

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIO-RAD LABORATORIES, INC.,
Petitioner,

v.

CALIFORNIA INSTITUTE OF TECHNOLOGY,
Patent Owner.

IPR2024-01451
Patent 11,827,921 B2

Record of Oral Hearing
Held: January 6, 2026

Before GRACE KARAFFA OBERMANN, TAWEN CHANG, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

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The above-entitled matter came on for hearing on Tuesday, January 6, 2026, commencing at 1:01 p.m., via video teleconference.

P R O C E E D I N G S

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COURT REPORTER: We are now going on record with IPR number 2024-01451.

JUDGE OBERMANN: Thank you.

COURT REPORTER: Now, the Judges' names -- you're welcome.

JUDGE OBERMANN: Thank you so much. Okay. Welcome to the PTAB. As we heard, this is the final hearing in IPR2024-01451. It involves all claims of U.S. Patent Number 11,827,921 B2. We'll start with an introduction of the panel. I am Judge Obermann. I'm here in Alexandria. And with me on the panel today are Judge Hardman appearing remotely and Judge Chang in the California courtroom with counsel.

I've looked over the record and I see no confidential documents or materials in the record. Nevertheless, I want to remind the parties that the hearing is open to the public. We have a public line open for this hearing, so we may have visitors on that line who we cannot see or hear. So I will ask you to please refrain from revealing confidential information during the hearing.

So let's start with introduction of counsel. Who do we have for Petitioner today?

MR. WALTER: Your Honors, this is Derek Walter of Jones Day. And I'm here with my colleagues in Jones Day, Bryan Brennan and Edward Reines.

JUDGE OBERMANN: Thank you. And Mr. Walter, will you be presenting all of the argument on behalf of Petitioner today?

1 MR. WALTER: I will be presenting all of the argument, yes.

2 JUDGE OBERMANN: Thank you. I'm going to ask everyone to
3 speak clearly into the microphone because I was having some difficulty
4 hearing Mr. Walter there for a moment. And who do we have for Patent
5 Owner?

6 MR. SALEN: Good morning, Your Honor. This is Jesse Salen
7 from Sheppard Mullin on behalf of the Patent Owner, California Institute of
8 Technology. And with me is my colleague from Sheppard Mullin, Jaime
9 Choi. And also in the room is general counsel from Caltech, Darren
10 Franklin.

11 JUDGE OBERMANN: Thank you. And I want to make sure I
12 have the pronunciation correct, is that Mr. Salen?

13 MR. SALEN: Yes, Your Honor.

14 JUDGE OBERMANN: Thank you. And Mr. Salen, will you be
15 presenting all of the argument for Patent Owner today?

16 MR. SALEN: I will.

17 JUDGE OBERMANN: Thank you so much. We do have one
18 preliminary matter, Petitioner's objections to demonstratives, limited to
19 Patent Owner's demonstratives 37 through 39. This involves Patent Owner's
20 citation in its sur-reply claim construction brief. Some information that was
21 provided that PO -- Petitioner argues would not have had adequate notice or
22 chance to respond to, that new evidence is in the form of materials that were
23 from a closed and unrelated IPR.

24 Mr. Salen, since you're Patent Owner's lead counsel, I'm going to
25 direct a couple of questions towards you. Did Patent Owner cite this
26 material for the first time in its claim construction sur-reply?

1 MR. SALEN: Yes, Your Honor.

2 JUDGE OBERMANN: And what's your basis for including that
3 material where our rules prohibit it?

4 MR. SALEN: It was responsive to arguments made in the
5 Petitioner's reply brief.

6 JUDGE OBERMANN: It may be responsive, but how do you get
7 around rule 42.23(b), which says a sur-reply may only -- may not be
8 accompanied by new evidence other than deposition transcripts of the cross-
9 examination of any reply witness?

10 MR. SALEN: Your Honor, we believe that what we cited wasn't
11 evidence but was authority from -- it was briefing on the docket from
12 another IPR or -- and it's used specifically to show positions were taken
13 from Bio-Rad that were contrary to the positions they took in the reply brief,
14 which is Paper 30. And so we cited in Paper 33 and -- so regarding the issue
15 -- and I guess to the extent that we're going to strike or exclude those slides
16 or demonstratives. Then we would also ask that the arguments made in
17 Paper 30 in the Petitioner's reply also be discredited or stricken because they
18 were outside the scope of claim construction.

19 JUDGE OBERMANN: I don't think you filed the paper. You've
20 waived that, haven't you?

21 MR. SALEN: Okay. That's fair, Your Honor.

22 JUDGE OBERMANN: Okay. So are you agreeing that the
23 material was improperly included in Paper 33?

24 MR. SALEN: Our position is that it was responsive and not
25 evidence but authority from another -- from the docket on the record
26 showing contradictory statements from Bio-Rad.

1 JUDGE OBERMANN: Do you plan to refer to demonstratives 37
2 through 39 during the hearing?

3 MR. SALEN: I'll take the Court's direction, Your Honor.

4 JUDGE OBERMANN: Okay. Let me hear from Petitioner.
5 What's your position on Patent Owner's assertion that this is not evidence but
6 merely authority?

7 MR. WALTER: I don't think it's authority. I think what they're
8 relying upon is statements that Bio-Rad had made in a closed IPR from five
9 years ago. It's an unrelated IPR, so it's not authority, it's evidence. They're
10 trying to say, here's Bio-Rad, who said something previously. I don't think
11 this is responsive. I think this was something they discovered late, and they
12 decided to lob it into a sur-reply claim construction brief when we have no
13 chance to respond.

14 And then they try to, you know, make it a -- they tried to devote
15 three slides to it in their final IPR hearing. And what's notable is they're not
16 even citing it for claim construction. They're citing it for the merit. So I
17 think it's just late argument. And it's evidence, it's not authority. And if it
18 comes in, then I've got more I want to say about *Dropworks*. And I don't
19 know if we want to spend our time arguing about *Dropworks* today.

20 JUDGE OBERMANN: Okay. Thank you so much. Do you have
21 anything to add, Mr. Salen?

22 JUDGE CHANG: Actually, can you -- I'm sorry, can we pause for
23 one minute? I think Judge Hardman is having some issues connecting, so --

24 JUDGE OBERMANN: Sure. Please let us know when you're
25 ready.

26 UNKNOWN SPEAKER: Well, I'm going to give her a different

1 connection, something that's more stable. Stand by, please.

2 Ms. Hardman, could you speak, please so that you pop up on
3 screen?

4 JUDGE HARDMAN: Yes. I am reconnected, I apologize.

5 JUDGE OBERMANN: Very good. Okay. We were at a point
6 where I was asking Mr. Salen to please respond to the argument that this
7 allegedly new material cited in the reply and in Patent Owner's
8 demonstratives 37 through 39, whether that is actually evidence or authority.

9 MR. SALEN: Yes, Your Honor. I reiterate the position that this is
10 on a docket based on public statements that were made to this Board and
11 panel that are contradictory to statements that are being made now. So we
12 think it's authority. We think that the *Dropworks* case -- I think the
13 statement was made that it was unrelated or an unrelated IPR.

14 It's true that they're different proceedings, but the specification of
15 that patent is the same exact specification as that issue in this case is prior
16 art, the Larson reference in the *Dropworks* case, the continuation of that
17 patent, the '310 Patent was at issue. So we think that is directly related. And
18 statements that were made in that proceeding to this panel by an attorney
19 should be credited and to the extent that they're contradictory from
20 statements made here today as authority.

21 JUDGE OBERMANN: Okay. Thank you very much. I think I
22 understand the positions. I will say up front that my inclination is that that is
23 new evidence, that it's not a deposition transcript of cross-examination, and
24 it appears on this record that it may have been improperly introduced in the
25 reply stage. With that said, I'm not going to prohibit Patent Owner's counsel
26 from referring to demonstratives 37 through 39. But please do it with the

1 understanding that at the end of the day, if the Board needs to rely on that
2 material, we may actually decide that it was improperly introduced.

3 So we are going to defer actually ruling on that. So you may use
4 the slides, but we take Patent Owner's observations about that material under
5 advisement.

6 So with that, are there any other preliminary matters that we need
7 to discuss before we begin arguments? I'll start with Petitioner's counsel.

8 MR. WALTER: Not from Petitioner.

9 JUDGE OBERMANN: Okay. How about Patent Owner's
10 counsel?

11 MR. SALEN: No. Not from Patent Owner's counsel.

12 JUDGE OBERMANN: Okay. I will let you know that I can't hear
13 you unless you turn on your microphones.

14 MR. SALEN: Sorry, Your Honor. Not from Patent Owner.

15 JUDGE OBERMANN: Thank you so much. Okay. So I am
16 looking at our hearing order, and I believe that we have given both sides 60
17 minutes of total time. And we're also providing both Petitioner and Patent
18 Owner with an opportunity to reserve some of that time for rebuttal or
19 surrebuttal. So starting with Petitioner, Mr. Walter, would you like to
20 reserve any of your 60 minutes for rebuttal?

21 MR. WALTER: Yes, Your Honor. I'd like to reserve 20 minutes.

22 JUDGE OBERMANN: Okay. Thank you so much. I am going to
23 put 40 minutes on my clock. And I believe that Judge Chang, in the
24 courtroom with you, is probably going to do the same. And I will start your
25 time beginning -- I'll begin your time when you start speaking, Mr. Walter.

26 MR. WALTER: All right. Thank you, Your Honor. The point

1 where I'd like to start is the question of claim construction of the single
2 sample volume where you have the supplemental briefing. I'm showing
3 Slide 3; here was the dispute between the parties. The dispute between the
4 parties was whether the term single sample volume does or does not include
5 a volume that is subsequently partitioned into droplets.

6 Now, I don't want to get into the background here because I don't
7 think it's a good use of time. I think this issue has been resolved. You can
8 see that when you get to Slide 11. During the supplemental response in the
9 claim construction phase, they said Patent Owner agrees with Petitioner.
10 The term single sample volume by itself can include volumes that are
11 subsequently partitioned into droplets.

12 Accordingly, there is no need for the Board to construe this term.
13 So that issue, I think that's been resolved. And I think it's been resolved so
14 that the construction we originally posed, plain and ordinary meaning, it
15 encompasses something that is partitioned and is something that is not
16 partitioned and --

17 JUDGE CHANG: Actually, Mr. Walter, let me just interrupt you
18 and ask you, I think this raises another question, which is that the claim also
19 requires that the amplification occurs in the same single sample volume
20 where the analytes are detected. So how do you -- in that case -- I
21 understand that the claim construction issue with respect to single sample
22 volume might include both. But how do you address that other issue that
23 also relates to this construction?

24 MR. WALTER: Okay. So I'll go right to that question. This is
25 one of the few responses they have with respect to Ground 1. Here's their
26 Slide 23 that I'm showing. They state, analytes are amplified in the same

1 single sample volume where detected, and they highlight down in orange. I
2 think this is the argument you're referring to.

3 And the theory is and always has been that you do amplify the
4 droplets in the same single sample volume where they're detected. And you
5 can see that in paragraph 79 of Larson. So you have your sample volume,
6 you partition into droplets, and then the droplets are collected. The droplets
7 as a whole are collected, they're put into a tube, a PCR thermal cycling tube,
8 and they're amplified.

9 So that single sample volume is the collection of droplets, this is
10 the original sample volume that's been partitioned into droplets. All the
11 droplets are collected, they're put in the tube. And they're amplified en
12 masse. You also see that in paragraph 193 of Larson. Approximately, 25
13 microliters of the PCR reaction mixture was collected as an emulsion in the
14 droplet generation chip and thermally cycling a DNA engine.

15 So they are -- all the droplets are collected, their sample are
16 collected together, and they're amplified en masse. We see that also on Slide
17 35, paragraph 34, of Dr. Batt's declaration. He explains exactly what
18 happens here. So they're all collected, they're amplified together in a tube.
19 And so you do detect the droplets in the same sample volume.

20 JUDGE CHANG: So to follow up on that, you agree that it's still
21 in compartmentalized form, correct? So how is that a single sample
22 volume?

23 MR. WALTER: Well, it's just like what they said in their original
24 infringement contentions in this case. You have your single sample volume,
25 you do something to the sample volume, you compartmentalize it, you split
26 it up into droplets. And then that single sample volume is put into the tube

1 and it's amplified as collected. There's no dispute. That's within the scope
2 of the claims now. That's agreed upon.

3 You'll see that on Slide 11. It's agreed. It can include volumes that
4 are subsequently partitioned into droplets. That's agreed. It's not disputed
5 anymore.

6 JUDGE OBERMANN: Well, listen, I don't care if you both agree
7 to a wrong claim construction. I'm not saying it's wrong. But we have a
8 duty to hit the right claim construction. And we have to approach that from
9 the words of the claim. And where are you finding this construction in the
10 words of the claim?

11 MR. WALTER: Well, I would flip it on the head. I would say if
12 you're going to take the construction that it does not include volumes that are
13 subsequently partitioned into droplets, you have to find some sort of
14 disclaimer or disavow or definition. And what you do see in the claim
15 language is you see nothing in the claim language that limits single sample
16 volume to something that's an individual droplet that's not partitioned. So
17 there's nothing in the claim language that would narrow it that way. That's
18 your first piece of evidence.

19 The second piece of evidence is you look at the specification.
20 There's nothing that limits it in the specification. It tells you that the single
21 sample volume can be a tube or a bottle. And then what's a key point here is
22 if you look at the specification, it tells you, you can use separation, but you
23 don't have to. Both embodiments are disclosed. So you can use this
24 compartmentalization if you want, but you don't have to. Our expert
25 described this in his brief.

26 This is Slide 15 I'm showing. He explained here that you don't

1 have to separate it. It has both the separation and the non-separated
2 embodiments. Both are in the scope of the claims. And this was unrebutted.
3 So not only is it agreed, but the intrinsic evidence in the form of the claim
4 language and the specification and the extrinsic evidence, none of which has
5 ever been rebutted, all fully supports our claim construction.

6 And now, if you start looking at the prior art, does it disclose
7 what's claimed? Yes, it does. It's disclosed in paragraph 79 and paragraph
8 193. It's exactly what they originally accused of infringing. Here's what I'm
9 showing. If you take a look at Slide 30, you know what it explains here is
10 you have this original sample volume.

11 A single PCR sample is partitioned to 20,000 droplets. It's that
12 original PCR sample that they pointed to. That's what they said infringed.
13 That's what the spec claims encompass. That's what the specification says
14 they encompass. And that's what the expert witness testimony --

15 JUDGE OBERMANN: Let me approach it a different way
16 because you keep going back to extrinsic evidence and I understand that
17 may be your strongest evidence. But I'm not convinced that the extrinsic
18 evidence can overcome some of the words that are in this claim. I see a
19 single sample volume that is singular and I see a plurality of M analytes in a
20 single sample volume. Explain to me how that covers a plurality of analytes
21 that are in a plurality of partitioned volumes.

22 MR. WALTER: Yes. So you can see it right here. If you look at
23 Slide 30, you can see the circle -- you can see the small circle. It's the
24 original sample volume. That original sample volume is now
25 compartmentalized. It's compartmentalized into droplets. And then if you
26 look, you can see here that there are multiple target analytes across the

1 multiple droplets. It's very clear.

2 JUDGE CHANG: So one other question for you. I understand
3 you did argue this in the petition at 30. I am wondering if you have pointed
4 to this idea that you've collected the droplets and then you amplified it that
5 way because it does seem that you've cited to reply but not in the petition.
6 Was this argument specifically about droplets being collected, amplified en
7 masse --

8 MR. WALTER: Well, it --

9 JUDGE CHANG: -- in the petition?

10 MR. WALTER: We think this always was because what we
11 always said from the get-go, in the IPR petition was that the sample volume
12 is subsequently partitioned in droplets. So we were kind of surprised to see
13 any rebuttal on this. And so we did point out in reply, yes, of course,
14 everybody knows that what you do is you collect the droplets into a tube and
15 you amplify it in the tube.

16 So we pointed this out in reply. There's never been any suggestion
17 that this is untimely or improper argument. They haven't moved to strike,
18 not this -- they had a chance to respond to it. They had a sur-reply, there's
19 been no response. Our expert opined on this. They didn't cross-examine
20 him on it. So it's unrebutted at this point. And it's right. It's not incorrect.
21 It's not just agreed but it's correct based on what's in the intrinsic evidence.
22 And it's logical.

23 JUDGE CHANG: Okay. Thank you.

24 MR. WALTER: So, you know, I think with that claim
25 construction issue -- I mean, I think the clearest point here is they did at one
26 point, they tried very hard to back away from this. You can see in their

1 Patent Owner's response. They tried to change this interpretation in the
2 District Court to exclude this. And they weren't allowed to do that. They
3 backed away.

4 And they backed away because I think they understand that their
5 original interpretation is the right one. So I think that that's really the only
6 issue there is on Ground 1. I think, you know, Ground 1 is based on this. I
7 think it should be resolved in our favor.

8 I'd like to move now to the obviousness argument, which is
9 Ground 3. I'm going to flip ahead to my slides now. I'm going to start with
10 obviousness based on Larson alone. I need to point out one preliminary
11 thing on this. I'm going through their slides just to avoid some confusion
12 later on. I noticed that they mislabeled some of the grounds.

