UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

- - -

- -x

CELLTRION, INC.,

Petitioner,

-against-

REGENERON PHARMACEUTICALS, INC.,

Patent Owner.

- -x

- - -

Case: IPR2023-00462

U.S. Patent No. 10,464,992

- - -

BELL WORKS

101 CRAWFORDS CORNER ROAD

HOLMDEL, NEW JERSEY 07733

OCTOBER 13, 2023

9:06 A.M.

ORAL DEPOSITION OF

DR. RALPH TARANTINO

REPORTED BY:

DANIELLE GRANT

JOB NO.: 6139587

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CELLTRION EXHIBIT - 1048
Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.

OCTOBER 13, 2023

10:37 a.m.

Deposition of DR. RALPH TARANTINO, held at the offices of Bell Works, Holmdel, NJ 07733-1976, pursuant to Notice before DANIELLE GRANT, a Shorthand Reporter and Notary Public of the State of New York.

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VIDEOGRAPHER: We're going on the record at 10:37 a.m. on October 13, 2023.

R A L P H T A R A N T I N O Ph.D, called as a witness, having been first duly sworn by Danielle Grant, a Notary Public within and for the State of New York, was examined and testified as follows:

MS. GREEN: Mr. Brausa, I would like to make a quick objection for the record, if you don't mind. We agreed to videotaping today, but I just want to make sure that you understand we do not agree at this point to submitting the videotape as evidence in this case to the PTAB. We would like to designate the videotape as confidential, and we also plan on asking the USPTO. To limit the use to this proceeding.

MR. BRAUSA: Understood. We'll take that under advisement.

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EXAMINATION

BY MR. BRAUSA:

Q All right. Good morning. Could you introduce yourself?

A Yes. I'm Ralph Tarantino.

Q Okay. And throughout the proceeding, I'll refer to you at Dr. Tarantino, if that's okay with you.

A That's fine.

Q Okay. Now, Dr. Tarantino, where do you currently work?

A I'm an independent consultant, and I work out of my only.

Q Okay. And what is the name of the company that you consult with?

A Steritech -- it's my company. It's called Steritech Solutions.

Q And this is a company that you founded in about 2011, correct?

A 2011, yes.

Q And why did you decide to found your own company?

A I left Hoffman LaRoche in 2010 and decided to do consulting and form an LLC,

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which I think is pretty common.

Q Okay. And you had been with Hoffman LaRoche for a fairy significant period of time prior to leaving to start your own company in 2011, correct?

A Yes.

MS. GREEN: Objection to form.

Q How long were you with Hoffman LaRoche?

A Approximately 30 years.

Q Okay. And you started at Hoffman LaRoche out of graduate school; is that correct?

A I started at Hoffman LaRoche -- no, actually, I started after I had my bachelor's degree, a pharmacist. And I had two terms. After I -- after I got my doctorate, I rejoined Hoffman LaRoche.

Q How many employees are there at Steritech Solutions?

A Just me.

Q Has that been the case since it was founded in 2011?

A Yes.

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Q What type of consulting work do you do at Steritech Solutions?

A I do -- in addition to consulting on patent litigation, I work with companies that are developing -- developing drugs. So formulation, development, consultation, scale up, and manufacture.

I've written regulatory portions for some -- some companies.

Q Okay. If we can focus on the portion of your consulting work that relates to working for companies rather than patent litigation first, why is it that a company might come to you as a consultant for those types of roles?

MS. GREEN: Objection. Scope.

A Generally because of my expertise in sterile products and formulation, but also non-sterile products. My CV, you know, points that out, I believe, my experience.

Q When you say sterile products and non-sterile products, on the other hand, what is the difference between those that you're drawing?

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A Well, sterile products -- I can give you an example, right? I mean, sterile products have no microorganisms in them. But, generally, it breaks down into what someone can take -- for instance, if it's oral, it doesn't have to be a tablet or capsule or anything else. But anything you inject into a person needs to be sterile, free of microorganisms.

Q Okay. What are some of the containers you can use for sterile products?

A That depends on the situation. But I think the broadest background is we will call LVPs and SVPs, small volume parenterals, large volume parenterals. Could be bags, and small volume -- parenterals are generally vials.

Q Are there any other types of containers for SVPs or small volume parenterals?

A They might be used with syringes, either disposable syringes.

Q Okay. I've seen reference to some of the larger prefilled syringes. Is that

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something you're familiar with?

A I've worked with prefilled syringes, yes.

Q And those are distinct from vials; that correct?

A They're distinct from vials in that the vial is actually placed in the syringe. There's actually a vial inside the syringe.

Q Okay. Have you heard of something called an ampoule?

A Yes.

Q What is that?

A An ampoule is a -- a container that is -- a glass container that is sealed, usually by melting the tip, and has been generally out of use, I would say in general use for 30 years, because of the dangers involved for not only the people administering the drug, but for the patients with shards and things like this.

Q One of the items on your CV is that you were an instructor for the FDA in some capacity; is that correct?

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A I gave a course several times, yes. And I think protein stability. And I don't have the exact name.

Q Okay. And what was -- you alluded to it, but what was the subject matter of the course that you taught?

A My recollection was they wanted to know about the stability and -- yeah, it's actually -- this even has -- actually was the stability of protein. Protein stability. Probably formulation and stability. It was along those areas. I think this was about 20 years ago. But that was generally the area, yeah.

Q And at the time, were you employed by Hoffman LaRoche, or was this after you founded your consulting company?

A No, I was employed by Hoffman LaRoche.

Q Okay. And why was is it the FDA hired you to instruct in this class?

A It was biotechnology products, protein products were fairly -- fairly new. And it was to give their investigators more

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of a heads-up when they did inspections on the things to look for.

Q Okay. And so you said this was about 20 years ago, so this is 2004, 2005 time frame?

A You know, roughly. Again, I think I have it in my CV, the exact date.

Q What types of things do you recall instructing the FDA inspectors to look for, be aware of when they were considering protein stability?

MS. GREEN: Objection. Scope.

A Yeah. I don't recall specifically. I would have to look at my -- you know, look at my slides, actually, that I don't have anymore but...

Q Okay. So there was a slide presentation --

A There was a slide --

Q -- that you used during -- and do you recall how long this --

(Whereupon, the court reporter requested clarification.)

MR. BRAUSA: Sorry about that. I

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think it's my fault.

Q The slide presentation that you were giving, do you recall how long this training program was that you would give?

MS. GREEN: Objection. Scope.

A You mean an individual session?

Q Correct.

A Maybe an hour, hour and a half. It's hard to recall.

Q Okay.

A The question is --

Q And how many people would attend these sessions from the FDA?

A That also is -- is hard to estimate. I mean, it was set in an auditorium of 50 to a hundred people, maybe. I don't -- I don't really -- you know.

Q Do you recall how many times you gave this type of training to the FDA?

A I believe --

MS. GREEN: Objection. Scope.

A Okay. Again, this is a while ago. I recall doing it twice.

Q Do you recall whether there were

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any particular stability concerns or issues that you identified in these presentation?

MS. GREEN: Objection. Scope.

A Not really. I had -- I probably took a model protein and discussed it.

Q Do you remember whether the presentation was focused on all proteins or, were there specific proteins that you were instructing on?

MS. GREEN: Objection. Scope.

A It was focused on all proteins with examples of proteins.

Q Do you recall whether you provided any slides or instruction relating to fusion proteins?

MS. GREEN: Objection. Scope.

A No. I don't recall.

Q Do you remember at the time you were providing these talks whether any fusion proteins had been approved for commercial use by the FDA?

A At that time, I don't recall if they had been. But I do recall, about that time, it did become an active area of

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investigation within Roche.

Q So when I use the phrase "fusion protein," is that a term of art that you understand?

A Yes.

Q What does that mean to you?

A It means it's a protein that's formed from two different -- you know, generally a bioengineered protein formed from two different genes, let's say, in the most general sense. So it's not just -- it's not just expressed as -- from one genetic sequence.

Q Okay. And fair to say fusion proteins are not naturally occurring proteins?

A Fusion proteins, well, my definition of a protein, the best definition is a poly -- is a polypeptide. So these are -- I wouldn't even say sythetically modified, but they are modified proteins.

Q And modified in what way?

A You could change the sequence of amino acids in the protein.

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Q Any other ways that you can modify proteins to make them fusion proteins?

A There probably are -- there probably are other ways, yeah.

Q Okay.

A Probably, but...

Q Is there a relationship between the amino acid sequence of a protein and the challenges you might encounter formulating it in into a stable formulation?

MS. GREEN: Objection. Scope.

A Proteins, fusion proteins and any other proteins are -- stability is generally indicated by the amino acid sequence. Some amino acids are more prone to certain degradation than -- degradation pathways than others. And the significance of secondary and tertiary structure is also important.

Q What do you mean when you say the significance of secondary and tertiary structure is also important?

A The secondary and tertiary structure could sometimes indicate how a

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protein will interact with a receptor, its three-dimensional structure, so to speak.

Q Okay. So when I see, for instance, that the structure of an antibody represented as a "Y," that's a two-dimensional simplification of the actual structure of an antibody, right?

MS. GREEN: Objection. Form.

A I mean, in -- when you see it, I don't know what you're looking at, but there could be three-dimensional representations. But, you know, I think you would need to be more -- you know, if you -- if you showed me the photo of what you're talking about, I could answer that more definitively.

Q You agree with me, though, that antibodies and all proteins, they are three-dimensional structures, right?

A They're three-dimensional structures, yes.

Q Okay. And you alluded to secondary, or you mentioned secondary and tertiary structure.

What is the primary structure of a

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protein?

A A primary is the -- is the sequence.

Q Okay. And then how does the secondary structure differ from the primary structure?

MS. GREEN: Objection. Form.

A There is a -- intermolecular bonds that occur that will actually change the three-dimensional shape. So if there is some intermolecular bonding, you may get a different three-dimensional structure than just a straight line of amino acids.

Q And how does the tertiary structure differ from the secondary structure?

A Well, that's one step further. If your secondary -- that's when these molecules bind with each other in some way to form a -- yet another structure.

Q Okay. And I have heard reference to multimeric protein.

Is that a term you are familiar with?

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MS. GREEN: Objection. Form.

Objection scope.

A A multimeric -- there are some -- there are some -- I've seen the term. I believe it usually refers to even higher orders of association.

Q Have you heard the term "multimerizing component"?

A Yes.

Q And what does that mean to you?

A Generally, it means a linker between two polypeptide chains.

Q Okay. And so does providing that link, providing that multimerization and linking those two polypeptides make those two polypeptides into multimer?

MS. GREEN: Objection. Form.

A Yes.

Q I've also heard reference to quaternary structure.

Is that something you are familiar with?

MS. GREEN: Objection. Form.

A Yes. Quaternary structure is an

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added level of -- so now you have molecules binding to each other from the tertiary -- as I described it, the tertiary structure.

Q If we take an antibody as an example protein, does it -- does it have -- it has primary structure, I take it?

A Yes.

Q And can the stability of that antibody in solution be affected by its primary structure?

MS. GREEN: Objection. Scope.

A Yes, it could be affected by its primary structure.

Q And how does the primary structure of a -- or how do (sic) the primary structure of a protein potentially impact the stability of that protein?

MS. GREEN: Objection. Form. Objection. Scope.

A Generally, it's a -- chemical reactions with individual amino acids.

Q And when you say, generally, there are chemical reactions with individual amino acids, how would that impact stability for

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the given sequence?

MS. GREEN: Objection. Form.

A Well, you can cleave these chains under certain circumstances.

Q [redacted]

MS. GREEN: Objection. Form.

A [redacted]

MS. GREEN: Objection. Form.

Objection scope.

[redacted]

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MS. GREEN: Objection. Form.
Objection scope.

MS. GREEN: Objection. Form.
Objection scope.

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[redacted]

MS. GREEN: Objection. Form. Objection scope.

[redacted]

Q You would agree with me, I think, that when you're trying to formulate a stable solution, it's a balancing process, right?

MS. GREEN: Objection. Form.

A Could you explain that?

Q Sure. Actually, why don't we come back to that. I want to go back to our discussion of different structures. We were talking about the primary structure of an antibody.

Does an antibody have a secondary structure?

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MS. GREEN: Objection. Form. Objection scope.

A I think that will depend on the antibody, right?

Q Okay. Well, in your work at Hoffman LaRoche, you were familiar with various commercial antibodies, right?

A Yes.

Q Okay. Are you familiar with trastuzumab?

MS. GREEN: Objection. Scope.

A Trastuzumab, not particularly. I am --

Q What about bevacizumab?

MS. GREEN: Objection. Scope.

A Again, yes, I'm familiar with the -- that they exist.

Q So but I -- I'm just trying to understand.

Are there some antibodies that don't have a secondary structure?

A It's a -- it's a possibility, sure.

Q Okay. If we talk about a

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monoclonal antibody, do most of them have secondary structures?

MS. GREEN: Objection. Form. Objection scope.

A Yeah -- okay. That's something I that couldn't answer.

Q You don't know whether most monoclonal antibodies have a secondary structure?

A Again, it depends on the -- it would depend on the molecule.

Q Okay. What is an example of a monoclonal antibody you have in mind that would not have a secondary structure?

MS. GREEN: Objection. Form.

A A secondary structure is -- really doesn't have to do with any class of -- particular of proteins. It's something that is observed in proteins, so I really can't make that type of -- you know, type of estimation.

Q So you can't tell me any monoclonal antibodies that don't have a secondary structure?

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A Not without looking at their structure.

Q Okay. Are there any antibodies that you have in mind that you can tell me do have a --

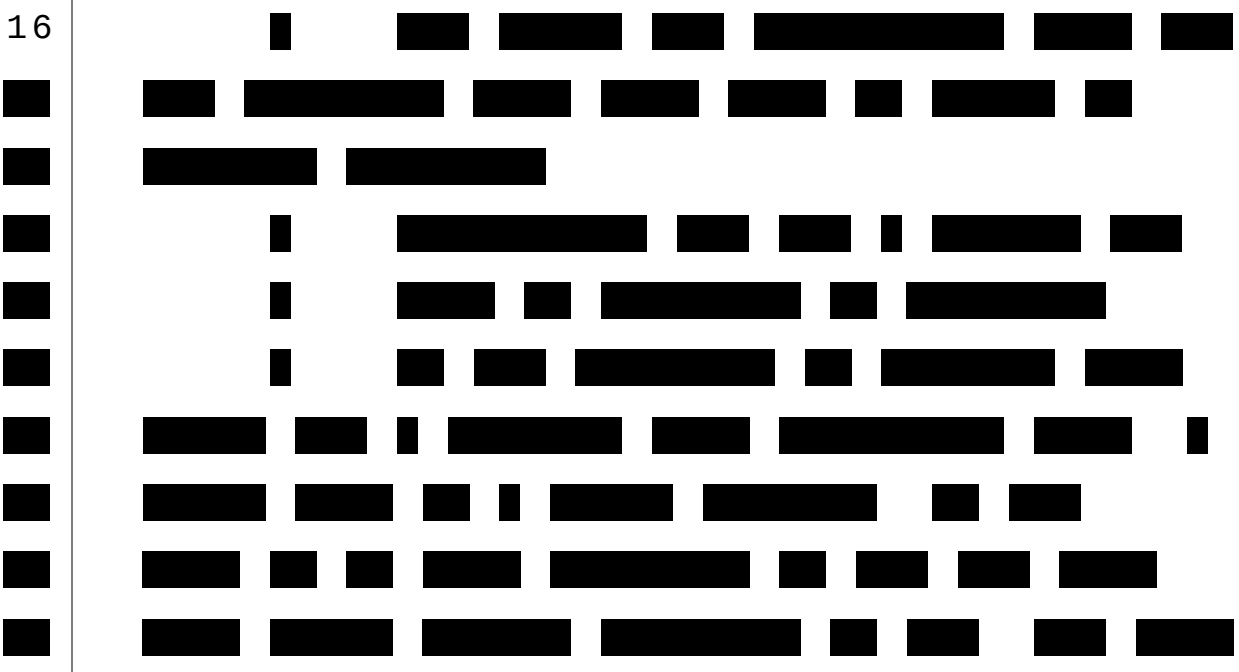
A Well --

Q -- secondary structure?

A -- like a --

MS. GREEN: Objection. Form.

A I'm sorry. I must be going too fast. But, again, it's the same -- I think it's the same -- the same discussion. This is molecule-specific and -- and I would need more information.



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[redacted]

MS. GREEN: Objection. Scope.

A It had a tertiary structure.

Q Okay. So is there a way that a molecule can have a primary and tertiary structure without having a secondary structure?

MS. GREEN: Objection. Scope.

Objection. Form.

A Possible.

[redacted]

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MS. GREEN: Objection. Scope.

MS. GREEN: Objection. Scope.

MS. GREEN: Objection. Scope.

MS. GREEN: Objection. Relevance.

Objection. Scope.

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[redacted]

MS. GREEN: Objection. Scope.

[redacted]

MS. GREEN: Objection. Scope.

[redacted]

Q Okay. Would you know in advance which amino acids you could change without having an impact on stability?

MS. GREEN: Objection. Scope.

Objection. Form.

A Yes. We would know which amino acids would probably give you increased degradation.

Q Okay. Which ones would those be in --

MS. GREEN: Objection --

Q -- daclizumab?

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MS. GREEN: -- objection. Scope.

A In general, methionines and tryptophans are oxidized more readily than other amino acids. Asparagine -- there are some -- I mean, that's -- that's sort of an example, yeah.

Q Okay. And would those same amino acids be amino acids that you could change in other proteins and have an impact on stability, too?

MS. GREEN: Objection. Scope.

A I'm not sure.

Your question is would I change the structure of a protein to be less stable?

I mean, is that what you're asking me?

Q I'm asking if you change the structure of a protein, if you change some amino acids, would you know in advance what impact that would have on stability?

MS. GREEN: Objection. Scope.

A You would -- you would know that you're putting in a -- an amino acid that is more prone to oxidation, let's say, if we

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take methionine.

Q Okay. Stability is not the only consideration, though, when developing a therapeutic protein product, is it?

MS. GREEN: Objection. Form.

A It's the major consideration, yes.

Q Okay. Do you ever consider efficacy as part of the formulation process?

MS. GREEN: Objection. Scope. Objection. Form.

A Of course, you do consider efficacy, but when you say, developing, to me that means the development of a formulation or the development of a molecule. I think the efficacy is a -- I wouldn't say a given, but of course it's -- the goal is safety and efficacy, right.

Q What about ease of use, is that ever a consideration in formulation?

MS. GREEN: Objection, relevance. Objection, scope.

A Nothing comes before potency, stability. Because the object of safety and efficacy.

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MS. GREEN: Objection, form.
Objection, scope.

MS. GREEN: Objection, form.
Objection, scope.

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MS. GREEN: Objection, form.
Objection, scope.

[redacted]

MS. GREEN: Objection, form.
Objection, scope.

[redacted]

MS. GREEN: Same objection.

[redacted]

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MS. GREEN: Same objection.

[redacted]

MS. GREEN: Objection, form.

Objection, scope. Objection relevance.

[redacted]

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[redacted]

MS. GREEN: Objection. Same objections.

[redacted]

MS. GREEN: Same objections.

[redacted]

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[redacted]

MS. GREEN: Same objections.

[redacted]

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[redacted]

A I'm going to hand you what's in the record already as Exhibit 1038.

(Exhibit No. 1038 Document titled, Guidance for Industry Container Closure Systems for Packaging Human Drugs and Biologics Chemistry, Manufacturing and Controls, a previously marked exhibit was referenced.)

Q Do you recognize this document, Dr. Tarantino?

A I've seen it before.

Q Okay. And do you recall when you've seen it before?

A Not really.

Q Do you recall looking at this document when preparing your declaration for this case?

A I don't -- I don't recall specifically.

Q What did you actually do to

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prepare for your deposition today?

MS. GREEN: Just -- you can talk in generals; don't talk about any specifics, Dr. Tarantino.

Q And maybe I can clarify. I'm not asking about any communications you had. I'm just asking what you did. So non substance of communications with counsel.

A I reviewed my reports and the -- my report and the -- and the prior art.

Q Okay. Do you recall any specific prior art that you reviewed?

A It's -- it's mentioned in my report.

Q Okay. You reviewed all the prior art mentioned in your report?

A I reviewed the prior art, yes.

Q Okay. And did you meet with counsel in preparation for today's deposition?

A Yes.

Q Who did you met with?

A I met with Rob, I believe, and Lora.

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Q And how long did you met with them?

A We met the last -- last three days.

Q And how long did you meet each day?

A Probably about five, six hours.

Q Okay. And you're being compensated for your time in this case, correct?

A Yes.

Q And I believe it's at $475 an hour?

A Yes.

Q Is that your ordinary consulting rate?

A Yes.

Q And you understand that counsel represents a company called Celltrion?

A Yes.

Q Have you worked with Celltrion previously?

A Yes, I have.

Q In what capacity?

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A Also, advice on pharmaceuticals.

Q When you say "advice on pharmaceuticals," in a technical capacity or a patent capacity?

A Patent capacity.

Q Okay. Have you ever separately consulted with Celltrion as part of your consulting business working with companies on their formulations and things like that?

MS. GREEN: Objection to form.

A Not that I recall.

Q All right. So you haven't advised Celltrion on formulations that should or shouldn't be used with any of their protein products?

A No, I haven't.

Q When were you first retained by Celltrion, if you recall?

A I don't recall exactly. Several years ago, perhaps.

Q Okay. And if we assume several years ago, and I won't hold you to the exact date, about how many times have you spent working with Celltrion in total?

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A How much -- what -- how much time working on reports or ...

Q Well, we'll get to that. My question is just overall, how many hours have you billed to Celltrion?

A I really don't know. I really don't know.

Q Is it more than a hundred?

A I doubt it.

Q Okay. And do you recall about how much you have been compensated by Celltrion in total?

A No, I don't.

Q More than a hundred thousand dollars?

A Not more than a hundred thousand dollars. Certainly not.

Q Okay. More than 50,000?

A I would really doubt it.

Q So less than 50,000?

A I would -- I would say.

Q And that's across all the matters that you have worked for Celltrion on?

A The two matters that I -- the two

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matters.

Q Okay. Are you aware that in this proceeding Samsung Bioepis has filed what's called a joinder petition?

A No, I'm not.

Q Okay. Were you aware that they separately submitted your declaration in support of their IPR petition?

A No, I am not.

Q Okay. Are you separately working with any counsel for Samsung relating to this IPR petition?

A No, I'm not.

Q And are you working with Samsung Bioepis on any matters currently?

A No.

Q Have you ever met with an individual named Ray Nimrod?

A No.

Q Matt Troutman?

A No.

Q If we can go back to Exhibit 1038. You said you recognized this document. Do you know what this document is?

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(Reporter clarification.)

A The guidance on container closure systems, yes. For packaging human drugs and biologics.

Q Do you know who publishes this document?

A The FDA.

Q Do you know who the intended audience of this document is?

MS. GREEN: Objection. Form.

A Yeah. Generally, people in chemistry manufacture and controls.

Q Okay. So this would be persons like yourself 20, 30 years ago when you were working as a formulation scientist at Hoffman LaRoche?

MS. GREEN: Objection. Form.

A People like myself, yeah.

Q All right. If we can turn to page 23 of this document. You see heading E refers Dry Products for Injection and Ophthalmic Drug Products?

A Yes.

