

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 ANDREW PARDOLL, M.D.

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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.

A P P E A R A N C E S

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1 P R O C E E D I N G S

2 ANDREW PARDOLL, 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 THE PETITIONER
8 BY MR. RATLIFF:

9 Q Good morning, Doctor, how are you?

10 A Good. How are you?

11 Q Excellent.

12 Would you please state your full name
13 for the record?

14 A My formal name is Andrew Pardoll. I go
15 by "Drew."

16 Q Please state your residence address.

17 A 19400 James Creek Court, Brookeville,
18 Maryland, 20833.

19 Q And, Doctor, you understand that you are
20 testifying under oath today, correct?

21 A I understand.

22 Q Is there any reason you cannot testify

1 truthfully today?

2 A No.

3 Q And, Doctor, you're currently employed
4 by The John Hopkins University School of Medicine;
5 is that right?

6 A That's not correct.

7 Q Who are you currently employed by?

8 A I am employed by The Johns Hopkins
9 University School of Medicine.

10 Q And do you understand that
11 The Johns Hopkins University School of Medicine --
12 strike that.

13 You understand that The John Hopkins
14 University owns the patent that is the subject of
15 the United States Patent and Trademark proceeding
16 we're in today, right?

17 A No, it's The Johns Hopkins, not
18 John Hopkins, but yes, I am aware of -- that
19 The Johns Hopkins University School of Medicine
20 owns the patent.

21 Q Let me try my question again. I thought
22 I said it, but let me try my question.

1 You understand that The Johns Hopkins
2 University owns the patent that is the subject of
3 the proceeding today?

4 A Yes.

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

7 Q Doctor, I'm going to show you a document
8 that's been marked as Exhibit 1001.

9 Do you recognize this document, Doctor?

10 A This is one of the patents that our
11 patent lawyers and the University has filed. So I
12 recognize it as that.

13 Q And have you read the patent before?

14 A I can't recall. There were many
15 versions and many patents, and I -- without being
16 able to go through it in some detail, I am not
17 sure that I have indeed read through it.

18 Q Okay. So sitting here today, it's fair
19 to say you're not quite certain if you've actually
20 read this patent; is that fair?

21 A I think it's fair to say that I'm not
22 certain if I had read through this particular

1 version of the patent, that's correct.

2 Q Now, Doctor, on February 4, 2020, you
3 executed a Declaration under 37 CFR 1.132, right?

4 A I believe that was -- I don't exactly
5 remember the date, but I remember that it was in
6 2020.

7 Q And the Declaration that you executed in
8 2020, you read that carefully before you executed
9 it, right?

10 A Right, I did.

11 Q And you read the entire Declaration
12 before you executed it, right?

13 A I believe so. Do you have a copy? It
14 would be helpful, because this was roughly half a
15 decade ago.

16 Q Sure.

17 (Exhibit 1002 was previously marked for
18 identification and was retained by Mr. Ratliff.)

19 Q Doctor, I'm handing you a copy of the
20 Declaration that you executed in February of 2020.
21 This is an excerpt of an exhibit that we've marked
22 in this case, Exhibit 1002. And so the excerpt is

1 your Declaration.

2 A Okay.

3 Q Now, did you read the entire Declaration
4 before you executed it, sir?

5 A So this was half a decade ago, but I'm
6 pretty sure that I did.

7 Q And when you executed your Declaration,
8 you understood it, right?

9 A I did.

10 Q And when you executed your Declaration,
11 you weren't confused by any of the things that you
12 said in your Declaration, right?

13 A No.

14 Q And when you executed your Declaration,
15 you weren't confused by anything that's in the
16 attachments to your Declaration, right?

17 A I would have to look at the attachments
18 to -- before -- since I am under oath, before
19 being able to accurately answer that question.
20 Are they here? Are the attachments here?

21 Q They are; you're actually looking at
22 one.

1 A This is Exhibit A. These are the
2 attachments?

3 Q They are.

4 A Okay. So I'm looking through my CV,
5 which looks like it's accurate at the time.
6 Posted a few more pages since then.

7 (Reviewing.)

8 Q And do you recall what the question is
9 that I asked you, sir?

10 A I believe so. But just as I'm looking
11 through, maybe if you could just ask it again.

12 Q Sure, sure.

13 You were not confused by anything in the
14 attachments that you attached to your Declaration,
15 correct?

16 A As I'm looking through the attachments
17 now, there's nothing that I'm seeing here that I
18 would say that I don't understand.

19 Q Okay. And did you prepare the
20 Declaration you executed by yourself, or did you
21 do that in conjunction with others?

22 MR. MILLER: Object to the form of the

1 question.

2 Go ahead, you can answer.

3 A This was prepared together in
4 conjunction with and with the help of our
5 attorneys.

6 Q And when you say "our attorneys," are
7 you referring to attorneys that work at The Johns
8 Hopkins University?

9 A These I don't remember specifically, but
10 these also included attorneys at
11 Fish & Richardson, with which Johns Hopkins works
12 on many patents.

13 Q And, Doctor, you prepared your
14 Declaration in support of the patentability of the
15 claims pending in United States Patent Application
16 Serial No. 16144549, correct?

17 A I can't answer because there were many
18 patents, and I don't know specifically, is -- what
19 that serial number refers to. Is that this patent
20 that you gave me? You mentioned a serial number.

21 Q So let me ask you a few questions, and
22 maybe we can help clarify.

1 If you could turn to the exhibit page at
2 the bottom to the front of your Declaration, page
3 No. 199?

4 A Page 199.

5 Q Very first page. You have that, sir?

6 A Uh-humh.

7 Q And there it says:

8 This is a Declaration under 37 CFR
9 1.132.

10 Right?

11 A That's correct.

12 Q And do you know what 37 CFR 1.132 is?

13 A No.

14 Q Now, if you turn to the next page, which
15 is page 200 of the exhibit, and turn your
16 attention to paragraph 15 at the top. Let me know
17 when you have it.

18 A Okay.

19 Q And if you can read paragraph 5 to
20 yourself and let me know when you're finished.

21 A (Reviewing.)

22 Okay.

1 Q So my question is, is it correct that
2 you prepared this Declaration in support of the
3 patentability of the claims pending in
4 United States Patent Application Serial No.
5 16144549?

6 A Sitting here today, half a decade later,
7 I imagine, because it says it, that in the process
8 of preparing the patent, a Declaration that I was
9 aware of that patent. But sitting here now,
10 again, half a decade later, I just don't remember.

11 Q And when you say you're aware of that
12 patent, what are you referring to?

13 A I'm just referring to what it says.

14 Q And do you think there's a reference to
15 a patent?

16 A Patented claims pending -- based on what
17 it says, I imagine that this is a patent that is
18 pending or at the time was pending before the
19 Patent and Trademark Office.

20 Q And are you talking about what your
21 Declaration says in paragraph 5?

22 A Simply referring to that.

1 Q Okay. And is it your understanding that
2 you were provided this Declaration in support of
3 the patentability of the claims pending in
4 United States Patent Application Serial No.
5 16144549?

6 A I'll answer the question the same way I
7 answered it when you just asked it, which is that
8 I imagine that to be the case based on what's
9 written here, because at the time that I signed
10 the Declaration, everything stated in the
11 Declaration I believed to be true -- at the case
12 -- at the time, but I can't remember back to
13 something like that. I'm a scientist. Five years
14 ago.

15 Q Okay. And when you say that you
16 provided the Declaration, who did you provide it
17 to?

18 A I'm actually not specifically sure who
19 it was provided to.

20 Q Do you have any general recollection as
21 to who your Declaration was provided to?

22 A No.

1 Q And, Doctor, you believe that you are a
2 co-inventor of the claims that were pending in
3 U.S. Patent Application No. 16144549, right?

4 A In order to answer that now, I would --
5 do you have a copy of this patent application?
6 I'd really like to take a look at it just to be
7 sure that I am being correct in my response.

8 Q Well, sitting here today I'm asking you
9 about the claims, I'm not asking you about the
10 patent application. I'm asking you about claims.

11 So my question is, do you believe that
12 you are a co-inventor of the claims that were
13 pending in U.S. Patent Application Serial No.
14 16144549?

15 A So the only -- in order to really answer
16 that sitting here today, since this was years and
17 years ago, it would be very helpful if you could
18 provide me with a copy of the claims.

19 Q So, Doctor, I'm handing you a document
20 that we're marking as a new exhibit. It's Exhibit
21 1149.

22

1 (Exhibit 1149 was marked for
2 identification and was retained by Mr. Ratliff.)

3 A Okay.

4 Q And if you could turn your attention to
5 the page where at the bottom it says page 14 of
6 245, and let me know when you have it.

7 A (Complying.)

8 Okay.

9 Q And I can represent to you, Doctor, that
10 this is the beginning of the claims that were
11 pending for the U.S. Patent Application Serial No.
12 16144549 at the time that your Declaration was
13 submitted to the Patent Office.

14 A Okay.

15 Q So my question for you, Doctor, is you
16 believe that you are a co-inventor of the claims
17 that were pending in U.S. Patent Application
18 Serial No. 16144549, right?

19 A Can you give me a moment to read through
20 the claims?

21 Q Sure.

22 A (Reviewing.)

1 Okay, so could you repeat the question,
2 then?

3 Q Doctor, you believe that you are a
4 co-inventor of the claims that were pending in
5 U.S. Patent Application Serial No. 16144549,
6 right?

7 A Looking through these, I'm not the real
8 expert who created the claim language, but the
9 gist of the invention, yes, I do.

10 Q Okay. I'm not asking if you were the
11 legal expert that created the claims. My question
12 is different.

13 Do you believe that you are a
14 co-inventor of the claims that were pending in the
15 United States Patent Application Serial No.
16 16144549 at the time you executed your
17 Declaration?

18 A Yes, I do.

19 Q Now, did you read each and every one of
20 these claims when you prepared and then executed
21 your Declaration?

22 A It was five years ago, and so I don't

1 specifically remember what I read through and what
2 I didn't. I probably did, but I honestly don't
3 remember five -- half a decade ago.

4 Q And sitting here today after just
5 looking at the claims, are you confused by
6 anything in the claims, the language or the
7 wording?

8 A So I'm a scientist and not a patent
9 lawyer, so the specific language I leave to our
10 attorneys. But the general gist of the invention
11 I am very familiar with.

12 Q And, Doctor, I'm not asking about the
13 general gist of the invention. I'm asking about
14 what you testified to in your sworn Declaration at
15 paragraph 5. There you talk about the claims,
16 right?

17 A Yes.

18 Q And so my question is, in paragraph 5
19 you say that you are a co-inventor of what's in
20 the claims, right?

21 A Yes.

22 Q So my question is, are you confused by

1 any of the language in the claims sitting here
2 today?

3 MR. MILLER: Objection to the form of
4 the question.

5 A Could you specify what you mean by
6 "confused"?

7 Q Do you understand what's written in the
8 claims sitting here today?

9 A I believe that I have a general
10 understanding in terms of how it translates to how
11 we would treat patients with mismatch repair
12 deficient cancers.

13 Q And are you confused by any of the
14 language in the claims sitting here today?

15 A Please specify what you mean by
16 "confused."

17 Q Do you understand the meaning of the
18 words that are in the claims sitting here today?

19 MR. MILLER: Objection to the form of
20 the question. Asked and answered.

21 A I understand the overall gist of the
22 invention, and that's really all that I can speak

1 to. I trust that our lawyers have translated that
2 general invention that I was a co-inventor of into
3 appropriate claims language.

4 Q And, Doctor, I understand that you have
5 positions and your counsel will have an
6 opportunity to potentially ask you questions,
7 okay, but this will go a lot smoother and easier
8 if you just focus on my question, okay?

9 So what I'm asking you is about the
10 language in the claims. Do you understand the
11 meaning of the words that are in the claims
12 sitting here today?