13 Ground 3, it includes obviousness based on Larson alone and it
14 also includes obviousness based on Larson and Saxonov. I just want to note
15 that their slides mislabel one of those grounds. And so I want to just point
16 that out so there's no confusion later on.

17 Now, this ground differs from Ground 1 because it is based on
18 taking the individual droplet as a single sample volume. It's like Ground 1
19 because a lot of the key points here are not disputed. And I want to start out
20 by looking at the claim language because for obviousness, we've got to talk
21 about the point of novelty is and what this claim is about.

22 The claims require that you have M analytes and F wavelengths.
23 And the wavelengths are the different colors. And the targets -- the number
24 of targets would be greater than the number of colors, which says that M is
25 greater than F. And what's important here is that this point of having more
26 targets than you have colors is what they've characterized as the point of

1 novelty.

2 You can see that in the Patent Owner's response where they talked
3 about how the inventors developed a technique where they can use fewer
4 fluorophores than the number of analyte molecules. And that's what they
5 pointed to as the advance over the prior art.

6 Now, with that in mind, we have to look at what the undisputed
7 competencies are of the skilled artisan. And that's shown here on Slide 44.
8 This is a portion of the expert declaration from our expert, Dr. Batt. Let's go
9 through these as we're -- the first point is that multiplex PCR, that's PCR of
10 multiple targets at the same time. That was standard competency of the
11 skilled artisan.

12 The next one, probes for multiplex PCR, that was also a standard
13 competency of the skilled artisan. The next one, measurement of analytes,
14 multiplex applications, also a skilled -- a competency of the skilled artisan.
15 And this next one is the big one, techniques for labeling probes and
16 detecting multiple targets using fewer differently colored fluorophores in the
17 number of polynucleotide targets. That's an undisputed competency of the
18 skilled artisan. But that's what they've characterized as the point of novelty,
19 okay?

20 And you can see here, Dr. Struhl, he's their expert, he confirms a
21 lot of this. I'm have a lot more to say about Dr. Struhl as we get into this.
22 But, you know, he agreed with our definition of the level of ordinary skill in
23 the art and different competencies. He says we were doing it. When was he
24 doing it?

25 He says he was doing it in 2002 or 2003. This is 10 years before
26 priority date. We asked him about the competencies -- well, actually, this is

1 -- Mr. Salen asked Dr. Struhl about the competencies. You have those four
2 bullets, would you have understood those concepts as of February 3rd,
3 2012? Yeah.

4 JUDGE CHANG: So let me -- hold on for a second. So as I
5 understood it, the claim was actually talking about unambiguously
6 identifying based on fewer fluorophores. So I understand detecting and
7 labeling are part of this. But I think they did add -- the claim does have the
8 term unambiguously. I think that was not part of the core competencies that
9 you introduced in your slides; is that correct?

10 MR. WALTER: Well, a few points on that, you know. First off, if
11 you're talking about multiplex detection, you got to be able to tell what's
12 actually there. So I think unambiguously is part of that. But the reason this
13 really matters is because when you look at how they've tried to distinguish
14 the prior art and try to say how their invention is different. They haven't
15 really focused on an unambiguous point.

16 And they focused on the idea of multiple targets in a single volume
17 of a single droplet. They focused on that point as the thing that's missing in
18 Larson. So it's not really the unambiguous, so that's why I'm focusing on
19 this, okay? So yeah, that's my response on that.

20 I think the other point here, here's Dr. Struhl again. Multiplex
21 PCR, this is multiple PCR that targets in the same volume, so it's not
22 magical. Okay. You know, you start looking at how do you actually
23 determine -- let me try to address your point a little more directly. How do
24 you determine unambiguously what targets are there?

25 Well, you assign different signals, different targets. And you do
26 that using different intensities, using multiple colors, or using fluorophores

1 to modulate the intensity. It says Larson and Saxonov for the patent all do
2 that. Saxonov and Larson reference, they do that at some level. So this stuff
3 was known. And the main reason I want to bring this up -- we're doing
4 obviousness now.

5 And when the level of ordinary skilled in the art is this high,
6 people know this much, it's really hard to see how they can contend these
7 patent claims are not obvious. And when you look at their responses to our
8 obviousness argument, you see that. Their main argument, which I'm
9 showing on Slide 50 -- and this is their overarching response -- is that
10 Larson doesn't teach multiple targets in a single droplet.

11 They say Larson teaches eliminating multiple targets in a single
12 droplet. Now, I want to be clear. Larson does talk about embodiments
13 where you have predominantly a single target in a droplet. It does have that;
14 it's there. But the other embodiments are there as well. And to suggest that
15 Larson eliminates those or doesn't contemplate using those embodiments, I
16 think, is just wrong. The evidence is overwhelming.

17 Here, I'm showing on Slide 51, paragraph 6 of Larson talks about
18 something called limiting dilution. Some reactions contain zero DNA
19 molecules, some reactions contain one, and frequently, some other reactions
20 contain multiple molecules.

21 Here's Slide 52. Some droplets may or may not contain multiple
22 nucleic acid molecules corresponding to limiting dilution. The invention is
23 compatible with all distributions of DNA loading that conform to limiting or
24 terminal dilution.

25 JUDGE CHANG: So background question, is Petitioner's position
26 that an analyte is a separate DNA molecule, or are you also taking a position

1 that an analyte could be multiple targets on a single DNA molecule?

2 MR. WALTER: I think -- we're actually focused on multiple DNA
3 molecules, you know. They have made a lot of arguments about how we're
4 trying to rely upon, actually, you know, multiple sequences on the same
5 DNA molecule. I don't think that's fair or accurate.

6 I think the way to think about it is what we've always thought
7 about for the purposes of this position is to analyze multiple DNA
8 molecules. And that's why we're talking about multiple molecules here,
9 okay, nucleic acid molecules. That's why I'm focusing on that.

10 It says methods of the invention can accommodate complications
11 arising from multiple occupancy. That's not two sequences in the same
12 molecule, that's multiple molecules.

13 Here's Slide 54, paragraphs 108, paragraphs 113, detection of
14 multiple target sequences in a single droplet. The number of droplets, each
15 having one or more sequences, TERT, RNaseP, E1a, SMN1 and SMN2, can
16 be determined from the scattered points. We are talking multiple molecules
17 in the same. Paragraph 129, 1 in 10 PCR+ droplets would be drop doubles.

18 It doesn't say eliminate them, it says you can recover the
19 contributions from each of the probes. And then it tells you if you want to
20 do higher degrees of multiplexing to change the dilution.

21 JUDGE OBERMANN: Where did you identify these
22 embodiments in the petition?

23 MR. WALTER: Well, so all of these -- you can see the cites on
24 the left, petition at 52, these two we pointed out in reply, petition at 55,
25 petition at 55, petition at 37. The petition was pretty clear that we thought
26 Larson disclosed multiple targets in a single molecule. So the cites are all

1 there. The one thing that's new, okay, and the one thing that they really
2 complain about -- and this is what they moved to strike -- is it turns out that
3 Larson, it doesn't just give all those other examples.

4 I discussed it actually, has a working example with real data where
5 you detected multiple targets in the same droplet? Here, you can see it on
6 Slides 58 and 59. Three populations are readily apparent. There's a very
7 small peak, it's not visible on the scale, but it tells you it's there. That
8 corresponded to droplets occupied by both genes. It's in the patent; it's there.

9 JUDGE CHANG: Yes. Now, I have a question about that,
10 because I think that goes to one of their claim construction arguments. So
11 two questions, one is, does this disclose, I think, two analytes? And if I'm
12 understanding correctly, these are plasmids, so they are separate DNA
13 molecules. But do you -- what's your position on whether the frequency has
14 to be more than one, so at least two, which means that the number of
15 analytes has to be at least three? How do you address that?

16 MR. WALTER: Well, you know, if you want to get to the claim
17 construction on F, right, the -- there's a dispute here. They say that the
18 number of targets has to be three or greater -- or I think it's two or greater.
19 You see, it's just -- I have to go back and double check to see what the actual
20 --

21 JUDGE CHANG: Three or greater, I believe, analytes.

22 MR. WALTER: Yes. You know, we have a dispute on that point.
23 Actually, you know what, I want to answer your question, but I don't want to
24 spend too much time on this. Now, the point I want to make here is that
25 Larson does contemplate more than one target per drop. I want to put that to
26 rest. They're right, you know, that our theory was based on the idea of

1 looking at three targets using two colors.

2 So I want to stick to that, okay? But what I'm trying to rebut is the
3 idea that Larson is focused solely on one target per drop. It's not.

4 JUDGE CHANG: But you would agree that if their -- if we adopt
5 their claim construction on F and M, then Figure 11 does not explicitly
6 disclose what's in the claim; is that correct?

7 MR. WALTER: Yeah. I would agree that it might render it
8 obvious, it wouldn't anticipate the claim. And our theory wasn't based on
9 Figure 11. Although it is noteworthy, you know. I asked our expert about
10 Figure 11 -- I'm showing Slide 60. I just asked him, I said, what's not in the
11 claims? You know, he couldn't tell me.

12 And his response to Figure 11 was to say, well, maybe it's wrong
13 and, hey, didn't make it up. They're continuing to push that. You can see
14 that in their Slide 42. They say maybe it's fake because it's not visible. It is
15 there.

16 JUDGE OBERMANN: Excuse me, Counsel. It's Judge
17 Obermann. I'm having a bit of a problem with that because I did read very
18 carefully your petition, and it seemed in the petition you were relying
19 exclusively on Figure 9. And then I do see a pivot in the reply, and I'm not
20 seeing any discussion of Figure 9 in your reply. I'm seeing everything about
21 Figure 11. Is that accurate or did --

22 MR. WALTER: Yes, it's accurate. And the reason it's accurate is
23 because there was no rebuttal on Figure 9. What we spent our time doing in
24 our reply was trying to rebut the contention that Larson is limited only to a
25 single target of the droplet. So what we did in our reply was we recapped all
26 the evidence that we identified in our petition and we introduced the

1 additional cross-examination on --

2 JUDGE OBERMANN: Where did you introduce Figure 11 in this
3 context in the petition?

4 MR. WALTER: In Figure 11 -- we didn't mention it in the
5 petition. This came in in the reply. And, you know, what I expect I'll do is
6 I'll respond in my 20 minutes of rebuttal on the motion to strike.

7 JUDGE OBERMANN: Well, I'm really having a problem with
8 that because I believe that the Federal Circuit has said that you can't shift
9 disclosures like that. It's really not fair to the Patent Owner because they
10 don't have a chance to come back in the sur-reply and address a different
11 disclosure that wasn't identified in the petition with declaratory -- declaration
12 evidence. So I'm having a really hard time. Have you abandoned in your
13 reply your original argument that Figure 9 forms the basis for the challenge?

14 MR. WALTER: No, absolutely not. Figure 9 is still the basis for
15 our challenge.

16 JUDGE OBERMANN: Okay. Maybe this is it. Let me ask you,
17 is this what you're doing with Figure 11? You're trying to use Figure 11 to
18 show that Figure 9 actually demonstrates that Larson contemplated the use
19 of multiple analytes in a single droplet?

20 MR. WALTER: It's not just Figure 9, it's Larson generally, yes.

21 JUDGE OBERMANN: Well, you say Larson generally, but do we
22 have to look at Figure 11 for an example of multiple analytes in a single
23 droplet, or is that in Figure 9?

24 MR. WALTER: No. I don't think you need to, because what
25 Larson is telling you is that the invention is -- and, you know, there's all the
26 other evidence we cited in our petition, right? Remember, Ground 3 is an

1 obviousness argument saying, look, someone would have found it obvious to
2 use Figure 9 with multiple targets in a single drop.

3 JUDGE OBERMANN: Yeah. But it's still critically important
4 that you direct us to the embodiment in Larson that you're advancing as the
5 basis for the modification. And you directed us in the petition to Figure 9.
6 And now, it feels like you're saying, well, you know, they came back and
7 they showed -- that's not really what we're relying on. We're relying on this
8 other embodiment in Figure 11, and that's good enough. I don't think that
9 you can shift that way in your reply.

10 MR. WALTER: No. I disagree with that very strongly. We're not
11 shifting to Figure 11. We're sticking with Figure 9.

12 JUDGE OBERMANN: Where do you say that in your reply?
13 Where do you mention Figure 9 in the reply?

14 MR. WALTER: Well, I have to go back -- I mean, look, whether
15 we mentioned Figure 9 or not, I'm telling you now, we are not shifting from
16 Figure 9.

17 JUDGE OBERMANN: Mm-hm.

18 MR. WALTER: The reason we brought up Figure 11 -- and if you
19 look at how we relied upon Figure 11, it was for the proposition that Larson
20 does contemplate multiple targets in a single droplet. We think the evidence
21 of that effect is overwhelming. That's what we were relying upon for, not
22 because we're trying to shift to a new invalidity theory. We're not trying to
23 do that. We're relying on --

24 JUDGE OBERMANN: Let me ask you this, does Figure 9
25 demonstrate that?

26 MR. WALTER: We think it does because Figure 9 --

1 JUDGE OBERMANN: Why?

2 MR. WALTER: I'm sorry?

3 JUDGE OBERMANN: Why? In view of everything that the
4 Patent Owner has come forward in their response, where are your multiple
5 analytes in the droplets of -- that are, you know, displayed in Figure 9?

6 MR. WALTER: Well, so look, if you're asking me, does the
7 example in Figure 9 say, okay, here's the examples of multiple droplets?
8 No, I don't think Figure 9 says that. But what our theory is, is that the
9 Larson patent -- if you look at the Larson patent, it's got overwhelming
10 disclosure telling you that you can use the invention with all the different
11 types of droplet loading, including droplet loading mechanisms, where
12 you're going to have multiple targets per droplet.

13 There's overwhelming evidence of that that you see in Slides 51
14 through 60. There's overwhelming evidence of that. And then you get to the
15 actual example, Figure 9 of Larson, and Larson discloses an approach in
16 Figure 9 where you're going to be able to distinguish -- let me go back here
17 in Figure 9. There is no dispute here that Figure 9 of Larson is going to
18 teach an approach where all the different combinations of targets in a droplet
19 are going to be distinguishable from one another. That's unrebutted. There's
20 never been any dispute on that.

21 The responsive argument has been, well, Larson Figure 9, it
22 doesn't actually talk about all the different combinations of targets that are
23 going to be in a droplet. And our position is, it doesn't have to, because the
24 patent overwhelmingly tells you that the patent is consistent.

25 JUDGE OBERMANN: Is your position that Figure 9 is revealing
26 data about a multiple occupancy situation?

1 MR. WALTER: Well, Figure 9 is a theoretical approach and it's
2 not revealing data, it's a theoretical proposed approach. And what it's doing
3 is it's revealing a scenario that's going to work with a multiple occupancy
4 situation because you're going to be able to distinguish the different
5 combinations of targets that are present, whether it's one target of one type, a
6 second target of another type, or different combinations of targets. And
7 that's unrebutted.

8 And Dr. Batt said, hey, look, a person of ordinary skill in the art
9 would recognize that. They would know from Figure 9 that the signals
10 you're going to get from the different combinations of targets are all going to
11 be distinguishable from one another. And they would be motivated to use it
12 with the multiple occupancy situation because Larson tells you --

13 JUDGE OBERMANN: Okay. I would like to just put a little
14 tickler there because you said that's unrebutted. I'd like your friend to take
15 note of that. And during their presentation, I'd like to hear whether that's
16 truly unrebutted. Thank you.

17 MR. WALTER: Okay. To be clear, what I contend is unrebutted
18 is this argument here that I have highlighted in yellow on Slide 34, the
19 signals from P1, P2, P3, P1+P2, P1+P3, they all have different intensities.
20 That's unrebutted. They've never rebutted that point. That's unrebutted.

21 Okay. You know, the main argument that they've made in
22 response to this is to say, well, Larson, it talks about excluding droplets that
23 have multiple targets from the analysis. And that is dead wrong. That is
24 absolutely dead wrong. That's just a flat-out mischaracterization. This is the
25 main response.

26 It's not to rebut what we've said about Figure 9, it's to say, well,

1 Larson excludes droplets with multiple targets. It's like paragraph 172 for
2 that point. And here's what it says, methods of the invention are able to
3 detect which droplets contain a heterogeneous population of molecules and
4 are able to exclude those droplets from the analysis. And that sounds good
5 for them if you stop there.

6 But what you have to recognize -- and I've shown this on Slide 64
7 -- is that this is in a section called polymerase error correction. This is
8 dealing with a scenario where you have a wild type, the target that gets
9 converted to a variant during polymerization. So it looks like you've got two
10 targets in your droplet, but really, what you've got is a polymerase error.

11 And what this patent talks about is how -- if you're in a situation
12 where you face that risk where you might have a polymerase error and bring
13 your wild type to a target, you really got to be sure, it tells you how to
14 distinguish those two situations. So that's what all this is about. All this is
15 about the polymerase error correction.

16 If you see that in paragraph 15, methods of the invention are able
17 to detect polymerase errors and are able to exclude them from the analysis.
18 This isn't saying we're going to exclude every droplet that has two targets
19 because those are bad things. You can't possibly be saying that because the
20 patent tells you that the invention is able to accommodate multiple
21 occupants.

