

**UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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MERCK SHARP & DOHME, LLC

Petitioner,

CERTIFIED COPY

- against -

THE JOHNS HOPKINS UNIVERSITY,

Patent Owner.

**CASE IPR2024-00240 (US Patent No. 11,591,393)
Ref. 52261-0005IP1**

**STENOGRAPHIC DEPOSITION:
ALFRED I. NEUGUT, M.D., Ph.D., MPH
Monday, January 6, 2025
7:01 a.m. - 11:13 a.m.**

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**Stenographic deposition of ALFRED I.
NEUGUT, M.D., Ph.D., MPH, taken at the offices
of Paul Hastings, LLP, MetLife Building, 200
Park Avenue, New York, New York, commencing at
7:01 a.m., before Deborah L. Williams, a
Certified Court Reporter.**

- - -

NO. 25-146130

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**JHU 2282
Merck Sharp v. Johns Hopkins
IPR2024-00648**

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1 **A P P E A R A N C E S : (Continued)**

2 **ALSO PRESENT:**

3 **Mark Stewart, Esquire, Merck**
4 **Karen Moreira, Esquire, Merck**

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I N D E X

WITNESS	PAGE NO.
ALFRED I. NEUGUT, M.D., Ph.D., MPH	
By Ms. McCormick.....	5

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E X H I B I T S

NO.	DESCRIPTION	PAGE MARKED
Exhibit 2041	Document with Post-it....	107
Exhibit 2042	'356 patent with highlighting.....	107

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P R O C E E D I N G S
7:01 a.m.

ALFRED I. NEUGUT, M.D., Ph.D., MPH,
having been first duly sworn or affirmed,
was examined and testified as follows:

- - -

EXAMINATION

- - -

BY MS. McCORMICK:

Q. Good morning, Dr. Neugut. My name is Madelyn McCormick, and I represent patent owner Johns Hopkins in this proceeding, and I'll be asking some questions today. Okay?

A. Yes.

Q. Before we start, I'm going to go over the ground rules for this deposition.

You understand you are under oath, correct?

A. Yes.

Q. You understand that means you have to tell the truth, the whole truth and nothing but the truth, correct?

A. Yes.

Q. And you'll do that today, correct?

1 A. Yes.

2 Q. You also understand that the
3 testimony you give today is just as important
4 as if you were in a courtroom or in front of
5 the PTAB panel, correct?

6 A. Yes.

7 Q. So you understand that you must give
8 truthful, complete and accurate testimony
9 today, correct?

10 A. Yes.

11 Q. If you ever don't understand my
12 question, please let me know. Okay?

13 A. Yes.

14 Q. So if you answer a question, it's
15 fair for me to assume that you understood the
16 question?

17 A. Yes.

18 Q. If you ever want to take back,
19 change or modify an answer you give in any way,
20 please let me know. Okay?

21 A. Yes.

22 Q. That way we can get truthful,
23 complete and accurate testimony today. Okay?

24 A. Yes.

25 Q. We'll take a break about every hour,

1 but if you ever feel like you need a break
2 sooner, please let me know, and we'll do that.
3 Okay?

4 A. Thank you.

5 Q. Is there any reason, medical or
6 otherwise, why you cannot give truthful,
7 complete and accurate testimony today?

8 A. No.

9 Q. If that ever changes at any point
10 today, please let me know right away. Okay?

11 A. Yes.

12 Q. Dr. Neugut, if we use the term MSI
13 today, will you understand that I'm referring
14 to microsatellite instability?

15 A. Yes.

16 Q. If we use the term dMMR, will you
17 understand that I'm referring to mismatch
18 repair deficiency?

19 A. Yes.

20 Q. And can we also agree for the sake
21 of efficiency that if I say MSI high, it will
22 also encompass dMMR?

23 A. Yes.

24 Q. And if you ever want to make a
25 distinction between the two, please let me

1 know. Okay?

