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

FORTE BIOSCIENCES, INC.,	§	
	§	CASE NO.:
Petitioner,	§	
	§	PGR2023-00014
Vs.	§	
	§	Patent No.
UNIVERSITY OF MASSACHUSETTS,	§	
	§	11,278,505
Patent Owner.	§	

****

ORAL DEPOSITION OF

DR. R. TODD PLOTT

23rd day of February, 2024

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ORAL DEPOSITION OF DR. R. TODD PLOTT, produced as a witness at the instance of the Patent Owner, and duly sworn, was taken in the above-styled and numbered cause on the 23rd day of February, 2024, from 8:59 a.m. to 5:03 p.m., before Daniel J. Skur, Notary Public and Certified Shorthand Reporter in and for the State of Texas, reported by stenographic means, at The Westin Dallas Southlake, 1200 East State Highway 114, Southlake, Texas, pursuant to the Federal Rules of Civil Procedure.
Job No. 6442446

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DR. R. TODD PLOTT
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DEPOSITION EXHIBITS
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P R O C E E D I N G S

DR. R. TODD PLOTT,

having been duly cautioned and sworn to tell the truth, the whole truth and nothing but the truth, testified as follows:

(8:59 a.m.)

EXAMINATION

BY MR. FELDSTEIN:

Q. Nice to see you again, Doctor.

A. Good morning.

Q. Mark Feldstein, again, for the patentor here. I confirmed with you before we started that you have a binder that contains all the exhibits that are cited in your declaration; that's correct?

A. I do.

Q. Including your -- I should clarify, your Reply Declaration, Exhibit 1047?

(Exhibit 1047 introduced.)

A. That's correct.

Q. Okay. And the exhibits that go to that Reply Declaration?

A. That's correct.

Q. Correct. And you said they're all unmarked copies?

A. Yes.

Q. Okay. And do you have anything else with you besides those materials? I see some stuff on the left-hand side.

A. There's some of my references that were not included in a tab, and they were just stuck to the side.

Q. Those are cited in the --

A. They are. It's just --

THE WITNESS: I'm sorry. We're talking over each other.

THE REPORTER: Thank you.

A. This is Xing.

BY MR. FELDSTEIN:

Q. You can just tell me the exhibit number.

A. I'm not sure.

Q. In the bottom right corner should be the exhibit number.

A. Oh, I see. 1007.

Q. Thank you.

And the other one?

A. And the other is 1008.

Q. And who is the author?

A. Harris.

Q. Okay. Can you turn in your Reply Declaration, Exhibit 1047, I just want to start

pretty much at the beginning, Paragraph 13?

You see in Paragraph 13: From my perspective as a medical practitioner who treats vitiligo.

What do you mean from your "perspective as a medical practitioner"?

A. As a medical doctor, as a individual who sees patients with vitiligo.

Q. And what is the perspective of a medical doctor with respect to the subject matter of the '505 patent?

MR. MILLS: Objection, form.

A. The subject is treating vitiligo, and that's a very important condition for patients. It's very disturbing for a lot of different reasons, but, you know, most -- most of it is impactful on their daily life.

BY MR. FELDSTEIN:

Q. Maybe I'm not asking this well, but if you look further down in Paragraph 13, you were referring to the level of skill of a person of ordinary skill in the art, correct?

A. Yes, that's correct.

Q. And you say that that person would have worked together with a team, with other qualified

individuals with expertise in medicine, immunology, molecular biology, cell biology, microbiology, pathology, biochemistry, peptide chemistry, or related fields.

And my question, what I'm trying to get at is: What is the distinct perspective, if any, of the medical practitioner relative to those other areas of expertise?

MR. MILLS: Objection to form.

A. I believe that a medical practitioner, as my reply says, would have worked together with a team with other qualified individuals with expertise in medicine, immunology, microbiology, cell biology, microbiology, pathology, biochemistry, peptide chemistry, or related fields.

In my particular case, my background is in pharmaceutical drug development, and I've had experience in working with all of these types of specialty fields. As well as today, I practice medicine and see patients and am involved in development of drugs as a consultant and work with these teams today.

BY MR. FELDSTEIN:

Q. So do you have expertise in peptide chemistry, or do you work with people who have

expertise in peptide chemistry?

A. I would only work with people who have expertise in peptide chemistry. I do not have that expertise.

Q. And what expertise does a peptide chemist have that is different from yours as a medical practitioner?

MR. MILLS: Objection to form.

A. A peptide chemist would be probably an individual with a chemistry degree, possibly a Ph.D., and would not be a medical doctor.

BY MR. FELDSTEIN:

Q. And what would you rely on a peptide chemist for in the role that you described?

What type of information would they provide that you wouldn't have otherwise?

MR. MILLS: Objection to form.

A. Well, one of the things that they might provide is insight into molecular structures as it might deal with medications or antibodies or peptides.

BY MR. FELDSTEIN:

Q. So the structure and function of peptides such as antibodies?

MR. MILLS: Objection, form.

A. Relative to peptides. I don't -- no, not antibodies, to peptides.

BY MR. FELDSTEIN:

Q. So the structure and function of antibodies is what the peptide chemist would provide beyond your perspective as a medical practitioner?

MR. MILLS: Objection to form.

A. No. I misspoke when I said antibodies. I meant to say peptides.

BY MR. FELDSTEIN:

Q. Sure. And I corrected it in the second question. The question that I re-asked was: A peptide chemist would provide structure -- or maybe I didn't correct it. I apologize. Let me start again.

A peptide chemist would provide structure function information for peptides beyond your perspective as a medical practitioner; is that correct?

MR. MILLS: Objection to form. Incomplete hypothetical.

A. So certainly they could provide some instruction beyond my expertise.

BY MR. FELDSTEIN:

Q. And are you an expert in biochemistry?

MR. MILLS: Objection to form.

A. No, I'm not.

BY MR. FELDSTEIN:

Q. And what would you rely on on a biochemistry expert to supplement your perspective as a medical practitioner?

MR. MILLS: Objection to form, incomplete hypothetical.

A. Well, in working as part of a team, I think that the biochemist may be able to help with cell lines and development of -- and testing of a biochemical product.

BY MR. FELDSTEIN:

Q. Sorry, testing of what?

A. Of a biochemical product, just to name a few things that they might do.

Q. And what do you mean, they would help with cell lines?

A. Well, in this -- in these documents, there are specific cell lines that are referred to, and some of those are grown in culture, some of them are characterized by proliferation assays or inhibition assays, and they would have expertise in that --

Q. The expertise --
A. -- to name one thing, anyway.
Q. They would have expertise in growing the cell lines?
A. They -- to name one thing, yes.
Q. They would have had expertise in testing the cell lines?
A. Yes, that's correct.
Q. And that would be expertise beyond your expertise as a medical practitioner, correct?
MR. MILLS: Objection to form, incomplete hypothetical.
A. Yes, they would have expertise in that area that I don't possess.
BY MR. FELDSTEIN:
Q. And would they have additional expertise beyond yours with respect to the molecular biology of the different cell lines?
A. Could you ask that again? I'm sorry.
Q. Would -- well, let me make it broader. I'm going to ask a different question first.
You also refer to working with people with expertise in molecular biology, cell biology, microbiology, correct?
A. That's correct.

Q. If we sum all those people together -- the molecular biologist, the cell biologist, the microbiologist, and the biochemist -- would they have expertise in the molecular biology of cell lines beyond yours as a medical practitioner?

MR. MILLS: Objection to form.

A. Well, I think it's pretty clear what we're talking about in my -- in this paragraph. This is a -- this says: Other qualified individuals, and that would be possibly a team, as it states in there.

And so individuals that have these variety of expertise would be individuals that a POSA would have interaction with. So each one of them, because they're a team, have special knowledge in their own individual areas. These are descriptions of those areas that an individual POSA would -- would work with and -- you know, and these individuals.

BY MR. FELDSTEIN:

Q. Okay. And maybe I need to ask a different question first. You list a series of individuals with expertise in a variety of topics, correct?

A. Yes, that's correct.

Q. And I trust you have expertise in medicine?
A. Yes, I do.
Q. Are you an expert in immunology?
A. No, I'm not an expert in immunology.
Q. Are you an expert in microbiology?
A. No, I'm not.
Q. Are you an expert in cell biology?
A. No, I'm not.
Q. Are you an expert in microbiology?
A. No, I'm not.
Q. Are you an expert in molecular biology?
A. No, I'm not.
Q. Are you an expert in pathology?
A. No, I'm not.
Q. Are you an expert in biochemistry?
A. No, I'm not.
Q. Are you an expert in peptide chemistry?
A. No, I'm not.
Q. Okay.
A. But I will follow on that I've had experience and training in those through my training in medical school that covers each of those areas, but when we're talking about something that is so specific as this, that's not what I do

every day. So I would want to work with a team of people that have those expertise.

Q. So what additional information would an immunologist have beyond what you already have from your perspective as a medical practitioner?

MR. MILLS: Objection to form, incomplete hypothetical.

A. Possibly one of the pieces of information they may have that I don't have is, you know, a very in-depth understanding of the complex nature of the, you know, inner workings of the cells and...

Q. Anything else an immunologist would have information on that you wouldn't have -- you don't have as a medical practitioner?

MR. MILLS: Objection to form, incomplete hypothetical.

A. Well, off the top -- the top of my head, that's the one that comes to mind.

BY MR. FELDSTEIN:

Q. Would an immunologist have additional expertise with respect to cytokines as compared to your perspective as a medical practitioner?

MR. MILLS: Objection, form.

A. They may have additional training in

cytokines; I also have training in cytokines. It's not -- a se- -- cytokines are not a secret, but they may have additional insights that I don't.

BY MR. FELDSTEIN:

Q. And what about with respect to cytokine signaling pathways, would the immunologist have more expertise and information than you as a medical practitioner?

A. Well, if -- the med- -- the medical information that's available to them is also available to me, and I can read that and understand that just like any of these team members, understanding that what we're talking about is a -- a group of individuals that have additional expertise that is a -- a bit more focused on these particular areas, as opposed to my expertise that's -- which is in dermatology.

Q. So with that explanation in mind, would the immunologist have additional expertise in cytokine signaling pathways beyond your expertise as a dermatologist?

MR. MILLS: Objection to form, incomplete hypothetical.

A. Like I said, I -- I -- I think if we're focused on a particular pathway, an individual

pathway, I can read and study and understand that just as well as the immunologist.

BY MR. FELDSTEIN:

Q. And how much --

A. So they may -- they may have a -- a broader knowledge about all pathways, but when we're talking about this particular pathway that we're here to discuss today, I -- I -- I feel expert in that.

Q. So you feel you know all there is to know compared to an immu- -- immunologist on IL-15 signaling pathway?

MR. MILLS: Objection to form.

A. Well, like I said, I have special training that -- that qualifies me as an expert in some of these fields. I don't know if I'd score higher on the immunology test than they did, but, you know, give it a try.

BY MR. FELDSTEIN:

Q. The question is you feel you know all there is to know on the IL-15 and signaling pathway as compared to an immunologist; is that correct?

MR. MILLS: Objection to form, incomplete hypothetical.

A. I -- I think you're asking me to -- to

answer a -- a -- a question that's -- that -- it is hypothetical, and I'll answer it in that, you know, I have -- I have special training in immunology. I've done a -- a fellowship in dermato-immunology and would feel qualified to say that I'm expertise in - in this area.

BY MR. FELDSTEIN:

Q. And so you have as much expertise in immunology of IL-15 signaling pathway as the expert immunologist that you refer to in Paragraph 13?

MR. MILLS: Objection, form.

A. No, like I said, this would be a -- a team effort, and we'd be looking for people with different points of view.

BY MR. FELDSTEIN:

Q. Right. But could you answer the question? Do you need it read back?

A. Well, I think your question is hypothetical, and I can't tell whether this imaginary person would have the same experience or more or less experience that -- than mine. I would tell you I'm quite confident in immunology, and I would -- I'd be very comfortable talking to them about their specialty.

Q. And I'm not sure what -- the thing is

hypothetical. I -- I'm referring to the immunologist that you refer to in Paragraph 13. Do you understand that? I'm not making up a separate immunologist.

A. Right.

Q. Okay. And so the question is, in your opinion, do you have as much expertise in immunology of the IL-15 signaling pathway as the expert immunologist that you refer to in Paragraph 13 of your declaration, Exhibit 1047.

MR. MILLS: Objection, form.

A. The -- I think the answer is yes, I would feel like I have -- have as much immunology experience with IL-15 as -- as the immunologist that I'm referring to in this -- in this location.

BY MR. FELDSTEIN:

Q. And if we can continue the same admittedly tedious task of going through this sentence, if I group together the molecular biologist, the cell biologist, microbiologist, what, if any, expertise do they have beyond yours as a medical practitioner who treats vitiligo?

MR. MILLS: Objection, form.

A. Well, one of the things that they're going to have that -- that I don't have is probably

an advanced degree, a Ph.D. in these specific areas. That gives them a much broader knowledge than the knowledge I've gained in -- in medical school and dermatology fellowship at the National Institutes of Health.

BY MR. FELDSTEIN:

Q. And a broader knowledge in what?

A. In their specific area of expertise.

Q. The next expert is a pathologist, correct, in the list?

A. Right.

Q. What's a pathologist?

A. This is someone that looks at the disease, in this case, in the skin or the hair follicles. A clinical pathologist might look at blood work, might be looking at tissues from -- from -- from people that come from surgery or biopsies to look at disease.

Q. The last identified expertise we talked about already was peptide chemistry, correct?

A. Yes.

Q. Why would the POSA work together with a peptide chemist?

A. Well, peptides are included in the patent and mentioned in the patent. So a POSA

would -- would work with that individual to address that particular part of the -- the questions that we're here to talk about.

Q. And why would a POSA work with an immunologist?

A. I -- I -- I think I answered that question above.

Q. Okay. Ask the question. The question is why would a POSA work with an immunologist?

A. Well, one reason they might work with an immunologist is that they -- they have a laboratory and experience that is where they are in the laboratory able to do experiments or do procedures to answer questions, as opposed to the POSA who's -- may be a medical practitioner in the clinic seeing patients.

Q. Would a POSA work together with someone having expertise in antibody structure function properties?

MR. MILLS: Objection, form.

A. The -- they might.

BY MR. FELDSTEIN:

Q. And is that in one of the named categories, or is that in the catchall-related field category in Paragraph 13?

A. I think it would be under the category of immunology.

Q. And do -- you had referred to your immunology training. Do you have expertise in antibody structure function properties?

MR. MILLS: Objection, form.

A. That's a broad question. I had a fellowship at the National Institutes of Health, and we studied a condition called pemphigus vulgaris that involves an antibody, so I have specific training in what antibodies do and how they bind. I do not have particular expertise on how to construct them from a building block standpoint, for example.

So I have certain expertise, and that's why an immunologist might have other expertise or a cell biologist, a molecular biologist. And that's why there would be a -- a need for a team approach.

BY MR. FELDSTEIN:

Q. The fellowship you referred to, you've referred to "fellowship" more -- more than once. Was it just one fellowship that you referred to?

A. That's correct.

Q. And when was that, about?

A. About 1992 to about '94. I'd refer you

to my curriculum vitae for exact years.

Q. You're looking at Exhibit 2005?

A. Right. It's Exhibit 2005.

(Exhibit 1005 introduced.)

Q. 1005?

A. 1005. On the first page at the bottom of the page, that's July of '92 to November of '93.

Q. And did you have any advanced research or training in immunology after that fellowship?

A. I did not.

Q. Okay. Now, in Paragraph 13, you identify yourself as a medical practitioner who treats vitiligo, correct?

A. That's correct.

Q. In your professional work, you don't advertise yourself as having any specialty or experience in treating vitiligo; is that correct?

MR. MILLS: Objection, form.

THE REPORTER: You might have to repeat that question for me.

BY MR. FELDSTEIN:

Q. In your professional work, you don't advertise yourself as having any specialized experience or focus in treating vitiligo, correct?

A. Well, as I sit here, I -- I don't

remember all of the advertisements that I've done or what everything has been said. If you look at my -- my curriculum vitae in 1005, you'll see that I have done research in vitiligo, and I was awarded first plash -- place in a national competition for that research as a -- as a resident. And vitiligo is one of the areas that, since my training in the early '90s, I've had -- has had a special place in my heart to -- to treat those patients. So when I -- I see those patients, I have always kept up with, you know, how to care for them in the -- in the most up-to-date best manner.

Q. And what specifically are you referring to in Exhibit 1005, in terms of your research and award?

A. On page 4 of my curriculum vitae, in the middle under: Honors and Awards. It's --

Q. Let me get there.

A. Okay.

Q. Okay.

A. It says: First place young investor -- investigator competition, journal of dermatologic surgery and oncology.

Q. And that was 1989?

A. That's correct.

Q. Have you been awarded any other awards with respect to vitiligo since 1989?

A. No, I have not.

Q. Okay. And then you -- you're referring to research on vitiligo; is that the same?

A. That's the award for the research.

Q. And is the research otherwise identified in Exhibit 1005?

A. If you'll look on page 8 under: Scientific Publications, Number 2: Repigmentation of vitiliginous skin by cultured cells pigment. And that's in pigment research.

Q. And that's 1989?

A. That's from '89. And also Number 4: A surgical treatment for vitiligo otologist cultured epithelial graphs.

Q. And that's from 1989?

A. That's from '89. That -- that -- those were the publications that let to that award.

Q. And then you have another publication, Number 5, on Modern Treatment Approaches for Vitiligo, correct?

A. Correct. It's a review article that did not involve research.

Q. And that's from 1990?

A. Correct.
Q. Has treatment of vitiligo changed between 1990 and 2017?
A. Not very much.
Q. Number 6, your interview on "Surgical Therapy of Vitiligo" in 1990, correct?
A. That's correct.
Q. Is that a scientific publication, in your view?
A. Well, this is an interview regarding my research, and it was published in a periodical, an audio periodical, a couple of dialogues in dermatology, which is --
Q. I'm sorry.
A. -- which is sort of the 1990s version of a podcast.
Q. And you consider that podcast-style interview to be a scientific publication of yours?
A. Yeah, I consider that, yes.
Q. Have you had any publications on vitiligo since 1990?
A. No, I have not.
Q. Have you conducted any research on vitiligo since the 1980s?
A. No, I have not.

Q. You were talking about whether you hold yourself out as having specialized training or focus on vitiligo and said you couldn't recall all possible advertisements.

Can you recall any advertisements where you've held yourself out as having special expertise or training or focus on vitiligo?

MR. MILLS: Objection to form.

A. Well, again, I don't remember everything, but I know that online, my profile includes inform- -- some of this information about my awards in vitiligo.

MR. FELDSTEIN: Can we mark Exhibit 2116 --

(Deposition Exhibit 2116 marked.)

BY MR. FELDSTEIN:

Q. -- which is from what I believe is your website.

Can you confirm this is from your dermatological practice's website, Doctor?

A. Yes, it is.

Q. And in the first paragraph, you -- it says that you have a special passion for treating patients suffering with acne, correct?

A. Yes, it says that.

Q. And that you have specialization and professional interests also include identifying solving complex skin conditions such as psoriasis, rosacea, atopic dermatitis as well as identifying and treating all types of skin cancer?

A. That's correct.

Q. And so this from your website doesn't identify you as having any specialized experience or focus on vitiligo, correct?

MR. MILLS: Objection to form.

A. One of the purposes for this document is to inform patients that might be considering consulting me on their skin conditions, and these are conditions that are very common and would be the conditions that were -- would be most likely to attract the largest number of patients, and they don't necessarily represent all of the areas that I would have expertise in.