13 If you don't, you don't, you can tell me
14 that.

15 MR. MILLER: Objection to the form of
16 the question. Asked and answered. Potentially
17 seeks a legal conclusion.

18 MR. RATLIFF: Counsel, speaking
19 objections are --

20 MR. MILLER: That is not a speaking
21 objection, counsel, and it is fully in accord with
22 the guidelines.

1 MR. RATLIFF: It's not. You're just
2 interrupting.

3 BY MR. RATLIFF:

4 Q So, Doctor --

5 MR. MILLER: You're spending time
6 arguing with me. I'm making my objections for the
7 record.

8 Q Doctor, do you understand the meaning of
9 the words in the claims?

10 MR. MILLER: Objection to the form of
11 the question, asked and answered. Potentially
12 seeks a legal conclusion.

13 A I would have to agree with counsel. I
14 understand the overall invention, because I was an
15 inventor, I was in the room when the concept came
16 together, bringing together cancer immunologists,
17 cancer immunotherapists and cancer geneticists for
18 the first time to really come up with this. So I
19 understand.

20 Again, the language was developed over a
21 number of years by our patent lawyers who listened
22 to what our scientific rendering of the invention

1 was and translated that into legal claims, and I
2 trust them.

3 Q Doctor, I'm not asking you if you trust
4 others. I'm asking about you right now, sitting
5 here today, do you understand the language of the
6 claims?

7 MR. MILLER: Objection to the form of
8 the question, asked and answered.

9 A And I understand the invention as it
10 teaches oncologists.

11 Q I'm not asking if you understand what
12 you believe is the so-called invention. I'm not
13 asking you that. I'm asking you very specifically
14 about the claims.

15 Sitting here today, do you have any
16 understanding about the meaning of the words that
17 are in the claims; yes or no?

18 MR. MILLER: Objection to the form of
19 the question. Asked and answered.

20 A I -- again, not being a patent lawyer,
21 cannot speak to the specific language. I do,
22 however, understand the key gist of the invention.

1 Q And what was the question I asked you,
2 Doctor?

3 A The question that you asked me is do I
4 understand the language in the claims.

5 Q Okay. And you understand I didn't ask
6 you if you understood the key gist of the
7 invention. You know that, right?

8 MR. MILLER: Objection. Argumentative.
9 Objection to the form of the question.

10 A I've given you my answer.

11 Q You didn't answer that question.

12 Doctor, again, this will go a lot easier
13 if you just listen to my questions and just answer
14 those questions.

15 So let's try this.

16 Is it your understanding -- well, let me
17 try it this way.

18 You state in your Declaration that the
19 solicitation for patients was first posted on
20 clinicaltrials.gov on June 12, 2013, right?

21 A I don't sitting here today specifically
22 recall the date, but that sounds about right.

1 Q Okay. And you would agree that what's
2 in your Declaration at tab D does not reflect what
3 was posted on clinicaltrials.gov in June of 2013,
4 correct?

5 A I'm sorry, could you refer me
6 specifically to where you're referring to in my
7 Declaration?

8 Q In your Declaration you have an Exhibit
9 D, right?

10 A Exhibit D, as in David?

11 Q Yes.

12 A (Reviewing.)

13 Okay, yes, I see it.

14 Q And you would agree that Exhibit D does
15 not reflect what was posted on clinicaltrials.gov
16 in June of 2013, correct?

17 MR. MILLER: Objection to the form of
18 the question.

19 A Yeah, I would have to -- if you could
20 restate the question so I'm sure that I
21 understand. So I have an Exhibit D.

22 Q Do you believe Exhibit D reflects what

1 was posted on clinicaltrials.gov in June of 2013?

2 MR. MILLER: Objection to the form of
3 the question.

4 A So when a clinical trial is initiated or
5 is in the process of initiated, it's posted on
6 clinicaltrials.gov. Very frequently as the trial
7 progresses, there are amendments to the trial and
8 updates on clinicaltrials.gov.

9 So I see here a clinicaltrials.gov
10 posting. It says first posted, June 12th, 2013.
11 Last posted, March 29, 2018. So -- and see up
12 here it says June 8th, 2018.

13 So, I don't know, but likely there were
14 updates, amendments, as there frequently are, over
15 the five years between June 2013 and June 2018.
16 But I was not a coinvestigator on the trial, and
17 so I didn't file the amendments, so I don't know.

18 Q So you don't know whether or not Exhibit
19 D reflects what was posted on clinicaltrials.gov
20 as of June of 2013?

21 MR. MILLER: Objection to the form of
22 the question.

1 A So this is a June 8, 2018, posting. Do
2 you have the copy of the original June 12, 2013,
3 posting?

4 Q I do, but my question -- I'm asking you
5 a different question.

6 You selected Exhibit D to include in
7 your Declaration, right?

8 A Apparently.

9 Q Okay. So my question --

10 A This was half a decade ago.

11 Q That's okay, Doctor, I'm entitled to ask
12 you questions.

13 A Okay.

14 Q It happens all the time in cases. Okay?

15 A (Nodding head.)

16 Q And if you don't know, you can say you
17 don't know, that's okay.

18 A Okay. So I don't know.

19 Q Okay, so here's my question.

20 What's reflected in Exhibit D, would you
21 agree that that was -- that does not include what
22 was posted in clinicaltrials.gov on June 12, 2013?

1 MR. MILLER: Objection to the form of
2 the question.

3 A Given that I don't have the June 12th,
4 2013 posting, as I sit here today, I do not know
5 the answer to that question.

6 Q And when you included Exhibit D in your
7 Declaration, you weren't including it to try to
8 say that Exhibit D reflected what was posted to
9 clinicaltrials.gov in June of 2013; is that right?

10 MR. MILLER: Objection to the form of
11 the question.

12 A I don't recall.

13 Q Well, turn your attention to paragraph
14 22 of your Declaration. And that's at page 205 of
15 the excerpt of the exhibit of 1002.

16 A Okay.

17 Q And would you agree, sir, that Exhibit D
18 is not a document that you attached to your
19 Declaration to show what was actually posted on
20 clinicaltrials.gov on June 12, 2013?

21 MR. MILLER: Objection to the form of
22 the question.

1 A Yeah, that was a complicated question.
2 Could you rephrase it in a more clear fashion?

3 Q Let's try it this way.

4 Was Exhibit D posted to
5 clinicaltrials.gov in June of 2013?

6 A So I don't recall this Exhibit D. Has a
7 date of 6/2018, so it may not be the case. And it
8 may have been referring to this as an update of
9 the original posting. But I'm not sure. I really
10 don't want to give an incorrect answer, so I'm
11 just really not sure. I mean, potentially this
12 was an update of the original posting.

13 Q Okay. And I'm not asking you if it was
14 an update. I'm asking if the document in Exhibit
15 D, the pages, the words that you see in Exhibit D,
16 do you believe that they were actually posted on
17 clinicaltrials.gov as of June 2013?

18 MR. MILLER: Objection to the form of
19 the question.

20 A Yeah, I'm just really not sure.

21 Q Okay.

22 A I would really have to see all of the

1 original compared to this and, you know, what were
2 the amendments, if any, and this was really not
3 something that I was following, because I was not
4 an investigator on the clinical trial.

5 Q And you realize Exhibit D bears a date
6 at the top of June 8, 2018?

7 A Yes.

8 Q And do you really believe that a
9 document bearing a date of June 8, 2018, was
10 posted on clinicaltrials.gov as of June of 2013?

11 MR. MILLER: Objection to the form of
12 the question.

13 Go ahead.

14 A So I don't know where that date came
15 from. I mean maybe it was printed out on that
16 date, but this could have been the original
17 posting. So I don't know what that date means.

18 So without having the original posting
19 from June 12, 2013, to be able to compare
20 directly, I can't answer your question.

21 Q And it was you that selected Exhibit D
22 to put in your Declaration, right?

1 MR. MILLER: Objection to the form of
2 the question.

3 A This Declaration was prepared together
4 with our patent attorneys, and I certainly
5 believed at the time that, you know, all the
6 statements -- and I actually believe now -- that
7 all the statements were correct to the best of my
8 knowledge. It doesn't mean that there weren't
9 some errors.

10 But again, with regard to your question
11 about whether I believe this particular document
12 in Exhibit D is in fact the June 12th, 2013, I'd
13 have to see the June 12th, 2013.

14 Again, I -- you know, when we Xerox off
15 documents, you know, sometimes the date that you
16 Xerox them is on the top. So I don't know what
17 that date means. And again, without having the
18 original one to compare, I can't answer the
19 question.

20 Q Right. I think maybe you don't even
21 know -- I don't think you understand the question.
22 So let me try this again.

1 You remember telling me earlier that you
2 weren't confused by anything in your attachments,
3 right? You remember testifying to that?

4 A I don't specifically remember the
5 question. What I do --

6 Q I'll ask you a different question.

7 A Okay.

8 Q So if you could turn your attention to
9 your Exhibit D and the page that has the number at
10 the bottom 277. Let me know when you're there.

11 A Okay. And so ask your question. I'm at
12 2 -- page 277.

13 Q No, the exhibit page. Are you at the
14 exhibit page 277?

15 A It says 277 of 567.

16 Q I think you're in the wrong exhibit.
17 Let's see. Do you have an Exhibit 1002? Do you
18 have Exhibit -- I gave you an excerpt, Exhibit
19 1002.

20 A So these are the -- these are the three
21 things that you gave me (indicating).

22 Q Doctor, let me see --

1 MR. MILLER: It doesn't have an exhibit
2 number on it, Preston.

3 Q Okay, so this is the correct document.

4 A This one (indicating)?

5 Q That one.

6 So that's Exhibit 1002, and it's an
7 excerpt.

8 A Okay, you'd like me to go to page 277?

9 Q 277.

10 A Okay.

11 Q That has the exhibit number on it.

12 A Okay, I'm on page 277.

13 Q And page 277 is a page from the Exhibit
14 D that you included in your Declaration, right?

15 A Yes, appears to be the case.

16 Q And you see that here on page 277 it
17 indicates in the document a last update posted of
18 March 29, 2018, correct?

19 A I'm sorry, ask one more time, please.

20 Q And it indicates in the document a last
21 update posted March 29, 2018, correct?

22 A So are you referring to -- now back to

1 this page (indicating)?

2 Q No. So let's go back to page 277.

3 A Okay. Okay, last update posted March 29
4 -- okay.

5 Q So you see in the document of your
6 exhibit there's a portion of the document reads:

7 Last update posted March 29, 2018.

8 Correct?

9 A Correct.

10 Q And there's a portion of the document
11 that indicates last verified March 2018, correct?

12 A Correct.

13 Q So my question for you is, do you
14 believe that the Exhibit D that you included in
15 your Declaration was posted on clinicaltrials.gov
16 in June of 2013, this exhibit?

17 A Again, since I didn't follow various
18 updates, for all I know, it could be the same.
19 Again, I can't really answer that question without
20 having the verified June 12th, 2013, posting to
21 compare it to.

22 Q And so it's your testimony today that

1 your Exhibit D that reflects dates of March 29,
2 2018, and March of 2018, at page 277 could
3 actually have been posted on clinicaltrials.gov in
4 June of 2013?

5 MR. MILLER: Objection to the form of
6 the question.

7 A That's not correct.

8 Q Okay.

9 A What I said was that in order for me to
10 answer the question as to whether this document is
11 or is not the same as the posting on June 12,
12 2013, I would have to see and review that document
13 and compare it head-to-head.

14 Q Okay. Let's take a look at another
15 exhibit.

16 (Exhibit 1005 was previously marked for
17 identification and was retained by Mr. Ratliff.)

18 Q Doctor, I'm going to hand you a document
19 that's been marked as Exhibit 1005. And I can
20 represent to you that this is a Study Record
21 reflecting what was posted to
22 clinicaltrials.gov -- strike that.

1 I can represent to you that this
2 reflects what was posted on clinicaltrials.gov in
3 June of 2013.

4 A Okay.

5 Q Okay. So my question for you, Doctor,
6 is take a moment to look at the Study Record
7 posting and let me know when you're finished.

8 A (Reviewing.)

9 Q Finished reviewing it?

10 A So I looked at this, and then let me go
11 back to Exhibit D.

12 (Reviewing.)

13 Q Exhibit D starts at page 271.

14 A Okay.

15 Q Okay. So I'll ask you questions, this
16 is the way it works. You ready?

17 A Okay.

18 Q So you would agree that the study
19 description in Exhibit D in your Declaration is
20 different than the study description in Exhibit
21 1005, right?

22 A You'll have to give me a moment to

1 compare them to see if they're the same or not.

2 Q And, Doctor, I didn't suggest I wasn't
3 going to give you a moment; I just have to ask the
4 question.

5 A Okay.

6 (Reviewing.)