2 A. Yes.

3 Q. Dr. Neugut, we're here today to talk
4 about seven declarations you've submitted for
5 this proceeding, correct?

6 A. I believe there were eight, but am I
7 incorrect?

8 Q. You are correct that there were
9 eight.

10 What do you have in front of you
11 here today?

12 A. So I have here a declaration of
13 '462. So for each, I have the declaration and
14 the patent. So that's '462, '491, '187, '219,
15 '287, '356, '974 and '975. Then I also have
16 the MSI study record and then a pile of
17 publications that are germane to the case.

18 Q. I see there's a Post-it note on the
19 top of that pile of documents germane to the
20 case.

21 What does that say?

22 A. That says, "July 10, 2015, date of
23 analysis for the patent claim."

24 That's just to keep it fresh in my
25 mind that that's the date that's relevant to

1 the litigation. I don't know if litigation is
2 the right word for this, but whatever you call
3 it.

4 Q. Litigation works just fine.

5 And so you have a copy of each of
6 your declarations, correct?

7 A. Yes.

8 Q. And is there any notes or markings
9 on each of those declarations in front of you?

10 A. I don't think there's anything.
11 There might have been a little highlighting in
12 one or two of them but nothing that's grammatic
13 or important.

14 Q. And then you also have a printout of
15 each patent for each of your declarations; is
16 that correct?

17 A. You're referring to this?

18 Q. Yes.

19 A. Yes.

20 Q. Perfect. So I'm going to refer to
21 seven declarations today, so not the '287
22 declaration. You can set that one aside.

23 A. Okay.

24 Q. Dr. Neugut, for each of your
25 declarations that you submitted in this case,

1 the exhibit numbering that you refer to is the
2 same across all of your declarations, correct?

3 A. I believe so, yes.

4 Q. And other than the -- let me take a
5 step back here.

6 All of the exhibit numbering is the
7 same except for the patent number, correct? So
8 Exhibit 1 is the patent for each declaration;
9 is that right?

10 MR. RATLIFF: I object to the form
11 of the question.

12 THE WITNESS: Can you ask the
13 question again?

14 BY MS. McCORMICK:

15 Q. Sure. The Exhibit 1 [sic] that's
16 referred to in each of your declarations is the
17 patent number for that declaration, correct?

18 A. Yes.

19 Q. And then Exhibit 2 [sic] is the file
20 history -- Exhibit 1002 is the file history or
21 the prosecution history for that patent that's
22 referred to in your declaration, right?

23 A. Yes.

24 Q. So other than Exhibits 1001 and
25 1002, all the other exhibits referred to in

1 your declaration, the numbering is the same,
2 correct?

3 A. Yes.

4 Q. Dr. Neugut, I'd like to go through
5 each of your declarations. We'll try to do
6 this as efficiently as possible. You have a
7 copy of yours. Are you okay referring to the
8 '356 declaration?

9 A. Is that the one you would like to
10 start with?

11 Q. Yes, please. Do you have your '356
12 declaration, Exhibit 1003, in front of you?

13 A. What does the 1003 refer to?

14 Q. It's the marking on the bottom of
15 the first page.

16 A. Oh, I'm sorry. Yes.

17 Q. So you have Exhibit 1003, your '356
18 declaration, in front of you, correct?

19 A. Yes.

20 Q. And if you could turn to page 90 of
21 Exhibit 1003, your '356 patent declaration.

22 A. Now, each of these has two page
23 numbers. Can we make an agreement as to which
24 page number we're going to use going forward so
25 I'm not confused each time?

1 Q. Yes, I would love to do that. Let's
2 refer to the exhibit numbering, which is going
3 to have the page in front of it, page 90 of 99
4 in the lower left-hand corner of each page.

5 Does that work for you?

6 A. Either one is fine, but it would be
7 easiest if we were consistent.

8 Q. I agree 100 percent.

9 All right. So on page 90 of
10 Exhibit 1003, your '356 patent declaration, do
11 you see your signature?

12 A. Yes.

13 Q. And you signed it on March 4, 2024;
14 is that right?

15 A. Yes.

16 Q. And this declaration you are opining
17 on patent number 10,934,356, correct?

18 A. Yes.

19 Q. And for the '356 patent, the claims
20 of this patent don't list a specific cancer
21 type, correct?

22 MR. RATLIFF: I object to the form
23 of the question.

24 BY MS. McCORMICK:

25 Q. We can refer to the patent itself,

1 if that would be helpful, Dr. Neugut.