BY MR. FELDSTEIN:

Q. Sure, but could you answer the question? The question was: This bio from your website doesn't identify you as having any specialized experience or focus on vitiligo, correct?

MR. MILLS: Objection to form.

A. This document doesn't mention my

interest in vitiligo.

BY MR. FELDSTEIN:

Q. You think there's another document on your website that does?

A. As I said, I don't remember everything that we've put on the website. I've been in practice for, you know, 15 years or so. There may be other documents.

Q. But do you think there are?

A. I know that there are other -- other documents. I had a practice that was separate from this practice prior to joining Epiphany, and I can't say whether or not there might be other documents for certain. I know that there are many other documents that I have out on the Internet about my background.

Q. And do you think that there are out there current documents identifying you as having any specialization or focus on vitiligo?

MR. MILLS: Objection, form.

A. As I sit here today, I don't know that there are certainly documents. I suspect that there are, but like I said, I had this experience. It was very pivotal in my career, and I often talk about that. So I wouldn't be surprised if I could

go back and find something --
BY MR. FELDSTEIN:
Q. Okay.
A. -- that mentioned vitiligo.
Q. Okay. You mentioned that -- or Exhibit 2116 mentions that your interests include psoriasis, correct?
A. That's correct.
Q. What is psoriasis?
A. Well, one of the ways -- one of the ways that we see psoriasis is a red patch that's scaly on the skin. It might be in particular distributions of elbows and knees, for example. It looks a certain way on the skin.
Is that what you are asking about?
Q. That's a fine answer.
Psoriasis is an autoimmune disease?
A. It -- it does involve the immune system.
Q. Do you treat any other autoimmune diseases besides psoriasis?
A. I treat atopic dermatitis, which is also an autoimmune condition.
Q. Any other autoimmune conditions that you treat?
A. We treated a condition called

hidradenitis suppurativa with...

Q. And that's an autoimmune disease?

A. That's an autoimmune disease.

Q. And what about alopecia areata; that's an autoimmune disease as well?

A. Yes, it is, and I treat that also.

Q. And vitiligo is an autoimmune disease?

A. Yes, it is.

Q. And you treat that?

A. I treat that as well.

Q. What do you use to treat psoriasis?

MR. MILLS: Objection, form.

A. We use many things, but one of the things that we use is agents that modify the immune system like Humira, which is an antibody, TNF alpha inhibitor. Just one of -- that's just one of many, many things.

BY MR. FELDSTEIN:

Q. Are there any other biologics that you use to treat psoriasis?

A. There's a very long list now.

Q. That you use?

A. That I use, yes.

Q. What besides Humira?

A. Would you like names of the drugs?

Q. Sure. The drug name, like the commercial name would be helpful.
A. Like Humira?
Q. Please.
A. One that we use quite a bit is Skyrizi.
Q. Okay. Is that also an antibody?
A. That's also an antibody.
We use a drug called Cimzia.
Q. Also an antibody?
A. Also an antibody.
Those are probably the primary ones that we use because those are the ones that insurance often covers, you know, but others are called Taltz.
Q. Is that an antibody?
A. It's an antibody.
Q. Any others?
A. There are others, but I'm -- I'm blanking on some of the names right now.
Q. Are these four, are they all anti-TNF alpha antibodies?
MR. MILLS: Objection to form, scope.
A. The -- the Humira and Cimzia are directed at anti-TNF. The others -- Skyrizi is directed at IL-17; and off the top of my head, I

don't remember what Taltz is directed at.
BY MR. FELDSTEIN:
Q. Do you have an understanding of how Skyrizi binds to IL-17; what specific epitope, for example?
MR. MILLS: Objection, form; outside the scope.
A. No, I've not looked into that.
BY MR. FELDSTEIN:
Q. Do you need that information to be able to use it, as a medical practitioner?
MR. MILLS: Objection, form; outside the scope.
A. No, I don't need that information.
BY MR. FELDSTEIN:
Q. And do you know where -- my boss thinks that Skyrizi is IL-23, not IL-17. Could that be correct?
A. It looks like he's got it up on his computer there. That could be.
Q. And if I rephrase the question that, do you know where specifically Skyrizi binds to IL-23, what epitope, for example?
A. I don't know.
Q. And you don't need to know that?

A. I don't need to know that.

MR. MILLS: My objections to the questions are outside the scope.

BY MR. FELDSTEIN:

Q. In terms of the two TNF alpha antibodies, do you know where -- what epitope, for example -- they bind to on TNF alpha?

MR. MILLS: Objection, outside the scope.

A. I don't know.

BY MR. FELDSTEIN:

Q. And you don't need to know?

A. I don't need --

MR. MILLS: Objection, outside the scope.

A. I do not need to know that.

BY MR. FELDSTEIN:

Q. And if you were given the structure of these antibodies, would you recognize the structure with the name?

MR. MILLS: Objection to form, outside the scope.

A. No, I would not.

BY MR. FELDSTEIN:

Q. And if you're given the amino acid

sequence, would you be able to identify what is the binding portion of the antibody?

MR. MILLS: Objection to form, outside the scope.

A. Yes, I could identify the binding portion of the antibody.

BY MR. FELDSTEIN:

Q. By looking at the amino acid sequence?

MR. MILLS: Objection, form, outside the scope.

A. No, not by looking at the amino acid sequence.

BY MR. FELDSTEIN:

Q. What do you use to treat vitiligo?

MR. MILLS: I'm going to object on the basis of scope. We've been going for about an hour, and most of your questions are not from his Rebuttal Declaration. You've deposed him once already, so the scope of the deposition is not anything having to do with the case. It's specifically with regard to the Rebuttal Declaration.

So if you don't have any questions about the Rebuttal Declaration, we can end the deposition.

BY MR. FELDSTEIN:

Q. Doctor, Paragraph 13 of your Rebuttal Declaration says you're a medical practitioner who treats vitiligo, correct?

A. It says that, yes.

Q. What do you use to treat vitiligo?

A. Most commonly, we use topical steroids to treat vitiligo because they're financially available to patients and most recently we've used a JAK inhibitor called Opzelura, which has been FDA-approved for vitiligo.

Q. That's topical Ruxolitinib?

A. Yes.

THE REPORTER: Say that again.

BY MR. FELDSTEIN:

Q. That's topical Ruxolitinib?

A. It's sometimes not available to patients for financial reasons.

Q. Do you use any other JAK inhibitors for treating vitiligo?

A. No, that's all that we use today.

Q. Are -- are you aware of any other JAK inhibitors that have been or can be used to treat vitiligo?

A. In medical practice, physicians are

allowed to use medications off label, and that's a possibility, but one that I've not availed myself of for a variety of reasons, possibly, but I've selected only to use Opzelura.

Q. Are you aware of any other specific JAK inhibitors that have been used off label to treat vitiligo?

A. I -- I am aware.

Q. Which ones?

A. There's one called Olumiant, which is also a JAK inhibitor for -- it's approved for alopecia areata.

Q. That's baricitinib?

A. Yes.

Q. Any others?

A. And -- and there's -- more recent one, Litfulo. I'm glad I don't have to spell all this, by the way.

Q. That's a Pfizer product?

A. That's correct, a Pfizer product. And it's also indicated for alopecia areata.

Q. Is there some common class effect among these JAK inhibitors that make them suitable for treating vitiligo?

MR. MILLS: Objection to form and scope.

A. Well, both of the products that we've talked about are JAK inhibitors. They're approved to treat alopecia areata. I'm not sure what you mean by "class effect."

BY MR. FELDSTEIN:

Q. There are three different JAK inhibitors that we've referred to, Ruxolitinib, baricitinib, and whatever Pfizer's Litfulo is, right?

A. Right.

Q. And they're all different small molecules; is that correct?

MR. MILLS: Objection to form. Objection to scope. And Dr. Plott's declaration is a Rebuttal Declaration. He's responding to Dr. Damsky's opinions, but this deposition seems to be not inquiring as to his rebuttal opinions.

BY MR. FELDSTEIN:

Q. They're all three different small molecules; is that correct?

MR. MILLS: Same objections.

A. Yes, they're small molecules.

BY MR. FELDSTEIN:

Q. And they're three different ones, correct?

MR. MILLS: Objection, outside the

scope.

A. They are, but I -- I'd like to answer questions that you have about my Rebuttal Declaration. Is -- is there a question about those molecules --

BY MR. FELDSTEIN:

Q. Yeah. And the question --

A. -- in -- in my -- for my declaration?

Q. The question -- you address JAK in your declaration, correct, the use of JAK inhibitors in your declaration, correct?

MR. MILLS: Objection, form.

BY MR. FELDSTEIN:

Q. Do you recall that?

A. Are you thinking about a particular place in my declaration?

Q. I'm just going to -- okay. Show -- Paragraph 65, for example, you're discussing JAK inhibitors such as tofacitinib?

A. What was the question?

Q. So let's just confirm. You address JAK inhibitors in your Reply Declaration, correct?

MR. MILLS: Objection, form.

A. What 65 says is that, you know, Dr. Damsky admitted inhibitors of downstream

signaling of IL-15 that also inhibit other cytokine signals can still be IL-15 inhibitors, and we've given a reference for that. And interfere on gamma are all upstream molecules of the JAK/STAT pathway that can signal through them, and given Exhibit 1046 and the location in that. Accordingly, you know, JAK 13 inhibitors such as tofacitinib inhibit signaling of each IL-2, IL-15 interferon-gamma.

(Exhibit 1046 introduced.)

BY MR. FELDSTEIN:

Q. And you've just essentially read back Paragraph 65 from your report, correct?

MR. MILLS: Objection, form.

A. Right.

BY MR. FELDSTEIN:

Q. Right.

A. Is there some question about that?

Q. Sure. The -- the question was much simpler, Doctor. Just to confirm, to make the record clear, you do address JAK inhibitors in your Reply Declaration, correct?

MR. MILLS: Objection, form.

BY MR. FELDSTEIN:

Q. Yes or no is what I'm looking for.

A. I've -- I've mentioned it in this one location, yes.

Q. Okay. And tofacitinib is a JAK inhibitor, correct?

A. It is.

Q. And is tofacitinib used off label for the treatment of vitiligo?

A. It could be.

Q. Okay. So we have four small chemical molecules that can be used -- excuse me. We have four -- let's start again.

You've identified four small molecule JAK inhibitors that can be used to treat vitiligo, correct?

MR. MILLS: Objection to form, outside the scope.

A. I believe in my Reply Declaration, I've mentioned only two of those.

BY MR. FELDSTEIN:

Q. In your testimony today, you've mentioned four, correct?

A. That's correct.

Q. And in your declaration, you address in the -- some specificity the signaling pathways by which JAK inhibitors -- that -- that JAK inhibitors

affect, correct? I'll -- I'll -- I'll re- -- restate that.

In your declaration, you address with some specificity signaling pathways that JAK inhibitors inhibit, correct?

MR. MILLS: Objection to form.

A. In -- in my Reply Declaration, I'm responding to Dr. Damsky's deposition where he -- he mentioned that, you know, an IL-15 inhibitor might include a -- a JAK inhibitor. He testified that, and I explain this in Paragraph 66, that JAK signaling is a biological effect of IL-15. And you could not categorically rule out that Ruxolitinib and tofacitinib are inhibitors of IL-15. I'm trying to set the record straight about that.

BY MR. FELDSTEIN:

Q. To your understanding, do the four JAK inhibitors that we've discussed have some in -- some common biological effect that makes them suitable for treating vitiligo?

MR. MILLS: Objection to form, outside the scope.

A. I -- I -- is there a question on -- in my declaration that refers to that?

BY MR. FELDSTEIN:

Q. That's my question, Doctor, the one I just asked. Do you need it read back?

MR. MILLS: Objection to scope.

A. Could you ask your question again?

BY MR. FELDSTEIN:

Q. To your understanding, do the four JAK inhibitors that we have discussed have some common biological effect that makes them suitable for treating vitiligo?

MR. MILLS: Objection, form, outside the scope of the Rebuttal Declaration.

A. I think that one of the effects that these molecules have is the ability to inhibit the JAK/STAT pathway in cells. They don't all do the same thing exactly, and they -- that's a pathway that seems to be important in vitiligo.

BY MR. FELDSTEIN:

Q. So that common effect of inhibiting the JAK/STAT pathway makes them suitable for treating vitiligo?

MR. MILLS: Objection to form, outside the scope.

A. I -- I believe that's the -- the most important mechanism for efficacy in -- in this particular case.

BY MR. FELDSTEIN:

Q. What does it mean that the JAK/STAT pathway is downstream of IL-15?

A. That means that IL-15 is binding with its receptors and creating a signal inside the cell that then causes phosphorylation of activation of the whole chain of events that -- that lead to -- to cell, you know, T cell activation and proliferation.

Q. And -- and I think you were pointing in the direction of the answer, but -- and I'm not sure I got an answer to the specific question of what does it mean that a JAK/STAT pathway is downstream of IL-15?

A. Well, I -- I think what you're looking for is that there is a whole series of chain events, and it starts with, you know, thing 1 and goes to thing 2 and then thing 3 and -- and that's a -- you know, what -- what we're saying is IL-15 is kind of a thing up here and closer to 1, and JAK is down here closer to 3. You know, it's -- it's -- it's something that happens after IL-15.

Q. It's something that happens after IL-15 does whatever IL-15 does?

A. That's correct.

Q. And a JAK inhibitor like tofacitinib or Ruxolitinib, that doesn't reduce the amount of circulating IL-15, correct?

MR. MILLS: Objection to form, incomplete hypothetical.

A. Those molecules are not acting directly on IL-15, but one of the things that could happen is to have a -- an indirect effect, I suppose on --

BY MR. FELDSTEIN:

Q. Are you aware of the documented indirect effect of a JAK inhibitor on the amount of circulating IL-15?

A. Well, again, we're -- you're outside the scope of my declaration in responding to Dr. Damsky. I'd like to get back to what I'm here to -- to discuss. Is there a -- a question in like my -- my response that --

Q. That's --

A. -- that has --

Q. That's the question, Doctor.

A. I -- I understand it's your question, but is it a question about my response?

Q. Are you aware of a documented indirect effect of JAK inhibitors on the amount of circulating IL-15?

MR. MILLS: Objection to form, outside the scope.

(Witness reviews document.)

(Exhibit 1007 introduced.)

A. So to try as best to answer your question, I'll refer you to Exhibit 1007 by Xing, and take you to page 5 under Figure Number 4. In this article, Dr. Xing has administered a JAK inhibitor in an alopecia model where the JAK inhibitor is shown in a -- and -- and under C, if you see Figure C, there's CD8+ T cells there. And so these are cells that are kept alive by IL-15 action. And by administering the JAK inhibitors, what you see is that those IL-15 stimulated CD8 cells are declined in the skin. See the -- the boxes on the left in Figure C, where the -- you see the number 21 in the vehicle and .55 and .28 in the -- the JAK inhibited.

So those cells numbers have declined. It may be an indirect way of monitoring the -- the IL-15, you know, it's an indirect way that IL-15s decline because there is a JAK inhibitor.

MR. MILLS: We've been going for about an hour. We ready for a break?

MR. FELDSTEIN: Can we finish this --

the Xing question, please?

MR. MILLS: He answered the question.

MR. FELDSTEIN: I'd like to finish asking about Xing, finish this part up. Is that okay? If you want to take a break, that's okay, but I'm happy to -- prefer to finish with the reference, if we can.

THE WITNESS: I'd like to take a break for just a moment.

MR. FELDSTEIN: Take a break.

(Recess held 10:07-10:16.)

BY MR. FELDSTEIN:

Q. In Paragraph 65 of your Reply Declaration, Exhibit 1047, where you see that "tofacitinib inhibits signaling of IL-15," is that what you're relying on, that you're pointing to in Xing for the basis for tofacitinib inhibiting IL-15?

MR. MILLS: Objection to form.

A. I'm not saying that tofacitinib inhibits IL-15. To be clear, what I'm saying is that it may have an indirect effect, as demonstrated in this figure, by reducing the -- ultimately reducing CD8+ T cells as evidence of that. So it's reducing the signaling that keeps these cells alive; therefore,

there's less IL-15 in the skin. You -- is that clear, I think?

BY MR. FELDSTEIN:

Q. I don't want to sound too absurd, but if you asphyxiated somebody, that would, in the same way, indirectly inhibit IL-15?

MR. MILLS: Objection, form.

A. I -- I missed that word.

BY MR. FELDSTEIN:

Q. If you asphyxiated someone, that would also indirectly inhibit IL-15 because the CD8+ T cells would likewise die?

MR. MILLS: Objection, form.

I don't think he's hearing the word.

A. Are you saying "asphyxiated" like if I strangled them?

BY MR. FELDSTEIN:

Q. Cut off the oxygen supply.

A. Oh. I think that's a hypothetical. I don't know quite how to respond to that.

Q. If you cut off oxygen supply to an in vivo system, it would -- CD8 cells wouldn't be able to produce IL-15, correct?

MR. MILLS: Objection to form, scope.

A. Yeah, I -- well, are you saying that

IL-15 is not going to be produced because the organism is dead or that there's just a lack of oxygen?

BY MR. FELDSTEIN:

Q. If there's a lack of oxygen -- does CD8 T cells need oxygen to reproduce?

MR. MILLS: Objection, form, scope.

A. I think you're asking a hypothetical. You know, I think we all know that cells need oxygen to survive.

BY MR. FELDSTEIN:

Q. So if you cut off the oxygen supply to CD8 cells, that would also reduce IL-15, correct?

MR. MILLS: Objection, form, scope.

A. Again, I can't answer a hypothetical.

BY MR. FELDSTEIN:

Q. It's a question of biology, not a hypothetical.

A. No, I don't think it's a question of biology. I think that there's a whole spectrum of -- you know, if you put a mouse in a chamber and then you looked at it in different places until it was dead, you didn't provide it any oxygen, you could probably, in the time that it takes that, there would probably be no change in the -- in the

cell counts. It happens so quickly there's not a possibility for cells to change. You know, they are what they are. They're right there, so -- but it's a hypothetical. I don't know that that's -- we have any information about that.

Q. You treat cancer, correct?

A. I'm a dermatologist. I do treat skin cancers.

Q. And do chemotherapy agents affect CD8 T cells?

MR. MILLS: Objection, form, outside the scope.

BY MR. FELDSTEIN:

Q. Do you know?

A. My treatments in the clinic are usually not with chemotherapy agents. We treat skin cancer, so it's a little different than treating cancers, you know, of other organs.

Q. So do you know if chemotherapy agents affect CD8 T cells?

MR. MILLS: Objection, scope.

A. It's not in my Reply Declaration. I don't know -- I don't have an answer for that.

BY MR. FELDSTEIN:

Q. Okay. Can you turn, Doctor, to Exhibit

1046?

MR. FELDSTEIN: If you want copies, we have copies. I have to offload them to you, too.

MR. MILLS: I'm okay. Thank you.

A. I have it here.

BY MR. FELDSTEIN:

Q. Okay. What is Exhibit 1046?

A. This is the deposition of William Damsky, Ph.D. -- M.D., Ph.D.

Q. And you're relying on the Damsky deposition transcript throughout your declaration, Exhibit 1046, correct?

MR. MILLS: Object to the form.

A. Yes.

BY MR. FELDSTEIN:

Q. Is that correct?

A. Yes, I did.

Q. And did you read the entirety of Exhibit 1046?

A. Yes, I did.

Q. And the portions that are cited in your declaration, are those things that you identified as -- or that were identified to you?

MR. MILLS: Objection, form.

