MORRISON
FOERSTER

Unofficial transcript for users of mofo.com

Speaker 1 (00:06):

The final case for argument is 18 1428, Neev versus Alcon. Please proceed.

Lisbeth Merrill (01:07):

Thank you. First, I want to say it's an honor to be here and thank you so much for your consideration. I'm Lisbeth Merrill and I represent the petitioner and plaintiff here, Dr. Joseph Neev. And there are two main issues that I'd like to discuss. And I was hoping to use my time equally between the two. The first is regarding the '199 patent and it's whether limiting claims to a preferred embodiment where the specification shows the invention is broader is appropriate. And the second is relating to the '926 patent. And it's whether admission by defendants to the FDA regarding the safety of their product in order to seek approval to sell this product to the public should have been permitted to go to the jury.

Speaker 1 (01:55):

Can I just ask you a logistical question about the '926, which is there's been a final, as I understand from the record, there's been a final action rejecting all of the claims by the patent office. What's the status of that proceeding?

Lisbeth Merrill (02:12):

There's been an appeal filed and that appeal is still pending. So the

Speaker 1 (02:15):
An appeal here or appeal before the board?

Lisbeth Merrill (02:18):
An appeal before, I'm not handling that case. It's but it's an appeal to the district court, correct? Yeah, no, to the, to the patent board. I apologize. Okay.

Speaker 3 (02:31):

Okay. So it's maybe still somewhere in the middle of the briefing in front of the patent board or

Lisbeth Merrill (02:36):

Yes. That's my understanding so there is a possibility, I mean, are we believe that there's a good chance it'll be overturned that there are some good issues. Otherwise we wouldn't be proceeding here and wasting the court's time in that regard.

Speaker 1 (02:51):

Here there's no validity issues pending on the '926. It's just the inference.

Lisbeth Merrill (02:56):

Before this court. No, there's none. It's just the issue. There, there's the issue about the inequitable estoppel that we raised. And then the other issue that I wanted to mainly focus on, which is whether in summary judgment, the judge was appropriate in not allowing the issue of the FDA admission to go in front of the jury. And we believe that that should have been something that went in front of the jury and not decided on summary judgment. So, so defendants responded to the question by the FDA asking, well, let me back up just a moment. The limitation in the patent of the '926, the second issue that I wanted to talk about requires no thermal damage further than five microns. Okay. And the defendants responded in a question directed to them by the FDA asking whether their laser causes thermal damage and the response under oath was there's no thermal damage. So no thermal damage is less than five microns. And our position is that all arguments by defendants should have gone to the weight of the evidence rather than serve as a complete bar to plaintiff's right to present these facts to the

Speaker 3 (04:04):

Did you submit any expert testimony or anything? My understanding is the sole source of evidence you have is this FDA submission. And then the other side came forward with an expert testifying that, well, whatever the contents of the FDA submission, you can't understand what's going on here as being a true zero micron thermal damage because that's a physical impossibility. And then explain that through an expert declaration. And so that to me then raises the question of why isn't this case similar to our Centricut opinion, where we said, okay there's evidence in the record that rebuts this allegation about how to interpret this FDA submission. And there isn't any expert testimony on the other side.

Lisbeth Merrill (05:00):

Well, the problem I have with the expert testimony is, first of all, you have an admission under oath as to the safety of the product you know to the FDA, okay, versus a highly paid expert who admit there's no evidence that they conducted any testing whatsoever on this. So these are just theoretical ideas that they're putting forth. And I think a reasonable jury should be given the opportunity to determine what has more weight. I mean, when we're as a member of the public, we are entitled to rely upon what defendants tell the FDA and I believe

Speaker 1 (05:33):

Their argument is that what they told the FDA says is that it lacks thermal side effects. And that is not the same as thermal damage, right?

Lisbeth Merrill (05:44):

So if you look at the request from the FDA, so it's at Appendix 3778, section 3 is where the issue was framed. It says, you've stated that the increase in the pulse rate from 15 kilohertz to 33 kilohertz does not adversely affect the safety or effectiveness of the cuts needed for the proposed indications. We've not provided adequate evidence. So, and then they ask that you provide adequate evidence on the following and they have three sections an A, B and C. And if you go to Appendix 3783, they have that section, the, the request and the request was temperature elevation data from tissue adjacent to cuts to confirm that the higher rate is not producing thermal damage. So it's the same thing we're talking about here in the patent claim is thermal damage. Is there thermal damage past where the laser is touching

the tissue, and their response to the FDA is at Appendix 3783 says as shown in figure 3B above, thermal side effects were not seen at any laser repetition rate tested.

