IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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SENJU PHARMACEUTICAL CO. LTD. KYORIN PHARMACEUTICAL CO., LTD. And ALLERGAN, INC.,	:	CIVIL ACTION
Plaintiffs,	:	
vs.	:	
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	:	
Defendants	:	
----------	:	NO. 11-0271 (SLR/MPT)
SENJU PHARMACEUTICAL CO., LTD. KYROIN PHARMACEUTICAL CO., LTD. and ALLERGAN, INC.,	:	
Plaintiffs,	:	
vs.	:	
HI-TECH PHARMACAL CO., INC.,	:	
Defendants	:	

- - -

Wilmington, Delaware
Wednesday, December 19, 2012
9:04 o'clock, a.m.

- - -

BEFORE: HONORABLE SUE L. ROBINSON, U.S.D.C.J.

- - -

Valerie J. Gunning
Official Court Reporter

APPEARANCES:

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-and-

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- - -

ALSO PRESENT:

BILL SCARFF, ESQ.
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P R O C E E D I N G S

(Proceedings commenced in the courtroom, beginning at 9:04 a.m.)

MR. BLUMENFELD: Good morning, your Honor.

THE COURT: Good morning, everyone. Full house. I guess we should make reintroductions and then we can get started on the agenda.

MR. BLUMENFELD: Good morning, your Honor.

THE COURT: Good morning.

MR. BLUMENFELD: Jack Blumenfeld for the plaintiffs. And at counsel table, Dick Kelly, Frank West, Tia Fenton, and Steve Baxter behind the table, all from Oblon Spivak. And Bill Scarff, in-house at Allergan, is with us today also.

THE COURT: All right. Thank you.

MS. KELLER: Good morning, your Honor. Karen Keller of Shaw Keller on behalf of Hi-Tech Pharmacal, and with me today is Jeff Castellano, also of my office.

THE COURT: All right.

MR. CASTELLANO: Good morning, your Honor.

THE COURT: Good morning.

MR. PHILLIPS: Good morning, your Honor. Jack Phillips for Lupin, and with me at counsel table is

Deanne Mazzochi, Anuj Wadhwa, and John Polivick, all of Rakoczy Molino Mazzochi & Siwik in Chicago.

THE COURT: All right. Thank you very much.

All right. I tried to understand the differences in the claim construction. I'm not sure I do. So you tell me what we should start with and I'm happy to go with the flow here.

MR. WEST: Your Honor, I might as well start with an explanation of what we believe the dispute is.

THE COURT: Yes. I would love to know what the dispute is.

MR. WEST: Okay.

THE COURT: And don't let me forget, I have a proposed trial schedule based on the time I have.

MR. WEST: Thank you, your Honor.

THE COURT: So don't let me forget to hand it out before the end of this.

MR. WEST: Your Honor, my name is Frank West. I'm with Oblon Spivak. We represent the plaintiffs.

And with respect to the claim construction, I believe the dispute is with respect to how the preamble of the re-examined claim 6 should be interpreted, and I will try to set forth what the plaintiffs believe the dispute is here.

The defendants are seeking to interpret a

truncated version of the preamble and the plaintiffs are seeking to have the full preamble interpreted.

What the plaintiffs believe the preamble means is consistent with the Court's definition of the original preamble of original claim 6, meaning the showing of an increased concentration of gatifloxacin in aqueous humor.

Although it's not too clear from the defendants' briefing, it appears as though the defendants are taking the position that the truncated version, showing a method for raising corneal permeability, should be interpreted to mean that in order to also have the flexibility to argue that the additional language of an aqueous liquid, I'm sorry, aqueous pharmaceutical gatifloxacin eyedrop solution could be used to say that additional components of the eyedrop solution should also be present in an increased concentration aqueous humor. They don't define what they also think should be required to be present in an increased concentration, but I think that is their position, and I will try to explain that further as I go along.

So the preamble of the re-examined claim 6 recites in full, quote, "a method for raising corneal permeability of an aqueous pharmaceutical gatifloxacin eyedrop solution," close quote.

Now, the preamble of the re-examined claim 6

differs from the preamble of the original claim 6, which recited a method for raising corneal permeability of gatifloxacin, and the difference between the two is the substitution of the words in re-examined claim 6, open quote, "of an aqueous pharmaceutical gatifloxacin eyedrop solution," close quote, for the words "of gatifloxacin in the original claim."

Now, the substitution of the words was not meant and did not change the scope of the claim, but only provided clarity by providing antecedent basis for the term, at the end of the re-examined claim of said gatifloxacin eyedrop solution.

Now, it's plaintiffs' position, consistent with the holding of this Court in the Apotex case, that the full preamble of re-examined claim 6 is a limitation and must be construed.

And plaintiffs believe that the preamble should be construed consistent with this Court's claim construction of the original preamble of claim 6 to mean showing an increased concentration of gatifloxacin in an aqueous humor, and we believe that this is consistent with the common and ordinary meaning of the preamble of re-examined claim 6 to one of ordinary skill in the art, and it's confirmed by the specification and the original and re-examined file histories of the '045 patent. And not to belabor the point,

our briefs set forth in detail, as well as Dr. Curatola's declaration, where we believe the support is for that interpretation.

But two specific points I would like to make. In both the prosecution of the original patent and the re-examination, the plaintiffs distinguished over the prior art by relying upon a showing of increased concentration of gatifloxacin, no other components in the aqueous humor. And in the notice of allowance of both the original patent and the re-examined patent, the Examiner found that the claims were patentable because of a showing of increased concentration of gatifloxacin, no other components in the aqueous humor.

So we believe that the proper interpretation of the full preamble of claim 6 is showing an increased concentration of gatifloxacin in an aqueous humor. And plaintiffs' interpretation is not only supported by the intrinsic record, but also the declaration of Dr. William Curatolo. While defendants argue Dr. Curatolo's declaration is extrinsic evidence and should be ignored, the fact is that Dr. Curatolo's declaration is under oath, and while not intrinsic evidence, it is still evidence and it's consistent with the intrinsic record.

Now, in contrast, defendants seek to truncate the preamble and interpret only the phrase "a method for

raising corneal permeability," and defendants assert that only this truncated portion of the preamble should be construed to mean showing an increased concentration of gatifloxacin in the aqueous humor.

And to support this interpretation, defendants rely solely on attorney argument. It's well established obviously that attorney argument is not evidence and defendants' arguments are not supported by evidence, whether it be intrinsic or extrinsic.

Now, defendants accuse the plaintiffs of gamesmanship in the exchange of claim construction terms, and to be blunt, as a Kansas farm boy raised on principles of sportsmanship, I really find that objectionable. But really, I think what the facts show is that there was a misunderstanding on both parties' parts until the time of the filing of the joint -- of claim construction statement with the Court.

And the fact is that the record attached to defendants' own brief and discussed at length by both parties in their own briefing establish that plaintiffs didn't engage in gamesmanship, but contrary to defendants' representations, plaintiffs responded to a new construction offered by the defendants on the day the joint claim construction was due, which indicated that the defendants would seek to construe the preamble inconsistent with the

specification file history, such that all components, or at least some additional components, in addition to gatifloxacin, must be shown to be present in an increased concentration in aqueous humor.

