1 UNITED STATES PATENT AND TRADEMARK OFFICE

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3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4

5 MERCK SHARPE & DOHME LLC,

6 Petitioner,

7 vs.

8 THE JOHN HOPKINS UNIVERSITY,

9 Patent Owner.

10

11 * HIGHLY CONFIDENTIAL *

12 _____

13

14 IPR2024-00622 (U.S. Patent No. 10,934,356)
IPR2024-00623 (U.S. Patent No. 11,325,974)
15 IPR2024-00624 (U.S. Patent No. 11,325,975)
IPR2024-00625 (U.S. Patent No. 11,339,219)
16 IPR2024-00647 (U.S. Patent No. 11,649,287)
IPR2024-00648 (U.S. Patent No. 11,643,462)
17 IPR2024-00649 (U.S. Patent No. 11,629,187)
IPR2024-00650 (U.S. Patent No. 11,634,491)
18

19 Job No.: 580483

20 Pages: 1 - 128

21 Stenographically Reported By:

22 Alison C. Webster, CSR, RPR, RMR, CRR, RDR

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3 * HIGHLY CONFIDENTIAL *
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5 DEPOSITION OF
6 NILS LONBERG, Ph.D.
7 Thursday, April 17, 2025
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13 Deposition of NILS LONBERG, Ph.D., produced as a
14 witness at the instance of the Petitioner, and duly sworn,
15 was taken in the above-styled and numbered cause on
16 Thursday, April 17, 2025, from 12:01 p.m. to 3:42 p.m.
17 Eastern Time, before Alison C. Webster, RPR, CRR, RMR, RDR,
18 CSR-6266 (Michigan); License No. 14559 (California);
19 License No. 084.004953 (Illinois); CSR-12432 (Texas),
20 reported by stenographic method, via videoconference,
21 pursuant to the Federal Rules of Civil Procedure and the
22 provisions stated on the record or attached hereto.

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19
20
21
22

1 T A B L E O F C O N T E N T S
2
3 Witness Page
4 NILS LONBERG, Ph.D.
5
6 EXAMINATION
7 BY MR. RATLIFF: 8
8 EXAMINATION
9 BY MR. MILLER: 113
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1 E X H I B I T I N D E X
2
3 Exhibit Page
4
5 (Exhibit attached to transcript.)
6
7 EXHIBIT 1116 77
8 Letter, May 9, 2013, Re: Phase 2 Study
9 of MK-3475 in Patients with
10 Microsatellite Unstable (MSI) Tumor
11 IPR2024-00622
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1 DEPOSITION OF NILS LONBERG, Ph.D.
2 Thursday, April 17, 2025
3
4 STENOGRAPHER: The attorneys participating
5 in this deposition and the witness have verified that
6 he is Nils Lonberg, Ph.D. In lieu of an oath
7 administered in person, the witness will visually
8 affirm his testimony in this matter is under penalty
9 of perjury.
10 The parties and their counsel consent to
11 this arrangement and waive any objections to this
12 manner of reporting or admissibility of the
13 transcript.
14 If there are any objections to proceeding
15 in this manner by any party, please state so now.
16 Hearing no objections, Dr. Lonberg, would
17 you please raise your right hand.
18 Do you swear or affirm the testimony you
19 are about to give in this matter will be the truth,
20 the whole truth, and nothing but the truth?
21 DR. LONBERG: I do.
22 STENOGRAPHER: Thank you.

1 You may proceed.
2 NILS LONBERG, Ph.D.,
3 was thereupon called as a witness herein, and after
4 having first been duly sworn to testify to the truth,
5 the whole truth and nothing but the truth, was
6 examined and testified as follows:
7 EXAMINATION
8 BY MR. RATLIFF:
9 Q. Doctor, please state your full name for the record.
10 A. Nils Lonberg.
11 Q. Please state your residence address.
12 A. 168 Bardet Road in Woodside, California.
13 Q. How are you feeling today?
14 A. Good.
15 Q. You understand that you are testifying under oath.
16 Right?
17 A. That's correct.
18 Q. Is there any reason you cannot testify truthfully
19 today?
20 A. No.
21 Q. Now, the last time we spoke was on December 20th of
22 2024, when you had your deposition taken in the IPR

1 proceeding as to the '393 patent.
2 Is it still correct that you are not a
3 medical doctor?
4 A. That is correct.
5 Q. Is it still correct that you have never prescribed
6 pembrolizumab to a cancer patient?
7 A. That is correct.
8 Q. And you have never prescribed any anti-PD-1 drug to a
9 cancer patient. Right?
10 A. I have not.
11 Q. And you have never prescribed any cancer treatment
12 therapy to a cancer patient. Right?
13 A. No, I have not.
14 Q. Now, since your deposition in the IPR proceeding as to
15 the '393 patent, you signed eight additional IPR
16 declarations on behalf of JHU. Right?
17 A. Did you say eight?
18 Q. I said eight.
19 A. That's correct.
20 Q. And so you signed a declaration as to the '356 patent
21 on January 11th, 2025; is that right?
22 A. That's correct.

1 Q. Do you have a copy of that declaration with you?
2 A. Yes, I do.
3 Q. You signed a declaration as to the '974 patent on
4 January 11th, 2025. Right?
5 A. That's correct.
6 Q. Do you have a copy of that declaration with you?
7 A. Yes, I do.
8 Q. You signed a declaration as to the '291 patent on
9 January 11th, 2025. Right?
10 A. '291, you said?
11 Q. '291, yes.
12 A. I'm looking for it. Sorry.
13 '291. You mean '219?
14 Q. That's right. '219, sorry about that. So let me try
15 that again.
16 You signed a declaration as to the '219
17 patent on January 11th, 2025. Right?
18 A. That's correct.
19 Q. Do you have a copy of that declaration with you?
20 A. Yes, I do.
21 Q. You signed a declaration as to the '287 patent on
22 January 23rd, 2025. Right?

1 A. Which one?
2 Q. '287 patent.
3 A. I don't have that.
4 Q. Do you have a declaration as to the '462 patent?
5 A. Yes, I do.
6 Q. And you signed a declaration as to the '462 patent on
7 January 23rd, 2025. Right?
8 A. That's correct.
9 Q. And do you have a copy of that with you?
10 A. Yes, I do.
11 Q. And you signed a declaration as to the '278 patent on
12 January 23rd, 2025. Right?
13 A. You said '278?
14 Q. Correct. Sorry. Sorry. You -- the '287 patent, you
15 don't have a copy of that; is that right?
16 A. No. '287 you already asked me about, and, yes, I
17 have that, I believe.
18 Q. Okay.
19 A. I have it, but I'm not -- I thought you already --
20 sorry.
21 Q. Let me -- let me just be sure. Let me just be sure
22 it's -- the record is clear.

1 You signed a declaration as to the '287
2 patent on January 23rd, 2025?
3 A. That is correct.
4 Q. And you have a copy of that. Right?
5 A. Yes, I do.
6 Q. And you signed a declaration as to the '187 patent
7 on --
8 A. Yes.
9 Q. -- January 23rd, 2025?
10 A. Yes. Yes, I did.
11 Q. And do you have a copy of that?
12 A. Yes, I do.
13 Q. And you signed a declaration as to the '491 patent on
14 January 23rd, 2025. Right?
15 A. Yes, I did.
16 Q. And you have a copy of that?
17 A. Yes, I do.
18 Q. And you signed a declaration as to the '975 patent on
19 January 11, 2025. Right?
20 A. That is correct.
21 Q. Do you have a copy of that?
22 A. Yes, I do.

1 Q. Now, did you read each of the eight patents at issue
2 in your declarations?
3 A. Yes, I did.
4 Q. And you read each of the eight patents in their
5 entirety. Right?
6 A. That's correct.
7 Q. When you read the eight patents, you understood them.
8 Correct?
9 A. Yes, I did.
10 Q. You were not confused by the contents of any of those
11 eight patents that you read. Correct?
12 A. I was not.
13 Q. You understood all claims of the eight patents that
14 you read. Correct?
15 A. That's correct.
16 Q. And if asked, you could explain the meaning of any
17 claim term or claim limitation in each of the eight
18 patents that you read. Right?
19 A. That's correct.
20 Q. Now, all of the claims in these eight patents are
21 directed to methods of treating cancer patients.
22 Correct?

1 A. Correct.
2 MR. MILLER: Objection to the form of the
3 question.
4 And, Dr. Lonberg, if you could just please
5 pause after that -- the question so I can interpose
6 objections.
7 BY MR. RATLIFF:
8 Q. Now, you agree that clinical oncologists treat cancer
9 patients. Correct?
10 A. That is correct.
11 Q. And in order for someone to practice the methods of
12 the claims of the eight patents that you read, they
13 would not need specialized experience researching
14 and/or developing new treatments for cancer. Right?
15 MR. MILLER: Objection to the form of the
16 question.
17 A. I would probably have to go through each of the
18 claims again to refresh my memory.
19 BY MR. RATLIFF:
20 Q. Well, let's take a look at the '356 patent. And turn
21 your attention to the claims of that patent.
22 A. Okay.

1 Q. So my question is, in order for someone to practice
2 the methods of the claims of the '356 patent, they
3 would not need specialized experience researching
4 and/or developing new treatments for cancer. Right?
5 A. That's correct.
6 Q. And looking at the claims of the '356 patent, you
7 would agree that the claim methods are for treating
8 cancer patients and not methods for conducting
9 immunology research. Right?
10 A. Immunology?
11 Q. Correct.
12 A. That's correct.
13 Q. And they're not methods for conducting genetics
14 research. Right?
15 A. That is correct.
16 Q. Do you have a copy of the '974 patent?
17 A. Yes, I do.
18 Q. Can you turn your attention to the claims of that
19 patent, please?
20 A. Yes.
21 Q. In order for someone to practice the methods of the
22 claims of the '974 patent, they would not need

1 specialized experience researching and/or developing
2 new treatments for cancer. Right?
3 A. That's correct.
4 Q. Looking at the claims of the '974 patent, you would
5 agree that the claim methods are for treating cancer
6 patients and not a method for conducting immunology
7 research. Right?
8 A. That's correct.
9 Q. And they're not methods for conducting genetics
10 research. Right?
11 A. They are not.
12 Q. Do you have a copy of the '975 patent?
13 A. Yes, I do.
14 Q. Will you please turn your attention to the claims of
15 that patent?
16 A. Okay.
17 Q. In order for someone to practice the methods of the
18 '975 patent, they would not need specialized
19 experience researching and/or developing new
20 treatments for cancer. Right?
21 A. That's correct.
22 Q. And looking at the claims of the '975 patent, you

1 would agree that the claim methods are for treating
2 cancer patients and not a method for conducting
3 immunology research. Right?
4 A. That's correct.
5 Q. And they're not methods for conducting genetics
6 research. Right?
7 A. That's correct.
8 Q. Do you have a copy of the '219 patent?
9 A. Yes, I do.
10 Q. Please turn your attention to the claims of that
11 patent.
12 A. Okay.
13 Q. In order for someone to practice the methods, the
14 claim methods of the '219 patent, they would not need
15 specialized experience researching and/or developing
16 new treatments for cancer. Right?
17 A. That's correct.
18 Q. Looking at the claims of the '219 patent, you would
19 agree that the claim methods are for treating cancer
20 patients and not methods for conducting immunology
21 research. Right?
22 A. That's correct.

1 Q. And they're not methods for conducting genetics
2 research. Right?
3 A. That is correct.
4 Q. Do you have a copy of the '287 patent?
5 A. Yes, I do.
6 Q. Will you please turn your attention to the claims of
7 that patent.
8 A. Okay.
9 Q. In order for someone to practice the claim methods of
10 the '287 patent, they would not need specialized
11 experience researching and/or developing new
12 treatments for cancer. Right?
13 A. That is correct.
14 Q. Looking at the claims of the '287 patent, you would
15 agree that the claim methods are for treating cancer
16 patients and not methods for conducting immunology
17 research. Right?
18 A. That is correct.
19 Q. And they're not methods for conducting genetics
20 research. Right?
21 A. That's correct.
22 Q. Do you have a copy of the '462 patent?

