

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EMBODY, INC., and ZIMMER BIOMET HOLDINGS, INC.,
Petitioner
v.
LIFENET HEALTH,
Patent Owner.

IPR2025-00248 (Patent 10,137,223 B2)
IPR2025-00249 (Patent 11,318,227 B2)

Record of Oral Hearing
Held: May 6, 2026

Before SHERIDEN K. SNEDDEDN, and CHRISTOPHER G. PAULRAJ,
and CHRISTOPHER C. KENNEDY.

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The above-entitled matter came on for hearing Wednesday,
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Office, 600 Dulany Street, Alexandria, Virginia.

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

1:01 p.m.

JUDGE PAULRAJ: All right. So good afternoon. This is the combined oral hearing for IPR 2025-00248 and IPR 2025-00249 before the Patent Trial and Appeal Board. I'm Judge Paulraj here in the room, and joining me by video are my fellow panel members, Judges Kennedy and Reimers.

Let's go ahead and start with appearances, starting with Petitioner's counsel first, and then Patent Owner's counsel.

MR. LEVINE: Howard Levine for Petitioners, and my partner Jennifer Swan from Hogan Lovells.

JUDGE PAULRAJ: All right. Thank you, Mr. Levine. Will you be presenting arguments today, or are you going to split time with your partner?

MR. LEVINE: I will be presenting arguments today.

JUDGE PAULRAJ: All right. Then let's turn it over to Patent Owner.

MS. WIEKER: Good afternoon. This is Amanda Wieker and George Davis from McGuire Woods for Patent Owner. And joining us today are Doug Wilson, Sam Pauly, and Jing-Song Chen from LifeNet, Patent Owner, and Jack Natney and Brooke Natney, Patent Owner's prosecution counsel.

JUDGE PAULRAJ: Welcome, everyone. And Ms. Wieker, are you going to present arguments for Patent Owner here?

MS. WIEKER: Yes, I will. Thank you.

1 JUDGE PAULRAJ: All right. Thank you. So I know
2 everyone's been through this before, so, that said, I'll go through kind
3 of the standard that I give before my hearings. So that's the fourth in
4 our hearing order. Each side will have 60 minutes to present their
5 arguments. We'll start with Petitioner first and then turn it over to
6 Patent Owner. Petitioner and Patent Owner may each reserve a
7 portion of their argument time for rebuttal and surrebuttal,
8 respectively. So I'll ask you when you come up to the podium to tell
9 me how much of your time you intend to reserve at the beginning of
10 your argument.

11 This will be a public hearing, and there may be members of the
12 public listening to the hearing. To the extent that parties anticipate
13 getting into any confidential information, please police yourself and
14 let us know if we're going to get into the confidential record, and we'll
15 remove the public line. Based on what I've seen of the record, I don't
16 anticipate any confidential documents, but I'm just getting that heads
17 up.

18 We did receive the parties' demonstratives, and we'll be able to
19 follow along with those demonstratives as you present your
20 arguments, but please make sure to state the slide number and any
21 other exhibit numbers and the page numbers, if you do refer to exhibit
22 numbers that you're referring to so that it's clear for the record. I'd
23 also remind the parties that the demonstratives themselves are not
24 going to be considered evidence in this proceeding, but they'll only be
25 used as a guide to us to the relevant evidence and arguments that are
26 in the record.

1 We're also in receipt of the parties' submissions regarding
2 improper new reply and surreply arguments. And as we mentioned in
3 our email, we'll take those objections under advisement, and you may
4 address those submissions as part of your argument today. However,
5 we won't be entertaining any type of objections precluding one side or
6 the other from presenting those objective to evidence. So what I don't
7 want to hear is, like, counsel interrupting the other side. So I would
8 like to make sure that the arguments are as clean as possible. Is that
9 understood?

10 MR. LEVINE: Yes, Your Honor.

11 JUDGE PAULRAJ: All right. So with that, Mr. Levine, the
12 floor is yours.

13 MR. LEVINE: Your Honor, would you like a copy of the
14 slides?

15 JUDGE PAULRAJ: Sure, I'll take a copy. I know we have two
16 judges that are remote that won't have the benefit, but I always like a
17 physical copy.

18 MR. LEVINE: Okay. May it please the Board. Howard
19 Levine for Petitioners. I'm here with my partner, Jennifer Swan. And
20 I'd like to start with the '223 patent, if I may. And what we have on
21 the slide is the '223 patent, which is Slide 5, Exhibit 1001. And here
22 we have the cover of the patent. And interesting on the cover is you
23 have a diagram, and the diagram is of an apparatus.

24 And as noted in the institution decision, the patent spends a lot
25 of time talking about the apparatus. And in fact, that is what the
26 patent invented. They invented an apparatus that they claimed would

1 be able to present aligned fibers based on the shape of the apparatus
2 and the rods. The patent talks about how they're able to get aligned
3 fibers that were different from what was in the prior art.

4 And based on that apparatus and the idea that it could get
5 aligned fibers, they tried to claim, essentially, not the apparatus --

6 JUDGE PAULRAJ: I'm sorry. I'm going to interrupt for a
7 second.

8 MR. LEVINE: Sure.

9 JUDGE PAULRAJ: I apologize. I did not start the clock, so I
10 should have done that.

11 MR. LEVINE: Okay.

12 JUDGE PAULRAJ: And I actually didn't hear how much time
13 you wanted for rebuttal.

14 MR. LEVINE: I'll take ten minutes for rebuttal.

15 JUDGE PAULRAJ: All right. So if you could hold on just one
16 second, I'll give you your full time. I think I've got some of that, but
17 I'll give you your full time.

18 MR. LEVINE: Sure.

19 JUDGE PAULRAJ: Because my technical bit. So let me make
20 sure that I'm getting this right. Sorry, you said ten minutes for
21 rebuttal?

22 MR. LEVINE: Ten minutes for rebuttal.

23 JUDGE PAULRAJ: Okay. I'll start the clock. You can have
24 your full time, so you don't need to start over again.

25 MR. LEVINE: Okay. Thank you, Your Honor.

26 JUDGE PAULRAJ: All right. So ready, go forward.

1 MR. LEVINE: Okay. So we were talking about the apparatus
2 and how the patent is talking about inventing an apparatus that allows
3 you to get aligned fibers. And because of that, and then instead of
4 claiming the apparatus, the patent seeks to claim the aligned fibers
5 from that apparatus, which is why the title is Aligned Fiber and
6 Method of Use Thereof.

7 The first line of the abstract is a scaffold comprising aligned
8 fiber. Alignment is mentioned some 100 times in the patent.
9 Example 2 of the patent refers to highly aligned fibers, and that's what
10 the invention seeks to claim based on the invention of this apparatus.
11 And that becomes a little bit more important when we discuss the
12 prosecution history.

13 And if you look at the next slide, and you can see it refers to
14 Figures 6 and 7, which refer to aligned heart basement membrane
15 fiber. Figure 7 also depicts aligned placenta and heart basement base
16 membrane.

17 Now although the patent claims collagen, and we'll get to how
18 that happened, it doesn't actually spin collagen. Collagen is
19 mentioned in a literary of different compounds you can use. They
20 actually spun heart base membrane. And Example 2 of the patent,
21 which is where these figures come from, talk about how they obtained
22 highly aligned fibers based on their device that they invented.

23 Exhibit 8, Figure 8, depicts an exemplary FFT analysis of the
24 fibers they obtained from spinning the heart basement membrane.
25 And the question is, well, what is FFT? Why do they do FFT? Well,
26 FFT, as they say in the specification, again this is at column 21, lines

1 26 to 31. FFT is a tool that measures alignment. That's all FFT does.
2 It's a tool that measures alignment. That's its sole purpose.

3 And here, the specification says, using the tool, they look for
4 patterns of aligned fiber and compare them to known aligned form
5 spectra as commonly used for pattern recognition. It's a visual
6 analysis. You look at patterns of what was known to be aligned, and
7 that was published in the prior art, in Dr. Simpson's paper, which we'll
8 get to. And you look at what they obtained, and then you determine
9 whether or not they're aligned. It's a pattern visual test.

10 And this is the specification of the patent, and it's describing the
11 FFT analysis that they used in the patent, and they incorporated it in
12 its entirety. So the entirety of the Ayres paper, and we refer to it in
13 the record as the Ayres 2008 paper, is incorporated by reference in its
14 entirety. Now this was a paper, and if we can go -- if you see that Dr.
15 Simpson is the lead, it's from his laboratory. Dr. Simpson was our
16 expert in this case. He provided testimony when he was deposed.

17 JUDGE PAULRAJ: So before we go on to the Simpson paper,
18 or the Ayres paper, maybe for the record, we'll refer to it as Ayres
19 2008 so that we're all on the same page --

20 MR. LEVINE: Yes.

21 JUDGE PAULRAJ: -- if that's clear. When I'm doing the
22 search for the transcript, we'll refer to it as Ayres 2008. Okay. But
23 before we go into that, obviously, I know counsel on the other side is
24 going to bring this up, but I'd like you to proactively address the major
25 peaks definition, which is obviously in the two paragraphs right
26 before the citation of the Ayres 2008 paper.

1 So I guess my question is, first of all, do you agree that it's a
2 lexicography definition? And second, in terms of balancing that
3 definition with your argument that the Ayres 2008 methodology
4 requires something other than an arithmetic approach, how do you
5 balance those two? And are they on equal footing in terms of what
6 Ayres 2008 teaches versus what's expressly defined in the patent, or
7 does one take precedent over the other?

8 MR. LEVINE: So our position is that lexicography does not
9 apply here in this case. That lexicography must be clear to a person of
10 ordinary skill in the art, unambiguous. And here, particularly the
11 definition that Patent Owner is proposing contradicts the specification,
12 contradicts Ayres 2008, is inconsistent with examples in the
13 specification, namely 8B, in which is acknowledged to be a random
14 and controlled sample, and that would fall within their definition.
15 And it's also inconsistent with the prosecution history, very
16 inconsistent.

17 And I'd be preempted a little bit of what I was going to say, but
18 if you look at the left, Figure 4E, that was what was at issue during the
19 prosecution. And you can see there are two primary peaks that come
20 out of sort of the baseline.

21 JUDGE PAULRAJ: And Counsel, we are looking at Slide 17?

22 MR. LEVINE: Slide 17, that's right. I skipped ahead to Slide
23 17. This is Huang 1, Exhibit 1008 that was discussed during
24 prosecution. And this is an example of what we believe is major
25 peaks. And in fact, during prosecution, we feel that the only
26 reasonable reading of the prosecution history is that the Patent Owner

1 agreed. And the Patent Owner said that 4E was covered by the claim,
2 but 4F wasn't.

3 JUDGE PAULRAJ: I guess my issue with this line of
4 argument, you did skip, as I noticed here, straight to the prosecution
5 history argument. And I know we have a sequence of intrinsic
6 evidence and extrinsic evidence that we go in terms of claim
7 destruction. I mean, at least I understand, correct me if I'm wrong, but
8 when you have a lexicography definition, I can take precedence. But
9 at least when it's a clear enough lexicography definition, I know
10 there's a dispute over whether it's a clear definition or not. When you
11 have a clear lexicography definition, that takes precedence over any
12 type of prosecution history-based claim construction argument. Is that
13 fair?

14 MR. LEVINE: I don't think so, Your Honor. Particularly, it
15 depends on how clear the prosecution history is. The prosecution
16 history is the undisputed record between the public and the patent
17 examiner about what the claim means. And a lot of times, the
18 prosecution history is not that dispositive. Here, we believe it is very
19 dispositive and shows exactly what is covered by the claim. That's
20 number one.

21 Number two, again, as Your Honor said, we don't believe there
22 is lexicography because it's not clear. And no person of ordinary skill
23 would give the numerical calculation that they're attributing to it. It's
24 not a specification. It's not in Ayres. It's not in any public case. The
25 first time we see this is in Dr. Mikos's expert report, who has never

1 done an FFT analysis. So again -- and it's not consistent with Ayres,
2 we believe.

3 JUDGE PAULRAJ: Okay. So let me push you on that a little
4 bit.

5 MR. LEVINE: Sure.

6 JUDGE PAULRAJ: I mean, your position, I understand your
7 position is that it's not clear. But it seems frankly pretty clear to me,
8 at least under Federal Circuit precedent, including the Alnylam case,
9 Alnylam v. Margeno case that Patent Owner cited, right? So there
10 was clear guidance in that case that seemed to kind of fall within the
11 scope of the sentence, right? So major peaks is in quotation marks,
12 right? So that tells you something.

13 It says refers to herein, or herein refers to, and then it gives an
14 explanation of what major peaks is. So I guess I'm trying to figure
15 out, leaving aside all the other evidence that I know you're going to
16 point to, you know, that definition itself, if you look at that, why isn't
17 that a definition?

18 MR. LEVINE: I guess number one, the cases say that in order
19 to be a definition, it has to be clear and ambiguous to impose it in the
20 field, and this one isn't. Second of all, even if, even if, which we do
21 not agree with, even if it was a definition, it doesn't say average peak
22 values. It says average peaks, and that does not mean what they say it
23 means. And Dr. Simpson put it in his supplemental declaration, it's a
24 visual test that compares the relative size of the peaks to what was
25 there before.

1 And that's exactly what was provided during prosecution. It
2 was exactly what was argued in the preliminary patent response. In
3 fact, in all phases of this case, until we got Dr. Mikos's report, which
4 was the explicit reason we contend, is to try to distinguish Huang2
5 relevant.

6 So yes, if you did have an absolute clear lexicography, that's not
7 the case here. We don't believe lexicography applies for two reasons.
8 One, because it's not clear, and therefore lexicography doesn't apply.
9 And even if you did, the definition that they're saying it means isn't
10 what it means. It can't mean that, given everything else.

11 JUDGE PAULRAJ: What's your response to the criteria that
12 set forth? And I don't have that case in front of me, but I'm sure
13 you're familiar with it, based on the significance to the argument here.
14 But, you know, it does, from my recollection of reading that case, that
15 it does say definition can be based on the fact that you have the term
16 in quotation marks, and when you say something along the lines of,
17 that term refers to something else. That's a definition, according to
18 Alnylam. So how do you respond to that particular legal question?

19 MR. LEVINE: I think in that case, those factors, or whether
20 they are attempting to give it a definition or not, is a separate question
21 about whether that definition in fact applies in the lexicography. And
22 for that to happen, it's got to be a clear, unambiguous definition. They
23 can define it, but it's got to be consistent with the rest of the
24 specification. And they can't take out a sentence out of the entirety of
25 the specification and contradict everything else. And so we think
26 we're perfectly consistent with the case law, Your Honor.

1 JUDGE PAULRAJ: All right. One more question. I'll let you
2 continue with where you were before. But is your visual, or Dr.
3 Simpson's visual approach, based on the Ayres 2008 paper and the
4 approach that he's taken in terms of analyzing these peaks, is that
5 inconsistent? Or more clearly, is that consistent with the definitional
6 approach that Patent Owner is taking? Tell me where the conflict
7 points are here.

