UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO LTD, Petitioner, vs. ALEXION PHARMACEUTICALS, INC., Patent Owner.	)	Case No. IPR2023-00933 Patent: 9,732,149 B2

VIDEO-RECORDED DEPOSITION OF CINDY IPPOLITI

New York, New York

Tuesday, February 20, 2024

Reported Stenographically By:
PATRICIA A. BIDONDE
Registered Professional Reporter
Realtime Certified Reporter
JOB#: SY008732

ALXN2106
IPR2023-00999

February 20, 2024
9:07 a.m.

Video-Recorded Deposition of CINDY IPPOLITI, held at the offices of Cooley LLP, 55 Hudson Yards, New York, New York, before Patricia A. Bidonde, Stenographer, Registered Professional Reporter, Realtime Certified Reporter, Certified eDepoze Court Reporter, Notary Public of the States of New York, New Jersey, and Connecticut.

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P R O C E E D I N G S

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THE VIDEOGRAPHER: We are now on the record. The time is 9:06 a.m. on February 20, 2024. Audio and video recording will continue to take place until all parties agree to go off the record. Please note that microphones are sensitive and may pick up whispering and private conversations.

This is the video-recorded deposition of Cindy Ippoliti in the matter of Samsung Bioepis Co., LTD., plaintiff, versus Alexion Pharmaceuticals, Inc. This deposition is being held at Cooley LLP, New York, New York.

My name is Christian Bidonde. I am the legal video specialist. The certified stenographer is Patricia Bidonde on behalf of TransPerfect Legal Solutions.

Counsel will state their appearances for the record. All those

appearing remotely will be noted for the record. Then the certified stenographer will swear in the witness.

MR. SOLOMON: Andrew Solomon with Cahill Gordon for Alexion, and with me is Andy Cochran also with Cahill Gordon, and we're also joined on the line with Christine Hlavka who is in-house counsel at Alexion.

MR. KNAUSS: Good morning. Dan Knauss from Cooley for petitioner, Samsung Bioepis.

C I N D Y I P P O L I T I, called as a witness, having been duly sworn by a Notary Public, was examined and testified as follows:

EXAMINATION BY

MR. SOLOMON:

Q. Good morning, Dr. Ippoliti. Would you please state your full name for the record.

A. Cindy Ippoliti.

Q. Great. And where do you live?

A. West New York, New Jersey.

Q. And where are you currently

employed?

A. NewYork-Presbyterian Hospital at this time.

Q. Have you had your deposition taken before?

A. Yes. Twice before.

Q. Twice before. What kind of cases were those?

A. One was -- very similar type of cases where --

Q. Patent cases?

A. -- patent cases.

Q. And were you on the brand or generic side of those cases?

A. Well, the first one, which was over -- close to ten years ago, it was the branded product. And then the last one, I guess, was going to be a generic product. Well, it was a new drug coming to market they were challenging. But it's a little bit different.

Q. And you submitted expert declarations in those cases as well?

A. Yes.

Q. Generally, what's your

understanding of the technology at issue in this case?

MR. KNAUSS: Objection to the form.

You may answer, Dr. Ippoliti.

A. The way that I understand it is that Samsung is contesting or petitioning for saying that the patents in question, specifically the ones that I'm addressing, were obvious at the time.

Q. And what's your understanding of the underlying technology of the patents?

A. That they -- I'm not quite sure I understand the question.

Q. Just in terms of broad strokes, subject matter of what the patents contain.

A. Right. They're talking about the sequencing of --

Q. Right.

A. -- the monoclonal antibody.

Q. And in the context of these proceedings involving Alexion and Samsung, you've offered opinions from the perspective of a person of ordinary skill in the art. Right?

A. Yes.

Q. And you've considered what a person of ordinary skill in the art would have understood regarding the patents at issue and the technology at issue in the proceedings prior to a certain date, which is March 15, 2007. Right?

A. Yes.

Q. So you've had your deposition taken before, so you understand this, but I'd like to walk you through a few ground rules.

First, I'll be asking questions, and you'll be giving me answers. Do you understand that?

A. Yes.

Q. And the court reporter is taking a record of what we say, and the videographer is also recording. So please give me verbal answers only, no head nods, no mm-hmms. Got it?

A. Yes.

Q. And as we've already seen, your counsel may object, but that's just for the record. You're to answer my questions unless your counsel specifically instructs you not

to. Okay?

A. Yes.

Q. And if you don't understand any of my questions or you need me to clarify, just please let me know. Sound good?

A. Yes.

Q. And if you answer, I'll assume that you understand the question. Is that fair?

A. Yes.

Q. And you also understand that you took an oath to tell the truth as if you were testifying live in court or before the patent office. Right?

A. Yes.

Q. Is there any reason that you can't give me any true and accurate testimony today?

A. No.

Q. And if you need a break at any point, please let me know. All I ask is that, if I ask you a question and you're answering, that we just finish your answer before we take the break. Sound good?

A. Yes.

Q. So you're here today on behalf of Samsung. Right?

A. Yes.

Q. And as you already alluded to, you understand that Samsung has filed five inter partes review petitions with the patent office, challenging the patentability of five of Alexion's patents covering the drug Soliris. Right?

A. Yes, eculizumab, yes.

Q. And you understand if I refer to these inter partes reviews as IPRs. Right?

A. Yes.

Q. And you're testifying today because you submitted four declarations to support Samsung's unpatentability positions in these IPR proceedings. Right?

A. Yes.

Q. So I'd like to introduce your declarations.

MR. SOLOMON: Yeah, we can mark this Ippoliti Exhibit 1.

(Ippoliti Exhibit 1, Declaration of Cindy Ippoliti regarding US Patent 9,718,880, submitted in Case

IPR2023-00998, marked for identification, as of this date.)

Q. And if you could just confirm that this document is your declaration regarding US Patent 9,718,880, and this was submitted in Case IPR2023-00998. Correct?

A. Yes.

Q. Okay.

(Ippoliti Exhibit 2, Declaration of Cindy Ippoliti regarding US Patent 9,725,504, submitted in Case IPR2023-00999, marked for identification, as of this date.)

Q. And this is Ippoliti Exhibit 2. Bear with me for a second while I get organized here. And this is regarding US Patent 9,725,504, submitted in Case IPR2023-00999. Right?