1 A. Yes, I do.
2 Q. Please turn your attention to the claims of that
3 patent.
4 A. Okay.
5 Q. And in order for someone to practice the claim methods
6 of the '462 patent, they would not need specialized
7 experience researching and/or developing new
8 treatments for cancer. Right?
9 A. Correct.
10 Q. Looking at the claims of the '462 patent, you would
11 agree that the claim methods are for treating cancer
12 patients and not methods for conducting immunology
13 research. Right?
14 A. That is correct.
15 Q. And they're not methods for conducting genetics
16 research. Right?
17 A. That is correct.
18 Q. Do you have a copy of the '187 patent?
19 A. Yes, I do.
20 Q. Please turn your attention to the claims of that
21 patent.
22 A. Okay.

1 Q. In order for someone to practice the claim methods of
2 the '187 patent, they would not need specialized
3 experience researching and/or developing new
4 treatments for cancer. Right?
5 A. That's correct.
6 Q. Looking at the claims of the '187 patent, you would
7 agree that the claim methods are for treating cancer
8 patients and not methods for conducting immunology
9 research. Right?
10 A. That's correct.
11 Q. And they're not methods for conducting genetics
12 research. Right?
13 A. That is correct.
14 Q. Do you have a copy of the '491 patent?
15 A. Yes, I do.
16 Q. Please turn your attention to the claims of that
17 patent.
18 A. Okay.
19 Q. In order for someone to practice the claimed methods
20 of the '491 patent, they would not need specialized
21 experience researching and/or developing new
22 treatments for cancer. Right?

1 A. That is correct.
2 Q. Looking at the claims of the '491 patent, you would
3 agree that the claimed methods are for treating cancer
4 patients and not methods for conducting immunology
5 research. Right?
6 A. That is correct.
7 Q. And they're not methods for conducting genetics
8 research. Right?
9 A. That is correct.
10 Q. Now, you understand that the alleged invention date
11 for each of the eight patents that we've been
12 discussing and that you read is July 10, 2015. Right?
13 MR. MILLER: Objection to the form of the
14 question.
15 A. You mean the priority date?
16 BY MR. RATLIFF:
17 Q. I'm asking about the alleged invention date, so let me
18 try my question again.
19 Do you understand that the alleged
20 invention date for each of the eight patents that you
21 read is July 10, 2015?
22 MR. MILLER: Objection to the form of the

1 question.
2 A. If by "invention date" you mean the priority date,
3 then that's correct.
4 BY MR. RATLIFF:
5 Q. Okay. And so as you understand it, the earliest
6 possible priority date for each of those eight patents
7 you read is July 10, 2015. Right?
8 A. That is my understanding.
9 Q. Now, in your eight declarations that we're discussing
10 today you used the phrase, quote, "at the time of the
11 invention," end quote.
12 You recall that. Right?
13 A. I'm sorry, for which -- for which declaration?
14 Q. I'm talking about all eight declarations concerning
15 the patents that we're discussing today.
16 A. I don't know if that's true or not.
17 Q. Okay. Well, let's take a look at your declaration as
18 to the '356 patent. It's Exhibit 2072. Do you have a
19 copy of that?
20 A. Yes, I do.
21 Q. And can you turn your attention to paragraph 17 in
22 that declaration, page 13?

1 A. Yes.
2 Q. And do you see, in paragraph 17, you use the phrase,
3 quote, "at the time of the invention," end quote?
4 A. Yes, I do.
5 Q. And can you turn to paragraph 29 of that same
6 declaration as to the '356 patent?
7 A. Yes.
8 Q. And are you looking at paragraph 29 on page 17?
9 A. Yes, I am.
10 Q. And do you see that you also use the phrase, quote,
11 "at the time of the invention," in that paragraph?
12 A. Yes.
13 Q. When you wrote, quote, "at the time of the invention"
14 in your '356 patent declaration, what did you mean by
15 that?
16 A. I was referring to the priority date.
17 Q. So when you refer to, quote, "at the time of the
18 invention," you were referring to the July 10, 2015,
19 date; is that right?
20 A. Yes, that is correct.
21 Q. Now, in preparation for your deposition today, did you
22 review each of your eight declarations that we're

1 discussing?
2 A. Yes, I did.
3 Q. And do you stand by the testimony in your eight
4 declarations?
5 A. Yes, I do.
6 Q. You're not confused by anything you testify to in your
7 eight declarations. Right?
8 A. That is correct.
9 Q. You signed each of those eight declarations under
10 penalty of perjury. Right?
11 A. That is correct.
12 Q. You understand that perjury is the act of
13 intentionally lying or making false statements while
14 under oath. Right?
15 MR. MILLER: Objection to the form of the
16 question.
17 A. I'm not a lawyer, but that sounds like a reasonable
18 understanding. That's the understanding that I would
19 have, yes.
20 BY MR. RATLIFF:
21 Q. And that's an understanding that you had when you
22 signed each of your eight declarations. Right?

1 A. That is correct.
2 Q. Now, in preparation for your deposition today did you
3 review the MSI-High Study Record, which is
4 Exhibit 1005?
5 A. Yes, I did.
6 Q. Do you have a copy of the MSI-High Study Record with
7 you?
8 A. No, I don't.
9 Q. And so let's put that in the Chat.
10 PLANET DEPOS TECH: Please stand by.
11 BY MR. RATLIFF:
12 Q. And, Doctor, please feel free to turn your attention
13 to the MSI-High Study Record, which is Exhibit 1005,
14 if you need it.
15 A. Okay. I have it.
16 Q. And we can also call that document the MSR for short
17 today; is that fair?
18 A. MSR. Okay.
19 Q. Now, I want to turn your attention back to your
20 declaration as to the '356 patent, Exhibit 2072. And
21 if you could turn to paragraph 106 in that
22 declaration. Let me know when you have it.

1 A. Okay.
2 Q. Now, in the first sentence you declare that, quote,
3 "as of the Critical Date of the '356 Patent, there was
4 little reason to suspect MSI-High cancer patients
5 (including MSI-High colorectal cancer patients) would
6 be particularly good candidates for PD-1 checkpoint
7 blockade therapy." Right?
8 A. "There was little reason to suspect MSI-High" --
9 "MSI-High cancer patients (including MSI-High
10 colorectal cancer patients) would be particularly
11 good candidates for PD-1 checkpoint blockade
12 therapy."
13 Q. And you declared that that was the case as of criteria
14 critical date of the '356 patent. Right?
15 A. That is correct.
16 Q. And by "critical date of the '356 patent," in the
17 sentence that you wrote, you meant July 10, 2015.
18 Right?
19 A. That is correct.
20 Q. Sitting here today, do you believe that is a truthful
21 and accurate statement as you wrote it?
22 A. Yes, I do.

1 Q. And you declared that statement was truthful and
2 accurate under penalty of perjury. Right?
3 A. That is correct.
4 Q. Now, contrary to the statement in the first sentence
5 of paragraph 106 of your '356 patent declaration, as
6 of July 10, 2015, the results of the clinical trial
7 described in the MSR were publicly known. Correct?
8 MR. MILLER: Objection to the form of the
9 question.
10 A. Are you referring to the ASCO presentation by Dr. Le
11 and the New England Journal of Medicine paper?
12 BY MR. RATLIFF:
13 Q. I am.
14 A. Yes.
15 Q. So you agree that as of July 10, 2015, the results of
16 the clinical study described in the MSR were
17 publically known. Correct?
18 A. That's correct. But they are not considered to be
19 prior art, as I understand it, because there is an
20 inventor exemption that goes back a year from the
21 critical date.
22 Q. Okay. So I'm focused on what you wrote in your first

1 sentence of paragraph 106. Do you see that?
2 A. That is correct.
3 Q. In your first sentence, do you say anything about
4 prior art?
5 A. No, but that is the implication because I'm referring
6 to the critical date.
7 Q. Okay. Now, you would agree that the results of the
8 clinical study described in the MSR would be reason to
9 suspect that MSI-High cancer patients would be
10 particularly good candidates for PD-1 checkpoint
11 blockade therapy. Correct?
12 MR. MILLER: I'm sorry, could you repeat
13 the question, please?
14 BY MR. RATLIFF:
15 Q. Doctor, did you hear the question?
16 MR. MILLER: I need to hear the question
17 again so that I can propound an objection if
18 necessary. Could you repeat it, please?
19 BY MR. RATLIFF:
20 Q. The results of the clinical study described in the MSR
21 would be reason to suspect that MSI-High cancer
22 patients would be particularly good candidates for

1 PD-1 checkpoint blockade therapy. Correct?
2 MR. MILLER: Objection to the form of the
3 question.
4 A. The MSR doesn't describe the results of the clinical
5 trial. It refers to the clinical trial that the
6 results came from.
7 BY MR. RATLIFF:
8 Q. Okay. Let me make sure you understand my question,
9 Doctor, because I don't think you answered it.
10 The results of the clinical study described
11 in the MSR would be reason to suspect that MSI-High
12 cancer patients would be particularly good candidates
13 for PD-1 checkpoint blockade therapy. Correct?
14 MR. MILLER: Objection to the form of the
15 question.
16 A. Yeah, I -- I am just not sure if the word "described"
17 is correct. The MSR refers to the clinical trial,
18 but it doesn't -- it doesn't describe the clinical
19 trial. One interpretation of the word "described" is
20 that it is more comprehensive.
21 BY MR. RATLIFF:
22 Q. In your view, the MSR announced the clinical trial; is

1 that right?
2 A. That is correct.
3 Q. So the results of the clinical trial announced in the
4 MSR would be reason to suspect that the -- that
5 MSI-High cancer patients would be particularly good
6 candidates for PD-1 checkpoint blockade therapy.
7 Correct?
8 MR. MILLER: Objection to the form of the
9 question.
10 A. They would certainly motivate further exploration.
11 BY MR. RATLIFF:
12 Q. Okay. Now, prior to July 10, 2015, clinicaltrials.gov
13 had publicly posted that BMS was conducting a Phase 2
14 study of a PD-1 checkpoint blockade therapy in
15 MSI-High cancer patients. Right?
16 A. That is my memory, yes.
17 Q. And the title of that Phase 2 trial was, quote, "A
18 Phase 2 Clinical Trial of Nivolumab and Nivolumab Plus
19 Ipilumumab in Recurrent and Metastatic Microsatellite
20 High Colon Cancer." Right?
21 A. I don't remember the full name of the trial.
22 Q. Okay. Well, let's take a look at the study record for

1 that trial, which is Exhibit 1053. And we'll put that
2 in the Chat. And let me know when you have it.
3 Do you have it, Doctor?
4 A. I'm downloading it.
5 Yes, I have it.
6 Q. Okay. So let me ask my question again. The title of
7 the Phase 2 trial that BMS was conducting, was, quote,
8 "A Phase 2 Clinical Trial of Nivolumab and Nivolumab
9 Plus Ipilimumab in Recurrent and Metastatic
10 Microsatellite High Colon Cancer." Right?
11 A. The title that I have is, "A Study of Nivolumab and
12 Nivolumab Plus Ipilimumab in Recurrent and Metastatic
13 Colon Cancer (CheckMate 142)."
14 Q. Okay. And you also see that there's an official
15 title. Correct?
16 A. Yes, I do.
17 Q. And the official title is, quote, "A Phase 2 Clinical
18 Trial of Nivolumab and Nivolumab Plus Ipilimumab in
19 Recurrent and Metastatic Microsatellite High Colon
20 Cancer." Right?
21 A. That is correct.
22 Q. You would at least agree that BMS suspected that

1 MSI-High cancer patients would be particularly good
2 candidates for PD-1 checkpoint blockade therapy as of
3 July 10, 2015 because it was conducting such a
4 clinical trial. Right?
5 MR. MILLER: Objection to the form of the
6 question.
7 A. We conducted many exploratory clinical trials in many
8 different indications, and at the time there was a
9 particular push to look at rare diseases, and this
10 was one of those rare diseases. But there was no
11 particular reason to think that this trial would be
12 successful.
13 BY MR. RATLIFF:
14 Q. Okay, let me try my question again because I didn't
15 ask you anything about whether or not the trial would
16 be successful.
17 My question is, you would agree that BMS
18 suspected that MSI-High cancer patients would be
19 particularly good candidates for PD-1 checkpoint
20 blockade therapy as of July 10, 2015, because it was
21 conducting such a clinical trial. Right?
22 MR. MILLER: Objection to the form of the

1 question. Asked and answered.
2 A. No.
3 BY MR. RATLIFF:
4 Q. Okay. Would you agree that prior to July 10, 2015, a
5 person of ordinary skill in the art would have been
6 aware of this BMS clinical study of MSI-High cancer
7 patients with PD-1 checkpoint blockade therapy?
8 A. Yes. And they would have been aware of many other
9 clinical trials that BMS was conducting using
10 nivolumab and using the nivolumab plus ipilimumab in
11 treating cancer, different cancer histologies.
12 Q. Okay. And I'm only asking questions right now about
13 this particular clinical trial, Doctor.
14 You would agree that prior to July 10,
15 2015, a person of ordinary skill would have been aware
16 of the 32 study record versions of BMS's clinical
17 trial spanning from February 10, 2014, through
18 July 3rd, 2015. Right?
19 MR. MILLER: Objection to the form of the
20 question.
21 A. You said 32?
22 BY MR. RATLIFF:

1 Q. Yes.
2 A. That appears to be correct.
3 Q. Are you aware of any public evidence suggesting that
4 BMS had given up or stopped its clinical trial of
5 MSI-High cancer patients with PD-1 checkpoint blockade
6 therapy?
7 A. I'm not aware of any such announcement by BMS.
8 Q. Are you aware of any public evidence stating that
9 BMS's clinical study would not support an
10 understanding that MSI-High cancer patients would be
11 particularly good candidates for PD-1 checkpoint
12 blockade therapy?
13 A. I am not aware.
14 Q. And on this issue of whether there would have been
15 reason to suspect that MSI-High cancer patients would
16 be particularly good candidates for PD-1 checkpoint
17 blockade therapy, you would agree that the MSI-High
18 Study Record, again, Exhibit 1005, would have been
19 known to a person of ordinary skill in the art as of
20 July 10, 2015. Right?
21 MR. MILLER: Objection to the form of the
22 question, in particular the predicate.