And when the plaintiffs inquired whether or not this was the case, we didn't get a direct response. We were just told that they -- that the defendants wanted to maintain their flexibility with respect to claim construction and so they refused to tell us whether or not that was the case. And even defendants' claim construction briefing to date fails to directly address that point.

Now, defendants also argue in their claim construction briefing that because plaintiffs changed the language of the preamble, the preamble must mean something different. And, again, this is attorney argument, it's not supported by the intrinsic record.

And as I said earlier, the intrinsic record shows that the change was solely made to provide clarity so that you would have an antecedent basis for said gatifloxacin eyedrop solution at the end of the claim.

And, in fact, if the re-examined claim were construed to require an increased concentration components other than gatifloxacin, there's no support whatsoever in the specification or the -- or the file histories for that

position, and that would have constituted new matter and gotten a rejection from the Patent Office.

So not only -- not only does the intrinsic record support plaintiffs' interpretation, but it's the only reasonable construction in light of the intrinsic evidence. And that is plaintiffs' position.

THE COURT: All right. Thank you very much.

MR. WEST: Thank you.

MS. MAZZOCHI: May I approach, your Honor? To try to -- because I anticipated the Court might have some questions on why we have the positions we do, I just made a few slides so I could highlight for you.

THE COURT: Okay.

(Ms. Mazzochi handed slides to the Court.)

MS. MAZZOCHI: Your Honor, I think if we start by taking a look at the third slide, this is where we have the head-to-head claim language comparison between claim 6 as it originally issued and then claim 6 as it issued in the re-examination certificate.

So if we start with both originally issued claim 6 and the re-examination certificate, claim 6, they both start off, a method for raising corneal permeability. At the outset, we thought that was the only thing that the plaintiffs wanted to construe. We said we agreed. We're going to abide by what the Court did in the first

Apotex case, so it does not appear that we have a dispute.

The problem is, is that they've now come in with an expert who is taking the position that if we look at the language that goes after a, a method for raising corneal permeability of, it says, of an aqueous pharmaceutical gatifloxacin eyedrop solution comprising, then it has a list of various ingredients that need to be in there at certain weight percentages.

Their expert is now taking the position that all of that language really means gatifloxacin and nothing else. Frankly, that, to me, is a lexicography definition. That's not something that is adhering to the ordinary plain meaning, which is an aqueous pharmaceutical gatifloxacin eyedrop solution that comprise these various elements.

So the question then that we have is since their expert -- and this is in paragraph 22, I believe, of his declaration -- since their expert is taking the position that that language, after the of means gatifloxacin and no other component from the eyedrop solution, our question was, well, where was that definition, that clear lexicography definition, ever actually given during prosecution?

And if we take a look at our slide number 5, the PTO Examiner, and this is from Mr., or Dr. Curatolo's

declaration. So these were the things that he was relying on.

The PTO Examiner specifically recognized that the prior art may affect the penetration toxicity of additives resulting in the increased corneal permeability of the solution. So that's not referring to increased corneal permeability of just one additive. They were talking about the entirety of the solution there.

When it came to the arguments that the patentees gave back to the PTO in response to some of the invalidity rejections, we can see one of them in our slide number 6, they are talking about corneal permeability and they said, we've carried out experimentation that demonstrates that compositions, including gatifloxacin and disodium edetate in the amounts recited in claim 12 and having pH in the range recited in claim 1, achieve unexpectedly superior corneal permeability.

So they are referring there to the compositions as a whole, not just to gatifloxacin itself.

Similarly, if we take a look at slide number 7, when they talked about this Court's decision, they said, the Court concluded that employing disodium edetate in an amount of about 0.01 weight per volume percent results in superior corneal permeability of gatifloxacin eyedrop formulations.

So there again they are characterizing to the PTO that it's the overall formulation that is achieving the supposedly superior corneal permeability.

And if we look at the next slide, when they were making arguments about unexpected results, would increase corneal permeability of such formulation. Improved corneal permeability demonstrated for the gatifloxacin eyedrop formulations, according to claim 12. Then again, they're not saying gatifloxacin to the exclusion of any other component in the formulation.

And then when it came to claim 6 in particular, they recognized that the PTO had rejected the claims by saying it would have been obvious to incorporate disodium edetate into a gatifloxacin eyedrop solution, and the argument that they made back to the Patent Office is that the prior art does not suggest incorporating disodium edetate in the particular amounts recited in claim 6 into a gatifloxacin eyedrop solution having the particular composition recited in claim 6 to improve the corneal permeability of such solution as required in claim 6.

So, again, when we take a look at the re-examination claim 6 and we look at the language that actually issued, the preamble language says, a method for raising corneal permeability of an aqueous pharmaceutical gatifloxacin eyedrop solution comprising all of these

various ingredients.

So all we're asking for is that a method for raising corneal permeability, and we set this forth on our slide number 10, should be construed as it was in Apotex, showing an increased concentration in the aqueous humor. But what has changed in the re-examined claim 6 compared to the original claim 6 is that original claim 6 said, permeability of gatifloxacin. The re-examined claim 6 says permeability of an aqueous pharmaceutical gatifloxacin eyedrop solution.

So that's the phrase essentially that should be -- that should be part of what they have to show the increased concentration of in the aqueous humor.

THE COURT: This is a very creative lawyering argument, but from a common sense point of view and from a claim construction point of view, I have to say that I'm a little confused for the following reasons.

Number one, we don't generally truncate a sentence. At least I don't.

Number two, it sounds like you're suggesting that the re-examined claim can be broader when, in fact, it can't be because it's the same ingredients in the original claim, the re-examined claim. That's the only thing supported in the intrinsic record.

So I don't even know -- I don't know how you're

going to spin this at trial, quite frankly. And it certainly makes some sense to me that the patentee incorporated into the preamble the language at the end of the claim that talks about eyedrop solutions.

So I, frankly, I'm not going to make a decision, because I don't usually in a bench trial. I want to see how you spin it, but I don't understand how you're going to spin it, and I don't think it makes any sense to me when I'm looking at this re-examined claim that has passed muster. And, yes, you can play this wordsmithing game you're doing, but I don't know why you would.

MS. MAZZOCHI: Well, your Honor, let me try to backtrack here.

First, I don't think that we're trying to truncate anything. My understanding from my read of the Apotex claim construction is that in the context of the preamble language in claim 6, which I think both sides agree was limiting there, it's limiting the -- the preamble language for the claim language is limiting here.

There was no need to construe of gatifloxacin in the original claim 6 because it was accepted. There was a plain meaning for "of gatifloxacin." Here, all we're saying is that when they say, "of an aqueous pharmaceutical gatifloxacin eyedrop solution," that that also likewise has a plain and ordinary meaning that does not require any

particular unique construction from the Court.

THE COURT: It would need a meaning for me because I don't understand what it is other than what is in the claim, which is gatifloxacin or its salt, and disodium edetate.

I mean, if you want to truncate this, then I don't want you to say plain and ordinary meaning when I don't know what the plain and ordinary meaning is.

Now, obviously, I'm not one of ordinary skill in the art, but that is the kind of vagueness going into a trial that, a bench trial that doesn't bother me too much, but certainly if this were a jury trial, I wouldn't allow it, because I don't know how it's going to play out. I don't know how you are going to use this plain and ordinary meaning at trial.

