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 IPR2024-00622, Patent No. 10,934,356;

12 IPR2024-00623, Patent No. 11,325,974;

13 IPR2024-00624, Patent No. 11,325,975;

14 IPR2024-00625, Patent No. 11,339,219;

15 IPR2024-00647, Patent No. 11,649,287;

16 IPR2024-00648, Patent No. 11,643,462;

17 IPR2024-00649, Patent No. 11,629,187;

18 IPR2024-00650, Patent No. 11,634,491.

19 _____

20 REMOTELY CONDUCTED DEPOSITION OF RICHARD GOLDBERG

21 Tuesday, April 15, 2025 - 8:58 a.m. EST

22 Job No. 579966

1 Pages 1 - 149
2 Reported by: April Reid, RPR, CRR (Stenographer)
3
4 All appeared remotely.
5
6 A P P E A R A N C E S
7
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16 ON BEHALF OF THE PATENT OWNER:
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1 A P P E A R A N C E S cont'd
2
3 ALSO PRESENT:
4 KAREN MOREIRA
5 WAYNE LeBLANC, JR. - realtime link only
6 KELLI WELCH, Remote Technician
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1 I N D E X

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RICHARD GOLDBERG PAGE
3
Examination by Ms. Stauring 5
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Examination by Dr. Brown-Marshall 117
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Examination by Ms. Stauring 134
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1 P R O C E E D I N G S
2 THE STENOGRAPHER: As we begin this
3 proceeding, I will ask our witness to please
4 raise your right hand.
5 THE WITNESS: (Complies.)
6 THE STENOGRAPHER: Do you swear or
7 affirm that the testimony you're about to
8 give will be the truth, the whole truth, and
9 nothing but the truth?
10 THE WITNESS: I do.
11 THE STENOGRAPHER: Thank you.
12 THEREUPON:
13 RICHARD GOLDBERG
14 being first duly sworn or affirmed to
15 testify to the truth, the whole truth, and
16 nothing but the truth, was examined and
17 testified as follows:
18 THE STENOGRAPHER: We may begin.
19 EXAMINATION
20 BY MS. STAURING:
21 Q. Good morning. My name is Jessica
22 Stauring with the Paul Hastings law firm, and I'm

1 appearing today for petitioner, Merck.
2 I'm joined today by Preston Ratliff,
3 also with the Paul Hastings law firm and appearing
4 for petitioner, Merck.
5 In addition, Merck in-house counsel,
6 Karen Moreira, is on the line. And Merck in-house
7 counsel Mark Stewart may join at some point today.
8 Good morning, Dr. Goldberg. How are you
9 feeling today?
10 A. I'm good. Thank you.
11 Q. You understand that you're testifying
12 under oath today; right?
13 A. I do.
14 Q. Is there any reason that you cannot
15 testify truthfully today?
16 A. No.
17 Q. You're being compensated at a rate of
18 $900 per hour in this matter; right?
19 A. That's correct.
20 Q. You understand that your deposition
21 today concerns eight declarations that you
22 prepared; right?

1 A. I do.
2 Q. One of the declarations that we're
3 discussing today relates to United States Patent
4 No. 11,934,356; right?
5 A. That's correct.
6 Do you mind if we just refer to them by
7 their last three digits? That's easier for me.
8 Q. Yes. That's fine me with me, as well.
9 You signed your '356 declaration on
10 January 11th, 2025; right?
11 A. I have it on the floor next to me. Let
12 me pick it up so I can confirm that.
13 So the '356 patent I signed on the
14 1st -- on January 11th, 2025.
15 Q. Another of your declarations that we're
16 discussing today relates to the '974 patent;
17 right?
18 A. Well, let's see.
19 Okay. Yes. I have that.
20 Q. And you signed your '974 declaration on
21 January 11th, 2025; right?
22 A. That's correct.

1 Q. Another one of your declarations that
2 we're discussing today relates to the '975 patent;
3 right?
4 A. Correct.
5 Q. And you signed your '975 declaration on
6 January 11th, 2025; correct?
7 A. That's correct.
8 Q. Another one of your deposit- --
9 declarations that we're discussing today relates
10 to the '219 patent; correct?
11 A. That's correct.
12 Q. And you signed your '219 declaration on
13 January 11th, 2025; right?
14 A. That's correct.
15 Q. Another one of your declarations that
16 we're discussing today relates to the '462 patent;
17 correct?
18 A. That's correct.
19 Q. And you signed your '462 declaration on
20 January 22nd, 2025; correct?
21 A. That's true.
22 Q. Another one of your declarations that

1 we're discussing today relates to the '491 patent;
2 right?
3 A. Yes.
4 Q. And you signed your '491 declaration on
5 January 22nd, 2025; right?
6 A. Yes.
7 Q. Another one of your declarations that
8 we're discussing today relates to the '187 patent;
9 right?
10 A. Yes.
11 Q. And you signed your '187 declaration on
12 January 22nd, 2025; right?
13 A. True.
14 Q. One of your declarations that we're
15 discussing today relates to the '287 patent;
16 right?
17 A. Yes.
18 Q. And you signed your '287 declaration on
19 January 11th, 2025; right?
20 A. No. According to my record, on
21 January 22nd, 2025.
22 Q. You signed your '287 declaration on

1 January 22nd, 2025; correct?
2 A. That's correct.
3 Q. And would you agree that your '287
4 declaration is substantially similar to the
5 declaration that you prepared and signed on
6 October 4th, 2024, in the '393 IPR proceeding?
7 DR. BROWN-MARSHALL: Object to the form
8 of the question.
9 A. So it's hard for me to understand
10 exactly what you mean by "substantially" the same.
11 For example, the '393 patent is 51 pages, while
12 there are 164 pages in the '974 patent. So there
13 are some -- there's some overlap, but they -- you
14 know, in my mind, they're not substantially
15 identical.
16 Q. Okay. Dr. Goldberg, my question was
17 about whether your '287 declaration is
18 substantially similar to the declaration that you
19 prepared and signed in the '393 proceeding.
20 DR. BROWN-MARSHALL: Object to the form
21 of the question.
22 A. So the '287 declaration is 150 pages

1 long, including the appendix. The part that does
2 not include my credentials is 52 pages long, in
3 the parts of it. And, I guess -- guess when I
4 look at it, the declaration without the appendix
5 is 52 pages long.
6 I haven't recently compared these two,
7 but I believe that much of the text is the same.
8 I didn't focus on the '393 patent
9 because that was discussed previously.
10 Q. Now, Dr. Goldberg, you have the eight
11 declarations that we're discussing today in front
12 of you; correct?
13 A. Well, beside me, yes.
14 Q. Do you have any other documents before
15 you, whether in hard copy or loaded to the
16 computer in front of you?
17 A. I have nothing open on my computer other
18 than this Zoom meeting.
19 I also do have a packet that has all of
20 the patents collated in a single binder separately
21 from the declarations.
22 Q. Okay. So you have your eight

1 declarations and the eight patents that we're
2 discussing today in the room with you?
3 A. I do.
4 Q. Are there any Post-It notes on any of
5 the documents that you have in the room with you
6 today?
7 A. No.
8 They're just as they were sent to me by
9 the Fish counsel.
10 Q. Are there any annotations on those
11 documents that you have in the room with you
12 today?
13 A. No.
14 Q. You looked at the eight patents at issue
15 in the proceedings that we're discussing today;
16 right?
17 A. I have.
18 Q. And you reviewed the claims of the eight
19 patents that we're discussing today; right?
20 A. I have.
21 Q. Dr. Goldberg, do you understand the
22 difference between an independent and a dependent

1 claim?
2 A. I believe I do, but I'd love to have you
3 explain it to me.
4 Q. What's your understanding of an
5 independent claim?
6 A. An independent claim is a claim that
7 stands on its own and a dependent claim is a claim
8 that is dependent on other claims.
9 So, for example, generally, claim 1 is
10 an umbrella claim, and the following claims in
11 that same patent are under that umbrella or could
12 be construed as being dependent on that claim 1.
13 Q. So let's take a look at the '974 patent.
14 Let me know when you have that in front of you.
15 A. Okay. I have that in front of me.
16 Q. The '974 patent has one independent
17 claim, claim 1; right?
18 A. Can you show me where that is? I
19 believe it's toward the end of the declaration.
20 So if I look at page 61 of my
21 declaration, is that what you're referring to?
22 Q. No, Dr. Goldberg. I'd like for you to

1 take a look at the '974 patent.
2 A. Okay.
3 Okay. I have the '974 patent in front
4 of me.
5 Q. The '974 patent has one independent
6 claim, claim 1; right?
7 A. Can you tell me on what -- which of the
8 31 pages that is on?
9 Q. Do you know where the patent claims can
10 be found in a patent?
11 A. Generally speaking, yes, but I'd like
12 you to help me find it so that I don't have to
13 page through every page.
14 Q. Do you know where the claims are located
15 in this '974 patent?
16 A. I'm looking for them now.
17 Q. Do you know where the patent claims are
18 located in this '974 patent that you reviewed as
19 part of your work in these matters?
20 DR. BROWN-MARSHALL: Objection, asked
21 and answered.
22 A. Okay. So I find now that they're on

1 page 31 of the 31 pages, at the very end of the
2 patent.
3 Q. Dr. Goldberg, are you familiar with the
4 claims of the '974 patent that you said that you
5 looked at as part of your work in connection with
6 this matter?
7 A. I am.
8 Q. The '974 patent has one independent
9 claim, claim 1; right?
10 A. Correct.
11 Q. And claim 1 is directed to a method of
12 treating an individual cancer patient; right?
13 A. That's what it states.
14 Q. You can set that patent aside for now,
15 Dr. Goldberg.
16 Let's take a look at the '975 patent.
17 A. Okay. I have the '975 patent in front
18 of me.
19 Q. The '975 patent has two independent
20 claims, claims 1 and 9; right?
21 A. I see the "method for treating cancer in
22 a patient in need thereof" as the statement at the

1 beginning of 1 and 9, yes.
2 Q. The '975 patent has two independent
3 claims, claims 1 and 9; right?
4 A. Yes.
5 Q. And claims 1 and 9 are each directed to
6 a method of treating an individual cancer patient;
7 right?
8 A. Can you give me a minute to read
9 claims 1 and 9 before I answer, please?
10 Can you ask me the question again,
11 please?
12 Q. Sure.
13 Claims 1 and 9 are each directed to a
14 method of treating an individual cancer patient;
15 right?
16 A. Correct.
17 Q. Let's take a look at the '219 patent.
18 A. Okay. I have that now.
19 Q. The '219 patent has one independent
20 claim, claim 1; right?
21 A. Correct.
22 Q. And claim 1 is directed to a method of

1 treating an individual cancer patient; right?
2 A. Correct.
3 Q. Let's take a look at the '287 patent.
4 A. Okay. I have that.
5 Q. The '287 patent has two independent
6 claims, claims 1 and 11; right?
7 A. Give me a moment to look at that.
8 Yes.
9 Q. Claim 1 is directed to a method of
10 treating an individual cancer patient; right?
11 A. Correct.
12 Q. And claim 11 is directed to a method of
13 reducing the risk of cancer progression in an
14 individual cancer patient; right?
15 A. Correct.
16 Q. Let's take a look at the '187 patent.
17 A. Okay. I have that.
18 Q. The '187 patent has two independent
19 claims, claims 1 and 11; right?
20 A. Let me confirm that. Just a moment.
21 Correct.
22 Q. And claim 1 is directed to a method of

1 treating an individual cancer patient; right?
2 A. That's correct.
3 Q. And claim 11 is directed to a method of
4 reducing the risk of cancer progression in an
5 individual cancer patient; right?
6 A. Let me just read that.
7 Correct.
8 Q. Let's take a look at the '356 patent.
9 A. Okay. I have that.
10 Q. The '356 patent has four independent
11 claims, claims 1, 11, 19, and 23; right?
12 A. Let me look at that, and I'll confirm in
13 a moment.
14 That's correct.
15 Q. Claims 1, 11, and 19 are each directed
16 to a method of treating an individual cancer
17 patient; right?
18 A. That's correct.
19 Q. And claim 23 is directed to a method of
20 treating cancer in a population of cancer
21 patients; right?
22 A. That's what it states.

1 Q. Okay. Let's take a look at the '462
2 patent.
3 A. Okay. I have that.
4 Q. The '462 patent has two independent
5 claims, claims 1 and 11; right?
6 A. Let me review that a moment.
7 Correct.
8 Q. And claim 1 is directed to a method of
9 treating an individual cancer patient; right?
10 A. Correct.
11 Q. Claim 11 is directed to a method of
12 prescribing a treatment for an individual cancer
13 patient; right?
14 A. Let me read that 'cause it's different
15 than claim 1.
16 Correct.
17 Q. Take a look at the '491 patent.
18 A. Okay. I have that.
19 Q. The '491 patent has two independent
20 claims, claims 1 and 16; right?
21 A. Correct.
22 Q. And claim 1 is directed to a method of

1 treating an individual cancer patient; right?
2 A. It is.
3 Q. And claim 16 is directed to a method of
4 reducing the risk of cancer progression or
5 increasing overall survival in an individual
6 cancer patient; right?
7 A. Correct.
8 Q. You can set the '491 patent aside,
9 Dr. Goldberg.
10 A. Okay.
11 Q. Now, you understand that the alleged
12 invention date of the eight patents that we're
13 discussing today is July 10th, 2015; right?
14 DR. BROWN-MARSHALL: Object to the form
15 of the question.
16 A. I understand that the patents were filed
17 July 11th, 2014 -- 2015. Sorry.
18 Q. Let me try my question again.
19 You understand that the alleged
20 invention date here of the eight patents that
21 we're discussing is July 10th, 2015; right?
22 DR. BROWN-MARSHALL: Object to the form

1 of the question.
2 A. So I know that that was when the patents
3 were filed. And if the date that the patents are
4 filed is the alleged invention date, then I agree
5 with your statement.
6 Q. Dr. Goldberg, do you believe that an
7 alleged invention date is different from a
8 priority date?
9 DR. BROWN-MARSHALL: Object to the form
10 of the question.
11 Q. Of the patent.
12 A. I'm not familiar with those terms.
13 Q. But you used the term "priority date"
14 throughout your declarations; right?
15 A. That was a date that was supplied to me
16 by counsel, so I used that term.
17 Q. And you used the term "priority date"
18 throughout the declarations that you prepared in
19 the proceedings that we're discussing here today;
20 correct?
21 A. Correct.
22 Q. What does the term "priority date" mean

1 to you as you use them in the declarations that
2 we're discussing today?
3 A. I assume that it means the date that the
4 patent was filed and recorded by the patent
5 office.
6 Q. Okay. And so you understand that the
7 priority date here is July 10th, 2015, for the
8 eight patents that we're discussing today; right?
9 A. I do.
10 Q. Do you understand that anything before
11 that July 10th, 2015, date is considered prior
12 art?
13 DR. BROWN-MARSHALL: Object. Object to
14 the form of the question.
15 A. That is not my understanding.
16 My understanding is that anything that
17 the inventors did to help create the invention is
18 not considered prior art.
19 Q. Let me try my -- let me try asking my
20 question a different way.
21 Do you understand that anything that's
22 publicly available before the July 10th, 2015,

1 date is considered prior art?
2 DR. BROWN-MARSHALL: Object to the form
3 of the question.
4 A. So I'm going to answer again the same
5 way, that the -- it's my understanding, according
6 to what counsel has informed me, anything that has
7 to do with the invention of the claims is not
8 considered prior art; and that prior art -- that
9 presentation and New England Journal paper
10 preceded the priority date. And so it was in the
11 public domain, but, as I understand it, is not
12 applicable to being considered as prior art.
13 Q. So if it's publicly available from --
14 but not from the named inventors, you understand
15 that is considered prior art; right?
16 DR. BROWN-MARSHALL: Object to the form
17 of the question.
18 A. As far as I understand it, that's a true
19 statement.
20 Q. Now, since the time of your deposition
21 on December 13th, 2024, in the '393 proceeding,
22 have you spoken with anyone other than the

1 attorneys representing JHU in connection with your
2 work on these matters?
3 A. I have spoken with several of the other
4 expert witnesses that have been retained by JHU.
5 Q. And who did you speak with?
6 A. My memory is that I spoke with the --
7 with Nils Lonberg, the -- who is one of the
8 witnesses with Dr. Dung Le, who is one of the
9 inventors with Dr. Luis Diaz, who's one of the
10 inventors, and also with the economics expert,
11 whose last name begins with an S, but I don't
12 remember his full name.
13 Q. And you've spoken with those individuals
14 since the time of your deposition on
15 December 13th, 2024?
16 A. That's correct.
17 Also present in those discussions were
18 the counsel from Fish.
19 Q. So when did you speak to Dr. Lonberg?
20 A. I don't remember the dates.
21 Q. How many times did you speak with
22 Dr. Lonberg?