22 JUDGE CHANG: So am I correct -- I think the Patent Owner
23 argued that, well, you can't really distinguish between polymerase errors
24 and, you know, situations where you have two intended targets. And it's
25 your position here basically, as I understand it, that yes, in certain situations,
26 you would basically eliminate everything with two potential targets. It

1 seems like potential targets because in certain situations, you want to be
2 very, very specific.

3 MR. WALTER: Exactly.

4 JUDGE CHANG: But in other embodiments, you would not
5 necessarily do that.

6 MR. WALTER: Exactly.

7 JUDGE CHANG: Okay.

8 MR. WALTER: Exactly. That's exactly what it is. And
9 everything they talked -- every passage that talks about excluding these
10 droplets, it's all about polymerase errors. So when we asked Dr. Struhl
11 about this, he says he has no idea why polymerase error is relevant. He said,
12 I'm not sure why it's relevant to anything.

13 It never even dawned on me why it's relevant, why I didn't opine
14 on it. This is Slide 68. The section in paragraphs 168 to 173, I think I
15 showed you earlier. He cited paragraph 172. He relied upon that. He says,
16 I don't remember opining on that. I mean, anything related to polymerase
17 error, I don't remember -- recall opining upon.

18 As I said, I don't think it's very important, which is why I didn't
19 opine on it. He didn't even know what he was relying upon. And I'm going
20 to say a little bit about Dr. Struhl at the end. So I'll use some of my 20
21 minutes to respond as to what he says on Figure 9. But the obviousness
22 argument, I don't think is unrebutted. It's unrebutted.

23 Figure 9 discloses a scheme where the different combinations of
24 targets would in fact be distinguishable. And Larson tells you that the
25 invention accommodates -- approaches where you're going to have multiple
26 targets per droplet. Based on that, it would have been obvious. And their

1 response has been to say, well, actually, Larson excludes those droplets.
2 That's wrong. That's absolutely wrong. That's been their only response.

3 JUDGE CHANG: So I do think they also make the argument that
4 there's -- so it sounds like you're not saying that there's embodiment in
5 Larson that actually teaches what Claim 1 says, assuming we adopt the
6 single volume -- sample volume construction, that each droplet -- but they
7 -- so they do make an argument that you have not, in your petition, provided
8 sufficient explanation why a person of skill in art will be motivated to sort of
9 combine these Figure 9, Figure 11, let's say, and use different -- sort of
10 different targets -- multiple targets.

11 MR. WALTER: Well, I think they make that argument, but I think
12 that's wrong. If you look at paragraph 337 and 338 of Dr. Batt's declaration,
13 Exhibit 102, he deals with expectation of success and motivation to
14 combine. He tells you how the patent already tells you, you can do multiple
15 targets. A person of ordinary skill in the art motivated to use Figure 9 with
16 multiple targets. I mean, it's unavoidable.

17 When you can't -- when you're doing Poisson loading, you can't
18 avoid it, it's going to be there. So that part isn't -- you know, they say that
19 there's no motivation to combine, but it's there, paragraphs 337 and 338,
20 reasonable expectation of success and motivation to combine.

21 JUDGE HARDMAN: Counsel, it's Judge Hardman. Are those
22 paragraphs 337 and 338 of that -- where can we find those discussed in the
23 petition?

24 MR. WALTER: It would be in the motivation to combine section.
25 I mean, I can get you the citation to where it is, but it is going to be in the
26 motivation to combine for Ground 3. I think if you --

1 JUDGE OBERMANN: Please be ready for --

2 MR. WALTER: I think it's, like, paragraph 331 to 338.

3 JUDGE OBERMANN: Please be ready to do that when you come
4 up for your rebuttal. But let's not waste time on it now.

5 MR. WALTER: Okay. So I want to go on to Ground 3. We also
6 have the Larson review of Saxonov, and I want to move to this quickly. The
7 only issue here -- and there's an important preliminary issue. The problem is
8 they decided not to address this in their Patent Owner's response. They said,
9 hey, look, we won on the issue that wasn't prior art in the institution
10 decision, so we're just going to skip it.

11 The Board made a preliminary determination; that's on Slide 84.
12 The Board cautioned everybody that if you don't put something in your
13 response then they can be waived. They decided not to put it in there.
14 That's the rule. That's Slide 86. If you don't put something in your Patent
15 Owner's response, that's waived. So we think their response on obviousness
16 of Saxonov and Larson has been waived.

17 JUDGE CHANG: Hold on. Even if they have waived the
18 argument, let's say, we -- I mean, the Board decides preliminarily whether
19 Petitioner has met the standard, right? Like, it's not just because they haven't
20 argued that we don't have a - I think, that we don't -- are you arguing that
21 we don't have an obligation then to decide whether or not Saxonov is prior
22 art?

23 MR. WALTER: I actually don't think you do. I don't think you
24 do.

25 JUDGE OBERMANN: Can I ask a question, please? In your
26 reply brief, are you relying on the same parts of Saxon (sic) that the Board

1 resolved in the decision on institution or are you raising different parts of
2 Saxon?

3 MR. WALTER: Same parts.

4 JUDGE OBERMANN: So you're rearguing the same parts.
5 You're not citing anything new in Saxon that was not cited in the petition?

6 MR. WALTER: No, we're not. Not to my knowledge, yeah.

7 JUDGE OBERMANN: So you're fully relying on this idea that
8 they waived the issue because they didn't raise it again in their response?

9 MR. WALTER: Yeah. You know, I think we also explained why
10 -- we actually did explain why Saxonov and the relevant parts of Saxonov
11 are prior art. We actually did explain that as well. You can see that -- you
12 can see the cites here where we explained where this is -- we discussed this
13 in our reply on page 20.

14 JUDGE OBERMANN: Okay.

15 MR. WALTER: So we do explain this --

16 JUDGE OBERMANN: Okay. Which demonstrative number are
17 you referring to, please?

18 MR. WALTER: I'm looking at Slides 90 and Slides 91.

19 JUDGE OBERMANN: Thank you.

20 MR. WALTER: So we cited this in paragraph 20 (PHONETIC).
21 The only issue is whether this figure is here. That's the only issue. And it is
22 -- if you look at the Saxonov patent filing, it tells you that what we're talking
23 about is a situation where you have three targets, so you're going to have
24 eight populations of droplets. And they show a figure here.

25 But if you look at the provisional that's in the provisional, it says
26 you can have three targets, you're going to generate eight clusters or

1 populations of data separated by intensity. When we cited that, that's in the
2 petition.

3 JUDGE OBERMANN: Did you argue this in the reply -- I'm
4 sorry, did you argue this in the reply?

5 MR. WALTER: Yes, we did.

6 JUDGE OBERMANN: At 20.

7 MR. WALTER: Yeah, at 20. We cited at 20 -- and, you know, we
8 also cited this in the prior art section in the petition at page 4. And I think
9 it's also at another page as well. It's in the prior art section. So this was
10 always there, you know. These tables are here. There's been no rebuttal on
11 this point because their position has always been, hey, we won at the
12 institution phase.

13 But that's not how this works. I actually don't think there's an
14 application. I think that's a problem. You can understand our position.
15 What are we supposed to do? We put some argument in reply. But we don't
16 really know what's on the table because they just decided to skip it from the
17 Patent Owner's response. It puts us in a bad spot.

18 All right. Now, I want to finish off with Dr. Struhl and I might eat
19 into my time, but I think this is worthwhile. I'm showing Slide 136. It's an
20 abuse of discretion to rely upon a testimony that has multiple contradictions
21 and that lacks credibility. And that's what we have here.

22 And I bring this up because it was actually hard to cross-examine
23 it. It puts us in a bad spot when we have an expert like this. And some of
24 the stuff he didn't know -- I mean, they cite some things. They say our
25 expert didn't know. Our expert did the same thing. It's nothing like this. He
26 cites the petition frequently in his expert declaration.

1 And, you know, the first thing you try to do is put the petition in
2 front of him during the deposition. And he says, I don't know what this is.
3 Petition for inter partes review, U.S. Patent Number 11,829 -- well, it looks
4 familiar, but I don't see it on my list, so I don't really know how to answer
5 the question. You don't recall what it is you refer to when you cite petition?
6 I don't remember. This is really telling.

7 Did you ever come across your citations to petition and ask
8 yourself, hey, I wonder what that is, maybe I should find out what it is I'm
9 citing. I didn't do that. You don't recall what it was when you were helping
10 to write this that you were citing to when you cited the petition in paragraph
11 17? He said at the time when I'm citing something, I looked, but now I don't
12 remember specifically what it is. That makes it really hard to cross-examine
13 someone.

14 Here's the next thing, priority date, he frequently invokes it. He's
15 got a section on it in his declaration, Slide 110. He invokes it for
16 obviousness. He says you got to look at things that does the priority date.
17 When you try to ask him about this, what's the priority date? I don't know.
18 You know, it's not, look, I need to go back and look at it, I don't remember at
19 off the top of my head.

20 Now, that will be forgivable, it's I don't know. I don't pay attention
21 to priority dates. That wasn't my job. So it's not just I don't remember, it's
22 like it's not relevant.

23 Slide 113. For the purposes of your opinions in this case, was
24 there any particular time point -- you know, any particular historical time
25 point that you use as the baseline time point for when you needed to render
26 your decision as of? Do you understand my question? No. You don't

1 understand what I might be getting at? No.

2 JUDGE OBERMANN: Oh, I think your time is up. Do you want
3 to use your --

4 MR. WALTER: I want to use just a few more to finish off Dr.
5 Struhl --

6 JUDGE OBERMANN: Okay.

7 MR. WALTER: -- and that might leave you with 18 or something
8 like that.

9 JUDGE OBERMANN: Okay.

10 MR. WALTER: He didn't consider historical development. I
11 didn't do a historical perspective at all. I can't give you a year. Why would I
12 care? That's on Slide 114. This is different from our expert, you know. He
13 doesn't even understand why it might be relevant. I didn't do a historical
14 analysis for anything.

15 Slide 115. Yeah. We know why this is relevant because you have
16 to put your mind back to the time of the invention. The *Phillips* standard for
17 claim construction cites the *Phillips* standard in this declaration. That's in
18 Slide 118. Claim construction, okay, it's got a section on claim construction.
19 You know what Phillips is? No, I don't really know completely what it
20 means. I don't know if what the *Phillips* standard is.

21 You know what *Philips* is? When you refer to *Phillips*, I assume
22 it's a person. You don't have opinions on claim construction? No, haven't
23 thought about it. Showed him the claims. Here's Claims 1 and 2, the first
24 step of the claim. Each of said at least 10 analytes is encoded as a value of
25 one component. I must say, I don't really completely understand what this
26 particular sentence means.

1 I'm not sure what they meant by one component. So I'm not sure
2 that -- the way this is written, I'm not sure what they meant. That's Slide
3 124. And he says, at Slide 125, I don't think the patent is really concerned
4 about the number of components, even though the claim says one
5 component. He says Claim 2 over and over. I probably shouldn't even be
6 opined on Claim 2 since I never looked at it.

7 But then he says, I looked at it, but I didn't opine on it. I'm not
8 going to get into the difference between Claim 1 and Claim 2. I haven't
9 analyzed Claim 2. This makes it really hard to do a cross-examination. It's
10 nearly impossible. One of the things you are aware of by now is we cited
11 their infringement contentions quite heavily both in our petition and our
12 expert declaration. Here's the expert declaration on this.

13 Why did you review the infringement contentions for the case? I
14 asked Dr. Struhl. I actually don't know the answer. Maybe just to know
15 that there was an infringement case. I didn't spend any time on
16 infringement, he says. Why did you review the infringement claim chart? I
17 don't remember actually. That's Slide 131.

18 Slide 132. I didn't pay much attention. I didn't review it, he says.
19 This goes on and on and on and on. Slide 133. I didn't spend any time on
20 infringement. We showed him the coding schemes that are all over the
21 petition and all over Dr. Batt's declaration. Do you see there, there's an
22 encoding scheme for the SARS-COV-2 kit? I have not seen -- I have not
23 paid attention to this before. I am not sure I've even seen it. I don't know
24 what this is.

25 This is out of context. It's not out of context. It was all over the
26 petition. It was all over Dr. Batt's declaration. It's kind of amazing that he

1 would say this. So look, we think this is an example where we have expert
2 witness testimony that is not reliable. It was detrimental to us. I think it
3 would be inappropriate for the Board to rely upon his testimony. So I'm
4 going to reserve the rest of my time unless there's further questions.

5 JUDGE OBERMANN: I'm not seeing any questions from the
6 panel. So I'm going to give you 17 minutes on rebuttal. Thank you so
7 much.

8 And Mr. Salen, when you're ready, I will -- well, let me ask you
9 first, would you like to reserve some time for surrebuttal?

10 MR. SALEN: Yes, Your Honor. I'd also like to reserve 20
11 minutes.

12 JUDGE OBERMANN: Okay. If you give me just a second, I just
13 want to make a note of 17 minutes left for Mr. Walter. And let me put 40
14 minutes on your clock. And Mr. Salen, when you're ready, I will begin the
15 clock running.

16 MR. SALEN: Okay. Thank you, Your Honor. So I'd like to
17 address several of the points that my colleague made. And in general, there
18 were several statements made about there not being any rebuttal in our
19 Patent Owner responses, and that's to certain arguments. And I'm going to
20 go through each of those.

21 But to be sure, we disagree on those points. And I'll start with
22 -- what we didn't hear much about at all is what the claim says. I think we
23 need to start with what the claim language is, because a claim requires more
24 than one limitation. And several times you've heard and seen in Bio-Rad's
25 -- in the Petitioner's response is that the certain elements of a claim might be
26 present in one embodiment of Larson. But they need to have all of the

1 elements present or at least rendered obvious. And that's simply not there.

2 So let's start with the claim language of the claim. So what is
3 claim 1? And I'll talk about claim 1 and just point out that there are other
4 claims at issue here. You haven't heard any discussion, and it's not -- you're
5 not going to find it in the petition either that really talks about why Claim 4,
6 for example, is anticipated. And all the focus in this case has been about
7 Claim 1. There aren't arguments that's anything more than conclusory
8 arguments about the other claims in this case.

9 JUDGE OBERMANN: Just to be clear with the arguments, the
10 arguments are pretty much the same for Claim 1 and Claim 14, because both
11 of those claims have these same limitations about the single sample?

12 MR. SALEN: We agree with that, Your Honor.

13 JUDGE OBERMANN: Okay.

14 MR. SALEN: So Claim 1 -- this is just to take a step back. This is
15 what Claim 1 requires. And I think I'm going to move through some of this
16 a little bit quickly because there doesn't seem to be a dispute about some of
17 these points. But start with the preamble and move on to the first wherein
18 clause, wherein each of the said analytes -- or at least wherein each of the
19 said at least M analytes is encoded as a value of one component or a
20 fluorescent -- of a fluorescent signal, thereby generating a coding scheme.

21 So that's the first element. You have to have a coding scheme that
22 codes these M analytes. So where is that in the specification? Just to show
23 you there's an example of this -- there's several examples, but here's one
24 example in Table 3 of the specification. I've highlighted it in yellow. You
25 can see this is an example with eight analytes. And they're labeled A
26 through G here with a control.

1 And the coding scheme that is shown in the coding table in Table
2 3. Then the next wherein clause is important here, wherein said
3 fluorescence signal comprises F wavelength components. Here, the example
4 in Table 3 shows four components. But what is F in the context of this?
5 How many -- because there -- at some point, I heard my colleague say that
6 he agreed -- I believe conceded that for the purpose of this claim the
7 minimum value of F is two.

8 We've seen some arguments after that in the reply that maybe F
9 could be one. And frankly, F can't be one. First of all, let's start with the
10 initial arguments from the petition. It seems to be that the institution
11 decision that the Board made was based on these arguments. And by over
12 that, we argue that --

13 JUDGE OBERMANN: I hate to interrupt because I know that you
14 are just entering the fray here, but did I hear you say that Petitioner has
15 admitted that F must be no less than two?

16 MR. SALEN: I heard that during his argument, Your Honor. But
17 I don't -- we don't have to rely on that. And if he wants to come back and
18 say no, F can be one, that's okay. But the first time we ever heard anything
19 from Bio-Rad from Petitioner about F being one was in their reply.

20 JUDGE OBERMANN: Okay. Thank you.

21 MR. SALEN: Yeah. In the petition, they based the whole
22 argument about what the prior art discloses based on F being two and M
23 being three. And the Board, when they instituted, Your Honor, latched on to
24 that argument. But I think it's real simple here. This is just plain English.

25 The claim term says where -- the second wherein clause we're
26 looking at, wherein set fluorescent signal comprises F wavelength

1 components. That's plural. It's repeated in the next wherein clause as well
2 that there are F wavelength components. And the Federal Circuit has told us
3 that in accordance with common English -- in English usage, you presume
4 that plural terms are for -- refer to two or more.

5 And that's what we have here. It's a plural term. Certainly, if the
6 Patent Owner wanted to make this claim broader, they could have done that
7 during prosecution when they were drafting the patent to specify that, no, F
8 doesn't have to be limited to two or more, it could be one which would make
9 the claim much broader, very broad.

