They have not and cannot demonstrate that. And just for
23 the record, Your Honor, our evidentiary support among others for
24 this difference between the different chemicals is in Exhibit 2073,
25 Dr. Brown's declaration. He goes into this at length. But on page

1 41, he discusses the alkyl group and this is in the '465, although
2 similar in the other ones.

3 Page 46, he discusses the glycosides. Page 50, he
4 discusses the n-dodecyl. And pages 120 to 123, he explains how
5 n-dodecyl- β -D-maltoside is different than dodecyl maltoside. But
6 to follow up on Your Honors more recent question to us about
7 collateral estoppel under the other elements of required for
8 collateral estoppel.

9 On Slide 12, I'd like to direct the panel to, again, the
10 difference in the claims. '876, the independent claim recited alkyl
11 glycoside. And yes, Patent Owner has pointed out that there are
12 dependent claims that recite dodecyl maltoside. And that is true,
13 but again, dodecyl maltoside is not claimed in two of the patents.
14 It is claimed in the '546 patent.

15 So let me address that, Your Honor. For collateral
16 estoppel, we should think about what issue they're asking collateral
17 estoppel to be applied for. First, they're asking collateral estoppel
18 to be applied on priority date. Do Neurelis' patents that are at issue
19 in these proceedings get priority to that earliest provisional?

20 So Your Honor, to be clear on this, priority date, we have
21 only asserted it for two of the patents, '414 and '786. Those are the
22 two patents that recite n-dodecyl- β -D-maltoside, the specific
23 chemical which Dr. Best will discuss some more, that is recited
24 expressly in the provisional and its incorporated document.

25 The '546 has a broader claim, dodecyl maltoside. And

1 we are not arguing priority date for that patent. We are for the
2 other two. So as the Board pointed out -- and we're on Slide 14, as
3 the Board pointed out in its institution decision, paper 13 of 22,
4 whether a species is described adequately under Section 112
5 versus whether a class generic inclusive of the species is described,
6 are not identical inquiries.

7 And that matters specifically for the '414 and '786 Patent.
8 Moving on to Slide 15, again, everything about that last case,
9 especially Exhibit 1040, the final written decision, was about alkyl
10 glycoside. We provide numerous sites here and in the briefing.
11 That's what the Board addressed in terms of the priority.

12 And they said that there would not be written description
13 support for the broad genus of the alkyl glycoside limitation.
14 Therefore, the claims are not entitled to the benefit of the
15 provisional. Our claims don't have that broad genus for priority
16 date. So it's a separate issue.

17 Second of all the -- for the '546 Patent, and this is on
18 Slide 16, which does have dodecyl maltoside, as the Board pointed
19 out in the institution, Patent Owner's only separate suggestion of
20 adequate written description for these subject dependent claims,
21 appears to have been relegated to a footnote.

22 And the parties did not join battle on that. And again,
23 that's for the '546 Patent. Moving on to Slide 18, the Board cites
24 the Purdue Pharma case. It says for collateral estoppel to apply
25 -- and that's consistent with the second element of Google versus

1 Hammond.

2 For collateral estoppel to apply, it does not apply to
3 issues that might have been, but were not actually litigated. And
4 the priority date of n-dodecyl- β -D-maltoside for '414 and '786
5 Patent was not actually litigated and could not have been because
6 it wasn't in the claims.

7 Next, in Slide 21, Petitioner seeks to apply collateral
8 estoppel on the obviousness inquiry. But again, and I'm moving to
9 Slide 26, this issue was not actually litigated on the dodecyl
10 maltoside. And we cite to page 27 of Exhibit 1040. Here on Slide
11 26, the Board held, Patent Owner does not present separate
12 arguments for any of the dependent claims.

13 And recall dodecyl maltoside, which is not claimed in the
14 '414 or '786 Patents, but is claimed in the '546. Dodecyl maltoside
15 was only in the dependent claims. And the Board held in the last
16 case that Patent Owner does not present separate arguments for
17 that.

18 JUDGE MAJORS: Mr. Tobin, I have a question about
19 this obviousness analysis and collateral estoppel. There's one issue
20 I've been struggling with. How do we apply the doctrine, if at all,
21 to arguments that Patent Owner has raised here? I'll characterize
22 them, but to the point of a skilled person wouldn't have wanted to
23 modify Gwozdz to address any bioavailability issue, or they
24 would've thought that tocopherol was unstable.

25 Those seem like those issues within an obviousness

1 framework, were well vetted by the earlier panel. So what do we
2 make -- I understand you're going to say, well, there's a difference
3 in the claim scope, but I just -- I'm wondering like how finely do
4 you peel this onion when you're dealing with collateral estoppel?

5 MR. TOBIN: Thank you for the question, Your Honor.
6 So again, collateral estoppel would not apply to those individual I
7 call it sub arguments. Collateral estoppel that Petitioner sought to
8 apply is on a broader level, such as obviousness, priority date. But
9 more directly on those specific issues, which I'll go to obviousness
10 that Your Honor asked about.

11 Obviousness, the ultimate inquiry is whether a person of
12 skill in the art would've been motivated to combine the references
13 with a reasonable expectation of success to arrive at the claimed
14 invention. So I think in Your Honor's question, you recognize that
15 the claim scope is different, but that claim scope anchors the
16 obviousness analysis.

17 The obviousness analysis has to be tethered to that scope
18 in reaching the claimant invention. And then last, Your Honor, the
19 third issue they try to apply collateral estoppel on, this is Slide 28,
20 is priority date of Gwozdz PCT. My colleague, Ms. Hurley, will
21 get into the merits of this case, why Gwozdz PCT does not get its
22 priority.

23 But on Slide 29, at Exhibit 1040 at 14, the Board held,
24 Patent Owner does not contest that Gwozdz is entitled to this filing
25 date. So going back to Judge Obermann's question about even if

1 the Board were to accept Petitioner's representation, although we
2 disagree with them about NDDM versus DDM, there's still other
3 elements of the collateral estoppel inquiry, such as whether
4 something was actually litigated.

5 Unless Your Honors have other questions about
6 collateral estoppel, I'll move on to the substantive merits of these
7 patents. So next on the agenda, Slide 30, priority date of the '414
8 and '786 Patents. My colleague, Dr. Best, will shortly take over
9 and get into some of the blaze marks issues that the Board has
10 pointed out, and the specifics of the written description.

11 But I think the one piece that Petitioner raised here today
12 is about maybe the incorporation wasn't specific enough. And I'm
13 on Slide 31. The provisional does several things. One, it uses the
14 right language, which is needed under rule §1.78. It says
15 incorporated herein by reference.

16 It doesn't hedge that language, say, partially incorporated
17 or incorporated to the extent appropriate as some other panels have
18 had to deal with. But it says the magic language, the appropriate
19 language, incorporated herein by reference, that's first. So it
20 complies with rule §1.78.

21 Second, it identifies a specific publication, the SIGMA
22 Catalog. Identifies a date of it, 1988. And even identifies the
23 pages. That's all that's needed. And this is the Callaway Golf
24 case. Host document must contain language clearly identifying the
25 subject matter which is incorporated and where it is to be found.

1 This is on Slide 33.

2 And this Petitioner absolutely does that. And this isn't
3 just some random obscure reference that's being incorporated.
4 Slide 34. Dr. Best asked Dr. Donovan about this specific catalog.
5 It's fair to say that back when the SIGMA Catalog was a physical
6 object, it was widely distributed amongst researchers in the field,
7 correct? Yes.

8 And Dr. Brown additionally talks about the SIGMA
9 Catalog, our expert in his testimony. So the incorporation
10 language was appropriate and was correct. Now, there is some -- a
11 little bit of discussion today about rule §1.57(d).

12 Unless Your Honor has specific questions about that
13 subject, I would -- we've identified several cases that are directly
14 on point for this, including the Neurent versus Foundry decision
15 from Judge Majors IPR2024-00669, that we cite the ex parte in the
16 Bridget case, the ex parte Misia case, Samsung versus Acqis, A-C-
17 Q-I-S, and MPEP § 608.01(p).

18 All of these are cited in our brief, paper 28, discussed
19 again in our surreply, paper 53. But since it wasn't presented today
20 by Petitioners, in the interest of time, I'll skip past. Unless, again,
21 Your Honors have questions on the § 608.01(p) or rule § 1.57. I'll
22 pass the clicker over to my colleague now, Dr. Best.

23 DR. BEST: Good morning, Your Honors. The first
24 issue I will address if we could go to Slide 45, is the written
25 description support in the provisional for the notion n-dodecyl-β-

1 D-maltoside. And I'll note first that the question here is whether
2 the application describes a composition including that element.

3 Not the use of the composition, that was the previous
4 case. Not whether the composition has any particular functional
5 abilities, that's not required by the claims. What is required is
6 whether the composition, whether a skilled artisan reading the
7 specification, including the SIGMA Catalog, would perceive,
8 would immediately perceive that all of the elements of the
9 composition are there.

10 I'll also note that there's no dispute that all of the
11 elements are there, say for n-dodecyl- β -D-maltoside. And just for
12 clarification, this issue, as Mr. Tobin explained, only applies to the
13 '414 and '786 Patents. The written description analysis begins, I
14 think, with Ariad, the Federal Circuit's leading case on the matter.

15 And what does Ariad say? If we go to Slide 46, Ariad
16 says that to describe a chemical substance, it suffices to state its
17 chemical name. It could do other things, but one thing one can do
18 is state its chemical name. And the question under Ariad is
19 whether within the four corners of the document, this is enough.

20 I'd like to address a comment from Judge Majors during
21 Mr. Landmon's presentation. I think there was a suggestion that
22 the specification must indicate what is the best or the item that the
23 inventor thought was the best item within a specification.

24 I must say, first, I'm unaware of any case cited by
25 Padagis that stands for that proposition. And I myself am also

1 unaware of any case that stands for that proposition. And I'll add
2 that it seems to be inconsistent with the notion that as I'm sure the
3 panelist states, various embodiments in the specification, and
4 claims only a subset of that.

5 If it's necessary to state which the best is, then I think that
6 exception follows the rule. And indeed, sounds more like a best
7 mode analysis. Slide 47.

8 JUDGE MAJORS: Yes.

9 DR. BEST: Yes.

10 JUDGE MAJORS: Dr. Best, I don't think that was my
11 point, if that's how it was understood. My point was there's this
12 argument, which I think you're going to get into next about blaze
13 marks. And I was remarking on the fact that the claims here,
14 because they used the consisting of terminology, they're closed to
15 only the four specific ingredients.