1 A. Yeah, that was a very long preamble. I'm not sure
2 that I remember the preamble, but I would agree that
3 the study record would have been known.
4 BY MR. RATLIFF:
5 Q. And you understand that more than two years passed
6 from the announcement of the clinical trial in the MSR
7 and JHU's alleged July 10, 2015, invention date.
8 Right?
9 MR. MILLER: Objection to the form of the
10 question.
11 A. The earliest version on record was June 10th of 2013,
12 and the critical date is July 10th, 2015.
13 BY MR. RATLIFF:
14 Q. So you understand that more than two years passed from
15 the announcement of the clinical trial in the MSR and
16 JHU's alleged invention date. Right?
17 MR. MILLER: Objection to the form of the
18 question.
19 A. There appears to be two years and one month between
20 the earliest version of the MSR -- the earliest
21 version posted in the MSR and the critical date.
22 BY MR. RATLIFF:

1 Q. And by "the critical date," we're talking about the
2 July 10, 2015, date. Right?
3 A. That is correct. And that would be two years and one
4 month.
5 Q. And in that more than two-year period, can you cite
6 for me any public statement where someone said that
7 the clinical trial announced in the MSR would not be
8 successful?
9 A. I am not aware of any such announcement.
10 Q. And in that more than two-year period, can you cite
11 for me any public article or any publication
12 whatsoever where it states that the clinical trial
13 announced in the MSR would not work?
14 A. Specifically pointing to the MSR?
15 Q. Let me try my question again. I want to be sure you
16 heard it.
17 In that more than two-year period, can you
18 cite for me any public article or any publication
19 whatsoever where it states that the clinical trial
20 announced in the MSR would not work?
21 A. So does that -- public statement have to refer
22 specifically to the MSR?

1 Q. That's what I'm asking.
2 A. I'm not aware of any public statements referring
3 specifically to the MSR.
4 Q. And in that more than two-year period, can you cite
5 for me any public article, statement, or publication
6 whatsoever where it states that the clinical trial
7 announced in the MSR would not support that MSI-High
8 cancer patients would be particularly good candidates
9 for PD-1 checkpoint blockade therapy?
10 A. Does that publication -- does that public statement
11 have to refer specifically to that clinical trial?
12 Q. Yes, that's what I'm asking about.
13 A. So it's not a publication that is talking about
14 MSI-High colorectal cancer patients, but doesn't
15 refer specifically to that trial.
16 Q. Let me try my question again. In the more than
17 two-year period that we've been discussing, can you
18 cite for me any public article, statement, or
19 publication whatsoever where it states that the
20 clinical trial announced in the MSR would not support
21 that MSI-High cancer patients would be particularly
22 good candidates for PD-1 checkpoint blockade therapy?

1 A. I'm just having trouble with direct or indirect
2 because are you asking if that public statement had
3 to directly refer to the clinical trial or if it
4 could provide evidence that the clinical trial would
5 not have worked?
6 Q. Doctor, I don't want to get into indirect. That's too
7 subjective. I'm asking for a specific citation to the
8 clinical trial announced in the MSR. So let me try my
9 question again.
10 In the more than two-year period that we've
11 been discussing, can you cite for me any public
12 article, statement, or publication whatsoever where it
13 states that the clinical trial announced in the MSR
14 would not support that MSI-High cancer patients would
15 be particularly good candidates for PD-1 checkpoint
16 blockade therapy, yes or no?
17 A. I'm not aware of any public statements that
18 specifically refer to that clinical trial and state
19 that the clinical trial would not have worked.
20 Q. So let's take a look at the MSR, which is
21 Exhibit 1005.
22 A. Okay.

1 Q. Now, the MSR includes a specific section describing
2 eligibility criteria for the trial announced in the
3 study record. Right?
4 A. That is correct. Yes.
5 Q. The MSR says that all sexes are eligible for the
6 study. Right?
7 A. That is correct.
8 Q. The MSR discloses that all eligible patients must meet
9 the inclusion criteria set forth, the number of items
10 4 through 10 underneath the heading Inclusion Criteria
11 that appears at page 5 of the MSR. Right?
12 A. That is correct.
13 Q. And as you understand it, the inclusion criteria
14 non-exhaustively includes adults following within any
15 of the study arms with measurable disease, adequate
16 organ function, willingness and ability to comply with
17 study procedures, and agreement to submit a biopsy of
18 their cancer. Right?
19 A. That is correct.
20 Q. And by "non-exhaustively," you mean that a patient can
21 be eligible for the study if they have other
22 characteristics and background so long as they do not

1 match any of the exclusion criteria listed on page 6
2 of the MSR; is that right?
3 A. Exclusion criteria begins on page 5.
4 Q. All right. So let me try my question again.
5 By "non-exhaustively," you mean that a
6 patient can be eligible for the study if they have
7 other characteristics or background so long as they do
8 not match any of the exclusion criteria listed in the
9 MSR. Right?
10 A. That is correct.
11 Q. And you would agree that the only exclusion criteria
12 disclosed in the MSR is the seven numbered items
13 underneath the heading Exclusion Criteria. Right?
14 A. That is correct.
15 Q. You would agree that the MSR does not teach excluding
16 patients of a certain race. Right?
17 A. That is correct.
18 Q. Race is not listed in the exclusion criteria. Right?
19 A. That is correct.
20 Q. And you would agree that the person of ordinary skill
21 would understand that persons of all races are
22 eligible for inclusion in the study because race is

1 not listed in the exclusion criteria. Right?
2 A. That is correct.
3 Q. And you know from the New England Journal of Medicine
4 article, Exhibit 1031, that patients of different
5 races were included in the study that was announced in
6 the MSR. Right?
7 A. I don't have the -- that exhibit in front of me.
8 Q. Well, do you know?
9 A. I would have to --
10 Q. Let me ask my question.
11 Do you know that patients of different
12 races were included in the study that was announced in
13 the MSR?
14 A. I don't remember with sufficient clarity to testify
15 under oath. I'd like to look at the exhibit.
16 Q. Okay. So let's take a look at Exhibit 1031, which is
17 the New England Journal of Medicine article that you
18 cite to in your declarations. We'll put that in the
19 Chat.
20 PLANET DEPOS TECH: And I apologize,
21 Counsel, can you repeat that exhibit number?
22 MR. RATLIFF: 1031.

1 PLANET DEPOS TECH: Thank you. Please
2 stand by.
3 BY MR. RATLIFF:
4 Q. Just let me know when you have it downloaded, Doctor.
5 A. Okay, I have it.
6 Q. So my question is, patients of different races were
7 included in the study that was announced in the MSR.
8 Right?
9 MR. MILLER: Objection to the form of the
10 question.
11 A. That is correct.
12 BY MR. RATLIFF:
13 Q. Now, I want to turn your attention back to the MSR,
14 and in particular, to exclusion criteria number 7.
15 Let me know when you have it.
16 A. Yes, I have it.
17 Q. The MSR discloses that if a patient is dependent on
18 drinking alcohol such that it would affect the
19 patient's ability to comply with study visits and
20 procedures, that patient cannot be included in the
21 study. Right?
22 A. It says, "Conditions, including alcohol or drug

1 dependence, or intercurrent illness that would affect
2 the patient's ability to comply with study visits and
3 procedures."
4 Q. Okay, I'm not asking for what it says, and my question
5 is not about drug dependence or intercurrent illness.
6 My question is specific about alcohol dependency. So
7 let me try my question again.
8 The MSR discloses that if a patient is
9 dependent on drinking alcohol such that it would
10 affect the patient's ability to comply with study
11 visits and procedures, that patient cannot be included
12 in the study. Right?
13 A. I'm trying to parse the grammar. Conditions, comma,
14 including alcohol or drug dependence, comma, or
15 intercurrent illness that would affect the patient's
16 ability to comply with study visits and procedures.
17 It may be from the grammar that
18 specifically it is intercurrent illness that would
19 affect the patient's ability to comply with study
20 visits and not necessarily alcohol dependence that
21 would affect the patient's ability to comply with
22 study visits and procedures.

1 Q. Okay. So sitting here today, you don't know whether
2 or not the study just excludes a patient that's
3 dependent on alcohol or if the study excludes a
4 patient that drinks alcohol such that it would affect
5 the patient's ability to comply with study visits and
6 procedures. Is that what you're saying?
7 A. I don't -- I don't know if someone who had an alcohol
8 dependence, but their alcohol dependence would not
9 affect their ability to comply with study visits and
10 procedures, would be included in the clinical trial.
11 It appears that anyone who had alcohol
12 dependence would be excluded from the clinical trial.
13 Q. Okay. Would you agree that it would be understood
14 from the MSR that if a patient socially drinks alcohol
15 but does not have an alcohol dependence, that patient
16 would still be eligible for the study and can be
17 included in the study?
18 A. I don't see any exclusion criteria that refers to
19 alcohol consumption in the absence of dependence.
20 Q. Okay. So you would agree that it would be understood
21 from the MSR that if a patient socially drinks
22 alcohol, was not alcohol dependent, that patient is

1 eligible for the study. Right?
2 A. That is correct.
3 Q. Now, let me turn your attention to exclusion
4 criteria 5. Let me know when you have it.
5 A. I have it.
6 Q. The MSR discloses that if a patient has received
7 another investigational product within 28 days prior
8 to receiving the study drug pembrolizumab, that
9 patient cannot be included in the study. Right?
10 A. That is correct.
11 Q. But you would agree that the MSR is making clear that
12 if a patient has received another investigational
13 product more than 28 days prior to receiving the study
14 drug, that patient is still eligible for the study and
15 can be included in the study. Right?
16 A. It depends on what that particular investigational
17 product was.
18 Q. Okay. So you would agree that the MSR is making clear
19 that if a patient has received another investigational
20 product more than 28 days prior to receiving the study
21 drug, that patient is still eligible for the study so
22 long as they meet the inclusion criteria and do not

1 match the other exclusion criteria listed in the MSR.
2 Right?
3 MR. MILLER: Objection to the form of the
4 question.
5 A. That was a -- an architecturally clumsy sentence, but
6 I believe you're referring to exclusion criteria
7 number 4, which reads, "Patients who have had prior
8 treatment with anti-PD-1, anti-PD-L1, anti-PD-L2,
9 anti-CD137, anti-OX-40, anti-CD40, or anti-CTLA-4
10 antibodies."
11 BY MR. RATLIFF:
12 Q. Again, I'm not sure if I got an answer to my question,
13 but let's talk about exclusion criteria number 4.
14 So, there, the MSR is disclosing that a
15 patient who has had prior treatments with anti-PD-1,
16 anti-PD-L1, anti-PD-L2, anti-CD137, anti-OX-40,
17 anti-CD40, or anti-CTLA-4 antibodies must be excluded
18 from the study. Right?
19 A. That is correct.
20 Q. So would you agree that the MSR is telling the reader
21 that if a patient had a prior treatment that is not
22 one of these listed therapies that we just talked

1 about, the patient is still eligible and may be
2 included in the study?
3 A. If they meet the inclusion criteria and do not meet
4 the other exclusion criteria.
5 Q. Okay. Now, is there anywhere in the MSR where the MSR
6 tells the reader to exclude from the study a patient
7 that has received at least one prior cancer therapy if
8 that patient has otherwise met both -- has met -- let
9 me try that again.
10 Is there anywhere in the MSR where the MSR
11 tells the reader to exclude from the study a patient
12 that has received at least one prior cancer therapy if
13 that patient has otherwise met the inclusion criteria
14 and does not match any of the exclusion criteria?
15 MR. MILLER: Objection to the form of the
16 question.
17 A. Other prior treatments except for the treatments
18 listed in exclusion criteria number 4 are not part of
19 the exclusion criteria.
20 BY MR. RATLIFF:
21 Q. Let me try my question again because I'm not sure you
22 answered it.