1 A. I think I've spoken with him a total of
2 twice, once before the prior deposition and once
3 after the -- once in January, January or February.
4 I believe it was January.
5 Q. And when you spoke with Dr. Lonberg in
6 January, was that in person?
7 A. No. It was by Zoom.
8 Q. And who was present during your
9 discussion with Dr. Lonberg in January?
10 A. I know that at least one of the Fish
11 counsel was present, but it may have been two; I
12 don't recall precisely.
13 Q. And what did you and Dr. Lonberg discuss
14 during the Zoom call in January?
15 A. We discussed parts of my declaration,
16 and he discussed parts of his declaration.
17 Q. And what parts of your declaration did
18 you discuss?
19 A. Well, my declaration addresses unmet
20 need. That's not his expertise. So I gave him a
21 brief overview of my arguments regarding unmet
22 need, and he was able to ask me questions. And

1 then I -- I -- he gave me a presentation about his
2 testimony regarding the development of
3 immuno-oncology drugs and pembrolizumab, as well
4 as nivolumab, and I was able to ask him questions.
5 Q. And did you rely on any information that
6 Dr. Lonberg provided to you in that conversation
7 in January in your declarations that we're
8 discussing today?
9 A. I don't have a specific memory of that,
10 but I think that I considered his remarks to be
11 supplementary and weren't -- not -- not items that
12 were addressed specifically in my declarations.
13 The declarations were substantially
14 completed by the time I talked with him.
15 Q. But you spoke with Dr. Lonberg before
16 signing your declarations on January 11th and
17 January 22nd, 2025?
18 A. I don't -- don't remember when I spoke
19 with him, so I can't answer that question.
20 To the best of my memory, my
21 declarations had been completed before we spoke.
22 Q. And when did you speak with Dr. Le after

1 your December 13th, 2024, deposition?
2 A. Again, I believe it was in January, but
3 it may have been in February.
4 Q. And did you speak with Dr. Le in person?
5 A. No. By Zoom.
6 Q. Who else was present for your discussion
7 with Dr. Le by Zoom?
8 A. Again, I don't have a specific memory,
9 but it was one or more members of counsel.
10 Q. And what did you and Dr. Le discuss
11 during your Zoom call?
12 A. My memory is that we principally
13 discussed the five-year survival data, which had
14 been newly acquired for the KEYNOTE trial that was
15 published in the New England Journal, in which I
16 participated in.
17 And we did that, in part, because there
18 was an intention to submit an ASCO abstract for
19 presentation, and those data were not publicly
20 known.
21 Q. Did you speak with Dr. Le only once
22 after your December 13th, 2024, deposition?

1 A. Yes, I believe that's correct.
2 Q. When did you speak with Dr. Diaz after
3 your December 13th, 2024, deposition?
4 A. So I did not speak to Dr. Diaz formally
5 for this preparation, but he and I see each other
6 at meetings and are social and speak about common
7 interests. And I believe that I spoke with him
8 once or twice about that at meetings in public
9 areas, and did not discuss specific items
10 regarding these proceedings.
11 Q. So you did not speak with Dr. Diaz in
12 connection with your work in these eight
13 proceedings after your December 13th, 2024,
14 deposition; is that correct?
15 A. We may have discussed the fact that we
16 were working -- both working on these issues, but
17 we didn't discuss specific items relevant to my
18 declaration.
19 Q. And when did you speak with Mr. Segers
20 after your December 13th, 2024, deposition?
21 A. Again, it was either in January or
22 February.

1 Q. And did you speak with Mr. Segers by
2 Zoom?
3 A. Yes.
4 Q. Was anybody else present for your
5 discussion with Mr. Segers?
6 A. One or more members of the Fish legal
7 team.
8 Q. How many times did you speak with
9 Mr. Segers after your December 13th, 2024,
10 deposition?
11 A. Once.
12 Q. What did you and Mr. Segers discuss when
13 you spoke?
14 A. So, again, I generally discussed items
15 in my declaration and answered questions that he
16 had about them. And he discussed items in his
17 declaration and answered my questions.
18 Q. Did you rely on anything that Mr. Segers
19 told you during that discussion in your eight
20 declarations that we're discussing here today?
21 A. I don't believe so.
22 Q. In your view, Dr. Goldberg, an

1 oncologist treating a cancer patient with KEYTRUDA
2 would only prescribe KEYTRUDA in accordance with
3 the FDA-approved indications on the drug labeling;
4 right?
5 DR. BROWN-MARSHALL: Object to the form
6 of the question.
7 A. So oncologists are licensed medical
8 doctors who have prescribing privileges, and they
9 can prescribe drugs that are FDA approved for any
10 indication in any way they choose.
11 Q. Is it your view that an oncologist
12 treating a cancer patient with KEYTRUDA would only
13 prescribe KEYTRUDA in accordance with the
14 FDA-approved indications on its labeling?
15 A. My -- I believe that's the same question
16 I just answered.
17 And the answer is no.
18 Q. In your view, would an oncologist
19 prescribe -- strike that.
20 In your view, would an oncologist have
21 prescribed KEYTRUDA to an MSI-high patient outside
22 the context of a clinical trial prior to May of

1 2017?
2 A. As I stated, an oncologist is a
3 physician with prescribing rights, and that
4 physician has the right to use any drug that is
5 available in the marketplace that has been FDA
6 approved for any indication in any way they
7 choose.
8 Q. So would an oncologist have prescribed
9 KEYTRUDA to an MSI-high patient outside the
10 context of the clinical trial prior to May of
11 2017?
12 DR. BROWN-MARSHALL: Objection, asked
13 and answered.
14 A. I'm going to say the same thing I just
15 said. An oncologist is a -- a licensed physician
16 who has the right to prescribe FDA-approved drugs
17 that are approved for any indication, to any
18 patient that they want to prescribe it to, whether
19 or not that is an FDA-approved indication or
20 whether there are guidelines that suggest that
21 that prescription is supported by data.
22 Q. Do you know if KEYTRUDA was prescribed

1 to MSI-high patients outside the context of
2 clinical trials prior to May of 2017?
3 A. I don't know that for a fact, with
4 respect to discussions that I had with individual
5 patients. However, I think it's likely that
6 physicians who have a right to prescribe drugs
7 might have just prescribed it in that
8 circumstance.
9 Q. Do you know if KEYTRUDA was prescribed
10 to MSI-high patients outside the context of a
11 clinical trial prior to July of 2015?
12 A. I don't have specific knowledge of that.
13 Q. In your view, would an oncologist have
14 prescribed KEYTRUDA as a first-line treatment to
15 an MSI-high colorectal cancer patient outside the
16 context of a clinical trial prior to June of 2020?
17 A. I think it's likely that it -- that
18 happened, but I don't have specific knowledge
19 about it.
20 Q. In your view, would an oncologist have
21 prescribed KEYTRUDA to an MSI-high endometrial
22 cancer patient outside the context of a clinical

1 trial prior to March of 2022?
2 A. As I understand it -- sorry. Did you
3 say "a first-line patient" in your question?
4 Q. I can ask my question again.
5 In your view, would an oncologist have
6 prescribed KEYTRUDA to an MSI-high endometrial
7 cancer patient outside the context of a clinical
8 trial prior to March of 2022?
9 A. I think that that was very likely since
10 there was an FDA indication for it and it was
11 approved -- mentioned as an approved option for
12 patients in the NCCN guidelines prior to that
13 time.
14 Q. In your view, would an oncologist have
15 prescribed KEYTRUDA as a first-line treatment to
16 an MSI-high colorectal cancer patient outside the
17 context of a clinical trial prio- -- prior to July
18 of 2015?
19 A. I don't have specific knowledge about
20 that, but there were -- were -- approximately
21 40 days elapsed from the ASCO presentation till
22 the time of the priority date, and so an

1 oncologist could have done that. It was not --
2 there was not an FDA-approved indication for that
3 and there would have been potential difficulty
4 getting insurance coverage for it, but it -- an
5 oncologist would have been within their rights to
6 do that.
7 Q. In your view, would an oncologist have
8 prescribed KEYTRUDA as a treatment for MSI-high
9 colorectal cancer patients outside the context of
10 a clinical trial prior to May of 2015?
11 A. I don't believe that they would have, as
12 the results of the Hopkins trial were not known
13 until Dr. Le's presentation, which was embargoed
14 before that date of presentation.
15 Q. In your view, were oncologists following
16 the NCCN guidelines as of July 10th, 2015, for
17 prescribing KEYTRUDA to cancer patients?
18 A. Some oncologists were, and some
19 oncologists likely weren't.
20 The guidelines are guidelines. They're
21 not binding.
22 Q. Now, you stopped treating cancer

1 patients in 2017; right?
2 A. Yes.
3 At the end of 2017, I left Ohio State
4 and went to West Virginia University, where I did
5 not have a regular medical practice. I did see
6 some patients in consultation in the hospital, but
7 did not treat them with pembrolizumab or other
8 drugs.
9 Q. You said that you left Ohio State at the
10 end of 2017; correct?
11 A. Correct. I'm sorry. The end of 2016.
12 I started at Ohio -- at West Virginia University
13 early in 2017.
14 Q. Okay. So you stopped treating
15 patients --
16 A. No. Let me get it straight. It was at
17 the end of 2017.
18 I'm going to look at my CV just to be
19 sure that I get the results correct. I'm looking
20 at the appendix to this just to be absolutely sure
21 of the dates.
22 Q. And your Appendix A begins on page --

1 around page 67 of your declarations.
2 A. Right. It depends on the specific
3 declaration.
4 I'm looking at the '326 patent, and it
5 begins on page 68.
6 Q. And the second page of your CV reflects
7 that you left Ohio State University in December of
8 2016; right?
9 A. That's correct.
10 Q. And the second page of your CV that's
11 Appendix A to your declarations reflects that you
12 started at West Virginia University in January of
13 2017; correct?
14 A. Correct.
15 Q. When did you stop treating cancer
16 patients?
17 A. I treated some cancer patients -- well,
18 I saw some cancer patients in the hospital at
19 West Virginia University in 2017 and 2018, as a --
20 while doing hospital consults, but I did not treat
21 them with anticancer drugs as a part of that.
22 Q. So did you -- you did not treat cancer

1 patients with anticancer drugs in 2017; is that
2 right?
3 A. Yes.
4 Q. So outside the context of a clinical
5 trial, did you treat any MSI-high cancer patients
6 with KEYTRUDA before you stopped treating
7 patients?
8 A. I believe that I treated a few. This
9 was eight or nine years ago. I know that I
10 treated four patients on the clinical trial. And
11 I think I treated two or three additional patients
12 after that.
13 Q. Where were you working when you treated
14 those two or three patients -- MSI-high cancer
15 patients with KEYTRUDA outside the context of a
16 clinical trial?
17 A. So that would have been at Ohio State
18 University.
19 Q. And that was before the May 2017
20 MSI-high approvals for KEYTRUDA to treat MSI-high
21 cancer patients; right?
22 A. That would have been -- it would have

1 been after the ASCO presentation, when that data
2 was known.
3 Q. So you treated MSI-high cancer patients
4 with KEYTRUDA outside the context of a clinical
5 trial before the May 2017 MSI-high FDA approvals
6 for KEYTRUDA; is that correct?
7 DR. BROWN-MARSHALL: Object. Object to
8 the form of the question.
9 A. I believe that's the case, yes.
10 Q. Before you stopped treating cancer
11 patients in 2017, did you ever treat a gastric
12 cancer patient with KEYTRUDA outside the context
13 of a clinical trial?
14 A. Not that I can re- --
15 DR. BROWN-MARSHALL: Objection.
16 Objection. Object to the form of the
17 question.
18 A. Not that I can recall.
19 Q. Now, you state in your declarations that
20 when you prescribe KEYTRUDA, you follow the
21 instructions on the KEYTRUDA labeling; correct?
22 A. That's correct.

1 Q. How did you use the KEYTRUDA labeling in
2 the treatment of your cancer patients?
3 A. Well, you gen- --
4 DR. BROWN-MARSHALL: Object. Object to
5 the form of the question.
6 A. So, in general, I did not read the
7 KEYTRUDA labeling. I relied upon my experience in
8 terms of choosing which patients to treat and what
9 dose to treat them with.
10 Q. So you did not read the KEYTRUDA
11 labeling in the treatment of your cancer patients
12 with KEYTRUDA; is that correct?
13 DR. BROWN-MARSHALL: Object to the form
14 of the question.
15 A. So, as I stated, I relied on my
16 experience.
17 I don't recall sitting down and reading
18 the KEYTRUDA labeling prior to preparing for this
19 expert-witness engagement.
20 Q. Now, when you treated cancer patients,
21 did you ever treat an MSI-high endometrial cancer
22 patient with KEYTRUDA outside the context of a

1 clinical trial?
2 A. My practice is limited to
3 gastrointestinal cancers, mainly colorectal
4 cancers, so I did not treat anybody who -- I only
5 treated colorectal cancer patients in my memory
6 and never any other -- patients with any other
7 type of cancer.
8 Q. So you've never used the KEYTRUDA
9 labeling to treat an MSI-high endometrial cancer
10 patient with KEYTRUDA; right?
11 A. I don't treat endometrial cancer.
12 Q. You never used the KEYTRUDA labeling to
13 treat an MSI-high endometrial cancer patient with
14 KEYTRUDA; right?
15 A. I thought I answered that question.
16 I don't treat endometrial cancer.
17 Q. My question's just a little bit
18 different, so let me try one more time.
19 You've never used the KEYTRUDA labeling
20 to treat an MSI-high endometrial cancer patient
21 with KEYTRUDA; right?
22 DR. BROWN-MARSHALL: Objection.

1 Objection, asked and answered.
2 A. That's correct.
3 I don't treat endometrial cancer
4 patients with any drugs. They're outside the
5 scope of my practice.
6 Q. As part of your work in the matters that
7 we're discussing today, did you speak with any
8 oncologists who have used the KEYTRUDA labeling to
9 treat an MSI-high endometrial cancer patient with
10 KEYTRUDA?
11 A. So I spoke to oncologists all the time.
12 I frequently lectured on the use of KEYTRUDA and
13 other immuno-oncology agents. I'm -- so I'm sure
14 that I spoke to GYN oncologists about that from
15 the lectern, but I don't recall speaking to them
16 one-on-one about it.
17 Q. And did you speak with any of those
18 oncologists that you just mentioned in connection
19 with your work in the matters that we're
20 discussing here today?
21 A. Well, I spoke with them about my
22 experience of participating in the Hopkins trials.