8 MR. LEVINE: So, I think, again in two respects. Dr.
9 Simpson's definition is what the claims mean, according to us, based
10 on everything. Prosecution history, specification, and claim language.
11 If in fact the word average is given significance, Dr. Simpson testified
12 that, you know, what an average is to me, being a person of ordinary
13 skill in the art of writing that paper, means that you have two claims
14 that stand out above the baseline.

15 So I think, in both senses, I think we are on the better side of
16 that argument, in a sense. Given that, particularly, the only expert
17 they have is Dr. Mikos, who's never done an FFT with an alignment
18 plot. He's never practiced the Ayres method. And he's interpreting
19 these claims in a way, he's an engineer, and I guess, you know, to a
20 hammer, everything is a nail. To an engineer, everything is a
21 mathematical problem. But there's no math in finding major peaks.
22 It's not in the patent. It's not anywhere else, except in Dr. Mikos's
23 report. The patent doesn't even identify the peaks in order to do that
24 average.

25 JUDGE PAULRAJ: I don't know if math is necessarily
26 required, even under Patent Owner's approach. But what I think is

1 required, and this is a dispute, right? In order to get a peak higher
2 than an average, you can't have all the peaks to be the same height,
3 right? You know, so in other words, if I just give you a data set of 2
4 and 2, what's the average of that? It's 2, right?

5 MR. LEVINE: Well, that is their -- I think that is their
6 mathematical test, that they have two peaks and the average would be
7 the same.

8 JUDGE PAULRAJ: But I don't need to calculate the average in
9 that example. I don't need to necessarily calculate an average to
10 figure out if something is higher than the average. Does that make
11 sense, or is that like --

12 MR. LEVINE: No, I understand what you're saying. And in
13 fact, and hopefully we'll get to this, is that their position requires there
14 to be some imperfections. And in fact the patent itself, which
15 incorporates Ayres, talks about that these extra humps are noise. So
16 their claim construction requires noise into the thing, so --

17 JUDGE PAULRAJ: I definitely want you to touch on the noise
18 versus peaks issue. I've been struggling with that issue in the LIPO
19 sets at that point.

20 MR. LEVINE: Okay. Let me go back a little bit. So again,
21 this is Ayres. This is Slide 9. And Slide 9 is, in fact, the Ayres paper,
22 and it's talking about the visual test, where it says the degree of
23 alignment present in the original data image is reflected by the height
24 and overall shape of the most prominent peaks in the alignment plot.
25 In the last sentence, the principal axis of fiber alignment is determined
26 by the position of the alignment peaks in the illustrated example,

1 Figures 1F and I. And here you have two primary peaks, just like we
2 say it is. Again, this is Ayres 2008, Exhibit 110, at 608 and 610.

3 In contrast, this is a random sample, where you have four
4 peaks, 90 degrees apart, not 180 degrees apart. 90 degrees apart, and
5 this is a classic example of a random sample.

6 JUDGE PAULRAJ: And what slides were you looking at last
7 time?

8 MR. LEVINE: Those are Slides 9 and 10, Your Honor. And
9 here we have, and this is Slide 11. This is also Ayres at page 614. Dr.
10 Simpson, in his paper, 2008 paper, which is incorporated into the
11 patent, did analysis of strands of spaghetti as a control. Now the test,
12 the FFT test, doesn't distinguish between materials. It's not AI. It's
13 not smart. A fiber is a fiber. And if you look at G, those are perfectly
14 straight fibers. There are no fibers that are misaligned. It's perfectly
15 straight. And that was a control, a test.

16 And if you look at the trace that corresponds to G, it is the two
17 black peaks that are at, if you take a look at those, are at 90 and 270.
18 And then you have this little hump at 180, and that little hump repeats
19 at 360 because it's a spectrum. So you have these two big peaks and
20 you have this little hump that's there.

21 And what does Ayres say about that little hump? The larger
22 peaks report the principal axis of alignment while the smaller peaks
23 correspond to background information, noise, and edge effects. This
24 is incorporated into the patent. It's a statement in the patent that the
25 Patent Owner is bound by, saying that small peak in a perfectly
26 aligned sample is noise.

1 JUDGE PAULRAJ: Are all small peaks in any FFT plot going
2 to be noise, or can they be attributed to something else?

3 MR. LEVINE: If it looks like that one, like that 180 peak, that
4 is a classic noise peak.

5 JUDGE PAULRAJ: Well, why does that look like a classic
6 noise peak versus -- and I'd have to go again to this. But if you can,
7 what Patent Owner's referred to as secondary alignment. You know,
8 if -- I've said noise, and correct me if I'm wrong again, is attributable
9 to artifacts in the actual FFT methodology, right? Whether or not it's
10 the image quality, the use of a mask, other things that are attributable
11 to the actual FFT methodology rather than attributable to the
12 properties of the fibers themselves, right?

13 MR. LEVINE: Correct.

14 JUDGE PAULRAJ: Could there be smaller peaks that are
15 attributable to the properties of the fibers themselves?

16 MR. LEVINE: According to the Ayres method, if there are
17 small peaks and they're not sort of large enough to show
18 misalignment, like for example, that's -- again it's a visual test. You
19 have to look at the visual evidence. So that's a perfect example.
20 Those are four peaks.

21 JUDGE PAULRAJ: Those are all noise peaks?

22 MR. LEVINE: No, those are alignment peaks.

23 JUDGE PAULRAJ: Okay.

24 MR. LEVINE: Those are all peaks going in different
25 alignments, as opposed to this. And that's what the paper is setting
26 up. It's setting up the test. While that peak, when you have perfectly

1 straight, that little bump is always at 180. There may be other times
2 when you have noise peaks. And in fact, Figure 3N from Ayres does
3 have noise peaks, and we'll get to that. But that hump, according to
4 the patent, is noise.

5 JUDGE PAULRAJ: That's the example where you have
6 misalignment, as you'll see on your demos for Slide 10. Is that right?

7 MR. LEVINE: Slide 10 is the one with the four peaks, right?

8 JUDGE PAULRAJ: Yeah, the four peaks --

9 MR. LEVINE: That's the ramp, yes.

10 JUDGE PAULRAJ: That sounds good.

11 MR. LEVINE: Yes.

12 JUDGE PAULRAJ: But let me follow up with that. So those
13 four peaks are an example, at least according to Ayres 2008 paper, of
14 peaks that occur when you have a random matrix, right? Is that like
15 the spaghetti strand situation? Is that what we're talking about?
16 Those four peaks would be what would result?

17 MR. LEVINE: Those four peaks are randomly aligned fibers.

18 JUDGE PAULRAJ: They're still aligned, they're just kind of
19 randomly aligned in any --

20 MR. LEVINE: In different directions.

21 JUDGE PAULRAJ: -- in every different direction.

22 MR. LEVINE: Right. And that's why you have four peaks in
23 the 90s, and it's not aligned in one direction where you would have
24 two peaks separated by 180 degrees.

1 JUDGE PAULRAJ: Okay. So will those four peaks always
2 necessarily be of the same intensity when you have randomly aligned
3 fibers?

4 MR. LEVINE: Not necessarily. Not necessarily.

5 JUDGE PAULRAJ: Okay.

6 MR. LEVINE: But, I mean, we have to look at what's in the
7 record in the examples that Dr. Simpson gave in the Ayres paper, and
8 this is a prototypical example of a random sample.

9 JUDGE PAULRAJ: So you can have a situation where you
10 might have alignment, say, in a predominantly vertical direction, and
11 you might have a secondary alignment, say, at a 45 degree angle, that
12 might result in a peak that's lower than the alignment that -- the peak
13 that corresponds to the predominant alignment --

14 MR. LEVINE: I have not seen an example of that in the record.

15 JUDGE PAULRAJ: Okay. Fair enough.

16 MR. LEVINE: I have not seen an example of that in the record.

17 JUDGE PAULRAJ: There's nothing in the record that shows
18 that type of alignment?

19 MR. LEVINE: No, no.

20 JUDGE PAULRAJ: Okay.

21 MR. LEVINE: And in fact, if you -- let's see. Go back to -- if
22 you look at C, so C is not aligned at all. And that's those jagged red
23 lines that are everywhere.

24 JUDGE PAULRAJ: Yes.

25 MR. LEVINE: Okay. So as opposed to G, which is perfectly
26 aligned with the hump. And if you compare G to AA, I mean, it looks

1 almost identical. You have the little hump noise in the beginning, and
2 then you have the two primary peaks. And in fact, in Figure 8B, you
3 have, again, a -- that's four peaks that are essentially the same size,
4 and that's a perfect example of a random sample.

5 And when we did the calculation that Patent Owner says is the
6 test, and in fact, when Dr. Mikos identified the peaks at his deposition,
7 turns out that that middle peak is smaller than the average, and the two
8 to the left and right are higher. And that would fall within their claim
9 construction, which cannot be the right result.

10 JUDGE PAULRAJ: Well, I guess, yeah. I mean, for 8B
11 especially, right? I know that's going to be an issue that's part of the
12 objections, but it's -- I mean, those peaks, you know, to the extent that
13 they're smaller, the middle peak, it's only slightly smaller. And I think
14 I looked at the numbers you provided and I calculated it's like a 2
15 percent deviation from the highest peak and the smallest peak, right?
16 So is that really a smaller peak, or is that what might be I think
17 considered, you know, just measurement error?

18 MR. LEVINE: So under our test, those are four peaks that are
19 essentially the same size as a random sample. Under their test, when
20 you have to actually identify the peaks, calculate the average, that
21 would be -- that would fall within Claim 1.

22 JUDGE PAULRAJ: So you're saying that at least their test, as
23 presented in their original Patent Owner response, would require any
24 deviation, no matter what it was, 0.01 percent smaller peaks, if that
25 results in a different average?

26 MR. LEVINE: Absolutely. You know, and in fact --

1 JUDGE PAULRAJ: Okay. And is that a realistic way a PSITA
2 would look at this, especially given that FFTs, like any type of
3 experimental methodology, there's going to have -- there's going to be
4 errors in these instruments. So why would you look at it with that
5 level of precision?

6 MR. LEVINE: Because that's why it's not a mathematical test.
7 That's why it's a visual test, where you look to see whether you have
8 two peaks or four peaks. And four peaks like that is a random sample,
9 and two would be in a line sample. And you don't do an average.
10 That is our whole point. And besides, if you were to calculate
11 statistics, I mean, how much lower would it have to be? There's no
12 statistics in the patent. They don't define how -- it's four
13 measurements. How would you even define statistics for four
14 measurements?

15 I mean, there's no explanation of whether that amount is
16 statistically greater, how greater it would have to be. And in fact, we
17 could have retained a statistician expert if this had been in the Patent
18 Owner's response. We didn't have that opportunity because it came in
19 the surreply.

20 All Dr. Mikos did in his report was he said, he only did 8A, he
21 looked at the peaks, and then he did an average. He didn't say, this is
22 significantly different. This thing just constitutes measurement error.
23 So again, our test, we don't get there. It's a visual test. Aligned on
24 8A, not aligned on 8B. Four versus two. And of course, Huang1 and
25 Huang2, which are prototypical examples of aligned scaffolds, we
26 believe would fall within the scope of that claim.

1 JUDGE PAULRAJ: Would you agree, or even taking their test
2 to face value, right? That the peaks at 90 degrees and 270 in Figure
3 8A are higher than the average of the peaks? I don't even need you to
4 calculate the average of those peaks. I don't need you to do the math,
5 right? Just looking at it visually, would you agree that's higher than
6 the average?

7 MR. LEVINE: Yes.

8 JUDGE PAULRAJ: All right. So that's my point, right? I
9 think you need to do the math to always figure out whether a peak is
10 higher than the average.

11 MR. LEVINE: But our point is, even if you had two, you
12 would be able to see whether it's higher than the -- in other words,
13 higher than the baseline, the average sort of result there. You
14 wouldn't have to have a third or fourth peak in order to see whether
15 you have two peaks that stand out from above the average. And in
16 fact that's, if you get back to it, that's exactly what Huang1 was.

17 I mean, Huang1, they said was within the scope of the claim.
18 And you can see, I would say, the average is sort of that baseline right
19 there. There's all kinds of little things there at the bottom. And you
20 have two peaks that stand out. If those aren't prominent peaks, what
21 are they? Are they minor peaks? Are they not peaks at all? I mean,
22 that's why, on our test, it's very simple to apply. If that's an aligned,
23 that's a major peak. And the random sample isn't. We have more than
24 two peaks, not separated by 180 degrees.

25 JUDGE PAULRAJ: And Counsel, I know I probably took you
26 off track, but --

1 MR. LEVINE: No, it's okay. This is why we're here. And I do
2 want to make this point. This is -- and again, I'm sorry for not
3 identifying the slides as well as I should. This is Slide 16. This is
4 Huang1, Exhibit 1008. Which is, in fact, a document that was
5 discussed during prosecution. And here, the authors of Huang1 said
6 that there are two peaks at 175 and 355. And the nanofibers were
7 highly arrayed along one direction. Now this 4E is pure TPU, and
8 that's important. It's pure TPU.

9 4F, they said, and this is important. Although two peaks could
10 be found, major peaks, the existence of other peaks indicate that some
11 nanofibers are not well aligned. So they're saying that's mixed.
12 There's mostly aligned, but some that are not aligned. In a sense,
13 that's what the Patent Owner is now saying is the definition. Some
14 most aligned, but some not aligned. And what did they say about
15 this? Well, the examiner rejected the claim because it had two
16 primary peaks at 175 and 355. And that was Slide 18.

17 And then if I go to Slide 19, this is the respondent's response.
18 The Patent Owner's response. And what did the Patent Owner say?
19 Did he argue? No. Those two peaks, there's no average. There's only
20 two. They can't be bigger. They can't be folded in the scope of the
21 claim. The Patent Owner didn't say anything like that. He said, the
22 examiner says that 4E, with those two peaks, are within the scope of
23 the claim.

24 And then they say, in contrast, Huang's electrospun fibers
25 comprising TPU, collagen, and chitin did not exhibit the degree of
26 alignment as recited in present Claim 1. So 4E does, and 4F doesn't.

1 It's pretty clear. FFT analysis of these fibers shows major peaks
2 closer than 180 degrees. And then, and why is that important?
3 Because 4F was collagen. And that was the point they were making
4 of the invention, that they were able to spin a line of collagen and no
5 one else could.

6 And so what did they do? And in fact, they even mentioned Dr.
7 Simpson because he's an expert in the field. He was the part of the
8 prior art. And they said Dr. Simpson and Huang¹ couldn't get aligned
9 collagen. They could only get aligned TPU within the scope of our
10 claim, which is that, exactly what we say the claim means. And so
11 what did they do? They amended the claim. I think in their surreply,
12 Patent Owner was saying, this is silence. They were silent during
13 prosecution.

14 Respectfully, we contend that they were not silent. That they
15 affirmatively argued about what the claim meant, and they amended
16 the claim to get over the prior art. To get over what was within their
17 claim. And that's why we think the prosecution in this case, because it
18 is -- it's a visual test when you're comparing pictures. Prosecution is
19 very important here.