1 Is there anywhere in the MSR where the MSR
2 tells the reader to exclude from the study a patient
3 that has received at least one prior cancer therapy if
4 that patient has met the inclusion criteria and does
5 not meet any of the exclusion criteria listed in the
6 MSR?
7 MR. MILLER: Objection to the form of the
8 question.
9 A. I don't see anywhere else in the exclusion criteria
10 for other treatments other than those in exclusion
11 criteria number 4.
12 BY MR. RATLIFF:
13 Q. Is there anywhere in the MSR where the MSR tells the
14 reader to exclude from the study a patient that has
15 had their tumor progress following a cancer therapy so
16 long as that patient otherwise meets the inclusion
17 criteria and does not meet any of the exclusion
18 criteria?
19 MR. MILLER: Objection to the form of the
20 question.
21 A. None of the exclusion criteria refers to progression.
22 BY MR. RATLIFF:

1 Q. So my question is a little bit different.
2 Is there anywhere in the MSR where the MSR
3 tells the reader to exclude from the study a patient
4 that has had their tumor progress following a cancer
5 therapy so long as that patient meets the inclusion
6 criteria and does not meet the exclusion criteria?
7 MR. MILLER: Objection to the form of the
8 question.
9 A. The only place in the MSR where that would come up
10 would be within the exclusion criteria, and there is
11 nothing in the exclusion criteria that mentions
12 progression.
13 BY MR. RATLIFF:
14 Q. Is there anywhere in the MSR where the MSR tells the
15 reader to exclude from the study a patient that has
16 metastatic disease so long as that patient meets the
17 inclusion criteria and does not meet any of the
18 exclusion criteria set forth in the MSR?
19 A. I don't see any -- any mention of "metastatic."
20 Q. Okay. And I didn't ask you if you saw any mention of
21 "metastatic." My question is different.
22 Is there anywhere in the MSR where it tells

1 the reader to exclude from the study a patient that
2 has metastatic disease so long as the patient meets
3 the inclusion criteria and does not meet the exclusion
4 criteria?
5 A. Metastatic disease is not part of the exclusion
6 criteria or the inclusion criteria.
7 Q. So is there anywhere in the MSR where you think it
8 tells the reader to exclude from the study a patient
9 that has metastatic disease?
10 A. No.
11 Q. Is there anywhere in the MSR where it tells the reader
12 to exclude from the study a patient that has
13 metastatic colorectal cancer?
14 A. To exclude patients with metastatic colorectal
15 cancer?
16 Q. Correct.
17 A. Again, I don't see any mention of the word
18 "metastatic" in either the inclusion criteria or the
19 exclusion criteria.
20 Q. Okay. So just know I'm not asking you for a mention
21 of the word. I'm asking for your understanding of the
22 MSR, as a person who I believe said you viewed this

1 from the perspective of a person of ordinary skill in
2 the art; is that right?
3 A. That is correct.
4 Q. So is there anywhere in the MSR where the MSR tells
5 the reader to exclude from the study a patient that
6 has metastatic colorectal cancer?
7 A. No.
8 Q. Now, on this question of whether the MSR teaches that
9 a cancer patient that had received a prior cancer
10 therapy is eligible for inclusion so long as the
11 patient does not meet any of the exclusion criteria,
12 you understand that all patients enrolled in the study
13 and reported on in the New England Journal of Medicine
14 article had received at least one prior cancer
15 therapy. Right?
16 A. Let me review the New England journal article.
17 MR. MILLER: And, Counsel, while the
18 doctor's doing that, we've been going for well over an
19 hour. Once he's answered your question, I'd like to
20 take a break.
21 A. In Table 1, under Demographic and Baseline
22 Characteristics of the patients, there is a set of

1 rows for previous therapies, and there were patients
2 with one, two, three, or greater than four therapies,
3 but there are no patients listed that had zero prior
4 therapy.
5 BY MR. RATLIFF:
6 Q. Okay. And you understand that for the --
7 MR. MILLER: And, again, Counsel, I asked
8 that we take a break after he answered. I'd like to
9 do that.
10 MR. RATLIFF: Dr. Lonberg, would you like
11 to take a break now?
12 THE WITNESS: Yes.
13 MR. RATLIFF: Okay, let's take a break.
14 (Off the record at 1:11 p.m.)
15 (Back on the record at 1:21 p.m.)
16 BY MR. RATLIFF:
17 Q. Now, Doctor, during the break did you speak with
18 counsel?
19 A. No, I did not.
20 Q. And, Doctor, before our break we were discussing the
21 New England Journal of Medicine article that reports
22 on the 41 patients from the clinical trial announced

1 in the MSR that were enrolled and treated from the
2 period of September 2013 through January 2015.
3 Do you recall that?
4 MR. MILLER: Sorry, I don't think my mic
5 was on. Objection to the form of the question.
6 BY MR. RATLIFF:
7 Q. Do you recall that, Doctor?
8 A. Recall that 41 patients were enrolled in the trial?
9 Q. Do you recall that -- right, we -- do you recall that
10 we were -- before the break, we were discussing the 41
11 patients that were enrolled in the trial that was
12 announced in the MSR?
13 A. Yes.
14 Q. Okay. And you understand that for the colorectal
15 cancer patients in that trial, all 32 patients had
16 received two prior cancer therapies. Right?
17 A. Yes, two or more.
18 Q. Okay. And that's consistent with Dr. Neugut's
19 understanding from the MSR that the colorectal cancer
20 patients participating in the study would have
21 generally received at least two other prior drug
22 therapies. Right?

1 A. I don't recall what Dr. Neugut put in this
2 declaration.
3 Q. Well, you read Dr. Neugut's declaration. Right?
4 A. That's correct.
5 Q. Let's take a look at Dr. Neugut's declaration as to
6 the '356 patent. It's Exhibit 1003. We'll put that
7 in the Chat.
8 PLANET DEPOS TECH: Please stand by.
9 BY MR. RATLIFF:
10 Q. And just let me know when you have it, Doctor.
11 Do you have it?
12 A. It hasn't appeared yet in the Chat.
13 Now I have it.
14 Q. Okay. Can you turn your attention to paragraph 77 of
15 Dr. Neugut's declaration which appears at numbered
16 page 45 of 99?
17 A. Yes.
18 Q. And you read Dr. Neugut's declaration. Right?
19 A. That is correct.
20 Q. And I believe you testified earlier that you
21 understand that for the colorectal cancer patients,
22 all 32 patients in the trial that was announced in the

1 MSR had received at least two prior cancer therapies.
2 Right?
3 A. That is correct.
4 Q. And that's consistent with what Dr. Neugut said was
5 his understanding from the MSR, that the colorectal
6 cancer patients participating in the study would have
7 generally received at least two other prior drug
8 therapies and had their cancer progress after those
9 drug therapies. Right?
10 A. Yes. In Dr. Neugut's declaration he writes that,
11 "Patients having metastatic and advanced colorectal
12 cancer would participate in a clinical study, like
13 the MSI-High Study, would have generally received at
14 least two other prior drug therapies."
15 Q. And Dr. Neugut's understanding is consistent with what
16 actually happened as to the colorectal cancer patients
17 in the trial that was announced in the MSR. Right?
18 MR. MILLER: Objection to the form of the
19 question.
20 A. That is correct.
21 BY MR. RATLIFF:
22 Q. And you understand that for the non-colorectal cancer

1 cohort, all patients had received one or more prior
2 cancer therapies. Right?
3 A. That is correct.
4 Q. And you understand that all 41 cancer patients treated
5 in the study had received one or more prior cancer
6 therapies. Right?
7 A. That is correct.
8 Q. And you understand that all 41 cancer patients treated
9 in the study had metastatic disease. Right?
10 A. That is correct.
11 Q. Okay. I want to make sure I understand your
12 testimony. Doctor, you're not saying that the MSR
13 teaches that cancer patients who have received at
14 least one prior cancer therapy are ineligible for the
15 clinical study announced in the MSR. Right?
16 A. There is no exclusion criteria in the MSR that refers
17 to metastatic disease.
18 Q. My question, are you saying that the MSR teaches that
19 cancer patients who have received at least one prior
20 cancer therapy are ineligible for the clinical study?
21 A. Oh, I'm sorry. I misremembered your question.
22 There is -- there is no general exclusion

1 for prior therapies, there's only exclusion for a
2 subset of specific therapies and for therapy -- for
3 investigational therapies within 28 days prior to
4 receiving the study drug.
5 Q. Okay. So you're not saying that the MSR teaches that
6 cancer patients who had received at least one prior
7 cancer therapy are ineligible for the clinical study.
8 Right?
9 A. That's correct.
10 Q. And so is it your opinion that the treatment method in
11 the MSR is not limited or does not require treatment
12 of only patients who have received at least one prior
13 cancer therapy?
14 A. That is correct.
15 Q. And you're not saying that the MSR teaches that cancer
16 patients who have not had their cancer progress after
17 at least one prior therapy are ineligible for the
18 clinical study. Right?
19 A. No, there's nothing in the MSR that specifies that.
20 Q. Okay. So your opinion is that the treatment method in
21 the MSR is not limited or does not require treatment
22 of only patients that have had their cancer progress

1 after at least one prior therapy. Right?
2 A. That is correct.
3 Q. And, Doctor, you're not saying that the MSR teaches
4 that cancer patients who have metastatic disease are
5 not eligible for the clinical study. Right?
6 A. That is correct.
7 Q. Your opinion is that the treatment method in the MSR
8 is not limited or does not require treatment of only
9 patients who have metastatic disease. Right?
10 A. That is correct.
11 Q. Now, Doctor, in your view, the MSR was updated in
12 January 2016 to require prior cancer treatment; is
13 that right?
14 A. I don't recall.
15 Q. Okay. So let's take a look at your declaration as to
16 the '356 patent, and this is Exhibit 2072. I think
17 you have a copy of that, Doctor.
18 A. Which declaration?
19 Q. It's your declaration as to the '356 patent.
20 A. Okay, I have that.
21 Q. Okay. Can you turn your attention to paragraph 96 of
22 that declaration? And let me know when you have it,

1 Doctor.
2 A. Yes, I have it.
3 Q. Okay. And in paragraph 96, you refer to a
4 January 2016 version of the MSI-High study record; is
5 that right?
6 A. I do, yes.
7 Q. And is that January 2016 study record version a
8 version that you looked up or was that a version that
9 counsel provided and suggested to you?
10 A. I don't recall.
11 Q. Sitting here today, you have no recollection one way
12 or another?
13 A. No.
14 Q. Do you have any recollection of going to
15 clinicaltrials.gov and searching for study record
16 versions of the MSI-High study?
17 A. I likely did, but I don't have a specific
18 recollection. I go to the clinicaltrials.gov all the
19 time.
20 Q. Okay. But when you go to the clinicaltrials.gov site
21 all the time, are you searching for study record
22 versions of the MSI-High study?