1 I -- which is relevant to the matters that we're
2 discussing here today.
3 Q. In preparing your declarations in the
4 eight proceedings that we're discussing today, did
5 you speak with any of those oncologists that you
6 mentioned?
7 A. Not that I recall.
8 At the time that I prepared these
9 documents, I was not -- not -- was not lecturing
10 as often because I had retired.
11 I did give one lecture in Portland,
12 Oregon that probably overlapped with the time of
13 the -- my engagement with Fish, but it mostly
14 focused on colorectal cancer.
15 Q. So as part of your work in preparing
16 your eight declarations that we're discussing
17 today, did you speak with any oncologist in
18 preparation of those declarations who have used
19 the KEYTRUDA labeling to treat an MSI-high
20 endometrial cancer patient with KEYTRUDA?
21 A. Not that I recall.
22 Q. And as part of your work in preparing

1 your eight declarations that we're discussing
2 today, did you speak with any oncologist in
3 preparation of those declarations who have used
4 the KEYTRUDA labeling to treat an MSI-high
5 colorectal cancer patient with KEYTRUDA as a
6 first-line therapy?
7 A. I don't recall any specific discussion
8 about that.
9 Q. And you stopped seeing cancer patients
10 before KEYTRUDA was approved for the treatment of
11 MSI-high endometrial cancer; right?
12 A. Assuming that it was approved in 2017, I
13 stopped treating patients with antineoplastic
14 drugs before its approval date.
15 Q. And you stopped seeing cancer patients
16 before KEYTRUDA was used -- approved for the
17 treatment of MSI-high colorectal cancer; right?
18 DR. BROWN-MARSHALL: Objection, asked
19 and answered.
20 A. So, as I mentioned, at the end of
21 December 2016, I stopped having regular clinics,
22 during which I treated patients with medications

1 to try and control their disease.
2 Q. And so you stopped seeing cancer
3 patients before KEYTRUDA was approved for the
4 treatment of MSI-high colorectal cancer; right?
5 A. So the answer is no. I stopped treating
6 patients. I continued to see patients as a
7 consultant.
8 Q. Let me try it -- my question again, and
9 I'll -- I'll rephrase it.
10 You stopped treating cancer patients
11 before KEYTRUDA was approved for the treatment of
12 MSI-high colorectal cancer; is that right?
13 A. I stopped prescribing drugs to treat
14 patients, specific anticancer drugs.
15 When I saw patients in consultation, I
16 may have recommended treatments with
17 non-chemotherapy or immuno-oncology agents, mainly
18 for supportive care purposes.
19 Q. So what evidence do you have that
20 reflects that an oncologist prescribing KEYTRUDA
21 to an MSI-high colorectal cancer patient as a
22 first-line therapy according to its labeling

1 necessarily practices the methods of treatment
2 described in the '219 patent?
3 A. So I don't have specific knowledge of
4 how oncologists practice.
5 Q. What evidence -- actually, strike that.
6 Dr. Goldberg, you write in your
7 declarations in -- I'll refer to the '356
8 declaration. At paragraph 88 --
9 A. Hold on.
10 Q. -- you write in your declarations that,
11 "At Ohio State University, we rapidly adopted
12 universal MSI testing for our patients and used
13 PD-1 inhibitors when appropriate."
14 Right?
15 A. Correct.
16 Q. In what time period are you referring to
17 with this statement?
18 A. So this would have been at the time that
19 I was departing from Ohio State and getting ready
20 to go to West Virginia University. We had a
21 research group that was in the forefront of
22 treatment of MSI-high cancers. And our research

1 group was preparing to do universal MSI testing in
2 our patients.
3 And that's something that we've written
4 editorials about. Although, those editorials
5 occurred after the time that I left. So I
6 continued to work with my colleagues and continued
7 to publish with them after I had departed.
8 Q. And so, with this statement, are you
9 referring to the 2016 time period?
10 DR. BROWN-MARSHALL: Object to the form
11 of the question.
12 A. That doesn't specify a time period.
13 Q. I'm asking you what you meant when you
14 wrote this statement in your declarations that
15 we're discussing today.
16 DR. BROWN-MARSHALL: Object to the form
17 of the question.
18 A. So can you be more specific with that
19 question, please?
20 Q. When you wrote in your declarations,
21 quote, "At Ohio State University, we rapidly
22 adopted universal MSI testing for our patients and

1 used PD-1 inhibitors when appropriate," end quote,
2 what time period were you referring to?
3 A. So I was referring to the time period
4 after I had left Ohio State University but when I
5 was still collaborating, as I do still collaborate
6 now, with investigators at Ohio State University.
7 Q. So when did Ohio State University,
8 quote, "rapidly adopt universal MSI testing"?
9 DR. BROWN-MARSHALL: Object. Objection,
10 asked and answered.
11 A. So they adopted it in 2017, and
12 thereafter.
13 Q. Did oncologists at Ohio State University
14 perform MSI testing on cancer patients prior to
15 2017?
16 DR. BROWN-MARSHALL: Object to the form
17 of the question.
18 A. So oncologists don't perform MSI
19 testing. They order that testing, which is then
20 performed either in-house in the pathology
21 laboratory or is a send-out test to a third-party
22 vendor.

1 Ohio State oncologists ordered MSI
2 testing frequently on patients because of our
3 research programs in Lynch syndrome and MSI-high
4 cases. Albert de la Chapelle, who was one of the
5 laboratory investigators who explained what the
6 cause of Lynch syndrome was, and under -- and
7 discovered microsatellite instability, was a
8 colleague at Ohio State. And so we were in the
9 vanguard of testing for MSI in our patients and in
10 our research.
11 Q. And did you order MSI testing in your --
12 for your patients before July 10th, 2015?
13 A. I ordered it as a part of determining
14 eligibility for the JHU trial.
15 I also ordered it as a part of my
16 referral practice and my regional practice when I
17 saw patients who had early onset colorectal
18 cancer, who had a family history of colorectal
19 cancer, or who had stage 2 colon cancer and I was
20 trying to determine appropriate chemotherapy
21 treatment after their surgery.
22 So the short answer is, yes, I did order

1 MSI testing frequently prior to 2015.
2 DR. BROWN-MARSHALL: Counsel, we've been
3 going for over an hour now. Is now a good
4 time to take a break?
5 MS. STAURING: Dr. Goldberg, would you
6 like to take a break?
7 THE WITNESS: That would suit me.
8 MS. STAURING: We can go off the record.
9 THE STENOGRAPHER: We're off the record.
10 (Recess in proceedings.)
11 THE STENOGRAPHER: We're back on the
12 record.
13 BY MS. STAURING:
14 Q. Dr. Goldberg, you participated in the
15 phase two study that you discuss in your
16 declarations with clinical trial number
17 NCT01876511; right?
18 A. I'll have to look up that number in
19 order to confirm it. Can you help me on what page
20 it is on my declaration?
21 Q. Sure. You can refer to paragraph 11 in
22 your '356 declaration.

1 A. Can you read me the number again,
2 please?
3 Q. Paragraph 11 in the '356 declaration?
4 A. No, that --
5 Q. And the clinical trial number is
6 NCT01876511.
7 A. That's correct.
8 Q. Now, if I refer to this study as the
9 "MSI-high study" today, will you understand what
10 I'm referring to?
11 A. I do, even though there were some MSS
12 patients included in the trial, but we can call it
13 the "MSI-high trial," if you'd like.
14 Q. Now, the study record for the MSI-high
15 study was posted to clinicaltrials.gov in June of
16 2013; right?
17 DR. BROWN-MARSHALL: Object to the form
18 of the question.
19 A. I believe that that's the correct date,
20 yes.
21 Q. And so that was publicly available as of
22 June 2013; right?

1 A. Yes.
2 Q. Prior to the posting of the MSI-high
3 study record on clinicalstrials.gov, it was known
4 that treatment with BMS's PD-1 inhibitor had led
5 to a complete response in an MSI-high colorectal
6 cancer patient; right?
7 DR. BROWN-MARSHALL: Object to the form
8 of the question.
9 A. So the Topalian trial treated a patient
10 that had a response to nitrous oxide, but it was
11 not known, as I understand it, if that patient was
12 MSI-high or not.
13 I don't know exactly when the Hopkins
14 team requested MSI testing on that patient.
15 Q. Dr. Goldberg, when you were preparing
16 your declarations, you were not aware of a
17 publication that reported that the complete
18 response of the colorectal cancer patient treated
19 with BMS's PD-1 inhibitor was MSI-high; is that
20 correct?
21 DR. BROWN-MARSHALL: Object to the form
22 of the question.

1 A. It's been awhile since I've read the
2 Topalian article, but my memory is that there was
3 no mention of MSI testing of the patients enrolled
4 in that trial in the paper that I read.
5 Q. And I'm not referring to the Topalian
6 paper that you're mentioning, so let me try my
7 question a different way.
8 Sitting here today, do you know if there
9 was a publication before July 10th, 2015,
10 disclosing that the colorectal cancer patient that
11 experienced a complete response when treated with
12 BMS's PD-1 inhibitor was MSI-high?
13 DR. BROWN-MARSHALL: Object to the form
14 of the question.
15 A. So I don't recall specific knowledge of
16 whether that was published.
17 I do know that the results were known at
18 the time that the Hopkins team wrote the trial in
19 2012, 2013. And it may have been in the public
20 domain. But I -- I don't have specific knowledge
21 or recollection of that.
22 Q. Would you agree that part of the

1 rationale for why a scientist or physician in the
2 field would conduct a phase two study of
3 pembrolizumab in patients with
4 microsatellite-unstable tumors was the complete
5 response in a single patient with MSI-high
6 colorectal cancer?
7 DR. BROWN-MARSHALL: Object to the form
8 of the question.
9 A. So I believe I covered that in my
10 declaration.
11 I'm looking for where I covered that.
12 Q. I'm just asking if -- sitting here
13 today, would you agree that part of the rationale
14 for why a scientist or a physician in the field
15 would conduct a phase two study of pembrolizumab
16 in patients with microsatellite-unstable tumors
17 was the complete response in a single patient with
18 MSI-high colorectal cancer treated with nivolumab?
19 DR. BROWN-MARSHALL: Object to the form
20 of the question.
21 A. So, sitting here today, I agree that --
22 that single patients who had a response to

1 nivolumab was what engendered the Hopkins trial.
2 Q. And would you agree that that would --
3 strike that.
4 Would you agree that part of the
5 rationale for why a scientist or a physician in
6 the field would conduct a phase two study of
7 pembrolizumab in patients with
8 microsatellite-unstable tumors was the complete
9 response in the MSI-high colorectal cancer patient
10 treated with nivolumab?
11 DR. BROWN-MARSHALL: Objection, asked
12 and answered.
13 A. I'm going to refer you to paragraph 59
14 of the '356 declaration where that is discussed in
15 detail.
16 Q. Dr. Goldberg, I'm asking your opinion.
17 Sitting here today, would you agree that
18 part of the rationale for why a scientist or a
19 physician in the field would conduct a phase two
20 study of pembrolizumab in patients with
21 microsatellite-unstable tumors was the known
22 complete response in the MSI-high colorectal

1 cancer patient treated with nivolumab?
2 DR. BROWN-MARSHALL: Objection, asked
3 and answered several times.
4 A. I'm going to read you paragraph 59.
5 "Rather than simply dismissing PD-1's [sic]
6 inhibitors' potential in colorectal cancer,
7 Dr. Topalian and her team sought to determine if
8 the one CRC patient who had a sustained response
9 to treatment had any distinguishing
10 characteristics. She and her team consulted with
11 Bert Vogelstein and members of his scientific
12 team. The Vogelstein lab was concentrating
13 focusing on elucidating genetic alterations that
14 occur as a part of colorectal cancer
15 carcinogenesis. Luis Diaz, a member of the
16 Vogelstein team, proposed that the responding CRC
17 patient might have a defect in the repair
18 mechanism that corrects errors that occur in DNA
19 replication as an explanation for the sensitivity
20 of that patient's tumor to nivolumab. This defect
21 is known as microsatellite instability and such
22 patients are classified as having MSI-high or

1 MSI-H tumors. The team went back to the patient's
2 pathologic specimen and learned that the tumor in
3 the responding patient was, indeed, MSI-high."
4 And the next section is titled "Thinking
5 Outside the Box," which is what the Hopkins team
6 did.
7 So the short answer is yes.
8 Q. So the short answer to my question is
9 yes; right?
10 DR. BROWN-MARSHALL: Objection.
11 A. Can you ask your question again, please?
12 Q. Sure.
13 I'm asking: As someone who considered
14 himself an expert in the field, would the complete
15 response of the MSI-high colorectal cancer patient
16 treated with nivolumab have been part of the
17 rationale for why a scientist or physician in the
18 field would conduct a phase two study of
19 pembrolizumab in patients with
20 microsatellite-unstable tumors?
21 DR. BROWN-MARSHALL: Objection, asked
22 and answered.

1 A. As an expert in the field, that finding
2 was part of the basis of doing this phase two
3 trial.
4 Q. And that would have been part of the
5 basis for why a scientist or physician in the
6 field would conduct a phase two study of
7 pembrolizumab in patients with
8 microsatellite-unstable tumors; right?
9 DR. BROWN-MARSHALL: Objection, asked
10 and answered.
11 A. That was the reason -- this -- this
12 group of scientists at Johns Hopkins University
13 wrote their protocol to test that.
14 Q. Do you know if that would have provided
15 rationale for other scientists or physicians in
16 the field to conduct a phase two study of
17 pembrolizumab in patients with
18 microsatellite-unstable tumors?
19 DR. BROWN-MARSHALL: Objection, outside
20 the scope of Dr. Goldberg's declaration.
21 A. No other scientists did that other than
22 the Hopkins team, but it's possible that other

1 scientists working in this field could have come
2 up with that idea. The fact is, they didn't.
3 Q. What about the scientists at BMS?
4 A. Well, the scientists at BMS declined to
5 fund this trial initially, and so they didn't
6 think it was a worthwhile question to answer, in
7 my estimation. Of course, Dr. Lonberg's testimony
8 addresses that more specifically.
9 Also, Dr. Le discusses that more
10 specifically.
11 Q. But, Dr. Goldberg, aren't you aware that
12 scientists at BMS, before July 10th, 2015, did
13 conduct a study to treat MSI-high colorectal
14 cancer patients with BMS's PD-1 inhibitor?
15 DR. BROWN-MARSHALL: Object to the form
16 of the question.
17 A. You know, I would refer you to
18 Dr. Lonberg's testimony. He was at BMS and had
19 inside knowledge of the timing and scientific
20 inquiries being launched by his team there.
21 Q. Dr. Goldberg, are you aware that the
22 scientists at BMS posted the study record before

1 July 10th, 2015, to clinicaltrials.gov for BMS's
2 study to treat MSI-high colorectal cancer patients
3 with its PD-1 inhibitor?
4 DR. BROWN-MARSHALL: Objection, outside
5 the scope of Dr. Goldberg's declaration.
6 A. Well, I read Dr. Lonberg's dec- --
7 declaration. And my recollection of it was that
8 the Hopkins team solicited the BMS team to let
9 them get nivolumab for this idea before they
10 solicited the Merck team; that the BMS team
11 declined to fund it; that once they heard that
12 there were responses being seen in the Hopkins
13 study, they decided to mount a study of their own.
14 And Dr. Lonberg expressed regret in his
15 testimony that the BMS team had declined to pursue
16 the study with the Hopkins team.
17 Q. Dr. Goldberg, didn't you see, in the
18 patent that you reviewed and that we're discussing
19 here today, the study records posted by BMS on
20 clinicaltrials.gov before July 10th, 2015,
21 referenced in those patents?
22 A. I did.