2 A. It's up to you.

3 Q. Let's look at the '356 patent. I
4 believe you have in front of you Exhibit 1001
5 and a claim in the back?

6 A. Yes.

7 Q. And page 30 of Exhibit 1001 for the
8 '356 patent, do you see a certain cancer type
9 listed in claim 1?

10 A. I'm sorry, what page is it of the
11 patent?

12 Q. Page 30 of 31 of the '356 patent.

13 MR. RATLIFF: His patents do not
14 have page numbers at the bottom.

15 THE WITNESS: The columns have
16 numbers, if that works for you, in my draft.
17 I don't know if you have that on your draft.

18 BY MS. McCORMICK:

19 Q. Yeah, no problem. Column 25.

20 A. Yes.

21 Q. I also see you have highlighting on
22 your copy of the patents, Dr. Neugut.

23 What have you highlighted there?

24 A. In claim 23, I just broke down the
25 claim into three or four parts with the

1 highlighting just to separate them.

2 Q. And what did you break the claim 23
3 down into, which parts?

4 A. A method for treating cancer in a
5 population of cancer patients in need thereof,
6 and then administering an effective amount of
7 pembrolizumab to patients in the population of
8 cancer patients, and then patients have a tumor
9 that exhibits a high microsatellite instability
10 (MSI high) or a mismatch repair deficiency
11 status, and said tumor having progressed
12 following a prior treatment, and then observing
13 an objective response rate of about 12 to 96
14 percent.

15 Q. Any other breakdowns?

16 A. No.

17 Q. And why did you break claim 23 down
18 into those five parts?

19 A. Just to have a better sense of what
20 was going on to see how it compared to claim 1
21 because it's a reprise on some level of claim
22 1. I just wanted to see how the two compared
23 to each other.

24 I don't believe I highlighted
25 anything else in -- anywhere else in any of the

1 other declarations -- I'm sorry, in any of the
2 other patents.

3 Q. And, Dr. Neugut, I would ask that
4 you keep your voice up. We have some blowers
5 back here.

6 A. I'm sorry.

7 Q. So what are the differences between
8 claim 1 and claim 23 that you notice?

9 A. As I'm sitting here now, I would
10 have to look at it for a few moments and think
11 about it. I don't have it fresh in my head.

12 Q. For the '356 patent, the population
13 of cancer patients being treated doesn't have a
14 specific cancer type, correct?

15 MR. RATLIFF: I object to the form
16 of the question.

17 THE WITNESS: That's correct.

18 BY MS. McCORMICK:

19 Q. If I call this cancer agnostic, will
20 you know what I mean?

21 MR. RATLIFF: I object to the form
22 of the question.

23 THE WITNESS: If you want to use
24 that term, that's okay with me.

25 BY MS. McCORMICK:

1 Q. Do you not like that phrase cancer
2 agnostic, or do you have a different phrase you
3 prefer rather than no cancer type specified?

4 A. It's not a scientific term, so -- I
5 don't know if it's a legal term. I mean, I
6 understand what it means in the context of this
7 patent because it presumably relates back to
8 the MSI study record and the context of what
9 we're talking about, but I don't like the term
10 cancer as a general entity. It doesn't refer
11 to -- it's not a good terminology in general,
12 but for our purposes if you want to call it
13 agnostic, I'm okay with that. I'll understand
14 what you mean.

15 Q. Are you aware that the FDA used that
16 term when it approved Keytruda for MSI high
17 regardless of cancer type?

18 MR. RATLIFF: I object to the form
19 of the question as well as to the premise of
20 the question.

21 THE WITNESS: I'm not aware, but if
22 that's the term they chose to use, it's okay
23 with me. Again, I understand what the term
24 means in the context that they're using it.

25 BY MS. McCORMICK:

1 Q. Just so we're on the same page, can
2 you tell me what you understand the term cancer
3 agnostic to mean in the context of these
4 patents or the '356 patent?

5 A. They're not defining the site of
6 origin.

7 Q. So the '356 patent claims a method
8 for treating cancer patients without specifying
9 the site of cancer origin, correct?