20 So let's get to Claim 1 of the '223 patent. And here we have
21 claim 1 of the '223 patent, and this is Slide 22. And this is -- '223
22 patent is Exhibit 1001 for the record. And again you have the scaffold
23 comprising one or more electric fibers comprising collagen where an
24 FFT analysis results the fibers have adjacent major peaks with about
25 180 parts from each other. 180 degrees apart from each other.

1 JUDGE PAULRAJ: Counselor, it's in your position that the
2 FFT clause, we'll just call it that. Anything after the wherein clause in
3 that Claim 1, right? The FFT clause. Is that just equivalent to saying
4 that the fibers are aligned? So if I said, you know, I crossed out
5 everything after the wherein and said the wherein fibers are aligned, is
6 that the same claims both in your view?

7 MR. LEVINE: So that was a question that I hadn't anticipated,
8 Your Honor. And I think --

9 JUDGE PAULRAJ: I try to keep everyone --

10 MR. LEVINE: Yeah, there are certainly other ways to show
11 alignment. For example, it could be wherein you have mechanical
12 testing. Wherein you have --

13 JUDGE PAULRAJ: I understand. But I'm thinking of whether
14 or not the equivalence here is whether or not. This is just another way
15 of saying that, a fancy way, you know, of saying that the fibers are
16 aligned. Because at the end of the day, and I'll certainly press Ms.
17 Wieker on this, but this is a product claim. It's not a method of
18 performing FFT. You're looking at the properties of the scaffold. So
19 is the property that's intended to be captured here just alignment, or is
20 there something else?

21 MR. LEVINE: No, you are correct. It is alignment. In FFT,
22 it's not -- in the context of this case, yes. If it has an FFT of two
23 peaks, 180 degrees apart, that is aligned. And if it's aligned and you
24 show it's aligned, it must have the two peaks 180 degrees apart. Does
25 that answer your question?

1 JUDGE PAULRAJ: I'll follow up with another question, and it
2 ties in with what we discussed earlier about noise or secondary. So
3 does that require perfect alignment? In other words, does every fiber
4 in that scaffold have to be directly, let's just pick vertical, directly
5 vertical or at least as close to vertical as possible?

6 MR. LEVINE: If you have the telltale two prominent peaks
7 that we've seen in Ayres 2008 in Huang1, if you have those two peaks
8 180 degrees apart, it is aligned. And that will show you that the
9 scaffold is aligned, and that's what all FFT does. And I think Dr.
10 Simpson said on those, if you want to say how aligned it is, there
11 could be a shoulder on one peak where it could be a little broader.

12 But in terms of this case, whether something is aligned, and
13 particularly if something is highly aligned like Patent Owner said
14 Example 2 was, or Huang2 where they proved it three different ways,
15 or Lee where they proved it three different ways, you must have those
16 two primary characteristics. That's our position.

17 Okay. So going back, so this is Slide 23. And the problem, so
18 they limited the claim during prosecution to only include collagen
19 because there was Huang1. The problem was Huang2, which was not
20 before the exam or during prosecution. That was noted during the
21 institution decision. And the point of Huang2 where they had
22 isotropic fibers and anisotropic fibers, which are a fancy way of
23 saying aligned and unaligned fibers.

24 And the whole point of Huang2 where they were trying to
25 figure out whether fibroblasts differentiated to myofibroblasts, which
26 is critical in all sorts of injury healing, all sorts of methods. And they

1 were trying to figure out whether they did better on aligned scaffolds
2 or unaligned scaffolds. That was the whole point. So they had to
3 make aligned and unaligned scaffolds to test that.

4 And they succeeded. And they found their hypothesis was that
5 it would matter, and it turns out it didn't matter. And both experts, it
6 doesn't happen a lot in this case, but both experts agreed that there's
7 no question that Huang2 is absolutely aligned.

8 Dr. Simpson also noted that they used mechanical testing,
9 which is the gold standard. It's destructive, but it's the gold standard.
10 And I think I skipped this when I was talking. One of the advantages
11 of the Ayres 2008 method is that it's not destructive.

12 JUDGE PAULRAJ: I wanted to briefly touch on that.

13 MR. LEVINE: Sure.

14 JUDGE PAULRAJ: I was trying to figure out what the whole
15 issue was. Was it destructive? Did we just go to the obviousness
16 ground for Lee? Is that the only reason why we're talking about that?

17 MR. LEVINE: Yes.

18 JUDGE PAULRAJ: Okay. All right. Thank you for that.

19 MR. LEVINE: Okay. And so this is Slide 26. And here we
20 have Huang2, the beautifully aligned fibers. And they did an FFT as
21 well. That has that one beautiful prominent peak showing how
22 aligned the sample is between 0 and 180 degrees, as noted in the
23 institution decision. And we just did this for comparison purposes.
24 This is Slide 27. Huang2 was following closely not Ayres 2008, but
25 Ayres 2006. And those are figures from Ayres 2006 that show the

1 one peak between 0 and 180, showing it's aligned, and comparing to
2 Huang2.

3 And then, as Your Honor recalls, at institution, the main
4 argument that was raised was that, well, Huang2 doesn't show two
5 peaks. It shows one peak. And therefore, if one peaks are on two
6 peaks, then Huang2 can't anticipate. But of course, Ayres says that,
7 and it's a well-known established scientific fact that the alignment
8 peaks are symmetrical. So if you have one peak between 0 and 180,
9 you're going to have two between 0 and 360. And I believe that issue
10 is off the table. I think Patent Owner agrees that there's two peaks in
11 Huang2 at this point.

12 So that was our position. We have two primary peaks, two
13 prominent peaks. It anticipates that claim. And now let's move over
14 to Lee. Now, Lee --

15 JUDGE PAULRAJ: Counsel, and I'd like you to do it at some
16 point. The sense in testing issues, especially whether or not -- I know
17 we've raised some concerns about it and Patent Owner has certainly
18 raised some concerns about it, whether or not the methodology was
19 sufficiently disclosed per our rule, right? So if you could touch on
20 that, certainly that would be helpful.

21 MR. LEVINE: So if we turn to, let's see, if we turn to Slide 62.

22 JUDGE PAULRAJ: And if you were going to get to that later,
23 I apologize for taking up your --

24 MR. LEVINE: No, it's okay. And I just wanted to introduce
25 this because I think these cases are very important, these three cases
26 that we cited in our briefs. And the central thrust of these three cases

1 is you can't require the prior art to have more detail than the patent.
2 The patent can't be entirely silent or be sparse on a particular aspect
3 and then require the prior art to show all of these different features.
4 And that applies not only to Dr. Simpson's testing, but to a lot of the
5 dependent claims.

6 A lot of the dependent claims are arguing there's no reasonable
7 expectation of success, but the patent is completely silent about how
8 to achieve these properties. So I just wanted to make that point in
9 case I don't get to it.

10 For Dr. Simpson's testing, and again for Huang2, we don't need
11 Dr. Simpson's testing at all, we believe. We believe Huang2 shows
12 the two peaks and we're within the scope of the claim and we think
13 that's fine.

14 JUDGE PAULRAJ: Let me just give you -- if we do agree with
15 Patent Owner's construction requiring higher than average, right?
16 And by extension, if that requires more than two peaks of the same
17 height in the plot --

18 MR. LEVINE: Then we do need Simpson's testing.

19 JUDGE PAULRAJ: You do need Simpson's testing?

20 MR. LEVINE: Yes, at that point.

21 JUDGE PAULRAJ: So that's when you need it, okay.

22 MR. LEVINE: Yeah, that's when we need it. Because I think
23 it's undisputed that Dr. Simpson has the noise peak in the middle,
24 which is what he said it was.

25 JUDGE PAULRAJ: So there's a sub-dispute there as to
26 whether or not that noise peak, as you characterize it, is actually what

1 would be considered a minor peak per Patent Owner's construction. Is
2 that right?

3 MR. LEVINE: Well, I think they're saying it is a minor peak. I
4 think Patent Owners are saying none of this is noise. I think they're
5 saying it's all --

6 JUDGE PAULRAJ: All right. So the whole question as to
7 what's noise versus what's a minor peak is also kind of something that
8 I would like some clarification from both sides on.

9 MR. LEVINE: Yeah, our position is that that's noise. That it's
10 all noise. Now if we lose and the Board adopts Patent Owner's
11 construction, then this would fall within the scope of that claim.

12 JUDGE PAULRAJ: Because it's still considered higher --

13 MR. LEVINE: A minor peak.

14 JUDGE PAULRAJ: -- a minor peak. But this minor peak is
15 not attributable to any specific feature of the fibers themselves in
16 Huang2. It's attributable to the presence or absence of a mask. Is that
17 correct?

18 MR. LEVINE: That would be our position. That would be our
19 position. And just to be clear, our position is that peak is noise and all
20 those peaks, those little peaks at 180, are noise.

21 JUDGE PAULRAJ: So when you added a mask, you got that
22 middle peak, that smaller peak. Is that --

23 MR. LEVINE: We did.

24 JUDGE PAULRAJ: And when you didn't have a mask, that
25 peak went away.

1 MR. LEVINE: Right. Which is not the usual case. Usually the
2 mask, it takes away -- it usually focuses and takes away the noise
3 more than adds it. Here, that little peak showed up when we had the
4 mask. And Dr. Simpson did it both ways and got the two primary
5 peaks.

6 JUDGE PAULRAJ: Okay. Why did that happen here?

7 MR. LEVINE: I don't know.

8 JUDGE PAULRAJ: That's a problem for your tech expert
9 there, right? I mean, we got a mask -- I mean, I think if you're getting
10 a peak from the use of a mask, and you would expect a mask to take
11 away peaks, isn't that a problem with methodology?

12 MR. LEVINE: No, I think it depends on the -- again, it
13 depends on the analysis and the brightfield microscopy he used. And
14 he did it both ways. And our position is that both -- he did the test, he
15 did an alternate testing to show with a mask, without a mask, and he
16 still got beautiful two primary peaks, which is all that. Everything
17 else in the middle is noise, is some form of noise.

18 JUDGE PAULRAJ: Right. And your position is that the Ayres
19 2008 paper allows enough flexibility where you can do it with a mask,
20 without a mask, and all you have to do is just make sure that you get
21 two major peaks of that. Is that right?

22 MR. LEVINE: That's right.

23 JUDGE PAULRAJ: Okay. As long as you get that, like all the
24 other minor peaks are noise or whatever it is, that kind of falls by the
25 wayside. Is that your position?

26 MR. LEVINE: Mm-hmm.

1 JUDGE PAULRAJ: Okay.

2 MR. LEVINE: And in fact, if you -- this is also, this is the
3 figure I was alluding to earlier in Ayres. This is Figure 3N, and I
4 wanted to make sure I got there. This is the Ayres 2008 paper,
5 Exhibit 1010. This is Slide 53. And this is the same scaffold. This is
6 the same scaffold. Both I and K are the exact same scaffold. I is, I
7 think on the paper it's blue, but here it's black. And you can see I has
8 these -- and I think you asked me at one point, are there examples of
9 other noise peaks other than the little hump at 180? Here are
10 examples of what we consider noise peaks.

11 And K, they put a mask on it and got rid of those noise peaks in
12 this particular example, and that's the red. Now, Ayres says the red,
13 with only two peaks, is an aligned sample. I mean, that's in the Ayres,
14 and therefore incorporated by reference into the patent.

15 JUDGE PAULRAJ: Doesn't that -- I'm trying to figure out how
16 this cuts, which way this cuts, right? You know, like, so we have in
17 the record, as you just pointed out, an example where a mask may
18 have introduced a peak. And then you have another example where a
19 mask took away a peak. So I guess I'm trying to figure out, first of all,
20 does that give me any guidance? Like, if I follow Ayres -- like I
21 understand your position that we don't even need to worry about those
22 peaks. Just look at the major peaks, right?

23 But I guess I'm also trying to see, like, if Patent Owner's
24 construction carries the day, and I don't know if it does. I'll frankly
25 say it's a close call, you know, on the clinical instruction issue. If
26 Patent Owner's construction carries the day and you do require minor

1 peaks, how do you determine whether or not a particular scaffold has
2 minor peaks?

3 MR. LEVINE: Yeah, the patent doesn't give you that
4 information. I mean, the only thing that the patent does is incorporate
5 Ayres, and that says that the larger peaks report the principal axis of
6 alignment while the smaller peaks correspond to background
7 information, noise, and edge effects. That's in the patent. The patent
8 doesn't tell you how to distinguish between noise and a peak.

9 And in fact, in the surreply, which I think you're noted to,
10 Patent Owner said, well, you don't count any of that because it's all
11 noise. So none of this would fall within the scope of the claim. But
12 again, I asked Dr. Mikos that in his deposition, and he said, no, I
13 would consider those peaks. So Patent Owner's taking a position that
14 Dr. Mikos contradicts. And the difference is, on our test, you don't
15 have to decide whether something is a noise peak or a minor peak of
16 non-alignment.

17 And if it is a minor peak of non-alignment, what did the Patent
18 Owner invent? I mean, the prior art had misaligned fibers and Huang
19 and Lee had completely aligned collagen fibers. What is the
20 invention? Sort of aligned collagen, but with some misalignment? I
21 mean, that doesn't make any sense. Our position is that's nonsensical,
22 but that's what the patent means. I mean, how is that distinguished
23 over the example in Huang1 where they said that they had mostly
24 alignments and some peaks that were not aligned?

25 So again, and then I asked Dr. Mikos, how can that be the case
26 where you have a scaffold where, depending on whether there's noise

1 or not, it's within or outside the claim? Essentially the same question
2 you asked me. And he said, the scaffold's the same, the analysis is
3 different. Well, that can't be right. You can't, depending on whether
4 there's noise, you can't have a scaffold that's either within or without
5 the scope of the claim. That would render the claim hopelessly
6 indefinite. And that's what Patent Owner's depending on, and we
7 think that's just not right. So I think we were --

8 JUDGE PAULRAJ: Before I distracted you, you were getting
9 into the Lee ground.

10 MR. LEVINE: Lee. Let's go back to Lee.

11 JUDGE PAULRAJ: Yeah. You have about eight minutes, but
12 I've been taking up a lot of your time. So I'll give you a few extra
13 minutes.

14 MR. LEVINE: Thank you. I appreciate that, Your Honor.
15 Lee, let's get back to Slide 29. So Lee, like Huang2, was essentially
16 investigating the alignment of fibers and how it affected the growth of
17 muscle cells in curing tissue injuries. And again, both Dr. Mikos and
18 Dr. Simpson agreed that Lee is completely aligned. Now, you'll hear
19 from Patent Owner. I think they have a slide showing a Dr. Simpson
20 paper where Dr. Simpson actually said, I know this isn't aligned, but
21 I'm saying it's aligned for simplicity.

22 That's not the case with Lee. Lee proved it three different
23 ways. They proved it with pictures, they proved it with software, not
24 FFT alignment that we're talking about, and they did mechanical
25 testing. Both experts agree that Lee is completely aligned. And I
26 asked Dr. Mikos that. He agreed.

