

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BOEPI CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2023-00442
Patent 10,130,681 B2

Record of Oral Hearing
Held: April 19, 2024

Before: JOHN G. NEW, SUSAN L. C. MITCHELL, and
ROBERT A. POLLOCK, *Administrative Patent Judges.*

APPEARANCES:

ON BEHALF OF THE PETITIONER:

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Dulany Street, Alexandria, Virginia.

P R O C E E D I N G S

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JUDGE NEW: Good afternoon, everybody, welcome to the Board. It's nice to see you all again. I'm Judge New. I'm joined here by my colleagues, Judge Mitchell, and Judge Pollock. And we're convened this afternoon to hear oral arguments in the matter of IPR 2023-00442, *Samsung Boepis, Company, Limited v. Regeneron Pharmaceuticals*. We note that IPR 2024-00201, Biocom Biologics and Regeneron Pharmaceuticals has been joined with this case.

This hearing relates to Claims 1, 3 to 11, 13, 14, 16, 24, and 26 of U.S. Patent Number 10,103,681 B2. We'll begin this afternoon by asking counsel for the parties to introduce yourselves. When doing so, please spell your name for the court reporter. And we'll begin with counsel for Petitioner, Samsung.

MR. TRAUPMAN: Good afternoon, Your Honors.

Matthew Traupman of Quinn Emanuel on behalf of Petitioner, Samsung Boepis. Traupman is T-R-A-U-P as in Paul, M-A-N. And with me today are my colleagues from Quinn Emanuel Landon Smith, and Elliot Choi.

JUDGE NEW: Welcome, Mr. Traupman. And counsel for Patent Owner, Regeneron?

MS. FISHMAN: Good afternoon, Your Honor. Deborah Fishman of Arnold and Porter on behalf of Patent Owner, Regeneron.

With me today are my colleagues Abbigail Struthers, and Alice Ho, also of Arnold and Porter on behalf of Regeneron. If I might just correct

1 the record, I do not believe there's any joinder proceeding joined to this IPR,
2 Your Honor.

3 JUDGE NEW: Two of them are joined – I will double check
4 the record on that. Thank you very much. Nice to see you again, Ms.
5 Fishman.

6 MS. FISHMAN: Thank you, Your Honor.

7 JUDGE NEW: Thank you. So, consisting with our joint
8 hearing order, each party has a total of 30 minutes for its presentation for a
9 total of 60 minutes for both parties. Petitioners may reserve a portion of up
10 to 10 minutes of their time to respond to arguments presented by the Patent
11 Owner.

12 And Patent Owner has been also been authorized to reserve
13 similar apportionment of time for their rebuttal. I ask you to be mindful that
14 the court reporter is transcribing this hearing. And so, when referring to a
15 particular demonstrative, please clearly identify it by slide number. That's
16 very important for the record so that it will be reflected in our transcript.

17 Please remember that this hearing is open to the public and that
18 the parties are to refrain from disclosing any confidential information during
19 the hearing and confidential information in a demonstrative exhibit. We are
20 in receipt of the parties' objections into evidence and Motions to Exclude
21 Exhibits.

22 However, we will reserve ruling upon the objections and the
23 motions at this time. We will subsequently later. And now, counsel for
24 Petitioner, you may proceed with your arguments after indicating the time
25 you'd like to reserve for rebuttal.

1 MR. TRAUPMAN: Thank you, Judge New. I would like to
2 reserve eight minutes of rebuttal, please. Let me show our slides I'm
3 presenting. Good afternoon, Your Honors, thank you for your time today.
4 I'm going to try to move expeditiously through the slides today. If we can
5 go to the next slide? As Your Honor mentioned, this is about the '681
6 patent. And here we have a bit of a lag, my apologies.

7 JUDGE NEW: Counsel we have the slides on our screen --

8 MR. TRAUPMAN: Yes, I --

9 JUDGE NEW: -- so, if you just want to call out the number of
10 the slide, we're happy to follow along.

11 MF. TRAUPMAN: Sure, if we go to Slide 2 -- if we could just
12 go to Slide 3, please? This is just a representative claim of the '681 patent as
13 Claim 1. Your Honors, I know, are very familiar with the general subject
14 matter of this claim. It's very much identical to what's been adjudicated
15 prior.

16 Of course, the key focus of this proceeding is what's in green,
17 the exclusion criteria recited in the claim. And if we go to the next slide,
18 Slide 4, just to show the ground, or the sole grounds that are presented in the
19 petition.

20 Of course, there's the Dixon reference which, again, I know
21 that Your Honors are very familiar with along with three additional
22 references, the CATT Study, MACTEL Study and the PIER Study.

23 If we can go forward two slides to Slide 6, as I mentioned, I
24 know the subject matter is very similar. As a matter of fact, the Claim 1 of
25 the -- this challenged '681 Patent here is identical to Claim 1 of the '338

1 Patent, which the Board previously found as anticipated by the Dixon
2 reference that the sole difference being the exclusion criteria that are recited
3 in Claim 1.

4 And we understand, we got the email from the Board yesterday
5 about the issue of claim construction, I'd like to -- of the exclusion criteria
6 and whether or not the exclusion criteria are to be given patentable weight.

7 Of course, our petition was presented agnostic on this point.
8 We filed it before the Board had even issued its institution decision in the
9 prior proceeding on the '681 Patent, which, of course, means it was before
10 the final written decision. It was also before Judge Kleeh in the Northern
11 District of West Virginia had issued his claim construction order on similar
12 limitations, again, related to exclusion criteria.

13 Of course, we appreciate that the Board -- both the Board and
14 Judge Kleeh have determined that the exclusion criteria are not to be give
15 patentable weight. And certainly, we agree with that position, and we
16 believe that, you know, the rationale adopted by the Board and Judge Kleeh
17 is appropriate and the exclusion criteria should not be given patentable
18 weight.

19 We're happy to address that in response to the Board's email
20 yesterday if additional briefing would be helpful on that point, we're happy
21 to provide additional briefing, although, to be frank, I'm not sure how much
22 additional ink could be spilled on this point beyond what's already been
23 presented. But again, we really look for the guidance from Your Honors as
24 to what you believe the most efficient way possible is.

25 I do believe, if we were given additional briefing on this point,

1 we would make the point that, consistent with the other claim constructions,
2 be believe collateral estoppel applies in this situation for the same reasons
3 some of the other constructions, which were also previously adjudicated by
4 the Board as set forth in our -- both our petition and our reply.

5 JUDGE NEW: Mr. Traupman, I read that portion of your brief
6 concerning collateral estoppel and I'm wondering if it really applies to this
7 case insofar as we don't have a decision yet from the Federal Circuit on
8 either the '881 Patent or on the -- of the '881 IPR or the 1225 IPR which
9 were these claims and the same patent.