7 Q And just so you're clear what the
8 question is, Doctor, would you agree that the
9 Study Record reflected in Exhibit D of your
10 Declaration is different than the Study Record
11 that's reflected in Exhibit 1005 with respect to
12 the study description?

13 A I do see some differences. Although,
14 when I look, for example, at the Summary, which is
15 what really is key, the Summary --

16 Q Doctor, my question is about --

17 A The Summary is word-for-word the same.
18 The groups look the same. There is a difference
19 in the date, and see -- I saw a difference -- this
20 lists 171 participants. I think I saw this
21 listing maybe 71 participants.

22 So it is potentially an update, although

1 -- so, these two do not appear to be identical
2 documents, although in substance they appear
3 pretty darn close.

4 Q Okay. So, Doctor, with all due respect,
5 I just ask you to focus on my questions. Your
6 counsel will have an opportunity to ask you
7 questions. And we just want to make this go easy
8 and smooth. We don't want to have to bring you
9 back, okay? So --

10 A It's a longer trip for you than it is
11 for me. I just had to walk down the --

12 Q If you're happy to come back, then
13 that's fine, we'll also find another day to come
14 back, that's fine. You're happy to come back?

15 MR. MILLER: Objection. Argumentative.

16 MR. RATLIFF: No, it's not
17 argumentative. The doctor suggested --

18 Q Doctor, are you happy to come back for
19 another day if we don't finish?

20 MR. MILLER: Counsel, you're not
21 entitled to have the doctor come back. You have
22 three hours today. I suggest you use it wisely.

1 Q Doctor --

2 A I suggest you use your three hours
3 wisely.

4 Q You're just listening to your counsel.
5 Just trying to make this go easy.

6 So focusing your attention on the study
7 description in the Study Record that's attached to
8 your Declaration and the Study Record that was
9 posted in June of 2013 in Exhibit 1005, would you
10 agree with me, Doctor, that in the Brief Summary
11 the words "for patients with MSI-negative cancer
12 with a mutator phenotype" are not included in the
13 Study Record that was posted in June of 2013?

14 A Yes. It does appear so.

15 Q And, Doctor, turning your focus to the
16 study description in the Study Record that you
17 include in your Declaration and the Study Record
18 that was posted in June of 2013, would you agree
19 with me that the Study Record that you posted
20 includes a statement about high tumor mutation
21 burden that does not appear in the Study Record
22 that was posted in June of 2013? And we're

1 looking at the study description.

2 A Where --

3 Q The study description. Sure. So we can
4 do --

5 A You just said refer to high tumor
6 mutation burden. Where in either of the study
7 descriptions does the term "high tumor mutation
8 burden" appear?

9 Q Sure. We'll walk through it.

10 So you have your Exhibit D?

11 A I'm missing something. Okay.

12 Q You have your Exhibit D right, sir?

13 A Uh-humh.

14 Q So turn to the page -- the second page
15 of that, which is page 272. Let me know when you
16 have it.

17 A Okay.

18 Q And you see at the top there, there's a
19 table, right?

20 A Yes.

21 Q And in the table you see the reference
22 to "high tumor mutation burden"?

1 A Okay. Is that -- I didn't take that to
2 be part of the Brief Summary. You referred to
3 the --

4 Q I didn't refer to the Brief Summary, and
5 that's why it's probably important to take it slow
6 and listen carefully.

7 A Okay.

8 Q Okay, I'm talking about the study
9 description. So you see in the study description
10 in the Study Record that's in your Declaration a
11 table, right, sir?

12 A Correct.

13 Q And in that table there's a reference to
14 "high tumor mutation burden," correct?

15 A Correct.

16 Q And would you agree that that reference
17 to high tumor mutation burden is not included in
18 the Study Record that was posted in June of 2013?

19 A If this is indeed the June 2013, I don't
20 see it.

21 Q Okay. So I want to go forward, and
22 let's look at the Study Design section of the

1 Study Record that's included in your Exhibit D.

2 Let me know when you have it.

3 A Okay, this is page -- this is on page
4 272?

5 Q It is, sir.

6 A Okay.

7 Q And do you see the reference in your
8 Study Record that's attached as Exhibit D to
9 "estimated enrollment, 171 participants"?

10 A Yes.

11 Q Would you agree that that reference is
12 not included in the Study Design portion of the
13 Study Record that was posted in June 2013?

14 A Which is this (indicating)?

15 Q Yes. "This" being Exhibit 1005.

16 A Right.

17 As I'm sitting here reading this, yes.

18 Q Now, turning your attention to the Arms
19 and Interventions -- sorry. Start that again.

20 Doctor, turning your attention to the
21 Arms and Interventions section of the Study Record
22 that's attached to your Declaration, let me know

1 when you're there.

2 A The Arms and Intervention, so what page
3 is that?

4 Q That's page 272.

5 A Okay.

6 Q You have it, sir?

7 A Got it.

8 Q And you see in the Arms and Intervention
9 section of the Study Record that you attached
10 there's a reference to a "experimental
11 MSI-negative and mutator phenotype arm"?

12 A Yes.

13 Q And would you agree, sir, that in the
14 Arms and Intervention section in the Study Record
15 that was posted in June of 2013, there's no such
16 reference?

17 A Yes.

18 Q Now, Doctor, turning your attention to
19 the Outcomes Measure section of the Study Record
20 that's attached at your Declaration, and this is
21 at page 273.

22 A Uh-humh.

1 Q Would you agree with me that the fourth
2 Primary Outcome Measure in the Study Record that's
3 attached to your Declaration is not found in the
4 Study Record that was posted in June of 2013?

5 A Yes.

6 Q Turning your attention to page 273 of
7 your -- the Study Record that was attached to your
8 Declaration, and looking specifically at the
9 Secondary Outcome Measures and looking at Item No.
10 6, would you agree with me that Item No. 6 was not
11 included in the Study Record that was posted in
12 June of 2013?

13 A This is under Secondary Outcome
14 Measures.

15 Q It is, sir.

16 A It appears not.

17 Q And can you turn your attention to the
18 Study Record attached to your Declaration at page
19 274 of the exhibit?

20 A Okay.

21 Q And looking at the Inclusion Criteria,
22 would you agree with me that Inclusion Criteria 11

1 and 12 are not included in the Study Record that
2 was posted in June of 2013?

3 A This is patients who have, those with
4 infection, with HIV, Hep B or Hep C and patients
5 with evidence of interstitial lung disease?

6 Q No. Let's go back to --

7 A I'm looking -- oh, this is Exclusion
8 Criteria, sorry.

9 Q No worries.

10 A So I'm sorry, so refer me again to what
11 you're --

12 Q Page -- so we're in your -- the -- we're
13 in the Study Record that you attach to your
14 Declaration at exhibit page 274.

15 A Okay.

16 Q And we're looking at the Inclusion
17 Criteria Nos. 11 and 12.

18 Do you see those, sir?

19 A Yeah, I'm reading them now.

20 Okay.

21 Q Do you agree with me, sir, that
22 Inclusion Criteria 11 and 12 are not found in the

1 Study Record that was posted in June of 2013?

2 A Appears that way.

3 Q Now, turning your attention to the Study
4 Record that was included in your Declaration and
5 at page 274, looking at the Exclusion Criteria,
6 would you agree with me that the Exclusion
7 Criteria Nos. 8 through 22 are not included in the
8 Study Record that was posted in June of 2013?

9 A Appears to be the case.

10 Q And, Doctor, looking at the Study Record
11 that's attached to your Declaration and turning
12 your attention to the exhibit page 275 --

13 A Okay.

14 Q -- would you agree with me that the
15 locations of Stanford University and then
16 Ohio State University, Providence Portland Medical
17 Center, University of Pennsylvania, University of
18 Pittsburgh Cancer Institute appearing at exhibit
19 page 276 of the Study Record in your Declaration,
20 do not appear in the Study Record that was posted
21 in June of 2013?

22 A Is this indeed the complete Study Record

1 that was posted in June 2013?

2 Q I made a representation -- Doctor, let
3 me try again. I made a representation to you.
4 You -- you're free to answer my question.

5 A So those sites are not listed on the
6 Exhibit 1005 which you represented to me as the
7 June 2012 posting.

8 Q I certainly didn't say June 2012, I'm
9 pretty sure.

10 A I'm sorry, June 2013.

11 MR. MILLER: Counsel, we've been going
12 for well over an hour. Is this a good time for a
13 break?

14 MR. RATLIFF: Sure.

15 (A recess was taken at 9:10 a.m.)

16 (Back on the record at 9:26 a.m.)

17 BY MR. RATLIFF:

18 Q Okay, welcome back.

19 Doctor, during the break did you discuss
20 this case?

21 A No.

22 Q During the break did you discuss any of

1 my questions?

2 A No.

3 Q Now, Doctor, if I could turn your
4 attention to the Study Record that you attached to
5 your Declaration, and looking at exhibit page 276.

6 A Uh-humh.

7 Q Doctor, at the top there there's a
8 reference to George Fisher. Do you see that?

9 A Yes.

10 Q And do you know George Fisher?

11 A I know who he is, but I don't know him
12 personally.

13 Q And he's indicated as a principal
14 investigator; is that right?

15 A Yes.

16 Q And is it your understanding that
17 George Fisher was a principal investigator for the
18 clinical trial with the number NCT01876511?

19 A Is that the Strom? I mean I don't --

20 Q Do you --

21 A This is 76511?

22 Q Are you familiar with the clinical trial

1 identifier NCT01876511?

2 A I'm reading it here.

3 Q Other than reading it, sitting -- before
4 coming to this deposition, were you ever familiar
5 with the clinical trial identifier NCT01876511?

6 MR. MILLER: Objection to the form of
7 the question.

8 Go ahead.

9 A I was generally aware of the trial that
10 Dr. Le and Dr. Diaz initiated, but to reiterate, I
11 was not a coinvestigator on the trial, so my
12 knowledge of the details of the trial, including
13 the various sites that were added to the trial, or
14 the principal investigators at each of the
15 individual sites, my knowledge is really minimal.
16 I'm not the person to ask about those specifics.

17 Q Okay, but I was asking about the
18 clinical trial identifier NCT01876511.

19 Before coming to your deposition today,
20 were you familiar with that number?

21 MR. MILLER: Objection to the form of
22 the question.

1 A I'm familiar with the trial, but I --

2 Q And I'm asking about the number.

3 A The number -- only in that the number is
4 here. So I am familiar with the trial that is
5 titled Phase 2 Study of MQ3475 in Patients with
6 Microsatellite Unstable Tumors, and as far as the
7 number is concerned, only in that I'm reading it
8 here. I don't pay attention to the clinical trial
9 identifier numbers on trials. I pay attention to
10 the -- what's in the trial.

11 Q And, Doctor, I'm not asking you what you
12 pay attention to. And again, this will go a lot
13 smoother if you just carefully listen to my
14 question, okay?

15 It's -- with all due respect -- because
16 if we have to make an application to have you come
17 back, then we'll do that, but it will go a lot
18 smoother. Just listen to my question.

19 I'm just asking just about the clinical
20 trial number, okay? That's what my question is
21 going to be about. If you don't know, you're not
22 familiar, you just say that. So let me ask my

1 question again.

2 Before coming to your deposition today,
3 were you familiar with the clinical trial number
4 NCT01876511?

5 MR. MILLER: Objection to the form of
6 the question.

7 A I was not familiar with the number.

8 Q Thank you.

9 And the day will go very quickly and
10 simple.

11 A (Nodding head.)

12 Q All right. And, Doctor, were you --
13 turning your attention to page 276, were you
14 familiar with the principal investigator John Hays
15 from The Ohio State University?

16 A No.

17 Q And do you know what a principal
18 investigator is, Doctor?

19 A Yes.

20 Q And in general, what is a principal
21 investigator?

22 A A principal investigator is the

1 individual that is primarily responsible for the
2 execution of the trial.

3 Q In looking and turning our attention
4 looking at page 276, there are one, two, three,
5 four, five, six principal investigators listed in
6 the Study Record in your Declaration; is that
7 right, sir?

8 A Yeah. When there are multiple sites on
9 a trial, each site has to have its own principal
10 investigator.

11 Q Okay. Now turning your attention to
12 page 271, this is the first page of the Study
13 Record in your Declaration.

14 A Okay.

15 Q And looking at the study description and
16 then underneath that, the Brief Summary. Let me
17 know when you're there, sir.