Lisbeth Merrill (06:55):

So their response and their statement of their thermal side effects was complete. It was in response to the FDA requests of whether there's thermal damage, and then they continue to state, therefore there's insufficient time for thermal energy to diffuse into the surrounding tissue. The absence of thermal side effects is one of the advantages of plasma mediated photo disruption for cut tissue cutting. So I understand that their statement says thermal side effects, but it was in direct response to the FDA request of whether there's thermal damage. I mean, the FDA understood it to be that. So with respect to, and then if you look at the statement, there's evidence from the experts and from their testimony that the lower the femtosecond rate. So if you go from 800 to 600, you'll get even less damages and less thermal side effects. And and then we show the wave light. There's evidence that their femtosecond is at 350 femtoseconds. So you're going to get their own scientists said the shorter wave pulse links result in less collateral damage to the surrounding tissues.

Speaker 3 (08:12):

Well, that’s interesting. You're the plaintiff and you're using, you know, all of these statements from the defendant side to prove your case of infringement. I'm just curious, why didn't you run any tests on the accused lasers to figure out whether or not they meet the claim limitations?

Lisabeth Merrill (08:31):

Well, I mean, when you have these lasers are used for eye surgery, okay, these lasers are marketed and the FDA has represented that they cause no damage. I mean, no one wants a laser to just cut into your eye and cause damage to the surrounding tissue. And that's what these are touted to do. And when you have an FDA statement as to the safety of it, that there's no damage. I mean, it, you know, whatever an expert says, I mean, that's the admission that's there. That should be sufficient. So turning to the preparation of the target region limitation, okay. The '199 patent teaches changing the scattering and the absorption characteristics of target material to affect how a laser interacts with the material. So claim one specifically says preparing the target region by spatially and temporally varying at least one absorption characteristic or scattering characteristic of the material. So basically you have light coming into the material and it's either going to be absorbed or scattered, and you make changes to the material to change how that light, the lasers who were doing the modification of the tissue are going to be affecting the tissue.

Lisbeth Merrill (09:46):

And so the court can made a construction that applies that reference or preparation or an agent and nothing in the claims talks about a preparation or agent. They say that the need in interpreted it later in summary judgment to mean that you have to add a substance. And the requested construction was actually a construction that was decided and approved by a previous court as well in the district, in the district of Delaware. So our position is that claims just as Kara Tech v. Stamps says claims, not the specification embodiments, define the scope of the patent protection. Patentee is entitled to the full scope of those claims and will not limit it to his preferred embodiment or import a limitation from the specification into the claims. And if you look at the plain meaning of preparing a target region by spatially or temporally varying at least one absorption characteristic of the material or scattering

characteristic of the material, this is easily understood. Nothing in the plain meaning implies requirement of a component or a substance, nothing in the plain meaning

Speaker 3 (10:55):

We do have cases though, don't we, that say when a particular claim limitation claim step is described repeatedly and consistently throughout the written description to be referring to something, then that something is understood to be part of the claim limitation. So if, if we were to read the specification here as consistently and repeatedly contemplating the addition of some kind of agent, application of some kind of agent to the preparation of the target region then, then wouldn't it be appropriate under that instance for the court to understand the preparation of a target region limitation to be all about adding an agent?

Lisbeth Merrill (11:46):

Right. I, I do understand that case. I think there's a GPNE was one of those that was cited and the language that was used in the cases when a patent repeatedly and consistently characterizes the claim term in a particular way, here we're not dealing with a claim term that's being characterized a certain way. The claim terms themselves are the preparing the target region by varying absorption characteristics or scattering characteristics, and material. And then what the other side is using doing is taking the word agent, which isn't even part of the claim term, and then trying to import it into the claim term using this law. But it's not even part of the claim term. It doesn't fall under this law. And second, you don't have a repeated and consistent characterization of a claim term. The word prepared in any form appears in the entire 90 page patent only three times.