1 So then there's a question, and this came up in the institution
2 decision. It was raised by Patent Owner in its preliminary response.
3 We didn't have an opportunity to respond. Responding in our papers
4 and now, is that we argue that Lee by itself also discloses this element
5 of the claim by describing aligned PCL collagen fibers. Lee discloses
6 aligned PCL collagen fibers that meet this element of the claim.

7 In other words, if you have truly aligned fibers and you prove it
8 three different ways, you must have those two FFT peaks. You have
9 to have them. And that's what Simpson said. An FFT analysis
10 measures the degree of fiber alignment, and FFT results show fibers
11 having adjacent peaks with about 180 degrees apart only occur when
12 the fibers are aligned. And this is in the petition. This is our
13 argument in the petition.

14 And then Dr. Simpson, he did testing that confirmed this was
15 the fact. And he took Lee's picture, he took the picture that was
16 unprovisional because it was a better picture, and he did an FFT on it,
17 and he got the two alignment primary peaks.

18 Now, there was an issue raised in Patent Owner's prior response
19 and in the institution's decision about inherency, about whether we
20 argued inherency. Inherency's usual fact pattern for inherency is
21 where the prior art, the acclaimed subject matter, is unrecognized or
22 unknown in the prior art. And then you repeat the example in the
23 prior art and lo and behold, you always get the claimed invention. So
24 usually there's no recognition or knowledge. Here, our position is
25 anyone reading Lee would understand and know and recognize that
26 you would get those two peaks.

1 In any event -- so that was our primary argument, but we also
2 had an alternative argument. And this is one of the formulations for
3 inherency. There are a lot of different ways to say it, but this is one.
4 Inherent anticipation requires merely that the disclosure of the prior
5 art is sufficient to show that the natural result flow from the
6 operation as taught in the prior art would result, would result, in the
7 claimed product.

8 And it's important that the test as done in the prior art would
9 give you the claimed product. The conditions can't be, you know,
10 different. Like, for example, that comes up in polymorph cases. And
11 what did we argue in our petition? We said this would show -- further
12 it was known at the time of the filing of Lee that an FFT analysis
13 could be performed, and this would show that the fibers were oriented
14 on the scaffold in Lee in an aligned manner. This is from the petition.
15 This would show, not could show, not may show, would show, which
16 is exactly the standard for inherency in the Federal Circuit.

17 And then we said to demonstrate it, Simpson ran an FFT. And
18 we cited just three particular -- three specific paragraphs, and one of
19 them was 190. And that's the other formulation of inherency. These
20 properties are a natural and necessarily present property of the fibers
21 that Lee discloses. So we believe, we argued both, that a skilled artist
22 would understand from Lee that it must have those, those fibers must
23 have the peaks, and in any event, it would be inherent because of
24 Simpson's testing and what we argued in the petition.

25 JUDGE REIMERS: Counsel, I know we keep going back to
26 this same issue, but I just want to make sure that it's clear on the

1 record, not only for you all, but for us. Could we go back to what we
2 were discussing before about the smaller peaks versus noise? And
3 could you provide for us what you feel is a differentiation between
4 what you consider to be, what would be considered a small peak, as
5 opposed to noise?

6 MR. LEVINE: Yeah. So our example, and I think this is the
7 best example because it's incorporated by reference into the patent, is
8 at Slide 11 and Slide 12. Here's a perfectly aligned scaffold of fibers.
9 It's a control sample, and there's that little hump at 180. And the
10 patent says, specifically, the large peaks report the principal axis of
11 alignment while the smaller peaks correspond to background
12 information, noise, and edge effects.

13 And in fact, every, I think every FFT that we've looked at, in
14 this case, Huang1, Huang2, Lee, it's pretty easy to determine whether
15 something is a peak or a noise visually. So here you have four peaks
16 that are random. Here you have two main alignment peaks and some
17 noise in the middle. Here you have two primary peaks. There's
18 Huang2. You can see how high they are. Then you have alignment --
19 you have different -- and the authors actually said you have some
20 aligned peaks in the example, but then you have also random things in
21 the example.

22 And then you have Dr. Simpson's testing of Lee, which is Slide
23 33, in which you have two primary peaks and then a bunch of noise
24 on the bottom. So that's our position, and it's hard because it's a visual
25 test. And that's why Ayres is a visual test, that's why everyone who's
26 ever done FFT is a visual test. No one has done a mathematical

1 calculation. Huang1 doesn't have even values on the y-axis. There
2 are no values on the y-axis. You couldn't do the test in Huang1
3 because there's no peak values. And in fact, the patent doesn't identify
4 peak values, and Dr. Mikos had a hard time even determining where
5 the peaks were.

6 So the idea that this is some rigid -- it's a picture's worth a
7 thousand words. And here when you have an FFT analysis, and the
8 SPESS is talking about pattern recognition, visually recognizing
9 patterns, and you look at the patterns, and you've got two -- Dr.
10 Simpson says it's a quick, easy, non-destructive test to confirm
11 alignment to see if you have the two alignment peaks.

12 And I think Patent Owner is -- I don't know what, they're
13 converting into something else because the patent says they invented
14 highly aligned fibers, and they were the first to do it. And now I think
15 they're saying, no, they're highly aligned, but with some
16 misalignment. How much, we're not telling you. The examples don't
17 say anything about misaligned. It's all about alignment. So I know
18 that's maybe not the most satisfying answer, but it's a visual test. And
19 I think looking at the different spectra is how you would assess that.

20 JUDGE REIMERS: Thank you for that clarification.

21 MR. LEVINE: So it looks like I'm almost out of time.

22 JUDGE PAULRAJ: I'll give you two more minutes.

23 MR. LEVINE: Two more minutes, okay. Your Honor, is there
24 any other particular issue I should go to in my remaining two
25 minutes? Do you want to go to '227?

1 JUDGE PAULRAJ: Sure. We can touch on, yeah, any specific
2 issues. And obviously there's a lot of overlap, but if there's any
3 specific issues worth discussing. I know there's a lot of issues in this
4 case, but --

5 MR. LEVINE: Yeah, there are.

6 JUDGE PAULRAJ: -- if you want to go to '227 --

7 MR. LEVINE: Let me quickly go to '227.

8 JUDGE PAULRAJ: -- well, you have two minutes.

9 MR. LEVINE: Because I think that was -- I think that's an
10 issue that was brought up. So this is Slide 70, in which we're talking
11 about the arguments we made in the petition about the combination of
12 Kuo and Haung2. And again, the patent doesn't actually treat a tendon
13 injury or treat a ligament injury. The patent is again about making the
14 apparatus for spinning this heart basement membrane fiber. So all of
15 you teaching in the patent, if there's not very much, it's all prophetic.

16 Kuo does a lot more than the patent does, and we argue that you
17 wouldn't combine Huang2 and Kuo, and this is what our petition
18 argued. We talked about Kuo, which is in the same field, discloses
19 electrospun collagen scaffolds that are seeded with cells and formed
20 into a desired shape to replace tissues, including muscles, ligament
21 tendons, and nerves, to repair various tissue injuries.

22 And importantly, we cite the abstract, and this paragraph 5 and
23 52, and we cite the abstract Kuo throughout our petition. And then we
24 say accordingly, a POSA would have been motivated and able to use a
25 scaffold comprising of fibers, the aligned fibers, not the scaffold plans

1 with fibroblasts, but the aligned fibers, as shown by FFT analysis
2 containing collagen, to treat tendon or nerve as taught by Kuo.

3 And in fact, what does Kuo teach? Kuo teaches as the first
4 step, starting with a flat sheet, an aligned scaffold, a flat sheet, which
5 is exactly what we argued in our petition. That you start with a flat
6 sheet, and then you add the cells later, and then you roll it later. So
7 we're basically saying that Huang2, you combine Huang2 and Kuo,
8 because Huang2 is the first step of Kuo. And Kuo says, and this is
9 essentially what we cite in our petition, as well as the abstract, it's
10 words basically saying what the abstract is.

11 And here we said, they say, well how do you make -- Kuo says,
12 how do you make the fibers? How do you actually make the fibers?
13 Well, they say you look at these different fields, and one of them is
14 the art in wound dressing, because that's very advanced, which is
15 exactly what Huang2 is. And in fact, Dr. Mikos said, Huang2
16 discloses the scaffold is used for skin and wound. It says, would
17 repair. It's a typo. It should be wound repair.

18 JUDGE PAULRAJ: Counsel, you're up on time. So thank you.

19 MR. LEVINE: Thank you very much, Your Honor. Thank
20 you, Your Honors.

21 JUDGE PAULRAJ: I'll give you a full ten minutes back for
22 rebuttal or reply.

23 MR. LEVINE: Thank you.

24 JUDGE PAULRAJ: While you're at it, you can also tell me
25 how much time you want for your rebuttal.

26 MS. WIEKER: Excuse me? I'm sorry.

1 JUDGE PAULRAJ: I don't know where you start your
2 paragraph. Just while you're at it, you can also tell me how much time
3 you want for your rebuttal.

4 MS. WIEKER: I'd like to reserve ten minutes for a rebuttal,
5 please. And is it okay to approach with a different copy?

6 JUDGE PAULRAJ: Yes. Ready whenever you are.

7 MS. WIEKER: Thank you. Good afternoon, and may it please
8 the Board. Before digging into the disputed issue of major peaks, I
9 had intended to start with several claim limitations that I thought
10 could be resolved on the undisputed record. But given the panel's
11 questions today, I'd like to --

12 JUDGE PAULRAJ: Let's focus on the disputes.

13 MS. WIEKER: Okay. So turning to the definition of major
14 peaks. The challenged independent claims recite a FFT analysis that
15 has adjacent major peaks. The specification provides an express and
16 unambiguous definition of this term, which is shown on Slide 6. The
17 major peaks herein refer to peaks higher than the average of the peaks
18 in the result. This is textbook lexicography. The definition bears all
19 the hallmarks. It is set off in quotation marks, it uses refer-to
20 language that conveys an intent to be definitional, and it is
21 unqualified.

22 Petitioner does not dispute that these features align with the
23 Federal Circuit's precedent, and that should be the end of the --

24 JUDGE PAULRAJ: So I'll ask the same question I asked Mr.
25 Levine. So do you believe Federal Circuit precedent -- and frankly,
26 this is pretty favorable for you in terms of what's considered a

1 definition. But do you believe under Federal Circuit precedent that
2 when you have a lexicography definition, that takes precedence over
3 all the other intrinsic evidence that might be in the record, including
4 the rest of the specification, whatever is incorporated by reference,
5 like the Ayres 2008, as well as the prosecution history? Does that
6 definition take precedence over everything else?

7 MS. WIEKER: I think that is what the Federal Circuit case law
8 supports, that the lexicography controls. And I think that --

9 JUDGE PAULRAJ: No matter what, like everything else, was
10 there a clear discipline, for example, for what major peaks with those
11 inconsistent with the definition?

12 MS. WIEKER: I'm not sure the Federal Circuit's resolved that
13 question of where there's an express and clear lexicography, but
14 everything else is, you know, misaligned with that, to use the core pun
15 for this case. But I don't think I've read that case, but I think the case
16 here is more clear, because we both have a clear lexicographic
17 definition, and in our view, the intrinsic record and extrinsic record
18 support that definition. And I'd like to walk you through some of that
19 support.

20 In our view, the claim construction inquiry should end with this
21 definition. But in its reply, Petitioner argued that Patent Owner both
22 belatedly raised this definition after institution, and that the definition
23 requires an elaborate multi-step mathematical calculation that isn't
24 described in the patent. We believe these criticisms are incorrect.

25 First, Patent Owner was not obligated to file a preliminary
26 response at all, let alone raise claim construction. The only pre-

1 institution obligation to construe claims was Petitioner's. And as
2 you'll see on Slide 7, Petitioner recited and accepted this definition in
3 its petition. They didn't argue the definition was unclear, or
4 inapplicable, or needed additional mathematical clarity. They did not
5 dispute this definition until their reply filed just months ago.

6 As to the argument that the definition requires an elaborate
7 multi-step analysis, the record doesn't bear that out. Petitioner
8 identified the POSITA as a PhD student with experience in
9 mathematical FFT analysis, and neither Petitioner nor Dr. Simpson,
10 their expert, argued that such a highly educated POSITA needed a
11 detailed explanation of how to calculate an average. In fact --

12 JUDGE PAULRAJ: So in your view, does the lexicography
13 definition require you to actually calculate a mathematical average in
14 order to meet the claim requirements?

15 MS. WIEKER: I think you could, as Dr. Mikos explained in
16 his report, you can do the math, if you want to.

17 JUDGE PAULRAJ: Do you need to do the math?

18 MS. WIEKER: You don't need to do the math. If you can
19 identify -- when looking at the figure, if you see major peaks and
20 minor peaks, you can understand where the average is.

21 JUDGE PAULRAJ: Correct. So I guess that's my question,
22 right? Is the dispute here whether you need to do the math or whether
23 or not there has to be major peaks and minor peaks? Is that kind of
24 the heart of the dispute?

25 MS. WIEKER: So in Patent Owner's view, and as the
26 definition requires, the major peaks are those that are higher than an

1 average. So to exceed an average, it is definitionally required that
2 there be minor peaks so that you can exceed the average. You can't
3 exceed an average if everything's the same, so --

4 JUDGE PAULRAJ: But I don't need to calculate that average
5 to figure out if there's something higher than an average.

6 MS. WIEKER: You could, but you don't have to. When we
7 asked Petitioner's expert about this definition in his deposition, this is
8 on Slide 8, he accepted this definition. He didn't ask for clarification
9 or qualification or any other thing. He just accepted the definition.
10 Although in our view the inquiry should end there, the intrinsic record
11 supports the specification's definition.

12 We'll start with Slide 9, which shows Figure 8A and Figure 8B.
13 Figure 8A picks two peaks at 90 and 270 degrees. And as Dr. Mikos
14 testified, that height plainly exceeds the average of the four peaks that
15 you see in the result. These are major peaks. As also shown, and as
16 we mentioned a moment ago, the claimed FFT result includes minor
17 peaks. This is innately required because major peaks are defined
18 relative to an average, so they mean an average can only be exceeded
19 if some peaks fall below it.

20 JUDGE PAULRAJ: We're certainly going to get into what we
21 discussed with Mr. Levine as to what's the difference between a minor
22 peak and noise, and what is that smaller peak right there. I'll try to
23 distinguish the word minor peak from just a smaller peak, if you can
24 make that distinction, which might encompass either noise or minor
25 peaks.

1 MS. WIEKER: Sure. There's actually no dispute in the record
2 regarding what is a peak. So the parties both agree that FFT peaks
3 reflect fiber alignment. This is cited in the petition at page 8. Any
4 variations in an FFT plot that do not reflect fiber alignment aren't
5 peaks. So for example, Dr. Simpson testified that noise, it typically
6 reflects ambient conditions. He also described it as ghosts in the
7 machine. Ghosts in the machine don't reflect fiber alignment.