Q Do you have an understanding of

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what an ophthalmic drug product -- product is?

MS. GREEN: Objection. Scope.

A Yes, I do.

Q What is it?

A It's one that's used in the eye.

Q Okay. Are you familiar with Lucentis?

A What's that?

Q Lucentis.

A I've heard of it. I'm not familiar with what it is, though.

Q Okay. In the first paragraph, it says that injectable dosage forms represent one of the highest risk drug products. Do you see that?

A Yes, I do.

Q Do you have an understanding as a formulation scientist why that is?

MS. GREEN: Objection. Form.

A Yes. I think it explains it in the next -- the next sentence. It's because of the sterility issue and injecting microorganisms into people.

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Q It then it goes on under the subheading of injectable drug products on page 24 to talk about potential packaging for SVPs and LVPs. Do you see that? It's the first paragraph on page 24, Exhibit 1038?

A Yes.

Q And remind me. SVP stands --

A I'm sorry. Can you repeat that? I was looking on the next page. What page?

Q Sure. Page 24.

A Okay.

Q The first paragraph.

A Okay.

Q And what does SVP stand for?

A Small volume parenteral.

Q Okay. And what does LVP stand for?

A Large volume parenteral.

Q And the FDA identifies several different packages for an SVP, correct?

A Yes.

Q It identifies a disposable cartridge, right?

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A Yes.
Q A disposable syringe?
MS. GREEN: Objection. Form.
Q Do you see that?
A Yes.
Q It identifies a vial, correct?
A Yes.
Q It identifies an ampoule, correct?
A Yes.
Q And then it identifies a flexible bag as well, correct?
A Yes, it does.
Q You would agree that, with the FDA, that these are all different types of packagings that an SVP may be put in, right?
MS. GREEN: Objection, form. Objection, relevance.
A I would agree they had this opinion in 1999.
And since then, even at that point, ampoules were generally frowned upon. I think I may have mentioned that previously. And in the U.S., probably there were no ampoule products, I would say, between 35 and

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40 years.

Q Okay. But at least in the FDA's guidance from 1999, they were still saying that an ampoule, along with syringe, cartridge, or bag were alternatives to a vial for packaging SVPs, correct?

MS. GREEN: Objection. Form.

A Yes. They say that there might be specific uses for ampoule. It's not generally regarded as a common dosage form.

Q Okay.

A Now, or in the time this patent was issued.

Q Okay. Do you recall citing any literature to support your view that ampoules were not common as of 2006?

MS. GREEN: Objection. Form.

A If I -- I don't recall if I included that in my report, but that's just a general knowledge of a POSA.

Q Remind me, what is a POSA?

A Person of ordinary skill in the art. And the fact that I have developed multiple products in various capacities over

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the 30, 35 years, and I have seen the decreased use, I've seen the problems and the issues with causing glass splinters, and I haven't literally seen an ampoule product in the U.S., again, probably 30, 35 years; it's hard to say exactly.

Q And when you say "ampoule product," you're referring to commercial products, right?

A When I say ampoule product I'm referring --

(Whereupon, the court reporter requested clarification.)

A When I say -- generally, I mean, commercial product, but that also includes a clinical product, you know, where once -- the issues remain the same for clinical and commercial products.

Q Okay. And then, of course, ampoule is not the only other type of packaging referred to as a possible -- a possibility for SVP by the FDA, correct?

A Yeah. They give other examples.

Q And a disposable syringe is one of

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those.

Is that the same as a prefilled syringe?

A Not necessarily.

Q What is a prefilled syringe?

A A prefilled syringe, it's -- to make it simple, a prefilled syringe has a small vial or a cartridge. That's really saying the same thing. And a prefilled syringe might be a fill right into the -- into the syringe, which is generally not done until the commercial stages. So you wouldn't run clinical studies with a prefilled syringe.

Q What about preclinical studies?

Have you ever used a prefilled syringe --

A Preclinical studies, you --

MS. GREEN: Objection. Form.

A -- preclinical studies, you definitely wouldn't.

Q Okay. And is that a hard and fast rule, or is that just based on your experience at Hoffman LaRoche?

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MS. GREEN: Objection. Form.

A It's not a rule. It's just the nature of the business. Developing a prefilled syringe, when you're working on experimental drugs or formulations, just isn't feasible. It's just -- takes -- not practical.

Q There are approved commercial products that are packaged in prefilled syringes, correct?

MS. GREEN: Objection. Form.

A Yeah. Probably. I mean, I am going to give you probably on that.

Q Okay. And what are some reasons why you might decide to use a prefilled syringe as the packaging for a commercial product?

MS. GREEN: Objection. Form.

Objection. Scope.

A Ease of use.

Q I think we can put this away. Earlier today, I was talking about -- I used the term "excipient," and I think you -- paraphrasing, you objected to my use of the

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term "excipient." I want to make sure I'm not using that term incorrectly.

Is that a term that you use in your work as a formulation scientist?

A Yes.

MS. GREEN: Objection. Form. Objection. Scope.

A Yes.

Q And what does "excipient" mean, from your perspective?

MS. GREEN: Objection. Form.

A It's a -- I think it -- a substance that you would add to a formulation to adjust its properties. And there is -- there are defined lists of excipients that formulators would use.

Q Okay. We talked about, as an example, sucrose.

Is sucrose an excipient?

MS. GREEN: Objection. Form.

A Sucrose could be an excipient, yes.

Q Okay. And I'm also familiar with something called "trehalose."

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Have you heard of that?

A Yes.

Q Is trehalose termed excipient?

A Trehalose --

MS. GREEN: Objection. Form.

A -- trehalose would be called an excipient.

Q Okay. And is sucrose termed excipient?

MS. GREEN: Objection. Form.

A Can you repeat that?

Q Yeah. Is sucrose also termed a excipient?

A Yeah. I thought you asked that already, but the answer is yes, sucrose is an excipient.

Q Okay. And within the general umbrella of excipients, do trehalose and sucrose belong to a certain class of excipients, or is there a more specific name that you would give to those two molecules besides excipient?

MS. GREEN: Objection. Form.

A Carbohydrates.

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Q Okay. So sucrose is a carbohydrate, and trehalose is termed carbohydrate?

MS. GREEN: Objection.

Q Okay. And they're not in -- oh, sorry.

(Whereupon, the court reporter requested clarification.)

A Oh, okay. Sucrose -- yes, sucrose and trehalose are carbohydrates.

Q They're not the only two carbohydrates despite that that's what they're termed?

MS. GREEN: Objection. Form.

A They're not the only two carbohydrates that are excipients, but they are, I guess, more commonly seen in injectable or sterile dosage form. If you opened it up to oral dosage forms, you might see more.

Q Okay. If we focus on injectable dosage forms, are there other molecules termed carbohydrates that are used as excipients?

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MS. GREEN: Objection. Form.

A Yes. There are other molecules, yes.

Q What other molecules are termed carbohydrates?

MS. GREEN: Objection. Form.

A Dextrose.

Q Are any other molecules termed carbohydrates?

MS. GREEN: Same objection.

A For sterile products, none really come to mind right now.

Q Is glycerol ever termed a carbohydrate?

MS. GREEN: Objection. Form.

A No, glycerol isn't a carbohydrate.

Q Is there a term or class used for glycerol as an excipient?

MS. GREEN: Objection. Form.

A You may see it on the solvents.

Q And so glycerol is termed solvent when we're talking excipients?

A In general.

MS. GREEN: Objection. Form.

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A In general.

Q Are -- how many other types -- again, if we're focusing on injectables, how many other excipients are termed solvents besides glycerol --

MS. GREEN: Objection. Form.

Q -- generally speaking?

A Probably less than five.

Q What other excipients are termed solvents?

MS. GREEN: Objection. Form.

A As a matter of fact, I don't think I could even think of five. Commonly -- Not even commonly, ethanol might be a solvent used.

Q Anything else that comes to mind?

MS. GREEN: Objection. Form.

A Some of the PEGs, polyethylene glycol.

(Whereupon, the court reporter requested clarification.)

THE WITNESS: PEGs. Polyethylene glycol.

Q PEGs are termed solvents as well?

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MS. GREEN: Objection. Form.

A In the category of injections, this is what we're talking about.

Q Yes.

A Some PEGs. PEGs are polymers with high molecular weight, they could be, that are -- at some molecular weights, or most, waxes. So when I say that they would be used as solvents, I'm referring to PEG 200 or PEG 400 in general.

Q Okay. And are Tweens a brand name for PEGs?

MS. GREEN: Objection. Form.

A No.

Q Okay. What are -- what are -- what is Tween 20?

MS. GREEN: Objection. Form.

A It's polysorbate.

Q And so is Tween 20 termed solvent or no?

MS. GREEN: Objection. Form.

A Tween 20 in the same classification that I have been using is called a "surfactant."

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Q Okay. And so Tween 80 is termed surfactant, too?

MS. GREEN: Objection. Form.

A Tween 80 is a surfactant.

Q And you're distinguishing between surfactants on the one hand and solvents on the other of injectable protein products?

MS. GREEN: Objection. Form. And objection. Misstates.

A Yes. The classification are, as I believe I have included in -- the classification of these molecules are solvents or surfactants are two different classes of excipients.

Q Okay. So we have solvents, surfactants, carbohydrates.

Are there other classes of excipients that are used in injectable protein products?

MS. GREEN: Objection. Form. Objection. Misstates.

A Well, surfactants and solvents aren't always used, so I think that depends on the type of injection, and what you're --

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you know, if you require a cosolvent, a solvent, then you will use a solvent.

Q Okay. And so how do you know what types of excipients you need to add to your formulation --

MS. GREEN: Objection. Form.

Q -- if any?

A If you're drug is insoluble, you would use a solvent.

Q So that's a reason you might use a solvent.

Why would you add a carbohydrate to your injectable solution --

MS. GREEN: Objection. Form.

Q -- or what are some of the reasons?

MS. GREEN: Same objection.

A A common reason is to adjust the osmotic pressure.

Q When you say "osmotic pressure", can you explain what you mean by that?

A The osmotic pressure is the -- what we call a colligative property that relates to the concentration of a solute in

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a solution.

Q Is that related to a concept I've referred -- heard referred to as osmolarity?

MS. GREEN: Objection. Form.

A Yes.

Q In what way?

A Well, osmolarity is just a measure of the osmotic pressure.

Q Okay. And so adding a carbohydrate can impact the osmolarity of a solution?

MS. GREEN: Objection. Form.

A Yes.

Q Is there any general trend in terms of how adding carbohydrate affects osmolarity?

Does it go up or down, or what is the scale?

MS. GREEN: Objection. Form.

A Well, as I mentioned, it's a colligative property which means it depends on the concentration.

Q Okay. And so for a fixed concentration of protein, what impact will

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adding a carbohydrate have on the osmolarity of the solution?

MS. GREEN: Objection. Form. Objection. Relevance.

A What do you mean by "impact"?

Q Just does it have an -- I guess I'll start there.

Does adding a carbohydrate have an impact on osmolarity of a solution?

MS. GREEN: Same objections.

A It may or may not depending on the concentration of the other ingredients and -- and the -- I'm not sure if you said peptide.

I'm not sure what you -- did you say protein or...

Q For a protein in --

A For a protein, yeah. It depends on the concentration of the -- of the other components of the formulation.

[redacted]

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MS. GREEN: Objection. Form. Objection. Scope.

[redacted]

Q Okay. And so it would vary depending on where you're injecting the solution, how much protein you have in the solution and the amount of other excipients in the solution; is that fair?

MS. GREEN: Objection. Form. Objection relevance.

A I'm sorry.

What would vary the...

Q The desired osmolarity --

A Yes.

Q -- I apologize.

A Yes. Yes.

Q Okay. And so to measure osmolarity, you would need to have all those variables set and then check what impact the

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addition of the carbohydrate has on the overall osmolarity of the -- of the solution?

MS. GREEN: Same objection.

A You would have all the -- you would have -- I'm sorry.

What did -- what did you say?

Q So how would you go about determining what impact, if any, the addition of a carbohydrate has on the osmolarity of an existing protein solution?

MS. GREEN: Same objection.

A Okay. You would -- this is a thing that can be done mathematically, as I mentioned. It really depends on the molecular weight. And you would look at the route of administration to determine the significance. That's how it would be done and -- yeah.

[redacted]

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MS. GREEN: Objection. Form. Objection. Scope. And we've been going about an hour, so when you -- thinking about a break.

MR. BRAUSA: Sure. We can take a break now.

MS. GREEN: Okay. Thank you.

VIDEOGRAPHER: The time on the video monitor is 11:40 a.m. We go off the record. This ends Media 1.

(Whereupon, at 11:40 a.m., a recess was taken to 12:00 p.m.)

(The proceeding resumed with all parties present.)

VIDEOGRAPHER: We're back on the record. The time on the video monitor is 12, noon. This starts Media 2.

Q Welcome back, Dr. Tarantino. Just before the break, I was asking whether you were familiar with a concept called "tonicity."

Do you recall that?

MS. GREEN: Objection. Scope. Objection. Relevance.

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A I remember. And I don't remember your question, though.

[redacted]

MS. GREEN: Same objections.

[redacted]

MS. GREEN: Same objections.

[redacted]

MS. GREEN: Objection. Scope.

Objection. Relevance.

[redacted]

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[redacted]

MS. GREEN: Objection. Scope.
Objection. Relevance.

[redacted]

MS. GREEN: Objection. Scope.
Objection. Relevance.

[redacted]

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[redacted]

MS. GREEN: Objection. Scope. Objection. Relevance.

[redacted]

MS. GREEN: Objection. Scope. Objection.

THE WITNESS: Okay.

MS. GREEN: Relevance.

THE WITNESS: I'm sorry. I keep forgetting.

[redacted]

MS. GREEN: Objection. Scope. Objection. Relevance.

Can I ask the witness to leave for one second?

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Leave and take off your --

MR. BRAUSA: I'm going to object to this. I'm not sure know what the basis is.

MS. GREEN: I can object in front of him if you want me to.

I'll leave that up to you.

MR. BRAUSA: That's fine, if you'd like?

We're not going to have the witness go off the record.

MS. GREEN: Okay. That's fine. His report has nothing to do with isotonicity. It seems like you're getting into litigation questions, and I would ask you to keep this section of isotonicity very short, or we should call the board. Because this has nothing to do with his report, which deals with formulation, not injectables or anything else, except to the extent that it relates to subcutaneous injection because that is what the reference he relied upon did.

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MR. BRAUSA: So I just fundamentally disagree on that. Reports about the obviousness of formulations and Part 1 of the components of a formulation for injection is the tonicity. And so it's highly relevant to the issues raised in the IPR.

MR. CERWINSKI: It's --

MR. BRAUSA: So I'm happy to ask the questions. If he doesn't have an answer to them, that's fine. But I'm not going to steer different questions about formulations different ways based on your views of relevance.

MR. CERWINSKI: Can you articulate how your questions relating to isotonicity relate to or are relevant to the opinions expressed in his report?

MR. BRAUSA: I'm not going to preview the relevance of them, because that's -- we're getting into attorney work product, frankly, which I'm not

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obligated to do. We have got a report about injectable liquid formulations. The tonicity is a component of liquid formulations, and therefore, I'm entitled to ask about it?

MR. CERWINSKI: A component that has nothing to do with his report. And we can ask the witness to leave. Again, I'll give you the opportunity to do that before I say my next statement.

Do you -- do you want him to stay in, or do you want him to leave?

MR. BRAUSA: I would like him to stay in so that the board can hear the coaching that's now going on.

MR. CERWINSKI: No, no.

MS. GREEN: Oh, no. We've have asked to have him so that there is no coaching.

MR. CERWINSKI: We're happy to have him leave, correct?

(Whereupon, the court reporter requested clarification.)

MS. GREEN: Sorry. Yeah. But

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that's why I had asked him to leave in the first place.

You said: No.

I said: Do -- are you not sure you want the witness to hear this?

So is not improper coaching; this is your -- this is your requirement that the witness stays in the room. If you don't want the coaching, he should leave the room. But we have the right to express our objections. You know, it's in the trial practice guide that these are not to be used for improper purposes, including building up litigation positions. And it -- and we want to make sure it's clear on the record that you're going to litigation positions, and you're not keeping your questions to what was in his report.

So we want to make sure that it's clear that this is not relevant to what he wrote in his report and that you're using this deposition for improper purposes.

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MR. CERWINSKI: And either you can explain the relevance to us now or explain it to the board, but you're going to have to explain it. And we're happy to hear that explanation with the witness outside of the room.

MR. BRAUSA: We can excuse the witness briefly. I'll object to this whole line of objection as it is improper, and the suggestion that the questions are for improper purpose is just incorrect?

MS. GREEN: We'll come get you --

THE WITNESS: I'll be right there.

MS. GREEN: -- Doctor. Okay. Thank you.

Adam, we've given you some leeway.

MR. CERWINSKI: Let the door close.

MS. GREEN: Okay. We have given you some leeway, and I have let the question go on. But now you're talking about injection, things that are more important to the clinical side of

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things. He is a formulator. He expressed his opinions on the formulation that was in the prior art. These types of concepts were not described in his declaration; these concepts were not discussed in the prior art he relied upon. So that's why. And we are aware of what went on in the Mylan trial and what the kinds of questions are there. And these are much more related to what went on into that previous trial than they are to this particular proceeding and the issues in this particular IPR.

The board is very firm on not using these proceedings for improper purposes. So if you want to continue to ask your questions, I just want to make it very clear on the record that this is something we're going to object to. And if you continue on it, I'm more than happy to get on a call with the board.

MR. BRAUSA: So if you want to

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call the board, that's fine. Very briefly, the relevance of this squarely at issue with the issues in his IPR. He's talking the obviousness of formulations based on the prior art. One of the considerations about motivation about reasonable expectation of success, to use, to not use certain formulations to draw parallels between post-priority formulations and prior art formulations is the tonicity of the solution. I understand he didn't talk about it. That's not my decision.

But certainly tonicity, it's a concept he's familiar with, it's a variable that's accounted for in the formulation, and it's directly relevant to his obviousness opinions.

MR. CERWINSKI: He didn't talk about it.

It's not in your pauper, right?

It's not in your reply. It's not in the patent --

MR. BRAUSA: I'm sorry.

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MR. CERWINSKI: -- right?

How is it relevant?

MR. BRAUSA: We have --

MR. CERWINSKI: How is it relevant to this patent?

MS. GREEN: No. But -- but --

MR. BRAUSA: Sorry. Let me finish with respect to that. The pauper is not our only opportunity. We're developing evidence for our response. We're not obligated to preview every argument we're going to raise. If you want to make this objection to the board, fine. I don't think I have a lot more questions about it. We can agree to disagree, but I don't think its productive to waste more time than we have already wasted today having debates about relevance on the record. You don't think it's relevant, fine. It's not for an improper purpose. I'm confident that the board won't see it that way, and we can move on after we establish whether he has any additional

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information about this subject.

MS. GREEN: I just have one more question is where do they talk about tonicity in any of the prior art?

MR. BRAUSA: The tonicity is an inherent, which is front and center in all of the material that he provided -- property of a formulation. That deals directly with the use of the formulation, the obviousness of different components and I just -- that's sort of the equivalent of saying, When did it talk about -- I don't know -- deamidation in the art or some other form of stability. It's front and center with the argument. So we can agree to disagree. I don't think it's going to be productive to keep going back and forth. If you feel strongly about it and you want to call the board, that's up to you.

MS. GREEN: I think we can agree that, if you tie this up pretty quickly, we can go on without calling

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the board. But I did want the objection on the -- on the -- on the record. I think it is important. I do think there are relevance issues, which is why I keep objecting to relevance. I keep -- I do think there are scope issues, which is why I keep objecting to scope. And we will be bringing this up before the board. Now, if -- again, you said you're almost done with that, that's great, let's get done with and move on.

MR. BRAUSA: Okay. I'll ask my questions. I can't control what you're going to do.

MS. GREEN: Well, you're the one who told me you're going to tie this up pretty quickly.

MR. BRAUSA: I'll tie it up in my view but I --

(Cross-talk.)

MR. CERWINSKI: So how many more questions do you have?

MR. BRAUSA: I'm not going to tell

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you that.

MR. CERWINSKI: Okay.

MR. BRAUSA: That's not appropriate.

MR. CERWINSKI: I have not heard an explanation of how this is relevant to -- to this --

(Cross-talk.)

MR. BRAUSA: I just told you the relevance. You may disagree with the relevance, which is fine.

MR. CERWINSKI: You didn't really explain.

MR. BRAUSA: I just explained that tonicity is an aspect of the formulation that has to do with obviousness of certain components or not.

MR. CERWINSKI: Not to this patent, which doesn't have a claim element --

MR. BRAUSA: I disagree.

MR. CERWINSKI: -- relating to tonicity.

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MR. BRAUSA: I disagree. It has excipients. Excipients impact tonicity. You know that.

MR. CERWINSKI: That's not an explanation of relevance.

MR. BRAUSA: We can agree to disagree.

MR. CERWINSKI: All right. Yeah. So how much longer, approximately, do you have?

MR. BRAUSA: Let's say five minutes max.

MR. CERWINSKI: Maybe we can take just a two-minute break here?

We can -- we can -- we're not going to talk to the witness.

I just want to -- you want to confer?

MS. GREEN: Yep.

MR. BRAUSA: We're going off the record at counsel's request?

VIDEOGRAPHER: The time on the video monitor is 12:11 p.m. We're off the record.

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(Whereupon, at 12:11 p.m., a recess was taken to 12:15 p.m.)

(The proceeding resumed with all parties present.)

VIDEOGRAPHER: We're back on the record. The time on the video monitor is 12:15 p.m.

MS. GREEN: Just to make it clear for the record, we object to this line of questioning for the same reasons that we discussed but you can continue.

MR. BRAUSA: Understood. Thank you.

Q Welcome back, Dr. Tarantino. Just a few moments ago you were you excused, and we stayed on the record for a bit and then went off the record.

During your time outside of the deposition room, did you talk with counsel?

A No, I did not.

Q Okay. And we took a break previously in this proceeding for about 15 minutes.

Do you recall that?

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A Yes.

Q And during that break, did you talk with counsel?

A No.

Q Okay. Before we broke, we were talking about the tonicity of a solution.

Do you recall that?

A Yes, I recall that.

[redacted]

MS. GREEN: Objection. Relevance. Objection scope.

[redacted]

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Objection. Scope. Objection. Form.

[redacted]

MS. GREEN: Objection. Form.

Objection. Relevance. Objection.

Scope.

[redacted]

MS. GREEN: Objection. Form.

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Objection. Relevance. Objection. Scope.

[redacted]

Q Okay. Are you familiar with Eylea?

MS. GREEN: Objection. Form.

A I've seen it as part of the -- as part of the references --

Q Okay.

A -- I used.

Q Do you know what Eylea is?

A I believe it's an ophthalmic drug product.

Q Do you know how it's administered?

MS. GREEN: Objection. Scope.

A Not -- not exactly. I think it's -- yeah.

Q I'm sorry.

Did I cut you off?

A No. You didn't cut me off.

Q Do you know whether tonicity is a factor for Eylea?

MS. GREEN: Objection. Relevance.

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Objection. Form. Objection. Scope.

Q Have you heard of aflibercept?

A Yes.

Q And do you know how aflibercept relates to Eylea?

A I believe it's the same active drug substance.

[redacted]

MS. GREEN: Objection. Form. Objection. Relevance. Objection. Scope.

