UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Merck Sharp & Dohme LLC,

Petitioner

v.

The Johns Hopkins University,

Patent Owner

_____

IPR2024-00240

U.S. Patent No. 11,591,393169

_____

Deposition of DUNG THI LE, M.D.

Thursday, January 9, 2025

9:03 a.m.

Job No.: 563063

Pages: 1 - 319

Reported By: Dawn M. Hart, RPR/RMR/CRR

Deposition of Dung Thi Le, M.D., held at the:

JOHNS HOPKINS - BLOOMBERG SCHOOL OF PUBLIC HEALTH
Roger and Flo Lipitz Center
1812 Ashland Avenue, 3rd Floor
Baltimore, Maryland 21205

Pursuant to Notice, before Dawn M. Hart, RPR/RMR and Notary Public in and for the State of Maryland.

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C O N T E N T S

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(Exhibits retained by Mr. Ratliff.)

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P R O C E E D I N G S

DUNG THI LE, M.D.

being first duly sworn or affirmed to testify to the truth, the whole truth, and nothing but the truth, was examined and testified as follows:

EXAMINATION BY COUNSEL FOR PETITIONER

BY MR. RATLIFF:

Q Good morning.

Would you please state your full name for the record.

A Dung Thi Le.

Q Please state your residence address.

A 12 Laurel Circle, Lutherville, Maryland, 21093.

Q How are you feeling today, Doctor?

A I am feeling okay.

Q And you understand that you're here today to give testimony under oath, right?

A Yes.

Q Is there any reason you cannot testify truthfully today?

A No.
Q You're still employed by The Johns Hopkins University; is that right?
A I am employed by Johns Hopkins University.
Q And you understand that The Johns Hopkins University owns the '393 patent that is the subject of the U.S. Patent and Trademark proceeding in this case, right?
A Yes.
Q And you refer to that '393 patent in your October 4, 2024, Declaration, right?
A Is it possible to see the Declaration?
Q Sure.
(Exhibit 2130 was marked for identification and was retained by Mr. Ratliff.)
Q So let me hand you a document that's been marked as Exhibit 2130.
A (Reviewing.)
Q Doctor, do you recognize this as a copy of your October 4, 2024, Declaration in this proceeding?

A (Reviewing.)
Q Do you understand my question, Doctor?
A Yes, I'm just looking at the document.
Q Okay. Let me know when you're ready.
A Can you point out to me where it refers to the patent? I just wanted to confirm.
Q Well, before I get to that, do you recognize this as a copy of your October 4, 2024, Declaration?
A Yes. The only thing I was just wondering is when I looked at it yesterday, I reread it, and there were a couple of spots that looked a little bit different. It might just be because I just read it quickly yesterday.
Q What spots look different to you?
A Oh, let's see.
(Reviewing.)
27. I mean, I do recognize the paragraph.
Q You're referring to paragraph 27?
A Yes.
Q And it looked different to you when you

read it yesterday?
A Yes.
Q And in what way did it look different?
A I just remember reading it for review, and I just don't remember reading that paragraph yesterday, but as far as I know, I mean I recognize these different paragraphs.
Q Okay. Was there anything else in your Declaration that struck you as looking different from your read yesterday?
A Not obviously.
Q And when you read your Declaration yesterday, did you understand it?
A Yes, I was just reviewing it in preparation.
Q And you weren't confused by anything that you said in your Declaration when you read it, right?
A No.
Q And you weren't confused by anything you read in your Declaration when you signed it, right?

A No.
Q Now, you can turn your attention to paragraph 4 of your Declaration. This is at page 3.
A (Nodding head.)
Q Do you see there in paragraph 4 you refer to the '393 patent?
A Yes.
Q And you're one of the seven named inventors of that '393 patent, right?
A I am one of the named inventors.
Q And you're one of the seven named inventors of the '393 patent, right?
A I am one of the inventors.
Q I understand that you're one of them.
Do you understand that there are seven inventors listed on that patent?
A I understand that there are other inventors listed on the patent.
Q So you don't know how many inventors are listed on the patent?
A I don't recall how many inventors are

listed on the patent.

Q Well, let's take a look.

(Exhibit 1001 was marked for identification and was retained by Mr. Ratliff.)

Q Let me hand you a document that's been marked as Exhibit 1001.

Let me know if you recognize it, Doctor.

A (Reviewing.)

Q Do you recognize the '393 patent, Doctor?

A I can't say that I -- I mean I haven't had a chance to look at every single page, but ...

Q Do you need to look at every single page of the '393 patent to recognize it as one of your patents?

A I cannot remember if I've seen this document. I can't recall.

Q Okay. But do you -- you did refer to it in your Declaration, right?

A Yes.

Q Turning your attention to the first page of the document, you see that you're one of seven

named inventors for the '393 patent?
A I see that, yes.
Q And it was JHU that applied for the '393 patent, right?
MR. MILLER: Objection. Form. Legal.
A It says here applicant, The Johns Hopkins University.
Q Okay. I understand that, but is it your understanding that it was JHU that applied for the '393 patent?
MR. MILLER: Same objections.
A Reading this document, it says the applicant is The Johns Hopkins University.
Q Do you understand that JHU applied for the '393 patent?
MR. MILLER: Objection. Form. Foundation. Leading.
MR. RATLIFF: Counsel, you can't get into speaking objections. You can object to form.
A Can you repeat the question?
Q Sure.
Do you understand that it was JHU that

applied for the '393 patent?
A I see here that the applicant is Johns Hopkins University.
Q I'm asking you a different question.
To your knowledge, do you understand that JHU applied for the '393 patent?
MR. MILLER: Objection. Form.
A I guess I don't understand the question, because it says here that the applicant is The Johns Hopkins University.
Q Okay. Did you apply for the '393 patent?
A I personally did not apply for the patent.
Q Okay. Do you understand that JHU submitted a provisional application on November 13, 2014?
A I do not recall any of the details.
Q And I'm not asking you if you recall any of the details, I'm just asking you, do you understand that JHU submitted a provisional application on November 13, 2014?

A I guess I don't know how to answer these questions. I don't recall.

Q You don't recall what?

A I don't recall an application on this date that you are mentioning.

Q Okay. So you don't recall ever seeing a provisional application dated November 13, 2014?

MR. MILLER: Objection. Form.

A I can't recall the date of any applications that I saw.

Q Do you recall ever seeing a provisional patent application concerning your alleged invention?

MR. MILLER: Objection. Form.

A I think there's some terms I don't understand. I don't know what "provisional" means so I can't under oath say that I can recall.

What was your question again?

Q Sure.

My question was, do you know whether or not JHU submitted a provisional patent application concerning your alleged invention?

A So I guess my answer is the same; I can't really say in terms of what you're asking me specifically.

Q Because you don't know what a provisional patent application is; is that right?

A I don't know the terms "provisional," and I don't know when things were submitted.

Q Okay.

(Exhibit 1030 was marked for identification and was retained by Mr. Ratliff.)

Q I'm going to hand you a document that's been marked as Exhibit 1030. Can you take a look at Exhibit 1030 and let me know if you recognize it, Doctor.

A (Reviewing.)

Am I allowed to ask questions?

Q Sure.

A What is this document?

Q Well, first, do you recognize the document?

A (Reviewing.)

Q If you don't recognize it, you can just

tell me that.

A (Reviewing.)

If I've seen it, it's been a while, so I don't recognize the document.

Q Okay. And do you see on the first page of the document there's a list of named inventors?

A Yes.

Q And your name is on that list, right?

A Yes.

Q And you see that there are five named inventors, right?

A Yes.

Q And you appreciate on the '393 patent there are seven named inventors, right?

A This is the '393 patent (indicating)?

Q I see you pointing to Exhibit 1001.

A Yes.

Q I think that's right.

So in Exhibit 1001, there's seven named inventors, right?

A I see seven inventors on the exhibit you mentioned.

Q Right.

And do you know why on Exhibit 1030 two inventors -- two named inventors, Dr. Pardoll and Dr. Topalian, are not included?

A I do not.

Q Do you know what Dr. Pardoll and Dr. Topalian's contributions were with respect to the alleged invention in this case?

MR. MILLER: Objection. Form.

A I think they contributed ideas.

Q What ideas did they contribute?

A Ideas related to an individual who responded to therapy.

Q And what specifically were those ideas?

A That there is something unique about a patient that responds to therapy.

Q And is it your testimony that both Dr. Pardoll and Dr. Topalian had that same contribution?

A I can't give specifics. I think it would be best to ask them.

Q Why can't you give specifics?

A I wasn't there in the room.
Q So is it fair to say you don't know Dr. Pardoll's or Dr. Topalian's contribution to the alleged invention of the '393 patent?
MR. MILLER: Objection. Form.
A Can you repeat the question?
Q Is it fair to say that sitting here today you do not know Dr. Pardoll's contribution to the alleged invention of the '393 patent?
A I don't understand the "contribution" part. What constitutes contribution. Can you rephrase that part or explain that part?
Q Do you have any opinion sitting here today a reason why Dr. Pardoll should be a named inventor of the '393 patent?
MR. MILLER: Objection. Form. Legal.
A Because Dr. Pardoll contributed to the formulation of the hypothesis.
Q And do you have any reason sitting here today why you think Dr. Topalian should be a named inventor of the '393 patent?
A For the same reason.

Q And did they come up with that same contribution at the same time?
A I don't know specifically when the individuals came up with the contribution in their heads.
Q When did the individuals tell you about this contribution?
A The individuals did not tell me specifically.
Q Okay. So why do you have the belief that Dr. Pardoll and Dr. Topalian did work that makes them worthy of being a named inventor of the '393 patent?
MR. MILLER: Objection. Form. Legal.
A Because they contributed to the hypothesis.
Q And sitting here today you don't know when that contribution -- strike that.
Sitting here today you don't know when that alleged contribution happened, right?
A A date?
Q Yes, I'm asking for a date. Sitting

here today you don't know the date when that alleged contribution happened, right?

A I can't tell you right this minute the date.

Q Okay. And looking -- turning your attention back to Exhibit 1030 --

A I'm sorry, which one is that one?

Q It's the one that's labeled 1030 at the bottom.

A Oh, got it.

MR. MILLER: In the bottom corner.

Q Do you have that?

So turning your attention to Exhibit 1030, you understand that Dr. Topalian and Dr. Pardoll are not listed as named inventors on this document, right?

A I see that their names are not listed under the inventors.

Q Right.

And do you have any reason sitting here today, or knowledge, why they're not listed as named inventors?

A No.

Q And do you see that the date of this document at the top refers to a November 13, 2014, filing date?

A Yes.

Q And do you have any recollection that a provisional application for your alleged invention was being filed on November 13, 2014?

A Again, I think I answered that question.

Q Let me try it again because I don't think I got an answer.

Do you have any recollection sitting here today of any provisional application being filed concerning your alleged invention?

A I do not have a recollection of dates of an application. I am still not a hundred percent sure when you say "provisional," if it's the application, if it's the same, because I don't understand what a provisional application is.

Q Do you have any recollection of this document that you're looking at, Exhibit 1030, ever being filed with the Patent Office?

A Have -- do I have a recollection of this exact document and every single page of this document. I don't -- I can't remember.

Q Okay. Can you turn your attention to page 14 of Exhibit 1030. And I'm referring to the page numbers at the bottom where it says page 14 of 37. Let me know when you have it.

A Page 14 of 37.

Q Do you have it?

A Yes, I'm looking at page 14 of 37.

Q Can you let me know if you recognize the text that's included in Exhibit 1030 on page 14 through page 18 of the exhibit?

A (Reviewing.)

I can't recall.

Q I want to make sure I understand your response.

Do you recognize any of the text that's found on page 14 through pages -- up to page 18 of Exhibit 1030?

MR. MILLER: Objection. Form.

A I can't recall specifically. It's been

a long time.

Q Do you have any general recollection of the text found on pages 14 through 18?

MR. MILLER: Objection. Form.

A I can't recall.

Q Did you contribute to the drafting of any of the text found on pages 14 through 18 of Exhibit 1030?

A (Reviewing.)

I can't recall.

Q You can't recall if you have a recollection. I'm asking you right now, do you have any recollection of whether you contributed to the preparation of the text found on pages 14 through 18 of Exhibit 1030.

A I cannot recall.

Q Do you know who contributed to the text that's shown on pages 14 through 18 of Exhibit 1030?

A I don't remember. I can't recall, or I don't know.

Q Okay. Now, is it your understanding

that by November 13, 2014, you had found that immune checkpoint inhibitors worked best in tumors with high mutation burdens?

A Can you repeat the question?

Q Is it your understanding that by November 13, 2014, you had found that immune checkpoint inhibitors worked best in tumors with high mutation burdens?

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

Q Did you ever find that immune checkpoint inhibitors work best in tumors with high mutation burdens?

A Did I personally?

Q Did you personally find that immune checkpoint inhibitors worked best in tumors with high mutation burdens?

A The science is typically a team, and I think the team at Hopkins did find that.

Q When you say "the team at Hopkins" --

A Oh, actually, can you repeat the question? What did you actually ask?

Q Try my question again.

Different question.

Did you ever find that immune checkpoint inhibitors worked in tumors with high mutation burdens? Did you ever find that?

A Did I ever find that? No.

Q By November 13, 2014, had you developed a treatment for cancer patients that displayed the microsatellite instability phenotype?

A Not by 2014. It's been a long time. The dates are throwing me off a little bit.

Q That's okay.

Earlier in one of your responses you said something about the JHU team. Who are you referring to?

A Well, it's a -- various people, but as you know, science is not -- or trials are not done by an individual, and there are people listed on the invention (indicating).

Q What do you mean by "people listed on the invention"? I saw you pointing to a document. Are you talking about the '393 patent?

A That's what I was pointing to.

Q And is that who you meant when you refer to the JHU team, the seven named inventors of the '393 patent?

A Can we go back to the original question? What am I answering again?

Q So let me try this.

By November 13, 2014, had Dr. Luis Diaz developed a treatment for cancer patients that display the microsatellite instability phenotype?

A Had we developed the treatment by 2014.

What do you mean by "developed a treatment"?

Q If you don't understand the question, you don't understand the question. Let me try it again.

I think you've already answered with respect to yourself. By November 13, 2014, had Dr. Luis Diaz developed a treatment for cancer patients that displayed the microsatellite instability phenotype?

MR. MILLER: Objection. Form.

A What do you mean by "developed"?

Q Same thing I meant when you answered my question before.

A What did you mean when you -- I just need clarification to make sure I'm understanding what you mean by "developed."

Q If you don't know, you don't know. Let me ask the question. A different question.

A I just need you -- a clarification of what you mean by "developed" so I could better answer the question.

Q Just means you don't know, that you don't have an answer.

So by November 13, 2014, had Dr. Bert Vogelstein developed a treatment for cancer patients that displayed the microsatellite instability phenotype?

MR. MILLER: Objection. Form.

A I think for clarity I need to understand what "developed" means.

Q So you just don't understand my question?

A I think there's a lot of nuance in the

word "development," so I just need to understand what you mean by "developed."

Q Have you ever used the word "developed" before?

A I have used the word "developed" before.

Q And have you ever used the word "developed" in the context of communicating with the U.S. Patent Office?

MR. MILLER: Objection. Form.

A I don't recall specifically.

Q Okay. By November 13, 2014, had Dr. Kenneth Kinzler developed a treatment for cancer patients that displayed the microsatellite instability phenotype?

MR. MILLER: Objection. Form.

A I mean I see what we're doing, but I still go back to the word "developed." If you could define that, I could try to answer it.

Q It should be defined in a way that you understand the word "developed."

A But I need to understand what you're asking, not how I interpret it. I don't

understand what you mean by "developed."

Q That's fine. If you don't have a response and you don't understand my question, that's fine.

So by November 13, 2014, had Dr. Diaz, Dr. Vogelstein, Dr. Kinzler, Dr. Papadopoulos, ever found that immune checkpoint inhibitors work best in tumors with high mutation burdens?

A Had they found. Can you repeat the question again?

Q Sure.

By November 13, 2014, had Dr. Diaz, Dr. Vogelstein, Dr. Kinzler, or Dr. Papadopoulos found that immune checkpoint inhibitors work best in tumors with high mutation burdens?

MR. MILLER: Objection. Form.

A No -- I feel like you're asking different questions that -- I need to focus on what you're actually asking, so no to the high tumor mutation burden.

Q And by November 13, 2014, had Dr. Papadopoulos developed a treatment for cancer

patients that displayed the microsatellite instability phenotype?

MR. MILLER: Objection. Form.

A It goes back to the same question. It depends -- I don't know what you mean by "developed."

Q Got it.

(Exhibit 1043 was marked for identification and was retained by Mr. Ratliff.)

Q Doctor, I'd like to hand you a document which has been marked as Exhibit 1043. Let me know if you recognize it.

A (Reviewing.)

I can't say that I specifically recognize this document.

Q Do you have any general recollection of Exhibit 1043?

A I can't recall that I have specifically seen this.

Q Did you contribute to any of the text that's found in Exhibit 1043 from pages 1 through page 41 of the exhibit?

A I can't say specifically that I contributed to the text.

Q Do you know if you contributed to any of the text that's found on pages 1 through 41 of Exhibit 1043?

A I can't say specifically. There's a lot of content in here.

Q Okay. But do you know if you contributed to any of the text that's found on pages 1 through 41 of Exhibit 1043?

A I don't remember.

Q Okay. Do you know who may have contributed to the preparation of the text that's found on pages 1 through 41 of Exhibit 1043?

A I don't -- I don't remember.

Q Okay. And if I can turn your attention to page 55 of Exhibit 1043. Let me know when you have it.

A Page 55 of 57.

Q You have it?

A Yes.

Q And I can represent to you that at page

55 of Exhibit 1043, this is the beginning of a filing receipt from the United States Patent Office.

Do you see on the first page that it refers to a filing date of July 10, 2015?

A I see the date on top of July 10, 2015.

Q Do you see on the document that it refers to the same list of five named inventors that we saw on Exhibit 1030?

A 1030, the inventors, yes.

MR. MILLER: And, Doctor, I know you're coming down with a cold. If you need to take a break, just let us know and we can take a break.

Q And then the list of named inventors that we see on page 55 of Exhibit 1043, it does not conclude named inventors Dr. Pardoll and Dr. Topalian, right?

A I'm sorry, you're asking me if page 55 has Dr. Pardoll and Topalian on it? It does not.

Q And do you know why Dr. Pardoll and Dr. Topalian are not listed as named inventors on this document that refers to a filing date of

July 10, 2015?

A I do not.

Q Can I turn your attention back to Exhibit 1030. Let me know when you have it.

A Yes.

Q And Exhibit 1030, this is the document that reflects a filing date of November 13, 2014, right?

A Yes.

Q And by this time, November 13, 2014, you did not expect to benefit directly from any future sales of pembrolizumab, right?

A Not that I recall.

Q And you did not expect to benefit directly from any future sales of pembrolizumab because JHU is an academic research institution that does not sell pharmaceuticals, right?

A Can you repeat that question?

Q You did not expect to benefit directly from any future sales of pembrolizumab because JHU is an academic research institution that does not sell pharmaceuticals, right?

A I do not recall.
Q Well, didn't you testify in your Declaration that you did not expect to benefit directly from any future sales of pembrolizumab because JHU is an academic research institution that does not sell pharmaceuticals?
A Can you repeat the question?
Q Didn't you testify in your Declaration that you did not expect to benefit directly from any future sales of pembrolizumab because JHU is an academic research institution that does not sell pharmaceuticals? That was your testimony, right?
A (Reviewing.)
MR. MILLER: Objection. Mischaracterizes the document.
A Can you point it out to me in the document?
Q Well, sitting here today, do you have any recollection of testifying in your Declaration that you did not expect to benefit directly from any future sales of pembrolizumab because JHU is

an academic research institution that does not sell pharmaceuticals?

MR. MILLER: Objection. Mischaracterizes the document.

MR. RATLIFF: Counsel, the speaking objections are improper. We can direct you to the Practice Trial Guide at page 128.

MR. MILLER: I'd just ask you to quote the document accurately.

MR. RATLIFF: Counsel, you can't do this.

BY MR. RATLIFF:

Q Doctor, do you understand my question?

A Which -- where are you referring to in this Declaration?

Q I'm not referring to the Declaration at all. I'm asking you right now, sitting here today, do you recall giving testimony in your Declaration stating that you did not expect to benefit directly from any future sales of pembrolizumab because JHU is an academic research institution that does not sell pharmaceuticals?

MR. MILLER: Objection. Form.

A (Reviewing.)

Q Do you understand my question, Doctor?

A I need a minute.

Q Sure.

A (Reviewing.)

Paragraph 19, is that what you're referring to?

Q Let me try my question again.

I'm asking you, sitting here today, do you recall testifying in your Declaration that you did not expect to benefit directly from any future sales of pembrolizumab because JHU is an academic research institution that does not sell pharmaceuticals?

MR. MILLER: Objection. Form.

A It says in this document, we also did not expect to benefit directly from any future sales of pembrolizumab because JHU is an academic research institution that does not sell pharmaceutical products.

Q And by "the document," you're referring

to your -- the testimony in your Declaration?

A Yes.

Q And do you recall making that statement, that you did not expect to benefit directly from any future sales of pembrolizumab because JHU is an academic research institution that does not sell pharmaceutical products?

A I don't recall specifically.

Q Okay. And just turning your attention to paragraph 19, that you're looking at, and when you write, "We also did not expect to benefit directly from any future sales of pembrolizumab because JHU is an academic research institution that does not sell pharmaceuticals products," who was the "we" that you're referring to?

A I -- I guess I specifically probably shouldn't speak for other people.

Q Okay. I'm not sure what that means. Let me try to get an answer to my question.

When you testified in your Declaration in paragraph 19, quote, we also did not expect to benefit directly from any future sales of

pembrolizumab because JHU is an academic research institution that does not sell pharmaceutical products, end quote, who is the "we" that you were referring to?

A "We" -- I probably should have said I because I should not speak for other people.

Q Okay. So in your copy of your Declaration, can you cross out "we" and put "I"? I think you should actually cross out "we also" and just say "I did not," right? That would make your testimony correct?

A (Complying.)

Q Would that make your testimony correct?

A That I did not expect, yes.

Q Okay. Sorry, Doctor, before that, can you just sign your name -- sign your initials, just so we know that the correction was made by you?

A I'm kind of sick. Do you want the pen back?

Q Sure.

A I have alcohol.

Q Okay, you can keep the pen.
A Okay.
Q I appreciate it.
A Sure.
Q And you made a comment earlier -- or you -- is it fair to say that you don't want to speak for anyone other than yourself in your Declaration; is that fair?
A I mean I guess it depends on the context. I just know here that I can speak for myself in this particular thing that I initiated, or initialed.
Q Got it.
And, Doctor, can you just describe for me the process in which you prepared your Declaration?
A We had lots of discussions and meetings about information, the contents.
Q And who's the "we" you're referring to?
A Members from the legal team.
Q And which members from the legal team are you referring to?

A I know this is bad, but I don't actually recall the specific individuals.

Q Do you recall the names of any of the individuals from the legal team?

A No.

Q Were any of those individuals from the legal team in-house lawyers from JHU?

A I don't -- I'm not sure.

Q Were any of the -- how many individuals were there?

A I don't know. I don't recall.

Q Do you have any general recollection as to how many individuals there were in these many conversations and meetings that you had to prepare your Declaration?

A No, I don't know.

Q And it's your testimony sitting here today you can't name a single individual that you spoke with during the process of preparing your Declaration that involved many conversations and meetings; is that your testimony?

A I don't recall specifically who was at

which meeting.

Q And, Doctor, understand, I'm not asking you who was at which meeting. That wasn't my question at all. So let me try my question.

And is it your testimony that sitting here today you can't name a single individual that you spoke with during the process of preparing your Declaration that involved many conversations and meetings; is that your testimony?

MR. MILLER: Objection. Form.

A There were a lot of different meetings so I can't remember who was at what and what was discussed at what meeting.

Q And, Doctor, understand, I'm not asking you who was at which meeting. I'm not asking that at all. My question is different.

My question is, sitting here today, can you name any individual that you spoke with during the process of preparing your Declaration that involved many conversations and meetings?

A I can name individuals who were at meetings and related to this whole process, but I

cannot recall who was at which meeting to discuss the contents of the Declaration because there were a lot of different meetings on different topics. Does that make sense?

Q Not to me, but which individuals are you talking about?

A That were at these various meetings?

Q Yes.

A I can name Todd Miller, and I can name Christie Brown Marshall, and that's probably because I met with them recently so I can remember. I'm not that great with names and faces.

Q Anyone else?

A I can't specifically name other individuals.

Q Do you have any general recollection of any other individuals that you met with in connection with this case?

A In the case or the Declaration?

Q So it's exactly what I said, so let me try that again. I said the case.

A Well, what does "the case" mean?
Q Okay, if you don't know what "the case" means, that's fine.
Do you have any recollection of which individuals you met with during the preparation of your Declaration?
A Those are the only two names I can specifically name related to the Declaration.
Q Okay. And sitting here today, are you comfortable with the content of your Declaration?
A Yes.
Q And are you familiar with the content of your Declaration?
A I am familiar with it.
Q When did you first learn that JHU was applying for a patent concerning your alleged invention?
A I don't remember.
Q Do you have any recollection sitting here today when you first learned that JHU was applying for a patent concerning your alleged invention?

A I don't remember the dates. I can't remember.
Q Do you know if it was in 2013?
A It was so long ago, I don't remember the dates.
Q What's "so long ago" to you?
A 2013 was a long time ago. I can't remember the dates, the order. That's why I keep referring to documents.
Q So your testimony today is you have no recollection when you first learned that JHU was applying for a patent concerning your alleged invention. Is that your testimony?
A I can't give you a specific date when I learned of it.
Q And, Doctor, understand, I'm not asking for a specific date. So let me try my question again.
Do you have any recollection when you first learned that JHU was applying for a patent concerning your alleged invention?
A I don't remember.

MR. MILLER: Counsel, we've been going for about an hour. Is this a good time for a break?

MR. RATLIFF: Doctor, would you like a break?