10 And since the final decision hasn't yet been reached in that, it
11 has been appealed ffrom the Board, the Federal Circuit is going to hear it
12 and presumably rule on it. It seems to me that Federal Circuit case law says
13 that a final decision hasn't really been reached on that yet and, therefore,
14 collateral estoppel can't be brought into play.

15 MR. TRAUPMAN: Well, I believe Your Honor would be
16 talking about the United Therapeutics case when you're talking about the
17 Federal Circuit case law. And if that's the case, we would respectfully
18 submit that this is a different procedural posture than what was at issue in
19 the United Therapeutics.

20 In United Therapeutics, that was an appeal from a District
21 Court case with a parallel IPR proceeding. And which case, the Federal
22 Circuit said, and this is really reflected in the procedure as to how an IPR
23 progresses, the claims aren't actually cancelled in that case, thereby creating
24 the preclusive effective which is what the Defendant was looking for in that
25 District Court proceeding that then was appealed to the Federal Circuit.

1 The Notice of Cancellation -- the Certificate of Cancellation is
2 an issue until either the time for appeal runs or the Federal Circuit mandates
3 the issues. That's not the situation we have here, Your Honor, in that
4 there's -- this is not a question of applying -- we're not asking collateral
5 estoppel because these claims are invalid.

6 I understand that the Board has already found the challenged
7 claim is invalid in the 1225 IPR involving Mylan. But the collateral
8 estoppel that we're looking to have applied is the claim's structure issue,
9 which is not the same as the cancellation of the claims, you know, following
10 appeal.

11 Regeneron has been fully heard on this point and the Board has
12 issued its claim instruction. But this all might be academic because, of
13 course, Your Honors, I believe all three of you were on that same panel. So,
14 I mean, you know, just before the claim construction -- or the collateral
15 estoppel issue is just redo the claim construction it -- anyway, so this might
16 be --

17 JUDGE NEW: Actually, should pass on -- leave that behind if
18 we can.

19 MR. TRAUPMAN: Yes, okay, very good. I don't know if
20 Your Honors have any other questions on the claim construction point on
21 patentable weight. We certainly agree with the Praxair is probably the lead
22 case on this point. And again, we think the rationale articulated in the final
23 written decision in the 1225 proceeding certainly should apply here.

24 And so, then, of course, just to move on to Slide 9, Your
25 Honors, the -- in the prior '881 IPR proceeding, again, everything except for

1 the exclusion criteria has already been found now two different times by the
2 Board to be disclosed by Dixon. So, let me just keep moving right along
3 here to Slide 10, so where the rubber hits the road to the extent we need to
4 worry about the exclusion criteria in a patentability analysis, of course, is the
5 prior art relating to the excluding criteria.

6 And if we go to Slide 11, we have three pieces of prior art, the
7 first one being the CATT Study from July of 2010 to -- and of course, the
8 CATT Study studied a prior art -- two prior art molecules, the bevacizumab,
9 also known as Avastin, and ranibizumab, also known as Lucentis. I believe
10 Your Honors are both familiar with these molecules.

11 And the key point here, and with all of this prior art is, the
12 method of administration is intravitreal injection. And as we've pointed out
13 in our petition, and then Dr. Chaum, our expert, has repeatedly pointed out,
14 it is the mode of administration that is the common thread. And what the
15 exclusion criteria are directed to preventing adverse events from. Again, this
16 intravitreal injection.

17 So, two -- the two relevant -- most relevant exclusion criteria
18 from the CATT Study are, again, excluding patients with active or recent,
19 within the last four weeks, intraocular inflammation, grade trace or above, in
20 the study eye, and active infectious conjunctivitis, keratitis, scleritis, or
21 endophthalmitis in either eye. I want to just, if I could, briefly address the
22 Motion to Exclude and the alleged unreliability of this reference, if I could,
23 Your Honors.

24 Just want to set the record straight, so, this prior art, reference
25 it's Exhibit 1031, was published on the University of Pennsylvania Medical

1 School's website, no later than July of 2010, which is early enough to be
2 prior art.

3 We submitted an authenticating affidavit from the internet
4 archive, also known as the Wayback Machine, certifying that the contents of
5 Exhibit 1031, the CATT exclusion criteria, were published in the prior art.

6 And of course, we cited many cases in our petition and in our
7 Opposition to the Motion to Exclude that set the internet archive
8 authenticating affidavits as to establish the publication and prior art status of
9 a reference.

10 And then, there's -- so, Patent Owner then seems to have a
11 secondary attack that, well, how do we know what this is? And some
12 question about the University of Pennsylvania, is it involved in any CATT
13 Study?

14 Well, Exhibit 1035 very clearly, I don't know if we can call it
15 up, very clearly shows that the University of Pennsylvania was the sponsor
16 of the CATT Study, but also, most significantly, is the responsible party for
17 providing information to the National Institutes of Health that is what ends
18 up on the clinical trial dot gov (clinicaltrial.gov) website.

19 So, we know that the CATT Study that the University of
20 Pennsylvania was intimately involved. And if we scroll down a little bit
21 here, this is Exhibit 1035, Your Honors. It's all right here, and of course, the
22 NCT Study and the name of the trial is all right here on clinical trials dot gov
23 (clinicaltrials.gov). The sponsored study's not going to change over time.

24 Patent Owner's response, well, this particular reference isn't
25 prior art. And that's true, but it shows, you know, the hallmark of reliability

1 of why the University of Pennsylvania would have the CATT Study
2 exclusion criteria on its website at a time in the prior art. And they also say,
3 well, there's no independent indicia of reliability within Exhibit 1031 itself.

4 But again, we respectfully disagree. Just look at 1031, we, of
5 course, know that the CATT Study's compared Avastin to Lucentis. You
6 can look in Dixon, the CATT Study's referenced in Dixon. The Dixon
7 reference says it's comparing Avastin and Lucentis. Of course, we know
8 that Dixon is prior art.

9 And then, you look on 1031, one of the -- what's one of the
10 contraindications? Patients including criteria, the patient should have no
11 contraindication to intravitreal injection of Lucentis or Avastin as specified
12 in the exclusion criteria below.

13 So, you're looking at this list of -- multi-page list of exclusion
14 criteria for a study that you know compares Avastin to Lucentis, and you see
15 within the four corners of that document exclusion criteria directed to the
16 drugs that are being studied in the CATT Study.