[redacted]

MS. GREEN: Objection. Form.

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Objection. Relevance. Objection.
Scope.

MS. GREEN: Objection. Form.
Objection. Relevance. Objection.
Scope.

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MS. GREEN: Objection. Objection. Form. Objection. Relevance. Objection. Scope.

MS. GREEN: Same objections.

MS. GREEN: Same objections.

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[redacted]

MS. GREEN: Objection. Form. Objection. Relevance. Objection. Scope.

[redacted]

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MS. GREEN: Objection. Form. Objection. Relevance. Objection. Scope.

[redacted]

MS. GREEN: Same objections.

[redacted]

MS. GREEN: Objection. Form. Objection. Relevance. Objection. Scope.

[redacted]

MS. GREEN: Objection. Form.

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Objection. Relevance. Objection.
Scope.

[redacted]

MS. GREEN: Same objections.

[redacted]

MS. GREEN: Same objections.

[redacted]

Q Can you answer my question?

MS. GREEN: Same objections.

[redacted]

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[redacted]

Q Dr. Tarantino, you have been deposed before, right?

A I have been deposed before.

Q How many times have you been deposed?

A I think -- I think ten. I think that might include testimony at trials. I don't know.

Q Okay. And so I skipped going over the rules of the road at the beginning.

But you understand that I ask questions and, if you understand the question, you're obligated to provide a response absent an objection from your counsel?

A Absence of objection from my counsel?

Q Instructing you not to answer.

A In all cases, in any of these, I have been sort of asked to comment on what is in my report and what I have given opinions on.

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Q Okay.

A So even on the other depositions, there seems to be a general treatise on chemical -- on stability and other attributes of protein formulations.

Q So your testimony is that your report doesn't have anything to do with physical stability?

A No.

MS. GREEN: Objection. Form. Objection. Misstates.

A It has nothing to do with mechanisms of physical stability or differences between denaturation.

Q Okay. Notwithstanding that view, can you tell me how denaturation is different than aggregation?

MS. GREEN: Objection. Form. Objection. Scope. Objection. Relevance.

A I think my answer was given already. It's not -- it's not a part of what I was asked to opine on.

Q I understand that, and I'm not

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trying to be rude.

But my question is do you know, and can you tell me how denaturation is different than aggregation?

MS. GREEN: Objection. Form. Objection. Scope. Objection. Relevance. Objection. Asked and answered.

A Well, if you understood what I said, then you would know why it's the same answer.

Q Okay. So you are refusing to answer my question; is that correct?

MS. GREEN: Objection. Misstates.

A If you find it in my report, I'll answer it. It's a -- it's a rehashing of pharmaceutical and protein formulation development. And, yeah, I answer -- I really did answer your question.

Q Okay. Maybe I didn't understand.

How is denaturation different than aggregation?

MS. GREEN: Objection. Asked and answered. Objection. Form.

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Objection. Relevance. Objection. Scope.

A I gave the answer that it was not something that I needed to consider to come up with my opinions.

Q It's not my question, Dr. Tarantino.

How is denaturation different than aggregation?

A Right. But --

MS. GREEN: Same objections.

A But I've given you that answer that I'm not going to give an opinion based on the fact that it was not in my -- what I was asked to opine on.

MR. BRAUSA: Counsel, we can keep doing this. If the witness is going to refuse to answer the questions that are directly relevant to the issues in his report, to deal with physical stability, we can have that call with the board. I don't know if we want to take a break, you can confer with the witness if you would like. But this

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question is something he identified in his own answer, denaturation; he said it's different than aggregation. I've asked a very simple question. I'm not sure why it's difficult to answer.

MR. CERWINSKI: Maybe because your question is confusing, so maybe you can go back at a break, look at the question, look at his answer, remind him of his answer, make a clear question that is relevant to his report and try that. Then I think the witness will answer --

MR. BRAUSA: Okay.

MR. CERWINSKI: -- right?

It's your questioning that is confusing the issue here, not his answers.

Q What part of the question, How is denaturation different than aggregation, do you find confusing, Dr. --

MR. CERWINSKI: You said --

MR. BRAUSA: -- Tarantino?

MR. CERWINSKI: -- he -- you said

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he gave a prior answer that you're following up on. Maybe start with that. It's your deposition but...

MR. BRAUSA: So we'll try that and then I think the record speaks for itself, so I think we will have that call with the board if this continues.

Q Do you know what denaturation is?

MS. GREEN: Objection. Relevance. Objection. Scope.

A In -- again, within the context of the patent, I wasn't, you know, asked to give an opinion on what denaturation was.

Q In the context of your 30 years' experience at Hoffman LaRoche and your consulting work as a formulation scientist since 2011, do you know what denaturation is, Dr. Tarantino?

A Yeah. Well, you know what, quite honestly, you've asked me multiple questions about my experience, okay?

And I would really like to stick to how denaturation applies to what I was asked to give an opinion on, and I think I have

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established with my CV, et cetera, what my background is.

Q And so based on your background, do you know what denaturation is?

MS. GREEN: Objection. Scope. Objection. Relevance.

A I think it's -- you can see what -- it's not -- it's something outside what needs to be -- what I was asked to opine on, right?

Q I understand that. That's not answering my question, though, Dr. Tarantino.

Do you understand what denaturation is?

MS. GREEN: Objection. Scope. Objection. Relevance. Objection. Asked and answered.

A Yeah. I believe, in a variety of ways, I have provided you that answer, and it's still outside the context of what I was asked to give opinions on.

Q Okay. Were you asked to give any opinions relating to physical stability of

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injectable protein formulations in your view?

MS. GREEN: Objection. Form. Objection. Privilege. His report reflects what he was asked to give opinions on, and I don't want him to give away any conversations between him and us about how we came to those opinions in his report. And I think that's privileged. So I instruct you not to answer.

Q Do you have any opinions, sitting here today, on physical stability as it relates to the claims of the patent you were asked to consider?

A Well, could you be more specific than that?

Q You -- what part of my question don't you understand?

A The physical stability is sort of -- it's just not -- it's not specific enough.

Is there a claim that you would like to point that out with or something

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here? Or would you just --

Q Why don't we try it this way?

MR. BRAUSA: And I think we will have that call with the board at a break, but we can do that in a few minutes when we break for lunch.

Q Let me hand you what's been previously marked as Exhibit 1006. Do you recognize this document, Dr. Tarantino?

A Not offhand, no.

Q Okay. So you don't know whether you considered this in rendering your opinions?

A I considered Chang. I don't know if this is exactly the same article.

Q Okay. Why don't you thumb through it and see if that refreshes your recollection?

And I can direct you to Table 6 on page 11 specifically.

A Okay. Well, I'll have to confirm this with it. I will have to look at my report.

Q And so the record is clear, you

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have a copy of Exhibit 1002, your expert report in this proceeding in front of you?

A Okay. If this is Exhibit 1002?

MS. GREEN: This is Exhibit 1002. This is Exhibit 1006.

THE WITNESS: Okay.

MS. GREEN: I apologize. I just wanted to clarify that he knew what he was looking at.

Q And in Exhibit 1002, your declaration, since you're questioning whether this was the same Chang you looked at, why don't I direct you to page -- or I'm sorry -- page 27 paragraph 68 and 69?

A Okay.

Q You see in paragraph 69, there is a reference to Exhibit 1006, Chang and 2002, correct?

A Yes.

Q And then, if you turn the page to page 28, you see Table 6 in your report?

A Yes.

Q That appears to be the same Table 6 in Chang Exhibit 1006 that you have

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in front of you, correct?

MS. GREEN: You mind if I direct him to the page?

MR. BRAUSA: I do, actually. Yes.

MS. GREEN: Okay. Because you already provided it, but that's fine.

A Yeah. I mean, there are a lot of tables in Chang. I'm just trying to find the one that you're --

Q It's Table 6, page 11. There is only one Table 6 in Chang I can represent for the record.

A Okay.

Q Can you confirm that Chang Exhibit 1006 is what you are referring to in paragraph 68 of your report, and 69?

A Yes.

Q Okay. Who wrote this report that we're looking at as Exhibit 1002, Dr. Tarantino?

A Me. I did.

Q Okay. And you wrote every line of it?

A Yes.

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Q Okay. And so if there are words added in brackets or parentheses in certain paragraphs, it was your decision to put those words in brackets or parentheses?

A In brackets and parentheses?

Q Uh-huh.

A It was -- of course, I, you know, discussed it with counsel, my draft of whatever paragraph it was.

Q Okay.

A But I -- it -- these are my opinions.

Q Okay. Why don't we go to paragraph 68 briefly?

A Okay.

Q Can you read paragraph 68 into the record for me?

A As of the priority date, it was well known the proteins were subject to several degradation pathways and mechanisms which can be grouped into either physical or chemical stability.

Q Okay. Do you see now where I was coming from with my questions about physical

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stability?

MS. GREEN: Objection. Misstates.

A I still don't have a specific question.

Q Okay. Well, what did you mean when you said "physical instability" in paragraph 68?

A I actually define it in paragraph 69.

Q Okay. And so can you read the third sentence that starts "physical instability" in paragraph 69?

A Physical instability refers to processes that cause changes in the protein confirmation, including aggregation or denaturation.

Q Okay. And so maybe I'll ask my question again.

What is the different between aggregation and denaturation?

A Aggregation or denaturation, in this -- in this context, was meant to be the formation of higher molecular weight species.

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Q The formation of higher weight molecular species.

Is that aggregation, or is it denaturation, or is it both?

A Could be -- it could be both.

Q Okay. Again, my question is what is the difference between aggregation on the one hand in this content and denaturation on the other, again, in this context?

A In this context and within my report, proteins that aggregate couldn't -- in some sense be denatured also, right?

That's the -- that's the point. I mean -- so...

Q So I understand these are two different types of physical instability -- right? -- in this context?

A In this context and in purely speaking, they are -- they are different types, but aggregation -- I mean, denaturation is more of a general, I guess, category.

Q Okay. In your report, you would agree with me that you identify both

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aggregation and denaturation as types of physical instability, right?

MS. GREEN: Objection. Misstates.

A Physical instability refers to processes that cause changes in the protein confirmation including aggregation or denaturation.

So what -- I mean...

Q So maybe we can do it this way.

What types of changes in protein confirmation are observed in aggregation?

A I mean, basically, if two molecules aggregate, the overall three-dimensional structure could be changed. It could be denatured.

Q Okay. And, again, you introduced the concept of denaturation. I just want to understand, because it's still not clear to me.

Is it your view, based on the usage in this report which you asked for, that denaturation and aggregation are different or not?

A In the -- in the literature, they

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were -- they were different processes but some aggregation could be considered denaturation.

Q Okay. What is an example of denaturation that would not be considered aggregation?

A If the molecule did form higher molecule weight species.

Q Is that commonly referred to as the protein unfolding?

A Is what commonly referred to -- is it...

Q Is the protein coming unfolded referred to as denaturation?

A Generally, it is. But it could be -- again, you're changing; you're unfolding, or you're, in some way, changing that three-dimensional structure.

Q What about proteolytic cleavage? Is that a form of denaturation?

MS. GREEN: Objection. Form.

A The term isn't normally used in that way, but it could -- it could lead to denaturation.

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Q Okay. How are you using the term "denaturation" when you wrote this expert report in paragraph 69?

A I think I was using it as I described to you.

Q So I had asked you about aggregation. I'm not sure I asked you about denaturation --

A Well, you asked me about the difference, right?

Q I did ask you about the difference. I don't think I got an answer, so I'm trying to understand what you meant by "denaturation" when you used that term in paragraph 69 of your report.

MS. GREEN: Objection. Misstates. Objection. Asked and answered.

A Well, yes, I did -- I did -- you did ask me that, and I believe that my answer was aggregation is the higher molecular weight species.

Q My question was about denaturation, and what do you mean by "denaturation"?

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A Yes, I think -- I believe I answered that, too. I think the denaturation -- aggregates, aggregation could be considered a form of denaturation.

Q What other forms of denaturation are there besides aggregation?

MS. GREEN: Objection. Form.

A Forms that, in some way, change the -- usually, the three-dimensional structure.

Q Okay. And are there terms given to other forms of denaturation besides aggregation?

MS. GREEN: Objection. Form.

A Besides -- are there terms given to denaturation?

No. Any term, I believe you mentioned one, "unfolding," but it's a wide -- it's a wide area -- it's a wide area of -- of a -- it's a wide area -- right? -- as we're talking about changing the three-dimensional structure of a -- of a protein.

Q Right. And so I'm trying to

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understand, in paragraph 69 of your report, you referred to aggregation, correct?

A Right.

Q And I understand your view that aggregation may be considered a form of denaturation; is that fair?

A That's fair. Yeah.

Q And then separately in your report, you reference denaturation, right?

MS. GREEN: Objection. Misstates.

Q Would you agree with me that your report refers to denaturation in the alternative to aggregation?

A As an alternative?

Actually, what I was referring to is protein confirmation, which includes aggregation or denaturation, right?

That's what I wrote.

Q Right. And what did you mean when you said "or denaturation"?

A I think of it -- I think I explained that. I've mentioned that aggregation can cause the change in structure and lead to a denatured protein.

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Q Okay. So is your testimony that there is no difference between aggregation and denaturation?

MS. GREEN: Objection. Misstates.

A No, I didn't say that. I said that aggregation and denaturation are physical changes that can change protein confirmation.

Q Okay. And so, again, my question is what is an example of a protein that undergoes denaturation without undergoing aggregation?

MS. GREEN: Objection. Form.

A A specific protein?

Q No, Dr. Tarantino.

What is an example of denaturation that doesn't involve aggregation?

Can you tell me that?

MS. GREEN: Objection. Badgering.

A Okay. I sort of answered this a few times. Unfolding of the third dimension -- of a three-dimensional structure.

Q Okay. Beyond unfolding, is there

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any other type of denaturation that doesn't involve aggregation?

A Well, first of all, I can't --

MS. GREEN: Objection -- objection. Form.

A I can't say it doesn't involve. It is possible that denatured, as I have been saying -- it could be both, okay?

It's hard to say that two proteins that changed their tertiary structure won't aggregate. It's -- that's not, you know, something that you can say.

Q Okay. Regardless of whether aggregation occurs, if a protein is unfolded, you would consider that denaturation, correct?

MS. GREEN: Objection. Form.

A Yes.

Q Okay. Are there any other changes in a protein confirmation, beyond aggregation, beyond protein unfolding, that you had considered denaturation?

MS. GREEN: Objection. Form.

A In general -- in general, a

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protein cleavage might lead to denaturation, but that's a very general term. Because proteins -- it depends on how that cleavage affects the confirmation, and it depends on the molecular weight maybe.

Q Are there any different types of aggregation in your view?

MS. GREEN: Objection. Form.

A I think, as a -- I pointed out, there is, in general, a covalent and non-covalent aggregation in the chapter from Chang.

Q And you would agree with the Chang reference that you cited, that those are two different problems that are referred to as stability problems that are observed in protein pharmaceuticals according to Dr. Chang?

A There are two different problems, maybe two different mechanisms -- right? -- I would say.

Q Okay. I'm just looking at Table 6.

The column -- the first column of

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Table 6 is identifying problems according to Dr. Chang, right?

A Yes.

Q And the title of the table is typical stability problems observed in protein pharmaceuticals, right?

A Yes, it's -- it's problems.

Q Okay.

A But she's referring and approach -- no, that -- she's referring to different methods of aggregation, problems is...

Q When you say "she is referring to," who are you referring to?

A I think -- I'm sorry. I don't know if I -- I thought she was a female. The author.

Q Do you know who Byeong Chang is?

A Personally?

No, I don't recall.

Q Were you referring to Susan Hershenson?

A I was referring to B.S. Chang, and I'm not -- yeah.

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Q All right. Okay. So you were referring to one of the authors of the paper.

Is that your testimony?

MS. GREEN: Objection. Misstates.

A I was referring to this article. It is written by more than one person, I realize, but B.S. Chang seems to be the lead --

Q Okay.

A -- author.

Q I'm not trying to be tricky. I just wanted to make sure you were referring to one of the authors of the article when you said "she," not --

A I'm --

Q -- anyone else?

A No. I was. I was in -- right.

Q Okay. And you would agree with me, though, in Table 6, cleavages is identified as a different problem from aggregation, right?

MS. GREEN: Objection. Misstates.

A Cleavage is -- has been identified

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as a separate problem.

Q And there are other problems, beyond aggregation, beyond no -- non-covalent aggregation, covalent aggregation and cleavages that are identified as stability problems in protein pharmaceuticals as well, right?

MS. GREEN: Objection. Misstates.

A The table indicates that there are other problems.

Q Can you tell me what those other problems are that Dr. Chang and Hershenson identify in the article that you relied on?

A Did you want me to read them from the tables?

Is that what --

Q Please.

A -- you're asking?

Okay. Dr. Chang refers to aggregation, both covalent and non-covalent, deamidation, forming of a cyclic imide, cleavages, oxidation, and surface denaturation or adsorption.

Q And do you agree that these are

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all typical stability problems observed in protein pharmaceuticals?

MS. GREEN: Objection. Misstates.

A It depends on the -- it depends on the protein pharmaceutical. I think Dr. Chang was sort of giving a -- a broad description of what might happen -- right? -- in a certain -- what might happen for proteins, usually, if the structure and all the other attributes would have to be present.

Q Well, it's not just Dr. Chang, is it?

You included Table 6 in its entirety in your report paragraph 69, right?

A Yes.

Q And so do you have any basis to disagree that these are all potential typical stability problems observed in protein pharmaceuticals?

A Yes. I mean, it's not -- again a POSA would know that, if, for instance, you didn't have the problem with sulfhydryl linkages, you wouldn't get certain type of

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aggregation. There are certain groups amenable to deamidation. If they weren't in your protein, you probably wouldn't -- you won't see that, actually. It's a very defined thing. So it's not something that could be applied just across the board.

Q Okay. Did you mention that, that it's not something that can be applied across the board anywhere in your report?

A I don't know, but I didn't mention that it was and I think, again, that would be the understanding of a POSA in reading this, or, you know, someone with my experience.

It does -- it does not happen to every -- if you don't have an asparagine, you're not going to see -- or a couple of other peptides -- you're not going to see -- you could also see this pH limitations, right?

I mean, so -- it's hard to just say this is -- it's not even hard, it would be incorrect to say that these apply to every protein.

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Q Sure. And I apologize. I wasn't intending to suggest that these will always be a problem in every formulation.

But when you are approaching a new formulation, these are typical stability problems that a formulation scientist, like yourself, would be aware of and need to account for?

MS. GREEN: Objection. Form.

A Some of them you could rule out by looking at the primary sequence, right?

If it doesn't have an oxidizable species, well, you're generally not going to be -- if it doesn't have a group that would be deamidated, well -- you know, that's what I am trying --

Q Sure.

A -- to say so...

Q Did you work, during your time at Roche with any protein pharmaceuticals that didn't have oxidated groups?

MS. GREEN: Objection. Relevance. Objection. Form.

A You know, that's -- that's

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actually -- when you talk about oxidation, it's a -- it's the extent. And methionine might be more prone to oxidation than, let's say, tryptophan. I mean, I -- there -- there were -- I mean, there were molecules without methionine but it's a -- it's a very broad statement.

Q Oxidation is actually identified as one of the typical stability problems in Table 6 from Chang, right?

MS. GREEN: Objection. Form.

A I don't see that language. Yeah.

Q It's the sixth problem down.

A No. I mean, I don't see her mentioning -- or Dr. Chang mentioning typical --

Q Well, Table 6 is called "Typical Stability Problems," right?

A Oh, okay. That's what you are talking about. Yeah.

Q And Column 1, it lists several problems, right?

MS. GREEN: Objection. Misstates.

A Column 1 mentions problems.

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Q Oxidation is one of the problems listed in Column 1, correct, Dr. Tarantino?

A Oxidation is listed in Column 1, but, again, it depends on the primary structure mostly.

Q The potential causes listed for oxidation can include light.

Do you see that?

A Yes.

Q Light is not part of the primary structure of a protein, is it?

MS. GREEN: Objection. Misstates.

A Those are listing causes, correct?

I mean, I'm not asking you if it's correct, but they're listing the causes that would promote oxidation of, let's say, the methionine fragment.

Q Is methionine an active oxidant species?

A An active --

MS. GREEN: Objection. Form.

A -- an active oxidant?

It is -- you mean does it oxidize anything?

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Q Correct.

A No. Methionine doesn't oxidize anything, but it could be oxidized.

Q Okay. So I guess what I'm wondering is in potential causes of oxidation in Chang Table 6 that you included in your report at paragraph 69, potential causes for oxidation are listed: As active oxidant species, Number 1; Number 2, free radicals; Number 3 metals; Number 4, light; and Number 5, impurity.

A Assuming that there --

MS. GREEN: Objection. Misstates.

A Assuming that there is something to be oxidized, that's what Dr. Chang is saying.

Q Okay. And then, in possible solutions, you see the last possible solution listed in Table 6 is methionine, right?

A Yes.

Q So help me understand how methionine is a solution if methionine is what is being oxidized?

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MS. GREEN: Objection. Form.

A Methionine or any other antioxidants would work by preferentially being oxidized so the methionine on your molecule is not oxidized.

Q Okay. And you agree including methionine in the sequence is a possible solution --

A No, not --

(Cross-talk.)

Q -- to --

MS. GREEN: Objection. Misstates.

A No, I don't -- I don't agree with that.

Q Okay. Help me understand.

What is meant by methionine as a possible solution to oxidation in Table 6 included in your report?

MS. GREEN: Objection. Asked and answered.

A Could you repeat the question?

Q Sure. How is methionine a possible solution to oxidation?

MS. GREEN: Objection. Asked and

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answered.

A I did -- I did answer that. And it would be as adding it to the formulation, not as putting additional methionine molecules in the protein.

Q Got it.

Would you consider, in that circumstance, where you add methionine to the formulation, albeit not as part of a sequence, would methionine be a excipient as we've used that term earlier today?

MS. GREEN: Objection. Form.

A If it's added to the formulation, it would generally be called a -- an excipient. Yes.

Q I've got just a few more questions, and then we can take a longer break or a break.

Can you tell me what the function of a buffer in solution if it has a buffer?

MS. GREEN: Objection. Form.

A A buffer maintains the pH of a solution.

Q Okay. And how does a formulator

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determine the pH that you want to maintain for a solution?

MS. GREEN: Objection. Form.

A By routine pH stability screening.

Q Okay. And so different formulations will have different pHs that are best for stability; is that fair?

MS. GREEN: Objection. Form.

A You would test one formulation at different pH values.

Q Okay. And then how does that pH testing determine which types of buffers you might want to include as an excipient?

MS. GREEN: Objection. Form.

Objection. Form. Sorry.

A The list of buffers that are excipients are listed with pKa values, and the maximum buffer capacity is at the pKa value. So that's how you would -- you would choose as buffer.

Q And there are different chemicals that are termed "buffer," right?

A There --

MS. GREEN: Objection. Form.

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A -- there are different chemicals that are called "buffers," yes.

Q Acetate, that is a buffer?

A Acetate buffer.

Q Histidine is another buffer I've heard about?

A Histidine could be a buffer.

Q I've heard something called McIlvaine being buffer.

Have you heard of that?

MS. GREEN: Objection. Form.

Q Maybe I'm misspeaking.

Have you heard of a McIlvaine buffer?