MR. MILLER: If you want a break, we can take a break or we can keep going, it's up to you.

THE WITNESS: If we keep going, the clock keeps ticking.

MR. MILLER: Let's keep going. I didn't know if you needed a --

THE WITNESS: I will need a break at some point to go to the bathroom.

MR. MILLER: You just let us know, okay?

BY MR. RATLIFF:

Q Now, Doctor, in your Declaration you testified that you have personal knowledge regarding your team's June 10, 2013, submission of information related to Clinical Trial No. NCT01876511, right?

A Can you repeat that question?

Q In your Declaration you testified that

you have personal knowledge regarding your team's June 10, 2013, submission of information related to Clinical Trial NCT01876511, right?

A Are you referring to page 9, paragraph 22?

Q No.

A No.

Q Let me ask my question again.

In your Declaration you testified that you have personal knowledge regarding your team's June 10, 2013, submission of information related to Clinical Trial NCT01876511, right?

Let me withdraw my question. Let me ask it a different way.

Do you have personal knowledge relating to your team's June 10, 2013, submission of information related to Clinical Trial NCT01876511?

A Do I have information? Is that what you asked?

Q That's not what I asked.

A Do I have -- I'm sorry.

Q Do you have personal knowledge relating

to your team's June 10, 2013, submission of information related to Clinical Trial NCT01876511?

A Do I have personal knowledge. I have knowledge.

Q Do you have personal knowledge relating to your team's June 10, 2013, submission of information related to Clinical Trial NCT01876511 to clinicaltrials.gov?

A You made a clarification. What do you mean by "personal"?

Q Have you ever used the term "personal knowledge"?

A I'm not sure.

Q Let me try my question again.

Do you believe that you have personal knowledge relating to your team's June 10, 2013, submission of information related to Clinical Trial NCT01876511 to clinicaltrials.gov?

A I guess I'm asking because you clarified personal versus knowledge. My knowledge is personal, so I guess yes.

Q Okay. And do you recall testifying in

your Declaration that you had -- that you have personal knowledge relating to your team's June 10, 2013, submission of information related to Clinical Trial NCT01876511 to clinicaltrials.gov?

I see you turning the page. Do you have any recollection of that?

A Do I have recollection of using the word "personal knowledge"?

Q No. That's not my question. Let me try my question again.

Do you have personal knowledge -- strike that.

Do you have a recollection of testifying in your Declaration that you have personal knowledge relating to your team's June 10, 2013, submission of information related to Clinical Trial NCT01876511 to clinicaltrials.gov?

A You asked me if I have personal knowledge. When you ask me if I have a recollection that I said in -- I knew about it -- I'm sorry, can you repeat the question?

Q Let me not repeat it.
A Okay.
Q So let me provide a different question.
A Okay.
Q Do you understand that your Declaration is testimony in this patent proceeding?
A Yes.
Q And do you understand that -- or did you intend for the words of your Declaration to be relied upon by the tribunal in this patent proceeding?
A I don't -- I am not sure what you mean by "tribunal."
Q Did you intend for the words that you write in your Declaration to be relied upon in this patent proceeding?
A Yes.
Q And do you recall testifying in this patent proceeding that you have personal knowledge relating to your team's June 10, 2013, submission of information related to Clinical Trial NCT01876511 to clinicaltrials.gov; yes or no?

A I do not recall specifically.
Q Okay. So let me turn your attention to paragraph 5 of your Declaration at page 3.
A (Complying.)
Q And do you see in paragraph 5 you testified that you have personal knowledge relating to your team's June 10, 2013, submission of information related to Clinical Trial NCT01876511 to clinicaltrials.gov?
A I do see that.
Q And when you wrote, "My team's June 10, 2013 submission," who were you referring to as your team?
A The individuals working on the submission.
Q And which individuals were those?
A That would be the regulatory individual and Dr. Diaz.
Q Which regulatory individuals?
A Dr. Durham, who might have been Dr. Uram at the time, I don't remember, it's been a long time, she got married -- is the individual I can

remember specifically that would be involved.

Q When you wrote "my team" in your Declaration, did you have an understanding of which individuals you were referring to?

A Doctor -- the regulatory team.

Q And which members constitute the regulatory team?

A So typically the supervisor is Dr. Durham. Ultimately she's responsible for this submission.

Q And, Doctor, understand, I'm not asking anything typical. I'm asking specifically who were the members of your team when you refer to it in paragraph 5 of your Declaration.

A Well, a submission would be the responsibility of the people involved, so it would be Dr. Durham's team and the IND sponsor, Dr. Diaz.

Q Okay, you just said "would be" in your response. I just want to be sure that we're clear. When you wrote your team -- your team's June 10, 2013 submission, what team members were

you specifically talking about?

MR. MILLER: Objection. Form.

A Dr. Durham and Dr. Diaz. Dr. Durham is -- leads the regulatory group, so she ultimately is part of my team.

Q Were you referring to any other team members?

A I was not specifically referring to any people. I was just referring to my team.

Q And who's your team? What are the members of your team?

A There are different members of different teams, but specifically at that time for the regulatory head was Dr. Durham.

Q Doctor, I'm just trying to find out -- you wrote in paragraph 5, "My team's June 10, 2013, submission." Are you able to tell us who were members of the team that you're referring to in paragraph 5 of your Declaration?

A I can tell you the important members of the team.

Q I'm not -- I don't want to know the

important members. I want to know who you were referring to when you wrote, "My team's June 10, 2013, submission" in paragraph 5. Are you able to tell us or not?

A I can tell you some of the people that were included were Dr. Durham and Dr. Diaz and myself.

Q Now, Clinical Trial NCT01876511, that's a clinical trial that's reflected in the study record that you refer to in your Declaration, right?

A The clinical trial -- say that one more time.

Q Clinical Trial NCT01876511 is the clinical trial reflected in the study record that you refer to in your Declaration, right?

A What's the study record?

Q Do you recall ever reviewing a study record in this case?

MR. MILLER: Objection. Form.

A That's very vague. I don't know what -- what do you mean by a "study record"?

Q Do you know what a clinical trial study record is?
A There are a lot of different meanings for "clinical trial study record," so I need to know specifically what you're asking me.
Q Did you review Exhibit 1005 as part of your work on this case?
A I think you might have to give me 1005.
Q Sure.
(Exhibit 1005 was marked for identification and was retained by Mr. Ratliff.)
Q Doctor, I'm handing you a copy of Exhibit 1005. Do you recall -- or did you ever -- did you review this document as part of your work on this case?
A Yes.
Q And what is it, to your knowledge?
A I see some dots on A and B, June 10, 2013, is a clinicaltrial.gov submission on June 10, 2013.
Q You told me what you see, but what is this document to your knowledge, Exhibit 1005?

A It's a submission to clinicaltrials.gov.
Q Okay. And you see on the front of the document it refers to study record versions?
A Study -- yes.
Q And is it your belief that Exhibit 1005 was submitted to clinicaltrials.gov?
A Is it my belief that this document was submitted?
Q Is it your belief that Exhibit 1005 was submitted to clinicaltrials.gov?
A Submitted.
MR. MILLER: Objection. Form.
A Clinicaltrials.gov -- it is my belief that there was a submission to clinicaltrials.gov for this NCT01876511.
Q Okay. So that wasn't my question. Let me back up and try something different.
Do you know what a clinical trial study record is?
A Through here? This -- what they mean by study record on this particular document?
Q No. I'm asking you, do you know what a

clinical trial study record is?
A We're talking in reference to a clinicaltrial.gov submission?
Q Yes.
A It looks like there are study record versions.
Q Do you know what a study record is?
A I don't know specifically what the term "study record" is referring to in this, but it's a record of the versions that are sent to clinicaltrials.gov.
Q And my question doesn't concern specifically Exhibit 1005. My question is, do you understand what a clinical trial study record is?
MR. MILLER: Objection. Form.
A You're talking with reference to this website, clinicaltrials.gov, a study version?
Q Doctor --
A A study record version.
Q -- have you ever used the term "study record" in this case?
A A lot. But not this. That's why I'm

trying to understand the context of "study record."

Q Well, you used the term "study record" in your Declaration, right?

A Can you show me?

Q Sure. Turn to paragraph 24 of your Declaration.

A (Complying.)

No, I'm sorry, paragraph --

Q Paragraph 24 at page 10. Let me know when you have that.

A Okay.

Q Do you see in paragraph 24 you used the term "study record"?

A (Reviewing.)

I see the term "study record."

Q And that's a term that you use in your Declaration, right?

A The word "study record" is used in this Declaration.

Q I'll start my question over again.

The term "study record" is a term that

you chose to include in your Declaration, right?

MR. MILLER: Objection. Form.

A Yes, the term "study record" is in my Declaration.

Q I'm not asking you if it's in your Declaration, I'm asking you if you chose to use that term "study record" in your Declaration. Or did someone else choose it?

MR. MILLER: Objection. Form.

A I signed the Declaration. It's my Declaration, so in effect I chose the word "study record."

Q And when you used the term "study record" in paragraph 24, what were you referring to?

A The NCT0205.06.

Q And what's that?

A That's a NCT number.

Q And so what is a study record as you understand it and as you refer to it in paragraph 24 of your Declaration?

A It's the record of NCT02054806.

Q And what does that mean to be a record of NCT02054806?

MR. MILLER: Objection. Form.

A It's something that's recorded for a study, NCT02054806.

Q Did you ever review the study record for NCT01876511?

A I reviewed the NCT02054806 on the clinicaltrials.gov.

Q Did you ever review the study record for NCT01876511 as part of your work in this case?

A Say that one more time. You're talking about this one (indicating)?

Q Did you ever review the study record for NCT01876511 as part of your work in this case?

MR. MILLER: Objection. Form.

A This record right here (indicating)?

Q I don't know what you're pointing to. What do you mean by "this"?

A This 1005.

I'm sorry, you switched from that study to this study. I'm a little bit -- I'm trying to

keep it straight.

Q Okay. So here's my question.

Did you ever review a study record for Clinical Trial NCT01876511 as part of your work on this case?

MR. MILLER: Objection. Form.

A Yes.

Q And is Exhibit 1005 the study record that you reviewed for Clinical Trial NCT01876511?

MR. MILLER: Objection. Form.

A I have reviewed this, or something that looks like this.

Q Is Exhibit 1005 the study record that you reviewed for Clinical Trial NCT01876511?

MR. MILLER: Objection. Form.

A Have I reviewed this, yes.

Q By "this," what are you referring to?

A This Merck Exhibit 1005.

Q So Merck Exhibit 1005 is a study record for NCT01876511?

MR. MILLER: Objection. Form.

A It's a study record, I guess. That's

what this is called, this is a study record.

Q So you understand that --

A There's a -- yeah, I think I'm getting stuck in what you're -- the semantics, but yes.

Q Let me make sure I have a clear answer to my question.

You reviewed Exhibit 1005, right?

A Yes.

Q And you cite it in your Declaration, right?

A This -- I cite it in my Declaration. We were just talking about the other study, so I would have to look to see if I cited a clinical -- a study report.

Q So, Doctor, I'm not -- can you show me where it is? I'm not talking about any study report.

So let's turn your attention back to Exhibit 1005. It's in front of you, right?

A Okay. I know, but you're asking me about my Declaration, so I'd like to -- when you ask me what's in the Declaration, I would like to

review the Declaration so that I keep it as honest and straight as possible because --

Q Okay. So I'm asking you now about Exhibit 1005.

A Yes.

Q And you have that in front of you, right?

A Yes.

Q And you reviewed it, right?

A Yes.

Q And it's a study record for Clinical Trial NCT01876511, right?

MR. MILLER: Objection. Form.

A It's a -- yes.

Q And the name of that clinical trial was entitled "Phase 2 Study of MK-3475 in Patients With Microsatellite Unstable MSI Tumors," right?

A That's what it says on the top of the page, yes.

Q And you refer to this study record, Exhibit 1005, in your Declaration, right?

A In paragraph 6.

Q So you refer to the study record, Exhibit 1005, in your Declaration, right?

MR. MILLER: Objection. Form.

A Exhibit 1005 is referred in the Declaration, yes.

Q Referred to in your Declaration, right?

A Yes.

Q And for the clinical trial that's reported on in Exhibit 1005, Merck collaborated with JHU to conduct that clinical trial, right?

A Merck is listed under Collaborator.

Q That wasn't my question Merck is listed as -- under Collaborator in the document. My question is different.

For the clinical trial that's reported on in the study record Exhibit 1005, Merck collaborated with JHU to construct the clinical trial, right?

MR. MILLER: Objection. Form.

A Can you repeat the question?

Q Merck collaborated with JHU to conduct the clinical trial that's reported on in the study

record Exhibit 1005, right?

MR. MILLER: Objection. Form.

A Merck is listed on page 3 as a collaborator.

Q And to your knowledge, Merck actually collaborated with JHU to conduct the clinical trial that's reported on in the study record, right?

MR. MILLER: Objection. Form.

A They provided drug, or agent, I guess, investigation agent.

Q So to your knowledge, Merck collaborated with JHU to conduct the clinical trial that's reported on in the study record, right?

MR. MILLER: Objection. Form.

A What do you mean by "collaborate"?

Q Have you ever used the word "collaborate" before?

A Do we have to do this every time? I just -- what is your definition? When -- you're asking me the question, so when you say "collaborate," what is your definition of

"collaborate"?

Q Do you know what a collaborator is in the context of a clinical trial?

A I don't know specifically what the definition for all collaborators are, but Merck provided drug.

Q Okay. I'm not asking for the definition for all collaborators.

For the clinical trial that's reported on in the study report, you were the principal investigator, right?

A I was the principal investigator.

Q As the principal investigator, you're responsible for supervising the overall conduct of the study, right?

A I am responsible for supervising the conduct of the study.

Q Let me try that again.

As the principal investigator, you were responsible for supervising the overall conduct of the study, right?

A The clinical trial? I was and -- yes,

and I am, yes.

Q And as part of your work as principal investigator, you've had interactions with Merck personnel, right?

A I have.

Q And to your knowledge, has Merck collaborated with JHU to conduct the clinical trial that's reported on in the study record?

MR. MILLER: Objection. Form.

A I think it means -- matters what you mean by "collaborate." Merck provided drug for the study. They're listed as a collaborator on page 3 of 6.

Q So let me try my question one more time.

Has Merck collaborated with JHU to conduct the clinical trial that's reported on in the study record?

MR. MILLER: Objection. Form.

Q Yes or no?

A Merck provided drug for the study.

Q Try it one more time.

And maybe this is your testimony.

Has Merck collaborated with JHU to conduct the clinical study that's reported on in the study record?

MR. MILLER: Objection. Form. Asked and answered multiple times.

A I feel like I need to know specifically what you mean by "collaborate," but it says Collaborator, Merck, and Merck provided drug for the study.

Q And when Merck provided drug for the study, did Merck charge JHU for that drug?

A No.

Q Did Merck provide any support other than providing drug to conduct the clinical trial that's reported on in the study record?

MR. MILLER: Objection. Form.

A So the study record is dated June 10, 2013. That's the study record we're referring to, correct?

Q Did Merck provide any support other than providing drug to conduct the clinical trial that's reported on in the study record?

MR. MILLER: Objection. Form.

A Merck provided some funding much later; I can't tell you when. Not as of June 10th, 2013.

Q And what do you mean by "much later"?

A I -- I don't recall, but I know that that is documented somewhere. That's something that could easily be found. I honestly do not recall the time frames of things.

Q And is your testimony -- is much later -- when you say "much later," do you have a year in mind?

A I don't.

Q And is it your testimony that prior to June 10, 2013, Merck did not provide any funding to conduct the clinical trial that's reported on in the study record?

MR. MILLER: Objection. Form.

A I don't recall any funding before June 10, 2013.

Q And do you recall if Merck provided any funding to support the clinical trial that's reported on in the study record prior to 2014?

MR. MILLER: Objection. Form.

A Is the study record referring to this June 10, 2013, study record, what was in the record as of June 10, 2013?

Q Let's try it again.

A Because we went on semantics about what we meant by "study record."

Q There's no semantics. You use the term "study record" in your Declaration, right?

MR. MILLER: Objection. Form.

Q You used the term "study record" in your Declaration, right?

MR. MILLER: Objection. Form.

Go ahead.

A Yes.

Q And you see on Exhibit 1005 it refers to study record versions, right?

A I'm sorry, where are we again?

Q Exhibit 1005.

A 1005. Yes, 1005.

Q It refers to study record versions?

A So we're referring to June 10, 2013?

Q Referring to study record, not referring to any particular time frame.

A These are done over different times. There's different information in different times. This is printed more recently because this wasn't printed on June 10, 2013.

Q So maybe -- let's just follow my question.

A Uh-humh.

Q You see Exhibit 1005 refers to the term "study record"?

A Yes.

Q And do you have any understanding of what that term means?

A "Study record" or "study record version"?

Q "Study record."

A "Study record" is a record of the study submitted to clinicaltrial.gov.

Q Okay. Now, I want to talk about the clinical trial that was reported on in the study record that we see here in Exhibit 1005. Okay?

So we're talking about Clinical Trial No. NCT01876511.

A So now we're talking about a trial, we're not talking about the submission?

Q We're talking about the trial.

A The actual trial.

Q And one of the IDs for that trial was MK3475-016. Do you recall that, right?

A Yes.

Q And I think you also have referred to this trial as KEYNOTE-16, right?

A Yes.

Q So let's talk about KEYNOTE-16.

In your view, has Merck collaborated with JHU to conduct KEYNOTE-16?

MR. MILLER: Objection. Form.

A I guess I'm not understanding how this is a different question about collaboration, KEYNOTE-16. Up to this point they had agreed to provide drug.

Q I don't know what point you're talking about.

A June 10, 2013.

Q Okay. So my question doesn't have a time frame. It's, sitting here, as of today, in your view, has Merck collaborated with JHU to conduct KEYNOTE-16?

MR. MILLER: Objection. Form.

A As of June 10, 2013, they're listed as Collaborator. They provided drug. At some point in the future, not here, and I can't tell you when, but they did provide funding.

Q In your view, as of today, would you say that Merck has collaborated with JHU to conduct the clinical trial that is KEYNOTE-16?

MR. MILLER: Objection. Form.

A I think I'm still not sure what you mean by "collaborated." They provided some things for the clinical trial. They provided drug. Is that considered collaboration?

Q It's your view. So let me ask my question again.

As of today, would you say that Merck has collaborated with JHU to conduct KEYNOTE-16?

MR. MILLER: Objection. Form. Asked and answered.

A Okay. Again, they provided drug initially as listed here on this document, Collaborator. And then at some point later, they provided funding.

Q And is it your belief that you're aware of all of the funding that Merck ever provided for KEYNOTE-16?

A Is it my belief that I'm aware? Do I believe that I'm aware?

Q Do you believe that you're aware of all of the funding that Merck ever provided for KEYNOTE-16?

A Do I believe -- I believe I'm aware.

Q Okay. And it's your testimony and belief that Merck did not provide funding to support KEYNOTE-16 prior to 2015?

A I can't give you a date. I don't remember.

Q Is it your testimony that Merck did not provide funding to support KEYNOTE-16 prior to

2014?

A I can't remember the dates. I just can't remember. It's --

Q And is it your belief that Merck did not provide funding to support KEYNOTE-16 prior to February of 2014?

A I can't remember the dates.

Q Now, in your Declaration when you testified about your team's June 10, 2013, submission to clinicaltrials.gov, can you tell us how that submission was made to clinicaltrials.gov?

MR. MILLER: Objection. Form.

A Made?

Q Yes. Was it a letter, was it an email? How was that submission made?

A It's not a letter or an email.

Q What was it?

A It's a web-based submission.

Q So your team's June 10, 2013, submission of information regarding KEYNOTE-16 to clinicaltrials.gov was an electronic submission?

MR. MILLER: Object to form.
A I don't recall specifically.
Q What's your general recollection?
MR. MILLER: Objection. Form.
A I can't recall specifically.
Q Do you have a general recollection?
MR. MILLER: Objection. Form.
A I can't recall specifically.
Q And, Doctor, I'm not asking you to recall specifically. I'm asking you if you have a general recollection. So let me try my question again.

Do you have a general recollection as to how your team's June 10, 2013, submission of information for KEYNOTE-16 was submitted to clinicaltrials.gov?

MR. MILLER: Objection. Form.
A I know that it was sub -- there is a submission to clinicaltrials.gov any time that you're about to initiate a trial, and the submission is drafted by the regulatory team, and the investigators review the submission. That's

the general recollection.

Q Okay. So your response was about any time that you're about to initiate a clinical trial. So my question is specifically about the June 10, 2013, submission that you referred to in your Declaration.

So my question is, with respect to that June 10, 2013 submission, do you have any recollection whatsoever what was the form in which that submission was made to clinicaltrials.gov?

A I can tell you that things are reviewed and it's the team that submits it.

Q With respect to the June 10, 2013, submission that you referred to in your Declaration, do you have any recollection whatsoever what was the form in which that submission was made to clinicaltrials.gov?

A I have recollection of review.

Q Do you have any recollection of what the form was in which that submission was made?

A I cannot say that I was there when someone pushed the button. Is that what you're

referring to are the --

Q No, I didn't say anything about pushing a button.

A Okay.

Q So let me try my question again.

Do you have any recollection whatsoever of the form of the June 10, 2013, submission that you referred to in your Declaration?

A The form. I have recollection of review.

Q Do you have any recollection if the submission that you referred to in your Declaration was made electronically?

A I don't have recollection of being there with the person when they submitted it, but I have recollection of review.

Q Do you know how the June 10, 2013, submission was provided to Clinical Trials?

A Do I know specifically? That would be easy to find out.

Q I'm not asking if you can go find out. I'm asking you, sitting here today, do you know

how the June 10, 2013, submission that you refer to in your Declaration was made to clinicaltrials.gov?

A The actual submit, I don't know if -- I cannot say that I was there when it was -- the button was submitted, or how -- that part of it. I can recall review for the submission.

Q I'm not asking you if you were there when a button was pushed. My question is different.

Do you know how the June 10, 2013, submission that you refer to in your Declaration was made to clinicaltrials.gov?

A Do I know how? I know that the regulatory team would confer with the team members and what goes into the document and then they would submit -- we would review it and they would submit it.

Q And you're saying "would." I'm asking you about facts. Okay?

A I know it was submitted on June 10, 2013.

Q And you testified that you have personal knowledge relating to your team's June 10, 2013, submission?

A I have personal knowledge of the submission, yes.

Q And so my question is, do you know how it was submitted to the FDA?

A Are you asking me if it was electronically submitted? Well, it's actually clinicaltrials.gov, it's not the FDA. Or it was mailed in; is that what you're asking me? I know that I reviewed it and it was submitted.

Q And do you know --

A And the submission date is listed as June 10, 2013.

Q And do you know if it was submitted to clinicaltrials.gov electronically?

A Do I know that. I don't know that. I know it was submitted and I know it was reviewed. I don't know -- because I didn't -- oftentimes our team members hit the buttons for us, or they might print it out as well and send it in. Sometimes

with the FDA you actually have to do both. So I know it was submitted.

Q Do you have a copy of June 10, 2013, submission in your files?

A Here?

Q In your files at work, do you have a copy of the June 10, 2013, submission?

A Do I personally have a copy right now in my files? The files are usually maintained by the regulatory team.

Q Do you have a copy of the June 10, 2013, submission in your files?

A Do I have a copy in my files?

This June 10, 2013, regulatory submission is in a file -- it should be in a file, a regulatory file.

Q So it's your belief that somewhere within JHU there is a copy of the June 10, 2013, submission?

A I don't know what you mean by "copy." There are -- there should be a documentation trail.

Q Do you know if there's a copy of the June 10, 2013, submission in any file at JHU?
A A copy of -- I can't specifically say that there is a copy.
Q Okay. So sitting here today you don't know if there's a copy of the June 10, 2013, submission to clinicaltrials.gov, right?
MR. MILLER: Objection. Form.
A I can't say that there's a copy.
Q Okay. But it's your belief that what was submitted to clinicaltrials.gov for KEYNOTE-16 was posted on the clinicaltrials.gov website on June 10, 2013, right?
A Say that one more time.
Q It's your belief that what was submitted to clinicaltrials.gov for KEYNOTE-16 was posted on the clinicaltrials.gov website on June 10, 2013, right?
A It is my belief that there was a submission back in June of 2013.
Q Are you finished with your response?
A That there was a submission? Yes.

Q So let me go back to my question.

Is it your belief that what was submitted on clinicaltrials.gov for KEYNOTE-16 was posted on the clinicaltrials.gov website on June 10, 2013?

MR. MILLER: Objection. Form.

A I'm -- I guess now you're referring to it as KEYNOTE-16. I actually don't know what it was referred to at the time.

So I can tell you that there was a submission for NCT01876511 in June of 2013.

Q And isn't NCT01876511 the same thing as KEYNOTE-16?

A Honestly, I don't understand the semantics, if it's the same thing. The NCT is a number provided by clinicaltrials.gov.

Q In your view, is there a difference between Clinical Trial No. NCT01876511 and KEYNOTE-16?

A KEYNOTE-16 -- you'd have to ask Merck how they come up with their numbers to identify things.

Q You used the term "KEYNOTE" in your Declaration, right?

A Let's see.

(Reviewing.)

Q Wait. Before you even look at your Declaration, you don't recall using the term "KEYNOTE-16" in your Declaration?

A I did use the term "KEYNOTE-16" in my Declaration.

Q So in your opinion, is there a difference between NCT01876511 and KEYNOTE-16?

MR. MILLER: Objection. Form.

A Is there a difference? All the numbers are created by the -- whoever needed it for documentation, for their purposes, so they're -- they're not the same.

Q So is it your testimony that the clinical trial that has been identified as NCT01876511 is not the same clinical trial as KEYNOTE-16?

MR. MILLER: Objection. Form.

Q Is that your testimony?

MR. MILLER: Objection. Form.

A It's not my testimony.

Q Okay. So let me try this.

Would you agree that the clinical trial that has been identified as NCT01876511 is the same clinical trial that you refer to as KEYNOTE-16 in your Declaration?