16 And so, as the argument goes, it's not just that there's
17 some laundry list of potential additives that might be included in
18 the composition, it's the notion that a skilled person would've had
19 to, even assuming SIGMA is incorporated, would've had to go and
20 pick n-dodecyl and only n-dodecyl for incorporation into that.

21 Now, you may say, well, they could have picked any of
22 the 150 plus detergents. It's all sufficiently described. So anyway,
23 that's what I was getting at. I was trying to home in on this idea
24 that it's really just the four components of the claim, and you have
25 to pick those ones.

1 DR. BEST: I think I understand your question, Your
2 Honor. I'd say, first, I don't believe that that argument has been
3 made by Padagis. So I think that's an important point to make with
4 respect to many of the points that were absent from their petition,
5 which I'll discuss in the fullness of time.

6 But I think more directly what -- if we go to Slide 49,
7 what does the provisional say about the composition? So I think
8 that's probably the most important question. There's again, no
9 dispute that the composition elements other than n-dodecyl- β -D-
10 maltoside are stated.

11 And what does the inventor say? In some embodiments,
12 in paragraph 150, in some embodiments, meaning the
13 embodiments that contain the composition components that there's
14 no dispute described, you can add an absorption enhancer. Or in
15 original Claim 17, it's described as an enhancer, in paragraph 152,
16 an enhancing agent.

17 But in any event, to any of the compositions described in
18 the claims, described in the specification can be added various
19 elements. And one of the things that can be added are one of the
20 biological detergents listed in the SIGMA Catalog. And there's no
21 dispute that the SIGMA Catalog lists the element in dodecyl- β -D-
22 maltoside.

23 That has been conceded by Dr. Donovan, for example.
24 And so, I am unaware of any consisting of case that requires, for
25 example, that the specification, because the claim states consisting

1 of, therefore have only one embodiment in the specification. And
2 certainly, Padagis decided not to.

3 JUDGE OBERMANN: It doesn't have to have one
4 embodiment, but we still have to be able to understand that an
5 ordinarily skilled artisan would immediately recognize that your
6 inventors had possession of the consisting of. So how do we get
7 there when we've got all these choices?

8 DR. BEST: That's exactly right, Your Honor. And I
9 think the answer is the inventor possessed. And it would be
10 immediately discerned that the inventor is possessed.
11 Compositions including diazepam, alcohols, tocopherol, and any
12 one of the elements that are listed in the SIGMA Catalog.

13 JUDGE OBERMANN: You said, including, but we
14 need consisting of. You're saying that doesn't make a difference?

15 DR. BEST: I'm saying that does not make a difference.

16 JUDGE OBERMANN: So in other words, we don't need
17 blaze marks, even though how many of these compounds would be
18 disclosed, including ones that include, but don't consist of. I mean,
19 that's a lot.

20 DR. BEST: So if I understand your question, I'm sure
21 there are many elements that are described -- embodiments that are
22 described in the specification. But I am unaware of any case
23 where there is a species-to-species match. Meaning a species in
24 the specification and a species in the claims where those are the
25 same species, and a written description has nevertheless not been

1 found.

2 Now, maybe this is the first case. I'll leave that for the
3 Federal Circuit. But I'm unaware of any case. The cases that have
4 been cited are quite different. For example, the Regents case that
5 Mr. Landmon says they apply very carefully in this circumstance.

6 Well, there the specification disclosed a broad genus that
7 was ill-defined by multiply dependent Markush claim. It wasn't
8 even clear what the specification disclosed. And the claims were
9 genus claims too. Similarly, the Fujikawa case that has been cited,
10 the specification disclosed genus claims, the claims were a small
11 sub genus of those.

12 It's interesting, actually, the Fujikawa case did contain
13 blaze marks, it just contained them in the wrong direction. If you
14 read the case carefully, the Federal Circuit cites in no fewer than
15 three instances that the Board found persuasive that the
16 specification expressed a preference against the claimed element,
17 the ultimately claimed composition.

18 And the Purdue Pharmaceutical case, very similar.
19 Broad disclosures in the specification, broad disclosures in the
20 claims, including by the way, functional requirements, which add
21 an additional level of, I think, question mark. And I think a
22 question mark that Judge Moore struggled with in deciding the
23 earlier case.

24 Because again, those were method of treatment claims,
25 which these are not. And to be clear, I'm not suggesting blaze

1 marks could not apply in some way or fashion to our circumstance.
2 Imagine, for example, that the claims that were under review, were
3 claims to benzodiazepine, alcohols, tocopherol, and a fatty acid, a
4 specific fatty acid, lauryl sulfate.

5 What would be the direction to that in the specification?
6 As we see on the screen, the only statement there is a genus, a
7 broad genus, fatty acids, which could contain, let's say maybe
8 infinite numbers of options there. There there's no species in the
9 specification, so it is really unclear what it is that the inventors
10 possessed at the time.

11 That's not our case. Our case has the species in the
12 specification. Again, assuming that the SIGMA Catalog is
13 incorporated, which I am for purposes of this argument. I think if
14 there are no further questions on this issue, I'll move on to the next
15 issue. If I could ask you Ms. Hurley to go to Slide 70. Oh, you're
16 next? I stand corrected. I will sit down for a moment.

17 MR. TOBIN: Your Honor, so David Tobin here for
18 Patent Owner. We're on Slide 53, claim construction. I'll be brief
19 for this part, and then Dr. Best will address how this claim
20 construction affects the obviousness that was set forth in the
21 petition.

22 So again, as panel pointed out, all three of the patents
23 require consisting of, and it's not just that this time around,
24 Petitioner didn't construe consisting of, which they did not in their
25 petition. But in the last case, they not only construed consisting of

1 as excluding anything else, particularly excluding water, even trace
2 amounts, they also said that the claim was indefinite if they don't
3 -- if it doesn't exclude trace amounts.

4 And as we've seen over spate of the last month or so, the
5 director has designated four different opinions on this issue when
6 one takes an indefiniteness position in District Court, and then tries
7 the wait and see approach, and doesn't take that position in the
8 IPRs.

9 And moving on to Slide 55, this is Exhibit 2050, the joint
10 claim construction brief. They say that the specification -- in
11 District Court, the specifications, few examples of formulations
12 having water, included in relatively small amounts, suggest that
13 even minuscule amounts can be material.

14 And again, they used Dr. Donovan at the IPRs, they used
15 the same expert in District Court. So you had one expert saying
16 very different things, and it's the same expert. Moving on to Slide
17 57, she says in District Court, it is my opinion that consisting of
18 transition language of the asserted patents does not allow for the
19 inclusion of small amounts of water.

20 Again, they don't address this in the petition at all.
21 Again, Slide 50 -- excuse me, Slide 58, paragraph 50 of Dr.
22 Donovan's declaration. This is the central focus of her declaration,
23 is that consisting of does not allow for small amounts of water in
24 the claim solutions or in the alternative, the patent claims are
25 indefinite.

1 So now, Your Honors, there's been some discussion
2 about how they, in District Court, yes, they filed this claim
3 construction brief, but then -- and we called them out on it in our
4 Patent Owner response. I'm on Slide 60. And then afterwards, the
5 day before they filed their Patent Owner reply, they take them all
6 again and say, oh, never mind, we're withdrawing allegedly what
7 we did in District Court, and Dr. Donovan's declaration saying you
8 can't have even small amounts of water, ignore that too.

9 And then they follow with their second declaration. But
10 as several recent cases from the director have held, and this is the
11 most applicable one, is the Ford Motor versus AutoConnect case,
12 IPR2025-01342, there again, and Patent Owner argues a plain
13 ordinary meaning in the petitions, but then served invalidity
14 contentions in the related District Court proceedings that argued all
15 the challenge claims are indefinite.

16 They did that in District Court as well. Patent Owner
17 -- excuse me, the director continued, in its briefing, Petitioner
18 states that it will stipulate to withdraw all indefiniteness arguments
19 against the challenge patents if the Board agrees to maintain.

20 And here again, they are withdrawing their District Court
21 contentions. Again, the day before their reply -- they filed their
22 reply brief, after the institution decision, after our Patent Owner
23 response, it's too late. And they have been inconsistent between
24 the petition where they just don't take an indefiniteness position,
25 don't discuss how the claims exclude even minuscule amounts of

1 water, and what they did in District Court. And then I'm going to
2 hand the baton over one last time to my colleague. Oh, yes, Your
3 Honor.

4 JUDGE MAJORS: Mr. Tobin, could I interrupt you for
5 a moment?

6 MR. TOBIN: Of course.

7 JUDGE MAJORS: I have a couple questions on this.
8 First, let's say we agreed with you about the allegations on
9 indefiniteness. Why is this an issue for the panel and not the
10 director, number one? Number two, what's the potential for
11 inconsistency at this point given that they've dropped their
12 contention of indefiniteness different from the Ford case, where at
13 the time Ford was simply saying that we would agree to drop this
14 if you maintain institution?

15 And then third, why does this not fit within the Tesla
16 exception where Gwozdz would teach either water inclusive or
17 water free formulations?

18 MR. TOBIN: So Your Honor, the first -- I was taking
19 notes, the first question was, is this a panel issue or a director
20 issue? The third one was about Gwozdz, if it includes or excludes
21 water. And can you repeat the second one, please?

22 JUDGE MAJORS: Yes. The second one was, what the
23 potential for inconsistency at this point that seems to be the
24 underlying point behind the director vacating these cases where
25 there's a potential for inconsistency with a determination by the

1 District Court. But now, as I understand the record, Petitioner
2 said, hey, we've dropped all of our indefinite allegations, there's no
3 potential for inconsistency.

4 MR. TOBIN: Yes, Your Honor. So let me address the
5 first one first. You asked about why should the panel address this
6 versus why should the director. So definitely the director can of
7 course sua sponte review what the director wants to review.

8 But in terms of why the panel should direct this
9 -- address this, is because it impacts the final written decision on
10 obviousness, as my colleague Dr. Best will explain shortly. And
11 this gets to Your Honor's third question, about Gwozdz inclusive
12 versus exclusive.

13 They didn't address in their petition how Gwozdz
14 excludes water. And all the more so in their petition, they
15 expressly cite embodiments where there is water, whether
16 minuscule or aqueous embodiments. And in the Tesla case, Your
17 Honor, I believe that's the one where the Petitioner actually
18 explained the differences, and why we're asserting one thing in
19 District Court versus asserting another thing in the IPR case, in the
20 IPR.