A. Yes.

(Ippoliti Exhibit 3, Declaration of Cindy Ippoliti regarding US Patent 10,703,809, submitted in Case IPR2023-01070, marked for identification, as of this date.)

Q. And then Exhibit 3 is your

declaration regarding US Patent 10,703,809, submitted in Case IPR2023-01070?

A. Yes.

(Ippoliti Exhibit 4, Declaration of Cindy Ippoliti regarding US Patent 10,703,809, submitted in Case IPR2023-01070, marked for identification, as of this date.)

Q. And finally, we have your declaration regarding US Patent 10,703,809, submitted in Case IPR2023-01070. Correct?

A. Yes.

Q. Great. And just for simplicity sake, you'll understand if I refer to a declaration by its associated patent. Right?

For instance, your declaration regarding US Patent 10,703,809, if I refer to it as the '809 declaration, that'll make sense?

A. Yes.

Q. Great.

MR. KNAUSS: Just a procedural point, Andrew, before you launch in, I noticed that the sticker versions are with the reporter.

(Discussion off the record.)

MR. KNAUSS: Sorry for the interruption.

MR. SOLOMON: All good.

Q. So who drafted your declarations?

A. You mean who actually typed the complete thing up or who drafted it?

Q. Yes, exactly.

A. So I did not type up the full thing. I put together a draft of it, and then that was taken and turned into the legalese that you guys all use, so that was inserted. And then I, you know, asked Cooley for additional resources and references, and then I was given a draft, and then reviewed the draft, made my revisions, comments, and then got the final version.

Q. Do you know how many conversations you had with counsel regarding the proceedings before the first draft?

A. I don't recollect exactly how many personal conversations we had, but I can tell you how many hours I spent doing that.

Q. And about how many hours did you spend?

A. About 12, 13 hours.

Q. Okay. And is everything in your declarations true and correct?

A. Yes.

Q. And you signed those declarations under penalty of perjury. Right?

A. Yes.

Q. Okay. And one more quick housekeeping tip. I'd like to introduce the underlying patents associated with each declaration. So bear with me for one more second.

(Ippoliti Exhibit 5, US Patent 9,718,880, marked for identification, as of this date.)

Q. So this is Exhibit 5, and it's US Patent 9,718,880. Correct?

A. Yes.

(Ippoliti Exhibit 6, US Patent 9,725,504, marked for identification, as of this date.)

Q. And then this is Exhibit 6, and it's the US Patent 9,725,504. Is that correct?

A. Yes.

(Ippoliti Exhibit 7, US Patent 10,703,809, marked for identification, as of this date.)

Q. Exhibit 7 is US Patent Number 10,703,809. Correct?

A. Correct.

(Ippoliti Exhibit 8, US Patent 10,590,189, marked for identification, as of this date.)

Q. And last, Exhibit 8 is Patent Number 10,590,189. Correct?

A. Correct.

Q. So you understand that these are the four patents at issue in the IPR proceedings where you've submitted declarations on Samsung's behalf. Correct?

A. Correct.

Q. And, again, you'll understand if I refer to these patents by the last three digits. So the '189 patent, for instance?

A. Yes.

Q. And if I refer to them collectively as the challenged patents, you'll understand that as well?

A. Yes.

Q. So when did you first see the challenged patents?

A. I actually don't remember. Many months ago. I honestly don't remember the exact date when I was contacted.

Q. But you received the patents prior to receiving the first draft of your declaration --

A. Yes.

Q. -- from Samsung?

A. Yes, I did.

Q. Okay. And starting with the '189 declaration, did you do your best to include all of the opinions you had regarding the patent ability of the '189 patent in your '189 declaration?

A. So can you clarify? I did not address all of the claims. I just addressed the ones that were in scope for me.

Q. Sure. But you did your best to include all of your opinions within the scope of those claims that you were asked to address within your '189 declaration. Correct?

A. Yes.

Q. And likewise, with regards to the

other three declarations, you did your best to include all of the opinions you had regarding the scope of those claims that you were asked to provide opinions on. Correct?

A. Correct.

Q. So you didn't hold any opinions back to be used at a later date. Correct?

A. Correct.

Q. And you're not planning on raising any new arguments or evidence later on in these proceedings that you could have presented in your declarations?

A. No.

Q. So I'd like to walk through your CV. So let's turn to your '809 declaration. And starting on page 45 of -- and I'll be referring generally to the stamped numbers on the bottom right corner of the various exhibits.

So starting on page 45, your CV is attached to your declaration as Exhibit A. Right?

A. Yes.

Q. And this version of your CV is current and accurate?

A. Yes.

Q. Are there any omissions that you'd like to add or anything that needs to be addressed?

A. The only thing that is very, very recent was my title changed from enterprise to senior enterprise director.

Q. Congratulations. Is your employment history otherwise accurately described in your CV?

A. Yes, it is.

Q. And is your education accurately described in your CV?

A. Yes, it is.

Q. So as you mentioned before, and as you were just eluding to, you are currently employed by NewYork-Presbyterian Hospital. Right?

A. Yes.

Q. And what are your current responsibilities in your senior position at NewYork-Presbyterian?

A. The same as they were in the other one.

Q. Okay.

A. But it was just a title change. So I currently oversee all clinical pharmacy services across all 11 sites. So we have 11 hospitals, and these are -- when I say "clinical pharmacy services," I mean overseeing the clinical pharmacists, not directly, but indirectly. They all have a dotted line to me. These are highly trained experts in their field who provide direct patient care.

But it also encompasses other clinical services that we provide, pharmacokinetic monitoring and the like, drug management. I oversee our drug information services. I oversee our subcommittees, which report up to F&T, so new drugs that are being brought into the formulary.

I oversee the ambulatory care network. And I also oversee the residency program, where we have 22 residents, pharmacy residents.

Q. So you're wearing many hats. And I see that you've been employed, and correct me if I'm wrong, at NewYork-Presbyterian back to at least to 2006. Is that correct?

A. Yeah. January 2006.

Q. And in your previous positions in NewYork-Presbyterian, did your responsibilities differ significantly than they do now?