Lisbeth Merrill (12:40):
So you, how could you possibly have a consistent and repeated characterization in that regard? And when you have, I mean, and you have other areas like for example in Appendix, and I'm getting into my rebuttal time, but in Appendix 171, and you have a distinct fourth exemplary method that doesn't refer to pat, to agents at all, you also have language that talks about the selective location may be naturally inserted or induced artificially. And you know I think I'll reserve some of this for rebuttal if it continues to come up because my time is short, but I thank you so much.

Speaker 3 (13:19):
Thank you.

Brian Matsui (13:31):

May it please the court, Brian Matsui on behalf of Alcon. The district court's judgment should be affirmed. I'd like to start with the '199 patent and then turn to the '926 patent. For the '199 patent, the district court construed a technical term in a technical field, preparing the target region of the target material by spatially or temporally varying. And it gave that term the only meaning that’s supported by the intrinsic record. Under this court's basic claim construction rules, when there is no single ordinary plain meaning to a term when the patent repeatedly and uniformly describes a term one way and does so with language like key to the present invention, the patentee cannot invade that context in the specification and contort his claims to something else.

Speaker 6 (14:19):

Well, let me tell you what is troubling about, about, about this. So what is your view of the, the court's action in striking the expert deposition and rebuttal?

Brian Matsui (14:34):

Of striking the expert testimony, your honor?

Speaker 3 (13:19):
Yes.

Brian Matsui (14:37):
Well, that was an enforcement of the local patent rules. It's under abuse of discretion standard, your honor.

Speaker 6 (14:44):

Never mind the standard. What is your view of what is achieved or not achieved by that action?

Brian Matsui (14:50):

I think that was entirely proper given the fact that the original infringement contentions in this case only discussed a patient interface for the preparing step. There was no discussion at all of anything like eyedrops that could satisfy the preparing limitation. And given that fact, the district court was well within its discretion to strike the expert submission in, in that case. I think that, you know, under this court's precedent, the only way that it would overturn the enforcement of local rules would be if it's unreasonable, arbitrary, or fanciful. And I think when we're talking about the fact that in the original infringement contentions, this additional way to practice the limitation, alleged way to practice the limitation was not at all disclosed, the district court certainly had it within its enforcement powers to set that aside and say that you could not rely upon that expert testimony.

Brian Matsui (15:49):

I think that if we take a step back step back and look at what Neev is arguing here, and that's very clear in his reply brief at pages 19 to 20, it's basically said, he's basically saying that all he needs to do is say that our accused device practices this element. And then once he said that he can come back at the end of the case later in the case before trial and say, these are all the ways now in which I think that your device practices that element, but the rules here require a much greater specificity. They require where and how each limitation in the asserted claim is found in the device. And he didn't do that. And so given that fact it is within the district court's power to enforce its local rules and strike the report. Again, and just one more point on this, Dr. Neev here never, he never asked to amend his infringement contentions. So we're looking at a situation where he just unilaterally changed his infringement contentions. And this is a case that was involved at the time when this case began, many multiple parties, a number of patents, it was very complex. There were a lot of deadlines that were missed. This is a case in which the district court had a lot of power under its case management rules to say that it was too late now for him to

Speaker 6 (17:11):

So you're saying that if issues are raised in the defense, that the plaintiff has no opportunity to respond to them if the issues were not foreseen and responded to before they were raised?

Brian Matsui (17:27):

I think that in that situation, Neev could have filed a motion to amend his infringement contentions. And then the district court could have decided what to do, how that was going to affect the proceedings and what steps should be taken. But here in this situation, he didn't do that. He just unilaterally changed his infringement theory and submitted expert testimony about something entirely different. And that's not the way that the process is supposed to work under the local rules.

Speaker 6 (17:57):

So the way the process is supposed to work is to provide a fair trial where each side has an opportunity to respond to what the other side raises and the, the, the local rules that have been adopted in patent cases certainly serve an important purpose because they avoid sandbagging the other side with new issues. But here there were arguments raised that this plaintiff had no opportunity to respond to.

Brian Matsui (18:32):

I don't see how the plaintiff had no opportunities to respond to these arguments. From the very beginning, Neev is the one that gets to say, this is the way in which the accused devices practice the limitations. He set forth his reasons why he thought that our devices practice these limitations. And then after fact discovery closes, he changes his theory. The district court in that situation has the right to say that would not be fair after discovery is closed.