21 Or at least the director said that the Petitioner has to
22 explain the differences in positions. They haven't explained the
23 difference here other than just saying, oh, never mind. What the
24 director was also concerned about, Your Honor, and this is the
25 Magnolia versus Kurin precedential case that came out just a

1 couple weeks ago.

2 And this is on Slide 67. Is that when there's no sufficient
3 reasoning, and it's suggesting that parties are taking a wait and see
4 approach, they took a wait and see approach, Your Honor. They
5 asserted indefiniteness in District Court. They filed their petition,
6 they got instituted.

7 And now that they've been instituted and they got called
8 out for it, they have allegedly withdrawn their indefiniteness
9 positions. Although I might add, it's unclear whether they actually
10 did withdraw them, because there's certainly language in their
11 invalidity contentions. And this is Exhibit 1107 at 328, Slide 63,
12 where the indefiniteness isn't quite dead yet in District Court.

13 JUDGE MAJORS: So I don't want to go too far down
14 the rabbit hole on this, but the petition was filed well before the
15 director's decisions in Revvo and Tesla and Ford, and all these
16 other ones, right?

17 MR. TOBIN: Yes, Your Honor. Correct.

18 JUDGE MAJORS: So what opportunity did Petitioner
19 have to explain a so-called inconsistent claim construction?

20 MR. TOBIN: I'd say, Your Honor, they had the same
21 opportunity that Tesla had, that Revvo had, that Terumo had, that
22 in all these positions, and they certainly after our Patent Owner
23 response where they (INDISCERNIBLE) consistency or why they
24 argued indefiniteness in District Court. They just asked the Board
25 for a mulligan and said, oh, never mind that, and here's a new Dr.

1 Donovan declaration.

2 JUDGE OBERMANN: Was the reply brief filed after
3 the decision in Magnolia Med Techs?

4 MR. TOBIN: No, it was not, Your Honor.

5 JUDGE OBERMANN: Thank you.

6 MR. TOBIN: Unless, Your Honor, the panel has any
7 other questions on this (INDISCERNIBLE) set forth in the
8 petition.

9 DR. BEST: Good morning, again. Could I ask that we
10 have Slide 72 brought up? So Mr. Tobin has just explained the
11 question of irreconcilable differences. I'm going to assume we're
12 all on the same page. That the claims do exclude water, and the
13 consisting of should be read in its plain and ordinary
14 (INDISCERNIBLE) contentions fail.

15 And here's why. First, Gwozdz. They rely in Gwozdz
16 on this embodiment. I don't choose it at random. This is the
17 embodiment they chose motivation to combine in the petition, and
18 there is no other. Mr. Landmon suggested, well, actually, there's
19 this other part of the document that we didn't refer to in the
20 petition, by the way.

21 Further, it should have been in the petition, first off. And
22 second off, it's actually irrelevant because what does this
23 embodiment say? (INDISCERNIBLE) pharmaceutical solutions,
24 meaning having all the other components in them. Meaning
25 benzodiazepine, alcohols, tocopherols, can formulate an objection,

1 e.g. solution or water.

2 Now, Mr. Landmon says the e.g., means, well, maybe we
3 don't need water. I don't think that's how English works. But also,
4 note that the sentence goes on to say, and a vitamin E solubilizing
5 agent. Well, you don't need a solubilizing agent in a non-aqueous
6 composition, you need it if you have water there.

7 Note by the way, that another new argument appearing
8 only in reply, the shift to wetting agent. Okay. Well, a wetting
9 agent, what is that? A wetting agent deals with water, deals with
10 modifying the surface tension of water. The disclosure here says
11 water is not excluded. And that's the disclosure they focus on both
12 for their motivation to combine. Next.

13 JUDGE MAJORS: Dr. Best.

14 DR. BEST: Yes.

15 JUDGE MAJORS: Maybe you're getting there, I'm
16 sorry to jump ahead, but what about the disclosure at Gwozdz page
17 6, the end of the alcohol paragraph? Quote, in this regard, the
18 ethanol is desirably 180 to 200 proof ethanol i.e., in the range of 90
19 to 100 percent ethanol. Why does that not sufficiently disclose
20 water free?

21 DR. BEST: Well, two points, one -- or maybe three.
22 One, the embodiment they rely on for motivation to combine is the
23 one that I have on screen. And that means this is what they're
24 saying is an embodiment that matters for figuring out obviousness.

25 Two, even Dr. Donovan conceded that 200 proof ethanol,

1 in her deposition, and I believe we cited in our Papers, includes
2 water, always includes water, always includes some amount of
3 water. And three, that's a sort of mixing and matching of
4 embodiments that we don't believe is appropriate for establishing
5 obviousness.

6 The petition needs to set out in detail why the claims lack
7 the consisting-of point that Your Honor, Judge Obermann was so
8 concerned with, and I think Your Honor, Judge Majors was so
9 concerned with in the context of the written description analysis.

10 JUDGE MAJORS: I have a follow-up question on that.
11 So --

12 DR. BEST: Sure.

13 JUDGE MAJORS: Let's assume for the moment that we
14 disagree with you and that the citation there on page 6 is perfectly
15 within the proper scope of the reply. How is that disclosure any
16 different than what's in -- I'm looking at the '786 patent, column 4,
17 roundabout line 33 to 43. You can go there if you'd like, but I'll
18 quote you the relevant part talking about alcohol.

19 DR. BEST: Sure.

20 JUDGE MAJORS: And then it says, quote, "In some
21 embodiments, the alcohol or glycol is free of water, dehydrated
22 USP. In some embodiments, the alcohol is ethanol, dehydrated
23 USP." So it seems to be -- I understand the argument that if you
24 go and you look at the USP document, it says you can never sort of
25 theoretically get pure alcohol that has not a scintilla of water in it.

1 But the patent itself describes free of water as dehydrated USP,
2 which I might say is the same thing that Gwozdz is telling you to
3 do there in page 6.

4 DR. BEST: I think I understand your question. I think
5 the answer, Your Honor, is it's that composition that the
6 embodiment on page 10, that I have on screen on Slide 72, it's that
7 embodiment and the other embodiments described in Gwozdz that
8 is the embodiment to which is then added water, to which is then
9 added water. And so the disclosures on which they rely, whether
10 or not you're talking about the question of whether the ethanol is
11 water free, the disclosure on which they rely includes water. If
12 there are no further questions, I'll proceed.

13 Next Meezan -- and can we just have Padagis's Slide 32?
14 Yeah, so on the left, and Mr. Landmon addressed this in his
15 presentation, what is the discussion in Meezan on which they rely
16 to establish a lack of water? It's not the rest of Meezan, I can tell
17 you. And the answer to that is because there's no other place in
18 Meezan that this phrasing applies, non-aqueous.

19 Every example is to put a polypeptide or a protein in an
20 aqueous solution and add an alkyl glycoside to it. Set that aside.
21 What does the paragraph actually say? It says, additionally, the
22 composition of the invention, meaning the invention otherwise
23 described in Meezan can have additionally added to it, a non-
24 aqueous agent, can have additionally added to it, a surfactant. That
25 is the context of Meezan. Even this passage, which is their key

1 passage, does not actually exclude the addition of water. If there
2 are no further questions on this issue, I will proceed.

3 N-dodecyl- β -D-maltoside. If we could go to Slide 84 of
4 our deck? Thank you. The second characteristic issue that the
5 petition fails to establish, and there's a great deal of discussion
6 about this, I think, in Mr. Landmon's presentation, is the petition
7 fails to establish that n-dodecyl- β -D-maltoside appears in the
8 asserted prior art. Now, this omission should be the end of the
9 analysis. There's no need to go further into motivation to combine.
10 There's no need to go further into, frankly, whether water is
11 included or whether there's priority for that matter because this is a
12 fundamental petition failure. Mr. Landmon described this as some
13 nomenclature confusion.

14 Actually, there's no dispute about what n-dodecyl- β -D-
15 maltoside is if we turn to Slide 85. Everyone agrees that n-
16 dodecyl- β -D-maltoside is a single-chemical composition having
17 the structure on the screen. And there's no dispute that every
18 claim of the '414 and '786 patents includes it. And there's also no
19 dispute that nowhere does Meezan, or any of the other asserted
20 prior art, use the phrase "n-dodecyl- β -D-maltoside".

21 86 please. There's also no dispute that the dodecyl
22 moiety can be linear or can be branched. And in the context of
23 Meezan, there's no dispute -- if we flip forward to Slide 93 -- that
24 Meezan describes DDM as branched. And this is the only place in
25 Meezan where there's structural discussion of what the DDM is,

1 and it says it's highly branched. Dr. Donovan, I asked the
2 question, whether she's aware of any place else in the specification
3 that says anything else about the structure of DDM, and she
4 answered that she did not know of any such place. And that's
5 correct because there is no such disclosure.

6 Now, go back to 86. What is Padagis's argument? It's
7 basically you should not believe your lying eyes. When it says
8 highly branched, it actually should mean long. When it says
9 dodecyl maltoside or dodecyl- β -D-maltoside or any other thing
10 that sort of sounds like dodecyl maltoside, what they really meant,
11 according to Ed Maggio, ten years later in another proceeding on
12 another patent, says something about n-dodecyl- β -D-maltoside.

13 I won't talk about admissibility. Ms. Hurley will be
14 addressing those issues. But the fact is if they wanted to rely on a
15 supposed amendment or a supposed inventor declaration, at a
16 minimum, it had to be raised in the petition. But there are other
17 issues, and they'll be addressed in the fullness of time.

18 Can we go to 87? I wrote this down, I think it's very
19 close to verbatim. Mr. Landmon says, no one would think, no
20 skilled artisan, would think to add an n to the dodecyl maltoside to
21 indicate that it's linear. Well, that's not true, and the Streitwieser
22 textbook, Exhibit 2051, says as much. It says straight chain
23 alkanes are called normal alkanes or simply n-alkanes to
24 distinguish them -- to distinguish them -- from the branched
25 alkanes, end quote.

1 If it were the case that you could not have a branched
2 dodecyl, for example, and call it branched dodecyl, this would be
3 surplusage. But it's not. Mr. Landmon said Streitwieser says you
4 don't need an n. Well, that's not correct. Streitwieser says you do
5 need an n to distinguish.

6 We'll go to 91. And I think there was some question or
7 some concern, let's say, that Dr. Donovan did not identify in the
8 petition any location where n-dodecyl- β -D-maltoside appears in
9 the asserted art. And I was curious about that myself. That's why
10 when I deposed her, I asked the question -- if we go to 92 -- do you
11 have an understanding of what the n prefix even means? Answer,
12 it escapes me at the moment. I even gave her a hint. Answer, I'm
13 not willing to state that I know that clearly right now.

