UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

RAVGEN, INC.	)	Docket No. A 20-CA-692 ADA
	)	
vs.	)	Austin, Texas
	)	
NATERA, INC., NSTX, INC.	)	February 9, 2021

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

RAVGEN, INC.	)	Docket No. A 20-CA-822 ADA
	)	
vs.	)	Austin, Texas
	)	
PERKINELMER, INC., PERKINELMER GENETICS, INC., BIOO SCIENTIFIC CORPORATION	)	February 9, 2021

TRANSCRIPT OF VIDEOCONFERENCE MARKMAN HEARING
BEFORE THE HONORABLE ALAN D. ALBRIGHT

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09:30:24 THE COURT: Good morning, everyone.

09:30:26 MR. DACUS: Good morning, Judge.

09:30:28 THE COURT: Suzanne, is everyone ready to go?

09:30:31 THE CLERK: I believe so.

09:30:33 THE COURT: Very good. If you could call the case, please, and then, I'd like to hear from counsel first for the plaintiff and then, for defendant, whoever's going to be speaking.

09:30:43 THE CLERK: Markman hearing in Civil Action 1:20-CV-692, styled, Ravgen, Incorporated vs. Natera, Incorporated and Others; and Case No. 1:20-CV-822, styled, Ravgen, Incorporated vs. PerkinElmer, Incorporated and Others.

09:31:03 THE COURT: Very good. Plaintiff's counsel.

09:31:07 MR. DACUS: Good morning, your Honor. This is Deron Dacus on behalf of the Plaintiff Ravgen. Also here with us from the Desmarais law firm and those who will be presenting argument today are Kerri-Ann Limbeek, Kyle Petrie, and Julie Thomsen. We also have John Desmarais here with us, your Honor. And lastly, but most importantly, we have two folks from our client Ravgen here, your Honor. We have Ravinder Dhallan, who is the CEO of Ravgen and the inventor on the patents-in-suit and, also, John Varney, who is the Director of Laboratory Operations at Ravgen. And we're ready to proceed, Judge.

09:31:45 THE COURT: Thank you, sir.

09:31:46 And let me take the time to thank the clients for
09:31:49 taking the time to attend. I very much appreciate them
09:31:53 doing that. It sounds to me like Mr. Desmarais is taking
09:31:55 the time to attend, as well, even if I'm not going to be
09:31:58 hearing from him, which is a disappointment in many ways,
09:32:01 but that's fine.

09:32:04 Mr. Hash, I could see you. I'm not sure who will
09:32:07 be speaking on behalf of your clients, but if you are,
09:32:10 great. If someone else is, I'd be happy to hear from
09:32:14 defendants.

09:32:14 MR. HASH: Good morning, your Honor. This is
09:32:16 Steve Hash from Baker Botts on behalf of Natera
09:32:19 Defendants. I will be speaking --

09:32:20 THE COURT: Did you walk your son to school
09:32:21 today? Oh, y'all don't walk to school anymore, are you?

09:32:24 MR. HASH: No. We haven't been to school at all,
09:32:27 so folks are just out at the ranch. It's actually as good
09:32:30 a place to go to school as you could think of.

09:32:33 THE COURT: I still miss being in Austin, seeing
09:32:36 you walking your son to school. That's a great thing.

09:32:40 MR. HASH: Yeah, we miss it, too, your Honor.

09:32:42 With me and presenting today will be Ms. Samoneh
09:32:46 Kadivar and Elizabeth Flannery. Also from Baker Botts, we
09:32:50 have Alex Piala. And from the client, we have senior IP

09:32:54 counsel Arka Chatterjee.

09:32:57 THE COURT: Thank you for the client

09:32:58 representation there, as well.

09:32:59 The first claim term we'll take up is "relative

09:33:04 amount of alleles/relative amount of the alleles." And

09:33:10 the Court's preliminary construction is plain and ordinary

09:33:14 meaning. And then, I'm going to hear from defense counsel

09:33:16 with respect to their proposed construction of "percentage

09:33:21 of alleles."

09:33:22 Who will be speaking on behalf of the defendant,

09:33:24 Mr. Hash?

09:33:25 MR. HASH: Ms. Kadivar.

09:33:27 THE COURT: Very good.

09:33:28 MS. KADIVAR: Good morning, your Honor.

09:33:30 THE COURT: I don't know that I've had the

09:33:31 privilege of having you in my court. Welcome. I wish we

09:33:34 were live in person but this is -- this is nice. Thank

09:33:38 you for being here.

09:33:40 MS. KADIVAR: Thanks for having us here and we

09:33:42 really appreciate your Honor taking the time to hear our

09:33:45 arguments. We know how busy you are. So if I can just

09:33:48 quickly share my screen here. Can you see that?

09:33:52 THE COURT: Yes, ma'am.

09:33:59 MS. KADIVAR: So we saw the Court's preliminary

09:34:01 claim construction yesterday noting that the term should

09:34:03 be accorded its plain and ordinary meaning, and we're in
09:34:05 complete agreement with that, your Honor. But our only
09:34:07 concern with leaving it at that is that our position has
09:34:09 been that the plain and ordinary meaning in light of the
09:34:12 intrinsic record is percentages of alleles.
09:34:15 Now, Ravgen has also been arguing that it should
09:34:17 be accorded its plain and ordinary meaning, but it's not
09:34:21 quite clear from their briefing what they're saying the
09:34:23 plain and ordinary meaning is. It seems to be the case
09:34:26 that they're suggesting that the plain and ordinary
09:34:29 meaning is the amount of one allele as compared to the
09:34:33 amount of one or more alleles, but that's completely
09:34:35 writing the term "relative" out of the claim.
09:34:37 So if we just take a quick look at the claim, it
09:34:40 expressly recites quantitating a ratio of the relative
09:34:42 amount of alleles. So Ravgen's plain and ordinary meaning
09:34:46 of, you know, comparing the amount of one allele as to the
09:34:48 amounts of one or more alleles is already embodied here in
09:34:53 the term "ratio." They're giving no meaning to the term
09:34:56 "relative" here, so they're just writing it out of the
09:34:58 claim, your Honor.
09:34:59 And so, we just wanted to raise our concern here
09:35:01 that leaving the construction at plain and ordinary
09:35:03 meaning when the parties are disputing that meaning. It
09:35:06 just doesn't give us very much clarity. And so, I'm just

09:35:09 going to leave it at that unless your Honor has any
09:35:11 questions for us.
09:35:11 THE COURT: Well, let me tell you this. And I
09:35:13 don't want to discourage a response from counsel for the
09:35:17 plaintiff. He or she is welcome to say whatever they care
09:35:21 to. But I get this on a relatively consistent basis where
09:35:27 I have a lawyer on one side or the other -- and it's both
09:35:31 sides. It's not particular one -- tells me, Judge, we're
09:35:35 good with the plain and ordinary meaning, but we're not
09:35:37 sure we're going to be good with what they say the plain
09:35:39 and ordinary meaning is.
09:35:41 And I don't see my role -- I've read all the
09:35:46 cases, I've handled a couple of Markmans now, but I still
09:35:49 don't see my role as where there's a word like "relative
09:35:53 amount" where someone is just saying it ought to be a
09:35:56 different word, it means kind of the same thing,
09:36:00 percentage, relative, of alleles. I don't think that's a
09:36:02 Markman construction issue.
09:36:05 The way I see it, for better or worse for you
09:36:08 all, is at some point, the plaintiff -- and I have
09:36:14 enormous respect for your firm. At some point, the
09:36:16 plaintiff is going to give you an expert report, and then,
09:36:21 he is going to say, or she is going to say, I believe that
09:36:26 the defendants' products infringe because they meet the
09:36:32 limitations of having a relative amount of alleles,

09:36:36 relative amount of the alleles, and he is then or she is
09:36:39 then going to say what they mean by that.
09:36:43 If the plaintiff's expert says something that you
09:36:48 think is not consistent with what the plain and ordinary
09:36:52 meaning of that is, you have two tools. One is on -- I'll
09:36:58 probably limit it to one or two claim terms. But if you
09:37:00 get their report and you say, this can't possibly be plain
09:37:05 and ordinary meaning, you can call me and say, we'd like a
09:37:07 mini Markman on this particular claim term.
09:37:09 This goes both ways. I'm not limiting it to
09:37:13 either side. But you can call and say, what Dr. Smith
09:37:15 says can't possibly be the plain and ordinary meaning.
09:37:19 I'll listen and if I determine that the plaintiff has
09:37:23 gotten too greedy in their infringement, defendants have
09:37:27 gotten too greedy in invalidity, I may say I agree, and
09:37:30 then, one side or the other is in bad shape. Because you
09:37:32 all are great lawyers. I know Mr. Desmarais, I know Mr.
09:37:36 Hash, I know Mr. Dacus. I mean, you all should certainly
09:37:39 be able to constrain yourself to what the plain and
09:37:42 ordinary meaning is.
09:37:42 But if you don't, that would be a bad time to
09:37:45 find out you got too greedy. Or you could each file a
09:37:51 motion for summary judgment and do the same thing, at
09:37:52 which time, you have the claim -- the expert report.
09:37:56 You'll have the expert's explanation at the deposition,

09:38:00 and you could say as a matter of law, Judge, this can't be
09:38:02 the plain and ordinary meaning.
09:38:05 And that's not a -- just a potential -- in the
09:38:13 case I'm going to starting on Tuesday, there were three
09:38:17 patents. There are now two patents because I granted a
09:38:21 motion for summary judgment on non-infringement on one of
09:38:24 the three patents. So that is where I prefer to take
09:38:29 these things up.
09:38:30 So on this one, let me ask you this. I've kind
09:38:34 of given away the answer, but if the attorney for the
09:38:37 Desmarais firm is someone -- I was going to say young, but
09:38:41 everyone on this call is young compared to me. But if the
09:38:44 person who is going to argue the matter is a relatively
09:38:48 new attorney, I would be happy to hear that attorney argue
09:38:52 and respond to the argument that I just went over.
09:39:00 MR. PETRIE: Your Honor, this is Kyle Petrie on
09:39:03 behalf of the Plaintiff Ravgen.
09:39:04 I understood what your Honor was saying. I'm
09:39:06 happy to leave it where you just left it. Unless there's
09:39:10 anything you have for me, I don't think there's anything
09:39:12 further that needs to be argued at this time.
09:39:13 THE COURT: And I won't make a comment on whether
09:39:15 or not I think you're a young lawyer either. So we will
09:39:19 -- I will go with plain and ordinary meaning for that one.
09:39:22 Next claim term, I won't read the whole thing,

09:39:25 but begins with "agent that inhibits cell lysis to
09:39:30 inhibit," and we'll go from there. Again, let me see,
09:39:38 since we have given plain and ordinary meaning and the
09:39:41 plaintiff has -- let me ask the plaintiff first just -- I
09:39:44 don't need argument if you agree, but if -- I would like
09:39:47 to see if the plaintiff does agree with the plain and
09:39:51 ordinary meaning is sufficient.
09:39:55 MS. LIMBEEK: Your Honor, Kerri-Ann Limbeek on
09:39:58 behalf of Plaintiff Ravgen.
09:40:00 I'll be arguing this term. Yes, we completely
09:40:02 agree with your Honor's construction that this term should
09:40:04 be given the plain and ordinary meaning.
09:40:06 THE COURT: Okay. Then I'll hear from counsel
09:40:08 for defendant. And then, if I need any response, Ms.
09:40:11 Limbeek, I'll be happy to hear from you.
09:40:15 MR. HASH: Good morning, your Honor. This is
09:40:16 Steve Hash for Natera.
09:40:19 And really just reiterating just kind of our
09:40:21 point on the last one, our concern is -- we're happy with
09:40:23 this construction. We do believe and we've argued that
09:40:26 this term has its plain and ordinary meaning. We just
09:40:29 want to make sure that that's -- that the plain and
09:40:32 ordinary meaning is not an invitation for any more monkey
09:40:37 business on the part of Ravgen.
09:40:39 And the reason why I think that's particularly