10 MR. RATLIFF: I object to the form
11 of the question.

12 THE WITNESS: Yes. I mean, I
13 suppose one could go further and say they're
14 also not defining the histology either.

15 Again, cancer is a generic term that
16 encompasses a multitude of entities. That's
17 why I don't care for it.

18 So I don't know what it really means
19 in this context or in general what it means,
20 but certainly they're not defining the site
21 and they're not defining the histology.

22 BY MS. McCORMICK:

23 Q. And if I say "cancer agnostic" today
24 when I'm asking you questions, will you
25 understand I mean not specifying the site of

1 origin or defining the histology?

2 A. Yeah.

3 MR. RATLIFF: I object to the form
4 of the question.

5 THE WITNESS: Yes.

6 BY MS. McCORMICK:

7 Q. Dr. Neugut, what was the process for
8 preparing your declaration related to the '356
9 patent?

10 A. The actual original draft? Well, we
11 have to go back earlier than that. I had
12 extensive meetings with the attorneys from Paul
13 Hastings that go back. I don't recall the
14 exact dates when we started, but it goes back
15 now I think a couple of years to discuss the
16 scientific issues in the case and the use of
17 pembrolizumab and the MSI study record and what
18 was involved generally in this case. So that
19 went on for quite a while.

20 And then that ultimately led to the
21 preparation of the declarations. We already
22 had a deposition about one of the declarations.
23 And they initially prepared the first draft of
24 the declaration based on our discussions, and
25 then I went over it carefully and made

1 revisions and ensured that it was accurate and
2 congruent with my own opinions and thoughts.
3 There might have been two or three drafts or
4 several until it was what I thought was
5 accurate and appropriate. And then I signed
6 off on it. I don't know what happens to it
7 after that, but that's when I signed it.

8 Q. And which declaration are you
9 talking about when you're describing the
10 process you just described?

11 A. All of them went through essentially
12 the same process. Of course -- in many
13 regards, they're very similar, so a lot of the
14 revisions are translatable from one to the
15 other. If I changed the literature review from
16 one to another, of course it would then
17 translate to the other documents. But all the
18 declarations went through the same process in
19 terms of preparation.

20 Q. Are there -- which declaration did
21 you do first?

22 A. As I sit here today, my recollection
23 is that '393 must have been the first because
24 that's the one we dealt with first. After
25 that, these are all to me -- they overlap, and

1 I don't know that one or another is different.
2 Several of them deal with colorectal cancer. I
3 suppose that's what you're pointing out now.
4 And some of them deal with cancer generically
5 or agnostically, if you want to use that term.
6 I don't know if we prepared the documents in
7 that order. I don't recall now. I don't
8 recall if that's the order in which we actually
9 prepared the documents. In my head, they
10 followed that order.

11 Again, within each category --
12 within the category of the three or four
13 documents that are colorectal cancer, I
14 wouldn't be able to tell you what the order is
15 of the three or four colorectal cancer patents,
16 how they -- the sequence of the three or four
17 colorectal cancer patents or the three or four
18 agnostic cancer patents once they're in that
19 category, but at least to me they fall into
20 those two groups.

21 Q. Were there any of your declarations
22 that followed a different process?

23 A. No.

24 Q. Any declarations you prepared that
25 took more time than the others?

1 A. I believe that the first one took
2 longer because all the innings were hard, and
3 the first one required more in-depth thinking,
4 and it also had text which had to be worked out
5 more carefully on the first go-around.

6 A lot of the text, as I'm sure
7 you're aware, was repeated or at least modified
8 in the other declarations over and over again,
9 so it had -- but the first time it took more
10 time to revise it so that it was properly
11 drafted. So the first one of course took more
12 time.

13 After that, I don't know if number
14 three took more time than number four or not,
15 but certainly number one took more time than
16 the others.

17 Q. So after the first declaration,
18 which I think you said was for the '393 patent,
19 the rest of the declarations took about the
20 same amount of time?