1 Q. So, as of July 10th, 2015, BMS was
2 already pursuing its own study to treat MSI-high
3 colorectal cancer patients with its PD-1
4 inhibitor; right?
5 DR. BROWN-MARSHALL: Object to the form
6 of the question.
7 A. So that's true.
8 And I would refer you to the answer that
9 I gave when you asked this question previously,
10 that I -- I garnered from reading Dr. Lonberg's
11 declaration about how that came to be.
12 But the fact is, yes, BMS started their
13 study between the time that Hopkins started their
14 study and the date that the patent was filed or
15 the patents were filed.
16 Q. And the person of ordinary skill in the
17 art would know that BMS was conducting its own
18 study to treat MSI-high colorectal cancer patients
19 with its PD-1 inhibitor before July 10th, 2015;
20 right?
21 DR. BROWN-MARSHALL: Object to the form
22 of the question.

1 A. BMS filed, as they were required to,
2 their study record with the federal government in
3 order to conduct their studies. It was a matter
4 of public record.
5 Q. And so the person of ordinary skill in
6 the art would know that BMS was conducting its own
7 study to treat MSI-high colorectal cancer patients
8 with its PD-1 inhibitor before July 10th, 2015;
9 right?
10 DR. BROWN-MARSHALL: Object to the form
11 of the question, asked and answered.
12 A. So I'll answer this for the fourth or
13 fifth time. Yes.
14 Q. Now, prior to the posting of the
15 MSI-high study record on clinicaltrials.gov,
16 nivolumab and pembrolizumab were showing efficacy
17 in melanoma and non-small cell lung cancer; right?
18 DR. BROWN-MARSHALL: Object to the form
19 of the question.
20 A. Are you referring to the BMS filing or
21 to the JHU filing? We were just talking about the
22 BMS trial.

1 Could you specify which study record you
2 are referring to, please.
3 Q. Sure.
4 So prior to the posting of the MSI-high
5 study record that you cite as Exhibit 1005 in your
6 declaration, nivolumab and pembrolizumab were
7 showing efficacy in melanoma and non-small cell
8 lung cancer; correct?
9 A. Yes.
10 Q. And that was more than two years before
11 the alleged invention date here; right?
12 DR. BROWN-MARSHALL: Object to the form
13 of the question.
14 A. I don't remember the dates, but it
15 preceded the filing of the study record.
16 Q. Part of the rationale as to why a
17 scientist or a physician in the field would
18 conduct a phase two study of pembrolizumab in
19 patients with microsatellite-unstable tumors is
20 the fact that, previously, nivolumab showed
21 activity in melanoma and non-small cell lung
22 cancer; right?

1 DR. BROWN-MARSHALL: Object to the form
2 of the question.
3 A. So nivolumab and pembrolizumab had shown
4 activity as PD-1 inhibitors in other tumor types.
5 And, in general, once activity like that is noted,
6 scientists will try and find other applications
7 for a drug that is successful in one disease, to
8 try and broaden its utility.
9 Q. Now, Merck, as the collaborator in the
10 MSI-high study, provided support for the MSI-high
11 study; right?
12 DR. BROWN-MARSHALL: Objection, outside
13 the scope of Dr. Goldberg's declaration.
14 A. So I would refer you to Dr. Le's
15 testimony because he was directly involved in
16 those discussions. I was only involved in them
17 secondhand, from what I was told and what I was
18 able to read.
19 Q. But Merck provided the pembrolizumab
20 used in the MSI-high study; right?
21 DR. BROWN-MARSHALL: Objection, outside
22 the scope of Dr. Goldberg's declaration.

1 A. So Merck had ownership of pembrolizumab,
2 and the only way to obtain it would have been to
3 have an agreement with Merck to provide a drug
4 that they owned and had sole ability to provide.
5 Q. And Merck did provide pembrolizumab used
6 in the MSI-high study; right?
7 A. I'll state it again, that Merck did
8 provide the pembrolizumab.
9 As I understand it, they did decline to
10 provide anything other than the drug for the
11 study, presumably because they thought it was not
12 likely to be productive.
13 Q. Throughout your involvement in the
14 MSI-high study, you were not involved in any
15 discussions with Merck regarding any financial
16 support of the MSI-high study; right?
17 A. That's correct.
18 Q. And you do not know from firsthand
19 knowledge if Merck ever made financial payments in
20 support of the MSI-high study; right?
21 A. Well, I read Dr. Le's declaration. And
22 in it, she stated that after initial results

1 looked promising, Merck decided to provide support
2 for it. But as is stated in my declaration, and I
3 don't remember what paragraph it is -- it's
4 par- -- paragraph 61, I'll read what I said there.
5 "I understand from conversations with the JHU
6 scientists that when they tried to interest the
7 research teams at both BMS and Merck in funding a
8 trial to test their hypothesis, neither company's
9 teams were interested. Despite this disappointing
10 news, the Hopkins team was determined to initiate
11 a clinical trial in CRC patients and patients with
12 other cancer types to test their hunch. They
13 devised a study..."
14 And I'll go on -- I'll skip a little bit
15 of that and say, "Because they were unable to
16 obtain pharmaceutical company funding, they funded
17 it with JHU resources and obtained additional
18 support through a grant from the charitable
19 organization Swim Across America. Merck's support
20 of the study was limited to providing the
21 pembrolizumab. While the Merck team approved the
22 study protocol, the study was designed, funded,

1 and executed by JHU researchers."
2 Q. Dr. Goldberg, do you recall my question?
3 A. Why don't you ask it again.
4 Q. You do not know from firsthand knowledge
5 if Merck ever made financial payments in support
6 of the MSI-high study; right?
7 DR. BROWN-MARSHALL: Objection, asked
8 and answered.
9 A. I -- I was not involved in any
10 discussions with Merck or with Merck and the
11 Hopkins team. My knowledge is as stated in my
12 declaration in paragraph 61, which I just read
13 into the record.
14 Q. So you do not know from firsthand
15 knowledge whether Merck ever made financial
16 payments in support of the MSI-high study; right?
17 DR. BROWN-MARSHALL: Objection, asked
18 and answered.
19 A. So I believe that's the fifth or sixth
20 time you've asked the same question. The answer
21 is "no."
22 Q. During your work on these matters that

1 we're discussing here today, have you ever seen a
2 document reflecting statements from Merck
3 declining to provide financial payments in support
4 of the MSI-high study?
5 DR. BROWN-MARSHALL: Object to the form
6 of the question.
7 A. I don't recall reading any documents by
8 Merck. I recall reading statements by Dr. Le and
9 Dr. Lonberg regarding that, but I don't have
10 firsthand knowledge of that through access to
11 anything written by Merck.
12 Q. So you have not seen a document
13 reflecting statements from Merck declining to
14 provide financial payments in support of the
15 MSI-high study; right?
16 A. Not that I --
17 DR. BROWN-MARSHALL: Objection.
18 Objection, asked and answered.
19 A. Not that I recall.
20 Q. You would agree that Merck's scientists
21 had experience with the safety profile of
22 pembrolizumab prior to the MSI-high study with

1 JHU; right?
2 DR. BROWN-MARSHALL: Objection, outside
3 the scope of Dr. Goldberg's declaration.
4 A. I would agree that Merck's scientists
5 knew about the toxicity of pembrolizumab through
6 their experience in treating patients with
7 melanoma and non-small cell lung cancer.
8 Q. And Merck already had an investigational
9 new drug application for pembrolizumab filed with
10 the FDA prior to the MSI-high study with JHU;
11 right?
12 DR. BROWN-MARSHALL: Objection, outside
13 the scope of Dr. Goldberg's declaration.
14 A. I don't have specific knowledge of that,
15 but I doubt that they could have pursued treatment
16 without an NDA.
17 THE STENOGRAPHER: Doctor, can you
18 please speak up. The last two answers have
19 been fading.
20 THE WITNESS: Okay. I took off my
21 headphones, but I'll put them back on if
22 that's better for you.

1 THE STENOGRAPHER: Thank you.
2 THE WITNESS: Okay.
3 Q. And, Dr. Goldberg, you cite Exhibit 2051
4 in your declaration; right?
5 A. Can you tell me where I cite it, please,
6 and what page or in what paragraph?
7 Q. Sure.
8 So if you refer to your '356 declaration
9 at paragraph 59, footnote 41, do you see that you
10 cite Exhibit 2051?
11 A. I do.
12 Q. And you reviewed that exhibit in the
13 preparation of your declarations that we're
14 discussing here today; right?
15 A. I did. Although, I haven't reviewed it
16 since the time of that declaration, so my memory
17 of it is non-fresh.
18 Q. And Exhibit 2051 states that Merck
19 reactivated IND development in mid-2010 for
20 pembrolizumab.
21 DR. BROWN-MARSHALL: Object to the form
22 of the question.

1 A. Show me where it states that so I can
2 confirm what you're asking.
3 MS. STAURING: Could the remote
4 technician please drop Exhibit 2051 in the
5 chat.
6 REMOTE TECHNICIAN: Please -- please
7 stand by.
8 Q. And please let me know when you have
9 that on your screen, Dr. Goldberg.
10 A. I will.
11 I keep getting an error message. Let me
12 see if I can...
13 I'm having trouble opening it. Acrobat
14 cannot.
15 THE WITNESS: Can the technician provide
16 me with any advice on that.
17 REMOTE TECHNICIAN: Yes, sir.
18 Do you know if it's an issue with
19 Acrobat itself?
20 THE WITNESS: It seems like it. So when
21 I -- I have Acrobat open. When I click on
22 it, I get a message saying, "An error has

1 been detected with a required application
2 library or file, and the product cannot
3 continue. Please reinstall the application."
4 So...
5 MS. STAURING: Dr. Goldberg, why don't
6 we do this. Can we please share page 7 of
7 Exhibit 2051 on the screen.
8 REMOTE TECHNICIAN: Please stand by.
9 A. Okay. That would be helpful.
10 DR. BROWN-MARSHALL: And, counsel, if
11 Dr. Goldberg wants to see more than just
12 page 7, you'll need to scroll so that he can
13 see the rest of the -- the rest of the -- the
14 exhibit.
15 A. Okay. I can see page 7. If you want to
16 point me to somewhere on that page.
17 Q. Right.
18 And do you see the sentence beginning --
19 or -- excuse me. Strike that.
20 Do you see in the third paragraph down,
21 it states, "Merck urgently reactivated IND
22 development in mid-2010"?

1 A. I see that.
2 Q. And so Merck already had an
3 investigational new drug application for
4 pembrolizumab filed with the FDA prior to the
5 MSI-high study with JHU; right?
6 DR. BROWN-MARSHALL: Objection,
7 mischaracterizes the document.
8 A. So it states that Merck reactivated the
9 IND. I don't know what was contained in the IND
10 from reading this.
11 Q. Dr. Goldberg, I'm not asking what was
12 contained in the IND.
13 My question is: Merck already had an
14 IND for pembrolizumab filed with the FDA prior to
15 the MSI-high study with JHU; right?
16 DR. BROWN-MARSHALL: Object to the form
17 of the question.
18 A. That's what it states in the page in
19 front of me.
20 MS. STAURING: You can take the document
21 down, please.
22 Q. So prior to the MSI-high study with JHU,

1 Merck had already begun working with the FDA on
2 regulatory filings regarding pembrolizumab; right?
3 DR. BROWN-MARSHALL: Object to the form
4 of the question.
5 A. I believe the fact that they filed an
6 IND suggests that Merck had begun working with the
7 FDA on testing pembrolizumab in cancer patients.
8 Q. And prior to the MSI-high study with
9 JHU, Merck was already conducting studies of
10 pembrolizumab in multiple tumor types; right?
11 DR. BROWN-MARSHALL: Object to the form
12 of the question.
13 A. So Merck had been testing pembrolizumab
14 in non-small cell cancer, melanoma, I believe in
15 non-Hodgkin's lymphoma, and bladder cancer. And
16 there may have been some other studies that they
17 were doing.
18 Q. And was all of that prior to the
19 MSI-high study with JHU?
20 A. Yes.
21 Q. Now, Dr. Goldberg, when Merck was
22 providing pembrolizumab for the MSI-high study,

1 how much do you think pembrolizumab was worth in
2 monetary value at that time?
3 DR. BROWN-MARSHALL: Objection, outside
4 the scope of Dr. Goldberg's declaration.
5 He's not an economics expert.
6 A. My expertise, I was asked to comment on
7 an unmet need, not on the economic impact of a --
8 of pembrolizumab.
9 Q. And I'm not asking for you to opine on
10 the economic impact of pembrolizumab. My
11 question's a little different.
12 So when Merck was providing
13 pembrolizumab for the MSI-high study that you
14 discuss in your declaration and that you
15 participated in, how much do you think
16 pembrolizumab was worth in monetary value at that
17 time?
18 DR. BROWN-MARSHALL: Objection, outside
19 the scope of Dr. Goldberg's declaration.
20 A. I have no idea.
21 Q. Do you know how much pembrolizumab --
22 strike that.

1 Do you know how much KEYTRUDA --
2 treatment with KEYTRUDA cost at the time that you
3 were treating patients with KEYTRUDA?
4 DR. BROWN-MARSHALL: Object to the form
5 of the question.
6 A. I do not. I am an academic oncologist,
7 and I have no knowledge of the cost of drugs, and
8 particularly none of pembrolizumab.
9 Q. Dr. Goldberg, what is an academic
10 oncologist?
11 A. An academic oncologist is someone, such
12 as myself, who's worked in teaching institutions
13 as described in my declaration, and who is paid a
14 salary that has no connection to the reimbursement
15 that the institution gets for the care that I
16 provide. Therefore, I am not focused on costs of
17 drugs, either to the institution or to the
18 patient.
19 Q. So as an oncologist who used to treat
20 patients with pembrolizumab, is it your testimony
21 that you have no knowledge of the cost of
22 pembrolizumab for those treatments?

1 DR. BROWN-MARSHALL: Objection, asked
2 and answered.
3 A. Well, it is my testimony that I do not
4 know how much pembrolizumab costs today or how
5 much it cost then.
6 Q. Do you have any idea how much it cost
7 when you were treating cancer patients?
8 A. When I was treating cancer patients on
9 the Hopkins trial, it was provided by Merck free
10 of charge.
11 I have no idea how much it costs. I
12 know it's expensive.
13 I also have read recently that it is --
14 that pembrolizumab is the most sold cancer drug,
15 and one that the -- that Medicare is negotiating
16 on price about. And -- and, therefore, you know,
17 it would be my contention that the Hopkins
18 invention was material to its success, justifying
19 this lawsuit.
20 Q. Prior to the MSI-high study with JHU,
21 Merck was already using a dose of 10 milligrams
22 per kilogram pembrolizumab every 14 days in the

1 treatment of cancer patients; right?
2 DR. BROWN-MARSHALL: Object to the form
3 of the question.
4 A. So there is quite a bit of variability
5 in the dosing of pembrolizumab used in different
6 studies.
7 In this study and in other studies, it
8 was 10 milligrams per kilogram every two weeks.
9 In other studies, it's 200 milligrams, not based
10 on patient's size or body weight, every
11 three weeks. In other studies, it's
12 400 milligrams every six weeks.
13 It isn't known what the optimal dose of
14 pembrolizumab is, but 10 milligrams per kilogram
15 is one effective dose that's been used in a number
16 of clinical trials.
17 Q. And so prior to the MSI-high study with
18 JHU, Merck was already using a dose of
19 10 milligrams per kilogram pembrolizumab every
20 14 days in the treatment of cancer patients;
21 right?
22 A. Correct.