17 So, we respectfully submit that -- that we -- that this is exhibit
18 is both admissible and reliable for the reasons I have -- I just explained. So,
19 that was the reason, sorry. Go back to the slides at Slide 12 is the MACTEL
20 Study. Again, the MACTEL Study is also directed to ranibizumab and
21 that's, again, unquestionably prior art from May 2008.

22 And last, going on to Slide 13, the third of our three excluding
23 criteria of references is the Pier Study, which is, again, from February of
24 2008. And it, again, is directed to ranibizumab.

25 Should have said, the MACTEL, of course, is an intravitreal

1 injection of ranibizumab, all of these drugs, as I'm sure Your Honors know
2 by now, are intravitreally injected. The exclusion criteria are all directed to
3 the safety, you know, trying to make these intravitreal injections as safe as
4 possible.

5 You don't want to inject into a patient with an infected eye
6 because you're penetrating the eyeball with a needle and you don't want to
7 bring any contaminants, any microorganisms into the back of the eye
8 because that leads to, as we showed in our petition, some very, very
9 debilitating side effects if that were to happen.

10 So, if we go forward to Slide 15, there was a claimed
11 construction issue that was raised then beyond the patentable weight, just to
12 be clear, what the meaning of the -- what the meaning of, in particular,
13 excluding criteria three is, Your Honors.

14 Patent Owner has proposed that excluding criteria three --
15 excluding criteria three states, any ocular or periocular infection within the
16 last two weeks prior to treatment. Their construction for that exclusion
17 criteria is those exact words with the additional clause, which is no longer
18 active at the time of treatment.

19 And as we explained in our reply, we believe their -- this
20 additional clause finds no support in the claim language of the claim. In
21 fact, that Your Honors can see, they're just grafting on an additional
22 limitation on to this claim term that's not found in the language of the
23 claims.

24 And it's also not supported by the specification. One other
25 point we made, and I'd like to reiterate is that this concept of being no

1 longer active or resolved, there's no clarity as to what that means, how that
2 would be determined. And then, just take a step back, the whole -- my
3 understanding of the whole point of this argument is that, well, Exclusion
4 Criteria 2 and Exclusion Criteria 3 needs to be separate and somehow non-
5 overlapping. But that -- we don't -- there hasn't been any indication by
6 Patent Owner why that should be the case.

7 And in fact, if you look at Exclusion Criteria 1, which deals
8 with inflammation, it very clearly overlapped with Exclusion Criteria 2. I
9 don't think there's any dispute in the record that inflammation and infection
10 oftentimes, maybe every time, go hand in hand, not every time, but very,
11 very, very commonly go hand in hand.

12 And so, you're going to have overlap between these two
13 criteria. And in fact, that's part of our point. These exclusion criteria are all,
14 again, directed to the same goal of making intravitreal injections safe.

15 And as an additional matter, if we go to Slide 17, Exclusion
16 Criteria 3-2, and Exclusion Criteria 3 are different because they are
17 clinically evaluated in a different manner. And you can see that clearly from
18 Dr. Do, Patent Owner's expert's testimony.

19 And she explains how a person would practice these claims.
20 You both conduct a physical examination of the patient, you use a slit lamp
21 and other tools in the ophthalmologist's office to conduct an examination of
22 the patient. Do they exhibit signs, physical signs, in the eye of an infection?
23 But then, you also -- and that's when you conduct a patient history. You ask
24 the patient, how you been feeling the last two weeks? Have you had any
25 problems with your eyes? Et cetera, et cetera. That's Exclusion Criteria 3.

1 So, they, again, are all directed to the same problem, the same
2 goal of making intravitreal injections safe, but they're clinically evaluated in
3 the clinic through different means. Next slide, 18, Dr. Chaum, Dr. Chaum
4 also didn't say that Exclusion Criteria 2 and Exclusion Criteria 3 are the
5 same.

6 As you can see, and the Patent Owner cited the part of exhibit --
7 of this testimony as the lines on Slide 18, line 22 -- page 122, lines 18 to 24
8 of Dr. Chaum's deposition, that's what they cite, or we pointed out that we
9 believe the citation was taken out of context.

10 And if you look at the question and answer immediately before
11 it, starting at line 9 to 16 of page 122, he explains the differences that
12 Exclusion Criteria 3 defines the timeframe of which there is an infection.
13 And that's exactly what the claims recite. And if we go to the next slide,
14 Slide 19, and this, again, this is the next page of Dr. Chaum's deposition,
15 page 123, the most relevant parts are lines 13 to 17, is a further explanation
16 from Dr. Chaum. It's the presence of the infection, whether it's active or
17 recent that doctors care about.

18 Again, that goes back to this whole point, the whole point of
19 why you have these exclusion criteria. You want to safely intravitreally
20 inject. So, again, he's not trying to say Exclusion Criteria 2 and 3 are the
21 same, but they certainly are related to one another. So, in my limited time
22 going forward, I'm going to go direct to Exclusion Criteria 3, so if you can
23 just go to page -- Slide 25.

24 There's really no dispute, Your Honors, I don't think, that the
25 prior art discloses and renders obvious Exclusion Criteria 2 and 3, or excuse

1 me, 1 and 2. It's really all -- most of the dispute in the papers have been
2 about Exclusion Criteria 3.

3 And we believe, certainly, that a person skilled in the art taking
4 all three of these references, Pier, MACTEL, and CATT, either individually
5 or together, would find Exclusion Criteria 3 which is any recent infection
6 within 14 days as an exclusion criteria to be obvious. And of course, as
7 Your Honors noted in the institution decision, and we certainly agree with,
8 no in haec verba. There's no in haec verba requirement for obviousness.

9 The question Your Honors need to ask is, what would a person
10 skilled in the art read in these exclusion criteria understand and would they
11 believe that Exclusion Criteria 3 is obvious? And we believe the answer is
12 certainly yes.

13 Again, the -- and as we've shown here on Slide 25, the
14 MACTEL Study and the Pier Study, the exclusion criteria, they are
15 excluding not just current infections or current inflammation, they're
16 excluding recent infection and inflammation. That's the point, that's the
17 key.

18 And so, if we go on to Slide 26, there's Dr. Chaum's testimony
19 explaining why, for instance, MACTEL. And MACTEL's exclusion of
20 chronic infection and a history of chronic infection over the last 30 days.
21 It's, again, teaching the same concept of the safety directed to an intravitreal
22 injection.

23 If we go to Slide 27, there's been some dispute here in the
24 record about, well, 30 days is not 14. Well, obviously, 30 days is longer
25 than 14. We, obviously, we know, 30 days is longer than 14 days. But

1 here's three patients with inflammation or infection in 28 or 30 days as in
2 the prior art, and also disclosing patients who have infection within 14 days.