A There are -- that's not -- I do not believe that's an individual buffer. There are a lot of solutions that might be need -- that might contain buffers in, let's say, sodium chloride that are use experimentallied.

Q Okay.

A So something like that, that's not a chemical.

Q Have you heard the term "McIlvaine

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buffer"?

A I'm not sure. I'm sure I have.

Q Okay. So sitting here today, you don't know what McIlvaine buffer is?

MS. GREEN: Objection. Misstates.

A I'm not sure I have -- I --

Q Okay. There is citrate buffer?

A There is a citrate.

Q And another one I've heard of is phosphate buffer?

A Phosphate is a commonly used buffer. Yeah.

Q Okay.

MR. BRAUSA: All right. Why don't we take a break?

We can go off the record.

VIDEOGRAPHER: The time on the video monitor is 1:09 p.m. We are off the record. This ends Media 2.

(Whereupon, at 1:09 p.m., a recess was taken to 1:54 p.m.)

(The proceeding resumed with all parties present.)

VIDEOGRAPHER: We are back on the

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record. The time on the video monitor is 1:54 p.m. This start Media 3.

Q Welcome back, Dr. Tarantino.

During the break, did you talk with counsel about your testimony?

A No, I did not.

Q When we broke for lunch, we were talking about Exhibit 1006.

Do you still have that in front you?

It's the article by Dr. Chang and Hershenson?

A Yes, I do.

Q Okay. And this is the article that you referenced, I think we established in paragraph 69 in your report?

A Yes.

Q And we were talking at length about Table 6, which you included in paragraph 69 in your report?

A Yes. Yes, we were.

Q And you would agree with me that the Table 6 that you included in your report lists several potential stability problems

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according to the authors in Column 1, right?

A As I mentioned previously, it mentions problems. You know, in reality, they're mechanisms that could be problems so...

Q Right. And then for each one of those problems in Column 1 identified in Table 6, Column 2 of Table 6, which you included in your report, lists one or more potential causes of that problem, right?

A Yes.

Q And then for each of the problems or the causes of the problem, there are also multiple solutions identified as possible in Column 3 of the report.

MS. GREEN: Objection. Misstates.

Q Do you agree with that?

A Column 3 is titled "Possible Solutions."

Q Is there anything in Table 6, which you included in your report, that you disagree with or think is inaccurate?

And, again, this is Table 6 from Exhibit 1006.

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A Not inaccurate but may need further explanation, as I have -- as I have mentioned.

Q Okay. Is there anything in particular, in response to my question, that you think needs further explanation?

A Well, I believe I've talked about oxidation and the deamidation as mechanisms that would occur depending upon the molecule.

Q If we go to paragraph 71 of your report -- now, we're back at Exhibit 1002 -- we see a Table 7 from the same Chang reference that is table -- or I'm sorry -- that is Exhibit 1006.

Do you see Table 7 in your report at paragraph 71?

A Yes, I do.

Q And that table is titled "Important Components of Protein Formulations."

Do you see that?

A Yes.

Q Do you see in the last -- or I'm

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sorry -- the first column of the table is titled "Formulation Variables"?

A Did you say that last -- I --

Q I'm sorry. Maybe I misspoke. The first column in Table 7 is titled "Formulation Variables."

A Yes.

Q And it lists several formulation variables, including pH, stabilizers, solubilizers, buffers in Rows 1 through 4.

A Yes, I see that.

Q And then you see there's a Row Number 5, and the formulations variables identified are a tonicity modifier and a bulking agent?

A Yes.

Q What -- do you agree that a tonicity modifier is an important component of a protein formulation?

A Again, it depends on the -- on the formulation and the intended route of administration, et cetera.

Q Okay. But you're not disagreeing that, for some formulations, the tonicity

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modifier can be an important variable?

MS. GREEN: Objection. Misstates.

A It's something, in a tonicity modifier, if needed, based on my previous comments, it would be -- it would be added.

Q The second column of Table 7 that included paragraph 71 of your report refers to "desired attributes."

Do you see that.

A Your page -- you're in?

Q Paragraph 71 of Exhibit 1002.

A Okay.

Q And you see Column 2 refers to "desired attributes"?

A Yes.

Q Is it your view that that refers to desired attributes of the formulation variables, what you want with pH, what you want with stabilizers, et cetera, that's desired?

MS. GREEN: Objection. Form.

A That columns mentioned desired attributes.

Q I guess I'm just asking for your

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understanding.

That's referring to desired attributes of the formulation, right?

MS. GREEN: Objection. Form.

A That includes desired attributes for the formulation.

Q Okay. And then the third column of Table 7 in paragraph 71 of your report refers to different examples of, for instance, a stabilizer, or different examples of solubilizers, correct?

MS. GREEN: Objection. Form.

A Yes. It -- it provides examples.

Q Okay. So for each of the formulation variables listed, there are different ways you can potentially achieve the desired attributes in your formulation, right?

MS. GREEN: Objection. Form.

A Could you repeat that, for each of the?

Q Yeah. For each of the formulation variables listed in Table 7, there are various examples provided of ways or

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excipients that you can use to try and accomplish the desired attribute in your formulation, right?

A There are different examples for each variable, which may or may not be an issue with a particular --

Q Okay.

A -- protein.

Q Would you agree with me that every protein has unique physiochemical characteristics and the potential to behave differently stability-wise in the presence of a particular excipient.

MS. GREEN: Objection. Form.

A No.

Q You think that statement is incorrect?

A Yeah, I think that statement is incorrect.

Q Okay. What aspect of that statement or what part of that statement do you think is incorrect?

MS. GREEN: Objection. Form.

A You can see the same mechanisms

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listed in different proteins.

Q Okay. Let me hand you what's been marked Exhibit 1013 previously.

(Exhibit No. 1013 Excerpts from a book titled, Protein Formulation and Delivery edited by Eugene J. McNally, a previously marked exhibit was referenced.)

MS. GREEN: Do you have an extra copy?

MR. BRAUSA: I'm sorry. I don't. There you go.

MS. GREEN: Thank you.

Q Do you recognize Exhibit 1013, Dr. Tarantino?

A Yes, I do.

Q Well, what is Exhibit 1013?

A This is the -- actually, the cover of the book "Protein Formulation and Delivery."

Q And are you familiar with this book before your work in this case?

A Yes, I was.

Q How so?

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A It's been a basic -- a basic book on protein formulation.

Q And do you recall citing to this chapter, this portion of this book in your declaration in this case?

A Yes.

MS. GREEN: Objection. Form.

Q And do you recall why you cited this book in your declaration in this case?

A If we could go to the citations, I think that would be easier.

Q Okay. I believe, in this case, you referenced having this book on your shelf at Hoffman LaRoche; is that correct?

MS. GREEN: Objection. Form.

A Yes, that's on my shelf at home --

Q Okay.

A -- now but...

Q And do you still consult this reference in your consulting work?

MS. GREEN: Objection. Form.

Objection. Relevance.

A I might, yes.

Q Do you know why or what reasons

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you consult?

A Well, we could --

MS. GREEN: Objection. Form.

A That would be simply, if you -- which doesn't seem to be -- an index of the topics in the books. So I might reference them depending on what I was looking into.

Q Okay. And without reviewing the book, do you ever recall disagreeing with any statements in the book in this particular chapter?

MS. GREEN: Objection. Form.

A Well, without reviewing the chapter, I couldn't say that.

Q Okay. Just a moment.

Can you turn to paragraph 156 in your report, which is on page 69?

A Okay.

Q And this is referring to McNally 2000, what we've seen as Exhibit 1013 that you have in front of you?

A Yes.

Q And then if you go to the next paragraph at 157, so it refers to

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"formulation optimization" in the second sentence.

Do you see that?

A Yes.

Q And then that formulization -- formulation optimization includes solubility studies, isotonicity concerns, solution stability studies, the effect of specific buffers in pH, the use of different excipients and many other consideration that were part of optimization of biologic formulations at the time, correct?

MS. GREEN: Objection. Misstates.

A Could you repeat that?

Q Maybe I can be a little more specific.

In paragraph 157, you note that McNally 2000 refers to isotonicity concerns or relates to isotonicity concerns, correct?

A Isotonicity concerns, yes, I see that.

Q What did you mean there when you referred to isotonicity concerns?

A I meant to formulations. Again,

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this depends on the route of administration, the length of time in administration and even the patient in some cases, where isotonicity would be important.

Q Okay. And so you would agree that, in certain concerns, that -- or, in certain formulations, isotonicity is a concern?

MS. GREEN: Objection. Form.

A The -- okay. The potency of the drug, the other attributes usually come before isotonicity and, again, it depends on where and how it's being injected.

Q Some other considerations that you identify in paragraph 157, based on McNally, are the effects of specific buffers in pH?

A Yes.

Q And so that's a variable that formulations like -- formulation scientists, like yourself, consider when they're developing a protein formulation?

MS. GREEN: Objection. Form.

A Yes, it is. And these tests are actually routine preformulation tests that

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we would perform to identify these attributes.

Q And another consideration variable to explore is the use of different excipients, fair?

A The use of different excipients? Okay.

Q Yeah.

A Yes.

Q And then paragraph 157, you also refer to "many other considerations."

Do you see that?

A No. Actually, I don't.

Q So it starts on the third line from the bottom of the paragraph after the use of different excipients, the next clause.

A pH, the use of different -- right. Different excipients and many other considerations that were part of routine optimization of biologic formulations.

Q Right.

A So this is in an optimization, not a discovery mode --

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Q Okay.

A -- right?

Q And so my question is actually what are the many other considerations that you were referring to in paragraph 157 of your report?

MS. GREEN: Objection. Form.

A Many other considerations, I think, would include, let's say, storage condition; let's say, presence of ions, you know, this type of thing. More -- more or less conditions rather than the basic components of the formulation.

Q Is whether the formulation is freezed and then thawed, is that one of the types of conditions that you're referring to here?

MS. GREEN: Objection. Form.

A Freeze-thaw is something that you would have to do from a regulatory standpoint.

Q Why is that?

A Well, if the product is, let's say, frozen sitting on a loading dock

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someplace, and, if it you just thaw it out, would it maintain its properties?

So those are very well-defined cycles that you would have to go through as part of the stability.

Q Okay. So doing a freeze-thaw cycle is one way to evaluate stability?

MS. GREEN: Objection. Form. Objection. Misstates.

A No. A freeze-thaw is the way to evaluate if you froze in solution, once thawed, maintains its characteristics and with -- is in specifications.

Q In your experience, have you ever observed aggregation after a solution is frozen and then thawed?

MS. GREEN: Objection. Form.

A Like -- I don't recall that I have.

Q Okay. As an expert in formulation science, would you think that freezing a solution and then thawing would have a potential impact on aggregation?

MS. GREEN: Objection. Form.

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A In general, most freeze-thaw cycles or studies that I remember, maybe all of them, did not have -- it presented no -- no problem.

Q Okay. In paragraph 157 of your report, you cite that the last portion says: ID, comma, 131 to 153.

Do you see that?

A Yes.

Q What does "ID" mean?

A It means the prior -- the prior reference --

Q McNally?

A -- McNally 2000.

Q So this is referring to the page numbers?

A Yes.

Q Okay. And so one of those pages included in this citation range is 145, right?

A Yes.

Q Can you turn to page 145 of Exhibit 1013?

A Yes.

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Q And you see there is a heading E called "Excipients"?

A Yes.

Q And the fifth line down, there's a sentence that begins "every protein has unique."

Do you see that?

A Yes.

Q Can you read that sentence into the record, please?

A Every protein has unique physicochemical properties and the potential to behave different stability-wise in the presence of a particular excipient.

Q Do you agree with that statement?

MS. GREEN: Objection. Form.

A Yeah. It's sort of -- I agree with it. The important part -- it says it does have the potential. But as I mentioned before, a lot has to do with the primary sequence, et cetera.

Q Do you agree with the statement that every protein has unique physiochemical characteristics?

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A They -- it may or it may not in my -- you know, in my experience.

Q So you think there are some proteins that do not have unique physiochemical characteristics.

Is that your testimony?

MS. GREEN: Objection. Misstates. Objection. Form.

A I believe that some proteins will behave the same, right? --

Q Okay.

A -- in terms of their degradation processes.

Q Do you recall whether you cited in any literature in your expert report in this case which observed two different proteins behaving the same?

MS. GREEN: Objection. Form.

A No, I don't -- I don't recall citing that. But as we have went through the Chang publication that listed mechanisms, we also went through McNally that listed standard optimum tests. So my discussion and my belief is that there are

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common mechanisms between proteins or Chang's article wouldn't apply. So that's -- yep. That's my answer. Yeah.

Q And so I guess I just want to make sure I understand.

Do you agree or disagree with the statement in McNally, which you cite in your report, in which the author says: Every protein has unique physical chemical characteristics?

MS. GREEN: Objection. Asked and answered.

A Yes. I believe that I said that it's not that simple to just -- you know, to take that sentence with regards to formulating a drug.

Q And so you disagree with that statement?

MS. GREEN: Objection. Misstates.

A Yeah, I -- you know, I didn't say that. This is a guidance for formulator, and I -- whereas I don't disagree with the statement, it would need to be further, I think, explained the point I'm talking, by

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McNally or really McGoff.

Q If we can go back to the Chang article, which was Exhibit 1006?

I want to go to page 2 of that article.

A Okay.

Q And if I could direct you to the paragraph at the top of the page?

There is a sentence is that says: Because proteins are complex molecules.

Do you see that?

A No, I -- what? The first paragraph?

Q Yeah, first partial paragraph that's above the first full paragraph, about the fifth line from the top.

A These proteins are complex molecules. Yes.

Q That sentence reads: Because proteins are complex molecules composed of numerous reactive chemical groups and delicate three-dimensional structures, identifying a set of conditions to keep all components stable is virtually impossible.

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Do you agree with that statement?

A No. I think virtually impossible is a bit of an overstatement because it's essentially saying that there are no stable protein formulations.

Q So you disagree with this statement in Exhibit 1006?

A Again, I think it could be -- it could be modified and expanded.

Q The next sentence says: In general, commercial therapeutic protein formulations are developed under the assumption that some degree of physiochemical changes will occur during storage and handling.

Do you agree with that statement?

MS. GREEN: Objection. Form.

A That's just an obvious statement. If you didn't make that assumption, there would be no reason to put anything on stability.

Q When you say "no reason to put anything on stability," what do you mean?

A Well, we do follow the stability

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of proteins and she said -- I don't know why I keep on saying that -- and peptides with the assumption that something might go wrong, which is true of small molecules, too.

Q Right. And I don't want to paraphrase it inaccurately.

But what you're saying is you do the stability testing because you need to see whether the formulation is, actually, stable, correct?

MS. GREEN: Objection. Misstates.

A You essentially do it to verify what you found in the preformulation stage.

Q Okay. Were there ever any product developments you were a part of at Hoffman LaRoche where you didn't do stability testing and just did preformulation work on a molecule?

MS. GREEN: Objection. Form.

A Could you be more specific because that really would depend on the stage?

In research, things drop out.

Q Okay. For -- let's focus on, for

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instance, the Zenapax product that we were talking about.

You did stability studies on those formulations, right?

MS. GREEN: Objection. Form. Objection. Scope.

A Yes, stability studies. It was a -- it was approved by the FDA, so that's why -- also to establish shelf life. Right.

Q And I think we talked, with Zenapax, the active molecule is a monoclonal antibody daclizumab?

A Yes.

Q And do you know whether Zenapax is still on the market today?

A I don't believe as Zenapax it is. I think daclizumab is probably still on the market --

Q Okay.

A -- but I don't believe it's that trade name.

Q Do you know if COS cell was used to express daclizumab?

MS. GREEN: Objection. Form.

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Objection. Relevance.

A No, I don't recall.

Q Okay. Do you recall whether it was a CHO cell?

MS. GREEN: Same objections.

A Yeah. I said I don't. Yeah. I don't recall.

Q Okay. Have you ever worked with NS0 host cells or NS zero host cells?

MS. GREEN: Objection. Form.

Objection. Relevance.

A No, I haven't. Not that I remember.

Q Have you ever worked with proteins expressed in E. coli?

MS. GREEN: Objection. Form.

Objection. Relevance. Objection.

Scope.

A Not monoclonal antibodies but I have, yes.

Q Okay. What proteins have you worked with that were expressed in E. coli?

MS. GREEN: Objection. Form.

Objection. Scope.

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A I -- this would -- I couldn't tell you exactly because this is a long time ago. But perhaps the interferons I worked on. And I can tell you I'm not really sure of that.

Q The interferons you worked on, that includes the Pegasus product?

MS. GREEN: Objection. Form.

A Pegasus is interferon.

Q Okay.

A Yes.

Q Do you know whether any carbohydrates were used in that formulation?

MS. GREEN: Objection. Scope. Objection. Form.

A I don't recall. No.

Q Do you have any view on whether interferon has unique physiochemical properties compared to antibodies?

MS. GREEN: Objection. Scope. Objection. Form.

A It went through the same types of tests, routine tests that I mentioned already. I can't recall anything. I can't

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recall anything unique, no.

Q If we can turn back to 1006, which is the Chang article that you cited in your report.

On the same page, page 2, the first full paragraph starts "realizing that."

And let me know when you're there?

A Realizing that it is impossible to develop a perfectly stable formulation, that paragraph?

Q That's exactly the clause I wanted to ask you about.

Do you agree with that statement?

MS. GREEN: Objection. Form.

A That would have to be defined a little bit more in terms of what Dr. Chang meant by "perfectly stable."

Q Okay. Did you provide that additional definition anywhere in your report in this proceeding?

A No, because I think it's sort of obvious that "perfectly stable" is sort of a nebulous term. You have to provide a stable

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formulation that has the required shelf life and is safe and efficacious.

Q During your time at LaRoche -- or Hoffman LaRoche, how big were the formulations departments that you were part of?

MS. GREEN: Objection. Form. Objection. Scope. Objection. Relevance.

A That depended on when -- on when that question was asked, and I don't -- I don't see the relevance, but organizations change with time.

Q So why don't we go to paragraph 11 of your report, Exhibit 1002?

A I'm at page 11.

Q Okay. And this refers to four new peptide protein products that you say you led formulation development of, correct?

MR. CERWINSKI: Paragraph 11, page 6.

Q Oh, I'm sorry. Yes. Page 6, paragraph 11. My fault.

A Okay. I'm on page 6.

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Q And I'm correct, this is saying that you led formulation development of four new peptide protein products, and then those four products are listed, correct?

MS. GREEN: Objection. Misstates.

A I let the formula -- the first line says: During this period, I led the formulation development of at least four new peptide protein products.

Is that what you are referring to?

Q That's correct.

A Okay.

Q What did leading the formulation development of the Pegasus product involve?

A It involved the combination of me and members of my group developing the formulation.

Q Okay. And do you recall about how many members of your group there were on the Pegasus Project?

A The members of my group at that time were approximately -- was five or six maybe.

Q Okay. And do you recall about how

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long it took to develop the formulation for Pegasus?

MS. GREEN: Objection. Relevance.

A No. I don't remember exactly how long it took.

Q Is it a couple of days, a couple of weeks, a couple of months, any general time frame you can provide?

A It's --

MS. GREEN: Objection. Relevance.

A It's a -- difficult to answer because Pegasus is pegylated interferon so...

(Whereupon, the court reporter requested clarification.)

MR. BRAUSA: Pegylated interferon.

A So I wouldn't say days, but I also wouldn't say years. And it -- a lot of it is waiting time, putting it on stability to make sure that you have the necessary stability to justified the shelf life.

Q Do you recall any stability challenges or obstacles with respect to the development of the Pegasus formulation?

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MS. GREEN: Objection. Relevance.

A No I don't -- I don't recall.

Q Mircera is the second product listed.

And you led formulation development for that product as well?

A Yes.

Q And my understanding is that that is a pegylated EPO or erythropoietin?

A That's PEG EPO, yes.

Q Okay. Team leading -- that you led for formulation on that also, five to six motion?

MS. GREEN: Objection. Relevance.

A Yes, it was the same -- the same team during that era. Yes.

Q Okay. And do you recall any particular stability challenges or obstacles you faced with respect to that formulation?

MS. GREEN: Objection. Form.

Objection relevance.

A No, I do not.

Q The next one is Zenapax, which we've talked about, and that's the

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formulation for the daclizumab antibody; is that fair?

A Yes.

Q And do you recall any particular stability challenges or obstacles you had with respect to that formulation?

MS. GREEN: Objection. Form. Objection relevance.

A No, I do not.

Q And then the last one is Fuzeon, which I believe is a peptide, not a protein product, correct?

A Yes.

Q Were there any stability obstacles that you encountered formulating fusion?

MS. GREEN: Objection. Form. Objection. Relevance.

A No. No, I do not recall any.

Q Okay. During your time at LaRoche, were there ever any projects that you led where you encountered stability challenges or obstacles?

MS. GREEN: Objection. Form.

A As I think I mentioned previously,

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these were identified early on and a remedy by one of the methods that we have discussed. So once the optimum pH was found, I would formulate up the optimum pH. If there were problems, as been mentioned with aggregation that I found in preformulation, generally, a surfactant was used, most often polysorbate 80, sometimes polysorbate 20. And that's pretty characteristic for protein molecules on the market in general.

Q Paragraph 11 also refers to your formulation experience involving fusion proteins such as TNFR-Ig fusion proteins?

A Yes.

Q Is that with -- and so that is a TNF receptor fused to a portion of an immunoglobulin?

A Yes.

Q Is that a product that -- or is that a project that led to a commercial project?

A Not at Hoffman LaRoche that I was aware of.

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Q Okay. Do you know whether that project got transferred to someone else that commercialized it?

MS. GREEN: Objection. Relevance.

A No, I don't -- you know, I don't recall. Projects either ended or were licensed. There is a variety of things that could happen to a project.

Q Did you ever work on a fusion protein that became known as etanercept?

MS. GREEN: Objection. Scope.

A Not that I can recall.

Q Okay. With respect to this TNFR-Ig fusion protein that you refer to here, do you recall the formulation that you developed?

A No, I don't recall the formulation.

Q Do you know whether it was liquid or lyophilized?

A It was probably liquid. As I mentioned, this was probably less than a year. I don't even -- I don't -- I just don't recall. It may have made it into

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clinical -- clinical studies, but I don't recall, though.

Q Okay. Do you recall whether it had a carbohydrate in it?

MS. GREEN: Objection. Relevance.

A If what had a carbohydrate, the --

Q The formulation of this TNFR-Ig fusion protein that you refer to in paragraph 11?

A No. I don't recall.

MS. GREEN: Objection. Form.

Q Do you know what the concentration of the protein was?

A No, I do not. This is at least 20 years ago.

Q Okay. Why did you feel it was important to refer to fusion proteins such as TNFR-Ig fusion proteins in your report?

MS. GREEN: Objection. Form.

A This is a standard description of projects that I have worked on, specifically proteins.

Q Do you know what buffer was used in this formulation?

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A No. As I said, I don't recall the formulation.

Q Do you recall the stability of that formulation?

A It was stable to do any preclinical studies that we did at the time.

Q Okay. Paragraph 13 of your report, on page 7, Exhibit 1002, refers to you leading the development of nine marketed parenteral drug products.

A Yes.

Q And these are nine marketed products in addition to the four we just talked about on paragraph 11, or do these include the four that we talked about in paragraph 11?

A No, these include the four.