Speaker 6 (19:04):

He would have to respond to the theory raised by the defense, a solid enough theory let it, let us say. But don’t the principles of fair trial require such an opportunity?

Brian Matsui (19:20):

I think that the Neev would have had, Neev had the opportunity here in this case to set forth infringement contentions that would address this limitation. He did. It's a matter of a fair trial for the defendant to know the way in which that limitation was practiced so it could conduct a scope discovery on the issues, so it could look at its invalidity contentions, based upon those infringement contentions. It's too late after discovery has closed, after invalidity contentions have already been submitted for him now to say, I have a new theory of infringement. But even setting that aside as a matter of fair process, if the case had changed in a way that he then wanted to introduce new infringement contentions, the appropriate mechanism for him to do that would have been to ask the district court to amend them. The inappropriate way for him to do that is to unilaterally change his infringement theory and spring that upon Alcon.

Brian Matsui (20:24):

Now I'd like to just, if your honors don't mind, I'd like to turn back to the '199 patent briefly on the claim construction issue, just to say that this is the type of case in which it repeatedly and uniformly discusses adding an agent in this technical term, this case is like the GPNE case. In fact, it's, it's a step further from that where there might've been a plain and ordinary meaning of the term node, which then was held to be a [pager]. But here, you're talking about a claim which has at Appendix 170, a section entitled principles of operation, use of doping agents and selective marking of targeted regions within the material. And the patent uses language like key to the practice of the present invention, and then just discusses the use of an agent. So you have in here a situation where you don't have a term in which there is a plain and ordinary meaning that a person would understand, a person with ordinary skill in the

art would understand, outside the context of the patent. And the only way that you can discern what that meaning is, is by looking to the specification. And when you look at the specification, the patent exclusively and consistently and uniformly describes using an agent in this claim. And so

Speaker 1 (21:44):

What about the other patent, the '926, and your friend's argument with respect to why the FDA submission was sufficient to create a reasonable question of fact, given that it appeared that the response was about thermal damage and not really about side effects.

Brian Matsui (22:03):

So again, I think just to reiterate Neev submitted no expert testimony about this document at all. It was about an issue that's entirely different than the '926 patent. What we have here is an FDA document in which Alcon already has an indication, and it wants to get an additional indication. And so what it's doing is it's doubling the pulse repetition rate, and the FDA wants to know if this is going to affect safety and efficacy. And in that context, what Alcon is saying is there's no such thermal side effects. And what it means is that it's not causing additional harm to the already approved indication. And so in order for Neev to have an argument here, based upon this FDA document, he would have to have some evidence that explained that when the FDA is talking about thermal damage and Alcon is talking about thermal side effects in the process of trying to get an additional indication

Brian Matsui (23:03):

that means the same thing with respect to the '926 patent of the very precise microscopic limitation of no more than five microns below the disruptions. And there is no evidence in here, there is an absolute and complete failure of proof. And so one could not imagine if this case did proceed to trial, that all Neev would have would be this FDA document and he would show that to the jury. That's not enough for a reasonable fact-finder to determine that this very specific limitation in the '926 patent of no more than five microns is satisfied. I think that if you look at what are

Speaker 3 (23:43):

What if Alcon’s submission to the FDA had said there's zero thermal damage?

Brian Matsui (23:51):

I think that that still, your honor, would depend upon the context because thermal damage for the FDA, when you're talking

Speaker 3 (23:56):

There’s 0.00 micron damage.

Brian Matsui (24:00):

If I think that yes, if it was talking about the specific limitation there’s zero microns of thermal damage from the cavity, then I think that that might be a different issue. But what we have here is no idea what thermal damage means in the context of the FDA submission. And I think that's important when you look at what our engineer explained in his deposition. He said that our engineer discussed, and this is at Appendix 4880, that when you're talking about the precise thermal damage in the '926 patent, it's different. He said, it's a matter of measurement, measurement. It's not the thermal damage as we

discussed, perceived, you know, observed by necessarily clinicians, but there is thermal damage and I don't know if five microns is a good threshold, it's likely deeper than five microns. And so what he's talking about is that if you're talking about clinicians, people that are using the laser, people that the FDA would be talking about to see if there are safety issues, you're talking about these microscopic amounts. And so there's no thermal damage, but if you're talking about in this very technical field, the no more than five microns, there's no evidence of that. And they don't know. And this again is Neev's burden to prove infringement, to offer evidence from what your reasonable jury could find infringement. And he did not do that here in this case. Unless your honors have any further questions, we would ask this court to affirm.