3 And that's not a teaching array, that's a very consistent
4 teaching, it's just really almost a line drawing exercise as to where -- what's
5 the cutoff for an intravitreal injection? And we've certainly seen no
6 testimony, no argument that there's anything inventive or non -- obviousness
7 about drawing the line at 14 days rather than 28 days or 30 days. There's
8 nothing in the record to support any argument to that effect. I'm just very
9 cognizant of my time, Your Honors, to keep moving on.

10 And Slide 29, again, this is just, I think, a very key and
11 fundamental point that I don't believe is disputed in the record which is that
12 the exclusion material and basic safety precautions. You are going to be --
13 the ophthalmologist knew very well in the prior art why -- how to -- how the
14 safety precautions you needed to take to do an intravitreal injection and they
15 took those safety precautions.

16 And that's the exact same reasoning and rationale behind the
17 claimed exclusion criteria here. And again, for the same reason we've heard
18 some arguments about motivation to combine. Well, you wouldn't look at
19 these particular prior art references when designing and figuring out how to
20 administer things intravitreally.

21 Again, the molecule that's being injected is not what matters,
22 it's the mode of administration that, certainly, a person skilled in the art
23 would have been motivated with a relatively new molecule, one that had not
24 yet been proved at the time of filing of the patent, would have to look at
25 what had been done with other recently approved and -- molecules that are

1 administered intravitreally as for guidance as to how you'd safely inject.

2 JUDGE NEW: And in terms of these, you wouldn't even
3 necessarily need to look at related molecules because it's the mode of
4 administration that's providing the risk here. So, almost any intravitreal
5 injection into an infected eye poses the same risk even if it's just
6 physiological saline?

7 MR. TRAUPMAN: Correct.

8 I would take out the almost any, I think it is any. It's the -- I
9 mean, if you just think about it, Judge New, you're piercing -- your eyeball
10 is a closed system. You're taking a needle and basically making, at least
11 temporarily, an open system. It's that act that's causing the concern here.

12 I'm out of time, Your Honors, but I just very briefly, on
13 secondary considerations, want to point out that there is no evidence in the
14 record that either the Eylea label or the practice of the physicians actually
15 practices the claims. And we addressed that in our papers.

16 JUDGE NEW: Thank you very much.

17 (Whereupon, the above-entitled matter went off the record.)

18 MS. FISHMAN: Do you have copies of the slides, Your
19 Honors?

20 JUDGE NEW: We do.

21 MS. FISHMAN: Okay.

22 (Whereupon, the above-entitled matter went off the record.)

23 MS. FISHMAN: I'd like to reserve five minutes of my time.

24 JUDGE NEW: Certainly.

25 (Whereupon, the above-entitled matter went off the record.)

1 JUDGE NEW: The slides on the screen are not particularly
2 helpful to us. We have them much closer here for our aging eyes.

3 MS. FISHMAN: Okay, great. Good afternoon, Your Honors.
4 I'd like to start with the question the Board posed which is, why should the
5 exclusion criteria of Claims 1 and 14 of the '681 Patent be construed as
6 limiting given the Board's prior decision in IPR 2022-01225?

7 And I guess the simple answer, from our perspective, is because
8 the record of argument and evidence in this proceeding that was developed
9 here is entirely -- So, there's a record of evidence argument developed in the
10 Mylan '681 IPR proceedings that is simply absent here.

11 Samsung never argued, and much, you know, while at oral
12 hearings, Samsung argues that it's agnostic on this point. Samsung never, in
13 this proceeding, argued that the exclusion criteria are not entitled to
14 patentable weight. And in fact, actually argued at institution that this was a
15 point of distinction over Mylan's '681 petition such that it shouldn't have
16 institution denied on general plastics grounds.

17 Likewise, the Board, in its institution decision, did not provide
18 notice that patentable weight would be an issue in this proceeding. And for
19 that reason, neither party developed evidence or argument around patentable
20 weight.

21 Under 5 USC Sections 554 and 556, an agency must timely
22 inform the parties of matters of fact and law asserted, must provide the
23 parties an opportunity for submission, consideration, acts, and argument, and
24 must allow a party to submit rebuttal evidence. None of that's happened in
25 this proceeding.

1 So, in Patent Owner's view, if the Board wishes to rule on the
2 basis – the same basis that it ruled in the 1225 proceeding, there are
3 essentially potential paths forward. One is that the parties and the Board
4 agree to introduce the record that was developed in IPR 12-25, the 25-2,
5 1225 here as it relates to patent void. The other is that the parties develop a
6 record here regarding patent void.

7 Now, it sounds like Samsung is amenable to resting on the
8 record that was previously developed. If that's the case, that would seem to
9 be the most expedient. Patent Owner does not object. But as a practical
10 matter, the concern the Patent Owner has is that if we proceed down the road
11 of a five-page brief or some such, it doesn't cure the prejudice to Patent
12 Owner in having a factual record in addition to argument.

13 And if we go down the path of developing an independent
14 record here, we have asymmetric bases for the ruling of the Board. So --

15 JUDGE NEW: Certain, Ms. Fishman, all the arguments that all
16 the evidence that has been developed by Patent Owner with respect to the
17 excluding criteria is a matter of record already, if not introduced into the
18 docket of these proceedings, it is a matter of public record in IPR --

19 MS. FISHMAN: That's correct.

20 JUDGE NEW: -- 01225. And those are records and evidence
21 that are accessible to anybody, including Patent Owner and Petitioner in this
22 case.

23 MS. FISHMAN: That's correct, Your Honor. But as a matter
24 of just, from an appellate record perspective, you know, were the Board to
25 rule on the same basis here as it did in the 1225, in the 1225, there's a factual

1 predicate for which arguments could be made on appeal. In this proceeding,
2 there are not.

3 JUDGE NEW: Right, but those arguments will have been
4 decided on that record by the Federal Circuit if the 01225, which as you
5 certainly know has been appealed in the Federal Circuit.

6 MS. FISHMAN: Agreed.

7 JUDGE NEW: So, once that's done, once that decision is made
8 one way or the other, it doesn't really much matter, does it? But it's on the
9 record.

10 MS. FISHMAN: To Patent Owner, it does not. And again,
11 assuming Samsung is agreeing to be bound, it shouldn't matter.

12 JUDGE NEW: All right, very good.

13 MS. FISHMAN: Yes. So, moving on then, while Patent
14 Owner obviously disagrees with the position on patentability (?), and as Your
15 Honor is aware, has appealed that decision. In the -- in addition to the
16 patentability(?) issue, which was not raised in this proceeding, the parties
17 have a dispute around claim construction of the exclusion criteria. I'm going
18 to rest on our briefs.