So if you want to suggest something to me now of what the meaning is of the second phrase, I'm happy to consider it. At some point, you are going to have to make it clear to me. Otherwise, this whole exercise will have just been churning fees that your client has to pay.

MS. MAZZOCHI: Sure. Well, your Honor, I mean, to me when it says gatifloxacin eyedrop solution, that's referring to the solution as a whole. Their expert is offering the opinion, which is not supported by the

specification or the statements made during prosecution, that when it's referring to a solution, that you should really strike out all of that language about solution and just have it mean gatifloxacin and no other components that could be in the solution. That was their expert declaration. I believe it was at paragraph 22.

He says, no other component. That is redefining what the solution is. And to us, if they're going to try to make an argument of redefinition of the term solution, then they needed to give it that kind of a lexicography definition, they needed to actually show where that is in the intrinsic record, and they have not done that.

And I think, quite frankly, they were trying to, in front of the Patent Office, give the appearance that there was something significant about it being the solution as a whole having increased corneal permeability. I don't think they have supported that with the specification. I don't think that those arguments that they made to the PTO to try to differentiate the prior art are valid on the merits.

But, nevertheless, I don't see anything supporting their expert's assertion that when you read aqueous pharmaceutical gatifloxacin eyedrop solution, you exclude every single component that could be in that solution except for gatifloxacin, because that's what

their expert declaration has put in, that's the extrinsic evidence and there is no support for that in the intrinsic record.

THE COURT: Tell me something. In the original claim 6, it referred to gatifloxacin eyedrop solution, did it not?

MS. MAZZOCHI: It says, a method for raising corneal permeability of gatifloxacin, which comprises incorporating disodium edetate into eyedrops containing gatifloxacin or its salt.

So I think if you look at how the language is being modified there, I think it's fine to say, well, what you are going to be focusing on in the aqueous humor is just the gatifloxacin, because I think the language is then clear that what they are saying is we want to raise the corneal permeability of -- of what? Of gatifloxacin.

In re-examined claim 6, they've now come back and they said, a method for raising corneal permeability of an aqueous pharmaceutical gatifloxacin eyedrop solution comprising. So they really have changed the nature of what is supposed to be subjected to this method for raising corneal permeability.

THE COURT: And so is this really a claim construction argument or is it something different than that? I mean, I guess I'm trying to figure out where this

all comes -- where the rubber meets the road here.

MS. MAZZOCHI: Sure, your Honor. And I think it really boils down to more the question of, can they prove each and every element of the claim language.

We have never perceived this as being a genuine claim construction issue because I don't think the -- because we don't think that there's anything ambiguous about what does it mean to be an eyedrop solution that has got various components in it in that sense. They are the ones who are coming back and saying, see all that new language that we added.

You know, before we said of gatifloxacin, now we've really we've expanded it to cover gatifloxacin in solutions and other things that may be contained within it. They are now coming back and trying to say, oh, no, no. Just interpret that as gatifloxacin and to the exclusion of everything else that's in that solution, and there's simply no support for that premise in the intrinsic record.

THE COURT: All right.

MS. MAZZOCHI: Thank you.

THE COURT: Thank you very much. Food for thought.

I will let plaintiffs' counsel respond, if you care to, and whether it was intentional or not, the added

language seems to have added some...

MR. WEST: Your Honor, I have a short response to this.

What is being proposed is inconsistent with the intrinsic record. In fact, the sole example relating to corneal permeability in the specification only talks about increasing the corneal permeability of gatifloxacin.

The only arguments presented to the -- to the Examiner and the only finding made by the Examiner related to increasing the concentration of gatifloxacin in the aqueous humor. And certainly we agree with you your Honor, that the re-examined claim could not be any broader, and that was the point that I was trying to make in my original discussion.

So we don't, quite frankly, see where defendants are going with this art. We do believe it's inconsistent with the intrinsic record.

Thank you.

THE COURT: All right. Thank you.

I guess, unless someone told me that this was dispositive somehow, I will not change my normal practice and I won't include my claim construction in my post-trial opinion.

What other issues are there? Are there other claim construction issues, or do we go on to trial

issues?

MS. MAZZOCHI: I think we're at trial issues, your Honor.

THE COURT: Okay. Let me -- Tinna, can you hand these out? They're the trial schedule. Unfortunately, you were double-booked. You're now only single-booked. That's the good news. The bad news it's the week of our annual admissions ceremony and I've got an oral argument scheduled on that Friday, as I tend to schedule my claim construction arguments. So I'm hopeful that this is sufficient time. As a bench trial, if you think we need more time, we can start earlier and go later. You need to let me know. Generally, I do have 8:30 proceedings and 4:30 proceedings, but, you know, we can go to extremes if we need to.

All right. Why don't we go plaintiffs' most important trial issue, defendants' most important, plaintiffs' next most important, defendants' next most important, go back and forth and see where we end up.

So plaintiffs' most important trial issue.

MR. WEST: Thank you, your Honor. Frank West again.

THE COURT: Yes.

MR. WEST: We would like to address the intervening rights issue. We believe there's still one outstanding issue.

Specifically, your order granted Lupin leave to amend its answer to add intervening rights as a defense, and in light of the Court's ruling, plaintiffs also believe that Hi-Tech will make a similar request and that the Court may very well grant that request. But, in fact, Hi-Tech's counsel called yesterday and asked whether plaintiffs would agree to that, and plaintiffs informed Hi-Tech that they would consider it if Hi-Tech agreed to provide discovery of its basis prior to trial. Hi-Tech refused.

And so while plaintiffs respectfully disagree with your decision, your decision did not address our request for discovery should you grant them the right.

THE COURT: I think I said we would discuss it; right? Well, I meant to say we should discuss it. So we should discuss it.

MR. WEST: All right. Great.

THE COURT: What kind of discovery is left for you to take in connection with this?

MR. WEST: Well, your Honor, neither defendant ever identified a basis for the alleged intervening rights, so, quite frankly, if it's simply the filing of the ANDA, we did extensive research trying to find where there's case law to support the administrative act like a filing of an ANDA will be sufficient to support intervening rights. We couldn't find anything to that effect. So the case law

traditionally requires some indication that there was a -- of an actual sale, or offer to sell, importation.

THE COURT: I don't think we found any case law that didn't support it, just no case law.

MR. WEST: That is correct, your Honor. You are correct.

And so absolute intervening rights require them to have actually engaged in otherwise infringing conduct.

THE COURT: Which you accuse them of; right? Well, an ANDA is statutorily --

MR. WEST: ANDA is statutory -- you know, the preparation work for it is not considered. You know, it's exempt from infringement.

And what the statute actually states with respect to intervening rights is that they have made, used, sold, offered for sale or imported. It does not discuss ANDA. So for absolute intervening rights, it actually requires one of those conducts in which, as far as we know, they have not engaged in because that would have been -- that would have been infringement of our patent and we would have asserted damages, and we certainly would have been -- we should have certainly been put on notice of that. And also it would have violated FDA law, which presumably the FDA wouldn't permit them to sell unauthorized unimproved

products.