1 DR. BROWN-MARSHALL: Objection, asked
2 and answered.
3 A. Correct.
4 Q. And the dose of pembrolizumab used in
5 the MSI-high study was 10 milligrams per kilogram
6 pembrolizumab every 14 days; right?
7 A. That's correct.
8 Q. Based on your review of the eight
9 patents that we're discussing today, the only dose
10 disclosed in those patents is 10 milligrams per
11 kilogram pembrolizumab every 14 days; right?
12 DR. BROWN-MARSHALL: Object to the form
13 of the question.
14 A. No. The answer to that is no.
15 Q. Are there other doses described in the
16 eight patents that we're discussing here today
17 other than 10 milligrams per kilogram
18 pembrolizumab every 14 days?
19 A. Yes.
20 Q. Let's take a look at the '356 patent.
21 A. Okay.
22 Q. Do you have that before you?

1 A. So you want the '356 patent, not my
2 declaration; correct?
3 Q. That's correct. The '356 patent.
4 A. Okay. I have it.
5 Q. Can you please show me where another
6 dosing regimen is described in the '356 patent
7 other than 10 milligrams per kilogram
8 pembrolizumab every 14 days?
9 A. So I'm reading the claim declarations.
10 It will take me a minute.
11 So what I see here, under claim 23, is,
12 "A method for treating cancer in a population of
13 cancer patients in need thereof, comprising:
14 Administering an effective amount of pembrolizumab
15 to patients in the population of cancer
16 patients..."
17 So as best I can tell, with a quick
18 reading of very small print, this patent does not
19 claim a specific dose. It claims an effective
20 amount.
21 Q. Okay. My -- my question was a little
22 bit different.

1 So my question was: Does the '356
2 patent describe a dosing regimen other than
3 10 milligrams per kilogram pembrolizumab every
4 14 days?
5 DR. BROWN-MARSHALL: Objection, asked
6 and answered.
7 A. According to my quick review, it does
8 not specify any dose other than an effective dose.
9 Q. So in your view, there are no doses
10 described in the '356 patent?
11 DR. BROWN-MARSHALL: Objection,
12 mischaracterizes previous testimony.
13 A. Would you like me to read the 31 pages
14 of the patent to be sure of that? Because I'm not
15 sure I can answer that without doing that. I'm
16 ready to do that, if you'd like me to.
17 Q. That's fine.
18 A. Okay. It will probably take me about
19 half an hour. I'm going to read every word
20 because you've asked me if it says anything in
21 these 31 pages, so.
22 I'm going to turn off my camera while

1 I'm reading.
2 Q. Doctor --
3 DR. BROWN-MARSHALL: Dr. Goldberg, you
4 cannot turn your camera off.
5 THE WITNESS: Okay. I'll leave it on.
6 I'm going to start reading.
7 Q. For efficiency, Doctor, maybe you can
8 read over the patent during the lunch break.
9 DR. BROWN-MARSHALL: Counsel, you asked
10 him a question about what's in the patent.
11 You need to give Dr. Goldberg the time to
12 answer your question accurately.
13 MS. STAURING: Counsel, please let me
14 finish my question.
15 DR. BROWN-MARSHALL: That wasn't a
16 question.
17 Q. Sir, you can -- Dr. Goldberg, or, you
18 can let me know if -- sitting here today, if you
19 know whether there is any specific dosing regimen
20 described in the '356 patent other than
21 10 milligrams per kilogram every 14 days?
22 DR. BROWN-MARSHALL: Object to the form

1 of the question.
2 Dr. Goldberg has asked for time to
3 review the reference.
4 A. So I can't answer your question until
5 I've reviewed the patent, which I'm doing now.
6 I'm trying to skim through the parts that are
7 irrelevant.
8 I'm on page 21 where I see that it
9 specifies in the study design that the study agent
10 was administered a 10 milligrams per kilogram
11 intravenously every 14 days.
12 Having said that, I didn't see that in
13 the patent claim.
14 I'm going to continue reading.
15 So on a quick reading of this, I see
16 that the study design describes on page 21 of the
17 patent that "The study agent, pembrolizumab
18 (Merck), was administered at 10 milligrams per
19 kilogram intravenously every 14 days."
20 When I read over the patent claims, I
21 don't see that a specific dose is specified.
22 Instead, on claim 23, it states, "administering an

1 effective amount of pembrolizumab to patients in
2 the population of cancer patients..."
3 So my understanding is that the patent
4 claims do not specifically claim a dose or a
5 patent -- a dose or a schedule in this particular
6 patent. Although, in others of the patents, there
7 are specific doses and schedules enumerated.
8 Q. So outside of the patent's claims in the
9 '356 patent, is there a dose described other than
10 10 milligrams per kilogram every 14 days?
11 DR. BROWN-MARSHALL: Objection, asked
12 and answered.
13 A. Not that I could see in a quick reading
14 of the patent. The only dose and schedule that I
15 saw was 10 milligrams per kilogram every
16 two weeks.
17 Q. And when you treated MSI-high cancer
18 patients with KEYTRUDA, outside the context of a
19 clinical trial, you did not use a dose of
20 10 milligrams per kilogram every 14 days; right?
21 DR. BROWN-MARSHALL: Object to the form
22 of the question.

1 A. I don't remember the specific dosing,
2 but it's less expensive than it appeared to be
3 effective to use 200 milligrams per kilogram. And
4 so that's likely what I would have -- or, I'm
5 sorry, 200 milligrams flat dosing, not based on
6 body weight. I believe that's what I used, but I
7 don't have a specific memory of it.
8 Q. Do you know how many MSI-high colorectal
9 cancer patients are being treated with
10 pembrolizumab today out of all of the different
11 types of cancer patients that receive
12 pembrolizumab?
13 DR. BROWN-MARSHALL: Object to the form
14 of the question.
15 A. I'm not sure how I could possibly know
16 that. I don't know that.
17 Q. Do you know how many indications
18 pembrolizumab is approved for by the FDA?
19 A. No.
20 Q. Do you know if it's more than 25
21 approved indications?
22 A. No.

1 Q. Do you have any idea how many
2 indications pembrolizumab is approved for by the
3 FDA?
4 A. You've asked that -- you've asked that
5 three times. And the answer is no.
6 If you ask it a fourth and a fifth time,
7 the answer will be no.
8 Q. Do you know how many MSI-high patients
9 are treated with pembrolizumab compared to other
10 patients -- strike that.
11 Do you know how many MSI-high patients
12 are treated with pembrolizumab compared to other
13 MSI-high patients treated with different
14 therapies?
15 A. I have no idea.
16 DR. BROWN-MARSHALL: Object. Object to
17 the form of the question. Also, outside the
18 scope of Dr. Goldberg's declaration.
19 A. I have no idea.
20 Q. Doctor, prior to the alleged invention
21 date, it was known that cancers other than
22 colorectal cancer were associated with

1 microsatellite instability; right?
2 DR. BROWN-MARSHALL: Object to the form
3 of the question.
4 A. Yes.
5 Q. Prior to the alleged invention date,
6 there were publications that taught that MSI-high
7 is observed in colorectal, gastric, and
8 endometrial cancers; right?
9 DR. BROWN-MARSHALL: Object to the form
10 of the question.
11 A. Yes.
12 Q. Prior to the alleged invention date, it
13 was known by the person of ordinary skill in the
14 art that endometrial cancer was associated with
15 MSI-high; right?
16 DR. BROWN-MARSHALL: Object to the form
17 of the question.
18 A. Yes.
19 Q. And the NCCN guidelines have recommended
20 testing MSI status in all endometrial cancer
21 patients since 2013; right?
22 DR. BROWN-MARSHALL: Object to the form

1 of the question.
2 A. I would have to review all of the NCCN
3 guidelines in order to answer that question.
4 Q. Well, you cite the NCCN guidelines in
5 your declarations; right?
6 DR. BROWN-MARSHALL: Object to the form
7 of the question.
8 A. Can we look at that exhibit, please? I
9 believe I cited one NCCN guideline in my
10 declarations.
11 Q. Sitting here today, do you know whether
12 the NCCN guidelines recommended MSI testing in all
13 endometrial cancer patients in 2013?
14 DR. BROWN-MARSHALL: Object to the form
15 of the question.
16 A. I'd like to review that exhibit before
17 answering that question.
18 Q. If you refer to your '356 declaration at
19 paragraph 77. Please let me know when you have
20 that, sir.
21 A. Okay. I have that.
22 Q. And do you see footnote 67 where you

1 cite the NCCN guidelines, Exhibit 1089?
2 A. I see that.
3 Q. And those guidelines are dated 2000 --
4 the year 2013; right?
5 A. Correct.
6 Q. And if you refer to this statement that
7 you write in paragraph 77, you write that MSI
8 testing is in the guidelines for patients with
9 endometrial cancer and cite Exhibit 1089; is that
10 correct?
11 DR. BROWN-MARSHALL: Objection,
12 mischaracterizes the document.
13 A. So the document states and references
14 our Exhibit 1089, that it mentions the use of MSI
15 testing for endometrial cancer. The
16 recommendations focus on making a diagnosis of
17 Lynch syndrome targeted in identifying individuals
18 and families with an inherited cancer
19 susceptibility syndrome. It was not used for
20 treatment determinations at that time or
21 recommended for that.
22 Q. Okay. My question is: The NCCN

1 guidelines have recommended testing MSI status in
2 all endometrial cancer patients since 2013; right?
3 DR. BROWN-MARSHALL: Object to the form
4 of the question.
5 A. Before I answer that, I'd like to review
6 Exhibit 1089, please.
7 Q. You can do that.
8 MS. STAURING: Can we please bring up
9 Exhibit 1089 at page 17.
10 DR. BROWN-MARSHALL: Counsel, can we
11 please drop it in the chat because
12 Dr. Goldberg's going to have to be able to
13 review the document, not just the one page
14 that you put up.
15 THE WITNESS: I hope I can open it.
16 REMOTE TECHNICIAN: Please stand by.
17 Q. Dr. Goldberg, we can try dropping it in
18 the chat, and if you're unable to download it,
19 then we'll have it shared on the screen.
20 A. That would be fine.
21 DR. BROWN-MARSHALL: So, Dr. Goldberg,
22 you should be able to click on it on the

1 chat, and then it will open up a box to save
2 it. You can just save it to your desktop and
3 then open the PDF from there.
4 THE WITNESS: I keep getting that same
5 error message.
6 REMOTE TECHNICIAN: If I may. There is
7 another way that we might be able to do this.
8 THE WITNESS: Okay.
9 REMOTE TECHNICIAN: Let me pull my notes
10 back up.
11 I'm going to post a link in the chat.
12 THE WITNESS: Great.
13 REMOTE TECHNICIAN: If you click on that
14 link, it should open a folder and a browser.
15 THE WITNESS: I clicked on it. And,
16 okay, I -- there are many folders. Which one
17 am I opening again?
18 REMOTE TECHNICIAN: Do you see
19 Exhibit 1089 part one?
20 THE WITNESS: I do.
21 REMOTE TECHNICIAN: Don't download it.
22 If you just click on the title, it should pop

1 up.
2 THE WITNESS: That worked. Thank you.
3 REMOTE TECHNICIAN: Very good. Thank
4 you.
5 A. So you wanted page 17?
6 Q. Yes, sir.
7 DR. BROWN-MARSHALL: And, Counsel, I'll
8 note that this is only part of Exhibit 1089.
9 REMOTE TECHNICIAN: Part -- part two is
10 also in the folder, ma'am.
11 DR. BROWN-MARSHALL: Okay. Thank you.
12 A. Okay. I have page 17 in front of me.
13 Q. Okay. And I'll ask my question again.
14 The NCCN guidelines have recommended
15 testing MSI status in all endometrial cancer
16 patients since 2013; correct?
17 DR. BROWN-MARSHALL: Object to the form
18 of the question.
19 A. No. It says, "Consider genetic
20 counseling/testing..."
21 Q. Are you finished with your answer,
22 Dr. Goldberg?

1 A. Well, let me read you what it says. It
2 says, "Consider genetic counseling/testing for
3 patients less than 50 years old" -- the vast
4 majority of patients with endometrial cancer are
5 over the age of 50 -- "and those with a
6 significant family history of endometrial and/or
7 colorectal cancer and/or selected pathological
8 risk features."
9 So clearly they're not recommending.
10 They're saying "consider." And they're clearly
11 not recommending it for all patients. They're
12 recommending that a physician consider it for
13 selected patients.
14 Q. Dr. Goldberg, what page are you reading
15 from?
16 A. I am reading from page 17 of 81, NCCN
17 guidelines version 1.2014, endometrial cancer.
18 It's in the -- under Surveillance in the left-hand
19 side of the -- the page.
20 Q. So, Dr. Goldberg, do you disagree that
21 the NCCN guidelines have recommended MSI status
22 testing in endometrial cancer patients since 2013?

1 DR. BROWN-MARSHALL: Objection, asked
2 and answered.
3 A. Would you like me to read it again? It
4 says, "Consider genetic counseling testing for
5 patients under 50, and those with a significant
6 family history of endometrial and/or colorectal
7 cancer and/or selected pathological risk
8 features."
9 That's a subset of patients with
10 endometrial cancer, not all patients.
11 Now, it does refer to item Q below,
12 where it says that some centers are doing it in
13 all patients. But this certainly doesn't
14 recommend that, it footnotes it.
15 Q. And I'm not asking you to read the
16 document, Dr. Goldberg. My question is a little
17 different. Let me try asking it a different way.
18 Would you agree that the NCCN guidelines
19 have recommended MSI testing in endometrial cancer
20 patients since 2013?
21 DR. BROWN-MARSHALL: Objection, asked
22 and answered.

1 A. I would agree that it has recommended it
2 in a subset of endometrial cancer patients for
3 genetic counseling purposes.
4 Q. You can minimize that document on your
5 screen, Dr. Goldberg.
6 A. Okay.
7 Q. Prior to the alleged invention date, it
8 was known by the person of ordinary skill in the
9 art that gastric cancer was associated with
10 MSI-high; right?
11 DR. BROWN-MARSHALL: Object to the form
12 of the question.
13 A. It is known that some patients with
14 gastric cancer have MSI-high tumors, correct.
15 Q. And prior to the alleged invention date,
16 it was known by the person of ordinary skill in
17 the art that gastric cancer was associated with
18 MSI-high; right?
19 DR. BROWN-MARSHALL: Objection, asked
20 and answered.
21 A. A subset of gastric cancer patients have
22 MSI-high tumors, yes.