10 If they wanted to do that, they could have been specific here. They
11 could have written the claim to say, where instead, fluorescent signal
12 comprises a wavelength component or one or more wavelength components.
13 They didn't say that. They said F wavelength components is plural.

14 And that's consistent with what the specification shows, Your
15 Honor. There's example after example in the '921 specification about
16 multiple wavelengths using multiple wavelength components to code more
17 than those number of wavelengths in a coding scheme, like what we showed.
18 So we heard that maybe this was contradicted during his deposition -- Dr.
19 Struhl's deposition testimony.

20 And I'll go and talk a little bit more about what Dr. Struhl said
21 during his deposition. Because a lot of these excerpts that you just saw
22 about -- from his deposition show some confusion, perhaps to questions that
23 were asked, and some of that's taken out of context. But to be sure, Dr.
24 Struhl in his declaration notes that F is at least two.

25 And in his deposition, after being asked these questions and
26 perhaps getting a little confused, we came back at the end of the deposition,

1 and I asked Dr. Struhl, read the claim language. Because perhaps he wasn't
2 looking at the whole claim, that first -- if we look again at the claim, there's
3 two different limitations here. The first one says, wherein each of said at
4 least M analytes is encoded as a value of one component of a fluorescent
5 signal.

6 If you look at that, you don't see the next in isolation. Maybe
7 there's some confusion about is it one, is it two? But the second limitation is
8 clear, wherein said fluorescent signal comprises F wavelength components.
9 And when I showed Dr. Struhl that and asked him, in view of the claim
10 language, what is your understanding of what the minimum value of F is?

11 And the clear answer was, I mean, it says it right here, F equals
12 two or is greater than two. So I don't think there's really a dispute there.
13 Sometimes witnesses get confused when they're asked questions in a
14 deposition. That's why both attorneys get to ask questions. And when Dr.
15 Struhl was confronted with the full language of the claim in context, he was
16 able to clarify that his declaration, where he said it the first time, was
17 accurate.

18 All right. So --

19 JUDGE HARDMAN: Counsel, it's Judge Hardman.

20 MR. SALEN: Yes.

21 JUDGE HARDMAN: Question, I'm just confused as to why we're
22 talking about claim construction of these terms. In your Patent Owner
23 response, you did not propose these terms for construction, so I'm not clear
24 on why this is an issue now.

25 MR. SALEN: Your Honor, I don't think it is, except that I believe
26 Bio-Rad said that there's a claim construction issue over F. I don't think

1 there is one. I think everybody's been saying the claim -- just read the claim
2 language. It's clear from the claim language in English that F is two and M
3 is three, because that's what the claim says. This is plain and ordinary
4 meaning when you read the claim and all the limitations. So I agree with
5 you, but I do think --

6 JUDGE HARDMAN: Do you think --

7 MR. SALEN: Yeah, sorry.

8 JUDGE HARDMAN: Do you need this construction of M is
9 greater than or equal to three, et cetera, for -- I see that it's applicable to
10 Petitioner's reliance on Figure 11A of Larson. But do you need this
11 construction for your rebuttal to the Ground 1 anticipation?

12 MR. SALEN: No, Your Honor. It's not necessary. The claim
13 -- but I do think it's important that we look at the entire claim language when
14 we're talking about anticipation. And you have to show that Larson
15 discloses each and every limitation. And I think that's just -- that's the
16 reason I wanted to walk through the limitations of the claim. But I agree
17 with you, Your Honor, and no, that construction is not necessary.

18 And just to be clear, the Board -- when the Board instituted, the
19 Board just going with what Bio-Rad had argued in their petition, agreed in
20 his institution decision that there's two colors, two wavelengths, three
21 targets. That's what the claim language says. That's what we need to find in
22 Larson.

23 So moving on, what's -- the next limitation is also important.
24 Probably the most -- one of the most important limitations that I want to talk
25 about, which is -- wherein said assay is capable of unambiguously detecting
26 the presence or absence of each of those three analytes in any combination

1 of presence or absence in a single sample volume.

2 And I think because we talk so much about it and because it's
3 important and there was a construction request, we should talk about that.
4 What does that mean? And I don't want to just focus on single sample
5 volume. The whole claim limitation has to be there. You have to
6 unambiguously detect the presence or absence of the three analytes, at least
7 in any combination of presence or absence, all of them in that -- inside of
8 that volume. That's what the claim says in clear language.

9 JUDGE OBERMANN: Can I stop you for just a minute?

10 MR. SALEN: Yeah.

11 JUDGE OBERMANN: Because I did want to ask you what is the
12 Patent Owner's position on Petitioner's Slide 30? This is the one that seems
13 to suggest that this is all in one sample. Can you explain Patent Owner's
14 position on that slide?

15 MR. SALEN: Sure. So first of all, Slide 30 doesn't show the prior
16 art. That's the slide -- and I think that was a misstatement on the record.
17 Slide 30 is about -- it cites to infringement contentions, extrinsic evidence,
18 so that's a first. When we're talking about --

19 JUDGE OBERMANN: Okay. So Slide 30 is not representing
20 anything that's disclosed in Larson.

21 MR. SALEN: That's right.

22 JUDGE OBERMANN: Thank you.

23 MR. SALEN: And it says --

24 JUDGE OBERMANN: I will ask another tickler for the record.
25 I'd like Patent Owner's position on that -- or I'm sorry, Petitioner's position
26 when it's your turn to rebut whether you agree that Slide 30 -- Petitioner's

1 Slide 30 does not relate to Larson -- or is not depicting an embodiment
2 disclosed in Larson. Thank you.

3 MR. SALEN: Yeah. And Your Honor, just to be clear, Slide 36 --

4 JUDGE HARDMAN: Counsel, before we move up Slide 30 -- it's
5 Judge Hardman with a question. On that Slide 30, there's the word
6 subsequently. Does that mean subsequent to amplification?

7 MR. SALEN: I think what the reference is, is that there's a -- no, I
8 think what the language on Slide 30 says that for all of Bio-Rad's infringing
9 -- this is from -- again, this is citing to Exhibit 1012 at page 20, which are
10 the infringement contentions for the Patent Owner. And the statement, it
11 says, for all of Bio-Rad's infringing ddPCR assays and kits, the detection is
12 performed in a single sample volume that is subsequently partitioned into
13 multiple droplets.

14 And from those infringement contentions, what it's saying is, okay,
15 if there was a single sample volume and it gets partitioned into droplets and
16 then the droplets is where the amplification occurs. It's worth pointing out
17 that the Patent Owner has, after looking at the evidence of infringement, has
18 dropped that reading from its infringement contentions. But that's not
19 important. I think it's --

20 JUDGE OBERMANN: I just want to go back because I don't
21 know that I heard an answer to Judge Hardman's question. Does the
22 partitioning step, does that occur before or after amplification in the kits that
23 are represented in Slide 30?

24 MR. SALEN: So Slide 30, I think, was an initial infringement
25 contention. I guess the answer is the intent of what's referenced here is that
26 there would be subsequent partitioning and then amplification after the

1 partitioning so that the -- so that's what's intended to be reflected in that
2 statement.

3 JUDGE OBERMANN: So I want to make clear, partitioning
4 occurs after amplification?

5 MR. SALEN: No. Partitioning occurs and then --

6 JUDGE OBERMANN: Oh, before.

7 MR. SALEN: Yeah.

8 JUDGE OBERMANN: Okay. So in other words, the final
9 wherein clause, if we accept that sample size -- or the sample has to be the
10 same sample that's in the first wherein clause with the M's and the F's. If
11 that has to be the same sample -- in other words, that final wherein clause
12 where the amplification has to occur in the same sample that's referred to
13 above would not occur because the amplification is occurring in a different
14 sample, one that's been partitioned.

15 MR. SALEN: That's right, Your Honor.

16 JUDGE OBERMANN: Thank you.

17 MR. SALEN: And that's the reason why Patent Owner dropped
18 this from their infringement contentions. And to be clear, Your Honor, the
19 issue here I think we want to look at -- we're talking about claim
20 construction now, if we want to talk about what is single sample volume.
21 And there is no dispute -- you know, I'll say that there is no dispute over the
22 whether or not single sample volume, that term can include a sample that's in
23 a vial or a sample that's been partitioned and you have a single droplet and
24 that's a single sample volume. There's no dispute on --

25 JUDGE OBERMANN: Let me ask you this though, is there a
26 dispute about whether single sample volume in the first part of the claim has

1 to be the same exact sample that's in the second part of the claim? In other
2 words, if you look at Claim 1, we have two wherein clauses that refer to a
3 sample. Does that have to be the same volume?

4 MR. SALEN: I don't -- I'm confused myself as to whether there's a
5 dispute. The claim language seems clear to me that there shouldn't be a
6 dispute. If you look at that last wherein clause, it says, wherein the analytes
7 are amplified in the single sample volume. That's the same single sample
8 volume -- or if we use claim interpretation in that wherein clause above,
9 that's highlighted in blue on slide -- on our Slide 11, that clause talks about a
10 single sample volume.

11 And then later in the claim at the end, we have the wherein clause.
12 And I'll skip to that part. Now, that's highlighted in blue on Slide 14, this is
13 wherein the analytes are amplified in the single sample volume. And the
14 question isn't what does that mean? I don't think there's a claim construction
15 issue. The language is clear in the claim. The question is what does the
16 prior art disclose?

17 JUDGE OBERMANN: I think there is a question on claim
18 construction, though, because I think they're suggesting that it doesn't
19 become a different sample volume if you divide it into 100 drops.

20 MR. SALEN: No. We disagree with that, that this is a dispute.

21 JUDGE OBERMANN: Why?

22 MR. SALEN: And we disagree -- and that's --

23 JUDGE OBERMANN: What's your basis? I mean, that's really,
24 to me, the heart of the issue. Why isn't it the same sample after it's
25 partitioned?

26 MR. SALEN: Sure. So I can -- I'm going to answer using a few

1 different references to cites in the record.

2 JUDGE CHANG: I do want to mention one sort of wrinkle on
3 that. I believe what Petitioner is arguing is not just that any droplet is the
4 same sample volume. It's the fact that in Larson, it's collected together
5 before they amplify it. And therefore, it's a collection of the droplet that was
6 the original sample volume. And I think they're saying compartmentalizing
7 does not change that to a different sample volume. So just as you're
8 addressing it, if you can address that point, that would be good. Thank you.

9 MR. SALEN: Thank you, Your Honor. And that's a perfect segue
10 because this is Larson. This is on Slide 15, and this is paragraphs 44 and 45
11 of Larson. And Larson has a lot of examples of this, and their expert talks
12 about it. But just as a couple of examples that we've talked about in our
13 petition, Larson talks about having millions of single molecule PCR
14 reactions to be performed in parallel for both -- each of the --

15 JUDGE OBERMANN: I'm already having a problem, I'm sorry.
16 Why are we looking at Larson to figure out what this claim means? I would
17 expect you to focus on the claim language minimally, you know. The
18 majority of your argument should be on the claim and then maybe look at
19 the specification. But I'd like an answer to Judge Chang's question; I think
20 it's an important one. And I don't think we look to Larson in order to
21 construe your claim.

22 MR. SALEN: Thank you, Your Honor. And I wasn't suggesting
23 that we were, so I'm sorry if I was misunderstood. So taking a step back, the
24 issue here is -- I don't think that the construction here of single sample
25 volume, as we said, there's no dispute. We agree that it's plain and ordinary
26 meaning. We agree that it can include both vials -- the vial and the droplet.

1 And the question then becomes, what does this last wherein clause
2 mean? What does that say? And in our view, if the prior art were an
3 infringing product, or however you're trying to read the claim, if you can
4 point into that prior art reference or -- and say, where -- answer this
5 question, where is the amplification occurring? Because that's what the
6 claim is about --

7 JUDGE OBERMANN: But you're assuming that once you
8 compartmentalize, that you're outside the claim. They could have written
9 this claim with that last wherein clause to say, a single sample volume that
10 has not been divided, but they didn't. So why can't we construe this claim
11 broadly to include a single sample volume that is compartmentalized prior to
12 the amplification step?

13 MR. SALEN: I think it's written -- Your Honor, thank you. I
14 think to answer your question, this is written to say, the single sample
15 volume -- one, singular -- and the analytes are amplified in that single
16 sample volume. So I agree with you that if it were plural, so wherein the
17 analytes are amplified in the sample volume or volumes or wherein the
18 analytes are amplified in the single or multiple samples volumes, then that
19 would be different. But there's always --

20 JUDGE OBERMANN: Let me just stop you for a second because
21 I really like what you just did. I'm not saying I agree with it or disagree with
22 it, but you right there really focused on the claim terms. And I heard you
23 refer to the word "the" and the word "single" as it appears in that very last
24 "within" clause, that to me may be persuasive. Is there anything in the
25 specification that supports the view that you just stated?

26 MR. SALEN: Your Honor, just that the specification talks about

1 both embodiments -- or it talks about a single sample volume being a droplet
2 and it also talks about a single sample volume being a vial. And the whole
3 point of the '921 Patent, if you go through the entire specification and look at
4 what it's doing, is saying we can do this encoding and decoding step to
5 unambiguously identify the presence or absence of multiple analytes inside
6 the single sample volume. And it doesn't matter if it's a droplet or a vial -- or
7 its saying it doesn't -- those --

8 JUDGE OBERMANN: I understand that. The question is -- we're
9 looking at a finite volume, which is the single sample volume as it appears
10 the first time in the claim. No question about that. No question that when
11 you look at the single sample volume as it appears the second time in the
12 claim, it's got to be the same volume.

13 It can't be some -- you know, one can't be a droplet in the first one
14 and then a whole separate thing in the second one. But we really need to
15 focus on whether the volume that's referred to in the first instance is the
16 exact same volume, whether partitioned or not.

17 MR. SALEN: Yeah. So I think to help with this, Dr. Struhl
18 explains -- looking at the specification, this is Slide 16. And Dr. Struhl
19 explains, based on the '921 Patent, that you can non-degenerately detect
20 within the single sample volume any combination in any single sample
21 volume, such as a vial, (CROSSTALK) --

22 JUDGE OBERMANN: I'm confused. I'm so sorry. I'm looking at
23 your -- Patent Owner's Exhibit 16, I'm not seeing anything about the expert
24 or the spec.

25 MR. SALEN: Demonstrative Slide 16?

26 JUDGE OBERMANN: Yeah. I see Claim 1 and I see -- oh,

1 maybe I have it wrong, no?

2 MR. SALEN: Yeah. It's Dr. Struhl's declaration, right?

3 JUDGE OBERMANN: This is Patent Owner's demonstratives?

4 MR. SALEN: No. I'm -- yes, I'm sorry, I'm looking at Patent
5 Owner's demonstrative Slide 16.

6 JUDGE OBERMANN: Oh, I'm sorry, my page numbers are off.
7 That's my page 19. Sorry about that. Thank you.

8 MR. SALEN: No problem. I apologize, Your Honor. The
9 numbers are a little small.

10 JUDGE OBERMANN: And do we actually have Dr. Struhl
11 directing us to an explanation from the spec?

12 MR. SALEN: So he cites to column 1, lines 46 through 47. And
13 in interpreting what's in the specification there based on -- right, so this is
14 talking -- yeah, so he's talking about what's in the '921 Patent.

15 JUDGE OBERMANN: Does that really answer the question
16 whether or not that same volume can be partition before amplification?

17 MR. SALEN: I think, Your Honor, the -- I think the issue here is a
18 logical one. The claim is not written in multitemporal parts. And I think if
19 we're trying to look back and say, okay, I can drink a glass of hot water.
20 And you wait for the water to cool down. And then drink the same glass of
21 water and say, okay, I just drank a glass of hot water.

22 No, that was room temperature water because you waited for it to
23 cool down. It's not, I drank a glass of water that was once hot and then cool
24 down and now -- I mean, I'm still drinking a glass of hot water. And again, I
25 can go back to that Apple case. This is plain English. And I think --

26 JUDGE OBERMANN: Well, I don't think that's quite right

1 because they wouldn't say you're still drinking a hot glass of water. But
2 they'd say that if you took that glass of water and poured it into five shot
3 glasses and it's still hot, you're still drinking that glass of water, it's still hot.
4 You just divided it into five parts.

5 MR. SALEN: I think if I drink one of those shot glasses of hot
6 water, then I think that I'm drinking eight glasses of hot water. But if I'm
7 drinking all of them, then I'm drinking multiple glasses of hot water. And I
8 think the claim language is clear here. We're talking in the singular. Where
9 again, I think going back to what you asked me about earlier, the claim
10 language says wherein the analytes are amplified in the single sample
11 volume. And we're talking about --

12 JUDGE OBERMANN: Yes.

13 MR. SALEN: Yeah. So I think that's going to Your Honor -- and
14 I know that -- I'd like to give you more, but I don't think there's really -- and
15 Petitioner here has the burden of proof of showing that there's something
16 different in the claim.