To the extent that they're possibly going to assert equitable intervening rights, that's based upon a substantial preparation to engage in infringing activities again. And the case law that we've been able to find talks about issues such as hiring sales personnel, whether or not they've made substantial investment in terms of manufacturing facilities devoted to the product, or whether there are existing and proposed contracts relating to the sale of these otherwise infringing products.

THE COURT: So just to cut to the chase here, what you need is a proffer to support their --

MR. WEST: Your Honor, we agree, but we'd like to know what evidence they're going to rely upon and, quite frankly, we'd like to depose the witness that they'll have at trial.

THE COURT: Right.

MR. WEST: Yes.

THE COURT: Yes. Okay. Well, let me hear from both defendants perhaps and see whether this was a wasted exercise on my part or whether there really is something to discover.

MR. CASTELLANO: Good morning, your Honor.

THE COURT: Good morning.

MR. CASTELLANO: I think plaintiffs are correct,

that at least with respect to Hi-Tech, since Lupin's motion did not pertain to us as well, we would, with the Court's permission, amend our answer.

I think the important point here is that plaintiffs have been on notice of this defense since March. We provided a response to their contention interrogatory that laid out the basis for our response -- for this defense, excuse me.

Specifically, Hi-Tech stated that, we contend that plaintiffs are barred from asserting the new and substantially changed claims during the ex parte re-examination against Hi-Tech under the doctrines of absolute and equitable intervening rights. Hi-Tech developed and manufactured the products at issue and prepared and filed ANDA numbers 203189 and 203190 before the ex parte re-examination certificate issued on October 25, 2011, and the new and amended claims became public.

So more than nine months ago plaintiffs were on notice of this defense, as Lupin noted in their briefs, and they conducted discovery with that knowledge, and they took the -- they noticed the deposition of several Hi-Tech employees and, in fact, took the deposition of our 30(b)(6) witness, who is our chief scientific officer, Dr. Egbaria.

In the notice of deposition, 30(b)(6) notice, they laid out numerous topics that could easily be

interpreted as going to intervening rights. They didn't specifically list intervening rights. But, for example, both of the ANDAs were topics that were identified for the 30(b)(6) deposition and related research development, manufacturing and testing of the ANDA products.

And then during the actual deposition they asked questions pertaining to those subjects, and I have a list here. But I mean --

THE COURT: Well, let me just make sure.

MR. CASTELLANO: Sure.

THE COURT: So your client, although you feel the need to amend your answer to actually assert intervening rights, which you never did until now, you presented it in a contention interrogatory, and the basis of your claim is that you made substantial preparations to actually make the product and then they came out with their re-examined claim? I mean, so there is something real happened. It wasn't just the filing of the ANDA?

MR. CASTELLANO: Correct, your Honor. Well, the ANDA itself is evidence of the substantial preparation that we made.

THE COURT: Well, theoretically, it is until the Federal Circuit tells me otherwise, because apparently there's not a whole lot of case law out there.

MR. CASTELLANO: Well, we also have the, you

know, the preparation activities that Hi-Tech actually performed, which we expect Dr. Egbaria to testify about and which plaintiffs were free to ask about at the deposition.

We believe -- I mean, just to go to your question about not amending our answer in terms of our, why we think this is in the case, we thought it was in the case as of March when we put it in our contention interrogatory response. We think it's subsumed under our noninfringement affirmative defense. But to the extent that the pleadings need to be amended now to bring them in line with the evidence that's going to be presented, we'd be happy to do that.

THE COURT: But you have an objection to -- in order to make sure that we're all on the same page at the same time, your client has an objection to having a short -- a supplemental focused 30(b)(6) deposition of your witness that goes directly to intervening rights so that -- I mean, I don't like surprises.

It strikes me that under the circumstances, it's not unreasonable to allow a three-hour deposition of this witness before he takes the stand.

MR. CASTELLANO: Well --

THE COURT: Because you have to introduce affirmative evidence; right? It's your defense.

MR. CASTELLANO: That is true, your Honor. And we would oppose an additional deposition. And in terms of the testimony that was actually sought at this deposition and given at the deposition, it included many pages of testimony about the testing done on the active pharmaceutical ingredient in the ANDA and on the actual ANDA products themselves, the decision to proceed with the development of the product, the process validation for the product, the sourcing of the API from a third party, plans to launch.

And it also included testimony about the Hi-Tech's knowledge of the '045 patent and the re-examination which, according to plaintiffs in their briefs, are actually relevant to the intervening rights question.

THE COURT: So you think the discovery has been done?

MR. CASTELLANO: I think they had the opportunity to do it, and if they didn't get it, that shouldn't be the -- the burden of their failure to do so shouldn't be placed on us at this time.

THE COURT: Well, I'm the one on the line here, so, okay. All right. Well, thank you very much.

I mean, it strikes me that under the circumstances, particularly with Hi-Tech and with the

contention interrogatory out there, I will hear from plaintiffs' counsel first. But it strikes me that this is not an unreasonable request to amend the answer if we need to to make the pleadings consistent with the discovery.

MR. CASTELLANO: Thank you. Your Honor, I will just add one quick thing.

THE COURT: Yes?

MR. CASTELLANO: We don't intend to introduce any additional documents. Everything we intend to rely on this for documentary evidence has already been produced and is on our exhibit list, so there will be no comprises in that regard.

THE COURT: Okay.

MR. CASTELLANO: Thank you.

THE COURT: All right. Let me hear from counsel for Lupin about additional discovery, and then I will get back to plaintiffs' counsel in terms of where we stand here.

MS. MAZZOCHI: Sure, your Honor. For what it's worth, I'm not going to belabor the points. We received similar deposition topics from the plaintiffs. We presented a 30(b)(6) witness on the preparation of the ANDA. They deposed three individuals as well who had knowledge about the ANDA preparation efforts. You know, for example, the

biostudy. That's obviously not an inexpensive undertaking. It's used to support the ANDA.

But, you know, we offered to the plaintiffs in the spirit of compromise, we would try -- so that we wouldn't have to bring it up in front of the Court, that we would give them a deposition, you know, briefly if they thought there was really something knew that they hadn't covered before.

We're happy -- you know, we're happy to do that if that takes the burden off the Court, a three-hour deposition, but, again, we're not planning on introducing any new witnesses or any new documents that we hadn't already produced before and any new witnesses who hadn't already been deposed before.

THE COURT: Well, I guess, depending on what the defendants' answer -- defendants' answers are to this question, there may or may not be a need for additional discovery.

If, in fact -- I understand there are no new documents, but I guess the question is, is there additional testimony that you all would want to present specifically to carry your burden of proving intervening rights? And, if so, I don't want any surprises. I think that the plaintiff should be able to take a deposition and make sure it understands the scope.

If, in fact, what you are saying is even though intervening rights wasn't specifically, arguably wasn't specifically in the case, that all you're relying on is the evidence with respect to your ANDA preparation and there's nothing more, then I'm not confident any further discovery is necessary.

So I mean if you are not sure, then I think we need to take a deposition so everyone understands what the scope of the defense is.

MS. MAZZOCHI: Right. And, you know, I'm not trying to speak on behalf of --

THE COURT: Right. I will go back to them.

MS. MAZZOCHI: -- of Hi-Tech. I don't know if there's anything supplementary that has occurred, you know, in the last couple of months, but certainly when we were contemplating substantial preparation, we were, in fact, focused on the substantial preparation that is needed to actually get the ANDA together and filed. Those are fixed costs. They're irretrievable costs.

