1 UNITED STATES PATENT AND TRADEMARK OFFICE

2 _____

3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4 _____

5 Merck Sharp & Dohme LLC,

6 Petitioner

7 v.

8 The Johns Hopkins University,

9 Patent Owner

10 _____

11 IPR2024-00240

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

13 _____

14 Deposition of DUNG THI LE, M.D.

15 Thursday, January 9, 2025

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

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6 1812 Ashland Avenue, 3rd Floor
7 Baltimore, Maryland 21205
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20 Pursuant to Notice, before Dawn M. Hart,
21 RPR/RMR and Notary Public in and for the State of
22 Maryland.

1 A P P E A R A N C E S
2 ON BEHALF OF THE PETITIONER:
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17
18 ALSO PRESENT: Karen Moreira, Esquire, Merck
19
20
21
22

1 C O N T E N T S

2 EXAMINATION OF DUNG THI LE, M.D. PAGE
3 By Mr. Ratliff 6

4 E X H I B I T S

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2 (Exhibits retained by Mr. Ratliff.)

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1 P R O C E E D I N G S
2 DUNG THI LE, M.D.
3 being first duly sworn or affirmed to
4 testify to the truth, the whole truth, and nothing
5 but the truth, was examined and testified as
6 follows:
7 EXAMINATION BY COUNSEL FOR PETITIONER
8 BY MR. RATLIFF:
9 Q Good morning.
10 Would you please state your full name
11 for the record.
12 A Dung Thi Le.
13 Q Please state your residence address.
14 A 12 Laurel Circle, Lutherville, Maryland,
15 21093.
16 Q How are you feeling today, Doctor?
17 A I am feeling okay.
18 Q And you understand that you're here
19 today to give testimony under oath, right?
20 A Yes.
21 Q Is there any reason you cannot testify
22 truthfully today?

1 A No.
2 Q You're still employed by The Johns
3 Hopkins University; is that right?
4 A I am employed by Johns Hopkins
5 University.
6 Q And you understand that The Johns
7 Hopkins University owns the '393 patent that is
8 the subject of the U.S. Patent and Trademark
9 proceeding in this case, right?
10 A Yes.
11 Q And you refer to that '393 patent in
12 your October 4, 2024, Declaration, right?
13 A Is it possible to see the Declaration?
14 Q Sure.
15 (Exhibit 2130 was marked for
16 identification and was retained by Mr. Ratliff.)
17 Q So let me hand you a document that's
18 been marked as Exhibit 2130.
19 A (Reviewing.)
20 Q Doctor, do you recognize this as a copy
21 of your October 4, 2024, Declaration in this
22 proceeding?

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

1 read it yesterday?
2 A Yes.
3 Q And in what way did it look different?
4 A I just remember reading it for review,
5 and I just don't remember reading that paragraph
6 yesterday, but as far as I know, I mean I
7 recognize these different paragraphs.
8 Q Okay. Was there anything else in your
9 Declaration that struck you as looking different
10 from your read yesterday?
11 A Not obviously.
12 Q And when you read your Declaration
13 yesterday, did you understand it?
14 A Yes, I was just reviewing it in
15 preparation.
16 Q And you weren't confused by anything
17 that you said in your Declaration when you read
18 it, right?
19 A No.
20 Q And you weren't confused by anything you
21 read in your Declaration when you signed it,
22 right?

1 A No.
2 Q Now, you can turn your attention to
3 paragraph 4 of your Declaration. This is at page
4 3.
5 A (Nodding head.)
6 Q Do you see there in paragraph 4 you
7 refer to the '393 patent?
8 A Yes.
9 Q And you're one of the seven named
10 inventors of that '393 patent, right?
11 A I am one of the named inventors.
12 Q And you're one of the seven named
13 inventors of the '393 patent, right?
14 A I am one of the inventors.
15 Q I understand that you're one of them.
16 Do you understand that there are seven
17 inventors listed on that patent?
18 A I understand that there are other
19 inventors listed on the patent.
20 Q So you don't know how many inventors are
21 listed on the patent?
22 A I don't recall how many inventors are

1 listed on the patent.
2 Q Well, let's take a look.
3 (Exhibit 1001 was marked for
4 identification and was retained by Mr. Ratliff.)
5 Q Let me hand you a document that's been
6 marked as Exhibit 1001.
7 Let me know if you recognize it, Doctor.
8 A (Reviewing.)
9 Q Do you recognize the '393 patent,
10 Doctor?
11 A I can't say that I -- I mean I haven't
12 had a chance to look at every single page, but ...
13 Q Do you need to look at every single page
14 of the '393 patent to recognize it as one of your
15 patents?
16 A I cannot remember if I've seen this
17 document. I can't recall.
18 Q Okay. But do you -- you did refer to it
19 in your Declaration, right?
20 A Yes.
21 Q Turning your attention to the first page
22 of the document, you see that you're one of seven

1 named inventors for the '393 patent?
2 A I see that, yes.
3 Q And it was JHU that applied for the '393
4 patent, right?
5 MR. MILLER: Objection. Form. Legal.
6 A It says here applicant, The Johns
7 Hopkins University.
8 Q Okay. I understand that, but is it your
9 understanding that it was JHU that applied for the
10 '393 patent?
11 MR. MILLER: Same objections.
12 A Reading this document, it says the
13 applicant is The Johns Hopkins University.
14 Q Do you understand that JHU applied for
15 the '393 patent?
16 MR. MILLER: Objection. Form.
17 Foundation. Leading.
18 MR. RATLIFF: Counsel, you can't get
19 into speaking objections. You can object to form.
20 A Can you repeat the question?
21 Q Sure.
22 Do you understand that it was JHU that

1 applied for the '393 patent?
2 A I see here that the applicant is
3 Johns Hopkins University.
4 Q I'm asking you a different question.
5 To your knowledge, do you understand
6 that JHU applied for the '393 patent?
7 MR. MILLER: Objection. Form.
8 A I guess I don't understand the question,
9 because it says here that the applicant is
10 The Johns Hopkins University.
11 Q Okay. Did you apply for the '393
12 patent?
13 A I personally did not apply for the
14 patent.
15 Q Okay. Do you understand that JHU
16 submitted a provisional application on
17 November 13, 2014?
18 A I do not recall any of the details.
19 Q And I'm not asking you if you recall any
20 of the details, I'm just asking you, do you
21 understand that JHU submitted a provisional
22 application on November 13, 2014?

1 A I guess I don't know how to answer these
2 questions. I don't recall.
3 Q You don't recall what?
4 A I don't recall an application on this
5 date that you are mentioning.
6 Q Okay. So you don't recall ever seeing a
7 provisional application dated November 13, 2014?
8 MR. MILLER: Objection. Form.
9 A I can't recall the date of any
10 applications that I saw.
11 Q Do you recall ever seeing a provisional
12 patent application concerning your alleged
13 invention?
14 MR. MILLER: Objection. Form.
15 A I think there's some terms I don't
16 understand. I don't know what "provisional" means
17 so I can't under oath say that I can recall.
18 What was your question again?
19 Q Sure.
20 My question was, do you know whether or
21 not JHU submitted a provisional patent application
22 concerning your alleged invention?

1 A So I guess my answer is the same; I
2 can't really say in terms of what you're asking me
3 specifically.
4 Q Because you don't know what a
5 provisional patent application is; is that right?
6 A I don't know the terms "provisional,"
7 and I don't know when things were submitted.
8 Q Okay.
9 (Exhibit 1030 was marked for
10 identification and was retained by Mr. Ratliff.)
11 Q I'm going to hand you a document that's
12 been marked as Exhibit 1030. Can you take a look
13 at Exhibit 1030 and let me know if you recognize
14 it, Doctor.
15 A (Reviewing.)
16 Am I allowed to ask questions?
17 Q Sure.
18 A What is this document?
19 Q Well, first, do you recognize the
20 document?
21 A (Reviewing.)
22 Q If you don't recognize it, you can just

1 tell me that.
2 A (Reviewing.)
3 If I've seen it, it's been a while, so I
4 don't recognize the document.
5 Q Okay. And do you see on the first page
6 of the document there's a list of named inventors?
7 A Yes.
8 Q And your name is on that list, right?
9 A Yes.
10 Q And you see that there are five named
11 inventors, right?
12 A Yes.
13 Q And you appreciate on the '393 patent
14 there are seven named inventors, right?
15 A This is the '393 patent (indicating)?
16 Q I see you pointing to Exhibit 1001.
17 A Yes.
18 Q I think that's right.
19 So in Exhibit 1001, there's seven named
20 inventors, right?
21 A I see seven inventors on the exhibit you
22 mentioned.

1 Q Right.
2 And do you know why on Exhibit 1030 two
3 inventors -- two named inventors, Dr. Pardoll and
4 Dr. Topalian, are not included?
5 A I do not.
6 Q Do you know what Dr. Pardoll and
7 Dr. Topalian's contributions were with respect to
8 the alleged invention in this case?
9 MR. MILLER: Objection. Form.
10 A I think they contributed ideas.
11 Q What ideas did they contribute?
12 A Ideas related to an individual who
13 responded to therapy.
14 Q And what specifically were those ideas?
15 A That there is something unique about a
16 patient that responds to therapy.
17 Q And is it your testimony that both
18 Dr. Pardoll and Dr. Topalian had that same
19 contribution?
20 A I can't give specifics. I think it
21 would be best to ask them.
22 Q Why can't you give specifics?

1 A I wasn't there in the room.
2 Q So is it fair to say you don't know
3 Dr. Pardoll's or Dr. Topalian's contribution to
4 the alleged invention of the '393 patent?
5 MR. MILLER: Objection. Form.
6 A Can you repeat the question?
7 Q Is it fair to say that sitting here
8 today you do not know Dr. Pardoll's contribution
9 to the alleged invention of the '393 patent?
10 A I don't understand the "contribution"
11 part. What constitutes contribution. Can you
12 rephrase that part or explain that part?
13 Q Do you have any opinion sitting here
14 today a reason why Dr. Pardoll should be a named
15 inventor of the '393 patent?
16 MR. MILLER: Objection. Form. Legal.
17 A Because Dr. Pardoll contributed to the
18 formulation of the hypothesis.
19 Q And do you have any reason sitting here
20 today why you think Dr. Topalian should be a named
21 inventor of the '393 patent?
22 A For the same reason.

1 Q And did they come up with that same
2 contribution at the same time?
3 A I don't know specifically when the
4 individuals came up with the contribution in their
5 heads.
6 Q When did the individuals tell you about
7 this contribution?
8 A The individuals did not tell me
9 specifically.
10 Q Okay. So why do you have the belief
11 that Dr. Pardoll and Dr. Topalian did work that
12 makes them worthy of being a named inventor of the
13 '393 patent?
14 MR. MILLER: Objection. Form. Legal.
15 A Because they contributed to the
16 hypothesis.
17 Q And sitting here today you don't know
18 when that contribution -- strike that.
19 Sitting here today you don't know when
20 that alleged contribution happened, right?
21 A A date?
22 Q Yes, I'm asking for a date. Sitting

1 here today you don't know the date when that
2 alleged contribution happened, right?
3 A I can't tell you right this minute the
4 date.
5 Q Okay. And looking -- turning your
6 attention back to Exhibit 1030 --
7 A I'm sorry, which one is that one?
8 Q It's the one that's labeled 1030 at the
9 bottom.
10 A Oh, got it.
11 MR. MILLER: In the bottom corner.
12 Q Do you have that?
13 So turning your attention to Exhibit
14 1030, you understand that Dr. Topalian and
15 Dr. Pardoll are not listed as named inventors on
16 this document, right?
17 A I see that their names are not listed
18 under the inventors.
19 Q Right.
20 And do you have any reason sitting here
21 today, or knowledge, why they're not listed as
22 named inventors?

1 A No.
2 Q And do you see that the date of this
3 document at the top refers to a November 13, 2014,
4 filing date?
5 A Yes.
6 Q And do you have any recollection that a
7 provisional application for your alleged invention
8 was being filed on November 13, 2014?
9 A Again, I think I answered that question.
10 Q Let me try it again because I don't
11 think I got an answer.
12 Do you have any recollection sitting
13 here today of any provisional application being
14 filed concerning your alleged invention?
15 A I do not have a recollection of dates of
16 an application. I am still not a hundred percent
17 sure when you say "provisional," if it's the
18 application, if it's the same, because I don't
19 understand what a provisional application is.
20 Q Do you have any recollection of this
21 document that you're looking at, Exhibit 1030,
22 ever being filed with the Patent Office?

1 A Have -- do I have a recollection of this
2 exact document and every single page of this
3 document. I don't -- I can't remember.
4 Q Okay. Can you turn your attention to
5 page 14 of Exhibit 1030. And I'm referring to the
6 page numbers at the bottom where it says page 14
7 of 37. Let me know when you have it.
8 A Page 14 of 37.
9 Q Do you have it?
10 A Yes, I'm looking at page 14 of 37.
11 Q Can you let me know if you recognize the
12 text that's included in Exhibit 1030 on page 14
13 through page 18 of the exhibit?
14 A (Reviewing.)
15 I can't recall.
16 Q I want to make sure I understand your
17 response.
18 Do you recognize any of the text that's
19 found on page 14 through pages -- up to page 18 of
20 Exhibit 1030?
21 MR. MILLER: Objection. Form.
22 A I can't recall specifically. It's been

1 a long time.
2 Q Do you have any general recollection of
3 the text found on pages 14 through 18?
4 MR. MILLER: Objection. Form.
5 A I can't recall.
6 Q Did you contribute to the drafting of
7 any of the text found on pages 14 through 18 of
8 Exhibit 1030?
9 A (Reviewing.)
10 I can't recall.
11 Q You can't recall if you have a
12 recollection. I'm asking you right now, do you
13 have any recollection of whether you contributed
14 to the preparation of the text found on pages 14
15 through 18 of Exhibit 1030.
16 A I cannot recall.
17 Q Do you know who contributed to the text
18 that's shown on pages 14 through 18 of Exhibit
19 1030?
20 A I don't remember. I can't recall, or I
21 don't know.
22 Q Okay. Now, is it your understanding

1 that by November 13, 2014, you had found that
2 immune checkpoint inhibitors worked best in tumors
3 with high mutation burdens?
4 A Can you repeat the question?
5 Q Is it your understanding that by
6 November 13, 2014, you had found that immune
7 checkpoint inhibitors worked best in tumors with
8 high mutation burdens?
9 A I don't recall dates -- the dates.
10 Q Did you ever find that immune checkpoint
11 inhibitors work best in tumors with high mutation
12 burdens?
13 A Did I personally?
14 Q Did you personally find that immune
15 checkpoint inhibitors worked best in tumors with
16 high mutation burdens?
17 A The science is typically a team, and I
18 think the team at Hopkins did find that.
19 Q When you say "the team at Hopkins" --
20 A Oh, actually, can you repeat the
21 question? What did you actually ask?
22 Q Try my question again.

1 Different question.
2 Did you ever find that immune checkpoint
3 inhibitors worked in tumors with high mutation
4 burdens? Did you ever find that?
5 A Did I ever find that? No.
6 Q By November 13, 2014, had you developed
7 a treatment for cancer patients that displayed the
8 microsatellite instability phenotype?
9 A Not by 2014. It's been a long time.
10 The dates are throwing me off a little bit.
11 Q That's okay.
12 Earlier in one of your responses you
13 said something about the JHU team. Who are you
14 referring to?
15 A Well, it's a -- various people, but as
16 you know, science is not -- or trials are not done
17 by an individual, and there are people listed on
18 the invention (indicating).
19 Q What do you mean by "people listed on
20 the invention"? I saw you pointing to a document.
21 Are you talking about the '393 patent?
22 A That's what I was pointing to.

1 Q And is that who you meant when you refer
2 to the JHU team, the seven named inventors of the
3 '393 patent?
4 A Can we go back to the original question?
5 What am I answering again?
6 Q So let me try this.
7 By November 13, 2014, had Dr. Luis Diaz
8 developed a treatment for cancer patients that
9 display the microsatellite instability phenotype?
10 A Had we developed the treatment by 2014.
11 What do you mean by "developed a
12 treatment"?
13 Q If you don't understand the question,
14 you don't understand the question. Let me try it
15 again.
16 I think you've already answered with
17 respect to yourself. By November 13, 2014, had
18 Dr. Luis Diaz developed a treatment for cancer
19 patients that displayed the microsatellite
20 instability phenotype?
21 MR. MILLER: Objection. Form.
22 A What do you mean by "developed"?

1 Q Same thing I meant when you answered my
2 question before.
3 A What did you mean when you -- I just
4 need clarification to make sure I'm understanding
5 what you mean by "developed."
6 Q If you don't know, you don't know. Let
7 me ask the question. A different question.
8 A I just need you -- a clarification of
9 what you mean by "developed" so I could better
10 answer the question.
11 Q Just means you don't know, that you
12 don't have an answer.
13 So by November 13, 2014, had
14 Dr. Bert Vogelstein developed a treatment for
15 cancer patients that displayed the microsatellite
16 instability phenotype?
17 MR. MILLER: Objection. Form.
18 A I think for clarity I need to understand
19 what "developed" means.
20 Q So you just don't understand my
21 question?
22 A I think there's a lot of nuance in the

1 word "development," so I just need to understand
2 what you mean by "developed."
3 Q Have you ever used the word "developed"
4 before?
5 A I have used the word "developed" before.
6 Q And have you ever used the word
7 "developed" in the context of communicating with
8 the U.S. Patent Office?
9 MR. MILLER: Objection. Form.
10 A I don't recall specifically.
11 Q Okay. By November 13, 2014, had
12 Dr. Kenneth Kinzler developed a treatment for
13 cancer patients that displayed the microsatellite
14 instability phenotype?
15 MR. MILLER: Objection. Form.
16 A I mean I see what we're doing, but I
17 still go back to the word "developed." If you
18 could define that, I could try to answer it.
19 Q It should be defined in a way that you
20 understand the word "developed."
21 A But I need to understand what you're
22 asking, not how I interpret it. I don't

1 understand what you mean by "developed."
2 Q That's fine. If you don't have a
3 response and you don't understand my question,
4 that's fine.
5 So by November 13, 2014, had Dr. Diaz,
6 Dr. Vogelstein, Dr. Kinzler, Dr. Papadopoulos,
7 ever found that immune checkpoint inhibitors work
8 best in tumors with high mutation burdens?
9 A Had they found. Can you repeat the
10 question again?
11 Q Sure.
12 By November 13, 2014, had Dr. Diaz,
13 Dr. Vogelstein, Dr. Kinzler, or Dr. Papadopoulos
14 found that immune checkpoint inhibitors work best
15 in tumors with high mutation burdens?
16 MR. MILLER: Objection. Form.
17 A No -- I feel like you're asking
18 different questions that -- I need to focus on
19 what you're actually asking, so no to the high
20 tumor mutation burden.
21 Q And by November 13, 2014, had
22 Dr. Papadopoulos developed a treatment for cancer

1 patients that displayed the microsatellite
2 instability phenotype?
3 MR. MILLER: Objection. Form.
4 A It goes back to the same question. It
5 depends -- I don't know what you mean by
6 "developed."
7 Q Got it.
8 (Exhibit 1043 was marked for
9 identification and was retained by Mr. Ratliff.)
10 Q Doctor, I'd like to hand you a document
11 which has been marked as Exhibit 1043. Let me
12 know if you recognize it.
13 A (Reviewing.)
14 I can't say that I specifically
15 recognize this document.
16 Q Do you have any general recollection of
17 Exhibit 1043?
18 A I can't recall that I have specifically
19 seen this.
20 Q Did you contribute to any of the text
21 that's found in Exhibit 1043 from pages 1 through
22 page 41 of the exhibit?

1 A I can't say specifically that I
2 contributed to the text.
3 Q Do you know if you contributed to any of
4 the text that's found on pages 1 through 41 of
5 Exhibit 1043?
6 A I can't say specifically. There's a lot
7 of content in here.
8 Q Okay. But do you know if you
9 contributed to any of the text that's found on
10 pages 1 through 41 of Exhibit 1043?
11 A I don't remember.
12 Q Okay. Do you know who may have
13 contributed to the preparation of the text that's
14 found on pages 1 through 41 of Exhibit 1043?
15 A I don't -- I don't remember.
16 Q Okay. And if I can turn your attention
17 to page 55 of Exhibit 1043. Let me know when you
18 have it.
19 A Page 55 of 57.
20 Q You have it?
21 A Yes.
22 Q And I can represent to you that at page

1 55 of Exhibit 1043, this is the beginning of a
2 filing receipt from the United States Patent
3 Office.
4 Do you see on the first page that it
5 refers to a filing date of July 10, 2015?
6 A I see the date on top of July 10, 2015.
7 Q Do you see on the document that it
8 refers to the same list of five named inventors
9 that we saw on Exhibit 1030?
10 A 1030, the inventors, yes.
11 MR. MILLER: And, Doctor, I know you're
12 coming down with a cold. If you need to take a
13 break, just let us know and we can take a break.
14 Q And then the list of named inventors
15 that we see on page 55 of Exhibit 1043, it does
16 not conclude named inventors Dr. Pardoll and
17 Dr. Topalian, right?
18 A I'm sorry, you're asking me if page 55
19 has Dr. Pardoll and Topalian on it? It does not.
20 Q And do you know why Dr. Pardoll and
21 Dr. Topalian are not listed as named inventors on
22 this document that refers to a filing date of

1 July 10, 2015?
2 A I do not.
3 Q Can I turn your attention back to
4 Exhibit 1030. Let me know when you have it.
5 A Yes.
6 Q And Exhibit 1030, this is the document
7 that reflects a filing date of November 13, 2014,
8 right?
9 A Yes.
10 Q And by this time, November 13, 2014, you
11 did not expect to benefit directly from any future
12 sales of pembrolizumab, right?
13 A Not that I recall.
14 Q And you did not expect to benefit
15 directly from any future sales of pembrolizumab
16 because JHU is an academic research institution
17 that does not sell pharmaceuticals, right?
18 A Can you repeat that question?
19 Q You did not expect to benefit directly
20 from any future sales of pembrolizumab because JHU
21 is an academic research institution that does not
22 sell pharmaceuticals, right?

1 A I do not recall.
2 Q Well, didn't you testify in your
3 Declaration that you did not expect to benefit
4 directly from any future sales of pembrolizumab
5 because JHU is an academic research institution
6 that does not sell pharmaceuticals?
7 A Can you repeat the question?
8 Q Didn't you testify in your Declaration
9 that you did not expect to benefit directly from
10 any future sales of pembrolizumab because JHU is
11 an academic research institution that does not
12 sell pharmaceuticals? That was your testimony,
13 right?
14 A (Reviewing.)
15 MR. MILLER: Objection.
16 Mischaracterizes the document.
17 A Can you point it out to me in the
18 document?
19 Q Well, sitting here today, do you have
20 any recollection of testifying in your Declaration
21 that you did not expect to benefit directly from
22 any future sales of pembrolizumab because JHU is

1 an academic research institution that does not
2 sell pharmaceuticals?
3 MR. MILLER: Objection.
4 Mischaracterizes the document.
5 MR. RATLIFF: Counsel, the speaking
6 objections are improper. We can direct you to the
7 Practice Trial Guide at page 128.
8 MR. MILLER: I'd just ask you to quote
9 the document accurately.
10 MR. RATLIFF: Counsel, you can't do
11 this.
12 BY MR. RATLIFF:
13 Q Doctor, do you understand my question?
14 A Which -- where are you referring to in
15 this Declaration?
16 Q I'm not referring to the Declaration at
17 all. I'm asking you right now, sitting here
18 today, do you recall giving testimony in your
19 Declaration stating that you did not expect to
20 benefit directly from any future sales of
21 pembrolizumab because JHU is an academic research
22 institution that does not sell pharmaceuticals?

1 MR. MILLER: Objection. Form.
2 A (Reviewing.)
3 Q Do you understand my question, Doctor?
4 A I need a minute.
5 Q Sure.
6 A (Reviewing.)
7 Paragraph 19, is that what you're
8 referring to?
9 Q Let me try my question again.
10 I'm asking you, sitting here today, do
11 you recall testifying in your Declaration that you
12 did not expect to benefit directly from any future
13 sales of pembrolizumab because JHU is an academic
14 research institution that does not sell
15 pharmaceuticals?
16 MR. MILLER: Objection. Form.
17 A It says in this document, we also did
18 not expect to benefit directly from any future
19 sales of pembrolizumab because JHU is an academic
20 research institution that does not sell
21 pharmaceutical products.
22 Q And by "the document," you're referring

1 to your -- the testimony in your Declaration?
2 A Yes.
3 Q And do you recall making that statement,
4 that you did not expect to benefit directly from
5 any future sales of pembrolizumab because JHU is
6 an academic research institution that does not
7 sell pharmaceutical products?
8 A I don't recall specifically.
9 Q Okay. And just turning your attention
10 to paragraph 19, that you're looking at, and when
11 you write, "We also did not expect to benefit
12 directly from any future sales of pembrolizumab
13 because JHU is an academic research institution
14 that does not sell pharmaceuticals products," who
15 was the "we" that you're referring to?
16 A I -- I guess I specifically probably
17 shouldn't speak for other people.
18 Q Okay. I'm not sure what that means.
19 Let me try to get an answer to my question.
20 When you testified in your Declaration
21 in paragraph 19, quote, we also did not expect to
22 benefit directly from any future sales of

1 pembrolizumab because JHU is an academic research
2 institution that does not sell pharmaceutical
3 products, end quote, who is the "we" that you were
4 referring to?
5 A "We" -- I probably should have said I
6 because I should not speak for other people.
7 Q Okay. So in your copy of your
8 Declaration, can you cross out "we" and put "I"?
9 I think you should actually cross out "we also"
10 and just say "I did not," right? That would make
11 your testimony correct?
12 A (Complying.)
13 Q Would that make your testimony correct?
14 A That I did not expect, yes.
15 Q Okay. Sorry, Doctor, before that, can
16 you just sign your name -- sign your initials,
17 just so we know that the correction was made by
18 you?
19 A I'm kind of sick. Do you want the pen
20 back?
21 Q Sure.
22 A I have alcohol.

1 Q Okay, you can keep the pen.
2 A Okay.
3 Q I appreciate it.
4 A Sure.
5 Q And you made a comment earlier -- or
6 you -- is it fair to say that you don't want to
7 speak for anyone other than yourself in your
8 Declaration; is that fair?
9 A I mean I guess it depends on the
10 context. I just know here that I can speak for
11 myself in this particular thing that I initiated,
12 or initialed.
13 Q Got it.
14 And, Doctor, can you just describe for
15 me the process in which you prepared your
16 Declaration?
17 A We had lots of discussions and meetings
18 about information, the contents.
19 Q And who's the "we" you're referring to?
20 A Members from the legal team.
21 Q And which members from the legal team
22 are you referring to?

1 A I know this is bad, but I don't actually
2 recall the specific individuals.
3 Q Do you recall the names of any of the
4 individuals from the legal team?
5 A No.
6 Q Were any of those individuals from the
7 legal team in-house lawyers from JHU?
8 A I don't -- I'm not sure.
9 Q Were any of the -- how many individuals
10 were there?
11 A I don't know. I don't recall.
12 Q Do you have any general recollection as
13 to how many individuals there were in these many
14 conversations and meetings that you had to prepare
15 your Declaration?
16 A No, I don't know.
17 Q And it's your testimony sitting here
18 today you can't name a single individual that you
19 spoke with during the process of preparing your
20 Declaration that involved many conversations and
21 meetings; is that your testimony?
22 A I don't recall specifically who was at

1 which meeting.
2 Q And, Doctor, understand, I'm not asking
3 you who was at which meeting. That wasn't my
4 question at all. So let me try my question.
5 And is it your testimony that sitting
6 here today you can't name a single individual that
7 you spoke with during the process of preparing
8 your Declaration that involved many conversations
9 and meetings; is that your testimony?
10 MR. MILLER: Objection. Form.
11 A There were a lot of different meetings
12 so I can't remember who was at what and what was
13 discussed at what meeting.
14 Q And, Doctor, understand, I'm not asking
15 you who was at which meeting. I'm not asking that
16 at all. My question is different.
17 My question is, sitting here today, can
18 you name any individual that you spoke with during
19 the process of preparing your Declaration that
20 involved many conversations and meetings?
21 A I can name individuals who were at
22 meetings and related to this whole process, but I

1 cannot recall who was at which meeting to discuss
2 the contents of the Declaration because there were
3 a lot of different meetings on different topics.
4 Does that make sense?
5 Q Not to me, but which individuals are you
6 talking about?
7 A That were at these various meetings?
8 Q Yes.
9 A I can name Todd Miller, and I can name
10 Christie Brown Marshall, and that's probably
11 because I met with them recently so I can
12 remember. I'm not that great with names and
13 faces.
14 Q Anyone else?
15 A I can't specifically name other
16 individuals.
17 Q Do you have any general recollection of
18 any other individuals that you met with in
19 connection with this case?
20 A In the case or the Declaration?
21 Q So it's exactly what I said, so let me
22 try that again. I said the case.

1 A Well, what does "the case" mean?
2 Q Okay, if you don't know what "the case"
3 means, that's fine.
4 Do you have any recollection of which
5 individuals you met with during the preparation of
6 your Declaration?
7 A Those are the only two names I can
8 specifically name related to the Declaration.
9 Q Okay. And sitting here today, are you
10 comfortable with the content of your Declaration?
11 A Yes.
12 Q And are you familiar with the content of
13 your Declaration?
14 A I am familiar with it.
15 Q When did you first learn that JHU was
16 applying for a patent concerning your alleged
17 invention?
18 A I don't remember.
19 Q Do you have any recollection sitting
20 here today when you first learned that JHU was
21 applying for a patent concerning your alleged
22 invention?

1 A I don't remember the dates. I can't
2 remember.
3 Q Do you know if it was in 2013?
4 A It was so long ago, I don't remember the
5 dates.
6 Q What's "so long ago" to you?
7 A 2013 was a long time ago. I can't
8 remember the dates, the order. That's why I keep
9 referring to documents.
10 Q So your testimony today is you have no
11 recollection when you first learned that JHU was
12 applying for a patent concerning your alleged
13 invention. Is that your testimony?
14 A I can't give you a specific date when I
15 learned of it.
16 Q And, Doctor, understand, I'm not asking
17 for a specific date. So let me try my question
18 again.
19 Do you have any recollection when you
20 first learned that JHU was applying for a patent
21 concerning your alleged invention?
22 A I don't remember.