1 A. I believe I have done that, but I don't have a
2 specific recollection.
3 Q. Okay. Now, Doctor, you appreciate that the
4 January 2016 study record version that you cite to in
5 paragraph 96 of your declaration as to the '356 patent
6 was posted after JHU's alleged July 10, 2015,
7 invention date. Right?
8 MR. MILLER: Objection to the form of the
9 question.
10 A. January 2016 is later than July 2015.
11 BY MR. RATLIFF:
12 Q. Okay. So let me try my question.
13 You appreciate that the January 2016 study
14 record that you cite to in your declaration, in
15 paragraph 96, as to the '356 patent was posted after
16 JHU's alleged July 10, 2015, invention date. Right?
17 MR. MILLER: Objection to the form of the
18 question.
19 A. After the critical date. Correct.
20 BY MR. RATLIFF:
21 Q. Okay. And when you -- when you say "critical date,"
22 it's the same date; the alleged invention date is the

1 same date as what you say is the critical date.
2 Right?
3 MR. MILLER: Objection to the form of the
4 question.
5 A. If you mean the same thing when you're saying
6 "invention date."
7 BY MR. RATLIFF:
8 Q. I absolutely mean the same thing.
9 A. Okay.
10 Q. Now, do you know why the eligibility criteria was
11 updated in the January 2016 study record that you cite
12 in paragraph 96 of your declaration as to the '356
13 patent?
14 A. No, I don't have any recollection.
15 Q. Did you speak with anyone at JHU to ask why the
16 eligibility criteria was updated in the January 2016
17 study record version?
18 A. Not that I can recall.
19 Q. Did you speak with anyone from Merck to ask why the
20 eligibility criteria was updated in the January 2016
21 study record version?
22 A. No.

1 Q. Now, you appreciate that the criteria of the
2 January 2016 study record only appeared after the
3 clinical trial results were announced for the 41
4 patients enrolled in the trial described in the MSR.
5 Right?
6 A. 2016 is after the publication of the New England
7 Journal paper, Exhibit 1031.
8 Q. Okay. So let me try my question. You appreciate that
9 the criteria of the January 2016 study record only
10 appeared after the clinical trial results were
11 announced for the 41 patients enrolled in the trial
12 that's described in the MSR. Right?
13 A. Yes. It's January 2016, which is after the date that
14 the Le, et al, paper was published.
15 Q. Okay. And you do understand that all 41 patients
16 enrolled and treated from that period of
17 September 2013 and January 2015 did fit the inclusion
18 criteria of the January 2016 study record. Right?
19 A. I don't have the January 2016 study record in front
20 of me, but they did all have prior therapy, if that's
21 what you mean.
22 Q. Well, let's take a look at that January 2016 study

1 record that you cite.
2 MR. RATLIFF: If we can put in the Chat
3 Exhibit 2165.
4 PLANET DEPOS TECH: Please stand by.
5 BY MR. RATLIFF:
6 Q. And please me know when you have it, Doctor.
7 A. Okay. I have it.
8 Q. Now, the study record that you're looking at, do you
9 recall actually reviewing this before you signed your
10 eight declarations?
11 A. Yes.
12 Q. So let me ask my question again. Do you understand
13 that all 41 patients enrolled and treated from the
14 period September 2013 and January 2015 did fit the
15 inclusion criteria of the January 2016 study record?
16 A. Yes. I was reading the inclusion criteria to make
17 sure that it hasn't changed.
18 Yes, it says they've added two different
19 inclusion criteria, patients within -- with colon
20 cancer must have received at least two prior cancer
21 therapy regimens and patients with other cancer types
22 must have received at least one prior cancer therapy.

1 Q. And it's your understanding that all 41 patients
2 enrolled and treated from the period September 2013
3 and January 2015 fit the inclusion criteria of the
4 January 2016 study record. Right?
5 A. That is my understanding.
6 Q. And you would agree that all of the enrolled and
7 treated patients fit the patient profile that
8 Dr. Neugut said would be included. Right?
9 A. Dr. Neugut said that they would have generally
10 received at least two other prior drug therapies,
11 referring to the clinical cancer -- the colorectal
12 cancer patient. And I don't see right now in his
13 declaration whether he refers to non-colorectal
14 cancer patients or not.
15 Q. All right, let's take a look at Dr. Neugut's
16 declaration. I think you had it before. That's the
17 '356 patent, that's Exhibit 1003.
18 A. Yes.
19 Q. And turn your attention to paragraph 77.
20 A. Yes, I'm looking at it.
21 Q. And you would agree that the patients -- the
22 colorectal cancer patients that were enrolled and

1 treated in the study fit the patient profile that
2 Dr. Neugut said would be included. Right?
3 A. He only refers to one particular aspect of the
4 patient profile here, and that is that they would
5 have generally received at least two other prior drug
6 therapies, and that is consistent with the study
7 record, the new inclusion criteria.
8 Q. Okay. And Dr. Neugut said, from his reading of the
9 MSR, that these particular patients would have
10 received prior therapies. Right?
11 MR. MILLER: Objection to the form of the
12 question.
13 A. I thought we just -- I thought I just answered that
14 previously. I don't understand the difference
15 between your question now and the previous question.
16 BY MR. RATLIFF:
17 Q. Maybe I missed the answer.
18 Is it correct that Dr. Neugut said that
19 these particular patients, the colorectal cancer
20 patients, would have received prior therapies?
21 A. That's correct.
22 Q. Can you take a look at Dr. Neugut's declaration as to

1 the '462 patent? And it's Exhibit 1003. And we can
2 put that in the Chat if you don't have it.
3 A. The '462 patent, you said?
4 Q. Yes, '462 patent.
5 A. I have the '462 patent.
6 Q. So what I'd like you to look at is Dr. Neugut's
7 declaration as to the '462 patent, which we should be
8 putting in the Chat. It's Exhibit 1003.
9 PLANET DEPOS TECH: Yes, sir, it is in the
10 Chat now.
11 BY MR. RATLIFF:
12 Q. So let me know when you have it.
13 A. Sorry.
14 Q. No worries.
15 A. Okay, I have it.
16 Q. And you read Dr. Neugut's declaration as to the '462
17 patent. Right?
18 A. Yes, I believe I did.
19 Q. And can you turn your attention to paragraph 65 of
20 that declaration?
21 Let me know when you have it.
22 A. I have it.

1 Q. Do you see where Dr. Neugut testifies in paragraph 65,
2 quote, "In the context of the MSI-High study record,
3 based on these disclosures, the person of ordinary
4 skill would have concluded that patients in the
5 MSI-High study would have generally received a prior
6 cancer therapy drug and had their solid tumors
7 progress after receiving that prior treatment," end
8 quote? Do you see that?
9 A. Yes, I see that.
10 Q. And Dr. Neugut's view of the MSR is consistent with
11 all of the patients that were actually treated in the
12 study. Right?
13 A. Yes, all of the patients had received prior therapy.
14 Q. And can you turn your attention to paragraph 67 of
15 Dr. Neugut's declaration?
16 A. Yes.
17 Q. And let me know when you have it.
18 A. I have it.
19 Q. And do you see there that Dr. Neugut testifies, quote,
20 "Patients having metastatic and advanced endometrial,
21 small bowel, and gastric cancer that would participate
22 in a clinical study, like the MSI-High Study, would

1 have generally received at least one prior drug
2 therapy, such as standard of care chemotherapy, and
3 had their cancers progress following that drug
4 therapy," end quote?
5 A. Yes, I see that.
6 Q. And Dr. Neugut's view of what the MSR teaches was
7 consistent with the endometrial, small bowel, and
8 gastric cancer patients that actually participated in
9 the study. Right?
10 MR. MILLER: Let me just, sorry, interpose
11 an objection to the form of the question.
12 Go ahead.
13 A. So all of the patients in the study had received at
14 least one prior therapy, and that is consistent with
15 the text in paragraph 67 from Dr. Neugut -- Neugut's
16 declaration.
17 BY MR. RATLIFF:
18 Q. Okay. And let me turn your attention to Dr. Neugut's
19 declaration as to the '356 patent. Let me know when
20 you have it.
21 PLANET DEPOS TECH: Please stand by.
22 A. '356 patent?

1 MR. MILLER: You already have that one,
2 right, Preston?
3 THE WITNESS: Yeah, yeah.
4 BY MR. RATLIFF:
5 Q. '356 patent, Doctor.
6 A. I have that.
7 Q. And can you turn your attention to paragraph 56?
8 A. Okay.
9 Q. And you see in paragraph 56 where Dr. Neugut
10 testifies, "Again based on the fact that the MSI-High
11 Study Record requires patients with 'measurable
12 disease' to receive an experimental treatment...the
13 standard of care dictated that these patients had
14 metastatic or advanced disease."
15 Do you see that?
16 A. He writes here, "the standard of care dictated that
17 these patients had metastatic or advanced disease."
18 Q. Right. And Dr. Neugut's view of what the MSR taught
19 is consistent with the patients that were treated in
20 the trial. Right?
21 MR. MILLER: Objection to the form of the
22 question.

1 A. I'm sorry, could you ask the question again?
2 BY MR. RATLIFF:
3 Q. Dr. Neugut's view of what the MSR teaches is
4 consistent with the patients that were treated in the
5 trial. Right?
6 MR. MILLER: Same objection.
7 A. Dr. Neugut writes that, "based on the fact that the
8 MSI-High Study Record requires patients with
9 'measurable disease' to receive an experimental
10 treatment...the standard of care dictated that these
11 patients had metastatic or advanced disease."
12 BY MR. RATLIFF:
13 Q. Right, that's what he wrote. And you understand that
14 all enrolled 41 patients that were treated had
15 metastatic or advanced disease. Right?
16 A. All 41 patients treated had, I believe, Stage 4, yes.
17 Q. And so that's consistent with Dr. Neugut's view of the
18 study record's teaching. Right?
19 MR. MILLER: Objection to the form of the
20 question.
21 A. I believe that Dr. Neugut is making a broader
22 statement here. He's saying the standard of care

1 dictates, and I can't come to that conclusion right
2 now. I don't have -- I don't have a clear idea of
3 what the standard of care would have dictated at that
4 point.
5 BY MR. RATLIFF:
6 Q. Okay. And on this question of what the standard of
7 care dictated, is that standard of care something that
8 a clinical oncologist would have to follow? You don't
9 know?
10 A. I don't think they would have to follow it.
11 Q. Okay. Is that standard of care applicable to a
12 clinical oncologist?
13 A. A clinical oncologist will defer to the standard of
14 care, yes.
15 Q. Now, let's take a look at paragraph 109 of your
16 declaration as to the '356 patent.
17 A. Okay.
18 Q. On paragraph 109, you testify that the JHU inventors,
19 quote, "would not have known or expected their
20 hypothesis to be true prior to conducting the...trial
21 described in the MSI-High Study Record," end quote.
22 Right?