So, you know, we think that -- and we think that when it comes to the dates of the re-examination and the notice that we had or lack thereof, particularly in view of when the timing of this Court's invalidity decisions, you know, we don't think there needs to be any discovery on those particular issues.

So maybe what might be the most prudent way for us to go about it would be to identify to the plaintiffs, do we think there's anything more, you know, separate and apart from the ANDA that we think we would introduce at trial that hasn't been previously identified. If there is, then we certainly would identify it. You know, we can agree to identify it no later than Monday, and then if they want to take a brief deposition on that new material, we'd be happy to let them take a new deposition on that score.

THE COURT: Okay.

MS. MAZZOCHI: I think that's fair.

THE COURT: All right. Thank you very much.

MS. MAZZOCHI: Thank you.

THE COURT: Let me go back to counsel for Hi-Tech before I go back to plaintiffs' counsel.

And I guess the question is this. If there's any evidence besides the evidence that is in the record already that you might be introducing, then there needs to be a deposition, because I'm not comfortable with the fact that the issue was kind of there but not really, and I want to make sure that, right or wrong about the substance of allowing it to go forward, I at least want there to be a fair record.

MR. CASTELLANO: Well, I think we would in general agree with the position of Lupin, although I would

say that pursuant to your Honor's rule about introducing documentary evidence through a witness, we would need, if we're going to a rely on the ANDA as the operative evidence for this defense, we will need to use a witness to introduce the relevant portions and to give it context. And to the extent those specific points were not raised at deposition, you know, we don't think there's a need for a deposition on that point. They have the ANDA. They know what's in it. We don't intend to have additional editorial testimony from the witness about it, of them to simply explain what it is. But I think most likely that would be the only thing beyond what's already in the record.

THE COURT: Well, I think by Monday both defendants need to identify the witness that you are going to use to introduce whatever this evidence is, and if they have not been queried about what you're going to be presenting, then plaintiffs can take a three-hour deposition of each one some time before trial, or at least some time before they testify.

MR. CASTELLANO: All right. Thank you, your Honor.

THE COURT: Thank you. All right.

Well, let me hear from plaintiffs' counsel. I mean, it strikes me that I have gone down this path, and I think at this point I will allow Hi-Tech to amend so that

the defendants are proceeding consistently, and if I'm wrong, I will certainly hear about it.

MR. WEST: I would just like to address a couple of points that both the defendants made. They said that all the exhibits they would be relying upon are on their exhibit list. Their exhibit list is 1,275 exhibits long, so we would have no clue what they are relying upon simply by that and my understanding is they'll be identifying the documents for us now.

To the extent they're relying upon the ANDA, well, that's thousands of pages long, so we don't know again what they're relying upon within the ANDA.

As for the deposition topics, the deposition topics for the 30(b)(6) witnesses, we had discussions with both defendants after those topics were served and removed topics that related to the finances, business, marketing, investment, because of Judge Thynge's order in January, which we briefed in the papers.

Judge Thynge -- the parties agreed that we would not be producing financial or cost for marketing data, and Judge Thynge agreed that we didn't have to produce that data as long as neither -- as long as plaintiffs weren't relying upon commercial success and as long as the defendants were relying upon a defense that required the presentation of that data. But she informed everyone that if that changed,

it was incumbent upon that party asserting that defense or that claim to provide the discovery. And, quite frankly, they are now asserting it, but they never provide the discovery, which I think is in contradiction of her order.

THE COURT: Well, I don't know whether they're contradicting it because I don't know that they're talking about financial data. But the point is this. And maybe I will amend this.

By 12/28, which I think is the Friday after Christmas, is it the Friday after Christmas, the defendants have to identify the witness or witnesses who is going to talk about this defense and the documents, and then you can decide whether you want to take your three-hour deposition.

MR. WEST: All right. Thank you, your Honor.

THE COURT: Thank you very much.

All right. I think we're going to defendants for their most important issue that's left. Oh, and I guess we need to get some kind of a motion or whether it is sufficient on the record about Hi-Tech being able to amend its answer, if it's necessary, to assert intervening rights. We need to have something with or without the transcript.

MR. CASTELLANO: Well, your Honor, we'll make the motion now on the record to amend both of our answers.

And we can file something, if you would like.

THE COURT: All right. It's granted consistent with our discussion.

MR. CASTELLANO: Thank you, your Honor.

THE COURT: All right. So what's the next issue from defendant?

MR. WADHWA: Good morning, your Honor.

THE COURT: Good morning.

MR. WADHWA: Anuj Wadhwa on behalf of Lupin.

Prior to this morning's conference, plaintiffs indicated that they would not be raising prevention of precipitation as a secondary consideration.

THE COURT: Number 1 is off.

MR. WADHWA: Number 1. I believe it addresses number 6 as well as well as their topic number 5.

THE COURT: Okay.

MR. WADHWA: We would just like some clarification based on that statement about certain witnesses that would be testifying at trial.

It's our understanding that Dr. Mahnken and Dr. Curatolo relate specifically to secondary considerations and so we would like confirmation they will not be testifying.

In addition, there are fact witnesses. Dr. Jamules (phonetic), Mr. Iemoto, and I believe Dr. Inada was also a prevention and precipitation witness. So we'd just

like confirmation on that issue.

MR. KELLY: Your Honor, perhaps later we could talk about the schedule because Mr. Wadhwa is correct, we will not be bringing on to testify Dr. Curatolo, Ms. Iemoto or Mr. Inada to talk about precipitation, and no one else is going to talk about precipitation unless the defendants raise it as well.

THE COURT: Okay. All right.

MR. WADHWA: Thank you.

THE COURT: Thank you. All right. Does that mean we're back to the plaintiffs for your next issue, or is there another --

MR. KELLY: Your Honor, if it please the Court, last week, Ms. Keller, on behalf of Hi-Tech, raised the question of whether or not we had properly vetted the issue of doctrine of equivalents infringement with respect to their claim 6, and, in particular, whether or not our expert reports, or report, actually went to that. And we were rather surprised because Dr. Stella, in two paragraphs, 134 and 159, specifically went to the question.

And the issue is, in claim 6, the EDTA is added to a gatifloxacin solution, and Hi-Tech actually reverses it and adds the gatifloxacin to a solution containing EDTA.

And our position is that is the equivalent for a variety of factual reasons, which we shouldn't bore the

Court with. But they're challenging whether or not our expert report was sufficient to have someone testify on this.

And what Dr. Stella specifically says, while Hi-Tech adds gatifloxacin to the solution after the addition of disodium edetate, I'm informed by counsel that case law permits the steps of a process, i.e., order or addition to be changed and infringement to be found.

It is further my opinion that when the addition of disodium edetate occurs before or after the addition of gatifloxacin, the same increased permeability would be obtained with that identical solution but without sodium edetate and would be achieved in the same manner by including sodium edetate in the eyedrop solution containing gatifloxacin.

So he has provided an explanation as to why the function, way, result test for doctrine of equivalents. We didn't exactly put a heading over doctrine of equivalents. That's what he explained. And so we'd like, you know, the issue of whether or not we can present it to be resolved one way or the other.