A. Are you asking whether I found these or

someone else found these?
BY MR. FELDSTEIN:
Q. Correct.
A. My response is it was a team approach. I -- I read this and -- and developed my responses in conjunction with Counsel.
Q. And the characterizations you make of Dr. Damsky's testimony throughout your declaration, was that, likewise, a team approach?
MR. MILLS: Objection, form.
A. I -- you know, I read his deposition and his declaration, and I saw areas where there were discrepancies between what he says and what those references say, and, you know, working with Counsel, put together my responses.
BY MR. FELDSTEIN:
Q. But more specifically, the characterizations you make of Dr. Damsky's testimony from Exhibit 1046, are those your characterizations, or are they, likewise, a team approach, those characterizations?
MR. MILLS: Objection to form.
A. I don't know what you mean by "characterizations." Can you explain?
BY MR. FELDSTEIN:

Q. Okay. We'll get to some.

Can you turn in Exhibit 1046 to page 93?

And you see at page 93, line 11, Dr. Damsky is being asked about Slide 8 in Exhibit 1043?

(Exhibit 1043 introduced.)

A. I see that on line 11.

Q. And I don't see that you reference Exhibit 1043 in your Reply Declaration.

Is that something you considered?

A. In making my response, I selected areas where I felt that Dr. Damsky was -- there were important areas of clarification needed in his interpretation of the documents that were selected. I didn't address every single item that he might have been asked about because sometimes there's not areas of -- of conflict that need to be addressed, and so I've picked out those areas that need clarification. And while it is an exhibit that's, you know, discussed in his deposition, it's not one that I felt needed to be included here.

Q. And you felt that because you considered Exhibit 1043 and decided it wasn't relevant to your opinions?

A. That's not what I'm saying. I'm saying

that -- that the responses that I've developed here are areas where there were discrepancies between maybe what Dr. Damsky -- how he characterized an individual topic or an item and felt that that particular item was needing to be addressed.

I haven't addressed everything that Dr. Damsky said, only the things that appeared to be important to -- that were either mistaken or inaccurate, in my opinion.

Q. And so just to be clear, you did not consider Exhibit 1043, correct?

MR. MILLS: Objection to form.

A. No, that's not what I said. I said that I did consider 1043, and I did not feel that it -- that that particular item needed to be addressed in my response.

BY MR. FELDSTEIN:

Q. So you considered everything that is discussed in Dr. Damsky's declaration?

MR. MILLS: Objection, form.

BY MR. FELDSTEIN:

Q. Every -- every reference?

A. I considered Dr. Damsky's -- I read all of his deposition, all of his declaration, and there are a lot of references, and I -- maybe

you're able to find something that I didn't read, but I can tell you that I've read and considered everything that is in his -- in his declaration and in his deposition with -- you know, within these -- his document -- this document.

Q. So just to be super clear, you considered every exhibit cited in Dr. Damsky's declaration, correct?

MR. MILLS: Objection to form.

A. With regard to your question in Exhibit 1043, I'll -- I'll say again that I -- I considered this -- this statement, that it was discussed here. I didn't feel like that it needed to be reproduced in my response, and so it's not included. That particular exhibit is not included in my response.

BY MR. FELDSTEIN:

Q. Okay. And I think you're answering a previous question. I'm trying to ask a different question and make it clear.

You considered Dr. Damsky's declaration, correct?

A. I did.

Q. And you considered every exhibit cited in Dr. Damsky's declaration, correct?

MR. MILLS: Objection to form.

A. You know, I -- I considered it extensively. Perhaps you could find something that I didn't have access to or didn't -- didn't read, but I'm not saying that I've conclusively read every single thing because there might have been something that was irrelevant, but if there's something about Exhibit 1043 you would like to know about, it's not in my Reply Declaration and I've not offered an opinion on it.

BY MR. FELDSTEIN:

Q. Well, I'm just trying to clarify what you reviewed from Dr. Damsky's declaration.

You reviewed, at least in part, every exhibit cited in Dr. Damsky's declaration, Exhibit 2005; is that correct or not?

(Exhibit 2005 introduced.)

MR. MILLS: Objection, form.

A. I -- I think I've answered the question, that I've considered everything that is in his Exhibit 1046. And what I've done is selected the items that were relevant to my reply, and I've, you know, extensively considered those items. I've looked at all this. You might be able to find something that I didn't see, but it would be the

exception rather than the rule.
BY MR. FELDSTEIN:
Q. Okay. We may not be communicating well.
Do you have Exhibit 2005 in your binder there?
A. Yes, I do.
Q. And what is Exhibit 2005?
A. This is the declaration of Dr. Damsky.
Q. And I trust you read the entirety of Exhibit 2005, correct?
A. I have.
Q. And did you read all of the exhibits that are cited in Exhibit 2005?
MR. MILLS: Objection, form.
A. I'm looking through his declaration. I don't see a list of his references.
Is there a list of his references that I could examine to answer your question?
BY MR. FELDSTEIN:
Q. I think you have to read through the entire declaration. I don't think there was a separate list.
Were you provided with all the exhibits cited in Dr. Damsky's declaration?
A. I don't have a list in his declaration,

so I can't, you know, compare those, to answer your question.

Q. Sorry. Do you know whether or not you were provided with all the exhibits cited in Dr. Damsky's declaration?

A. I -- I -- I believe so.

Q. And do you know whether --

A. But I don't have a list, you know.

Q. And do you know whether you reviewed all of those exhibits?

A. Yes, I did.

Q. Okay. And in your Reply Declaration, Exhibit 1047, you address those exhibits with which you took some issue; is that correct?

MR. MILLS: Objection, form.

BY MR. FELDSTEIN:

Q. And I think --

A. I think you mean --

Q. -- the Reply Declaration is 1046.

A. -- 1046 instead of '7.

Q. It got transcribed wrong.

A. Can you state your question again?

Q. In your Reply Declaration, Exhibit 1046, you addressed all the exhibits cited in the Damsky declaration with which you had some issue; is that

correct?

MR. MILLS: Objection, form.

A. Yes, that's correct.

BY MR. FELDSTEIN:

Q. And now if we could go back to where we started, Exhibit 1046, which was the transcript -- excuse me. Well, you know what, we may have to back up. You confused me, Doctor. So your declaration is Exhibit 1047; is that correct? Can we agree on that? Probably your loose papers in front of you. It's probably your loose papers in front of you.

A. That's correct, 1047 is my Reply Declaration.

Q. All right. And so to -- to re- -- redo the questioning from before with the correct exhibit number, in your Reply Declaration, Exhibit 1047, you addressed all the exhibits cited in the Damsky declaration with which you had some issue; is that correct?

MR. MILLS: Objection, form.

A. That's correct.

BY MR. FELDSTEIN:

Q. Okay. Now go back to Exhibit 1046, which was the transcript. Do you have that in

front of you, correct?

A. Yes, I do.

Q. And you read all the exhibits that are cited in Exhibit 1046; is that correct? If you're looking for a listing, there is at least -- at least a partial listing beginning on Page 3.

A. Yes, I'm looking for a list.

If this is the entire list on page 3 of Exhibit 1047 -- '6, yes, I've read all of these exhibits.

Q. Okay. And you addressed -- of -- of those exhibits on page 3 of 1046, you addressed in your Reply Declaration those that you thought were relevant, correct?

MR. MILLS: Objection, form.

A. Well, those are some of the ones that I addressed, yes.

BY MR. FELDSTEIN:

Q. The ones you didn't address, they weren't relevant to your opinions in Exhibit 1047; is that correct?

A. Yes, that's correct.

Q. Okay. Now, go back to where we started earlier, page 93 of Exhibit 1046.

A. I'm on -- I'm on page 93.

Q. And, again, we're at the question that begins at Line 11. It's referring to Slide 8 of Exhibit 1043, correct?

A. Right. He's asking the question on this Slide 8 in Exhibit 1043. You give a list of cytokines.

Q. Right. And then on page 94, you see the question at line 5?

A. The question is: Do you disagree with what you wrote here on Slide 8 on Exhibit 1043? And Exhibit 1043 is Medical Dermatology Society Annual Meeting, March 24, 2022, entitled: JAK Inhibitors in Dermatology, What to Know About These New, quote, unquote, New Kids on the Block.

Q. And you saw in the earlier question, that what's shown on Slide 8 is a list of cytokines, correct?

A. I don't -- I don't have a copy of that Slide 8 in front of me.

Q. The question on page 93 that you read into the record from line 11, it describes Slide 8 as having a list of cytokines?

MR. MILLS: Objection, form.

A. It asks a question about a list of cytokines. I -- I don't have the slide in front of

me, so I -- I'm not sure what's being referred to here.

BY MR. FELDSTEIN:

Q. Okay. And do you see the -- you -- you had read a minute ago the question that is on page 94, lines 5 through 6. And can you read the answer to that?

A. Dr. Damsky's answer was: I don't disagree with it. I would just say it is more complicated than that. This is part of an educational talk that often starts simple.

Q. And would you mind, could -- can you just read the next question and answer?

A. The next question is: So cytokine activation of JAK/STAT pathways may be more complicated than what is depicted on Slide 8, comma, but you do agree that IL-2 interferon-gamma and IL-15 are cytokines that signal via JAK/STAT, correct, question mark.

Q. And the answer?

A. The answer Dr. Damsky gives is, quote: The pathways are well-known, period. I just want to reiterate that I think it's more than grouping them together here that is perhaps a bit simplistic, period.

Q. And -- and so in context, what do you understand at page 94, line 8 of Exhibit 1046 where it says: It is more complicated than that. What do you understand is being described as "more complicated"?

A. All right. I'm -- I'm -- I'm trying to re- -- understand how this relates to my responses, my Reply Declaration. Is there -- is there something in -- in my reply that you have a question about that relates to this? I'm -- I'm glad to try to answer that.

Q. That's my question, Doctor. Unless you're directed not to answer, I'd appreciate that you answer. Do you need the question read back?

A. It would appear that Dr. Damsky has a slide that he's presented at a talk, and he is trying to explain that his slide is a simplistic diagram of what he's showing, and I don't have a copy of the slide. And he's saying that -- he says: I would just say it's more complicated than that. It -- it -- it says what it says.

Q. So you don't know what he's saying is simplified versus more complicated? The subject matter that is simplified is more complicated?

MR. MILLS: Objection to form.

A. Again, I think he has a slide, he's trying to say that in the diagram that he has in the slide, which I don't have in front of me, is a simplistic diagram and that whatever it is he's depicting is more complicated.

BY MR. FELDSTEIN:

Q. So you understand there's a -- a diagram on Slide 8 of Exhibit 1043?

A. That's what the question asks about.

Q. Do you have any specialized knowledge, skill, experience, training, or education to interpret and provide opinions on deposition testimony?

MR. MILLS: Objection to form.

A. No, I have no special training on deposition testimony. I have training as a medical doctor, as a dermatologist, just as Dr. Damsky has training as a dermatologist. And as one dermatologist to the other, I can understand what he might be talking about here.

BY MR. FELDSTEIN:

Q. But you don't understand what he's saying is more complicated versus simple --

MR. MILLS: Objection, form.

BY MR. FELDSTEIN:

Q. -- on page 94 of Exhibit 1046, correct?
A. I -- I think it's simple to understand. I think the words speak for themselves.
Q. But you don't know what subject matter he's saying is simplified versus complicated from Exhibit 1046?
A. He has a -- he has a sma- --
MR. MILLS: You got to let him finish.
THE WITNESS: I'm sorry.
MR. MILLS: Give me a chance to object, and then you would start your answer, okay?
Objection, form.
A. He's looking at Slide 8. It has a diagram on it. He's saying this is an educational talk, we're trying to make this simple. And he's explaining in response to this question that it's more complicated than what's depicted on this diagram.
BY MR. FELDSTEIN:
Q. Okay. Can you turn to page 121 of Exhibit 1046. And can you -- you can just read it to yourself, you don't have to read it into the record, the question that begins on line 7, and then the answer goes through line 16.
(Witness reviews document.)

BY MR. FELDSTEIN:

Q. Have you read those -- question-and-answer, Doctor?

A. Yes, I'm thinking about the -- the question.

Q. Well, I haven't asked the question yet. I just wanted you to read it.

A. Well, I'm thinking about it. Go ahead with your question.

Q. Do you agree or disagree with Dr. Damsky's answer to the question on line 7, page 121 of Exhibit 1046?

MR. MILLS: Objection, form and scope.

A. Well, I -- I -- I don't completely agree with his -- his answer. I would have answered that in a different way.

BY MR. FELDSTEIN:

Q. What would your answer have been?

MR. MILLS: Objection to form, outside the scope.

A. What the question is asking about is a treatment that eliminates the pigmenting cells from the skin. And so when those pigment cells are gone, there's no returning those cells to the skin, so it's not complicated, the cells are gone.

There's no return. It's as simple as that, that you've eliminated the pigmenting cells, and they're not coming back. And it's really that, you know, they're -- they're dead, they're gone, they're not coming back. It's not complicated.

BY MR. FELDSTEIN:

Q. Dr. Damsky's testimony on page 121, he's not saying that the effects of inhibiting IL-15 or the IL-15 receptor are complicated. Do you agree with that?

MR. MILLS: Objection to form.

A. Well, I think what Dr. Damsky's saying is that in thinking about the mechanisms that might be involved, they -- you know, he -- I -- I don't know what he's thinking about there, but it seems like he's thinking about the mechanisms of the melanocyte destruction, and -- and that could be complicated. But when you've been treated with this type medicine and the melanocytes are gone, there's not -- the question's asking about reversing the lack of pigmentation, and there's not a reversal because the melanocytes are absent.

BY MR. FELDSTEIN:

Q. Thank you for the answer. I'm not sure I fully understood or got the response I was

seeking. We can ask it again maybe hopefully more clearly.

Do you have an opinion one way or another on whether the testimony Dr. Damsky gave on page 121, lines 11 through 16 of Exhibit 1046 was addressing complexity of inhibiting IL-15 or the IL-15 receptor?

MR. MILLS: Objection to form.

A. It seems like Dr. Damsky may have those pathways in mind when he's thinking of this and responding that it's complicated, and he's -- he's -- he's correct, those things are complicated. What is -- the question is about the reversal of pigmentation in the skin, and my answer is that when you're treated with this -- this particular agent, MBEH, it kills the melanocytes and they're gone. And so I -- I -- I'm saying -- I'm thinking about this in a different way than maybe Dr. Damsky is, to -- to answer this question, so my response would have been different.

But I think that Damsky's thinking about mechanisms that are involved in melanocyte destruction, and that is complicated.

BY MR. FELDSTEIN:

Q. And so you have the opinion that

Dr. Damsky, in his mind, was thinking about the complexity of inhibiting IL-15 or the IL-15 receptor when answering on page 121?

MR. MILLS: Objection to form.

A. I mean, you're asking me to read Dr. Damsky's mind here and -- and like I'm saying, that he's referring to mechanisms, that he's characterizing them as complicated.

He's referring to this treatment that involves melanocyte destruction. I think that he's thinking about the mechanism that that destruction occurs, and he's explaining that he feels that it's complicated.

What I'm saying is that my answer to that question would have been different than his answer.

BY MR. FELDSTEIN:

Q. And his answer to that question didn't reference inhibiting IL-15 or the IL-15 receptor, correct?

MR. MILLS: Objection to form.

A. Like I said, I can't read Dr. Damsky's mind, what he's thinking about here, but I don't see the words "IL-15" written on this page.

BY MR. FELDSTEIN:

Q. Okay. And he didn't say on page 121 that inhibiting the -- inhibiting IL-15 or the IL-15 receptor is complicated, correct?

MR. MILLS: Objection to form.

A. Like I said, I believe that Dr. Damsky's thinking of the mechanisms that are involved, and he's -- he was characterizing them as being complicated.

BY MR. FELDSTEIN:

Q. So you are reading his mind.

MR. MILLS: Objection, form.

A. No response.

BY MR. FELDSTEIN:

Q. You're testifying to what you believe Dr. Damsky is thinking, correct?

MR. MILLS: Objection to form, mischaracterizes the testimony.

A. I'm -- I've given you my answer.

BY MR. FELDSTEIN:

Q. Okay. And I understand what you're saying is that you're effectively reading his mind for what he was thinking when he was testifying?

MR. MILLS: Objection to form.

BY MR. FELDSTEIN:

Q. If that's not correct, then I've

misunderstood you.

MR. MILLS: Mischaracterizes the testimony.

A. Let me say again, maybe in different words and -- so that I'm not misunderstood.

Dr. Damsky is asked about a medical treatment for vitiligo that removes the remaining pigment cells, melanocytes, from the skin, and he's asked if that can be reversed.

He said that he felt like the reversal would be complicated because we don't fully understand the mechanism why MBEH is doing what it does and whether we can call it vitiligo or we have to call it something else. He believes it's complicated. He's thinking about -- he says the word "mechanisms" and why MBEH is doing what it does, and he's talking about the possibility that being reversed.

I read that, that he's thinking about -- you know, that in the context of vitiligo -- like he says: We can call it vitiligo, or we can call it something else. So I think that he's thinking about all these mechanisms that we've been talking about here today.

Q. Can you turn to page 140 of

Exhibit 1046?

Would you mind just reading into the record the question that begins on line 4 of page 140 of 1046?

A. Sure.

MR. MILLS: Objection, scope.

A. Can you explain at a high level, comma, in a sentence or two, comma, what the thought is behind the role of oxidative stress in causing vitiligo?

BY MR. FELDSTEIN:

Q. And whether you would answer the question differently yourself, do you agree that Dr. Damsky gave an answer within the scope of the question at line 7 through 9?

MR. MILLS: Objection to form, foundation, outside the scope of the Rebuttal Declaration.

A. Like I said, I have no expertise in evaluating deposition testimony.

BY MR. FELDSTEIN:

Q. And the answer at line 7 through 9 of Exhibit 140 [sic], it doesn't reflect a lack of understanding of the theory of oxidative stress in vitiligo, correct?

MR. MILLS: Objection to form, outside the scope.

A. I think that Dr. Damsky doesn't show any understanding of oxidative stress in this particular response.

BY MR. FELDSTEIN:

Q. Is it not the case that part of the theory of how oxidative stress triggers vitiligo is that stress signals may relate to the pathogenesis of vitiligo?

Do you disagree with that?

MR. MILLS: Objection to form.

A. Again, reviewing the question asked, what -- what the thought is -- what's the thought behind the role of oxidative stress in causing vitiligo. It's just repeating the word stress signals. Oxidative stress has to do with, you know, oxygen and in particular forms of oxygen that are at higher energies causing damage to the melanocytes, and this isn't really addressing that very well.

It doesn't mention anything about, you know, that it's oxygen doing this. I mean, he's just repeating the word "stress" and the higher energies with hydrogen peroxide's involvement.

This is a dermatologist, and he's an individual who is focused on vitiligo. I would hope that he would have a better explanation than that.

BY MR. FELDSTEIN:

Q. And in your explanation, the damage to the melanocytes, that's the triggering event for the autoimmune response; is that correct?

MR. MILLS: Objection, form, scope.

A. Well, it's a -- the oxidative stress theory. It's just a theory of how melanocyte destruction would occur, and it's -- it's one of many theories. The idea there is that the -- the oxygen, having additional energies like in peroxides, damage the melanocytes; and I think I've -- I think that's what you're looking for.

BY MR. FELDSTEIN:

Q. And then that damaged melanocyte, that's what then induces the autoimmune overactivity; is that correct?

MR. MILLS: Objection to form.