A KEYNOTE-16 refers to the Merck identification of a study. NCT0187655 [sic] is a clinicaltrials.gov registration number for a clinical trial. And then there's also a number for Hopkins. Hopkins has their own number.

Q Would you agree that this clinical trial that has been identified as NCT01876511 is the same clinical trial that you refer to in your Declaration as KEYNOTE-16?

MR. MILLER: Objection. Form.

A NCT01876511 encompasses KEYNOTE-016 and J1365.

Q Let's try this one more time.

Would you agree that the clinical trial that has been identified as NCT01876511 is the

same clinical trial that you refer to in your Declaration as KEYNOTE-16?

MR. MILLER: Objection. Form.

A I guess I just am trying to clarify NCT is actually a clinical trial. It's a number. But NCT01876511 is, encompasses KEYNOTE-016. We're talking about the same thing, yes. Sort of. Again, I'm getting stuck on the -- what the words actually mean, but ...

Q Well, one we word we're talking about is KEYNOTE-16 that you use in your Declaration, right?

A Yes.

Q And another word that we're talking about is NCT01876511 that you use in your Declaration, right?

A Yes.

Q And those are references to the same clinical trial, right?

MR. MILLER: Objection. Form.

A It's Merck's reference -- Merck identifies it as KEYNOTE-16.

Q And you in your Declaration identify it as KEYNOTE-16, right?

MR. MILLER: Objection. Form.

A I state that these studies were referred to by Merck in its application to the FDA as KEYNOTE-16 and KEYNOTE-164. Is that what you're referring to?

Q No.

Don't you refer to the Clinical Trial No. NCT01876511 as KEYNOTE-16 in your Declaration?

I see you turn to your Declaration. Do you not recall what's in your Declaration?

A I mean I recall some things in the Declaration, but we've written a lot of different things, so I just -- since you're asking me what's in the Declaration, I would like to look at the Declaration.

Q So my question is clear. In your Declaration, don't you refer to the clinical trial with the number NCT01876511 as KEYNOTE-16?

A KEYNOTE-16 is mentioned in the Declaration on page 2. These studies were

referred by Merck in its application to the FDA as KEYNOTE-16.

Q You refer to KEYNOTE-16 in several places in your Declaration, right?

A I see it in another spot, yes.

Q And KEYNOTE-16, it's the same clinical trial that is the clinical trial that's been identified as NCT01876511, right?

MR. MILLER: Objection. Form.

A It's -- KEYNOTE-16 is -- matches up to this NCT. I guess I'm getting lost in the questioning.

Q They're the same clinical trial, right?

MR. MILLER: Objection. Form.

A As opposed to a different clinical trial? It's --

Q Do you believe sitting here today that KEYNOTE-16 is a different clinical trial than the clinical trial with the number NCT01876511? Is that your testimony?

A No, that's not what I'm saying.

Q So don't you agree that KEYNOTE-16 --

A I agree --
Q -- refers to the same clinical trial that has been identified as NCT01876511?
MR. MILLER: Objection. Form.
A It is a trial that is referred in this, in the NCT01876511. This is Merck's name for this -- the reference to this clinical trial.
Q So we're talking about one clinical trial that has been referred to by you as KEYNOTE-16, and you also refer to it as NCT01876511, right?
MR. MILLER: Objection. Form.
A I refer to this clinical trial NCT01876511, and we're talking about the study that Merck refers to as KEYNOTE-16.
Q There's only one study, right?
A There --
MR. MILLER: Objection.
A Yes.
MR. MILLER: Objection. Form.
Q Yes, there's only one study?
MR. MILLER: Objection. Form.

Wait. You need to pause.

You need to pause.

Objection. Form. Go ahead.

Q So my question is, for that one study in your Declaration, you refer to it as KEYNOTE-16, and sometimes you refer to it as NCT01876511, right?

MR. MILLER: Objection. Form.

A I sometimes refer to this NCT number, which is a registration for clinicaltrial.gov, sometimes I refer to it as KEYNOTE-16, sometimes, in the Declaration. I don't see it on this submission. That's all I was saying.

Q Okay. So let's focus on my question. I just want to be sure that --

A They have a secondary ID, I guess is what they call it.

Q I just want to be clear.

KEYNOTE-16, that clinical trial, is the same clinical trial that you refer to in your Declaration as NCT01876511, right?

MR. MILLER: Objection. Form.

A It's -- there is one clinical trial that is -- that we're talking about; is that what you're --

Q Yes. There's one clinical trial that we're talking about.

A Yes. I'm not talking about some other clinical trial.

Q And sometimes that one clinical trial, you refer to it as KEYNOTE-16, right?

A 16 -- yes. It says these studies are referred to by Merck as application to FDA's KEYNOTE-16.

Q So that one clinical trial, you have referred to it as KEYNOTE-16 in your Declaration, right?

I see you paging through your Declaration.

A Yes.

Q Let me withdraw that question.

A Okay.

Q The one clinical trial that we're talking about, have you ever, at any point in

time, referred to it as KEYNOTE-16?

A The one clinical trial -- have I ever -- yes.

THE WITNESS: Can we take that break now?

MR. MILLER: Yep.

MR. RATLIFF: Sure.

(A recess was taken at 11:03 a.m.)

(Back on the record at 11:19 a.m.)

BY MR. RATLIFF:

Q So I'd like to turn your attention to Exhibit 1005. Do you have that in front of you?

A Yes.

Q And is it correct that the recruitment of patients for KEYNOTE-16 began after August 27, 2013?

A The recruitment of patients for the clinical trial occurred sometime after June 10th, 2013.

Q Okay. When you say "clinical trial," you're referring to KEYNOTE-16?

MR. MILLER: Objection. Form.

A Can I refer to it as just "the trial"? We're talking about one trial.

Q So when you say "the trial," you're referring to KEYNOTE-16 or the same thing as NCT01876511; is that fair?

MR. MILLER: Objection. Form.

A I would like to refer to the trial as J1365 because I'm getting thrown off by -- we're talking about a clinical trial.

Q You would like to refer to it as what?

A J1365.

Q And you realize that nowhere in your Declaration you've ever referred to it by that identifier, right?

A I am realizing that now.

Q So let's refer to it as "the trial." There's only one trial, right?

A Yes, let's refer to it as "the trial."

Q Got it.

Now, during the break, did you speak to your counsel about any of my questions or this case?

A I spoke to him about some frustration about semantics.

Q Okay. So let me ask my question again.

Do you --

A And he said we're not supposed to talk about the trial. So then we came in and joked with her about some court reporting.

Q So did you have any other conversation with your counsel about any of my questions or this case?

A The frustration about going over semantics and why you can't just explain to me the definition of something. Just the semantics --

Q Okay.

A -- not like all these different questions that you're asking me.

Q Okay. So let me just try my question again so we're clear.

Other than what you say is "frustration about semantics," did you speak with counsel about any of my questions or this case?

A The semantics of the questions, and he

said we're not supposed to talk about the deposition.

Q So, Doctor, just so we understand, other than your discussion with counsel about what you believe are semantics, did you speak with counsel about any of my questions or this case?

A The semantics ones. I said, I don't understand the semantics, why we keep going over trial, NCT, KEYNOTE-16. We're talking about one trial.

So I guess going over some issues about the questions because that was about the semantics which was in your question that we kept going back and forth on. But semantics. I was frustrated about going over the semantics, why we keep calling things different things. We're referring to one trial.

Q Okay.

A I mean I don't know, maybe you can explain it to me. I don't know why we keep going over -- we're just -- you're talking about a particular -- when we say "trial," we're referring

to clinical trial, a clinical trial, one clinical trial that we're referring to.

Q So let's focus on my question, Doctor.

So I'm not asking you about your counsel -- your conversation with counsel about semantics --

A Yes.

Q -- about what you say is alleged semantics. I'm not asking about that. Do you understand that?

So my question is, other than that, did you have any discussions with counsel about any of my questions or this case?

A I told you about which question I discussed, and it was why it's -- not specifically about the questions, it was about the trial, why we keep taking about NCT versus KEYNOTE-16.

It's frustrating why he keeps asking me the same thing. And he said we're not supposed to talk about the trial -- I mean not the trial, the deposition, whatever this is. We're not supposed to talk about the deposition.

Q Did you have any other discussion with counsel about this case or my questions?

A I only discussed that I was very frustrated with this back-and-forth when I feel like I've answered a question or about semantics of "a trial," I mean, not the trial. I'm getting confused again.

Just going over and over again about a trial. We know what trial we're talking about. We know there is a submission, we know there is a trial, and I guess I don't know why you -- I feel like you're trying to confuse me, that's all.

And that's not what I said to him. I just said it's confusing, and I don't know why we keep going back and forth, and I was frustrated.

Q And, Doctor, you seem to be raising your voice in response to my question. Are you okay?

A I'm okay.

Q So, Doctor --

A Yes.

Q -- other than the conversations that you just explained to me that you had with counsel

during the break, did you have any other conversation with counsel about my questions or this case?

MR. MILLER: Objection. Form. Asked and answered now multiple times.

A I talked about my frustration about going over semantics.

Q You understand I'm not asking about that. We're past that.

A You asked me what we talked about.

Q No, that's not right. So let me try my question again. I'll go slower.

I'm excluding from my question any discussion you had about alleged semantics. Other than your discussion with counsel about alleged semantics, did you have any discussion with counsel about any of my questions or this case?

A Yes, the trial. I didn't understand why we kept going over NCT trial, KEYNOTE-16. We're talking about one trial. That was the other discussion. And he said we're not supposed to talk about the deposition.

Q Okay. So let's talk about the trial.

Is it correct that the recruitment of patients for the trial began after August 27, 2013?

A I can tell you that the trial recruitment -- I guess it depends on what you mean by "recruitment."

Q How did you -- I mean how you meant recruitment when you used that term in your Declaration.

A Recruitment usually means when you can actually start putting patients -- like it's actually open, the study is open, and you can recruit.

Q Okay. So is it correct that for the trial, recruitment of patients began after August 27, 2013?

A Recruitment does not start when you do the submission. Recruitment starts after you have all the approvals and things are set to go. So the recruitment occurred after.

Again, when you give me dates, I just

got to get a little confused.

Q Doctor --

A We could not recruit in June.

Q But, Doctor, you used dates in your Declaration, right?

A Yes, because I can look at things.

Q Were you confused about dates that you talked about in your Declaration?

A But I can doublecheck things.

Q No, different question.

A When --

Q I'm not asking if you can -- Doctor, I'm asking were you confused about any of the dates that you talk about in your Declaration?

A I -- not specifically when I was doing the Declaration and looking at things to --

Q Were you confused about any of the dates that you talked about in your Declaration?

A I mean we'd have to go over every specific date, but at the time when you sign the Declaration, you can look at things.

Q Doctor, were you confused about any of

the dates that you talked about in your Declaration?

MR. MILLER: Objection. Form. Asked and answered.

A Was I confused about any of the dates --

Q Let me withdraw that question.

Are you confused about any of the dates that you talk about in your Declaration?

A Can I recite them to you without looking at the Declaration? I cannot recite them to you.

Q That wasn't my question. I didn't ask you to recite any dates. I'm just asking you, you're familiar with your Declaration, right?

A Yes.

Q So I'm asking you, are you confused sitting here today about any of the dates that you refer to in your Declaration?

A What do you mean by "confused"?

MR. MILLER: Objection.

Sorry. Just pause so I can interpose an objection.

Objection. Form. Asked and answered.

Go ahead.

Q Are you confused by any of the dates that you refer to in your Declaration?

MR. MILLER: Same objection.

A I don't like the term "confused." I like to verify when you ask me about things because the document is in front of me, so ...

Q Is it correct that the recruitment of patients for the trial began after August 27, 2013?

A The recruitment occurred after a particular date. I can tell you it doesn't occur right away. It does not occur in June.

Q And for the trial, didn't you testify in your Declaration that the recruitment of patients began after August 27, 2013?

A (Reviewing.)

MR. MILLER: Objection. Form.

Q I see you paging through your Declaration. Do you recall right now without paging through your Declaration whether or not you testified that the recruitment of patients for the

trial occurred after August 27, 2013?

Do you understand my question, Doctor?

A Yeah, I do understand your question, and I looked at this document just yesterday so I just want to confirm.

(Reviewing.)

Q And I want you to appreciate that my question is not asking you to look at your Declaration. I'm just saying, right now, without looking through your Declaration, do you have any recollection testifying that the recruitment of patients for the trial occurred after August 27, 2013?

A I cannot specify the date.

Q So you don't have a recollection, right?

A I don't have a recollection right this minute of entering a date.

Q And that's fine.

Let me turn your attention to paragraph 22 of your Declaration at page 9. And let me know when you have it.

A 22.

(Reviewing.)

I am there.

Q Can you read paragraph 22 to yourself and let me know when you're finished.

A (Reviewing.)

Yes.

Q And after reading paragraph 22 to yourself, does it refresh your recollection as to your testimony in your Declaration in paragraph 22?

A Yeah. The last line says:

We received IRB approval for the clinical trial on July 3rd, 2013, and our clinical trial number was activated on August 27, 2013, after which we were allowed to begin recruiting patients.

Q Okay. So based upon a refreshed recollection, is it correct that the recruitment of patients for the trial began after August 27, 2013?

A It was activated on August 27, 2013. I guess it depends what you mean by "recruited," but

you can't put patients on a trial until after it's activated.

Q Is it correct that the recruitment of patients for the trial began after August 27, 2013?

A You can't recruit a patient, put a patient -- put a patient on a trial until after it's activated.

Q And we're talking specifically about the trial, the one trial we're talking about in this case.

Okay, so here's my question.

Is it correct that for the trial you were not allowed to begin recruiting patients until after August 27, 2013?

A It is fair to say we can't recruit patients until the trial is activated.

Q Okay. I'm not asking about any trial, I'm asking about a very specific trial. I'm asking about KEYNOTE-16, okay? So I want you to understand I'm not asking about "a trial."

A Okay.

Q I'm asking about KEYNOTE-16.

So here's the question.

With respect to KEYNOTE-16, is it correct that you were not able to begin to recruit patients until after August 27, 2013?

MR. MILLER: Objection. Form.

A The trial was activated on August 27, 2013. This trial. We were allowed to recruit after it was activated.

Q So is it correct that the recruitment of patients for the trial began after August 27, 2013?

A Recruiting, putting patients on trial could not occur before August 27, 2013.

Q And the recruiting of patients for the trial did not occur before August 27, 2013, right?

A We cannot enroll patients on a trial before it's activated.

Q I'm not asking about a trial. I'm asking specifically about KEYNOTE-16. So here's my question.

As principal investigator for

KEYNOTE-16, is it correct that the recruitment of patients did not occur until after August 27, 2013?

A We could not recruit patients -- we could not put patients on the trial before August 27, 2013.

Q So then is it correct that the recruitment of patients for the study began after August 27, 2013?

A It was allowed to begin after.

Q After what?

A After it was activated.

Q So let me try my question again. Let me ask it this way.

When were you first allowed to recruit patients for KEYNOTE-16?

MR. MILLER: Objection. Form.

A I know it was not before August 27, 2013.

Q Okay.

A There's just a lot of steps. So to actually be recruit -- I know that you can't

recruit before August 27, 2013.

Q So for KEYNOTE-16, the recruitment of patients began on August 27, 2013 or after?

MR. MILLER: Objection. Form.

A I just can't -- I can only say that we could not recruit before it was activated. It was activated on August 27, 2013.

Q And so as principal investigator for KEYNOTE-16, you can't tell me whether or not the recruitment of patients for the study began on or after August 27, 2013; is that your testimony?

A I can tell you that it did not occur before August 27, 2013.

Q Can you tell me if it occurred after August 27, 2013?

A What's the difference?

Q Because I'm asking if it occurred after.

A Did we recruit patients sometime after August 27, 2013. We recruited patients sometime after August 27, 2013.

Q Okay. And is it correct that for the trial, the recruitment of patients began after

August 27, 2013?

A You recruited -- you couldn't recruit patients -- you were allowed to recruit patients sometime after it's activated, and it was activated on August 27, 2013.

Q Okay. Let me ask it one more time.

As principal investigator for KEYNOTE-16, is it correct that the recruitment of patients for that study began after August 27, 2013?

A I can tell you that we were allowed to begin sometime after, on or after August 27, 2013.

Q Allowed to begin recruiting of patients?

A We were allowed to begin recruiting patients after.

Q Are you finished with your response?

A Yes.

Q Okay. So let me try it again because you said "after" and I didn't hear a date.

A Oh. After August 27, 2013, on or after, we were allowed to begin recruiting patients.

Q For KEYNOTE-16?

A For the trial.
Q Okay. So after -- on or after August 27, 2013, you were allowed to begin recruiting patients for the trial, correct?
A Sometime. Sometime, yes, we were allowed to begin sometime after. I can just tell you that you cannot recruit patients before the study is activated.
Q And as principal investigator, you can't tell us whether or not on or after August 27, 2013 the recruitment of patients began for the trial?
MR. MILLER: Objection. Form.
Q Is that your testimony?
MR. MILLER: Apologies.
Objection. Form.
A I can tell you that we could not recruit patients before August 27, 2013.
Q And you can't tell me whether or not the recruitment of patients for the trial began on or after August 27, 2013, right?
A I can tell you that you can't recruit patients before because it has to be activated.

Q Okay. That's your testimony.

Is it correct that before your work with pembrolizumab, oncologists had already given pembrolizumab to cancer patients?

A Say that one more time.

Q Is it correct that before your work with pembrolizumab, oncologists had already given pembrolizumab to cancer patients?

A Oncologists had given -- I don't know what it was referred to at the time. Before -- you're talking about before we did the submission on June 10, 2013?

It's been a long time. The drug names have changed, but before June 10, 2013, oncologists did give -- I think it might have been called MK-3475 on -- so I guess that's what you were asking me. Yes. I don't know that it was called pembrolizumab at that time.

Q In your view, is there a difference between MK-3475 and pembrolizumab? It's the same chemical compound, right?

A MK-3475 is pembrolizumab, but you asked

me -- I wasn't sure if you were referring to at that time. You said before we started our work if oncologists had given pembrolizumab, and I believe at the time it wasn't called pembrolizumab, but yes, oncologists had given this agent to patients with cancer.

Q So it's correct that before your work with pembrolizumab, oncologists had already given pembrolizumab to cancer patients?

MR. MILLER: Objection. Form.

A They had given pembrolizumab, or a variation, MK-3475, or a different name for it, I guess, to patients with cancer.

Q And is it correct that before the work of any of your team, oncologists had already given pembrolizumab to cancer patients?

A With work of any of my team.

Can you repeat the question?

Q Is it correct that before your team's work with pembrolizumab, oncologists had already given pembrolizumab to cancer patients?

A Before our work -- what does "our work"

mean?

Q When did you start working with pembrolizumab?

A You mean actually administering the MK-3475? Is that what you mean by "work with"?

Q When did you start administering pembrolizumab to cancer patients?

A Sometime during the conduct of the clinical trial. I can't give you the exact date of the first administration.

Q Can you give me the year of the first administration?

A 2013 -- no. Actually, I can tell you that we -- I can tell you approximately that time frame. I can't give you the exact date.

Q Do you realize I'm not asking you the exact date, right?

A Yeah. I'm giving you the time frame because these things sometime take a lot longer in real life than it does on paper, so I can give you a time frame.

Q Do you know what my question was to you?

A Can you give me the exact year, and I said I can't give you the exact year, I can give you a time frame.

Q That wasn't my question.

A Oh, yes.

Q Can you give me the year when your team first administered pembrolizumab to cancer patients?

A Okay. So now we're talking about teams, and I'd like to only speak for myself because I don't know who you're referring to when you say "team."

As far as I can remember, it would have been sometime within this study, the clinical trial. And I think when you say "pembrolizumab," we're talking about MK-3475.

Q So when I refer to "your team," I'm referring to the same team that you testified about in your Declaration, for example, in paragraph 14.

I see you turning to your Declaration.

A Yes, I am turning to my Declaration.

Q You are aware that throughout your Declaration you refer to, quote, my team, right?

MR. MILLER: Objection. Form.

A Yes, I refer to my team.

Q So that's the team I'm referring to.

A Okay.

Q So let me try my question again.

Do you know when your team first administered pembrolizumab to a cancer patient?

MR. MILLER: Objection. Form.

A So in paragraph 14, my team -- we're talking about the IND application, which includes regulatory people. When you ask me when MK-3475 was administered, I usually think about that as like given, which is not really the same team. So I get confused when you use the word "team."

But I can tell you that the first patient or subject on the trial that we're referring to received MK-3475 approximately in the 2013-2014 time frame.

Q Did the first patient in the trial receive pembrolizumab in 2013?

A I would have to review again any of the source documents for the date.

Q So sitting here today you don't know whether or not the first patient to receive pembrolizumab in the trial received it in 2013, right?

A Sitting here today I would have to look at some documents and records.

Q So sitting here today you don't know when the first patient received pembrolizumab in --

A Sitting here today --

Q -- in the trial, right?

A Okay. Sorry. Regroup. What was your question again?

Q Sitting here today --

A Yes, I'm sitting here today.

Q -- you do not know when the first patient received pembrolizumab in the trial, right?

A Sitting here today, right this minute, I cannot tell you the exact date on when the first

patient in the trial received the drug MK-3475.

Q Sitting here today, can you tell me the year when the first patient received pembrolizumab in the trial?

A Sitting here today, I would need some access or a review to confirm the year.

Q Sitting here today, do you know the year when the first patient received pembrolizumab in the trial?

A The issue with the year is that the year is 2013-2014. So if I knew the exact date, I could tell you the year.

Q So let me try my question again.

Do you know whether or not the first patient in the trial received pembrolizumab in 2013?

A Sitting here today, I cannot tell you if the first patient in the trial received MK-3475 in 2013.

Q And MK-3475 is pembrolizumab, right?

A Some people -- yeah, at some point it became known as pembrolizumab. I don't know -- I

can't remember when.

Q I'm not asking you when, but it's the same chemical compound, MK-3475 and pembrolizumab, they're the same chemical compound, right?

MR. MILLER: Objection. Form.

A That's my understanding.

Q Okay.

A Okay.

Q So sitting here today, do you know whether or not the first patient in the trial received pembrolizumab in 2014?

A Sitting here today, I would need to look at the records again to see exactly when the very first dose was given.

Q I'm not asking you about exactly when the very first dose was given. Different question.

A Okay.

Q Sitting here today, do you know whether the first patient in the trial received pembrolizumab in 2014?

A Sitting here today, the first patient

received -- oh, on this trial received MK-3475 somewhere in 2013 or 2014.

Q Okay. I'm not asking you about 2013. My question is about 2014.

Sitting here today, do you know whether or not the first patient to receive pembrolizumab in the trial received it in 2014?

A I cannot tell you if the first patient on this trial received the first infusion of MK-3475 in 2014.

Q Okay. And again, by MK-3475 you're talking about pembrolizumab, right?

A At the time it was referred to as MK-3475.

Q But they're the same chemical compound, right?

MR. MILLER: Objection. Form.

A As far as my understanding.

Q They're the same chemical compound, right?

MR. MILLER: Objection. Form.

A As far as my understanding.

Q I'm not sure that's an answer to my question.

MK-3475 and pembrolizumab are the same chemical compound, right?

MR. MILLER: Objection. Form. Asked and answered.

A It's -- as far as my understanding.

Q As far as your understanding, what?

A As far as my understanding, MK-3475 is the same as pembrolizumab, which it wasn't at the time, at the time it was not called pembrolizumab.

Q And in your Declaration, you refer to, quote, my team, several times, right?

A Yes.

Q And is it your testimony here today that when you refer to "my team" in your Declaration, you're referring to different teams at different points in your Declaration?

A In my Declaration, when I say "team," I'm referring to people have different jobs on the team. So I didn't specifically say I and this person and that person.

Q Let's make sure this is really clear.
Turning to paragraph 5 of your Declaration on page 3 you used the term "my team." Do you see that?
A I'm sorry, what paragraph?
Q Turning to paragraph 5 --
A Paragraph 5, on page 3.
Q -- of your Declaration on page 3 --
A Uh-humh.
Q -- you used the term "my team." Do you see that?
A Oh, you mean my team's June 10th, 2013, submission?
Q You see that, right?
A Yes.
Q When you refer to "my team" there, who were the individuals that you were referring to by name?
A The team is the people who ultimately are responsible for the submission.
Q And what are their names?
A The people who are responsible? The

people who are responsible are Jenn Durham and then Dr. Diaz. Those are people that, primarily the people who are responsible for it. Whether somebody else submits the button or puts it on -- you know, that's the team. That's the core responsible team.

Q So who are the members of the team that you were referring to in paragraph 5?

A Dr. Durham's team and Dr. Diaz's team. So that's me and Dr. Diaz, and then the regulatory team is run by Dr. Durham.

Q Who's on Dr. Durham's team, as you're referring to it here in paragraph 5?

MR. MILLER: Objection. Form.

A I can't recall back in 2013 who her team members were.

Q And who was Dr. Diaz's team as you were referring to in paragraph 5?

MR. MILLER: Objection. Form.

A Well, it involved at least Dr. Diaz and myself and Dr. Durham.

Q Who else does it involve?

A I can't specifically say.
Q When you wrote "my team" here, did you have in mind specific individuals?
A I had specific individuals in the sense that there are people responsible for the submissions, Dr. Durham's team and Dr. Diaz's team. Dr. Durham is part of Dr. Diaz's team. I am part of Dr. Diaz's team. So I'm primarily referring to the responsible people.
Now, I can't say if there are other individuals because Hopkins has a lot of individuals who work on a lot of different things, but when I'm talking about "my team," I'm talking about the responsible members.
Q In paragraph 11 of your Declaration, at page 5, you refer to "my team."
A I'm sorry, one more time. Paragraph 5 of --
Q No.
A I'm sorry.
Q Let me turn your attention to paragraph 11 of your Declaration at page 5.