Ms. Keller did refer us to a decision by Judge Sleet to support its position, Edwards Life Sciences v. Corevalve. It's completely different facts, your Honor.

THE COURT: Well, I was just going to say,

generally, experts use the right words and don't give you any substance. Here, it sounds like the expert gave you some substance and just didn't use that heading.

So I mean I guess I need to hear from defendants, but it strikes me that's a doctrine of equivalents argument.

MR. KELLY: Thank you, your Honor.

THE COURT: Okay.

MS. KELLER: Your Honor, plaintiffs' conclusory expert statements and barebones interrogatory responses are insufficient to assert this claim.

THE COURT: Well, as I said, though, that was much less -- I mean, well, so forget the interrogatories.

MS. KELLER: Sure.

THE COURT: I'm focused on what was read to me, and he says that the order of adding ingredients is an insubstantial change. Now, to me, that's more than I get from a lot of experts, but you're saying that's insufficient, that there should have been more, or you're saying that because the phrase doctrine of equivalents wasn't thrown in there, that it's insufficient?

MS. KELLER: No. I think, I think, your Honor, we agree, plaintiffs do not need to use any kind of magic words or specific language, but they did need to present

evidence to establish what function, way and result of both the claimed invention and the accused products are, and why those functions, ways and results are substantially the same.

The Federal Circuit has said that they must present evidence and argument concerning the doctrine in each of its elements. It cannot be subsumed in their literal infringement argument. They need to rely on a detailed description supporting this doctrine of equivalents argument that links the argument as to the insubstantiality of the differences between the claimed invention and the accused product to the present evidence on a limitation-by-limitation basis.

In this situation, your Honor, Dr. Stella's report is very broad and in this section is actually addressing literal infringement. The order -- and whether the order of -- the claim language -- let me take a step back here, your Honor.

The claim language that is at issue here is the limitation that it incorporate about .01 percent weight, .01 weight per volume percent disodium edetate into said gatifloxacin eyedrop solution. And as plaintiffs mention, Hi-Tech does not incorporate the disodium edetate into gatifloxacin solution, but instead incorporates the gatifloxacin into the disodium edetate.

So what plaintiffs are trying to do here is make a doctrine of equivalents argument out of what is their literal infringement argument, and the Federal Circuit has been clear that you cannot subsume this -- their doctrine of equivalents argument into a literal infringement argument.

Dr. Stella's report does not provide any limitation-by-limitation discussion.

THE COURT: But isn't that discussion limited to one part of the limitation, the incorporation?

MS. KELLER: I mean, one could maybe postulate that that is true, but when Dr. Stella went into his claim charts, there's, again, no mention of this doctrine of equivalents supposed argument that they're making. There's no mention of doctrine of equivalents in the standards section of Dr. Stella's report. There's no further mention of the order, possibility of the order changing within the claim charts of Dr. Stella's report.

And the interrogatory response, I know your Honor said to not be concerned about that at this point, but as far as notice goes to Hi-Tech of this doctrine of equivalents argument, was a form generic response that they're relying on literal or infringement or under the doctrine of equivalents. And all of their subsequent analysis contained no claim chart or element-by-element

analysis under the doctrine of equivalents, no description of how the accused ANDA products meet the function, way, result test or the insubstantial differences test in any way whatsoever. It was solely based on a literal infringement argument.

THE COURT: Well, tell me something. Did your -- clearly, the language that was read to me was in the expert report, and did your expert respond to that?

MS. KELLER: No, your Honor, because as far as our reading of this, this was solely with regard to their literal infringement argument and they were trying to argue that there can still be literal infringement even if the order is changed.

THE COURT: And he didn't say there couldn't be literal infringement if the order is changed?

MS. KELLER: No, your Honor.

THE COURT: Well, so I'm, quite frankly, here we are again. I'm not sure -- so you've got one expert saying, under the heading literal infringement, you can literally infringe, and it does not matter whether you -- what order you add the ingredients?

MS. KELLER: To be fair, your Honor, there's no heading that says literal infringement. I think it's just infringement.

THE COURT: Okay.

MS. KELLER: But there's no mention of anything other than literal infringement.

THE COURT: Okay. So you've got one expert saying there's infringement regardless of which ingredient is added first. You've got another expert saying nothing about the order of incorporation.

MS. KELLER: Correct. Our expert -- and correct me if I'm wrong, I will defer to Jeff Castellano here, but the defendants' experts are opining primarily that plaintiffs have not met their burden to prove infringement.

THE COURT: Well, I'm, frankly, not sure whether there's a doctrine of equivalents issue at all, and at this point I'm going to allow the expert to testify and see what shakes out, because I'm not -- if you don't have to use the words and there was clear notice that the order, that one expert says the order of how you add things isn't important, then it strikes me that there's no unfair notice as to the facts of his expert opinion. And I'm not sure the label, you know, I'm not sure how to handle this without hearing the testimony.

So I'm not committing to saying that that isn't a bona fide doctrine of equivalents argument, but certainly I'm troubled by the fact that it was in the report and that,

you know, it was not responded to buy other experts. I'm not quite sure what to make of that.

So the testimony can come in and I will just do with it what I do at the end of the day. All right.

MS. KELLER: Just to clarify, your Honor, I think we requested the testimony be consistent and limited to the scope of what's in the paragraphs of his report.

THE COURT: Well, certainly, that's true. You can't expand on it. He said this and that's all he can say. All right?

MR. KELLY: We understand, your Honor.

THE COURT: All right.

MR. KELLY: Thank you.

THE COURT: All right. Good.

All right. So I don't know where we are. I guess defendants' next issue.

MR. POLIVICK: Good morning, your Honor. John Polivick for defendants.

THE COURT: All right.

MR. POLIVICK: I've going to be addressing Dr. Mayo's, one of plaintiffs' statistical experts, failure to disclose data that he used in one of his analyses, and it is his correspondence to plaintiffs' miscellaneous issue number 9 and defendants' miscellaneous issue number 2.

Dr. Mayo, again, plaintiffs statistical expert, performed several statistical analyses that were described in his expert reports. For all but one of them, he disclosed the exact data that he analyzed, but for one of them, he did not.

Now, for that study, he, it was -- well, Senju, one of the plaintiffs, conducted a series of corneal permeability studies. They were separate, small corneal permeability studies and plaintiffs purportedly produced the underlying data for those studies to us. That was in the form of a 1600-page document that contained just basically numbers indecipherable to a normal person.

And Dr. Mayo took some of the data from some of those studies and some data from other studies. We don't know which studies. We don't know what data. But he picked this data from the 1600-page document and he combined it all together. He then built his own statistical model for the purposes of this litigation, stuck the secret data into his model, and out comes this conclusion, which obviously supports plaintiffs' positions.

We deposed Dr. Mayo and asked him what data he used. He doesn't know. We gave him the 1600-page document and said, could you point to the data that you used. He couldn't do it. Well, why couldn't he do it? Because he had help. Who helped him? He doesn't know. Was it

somebody from plaintiffs' counsel's firm? He does not know. Somebody from one of the plaintiffs? He doesn't know. Apparently, this person had some familiarity of the underlying studies, but he didn't know who they were.

So did he select the correct data? We have no idea. We don't know what data he selected. And you won't hear us cross-examine Dr. Mayo about the specific issue because he has shielded himself from any effective cross-examination.