09:40:43 relevant here, if I could share my screen if that's
09:40:47 shared, it's a little bit more pointed in this because if
09:40:50 Ravgen's going to continue to argue that the plain and
09:40:53 ordinary meaning is mechanistic versus functional, which
09:40:55 is what the plain and ordinary meaning of this term
09:40:57 clearly is, if so, we can finish this today, your Honor.
09:41:01 I mean, we took the deposition of their expert,
09:41:05 and as you can see, unsolicited from me, he admitted that
09:41:10 the construction that he was sought -- he sought to defend
09:41:13 and that Ravgen put forward is a long, 54-word definition
09:41:17 that included mechanistic limitations like direct versus
09:41:23 indirect, endogenous versus exogenous, that find no
09:41:26 support whatsoever in the intrinsic or extrinsic record
09:41:29 and actually read out claim embodiments that he
09:41:32 understands that based upon his analysis -- and he spent
09:41:34 five-and-a-half hours tripping over himself walking back
09:41:37 from his arguments, but he understands that the
09:41:40 construction he put forward is indefinite. And so, we
09:41:43 just want to avoid the issue of having this slide come up
09:41:49 again when they're already on record acknowledging that
09:41:53 their 54-word construction is indefinite.
09:41:56 THE COURT: Well, I get that you have Dr. Grody
09:41:58 making these statements. And, you know, certainly if he
09:42:03 has to, for lack of better word, amend or supplement what
09:42:07 he said there to clarify it for you all, then at some

09:42:10 point, a jury or I could determine whether or not he was
09:42:16 not correct or whether he misspoke.
09:42:18 But let me hear from -- were you done, Mr. Hash?
09:42:21 If you wanted to say more, I didn't mean to interrupt you.
09:42:24 MR. HASH: That's it, your Honor.
09:42:25 THE COURT: If I could hear from counsel for the
09:42:27 plaintiff, please.
09:42:30 MR. ALLEN: Your Honor, this is Stacy Allen. I
09:42:32 represent PerkinElmer, and we missed a chance to make out
09:42:39 appearances and note for the record who will be speaking.
09:42:41 I think PerkinElmer also wanted to address this term.
09:42:45 THE COURT: Okay. Let me --
09:42:47 MR. ALLEN: I'm fortunate to have the gen --
09:42:49 THE COURT: Hold on one second.
09:42:51 MR. ALLEN: Sure.
09:42:52 THE COURT: I could barely hear you. Let me see
09:42:54 if it's on my end, and if it's not, then I'll have you
09:42:57 speak up. Okay. I heard enough of that, Mr. Allen, but
09:43:00 if you could just speak a little louder, it would help me,
09:43:03 please.
09:43:04 MR. ALLEN: Is this better?
09:43:06 THE COURT: Yes, sir.
09:43:07 MR. ALLEN: Okay, your Honor.
09:43:08 I'm with Jackson Walker. And with me today from
09:43:11 the Day Pitney firm in Hartford are Elizabeth Alquist,

09:43:16 Sean Park and John Tropp. Sean Park, who is genuinely
09:43:21 young, will be arguing this point. And along with us
09:43:24 today, we have two inhouse counsel from PerkinElmer, Kevin
09:43:30 Oliver and Daryl Achilles.
09:43:33 THE COURT: Very nice. And so, I'm happy to hear
09:43:35 from -- I'm happy to hear an argument from -- and I
09:43:38 apologize, I didn't realize I wasn't getting everyone in.
09:43:40 I certainly -- I will tell you, you don't have a lawyer
09:43:44 that is persuasive enough probably to change my mind on
09:43:47 the first claim term. I was pretty -- I'm pretty sure
09:43:52 about that. But I'm happy to hear whatever your client
09:43:56 would like to -- and let me thank the client
09:43:58 representatives for being here. But I'm happy to hear the
09:44:02 -- I guess what you all would like to argue is that this
09:44:04 is indefinite. I'm happy to hear that.
09:44:14 Counsel, you're on mute.
09:44:17 MR. PARK: Thank you, your Honor. And thank you
09:44:20 again for granting the pro hoc motions and allowing us to
09:44:23 be here. And I will share my screen quickly.
09:44:34 We have some new arguments in relation to the
09:44:39 agent limitation, which, as you noted, we do contend is
09:44:44 indefinite. And one of the things that Ravgen has stated
09:44:52 in relation to this term is that it admits the term is
09:44:55 broad, but writes several times that breadth is not
09:45:00 indefinite. But PerkinElmer is not arguing that the claim

09:45:03 terms are indefinite solely because they're broad. It's
09:45:06 the converse of that. It's the claims are broad because
09:45:08 they're indefinite.
09:45:09 And we put down the legal standards for the
09:45:14 indefiniteness, especially in relation to the Markush
09:45:17 term, and we've argued that point. So we will quickly
09:45:21 move through some of those arguments, if you don't mind.
09:45:24 And here, the Markush group does not provide with
09:45:32 reasonable certainty what the agents are. The highest
09:45:37 level membrane stabilizer, cross-linker and cell lysis
09:45:40 inhibitors are vague terms that do not together belong to
09:45:44 any subgroup. They don't share any structural similarity
09:45:47 or common use flowing from a substantial structural
09:45:51 feature. And we can focus on the membrane stabilizer
09:45:59 term, first. And it has been admitted by Dr. Grody that
09:46:03 there's no common structure there and the term is entirely
09:46:08 functional. And while some functional claims are allowed,
09:46:12 there's no guideline or objective standard in the asserted
09:46:16 patents on how to determine something is a membrane
09:46:20 stabilizer.
09:46:21 We've discussed the unlimited examples in the
09:46:24 briefs, so I will not go over those examples again. But I
09:46:30 believe it's important to reiterate that even Dr. Grody,
09:46:33 who is a person of extraordinary skill in the art, does
09:46:36 not know whether most of the enumerated substances are

09:46:42 actually membrane stabilizers. And also, many of the
09:46:44 examples are known for other functions primarily, instead
09:46:46 of stabilizing cell membrane such as glucose and vitamin.
09:46:50 We've gone through the example of aldehydes and
09:46:54 the examination of Dr. Grody with respect to that term.
09:46:57 Aldehydes include potentially infinite amount of
09:47:01 substances, and Dr. Grody repeatedly admits that he does
09:47:04 not know how to determine whether a particular aldehyde
09:47:08 would belong to the class of membrane stabilizer. He said
09:47:12 this goes beyond my expertise, way beyond anything I've
09:47:14 done. I couldn't design such an experiment now. Now as
09:47:18 in 2021, which is 20 years after the filing dates of the
09:47:22 patents, after numerous advancements made in the biology
09:47:26 field. And he implied that a POSITA would not be able to
09:47:31 determine that and it would have to be a Nobel laureate,
09:47:35 which is far beyond anything that either party has
09:47:38 suggested for the level of skill in the art.
09:47:44 For the cell lysis inhibitor term, it's similarly
09:47:49 without any common structure and also entirely functional.
09:47:53 Again, as a functional term, the patents do not provide
09:47:56 any guideline or objective standard on how to determine
09:47:59 something is a cell lysis inhibitor. We've discussed it
09:48:04 open-ended, unlimited examples in the briefs. And we
09:48:06 would like to focus on this, just the nature of the term
09:48:11 that's specifically for everyone's benefit.

09:48:14 Cell lysis inhibitor is not a term of art. It's
09:48:18 amalgamation of known words. Cell lysis, on the one hand,
09:48:22 and inhibitor, on the other one. And we thought it would
09:48:28 be useful to use an example here, which is apple pie
09:48:33 launcher. We know what apple pie means and we know what
09:48:37 launcher means, but maybe with the exception of very small
09:48:40 group of individuals, I think we can agree that apple pie
09:48:45 launcher would not provide a reasonable notice about the
09:48:47 scope. Just because we can combine two terms with no
09:48:49 meanings does not mean the result is sufficiently
09:48:53 definite.
09:48:53 And then, the Supreme Court in the Nautilus case
09:48:57 expressly noted that ascribing some meaning to a term
09:49:00 isn't sufficient to make the term definite. It's the
09:49:03 reasonable notice to the person of ordinary skill. And
09:49:06 we've gone back and forth with Dr. Grody about this term,
09:49:09 and he admitted that he cited zero publication in support
09:49:14 for this cell lysis inhibitor term. And in the
09:49:19 deposition, he admitted that the very dictionary that he
09:49:21 used to define the word "cell lysis" does not include a
09:49:24 definition for cell lysis inhibitor.
09:49:28 He was asked about the fact that there's only one
09:49:32 printed publication that used the term "cell lysis
09:49:35 inhibitor" before 2001, and he was tongue-tied. Most
09:49:39 damningly of all is that the named inventor of this

patent, Dr. Dhallan, who's present here, he did not use the term "cell lysis inhibitor" in his own papers that were published in 2004 and 2007. Those papers are cited in the complaint and submitted as Exhibits 36 and 38.

We believe that's telling that this term "cell lysis inhibitor" is not a term of art that was used in the field; rather, it's that it's just amalgamation of known words that was used in the patent that is incredibly broad and indefinite. We've discussed some of the further discussions about Dr. Grody's admissions about ability to test something is a cell lysis inhibitor, so we will leave it on the record as briefed in the documents.

In summary, your Honor, again, the agent limitation is indefinite because the claims read in light of the specification and prosecution history do not inform a person of ordinary skill about the scope. Especially when it comes to the Markush group, a person of ordinary skill would not be able to determine the members of the Markush group. And again, that the agent limitation is not indefinite because it's broad, but broad because it is indefinite.

Thank you, your Honor.

THE COURT: Counsel for plaintiff.

MS. LIMBEEK: Thank you, your Honor.

If I could pull up slide 9. Your Honor, your

09:51:34 Honor's preliminary construction --
09:51:36 THE COURT: May I ask you a question?
09:51:38 MS. LIMBEEK: Sure.
09:51:39 THE COURT: I heard counsel's argument that at
09:51:46 the period of time when this application was filed,
09:51:49 weren't there known agents that could be used for -- as
09:51:52 inhibitors for this process? I mean, I've heard him
09:51:57 arguing that this was kind of squishing together two claim
09:52:00 terms that didn't have meaning, but wasn't it pretty
09:52:03 well-known that different -- that there were different
09:52:06 inhibitors at the time?
09:52:08 MS. LIMBEEK: Yes. And in fact, your Honor, I
09:52:12 think that's part of the crux of what makes this not
09:52:16 indefinite. If we could go actually to slide 57, I think
09:52:30 the prosecution history actually makes clear here that
09:52:34 there were well-known agents that inhibited cell lysis
09:52:40 from the particular group, the particular Markush group,
09:52:44 membrane stabilizers, cross-linkers and cell lysis
09:52:47 inhibitors. Those were known in the art for preventing
09:52:50 cell lysis in other contexts.
09:52:52 So, for example, for preserving intact cells so
09:52:56 that you can look at the contents of the cells, the
09:53:01 nucleic acids from inside the cell. And what was really
09:53:04 novel about the claimed invention was the use of those
09:53:07 particular compounds in the context of analyzing free