18 A I'm there.

19 Q And do you see in the first sentence
20 underneath the Brief Summary there's a reference
21 to the study looking at pembrolizumab in three
22 different patient populations?

1 A Yes.

2 MR. MILLER: Sorry, objection to the
3 form of the question.

4 Q Okay. And, Doctor, after that first
5 sentence, you see that the Brief Summary goes on
6 to talk about four different patient populations,
7 right, sir?

8 A Yes.

9 Q And would you agree that the fourth
10 patient population indicated is patients with
11 MSI-negative cancer with a mutator phenotype?

12 A Yes.

13 Q And that fourth patient population is
14 not referred to in the June 2013 Study Record,
15 right?

16 A If this (indicating) is that, then yes.

17 Q And by "this," you were pointing to
18 Exhibit --

19 A Exhibit --

20 Q -- 1005?

21 A Correct.

22 Q Now, Doctor, if you could turn your

1 attention to your Declaration and looking at page
2 200 -- it's the exhibit page 200. Let me know
3 when you're there.

4 A Okay.

5 Q And if you could turn your attention
6 specifically to paragraph 7 of your Declaration.

7 A Okay.

8 Q And paragraph 7 is a paragraph that you
9 wrote; is that right?

10 A I certainly compiled it. It was the
11 document in conjunction with the lawyers. I can't
12 remember specifically what words came from what,
13 but I certainly did agree that what was written
14 here in the Declaration --

15 Q Okay.

16 A -- was correct to the best of my
17 knowledge and certainly reflected my significant
18 input.

19 Q Okay. And, Doctor, in paragraph 7 you
20 wrote:

21 A scientist or physician in the field.

22 Do you see that?

1 A I do.

2 Q And what did you mean by "scientist or
3 physician in the field"?

4 A By "scientist," I mean a cancer
5 researcher. By "physician" I mean a treating
6 oncologist.

7 Q And by "field," what did you mean?

8 A The field of oncology, or cancer, the
9 same.

10 Q And in paragraph 7 of your Declaration,
11 you also talk about, quote, the date of our
12 invention, end quote.

13 Do you see that?

14 A I'm sorry, where -- oh, yes, yes. Yes.

15 Q And so my question for you, when you
16 wrote, quote, the date of our invention, end
17 quote, what date were you referring to?

18 A So my understanding was that the date of
19 the invention filing was July of 2015.

20 Q And that's the date that you were
21 thinking of when you wrote this paragraph and
22 signed it?

1 A I think so.

2 Q Okay.

3 A With the caveat being that this was half
4 a decade ago. So that is my recollection.

5 Q And, Doctor, in that same sentence that
6 we're looking at in paragraph 7 of your
7 Declaration, you write, quote, at the time of the
8 invention, end quote.

9 Do you see that?

10 A At the -- so I see "at the date of our
11 invention." Is there another --

12 Q So if you keep reading on in that same
13 paragraph 7 --

14 A Okay.

15 Q -- there's the language --

16 A Yes.

17 Q -- quote, at the time of the invention,
18 end quote.

19 Do you see that?

20 A I do.

21 Q And what date did you have in mind with
22 your reference to "at the time of the invention"?

1 A So the conception of the invention was
2 in 2012. The date of the filing was July of 2015.
3 I don't specifically remember whether I was
4 referring to -- which I was referring to when I
5 indicated the time of the invention, but the
6 reality is that no scientist or physician in the
7 field before Dr. Le presented the results of the
8 trial, which was to test our hypothesis at the
9 ASCO meeting in 2015, would have expected an
10 improved outcome for patients with tumors having
11 mismatch repair deficiency.

12 Q And, Doctor, I understand you have
13 positions, and we may get there, and your counsel
14 may have an opportunity to ask you questions. I'm
15 just looking for an answer to my question. So let
16 me try it again.

17 I'm asking specifically about this
18 language that you wrote in your Declaration and
19 whether or not sitting here today you know what it
20 means. That's what I'm asking, Doctor. So let me
21 ask my question again.

22 So when you wrote in your Declaration at

1 paragraph 7, "at the time of the invention,"
2 sitting here today, Doctor, do you have a memory,
3 recollection, of what date you had in mind when
4 you wrote that language in paragraph 7 and
5 executed your Declaration?

6 A I don't.

7 Q Okay. Now, Doctor, before the clinical
8 trial reflected in the Study Record that was
9 posted in June of 2013 began, would you agree that
10 it was reasonable for a scientist or a person in
11 the field to anticipate that there would be a
12 greater number of clinical responses in the
13 MSI-high group than the MSI stable group?

14 A I do not.

15 Q And before the clinical trial that's
16 described in the Study Record that was posted in
17 June of 2013 began, did you anticipate that there
18 would be a greater number of clinical responses in
19 the MSI-high patients than the MSI stable
20 patients?

21 A I did not. Having had many failures in
22 clinical trials in oncology, I was hopeful, but

1 most clinical trials, no matter how good the idea,
2 fail, and I'm certainly no exception with my
3 experience.

4 So for that reason, I did not anticipate
5 that there would be an approved outcome in MSI
6 patients versus not.

7 Q Doctor, before the clinical trial
8 described in the Study Record that was posted in
9 June 2013 began, did any of your colleagues at
10 The Johns Hopkins University anticipate that there
11 would be a greater number of clinical responses in
12 the MSI-high patient group than the MSI stable
13 group?

14 MR. MILLER: Objection to the form of
15 the question.

16 A I'm not aware that that was the case.

17 Q Okay.

18 A We were very hopeful. It was a great --

19 Q Doctor --

20 A -- novel unanticipated idea.

21 Q -- I know you have --

22 MR. MILLER: Counsel, let him finish.

1 Q I know you have --

2 MR. MILLER: Go ahead.

3 Q -- positions.

4 MR. MILLER: Counsel, let him finish his
5 statement.

6 Go ahead.

7 A And so we were hopeful, but human cancer
8 is very complicated, and we get defeated more than
9 we win.

10 Q And again, Doctor, I just ask you to
11 focus on my questions. We have limited time here,
12 and that's part of the reason that we may have to
13 request you to come back, and I know you seemed to
14 suggest that you'd be happy to do that. We can
15 come down by train. We're in New York, it's not
16 too far.

17 So, Doctor, I have a question about
18 another paragraph in your Declaration. So if you
19 could turn to exhibit page 203. And let me know
20 when you have it, Doctor.

21 A Okay.

22 Q And turning your attention to paragraph

1 14.

2 A Uh-humh.

3 Q And in paragraph 14 you reference an
4 anti-PD-1 antibody with a number BMS-936558.

5 Do you see that?

6 A I do.

7 Q And is that a reference to nivolumab?

8 A That is indeed the antibody that came to
9 be known as nivolumab.

10 Q Okay. And in the trial that you refer
11 to about nivolumab, there was one colorectal
12 patient who had a complete response for more than
13 21 months, right?

14 A Correct.

15 Q Now, would you agree that that finding
16 is fairly and appropriately characterized as
17 statistically meaningless?

18 A Considering that the next 30 patients
19 did not respond, I would say yes.

20 Q And the colorectal cancer patient who
21 experienced a complete response in that study was
22 MSI-high, right?

1 A Ultimately they turned out to be such
2 when we asked the treating physician to send a
3 sample for testing. Yes. We didn't know that at
4 the time.

5 Q Didn't ask you what you knew at the
6 time. Just asking about the patient, Doctor.

7 A Uh-humh.

8 Q You appreciate that?

9 A Uh-humh.

10 Q Okay.

11 MR. MILLER: Counsel, we'll get done --
12 you'll use your time more efficiently if you stop
13 arguing with the witness and simply ask questions.
14 He was responding to your last question.

15 Q Doctor, now, part of the rationale as to
16 why -- well, let me try it this way.

17 Doctor, part of the rationale as to why
18 scientists or physicians in the field would
19 conduct a Phase 2 study of pembrolizumab in
20 patients with microsatellite unstable tumors is
21 the complete response in a single patient with
22 colorectal cancer, right?

1 MR. MILLER: Objection to the form of
2 the question.

3 A Could you rephrase that question?

4 Q Let me try it this way.

5 (Exhibit 1013 was previously marked for
6 identification and was retained by Mr. Ratliff.)

7 Q So, Doctor, I'm going to hand you an
8 exhibit that's been marked as Exhibit 1013. And
9 you recognize Exhibit 1013, right?

10 A I do.

11 (Exhibit 2024 was previously marked for
12 identification and was retained by Mr. Ratliff.)

13 Q And also hand you a document that's been
14 labeled as Exhibit 240.

15 A Uh-humh.

16 Q And, Doctor, you recognize Exhibit 240,
17 right?

18 A I do.

19 Q And let me correct that. I believe it's
20 Exhibit 2024, actually. JHU Exhibit 2024.

21 So, Doctor, you recognize JHU Exhibit
22 2024, right?

1 A Yes.

2 Q Now, would you agree, Doctor, that part
3 of the rationale as to why a scientist or
4 physician in the field would conduct a Phase 2
5 study of pembrolizumab in patients with
6 microsatellite unstable tumors is the complete
7 response in a single patient with colorectal
8 cancer as reported in JHU Exhibit 2024 and Merck
9 Exhibit 1013?

10 MR. MILLER: Objection to the form of
11 the question.

12 A Which is Exhibit 1013?

13 Q 1013 is the paper with the first name --

14 A Oh, this.

15 Q -- author, Topalian.

16 A Okay. So could you restate the
17 question?

18 Q Sure.

19 Would you agree, Doctor, that part of
20 the rationale as to why a scientist or physician
21 in the field would conduct a Phase 2 study of
22 pembrolizumab in patients with microsatellite

1 unstable tumors is the complete response in a
2 single patient with colorectal cancer as reported
3 in Merck Exhibit 1013 and JHU Exhibit 2024?

4 MR. MILLER: Objection to the form of
5 the question.

6 A No.

7 Q Okay. And, Doctor, would you agree that
8 part of the rationale as to why a scientist or a
9 physician in the field would conduct a Phase 2
10 study of pembrolizumab in patients with
11 microsatellite unstable tumors is the showing of
12 pembrolizumab of activity in multiple tumor types,
13 including melanoma and non-small cell lung cancer?

14 MR. MILLER: Objection to the form of
15 the question.

16 A No.

17 Q And, Doctor, would you agree that part
18 of the rationale as to why a scientist or
19 physician in the field would conduct a Phase 2
20 study of pembrolizumab in patients with
21 microsatellite unstable tumors is the fact that
22 previously nivolumab showed activity in melanoma?

1 MR. MILLER: Objection to the form of
2 the question.

3 A No.

4 Q Now, Doctor, if we could turn to your
5 Declaration, and this is exhibit page 18 -- sorry,
6 try that again. Let's turn to your Declaration,
7 exhibit page 204.

8 A Okay.

9 Q And turning your attention to paragraph
10 18. Let me know when you have it.

11 A Got it.

12 Q Now, in paragraph 18, you write:

13 Dr. Vogelstein and his group.

14 Do you see that?

15 A I do.

16 Q And when you refer to Dr. Vogelstein's
17 group, who specifically did you mean?

18 A Dr. Vogelstein, Dr. Kinzler,

19 Dr. Papadopoulos, and Dr. Diaz.

20 Q Anyone else?

21 A There were certainly many students and
22 postdoctoral Fellows that have trained in

1 Dr. Vogelstein's group, some of whom probably
2 continue to work on it, but among the people at
3 Hopkins and the people that were involved in this
4 landmark brainstorming session, those were the
5 four people.

6 Q Okay. Now, if I could turn your
7 attention to exhibit page 205 -- and again, we're
8 in your Declaration -- and specifically looking at
9 paragraph 22. Let me know when you have it.

10 A Got it.

11 Q In paragraph 22 do you see where you
12 refer to, quote, the research team at Hopkins, end
13 quote?

14 A (Reviewing.)

15 Yes.

16 Q And when you wrote "the research team at
17 Hopkins," who were you referring to?

18 A That's a large team, certainly led by
19 Drs. Le and Diaz, but also included research
20 nurses, clinical coordinators, data managers, the
21 large group of people that is involved when one
22 initiates and executes a clinical trial.