Did he -- assuming he could pick the correct data, did he analyze it appropriately? Nobody knows. Nobody knows what he did. Our experts would love to have this data so that they could analyze it under whatever methods they think are more appropriate and then they could tell you what the answers would be under that situation. But, again, he has shielded himself from any real criticisms because the data he used has always been a secret.

Did he make some simple mathematical error? Again, nobody knows. We basically have to trust Dr. Mayo, that he selected the correct data, he analyzed it appropriately, his math was perfect.

And so his analysis of this data has not been properly vetted through the discovery process. He has shielded himself from any criticisms. They failed to comply with Rule 26, which requires the mandatory disclosure of the

facts and data the expert relied upon.

THE COURT: So do I need to review his deposition because attorney argument is not going to help me at all.

MR. POLIVICK: Sure. I have it right here.

THE COURT: Okay.

MR. POLIVICK: I can show you portions or read in portions.

THE COURT: No. Don't read in portions. I think it's something I want to take a look at and I will get back to you on this.

But I think what I need is whatever the -- I need the deposition highlighted by both defendants and plaintiffs so that I get the full scope of what you all are claiming he knew and didn't know and whether there really has been a fair opportunity to vet his statistical analysis. I think as much as I'd love to hear you argue, I don't think that's going to be helpful to me.

So you will need to work with plaintiffs' counsel to get me one copy with highlighting. I like highlighting. I need colors to keep me awake. So highlighted deposition or depositions, and just produce it to me in the next week or so so that we can take a look at it and get it back to you well before trial.

MR. BAXTER: May I offer a few comments with

regard to plaintiffs' side?

THE COURT: Well, sure.

MR. BAXTER: Thank you.

THE COURT: Unless you're saying defendants are correct, I'm not sure what it's going to add to the deposition.

MR. BAXTER: Well, it refers to other opportunities the plaintiffs had to ascertain this information, or defendants had to ascertain this information.

Plaintiffs first identified the document in question last January, almost a year ago. In response to two interrogatories by defendants, one with regard to reduction to practice, a second interrogatory with regard to secondary considerations, Senju identified only two documents, the report in question and the 1600-page raw data, the data used. Those were the only two documents that Senju indicated related to reduction to practice the experiments in the patents, or unexpected results.

Last April we received a 30(b)(6) notice, and many of the topics covered reduction to practice and the unexpected results despite the fact -- and we noted that we designated Mr. Inada, one of the inventors of the patent, to address these topics. Despite the fact that we had only identified these two documents as relating to conception and

reduction to practice for the examples of the patent and the unexpected results, defendants didn't even mark those documents as exhibits during the 30(b)(6) deposition. They didn't ask him a single question about the data underlying the Table 7.

THE COURT: He's not the one who did the --

MR. BAXTER: He was the one who was designated to talk about the -- the explanation, recordation in the notebook. Now, Mr. -- Dr. -- later on, and another thing is they first received Professor Mayo's expert report in August. They didn't raise this question about which specific pages from the 1600-page document he pulled the data from until during his deposition. And even after -- and he just couldn't remember at his deposition. He told them he had the information back in his office. They never followed up.

We've never denied them the opportunity to ask which specific -- you know, we told them this document in January. We gave them a 30(b)(6) witness on this document. And the expert said he had the specific page numbers in his office. He just couldn't remember the specific page numbers during his deposition.

THE COURT: So despite all this back and forth, you just didn't come forward and say, listen. If there's any problem, these are the pages that I used to perform this

analysis? Has it just been simmering, and so here we are a couple weeks before trial?

MR. BAXTER: They never followed up until we got this notice. We're willing to give them those pages.

THE COURT: Well, why don't you do that.

MR. BAXTER: Yes.

THE COURT: And then we'll see if there's an issue. If there's an issue, I will need to see his deposition. So you need to do that promptly.

MR. BAXTER: Okay.

THE COURT: All right. Then I will need to see the deposition if there's still an issue.

And, quite frankly, I mean, I have not seen the deposition. Whatever questions he couldn't answer in the deposition, you need to provide the information. And under those circumstances, if I'm going to allow him to testify, once again, there might be a need for a short re-deposition.

MR. BAXTER: We understand.

THE COURT: All right. All right. So what's the next issue? I think it's plaintiffs' turn.

MR. KELLY: You're right, your Honor.

Again, if it please the Court, the issue we have is that we went through the entire case with defendants never raising an issue of enablement at all, not in any

interrogatory responses, and, in fact, Lupin affirmatively said they weren't raising an enablement defense.

And in the opening expert reports of the defendant on the invalidity question, there's no question -- nothing is raised about enablement. And when we get the expert reply report of Dr. George M. Grass, at paragraph 20, for the first time, we see raised enablement.

And we think that this is simply, they waited too long to raise this, especially when Lupin affirmatively stated they weren't raising it as recently as October 9th, I believe, of this year. And --

THE COURT: So enablement wasn't raised until the reply?

MR. KELLY: That's correct, your Honor. A month later, on November 9th, 2012, or at least that's the date it's dated. So we just think that's not fair, to at this point be bringing in enablement as a defense.

THE COURT: All right. Let's hear from defendants' counsel. It sounds late when you've got the burden of proof.

MR. WADHWA: First off, your Honor, I'd like to just clarify that our interrogatory responses actually say, at this time we are not currently asserting any enablement defenses under 112, but we reserve the right to in the future. Notwithstanding that, I believe that this is just a

mischaracterization.

In Dr. Grass' August 27th report, he provides an analysis of the prior art. In rebuttal, Dr. Stella, plaintiffs' expert, in his October 12th report, says, look at all these tests that provide secondary consideration of unexpected results. In Dr. Grass' November 9th reply report, he says, look. I've looked at all these tests, and these tests do not support your contention of an unexpected result.

THE COURT: No longer in the case.

MR. WADHWA: I'm sorry?

THE COURT: Unexpected results are no longer in the case.

MR. WADHWA: Well, unexpected prevention of precipitation, but with respect to claims 12 through 16, they're still asserting a secondary consideration of increased corneal permeability as a secondary consideration.

So Dr. Grass has looked at all of these studies that Dr. Stella raises for increased permeability as a secondary consideration of unexpected results and said these studies don't support what you're trying to say.

Now, to the extent that Dr. Stella is going to come in and give testimony or any other factual assertions coming in at trial that may support a 112 defense, we're certainly going to reserve our right under Federal Rule of

Civil Procedure 15(b) to ensure that the final judgment informs with the proof presented at trial.

THE COURT: Isn't that inconsistent with the whole notion of expert reports and fair notice and vetting discovery?

MR. WADHWA: Well, your Honor, I believe that Dr. Grass' statements were simply in rebuttal to Dr. Stella's assertion of secondary considerations, so I believe that they were timely.

THE COURT: Well, but that's a different thing than saying lack of enablement. I mean, to say that your evidence regarding secondary considerations isn't viable, isn't believable, is wrong, is different than saying these are not enabled. I mean, that's -- you know, that's a whole different instruction. So I'm not confident that you can affirmatively assert a defense as opposed to asserting a defense to their defense.

MR. WADHWA: Well, and I think Dr. Grass' reply report simply says that. He's only talking about these studies at this point and is saying these studies are not adequate.