A. They did. I have -- when I first started at NewYork-Presbyterian, so prior to that, I was at MD Anderson. And when I came to NewYork-Presbyterian, I started rounding on the bone marrow transplant service and then the leukemia service.

We have a robust service, actually. It's actually larger than Memorial. So I was providing direct patient care to the patients on the leukemia service. Then I took on additional roles of overseeing while still providing direct patient care of overseeing our oncology infusion sites. So two very large ambulatory infusion centers.

I've always overseen oncology services, but my boss doesn't like me to refer to that because she says that clinical falls under oncology, so I still continue to oversee the oncology pharmacy services across our enterprise.

Q. In your professional capacity, have you worked directly with eculizumab or Soliris?

A. Yes, I have.

Q. And is that administering it to patients? What, I guess, were the -- was your involvement?

A. So my involvement is -- so, like I said, I would provide direct patient care to -- so we would be considered mid-level providers --

(Stenographer clarification.)

-- which means that we make rounds and provide direct patient care to the patients. Clinical pharmacists routinely write the orders for the patients. So that was one of the hats I would wear when I was actually directly taking care of patients. And so we would pen the orders, basically, for the patients.

Drugs like Soliris don't need a co-signature by an attending. Only those that are considered cytotoxic chemo. So we would have occasion to order it.

And then the other side of it was

as overseeing the infusion center, which is where Soliris is often given. We, sort of -- I would help with, you know, developing the work flow. So we don't directly administer medications, IV medications, we are not credentialed to do that. But we can, you know, take it everywhere.

So I would oversee the staff compounding the drug, deal with purchasing if needed, compounding the drug, and then obviously take it through that entire process, and then a technician usually delivers the drug to the nurse to administer it to the patient.

Q. Thank you.

Flipping back into your declaration now. If you could turn to paragraph 7 for me. And that's on page 5. Can you describe your role as a study chairman or principal investigator in those 19 clinical trials that you referenced in this paragraph?

A. Yeah, so most of my role in the clinical trials was oftentimes either doing -- following the patients and recording adverse events that we would see, all the way to data analysis for a few studies, like the IVIG

study that I did back then. That was my own idea, and I wrote the protocol and put it through the IRB.

Other times, one trial I was involved in I actually was drawing blood on the patients, checking for drug levels. But again, that was in Texas where they were a little bit more lenient with what clinical pharmacists can do. New York is very different.

So my involvement was usually around either helping with the development of the protocol, collecting the data, observing the patients, and recording their adverse events.

I did have a focus on that and an interest in that, and then helping with the data analysis and the publication.

Q. Great. Were any of those clinical trials related to Soliris?

A. No, they were not.

Q. And do your responsibilities as a co-investigator differ significantly from what you just described?

A. Not really.

Q. Okay. Would you consider yourself an expert in pharmacology?

MR. KNAUSS: Object to the form.

You may answer.

A. I would not say it's my area of expertise, but do I understand basic pharmacology? Yes.

Q. How would you describe your area of expertise?

A. I'm more of a clinician. So, sort of, at the bedside helping make decisions on patients.

Q. Sure. Do you consider yourself an expert in antibody-based drug development?

MR. KNAUSS: Object to the form.

You may answer.

A. I am not a drug developer, no.

Q. Okay. And what about formulation or commercialization of an antibody-based drug?

MR. KNAUSS: Object to the form.

You may answer.

A. But I consider myself expert. I'm sure there are people that are actually paid to do that work. But do I understand the

general concepts and understand what place it plays in a pharmacy in drug delivery to the patient? Yes.

Q. Sure. So have you ever been directly involved in the development of a drug before?

MR. KNAUSS: Objection to the form.

You may answer.

A. I have never been directly involved. I do not work for pharma.

Q. Okay. So sticking with your '809 declaration. In reviewing your four declarations, it seems, to me, that the '809 declaration is generally encompassing of your opinions across those four declarations.

Is that a fair assessment?

MR. KNAUSS: Object to the form.

Answer if you are able to.

A. I think I understand the question that you're asking, which is am I opining on the four?

Q. Right. And the limitations that exist in the '809 declaration exist elsewhere. It's also the longest declaration, so I think

it's, sort of, encompassing of the limitations that we see in the other three. Right?

A. Yes.

Q. And just for simplicity sake, because of that, I'll be referring to the '809 declaration today to guide our discussions.

And in each of your declarations, you state that your opinions pertain specifically to the underlying limitations of the relevant claims. Right?

A. Yes.

Q. So as stated in paragraph 30 in the '809 declaration -- I'll give you time to get there. Now I have to find it. So the top of page 20.

A. Where is paragraph 30?

Q. Paragraph 30, top of page 24. So in that paragraph, you state that your opinions are limited to claims 1 through 5, 7, and 20. Right?

A. Yes.

MR. KNAUSS: Object to the form.

But it's fine.

Q. So from those claims, your opinions are related to the following

limitations: From claim 1, "intravenously administering." Right?

A. Right.

Q. From claim 2, "wherein the antibody is formulated in a pharmaceutical composition comprising a single unit dosage form." Right?

A. Yes.

Q. From claim 3, "wherein the single unit dosage form is a 300 milligram single unit dosage form"?

A. Yes.

Q. From claim 4, "wherein the pharmaceutical composition comprises a 300 milligram single-use formulation of 30 milliliters of a 10 milligram per milliliter sterile, preservative-free solution." Right?

A. Yes.

Q. From claim 5, "wherein the antibody is diluted to a concentration of 5 milligrams per milliliter prior to administration." Right?

A. Yes.

Q. From claim 7, "wherein the

antibody is administered to the patient at a dosage level of between 5 milligrams per kilogram and 50 milligrams per kilogram per patient per treatment." Right?

A. Yes.

Q. And from claim 20, "wherein the antibody is administered to the patient at a dosage level of between 5 milligrams per kilogram and 50 milligrams per kilogram per patient per treatment." Right?

A. Yes.

Q. And you haven't provided any of your own opinions that specifically pertain to the limitations, a heavy chain consisting of Sequence ID Number 2 and a light chain consisting of Sequence ID Number 4, as stated in claim 1. Right?

A. Correct, I am not opining on those.

Q. So if we turn to paragraph 35 of your '809 declaration, and that is at the bottom of page 27. Are you there?

You provide brief summaries of the prior art that's to be discussed in your declaration. Right?