8 JUDGE PAULRAJ: Right. So your definition of a minor peak
9 is still something that requires some kind of reflection of fiber
10 alignment, something physical in the fibers themselves --

11 MS. WIEKER: That's correct.

12 JUDGE PAULRAJ: -- rather than some type of attribution to
13 the FFT methodology.

14 MS. WIEKER: Right. Attributes of the FFT methodology may
15 impart noise to an FFT result, but they don't reflect the fiber
16 alignment.

17 JUDGE PAULRAJ: And how do you distinguish, just looking
18 at an FFT plot, whether something's a minor peak attributable to the
19 fiber alignment rather than some kind of noise attributable to the use
20 of a mask, for example.

21 MS. WIEKER: Sure. So both experts actually agree on that
22 point as well. They both testified in their depositions that a noise is
23 going to be reflected by small up-and-down movements of the FFT
24 trace line in the plot. Dr. Mikos testified it's small up-and-down with
25 equal probability of going up and down. Basically a jagged little
26 movement. Dr. Simpson said the same thing in his. Dr. Mikos also

1 testified that you could perform a signal-to-noise analysis to
2 determine what's a peak versus what is noise, but visually both experts
3 testified that a noise fluctuation is small movement up and down.

4 Now in his reply declaration, Dr. Simpson talks about noise
5 being a peak, for example, in his Huang testing, but that conflicts with
6 his testimony in his deposition. He said noise is reflected by small up-
7 and-down movement. Does that answer your question?

8 JUDGE PAULRAJ: It certainly gives me a lot to think about.
9 Thank you.

10 JUDGE KENNEDY: Counsel, this is Judge Kennedy. I have a
11 quick question for you. So given your apparent position that the claim
12 requires there to be minor peaks, is it also your position that the claim
13 excludes a perfectly aligned scaffold?

14 MS. WIEKER: So the claim is directed to a real-world
15 manufactured scaffold. For example, we've got this slide up here, and
16 I'll direct you to Slide 9, as you see in Figure 8A. The claim is
17 directed to a real-world scaffold that has a principal axis of alignment
18 that's represented by major peaks and additional axes of alignment
19 reflected by minor peaks. And you can see that in the SEM image
20 that's in the upper left of the slide.

21 So for example, the Ayres spaghetti strand example, that is
22 perfectly aligned fibers, but it does not produce this FFT result
23 because it does not have the major and minor peaks that are
24 definitionally required.

1 JUDGE KENNEDY: So your claim, whether you want to call
2 it a real-world scaffold or a slightly misaligned scaffold, your claim
3 would require there to be at least some misalignment?

4 MS. WIEKER: Some minor peaks, yes. And as we just
5 discussed, the peaks reflect fiber alignment, so it's going to be an
6 additional or secondary axis of alignment.

7 JUDGE KENNEDY: Given your specifications focus on
8 alignment, is there any statement in the specification that makes clear
9 that some misalignment is actually required, or you just have to read
10 that into the definition of major peaks?

11 MS. WIEKER: So here, the patentee certainly could have
12 claimed aligned fibers had they intended that to cover their invention,
13 but what they did was elect to provide a specific definition that
14 requires an FFT result with major peaks and define those major peaks
15 as higher than an average. And there's no way to understand that clear
16 definition except from its requirement that there be minor peaks that
17 are exceeded.

18 JUDGE KENNEDY: Understood.

19 JUDGE PAULRAJ: Did your view, just to follow up on what
20 Judge Kennedy asked, then your view is that the peaks shown in the
21 Ayres 2008 paper don't actually reflect what's required by the claims?

22 MS. WIEKER: So to be clear, the spaghetti model of perfectly
23 aligned fibers.

24 JUDGE PAULRAJ: Are there any examples, I know there's a
25 few FFT plots in Ayres 2008. Are there any examples in Ayres 2008
26 that would meet your claim requirements?

1 MS. WIEKER: Not that were identified by Petitioner.

2 JUDGE PAULRAJ: Okay. And there's nothing in the record
3 that suggests one way or another?

4 MS. WIEKER: I don't believe so.

5 JUDGE PAULRAJ: Okay.

6 MS. WIEKER: So while we're staying on Slide 9 and
7 anticipating your next questions about Figure 8B, Petitioner's
8 contention that this violates the definition because two peaks appear
9 fractionally higher than others when measured with a precision
10 micrometer is unreasonable.

11 First, as explained in our briefing and shown on the slide, Dr.
12 Simpson's alleged measurements upon which this argument is gauged
13 is speculative. As you see in Figure 8B, the x-axis of the plot cuts off
14 at 350 degrees. Now that peak that would be -- that would span 360
15 to 0 degrees, you can't see the apex of that peak as Dr. Mikos testified
16 in his deposition.

17 So it is equally consistent with this figure that the peak is higher
18 than Dr. Simpson alleges to have measured, which would impact the
19 average that he allegedly calculated. To that end, Petitioner's Slide 57
20 misrepresents Dr. Mikos's testimony on this point.

21 JUDGE PAULRAJ: I thought this was no longer a dispute
22 about the fact that based on the symmetrical nature of the FFT
23 analysis, whenever you get, say, at 90, you're going to necessarily get
24 a 270.

25 MS. WIEKER: So this actually doesn't impact that discussion
26 at all. My point is that Dr. Simpson alleges that he took a precision

1 micrometer and measured the peak height at 360 degrees. But our
2 view is that we can't rely on that testing by him at all because the peak
3 height is not visible at 360 degrees.

4 JUDGE PAULRAJ: Can we assume, based on the nature of
5 what we know about the FFT process, that when you get a peak, and I
6 know we don't have an exact number here, but like, I'll just say for
7 Figure 8B, we'll just say that peaks are 180 degrees, because of the
8 symmetrical nature, the next peak will be at 360. Can we make that
9 assumption reasonably?

10 MS. WIEKER: I think if you make that assumption, then Dr.
11 Simpson's testimony that this falls within the scope of the claims falls
12 apart. Because by his analysis, these peaks would have to be
13 identical, right? And then, in that case, there is no height difference
14 that leads to this average being --

15 JUDGE PAULRAJ: Well, that's a dispute, right? That's a
16 dispute as to whether or not your -- what Petitioner identified as a
17 height difference. And I point to Mr. Levine, I think it was something
18 like a 2 percent difference in the peaks in 8B, whether that's still a
19 legitimate height difference that might create major and minor peaks
20 under your construction. What's your point as to that?

21 And then, by extension, I am concerned about the shifting
22 standards approach here. I know you're not obligated to construe in
23 the preliminary response, but we did get a construction in the patent
24 on a response, and then now in the surreply, we did get an additional
25 tag on that it's not just that definitional construction, now you have to

1 take into account statistical significance and measurement errors, et
2 cetera. So it missed those points for me.

3 MS. WIEKER: Sure. So to be abundantly clear, Patent
4 Owner's view is that the lexicographic definition controls. We --

5 JUDGE PAULRAJ: Okay. Where's the statistical significance
6 part of the lexicographical definition?

7 MS. WIEKER: This is attacking Dr. Simpson's reply testimony
8 that misappropriately reads Figure 8B into that definition. He did not
9 testify that a POSITA reading, looking at Figure 8B, would agree with
10 him that it falls within the scope of the claims. He testified that he
11 took out a precision micrometer and identified these height
12 differences. And our view is that it's unreasonable.

13 JUDGE PAULRAJ: But that goes to your construction though,
14 doesn't it? I mean, your view is, you're inviting Dr. Simpson's point
15 that 8B falls within the scope of the claims by then saying that, wait,
16 that it actually is -- falls within the scope of the claims under Patent
17 Owner's construction by making the point that, well, our construction
18 actually requires some type of statistical significance in order to
19 actually have that difference in peak height.

20 MS. WIEKER: No. In our view, the definition is clear that
21 major peaks require the height to exceed an average.

22 JUDGE PAULRAJ: So can I then take out the part about
23 whether you require statistical significance in assessing the claim
24 scope?

1 MS. WIEKER: The statistical significance doesn't impact the
2 claim scope. It impacts whether we consider this argument raised by
3 Dr. Simpson.

4 JUDGE PAULRAJ: Understood. All right. So we do have to
5 construe the claims. It looks like construction is going to be a key
6 issue. So when we construe it, do I have to add on the part about
7 statistical significance in order to fully give no effect to the claim
8 scope?

9 MS. WIEKER: So the definition controls, and the question is
10 whether a POSITA looking at Figure 8B would find that to exceed the
11 average the way the specification requires. In our view, there's no
12 evidence that they would. Dr. Simpson doesn't testify to that. He
13 simply measured the difference and said it's higher than the average.
14 But as we pointed out, that measurement is speculative, and we don't
15 believe his reply testimony is entitled to any weight.

16 JUDGE PAULRAJ: Okay. Thank you.

17 MS. WIEKER: Moving to slide --

18 JUDGE REIMERS: So Counsel, I have a real quick question
19 there on Slide 9 for Figure 8B. So is your position then for 8B that
20 they pretty much all would be considered major peaks of what we're
21 seeing there? I know that you had mentioned that it does not expand
22 out to 360, so we cannot see that. But I'm trying to -- I mean, I can
23 clearly see that from Figure 8A, but from Figure 8B, I'm trying to
24 figure out how it is that you would interpret what's being illustrated at
25 Figure 8B.

1 MS. WIEKER: Sure. So in our view, Figure 8B, as the
2 specification makes clear, is an FFT plot of random fibers where there
3 are no major peaks. I'm going to jump ahead a few slides to Dr.
4 Simpson's testimony during his deposition. I'm now on Slide 14
5 because I think this answers your question. So Dr. Simpson testified
6 here in the FFT plot labeled C, which has peaks of nearly identical
7 height. He said, I would not refer to that as a major peak because
8 those peaks are essentially very similar in height. So we're not
9 requiring dead-on identical height. That's not how he interpreted the
10 claim.

11 He contrasts this with Figure F on Slide 14 where he says, these
12 do reflect major peaks because, as you'll see, around 180 degrees,
13 there's this smaller peak with two larger peaks on either side.

14 So I'm going to turn back to the slide you asked about, Figure 9.
15 And I think what we're seeing in Figure 8B is just like what Dr.
16 Simpson testified to in his deposition where he said this does not
17 reflect major peaks. It reflects peaks of essentially the same height.

18 JUDGE PAULRAJ: And just to clarify for the record, when
19 you refer to the peaks on Slide 14, those came from the Ayres 2008
20 reference. Is that --

21 MS. WIEKER: Yes, these were -- he pointed to his 2008 paper
22 here.

23 JUDGE PAULRAJ: Right. And your view is that that's a peak
24 plot on the bottom of that slide corresponding to Figure 1F in Ayres,
25 that shows major and minor peaks that would meet your claim
26 construction. Is that right?

1 MS. WIEKER: Yes. We have no testimony that Figure F
2 there, that those are anything other than peaks.

3 JUDGE PAULRAJ: Other than peaks, and that's peaks -- so
4 your assumption is that those are peaks. You don't have testimony
5 whether that is noise or you don't have any testimony that is peaks.

6 MS. WIEKER: That's correct.

7 JUDGE PAULRAJ: But is it -- so we don't know, the record
8 doesn't say whether they're noise or peaks.

9 MS. WIEKER: I don't believe Petitioner addressed that. Our
10 view is that both experts have been clear that noise is going to be
11 reflected by jagged up and down, like for example, in the Lee testing
12 that Dr. Simpson produced.

13 JUDGE PAULRAJ: So these look like peaks to you.

14 MS. WIEKER: That's right.

15 JUDGE PAULRAJ: And that's why we should consider those
16 to be peaks. On the other hand, what you're saying is that those -- the
17 FFT plot above, is that all noise to you? I mean, the four what looks
18 like peaks to me?

19 MS. WIEKER: No. So the context of this portion of Ayres
20 2008, this is a test of a random sample. And this reflects the
21 alignment, the lack of alignment of that random sample.

22 JUDGE PAULRAJ: Okay. All right. And as we get further
23 down, I know it's not on the screen here, but if you haven't
24 demonstrated, I don't know if we need to pull it up, but I'm referring
25 for the record into Exhibit 1010 of the Ayres 2008 paper plot I. On
26 that same figure, Figure 1I, there's what looks like to be more

1 alignment, at least visually, on the SEM -- I'm sorry, the right field
2 images.

3 And I'll give you time to look at it if you need to. But the
4 corresponding FFT plot on that is that, again, the thing that really
5 helps us to kind of pin down this distinction between minor peaks and
6 noise is that minor peaks and noise. If you can look at Ayres 2008,
7 Exhibit 1010. And now I'll just direct you to page 7 of 20 on the
8 record for that exhibit.

9 MS. WIEKER: Yeah. So looking at Figure I, and Dr. Simpson
10 actually continued on in his deposition on that larger page there on
11 Slide 14 to say that, yes, that also reflects major peaks because you've
12 got the small peak, the minor peak, reflected by or opposed on either
13 side by the taller adjacent peaks. And importantly, if you look at the
14 SEM images of the fibers upon which the FFTs were based, this is on
15 page 608 of Exhibit 1010, you'll see varying levels of alignment in
16 those figures that correspond to those peaks.

17 JUDGE PAULRAJ: So then my next question, then let's turn to
18 Simpson's testing. Because, again, I think your position is that
19 Simpson's testing just put up, you know, a bunch of noise that they're
20 kind of relying upon to satisfy the lexicography definition. And then
21 so if you look at -- I don't know if you have it on the slide here.
22 Maybe Petitioner doesn't. They are demonstratives, but I'm looking at
23 Exhibit 1003, page 56 of the record.

24 MS. WIEKER: And it's Dr --

25 JUDGE PAULRAJ: Yes, that's exactly it. So there you go. So
26 that smaller peak in the middle, is that noise or is that a minor peak?

1 MS. WIEKER: And for the remote judges, just to clarify, we're
2 on Slide 16 now. Dr. Simpson's testing from his original declaration
3 at the bottom. So Dr. Simpson's testimony is unclear on this point.
4 He testifies in his reply declaration that this is a minor peak that
5 would satisfy the express definition from the specification.

6 JUDGE PAULRAJ: And what's Dr. Mikos's position in
7 response to that?

8 MS. WIEKER: Well, we weren't allowed to file a supplemental
9 declaration.

10 JUDGE PAULRAJ: But we got this from the original
11 declaration. We got this in Exhibit 1003.

12 MS. WIEKER: Oh, right. Okay. So yes, we got this figure
13 from Dr. Simpson. Dr. Mikos's view is that, first, we shouldn't be
14 crediting this testing because it --

15 JUDGE PAULRAJ: Leave the standard procedure.

16 MS. WIEKER: Yes. Second, this is an anticipation ground.
17 And the Huang figure, as you see at the top of Slide 16, shows a broad
18 peak without any minor peaks at all. So to the extent the Board agrees
19 with us that the definition of the specification controls, that definition
20 requires minor peaks. And Huang doesn't disclose any minor peaks.
21 There's no --

22 JUDGE PAULRAJ: We also talked about inherency theory
23 here. So frankly, I think the question of what Huang discloses in that
24 plot, that's one point. But I guess my question is, does that smaller
25 peak in Dr. Simpson's actual FFT testing, is that what you called --
26 you know, we talked about this in the context of the Ayres peaks,

1 right? If it looks like it's not a bunch of smaller jagged peaks, like you
2 said, that might be considered noise. Frankly, visually looking at that,
3 it looks very similar to what we saw in the Ayres 2008 paper. So
4 explain the distinction if you see any.