19 JUDGE NEW: I'm sorry, Counsel, I'm having a little trouble
20 hearing you.

21 MS. FISHMAN: Oh, really?

22 JUDGE NEW: Could you speak a little closer?

23 MS. FISHMAN: Sure, can you hear me now?

24 JUDGE NEW: Yes, thank you.

25 MS. FISHMAN: Okay. The parties have a dispute on a claim

1 construction, how the exclusion criteria are to be construed. And as set
2 forth -- I'm going to rely on our papers, but the principle dispute is that the
3 way in which Petitioner is construing Exclusion Criteria 3 would subsume
4 Exclusion Criteria 2 and for a number of reasons, in our view, that violates
5 fundamental tenants of claim construction.

6 I'd like to spend my time, however, first, addressing an issue
7 raised by Petitioner, the Motion to Exclude issue, and then, focusing on the
8 fact that we believe that Petitioner has failed to demonstrate in this
9 proceeding the obviousness of the claims as a whole. But specifically, the
10 obviousness of the exclusion criteria limitations in EC3, in particular.

11 JUDGE NEW: Ms. Fishman, I just want to stop you for one
12 second and step back just for a moment. You said that your position that --
13 or Petitioner's position that, basically, Exclusion Criteria 3 is subsumed into
14 Exclusion Criteria 2 violates basis principles or tenants of claim
15 construction.

16 What if it's just a badly written limitation? What if it's just a
17 poorly written thing that does subsume it, that doesn't mean we're going to
18 start introducing new limitations as it seems like you are suggesting in your
19 construction into that third limitation. In other words, to give it some sort of
20 separable distance from the two.

21 MS. FISHMAN: Well, first of all, I think the plain and
22 ordinary of each of the limitations is that Limitations Number 1 and 2 have
23 to do with at the time of treatment. And Limitation Number 3, on its face,
24 has to do with historic or prior infection.

25 JUDGE NEW: The plain language of Exclusion Criteria 3

1 seems to suggest that's not true. In other words, if you had developed an
2 infection three days before the test and it was still raging in your eye, that
3 would certainly fall within the plain language of 3. I don't see how you get
4 into some sort of criterion saying that it has to be -- the criterion has to be,
5 what's the exactly language you used?

6 MS. FISHMAN: Prior infection?

7 JUDGE NEW: Yes, prior infection or one that has been no
8 longer active is the word.

9 MS. FISHMAN: Right. So, if we, for example, you can see
10 the exclusion criteria limitations at, for example, our Slide 8 or, you know,
11 there are a number of slides where it's shown. So, first of all, the plain
12 language of the claim are both it's a method of treatment claim. The plain
13 language of the claim for Exclusion Criteria 1 and 2 talk about active, active
14 intraocular inflammation, active ocular or periocular infection.

15 In contrast, Exclusion Criteria 3 talks about two weeks, excuse
16 me, it's infection within the two weeks prior to treatment. The record
17 evidence in this proceeding, and indeed, I'll point to Petitioner's Slide 17, is
18 that when the POSA examines a patient or subject for eligibility, they are, on
19 physical exam, ascertaining whether or not there is active infection or active
20 inflammation.

21 In contrast to determine whether or not there is -- there was
22 prior infection, they look at medical history. There is zero evidence in this
23 record that when somebody's being assessed and it's determined that they
24 have a current infection or current inflammation, that the practitioner asks
25 when did that start? There's just nothing on that.

1 Rather, both parties' experts have testified that, in distinction of
2 sort of demonstrating that there's -- so, for active and -- active infection and
3 active inflammation, a physical -- pardon me -- physical examination is what
4 reveals the presence of those characteristics.

5 In contrast, for the prior infection, it's based on medical history,
6 medical records. And Dr. Do was questioned about this extensively at her
7 deposition exactly the question that you put to me which is, well, if
8 somebody walked in and has an active infection now, but it started three
9 days ago, doesn't that check two boxes? And her testimony was, that's not
10 how we assess it. If somebody comes in with a current active infection now,
11 I use that as a basis to decide whether or not I'm going to treat. I don't ask
12 them about historical infection. And, and I'll get to this in a moment, the
13 whole premise of Petitioner's case is that there is some huge overwhelming
14 threat or risk from recent infection.

15 You know, recent infection, infection that's not ongoing, not
16 assessed on physical exam. But there's zero evidence to bear it out. I know
17 it sounds like an appeal in theory, but maybe if you recently had some
18 infection, there could be residual flora and that that was a big concern.

19 But as we'll go through, none of their references on EC3 and
20 none of their background references actually point to the idea that a resolved
21 infection, that a historical infection, even if it's recent, causes concern for
22 the physicians.

23 JUDGE NEW: How do we determine if an infection's no
24 longer active? How does a person of ordinary skill in the art determine if an
25 infection is no longer active?

1 MS. FISHMAN: It's based on physical exam. And it is
2 undisputed, both parties' experts agree that you can ascertain, and that's how
3 they ascertain it. In fact, in deposition, I asked Dr. Chaum, well, if you have
4 concerns about residual infection, do you culture the eye, right, if you've got
5 concerns? He said, that is not my practice.

6 That is not his standard practice. And in fact, if I can refer the
7 Board to -- this is a background reference that Petitioner cited, it's Exhibit
8 1059. And it's one of the many background references that purportedly
9 stands for risks of intravitreal injection. The -- and I'll, again, I'll come back
10 to this, but the gist of all of the background references is that injecting itself
11 can lead to potential infection.

12 But there is zero explanation or concern in any of these
13 references about prior or recent resolved infection being a risk at the time of
14 the operative procedure. And in fact, Exhibit 1059 at page 19 says that the
15 pre-operative administration of prophylactic antibiotics is not routine.

16 In other words, when a person comes in with active infection,
17 or a person comes in that's suspected of having active infection in the eye or
18 active inflammation, it may be that there on physical exam, practitioners
19 make the decision not to treat.

20 But overwhelmingly, the practice, as reflected in Petitioner's
21 own background references is that if there's no visual suspicion, if there's no
22 current infection, it is not common practice to pre-treat because there's a risk
23 of some historical infection. That might seem like that's a great idea, but
24 that's not borne out in the art.

25 JUDGE NEW: I'm not sure we're talking about pre-treatment

1 here because the MACTEL Study and the CATT Study both talk about a
2 history of ocular or periocular infection within 30 days. It seems to me that
3 that's basically coming into the same category as we're seeing in Exclusion
4 Criteria 3. We can talk about the number of days as another topic, I'm
5 talking about --

6 MS. FISHMAN: I understand, but --

7 JUDGE NEW: -- this is --

8 MS. FISHMAN: I think we can talk about it together, Your
9 Honor. I don't believe MACTEL or CATT discloses or teaches EC3. So,
10 first of all, let's start with MACTEL. MACTEL, and our Slide 23,
11 MACTEL excludes historic infection only if it was chronic. Right?