1 MR. MILLER: Counsel, we've been going
2 for about an hour. Is this a good time for a
3 break?
4 MR. RATLIFF: Doctor, would you like a
5 break?
6 MR. MILLER: If you want a break, we can
7 take a break or we can keep going, it's up to you.
8 THE WITNESS: If we keep going, the
9 clock keeps ticking.
10 MR. MILLER: Let's keep going. I didn't
11 know if you needed a --
12 THE WITNESS: I will need a break at
13 some point to go to the bathroom.
14 MR. MILLER: You just let us know, okay?
15 BY MR. RATLIFF:
16 Q Now, Doctor, in your Declaration you
17 testified that you have personal knowledge
18 regarding your team's June 10, 2013, submission of
19 information related to Clinical Trial No.
20 NCT01876511, right?
21 A Can you repeat that question?
22 Q In your Declaration you testified that

1 you have personal knowledge regarding your team's
2 June 10, 2013, submission of information related
3 to Clinical Trial NCT01876511, right?
4 A Are you referring to page 9, paragraph
5 22?
6 Q No.
7 A No.
8 Q Let me ask my question again.
9 In your Declaration you testified that
10 you have personal knowledge regarding your team's
11 June 10, 2013, submission of information related
12 to Clinical Trial NCT01876511, right?
13 Let me withdraw my question. Let me ask
14 it a different way.
15 Do you have personal knowledge relating
16 to your team's June 10, 2013, submission of
17 information related to Clinical Trial NCT01876511?
18 A Do I have information? Is that what you
19 asked?
20 Q That's not what I asked.
21 A Do I have -- I'm sorry.
22 Q Do you have personal knowledge relating

1 to your team's June 10, 2013, submission of
2 information related to Clinical Trial NCT01876511?
3 A Do I have personal knowledge. I have
4 knowledge.
5 Q Do you have personal knowledge relating
6 to your team's June 10, 2013, submission of
7 information related to Clinical Trial NCT01876511
8 to clinicaltrials.gov?
9 A You made a clarification. What do you
10 mean by "personal"?
11 Q Have you ever used the term "personal
12 knowledge"?
13 A I'm not sure.
14 Q Let me try my question again.
15 Do you believe that you have personal
16 knowledge relating to your team's June 10, 2013,
17 submission of information related to Clinical
18 Trial NCT01876511 to clinicaltrials.gov?
19 A I guess I'm asking because you clarified
20 personal versus knowledge. My knowledge is
21 personal, so I guess yes.
22 Q Okay. And do you recall testifying in

1 your Declaration that you had -- that you have
2 personal knowledge relating to your team's
3 June 10, 2013, submission of information related
4 to Clinical Trial NCT01876511 to
5 clinicaltrials.gov?
6 I see you turning the page. Do you have
7 any recollection of that?
8 A Do I have recollection of using the word
9 "personal knowledge"?
10 Q No. That's not my question. Let me try
11 my question again.
12 Do you have personal knowledge -- strike
13 that.
14 Do you have a recollection of testifying
15 in your Declaration that you have personal
16 knowledge relating to your team's June 10, 2013,
17 submission of information related to Clinical
18 Trial NCT01876511 to clinicaltrials.gov?
19 A You asked me if I have personal
20 knowledge. When you ask me if I have a
21 recollection that I said in -- I knew about it --
22 I'm sorry, can you repeat the question?

1 Q Let me not repeat it.
2 A Okay.
3 Q So let me provide a different question.
4 A Okay.
5 Q Do you understand that your Declaration
6 is testimony in this patent proceeding?
7 A Yes.
8 Q And do you understand that -- or did you
9 intend for the words of your Declaration to be
10 relied upon by the tribunal in this patent
11 proceeding?
12 A I don't -- I am not sure what you mean
13 by "tribunal."
14 Q Did you intend for the words that you
15 write in your Declaration to be relied upon in
16 this patent proceeding?
17 A Yes.
18 Q And do you recall testifying in this
19 patent proceeding that you have personal knowledge
20 relating to your team's June 10, 2013, submission
21 of information related to Clinical Trial
22 NCT01876511 to clinicaltrials.gov; yes or no?

1 A I do not recall specifically.
2 Q Okay. So let me turn your attention to
3 paragraph 5 of your Declaration at page 3.
4 A (Complying.)
5 Q And do you see in paragraph 5 you
6 testified that you have personal knowledge
7 relating to your team's June 10, 2013, submission
8 of information related to Clinical Trial
9 NCT01876511 to clinicaltrials.gov?
10 A I do see that.
11 Q And when you wrote, "My team's June 10,
12 2013 submission," who were you referring to as
13 your team?
14 A The individuals working on the
15 submission.
16 Q And which individuals were those?
17 A That would be the regulatory individual
18 and Dr. Diaz.
19 Q Which regulatory individuals?
20 A Dr. Durham, who might have been Dr. Uram
21 at the time, I don't remember, it's been a long
22 time, she got married -- is the individual I can

1 remember specifically that would be involved.
2 Q When you wrote "my team" in your
3 Declaration, did you have an understanding of
4 which individuals you were referring to?
5 A Doctor -- the regulatory team.
6 Q And which members constitute the
7 regulatory team?
8 A So typically the supervisor is
9 Dr. Durham. Ultimately she's responsible for this
10 submission.
11 Q And, Doctor, understand, I'm not asking
12 anything typical. I'm asking specifically who
13 were the members of your team when you refer to it
14 in paragraph 5 of your Declaration.
15 A Well, a submission would be the
16 responsibility of the people involved, so it would
17 be Dr. Durham's team and the IND sponsor,
18 Dr. Diaz.
19 Q Okay, you just said "would be" in your
20 response. I just want to be sure that we're
21 clear. When you wrote your team -- your team's
22 June 10, 2013 submission, what team members were

1 you specifically talking about?
2 MR. MILLER: Objection. Form.
3 A Dr. Durham and Dr. Diaz. Dr. Durham
4 is -- leads the regulatory group, so she
5 ultimately is part of my team.
6 Q Were you referring to any other team
7 members?
8 A I was not specifically referring to any
9 people. I was just referring to my team.
10 Q And who's your team? What are the
11 members of your team?
12 A There are different members of different
13 teams, but specifically at that time for the
14 regulatory head was Dr. Durham.
15 Q Doctor, I'm just trying to find out --
16 you wrote in paragraph 5, "My team's June 10,
17 2013, submission." Are you able to tell us who
18 were members of the team that you're referring to
19 in paragraph 5 of your Declaration?
20 A I can tell you the important members of
21 the team.
22 Q I'm not -- I don't want to know the

1 important members. I want to know who you were
2 referring to when you wrote, "My team's June 10,
3 2013, submission" in paragraph 5. Are you able to
4 tell us or not?
5 A I can tell you some of the people that
6 were included were Dr. Durham and Dr. Diaz and
7 myself.
8 Q Now, Clinical Trial NCT01876511, that's
9 a clinical trial that's reflected in the study
10 record that you refer to in your Declaration,
11 right?
12 A The clinical trial -- say that one more
13 time.
14 Q Clinical Trial NCT01876511 is the
15 clinical trial reflected in the study record that
16 you refer to in your Declaration, right?
17 A What's the study record?
18 Q Do you recall ever reviewing a study
19 record in this case?
20 MR. MILLER: Objection. Form.
21 A That's very vague. I don't know what --
22 what do you mean by a "study record"?

1 Q Do you know what a clinical trial study
2 record is?
3 A There are a lot of different meanings
4 for "clinical trial study record," so I need to
5 know specifically what you're asking me.
6 Q Did you review Exhibit 1005 as part of
7 your work on this case?
8 A I think you might have to give me 1005.
9 Q Sure.
10 (Exhibit 1005 was marked for
11 identification and was retained by Mr. Ratliff.)
12 Q Doctor, I'm handing you a copy of
13 Exhibit 1005. Do you recall -- or did you ever --
14 did you review this document as part of your work
15 on this case?
16 A Yes.
17 Q And what is it, to your knowledge?
18 A I see some dots on A and B, June 10,
19 2013, is a clinicaltrial.gov submission on
20 June 10, 2013.
21 Q You told me what you see, but what is
22 this document to your knowledge, Exhibit 1005?

1 A It's a submission to clinicaltrials.gov.
2 Q Okay. And you see on the front of the
3 document it refers to study record versions?
4 A Study -- yes.
5 Q And is it your belief that Exhibit 1005
6 was submitted to clinicaltrials.gov?
7 A Is it my belief that this document was
8 submitted?
9 Q Is it your belief that Exhibit 1005 was
10 submitted to clinicaltrials.gov?
11 A Submitted.
12 MR. MILLER: Objection. Form.
13 A Clinicaltrials.gov -- it is my belief
14 that there was a submission to clinicaltrials.gov
15 for this NCT01876511.
16 Q Okay. So that wasn't my question. Let
17 me back up and try something different.
18 Do you know what a clinical trial study
19 record is?
20 A Through here? This -- what they mean by
21 study record on this particular document?
22 Q No. I'm asking you, do you know what a

1 clinical trial study record is?
2 A We're talking in reference to a
3 clinicaltrial.gov submission?
4 Q Yes.
5 A It looks like there are study record
6 versions.
7 Q Do you know what a study record is?
8 A I don't know specifically what the term
9 "study record" is referring to in this, but it's a
10 record of the versions that are sent to
11 clinicaltrials.gov.
12 Q And my question doesn't concern
13 specifically Exhibit 1005. My question is, do you
14 understand what a clinical trial study record is?
15 MR. MILLER: Objection. Form.
16 A You're talking with reference to this
17 website, clinicaltrials.gov, a study version?
18 Q Doctor --
19 A A study record version.
20 Q -- have you ever used the term "study
21 record" in this case?
22 A A lot. But not this. That's why I'm

1 trying to understand the context of "study
2 record."
3 Q Well, you used the term "study record"
4 in your Declaration, right?
5 A Can you show me?
6 Q Sure. Turn to paragraph 24 of your
7 Declaration.
8 A (Complying.)
9 No, I'm sorry, paragraph --
10 Q Paragraph 24 at page 10. Let me know
11 when you have that.
12 A Okay.
13 Q Do you see in paragraph 24 you used the
14 term "study record"?
15 A (Reviewing.)
16 I see the term "study record."
17 Q And that's a term that you use in your
18 Declaration, right?
19 A The word "study record" is used in this
20 Declaration.
21 Q I'll start my question over again.
22 The term "study record" is a term that

1 you chose to include in your Declaration, right?
2 MR. MILLER: Objection. Form.
3 A Yes, the term "study record" is in my
4 Declaration.
5 Q I'm not asking you if it's in your
6 Declaration, I'm asking you if you chose to use
7 that term "study record" in your Declaration. Or
8 did someone else choose it?
9 MR. MILLER: Objection. Form.
10 A I signed the Declaration. It's my
11 Declaration, so in effect I chose the word "study
12 record."
13 Q And when you used the term "study
14 record" in paragraph 24, what were you referring
15 to?
16 A The NCT0205.06.
17 Q And what's that?
18 A That's a NCT number.
19 Q And so what is a study record as you
20 understand it and as you refer to it in paragraph
21 24 of your Declaration?
22 A It's the record of NCT02054806.

1 Q And what does that mean to be a record
2 of NCT02054806?
3 MR. MILLER: Objection. Form.
4 A It's something that's recorded for a
5 study, NCT02054806.
6 Q Did you ever review the study record for
7 NCT01876511?
8 A I reviewed the NCT02054806 on the
9 clinicaltrials.gov.
10 Q Did you ever review the study record for
11 NCT01876511 as part of your work in this case?
12 A Say that one more time. You're talking
13 about this one (indicating)?
14 Q Did you ever review the study record for
15 NCT01876511 as part of your work in this case?
16 MR. MILLER: Objection. Form.
17 A This record right here (indicating)?
18 Q I don't know what you're pointing to.
19 What do you mean by "this"?
20 A This 1005.
21 I'm sorry, you switched from that study
22 to this study. I'm a little bit -- I'm trying to

1 keep it straight.
2 Q Okay. So here's my question.
3 Did you ever review a study record for
4 Clinical Trial NCT01876511 as part of your work on
5 this case?
6 MR. MILLER: Objection. Form.
7 A Yes.
8 Q And is Exhibit 1005 the study record
9 that you reviewed for Clinical Trial NCT01876511?
10 MR. MILLER: Objection. Form.
11 A I have reviewed this, or something that
12 looks like this.
13 Q Is Exhibit 1005 the study record that
14 you reviewed for Clinical Trial NCT01876511?
15 MR. MILLER: Objection. Form.
16 A Have I reviewed this, yes.
17 Q By "this," what are you referring to?
18 A This Merck Exhibit 1005.
19 Q So Merck Exhibit 1005 is a study record
20 for NCT01876511?
21 MR. MILLER: Objection. Form.
22 A It's a study record, I guess. That's

1 what this is called, this is a study record.
2 Q So you understand that --
3 A There's a -- yeah, I think I'm getting
4 stuck in what you're -- the semantics, but yes.
5 Q Let me make sure I have a clear answer
6 to my question.
7 You reviewed Exhibit 1005, right?
8 A Yes.
9 Q And you cite it in your Declaration,
10 right?
11 A This -- I cite it in my Declaration. We
12 were just talking about the other study, so I
13 would have to look to see if I cited a clinical --
14 a study report.
15 Q So, Doctor, I'm not -- can you show me
16 where it is? I'm not talking about any study
17 report.
18 So let's turn your attention back to
19 Exhibit 1005. It's in front of you, right?
20 A Okay. I know, but you're asking me
21 about my Declaration, so I'd like to -- when you
22 ask me what's in the Declaration, I would like to

1 review the Declaration so that I keep it as honest
2 and straight as possible because --
3 Q Okay. So I'm asking you now about
4 Exhibit 1005.
5 A Yes.
6 Q And you have that in front of you,
7 right?
8 A Yes.
9 Q And you reviewed it, right?
10 A Yes.
11 Q And it's a study record for Clinical
12 Trial NCT01876511, right?
13 MR. MILLER: Objection. Form.
14 A It's a -- yes.
15 Q And the name of that clinical trial was
16 entitled "Phase 2 Study of MK-3475 in Patients
17 With Microsatellite Unstable MSI Tumors," right?
18 A That's what it says on the top of the
19 page, yes.
20 Q And you refer to this study record,
21 Exhibit 1005, in your Declaration, right?
22 A In paragraph 6.

1 Q So you refer to the study record,
2 Exhibit 1005, in your Declaration, right?
3 MR. MILLER: Objection. Form.
4 A Exhibit 1005 is referred in the
5 Declaration, yes.
6 Q Referred to in your Declaration, right?
7 A Yes.
8 Q And for the clinical trial that's
9 reported on in Exhibit 1005, Merck collaborated
10 with JHU to conduct that clinical trial, right?
11 A Merck is listed under Collaborator.
12 Q That wasn't my question Merck is listed
13 as -- under Collaborator in the document. My
14 question is different.
15 For the clinical trial that's reported
16 on in the study record Exhibit 1005, Merck
17 collaborated with JHU to construct the clinical
18 trial, right?
19 MR. MILLER: Objection. Form.
20 A Can you repeat the question?
21 Q Merck collaborated with JHU to conduct
22 the clinical trial that's reported on in the study

1 record Exhibit 1005, right?
2 MR. MILLER: Objection. Form.
3 A Merck is listed on page 3 as a
4 collaborator.
5 Q And to your knowledge, Merck actually
6 collaborated with JHU to conduct the clinical
7 trial that's reported on in the study record,
8 right?
9 MR. MILLER: Objection. Form.
10 A They provided drug, or agent, I guess,
11 investigation agent.
12 Q So to your knowledge, Merck collaborated
13 with JHU to conduct the clinical trial that's
14 reported on in the study record, right?
15 MR. MILLER: Objection. Form.
16 A What do you mean by "collaborate"?
17 Q Have you ever used the word
18 "collaborate" before?
19 A Do we have to do this every time? I
20 just -- what is your definition? When -- you're
21 asking me the question, so when you say
22 "collaborate," what is your definition of

1 "collaborate"?
2 Q Do you know what a collaborator is in
3 the context of a clinical trial?
4 A I don't know specifically what the
5 definition for all collaborators are, but Merck
6 provided drug.
7 Q Okay. I'm not asking for the definition
8 for all collaborators.
9 For the clinical trial that's reported
10 on in the study report, you were the principal
11 investigator, right?
12 A I was the principal investigator.
13 Q As the principal investigator, you're
14 responsible for supervising the overall conduct of
15 the study, right?
16 A I am responsible for supervising the
17 conduct of the study.
18 Q Let me try that again.
19 As the principal investigator, you were
20 responsible for supervising the overall conduct of
21 the study, right?
22 A The clinical trial? I was and -- yes,

1 and I am, yes.
2 Q And as part of your work as principal
3 investigator, you've had interactions with Merck
4 personnel, right?
5 A I have.
6 Q And to your knowledge, has Merck
7 collaborated with JHU to conduct the clinical
8 trial that's reported on in the study record?
9 MR. MILLER: Objection. Form.
10 A I think it means -- matters what you
11 mean by "collaborate." Merck provided drug for
12 the study. They're listed as a collaborator on
13 page 3 of 6.
14 Q So let me try my question one more time.
15 Has Merck collaborated with JHU to
16 conduct the clinical trial that's reported on in
17 the study record?
18 MR. MILLER: Objection. Form.
19 Q Yes or no?
20 A Merck provided drug for the study.
21 Q Try it one more time.
22 And maybe this is your testimony.

1 Has Merck collaborated with JHU to
2 conduct the clinical study that's reported on in
3 the study record?
4 MR. MILLER: Objection. Form. Asked
5 and answered multiple times.
6 A I feel like I need to know specifically
7 what you mean by "collaborate," but it says
8 Collaborator, Merck, and Merck provided drug for
9 the study.
10 Q And when Merck provided drug for the
11 study, did Merck charge JHU for that drug?
12 A No.
13 Q Did Merck provide any support other than
14 providing drug to conduct the clinical trial
15 that's reported on in the study record?
16 MR. MILLER: Objection. Form.
17 A So the study record is dated June 10,
18 2013. That's the study record we're referring to,
19 correct?
20 Q Did Merck provide any support other than
21 providing drug to conduct the clinical trial
22 that's reported on in the study record?

1 MR. MILLER: Objection. Form.
2 A Merck provided some funding much later;
3 I can't tell you when. Not as of June 10th, 2013.
4 Q And what do you mean by "much later"?
5 A I -- I don't recall, but I know that
6 that is documented somewhere. That's something
7 that could easily be found. I honestly do not
8 recall the time frames of things.
9 Q And is your testimony -- is much
10 later -- when you say "much later," do you have a
11 year in mind?
12 A I don't.
13 Q And is it your testimony that prior to
14 June 10, 2013, Merck did not provide any funding
15 to conduct the clinical trial that's reported on
16 in the study record?
17 MR. MILLER: Objection. Form.
18 A I don't recall any funding before
19 June 10, 2013.
20 Q And do you recall if Merck provided any
21 funding to support the clinical trial that's
22 reported on in the study record prior to 2014?

1 MR. MILLER: Objection. Form.
2 A Is the study record referring to this
3 June 10, 2013, study record, what was in the
4 record as of June 10, 2013?
5 Q Let's try it again.
6 A Because we went on semantics about what
7 we meant by "study record."
8 Q There's no semantics. You use the term
9 "study record" in your Declaration, right?
10 MR. MILLER: Objection. Form.
11 Q You used the term "study record" in your
12 Declaration, right?
13 MR. MILLER: Objection. Form.
14 Go ahead.
15 A Yes.
16 Q And you see on Exhibit 1005 it refers to
17 study record versions, right?
18 A I'm sorry, where are we again?
19 Q Exhibit 1005.
20 A 1005. Yes, 1005.
21 Q It refers to study record versions?
22 A So we're referring to June 10, 2013?

1 Q Referring to study record, not referring
2 to any particular time frame.
3 A These are done over different times.
4 There's different information in different times.
5 This is printed more recently because this wasn't
6 printed on June 10, 2013.
7 Q So maybe -- let's just follow my
8 question.
9 A Uh-humh.
10 Q You see Exhibit 1005 refers to the term
11 "study record"?
12 A Yes.
13 Q And do you have any understanding of
14 what that term means?
15 A "Study record" or "study record
16 version"?
17 Q "Study record."
18 A "Study record" is a record of the study
19 submitted to clinicaltrial.gov.
20 Q Okay. Now, I want to talk about the
21 clinical trial that was reported on in the study
22 record that we see here in Exhibit 1005. Okay?

1 So we're talking about Clinical Trial No.
2 NCT01876511.
3 A So now we're talking about a trial,
4 we're not talking about the submission?
5 Q We're talking about the trial.
6 A The actual trial.
7 Q And one of the IDs for that trial was
8 MK3475-016. Do you recall that, right?
9 A Yes.
10 Q And I think you also have referred to
11 this trial as KEYNOTE-16, right?
12 A Yes.
13 Q So let's talk about KEYNOTE-16.
14 In your view, has Merck collaborated
15 with JHU to conduct KEYNOTE-16?
16 MR. MILLER: Objection. Form.
17 A I guess I'm not understanding how this
18 is a different question about collaboration,
19 KEYNOTE-16. Up to this point they had agreed to
20 provide drug.
21 Q I don't know what point you're talking
22 about.

1 A June 10, 2013.
2 Q Okay. So my question doesn't have a
3 time frame. It's, sitting here, as of today, in
4 your view, has Merck collaborated with JHU to
5 conduct KEYNOTE-16?
6 MR. MILLER: Objection. Form.
7 A As of June 10, 2013, they're listed as
8 Collaborator. They provided drug. At some point
9 in the future, not here, and I can't tell you
10 when, but they did provide funding.
11 Q In your view, as of today, would you say
12 that Merck has collaborated with JHU to conduct
13 the clinical trial that is KEYNOTE-16?
14 MR. MILLER: Objection. Form.
15 A I think I'm still not sure what you mean
16 by "collaborated." They provided some things for
17 the clinical trial. They provided drug. Is that
18 considered collaboration?
19 Q It's your view. So let me ask my
20 question again.
21 As of today, would you say that Merck
22 has collaborated with JHU to conduct KEYNOTE-16?

1 MR. MILLER: Objection. Form. Asked
2 and answered.
3 A Okay. Again, they provided drug
4 initially as listed here on this document,
5 Collaborator. And then at some point later, they
6 provided funding.
7 Q And is it your belief that you're aware
8 of all of the funding that Merck ever provided for
9 KEYNOTE-16?
10 A Is it my belief that I'm aware? Do I
11 believe that I'm aware?
12 Q Do you believe that you're aware of all
13 of the funding that Merck ever provided for
14 KEYNOTE-16?
15 A Do I believe -- I believe I'm aware.
16 Q Okay. And it's your testimony and
17 belief that Merck did not provide funding to
18 support KEYNOTE-16 prior to 2015?
19 A I can't give you a date. I don't
20 remember.
21 Q Is it your testimony that Merck did not
22 provide funding to support KEYNOTE-16 prior to

1 2014?
2 A I can't remember the dates. I just
3 can't remember. It's --
4 Q And is it your belief that Merck did not
5 provide funding to support KEYNOTE-16 prior to
6 February of 2014?
7 A I can't remember the dates.
8 Q Now, in your Declaration when you
9 testified about your team's June 10, 2013,
10 submission to clinicaltrials.gov, can you tell us
11 how that submission was made to
12 clinicaltrials.gov?
13 MR. MILLER: Objection. Form.
14 A Made?
15 Q Yes. Was it a letter, was it an email?
16 How was that submission made?
17 A It's not a letter or an email.
18 Q What was it?
19 A It's a web-based submission.
20 Q So your team's June 10, 2013, submission
21 of information regarding KEYNOTE-16 to
22 clinicaltrials.gov was an electronic submission?

1 MR. MILLER: Object to form.
2 A I don't recall specifically.
3 Q What's your general recollection?
4 MR. MILLER: Objection. Form.
5 A I can't recall specifically.
6 Q Do you have a general recollection?
7 MR. MILLER: Objection. Form.
8 A I can't recall specifically.
9 Q And, Doctor, I'm not asking you to
10 recall specifically. I'm asking you if you have a
11 general recollection. So let me try my question
12 again.
13 Do you have a general recollection as to
14 how your team's June 10, 2013, submission of
15 information for KEYNOTE-16 was submitted to
16 clinicaltrials.gov?
17 MR. MILLER: Objection. Form.
18 A I know that it was sub -- there is a
19 submission to clinicaltrials.gov any time that
20 you're about to initiate a trial, and the
21 submission is drafted by the regulatory team, and
22 the investigators review the submission. That's

1 the general recollection.
2 Q Okay. So your response was about any
3 time that you're about to initiate a clinical
4 trial. So my question is specifically about the
5 June 10, 2013, submission that you referred to in
6 your Declaration.
7 So my question is, with respect to that
8 June 10, 2013 submission, do you have any
9 recollection whatsoever what was the form in which
10 that submission was made to clinicaltrials.gov?
11 A I can tell you that things are reviewed
12 and it's the team that submits it.
13 Q With respect to the June 10, 2013,
14 submission that you referred to in your
15 Declaration, do you have any recollection
16 whatsoever what was the form in which that
17 submission was made to clinicaltrials.gov?
18 A I have recollection of review.
19 Q Do you have any recollection of what the
20 form was in which that submission was made?
21 A I cannot say that I was there when
22 someone pushed the button. Is that what you're

1 referring to are the --
2 Q No, I didn't say anything about pushing
3 a button.
4 A Okay.
5 Q So let me try my question again.
6 Do you have any recollection whatsoever
7 of the form of the June 10, 2013, submission that
8 you referred to in your Declaration?
9 A The form. I have recollection of
10 review.
11 Q Do you have any recollection if the
12 submission that you referred to in your
13 Declaration was made electronically?
14 A I don't have recollection of being there
15 with the person when they submitted it, but I have
16 recollection of review.
17 Q Do you know how the June 10, 2013,
18 submission was provided to Clinical Trials?
19 A Do I know specifically? That would be
20 easy to find out.
21 Q I'm not asking if you can go find out.
22 I'm asking you, sitting here today, do you know

1 how the June 10, 2013, submission that you refer
2 to in your Declaration was made to
3 clinicaltrials.gov?
4 A The actual submit, I don't know if -- I
5 cannot say that I was there when it was -- the
6 button was submitted, or how -- that part of it.
7 I can recall review for the submission.
8 Q I'm not asking you if you were there
9 when a button was pushed. My question is
10 different.
11 Do you know how the June 10, 2013,
12 submission that you refer to in your Declaration
13 was made to clinicaltrials.gov?
14 A Do I know how? I know that the
15 regulatory team would confer with the team members
16 and what goes into the document and then they
17 would submit -- we would review it and they would
18 submit it.
19 Q And you're saying "would." I'm asking
20 you about facts. Okay?
21 A I know it was submitted on June 10,
22 2013.

1 Q And you testified that you have personal
2 knowledge relating to your team's June 10, 2013,
3 submission?
4 A I have personal knowledge of the
5 submission, yes.
6 Q And so my question is, do you know how
7 it was submitted to the FDA?
8 A Are you asking me if it was
9 electronically submitted? Well, it's actually
10 clinicaltrials.gov, it's not the FDA. Or it was
11 mailed in; is that what you're asking me? I know
12 that I reviewed it and it was submitted.
13 Q And do you know --
14 A And the submission date is listed as
15 June 10, 2013.
16 Q And do you know if it was submitted to
17 clinicaltrials.gov electronically?
18 A Do I know that. I don't know that. I
19 know it was submitted and I know it was reviewed.
20 I don't know -- because I didn't -- oftentimes our
21 team members hit the buttons for us, or they might
22 print it out as well and send it in. Sometimes

1 with the FDA you actually have to do both. So I
2 know it was submitted.
3 Q Do you have a copy of June 10, 2013,
4 submission in your files?
5 A Here?
6 Q In your files at work, do you have a
7 copy of the June 10, 2013, submission?
8 A Do I personally have a copy right now in
9 my files? The files are usually maintained by the
10 regulatory team.
11 Q Do you have a copy of the June 10, 2013,
12 submission in your files?
13 A Do I have a copy in my files?
14 This June 10, 2013, regulatory
15 submission is in a file -- it should be in a file,
16 a regulatory file.
17 Q So it's your belief that somewhere
18 within JHU there is a copy of the June 10, 2013,
19 submission?
20 A I don't know what you mean by "copy."
21 There are -- there should be a documentation
22 trail.

1 Q Do you know if there's a copy of the
2 June 10, 2013, submission in any file at JHU?
3 A A copy of -- I can't specifically say
4 that there is a copy.
5 Q Okay. So sitting here today you don't
6 know if there's a copy of the June 10, 2013,
7 submission to clinicaltrials.gov, right?
8 MR. MILLER: Objection. Form.
9 A I can't say that there's a copy.
10 Q Okay. But it's your belief that what
11 was submitted to clinicaltrials.gov for KEYNOTE-16
12 was posted on the clinicaltrials.gov website on
13 June 10, 2013, right?
14 A Say that one more time.
15 Q It's your belief that what was submitted
16 to clinicaltrials.gov for KEYNOTE-16 was posted on
17 the clinicaltrials.gov website on June 10, 2013,
18 right?
19 A It is my belief that there was a
20 submission back in June of 2013.
21 Q Are you finished with your response?
22 A That there was a submission? Yes.

1 Q So let me go back to my question.
2 Is it your belief that what was
3 submitted on clinicaltrials.gov for KEYNOTE-16 was
4 posted on the clinicaltrials.gov website on
5 June 10, 2013?
6 MR. MILLER: Objection. Form.
7 A I'm -- I guess now you're referring to
8 it as KEYNOTE-16. I actually don't know what it
9 was referred to at the time.
10 So I can tell you that there was a
11 submission for NCT01876511 in June of 2013.
12 Q And isn't NCT01876511 the same thing as
13 KEYNOTE-16?
14 A Honestly, I don't understand the
15 semantics, if it's the same thing. The NCT is a
16 number provided by clinicaltrials.gov.
17 Q In your view, is there a difference
18 between Clinical Trial No. NCT01876511 and
19 KEYNOTE-16?
20 A KEYNOTE-16 -- you'd have to ask Merck
21 how they come up with their numbers to identify
22 things.

1 Q You used the term "KEYNOTE" in your
2 Declaration, right?
3 A Let's see.
4 (Reviewing.)
5 Q Wait. Before you even look at your
6 Declaration, you don't recall using the term
7 "KEYNOTE-16" in your Declaration?
8 A I did use the term "KEYNOTE-16" in my
9 Declaration.
10 Q So in your opinion, is there a
11 difference between NCT01876511 and KEYNOTE-16?
12 MR. MILLER: Objection. Form.
13 A Is there a difference? All the numbers
14 are created by the -- whoever needed it for
15 documentation, for their purposes, so they're --
16 they're not the same.
17 Q So is it your testimony that the
18 clinical trial that has been identified as
19 NCT01876511 is not the same clinical trial as
20 KEYNOTE-16?
21 MR. MILLER: Objection. Form.
22 Q Is that your testimony?