Speaker 6 (25:30):

Thank you.

Lisbeth Merrill (25:45):

So just quickly, in the '199 patent, places where we don't have an agent or a substance, it says at column 42, 56 through 65, it's in Appendix 171. And I apologize, actually, in our briefs, it says Appendix 172, but it's actually 171. And it says distinct fourth exemplary method agnostic to have it. So I'm saying that this is a distinct exemplary method that's agnostic of how the material characteristics are modified. So actually, I'm sorry, I apologize. This is Appendix 160, column 20, 42 through 54. It talks about utilizing preferential time dependent and/or space dependent marking of the target region. And this refers to temporally or spatially modifying the target material characteristics without any reference to an agent. And then at Appendix, what I mentioned before, Appendix 171, which is column 42, 56 through 65, it discusses selective locations within the target material's surface may possess properties that enhance their scattering and or absorption, such selective location may occur naturally or may be inserted or induced artificially by the operator. Additionally, we have other references, for example, Appendix 154, which is called

Speaker 3 (27:16):

Sorry, you were at A. 171, column 42, which lines were you at?

Lisbeth Merrill (27:21):

56 through 65.

Speaker 3 (27:25):
56 through 65. That's column 42?

Lisbeth Merrill (27:33):

Yeah. That's I believe that's correct. Let me see

Speaker 3 (27:38):

I mean line 55 talks about how figure 6B illustrates selective deposition of absorbing instances of various shapes, right? So before time and space dependent selective interactions within the three-dimensional material volume. And so at least that passage is contemplating the positive and absorbing agents.

Lisbeth Merrill (28:01):

Except, however, all those references at if you look at figure 6, 306, 310, and 312 are all below the surface. And so we, we, it talks about adding it may be naturally done or inserted or induced artificially. So it's contemplating inducing changes in the target tissue below the surface. I mean, the only, I mean, if not actually, I mean, the only way you could insert a substance would be like through a needle or something. But I mean, if you, if you continue on to other references, it talks about doping agents are added to the material, being a blade before it, it says optionally, optionally, doping agents are added to the material and that's at Appendix 154, column 7, 34 through 38. And then another reference says the option to spatially and/or temporarily control the addition of doping agents, Appendix 155, 156. This is column 10, 63 through 11, line 7. And then there's another reference. It says, even this is Appendix 171 , column 42, 3 through 5, even often small residual modifications to the surface follow the interaction with the laser source, act as a subsequent absorbing agent and perpetrate the process at any desired pulse repetition. So here we have a defect that acts as an absorbing agent and there was nothing added, no substance and that as required by the court's construction.

Lisbeth Merrill (29:43):

So I think, oh, I still have a little bit more time. I thought it was. Oh, no, I'm out. Oh yes. Just just two final thoughts. I'm sorry. I'll be very quick. So with the what your honor Judge Newman was asking about on the substance that adding the drops from my perspective, when you add drops, you change the density and the same thing happens when you add compression. The patent is about changing the density of the material and the timing didn't allow an opportunity to amend. Counsel on the other side had tried to do that with the related case and wasn't allowed on the depositions, however, disclosed everything. And so did the report. So there was plenty of opportunity to take a look at this, to ask about it and, and to discuss it. And so, but the, the timetable was pretty compressed and we'd even asked at one point for a stay because of the patent re exam that was going on in the '926, and that was denied as well.

Lisbeth Merrill (30:49):

So and then I think that that covers, oh, just generally with the final point with the, with the limitation on the '199 is once as you have in Phillips, once you begin to include elements not mentioned in the claim in order to limit such claim, we never know where to stop. And here there's no mention in claim one, and there's no basis of importing that claim the limitation of applying a preparation is completely created. It's not in the language of claim one. And a limitation the district court then interpreted as summary judgment to require the application of a substance. So it's these two points, steps that were taken that required it. So from my perspective, the original construction, if you didn't view agent as a substance would have been fine, but when the court reviewed, interpreted that to mean a substance that had to be applied, then that's where the real problems began. Thank you so much for your time.

Speaker 1 (31:52):

Thank you. The case is submitted. That concludes our proceeding.