09:53:13 nucleic acids that are circulating outside of cells, and
09:53:15 that's part of what makes -- and so, those categories were
09:53:21 certainly well-known.
09:53:22 What counsel for the defendants seem to be
09:53:26 arguing is that your Honor should construe cell lysis
09:53:31 inhibitor to mean the same thing as agent that inhibits
09:53:36 cell lysis. And if we go back to slide 9 where you can
09:53:46 see the full limitation, that's improper because it
09:53:48 completely reads out the Markush group, which requires not
09:53:54 only the first requirement shown in green there is that
09:53:57 the agent inhibits lysis of cells, has to actually reduce
09:54:01 the lysis of cells if cells are present.
09:54:04 But also, there's a separate requirement that the
09:54:07 agent be selected from a particular group of compounds,
09:54:12 and that's this Markush group, membrane stabilizer,
09:54:15 cross-linker and cell lysis inhibitor. And these were all
09:54:17 known in the art, those were -- many compounds were known
09:54:20 in the art that fell into each of those groups, and it
09:54:24 didn't include every single compound that might even
09:54:28 indirectly result in a reduction in cell lysis.
09:54:33 And the defendants skip over their prior
09:54:36 arguments about anticoagulants and chelators like EDTA and
09:54:41 it dodged the substances: and the reason they skip over
09:54:43 that is that throughout the intrinsic record, the patentee
09:54:47 makes very clear that things like anticoagulants which may

09:54:52 be added to a sample in order to prevent clotting and
09:54:57 thereby, you know, indirectly reduce cell lysis because
09:55:00 they prevent clotting, and during clotting, cell lysis can
09:55:04 occur, yes, that may be one way to prevent a process in
09:55:10 which lysis occurs and, therefore, indirectly reduces cell
09:55:14 lysis. But the patents make very, very clear that those
09:55:19 types of substances are not within the three claimed
09:55:23 categories of compounds that are at issue in the Markush
09:55:27 group.
09:55:28 And that's what really matters here. And if we
09:55:36 go to slide 56, I think Federal Circuit case that really
09:55:44 is applicable here regarding indefiniteness is the BASF
09:55:49 case. And in that case, the Federal Circuit actually
09:55:52 dealt with a very similar term, a couple of terms
09:55:56 requiring a particular material composition effective for
09:56:01 catalyzing particular reaction. And even though there was
09:56:05 testimony that there was a limitless number of materials
09:56:08 that, you know, would work to catalyze those compounds and
09:56:11 even though the specification didn't provide an exhaustive
09:56:14 list, the Federal Circuit reasoned that those terms were
09:56:20 still bounded because the intrinsic record made clear that
09:56:24 it was the claimed arrangement of the catalysts, rather
09:56:27 than the selection of particular catalysts, that
09:56:30 purportedly renders the inventions claimed a patentable
09:56:35 advance over the prior art.

09:56:37 And so, as a result, the claims in the
09:56:38 specification let the public know that any known catalyst
09:56:41 can be used as long as they play their claimed role in the
09:56:45 claimed architecture. And that's exactly the same as the
09:56:48 case here where it's not that these categories of
09:56:55 compounds, membrane stabilizer, cross-linker and cell
09:57:00 lysis inhibitor, those were all known categories of
09:57:02 compounds, but the novel invention was the use of them
09:57:05 with cell-free DNA.
09:57:08 And so, similar to the BASF case, the claims in
09:57:13 the specification here let the public know that any known
09:57:17 membrane stabilizer, cross-linker, cell lysis inhibitor
09:57:19 can be used as long as it plays the claimed role in the
09:57:22 claimed architecture.
09:57:27 And, your Honor, I'd like to address the
09:57:33 arguments that defendants were making regarding this
09:57:38 apparent never-ending investigation. So if we could go to
09:57:41 slide 62, please. So I think defendants' arguments here
09:57:52 really are premised on a misunderstanding of the law
09:57:54 because the law does not require that for a claim to be
09:57:59 definite, that a potential infringer knows ex ante every
09:58:04 single compound that might infringe the claim and be able
09:58:07 to determine whether every single potential agent
09:58:11 infringes the claims. And that's really what the
09:58:13 defendants are arguing here with this never-ending

09:58:17 investigation.

09:58:18 In fact, the Federal Circuit has explained that
09:58:22 the difficulty or complexity of the infringement analysis
09:58:25 does not necessarily speak to whether or not a claim is
09:58:28 definite. And if we take a look at slide 63, please, if
09:58:33 you actually look at the testimony that the defendants are
09:58:37 relying on for this never-ending investigation, what
09:58:40 that's referring to is the hypothetical path of analyzing
09:58:44 the chemical mechanism of every single compound that could
09:58:47 be used as a membrane stabilizer, cross-linker, or cell
09:58:52 lysis inhibitor.

09:58:52 The context of that statement is that the
09:58:55 examples in the specification of those three categories of
09:59:00 compounds are merely exemplary. They're not an exclusive
09:59:04 list, and they're just representative compounds because
09:59:07 the lists say including, but not limited to. And so, this
09:59:13 is not an indefiniteness issue. This is an issue of --
09:59:20 that there are many compounds that could meet the
09:59:22 boundaries of those three categories of compounds.

09:59:33 And in fact, if you look on -- so looking at
09:59:38 slide 64, Dr. Grody says he did not analyze every single
09:59:46 potential example of those three categories of compounds.
09:59:50 Instead, he was focused on the broader classes and what
09:59:53 the broader classes of compounds meant, membrane
09:59:56 stabilizer, cross-linker and cell lysis inhibitor. And

10:00:00 the next slide, please.

10:00:02 And what he also testified is that it would actually be straightforward to assess whether or not a compound is a cell lysis inhibitor. When he was asked about the potential compound that was -- to figure out whether or not a compound was a cell lysis inhibitor, he said that's actually pretty straightforward. You can review the literature, you could read the specs of commercial literature -- of commercial supply company that sells it, and you could try it out in the lab, and that's because as I manufactured before, these categories of compounds were well-known in the art for use in other contexts. For example, for fixing cells so that you can analyze the contents of the cells.

10:00:44 And next slide, please. And that's the same thing with the membrane stabilizer category when he was asked about a hypothetical compound and whether or not it's going to fit into the category of membrane stabilizer, he said he looked it up to see whether that's one of the listed applications and that he could also test it out in the lab. And so, you know, first and foremost, you'd look it up because these are all -- you know, there were many of these types of compounds that were known in the art.

10:01:12 And then, he says you can test it out in a lab.

10:01:16 And yes, that's a cell biology task and that's not within
10:01:20 his expertise, but he had an idea of exactly how you would
10:01:23 be able to study the mechanism, as you can see here,
10:01:27 using, for example, radioactively labelled aldehydes to
10:01:32 see where they end up on the cell, and so on.
10:01:35 And so, defendants' arguments about this being --
10:01:39 it being impossible to figure out -- for a person of
10:01:43 ordinary skill in the art to figure out what actually fits
10:01:46 in the category, they really missed the point for
10:01:48 definiteness because, as we talked about with the law,
10:01:52 what actually matters for definiteness is not how
10:01:55 difficult it is to figure out whether a particular
10:01:58 hypothetical compound infringes or how long it would take
10:02:01 to go through and test every single compound that might be
10:02:05 a cell lysis inhibitor, or a membrane stabilizer, or a
10:02:09 cross-linker. Rather, what matters is whether or not the
10:02:15 terms are bounded.
10:02:17 And actually, if we turn to slide 58, defendants'
10:02:24 own experts confirmed that whether or not they're broad,
10:02:29 these categories are bounded and they would understand
10:02:33 those boundaries. First, we asked defendants' expert
10:02:37 about cross-linkers. He said he understood what
10:02:40 crosslinking meant. He understood that there are
10:02:42 boundaries to the term "cross-linker." And in fact,
10:02:45 there's a common functionality, which is covalently

10:02:49 crosslinking polymers.

10:02:51 And then, skipping to slide 60, the same thing
10:02:55 for membrane stabilizer. He confirmed that there are
10:03:00 boundaries on the category of membrane stabilizers.
10:03:04 They're only substances that are capable of stabilizing
10:03:08 the membranes of cells. And he confirmed that there's a
10:03:11 common functionality that they stabilize cell membranes.
10:03:16 That's what they're supposed to be.

10:03:18 And then, finally, looking at on slide 61, in
10:03:22 discussing Dr. Grody's assertion which is based on the
10:03:28 extensive evidence within the intrinsic record
10:03:31 distinguishing between cell lysis inhibitors that actually
10:03:37 preserve and protect the cell and the structure of the
10:03:40 cell throughout processing versus just preventing a
10:03:43 process that might result in physical stress to the cells,
10:03:48 looking at Dr. Grody's understanding and articulation of
10:03:55 cell lysis inhibitors as protecting and preserving the
10:03:57 structural integrity of the cell membrane, he understood
10:04:00 that that was a boundary on a particular category of
10:04:03 substances, as well.

10:04:04 And in fact -- this is really important -- the
10:04:08 last question and answer on this slide, not all substances
10:04:11 that reduce cell lysis do so by protecting and preserve --
10:04:16 or preserving the structural integrity of the cell
10:04:19 membrane. And defendants' expert, he said that's what

10:04:21 I've been saying all along. There are many different
10:04:24 mechanisms at how to get to cell lysis inhibition, and
10:04:28 that's really the point here. The first requirement in
10:04:31 the claim is that the agent actually reduces cell lysis;
10:04:35 and the second requirement is that it's one of these three
10:04:38 particular categories of compounds in the Markush group.
10:04:41 And there is a difference between a cell lysis inhibitor,
10:04:45 and that is a bounded category and just anything that can
10:04:50 be used to reduce cell lysis.
10:04:56 And so, the last thing that I just want to point
10:05:02 out with respect to defendants' arguments is on slide 68
10:05:08 here, and that's the PerkinElmer Defendants seem to argue
10:05:12 that there's no structural similarity between the claimed
10:05:17 agents and that that renders the Markush group indefinite.
10:05:20 But first of all, there's actually a difference in the law
10:05:24 between what's proper and what's indefinite. And these
10:05:29 Markush groups, the Markush group in the claims are
10:05:33 definite because as we just saw from the testimony from
10:05:35 the defendants' own expert, each of the categories in the
10:05:37 Markush group is bounded, and they all have a common
10:05:42 functionality of inhibiting cell lysis.
10:05:47 But in any event, the Federal Circuit in the
10:05:50 Lexington Luminance case cited here, explained that
10:05:56 whether or not a Markush group is proper is a totally
10:06:00 different inquiry than whether or not it's indefinite.

10:06:03 And the correcting phrase for indefiniteness is -- for the
10:06:07 Markush group is exactly the same as it is in other
10:06:10 contexts. And it's the test that's in Nautilus, whether
10:06:13 the claim, in light of the specification, informs one
10:06:18 skilled in the art with reasonable certainty of the scope
10:06:20 of the invention, and that's exactly what the claim
10:06:25 limitation does for the agent limitation.
10:06:29 And so, that's why, your Honor, we agree with
10:06:33 your construction of plain and ordinary, and we think that
10:06:38 this claim term is completely clear and is not indefinite.
10:06:45 So unless you have further questions.
10:06:48 THE COURT: I don't. The lawyers on the call who
10:06:51 know me may be skeptical when I say this, but I like the
10:06:55 fact that the cases like BASF that you've talked about, I
10:06:59 actually know what they stand for. So it's a -- it's nice
10:07:03 when you all talk about cases.
10:07:04 Let me tell you one of the problems here that
10:07:07 I'll be transparent that the defendants have, and it's
10:07:10 through no fault of their own other than, you know, I have
10:07:14 one defendant who is telling me that the claim term is
10:07:19 indefinite and the other defendant is telling me not only
10:07:24 is it not indefinite, but there is a very specific
10:07:29 construction for it. It's not even plain and ordinary
10:07:31 meaning, it means this, which is, you know, just the way
10:07:36 it is when you have multiple defendants who are taking

10:07:38 inconsistent positions.

10:07:41 But here, you have a situation where, number one, I'm skeptical that it is indefinite for the reasons that counsel argued for PerkinElmer, and I am skeptical that I should limit what this means to EDTA. I'm happy -- I'm free -- I'm pretty comfortable with respect to -- hold on one second. I'm pretty comfortable with respect to it not being indefinite, but I would be happy to hear from Natera counsel if there's any -- I think it's Mr. Hash -- but if there's any basis for limiting it in this manner. I'd be happy to hear a response to that question.

