IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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ELAN PHARMA INTERNATIONAL LIMITED,	:	Civil Action
Plaintiff,	:	
v.	:	
ABRAXIS BIOSCIENCE INC.,	:	
Defendant.	:	No. 06-438-GMS

- - -

Wilmington, Delaware
Thursday, May 29, 2008
11:30 a.m.
Telephone Conference

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge

APPEARANCES:

JOHN G. DAY, ESQ.
Ashby & Geddes
-and-
PAUL FEHLNER, ESQ.,
STEPHEN SCHEVE, ESQ. (Houston, Texas), and
JEFFREY SULLIVAN, ESQ.
Baker Botts LLP
(New York, New York)
-and-
GREGORY BOKAR, ESQ.
Counsel - Elan Drug Delivery

Counsel for Plaintiff

APPEARANCES CONTINUED:

MICHELLE BUDICAK, ESQ.
Young Conaway Stargatt & Taylor, LLP
-and-
MICHAEL A. JACOBS, ESQ., and
EMILY EVANS, ESQ.
Morrison & Foerster
(San Francisco, California)

Counsel for Defendant

THE COURT: Good morning, counsel. Counsel, who is on the line for Elan this morning?

MR. SCHEVE: Good morning, Your Honor. From Elan this morning you have John Day at Ashby & Geddes locally, Steve Scheve, Jeff Sullivan, and Paul Fehlner from Baker & Botts, and also Greg Bokar, Elan's vice president for intellectual property and litigation.

THE COURT: Good morning. For Abraxis.

MS. BUDICAK: Good morning, Your Honor. Michelle Budicak at Young Conaway, Delaware counsel for Abraxis. With me on the line is Michael Jacobs of Morrison & Foerster, as well as Emily Evans from Morrison & Foerster.

THE COURT: Good morning. Counsel, is it the case that both sides asked for the call or one or the other?

MR. JACOBS: This is our initiation, Your Honor.

THE COURT: Mr. Jacobs, go ahead.

MR. JACOBS: Your Honor, I am on a speaker. I will try and make sure we don't over-speak the Court. We

are set up over here. The trial site isn't perfect yet.

The Court may have seen the filings that have been coming in, the notice of service. We have gotten six additional expert reports from Elan since the pretrial conference. It's rather extraordinary. They range from a damages report to a new theory of infringement to an expert report by an expert, Berkland, on critiquing x-ray powder diffraction. The Court's order on our Motions in Limine 1 and 4 ordered that only Brittain could critique our x-ray powder diffraction.

We think that the standard for supplemental or additional expert reports in the week before trial should be really, really, really good cause. And Elan can't possibly meet that standard.

We would ask that the Court strike these expert reports.

THE COURT: Go ahead.

MR. JACOBS: If the Court would like, I could detail a little bit more our concerns with these reports.

THE COURT: Let's get a general reaction. I will take that as a general opening comment. Let's see if we can short-circuit this. Maybe we won't be able to.

Mr. Scheve.

MR. SCHEVE: I will do my best, Judge. Thank you for taking time from what I know is a very busy

schedule.

Judge, I need to give you a little background.

You will recall at the pretrial conference an issue arose about a witness named Katherine Melody, who is with a company called Micron Laboratories. Since the initial Rule 26 conference in this case, Abraxis has taken the position, both with Elan and with the Court, that the product is amorphous. It was not until February 1, 2008, five and a half months after the close of discovery, and without ever identifying Ms. Melody in responses to discovery, that Abraxis listed her as a witness for them in the case and produced four discrete, edited or cropped pages from some lab notebooks which purport to support their x-ray powder diffraction evidence in this case.

We moved to exclude her, Your Honor. Your Honor said that she would be allowed to testify, but you said that she must be produced for deposition.

Her deposition was taken last Wednesday, May the 21st. It was a bombshell, and undercuts everything that Abraxis has been telling Your Honor and the world since the start of this case.

She testified that Micron Labs routinely advises its clients that in order to have interpretable data one needs to have two things: particle size standards and limits of detection. She says that they are advised of that

because these are spelled out in the United States Pharmacopeia.

Abraxis did not do the control testing to allow anyone to determine crystallinity in Abraxane. They did no particle size standards. They did not establish limits of detection. All Abraxis did was to provide them powder and ask that x-ray powder diffraction be performed.