A Paragraph 11 at page 5. Yes.
Q Do you see there you refer to, quote, my team?
A Yes.
Q Who were the members of your team that you were specifically referring to here in paragraph 11 of your Declaration?
A Who designed the study? I can remember myself and Dr. Diaz specifically. Well, and typically when you design a study, you have a statistician that helps you with numbers. Those are the people I can remember specifically.
Q So who were the people that you were referring to when you wrote "my team" in paragraph 11 of your Declaration?
A I can specifically state that it would at least involve me and Luis, or Dr. Diaz, I'm sure.
Q Okay. And when you prepared your Declaration, you prepared it with thought and care, right?
A I did.

Q And when you prepared your Declaration, you were conscious of the choice of words that you used, right?
A I tried to be, but --
Q And when you prepared your Declaration, you were conscious of the terminology that you used in your Declaration, right?
A Yes.
Q And when you signed your Declaration, you weren't confused about the terminology or phrasing that you used in your Declaration, right?
A Well, sometimes the clarity of words might have been better used by pronouns with specific names. I don't --
Q When you signed your Declaration, you weren't confused about the terminology or phrasing that you used in your Declaration, right?
A When I signed my Declaration and used words to like "teams," that just meant that I did not do everything myself and included other individuals. So that's how -- so "team" might be different depending on where it is in the

document.

Q Do you understand that I'm not asking about "team"?

A No, I don't understand.

Q So let me try my question again.

When you signed your Declaration, you weren't confused about the terminology or phrasing that is used throughout your Declaration in all of the paragraphs of your Declaration, right? Or were you confused?

A I -- some of the words could have been more specific.

Q Are you finished with your response?

A I think so.

Q Okay. So let's turn to paragraph 13 of your Declaration, at page 6. Let me know when you're there.

A Page 6, 13.

Q Are you there?

A Yeah.

Q You see that you use the terminology, quote, my team in paragraph 13?

A Yes.
Q And who were the members of your team that you were referring to in that paragraph?
A I can tell you it at least involved me and Luis and the statistician.
Q Okay. And I'm not asking for "at least," I want to know everyone you were thinking about when you wrote the terminology, quote, my team, and signed your Declaration.
Who are those people that you were thinking about as being a part of, quote, my team in paragraph 13 of your Declaration?
A I can say that my team included me and Luis and our statistician. I cannot specifically say -- those are the ones that I can definitely remember.
Q Okay. Turning your attention to paragraph 14 of your Declaration, do you have that?
A Yes.
Q And you see there that you used the terminology, quote, my team?

A Yes.
Q And in that paragraph, who were the members of, quote, my team that you were specifically referring to when you chose this language for your Declaration and signed it?
A My team would be the people who are responsible for the IND application.
Q And who were those people, by name?
A Again, it would be Dr. Diaz and myself. The people required to file an IND would be Dr. Durham's team.
Q And who was on Dr. Durham's team?
A I can't remember Dr. Durham's -- I just can't remember. It was a long time ago. I don't know who was on her team.
Q Was Dr. Pardoll on her team?
A Dr. Pardoll is not supervised by Dr. Durham.
Q I didn't ask whether or not Dr. Pardoll was supervised by Dr. Durham, I asked a different question.
So my question is, was Dr. Pardoll on

Dr. Durham's team?

A Okay. So, again, this goes back to what we mean by -- when I'm saying "team," I mean, Dr. Durham's group is a regulatory group, so it's kind of her supervisory role over her regulatory.

So that's what I mean by when I say -- that's not even in here. We're talking about Dr. Durham's team, which is not even on here. I think it depends on where we're using the word "team" in the context of what we're talking about.

Q And, Doctor, you do appreciate my questions --

A No, I don't.

Q Okay. Okay. Let me make it clear.

My question is specifically about your use of the terminology, quote, my team in paragraph 13 of your Declaration.

A Paragraph 14. 14, or 13? I'm sorry, I thought you said 14.

Q You're right. My question is specifically about paragraph 14.

A You can see where "team," depending

where you use it, can be very confusing.

Q I can't really.

So let's turn to -- we're looking at paragraph 14 --

A Yes, okay.

Q -- of your Declaration.

A Yes.

Q And you say here that it includes Dr. Durham's team.

A That's -- an IND is drafted by the regulatory team, which is run by Dr. Durham.

Q You say here --

A Yes.

Q You testified that when you used the terminology "my team" in paragraph 14, you were referring to, in part, Dr. Durham's team, right?

A I'm referring to, in part, Dr. Durham's team, the regulatory team, yes.

Q And my question is, was Dr. Pardoll a member of Dr. Durham's team?

A When you say Dr. Durham's team and I'm referring to Dr. Durham's team, I'm talking about

her regulatory team. Dr. Pardoll is not part of the regulatory team.

Q Was Dr. Pardoll a member of Dr. Durham's regulatory team?

A Dr. Durham runs a regulatory team and Dr. Pardoll is not a member of the regulatory team.

Q Was Dr. Pardoll, to your knowledge, ever a member of Dr. Durham's regulatory team?

A When I say Dr. Durham's team, I'm referring to her regulatory staff, her team. Dr. Pardoll is not part of the people that Dr. Durham supervises. That's what I'm referring to when I say Dr. Durham's team.

Q So was Dr. Pardoll a member of Dr. Durham's team as you refer to it here in paragraph 14 of your Declaration?

A Dr. Pardoll --

MR. MILLER: Just stop.

Objection. Form.

Go ahead.

A Dr. Pardoll is not a member of

Dr. Durham's regulatory team. And when I say "team" when referring to Dr. Durham, I'm talking about the people that she supervises.

Q Was Dr. Topalian a member of Dr. Durham's regulatory team?

A Dr. Topalian was not supervised by Dr. Durham and not part of her regulatory team, which I'm referring to the people that she supervises.

Q Was Dr. Papadopoulos a part of Dr. Durham's regulatory team?

A Dr. Papadopoulos was not part of Dr. Durham's regulatory team.

Q Was Dr. Kinzler part of Dr. Durham's regulatory team?

A Dr. Kinzler was not part of Dr. Durham's regulatory team.

Q Was Dr. Vogelstein part of Dr. Durham's regulatory team?

A Dr. Durham was not part of Dr. -- say that one more time. Who are we talking about now? Dr. Vogelstein?

Q Was Dr. Vogelstein a part of Dr. Durham's regulatory team?

A Dr. Vogelstein was not a part of Dr. Durham's regulatory team, the team for which she supervised.

Q Let me turn your attention to paragraph 19 of your Declaration. Let me know when you have it. Do you have it?

A I'm sorry, you said paragraph 19?

Q Yes.

A Okay. Yes.

Q Do you see in paragraph 19 you use the terminology, quote, my team?

A I guess I did use the word "my team."

Q And when you used the phrasing "my team," which members of the team by name were you referring to in this paragraph of your Declaration?

A I can say at least myself and Luis, as far as I know.

Q Are you not sure which members of the team you meant when you wrote this in your

Declaration and signed it?

A I mean that's what I meant, really any members. I'm not aware that I was --

Q When you say you meant any members, what does that mean? Is that anyone employed by JHU?

A No. No, that's not what I'm saying. I'm just saying -- I mean specifically?

Q Right. Specifically I'd like to know when you wrote the term "my team" in paragraph 19, who were the members that you were referring to?

A It included myself and Dr. Diaz.

Q Did it include anyone else?

A (Shaking head.)

Q I see you shaking your head.

A I mean it could have included other people. When I was writing this sentence, was I thinking about all of these individuals? I wasn't thinking of all of these individuals.

Q And all of what individuals are you talking about?

A Like, you know, anybody at Hopkins. I don't know. I just said my team were not employed

by Merck or any other company to conduct our initial study.

Q When you wrote "my team," sitting here today, which people do you think this is referring to, or did you intend it to refer to?

A I can only say that I was not paid by Merck, and I do not believe Luis was paid by Merck.

Q Do you know what question I asked you?

Do you know what question I asked you?

A Can you repeat the question?

Q When you wrote "my team," sitting here today, which people do you think this is referring to, or did you intend it to refer to?

A Sitting here today, I believe I meant I was talking about myself and Dr. Diaz.

Q Can you turn your attention to paragraph 26 of your Declaration?

A 26, page 11.

Q Do you have it?

A Yes.

Q Do you see there that you referred to

and used the term, quote, my team?

A Yes.

Q And who were you referring to in this paragraph of your Declaration by the term "my team"?

A I think this could refer to anybody involved. When I say "my team," it would be hopeful that the hypothesis would be supported.

Q And I'm not asking what it could refer to, I'm asking specifically what did it refer to when you used this terminology to prepare your Declaration and you signed your Declaration.

A The people involved in the study.

Q And which people are that? Who are those people?

A Well, there -- that is -- a lot of people were hopeful. It would include me, it would include all the inventors, it would include the regulatory team, it would include anyone who was involved in the protocol would be hopeful that it would work.

Q So other than the named inventors, the

regulatory people, who did you consider involved with the protocol?

A I can't give you specific names.

Q Okay.

A There's a lot of people involved in a protocol.

Q When you refer to "my team" in paragraph 26 of your Declaration, can you give me specific names as to who those people were that you're referring to?

MR. MILLER: Objection. Form. Asked and answered.

A Specifically? I would say people involved in the protocol.

Q And who is that?

A Myself, all the people who were involved in the hypothesis.

Q And who is that?

A Well, it dates back to the idea. Luis. It's kind of hard to refer to my superiors as my team. Dr. Durham, the research nurse, the inventors. Everyone was hopeful that it would --

could potentially work.

Q When you say "inventors," who are you referring to?

A The people involved in the ideas.

Q Who was that?

A Luis, Bert, Nick, Suzanne, Drew. Did I miss any of the inventors?

Q Are you finished with your answer?

A I think I missed Ken. And Ken.

Q So you were just turning to the '393 patent; is that right?

A Actually, whatever this one is.

Q What one is that?

A 1030, I think.

Q Okay.

A I think it's on both, actually.

Q Now, using the same definition of "my team" that you used in paragraph 26 of your Declaration, is it correct that before your team's work with pembrolizumab, oncologists had already given pembrolizumab to cancer patients?

A MK-3475 had been given to cancer

patients as part of experimental trials.

Q Is it correct that before your team's work with pembrolizumab, oncologists had already given pembrolizumab to cancer patients?

A Are we going back to the "my team"? I guess it depends on which "my team" you're talking about, but it is correct that before we administered MK-3475 on this clinical trial, that oncologists had given MK-3475 to patients with cancer.

Q Okay. So let me try my question using the same definition of "my team" that you used in paragraph 26 of your Declaration.

A Okay.

Q Is it correct that your team's -- let me start that again.

Using the definition of "my team" that you had in paragraph 26 of your Declaration, is it correct that before your team's work with pembrolizumab, oncologists had already given pembrolizumab to cancer patients?

A It is correct that before -- can you

repeat the question? We were not the first people to give MK-3475 to cancer patients. Is that what you're asking?

Q No, but that's -- that's fine. Thank you for that.

Do you have Exhibit 1005 in front of you?

A Yes.

Q Would you agree that at the time of the study records posting, MSI testing was already standardized and performed in CLIA-certified laboratories without the need for assay development?

MR. MILLER: Objection. Form.

A I'm sorry, what was the question again?

Q Would you agree that at the time of the study records posting on clinicaltrials.gov, MSI testing was already standardized and performed in CLIA-certified laboratories without need for assay development?

A At the time --

MR. MILLER: I'm sorry.

Objection. Form.

Go ahead.

A At the time of this posting in June of 2013, MSI testing could be performed in CLIA-certified labs; is that what you're asking?

Q No.

A No, no.

Q Would you agree that at the time of the study records posting, MSI testing was already standardized and performed in CLIA-certified laboratories without need for assay development?

MR. MILLER: Objection. Form.

A I think it depends on the context. There -- at the time of 2013, there were CLIA-certified -- MSI testing could be done in CLIA-certified labs.

Am I still missing it?

Q You are.

At the time of the study records posting, would you agree that MSI testing was already standardized?

MR. MILLER: Objection. Form.

A At the time of the posting, MSI testing could be performed in CLIA-certified labs. Not all MSI testing was standardized.

Does that make sense?

Q So would you agree that at the time of the study records posting, MSI testing was already standardized and performed in CLIA-certified laboratories without need for assay development?

MR. MILLER: Objection. Form.

A That's actually a very complicated question you're asking.

At the time of this posting, MSI testing could be performed in CLIA-certified labs. And that is, in a CLIA-certified lab, they do standardization. So I don't know if that's what you mean.

Q At the time of the study records posting, do you agree that MSI testing was standardized?

MR. MILLER: Objection. Form.

A I don't -- I don't know that I agree that it was standardized. You could -- at the

time of this posting, you could test for MSI in a CLIA-certified lab.

Q I just want to make sure I understand your testimony.

At the time of the study records posting, do you agree that MSI testing was already standardized?

MR. MILLER: Objection. Form. Asked and answered.

A I think that there may be some technical understanding issues.

At the time of the testing -- I mean -- I'm sorry, at the time of this posting in June 2013, you could get CLIA-certified testing of MSI, microsatellite instability status.

Q I'll try one more time.

At the time of the study records posting, would you agree that MSI testing was already standardized and performed in CLIA-certified laboratories without need for assay development?

MR. MILLER: Objection. Form. Asked

and answered.

A At the time of this posting, you could get MSI testing in a CLIA-certified lab.

Q And was MSI testing already standardized at the time of the posting?

A What do you mean by "standardized"?

MR. MILLER: Sorry.

THE WITNESS: Okay.

MR. MILLER: But that's fine.

Q Do you not know what the term "standardized" means?

A I think it has some technical aspects to it when we're talking about labs, so I guess what do you mean by "standardized"?

Q Let me try it this way.

If someone said to you that at the time of the study records posting, quote, MSI testing is already standardized and performed in CLIA-certified laboratories without need for assay development, end quote, would you believe that's a truthful and correct statement?

MR. MILLER: Objection. Form.

A If someone told me in June 2013 if you could perform MSI in a CLIA-certified -- can you repeat the question? I'm sorry.

Q Sure.

If someone told you at the time of the study records posting that, quote, MSI testing is already standardized and performed in CLIA-certified laboratories without need for assay development, end quote, do you believe that would be a truthful and accurate statement?

MR. MILLER: Objection. Form.

A I believe that it requires context.

Q So sitting here today, do you have any understanding what it means, quote, MSI testing is already standardized and performed in CLIA-certified laboratories without need for assay development, end quote?

MR. MILLER: Objection. Form.

A I can tell you in 2013 you could get MSI testing in a CLIA-certified lab.

Q And can you tell me whether or not you understand the sentence, quote, MSI testing is

already standardized and performed in CLIA-certified laboratories without need for assay development, end quote?

A I could tell you that MSI testing in 2013 could be performed in CLIA-certified labs. You're talking about the standardization part, is that what you're asking about?

Q My statement talked about standardized, right. Do you recall that?

A Yes. I'm -- I guess I'm trying to figure out what you're asking about standardization.

Q Are you confused about the terminology "standardized"?

MR. MILLER: Objection. Form.

Go ahead.

A I'm confused -- I just -- can you just repeat the question, maybe in a different way?

Q Do you understand the statement:

MSI testing is already standardized and performed in CLIA-certified laboratories without need for assay development?

A I understand that to mean that you can get MSI testing in a CLIA-certified lab.

Q Okay. And was that true at the time of the study records posting?

A That you could get MSI testing in a CLIA-certified lab at the time of the study posting? You could get MSI testing in a CLIA-certified lab at the time of the posting.

Q And was that MSI testing already standardized at the time of the posting?

MR. MILLER: Objection. Form.

A Was it standardized? I think it depends on the context.

Q Have you ever wrote in the context of any of your work with pembrolizumab that MSI testing was standardized?

A I would have to doublecheck the wording that was used in any of my works. It would require that I look at a lot of documents.

Q Do you recall ever writing in the context of any of your work with pembrolizumab that MSI testing is already standardized and

performed in CLIA-certified laboratories without need for assay development?

A I can recall that we said that MSI testing could be performed in CLIA-certified labs.

Q My question is different. It's not about if it could be performed, I'm asking you do you recall ever saying in the context of any of your work with pembrolizumab that MSI testing is already standardized and performed in CLIA-certified laboratories without need for assay development?

A That would be -- depend on the context.

Q Do you ever recall saying it in any context?

A That MSI testing could occur --

Q No.

A -- in CLIA-certified labs?

Q No. Try it one more time.

Do you ever recall in any context ever saying MSI testing is already standardized and performed in CLIA-certified laboratories without need for assay development?

A MSI testing in 2013 could be performed in CLIA-certified labs.

Q That's your response to my question?

A I guess I'm not understanding your nuance, but yes, you could perform MSI testing in CLIA-certified labs.

Q At the time of the study records posting, would you agree that pembrolizumab was known strongly to enhance T lymphocyte immune responses in cultured blood cells from healthy donors, cancer patients and primates?

A You're asking me to remember what I knew at that time? Say the question again. At the time of this posting, did I know that pembrolizumab, what? Say that one more time.

Q At the time of the study records posting, would you agree that pembrolizumab was known to strongly enhance T lymphocyte immune responses in cultured blood cells from healthy human donors?

A I cannot specifically say that on June 2013, that I knew that.

MR. MILLER: Counsel, is this a good time for a lunch break?

MR. RATLIFF: Not for me. I have some more questions.

MR. MILLER: Do you need a break, Dr. Le?

THE WITNESS: What time is it? How long have we been doing this? Three hours?

MR. MILLER: Three hours plus.

THE WITNESS: It's almost 1:00. Yeah, actually it would be a good time to probably eat something.

MR. RATLIFF: You sure you don't want to finish a few more questions about this and then we can start -- then we can take our lunch?

THE WITNESS: I just want to have something very small, if that's okay. I would like to keep going so we can finish. Can we just have a quick break to eat?

MR. RATLIFF: Sure.

(A recess was taken at 12:40 p.m.)

AFTERNOON SESSION (1:49 p.m.)

BY MR. RATLIFF:

Q Welcome back, Doctor.

A Thank you.

Q Doctor, during the lunch break, did you discuss any of my questions or this case with counsel?

A I did not discuss the questions or the case.

Q Okay. Now, at the time of the study records posting, was it known that pembrolizumab strongly enhances T lymphocyte immune responses in cultured blood cells from cancer patients?

A Was it known? Did I know, or was it known?

Q Was it known.

A I don't know what was known at what time.

Q Okay. At the time of the study records posting, did you know whether or not pembrolizumab enhances T lymphocytes immune responses in cultured blood cells from cancer patients?

A I do not recall if -- at the time of the

posting if I knew at the exact time of this posting.

Q Okay. Do you know whether by July 10, 2015, it was known that pembrolizumab strongly enhances T lymphocyte immune responses in cultured blood cells from cancer patients?

A I -- can you repeat the question? I'm sorry.

Q Do you know whether by July 10, 2015, it was known that pembrolizumab strongly enhances T lymphocyte immune responses in cultured blood cells from cancer patients?

A I don't remember specifically. I don't remember.

Q Do you have any general recollection?

A I don't have general recollection of the dates.

Q At the time of the study records posting, was there accumulating evidence showing the correlation between tumor-infiltrating lymphocytes in cancer tissue and favorable prognosis in various malignancies?

A Was -- was it known at the time of this posting, this submission -- can you repeat the question?

Q Sure.

At the time of the study records posting, was there accumulating evidence showing a correlation between tumor-infiltrating lymphocytes in cancer tissue and favorable prognosis of various malignancies?

A At the time of the posting was there accumulating evidence? Say that one more time.

Q At the time --

A T cells -- I'm sorry, go ahead.

Q At the time of the study records posting, was there accumulating evidence showing a correlation between tumor-infiltrating lymphocytes in cancer tissue and favorable prognosis in various malignancies?

A I don't recall the dates.

Q Do you have any recollection when that was recalled -- sorry.

Do you have any recollection when that

was known?
A When there was accumulating evidence?
Q Yes.
A I can't give you the dates.
Q So no recollection sitting here today?
MR. MILLER: Objection. Form.
A I don't have any recollection about the exact dates.
Q Okay.
(Exhibit 1116 was marked for identification and was retained by Mr. Ratliff.)
Q I'd like to show you a document which is a new exhibit that's been marked as Exhibit 1116.
Doctor, let me know if you recognize Exhibit 1116.
A (Reviewing.)
Q Do you understand my question, Doctor?
A You asked me if I recognized this very long document, so I'd like to see what is in it.
(Reviewing.)
Q Do you not know what the document is from the cover page of the document?

A Whatever is in this entire document is -- the cover page says this is a new IND submission.

Q So do you know what Exhibit 1116 is?

A Exhibit 1116 appears to be the new IND submission dated May 9, 2013.

Q And is this exhibit the IND submission that you referred to in your Declaration?

A There is reference to an IND application, yes.

Q So Exhibit 1116, is this the IND submission that you referred to in your Declaration?

A This appears to be an IND submission. I couldn't go through all the pages.

Q Okay. You can go through the pages if you would like.

A Okay.

Q Just understand, I'm not asking if it appears to be an IND submission. I'm asking you is this the IND submission that you referred to in the sworn testimony in your Declaration.

A I am referring to an IND submission when -- back when we submitted the IND for the clinical trial.

Q Okay. And is this the IND submission that you were referring to in your Declaration, Exhibit 1116?

A This looks like the IND submission, but I have not had a chance to look through it in its entirety.

Q Okay. Well, look through it in its entirety and let me know.

A (Reviewing.)

This appears to be the IND submission.

Q And the IND was submitted on May 9, 2013; is that correct?

A The IND is -- the date on the IND is May 9th, on this letter, cover letter.

Q Was the IND submitted on May 9, 2013?

A What do you mean by "submitted"?

Q Was the IND filed on May 9, 2013?

A Was the IND filed? There is a date associated with this IND of May 9th, 2013.

Q Okay. So my question is, was this IND filed with the FDA on May 9, 2013?
A The FDA -- was this IND filed? I can see that the IND -- the letter has a date of May 9, 2013.
Q And was the IND that you testify about in your Declaration filed with the FDA on May 9, 2013?
A The IND that I testified about was filed in 2013.
Q And was the IND that you testified about filed on May 9, 2013?
A The IND was filed in May of 2013.
Q Was the IND filed on May 9, 2013?
A I know we filed the IND in May of 2013.
Q Do you know whether or not you filed the IND with the FDA on May 9, 2013?
A I see that the date is May 9, 2013. I know we filed an IND with the FDA in 2013, May 2013.
Q So my question is, do you know whether or not on May 9, 2013, if you filed the IND with

the FDA?

A I know that, I know that this is dated the 9th. Do I know for sure that it wasn't sent on the 10th, like in the mail and they received it? I don't know what file -- I just know that it was filed in May 2013.

Q You don't know what file did you say?

A When you say "file," we filed, we submitted --

Q Doctor, you realize in your Declaration, paragraph 14, you write that your team filed an IND with the FDA for the proposed clinical trial, right?

A Correct.

Q So you used the term "filed," right?

A Uh-huh.

Q So my question simply is, do you know whether or not the IND for the trial was filed on May 9, 2013; yes or no?

A I do not know specifically on May 9th, 2013, that it was filed on May 9th, 2013.

Q Okay. Did you review the IND before it

was filed?

A I reviewed the IND, parts of the IND before it was filed.

Q Did you --

A So everything -- it comes in parts, and that's what I was noticing, there was a double of something, like here.

Q Did you only review parts of the IND before it was filed or did you review the entire IND before it was filed?

A The parts make up the entire IND. I reviewed the IND before it was filed.

Q Did you review the entire IND before it was filed?

A I reviewed the entire IND before it was filed.

Q And when you reviewed the IND before it was filed, did you see any errors in what was written to the FDA?

A Did I personally see errors? I don't recall.

Q You don't recall if you saw any errors?

A I don't recall.
Q And sitting here today, are you aware of any errors that are in the IND filing for the trial?
A I can't say I'm aware. It's been a long time since I read it cover-to-cover.
Q So sitting here today, you're not aware of any errors in the IND filing; is that right?
A Sitting here today, I am not aware of any errors in the IND filing.
Q Okay. And is it your understanding that when your team submitted the IND to the FDA for trial, your team tried to be truthful and accurate in what it said to the FDA?
A Yes.
Q And was it the intent for the FDA to rely upon your statements in the IND about the proposed trial?
A Can you repeat that? Rely on the statements, like -- I'm sorry, just repeat the question.
Q When your team submitted the IND for the

trial, was it the intent for the FDA to be able to rely upon the statements that your team made in the IND?

A Yes.

Q Okay. Can I turn your attention to page 37 of 199 in Exhibit 1116.

A Page 37. Yes.

Q And you see at the bottom there is a section labeled 2.2 MK-3475?

A Uh-humh.

Q Do you see in the second sentence you and your team write:

Accumulating evidence shows a correlation between tumor-infiltrating lymphocytes in cancer tissue and favorable prognosis in various malignancies?

A I can read that.

Q And you believed that when you submitted it to the FDA, right?

A I believe that there were -- was a correlation in some cancers, that tumor-infiltrating lymphocytes, they may be

associated with favorable prognosis.

Q Don't you say that accumulating evidence shows a correlation?

A Accumulating evidence shows -- it says, accumulating evidence shows a correlation.

Q Right. So you and your team, you told the FDA that accumulating evidence shows a correlation between tumor-infiltrating lymphocytes in cancer tissue and favorable prognosis in various malignancies, right?

A Actually, page 37, it says:

Accumulating evidence shows a correlation between tumor-infiltrating lymphocytes in cancer tissue and favorable prognosis.

Q Let me try this again. I'm not sure why you didn't read everything that was in my question. Let me try it again.

A Okay.

Q In the IND that you and your team filed, you represented to the FDA that there was, quote, accumulating evidence shows a correlation between tumor-infiltrating lymphocytes in cancer tissue

and favorable prognosis in various malignancies, end quote, right?

A Yes, on this document, it says:

Accumulating evidence shows a correlation between tumor-infiltrating lymphocytes in cancer tissue and favorable prognosis in various malignancies.

Q And that was you and your team's representations to the FDA, right?

A Yes.

Q And you and your team, you cited references to support that representation, right?

A Yes.

Q And you cited 36 references to support that representation, right?

A I'm not sure.

Q Well, do you see that you cited references 12 through 47? Do you see that?