17 JUDGE OBERMANN: Right.

18 MR. SALEN: This is the plain language of the claim.

19 JUDGE OBERMANN: Okay.

20 MR. SALEN: And I don't think they've shown it.

21 JUDGE OBERMANN: Okay. Thank you. That's helpful.

22 MR. SALEN: And based on that, then you have to read the claim
23 on the prior art reference. And the prior art reference here that we're reading
24 the claim on is Larson. That's what the Petitioner has cited as their basis for
25 ground -- for all of their grounds, their primary basis. And what does Larson
26 say? And Larson talks about the reaction occurring -- any reaction occurs in

1 each of those droplets, so the reaction occurs within the droplet.

2 And we know that because -- and Dr. Struhl testified about it. But
3 Dr. Batt has also talked about how you detect -- and this is just more
4 conceptual. What's going on -- you know, when you talk about using digital
5 PCR, how are you actually detecting signals? The digital PCR reaction
6 occurs using these things called TaqMan probes.

7 I'm not going to spend a lot of time on this. But the point of this
8 slide is to show -- and this is Slide 18, citing to Dr. Batt's testimony about
9 what's going on is that wherever you're getting the signal out of the droplet,
10 that's where the reaction is occurring. The reaction occurs in any -- in a
11 sequence that results in a signal coming out using the digital PCR
12 methodology that's described in the Larson reference. So each of those
13 droplets produces a signal because each of those droplets has a reaction
14 going on inside of it.

15 So I'm going to just skip ahead because I'd like to address -- and I
16 think I have about 14 minutes left here, and I'd like to address the grounds, if
17 that's okay, unless Your Honor has more questions about claim construction.

18 JUDGE OBERMANN: I don't.

19 JUDGE CHANG: Actually, I do have one, but it's not related to
20 the issue that you specifically raised. And you can answer this question
21 whenever you get to a good point. But the claim does say it's an assay that's
22 capable, right, of unambiguous detecting. And again, in the third clause is
23 wherein an assay is capable of unambiguous detecting.

24 I think in the Patent Owner response, a lot of times you say, well,
25 Larson doesn't disclose an actual situation where you had the detection of
26 the presence of multiple analytes. I guess my question is -- this does go a

1 little to claim construction -- what is the assay capable, regardless of whether
2 they actually did detect multiple analytes? And you can answer that
3 whenever you get to the point.

4 MR. SALEN: Thank you, Your Honor. I think I can probably
5 jump into that now actually. So let's talk about Ground 1. Ground 1 is
6 anticipation based on Larson. And the point is for anticipation, Petitioner
7 had the burden of proving that each and every limitation, you know, is met.
8 And the only evidence you really looked at from the Petitioner isn't about
9 the claim but about what Patent Owner's infringement contentions set in
10 order that that's extrinsic evidence.

11 But more than that, the claim language is really where we need to
12 focus. So let me just -- because I can talk about this a little bit with respect
13 to second ground, I think it's a little bit easier. So what's the evidence in
14 Larson that you can have three analytes, two color channels, and
15 unambiguously detect the presence or absence of any combination of these
16 analytes -- three analytes within a single sample volume?

17 And here's what Bio-Rad points to, to start -- and Your Honors
18 recognize, it's really Figure 9, that's what's in the petition. They only
19 brought in Figure 11 after the fact. And I'll address Figure 11. But I want to
20 focus on what they initially said because there's a problem here. They talk
21 about, okay, there's a reaction that occurs, first of all, in the droplets, in
22 Larson, this is what's being explained here.

23 And they say, okay, there's two colors and three targets in this
24 reaction. I'm on Slide 29 now. And this is the primary part of the figure that
25 they focus on to tell you that you can unambiguously detect the presence or
26 absence of those three targets in any combination within the single sample

1 volume. And first of all, I'd like to point out -- this is Slide 29, but the figure
2 -- the table here is from Exhibit 1002, so that's actually Dr. Batt's
3 declaration.

4 That's not a figure that appears in Larson. What appears in Larson
5 is Figure 9C. And Figure 9C and paragraph 121 are the sole teachings that
6 they're relying on in Larson for this proposition. And they show you in one
7 color, there's two different intensities. And they said this is eyeballing it, I
8 guess, that this is about .4 and about .2 in that Figure 9C that those are
9 distinguished targets one and three.

10 But to be sure, those are different droplets -- those are different
11 signals coming out of different droplets in Larson because -- why do we
12 know that? Because Larson teaches -- and I'm going to talk about this in a
13 minute -- that you dilute the sample down to terminal dilution, where you're
14 statistically probabilistically assured that you have a single target in each of
15 these droplets so that you don't have the problem of how you distinguish
16 between targets one and three when they're in the same droplet.

17 JUDGE CHANG: Wait, so I do have questions about that. One, I
18 think Larson also talks about limited -- limiting or limited, I can't remember
19 -- dilution, which means that you will have some multiple occupancy cases.
20 So I don't believe that they said terminal dilution is the only method, it's an
21 embodiment. So that's the first issue.

22 And the second issue, I guess -- if you can go back to Figure 9, if
23 you had that Figure. So I think here, Figure 9A, I think it's one single
24 molecule with three targets. So I actually -- so tell me if I'm wrong, but my
25 understanding is that in each droplet you would actually have multiple
26 targets, not multiple molecules necessarily but multiple targets. So I'm not

1 sure that you are correct that when you say intensity one, two, and three, that
2 they're all in different droplets.

3 MR. SALEN: So with respect to the limited -- limiting dilution,
4 we agree with you that that's also an embodiment discussed in Larson. But
5 the point -- and I'll go through this a little bit more, but the point of Larson is
6 to try to avoid looking at multiple -- and I think we've been -- both sides
7 have conflated the word analyte or molecule with the word target.

8 So Your Honor, I take your point that the issue here, when you
9 have -- they're trying to get to single molecule droplets and not necessarily
10 single target droplets. So I agree with that. And the claim language, to be
11 sure, talks about analytes being amplified in a single sample volume. So
12 that's --

13 JUDGE OBERMANN: I'm sorry. I heard your friend argue that
14 Larson does not exclude the multiple occupancy droplets and that -- I think
15 that they were arguing that Larson actually includes them in the analysis. I
16 assume that you disagree with that and that they are excluded?

17 MR. SALEN: Yes, Your Honor. We absolutely disagree with
18 that. But that's what Larson shows. And I can walk through that. So first of
19 all, we can start with the original embodiment that was -- that the actual
20 embodiment that the petition was based on, which is Figure 9. And Figure 9
21 specifically says that you're looking at a single molecule amplification to
22 produce the fluorescence burst of a quantized intensity. So that's specifically
23 what Figure 9 and paragraph 121 are about.

24 But let me -- based on time, let me just go through and talk about
25 this problem. So first of all -- well, let me step back to slide -- I just want to
26 show you, again, the proof that they put in. And this is Slide 29 again. So I

1 heard an argument from the other side -- and that this is -- it's un rebutted that
2 Larson can unambiguously -- teaches unambiguously detecting one, two, or
3 three targets in a single sample volume.

4 It doesn't tell you how to do that here. It doesn't tell -- it tells you
5 -- one, it tells you target three at these two different intensities. It doesn't tell
6 you the combination. It doesn't tell you how to unambiguously detect these
7 in any combination of presence or absence, meaning what happens when all
8 three are present? How do you know? What does Larson tell you? And
9 -- sorry, I went backwards.

10 And the problem is Larson doesn't tell you. And Dr. Batt agreed.
11 We asked Dr. Batt the question, Larson doesn't say anything about
12 microdroplets containing targets one, two, and 3, does he? Is Batt's answer
13 containing all three of them? Is that what you're asking? Question, he
14 doesn't say this, correct? He answered, he doesn't account for those. He
15 doesn't say that per se. So that's on Slide 32.

16 And then Bio-Rad also ignores the other part of the embodiment in
17 Figure 9, which is Figure 9D, which also only shows you targets in the VIC
18 channel being present in single droplets or targets in the FAM channel being
19 present in single droplets but doesn't show you -- you don't see anything that
20 shows the multiple occupancy droplets here.

21 And Dr. Batt agreed with that. This is Slide 33, talking about Dr.
22 Batt's testimony that, yeah, Figure 9D doesn't show you that. It doesn't show
23 you how to do the common matrix (PHONETIC). So the point is, what does
24 Larson actually teach you? Dr. Batt was asked a lot about this during his
25 deposition. So the point is Larson's primary goal is to teach single -- how to
26 do things -- how to do these detections using single occupancy droplets.

1 Because they're trying to get to a point where they don't have to worry about
2 problems that cause when you have multiple occupancy droplets.

3 And there are several that Dr. Batt recognized from Larson's spec.

4 But here, Dr. Batt was asked -- and those issues that Larson avoids by
5 having only one template molecule per droplet. That's what he says in
6 paragraph 100, correct? Try going to the top, paragraph 100 of Larson.

7 Answer, so if you're looking for the phrase that says these issues are avoided
8 in droplet PCR, that's correct. It says there's only one when talking again
9 about one template molecule.

10 JUDGE CHANG: So I understand that Larson does talk about a
11 preferred embodiment where you have one single -- or one embodiment
12 where you have one single molecule. But isn't there a law that says, prior art
13 is prior art is for all it teaches, including unpreferred embodiments and
14 doesn't -- I think, Larson say explicitly that you could have multiple
15 occupancy and that you might just require a more dilute sample?

16 MR. SALEN: Sure. Larson acknowledges that it happens based
17 on statistics, but Larson doesn't teach you that in the claim. And we have to
18 go back to the claim. You have to -- Larson has to teach you how to
19 unambiguously detect the presence or absence of all of those molecules
20 within a single sample.

21 Larson doesn't tell you that because Larson tells you there's
22 problems with even trying to do that. So you don't look at those, you look at
23 -- you statistically look at the ones where there are single molecules, single
24 occupancy. And it's not just in one place, it's all over Larson. It's the entire
25 point of Larson. Dr. Batt explained why this is the case in Larson.

26 JUDGE CHANG: Actually, let me point you to -- specifically to

1 one paragraph in Larson just so you can address in your rebuttal. But in
2 paragraph 129, which I think is cited in the petition, I'm not sure I'll go back
3 and look at that. But it does tell you -- and I think petitioner referred to this
4 in their presentation -- that if you have -- you know, multiplex assay can
5 require more dilute sample. If there's 10 percent occupancy, then you have 1
6 percent of multiple occupancy.

7 And then you can do this -- you know, sometimes you might have
8 a situation where you have a brighter intensity because of the double
9 occupancy. But you can fix it by figuring out, for example, you know, probe
10 one plus probe two. And you can sort of figure it out by -- it seems to me
11 -- dealing with intensities and adding them. So how do you address that
12 paragraph?

13 MR. SALEN: So it tells you maybe how it is -- first of all, I think
14 that was right before, these are -- this is parts of the specification that weren't
15 in the petition, that weren't relied on. But I think this is about Figure 11
16 when they're leaning up to -- is that -- Your Honor, is that what you're
17 talking about?

18 JUDGE CHANG: No. I think it's paragraph 129 of Larson.

19 MR. SALEN: Let me -- right. So yes, so Larson talks about that.
20 But again, I don't think that they're telling you how to -- there's not a way
21 that you can distinguish between all three of those in any combination of
22 presence or absence that's taught here. It says that -- it tells you, okay, you
23 can look at the intensity and try to figure it out. It doesn't tell you how to do
24 that or what the codes would be or whatnot. So there's no teaching of
25 actually how to do this.

26 And for the most part, Larson is telling you, don't do that. And let

1 me just go back to -- Your Honor, I can try to answer the question a bit more
2 clearly. But I believe that the point is here that Larson doesn't have a
3 teaching of how -- in a single molecule how to distinguish between any
4 combination of presence or absence of each of the at least three targets.

5 In a situation, there's two color channels. The only place that's
6 ever pointed to by Petitioner in their petition as to where that's taught is
7 Figure 11. I think (CROSSTALK) --

8 JUDGE CHANG: I don't think that's quite right. I'm sorry. I'm
9 looking at the petition, and on page 52 of the petition, they argue Larson
10 expressly teaches that there may be multiple targets in a single individual
11 droplet and that its methods accommodate such multiple occupancy
12 situations. And they cite paragraph 129 in Larson.

13 MR. SALEN: So I agree with that. I think the point is that the
14 petition wants you to look at that, okay, sure, there's multiple occupancy
15 droplets. But the point is you have to do the entire claim in that droplet.
16 You have to unambiguously distinguish between the presence or absence of
17 at least three targets, three analytes within that droplet.

18 And Larson doesn't teach you that just by acknowledging the fact
19 that they may exist, the multiple occupancy droplets, they teach you how to
20 identify multiple occupancy droplets, but they don't tell you how to
21 distinguish between the actual analytes or sequences.

22 JUDGE CHANG: So I think this might be a reason why it's
23 confusing, because we are confusing sort of target sequences with multiple
24 occupancy. As I understand Petitioner's argument, what they are trying to
25 say is Figure 9 shows that you can detect three different sequences using two
26 fluorophores on the same molecule, granted.

1 But then in Figure 11, they show that you could have two
2 plasmids, which means two different molecules in the same cell, in the same
3 droplet. And they're saying that if you combine these two -- and I have a
4 question to the Petitioner about their motivation to combine.

5 But they're saying if you combine these two, then you could get the
6 -- sorry, then you could get the claim. I think that's their argument. And I
7 have a question about their motivation combine. But I think your time is up.

8 MR. SALEN: Okay. May I just take a --

9 JUDGE CHANG: Sure, you can.

10 MR. SALEN: Two more minutes and then --

11 JUDGE CHANG: Sure, go ahead.

12 MR. SALEN: So I'd just like to point out that I agree. I think that
13 maybe what they were trying to get at when they realized they had a
14 problem with Figure 9 by itself, that they tried to shift to figure -- using
15 Figure 11. I don't see anywhere in the reply or the petition where they say
16 combine those two things and here's why you would do it. Certainly, that is
17 an evidence that we've been given that we have an opportunity to argue
18 about.

19 But I will point out motivation to combine more generally. Why
20 does -- you know, again, this is about single occupancy and about the
21 dilution issue with Larson. Dr. Batt talked about in his testimony here and
22 explained based on what Larson teaches, all of the problems that you have
23 with multiple occupancy droplets is based on Larson.

24 And he identified, for example, that there's -- you have a problem
25 with bias from allele specific PCR, that you have a problem with
26 overlapping probes, that there's a problem with having competition between

1 different amplicons that results in various yields. And these problems he
2 identified, he said -- he didn't consider any of those.

3 He didn't consider that these would be problems if you combine.
4 He doesn't talk about why you would solve these problems. In fact, Larson
5 really teaches away from that. So I think that's -- I think it's really important
6 to focus on what Dr. Batt said about that because he said that Larson teaches
7 about all these problems, but he didn't consider them.

8 And I won't focus on the *Dropworks* case because I know the issue
9 and I don't have time. So I would just point out that Bio-Rad in this
10 previous case basically said the same thing about Larson. They said Larson
11 teaches single occupancy.

12 And here's the crux of it, Dr. Batt says, hey, why would you
13 modify Larson? What's the motivation to combine? We asked him lots of
14 questions, combining Larson with -- or modifying Larson by itself or
15 combining Larson with Saxonov, for example, in the Ground 3. And his
16 argument was, hey, because if you don't have to dilute the sample as much,
17 it's cost effective. That's the motivation to combine that he talked about.

18 And we asked him, well, if you do that, if you keep the number of
19 analyte droplets the same but just acquire data from them, is that an option?
20 That's one of the options he gave as to how you would modify Larson. He
21 said, just keep it the same but look at those double occupancy droplets. And
22 he said, yeah, you could do that.

23 But how does that motivation -- you're not saving any cost. He
24 says the motivation for not diluting the sample as much is to save cost. But
25 you're not -- but here, there is no change in the dilution in option one that he
26 suggests for modifying Larson.

1 So what's the second option, he says -- on how to modify Larson,
2 he says, well, don't run a terminal dilution. Don't run at limiting dilution.
3 Increase the concentration so that -- and now, you can look at the double
4 occupancy droplets. And supposedly, Larson tells you how to do that. And
5 what did Dr. Batt say? He said, well, he says, that's the option.

6 He said, I do less dilute samples so I could look at multiple
7 occupancy. And the problem is he completely ignored all the things we just
8 talked about. The problems with the multiple occupancy that Larson tells
9 you are there and doesn't tell you how to solve. And Dr. Batt didn't consider
10 any of those.

11 And the Federal Circuit says that you need to consider the pros,
12 both the downsides and the -- I'm sorry, I'm skipping through. I'm going to
13 stop there I think, just because I'm three minutes into my rebuttal time if
14 that's okay, unless you have further questions.

15 JUDGE OBERMANN: I do have a question. And what I'm going
16 to do, I'm going to stop your clock and I'm going to give you your full 20
17 minutes on rebuttal. And I'm going to add three minutes to the -- your
18 friend's time so that it's equal. Any objection to that from your -- from
19 Petitioner's counsel?

20 MR. WALTER: No, Your Honor.

21 JUDGE OBERMANN: Thank you. And I did have one question
22 for you before you sit down, Mr. Salen. Did Patent Owner waive, in the trial
23 phase response, any argument that Saxonov is not prior art?