Ms. Melody then testified, and she used the word surprised, she would be advised to hear that her testing would be the basis for claiming amorphousness, because in order to make such a conclusion one would need to test to determine the limits of detection, which was never done. She further testified that when dealing with nanoparticles, x-ray powder diffraction is less conclusive, and as a result it's important to have a control, for a control, a nano-sized standard, which was not done.

She said, I still don't know if it's amorphous or crystalline.

Importantly, we learned at the deposition that Abraxis had submitted samples for further testing in 2007, after this lawsuit was filed, none of which had ever been produced to my client. It was produced the evening before the deposition that Your Honor ordered and which took place last Tuesday.

What they produced were various lab notebooks

and various reports. But we learned during the course of the deposition that there was a whole wealth of other laboratory notebook information that had never been produced. And it was only produced to us yesterday.

Against that backdrop, Your Honor, we received from Your Honor last week the clarification order. We know the Court is extremely busy and overloaded due to circumstances that the Senate of the United States has not deemed appropriate to deal with, which creates a tremendous amount of work for Your Honor.

We further assumed that if Your Honor took the time to issue a clarification order, it was important that we submit it to our experts.

What we did is this.

After the deposition of Katherine Melody, we submitted that information to Dr. Berkland and said, please consider this. In addition, after Your Honor's clarification order of last week, we submitted that to two of our experts, Dr. Byrn and Dr. Munson. Dr. Byrn is our state of the art expert. Dr. Munson is the one who has performed solid state nuclear magnetic resonance testing to determine crystallinity within Abraxane.

We asked him three questions. Number one: Does this change your opinion? If so, how so? That is the second question. Number three: If your opinions are not

changed, are you able to supplement your reports to track the language of the Court's clarification order? Knowing, Your Honor, that it is important that they be in tune with how Your Honor has construed the terms, and that if they don't articulate their opinions in a manner which is consistent with Your Honor's construction, all we will hear from Abraxis is, the opinions shouldn't be offered. They should be excluded.

What has become very, very clear here, Your Honor, is this is part of an overall plan to tie Elan's hands, not identify the people who did this Micron testing, not tell us that they had done x-ray powder diffraction testing, until last Tuesday, the day before Ms. Melody's deposition, that there was testing in 2007.

They still produce documents to us just yesterday. And now they want to exclude these supplemental reports that were brought about by Melody's deposition and by Your Honor's clarification order, so that they can, number one, prevent those reports from being amended or supplemented, and then stand up before Your Honor on Monday and say, Your Honor, they shouldn't be allowed to offer this testimony.

The other thing, Your Honor, relates to our damages expert. This is Mr. Jarosz. There is an interrogatory that asked them to supplement or to provide

information about sales of Abraxane going straight to damages. The Federal Rules, of course, require that they supplement their discovery seasonally. They didn't do that for us. So Mr. Jarosz, when he got access to quarterly sales information for the first quarter of 2008, in order to come up with a number against which to multiply a royalty rate, supplemented his report to reflect that new information.

Secondly, there was a document called the Korean Green Cross Agreement, where Abraxis licensed its product Abraxane to a company in Korea. We asked for a copy of it at the deposition of their economist. It was not forthcoming. And it wasn't until sometime in the last six weeks that we had to write Abraxis back and say, please produce it. That information was recently produced. My notes suggest it was produced on April 7th of '08.

And Mr. Jarosz, the economist, is addressing the updated financial information that we never got from Abraxis. We had to go out and search for it, once the first quarter data was submitted.

And secondly, the Korean agreement, which wasn't provided to us until April the 7th. Of course, we couldn't forward it on until April the 8th.

But, Your Honor, I will shut up. This is an effort to do nothing but hand-tie our case. These were very

discrete supplements. The suggestion that we put in some new infringement theory is absolutely without basis. We went to Dr. Munson and said, look at Your Honor's clarification order. Look at the language. It appears to us, there was a "Whereas" clause, Your Honor, that we said you need to look at this. It says, whereas something would reject an argument that a purely amorphous product could infringe the '363. We said look at that and then look at the later language about the medicament within the particles. And he addressed only those in his supplemental report.

He says his opinion doesn't change. He says, in a manner that is absolutely consistent with his prior report, that there are particles wherein the crystalline medicament is entirely crystalline, utilizing that word "entirely," which, Your Honor, had not appeared back in your August of 2007 Markman order.