14 Now, Mr. Landmon says this was confusion. With all
15 due respect, I was there and she was not confused. She didn't
16 know. Mr. Landmon says we could have deposed her again to
17 understand better her reply arguments in her second declaration
18 that are informed by us coming to the deposition and telling them
19 the problem with their petition, which they obviously did not
20 perceive.

21 Well, here's the problem with that. It's not in the petition.
22 It's not like a deposition is going to cure that. And that's a fatal
23 flaw under the Par Pharmaceutical case and other cases that we've
24 cited in our Papers.

25 Let's go to 98. So seeing these problems, what does

1 Padagis do? Well, backfill. First backfill, IUPAC applies. No one
2 disputes it. Well, that's wrong. We do dispute that IUPAC
3 applies. We made the point -- thank you. We made the point in
4 our Papers to that effect.

5 And by the way, I defy Padagis or anyone to read these
6 three pages of the IUPAC, and find where it says what Dr.
7 Donovan says it says. In fact, she doesn't really explain this
8 argument at all. And we know it's wrong because the textbook
9 says you can use the n.

10 In fact, should use the n to distinguish the n-dodecyl, the
11 linear form, the form that the claims require. Second attempt at
12 backfill. There was this amendment, the supposed amendment.
13 Well, the supposed amendment, if we go to Slide 99, says, go to
14 longer. It's not branched. It's not branched.

15 And your lying eyes deceive you. It's not branched, it's
16 longer. I'll explain in a moment that that doesn't help, and in fact,
17 actually makes things worse on the motivation to combine. But in
18 any event, this is a document not cited in the petition, not part of
19 the actual asserted prior art, not a printed publication, not a patent,
20 not reliable upon.

21 Finally, I addressed this before, I'll just say again, Slide
22 101, an inventor declaration from 2013 in a different patent
23 characterizing a different patent at a different time. And I'm sure
24 the panel is well aware that there's a great deal of skepticism and
25 very little weight should be given to post-dated unsupported

1 incontemporary documentation inventor testimony.

2 And that's setting aside the fact that it's not cited in the
3 petition. It's not cited in Dr. Donovan's declaration 1062, and it's
4 otherwise inadmissible as Ms. Hurley will explain. If we could go
5 to 102. The final issue I'll discuss is motivation to combine.

6 Now, Your Honor, Judge Majors raised the question,
7 why are the differences between the motivation to modify Gwozdz
8 or the motivation to then combine it with Meezan that are new in
9 this issue that were not addressed earlier? I think Mr. Tobin
10 addressed that issue fine and I don't want to go back on it.

11 What I'm going to do is something a little different.
12 Which is, I think there's a really clarifying way to look at, if you
13 were a skilled artisan in 2008, what do you do? Well, even if that
14 skilled artisan picks up Gwozdz and says, you know, I want to
15 modify this.

16 And even if that same skilled artisan says, given the
17 panoply of possible prior art, you know, I want to modify it with
18 Meezan. Then what? Then what? That's the last question that has
19 to be answered. That's a question that in the prior proceeding only
20 pertained to alkyl glycosides.

21 It was almost not a question at all, because nearly every
22 paragraph of Meezan discusses alkyl glycosides. That's not the
23 issue here though. And that's the issue in which I'll focus the
24 remainder of my presentation. Slide 134, please. So what does
25 that person of ordinary skill do picking up Meezan?

1 Well, what does Meezan disclose? Meezan discloses
2 endless numbers of alkyl glycosides. This was of course one of
3 the problems with trying to find support for alkyl glycosides in our
4 -- in the previous proceeding. Well, how do you choose?

5 Because our claims don't require, quote unquote, alkyl
6 glycosides generally, they require dodecyl maltoside for the '546
7 Patent, or n-dodecyl- β -D-maltoside for the other two patents.
8 Well, you might look at, what does Meezan say it's preferred?

9 Well, I'll go to the paragraph that actually says what's
10 preferred. It's not the paragraph they cite, and I'll address that in a
11 moment. The paragraph that says, what is actually preferred,
12 ranges of compounds, having nine to 24 carbon atoms. Any one of
13 those having any one of various sugars.

14 And in reality, having the combination of those issues,
15 that's what Meezan says is preferred. But fine, let's go to the
16 paragraph they highlight, 7. By the way, paragraph 157
17 presentation today, not present to my understanding in either the
18 petition or Dr. Donovan's opening declaration.

19 But again, set that aside. What do they say is preferred?
20 Well, preferred doesn't appear in this paragraph, so they have to
21 interpret. And they say, well, dodecyl, tridecyl and tetradecyl- β -
22 D-maltosides are, quote, more effective. Okay. What are they
23 more effective for?

24 They are more effective for ocular administration of
25 insulin in an aqueous solution. So the leap of logic is, the person

1 of ordinary skill, who's very intensely trying to figure out, I want
2 an intranasal composition of benzodiazepines, I want it to be non-
3 aqueous.

4 But actually, I'm going to look at the paragraph that talks
5 about aqueous administration of eyedrops of insulin. Okay. Let's
6 accept that. It's wrong. We set out why it's wrong in our Papers,
7 but let's accept that. What are the options there? That's three
8 options.

9 Actually, more than three options, because it says, longer
10 chains. Longer chain. Probably longer chains ring a bell. I
11 discussed a few moments ago. That's what they say Meezan
12 should say, it should say longer chains. Well, okay, fine. Longer
13 chains would be more effective, like up to 24 carbon atoms as we
14 saw in paragraph 58 of Meezan.

15 But again, anyway, let's just say they're right. Let's just
16 say this is three options. What does the law require? Virtek
17 Vision. You have to have a specific reason to select what is
18 ultimately in the claims. That is what Virtek Vision says. Think
19 of the Virtek Vision case.

20 Virtek Vision had a piece of prior art that disclosed two
21 options for a claimed invention. The claimed invention was a way
22 of 3D mapping, sort of laser protections like I suspect we're going
23 to see on some of our buildings here in the next month.

24 And it disclosed two ways that the claims required doing
25 that in a 3D coordinate system. Specification of the asserted art

1 said you could do a 3D coordinate system, or you could do vectors.
2 Gave you no reason to select amongst them. Patent challenger
3 gave no reason to select amongst them.

4 Federal Circuit, not enough, not a motivation to combine.
5 They cite, and I think Mr. Jones addressed this, the Fulton case.
6 Let's think about what the Fulton case was. What was the Fulton
7 case? Well, that's a case about shoe treads.

8 And the shoe treads that were required by the claims had
9 these hexagonal projections to help have much better grip on the
10 world. The principal piece of prior art that was asserted, what did
11 that disclose? It disclosed various geometrical shoe tread designs,
12 not hexagonal. But what else did it do?

13 It said go forth and modify, go find more geometric
14 projections. That would be a great idea. What else was present in
15 that case? There was no dispute that the person of ordinary skill
16 would have found the hexagonal option more beneficial than
17 others.

18 And it was in that circumstance, a pre-KSR case back in
19 2004, long before Virtek Vision, long before, Your Honor, Judge
20 Obermann's opinion in the GCE case, which I think we cited.
21 Long before that, when you had all these directions pointing to the
22 claimed invention. Okay, fine, go to the claimed invention, maybe
23 it's obvious.

24 That's not what we have here though. But what we have
25 here is the Virtek Vision circumstance. What we have here is no

1 reason, no reason. Even amongst the three options that they
2 choose as their best disclosure to choose any one of them. And by
3 the way, none of them is n-dodecyl- β -D-maltoside, because it's
4 nowhere in there. So I think I'll stop here unless folks have further
5 questions. And yes, go ahead.

6 JUDGE OBERMANN: I have a question on the one
7 case that is before us that doesn't require the normal form.

8 DR. BEST: Sure.

9 JUDGE OBERMANN: 157 does say dodecyl maltoside.
10 That's enough, right? For that one case?

11 DR. BEST: I'm sorry, explain the question one more,
12 what the one case is.

13 JUDGE OBERMANN: Well, the one case -- we have
14 two cases that claim the normal maltoside. And then we have the
15 third case, I think it's the '464 case where it's just the dodecyl
16 without the n. And I'm looking at paragraph 157, and it seems like
17 it does direct one to dodecyl D maltosides.

18 DR. BEST: I understand your question. So the one case,
19 the '546 patent only requires dodecyl maltoside. I think under
20 Virtek Vision and like cases, having three options is not enough,
21 because there's no reason that's been given why you would select
22 any one of those options.

23 JUDGE OBERMANN: Well, aren't all three of them just
24 as obvious?

25 DR. BEST: Well, I think that's not what the thrust of the

1 Virtek Vision case says. And I think again, the GCE case on
2 whose panel you sat, Your Honor, Judge Obermann, you need a
3 reason, meaning the petition must set forth a reason why the
4 skilled artisan would make a choice. And that choice being the
5 claimed invention. And there's nothing in Dr. Donovan's
6 testimony about that.

7 JUDGE OBERMANN: Okay. And you're saying that
8 paragraph 157 was not cited until the reply brief?

9 DR. BEST: That's what I saw, Your Honor. If Padagis
10 can relieve me of that belief, that's fine, but I didn't see it and I
11 looked.

12 JUDGE OBERMANN: Okay. Thank you.

13 DR. BEST: Thank you, Your Honors.

14 JUDGE MAJORS: Dr. Best, before you sit down and --

15 DR. BEST: Sure.

16 JUDGE MAJORS: -- I apologize. We'll make sure that
17 your LEAP practitioner gets sufficient time.

18 DR. BEST: Of course.

19 JUDGE MAJORS: This is really just more for
20 housekeeping.

21 DR. BEST: Sure.

22 JUDGE MAJORS: And the Cartt reference, is Patent
23 Owner still disputing that Cartt is prior art?

24 DR. BEST: I think that that argument is largely off the
25 table, is my recollection. If I am wrong in that assessment, we will

1 let you know before the end of our discussion today, I assure you.

2 But I think that's right.

3 JUDGE MAJORS: Okay. I would appreciate that. And
4 I just want to confirm on the record, and this is not -- I'm not trying
5 to trap you, I know --

6 DR. BEST: Sure.

7 JUDGE MAJORS: -- Patent Owner disagreed with our
8 resolution on the certificate of correction, but Patent Owner agrees
9 that for purposes of going forward to the final stage, the issue is
10 moot about the safe harbor under § 103(c)(2) and Patent Owner is
11 not relying on the Cartt declarations -- I forget the names of the
12 other two inventors, I'm sorry.