A. That might be one of the explanations. It could be that that simply kills the melanocyte and that's the end of it. There's -- you know, it's a theory, so there's lots of variety of explanations, but none of those are demonstrated

here.
BY MR. FELDSTEIN:
Q. Can you turn to page 159 of Exhibit 1046?
A. I'm there.
Q. You can read -- just to yourself is fine -- the question at 159, line 20, through the answer at page 160, line 3. Let me know when you've read that.
(Witness reviews document.)
A. Are you asking about the question that begins on line 20 and then the response on 25, going over to the next page ending at line 3?
BY MR. FELDSTEIN:
Q. Correct.
A. What are you asking about that?
Q. And you had read that prior to submitting your declaration, Exhibit 1047, correct?
A. Yes, I had.
Q. And so you understood that Dr. Damsky testified that administering a therapeutically effective amount of tofacitinib to a subject in need thereof would not satisfy Claim 1?
MR. MILLS: Objection to form.
(Witness reviews document.)

A. Let me answer your question by referring you back to my reply deposition -- declaration on page 38, paragraph 66, where I've addressed all this in my declaration -- or the Reply Declaration.

In the second sentence: Dr. Damsky testified that JAK signaling is a biological effect of IL-15, and he could not categorically rule out that ruxolitinib or tofacitinib are inhibiters of IL-15.

I've provided the references from his testimony. He's -- he's a bit clear in quite a few places that are listed here in 66 about his opinion, and so I've pointed out this -- you know, this point that he's made about IL JAK inhibitors being a biological effect of 15.

You're asking about this particular part of it. It seems like he's changed his tune here about: Do you agree that administering a therapeutically effective amount of tofacitinib to a subject in need of treatment satisfies Claim 1?

He said that he didn't think that people would think that tofacitinib or any JAK inhibitor was acting through interferon-gamma in vitiligo.

To me, that doesn't really answer the question that was asked.

Of course, you know, he's talking about downstream effects from the JAK inhibitor, so I'm going to refer you to, you know, my responses that are in Paragraph 66 for whether or not he thinks that the JAK inhibitor would be -- fall under one of the claims.

He says that in more than one place.

BY MR. FELDSTEIN:

Q. Okay. My question is really much simpler, Doctor. It was just whether you, Dr. Plott, understood -- at the time that you wrote your declaration, Exhibit 1047, whether you understood that Dr. Damsky had testified that administering a therapeutically effective amount of tofacitinib to a subject in need thereof would not satisfy Claim 1.

Did you understand that he had so testified?

MR. MILLS: Objection to form, mischaracterizes the testimony.

A. He's testified on both sides of that. He thinks it does. Here, he may say he doesn't. My characterization of his testimony is that he's -- he's testifying that it falls under the claims of Claim 1 because he stated that in several

places in his testimony.
BY MR. FELDSTEIN:
Q. Doctor, I'm just trying to find out if you, personally, were aware of this testimony, page 159, line 20, to 160, line 3, at the time that you wrote your declaration, Exhibit 1047. Were you aware of it?
A. Yes, I was aware of that.
Q. Okay.
MR. MILLS: We've been going about an hour. Are we ready for a break?
MR. FELDSTEIN: If you wouldn't mind, I have one more section in here. We can break, of course, if you want, but I have one more set of testimony I'd like to ask about, and then we can maybe be done with the exhibit. Up to you.
THE WITNESS: I'm fine to continue.
BY MR. FELDSTEIN:
Q. Okay. Can you turn to page 235 of Exhibit 1046? Actually, we can start on page 234. There's a question, line 20, and then read through the answer on 235, line 12, and just read that to yourself.
(Witness reviews document.)
BY MR. FELDSTEIN:

Q. Have you read the testimony, Doctor?
A. Yes, I've read that.
Q. And similar to the last question, I want to find out if you, Dr. Plott, were personally aware of Dr. Damsky's testimony on page 235 of Exhibit 1046 clarifying that what he was referring to was an appropriate balance of safety and efficacy?
MR. MILLS: Objection, form, mischaracterization of testimony.
A. My understanding of what Dr. Damsky is saying here is not that he's waiting for safety and efficacy, that he is replying in the video that was shown that he has his fingers crossed, hoping that this was going to work. What he's talking about is that it would have efficacy, that the product would -- it would do what it was intended to do. He didn't know whether it would or it wouldn't, and so he's using that expression. He's got his fingers crossed that it's going to work.
BY MR. FELDSTEIN:
Q. So again, Dr. Plott, I'm just trying to find out if you were personally aware of the clarification that Dr. Damsky provided on page 235, lines 7 through 12, when you submitted your

declaration, Exhibit 1047?

MR. MILLS: Objection, form.

A. Yes, I'm perfectly aware of what he said here. It's just not what he said in the video.

MR. FELDSTEIN: Do you want to take a break now?

(Recess held 11:23-11:32.)

BY MR. FELDSTEIN:

Q. So when I told you we were done with Exhibit 1046, I lied. I have one more question. If you don't mind turning to page 159 where we were before, 1046?

A. I'm there, 159.

Q. The question-and-answer that we looked at beginning at line 20 of 159 through line 3 of 160, do you have an opinion yourself in response to the question of whether administering a therapeutically effective amount of tofacitinib to a subject in need thereof satisfies Claim 1 of the '505 patent?

MR. MILLS: Objection to form, scope.

(Witness reviews document.)

A. I'm looking to see if I've offered an opinion on -- on that. I -- I don't believe I've offered my opinion, and I wouldn't want to opine on

that.
BY MR. FELDSTEIN:
Q. So do you have an opinion one way or another of whether tofacitinib is an inhibitor within the scope of Claim 1 of the '505 patent?
A. I -- I -- I don't believe I've provided an opinion or offered anything. I'm not prepared to offer opinion on that today, so --
Q. And --
A. -- I don't have that in my re- -- my -- my Reply Declaration.
Q. And so when offering opinions in Exhibit 1047, you didn't consider whether administering tofacitinib -- excuse me. Start again.
When offering your opinions in Exhibit 1047, you didn't consider whether or not tofacitinib is an inhibitor within the meaning of Claim 1 of the '505 patent; is that correct?
MR. MILLS: Objection to form, mischaracterizes testimony.
A. The -- the purpose of my -- my declaration is to respond to the things that Dr. Damsky said in particular where we have -- have differences. It's not about what I think or my

opinions about things, and I've not offered an opinion about this, whether tof- -- tofacitinib is -- falls under the claims of patent or not.

BY MR. FELDSTEIN:

Q. Right. And I'm asking -- I think we established that in a previous question. I'm asking you now --

A. Right.

Q. -- when offering opinions that you did offer in Exhibit 1047, had you considered whether or not tofacitinib was an inhibitor within the meaning of Claim 1 of the '505 patent. Is that something that you had considered before offering your opinions in Exhibit 1047?

MR. MILLS: Objection, form.

A. I'm con- -- I'm -- I'm cons- -- I'm considering doc- -- Dr. Damsky's opinions about that in my declaration. I've not offered an opinion about what I think, so I've not -- I -- I -- I just simply don't have an opinion to offer you about that today.

BY MR. FELDSTEIN:

Q. And -- and beyond not having an opinion, did you or did you not even consider that question before offering your opinions in Exhibit 1047?

MR. MILLS: Objection, form.

A. I -- I think I've answered your question as best that I can.

BY MR. FELDSTEIN:

Q. You can't tell me whether or not you considered the question before offering your opinions in Exhibit 1047?

MR. MILLS: Objection to form.

A. I -- I -- I'm saying that I haven't discussed that in my reply, and I'm not able to -- to give that to you today.

BY MR. FELDSTEIN:

Q. Okay. You address in your Reply Declaration different possible causes of vitiligo, correct? It's a topic you cover?

A. I -- I'm providing a reply about what Dr. Damsky said about those possible causes.

Q. Is this -- I'm going to hand you Exhibit 2053, Doctor.

(Exhibit 2053 introduced.)

BY MR. FELDSTEIN:

Q. This is an exhibit that was addressed in Dr. Damsky's declaration you considered, correct?

A. It was considered in his declaration or in his deposition?

Q. His declaration, sir. If you're looking in Exhibit 2005, it's addressed in Paragraph 32. And so you've considered Exhibit 2053, correct?

A. Yes, I -- I see Paragraph 32 in Exhibit 2005.

Q. And you told me you considered all the exhibits cited in Exhibit 2005, correct?

A. I -- I -- I think we were looking for a list of those, and we couldn't find one, so I can tell you that I've completely read his declaration and -- and considered 2005. If -- if you're asking have I considered this article?

Q. Exhibit 2053 is my next question, yes.

A. Yes, I've -- I've considered this article.

Q. Okay. And if you turn in Exhibit 2053 to page 3.

MR. MILLS: Objection, outside the scope.

BY MR. FELDSTEIN:

Q. The bottom left of page 3 is referring to occupational contact or chemical leukoderma, correct?

MR. MILLS: Objection, outside the scope.

A. I -- I see that paragraph.

BY MR. FELDSTEIN:

Q. And those are being used synonym- -- synonymously, occupational, contact or chemical leukoderma; is that correct?

MR. MILLS: Objection, outside the scope.

A. You mean that these terms are being used in a -- a -- a general way? You -- you said generically? Is -- is that what you're -- you're asking?

BY MR. FELDSTEIN:

Q. I said synonymously that occupational, comma, contact, comma, chemical leukoderma, they're all referring to the same thing, is that correct, or am I misunderstanding the reference?

MR. MILLS: Objection to form, outside the scope.

A. Well, I think these are referring to the -- the way that depigmentation in the skin might occur, and these are different ways. They're not referring to them in the -- in the same sense. A -- a POSA would understand that these are slightly different ways of getting to the -- the same depigmentation.

BY MR. FELDSTEIN:

Q. I -- I mean, I -- I don't know. You're the expert here, but the sentence says: Occupational, comma, contact, comma, chemical leukoderma describes depigmentation that is induced by exposure to phenols or similar chemicals.

Isn't that saying that occupational, contact and chemical leukoderma all describe depigmentation induced by exposure to phenols or similar chemicals?

MR. MILLS: Objection to form, outside the scope.

A. It's -- no, it's -- it -- it's not saying that all occupational, contact, or chemical leukoderma is produced by phenols. It's saying that in the case of occupational derm- -- you know, leukoderma, one of the causes might be phenols or similar chemicals. One of the causes of contact leukoderma could be phenols or similar chemicals, or chemical leukoderma, one of the causes might be phenols or similar chemicals.

It's -- it's taking the case that these leukodermas are induced by exposure to phenols and similar chemicals.

BY MR. FELDSTEIN:

Q. Right. So those are the inducing causes of the leukoderma, correct?

MR. MILLS: Objection to form, outside the scope.

A. It's saying that phenols or similar chemicals might be one of the causes in these particular cases.

BY MR. FELDSTEIN:

Q. Causes of the leukoderma?

A. Of the leukoderma.

Q. And if you continue, and read anything you need, but if you continue on to the second column of page 3 of Exhibit 2053, do you see where it says: The disease is indistinguishable from classic vitiligo by clinical examination or histology, and therefore, chemical leukoderma does not appear to be distinct from vitiligo, but may be better classified as chemically-induced vitiligo. See that?

MR. MILLS: Objection to form, outside the scope.

A. I -- I see that it says that, that's correct.

BY MR. FELDSTEIN:

Q. And you agree that by 2017, the art

taught that chemically-induced vitiligo is not a distinct disease, it's just addressing the inducing trigger?

MR. MILLS: Objection to form, outside the scope, mischaracterizes the document.

(Witness reviews document.)

A. I understand your question to ask, is this -- this -- this paper is saying that: Quote, chemical leukoderma does not appear to be distinct from vitiligo, but may be better classified as chemically-induced vitiligo. And that opinion is based on the fact that, up above, it says that it's not different when you look at it clinically from the -- the -- standing across the room or when you look at it und- -- as a piece of skin under a microscope. It just see -- you just see that the melanocytes are gone. I -- I see that -- that it says that. Is there a question about that?

BY MR. FELDSTEIN:

Q. It's typical for autoimmune diseases, that the disease -- it -- let me back up.

You treat a variety of autoimmune diseases, correct?

A. Yes.

Q. And the triggering event may be unknown

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for the autoimmune disease, correct?

MR. MILLS: Objection to form, scope.

A. That's correct.

BY MR. FELDSTEIN:

Q. And, in fact, it's probably common that the triggering event is unknown, correct?

MR. MILLS: Objection to form, scope.

A. It -- it -- it could be, and -- and many times it -- it is unknown.

BY MR. FELDSTEIN:

Q. And an essential characteristic of an autoimmune disease is that the disease is the same regardless of the mechanism for onset or trigger, correct?

MR. MILLS: Objection to form, scope.

A. Well, what we just agreed upon was that the mechanisms might be different there. It's -- it might -- the triggers may be different in a particular condition. They may come from different places, and in this case, this is referring to chemical leukoderma where the skin looks the same. The reason for that leukoderma might be chemically induced, and so these authors are saying that we should really call these things, you know, chemically-induced vitiligo because if we

understand that mechanism of -- that the chemical has caused this, then that would be an explanation that we should include in what we call it. You know, it explains where it came from.

BY MR. FELDSTEIN:

Q. Maybe I'm not understanding. An autoimmune disease at a super oversimplified view is that your immune system is overactive in some way that it's attacking the body, correct?

MR. MILLS: Objection to form.

A. Right, by definition, the body is attacking itself.

BY MR. FELDSTEIN:

Q. And there can be different triggers that cause the immune system to go out of order and do that, correct?

MR. MILLS: Objection to form.

A. Well, again, you know, the real cause of vitiligo, which is our topic, is unknown, and there can be many different reasons for that -- the -- for the body's immune system to go into dysregulation, right?

BY MR. FELDSTEIN:

Q. Dysregulation is a good word.

And the mechanism that causes such as

chemically induced, that's just the trigger that then sets the immune system into dysregulation, correct?

MR. MILLS: Objection to form, scope.

A. Well, in this case, what we're talking about is a chemical cause, that the chemical that is involved is creating vitiligo. So what we're saying about that is that the immune system is probably not involved in that case, in directly causing the vitiligo. We're getting exposure to phenols or chemicals that absorbed into the -- into the skin, kill the pigmenting cells, and the immune system really is not involved in that instance.

BY MR. FELDSTEIN:

Q. So even though the previous sentence says, in Exhibit 2053: While depigmentation initially starts at sites of exposure, the development of more remote lesions with progression to a more widespread, typical pattern is common, you are reading -- your understanding is that chemically-induced vitiligo is not an autoimmune disease?

MR. MILLS: Objection, form, outside the scope of the Rebuttal Declaration.

A. And that -- that statement references

Reference 21 in this article, which is a review article that I don't have here in front of me, so I'm not, you know, familiar with where they -- where they're going with that.

But what we're talking about, though, and what's clear from this first sentence that we began with is that -- that there are types of leukodermas that are caused by phenols and similar chemicals. You know, when people get these things on their skin, they don't understand what it's causing, and you know, they -- those can -- can -- chemicals get everywhere and spread, and they don't know about it, for example, and maybe they don't know about it until sometime later.

My understanding, and I believe what is discussed here is that these are chemicals that cause the destruction of melanocytes, and it looks like that it's the same as the vitiligo that's -- we know has an autoimmune component to it because it looks the same under the microscope and in the clinic, but this is really -- it's really different from the autoimmune vitiligo that we've been thinking about because it's -- you know, in this case they say: Better classified as chemically-induced vitiligo.

BY MR. FELDSTEIN:

Q. Once again, you're reading chemically-induced vitiligo to be a nonautoimmune disease?

MR. MILLS: Objection, form, outside the scope, incomplete hypothetical.

A. By its name, I believe that's what it's intending to communicate and that's why they are pointing to that chemically-induced vitiligo is -- does not have an immune system component.

BY MR. FELDSTEIN:

Q. Is that your belief, also, that chemically-induced vitiligo does not have an autoimmune component?

MR. MILLS: Objection to form, incomplete hypothetical, outside the scope of the Rebuttal Declaration.

A. Yeah, I'm not offering an opinion about that in my response. I'm just reading to you what's in here. I think it speaks for itself.

BY MR. FELDSTEIN:

Q. And do you have an opinion on whether chemically-induced vitiligo is --

A. I've not offered my opinion.

Q. I'm sorry. Just let me ask the question

again. Do you have an opinion on whether chemically-induced vitiligo does or does not have an autoimmune component?

MR. MILLS: Objection to form, scope.

A. Yeah. As I mentioned, I've not offered an opinion about that in my response declaration, so --

BY MR. FELDSTEIN:

Q. Do you have --

A. -- I'm not -- I'm not able to offer an opinion on that today.

Q. Do you have an opinion on whether or not oxidative stress-induced vitiligo does or does not have an autoimmune component?

A. I'd give you the same response. I haven't offered an opinion on that in my reply deposition.

Q. In Paragraph 47 of your declaration, Exhibit 1047, when you refer, in the first sentence, for example, to "causes," are you making any distinction between an initial trigger and the subsequent autoimmune response?

(Witness reviews document.)

A. All right. I'm trying to understand what your question is with regard to 47, because in

47 -- you know, I can read it into the record, but it's -- it's almost entirely the testimony of Dr. Damsky discussing the variety of distinct causes of vitiligo.

Is there a question about --

BY MR. FELDSTEIN:

Q. I'm trying to understand how you are using the term "causes," and let me try to get at it a little bit differently, if that's not working.

MR. FELDSTEIN: May I have Exhibit 2060?

(Exhibit 2060 introduced.)

A. Let me address that for this. I'm not talking about causes here. Dr. Damsky is talking about causes.

BY MR. FELDSTEIN:

Q. Are you offering any opinions on what causes vitiligo --

MR. MILLS: Objection.

BY MR. FELDSTEIN:

Q. -- in your declaration, Exhibit 1047?

MR. MILLS: Objection, form.

A. No. I'm providing -- I'm providing responses in Paragraph 47 regarding what Dr. Damsky said. I've not offered opinion in this paragraph about the causes of vitiligo.

BY MR. FELDSTEIN:

Q. So in your declaration, 1047, as a whole, are you offering any opinions regarding the causes of vitiligo?

MR. MILLS: Objection, form.

A. You know, I'm not offering my opinions. I'm responding to what Dr. Damsky's testimony has been in the document as a whole.

BY MR. FELDSTEIN:

Q. What about Paragraph 48; are you offering any opinions of your own on causes of vitiligo?

(Witness reviews document.)

A. Paragraph 48 is a -- mostly a summary of the discussions that Dr. Damsky's had regarding research, you know, in some of these different causes of vitiligo. I've not offered an opinion about that in this paragraph.

BY MR. FELDSTEIN:

Q. So Paragraph 48, you're not offering any opinions regarding the causes of vitiligo.

MR. MILLS: Objection, form. Mischaracterizes testimony.

(Witness reviews document.)

A. Paragraph 48 is a description of what

Dr. Damsky said. I haven't offered an opinion about the causes of vitiligo in this paragraph.

BY MR. FELDSTEIN:

Q. What do you mean by "causing vitiligo" in Paragraph 48?

A. Paragraph 48 is really a review of Dr. Damsky's responses about these different causes for vitiligo. We've discussed neural causes, nonsegmental generalized vitiligo, chemical-produced vitiligo, something -- milanocytogoragraphy (phonetic), which is a theory. There's a list of references of the discussion that he's had.

And my comment about all of that is that even if the CD8+ T cells play a role in melanocyte destruction for all types of vitiligo, even if that were the case, right, the efficacy of inhibiting CD8+ T cells depends not only on treating a key mechanism but it also depends on the ability to treat different root causes.

Do you see that?

Q. Yeah. I just want to know what you mean by "causing vitiligo." Those are your words on line 3 of Paragraph 48. What do you mean by "causing vitiligo"?

A. Well, in this case, what we're discussing is, as -- as we've seen in Exhibit 2053, that we're talking about a chemically-induced leukoderma, we're talking about maybe oxidative damage that causes leukoderma, we're talking about different causes of the appearance of the skin being without pigment and how those -- like in this Exhibit 2053, they can be indistinguishable from each other from a clinical standpoint and a histology standpoint because the skin appears without pigment and it appears to have no melanocytes when I look at it under the microscope.