10:08:31 MR. HASH: And, your Honor, this is Steve Hash.

10:08:33 We are not asking you in any way, shape or form to limit this claim. No -- that's what Ravgen's asking you to do. We want the plain and ordinary meaning and this to be broadly read.

10:08:45 Just if I could, you know, to that point, I hope you understand, your Honor, we're not saying that this claim needs to be limited to EDTA. All we're saying is, the plain and ordinary meaning encompasses all molecules that inhibits cell lysis. That Ms. Limbeek talked about this Markush group and the Markush group being an agent that inhibits cell lysis and then, reciting a cell lysis inhibitor, and somehow that the cell lysis inhibitor must mean something different. That's not true.

10:09:15 What you have here is a recursive Markush group,
10:09:18 and the Markush group is representative of a couple of
10:09:21 things that may have an inhibitory effect, membrane
10:09:26 stabilizers and cross-linkers, and then, you have this
10:09:30 catch-all that they've put in to encompass everything that
10:09:32 the cell lysis is under. Ms. Limbeek's representation,
10:09:36 your Honor, that cell lysis inhibitors were well-known in
10:09:38 the art, that's false. That is not true. I am perhaps,
10:09:43 unfortunately, burdened with the fact that I am a person
10:09:45 of ordinary skill in this art. I worked a lot in this
10:09:49 space, and coming into this litigation, I have never heard
10:09:52 of a cell lysis inhibitor before. I know what those words
10:09:54 mean and I understand what a cell lysis inhibitor would
10:09:57 do, but I have never heard to -- a molecule referred to as
10:09:59 a cell lysis inhibitor.
10:10:01 The molecules that they've pointed out, and Dr.
10:10:04 Grody confirmed this, things like formaldehyde are
10:10:06 preservatives and fixatives. Dilantin and other
10:10:11 molecules, they all have functional specifications, but
10:10:14 nobody refers to them as cell lysis inhibitors. And, you
10:10:19 know, we've put that question to Dr. Grody, again and
10:10:23 again and again, and he could point to not a single
10:10:26 example in the art of a molecule referred to as a cell
10:10:31 lysis inhibitor. He said I didn't do that search. But he
10:10:35 couldn't point to a single reference that referred to

10:10:37 anything as a cell lysis inhibitor.

10:10:39 I did that search. I went to Pub Med. I plugged
10:10:42 in cell lysis inhibitor and came up with two compounds
10:10:45 that were actually referred to in the art as cell lysis
10:10:48 inhibitor. And the problem for Ravgen, the problem for
10:10:51 Dr. Grody in that aspect is that those two compounds act
10:10:59 indirectly. They have this definition of indirect and
10:11:02 direct. I don't know what that means. Those aren't terms
10:11:04 of art, direct and indirect effects. But based upon what
10:11:08 they're explaining to be indirect, the only thing that the
10:11:11 art ever calls a cell lysis inhibitor have this indirect
10:11:16 effect.

10:11:17 So what they're saying is, a person of ordinary
10:11:24 skill would understand a cell lysis inhibitor and perhaps
10:11:27 that's true, your Honor, but what a person of ordinary
10:11:29 skill in the art is going to understand a cell lysis
10:11:31 inhibitor to be is something that inhibits cell lysis, and
10:11:34 that's all that we are asking. Understand what the
10:11:37 invention here is, what the goal, the subject matter of
10:11:41 the invention, understand what the goal of the subject
10:11:43 matter of this patent is. This is important.

10:11:44 What they're talking about is --

10:11:47 THE COURT: Mr. Hash, I think what you've just
10:11:49 said is that what your concern is is that a cell -- cell
10:11:59 lysis inhibitor must be able to inhibit the lysis of

10:12:03 cells.

10:12:04 Did I quote you correctly?

10:12:06 MR. HASH: No. The opposite, your Honor.

10:12:07 THE COURT: Okay. Say that line again. I want

10:12:10 to make sure I heard you correctly.

10:12:12 MR. HASH: Let me share my screen with you

10:12:13 because we can pull it straight out of the patent, your

10:12:16 Honor. Can you see --

10:12:20 THE COURT: I'm sorry. Yes, opposite. All

10:12:21 you're saying is, an agent that inhibits cell lysis must

10:12:26 inhibit the -- must inhibit cell lysis. Is that closer to

10:12:30 what you said?

10:12:31 MR. HASH: Exactly, your Honor. And if you look

10:12:33 at example 4 of the patent --

10:12:34 THE COURT: Hold on. That's really pretty easy

10:12:37 English. Let me hear from --

10:12:39 MR. HASH: Yes.

10:12:40 THE COURT: Let me hear from Ms. -- I appreciate

10:12:42 your passion. It's rare I get such passion during a

10:12:45 Markman hearing and it's enjoyable. But let me hear from

10:12:49 Ms. Limbeek as to whether plaintiff disagrees that an

10:12:54 agent that inhibits cell lysis must be able to inhibit

10:12:58 cell lysis.

10:13:03 MS. LIMBEEK: Thank you, your Honor.

10:13:04 Yes. That is one of the requirements of the

10:13:07 claim. Of course, an agent that inhibits lysis must be
10:13:10 able to actually reduce cell lysis. A cell lysis
10:13:14 inhibitor is a more specific category of compounds. So if
10:13:19 I could pull up slide 18, which is example 4, which is the
10:13:24 example that defendants' counsel was discussing, I think
10:13:29 this will clarify a little bit what we're talking about
10:13:32 here.
10:13:33 So in example 4, the patent is discussing plasma
10:13:44 samples that were prepared using EDTA as an anticoagulant
10:13:48 to prevent clotting. That's just by definition, that's
10:13:52 how plasma is prepared. It's by definition is the liquid
10:13:59 portion of blood that has not been allowed to clot. And
10:14:02 what the patent says is, it did this experiment on plasma.
10:14:09 So all of the samples were treated with EDTA, an
10:14:12 anticoagulant to prevent clogging to prepare the plasma,
10:14:17 and then, the patent tested what it describes -- these are
10:14:21 the words from the patent as the absence of inhibitors of
10:14:26 cell lysis, and that's blood samples treated with EDTA,
10:14:29 the anticoagulant, and the presence of inhibitors of cell
10:14:34 lysis. And that's blood samples treated with EDTA plus
10:14:36 formaldehyde. So formaldehyde -- it says formaldehyde is
10:14:39 the cell lysis inhibitor. EDTA is just an anticoagulant
10:14:43 that is used to prepare plasma, and that's the absence of
10:14:48 inhibitors of cell lysis.
10:14:49 And the quote at the bottom of this slide is the

10:14:52 quote that defendants are relying on and that that quote
10:14:56 says in its entirety, in this example, formaldehyde was
10:15:00 used to prevent lysis of cells, however, any agent that
10:15:04 prevents lysis of cells or increases structural integrity
10:15:06 of the cells could be used.
10:15:07 And so, what the defendants are trying to do here
10:15:10 is, they're trying to expand the term "cell lysis
10:15:15 inhibitor" to include anticoagulants that are used to
10:15:21 prevent clotting because under the defendants' theory, by
10:15:24 preventing clotting, clotting can cause physical stress to
10:15:29 cells during -- as a side effect of that process and,
10:15:32 therefore, can cause cell lysis.
10:15:34 And so, defendants are arguing here that that
10:15:37 means that any anticoagulant that prevents clotting is
10:15:42 necessarily a cell lysis inhibitor. And what we're saying
10:15:44 is that the intrinsic record makes very clear that that is
10:15:49 a completely separate category of compounds. They are not
10:15:53 cell lysis inhibitors. Whether or not an anticoagulant --
10:15:57 the use of an anticoagulant to prevent clotting may reduce
10:16:01 cell lysis doesn't make it a cell lysis inhibitor.
10:16:03 THE COURT: I've got you now. If you all will
10:16:05 hold on just for a second.
10:19:43 Here's what I'm going to do. I understand the
10:19:44 fight here now. And I think this is something at least at
10:19:50 the moment -- and maybe I'll change my mind at the summary

10:19:54 judgment stage. But I think right now is not the time to
10:20:00 fight over whether or not an agent that inhibits cell
10:20:09 lysis would or would not include something like
10:20:11 anticoagulant.
10:20:12 I think there will be a fight over what people
10:20:16 skilled in the art at the time would have believed. And I
10:20:18 think at least for now, I'm convinced that that is a issue
10:20:23 for the jury to decide and they could hear competitive --
10:20:28 competing arguments from the experts to help make that
10:20:31 decision.
10:20:32 That being said, when the experts actually put
10:20:36 pen to paper and have the expert reports, if one side or
10:20:40 both sides think that it should be decided as a matter of
10:20:45 law, you all are free to file summary judgment motions,
10:20:48 and I will take it up then. But I do -- I understand the
10:20:51 issue. At the moment, I'm persuaded that's something that
10:20:55 the jury can resolve, and I will not adopt either of the
10:20:59 constructions that the parties have proffered. I'll stick
10:21:03 with plain and ordinary meaning. And the experts will be
10:21:06 able to opine on what they think that is, whether or not
10:21:10 it includes anticoagulants like EDTA or not.
10:21:14 The next claim term is if --
10:21:18 MR. PARK: Your Honor, I apologize. May I be
10:21:22 briefly heard on the BASF case and some of the other cases
10:21:27 that counsel discussed?

10:21:29 THE COURT: I'm good. Thank you.

10:21:31 Next claim term is "if cells are present." Let me start with the plaintiff. Who will be speaking on behalf of plaintiff?

10:21:45 MS. LIMBEEK: I will, your Honor. Kerri-Ann Limbeek on behalf of the plaintiff.

10:21:51 THE COURT: And what is the -- I'm sorry. What is the plaintiff's position with regard to if cells are present?

10:21:56 MS. LIMBEEK: Your Honor, we agree with the Court's preliminary construction in this regard that if cells are present conditions, the functionality of the agent inhibits lysis of cells, impedes cell lysis, et cetera.

10:22:14 THE COURT: Who will be arguing on behalf of the defendant? And from now on, if it's more than one person, if whoever goes first will let me know if there's a second person. Mr. Hash, I'll plan on your folks going first for defendants and if you will -- when you finish or your team finishes, if you'll let me know if the other defendant wants to argue, I'll be happy to hear from them, as well.

10:22:36 So, Mr. Hash, who will argue the claim term "if cells are present"?

10:22:41 MR. HASH: Thank you, your Honor. Ms. Flannery will be handling this term.