1 Q. I'm not sure that that answers my
2 question.
3 My question is: Prior to the alleged
4 invention date, it was known by the person of
5 ordinary skill in the art that gastric cancer was
6 associated with MSI-high; correct?
7 DR. BROWN-MARSHALL: Objection, asked
8 and answered.
9 A. So the answer is no. Most gastric
10 cancers are not MSI-high, just like most colon
11 cancers are not MSI-high.
12 Q. So prior to the alleged invention date,
13 it was known by the person of ordinary skill in
14 the art that some gastric cancers were associated
15 with MSI-high; is that correct?
16 A. That -- that is correct.
17 Q. Prior to the alleged invention date,
18 there were publications that taught that MSI-high
19 is observed in tumors other than colorectal,
20 gastric, and endometrial cancers at lower
21 frequencies as well; right?
22 DR. BROWN-MARSHALL: Object to the form

1 of the question.
2 A. It was known that other tumor types had
3 MSI-high cancers in a subset of patients. I don't
4 know the specific data about frequency.
5 Q. And that was known prior to the alleged
6 invention date; right?
7 DR. BROWN-MARSHALL: Object to the form
8 of the question.
9 A. Correct.
10 Q. Prior to the alleged invention date, the
11 person of ordinary skill would know that MSI-high
12 is associated with some small bowel cancers;
13 right?
14 DR. BROWN-MARSHALL: Object to the form
15 of the question.
16 A. The answer would be yes, that small
17 bowel cancer -- a subset of small bowel cancers
18 are MSI-high.
19 Q. And prior to the alleged invention date,
20 the person of ordinary skill would know that
21 MSI-high is associated with some stomach cancers;
22 right?

1 DR. BROWN-MARSHALL: Object to the form
2 of the question.
3 A. So gastric cancers and stomach cancers
4 are the same tumors. They're synonyms for each
5 other. And we've already established that some
6 gastric or stomach tumors are MSI-high.
7 Q. And that would have been known prior to
8 the alleged invention date; right?
9 A. Correct.
10 DR. BROWN-MARSHALL: Object to the form
11 of the question.
12 A. Correct.
13 Q. Prior to the alleged invention date, the
14 person of ordinary skill would know that MSI-high
15 is associated with some urinary tract cancers;
16 right?
17 DR. BROWN-MARSHALL: Object to the form
18 of the question.
19 A. It's correct that a subset of urinary
20 tract cancers are MSI-high.
21 Q. And prior to the alleged invention date,
22 the person of ordinary skill in the art would know

1 that MSI-high is associated with some ovarian
2 cancers; right?
3 DR. BROWN-MARSHALL: Object to the form
4 of the question.
5 A. A person of -- a POSA would have known
6 that a subset of patients with ovarian cancers
7 have tumors that are MSI-high.
8 Q. Now, in your view, a long-felt need
9 existed for an FDA-approved treatment of MSI-high
10 cancers; right?
11 A. Correct.
12 Q. Prior to the alleged invention date, it
13 was known that Merck and JHU were collaborating on
14 the phase two study to treat patients with
15 microsatellite-unstable tumors with pembrolizumab;
16 right?
17 DR. BROWN-MARSHALL: Object to the form
18 of the question.
19 A. Can you read the question again, please?
20 I -- I missed part of the beginning.
21 Q. Sure.
22 Prior to the alleged invention date, it

1 was known that Merck and JHU were collaborating on
2 a phase two study to treat patients with
3 microsatellite-unstable tumors with pembrolizumab;
4 right?
5 DR. BROWN-MARSHALL: Same objection.
6 A. Yes. Yes. That data was presented in
7 ASCO.
8 Q. And it was known by the publication of
9 the MSI-high study record on clinicaltrials.gov in
10 June 2013; right?
11 DR. BROWN-MARSHALL: Object to the form
12 of the question.
13 A. Can you be more specific about what "it"
14 is referring to? You said "it" was known. What
15 was known?
16 Q. Prior to the alleged invention date, it
17 was known, based on the publication of the
18 MSI-high records at clinicaltrials.gov in June of
19 2013, that Merck and JHU were collaborating on a
20 phase two study to treat microsatellite-unstable
21 tumors with pembrolizumab; right?
22 DR. BROWN-MARSHALL: Object. Object to

1 the form of the question.
2 A. So I would need to read the study
3 records to see whether it states that Merck was
4 collaborating with JHU in order to answer your
5 question.
6 Q. And, Doctor, you reviewed the MSI-high
7 study record in preparation of your declaration
8 that we're discussing here today; right?
9 A. I did, but I did not review it recently
10 to look at the specific point about whether it
11 states "collaboration" or not.
12 Q. We can take a look at the MSI-high study
13 record, which is Exhibit 1005.
14 MS. STAURING: If we can have that
15 placed in the chat, please.
16 THE WITNESS: Could you do it as a link
17 again? My -- last time, that seemed to be
18 the most effective way.
19 REMOTE TECHNICIAN: I will upload that
20 folder. It may take a moment, and you'll
21 just need to refresh the page.
22 THE WITNESS: So I have the Adobe

1 Acrobat file, but I suspect that won't work
2 again.
3 Did you -- did you use it as a link like
4 you did last time, Kelli?
5 REMOTE TECHNICIAN: Yes, sir. It should
6 be the same link that's in the chat. It
7 should open in a browser window.
8 THE WITNESS: Yeah. Okay. That's
9 right.
10 REMOTE TECHNICIAN: If you just refresh
11 that page, it should be there.
12 THE WITNESS: Yep. Got it. That's
13 true. It had all the files, didn't it?
14 A. Okay. So which exhibit is this again?
15 Q. It's Exhibit 1005, Doctor.
16 A. Okay. I see it.
17 THE WITNESS: It says the list is empty,
18 whatever that means.
19 REMOTE TECHNICIAN: Sorry, sir. That's
20 what the pa- -- the web page says?
21 THE WITNESS: Yes. So there's a --
22 REMOTE TECHNICIAN: If you refresh the

1 page, does it still say that?
2 THE WITNESS: Let me try.
3 Okay. Now it came up. I got it.
4 REMOTE TECHNICIAN: Very good.
5 A. Okay. So --
6 Q. Do you have Exhibit 1005 downloaded
7 before you?
8 A. I do. I'm trying to see if...
9 Okay. So, yes, I do have it downloaded
10 in front of me now.
11 Q. Now, if you scroll to page 3 of
12 Exhibit 1005, you see Merck listed as a
13 collaborator; correct?
14 A. Okay. So, yes, I see Merck listed as a
15 collaborator.
16 Q. So prior to the alleged invention date,
17 it was known that Merck and JHU were collaborating
18 on a phase two study to treat patients with
19 microsatellite-unstable tumors with pembrolizumab;
20 right?
21 DR. BROWN-MARSHALL: Object to the form
22 of the question.

1 A. Yes.
2 Q. You can minimize Exhibit 1005,
3 Dr. Goldberg.
4 DR. BROWN-MARSHALL: Counsel, we've been
5 going for about an hour and 15 minutes. Is
6 now a good place to take a break?
7 MS. STAURING: Doctor, would you like to
8 take a break?
9 THE WITNESS: I think we could go -- how
10 about if we shoot toward noon and then take a
11 lunch break. Is that all right?
12 If anyone else needs a break, I'm okay
13 with a bio break for other people, if that's
14 necessary.
15 MS. STAURING: That works well here,
16 Dr. Goldberg.
17 THE WITNESS: So would you like a bio
18 break for other people? Is that what we're
19 saying?
20 MS. STAURING: No. We can go to --
21 THE WITNESS: We can go to --
22 MS. STAURING: We can continue until

1 noon, and then we can take a lunch break.
2 THE WITNESS: All right. That's fine.
3 Q. Prior to the alleged invention date, BMS
4 published a study record on clinicaltrials.gov
5 describing a study to treat MSI-high colorectal
6 cancer patients with its PD-1 inhibitor; right?
7 DR. BROWN-MARSHALL: Object to the form
8 of the question, asked and answered.
9 A. So, yes, we discussed that. And that's
10 true.
11 Q. Do any of the claims of the eight
12 patents that you reviewed as part of your work in
13 the matters that we're discussing today have a
14 requirement that the treatment claimed be FDA
15 approved?
16 A. Not to my knowledge.
17 There are a lot of claims, and I -- and
18 I don't have specific memory of all of them, but I
19 don't remember seeing anything about FDA approval
20 in the claims.
21 DR. BROWN-MARSHALL: Dr. Goldberg, if
22 you need to refer to the claims themselves,

1 you can.
2 Q. Dr. Goldberg, in your view, outside the
3 context of a clinical trial, does an oncologist
4 use the KEYTRUDA labeling to treat populations of
5 cancer patients?
6 DR. BROWN-MARSHALL: Object to the --
7 wait. Let me get my objection on the record,
8 Dr. Goldberg.
9 THE WITNESS: Sorry.
10 DR. BROWN-MARSHALL: Object to the form
11 of the question.
12 A. Oncologists treat individual patients.
13 They don't treat populations of patients.
14 Q. In your view, an oncologist following
15 the MSI-high-related indications on the KEYTRUDA
16 labeling would necessary -- necessarily practice
17 the claims of the -- the patents that we're
18 discussing here today; right?
19 A. Well, as we said before, any oncologist
20 is licensed to prescribe any FDA-approved drug
21 treatment, whether within or outside of
22 indications.

1 Q. Dr. Goldberg, the KEYTRUDA labeling that
2 you rely upon and cite in your declarations does
3 not instruct an oncologist to administer
4 pembrolizumab to a colorectal cancer patient that
5 is not MSI-high; right?
6 DR. BROWN-MARSHALL: Object to the form
7 of the question.
8 A. It does not instruct a patient -- an
9 oncologist to give it to a patient who is not
10 MSI-high. So what the patent instructs is to give
11 it to patients with colorectal cancer who are
12 MSI-high. There are no claims that I am aware
13 of -- that I can recall for treating non-MSI-high
14 patients in the patents.
15 Q. And my question, Doctor, is about the
16 KEYTRUDA labeling. So let me try to ask that in a
17 different way.
18 Does the KEYTRUDA labeling that you rely
19 upon and cite in your declarations instruct an
20 oncologist to administer pembrolizumab to a
21 colorectal cancer patient that is not MSI-high?
22 DR. BROWN-MARSHALL: Object to the form

1 of the question.
2 A. So there are many revisions of the
3 KEYTRUDA labeling. I would need to look at the
4 one that you're specifically referring to in order
5 to answer your question.
6 Q. Does the KEYTRUDA labeling that you rely
7 upon and cite in your declarations instruct an
8 oncologist to compare the outcome of an MSI-high
9 colorectal cancer patient treated with
10 pembrolizumab with the outcome of a colorectal
11 cancer patient that is not MSI-high treated with
12 pembrolizumab?
13 DR. BROWN-MARSHALL: Object to the form
14 of the question.
15 A. Can we pull up the KEYTRUDA labeling
16 that is referenced in my declaration, please? I
17 don't know what page that exhibit is noted on. Do
18 you know?
19 Q. I'm just asking: Sitting here today,
20 based on your review of the KEYTRUDA labeling for
21 your work in this matter, does the labeling
22 instruct an oncologist to compare the outcome of

1 an MSI-high colorectal cancer patient treated with
2 pembrolizumab with the outcome of a colorectal
3 cancer patient treated with pembrolizumab that is
4 not MSI-high?
5 DR. BROWN-MARSHALL: Objection, asked
6 and answered.
7 Dr. Goldberg asked to see the labeling.
8 A. I believe it's my right to see the
9 labeling, if it's a -- an exhibit that's cited in
10 my declaration. I would like to see the labeling.
11 Q. We can take a look at the labeling that
12 you cite in your declaration.
13 A. Thank you.
14 Q. Let's take a look at Exhibit 2129.
15 REMOTE TECHNICIAN: That's uploading to
16 that folder now. It may take a moment. And
17 you may need to refresh the page.
18 THE WITNESS: All right.
19 MS. STAURING: Thank you.
20 REMOTE TECHNICIAN: I'm -- I am also
21 providing it in the chat for convenience.
22 THE WITNESS: I keep refreshing, and it

1 wasn't there yet.
2 REMOTE TECHNICIAN: It is a larger file.
3 It is taking a moment, but it should be there
4 now.
5 THE WITNESS: Okay. Got it.
6 Q. Do you have Exhibit 2129 before you,
7 Dr. Goldberg?
8 A. Just -- the list is empty. I don't
9 know -- okay. I have Exhibit 2129 in front of me.
10 And I'm looking for...
11 So there is a portion of it that says
12 "Microsatellite Instability-High or Mismatch
13 Repair Deficient Colorectal cancer."
14 And it does not state anything about
15 treatment of MSS colorectal cancer.
16 Q. And so does the KEYTRUDA labeling
17 instruct an oncologist to compare the outcome of
18 an MSI-high colorectal cancer patient treated with
19 pembrolizumab with the outcome of a colorectal
20 cancer patient that is not MSI-high treated with
21 pembrolizumab?
22 DR. BROWN-MARSHALL: Object to the form

1 of the question.
2 A. So I don't see any statement in the
3 label asking an oncologist to compare one patient
4 to another. I'm only looking at page 1. I don't
5 know how many pages there are in this exhibit.
6 DR. BROWN-MARSHALL: And, Dr. Goldberg,
7 feel free to look through the exhibit, if you
8 need to, to answer the questions.
9 A. There are 93 pages. Can you point me to
10 any specific page in the 93 pages?
11 Q. I don't think it's there, Dr. Goldberg.
12 That's why I'm asking your view, based on your
13 review of the KEYTRUDA labeling in preparation of
14 your declarations that we're discussing here
15 today.
16 A. Okay. Then I would like to review the
17 document before I answer. I can skim through most
18 of it, and I'll look only for the parts that are
19 relevant to colorectal cancer.
20 Q. Okay. That's fine, Doctor.
21 A. Okay. Would you ask me your question
22 again, please?