1 MR. MILLER: Objection. Form.
2 A It's not my testimony.
3 Q Okay. So let me try this.
4 Would you agree that the clinical trial
5 that has been identified as NCT01876511 is the
6 same clinical trial that you refer to as
7 KEYNOTE-16 in your Declaration?
8 A KEYNOTE-16 refers to the Merck
9 identification of a study. NCT0187655 [sic] is a
10 clinicaltrials.gov registration number for a
11 clinical trial. And then there's also a number
12 for Hopkins. Hopkins has their own number.
13 Q Would you agree that this clinical trial
14 that has been identified as NCT01876511 is the
15 same clinical trial that you refer to in your
16 Declaration as KEYNOTE-16?
17 MR. MILLER: Objection. Form.
18 A NCT01876511 encompasses KEYNOTE-016 and
19 J1365.
20 Q Let's try this one more time.
21 Would you agree that the clinical trial
22 that has been identified as NCT01876511 is the

1 same clinical trial that you refer to in your
2 Declaration as KEYNOTE-16?
3 MR. MILLER: Objection. Form.
4 A I guess I just am trying to clarify NCT
5 is actually a clinical trial. It's a number. But
6 NCT01876511 is, encompasses KEYNOTE-016. We're
7 talking about the same thing, yes. Sort of.
8 Again, I'm getting stuck on the -- what the words
9 actually mean, but ...
10 Q Well, one we word we're talking about is
11 KEYNOTE-16 that you use in your Declaration,
12 right?
13 A Yes.
14 Q And another word that we're talking
15 about is NCT01876511 that you use in your
16 Declaration, right?
17 A Yes.
18 Q And those are references to the same
19 clinical trial, right?
20 MR. MILLER: Objection. Form.
21 A It's Merck's reference -- Merck
22 identifies it as KEYNOTE-16.

1 Q And you in your Declaration identify it
2 as KEYNOTE-16, right?
3 MR. MILLER: Objection. Form.
4 A I state that these studies were referred
5 to by Merck in its application to the FDA as
6 KEYNOTE-16 and KEYNOTE-164. Is that what you're
7 referring to?
8 Q No.
9 Don't you refer to the Clinical Trial
10 No. NCT01876511 as KEYNOTE-16 in your Declaration?
11 I see you turn to your Declaration. Do
12 you not recall what's in your Declaration?
13 A I mean I recall some things in the
14 Declaration, but we've written a lot of different
15 things, so I just -- since you're asking me what's
16 in the Declaration, I would like to look at the
17 Declaration.
18 Q So my question is clear. In your
19 Declaration, don't you refer to the clinical trial
20 with the number NCT01876511 as KEYNOTE-16?
21 A KEYNOTE-16 is mentioned in the
22 Declaration on page 2. These studies were

1 referred by Merck in its application to the FDA as
2 KEYNOTE-16.
3 Q You refer to KEYNOTE-16 in several
4 places in your Declaration, right?
5 A I see it in another spot, yes.
6 Q And KEYNOTE-16, it's the same clinical
7 trial that is the clinical trial that's been
8 identified as NCT01876511, right?
9 MR. MILLER: Objection. Form.
10 A It's -- KEYNOTE-16 is -- matches up to
11 this NCT. I guess I'm getting lost in the
12 questioning.
13 Q They're the same clinical trial, right?
14 MR. MILLER: Objection. Form.
15 A As opposed to a different clinical
16 trial? It's --
17 Q Do you believe sitting here today that
18 KEYNOTE-16 is a different clinical trial than the
19 clinical trial with the number NCT01876511? Is
20 that your testimony?
21 A No, that's not what I'm saying.
22 Q So don't you agree that KEYNOTE-16 --

1 A I agree --
2 Q -- refers to the same clinical trial
3 that has been identified as NCT01876511?
4 MR. MILLER: Objection. Form.
5 A It is a trial that is referred in this,
6 in the NCT01876511. This is Merck's name for
7 this -- the reference to this clinical trial.
8 Q So we're talking about one clinical
9 trial that has been referred to by you as
10 KEYNOTE-16, and you also refer to it as
11 NCT01876511, right?
12 MR. MILLER: Objection. Form.
13 A I refer to this clinical trial
14 NCT01876511, and we're talking about the study
15 that Merck refers to as KEYNOTE-16.
16 Q There's only one study, right?
17 A There --
18 MR. MILLER: Objection.
19 A Yes.
20 MR. MILLER: Objection. Form.
21 Q Yes, there's only one study?
22 MR. MILLER: Objection. Form.

1 Wait. You need to pause.
2 You need to pause.
3 Objection. Form. Go ahead.
4 Q So my question is, for that one study in
5 your Declaration, you refer to it as KEYNOTE-16,
6 and sometimes you refer to it as NCT01876511,
7 right?
8 MR. MILLER: Objection. Form.
9 A I sometimes refer to this NCT number,
10 which is a registration for clinicaltrial.gov,
11 sometimes I refer to it as KEYNOTE-16, sometimes,
12 in the Declaration. I don't see it on this
13 submission. That's all I was saying.
14 Q Okay. So let's focus on my question. I
15 just want to be sure that --
16 A They have a secondary ID, I guess is
17 what they call it.
18 Q I just want to be clear.
19 KEYNOTE-16, that clinical trial, is the
20 same clinical trial that you refer to in your
21 Declaration as NCT01876511, right?
22 MR. MILLER: Objection. Form.

1 A It's -- there is one clinical trial that
2 is -- that we're talking about; is that what
3 you're --
4 Q Yes. There's one clinical trial that
5 we're talking about.
6 A Yes. I'm not talking about some other
7 clinical trial.
8 Q And sometimes that one clinical trial,
9 you refer to it as KEYNOTE-16, right?
10 A 16 -- yes. It says these studies are
11 referred to by Merck as application to FDA's
12 KEYNOTE-16.
13 Q So that one clinical trial, you have
14 referred to it as KEYNOTE-16 in your Declaration,
15 right?
16 I see you paging through your
17 Declaration.
18 A Yes.
19 Q Let me withdraw that question.
20 A Okay.
21 Q The one clinical trial that we're
22 talking about, have you ever, at any point in

1 time, referred to it as KEYNOTE-16?
2 A The one clinical trial -- have I ever --
3 yes.
4 THE WITNESS: Can we take that break
5 now?
6 MR. MILLER: Yep.
7 MR. RATLIFF: Sure.
8 (A recess was taken at 11:03 a.m.)
9 (Back on the record at 11:19 a.m.)
10 BY MR. RATLIFF:
11 Q So I'd like to turn your attention to
12 Exhibit 1005. Do you have that in front of you?
13 A Yes.
14 Q And is it correct that the recruitment
15 of patients for KEYNOTE-16 began after August 27,
16 2013?
17 A The recruitment of patients for the
18 clinical trial occurred sometime after June 10th,
19 2013.
20 Q Okay. When you say "clinical trial,"
21 you're referring to KEYNOTE-16?
22 MR. MILLER: Objection. Form.

1 A Can I refer to it as just "the trial"?
2 We're talking about one trial.
3 Q So when you say "the trial," you're
4 referring to KEYNOTE-16 or the same thing as
5 NCT01876511; is that fair?
6 MR. MILLER: Objection. Form.
7 A I would like to refer to the trial as
8 J1365 because I'm getting thrown off by -- we're
9 talking about a clinical trial.
10 Q You would like to refer to it as what?
11 A J1365.
12 Q And you realize that nowhere in your
13 Declaration you've ever referred to it by that
14 identifier, right?
15 A I am realizing that now.
16 Q So let's refer to it as "the trial."
17 There's only one trial, right?
18 A Yes, let's refer to it as "the trial."
19 Q Got it.
20 Now, during the break, did you speak to
21 your counsel about any of my questions or this
22 case?

1 A I spoke to him about some frustration
2 about semantics.
3 Q Okay. So let me ask my question again.
4 Do you --
5 A And he said we're not supposed to talk
6 about the trial. So then we came in and joked
7 with her about some court reporting.
8 Q So did you have any other conversation
9 with your counsel about any of my questions or
10 this case?
11 A The frustration about going over
12 semantics and why you can't just explain to me the
13 definition of something. Just the semantics --
14 Q Okay.
15 A -- not like all these different
16 questions that you're asking me.
17 Q Okay. So let me just try my question
18 again so we're clear.
19 Other than what you say is "frustration
20 about semantics," did you speak with counsel about
21 any of my questions or this case?
22 A The semantics of the questions, and he

1 said we're not supposed to talk about the
2 deposition.
3 Q So, Doctor, just so we understand, other
4 than your discussion with counsel about what you
5 believe are semantics, did you speak with counsel
6 about any of my questions or this case?
7 A The semantics ones. I said, I don't
8 understand the semantics, why we keep going over
9 trial, NCT, KEYNOTE-16. We're talking about one
10 trial.
11 So I guess going over some issues about
12 the questions because that was about the semantics
13 which was in your question that we kept going back
14 and forth on. But semantics. I was frustrated
15 about going over the semantics, why we keep
16 calling things different things. We're referring
17 to one trial.
18 Q Okay.
19 A I mean I don't know, maybe you can
20 explain it to me. I don't know why we keep going
21 over -- we're just -- you're talking about a
22 particular -- when we say "trial," we're referring

1 to clinical trial, a clinical trial, one clinical
2 trial that we're referring to.
3 Q So let's focus on my question, Doctor.
4 So I'm not asking you about your
5 counsel -- your conversation with counsel about
6 semantics --
7 A Yes.
8 Q -- about what you say is alleged
9 semantics. I'm not asking about that. Do you
10 understand that?
11 So my question is, other than that, did
12 you have any discussions with counsel about any of
13 my questions or this case?
14 A I told you about which question I
15 discussed, and it was why it's -- not specifically
16 about the questions, it was about the trial, why
17 we keep taking about NCT versus KEYNOTE-16.
18 It's frustrating why he keeps asking me
19 the same thing. And he said we're not supposed to
20 talk about the trial -- I mean not the trial, the
21 deposition, whatever this is. We're not supposed
22 to talk about the deposition.

1 Q Did you have any other discussion with
2 counsel about this case or my questions?
3 A I only discussed that I was very
4 frustrated with this back-and-forth when I feel
5 like I've answered a question or about semantics
6 of "a trial," I mean, not the trial. I'm getting
7 confused again.
8 Just going over and over again about a
9 trial. We know what trial we're talking about.
10 We know there is a submission, we know there is a
11 trial, and I guess I don't know why you -- I feel
12 like you're trying to confuse me, that's all.
13 And that's not what I said to him. I
14 just said it's confusing, and I don't know why we
15 keep going back and forth, and I was frustrated.
16 Q And, Doctor, you seem to be raising your
17 voice in response to my question. Are you okay?
18 A I'm okay.
19 Q So, Doctor --
20 A Yes.
21 Q -- other than the conversations that you
22 just explained to me that you had with counsel

1 during the break, did you have any other
2 conversation with counsel about my questions or
3 this case?
4 MR. MILLER: Objection. Form. Asked
5 and answered now multiple times.
6 A I talked about my frustration about
7 going over semantics.
8 Q You understand I'm not asking about
9 that. We're past that.
10 A You asked me what we talked about.
11 Q No, that's not right. So let me try my
12 question again. I'll go slower.
13 I'm excluding from my question any
14 discussion you had about alleged semantics. Other
15 than your discussion with counsel about alleged
16 semantics, did you have any discussion with
17 counsel about any of my questions or this case?
18 A Yes, the trial. I didn't understand why
19 we kept going over NCT trial, KEYNOTE-16. We're
20 talking about one trial. That was the other
21 discussion. And he said we're not supposed to
22 talk about the deposition.

1 Q Okay. So let's talk about the trial.
2 Is it correct that the recruitment of
3 patients for the trial began after August 27,
4 2013?
5 A I can tell you that the trial
6 recruitment -- I guess it depends on what you mean
7 by "recruitment."
8 Q How did you -- I mean how you meant
9 recruitment when you used that term in your
10 Declaration.
11 A Recruitment usually means when you can
12 actually start putting patients -- like it's
13 actually open, the study is open, and you can
14 recruit.
15 Q Okay. So is it correct that for the
16 trial, recruitment of patients began after
17 August 27, 2013?
18 A Recruitment does not start when you do
19 the submission. Recruitment starts after you have
20 all the approvals and things are set to go. So
21 the recruitment occurred after.
22 Again, when you give me dates, I just

1 got to get a little confused.
2 Q Doctor --
3 A We could not recruit in June.
4 Q But, Doctor, you used dates in your
5 Declaration, right?
6 A Yes, because I can look at things.
7 Q Were you confused about dates that you
8 talked about in your Declaration?
9 A But I can doublecheck things.
10 Q No, different question.
11 A When --
12 Q I'm not asking if you can -- Doctor, I'm
13 asking were you confused about any of the dates
14 that you talk about in your Declaration?
15 A I -- not specifically when I was doing
16 the Declaration and looking at things to --
17 Q Were you confused about any of the dates
18 that you talked about in your Declaration?
19 A I mean we'd have to go over every
20 specific date, but at the time when you sign the
21 Declaration, you can look at things.
22 Q Doctor, were you confused about any of

1 the dates that you talked about in your
2 Declaration?
3 MR. MILLER: Objection. Form. Asked
4 and answered.
5 A Was I confused about any of the dates --
6 Q Let me withdraw that question.
7 Are you confused about any of the dates
8 that you talk about in your Declaration?
9 A Can I recite them to you without looking
10 at the Declaration? I cannot recite them to you.
11 Q That wasn't my question. I didn't ask
12 you to recite any dates. I'm just asking you,
13 you're familiar with your Declaration, right?
14 A Yes.
15 Q So I'm asking you, are you confused
16 sitting here today about any of the dates that you
17 refer to in your Declaration?
18 A What do you mean by "confused"?
19 MR. MILLER: Objection.
20 Sorry. Just pause so I can interpose an
21 objection.
22 Objection. Form. Asked and answered.

1 Go ahead.
2 Q Are you confused by any of the dates
3 that you refer to in your Declaration?
4 MR. MILLER: Same objection.
5 A I don't like the term "confused." I
6 like to verify when you ask me about things
7 because the document is in front of me, so ...
8 Q Is it correct that the recruitment of
9 patients for the trial began after August 27,
10 2013?
11 A The recruitment occurred after a
12 particular date. I can tell you it doesn't occur
13 right away. It does not occur in June.
14 Q And for the trial, didn't you testify in
15 your Declaration that the recruitment of patients
16 began after August 27, 2013?
17 A (Reviewing.)
18 MR. MILLER: Objection. Form.
19 Q I see you paging through your
20 Declaration. Do you recall right now without
21 paging through your Declaration whether or not you
22 testified that the recruitment of patients for the

1 trial occurred after August 27, 2013?
2 Do you understand my question, Doctor?
3 A Yeah, I do understand your question, and
4 I looked at this document just yesterday so I just
5 want to confirm.
6 (Reviewing.)
7 Q And I want you to appreciate that my
8 question is not asking you to look at your
9 Declaration. I'm just saying, right now, without
10 looking through your Declaration, do you have any
11 recollection testifying that the recruitment of
12 patients for the trial occurred after August 27,
13 2013?
14 A I cannot specify the date.
15 Q So you don't have a recollection, right?
16 A I don't have a recollection right this
17 minute of entering a date.
18 Q And that's fine.
19 Let me turn your attention to paragraph
20 22 of your Declaration at page 9. And let me know
21 when you have it.
22 A 22.

1 (Reviewing.)
2 I am there.
3 Q Can you read paragraph 22 to yourself
4 and let me know when you're finished.
5 A (Reviewing.)
6 Yes.
7 Q And after reading paragraph 22 to
8 yourself, does it refresh your recollection as to
9 your testimony in your Declaration in paragraph
10 22?
11 A Yeah. The last line says:
12 We received IRB approval for the
13 clinical trial on July 3rd, 2013, and our clinical
14 trial number was activated on August 27, 2013,
15 after which we were allowed to begin recruiting
16 patients.
17 Q Okay. So based upon a refreshed
18 recollection, is it correct that the recruitment
19 of patients for the trial began after August 27,
20 2013?
21 A It was activated on August 27, 2013. I
22 guess it depends what you mean by "recruited," but

1 you can't put patients on a trial until after it's
2 activated.
3 Q Is it correct that the recruitment of
4 patients for the trial began after August 27,
5 2013?
6 A You can't recruit a patient, put a
7 patient -- put a patient on a trial until after
8 it's activated.
9 Q And we're talking specifically about the
10 trial, the one trial we're talking about in this
11 case.
12 Okay, so here's my question.
13 Is it correct that for the trial you
14 were not allowed to begin recruiting patients
15 until after August 27, 2013?
16 A It is fair to say we can't recruit
17 patients until the trial is activated.
18 Q Okay. I'm not asking about any trial,
19 I'm asking about a very specific trial. I'm
20 asking about KEYNOTE-16, okay? So I want you to
21 understand I'm not asking about "a trial."
22 A Okay.

1 Q I'm asking about KEYNOTE-16.
2 So here's the question.
3 With respect to KEYNOTE-16, is it
4 correct that you were not able to begin to recruit
5 patients until after August 27, 2013?
6 MR. MILLER: Objection. Form.
7 A The trial was activated on August 27,
8 2013. This trial. We were allowed to recruit
9 after it was activated.
10 Q So is it correct that the recruitment of
11 patients for the trial began after August 27,
12 2013?
13 A Recruiting, putting patients on trial
14 could not occur before August 27, 2013.
15 Q And the recruiting of patients for the
16 trial did not occur before August 27, 2013, right?
17 A We cannot enroll patients on a trial
18 before it's activated.
19 Q I'm not asking about a trial. I'm
20 asking specifically about KEYNOTE-16. So here's
21 my question.
22 As principal investigator for

1 KEYNOTE-16, is it correct that the recruitment of
2 patients did not occur until after August 27,
3 2013?
4 A We could not recruit patients -- we
5 could not put patients on the trial before
6 August 27, 2013.
7 Q So then is it correct that the
8 recruitment of patients for the study began after
9 August 27, 2013?
10 A It was allowed to begin after.
11 Q After what?
12 A After it was activated.
13 Q So let me try my question again. Let me
14 ask it this way.
15 When were you first allowed to recruit
16 patients for KEYNOTE-16?
17 MR. MILLER: Objection. Form.
18 A I know it was not before August 27,
19 2013.
20 Q Okay.
21 A There's just a lot of steps. So to
22 actually be recruit -- I know that you can't

1 recruit before August 27, 2013.
2 Q So for KEYNOTE-16, the recruitment of
3 patients began on August 27, 2013 or after?
4 MR. MILLER: Objection. Form.
5 A I just can't -- I can only say that we
6 could not recruit before it was activated. It was
7 activated on August 27, 2013.
8 Q And so as principal investigator for
9 KEYNOTE-16, you can't tell me whether or not the
10 recruitment of patients for the study began on or
11 after August 27, 2013; is that your testimony?
12 A I can tell you that it did not occur
13 before August 27, 2013.
14 Q Can you tell me if it occurred after
15 August 27, 2013?
16 A What's the difference?
17 Q Because I'm asking if it occurred after.
18 A Did we recruit patients sometime after
19 August 27, 2013. We recruited patients sometime
20 after August 27, 2013.
21 Q Okay. And is it correct that for the
22 trial, the recruitment of patients began after

1 August 27, 2013?
2 A You recruited -- you couldn't recruit
3 patients -- you were allowed to recruit patients
4 sometime after it's activated, and it was
5 activated on August 27, 2013.
6 Q Okay. Let me ask it one more time.
7 As principal investigator for
8 KEYNOTE-16, is it correct that the recruitment of
9 patients for that study began after August 27,
10 2013?
11 A I can tell you that we were allowed to
12 begin sometime after, on or after August 27, 2013.
13 Q Allowed to begin recruiting of patients?
14 A We were allowed to begin recruiting
15 patients after.
16 Q Are you finished with your response?
17 A Yes.
18 Q Okay. So let me try it again because
19 you said "after" and I didn't hear a date.
20 A Oh. After August 27, 2013, on or after,
21 we were allowed to begin recruiting patients.
22 Q For KEYNOTE-16?

1 A For the trial.
2 Q Okay. So after -- on or after
3 August 27, 2013, you were allowed to begin
4 recruiting patients for the trial, correct?
5 A Sometime. Sometime, yes, we were
6 allowed to begin sometime after. I can just tell
7 you that you cannot recruit patients before the
8 study is activated.
9 Q And as principal investigator, you can't
10 tell us whether or not on or after August 27, 2013
11 the recruitment of patients began for the trial?
12 MR. MILLER: Objection. Form.
13 Q Is that your testimony?
14 MR. MILLER: Apologies.
15 Objection. Form.
16 A I can tell you that we could not recruit
17 patients before August 27, 2013.
18 Q And you can't tell me whether or not the
19 recruitment of patients for the trial began on or
20 after August 27, 2013, right?
21 A I can tell you that you can't recruit
22 patients before because it has to be activated.

1 Q Okay. That's your testimony.
2 Is it correct that before your work with
3 pembrolizumab, oncologists had already given
4 pembrolizumab to cancer patients?
5 A Say that one more time.
6 Q Is it correct that before your work with
7 pembrolizumab, oncologists had already given
8 pembrolizumab to cancer patients?
9 A Oncologists had given -- I don't know
10 what it was referred to at the time. Before --
11 you're talking about before we did the submission
12 on June 10, 2013?
13 It's been a long time. The drug names
14 have changed, but before June 10, 2013,
15 oncologists did give -- I think it might have been
16 called MK-3475 on -- so I guess that's what you
17 were asking me. Yes. I don't know that it was
18 called pembrolizumab at that time.
19 Q In your view, is there a difference
20 between MK-3475 and pembrolizumab? It's the same
21 chemical compound, right?
22 A MK-3475 is pembrolizumab, but you asked

1 me -- I wasn't sure if you were referring to at
2 that time. You said before we started our work if
3 oncologists had given pembrolizumab, and I believe
4 at the time it wasn't called pembrolizumab, but
5 yes, oncologists had given this agent to patients
6 with cancer.
7 Q So it's correct that before your work
8 with pembrolizumab, oncologists had already given
9 pembrolizumab to cancer patients?
10 MR. MILLER: Objection. Form.
11 A They had given pembrolizumab, or a
12 variation, MK-3475, or a different name for it, I
13 guess, to patients with cancer.
14 Q And is it correct that before the work
15 of any of your team, oncologists had already given
16 pembrolizumab to cancer patients?
17 A With work of any of my team.
18 Can you repeat the question?
19 Q Is it correct that before your team's
20 work with pembrolizumab, oncologists had already
21 given pembrolizumab to cancer patients?
22 A Before our work -- what does "our work"

1 mean?
2 Q When did you start working with
3 pembrolizumab?
4 A You mean actually administering the
5 MK-3475? Is that what you mean by "work with"?
6 Q When did you start administering
7 pembrolizumab to cancer patients?
8 A Sometime during the conduct of the
9 clinical trial. I can't give you the exact date
10 of the first administration.
11 Q Can you give me the year of the first
12 administration?
13 A 2013 -- no. Actually, I can tell you
14 that we -- I can tell you approximately that time
15 frame. I can't give you the exact date.
16 Q Do you realize I'm not asking you the
17 exact date, right?
18 A Yeah. I'm giving you the time frame
19 because these things sometime take a lot longer in
20 real life than it does on paper, so I can give you
21 a time frame.
22 Q Do you know what my question was to you?

1 A Can you give me the exact year, and I
2 said I can't give you the exact year, I can give
3 you a time frame.
4 Q That wasn't my question.
5 A Oh, yes.
6 Q Can you give me the year when your team
7 first administered pembrolizumab to cancer
8 patients?
9 A Okay. So now we're talking about teams,
10 and I'd like to only speak for myself because I
11 don't know who you're referring to when you say
12 "team."
13 As far as I can remember, it would have
14 been sometime within this study, the clinical
15 trial. And I think when you say "pembrolizumab,"
16 we're talking about MK-3475.
17 Q So when I refer to "your team," I'm
18 referring to the same team that you testified
19 about in your Declaration, for example, in
20 paragraph 14.
21 I see you turning to your Declaration.
22 A Yes, I am turning to my Declaration.

1 Q You are aware that throughout your
2 Declaration you refer to, quote, my team, right?
3 MR. MILLER: Objection. Form.
4 A Yes, I refer to my team.
5 Q So that's the team I'm referring to.
6 A Okay.
7 Q So let me try my question again.
8 Do you know when your team first
9 administered pembrolizumab to a cancer patient?
10 MR. MILLER: Objection. Form.
11 A So in paragraph 14, my team -- we're
12 talking about the IND application, which includes
13 regulatory people. When you ask me when MK-3475
14 was administered, I usually think about that as
15 like given, which is not really the same team. So
16 I get confused when you use the word "team."
17 But I can tell you that the first
18 patient or subject on the trial that we're
19 referring to received MK-3475 approximately in the
20 2013-2014 time frame.
21 Q Did the first patient in the trial
22 receive pembrolizumab in 2013?

1 A I would have to review again any of the
2 source documents for the date.
3 Q So sitting here today you don't know
4 whether or not the first patient to receive
5 pembrolizumab in the trial received it in 2013,
6 right?
7 A Sitting here today I would have to look
8 at some documents and records.
9 Q So sitting here today you don't know
10 when the first patient received pembrolizumab
11 in --
12 A Sitting here today --
13 Q -- in the trial, right?
14 A Okay. Sorry. Regroup. What was your
15 question again?
16 Q Sitting here today --
17 A Yes, I'm sitting here today.
18 Q -- you do not know when the first
19 patient received pembrolizumab in the trial,
20 right?
21 A Sitting here today, right this minute, I
22 cannot tell you the exact date on when the first

1 patient in the trial received the drug MK-3475.
2 Q Sitting here today, can you tell me the
3 year when the first patient received pembrolizumab
4 in the trial?
5 A Sitting here today, I would need some
6 access or a review to confirm the year.
7 Q Sitting here today, do you know the year
8 when the first patient received pembrolizumab in
9 the trial?
10 A The issue with the year is that the year
11 is 2013-2014. So if I knew the exact date, I
12 could tell you the year.
13 Q So let me try my question again.
14 Do you know whether or not the first
15 patient in the trial received pembrolizumab in
16 2013?
17 A Sitting here today, I cannot tell you if
18 the first patient in the trial received MK-3475 in
19 2013.
20 Q And MK-3475 is pembrolizumab, right?
21 A Some people -- yeah, at some point it
22 became known as pembrolizumab. I don't know -- I

1 can't remember when.
2 Q I'm not asking you when, but it's the
3 same chemical compound, MK-3475 and pembrolizumab,
4 they're the same chemical compound, right?
5 MR. MILLER: Objection. Form.
6 A That's my understanding.
7 Q Okay.
8 A Okay.
9 Q So sitting here today, do you know
10 whether or not the first patient in the trial
11 received pembrolizumab in 2014?
12 A Sitting here today, I would need to look
13 at the records again to see exactly when the very
14 first dose was given.
15 Q I'm not asking you about exactly when
16 the very first dose was given. Different
17 question.
18 A Okay.
19 Q Sitting here today, do you know whether
20 the first patient in the trial received
21 pembrolizumab in 2014?
22 A Sitting here today, the first patient

1 received -- oh, on this trial received MK-3475
2 somewhere in 2013 or 2014.
3 Q Okay. I'm not asking you about 2013.
4 My question is about 2014.
5 Sitting here today, do you know whether
6 or not the first patient to receive pembrolizumab
7 in the trial received it in 2014?
8 A I cannot tell you if the first patient
9 on this trial received the first infusion of
10 MK-3475 in 2014.
11 Q Okay. And again, by MK-3475 you're
12 talking about pembrolizumab, right?
13 A At the time it was referred to as
14 MK-3475.
15 Q But they're the same chemical compound,
16 right?
17 MR. MILLER: Objection. Form.
18 A As far as my understanding.
19 Q They're the same chemical compound,
20 right?
21 MR. MILLER: Objection. Form.
22 A As far as my understanding.

1 Q I'm not sure that's an answer to my
2 question.
3 MK-3475 and pembrolizumab are the same
4 chemical compound, right?
5 MR. MILLER: Objection. Form. Asked
6 and answered.
7 A It's -- as far as my understanding.
8 Q As far as your understanding, what?
9 A As far as my understanding, MK-3475 is
10 the same as pembrolizumab, which it wasn't at the
11 time, at the time it was not called pembrolizumab.
12 Q And in your Declaration, you refer to,
13 quote, my team, several times, right?
14 A Yes.
15 Q And is it your testimony here today that
16 when you refer to "my team" in your Declaration,
17 you're referring to different teams at different
18 points in your Declaration?
19 A In my Declaration, when I say "team,"
20 I'm referring to people have different jobs on the
21 team. So I didn't specifically say I and this
22 person and that person.

1 Q Let's make sure this is really clear.
2 Turning to paragraph 5 of your
3 Declaration on page 3 you used the term "my team."
4 Do you see that?
5 A I'm sorry, what paragraph?
6 Q Turning to paragraph 5 --
7 A Paragraph 5, on page 3.
8 Q -- of your Declaration on page 3 --
9 A Uh-humh.
10 Q -- you used the term "my team." Do you
11 see that?
12 A Oh, you mean my team's June 10th, 2013,
13 submission?
14 Q You see that, right?
15 A Yes.
16 Q When you refer to "my team" there, who
17 were the individuals that you were referring to by
18 name?
19 A The team is the people who ultimately
20 are responsible for the submission.
21 Q And what are their names?
22 A The people who are responsible? The

1 people who are responsible are Jenn Durham and
2 then Dr. Diaz. Those are people that, primarily
3 the people who are responsible for it. Whether
4 somebody else submits the button or puts it on --
5 you know, that's the team. That's the core
6 responsible team.
7 Q So who are the members of the team that
8 you were referring to in paragraph 5?
9 A Dr. Durham's team and Dr. Diaz's team.
10 So that's me and Dr. Diaz, and then the regulatory
11 team is run by Dr. Durham.
12 Q Who's on Dr. Durham's team, as you're
13 referring to it here in paragraph 5?
14 MR. MILLER: Objection. Form.
15 A I can't recall back in 2013 who her team
16 members were.
17 Q And who was Dr. Diaz's team as you were
18 referring to in paragraph 5?
19 MR. MILLER: Objection. Form.
20 A Well, it involved at least Dr. Diaz and
21 myself and Dr. Durham.
22 Q Who else does it involve?

1 A I can't specifically say.
2 Q When you wrote "my team" here, did you
3 have in mind specific individuals?
4 A I had specific individuals in the sense
5 that there are people responsible for the
6 submissions, Dr. Durham's team and Dr. Diaz's
7 team. Dr. Durham is part of Dr. Diaz's team. I
8 am part of Dr. Diaz's team. So I'm primarily
9 referring to the responsible people.
10 Now, I can't say if there are other
11 individuals because Hopkins has a lot of
12 individuals who work on a lot of different things,
13 but when I'm talking about "my team," I'm talking
14 about the responsible members.
15 Q In paragraph 11 of your Declaration, at
16 page 5, you refer to "my team."
17 A I'm sorry, one more time. Paragraph 5
18 of --
19 Q No.
20 A I'm sorry.
21 Q Let me turn your attention to paragraph
22 11 of your Declaration at page 5.