13 DR. BEST: Sure, no problem. I think the short answer
14 is, yes. Pending our right of review and appeal, there will be
15 nothing in the final written decision that relies on any of the
16 material that's in those declarations.

17 JUDGE MAJORS: Thank you.

18 DR. BEST: Certainly.

19 JUDGE REIMERS: And I just have one follow up. And
20 again, we will make sure that your LEAP practitioner has enough
21 time.

22 DR. BEST: Certainly.

23 JUDGE REIMERS: Referring back please to that
24 paragraph 157.

25 DR. BEST: Yes.

1 JUDGE REIMERS: We saw that it was dodecyl and two
2 other additional. So I want to make sure that I understand where
3 you're coming from. I know you said there has to be a reason. Are
4 you saying that -- I'm trying to understand, are you saying that
5 there's three choices there, why would you choose one over the
6 others?

7 DR. BEST: Well, I'm saying various things. That's one
8 of the things that I'm saying. That's sort of at the end of a chain of
9 thought, though. The first thing is Meezan discloses myriad
10 options. Of those it describes, still a lot, but less as, quote unquote,
11 preferred, not in paragraph 157, somewhere else.

12 And then even if you go to paragraph 157, which again,
13 not in the petition, there are still three -- I think a fair reading
14 suggests that several other alkyl maltosides are also effective. And
15 it says that longer chains, e.g., Mr. Landmon loves e.g., when it's
16 in Gwozdz, e.g., these three.

17 So I think that if you accept that the e.g., isn't there and
18 it's only three, and you accept that this is something that can be
19 relied upon, it's still the case that there's no reason it's been
20 expressed by Dr. Donovan or the petition, why to select any one of
21 them.

22 JUDGE REIMERS: Okay. Thank you. Thank you for
23 that clarification.

24 DR. BEST: Certainly, Your Honor. Anything else?
25 Going once, going twice. All right. I'll sit down.

1 MS. HURLEY: Good morning, Your Honor. Hannah
2 Hurley for Patent Owner. I'll be covering the priority date of
3 Gwozdz PCT, and then move on to Cartt, and end with the various
4 motions to strike and exclude. So in order for Gwozdz PCT to be
5 prior art, the cited content must be adequately supported by the
6 written description of the provisional application. This is from in
7 re Riggs, and on Slide 151.

8 On Slide 152, Petitioner relies on penetration enhancers
9 as part of its motivation to combine Gwozdz PCT and Meezan.
10 On Slide 152, there's an excerpt from their petition, page 27, where
11 they quote, penetration enhancer language. However, this
12 language is not found in the Gwozdz provisional.

13 And as Your Honors previously agreed on Slide 153 of
14 the decision granting institution, this penetration enhancer
15 language is not actually found in the Gwozdz provisional. And
16 Slide 154, if you compare the provisional to the PCT, you can see
17 that this penetration enhancer language is not -- is missing from
18 the PCT.

19 And since this phrase is not in the provisional, this
20 portion is not prior art. I'll move on to Cartt 74. So in the '466
21 proceeding for the '786 Patent, Petitioner has an additional ground
22 of invalidity as seen on Slide 156, and page six of their petition.

23 This newly asserted ground is based on Exhibit 1065,
24 and specifically refers to Claims 20 and 21 of the '786 Patent.
25 Petitioner's only argument for its motivation to combine is that all

1 these references, Gwozdz PCT, Meezan, and Cartt are directed to
2 benzodiazepine nasal formulations.

3 That's from their petition on Slide -- on page 62.

4 However, any motivation to combine Gwozdz PCT, Meezan, and
5 Cartt is hindsight because Cartt is directed to particular
6 formulations of benzodiazepines which are used in a suspension.

7 And you can see this on Slide 157, there's an excerpt of
8 Cartt's abstract in paragraph 15, particulate formulations and
9 suspensions. There's more examples of Cartt describing
10 suspensions on Slide 158 and Slide 159. Petitioner's expert, Dr.
11 Donovan, agrees on this point.

12 On Slide 160, there's an excerpt from her deposition
13 where we asked her if there's any examples that were not directed
14 to particulates, and she agreed every example contains particulates,
15 which is indicative of a suspension. if Your Honors have no
16 questions, I'll move on to Petitioner's motion to strike.

17 JUDGE MAJORS: Ms. Hurley, I have a question. This
18 is Judge Majors.

19 MS. HURLEY: Yes.

20 JUDGE MAJORS: Didn't the Board panel in the '451
21 IPR reject the notion that Cartt was limited to particulate
22 formulations?

23 MS. HURLEY: I believe they did. If no further
24 questions, Petitioner's Motion to strike. As Petitioner has brought
25 up, they have moved to strike inventor declarations Exhibits 2045,

1 2046, and 2047. As an initial matter, Petitioner's motion to strike
2 seeks to expunge these exhibits.

3 And rather than give them no weight, and Patent Owner
4 in its own motions to strike, seeks to only give those respective
5 exhibits no weight. Expungement is not necessary. And if the
6 Board believes that these declarations are improper, respectfully
7 Your Honors should just simply not consider or give these
8 declarations no weight.

9 These inventor declarations were drafted and executed to
10 support the argument that Gwozdz PCT does not qualify as prior
11 art. The parties agree on this point, as seen on Slide 162, which
12 has an excerpt of Petitioner's motion to strike at page 2. This is an
13 extremely limited scope, and any cross-examination would've been
14 limited to this scope.

15 Slide 163, since the Board denied Patent Owner's leave
16 -- request for leave to seek a certificate of correction to add
17 evidence of a joint research agreement under § 103(c)(2), Patent
18 Owner cannot meet the third requirement at this time. And 164,
19 Petitioner agrees that Patent Owner's argument is moot.

20 There is no need to strike something at this time that is
21 moot for the purposes of the final written decision. And the Board
22 has full discretion to simply disregard this argument. If Your
23 Honors have no questions, I'll move on to the motion to strike.

24 So as referenced by my colleagues, Patent Owner also
25 has a motion to strike pending review from the Board. For the first

1 time in reply, Petitioner has brought up a proposed amendment
2 that meets on specification made during Prosecution. And this is a
3 new argument.

4 As shown on Slide 167, this purports to amend paragraph
5 117 of Meezan from highly branched to long. This amendment
6 was not part of the printed publication, and that was cited as prior
7 art against the challenge patents. Patent Owner believes that this
8 should be stricken from the record and given no weight because it
9 is not part of the patent publication.

10 This amendment was never accepted by the patent office,
11 and was uncited in the petition and Petitioner's reply. The petition
12 and Dr. Donovan never used the term linear or branch. This is a
13 completely new argument made in reply that should be given no
14 weight.

15 The next contested exhibit is Exhibit 1076, this is on
16 Slide 169. And this is also an excerpt from the Prosecution -- from
17 a Prosecution history, but this time it's a completely different
18 patent. Exhibit 1076 purports to be a declaration by one of the
19 inventors, Edward Maggio.

20 He's a named inventor on both Meezan and the challenge
21 patents. But as mentioned previously, this declaration was filed in
22 September of 2013, which is much later than the priority date of
23 the challenge patents. And I'm still on Slide 169. Mr. Maggio
24 refers to dodecyl- β -D-maltoside as n-dodecyl- β -D-maltoside.

25 But he's referring to a separate invention from a different

1 patent. And it's actually related to cerebral spinal fluid of the
2 central nervous system. This is a completely new theory made in
3 reply by Petitioner. And Petitioner points to no disclosure of the
4 claimed species and dodecyl- β -D-maltoside. And as discussed
5 previously Dr. Donovan did not know the meaning of n. I won't
6 rehash it. And I'll move on to the motion --

7 JUDGE MAJORS: Ms. Hurley.

8 MS. HURLEY: Yes.

9 JUDGE MAJORS: Ms. Hurley, before you go on to that,
10 I think you were just going to go to the motion to exclude --

11 MS. HURLEY: Yes.

12 JUDGE MAJORS: -- but while we're on this particular
13 Slide 169, Judge Obermann asked a question about why this isn't
14 hearsay.

15 MS. HURLEY: Yes.

16 JUDGE MAJORS: Maybe you could explain for us why
17 Patent Owner says it is hearsay.

18 MS. HURLEY: So as everybody agrees, this is an out of
19 court statement, and we believe it is used for the truth of the matter
20 asserted. Dr. Donovan specifically refers to this part, and she
21 believes that it is true. So we believe that it would be hearsay.

22 JUDGE OBERMANN: It's under oath. And my
23 understanding is this declarant is deceased. Correct?

24 MS. HURLEY: Yes. That is also my understanding.

25 JUDGE OBERMANN: So there is no opportunity to

1 cross them or anything like that?

2 MS. HURLEY: That is true, yes.

3 JUDGE OBERMANN: Is that an exception to the
4 hearsay rule?

5 MS. HURLEY: I believe that is an exception to the
6 hearsay rule, but I think given the other circumstances surrounding
7 this declaration, that it shouldn't be relied upon in this proceeding.

8 JUDGE OBERMANN: Okay. Thank you.

9 MS. HURLEY: Thank you. If there's no further
10 questions, I'll move on to the motion to exclude, which is -- so
11 Patent Owner also filed a motion to exclude on Exhibits 1073,
12 1074, 1075, 1076, and 1080. And as you know, Your Honors have
13 discretion to exclude or give no weight to these exhibits that are
14 uncited by Petitioner.

15 And as seen on Slide 173, the vast majority of these
16 exhibits were not cited by Petitioner. For instance, 1074 and 1080
17 were not cited by Petitioner or Dr. Donovan. And for most of the
18 other exhibits, Petitioner improperly left Dr. Donovan to do all the
19 analysis and citation.

20 And I would like to call out Exhibit 1076, which
21 Petitioner conceded in its opposition that Exhibit 1076 was not
22 relied upon by Petitioner or Dr. Donovan in the '546 proceeding.
23 That's '546 Patent proceeding. Patent Owner also believes that
24 Exhibits 1075 and 1076 should be excluded for hearsay, as Your
25 Honors know.

1 And Petitioner does not contest that these statements are
2 out of Court statements. 1075, Dr. Donovan does appear to rely on
3 this statement for the truth of the matter asserted. She refers to it
4 as the correct Meezan specification that specifically emphasizes
5 that DDM has a long alkyl chain.

6 In its briefing, Petitioner submitted that Rule 703 would
7 apply, but this only makes its expert Dr. -- this only allows Dr.
8 Donovan to discuss the exhibits, it does not create admissibility for
9 the underlying exhibits.