Q Okay. So there are five additional marketed products you worked with or led development of at Roche?

A That reached -- yeah, that I worked on.

MS. GREEN: Objection. Misstates.

Q Okay.

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A That -- I mean that I recall. There might have been -- there might have been more.

Q Okay.

A But those are the nine that --

(Cross-talk.)

Q What are the five additional ones that we haven't touched on that you recall?

MS. GREEN: Objection. Misstates.

A I worked on -- I could tell you probably two. One would be Bactrim IV, and there were some solid dosage forms in there -- or really semisolid like Accutane.

Q If we limit ourselves to liquid protein formulations, is it just the first one that you mentioned?

MS. GREEN: Objection. Form.

A I'm sorry.

What's the first one that I mentioned?

Q Well --

A You mean the first one in on the list?

Q No. Why don't we get -- do it

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this way?

Of the five additional products that are referenced in paragraph 13, in addition to the four in paragraph 11, were any of those liquid protein formulations?

MS. GREEN: Objection. Misstates. Objection. Form.

A Yeah. I don't recall. I don't have the list of -- I believe it might be in my CV. I don't have the list of the nine, but as I mentioned, I was also a CMC leader. So it could have been in that respect, too.

Q Okay. And I take it, from that answer, that you don't recall the formulations of any of those products that you worked on?

A Without the list -- actually -- no. Maybe -- it's not really relevant but it's Accutane. It is a semisolid and I -- which is sort of different. It was an oleaginous base, but no, I wouldn't be comfortable in talking about the formulations. Some of these products have been on the market for a long time, and some

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of these are line extensions; it could be.

Q Let me hand you a copy of your CV that you referenced, which is 1003 in the record.

(Exhibit No. 1003 Curriculum Vitae of Ralph Tarantino, RPh, Ph.D, a previously marked exhibit was referenced.)

Q This is an accurate copy of your CV, I take it, Dr. Tarantino?

MS. GREEN: Objection. Form.

A If this is what was -- I submitted, it is.

Q And in your areas of expertise, one of the areas listed is inter partes patent review?

A Yes.

Q Another one is patent infringement, slash, validity.

A Yes.

Q Another one it is claim construction?

A Yes.

Q Another area of your expertise is

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expert reports?

A Yes, that's there. Sure.

Q And another area of expertise is testimony in patent litigation; is that fair?

A Correct.

Q Okay. Did you have any of those areas of expertise before you founded Steritech Solutions in 2011?

MS. GREEN: Objection. Relevance.

A Commenting on patent infringement and validity. From an internal standpoint, I did. I was often asked to comment on patents that Roche was interested in one way or another.

Q Okay. Do you ever recall -- actually, I'll withdraw that.

When you set up Steritech Solutions in 2011, did you have a plan to serve as an expert in patent litigation proceedings?

MS. GREEN: Objection. Relevance.

A No, I didn't.

Q Okay. When did you first get

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retained in patent matter, either an inter partes review or a litigation or something like that?

MS. GREEN: Objection. Form.

A Well, I think I have supplied that information. Again, we're bordering on things I don't see are relevant, but I think the first time was -- I believe it was 2013.

Q Okay. And page 5 of your CV that you provided in this proceeding, you list out all the expert reports that you've served. It goes on to page 6.

A Yes.

Q And so fair to say the earliest example I see in this list that you include in your CV is from 2012 to 2013?

It's the last bullet in this list.

A Maybe we're looking at the wrong list.

What page are you on?

Q Page 5 and 6 of Exhibit 1003.

A Yes, I think that's the -- okay. I did this in reverse chronological order. Okay. I'm on that second page. I don't

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know what you are referring to.

Q So I'm on the fifth page and the sixth page.

Is that where you're at?

A Yes.

Q I'm just trying to understand. It looks like you were providing expert reports that you listed in your CV, which lists your areas of expertise as expert reports.

And those span from 2012, being the first one listed, and then the most recent at the top of the list was 2019, correct?

A That's correct. I'm not -- I'm not sure if it's totally updated, but may have been more after 2019. Oh, and certainly there is this one.

Q Right. And so you anticipated a question I'll have in just a moment, but I want to just make sure.

It's -- from 2012 to 2019, it looks to me like, at least every year therein you were authoring at least one expert report; is that fair?

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MS. GREEN: Objection. Relevance.

A I don't know if that is exactly true.

Q Okay. From 2019 to 2023, do you recall how many expert reports you have authored?

MS. GREEN: Objection. Form.

A Besides this one, maybe two that I can recall.

Q Okay. Do you recall whether, in any of these proceedings, you have ever taken the position that a claimed formulation is not obvious?

MS. GREEN: Objection. Relevance.

A I don't -- I don't recall.

Q Okay. You don't recall one way or the other, or you haven't taken that position previously?

A I've generally worked providing guidance to -- I'm going to -- I'll say both sides, for lack of a better word I can think up, so that's a possibility. I just -- I can't -- I certainly recall the cases and would feel uncomfortable providing

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information that might be confidential.

Q Sure. And I'm not asking you to did that.

Can you tell me what's the percentage -- I think at the outset of today's discussions, you mentioned that, in your consulting work, you do some consulting for companies that's not related to inter partes review, patent infringement, validity, claim construction, expert reports or testimony in patent litigation, which are areas of your expertise, but you also, of course, do provide consulting in those types of matters.

What is the split in your -- in your current business in terms of litigation, patent-type matters versus consulting with companies?

MS. GREEN: Objection. Form.

Objection. Relevance.

A Okay. Again, that's hard -- that's difficult to say. It goes in -- there are times it could be a hundred percent consultation to pharmaceutical

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companies, and there's times it could be a hundred percent discussing or providing guidance to -- on patent issues so...

Q What is the current split, roughly?

MS. GREEN: Objection. Relevance. Objection. Form.

A The current split is probably 50/50.

Q Okay. Without getting into the specifics, what companies are you current consulting with on non-patent matters?

A How can I not get into the specifics?

Q I don't want know the specifics of the work. If the name of the company is confidential, you can tell me that. I'm not trying to --

A Well, the name of the -- in this case, the name of the company, I think, is -- I wouldn't feel comfortable revealing it due to the nature of their business.

Q Okay. We can put your CV -- or, actually, there was one question I had with

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respect to your CV, 1003.

If you go to page 4, it refers to key industry achievements?

You see that?

A Yes.

Q And this, again, refers to your leadership role in development of nine marketed products. I didn't see any of those nine products listed in your CV.

Did I miss it?

A I may have -- I may have taken it out.

Q Okay. Do you know why you took it out, if you did?

MS. GREEN: Objection. Relevance.

A I am generally cautious about put -- naming specific products. That's the only thing I could -- I could think of.

Q Okay.

MS. GREEN: Adam, we've going about an hour.

Is it possible just to take a quick break so that we can use the restroom after lunch?

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MR. BRAUSA: Sure.

MS. GREEN: Okay. Thank you.

No longer than ten minutes --

THE WITNESS: No, I --

MS. GREEN: -- 3:00.

THE WITNESS: -- don't think so. I don't need longer than ten minutes.

VIDEOGRAPHER: The time on the video monitor is 2:50 p.m. We're off the record. This ends Media Unit 3.

(Whereupon, at 2:50 p.m., a recess was taken to 3:04 p.m.)

(The proceeding resumed with all parties present.)

VIDEOGRAPHER: We are back on the record. The time on the video monitor is 3:04 p.m. This is Media Unit 4.

Q Welcome back, Dr. Tarantino.

During the break, did you chat with counsel at all?

A No, I did not.

Q We've been talking about some of the projects you had at Hoffman LaRoche, where you led formulation development, and I

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believe there were not any at the -- none of the projects involved any reviewed significant stability concerns or issues; is that fair?

A None of the projects.

Are you talking about the nine?

Q Correct.

A Some of the solid -- actually, just one of the solid ones did, but other than that, I don't recall any of them.

Q Okay. Beyond that one with the solid formulation, were there any projects you worked on at Hoffman LaRoche that involved significant stability challenges that you weren't able to overcome?

MS. GREEN: Objection. Relevance.

A A project was never dropped because of stability reasons that we couldn't overcome.

Q Okay. And was there any uniform target at Hoffman LaRoche for acceptable levels of aggregation in a liquid formulation?

MS. GREEN: Objection. Relevance.

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Objection. Form.

A Aggregates or impurities. So if there are guidelines -- I don't recall if there were specific guidelines on aggregates, and I doubt it. But it would depend on the -- what was observed.

Q Okay. What do you mean by? That it would depend on what was observed?

A Well, early on in -- I will call it biotech development, antibodies or antibody formation could be a problem caused by aggregates. But it was sort of cleaned up in the later years.

Q When you say "sort of cleaned up," what do you mean?

A Well, I think as technology advanced, et cetera, it became -- molecules were characterized better, et cetera, and it became less of an issue.

Q Okay. And do you recall when that better characterization started taking place or was completed?

A Well, I mean it's ongoing until now, but I think maybe in the late -- top of

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my head, I would say maybe late '90s, early 2000s --

Q I --

A -- maybe before.

Q -- oh, I'm sorry. I didn't mean to cut you off.

Were you finished?

A Yes.

Q In your report, which we've looked at -- it's Exhibit 1002 -- you offer an opinion that the Fraser reference anticipates the claims that you are addressing, correct?

A Yes.

Q And you also have a separate opinion that, even if Fraser doesn't anticipate, the claims would be obvious, in your view, based on a certain combination of references?

A Yes.

Q In terms of putting the report together, I know, previously, you testified that this is -- these are your opinions.

But in the prior art and the

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materials that are cited in your report, did you identify those or were those provide to you by counselor?

MS. GREEN: Objection. Privilege. We're getting -- starting to get into privilege.

So just a yes or no -- or not yes or no but just a very quick answer. Don't get into any specifics.

A As most of my report, things were discussed with counsel.

Q Okay. Maybe I can be a little more specific.

Did you find the Fraser reference, or was it provided to you?

A Fraser may have been provided to me. I don't really -- I don't really recall.

Q Prior to your work in this case, do you recall reading the Fraser publication in your work at Hoffman LaRoche?

A No, I don't recall reading it.

Q Okay. What about -- and, for the record, Fraser is Exhibit 1009 in the

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proceeding.

(Exhibit No. 1009 Fraser article from February 2005, a previously marked exhibit was referenced.)

Q Exhibit 1010 is a reference that is referred to in your report as Holash?

(Exhibit No. 1010 Holash article from August 20, 2002, a previously marked exhibit was referenced.)

A Yes.

Q Do you recall whether you found that reference, or it was provided to you?

MS. GREEN: Objection. Relevance.

A As I mentioned -- the prior art that I mentioned, probably after Fraser -- I'm not totally sure of that -- was sort of collaborative. I did my search, and we discussed it.

Q Okay. Do you recall whether you found Holash, though, or it was provided to you?

A No, I don't recall.

Q Okay. What about -- there is also a reference you refer to as the Wulff

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reference, Exhibit 1016.

(Exhibit No. 1016 Wulff article from July 2002, a previously marked exhibit was referenced.)

Q Do you recall whether you found that, or it was provided to you?

MS. GREEN: Objection. Relevance. Objection. Form.

A I -- no, I don't -- I don't recall.

Q Okay. Are there any references that you do recall finding yourself?

MS. GREEN: Objection. Relevance.

A I would have to go through the list of references but, certainly -- if you would like, I could do that. But, certainly, McNally --

Q Okay.

A -- certainly Chang, et cetera -- not et cetera so -- but I do recall those. Sure.

Q Got it. And prior to your involvement in this case, had you reviewed Exhibit 1001, what we've seen referred to as

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the '992 Patent?

A No. Prior to this case, I haven't looked at the '992 Patent.

Q And prior to this case, were you familiar at all with the development history of the product that's now known as Eylea?

MS. GREEN: Objection. Relevance.

A Prior to this case, no.

Q Prior to this case, were you familiar with VEGF antagonists?

MS. GREEN: Objection. Relevance.

A Yes, the -- they're sort of a general category of proteins. Sure.

Q Okay. And have you worked with any specific VEGF inhibitors --

MS. GREEN: Objection. Relevance.

Q -- prior to this case?

A Not that I recall.

Q If I can direct you to page 14, paragraph 41 of your report, Exhibit 1002?

Do you see the first sentence?

A I guess I lost the middle of my report here.

Q Oh, sorry?

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A Page 14?

Q Page 14, paragraph 41.

A Okay.

Q And here, you state that, in your view, the '992 Patent concerns stable formulations of aflibercept and other VEGF inhibitor proteins?

A I'm sorry. I don't see that exactly.

Where was it?

Q Are you on paragraph 41?

A Oh, no, paragraph 45. My -- okay.

I got a little -- what page are you on?

Q Page 14?

A Page 14, paragraph 41?

Q Correct.

A Okay. I got it.

Q And you see sentence that says: The '992 patent concerns stable formulations of aflibercept?

A Yes.

Q What was the basis for that statement in your report?

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A The basis for it was, I guess what the '992 Patent claims.

Q Do you know whether the '992 Patent ever refers to aflibercept?

A Yes. It refers to aflibercept. Yes.

Q Do you know where it refers to aflibercept by name?

A I would need a copy of the '992 Patent.

Q Okay. Exhibit 1001 has been previously marked in the case. It's U.S. Patent 10464992.

I'm sorry, Dr. Tarantino. I have got to pass it through the reporter. I'm not being rude, not handing it to you directly.

A I don't recall that it mentions aflibercept in this -- in the patent. But it was clear by the description of it and the definition. It was clear from Regeneron's publications and patents and even the -- even what was published about Eylea that it was -- it was described as

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described in these claims.

Q Okay. So just so we're on the same page, is it your view that the '992 Patent, Exhibit 1001, refers to aflibercept by name?

MS. GREEN: Objection. Form.

A No. I said I don't recall. I would have to read through the specifications but, in the claims, it was clear that it was aflibercept.

Q Okay. Why don't we turn to the claims in Exhibit 1001?

And they're in Column 19 and 20.

A Okay.

Q Which portion of the claims make it clear that this is aflibercept?

A The immunoglobulin-like Ig domain two, VEGF receptor and Ig domain three of the second VEGF receptor and Ig domain of the second VEGF receptor in a multimerizing components is what is present in a number of -- of Regeneron publications.

Q Okay. And is it your testimony that the only protein that would compromise

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these two VEGF receptors and a multimerizing component is aflibercept?

MS. GREEN: Objection. Form.

A Yes.

Q Why don't we go to paragraph 57 of your report back in Exhibit 2 -- 1002?

A Okay.

THE WITNESS: Could I ask that somebody just -- this got out of order, put that in order or --

MS. GREEN: Yeah.

THE WITNESS: -- should I do it or...

MR. BRAUSA: Let's go off the record just briefly.

THE WITNESS: Okay.

VIDEOGRAPHER: The time on the video monitor is 3:18 p.m. We're off the record.

(Whereupon, at 3:18 p.m., a recess was taken to 3:19 p.m.)

(The proceeding resumed with all parties present.)

VIDEOGRAPHER: We're back on the

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record. The time on the video monitor is 3:19 p.m.

Q All right. If we can turn to paragraph 57 on page 21 of Exhibit 1002 of your report in this proceeding?

A Yes.

Q And this is talking about aflibercept, the VEGF inhibitor developed by Regeneron?

A Yes.

Q The second sentence says: It's also known to scientists by VEGF trap R1+R2 and VEGF trap.

Do you see that?

A Yes.

Q Prior to your involvement in this case, had you ever referred to aflibercept as VEGF trap R1+R2 or VEGF trap?

A Probably not.

Q Okay. And then the last sentence says that the structure of aflibercept is depicted below taken from Figure 1 of Exhibit 1016, which is Wulff, right?

A Yeah. I'm pretty sure that's

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Wulff --

Q Okay.

A -- as I see it.

Q You're pretty sure that's Wulff or --

A Well, I must see it. I must have it here in the --

Q Just to be clear, I think you referred to --

A Oh, it doesn't.

Q -- it as --

A Okay.

Q -- Wulff in paragraph 57?

A I just wanted to confirm. Yeah.

Q And do you know if Wulff calls what's shown in paragraph 57 of your report "aflibercept"?

A I don't -- I don't recall if he calls it "aflibercept." But, as I mentioned, a very specific to me VEGF R1 and R2 was aflibercept. And it's not totally uncommon for the names of drugs to be assigned, and sometimes they're not assigned, in early research --

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Q Okay.

A -- the actual names.

Q And so sometimes the names are assigned early on; sometimes they're not.

That's your testimony?

MS. GREEN: Objection. Misstates.

A Sometime -- someplace within the development process a name is assigned.

Q Okay. Just to be clear, in preparing your report for this proceeding, beyond the citations that are included in the report, do you have any personal knowledge of Regeneron's development processes or Regeneron's naming conventions as a company?

MS. GREEN: Objection. Form.

Objection. Relevance.

A No, I don't. I'm speaking about, from my experience, what's common in the industry. And I think that's what I said.

Q Okay. But you don't know anything about Regeneron specifically and how they name their products or how their process works for naming products and when it

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happens in the development process?

MS. GREEN: Objection. Form. Objection. Relevance.

A No, I don't. But there is a lot that goes into consideration with a name. And as I said, in my experience, this happens someplace --

Q Okay.

A -- along the way.

Q So if we're looking at this Figure 1 from Exhibit 1016 and Wulff, the molecule shown on the right is referred to here as, I guess, Molecule C, and then it says: VEGF trap R1+R2.

Correct?

A Right.

Q And you say that this picture shows the structure of aflibercept in paragraph 57, right?

A Yes. It's a -- it's a schematic of the -- of the structure identifying the domains. Exactly.

Q Okay. And this figure does not refer to this structure as aflibercept,

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correct?

A Yes. In light of what I've said about this, a POSA would know that this is aflibercept based on the publications of Regeneron.

Q In terms of the structure shown here, does this show primary structure of VEGF trap R1+R2?

A It doesn't show the primary structure. It's, again, really a schematic of the different domains and components.

Q Okay. And what are the different domains and components that are shown in this schematic in paragraph 57 of your report, Figure 1 from Wulff?

A Well, they're indicated by 1, 2, 3, numbers, and also the multimerizing agent is sort of indicated by the line that -- actually, the FC portion.

Q Got it.

And so what's shown, if we're focused on the molecule labeled as "Molecule C" in Figure 1, it shows that the FC portion -- that's the multimerizing

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component in your view?

MS. GREEN: Objection. Form.

A Yes.

Q And there is an amino sequence associated with FC regions, correct?

A Yes.

Q And is the amino acid sequence for an FC region the same in every molecule --

MS. GREEN: Objection. Form.

Q -- that includes an FC region?

MS. GREEN: Objection. Form.

A It may not be, but they did provide -- and now I would really like to take a look at -- or let me -- just give me a second.

Q Is there something that you're looking for, Dr. Tarantino?

A I'm looking for my references in which Regeneron published the sequences. Certainly, I know the '309 publication and the sequence. And I'm looking for others, but it's in my -- it's in my report.

Q Is the '309 publication a reference that you found, or was it provided

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to you?

MS. GREEN: Objection. Relevance.

A I don't -- I don't -- I don't recall.

Q Do you know if the '309 publication is cited in any of the other prior art you rely on in your report?

MS. GREEN: Objection. Relevance.

A Again, I need a copy of that before I make further comments.

Q I want to limit my questions at this time to the Wulff reference, which we were discussing back at page 50 -- or I'm sorry -- paragraph 57 at the top of line 22 in Figure 1 from Wulff you included in your report?

A Okay.

Q We had talked about the FC region and then I think what I also see is the domains, 3 and 2, from R1, Receptor 1, and R2, Receptor 2, right?

MS. GREEN: Objection. Form.

A R1 and R2, yes.

Q And "R" stands for receptor?

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A Yes.

Q Okay. And so this is saying, as the figure identifies, that when it says "R1," that means Domain 2 or VEGF Receptor 1 and then R2 refers to Domain 3 of VEGF Receptor 2; is that fair?

MS. GREEN: Objection. Form.

A Yes.

Q And in this figure, when it refers to those domains as R1 and R2, it doesn't provide any specific nucleic acid or amino acids sequence, does it?

A Within its figure, specifically Wulff -- but, as I mentioned, I looked at several documents that had the sequence; I believe 309 was one of them, and it clearly, in my opinion, was a development project for this sequence. So I don't recall if Wulff said specifically aflibercept, maybe it didn't, but it was part of a series of publications that I have quoted.

Q There is also, in the schematic shown on paragraph 57 at the top of line 22 of your report, between the FC region shown

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and then the Domain 3 of R2 or Receptor 2, there is sort of a -- it almost looks like a slingshot.

Do you see those sticks that connect the FC region to Domain 3?

A Yes.

Q Do those correspond to amino acids in the actual molecule show of Figure 1?

A As far as I know from this schematic, they would. There was no mention of non-protein -- no mention that there -- it was not a protein.

Q And are those -- those sticks that are shown connecting Domain 3 or R2 to the FC region, are those -- is there a name for that type of sequence and practice?

MS. GREEN: Objection. Form.

A A name for sticks?

I think the construction of this protein is as indicated, and two fusion polypeptides or proteins connected to the FC region. I don't know exactly if the sticks are -- have anything other than illustrative purposes.

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Q Okay. Are you familiar with a term called "linking or bridging sequences"?

MS. GREEN: Objection. Form.

A Sure. Yes.

Q What is a linking or bridging sequence?

MS. GREEN: Objection. Form.

A Something -- I -- it's sort of obvious that you would have a sequence that would link two proteins to one another, or I would think mostly it would be in proteins, yes.

Q And do you know whether the protein shown in the schematic at Figure 1 from Wulff identified as VEGF trap R1+R2 has any linking sequences in it?

MS. GREEN: Objection. Form.

A Again, the most that I have seen is -- sequences which are consistent. And I don't recall seeing a linking sequence other than the reference to the linking to the FC region.

Q Okay. So you don't know whether they were linking sequences between R1 and

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R2 in the protein shown in Figure 1 of Wulff?

MS. GREEN: Objection. Misstates.

A Yeah. That's -- someplace in this schematic, obviously, they're linked to the FC region.

Q Okay.

A So I haven't given that particular -- you know, I didn't see it as being a relevant factor.

Q To the extent there are linking sequences in the -- in the molecules shown in Figure 1 of Wulff, those amino acids would be part of the primary sequence of the protein, right?

MS. GREEN: Objection. Form.

A The sequence, as I have seen, is -- consists of, yes, of one of the -- actually, I'll call it a monomer for now --

(Whereupon, the court reporter requested clarification.)

THE WITNESS: A monomer -- monomer, right?

A A sequence of monomer plus the FC

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portion. Yes.

Q Okay. So I guess I want to just understand.

When we're talking about linking sequences, those are amino acids, right?

A As far as I have known and I have seen within this -- in these publications, they are amino acids. Yes.

Q Okay. And so by that -- by virtue of that, the linking sequences are part of the primary structure of the protein shown in Figure 1 of Wulff?

A Again, as far as I know, the sequences provided cover the entire molecule.

Q Okay. And just to confirm, again, limiting ourselves just to Wulff in this figure, Wulff doesn't provide the amino acid sequences for any linking or bridging sequences that are present in the schematic shown as Item C in Figure 1?

MS. GREEN: Objection. Form.

A Okay. Now, I am going to request a copy of Wulff, because I have made a lot

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of comments on it without seeing it.