24 MR. SALEN: No, Your Honor. So in the first instance, we
25 addressed Saxonov being prior art and explained that we agreed with all the
26 reasons that the Board found for not being prior art and --

1 JUDGE OBERMANN: And that's in your response?

2 MR. SALEN: And that's in the response. And then Petitioner, in
3 its Petitioner's reply, brought up for the first time a new figure in Saxonov
4 that I haven't discussed or talked about, which is Figure 4, and said, hey,
5 hold on a second, Saxonov teaches some more stuff.

6 JUDGE OBERMANN: Okay. That was my question to your
7 friend. And I heard Mr. Walter say that they've cited nothing from Saxonov
8 in the reply that was not in the petition. And you disagree with that?

9 MR. SALEN: I disagree with that. Figure 4 wasn't discussed in
10 the petition. It was discussed in the reply and we responded to those
11 arguments.

12 JUDGE OBERMANN: And is there anything -- any other
13 disclosures from Saxonov that were cited in the reply but not in the petition?

14 MR. SALEN: No, Your Honor. And for that reason, we think that
15 the Board's reasoning was sound in its institution decision because nothing
16 new was added to explain how those embodiments in Saxonov would have
17 been carried over from the provisional to make Saxonov prior art.

18 JUDGE OBERMANN: Yes. Okay. Thank you very much.
19 That's all I have. Let's see if any of my panelists -- co-panelists have a
20 question.

21 JUDGE CHANG: Not right now. Thank you.

22 JUDGE OBERMANN: Okay. So with that, we will hear rebuttal
23 from -- I'm sorry, from Mr. Walter. And I will set your time to 20 minutes.
24 And I will not start your time until you begin speaking.

25 MR. WALTER: Thank you, Your Honors. I'll start with Ground
26 1. So here's -- okay. So here is Slide 30. And this is from their

1 infringement contentions And, you know, there was an argument that this is
2 not disclosing what's in prior art. And I think that's very much wrong. I
3 think what we have here is, you know, we have -- I think one of the -- I can't
4 remember, was this -- if it was Judge Hardman, but the question was raised,
5 look, isn't the question here, can the sample volume in a single sample
6 volume be partitioned into droplets? I think that is the question.

7 JUDGE OBERMANN: Look, I have a question. Where did this
8 figure come from? The one that actually has pictures in it, not the text, but
9 I'm looking at Figure 30 -- or I'm looking at Slide 30. Where did that
10 -- where is Figure 1.3? What's that from?

11 MR. WALTER: And this whole image right here that's in the box,
12 that is from their infringement contentions. And Figure 1.3 comes from a
13 Bio-Rad product manual.

14 JUDGE OBERMANN: So that's not in Larson.

15 MR. WALTER: Well, that's -- this is -- this figure -- you're
16 asking, does this exact figure appear in Larson? No. But the substance of
17 this figure is in Larson.

18 JUDGE OBERMANN: Where?

19 MR. WALTER: Okay. It's in paragraph 79 and 193. Okay. I'll
20 show you where that is right now. Because what's being shown here is
21 -- what's being shown in that figure on Slide 30 is that you take your single
22 sample volume, you partition into droplets, and then you amplify a
23 collection of droplets en masse as a single volume. That's what's shown in
24 paragraph 79.

25 Once the final droplets are produced by any of the droplet-forming
26 embodiments above or by any other embodiments, the droplets are thermal

1 cycle, certain embodiments, the droplets are collected off chip as an
2 emulsion in a PCR thermal cycling tube and then thermally cycled in a
3 conventional thermal cycler. That's the same thing that's on Slide 30. It's
4 also in paragraph 193.

5 Approximately 25 microliters of the PCR reaction mixture was
6 collected in this emulsion from the droplet generation chip and thermally
7 cycled in a DNA engine. That's a thermal cycle. That's the same thing that's
8 in Figure 30. So to say that this is just what's accused and it's not what's in
9 the prior art, that's not right. It's the same thing in substance.

10 Yeah, I agree, it's not the same figure, but it's the same thing in
11 substance. So I don't think it's fair to say, yeah, that's not what's in the prior
12 art. It is what's in the prior art.

13 Now, there's the question that was asked, you know, isn't the
14 dispute here about whether the claim should encompass droplets that are
15 partitioned -- excuse me, whether it should compass sample volumes that are
16 partitioned that are divided up into droplets? Does it encompass that? And
17 Mr. Salen was asked, you know, where is that addressed?

18 He pointed to something in the claim language that I don't think
19 addresses the question. He was asked, you know, where else can you point
20 to? And he pointed to some testimony from Dr. Struhl. Well, we do have
21 this question answered. There's a specification that tells you the invention
22 could be used with separation. You don't have to use it.

23 The next passage says, no separation is necessary. So it says, you
24 can use separation, that's the compartmentalization, but you don't have to use
25 it.

26 JUDGE OBERMANN: How do we know that's actually talking

1 about compartmentalizing a sample this way?

2 MR. WALTER: Okay.

3 JUDGE OBERMANN: That just doesn't really ring true to me.

4 MR. WALTER: Okay. Well, part of the problem is, is that in this
5 patent -- you know, the one thing they don't want to talk about is that there
6 aren't actually any droplet embodiments. So you have to look at what's
7 being contemplated in here and you have to look at it through the lens of the
8 skilled artisan. The only person who's done that is Dr. Batt.

9 I'm showing his testimony on Slide 15. He says, the claims and
10 specification do not prohibit analytes from being compartmentalized or
11 separated for analysis.

12 JUDGE OBERMANN: Well, that's great, but that's extrinsic.
13 And, you know, I'm a judge here and I can read the spec. And I'm reading
14 that spec. And I don't see anything when they -- that you cite -- you know, I
15 think -- one, two, three, four -- five columns that say the same thing about
16 any combination or presence or absence without immobilization, separation
17 as dichotomy. That doesn't tell me that this is permitting single droplets that
18 contain or a separation of that sample in the claim.

19 MR. WALTER: Yeah. And I think the thing is, what I'm trying to
20 reason I'm pointing to Dr. Batt is because you do have to look at how a
21 person of ordinary skill in the art would read that.

22 JUDGE OBERMANN: Why does that tell us that they're
23 contemplating a situation where amplification occurs in a smaller volume
24 than the single sample that's referred to in the first part of the claim?

25 MR. WALTER: It's not. It's the same sample volume. It's a
26 sample volume that's been compartmentalized. And then the

1 compartmentalized volume is placed in the tube. And the amplification
2 happens across all those droplets at the same time.

3 JUDGE OBERMANN: So you're saying that there is no
4 compartmentalization, that there -- I may be really, you know, off base here,
5 so correct me. But you're saying -- I'm looking at Claim 1. And you're
6 saying that you are capable of unambiguously detecting the presence or
7 absence of each -- of said, at least, M analytes in any combination of
8 presence or absence in a single sample volume that that can occur across a
9 glass of water that's been divided into five shot glasses.

10 MR. WALTER: Yes. That's exactly what happens.

11 JUDGE OBERMANN: So in other words, you're not recombining
12 those five shot glasses into one glass before you do the amplification.

13 MR. WALTER: Right.

14 JUDGE OBERMANN: Because I feel like I'm hearing you say,
15 when I look at Slide 30, that somehow those divided samples are being
16 rejoined in the second test tube.

17 MR. WALTER: Yeah. What actually happens is the sample is
18 sucked through a tube, and as it goes through that tube, it passes through a
19 microfluidic junction which partitions it into a -- into droplets. And then the
20 droplets are recollected in the tube. So you have the original volume and it's
21 recollected in a tube and it's in a compartmentalized form.

22 JUDGE OBERMANN: Wait a minute, can -- I want to really
23 understand this. When you say it's recollected in that second tube in
24 compartmentalized form, what do you mean? Because I'm looking at the
25 volume and it looks like it's one volume.

26 MR. WALTER: Yeah. What you have is -- you know, what's

1 shown here is nine droplets. But what you have in the second tube is a
2 collection of droplets. It's the same original sample volume, it's just been
3 compartmentalized, it's been divided up into droplets.

4 JUDGE OBERMANN: And may I ask another question? The
5 actual amplification, is that occurring between these two vials, in other
6 words, those dots? So in other words, you said that it gets sucked through, it
7 gets analyzed in droplet form, and then those droplets are being shown in a
8 second vial after amplification?

9 MR. WALTER: Yes. What's being shown here is post-
10 amplification.

11 JUDGE OBERMANN: So where is amplification occurring in this
12 Figure 1.3 from the kits?

13 MR. WALTER: I think amplification here is being shown -- you
14 can see the gray bubbles, it kind of expands.

15 JUDGE OBERMANN: So the amplification is actually being
16 performed in the individual droplets before they're reconnected in that
17 second vial?

18 MR. WALTER: No. They're always in that tube -- they were
19 always in that tube. What you do is you take your vial, you put the whole
20 vial in the thermal cycle, the amplification happens in the thermal cycler.

21 JUDGE CHANG: So am I right that basically you're saying you
22 have droplets and they're not miscible with each other. So when you put
23 them all in a tube, they remain in droplet form, but they are all in the same
24 tube. And then you do the amplification, is that -- so they don't combine,
25 right?

26 MR. WALTER: Yes.

1 JUDGE CHANG: Okay.

2 MR. WALTER: Yes. Exactly. And that's exactly what they
3 accuse of infringing. And, you know, this matters -- I mean, this -- our
4 expert has looked at the specification. He's talked about how it says you can
5 use separation. And he's explained what this means. This could be done
6 using a widely used technique called droplet-based microfluidics, which
7 involves separating a single sample volume into uniform droplets in
8 picoliters to nanoliters. All of which are then suspended in an immiscible
9 fluid and analyzed en masse.

10 '921 specification describes both separate and non-separated
11 cereals, stating the invention could be used with separation if desired. This
12 is correct and it's unrebutted. There's nothing wrong with it. I don't see any
13 reason to be skeptical about it. It's correct and it's unrebutted. They didn't
14 cross-examine him. They've never disputed this and never submitted their
15 own competing (CROSSTALK) --

16 JUDGE OBERMANN: Can I ask? It's probably a dumb question,
17 but I'm still looking at Petitioner's demonstrative 30, this Figure 1.3, the first
18 volume that's on the left, what form is that taken? Are there still droplets
19 that contain a single target, or are they somehow miscible in there?

20 MR. WALTER: As I understand this, the tube on the left, what I
21 understand is happening -- and I hope I'm right about this, what I understand
22 is happening is that tube on the left, it is droplets. And then the tube on the
23 right is showing after amplification. And that's why you might see multiple
24 copies of DNA in some of the droplets instead of just for two targets.

25 JUDGE OBERMANN: I'm not understanding. Is there a
26 difference between the form of, you know, droplets to the immiscible liquid

1 as between these two vials on the right and the left?

2 MR. WALTER: No. I don't think so. I think the only difference
3 is that one is before amplification, one is after.

4 JUDGE OBERMANN: Okay. So in other words, the figure on the
5 left, in Figure 1.3, the vial on the left also has the target of interest present as
6 a single target in a drop?

7 MR. WALTER: Yes. And, you know, you could have multiple
8 targets in a droplet, too, because you're doing Poisson loading.

9 JUDGE OBERMANN: Right.

10 MR. WALTER: What I understand is on the right is that you've
11 taken the tube, you've put it in a thermal cycler. So on the right, you have
12 amplifying.

13 JUDGE OBERMANN: And your position is that Larson does the
14 same thing because they don't actually remove the droplets that contain
15 multiple targets.

16 MR. WALTER: Well, our position is that Larson does the same
17 thing. Because what it describes doing is taking your sample, partitioning it
18 into droplets, and collecting all those droplets together. Some of those
19 droplets are going to have DNA, and then you amplify those droplets as a
20 collection. That's disclosed in paragraph 79 and 193.

21 JUDGE OBERMANN: Okay. But if we agree that -- well, this is
22 getting really confusing to me now. Because I didn't realize until right now
23 that your position is there's really no new separation that occurs between
24 -- prior to and after amplification; is that right?

25 MR. WALTER: Yeah, that's right. There isn't -- there's the -- you
26 have the droplets, all of them are collected together, and they're amplified

1 altogether.

2 JUDGE OBERMANN: And they never are separated in some way
3 to be amplified. They're just in there.

4 MR. WALTER: For amplification, they are not separated. That's
5 right.

6 JUDGE OBERMANN: I wish you had put this in your petition,
7 frankly.

8 MR. WALTER: It was kind of surprising to get this rebuttal
9 argument from them. So we have addressed it in our reply. And like I said,
10 it's never been disputed. It's never been suggested, it's just untimely or
11 improper.

12 JUDGE CHANG: Let me ask you a question just to -- I just want
13 to clarify. So for Ground 1, let's say we adopt a position that
14 compartmentalization means that it is not the same single volume. By
15 having, you know, divided into multiple droplets, does your Ground 1 then
16 go away? Is it entirely dependent on this claim construction?

17 MR. WALTER: Yeah. It does depend on that. And conversely, if
18 you adopt our construction, I don't think there's a response. I think the
19 response goes away.

20 JUDGE CHANG: Okay.

21 MR. WALTER: And frankly, I think our construction should be
22 adopted. We supported all along the citation to extrinsic evidence. We have
23 un rebutted expert testimony on what the specification means. And that
24 matters.

25 JUDGE CHANG: Okay. And also, just to be clear, so in your
26 Ground 1, your idea -- your position is that for unambiguous detection, it's

1 because you're separating the droplets, most of which contains one single
2 target DNA -- or one single molecule; is that correct? Or is that still
3 dependent on Figure 9, multiple -- different --

4 MR. WALTER: Well, Figure 9 -- we rely upon Figure 9 for
5 Ground 3.

6 JUDGE CHANG: Right.

7 MR. WALTER: And for Ground 3, we rely upon the single
8 droplet as the sample volume. Should I turn to Ground 3?

9 JUDGE CHANG: No. Actually, just to be sure, so for Ground 1,
10 you are relying on the fact that you separate into droplets and you have
11 different DNAs in each droplet. And that's how you're saying it's
12 unambiguously determining multiple analytes with fewer than --

13 MR. WALTER: Yes.

14 JUDGE CHANG: Okay. Got it. Thanks.

15 JUDGE OBERMANN: I have one more question for you on this
16 topic. How can F be one in Claim 1 and 14 if the claim itself refers to a
17 plurality of F wavelength components?

18 MR. WALTER: Well, so let's see if I can put the claim here. I
19 think that -- frankly, I don't think that's a very good argument. Because it
20 doesn't say a plurality of F wavelengths components, it says F wavelength
21 components. They want to use a variable to describe it. And when you use
22 a variable, you're going to default to the plural, and the plural is going to
23 encompass both the singular and the plural.

24 JUDGE OBERMANN: And that's your argument is that
25 components can embrace the singular?

26 MR. WALTER: Yes. Because they use a variable. They want to

1 define it in terms of a variable, said F wavelength components comprises F
2 wavelength components. If you're going to define it in terms of a variable
3 that way, you're going to use the plural so that it encompasses both the
4 singular and the plural. That's the way everybody would do it.

5 JUDGE OBERMANN: Did you argue this anywhere in your reply
6 or your petition?

7 MR. WALTER: I don't think we --

8 JUDGE OBERMANN: Well, we had claim construction briefs
9 that stood alone. Did you argue it in the claim construction briefs?

10 MR. WALTER: Well, the claim construction briefs were only
11 asking about a single sample volume. It didn't ask about this, so I didn't
12 address it there. I don't think we did address this in the brief because I think
13 this argument about the plural wavelength components, I think that only
14 came in the first time in their last brief, to be honest with you.

15 JUDGE OBERMANN: Okay. Well, I'll ask your friend that.
16 Thank you.

17 MR. WALTER: Okay. May I turn to Ground 3?

18 JUDGE OBERMANN: That's fine with me.

19 JUDGE CHANG: And just before you go there, I really do want
20 to -- for Ground 3, I really do want you to address the motivation to combine
21 issue as well as where it is in the petition.

22 MR. WALTER: Well, let's do that. Let's just do that right now.
23 Okay. So I'll just show you where -- this is Dr. Batt's declaration, okay?
24 And --

25 JUDGE OBERMANN: What are we referring to? Are you
26 referring to a slide or to the petition?

1 MR. WALTER: This is Dr. Batt's declaration in support of
2 petition. And this material, it appears at 331, paragraphs 331 to 338, and --

3 JUDGE OBERMANN: That reminds me, we asked you to find
4 out when you were sitting down whether or not paragraphs 337 and 338
5 were actually cited in the petition?

6 MR. WALTER: They were indeed. That's just what I was getting
7 to.

8 JUDGE OBERMANN: Oh, thank you.

9 MR. WALTER: They were cited on page 57 of the petition in
10 support of our ground -- our argument that Larson alone would render the
11 claim obvious. So all this is discussed here. You see in paragraph 332 and,
12 you know, this is what's in the petition. Same argument. Larson teaches a
13 Poisson distribution using limited dilution. Some reactions contain zero
14 DNA molecules, some reactions contain one, and frequently, some others
15 contain multiple molecules.

16 Larson discloses terminal dilution where the vast majority contain
17 either one or zero target. So Dr. Batt explains how both are there, okay?
18 Larson also discloses, described in droplet formation, the invention is
19 compatible for all distributions of DNA loading that can form a limiting or
20 terminal dilution.