10:22:44 MS. FLANNERY: Good morning, your Honor.
10:22:48 So I will share my screen.
10:22:54 THE COURT: Ms. Flannery, I don't think I've had
10:22:57 you in my court either. Welcome. It's a pleasure to have
10:22:59 you.
10:22:59 MS. FLANNERY: Yes. That's correct. I don't
10:23:01 think I've been in your court. It's a pleasure to be
10:23:03 here.
10:23:04 All right. Can you see that, your Honor? Your
10:23:17 Honor, are you able to see my screen?
10:23:19 THE COURT: Yes, ma'am.
10:23:20 MS. FLANNERY: Okay. Great.
10:23:22 So I think, your Honor, given the Court's
10:23:25 tentative, I think the main purpose of my argument really
10:23:28 is to point out that, indeed, we do disagree. I think
10:23:30 this argument is a little bit differently situated from
10:23:33 the ones that you've heard so far this morning in that the
10:23:36 Court's tentative doesn't seem to be adopting plain and
10:23:39 ordinary meaning. It does seem to be adopting the
10:23:42 plaintiff's proposed construction, which is that if cells
10:23:45 are present, conditions -- the statements about inhibiting
10:23:49 cell lysis as opposed to the presence of the agent that
10:23:52 inhibits the lysis of cells.
10:23:54 And we think that's wrong for a couple of reasons
10:23:57 that I want to briefly highlight. So the plaintiff's main

10:24:01 position for their -- reason for their position was that
10:24:04 somehow, if cells are present needed to clarify ambiguity
10:24:08 about whether or not the agent would actually act to
10:24:11 inhibit the lysis of cells if they were not present. But
10:24:17 your Honor, we would submit that there really is no
10:24:18 ambiguity in the claim language as written. It's very
10:24:22 clear that it talks about the sample comprising an agent
10:24:26 that inhibits the lysis of cells.
10:24:28 And the statement that inhibits the lysis of
10:24:32 cells, as I think was argued with regard to that agent
10:24:34 term just a second ago, is simply a statement of the
10:24:38 capability. And I don't think there seems to be -- there
10:24:40 doesn't seem to be a dispute over the fact that it is
10:24:43 simply stating what the agent is capable of doing.
10:24:45 And notably in this claim, at least as written,
10:24:48 there is no specific statement that -- there are no
10:24:53 affirmative step of the agent actually inhibiting cell
10:24:57 lysis. We would know how to write a claim like that. It
10:24:59 would say, for example, you have an active step of saying
10:25:03 isolating free fetal nucleic acid, if inhibiting cell
10:25:06 lysis was truly an active step that needed to be done in
10:25:10 this claim as written, it would state, inhibiting cell
10:25:12 lysis as an active step; but the claim as written doesn't.
10:25:15 The primary problem we have with Ravgen's
10:25:19 position in the tentative construction is that it seeks to

10:25:22 write that in. I'll go back one slide. If we take what
10:25:27 Ravgen's position, reason for its construction is true, if
10:25:31 the reason if cells are present is in the claim is to
10:25:36 establish that if cells aren't present, then that action
10:25:39 isn't needed, then the converse must be true. If cells
10:25:42 are present, then, indeed, there must be an active step of
10:25:46 the cells actually inhibiting cell lysis.
10:25:48 But the claims don't actually say that. They
10:25:51 never do. And so, by adopting the Court's -- by adopting
10:25:53 that tentative construction, one of the problems we see,
10:25:56 your Honor, is that that is writing into the claim an
10:25:59 active step of inhibiting cell lysis, and we just don't
10:26:02 think that's there. And in fact, one of the other big
10:26:05 problems of doing that is that we think that that would
10:26:07 write out one of the claimed -- one of the claim narrower
10:26:11 embodiments, claim 92 of the 277 patent.
10:26:15 I don't have a slide for that, but I can -- if
10:26:21 I'm good enough, I can bring it up. Can you see claim 92
10:26:25 there, your Honor?
10:26:29 THE COURT: (Moving head up and down.)
10:26:30 MS. FLANNERY: Okay. So claim 92 recites that
10:26:33 formalin, which is one of the agents -- undisputed, one of
10:26:35 the agents that inhibits cell lysis, is present in an
10:26:38 amount, the final concentration of formalin is as low as
10:26:41 .0001 percent. So it's present in this minuscule amount.

10:26:47 When we asked Dr. Grody about that amount in his
10:26:51 deposition -- and I'm going to switch my screen share
10:26:54 again. Bear with me. When we asked Dr. Grody about this
10:27:02 at his deposition, we asked him, can something that has a
10:27:06 .001 percent ability of preserving the structural
10:27:10 integrity, would that be a cell lysis inhibitor? He kind
10:27:12 of danced around a little bit, but ultimately he said no.
10:27:15 You wouldn't actually get that effect.
10:27:16 So this crystallizes the problem that we have
10:27:20 with the plaintiff's construction is that it seems to be
10:27:23 reading in a statement that something inhibits cell lysis.
10:27:26 If that's the meaning, we'll go forward with that. But we
10:27:28 think that's contrary to the claim's plain meaning, and
10:27:31 it's contrary to what the dependent claims talk about
10:27:33 because they don't. They don't require that. But if
10:27:37 that's your Honor's construction, then that's what we'll
10:27:39 go with.
10:27:41 The other problem that we have -- I'm sorry. Go
10:27:44 ahead.
10:27:44 THE COURT: I'm not sure what you mean by if
10:27:47 that's the Court's -- if you were saying if I'm adopting
10:27:50 what the expert said. My construction is my construction
10:27:57 and it's really independent in large part because of total
10:28:02 ignorance of whatever was said at a deposition, which may
10:28:08 or may not be -- this person may not even be an expert at

trial.

And so, I would caution you. I'm not sure what you meant by if that's what I mean by tethering it to what a third party said that my -- and I'm not criticizing you. I just want to put on the record, you made sort of a hypothetical question, and the answer is, no to the extent if you were saying that I'm adopting or saying that whatever that person said at a deposition is correct or incorrect. I'm not -- I'm expressing no opinion on that. My construction is my construction.

MS. FLANNERY: Oh, and I certainly -- and I apologize for the lack of clarity. I appreciate you pointing that out so that I know --

THE COURT: No need to apologize. You know, I just want you guys to know I'm listening. So.

MS. FLANNERY: No, no. And I appreciate that.

The only point there that I was trying to make is, if your Honor adopts the tentative construction which is to say that if cells are present modifies whether or not the agent actually inhibits cell lysis, whether or not it actually performs that function, then the only understanding we can apply there is that the claim itself actually requires that if cells are present, then the agent will, indeed, perform the active step of inhibiting cell lysis.

10:29:30 And maybe that's -- and I don't know if plaintiff
10:29:33 disputes that or not, but that's logical understanding of
10:29:36 what their proposal would mean. And we just think it's
10:29:41 incorrect at the claim construction stage because it would
10:29:43 read in that affirmative statement that wasn't written in.
10:29:46 Does that make sense?
10:29:46 THE COURT: It makes total sense. But again,
10:29:49 what I'm -- what I anticipate will happen is that the
10:29:52 plaintiff will have an expert who will say the if cells
10:29:56 are present portion of the entire claim term is met and
10:30:01 then, explain why, and you will have -- doesn't meet my
10:30:05 construction or not. If you disagree after you get the
10:30:09 plaintiff's infringement report and you depose him that he
10:30:15 is, in fact, complying with my claim construction, that's
10:30:19 for down the road.
10:30:20 I appreciate what you're saying and you give it
10:30:24 -- what I don't know here is whether or not someone else
10:30:26 on defense side wants to say anything. If they do, if
10:30:31 they'll just hold that. And if I can hear from
10:30:34 plaintiff's counsel, just go ahead and go on the record
10:30:36 and say anything in response to that. But I'm pretty
10:30:39 comfortable with my claim -- with the proposed claim
10:30:43 construction, but happy to hear from plaintiff, and then,
10:30:47 I'll come back to the other defense counsel if there's
10:30:48 anything they'd like to add.

10:30:53 MS. LIMBEEK: Thank you, your Honor. Kerri-Ann
10:30:55 Limbeek on behalf of plaintiff.
10:30:57 If we could just take a quick look at slide 71.
10:31:01 And I'll be brief because I think, your Honor, the
10:31:04 preliminary construction that you provided got it exactly
10:31:08 right. And this is just to show in context of claim 55
10:31:14 exactly what this -- how this phrase comes up.
10:31:18 And as you can see from the plain language, the
10:31:22 if cells are present is a clause right after inhibits
10:31:25 lysis of cells, which is a function of the agent in the
10:31:28 claim term, and what defendants are arguing here is that
10:31:35 if cells are present actually conditions and whether or
10:31:40 not the agent needs to be included at all. And so,
10:31:42 really, if you look at the claim language, which is what
10:31:45 they're arguing, is that if cells are present modifies
10:31:49 whether or not the sample comprises an agent.
10:31:51 And in the plain language of the claim, the
10:31:56 sample comprises two things. First, free fetal DNA and
10:32:00 second, this agent that inhibits cell lysis and so that.
10:32:06 So that reading really makes no sense because, of course,
10:32:08 the sample needs to comprise free fetal DNA. It's a
10:32:12 method for determining the sequence of a locus of interest
10:32:16 on free fetal DNA, and that's not dependent on whether or
10:32:18 not cells are present.
10:32:18 And so, as your Honor recognizes the claim

10:32:24 construction, the if cells are present merely conditions
10:32:29 the phrase right before it, the function of the agent,
10:32:32 which is that it inhibits lysis of cells. It can only do
10:32:36 that if cells are actually present. If there are no cells
10:32:38 present, then the agent obviously cannot inhibit lysis of
10:32:42 those cells. And there's just no test to determine,
10:32:44 whether or not cells are present before, you know, knowing
10:32:49 whether or not the agent is actually required by the
10:32:52 claim.
10:32:54 And unless your Honor has any questions, that's
10:32:57 -- I think that's all.
10:32:58 THE COURT: I don't.
10:32:59 Anything else? And, Ms. Flannery, I interrupted
10:33:02 you, which I'm doing more and more of now because I do
10:33:04 better if I hear back and forth. Ms. Flannery, so is
10:33:09 there anything else that you wanted to say?
10:33:10 MS. FLANNERY: Just one brief point, your Honor.
10:33:12 And I don't mind the interruption. I appreciate it. I
10:33:15 welcome it.
10:33:15 The only thing I want to say is in direct
10:33:17 response to what Ms. Limbeek just said is that somehow, of
10:33:22 course, the claim is agnostic as to whether there are
10:33:28 cells present or not that somehow, that claim is saying
10:33:32 that the agent is there, no matter what. That's simply
10:33:36 not correct because we would know how to write that claim.

10:33:40 If the claim was intended to read that the sample comprise
10:33:45 the agent, irrespective of whether there were cells or
10:33:48 not, this is how it would be written. It would simply
10:33:51 state as a claim -- as a typical claim says that the
10:33:54 sample comprises the agent that inhibits cell lysis. Full
10:33:57 stop.
10:33:58 Of course, you know, the Markush would follow and
10:34:01 we've tried to lay that out, but you wouldn't have this
10:34:04 qualifier that says that. So this notion that their claim
10:34:07 as written is agnostic that the sample comprises the
10:34:09 agent, regardless of whether cells are present, reads out
10:34:13 that limitation. That is the problem with their
10:34:15 interpretation because they require reading this out, not
10:34:19 giving it meaning. That's the only point I wanted to
10:34:23 make, your Honor.
10:34:26 THE COURT: I'm sorry. I was on mute.
10:34:30 Is there anything any other defense counsel would
10:34:33 like to add before I make my decision?
10:34:39 MR. PARK: This is Sean Park for PerkinElmer.
10:34:42 PerkinElmer does not have a position on that term, your
10:34:44 Honor.
10:34:44 THE COURT: Okay. I'll be back in a few seconds.
10:36:36 Let's go back on the record. Counsel, long day.
10:36:39 The Court is going to go with the preliminary claim
10:36:42 construction and make it its final construction.