That is what we did. These reports are, I think the longest is ten pages, but most of them are in the five- to six-page-in-length area, with, of course, the caption taking up the entire first page.

We have attempted to follow the rules. We understand the importance of the Court's language. We understand the Court's role in construing terms. We went back to our experts immediately and said, please look at

this order. Do your reports need to be supplemented in light thereof?

That is what we did.

THE COURT: Okay. Bear with me just a second before you respond, Mr. Jacobs.

(Pause.)

THE COURT: Mr. Jacobs, I am sorry.

MR. JACOBS: Your Honor, let's set Melody aside for a minute. We can come back to that, because Mr. Scheve has vastly overstated what happened at her deposition.

Setting Melody aside, marching through them, let's start with Munson, who has turned into their lead infringement expert.

In Munson's original report, he had one fragmentary reference to the possibility that individual particles might be more crystalline than Abraxane as a whole. The sentence was this: Samples that are on average from 3.5 percent to 12 percent crystalline such as those discussed above include individual particles that are mostly crystalline.

That was the entirety of the expert report last fall.

Munson was asked about that sentence at his expert deposition. He really did not want to answer the question. He asked how long was on the videotape. He had

to be instructed twice by Mr. Sullivan that he needed to answer the question. Then he went on, went on a lengthy exegesis on really an unrelated topic, and gave no foreshadowing of what he was about to say in the supplemental report we received yesterday.

In that report, he notes his original sentence, individual particles that are mostly crystalline, and then he attempts to quantify the number of particles in Abraxane that are entirely crystalline. And he says, well, there are two trillion -- there are probably two trillion particles in which there is a portion of the paclitaxel that is crystalline. Of these two trillion particles, it is my opinion that most of them contain paclitaxel that is entirely crystalline.

So we have gone from individual particles that are mostly crystalline, a half-expressed thought, to a quantification of particles that are entirely crystalline. That, in turn, is based on an entirely new theory that we haven't had advanced before to us. It is called the theory of nucleation, the nucleation theory of crystallization, which is, as stated by Munson here, when one crystallizes a substance, it usually becomes completely or essentially completely crystalline.

I think I can prove the newness of this in several different ways. One is just by way of the

comparison with the earlier report and the early sentence -- and the fragmentary sentence about mostly crystalline particles there.

But as the Court will recall, as recently as a week ago, Elan submitted a motion for reconsideration in which all of the evidence advanced in that motion was that particles are not entirely crystalline or entirely amorphous. They are within some sort of gradient or variable quantities.

There are two paragraphs in which that is elaborated at great length as a way of saying that the Court's clarification of the claim construction is wrong.

Now we have a supplemental report for Munson which goes the other direction, and says, no, no, no. They are entirely crystalline and I can tell you how many of them there are.

By the way, the quantifications are not detailed. He doesn't explain how he gets to two trillion. We can guess. But it's not explained. Of course, all of the work we had done in analyzing Munson's 50-percent error rate to get above ten percent, the doubling from four percent to get to eight percent, all of that is now out the window because it appears he is not relying on that argument at all.

Munson nowhere mentioning Melody. So Melody has

nothing to do with this theory. This was a theory that Munson and Elan could have articulated along the way. There should be no surprise, based on the Court's original claim construction, that the particles' medicament had to be entirely crystalline. There should be no surprise whatsoever.

Of course, he had this half-fragment that individual particles could be mostly crystalline.

If we had this report back in September, our approach to challenging Munson's expert testimony would have gone off on a very different path. We now would have been looking for not particles that are in some sense sort of, this whole crystalline phase issue that they were articulating, we would have been attacking a report that says, I know that there are some billions or trillions of particles in Abraxane that are entirely crystalline.

If we had the nucleation theory in September, we would have gone off and embarked on attacking the nucleation theory.

So that's Munson. Munson, you don't need to hear about from Melody, because Munson doesn't mention Melody.

Let me turn to Berkland. Berkland is directly in violation of the Court's order on 1 and 4. Yes, Berkland references Melody. But much of his report is not based on

Melody's testimony at all. It is based on things that have long been available to them, including all the reports from a year ago that had Melody's name on them and Micron's name on them, and had the USP referenced.

So the newness argument for Berkland is very powerful as well.