12 And specifically points to ocular herpes zoster, a known
13 chronic infection. In the record that was developed after this Board's
14 institution decision, it shows that the rationale for excluding chronic
15 infection is different than any rationale for excluding historic infection.

16 Specifically, it is undisputed that chronic infection, unlike other
17 infections, is characterized by recurrence, and that the rationale for
18 excluding recent chronic infection is a heightened risk of recurrence. In
19 other words, a heightened risk that the patient will get active infection while
20 on treatment. That does not apply to other non-chronic infection. Right?

21 And so, MACTEL's exclusion of historic chronic infection,
22 therefore, does not teach or disclose excluding any or all ocular infection
23 that is a result. Right? What it teaches is that where somebody has had a
24 recent chronic infection, and that points towards developing a new infection,
25 that could be a reason to exclude them from a clinical study, specifically

1 where, as even Dr. Chaum has acknowledged in the context of a clinical
2 study, recurrence or inflammation or any of these things can confound your
3 study data.

4 This is argued at our POR at page 50, and it's in Dr. Chaum's
5 deposition testimony, Exhibit 2384, page 209, 6-19, and also 2321 through
6 24-2. Again, the rationale for MACTEL's exclusion of chronic historic
7 infection does not provide a rationale for excluding resolved infection or
8 resolved acute infection. It just simply doesn't apply.

9 And that's where we get into Petitioner then trying to stretch
10 MACTEL's disclosure to suggest that exclusion of current acute infection
11 teaches EC3's exclusion of prior historic infection. But first of all, again --

12 JUDGE NEW: Let me just stop you here quickly and ask a
13 quick question.

14 MS. FISHBURN: Sure, sure.

15 JUDGE NEW: EC3 says any ocular or periocular infection.
16 Does that not include chronic as well as acute?

17 MS. FISHBURN: Any -- so, I believe any -- first of all, our
18 position is any doesn't have special meaning. But ocular or periocular
19 infection would include chronic. It would include -- well, it would include
20 chronic. It would include acute. It would include all types of infections,
21 yes.

22 JUDGE POLLOCK: And it would include the active infection
23 of a patient?

24 MS. FISHMAN: No, historic would not include active. In our
25 view --

1 JUDGE POLLOCK: Of any ocular or periocular infection in
2 the last two weeks, would that not -- if I come in and I have an eye infection,
3 so that's it, my doctor can see --

4 MS. FISHMAN: Yes.

5 JUDGE POLLOCK: -- and it didn't just happen when I
6 walked in the door, I have had this, I assume, had it in that last two weeks,
7 why wouldn't that satisfy that third criteria?

8 MS. FISHMAN: The record in this proceeding is that those are
9 non-overlapping. And Dr. Do gave extensive testimony on this, that when
10 they -- when the POSA is reviewing the exclusion criteria, if you come in
11 with a current acute infection or any kind of infection, a current infection,
12 you will -- you may be excluded from treatment on that basis.

13 You're not separately going to be evaluated to find out if you
14 also had historic infection or if you also had infection in the last two weeks.

15 JUDGE POLLOCK: But it doesn't matter whether I'm
16 evaluated or not, that -- the reality is that I have an ocular or periocular
17 infection within the last two weeks. I mean, you would know.

18 MS. FISHMAN: But that, again, that is not --

19 JUDGE POLLOCK: Where in your claim does it say I have
20 to -- the doctor has to make that step?

21 MS. FISHMAN: Well, let me explain it this way. The
22 Exclusion Criteria 3 requires a two-week waiting period. In our view, it
23 requires a two-week waiting period. Whereas MACTEL and CATT, and I'll
24 get to CATT in a minute in terms of intraocular inflammation, requires a 30-
25 day waiting period.

1 I think the way the Board is thinking about these things which
2 is that, somehow this is a genus claim. No, this is not a genus claim. If a
3 person practicing our claims had an infection that resolved three days ago,
4 they have to wait another 11 days before they could receive treatment.
5 Under CATT and MACTEL, if they had had a chronic infection that
6 resolved three days ago, they'd have to wait another 27 days before they
7 could receive treatment.

8 And this concept that it's a waiting period and not a range, this
9 is not a ranges case. The ranges case that Your Honors have referred to in re
10 Peterson, Genentech, those are cases where the claims literally say, from
11 about to about. These are not ranges. This is a waiting period, a set waiting
12 period that the patient has to undergo. And in fact, Petitioner acknowledges
13 as much in its reply at page 14. So, these are not subsumed.

14 JUDGE POLLOCK: But let me ask you on these two trainings,
15 so, you're saying it has to be an infection that as resolved? But --

16 (CROSSTALK)

17 MS. FISHMAN: Correct, its historical infection, correct.

18 JUDGE POLLOCK: I'm coming in, I had an infection and my
19 eye looks good. So, I've passed the first two criteria.

20 MS. FISHMAN: Yes.

21 JUDGE POLLOCK: But I tell my doctor, well, I've had this
22 infection the last, you know, two -- a week and a half ago.

23 MS. FISHMAN: Correct.

24 JUDGE POLLOCK: But that's not how it's written in that
25 EC3. It says any ocular or periocular infection within the last two weeks

1 prior to treatment. It's not limiting me to resolve the infections, right? It's
2 any ocular or periocular infection?

3 MS. FISHMAN: So, we do not -- and just common grammar is
4 that any is modified ocular or periocular infection, it's not modifying the
5 person time. And what it's saying is, you can't have had any kind of
6 infection in the two weeks prior to treatment.

7 JUDGE POLLOCK: So, why wouldn't that overlap with EC2?

8 MS. FISHMAN: Because --

9 JUDGE POLLOCK: Because you're talking about any
10 infection. You're not saying it's resolved.

11 MS. FISHMAN: Because it --

12 JUDGE POLLOCK: I mean, that's how you're reading it, or it
13 seems to me that's how you're reading it. It has to be a resolved infection.

14 MS. FISHMAN: It is, it is how we're reading it because --

15 JUDGE POLLOCK: Okay.

16 MS. FISHMAN: -- under EC3, it says, any kind of infection,
17 right, that you can't -- you're excluded if you had any kind of infection in
18 the two weeks prior to treatment, meaning, if you had an infection, a historic
19 infection, you would have to wait at least two weeks before you'd be eligible
20 for treatment.