A Uh-humh.

Q In references 12 through 47, we can find those Reference sections of the IND beginning on exhibit page 74; is that right?

A Okay. It was reference what through -- I can't remember.
Q It was references 12 through 47, right?
A Okay.
Q Is that right?
You're saying okay. I just want to be sure that's an affirmative yes.
A I have to flip back, but I believe you said that 12 through 47. What page was the other one?
Q So the References section of the IND that we've been looking at begins on page 74, right?
A Right, but you told me -- you asked me if it, particular references, so --
Q Let's just take it in steps.
A Where was that?
Q No worries.
So let me give you a Post-it, and can you put the Post-it on page 74 of Exhibit 1116?
A (Complying.)
Q And page 74 begins a section listing

references that you cited to the FDA, right?

A Yes.

Q Okay. So now let's turn our attention to page 37, the exhibit page, and I'll give you another Post-it and you can put on that page.

A (Complying.)

Q So my question is, when you and your team represented to the FDA that accumulating evidence shows a correlation between tumor-infiltrating lymphocytes in cancer tissue and favorable prognosis in various malignancies, you cited references Nos. 12 through 47 to support that representation, right?

A Yes.

Q And references No. 12 through 47, if you add them up, that's 36 references, right?

A Yes. It's not 35, right, it's 36. We count the first and the last. It would be 36.

Q Now, for references 12 through 47, those were all available to the public before July 10, 2015, right?

A I'm sorry, can you repeat the question?

Q For references 12 through 47 --
A 12 through 47. Oh, all the references that you just mentioned.
Q For references 12 through 47 --
A Okay.
Q -- those were all available to the public before July 10, 2015, right?
A Yes, it appears so.
Q And you would agree that another drug similar to pembrolizumab is nivolumab, right?
MR. MILLER: Objection. Form.
A Nivolumab is similar. There are some similarities, yes.
Q You would agree that pembrolizumab is very similar to nivolumab, right?
MR. MILLER: Objection. Form.
A I would agree that pembrolizumab is an antibody that targets PD-1, and I would agree that nivolumab is an antibody that targets PD-1.
Q And wouldn't you also agree that pembrolizumab is very similar to nivolumab?
MR. MILLER: Objection. Form.

A I don't have direct knowledge of the actual structure to know that it is very similar. I know that pembrolizumab targets PD-1, and I know that nivolumab targets PD-1.

Q Didn't you and your team tell the FDA in your IND submission that pembrolizumab is very similar to nivolumab?

A In the submission did we say it is very similar -- I don't know that we used the words "very similar."

Q And sitting here today, would you agree that pembrolizumab is, quote, very similar to nivolumab?

MR. MILLER: Objection. Form.

A I would agree that pembrolizumab in some ways is similar to nivolumab.

Q So my question is different.

Sitting here today, would you agree that pembrolizumab is, quote, very similar to nivolumab, end quote?

MR. MILLER: Objection. Form.

A I would agree that pembrolizumab is

similar to nivolumab.

Q And is it correct that you would not agree that pembrolizumab is very similar to nivolumab?

MR. MILLER: Objection. Form.

A I would agree that pembrolizumab has similarities to nivolumab.

Q And is it correct that you would not agree that pembrolizumab is very similar to nivolumab?

MR. MILLER: Objection. Form.

A I would agree that they are similar.

Q Would you agree that they are very similar?

MR. MILLER: Objection. Form.

A I agree that they are similar.

Q Would you agree that they're very similar?

MR. MILLER: Objection. Form. Asked and answered now six times.

A I -- I agree that they're similar.

Q I'm asking you a different question.

Would you agree that they're very similar?

MR. MILLER: Objection. Form. Asked and answered.

A I agree that they're similar.

Q Okay. And did you understand when you and your team submitted the IND to the FDA that making a willfully false statement is a criminal offense?

A Yes.

Q Now, you would agree that pembrolizumab has the same mechanism of action as nivolumab?

MR. MILLER: Objection. Form.

A I agree that pembrolizumab and nivolumab target PD-1.

Q Does pembrolizumab have the same mechanism of action as nivolumab?

MR. MILLER: Objection. Form.

A All drugs work slightly differently.

Q I'm not discussing about all drugs, I'm only asking about two drugs.

A Okay.

Q Hold on, I'm not finished with my question.

To make it clear and easy for you, I'm only asking about two drugs, pembrolizumab and nivolumab. Those are the only two I'm asking about.

So my question is, do you agree that pembrolizumab has the same mechanism of action as nivolumab?

MR. MILLER: Objection.

Q Yes or no?

MR. MILLER: Objection. Form.

A I agree that they have a similar mechanism of action, that they target PD-1.

Q Do they have the same mechanism of action?

MR. MILLER: Objection. Form.

A Mechanism of action. I agree that they have a similar mechanism of action.

Q Would you agree that preclinical studies have suggested that pembrolizumab and nivolumab have similar potency?

A Would I agree that preclinical studies -- I can't answer that question.

Q Why not?

A Because I don't, I don't remember. I don't know.

Q So sitting here today, you don't know whether or not preclinical studies have suggested that pembrolizumab and nivolumab have similar potencies?

A I don't recall. And can you repeat the question?

Q Sitting here today, do you know whether or not preclinical studies have suggested that pembrolizumab and nivolumab have similar potency?

A Potency. What do you mean by "potency"?

Q The same thing that you and your team meant when you used the term "potency" in the IND that you filed with the FDA.

A Okay. So I'd have to see what the reference to the word "potency" is. It's sort of a technical term, so --

Q What does that technical term "potency"

mean to you?

A Can you show me where in the document it is?

Q What does the technical term "potency" mean to you? Does it have several meanings in your view?

A I think potency -- I don't recall where it is in this very large document, how they're referring to potency, so I'd have to look at it.

Q But you know -- I just want to be clear. I'm not asking if you recall where the word "potency" is in the filed IND. I'm not asking that. I'm asking you, do you have a definition for the technical term "potency"?

A I don't have a definition for the technical term "potency."

Q And does the technical term "potency" mean anything to you in the context of pharmaceutical clinical trials?

A Does it have any -- I mean I think it tends to be kind of specific to the protocol, the definition of potency.

Q Okay. So let's take a look at page 61 of Exhibit 1116.
A The same exhibit. Page 61?
Q Yes. Let me know when you have it.
A Yes.
Q You have it?
A Uh-humh.
Q So I'd like to turn you to Section 8.9, Patient Care Applications.
A Okay.
Q And do you see the representation that you and your team made to the FDA stating that pembrolizumab has the same mechanism of action as nivolumab?
A I do.
Q And do you see the representation that your team made to the FDA stating that preclinical studies have suggested that pembrolizumab and nivolumab have similar potency?
A I do.
Q And do you see the representation that you and your team made to the FDA that PK modeling

has suggested similar human PK for pembrolizumab and nivolumab?

A I'm sorry, can you point that out again?

Q Do you see the representation that you and your team made to the FDA that PK modeling has suggested similar human PK for pembrolizumab and nivolumab?

A I do -- no, wait. For MK-3475 and BMS-936558.

Q And are you really taking the position that MK-3475 is not pembrolizumab?

A No, I'm just saying this is what it says in the document. I can't remember off the top of my head if nivolumab is BMS-936558. You asked me specifically about nivolumab. So I'm just saying I can see that it says MK-3475 has the same mechanism of action as BMS-936518, and in his question, he was referencing nivolumab.

And so I was just reading the numbers back because I don't know off the top of my head what the number for nivolumab is.

Q So is it your testimony sitting here

today that you don't know whether or not BMS-936558 is nivolumab?

A I can't without looking at it. And you can easily find it by putting it in a computer to confirm.

Q I'm not asking about confirmation; I'm just saying, you, sitting here today as the principal investigator for KEYNOTE-16 and someone that has cited publications regarding nivolumab, is it your testimony that you do not know whether or not BMS-936558 is the chemical compound nivolumab?

A I can tell you I cannot tell you for sure right this minute just looking at this number. It makes sense that that's what you're talking about.

Q Right. So right now, sitting here today, you don't know whether or not BMS-936558 is nivolumab, right?

A I do not, but it would be very easy to look up.

Q Okay.

(Exhibit 1118 was marked for identification and was retained by Mr. Ratliff.)

Q Doctor, I'd like to hand you a document which is a new exhibit that's been marked as Exhibit 1118.

Can you let me know if you recognize it?

A Document 1118. It is --

MR. MILLER: Don't -- the Court Reporter needs to take down all the words you're saying, so just be mindful of that.

A (Reviewing.)

Form 1571, from Dr. Diaz, dated June 11, 2013. And there's a cover letter dated June 3rd, 2013, that is -- it says IND 118566S01 signed by Dr. Diaz. And then on it there is an attachment with the tracked version of a protocol.

Q So do you recognize Exhibit 1118?

A Yes.

Q And what do you recognize it to be?

A I recognize it to be -- I don't know the technical term for it, but amendment, supplement. I guess I could make sure. It's technically date

of submission, so it's a submission to the IND.

Q And by the "IND," you're referring to the IND for the trial; is that right?

A IND 118566S -- actually, IND118566.

Q And that's an IND for KEYNOTE-16; is that right?

A What do you mean "for"?

Q It's an IND relating to KEYNOTE-16, right?

A It is an IND relating to the trial that we've been talking about, yes.

Q And did you review this IND before it was submitted to the FDA?

A I reviewed the IND submission for the contents of the IND submission.

Q Did you review the contents of the IND submission reflected in Exhibit 1118 before it was submitted to the FDA?

A I reviewed the Exhibit 1118.

Q Are you finished with your response?

A Yes.

Q Okay. So that wasn't my question.

So I'm asking not if you reviewed it at any point in time ever. My question is different.

Did you review the IND submission that's reflected in Exhibit 1118 before it was submitted to the FDA?

A I reviewed the IND11856 before it was submitted, yes.

Q Okay. Now, Doctor, you're familiar with breakthrough therapy designation approvals, right?

A I am somewhat familiar with breakthrough therapy designation.

Q Well, don't you in your sworn testimony for this case talk about breakthrough therapy designations?

MR. MILLER: Objection. Form.

Q I think you're paging through your Declaration.

A Yep.

Q Just sitting here today, without looking at your Declaration, do you know whether or not you testify about breakthrough therapy designations?

A I --
Q Or do you have to look at your Declaration to determine that?
A It's sitting in front of me so I just feel more comfortable looking through my Declaration since you're asking me specifically about what's in my Declaration. Just like if I wanted to confirm a drug, I would doublecheck that nivolumab is 936558.
Q Let me try my question again.
Sitting here today, without looking at your Declaration, do you know whether or not you testify about breakthrough therapy designations; yes or no?
A I can remember discussing breakthrough therapy designations.
Q Okay. So now, are you familiar with breakthrough therapy designations?
MR. MILLER: Objection. Form.
A I'm familiar with some of breakthrough therapy designations, some of the idea of the breakthrough therapy designations.

Q And is it your belief that breakthrough therapy designation approvals are rarely given by the FDA?

A I do believe that they are rarely given by the FDA.

Q Okay. Would you agree that pembrolizumab is one of the first 10 drugs to ever receive a breakthrough therapy designation approval?

A Would I agree that pembrolizumab is one of the first 10 drugs that ever received breakthrough therapy designation. I can't comment on that.

Q Sitting here today, do you know whether or not pembrolizumab was one of the first 10 drugs to ever receive a breakthrough therapy designation approval?

A I don't know if it was one of the first 10 drugs.

(Exhibit 1130 was marked for identification and was retained by Mr. Ratliff.)

Q I'd like to hand you a new document

that's been marked as Exhibit 1130. And, Doctor, I can represent to you that document 1130 is a document that we downloaded from the FDA's website entitled "CDER Breakthrough Therapy Designation Approvals Data as of December 31st, 2023."

Do you have the document in front of you?

A Exhibit 1130?

Q That's right.

A Yes.

Q And can you see in document 1130 that it reports on the breakthrough therapy designation approvals that were given by the FDA as of December 31, 2023?

A As of December 31, 2023.

Q You see that, right?

A Yes, I can see it says "CDER Breakthrough Therapy Designation Approvals."

Q And CDER is part of the FDA, right?

A I'm not a hundred percent sure how the structure works.

Q You don't know whether or not CDER is

one part of the FDA; is that your testimony?

A I'm not a hundred percent sure. Sometimes I have to doublecheck what departments and things go with which. But it is part of the Government.

Q Didn't you testify in your Declaration that breakthrough therapy designations are given by the FDA?

A That is my understanding, that they're given by the FDA.

Q Okay. And you don't know whether or not CDER is part of the FDA; is that your testimony?

A I know that it's part of a structure. I don't know how it is part versus it -- how they interact. But you're telling me it's part of the FDA.

Q I'm not asking you if they interact. I'm just asking you do you know whether or not CDER is part of the FDA?

A I cannot say for sure that CDER is part of the FDA.

Q And do you see here in this document it

reflects that Keytruda® was one of the first 10 drugs to ever receive breakthrough therapy designation approval?

MR. MILLER: Objection. Form.

A It says it's one of the first 10 drugs --

(Reviewing.)

You're asking me to count the number of drugs?

Q Sure, you can count them.

A (Complying.)

10. I see what you're talking about. No. 10.

Q So here's my question. Do you --

A I don't know if it's one of the first 10. I just know that -- I don't know that they started giving breakthrough therapy designation November 1, 2013. If that's the case, then it's one of the first 10. But I don't know when the process actually started. Maybe it's been going on since 2002, I don't know.

Q So sitting here today, you don't have

any idea when breakthrough therapy designation approvals ever started, right?

A I don't know. I don't know when they started.

Q And you see here in this document on page 2 of Exhibit 1130 that Keytruda®, that pembrolizumab received a breakthrough therapy designation approval on September 4, 2014, right?

A Breakthrough therapy designation approval. Keytruda® received a -- I don't know. I don't remember what "BLA" stands for. September -- on this chart, it says September 4, 2014, for the treatment of patients with melanoma, essentially, some very -- some set of melanoma.

Q You see here in the document on page 2 of Exhibit 1130 that pembrolizumab received a breakthrough therapy designation approval on September 4, 2014, right?

A I see on the very top of this table, which I presume is part of this table titled on the first page, and that there's nothing in between, that pembrolizumab received breakthrough

therapy, a CDER breakthrough therapy designation, and the date, approval date is September 4, 2014, for the treatment of patients with unresectable or metastatic melanoma and disease progression following pembrolizumab and if BRAF V600 mutation positive A B-RAF inhibitor.

Q Did you and you team have any involvement in the work to lead to that breakthrough therapy designation approval on September 4, 2014?

A I did not -- I do not treat melanoma.

Q I didn't ask you if you treated melanoma.

Did you and your team have any involvement in the work that led to the breakthrough therapy designation approval for Keytruda® on September 4, 2014?

A I can only speak for myself. I did not have any involvement.

Q Okay. And I think you said earlier, if you look to the left-hand side of the document, it refers to "BLA." Do you see that?

A Uh-humh.
Q And is it your testimony that you don't know what "BLA" means?
A I would have to look it up to review.
Q And do you know what "NDA" means?
A Probably. I could guess.
Q What's your guess for NDA?
A New Drug Application.
Q Okay. Do you have a guess for BLA?
A Biologics -- again, it's better to look it up rather than guessing.
Q Sitting here today, you just don't know, right?
A I would need to confirm.
Q Do you have a guess or do you need to confirm?
A I did guess.
Q What was your guess?
A That -- biologics. B for biologics.
Q Okay. So let's turn to page 3 of Exhibit 1130.
A Okay. Page 3.

Q And do you see on page 3 it reflects a second breakthrough therapy designation approval for pembrolizumab on October 2nd, 2015?

A I see that there is a breakthrough therapy designation on that same BLA125514.

Q And do you see that reflects a second breakthrough therapy designation approval for pembrolizumab?

A I see that there is an approval for pembrolizumab on October 2nd, 2015, for the treatment of patients with metastatic PD-L1 positive non-small cell lung cancer as determined by FDA-approved test with disease progression on or after platinum-containing chemotherapy.

Q And that's a different breakthrough therapy designation approval than the one that's reported on page 2 of Exhibit 1130, right?

A It's a different one. It is one -- it's a different disease indication.

Q And it's a different breakthrough therapy designation approval, right?

A I don't know how they number their

approvals.

Q So sitting here today, do you believe that it's the same breakthrough therapy designation approval?

A The same approval? I --

Q No, I didn't say that. I just want to stop you.

Sitting here today, do you believe that the breakthrough therapy designation approval that we saw on page 2 of Exhibit 1130 is the same as the breakthrough therapy designation approval that we see on page 3 of Exhibit 1130?

A It's the same -- it's a different treatment. It's a different patient population.

Q And it's a different breakthrough therapy designation approval, right?

A There's a different date.

Q Because it's a different breakthrough therapy designation approval, right?

MR. MILLER: Objection. Form.

A I can see that it's a different date.

Q Other than that, you don't know whether

it's the same or not, right?

A It's a different indication.

Q But you don't know whether or not it's a different breakthrough therapy designation approval, right?

A It's a -- it has a different approval date and a different indication.

Q Okay. Let's turn to page 4 of 1130.

A Page 4.

Q Do you see page 4 reflects a breakthrough designation therapy approval for pembrolizumab that was given on December 18, 2015?

A Pembrolizumab, December 18, 2015, treatment of patients -- it was for treatment of patients with unresectable or metastatic melanoma.

Q Are you finished your response?

A Yes.

Q Okay. So let's try to answer my question.

Do you see on page 4 of Exhibit 1130 it reflects a breakthrough therapy designation approval for pembrolizumab that was given on

December 18, 2015 --

A I see --

Q -- yes or no?

A I see there was an approval on December 18, 2015, for the treatment of patients with unresectable or metastatic melanoma.

Q Were you and your team involved in that work?

A I was not involved in that work.

Q And let's turn back to page 3 of Exhibit 1130. For the breakthrough therapy designation approval that's indicated for pembrolizumab on October 2nd, 2015, were you and your team involved in that work?

A Say that one more time. I'm sorry, what page are we talking about now?

Q We're talking about page 3.

A 3.

Q So on page 3 of Exhibit 1130 for the breakthrough therapy designation approval that's indicated for pembrolizumab on October 2nd, 2015, were you and your team involved in that work?

A I do not recall being involved in this work.

Q Were you involved in this work?

A I don't remember. I don't remember being involved in it.

Q If you could turn to page 7 of Exhibit 1130. Let me know when you're there.

A Page 7. I'm on page 7.

Q Do you recall at the top of page 7 it reflects a breakthrough therapy designation approval for pembrolizumab on March 14, 2017?

A I see that there is a March 14, 2017 approval for treatment of patients with refractory classical Hodgkins lymphoma or those who have relapsed after three or more prior lines of therapy.

Q And when you say "approval," you're talking about an approval for pembrolizumab, right?

A No. The March 14, 2017, is in the same table, assuming it's the table that starts on this first page -- actually, I don't know what the

approval date refers to. It just says approval date. Is this the approval date -- what's being approved on this date? The breakthrough therapy designation?

Q If you don't know, you don't know.

A Okay.

Q Let's go back to what you were saying.

Let's look at Exhibit [sic] 7.

A Okay.

Q Do you know -- let me ask -- I'll ask the question this way.

Page 7, Exhibit 1130, do you see that it reflects a breakthrough therapy designation approval date for pembrolizumab of March 14, 2017?

MR. MILLER: Objection. Form.

A I think as we went through this table, and then you asked me if it's an approval date, then I'm actually not clear what this approval date is referring to --

Q Okay.

A -- based on this table.

Q So do you see on page 7 of Exhibit 1130

it reflects some approval date for pembrolizumab?

A Yeah, I don't know what -- what was approved. I don't know what that approval date refers to.

Q And you have no clue whether or not that approval refers to the indication that's right next to the date?

A I -- yeah, I don't -- I don't know because they weren't clear in their, the way they made the approval date, what they were -- what approval they were referring to.

Q So it's your view that this CDR wasn't clear in this table?

A This CDR?

Q Is it your view that the CDR was not clear --

A Oh, you're talking CDER. This table, whoever made this table?

Q Correct.

Is it your view that whoever made this table was unclear in listing what is reflected by the approval date?

A I guess I agree because I'm not sure what is reflected by the approval date.

Q So is it your testimony that this chart is unclear to you?

A It is my testimony that it is not clear to me what this approval date refers to.

Q Okay. And so you don't know whether the approval date refers to a breakthrough designation approval, right?

A Correct, I don't know what the approval date is.

Q But you do know that -- the first page of the document, there's a heading in bold stating "CDER Breakthrough Therapy Designation Approvals," right?

A Yes. And that's why I thought we were talking about a date that there was a breakthrough therapy designation. But then you asked me is it clear that that is the date of the approval. So then I thought you were talking about an FDA approval for the actual drug, and that's why -- then that made me not clear what the approval date

is actually referring to.

Q Do you know what a breakthrough therapy designation approval date is?

A It would be the date that something receives a breakthrough therapy designation.

Q Are you sure about that?

A I'm assuming that that's what that is. It's a -- if you call it a breakthrough therapy designation date.

Q Let me try -- I just want to be sure your testimony is clear.

Do you know what a breakthrough therapy designation approval date is?

A Do I know exactly what the approval date is?

Q No, that's not my question. Do you know -- I didn't say exactly. Let me try my question again.

Do you know what a breakthrough therapy designation approval date is?

A Do I know -- a breakthrough therapy designation date is the date of the breakthrough

therapy designation.

Q Maybe you're not hearing me because my question was about a breakthrough therapy designation approval date.

So the question is, breakthrough therapy designation approval date, do you know what that is?

A Breakthrough therapy designation approval date is the date of the breakthrough therapy designation.

Q Are you sure about that?

A Well, that's what you just said, breakthrough --

Q It's not what I said. I just want to see, are you sure about that? Is that your testimony?

A Can you repeat the question?

Q Do you know what a breakthrough therapy designation approval date is?

A A breakthrough therapy designation approval date is what you said, a breakthrough therapy designation approval date. But I don't

know if this approval date refers to a breakthrough therapy designation approval date. You see what I'm saying? Do you -- can you tell definitively what that approval date is referring to?

Q Do you know when was the breakthrough therapy designation approval date for the breakthrough therapy designation that you referred to in your Declaration?

A I always have to review dates with source. I can't say 2012, 2015, without looking at the -- without looking at documents.

Q Is it fair --

A Just like I wouldn't be able to tell you if I asked you what you just asked me about any of these dates, if you could remember the actual date even though you've seen it or you believe the source.

Q So is it fair to say sitting here today, you do not know when was the breakthrough therapy designation approval date for any of the pembrolizumab indications that you refer to in

your Declaration?

A I cannot specifically give you the dates --

Q Can you generally --

A -- today.

Q Sitting here today, can you generally give me the dates for any breakthrough therapy designation approval that you referred to in your Declaration?

MR. MILLER: Objection. Form.

A I cannot generally give you any specific dates without review.

Q Do you know whether or not pembrolizumab received a breakthrough therapy designation for unresectable or metastatic MSI high colorectal cancer?

A I believe that pembrolizumab received a breakthrough therapy designation -- can you repeat the question?

Q Do you know whether or not pembrolizumab received a breakthrough therapy designation for unresectable or metastatic MSI high colorectal

cancer?

A Pembrolizumab received a breakthrough therapy designation.

Q Are you finished with your answer?

A Yes.

Q Do you know whether or not pembrolizumab received a breakthrough therapy designation for any non-colorectal cancer?

A Any non-colorectal cancer ever?

Q Yes.

A You just told me that it received a bunch of breakthrough therapy designations for non-colorectal cancers.

Q I don't think I've told you anything. I've been asking you questions. So let me ask my question. Let me -- I'll ask a different question.

Do you know whether or not pembrolizumab ever received a breakthrough therapy designation for unresectable or metastatic MSI high non-colorectal cancer?

A One more time. Do I know if --

Q Do you know whether or not pembrolizumab ever received a breakthrough therapy designation for unresectable or metastatic MSI high non-colorectal cancer?

A I believe that pembrolizumab received a breakthrough therapy designation for MSI high non-colorectal cancer.

Q Do you know how many breakthrough therapy designations approvals pembrolizumab has received from the FDA?

A I do not.

Q Do you know whether or not pembrolizumab has received more than five breakthrough therapy designation approvals from the FDA?

A I think that you just went through -- I don't know how many we just went through. Three? Is there more on this page?

Q We can go back to it. So we saw reference to a breakthrough therapy designation approval on page 2 of Exhibit 1130, right?

A Yes, the top one.

Q And we saw a breakthrough therapy

designation approval for pembrolizumab on page 3 of Exhibit 1130, right?

A Lung cancer.

Q Is that right?

A Yes.

Q And we saw a breakthrough therapy designation approval for pembrolizumab on page 4 of Exhibit 1130, right?

A Yes.

Q On page --

A Four. That's four.

Q That's four.

Well, that's page 4. That's the third one, though.

A Oh, three.

Q And if you turn to page 7 of Exhibit 1130, we see a fourth breakthrough therapy designation approval for pembrolizumab, right?

A Page 7, the top one.

Q That's right?

A Yes.

Q And if we turn to page 8 of Exhibit

1130, we see a fifth breakthrough therapy designation approval for pembrolizumab, right?

A I'm sorry, what page are you on?

Q Page 8 of Exhibit 1130.

A Page 8. No. 5, fifth, yes. Are you asking me if there's more than five?

Q I did.

A Okay. So there was not more -- there was not more than five as of the May 18. No. 5 was May 18, 2017.

Q Okay. And there were five breakthrough designation approvals for pembrolizumab before any breakthrough therapy designation approval for pembrolizumab with respect to MSI high phenotypes, right?

MR. MILLER: Objection. Form.

A As far as I can see, based on these charts, the charts state these approval dates, whatever this approval refers to. If these are breakthrough therapy designation date approvals datewise, I don't know what the actual approval date refers to.

Q All right. I'll try my question again. Maybe you'll have the same response.

And there were five breakthrough therapy designation approvals for pembrolizumab before any breakthrough therapy designation approvals for pembrolizumab with respect to MSI high phenotypes, right?