1 Q. Sure.
2 The KEYTRUDA labeling that you rely upon
3 and cite in your declaration does not instruct an
4 oncologist to compare the outcome of an MSI-high
5 colorectal cancer patient treated with
6 pembrolizumab with the outcome of a colorectal
7 cancer patient that is not MSI-high treated with
8 pembrolizumab; correct?
9 DR. BROWN-MARSHALL: Object to the form
10 of the question.
11 A. Upon my quick skimming of this 91-page
12 [sic] document, I agree that the document does not
13 instruct that.
14 Q. You can put that exhibit aside, Doctor.
15 Let's take a look at Exhibit 2300 that
16 you cite in your declaration.
17 MS. STAURING: If we could have that
18 provided as a link and dropped in the chat.
19 REMOTE TECHNICIAN: Uploading now.
20 THE WITNESS: I keep refreshing. I'll
21 let you know when I've got it.
22 REMOTE TECHNICIAN: It may take just a

1 moment.
2 It should be available now.
3 THE WITNESS: Yeah. I'm just loading it
4 now.
5 A. Okay. I have Exhibit 2300 in front of
6 me. It highlights prescribing information.
7 Q. The KEYTRUDA labeling that you cite in
8 your declarations as Exhibit 2300 indicates that
9 pembrolizumab is approved to treat endometrial
10 cancer that is not MSI-high; right?
11 DR. BROWN-MARSHALL: Object to the form
12 of the question.
13 A. I'm reading it now.
14 So on page 1, it states that, "In
15 combination with lenvatinib for the treatment of
16 patients with advanced endometrial cancer that is
17 not MSI-high..."
18 So the answer to your question is yes.
19 Q. And you'd agree with me that the
20 KEYTRUDA labeling that you cite in Exhibit 2300
21 does not tell an oncologist that the outcome of an
22 MSI-high endometrial cancer patient treated with

1 pembrolizumab would be improved, as compared to an
2 endometrial cancer patient that is not MSI-high
3 treated with pembrolizumab; right?
4 DR. BROWN-MARSHALL: Object to the form
5 of the question.
6 A. I don't see anywhere in this document
7 where it advises comparison of subsets of
8 patients. So the answer to your question is: It
9 does not show that.
10 Q. And the KEYTRUDA labeling that you cite
11 in your declarations as Exhibit 2129 and 2300 does
12 not instruct an oncologist to administer
13 pembrolizumab to a population of cancer patients;
14 right?
15 DR. BROWN-MARSHALL: Object to the form
16 of the question.
17 A. So can we look at each one separately?
18 You're asking -- what -- what is the first one of
19 the exhibits you'd like me to review?
20 Q. I'm just asking: Sitting here today,
21 based on your review of the KEYTRUDA labeling that
22 you cite in your declarations, that labeling does

1 not instruct an oncologist to administer
2 pembrolizumab to a population of cancer patients;
3 right?
4 DR. BROWN-MARSHALL: Object to the form
5 of the question.
6 A. So oncologists treat one patient at a
7 time. And I don't believe that this label
8 instructs treatments of populations of patients.
9 MS. STAURING: Dr. Goldberg, why don't
10 we take our lunch break a few minutes early.
11 THE WITNESS: Okay. What time will we
12 reconvene?
13 MS. STAURING: We'll go off the record,
14 if that's okay with you, Doctor.
15 THE WITNESS: That's fine.
16 THE STENOGRAPHER: We're off the record.
17 (Recess in proceedings.)
18 THE STENOGRAPHER: We're back on the
19 record.
20 BY MS. STAURING:
21 Q. Dr. Goldberg, during the breaks today,
22 did you speak with anyone regarding the testimony

1 that you're providing during this deposition?
2 A. Oh, I did have a brief call with
3 Christina Brown-Marshall, during which we did not
4 discuss the substance of my discussion.
5 Q. Doctor, as a person of ordinary skill in
6 the field, when you see reference to MSI-high
7 non-colorectal cancer, what kind of cancers come
8 to mind for you?
9 DR. BROWN-MARSHALL: Object to the form
10 of the question.
11 A. So MSI-high can occur in any kind of
12 solid tumor. So I could start at the top, you
13 know, brain, head and neck, lung, esophagus,
14 gastric, pancreatic, small intestine, colon, anal,
15 breast, melanoma, Merkel cell cancer. I must have
16 forgotten something.
17 Q. As a person of skill in the field, when
18 you see reference to non-MSI-high colorectal
19 cancer, does endometrial cancer come to mind?
20 DR. BROWN-MARSHALL: Object to the form
21 of the question.
22 A. A percentage of endometrial cancers are

1 MSI-high, yes.
2 Q. And so does endometrial cancer come to
3 mind when you see reference to MSI-high
4 non-colorectal cancers?
5 DR. BROWN-MARSHALL: Object to the form
6 of the question.
7 A. Yes.
8 Q. As a person -- a person of skill in the
9 field, when you see reference to MSI-high
10 non-colorectal cancers, does gastric cancer come
11 to mind?
12 DR. BROWN-MARSHALL: Object to the form
13 of the question.
14 A. I believe it was listed among the items
15 that I stated when you asked me what comes to
16 mind. So the answer is yes.
17 Q. As a person of skill in the field, when
18 you see reference to MSI-high non-colorectal
19 cancers, does small bowel cancer come to mind?
20 DR. BROWN-MARSHALL: Object to the form
21 of the question.
22 A. Yes.

1 MS. STAURING: Dr. Goldberg, I don't
2 have any further questions for you today.
3 Your counsel may have some questions and
4 after that I may have some additional
5 questions, but I do not have any further
6 questions for you at this time.
7 DR. BROWN-MARSHALL: Okay. Counsel, can
8 we take a break --
9 MS. STAURING: Yes.
10 DR. BROWN-MARSHALL: -- so that I can
11 figure out if we need to ask additional
12 questions?
13 MS. STAURING: Sure. We can go off the
14 record.
15 DR. BROWN-MARSHALL: Okay. Thank you.
16 THE STENOGRAPHER: We're off the record.
17 (Recess in proceedings.)
18 THE STENOGRAPHER: We're back on the
19 record.
20 EXAMINATION
21 BY DR. BROWN-MARSHALL:
22 Q. Dr. Goldberg, I have a few questions for

1 you.
2 Do you remember testifying previously
3 that you had no specific evidence of how
4 oncologists practice?
5 A. Yes.
6 I may have actually answered that in a
7 confusing way.
8 You know, I certainly have evidence of
9 how oncologists practice because I was lecturing
10 them, I was talking to them all the time. I can't
11 say that I could -- I didn't have evidence about
12 how every oncologist practiced. So I'd like to
13 clarify that.
14 Q. Okay. And you were a -- previously a
15 treating oncologist; is that correct?
16 A. That's correct.
17 Q. Okay. How long were you a treating
18 oncologist?
19 A. I started treating cancer patients in
20 1982.
21 Q. Okay. And you stopped in?
22 A. As we showed today, at the end of -- I

1 stopped in 2017. 2016 I stopped treating patients
2 with anticancer drugs but continued to see
3 patients and to supervise physicians and discuss
4 their patients with them.
5 Q. Okay. And you previously testified that
6 you worked as an academic oncologist; is that
7 correct?
8 A. That's correct.
9 Q. Okay. And as part of being an academic
10 oncologist, you supervised the training of other
11 oncologists; correct?
12 A. That's --
13 MS. STAURING: Objection, outside the
14 scope.
15 Q. You can answer, Dr. Goldberg.
16 A. Yeah.
17 So it was my job to mentor young
18 physicians as well as fellows and trainees. So I
19 would supervise them and often discuss patients
20 with them and -- and develop treatment plans with
21 them.
22 Q. And over the course of your career, have

1 you attended conferences related to the practice
2 of oncology?
3 A. Many, many, many.
4 Q. Okay. And during the course of your
5 career, did you give lectures related to how
6 oncologists practice?
7 A. Yes.
8 Q. Okay. And so from those activities, do
9 you have an understanding of how oncologists
10 generally practice?
11 MS. STAURING: Objection, leading.
12 A. So I have a lot of contact with
13 oncologists. Of course, I supervised many at UNC,
14 Ohio State, and West Virginia University. Also,
15 I -- I am involved in research, where I interact
16 with many oncologists. And I gave lectures both
17 to academic groups in big international
18 conferences as well as to community groups. I --
19 and in the latter part of my career, have often
20 focused on management of patients with MSI-high
21 tumors by using immuno-oncology agents.
22 Q. And did you rely on all of that

1 knowledge that you've gained over the course of
2 your career in formulating the opinions in your
3 declarations?
4 MS. STAURING: Objection, leading.
5 A. I relied on all of my experience as a --
6 an expert in the field to generate my
7 declarations.
8 Q. Okay. And, Dr. Goldberg, do you
9 remember testifying previously that oncologists
10 are licensed medical doctors who have prescribing
11 privileges and they can prescribe drugs that are
12 FDA approved for any indication in any way they
13 choose?
14 A. I remember saying that.
15 Q. Okay. Are there any other
16 considerations that an oncologist would consider
17 in prescribing a drug like pembro?
18 MS. STAURING: Objection, leading.
19 A. So, there are many considerations.
20 First would be the data. And, you know, how the
21 data supported treatment in the particular
22 patient's circumstance, meaning what stage of

1 cancer, where the cancer originated, what their
2 prior treatments have -- have been.
3 They would also -- they would also
4 consider co-morbidities, age, patient's treatment
5 goals, and insurance coverage, in the circumstance
6 of an expensive drug like this.
7 So there are a myriad of considerations
8 that go into how to make specific treatment
9 decisions for specific patients.
10 Q. How does insurance coverage play into
11 the decision of whether to prescribe a drug like
12 pembro?
13 A. Well, so often an oncologist such as
14 myself, or the individuals I was supervising,
15 would decide they thought that a treatment was in
16 the best interest of a patient. They would then
17 order that treatment. And then it would fall to
18 others in our care team to both write the orders
19 for that, which I would then sign or my trainees
20 would then sign, and also to determine whether
21 there was going to be insurance coverage.
22 And in some circumstances, for example,

1 where the patient might be eligible for Medicaid
2 but didn't have Medicaid, we would help them apply
3 for Medicaid so that they would have coverage.
4 And, at times, I would end up having to
5 talk to a pharmacy benefit manager to try and
6 determine if my desire to give a treatment could
7 be covered, even if it was initially denied.
8 Q. How do FDA-approved indications play
9 into the decision by insurance to cover a drug
10 like pembro?
11 MS. STAURING: Objection, leading.
12 A. So insurance considerations can be
13 somewhat mysterious.
14 In general, if something is covered by
15 NCTN guidelines in FDA approvals, there's an
16 evidence base to suggest that it's safe and
17 effective in the management of the specific
18 conditions for which being -- for which it's being
19 prescribed. But that didn't always guarantee that
20 an insurance company would agree to pay for it.
21 Q. So you previously testified that you
22 know that pembro is expensive; correct?

1 A. I do know that it's expensive, but I
2 don't know specifically how much for
3 100 milligrams or 200 milligrams, would cost.
4 I would assume that there are probably
5 different prices for the same dose, depending on
6 who's buying and what their agreements are with
7 the company or with their vendors.
8 Q. And who pays for an expensive drug like
9 pembro if insurance declines to pay?
10 A. Well, a patient would be responsible for
11 it. They would be billed for it, but they -- that
12 doesn't guarantee that their bills would be paid.
13 Q. Dr. Goldberg, I'd like to direct you to
14 your '356 declaration, paragraph 82.
15 A. I have '356 in front of me. And I have
16 paragraph 82 in front of me.
17 Q. Okay. And, Dr. Goldberg, you -- you
18 informed me that you would like to make a
19 correction to paragraph 82. What is that
20 correction?
21 MS. STAURING: Objection, beyond the
22 scope.

1 A. So, you know, as we discussed, I
2 continued to see patients in 2017. I also
3 supervised other physicians who were administering
4 KEYTRUDA to GI cancer patients. And when we had
5 our conversations about treatment strategies, we
6 would do so within the instructions of the
7 KEYTRUDA label.
8 Q. Okay. So in paragraph 82, when you
9 state, "I know that other physicians who
10 administer KEYTRUDA do, too," is that referring to
11 those supervising physicians that you just
12 mentioned?
13 MS. STAURING: Objection, leading,
14 beyond the scope.
15 A. So I -- it would include those
16 physicians, but it would also include physicians
17 in other practices who would want to practice
18 within the scope of practice approved by NCTN
19 guidelines and enumerated in the KEYTRUDA label.
20 Q. Okay. So after May 2017, were any
21 oncologists at West Virginia prescribing pembro
22 for MSI-high cancers?

1 MS. STAURING: Objection, beyond the
2 scope.
3 A. Yes.
4 Q. Okay. And did you have any discussions
5 with those oncologists regarding how they were
6 prescribing pembro for MSI-high cancers?
7 MS. STAURING: Objection, beyond the
8 scope.
9 A. So we had discussions about when to use
10 pembrolizumab and we had discussions about the
11 potential dosing regimens that had been shown to
12 be active. I wasn't specifically directive to
13 them about which of those potential options they
14 should use.
15 Q. Okay. And how are prescriptions for
16 pembro for MSI-high cancers handled at West
17 Virginia?
18 MS. STAURING: Objection, beyond the
19 scope.
20 A. So like in most academic centers, like
21 was the practice at both UNC and Ohio State before
22 WVU, we have a team of people that manages our GI

1 cancer patients that include a physician, often a
2 trainee, often a nurse practitioner or a
3 physician's assistant. And they -- pharm D. And,
4 in general, the pharm D is told what we would like
5 to do with the patient, and then they write the
6 orders, which we sign, and then they initiate the
7 process by which drug coverage is ascertained and
8 a delivery plan is made.
9 Q. And does that delivery plan incorporate
10 the instructions that are contained within the
11 KEYTRUDA label for -- for pembro?
12 MS. STAURING: Objection, beyond the
13 scope.
14 A. Generally, yes.
15 Q. Okay. Dr. Goldberg, do you remember,
16 you were previously asked about a comparison with
17 the outcome of a colorectal cancer patient that is
18 not MSI-high treated with pembrolizumab?
19 A. Yes, I remember that.
20 Q. Okay.
21 A. That's a specific item in one of the
22 patents that we discussed; is that right?

1 Q. Well, why don't we go to your -- before
2 we do that, one more question about the correction
3 to paragraph 82.
4 Would that correction to paragraph 82 in
5 the '356 -- in your '356 declaration also be
6 applicable to the similar paragraphs in the other
7 seven of your declarations?
8 A. Yes.
9 MS. STAURING: Objection, leading.
10 A. I -- yes, that correction should apply
11 to the other paragraphs that state the same thing
12 in the other declarations.
13 Q. Okay. If you would, Dr. Goldberg, go to
14 your '974 declaration.
15 A. Okay. What page?
16 Q. Okay. And if you would go to page 64.
17 A. Okay. I'm on page 64.
18 Q. Okay. And do you see there's a gray box
19 with the claim 1[c] limitation, "wherein, the
20 patient exhibits an outcome that is improved as
21 compared to a corresponding outcome that would be
22 observed in a reference patient that has been

1 administered pembrolizumab; wherein, the reference
2 patient has a tumor that does not exhibit an
3 instability of the one or more microsatellite
4 markers or a deficiency of the one or more
5 mismatch repair markers"?
6 Do you see that?
7 MS. STAURING: Objection, leading.
8 A. I see that.
9 Q. Okay. What is your understanding of
10 what is a reference patient?
11 A. Well --
12 MS. STAURING: Objection, beyond the
13 scope.
14 A. So I -- I think at the time that I
15 answered the questions that Jessica directed to me
16 about those, I wasn't perfectly clear on what a
17 reference patient means.
18 I -- now that I've thought about it a
19 little more, I'm going to bring up as a reference
20 table 49, which is on the next page, page 65. And
21 I particularly focus on KEYNOTE 16, which is in
22 the top line of that chart, in which I treated

1 with other investigators in the JHU study patients
2 who were both MSS and MSI-high.
3 And so I think in that reference, which
4 was published in The New England Journal of
5 Medicine and subsequently updated in Science, a
6 reference patient who was non-MSI-high would be
7 exemplified by the patients who were recruiting to
8 R&D of that trial.
9 Q. All right. So, in your opinion, does
10 the KEYTRUDA label instruct a physician to compare
11 the outcome of the MSI-high colorectal cancer
12 patient treated with pembro to a reference MSS
13 patient?
14 A. Yes. I --
15 MS. STAURING: Objection.
16 THE WITNESS: Are you done?
17 A. I -- you know, I -- I understand this
18 sentence better than I did previously. And the
19 answer is yes.
20 Q. Okay. Dr. Goldberg, if you would go
21 back to your '356 declaration.
22 A. Okay.