A. Correct.
Q. And these are the core documents that you rely on in support of your opinions. Right?
MR. KNAUSS: Object to the form.
You may answer.
A. I use them as references, for sure.
MR. SOLOMON: I'd like to introduce Exhibit 9.
Q. And this is the Bell publication.
(Ippoliti Exhibit 9, Patent application published by Leonard Bell dated September 1, 2005, marked for identification, as of this date.)
Q. And you're familiar with this document. Right?
A. I have reviewed it.
Q. Can you briefly explain your understanding of the document?
A. And where it pertains to me, I mean, that's a document about its patent of -- looking at eculizumab. But where it pertains to me specifically is a review of the dosing specifically.

Q. And this is a US patent application that was published on September 1, 2005. Right?

A. Yes, 2005.

Q. So a POSA, as of March 15, 2007, would have had no reason to doubt the truth and accuracy of Bell. Right?

A. Correct.

Q. And as you said before, you rely on Bell in your declarations to support a number of your opinions. Right?

A. Yes.

Q. If you could turn to paragraph 51 of your declaration, and that's on page 34. And this paragraph discusses the 300 milligram single unit dosage form limitation that's found in claim 3 of the '809 patent. Right?

A. Yes.

Q. And at the end of this paragraph, your conclusion regarding this limitation is that a POSA would have been motivated to choose a single-use dosage form of 300 milligrams. Correct?

A. Correct.

Q. And in reaching that conclusion,

you rely in part on the teachings of Bell. Right?

A. Yes.

Q. Because Bell expressly taught a 600 milligram dose of eculizumab. Right?

A. That was used in the Phase II trial, yes.

Q. And Bell also expressly taught a 900 milligram dose of eculizumab. Correct?

A. Correct, for maintenance.

Q. Does Bell expressly disclose a 300 milligram dose of eculizumab?

A. No, he does not. He was merely stating the doses for the patients.

Q. Okay. So returning to paragraph 51 of your declaration, in the third sentence, you state that a 300 milligram dose would "best support convenience and scaling as necessary to the needed 600 or 900 milligram dose amounts." Right?

A. Correct.

Q. And you don't cite to any documents as support for this statement in your declaration. Right?

A. I used my experience of 15 years

at that point, that most drug products that are released are in some mathematical equation equaling that dose. And from a pharmacy stand- -- both IV and oral meds are always in some, you know, either two of this or whatever.

And so it would not make sense to have created a 6- or a 900 milligram vial from a pharmacy stand- -- from a manufacturing standpoint. As I said, I'm not an expert in manufacturing, but there are plenty of cases over the years where you choose one size because why would you have two separate sizes from a manufacturing standpoint? We've seen some examples of that.

And -- but from a pharmacy standpoint, you always want a vial size that can make multiple if there are multiple doses available, or dosing schedules available, you would want to be able just to have one product on the shelf, just from an inventory standpoint and also simple math.

Q. Sure. But Bell doesn't contain any discussion of convenience or scaling or pharmacy stocking. Correct?

MR. KNAUSS: Object to the form.
Answer if you know.
A. No.
Q. And would Bell have guided a POSA to determine the optimal amount of vials to be used to administer this treatment to a patient?
MR. KNAUSS: Object to the form.
You may answer.
A. I mean, researchers don't usually opine on the final dosage form that the manufacturer is going to make. That is done oftentimes by pharmacists who sit in pharma companies.
Q. And in that same paragraph 51 in your declaration, you go on to say that a larger single-size vial "would unnecessarily create a situation causing waste" or costly -- or "waste of costly antibody treatments." Is that right?
A. Correct.
Q. And again, do you cite to any document in your declaration to support that statement?
A. No. I think my 15 years of

experience at that point.

Q. And again, Bell is not concerned with waste or the cost of antibody treatments. Right?

MR. KNAUSS: Object to the form.

You may answer.

A. No, they're not but hospitals certainly are.

Q. On page 35, same paragraph, you then go on to say:

"A pharmacy also would not prefer to stock (nor, presumably, would a drug company prefer to make) two different vial amounts of 600 and 900 milligrams each. This would unnecessarily complicate antibody supply services, inventory tracking, and also unnecessarily create the risk of an incorrect dose."

Right?

A. Correct.

Q. And again, same questions: Do you cite to any documents to support these statements?

A. No. Just the common practice,

accepted practices in medicine and pharmaceutical products.

Q. Elsewhere in your declarations, you cite the Avastin 2004 package insert in your declarations. Is that correct?

A. That's correct.

MR. SOLOMON: I'd like to introduce that label as Exhibit 10.

(Ippoliti Exhibit 10, Avastin 2004 package insert, marked for identification, as of this date.)

Q. And before I discuss the label, if -- the common practices in the pharmaceutical industry you speak of, or from pharmacists' perspective you speak of, were common practices, they would be in the literature. Right?

MR. KNAUSS: Objection, calls for speculation.

A. I highly doubt it. Nobody would publish a paper on what size of a vial is best.

Q. But you think minimizing waste would --

MR. KNAUSS: Hold on a second,

Andrew.

Were you done with your answer?

THE WITNESS: I guess.

MR. KNAUSS: Okay. And maybe if you just speak a little louder --

THE WITNESS: Okay.

MR. KNAUSS: -- Dr. Ippoliti.

Thanks.

Go ahead.

BY MR. SOLOMON:

Q. But minimizing waste in a hospital or pharmacy setting seems like an, you know, something worth writing about. Correct?

MR. KNAUSS: Object to the form.

A. Does it add to the body of the science? Probably not. Either probably -- possibly publications and throwaway nonpeer review journals like Hospital Pharmacy talking about waste? I'm sure there are.

Q. Have you sought out any such articles?

A. No. This is common knowledge amongst any high-performing organization, any organization, frankly.

Q. Fair enough. Turning our attention back to the Avastin label that you cite in your declarations. You say in your declarations that Avastin is an antibody that you were personally familiar with before 2007. Is that right?

A. Yes. I worked with Avastin.

Q. Okay. So on page 2 of the label under the heading "Description," halfway down about at line 44, it reads:

"Avastin is supplied in 100 milligram and 400 milligram preservative-free, single-use vials to deliver 4 milliliters or 16 milliliters of Avastin."