A I can tell you that there are five on this chart listed with something that says "approval date" before the one that refers to MSI.

Q Okay.

A So now I see -- yeah, I'm still not sure what that approval date refers to.

Q Right. And if you turn to page 9 of Exhibit 1130, do you see reference to any breakthrough therapy designation approval date for pembrolizumab?

A You mean on the page 9, the very top one?

Q And that very top one reflects a date of May 23, 2017. Do you see that?

A I do.

Q Does that date mean anything to you at all?
A That date is --
Q I see you're looking at your Declaration.
A Yeah. I'm just trying to get all the dates straight.
Has to do with this, treatment of adult and pediatric patients, unresectable or metastatic microsatellite instability high or mismatched pair- deficient solid tumors that have progressed following prior treatment and have no satisfactory alternative treatment options, or metastatic microsatellite instability high, MSI high, or mismatched pair-deficient colorectal cancer that has progressed following treatment with a fluoropyrimidine acciplatin intermecan (phonetic).
Q Do you know what my question was?
A Can you repeat the question?
Q Do you know what my question was?
A I need you to repeat the question.
Q Why do you need me to repeat it? My

question is, do you know what my question --

A I can't remember. There's a lot of information that goes through. If you could repeat the question.

Q All right. Turning your attention to --

A You asked me very specific questions. I just want to make sure I get straight what you're asking me.

Q I try to ask specific questions.

Turning to page 7, Exhibit 1130.

A Page 7. 1130, going to page 7. Still on --

Q Are you there?

A Yes.

Q Did you and your team have anything to do with the breakthrough therapy designation approval that's for Keytruda® reflected on this page?

A Did I or my team? I do not recall having any involvement.

Q Okay. And so turning your attention to page 8 of Exhibit 1130, did you or any members of

your team have any involvement with the breakthrough therapy designation for pembrolizumab reflected on this page?

A Did I or any members of my team. Did I or any members of my team -- I guess do -- did we have involvement with the approval? Did we have involvement -- I guess I don't really know what you mean "involvement."

Q Did you have involvement with any of the clinical studies that led to the approval for pembrolizumab reflected on this page?

A Did I have any involvement in the trial that led to this approval?

Q No, I didn't say the trial. I said the clinical studies. Let me try -- I'll say it slower.

Did you or any members of your team have involvement with any of the clinical studies that led to the breakthrough therapy designation approval for pembrolizumab reflected on page 8 of Exhibit 1130?

A Okay. The clinical -- so how -- can you

clarify why you corrected me when I said trial and you said no, study? I need to make sure we're talking about the same thing.

Q Let me try my question again. Either you understand it or you don't.

Did you or any members of your team have involvement with any of the clinical studies that led to the breakthrough therapy designation approval for pembrolizumab reflected on page 8 of Exhibit 1130?

A Can you define "clinical study"?

Q Do you not know what a clinical study is, Doctor?

A Everything has a definition and with -- sometimes I can't really understand what you're asking me, so I just need clarification because you corrected me when I said "trial." You don't mean trial, you said "study." I'm trying to find out what you mean "study" if I need to be corrected when I said "trial."

Q So, Doctor, in your Declaration at paragraph 35 you say that receiving breakthrough

designation is rarely given by the FDA, right?

A 35, sought and received breakthrough therapy designation. Receiving breakthrough designation is substantially, the process -- blah, blah, blah. The designation is rarely given by FDA, which needs to seek compelling data to do so. The designation is rarely given by the FDA.

Yes, I do see that.

Q Do you believe that receiving breakthrough designation is rarely given by the FDA?

A Yeah, I do.

Q And what do you mean by "rarely"?

A It's not -- it's more often not, that it's not given -- I mean more often not given for any -- if you consider all the millions of, or thousands, I don't really know the numbers of drugs out there, and all the potential indications even within each disease and stage, the denominator is quite large and so I think it's rare.

I mean I've been doing this for a very

long time. I have not been involved in a lot of studies where there's been breakthrough therapy designations, so I believe it's rare. I don't believe -- I believe that statement.

Q Do you understand that obtaining a breakthrough therapy designation must be requested?

A Do I understand ... rather than it just being given?

Q Correct.

A I suppose. The FDA doesn't come and just bless people with them.

Q So you do understand that in order to receive a breakthrough therapy designation, you have to request it, right?

A That's what you're telling me.

Q I'm asking you. Do you know whether or not to receive a breakthrough therapy designation it has to be requested?

A I don't know if there are alternative ways to receive breakthrough therapy designation.

Q What are the ways that you know of by

which a breakthrough therapy designation can be received?

A I imagine that there's ways to request it, to have the FDA to review it, and then there's probably -- I don't know if there are alternative ways to get a breakthrough therapy designation.

Q Do you know how many breakthrough therapy designation requests were received by the FDA in 2012?

A No.

Q Do you know how many breakthrough therapy designation requests were received by the FDA in 2013?

A No.

Q Do you know how many breakthrough therapy designation requests were received by the FDA in any of the years from 2014 through 2023?

A I do not.

MR. MILLER: Counsel, we've been going well over an hour. Good time for a break?

MR. RATLIFF: Doctor, would you like to take a break, or we can keep going.

THE WITNESS: What time is it?
MR. MILLER: 3:15.
THE WITNESS: 3:15. And we still have how long?
MR. MILLER: Do you need a break?
THE WITNESS: Well, I just need to time my breaks because I'm -- I shouldn't sit for very long.
MR. MILLER: We've been going for more than an hour now.
THE WITNESS: Yeah, if we could take a break, and then how many more hours left do we have?
MR. RATLIFF: Let's take a break first; we'll figure that out.
(A recess was taken at 3:14 p.m.)
(Back on the record at 3:29 p.m.)
BY MR. RATLIFF:
Q And, Doctor, during the break, did you discuss this case or any of my questions?
A No, I did not discuss this case or any of your questions.

Q Doctor, do you know in the period of October 1st, 2023, through September 30, 2024 how many breakthrough therapy designations requests were received by the FDA?

A I'm sorry, you said -- the answer is no.

Q Okay.

(Exhibit 1128 and Exhibit 1129 were marked for identification and were retained by Mr. Ratliff.)

Q Doctor, I'd like to hand you a new exhibit which has been marked as Exhibit 1128. And I'll also hand you a document which is a new exhibit that's been marked as Exhibit 1129.

Doctor, I can represent to you that Exhibit 1128 and Exhibit 1129 are documents that were downloaded from the FDA's website.

Exhibit 1128 is entitled "CDER Breakthrough Therapy Designation Requests Received By Fiscal Year," and the document which is Exhibit 1129 bears the title "CDER Breakthrough Therapy Designation Requests Received By Fiscal Year."

Doctor, do you recall ever looking at

CDER's Breakthrough Therapy Designation Requests Received by Fiscal Year?

A No.

Q And looking at Exhibit 1128, do you see the asterisk at the bottom of the page and there's a sentence following the asterisk?

A Yes.

Q And do you see that in the sentence it reads:

Breakthrough therapy designation was enacted in the Food and Drug Administration Safety and Innovation Act on July 9, 2012.

Do you see that?

A Yes.

Q And does that refresh your memory at all when breakthrough therapy designations were being received by the FDA?

MR. MILLER: Objection. Form.

A Does it -- no.

Q Turning your attention back to Exhibit 1130, this is the CDER breakthrough therapy designation approvals document.

A Sorry, you said 1130?
Q That's correct.
A Yes.
Q And in Exhibit 1130, do you see that it refers to several different drugs?
A I'm sorry, can you repeat the question?
Q In looking at Exhibit 1130, do you see that it refers to many different drugs?
A I see that there are many drugs on this table. Is that what you're asking?
Q That is what I'm asking.
So there are many different drugs in the table that's reflected in Exhibit 1130, right?
A There are different drugs. I mean I guess "many" is -- there are drugs.
Q Would you say that there are many different drugs that are reflected --
A I would say that there are several different drugs.
Q -- in Exhibit 1130?
A There are several different drugs reflected in Exhibit 1130.

Q Okay, that's great, because the word "several" is where I started.

So looking at Exhibit 1130, of the several different drugs that are reflected in this exhibit, would you agree that pembrolizumab is the drug with the most breakthrough therapy designation approvals?

A I'd have to sit down and look at every single one and put them on a table and see how many there are.

Q Sitting here, you don't know whether or not pembrolizumab is the top drug with the most breakthrough therapy designation approvals, right?

A Yeah, I can't tell -- no, I can't. I can't quickly go through 34 pages and tell you. I cannot tell you how many of these are pembrolizumab.

Q And just to be clear, Doctor, I'm not asking you to go through 34 different pages. My question is different.

It's just, sitting here today, do you know whether or not pembrolizumab has the most

breakthrough therapy designation approvals of any drug?

A Sitting here today, I do not know if pembrolizumab has the most breakthrough therapy designations of any drug on this table that lists therapies from 2013 to 2023.

Q And would it surprise you if pembrolizumab had the most breakthrough therapy designation approvals of any drug?

A I can't say that I have thought about which drug has the most breakthrough therapy designations.

Q So let's try my question.

Would it surprise you if pembrolizumab had the most breakthrough therapy designation approvals of any drug?

A I can't say I know enough to be surprised or not surprised.

Q And would you consider yourself a practicing oncologist, Doctor?

A Am I a practicing oncologist? I am an oncologist that sees patients. I am a practicing

oncologist, yes.

Q And do you prescribe pembrolizumab to patients?

A Do I prescribe pembrolizumab to patients. I prescribe pembrolizumab to patients, yes.

Q And would you agree that pembrolizumab is a good drug?

MR. MILLER: Objection. Form.

A Do I believe that pembrolizumab is a good drug? Whoo, that's a loaded question. What do you mean by "good"?

Q In your view, do you agree that pembrolizumab is a helpful drug for patients?

MR. MILLER: Objection. Form.

A Do I believe that pembrolizumab is a helpful drug in patients; is that what you asked?

Q No. Do you believe that pembrolizumab is a helpful drug for patients?

MR. MILLER: Objection. Form.

A How is that different from the question before? Do I believe that pembrolizumab is an

effective drug for -- helpful drug for patients.

Q So let me try it this way. I'm just going to ask the question.

A Okay.

Q Do you believe that pembrolizumab is a helpful drug for patients?

MR. MILLER: Objection. Form.

A I feel like you're asking me the same thing each time. Do I believe that pembrolizumab is a helpful drug for patients?

Q (Nodding head.)

A Yes, that's what you're asking me?

Q That's the question.

A I believe that pembrolizumab is a helpful drug in some patients.

Q And do you believe that pembrolizumab is an effective drug for patients?

MR. MILLER: Objection. Form.

A I believe that pembrolizumab is an effective drug in some patients.

Q And would you agree that pembrolizumab is a chemical compound that has properties that

help patients?

MR. MILLER: Objection. Form.

A Can you repeat the question?

Q Would you agree that pembrolizumab is a chemical compound that has properties that help patients?

A Chemical compound -- how is that different from the prior question?

Q I just have to ask you questions. If you don't think it's different, then you can just provide your response.

A Okay.

Q Let me try it again.

Would you agree that pembrolizumab is a chemical compound that has properties that help patients?

MR. MILLER: Objection. Form.

A I believe that pembrolizumab helps patients, or some patients.

Q My question is different.

My question is, would you agree that pembrolizumab is a chemical compound that has

properties helpful for patients?

MR. MILLER: Objection. Form.

A Can you define "chemical compound"? I'm trying to figure out how your question is different.

Q Do you know what a chemical compound is?

A I don't know specifically what you're referring to when you say "chemical compound."

Q Would you consider pembrolizumab a chemical compound?

A Chemical compound? I need a definition for chemical compound.

Q Let me try my question again.

Would you consider pembrolizumab a chemical compound?

MR. MILLER: Objection. Form.

A I consider pembrolizumab an antibody.

Q Do you consider pembrolizumab an antibody that has helpful properties for patients?

MR. MILLER: Objection. Form.

A Do I believe that pembrolizumab is an antibody that is helpful to patients is the

question?

Q No.

A I'm sorry, what's the question?

Q Do you believe that pembrolizumab is an antibody that has properties that is helpful to patients?

MR. MILLER: Objection. Form.

A Do I believe that pembrolizumab is an antibody that has properties that is helpful to patients? What do you mean by "properties"? How is that different than pembrolizumab -- I'm just trying to understand your question.

Q If you don't understand my question, that's fine. I'll try it again. If you don't understand, that means you are not able to answer it.

Do you believe that pembrolizumab is an antibody that has properties that is helpful to patients?

A I believe that pembrolizumab is an antibody that is helpful to some patients.

Q And do you believe that pembrolizumab is

an antibody that has properties that is helpful for patients?

MR. MILLER: Objection. Form.

A I'm sorry, I'm not grasping you asking me different questions. I believe that pembrolizumab is an antibody that is helpful to some patients.

Q Would you agree that pembrolizumab is a wonderful antibody?

A Wonderful? That's a, that's a weird way to describe anything, I guess.

Q Well, if you don't agree, it's fine.

You've never used the word "wonderful" to describe anything?

A No, I'm not saying that. I can't recall specifically.

Q Let me try my question again.

Would you agree that pembrolizumab is a wonderful antibody for patients?

MR. MILLER: Objection. Form.

A "Wonderful" is not a word that I think I would use to describe. I think pembrolizumab is a

good antibody for some patients.

Q And would you agree that pembrolizumab intrinsically has healing properties for cancer patients?

MR. MILLER: Objection. Form.

A Okay. Do I believe that pembrolizumab has intrinsic healing properties -- I need some -- can you like ask that question in a different way?

Q Let me try it again. Maybe see if you understand.

I know your counsel is laughing. You started laughing as well.

A I'm sorry, I don't mean to.

Q Let me try it again.

Would you agree that pembrolizumab intrinsically has healing properties for cancer patients?

MR. MILLER: Objection. Form.

A Can you word that in a different way? Like an example of something that would have an intrinsic healing --

Q I can't. If you don't understand the

question, you can just say you don't understand the question.

A I don't understand the question.

Q Okay. Would you agree that pembrolizumab intrinsically has properties that are helpful to some cancer patients?

MR. MILLER: Objection. Form.

A I think I'm still hung up on -- I don't know what you're asking. What do you mean does it have intrinsic properties?

Q So you're not able to answer the question?

A No.

Q Okay. Ask you to turn your attention to Exhibit 1001. I think that's a copy of the '393 patent. It's at the bottom of your pile there, Doctor.

A (Complying.)

Q You have it?

A Uh-humh.

Q Have you read the '393 patent claims?

A Have I read the claims? I don't recall

specifically.

Q Have you read the '393 patent?

A The actual patent, this entire document?

Q Try my question again.

Have you read the '393 patent?

A This is the patent?

Q Doctor, you recall in your Declaration you referenced the '393 patent, right, the Declaration that you put in this case?

A Yes, I think we talked about that earlier today.

Q We did.

And so my question is, have you ever read the '393 patent on which you are a named inventor?

A I have not read the entirety of this -- every page of this document, no.

Q And have you ever read the claims of the '393 patent on which you're a named inventor?

A I don't recall specifically the claims.

Q Have you ever read sheets 1 through 13 of the '393 patent on which you are a named

inventor?

A Have I ever read page -- I'm sorry, again.

Q Have you ever read sheets 1 through 13 of the '393 patent?

A I recognize some of these figures.

Q Are you finished with your answer?

A Yes.

Q Because -- let's try my question.

So my question wasn't about whether you recognize some of the figures in the sheets. My question was different.

And my question is, have you ever read sheets 1 through 13 of the '393 patent?

A I don't recall reading all of the details in page 1 through 13 of this document.

Q And when you say "page 1 through 13," are you referring to sheets 1 through 13?

A Oh, I don't know. You in the past were calling things pages, and it says page.

Q So, Doctor, my question is about sheets. We'll try it a little bit different way.

I want to turn your attention to the page numbers at the bottom of this exhibit, '393. Did you ever read at any point in time the contents of pages 21 through 31 in Exhibit 1001?

A Page 21 through 31. I don't recall that I have read all the content in this -- I'm sorry, you said page 21 through?

Q 31.

A 31.

Q You finished with your answer?

A Yes.

Q Okay. So let me get it because your answer wasn't clear to me.

Have you ever read at any point in time the contents of pages 21 through 31 in Exhibit 1001, which is the patent for which you are a named inventor?

A Have I read pages 21 through 31 as part of this United States Patent -- this thing, U.S. 11,591,393 B2, February 2023?

Q Right. What you're saying and referring to as "this thing," this is the patent on which

you're named as an inventor and the patent that you reference in your Declaration, right? That's what "this thing" is, right?

A This patent No. --

Q You need to --

A This one, where I understand that Merck has challenged the validity of the claims of the '393 patent; is that what you're referring to?

Q Do you know what the '393 patent is?

A This says this is '393.

Q Was Exhibit 1001 what you're referring to when you mentioned the '393 patent in paragraph 4 of your Declaration?

A I understand that Merck has challenged the validity of the claims of the '393 patent.

Q I didn't ask you to read it. My question is different.

When you refer to the '393 patent in paragraph 4 of your Declaration, were you referring to Exhibit 1001?

A I was referring to the '393 patent.

Q And is Exhibit 1001 the '393 patent on

which you're listed as a named inventor?

A Exhibit 1 says Patent No. U.S. 11,591,393 B2.

Q And is Exhibit 1001, to your knowledge, the '393 patent that you refer to in your Declaration?

A I -- what I say here is, I understand that Merck has challenged the validity of the claims of the '393 patent.

Q Right. And I didn't ask you -- I did not ask you what you said in paragraph 4 of your Declaration.

A Okay.

Q In paragraph 4 of your Declaration you reference a '393 patent, right?

A Yes.

Q So my question is, is Exhibit 1001, is that the '393 patent that you reference in your Declaration?

A This says Patent No. U.S. 11,591,393 B2.

Q And by "this," you're referring to the 1001, Exhibit 1001?

A At the top of Exhibit 1001 it says Patent No. U.S. 11,591,393 B2.

Q And, Doctor, do you know whether or not Exhibit 1001 is the '393 patent that you refer to in your Declaration?

A In the Declaration I say:

I understand that Merck has challenged the validity of the claims of the '393 patent.

Q Are you finished with your response?

A Yes.

Q Doctor, do you know whether or not Exhibit 1001 is the '393 patent that you refer to in your Declaration?

A I see here it says Patent No. U.S. 11,591,393 B2.

Q And when you say you see "here," what are you referring to?

A At the top of this document, Merck Exhibit, I guess EX 1001, page 1 of 34, it says Patent No., at the top, U.S. 11,591,393 B2.

Q And do you know whether or not Exhibit 1001 is a copy of the '393 patent that you refer

to in your Declaration; yes or no?

A I state in the Declaration that I understand that Merck has challenged the validity of the claims of the '393 patent.

Q Doctor, have you ever read the contents of pages 8 through 20 of Exhibit 1001?

A Page 8 --

Q Pages 8 through 20. I'm referring to the exhibit number pages.

A Oh, I see the sheets up here now.

Okay. Page 8 through -- have I seen these figures?

Q No, I didn't ask you if you've seen them. Did you ever read the contents of pages 8 through 20 of Exhibit 1001?

A I recognize the figures and the tables.

Q So have you ever read the contents of pages 8 through 20 of Exhibit 1001?

MR. MILLER: Objection. Form.

A The content are the figures and the table.

Q So have you ever read the contents of

pages 8 through 20 of Exhibit 1001?

A Have I read them. I have seen the figures in pages 8 -- I've seen the figures and the tables.

Q Did you prepare any of the figures and tables or any of the contents found on pages 8 through 20 of Exhibit 1001?

A Did I prepare the figures or the tables. I believe that I helped to prepare the content in the figures and the tables.

Q Can I turn your attention to page 33 of Exhibit 1001?

A Page 33 of 34?

Q Yes. Do you have that?

A Yes.

Q And sitting here today, do you know whether or not this is a copy of the '393 patent that you refer to in your Declaration?

MR. MILLER: Objection. Form. Asked and answered many, many times.

A Yeah, I -- it's the same --

Q So the answer -- do you know?

A I know that Merck has challenged the validity of the claims in the '393 patent, and I know that on several pages, including the front page, it says U.S. 11,591,392 B2.

Q So do you know whether or not this is the '393 patent that you're referring to in your Declaration?

Can you answer my question, Doctor?

A Yeah. So I said that I understand that Merck has challenged the validity of the claims in the '393 patent, and this here says U.S. 11,591,393 B2.

Q Do you know whether or not when you refer to the '393 patent in your Declaration you're talking about Exhibit 1001 or if you're talking about some other patent?

A I know that Merck has challenged the validity of the claims of the '393 patent.

Q Are you finished with your response?

A Yes.

Q So looking at page 33 of Exhibit 1001, do you see claim 1 listed there?

A Page 33. "We claim," that one?
Q Yes, that one.
Do you see claim 1 beginning at line 40?
A Okay. Line -- well, I guess it's line 40. Yeah.
Q Do you practice the method of that claim in your work as an oncologist?
MR. MILLER: Objection. Form. Legal.
A Do I practice the method of the claim. A method of treating MSI high, or in treating colorectal in a human --
MR. MILLER: The Court Reporter needs to take down what you're --
A I'm trying. It's very long. A method --
MR. MILLER: Just read to yourself.
THE WITNESS: Oh, okay.
Q You were saying what was very long, the claim?
A I'm just want to read the whole thing. You said just read 1, No. 1.
Q No, that wasn't my -- my question is

different.

My question is, do you practice the method of claim 1 in your work as an oncologist?

MR. MILLER: Objection. Form. Legal.

A What does "practicing a method" mean?

Q If you don't know, then you don't know. Just tell me you don't understand my question.

A I don't understand your question.

Q Fair enough.

Looking at claim 31, do you practice the method of that claim in your work as an oncologist?

A Do I practice the method? I mean I think it's the same thing. I don't know what you mean by "practice the method."

Q For claim 31, do you ever perform the steps of the method described in that claim?

MR. MILLER: Objection. Form. Legal.

A Do I perform -- I'm sorry, what was the question?

Q In your work as an oncologist --

A Okay, as an oncologist.

Q -- do you practice -- strike that.
In your work as an oncologist, do you ever perform the method described in claim 31?
MR. MILLER: Objection. Form. Legal.
A Do I practice the method?
Q Do you understand what claim 31 says?
A I'd have to read it and --
(Reviewing.)
In the method -- I don't -- I don't completely understand what you mean by "do I practice the method." I don't know that oncologists practice methods, so I'm not sure what you mean.
Q So let's try to focus on my question. My question is different.
Do you understand the methods that are described in claims 31, 33, 35, 37, 39, and 41?
MR. MILLER: Objection. Form. Legal.
A Do I, as a practicing oncologist, practice the methods? I mean --
Q Do you know what I asked you?
A What did you ask me?

Q Do you know?
A You asked me -- can you repeat it?
Q Do you understand the methods that are described in claims 31, 33, 35, 37, 39 and 41?
MR. MILLER: Objection. Form. Legal.
A Do I understand the methods? A method of claim 1.
Can you phrase it in a different way?
Q No. Are you able to answer my question?
A I can't answer your question.
Q Do you understand the methods of any of the patent claims listed on pages 33 and 34 of Exhibit 1001?
MR. MILLER: Objection. Form. Legal.
A What do you mean by "understand the methods"? Do I understand the science in here, the numbers? What do you mean by "methods"?
Q Can you tell me for any claim whether an oncologist practices the methods of any of the claims we see on pages 33 and 34 of Exhibit 1001?
MR. MILLER: Objection. Form. Legal.
A Do oncologists practice methods.

Oncologists practice methods. I don't know if oncologists practice methods. I feel like "methods" is referring to something very specific.

Q And do you understand that each of the claims describe a method?

MR. MILLER: Objection. Form. Legal.

A Can you clarify "method"?

Q Let me turn your attention to page 33 of the exhibit. Looking at column 25, about line 39, do you see where it says, "We claim"?

A Page 33, yes.

Q You see that?

A Uh-humh.

Q Who does the "we" refer to?

A I didn't write this. No.

Q I didn't ask you if you wrote it, I'm asking you who does the "we" refer to.

A That sounds like my interpretation of something somebody wrote.

Q Do you know what the "we" refers to?

MR. MILLER: Objection. Form. Legal.

Q When it says "We claim" in Exhibit 1001,

do you know what the "we" refers to, or who?

MR. MILLER: Objection. Form. Legal.

Q If you don't know, you can just say that.

A I don't know.

Q Can you turn your attention to Exhibit 1005. I see it near the top of your pile. Do you have that?

A Exhibit 1005.

Q Right. And this is the study record that we've been talking about for the trial, right?

A The clinical trial submission.

Q And you are aware that this is not the actual submission, right?

A The document -- somebody printed this document. The -- it's specifying A and B, June 10, 2013, printed it on clinicaltrials.gov.

Q Yes, this document was printed from clinicaltrials.gov, right?

A Well, I'm assuming. I don't know who printed the document.

Q But you cite this document in your Declaration, right?
A I cite this document.
Q Is it your testimony that you don't know what Exhibit 1005 is; is that your testimony?
A 1005 is the -- reflects the June 10, 2013 information submitted June 10, 2013.
Q For the trial, right?
A Now we're getting back to the word --
MR. MILLER: Objection. Form.
Q For KEYNOTE-16, right?
MR. MILLER: Objection. Form.
A This appears to be an archive. So it was printed from clinicaltrials.gov of what was submitted for the June 10th -- it was first submitted June 10, 2013.
Q And that reflects the June 10, 2013 submission for KEYNOTE-16, right?
MR. MILLER: Objection. Form.
A It reflects the submission for the clinicaltrials.gov submission for the trial.
Q Okay. And the rationale for conducting

the trial included the fact that pembrolizumab was showing activity in multiple tumor types, including melanoma and non-small cell lung cancer, right?

MR. MILLER: Objection. Form.

A Are you asking about this document?

Q No. I'm asking about the rationale for doing the trial that's described in Exhibit 1005. So here's my question.

A Rationale.

Q The rationale for conducting the trial included the fact that pembrolizumab was showing activity in multiple tumor types, including melanoma and non-small cell lung cancer, right?