So to the extent that there's an oxidative damage causing that or a chemical or part of the immune system causing the vitiligo means something that ends in the skin having the absence of pigment and the absence of melanocytes.

MR. FELDSTEIN: Can I get Exhibit 2060? Did we already give it to him?

Did I give it to you? Who -- I didn't hand you 2060, did I?

Oh, here it is.

BY MR. FELDSTEIN:

Q. I'm going to hand you Exhibit 2060, Doctor. This is something I believe you considered

in Dr. Damsky's declaration; is that correct?

A. Again, I don't have a list of his exhibits, but I trust that's the case.

Q. If it was in there, you considered it?

A. Yes, I trust that's the case.

Q. Okay. I want to use that figure to try to understand what you're describing. If you could turn to page 14 of 16. There's numbering at the bottom of Exhibit 2060.

MR. MILLS: If you can just pause your question for just a second.

MR. FELDSTEIN: Let me know when you're both ready.

(Witness reviews document.)

BY MR. FELDSTEIN:

Q. Both ready?

A. Ready.

Q. So what the caption of the figure says is that: Vitiligo pathogenesis begins with altered melanocytes that exhibit an elevated cellular stress response. This triggers autoimmunity which targets melanocytes for destruction, resulting in focal depigmentation.

And I'm trying to understand if when you're using the word "causes," you're consistent

with this diagram, the left-hand side, this elevated cellular stress?

MR. MILLS: Objection, form.

BY MR. FELDSTEIN:

Q. Are you using causes consistent with that description depiction, or are you using causes in, for example, Paragraph 48 of your declaration typically.

A. I'm using causes in the sense that whatever the upstream pathogenesis is, it causes ends in -- no melanocytes in the skin microscopically and the absence of pigment in the skin, and in a general kind of way, we call that vitiligo. We know that vitiligo is caused by many things.

That upstream event, that end results in the skin being without pigment and without melanocytes histologically, may have a number of different -- there may be a number of different reasons.

Q. And this Exhibit 2060, Figure 1, and it's capped, and it's describing that initial upstream event as a trigger for autoimmunity, right?

MR. MILLS: Obj- -- objection, form and

scope.

A. Well, I would agree that this diagram and the description is dej- -- is describing one of the possible causes for vitiligo.

BY MR. FELDSTEIN:

Q. Right. I was just trying to get the terminology right so -- so we could talk, that in Figure 1 of Exhibit 2060, the initial upstream event is described as the event that triggers autoimmunity. Are -- are we on the same page?

MR. MILLS: Objection to form, scope.

A. I'm comfortable saying that this is, you know, one of the mechanisms that might occur. There might be other things that occur. There might not be any immune system involvement. It might just be destruction of melanocytes. If we're talking about, you know, all the things that we've talked about in this -- in the last hour, this is one of the ways that autoimmunity can destroy melanocytes.

BY MR. FELDSTEIN:

Q. Okay. And -- and just, again, just for terminology, you refer to upstream -- maybe you didn't say it then, but you refer to upstream something -- I'm going to call it "upstream event."

That initial upstream event, that is what Exhibit 2060, Figure 1, is saying triggers the autoimmunity; is that right?

MR. MILLS: Objection to form, scope.

A. Well, in this particular case of Figure 1, it's hypothesizing that antioxidants, question mark on the figure, might lead to melanocyte stress, right? And that that would be the upstream event in this case. But there could be other things that would be in there, and not just this; for example, what we've been talking about as chemically-induced vitiligo, where there could be a chemical or some other event that wipes out the melanocyte without it needing to stimulate the immune system.

BY MR. FELDSTEIN:

Q. Here, what's being depicted, is an upstream event that then triggers autoimmunity, correct?

MR. MILLS: Objection to form, scope.

A. That's my understanding, yes.

BY MR. FELDSTEIN:

Q. Okay. And when you use the word "causes vitiligo" in Paragraph 48, are you similarly referring to a trigger, or are you referring to

something broader of the entire disease process?

A. No, we're -- we're really trying to use the word "causes" to mean the upstream event that leads to the destruction of melanocytes and the absence of pigment in the skin.

Q. And so when you're referring to "causes," you are or are not talking about the thing that triggers autoimmunity, or are you talking about something broader than that?

A. We're -- we're talking about something different than that when we talk about causes in general. Are you talking a- -- are you asking about this particular paragraph, how this is being used or --

Q. Yeah. In --

A. -- just sort of in general?

Q. In -- in, for example, Paragraph 48 of Exhibit 1047, where you refer to "causing vitiligo," what you're saying in terms of a causative event, you're talking about something different than what's in Exhibit 2060, correct?

MR. MILLS: Objection to form.

A. So let me read back to 48: Chemicals produced by the body in response to stress or that the breakdown of enzymes designed to protect the

body from oxidative damage were causing vitiligo. In this paragraph what I'm saying is that these upstream events where they re- -- end in depigmentation, at least in some of these patients, are produced by chemicals that the body uses in a good way, but then become bad. And some of those causes are -- you know, in this Figure 1, Exhibit 2060, is describing one way that the body's stress can stimulate the immune system.

Previously, we were talking about chemicals that simply killed the body's im- -- melanocytes, and because those are different upstream events, there's -- there are different causes for vitiligo, and that's one of the things that we're -- I'm trying to point out about Dr. Damsky's testimony, is that there are a lot of different causes for vitiligo, a lot of different upstream events that result in this depigmentation, and sometimes the body's immune system may not be involved. Sometimes it -- it might be involved. It's complicated. It's not as simple as give this antibody, it goes away.

BY MR. FELDSTEIN:

Q. And so what I'm try- -- just trying to figure out, Doctor, is when you refer to in this

causing vitiligo in Paragraph 48 of Exhibit 1047, you're referring to causation, the causative event differently than the way Exhibit 2060 depicts the triggering event; is that correct?

MR. MILLS: Objection to form, asked and answered.

A. No, I think that I -- I -- I disagree. I -- I -- I think that what is described here is -- you know, is generally represented in Figure 1 on 2060.

BY MR. FELDSTEIN:

Q. And when you say "here", you're referring to Paragraph 48 again?

A. Right. Paragraph 48.

Q. Okay. Great.

MR. MILLS: We're a little short from three hours, but it is close to lunchtime. So I figured I would just check in with you. Do you want to go for another ten minutes, or are you at a good stopping point.

MR. FELDSTEIN: I'm fine here if everyone wants to break.

MR. MILLS: Do you want to chat? Let's go off the record.

(Recess held 12:26-12:56.)

BY MR. FELDSTEIN:

Q. Can you turn in your exhibits, Doctor, to Exhibit 1018. I believe it should be in the set of materials you brought.

(Exhibit 1018 introduced.)

A. I'm there.

Q. And this reference covers -- addresses two antibodies. One code named 146B7, right?

A. Right.

Q. And you have associated that Code Number 146B7 with HuMax IL-15, right?

A. That's correct, on Page 1571 in the area of conflict of interest. It states that: JenLab develops monoclonal antibody 146B7, in parentheses, HuMax, H-U-M-A-X-IL-15.

Q. And HuMax-IL 15 is also known as Amgen 714, correct?

A. That's correct.

Q. And then Exhibit 1018 has a second antibody 404E4, correct?

A. That's correct.

Q. And they operate -- they bind by different mechanisms; is that right? Or excuse me. Let me say that again. They inhibit the IL-15 pathway by different mechanisms, correct?

A. That's correct.

Q. One binds to IL-15. That's Amgen 714, correct?

A. Binds IL-15 at the site that IL-15 interacts with gamma --

Q. And then --

A. -- receptor.

Q. -- 404E4 binds to the IL-15 receptor, correct?

MR. MILLS: Objection to form.

A. So on page 1579 of that reference, on the left-hand column in the middle of the second paragraph, it says: Antibody 404E4 represents a classical inhibitory antibody that competes with IL-15 receptor alpha for the binding to IL-15. So what that's saying is that 404E4 binds to IL-15 at the alpha interaction site.

BY MR. FELDSTEIN:

Q. Okay. So both antibodies bind to IL-15, just different epitopes of IL-15; is that correct?

A. That's correct.

Q. Okay. Thank you. And as shown in Figure 1C, even though they bind to different epitopes of IL-15, they both inhibit IL-15-induced T cell proliferation, correct?

MR. MILLS: Objection, form.

A. Right. Both antibodies in this in vivo proliferation assay seem to reduce the -- the proliferation I- -- IL-15. They reduced to IL-15-induced proliferation.

BY MR. FELDSTEIN:

Q. And the --

A. It then ends at in vivo assay.

Q. And they just do so with different affinities, basically different IC50s?

MR. MILLS: Objection, form.

A. And so back to Page 1579 of that exhibit, left-hand column, third paragraph, the -- the difference between monoclonal antibody 146 beta 7 and 404E4 IC50 values, that's the me- -- the measurement of inhibition concentration that inhibited 50 percent, values observed in proliferation inhibition experiments taking into account that their affinity for IL-15 is comparable, it says there.

So their affinity for IL-15 was comparable. Figure 1C, the one -- that's the one that you're referring to, and -- and that's what that's talking about, that the affinity for those two antibodies appear to be the same.

BY MR. FELDSTEIN:

Q. And so notwithstanding the binding is different epitopes, biologically the net effect of inhibiting IL-15-induced T cell proliferation, the net effect is the same accounting for the affinities, correct?

MR. MILLS: Objection to form, incomplete hypothetical.

A. Well, it's -- it's -- it's different than that. So reading on in that same location, you start here in that just -- just after it says Figure 1C there, it says: IL-15 binds to the IL-15 receptor alpha chain with high affinity, and a receptor blocking antibody and like 404E4, thus exhibit needs to exhibit a high affinity or to be used at a very high concentration to be effective. Antibody 146B7 may act more potently, as it does not need to compete with IL-15 for the IL-15 receptor alpha binding, and solely needs to interfere with the IL-15 receptor alpha gamma assembly.

And this hypothesis was supported by experiments where monoclonal antibody 146B7 was shown to be much more efficacious in inhibiting IL-15-induced effects. And that's referring to

Figure 1C.

So this is saying that these antibodies can bind IL-15, and they're doing it in different places, and because it's different, they have different effects. One would need to be administered at a high concentration. One doesn't have to be administered at a high conc- -- concentration. And one is more efficient than the other.

BY MR. FELDSTEIN:

Q. So I'm not sure that I follow what you're saying consistent with the reference. What I understood the reference to say is both antibodies inhibit IL-15-induced T cell proliferation. Do we agree with that?

MR. MILLS: Objection to form.

A. Well, do they inhibit it in -- is it -- is it changed when you administer one of these antibodies? I -- yes, it is, but that change is different depending on the concentrations and the antibody that's used. So no, they're not inhibiting the proliferation in the same way.

BY MR. FELDSTEIN:

Q. Okay.

A. Or at the -- in the -- to the same

extent.

Q. Okay. I'm trying to just do it in baby steps, okay? Question Number 1: Does Exhibit 2018 -- excuse me, 1018, report that both antibodies inhibit IL-15-induced T cell proliferation?

(Exhibit 2018 introduced.)

MR. MILLS: Objection, form.

A. I'll -- I'll continue reading in that paragraph to answer your question.

BY MR. FELDSTEIN:

Q. Okay.

A. Okay. Because I think the answer is spelled out here. It says at the -- on the left-hand column on page 1579, at the bottom of that column: In another type of experiment in which IL-15 was added to cells prior to addition of the antibodies, monoclonal antibody 404E4 did not block IL-15-induced proliferation in concentrations up to 10 micrograms per ML, comma, whereas antibody 146B7 inhibited efficiently with a similar IC50 as in experiments where monoclonal antibody 146B7 was pre- -- preincubated with IL-15.

I think that answers your question.

Q. I'm not sure it does.

Looking at Figure 1C of Exhibit 1018,

does Figure 1C of Exhibit 1018 show that both antibodies inhibit IL-15-induced T cell proliferation?

MR. MILLS: Objection, form.

A. I think you're looking for an answer of -- with either one of these antibodies, is IL-15 proliferation inhibited, yes or no?

And the answer is yes. With both antibodies, they're inhibited, but they're -- that inhibition is a very different one from the other and does not -- is remarkably different; and it's explained, kind of, in this paragraph on the left-hand side about how they're similar and then how they're different.

Q. And with respect to the difference in terms of affinity, the suggestion in Exhibit 1018 is that for a lower affinity antibody or a lower affinity effect, use a higher concentration of the antibody, correct?

MR. MILLS: Objection, form.

A. That's what I believe the author is saying, that it would require -- to attain the same amount of activity, it would be required to have a high concentration to have the same effect.

BY MR. FELDSTEIN:

Q. And that's not some novel insight for Exhibit 1018. It's routine that if you have a lower affinity drug compared to a higher affinity drug, you just use more of the lower affinity drug to get equal effect, right?

MR. MILLS: Objection to form, incomplete hypothetical.

A. Yes. That would be a strategy for overcoming the inefficiency.

BY MR. FELDSTEIN:

Q. I'm going to move on to Exhibit 1049, which I think should also be in your binder.

(Exhibit 1049 introduced.)

A. I'm there.

BY MR. FELDSTEIN:

Q. And this is a 2003 paper on HuMax-IL-15, the same antibody that we saw earlier in Exhibit 1018, correct?

A. That's correct.

Q. And also known as Amgen 714?

A. That's correct.

Q. And what Exhibit 1049 reports is the use of HuMax-IL-15 in rheumatoid arthritis patients, correct?

A. That's correct.

Q. And it reports: Substantial improvement in disease activity after administering Amgen 714, correct?

A. That's what it says in the "Results" section there.

Q. Okay. And the "Results" section also says that HuMax-IL-15 was tolerated -- excuse me, was well-tolerated clinically, comma, with no significant effects on T cell lymphocyte subset and natural killer T cell numbers.

(Reporter clarification.)

BY MR. FELDSTEIN:

Q. With no significant effects on T cell lymphocyte subset and natural killer cell numbers.

A. I see that those words are there, yes, uh-huh.

Q. And those are good things, well-tolerated with no significant effects on T cell -- excuse me, T lymphocyte subset and natural killer cell numbers, correct?

MR. MILLS: Object to form.

A. That's what it says, yes.

BY MR. FELDSTEIN:

Q. Can you turn to Exhibit 1050 in your binder?

(Exhibit 1050 introduced.)

A. I'm there.

BY MR. FELDSTEIN:

Q. What is Exhibit 1050?

A. This is a snapshot from the website called ClinicalTrials.gov. The purpose of this website is to provide information on trials that have been conducted or are ongoing. It's a requirement that trials be registered at this site so -- primarily for where patients would be able to find clinical studies and participate in them.

Q. Is it a requirement for clinical trials globally or just clinical trials that are being conducted in the U.S.?

A. It's for -- certainly for clinical trials that are under an IRB in the United States, but when we look at, you know, what's listed here, there's trials from all countries in the world. I don't know about other countries.

Q. Are you aware of separate government reportings of clinical trial information?

A. I don't know whether there is or there is not.

Q. You're not familiar with --

A. Yeah. I'm just not --

Q. You're not familiar with one in Australia, for example?

A. Just not one that I had an occasion to come across.

Q. Okay. Exhibit 1050, there's no report that Amgen 714 was not effective in rheumatoid arthritis, correct?

A. If you're asking about this specific exhibit, there's nothing in this -- this information, and it's really not the purpose of this type of website to provide all that results information. This is information that there's a study that's occurred or is ongoing, and so it's not that -- it wouldn't be anticipated by someone looking at this website to find the results of a study.

Q. And just to --

A. And they haven't listed the results of the study.

(Exhibit 1051 introduced.)

BY MR. FELDSTEIN:

Q. And just for completeness, Exhibit 1051, there's also no indication in there that Amgen 714 couldn't have efficacy in severe psoriasis subjects, correct?

A. Well, in this study, in this reference, we're given a clue that there was something amiss going on, and the clue is that in Exhibit 1051, on the second page, that the actual enrollment of this study was 22 patients, and at the top of that page, it says that they had intended to enroll 66 patients.

So knowing what, you know, we know about studies, there's something going on to give you a clue to dig a little bit deeper when they stop enrollment with only a third of the patients.

Q. But to be clear, Exhibit 1051 doesn't indicate that whatever issue there may or may not have been, the issue was efficacy, correct?

A. It doesn't tell us why the study was stopped short.

Q. Okay. Move on to Exhibit 1052.

(Exhibit 1052 introduced.)

BY MR. FELDSTEIN:

Q. What is Exhibit 1052?

A. 1052 is entitled "Safety and Efficacy of AMG 714 in adults with celiac disease exposed to gluten challenge: A Phase II(a), randomized, double-blind, placebo-controlled study."

Q. And Exhibit 1052 does have results in

it, correct?

A. On the third page, it says under "Interpretation": The primary endpoint, comma, change in the VHCD ratio from baseline to 12 weeks of treatment in patients with celiac disease undergoing gluten challenge, was not significantly different between placebo and AMG 714 at either the 150 milligram or 300 milligram. Effects on intracellular [sic] lymphocyte density and symptoms suggest that further research with AMG 714 may be warranted in patients with non-responsive celiac disease.

Q. And you may have read that wrong. It's not "intracellular," it's "intraepithelial," correct?

A. I'm sorry, "intraepithelial lymphocyte density."

Q. What's the relevance of intraepithelial lymphocyte density to celiac disease?

MR. MILLS: Objection to form and scope.

A. Well, the in vivo, in life in patients, hope that would be that the lymphocytes, the activated T cells that are accumulating there would be changed, right? And the thing that's happening is that whether they were changed or not, it didn't

matter because it didn't change the lining of the -- of the intestine. The patients with celiac disease have a thing called villus height to crypt depth, and that's a measure of their disease activity. That's what they mean by VHCD. That didn't change any throughout this process.

Is that what you're talking -- that this is an in vivo study?

BY MR. FELDSTEIN:

Q. No. Sticking with what I asked you about, the intraepithelial lymphocytes, is it desirable to minimize increases therein in celiac patients?

MR. MILLS: Objection, form, scope.

BY MR. FELDSTEIN:

Q. Do you know?

A. Well, I'm not a gastrointestinal physician, but it's something that they mentioned here, so I suppose that it was important to them, but I -- I'm not an expert in that. I can't speak to that.

Q. And you referred to the villus height to crypt depth. What is that?

A. That's mentioned over on the second page of that just across the -- this is their -- the

primary endpoint, primary efficacy endpoint was the percentage change from baseline to Week 12 in villus height to crypt death.

So in the intestine, there is villi, little projections up and down, and those get shortened, which reduces the surface area in the intestine, and is a measure of their -- their disease.

Q. What's a primary endpoint in a clinical study?

A. That's the measure that we're going to use to decide if this drug or test article works or not.

Q. And what's a secondary endpoint?

A. That would be a measurement that might be a signal that the primary thing is doing what it's supposed to be doing, it's not happening by chance.

Q. And is that the only meaning to get from a secondary endpoint on whether or not the primary is by chance or not?

A. Secondary endpoint, you know, one of the other things that you might look at that is, is it -- it's a signal that -- of the things that you might be expecting to happen. They might be

expecting for the intraepithelial lymphocytes to change.

Q. What you're expecting if the drug works is this endpoint, right?

MR. MILLS: Objection to form.

A. The secondary endpoint doesn't tell us if the drug works.

BY MR. FELDSTEIN:

Q. And I just -- I'm trying to -- maybe I didn't ask it well, but you said what you would expect. You're describing the secondary endpoint based on what you'd expect; and I didn't understand if, when you said what you expect, is what you expect if the drug is working or what you expect if the disease is just progressing or something else.