Do you see that?

A. Mm-hmm.

Q. So Avastin was manufactured and supplied in two different dosage forms. Correct?

A. Mm-hmm.

Q. Okay. You also cite the Rituxan label in your declaration. Is that correct?

A. Yes.

Q. And Rituxan is also an antibody

that you were personally familiar with before 2007. Right?

A. Yes.

(Ippoliti Exhibit 11, Rituxan label description dated November 1997, marked for identification, as of this date.)

Q. This is Exhibit 11 and it's the Rituxan label as cited in Dr. Ippoliti's declaration.

And on page 1 -- and I apologize for the size of this text here, but this is how the exhibit was given -- in the third paragraph, it states that:

"Rituxan is supplied at a concentration of 10 milligrams per milliliter in either 100 milligrams (10 milliliter) or 500 milligrams (50 milliliter)."

Do you see that?

A. Yes.

Q. And so Rituxan is another example, prior to 2007, that was supplied and manufactured in two different dosage amounts. Right?

A. Yeah. And there's a reason for that. So --

Q. But that was a limited question.

A. One dose is a flat dosing and -- which Soliris is -- and one is a milligram per kilo or a metered squared dosing. So you have to be able to account for differences in body weight amongst people and then create strengths that you know will hit the majority of the population so as to minimize waste.

Q. Are you aware of any other antibody-based products, prior to 2007, that would have been manufactured and supplied in multiple dosage forms?

A. You mean multiple package sizes?

Q. Correct.

MR. KNAUSS: Sorry. Did your question say drugs or antibody drugs? I just didn't hear you.

MR. SOLOMON: Antibody-based drugs.

MR. KNAUSS: Is the question clear to you, Dr. Ippoliti?

THE WITNESS: Yeah. But I'm trying to recollect the size of some of

the others at the time.

A. But, again, most of the agents, most antibody agents/chemotherapy agents are all either weight-based on some level, where this was the difference with Soliris, it was flat dosing.

Q. Sure. Dr. Ippoliti, do you mention flat dosing at all in your declaration?

A. No, I don't.

Q. You don't. And why is that?

MR. KNAUSS: Object to the form. You may answer.

A. Because it's obvious that it was flat dosing.

MR. SOLOMON: I'd next like to introduce the Wang reference, which you also cite to in your declarations. And this is Exhibit Number 12.

(Ippoliti Exhibit 12, Wang Patent Application Publication dated December 8, 2005, marked for identification, as of this date.)

Q. And again, you're familiar with this document. Correct?

A. Correct.

Q. And this is a US patent application that was published on December 8, 2005. Correct?

A. Correct.

Q. And it's titled:

"Nebulization of Monoclonal Antibodies For Treating Pulmonary Diseases." Right?

A. Correct.

Q. And a POSA, as of March 15, 2007, you would have had no reason to doubt the truth and accuracy of Wang. Right?

A. Correct.

Q. And you rely on Wang in your declarations to support a number of your opinions. Right?

A. Correct.

Q. In part, you rely on Wang for teaching the 10 milligram per milliliter concentration limitation. Is that right?

A. Correct.

Q. And if we turn to Wang on page 25, right before paragraph 68, Wang discloses here that:

"The antibody may be stable in a formulation at a concentration ranging from 1 microgram per milliliter to 200 micrograms per milliliter."

Do you see that?

A. Yes.

MR. KNAUSS: He meant to say milligram.

MR. SOLOMON: Yes, correct. Thank you.

Q. And if we turn to page 11 of Wang, and we look at Figure 10. This Figure is titled "Example of Suitable Formulations." And Formulation 1 references a monoclonal antibody from 1 to 30 milligrams per milliliter. Right?

A. Correct.

Q. And according to paragraph 25 on page 20, which references Figure 10 --

MR. KNAUSS: We're in the declaration now?

MR. SOLOMON: Still in Wang, paragraph 25.

MR. KNAUSS: Thank you.

(Discussion off the record.)

Q. So according to this paragraph, Figure 10 shows "exemplary formulations suitable for nebulization of an antibody." Right?

A. Correct.

Q. So if we turn back to Figure 10, does Figure 10 expressly use the term "eculizumab" anywhere?

A. No, it does not.

Q. And Formulation 1, listed on the left-hand side of Figure 10, simply describes a monoclonal antibody with no name or indication of any specific monoclonal antibody. Is that right?

A. Correct.

Q. And on the right-hand side, Formulation 2 doesn't even list a monoclonal antibody, let alone a generic one like the left-hand side. Right?

A. Correct.

Q. And if we turn to paragraph 170 on page 33. About halfway down, in reference to Figure 10, this paragraph simply says "anti-C5 antibody." Right? Without any reference to eculizumab specifically?

A. Correct. Although eculizumab is an anti-C5 antibody.

Q. Sure. If we go down to the next paragraph, 171, Wang discloses that eculizumab:

"At 30 milligrams per milliliter can be effectively and efficiently nebulized by a conventional nebulizer."

Is that right?

A. Correct.

Q. Does Wang ever specifically discuss a concentration of 10 milligrams per milliliter?

A. It does not. What was 30 milligrams per ml, I mean, was within the range of the Figure 10, which was 1 to 30.

Q. Sure. But it's never expressly listed? The words "10 milligram per milliliter" don't appear anywhere in Wang?

A. No, it's not.

Q. Okay. Simple math question: 900 and 600 are both divisible by 150 as well. Correct?

A. Correct.

Q. And then if we follow that down,

they're both divisible by 100?

A. Yes.

Q. And they're both divisible by 75, and they're both divisible by 50. Right?

A. Correct.

Q. And does any of the prior art that you rely on tell a POSA the proper amount of vials to divide the total dosage form -- total dosage amount?

MR. KNAUSS: Object to the form.

You may answer, if you may.

A. If your question is: Is there anything that states that I would prefer to use two vials versus ten vials? No. But if you're the person compounding in the satellite under sterile conditions, it takes a very long time to open and withdraw using ten vials -- which in current practice, would actually be a red flag that the dose was inappropriate -- versus just using two vials.

Also putting ten vials on my shelf for every single dose would be obscene and very costly.