21 These disclosures, Larson is explicitly teaching that his assays
22 work when a single droplet contains multiple target analytes. And he cites
23 that. Then he goes on and says, in paragraph 333, Figure 9 shows one such
24 way to accommodate these complications.

25 Okay. And then he shows -- in Figure 9, he shows the three targets
26 here. He shows the figure here. And then Dr. Batt goes on to explain how,

1 using this scheme, you're going to be able to distinguish the different
2 combinations of targets. You see this in paragraph 336. The signals P1, P2,
3 P3, P1+P2, P1+P2, P2+P3, P1, different intensities combination are additive
4 and where each sum to unique values in each of the two colors used. He
5 explains that. That's never -- it's never been challenged.

6 And then he goes on and he explains why there would be a
7 reasonable expectation of success. He tells you, you can do it because it
8 tells you -- the patent tells you, you can handle multiple occupancy. And
9 then he tells you in paragraph 338 why a person would have been able to be
10 motivated to use this. So this is all there. And it's recited on page 57 of the
11 petition.

12 JUDGE CHANG: Okay. So I think Patent Owner's argument here
13 is that you have to consider both, when they say this is not desirable and
14 when they say it is -- you know, it can be done. So I guess the question
15 there is --

16 MR. WALTER: Okay.

17 JUDGE CHANG: -- if they keep telling you that it's not desirable,
18 why would you then go ahead and combine and do this?

19 MR. WALTER: Okay. Because first off, Larson doesn't tell you
20 it's not desirable. It tells you that the invention can accommodate multiple
21 occupancy situations. The main argument that they make for why it's not
22 desirable comes from -- it comes from the -- it really comes from the
23 extrinsic evidence. It really comes from -- okay.

24 They identified a number of challenges that go along when you try
25 to do multiple PCRs in the same reaction. And all of those things is true.
26 You have those challenges. The issue is the people of skill in the art knew

1 how to overcome those challenges. Multiplex PCR, that's doing multiple
2 PCR reaction at the same time, that was known. People knew how to do it.
3 It was a standard technique in the toolkit of the skilled artisan.

4 Now, they pointed to something we said in *Dropworks* to try to
5 establish that this is wrong and this is what they've agreed to for this case.
6 Let's look at *Dropworks*. And I think it would probably
7 (INDISCERNIBLE).

8 JUDGE OBERMANN: We're letting you go over and I will add
9 the time also to your opposing counsel's time.

10 MR. WALTER: Here's the claim from that *Dropworks* case. The
11 first thing I want to note is that this was a claim that said amplifying a single
12 target sequence.

13 JUDGE OBERMANN: What are we looking at, please?

14 MR. WALTER: Okay. So what I'm looking at here, what I'm
15 showing you right now is the petition from that case. And I'm just showing
16 it so you can see the claim.

17 JUDGE OBERMANN: Can I pull it up somewhere? I mean, what
18 are we looking at? Is it on a slide? Is it in a brief?

19 MR. WALTER: It's the petition from IPR2012 -- 2021-00212.

20 JUDGE OBERMANN: Is this the material that's the subject of the
21 motion to strike -- or no, the objections to the demonstratives?

22 MR. WALTER: Yeah. And this is why I said, look, you know, if
23 he's going to -- he raised *Dropworks*. He said, look what they said in the
24 *Dropworks* case. And now, I feel like I have to respond, I have to say
25 something about *Dropworks*. That's what I'd like to do. I think it's relevant.
26 I think it's going to show that --

1 JUDGE OBERMANN: I'll let you proceed. But again, we're
2 holding in abeyance any decision on --

3 MR. WALTER: Okay.

4 JUDGE OBERMANN: -- their objections to this.

5 MR. WALTER: Very good. The claim in this case, it dealt with a
6 single target sequence. So we're talking about claims that deal with single
7 target sequences, okay? It's kind of the opposite situation. So trying to rely
8 upon this doesn't really make a whole lot of sense.

9 But look what Bio-Rad said about the specification in this case.
10 This is the same thing. This is from the Patent Owner's response in this
11 case. They said the '310 Patent also teaches that by detecting combined
12 signal based on both intensity and wavelength, the number of detectable
13 targets may increase multiplicatively.

14 One embodiment, for example, the '310 presents a detailed method
15 where up to nine targets may be detected using two colors by measuring the
16 relative intensity values of both colors. That's the paragraph 129 stuff.
17 That's what we're saying about this five years ago. And then let's look at
18 this. Let's look at -- what I'm showing you now is the expert declaration.

19 This is an expert, this is Dr. Weigel's declaration. This is Exhibit
20 1002 from this IPR. Dr. Weigel is their expert now. It's Caltech's expert.
21 They're relying upon him. In this tribunal in another IPR in the '797 Patent,
22 they didn't like Dr. Struhl based on his performance in this case. So they're
23 switching to Dr. Weigel. And they're relying upon him in the District Court.
24 He submitted this declaration many years ago. Let's look at what he says.

25 JUDGE OBERMANN: I'm going to let you know that I'm only
26 going to let you go five minutes over. So you're at 3:26 --

1 MR. WALTER: Okay.

2 JUDGE OBERMANN: -- you have a minute and a half.

3 MR. WALTER: Okay. He says -- he quotes the '310 Patent. He
4 says, terminal dilution, the vast majority of reactions contain either one or
5 zero target DNA molecules and acknowledges that some reactions may
6 contain multiple molecules following the partition of the Poisson
7 distribution. He goes on and he talks about other disclosure in the '310
8 patent, same specification.

9 And he says, methods for non-Poisson loading of droplets are
10 known to those familiar with the art and include, but are not limited to,
11 active sorting of droplets. The description of the (INDISCERNIBLE)
12 assumes Poisson loading of droplets, but such description is not intended to
13 exclude non-Poisson loading. So they're contemplating other types of
14 loading of droplets. But look what he says here.

15 JUDGE OBERMANN: Which slide are we on?

16 MR. WALTER: This is not a slide. I don't have slides because
17 they put this in with their demonstratives and I didn't know they were going
18 to use this because it suddenly popped up in their sur-reply brief.

19 JUDGE OBERMANN: I see.

20 MR. WALTER: So I have to -- this is all I can do.

21 JUDGE CHANG: So this is exhibit -- sorry, can you repeat the
22 exhibit number?

23 MR. WALTER: This is Exhibit 1002 from the *Dropworks* IPR.
24 This is the expert they're relying upon. Now, this is my last point. Look at
25 what he says here, multiplex PCR was known in the art to be compatible
26 with digital PCR techniques. This is what he's saying five years ago.

1 Paragraph 74, the multiple types of PCR at the same optical scan described
2 above is used to assess multiple different target molecules, either in the same
3 reaction volume -- or in parallel in the same reaction volume.

4 All the challenges that they're pointing out that say that the Larson
5 doesn't teach, that they're saying would render it obvious, he's telling you
6 this was known. Their expert is what they're relying upon now. It's telling
7 you what was known. Running PCR on multiple targets at once in the same
8 reaction vial was known to those of ordinary skill in the art as a routine and
9 conventional way to increase the efficiency of PCR assay.

10 So this argument they're making about, hey, you didn't deal with
11 the drawbacks, well, their expert in this case, Dr. Struhl, he says everybody
12 knew all the competencies, including multiplex PCR. And in the *Dropworks*
13 case, the expert that they like now said the exact same thing. So we're all are
14 now in the obviousness --

15 JUDGE OBERMANN: Okay. You are now coming up on six
16 minutes. So I'm going to ask you to please wrap up.

17 MR. WALTER: And that was my final point, unless there's further
18 questions.

19 JUDGE CHANG: So just one quick point. This is not an exhibit
20 in this case. Is that what you're saying? This is an exhibit in the previous
21 Bio-Rad IPR, so it's not an exhibit in this case?

22 MR. WALTER: That is correct.

23 JUDGE CHANG: Okay.

24 JUDGE OBERMANN: But did I hear you say that Patent Owner
25 cited it in their sur-reply?

26 MR. WALTER: No, they did not. They brought in the

1 *Dropworks*. What they did was they picked the parts they liked from the
2 Patent Owner's response and then they left out the rest of the context.

3 JUDGE OBERMANN: But did they cite from the prior IPR?

4 MR. WALTER: Yes. They did -- when I say sur-reply, it means
5 sur-reply claim construction brief.

6 JUDGE OBERMANN: Okay. And then you, in your main brief,
7 your main sur-reply, brought this evidence in from the prior IPR into the
8 main brief?

9 MR. WALTER: No. We never brought this. This is the first time
10 we're mentioning this. And the first time we're mentioning this is because
11 the first time we saw *Dropworks* was in their sur-reply claim construction
12 brief. So we didn't have any slides on it. And so now, we see slides on it.
13 Now, I feel like I've got to respond --

14 JUDGE OBERMANN: Oh, I see.

15 MR. WALTER: -- because I'm trying to make it a key point.

16 JUDGE OBERMANN: I gotcha. Okay. Yeah. So in other words
17 --

18 MR. WALTER: That's why I want to respond because they kept
19 -- they selected the parts selectively from *Dropworks* and I've got to put in
20 the rest of the context.

21 JUDGE OBERMANN: I got you. So they actually did put in
22 some material from that prior proceeding. They didn't just -- you know, did
23 they put in an exhibit in their claim construction brief from the prior IPR?

24 MR. WALTER: What they tried to do was they tried to just cite to
25 the docket and said, hey, it's okay because we're just citing the docket. That
26 was Mr. Salen's argument before we started the oral argument here today.

1 JUDGE OBERMANN: I gotcha. Okay.

2 MR. WALTER: Okay. Any further questions?

3 JUDGE CHANG: Not for me. Thank you.

4 JUDGE OBERMANN: Okay. I let you go for by seven and a half
5 minutes. So I'm going to put 27 and a half minutes on the clock for Mr.
6 Salen. Hopefully, you won't need it all. But let me just put that on the
7 clock. And then when you're ready to begin speaking, I will begin the clock
8 running.

9 MR. SALEN: Sure, Your Honor. Thank you. I think just to start,
10 I'd like to address -- I'm not going to do this with a slide. I just want to talk
11 briefly about the single sample volume. My colleague made some points
12 about the fact that there's some disclosure in -- again, the first part was on
13 their Slide 30 that there's disclosure of this vial, that it's kind of drawn in a
14 schematic on Slide 30 of Bio-Rad's presentation. And that shows a
15 collection of droplets.

16 And in each of those droplets, there's potentially some analyte -- or
17 not analyte, and there's other chemistry and that's what we call probes that
18 exist in those droplets. And so after those droplets are made, the thermal
19 cyclers run on those, and a reaction occurs within each of those droplets.
20 That's what they're showing in the infringement contention -- in our
21 infringement contentions that really have been amended since then.

22 But in addition to that, that thermal cycling that's happening, they
23 say, oh, this is also disclosed in Larson. This is exactly the same thing that
24 Larson discloses. And you can have a sample what they call -- and I don't
25 know how you say it's a single sample, but they're saying it's a single
26 sample, and then you divide it up into several other sub-samples, these little

1 droplets. Each of those then contains analytes. And in those droplets, the
2 reaction is run -- a thermal cycle is run, and a reaction occurs in each of
3 those droplets.

4 And to be clear, the claim language is clear on this. So maybe I
5 think we can just go back, because I just want to make this point one more
6 time. I think it's important just to highlight, we're not focused on extrinsic
7 evidence. We're not focused on what an expert said here.

8 We're just focused simply on the claim language that says wherein
9 the analytes -- this is on Slide 16 of our Patent Owner's demonstratives,
10 wherein the analytes are amplified in the single sample volume. Certainly, if
11 Petitioner meant that this could happen across several -- I'm sorry, Patent
12 Owner meant that this could happen across several different shot glasses that
13 have been where the water has been poured out of each of the eight glasses
14 -- these different shot glasses, whether or not you heat one of those up or
15 five of those up to get your hot water, the reaction is occurring in each one
16 of those glasses.

17 In other words, the analytes in this case -- we're talking about now
18 from the analogy back to the droplet creation, the analytes inside each of
19 those droplets are thermally cycled, and a reaction occurs within each of
20 those droplets. And I think there is a question about, well, are those always
21 together? No, they're not always together.

22 And it's clear from the specification of Larson when it explains
23 how this works in the prior art in Larson that they're citing and relying on, if
24 you look at Figure 3, Figure 3A, 3B, and 3C, and the description that
25 surrounds those, it tells you that each -- and after the reaction is performed,
26 these droplets are pulled out and they're analyzed individually. Each one's

1 interrogated by a laser. And this is what's shown in Figure 3C of Larson.

2 And so each one of these droplets has individual significance. And
3 certainly, the claim language, when you talk about being able to do this
4 entire claim within a single sample volume, and it's the same single sample
5 volume where the analytes are amplified, it doesn't make any sense to say,
6 oh, but that could read on multiple of these sample volumes because the
7 reaction is being performed across a vial. And even though there's millions
8 of little reactions that occur inside each of these different droplets, it's really
9 one big single sample volume.

10 And I think that's a big stretch based on what the claim language
11 and explaining what the claim language says. And when you read that claim
12 language on Larson, Larson again was clear in paragraphs 44 and 45 that
13 we're not talking about a single reaction that occurs in one big sample
14 volume that's been partitioned. We're talking about millions of single
15 molecule PCR reactions to be performed in parallel.

16 So these reactions are occurring at the same time. Each of these
17 droplets has a reaction occurring in it if it has an analyte in it to be amplified.
18 So that's the first point on single sample volume that I wanted to respond to.
19 Maybe I'll stop --

20 JUDGE OBERMANN: I'm sorry. No. Actually, I just have a
21 question. Because what you're saying makes sense to me. But I feel like it's
22 pulling in the other part of the claim. And please explain it to me if I'm
23 incorrect or what your position of this is. But if you truly have an F of -- an
24 F equal to one, if claim -- if for some reason your friend is correct and that
25 wavelength components embrace as the singular F, which would mean that
26 M is two, which means we have at least two targets in our sample that

1 eventually is amplified.

2 If that's true, when you have a single one -- well, if you were to
3 have a sample that -- you know, a shot glass that has a single one, you're not
4 able to tell the presence or absence in that sample, which is the shot glass,
5 what's there and what's not? In other words, does that bring in the earlier
6 wherein clause about the capability of unambiguously detecting the presence
7 or absence of each M in any combination of presence or absence? Can you
8 do that? For example, in the embodiment that I understand is from your kit,
9 but in Petitioner's Exhibit 30, is that possible when you have one analyte in
10 each bubble or each droplet?

11 MR. SALEN: Okay. So if there's only one analyte in each
12 droplet, then this -- the whole claim -- the whole prior art reference falls
13 apart because there's no way you would have M analytes -- even if it's two,
14 okay, there's only one. But I think I understand what you're saying, assume
15 that F is one, for argument's sake; is that right?

16 JUDGE OBERMANN: Yeah. Assume that F is one --

17 MR. SALEN: Okay.

18 JUDGE OBERMANN: -- that makes M at least two, because M
19 has to be greater than F, right?

20 MR. SALEN: Yeah, that's right. And in that situation, I think
21 what -- the only evidence that we've looked at is Figure 11 from Larson that
22 the Bio-Rad or Petitioner has pointed to is Figure 11 from Bio-Rad that says,
23 hey, look, you can distinguish between -- and the point is the claim says you
24 have to be able to distinguish between all of the analytes -- all of the M
25 analytes in any combination of presence or absence, so that means zero, one,
26 or both.

1 JUDGE OBERMANN: Right.

2 MR. SALEN: And the only place where there's evidence of trying
3 to distinguish between both of them versus one or the other in any of the
4 prior art exhibit is Figure 11. And Figure 11, the problem is the whole
5 disclosure that they point to for Figure 11 as to why you can distinguish
6 between -- you can identify the presence of two or a multi-occupancy
7 droplet that has both targets in it is a statement in the specification that says
8 there might be a peak here. But you can't see it. And Figure 11 doesn't
9 show it.

10 And so a person with ordinary skill in the art looking at Figure 11,
11 it doesn't teach you how to actually distinguish that. And I think that's the
12 point. Even in the situation where F is one, Larson doesn't tell you how to
13 distinguish between these different combinations unambiguously.

14 JUDGE OBERMANN: Aren't there more than three
15 combinations? It could be if M is two, you could have none, you could have
16 A, you could have B, you could have AA, or you could have BB. Aren't
17 there five possibilities that you need to be able to resolve?

18 MR. SALEN: Your Honors, no. Really, AA and BB don't really
19 happen because of the way that the reaction occurs. You're either going to
20 have A --

21 JUDGE OBERMANN: Oh, okay.

22 MR. SALEN: -- or you can have B or you can have A+B or you
23 can have zero. So I think there's --

24 JUDGE OBERMANN: Oh, okay. So if there's two Ms, you only
25 need to identify the presence of one of them to meet this claim.

26 MR. SALEN: You have to be able to distinguish between those

1 four different scenarios.

2 JUDGE OBERMANN: What if four -- none --

3 MR. SALEN: A --

4 JUDGE OBERMANN: B.

5 MR. SALEN: B, or A and B.

6 JUDGE OBERMANN: Okay. And you're saying that Larson can't
7 do that. Why?

8 MR. SALEN: Larson doesn't teach you how to do that.

9 JUDGE OBERMANN: Right.

10 MR. SALEN: It explains that that scenario could happen. It says,
11 yeah, there might be this small peak in Figure 11, but it doesn't show it.