MR. MILLER: Objection. Form.

A The rationale for the clinical trial -- I mean I think it was much more than that. I don't know what you're saying, the rationale. The rationale was that it worked in cancers; is that what you're saying?

Q Is that what you think you heard?

A No. Can you repeat what you --

Q Sure.

The rationale for conducting the trial included the fact that pembrolizumab was showing activity in multiple tumor types, including melanoma and non-small cell lung cancer, right?

MR. MILLER: Objection. Form.

A The background of the trial did include that pembrolizumab was showing activity in melanoma.

Q Okay. I'm not sure why you keep changing -- you're changing my words. I'm not asking about the background. I'm asking about the rationale, not the background. So here's my question:

Do you agree that the rationale for conducting the trial included the fact that pembrolizumab was showing activity in multiple tumor types, including melanoma and non-small cell lung cancer?

MR. MILLER: Objection. Form.

Q Yes or no?

A I think it goes back to what you mean by

"rationale" and what document we're talking about.

Q Didn't you use the term "rationale" when referring to the trial when you made an IND submission to the FDA?

A Did I -- sorry.

Q Didn't you use the term "rationale" when referring to the trial when you and your team made an IND submission to the FDA?

A I'd have to look at that document again.

Q So sitting here today, you don't know whether or not you and your team used the term "rationale" when -- wait -- when you and your team made an IND submission to the FDA for the trial?

A When we made an IND submission to the FDA, did we use the term "rationale" in the document; is that what you're asking?

Q I'll just let that be your testimony if you think that's what I'm asking.

Would you agree that the rationale for the trial included the fact that a different PD-1 blocking antibody nivolumab also showed activity in melanoma and in non-small cell lung cancer?

A Say that one -- nivolumab -- I'm getting confused. What are you asking?

Q Would you agree --

A Would I agree.

Q -- that the rationale for the trial included the fact that a different PD-1 blocking antibody nivolumab also showed activity in melanoma?

A Would I agree that the rationale --

MR. MILLER: Sorry. Objection. Form.

Go ahead when you're ready.

A Would I agree that the rationale for the trial is that pembrolizumab worked in melanoma?

Q Would you agree that the rationale for the trial included the fact that a different PD-1 blocking antibody, nivolumab, showed activity in melanoma?

MR. MILLER: Objection. Form.

A The rationale for the trial. What are you referring to when you say "the rationale for the trial?" Which document are we talking about?

Q I'm not talking about a particular

document. You were the principal investigator for the trial, right?

A I was a principal investigator for a trial, yes.

Q I didn't ask you if you were the principal investigator for a trial. You were the principal investigator for the trial, right?

A Yes.

Q And I'm asking you, would you agree that part of the rationale for that trial included the fact that a different PD-1 blocking antibody, nivolumab, also showed activity in melanoma?

MR. MILLER: Objection. Form.

A I would feel more comfortable looking at the trial and what was written in the rationale to -- I guess that's it.

Q Do you recall, sitting here today, what was the rationale for the trial for which you were the principal investigator?

A Do I recall the rationale for the trial. The rationale for the trial. Do I recall everything we put in the trial document? I don't

recall everything that was put in the trial protocol.

Q Do you think I asked you if you recalled everything that was put in the trial protocol? Is that what you think I asked?

A I think you asked me the rationale for the protocol, and this is a long time ago so I'd like to look at the rationale in the protocol.

Q Okay. So I didn't ask you what you think I asked you. So let me try it again.

Do you recall the rationale for the trial for which you were the principal investigator, sitting here today; yes or no?

MR. MILLER: Objection. Form.

A I cannot say I can recall everything that was in the rationale for the trial that we are discussing.

Q And do you recall whether or not the rationale for the trial included the fact that there was a complete response in a single patient with colorectal cancer?

MR. MILLER: Objection. Form.

A I don't recall if it was in the rationale. I recall that there was a patient with colon cancer.

Q Doctor, can you turn your attention to Exhibit 116 [sic]. This is the IND submission. In particular, if you can turn your attention to page 76 of the document.

A 116.

Q There's three 1s, 1116.

A Okay. What page is that?

Q 76.

Let me know when you have it.

A 76 of 199, or 76 of the document?

Q 76 of 199. Referring to the exhibit page.

A Okay.

Q I see you have it. The doctor understood.

So looking at page 76 of Exhibit 1116, I'd like to turn your attention to the entry which is No. 28.

A The entry which is No. 28.

Q Do you see that?
A Yes.
Q And that's a reference by Topalian; do you see that?
A Yes.
Q And are you familiar with that reference?
MR. MILLER: Objection. Form.
A Am I familiar with it? I'd feel more comfortable with it in front of me to know exactly which reference that is.
Q Do you recall what Topalian's about?
A She's written a lot of papers.
Q I didn't ask if she's written a lot of papers. I'm asking specifically about this reference that you and your team cite in the IND submission.
So my question is, do you recall this paper, sitting here today?
A I -- I recall a paper around that time frame that Suzanne was the author on.
Q Okay.

(Exhibit 1013 was marked for identification and was retained by Mr. Ratliff.)

Q Let me just show you a copy of the paper that you reference in the IND. It's Exhibit 1013.

A Okay, Exhibit 1013.

(Reviewing.)

Q Do you recall reviewing or looking at this document within the last year?

A Within the last year? Have I read it in any entirety in the last year? I don't recall reading this within the last year.

Q Do you recall looking at it within the last year?

A Within the last year? I can't say specifically when I last looked at this.

Q Do you recall looking at this document within the last six months?

A I can't recall if I looked at the document in its entirety in the last six months.

Q Did you look at the document in any shape, form or fashion within the last six months?

A Did I look at the document in any shape,

form and fashion in the last six months?

(Reviewing.)

I don't recall specifically.

Q Okay. But you're familiar with this reference, right?

A I am familiar with this reference.

Q And when you referred to Exhibit 1013 in your submission to the FDA, you didn't tell the FDA that the study referred to in Exhibit 1013 was resoundingly unsuccessful, right?

A Did I -- did we tell the FDA -- did we go over the specifics of this study and say it was unsuccessful?

Q When you referred to Exhibit 1013 in your IND submission, you didn't tell the FDA that Exhibit 13 [sic] reflected a resoundingly unsuccessful study, right?

Do you understand the question, Doctor?

A Yeah. I'm just trying to look at the actual paper to see what it said in the background. When you reference, reference 28 ...

(Reviewing.)

When we reference 28, we said:

Previously activity of a different PD-1 blocking antibody, BMS-936558, a fully humanized monoclonal IgG4 antibody, also showed activity in melanoma, non-small cell lung cancer and a complete response in a single patient with colorectal cancer.

Q And you're talking about the rationale for doing the study that you and your team wrote in the IND, right?

A Yes, the rationale.

Q So my question is, you didn't tell the FDA that Exhibit 1013 referred to a prior study where a checkpoint inhibitor was resoundingly unsuccessful, right?

A Did we tell the FDA that that study was unsuccessful?

Q Did you tell the FDA that that study was resoundingly unsuccessful?

A Nowhere in here did we say to the FDA that this PD-1 blocking antibody was resoundingly unsuccessful.

Q When you say "in here," your IND submission, right?

A I'm referring to a document here, document Exhibit 1116.

Q Okay. Did you ever at any point in time tell the FDA that the study reflected in Exhibit 1013 was resoundingly unsuccessful?

A Did we tell the FDA that this entire study was resoundingly unsuccessful. No, we did not tell the FDA that this NCT00730639 was resoundingly unsuccessful.

Q And you didn't tell the FDA that based upon the data in Exhibit 1013, colorectal cancer patients should not be understood to be candidates for anti-PD-1 therapy, right?

A Say that one more time.

Q You didn't tell the FDA that based upon the data in Exhibit 1013, colorectal cancer patients should not be understood to be candidates for anti-PD-1 therapy, right?

A That's correct, we did not tell the FDA that.

Q I'd like to turn your attention to page 77 of 199 of Exhibit 1116. Let me know when you have it.

A Okay, I'm sorry, what page?

Q 77.

A 77. Here we go. Okay.

Q And if I could turn your attention to reference 51.

A Reference 51. Yes.

Q And are you familiar with that reference 51?

A I am familiar with the reference 51.

Q And you cited reference 51 to the FDA as part of the rationale for conducting the trial, right?

A Yes.

Q And you didn't tell the FDA at any point in time that the study reflected in the Brahmer paper was resoundingly unsuccessful, right?

A No, we did not tell the FDA that the study in refractory solid tumors was resoundingly unsuccessful.

Q You didn't tell the FDA ever that based upon the data for colorectal cancer patients in the Brahmer paper, colorectal cancer patients should not be understood to be candidates for PD-1 therapy, right?

MR. MILLER: Objection. Form.

A In this FDA submission -- you're asking if we said in here that colorectal cancer patients should never receive PD-1?

Q No, my question is different.

Did you ever, at any point in time, you or any of your team members, ever tell the FDA that based upon the data in the Brahmer paper, colorectal cancer patients should not be understood to be candidates for anti-PD-1 therapy?

MR. MILLER: Objection. Form.

A Did we tell the FDA that colorectal cancer patients should never -- no, we did not tell the FDA that colon cancer patients should never receive therapy.

Q Okay. So let's try my question.

Did you ever at any point in time tell

the FDA that based on the data in the Brahmer paper, colorectal cancer patients should not be understood to be candidates for anti-PD-1 therapy?

MR. MILLER: Objection. Form.

A We did not tell the FDA that colon cancer patients should not be a candidate for anti-PD-1 therapy.

Q You're missing part of my question. Part of my question is very specific to this paper that we've been discussing, the Brahmer paper. Let me try my question again.

Did you ever at any point in time tell the FDA that based on the data in the Brahmer paper, colorectal cancer patients should not be understood to be candidates for anti-PD-1 therapy?

MR. MILLER: Objection. Form.

A We never say based on the Brahmer paper colon cancer patients should not receive anti-PD-1 therapy.

Q Did you or anyone on your team ever, at any point, tell the FDA that based upon the data in the Brahmer paper, colorectal cancer patients

should not be understood to be candidates for anti-PD-1 therapy?

MR. MILLER: Objection. Form.

A I'm sorry, I think I'm getting tired. It seems like the same question. Can you repeat the two questions?

Q There's only one question.

So the question is, did you or anyone in your team ever, at any point, tell the FDA that based upon the data in the Brahmer paper, colorectal cancer patients should not be understood to be candidates for anti-PD-1 therapy?

A I --

MR. MILLER: I'm sorry.

Objection. Form.

Go ahead.

A I did not tell the FDA that colon cancer patients should not be candidates for anti-PD-1 therapy in this application.

Q Try my question again.

You hear me when I say Brahmer paper, right?

A Yes.
Q So I just want to make sure that's in your response.
Did you or anyone on your team ever, at any point, tell the FDA that based upon the data in the Brahmer paper, colorectal cancer patients should not be understood to be candidates for anti-PD-1 therapy?
MR. MILLER: Objection. Form.
A We did not tell the FDA that colon cancer patients, based on the Brahmer paper, should not be candidates for anti-PD-1 therapy.
Q And did you or anyone on your team ever tell the FDA that based upon the complete response in a single patient with colorectal cancer with respect to nivolumab, colorectal cancer patients should not be understood to be candidates for anti-PD-1 therapy?
MR. MILLER: Objection. Form.
A Say that one more time.
Q Did you or anyone on your team ever tell the FDA that based upon the complete response in a

single patient with colorectal cancer with respect to nivolumab, colorectal cancer patients should not be understood to be candidates for anti-PD-1 therapy?

MR. MILLER: Objection. Form.

A That -- I guess I'm a little bit lost. Why would we tell FDA you can't treat something based on a response?

Q I'm not suggesting one way or another; I'm just asking the question.

A Okay.

Q Do you have an answer to the question?

A Okay, can you repeat the question?

Q Did you or anyone on your team ever tell the FDA that based upon a complete response in a single patient with colorectal cancer with respect to nivolumab, colorectal cancer patients should not be understood to be candidates for anti-PD-1 therapy?

MR. MILLER: Objection. Form.

A I did not tell the FDA that colon cancer patients, based on a complete response in a single

patient with, a colorectal cancer patient should not be candidates for anti-PD-1 therapy.

Q Okay. And can I turn your attention to page 39?

A Page 39.

Q Of Exhibit 1116. And I'm referring to the exhibit page.

A 1116, page 39. 39 of 199?

Q That's right.

A Okay.

Q Do you have it?

A Yep.

Q And you see the section that's entitled Rationale?

A Yes.

Q To your knowledge, did the FDA ever challenge the rationale that you and your team set forth in Section 2.4 entitled Rationale?

A Did they -- did the FDA ever challenge the rationale to my knowledge. Did they ever challenge the rationale. You mean did they ever challenge anything in these two paragraphs when

you're -- or actually three paragraphs?

Q Did the FDA ever challenge anything that you and your team said in the Rationale section?

A I can't recall that they challenged the rationale.

Q Sitting here today, do you know whether the FDA ever challenged the rationale that you set forth in the IND submission for the trial?

A Did they challenge it. What do you mean by "challenge"?

Q Did they ever question it? Did they ever say it was wrong? Did they ever say it was unreasonable? Did they ever say it was illogical?

A No. Illogical, no, the FDA never said it was illogical, to my knowledge.

Q Can you turn your attention to Exhibit 1119?

A Which one?

Q Maybe you don't have it. You can --

MR. MILLER: Do you need a break?

A I'm being buried in exhibits.

Q So, Doctor, I'd like to mark as a new

exhibit, Exhibit 1119.

(Exhibit 1119 was marked for identification and is attached to the transcript.)

Q Can you take a look at that exhibit and let me know if you recognize it?

A Let's see. 7/15 --

MR. MILLER: When you talk, the Court Reporter needs to take down your words.

THE WITNESS: I'm sorry, I'm just reading. 7/15/2013.

MR. MILLER: Just think quietly and then respond.

THE WITNESS: Okay, got it. Sorry.

Q Do you recognize Exhibit 1119, Doctor?

A 1119. I recognize Exhibit 1119.

Q And what is it?

A It is a packet of documents that communicates with the FDA through the IND.

Q And is this a packet that concerns the trial that we've been discussing today?

A Yes.

Q And if you turn to exhibit page 4 of

126, do you see that there is a letter from --
A Page 4.
Q -- JHU to the FDA?
A Page 4. Yes.
Q And that letter refers to two attachments; is that right?
A It actually has four. It refers to four attachments.
Q Four attachments.
And so what's the first attachment that it refers to?
A IRB approval letter.
Q Okay. And the IRB that's referred to in the approval letter, is that an IRB from JHU?
A It's an IRB as a part of Hopkins, yes.
Q So is it correct that JHU had to give an IRB approval to conduct the trial?
A The IRB had to give approval to conduct the trial.
Q And did the IRB give that approval to conduct the trial?
A The IRB gave the approval to conduct the

trial.

Q And is attachment 1 the Johns Hopkins IRB approval letter?

A The datewise date of -- reading date of expiration --

(Reviewing.)

It is a letter that says new application approval.

Q Is attachment 1 the Johns Hopkins IRB approval letter for the trial?

A It is a letter from the IRB that is a new application approval, and it's referring to the Phase 2 study of MK-3475 in patients with microsatellite unstable MSI high MSI tumors.

Q That's the trial we've been talking about all day, right?

A It is the trial that we've been talking about today, yes.

Q And attachment 2 --

A Attachment 2.

Q -- in this exhibit, can you tell me what it is?

A Attachment 2 is dated 5 -- protocol Version 1.1.

(Reviewing.)

It's a protocol. It's an approved protocol, Version 1.1.

Q It's an approved protocol for the trial that we've been talking about all day?

A It is the protocol that -- I mean the trial that we've been talking about all day.

Q And is this a protocol that you and your team prepared?

A It is a protocol that I helped prepare.

Q Right. And the protocol that you helped prepare, it includes a rationale for conducting the trial, right?

A A protocol for section --

Q And if it helps, I can turn your attention to page 20 of 126 of the exhibit.

A Okay. Yes, rationale. 2.4, Rationale.

Q Right. So the protocol that you helped prepare, it includes a rationale for conducting the trial, right?

A It includes a rationale. Yes, there is a rationale for conducting the trial.

Q Right. And that rationale for conducting the trial spans pages 20 through 21 of Exhibit 1119, right?

A The Rationale section spans pages 20 and 21.

Q Did the Johns Hopkins IRB Approval Board ever question, challenge the rationale that you set forth in Exhibit 19 [sic] for conducting the trial?

MR. MILLER: Objection. Form.

A I don't recall specifically.

Q Do you have any general recollection of the Johns Hopkins IRB ever questioning or challenging the rationale that you set forth in Exhibit 1119?

MR. MILLER: Objection. Form.

A Do I have any recollection that the IRB had any challenged -- challenged anything set forth in Section 2.4?

Q That's right, the Rationale section,

2.4.

A I do not have any recollection that the IRB challenged Section 2.4.

MR. MILLER: Counsel, is this a good time for a break? We've been going for a little over an hour.

MR. RATLIFF: Doctor, would you like to take a break or keep going?

MR. MILLER: We should take a break.

THE WITNESS: I think I need coffee.

MR. RATLIFF: Up to you, Doctor.

MR. MILLER: Let's take a break.

MR. RATLIFF: Okay, we can take a break.

(A recess was taken at 4:47 p.m.)

(Back on the record at 5:05 p.m.)

BY MR. RATLIFF:

Q Doctor, you have never been employed by the petitioner in this matter, Merck, right?

A Employed? Define "employed."

Q Never been an employee of Merck, right?

A Can you define "employee"?

Q Do you know what an employee is?

A There may be different definitions. I just want to make sure I'm able to answer it accurately.

Q Have you ever -- do you consider yourself to have ever been employed by Merck at any point in time?

A Can you define "employment"?

Q I'll just try my question again.

Do you consider yourself to ever have been employed by Merck at any point in time?

A I don't consider myself to have been employed by Merck.

Q Have you ever attended any Merck internal employee meeting where pembrolizumab was discussed?

A Internal employee meeting where pembrolizumab was -- internal employee. I am not sure the context of the meetings I've been in, if they were ever internal employee meetings. What does that mean, "internal"? What is the definition of an internal employee meeting?

Q If you don't understand my question, you

can just say that.

A I don't understand what you mean by an internal employee meeting.

Q Okay. Now, in paragraph 34 of your Declaration you refer to, quote, the Merck personnel, end quote, right?

A Yes.

Q Do you see that?

A Yes, it says the Merck personnel.

Q And the Merck personnel there, you're referring to Merck personnel that were involved with the trial that we've been discussing all day today?

A There were different Merck personnel along the way. Now, in 34 -- I just need to read it again. Sorry.

(Reviewing.)

Okay, go ahead.

Q The Merck personnel that you refer to in paragraph 34 of your Declaration, those are the Merck employees that were involved with the trial that we've been discussing all day, right?

A The Merck personnel -- it sort of depends. When I say -- the Merck personnel involved with our study, to my observation, did not initially act as it was expected to be successful, and certainly as successful as it was.

I can't name those personnel. It's been a long time.

Q Wait a minute. So you wrote a sentence and testified in paragraph 34 about your observations of Merck personnel; is that right?

A They were my observations.

Q Right. And I'm asking you, can you name the Merck personnel whose observations you're testifying about in your Declaration?

A I can't specify their names.

Q How many of them are there that you were thinking of when you testified about your observations of Merck personnel in paragraph 34 of your Declaration?

A I don't have a specific number.

Q Do you have a general number?

A I don't have a general number.

Q And is your testimony, sitting here today, that you can't name a single individual that you're referring to when you write "Merck personnel" in paragraph 34 of your Declaration?

A I can remember a face of a person. But it's not just one person. It's the -- it was just my observation that --

Q How many people was it?

A I don't know. I can't tell you how many people it was. I didn't -- I can't tell you.

Q And when you testified to this in paragraph 34 of your Declaration, about the observations that you had of the Merck personnel, did you have anything in mind in terms of how many people it was?

A You know, this is not like a particular point in time. It's like the Merck personnel. There was no -- when you have like an excited company, typically there's a lot of, you know, funding and all kinds of things. I mean these are just an observation. It's just an observation.

I do -- there were people involved in

the beginning that we had discussed the study with. I am not good with names. I can't remember their names.

Q Okay. In your responses to my questions you said that, quote, I can remember a face of a person.

A Uh-huh.

Q The face of the person that you can remember, what did that look like?

A (Witness laughing.)

Q You're laughing; I'm not sure why.

A I mean I don't know how to describe someone. I mean he was Caucasian, male. I can remember --

Q Did he have short hair or long hair?

A There were no long-haired personnel in the study. I mean no men with long hair.

Q Did he have short hair?

A Just regular hair.

Q What is "regular hair" in your opinion?

A Regular hair. Not short, not like super short and not long.

Q What color was the hair of this face that you can remember?
A Dark.
Q Dark as in black, dark as in brown, what color?
A Dark brown to black.
Q Did this person have a mustache?
A I don't recall. It's been a long time.
Q Well, you're the one that just testified that you can remember a face of a person.
A Okay.
Q So this face that you can remember, you don't recall the face that you can remember, whether or not it has a mustache?
A I can remember a Caucasian male with brown hair.
Q Did this face have a mustache?
A Did this face -- I don't recall.
Q Did the face have a beard?
A I don't recall. These were not physical observations. This is -- the idea is that it was not a lot of resources put into this. That it

just wasn't expected to be successful or certainly as successful. It's just an opinion.

Q Doctor, I'm asking you about this alleged face that you can remember of a person.

A Okay.

Q Anything else you can tell us about what this face looked like?

A He was thin.

Q How thin?

A I don't know. I don't know how to describe thinness. He wasn't overweight. He was a normal thin healthy face.

Q Healthy face, is that what you said?

A Uh-humh. I just mean not too, not too taut and not too overweight. Just a normal -- just normal thin.

Q If you saw this face at a picture today, would you recognize it?

A I can't say for sure.

Q Do you know how many Merck employees were involved in the clinical trial that we've been discussing all day?

MR. MILLER: Objection. Form.

A Do I know how many personnel were involved with our study? What do you mean by "involved"?

Q So first of all, I didn't ask you if you knew how many personnel were involved with the trial we've been discussing all day, so let me try my question again.

Do you know how many Merck employees were involved in the clinical trial that we've been discussing all day?

A Do I know how many Merck employees were involved in the clinical trial. So the -- I think we're talking about different people at different times.

Q I'm sorry, I don't understand that. I'm not asking you about your Declaration, I'm asking you about the trial that we've been discussing all day.

A Uh-humh.

Q So my question is, do you know how many Merck employees were involved with the trial that

we've been discussing all day?

MR. MILLER: Objection. Form.

A What do you mean by "involved"?

Q I mean involved in the same way that you meant it in paragraph 34 of your Declaration. You used the term "involved."

A Yeah. So, again, I think it depends on which part we're talking about, and I cannot tell you for each part how many Merck employees were involved.

(Ms. Moreira left the deposition.)

Q Can you tell us for any part how many Merck employees were involved?

MR. MILLER: Objection. Form.

A How many Merck employees were involved. What do you mean by "involved"?

Q I mean involved in the same way that you meant it in paragraph 34 in your Declaration when you used that term, "involved."

A Okay. I cannot tell you how many people I am referring to specifically.

Q You finished with your response?

A Yes.
Q You said how many people you're referring to specifically. Specifically to what?
Oh, if you're pointing to paragraph 34, we're beyond that. I already have your testimony about the face --
A Okay.
Q -- that you believe you can remember. I have that testimony.
A Okay.
Q So I'm asking you a different question.
The question is, do you know how many Merck employees were involved with the clinical trial that we've been discussing all day today?
A How many Merck employees were involved. I cannot tell you.
Q Do you know the name of any Merck employee that was involved with the clinical trial that we've been discussing all day today?
A Do I know the name of any Merck employee. I can't recall the name of any -- what was the question? We're past the numbers, we're

to names. I can see one of the people. Like I'm bad with names.

Q Do you know the name of any Merck employee that was involved with the clinical trial that we've been discussing all day today?

A Do I know the name. I do not know the name of the personnel. I do not know the names.

Q I'm not asking you if you know all the names. I'm asking you do you know the name of any Merck employee that was involved with the clinical trial that we've been discussing all day today.

A I do not know the names of the personnel. I recall, but I can't recall exactly. I can come up with one name of a person that was in some communication somewhere, but I can't remember the context of the communication.

Q And what was the name of that person?

A Amy.

Q Amy who?

A Amy Meister.

Q Do you know the name of anyone else that you believe was involved?

A That's the only name I can remember of somebody that we communicated with in regards to our study, our trial.

Q In regards to the trial that we've been discussing all day, right?

A I don't remember -- I can't remember at what point, I just remember that name. I can't remember the context.

Q And in your testimony today you said that you can see one of the people. What did -- what does that one of the people look like that you can see?

MR. MILLER: Objection. Form.

A I think we already answered that question.

Q No, this is a different question. So I'm not asking about the face.

A Okay.

Q We're past that. I asked you do you know the name of any Merck employee that was involved with the clinical trial that we've been discussing all day today.

Your response, do I know the name of any Merck employee. I can't recall the name of any -- what was the question? We're past the numbers, we're to names. I can see one of the people. Like I'm bad with names.

So when you said, I can see one of the people --

A Uh-huh.

Q -- what does that person look like?

A It's that same person.

Q The same person that you don't know if that person had a mustache or a beard; is it that same person?

A I don't recall a mustache or a beard. I mean this is sort of in the context of the funding, knowing that funding --

Q So in your Declaration, you used the terminology "initial study." And so if I can turn your attention to paragraph 19 of your Declaration.

A Paragraph 19.

Q Let me know when you're there.

A (Reviewing.)
Q Are you there?
A Yes.
Q And do you see in the second sentence you testify about, quote, initial study, end quote?
A Yes.
Q What do you mean by "initial study"?
A I'm not paid by Merck or other company to conduct our initial study. It's probably better worded as conduct our study initially. The funding came later.
Q How is it better worded? If you still have that pen, why don't you write in how it's better worded.
A (Complying.)
Q Initial it, please.
A (Complying.)
Q And so what did you change?
A "My team and I were not paid by Merck or any other company to initiate the trial."
Q Okay. In the third sentence in your

paragraph 19 you write, quote, the initial phase, end quote.