THE COURT: All right. Well, that's different than lack of enablement. I don't think you've properly raised lack of enablement. If you want to preserve your right at some point in trial to say you think you did,

that's fine. But to assert enablement as a separate defense that I have to address, I don't think that has been done properly. Okay?

MR. WADHWA: Okay.

THE COURT: All right. All right. Defendants' next issue, if there is one.

(Pause.)

THE COURT: I only see number 5. Is that still at issue?

MS. MAZZOCHI: Your Honor, I think we've completed the things that were on our list, so the only remaining issues are on plaintiffs' list. But one thing I did want to address with the Court, and we can certainly do that now, is going to be the actual order of trial.

Our understanding is that, and I don't know whether plaintiffs are going to agree or not, but because there are both infringement and invalidity issues in the case, we would assume that the plaintiffs would go first, put on their infringement case. We would then go next with our witnesses, who would respond to infringement, put on our invalidity case. Then they would put on whoever they're going to call to do secondary considerations in rebuttal to our infringement case, and then we will have a brief opportunity to respond to their secondary considerations evidence.

THE COURT: It sounds right to me.

MS. MAZZOCHI: Okay. Just making sure on that.

THE COURT: Yes.

MS. MAZZOCHI: Thank you.

THE COURT: Yes. Thank you.

All right. It's in the plaintiffs' court again.

MR. PHILLIPS: Your Honor, just to be clear on the record, you were asking about number 5 on defendants' list. We think that's subsumed under the precipitation agreement.

THE COURT: Oh, okay. Thank you very much, Mr. Phillips.

MR. PHILLIPS: Thank you.

THE COURT: I crossed it out, but I didn't quite know why. Thank you.

So plaintiffs have a lot of issues left.

MR. WEST: Your Honor, you'll be pleased to hear this is going to be the final issue we'd like to raise.

THE COURT: Oh.

MR. WEST: And this relates to number 7 and whether or not the defendants should be permitted to rely upon combinations that their experts didn't include in their expert report. And subsequent to the filing of the pretrial order, we also received the defendants' 282 notice, and we,

quite frankly, would just like confirmation also that combinations that weren't set forth in the expert reports, again, would not be relied upon to assert obviousness. And that's really the only issue here.

THE COURT: It sounds like an easy one, but let me hear from defendants.

MR. WADHWA: Your Honor, I think what Mr. West just raised is a different issue than what's listed in number 7.

THE COURT: Well, I think it's two issues.

MR. WADHWA: Okay.

THE COURT: Number 7 plus the 282 notice.

MR. WADHWA: And with respect to that, we certainly have no intention of raising any new combinations of prior art that are not in the pretrial order or interrogatories or, you know, previously presented in the papers.

THE COURT: Well, they have to be presented by the expert, I think.

MR. WADHWA: And presented by the expert.

THE COURT: All right.

MR. WADHWA: That's correct.

THE COURT: Okay. All right.

MR. WADHWA: And then with respect to number 7, these two particular references, I didn't really hear

Mr. West's opinion on them, but --

THE COURT: I think they said that the combinations themselves weren't addressed by your experts. That's what I understood.

MR. WADHWA: I don't think that necessarily goes to the admissibility of these two articles and our experts are not relying on these two particular references for any combinations of anything we're relying on. I think that that addresses the issue.

THE COURT: Beats me. Does it?

MR. WEST: I believe so, your Honor.

THE COURT: Okay.

MR. WEST: As long as they're not relying upon combinations outside the expert reports, we're fine.

THE COURT: Okay.

MR. WEST: Thank you, your Honor.

THE COURT: All right. All right. So the trial -- are there any other issues that we should be addressing now? Is the trial schedule -- Mr. Kelly, you mentioned something about the trial schedule being too short, too long?

MR. KELLY: Not too -- not too -- we have dropped -- by dropping the secondary considerations, we've dropped three witnesses off the top of my head, which should actually shorten the amount of time. The only thing --

that would normally tell me to tell you that we don't need all these days, but we've got 1200-some-odd exhibits from the other side, and looking at their pretrial order, it seems like they want to retry the Apotex case and simultaneous invention and everything. If that's the case, it probably would take four days. It might not go Friday.

THE COURT: All right. I won't take any time away from you.

One thing you need to let me know, sometimes in bench trials, and I don't want to put an added burden on Valerie.

I allow -- when I'm looking at your designations for depositions, they seem extremely long, and I don't what you actually intend to do with that once you get down to the nitty-gritty. But I, quite frankly, find depositions read in court helpful. I pay attention. Although I will read them, it's just better for me to hear that information.

But I'm willing, if you've got hours and hours of depositions to read or play in the court, to give you each two hours to submit, of deposition, to her to include in the transcript as though they had been here or read here. I don't think it's as effective way to present testimony, and I don't want any -- but, nevertheless, and I don't want, I don't necessarily want controversial testimony to go in that way or critical documents to come in through that.

But talk to each other.

All I'm saying is, talk to each other on the first day of trial. Certainly, we can talk about supplementing the in-court record with deposition designations if you both agree that it's appropriate and we can put some fine-tuning to it.

MR. KELLY: Thank you.

THE COURT: Okay? And I actually didn't mean to say two hours each party, because that would be a lot. But two hours combined, everybody. If there's two hours of deposition designations that you find are necessary for your record, but not -- anyway, all right. That's the offer out there.

All right. What else do we need to address? Yes?

MS. MAZZOCHI: Your Honor, the one thing, if I could just respond in terms of a number of exhibits, since that seems to have been a concern for the plaintiffs, is that we had submitted to the plaintiffs recently, we took some of your Honor's proposed findings of fact from the Apotex case, submitted them to the plaintiffs to say, will you stipulate to these facts, and they have declined to do so as of today.

So one of the reasons why we essentially included on our exhibit list all of the materials from the

Apotex case is that if they're really not going to agree to your Honor's prior filings, you know, or your Honor's prior findings. You know, I mean, we're not looking to retry the Apotex case, but plaintiffs' position at this point in time is essentially going to obligate us to put more of that evidence back into the record than we think we otherwise should have to.

THE COURT: All right.

MR. KELLY: Your Honor, we received that -- we had extensive discussions on agreed-to facts, stipulated facts that are in the pretrial order. There was a lot of give-and-take. This list, which is over a hundred, comes in Saturday night. And, quite frankly, there are things in there that we will try to agree to, we'll try to reach out. There are things that we don't agree with.

And they have truncated some of your Honor's rulings, which leaves us a little bit concerned, because the prior art here, we're dealing with a different claim. But we certainly intend to go through that list and see if there's a way that we can.

THE COURT: Okay.

MR. KELLY: There are some things we'd like them to stipulate to as well to make this an easier case.

THE COURT: All right. Well, I'm satisfied that you'll operate in good faith and try to present this fairly

and efficiently.

MR. KELLY: Thank you, your Honor.

THE COURT: And not re-do facts that shouldn't be in dispute. Not necessarily my findings, but anything. Okay.

Counsel, to the extent you can, have a wonderful holiday season, and I look forward to seeing you next year. Thank you.

(Counsel respond, "Thank you, your Honor.")

(Court recessed at 10:28 a.m.)

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