But the killer here is that Your Honor issued an order that said Brittain is the only one who is going to criticize Abraxis's x-ray powder diffraction -- I'm sorry, that Brittain is the only one. Now they are submitting an additional report from Berkland.

Maybe if we focus on those two, we can make some focused progress, Your Honor.

THE COURT: Mr. Scheve, let's do that. Let's focus our attention for now on Munson and Berkland.

MR. SCHEVE: All right. I will start with Berkland, because I think that's the shortest, Your Honor.

As Your Honor knows, a motion in limine doesn't preserve anything for appeal. So in order for me to preserve for appellate review Your Honor's decision that I am limited, in other words, I am not free to pick between Dr. Berkland and Dr. Brittain, we felt it necessary to supplement his report.

We expected to go before Your Honor outside the presence of the jury, offer that testimony. I frankly, Your

Honor, expected that Your Honor would again, at the time of trial, rule in the way consistent with your in limine notion. But the suggestion that I have done something wrong -- and Mr. Jacobs knows it, the only way I can preserve this issue for appeal is to supplement his report, because I understand Your Honor has said if it is not in the report it can't be offered, and then make an offer of proof, if Your Honor said it can't be heard by the jury.

That is why I did what I did, to protect my rights.

And the notion that it should be stricken, when Mr. Jacobs knows I have to do that in order to preserve rights, is simply again another desperate position to try to make sure that the truth -- and I think that is what this process is about, is to get the truth to come out. And Dr. Berkland attended the deposition of Melody, Ms. Melody last week. And that's the first time that he had heard anything about how they had customarily told their customers, including Abraxis, you have to do these standards, you have to do the particle size standards, you have to create the appropriate standards against USP, and that Abraxis chose not to do it. That's the first time that any of that came out and the first time that he had heard testimony that to this day she doesn't know if it is either crystalline or amorphous based on that x-ray powder diffraction because

those standards were not done.

THE COURT: Before you go on to Munson, I do have a question, Mr. Scheve.

Why not supplement Brittain's report instead? Why did you make that election? Was it because of your assessment of how one goes about preserving the appellate rights?

MR. SCHEVE: Yes, sir. That was my primary purpose. And Dr. Brittain has already expressed all of his criticisms in depositions about the x-ray powder diffraction that was done.

THE COURT: Why don't you go on to Munson then.

MR. SCHEVE: Yes, sir.

Here is what is happening, Your Honor, and what Mr. Jacobs -- as they say, here is the rest of the story.

The particles that are contained -- let me back up.

Abraxane is nine parts amorphous albumin and one part paclitaxel. In their documents, which we will demonstrate at trial, they did some separation of this free albumin, meaning this unbound albumin, and did some calculations of how much paclitaxel and how much albumin is in the particles. And their own conclusion is that 95 percent of that albumin is free.

We have got these particles, which according to

their own documents submitted to the FDA are 88-percent paclitaxel and 12-percent amorphous albumin.

What Dr. Munson testified to in light of what Your Honor's claim construction was -- I said testified. What he put in his report, which tracked again Your Honor's claim construction of August of 2007, which construed the phrase consisting essentially of crystalline medicament, surface modifier and other ingredients that do not affect the basic and novel properties of the invention, by definition, those particles, 18 percent of them are amorphous, of the particles.

When Your Honor issued the clarification, and that's why he said in his report that, of his opinion in August of last year, that there are particles contained in that product that are mostly crystalline, because by definition, if we are talking about it as a particle, it is going to be 82-percent paclitaxel and 18-percent amorphous albumin.

When Your Honor clarified last week, and there is the "Whereas" clause, and I actually looked up the word whereas, and the phrase has the meaning, it is taken as fact, whereas it is taken as fact that an amorphous product, a largely amorphous product could not infringe the '363, we asked him, what would your opinion be if that is the Court's construction. And his report says --

THE COURT: That is not the Court's construction. I fear that I have created controversy where I was making an effort to give the parties clarity, which, with the benefit of hindsight, I had given in the issuance of the first order and the infamous footnote in question. I reject that notion, Mr. Scheve. But go ahead.