Q Wulff is previously marked Exhibit 1016 in the record.

A Okay. Wulff includes the description that I have made in the patent and, as I said, I've seen no delineation of parts of that molecule other than the molecule mentioned in the '992 Patent. So to say it doesn't have a linking sequence is probably -- I mean, obviously, it needs to be -- it needs to be linked.

I think the linking sequence is -- to me, from what I have read, a difference -- a different story and sort of irrelevant when you have the -- you actually have the sequence of the entire protein.

Q Okay. I just want to make sure I understand.

The linking sequence is part of the entire sequence of any protein that contains a linking sequence, right?

A To be accurate, it should.

Q If we, again, are just looking at Exhibit 1016 in this Figure 1, there are

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also sticks between Domains 2 and 3 shown in the schematic.

Do you see that?

A Yes.

Q Do you know whether those correspond to amino acids, the sticks?

A Again, from the -- from the sequence and -- and the fact that it is a protein, you would have to assume it's -- they are amino acids.

Q And I guess my question is, looking at this schematic, would you interpret that there are amino acids in between R1 and R2 or are R1 and R2 just used directly together?

MS. GREEN: Objection. Form.

A Sticks in a -- in a diagram, it could be possible that domains are linked by peptide links without a linking agent. It's -- I mean, that is a possibility.

Q And I have the same question about -- you see there are sort of some sticks at the top of Domain 2 on each side of the diagram?

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You see those sticks sort of jutting out from the top?

A You're on the Diagram C?

Q Yep. Same figure.

A I see -- I see the sticks.

Q And those sticks jutting out from the top of Domain 2 of R1 on both the left and right, do those correspond to amino acid sequences?

MS. GREEN: Objection. Form.

A In the context of aflibercept or this -- or of aflibercept, the assumption would be that they are amino acids if they truly actually represent something, because it's a schematic.

Q Okay. Well, I'm just asking in the context of this, which you agree isn't labeled aflibercept, is it?

MS. GREEN: Objection. Form.

A Yeah. I think I mentioned a few times that the structure indicated in the patent was eventually called aflibercept. Although Wulff doesn't state it, you didn't want me to comment on other -- the

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publications or patents or patent applications or communications with the patent office that do mention it. So -- and to interpret sticks on a -- on, basically, a schematic, I think a POSA doesn't want to read too much into anything, especially when the sequence is known.

Q Well, in fairness, Dr. Tarantino, it's in paragraph 57 of your report where you present the schematic and say that that's the structure of aflibercept.

So you at least focused on it in paragraph 57 of your report, right?

A But in the same --

MS. GREEN: Objection. Misstates. Objection. Form.

A -- but in the same manner, I think it's -- it's fine to use a schematic for general understanding. But to actually see what the molecule is is a different story.

Q What is your understanding of the legal standard for "inherent anticipation"?

A Inherent -- inherency -- I mean, inherent anticipation, are you talking

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about -- I think those are two different terms, right?

Inherency is the natural -- is the natural property of -- a property that's inherent or intrinsic in whatever you are talking about. That is my understanding of it.

Q Okay. What is your understanding of the legal standard for "anticipation"?

A That all of the -- okay. All the claims can be met or can be seen to be obvious based on one publication.

Q Okay. And what is your understanding as to whether, if a publication has a list of references at the end of it, are those references considered part of the publication for anticipation purposes?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A Yeah. That I don't -- that -- yeah. That's difficult to say. Certainly, they're not for -- in general, you could --

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you could have publication -- you could -- you could have references that are -- are wider or broader than what is in the publication. The simple answer is I don't know from a legal standpoint.

Q Okay. In rendering the opinions you provided in this case, how did you treat references that are cited in a reference but not incorporated, by reference, into that reference?

Were they separate, or were they part of the same reference?

MS. GREEN: Objection. Form.

A Could you give me an example where I did that?

Q So if we look at -- let's just go to Fraser, which is Exhibit 1009 in the record.

You are familiar with this reference, correct, Dr. Tarantino?

A Yes.

Q And it's your opinion that Fraser anticipates the challenged claims of the '992 Patent?

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A Yes, it is.

Q And so, for example, at the end of Fraser on page 1122, there is a list of 30 different references.

Do you see that?

A Yes.

Q And that's pretty common with respect to scientific publications like this; they refer to the work of others?

MS. GREEN: Objection. Form.

A The work of others?

Not necessarily. It could be their work or of anyone's work.

Q Okay. In your practice, have you ever published anything, Dr. Tarantino?

A Yes.

Q And in your publications, have you ever included a list of references?

A Sure. Yes.

Q Have those references ever included the work of others?

MS. GREEN: Objection. Relevance.

A Okay. Yes, they've included the work of others.

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Q Okay. And do you consider the references that you cited at the end of your publications to be part of the disclosure of your publication?

MS. GREEN: Objection. Relevance. Objection. Form.

A The disclosure of my publication?

Q Uh-huh.

A As I said, prior to it, it -- it really depends.

Q Okay. Well, let's look at Reference Number 1 in Fraser, and you see it lists Hazard (ph), T.M. and Stouffer (ph), R.L. as the authors?

A Yes.

Q When evaluating and determining and analyzing whether Fraser anticipates any claims of the '992 Patent, did you consider this Hazard reference to be part of the disclosure of the Fraser reference?

MS. GREEN: Objection. Form.

A Again, I think "disclosure" is a legal term. As a scientist, it's a quoted reference and parts of it might -- and might

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actually be cited in the publication, right?

Q When you say "they're cited in the publication," I mean, it's a reference.

Are all these cited in the publication?

A Right. So I don't think that's a -- I don't think what I'm saying is incorrect. So part of this publication was cited -- okay, part of the reference was cited in the publication, either directly or in some way. Right.

Q And so when you were considering and analyzing whether the Fraser reference anticipates any claims, did you consider any parts of these reference that are listed at 1 through 30 to be part of what Fraser teaches?

MS. GREEN: Objection. Form.

A I believe I considered Holash. I'm pretty sure that is the publication. Also, Regeneron article, and there's articles by Wulff, and there's references within Fraser that point to Holash.

Q Okay. And because of those

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references, it sounds like you combined the disclosures of Holash, Wulff with what's in Fraser as part of your anticipation opinions; is that fair?

MS. GREEN: Objection. Misstates. Objection. Form.

A I -- yeah. I combined the -- I combined the -- the disclosures of Wulff and Holash and Pott and others that I've indicated --

(Whereupon, the court reporter requested clarification.)

THE WITNESS: Wulff, W-U-L-F-F.

A -- with the significant part being there that they were all from Regeneron and, I think, relevant to my opinion about Trailer.

Q Relevant to your anticipation opinion --

A Yeah.

Q -- if we can be clear?

If we can go back to your report, I want to go to paragraph 58 on page 22. It's just below the Figure 1 from Wulff that

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we were considering. And this refers, again, to aflibercept.

And it says that: Aflibercept works by binding to VEGF and therefore, quote, trapping it before it combined to VEGF receptors on the cell surface.

Correct?

A Yes.

Q And so in Molecule C that we see above this paragraph, it's that trapping function that is referred to as "trap" in the nomenclature shown in Figure 1 of Wulff, correct?

MS. GREEN: Objection. Form. Objection. Misstates.

A Could you repeat that question? It was a little long.

Q Yeah. Figure 1 of Wulff, just above paragraph 58, Molecule C is referred to as "VEGF trap," right?

MS. GREEN: Objection. Form. Objection. Misstates.

A Aflibercept works by binding to VEGF and thereby -- therefore trapping it.

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Is that the sentence.

Q That's the sentence but I wanted to understand if it relates to Figure 1 and the use of the word "trap" in the nomenclature for the molecule that's shown in Figure C of Figure 1 from Wulff?

MS. GREEN: Objection. Form.

A That -- well, that is aflibercept in my opinion, and it's a straight statement of how it -- how it works.

Q Okay. I guess my question is a little different. Let's just focus on Figure 1.

It refers to Molecule C as VEGF trap R1+R2, correct?

A Yes.

Q And VEGF stands for vascular endotheolic -- endothelial growth factor?

A Yes.

Q What does the "trap" refer to in the name of that molecule shown as Item C in Figure 1 of Wulff?

MS. GREEN: Objection. Form.

A The trap is what Regeneron decided

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to call the molecule because it traps -- it traps VEGF. I don't know if it -- it corresponds to anything specific. But a POSA reading that would say, Okay, it's a VEGF trap and it has this R1 and R2 sequence, which has been identified by Regeneron.

Q So just to be clear, a POSA reading this would read the word "trap" and understand that refers to the function; it's trapping VEGF?

MS. GREEN: Objection. Form. Objection. Misstates.

A I think it would indicate that it's -- that VEGF -- that this molecule is, essentially -- a trap is -- "trap" refers to the molecule, but as I've said, this is how Regeneron, in a number of places, has referred to the sequences that I have mentioned.

Q And so it's your testimony that, when Regeneron said "VEGF trap," they were referring to a specific amino acid sequence?

MS. GREEN: Objection. Misstates.

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A No, they weren't. A VEGF trap, when they added the R1 and R2, then they were.

Q Okay. So help me understand, when Regeneron referred to VEGF trap without the R1+R2, it's your testimony that that refers to more than one different protein?

MS. GREEN: Objection. Form.

A I've seen, in early publications by Regeneron, them use that term. But VEGF trap alone is not -- not very descriptive.

Q Why not?

A Because you don't know -- for instance, there is no indication it even has to be a protein.

Q Okay. And R1+R2 adds a little additional specificity; it that fair?

MS. GREEN: Objection. Form.

A It's not just a little additional; they have described the sequences of R1 and R2.

Q R1 --

A So it's --

Q Oh, I'm sorry. Go ahead.

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A No. It's a -- it's a definitive sequence that they have used a description throughout development to refer to this molecule.

Q Just so I understand, your statement -- your testimony is that R1+R2 is a definitive statement of how Regeneron referred to this molecule?

MS. GREEN: Objection. Form. Objection. Misstates.

A No, I didn't say that. I said the term VEGF trap R1 and R2, in numerous publications and patents and communications with the patent office, referred to a specific sequence that is aflibercept.

Q In any of those publications, did Regeneron state that only aflibercept satisfies the definition of VEGF trap R1+R2?

MS. GREEN: Objection. Form.

A That only aflibercept -- I'm not -- I'm not sure I understand that.

Q So I guess what I'm wondering is -- I think we established the VEGF trap standing alone isn't enough to convey a

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particular primary sequence of a protein, right?

MS. GREEN: Objection. Form.

A VEGF trap alone doesn't supply a sequence, but adding the R1 and R2, in light of what they have published, in light of the sequences that have been published, does.

Q And R1, just as a reminder, that stands for receptor -- or I'm sorry -- that's referring to the Receptor 1 of VEGF Domain 2?

A It refers -- it refers to the part of the molecule that will react with VEGF R1.

Q Right. And R2 is also the part of the molecule that will react with VEGF R2, right?

A Yes.

MS. GREEN: Objection. Form.

THE WITNESS: Oh, I'm sorry. I keep breaking the rule.

Q And there are different sequences as a matter of -- well, they -- withdraw that.

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There are different sequences that could potentially react with VEGF R1, right?

MS. GREEN: Objection. Form.

A Different sequences within what?

Q Just different sequences.

MS. GREEN: Same objection.

A To react with what?

Q To react with VEGF R1.

A Possibly, but I really don't -- I don't know. These are -- I know these are pretty specific interactions.

Q Okay. And I think I misspoke.

I -- there are different sequences that combine R1 and R2 that could trap VEGF, right?

MS. GREEN: Objection. Form.

Q You could have different linker sequences, for example?

A There are different sequences that could combine with the receptors.

Is that what you are asking?

Q You could have R1 and R2, as specified in Wulff Figure 1, as part of a protein with the schematic shown in Figure 1

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but with a different sequence between two proteins, right?

MS. GREEN: Objection. Form.

A The different sequence between R1 and R2?

Q Correct.

You could have a different linker sequence, for example?

Again --

MS. GREEN: Objection. Form.

A -- this was -- it's in the prior art in the publication, what R1 and R2 was with the specific added indicator of -- that they were, in some way, modified to increase the pharmacokinetics. So that's in the prior art knowledge.

Q Do you recall whether any of the prior art referred to R1+R2 as a functional group that included different sequences --

MS. GREEN: Objection. Form.

Q -- or is your testimony that R1+R2 always refers to the same sequence?

MS. GREEN: Objection. Form. And Objection. Misstates.

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A As far as I know, it referred to the same sequence.

Q I'm going to hand you what's been marked, for the record, as Exhibit 2013. It is a patent application U.S. 20060058234 listing Daly, et al., as inventors.

(Exhibit No. 2013 U.S. Patent No. 2006/0058234 A1, a previously marked exhibit was referenced.)

Q Have you seen this document before, Dr. Tarantino?

A I don't believe so.

Q Okay. And do you recall whether you reviewed this document in preparing your declaration in this case?

A I reviewed something authored by Papadopoulos, but I don't recall --

Q Okay.

A -- if it was this one.

Q And do you recall whether you looked at -- well, I think you answered the question.

But do you recall whether you looked at this Exhibit 2013 in preparation

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for your deposition today?

A No. As I said, I don't -- I -- Papadopoulos is familiar but Daly is, right now, not.

Q Okay. The title of this is "VEGF Traps -- in the plural -- And Therapeutic Uses Thereof."

Do you see that?

A Yes.

Q And does that suggest to you that there is more than one molecule that Regeneron referred to as a "VEGF trap"?

MS. GREEN: Objection. Form.

A Just by the title, I think it -- I said VEGF traps, in general, describes a function. And I would have to read the whole thing so I don't -- or go over a good part of it to see exactly what they meant.

Q Okay. And without reviewing the whole patent, do you know whether this describes producing VEGF traps and host cells other than CHO cells?

A Well, how would -- how would I know that without looking through the

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article?

Q You reviewed the '319 publication as part of your preparation for your opinions in this case, right?

A Yes.

Q Do you know whether it refers to production of VEGF traps in host cells other than CHO cells?

A Offhand, no, I don't.

Q This is a thick one. Exhibit 1029 in the case, it's the '319 publication.

(Exhibit No. 1029 PCT WO 00/75319 A1, a previously marked exhibit was referenced.)

Q And this is the '319 publication that you relied upon in your anticipation opinions, correct?

A Yes.

Q Did you review this entire document?

A Most of it, or parts, I suppose.

Q Okay. Do you recall whether you looked at the claims in this document? You might be looking for page 91.

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A Oh, okay. Okay.

Q And this is where the claims start in this document, correct?

A Yes.

Q Do you recall whether you reviewed these as part of forming your opinions in this case?

A Probably.

Q Okay. If you can turn to page 94?

A Okay.

Q And I can direct you to Claim 17. Let me know when you're there.

A I'm there.

Q Okay. And this claim is talking about a host vector system using a suitable host cell where that suitable host cell is a bacterial cell, a yeast cell, an insect cell, or mammalian cell?

A Yes.

Q And do you recall reviewing this claim --

A I've seen it.

Q -- as part of rendering your opinions about the '319 publications?

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A Yes. I've seen this claim.

Q Okay. And Claim 18 refers to a suitable host cell as E. coli, correct?

A Yes.

Q And Claim 19 refers to a suitable host cell as being a COS cell or C-O-S cell. Do you see that?

A Yes.

Q What is a COS cell?

A I -- I don't recall at this time. I believe it's a mammalian cell, but I'm not sure.

(Whereupon, the court reporter requested clarification.)

THE WITNESS: Mammalian.

A But I'm not very positive of that.

Q Okay.

A It's not very common.

Q Beyond those mammalian host cells and the CHO cells, which you mentioned in your report, are there other mammalian host cells that you're familiar with for recombinant protein production?

MS. GREEN: Objection. Form.

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A No.

Q You're not familiar with Hecht 293 or AGK 293?

A There are some other ones, but CHO is the -- CHO cells are the predominant mammalian cells in my experience.

Q And I think we touched on it earlier, but are you familiar with NS0 host cells.

MS. GREEN: Objection. Form.

A NS0?

Q Correct.

A As I said, most of what I have been involved with has been CHO sells or -- yes, CHO cells.

Q Are you familiar with SP20 host cells?

Have you ever heard of those?

MS. GREEN: Objection. Form.

A Specific names of cells, I may have come across, but I am familiar that there are some mammalian cells that could be used. But the advantages of CHO sells are -- the consistent use of them make them

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optimum.

Q And I think we touched on this earlier today, but do you remember what host cell was used to produce daclizumab?

MS. GREEN: Objection. Relevance. Objection. Form.

A No, I don't. And if I did, I don't believe I could tell you that.

Q Okay. I'm going to go ahead and actually mark an exhibit as 2046.

(Whereupon, a Zenapax summary document was marked as Deposition Exhibit No. 2046 for identification, as of this date.)

Q Have you ever seen this document before, Dr. Tarantino?

A It looks like the summary -- the summary document.

Q Summary document for Zenapax?

A Yeah. It looks like that, possibly the package insert.

Q Okay.

A I don't really -- it's hard to say.

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Q Okay.

A They're not much different.

Q So can you turn to page 10 of Exhibit 2046?

A Yes.

Q And there are some instructions for administration?

A Okay.

Q The first bullet at the end of it, in all caps, it says: Do not shake.

Do you see that?

A Yes.

Q Do you recall why that was an instruction for Zenapax?

MS. GREEN: Objection. Relevance.

A What I'm looking for is the -- is the formulation that you mentioned and then I can answer your question.

Q Sure. I think it's the third full paragraph on page 1 under the description?

A Yes. Okay. As I -- as I mentioned before, that statement was often put in because -- because of the polysorbate 80. If you shake it, especially

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in a product -- well, any product, you will get just a foamy mess -- a foamy mess that will be difficult to withdraw accurately.

Q Is the same true of polysorbate 20?

A It --

MS. GREEN: Objection. Form.

A The same is true for polysorbate 20.

Q The second bullet says that: Parenteral drug products should be inspected visually for particulate matter and discoloration before administration. If particulate matter is present or the solution colored, do not use.

Why would there be particulate matter or why is there a potential for there to be particulate matter in a parenteral drug product?

MS. GREEN: Objection. Form.

A The simple answer, either it was introduced during manufacturing or something went wrong with the formulation in terms of storage.

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Q Okay. And particulate matter would be an indicator of instability, at a general level, for that particular --

A No, not necessarily. It could just be --

MS. GREEN: Objection. Form. Thank you.

THE WITNESS: You think I'd get this by now.

A But, no, not necessarily. If you have some downstream contamination during manufacturing that wasn't picked up in visual inspection, it could be -- it could be that. It would have to be investigated. Yeah.

Q Okay. And what about discoloration?

What would be the cause of discoloration in a parenteral drug product?

MS. GREEN: Objection. Form.

A It's very -- it's very similar. Contaminants would discolor. Sometimes solutions of any drugs stored at not-the-optimum conditions might be a part

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of their degradation.

Q Okay. The fifth bullet down says that: This particular product is administered intravenously within four hours.

Do you see that?

A Yes.

Q And it says: If it must be held longer, it should be refrigerated between 2 to 8 degrees Celsius for up to 24 hours.

And then, after 24 hours, the instructions for administration say: The prepared solution should be discarded.

A Okay.

Q Do you recall why the prepared solution should be discarded after 24 hours?

MS. GREEN: Objection. Form.

A Twenty-four hours is a standard format for injectable products that are reconstituted or diluted, where the concern is that you contaminated the product and you're actually -- microbial growth will -- you know, will take place. So, for this -- yeah, that's -- that's the -- again, that's

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the, generally, across-the-board condition.

Q Okay. And so 24 hours is the general condition, even if it's refrigerated?

MS. GREEN: Objection. Form.

A Even if it's refrigerated?

Well, I believe 2 to 8 degrees was the storage conditions for the Zenapax, right?

Q That's my understanding of what it said.

A Right.

Q I was just confirming that, after 24 hours, that's referring to after 24 hours of storage after 2 to 8 -- at 2 to 8 degrees C.

A Right. So it's -- those are the conditions under which it could be -- could be stored.

Q Okay. There is -- the last paragraph of this says: How supplied.

Do you see that?

A Yes.

Q And it says that -- in the third

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paragraph that: Vials should be stored between temperatures of 2 to 8 C, semicolon, do not shake or freeze.

Do you see that?

A Yes.

Q And I think we talked about why the instructions for not shaking is there.

That is to prevent the foaming from the polysorbate, fair?

A Yes.

Q Why is the instruction not to freeze the vial containing Zenapax?

MS. GREEN: Objection. Form.

A Specifically -- I don't -- I don't remember specifically. But any liquid is not -- even a small molecule, it's a -- you're changing the phase. In this -- in this case, I don't recall there being a specific problem. I tend to not believe it was because the freeze-thaw cycles showed us that. But that's generally the -- that's generally the reason.

Q I'm sorry.

What is generally the reason?

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A Well, in general, it's -- you don't want your product -- what you have -- what you -- was approved was your solution product. So it's a general precaution that you don't want it frozen, in general. It could be there was a specific problem with freeze-thaw but I just don't -- you know, I don't recall it.

Q Got it. You would need to see the data, the freeze-thaw cycle or something that shows what happens to the liquid formulation if you freeze it and thaw it to know that?

MS. GREEN: Objection. Form.

A To know if?

Q To know if there is a problem or not with freezing the solution.

A To know if there is a significant problem. But a lot of things are just -- I don't know if it's just a standard disclaimer. I mean, let's face it, storage conditions are 2 to 8 degrees. So people will put things in freezers. On the other hand, they'll leave them in their glove

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compartment. I mean, so there is general -- there's general guidelines as to what you should do with the dosage form, a liquid dosage.

Q And another one of the guidances here is to protect the solution against direct light, right?

MS. GREEN: Objection. Form.

A Yeah. Is that one of these bullets?

Q It's in the how supplied. It's right after the "do not shake or freeze" instruction?

A It's not one of these bullets?

Q Sorry. It's not one of the bullets. It's in the "how supplied" paragraph that we were looking at.

A Oh, how supplied.

Q And there's a sentence that says: Protect un-diluted solution against direct light.

A Yes. Okay.

Q Do you know why direct light would be a concern?

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MS. GREEN: Objection. Form.

A Again, I don't remember the -- Zenapax's particular problems. But, in general, light can act -- there are drugs that are photosensitive, and there are drugs that are -- that get oxidized and it can be -- can be accelerated by light. In general, you try to stay as close to your label conditions as you can.

Q The last sentence says: The diluted medication is stable for 24 hours at 4 degrees C or for four hours at room temperature.

Correct?

A Yes.

Q Does that suggest that the diluted medication becomes unstable after 24 hours at 4 C or after four hours at room temperature?

MS. GREEN: Objection. Form.

A This has to do with -- as I mentioned, there is a microbial concern.

Q Uh-huh.

A And this is -- it's also tested.

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And typically, you would have diluents that are commonly used.

(Whereupon, the court reporter requested clarification.)

THE WITNESS: Commonly used diluents.

A And you would check if your product is diluted, if there is a -- if there is a stability problem.

Q Right. Understood.

I guess I'm trying to understand, does this suggest that there was a stability problem after 24 hours at 4 degrees C?

MS. GREEN: Objection. Form.

A No. It doesn't suggest that. It could be -- a microbial growth. It could be the issue there or -- I don't recall there being that type of stability or any type of stability or problem with that. So it could possibly be stability, but it's a precaution that you would -- you would take.