10 And I think as Your Honors pointed out, there is no
11 indication that experts in the field would reasonably rely on such
12 documents, the file history of the patent specifically. And if there
13 are no further questions, I'll leave the rest of the time for rebuttal.

14 JUDGE MAJORS: Thank you.

15 MS. HURLEY: Thank you.

16 MR. LANDMON: May I proceed?

17 JUDGE OBERMANN: Yes.

18 MR. LANDMON: Thank you. So I'll use the first part
19 of our time and then turn over the remainder of our time to our
20 LEAP candidate, Mr. Jones, to address a couple of issues including
21 the issues raised on the motions. So I want to start with our Slide
22 41, and start with something that was not addressed by Neurelis'
23 Counsel.

24 And that's notable. And we said this, we've said this in
25 our Papers. That's the fact that in their patent, and in their

1 Prosecution history of the very patented issue, they said that the
2 disclosure of dodecyl- β -D-maltoside supported a claim to n-
3 dodecyl- β -D-maltoside. We explained that there is no use of the n
4 throughout their specification.

5 They never use it, never rely on it, but they rely on the
6 disclosure of dodecyl- β -D-maltoside. If it's sufficient in the patent
7 specification to support a claim to NDDM to just have DDM, it
8 should be sufficient in Meezan, and they shouldn't be allowed to
9 argue otherwise.

10 JUDGE OBERMANN: Why shouldn't we vacate our
11 DIs in view of Magnolia Med Techs?

12 MR. LANDMON: In terms of the claim construction
13 issue, Your Honors?

14 JUDGE OBERMANN: Yes.

15 MR. LANDMON: Yes. So I think there are a couple of
16 things at issue there. Just pardon me. Couple of things. First, I do
17 agree that if this is an issue, it's an issue for the director, it's not an
18 issue for the panel. I know Judge Majors --

19 JUDGE OBERMANN: Magnolia Med Techs is now
20 precedential on the Board. I don't view it that way.

21 MR. LANDMON: Sure. Understand that, that's our
22 view. But I think more importantly, there is no inconsistency
23 between the positions here and the positions of the District Court.
24 Frankly, there never was an inconsistency. Once we got the
25 director's guidances from these different cases, we went to the

1 Court and said, all right, to remove any doubt that there could be
2 any inconsistency we are from now and forever, not asserting
3 indefiniteness and not asserting any sort of claim construction for
4 consisting of.

5 And I think that's what makes this case different than the
6 cases, the Magnolia case and others that were cited, that we no
7 longer have these positions in the District Court. And --

8 JUDGE OBERMANN: I've been on cases where that
9 didn't matter.

10 MR. LANDMON: Sure. We also don't believe there
11 was ever an inconsistency. We always believe --

12 JUDGE OBERMANN: About indefiniteness. That's a
13 real issue.

14 MR. LANDMON: Yes. There was an indefiniteness
15 position. Obviously, those positions were taken before the
16 director's decisions came out. Once these director decisions came
17 out, we have now removed that. That's --

18 JUDGE OBERMANN: Why it matters -- I mean, all
19 these other Petitioners were in the same position as you. Ford,
20 Tesla. I mean, they had this basically applied retroactively to
21 them. How do we get around that?

22 MR. LANDMON: Because what they didn't do is they
23 didn't remove the doubt and they didn't remove it from the District
24 Court proceedings. In other words, they said, we're going to keep
25 our positions in the District Court contingent upon what happens in

1 the IPR. We haven't done that. We've withdrawn those positions
2 from the District Court.

3 They are no longer at issue in the District Court. We
4 submitted Papers to this body to show that there's no claim
5 construction on consisting of, there's no indefinite position on
6 consisting of. And that's what makes our case different is we
7 haven't, I think they used the word hedge our bets.

8 We haven't said, hey, we're going to reserve this for later
9 after this Board makes a determination. We've removed any
10 alleging inconsistencies in that case from now going forward. Your
11 Honors, if I may turn to a couple more issues on the NDDM issue.

12 First, I did want to address in regards to Dr. Donovan's
13 deposition testimony, obviously there's a dispute over that
14 deposition testimony. But one thing I did want to make clear, Dr.
15 Donovan and us were never on notice that Neurelis was raising
16 any sort of nomenclature issues.

17 So Judge Reimers, to your question earlier about, well,
18 shouldn't she know -- shouldn't she have known what they were
19 talking about? It was never made an issue. They didn't raise this
20 issue in their preliminary response, not that they were obligated to
21 necessarily raise it.

22 But we weren't put on notice and she wasn't put on
23 notice. So she didn't even know that there was an issue when she
24 was asked this question out of the blue at her deposition. But I
25 also wanted to address, and if we could turn to our Slide 94.

1 We didn't have this slide up on the screen during my
2 earlier presentation, but as to whether in the petition and in Dr.
3 Donovan's original declaration, there was any indication, I know
4 we discussed this paragraph, paragraph 151 of Dr. Donovan's
5 original declaration.

6 I know Your Honors and Judge Obermann in particular,
7 you had some questions whether that was sufficient, whether she
8 went far enough. What I didn't point to, and that was my fault, I
9 should have pointed that in our original presentation. But if you
10 see the footnote that's up on the screen, it's to the left up on the
11 screen.

12 She has this footnote in her declaration, again, her
13 original declaration. It is cited in our petition, it's in her original
14 declaration. She states the terms dodecyl maltoside and n-dodecyl-
15 β -D-maltoside are understood to be the same compound. And the
16 terms are generally considered interchangeable.

17 I think that's pretty clear what she's saying. She's saying
18 on record, it is in her declaration, it was cited in our petition. I
19 wasn't quick enough to raise it earlier, but I think that makes it
20 clear that we always had this position from --

21 JUDGE OBERMANN: Where is that? I'm sorry,
22 Counsel, where is that?

23 MR. LANDMON: I'm sorry. Yes, so it's in her
24 declaration. Paragraph 151 was a paragraph we were talking
25 about, but it's footnote 3 in her declaration. So her declaration,

1 sorry, is Exhibit 1062.

2 JUDGE OBERMANN: This is her first declaration?

3 MR. LANDMON: Her original declaration.

4 JUDGE OBERMANN: Okay. And it's what paragraph?

5 MR. LANDMON: So paragraph 151 then has a footnote

6 3. So it would then be the footnote 3 at the bottom of the page.

7 JUDGE OBERMANN: And could you read the footnote
8 to me because I'm having trouble locating it?

9 MR. LANDMON: Sure. Yes. No, and I apologize. The
10 footnote says, so she has the statement up on the screen that a
11 POSA would routinely select n-dodecyl- β -D-maltoside to add the
12 Gwozdz solution. In the footnote then says the terms dodecyl
13 maltoside and n-dodecyl- β -D-maltoside are understood to be the
14 same compound, and the terms are generally considered
15 interchangeable.

16 JUDGE OBERMANN: Okay. And that's a footnote to
17 paragraph 151, which you did cite in the petition.

18 MR. LANDMON: Yes. So we cite this paragraph in the
19 petition, we cited at paragraph -- sorry, page 41 of our petition.

20 JUDGE OBERMANN: Thank you.

21 MR. LANDMON: We do cite it again on reply, but I
22 think the petition is what you were asking about before.

23 JUDGE MAJORS: Mr. Landmon, I have a question
24 about that. I thought one of the answers you gave to one of the
25 very first questions of this hearing is that dodecyl maltoside is not

1 the same thing as the n-dodecyl- β -D-maltoside.

2 MR. LANDMON: So --

3 JUDGE MAJORS: That seems to be inconsistent with
4 what Dr. Donovan is saying right here.

5 MR. LANDMON: Yes. And I apologize for any
6 confusion I had in the chemistry when I was asked that question
7 earlier as Meezan uses the term dodecyl -- sorry. Yes. As Meezan
8 uses the term dodecyl maltoside, Meezan is clear that that also
9 means dodecyl- β -D-maltoside. And then it's Dr. Donovan's
10 position and our position throughout that, that is the same as n-
11 dodecyl- β -D-maltoside.

12 JUDGE MAJORS: One further point which I just noted.
13 This footnote is missing in the corresponding declaration for the
14 '455 proceeding. Did you notice that?

15 MR. LANDMON: There may have been an oversight in
16 not including the footnote in that declaration.

17 JUDGE MAJORS: Okay. Thank you.

18 MR. LANDMON: So on the same NDDM issue, I just
19 wanted to address a couple of other issues that Patent Owner's
20 Counsel addressed. And first, if we could turn to our Slide 35.
21 Counsel for Patent Owner addressed Streitwieser reference and
22 addressed how it's their position that the Streitwieser reference
23 says that you need to include the n prefix.

24 But there are a couple of important disclosures in
25 Streitwieser that Dr. Donovan points out in her reply declaration.

1 Here's one, and on our next slide, I'll show you a second. But first
2 focusing on this one, as you see, and we've highlighted here to the
3 right, dodecane is listed on the right, it is not listed as n-dodecane,
4 even though it is referring to the 12-carbon straight chain alkane.

5 And if we turn to the next page, this becomes, I think
6 even a little -- sorry, the next slide, Slide 36 becomes a little
7 clearer. Streitwieser also references pentane. And again, pen
8 means five, so there's five carbons in this. We've got the straight
9 chain carbon to the left, and then you have two branch chains to
10 the right.

11 Again, listed in Streitwieser, pentane is the straight chain,
12 does not say n-pentane it says pentane. And then Streitwieser goes
13 on to show, okay, when there is a branch, let's add a prefix. So
14 you have isopentane, and neopentane to show the two prefixes.

15 And that's what Dr. Donovan explains is the normal
16 IUPAC nomenclature or how you identify drug compounds. Give
17 me a moment. I just want to briefly address one comment too
18 made -- Counsel for Neurelis focused on, what they say is the
19 embodiment in Gwozdz that we rely on. And this relates to the
20 issue of water and saline solution.

21 What's key here is Gwozdz has every piece of prior art.
22 There is prior art for all that it teaches. And I had up on the screen
23 when I was talking earlier. Judge Majors, I think you asked about
24 it, the 100 percent ethanol. And Gwozdz is prior art for that
25 teaching as well. And I think that needs to be kept in mind as well.

1 Unless the panel has any further questions, I'll turn it over to Mr.
2 Jones to address a couple issues including the motions.

3 JUDGE MAJORS: Real quickly, Mr. Landmon.

4 MR. LANDMON: Mm-hm.

5 JUDGE MAJORS: Petitioner agrees that the recitation
6 of penetration enhancers, that that's not prior art within Gwozdz,
7 right?