1 Q And in paragraph 22 of your Declaration
2 you write:

3 It was, however, the research team at
4 Hopkins who secured IBR approval, conducted and
5 paid for the study.

6 Right?

7 MR. MILLER: Objection to the form of
8 the question. Counsel, you misspoke.

9 A You said IBR, it's IRB.

10 Q All right. So let's try it again.

11 Doctor, in your Declaration you
12 testified:

13 It was, however, the research team at
14 Hopkins who secured IRB approval, conducted and
15 paid for the study.

16 Right?

17 A Yes.

18 Q And when you say, "it was the research
19 team at Hopkins who conducted the study," are you
20 aware of all the people that conducted the study?

21 A There are a lot of people involved, and
22 that statement refers broadly to the scientists,

1 again, the physicians leading the study, other
2 physicians that were seeing patients on the study,
3 research nurses, data managers, clinical
4 coordinators. A large team.

5 Q And this large team that you're
6 referring to, they were all folks at Hopkins; is
7 that your testimony?

8 A At the initiation of the study, yes.

9 Q Okay. I'm not asking about the
10 initiation of the study, I'm asking about what you
11 testified to in your Declaration.

12 In your Declaration you testified --

13 A Well, I was referring to --

14 Q Doctor, the way this works --

15 MR. MILLER: You need to let him ask the
16 question, then you can answer.

17 Q Doctor, in your Declaration you
18 testified:

19 It was the research team at Hopkins who
20 secured IRB approval, conducted and paid for the
21 study.

22 A Yes.

1 Q So my question is, are you aware of all
2 the people that conducted the study?

3 MR. MILLER: Let me -- objection to the
4 form of the question.

5 Go ahead.

6 A Could you clarify what you mean by
7 "aware of"?

8 Q Well, let me ask it this way.

9 We talked earlier about a
10 Dr. George Fisher who was at Stanford University.
11 Is it your testimony that Dr. George Fisher was
12 not a part of conducting the study?

13 A No. What I --

14 Q Doctor --

15 A Okay.

16 Q -- if you have a position --

17 A I just wanted to clarify what I meant by
18 "no."

19 Q And how that works is your attorney can
20 clarify after I finish my questions.

21 MR. MILLER: Dr. Pardoll, if your
22 testimony is unclear at this point, you are more

1 than entitled to clarify it.

2 MR. RATLIFF: It's not.

3 Q So, Doctor --

4 MR. MILLER: Go ahead if you have more
5 to say.

6 A Yeah, I'd really like to clarify. I
7 think it's important that I have the opportunity
8 to clarify it. So --

9 Q And we may have time to come back.

10 MR. MILLER: Yeah, but he can do it now.
11 Go ahead.

12 A When the study was initiated, it was all
13 Hopkins people, came out of Hopkins. Once the
14 study is written and executed, then what happens
15 when it starts at one institution, but it is
16 gleaned that in order to recruit patients at a
17 reasonable pace, that other institutions need to
18 participate, and certainly in this case, Drs. Diaz
19 and Le contacted colleagues of theirs at other
20 institutions to describe the study and bring them
21 on board. That occurred.

22 The pace at which it occurred and

1 exactly what time various other institutions
2 joined the study that had been written by Drs. Le
3 and Diaz, I don't know, since I was not an
4 investigator on the study and was not aware of its
5 execution to that level of detail.

6 Q And, Doctor, in your testimony in
7 paragraph 22 of your Declaration, you don't say
8 anything about initiation of the study, right?

9 A (Reviewing.)

10 MR. MILLER: Objection to the form of
11 the question.

12 Go ahead.

13 A I don't specifically use that term.

14 Q Right, you don't use the term
15 "initiation of the study," right?

16 A That is correct.

17 Q And in your testimony in paragraph 22 of
18 your Declaration you weren't trying to give the
19 impression that only folks at Hopkins conducted
20 the study, were you?

21 A No. The study was written and conceived
22 essentially exclusively at Hopkins. But the

1 conduct of the study clearly involved bringing
2 other institutions on board to the study that was
3 conceived and written by the Hopkins team.

4 Q And, Doctor, you understand that Merck
5 was a collaborator for this study, right?

6 MR. MILLER: Objection to the form of
7 the question.

8 A Merck provided the drug.

9 Q That wasn't my question, Doctor.

10 You understand that Merck was a
11 collaborator for the study, right?

12 MR. MILLER: Objection to the form of
13 the question. Asked and answered.

14 Q If you don't understand, you can tell me
15 that.

16 A So --

17 Q Let me try my question, Doctor, because
18 again, I understand you have a position.

19 A I'm about to answer.

20 Q Okay. But I just want to make sure
21 we're clear. I don't want to waste your time. So
22 here's my question.

1 You understand, Doctor, that Merck was a
2 collaborator for this clinical study, right?

3 MR. MILLER: Objection to the form of
4 the question. Asked and answered.

5 A When I as a scientist give a re-agent to
6 another laboratory to do an experiment in which
7 they conceived and executed and they simply asked
8 me for my re-agent, I do not consider myself a
9 collaborator because I simply provided a re-agent.

10 Based on my personal bar for what is a
11 collaborator, since Merck only provided the drug
12 at the request, suggestion, and ideas presented to
13 them by Hopkins, I personally do not consider
14 Merck a collaborator.

15 Q Okay. You understand I wasn't asking
16 how you thought about yourself in some
17 hypothetical as being a collaborator, right? I
18 was asking about Merck. You understand that,
19 right?

20 MR. MILLER: Objection to the form of
21 the question. Argumentative.

22 Q Do you understand that, Doctor?

1 A I understand --

2 MR. MILLER: Same objections.

3 A -- that you asked me if I understood
4 that Merck was a collaborator, and I responded
5 with the reasoning as to why I personally did not
6 consider Merck to be a collaborator, since all
7 they did was provide a re-agent, and all the
8 ideas, conceptualizations and execution of the
9 initial study were done at Hopkins.

10 Q And what do you mean by "initial study,"
11 Doctor? What time frame is that and what study is
12 that?

13 A I am referring to the study that
14 generated the patient data that went into the
15 patent application and that was revealed first
16 publicly in the 2015 New England Journal paper
17 concomitantly with Dr. Le's presentation at ASCO.

18 Q And is it your testimony and belief that
19 for the period that included all of that data,
20 Merck never provided any financial support for
21 what you call the initial study; is that right?

22 A My understanding is that the study that

1 was presented at ASCO in 2015 was not paid for by
2 Merck. But I might also indicate that simply
3 providing funding does not make the entity that
4 simply provides funding a collaborator.

5 Q All right. Doctor, I think you're
6 not -- just try to listen to my question
7 carefully, because I didn't ask you if Merck paid
8 for the entire study. I'm asking a different
9 question. I'm asking about providing support with
10 financial funding. That's what I'm asking about.
11 So let me try my question again.

12 For what you call the initial study,
13 Doctor, is it your belief that Merck never
14 provided any support in terms of financial funding
15 for the study?

16 MR. MILLER: Objection to the form of
17 the question. Asked and answered.

18 A My understanding is that Merck did not
19 provide financial support for the initial study.

20 Q And, Doctor, you are aware that the
21 Declaration that you -- strike that.

22 Doctor, you are aware that the Study

1 Record you included in your Declaration identifies
2 Merck as a collaborator for the study, right?

3 A I don't specifically remember what was
4 on the Study Record that was included with my
5 Declaration.

6 Q All right. Well, let's see if we can
7 refresh your recollection.

8 So if you could turn to exhibit page
9 271, which is the very first page of the Study
10 Record that you included in your Declaration. And
11 let me know when you have it, Doctor.

12 A Okay.

13 Q And you see right there, Doctor, that in
14 the Study Record that you included in your
15 Declaration, Merck is identified as the
16 collaborator for the study, right?

17 A Yes.

18 Q But it's your opinion that Merck is not
19 a collaborator -- was not a collaborator for the
20 study -- let me try again.

21 But it's your opinion that Merck was not
22 a collaborator for the study, right?

1 A Not according to my definition of what a
2 collaborator is.

3 Q And, Doctor, you understand that in the
4 Study Record that was posted in June of 2013, the
5 very first posting, Merck was identified as a
6 collaborator for the study, right?

7 A Are you referring to Exhibit 1005?

8 Q Correct.

9 A Can you point me to where it says that?

10 Q I'm just asking you -- if sitting here
11 today you're not aware, you can just tell me that.

12 A I'm obviously not aware.

13 Q Okay, that's fine. Then you can put it
14 aside.

15 Now, I want to turn your attention back
16 to your Declaration, and looking at exhibit page
17 205, paragraph 22. Let me know when you're there.

18 A Paragraph 22?

19 Q Yes.

20 A Uh-humh.

21 Q Now, in paragraph 22 you testify that it
22 was the research team at Hopkins that paid for the

1 study, right?

2 A That is what it says.

3 Q And when you say "paid for the study,"
4 again, are you talking about the so-called initial
5 period that goes from enrolling patients to the
6 presentation by Dr. Le in 2015?

7 A Those -- I'm referring to the initiation
8 of the study and enrollment and evaluation of the
9 patients that Dr. Le presented publicly in -- at
10 ASCO 2015.

11 Q And is it your view, Doctor, that an
12 organization by the name of Swim Across America
13 did not provide any financial support for the
14 study?

15 A Yes, they did. So --

16 Q Okay.

17 A May I clarify?

18 Q I think I already have an answer to my
19 question.

20 So in paragraph 22 of your Declaration,
21 your sworn testimony, you didn't refer to
22 Swim Across America, right?

1 A That is correct.

2 Q Okay. And is it --

3 A But --

4 Q Is it your view, Doctor, that the
5 National Institutes of Health did not provide any
6 financial support for the study?

7 A I don't specifically remember whether or
8 not NIH -- any NIH funding was utilized. I don't
9 think so, but I don't know the specifics.

10 Q But your testimony in paragraph 22 of
11 your Declaration is that it was only the research
12 team at Hopkins that paid for the study, right?
13 That's your testimony, right?

14 A When an academic research team does an
15 experiment, laboratory or clinical, we don't --
16 when we refer to paying for it, we refer to the
17 time and effort that went into raising the money
18 from various sources, foundations such as
19 Swim Across America, et cetera, et cetera, to pay
20 for all of the personnel and all that goes into
21 conducting an experiment or a trial. That is what
22 I was referring to.

1 We do not ask the members of the
2 research team to pay out of their own pocket. So
3 when one says "pay," one refers to having raised
4 the money through various sources to pay.

5 Q Okay. So are we to understand your
6 testimony, Doctor, in paragraph 22 of your
7 Declaration to mean that it wasn't folks at
8 Hopkins who actually paid for the study, but it
9 was other individuals and organizations; is that
10 right?

11 A When I, as any academic, refer to as
12 "paid," it is implicit that we mean raised the
13 money from various sources to pay for the study.
14 We are not referring to paying out of our pocket.

15 Q So let me try my question again because
16 I'm not sure I got an answer.

17 Doctor, in paragraph 22 of your
18 Declaration, that testimony, you weren't
19 suggesting that there were folks at Hopkins who
20 actually paid for the study, but instead --

21 A No --

22 Q -- there were other individuals and

1 organizations that paid for the study, right?

2 MR. MILLER: Objection to the form of
3 the question. Asked and answered.

4 A I was not referring to the members of
5 the team paying out-of-pocket. I was referring to
6 members of the team raising the money from other
7 sources, including private philanthropists,
8 foundations, to cover the cost of the study.

9 Q And, Doctor, did you ever see any
10 records of the funding for the study?

11 A No.

12 Q And you never saw any invoices
13 reflecting any of the funding for the study; is
14 that right?

15 A That's correct.

16 Q Now, Doctor, you are familiar with a
17 Dr. Nils Lonberg, right?

18 A Yes.

19 Q And would you say that you and
20 Dr. Lonberg are friendly?

21 A We were colleagues over many years.

22 Q And would you say that you and

1 Dr. Lonberg are friendly?

2 A I'm friendly with all of the wonderful
3 colleagues that help us develop drugs for cures
4 for cancer.

5 Q But, Doctor, I'm not asking about all
6 individuals, I'm only asking about Dr. Lonberg.

7 A Yeah.

8 Q So let me try my question again. It's
9 only about Dr. Lonberg.

10 A Yes, we were friendly.

11 Q Did you tell Dr. Lonberg that Merck did
12 not provide any funding for the study?

13 A I don't recall saying that.

14 Q Now, Doctor, would you agree that Merck
15 had an instinct to utilize a biomarker in clinical
16 development of pembrolizumab?