10:36:45 And I also feel compelled. One of the counsel
10:36:49 asked if he could say something additionally, and I didn't
10:36:53 let him. I usually do, but here, I just want to put on
10:36:57 the record, I'm pretty familiar with those cases already.
10:37:01 And also, we have just a lot of claim terms, I'm trying to
10:37:06 get through here, and I think the time is better spent.
10:37:08 So I didn't mean to sound impolite. If we get to
10:37:12 the end and we have time, and you feel like there's
10:37:16 something you could add to the Court that would help me,
10:37:19 I'll be happy to give you back that time. But let's move
10:37:21 on to "free fetal DNA isolated" and a couple of other
10:37:27 terms.
10:37:29 I'm assuming the plaintiff is okay with the
10:37:33 Court's construction because it's plain and ordinary
10:37:36 meaning as they suggested. So I'm happy to hear from
10:37:38 defense counsel with respect to this claim term.
10:37:44 MR. HASH: Thank you, your Honor. Steve Hash on
10:37:46 behalf of Natera. If you'll just indulge me briefly, your
10:37:50 Honor.
10:37:50 I did want to just briefly talk about what the
10:37:56 invention here is really about. I know you've seen the
10:37:59 technical tutorial, but I think just five minutes more.
10:38:02 Understand cell free DNA is DNA that is outside of a cell
10:38:07 circulating in the blood of an organism. There are
10:38:10 typically the lion's share of the DNA is found within

10:38:14 cells, but because in your body, cells are dying, cells
10:38:18 are lysing, just as a normal process of their cell life,
10:38:24 when they do that, they dump their contents into the
10:38:27 bloodstream, and that results in, among other things being
10:38:29 there, this cell -- what's called cell free DNA. DNA that
10:38:35 is not associated with the cell.
10:38:35 Cell free DNA has been known for decades. Back
10:38:40 into the '30s or '40s, people have detected the presence
10:38:43 of free DNA in blood. And, you know, when you think about
10:38:47 it, as we sit here, we all have free DNA circulating in
10:38:51 our blood. And unless you have some sort of blood-born
10:38:57 pathogen or sepsis, presumably 99.9, if not 100 percent,
10:39:03 of that cell free DNA is going to be your DNA. It is
10:39:06 going to be the DNA of the organism whose blood it is
10:39:09 because it is their cells that are being lysed and their
10:39:12 cells that are being contacted with the blood.
10:39:15 Now, the one situation where that is slightly
10:39:17 different is in a pregnant female, and in that situation,
10:39:24 you know, there is the presence of another organism within
10:39:27 the individual, that fetus. And to a limited extent,
10:39:33 there's a limited amount of contact between the fetus and
10:39:38 the mother through -- across the amniotic sac and across
10:39:42 the placenta. And so, some limited amount of fetal cells
10:39:48 and fetal DNA may leak into the blood, right? But it's a
10:39:52 very small amount.

10:39:53 Typically -- and this is from the patent and what
10:39:56 folks have found is, about between one and 10 percent of a
10:40:01 mother's cell free DNA can be fetal, right? So in the
10:40:09 body, any pregnant female, the max that you're going to
10:40:14 see is 10 percent, maybe up to 20 percent, but that's
10:40:18 about the -- and that's not at all surprising or expected
10:40:22 because what we're talking about is a mother here and her
10:40:25 blood and her cells primarily with some amount of leakage
10:40:31 into that of fetal DNA.
10:40:33 So what essentially the invention here that we're
10:40:37 talking about in these claims and what this isolation term
10:40:41 relates to is the introduction -- so when the blood is
10:40:48 removed from the mother because the fetal DNA is there and
10:40:50 things can be determined from that fetal DNA about the
10:40:54 health of the fetus, but what this -- the subject matter
10:40:59 of this patent talks about is essentially adding a
10:41:03 preservative to that blood to reduce the lysis of the
10:41:10 maternal cells.
10:41:10 Now, as you understand, we're saying that could
10:41:12 be any number of preservatives that as long as they
10:41:17 inhibit cell lysis. But what the goal of the person of
10:41:19 ordinary skill there is to have as much fetal DNA in there
10:41:24 and not dilute that with the lysis of maternal cells
10:41:29 through coagulation or other process. So that's the goal
10:41:34 and that's achieved by including the preservative.

10:41:36 Your Honor, preservatives are well-known in the
10:41:40 art. As you know, I think you understand, I live out in
10:41:43 the country. We've got blackberry bushes all over the
10:41:49 place, and around about April, my kids are going to go out
10:41:54 with a five-gallon bucket and collect about five gallons
10:41:57 worth of blackberries. They'll eat probably a handful and
10:42:03 then, we'll be stuck with five gallons of blackberries,
10:42:06 which my wife will then take and boil down and put some
10:42:10 pectin in to preserve them and make preserves.
10:42:11 Adding a preservative to preserve a sample is old
10:42:17 as time itself. They've been salting meat, adding,
10:42:21 preservatives, formaldehyde, that is well-known. And
10:42:22 frankly, when this patent came to the patent office, the
10:42:44 patent office saw and said essentially what you're saying
10:42:47 is, you're adding a preservative to this sample. That's
10:42:51 not novel and not obvious. That's probably the most
10:42:54 obvious thing I've ever heard.
10:42:56 So what the patentee did was, they came back and
10:42:59 they say said no, no, no, no, no. When we're adding
10:43:02 formaldehyde, a simple organic compound, carbon and oxygen
10:43:07 and two hydrogens, to this sample, we're getting a
10:43:12 surprising and unexpected amount of fetal DNA. We are
10:43:19 significantly and unexpectedly increasing the portion of
10:43:22 fetal versus maternal DNA.
10:43:25 What the patentee is saying there is, it's not

10:43:27 just the 10 percent DNA that you would see in plasma.
10:43:32 We're actually increasing that. It is surprising. It is
10:43:37 unexpected that that would occur. Frankly, it's
10:43:42 inexplicable and, frankly, irreproducible. What the
10:43:46 patentee is saying -- we're not just talking about a
10:43:51 preservative here. We're talking about something that
10:43:54 increases the amount of fetal DNA. And what you have that
10:44:01 the patentee points to is the examples in the patent.
10:44:04 Now, the patent acknowledges, as I just said, you
10:44:08 know, one to 12 to 20 percent fetal DNA is the most you're
10:44:13 going to see in plasma. Again, we're talking about the
10:44:15 mother. The mother's DNA is going to be 80 to 90 percent
10:44:19 because that's just what the organism is. The most you're
10:44:22 going to see in circulating blood is 10 to 20 percent.
10:44:24 Lok, your Honor, they're claiming and they're
10:44:27 pointing the patent office to the fact that they are
10:44:31 isolating 25, 50, 100 percent fetal DNA. So what the
10:44:41 inventor is saying is surprising, unexpected, frankly
10:44:45 again, inconceivable and irreproducible, is that we -- by
10:44:50 the simple addition of a preservative formalin, we are
10:44:56 increasing the amount of fetal DNA substantially above --
10:44:59 almost an order of magnitude above the natural amount of
10:45:05 fetal DNA that's present.
10:45:08 And all we're asking, your Honor, is that somehow
10:45:10 be reflected in the claim construction. They're saying

this is surprising, this is what the invention is, and that has to be -- and that's how they've garnered allowance from the patent office, and that somehow has to be reflected in the claim constructions. So be it through maintaining or increasing, but there must be something reflected in the construction that what the invention is capable of is increasing the proportion of fetal DNA of maternal because that's what they told the patent office was the surprising, unexpected result of their invention.

Everybody knows to put preservatives in stuff. What they're saying is, that's not what we're doing here. We're achieving this result and that has to be reflected there the claims.

THE COURT: The problem we have on Zoom, Mr. Hash, is I'm not sure if you're done unless you let me know that you're done.

MR. HASH: Oh, I'm sorry. Yes. If you any questions, please. As you know, I like talking about the technology, so any questions you have about the technology, please don't hesitate.

THE COURT: So you all suffer from the fact that I actually had some cases in this area. Unlike the cases I had with Mr. Desmarais, I actually won some of these. So I'm enjoying this, as well, Mr. Hash. I enjoy this discussion. I got to represent a very wonderful M.D.,

10:46:52 Ph.D., so we talked a lot about this type of stuff, too.
10:46:55 Was there anything else that the other defendant
10:47:00 wanted to say anything before I move to the plaintiff?
10:47:05 MR. PARK: Not on this term, your Honor. Thank
10:47:06 you.
10:47:07 THE COURT: Counsel for plaintiff?
10:47:11 MR. PETRIE: Your Honor, Kyle Petrie on behalf of
10:47:14 Ravgen.
10:47:15 So what counsel's asking you to do today, your
10:47:16 Honor, is to construe isolating such that it increases the
10:47:20 proportion of free fetal DNA versus maternal DNA. And I
10:47:25 want to start out by first addressing one of the points
10:47:29 Mr. Hash just made is that previously in the art, you were
10:47:32 only able to recover about one to 10 percent of fetal DNA
10:47:36 from a sample, and it's very clear why that is.
10:47:38 It's because when you were doing those
10:47:40 measurements, they were not adding agents that inhibit
10:47:43 cell lysis, which is what the patentee represented to the
10:47:47 patent office was the inventive unexpected aspect of these
10:47:51 claims. And if we could pull up slide 90 from plaintiff's
10:47:56 motion slide, please. I just want to show your Honor
10:47:59 exactly where in the patent they make this very clear.
10:48:02 It's underlined in red there.
10:48:04 The patentee is saying the addition of cell lysis
10:48:07 inhibitors, cell membrane stabilizers, or cross-linkers to

10:48:12 maternal blood can increase the relative percentage of
10:48:15 fetal DNA. So it is the fact that you're adding this
10:48:19 agent that when previously you weren't adding, you were
10:48:21 not able to see as much of this fetal DNA because it was
10:48:26 all getting diluted by the maternal samples. So that's
10:48:29 what we're seeing here.
10:48:30 I just want to make very clear for your Honor,
10:48:32 too, again, they're asking you to construe the term
10:48:35 "isolating." Nothing about the term "isolating" is -- the
10:48:41 patent doesn't provide any crazy new novel way of
10:48:45 separating fetal DNA from maternal DNA. What they're
10:48:49 doing, your Honor, is adding an agent that when you use
10:48:54 the standard isolating techniques, you're going to end up
10:48:56 with a higher proportion of fetal DNA relative to what you
10:48:59 would have found without that agent.
10:49:01 And so, we go ahead to slide 94, please, I'd like
10:49:06 to go through example 4 from the patent. Again, this is
10:49:09 the example that the patentee pointed to during
10:49:12 prosecution that this is the unexpected result we're
10:49:16 seeing, look at example 4. They're using -- example 4
10:49:20 from the patent explicitly says DNA was isolated using the
10:49:24 Qiagen Midi kit. And what that is, your Honor, is a
10:49:28 standard isolating kit that removes fetal and maternal DNA
10:49:33 from plasma so that it can later be studied. And this is
10:49:36 the exact example that the patent pointed to during

10:49:40 prosecution to say this is the unexpected result we're
10:49:43 getting.
10:49:43 So for the defendant to turn around and say
10:49:46 isolating has to mean we're increasing the proportion of
10:49:49 fetal to maternal DNA, it's just not consistent with
10:49:52 what's in the patent or with what the patentee actually
10:49:54 said to the patent office. And then, if there's anything
10:50:01 else, your Honor, I think that's the main point that I was
10:50:03 looking to address based on what Mr. Hash presented there.
10:50:07 THE COURT: Mr. Hash, any response?
10:50:10 MR. HASH: Yes, your Honor.
10:50:12 It seems we're in agreement. Mr. Petrie is
10:50:16 saying that the invention is actually allowing for the
10:50:21 isolation of more than the endogenous amount of DNA.
10:50:27 Ravgen reports the endogenous amount of DNA and, you know,
10:50:31 says it's 11 percent, and then, they're reporting to the
10:50:35 patent office and saying surprising unexpected result,
10:50:38 it's a hundred percent. So that's what he's referring to.
10:50:43 And if I can share the screen again, your Honor,
10:50:48 again, we seem to be agreeing as to what the invention is,
10:50:52 which is, it is achieving a hundred percent DNA isolation
10:51:00 by the addition of the agent. Now, they point to this --
10:51:03 because that's what the claim calls for, your Honor. It's
10:51:06 free fetal DNA isolated. So what they're saying the
10:51:11 invention is, what Mr. Petrie just said is by the addition

10:51:14 of this, we're substantially increasing the amount of free
10:51:20 fetal DNA isolated. Something about -- something magical
10:51:23 about formaldehyde allows for the isolation of DNA beyond
10:51:29 what's occurring within the mother.
10:51:32 Somehow you're either removing maternal DNA or
10:51:36 you're destroying it, or whatever. But to achieve a
10:51:40 hundred percent fetal DNA from the mother, which is what
10:51:44 Mr. Petrie just said was surprising and unexpected, can
10:51:47 only occur if you're somehow increasing the portion of
10:51:51 fetal DNA. That's what they carried to the patent office,
10:51:54 and all that we're asking, your Honor, is that somehow be
10:51:57 reflected in the claim. It need not be in the
10:51:59 construction that we're proposing.
10:52:00 But if you're going to the patent office saying
10:52:02 this is what my invention is, that's how it's different
10:52:04 from just adding the preservative that anybody knows to
10:52:08 add, then you have to own up to that and bind to it, and
10:52:12 Mr. Petrie seems to do that. He goes, yeah, the invention
10:52:15 is great because this is what we're isolating, 50, 100
10:52:18 percent DNA. Just reflect that in the claims.
10:52:23 Do you have any questions, your Honor?
10:52:25 THE COURT: I don't.
10:52:26 Mr. Petrie.
10:52:28 MR. PETRIE: Yeah. Just a few brief points,
10:52:31 though, your Honor.