1 MR. MILLER: Objection. Form of the
2 question. Misquotes the document.
3 A. What I write is, "Put simply, the inventors of the
4 '356 Patent would not have known or expected their
5 hypothesis to be true prior to conducting the
6 speculative and experimental trial described by the
7 MSI-High Study Record. They performed the study not
8 with the goal of achieving FDA approval for an
9 indication they expected to succeed, but to
10 investigate whether their abstract theory had any
11 validity to it whatsoever."
12 BY MR. RATLIFF:
13 Q. And do you stand by that statement and declaration
14 sitting here today?
15 A. Yes, I do.
16 Q. And did you speak to Dr. Le or any one of the named
17 JHU inventors before you made that statement in your
18 '356 patent declaration?
19 A. I have not spoken to Dr. Le in probably over ten
20 years, and I have not spoken to any of the other
21 inventors since beginning work on this case.
22 Q. Okay, so let me try my question again because I don't

1 think you've answered it. I didn't ask you generally
2 if you spoke to Dr. Le or any of the named JHU
3 inventors. My question is different.
4 Did you speak to Dr. Le or any of the named
5 JHU inventors before you made this statement that
6 appears in paragraph 109 of your '356 declaration?
7 A. I spoke with Dr. Le over ten years ago, and that's
8 prior to making this declaration.
9 Q. Okay. And when you spoke with Dr. Le, did you ask
10 Dr. Le whether the statement that you were making was
11 true?
12 A. I have no recollection.
13 Q. Did you ever ask JHU's counsel in these IPR
14 proceedings if that the statement that you made in
15 paragraph 109 was truthful and accurate before you
16 declared and made that statement in your declarations?
17 A. You're asking me to disclose conversations with
18 counsel?
19 Q. Yes, there's nothing privileged about that.
20 A. Okay. I have no recollection of such a conversation.
21 Q. Okay. Do you know if JHU scientists ever told the
22 FDA, prior to enrolling patients in the trial

1 described in the MSR, that part of the rationale for
2 the study was that pembrolizumab was showing activity
3 in multiple tumor types, including melanoma and
4 non-small cell lung cancer?
5 A. Could you repeat that?
6 Q. Sure.
7 Do you know if JHU scientists ever told the
8 FDA, prior to enrolling patients in the trial
9 described in the MSR, that part of the rationale for
10 that trial was that pembrolizumab was showing activity
11 in multiple tumor types including melanoma and
12 non-small cell lung cancer?
13 A. I don't recall any conversation or communication back
14 and forth between the FDA and JHU scientists. I
15 don't -- I don't have a recollection of such a
16 document.
17 Q. Okay. Would you have wanted to know or have a
18 recollection of whether or not any of JHU's scientists
19 told the FDA that part of the rationale for the study
20 was that pembrolizumab was showing activity in
21 multiple tumor types, including melanoma and non-small
22 cell lung cancer, before making the statements that

1 you made in paragraph 109 of your '356 patent
2 declaration?
3 A. I don't think it would be necessary for me to know
4 whether or not they communicated with the FDA on that
5 specific topic because I knew that pembrolizumab was
6 active in those histologies.
7 Q. Okay. And you do -- well, let me ask you, Doctor, in
8 paragraph 109, aren't you referring to what the named
9 inventors of the '356 patent would have known or not
10 known?
11 A. Yes.
12 Q. Okay. Do you know if JHU scientists ever told the
13 FDA, prior to enrolling patients in the trial
14 described in the MSR, that part of the rationale for
15 the study was that previously nivolumab showed
16 activity in melanoma and non-small cell lung cancer?
17 A. I already told you that I'm not aware, sitting here
18 right now, of specific communication between the JHU
19 scientists and the FDA.
20 Q. Okay. So is the answer to my question, you don't
21 know?
22 I just have to ask the question, Doctor, so

1 let me try my question again, just so -- just so we're
2 clear.
3 Do you know if JHU's scientists ever told
4 the FDA, prior to enrolling patients in the trial
5 described in the MSR, that part of the rationale for
6 the study was that previously nivolumab showed
7 activity in melanoma and non-small cell lung cancer?
8 A. I am not aware, sitting here right now, of any
9 specific communication between the JHU scientists and
10 the FDA.
11 Q. And do you know if JHU scientists ever told the FDA,
12 prior to enrolling patients in the trial described in
13 the MSR, that part of the rationale for the study was
14 the complete response of a single colorectal cancer
15 patient known to have an MSI positive tumor?
16 A. I, sitting here right now, can't recall any specific
17 communication between the JHU scientists and the FDA.
18 Q. Doctor, have you ever read any parts of an IND
19 submission?
20 A. Yes.
21 Q. And is reading an IND submission something that you've
22 done before as part of your work as a scientist?

1 A. Yes.
2 Q. So let me show you a new exhibit.
3 MR. RATLIFF: We're going to mark it as
4 Exhibit 1116 as to all of the eight IPR proceedings
5 for which this deposition pertains, and we'll put the
6 new Exhibit 1116 in the Chat.
7 MARKED FOR IDENTIFICATION:
8 EXHIBIT 1116
9 2:03 p.m.
10 PLANET DEPOS TECH: Uploading now.
11 BY MR. RATLIFF:
12 Q. And, Doctor, just let me know when you have the
13 exhibit.
14 A. I have it now.
15 Q. So, Doctor, first question is, have you seen this
16 document before?
17 A. I don't recall.
18 Q. I can represent to you that this is a copy of an IND
19 submission by JHU that was provided to Merck as part
20 of these IPR proceedings.
21 [redacted]
22 [redacted]

1 [redacted]
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7 [redacted]
8 MR. MILLER: And, Counsel, while we're
9 waiting for the doctor to read this, I'd like to
10 designate the transcript "Highly Confidential" under
11 the -- just as highly confidential, given this
12 document is so designated.
13 MR. RATLIFF: Your designation does not
14 make the entire deposition transcript highly
15 confidential.
16 MR. MILLER: That's fine.
17 MR. RATLIFF: We can --
18 MR. MILLER: So this document certainly is
19 highly confidential and testimony concerning it will
20 be.
21 MR. RATLIFF: So we can deal with what
22 portions would be under seal after the deposition.

1 A. [redacted]

2 BY MR. RATLIFF:

3 Q. [redacted]

4 [redacted]

5 [redacted]

6 [redacted]

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9 [redacted] [redacted]

10 [redacted] [redacted]

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1 MR. MILLER: -- form of the question.

2 A. [redacted]

3 [redacted]

4 [redacted]

5 [redacted]

6 [redacted]

7 [redacted]

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15 [redacted]

16 [redacted]

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18 [redacted]

19 [redacted]

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21 [redacted]

22 [redacted]

1 You agree with that --

2 A. [redacted]

3 [redacted]

4 [redacted]

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9 STENOGRAPHER: Dr. Lonberg, if you could
10 just pause for a second at the end of the question to
11 make sure I am getting Mr. Miller's objections, that
12 would be great. Thanks.
13 BY MR. RATLIFF:
14 Q. [redacted]
15 [redacted]
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1 Q. [redacted]
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15 [redacted]
16 [redacted]
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18 [redacted]
19 [redacted]
20 [redacted]
21 BY MR. RATLIFF:
22 Q. Okay. Now, in your declaration as to the '356 patent

1 and as to the other patents, you refer to the clinical
2 study described in the MSR as, quote, an abstract
3 theory. Right?
4 A. Where in the declaration do I say that?
5 Q. Do you -- sitting here today, do you not recall using
6 the term "abstract theory"?
7 A. Not with sufficient clarity to testify under oath.
8 I'd like to review the document, so I'll --
9 Q. Doctor --
10 A. -- I'll start doing that.
11 Q. Doctor, what in your view --
12 A. No, I'm reading -- I'm reading the document so that I
13 can find it.
14 Q. Find what?
15 A. Find the statement that you just referred to.
16 Q. Okay, Doctor, I'll rescind that question. I'm on to a
17 new question.
18 A. Okay.
19 Q. My question is, what, in your view, is an abstract
20 theory?
21 A. I would -- I would use language like that to refer to
22 a hypothesis as opposed to a theory that has been

1 proven.
2 Q. Okay. So in your view, an abstract theory is
3 equivalent to a hypothesis; is that fair?
4 A. That would be the way I would use that language.
5 Q. [redacted]
6 [redacted]
7 [redacted]
8 [redacted]
9 [redacted]
10 [redacted]
11 MR. MILLER: Counsel, we've been going for
12 over an hour. I'd like to take a break.
13 MR. RATLIFF: Dr. Lonberg, would you like
14 to take a break?
15 THE WITNESS: Yes.
16 MR. RATLIFF: Let's take a break.
17 (Off the record at 2:26 p.m.)
18 (Back on the record at 2:39 p.m.)
19 BY MR. RATLIFF:
20 Q. Doctor, during the break did you speak with counsel?
21 A. No, I did not.
22 Q. Now, you understand that the FDA gave approval to

1 conduct the trial that's described in the MSR. Right?
2 A. That is correct.
3 Q. And is it your view that the FDA gives pharmaceutical
4 companies, universities, entities, individuals
5 approval to pursue abstract theories in critically ill
6 cancer patients --
7 A. Yes.
8 Q. -- such as --
9 A. Yes, they do.
10 Q. Okay. So let me -- let me just make sure I finish my
11 question.
12 Is it your view that the FDA gives
13 pharmaceutical companies, universities, entities, and
14 individuals approval to pursue abstract theories in
15 critically ill cancer patients such as the patient
16 population to which the MSR is directed?
17 A. Yes.
18 Q. And when you -- when you talk about an abstract
19 theory, you have in mind it's a hypothesis; is that
20 right?
21 A. That is correct.
22 Q. [redacted]

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12 Q. All right. And do you -- do you have an understanding
13 as to how you would use the term, quote, an
14 investigation -- "an invitation to investigate," end
15 quote?
16 A. I would use that in the context of an IND. That's
17 what an IND is. It is request to initiate an
18 investigation.
19 Q. And would you use that -- and would you use that
20 terminology in any other context, or have you?
21 A. I don't recall.
22 Q. Sitting here today, would you refer to all clinical

1 studies as, quote, "invitations to investigate," end
2 quote?
3 A. That seems reasonable. I'm not sure I would use that
4 particular phrase, but I would understand that.
5 Q. Okay. What clinical studies would you call, quote,
6 "an invitation to investigate," end quote, if not all?
7 A. I don't understand the question.
8 Q. Are there certain clinical studies or clinical trials
9 that you would describe as, quote, "an invitation to
10 investigate," end quote?
11 A. All clinical trials are investigative by nature, and
12 I'm not quite sure why you are putting "invitation"
13 in front of that. I'm not quite sure what you're --
14 where you're going with this.
15 Q. I'm just trying to understand how you use or may have
16 used the terminology, quote, "an invitation to
17 investigate."
18 A. I don't --
19 Q. I guess, can you -- go ahead.
20 A. I don't have any recollection of using that
21 particular phrase.
22 Q. Okay. And just sitting here today, is there any

1 meaning that you would subscribe to, quote, "an
2 invitation to investigate," end quote, as applied to a
3 clinical trial described in the study record?
4 A. They're all investigative -- investigational by
5 nature. I don't -- I don't quite understand the
6 context that you're putting the word "invitation."
7 Who are you inviting?
8 Q. Okay. And I'm just -- I'm just talking about
9 terminology that you may have used, the phrase
10 "invitation to investigate."
11 A. I don't have any recollection of using that phrase.
12 Sorry.
13 Q. Okay. And sitting here today, you don't have any
14 recollection of using that phrase in connection with
15 your work as a scientist; is that right?
16 A. I don't have any specific recollection of that
17 phrase, of using -- of my using that phrase.
18 Q. Did you have any recollection of ever using that
19 phrase, quote, "an invitation to investigate," end
20 quote, in these eight IPR proceedings?
21 A. I may have, but I -- I've written a lot, but I don't
22 have a specific recollection of that phrase.

1 Q. Okay. Is that a phrase that you commonly use in the
2 course of your work?
3 A. No, but it's plain English.
4 Q. Okay. And in that plain English to you, what does it
5 mean as applied to a clinical trial described in a
6 study record?
7 A. It would be an invitation to investigate. I'm sorry,
8 I don't understand. I don't understand the question.
9 Q. Other than the words --
10 A. Invite? You're asking -- you're asking someone to
11 investigate.
12 Q. Asking who? Is it anyone to investigate? What are
13 you --
14 A. I don't know the context of the phrase. I don't know
15 what you're talking about.
16 Q. Okay. Fair enough.
17 Would you agree that nowhere in the New
18 England Journal of Medicine article, Exhibit 1031,
19 that you cite, does it refer to the clinical trial
20 described in the MSR as, quote, "an abstract theory,"
21 end quote? You would agree with that. Right?
22 A. I'm reading it.