1 A Paragraph 11 at page 5. Yes.
2 Q Do you see there you refer to, quote, my
3 team?
4 A Yes.
5 Q Who were the members of your team that
6 you were specifically referring to here in
7 paragraph 11 of your Declaration?
8 A Who designed the study? I can remember
9 myself and Dr. Diaz specifically. Well, and
10 typically when you design a study, you have a
11 statistician that helps you with numbers. Those
12 are the people I can remember specifically.
13 Q So who were the people that you were
14 referring to when you wrote "my team" in paragraph
15 11 of your Declaration?
16 A I can specifically state that it would
17 at least involve me and Luis, or Dr. Diaz, I'm
18 sure.
19 Q Okay. And when you prepared your
20 Declaration, you prepared it with thought and
21 care, right?
22 A I did.

1 Q And when you prepared your Declaration,
2 you were conscious of the choice of words that you
3 used, right?
4 A I tried to be, but --
5 Q And when you prepared your Declaration,
6 you were conscious of the terminology that you
7 used in your Declaration, right?
8 A Yes.
9 Q And when you signed your Declaration,
10 you weren't confused about the terminology or
11 phrasing that you used in your Declaration, right?
12 A Well, sometimes the clarity of words
13 might have been better used by pronouns with
14 specific names. I don't --
15 Q When you signed your Declaration, you
16 weren't confused about the terminology or phrasing
17 that you used in your Declaration, right?
18 A When I signed my Declaration and used
19 words to like "teams," that just meant that I did
20 not do everything myself and included other
21 individuals. So that's how -- so "team" might be
22 different depending on where it is in the

1 document.
2 Q Do you understand that I'm not asking
3 about "team"?
4 A No, I don't understand.
5 Q So let me try my question again.
6 When you signed your Declaration, you
7 weren't confused about the terminology or phrasing
8 that is used throughout your Declaration in all of
9 the paragraphs of your Declaration, right? Or
10 were you confused?
11 A I -- some of the words could have been
12 more specific.
13 Q Are you finished with your response?
14 A I think so.
15 Q Okay. So let's turn to paragraph 13 of
16 your Declaration, at page 6. Let me know when
17 you're there.
18 A Page 6, 13.
19 Q Are you there?
20 A Yeah.
21 Q You see that you use the terminology,
22 quote, my team in paragraph 13?

1 A Yes.
2 Q And who were the members of your team
3 that you were referring to in that paragraph?
4 A I can tell you it at least involved me
5 and Luis and the statistician.
6 Q Okay. And I'm not asking for "at
7 least," I want to know everyone you were thinking
8 about when you wrote the terminology, quote, my
9 team, and signed your Declaration.
10 Who are those people that you were
11 thinking about as being a part of, quote, my team
12 in paragraph 13 of your Declaration?
13 A I can say that my team included me and
14 Luis and our statistician. I cannot specifically
15 say -- those are the ones that I can definitely
16 remember.
17 Q Okay. Turning your attention to
18 paragraph 14 of your Declaration, do you have
19 that?
20 A Yes.
21 Q And you see there that you used the
22 terminology, quote, my team?

1 A Yes.
2 Q And in that paragraph, who were the
3 members of, quote, my team that you were
4 specifically referring to when you chose this
5 language for your Declaration and signed it?
6 A My team would be the people who are
7 responsible for the IND application.
8 Q And who were those people, by name?
9 A Again, it would be Dr. Diaz and myself.
10 The people required to file an IND would be
11 Dr. Durham's team.
12 Q And who was on Dr. Durham's team?
13 A I can't remember Dr. Durham's -- I just
14 can't remember. It was a long time ago. I don't
15 know who was on her team.
16 Q Was Dr. Pardoll on her team?
17 A Dr. Pardoll is not supervised by
18 Dr. Durham.
19 Q I didn't ask whether or not Dr. Pardoll
20 was supervised by Dr. Durham, I asked a different
21 question.
22 So my question is, was Dr. Pardoll on

1 Dr. Durham's team?
2 A Okay. So, again, this goes back to what
3 we mean by -- when I'm saying "team," I mean,
4 Dr. Durham's group is a regulatory group, so it's
5 kind of her supervisory role over her regulatory.
6 So that's what I mean by when I say --
7 that's not even in here. We're talking about
8 Dr. Durham's team, which is not even on here. I
9 think it depends on where we're using the word
10 "team" in the context of what we're talking about.
11 Q And, Doctor, you do appreciate my
12 questions --
13 A No, I don't.
14 Q Okay. Okay. Let me make it clear.
15 My question is specifically about your
16 use of the terminology, quote, my team in
17 paragraph 13 of your Declaration.
18 A Paragraph 14. 14, or 13? I'm sorry, I
19 thought you said 14.
20 Q You're right. My question is
21 specifically about paragraph 14.
22 A You can see where "team," depending

1 where you use it, can be very confusing.
2 Q I can't really.
3 So let's turn to -- we're looking at
4 paragraph 14 --
5 A Yes, okay.
6 Q -- of your Declaration.
7 A Yes.
8 Q And you say here that it includes
9 Dr. Durham's team.
10 A That's -- an IND is drafted by the
11 regulatory team, which is run by Dr. Durham.
12 Q You say here --
13 A Yes.
14 Q You testified that when you used the
15 terminology "my team" in paragraph 14, you were
16 referring to, in part, Dr. Durham's team, right?
17 A I'm referring to, in part, Dr. Durham's
18 team, the regulatory team, yes.
19 Q And my question is, was Dr. Pardoll a
20 member of Dr. Durham's team?
21 A When you say Dr. Durham's team and I'm
22 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

1 Dr. Durham's regulatory team. And when I say
2 "team" when referring to Dr. Durham, I'm talking
3 about the people that she supervises.
4 Q Was Dr. Topalian a member of
5 Dr. Durham's regulatory team?
6 A Dr. Topalian was not supervised by
7 Dr. Durham and not part of her regulatory team,
8 which I'm referring to the people that she
9 supervises.
10 Q Was Dr. Papadopoulos a part of
11 Dr. Durham's regulatory team?
12 A Dr. Papadopoulos was not part of
13 Dr. Durham's regulatory team.
14 Q Was Dr. Kinzler part of Dr. Durham's
15 regulatory team?
16 A Dr. Kinzler was not part of Dr. Durham's
17 regulatory team.
18 Q Was Dr. Vogelstein part of Dr. Durham's
19 regulatory team?
20 A Dr. Durham was not part of Dr. -- say
21 that one more time. Who are we talking about now?
22 Dr. Vogelstein?

1 Q Was Dr. Vogelstein a part of
2 Dr. Durham's regulatory team?
3 A Dr. Vogelstein was not a part of
4 Dr. Durham's regulatory team, the team for which
5 she supervised.
6 Q Let me turn your attention to paragraph
7 19 of your Declaration. Let me know when you have
8 it. Do you have it?
9 A I'm sorry, you said paragraph 19?
10 Q Yes.
11 A Okay. Yes.
12 Q Do you see in paragraph 19 you use the
13 terminology, quote, my team?
14 A I guess I did use the word "my team."
15 Q And when you used the phrasing "my
16 team," which members of the team by name were you
17 referring to in this paragraph of your
18 Declaration?
19 A I can say at least myself and Luis, as
20 far as I know.
21 Q Are you not sure which members of the
22 team you meant when you wrote this in your

1 Declaration and signed it?
2 A I mean that's what I meant, really any
3 members. I'm not aware that I was --
4 Q When you say you meant any members, what
5 does that mean? Is that anyone employed by JHU?
6 A No. No, that's not what I'm saying.
7 I'm just saying -- I mean specifically?
8 Q Right. Specifically I'd like to know
9 when you wrote the term "my team" in paragraph 19,
10 who were the members that you were referring to?
11 A It included myself and Dr. Diaz.
12 Q Did it include anyone else?
13 A (Shaking head.)
14 Q I see you shaking your head.
15 A I mean it could have included other
16 people. When I was writing this sentence, was I
17 thinking about all of these individuals? I wasn't
18 thinking of all of these individuals.
19 Q And all of what individuals are you
20 talking about?
21 A Like, you know, anybody at Hopkins. I
22 don't know. I just said my team were not employed

1 by Merck or any other company to conduct our
2 initial study.
3 Q When you wrote "my team," sitting here
4 today, which people do you think this is referring
5 to, or did you intend it to refer to?
6 A I can only say that I was not paid by
7 Merck, and I do not believe Luis was paid by
8 Merck.
9 Q Do you know what question I asked you?
10 Do you know what question I asked you?
11 A Can you repeat the question?
12 Q When you wrote "my team," sitting here
13 today, which people do you think this is referring
14 to, or did you intend it to refer to?
15 A Sitting here today, I believe I meant I
16 was talking about myself and Dr. Diaz.
17 Q Can you turn your attention to paragraph
18 26 of your Declaration?
19 A 26, page 11.
20 Q Do you have it?
21 A Yes.
22 Q Do you see there that you referred to

1 and used the term, quote, my team?
2 A Yes.
3 Q And who were you referring to in this
4 paragraph of your Declaration by the term "my
5 team"?
6 A I think this could refer to anybody
7 involved. When I say "my team," it would be
8 hopeful that the hypothesis would be supported.
9 Q And I'm not asking what it could refer
10 to, I'm asking specifically what did it refer to
11 when you used this terminology to prepare your
12 Declaration and you signed your Declaration.
13 A The people involved in the study.
14 Q And which people are that? Who are
15 those people?
16 A Well, there -- that is -- a lot of
17 people were hopeful. It would include me, it
18 would include all the inventors, it would include
19 the regulatory team, it would include anyone who
20 was involved in the protocol would be hopeful that
21 it would work.
22 Q So other than the named inventors, the

1 regulatory people, who did you consider involved
2 with the protocol?
3 A I can't give you specific names.
4 Q Okay.
5 A There's a lot of people involved in a
6 protocol.
7 Q When you refer to "my team" in paragraph
8 26 of your Declaration, can you give me specific
9 names as to who those people were that you're
10 referring to?
11 MR. MILLER: Objection. Form. Asked
12 and answered.
13 A Specifically? I would say people
14 involved in the protocol.
15 Q And who is that?
16 A Myself, all the people who were involved
17 in the hypothesis.
18 Q And who is that?
19 A Well, it dates back to the idea. Luis.
20 It's kind of hard to refer to my superiors as my
21 team. Dr. Durham, the research nurse, the
22 inventors. Everyone was hopeful that it would --

1 could potentially work.
2 Q When you say "inventors," who are you
3 referring to?
4 A The people involved in the ideas.
5 Q Who was that?
6 A Luis, Bert, Nick, Suzanne, Drew. Did I
7 miss any of the inventors?
8 Q Are you finished with your answer?
9 A I think I missed Ken. And Ken.
10 Q So you were just turning to the '393
11 patent; is that right?
12 A Actually, whatever this one is.
13 Q What one is that?
14 A 1030, I think.
15 Q Okay.
16 A I think it's on both, actually.
17 Q Now, using the same definition of "my
18 team" that you used in paragraph 26 of your
19 Declaration, is it correct that before your team's
20 work with pembrolizumab, oncologists had already
21 given pembrolizumab to cancer patients?
22 A MK-3475 had been given to cancer

1 patients as part of experimental trials.
2 Q Is it correct that before your team's
3 work with pembrolizumab, oncologists had already
4 given pembrolizumab to cancer patients?
5 A Are we going back to the "my team"? I
6 guess it depends on which "my team" you're talking
7 about, but it is correct that before we
8 administered MK-3475 on this clinical trial, that
9 oncologists had given MK-3475 to patients with
10 cancer.
11 Q Okay. So let me try my question using
12 the same definition of "my team" that you used in
13 paragraph 26 of your Declaration.
14 A Okay.
15 Q Is it correct that your team's -- let me
16 start that again.
17 Using the definition of "my team" that
18 you had in paragraph 26 of your Declaration, is it
19 correct that before your team's work with
20 pembrolizumab, oncologists had already given
21 pembrolizumab to cancer patients?
22 A It is correct that before -- can you

1 repeat the question? We were not the first people
2 to give MK-3475 to cancer patients. Is that what
3 you're asking?
4 Q No, but that's -- that's fine. Thank
5 you for that.
6 Do you have Exhibit 1005 in front of
7 you?
8 A Yes.
9 Q Would you agree that at the time of the
10 study records posting, MSI testing was already
11 standardized and performed in CLIA-certified
12 laboratories without the need for assay
13 development?
14 MR. MILLER: Objection. Form.
15 A I'm sorry, what was the question again?
16 Q Would you agree that at the time of the
17 study records posting on clinicaltrials.gov, MSI
18 testing was already standardized and performed in
19 CLIA-certified laboratories without need for assay
20 development?
21 A At the time --
22 MR. MILLER: I'm sorry.

1 Objection. Form.
2 Go ahead.
3 A At the time of this posting in June of
4 2013, MSI testing could be performed in
5 CLIA-certified labs; is that what you're asking?
6 Q No.
7 A No, no.
8 Q Would you agree that at the time of the
9 study records posting, MSI testing was already
10 standardized and performed in CLIA-certified
11 laboratories without need for assay development?
12 MR. MILLER: Objection. Form.
13 A I think it depends on the context.
14 There -- at the time of 2013, there were
15 CLIA-certified -- MSI testing could be done in
16 CLIA-certified labs.
17 Am I still missing it?
18 Q You are.
19 At the time of the study records
20 posting, would you agree that MSI testing was
21 already standardized?
22 MR. MILLER: Objection. Form.

1 A At the time of the posting, MSI testing
2 could be performed in CLIA-certified labs. Not
3 all MSI testing was standardized.
4 Does that make sense?
5 Q So would you agree that at the time of
6 the study records posting, MSI testing was already
7 standardized and performed in CLIA-certified
8 laboratories without need for assay development?
9 MR. MILLER: Objection. Form.
10 A That's actually a very complicated
11 question you're asking.
12 At the time of this posting, MSI testing
13 could be performed in CLIA-certified labs. And
14 that is, in a CLIA-certified lab, they do
15 standardization. So I don't know if that's what
16 you mean.
17 Q At the time of the study records
18 posting, do you agree that MSI testing was
19 standardized?
20 MR. MILLER: Objection. Form.
21 A I don't -- I don't know that I agree
22 that it was standardized. You could -- at the

1 time of this posting, you could test for MSI in a
2 CLIA-certified lab.
3 Q I just want to make sure I understand
4 your testimony.
5 At the time of the study records
6 posting, do you agree that MSI testing was already
7 standardized?
8 MR. MILLER: Objection. Form. Asked
9 and answered.
10 A I think that there may be some technical
11 understanding issues.
12 At the time of the testing -- I mean --
13 I'm sorry, at the time of this posting in
14 June 2013, you could get CLIA-certified testing of
15 MSI, microsatellite instability status.
16 Q I'll try one more time.
17 At the time of the study records
18 posting, would you agree that MSI testing was
19 already standardized and performed in
20 CLIA-certified laboratories without need for assay
21 development?
22 MR. MILLER: Objection. Form. Asked

1 and answered.
2 A At the time of this posting, you could
3 get MSI testing in a CLIA-certified lab.
4 Q And was MSI testing already standardized
5 at the time of the posting?
6 A What do you mean by "standardized"?
7 MR. MILLER: Sorry.
8 THE WITNESS: Okay.
9 MR. MILLER: But that's fine.
10 Q Do you not know what the term
11 "standardized" means?
12 A I think it has some technical aspects to
13 it when we're talking about labs, so I guess what
14 do you mean by "standardized"?
15 Q Let me try it this way.
16 If someone said to you that at the time
17 of the study records posting, quote, MSI testing
18 is already standardized and performed in
19 CLIA-certified laboratories without need for assay
20 development, end quote, would you believe that's a
21 truthful and correct statement?
22 MR. MILLER: Objection. Form.

1 A If someone told me in June 2013 if you
2 could perform MSI in a CLIA-certified -- can you
3 repeat the question? I'm sorry.
4 Q Sure.
5 If someone told you at the time of the
6 study records posting that, quote, MSI testing is
7 already standardized and performed in
8 CLIA-certified laboratories without need for assay
9 development, end quote, do you believe that would
10 be a truthful and accurate statement?
11 MR. MILLER: Objection. Form.
12 A I believe that it requires context.
13 Q So sitting here today, do you have any
14 understanding what it means, quote, MSI testing is
15 already standardized and performed in
16 CLIA-certified laboratories without need for assay
17 development, end quote?
18 MR. MILLER: Objection. Form.
19 A I can tell you in 2013 you could get MSI
20 testing in a CLIA-certified lab.
21 Q And can you tell me whether or not you
22 understand the sentence, quote, MSI testing is

1 already standardized and performed in
2 CLIA-certified laboratories without need for assay
3 development, end quote?
4 A I could tell you that MSI testing in
5 2013 could be performed in CLIA-certified labs.
6 You're talking about the standardization part, is
7 that what you're asking about?
8 Q My statement talked about standardized,
9 right. Do you recall that?
10 A Yes. I'm -- I guess I'm trying to
11 figure out what you're asking about
12 standardization.
13 Q Are you confused about the terminology
14 "standardized"?
15 MR. MILLER: Objection. Form.
16 Go ahead.
17 A I'm confused -- I just -- can you just
18 repeat the question, maybe in a different way?
19 Q Do you understand the statement:
20 MSI testing is already standardized and
21 performed in CLIA-certified laboratories without
22 need for assay development?

1 A I understand that to mean that you can
2 get MSI testing in a CLIA-certified lab.
3 Q Okay. And was that true at the time of
4 the study records posting?
5 A That you could get MSI testing in a
6 CLIA-certified lab at the time of the study
7 posting? You could get MSI testing in a
8 CLIA-certified lab at the time of the posting.
9 Q And was that MSI testing already
10 standardized at the time of the posting?
11 MR. MILLER: Objection. Form.
12 A Was it standardized? I think it depends
13 on the context.
14 Q Have you ever wrote in the context of
15 any of your work with pembrolizumab that MSI
16 testing was standardized?
17 A I would have to doublecheck the wording
18 that was used in any of my works. It would
19 require that I look at a lot of documents.
20 Q Do you recall ever writing in the
21 context of any of your work with pembrolizumab
22 that MSI testing is already standardized and

1 performed in CLIA-certified laboratories without
2 need for assay development?
3 A I can recall that we said that MSI
4 testing could be performed in CLIA-certified labs.
5 Q My question is different. It's not
6 about if it could be performed, I'm asking you do
7 you recall ever saying in the context of any of
8 your work with pembrolizumab that MSI testing is
9 already standardized and performed in
10 CLIA-certified laboratories without need for assay
11 development?
12 A That would be -- depend on the context.
13 Q Do you ever recall saying it in any
14 context?
15 A That MSI testing could occur --
16 Q No.
17 A -- in CLIA-certified labs?
18 Q No. Try it one more time.
19 Do you ever recall in any context ever
20 saying MSI testing is already standardized and
21 performed in CLIA-certified laboratories without
22 need for assay development?

1 A MSI testing in 2013 could be performed
2 in CLIA-certified labs.
3 Q That's your response to my question?
4 A I guess I'm not understanding your
5 nuance, but yes, you could perform MSI testing in
6 CLIA-certified labs.
7 Q At the time of the study records
8 posting, would you agree that pembrolizumab was
9 known strongly to enhance T lymphocyte immune
10 responses in cultured blood cells from healthy
11 donors, cancer patients and primates?
12 A You're asking me to remember what I knew
13 at that time? Say the question again. At the
14 time of this posting, did I know that
15 pembrolizumab, what? Say that one more time.
16 Q At the time of the study records
17 posting, would you agree that pembrolizumab was
18 known to strongly enhance T lymphocyte immune
19 responses in cultured blood cells from healthy
20 human donors?
21 A I cannot specifically say that on
22 June 2013, that I knew that.

1 MR. MILLER: Counsel, is this a good
2 time for a lunch break?
3 MR. RATLIFF: Not for me. I have some
4 more questions.
5 MR. MILLER: Do you need a break,
6 Dr. Le?
7 THE WITNESS: What time is it? How long
8 have we been doing this? Three hours?
9 MR. MILLER: Three hours plus.
10 THE WITNESS: It's almost 1:00. Yeah,
11 actually it would be a good time to probably eat
12 something.
13 MR. RATLIFF: You sure you don't want to
14 finish a few more questions about this and then we
15 can start -- then we can take our lunch?
16 THE WITNESS: I just want to have
17 something very small, if that's okay. I would
18 like to keep going so we can finish. Can we just
19 have a quick break to eat?
20 MR. RATLIFF: Sure.
21 (A recess was taken at 12:40 p.m.)
22 AFTERNOON SESSION (1:49 p.m.)

1 BY MR. RATLIFF:
2 Q Welcome back, Doctor.
3 A Thank you.
4 Q Doctor, during the lunch break, did you
5 discuss any of my questions or this case with
6 counsel?
7 A I did not discuss the questions or the
8 case.
9 Q Okay. Now, at the time of the study
10 records posting, was it known that pembrolizumab
11 strongly enhances T lymphocyte immune responses in
12 cultured blood cells from cancer patients?
13 A Was it known? Did I know, or was it
14 known?
15 Q Was it known.
16 A I don't know what was known at what
17 time.
18 Q Okay. At the time of the study records
19 posting, did you know whether or not pembrolizumab
20 enhances T lymphocytes immune responses in
21 cultured blood cells from cancer patients?
22 A I do not recall if -- at the time of the

1 posting if I knew at the exact time of this
2 posting.
3 Q Okay. Do you know whether by July 10,
4 2015, it was known that pembrolizumab strongly
5 enhances T lymphocyte immune responses in cultured
6 blood cells from cancer patients?
7 A I -- can you repeat the question? I'm
8 sorry.
9 Q Do you know whether by July 10, 2015, it
10 was known that pembrolizumab strongly enhances T
11 lymphocyte immune responses in cultured blood
12 cells from cancer patients?
13 A I don't remember specifically. I don't
14 remember.
15 Q Do you have any general recollection?
16 A I don't have general recollection of the
17 dates.
18 Q At the time of the study records
19 posting, was there accumulating evidence showing
20 the correlation between tumor-infiltrating
21 lymphocytes in cancer tissue and favorable
22 prognosis in various malignancies?

1 A Was -- was it known at the time of this
2 posting, this submission -- can you repeat the
3 question?
4 Q Sure.
5 At the time of the study records
6 posting, was there accumulating evidence showing a
7 correlation between tumor-infiltrating lymphocytes
8 in cancer tissue and favorable prognosis of
9 various malignancies?
10 A At the time of the posting was there
11 accumulating evidence? Say that one more time.
12 Q At the time --
13 A T cells -- I'm sorry, go ahead.
14 Q At the time of the study records
15 posting, was there accumulating evidence showing a
16 correlation between tumor-infiltrating lymphocytes
17 in cancer tissue and favorable prognosis in
18 various malignancies?
19 A I don't recall the dates.
20 Q Do you have any recollection when that
21 was recalled -- sorry.
22 Do you have any recollection when that

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

1 A Whatever is in this entire document
2 is -- the cover page says this is a new IND
3 submission.
4 Q So do you know what Exhibit 1116 is?
5 A Exhibit 1116 appears to be the new IND
6 submission dated May 9, 2013.
7 Q And is this exhibit the IND submission
8 that you referred to in your Declaration?
9 A There is reference to an IND
10 application, yes.
11 Q So Exhibit 1116, is this the IND
12 submission that you referred to in your
13 Declaration?
14 A This appears to be an IND submission. I
15 couldn't go through all the pages.
16 Q Okay. You can go through the pages if
17 you would like.
18 A Okay.
19 Q Just understand, I'm not asking if it
20 appears to be an IND submission. I'm asking you
21 is this the IND submission that you referred to in
22 the sworn testimony in your Declaration.

1 A I am referring to an IND submission
2 when -- back when we submitted the IND for the
3 clinical trial.
4 Q Okay. And is this the IND submission
5 that you were referring to in your Declaration,
6 Exhibit 1116?
7 A This looks like the IND submission, but
8 I have not had a chance to look through it in its
9 entirety.
10 Q Okay. Well, look through it in its
11 entirety and let me know.
12 A (Reviewing.)
13 This appears to be the IND submission.
14 Q And the IND was submitted on May 9,
15 2013; is that correct?
16 A The IND is -- the date on the IND is
17 May 9th, on this letter, cover letter.
18 Q Was the IND submitted on May 9, 2013?
19 A What do you mean by "submitted"?
20 Q Was the IND filed on May 9, 2013?
21 A Was the IND filed? There is a date
22 associated with this IND of May 9th, 2013.

1 Q Okay. So my question is, was this IND
2 filed with the FDA on May 9, 2013?
3 A The FDA -- was this IND filed? I can
4 see that the IND -- the letter has a date of
5 May 9, 2013.
6 Q And was the IND that you testify about
7 in your Declaration filed with the FDA on May 9,
8 2013?
9 A The IND that I testified about was filed
10 in 2013.
11 Q And was the IND that you testified about
12 filed on May 9, 2013?
13 A The IND was filed in May of 2013.
14 Q Was the IND filed on May 9, 2013?
15 A I know we filed the IND in May of 2013.
16 Q Do you know whether or not you filed the
17 IND with the FDA on May 9, 2013?
18 A I see that the date is May 9, 2013. I
19 know we filed an IND with the FDA in 2013,
20 May 2013.
21 Q So my question is, do you know whether
22 or not on May 9, 2013, if you filed the IND with

1 the FDA?
2 A I know that, I know that this is dated
3 the 9th. Do I know for sure that it wasn't sent
4 on the 10th, like in the mail and they received
5 it? I don't know what file -- I just know that it
6 was filed in May 2013.
7 Q You don't know what file did you say?
8 A When you say "file," we filed, we
9 submitted --
10 Q Doctor, you realize in your Declaration,
11 paragraph 14, you write that your team filed an
12 IND with the FDA for the proposed clinical trial,
13 right?
14 A Correct.
15 Q So you used the term "filed," right?
16 A Uh-huh.
17 Q So my question simply is, do you know
18 whether or not the IND for the trial was filed on
19 May 9, 2013; yes or no?
20 A I do not know specifically on May 9th,
21 2013, that it was filed on May 9th, 2013.
22 Q Okay. Did you review the IND before it

1 was filed?
2 A I reviewed the IND, parts of the IND
3 before it was filed.
4 Q Did you --
5 A So everything -- it comes in parts, and
6 that's what I was noticing, there was a double of
7 something, like here.
8 Q Did you only review parts of the IND
9 before it was filed or did you review the entire
10 IND before it was filed?
11 A The parts make up the entire IND. I
12 reviewed the IND before it was filed.
13 Q Did you review the entire IND before it
14 was filed?
15 A I reviewed the entire IND before it was
16 filed.
17 Q And when you reviewed the IND before it
18 was filed, did you see any errors in what was
19 written to the FDA?
20 A Did I personally see errors? I don't
21 recall.
22 Q You don't recall if you saw any errors?

1 A I don't recall.
2 Q And sitting here today, are you aware of
3 any errors that are in the IND filing for the
4 trial?
5 A I can't say I'm aware. It's been a long
6 time since I read it cover-to-cover.
7 Q So sitting here today, you're not aware
8 of any errors in the IND filing; is that right?
9 A Sitting here today, I am not aware of
10 any errors in the IND filing.
11 Q Okay. And is it your understanding that
12 when your team submitted the IND to the FDA for
13 trial, your team tried to be truthful and accurate
14 in what it said to the FDA?
15 A Yes.
16 Q And was it the intent for the FDA to
17 rely upon your statements in the IND about the
18 proposed trial?
19 A Can you repeat that? Rely on the
20 statements, like -- I'm sorry, just repeat the
21 question.
22 Q When your team submitted the IND for the

1 trial, was it the intent for the FDA to be able to
2 rely upon the statements that your team made in
3 the IND?
4 A Yes.
5 Q Okay. Can I turn your attention to page
6 37 of 199 in Exhibit 1116.
7 A Page 37. Yes.
8 Q And you see at the bottom there is a
9 section labeled 2.2 MK-3475?
10 A Uh-humh.
11 Q Do you see in the second sentence you
12 and your team write:
13 Accumulating evidence shows a
14 correlation between tumor-infiltrating lymphocytes
15 in cancer tissue and favorable prognosis in
16 various malignancies?
17 A I can read that.
18 Q And you believed that when you submitted
19 it to the FDA, right?
20 A I believe that there were -- was a
21 correlation in some cancers, that
22 tumor-infiltrating lymphocytes, they may be

1 associated with favorable prognosis.
2 Q Don't you say that accumulating evidence
3 shows a correlation?
4 A Accumulating evidence shows -- it says,
5 accumulating evidence shows a correlation.
6 Q Right. So you and your team, you told
7 the FDA that accumulating evidence shows a
8 correlation between tumor-infiltrating lymphocytes
9 in cancer tissue and favorable prognosis in
10 various malignancies, right?
11 A Actually, page 37, it says:
12 Accumulating evidence shows a
13 correlation between tumor-infiltrating lymphocytes
14 in cancer tissue and favorable prognosis.
15 Q Let me try this again. I'm not sure why
16 you didn't read everything that was in my
17 question. Let me try it again.
18 A Okay.
19 Q In the IND that you and your team filed,
20 you represented to the FDA that there was, quote,
21 accumulating evidence shows a correlation between
22 tumor-infiltrating lymphocytes in cancer tissue

1 and favorable prognosis in various malignancies,
2 end quote, right?
3 A Yes, on this document, it says:
4 Accumulating evidence shows a
5 correlation between tumor-infiltrating lymphocytes
6 in cancer tissue and favorable prognosis in
7 various malignancies.
8 Q And that was you and your team's
9 representations to the FDA, right?
10 A Yes.
11 Q And you and your team, you cited
12 references to support that representation, right?
13 A Yes.
14 Q And you cited 36 references to support
15 that representation, right?
16 A I'm not sure.
17 Q Well, do you see that you cited
18 references 12 through 47? Do you see that?
19 A Uh-humh.
20 Q In references 12 through 47, we can find
21 those Reference sections of the IND beginning on
22 exhibit page 74; is that right?