Q. Sure. So if Bell recently teaches 150 milligrams as a divisible amount

of 600 and 900, and we assume a 30 milliliter volume, that would put us at a concentration of 5 milligrams per milliliter, which is taught by Wang. Correct?

A. Can you rephrase the question? I wasn't really following it.

Q. Sure.

You agree that 5 milligrams per milliliter concentration falls within the range that was taught by Wang. Right?

A. Yes.

MR. SOLOMON: Ten-minute break sound good?

MR. KNAUSS: That's fine.

THE VIDEOGRAPHER: The time now is 10:00 a.m. This concludes Media 1. Off the record.

(Recess taken from 10:00 a.m. to 10:19 a.m.)

THE VIDEOGRAPHER: The time now is 10:19 a.m. This begins Media 2. On the record.

BY MR. SOLOMON:

Q. Great. Let's take a look at another document that you cited in your

declaration. This is the Daugherty reference, 2006.

(Ippoliti Exhibit 13, "Formulation and Delivery Issues for Monoclonal Antibody Therapeutics" by Ann L. Daugherty and Randall J. Mrsny, marked for identification, as of this date.)

Q. This is Exhibit 13. And you're familiar with this paper?

A. Yes.

Q. It's titled "Formulation and delivery issues for monoclonal antibody therapeutics," and it's by Ann L. Daugherty and Randall J. Mrsny, and I'll refer to this as Daugherty.

And you rely on Daugherty in support of some of your opinions in your declarations. Right?

A. Yes.

Q. Are you familiar with either of the authors of this paper?

A. No, I'm not.

Q. But from the abstract page, these are folks in the industry from Genentech and

the center for drug delivery biology at Cardiff University.

Do you see that?

A. Yes.

Q. And would you say those are reputable organizations within the industry?

A. Yes.

Q. So a POSA, as of March 15, 2007, would have had no reason to doubt the truth and accuracy of Daugherty. Right?

A. Correct.

Q. If we start at the abstract, in the second-to-last sentence, which is exhibit -- page 3, the authors state:

"With this success, however, has come a series of technical challenges in the formulation of antibody-based materials to maintain sufficient stability in a variety of configurations and sometimes at particularly high concentrations. This review focuses on issues related to identifying and verifying stable antibody-based formulations."

Do you see that?

A. Yes.

Q. If we turn to page 5 of this exhibit, the top left-hand column, sentence beginning with the word "Novel," the authors state:

"Novel concerns then related to the development of stable formulations and delivery strategies for such large amounts of a complex molecule. Understanding product instability with regard to physiochemical and thermodynamic events becomes more and more critical to ensure market success."

Do you see that?

A. Yes.

Q. Then on the next page, the beginning of Section 3 titled "General concerns for antibody formulations," the authors state:

"Due to their proteinaceous nature, antibodies present generic formulation issues that are similar for most protein therapeutics. Proteins, in general, can be degraded under conditions when they are exposed to

heat, freezing, light, pH extremes, agitation, sheer stress, some metals, and organic solvents."

Do you see that?

A. Yes.

Q. And on the next page, page 7, the sentence starting with "A priori."

A. With -- starting with what?

Q. "A priori," kind of, middle, top right hand on page 7, right-hand column.

A. Oh, right-hand column.

Q. It's further up.

A. (Document review.)

Okay. I see it.

Q. Got it? Okay. And the authors say:

"A priori, one might assume that by finding a stable formulation for one of these antibody drugs, that such a formulation would be good for most if not all similar antibodies. If this were borne out by experience, there would be no need for a review such as this. Instead, each antibody seems to have a unique personality related to its

requirement for stability; a phenomenon derived from the fact that the small differences between these antibodies are focused on surface-exposed amino acid differences that stipulate antigen specificity. Thus, the interfacial surface of each antibody drug is unique, and thus requires specific formulation components to provide maximal stability and retention of activity."

Do you see that?

A. Yes.

Q. Do you agree generally with the authors of Daugherty, that each antibody has its own requirements for stability?

A. Yes.

Q. So a person of ordinary skill in the art wouldn't just assume that a known formulation would work for a new antibody. Right?

A. Correct.

Q. And again, on page 7, right-hand column, the second full sentence of that middle paragraph, the authors say in that sentence:

"It is the recognition of a stability indicating parameter (or several parameters) that allows the formulation scientist to focus in on what is critical to development of a successful product."

Do you see that?

A. Yes.

Q. And after outlining stability issues for antibody formulations in Section 4, which begins on page 7, the authors then go on to discuss strategies to stabilize antibody formulations in Section 5, which is on page 11. Right?

A. Correct.

Q. Is it fair to say that the authors of Daugherty viewed maintaining stability as one of the key challenges in formulating an antibody-based drug product?

A. Yes.

Q. And you agree that maintaining stability is one of the key challenges that needs to be addressed in a drug -- or antibody-based formulation?

A. Yes.

Q. And at the beginning of Section 5, the bottom left-hand corner of page 11, the authors state:

"While liquid antibody formulations are less expensive, faster to develop, and generally easier to prepare for administration than alternative formulation approaches, liquid antibody formulations are prone to oxidation, deamidation, aggregation, and fragmentation as discussed above."

Do you see that?

A. Yes.

Q. And then a few lines later in that same paragraph, the authors conclude "Thus, water is a big problem for stabilizing antibody-based drugs."

Do you see that?

A. Yes.

Q. If we turn to Table 1 on page 14. This table shows formulations of approved products. Right?

A. Yes.

Q. And in the "formulation concentration" column, we see two products.

Rituxan and Remicade are listed with 10 milligram per milliliter concentrations. Right?

A. Yes.

Q. And the other concentrations listed a range from a minimum of 1 milligram per milliliter to a maximum of 125 milligrams per milliliter. Right?

A. Correct.

Q. If we could flip back to your declaration, the '809 declaration at paragraph 53. And near the beginning of that paragraph, you state "it was commonplace by 2007 for" -- strike that.

From the beginning of the paragraph, you say:

"Regarding the 30 milliliters at 10 milligrams per milliliter limitation, it was commonplace, by 2007, for antibody therapies to be supplied in a liquid solution that could easily be drawn into a syringe and added to IV bags for infusions."

Do you see that?