21 That's how the -- and the intrinsic record is in accord in that, in
22 the view study exclusion criteria which are detailed in Example 4 in the
23 patent, it's not just that these are listed as separate exclusion criteria, they are
24 applied as separate exclusion criteria by the study investigators.

25 So, they're applying these separately. If you have active

1 infection, active inflammation when you come into the study, you're not
2 going to be eligible for treatment. Separately, if you had any infection in the
3 two weeks prior to screening, you're not going to be eligible for treatment.
4 So, it's a separate historic exclusion criteria. That is how we're reading it.

5 And then, on your point in terms of, or at least Petitioner's
6 claim, in terms of any modifying the time course, again, it's Patent Owner's
7 perspective that it doesn't have special meaning, if it has any meaning at all.
8 It's not modifying the kind of infection.

9 And if you look at the intrinsic record and you look at Example
10 4 and the list of exclusion criteria, you can see that any is typically coupled
11 with historic condition. And it doesn't have special meaning here. It
12 doesn't modify anything in particular.

13 Again, I hope that answered your question, but yes, we are
14 reading it as it had to resolve and it had to be resolved for two weeks prior to
15 treatment you'd be eligible for treatment under this claim.

16 JUDGE POLLOCK: Okay, I understand how you're reading it.
17 And I think, even if I disagreed with Petitioner that any doesn't modify the
18 claim period, why wouldn't it still encompass active infection? Because any
19 ocular or periocular infection would be any infection after the word
20 historical. And then, you have within the last two weeks prior to treatment.
21 So, if I've still had it, then it's still within that two-week period, but it could
22 be historical, too. It just seems to me, 2 and 3 overlap --

23 MS. FISHMAN: Well --

24 JUDGE POLLOCK: -- and it can have record that teaches 2,
25 you're also teaching 3 when we're talking about active infection. I'm not

1 seeing how you get this --

2 (CROSSTALK)

3 MS. FISHMAN: Okay, so, two responses to that. One is,
4 obviously, our claim construction is different. But even if that is how you
5 construe the claim, respectfully, we would say that that does not solve
6 Petitioner's obviousness problem because Exclusion Criteria 3 requires that
7 exclusion of the entire scope of EC3 be in the prior art. And it is undisputed
8 that historic resolved infection falls within the scope of EC3. And so, it's
9 not (INDISCERNIBLE) situation. What EC3 says, is that you're basically --
10 well, so, EC1 and EC2 are active infection. EC3 says, any infection, you
11 know, two weeks prior to treatment.

12 We read that as historical. Even if you read it as including
13 acute or including active in the two weeks, it has to also include historical.
14 And if it also includes historical, there is zero teaching in the art about
15 excluding historical infection, that that was a concern or that that was a
16 motivation to do so. And so --

17 JUDGE POLLOCK: So, what you're saying, they just haven't
18 shown the rest. So, even if we read it the way I'm talking about where
19 active infection would also be within EC3, they haven't shown -- and I agree
20 with you, it should include historical, even at 2, because you're talking about
21 within the last two weeks.

22 It actually doesn't tell me that it has to be active or it's not
23 resolved. So, I would assume historical in here, too. You're saying, they
24 haven't shown the full breadth of that --

25 MS. FISHMAN: Correct.

1 JUDGE POLLOCK: -- limitation.

2 MS. FISHMAN: Correct.

3 JUDGE POLLOCK: Okay.

4 MS. FISHMAN: Correct. And I'd like to turn now to CATT
5 because I want to explain why CATT also does not disclose or teach historic
6 infection. So, if you can turn to Slide 27? Slide 27 has the exclusion criteria
7 that Petitioner's are relying on. And so, Petitioner's relying on CATT's
8 disclosure of historic within four weeks intraocular inflammation to try to
9 disclose or teach exclusion of historic infection. But there are a couple
10 significant problems with this argument.

11 First, Petitioner ignores that the CATT exclusion criteria is
12 directed specifically to subset of inflammation, intraocular inflammation.
13 And the record developed post-institution demonstrates the intraocular
14 inflammation does not correspond to all or even most ocular and periocular
15 infection. Testimony from both parties' experts confirmed that ocular and
16 periocular infections are often not associated with intraocular inflammation.

17 In fact, the only intraocular inflammation that Dr. Chaum has
18 identified that presents with intraocular inflammation is endophthalmitis.
19 Accordingly, CATT's historic intraocular inflammation exclusion criteria
20 does not inherently exclude all or even most ocular or periocular infections.
21 And I will go over my time.

22 Second, it is undisputed that infection and inflammation meant
23 different things to the POSA and that the POSA would not use one to mean
24 the other.

25 Both experts agree, and now I'm on Slide 28, that the

1 inflammation and infection have different meanings, and that the rationale
2 for excluding inflammation were different than that for excluding infection,
3 as Dr. Do explains in the testimony cited here.

4 Moreover, the record evidence demonstrates that inflammation
5 and, in particular, intraocular inflammation is not a good proxy for infection.
6 Prior art trials, including the CATT trial in which Petitioner relies, have
7 separate exclusion criteria directed to inflammation versus infection.

8 CATT, again, if you go back to Slide 27, which Petitioner relies
9 on for its exclusion of intraocular inflammation has a separate exclusion
10 criteria for, and I'm quoting, active conjunctivitis, keratitis, scleritis, or
11 endophthalmitis in either eye. Okay? That's the CATT current infection
12 exclusion criteria.

13 CATT's exclusion criterion for intraocular inflammation would
14 not correspond to most of the infections listed in CATT's exclusion criteria
15 for ongoing infection. And moreover, inflammation is only excluded in the
16 study eye, whereas, in CATT, active infection, the ones listed, were
17 excluded in both eyes. That was the basis for exclusion.

18 So, the very evidence on which Petitioner relies shows that
19 excluding inflammation, excluding a history of inflammation does not teach,
20 and the POSA would not understand it to reach infection. In short,
21 Petitioner's own evidence suggests that inflammation is not and never was
22 used as a proxy for excluding infections.

23 We've already addressed in our papers that these are not ranges
24 and, therefore, there's a teaching away. The last thing I'd like to address,
25 and I realize I may run out of time for rebuttal, is that the standard of care

1 theory.

2 So, unable to align references to the Exclusion Criteria 3,
3 Petitioner advances a standard of care theory. But there is no evidentiary
4 support for it. If you look at Slide 33, Petitioner's expert admits he does not
5 know whether other physicians assess for or exclude patients with recent
6 infection.

7 So, his testimony's conclusory. Slide 34, his expert – their
8 expert could point to no reference that supported the theory that excluding
9 recent infection was, in fact, standard of care.