1 Q. You're reading what?
2 A. The Exhibit 1031.
3 Q. Okay. So after the abstract, they begin the test of
4 the paper on page 2510, and in the second paragraph
5 they state, "We hypothesized that this patient had
6 mismatch-repair deficiency." And then, "Our
7 hypothesis was correct." And then they come up --
8 they state the hypothesis -- that the study's based
9 on, they hypothesized "that mismatch repair-deficient
10 tumors are more responsive to PD-1 blockade than are
11 mismatch repair-proficient tumors."
12 So they're testing a hypothesis which I
13 would -- a hypothesis is different from a theory, in
14 that a theory is a proven hypothesis or a hypothesis
15 that has been tested and there's data to support it.
16 But if it's an abstract, it means that it -- it has
17 not yet been tested. It's only abstract, so it's a
18 hypothesis.
19 And then they state that, "To test this
20 hypothesis, we initiated a phase 2 clinical trial to
21 evaluate immune checkpoint blockade in patients whose
22 tumors had or did not have mismatch-repair

1 deficiency."
2 And then...
3 STENOGRAPHER: And, Dr. Lonberg, while
4 you're looking for that, I need you to read clearly so
5 I can understand you. I don't have the document in
6 front of me.
7 THE WITNESS: Okay.
8 BY MR. RATLIFF:
9 Q. Were you finished with your response, Doctor?
10 A. I'm looking at the discussion right now. "Support
11 the hypothesis that mismatch repair-deficient tumors
12 are more responsive to PD -- 1 blockade than are
13 mismatch repair-proficient tumors."
14 STENOGRAPHER: Again, Dr. Lonberg, I cannot
15 understand and type that quickly.
16 MR. MILLER: Doctor, just read that passage
17 again more slowly.
18 A. "The data," and then I'm going to skip over part of
19 it, "support the hypothesis that mismatch
20 repair-deficient tumors are more responsive to PD-1
21 blockade than are mismatch repair-proficient tumors."
22 So they discuss hypotheses and hypothesis

1 testing and then the results of the testing of the
2 hypothesis. So they seem to reduce an abstract theory
3 into an actual theory.
4 BY MR. RATLIFF:
5 Q. Doctor, do you know what was the question I asked you?
6 A. Could you repeat the question?
7 Q. No. Do you know what was the question that I asked
8 you? I don't want to waste time.
9 A. The best way to not waste time is for you to repeat
10 the question.
11 Q. Okay. Okay. Would you agree that nowhere in the New
12 England Journal of Medicine article, Exhibit 1031,
13 that you cite, does it refer to the clinical trial
14 described in the MSR as, quote, "an abstract theory,"
15 end quote.
16 A. No, they don't use -- I don't see anywhere where they
17 use the phrase "abstract theory."
18 Q. And would you agree that nowhere in the New England
19 Journal of Medicine article, Exhibit 1031, that you
20 cite, does it refer to the clinical trial described in
21 the MSR as, quote, "an invitation to investigate," end
22 quote?

1 A. I don't see that phrase used.
2 Q. Doctor, let's take a look at the '356 patent. I
3 believe you have a copy of that with you.
4 A. Yes.
5 Q. Now, when you read this patent, you saw that it
6 discloses treating three cohorts of patients. Right?
7 Doctor, I'm not sure if you heard me. When
8 you read this patent specification, you saw that it
9 discloses treating three cohorts of patients. Right?
10 A. Yes. In Example 4 of the patent, they disclose
11 cohorts A, B, and C.
12 Q. Okay. And one cohort is the MSI-High colorectal
13 cancer patients. Right?
14 A. Yes.
15 Q. And that is cohort A. Right?
16 A. Well, in Example 4 they refer to Table 1, and Table 1
17 has three different cohorts, but they don't label
18 them cohorts A, B, or C.
19 Q. Okay. But you read the entire patent specification.
20 Right?
21 A. That is correct.
22 Q. I think you told me earlier that, when you read it,

1 you understood the patent specification. Right?
2 A. That is correct.
3 Q. You told me that you weren't confused by anything in
4 the patent specification. Correct?
5 A. That is correct.
6 Q. Can you turn your attention to column 8 of the '356
7 patent, and in particular, turning your attention to
8 lines 20 through 27.
9 A. Did you say column 8?
10 Q. 8.
11 A. Okay.
12 Q. And turning your attention to the lines 20 to 27, can
13 you read those to yourself and let me know when you're
14 finished.
15 A. Yes.
16 Q. Okay. So of the three cohorts of patients that this
17 patent specification discloses as being treated, one
18 cohort is the MSI-High colorectal cancer patients.
19 Right?
20 A. That is correct. It's MMR deficient, is the language
21 used.
22 Q. Right. But that's the same thing as MSI-High. Right?

1 A. Yes.
2 Q. And that cohort is cohort A. Right?
3 A. That's correct.
4 Q. Another cohort that this patent specification
5 discloses treating is MSS colorectal cancer patients.
6 Right?
7 A. That is correct.
8 Q. And that means microsatellite stable colorectal cancer
9 patients. Right?
10 A. That is correct.
11 Q. And that is cohort B. Right?
12 A. That is correct.
13 Q. And the third cohort is MSI-High non-colorectal cancer
14 patients. Right?
15 A. That is correct.
16 Q. Now, for cohort B, the microsatellite stable
17 colorectal cancer patients, the patent specification
18 reports that, at 20 weeks, those patients in that
19 cohort had a new related progression-free survival
20 rate of 11 percent. Right?
21 A. I'm sorry, what -- at what date?
22 Q. At 20 weeks.

1 A. 20 weeks.
2 Q. Doctor, do you understand my question?
3 A. Yes, I'm looking for the 20-week number.
4 Q. Okay. I don't know if it helps you, but you can
5 direct your attention to column 16 of the '356 patent,
6 about lines 35 through 37.
7 Doctor, do you want to hear my question
8 again?
9 A. No, I'm looking at it.
10 Q. Okay.
11 A. The 20-week irPFS listed here for cohort B is
12 11 percent.
13 Q. Right. So for cohort B, the '356 patent specification
14 reports that for those microsatellite stable
15 colorectal cancer patients, at 20 weeks those patients
16 in that cohort had an immune-related, progression-free
17 survival of 11 percent. Right?
18 A. That is correct.
19 Q. So is it fair to say that treatment with pembrolizumab
20 gave some benefit to some microsatellite stable
21 patients in the study described in the MSR?
22 MR. MILLER: Object to the form of the

1 question.
2 A. I don't think that this data demonstrates that one
3 way or another. Hard to interpret it that way.
4 BY MR. RATLIFF:
5 Q. Okay. But is it fair to say that the '356 patent
6 specification discloses treating microsatellite stable
7 patients with pembrolizumab?
8 A. That is correct.
9 Q. Now, in your eight declarations for these IPR
10 proceedings, you allege that prior to the release of
11 the MSR trial results there was substantial skepticism
12 from experts that such a study was worth performing.
13 Do you recall that?
14 A. I'd like to see the language, that specific language
15 that you just used. Can you --
16 Q. Okay, so -- sure. But so let's take a look at your
17 declaration as to the '356 patent. It's Exhibit 2072.
18 A. Okay.
19 Q. Let me know when you have it.
20 A. I have it.
21 Q. And if you could turn your attention to paragraph 187.
22 And if you could just read the first sentence to

1 yourself and let me know when you're finished reading
2 that first sentence of paragraph 187.
3 Doctor, are you still reading that first
4 sentence of paragraph 187?
5 A. Sorry, I was reading the entire paragraph. Yes, I
6 read the first sentence.
7 Q. Okay. And so my question is about this first
8 sentence. When you say "prior to the trial results"
9 in your first sentence of paragraph 187 of your
10 declaration, are you referring to prior to the
11 issuance of the New England Journal of Medicine
12 article, Exhibit 1031?
13 A. Prior to Dr. Le's presentation at ASCO.
14 Q. That's what you mean by the actual release of the
15 trial results; is that right?
16 A. Yes.
17 Q. Now let's take a look at the '356 patent. I believe
18 you have a copy of it.
19 A. Yes.
20 Q. And can you turn your attention to the claims of that
21 patent?
22 A. Yes.

1 Q. And in particular, can you look at Claim 23 of the
2 patent, which is at column 28 of the patent?
3 A. Yes.
4 Q. And you read Claim 23 as part of your work in the --
5 A. Yes.
6 Q. -- IPR proceedings?
7 A. Yes.
8 Q. Claim 23 requires treating a population of cancer
9 patients. Right?
10 A. That is correct.
11 Q. And a population of cancer patients is more than one
12 patient. Right?
13 A. That is correct.
14 Q. And I understand that you're not a medical doctor, but
15 is it your opinion that an oncologist prescribing
16 Keytruda to a cancer patient, according to the
17 Keytruda labeling, would be treating a population of
18 cancer patients?
19 A. If they were part of a group or a hospital clinic
20 that was treating multiple patients then, yes, they
21 would be contributing to the treatment of the
22 population of cancer patients.

1 Q. Okay. So let me make sure I understand your
2 testimony.
3 So is it your opinion that an oncologist
4 who prescribes Keytruda to a cancer patient, according
5 to the Keytruda labeling, would be treating a
6 population of cancer patients?
7 A. If they were part of a group that -- that treated
8 multiple patients or if they had treated multiple
9 patients. Because that treatment of the single
10 patient would be then contributing to treating the
11 population of patients.
12 Q. Okay, I don't think you understand my question, then.
13 Let me try it again.
14 Is it your opinion that an oncologist that
15 prescribes Keytruda to a single cancer patient,
16 according to the Keytruda labeling, would they be
17 treating a population of cancer patients?
18 A. So they had never treated a cancer patient before,
19 that fell within the category of MSI-High or
20 mismatched repair-deficient and had progressed
21 following prior treatment?
22 Q. We can take that first. Yes.

1 A. If they had never treated any other patients and they
2 were not part of an oncology group practice or they
3 were not part of a hospital group, and so this was
4 the only experience they had with treating an
5 MSI-High or mismatched repair-deficient patient that
6 had progressed following prior treatment, then they
7 would not be practicing the claim of treating a
8 population.
9 Q. Okay. And so is it your opinion that if there is an
10 oncologist in a group of oncologists where one of
11 those oncologists prescribes Keytruda to a cancer
12 patient according to the Keytruda labeling, that
13 oncologist would be treating a population of cancer
14 patients?
15 A. If within that group other patients like that had
16 been treated, then by treating that single patient
17 they would have contributed to treating a population.
18 Q. And you keep saying "contributed to treating a patient
19 population." Are they actually -- is that single
20 oncologist treating a population by prescribing to a
21 single cancer patient, as you understand it? I
22 recognize you're not a medical doctor.

1 A. That group had practiced that method of treating the
2 population, and that individual physician would have
3 been part of that group.
4 Q. And is it your opinion that Claim 23 is directed to a
5 group of prescribing oncologists as opposed to a
6 single prescribing oncologist?
7 A. It could be. It would -- it would -- it would
8 include both.
9 Q. Okay. Now, Doctor, I asked you a question earlier,
10 and part of your response related to Dr. Le's
11 presentation at ASCO. Do you recall when that
12 presentation was made?
13 A. My recollection is it was around May 28th, 29th, 30,
14 31, in that range, of 20 -- of May of 2015.
15 Q. Okay.
16 MR. RATLIFF: Doctor, maybe let's take a
17 break now for about ten minutes. I may be able to
18 wrap this up. And how this works is, at the
19 conclusion of my questions your counsel may have an
20 opportunity to ask you questions, and then I would
21 again have an opportunity to ask you further
22 questions. But we'll see where things go.

1 THE WITNESS: Okay.
2 MR. RATLIFF: Let's take a break now.
3 (Off the record at 3:14 p.m.)
4 (Back on the record at 3:23 p.m.)
5 BY MR. RATLIFF:
6 Q. Doctor, during the break did you speak with your
7 counsel?
8 A. No, I did not.
9 Q. Now, in providing responses to the questions that I
10 have asked so far, you didn't intend to put any
11 hidden, ambiguous meanings in your responses. Right?
12 A. No, I did not.
13 Q. You didn't provide a response --
14 MR. MILLER: I apologize, my microphone was
15 off. I object to the form of the prior question.
16 Go ahead, Preston.
17 BY MR. RATLIFF:
18 Q. In providing responses to the questions that I have
19 asked so far, you tried to be as clear as possible.
20 Right?
21 A. Yes.
22 Q. And in providing responses to the questions that I've

1 asked so far, you tried to be complete to the best of
2 your ability. Right?
3 A. Yes.
4 Q. And sitting here right now, you're not aware of any
5 responses that you gave that were unclear or wrong.
6 Right?
7 A. I don't have any recollection of incorrect responses,
8 no.
9 MR. RATLIFF: So, Doctor, at this time I
10 have no further questions for you, but I may have
11 questions should your counsel ask you additional
12 questions.
13 MR. MILLER: Thank you, Counsel.
14 I just have a couple of questions, Doctor.
15 EXAMINATION
16 BY MR. MILLER:
17 Q. Same rules apply when I ask you questions as they did
18 when counsel for Merck was asking you questions.
19 Please pause when I ask you a question so that he can
20 interpose any objections he desires to make. Is that
21 okay, Doctor?
22 A. Yes.