MR. SCHEVE: But if I can just explain, Your Honor. I asked him first, I said, if this were the construction, what would your opinion be. And his report says, if that's the construction, then it doesn't infringe. Then I said, assume that what we are talking about here is that the word product meant medicament, that we are talking about the medicament within the particles. Does that change your opinion? And he said no. And I said, in what way? And he said, well, it would serve to reduce the number of infringing particles. But, you know, we are talking 60 trillion particles within Abraxane, and if you take the most conservative number, my three and a half percent, and multiply it by 60 trillion, he said there are around two trillion particles that contain crystallinity.

Then he did further calculations and said, conservatively, the most conservative assumption I have is that the number of infringing particles is in the billions. And I said, can you articulate that then in a way that's consistent with the Court's construction.

And so all he did was to say, there are particles wherein the medicament is entirely crystalline and those numbers would be in the billions.

All I have tried to do, Your Honor, is give him your clarification order and say it's important that we track the Court's construction language. Can you still offer an opinion that meets this? Because, Your Honor, if he had said, no, I can't, then I as an officer of the Court would be faced with the issue of can we proceed or not.

THE COURT: I think he should have been able to do that based on the original order.

Go ahead, Mr. Jacobs. Let's hear a response.

MR. JACOBS: First on Berkland. You know, there is a way to make an offer of proof or to say I am making an offer of proof. You say this is an offer of proof. That's not what we got. We got a supplemental expert report.

So if what he is saying is he doesn't plan to offer that testimony at trial, it's just an offer of proof, fine, he can make whatever offers of proof he wishes.

On Munson, I think Your Honor has it exactly right. The point of the clarification of the claim construction was this was always in the claim construction. Footnote 4 rejected "a portion of." We are seeing another variation on the "a portion of" theory. We are seeing a variation on the "a portion of" theory that not only should

and could have been forecast from the original claim construction, but really represents kind of the just before trial version of hiding the ball.

It's really quite extraordinary that when the issue has always been whether there is crystallinity in Abraxane from the very first case management conference, now we are getting a quantification of the supposed number of crystalline particles in Abraxane.

To say that Munson did calculations, where are the calculations? Are we once again going to hear more at trial that we haven't had a chance to develop pretrial? There are no calculations set forth here.

So I think this is all, this really is, as I started to get worked up to say, Your Honor, this is hiding the ball at its most extreme, in its most extreme form.

THE COURT: Okay.

MR. SCHEVE: May I respond, Your Honor?

THE COURT: Well, I think I have made -- you had already anticipated the Court's ruling, Mr. Scheve. Please respond briefly.

MR. SCHEVE: Your Honor, the position we are in is, if it was so clear, why was the Court issuing a clarification? And we took that very seriously.

THE COURT: And I think I have already addressed that issue. Perhaps I muddied the waters. If that is the

case, and it does appear to be, indeed, the case, my apologies to both sides. It seems, with the benefit of hindsight and listening to this argument, that I should have left stand the original order and let the parties have at it based upon my original claim construction order.

And you correctly anticipate my ruling as to Berkland and Munson, Mr. Scheve.

I am going to reject the offers of proof, and order that the supplemental reports be removed or struck from the record.

Let's talk about, I guess Melody is a discrete issue. Is Melody a separate issue?

MR. JACOBS: Your Honor, I think Melody was -- the Berkland report was about Melody. So as we look at the other reports, frankly, Your Honor, I think on the other reports we are okay dealing with them closer in -- well, Manning.

Emily Evans is here with me, Your Honor. Let's just talk briefly about Manning.

MR. SCHEVE: Your Honor, can I get some clarification on Dr. Munson?

THE COURT: I am afraid to clarify anything, Mr. Scheve. Go ahead.

MR. SCHEVE: Your Honor, I have a witness who put in his report that those particles were mostly

crystalline because he was focusing at that time on the August order. Do I understand, Your Honor, that I would not be allowed to ask him at trial do you have an opinion whether it contains particles that infringe under the Court's construction order?

THE COURT: Under the Court's original construction order? He has opined on that. Right? He has opined with the Court's original order in mind, in other words.

MR. SCHEVE: Yes, sir.

THE COURT: Well, I see no reason that you can't have him discuss that with the jury.

MR. SCHEVE: Okay.

THE COURT: Mr. Jacobs, any difficulties with that?