10 And as discussed, neither CATT nor MACTEL discloses or
11 teaches excluding any or all historic or prior infection. At best, MACTEL
12 teaches the excluding of chronic infection. But as we discussed, there could
13 be a very different rationale for that which is, it points towards assumed to
14 happen current infection.

15 Moreover, none of Petitioner's additional asserted references,
16 and this corresponds to my Slides 35 and 36, disclose its alleged standard of
17 care, i.e., that people had a concern and would exclude the prior infection.

18 Again, standing here now, we may think, well, that would make
19 sense. None of the art bears it out and it was not practice at the time.

20 Respectfully, I'll save one minute for rebuttal in case I need it.
21 Thank you, Your Honors.

22 JUDGE NEW: Thank you, Ms. Fishman. You've got seven
23 minutes left.

24 MR. TRAUPMAN: Thank you, Your Honors, and I'll try to
25 use less than all of that. Let me briefly just address on the patentable weight

1 issue, we -- I've heard for the first time about just incorporating the record
2 from the 1225 proceeding. With Your Honors' permission, I want to talk
3 that a little with my client. But there's a good chance we'll be amendable to
4 that if that's how Your Honors would like to proceed.

5 JUDGE NEW: Yes, please inform us about that decision, Counsel.

6 MR. TRAUPMAN: Yes, I'll just send an email to trials, is that --

7 JUDGE NEW: That'll be fine.

8 MR. TRAUPMAN: -- appropriate matter? Very good, I will do
9 so. Just know that it's already the weekend in Korea, Your Honors, so, I'll
10 do my best. So, let me just briefly then address the claim construction as the
11 meaning of the claim terms and we've had all this story about overlap.
12 Again, I just want to reiterate, EC1, EC2, EC3, they all overlap, that's the
13 exact point, in our view.

14 And you're going to very likely have the patient who can tick
15 potentially all three boxes if an infection causes inflammation and is current,
16 yes, you would fall within all three exclusion criteria. And there's nothing
17 about the claim history criteria that which leads you to lead a person of skill
18 in the art to think this needs to be one or two or three. That's not how
19 they're structured and that's not their purpose. And we think that is a key
20 point to take across.

21 But another -- and our related point, Counsel for Patent Owner
22 talked about, allegedly, there nothing being in the record that says, well, if
23 your patient presents with an active infection eye, there's active
24 inflammation as well, they're not going to ask when did that start?

25 I mean, I go to Slide 17 of our presentation and I look at Dr. Do's

1 testimony, that's not consistent with her testimony. She says, I assess
2 patients every time I do an intravitreal injection by doing two things, a
3 physical examination and a history. She doesn't say, oh, you're presenting
4 with an active infection or active inflammation. I'm not going to ask when
5 that started, I mean, that just defies common sense and that's certainly not
6 what the record shows.

7 So, and another point that Counsel for Petitioner brought up, Dr.
8 Chaum's testimony that he doesn't culture – doesn't do a swab of the eye
9 and grow something on a petri dish to figure out what something could
10 result. That again, in our view, proves the point, a patient might be on a
11 regimen of antibiotics or have no longer be showing redness or
12 inflammation. They might still have flora, that's what we pointed out in our
13 papers and that's exactly why you take a history because you might not
14 have, you know, a patient who presents on the day of a potential injection
15 with inflammation or other signs of infection. And so, again, we think that
16 that proves our point.

17 Again, the 1059 talking about prophylactic antibiotics, again, that's
18 not the point either. It's taking the conjunction of a present physical
19 examination and a medical history. What I, again, and just my last point
20 unless Your Honors have any questions is, what I heard on the presentation
21 was a bunch of disassembling of this piece of the prior of the prior art or this
22 particular part of any of this prior art. And yes, we will stipulate, there's no
23 in haec verba to say, Exclusion Criteria 3 verbatim in the prior art.

24 Our point is to take the teachings of all these prior art references,
25 how they're -- how a physician would apply those exclusion criteria to

1 determine whether a patient met those exclusion criteria, what the purpose
2 behind the prior art exclusion criteria are, and what the POSA would have
3 understood from those exclusion criteria, and does that render the claim
4 Exclusion Criteria 3 obvious? We think the answer is unequivocally yes.
5 And so, unless Your Honors have any questions, I don't have anything
6 further to add.

7 JUDGE NEW: Thank you very much, Mr. Traupman. And Ms.
8 Fishman, you've got one minute.

9 MS. FISHMAN: I know, and I'll make count, Your Honor.

10 JUDGE NEW: I'm sure you'll be pithy.

11 MS. FISHMAN: Yes. So, I wanted to respond to Mr. Traupman's
12 comment about Dr. Do's testimony. What -- so, in a way, he's
13 mischaracterizing. She's not testifying about her practice. The testimony he
14 cites, and it's on Slide 17 of his presentation, is her testimony on how a
15 POSA would practice the claims. And what she says is that, in order to
16 assess intraocular inflammation or ocular or periocular infection, they were
17 known to have a range of presentations and that you'd -- it would not be
18 apparent absent examination by a trained clinician. Right?

19 So, again, she's saying, you would assess for those on physical
20 examination by a trained clinician. Or, alternatively, in the case of any
21 ocular or periocular infection within the last two weeks prior to treatment,
22 absent or claimed by the patient on the patient's medical records.

23 This testimony does not, in my view, support Petitioner's
24 argument. It supports Patent Owner's argument which is that these are
25 different and separately assessed for exclusion criteria. Nothing further,

1 Your Honors, unless you have questions.

2 JUDGE NEW: I just would like to make clear what I think I
3 understand you said with respect to additional briefing, if you represent I
4 think the Petitioner is content to rely on the record from the 01225 and the
5 evidence developed along with it in that proceeding, you would be all right
6 with that as the Patent Owner as well?

7 MS. FISHMAN: That is correct, and in our view, it would be
8 preferable than creating a new symmetrical record for Your Honor.

9 JUDGE NEW: Great, I just wanted to be absolutely clear on that.
10 Thank you very much.

11 MS. FISHMAN: Thank you, Your Honors.

12 JUDGE NEW: Any other questions?

13 (NO AUDIBLE RESPONSE)

14 JUDGE NEW: All right, there being no other questions from the
15 panel, I'd like to thank you both for an interesting discussion, well argued.
16 We have now taken this matter under advisement and a decision will issue in
17 due course. We will hope to hear from you, Mr. Traupman, regarding your
18 client's wishes at the nearest opportunity possible. We stand adjourned. I
19 would ask you to please remain to answer any other questions from the court
20 reporter. And we are off the record.

21 (Whereupon, the above-entitled matter went off the record at 2:04
22 p.m.)

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