1 Q. So earlier today you talked about the phrase "abstract
2 theory." Do you recall that?
3 A. Yes.
4 Q. And I believe you testified that that phrase is
5 generally synonymous to you with the word
6 "hypothesis"; is that correct?
7 A. That's correct.
8 Q. Now, you also used the phrase "invitation to
9 investigate." Is that an invitation to investigate a
10 hypothesis?
11 MR. RATLIFF: I object to the form of the
12 question.
13 A. It could be an invitation to investigate a
14 hypothesis.
15 BY MR. MILLER:
16 Q. Does the -- to your recollection, and we can bring it
17 up if necessary, does the New England Journal of
18 Medicine article by Dr. Le, et al, refer to an
19 investigation to investigate a -- sorry, let me just
20 reask that.
21 Does the New England Journal of Medicine
22 article from 2015 by Dr. Le, et al, reference an

1 invitation to investigate a hypothesis or otherwise
2 discuss a hypothesis that the inventors had?
3 MR. RATLIFF: I object to the form of those
4 questions.
5 A. Yes, it's quite clear from the New England Journal
6 paper that they are investigating a hypothesis.
7 BY MR. MILLER:
8 Q. You were asked some questions by counsel about the
9 '356 patent Claim 23. Do you recall that?
10 A. Yes.
11 Q. And you talked about a doctor who had not treated a
12 patient according to the claimed method previously.
13 Do you recall that?
14 A. Yes.
15 Q. Now, if that doctor who had not treated a patient
16 according to the method of Claim 23 previously treats
17 a patient according to the method and then treats
18 another patient according to the method, has that
19 doctor practiced Claim 23?
20 MR. RATLIFF: I object to the form of the
21 question as well as to the premise of the question.
22 A. Yes, because they have treated a plurality of

1 patients, and "population" refers to a plurality.
2 BY MR. MILLER:
3 Q. And if the doctor treated only one patient, but that
4 data from the treatment of that one patient was known
5 or used by other doctors, would the method be
6 practiced?
7 MR. RATLIFF: I object to the form of the
8 question as well as objecting as beyond the scope.
9 A. I'm sorry, can you repeat the question?
10 BY MR. MILLER:
11 Q. Yeah, yeah. So let's say this doctor treats a single
12 patient according to the method of Claim 23. All
13 right?
14 MR. RATLIFF: I object to the form of the
15 question and object as beyond the scope.
16 BY MR. MILLER:
17 Q. Do you understand the predicate that I'm laying out,
18 Doctor?
19 MR. RATLIFF: Same objections.
20 A. I believe so, yes.
21 BY MR. MILLER:
22 Q. All right. And if this doctor who has treated this

1 one patient is part of a group of oncologists -- let
2 me withdraw that.
3 Let's say this one doctor who has treated
4 this one patient one time has a medical partner who's
5 also an oncologist. Are you with me so far?
6 MR. RATLIFF: I object to the form of the
7 question as well as the question as being beyond the
8 scope.
9 A. Yes.
10 BY MR. MILLER:
11 Q. Now, let's say the doctor's partner, the other
12 oncologist, also treats a patient according to the
13 method of Claim 23. Have both doctors practiced
14 Claim 23?
15 A. Yes.
16 MR. RATLIFF: I object to the form of the
17 question as well as the question being beyond the
18 scope.
19 THE WITNESS: Sorry, I apologize for
20 answering too quickly.
21 A. Yes, collectively they have.
22 BY MR. MILLER:

1 Q. So let's take this further. The one doctor treats one
2 patient according to the method of Claim 23, and that
3 doctor is part of a medical practice with other
4 oncologists who also perform the method of Claim 23.
5 Has the one doctor and the other doctors in
6 the practice performed the method of Claim 23?
7 MR. RATLIFF: Objection. Beyond the scope.
8 Object to the form of the question.
9 A. Yes.
10 MR. MILLER: Thank you, Doctor, that's all
11 the questions I have for you at this time.
12 RE-EXAMINATION
13 BY MR. RATLIFF:
14 Q. Doctor, you had a conversation as part of these
15 proceedings with Dr. Richard Goldberg. Right?
16 MR. MILLER: Objection. This is beyond the
17 scope of my redirect.
18 But go ahead.
19 A. I had more than one conversation.
20 BY MR. RATLIFF:
21 Q. Right. And as you understand it, Dr. Goldberg was a
22 practicing oncologist. Right?

1 A. That's correct.
2 Q. And you've never been a practicing oncologist. Right?
3 A. That's correct.
4 Q. And, Doctor, have you ever seen any testimony that
5 Dr. Goldberg has given regarding Claim 23 of the '356
6 patent?
7 A. No, I have not.
8 Q. And, Doctor, do you have any respect or confidence in
9 the opinions that Dr. Goldberg has formulated for
10 these IPR proceedings?
11 MR. MILLER: Objection to the form of the
12 question.
13 A. Yes, I have respect for the conclusions that I have
14 seen.
15 BY MR. RATLIFF:
16 Q. And on this question -- strike that.
17 On these questions as to whether or not a
18 clinician would practice the method of Claim 3 --
19 strike that.
20 On these questions of whether or not a
21 clinician would practice the method of Claim 23 of the
22 '356 patent, do you believe that the board, in these

1 IPR proceedings, should take note of what Dr. Goldberg
2 has said about those questions?
3 MR. MILLER: Objection to the form of the
4 question. Beyond the scope of Dr. Lonberg's opinions.
5 A. I have not seen what Dr. Goldberg said, so I don't --
6 I have no opinion.
7 BY MR. RATLIFF:
8 Q. Okay. And on these questions of whether or not a
9 clinician would practice the method of Claim 23 of the
10 '356 patent, would you defer to the analysis and
11 opinions of Dr. Goldberg as a former practicing
12 oncologist?
13 MR. MILLER: Objection to the form of the
14 question.
15 A. Not before seeing the analysis and opinions.
16 BY MR. RATLIFF:
17 Q. And as someone that has never been a medical doctor,
18 is it your belief that your opinion as to the conduct
19 of a practicing oncologist should carry more weight
20 than the opinion of a practicing oncologist as to the
21 method of Claim 23 of the '356 patent?
22 MR. MILLER: Objection to the form of the

1 question.
2 A. I don't understand what you mean by "conduct." Do I
3 have an opinion as to how an oncologist should
4 conduct their work?
5 BY MR. RATLIFF:
6 Q. Let me try my question again. As someone that has
7 never been a medical doctor, is it your belief that
8 your opinion as to whether or not a practicing
9 oncologist would be practicing the Claim 23 of the
10 '356 patent should carry more weight than the opinion
11 of someone that has actually been a practicing
12 oncologist that has prescribed Keytruda?
13 MR. MILLER: Objection to the form of the
14 question.
15 A. That seems hypothetical, and I would have to see the
16 opinion or analysis before drawing a conclusion.
17 BY MR. RATLIFF:
18 Q. Sitting here today, would you say that your opinion
19 should carry more weight than a practicing oncologist
20 as to whether or not an oncologist would be practicing
21 the method of Claim 23 of the '356 patent?
22 MR. MILLER: Objection to the form of the

1 question.
2 BY MR. RATLIFF:
3 Q. Or do you not know, sitting here today?
4 A. I would -- I would have to see the actual opinion. I
5 wouldn't be able to come to a conclusion in the
6 abstract.
7 Q. Okay. And would you agree that it's not possible to
8 observe an objective response rate of between 12 to
9 96 percent from treating a single cancer patient?
10 MR. MILLER: Objection to the form of the
11 question.
12 BY MR. RATLIFF:
13 Q. It looks like you're pondering, Doctor. Let me help
14 you. Let me turn your attention to Claim 23 of the
15 '356 patent. Let me know when you have it in front of
16 you.
17 A. Yes, I have it in front of me.
18 Q. And do you see the part of the claim that talks about,
19 quote, "observing an objective response rate of about
20 12% to 96% in the population of cancer patients after
21 administration of pembrolizumab," end quote?
22 A. Yes.

1 Q. And would you agree that it's impossible to observe an
2 objective response rate of about 12 percent to
3 96 percent from treating a single cancer patient?
4 MR. MILLER: Objection to the form of the
5 question.
6 A. No. And that's why it refers to "in the population."
7 And the population is a plurality of patients.
8 BY MR. RATLIFF:
9 Q. There might have been a double negative in your
10 response, so let me ask the question again.
11 Would you agree that it is impossible to
12 observe an objective response rate of about 12 percent
13 to 96 percent when treating a single cancer patient?
14 MR. MILLER: Objection to the form of the
15 question.
16 A. No, and that's why this limitation refers to "of
17 about 12% to 96% in the population." And
18 "population" refers to a plurality of patients.
19 BY MR. RATLIFF:
20 Q. Let me try my question again. Do you believe -- and
21 I'll change it because I want to avoid the double
22 negative.

1 Do you believe that it's possible to
2 observe an objective response rate of about 12 percent
3 to 96 percent in a population of cancer patients if
4 you're only treating a single cancer patient?
5 MR. MILLER: Objection to the form of the
6 question.
7 A. Well, you could be treating a single cancer patient,
8 but in the context of others within your group who
9 are also treating cancer patients, in which case
10 collectively you would be observing. It's possible
11 to observe an objective response rate of about
12 12 percent to 96 percent in that population that was
13 collectively treated.
14 BY MR. RATLIFF:
15 Q. All right, let me try my question one more time.
16 Do you believe that it's possible to
17 observe an objective response rate of about 12 percent
18 to 96 percent in a population of cancer patients from
19 treating only a single cancer patient?
20 MR. MILLER: Objection to the form of the
21 question. Asked and answered.
22 A. Yes, if that single patient was within that

1 population.
2 BY MR. RATLIFF:
3 Q. Okay.
4 MR. RATLIFF: I have no additional
5 questions for you, Doctor.
6 MR. MILLER: Doctor, just a couple more
7 questions. Same guidelines apply.
8 RE-EXAMINATION
9 BY MR. MILLER:
10 Q. In the context of Claim 23 of the '356 patent, did you
11 conduct your own independent analysis of that claim in
12 view of the patent itself and other materials that
13 would be known to a person of skill in the art?
14 MR. RATLIFF: I object to the form of the
15 question.
16 A. Yes, I did.
17 BY MR. MILLER:
18 Q. And, Doctor, did you also review Dr. Goldberg's
19 written declarations with regard to -- sorry.
20 Did you also review Dr. Goldberg's written
21 declaration with regard to the '356 patent and,
22 specifically, Claim 23?

1 A. Yes, I did.
2 Q. And, Doctor, while you're not an oncologist, have you
3 worked with oncologists throughout your career?
4 MR. RATLIFF: I object to the form of the
5 question. Objection, beyond the scope.
6 A. I have worked with many oncologists and I've had
7 oncologists reporting to me.
8 MR. MILLER: Thank you, Doctor, that's all
9 the questions I have.
10 MR. RATLIFF: No questions, Doctor.
11 STENOGRAPHER: Anything further for the
12 record?
13 MR. RATLIFF: Nothing further.
14 (Proceedings concluded at 3:42 p.m.)
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1 CERTIFICATE OF NOTARY

2

3 STATE OF MICHIGAN)
) SS
4 COUNTY OF OAKLAND)

5

6 I, ALISON WEBSTER, stenographic
reporter and notary public in and for the state of
7 Michigan do hereby certify:
That the deposition of NILS LONBERG,
8 Ph.D. was taken before me via videoconference on
the date hereinbefore set forth; that the foregoing
9 questions and answers were recorded by me
stenographically and reduced to computer
10 transcription; that this is a true, full, and
correct transcript of my stenographic notes so
11 taken; and that I am not related to, nor of counsel
to, either party nor interested in the event of
12 this cause.
I further certify that the adverse party
13 was represented by counsel at the deposition.
I further certify that the deposition of
14 NILS LONBERG, Ph.D., occurred via Zoom videoconference
on Thursday, April 17, 2025, commencing at 12:01 p.m.,
15 and ending at 3:42 p.m.

16

17

18

19 Alison C. Webster
20 ALISON C. WEBSTER, CSR-6266, RPR, RMR, CRR, RDR
Notary Public, Oakland County, Michigan
21 My commission expires: May 1, 2029

22

1 ACKNOWLEDGMENT OF DEPONENT
2
3
4 I, NILS LONBERG, Ph.D., do hereby
5 acknowledge that I have read and examined the
6 foregoing testimony and the same is a true, correct,
7 and complete transcription of the testimony given by
8 me and any corrections appear on the attached errata
9 sheet signed by me.
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19 _____ _____
20 (SIGNATURE) (DATE)
21
22