1 A Okay. It was reference what through --
2 I can't remember.
3 Q It was references 12 through 47, right?
4 A Okay.
5 Q Is that right?
6 You're saying okay. I just want to be
7 sure that's an affirmative yes.
8 A I have to flip back, but I believe you
9 said that 12 through 47. What page was the other
10 one?
11 Q So the References section of the IND
12 that we've been looking at begins on page 74,
13 right?
14 A Right, but you told me -- you asked me
15 if it, particular references, so --
16 Q Let's just take it in steps.
17 A Where was that?
18 Q No worries.
19 So let me give you a Post-it, and can
20 you put the Post-it on page 74 of Exhibit 1116?
21 A (Complying.)
22 Q And page 74 begins a section listing

1 references that you cited to the FDA, right?
2 A Yes.
3 Q Okay. So now let's turn our attention
4 to page 37, the exhibit page, and I'll give you
5 another Post-it and you can put on that page.
6 A (Complying.)
7 Q So my question is, when you and your
8 team represented to the FDA that accumulating
9 evidence shows a correlation between tumor-
10 infiltrating lymphocytes in cancer tissue and
11 favorable prognosis in various malignancies, you
12 cited references Nos. 12 through 47 to support
13 that representation, right?
14 A Yes.
15 Q And references No. 12 through 47, if you
16 add them up, that's 36 references, right?
17 A Yes. It's not 35, right, it's 36. We
18 count the first and the last. It would be 36.
19 Q Now, for references 12 through 47, those
20 were all available to the public before July 10,
21 2015, right?
22 A I'm sorry, can you repeat the question?

1 Q For references 12 through 47 --
2 A 12 through 47. Oh, all the references
3 that you just mentioned.
4 Q For references 12 through 47 --
5 A Okay.
6 Q -- those were all available to the
7 public before July 10, 2015, right?
8 A Yes, it appears so.
9 Q And you would agree that another drug
10 similar to pembrolizumab is nivolumab, right?
11 MR. MILLER: Objection. Form.
12 A Nivolumab is similar. There are some
13 similarities, yes.
14 Q You would agree that pembrolizumab is
15 very similar to nivolumab, right?
16 MR. MILLER: Objection. Form.
17 A I would agree that pembrolizumab is an
18 antibody that targets PD-1, and I would agree that
19 nivolumab is an antibody that targets PD-1.
20 Q And wouldn't you also agree that
21 pembrolizumab is very similar to nivolumab?
22 MR. MILLER: Objection. Form.

1 A I don't have direct knowledge of the
2 actual structure to know that it is very similar.
3 I know that pembrolizumab targets PD-1, and I know
4 that nivolumab targets PD-1.
5 Q Didn't you and your team tell the FDA in
6 your IND submission that pembrolizumab is very
7 similar to nivolumab?
8 A In the submission did we say it is very
9 similar -- I don't know that we used the words
10 "very similar."
11 Q And sitting here today, would you agree
12 that pembrolizumab is, quote, very similar to
13 nivolumab?
14 MR. MILLER: Objection. Form.
15 A I would agree that pembrolizumab in some
16 ways is similar to nivolumab.
17 Q So my question is different.
18 Sitting here today, would you agree that
19 pembrolizumab is, quote, very similar to
20 nivolumab, end quote?
21 MR. MILLER: Objection. Form.
22 A I would agree that pembrolizumab is

1 similar to nivolumab.
2 Q And is it correct that you would not
3 agree that pembrolizumab is very similar to
4 nivolumab?
5 MR. MILLER: Objection. Form.
6 A I would agree that pembrolizumab has
7 similarities to nivolumab.
8 Q And is it correct that you would not
9 agree that pembrolizumab is very similar to
10 nivolumab?
11 MR. MILLER: Objection. Form.
12 A I would agree that they are similar.
13 Q Would you agree that they are very
14 similar?
15 MR. MILLER: Objection. Form.
16 A I agree that they are similar.
17 Q Would you agree that they're very
18 similar?
19 MR. MILLER: Objection. Form. Asked
20 and answered now six times.
21 A I -- I agree that they're similar.
22 Q I'm asking you a different question.

1 Would you agree that they're very
2 similar?
3 MR. MILLER: Objection. Form. Asked
4 and answered.
5 A I agree that they're similar.
6 Q Okay. And did you understand when you
7 and your team submitted the IND to the FDA that
8 making a willfully false statement is a criminal
9 offense?
10 A Yes.
11 Q Now, you would agree that pembrolizumab
12 has the same mechanism of action as nivolumab?
13 MR. MILLER: Objection. Form.
14 A I agree that pembrolizumab and nivolumab
15 target PD-1.
16 Q Does pembrolizumab have the same
17 mechanism of action as nivolumab?
18 MR. MILLER: Objection. Form.
19 A All drugs work slightly differently.
20 Q I'm not discussing about all drugs, I'm
21 only asking about two drugs.
22 A Okay.

1 Q Hold on, I'm not finished with my
2 question.
3 To make it clear and easy for you, I'm
4 only asking about two drugs, pembrolizumab and
5 nivolumab. Those are the only two I'm asking
6 about.
7 So my question is, do you agree that
8 pembrolizumab has the same mechanism of action as
9 nivolumab?
10 MR. MILLER: Objection.
11 Q Yes or no?
12 MR. MILLER: Objection. Form.
13 A I agree that they have a similar
14 mechanism of action, that they target PD-1.
15 Q Do they have the same mechanism of
16 action?
17 MR. MILLER: Objection. Form.
18 A Mechanism of action. I agree that they
19 have a similar mechanism of action.
20 Q Would you agree that preclinical studies
21 have suggested that pembrolizumab and nivolumab
22 have similar potency?

1 A Would I agree that preclinical
2 studies -- I can't answer that question.
3 Q Why not?
4 A Because I don't, I don't remember. I
5 don't know.
6 Q So sitting here today, you don't know
7 whether or not preclinical studies have suggested
8 that pembrolizumab and nivolumab have similar
9 potencies?
10 A I don't recall. And can you repeat the
11 question?
12 Q Sitting here today, do you know whether
13 or not preclinical studies have suggested that
14 pembrolizumab and nivolumab have similar potency?
15 A Potency. What do you mean by "potency"?
16 Q The same thing that you and your team
17 meant when you used the term "potency" in the IND
18 that you filed with the FDA.
19 A Okay. So I'd have to see what the
20 reference to the word "potency" is. It's sort of
21 a technical term, so --
22 Q What does that technical term "potency"

1 mean to you?
2 A Can you show me where in the document it
3 is?
4 Q What does the technical term "potency"
5 mean to you? Does it have several meanings in
6 your view?
7 A I think potency -- I don't recall where
8 it is in this very large document, how they're
9 referring to potency, so I'd have to look at it.
10 Q But you know -- I just want to be clear.
11 I'm not asking if you recall where the word
12 "potency" is in the filed IND. I'm not asking
13 that. I'm asking you, do you have a definition
14 for the technical term "potency"?
15 A I don't have a definition for the
16 technical term "potency."
17 Q And does the technical term "potency"
18 mean anything to you in the context of
19 pharmaceutical clinical trials?
20 A Does it have any -- I mean I think it
21 tends to be kind of specific to the protocol, the
22 definition of potency.

1 Q Okay. So let's take a look at page 61
2 of Exhibit 1116.
3 A The same exhibit. Page 61?
4 Q Yes. Let me know when you have it.
5 A Yes.
6 Q You have it?
7 A Uh-humh.
8 Q So I'd like to turn you to Section 8.9,
9 Patient Care Applications.
10 A Okay.
11 Q And do you see the representation that
12 you and your team made to the FDA stating that
13 pembrolizumab has the same mechanism of action as
14 nivolumab?
15 A I do.
16 Q And do you see the representation that
17 your team made to the FDA stating that preclinical
18 studies have suggested that pembrolizumab and
19 nivolumab have similar potency?
20 A I do.
21 Q And do you see the representation that
22 you and your team made to the FDA that PK modeling

1 has suggested similar human PK for pembrolizumab
2 and nivolumab?
3 A I'm sorry, can you point that out again?
4 Q Do you see the representation that you
5 and your team made to the FDA that PK modeling has
6 suggested similar human PK for pembrolizumab and
7 nivolumab?
8 A I do -- no, wait. For MK-3475 and
9 BMS-936558.
10 Q And are you really taking the position
11 that MK-3475 is not pembrolizumab?
12 A No, I'm just saying this is what it says
13 in the document. I can't remember off the top of
14 my head if nivolumab is BMS-936558. You asked me
15 specifically about nivolumab. So I'm just saying
16 I can see that it says MK-3475 has the same
17 mechanism of action as BMS-936518, and in his
18 question, he was referencing nivolumab.
19 And so I was just reading the numbers
20 back because I don't know off the top of my head
21 what the number for nivolumab is.
22 Q So is it your testimony sitting here

1 today that you don't know whether or not
2 BMS-936558 is nivolumab?
3 A I can't without looking at it. And you
4 can easily find it by putting it in a computer to
5 confirm.
6 Q I'm not asking about confirmation; I'm
7 just saying, you, sitting here today as the
8 principal investigator for KEYNOTE-16 and someone
9 that has cited publications regarding nivolumab,
10 is it your testimony that you do not know whether
11 or not BMS-936558 is the chemical compound
12 nivolumab?
13 A I can tell you I cannot tell you for
14 sure right this minute just looking at this
15 number. It makes sense that that's what you're
16 talking about.
17 Q Right. So right now, sitting here
18 today, you don't know whether or not BMS-936558 is
19 nivolumab, right?
20 A I do not, but it would be very easy to
21 look up.
22 Q Okay.

1 (Exhibit 1118 was marked for
2 identification and was retained by Mr. Ratliff.)
3 Q Doctor, I'd like to hand you a document
4 which is a new exhibit that's been marked as
5 Exhibit 1118.
6 Can you let me know if you recognize it?
7 A Document 1118. It is --
8 MR. MILLER: Don't -- the Court Reporter
9 needs to take down all the words you're saying, so
10 just be mindful of that.
11 A (Reviewing.)
12 Form 1571, from Dr. Diaz, dated June 11,
13 2013. And there's a cover letter dated June 3rd,
14 2013, that is -- it says IND 118566S01 signed by
15 Dr. Diaz. And then on it there is an attachment
16 with the tracked version of a protocol.
17 Q So do you recognize Exhibit 1118?
18 A Yes.
19 Q And what do you recognize it to be?
20 A I recognize it to be -- I don't know the
21 technical term for it, but amendment, supplement.
22 I guess I could make sure. It's technically date

1 of submission, so it's a submission to the IND.
2 Q And by the "IND," you're referring to
3 the IND for the trial; is that right?
4 A IND 118566S -- actually, IND118566.
5 Q And that's an IND for KEYNOTE-16; is
6 that right?
7 A What do you mean "for"?
8 Q It's an IND relating to KEYNOTE-16,
9 right?
10 A It is an IND relating to the trial that
11 we've been talking about, yes.
12 Q And did you review this IND before it
13 was submitted to the FDA?
14 A I reviewed the IND submission for the
15 contents of the IND submission.
16 Q Did you review the contents of the IND
17 submission reflected in Exhibit 1118 before it was
18 submitted to the FDA?
19 A I reviewed the Exhibit 1118.
20 Q Are you finished with your response?
21 A Yes.
22 Q Okay. So that wasn't my question.

1 So I'm asking not if you reviewed it at
2 any point in time ever. My question is different.
3 Did you review the IND submission that's
4 reflected in Exhibit 1118 before it was submitted
5 to the FDA?
6 A I reviewed the IND11856 before it was
7 submitted, yes.
8 Q Okay. Now, Doctor, you're familiar with
9 breakthrough therapy designation approvals, right?
10 A I am somewhat familiar with breakthrough
11 therapy designation.
12 Q Well, don't you in your sworn testimony
13 for this case talk about breakthrough therapy
14 designations?
15 MR. MILLER: Objection. Form.
16 Q I think you're paging through your
17 Declaration.
18 A Yep.
19 Q Just sitting here today, without looking
20 at your Declaration, do you know whether or not
21 you testify about breakthrough therapy
22 designations?

1 A I --
2 Q Or do you have to look at your
3 Declaration to determine that?
4 A It's sitting in front of me so I just
5 feel more comfortable looking through my
6 Declaration since you're asking me specifically
7 about what's in my Declaration. Just like if I
8 wanted to confirm a drug, I would doublecheck that
9 nivolumab is 936558.
10 Q Let me try my question again.
11 Sitting here today, without looking at
12 your Declaration, do you know whether or not you
13 testify about breakthrough therapy designations;
14 yes or no?
15 A I can remember discussing breakthrough
16 therapy designations.
17 Q Okay. So now, are you familiar with
18 breakthrough therapy designations?
19 MR. MILLER: Objection. Form.
20 A I'm familiar with some of breakthrough
21 therapy designations, some of the idea of the
22 breakthrough therapy designations.

1 Q And is it your belief that breakthrough
2 therapy designation approvals are rarely given by
3 the FDA?
4 A I do believe that they are rarely given
5 by the FDA.
6 Q Okay. Would you agree that
7 pembrolizumab is one of the first 10 drugs to ever
8 receive a breakthrough therapy designation
9 approval?
10 A Would I agree that pembrolizumab is one
11 of the first 10 drugs that ever received
12 breakthrough therapy designation. I can't comment
13 on that.
14 Q Sitting here today, do you know whether
15 or not pembrolizumab was one of the first 10 drugs
16 to ever receive a breakthrough therapy designation
17 approval?
18 A I don't know if it was one of the first
19 10 drugs.
20 (Exhibit 1130 was marked for
21 identification and was retained by Mr. Ratliff.)
22 Q I'd like to hand you a new document

1 that's been marked as Exhibit 1130. And, Doctor,
2 I can represent to you that document 1130 is a
3 document that we downloaded from the FDA's website
4 entitled "CDER Breakthrough Therapy Designation
5 Approvals Data as of December 31st, 2023."
6 Do you have the document in front of
7 you?
8 A Exhibit 1130?
9 Q That's right.
10 A Yes.
11 Q And can you see in document 1130 that it
12 reports on the breakthrough therapy designation
13 approvals that were given by the FDA as of
14 December 31, 2023?
15 A As of December 31, 2023.
16 Q You see that, right?
17 A Yes, I can see it says "CDER
18 Breakthrough Therapy Designation Approvals."
19 Q And CDER is part of the FDA, right?
20 A I'm not a hundred percent sure how the
21 structure works.
22 Q You don't know whether or not CDER is

1 one part of the FDA; is that your testimony?
2 A I'm not a hundred percent sure.
3 Sometimes I have to doublecheck what departments
4 and things go with which. But it is part of the
5 Government.
6 Q Didn't you testify in your Declaration
7 that breakthrough therapy designations are given
8 by the FDA?
9 A That is my understanding, that they're
10 given by the FDA.
11 Q Okay. And you don't know whether or not
12 CDER is part of the FDA; is that your testimony?
13 A I know that it's part of a structure. I
14 don't know how it is part versus it -- how they
15 interact. But you're telling me it's part of the
16 FDA.
17 Q I'm not asking you if they interact.
18 I'm just asking you do you know whether or not
19 CDER is part of the FDA?
20 A I cannot say for sure that CDER is part
21 of the FDA.
22 Q And do you see here in this document it

1 reflects that Keytruda® was one of the first 10
2 drugs to ever receive breakthrough therapy
3 designation approval?
4 MR. MILLER: Objection. Form.
5 A It says it's one of the first 10
6 drugs --
7 (Reviewing.)
8 You're asking me to count the number of
9 drugs?
10 Q Sure, you can count them.
11 A (Complying.)
12 10. I see what you're talking about.
13 No. 10.
14 Q So here's my question. Do you --
15 A I don't know if it's one of the first
16 10. I just know that -- I don't know that they
17 started giving breakthrough therapy designation
18 November 1, 2013. If that's the case, then it's
19 one of the first 10. But I don't know when the
20 process actually started. Maybe it's been going
21 on since 2002, I don't know.
22 Q So sitting here today, you don't have

1 any idea when breakthrough therapy designation
2 approvals ever started, right?
3 A I don't know. I don't know when they
4 started.
5 Q And you see here in this document on
6 page 2 of Exhibit 1130 that Keytruda®, that
7 pembrolizumab received a breakthrough therapy
8 designation approval on September 4, 2014, right?
9 A Breakthrough therapy designation
10 approval. Keytruda® received a -- I don't know.
11 I don't remember what "BLA" stands for.
12 September -- on this chart, it says September 4,
13 2014, for the treatment of patients with melanoma,
14 essentially, some very -- some set of melanoma.
15 Q You see here in the document on page 2
16 of Exhibit 1130 that pembrolizumab received a
17 breakthrough therapy designation approval on
18 September 4, 2014, right?
19 A I see on the very top of this table,
20 which I presume is part of this table titled on
21 the first page, and that there's nothing in
22 between, that pembrolizumab received breakthrough

1 therapy, a CDER breakthrough therapy designation,
2 and the date, approval date is September 4, 2014,
3 for the treatment of patients with unresectable or
4 metastatic melanoma and disease progression
5 following pembrolizumab and if BRAF V600 mutation
6 positive A B-RAF inhibitor.
7 Q Did you and you team have any
8 involvement in the work to lead to that
9 breakthrough therapy designation approval on
10 September 4, 2014?
11 A I did not -- I do not treat melanoma.
12 Q I didn't ask you if you treated
13 melanoma.
14 Did you and your team have any
15 involvement in the work that led to the
16 breakthrough therapy designation approval for
17 Keytruda® on September 4, 2014?
18 A I can only speak for myself. I did not
19 have any involvement.
20 Q Okay. And I think you said earlier, if
21 you look to the left-hand side of the document, it
22 refers to "BLA." Do you see that?

1 A Uh-humh.
2 Q And is it your testimony that you don't
3 know what "BLA" means?
4 A I would have to look it up to review.
5 Q And do you know what "NDA" means?
6 A Probably. I could guess.
7 Q What's your guess for NDA?
8 A New Drug Application.
9 Q Okay. Do you have a guess for BLA?
10 A Biologics -- again, it's better to look
11 it up rather than guessing.
12 Q Sitting here today, you just don't know,
13 right?
14 A I would need to confirm.
15 Q Do you have a guess or do you need to
16 confirm?
17 A I did guess.
18 Q What was your guess?
19 A That -- biologics. B for biologics.
20 Q Okay. So let's turn to page 3 of
21 Exhibit 1130.
22 A Okay. Page 3.

1 Q And do you see on page 3 it reflects a
2 second breakthrough therapy designation approval
3 for pembrolizumab on October 2nd, 2015?
4 A I see that there is a breakthrough
5 therapy designation on that same BLA125514.
6 Q And do you see that reflects a second
7 breakthrough therapy designation approval for
8 pembrolizumab?
9 A I see that there is an approval for
10 pembrolizumab on October 2nd, 2015, for the
11 treatment of patients with metastatic PD-L1
12 positive non-small cell lung cancer as determined
13 by FDA-approved test with disease progression on
14 or after platinum-containing chemotherapy.
15 Q And that's a different breakthrough
16 therapy designation approval than the one that's
17 reported on page 2 of Exhibit 1130, right?
18 A It's a different one. It is one -- it's
19 a different disease indication.
20 Q And it's a different breakthrough
21 therapy designation approval, right?
22 A I don't know how they number their

1 approvals.
2 Q So sitting here today, do you believe
3 that it's the same breakthrough therapy
4 designation approval?
5 A The same approval? I --
6 Q No, I didn't say that. I just want to
7 stop you.
8 Sitting here today, do you believe that
9 the breakthrough therapy designation approval that
10 we saw on page 2 of Exhibit 1130 is the same as
11 the breakthrough therapy designation approval that
12 we see on page 3 of Exhibit 1130?
13 A It's the same -- it's a different
14 treatment. It's a different patient population.
15 Q And it's a different breakthrough
16 therapy designation approval, right?
17 A There's a different date.
18 Q Because it's a different breakthrough
19 therapy designation approval, right?
20 MR. MILLER: Objection. Form.
21 A I can see that it's a different date.
22 Q Other than that, you don't know whether

1 it's the same or not, right?
2 A It's a different indication.
3 Q But you don't know whether or not it's a
4 different breakthrough therapy designation
5 approval, right?
6 A It's a -- it has a different approval
7 date and a different indication.
8 Q Okay. Let's turn to page 4 of 1130.
9 A Page 4.
10 Q Do you see page 4 reflects a
11 breakthrough designation therapy approval for
12 pembrolizumab that was given on December 18, 2015?
13 A Pembrolizumab, December 18, 2015,
14 treatment of patients -- it was for treatment of
15 patients with unresectable or metastatic melanoma.
16 Q Are you finished your response?
17 A Yes.
18 Q Okay. So let's try to answer my
19 question.
20 Do you see on page 4 of Exhibit 1130 it
21 reflects a breakthrough therapy designation
22 approval for pembrolizumab that was given on

1 December 18, 2015 --
2 A I see --
3 Q -- yes or no?
4 A I see there was an approval on
5 December 18, 2015, for the treatment of patients
6 with unresectable or metastatic melanoma.
7 Q Were you and your team involved in that
8 work?
9 A I was not involved in that work.
10 Q And let's turn back to page 3 of Exhibit
11 1130. For the breakthrough therapy designation
12 approval that's indicated for pembrolizumab on
13 October 2nd, 2015, were you and your team involved
14 in that work?
15 A Say that one more time. I'm sorry, what
16 page are we talking about now?
17 Q We're talking about page 3.
18 A 3.
19 Q So on page 3 of Exhibit 1130 for the
20 breakthrough therapy designation approval that's
21 indicated for pembrolizumab on October 2nd, 2015,
22 were you and your team involved in that work?

1 A I do not recall being involved in this
2 work.
3 Q Were you involved in this work?
4 A I don't remember. I don't remember
5 being involved in it.
6 Q If you could turn to page 7 of Exhibit
7 1130. Let me know when you're there.
8 A Page 7. I'm on page 7.
9 Q Do you recall at the top of page 7 it
10 reflects a breakthrough therapy designation
11 approval for pembrolizumab on March 14, 2017?
12 A I see that there is a March 14, 2017
13 approval for treatment of patients with refractory
14 classical Hodgkins lymphoma or those who have
15 relapsed after three or more prior lines of
16 therapy.
17 Q And when you say "approval," you're
18 talking about an approval for pembrolizumab,
19 right?
20 A No. The March 14, 2017, is in the same
21 table, assuming it's the table that starts on this
22 first page -- actually, I don't know what the

1 approval date refers to. It just says approval
2 date. Is this the approval date -- what's being
3 approved on this date? The breakthrough therapy
4 designation?
5 Q If you don't know, you don't know.
6 A Okay.
7 Q Let's go back to what you were saying.
8 Let's look at Exhibit [sic] 7.
9 A Okay.
10 Q Do you know -- let me ask -- I'll ask
11 the question this way.
12 Page 7, Exhibit 1130, do you see that it
13 reflects a breakthrough therapy designation
14 approval date for pembrolizumab of March 14, 2017?
15 MR. MILLER: Objection. Form.
16 A I think as we went through this table,
17 and then you asked me if it's an approval date,
18 then I'm actually not clear what this approval
19 date is referring to --
20 Q Okay.
21 A -- based on this table.
22 Q So do you see on page 7 of Exhibit 1130

1 it reflects some approval date for pembrolizumab?
2 A Yeah, I don't know what -- what was
3 approved. I don't know what that approval date
4 refers to.
5 Q And you have no clue whether or not that
6 approval refers to the indication that's right
7 next to the date?
8 A I -- yeah, I don't -- I don't know
9 because they weren't clear in their, the way they
10 made the approval date, what they were -- what
11 approval they were referring to.
12 Q So it's your view that this CDR wasn't
13 clear in this table?
14 A This CDR?
15 Q Is it your view that the CDR was not
16 clear --
17 A Oh, you're talking CDER. This table,
18 whoever made this table?
19 Q Correct.
20 Is it your view that whoever made this
21 table was unclear in listing what is reflected by
22 the approval date?

1 A I guess I agree because I'm not sure
2 what is reflected by the approval date.
3 Q So is it your testimony that this chart
4 is unclear to you?
5 A It is my testimony that it is not clear
6 to me what this approval date refers to.
7 Q Okay. And so you don't know whether the
8 approval date refers to a breakthrough designation
9 approval, right?
10 A Correct, I don't know what the approval
11 date is.
12 Q But you do know that -- the first page
13 of the document, there's a heading in bold stating
14 "CDER Breakthrough Therapy Designation Approvals,"
15 right?
16 A Yes. And that's why I thought we were
17 talking about a date that there was a breakthrough
18 therapy designation. But then you asked me is it
19 clear that that is the date of the approval. So
20 then I thought you were talking about an FDA
21 approval for the actual drug, and that's why --
22 then that made me not clear what the approval date

1 is actually referring to.
2 Q Do you know what a breakthrough therapy
3 designation approval date is?
4 A It would be the date that something
5 receives a breakthrough therapy designation.
6 Q Are you sure about that?
7 A I'm assuming that that's what that is.
8 It's a -- if you call it a breakthrough therapy
9 designation date.
10 Q Let me try -- I just want to be sure
11 your testimony is clear.
12 Do you know what a breakthrough therapy
13 designation approval date is?
14 A Do I know exactly what the approval date
15 is?
16 Q No, that's not my question. Do you
17 know -- I didn't say exactly. Let me try my
18 question again.
19 Do you know what a breakthrough therapy
20 designation approval date is?
21 A Do I know -- a breakthrough therapy
22 designation date is the date of the breakthrough

1 therapy designation.
2 Q Maybe you're not hearing me because my
3 question was about a breakthrough therapy
4 designation approval date.
5 So the question is, breakthrough therapy
6 designation approval date, do you know what that
7 is?
8 A Breakthrough therapy designation
9 approval date is the date of the breakthrough
10 therapy designation.
11 Q Are you sure about that?
12 A Well, that's what you just said,
13 breakthrough --
14 Q It's not what I said. I just want to
15 see, are you sure about that? Is that your
16 testimony?
17 A Can you repeat the question?
18 Q Do you know what a breakthrough therapy
19 designation approval date is?
20 A A breakthrough therapy designation
21 approval date is what you said, a breakthrough
22 therapy designation approval date. But I don't

1 know if this approval date refers to a
2 breakthrough therapy designation approval date.
3 You see what I'm saying? Do you -- can you tell
4 definitively what that approval date is referring
5 to?
6 Q Do you know when was the breakthrough
7 therapy designation approval date for the
8 breakthrough therapy designation that you referred
9 to in your Declaration?
10 A I always have to review dates with
11 source. I can't say 2012, 2015, without looking
12 at the -- without looking at documents.
13 Q Is it fair --
14 A Just like I wouldn't be able to tell you
15 if I asked you what you just asked me about any of
16 these dates, if you could remember the actual date
17 even though you've seen it or you believe the
18 source.
19 Q So is it fair to say sitting here today,
20 you do not know when was the breakthrough therapy
21 designation approval date for any of the
22 pembrolizumab indications that you refer to in

1 your Declaration?
2 A I cannot specifically give you the
3 dates --
4 Q Can you generally --
5 A -- today.
6 Q Sitting here today, can you generally
7 give me the dates for any breakthrough therapy
8 designation approval that you referred to in your
9 Declaration?
10 MR. MILLER: Objection. Form.
11 A I cannot generally give you any specific
12 dates without review.
13 Q Do you know whether or not pembrolizumab
14 received a breakthrough therapy designation for
15 unresectable or metastatic MSI high colorectal
16 cancer?
17 A I believe that pembrolizumab received a
18 breakthrough therapy designation -- can you repeat
19 the question?
20 Q Do you know whether or not pembrolizumab
21 received a breakthrough therapy designation for
22 unresectable or metastatic MSI high colorectal

1 cancer?
2 A Pembrolizumab received a breakthrough
3 therapy designation.
4 Q Are you finished with your answer?
5 A Yes.
6 Q Do you know whether or not pembrolizumab
7 received a breakthrough therapy designation for
8 any non-colorectal cancer?
9 A Any non-colorectal cancer ever?
10 Q Yes.
11 A You just told me that it received a
12 bunch of breakthrough therapy designations for
13 non-colorectal cancers.
14 Q I don't think I've told you anything.
15 I've been asking you questions. So let me ask my
16 question. Let me -- I'll ask a different
17 question.
18 Do you know whether or not pembrolizumab
19 ever received a breakthrough therapy designation
20 for unresectable or metastatic MSI high
21 non-colorectal cancer?
22 A One more time. Do I know if --

1 Q Do you know whether or not pembrolizumab
2 ever received a breakthrough therapy designation
3 for unresectable or metastatic MSI high
4 non-colorectal cancer?
5 A I believe that pembrolizumab received a
6 breakthrough therapy designation for MSI high
7 non-colorectal cancer.
8 Q Do you know how many breakthrough
9 therapy designations approvals pembrolizumab has
10 received from the FDA?
11 A I do not.
12 Q Do you know whether or not pembrolizumab
13 has received more than five breakthrough therapy
14 designation approvals from the FDA?
15 A I think that you just went through -- I
16 don't know how many we just went through. Three?
17 Is there more on this page?
18 Q We can go back to it. So we saw
19 reference to a breakthrough therapy designation
20 approval on page 2 of Exhibit 1130, right?
21 A Yes, the top one.
22 Q And we saw a breakthrough therapy

1 designation approval for pembrolizumab on page 3
2 of Exhibit 1130, right?
3 A Lung cancer.
4 Q Is that right?
5 A Yes.
6 Q And we saw a breakthrough therapy
7 designation approval for pembrolizumab on page 4
8 of Exhibit 1130, right?
9 A Yes.
10 Q On page --
11 A Four. That's four.
12 Q That's four.
13 Well, that's page 4. That's the third
14 one, though.
15 A Oh, three.
16 Q And if you turn to page 7 of Exhibit
17 1130, we see a fourth breakthrough therapy
18 designation approval for pembrolizumab, right?
19 A Page 7, the top one.
20 Q That's right?
21 A Yes.
22 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.

1 Q All right. I'll try my question again.
2 Maybe you'll have the same response.
3 And there were five breakthrough therapy
4 designation approvals for pembrolizumab before any
5 breakthrough therapy designation approvals for
6 pembrolizumab with respect to MSI high phenotypes,
7 right?
8 A I can tell you that there are five on
9 this chart listed with something that says
10 "approval date" before the one that refers to MSI.
11 Q Okay.
12 A So now I see -- yeah, I'm still not sure
13 what that approval date refers to.
14 Q Right. And if you turn to page 9 of
15 Exhibit 1130, do you see reference to any
16 breakthrough therapy designation approval date for
17 pembrolizumab?
18 A You mean on the page 9, the very top
19 one?
20 Q And that very top one reflects a date of
21 May 23, 2017. Do you see that?
22 A I do.