17 MR. MILLER: Objection to the form of
18 the question. Question appears to exceed the
19 scope of the Board's Order. I'll allow it as
20 foundation.

21 MR. RATLIFF: You don't control what's
22 allowed.

1 MR. MILLER: I absolutely do, Preston,
2 and if you go beyond the scope of the Board's
3 Order, I will instruct the witness not to answer.
4 So you're on notice of that.

5 MR. RATLIFF: Would you like to call the
6 Board now? We can do it.

7 MR. MILLER: I told you I'm going to
8 allow the witness to answer this question because
9 I think at this point it's foundational.

10 BY MR. RATLIFF:

11 Q Did you hear the question, Doctor? Do
12 you remember it?

13 A Please repeat the question.

14 Q Absolutely.

15 You would agree that Merck had an
16 instinct to utilize a biomarker in clinical
17 development of pembrolizumab, correct?

18 MR. MILLER: Objection to the form of
19 the question. Question appears to be beyond the
20 scope of the Board's Order, but I will allow it at
21 this point.

22 Go ahead.

1 A I do not agree.

2 Q And you know of a Dr. Peter Kim who was
3 one time President of Merck, right?

4 A That is incorrect.

5 Q Do you know of Dr. Peter Kim?

6 A Yes.

7 Q And Dr. Peter Kim, as you understand,
8 was never President of Merck?

9 A That's correct. He was head of R&D.

10 Q Okay. Would you agree that a hallmark
11 of Dr. Kim's tenure at Merck was a strong emphasis
12 on biomarkers?

13 MR. MILLER: Objection. This question
14 goes beyond the scope of the Board's Order.
15 Counsel, I'll allow you to make a proffer as to
16 where this is covered by the Board's Order, and we
17 can excuse Dr. Pardoll if you would like. But if
18 you are unwilling to do so, I will instruct him
19 not to answer.

20 Q Doctor, would you agree that a hallmark
21 of Dr. Kim's tenure at Merck was a strong emphasis
22 on biomarkers?

1 MR. MILLER: Same objection. Same
2 comments about the scope of the question.
3 Counsel, it is beyond the scope of the Board's
4 Order. If you have a proffer as to how it is not,
5 I'd like to hear it. Otherwise, I will instruct
6 the witness not to answer.

7 Q Doctor, do you agree that a hallmark of
8 Peter Kim's tenure at Merck was a strong emphasis
9 on biomarkers?

10 MR. MILLER: Doctor, because the
11 question goes beyond the scope of the Board's
12 Order, and because counsel has not indicated a
13 willingness to explain how I'm incorrect in that
14 view, I will instruct you not to answer.

15 Q You going to follow counsel's
16 instruction?

17 A I always do.

18 Q Okay. So let's take a break, and we'll
19 excuse you, Doctor, and me and your counsel can
20 talk.

21 A Okay.

22 (The Witness left the room.)

1 MR. RATLIFF: So counsel, that is an
2 improper instruction. I'm asking questions about
3 the Declaration that the doctor submitted.

4 MR. MILLER: Okay. Tell me where
5 Dr. Kim is referenced in his Declaration.

6 MR. RATLIFF: Do you not know anything
7 about this Declaration?

8 MR. MILLER: Is Dr. Kim referenced in
9 this Declaration?

10 MR. RATLIFF: He is referenced in the --

11 MR. MILLER: Where?

12 MR. RATLIFF: Do you not know?

13 MR. MILLER: Where? I am unaware of
14 Dr. Kim being referenced in the text of this
15 Declaration. If you want to point it out, that's
16 why I asked you to make a proffer. If you can
17 show it to me, I'll allow him to answer. It's
18 really that simple.

19 MR. RATLIFF: No, it's not that simple.
20 Let's not be tricky here. I'm --

21 MR. MILLER: Hardly being tricky.

22 MR. RATLIFF: I'm talking about the

1 Declaration.

2 MR. MILLER: Fine. Tell me where you're
3 pointing to.

4 MR. RATLIFF: So don't say the text of
5 the Declaration. I'm talking about the
6 Declaration.

7 MR. MILLER: Preston, you're wasting
8 time. Just tell me where you're pointing to.
9 Just tell me.

10 MR. RATLIFF: All I -- I'm trying to
11 slow you down.

12 MR. MILLER: You don't need to slow me
13 down, you just need to answer and we can get
14 going.

15 MR. RATLIFF: No, I do think I need to
16 slow you down because we're getting a little
17 excited.

18 Okay. So I'm talking about the
19 Declaration. The Declaration has attachments and
20 exhibits. You understand that, right?

21 MR. MILLER: Preston --

22 MR. RATLIFF: Do you understand that?

1 MR. MILLER: Preston --

2 MR. RATLIFF: I'm trying to make sure
3 we're on the same page.

4 MR. MILLER: Preston, you're being
5 ridiculous. Point me. It's really that easy.

6 MR. RATLIFF: Do you understand that?

7 MR. MILLER: Preston, I'm not getting
8 deposed; we're meeting or conferring.

9 MR. RATLIFF: We are.

10 MR. MILLER: I have a question for you,
11 please answer it. You're wasting time.

12 MR. RATLIFF: I'm not wasting any time.

13 MR. MILLER: Are you unwilling to point
14 me to where Dr. Kim and this question are
15 supported in the Declaration?

16 MR. RATLIFF: I don't know why you would
17 ask me that, because I'm trying to explain and get
18 you there.

19 MR. MILLER: Good, tell me.

20 MR. RATLIFF: Okay. So let's start
21 again so we're at the base.

22 So you understand that there's a

1 Declaration from the doctor and it has exhibits,
2 right? Do you understand that? I don't want to
3 just keep --

4 MR. MILLER: Preston, I'm not being
5 deposed. Point me --

6 MR. RATLIFF: I'm not suggesting you're
7 being deposed.

8 MR. MILLER: Point me to what you're
9 referring to and we'll get going.

10 MR. RATLIFF: I'm referring to the
11 exhibits that are attached --

12 MR. MILLER: Where?

13 MR. RATLIFF: -- to the Declaration.

14 MR. MILLER: What page? That's all you
15 have to tell me. Point me to a page and we'll get
16 going.

17 MR. RATLIFF: You can go to exhibit page
18 377.

19 MR. MILLER: (Reviewing.)
20 You want to give me a paragraph?

21 MR. RATLIFF: You can look at the first
22 paragraph underneath where it says, "There is no

1 line," and you'll see there, counsel, a reference
2 to Dr. Peter Kim.

3 MR. MILLER: All right. Preston, that's
4 fine, but where is anything about Dr. Kim and
5 biomarkers or whatever your question was when all
6 of this started?

7 I see Dr. Kim's name, I also see
8 Dr. Brahmer's name. Where does it say that he has
9 a strong emphasis on biomarkers? That was your
10 question. You say:

11 Do you agree that a hallmark of
12 Peter Kim's tenure at Merck was a strong emphasis
13 on biomarkers?

14 Where is that?

15 MR. RATLIFF: Counsel, you're really
16 wasting time here.

17 MR. MILLER: Where is it?

18 MR. RATLIFF: Why are you elevating your
19 voice?

20 MR. MILLER: Because you are not
21 answering my question. It's a really simple
22 question.

1 MR. RATLIFF: Counsel --

2 MR. MILLER: Preston --

3 MR. RATLIFF: -- is trying to intimidate
4 me. Please don't do that.

5 MR. MILLER: I'm not trying to
6 intimidate, I'm trying to get you to answer a
7 simple question so we can get moving in the
8 deposition. You're wasting time.

9 MR. RATLIFF: But, counsel I'm just --

10 MR. MILLER: Preston, tell me where that
11 is.

12 MR. RATLIFF: Now, you don't --

13 MR. MILLER: See, I can do your voice,
14 too. Tell me, point me to a page.

15 MR. RATLIFF: Counsel, you don't have to
16 be animated. And you're smiling.

17 MR. MILLER: I'm not being animated.

18 MR. RATLIFF: This is not --

19 MR. MILLER: And I am smiling because
20 it's ridiculous.

21 MR. RATLIFF: It is not a game.

22 MR. MILLER: It is ridiculous. It is a

1 game. This record is going in front of the Board.
2 This is going to look really bad for you.

3 Point me to a page that supports your
4 position that your question is within the scope of
5 the Board's Order. If you can't, I will maintain
6 my instruction to the witness. If you can satisfy
7 this very simple request, I will withdraw the
8 instruction to the witness. It's your call. I
9 will wait.

10 MR. RATLIFF: I really ask that you
11 don't try to intimidate me and make threats like
12 that. That's just not really professional. It's
13 not how the Board wants us to communicate.

14 So you know the deposition is about his
15 Declaration, which has been authorized by the
16 Board. And so I'm asking questions about his
17 Declaration and the exhibits that the doctor
18 attached. The exhibits that the doctor said he
19 wasn't confused about. He testified about that
20 today.

21 So you can take a look at exhibit page
22 373, and let me know when you're there.

1 MR. MILLER: Yep. Where?

2 MR. RATLIFF: And underneath the heading
3 Saved by the Biomarker, if you go to the second
4 paragraph underneath there, there's a reference to
5 Dr. Kim, and in that reference --

6 MR. MILLER: Preston, I'll withdraw the
7 instruction. All you needed to have done about 15
8 minutes ago was pointed me right to there and we
9 would have been done. Okay?

10 MR. RATLIFF: Counsel, that's not true,
11 but thank you.

12 MR. MILLER: That is absolutely true,
13 and that is what I would have done and it's what
14 I've just done now really quickly. So you don't
15 need to waste our time with nonsense.

16 MR. RATLIFF: Counsel, you don't have to
17 elevate your voice.

18 MR. MILLER: Preston, you're making a
19 record that is incorrect.

20 I'm going to go get Dr. Pardoll and
21 we'll resume.

22 MR. RATLIFF: Please do.

1 (The Witness returned.)

2 BY MR. RATLIFF:

3 Q Doctor, I believe we're still on the
4 record.

5 A Okay.

6 Q We'll get started. And apologies for
7 the delay. It's counsel -- your counsel has --
8 withdrew the objection, so I think we're all
9 clear, and I know you have -- I think you have
10 somewhere to go. I really just want to make this
11 easy for you.

12 A Okay.

13 Q Okay. So, Doctor, would you agree that
14 a hallmark of Dr. Kim's tenure at Merck was a
15 strong emphasis on biomarkers?

16 A I truly have no idea what his emphasis
17 was when he was Director of R&D at Merck.

18 Q Okay. And you're familiar with
19 Dr. Roger Perlmutter, right?

20 A Yes.

21 Q And would you agree that the key impact
22 that Dr. Perlmutter had on the pembro clinical

1 development program was recognizing pembrolizumab
2 as an exceptional asset and redirecting virtually
3 all work at Merck towards that program?

4 A I do not.

5 Q And is it your understanding that
6 Dr. Perlmutter told everyone in Research at Merck
7 to stop what you're doing now, we got to do this?

8 A I have no idea what he told the folks at
9 Merck.

10 Q And would you agree that Dr. Perlmutter
11 recognized that pembro wasn't just a promising
12 product in Merck's portfolio, it was more valuable
13 than the entire rest of the portfolio put
14 together?

15 MR. MILLER: Objection to the form of
16 the question.

17 Go ahead.

18 A I have no idea what he said or directed
19 to the Merck folks. I do know that pembro was
20 pulled out of the freezer when somebody at Merck
21 heard a presentation about nivo and that was
22 before, and Merck began working on it before

1 Dr. Perlmutter came back to Merck from Amgen.

2 Q And Doctor, again, I understand you have
3 positions and there's probably lots of things that
4 you know, but I just want to focus on my question,
5 okay?

6 A (Nodding head.) I was. I was
7 clarifying my response to your question.

8 Q That's what you think you were doing?

9 A That is what I was doing.

10 Q Okay. And, Doctor, would you agree that
11 Dr. Perlmutter's resourcing of pembro work to the
12 exclusion of most other activities reflected his
13 conviction?