Can you explain what you meant by "expect" in the context of the secondary endpoint?

MR. MILLS: Objections to form and scope.

A. In -- in speaking generally about clinical trials, we put in secondary end points to give us clues about if what we're seeing in the clinic is, you know, headed in the right direction for efficacy. We make that determination by the primary endpoint, this is how we're going to decide

if this drug wins or not. I suppose second place for that is a secondary endpoint.

It -- it wouldn't -- you know, and if you -- let me bounce back to Exhibit 1049. You'll see that while Baslund describes substantial improvements in disease activity as you've read previously. Baslund also -- what -- what Baslund is showing is that in cell proliferation studies, he's talking about here in vitro, HuMax-IL-15 was doing what they were hoping it would do, right? It was -- they were hoping that it would suppress activated T cells in -- in culture and what they -- that's what they saw.

But what he also says is when they -- they take it and they're using it for a different indication; in this case, it's the same antibody in celiac disease, which is a condition that -- that there was obvious interest, he didn't see any efficacy of that, didn't make any difference in the -- in the condition. The -- the VHCD didn't change after therapy.

Q. Don't want to cut you off, but are you done?

A. I -- yes, I'm...

Q. Exhibit 1052 reports efficacy --

statistically significant efficacy in two secondary end points, correct?

MR. MILLS: Objection to form, scope.

BY MR. FELDSTEIN:

Q. And I can point you there if you're not familiar with that.

A. Sure.

Q. If you're on Page 2 of 4, The Findings. And a little bit more than halfway down, there's a line that begins -- there's a line that begins "significantly," and then the first full sentence begins: The density of CD3 positive intraepithelial lymphocytes increased in all groups with smaller increases in the 300-milligram group. And then it has some data versus placebo, and it has a P value of .03. Do you see that?

MR. MILLS: Objection to form, scope.

A. Okay.

BY MR. FELDSTEIN:

Q. So do you agree that Exhibit 1052 is reporting statistically significant effect of Amgen 714 at 300 milligrams on a secondary endpoint of intraepithelial lymphocyte density?

MR. MILLS: Objection to form, outside the scope.

A. It -- it doesn't say that this was a secondary endpoint or -- or what they were considering, except that it wasn't the primary endpoint, but it does say the density of CD3+ intraepithelial lymphocytes increased in all groups with smaller increases in the 300-milligram group versus placebo.

BY MR. FELDSTEIN:

Q. I thought we read in the --

A. Yeah.

Q. -- section above that, the CD3+ intraepithelial lymphocyte density was a secondary endpoint in the same page, the prior section --

MR. MILLS: Objection to form, outside the scope.

BY MR. FELDSTEIN:

Q. -- isn't that right?

A. Oh, you're correct. And the paragraph above it says: Secondary end points were CD3+ intraepithelial lymphocyte density.

(Interruption by the reporter for clarification.)

A. Secondary end points were CD3+ intraepithelial lymphocyte density.

BY MR. FELDSTEIN:

Q. And so Amgen 714 300-milligrams showed statistically significant effects in that secondary endpoint relative to placebo according to Exhibit 1052, correct?

MR. MILLS: Objection to form, outside the scope.

A. They mention that it's a nominal difference, right?

BY MR. FELDSTEIN:

Q. P.03 is statistically significant, correct?

A. Right. Then -- but before that, they mention nominal.

Q. Right. And I'm just asking about P.03 is statistically significant, correct?

A. We -- we consider that statistically significant.

Q. Okay. And then the next sentence refers to clinical symptoms, says: Clinical symptoms were ameliorated with Amgen 714 treatment between baseline and week 12 particularly diarrhea as measured by BSFS, and then it provides P value .01 for the 150-milligram group versus placebo, and a P value of .0002 for the 300-milligram Amgen 714, correct?

MR. MILLS: Objection to form, outside the scope.

A. Yes, that's what that says.

BY MR. FELDSTEIN:

Q. And so Exhibit 1052 is reporting clinically -- excuse me. Start again.

Exhibit 1052 is reporting statistically significant effects for Amgen 714 on the secondary endpoint of clinical symptoms, correct?

MR. MILLS: Objection to form, outside the scope.

A. Clinical symptoms relative to -- to diarrhea, right.

BY MR. FELDSTEIN:

Q. And that's the secondary endpoint?

A. That's -- that's the secondary endpoint.

Q. Okay.

A. But I maintain that, you know, the -- the primary endpoint is how we decide whether something works or not.

Q. Okay.

A. And it's interesting that there's secondary end points that meet their goal, but in the end, the -- the conclusions were that it -- this product didn't work for celiac disease.

Q. Well, the conclusion was that the effects on intraepithelial lymphocyte density and symptoms suggest that further research of Amgen 714 may be warranted in patients with nonresponsive celiac disease. It wasn't that it should be abandoned, it should be pursued, in fact, right?

MR. MILLS: Objection, form.

BY MR. FELDSTEIN:

Q. You looking for something, Doctor?

A. I'm -- I'm -- yeah, I'm looking -- I thought that I had -- I think -- I thought I had read the published report about this study somewhere, and I'm just not able to find it right now.

Q. I'm not sure which one you mean, so...

A. I'm sorry. The celiac --

Q. No, I -- no, I think I understand.

A. The celiac.

Q. I think I understand what you're asking, but I'm not sure what reference you mean.

A. Yeah, I...

Q. Anyhow, can we just stick to Exhibit 1052?

A. Sure. Is there a question on that that I can answer?

Q. Yeah. The question was that Exhibit 1052 suggests continuing to develop Amgen 714 for nonresponsive celiac disease, correct?

MR. MILLS: Objection, form.

A. That was their -- their conclusion at the end of page 3 of 4.

BY MR. FELDSTEIN:

Q. Okay.

A. And I'll say that -- that when things are not successful, that's often the conclusion, gosh, we should continue to do research on this. You know, it's a science experiment, so, you know, continue to do more science experiments. It's not an unusual conclusion.

Q. So you don't take them at their word?

MR. MILLS: Objection, form.

A. I just think it's a hopeful statement.

BY MR. FELDSTEIN:

Q. When you submitted your declaration, Exhibit 1046 -- excuse me. When you had submitted your declaration, 1047, had you appreciated that Exhibit 1052 reported statistically significant effects of Amgen 714 for two secondary end points?

MR. MILLS: Objection, form.

A. I certainly considered that, but it

didn't meet the primary endpoint, and that's the measure that we use to determine whether something works or not.

BY MR. FELDSTEIN:

Q. But you knew and had your mind that Exhibit 1052 had reported statistically significant effects on two secondary end points, yes?

A. I -- I said yes to that.

Q. Okay. Can we move on to Exhibit 1016, which also should be in your binder?

(Exhibit 1016 introduced.)

A. Okay. I'm there.

BY MR. FELDSTEIN:

Q. And this is a 2006 publication, correct?

A. That's correct.

Q. Can you turn to Page 500. It's the last page of the text before all the references.

MR. MILLS: Objection, form.

BY MR. FELDSTEIN:

Q. Okay. Page 500.

MR. MILLS: Objection to form.

BY MR. FELDSTEIN:

Q. Is it 600?

A. 600.

Q. 600, okay. My copy's not -- okay. You

with me on page 600?

A. I'm there.

Q. So on the left-hand side under the heading: Targeting -- excuse me, Therapeutic Targeting of IL-15 Or Its Receptor. A little bit more than halfway down, it says: The administration of antibody specific for IL-15 has been effectively used in mouse models of autoimmune disease, including psoriasis, period. Furthermore, such an antibody had shown efficacy in a Phase I, II excuse me, I/II clinical trial involving patients with rheumatoid arthritis.

Right, you're familiar with that?

A. I see that, yes.

Q. And so by 2006, persons of ordinary skill knew that an antibody specific for IL-15 had shown efficacy in a Phase I/II clinical trial for rheumatoid arthritis, correct?

MR. MILLS: Objection, form.

A. Well, I think that persons of the skill would -- would understand that, but in my reply deposition -- declaration, Dr. Damsky mixed that up. And part of my response is trying to set the record straight on that.

BY MR. FELDSTEIN:

Q. Okay.
A. The --
Q. And then -- I'm sorry. Go ahead.
A. The -- you know, Dr. Damsky -- this is in my Paragraph 16 of my Reply Declaration. Dr. Damsky, you know, argues that this publication referenced MiK-Beta-1.
(Interruption by the reporter for clarification.)
A. M-I-C -- M-I -- I'm sorry, M-I-K-Beta-1.
Specific for IL-15 receptor data. CD122 was in Phase I/II clinical trials. And that's not what Waldmann said, and he -- he's quoting Waldmann, and I think it's important to make that distinction, and it's -- it's an important distinction to make. He's -- he's -- Dr. Damsky misstated that.
Q. In -- still on Page 600 of Exhibit 1016, in the right-hand column, the second full sentence begins: In an effort to test. Do you see that?
A. Yes, I see that.
Q. And so by 2006, a person of ordinary skill would have known that clinical trials of MiK-Beta-1 were being initiated in patients with rheumatoid ars- -- arthritis, among other

conditions, correct?

MR. MILLS: Objection to form.

A. Right. This -- this explains that a -- a clinical trial of MiK-Beta-1 had not been initiated, but would be in the process of being initiated.

BY MR. FELDSTEIN:

Q. Okay. So as of 2006, the report was that one IL-15 antibody had already completed Phase I/II clinical trials for RA, and one -- a different one being initiated in the RA patients, correct?

MR. MILLS: Objection, form.

A. Let me be very precise about that, which is that what -- what Waldmann says is that Phase I/II clinical studies were underway with an antibody that was directed at IL-15. Waldmann says that MiK, M-I-K, Beta-1, which is an antibody directed at the beta receptor -- not IL-15, but at the beta receptor -- was going to be entering clinical trials.

And this is an important distinction because Dr. Damsky didn't make the distinction between antibodies that are directed at IL-15 and antibodies that are directed at the, in this case, beta receptor.

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BY MR. FELDSTEIN:

Q. Okay. Thanks for clarifying that.

Going to move on to Exhibit 1012, which I think is also in your binder.

(Exhibit 1012 introduced.)

BY MR. FELDSTEIN:

Q. Another Waldmann publication on MiK-Beta-1, this from one 2013.

A. I'm there.

Q. What's being studied in the Phase I trial in Exhibit 1012?

Well, do you even -- one step at a time: What is a Phase I trial?

A. A Phase I trial is, in the sense of, you know, all drug development, the first trials that are done in humans to look at mostly toxicity. They're going to give doses that might be higher than they think or work up the doses that are higher than they think to identify what are the side effects of this -- of this drug. What they -- what they are not are studies to look at dose. They're not studies to look at efficacy.

Q. Okay. And what is the Phase I study in Exhibit 1012, a Phase I study, what's being studied?

A. This is a study of humanized version of the MiK-Beta-1 antibody.

Q. In what kind of patients?

A. These are patients with, the title tells us, "T-cell large granular lymphocytic leukemia."

Q. What is T-cell large granular lymphocytic leukemia?

A. I'm just a dermatologist and not a hematologist, so I'm just going to call that a leukemia, a type of blood cancer.

Q. Okay. Is it an autoimmune disease?

A. Well, it's a type of cancer that the primary cell type is of a T cell, so I don't think that it would be characterized as a autoimmune disease as much as it is a cancer.

Q. And the T cell is a cancerous T cell, not a normal T cell, correct?

A. Again, I'm not a hematologist, but they call it leukemia. That's a type of blood cancer.

Q. Is it your understanding that Exhibit 1012 reports that there was no efficacy found with humanized MiK-Beta-1 in these leukemia patients?

MR. MILLS: Objection, form. Objection to scope.

(Witness reviews document.)

A. The -- in the discussion on page 482, on the right-hand column, a couple sentences down, it starts with: Several factors may be responsible for this lack of efficacy, including that the duration of the receptor blockade achieved by a single-dose administration of human MiK-Beta-1 may not be sufficient.

So it's my interpretation that it was not effective, and he's listing the reasons for some of that here in this paragraph.

BY MR. FELDSTEIN:

Q. Does that make sense, that single-dose administration may be a factor in not showing efficacy?

A. Of all the reasons that that could be, that could be one of those reasons. I'd agree.

Q. And a single-dose administration, part of the way a Phase I study may be done where it's checking for safety signals and maybe PK?

A. Right. It wouldn't be unusual for a Phase I to have just a single dose.

Q. But most biologics, most drugs treat with more than a single dose when you're trying to treat a patient?

MR. MILLS: Objection, form.

A. I'd say it's more common to have more than one dose, but there are drugs that just require one doze.

BY MR. FELDSTEIN:

Q. Okay. Can you turn to the next paragraph on page 482? It says: The LGL cells in the monoclonal phase of disease did not produce nor require --

The same page, the next paragraph.

A. On the left-hand column?

Q. On the right-hand column, page 482, the next paragraph, the last full paragraph on page 482 on the right.

A. Okay.

Q. It begins "The LGL cells." Do you see that?

A. Right.

Q. "The LGL cells in the monoclonal phase of disease did not produce nor require IL-2 or IL-15 for their survival." Do you see that?

MR. MILLS: Objection, form.

A. I see that it says that, yes.

BY MR. FELDSTEIN:

Q. Is that different, to your

understanding, than the CD8 T cells that are involved in autoimmune responses?

MR. MILLS: Objection, form, scope.

A. You know, I trust what they say here, that these cells don't require IL-15 or IL-2 for their survival. It's -- that's different from what the -- what our NK cells and CD8+ T cells require in vitiligo.

BY MR. FELDSTEIN:

Q. They are IL-15 dependent, correct?

A. That's our understanding, yes.

Q. Okay. Can we turn to Paragraph 32 of your declaration. It's Exhibit 1047.

MR. MILLS: We've been going about an hour. Are you changing direction?

MR. FELDSTEIN: It's still MiK-Beta-1. It's my last set of questions on MiK-Beta-1.

MR. MILLS: Maybe ten more minutes?

MR. FELDSTEIN: Yeah.

MR. MILLS: Okay.

A. You're on page 32?

BY MR. FELDSTEIN:

Q. Paragraph 32, sorry. Page 18, Paragraph 32.

(Witness reviews document.)

A. Okay. I've got it here.

BY MR. FELDSTEIN:

Q. In the last sentence of the paragraph, you say: However, a review of ClinicalTrials.gov confirms that the only clinical trial of MiK-Beta-1 was a Phase I study that Waldmann 2006 reported had already been completed. Right?

A. Right, that's what it says.

Q. What's the relevancy of that statement to your opinions? Why does that matter?

A. It matters because Dr. Damsky selectively ignored information that's available to him in characterizing that this -- an anti-CD122 antibody would be effective. He's skipped over that and ignored the fact that MiK-Beta-1 had been studied in this leukemia trial previously and it was not brought any further. So it's -- it's quite clear that, for whatever reason, there was not going to be a therapy that people wished to continue to pursue in that leukemia indication.

It's also relevant in that he's talking about, as I quoted, an effort to test a hypothesis. The use of these is not -- is uncertain that they would work. In fact, there's not any evidence in any of the references that we've covered that

MiK-Beta-1 is something that's going to come to my clinic in Keller, Texas. Right? It's not going to be something that becomes a therapy because there's just no evidence for that working based on any of this literature, anything that I can find.

So Dr. Damsky's ignored some of those reports, and I think it's important to set the record straight about the real efficacy of -- of an antibody to CD122.

Q. To come to your clinic in Keller, Texas, it has to be FDA approved, correct?

A. It should be, and it should be FDA approved for that indication.

Q. Okay.

A. It should tell me what the risks are and what the benefits can be, and for -- a practitioner needs to be able to communicate that to a patient, and we decide that -- that the risks are worth the good that might come from it.

Q. And that level of proof is something you're factoring into the opinions that you're providing in this case; is that fair?

MR. MILLS: Objection, form, mischaracterized the testimony.

A. I'm talking to you about the -- the

level of safety and efficacy that's needed for me to use it in the clinic, and that's a bit different than what's being done in these Phase I/II clinical trials, whether something works or something in the clinical trials is judged, again, by the primary endpoint that we talked about.

The studies that we've reviewed in this case, Dr. Damsky's given his responses are, haven't shown us that an antibody like MiK-Beta-1 that targets CD122 has efficacy in any of the primary endpoints that were -- were here, and he overlooks that in his statements. I think it's important to point out that -- that there's not ever been any efficacy demonstrated in humans.

BY MR. FELDSTEIN:

Q. And is it important to demonstrate efficacy in humans for your opinions in this case?

MR. MILLS: Objection, form.

A. Well, I would hope that it -- at least for someone to say that an antibody to IL-15 or an IL-15 receptor can meet a primary endpoint in a clinical study, that's a start. It doesn't have to be FDA approved, but it has to at least meet a milestone that the investigators would say, you know, this is worthwhile moving forward. It's a

little bit gratuitous to not meet the primary endpoint, but to say, oh, well, we should continue doing research on this. If it didn't meet the primary endpoint, let's move on to something that may have a better opportunity.

MR. MILLS: Okay -- used our...

MR. FELDSTEIN: Yeah, that's fine. I didn't get where I was going, but that's fine. We can stop.

(Recess.)

MR. MILLS: Off the record.

(Recess held 2:08-2:20.)

BY MR. FELDSTEIN:

Q. So we did a little tangent from Paragraph 32 of your declaration. Can we go back to Paragraph 32?

A. Okay.

Q. And can you -- I apologize, but explain again why it's important that there was only -- why is it important to your opinions that there was only one clinical study of MiK-Beta-1, specifically the Phase I study that Waldmann 2006 reported?

MR. MILLS: Objection, form.

A. Well, let's go back to Waldmann.

BY MR. FELDSTEIN:

Q. Waldmann 2006 is Exhibit 1016.

A. And this case -- this is the Waldmann of 2006 is what's mentioned in 32.

Q. Page 600 does, in fact, mention a Phase I clinical trial involving administration of a mouse version of Mik-Beta-1 to patients with T-cell large granular lymphocyte leukemia. Top right.

(Witness reviews document.)

A. So I understand your question, you're asking me why was it important?

BY MR. FELDSTEIN:

Q. Do you want me to ask the question again?

A. Yeah, I'm sorry.

Q. Referencing Paragraph 32 of Exhibit 1047, why is it important to your opinion that there was only one clinical study of MiK-Beta-1, specifically the Phase I study reported in Waldmann 2006?

MR. MILLS: Objection to form.

A. Well, one reason it's important to point that out is that Dr. Damsky, in his declaration, had mischaracterized that there was a Phase I/II study going on with MiK-Beta. There was not a

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Phase I/II study going on with MiK-Beta that Waldmann's talking about, right? He's not talking about that. He's talking about HuMax-IL-15, that's an antibody directed against IL-15. MiK-Beta-1 is an antibody directed against the beta receptor.

And the reason it's important to point this out is that this is really a critical difference, the direction of these antibodies that have been -- that Damsky's confused is an antibody that's directed against IL-15, an antibody that's directed against the beta site. He's overlooked the point that there was a study -- there was a Phase I, it turns out. Waldmann doesn't specifically, you know, point to this in clinicaltrials.gov, but it was known in the art. It's available on clinicaltrials.gov, but it was overlooked by Damsky in his declaration referring to Waldmann.

BY MR. FELDSTEIN:

Q. Okay. In fact, the Phase I trial of MiK-Beta-1 in Waldmann 2006 is not the only clinical trial MiK-Beta-1, right? Didn't we see in Waldmann 2013, Exhibit 1012, a different Phase I study?