1 Q. And go to page 61.
2 A. Okay.
3 Q. Okay. And you previously testified that
4 oncologists treat individual patients; correct?
5 A. That's correct.
6 Q. Okay. And claim 23 of the '356 patient
7 recites "a method for treating cancer in a
8 population of cancer patients in need thereof";
9 correct?
10 A. Correct.
11 Q. Okay. What is your understanding of
12 what a "population of cancer patients" is?
13 MS. STAURING: Objection, beyond the
14 scope.
15 A. So it's a little bit confusing. A
16 population of patients in my practice would mean,
17 for example, every patient in my practice who has
18 microsatellite instability-high colorectal cancer
19 who had been previously treated. So I would have
20 a numerator of each individual patient and a
21 denominator, all the patients in my practice.
22 Q. Okay. So in your understanding, does

1 the KEYTRUDA labeling instruct a physician to
2 treat a population of cancer patients according to
3 claim 23 of the '356 patent?
4 MS. STAURING: Objection, leading.
5 A. So, I guess, my understanding would be
6 that what this instructs is that if you have a
7 patient who's MSI or if you have a group of
8 patients who are MSI-high, you should consider
9 using this treatment, which has been shown to be
10 effective in that population of patients.
11 Q. Okay. And, Dr. Goldberg, if you would
12 go to your '462 declaration, please.
13 A. Just a minute. It's on the floor here.
14 Q. And go to page 62.
15 A. Okay.
16 Q. Okay. And --
17 A. Hang on just a second.
18 Okay. Got it.
19 Q. Okay. And do you remember counsel
20 asking you questions previously about whether
21 endometrial, gastric, small bowel, and ovarian
22 cancer would be associated with MSI-high cancers?

1 A. Yes.
2 Q. Okay. And do you see in the gray box on
3 page 62 of your '462 declaration, the claim 1
4 preamble recites: "A method for treating a
5 patient having a solid tumor selected from the
6 group consisting of endometrial cancer, small
7 bowel cancer, gastric cancer, ampullary cancer,
8 cholangiocarcinoma, pancreatic cancer, prostate
9 cancer, breast cancer, esophageal cancer, liver
10 cancer, ovarian cancer, uterine cancer, cervical
11 cancer, bladder cancer, testicular cancer, and
12 oral cancer"?
13 Do you see that?
14 A. Yes.
15 MS. STAURING: Objection, leading,
16 beyond the scope.
17 Q. Okay. As of July 10th, 2015, would a
18 POSA immediately identify this specific group of
19 16 cancers as the entire group of cancer types
20 associated with MSI-high?
21 MS. STAURING: Objection, beyond the
22 scope.

1 A. No. The -- any patient with a solid
2 tumor can be MSI-high.
3 This is a subset of those patients.
4 DR. BROWN-MARSHALL: No further
5 questions.
6 MS. STAURING: Counsel, can we please
7 take a five-minute break?
8 DR. BROWN-MARSHALL: Sure.
9 MS. STAURING: We're off the record.
10 THE STENOGRAPHER: We're off the record.
11 (Recess in proceedings.)
12 THE STENOGRAPHER: We are back on the
13 record.
14 EXAMINATION
15 BY MS. STAURING:
16 Q. Dr. Goldberg, after the conclusion of my
17 questioning today, you had a conversation with
18 Ms. Brown-Marshall; right?
19 A. Correct.
20 DR. BROWN-MARSHALL: Object to the form
21 of the question.
22 Q. When you had this conversation with

1 Ms. Brown-Marshall after the conclusion of my
2 questioning today, what did you discuss?
3 A. We discussed items in my testimony.
4 Q. And which items in your testimony did
5 you discuss during that conversation with
6 Ms. Brown-Marshall?
7 A. The items that she then questioned me
8 about during her session of questioning.
9 Q. At the conclusion of my questioning
10 today, before your conversation with
11 Ms. Brown-Marshall, were you confused by the
12 testimony that you provided today?
13 DR. BROWN-MARSHALL: Object to the form
14 of the question.
15 A. So you asked a lot of questions, and you
16 asked a lot of questions where you were asking a
17 variation on the same question repeatedly. I --
18 and so I think that there were some areas where I
19 wasn't perfectly clear.
20 And an example of that is the discussion
21 about comparing an MSI-high patient to an MSS
22 patient, reference patient. So I was a bit

1 confused about the meaning of a "reference
2 patient."
3 Q. My question was a little different,
4 Dr. Goldberg.
5 And my question was whether you thought
6 that you were confused or unclear in your
7 testimony that you provided today at the
8 conclusion of my questioning, before your
9 conversation with Ms. Brown-Marshall.
10 DR. BROWN-MARSHALL: Object to the form
11 of the question. Asked and answered.
12 A. So I had some areas that we discussed
13 that lacked clarity for me, which I discussed with
14 Ms. Brown-Marshall and got some additional clarity
15 on during our discussion.
16 Q. And the topics that you testified to --
17 actually, strike that.
18 Before Ms. Brown-Marshall raised, during
19 your conversation with her, this supposed lack of
20 clarity, were you confused or did you feel unclear
21 by the testimony that you provided today at the
22 conclusion of my questioning?

1 DR. BROWN-MARSHALL: Objection. Object
2 to the form of the question, asked and
3 answered.
4 A. I'm not sure quite how to answer that.
5 Can you ask me the question again?
6 Q. Sure.
7 Before Ms. Brown-Marshall raised the
8 topics -- actually, strike that.
9 Before Ms. Brown-Marshall raised a
10 supposed lack of clarity in your testimony during
11 your conversation after the conclusion of my
12 questioning, were you at all confused or unclear
13 about the testimony that you provided today?
14 DR. BROWN-MARSHALL: Objection, assumes
15 facts not in evidence.
16 A. So I stand by the testimony that I gave
17 today.
18 Q. You stand by the testimony that you gave
19 to me before your conversation with
20 Ms. Brown-Marshall; right?
21 DR. BROWN-MARSHALL: Objection,
22 mischaracterizes previous testimony.

1 A. I stand by the testimony that I gave
2 both before and after I had my discussion with
3 Ms. Brown-Marshall.
4 Q. Dr. Goldberg, if you believe that the
5 KEYTRUDA labeling instructs the physician to
6 compare the outcome of a MSI-high colorectal
7 cancer patient treated with pembrolizumab to a
8 reference MSS colorectal cancer patient treated
9 with pembrolizumab, can you identify any physician
10 that you know that has done this comparison to a
11 reference patient in your treatment of an MSI-high
12 colorectal cancer patient?
13 DR. BROWN-MARSHALL: Object to the form
14 of the question.
15 A. So I don't think that this statement
16 reflects the way that physicians think.
17 I think that physicians looked at the
18 New England Journal paper, that Dr. Le is the co-
19 -- first author on and said -- and interpreted
20 that as: MSI-high patients did respond to
21 pembrolizumab. Not all of them, but some of them.
22 And MSS colorectal cancer patients did not. And,

1 therefore, they would not have evidence to support
2 treating an MSS colorectal cancer patient with
3 pembrolizumab, based on the leading report.
4 Q. So, Dr. Goldberg, is it your testimony
5 that the KEYTRUDA labeling does not instruct a
6 physician to compare the outcome of an MSI-high
7 colorectal cancer patient treated with
8 pembrolizumab with the outcome of a colorectal
9 cancer patient treated with pembrolizumab that is
10 not MSI-high?
11 DR. BROWN-MARSHALL: Object to the form
12 of the question, mischaracterizes previous
13 testimony.
14 A. So can we pull up that gray box that we
15 referred to? I don't remember whether it was in
16 the '326 patent or one of the others -- that has
17 that specific instruction in it and uses the term
18 "reference patient."
19 Q. Dr. Goldberg, I'm asking if, sitting
20 here today, it's your testimony -- is it your
21 testimony that the KEYTRUDA labeling instructs a
22 physician to compare the outcome of an MSI-high

1 colorectal cancer patient with the outcome of a
2 colorectal cancer patient that is not MSI-high
3 treated with pembrolizumab?
4 DR. BROWN-MARSHALL: Object to the form
5 of the question.
6 A. So whichever patent that is does
7 instruct a physician to compare an MSI-high
8 colorectal cancer patient to an MSS reference
9 patient, reference patient.
10 Q. And, Dr. -- and, Dr. Goldberg, I'm not
11 asking about the patent. I'm asking about the
12 KEYTRUDA labeling. So let me try my question
13 again.
14 Does the KEYTRUDA labeling instruct a
15 physician to compare the outcome of an MSI-high
16 colorectal cancer patient treated with
17 pembrolizumab with the outcome of a colorectal
18 cancer patient that is not MSI-high treated with
19 pembrolizumab?
20 DR. BROWN-MARSHALL: Object to the form
21 of the question.
22 A. I would like to find the place in my

1 declaration that states that. It may take me a
2 minute. I'm not sure which patent it's in. Can
3 you help me, so I don't have to look at them all?
4 Q. Dr. Goldberg, I don't think that you
5 write that in your declaration.
6 A. No, I -- I imported that piece of the
7 pembrolizumab package insert into my declaration.
8 So it's written in my declaration.
9 Q. Let me try the question again right now.
10 Does the KEYTRUDA labeling instruct a
11 physician to compare the outcome of an MSI-high
12 colorectal cancer patient treated with
13 pembrolizumab with the outcome of a colorectal
14 cancer patient that is not MSI-high treated with
15 pembrolizumab?
16 DR. BROWN-MARSHALL: Object to the form
17 of the question.
18 Counsel, Dr. Goldberg said that he
19 needed to refer to his declaration. You
20 should let him do that.
21 A. Somebody give me a hint in which
22 declaration that is so I can focus, I can look and

1 not waste anybody's time.
2 Q. Dr. Goldberg, I don't think that
3 that's --
4 A. I've found it. Never mind.
5 Q. -- written in your declaration.
6 A. So in my declaration on page 64, it
7 states, "A KEYTRUDA label instructs physicians to
8 use KEYTRUDA to treat cancer in a patient wherein
9 treatment in accordance with the label results in
10 an outcome that is improved as compared to a
11 corresponding outcome that would be observed in a
12 reference patient whose tumor is not MSI-high or
13 dMMR."
14 So that is clearly stated on page 64 of
15 my declaration. How can you say that I didn't say
16 that?
17 Q. My question is different, Dr. Goldberg.
18 My question is: Does the KEYTRUDA
19 labeling instruct a physician to compare the
20 outcome of an MSI-high colorectal cancer patient
21 treated with pembrolizumab with the outcome of a
22 colorectal cancer patient that is not MSI-high

1 treated with pembrolizumab?
2 DR. BROWN-MARSHALL: Objection to the
3 form of the question, and asked and answered.
4 A. So I've read you what the KEYTRUDA label
5 instructs, and it instructs what you just asked.
6 Q. Can you identify any doctor by name that
7 has ever done that comparison in the treatment of
8 an MSI-high colorectal cancer patient according to
9 the KEYTRUDA labeling?
10 DR. BROWN-MARSHALL: Object to the form
11 of the question, asked and answered.
12 A. I could not identify a specific
13 physician by name that has done that.
14 Q. Dr. Goldberg, you testified earlier that
15 it was your job to mentor young physicians, as
16 well as fellows and trainees; and that you would
17 supervise them and often discuss patients with
18 them. Do you recall that?
19 A. Yes.
20 Q. Sitting here today, can you identify by
21 name any one of those individuals who has ever
22 prescribed KEYTRUDA to an MSI-high colorectal

1 cancer patient according to the KEYTRUDA labeling
2 and made a comparison of that patient's outcome to
3 the outcome of a colorectal cancer patient that is
4 not MSI-high treated with pembrolizumab?
5 DR. BROWN-MARSHALL: Objection, beyond
6 the scope.
7 A. So I think every patient [sic] that
8 prescribes pembrolizumab to an MSI-high colorectal
9 cancer patient would be aware of the -- the New
10 England Journal paper from 2014/2015. I -- and,
11 therefore, would understand not to use
12 pembrolizumab in MSS patients and to use it in
13 MSI-high patients.
14 I don't understand if that's really a
15 comparison or it's just an analysis of data in the
16 literature.
17 Q. Okay. So let me try my question again
18 because I asked you to identify by name a
19 physician. So let me try again.
20 Sitting here today, can you identify by
21 name any one of those individuals that you
22 mentioned earlier as fellows or trainees who has

1 prescribed KEYTRUDA to an MSI-high colorectal
2 cancer patient according to the KEYTRUDA labeling
3 and made a comparison of that patient's outcome to
4 the outcome of a colorectal cancer patient that is
5 not MSI-high treated with pembrolizumab?
6 DR. BROWN-MARSHALL: Objection, beyond
7 the scope, asked and answered.
8 A. I'm going to say no, because I don't
9 think doctors think the way that that is stated.
10 The clinical trial made the comparison
11 and the doctor would know to use KEYTRUDA in
12 MSI-high patients with metastatic colorectal
13 cancer.
14 Q. All right. Dr. Goldberg, do you feel
15 like there is any lack of clarity about what you
16 just testified to in response to my questions?
17 DR. BROWN-MARSHALL: Object to the form
18 of the question.
19 A. There may be lack of clarity to you.
20 I'm trying to be as clear as I can be for what I
21 consider to be a rather strange statement in the
22 label. It's not the way physicians think.

1 Q. Okay. But you don't think that you have
2 been unclear in your responses to my questions;
3 right?
4 DR. BROWN-MARSHALL: Objection.
5 A. I've tried my best --
6 DR. BROWN-MARSHALL: Object to the form
7 of the question.
8 A. I've tried my best to answer your
9 questions.
10 Q. And I'm asking you about the clarity of
11 your responses. And so let me try my question
12 again.
13 I appreciate that you're trying your
14 best. My question is: You don't think that you
15 have been unclear in your responses to my
16 questions; right?
17 DR. BROWN-MARSHALL: Objection, asked
18 and answered.
19 A. I am trying my best to respond to your
20 questions.
21 Q. And you do not think that you have been
22 unclear in your responses to my questions;

1 correct?
2 DR. BROWN-MARSHALL: Objection, asked
3 and answered.
4 A. I do not believe I am being unclear in
5 my answer to your question.
6 MS. STAURING: Okay. I don't have any
7 further questions, Dr. Goldberg. I'd like to
8 thank you for your time.
9 DR. BROWN-MARSHALL: No further
10 questions here.
11 THE WITNESS: Okay.
12 THE STENOGRAPHER: We're off the record.
13
14
15
16 AND FURTHER THIS DEPONENT SAITH NOT.
17 SIGNATURE RIGHTS RESERVED.
18 (Deposition concluded at 1:38 p.m.)
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21 * * * * *
22

1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC
2 I, April Reid, Registered Professional
3 Reporter, Certified Realtime Reporter and Notary
4 Public within and for the State of Florida do
5 hereby certify:
6 That RICHARD GOLDBERG, M.D., the witness
7 whose deposition is hereinbefore set forth, was
8 duly sworn by me before the commencement of such
9 deposition and that such deposition was taken
10 before me and is a true record of the testimony
11 given by such witness.
12 I further certify that the adverse
13 party, THE JOHNS HOPKINS UNIVERSITY, was
14 represented by counsel at the deposition.
15 I further certify that the deposition of
16 RICHARD GOLDBERG, M.D., occurred remotely via Zoom
17 on TUESDAY, APRIL 15, 2025 from 8:58 a.m. Eastern
18 Standard Time to 1:38 p.m. Eastern Standard Time.
19 I further certify that I am not related
20 to any of the parties to this action by blood or
21 marriage, I am not employed by or an attorney to
22 any of the parties to this action, and that I am

1 in no way interested, financially or otherwise, in
2 the outcome of this matter.
3 IN THE WITNESS WHEREOF, I have hereunto set my
4 hand this 17th day of April, 2025.
5 My commission expires: August 22, 2027.
6 _____
7 April Reid, RPR, CRR, Notary Public
8 State of Florida, County of Orange
9 Commission No. 455787/HH 436060
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