5 MS. WIEKER: I'm going to try to. And I think it actually does
6 matter, the conflict with Huang itself. Because I understand we're in
7 an inherency world here.

8 JUDGE PAULRAJ: Right.

9 MS. WIEKER: And what Petitioner is --

10 JUDGE PAULRAJ: Because, again just to be clear, even if
11 Huang doesn't disclose any FFT plot, yeah, obviously they have that
12 to bring it in. But we'd still be dealing with this question as to
13 whether Huang's scaffolds would inherently meet that property. And
14 the claim talks about a property here. It's a property, whether or not
15 it's explicitly disclosed. It's an inherency case, frankly. That's an
16 inherency case --

17 MS. WIEKER: Right. And I think our view is that Petitioner's
18 burden is to show that Huang's scaffold necessarily presents minor
19 peaks, right? And so Dr. Simpson testified that he normalized his
20 testing results so that it could be compared with Huang's scaffold --
21 I'm sorry, with Huang's FFT results. And they, although they purport
22 to test the same fibers, they reached entirely different conclusions.

23 So for example, as you see on the Slide 16 under B, they tested
24 different images. And as you see under C, the FFT results convey
25 information about fundamentally different fibers. So Dr. Simpson
26 testified, for example, that the breadth of the FFT peak indicates that

1 more than one axis of alignment may be present. And that's what we
2 see in Huang's image. But if you look at Dr. Simpson's FFT, that
3 narrower peak indicates more uniform fiber alignment.

4 So when we -- Petitioner has to show that that scaffold, that
5 Huang Scaffold, necessarily includes these minor peaks, but the
6 results of his testing reflect totally different outcomes than Huang
7 itself. For example, the second thing under C, we've got an 83 percent
8 higher result from Dr. Simpson, even though he purports to have
9 tested the same image, and that impacts the onset of an isotropic
10 reappropriation.

11 JUDGE PAULRAJ: There's all these variations. I agree,
12 there's differences, right? You know, clearly there's visual differences
13 between the two plots that we see on Slide 16. Are all these
14 differences just due to choices that the skilled artist can make in
15 following Ayres 2008's methodology?

16 And I'll just use the clear example, the use of a mask versus not
17 a mask. Is that like -- because there's, Ayres 2008 doesn't give you
18 like a clear, you know, coming from a chemistry background, like a
19 clear protocol, right? You know, like this -- it does give you, like, all
20 right, you can use these options. It gives you several options. At least
21 that's the way I read it, right?

22 And if a skilled artist can choose certain things in terms of
23 whether or not, how many images you want to average out, which I
24 think is Petitioner's argument as to why there's such a smooth graph in
25 the top graph in Huang2 versus just taking one plot. And again,
26 whether you use a mask or not, which can then introduce artifacts,

1 whether you want to call it a minor peak versus noise. Isn't that all
2 part of why you might get variances here?

3 MS. WIEKER: I don't think so, because at the end of the day,
4 Dr. Simpson's 2008 Ayres paper test reports that the FFT is giving
5 you information about those aligned fibers that are tested. And at the
6 end of the day, the two FFT results we have on Slide 16 convey
7 fundamentally different information about the underlying fibers that
8 Dr. Simpson tells us are the same.

9 JUDGE PAULRAJ: So maybe -- is it fair to say that the FFT
10 analysis in Ayres 2008, it tells you one big thing. It tells you where
11 the major peaks are, right? It tells you at least -- when I say major
12 peaks -- actually, I apologize for that. It tells you where the
13 predominant alignment is, right? I don't want to use major peaks
14 because that's kind of a disputed term. But it gives you the highest
15 peaks there, regardless of whether there's noise, regardless of all those
16 other factors.

17 But where I see it in the record is a lot of confusion as to
18 whether you can kind of manipulate it, for lack of a better term, the
19 methodology in such a way that you might or might not meet the
20 claim requirements under your construction.

21 And then that kind of gets into what I think Mr. Levine hinted
22 at, like it raises a whole host of indefiniteness issues as to how a
23 competitor would be able to know whether or not their peaks -- if they
24 did an analysis of their scaffolds and then they used a mask and they
25 didn't use a mask, and you got some one example where you got what
26 you would characterize as minor peaks and another example where

1 you didn't, right? How do you determine the claim scope under that
2 construction?

3 MS. WIEKER: So I'm going to try to avoid indefiniteness
4 responses in this answer.

5 JUDGE PAULRAJ: But frankly, I think you're going to have
6 to grapple with it because your construction potentially opens up this.
7 I know we're not dealing with indefiniteness. We know it's an IPR.
8 Of course, we're not going to find these claims invalid. But if the
9 point is that you're going to construe the claims in a manner that could
10 potentially open up a whole host of indefiniteness issues, I would
11 certainly want to know that. I don't want to construe a claim that
12 would render the claims invalid in a manner that would render the
13 claims invalid. So address that point if you can.

14 MS. WIEKER: Right, I will. And I'm going to try to ground it
15 in the images we have before us. So at the end of the day, Petitioner
16 needs to show that Huang's fibers necessarily present minor peaks
17 under the construction we advance. And our view is that, you know,
18 taking their testing as they gave it to us, Dr. Simpson testifies that
19 what the smaller peaks about midway through that lower figure, he
20 testifies those are noise, not minor peaks.

21 Now if they are noise, they would also appear in Huang's
22 image, but they don't. So either they're noise and they're not minor
23 peaks or it's an inaccurate testing of Huang's image. But it can't be
24 both ways. And I'm just going to skip to the next slide, Slide 17. The
25 Federal Circuit's clear that where an expert's testimony conflicts with

1 the record, and especially here where it's an anticipation case, inherent
2 anticipation, to be clear --

3 JUDGE PAULRAJ: Is that -- I'm having a hard time
4 transferring those cases. Are those inherency cases?

5 MS. WIEKER: So these are about the role of expert testimony
6 --

7 JUDGE PAULRAJ: Of course, an expert can't supply a
8 missing limitation. We know that. I mean, that's not new to me. But
9 I think the question is whether or not an expert can testify as to an
10 inherent property of what's disclosed in the prior art.

11 MS. WIEKER: And in our view, yes, an expert can testify to
12 an inherent property, but not when they're -- the testing upon which
13 their testimony is based expressly conflicts with the anticipatory
14 reference. Does that answer your question?

15 JUDGE PAULRAJ: It helps. Thank you.

16 MS. WIEKER: Okay. So I'd like to turn back --

17 JUDGE KENNEDY: Counsel, one more question while we're
18 on this slide. Still looking at Slide 16. So is it your view that in the
19 actual top image there on Huang2, that that scaffold would simply be
20 too aligned to fall within the scope of your claim because it only has
21 the one major peak and it's simply too aligned?

22 MS. WIEKER: Whether it's too aligned or not, I don't know. I
23 know it does not fall within the claim because it simply isn't --

24 JUDGE KENNEDY: Well, perfect alignment would
25 essentially be the only reason that you would only get one peak like
26 that, correct?

1 MS. WIEKER: I'm not sure the record answers that question.

2 JUDGE KENNEDY: Well, you're familiar with the record. So
3 can you tell me other reasons that a scaffold of fibers might only give
4 a single peak at 90 degrees like that?

5 MS. WIEKER: So I think the clearest example is the Ayres
6 paper, which is, as you know, similar to this figure. It's a single peak.
7 There are no minor peaks, and that does not fall within the scope of
8 the claim.

9 JUDGE KENNEDY: Because it's too perfectly aligned.

10 MS. WIEKER: In Ayres, yes, absolutely. It's spaghetti models
11 that were laid out for that very reason.

12 JUDGE KENNEDY: Is Huang's scaffold spaghetti models, or
13 is it a real-world scaffold?

14 MS. WIEKER: It is a real-world scaffold. And what --

15 JUDGE KENNEDY: So how could it possibly only have one
16 peak like that at 90 degrees? So you earlier said that real-world
17 scaffolds couldn't be that aligned.

18 MS. WIEKER: Right. And this is the reference that Petitioner
19 alleges anticipates. You know, it's Petitioner's burden to show that
20 this reads on the claim. And, in our view, the claim requires minor
21 peaks that Huang doesn't disclose.

22 JUDGE KENNEDY: So even though it's a real-world scaffold,
23 it's nevertheless somehow too aligned to have had minor peaks?

24 MS. WIEKER: So Dr. Simpson's Ayres 2008 paper talks about
25 a broad peak like this. And it describes a broad peak as having, let me
26 find, I just want to find the right words for you. It's a -- broad peak

1 indicates that more than one axis of alignment may be present, while a
2 narrow peak indicates more uniform alignment. In our view, that
3 Huang image is a broad peak. It goes 0 to 180 degrees. That
4 indicates that more than one axis may be present. This is, I'm sorry,
5 I'm quoting from Exhibit 1010 at page 610.

6 So, at the end of the day, we come back to Petitioner's burden to
7 demonstrate that the prior art anticipates, and this figure provided by
8 the prior art lacks a required claim limitation.

9 JUDGE KENNEDY: Okay. Thank you.

10 MS. WIEKER: Thank you.

11 JUDGE PAULRAJ: If I could follow up on what Judge
12 Kennedy said and your response to that. So you point out that if you
13 have more than one axis of alignment, you can have a broad peak like
14 what Huang showed for its real-world scaffold. And by the way,
15 those real-world scaffolds were spun using electrospinning using the
16 same --

17 MS. WIEKER: Correct.

18 JUDGE PAULRAJ: -- methodology in the patent, right? But is
19 it your position that, other than a broad peak, you can also have real-
20 world scaffolds, maybe different real-world scaffolds from what
21 Huang teaches that might not have a broad peak, but have what you've
22 identified and characterized as minor peaks?

23 MS. WIEKER: Yes.

24 JUDGE PAULRAJ: Is that right?

25 MS. WIEKER: Figure 8A of the patent shows a real-world
26 scaffold.

1 JUDGE PAULRAJ: Do we know that? Is there anything in the
2 patent or in the record that says that that smaller peak in Figure 8A is
3 due to what you've characterized as misalignment versus noise?

4 MS. WIEKER: I'm going to turn back to Slide, excuse me,
5 Slide 9 just so we can be looking at the same figure. So Figure 8A in
6 the upper left corner, this is an SEM image of the claimed fibers. So
7 it reflects a primary axis of alignment, which, you know, you see in
8 the FFT result as major peaks, and it reflects secondary axes of
9 alignment in those non-perfectly aligned fibers that appear in the FFT
10 plot as the minor peaks. Dr. Simpson testified that this is how a
11 person of skill in the art would understand the '223 patent.

12 JUDGE PAULRAJ: There's nothing in the patent that talks
13 about it, but focuses on the secondary alignment in Figure 8A.

14 MS. WIEKER: That's correct. And to be clear, the
15 specifications written for a person of skill in the art, what Dr. Mikos
16 testified.

17 JUDGE PAULRAJ: Understood. Okay. So at the end of the
18 day, again, frankly, what is the difference in Huang2's, quote-unquote,
19 aligned scaffolds, versus what's shown in Figure 8A that would result
20 in two different FFT plots?

21 MS. WIEKER: So again, I'm going to come back to the
22 burden. The specification defines major peaks. And in our view, it is
23 Petitioner's burden to show that that definition is met in the Huan2,
24 and it just, it doesn't.

25 JUDGE PAULRAJ: And so the burden, you're going to rest it
26 on burden of proof at that point?

1 MS. WIEKER: Right. The burden never shifts to Patent
2 Owner to disprove why Huang's FFT plot is the way it is.

3 JUDGE PAULRAJ: Right.

4 MS. WIEKER: All we know is that it's an anticipation ground,
5 and Petitioner advances an FFT plot that lacks minor peaks that are
6 definitionally required.

7 JUDGE PAULRAJ: Okay.

8 MS. WIEKER: I'd like to briefly turn to Petitioner's definition,
9 which is shown here on Slide 10. In our view, even under Petitioner's
10 construction, which requires this visual assessment of relative sizes,
11 Huang still does not satisfy the claim limitation. An FFT plot like
12 that, shown here with a single peak or with peaks of identical height,
13 lack major peaks because the visual assessment that Petitioner says is
14 required shows that the relative sizes of the peaks are identical.
15 Neither is major.

16 Finally, Petitioner argues that the specification's expressed
17 definition does not align with the FFT results in the Ayres paper. But
18 this fails, again, for two reasons. First, the patent applicant may
19 define claim terms as they choose regardless of the prior art. The
20 Ayres paper does not utilize the claim language of major peaks. It has
21 no bearing on the construction of the claim language, and Petitioner
22 offers no case law to support its contention that an incorporated
23 publication's usage of different terminology should control over the
24 specification's own lexicographic definition of the actual claim term.

25 I see I have 11 minutes left. And unless there are more
26 questions on major peaks, I'd like to turn to some of the other issues.

1 JUDGE PAULRAJ: You can go ahead.

2 MS. WIEKER: Okay. I'd like to turn to Slide 25, Claim 2 of
3 the '223 Patent. Claim 2 requires that the, quote, electrospun fibers of
4 Claim 1 comprise Type I collagen in its native triple helical structure.
5 Petitioner asserts anticipation, but longingly are silent as to the
6 structure of their electrospun fibers. Allegations about the original
7 source of collagen, which is shown here on Slide 26 from the petition,
8 that does not speak to the resulting fiber structure after
9 electrospinning.

10 The allegations also fail to establish inherency. The record is
11 clear that electrospinning collagen with certain fluoroalcohols, like
12 HFIP or HFP, necessarily transforms collagen into gelatin, which
13 lacks triple helical structure.

14 JUDGE PAULRAJ: Now the patent uses HFIP, doesn't it?

15 MS. WIEKER: It does, in some examples, for sure.

16 JUDGE PAULRAJ: Okay. So those would not result in a
17 native triple helical structure for its electrospun collagen fibers?

18 MS. WIEKER: No. The Petitioner in making that argument
19 overlooks the undisputed testimony, but the challenged patent fibers
20 were made with protective biomolecules that preserve the bioactivity
21 of collagen in the presence of HFIP. Petitioner doesn't dispute that
22 fact and does not allege that Huang or Lee have similar protective
23 biomolecules.

24 JUDGE PAULRAJ: I'm sorry. If you could refer directly to
25 what you're talking about in the patent. Just for my own record.

1 MS. WIEKER: Sure. So from the patent, it's the examples
2 given in the later columns. My colleague is going to look up that cite
3 and I'll give it to you. And then the testimony about the protective
4 biomolecules comes at Exhibit 1220, page 124, lines 14 through 19,
5 and 127, 17, through page 128, line 1. This is also discussed in our
6 surreply at page 18. It is undisputed that both Huang and Lee use
7 HFIP, among other denaturing compounds, as shown in Slides 28 and
8 29.