MR. JACOBS: Your Honor, I think what Mr. Scheve is indirectly exposing is a slightly different variation on a theme. Recall that what Munson says in his original report is individual particles that are mostly crystalline. Then Elan reads the Court's clarification and writes to the Court, we don't have an infringement theory anymore. And we agree with that. We agree, we thought they didn't have an infringement theory last August. But they kept the case alive. But they told, they wrote to the Court and said three times in the request for clarification, we don't have

an infringement theory anymore.

Now they have told the Court that they gave the Court's order to Munson and said, can you come up with an infringement theory? And Munson is saying, yes, I can. But that report has now been stricken. So the question is, how can they have it both ways? How can they represent to the Court that they don't have an infringement theory, have Munson's report be stricken, and still have an infringement theory?

THE COURT: Mr. Scheve.

MR. SCHEVE: Your Honor, the statements made in our motions in limine last week went to the "Whereas" clause, whereas, again, taken from Webster's Dictionary says --

THE COURT: Counsel, given the fact that, indeed, I do have limited time, I am going to stick by what I said originally, in my original ruling. Should we need to address this further in realtime, I will do that. Okay?

But as to your request for clarification, I think I have been as clear as I possibly can be at this point. But I will not get exorcised if you want to, feel it appropriate to, I will say renew, for lack of a better word, at least your request for clarification.

MR. SCHEVE: Thank you, Your Honor.

THE COURT: So we were talking about Melody.

MR. JACOBS: Your Honor, there are no -- to my knowledge, there are no other Melody-related issues. There were some other supplemental reports. But I think we could deal with them in realtime.

The one I would flag for everybody, especially, is Manning. But as I say, I think we can deal with that in realtime.

THE COURT: All right, then. So of those witnesses teed up initially, we still have Byrn and I guess Jarosz to talk about?

MR. JACOBS: Jarosz is the damages theory. Again, I think we can deal with that in realtime. What Byrn did was re-do his obviousness analysis. It's a mix of re-do based on the Court's claim construction and things he should have done earlier. Again, I think we can deal with that in realtime.

THE COURT: Do you agree with that, Mr. Scheve?

MR. SCHEVE: Certainly, it can be dealt with in realtime. But I don't believe -- as you know my position, Your Honor, there is no issues to be dealt with.

THE COURT: I understand your position, yes.

Okay. An issue of mine. Have you filed -- let me ask it this way. Have you been able to agree on a set of preliminary instructions?

MR. JACOBS: Your Honor, we have been trying to

get some responses from Elan on this. I am just checking my e-mail. It looks like something may have finally --

MR. SCHEVE: It was filed a few minutes ago, Your Honor.

THE COURT: Is it an agreed-upon set?

MR. SULLIVAN: Your Honor, it is an almost-agreed-upon set.

THE COURT: All right.

MR. SULLIVAN: But it is a set that complies with the Court's instructions to provide clean language with objections set forth elsewhere.

THE COURT: Okay. In other words, what you have filed is in an effort to preserve appellate issues.

MR. SULLIVAN: Exactly.

THE COURT: Would you please file --

MR. JACOBS: It is not just appellate, Your Honor. I think there are some other things that we would like the Court to take a look at.

THE COURT: That is what I am interested in knowing, whether there are things that we need to attend. So can you just tell me -- I haven't pulled that yet, because it was just filed -- if you have a set in front of you, what pages, or at least what instructions are at issue, if not the pages?

MR. SULLIVAN: Your Honor, I think the

submission sets it forth pretty clearly.

THE COURT: Here is the thing, Mr. Sullivan. I am just wanting to know that I will know when, and Ms. Walker has just gone to try to retrieve this, the distinction between issues that I need to address for Munson and those that I don't, because they are merely highlighted in the interests of the preservation of appellate rights.

MR. JACOBS: Your Honor, I think it's really actually a pretty small issue. There is a word must and a word shall. And we don't need to give you a lot of argumentation on all this. You just need to call this one. It is highlighted in the comments.

The other objections, they are serious objections. But I understand that the Court might not want to -- I understand the Court's position on whether to decide those in advance.

MR. SULLIVAN: I will differ with that only to the extent, sir, that Elan has objected on two grounds, Abraxis has objected on five grounds. Those are set forth in a cover sheet. Elan objects to issues of unenforceability being submitted to the jury and the use of the mandatory language must versus the word should. Abraxis objects to --

THE COURT: Did I not already rule on the issue of enforceability being submitted to the jury?

MR. SULLIVAN: Yeah. And I think, sir --

THE COURT: "Yeah"? You mean yes?