1 Q Does that date mean anything to you at
2 all?
3 A That date is --
4 Q I see you're looking at your
5 Declaration.
6 A Yeah. I'm just trying to get all the
7 dates straight.
8 Has to do with this, treatment of adult
9 and pediatric patients, unresectable or metastatic
10 microsatellite instability high or mismatched
11 pair- deficient solid tumors that have progressed
12 following prior treatment and have no satisfactory
13 alternative treatment options, or metastatic
14 microsatellite instability high, MSI high, or
15 mismatched pair-deficient colorectal cancer that
16 has progressed following treatment with a
17 fluoropyrimidine acciplatin intermecan (phonetic).
18 Q Do you know what my question was?
19 A Can you repeat the question?
20 Q Do you know what my question was?
21 A I need you to repeat the question.
22 Q Why do you need me to repeat it? My

1 question is, do you know what my question --
2 A I can't remember. There's a lot of
3 information that goes through. If you could
4 repeat the question.
5 Q All right. Turning your attention to --
6 A You asked me very specific questions. I
7 just want to make sure I get straight what you're
8 asking me.
9 Q I try to ask specific questions.
10 Turning to page 7, Exhibit 1130.
11 A Page 7. 1130, going to page 7. Still
12 on --
13 Q Are you there?
14 A Yes.
15 Q Did you and your team have anything to
16 do with the breakthrough therapy designation
17 approval that's for Keytruda® reflected on this
18 page?
19 A Did I or my team? I do not recall
20 having any involvement.
21 Q Okay. And so turning your attention to
22 page 8 of Exhibit 1130, did you or any members of

1 your team have any involvement with the
2 breakthrough therapy designation for pembrolizumab
3 reflected on this page?
4 A Did I or any members of my team. Did I
5 or any members of my team -- I guess do -- did we
6 have involvement with the approval? Did we have
7 involvement -- I guess I don't really know what
8 you mean "involvement."
9 Q Did you have involvement with any of the
10 clinical studies that led to the approval for
11 pembrolizumab reflected on this page?
12 A Did I have any involvement in the trial
13 that led to this approval?
14 Q No, I didn't say the trial. I said the
15 clinical studies. Let me try -- I'll say it
16 slower.
17 Did you or any members of your team have
18 involvement with any of the clinical studies that
19 led to the breakthrough therapy designation
20 approval for pembrolizumab reflected on page 8 of
21 Exhibit 1130?
22 A Okay. The clinical -- so how -- can you

1 clarify why you corrected me when I said trial and
2 you said no, study? I need to make sure we're
3 talking about the same thing.
4 Q Let me try my question again. Either
5 you understand it or you don't.
6 Did you or any members of your team have
7 involvement with any of the clinical studies that
8 led to the breakthrough therapy designation
9 approval for pembrolizumab reflected on page 8 of
10 Exhibit 1130?
11 A Can you define "clinical study"?
12 Q Do you not know what a clinical study
13 is, Doctor?
14 A Everything has a definition and with --
15 sometimes I can't really understand what you're
16 asking me, so I just need clarification because
17 you corrected me when I said "trial." You don't
18 mean trial, you said "study." I'm trying to find
19 out what you mean "study" if I need to be
20 corrected when I said "trial."
21 Q So, Doctor, in your Declaration at
22 paragraph 35 you say that receiving breakthrough

1 designation is rarely given by the FDA, right?
2 A 35, sought and received breakthrough
3 therapy designation. Receiving breakthrough
4 designation is substantially, the process -- blah,
5 blah, blah. The designation is rarely given by
6 FDA, which needs to seek compelling data to do so.
7 The designation is rarely given by the FDA.
8 Yes, I do see that.
9 Q Do you believe that receiving
10 breakthrough designation is rarely given by the
11 FDA?
12 A Yeah, I do.
13 Q And what do you mean by "rarely"?
14 A It's not -- it's more often not, that
15 it's not given -- I mean more often not given for
16 any -- if you consider all the millions of, or
17 thousands, I don't really know the numbers of
18 drugs out there, and all the potential
19 indications even within each disease and stage,
20 the denominator is quite large and so I think it's
21 rare.
22 I mean I've been doing this for a very

1 long time. I have not been involved in a lot of
2 studies where there's been breakthrough therapy
3 designations, so I believe it's rare. I don't
4 believe -- I believe that statement.
5 Q Do you understand that obtaining a
6 breakthrough therapy designation must be
7 requested?
8 A Do I understand ... rather than it just
9 being given?
10 Q Correct.
11 A I suppose. The FDA doesn't come and
12 just bless people with them.
13 Q So you do understand that in order to
14 receive a breakthrough therapy designation, you
15 have to request it, right?
16 A That's what you're telling me.
17 Q I'm asking you. Do you know whether or
18 not to receive a breakthrough therapy designation
19 it has to be requested?
20 A I don't know if there are alternative
21 ways to receive breakthrough therapy designation.
22 Q What are the ways that you know of by

1 which a breakthrough therapy designation can be
2 received?
3 A I imagine that there's ways to request
4 it, to have the FDA to review it, and then there's
5 probably -- I don't know if there are alternative
6 ways to get a breakthrough therapy designation.
7 Q Do you know how many breakthrough
8 therapy designation requests were received by the
9 FDA in 2012?
10 A No.
11 Q Do you know how many breakthrough
12 therapy designation requests were received by the
13 FDA in 2013?
14 A No.
15 Q Do you know how many breakthrough
16 therapy designation requests were received by the
17 FDA in any of the years from 2014 through 2023?
18 A I do not.
19 MR. MILLER: Counsel, we've been going
20 well over an hour. Good time for a break?
21 MR. RATLIFF: Doctor, would you like to
22 take a break, or we can keep going.

1 THE WITNESS: What time is it?
2 MR. MILLER: 3:15.
3 THE WITNESS: 3:15. And we still have
4 how long?
5 MR. MILLER: Do you need a break?
6 THE WITNESS: Well, I just need to time
7 my breaks because I'm -- I shouldn't sit for very
8 long.
9 MR. MILLER: We've been going for more
10 than an hour now.
11 THE WITNESS: Yeah, if we could take a
12 break, and then how many more hours left do we
13 have?
14 MR. RATLIFF: Let's take a break first;
15 we'll figure that out.
16 (A recess was taken at 3:14 p.m.)
17 (Back on the record at 3:29 p.m.)
18 BY MR. RATLIFF:
19 Q And, Doctor, during the break, did you
20 discuss this case or any of my questions?
21 A No, I did not discuss this case or any
22 of your questions.

1 Q Doctor, do you know in the period of
2 October 1st, 2023, through September 30, 2024 how
3 many breakthrough therapy designations requests
4 were received by the FDA?
5 A I'm sorry, you said -- the answer is no.
6 Q Okay.
7 (Exhibit 1128 and Exhibit 1129 were
8 marked for identification and were retained by Mr.
9 Ratliff.)
10 Q Doctor, I'd like to hand you a new
11 exhibit which has been marked as Exhibit 1128.
12 And I'll also hand you a document which is a new
13 exhibit that's been marked as Exhibit 1129.
14 Doctor, I can represent to you that
15 Exhibit 1128 and Exhibit 1129 are documents that
16 were downloaded from the FDA's website.
17 Exhibit 1128 is entitled "CDER
18 Breakthrough Therapy Designation Requests Received
19 By Fiscal Year," and the document which is Exhibit
20 1129 bears the title "CDER Breakthrough Therapy
21 Designation Requests Received By Fiscal Year."
22 Doctor, do you recall ever looking at

1 CDER's Breakthrough Therapy Designation Requests
2 Received by Fiscal Year?
3 A No.
4 Q And looking at Exhibit 1128, do you see
5 the asterisk at the bottom of the page and there's
6 a sentence following the asterisk?
7 A Yes.
8 Q And do you see that in the sentence it
9 reads:
10 Breakthrough therapy designation was
11 enacted in the Food and Drug Administration Safety
12 and Innovation Act on July 9, 2012.
13 Do you see that?
14 A Yes.
15 Q And does that refresh your memory at all
16 when breakthrough therapy designations were being
17 received by the FDA?
18 MR. MILLER: Objection. Form.
19 A Does it -- no.
20 Q Turning your attention back to Exhibit
21 1130, this is the CDER breakthrough therapy
22 designation approvals document.

1 A Sorry, you said 1130?
2 Q That's correct.
3 A Yes.
4 Q And in Exhibit 1130, do you see that it
5 refers to several different drugs?
6 A I'm sorry, can you repeat the question?
7 Q In looking at Exhibit 1130, do you see
8 that it refers to many different drugs?
9 A I see that there are many drugs on this
10 table. Is that what you're asking?
11 Q That is what I'm asking.
12 So there are many different drugs in the
13 table that's reflected in Exhibit 1130, right?
14 A There are different drugs. I mean I
15 guess "many" is -- there are drugs.
16 Q Would you say that there are many
17 different drugs that are reflected --
18 A I would say that there are several
19 different drugs.
20 Q -- in Exhibit 1130?
21 A There are several different drugs
22 reflected in Exhibit 1130.

1 Q Okay, that's great, because the word
2 "several" is where I started.
3 So looking at Exhibit 1130, of the
4 several different drugs that are reflected in this
5 exhibit, would you agree that pembrolizumab is the
6 drug with the most breakthrough therapy
7 designation approvals?
8 A I'd have to sit down and look at every
9 single one and put them on a table and see how
10 many there are.
11 Q Sitting here, you don't know whether or
12 not pembrolizumab is the top drug with the most
13 breakthrough therapy designation approvals, right?
14 A Yeah, I can't tell -- no, I can't. I
15 can't quickly go through 34 pages and tell you. I
16 cannot tell you how many of these are
17 pembrolizumab.
18 Q And just to be clear, Doctor, I'm not
19 asking you to go through 34 different pages. My
20 question is different.
21 It's just, sitting here today, do you
22 know whether or not pembrolizumab has the most

1 breakthrough therapy designation approvals of any
2 drug?
3 A Sitting here today, I do not know if
4 pembrolizumab has the most breakthrough therapy
5 designations of any drug on this table that lists
6 therapies from 2013 to 2023.
7 Q And would it surprise you if
8 pembrolizumab had the most breakthrough therapy
9 designation approvals of any drug?
10 A I can't say that I have thought about
11 which drug has the most breakthrough therapy
12 designations.
13 Q So let's try my question.
14 Would it surprise you if pembrolizumab
15 had the most breakthrough therapy designation
16 approvals of any drug?
17 A I can't say I know enough to be
18 surprised or not surprised.
19 Q And would you consider yourself a
20 practicing oncologist, Doctor?
21 A Am I a practicing oncologist? I am an
22 oncologist that sees patients. I am a practicing

1 oncologist, yes.
2 Q And do you prescribe pembrolizumab to
3 patients?
4 A Do I prescribe pembrolizumab to
5 patients. I prescribe pembrolizumab to patients,
6 yes.
7 Q And would you agree that pembrolizumab
8 is a good drug?
9 MR. MILLER: Objection. Form.
10 A Do I believe that pembrolizumab is a
11 good drug? Whoo, that's a loaded question. What
12 do you mean by "good"?
13 Q In your view, do you agree that
14 pembrolizumab is a helpful drug for patients?
15 MR. MILLER: Objection. Form.
16 A Do I believe that pembrolizumab is a
17 helpful drug in patients; is that what you asked?
18 Q No. Do you believe that pembrolizumab
19 is a helpful drug for patients?
20 MR. MILLER: Objection. Form.
21 A How is that different from the question
22 before? Do I believe that pembrolizumab is an

1 effective drug for -- helpful drug for patients.
2 Q So let me try it this way. I'm just
3 going to ask the question.
4 A Okay.
5 Q Do you believe that pembrolizumab is a
6 helpful drug for patients?
7 MR. MILLER: Objection. Form.
8 A I feel like you're asking me the same
9 thing each time. Do I believe that pembrolizumab
10 is a helpful drug for patients?
11 Q (Nodding head.)
12 A Yes, that's what you're asking me?
13 Q That's the question.
14 A I believe that pembrolizumab is a
15 helpful drug in some patients.
16 Q And do you believe that pembrolizumab is
17 an effective drug for patients?
18 MR. MILLER: Objection. Form.
19 A I believe that pembrolizumab is an
20 effective drug in some patients.
21 Q And would you agree that pembrolizumab
22 is a chemical compound that has properties that

1 help patients?
2 MR. MILLER: Objection. Form.
3 A Can you repeat the question?
4 Q Would you agree that pembrolizumab is a
5 chemical compound that has properties that help
6 patients?
7 A Chemical compound -- how is that
8 different from the prior question?
9 Q I just have to ask you questions. If
10 you don't think it's different, then you can just
11 provide your response.
12 A Okay.
13 Q Let me try it again.
14 Would you agree that pembrolizumab is a
15 chemical compound that has properties that help
16 patients?
17 MR. MILLER: Objection. Form.
18 A I believe that pembrolizumab helps
19 patients, or some patients.
20 Q My question is different.
21 My question is, would you agree that
22 pembrolizumab is a chemical compound that has

1 properties helpful for patients?
2 MR. MILLER: Objection. Form.
3 A Can you define "chemical compound"? I'm
4 trying to figure out how your question is
5 different.
6 Q Do you know what a chemical compound is?
7 A I don't know specifically what you're
8 referring to when you say "chemical compound."
9 Q Would you consider pembrolizumab a
10 chemical compound?
11 A Chemical compound? I need a definition
12 for chemical compound.
13 Q Let me try my question again.
14 Would you consider pembrolizumab a
15 chemical compound?
16 MR. MILLER: Objection. Form.
17 A I consider pembrolizumab an antibody.
18 Q Do you consider pembrolizumab an
19 antibody that has helpful properties for patients?
20 MR. MILLER: Objection. Form.
21 A Do I believe that pembrolizumab is an
22 antibody that is helpful to patients is the

1 question?
2 Q No.
3 A I'm sorry, what's the question?
4 Q Do you believe that pembrolizumab is an
5 antibody that has properties that is helpful to
6 patients?
7 MR. MILLER: Objection. Form.
8 A Do I believe that pembrolizumab is an
9 antibody that has properties that is helpful to
10 patients? What do you mean by "properties"? How
11 is that different than pembrolizumab -- I'm just
12 trying to understand your question.
13 Q If you don't understand my question,
14 that's fine. I'll try it again. If you don't
15 understand, that means you are not able to answer
16 it.
17 Do you believe that pembrolizumab is an
18 antibody that has properties that is helpful to
19 patients?
20 A I believe that pembrolizumab is an
21 antibody that is helpful to some patients.
22 Q And do you believe that pembrolizumab is

1 an antibody that has properties that is helpful
2 for patients?
3 MR. MILLER: Objection. Form.
4 A I'm sorry, I'm not grasping you asking
5 me different questions. I believe that
6 pembrolizumab is an antibody that is helpful to
7 some patients.
8 Q Would you agree that pembrolizumab is a
9 wonderful antibody?
10 A Wonderful? That's a, that's a weird way
11 to describe anything, I guess.
12 Q Well, if you don't agree, it's fine.
13 You've never used the word "wonderful"
14 to describe anything?
15 A No, I'm not saying that. I can't recall
16 specifically.
17 Q Let me try my question again.
18 Would you agree that pembrolizumab is a
19 wonderful antibody for patients?
20 MR. MILLER: Objection. Form.
21 A "Wonderful" is not a word that I think I
22 would use to describe. I think pembrolizumab is a

1 good antibody for some patients.
2 Q And would you agree that pembrolizumab
3 intrinsically has healing properties for cancer
4 patients?
5 MR. MILLER: Objection. Form.
6 A Okay. Do I believe that pembrolizumab
7 has intrinsic healing properties -- I need some --
8 can you like ask that question in a different way?
9 Q Let me try it again. Maybe see if you
10 understand.
11 I know your counsel is laughing. You
12 started laughing as well.
13 A I'm sorry, I don't mean to.
14 Q Let me try it again.
15 Would you agree that pembrolizumab
16 intrinsically has healing properties for cancer
17 patients?
18 MR. MILLER: Objection. Form.
19 A Can you word that in a different way?
20 Like an example of something that would have an
21 intrinsic healing --
22 Q I can't. If you don't understand the

1 question, you can just say you don't understand
2 the question.
3 A I don't understand the question.
4 Q Okay. Would you agree that
5 pembrolizumab intrinsically has properties that
6 are helpful to some cancer patients?
7 MR. MILLER: Objection. Form.
8 A I think I'm still hung up on -- I don't
9 know what you're asking. What do you mean does it
10 have intrinsic properties?
11 Q So you're not able to answer the
12 question?
13 A No.
14 Q Okay. Ask you to turn your attention to
15 Exhibit 1001. I think that's a copy of the '393
16 patent. It's at the bottom of your pile there,
17 Doctor.
18 A (Complying.)
19 Q You have it?
20 A Uh-humh.
21 Q Have you read the '393 patent claims?
22 A Have I read the claims? I don't recall

1 specifically.
2 Q Have you read the '393 patent?
3 A The actual patent, this entire document?
4 Q Try my question again.
5 Have you read the '393 patent?
6 A This is the patent?
7 Q Doctor, you recall in your Declaration
8 you referenced the '393 patent, right, the
9 Declaration that you put in this case?
10 A Yes, I think we talked about that
11 earlier today.
12 Q We did.
13 And so my question is, have you ever
14 read the '393 patent on which you are a named
15 inventor?
16 A I have not read the entirety of this --
17 every page of this document, no.
18 Q And have you ever read the claims of the
19 '393 patent on which you're a named inventor?
20 A I don't recall specifically the claims.
21 Q Have you ever read sheets 1 through 13
22 of the '393 patent on which you are a named

1 inventor?
2 A Have I ever read page -- I'm sorry,
3 again.
4 Q Have you ever read sheets 1 through 13
5 of the '393 patent?
6 A I recognize some of these figures.
7 Q Are you finished with your answer?
8 A Yes.
9 Q Because -- let's try my question.
10 So my question wasn't about whether you
11 recognize some of the figures in the sheets. My
12 question was different.
13 And my question is, have you ever read
14 sheets 1 through 13 of the '393 patent?
15 A I don't recall reading all of the
16 details in page 1 through 13 of this document.
17 Q And when you say "page 1 through 13,"
18 are you referring to sheets 1 through 13?
19 A Oh, I don't know. You in the past were
20 calling things pages, and it says page.
21 Q So, Doctor, my question is about sheets.
22 We'll try it a little bit different way.

1 I want to turn your attention to the
2 page numbers at the bottom of this exhibit, '393.
3 Did you ever read at any point in time the
4 contents of pages 21 through 31 in Exhibit 1001?
5 A Page 21 through 31. I don't recall that
6 I have read all the content in this -- I'm sorry,
7 you said page 21 through?
8 Q 31.
9 A 31.
10 Q You finished with your answer?
11 A Yes.
12 Q Okay. So let me get it because your
13 answer wasn't clear to me.
14 Have you ever read at any point in time
15 the contents of pages 21 through 31 in Exhibit
16 1001, which is the patent for which you are a
17 named inventor?
18 A Have I read pages 21 through 31 as part
19 of this United States Patent -- this thing, U.S.
20 11,591,393 B2, February 2023?
21 Q Right. What you're saying and referring
22 to as "this thing," this is the patent on which

1 you're named as an inventor and the patent that
2 you reference in your Declaration, right? That's
3 what "this thing" is, right?
4 A This patent No. --
5 Q You need to --
6 A This one, where I understand that Merck
7 has challenged the validity of the claims of the
8 '393 patent; is that what you're referring to?
9 Q Do you know what the '393 patent is?
10 A This says this is '393.
11 Q Was Exhibit 1001 what you're referring
12 to when you mentioned the '393 patent in paragraph
13 4 of your Declaration?
14 A I understand that Merck has challenged
15 the validity of the claims of the '393 patent.
16 Q I didn't ask you to read it. My
17 question is different.
18 When you refer to the '393 patent in
19 paragraph 4 of your Declaration, were you
20 referring to Exhibit 1001?
21 A I was referring to the '393 patent.
22 Q And is Exhibit 1001 the '393 patent on

1 which you're listed as a named inventor?
2 A Exhibit 1 says Patent No. U.S.
3 11,591,393 B2.
4 Q And is Exhibit 1001, to your knowledge,
5 the '393 patent that you refer to in your
6 Declaration?
7 A I -- what I say here is, I understand
8 that Merck has challenged the validity of the
9 claims of the '393 patent.
10 Q Right. And I didn't ask you -- I did
11 not ask you what you said in paragraph 4 of your
12 Declaration.
13 A Okay.
14 Q In paragraph 4 of your Declaration you
15 reference a '393 patent, right?
16 A Yes.
17 Q So my question is, is Exhibit 1001, is
18 that the '393 patent that you reference in your
19 Declaration?
20 A This says Patent No. U.S. 11,591,393 B2.
21 Q And by "this," you're referring to the
22 1001, Exhibit 1001?

1 A At the top of Exhibit 1001 it says
2 Patent No. U.S. 11,591,393 B2.
3 Q And, Doctor, do you know whether or not
4 Exhibit 1001 is the '393 patent that you refer to
5 in your Declaration?
6 A In the Declaration I say:
7 I understand that Merck has challenged
8 the validity of the claims of the '393 patent.
9 Q Are you finished with your response?
10 A Yes.
11 Q Doctor, do you know whether or not
12 Exhibit 1001 is the '393 patent that you refer to
13 in your Declaration?
14 A I see here it says Patent No. U.S.
15 11,591,393 B2.
16 Q And when you say you see "here," what
17 are you referring to?
18 A At the top of this document, Merck
19 Exhibit, I guess EX 1001, page 1 of 34, it says
20 Patent No., at the top, U.S. 11,591,393 B2.
21 Q And do you know whether or not Exhibit
22 1001 is a copy of the '393 patent that you refer

1 to in your Declaration; yes or no?
2 A I state in the Declaration that I
3 understand that Merck has challenged the validity
4 of the claims of the '393 patent.
5 Q Doctor, have you ever read the contents
6 of pages 8 through 20 of Exhibit 1001?
7 A Page 8 --
8 Q Pages 8 through 20. I'm referring to
9 the exhibit number pages.
10 A Oh, I see the sheets up here now.
11 Okay. Page 8 through -- have I seen
12 these figures?
13 Q No, I didn't ask you if you've seen
14 them. Did you ever read the contents of pages 8
15 through 20 of Exhibit 1001?
16 A I recognize the figures and the tables.
17 Q So have you ever read the contents of
18 pages 8 through 20 of Exhibit 1001?
19 MR. MILLER: Objection. Form.
20 A The content are the figures and the
21 table.
22 Q So have you ever read the contents of

1 pages 8 through 20 of Exhibit 1001?
2 A Have I read them. I have seen the
3 figures in pages 8 -- I've seen the figures and
4 the tables.
5 Q Did you prepare any of the figures and
6 tables or any of the contents found on pages 8
7 through 20 of Exhibit 1001?
8 A Did I prepare the figures or the tables.
9 I believe that I helped to prepare the content in
10 the figures and the tables.
11 Q Can I turn your attention to page 33 of
12 Exhibit 1001?
13 A Page 33 of 34?
14 Q Yes. Do you have that?
15 A Yes.
16 Q And sitting here today, do you know
17 whether or not this is a copy of the '393 patent
18 that you refer to in your Declaration?
19 MR. MILLER: Objection. Form. Asked
20 and answered many, many times.
21 A Yeah, I -- it's the same --
22 Q So the answer -- do you know?

1 A I know that Merck has challenged the
2 validity of the claims in the '393 patent, and I
3 know that on several pages, including the front
4 page, it says U.S. 11,591,392 B2.
5 Q So do you know whether or not this is
6 the '393 patent that you're referring to in your
7 Declaration?
8 Can you answer my question, Doctor?
9 A Yeah. So I said that I understand that
10 Merck has challenged the validity of the claims in
11 the '393 patent, and this here says U.S.
12 11,591,393 B2.
13 Q Do you know whether or not when you
14 refer to the '393 patent in your Declaration
15 you're talking about Exhibit 1001 or if you're
16 talking about some other patent?
17 A I know that Merck has challenged the
18 validity of the claims of the '393 patent.
19 Q Are you finished with your response?
20 A Yes.
21 Q So looking at page 33 of Exhibit 1001,
22 do you see claim 1 listed there?

1 A Page 33. "We claim," that one?
2 Q Yes, that one.
3 Do you see claim 1 beginning at line 40?
4 A Okay. Line -- well, I guess it's line
5 40. Yeah.
6 Q Do you practice the method of that claim
7 in your work as an oncologist?
8 MR. MILLER: Objection. Form. Legal.
9 A Do I practice the method of the claim.
10 A method of treating MSI high, or in treating
11 colorectal in a human --
12 MR. MILLER: The Court Reporter needs to
13 take down what you're --
14 A I'm trying. It's very long. A
15 method --
16 MR. MILLER: Just read to yourself.
17 THE WITNESS: Oh, okay.
18 Q You were saying what was very long, the
19 claim?
20 A I'm just want to read the whole thing.
21 You said just read 1, No. 1.
22 Q No, that wasn't my -- my question is

1 different.
2 My question is, do you practice the
3 method of claim 1 in your work as an oncologist?
4 MR. MILLER: Objection. Form. Legal.
5 A What does "practicing a method" mean?
6 Q If you don't know, then you don't know.
7 Just tell me you don't understand my question.
8 A I don't understand your question.
9 Q Fair enough.
10 Looking at claim 31, do you practice the
11 method of that claim in your work as an
12 oncologist?
13 A Do I practice the method? I mean I
14 think it's the same thing. I don't know what you
15 mean by "practice the method."
16 Q For claim 31, do you ever perform the
17 steps of the method described in that claim?
18 MR. MILLER: Objection. Form. Legal.
19 A Do I perform -- I'm sorry, what was the
20 question?
21 Q In your work as an oncologist --
22 A Okay, as an oncologist.

1 Q -- do you practice -- strike that.
2 In your work as an oncologist, do you
3 ever perform the method described in claim 31?
4 MR. MILLER: Objection. Form. Legal.
5 A Do I practice the method?
6 Q Do you understand what claim 31 says?
7 A I'd have to read it and --
8 (Reviewing.)
9 In the method -- I don't -- I don't
10 completely understand what you mean by "do I
11 practice the method." I don't know that
12 oncologists practice methods, so I'm not sure what
13 you mean.
14 Q So let's try to focus on my question.
15 My question is different.
16 Do you understand the methods that are
17 described in claims 31, 33, 35, 37, 39, and 41?
18 MR. MILLER: Objection. Form. Legal.
19 A Do I, as a practicing oncologist,
20 practice the methods? I mean --
21 Q Do you know what I asked you?
22 A What did you ask me?

1 Q Do you know?
2 A You asked me -- can you repeat it?
3 Q Do you understand the methods that are
4 described in claims 31, 33, 35, 37, 39 and 41?
5 MR. MILLER: Objection. Form. Legal.
6 A Do I understand the methods? A method
7 of claim 1.
8 Can you phrase it in a different way?
9 Q No. Are you able to answer my question?
10 A I can't answer your question.
11 Q Do you understand the methods of any of
12 the patent claims listed on pages 33 and 34 of
13 Exhibit 1001?
14 MR. MILLER: Objection. Form. Legal.
15 A What do you mean by "understand the
16 methods"? Do I understand the science in here,
17 the numbers? What do you mean by "methods"?
18 Q Can you tell me for any claim whether an
19 oncologist practices the methods of any of the
20 claims we see on pages 33 and 34 of Exhibit 1001?
21 MR. MILLER: Objection. Form. Legal.
22 A Do oncologists practice methods.

1 Oncologists practice methods. I don't know if
2 oncologists practice methods. I feel like
3 "methods" is referring to something very specific.
4 Q And do you understand that each of the
5 claims describe a method?
6 MR. MILLER: Objection. Form. Legal.
7 A Can you clarify "method"?
8 Q Let me turn your attention to page 33 of
9 the exhibit. Looking at column 25, about line 39,
10 do you see where it says, "We claim"?
11 A Page 33, yes.
12 Q You see that?
13 A Uh-humh.
14 Q Who does the "we" refer to?
15 A I didn't write this. No.
16 Q I didn't ask you if you wrote it, I'm
17 asking you who does the "we" refer to.
18 A That sounds like my interpretation of
19 something somebody wrote.
20 Q Do you know what the "we" refers to?
21 MR. MILLER: Objection. Form. Legal.
22 Q When it says "We claim" in Exhibit 1001,

1 do you know what the "we" refers to, or who?
2 MR. MILLER: Objection. Form. Legal.
3 Q If you don't know, you can just say
4 that.
5 A I don't know.
6 Q Can you turn your attention to Exhibit
7 1005. I see it near the top of your pile. Do you
8 have that?
9 A Exhibit 1005.
10 Q Right. And this is the study record
11 that we've been talking about for the trial,
12 right?
13 A The clinical trial submission.
14 Q And you are aware that this is not the
15 actual submission, right?
16 A The document -- somebody printed this
17 document. The -- it's specifying A and B,
18 June 10, 2013, printed it on clinicaltrials.gov.
19 Q Yes, this document was printed from
20 clinicaltrials.gov, right?
21 A Well, I'm assuming. I don't know who
22 printed the document.

1 Q But you cite this document in your
2 Declaration, right?
3 A I cite this document.
4 Q Is it your testimony that you don't know
5 what Exhibit 1005 is; is that your testimony?
6 A 1005 is the -- reflects the June 10,
7 2013 information submitted June 10, 2013.
8 Q For the trial, right?
9 A Now we're getting back to the word --
10 MR. MILLER: Objection. Form.
11 Q For KEYNOTE-16, right?
12 MR. MILLER: Objection. Form.
13 A This appears to be an archive. So it
14 was printed from clinicaltrials.gov of what was
15 submitted for the June 10th -- it was first
16 submitted June 10, 2013.
17 Q And that reflects the June 10, 2013
18 submission for KEYNOTE-16, right?
19 MR. MILLER: Objection. Form.
20 A It reflects the submission for the
21 clinicaltrials.gov submission for the trial.
22 Q Okay. And the rationale for conducting

1 the trial included the fact that pembrolizumab was
2 showing activity in multiple tumor types,
3 including melanoma and non-small cell lung cancer,
4 right?
5 MR. MILLER: Objection. Form.
6 A Are you asking about this document?
7 Q No. I'm asking about the rationale for
8 doing the trial that's described in Exhibit 1005.
9 So here's my question.
10 A Rationale.
11 Q The rationale for conducting the trial
12 included the fact that pembrolizumab was showing
13 activity in multiple tumor types, including
14 melanoma and non-small cell lung cancer, right?
15 MR. MILLER: Objection. Form.
16 A The rationale for the clinical trial --
17 I mean I think it was much more than that. I
18 don't know what you're saying, the rationale. The
19 rationale was that it worked in cancers; is that
20 what you're saying?
21 Q Is that what you think you heard?
22 A No. Can you repeat what you --

1 Q Sure.
2 The rationale for conducting the trial
3 included the fact that pembrolizumab was showing
4 activity in multiple tumor types, including
5 melanoma and non-small cell lung cancer, right?
6 MR. MILLER: Objection. Form.
7 A The background of the trial did include
8 that pembrolizumab was showing activity in
9 melanoma.
10 Q Okay. I'm not sure why you keep
11 changing -- you're changing my words. I'm not
12 asking about the background. I'm asking about the
13 rationale, not the background. So here's my
14 question:
15 Do you agree that the rationale for
16 conducting the trial included the fact that
17 pembrolizumab was showing activity in multiple
18 tumor types, including melanoma and non-small cell
19 lung cancer?
20 MR. MILLER: Objection. Form.
21 Q Yes or no?
22 A I think it goes back to what you mean by

1 "rationale" and what document we're talking about.
2 Q Didn't you use the term "rationale" when
3 referring to the trial when you made an IND
4 submission to the FDA?
5 A Did I -- sorry.
6 Q Didn't you use the term "rationale" when
7 referring to the trial when you and your team made
8 an IND submission to the FDA?
9 A I'd have to look at that document again.
10 Q So sitting here today, you don't know
11 whether or not you and your team used the term
12 "rationale" when -- wait -- when you and your team
13 made an IND submission to the FDA for the trial?
14 A When we made an IND submission to the
15 FDA, did we use the term "rationale" in the
16 document; is that what you're asking?
17 Q I'll just let that be your testimony if
18 you think that's what I'm asking.
19 Would you agree that the rationale for
20 the trial included the fact that a different PD-1
21 blocking antibody nivolumab also showed activity
22 in melanoma and in non-small cell lung cancer?