9 In light of these teachings, Dr. Mikos testifies that the
10 electrospun fibers necessarily would have denatured collagen lacking
11 triple helical structure. Petitioner's reply does not dispute the
12 denaturing effects of these compounds, but wrongly argues that the
13 claim does not require triple helical form after electrospinning, triple
14 helical structure after storage or cell culture. Respectfully, these miss
15 the point.

16 Claim 2 is specifically limiting the electrospun fibers of Claim
17 1, so it must have that form after electrospinning, which is required by
18 the claim language. Second, there's no dispute that the denaturing
19 effects of HFIP occur prior to storage. And third, Huang and Lee, the
20 scaffolds relied upon in the petition were cultured with cells and
21 exposed to FBS fetal bovine serum, which Dr. Mikos testifies also
22 denatures --

23 JUDGE PAULRAJ: Well, so on that point, the claims
24 definitely don't require cells, right? And certainly don't require
25 cultured cells there. So why is it necessary that you would have to
26 take into account whether FBS would denature? I think you have,

1 frankly, have a stronger argument for the HFIP issue, but I'm curious
2 about it.

3 MS. WIEKER: No, the HFIP issue definitely, I mean, resolves
4 this dispute.

5 JUDGE PAULRAJ: Okay.

6 MS. WIEKER: But I'm going to answer your question, both
7 because you asked it and it applies to Claim 3 as well, which I'd like
8 to turn to in a minute.

9 JUDGE PAULRAJ: Right.

10 MS. WIEKER: The petition, there's no dispute that the claim
11 does not require cell culture. But all of the embodiments that
12 Petitioner relies upon as anticipating these claims are scaffolds with
13 cultured cells. Petitioner referenced in its argument today, this is the
14 very point of Huang2, is to see how those cells, those seeded cells
15 perform on the different scaffolds.

16 JUDGE PAULRAJ: Okay, but Huang2 obviously had to build
17 a scaffold before adding cells to it. So at that point, when Huang2
18 teaches building the scaffold before adding cells, there's no FBS
19 added to it. So that part of the denaturing, or whatever you're saying
20 is, whether it's Claim 2 or Claim 3, that might result in Claim 3, the
21 claim being put out due to FBS, right? That's not present.

22 MS. WIEKER: So the Petitioner relies -- so again, Petitioner's
23 burden here to show that the prior necessarily has these claim
24 elements, and Petitioner relies on a seeded scaffold. So at the end of
25 the day, it's their burden to show that these limitations are necessarily
26 present, and the record is undisputed that the presence of these

1 denaturing compounds and fetal bovine serum will denature the
2 collagen and will lead to the absorption of calcium in the scaffold. So
3 again, it turns on Petitioner's burden and what they alleged in their
4 petition.

5 I'd like to turn next, with five minutes remaining, to Claim 4 on
6 Slides 37 and 38, and jump ahead in the demonstratives. Claim 4
7 requires an average porosity of 60 to 90 percent. Petitioner seems to
8 agree that Huang does not anticipate. Slide 2 of its demonstratives
9 does not list anticipation by Huang, despite its presence in the
10 petition. That concession is appropriate, given that Huang is silent
11 regarding any specific porosity percentage. Huang's scaffolds contain
12 aligned fibers, which the record also conclusively demonstrates
13 suffers from lower porosity than non-aligned scaffolds.

14 Turning to slide 40, Lee is similarly silent regarding specific
15 porosity percentage and also discloses aligned fibers. Generic
16 references to high porosity are insufficient to anticipate a specifically
17 claimed range.

18 JUDGE PAULRAJ: Why isn't porosity just a result-effective
19 variable?

20 MS. WIEKER: So in this, I'm going to answer your question in
21 two stages. First, we're at an anticipation argument for Huang and
22 Lee, and there is no allegation of result-effective variable.

23 JUDGE PAULRAJ: Well, yeah. I mean, I think there's
24 obviously obviousness grounds for both Huang, in terms of Ground 2,
25 specifically focused on Claim 4, right?

26 MS. WIEKER: Correct.

1 JUDGE PAULRAJ: And that seems to be more in line with a
2 potential result-effective variable argument.

3 MS. WIEKER: Sure.

4 JUDGE PAULRAJ: And then the Lee Ground 4, which is
5 obviousness, I don't know if that gets its area there.

6 MS. WIEKER: Lee, the obviousness analysis is on the FFT
7 limitation. It's not on porosity. But turning to Kumbar, I'm going to
8 jump ahead to Slide 42. Petitioner did not argue result-effective
9 variable, and Petitioner did not identify any reference that's analogous
10 to Huang's PCL and collagen scaffold. So Petitioner instead relied on
11 Kumbar, which is shown here on Slide 42.

12 And effectively, in our view, this is an apples-to-oranges
13 comparison. They did not argue result-effective variable. They
14 argued that Kumbar's porosity could be applied to Huang. So Kumbar
15 itself tells us, as we see on the slide, that a scaffold's porosity depends
16 directly on the electrospinning parameters, including the specific
17 polymer or copolymer that is electrospun. And this is because
18 different polymers have different molecular weights, different
19 viscosities, and those directly determine porosity.

20 So here, Kumbar teaches a pure collagen scaffold, either cross-
21 linked or non-cross-linked, but pure collagen. And Huang teaches a
22 three to one copolymer blend of PCL and collagen. Likewise,
23 Kumbar's scaffolds are not aligned, which there's ample testimony
24 that aligned scaffolds have lower porosity than non-aligned scaffolds.

25 So looking at these two references, attempting to impose
26 Kumbar's porosity on Huang's scaffold just is simply untenable in

1 view of the different electrospinning parameters, which Petitioner's
2 reference tells us dictates porosity. On reply, Petitioner, I think, gets
3 close to your result-effective variable analysis, which was absent from
4 the petition, and says that a POSITA could simply adjust those
5 electrospinning parameters.

6 But turning to Slide 43, this is an excerpt of the petition. As
7 shown here, the petition never talked about adjusting electrospinning
8 parameters. They talked about freeze-drying, salt-leaching, or gas-
9 foaming, not adjusting electrospinning parameters to alter fiber
10 diameter, excuse me. That shifting is impermissible on reply. And
11 even engaging in that new theory, Petitioner still fails.

12 They do not account for the fiber alignment of Huang. So even
13 if somebody was inclined to adjust electrospinning parameters, even
14 though we've not been given a reason to do so, even if they did,
15 Petitioner still doesn't tell us about the fiber alignment. And if they
16 maintain Huang's aligned fiber morphology, we will have lower
17 porosity by virtue of those closely aligned and tightly packed fibers.

18 I'd like to turn quickly to the '249 patent. I'm sorry, the 249
19 IPR, in my remaining time, in regarding crosslink fibers. Turning to
20 Slide 51 --

21 JUDGE PAULRAJ: And Ms. Wieker, I'll give you two extra
22 minutes as well, since we took up the same amount of time.

23 MS. WIEKER: Thank you. I appreciate that. Huang does not
24 crosslink. There's no dispute. Huang achieved stable fibers through a
25 different path, blending PCL with collagen in a three to one ratio. Dr.
26 Mikos testifies this produced a very stable compound. And as shown

1 on Slide 52, the record confirms that PCL exhibits long-term
2 degradation of three to four years. By contrast, crosslinked collagen
3 degrades much more quickly, for example, in four to eight weeks, in
4 the example of Bio men , shown on Slide 52.

5 Dr. Simpson, Petitioner's expert, agreed that PCL-collagen
6 blend will degrade at a rate approximating that of PCL, again, which
7 is much longer than collagen. With three times more PCL than
8 collagen, Huang's scaffold was already more stable than crosslinked
9 collagen, and a POSITA wouldn't have further crosslinked it.

10 Turning to Slide 53, the Petitioner relies on Minel for its
11 statement that crosslinking will decrease the rate of degradation. To
12 be sure, that is true when considering pure crosslinked collagen like
13 Minel discloses, but again, it's inapposite when considering the more
14 stable blend that Huang achieved.

15 Turning to Slide 55, the record is replete with many undisputed
16 reasons that a POSITA would not have crosslinked Huang's stable
17 fibers, including cost and complexity. And as Dr. Simpson discussed
18 in an earlier paper, his own lab blended collagen with synthetic
19 polymers specifically to avoid these disadvantages of crosslinking,
20 like reduced biocompatibility and increased toxicity and calcification.
21 Absent any supported motivation to crosslink, the record demonstrates
22 that a POSITA would have avoided those disadvantages, which were
23 well known.

24 Finally, turning quickly to tendon, ligament, and nerve repair.
25 Huang and Lee do not treat these tissues, and a POSITA would not
26 have done so in view of Kuo for several independent reasons, which

1 are identified here on Slide 59. The Board needs only agree with us
2 on one reason, to find that Petitioner fails its burden.

3 The first issue, rolled scaffold. The Board preliminarily
4 recognized that Huang did not roll its scaffold and that Petitioner had
5 not presented any rationale to modify Huang to mimic, quote, rolled
6 scaffold. Despite that preliminary finding, Petitioner's reply suggests
7 that they would. Again, this goes to Petitioner's prima facie case, and
8 it comes too late. It's an impermissible shift in position. Even had it
9 been proposed earlier, this fails. Dr. Simpson himself, shown here on
10 slide 61, testifies to numerous reasons a POSITA would avoid rolling
11 a scaffold.

12 Turning to Slide 62. Independently, the record is clear that the
13 scaffolds disclosed by Huang and Lee, which are shown on this Slide
14 62, are just simply structurally incompatible with repair of these
15 tissues. The elastic modulus of a scaffold is effectively a measure of
16 its stiffness, and it must match that of the targeted tissue to be
17 repaired.

18 JUDGE PAULRAJ: Thank you, Ms. Wieker. I think we got
19 the point, and your time's up.

20 MS. WIEKER: Okay. Thank you.

21 JUDGE PAULRAJ: All right. We'll give you your full ten
22 minutes again for your rebuttal.

23 MS. WIEKER: Appreciate that.

24 JUDGE PAULRAJ: You can just do this the old-fashioned
25 way.

26 MR. LEVINE: Yeah, we'll do it with the handouts.

1 JUDGE PAULRAJ: All right. Yeah, if the judges on the
2 screen can follow along.

3 MR. LEVINE: Do you have handouts of this that I can refer
4 to? Okay.

5 JUDGE PAULRAJ: Just make sure to refer to them, especially
6 now that we can't follow along on the screen.

7 MR. LEVINE: So, I think what I just heard from Patent
8 Owner's argument, that they agree that Huang2 is aligned. They agree
9 that Lee is aligned. They must have the two primary peaks. We think
10 that's all you need to show anticipation. And Huang1 is a real-world
11 scaffold, both of them. Huang2 is a real-world scaffold. They both
12 have the two primary peaks. In fact, the random scaffold with
13 Huang2 now seems like it would fall under their claim construction,
14 mostly aligned with some minor peaks in this alignment. So we think
15 that is not the correct test.

16 If you turn to Slide 41, and I just want to make this point
17 because it's important. They keep on relying on Dr. Simpson's
18 testimony. Dr. Simpson was not deposed. They could have deposed
19 Dr. Simpson after the Patent Owner's response. They didn't. They
20 deposed him before they filed a Patent Owner response. At that point,
21 they had not raised this claim construction. So it's not like Dr.
22 Simpson was aware of their claim construction and was responding to
23 it.

24 And I think it's very unfair the way they're characterizing his
25 testimony. He was not asked if two peaks alone, 180 degrees apart,
26 would be within the scope of the claim. He just was not asked that.

1 They are conflating his testimony on four peaks in a random sample
2 that he was saying they're not alignment peaks. That's what he meant.
3 Again, he wasn't aware. This wasn't even an issue in the case at the
4 time he was deposed.

5 Dr. Simpson, on paragraphs 11 and 12 of his reply expert
6 report, specifically responds to their claim construction about needing
7 minor peaks and explains that's not correct. In fact, the first time I
8 think Patent Owner actually argued this, that you must have minor
9 peaks, was in their surreply at page 8. That was the first time they had
10 the mathematical average, but this is the first time they specifically
11 came out and said, we need minor peaks in order to fall within the
12 scope of the claim.

13 And where does that even come from? What is the cite for
14 that? I mean, The only cite they have is Dr. Mikos, who's testifying to
15 that. Ayres does not say that. Ayres says the opposite. Ayres says
16 exactly what I read several times, that that minor hump is a noise
17 peak. That's in the specification of the '233 patent. They can't run
18 away from that. Dr. Mikos may be an expert in many things, but he is
19 not an expert in FFT analysis, particularly the Ayres method.

20 And the idea that Dr. Mikos knows how to analyze FFT
21 alignment plots when he never did one, never published in one, and he
22 knows more about it than Dr. Simpson, who's the author of the paper
23 and who published it and did the testing in this case and applied the
24 correct parameters, we think shows in terms of credibility issue
25 between Dr. Simpson and Dr. Mikos. I don't think there's a question.

1 One has no experience, and one has all the experience. And we think
2 that's an important fact.

3 JUDGE REIMERS: Counsel, I do have a question though.
4 Inherently though, if you had something major, wouldn't you also
5 have to have something minor? Otherwise the major, it becomes
6 superfluous. That means that that term means nothing. So wouldn't
7 you have to have something, a minor peak, if you do have a major
8 peak?

9 MR. LEVINE: No, you would not. You would not. In fact, if
10 you look at Slide 17, which is Figure 4E, that's Huang1, real-world
11 scaffold, those are two major. I don't see how anyone else could
12 describe those as two major peaks. I mean, they're not minor peaks.
13 They are major peaks. They come out of the background. And if you
14 say this background is this average, they come out of that. Now in
15 terms of that -- and that brings up a point of lexicography. We don't
16 think lexicography applies. But even if it does, what does the term
17 average mean in this context?

18 The Federal Circuit has said, even if you apply lexicography,
19 the words of the definition that you're using must be clear and
20 ambiguous. And in fact, in the case we cite, that Kumbar case at the
21 Federal Circuit, the Federal Circuit applied that definition, but said,
22 remanded, because the definition itself was ambiguous. Here, to the
23 extent they're saying this average requires a mathematical calculation,
24 that's just not true. And we think it's correct and contradicts with the
25 rest of the specification.

1 JUDGE REIMERS: Well, I think, though, Patent Owner's
2 counsel was saying that it does not require a mathematical calculation.

3 MR. LEVINE: Yes. And in fact, thank you for that. And in
4 fact, that is the first time we've heard that. That argument wasn't even
5 in the surreply. So originally --

6 JUDGE REIMERS: But just getting back to my question about
7 the major peaks versus also inherently having something minor. If
8 you're taking an average of the peaks, that would mean that you'd
9 have to have something other than major peaks in there, correct?
10 Otherwise, you're just always taking an average of what's considered
11 to be a major peak. Is that correct?