MR. SULLIVAN: Sir, I think, yes, that's true. And I think that potentially the word must versus the word shall or should will be up to the Court's sound discretion.

THE COURT: Here is the thing. If they are issues I have already ruled upon, and it sounds like this is at least one, they have been ruled on.

MR. SULLIVAN: Your Honor, we have tried very assiduously, and certainly Elan has removed all of its objections to instructions on the '025, because the Court has made it clear that the '025 will be in issue, so we have tried to facilitate things for the Court and the jury.

THE COURT: Here is what we will do. I will take a look. If I need to get you back on the phone, I will.

What's next, if anything?

MR. JACOBS: That is all that really prompted the call, Your Honor. I hope we don't get any more supplemental reports, because we are trying to get ready for trial. It would be helpful to know if this is the last one.

MR. SULLIVAN: I will only note on Elan's behalf, just for the record, that Dr. Berkland's report was largely or entirely prompted by the very recent testimony of Ms. Melody, which took place last week.

THE COURT: Mr. Scheve made that amply clear. I really don't have time for a rehash, counsel.

MR. SULLIVAN: I apologize, Your Honor.

THE COURT: I have the preliminary instructions in front of me. Let me just page through them while I have you all here to see if we can benefit from the fact that we are all on the line.

You said there is a cover sheet.

MR. JACOBS: There is a comment, is where the objections are laid out.

THE COURT: I see.

Did we agree or not that the video was going to be used in this case?

MR. JACOBS: We did, Your Honor.

THE COURT: Mr. Scheve, we did have that agreement. Right?

MR. SCHEVE: You are correct, Your Honor.

THE COURT: Do, then, counsel, believe that we need 1.7?

MR. JACOBS: Let me jump ahead, Your Honor. Sorry.

No, Your Honor, I do not think that we need -- I think a summary of the patent issues is technically in 1.7. Yes, it is.

THE COURT: Yes, it is. I think you can modify

this a little more, because the video covers at least the first part, up to the heading Summary of Patent Issues. Doesn't it?

MR. JACOBS: Why don't we work on that some more, Your Honor.

THE COURT: So the comments say, in part, that the parties maintain several outstanding objections to the instructions. We have Elan's objection to enforceability, reference to unenforceability. That's been dealt with. We have this "must" issue, I will look at that, in the fifth sentence of the first paragraph of Instruction 1.6.

Then these Abraxis objections, these have been previously raised? There are five in number?

MR. JACOBS: They have been raised in the sense that they surfaced in the actual jury instructions. And our argument, if you will, on these issues is in the submission to the Court of the actual jury instructions.

THE COURT: But they are not in the preliminary instructions? They are not issues extant in the preliminary instructions?

MR. JACOBS: They are extant in the sense that there are references, for example, to willful infringement or the presumption of validity in the preliminary instructions; hence, the objection here.

MR. SULLIVAN: Sir, just to clarify. In the

pretrial order, all of the objections of both parties should be stated.

THE COURT: Okay. I will take a look, and then we will issue probably another oral order.

But what I expect at this point is for 1.7 to be edited in accordance with our earlier discussion and now just recent discussion.

I will take a look at the balance.

Okay? All right, counsel. Thank you.

MR. SCHEVE: Your Honor, I apologize. But I have to raise this with you.

You recall at the pretrial conference, we dealt with the so-called Atwood exception.

THE COURT: The Atwood exception, okay.

MR. SCHEVE: Dr. Atwood two and a half months after his deposition supplemented his report. You allowed it and didn't allow us to take his deposition. And the question was raised about rebuttal and what's in the reports. And Your Honor said on repeated occasions, and I can find the quotes and the pages in the transcript for you if necessary, but you said, well, we may have to have an Atwood exception. Among the things that Dr. Munson did was to supplement to deal with the supplemental material provided by Dr. Atwood. Do I understand that that portion of his supplemental report is going to be stricken, too?

MR. JACOBS: Your Honor, that is the first supplemental report we got for Munson. That is something again that I think we can deal with on the fly.

THE COURT: All right. Do you agree with that, Mr. Scheve?

MR. SCHEVE: We certainly can.

THE COURT: Okay. All right, counsel. Thank you.

(Conference concluded at 12:15 p.m.)

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Reporter: Kevin Maurer