A. Yes.

Q. Do you think the ease of drawing into a syringe and adding to IV bags is a serious consideration for a POSA who formulates an antibody-based product?

MR. KNAUSS: Object to the form.

You can answer.

A. Does volume make a difference when you're compounding? Yes. Is it better to have a smaller volume or reasonable volume? Well, the syringes that we use to draw medications out are maximum of 60 ml syringes, which you never want to have anything close to 60 because, your plunger falls out, drug falls all over the table.

But -- so if you could optimize that and make things easier, of course.

Q. But do you think the POSA who formulates an antibody-based product would be more concerned with establishing the stability of the product or the ease of administration of the product?

A. Stability of the product is always the driver.

Q. In paragraph 54 of your declaration, you, sort of, expound on what you

were just talking about. And you say that:

"30 milliliters is neither such a small volume that there would be concern about successfully drawing all the drug substance into a syringe, nor such a large volume as to be impractical to draw using a standard syringe or impractical to dilute into an IV solution for infusion into the patient."

Right?

A. Correct.

Q. Again, do you think a POSA, when formulating an antibody-based drug product, is concerned with the practicalities of drawing the product into a syringe?

MR. KNAUSS: Asked and answered.

You may answer.

A. Yeah, I do think so, because if the volume is too small, it gets stuck in your syringe. So that's a problem. Right? There's always loss in the bevel of a syringe, so if it's a very small volume, like a couple of cc's, there is a large error in that.

And if it's too large, it

actually is difficult. And when deciding on adding drugs to formulary, these things are taken into serious consideration, whether you can actually do it in a reasonable amount of time and deliver it to the patient safely, maintaining all the quality and safety features. So, yes, it is under -- it should be under consideration.

Q. Do the authors of the Daugherty paper, when discussing generally the formulation and delivery issues for monoclonal antibody therapeutics, take syringe draw into account as one of the challenges that needs to be overcome?

A. No, this paper was addressing how to formulate these, you know, and the complexities of that, of monoclonal antibodies.

Q. But you don't cite anything in your declaration as of 2007 that shows that a POSA would have been concerned of the constraints of a syringe. Right?

A. No, I don't. That, again, is based on years of experience and working in and delivering drugs to patients. And to take

that further, there are drugs that we have not added to formulary because they are too complex and they cannot be operationalized.

Q. When you talk about 30 milliliters as being a particularly practical volume to work with, what would you consider the limits on that practicality?

MR. KNAUSS: Objection to the form.

You may answer.

A. Anything too small, like I've already alluded to, 5 cc's or less, is actually quite difficult to draw up without significant dilution. And anything going over 50 mls would be -- but again, if we were already saying that the concentration was 30 milligrams per ml, then the 30 mls was obvious if we were targeting a 300 milligram vial.

Q. Do either Bell or Wang make express reference to a 30 milliliter volume?

A. No, they don't. Though, Wang does state that albeit a nebulized solution, still a solution, an aqueous solution, that the drug was stable. It's in the diagram,

looking at the HPLC, specifically around eculizumab, that it maintained its concentration or its stability.

Q. If we could go back to Bell. Can you walk me through specifically what made you choose a 300 milligram dose as it relates to Bell's disclosure of 600 and 900 milliliter doses?

A. Again, I think I've already addressed that but we knew the doses were 600 and 900 milligrams. Induction was 600, maintenance was 900. And just doing easy simple math and what would be a good dosage form to have where I could treat all patients with just having one product on my shelf.

Q. Right. But you didn't pull that 300 milligram value from the patents. Right?

MR. KNAUSS: Object to the form.

A. I'm not sure I understand "from the patent."

Q. In other words, you weren't operating with hindsight of what the patent had disclosed and then applying that to Bell's 600 and 900 milligram disclosures, were you?

A. And I just think it's simple math

and obvious that 300 makes the most sense if dealing with a 600 and 900 milligram dosing regimen.

Q. You agree that Bell discloses a potential range of dosages. Right?

A. The Phase II specifically use 600 and 900.

Q. But as we discussed earlier, you can divide 600 and 900 into multiple ways?

A. True.

Q. You'd have to supply an additional step that 300 is the most logical because of your experience. Correct?

A. Correct.

Q. But 600 and 900 can be subdivided, as we discussed earlier, into a number of different values?

MR. KNAUSS: Asked and answered.

A. Correct. But that doesn't make any sense if I can get at it with fewer vials, fewer inventory, fewer workload. It takes time to do these things.

And you have a patient sitting there with a horrible disease, and I don't want to sit there all day waiting for me to

compound a drug. So it's about patient's quality of life. And you try to make things as easy as possible at the end of the day. And as efficient as possible.

Q. Understood.

And similarly, you didn't take 10 milligrams per milliliter from the patents and apply that retroactively to the disclosure of Wang, which also teaches a range from 1 to 30 milligrams per milliliter. Right?

A. Correct. It's within the range of 1 to 30. And remember, you're talking about 2007, before we had electronic medical records that did smart math. Everything was a manual calculation.

And so if you could pick something that was easily divisible and, you know, we can all divide by ten or multiply by ten. Right? So -- but, again, you're driven by the stability, as Daugherty said. But if I have a range, just picking within the range.

Q. Do you know how changes in concentration impact the stability of a drug product?

MR. KNAUSS: Object to the form.

A. I'm not an expert but I do know that changes in concentration can affect stability, and that's why most agents have a specific range of when you dilute them and how long they're stable for, yes.

When compounding, we have a range. 250, 300, whatever.

Q. Do you know if decreasing concentration generally improves stability of an antibody drug product?

A. It can go either way.

Q. It can go either way. Would a 25 milliliter volume be a practical amount for you to work with?

A. Sure.

Q. You'd have no problems with that?

A. No, I would not.

Q. So because Bell and Wang both each -- both teach a potential range of values that could be pulled from them, I'm curious if a few examples would have been taught by Bell and Wang according to the same logic that you applied to get to 300 and 10.

Do you agree that 100 milligrams could have flowed reasonably from the

disclosure of Bell since it's divisible -- since 600 and 900 are both divisible by 100?

A. Sure.

Q. Sure. And if we assume a 25 milliliter volume, which you just said would be practical to work with, that would put us at a 4 milligram per milliliter concentration.