12 MR. LEVINE: If you're doing a numerical mathematical
13 average where you're assessing peak values, which is impossible by
14 the way to do on Huang1, because there are no peak values, which
15 was the thing they said was within the scope of the claim during
16 prosecution. So if it's a visual average, you can say it stands out
17 among the rest.

18 And in fact, Dr. Simpson specifically said that in his surreply
19 and when he offered his testimony, when he actually considered their
20 claim construction, where he wasn't surprised at the deposition
21 because it wasn't there. That was the definition that Dr. Simpson
22 gave. It's a visual average. It looks above, and that's the test that he is
23 doing for his analysis.

24 And that was the other point I was going to make, is that we've
25 been getting now shifting claim constructions throughout this case.
26 They didn't raise it during prosecution at all. They didn't raise it in

1 their preliminary response. They only said two peaks. In their Patent
2 Owner response, they said four peaks. And then in the surreply, now
3 we have you don't count noise peaks and you've got to use statistics.
4 And now we have, well, maybe it can be a visual average.

5 Maybe you don't have to apply math because the '223 patent
6 didn't do any math, obviously. We think whatever the test is, and
7 whatever average means, if you have two primary peaks that stand
8 out, that shows alignment. And that is what -- I mean, and the idea
9 that they get a patent for having worse alignment than Huang2 and
10 Lee, that makes no -- I mean, what is the point of that invention then?
11 That was what they were distinguishing over the prior art. They made
12 this gadget, this apparatus that could give you super highly aligned
13 fibers. So again, we think that Patent Owner is just wrong with that.

14 If I could turn to Slide 51. Again, the only place where this
15 minor peaks comes in is the surreply, and the only evidence for that is
16 Dr. Mikos. There's no other evidence in the record. And instead in
17 51, we have Ayres, a statement in Ayres. Corporate and patent says
18 the larger peaks report principal axis of alignment while smaller peaks
19 correspond to background information, noise, and edge effects. And
20 we think they're bound by that.

21 In addition, they said that Huang2 is somehow inconsistent with
22 Dr. Simpson's testing. They both completely show alignment. They
23 both show their aligned spectra. They both have the two primary
24 peaks. And the cases that they cite in their brief about an expert
25 testimony being inconsistent are sort of black and white issues. The

1 specification prior art says X ,and their expert said Y. And the
2 Federal Circuit said, well, you don't have to take that into account.

3 JUDGE PAULRAJ: Mr. Levine, let's shift gears a little bit.

4 MR. LEVINE: Sure.

5 JUDGE PAULRAJ: I know we've kind of hammered down on
6 the major risk-managing issue a lot, but I do want to give you some
7 time. If I could give you two minutes to address any specific issues
8 you want to address about these dependent claims and speak more
9 about specific issues.

10 MR. LEVINE: Yes, so we could -- let's see.

11 JUDGE PAULRAJ: Pick your best arguments.

12 MR. LEVINE: Yeah, let's, I mean, I'd like to go to pages 91,
13 Slides 91 and 92. Again, and this is what I was saying before with the
14 patent. The patent does not give any guidance, no guidance at all,
15 about how to maintain collagen in its triple structure. All it says is
16 start with collagen. And in fact, in Slide 90, I'm sorry, I said it's 90,
17 91. That's the listing of collagen.

18 Patent Owner's counsel talked about molecules protecting the
19 heart base membrane. It's heart base membrane, it's not collagen. It
20 may be some Type IV collagen, but that's not even type I within the
21 scope of the claim. That's just wrong. And if you look, Huang2 and
22 the '233 patent both use Type I collagen. And all it has to do is
23 comprise some Type I collagen.

24 JUDGE PAULRAJ: So your position is still that as long as it's
25 in triple helical form for the electrospinning, that's enough?

1 MR. LEVINE: That is our position. And our position also,
2 Counsel said it's undisputed that we agree that the solvent in 91 would
3 denature the collagen. We absolutely dispute it. Not only do we
4 dispute it, if you take a look at Slide 92, Slide 92 is a publication by
5 Dr. Mikos who is citing Dr. Simpson. He cites Dr. Simpson six times
6 in this article. Dr. Simpson is an expert in electrospinning.

7 And what does Dr. Mikos say, quoting Dr. Simpson, the
8 spinning of collagen's Type I and Type III is feasible using the HFP
9 solvent. And then it says, collagen fiber diameters were achieved.
10 These fibers possess the 67 nanometer banding pattern observed in
11 native collagen.

12 JUDGE PAULRAJ: So what I'm seeing here in 92 is that there
13 was electrospun collagen using the HFP solvent and the native
14 collagen that was resulting from this. I assume native collagen is
15 another way of saying in the state of triple helical form.

16 MR. LEVINE: Exactly, exactly. And it says it possessed this
17 typical 67 nanometer banding pattern observed in natural. This is by
18 Dr. Mikos citing Dr. Simpson. Now in their surreply, they say, well,
19 we can ignore this because it's a review article, which I don't
20 understand exactly. In fact, not only did Dr. Simpson testify to this
21 fact. This is the both experts agreeing before the case, before this case
22 came into being. And we think it's the most credible and powerful
23 evidence they have.

24 JUDGE PAULRAJ: Okay. All right, thank you. I think that's
25 your time for now.

26 MR. LEVINE: Okay.

1 JUDGE PAULRAJ: So we'll take it under advisement. Thank
2 you.

3 MR. LEVINE: Thank you, Your Honor.

4 JUDGE PAULRAJ: All right, Ms. Wieker.

5 MS. WIEKER: Thank you. I'd like to start with major peaks
6 briefly. Petitioner's argument that this is shifting focus claimed
7 instructions inappropriate. As we explained, it was Petitioner's burden
8 to identify its claim construction, and it identified the specification's
9 definition and did not propose any other construction. Dr. Simpson
10 agreed with that definition in his declaration and in his deposition.
11 There is no surprise here. Rather than acknowledge that, Petitioner
12 attempts to shift the burden to Patent Owner to have done this earlier,
13 and that's simply inappropriate.

14 Next, Petitioner just now argued that the idea of minor peaks
15 came about in the surreply. That's simply incorrect. It was raised in
16 our Patent Owner response. And if you look at Dr. Mikos's
17 declaration, which is Exhibit 2015, starting at paragraph 58, he
18 testified that minor peaks are required. This has been in the record
19 since the post-institution Patent Owner response was filed.

20 In response to Judge Reimers's question, Petitioner's counsel
21 argued that it's clear that Huang discloses major peaks. They couldn't
22 be minor peaks. But it's unclear to me where that opinion comes
23 from. It shows a single peak, and under the express definition in the
24 specification, we need comparison to an average. We need it to
25 exceed an average. That doesn't happen.

1 And under Petitioner's definition, they themselves require a
2 relative comparison, and a relative comparison requires two things to
3 compare. A single peak, there's no basis upon which we can conclude
4 that that is major, even under their definition.

5 Finally, two last points. Petitioner argued that there's no
6 dispute that Huang, Lee, and Ayres disclose aligned fibers. But again,
7 that is not what the claims require. The claims require a specific FFT
8 analysis and result that is not present in those references. Ayres's
9 model of spaghetti shows us that fibers can be aligned but not satisfy
10 that limitation.

11 And Dr. Simpson's own testimony, not testimony, I'm sorry.
12 Dr. Simpson's own statement in a prior publication used the word
13 aligned to describe random fibers. These are shown on Slide 21 of
14 Patent Owner's demonstratives. He chose to call them aligned even
15 though they were effectively random fibers. The SEM image is
16 depicted on that slide.

17 Finally, Petitioner's counsel just referenced Type IV collagen.
18 I'm not sure where that came from. It's certainly not an argument
19 from its reply. Regarding HFP, Exhibit 2019, submitted with Patent
20 Owner's response, discusses at great length that the presence of HFP
21 with collagen will denature the compounds by necessity.

22 Turning to Petitioner's argument about Slide 92, the review
23 article that they cite, they raised this with Dr. Mikos during his
24 deposition. As he said, it's a reference to a different publication. We
25 were not provided that different publication, so we don't know what

1 protective bio-molecules were present in that reference about which
2 Petitioner's counsel just testified. It could be --

3 JUDGE PAULRAJ: I'm sorry. Are you saying that Slide 92 is
4 not part of the record?

5 MS. WIEKER: No.

6 JUDGE PAULRAJ: So the paper cited in Slide 92 is not part of
7 the record?

8 MS. WIEKER: So Exhibit --

9 JUDGE PAULRAJ: 1209?

10 MS. WIEKER: -- 1209 is a review article, and that statement
11 that they point to in that review article is discussing yet another article
12 that Petitioner didn't put into the record. We note this in our surreply
13 in a footnote, and Dr. Mikos objected to it in his deposition. So we
14 have no information about that other publication, because it just
15 simply wasn't given to the witness.

16 JUDGE PAULRAJ: And you had an opportunity to file a
17 surreply. Is this --

18 MS. WIEKER: We could file a surreply, but we weren't
19 permitted new evidence.

20 JUDGE PAULRAJ: Well, you could've asked. But that said,
21 so are you saying that when you have a review article like this, you
22 should kind of discount it because somehow all the cited references in
23 that review article were not also made part of the record?

24 MS. WIEKER: So our point is that Petitioner is saying that
25 HFIP does not necessarily degrade collagen, and their sole piece of
26 evidence to support that is this one statement shown on Slide 92.

1 Our view is that we have no idea why collagen may not have
2 been denatured there. It could be, like in the patent, there are
3 protective biomolecules that prevented the denaturation. But again,
4 Petitioner's burden here is to show that there are necessarily present
5 triple helical structure, and this reference is simply insufficient to
6 overcome Dr. Mikos's testimony and Exhibit 2019, which clearly
7 demonstrate that it was well known that HFIP will denature collagen.

8 JUDGE PAULRAJ: Okay. And you mentioned something that
9 I asked you earlier that your colleague was talking about, the type
10 thing --

11 MS. WIEKER: Yes, he gave it to me. I'm sorry.

12 JUDGE PAULRAJ: -- the collagen, yes.

13 MS. WIEKER: Yeah. So in the '223 patent, which is Exhibit
14 1001 of the 248 IPR, column 12, lines 42 through 67, discuss different
15 bioactive fibers that are added -- different bioactive factors added to
16 the fibers. And then the four examples discuss, for example, heart
17 basement membrane. That is what Dr. Mikos testified about. He said
18 there are protective biomolecules, including proteoglycans, that
19 protect the collagen in heart basement membrane.

20 JUDGE PAULRAJ: And that would have protected it, at least
21 by Dr. Mikos --

22 MS. WIEKER: Exactly.

23 JUDGE PAULRAJ: -- from denaturing. Even though it was in
24 the presence of HFIP.

25 MS. WIEKER: That's right.

26 JUDGE PAULRAJ: Okay.

1 MS. WIEKER: And all of that is cited in addition in our
2 surreply.

3 JUDGE PAULRAJ: So let me kind of ask. I know we
4 probably had this issue a lot. But when we're talking about the FFT
5 clause, or what I'll call the FFT clause, everything after the wherein
6 clause in Claim 1 of the '223 patent, right? What physical property of
7 the scaffold is that FFT requirement intended to capture?

8 MS. WIEKER: So it's intended to capture what is shown in
9 Figure 8A, the SEM image there. So you've got a scaffold, an
10 electrospun scaffold, comprising collagen where you have a primary
11 axis of alignment reflecting the major peaks in the FFT plot and
12 secondary axis of alignment reflecting the minor peaks that are
13 necessarily required by the definitional average.

14 JUDGE PAULRAJ: So, if I were to then kind of take a cross
15 out, and I may not be as precise as what you might want with FFT
16 analysis, but if I were to cross out the FFT analysis, the language
17 would just say wherein, the scaffold has major peaks, I'm sorry, a
18 major degree of axis of alignment and a secondary axis of alignment,
19 is that enough to capture what's presiding in that FFT clause?

20 MS. WIEKER: That's certainly closer than Petitioner's attempt
21 to replace it with aligned fibers.

22 JUDGE PAULRAJ: Okay. So it's not just aligned. It's
23 certainly not perfectly aligned. You've kind of gotten that point
24 across. We're not talking about real-world idealized alignment. You
25 know, when you do electrospinning, you're naturally going to get,
26 whether you want to call it misalignment or secondary alignment.

1 Something where it's not perfect in terms of just going up and down
2 the vertical axis.

3 MS. WIEKER: That's necessarily required by the
4 electrospinning process where there's some space between the
5 spinneret from which the electrospinning polymer is injected to the
6 collector --

7 JUDGE PAULRAJ: Where in the record is that before? I don't
8 have it --

9 MS. WIEKER: Let me point you to even just the figures.
10 Okay. So again, looking at the '223 patent, those specifications are
11 the same. You've got this. Figure 5 is the best example. You've got
12 the syringe pump to the right, and this is where your polymer is being
13 injected from, and then that travels a distance to your collector rods on
14 the left, upon which, by virtue of the forces in the electric field.

15 JUDGE PAULRAJ: So that shows me the apparatus.

16 MS. WIEKER: Correct.

17 JUDGE PAULRAJ: And again, I want to be very careful
18 because obviously I don't want to confine the record to what it is.
19 You point to Figure 5 --

20 MS. WIEKER: Understood.

21 JUDGE PAULRAJ: -- is there any expert testimony saying that
22 along the lines of, if you look at Figure 5 and the general
23 electrospinning process, you're going to necessarily get a secondary
24 alignment as a result of electrospinning, as an inherent property of the
25 electrospinning process?

1 MS. WIEKER: So Dr. Mikos testifies to this inherent property
2 in his discussion of minor peaks, paragraph 58 of the Exhibit 2015
3 and the 248 IPR?

4 JUDGE PAULRAJ: Okay. That's enough for me. I'll just refer
5 to that. Thank you.

6 MS. WIEKER: Okay. Thank you. Absent any other questions,
7 I'll give back my 30 seconds.

8 JUDGE PAULRAJ: Thank you, Counsel.

9 MS. WIEKER: Thank you.

10 MR. LEVINE: Your Honor, can I give you one citation that I
11 was missing?

12 JUDGE PAULRAJ: If it's in response to a specific question I
13 asked --

14 MR. LEVINE: Yes, yes. It's on the heart base membrane
15 having type IV collagen. I just wanted to cite where it was in the
16 record.

17 JUDGE PAULRAJ: Okay. Fair enough.

18 MR. LEVINE: It's paragraph 46 of Exhibit 1219, which is Dr.
19 Simpson's reply declaration.

20 JUDGE PAULRAJ: Okay. Thank you, Counsel.

21 MR. LEVINE: Thank you.

22 JUDGE PAULRAJ: With that, the record is closed. And thank
23 you, counsel, for your insights, coming in and presenting your
24 arguments. We'll take the matter under advisement. And have a good
25 rest of the day.

1 (Whereupon, the above-entitled matter went off the record at
2 3:17 p.m.)

IPR2025-00248 (Patent 10,137,223 B2)
IPR2025-00249 (Patent 11,318,227 B2)

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