8 MR. LANDMON: Yes, Your Honor. We think that
9 issue is irrelevant because the motivation really hinges on much
10 more, as I talked about the first time when I was up.

11 JUDGE MAJORS: Okay. Thank you.

12 MR. LANDMON: Thank you, Your Honors.

13 MR. JONES: Your Honors, I'm going to respond
14 quickly to a couple points. If we could go to Slide 67 actually. So
15 Counsel argued that Meezan would not have motivated a POSA to
16 choose DDM or to use DDM. And that it was somehow not one of
17 the preferred alkyl maltosides that was focused on in Meezan.

18 But as I explained earlier, that's just not true. There's
19 hard data provided in Meezan to show that DDM was effective.
20 And Dr. Donovan's declaration supports that point. And Dr.
21 Brown does not even dispute that point in his testimony either.
22 There certainly is one limited example here, one test where it was
23 described as ineffective.

24 But this is not a situation where Meezan didn't explain
25 with sufficiency that DDM was effective. It certainly started by

1 describing alkyl maltosides generally. And as Counsel explained,
2 it honed down and focused on a few other ones. And DDM was
3 one of those.

4 And Meezan certainly provides more than enough
5 motivation for a POSA to use DDM for those reasons. Counsel
6 also focused on the in re Fulton case, and argued that it was -- it
7 shouldn't apply here. First, for the reasons I just explained, I think
8 that's incorrect.

9 I think Fulton does apply to this exact situation where
10 there are a handful of effective examples in the prior art, DDM
11 being one of them. But in any case, there certainly is plenty of
12 other Federal Circuit case law that supports this point, and it is on
13 all fours with this exact situation. I'm also going to quickly
14 address the motions.

15 I think Mr. Landmon certainly addressed a lot of those
16 issues. but one point I'd like to make is that Patent Owner here is
17 moving to strike or exclude certain exhibits arguing that they're
18 new on reply. And again, I would refer the Board to our briefing
19 on this issue where we certainly don't agree with that
20 characterization.

21 But I think more importantly, the Board is certainly
22 allowed to determine how much weight to give these exhibits
23 without striking or excluding them. That's not necessary here.
24 And in the first instance, it shouldn't happen because they are
25 relied on by the experts and Petitioner.

1 The last point I want to quickly address is the hearsay
2 objection. I think Counsel sort of acknowledged that at least
3 Exhibit 1076 falls squarely within a hearsay exception, excuse me.
4 And the same should be true for Exhibit 1075 as well.

5 And regardless, I think the -- again, the bigger point to
6 keep in mind is that we are not relying on these for the truth of the
7 matter asserted. There are instances where Petitioners or parties
8 try to rely on data or testing from a specification to say that this
9 firmly establishes as a matter of truth, that something was in the
10 prior art.

11 We're simply pointing to these exhibits and these
12 statements from Dr. Maggio as supporting evidence for how a
13 POSA would interpret and understand Meezan as well as the
14 nomenclature issues. We're not pointing to these exhibits and
15 saying they establish as a matter of truth that DDM means NDDM
16 or anything like that. They're sort of additional points that support
17 our position for how a POSA would view these issues.

18 JUDGE MAJORS: Mr. Jones?

19 MR. JONES: Yes, sir.

20 JUDGE MAJORS: I'm not sure I agree that at least with
21 respect to Exhibit 1076, that Petitioner's not trying to use it for the
22 truth. I mean, isn't the point of that exhibit to say that when a
23 POSA says DDM, they mean NDDM? That seems like it's being
24 used for the truth. No?

25 MR. JONES: Yes. But I think it speaks to how a POSA

1 would interpret these issues. It doesn't establish as a matter of fact
2 that DDM means NDDM. So I think that's where the difference is.
3 And regardless, I think like we've just established, that one
4 squarely falls within a hearsay exception, even if you do consider
5 it.

6 JUDGE MAJORS: What exception is that?

7 MR. JONES: So if we go to Slide 103. So Exhibit 1076
8 I think definitely satisfies the residual exception under Rule 807 as
9 was already noted. Unfortunately, Dr. Maggio is now deceased.
10 He submitted this sworn declaration to the patent office where he
11 offered this statement. And so I think Exhibit 1076 definitely falls
12 within the residual exception of Rule 807.

13 JUDGE MAJORS: Well, I mean, I might be a little bit
14 rusty on my evidence law, but I think the way it works with a prior
15 declaration or prior testimony is it's a two-part test. You have to
16 first show that the declarant is unavailable, and I accept the
17 representation that this gentleman has died.

18 But then there has to have been an opportunity for the
19 person against whom the testimony is being used to have some
20 opportunity and motive to cross that testimony. But where did
21 Patent Owner have that opportunity here?

22 MR. JONES: So I think that the question is whether his
23 declaration was more probative on the point than any other
24 testimony that could be obtained now. And the answer is
25 obviously we can't get any testimony now. And certainly, Patent

1 Owner was arguably working with Dr. Maggio when this
2 declaration was submitted in the first instance back when this was
3 filed. So I think for those reasons it would still fall within the
4 residual exception.

5 JUDGE OBERMANN: So does it make a difference that
6 the declaration that you're relying on actually came from Patent
7 Owner under these circumstances?

8 MR. JONES: So that's a loaded question, obviously,
9 with the ownership issues that we're still contesting. But I think
10 certainly Dr. Maggio is an inventor on both the challenge patents
11 here and the Meezan application. So in that sense he was involved
12 with both. Apologies if that's not a clear answer. Unless Your
13 Honors have any further questions, I think that's all for Petitioner.

14 JUDGE OBERMANN: Thank you.

15 MR. JONES: Thank you.

16 MR. TOBIN: Your Honor, I just need to switch over the
17 cable, please. And now good afternoon, Your Honors. David
18 Tobin for Patent Owner. For our surrebuttal, I'll go first and then
19 we'll make sure Ms. Hurley, she'll go second, and then Dr. Best
20 will go third. Your Honor, I do want to address one of the points
21 on the claim construction.

22 Judge Obermann asked that just because they withdrew
23 their indefiniteness for claim construction in District Court, so
24 what? And Your Honor is correct. That's exactly the facts in the
25 Ford Motor case. The issue is, so what? But also from a factual

1 matter, they didn't really withdraw their indefiniteness in District
2 Court.

3 So I have Slide 61 on this slide. And again, on March
4 30th, the day before their Patent Owner reply, we get this
5 stipulation of consisting of in District Court, which what it did was
6 it took the indefiniteness of consisting of off the table for purposes
7 of claim construction in Delaware. That's Exhibit 1083.

8 Again, the following day we get reply and a new
9 Donovan declaration. But then on May 8th, now there's multiple
10 defendants in Delaware, we get a set of joint invalidity contentions
11 where lo and behold, indefiniteness of consisting of is still in those
12 contentions.

13 And it's Exhibit 1107, which Petitioner recently
14 submitted to the Board pursuant to authorization. And I'll show
15 those shortly. So again, it's kicking the can down the road a little
16 bit. Whereas we were in the midst of claim construction in
17 Delaware where they had a full Dr. Donovan declaration on why
18 consisting of is indefinite.

19 And getting ready for the hearing, then get the
20 stipulation, oh, a District Court Judge, you don't need to construe
21 this term. We don't have a claim construction dispute anymore on
22 consisting of. But May 8th, and this is Slide 62, Exhibit -- excuse
23 me, Slide 63, Exhibit 1107.

24 This was in the joint invalidity contentions served, again,
25 in May just last month. And in the joint invalidity contentions of

1 which Padagis, Petitioner here was a party, it states -- this is
2 Exhibit 1107, page 328. As Padagis explained in its preliminary
3 invalidity contentions with respect to the '546, '414 and '786
4 Patents, to the extent the claims of the '546, '414 and '786 Patents
5 allow for the presence of water, the phrase pharmaceutical solution
6 consisting of is indefinite because a POSA would lack reasonable
7 certainty about whether the claimed pharmaceutical solution can
8 contain water.

9 And then they take that same argument in the next
10 sentence for the same reasons discussed for our patents here today,
11 the phrase pharmaceutical solution consisting of recited is
12 indefinite in yet another one of Patent Owner's patents.

13 Next paragraph. So again, Your Honor's question, we
14 agree with. If they withdrew their indefiniteness of District Court,
15 again, after they filed the petitions, filed the Board institutes, and
16 now they seek a mulligan, so what? Under Ford, they can't do
17 that.

18 But they didn't really do that. They just kicked the can
19 down the road and they're saving indefiniteness for a later day.
20 Not through claim construction, but for invalidity expert reports on
21 a later day. Unless the panelists have questions on this issue, I'll
22 turn the baton over to Ms. Hurley.

23 MS. HURLEY: Hello again. So a few things were
24 brought up. I would like to clarify that Cartt was considered by the
25 PTAB in the previous IPR, but we do not believe the issue is

1 material to the final written decision, and would be -- and would
2 not be entitled to collateral estoppel with regard to these patents in
3 the IPR.

4 On the § 103(c)(2) issue, we would like to agree with
5 Your Honors that the inventors would be deposed in the parallel
6 District Court litigation. So there is plenty of time for them to be
7 deposed. I believe that those will be going through next month.

8 And on the hearsay exceptions to Exhibits 1075 and
9 1076, we would like to note that it's Petitioner's burden to bring
10 forward these hearsay exceptions. And if I misspoke, I did not
11 mean to misspeak, but we do not agree that 1075 or 1076 fall
12 within a hearsay exception.

13 I believe the dying or deceased exception is only if the
14 declarant made the statement while they were dying. And there is
15 no indication that that happened. And if Your Honors have no
16 further questions, I'll leave it to Dr. Best.

17 JUDGE OBERMANN: Thank you.

18 MS. HURLEY: Thank you.

19 DR. BEST: Good afternoon, Your Honors. Or I guess
20 still good morning perhaps, Judge Majors. I'd like to first clarify,
21 there's been a shifting sands approach, I think, to some of the
22 arguments in Padagis' case. And I think there's been a shifting
23 sands approach to what DDM is and what NDDM is.

24 There is no question that NDDM is a single species of a
25 broader genus called DDM, dodecyl maltoside. There is no

1 question that is the case. Mr. Landmon points to a footnote in Dr.
2 Donovan's declaration that says they're the same, that has no
3 citation, that I guess we're supposed to rely on her expertise, where
4 when I asked her the question, she says, I don't know what this
5 even means.

6 And I gave her the opportunity to explain. Because I
7 knew that wasn't true, and I wanted her to explain what her basis
8 was.