What did you mean by "initial phase"?

A Sort of the same as the prior, the initial part of the study.

Q Sort of the same, I'm not sure I understand what that means. Is it the same or is it different?

A Merck did not provide any financial support to initiate the study or trial.

Q So is it better -- is that the better way to say it or is that what you intended?

A It's probably a better way to say it, because fewer things to --

Q So can you make that correction in your Declaration, then, using the pen.

A (Complying.)

Q And please initial the correction when you're finished.

A (Complying.)

Q So can you please tell us how that sentence reads as you've corrected it?

A "In fact, Merck" -- oh, I'm sorry.

"In fact, Merck did not provide any financial support for the initiation or conduct of the trial until later."

Q Later than what?

A I told you that I can't remember the dates of the funding.

Q So when you say "later," you don't have any recollection as to what date you mean by "later"; is that fair?

A I think it's fair to say that the financial support came later.

Q Later than what?

A Sometime later.

Q So your testimony is that the support came sometime later than what?

A I don't really have a clarification. There's documentation of the funding, so I think that's what we could refer to for that "later."

Q I don't understand your reference point. Later than what? If I'm going to look for documentation, then what's the reference point for

"later"?

A Later during the conduct of the trial.

Q Later than what, though?

A Later than the initial -- initiation and through the conduct of the trial.

Q And when, in your view, is the initiation and early conduct of the trial? What time frame is that?

A I don't know when the funding came, so the point of that is just to say that the funding came later. It wasn't during the initiation or during the early conduct of the trial. And there's a paper documentation of when that is, so I don't want to guess that. That is the -- that's the intent.

Q But when you say the early conduct of the trial, what time frame are you talking about? Was that one week into the trial, was it two weeks, was it before patients were enrolled? Do you have any idea what time frame you're talking about?

A I -- no, it wasn't before patients were

enrolled.

Q So what time frame are you talking about?

A I don't -- I can't say -- it's -- I can't remember when we got funding for the trial.

Q Do you have any recollection of ever asking Merck for funding for the trial before patients were enrolled?

A Before patients were enrolled. The -- do I, specifically me, have recollection did I ask them for money? I don't have recollection of me specifically asking them for money.

Q Do you know if anyone at JHU ever asked Merck for money to fund the trial before patients were enrolled?

A I think that you would have to ask the other individuals.

Q You're saying I need to ask other individuals if you know if anyone at JHU has ever asked Merck for money to fund the trial before patients were enrolled; is that your testimony? I have to ask other individuals about what you know;

is that what you're saying?

MR. MILLER: Objection. Form.

A Do I know if -- can I confirm that they asked. I cannot confirm that they asked. I think you have to ask them specifically. I cannot recall if I asked them specifically for money.

Q I'm going to try to --

A Okay.

Q -- try my question again.

Do you know if anyone at JHU ever asked Merck for money to fund the trial before patients were enrolled?

A I do not know. I cannot recall if anyone at Hopkins asked Merck for money.

Q Are you finished with your response?

A Uh-humh.

Q So let me try my question again because you didn't answer the question.

Do you know if anyone at JHU ever asked Merck for money to fund the trial before patients were enrolled?

A Do I know. I know that there have been

conversations about that, but I cannot give you a time on when those conversations were. The timelines are starting to blur together to me.

Q Conversations about what?

A About Merck not funding the trial.

Q Do you know if anyone at JHU ever asked Merck for money to fund the trial before patients were enrolled?

A I do not know. I cannot recall specifically.

Q Do you have any general recollection whether or not anyone at JHU ever asked Merck for money to fund the trial before patients were enrolled?

A The recollection that I have, I can't tell you exactly when these conversations were, but there were conversations about Merck not supporting the study financially.

Q Let me try my question again because I want to be sure I get a clear answer to it.

Do you know if anyone at JHU ever asked Merck for money to fund the trial before patients

were enrolled?

A I cannot confirm that I was present when somebody asked. I can tell you I can have a recollection. I can't tell you when exactly conversations with individuals that money was asked for, but I cannot tell you when. It was typically, you know, in the context of funding the trial.

Q So is it your testimony today that someone at JHU asked Merck to fund the trial with money prior to patients being enrolled?

A I cannot confirm that. I cannot say one way or the other. I can't recall. I can't recall a specific time.

Q In paragraph 28 of your Declaration you talk about a, quote, initial small study, end quote. What did you mean by that terminology?

A (Reviewing.)

I meant the data we obtained from eventually our initial patients.

Q Who were your initial patients?

A Who were they? They were --

MR. MILLER: I'll caution you not to reveal any names.

THE WITNESS: Oh, yeah, of course not.

Q What was the group of initial patients that you're talking about?

A The patients that were enrolled on the study and got treatment, or the trial.

Q So when you're referring to "initial small study," are you talking about the trial that we've been discussing all day today?

A The data we obtained from our initial small study. So I'm referring to the data from the initial patients on the study.

Q What group were the initial patients on the study?

MR. MILLER: Objection. Form.

A What group were the initial patients on the study?

Q How do you define the initial patients on the study? What group is that?

A I don't have an absolute number. I can't -- the first group of patients on the study.

Q What was the first group of patients?
MR. MILLER: Objection. Form.
A What was the first group?
Q Well, Doctor, you wrote "initial small study." I'm trying to understand what do you mean by "initial"? What period is this initial period?
A I mean that initially, during the first -- I don't know about the number. Like I don't know the months. I don't know what time it was. I can tell you that in the first -- and I can't tell you how many, I just can't tell you. I can just tell you that patients responded.
Q Why did you call it the "initial small study"?
A Because, we emphasized the "small" because the way it was -- you get -- people were responding after several patients had enrolled.
Q So what is the "initial small study"?
A It's the initial -- I don't know. I should not use the word "initial." The first group of patients treated with MK-3475 on the trial.

Q And what was that first group of patients? How many were in that group?
A I wasn't referring to a specific number.
Q And when you wrote this Declaration and signed it, didn't you say that you read it carefully before you signed it?
A I did read it carefully.
Q And your choice of words that you used and terminology in this Declaration before you signed it were the choice that you wanted to use, right?
A Yeah.
Q So I'm asking you, what did you mean by "initial small study"?
A I meant the first few patients.
Q And how many is the first few patients?
A So the reason I was vague is because I don't have a number. I could go back and look at every single study record and make up a number, but it's really just the first few patients.
Q So you were intentionally being vague in your testimony here?

A Because I didn't have a number.
Q Did you ever look at the data for this initial group of patients as you were preparing your Declaration?
A Have I ever looked at the data. Have I looked at our data?
Q No, you didn't think I said that, did you? Let me try that again.
Did you ever look at the data for this initial group of patients -- here's the key -- as you were preparing your Declaration?
A Have I ever looked at the data as preparing for the Declaration.
Q Let me try this again.
Did you ever look at the data for this initial group of patients as you were preparing your Declaration?
A Did I ever look at the data -- have I ever looked at the data --
Q Do you understand my question?
A I cannot say when I looked at the data. I often look at the data, so I can't say it was

before or during. I can tell you that we saw responses in the first few patients.

Q Okay. I want you to tell me about what you wrote and what you testified about in your Declaration.

A Okay.

Q So in your Declaration you testified, quote, the data we obtained from our initial small study were, end quote. So I'm trying to find out what data was that.

A The responses, or the -- that here we say anecdotally our patients felt better. So there was different kinds of data.

Q And what was the time frame of this data that you're referencing in your Declaration?

A The time frame of the data. The data we obtained from our initial -- again, it's the early patients, what happened to the patients who were early in the study.

Q And what time frame is that, the early patients? Do you know?

A I don't know specifically. I mean it's

a -- in general, we knew early that it was very active.

Q I'm not asking generally, I'm asking specifically about what you wrote.

A Okay.

Q So for what you wrote and testified to in your Declaration, what is the time frame for this data, for these data that you obtained from what you say is, quote, an initial small study, end quote?

A I can't give you a specific number. I can say that we enrolled patients on the study, and they were treated, and data came in over time, but it was within the first few patients we became hopeful that things were working based on these things.

Q Let's turn to paragraph 34 of your Declaration. Let me know when you're there.

Are you there, Doctor?

A (Nodding head.) Yes.

Q Do you see in paragraph 34 you used the terminology "initial small study" in the last

sentence of paragraph 34? Do you see that, Doctor?

A Yes.

Q What did you mean by "initial small study" when you wrote that in paragraph 34 of your Declaration?

A That Merck later provided funding to enroll additional patients.

Q That's what you meant by the terminology "initial small study"? That means Merck later provided funding to enroll additional patients; is that your testimony?

A Yeah, they did not provide financial support for our initial small study.

Q Let me make sure this is clear.

What did you mean by the phrasing "initial small study" when you wrote that in your Declaration?

A That they did not agree to provide financial support for our initial small study.

Q So "initial small study" in your view means "they didn't agree to provide financial

support for our initial small study;" is that your testimony?

A So what I recall is --

Q I'm not asking what you recalled, Doctor, I'm asking you specifically about this terminology that you wrote in your Declaration. And you signed off on this terminology, right?

A Yes.

Q And it says "initial small study," right?

A Yes.

Q So what is this "initial small study" that you're referring to?

MR. MILLER: You should feel free to continue answering as you were before you were interrupted by counsel.

A So the initial small study, when I'm referring to all this, has to do with the funding. Merck later provided funding to enroll additional patients.

Q Okay. I can ask you questions about later, but let me try this.

What did you mean by "initial small study," do you know?

A The initial part of the study. Later they provided funding.

Q What's the initial part of the study? I'm not asking you anything about funding. I'm asking, when you say "initial small study," what did you mean?

A The earlier parts of the trial.

Q And what were the earlier parts of the trial?

A Earlier parts of the trial were -- I don't know exactly the times -- the time. You're talking about the time?

Q I'm talking about what you refer to -- you're the one who's writing "initial small study." So my question is, what did you mean by that, what time frame?

A I don't know the time frame. I can tell you that the funding came later. I can tell you that the -- I did not specifically -- I don't recall the conversations about the funding with me

and Merck.

Q I'm not asking you anything about funding. You say the initial small study relates to the early parts of the trial, right?

A Yes, but that's the context of the conversation about what -- when I was talking about the initial study.

Q So what are the early parts of the clinical trial as you understand it?

A The earlier parts of the study, of the earlier parts of enrollment.

Q And when was that? When is the earlier parts of enrollment?

A It started sometime in 2013. I don't know at what point the funding came in.

Q So what is the earlier parts of the trial?

Let me try this way.

Are you defining the earlier parts of the trial based upon your view when you believe Merck funded the trial with money?

A Can we go back to the very specific

areas we're talking about it?

Q Let's go back to this. Very clear.

A Okay.

Q The term "initial small study" that you wrote in your Declaration, what does that mean?

A The -- just initial part when we, when we started the study. Merck specifically in a contract stated that there is no funding and that the Swim Across America would fund it.

So there was sometime later, I don't know when exactly, when there was funding that came from Merck. I cannot say specifically the conversations around how that funding came. I can only say what I -- what -- I don't recall being a participant in those conversations.

Q But, Doctor, I'm not asking you anything about funding. I'm asking you about what you meant when you wrote the terminology "initial small study." What are you referring to? What is the initial small study?

A I'm referring to the initial part of the study.

Q And how do you define the initial part of the study?
A The earlier parts of the study.
Q How do you define the earlier parts of the study?
A The initiation of the study. Some period of treatment of patients on the study.
Q And when you say "some period of treatment," what period of treatment are you talking about?
A When we say -- what -- I don't have a number. I just --
Q Okay. That's fair. If you don't have a number, then you don't have a number.
Let me turn your attention to paragraph 41 of your Declaration.
In paragraph 4 [sic] you use the terminology "initial MSI clinical trial." Do you see that?
A Uh-huh.
Q What does that terminology mean, "initial MSI clinical trial"?

A Initial -- the funded -- our initial MSI clinical trial. We are referring to the trial in -- the same trial that we've been talking about.

Q So when you say "initial MSI clinical trial," you're talking about the trial that we've been discussing all day today?

A That would -- the initial MSI clinical trial is the first MSI clinical trial. I guess initial funded, our first, initial. The one that happened initially.

Q Doctor, you know what you wrote and what you intended when you wrote the words "initial MSI clinical trial" in paragraph 41 of your Declaration, right?

A Uh-humh.

Q Does the initial MSI clinical trial that you refer to in your Declaration at paragraph 41 refer to KEYNOTE-16?

A The clinical trial that I'm referring to for the initial -- where the initial patients were treated were, is KEYNOTE-16.

Q Now, Doctor, your copy of your

Declaration where you made several corrections, we're going to mark that as a new exhibit, Exhibit 1145.

(Exhibit 1145 was marked for identification and is attached to the transcript.)

Q And counsel will provide you copies after we have an opportunity to make copies of that exhibit.

Now, if I could turn your attention to paragraph 24 of your Declaration. Let me know when you have that, Doctor.

A Okay.

Q And in paragraph 24 of your Declaration, you testify, quote, even though using the PD-L1 biomarker seemed like a promising approach, Merck's clinical testing showed that it did not work, end quote.

Do you recall giving that testimony?

A Can you repeat that? You're just reading 24?

Q In paragraph 24 of your Declaration you give the testimony, quote, even though using the

PD-L1 biomarker seemed like a promising approach, Merck's clinical testing showed that it did not work, end quote.

A Yes, I see that.

Q And that's testimony that you gave in this case, right?

A I said that the PD-L1 biomarker seemed like a promising approach, yes.

Q And you're not suggesting that the PD-L1 biomarker with respect to pembrolizumab was unsuccessful, are you?

A Unsuccessful. This is specifically talking about PD-L1 selection of colon cancer patients.

Q So you're not suggesting by your testimony in paragraph 24 of your Declaration that the PD-L1 biomarker with respect to pembrolizumab was unsuccessful; is that right?

A What I am suggesting here, we're talking specifically about PD-L1 biomarker testing in colon cancer patients, to identify patients for treatment with pembrolizumab. That's what this is

referring to.

Q So you're not suggesting in paragraph 24 of your Declaration that this PD-L1 biomarker with respect to pembrolizumab was not a promising approach for cancers other than colorectal cancer, right?

A This is specifically saying that while it seemed like a promising approach, PD-L1 is not a -- was not promising for patients with colon cancer.

Q Okay. And so would you agree that PD-L1 with respect to pembrolizumab was a promising approach for other forms of cancer?

A Are we talking about back then?

Q Talking about right now.

A Right now is PD-L1 a promising approach or a proven approach?

Q Let's take it in steps.

A Okay.

Q Would you agree today that the PD-L1 biomarker with respect to pembrolizumab has been a proven approach for multiple forms of cancer?

A I actually cannot answer that question without reviewing the literature today. There's been lots of changes.

Q Are you familiar with the package insert for pembrolizumab?

A Am I familiar with the package insert. I am -- their -- I'm familiar with package insert, their -- yes, I'm familiar with it.

Q Okay. And don't you understand from the package insert that the PD-L1 biomarker for pembrolizumab has been proven with respect to non-small cell lung cancer?

A I'd have to review the package insert, to be honest with you. It's been a while that I looked at lung cancer data.

Q And you've been a clinical trial investigator for pembrolizumab; is that fair?

A That's fair. But I treat GI cancers.

Q Okay. I didn't ask you whether or not you -- what type of the cancer you treat.

Sitting here today, do you know whether or not the PD-L1 biomarker has been shown to be a

proven approach for treating non-small cell lung cancer?

A I cannot recall the specifics of the data. The data has evolved a lot. I can tell you as a GI cancer oncologist, I have not used PD-L1 for selection of patients for pembrolizumab.

Q And you're not taking the position in this case that the PD-L1 biomarker has never been a promising approach for pembrolizumab treatment of various cancer patients, right?

A I'm not -- it depends on what you mean by "promising." But again, the data is mixed and always evolving.

Q I mean promising by the same way you use it in your Declaration.

Let me try that again.

You're not taking the position in this case that the PD-L1 biomarker has never been a promising approach for pembrolizumab treatment of various cancer patients, right?

A I am not saying that PD-L1 has not -- is -- okay. I am not saying that the PD-L1

biomarker has never been promising. That's not what I'm saying.

Q And you're not saying that the PD-L1 biomarker with respect to pembrolizumab has never been promising, right?

A I am not saying with respect to pembrolizumab that the PD-L1 as a biomarker has never been promising.

Q Okay. Let me let you take a look at an exhibit. This is, I believe, a new exhibit, 1134.

(Exhibit 1134 was marked for identification and is attached to the transcript.)

Q Let me know if you recognize it, Doctor.

A This is -- Exhibit 1134 -- on top of it is "Highlights do not include all information needed to use Keytruda® effectively."

This is a package label, or insert for Keytruda®.

Q Keytruda® is pembrolizumab, right?

A Correct.

Q So you recognize this as the package insert for pembrolizumab; is that right?

MR. MILLER: Objection. Form.

A This looks like a package insert for pembrolizumab.

Q Right.

And do you see here in terms of the Indication and Usage section of the package insert it shows that with respect to pembrolizumab, that the PD-L1 biomarker has been shown to be a proven approach for treating various forms of cancer, right?

A (Reviewing.)

Q Do you understand the question?

A Yeah. I'm just scanning all these different things to see, and focusing on the PD-L1 -- when I find PD-L1 on the document.

I mean just quickly looking at this where I can spot PD-L1, PD-L1, you can use pembrolizumab as a single agent for the first line treatment of patients with non-small cell lung cancer expressing PD-L1 as determined by an FDA-approved test.

It's under non-small cell lung cancer --

one, two, three, four, five -- six different bullets for non-small cell lung cancer, and the other five bullets does not require PD-L1 testing.

Q And of the six bullets that you just mentioned under non-small cell lung cancer, you agree with me that two of those bullets reflect --

A I'm sorry, there might be --

Q -- two different indications --

A I'm sorry.

Q And of the six bullets that you just mentioned under non-small cell lung cancer, you would agree with me that two of those bullets reflect using pembrolizumab in situations where the PD-L1 biomarker is expressed, right?

A Single agent for the first line treatment of the patients with --

MR. MILLER: Don't read out loud.

THE WITNESS: Sorry, sorry.

Q Doctor, are you having difficulty understanding the package insert?

A It's just a lot of information. I just want to be careful reading it.

Q Okay.

A I'm trying to see if these are actually two different patient populations because you asked me of the two, I see PD-L1 of the two, so I'm just carefully trying to understand what the patient population is.

Q Let me ask a different question, then.

Under non-small cell lung cancer, for pembrolizumab, you do understand from the package insert that there's six different indications that pembrolizumab has, right?

A Yes. I'm trying to see the difference between the third and the fourth.

(Reviewing.)

Yes. So it looks like you can use PD-L -- you can use pembrolizumab in a non-small cell lung cancer by itself if you have a tumor proportion score of greater than or equal to 1.

Q You would agree that under the non-small cell lung cancer heading, for the pembrolizumab indications, indications 3 and 4 include indications involving expression of the PD-L1

biomarker, right?

A Yes, I would agree that in non-small cell lung cancer you can use pembrolizumab in certain situations that are very specific if the PD-L1 TPS is greater than or equal to one percent.

Q And would you agree under the heading Head and Neck Squamous Cell Cancer, the second bullet shows that the PD-L1 biomarker has been proven for treatment of that form of cancer with pembrolizumab, right?

A I can say it's been approved under -- on this package insert for head and neck cancer as a single agent for the first line treatment of patients with metastatic or with unresectable recurrent HNSCC whose tumors express PD-L1 CPS greater than or equal to 1.

Q Would you agree, Doctor, that the PD-L1 biomarker approach with respect to pembrolizumab has resulted in several forms of approvals for treating cancer?

MR. MILLER: Objection. Form.

A I would say that PD-L1 can be used to

select patients for single-agent therapy in a subset of patients with cancer. It -- typically. But they often also can be given with chemo and you wouldn't need PD-L1.

So I think there is still, there's still a lot of data that sometimes changes the indication. But yes, you can use PD-L1 in a few of these bullet points on this page of, I don't know how many different indications. Actually, I don't even -- it's actually two pages of indication -- no, wait, one and a half pages of indications. So there are places where you can use PD-L1.

Q Let's try my question. My question is different than I think what you're responding to.

So my question is, would you agree, Doctor, that the PD-L1 biomarker approach with respect to pembrolizumab has resulted in several forms of FDA approvals for treating various cancers?

A I would agree that PD-L1 biomarker has resulted in several approvals to use pembrolizumab

in different types of cancers. But in a vast majority, it's not used. In a vast majority of these indications it is not used.

Q And how many times does the package insert for Keytruda® reflect that the PD-L1 biomarker approach with respect to pembrolizumab has resulted in several FDA approvals of treating various forms of cancers?

A You want me to count on these?

Q Yes, please.

A Okay.

Q And we can take them in turns. We can start with non-small cell lung cancer. How many FDA approvals using the biomarker approach with respect to that form of cancer?

(A discussion was held off the record.)

MR. RATLIFF: We're not done.

MR. MILLER: Yeah, we're done.

MR. RATLIFF: We're not done.

MR. MILLER: We can go on the record. I'll put it on the record. We're done.

MR. RATLIFF: I didn't pass the witness.

MR. MILLER: You're done. Your seven hours are over. Take a look at the numbers. If you can make an argument that we are not under -- not over seven, I'll happily listen to it. Otherwise, we're done.

MR. RATLIFF: I don't --

MR. MILLER: Preston, we're done.

MR. RATLIFF: I don't need to make an argument.

MR. MILLER: Okay.

MR. RATLIFF: Counsel --

MR. MILLER: We can go back on the record.

MR. RATLIFF: She's already on -- we're already on the record.

BY MR. RATLIFF:

Q So, Doctor, you were responding to my question.

MR. MILLER: No, she wasn't.

For the record, the Court Reporter had calculated the time on the record, and I've identified an error in the calculation. At this

point we're well over the seven-hour limit and this deposition is concluded.

MR. RATLIFF: The deposition has not concluded.

MR. MILLER: You can go talk to the Board about it.

MR. RATLIFF: If you're pulling the witness, then you do that on your own prerogative, and you do that at the risk of whatever may come from it.

MR. MILLER: Okay. No worries. We're done.

MR. RATLIFF: So --

MR. MILLER: You can go. You can leave the room.

MR. RATLIFF: Can you finish answering my question?

MR. MILLER: You can leave the room.

I tried to give you leeway, Preston, and if you want to act like that, we're going to be done.

So, Doctor, you can leave.

MR. RATLIFF: Counsel --

MR. MILLER: If you want to look at the tally --

MR. RATLIFF: Counsel --

MR. MILLER: I'm just going to read it on the record.

MR. RATLIFF: Counsel, you had the opportunity to check the timing earlier when Madam Court Reporter announced timing for the deposition and said that both counsel are free to check the timing, to check the math. It was your prerogative not to do that. I have some more questions for the doctor, and if you're going to pull the witness, then that's your prerogative, and what may come, may come.

MR. MILLER: Okay.

MR. RATLIFF: But I'd like to ask the questions.

BY MR. RATLIFF:

Q And so, Doctor --

MR. MILLER: Well, no, we are done. It is my prerogative, and we are concluded.

Doctor, you can leave.

MR. RATLIFF: All right. So just note for the record --

THE COURT REPORTER: Before we go, I just want to make sure we have -- she's put her hands on exhibits, so I want to make sure, are we attaching, is she taking? I want that clear.

MR. RATLIFF: She's not taking the exhibits. We --

THE COURT REPORTER: Not "she," the doctor.

MR. RATLIFF: The doctor is not taking the exhibits. I'm going to mark that scribble as a new exhibit.

THE WITNESS: I don't -- can't tell what I made.

MR. RATLIFF: And we'll make that scribble new Exhibit 1146.

(Exhibit 1146 was marked for identification and is attached to the transcript.)

MR. RATLIFF: And so we'll make copies of that, and note for the record that the new

exhibit was being prepared as the doctor was answering my last question.

And, Doctor, are you going to follow your counsel's advice and just leave, or are you willing to respond to the questions that I have for you?

THE WITNESS: I'm going to follow my counsel's advice.

MR. RATLIFF: All right. Counsel, as I stated before, you are pulling the witness, because I have not passed the witness, over our objection.

MR. MILLER: Understood. And for the record, the Court Reporter -- I proceeded with the deposition so as not to be disruptive. The Court Reporter took a break. I asked to see her records of the timing. There was an entry which is identified as No. 3, which indicated a start time of 1:49 and a stop time of 3:14.

The Court Reporter had calculated that to be 1 hour and 3 minutes. It is actually 1 hour and 25 minutes, which puts us well over the seven

hours that you are allotted for this deposition, so the deposition is concluded.

MR. RATLIFF: And for the record, counsel, you had the opportunity to check the math earlier, and you did not.

I only have a few more questions for you, Doctor.

MR. MILLER: We're done.

MR. RATLIFF: But if counsel is going to pull the witness, then that's what's going to happen.

MR. MILLER: Counsel is pulling the witness because we are well over seven hours.

Thank you.

MR. RATLIFF: Well, it's unfortunate --

MR. MILLER: Have a good flight.

MR. RATLIFF: -- how this ended, and I'd like to thank Madam Court Reporter for her services today.

(Off the record at 6:23 p.m.)

ACKNOWLEDGMENT OF DEPONENT

I, Dung Thi Le, M.D., do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me, and any corrections appear on the attached Errata sheet signed by me.

_____ _____

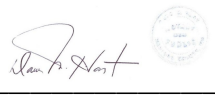
(DATE) (SIGNATURE)

CERTIFICATE OF SHORTHAND REPORTER

I, Dawn M. Hart, the officer before whom the foregoing deposition was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that said testimony was taken by me stenographically and thereafter reduced to typewriting under my direction; that reading and signing was not discussed; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 13th day of January, 2025.

My commission expires:
January 2, 2029



_____

NOTARY IN AND FOR THE
STATE OF MARYLAND