Q Okay. And the fifth bullet down in the instructions for administration, I think this language relates to the stability

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language we looked at.

And it says: After 24 hours, the prepared solution should be discarded.

Do you see that?

A Yes.

Q And do you know why there was an instruction to discard the prepared solution after this 24-hour period?

A Yeah. That is --

MS. GREEN: Objection. Form. Objection. Asked and answered.

A That specifically highlights the microbial growth. So if you have any questions about microbial growth, you want the pharmacist or nurse to throw it out -- right? -- so nobody else gets it.

Q Can microbial growth influence aggregation?

MS. GREEN: Objection. Form.

A I've never seen that. No.

Q Okay. And do recall --

MS. GREEN: Adam, just so you know, I don't know how much longer you have with this particular document, but

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we've been going since 3:05, and it's now 3:25, so about 80 minutes. So I don't know when you want to finish this part up.

Q Do you recall, with respect to Zenapax, whether there was a specific microbial growth concern that led to this instruction to discard the prepared solution after 24 hours?

MS. GREEN: Objection. Form. Objection. Asked and answered.

A It doesn't contain a preservative so, of course, there is a -- there is a concern with microbial stability.

Q Okay.

MR. BRAUSA: Why don't we take a break?

MS. GREEN: Thank you.

VIDEOGRAPHER: The time on the video monitor is 4:26 p.m. We're off record. This end Media 4.

(Whereupon, at 4:24 p.m., a recess was taken to 4:43 p.m.)

(The proceeding resumed with all

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parties present.)

VIDEOGRAPHER: We're back on the record. The time on the video monitor is 4:43 p.m. This the beginning of video five.

Q Earlier in the day, I was asking you about your understanding of anticipation and inherency.

Do you recall that?

A Yes.

Q And I think you testified that inherency and anticipation are two different things; is that accurate?

A Yeah. As I -- as I understand them, inherency is different than an -- different than anticipation. I mean, again, I'm not an attorney but...

Q Sure. How often does something need to occur or be present for it to be inherent?

MS. GREEN: Objection. Calls for a legal conclusion.

A I've only thought of it in terms of properties.

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Q Okay. In the context of properties.

A In the context of properties?

Q Yeah. What is an inherent property?

A An inherent property, again, is an intrinsic property. I'm not sure I could give a better answer. What is -- what a -- whatever the substance is or thing is, it's an inherent property. That's intrinsic. It's part of the item that you're talking about naturally, I guess, naturally intrinsic maybe.

Q Okay. So is it fair to say inherent means it's always present?

MS. GREEN: Objection. Calls for a legal conclusion.

A Yeah. That does -- I mean, I'm not sure. It's a -- it's a property -- that's a -- that's a tough -- yeah. That is a tough question. I think it's a little more -- I think it is a legal question.

Q Well, you would agree with me that portions of your report you say there are

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inherent properties in certain formulations, right?

A Yes.

Q What did you mean when you said the properties were inherent in the formulation?

MS. GREEN: Objection. Form.

A They were in -- they were intrinsic. They were a -- naturally part of whatever item I was -- I was discussing.

Q And so does that mean they're always present or sometimes present, usually present?

MS. GREEN: Objection. Calls for a legal conclusion. Objection. Form.

A Yeah. Again, I would have to say that I don't know what that means. I mean, legally, it would be a stretch for me to take a shot at that.

Q Okay. And, legally, it would be a stretch for you to take a shot at defining how often something must be present for it to be considered inherent?

MS. GREEN: Objection. Form.

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A I think the best definition that I can give is it's an intrinsic property, a naturally occurring property. That's what I know.

Q Well, maybe -- let's try it with -- in the context of stability. Let's say we have a formulation. You have 100 vials of the same formulation. Ninety-nine out of a hundred of them show aggregation less than 5 percent, but one of the vials has aggregation of 10 percent.

Is aggregation of less than 5 percent inherent in that formula?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A I'd have to answer it the same -- the same way. If one vial was -- the property needs to be an intrinsic, you know, whatever it is, naturally occurring. That's the extent of what I can tell you on that.

Q So in the example I gave you, with respect to the stability and aggregation, 99 of them have less than 5 percent aggregate;

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one of them has greater than 5 percent aggregate.

A What you.

Q Can you tell me whether that's an inherent property of the --

(Cross-talk.)

A What are you saying is the inherent property?

MS. GREEN: Objection.

Q The amount of aggregation.

MS. GREEN: Objection. Form.

A It could be.

Q Okay. Even though one of them has greater than 5 percent aggregation, one of the formulations in my example?

A You have 99, and then you have one that isn't?

Q Uh-huh.

A That's sort of an aberration.

Q And so would that be inherent?

A You're filling the same formulation, right?

Q Uh-huh.

A A stability would be, in that

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case, an inherent property if -- if one of them -- the scenario that you presented is one that's not typical.

You put an outlier in there, right?

Q Well, I don't know if it's an outlier or not. It's just one of the hundred had a different stability profile than the other 99.

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A Well, as I -- as I mentioned, that's a -- that is not -- if an inherent property is stability and it can very well be, that one vial would not throw out the inherency.

Q Okay. You also talk about obviousness in your report, correct?

A Yes.

Q What is the difference between anticipation and obviousness?

MS. GREEN: Objection. Form. Objection. Calls for legal conclusion.

A Okay. I believe a inherency or --

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I'm sorry. That's not what you asked.

You asked for obviousness?

Q Correct.

A And --

Q And how does that differ at all from anticipation?

A Oh, anticipation of -- my understanding of it is that one reference would make obvious all the claims, as opposed to multiple efforts -- you know, multiple references and obviousness.

Q Okay. And so, in both instances, you're evaluating obviousness it's just a matter of how many references you're using?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A That's my understanding of it, yes.

Q Okay. Does inherency have anything to do with obviousness in the opinions that you have rendered in this case?

MS. GREEN: Objection. Form.

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A I believe most of my opinions on obviousness include inherency arguments, but I'm not --

(Whereupon, the court reporter requested clarification.)

THE WITNESS: Include --

A I really have to, you know, at this point, look at it again. But my major opinion that, based on Fraser, the claims would be obvious based on the prior art that I mentioned.

Q Okay. Do you have -- and I understand you're not a lawyer.

Do you have any understanding of the legal requirements for inherency if you're using that as part of an obviousness analysis?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A No, I don't know.

Q Okay. Have you ever -- do you know whether something is obvious if it's just obvious to try?

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MS. GREEN: Objection. Calls for a legal conclusion. Objection. Form.

A Obvious to try?

It's -- my understanding is that the claim is obvious. I can't think of a better word, but it would be taught in the prior art.

Q Okay. If something might be something, for instance, a formulation that you might want to try, but you don't know whether it's going to be stable or not before you try it, would that be obvious in terms of the opinions that you have rendered in this case?

A I think it depends -- would depend on the formulation, right?

I -- would it be obvious that a formulation is -- I'm not sure. I'm not sure what you are asking here.

Q I guess what I'm trying to ask -- and maybe it's getting late in the day -- is, if there is something that is something you might want to try, a formulation that you might want to try, the prior art directs

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you to try this formulation but you don't know whether it's going to work or you don't have any reason to think it's going to work or not, is that something that would be obvious as you have concluded in this case?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A Yes. I don't -- my understanding, I don't believe it. If a -- if a formulation is obvious, then I think it's -- the results that you get from that formulation might be a different -- a different story.

Q Okay. Can we go to paragraph 70 in your report, Exhibit 1002, page 28?

A Okay.

Q I had asked you about who put text in your report in parentheses or brackets earlier in the day, and paragraph 70 has one of these instances where it talks about recombinant proteins produced for therapeutic use in cell culture, and then there's a parenthetical that says: Usually

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CHO cells.

Do you see that?

A Which paragraph?

Q Paragraph 70, page 28.

A Yeah. I would have put this in.

Q Okay. And by "usually CHO cells," that means not always CHO cells, right?

MS. GREEN: Objection. Form.

A Usually -- yeah. "Usually" means usually --

Q Okay.

A -- predominantly. I don't have a lot of --

Q As part of your work in this case, did you go back and look at how often CHO cells were used to produce commercial recombinant protein products?

MS. GREEN: Objection. Relevance. Objection. Form.

A Commercial products?

Q Uh-huh.

A I looked in the references that I have, and my own knowledge.

That is a bit of information that

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is -- would be a little bit difficult to find, right?

Obviously, mammalian cells are preferred for something you're going to give to humans.

Q Why is that?

MS. GREEN: Objection. Form.

A Because humans are mammals.

Q So -- sorry. I thought -- I didn't want to cut you off. I understand humans are mammals.

A Okay.

Q Why does that mean that you would use -- or want to use mammalian host cells to express recombinant proteins?

MS. GREEN: Objection. Form.

A Because they're as close as you can get to humans with respect to how the -- how they're expressed, let's say. That does -- could vary by species, et cetera.

Q Just to be clear, CHO stands for Chinese hamster ovary cell.

That's the type of cells those are?

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A Right.

Q And so the mammal in this is what is called a "Chinese hamster"?

A Yes.

Q As of 2006, were there human cell lines that could be used for recombinant protein production?

MS. GREEN: Objection. Form.

A I don't -- I am not sure if they were used on a -- I mean, that's a -- that's actually a controversial topic. And in 2006, I don't know if you -- if you could use human cells.

Q Do you know whether you could use -- whether there were any monkey cells available for recombinant protein production in 2006?

MS. GREEN: Objection. Form.

A Again, I think my comment regards CHO cells as being common, being easy to keep in cell culture, et cetera, et cetera. You could -- I think that is a different question. That's actually not -- sort of not in the, you know, comparising --

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comparing them in terms of there is a lot of factors that go into comparing it with regard to CHO cells, right?

They have to be reproducible, a whole -- a whole bunch of factors.

Q But, certainly, your testimony isn't that CHO cells were the only possible host cell that could have been used in 2006 to produce recombinant proteins, right?

MS. GREEN: Objection. Misstates.

Objection. Form.

A My testimony is that everything I have seen would indicate Regeneron has used CHO cells from the very beginning.

Q So my question was a little different. I didn't actually ask anything about Regeneron.

I'm just asking, in terms of recombinant protein production, in 2006, you were employed at Hoffman LaRoche, right?

A Yes.

Q Were CHO cells the only recombinant host cells that you were looking at Hoffman LaRoche?

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MS. GREEN: Objection. Form. Objection. Relevance.

A Maybe, maybe not. I -- it is difficult to say.

Q So maybe, maybe not, is your testimony?

MS. GREEN: Objection. Form.

A Again, that's sort of confidential Roche information.

Q The cell lines used to produce Roche's or Genentech's commercial products isn't confidential, is it?

It's on the label.

MS. GREEN: Objection. Form. Objection. Relevance.

A I don't know if it's always on the label.

Q Okay. Let's go to paragraph 56 of your report, page 20.

A Okay.

Q And this is talking about some antiangiogenic VEGF inhibitors that were developed at Genentech, correct?

A Which paragraph?

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Q Paragraph 56, page 20 of Exhibit 1002.

A Okay. I'm on paragraph 56.

Q Okay. This refers to bevacizumab, a humanized monoclonal antibody.

A Yeah.

Q Do you see that?

A Yes.

Q Do you know whether that corresponds to a commercial product marketed by Genentech?

MS. GREEN: Objection. Relevance.

A No, I don't.

Q Okay. So you don't know whether or not the same as Avastin or the active ingredient in Avastin?

A No, I don't recall.

Q Do you know what host cell is used to express bevacizumab?

MS. GREEN: Objection. Relevance.

A No. And I believe that was a Genentech -- original Genentech -- it was an original Genentech product. And, actually, that information was not shared with Roche

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until they decided to merge or whatever that was.

Q And you were at Roche when Genentech was acquired by LaRoche?

A It was --

MS. GREEN: Objection. Form. Objection. Relevance.

A I can't really comment on the -- on the exact date. It was sort of around then. I don't know. Yeah.

Q But it sounds like you don't know what host cells was used to produce bevacizumab?

MS. GREEN: Objection. Form.

A No. I wouldn't be privy to that information.

Q Okay. And then you also refer to ranibizumab in paragraph 56 of your report, correct?

A Right.

Q And what type of molecule is ranibizumab?

A It's a monoclonal antibody.

Q Is it a full length antibody or a

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fragment?

Do you know?

A No, I don't know. These are examples of antibodies.

Q Okay. So at the top of page 21, your report says: Another was ranibizumab, a modified fragment of the bevacizumab antibody.

Do you see that?

A Yes, I do.

Q How did you know that to put it in your report?

MS. GREEN: Objection. Form. Objection. Relevance.

A Yeah. I mean, I did give the references that I used, Ferrara and Rudge.

(Whereupon, the court reporter requested clarification.)

A Ferrara, you could see earlier in that paragraph, and Rudge.

Q And it's your testimony that one of those references specifies that ranibizumab is a modified fragment of the bevacizumab antibody?

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MS. GREEN: Objection. Form. Objection. Misstates.

A Yes. Well, I don't recall it specifically. I do quote -- I do cite Rudge.

Q And do you know what host cell was used to express ranibizumab?

MS. GREEN: Objection. Relevance. Objection. Form.

A No, I don't offhand. I'm not sure if the publication that I cited reveals it, but that specific information, yes.

Q Does the fact that, at least according to your report, ranibizumab is a modified fragment of bevacizumab tell you anything about the likely host cell used for ranibizumab?

MS. GREEN: Objection. Form.

A Oh, I don't think it -- it agrees with my opinion that's it obvious to use CHO cells, and they are the primary host cells used in production of proteins.

Q Why does that statement, that ranibizumab is a modified fragment of the

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bevacizumab antibody agree with your statement about CHO cells?

MS. GREEN: Objection. Form.

A No. I said my statement about CHO cells is that it was very common and a dominant way of dominant host cells. That's what I said. I would have to go back to these publications to see if they mentioned specifically the host cells.

Q Okay. And without doing that, you can't tell me what cells were used for bevacizumab or ranibizumab?

A No, I couldn't tell you specifically.

Q Can we go back to paragraph 37 of your report?

A I'm sorry.

Paragraph 37?

Q Yes, page 13.

A Okay.

Q This is, again, in Exhibit 1002. This is a paragraph about secondary evidence that you state may weight against a finding that a claimed invention would have been

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obvious.

Do you see that?

A Yes.

Q And then it lists some types of secondary evidence?

A Yes.

Q Do you know whether this list is exhaustive in terms of the types of secondary evidence that's shown on obviousness?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A No. I don't believe I would have worded it that way.

I did say: Such secondary evidence may be.

Q Okay. Are there other factors or items of secondary evidence that you consider relevant to obviousness?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A I -- yeah. I mean, I did say

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that: Such secondary evidence may include.

And I provided a list and, in my conclusions of obviousness, I also had a statement on secondary evidence.

Q And my question actually was about that statement.

Did you do any independent investigation as to whether there was any evidence of commercial success of -- in Regeneron products due to the features of the claimed invention?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

Q I think paragraph 186 may be what you're looking for, Dr. Tarantino.

A Yes. Okay. So I'm not aware of any relevant -- relevant secondary evidence was my conclusion. So it wasn't an area that -- you know, I think the secondary evidence -- the extent of it and what could be was sort of not really relevant.

Q Did you look at all?

A Usually, information like this in

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the past is -- you know, might be supplied from the client, et cetera.

Q Okay. And you weren't supplied with any such information for the purposes of this opinion?

MS. GREEN: Objection. Form.

And be careful. I would -- you're -- we're treading on privilege here so just be -- we're treading on privilege here so just be careful how you answer.

A I had no reason to believe there was secondary evidence.

Q Did you look at whether Genentech's -- or I'm sorry -- whether Regeneron's products are commercially successful?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A I didn't -- no, I didn't look at -- I didn't look at that.

Q Okay. Do you have a view on whether Regeneron's Eylea product is

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commercially successful or not?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A I don't know if it's commercially successful.

Q Did you look to see whether anyone expressed surprise that Regeneron was able to stabilize aflibercept in the Eylea product?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A That anyone was surprised?

Q Yeah.

A Again, if I don't have secondary evidence -- the secondary evidence would only support my opinion of not obviousness, and that was my statement, that I didn't have any evidence.

Q Okay. And just to confirm, I'm not trying to be tricky here.

You didn't look for any evidence of secondary considerations, right?

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You're just not aware of them?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A What page was the original comment on?

Q Paragraph 37, pages 13 and 14 of Exhibit 1002.

A No. I think that's -- those are part of the overall -- if you're looking at the literature, et cetera, I think that's -- you know, it sort of -- it sort of would come up in reviewing in the literature.

Q Right. I guess my question is did you do any independent investigation to see, for example, whether Regeneron's products were commercially successful or whether they tried and failed to stabilize any fusion proteins in formulation?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion. Objection. Asked and answered.

A Yeah. I think I did answer the

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question already. Then coming across -- I believe I stated, reviewing the project, some of these topics -- in reviewing the literature, some of these topics may have -- may have come up.

Q And in what literature did these topics come up?

MS. GREEN: Objection. Form.

A When you do have a project, you might, just generally, look at the molecule -- look at the product. But in, you know, reality -- I mean, we're talking about the VEGF Trapped R1 aflibercept so, I mean, commercial success is -- is not what I looked at specifically.

Q Would you agree that it's necessary to have a stable product if you want it to be commercially successful?

MS. GREEN: Objection. Form.

Objection. Asked and answered.

A Is it necessary?

It's necessary to establish a shelf life and generate any stability data that would support that shelf life.

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Q In your time at Hoffman LaRoche in the various projects that you led that are referenced in your CV and expert report, do you consider any of those products to have been a commercial success?

MS. GREEN: Objection. Relevance. Objection. Form.

A Yes, I do.

Q Which ones?

MS. GREEN: Objection. Form. Objection. Privileged to the extent that you can't say.

A Okay. That means I can't say so...

MS. GREEN: No. To the -- to the extent that you're -- if you -- if you can -- if you feel like you could say given the work you did at Hoffman LaRoche.

Q Just to be clear, the question is which ones are commercially -- do you consider commercially successful?

I'm not sure how that would implicate privileged information.

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MS. GREEN: Objection. Legal conclusion then because --

A Okay. I -- the answer I can give you is -- is a -- I'm not sure of the legal conclusion, but most of them were. I know Accutane definitely was, not relevant to this case. And commercially successful, I think that is a term that you would need to define more.

Q Well, if we go back to paragraph 37 in your report, it refers to commercial success of a product, right?

A Right.

Q How are you using that term?

A I'm using --

MS. GREEN: Objection. Form.

A Okay. I'm using that term. It's not specifically -- not acknowledging the -- even acknowledging or knowing the profits, et cetera, but is the project -- is it still on the market, is -- does it sell well, that type of thing. Of course, I knew this for Roche, Roche compounds, Genentech compounds.

(Whereupon, the court reporter

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requested clarification.)

A So, yeah, I wouldn't say Genentech compounds. Genentech compounds, I wouldn't know any more than anybody in this room.

Q So I was just asking about the compounds you worked on, to be clear.

A The compounds I worked on, I don't believe I have the list of nine anymore. But a -- I could only give you an estimate of my impressions.

Q Okay. And that's just what I'm trying to understand.

I think you said you considered Accutane to be a commercial success?

A Yes.

Q Do you have any views on whether it would have been a commercial success if it had stability issues?

MS. GREEN: Objection. Form.

A It did have stability issues, and it was still a commercial success. Yeah.

Q Okay. What were the stability issues it had?

MS. GREEN: Objection. Relevance.

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A Okay. Isoretinoic acid is easily oxidized, so it was placed in a -- again, I don't want to -- I can't tell you exactly the vehicle, I don't believe. But it was placed in a vehicle that there was a little -- little probability of it being oxidized, and it was also protected from oxygen. And it's also in a soft gel and capsule as opposed to a tablet that would be exposed to oxygen.

Q Okay. And those are examples of steps you took to minimize the degradation pathway of oxidations, but it didn't eliminate it entirely?

MS. GREEN: Objection to form.

A It eliminated it to the extent that it was -- that it met the specifications that we had for it and agreed to with the FDA.

Q Right. And those specifications, in terms of stability, will differ from product to product, protein to protein, right?

MS. GREEN: Objection. Form.

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A The specifications, the actual -- I'm talking about potency here. I'm not sure what you are talking about, if it's anything different.

Q Well, you said it met the specification that you agreed to with the FDA.

A That's right, and I was speaking of impurities, potency.

Q Okay. And those impurities and potency specifications will vary by products and by product, right?

A They'll --

MS. GREEN: Objection. Form.

A They'll vary by product but there are guidelines, just like the one that I believe was in my report. I might have said there wasn't. There were specifications -- there are guidelines. There are guidelines about what is acceptable in term of impurities.

(Whereupon, the court reporter requested clarification.)

THE WITNESS: Impurities.

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Q If we can go back to your report at paragraph 70 and 71 on pages 28 and 29?

And above paragraph 71, there are two schematics shown, right?

A Yes.

Q And on the left, we see the schematic of VEGF trap R1+R2 from what I think is the same figure as in Wulff, Figure 1 we looked at earlier today --

A Right.

Q -- fair?

And then that's shown next to a schematic of what's just labeled "antibody."

Do you see that?

A Yes.

Q Why did you put these two schematics side by side in your report?

MS. GREEN: Objection. Form.

A Just to indicate the similarity in structures -- in the overall structures.

Q Okay. You would agree with me there are differences between VEGF trap R1+R2 structure shown in the schematic and the schematic labeled "antibody," correct?

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MS. GREEN: Objection. Form.

A Yeah, there are differences.

Q Okay. What are some of those differences?

A I -- I --

MS. GREEN: Objection. Form.

A I think the existence of a single R1+R2, a single chains as opposed to multiple chains in the antibody.

Q Okay. And so VEGF trap, shown in paragraph 71, is a diamer of the antibodies.

That's one difference, right?

MS. GREEN: Objection. Form.

A That's one difference.

Q Okay. Antibodies also have heavy chains and light chains, right?

MS. GREEN: Objection. Form.

A Yes.

Q VEGF trap doesn't have a heavy chain and light chain, does it?

MS. GREEN: Objection. Form.

A VEGF trap is described by the -- I'll call them "monomers" or "polypeptides."

Q Okay. Do you consider antibodies

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to be trap proteins as that term is used?

MS. GREEN: Objection. Form.

A It's not usually used that way, no.

Q I also see reference on the diagram of an antibody to a hinge region.

Do you see that?

A Yes.

Q Does VEGF trap R1+R2 have a hinge region?

MS. GREEN: Objection. Form.

A Yeah. I am -- again, this goes back to the chains or the lines in between them. I've never seen it referred to as that. And it's a fusion protein, so I'm hesitant to say that it does.

Q And I see the antibody schematic has a "C" and a "V" that refers to a constant domain and a variable domain on both the heavy and light chains?

A Yes.

Q VEGF trap R1+R2 does not have variable domains, does it?

MS. GREEN: Objection. Form.

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A Not that I am -- not that I am aware of, but the whole point of this was that it's a protein, similar in shape, really, to an antibody.

Q And here you say they're similar in shape because they're both, quote, Y-shaped?

A They're Y-shaped. They have an FC region, et cetera.

Q Now, in reality, though, these are both three-dimensional proteins; they're not Y-shaped like they're shown in these schematics?

MS. GREEN: Objection. Form.