12 JUDGE OBERMANN: And we -- okay.

13 MR. SALEN: It doesn't tell you that -- anyone is actually -- and so
14 I would tell you it's not enabled prior art.

15 JUDGE OBERMANN: And which paragraph does Larson
16 describe that for Figure 11?

17 MR. SALEN: I think that was -- if I'm correct, I believe that's in
18 here. I have a slide on it, Your Honor. It's in their slides as well, but --

19 JUDGE CHANG: While you're locating it, can I just -- looking for
20 it, let me just ask a question. I remember Larson does say that it's not shown
21 at this scale. But wouldn't a skilled artisan just change the scale? I mean, I
22 think the reason it's not shown is because one of the peak is so large that you
23 can't really -- like, it wouldn't make sense. Like, the figure would be huge.
24 But can't you just change the scale and you'll be able to see all three?

25 MR. SALEN: So Larson doesn't tell you how to do that is I think
26 the point. So yeah. So this is the cite. So this is Figure 11A, it's paragraphs

1 130 through 31. And again, this is subject to our motion to strike because
2 this was never raised in the petition, never argued or discussed. And we also
3 think that the parties have already agreed, at least in the petition phase and
4 with the Board, that F is two and the language is right.

5 But if you get past all of that and say, okay, well, F could be one
6 and Larson tells you how to distinguish these things. But the Figure 11
7 doesn't actually show it. It just tells you that there's -- hey, there's probably
8 this peak here, but it doesn't actually show you how to distinguish that peak.
9 So even if a skilled artisan will know, okay, well, I can increase the
10 resolution, Larson doesn't tell you what resolution do you actually need to
11 increase it to.

12 How can you actually determine if there's a peak there? How big
13 does it have to be to get beyond the noise? And really, the whole point of
14 Larson is to say, hey, there's going to be these situations where there's some
15 noise out there where you have potentially droplets that have multiple
16 analytes in them. And we just ignore the noise and we dilute the sample
17 enough so that you get a really strong signal when you have target A, and
18 you get a really strong signal when you have target B in a droplet.

19 But in the case where you have targets A and B in the droplet,
20 we're going to dilute the sample enough so that we're not seeing those.
21 We're only going to have single occupancy so that there's a very small peak,
22 exactly what it's saying here. There could be a small peak, but we're not
23 looking at it. And then Larson teaches you that there's problems when you
24 have multiple molecules in the same droplet.

25 Okay. So Your Honor, is that -- do you have more questions on
26 this?

1 JUDGE CHANG: Yeah. No. I understand what you're saying. I
2 guess what I understand Larson to be saying is that the reason it's not shown
3 on the scale is not because it's, you know, indistinguishable from the noise.
4 I think what they're saying is because one of the peak is so large, the one that
5 has a single molecule -- the two that has single molecule, that if you actually
6 try to show the small peak, it will kind of block the figure tremendously.

7 And that's why they're not showing it. But I don't -- at least I'm not
8 understanding them as saying it's indistinguishable from the noise. Because
9 otherwise, they wouldn't say there's a small peak there; is that fair?

10 MR. SALEN: That's fair, Your Honor. I think my point wasn't -- I
11 think I was making two different points. I wasn't trying to say that that's
12 why the small peak is not visible. But I think the point is, and it's just a fact,
13 Larson doesn't show you that peak. It doesn't tell you how big it is. It
14 doesn't tell you how -- when it gets big enough that you can say it's there. It
15 doesn't tell you these things.

16 And if it doesn't tell you those things, they're not evidence in this
17 case. It's enough to say, what we haven't shown you in a patent is that we
18 can do anti-gravity. And therefore, anti-gravity -- but you could, we're just
19 not showing it to you. I think it's the same issue here. They're telling you,
20 yeah, there's probably a peak there, but we're not going to show it to you.

21 So how are we supposed to know what Larson's actually teaching
22 us if they're saying there's something that's not there? So I think that was the
23 point, Your Honor.

24 JUDGE CHANG: Okay. Thank you.

25 MR. SALEN: And just to go on this obviousness argument
26 because I think we're clear -- everyone's, for the most part, agreed that F

1 really is plural. I've heard my colleague say, well, no, there's a situation
2 where you can read this differently. But they never argued it in the petition.

3 And just to be clear, I think the reason that was presented was, hey,
4 that's because we never argued in the petition and then we never argued it in
5 our reply because the Patent Owner didn't bring it up in the Patent Owner
6 response. And that's not true, Your Honor. The Patent Owner did bring it
7 up in the Patent Owner response. So I believe that's -- on my note, I'll just
8 -- here, so this is on page 12 of paper -- of the Patent Owner response, which
9 is I believe -- is that Paper 17? Is that right?

10 There's a Patent Owner response in this slide, Your Honor, I just
11 had a misnumbering on my papers. There's a description of what -- in this
12 statement of F being greater than or equal to two and the different reasons
13 why it's greater than or equal to two and --

14 JUDGE OBERMANN: Are we looking at page 17 of the
15 response?

16 MR. SALEN: No. Page 12, Your Honor.

17 JUDGE OBERMANN: Thank you.

18 MR. SALEN: So I would cite there -- but then I would also bring
19 up the point that the reason that we didn't address it even more -- in more
20 detail in the Patent Owner response is because it wasn't in the petition. The
21 petition started off with F equals 2 and M equals three, that's -- and that's
22 what they're trying to explain that Larson shows in Figure 9.

23 That was the whole point of the petition. And that's what the
24 Board looked at, at the first institution decision. And that's what we were
25 responding to in our Patent Owner response. So we thought we were just
26 confirming something that everyone had already agreed on. The argument

1 about F being only one and about it being, oh, this is a variable, so you can
2 read it differently than plain English, that argument has never been made by
3 anybody until today.

4 So Your Honor, that's just not on the record. And we talked about
5 something being unrebutted. I think that here, there's unrebutted evidence
6 that in this plural form that F -- that the language requires F to be two. So
7 I'd like to -- are there questions on -- more questions on F?

8 Okay. So I would like to just briefly talk about the motivation to
9 combine. And I think this is going to be my last few points here. So we
10 went through this with Dr. Batt. And I think that the issue here is -- so this
11 is from the Enfish case. So the whole argument about -- that Petitioner has
12 made about combining Larson with Saxonov and its -- I'll talk about Ground
13 3 in two parts because I think there's a single reference obviousness
14 statement in Ground three, and then they say there's also a combination with
15 Saxonov in Ground 3.

16 And I think my colleague corrected us at the beginning to make
17 sure that was clear. And we agree with that. But that's the statement -- so
18 let me just talk first of all about the Saxonov combination. Now, we don't
19 think Saxonov should ever even be considered at this point because as we've
20 stated, it's not prior art. And they've introduced new evidence that's the
21 subject of our motion to strike as part of Saxonov.

22 That aside, the whole argument -- the whole motivation to combine
23 Larson with Saxonov that we've seen anywhere from Dr. Batt or from
24 Petitioner is that they're the exact same disclosure. And they're referring
25 specifically to Saxonov's Figure 4 and Larson's Figure 11, both, you know,
26 or I should say neither of which were ever mentioned in the petition for this

1 purpose and certainly not a motivation to combine.

2 But the argument that they made in their reply is, hey, look, you
3 would combine -- you'd be motivated to combine Larson's Figure 11 and
4 Saxonov's Figure 4 to get to the invention because they disclose the same
5 thing. That doesn't make any sense, Your Honor. And the Federal Circuit
6 has told us we can't do that. Assuming that references are similar, that's not
7 sufficient to give motivation to combine.

8 And particularly, if they're the same thing, why would we modify
9 Saxonov or Larson? Why would you modify Larson to fix something or to
10 change something with Saxonov when Saxonov just discloses the same thing
11 as Larson, according to the Petitioner? So we asked Dr. Batt about this in
12 his deposition. Is there any shortcoming of the methodology for determining
13 multiple targets in a single wavelength that are thought by Larson, I should
14 say taught, taught by Larson that Saxonov cures?

15 The answer is, as I stated before, I haven't done that analysis and I
16 haven't compared those two at that level of question. Confirming this last
17 question, and you don't have any opinion about any particular shortcoming
18 of the methodology disclosed in Saxonov that you believe Larson cures,
19 correct? I haven't done that analysis.

20 So Dr. Batt didn't consider whether or not there was a reason to
21 combine these two references. He didn't do it. He didn't think about it. He
22 just said they look the same.

23 And then I think it's really important just to highlight another point
24 here which is -- and we talked about this briefly before I hit on it, but I don't
25 think I have the case, and this is the *Arctic Cat* case that the Federal Circuit
26 said that the Board - in our analysis, all of us should weigh the benefits and

1 drawbacks of the modifications against each other to determine whether the
2 review of motivation to combine.

3 And Dr. Batt was asked about this. Did you consider any of the
4 droplets? I'm on Slide 41. I want to make sure we're on the record with that.
5 Question, when discussing the reasonable expectations of success, you didn't
6 discuss any of the downsides that Larson teaches with respect to determining
7 multiple analytes in the droplet, correct? The answer, is that my
8 responsibility?

9 I'm saying -- as I said here, a POSA would have a reasonable
10 expectation of success. It goes on later on in that same answer. And your
11 expectation is that I'm going to sit here and discuss why it's not going to
12 work? Is that what you're asking me to do? And the question, you didn't
13 account for any of those reasons why it might not work, correct? Answer,
14 right. And that's on the record.

15 And just to go back to what are the shortcomings? Again, and we
16 looked at the slide earlier, but this is Slide 35, and I think it's really
17 important. This isn't just Dr. Batt testifying about what he thinks, but he's
18 testifying about what he understands Larson to have taught. And there's a
19 series of questions that Dr. Batt answered where he went through multiple
20 shortcomings of doing multiple occupancy of modifying Larson and
21 -- because that's the modification that the Petitioner is asking us to make,
22 say, okay, assume for a second that we're right, F equals two, M equals
23 three.

24 Well, I think we're good with that. And that single sample volume
25 is a droplet because that's where the reactions occur.

26 JUDGE OBERMANN: Is this from -- this is Patent Owner's

1 demonstrative 35?

2 MR. SALEN: This is Patent Owner's demonstrative 35.

3 JUDGE OBERMANN: Thank you.

4 MR. SALEN: With that all in mind, the argument under Ground 3
5 for the single reference argument -- obviousness is that a person of ordinary
6 skill in the art would have allegedly been motivated to modify the Larson
7 reference to make it a multi-occupancy scenario where you have lots of
8 molecules, M equals three, at least three of them in each of these droplets or
9 in some of the droplets.

10 And you could unambiguously determine which of those -- all of
11 those combinations. And by the way, we talked about four being the case
12 for two targets. But when you start adding more analytes is -- you go up in
13 powers of complexity and how hard it is to distinguish between these things.
14 So when you get up to 8, for example, there's 256 different possible
15 combinations that you can have that the '921 Patent teaches you.

16 And you have to distinguish all those unambiguously. So Dr. Batt
17 answering questions about why there are shortcomings in Larson -- or why
18 Larson teaches shortcomings, he says -- question, Larson describes several
19 downsides of detecting multiple analytes in a droplet; is that correct?
20 Answer, as a general statement, yes. And that includes bias from allele
21 specific PCR; is that correct?

22 That's correct, yes. And one of the downsides Larson describes
23 with detecting multiple analytes is a droplet bias -- this is bias from
24 competition because different amplicons -- specific amplicons, correct?
25 Answer, it states specifically, these results in varying yields between
26 different -- I'm sorry, these results in varying yields between competing

1 amplicons, which can result in a non-uniform amplicon yield.

2 He goes on, it is a complexity, correct? Yes, it's a consideration.
3 Paragraph 123 of Larson, Larson describes another challenge as a possibility
4 of cross reactivity, correct -- or sorry, as a possibility of cross reactivity,
5 correct? And the answer was yes. I don't like the word cross reactivity, but
6 yes. And the last question, and Larson, in paragraph 129, describes the
7 downside of an error that results from overlapping probes, correct? Yes, it
8 does speak to overlapping, yes.

9 Dr. Batt didn't consider any of these downsides or tell you why his
10 -- or his combination or modification to Larson would have addressed any of
11 these. Larson, in fact, teaches away from using multiple occupancy droplets,
12 which is something that the '921 Patent resolves.

13 So with that, Your Honor, I just would like to end on the claim
14 language itself, unless there are other questions.

15 JUDGE CHANG: Yeah. I do have actually just two questions,
16 one very fast. So same thing I asked the Petitioner. So if we were to adopt
17 the Petitioner's argument that the compartmentalized droplets are basically
18 the same single volume, would you say then that we should rule for
19 Petitioner in Ground 1 in terms of anticipation? Is that dispositive in the
20 claim construction?

21 MR. SALEN: So Your Honor, I don't think I would concede that
22 it's dispositive because I think that what's missing from the Larson reference
23 is a teaching that you have to do all of these things in combination. I think
24 this is the problem. Petitioner had the burden of showing not just that one of
25 these claim limitations happens, but that all of them are taught by Larson.

26 And Larson just doesn't teach you how to do each of these

1 limitations where you code M analytes to a value of the fluorescent signal.
2 It doesn't tell you that you can unambiguously detect the presence or absence
3 of each of those M analytes in any combination, any combination of
4 presence or absence in the combination.

5 Again, if we have three -- now, we're three to the second, so that's
6 eight different -- did I get that right? I'm sorry. Or maybe it's two to the
7 third. Sorry. It's eight different combinations. And then you have to detect
8 presence or absence of each of those different combinations, right, in
9 -- within the single sample volume. So we disagree very strongly that same
10 -- I don't think it's a claim construction issue because single sample volume
11 here we agree with the construction.

12 We just disagree with how you read it on the prior art because of
13 that wherein clause at the end. But even if you were to take the position that
14 Larson somehow teaches that you can do is -- a reaction in a single sample
15 volume that's been partitioned, we still don't think Larson teaches all of these
16 claim elements and how to unambiguously distinguish between each of the
17 different targets in any combination of presence or absence in that single
18 sample volume.

19 JUDGE CHANG: Okay. So the next question -- I'm going to try
20 to be fast, we have about a minute left. But if you go to your demonstrative
21 28, that's Figure 9A, I think, from Larson. I just want to make sure I
22 understand. It's 28, and I'll just ask my question. Do you agree -- so I think
23 I began in your earlier presentation asked -- the claim only requires
24 something that's capable of ambiguously detecting. If you look at Figure 9,
25 would you agree that this teaches you how to unambiguously detect three
26 target sequences using two fluorophores, or do you think it does not teach

1 you that?

2 MR. SALEN: I don't think it teaches you how to do that in any
3 combination of presence or absence. There's a missing combination.

4 JUDGE CHANG: Okay. If you go to -- very quickly, go to 31.
5 So if you look at -- sorry, 31.

6 MR. SALEN: Oh, on my slide.

7 JUDGE CHANG: So in these, you see four different clusters. Are
8 there droplets that's duplicates in each of these four clusters? Because
9 basically, some droplets will have the same -- well, it's a single molecule but
10 will have two different targets. And that's what is shown in each of these
11 -- like, there might be multiple droplets represented in these clusters. Am I
12 understanding that correctly?

13 MR. SALEN: No, Your Honor. What's shown here are only the
14 single molecule, single occupancy droplets, because where you would have
15 multiple droplet -- multiple occupancy droplets is somewhere in between
16 -- so if you look at the 125 to 150 intensity in the VIC scale, that's where the
17 first cluster -- do you see that cluster there --

18 JUDGE CHANG: Right.

19 MR. SALEN: -- that's sitting on the left? And then if you look at
20 the -- about the 200 intensity in the FAM scale, you'd see a cluster there.
21 But what's not shown is what happens when you have both of those targets.
22 You would expect that there's some cluster somewhere sitting in space in
23 between FAM and VIC that has both of those in there, and you don't see it.

24 JUDGE CHANG: Okay. Because target one, it seems like in
25 Figure 9, it has one molecule with three targets on it. And if you have one
26 molecule with three targets on it, each of them has a single color, right? So

1 why would there be -- if you have both target 1 and target 2, why would you
2 have something in the middle as opposed to --

3 MR. SALEN: I'm sorry, you're saying target 1 and target 2 are in
4 the same -

5 JUDGE CHANG: Yup.

6 MR. SALEN: Well, it doesn't tell you how to -- maybe, I don't
7 know. So I think the answer is I don't know.

8 JUDGE CHANG: Okay. Thank you.

9 MR. SALEN: Okay. All right. Your Honors, I don't have
10 anything further. So I just would encourage you to look at the claim
11 language because that's where we should focus.

12 JUDGE OBERMANN: Thank you very -- oops, thank you,
13 Counsel. I'm just going to pause for a second to make sure neither of my
14 panelists have any further questions for anyone. No? Okay. Well, with
15 that, thank you, Counsel. We really appreciate your level of preparedness
16 today. Your presentations were very helpful. The case is submitting
17 -- submitted and the hearing is concluded.

18 (Whereupon, the above-entitled matter went off the record at 3:39
19 p.m.)

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