1 A Say that one -- nivolumab -- I'm getting
2 confused. What are you asking?
3 Q Would you agree --
4 A Would I agree.
5 Q -- that the rationale for the trial
6 included the fact that a different PD-1 blocking
7 antibody nivolumab also showed activity in
8 melanoma?
9 A Would I agree that the rationale --
10 MR. MILLER: Sorry. Objection. Form.
11 Go ahead when you're ready.
12 A Would I agree that the rationale for the
13 trial is that pembrolizumab worked in melanoma?
14 Q Would you agree that the rationale for
15 the trial included the fact that a different PD-1
16 blocking antibody, nivolumab, showed activity in
17 melanoma?
18 MR. MILLER: Objection. Form.
19 A The rationale for the trial. What are
20 you referring to when you say "the rationale for
21 the trial?" Which document are we talking about?
22 Q I'm not talking about a particular

1 document. You were the principal investigator for
2 the trial, right?
3 A I was a principal investigator for a
4 trial, yes.
5 Q I didn't ask you if you were the
6 principal investigator for a trial. You were the
7 principal investigator for the trial, right?
8 A Yes.
9 Q And I'm asking you, would you agree that
10 part of the rationale for that trial included the
11 fact that a different PD-1 blocking antibody,
12 nivolumab, also showed activity in melanoma?
13 MR. MILLER: Objection. Form.
14 A I would feel more comfortable looking at
15 the trial and what was written in the rationale to
16 -- I guess that's it.
17 Q Do you recall, sitting here today, what
18 was the rationale for the trial for which you were
19 the principal investigator?
20 A Do I recall the rationale for the trial.
21 The rationale for the trial. Do I recall
22 everything we put in the trial document? I don't

1 recall everything that was put in the trial
2 protocol.
3 Q Do you think I asked you if you recalled
4 everything that was put in the trial protocol? Is
5 that what you think I asked?
6 A I think you asked me the rationale for
7 the protocol, and this is a long time ago so I'd
8 like to look at the rationale in the protocol.
9 Q Okay. So I didn't ask you what you
10 think I asked you. So let me try it again.
11 Do you recall the rationale for the
12 trial for which you were the principal
13 investigator, sitting here today; yes or no?
14 MR. MILLER: Objection. Form.
15 A I cannot say I can recall everything
16 that was in the rationale for the trial that we
17 are discussing.
18 Q And do you recall whether or not the
19 rationale for the trial included the fact that
20 there was a complete response in a single patient
21 with colorectal cancer?
22 MR. MILLER: Objection. Form.

1 A I don't recall if it was in the
2 rationale. I recall that there was a patient with
3 colon cancer.
4 Q Doctor, can you turn your attention to
5 Exhibit 116 [sic]. This is the IND submission.
6 In particular, if you can turn your attention to
7 page 76 of the document.
8 A 116.
9 Q There's three 1s, 1116.
10 A Okay. What page is that?
11 Q 76.
12 Let me know when you have it.
13 A 76 of 199, or 76 of the document?
14 Q 76 of 199. Referring to the exhibit
15 page.
16 A Okay.
17 Q I see you have it. The doctor
18 understood.
19 So looking at page 76 of Exhibit 1116,
20 I'd like to turn your attention to the entry which
21 is No. 28.
22 A The entry which is No. 28.

1 Q Do you see that?
2 A Yes.
3 Q And that's a reference by Topalian; do
4 you see that?
5 A Yes.
6 Q And are you familiar with that
7 reference?
8 MR. MILLER: Objection. Form.
9 A Am I familiar with it? I'd feel more
10 comfortable with it in front of me to know exactly
11 which reference that is.
12 Q Do you recall what Topalian's about?
13 A She's written a lot of papers.
14 Q I didn't ask if she's written a lot of
15 papers. I'm asking specifically about this
16 reference that you and your team cite in the IND
17 submission.
18 So my question is, do you recall this
19 paper, sitting here today?
20 A I -- I recall a paper around that time
21 frame that Suzanne was the author on.
22 Q Okay.

1 (Exhibit 1013 was marked for
2 identification and was retained by Mr. Ratliff.)
3 Q Let me just show you a copy of the paper
4 that you reference in the IND. It's Exhibit 1013.
5 A Okay, Exhibit 1013.
6 (Reviewing.)
7 Q Do you recall reviewing or looking at
8 this document within the last year?
9 A Within the last year? Have I read it in
10 any entirety in the last year? I don't recall
11 reading this within the last year.
12 Q Do you recall looking at it within the
13 last year?
14 A Within the last year? I can't say
15 specifically when I last looked at this.
16 Q Do you recall looking at this document
17 within the last six months?
18 A I can't recall if I looked at the
19 document in its entirety in the last six months.
20 Q Did you look at the document in any
21 shape, form or fashion within the last six months?
22 A Did I look at the document in any shape,

1 form and fashion in the last six months?
2 (Reviewing.)
3 I don't recall specifically.
4 Q Okay. But you're familiar with this
5 reference, right?
6 A I am familiar with this reference.
7 Q And when you referred to Exhibit 1013 in
8 your submission to the FDA, you didn't tell the
9 FDA that the study referred to in Exhibit 1013 was
10 resoundingly unsuccessful, right?
11 A Did I -- did we tell the FDA -- did we
12 go over the specifics of this study and say it was
13 unsuccessful?
14 Q When you referred to Exhibit 1013 in
15 your IND submission, you didn't tell the FDA that
16 Exhibit 13 [sic] reflected a resoundingly
17 unsuccessful study, right?
18 Do you understand the question, Doctor?
19 A Yeah. I'm just trying to look at the
20 actual paper to see what it said in the
21 background. When you reference, reference 28 ...
22 (Reviewing.)

1 When we reference 28, we said:
2 Previously activity of a different PD-1
3 blocking antibody, BMS-936558, a fully humanized
4 monoclonal IgG4 antibody, also showed activity in
5 melanoma, non-small cell lung cancer and a
6 complete response in a single patient with
7 colorectal cancer.
8 Q And you're talking about the rationale
9 for doing the study that you and your team wrote
10 in the IND, right?
11 A Yes, the rationale.
12 Q So my question is, you didn't tell the
13 FDA that Exhibit 1013 referred to a prior study
14 where a checkpoint inhibitor was resoundingly
15 unsuccessful, right?
16 A Did we tell the FDA that that study was
17 unsuccessful?
18 Q Did you tell the FDA that that study was
19 resoundingly unsuccessful?
20 A Nowhere in here did we say to the FDA
21 that this PD-1 blocking antibody was resoundingly
22 unsuccessful.

1 Q When you say "in here," your IND
2 submission, right?
3 A I'm referring to a document here,
4 document Exhibit 1116.
5 Q Okay. Did you ever at any point in time
6 tell the FDA that the study reflected in Exhibit
7 1013 was resoundingly unsuccessful?
8 A Did we tell the FDA that this entire
9 study was resoundingly unsuccessful. No, we did
10 not tell the FDA that this NCT00730639 was
11 resoundingly unsuccessful.
12 Q And you didn't tell the FDA that based
13 upon the data in Exhibit 1013, colorectal cancer
14 patients should not be understood to be candidates
15 for anti-PD-1 therapy, right?
16 A Say that one more time.
17 Q You didn't tell the FDA that based upon
18 the data in Exhibit 1013, colorectal cancer
19 patients should not be understood to be candidates
20 for anti-PD-1 therapy, right?
21 A That's correct, we did not tell the FDA
22 that.

1 Q I'd like to turn your attention to page
2 77 of 199 of Exhibit 1116. Let me know when you
3 have it.
4 A Okay, I'm sorry, what page?
5 Q 77.
6 A 77. Here we go. Okay.
7 Q And if I could turn your attention to
8 reference 51.
9 A Reference 51. Yes.
10 Q And are you familiar with that reference
11 51?
12 A I am familiar with the reference 51.
13 Q And you cited reference 51 to the FDA as
14 part of the rationale for conducting the trial,
15 right?
16 A Yes.
17 Q And you didn't tell the FDA at any point
18 in time that the study reflected in the Brahmer
19 paper was resoundingly unsuccessful, right?
20 A No, we did not tell the FDA that the
21 study in refractory solid tumors was resoundingly
22 unsuccessful.

1 Q You didn't tell the FDA ever that based
2 upon the data for colorectal cancer patients in
3 the Brahmer paper, colorectal cancer patients
4 should not be understood to be candidates for PD-1
5 therapy, right?
6 MR. MILLER: Objection. Form.
7 A In this FDA submission -- you're asking
8 if we said in here that colorectal cancer patients
9 should never receive PD-1?
10 Q No, my question is different.
11 Did you ever, at any point in time, you
12 or any of your team members, ever tell the FDA
13 that based upon the data in the Brahmer paper,
14 colorectal cancer patients should not be
15 understood to be candidates for anti-PD-1 therapy?
16 MR. MILLER: Objection. Form.
17 A Did we tell the FDA that colorectal
18 cancer patients should never -- no, we did not
19 tell the FDA that colon cancer patients should
20 never receive therapy.
21 Q Okay. So let's try my question.
22 Did you ever at any point in time tell

1 the FDA that based on the data in the Brahmer
2 paper, colorectal cancer patients should not be
3 understood to be candidates for anti-PD-1 therapy?
4 MR. MILLER: Objection. Form.
5 A We did not tell the FDA that colon
6 cancer patients should not be a candidate for
7 anti-PD-1 therapy.
8 Q You're missing part of my question.
9 Part of my question is very specific to this paper
10 that we've been discussing, the Brahmer paper.
11 Let me try my question again.
12 Did you ever at any point in time tell
13 the FDA that based on the data in the Brahmer
14 paper, colorectal cancer patients should not be
15 understood to be candidates for anti-PD-1 therapy?
16 MR. MILLER: Objection. Form.
17 A We never say based on the Brahmer paper
18 colon cancer patients should not receive anti-PD-1
19 therapy.
20 Q Did you or anyone on your team ever, at
21 any point, tell the FDA that based upon the data
22 in the Brahmer paper, colorectal cancer patients

1 should not be understood to be candidates for
2 anti-PD-1 therapy?
3 MR. MILLER: Objection. Form.
4 A I'm sorry, I think I'm getting tired.
5 It seems like the same question. Can you repeat
6 the two questions?
7 Q There's only one question.
8 So the question is, did you or anyone in
9 your team ever, at any point, tell the FDA that
10 based upon the data in the Brahmer paper,
11 colorectal cancer patients should not be
12 understood to be candidates for anti-PD-1 therapy?
13 A I --
14 MR. MILLER: I'm sorry.
15 Objection. Form.
16 Go ahead.
17 A I did not tell the FDA that colon cancer
18 patients should not be candidates for anti-PD-1
19 therapy in this application.
20 Q Try my question again.
21 You hear me when I say Brahmer paper,
22 right?

1 A Yes.
2 Q So I just want to make sure that's in
3 your response.
4 Did you or anyone on your team ever, at
5 any point, tell the FDA that based upon the data
6 in the Brahmer paper, colorectal cancer patients
7 should not be understood to be candidates for
8 anti-PD-1 therapy?
9 MR. MILLER: Objection. Form.
10 A We did not tell the FDA that colon
11 cancer patients, based on the Brahmer paper,
12 should not be candidates for anti-PD-1 therapy.
13 Q And did you or anyone on your team ever
14 tell the FDA that based upon the complete response
15 in a single patient with colorectal cancer with
16 respect to nivolumab, colorectal cancer patients
17 should not be understood to be candidates for
18 anti-PD-1 therapy?
19 MR. MILLER: Objection. Form.
20 A Say that one more time.
21 Q Did you or anyone on your team ever tell
22 the FDA that based upon the complete response in a

1 single patient with colorectal cancer with respect
2 to nivolumab, colorectal cancer patients should
3 not be understood to be candidates for anti-PD-1
4 therapy?
5 MR. MILLER: Objection. Form.
6 A That -- I guess I'm a little bit lost.
7 Why would we tell FDA you can't treat something
8 based on a response?
9 Q I'm not suggesting one way or another;
10 I'm just asking the question.
11 A Okay.
12 Q Do you have an answer to the question?
13 A Okay, can you repeat the question?
14 Q Did you or anyone on your team ever tell
15 the FDA that based upon a complete response in a
16 single patient with colorectal cancer with respect
17 to nivolumab, colorectal cancer patients should
18 not be understood to be candidates for anti-PD-1
19 therapy?
20 MR. MILLER: Objection. Form.
21 A I did not tell the FDA that colon cancer
22 patients, based on a complete response in a single

1 patient with, a colorectal cancer patient should
2 not be candidates for anti-PD-1 therapy.
3 Q Okay. And can I turn your attention to
4 page 39?
5 A Page 39.
6 Q Of Exhibit 1116. And I'm referring to
7 the exhibit page.
8 A 1116, page 39. 39 of 199?
9 Q That's right.
10 A Okay.
11 Q Do you have it?
12 A Yep.
13 Q And you see the section that's entitled
14 Rationale?
15 A Yes.
16 Q To your knowledge, did the FDA ever
17 challenge the rationale that you and your team set
18 forth in Section 2.4 entitled Rationale?
19 A Did they -- did the FDA ever challenge
20 the rationale to my knowledge. Did they ever
21 challenge the rationale. You mean did they ever
22 challenge anything in these two paragraphs when

1 you're -- or actually three paragraphs?
2 Q Did the FDA ever challenge anything that
3 you and your team said in the Rationale section?
4 A I can't recall that they challenged the
5 rationale.
6 Q Sitting here today, do you know whether
7 the FDA ever challenged the rationale that you set
8 forth in the IND submission for the trial?
9 A Did they challenge it. What do you mean
10 by "challenge"?
11 Q Did they ever question it? Did they
12 ever say it was wrong? Did they ever say it was
13 unreasonable? Did they ever say it was illogical?
14 A No. Illogical, no, the FDA never said
15 it was illogical, to my knowledge.
16 Q Can you turn your attention to Exhibit
17 1119?
18 A Which one?
19 Q Maybe you don't have it. You can --
20 MR. MILLER: Do you need a break?
21 A I'm being buried in exhibits.
22 Q So, Doctor, I'd like to mark as a new

1 exhibit, Exhibit 1119.
2 (Exhibit 1119 was marked for
3 identification and is attached to the transcript.)
4 Q Can you take a look at that exhibit and
5 let me know if you recognize it?
6 A Let's see. 7/15 --
7 MR. MILLER: When you talk, the Court
8 Reporter needs to take down your words.
9 THE WITNESS: I'm sorry, I'm just
10 reading. 7/15/2013.
11 MR. MILLER: Just think quietly and then
12 respond.
13 THE WITNESS: Okay, got it. Sorry.
14 Q Do you recognize Exhibit 1119, Doctor?
15 A 1119. I recognize Exhibit 1119.
16 Q And what is it?
17 A It is a packet of documents that
18 communicates with the FDA through the IND.
19 Q And is this a packet that concerns the
20 trial that we've been discussing today?
21 A Yes.
22 Q And if you turn to exhibit page 4 of

1 126, do you see that there is a letter from --
2 A Page 4.
3 Q -- JHU to the FDA?
4 A Page 4. Yes.
5 Q And that letter refers to two
6 attachments; is that right?
7 A It actually has four. It refers to four
8 attachments.
9 Q Four attachments.
10 And so what's the first attachment that
11 it refers to?
12 A IRB approval letter.
13 Q Okay. And the IRB that's referred to in
14 the approval letter, is that an IRB from JHU?
15 A It's an IRB as a part of Hopkins, yes.
16 Q So is it correct that JHU had to give an
17 IRB approval to conduct the trial?
18 A The IRB had to give approval to conduct
19 the trial.
20 Q And did the IRB give that approval to
21 conduct the trial?
22 A The IRB gave the approval to conduct the

1 trial.
2 Q And is attachment 1 the Johns Hopkins
3 IRB approval letter?
4 A The datewise date of -- reading date of
5 expiration --
6 (Reviewing.)
7 It is a letter that says new application
8 approval.
9 Q Is attachment 1 the Johns Hopkins IRB
10 approval letter for the trial?
11 A It is a letter from the IRB that is a
12 new application approval, and it's referring to
13 the Phase 2 study of MK-3475 in patients with
14 microsatellite unstable MSI high MSI tumors.
15 Q That's the trial we've been talking
16 about all day, right?
17 A It is the trial that we've been talking
18 about today, yes.
19 Q And attachment 2 --
20 A Attachment 2.
21 Q -- in this exhibit, can you tell me what
22 it is?

1 A Attachment 2 is dated 5 -- protocol
2 Version 1.1.
3 (Reviewing.)
4 It's a protocol. It's an approved
5 protocol, Version 1.1.
6 Q It's an approved protocol for the trial
7 that we've been talking about all day?
8 A It is the protocol that -- I mean the
9 trial that we've been talking about all day.
10 Q And is this a protocol that you and your
11 team prepared?
12 A It is a protocol that I helped prepare.
13 Q Right. And the protocol that you helped
14 prepare, it includes a rationale for conducting
15 the trial, right?
16 A A protocol for section --
17 Q And if it helps, I can turn your
18 attention to page 20 of 126 of the exhibit.
19 A Okay. Yes, rationale. 2.4, Rationale.
20 Q Right. So the protocol that you helped
21 prepare, it includes a rationale for conducting
22 the trial, right?

1 A It includes a rationale. Yes, there is
2 a rationale for conducting the trial.
3 Q Right. And that rationale for
4 conducting the trial spans pages 20 through 21 of
5 Exhibit 1119, right?
6 A The Rationale section spans pages 20 and
7 21.
8 Q Did the Johns Hopkins IRB Approval Board
9 ever question, challenge the rationale that you
10 set forth in Exhibit 19 [sic] for conducting the
11 trial?
12 MR. MILLER: Objection. Form.
13 A I don't recall specifically.
14 Q Do you have any general recollection of
15 the Johns Hopkins IRB ever questioning or
16 challenging the rationale that you set forth in
17 Exhibit 1119?
18 MR. MILLER: Objection. Form.
19 A Do I have any recollection that the IRB
20 had any challenged -- challenged anything set
21 forth in Section 2.4?
22 Q That's right, the Rationale section,

1 2.4.
2 A I do not have any recollection that the
3 IRB challenged Section 2.4.
4 MR. MILLER: Counsel, is this a good
5 time for a break? We've been going for a little
6 over an hour.
7 MR. RATLIFF: Doctor, would you like to
8 take a break or keep going?
9 MR. MILLER: We should take a break.
10 THE WITNESS: I think I need coffee.
11 MR. RATLIFF: Up to you, Doctor.
12 MR. MILLER: Let's take a break.
13 MR. RATLIFF: Okay, we can take a break.
14 (A recess was taken at 4:47 p.m.)
15 (Back on the record at 5:05 p.m.)
16 BY MR. RATLIFF:
17 Q Doctor, you have never been employed by
18 the petitioner in this matter, Merck, right?
19 A Employed? Define "employed."
20 Q Never been an employee of Merck, right?
21 A Can you define "employee"?
22 Q Do you know what an employee is?

1 A There may be different definitions. I
2 just want to make sure I'm able to answer it
3 accurately.
4 Q Have you ever -- do you consider
5 yourself to have ever been employed by Merck at
6 any point in time?
7 A Can you define "employment"?
8 Q I'll just try my question again.
9 Do you consider yourself to ever have
10 been employed by Merck at any point in time?
11 A I don't consider myself to have been
12 employed by Merck.
13 Q Have you ever attended any Merck
14 internal employee meeting where pembrolizumab was
15 discussed?
16 A Internal employee meeting where
17 pembrolizumab was -- internal employee. I am not
18 sure the context of the meetings I've been in, if
19 they were ever internal employee meetings. What
20 does that mean, "internal"? What is the
21 definition of an internal employee meeting?
22 Q If you don't understand my question, you

1 can just say that.
2 A I don't understand what you mean by an
3 internal employee meeting.
4 Q Okay. Now, in paragraph 34 of your
5 Declaration you refer to, quote, the Merck
6 personnel, end quote, right?
7 A Yes.
8 Q Do you see that?
9 A Yes, it says the Merck personnel.
10 Q And the Merck personnel there, you're
11 referring to Merck personnel that were involved
12 with the trial that we've been discussing all day
13 today?
14 A There were different Merck personnel
15 along the way. Now, in 34 -- I just need to read
16 it again. Sorry.
17 (Reviewing.)
18 Okay, go ahead.
19 Q The Merck personnel that you refer to in
20 paragraph 34 of your Declaration, those are the
21 Merck employees that were involved with the trial
22 that we've been discussing all day, right?

1 A The Merck personnel -- it sort of
2 depends. When I say -- the Merck personnel
3 involved with our study, to my observation, did
4 not initially act as it was expected to be
5 successful, and certainly as successful as it was.
6 I can't name those personnel. It's been
7 a long time.
8 Q Wait a minute. So you wrote a sentence
9 and testified in paragraph 34 about your
10 observations of Merck personnel; is that right?
11 A They were my observations.
12 Q Right. And I'm asking you, can you name
13 the Merck personnel whose observations you're
14 testifying about in your Declaration?
15 A I can't specify their names.
16 Q How many of them are there that you were
17 thinking of when you testified about your
18 observations of Merck personnel in paragraph 34 of
19 your Declaration?
20 A I don't have a specific number.
21 Q Do you have a general number?
22 A I don't have a general number.

1 Q And is your testimony, sitting here
2 today, that you can't name a single individual
3 that you're referring to when you write "Merck
4 personnel" in paragraph 34 of your Declaration?
5 A I can remember a face of a person. But
6 it's not just one person. It's the -- it was just
7 my observation that --
8 Q How many people was it?
9 A I don't know. I can't tell you how many
10 people it was. I didn't -- I can't tell you.
11 Q And when you testified to this in
12 paragraph 34 of your Declaration, about the
13 observations that you had of the Merck personnel,
14 did you have anything in mind in terms of how many
15 people it was?
16 A You know, this is not like a particular
17 point in time. It's like the Merck personnel.
18 There was no -- when you have like an excited
19 company, typically there's a lot of, you know,
20 funding and all kinds of things. I mean these are
21 just an observation. It's just an observation.
22 I do -- there were people involved in

1 the beginning that we had discussed the study
2 with. I am not good with names. I can't remember
3 their names.
4 Q Okay. In your responses to my questions
5 you said that, quote, I can remember a face of a
6 person.
7 A Uh-huh.
8 Q The face of the person that you can
9 remember, what did that look like?
10 A (Witness laughing.)
11 Q You're laughing; I'm not sure why.
12 A I mean I don't know how to describe
13 someone. I mean he was Caucasian, male. I can
14 remember --
15 Q Did he have short hair or long hair?
16 A There were no long-haired personnel in
17 the study. I mean no men with long hair.
18 Q Did he have short hair?
19 A Just regular hair.
20 Q What is "regular hair" in your opinion?
21 A Regular hair. Not short, not like super
22 short and not long.

1 Q What color was the hair of this face
2 that you can remember?
3 A Dark.
4 Q Dark as in black, dark as in brown, what
5 color?
6 A Dark brown to black.
7 Q Did this person have a mustache?
8 A I don't recall. It's been a long time.
9 Q Well, you're the one that just testified
10 that you can remember a face of a person.
11 A Okay.
12 Q So this face that you can remember, you
13 don't recall the face that you can remember,
14 whether or not it has a mustache?
15 A I can remember a Caucasian male with
16 brown hair.
17 Q Did this face have a mustache?
18 A Did this face -- I don't recall.
19 Q Did the face have a beard?
20 A I don't recall. These were not physical
21 observations. This is -- the idea is that it was
22 not a lot of resources put into this. That it

1 just wasn't expected to be successful or certainly
2 as successful. It's just an opinion.
3 Q Doctor, I'm asking you about this
4 alleged face that you can remember of a person.
5 A Okay.
6 Q Anything else you can tell us about what
7 this face looked like?
8 A He was thin.
9 Q How thin?
10 A I don't know. I don't know how to
11 describe thinness. He wasn't overweight. He was
12 a normal thin healthy face.
13 Q Healthy face, is that what you said?
14 A Uh-humh. I just mean not too, not too
15 taut and not too overweight. Just a normal --
16 just normal thin.
17 Q If you saw this face at a picture today,
18 would you recognize it?
19 A I can't say for sure.
20 Q Do you know how many Merck employees
21 were involved in the clinical trial that we've
22 been discussing all day?

1 MR. MILLER: Objection. Form.
2 A Do I know how many personnel were
3 involved with our study? What do you mean by
4 "involved"?
5 Q So first of all, I didn't ask you if you
6 knew how many personnel were involved with the
7 trial we've been discussing all day, so let me try
8 my question again.
9 Do you know how many Merck employees
10 were involved in the clinical trial that we've
11 been discussing all day?
12 A Do I know how many Merck employees were
13 involved in the clinical trial. So the -- I think
14 we're talking about different people at different
15 times.
16 Q I'm sorry, I don't understand that. I'm
17 not asking you about your Declaration, I'm asking
18 you about the trial that we've been discussing all
19 day.
20 A Uh-humh.
21 Q So my question is, do you know how many
22 Merck employees were involved with the trial that

1 we've been discussing all day?
2 MR. MILLER: Objection. Form.
3 A What do you mean by "involved"?
4 Q I mean involved in the same way that you
5 meant it in paragraph 34 of your Declaration. You
6 used the term "involved."
7 A Yeah. So, again, I think it depends on
8 which part we're talking about, and I cannot tell
9 you for each part how many Merck employees were
10 involved.
11 (Ms. Moreira left the deposition.)
12 Q Can you tell us for any part how many
13 Merck employees were involved?
14 MR. MILLER: Objection. Form.
15 A How many Merck employees were involved.
16 What do you mean by "involved"?
17 Q I mean involved in the same way that you
18 meant it in paragraph 34 in your Declaration when
19 you used that term, "involved."
20 A Okay. I cannot tell you how many people
21 I am referring to specifically.
22 Q You finished with your response?

1 A Yes.
2 Q You said how many people you're
3 referring to specifically. Specifically to what?
4 Oh, if you're pointing to paragraph 34,
5 we're beyond that. I already have your testimony
6 about the face --
7 A Okay.
8 Q -- that you believe you can remember. I
9 have that testimony.
10 A Okay.
11 Q So I'm asking you a different question.
12 The question is, do you know how many
13 Merck employees were involved with the clinical
14 trial that we've been discussing all day today?
15 A How many Merck employees were involved.
16 I cannot tell you.
17 Q Do you know the name of any Merck
18 employee that was involved with the clinical trial
19 that we've been discussing all day today?
20 A Do I know the name of any Merck
21 employee. I can't recall the name of any -- what
22 was the question? We're past the numbers, we're

1 to names. I can see one of the people. Like I'm
2 bad with names.
3 Q Do you know the name of any Merck
4 employee that was involved with the clinical trial
5 that we've been discussing all day today?
6 A Do I know the name. I do not know the
7 name of the personnel. I do not know the names.
8 Q I'm not asking you if you know all the
9 names. I'm asking you do you know the name of any
10 Merck employee that was involved with the clinical
11 trial that we've been discussing all day today.
12 A I do not know the names of the
13 personnel. I recall, but I can't recall exactly.
14 I can come up with one name of a person that was
15 in some communication somewhere, but I can't
16 remember the context of the communication.
17 Q And what was the name of that person?
18 A Amy.
19 Q Amy who?
20 A Amy Meister.
21 Q Do you know the name of anyone else that
22 you believe was involved?

1 A That's the only name I can remember of
2 somebody that we communicated with in regards to
3 our study, our trial.
4 Q In regards to the trial that we've been
5 discussing all day, right?
6 A I don't remember -- I can't remember at
7 what point, I just remember that name. I can't
8 remember the context.
9 Q And in your testimony today you said
10 that you can see one of the people. What did --
11 what does that one of the people look like that
12 you can see?
13 MR. MILLER: Objection. Form.
14 A I think we already answered that
15 question.
16 Q No, this is a different question. So
17 I'm not asking about the face.
18 A Okay.
19 Q We're past that. I asked you do you
20 know the name of any Merck employee that was
21 involved with the clinical trial that we've been
22 discussing all day today.

1 Your response, do I know the name of any
2 Merck employee. I can't recall the name of any --
3 what was the question? We're past the numbers,
4 we're to names. I can see one of the people.
5 Like I'm bad with names.
6 So when you said, I can see one of the
7 people --
8 A Uh-huh.
9 Q -- what does that person look like?
10 A It's that same person.
11 Q The same person that you don't know if
12 that person had a mustache or a beard; is it that
13 same person?
14 A I don't recall a mustache or a beard. I
15 mean this is sort of in the context of the
16 funding, knowing that funding --
17 Q So in your Declaration, you used the
18 terminology "initial study." And so if I can turn
19 your attention to paragraph 19 of your
20 Declaration.
21 A Paragraph 19.
22 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

1 paragraph 19 you write, quote, the initial phase,
2 end quote.
3 What did you mean by "initial phase"?
4 A Sort of the same as the prior, the
5 initial part of the study.
6 Q Sort of the same, I'm not sure I
7 understand what that means. Is it the same or is
8 it different?
9 A Merck did not provide any financial
10 support to initiate the study or trial.
11 Q So is it better -- is that the better
12 way to say it or is that what you intended?
13 A It's probably a better way to say it,
14 because fewer things to --
15 Q So can you make that correction in your
16 Declaration, then, using the pen.
17 A (Complying.)
18 Q And please initial the correction when
19 you're finished.
20 A (Complying.)
21 Q So can you please tell us how that
22 sentence reads as you've corrected it?