A That's -- that's difficult -- that's difficult to say. Three-dimensional doesn't mean it's not Y-shaped. It depends on the rigidity of the bonds, et cetera.

Q And speaking of bonds, on the antibody, I see several disulfide bonds shown.

VEGF trap R1+R2 doesn't have disulfide bonds between the chains, does it?

MS. GREEN: Objection. Form.

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A I'm not sure if it has disulfide bonds.

That's a -- it is a common way to link proteins, right?

Q My understanding is antibodies also have what are called intrachain disulfide bonds.

Are you aware of that?

MS. GREEN: Objection. Form.

A Any protein can have intramolecular disulfide bonds.

Q And do you know what their antibodies do?

A What their antibodies do?

Q Correct.

A It's a -- certainly a possibility --

Q Okay.

A -- that they link --

Q But do you know one way or the other?

A Disulfide bonds are, again, mono -- antibodies are -- that's a pretty broad term. You would have to look at the

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specific antibody.

Q So some antibodies might have disulfide bonds intrachain or molecularly; some antibodies might not.

Is that your testimony?

MS. GREEN: Objection -- objection. Form.

A They might have other mechanisms of being linked.

Q Do you know whether VEGF trap R1+R2 shown at the top of page 29 in your report has any disulfide bonds holding it together?

MS. GREEN: Objection. Form.

A Okay. I don't -- well, actually, I don't recall what the mechanism is --

Q All right.

A -- holding it together.

Q Do you know whether antibodies are what are referred to as "glycosolated proteins"?

MS. GREEN: Objection. Form.

A Again, my experience that some glycosolated proteins, some could be -- some

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proteins could be glycosolated and others might not be.

Q And does the glycosolation pattern of a protein, can that have a potential impact on the stability of the molecule?

MS. GREEN: Objection. Form. Objection. Scope.

A It's part of the molecule so, in general -- generally, if a protein is supplied as a glycosolated version, that's -- that's what you would have to -- that's what you have to work with to formulate it.

Q Okay. And do you know whether VEGF trap R1+R2, as shown in Figure 1 of Wulff on page 29 of your report, is a glycosolated protein or not?

MS. GREEN: Objection. Form.

A No. I don't -- I have not come across that, that it was.

Q Do you know whether the host cell system used to express a recombinant protein can have the impact on the glycosolation pattern for the protein?

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A It might. It might have.

Q And is there any general guidance in terms of the impact the host cell might have on glycosolation for a given protein?

MS. GREEN: Objection. Form.

A No. I don't -- I don't have an opinion on that.

Q If we can go to paragraph 59 in your report?

A Okay.

Q The second sentence of this paragraph states that: One such reference was Holash, in which Regeneron explained aflibercept demonstrates prolonged in vivo pharmacokinetics and pharmacodynamics, lacks nonspecific toxicities, and can effectively suppress the growth and vascularization in a number of different tumors -- or a number of different types of tumors in vivo.

Correct?

A Yes.

Q And I notice that, in your report, aflibercept isn't within the quotation marks from Holash lab, fair?

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A I -- oh, within the quotation marks.

It's not within the -- of direct quote, is that what you're saying?

Q That's correct.

A Right. But as I mentioned before, there was a lot of evidence, to me, that it was aflibercept based on, you know, the sequences revealed, et cetera.

Q Holash itself doesn't refer to aflibercept by name, does it?

MS. GREEN: Objection. Form.

A I don't -- I don't believe it does, but it does identify VEGF trap R1+R2, which is the name for aflibercept.

Q I understand that's your opinion.

Holaah, the reference itself, that's referenced in paragraph 59 of your report, doesn't use the term "aflibercept" in there, does it?

A I don't believe so.

Q If we can go to paragraph 62?

This is also talking about Holash, correct?

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A Yes.

Q And we, again, see some quotes throughout the paragraph, which goes onto page 24 of Exhibit 1002.

Do you see that.

A There is some quotes regarding VEGF trap R1+R2; is that what you mean?

Q That's correct.

A Okay. Yes.

Q And then, again, going back to my question about language in brackets, in some quotations after VEGF, dash, trap R1+R2, in brackets the word "aflibercept" has been added.

Do you see that?

A Yes.

Q And then in the last sentence of the paragraph, in the quote, after VEGF trap, in brackets, again, the word "aflibercept" has been added, right?

A I just see VEGF trap R1+R2.

It's just VEGF trap?

Q Yes. The last sentence in paragraph 62.

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A Yes.

Q It just refers to VEGF trap, VEGF trap R1+R2, but there's still a bracketed aflibercept following it, right?

MS. GREEN: Objection. Form.

A Yes. Yes.

Q Okay. And the significance of the brackets is that the word "aflibercept" doesn't actually appear in the quote, correct?

MS. GREEN: Objection. Form.

A Yes. Most likely that it means that. But if you take that out of context with the rest of my opinion, I was just providing the reader with my opinion that this was aflibercept based on what I have indicated already.

Q Again, I understand that is your opinion.

But here you don't actually say that aflibercept doesn't appear in the quote; you just put it in brackets within the quotation marks, right?

MS. GREEN: Objection. Form.

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Objection. Relevance.

A I think that indicates what my opinion is. I don't -- I don't see -- I am not sure what your question is.

Q I guess my question is why did you feel it was important to quote Holash but then add aflibercept in brackets to the quotations you identified?

A Because my opinion is that what Holash was talking about was aflibercept, and I put it in brackets. I certainly wouldn't want to indicate a direct quote or words, whatever.

Q Okay. And Holash is part of the combination you used for anticipation?

MS. GREEN: Objection. Form.

Objection. Misstates.

A It was part of the references that I used, but anticipation was -- I was, obviously, only talking about Fraser and his -- his comments on the molecule and his cite -- basically citing Holash.

Q Okay. And so you did rely on Holash to the extent Fraser cited to it?

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MS. GREEN: Objection. Misstates.

A Holash was one in a series of publications by Regeneron that supported what I said and showed that VEGF trap R1+R2 was what was being discussed.

Q Okay. And you relied on that entire series of Regeneron publications for the purposes of your opinions in this report, right?

MS. GREEN: Objection. Misstates.

A I relied on the entire series that are in my report, noting that, as time went on, let's say, or something, the protein was identified as VEGF trap R1+R2.

Q What is your understanding, if any, of when it's appropriate to rely on post-priority, meaning post-2006, materials as part of your anticipation or obviousness analysis?

MS. GREEN: Objection. Form.

A My opinion is, if a property has demonstrated post-prior art, that it existed before -- an inherent property existed before the prior art date.

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Q Does it matter, for anticipation purposes, whether the alleged inherent property was expected?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A All I can comment on is that the properties that I mentioned were inherent to the formulation. I -- I don't see any other thing I can comment on.

Q Okay. And so for obviousness purposes, does it matter, for your analysis, whether the inherent property that you have identified was expected by a POSA or is that insignificant?

MS. GREEN: Objection. Form. Objection. Calls for a legal conclusion.

A If something was taught in the prior art, it was -- it was obvious. The other factors surrounding it, I am -- you know, I'm not -- I'm not sure from a legal standpoint.

Q If we can turn to paragraphs 84

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through 87 of your report -- or actually, I'm sorry -- 82 through 87 of your report?

It spans pages 37 through 39 of this Exhibit 1002.

A Which paragraph?

Q Eighty-two through 87.

A Okay.

Q And my understanding of these paragraphs is that it's providing the stability data in the prior art for various formulations; is that fair?

A Yes.

Q And in each of the instances reflected in paragraphs 82 through 87, it's talking about antibodies, not Fusion proteins, right?

A I think there were -- I think Kaisheva is a -- is an antibody.

(Whereupon, the court reporter requested clarification.)

THE WITNESS: Kaisheva is an antibody.

Q Why don't -- so Kaisheva is paragraph 83.

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Why don't we start with 82, which refers to W0801?

And I can give you the exhibit, if you need. It's 1030.

But my understanding is that that is a humanized antibody protein formulation for trastuzumab?

A Yes. Okay.

Q And then paragraph 83, Kaisheva 316 is also about antibody formulations?

A It's about antibodies, yes.

Q What about paragraph 85, which refers to the Liu reference, Exhibit 1026?

A Yes.

Q Paragraph 86 is Kaisheva 417. It's also antibody formulations, this time, daclizumab antibody that we talked about earlier, right?

A Yes.

Q And then finally paragraph 87 is referring to a '586 Patent, Exhibit 1018, that also reports an antibody formulation having certain stability characteristics,

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right?

A Yes.

Q And each of these references referred to in paragraphs 82 through 87, they all have different formulations -- right? -- in addition to different antibodies?

MS. GREEN: Objection. Form.

A Some of them have difficult formulations, yes.

Q Do any of them have the same formulation?

A I don't -- I don't recall.

Q Okay. Did you do any comparison between the formulations for the antibodies in paragraphs 82 through 87 of your report and the formulations for the fusion protein in Fraser?

A That wasn't the -- I think the point of this was that a greater than 98 percent native confirmation is something -- a routine target in proteins and in monoclonal antibodies and in any pharmaceutical.

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Q Right. But with respect to that last point, about any pharmaceutical, you didn't cite any references for any pharmaceuticals other than monoclonal antibody formulations, right?

MS. GREEN: Objection. Form.

A I didn't cite any references to -- yes, I cited references to monoclonal antibodies.

Q And I understand your view as to the purpose of these paragraphs, but my question was just from a factual standpoint.

It doesn't look to me like anywhere in your report you went through the formulations reported in each of these references in paragraphs 82 through 87 of your report and compared those to the formulation reported in the Fraser reference; is that fair?

A That's fair, but that was irrelevant to my point.

Q The formulations reported in the prior art are irrelevant to your point?

A The formulations for the point I'm

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making here is about 98 percent. And most of them would have -- while I didn't do that, it's very common to have a buffer. And if you can see, some of them have buffers, have Tweens, and it wasn't relative. The relative point -- it wasn't relevant to the point I'm trying to make --

Q The --

A -- than even sucrose -- right? -- in some examples.

Q Right. And so the specifics of the formulation used in 82 through 87 included in your expert report wasn't relevant to your opinions about Fraser?

MS. GREEN: Objection. Form.

Objection. Asked and answered.

A To the 98 percent indicated in one of the claims.

Q Well, if you change the formulation of these, that might change the percent monitored observed over time, right?

MS. GREEN: Objection. Form.

A I mean, again, I've asked -- I've answered your question why they're here.

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They're examples of monoclonal antibodies, which are, I will say, structurally similar. I agree there are differences, but they're proteins and -- for pharmaceutical use, and 98 percent is not a -- an unheard-of potency or assay or however you want to put it. In this particular patent, they want to -- they call it "native confirmation."

Q But you agree with me -- and my question was actually about the formulations and whether varying any of the formulations here could potentially change the percent monomer observed.

Do you have an opinion on that?

A Well, I think it's the percent monomer of -- which -- are you specifically talking about --

Q So --

A -- something?

Q Sure. Paragraph 84. You've mentioned 98 percent several times. Paragraph 84, you talk about all three formulations contained above 98 percent monitor -- monomer as measure by SEC?

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A Okay.

Q Were you referring to something else when you were talking about 98 percent?

MS. GREEN: Objection. Form.

A No. I was -- I was talking about a 98 percent monomer -- monomer, because the inventors in '992 chose that as a indication of native confirmation when, in reality, it isn't. So what I was -- I just show that in terms of aggregation.

Q And, in fact, above paragraph 84, there is a table from Kaisheva talking about percent monomer as well, right?

A Paragraph 84?

Q Page 38.

A Percent monomer, yes.

Q And so my question is, if you change the formulations that are showed above that table on page 38 of your report, you expect to get different percentage monomer values after a month or after three months, right?

MS. GREEN: Objection. Form.

A That would be detected in routine

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testing, basically, the components that you see and their functions. So you would -- you would -- you would know that.

Q Right. And there could be changes.

You wouldn't expect the percent monomer to be the same if you varied the formula, would you?

MS. GREEN: Objection. Form.

A It depends how much you vary the formulation.

Q And you would need to do the stability testing to find out?

MS. GREEN: Objection. Form.

A This is called "preformulation testing," so it's different than stability testing that you would use to support the product. It's short-term experiments to see if your selected concentrations are -- are acceptable.

Q Okay. But I guess I'm -- maybe I'm not asking the question precisely. If I change the formulation shown on page 38 -- let's focus on Formulation 1.

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You see that, paragraph 113 from Kaisheva 316?

A Yes.

Q If I change that formulation, let's say I increase the sucrose, took out the Tween, that might impact the percent monomer I see over time, right?

MS. GREEN: Objection. Form.

A The word is "might." There are critical concentrations. It depends on how you ran the experiment. There is something called critical micelle concentration, above which you may not see changes. Buffers, you may not see changes depending upon concentration. So I think it depends on -- actually, it depends on the experiment. It's -- you couldn't make a blanket statement that you would definitely see changes in preformulation. You may not.

Q Right. And it might depend on the protein, too, right?

MS. GREEN: Objection. Form.

A It will depend on -- what -- if see -- as I mentioned earlier, the reactive

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groups, let's call them, they could -- they might -- you might see that you would predict -- you could perhaps see -- a -- differences, if it was with or without a certain amino acid. I mean, that's -- I think I -- well, I mean, that's true.

Q Okay.

MR. BRAUSA: I might suggest we take a short break. I think I'm nearing the end of my questions. I just need to clean up my notes, and we can come back.

MS. GREEN: Okay. How long do you need?

VIDEOGRAPHER: The time on the video monitor is 5:56 p.m. We're off the record. This ends Video 5.

(Whereupon, at 5:56 p.m., a recess was taken to 6:15 p.m.)

(The proceeding resumed with all parties present.)

VIDEOGRAPHER: We're back on the record. The time on the video monitor is 6:15 p.m. This is the Media 6.

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Q All right. Welcome back, Dr. Tarantino.

During the break, did you chat with counsel at all?

A No.

Q If I could direct you to page 45 of Exhibit 1002, your report, and Footnote 5, please?

And here you say that: In your experience, once a protein biologic, like aflibercept, has entered human clinical trials, a manufacturer does not make substantial chains to the method of manufacture, e.g., switching to an entirely new cell culture to express the protein.

Correct?

A Yes.

Q And do you stand by that statement today?

A Yes, I do.

Q I think we established Fraser doesn't explicitly refer to aflibercept, correct?

MS. GREEN: Objection. Form.

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A He doesn't use the word "aflibercept."

Q And Holash doesn't use the word "aflibercept"?

A I don't -- I don't believe so.

Q And Wulff doesn't use the word "aflibercept"?

A I don't believe Wulff uses the word also, but, as I explained, it was aflibercept.

Q And the '319 publication doesn't use the word "aflibercept"?

A The same is true for '319.

Q Okay. And the '309 publication, which you mentioned, doesn't use the word "aflibercept"?

A I don't believe it does, no.

Q Okay. And do any of those references relate to or describe human clinical trials?

A Yes, the term "clinical trials" is used. I think Fraser might use it or Holash, but I do note the clinical trials -- I can find it, if you like -- were revealed,

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if that's the correct word, by Regeneron as early as 2002.

Q Okay. Frasier's article is about some testing of VEGF trap in monkeys, right?

MS. GREEN: Objection. Form.

A I believe Fraser -- you gave me Fraser, didn't you?

Yes.

Q Yes. I think it's Exhibit 1009, if you can find it in your stack?

A Fraser refers to VEGF trap R1+R2, and it was, I believe, in marmosets, but it was a primate species.

Q Okay. And title refers to -- and I may mispronounce this -- macaque?

A Yeah. It's macaque usually.

Q Okay. Those are monkeys -- right? -- primates?

A Yes. I believe they are actually monkeys.

Q Okay. And so this isn't referring to any results in humans, correct?

MS. GREEN: Objection. Form.

A Frasier's -- yeah. I don't --

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Frasier's studies was in marmosets, yes --

Q If I can direct your attention --

A -- or macaques so...

Q Say that again?

A I'm sorry. The title is Macaque, and he uses the term "marmoset" but that's a -- they're both primates.

Q Okay. If I could direct you to page 48 of your report, Footnote 6?

Do you see that?

A Yes.

Q And here you're acknowledging that the Dix's formulation, which is a post-priority date formulation, is VGT-FS405, whereas the lot number for the Fraser formulation that you rely on as prior art is different, it's VETF01001T, right?

MS. GREEN: Objection. Form.

A It's -- that -- that is what I have indicated in -- in the footnote, but it's the formulation that Regeneron did claim was used in Fraser.

Q My question is just about the footnote.

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Fraser and Dix formulations had different lot numbers, right?

A They may have different -- that may have different lot numbers. Yeah.

Q Well, they -- it's not "they may have"; they do, right?

A So they --

Q That's what you're saying --

A They have different --

Q -- in Footnote 6.

A -- lot numbers, but that's irrelevant. The composition is the same. You could have different lot numbers.

Q The second sentence in Footnote 6 is where you state that: The formulations are described as being part of the same project VEGF-SS017, right?

A Yes.

Q Did you do any investigation as to whether there were lot numbers with different formulations used in project VEGF-SS017?

MS. GREEN: Objection. Form. Objection. Relevance.

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A I would need the Dix -- the Dix reference to answer that. But I'm sorry.

What was your question again?

Maybe it's simple; maybe it isn't.

Q Do you know whether there were any lots with different formulations used as part of VEGF-SS017 project?

A I would have to confirm that that's what Dix used as the -- as the project number.

Q Okay. And do you know how many lots were part or were produced as part of VEGF-SS017 project?

MS. GREEN: Objection. Form. Objection. Relevance.

A No. I would really need the -- one of my references to answer this for you.

Q Okay.

MR. BRAUSA: I think that's all I have. Thank you very much for your time, Dr. Tarantino.

MS. GREEN: We have one redirect question.

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BY MS. GREEN:

Q Dr. Tarantino, can you please turn to page 11 of your declaration?

And from paragraphs 27 to 31, you discuss what you understand anticipation to be; isn't that correct?

A Yes.

MR. BRAUSA: Objection. Leading. And this is kind of awkward. You have got to give me time to objection, now, Dr. Tarantino.

Q Did you use these -- this guidance that is set forth in your -- in your declaration in forming your opinions?

MR BRAUSA: Objection. Leading.

A Yes, I did.

Q So at paragraphs 32 to 37 is titled "obviousness," correct?

A Yes.

Q And what do you discuss here in these paragraphs 32 to 37?

A We -- I discuss what it requires for a patent claim to be obvious.

Q And did you use this guidance in

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formulating your opinion?

MR BRAUSA: Objection. Leading?

A Yes, I did.

Q Okay.

MS. GREEN: Thank you. We have no more redirect.

MR BRAUSA: Just a brief recross.

BY MR. BRAUSA:

Q Paragraphs 27 through 37 of your report that you were just asked about, do you have those in front of you still?

A Paragraph 27?

Q Correct, through 37.

A I have paragraph 27, yes.

Q And paragraphs 27 through 37 of your report, who wrote those?

A I wrote those.

Q Okay. You wrote those on your own?

A No. I didn't write them on my own. Of course, they needed to be checked by counsel.

Q Okay. And if there are any errors in these legal standards, that's based on

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error and what you were instructed by counsel, correct?

A Unless there were, you know, other errors but, in general, that's correct.

Q Okay. And if there are omissions in these paragraphs about the legal standard for anticipation or obviousness, that's because you weren't informed of any material that is omitted by counsel?

MS. GREEN: Objection. Form.

A I'm sorry.

You said there's any errors?

Q Any omissions.

A Yeah, I may not, you know, pick that up by myself.

Q Okay. Do you recall whether you took out any paragraphs of these sections in your report?

A No, I don't recall.

MR. BRAUSA: Okay. Thank you.

MS. GREEN: Thank you. We have just one quick thing. We noticed -- or actually, I shouldn't say "we noticed." Dr. Tarantino noticed, as we were going

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through his declaration, a couple of errors. We can just -- it's just a basic -- a typo. We can either tell you what they are here or we can ask the board if we can submit a corrected declaration. But they're really very minor.

MR. BRAUSA: Why don't we go ahead and do it now so, if I have any questions about the corrections, I can ask him.

MS. GREEN: Okay. Let me just make sure I've got the right page. It's at paragraph 92 and 98 of the declaration. And, if you want, I can let Dr. Tarantino talk about this, but it's mostly -- I don't remember if he remembered the paragraph number.

So in paragraph 92 in the penultimate line, it says: Higher than 99 millimolar sodium chloride, that's the formulation used in Fraser. Fraser used a 100 millimolar. So it really is a typo.

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MR. BRAUSA: Okay.

MS. GREEN: And it's the same thing at paragraph 98, the last line on page 46.

That's it.

MR BRAUSA: That's it?

MS. GREEN: That's it.

MR. BRAUSA: All right. No further questions.

MS. GREEN: Thank you.

VIDEOGRAPHER: We're going off the record at 6:29 p.m. This concludes today's testimony given by Dr. Ralph Tarantino. The total number of video units used was six and will be retained by Veritext Legal Solutions. Thank you. We are off the record.

(Concluded at 6:29 p.m.)

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CERTIFICATE

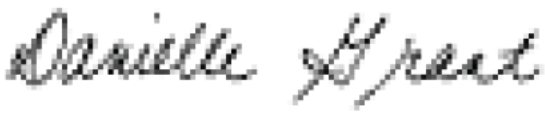
STATE OF NEW YORK)
)ss:
COUNTY OF RICHMOND)

I, DANIELLE GRANT, a Certified Shorthand Reporter and Notary Public within and for the State of New York, do hereby certify:

the above statement hereinbefore set forth, is a true record of the proceedings.

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 17th day of October, 2023.



DANIELLE GRANT

CELLTRION EXHIBIT - 1048
Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.

ADAM R. BRAUSA, ESQ.

abrausa@mofo.com

October 17, 2023

RE: CELLTRION V. REGENERON PHARMACEUTICALS

OCTOBER 13, 2023, DR. RALPH TARANTINO, JOB NO. 6139587

The above-referenced transcript has been completed by Veritext Legal Solutions and review of the transcript is being handled as follows:

__ Per CA State Code (CCP 2025.520 (a)-(e)) – Contact Veritext to schedule a time to review the original transcript at a Veritext office.

__ Per CA State Code (CCP 2025.520 (a)-(e)) – Locked .PDF Transcript - The witness should review the transcript and make any necessary corrections on the errata pages included below, notating the page and line number of the corrections. The witness should then sign and date the errata and penalty of perjury pages and return the completed pages to all appearing counsel within the period of time determined at the deposition or provided by the Code of Civil Procedure.

__ Waiving the CA Code of Civil Procedure per Stipulation of Counsel - Original transcript to be released for signature as determined at the deposition.

__ Signature Waived – Reading & Signature was waived at the time of the deposition.

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__ Federal R&S Requested (FRCP 30(e)(1)(B)) – Locked .PDF Transcript - The witness should review the transcript and make any necessary corrections on the errata pages included below, notating the page and line number of the corrections. The witness should then sign and date the errata and penalty of perjury pages and return the completed pages to all appearing counsel within the period of time determined at the deposition or provided by the Federal Rules.

_X_ Federal R&S Not Requested - Reading & Signature was not requested before the completion of the deposition.

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CELLTRION V. REGENERON PHARMACEUTICALS

DR. RALPH TARANTINO (#6139587)

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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VERITEXT LEGAL SOLUTIONS

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