And 4 milligrams per milliliter would flow reasonably from the disclosure of Wang. Right?

A. Yes. But still within the range, still 1 to 30.

Q. Sure. And by that same logic, 150 milligrams, as we discussed, would flow reasonably from the disclosure of Bell. Right?

A. It would.

Q. And if we use your same 30 milliliters of volume, that would give us 5 milligrams per milliliter of concentration, which is also within the range disclosed by Wang. Right?

A. Correct. But again, I go back to

why would I have multiple vials if I can just have a few on my shelf, like two to three at any given moment?

Q. But if presented with overriding stability concerns, a POSA could have reasonably followed any one of those paths to get at the final product that we have in the patents. Is that fair?

MR. KNAUSS: Hypothetical.

But you may answer.

A. Yes.

MR. SOLOMON: We'll take another ten-minute break.

MR. KNAUSS: Okay.

MR. SOLOMON: Thank you.

THE VIDEOGRAPHER: The time now is 10:44 a.m. This concludes Media 2. Off the record.

(Recess taken from 10:44 a.m. to 11:02 a.m.)

THE VIDEOGRAPHER: The time now is 11:02 a.m. This begins Media 3. On the record.

BY MR. SOLOMON:

Q. If we could turn to page 12 of

your '809 declaration, paragraph 17. And at the top of this paragraph, you state that you've "reviewed Dr. Ravetch's statement of the level of ordinary skill in the field," and you "agree with it and have applied it in reaching the opinions expressed in this declaration."

Is that correct?

A. Correct.

Q. And it goes on to state that:

"Specifically, Dr. Ravetch opines (and I agree) that a POSA, as of March 2007, would have knowledge of the scientific literature and have skills relating to the design and generation of antibodies."

Do you believe that you have the requisite skills relating to the design and generation of antibodies that this definition envisions?

A. No, I don't. That was left up to Dr. Ravetch.

Q. Okay. Next, it references the complement system. Do you believe that you have the requisite knowledge of the complement

system as described in this definition of a POSA?

A. Not in drug development or drug sequencing.

Q. Okay. But then references the application of antibodies as therapeutics before March 15, 2007. Do you have the skills in the application of antibodies as therapeutics that this POSA definition describes?

A. In the application of antibodies as therapeutic in the treatment of patients, yes, I have experience in that.

Q. So do you believe that you're a POSA according to this definition?

A. I think if you go down further where it says a POSA would have worked as "part of a multidisciplinary team and drawn upon," so, you know, by 2007, I had been in clinical pharmacy for 15 years, plus my education, worked at the number one cancer hospital in the country, if not the world, and it has been that way for a lot of years.

And, you know, MD Anderson, up until I moved to New York, where we did

provide these drug therapies to patients, I also, at that time, or prior to that time, had done a significant amount of research in drugs that were in, you know, in clinical trials.

But I was well aware of the treatment of patients and the use of antibodies in treating patients.

Q. And you beat me to this portion of the definition. I was about to get there. And you might have just stated some of this. In the context of a multidisciplinary team, can you described the skills that you would contribute as a team member?

A. Yeah, so, as I said, clinical pharmacists are seen as mid-level providers, and so my role on the medical team, both when I was at MD Anderson and also at NewYork-Presbyterian, was that I would round with the medical team, and the medical team was made up of an attending physician, myself or another clinical pharmacist, and a nurse practitioner. We rarely had medical fellows.

So my responsibility on the team was to help provide information to the physician on the drug dosing, whether there

needed to be dose modifications based on end organ function, dysfunction, age, the like.

And we actually wrote the orders. So it was my responsibility to hand write all the orders for the patients, to include their chemotherapy or bio therapy.

I also created the order sets that were used, again, long before the electronic medical record existed. I took it upon myself to, in a Word document, create the order sets, which, sort of, made it safer because somebody could actually read them because they were typed, and then we would just input the specific data for the patient, and it would default to, similar to what we currently do, with the electronic medical records, just not quite as smart.

Q. Sure. And you touched on -- you started to touch on the last portion of this definition, which states that, as part of a team, you may help solve a given problem.

Can you describe the source of problems that you would help to solve in a team of this nature?

A. So at the time, I was doing bone

marrow transplantation.

(Stenographer clarification.)

A. And so because my training is all clinical or predominantly clinical, I would identify the patients newly diagnosed with graft-versus-host disease, help drive the therapies for that, ensure standardization of therapies.

You practice almost on the level of being a physician without the physical exam skills.

Q. And the problems that you just described, do you think these were taken into consideration when the inventors were formulating eculizumab?

MR. KNAUSS: Calls for speculation.

You may answer.

A. Likely not.

(Continued on the next page.)

MR. SOLOMON: No further questions.

THE VIDEOGRAPHER: The time now is 11:09 a.m. This concludes Media 3 of 3 of today's deposition. Off the record.

(Time noted: 11:09 a.m.)

- - -

A C K N O W L E D G M E N T

STATE OF)
: ss
COUNTY OF)

I, CINDY IPPOLITI, hereby certify that I have read the transcript of my testimony taken under oath in my deposition of February 20, 2024; that the transcript is a true, complete, and correct record of my testimony, and that the answers on the record as given by me are true and correct.

_____
CINDY IPPOLITI

Signed and subscribed to
before me this _____
day of _____, 2024.

_____
Notary Public

C E R T I F I C A T E

STATE OF NEW YORK)
: ss.
COUNTY OF NASSAU)

I, PATRICIA A. BIDONDE, a Notary Public within and for the State of New York, do hereby certify:

That CINDY IPPOLITI, the witness whose deposition is hereinbefore set forth, was duly sworn by me, and that such deposition is a true record of the testimony given by the witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this day, February 20, 2024.

_____
PATRICIA A. BIDONDE
Stenographer
Registered Professional Reporter
Realtime Certified Reporter

I N D E X

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E R R A T A

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

E R R A T A

ERRATA SHEET FOR THE TRANSCRIPT OF:

Case Name: Samsung v Alexion

Dep Date: February 20, 2024

Deponent: Cindy Ippoliti

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Cindy Ippoliti

Signed and subscribed to before me

this ____ day of _____, 2024

_____

Notary Public

A

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