A. But just looking at Waldmann 2006, he --

when he talks about MiK-Beta-1, he's mostly talking about the -- the opportunity for -- for that. I -- let me find that in his -- remind me of that exhibit.

Q. Waldmann 2006?

A. Yes.

Q. Exhibit 1012 -- correction, 1016.

A. All right. So here on Page 600, again, back -- we've -- we've read this sentence before in an effort to test the hypothesis, okay? It's a hypothesis, that the IL-15 has a role in the pathogenesis of certain immune -- autoimmune diseases. Clinical trials of MiK-Beta-1 are being initiated in patients with multiple sclerosis, rheumatoid arthritis, refractory celiac disease and HTLV-1 associated tropical spastis -- spastic paresis.

The only -- it says: Only minimal toxicity was observed in a Phase I clinical trial that involved the administration of the mouse version of MiK-Beta-1 to patients with T-cell large granular lymphocytic leukemia. And there he -- he references Number 15 -- sorry, 25, not 15.

Q. So the Phase I clinical trial involving the administration of a mouse version of MiK-Beta-1

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to patients with T-cell large granular lymphocytes, is that the Phase I study you're referring to in the last sentence of Paragraph 32 of your declaration, Exhibit 1047?

MR. MILLS: Objection, form.

A. Yes, that's the only Phase I study that Waldmann 2006 of MiK-Beta-1 refers to.

BY MR. FELDSTEIN:

Q. And you reviewed clinical trials and believe clinical trials to reported -- that that study reported in Exhibit 1016 is the only study of MiK-Beta-1, correct?

MR. MILLS: Objection to form, foundation, mischaracterizes the testimony, scope.

(Witness reviews document.)

A. The study with -- this Phase I study that he's talking about here involves a mouse version of a monoclonal antibody MiK-Beta-1 to these people. This is the only one that -- that Waldmann talks about, but we just finished discussing another trial that...

BY MR. FELDSTEIN:

Q. Are you looking for Exhibit 1012?

(Interruption by the reporter for clarification.)

BY MR. FELDSTEIN:

Q. Are you looking for Exhibit 1012?

A. Right. This is the -- the study that --

Q. Do you want separate copies of these that were out of the binder? Just -- just look at this --

(Simultaneous conversation.)

A. No, I -- I have -- I have 1012 here, but I --

BY MR. FELDSTEIN:

Q. Okay. I was just -- you flipped around so much, I was trying to help you.

A. Yeah, I'm -- the binder makes it difficult, but this is the study -- the published report of the study that is -- I'm sure is also in the ClinicalTrials.gov that -- that we've been talking about where MiK-Beta-1 is used. And this is a humanized, so this antibody is designed to be better in people than in mice. The -- the study that's mentioned in Waldmann is an antibody that's -- that comes from a mouse. It's slightly -- it's slightly different. There's a nuance, and there were -- and there were two trials in this. Had -- had Waldmann, you know, knewn -- known what was in the future, you -- he -- he probably would have

mentioned this leukemia trial also because it's his publication, but there are two trials in -- in this large cell leukemia with different -- slightly different versions of MiK-Beta-1.

Q. You say in Paragraph 32: A review of clinicaltrials.gov confirms. That's a review you conducted, correct?

A. Right, I -- I conducted a trial, a -- a review of clinical trials, yeah.

Q. A review of ClinicalTrials.gov confirms that the only clinical trial of MiK-Beta-1 was the Phase I study that Waldmann 2006 reported. That's just not accurate, is it, because as you know, there's a different study reported in Waldmann 2013, Exhibit 1012, correct?

MR. MILLS: Objection to form, mischaracterizes the testimony.

A. Let me -- let me point out what you just read because that's not correct at all. I'm talking about Waldmann 2006. I'm talking about the publication that Waldmann did, 2006, that is Exhibit 1016. What he said in there was that there was -- we just read on Page 600, a Phase I study, clinical trial that involved administration of a mouse version of MiK-Beta-1 to patients with T-cell

large granular lymphocytic leukemia, and it references Number 25. That's what he said about that. That's what Waldmann said.

Independent of Waldmann 2006 is a -- is a second trial in that same condition using a humanized version, not a mouse version as was done in the first study, but a humanized version of MiK-Beta-1, and that's the study that we've already gone over.

Q. And clinicaltrials.gov reports still other MiK-Beta-1 studies beyond those, doesn't it?

MR. MILLS: Objection, form, foundation.

A. It does, and Waldmann 2006 told us that there was going to be some there --

BY MR. FELDSTEIN:

Q. Okay.

A. -- right?

Q. And do you recall how many -- when you looked at clinicaltrials.gov, do you recall how many MiK-Beta-1 studies were reported on clinicaltrials.gov?

A. I'll have to go back to that exhibit and count them. I'm happy to do that.

Q. I -- I don't see that there's an exhibit. You don't cite any exhibit in

Paragraph 32. You just say you reviewed clinicaltrials.gov. But if you do go to an exhibit, let me know what number you're on, please.

(Exhibit 1055 introduced.)

A. So Exhibit 1055, you see at the top of that, there's a -- a search term: Human MiK-Beta-1?

BY MR. FELDSTEIN:

Q. Okay.

A. And then following that is a list of the three studies that were found in clinicaltrials.gov by doing that search.

Q. You did this search, Doctor?

A. This was -- was done by the team.

Q. "The team," being the lawyers?

A. The lawyers.

(Interruption by the reporter for clarification.)

BY MR. FELDSTEIN:

Q. The lawyers.

I'm going to mark as Exhibit 2117.

Can you mark that, please?

(Simultaneous conversation.)

MR. MILLS: I'm going to object to the document on the basis of being outside the scope.

(Deposition Exhibit 2117 marked.)

MR. MILLS: Dr. Plott's declaration is a reply, a Rebuttal Declaration. He's responding to Dr. Damsky's opinions about Waldmann 2006 and 2013, so this goes beyond the scope. The deposition is limited to discussing existing documents. I also object to the document on the basis of relevance and the lack of responsiveness.

BY MR. FELDSTEIN:

Q. Doctor, you -- some other lawyers did a search of clinicaltrials.gov for MiK-Beta-1 and came up with four studies. Do you see that on Exhibit 2117?

MR. MILLS: Objection, form. Objection, scope.

A. You know, as I've stated before, my purpose for being here today is to respond to questions you might have about this Reply Declaration. This is a new document that, you know, I've not considered in that, so I'm not able to give you an- -- anything about that.

BY MR. FELDSTEIN:

Q. You're not able to give an opinion whether there are four clinical trials listed, that's beyond your ability sitting here today,

Doctor?

MR. MILLS: So object to the question as outside the scope. This document doesn't contain any information as to the dates. It's not responsive to his declaration, which is limited to rebuttal to Dr. Damsky's opinion.

BY MR. FELDSTEIN:

Q. Can you answer the question, Doctor?

A. I'm not able to provide you a response. My re- -- my response is I -- I haven't reviewed this document. I'm not able to provide an opinion about it.

Q. Well, can you read Study Title Number 1?

MR. MILLS: Objection on the basis of scope.

BY MR. FELDSTEIN:

Q. In the record, please.

MR. MILLS: Objection on the basis of scope.

A. I -- I've given you the answer I can --

BY MR. FELDSTEIN:

Q. What question do you think you've given me the answer to?

A. I'm -- I've not reviewed this document. I'm not going to be able to provide you an opinion

about this.

Q. Can you attest to the accuracy of Exhibit 1055?

A. The accuracy is that this is a search done at 4:35 p.m. on December 5th, '23, you know, looked for the search term "Human MiK-Beta-1." I have no reason to think that it's an incomplete list of the studies that were available in clinicaltrials.gov at that time.

Q. Do you have any personal knowledge that the search terms were put in correctly?

A. I can see the search terms. I see that they're put in correctly for identifying Human MiK-Beta-1.

Q. Can you even testify from personal knowledge that this is actually a printout from clinicaltrials.gov and not a document that was mocked up?

MR. MILLS: I object to the question. Dr. Plott is here as an expert. He's allowed to rely on materials that experts in his field would reasonably rely upon.

A. Are you suggesting that, you know, this is fabricated somehow?

BY MR. FELDSTEIN:

Q. I'm asking what your personal knowledge is of Exhibit 1055.

A. My -- my knowledge of this is that this is an accurate search for Human, okay, HU, MiK-Beta-1.

Q. And what field was Human MiK-Beta-1 entered into to conduct the search?

A. It entered into clinicaltrials.gov into the -- into the search engine that the U.S. Government maintains.

Q. Have you personally ever searched on clinicaltrials.gov?

A. Of course I have.

Q. And do you understand that there are different fields to search?

A. You can use different search terms.

Q. My question is --

A. So another search term might be not -- not using HU. Another search term might be MiK-Beta-1, and that might give you different results.

Q. My question was do you have an understanding of the different search fields to use in clinicaltrials.gov?

A. Yes, there's -- there's subjects,

there's authors, there's compounds. Is that what you're referring to?

Q. Yeah, and what field was searched for Exhibit 1055?

A. This is for the compound Human MiK-Beta-1.

Q. You have personal knowledge that it was put into a field called compound?

A. I don't have that information on -- on this.

Q. So, then, why did you say it was for compound in response to my question about what field was searched?

A. Because the compound is human MiK-Beta-1.

Q. I asked you what field was searched.

A. It doesn't tell me what field was searched.

Q. Okay. And so do you -- okay. Move on.

Do you think that there's a field called "compound" in clinicaltrials.gov?

MR. MILLS: Objection, form.

A. I -- off the top of my head, I don't know.

BY MR. FELDSTEIN:

Q. Can we go in your declaration to Paragraph 14, page 6 in Exhibit 1047?

Are you there?

A. Yes.

Q. You have a heading about "Inhibitors of IL-15 or the IL-15 Receptor Were Not Recognized to Have Class-Wide Efficacy for Treating Autoimmune Conditions," correct?

A. That's correct.

Q. Are you aware to what extent class-wide efficacy for IL-15 or IL-15 receptor inhibitors was reported in literature?

MR. MILLS: Objection to form and scope.

A. My comments are about Dr. Damsky's testimony, and he has -- he's waffled on some of that where he said he thinks there's a classified effect, but then he's pointing to other places in his references where there's not a classified effect. And in reviewing his -- his testimony and his references, there's -- the literature repeats over and over that there's not a class-wide effect for inhibition of IL-15 or IL-15 receptors.

BY MR. FELDSTEIN:

Q. So, in your opinion, the literature does not report class-wide efficacy for inhibition of

IL-15 or IL-15 receptors? That's what you're saying; is that correct?

MR. MILLS: Objection to form, scope.

A. Yes, I'm saying actually that IL -- the literature is saying that there's actually the opposite of that where it's, for example, in HuMax-IL-15 does one thing in vitro, in the laboratory, and it does another thing in the clinic.

Finch documents an antibody to the alpha receptor of IL-15 that does one thing in one place and another thing in another place. There's pretty extensive representation in the literature that we've cited where there's not a classified effect.

BY MR. FELDSTEIN:

Q. Can you turn to page 37 of your declaration, Paragraph 64?

You're addressing assays in Paragraph 64, among other things, correct?

(Witness reviews document.)

A. I'm really just repeating what Dr. Damsky said about in vitro IL-15 assays.

Is there a -- a question about that?

BY MR. FELDSTEIN:

Q. My question is how much familiarity or

expertise do you have with assays for inhibition of IL-15 or IL-15 receptor?

A. If you're -- if you're asking about understanding what's read on the page, I understand what's read on the page. I have specific training and knowledge about that, but as we've discussed when we started about the team approach with the different individuals of other specific purposes, if you needed me to go to the bench and do a proliferation assay, I'd call in another team member.

Q. What's your understanding of the state of the art as of 2017 for assays to measure inhibition of IL-15 or IL-15 receptor?

MR. MILLS: Objection to form, outside the scope.

A. Well, I think that's the question Dr. Damsky is trying to answer here as well is, well, what -- what makes an IL-15 inhibitor. Now, is it proliferation assay? Well, maybe it's the phosphorylation assay. Well, maybe there's, Dr. Damsky says, no absolute standard. And, you know, you just have to do a little science experiment to figure that out, you know.

That's part of the problem, is that

this -- this whole patent requires us to do a lot of experimentation, and it's unpredictable how that's going to work out in order to figure out if there is a molecule that's producing an IL-15 inhibition.

BY MR. FELDSTEIN:

Q. Respectfully, Doctor, I don't think that that's responsive to what I asked you.

My question is: What is your understanding of the state of the art as of 2017 for assays to measure inhibition of IL-15 or IL-15 receptors?

MR. MILLS: Objection to form, scope, asked and answered.

A. Right, I think that I answered your question.

Now, one of those assays would be the proliferation assay, as Dr. Damsky's pointed out. Another one might be this phosphorylation assay. There's -- as Dr. Damsky says, there's no absolute standard. We can put our finger on this one thing.

Part of the reason that there's no absolute standard is that there are antibodies that bind to different parts. Some of them bind to different parts of the IL-15. Some of them bind to

different receptors. So there's not one thing that we point to.

BY MR. FELDSTEIN:

Q. Can you explain to me what was understood about proliferation assays as of 2017?

MR. MILLS: Objection to form, scope, asked and answered.

A. Are you asking about a particular part of the proliferation assay? That's a question a mile wide.

BY MR. FELDSTEIN:

Q. No, just in general: What was known about proliferation assays for IL-15 as of 2017?

MR. MILLS: Objection to form, scope, asked and answered.

A. One of the things that would be understood about that is that IL-15 is trying to -- you know, IL-15 stimulates the T lymphocytes -- activated T lymphocytes to proliferation, and so if you were to have an assay that you added IL-15, it caused self-proliferation, but then you put in an antibody and it inhibited that proliferation, then you say: Ah, maybe this is important. Let's do some other studies and figure out, you know, what this means.

Q. And were proliferation assays for IL-15, as you described, routinely used as of 2017?

MR. MILLS: Objection to form, scope.

A. Yes, they're used in most of these studies that we've referenced.

BY MR. FELDSTEIN:

Q. Okay.

MR. FELDSTEIN: This one.

BY MR. FELDSTEIN:

Q. I'm going to hand you Exhibit 2018, Doctor. This is something in Dr. Damsky's report that I trust you've considered; is that right?

A. Again, I don't have a list of his exhibits, but I'll accept that this was -- this was there.

Q. Do you have an understanding of the general subject matter of Exhibit 2018?

MR. MILLS: Objection as to scope.

A. This deals with delayed-type hypersensitivity, and as a clinician, that's something I see in the clinic. I'll do the best to answer your questions.

BY MR. FELDSTEIN:

Q. It refers to an antagonist IL-15 mutant/Fc gamma 2a protein.

MR. MILLS: Objection, scope.

BY MR. FELDSTEIN:

Q. Correct?

A. That's what's in the title.

Q. Do you have an understanding of what that is?

MR. MILLS: Objection, scope.

A. It tells us in the abstract here that the receptor site-specific antagonism IL-15, this mutant has a protein that's kind of grafted onto it to change the IL-15 molecule that results in prolonged half-life in life, in an animal.

BY MR. FELDSTEIN:

Q. Is this mutant/Fc gamma 2a protein, would it be termed a "mutein"?

MR. MILLS: Objection, scope.

(Witness reviews document.)

A. Well, a brief, just scanning the article, I don't see that the authors called that molecule that name, but it sounds like it would fit, doesn't it?

BY MR. FELDSTEIN:

Q. Can you turn to Exhibit 1001, the '505 patent?

(Exhibit 1001 introduced.)

A. I'm there.
BY MR. FELDSTEIN:
Q. Turn to Column 40.
A. Okay.
Q. At lines 23 to 24, there's a citation to Kim, Y.S.
MR. MILLS: Objection, scope.
BY MR. FELDSTEIN:
Q. Do you see that?
A. Right, Kim, Y.S.
Q. That's the same as Exhibit 2018, correct?
MR. MILLS: Objection, scope.
A. Yes.
BY MR. FELDSTEIN:
Q. And Kim, Y.S. -- Kim -- the Kim reference in Exhibit 2018, you understand, is incorporated by reference into the specification of the '505 patent?
MR. MILLS: Objection, scope.
A. Yes, I understand that.
BY MR. FELDSTEIN:
Q. Can you turn to -- it should be in your binder -- Exhibit 2028?
(Exhibit 2028 introduced.)

A. I don't have 2028.
BY MR. FELDSTEIN:
Q. I have a copy.
A. If you have a copy. Thank you.
Q. Are you familiar with Exhibit 2028, Doctor?
A. Yes, I see it.
Q. It's a patent that was filed like 2014. Do you see that on the left-hand side, PCT Filed?
MR. MILLS: Objection, scope.
A. Right. It says June 27th, 2014.
BY MR. FELDSTEIN:
Q. And if you go in to Column 2, which is on the sixth page of the document, the patent is addressing fusion proteins, correct?
MR. MILLS: Objection, scope.
BY MR. FELDSTEIN:
Q. I'll point you specifically to line 23-24.
MR. MILLS: Objection, scope.
A. Okay. I see that paragraph, yeah.
BY MR. FELDSTEIN:
Q. Okay. Can you explain what a fusion protein is?
MR. MILLS: Objection, scope.

A. This is where they have taken parts of -- must be two different proteins, and splice them together. It's kind of a -- if you think of taking two different parts and putting two things together.

BY MR. FELDSTEIN:

Q. And in Column 2 at line 58, it says: The artisan skilled in the art can easily select the most appropriate Fc domain. And then it has a citation.

Do you see that?

MR. MILLS: Objection, scope.

A. Which line is it?

BY MR. FELDSTEIN:

Q. 57.

A. 57. Okay. I see it now.

Q. What do you understand that to mean?

MR. MILLS: Objection, scope.

A. Well, what this is considering is that people that are familiar with antibodies, people skilled in the art, know that the Fc fragment is referred to the -- the fragment of the antibody that's constant. And in that particular portion of it, it binds complement, something that binds complement. And it's fairly well-known what part

of the antibody does that, so I think they're just saying, gosh, if you've got, you know, some biochemistry background, you would be able to pick out that this part of the antibody binds complement. People would understand that. And there's a reference for that.

BY MR. FELDSTEIN:

Q. And I take it you agree with that statement?

MR. MILLS: Objection to scope.

A. I agree with that statement.

BY MR. FELDSTEIN:

Q. Can we turn to Column 7?

It's on page 9 of Exhibit 2028.

MR. MILLS: Objection, scope.

A. Which column?

BY MR. FELDSTEIN:

Q. Column 7.

A. Okay.

Q. There's a paragraph beginning at line 25, and I don't think we need to read the whole thing into the record, but it begins: The method -- This method may be used to treat a patient who is suffering from an autoimmune disease, including, but not limited to the

following: One, rheumatoid arthritis, and then it continues for seven categories. Do you see that?

MR. MILLS: Objection, scope.

A. I see that, yes.

BY MR. FELDSTEIN:

Q. And based on your familiarity with Exhibit 2028, would you agree that the fusion protein that's disclosed in Exhibit 2028 was not tested in any of these conditions?

MR. MILLS: Objection to form and scope.

A. Well, I'm -- you know, again, I'm here to provide you my responses to Dr. Damsky's testimony. Is there something about that testing of these things that he said that you would like for me to respond to? I -- I haven't, you know, found issue with anything that he said about this, so I've not included that in my reply.

Is there something about my reply that -- that you would like to know something about my declaration that you'd like to know about?

BY MR. FELDSTEIN:

Q. Doctor, unless your counsel directs you not to answer, I'd appreciate that you, in fact, answer. The question is based on your familiarity with Exhibit 2028, would you agree that the fusion

protein disclosed therein was not tested on any of the conditions in Column 7, line 25 through 39?