14 MR. MILLER: Objection to the form of
15 the question.

16 A I have no idea what his conviction was.

17 Q Would you agree that Dr. Perlmutter bet
18 both his career in Merck's enterprise on the
19 pembro program?

20 MR. MILLER: Objection to the form of
21 the question.

22 A I have no clue.

1 Q And would you agree that the success of
2 the pembro clinical development program is
3 directly attributable to Dr. Perlmutter's
4 intrinsically good judgment and instinctive
5 boldness?

6 MR. MILLER: Objection to the form of
7 the question.

8 A No.

9 Q And would you agree that the success of
10 the pembro clinical development program reflects
11 Dr. Perlmutter's decades of experience in drug
12 development?

13 MR. MILLER: Objection to the form of
14 question.

15 A No.

16 Q Would you agree that the success of the
17 pembro clinical development program reflects that
18 Dr. Perlmutter had the perspective to recognize
19 something truly special when he saw it?

20 MR. MILLER: Objection to the form of
21 the question.

22 A No.

1 Q And would you agree that pembro's rapid
2 route to market and to patients reflects a
3 commitment by Merck to develop the drug pembro?

4 MR. MILLER: Objection to the form of
5 the question.

6 A I believe that the clinical groups at
7 Merck were committed to actively developing pembro
8 in cancer.

9 Q Okay. I think I appreciate that. Let
10 me just try my question again just to make sure I
11 understand.

12 Would you agree that pembro's rapid
13 route to market and to patients reflects a
14 commitment by Merck to develop the drug pembro?

15 MR. MILLER: Objection to the form of
16 the question.

17 A Yes.

18 Q Now, Dr. Vogelstein is one of your
19 colleagues; is that fair?

20 A Yes.

21 Q And is it fair to say that at some point
22 Dr. Vogelstein picked up the phone and proposed a

1 Phase 2 study of pembrolizumab in patients with
2 microsatellite unstable tumors to Merck?

3 MR. MILLER: Objection to the form of
4 the question.

5 A Fundamentally, yes.

6 Q And when Dr. Vogelstein picked up that
7 phone and proposed that clinical study to Merck,
8 the plan was that Hopkins would both conduct and
9 pay for the study, right?

10 MR. MILLER: Objection to the form of
11 the question.

12 A That's my understanding from
13 Dr. Vogelstein.

14 Q Right.

15 And is it fair to say when
16 Dr. Vogelstein picked up the phone and made that
17 call to Merck, all he was proposing that Merck do
18 is to provide the drug pembro?

19 MR. MILLER: Objection to the form of
20 the question.

21 A With a caveat that I wasn't on the call,
22 my understanding is yes.

1 Q Doctor, I want to be efficient with
2 time, so maybe we could take a break now and then
3 come back, if that works for you?

4 A Works for me.

5 MR. RATLIFF: Okay, let's take a break.

6 (A recess was taken at 10:37 a.m.)

7 (Back on the record at 10:55 a.m.)

8 BY MR. RATLIFF:

9 Q So, Doctor, earlier today you testified
10 that the study was written and conceived
11 essentially exclusively at Hopkins.

12 Do you recall that testimony?

13 A I do.

14 Q Okay. And when you say "essentially
15 exclusively at Hopkins," are you referring to the
16 fact that others may have contributed to writing
17 the study?

18 A Since I didn't participate in actually
19 writing the study, I certainly can't comment for
20 100 percent sure that Dr. Le didn't have a
21 conversation with a colleague that might have
22 contributed a small element. And so that's why I

1 used the term "essentially."

2 Q And since you didn't participate in the
3 actual writing of the study, can you comment on
4 whether or not employees from Merck helped in the
5 writing of the study?

6 A No.

7 Q If you could turn to the Study Record
8 that's posted -- strike that.

9 If you could turn to the Study Record
10 that was posted in June of 2013. So yes, Exhibit
11 1005.

12 A (Complying.)

13 Q And if you could turn your attention to
14 page 4 of that exhibit, and let me know when you
15 have it.

16 A Uh-humh.

17 Q Okay. And if I could turn your
18 attention to the Arms and Intervention section of
19 page 4.

20 A Uh-humh.

21 Q And sorry, just for the record, I think
22 your "uh-humhs" have to be converted to a yes.

1 A Yes, sorry, yes.

2 Q Let me -- thank you. Let me just say it
3 so the record is clear, so can you turn to the
4 Arms and Intervention section of the Study Record
5 at page 4.

6 A Yes.

7 Q And you see for the assigned
8 interventions there is a dosing for the three arms
9 indicated for the study, right?

10 A Yes.

11 Q And the dosing is 10 milligrams per
12 kilogram every 14 days of pembrolizumab, correct?

13 A Yes.

14 Q And that's the dosing for each of the
15 three arms, right?

16 A Yes.

17 Q And do you know whether or not any Merck
18 employee contributed to -- strike that.

19 Do you know whether or not any Merck
20 employee gave input as to what the dosing would be
21 for the three arms that are described in the
22 study?

1 A I -- subsequent to the completion of the
2 trial, I heard that Merck had made some
3 suggestions with regard to dosing and timing, but
4 since I was not involved in writing the trial, I
5 have no knowledge of any of those specifics.

6 Q Okay. And if we could turn back to your
7 Declaration. And this is in Exhibit 1002.

8 A Uh-humh.

9 Q And in particular let's look at exhibit
10 page 206 and paragraph 23.

11 A (Complying.)

12 Okay.

13 Q Do you have it, Doctor?

14 A Yes.

15 Q And do you see where you testify, quote,
16 on May 30th, 2015, my colleagues and I published
17 the results of our study?

18 A Yes.

19 Q Okay. And when you're testifying there,
20 you're talking about this New England Journal of
21 Medicine article with the first author Dr. Le; is
22 that right?

1 A Yes.

2 (Exhibit 1031 previously was marked for
3 identification and was retained by Mr. Ratliff.)

4 Q So let me show you a copy of that
5 New England Journal of Medicine article.

6 A I have a copy.

7 Q I believe you have a different one.

8 A Yes, this one, okay.

9 Q I just handed you what's been previously
10 marked as Merck Exhibit 10 -- sorry. I just
11 handed you what's been previously marked as Merck
12 Exhibit 1031.

13 A Yes.

14 Q And do you recognize Exhibit 1031 as
15 The New England Journal of Medicine article that
16 you were testifying about in paragraph 23 of your
17 Declaration?

18 A Yes.

19 Q And in your Declaration when you
20 testified, "My colleagues and I published the
21 results of our study" in that New England Journal
22 of Medicine article, who were you referring to by

1 "my colleagues and I"?

2 A I was referring to the coauthors on the
3 study that were from Hopkins.

4 Q Okay. And when you say "the coauthors
5 that were on the study from Hopkins," who was
6 that?

7 A Are you referring to the coauthors from
8 Hopkins or the coauthors on the study total?
9 Because there are coauthors on the study that were
10 not from Hopkins.

11 Q So I'm trying to say when you say "my
12 colleagues and I published," who were you
13 referring to by "my colleagues"? And I -- so we
14 know it's yourself you're referring to, but who
15 are your colleagues there that you were testifying
16 about?

17 A I was referring to the other coauthors
18 on the study without really, I have to say,
19 probably -- this was five years ago -- specifying
20 specifically whether they were coauthors from
21 Hopkins or from other institutions.

22 Q Okay. So when you --

1 A I was referring to the coauthors.

2 Q The coauthors, right. Okay.

3 And so the coauthors that we see on
4 Exhibit 1031, which is The New England Journal of
5 Medicine article, refers to individuals who were
6 employees at The Johns Hopkins University, right?

7 A About two-thirds of the authors.

8 Q Right.

9 And the coauthors also includes
10 individuals who were employees of Merck, correct?

11 A I would have to look and see. I don't
12 specifically remember if there were -- was anybody
13 from Merck as a coauthor.

14 Q Okay, go ahead, you can do that. You
15 have Exhibit 1031 in front of you, which is
16 The New England Journal of Medicine article, and
17 let me know if you recognize any coauthors who
18 were employees of Merck.

19 A (Reviewing.)

20 So I don't recognize any of the
21 coauthors specifically as being at Merck, so I'm
22 looking at the appendix.

1 (Reviewing.)

2 So I see an MK is listed as being at
3 Merck. I have no idea who MK is.

4 Q Okay. So -- but to your knowledge,
5 sitting here today, at least one of the coauthors
6 of The New England Journal of Medicine article was
7 identified as an employee of Merck, right?

8 A Yes, as I just saw in the appendix.

9 Q And of the coauthors, there are
10 individuals who are affiliated with Swim Across
11 America listed, right?

12 A (Reviewing.)

13 So I'm not seeing -- I could just be
14 missing it in the appendix, which is where the
15 authorship attribution is listed. I don't --
16 you'll have to point out. I don't see Swim Across
17 America.

18 Q Okay, I'm asking you. So do you --

19 A Swim Across America is a foundation that
20 provides funding for cancer research. So I would
21 be certainly surprised if a full-time member of
22 Swim Across America was a coauthor.

1 Q Okay. I'm asking maybe a different
2 question.

3 So you would agree that among the
4 coauthors' affiliations, one of those affiliations
5 includes Swim Across America, right?

6 A Oh, no. That refers to -- so oftentimes
7 when a foundation funds work in a laboratory,
8 their name will go on to the laboratory. And
9 so -- and so in order to acknowledge the funding
10 organization, the name of the laboratory is
11 included.

12 So the four folks there, I'm guessing
13 that some of their salaries was supported by
14 Swim Across America. So they were affiliated with
15 the Swim Across America Laboratory at
16 Johns Hopkins, I think.

17 Q And just turning your attention to the
18 first page of The New England Journal of Medicine
19 article, which is Merck Exhibit 1031, do you know
20 why there is this group of coauthors for this
21 paper? Why these individuals are listed?

22 A In general, the lead authors on a paper,

1 which in this case are Drs. Lee and Dr. Diaz, make
2 the judgments as to who has contributed to the
3 manuscript to the level that merits coauthorship.

4 Q And do you know -- I guess I've seen
5 throughout your Declaration, there's some
6 references to Dr. Topalian?

7 A Yes.

8 Q And do you know why Dr. Topalian is not
9 listed amongst the group of coauthors on Exhibit
10 1031?

11 A No, you'd really have to ask Dr. Le or
12 Dr. Diaz.

13 Q You can put that aside.

14 So, Doctor, can you just turn your
15 attention to the first page of your Declaration,
16 and this is the excerpt from Exhibit 1002.

17 And my question for you is, when was the
18 first time that you appreciated that The Johns
19 Hopkins University was applying for a patent
20 concerning the subject matter that we're talking
21 about?

22 A This was a decade ago, and so I do

1 not -- and I do not remember.

2 Q And sitting here today you don't have
3 any general recollection of whether or not it was
4 about the time of your Declaration execution,
5 which is February 2020, when you first appreciated
6 that The Johns Hopkins University was applying for
7 a patent concerning the subject matter that we've
8 been discussing today?

9 A No. No, let me clarify.

10 I was aware of that long before 2020.

11 Q And how much long before 2020 were you
12 aware that The Johns Hopkins University was
13 applying for a patent concerning the subject
14 matter that we've been discussing today?

15 A It was in the 2014-2015 range.

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

18 Q Now, let me show you a document that has
19 been marked as Exhibit 1030.

20 And, Doctor, can you take a look at
21 Exhibit 1030 and let me know if you recognize it.

22 A (Reviewing.)

1 I don't know that I specifically
2 recognize the document, but I recognize this as an
3 early version of a filing.

4 Q A filing?

5 A On the treatment of patients whose
6 tumors were tested to be MSI-high with anti-PD-1.
7 But I don't -- I don't remember the specific
8 document, per se. This was, again, more than a
9 decade ago.

10 Q And I can represent to you that this
11 document was mailed on December 2nd of 2014. I
12 think you'll see December 2nd, 2014, on the
13 document, sir.

14 A Okay.

15 Q And so my question for you is, do you
16 see on the face of the document there is a listing
17 of named inventors?

18 A Yes.

19 Q And we see in that listing Dr. Diaz,
20 right?

21 A Uh-humh.

22 Q We --

1 A Yes.

2 Q We see Dr. Vogelstein, correct?

3 A Yes.

4 Q We see Dr. Kinzler, correct?

5 A Yes.

6 Q We see Dr. Papadopoulos, correct?

7 A Yes.

8 Q And we see Dr. Le, correct?

9 A Yes.

10 Q Do you know why your name is not listed
11 on the face of this document, Doctor?

12 A No. At some point -- and again in the
13 2014-2015 -- I was contacted, I think initially by
14 our Tech Transfer Office, and there were various
15 discussions, but essentially indicated that there
16 was a general consensus that Dr. Topalian and
17 myself should be added as co-inventors to this
18 patent. That happens very commonly.