10:52:31 I don't think that the patentee said to the
10:52:35 patent office that he's increasing the amount of fetal DNA
10:52:38 that exists in a person. That's just not possible. What
10:52:42 is in a mother while she's carrying a baby with an amount
10:52:47 of fetal DNA in there, that's going to be a fairly
10:52:50 constant number throughout the different periods of
10:52:53 gestation. But what is happening is, we're preventing
10:52:57 maternal cell lysis through the addition of the agent that
10:53:02 stops that dilution so that when you do use these standard
10:53:06 isolating techniques as disclosed in the patent, you're
10:53:09 going to see a higher percentage than you would have seen
10:53:12 without using any agent at all.
10:53:13 And counter to what Mr. Hash was just saying,
10:53:17 it's the isolating technique -- they're using standard
10:53:23 isolating techniques that don't possibly isolate, that
10:53:26 cannot separate maternal from fetal. They're being
10:53:29 isolated at the same time. So the isolation step can't
10:53:32 possibly increase the amount of recoverable fetal DNA in
10:53:40 this case.
10:53:42 THE COURT: I'll be back in a few seconds.
10:55:25 If we can go back on the record. The Court
10:55:28 agrees with the plaintiff's argument that I don't believe
10:55:32 that the proffered construction offered by the defendant
10:55:36 for free fetal DNA isolated and the other claim
10:55:42 constructions that include the word or some form of the

10:55:44 word "isolating," I don't believe the proffered
10:55:49 construction's correct. The Court's going to maintain its
10:55:52 construction of plain and ordinary meaning.
10:55:53 The next claim term we'll take up is "determining
10:55:59 sequence of a locus interest." Because I had proffered a
10:56:06 preliminary claim construction of plain and ordinary
10:56:08 meaning, I will start with the defendants' proposed
10:56:12 construction.
10:56:17 MR. PARK: Thank you, your Honor.
10:56:20 So we understand the Court chose the plain and
10:56:26 ordinary meaning, but we wanted to understand exactly the
10:56:29 scope of that term because the parties agree the patentee
10:56:42 defined the word --
10:56:43 THE COURT: Let me interrupt you here, too, just,
10:56:46 again, in an effort to be transparent because, for better
10:56:50 or worse, you all are stuck with me in this case. When I
10:56:55 get a proposal from someone, I see -- I hear two reasons
10:57:01 at least for Markman constructions. One is, it may aid
10:57:04 the jury to know something if I construe it and they can
10:57:09 understand it better. The other is the one I think you're
10:57:13 more identifying here is to put some kind of brackets
10:57:17 around it.
10:57:18 But I will tell you, I'm always skeptical when I
10:57:24 take a -- you take a phrase that is eight words, seven
10:57:29 words, "determining the sequence of a locus of interest,"

10:57:33 and turn it into something that is eight, or nine, or 10
10:57:38 lines long, which in my opinion, would make it even more
10:57:43 difficult for the jury to understand this language, not --
10:57:48 your proposed construction, I'm just saying, is more
10:57:51 difficult to understand than the claim term itself, which
10:57:56 I just -- I'm putting on the record and so you know and
10:57:59 your clients are attending, or at least client
10:58:01 representatives. That is always a difficult thing for me
10:58:04 to accept.
10:58:05 Now, I'm looking forward to hearing your argument
10:58:08 as to why I need to construe what determining the sequence
10:58:12 of a locus of interest is because a POSITA would not be
10:58:17 able to do that. Your experts wouldn't be able to do that
10:58:20 without your construction. But I'll put on the record
10:58:22 that it is very difficult for me to go with claim
10:58:27 constructions that are more difficult to understand just
10:58:33 for the purpose of limiting what words like "determining
10:58:37 the sequence of a locus of interest" mean.
10:58:42 MR. PARK: Understood, your Honor. Thank you.
10:58:45 I think here, it's a somewhat unique situation
10:58:50 because the patent provides a specific definition for --
10:58:56 at least parts of the term. They defined the word
10:59:01 "sequence," they defined the words "locus of interest."
10:59:04 We have the excerpts from the patents here, and both
10:59:07 parties agree that lexicography is there. And Ravgen says

10:59:12 that's consistent with the plain and ordinary meaning and
10:59:15 we agree with that.
10:59:17 So one, we wanted to understand that, you know,
10:59:21 these expressly defined meanings of the terms is included
10:59:29 in the plain and ordinary meaning that the Court is
10:59:32 adopting.
10:59:33 THE COURT: And let me stop you there. Unless
10:59:35 plaintiff has some objection -- to the extent, for
10:59:41 example, you said the parties agreed, I'm assuming you
10:59:45 accurately state what the other side does, if in the
10:59:49 patent, it says by a locus of interest intended, that is
10:59:55 going to be the plain and ordinary meaning of that portion
10:59:56 of the claim term. That's what locus -- if to get it
11:00:00 allowed, the plaintiff said this is what we mean by locus
11:00:03 of interest, then that's what it's going to mean. If
11:00:09 that's helpful.
11:00:10 MR. PARK: Thank you, your Honor. Yes. Thank
11:00:12 you, your Honor.
11:00:13 And so, the only remaining issue that is
11:00:18 PerkinElmer's election of the word "ascertain" for the
11:00:20 proposed definition. So it doesn't increase the number of
11:00:23 the words other than the express definitions provided by
11:00:26 the patentee. It just clarifies what the patentee meant
11:00:30 by determine because, as we saw in the previous slide, the
11:00:36 definition and, also, so the plain and ordinary --

11:00:40 THE COURT: Counsel.

11:00:41 MR. PARK: Yes, your Honor.

11:00:42 THE COURT: I don't want you leaving here feeling like I'm just picking on you because I don't think we've ever even met. So I'm really not. However, I think, again, I like to put on the record the way my philosophy of Markmans, I almost never take a word that the lexicographer or the -- whoever drafted this for the inventor used the word "determined," and you want me to take a dictionary and switch it and use the word "ascertain." I almost never do that. I mean, I never -- a jury of seven folks understands what the word "determining" means. They don't need me to tell -- they don't need me to tell them that determining means ascertain.

11:01:29 And so -- and I also -- I'm saying all of this on the record because hopefully people are watch in, and it will help them understand better how I do Markmans. And also, I very much hope to have all of you in a hundred more cases. I love having great lawyers involved. Mr. Hash's enthusiasm is a great way to start off any Tuesday morning.

11:01:53 But you're not going to get very far with me by asking me to swap out "determining" for "ascertain."

11:02:01 MR. PARK: Yes. Thank you, your Honor. We just

11:02:03 wanted to point out that the ordinary meaning of determine
11:02:06 is to ascertain. So that's --
11:02:08 THE COURT: Well, then, why do we need it? If
11:02:12 the ordinary word -- if the ordinary meaning of
11:02:15 determining is ascertaining, why can't we just leave
11:02:19 determining and assume the jury will understand what that
11:02:22 means? If that's what it means in this context, then I
11:02:27 don't need to tell them what determining is. Why would I
11:02:30 switch this word out? I would think more importantly for
11:02:34 you, if the jury couldn't understand what determining
11:02:38 meant, then we might need to help them. But here, I can't
11:02:42 imagine they don't know what determining means.
11:02:47 MR. PARK: Understood, your Honor --
11:02:49 THE COURT: But I'm -- I'm sorry. But I just --
11:02:50 you know, that's not a persuasive argument for me.
11:02:58 MR. PARK: Understood, your Honor.
11:03:00 THE COURT: Is there anything else you wanted to
11:03:01 argue with regard to this term?
11:03:04 MR. PARK: Not on this term, your Honor.
11:03:07 THE COURT: The Court is going to take the
11:03:12 preliminary construction of plain and ordinary meaning and
11:03:15 make it its final construction.
11:03:18 I'll move on to the word "formalin," and since
11:03:22 both sides have proposed a construction, I will start with
11:03:27 the plaintiff, and I'll ask the plaintiff if they would

like to argue for their proposed construction or whether they are satisfied with the Court's construction of plain and ordinary meaning.

MS. LIMBEEK: Thank you, your Honor. Kerri-Ann Limbeek on behalf of the plaintiff.

Your Honor, we're satisfied with the Court's preliminary construction of plain and ordinary meaning.

THE COURT: Okay. Counsel for defendant.

MR. PARK: Yes, your Honor. Well, we do agree it is the plain and ordinary meaning, but again, we're not sure which of the proposed constructions describes that meaning. So if you don't mind, I will share my screen.

THE COURT: Let me try this. Is it not an aqueous or an aqueous solution of formaldehyde? Are you saying formalin is not that?

MR. PARK: It's a little more than that in that there's a specific --

THE COURT: No. I'm sorry. So your position is that formalin is not -- that they are incorrect. Because here's the way I see it. I think you're both right. I think it is -- it could be an aqueous solution of formaldehyde. It could be a stock solution of formaldehyde usually at 37 percent weight of volume. I'm just saying I didn't see anything in this patent or in the specification, and my clerk who has a background in this

11:04:54 field of technology, neither of us saw anything that
11:04:58 requires me to give a construction for formalin that it is
11:05:04 either of your constructions.
11:05:11 MR. PARK: Your Honor, it is correct that the
11:05:14 patent themselves do not spell out what formalin is, but
11:05:19 that's just because the common understanding of formalin
11:05:23 does include a reference point for the percentage. And if
11:05:30 you don't mind, I will share the screen just to
11:05:33 demonstrate the point.
11:05:36 Formalin is generally a saturated solution of
11:05:42 formaldehyde, which is 37 percent weight volume. So
11:05:45 hundred percent formalin would be 37 percent. You can
11:05:49 dilute it to 10 percent of formalin is 3.7 percent. And
11:05:55 almost every exhibit submitted by either party confirm
11:06:01 that. So Exhibit 12 submitted by Ravgen says since
11:06:05 hundred percent formalin contains 40 percent formaldehyde,
11:06:08 one to 10 dilution would contain four percent
11:06:12 formaldehyde. Exhibit 13 and 17, which is a Webster's
11:06:15 Dictionary, also contains a reference concentration for
11:06:19 that.
11:06:20 Exhibit 18, which was disclosed by, Ravgen, but
11:06:24 submitted by PerkinElmer, also expressly says it is made
11:06:27 of 37 percent formaldehyde. And lastly, Exhibit 19,
11:06:32 again, disclosed by Ravgen and submitted by PerkinElmer,
11:06:36 which is a technical dictionary, says formalin is an