1 A "In fact, Merck" -- oh, I'm sorry.
2 "In fact, Merck did not provide any
3 financial support for the initiation or conduct of
4 the trial until later."
5 Q Later than what?
6 A I told you that I can't remember the
7 dates of the funding.
8 Q So when you say "later," you don't have
9 any recollection as to what date you mean by
10 "later"; is that fair?
11 A I think it's fair to say that the
12 financial support came later.
13 Q Later than what?
14 A Sometime later.
15 Q So your testimony is that the support
16 came sometime later than what?
17 A I don't really have a clarification.
18 There's documentation of the funding, so I think
19 that's what we could refer to for that "later."
20 Q I don't understand your reference point.
21 Later than what? If I'm going to look for
22 documentation, then what's the reference point for

1 "later"?
2 A Later during the conduct of the trial.
3 Q Later than what, though?
4 A Later than the initial -- initiation and
5 through the conduct of the trial.
6 Q And when, in your view, is the
7 initiation and early conduct of the trial? What
8 time frame is that?
9 A I don't know when the funding came, so
10 the point of that is just to say that the funding
11 came later. It wasn't during the initiation or
12 during the early conduct of the trial. And
13 there's a paper documentation of when that is, so
14 I don't want to guess that. That is the -- that's
15 the intent.
16 Q But when you say the early conduct of
17 the trial, what time frame are you talking about?
18 Was that one week into the trial, was it two
19 weeks, was it before patients were enrolled? Do
20 you have any idea what time frame you're talking
21 about?
22 A I -- no, it wasn't before patients were

1 enrolled.
2 Q So what time frame are you talking
3 about?
4 A I don't -- I can't say -- it's -- I
5 can't remember when we got funding for the trial.
6 Q Do you have any recollection of ever
7 asking Merck for funding for the trial before
8 patients were enrolled?
9 A Before patients were enrolled. The --
10 do I, specifically me, have recollection did I ask
11 them for money? I don't have recollection of me
12 specifically asking them for money.
13 Q Do you know if anyone at JHU ever asked
14 Merck for money to fund the trial before patients
15 were enrolled?
16 A I think that you would have to ask the
17 other individuals.
18 Q You're saying I need to ask other
19 individuals if you know if anyone at JHU has ever
20 asked Merck for money to fund the trial before
21 patients were enrolled; is that your testimony? I
22 have to ask other individuals about what you know;

1 is that what you're saying?
2 MR. MILLER: Objection. Form.
3 A Do I know if -- can I confirm that they
4 asked. I cannot confirm that they asked. I think
5 you have to ask them specifically. I cannot
6 recall if I asked them specifically for money.
7 Q I'm going to try to --
8 A Okay.
9 Q -- try my question again.
10 Do you know if anyone at JHU ever asked
11 Merck for money to fund the trial before patients
12 were enrolled?
13 A I do not know. I cannot recall if
14 anyone at Hopkins asked Merck for money.
15 Q Are you finished with your response?
16 A Uh-humh.
17 Q So let me try my question again because
18 you didn't answer the question.
19 Do you know if anyone at JHU ever asked
20 Merck for money to fund the trial before patients
21 were enrolled?
22 A Do I know. I know that there have been

1 conversations about that, but I cannot give you a
2 time on when those conversations were. The
3 timelines are starting to blur together to me.
4 Q Conversations about what?
5 A About Merck not funding the trial.
6 Q Do you know if anyone at JHU ever asked
7 Merck for money to fund the trial before patients
8 were enrolled?
9 A I do not know. I cannot recall
10 specifically.
11 Q Do you have any general recollection
12 whether or not anyone at JHU ever asked Merck for
13 money to fund the trial before patients were
14 enrolled?
15 A The recollection that I have, I can't
16 tell you exactly when these conversations were,
17 but there were conversations about Merck not
18 supporting the study financially.
19 Q Let me try my question again because I
20 want to be sure I get a clear answer to it.
21 Do you know if anyone at JHU ever asked
22 Merck for money to fund the trial before patients

1 were enrolled?
2 A I cannot confirm that I was present when
3 somebody asked. I can tell you I can have a
4 recollection. I can't tell you when exactly
5 conversations with individuals that money was
6 asked for, but I cannot tell you when. It was
7 typically, you know, in the context of funding the
8 trial.
9 Q So is it your testimony today that
10 someone at JHU asked Merck to fund the trial with
11 money prior to patients being enrolled?
12 A I cannot confirm that. I cannot say one
13 way or the other. I can't recall. I can't recall
14 a specific time.
15 Q In paragraph 28 of your Declaration you
16 talk about a, quote, initial small study, end
17 quote. What did you mean by that terminology?
18 A (Reviewing.)
19 I meant the data we obtained from
20 eventually our initial patients.
21 Q Who were your initial patients?
22 A Who were they? They were --

1 MR. MILLER: I'll caution you not to
2 reveal any names.
3 THE WITNESS: Oh, yeah, of course not.
4 Q What was the group of initial patients
5 that you're talking about?
6 A The patients that were enrolled on the
7 study and got treatment, or the trial.
8 Q So when you're referring to "initial
9 small study," are you talking about the trial that
10 we've been discussing all day today?
11 A The data we obtained from our initial
12 small study. So I'm referring to the data from
13 the initial patients on the study.
14 Q What group were the initial patients on
15 the study?
16 MR. MILLER: Objection. Form.
17 A What group were the initial patients on
18 the study?
19 Q How do you define the initial patients
20 on the study? What group is that?
21 A I don't have an absolute number. I
22 can't -- the first group of patients on the study.

1 Q What was the first group of patients?
2 MR. MILLER: Objection. Form.
3 A What was the first group?
4 Q Well, Doctor, you wrote "initial small
5 study." I'm trying to understand what do you mean
6 by "initial"? What period is this initial period?
7 A I mean that initially, during the first
8 -- I don't know about the number. Like I don't
9 know the months. I don't know what time it was.
10 I can tell you that in the first -- and I can't
11 tell you how many, I just can't tell you. I can
12 just tell you that patients responded.
13 Q Why did you call it the "initial small
14 study"?
15 A Because, we emphasized the "small"
16 because the way it was -- you get -- people were
17 responding after several patients had enrolled.
18 Q So what is the "initial small study"?
19 A It's the initial -- I don't know. I
20 should not use the word "initial." The first
21 group of patients treated with MK-3475 on the
22 trial.

1 Q And what was that first group of
2 patients? How many were in that group?
3 A I wasn't referring to a specific number.
4 Q And when you wrote this Declaration and
5 signed it, didn't you say that you read it
6 carefully before you signed it?
7 A I did read it carefully.
8 Q And your choice of words that you used
9 and terminology in this Declaration before you
10 signed it were the choice that you wanted to use,
11 right?
12 A Yeah.
13 Q So I'm asking you, what did you mean by
14 "initial small study"?
15 A I meant the first few patients.
16 Q And how many is the first few patients?
17 A So the reason I was vague is because I
18 don't have a number. I could go back and look at
19 every single study record and make up a number,
20 but it's really just the first few patients.
21 Q So you were intentionally being vague in
22 your testimony here?

1 A Because I didn't have a number.
2 Q Did you ever look at the data for this
3 initial group of patients as you were preparing
4 your Declaration?
5 A Have I ever looked at the data. Have I
6 looked at our data?
7 Q No, you didn't think I said that, did
8 you? Let me try that again.
9 Did you ever look at the data for this
10 initial group of patients -- here's the key -- as
11 you were preparing your Declaration?
12 A Have I ever looked at the data as
13 preparing for the Declaration.
14 Q Let me try this again.
15 Did you ever look at the data for this
16 initial group of patients as you were preparing
17 your Declaration?
18 A Did I ever look at the data -- have I
19 ever looked at the data --
20 Q Do you understand my question?
21 A I cannot say when I looked at the data.
22 I often look at the data, so I can't say it was

1 before or during. I can tell you that we saw
2 responses in the first few patients.
3 Q Okay. I want you to tell me about what
4 you wrote and what you testified about in your
5 Declaration.
6 A Okay.
7 Q So in your Declaration you testified,
8 quote, the data we obtained from our initial small
9 study were, end quote. So I'm trying to find out
10 what data was that.
11 A The responses, or the -- that here we
12 say anecdotally our patients felt better. So
13 there was different kinds of data.
14 Q And what was the time frame of this data
15 that you're referencing in your Declaration?
16 A The time frame of the data. The data we
17 obtained from our initial -- again, it's the early
18 patients, what happened to the patients who were
19 early in the study.
20 Q And what time frame is that, the early
21 patients? Do you know?
22 A I don't know specifically. I mean it's

1 a -- in general, we knew early that it was very
2 active.
3 Q I'm not asking generally, I'm asking
4 specifically about what you wrote.
5 A Okay.
6 Q So for what you wrote and testified to
7 in your Declaration, what is the time frame for
8 this data, for these data that you obtained from
9 what you say is, quote, an initial small study,
10 end quote?
11 A I can't give you a specific number. I
12 can say that we enrolled patients on the study,
13 and they were treated, and data came in over time,
14 but it was within the first few patients we became
15 hopeful that things were working based on these
16 things.
17 Q Let's turn to paragraph 34 of your
18 Declaration. Let me know when you're there.
19 Are you there, Doctor?
20 A (Nodding head.) Yes.
21 Q Do you see in paragraph 34 you used the
22 terminology "initial small study" in the last

1 sentence of paragraph 34? Do you see that,
2 Doctor?
3 A Yes.
4 Q What did you mean by "initial small
5 study" when you wrote that in paragraph 34 of your
6 Declaration?
7 A That Merck later provided funding to
8 enroll additional patients.
9 Q That's what you meant by the terminology
10 "initial small study"? That means Merck later
11 provided funding to enroll additional patients; is
12 that your testimony?
13 A Yeah, they did not provide financial
14 support for our initial small study.
15 Q Let me make sure this is clear.
16 What did you mean by the phrasing
17 "initial small study" when you wrote that in your
18 Declaration?
19 A That they did not agree to provide
20 financial support for our initial small study.
21 Q So "initial small study" in your view
22 means "they didn't agree to provide financial

1 support for our initial small study;" is that your
2 testimony?
3 A So what I recall is --
4 Q I'm not asking what you recalled,
5 Doctor, I'm asking you specifically about this
6 terminology that you wrote in your Declaration.
7 And you signed off on this terminology, right?
8 A Yes.
9 Q And it says "initial small study,"
10 right?
11 A Yes.
12 Q So what is this "initial small study"
13 that you're referring to?
14 MR. MILLER: You should feel free to
15 continue answering as you were before you were
16 interrupted by counsel.
17 A So the initial small study, when I'm
18 referring to all this, has to do with the funding.
19 Merck later provided funding to enroll additional
20 patients.
21 Q Okay. I can ask you questions about
22 later, but let me try this.

1 What did you mean by "initial small
2 study," do you know?
3 A The initial part of the study. Later
4 they provided funding.
5 Q What's the initial part of the study?
6 I'm not asking you anything about funding. I'm
7 asking, when you say "initial small study," what
8 did you mean?
9 A The earlier parts of the trial.
10 Q And what were the earlier parts of the
11 trial?
12 A Earlier parts of the trial were -- I
13 don't know exactly the times -- the time. You're
14 talking about the time?
15 Q I'm talking about what you refer to --
16 you're the one who's writing "initial small
17 study." So my question is, what did you mean by
18 that, what time frame?
19 A I don't know the time frame. I can tell
20 you that the funding came later. I can tell you
21 that the -- I did not specifically -- I don't
22 recall the conversations about the funding with me

1 and Merck.
2 Q I'm not asking you anything about
3 funding. You say the initial small study relates
4 to the early parts of the trial, right?
5 A Yes, but that's the context of the
6 conversation about what -- when I was talking
7 about the initial study.
8 Q So what are the early parts of the
9 clinical trial as you understand it?
10 A The earlier parts of the study, of the
11 earlier parts of enrollment.
12 Q And when was that? When is the earlier
13 parts of enrollment?
14 A It started sometime in 2013. I don't
15 know at what point the funding came in.
16 Q So what is the earlier parts of the
17 trial?
18 Let me try this way.
19 Are you defining the earlier parts of
20 the trial based upon your view when you believe
21 Merck funded the trial with money?
22 A Can we go back to the very specific

1 areas we're talking about it?
2 Q Let's go back to this. Very clear.
3 A Okay.
4 Q The term "initial small study" that you
5 wrote in your Declaration, what does that mean?
6 A The -- just initial part when we, when
7 we started the study. Merck specifically in a
8 contract stated that there is no funding and that
9 the Swim Across America would fund it.
10 So there was sometime later, I don't
11 know when exactly, when there was funding that
12 came from Merck. I cannot say specifically the
13 conversations around how that funding came. I can
14 only say what I -- what -- I don't recall being a
15 participant in those conversations.
16 Q But, Doctor, I'm not asking you anything
17 about funding. I'm asking you about what you
18 meant when you wrote the terminology "initial
19 small study." What are you referring to? What is
20 the initial small study?
21 A I'm referring to the initial part of the
22 study.

1 Q And how do you define the initial part
2 of the study?
3 A The earlier parts of the study.
4 Q How do you define the earlier parts of
5 the study?
6 A The initiation of the study. Some
7 period of treatment of patients on the study.
8 Q And when you say "some period of
9 treatment," what period of treatment are you
10 talking about?
11 A When we say -- what -- I don't have a
12 number. I just --
13 Q Okay. That's fair. If you don't have a
14 number, then you don't have a number.
15 Let me turn your attention to paragraph
16 41 of your Declaration.
17 In paragraph 4 [sic] you use the
18 terminology "initial MSI clinical trial." Do you
19 see that?
20 A Uh-huh.
21 Q What does that terminology mean,
22 "initial MSI clinical trial"?

1 A Initial -- the funded -- our initial MSI
2 clinical trial. We are referring to the trial in
3 -- the same trial that we've been talking about.
4 Q So when you say "initial MSI clinical
5 trial," you're talking about the trial that we've
6 been discussing all day today?
7 A That would -- the initial MSI clinical
8 trial is the first MSI clinical trial. I guess
9 initial funded, our first, initial. The one that
10 happened initially.
11 Q Doctor, you know what you wrote and what
12 you intended when you wrote the words "initial MSI
13 clinical trial" in paragraph 41 of your
14 Declaration, right?
15 A Uh-humh.
16 Q Does the initial MSI clinical trial that
17 you refer to in your Declaration at paragraph 41
18 refer to KEYNOTE-16?
19 A The clinical trial that I'm referring to
20 for the initial -- where the initial patients were
21 treated were, is KEYNOTE-16.
22 Q Now, Doctor, your copy of your

1 Declaration where you made several corrections,
2 we're going to mark that as a new exhibit, Exhibit
3 1145.
4 (Exhibit 1145 was marked for
5 identification and is attached to the transcript.)
6 Q And counsel will provide you copies
7 after we have an opportunity to make copies of
8 that exhibit.
9 Now, if I could turn your attention to
10 paragraph 24 of your Declaration. Let me know
11 when you have that, Doctor.
12 A Okay.
13 Q And in paragraph 24 of your Declaration,
14 you testify, quote, even though using the PD-L1
15 biomarker seemed like a promising approach,
16 Merck's clinical testing showed that it did not
17 work, end quote.
18 Do you recall giving that testimony?
19 A Can you repeat that? You're just
20 reading 24?
21 Q In paragraph 24 of your Declaration you
22 give the testimony, quote, even though using the

1 PD-L1 biomarker seemed like a promising approach,
2 Merck's clinical testing showed that it did not
3 work, end quote.
4 A Yes, I see that.
5 Q And that's testimony that you gave in
6 this case, right?
7 A I said that the PD-L1 biomarker seemed
8 like a promising approach, yes.
9 Q And you're not suggesting that the PD-L1
10 biomarker with respect to pembrolizumab was
11 unsuccessful, are you?
12 A Unsuccessful. This is specifically
13 talking about PD-L1 selection of colon cancer
14 patients.
15 Q So you're not suggesting by your
16 testimony in paragraph 24 of your Declaration that
17 the PD-L1 biomarker with respect to pembrolizumab
18 was unsuccessful; is that right?
19 A What I am suggesting here, we're talking
20 specifically about PD-L1 biomarker testing in
21 colon cancer patients, to identify patients for
22 treatment with pembrolizumab. That's what this is

1 referring to.
2 Q So you're not suggesting in paragraph 24
3 of your Declaration that this PD-L1 biomarker with
4 respect to pembrolizumab was not a promising
5 approach for cancers other than colorectal cancer,
6 right?
7 A This is specifically saying that while
8 it seemed like a promising approach, PD-L1 is not
9 a -- was not promising for patients with colon
10 cancer.
11 Q Okay. And so would you agree that PD-L1
12 with respect to pembrolizumab was a promising
13 approach for other forms of cancer?
14 A Are we talking about back then?
15 Q Talking about right now.
16 A Right now is PD-L1 a promising approach
17 or a proven approach?
18 Q Let's take it in steps.
19 A Okay.
20 Q Would you agree today that the PD-L1
21 biomarker with respect to pembrolizumab has been a
22 proven approach for multiple forms of cancer?

1 A I actually cannot answer that question
2 without reviewing the literature today. There's
3 been lots of changes.
4 Q Are you familiar with the package insert
5 for pembrolizumab?
6 A Am I familiar with the package insert.
7 I am -- their -- I'm familiar with package insert,
8 their -- yes, I'm familiar with it.
9 Q Okay. And don't you understand from the
10 package insert that the PD-L1 biomarker for
11 pembrolizumab has been proven with respect to
12 non-small cell lung cancer?
13 A I'd have to review the package insert,
14 to be honest with you. It's been a while that I
15 looked at lung cancer data.
16 Q And you've been a clinical trial
17 investigator for pembrolizumab; is that fair?
18 A That's fair. But I treat GI cancers.
19 Q Okay. I didn't ask you whether or not
20 you -- what type of the cancer you treat.
21 Sitting here today, do you know whether
22 or not the PD-L1 biomarker has been shown to be a

1 proven approach for treating non-small cell lung
2 cancer?
3 A I cannot recall the specifics of the
4 data. The data has evolved a lot. I can tell you
5 as a GI cancer oncologist, I have not used PD-L1
6 for selection of patients for pembrolizumab.
7 Q And you're not taking the position in
8 this case that the PD-L1 biomarker has never been
9 a promising approach for pembrolizumab treatment
10 of various cancer patients, right?
11 A I'm not -- it depends on what you mean
12 by "promising." But again, the data is mixed and
13 always evolving.
14 Q I mean promising by the same way you use
15 it in your Declaration.
16 Let me try that again.
17 You're not taking the position in this
18 case that the PD-L1 biomarker has never been a
19 promising approach for pembrolizumab treatment of
20 various cancer patients, right?
21 A I am not saying that PD-L1 has not --
22 is -- okay. I am not saying that the PD-L1

1 biomarker has never been promising. That's not
2 what I'm saying.
3 Q And you're not saying that the PD-L1
4 biomarker with respect to pembrolizumab has never
5 been promising, right?
6 A I am not saying with respect to
7 pembrolizumab that the PD-L1 as a biomarker has
8 never been promising.
9 Q Okay. Let me let you take a look at an
10 exhibit. This is, I believe, a new exhibit, 1134.
11 (Exhibit 1134 was marked for
12 identification and is attached to the transcript.)
13 Q Let me know if you recognize it, Doctor.
14 A This is -- Exhibit 1134 -- on top of it
15 is "Highlights do not include all information
16 needed to use Keytruda® effectively."
17 This is a package label, or insert for
18 Keytruda®.
19 Q Keytruda® is pembrolizumab, right?
20 A Correct.
21 Q So you recognize this as the package
22 insert for pembrolizumab; is that right?

1 MR. MILLER: Objection. Form.
2 A This looks like a package insert for
3 pembrolizumab.
4 Q Right.
5 And do you see here in terms of the
6 Indication and Usage section of the package insert
7 it shows that with respect to pembrolizumab, that
8 the PD-L1 biomarker has been shown to be a proven
9 approach for treating various forms of cancer,
10 right?
11 A (Reviewing.)
12 Q Do you understand the question?
13 A Yeah. I'm just scanning all these
14 different things to see, and focusing on the
15 PD-L1 -- when I find PD-L1 on the document.
16 I mean just quickly looking at this
17 where I can spot PD-L1, PD-L1, you can use
18 pembrolizumab as a single agent for the first line
19 treatment of patients with non-small cell lung
20 cancer expressing PD-L1 as determined by an
21 FDA-approved test.
22 It's under non-small cell lung cancer --

1 one, two, three, four, five -- six different
2 bullets for non-small cell lung cancer, and the
3 other five bullets does not require PD-L1 testing.
4 Q And of the six bullets that you just
5 mentioned under non-small cell lung cancer, you
6 agree with me that two of those bullets reflect --
7 A I'm sorry, there might be --
8 Q -- two different indications --
9 A I'm sorry.
10 Q And of the six bullets that you just
11 mentioned under non-small cell lung cancer, you
12 would agree with me that two of those bullets
13 reflect using pembrolizumab in situations where
14 the PD-L1 biomarker is expressed, right?
15 A Single agent for the first line
16 treatment of the patients with --
17 MR. MILLER: Don't read out loud.
18 THE WITNESS: Sorry, sorry.
19 Q Doctor, are you having difficulty
20 understanding the package insert?
21 A It's just a lot of information. I just
22 want to be careful reading it.

1 Q Okay.
2 A I'm trying to see if these are actually
3 two different patient populations because you
4 asked me of the two, I see PD-L1 of the two, so
5 I'm just carefully trying to understand what the
6 patient population is.
7 Q Let me ask a different question, then.
8 Under non-small cell lung cancer, for
9 pembrolizumab, you do understand from the package
10 insert that there's six different indications that
11 pembrolizumab has, right?
12 A Yes. I'm trying to see the difference
13 between the third and the fourth.
14 (Reviewing.)
15 Yes. So it looks like you can use
16 PD-L -- you can use pembrolizumab in a non-small
17 cell lung cancer by itself if you have a tumor
18 proportion score of greater than or equal to 1.
19 Q You would agree that under the non-small
20 cell lung cancer heading, for the pembrolizumab
21 indications, indications 3 and 4 include
22 indications involving expression of the PD-L1

1 biomarker, right?
2 A Yes, I would agree that in non-small
3 cell lung cancer you can use pembrolizumab in
4 certain situations that are very specific if the
5 PD-L1 TPS is greater than or equal to one percent.
6 Q And would you agree under the heading
7 Head and Neck Squamous Cell Cancer, the second
8 bullet shows that the PD-L1 biomarker has been
9 proven for treatment of that form of cancer with
10 pembrolizumab, right?
11 A I can say it's been approved under -- on
12 this package insert for head and neck cancer as a
13 single agent for the first line treatment of
14 patients with metastatic or with unresectable
15 recurrent HNSCC whose tumors express PD-L1 CPS
16 greater than or equal to 1.
17 Q Would you agree, Doctor, that the PD-L1
18 biomarker approach with respect to pembrolizumab
19 has resulted in several forms of approvals for
20 treating cancer?
21 MR. MILLER: Objection. Form.
22 A I would say that PD-L1 can be used to

1 select patients for single-agent therapy in a
2 subset of patients with cancer. It -- typically.
3 But they often also can be given with chemo and
4 you wouldn't need PD-L1.
5 So I think there is still, there's still
6 a lot of data that sometimes changes the
7 indication. But yes, you can use PD-L1 in a few
8 of these bullet points on this page of, I don't
9 know how many different indications. Actually, I
10 don't even -- it's actually two pages of
11 indication -- no, wait, one and a half pages of
12 indications. So there are places where you can
13 use PD-L1.
14 Q Let's try my question. My question is
15 different than I think what you're responding to.
16 So my question is, would you agree,
17 Doctor, that the PD-L1 biomarker approach with
18 respect to pembrolizumab has resulted in several
19 forms of FDA approvals for treating various
20 cancers?
21 A I would agree that PD-L1 biomarker has
22 resulted in several approvals to use pembrolizumab

1 in different types of cancers. But in a vast
2 majority, it's not used. In a vast majority of
3 these indications it is not used.
4 Q And how many times does the package
5 insert for Keytruda® reflect that the PD-L1
6 biomarker approach with respect to pembrolizumab
7 has resulted in several FDA approvals of treating
8 various forms of cancers?
9 A You want me to count on these?
10 Q Yes, please.
11 A Okay.
12 Q And we can take them in turns. We can
13 start with non-small cell lung cancer. How many
14 FDA approvals using the biomarker approach with
15 respect to that form of cancer?
16 (A discussion was held off the record.)
17 MR. RATLIFF: We're not done.
18 MR. MILLER: Yeah, we're done.
19 MR. RATLIFF: We're not done.
20 MR. MILLER: We can go on the record.
21 I'll put it on the record. We're done.
22 MR. RATLIFF: I didn't pass the witness.

1 MR. MILLER: You're done. Your seven
2 hours are over. Take a look at the numbers. If
3 you can make an argument that we are not under --
4 not over seven, I'll happily listen to it.
5 Otherwise, we're done.
6 MR. RATLIFF: I don't --
7 MR. MILLER: Preston, we're done.
8 MR. RATLIFF: I don't need to make an
9 argument.
10 MR. MILLER: Okay.
11 MR. RATLIFF: Counsel --
12 MR. MILLER: We can go back on the
13 record.
14 MR. RATLIFF: She's already on -- we're
15 already on the record.
16 BY MR. RATLIFF:
17 Q So, Doctor, you were responding to my
18 question.
19 MR. MILLER: No, she wasn't.
20 For the record, the Court Reporter had
21 calculated the time on the record, and I've
22 identified an error in the calculation. At this

1 point we're well over the seven-hour limit and
2 this deposition is concluded.
3 MR. RATLIFF: The deposition has not
4 concluded.
5 MR. MILLER: You can go talk to the
6 Board about it.
7 MR. RATLIFF: If you're pulling the
8 witness, then you do that on your own prerogative,
9 and you do that at the risk of whatever may come
10 from it.
11 MR. MILLER: Okay. No worries. We're
12 done.
13 MR. RATLIFF: So --
14 MR. MILLER: You can go. You can leave
15 the room.
16 MR. RATLIFF: Can you finish answering
17 my question?
18 MR. MILLER: You can leave the room.
19 I tried to give you leeway, Preston, and
20 if you want to act like that, we're going to be
21 done.
22 So, Doctor, you can leave.

1 MR. RATLIFF: Counsel --
2 MR. MILLER: If you want to look at the
3 tally --
4 MR. RATLIFF: Counsel --
5 MR. MILLER: I'm just going to read it
6 on the record.
7 MR. RATLIFF: Counsel, you had the
8 opportunity to check the timing earlier when Madam
9 Court Reporter announced timing for the deposition
10 and said that both counsel are free to check the
11 timing, to check the math. It was your
12 prerogative not to do that. I have some more
13 questions for the doctor, and if you're going to
14 pull the witness, then that's your prerogative,
15 and what may come, may come.
16 MR. MILLER: Okay.
17 MR. RATLIFF: But I'd like to ask the
18 questions.
19 BY MR. RATLIFF:
20 Q And so, Doctor --
21 MR. MILLER: Well, no, we are done. It
22 is my prerogative, and we are concluded.

1 Doctor, you can leave.
2 MR. RATLIFF: All right. So just note
3 for the record --
4 THE COURT REPORTER: Before we go, I
5 just want to make sure we have -- she's put her
6 hands on exhibits, so I want to make sure, are we
7 attaching, is she taking? I want that clear.
8 MR. RATLIFF: She's not taking the
9 exhibits. We --
10 THE COURT REPORTER: Not "she," the
11 doctor.
12 MR. RATLIFF: The doctor is not taking
13 the exhibits. I'm going to mark that scribble as
14 a new exhibit.
15 THE WITNESS: I don't -- can't tell what
16 I made.
17 MR. RATLIFF: And we'll make that
18 scribble new Exhibit 1146.
19 (Exhibit 1146 was marked for
20 identification and is attached to the transcript.)
21 MR. RATLIFF: And so we'll make copies
22 of that, and note for the record that the new

1 exhibit was being prepared as the doctor was
2 answering my last question.
3 And, Doctor, are you going to follow
4 your counsel's advice and just leave, or are you
5 willing to respond to the questions that I have
6 for you?
7 THE WITNESS: I'm going to follow my
8 counsel's advice.
9 MR. RATLIFF: All right. Counsel, as I
10 stated before, you are pulling the witness,
11 because I have not passed the witness, over our
12 objection.
13 MR. MILLER: Understood. And for the
14 record, the Court Reporter -- I proceeded with the
15 deposition so as not to be disruptive. The Court
16 Reporter took a break. I asked to see her records
17 of the timing. There was an entry which is
18 identified as No. 3, which indicated a start time
19 of 1:49 and a stop time of 3:14.
20 The Court Reporter had calculated that
21 to be 1 hour and 3 minutes. It is actually 1 hour
22 and 25 minutes, which puts us well over the seven

1 hours that you are allotted for this deposition,
2 so the deposition is concluded.
3 MR. RATLIFF: And for the record,
4 counsel, you had the opportunity to check the math
5 earlier, and you did not.
6 I only have a few more questions for
7 you, Doctor.
8 MR. MILLER: We're done.
9 MR. RATLIFF: But if counsel is going to
10 pull the witness, then that's what's going to
11 happen.
12 MR. MILLER: Counsel is pulling the
13 witness because we are well over seven hours.
14 Thank you.
15 MR. RATLIFF: Well, it's unfortunate --
16 MR. MILLER: Have a good flight.
17 MR. RATLIFF: -- how this ended, and I'd
18 like to thank Madam Court Reporter for her
19 services today.
20 (Off the record at 6:23 p.m.)
21
22 ACKNOWLEDGMENT OF DEPONENT

1 I, Dung Thi Le, M.D., do hereby acknowledge
2 that I have read and examined the foregoing
3 testimony, and the same is a true, correct and
4 complete transcription of the testimony given by
5 me, and any corrections appear on the attached
6 Errata sheet signed by me.
7
8
9 _____ _____
10 (DATE) (SIGNATURE)
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1 CERTIFICATE OF SHORTHAND REPORTER
2 I, Dawn M. Hart, the officer before whom the
3 foregoing deposition was taken, do hereby certify
4 that the foregoing transcript is a true and
5 correct record of the testimony given; that said
6 testimony was taken by me stenographically and
7 thereafter reduced to typewriting under my
8 direction; that reading and signing was not
9 discussed; and that I am neither counsel for,
10 related to, nor employed by any of the parties to
11 this case and have no interest, financial or
12 otherwise, in its outcome.
13 IN WITNESS WHEREOF, I have hereunto set my
14 hand and affixed my notarial seal this 13th day
15 of January, 2025.
16 My commission expires:
17 January 2, 2029
18
19 _____
20 NOTARY IN AND FOR THE
21 STATE OF MARYLAND
22