19 Q And who from the Tech Transfer Office
20 made that call?

21 MR. MILLER: Objection to -- objection
22 to the form of the question.

1 A I think it was Christy Wyskiel, who's
2 the head of JHTV, but I -- again, this was a
3 decade ago, so I can't say with absolute certainty
4 who it was.

5 Q And who was part of those discussions
6 that you had about whether or not you and
7 Dr. Topalian should be listed as co-inventors with
8 respect to the subject matter that we've been
9 discussing here today?

10 A I recall that there were some
11 discussions, you know, beyond JHTV with the
12 co-inventors and also with our lawyers.

13 MR. MILLER: Doctor, just at this point
14 I'll caution you not to reveal the substance of
15 the conversations, but if you're talking at a high
16 level, that's fine.

17 A That's easier, because I don't remember
18 the specifics other than there was a consensus
19 that we should be included as co-inventors.

20 Q And you said you were having these
21 discussions with, quote, our lawyers. Who did you
22 mean by "our lawyers"?

1 A The Fish & Richardson's lawyers.

2 Q And did it also include lawyers that
3 worked internally at The Johns Hopkins University?

4 A I don't remember.

5 Q And who from the Fish & Richardson law
6 firm do you recall were a part of those
7 discussions?

8 THE WITNESS: Was that covered by
9 attorney/client privilege?

10 MR. MILLER: No, you can identify
11 lawyers if you recall them.

12 A I recall this guy (indicating).

13 Q Okay. And by "this guy" you're
14 referring to Mr. Todd Miller?

15 A Yes, Mr. Todd Miller.

16 Q And beyond Mr. Todd Miller, who from the
17 Fish & Richardson law firm do you recall were part
18 of those discussions about adding you, Doctor, and
19 Dr. Topalian as a co-inventor concerning the
20 subject matter that we've been talking about
21 today?

22 A Mr. Miller is the only person that I

1 specifically remember. I do remember a conference
2 call where there were other people, but Mr. Miller
3 is the only specific person that I remember from
4 those conversations.

5 MR. MILLER: Because he's very
6 memorable.

7 THE WITNESS: Completely memorable.

8 MR. MILLER: Go ahead.

9 Q And Doctor, how many conversations,
10 discussions were there concerning this subject
11 matter of potentially adding you and Dr. Topalian
12 as co-inventors concerning the subject matter that
13 we've been discussing?

14 A I don't remember. Certainly not many.
15 There was no contention about ultimately adding us
16 as co-inventors. But I don't remember the exact
17 number.

18 Q Okay.

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

21 Q Doctor, I'm going to hand you another
22 document, and this has been marked as Merck

1 Exhibit 1043.

2 A Okay.

3 Q And can you just look at Exhibit 1043
4 and let me know if you recognize it.

5 A (Reviewing.)

6 Can I ask what the date of this document
7 was?

8 Q You can ask.

9 A Okay. What was the date of the
10 document?

11 Q So I'm just going to ask you if you
12 recognize it. Sort of the way this works is you
13 don't -- you can ask me questions, I don't really
14 have to respond to them, and if you don't know,
15 that's okay.

16 A So among so many documents that I've
17 seen over the past decade, I do not specifically
18 recognize this document.

19 Q Okay. That's fine.

20 Do you know if at all -- I know you
21 don't specifically recognize this document, but do
22 you -- do you know if this document -- you can

1 take your time and look at it -- seems to reflect
2 the subject matter that we've been discussing
3 today or not?

4 MR. MILLER: Objection to the form of
5 the question.

6 A I would really need to read through the
7 document more carefully. Do you want me to do it
8 now? I can do it, but without really reading
9 through it in more detail, since I don't
10 specifically recognize it, I really could not
11 answer accurately --

12 Q Okay.

13 A -- that question.

14 Q And I appreciate that, Doctor, I want to
15 be efficient with your time. I certainly respect
16 your time.

17 A I've seen figures that I recognize, but
18 I really don't know what this document is.

19 Q Understood.

20 Doctor, I do have one question. If you
21 could turn to page 44 of Exhibit 1043.

22 A (Complying.)

1 Q And just let me know when you're there,
2 Doctor.

3 A Okay. I'm here.

4 Q And on page 44 we see a listing of
5 inventors. Dr. Luis Diaz's name is there,
6 Dr. Vogelstein, Dr. Kinzler, Dr. Papadopoulos, and
7 Dr. Le are listed on this page, right?

8 A Yes.

9 Q And I appreciate that you don't
10 recognize the document, but I just need to ask the
11 question.

12 Do you have any understanding of why
13 your name is not listed on this page, Doctor?

14 A Being as I don't recognize the document,
15 no.

16 Q And do you have any understanding why
17 Dr. Topalian's name is not listed on this page?

18 A No.

19 Q Okay. So you can put that aside,
20 Doctor, and if you could place in front of you a
21 copy of your Declaration. And again, this is
22 Exhibit 1002, and we're looking at an excerpt of

1 it.

2 A Uh-humh.

3 Q And if I could turn your attention to
4 page 205 of Exhibit 1002. And this is a page in
5 your Declaration. 1002?

6 A Uh-huh. Okay.

7 Q Okay. And on 205 we have a first
8 paragraph that -- it's paragraph 20, right?

9 A Right.

10 Q I just want to be sure I'm understanding
11 your testimony. In paragraph 20 you're not making
12 any comments about Merck, right?

13 A No.

14 Q And in paragraph 21 you're not making
15 any comments about Merck, right?

16 A No.

17 Q Okay. So let's move to the next page,
18 which is page 206 of Exhibit 1002. We're still in
19 your Declaration.

20 A Uh-humh.

21 Q And in paragraph 23 you're not making
22 any comments about Merck, right?

1 Well, let me withdraw that question,
2 because I do see Merck listed there.

3 In paragraph 23 you're not making any
4 comments about something that Merck believed or
5 didn't believe, right?

6 MR. MILLER: Objection to the form of
7 the question.

8 A No, we're simply referring to the
9 antibody used as being from Merck.

10 Q Right.

11 And in paragraph 24 you're not providing
12 any testimony about something that Merck believed
13 or didn't believe, right?

14 MR. MILLER: Objection to the form of
15 the question.

16 A No.

17 Q And in paragraph 25 you're also not
18 making any comments about something that Merck
19 believed or didn't believe, right?

20 MR. MILLER: Objection to the form of
21 the question.

22 A That's correct.

1 Q I should go back to page 205, so just
2 the preceding paragraph or page in your
3 Declaration. Sorry about that.

4 A Uh-humh.

5 Q So we're at exhibit page 205, and
6 turning your attention to paragraph 22 of your
7 Declaration, there you're not making any comments
8 about something that Merck believed or didn't
9 believe, right?

10 MR. MILLER: Objection to the form of
11 the question.

12 A That's right.

13 Q Let's go back up to paragraph 20. And
14 in paragraph 20 you're not making any testimony
15 there about something that the industry believed
16 or didn't believe, right?

17 MR. MILLER: Objection to the form of
18 the question.

19 A (Reviewing.)

20 Nobody outside of this small group of
21 ours was in any way, shape or form thinking about
22 MSI related to cancer immunotherapy, so no.

1 Q The answer to my question is no?

2 MR. MILLER: Objection.

3 Go ahead.

4 Asked and answered.

5 Q Let me try my question -- I just want to
6 be sure.

7 In paragraph 20 you're not making any
8 statement or testimony about something that the
9 industry believed or didn't believe, right?

10 MR. MILLER: Objection to the form of
11 the question, asked and answered.

12 A That's right.

13 Q And at paragraph 21, same question,
14 you're not making any statement or comment about
15 something that the industry believed or didn't
16 believe, right?

17 MR. MILLER: Objection to the form of
18 the question.

19 A That's right.

20 Q And in paragraph 22 you're not making
21 any statement, comment or testimony about
22 something that the industry believed or did not

1 believe, right?

2 MR. MILLER: Objection to the form of
3 the question.

4 A That's right.

5 Q And turning to the next page, page 206,
6 and turning your attention to paragraph 23 of your
7 Declaration, in paragraph 23 you're not making any
8 statement or comment about something that the
9 industry believed or did not believe, correct?

10 MR. MILLER: Objection to the form of
11 the question.

12 A That's right.

13 Q And in paragraph 24 of your Declaration
14 you're not making any comment about something that
15 the industry believed or did not believe, correct?

16 MR. MILLER: Objection to the form of
17 the question.

18 A Correct.

19 Q And in paragraph 25 you're not making
20 any comment about something that the industry
21 believed or did not believe, correct?

22 MR. MILLER: Objection to the form of

1 the question.

2 A Yes.

3 MR. MILLER: Preston, could we take a
4 break for one second?

5 MR. RATLIFF: Sure.

6 (A recess was taken at 11:29 a.m.)

7 (Back on the record at 11:35 a.m.)

8 BY MR. RATLIFF:

9 Q Doctor, during the conduct of the
10 clinical trial that we've been discussing today,
11 are you aware of any individual from Merck being
12 involved in the conduct of conducting that
13 clinical study?

14 MR. MILLER: Objection to the form of
15 the question.

16 A No, I'm not.

17 Q And do you know one way or another
18 whether or not there were individuals from Merck
19 that were communicating with what you call the
20 Johns Hopkins team in the planning, running,
21 conducting of the clinical study that we've been
22 discussing all day?

1 A No, I'm not.

2 Q You don't know one way or another?

3 A I don't know one way or the other.

4 MR. RATLIFF: So Doctor, at this time, I
5 don't have any further questions for you. Your
6 counsel may have questions for you, and then
7 afterwards we'll see where things go.

8 But I will say that it's absolutely an
9 honor to meet you, Doctor, and certainly
10 appreciate your time and appreciate your
11 commitment and care for patients suffering from
12 cancer.

13 THE WITNESS: I appreciate those kind
14 words. I really do.

15 MR. RATLIFF: I pass the witness.

16 MR. MILLER: Thank you.

17 EXAMINATION BY COUNSEL FOR THE RESPONDENT

18 BY MR. MILLER:

19 Q Doctor, I just have really one question.
20 If you could pull out Exhibit 1031.
21 Are you with me?

22 A Yes.

1 Q And this is the May 30, 2015,
2 New England Journal article that you were
3 referencing a couple of times during the
4 deposition?

5 A Yes.

6 Q And then you were asked questions by
7 counsel about the coauthors that are listed. Do
8 you recall that?

9 A Yes.

10 Q And there was some testimony -- and
11 correct me if I've got this wrong -- you said
12 something about MK being listed on -- in the
13 appendix on page 10 of 12 of the document?

14 A Yes. At the very end of the appendix --

15 Q I see.

16 A -- there's M -- Merck Kenilworth and
17 North Wales, MK.

18 Q Okay. I'm just going to direct your
19 attention to page 2 of 12, and the right-hand
20 column, midway down, you see a section entitled
21 Study Oversight?

22 A Uh-humh. Yes.

1 Q Yes.

2 And then could you just read aloud the
3 last sentence of the paragraph that is under Study
4 Oversight heading.

5 A Merck donated the study drug and
6 reviewed the final drafts of the protocol and of
7 this manuscript before submission. They did not
8 participate in the analysis of the data.

9 Q Is that your recollection of what
10 Merck's contribution was?

11 A I -- in the process of analyzing the
12 data to write the paper that I was involved in,
13 did not -- do not recall anybody from Merck being
14 involved in that process.

15 MR. MILLER: Thank you. No further
16 questions.

17 MR. RATLIFF: I have no questions for
18 you, Doctor. Thank you very much.

19 (Off the record at 11:39 a.m.)
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ACKNOWLEDGMENT OF DEPONENT

I, Andrew Pardoll, M.D., do hereby
acknowledge that I have read and examined the
foregoing testimony, and the same is a true,
correct and complete transcription of the
testimony given by me, and any corrections appear
on the attached Errata sheet signed by me.

(DATE)

(SIGNATURE)

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 28th 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