11:06:40 aqueous solution of formaldehyde, usually 37 percent
11:06:45 formaldehyde by weight.
11:06:46 So I understand that the patents do not specify
11:06:53 this aspect, but that's because it's a common
11:06:55 understanding by those persons of skill in the art.
11:07:07 THE COURT: I understand it. But for me to give
11:07:10 this construction, I looked at any number of places. I
11:07:15 looked up formalin and in every one of them, they said a
11:07:18 common concentration is that. But I didn't see anything
11:07:23 where in the patent that requires me to give your -- where
11:07:31 anything that requires me to give your construction.
11:07:42 MR. PARK: Understood, your Honor.
11:07:55 THE COURT: I'm waiting on you. I don't know if
11:07:56 you're waiting on me, but that was a question. It may not
11:07:59 have been a very good one, but did you hear me?
11:08:02 MR. PARK: I'm sorry. I thought you were making
11:08:04 a statement. I must have missed the question.
11:08:08 THE COURT: If you have something in the patent
11:08:10 that you can show me where that they said formalin has to
11:08:16 be a stock solution of formal -- I mean, especially a word
11:08:20 like "formalin," I mean, again, I feel like I'm doing too
11:08:23 much preaching, you know, but when people are writing
11:08:25 patents and they're using words like "formalin," it seems
11:08:30 to me that they know what -- the world is going to know
11:08:34 what it means, and it has a plain and ordinary meaning

11:08:39 that doesn't deserve a construction unless they said in it
11:08:44 the word "formalin" -- I mean, just you look at the -- you
11:08:48 know, right before we had, I think it was, locus of
11:08:51 interest where they said this is what it means, but here,
11:08:55 they didn't.
11:08:56 So -- well at any rate, I'm going to adopt the
11:09:00 plain and ordinary meaning for this. I think one skilled
11:09:04 in the art would know what formalin is. And I don't
11:09:06 anticipate either expert taking the position that it has
11:09:08 or doesn't have -- that uses or doesn't use formalin that
11:09:12 is beyond that scope. I'll be back in just a second.
11:13:23 Mr. Park, earlier -- we wrapped up more quickly
11:13:26 than I thought we would. If you'd like to go back and
11:13:29 make your points on the record, especially if there was
11:13:32 anything you wanted to say about that claim term that
11:13:36 wasn't covered in your briefs, I'm happy to hear it at
11:13:39 this time.
11:13:44 MR. PARK: Thank you, your Honor.
11:13:46 So it goes to the BASF case that attorney Limbeek
11:13:53 mentioned, and I believe that case is very distinguishable
11:13:58 that the Federal Circuit in that case noted the extrinsic
11:14:03 evidence provided testing conditions to determine whether
11:14:07 something is a composition A or B that were claimed, and
11:14:10 experts of both parties in that case agreed that objective
11:14:13 tests were well-known.

11:14:14 Here, it's the polar opposite. The intrinsic
11:14:19 evidence does not tell us how to determine something is a
11:14:22 membrane stabilizer or cell lysis inhibitor. And also,
11:14:26 both experts agree that they would not be able to
11:14:28 determine or perform an experiment to determine that.
11:14:32 Attorney Limbeek had a slide that mentioned Dr. Grody's
11:14:36 comment about a radioactively labelled aldehyde. And I
11:14:41 just wanted to state for the record that the radioactive
11:14:46 experiment was not something that Dr. Grody knew how to
11:14:50 do. I will read from the transcript, page 299 where he
11:14:55 says: I wouldn't expect to be some kind of hotshot cell
11:14:58 biologist, you know, that's doing radioisotopic membrane
11:15:03 experiments. As you guys well know, a POSITA is not some
11:15:06 guy off the street, but it's not a Nobel laureate. It's
11:15:09 someone in the middle.
11:15:10 So that's what I wanted to say. Thank you, your
11:15:13 Honor.
11:15:13 THE COURT: And thank you for that.
11:15:15 Any response to that by plaintiffs?
11:15:19 MS. LIMBEEK: Yes, your Honor. Kerri-Ann Limbeek
11:15:23 on behalf of plaintiff.
11:15:24 I just want to reiterate that I think, once
11:15:28 again, the defendant's argument misses the point on the
11:15:32 definiteness inquiry. It's not, you know, whether or not
11:15:36 the particular expertise of plaintiff's expert on claim

11:15:43 construction has particular experience with every
11:15:48 experiment that might be useful in determining whether,
11:15:51 you know, the mechanism by which a particular compound,
11:15:57 you know, preserves a cell membrane is not really the
11:16:00 relevant inquiry.
11:16:02 You know, we'll get to the infringement analysis
11:16:05 and we'll get to the validity analysis down the line, as
11:16:08 your Honor has acknowledged, and then, we'll determine,
11:16:13 you know, whether or not particular compounds infringe.
11:16:16 But what matters for definiteness is whether these
11:16:21 categories are bounded. And I think that is very clear in
11:16:26 the record that there are clear boundaries of what
11:16:29 qualifies as a cell membrane stabilizer, et cetera.
11:16:33 And so, whether or not there's a hypothetical
11:16:35 compound that is out there that may require some testing
11:16:39 to figure out whether or not it is a cell membrane
11:16:42 stabilizer, it really misses the point. And so, I think
11:16:48 that, you know, the testimony that counsel for defendants
11:16:54 pointed to is not relevant to the indefiniteness inquiry.
11:16:59 THE COURT: Any response to that?
11:17:02 MR. PARK: Yes, your Honor.
11:17:03 PerkinElmer is not saying a person of ordinary
11:17:09 skill would have to know every condition or every test.
11:17:11 We're saying there's not one test disclosed by the patents
11:17:16 or Dr. Grody. And attorney Limbeek's argument doesn't

11:17:24 really address that point that the only even speculative
11:17:28 experiment that was proposed by Dr. Grody isn't something
11:17:30 that he -- it was said that he knows how to do.
11:17:35 THE COURT: Anything else from plaintiff?
11:17:39 MS. LIMBEEK: I think, your Honor, it just goes
11:17:44 back to the point from the BASF case that we've been
11:17:49 discussing this whole time that these were categories of
11:17:51 agents and that the defendants are saying, you know, these
11:17:54 are well-known categories of compositions that were used
11:17:57 to preserve cells.
11:17:59 And so, you know, in the testimony we discussed
11:18:04 earlier, you know, the first thing that a person of
11:18:06 ordinary skill in the art in determining whether or not a
11:18:09 compound falls into one of those categories would do is
11:18:12 just to look in the literature and look at the product
11:18:14 specification. And so, you know, that the plaintiff has
11:18:19 come up with some hypothetical compounds that may require
11:18:24 additional testing really, you know, once again, is not
11:18:26 relevant, I think, to indefiniteness inquiry.
11:18:30 THE COURT: Very good. Thank you.
11:18:32 The Court is going to maintain its -- the
11:18:35 construction that it proffered.
11:18:37 I note that we have trials set in these cases for
11:18:41 later this year. As you all know, I'm not a big
11:18:48 I-want-cases-that-settle judge. I think having -- getting

11:18:52 trials is the very best part of my job. And having trials
11:18:56 and have exceptional lawyers like all of you is the very
11:18:59 best part of being a trial judge. So I look forward --
11:19:04 let me say, I think settlements are great. I think if you
11:19:07 can settle a case, you should. I think it works out for
11:19:10 your clients the best. But I'm equally happy -- my method
11:19:15 of getting you settled is, you have trial dates and we'll
11:19:19 meet them.
11:19:20 Couple of things for those of you who have not
11:19:23 been in front of me at the end of a Markman. I haven't
11:19:25 talked to you about this. If your trial date, for
11:19:29 example, is November 1st of 2021, that really means that
11:19:36 you're going to be picking the jury the Thursday or Friday
11:19:38 before with my magistrate judge. Hopefully by then, we
11:19:44 will be far enough along in the COVID process.
11:19:49 What I'm doing next week with the Intel trial is,
11:19:51 we're going to voir dire the jurors one at a time in the
11:19:56 witness box with Plexiglass. I'm hoping we're past
11:20:01 needing to do that by November. Assuming we are, what you
11:20:05 should plan on having is a 15-person panel, four strikes
11:20:11 per side, winding up with a seven-person jury. If they
11:20:15 all get through the end of trial, then it will have to be
11:20:20 a unanimous verdict.
11:20:21 The way we do the voir dire is, my magistrate
11:20:26 judge does the voir dire. He usually takes about an hour.

11:20:29 He's very good. He's very patient, unlike me, he asks a
11:20:34 lot of questions. He's very nice to people, again, unlike
11:20:38 me. And he really gets a lot of juice out of the squeeze.
11:20:41 He does a very good job. When he finishes, plaintiff will
11:20:45 get 30 to 45 minutes to ask their questions. And then,
11:20:50 defendant will get the same amount of time to ask theirs
11:20:53 and, again, four strikes per side.
11:20:55 So that's pretty much I want everyone to be
11:21:00 planning on. Obviously we'll have a pretrial hearing in
11:21:03 advance of it where I will rule on limine, Daubert,
11:21:07 motions for summary judgment, and all that.
11:21:08 I'll start with the plaintiff just because Ms.
11:21:12 Limbeek is sitting in front of me on my camera, or Mr.
11:21:16 Desmarais, either. Is there anything else we need to take
11:21:19 up this morning?
11:21:23 MR. DESMARAIS: Hi, your Honor. This is John
11:21:25 Desmarais. It's nice to see you again and sorry I didn't
11:21:27 argue any of the terms, but as you could see, my great
11:21:30 associate team did a wonderful job. And nothing else to
11:21:33 take up from the plaintiff. We're looking forward to
11:21:34 trying this case before your Honor in November.
11:21:36 THE COURT: Me, too. Very much.
11:21:38 Mr. Hash.
11:21:39 MR. HASH: Nothing from Natera, your Honor.
11:21:41 Thank you so much for your time.

11:21:42 THE COURT: Anyone -- Mr. Park?

11:21:45 MR. PARK: Nothing further, your Honor. Thank you.

11:21:47 THE COURT: Okay. I hope you all be safe out there. Let me tell you something else we're doing. Mr. Desmarais' firm was involved in it last week. I think what I will be trying to do, moving forward with hearings, is giving lawyers the option to attend in person or by Zoom -- simultaneously in person in the courtroom or by Zoom.

11:22:12 Mr. Desmarais, if your folks thought -- I thought it went great last weak at the Markman we had. Mr. Desmarais' team had local counsel attend in person, but they appeared I thought mostly from New York, but I couldn't necessarily tell where from. But we did it in the courtroom. The Susman folks were live. They argued at the podium. The Desmarais attorneys that did a great job argued by Zoom.

11:22:38 And I thought it went -- I thought it went exceptionally well, and moving forward, I want everyone to know, I'm totally open to doing hearings all in person, hearings all by Zoom, or whatever hybrid we can do. But I thought it was -- it was very nice for me to have lawyers in the courtroom again. And I thought -- but I thought the lawyers that were attending by Zoom felt like they got

11:23:03 adequate -- they got an adequate opportunity, as well.

11:23:06 So I hope you all have a wonderful day. Be safe

11:23:08 out there. And I look forward to seeing you in person

11:23:11 hopefully before the end of the year. Take care.

11:23:14 MS. LIMBEEK: Thank you, your Honor.

11:23:16 MR. PARK: Thank you.

11:23:18 MR. HASH: Thank you, your Honor.

(Proceedings concluded.)

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UNITED STATES DISTRICT COURT)
WESTERN DISTRICT OF TEXAS)

I, LILY I. REZNIK, Certified Realtime Reporter, Registered Merit Reporter, in my capacity as Official Court Reporter of the United States District Court, Western District of Texas, do certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

I certify that the transcript fees and format comply with those prescribed by the Court and Judicial Conference of the United States.

WITNESS MY OFFICIAL HAND this the 17th day of February, 2021.

/s/Lily I. Reznik
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