MR. MILLS: I'm going to object to the question on the basis of scope. Dr. Plott's declaration is a Rebuttal Declaration that addresses Dr. Damsky's opinions. Dr. Plott's indicated the -- the questions you're asking about do not relate to his Rebuttal Declaration, and if you don't have any questions about the Rebuttal Declaration, then you can end your questioning.

MR. FELDSTEIN: Your speaking objection is improper, Counsel.

BY MR. FELDSTEIN:

Q. Can you answer the question, Doctor?

MR. MILLS: So it's improper to use a cross-examination to go outside the scope to ask questions that are not within the scope of the cross-examination.

BY MR. FELDSTEIN:

Q. Can you answer the question, Doctor?

A. I'm sorry. I didn't hear what your question was.

MR. FELDSTEIN: Dan, could you read back the question that begins at 151:06.

(Record read.)

MR. MILLS: Object to the question as outside the scope.

A. I don't have a response for you. It's outside of the declaration that I've provided. So if you have a question about my responses to doc-- Dr. Damsky's issue that's in my -- my declaration, I'm happy to answer that, but this is not something that I've addressed in my declaration.

BY MR. FELDSTEIN:

Q. In offering your opinion that inhibitors of IL-15 or the IL-15 receptor were not recognized to have class wide efficacy for treating autoimmune conditions, did you conduct any independent research?

A. No, I did not.

Q. And in offering that opinion, did you read the disclosure -- consider the disclosures of all the references cited in Appendix A for whether or not they recognized -- excuse me, I'm going to start again.

In offering that opinion that inhibitors of IL-15 or the IL-15 receptor were not recognized to have class-wide efficacy for treating autoimmune conditions, did you consider the disclosures of all

references in Dr. Damsky's Appendix A for whether or not they disclosed class-wide efficacy?

MR. MILLS: Objection to form.

A. Dr. Damsky's disclosure in Appendix A, I believe is what you're referencing, is about a Texas-mile wide. It includes fusion proteins, nucleotides, muteins, antibodies, and considering all that, the -- the '505 patent really only considers one -- one specific thing that it's done a test on, the CHM VC 7 antibody, and it only did that in a mouse model that was contrived. It might represent vitiligo in that model in that particular instance.

And of -- of all the things that are mentioned in Dr. Damsky's deposition, in his declaration in Appendix A, that's really the only thing that -- that's been tested in the '505 patent. He's got, you know, everything but the kitchen sink in there. It's -- it's very broad; the claims are very broad.

So yes, I considered his -- the compounds that he has in Appendix A, and I considered them relative to his declaration and what he said about them, and I'll -- I'll leave it at that.

BY MR. FELDSTEIN:

Q. Do you consider to what extent the references cited in Dr. Damsky's Appendix A reflected an understanding that there was a class-wide effect for inhibition of IL-15 or IL-15 receptor?

MR. MILLS: Objection, form.

A. Dr. Damsky's opinion -- declaration Appendix A lists a -- a long, long list of -- of things that -- the -- the great majority of which have never been tested in -- in -- in vitiligo. The -- the only thing that's -- that really is mentioned that's been tested in that -- in the '505 patent, and he lists things -- most 80 percent of what he lists is not in the patent.

The only thing that's been tested is this one antibody that we don't have a sequence for, we don't have information about, and in the patent it's a black box whether or not even that would work. It's going to require a person of ordinary skill, a great deal of trial and testing to understand if that -- that could work in people.

BY MR. FELDSTEIN:

Q. Are -- are you not understanding my question, sir, or are you purposely answering a

different question?

MR. MILLS: Objection, argumentative.

A. I'm -- I'm trying to answer your question.

BY MR. FELDSTEIN:

Q. Okay.

A. Maybe I -- maybe ask me again.

Q. Did you consider to what extent the references cited in Dr. Damsky's Appendix A reflected an understanding that there was class-wide efficacy for inhibition of IL-15 or IL-15 receptors?

MR. MILLS: Objection, form, asked and answered.

A. I suppose I'm having difficulty answering your question because I disagree that there's a class-wide effect of IL-15 or IL-15 receptors.

BY MR. FELDSTEIN:

Q. And I'm just trying to find out did you consider whether those references contrary to your opinion reflect an understanding that there was a class-wide efficacy? Did you consider all those references for whether or not they reflected an understanding in the art of a class-wide efficacy?

MR. MILLS: Objection to form, asked and answered.

A. I'll tell you that I -- I genuinely looked at the references to see if there was, but I don't see that there is. I -- I think that the -- the Appendix A, as well as the references, the exhibits that we've talked about today, point us in a direction that says there's not a class-wide effect.

BY MR. FELDSTEIN:

Q. Okay. And we were talking about Exhibit 2028, do you recall? It was a document I handed to you, I think.

A. Right.

Q. And I was asking you about the therapeutic uses in Column 7; do you recall?

A. I remember that, yes.

Q. And I'd like to get to the -- the question of whether this reference, Exhibit 2028, is reflecting an understanding in the art that there was a class-wide -- there was an understanding that there was a class-wide efficacy for IL-15 inhibitors to treat IL-15-mediated diseases.

MR. MILLS: Object to the question on

the basis of form, and it's outside the scope.
BY MR. FELDSTEIN:
Q. You know, I'll withdraw the question. So my question now, Doctor, is Exhibit 2028, Column 7, lines 25 through 39, does the author's disclosure of that their fusion protein is suitable for this range of autoimmune diseases reflect an understanding that IL-15 and IL-15 receptor inhibitors had class-wide efficacy for treating autoimmune diseases?
MR. MILLS: Object to the question on the basis of form, and it's outside the scope. This portion of the document was not relied on by Dr. Damsky. It's not addressed in the Rebuttal Declaration, and it's not appropriate for discussion for the deposition.
A. I -- I -- I think I've answered your question as best as I can.
BY MR. FELDSTEIN:
Q. You didn't answer that question ever, Doctor.
(Simultaneous conversation.)
A. I told you what my response was.
BY MR. FELDSTEIN:
Q. What is your response?

A. My response is that I've not addressed this in my declaration. It was not an issue that I addressed regarding Dr. Damsky's responses in his declaration, and I'm here to answer questions about my declaration.

MR. MILLS: So we're at the time to take a break.

(Recess held 3:23-4:23.)

BY MR. FELDSTEIN:

Q. Dr. Plott, I -- I'm sorry if I was taking up too much of your time earlier asking questions that didn't seem relevant. I'm going to try to short-circuit my questions for the next few references, and I just need to know whether you considered what I asked -- what I'm going to ask whether you considered. And if you did, great, we'll talk about it; and if you didn't, you didn't.

Okay. So that's the premise of what I'm doing. I'm going to try and make it more efficient than the way we did it before.

A. Okay.

Q. And each of the references are things that are cited in your declaration, and so I assume they're in your folder, but you'll have to tell me if they're not, okay?

A. Okay.

Q. So Exhibit 2024, do you have that in your binder?

(Exhibit 2024 introduced.)

A. I happened to have already been turned to it.

BY MR. FELDSTEIN:

Q. Okay. Fantastic. And so here's my question, my first question about Exhibit 2024, did you consider whether this reference has any disclosure reflecting the understanding that inhibitors of IL-15 and IL-15 receptor have class-wide efficacy for treating autoimmune conditions?

MR. MILLS: Objection, scope.

A. To give you the most direct answer that -- to the extent that Dr. Damsky referred to it and used it for that, and it's included in here, I -- I considered it. It's certainly part of the references that I've read through and -- and pondered. I have to skim through my -- my declaration to -- to see, you know, what we said about that.

BY MR. FELDSTEIN:

Q. So then we can discuss information in

Exhibit 2024 to see whether it reflects an understanding that inhibitors of IL-15 and IL-15R have class-wide efficacy for treating autoimmune conditions?

MR. MILLS: Objection, scope.

A. I was referring to Dr. Damsky's reference to 2024, at least in my Paragraph Number 80. Maybe it's other places. This is where I remember it being. And I didn't consider it in terms of, you know, specifically a class-wide effect. I found that -- that Dr. Damsky in his declaration had -- had counted molecules and miscounted those molecules.

And so my discussion about that has mostly been to correct the record with regard to the number of molecules that this reference discloses.

BY MR. FELDSTEIN:

Q. I'm sorry, what paragraph are you in of your expert report?

A. I'm in 80 on page 45, and it spills over into Paragraph 82 and 83.

Q. Beyond the subject matter of Exhibit 2024 that you address in Paragraphs 80 through 83 of your declaration, did you consider

whether other disclosures in Exhibit 2024 reflect an understanding that inhibitors of IL-15 and IL-15 receptor have class-wide efficacy for treating autoimmune conditions?

MR. MILLS: Objection, scope.

A. Are you asking if in other exhibits I was considering that or -- you said other than Exhibit 2024.

Are you saying all the other exhibits with the exception of 2024?

BY MR. FELDSTEIN:

Q. Other than -- in Paragraphs 80 through 83, you address certain subject matter of Exhibit 2024, correct?

A. Correct. The matter that I'm addressing is the counts for the number of inhibitors and in -- the issue that I was addressing with this reference is that Dr. Damsky counts reagents as inhibitors and the reference doesn't give them as inhibitors. It gives them as reagents in order to make the thing that's doing the inhibition, right?

Q. And so my question is: Beyond the subject matter of Exhibit 2024 that you address in Paragraphs 80 through 83 of your declaration, did you consider whether other parts of Exhibit 2024

reflect an understanding that inhibitors of IL-15 and IL-15 receptor have class-wide efficacy for treating autoimmune conditions?

MR. MILLS: Objection, scope.

A. No, I did not.

BY MR. FELDSTEIN:

Q. Okay. And similarly, beyond the subject matter of Exhibit 2024 that you address in Paragraphs 80 through 83 of your declaration, did you consider whether Exhibit 2024 discloses any assays generally suitable for evaluating inhibition of IL-15 and IL-15 receptor?

MR. MILLS: Objection, scope.

(Witness reviews document.)

A. In my -- in my Reply Declaration, I did not mention any of the assays that might be evaluated for inhibition relative to this exhibit.

BY MR. FELDSTEIN:

Q. Exhibit 2024?

A. Exhibit 2024.

Q. Okay. Okay.

Done with Exhibit 2024.

Can we move on to Exhibit 2013, which I think also should be in your collection, but if not, let me know.

(Exhibit 2013 introduced.)

A. I've got it.

BY MR. FELDSTEIN:

Q. And I think that you reference Exhibit 2013 in Paragraphs 24, 25, 31, and 40 of your declaration.

Do you agree with that?

A. Right. I don't have a search engine, so I'll trust what you say about that.

Q. Okay. Beyond what portions of Exhibit 2013 you address in your declaration, Exhibit 1047, did you consider whether Exhibit 2013 has any disclosure reflecting the understanding that inhibitors of IL-15 and IL-15 receptor have class-wide efficacy for treating autoimmune conditions?

MR. MILLS: Objection, scope.

A. And the answer is yes, and in Paragraph 24 -- let me read in what we -- what was considered, is that --

BY MR. FELDSTEIN:

Q. And, Doctor, I'll let you read it in, but I just want to make it clear, my question is: Beyond the portions of 2013 that you address in your declaration, I want to know if you considered

whether other parts of Exhibit 13 [sic] has any disclosure reflecting the understanding that inhibitors of IL-15 and IL-15 receptor have class-wide efficacy for treating autoimmune conditions? I'm just trying to clarify my question.

A. Right.

Q. Answer however you want.

A. To the extent that I considered 2013 in my reply to Dr. Damsky and the things that I looked at, I represented in my declaration.

Q. Okay.

A. And I'll leave it at that.

Q. Okay. And a similar question but for assays: Beyond what portions of Exhibit 2013 you address in your declaration, Exhibit 1047, did you consider whether Exhibit 2013 has any disclosure of assays generally suitable for evaluating inhibition of IL-15 and IL-15 receptor?

MR. MILLS: Objection, scope.

A. And I'll give you the same kind of answer with regard to assays. And so with regard to that 2013 exhibit, to the extent that I considered assays, I've represented that in my declaration.

BY MR. FELDSTEIN:

Q. Okay. We're going to move on to Exhibit 2014, which should also be in your binder, I think.

(Exhibit 2014 introduced.)

BY MR. FELDSTEIN:

Q. And I think per my notes and for your reference, I think you address Exhibit 2014 in Paragraphs 24, 25, 31, and 40 of your declaration.

And so similar to my questions before: Beyond the portions of Exhibit 2014 you address in your declaration, Exhibit 1047, did you consider whether Exhibit 10 -- 2014, excuse me -- Exhibit 2014 has any disclosure reflecting an understanding that inhibitors of IL-15 and IL-15 receptor have class-wide efficacy for treating autoimmune conditions?

MR. MILLS: Objection, scope.

A. So to the extent that I considered class-wide efficacy, I've represented that in my responses to Dr. Damsky's declaration.

BY MR. FELDSTEIN:

Q. Okay. And this will be boring for you but -- and I apologize, but I'm going to ask the --

A. I understand.

Q. -- other question.

A. I understand.

Q. Beyond what portions of Exhibit 2014 you address in your declaration, Exhibit 1047, did you consider whether Exhibit 2014 discloses any assays generally suitable for evaluating inhibition of IL-15 and IL-15 R?

MR. MILLS: Objection, scope.

A. And, again, to the extent that I considered assays, I've represented that in my reply.

BY MR. FELDSTEIN:

Q. Okay. The last one, Doctor. 2015, Exhibit 2015, please.

(Exhibit 2015 introduced.)

BY MR. FELDSTEIN:

Q. And just for your reference, my notes are that Exhibit 2015 is cited in Paragraphs 24, 25, 31, 40, 54, 68, and 69 of your declaration, Exhibit 1047.

And so, no surprise. My question is: Beyond portions of Exhibit 2015 that you address in your declaration, Exhibit 1047, did you consider whether Exhibit 2015 has any disclosure reflecting an understanding that inhibitors of IL-15 and IL-15

receptor have class-wide efficacy for treating autoimmune conditions?

MR. MILLS: Objection, scope.

A. And I've represented in my reply the consideration I gave to this reference with regard to class-wide effect.

BY MR. FELDSTEIN:

Q. Beyond what portions of Exhibit 2015 you address in your declaration, Exhibit 1047, did you consider whether Exhibit 2015 discloses any assays generally suitable for evaluating inhibition of IL-15 and IL-15 receptor?

MR. MILLS: Objection, scope.

A. Again, I've represented in my response to Dr. Damsky's declaration any mention of assays with regard to this reference. What I've considered is in my declaration.

MR. FELDSTEIN: Okay. That's all we have, Doctor. Thank you for your time.

MR. MILLS: Let's take a break.

(Recess held 4:50-4:59.)

EXAMINATION

BY MR. MILLS:

Q. Dr. Plott, do you recall being asked during your cross-examination, in offering your

opinions, that inhibitors of IL-15 or the IL-15 receptor were not recognized to have class-wide efficacy for treating autoimmune conditions, did you conduct any independent research? Do you recall that question?

A. I do.

Q. What did you mean -- what was your understanding of the term "independent research" when you answered that question?

A. Well, I was responding to did I go to the laboratory and pull up any test tubes or petri dishes to test some of this, and the answer that I gave was, no, that I did not do that. I suppose if you consider independent research being did I go and do reviews and look at the literature, yes, I did that.

Q. Okay. Do you recall being asked about Exhibit 1018?

A. Right, 1018.

Q. Sorry, what was your answer?

A. Yes, I remember.

Q. Okay. Do you recall being asked questions about Figure 1C of Exhibit 1018?

A. I do, yes.

Q. Okay. I believe during the

cross-examination, a couple of times you used the words "in vivo" when describing the experiment in Figure 1C. So my question is: The experiment that's described in Figure 1C, is that an in vivo experiment or an in vitro experiment?

A. Two places where I said "in vivo," I misspoke. These are in vitro experiments.

Q. And how do you know that?

A. Well, the -- in looking at this figure, these are done in -- in the laboratory in petri dishes, so to speak. They're not done in living organisms.

Q. Do you recall being asked questions during your cross-examination about what materials you considered in providing your rebuttal opinions to Dr. Damsky?

A. Yes, over and over.

Q. Okay. Could you tell us how it was that you went about deciding what materials you would consider in preparing your Rebuttal Declaration for Dr. Damsky?

A. Well, I read all of Dr. Damsky's declaration and his deposition and found areas where I felt that they departed from my interpretation of the literature and focused in on

those areas where I felt that there was discrepancies that needed to be clarified in the record. That's -- that's primarily the focus of my response.

MR. MILLS: Thank you. No further questions.

MR. FELDSTEIN: I do have one follow-up question, Doctor.

FURTHER EXAMINATION

BY MR. FELDSTEIN:

Q. In terms of independent research, independent literature research that you did, did you consider any literature, any references beyond what are cited in your declarations?

A. No. These are the articles that -- that I've referred to.

Q. So any literature research you did, those references are reflected in your declarations?

A. That's correct.

MR. FELDSTEIN: Okay. Thank you. Nothing further.

MR. MILLS: The deposition is over. The witness reserves the right to read and sign.

(Deposition concluded at 5:03 p.m.)

ACKNOWLEDGMENT

I, DR. R. TODD PLOTT, hereby acknowledge that I have read the transcript of my testimony taken under oath in my deposition on 23rd day of February, 2024; that the transcript is a true, complete and correct record of my testimony; and that the answers on the record as given by me are true and correct.

_____

DR. R. TODD PLOTT

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

_____

Notary Public

REPORTER'S CERTIFICATION

I, DANIEL J. SKUR, CSR and Notary Public in and for the State of Texas, hereby certify that the witness was duly sworn and that this transcript is a true record of the testimony given by the witness;

That pursuant to Rule 30 of the Federal Rules of Civil Procedure, signature of the witness was reserved by the witness or other party before the conclusion of the deposition;

I further certify that I am neither counsel for, related to, nor employed by any of the parties or attorneys in the action in which this proceeding was taken. Further, I am not a relative or employee of any attorney of record in this cause, nor am I financially or otherwise interested in the outcome of the action.

Subscribed and sworn to by me this day, the 24th day of February, 2024.

Daniel J. Skur, CSR
Notary Public, State of Texas
My Commission Expires 7/7/2026
Veritext Legal Solutions
Texas Firm Registration No. 571
300 Throckmorton Street, Suite 1600
Fort Worth, TX 76102
800.336.4000

ERRATA SHEET FOR THE TRANSCRIPT OF:

DR. R. TODD PLOTT

CASE NAME:

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORTE BIOSCIENCES, INC., Petitioner,	§	CASE NO.:
Vs.	§	PGR2023-00014
UNIVERSITY OF MASSACHUSETTS, Patent Owner.	§	Patent No. 11,278,505

DEP DATE: 23rd day of February, 2024

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DR. R. TODD PLOTT

Jad A. Mills

jmills@wsgr.com

February 26, 2024

Forte Biosciences, Inc. v. University Of Massachusetts

2/23/2024, DR. R. TODD PLOTT (#6442446)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at Calendar-PNW@Veritext.com

Return completed errata within 30 days from receipt of testimony.

If the witness fails to do so within the time allotted, the transcript may be used as if signed.

Yours,

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Forte Biosciences, Inc. v. University Of Massachusetts

DR. R. TODD PLOTT (#6442446)

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DR. R. TODD PLOTT Date

Forte Biosciences, Inc. v. University Of Massachusetts
DR. R. TODD PLOTT(#6442446)

ACKNOWLEDGEMENT OF DEPONENT

I, DR. R. TODD PLOTT, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

_____ _____

DR. R. TODD PLOTT Date

*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS

_____ DAY OF _____, 20___.

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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 represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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