9 JUDGE OBERMANN: But does this take out of the
10 equation the question whether all this reply evidence, including the
11 textbook and the IUPAC evidence is improperly raised in the reply
12 because it should have been in the petition, if we have that hook
13 now in the petition so that all the reply evidence gets considered as
14 well too. Correct?

15 DR. BEST: I think it cuts the other direction, Your
16 Honor. I think that says that if they really thought the context of
17 Meezan describes, when it says dodecyl maltoside, it means
18 NDDM, that should have been in the petition.

19 JUDGE OBERMANN: Well, we now have this footnote
20 where they actually -- we have some evidence in the petition
21 expressly making that point. So unless you contested it in your
22 POR or your response, really no reason to elaborate on it. It's there
23 in the footnote. So by addressing it in your response, doesn't that
24 open the door to all of this reply evidence?

25 DR. BEST: I disagree. I think the point is that if they

1 really thought that this was true, and this was a thing to say, and by
2 the way it isn't, and we'll see in Meezan that that can't be the case,
3 not only -- not my opinion, who cares about my opinion. It's not
4 the case.

5 But the point is that if that was the thought process, I'm
6 Dr. Donovan, I'm going to testify that Meezan, don't know where
7 it says n-dodecyl- β -D-maltoside. And I can read it, I could do a
8 word search, I can figure that out. It's hiding in plain sight.

9 JUDGE OBERMANN: I understand what you're saying,
10 but you're just giving us reasons why the reply evidence is not
11 persuasive. But you no longer have an argument that it was
12 improperly raised because the issue was not joined in the petition.

13 DR. BEST: Your Honor, respectfully I disagree. But if
14 that's the final --

15 JUDGE OBERMANN: No, I'd like to know.
16 Sometimes I sound forceful, it doesn't mean that I've agreed with
17 any party. But I would like you to address the question of whether
18 that reply evidence is proper now, because they did raise it in that
19 footnote in the -- cited in the petition.

20 Because I think there was a good argument until they
21 raised that footnote that this was an element of the petition, this
22 was an element of their case in chief. They needed to address the
23 identity between -- their view that there's an identity between those
24 two moieties. They did address it in that footnote. So doesn't that
25 open the door to you contesting it in your response and this being

1 proper reply evidence?

2 DR. BEST: Well, so first off, I think the answer is no
3 because it -- first off, it's not even in all of the petitions --

4 JUDGE OBERMANN: Right.

5 DR. BEST: It's only the '786.

6 JUDGE OBERMANN: That's a problem. I agree.

7 DR. BEST: That's a problem. Number two, I mean, I
8 don't know how else to put it, it's not true. And we can see that it's
9 not true. And I'll put up Meezan to show that --

10 JUDGE OBERMANN: I understand. I understand that
11 you are contesting that point.

12 DR. BEST: Sure.

13 JUDGE OBERMANN: I'm really getting at whether you
14 have the additional argument that all that reply evidence is
15 improper because it should have been raised in the petition instead.

16 DR. BEST: So as I understand it, the thrust of that
17 footnote is that the n is unnecessary. That's what I understand the
18 thrust of that footnote to be. That is not what I understand the
19 thrust of the vast majority of the new evidence to be. So if we put
20 up our Slide 93, please. Mr. Landmon referred to the context in
21 Meezan of DDM.

22 What is the context in Meezan of DDM? It's that it's
23 highly branched. What has essentially all of this new evidence
24 been about? We get to look at a supposed amendment that's not a
25 piece of this document saying that it's no longer highly branched,

1 even though that's what the words say.

2 We get to look at this inventor declaration from 10 years
3 later from after the time that the spec was filed and say, oh,
4 actually it's not highly branched. That is not proper response to the
5 position. Actually, Meezan says it's highly branched. If Your
6 Honor has further questions on that, I'll do them, but otherwise I'll
7 move on.

8 JUDGE OBERMANN: Okay. Thank you.

9 DR. BEST: Bear with me a moment. Can we go to Slide
10 96, please? One further point that my colleague reminds me. It's
11 improper that evidence be provided to support without new
12 exhibits. It's improper to bring new exhibits at a later point in
13 time. And I think even whether or not the Court agrees that it's
14 appropriate to say, oh, I now have this footnote, I get to bring it in.
15 You don't get to bring in new exhibits. I don't think that's
16 appropriate.

17 JUDGE OBERMANN: It's not a new theory of
18 invalidity, it's the same theory of invalidity. And you've
19 questioned the sufficiency of that footnote in your reply. So why
20 isn't all of this new evidence proper to respond to that?

21 DR. BEST: Because I think the thrust of the regulation
22 says you don't get to bring in new evidence. And to say that it's
23 not a new theory of invalidity --

24 JUDGE OBERMANN: How do you distinguish that?
25 You're telling me that under no circumstances in a reply, can a

1 Petitioner bring in new evidence?

2 DR. BEST: Absolutely not, Your Honor. That's not my
3 position.

4 JUDGE OBERMANN: What is your position?

5 DR. BEST: My position is that you cannot bring in new
6 evidence that goes to an issue as to which, again, setting aside the
7 fact this isn't in the '414 proceeding, new evidence that goes to an
8 issue that was not actually argued, was not actually explained, was
9 not actually given any support in, for example, a textbook, or in,
10 for example, the IUPAC nomenclature, or in, for example,
11 anything else that was readily apparent, that was in plain view to
12 use my criminal procedure colleagues' views. Anything else or I'll
13 --

14 JUDGE OBERMANN: I don't think so. Thanks.

15 DR. BEST: So if we could go to our Slide 41. I think
16 Mr. Landmon suggested that -- 41. Never mind. Never mind.
17 There's Slide 41, actually. Mr. Landmon suggested that by -- that
18 there's no indication in the specification of our patents of the n-
19 dodecyl, and therefore it's not something that we understood.

20 This obviously ignores the fact of the SIGMA Catalog,
21 which says n-dodecyl- β -D-maltoside. And I understand they have
22 a view that we don't get to rely on that. And I understand they
23 have a view, it doesn't direct one to the exact claimed embodiment.
24 But it certainly says it, and we certainly thought that it said it.

25 And that's why we told the examiner during the

1 Prosecution of the '786 and '414 Patents, that this supports, this
2 being the SIGMA Catalog, supports the limitation of the claims.
3 So the notion that there was some sort of admission otherwise is
4 not correct.

5 Mr. Jones suggested-- and could we see our Slide 135?
6 Mr. Jones suggested that we can test whether dodecyl maltoside is
7 one of the preferred maltosides. He suggested that we agree it's
8 one of the preferred maltosides. And we agree. Let there be no
9 mistake.

10 If you look at paragraph 58 of Meezan, Slide 135,
11 absolutely it's the case that dodecyl maltoside is one of the
12 elements that's described in that specification passage, along with a
13 legion of others. They are a legion because they're many.

14 I note also that there was no response during rebuttal to
15 the notion that paragraph 157 of Meezan, on which we spent some
16 time during my previous discussion, there's no suggestion that that
17 actually was presented in the petition or in Dr. Donovan's original
18 declaration. So it seems that that -- seems my belief was true.

19 There is, by the way, some indication in Meezan what a
20 person of ordinary skill might have selected. And the answer is
21 tetradecyl maltoside. And why is that the answer? Well, every
22 example in Meezan examines tetradecyl maltoside. Tetradecyl
23 maltoside is shown to be the most effective of the particular
24 compounds that were tested. Tetradecyl maltoside was the only
25 compound that made it into Meezan's claims in this application.

1 Now, I'm not saying that's a teaching away from
2 anything, but I am saying it's a teaching toward tetradecyl
3 maltoside. And if there's anything that a person of ordinary skill
4 would take from Meezan, other than what do I do, because there's
5 so much disclosed here, it would be to add tetradecyl maltoside.
6 And there's no dispute that that is not the compound of any of our
7 claims in any of the challenge patents in these proceedings.

8 JUDGE MAJORS: Dr. Best if I could --

9 DR. BEST: Sure.

10 JUDGE MAJORS: -- ask a clarifying question on that.

11 DR. BEST: Yes.

12 JUDGE MAJORS: Because I want to make sure I
13 understand the position. So I'm looking at paragraph 157 of
14 Meezan. It says, and I'll let you get to it if you'd like. But they're
15 talking about doing the studies, and they give as an example, they
16 say dodecyl- β -D-maltoside --

17 DR. BEST: Yes.

18 JUDGE MAJORS: -- and they list some others. They
19 are more effective. I think is what you're getting at the three,
20 right? So fine, let's say we accept the position that if a skilled
21 person was going to select one of these, they'd select the TDM.
22 Let's even say it's the best. How do we get around the law that
23 says obviousness doesn't have to be the best solution, and in fact
24 can even be an inferior solution provided there's enough reason for
25 the skilled person to have done it?

1 DR. BEST: I think it's that last clause of your question
2 that's the real key, Your Honor. There has to be reason for a
3 person of ordinary skill to have done it. And there's no reason
4 that's been expressed in any of the now multiple declarations that
5 Dr. Donovan has applied in the petition where it needed to appear
6 in the Petitioner's reply.

7 Nowhere where there's a suggestion that NDDM or
8 dodecyl maltoside is the selection to make amongst the options
9 available in Meezan. And this is why I keep going back to the
10 Virtek Vision case because I think it's just so clear that it is
11 necessary to establish a motivation to combine, to provide some
12 reason, any reason that is legally recognizable to select one versus
13 the other.

14 And remember, in Virtek Vision there were only two
15 options. In the GCE control case, there were only two options.
16 You could put the spring at one end of a cartridge or at the other
17 end of a cartridge. But there was no reason given to select the one
18 option that was in the claims. So too here.

19 If there are any questions, I will attempt to address them.
20 Otherwise, I will thank you all for your time and patience dealing
21 with -- and definitely the court reporter's patience dealing with
22 some very complicated work.

23 JUDGE MAJORS: No further questions from me.

24 DR. BEST: Thank you.

25 JUDGE REIMERS: Nothing further. Thank you.

1 DR. BEST: Thank you.

2 JUDGE MAJORS: All right. I'll go ahead and wrap up
3 then. What I would like is for, Counsel, if you could hang behind
4 for just a couple minutes, if our court reporter has any questions
5 about spellings or words that she may have missed. That would be
6 much appreciated. And with that, we are adjourned.

7 MR. LANDMON: Thank you, Your Honor.

8 (Whereupon, the above-entitled matter went off the
9 record at 12:33 p.m.)