21 MR. RATLIFF: I object to the form
22 of the question.

23 THE WITNESS: I don't recall
24 significant differences in the amount of
25 time.

1 Some of them here, even in my
2 recollection, have more claims than others.
3 I was never sure why. A few of them have
4 eight to ten claims. A few have 25 or more
5 claims. At least in my reviewing them and
6 the declarations that resulted -- reviewing
7 the patents and then the declarations that
8 resulted from those patents, it did take
9 more time for me to do those simply because
10 of the content, the length of the content
11 and the issues that were involved in that.
12 So those did take longer.

13 So if you want to consider or think
14 that the amount of time each declaration
15 took was proportional to the number of
16 claims that were inherent in each, that is
17 very likely, but I did not keep a clock and
18 formally keep track, but I would -- I am
19 certain that the longer claims -- the longer
20 patents in terms of claims took more time to
21 prepare the declarations.

22 BY MS. McCORMICK:

23 Q. You had spoken about the
24 declarations in terms of groups. You had a CRC
25 group, cancer generically or cancer agnostic

1 group, and then we think of there being a third
2 group of patents that have claims that list out
3 the cancers.

4 Do you think of that as a third
5 group?

6 MR. RATLIFF: I object to the form
7 of the question.

8 THE WITNESS: Not to my way of
9 thinking, but I might see where -- again,
10 I'm thinking of it in a certain way. It's
11 not in my way of thinking, but maybe there
12 are reasons why that might be separately
13 grouped.

14 There may be issues or things that
15 are related to the specification of the
16 cancer types that are there, but, again,
17 those are the cancers just specifying what's
18 in the non-colorectal cancer category of
19 cancer.

20 BY MS. McCORMICK:

21 Q. We'll keep going through your
22 declarations, and I think we'll get to this
23 third group.

24 Do you have your '219 patent
25 declaration in front of you, Dr. Neugut?

1 A. Ready.

2 Q. You have your '219 patent
3 declaration in front of you?

4 A. Yes.

5 Q. And it's also marked Exhibit 1003,
6 so I'll refer to it as the '219 patent
7 declaration. Okay?

8 A. Yes.

9 Q. And if you turn to page 66 of 75 of
10 your '219 declaration, do you see your
11 signature?

12 A. Yes.

13 Q. And you signed this '219 declaration
14 on March 4, 2024?

15 A. Yes.

16 Q. And the '219 patent is also claiming
17 methods of treating MSI high patients without
18 referring to the cancer type, correct?

19 MR. RATLIFF: I object to the form
20 of the question.

21 THE WITNESS: Yes.

22 BY MS. McCORMICK:

23 Q. Is it fair if I group this with the
24 '356 patent as referring to cancer agnostic
25 patients?

1 A. If you like.

2 Q. Will you understand what I mean?

3 A. Yes.

4 Q. Did you do anything different, or
5 did this '219 declaration preparation stand out
6 to you in any way?

7 MR. RATLIFF: I object to the form
8 of those questions.

9 THE WITNESS: I thought, just like
10 the other, my charge in reviewing these was
11 in understanding or determining whether the
12 claims as they are listed for '356 or for
13 this were described in the study record, and
14 for both of these they were all in the study
15 record. After that, it didn't matter to me
16 what might or might not be included in the
17 patent claims or in the documents. So that
18 was all I cared about.

19 BY MS. McCORMICK:

20 Q. Did you do anything different to
21 prepare your '219 patent declaration than you
22 did for the other declarations you submitted
23 for this dispute?

24 A. I followed the same procedure.
25 Again, this all built off the original extended

1 generic global discussions of the science
2 involved in MSI and of treatment of colon
3 cancer and the cancer in general with regard to
4 MSI and of the conduct of trials, et cetera,
5 and then the preparation of -- and then the
6 preparation of the draft for the declaration by
7 counsel and the revisions that were made by me
8 and drafts going back and forth until it
9 reached a satisfactory version which I was
10 comfortable signing so that it could be
11 submitted to you.

12 Q. And what you just described is the
13 process you did for preparing the '219 patent
14 declaration, right?

15 A. That's correct.

16 Q. Dr. Neugut, do you have the '974
17 patent declaration in front of you?

18 A. Yes.

19 Q. Will you turn to page 72 of 81 of
20 the '974 patent declaration?

21 A. Okay.

22 Q. And do you see your signature?

23 A. Yes.

24 Q. And did you sign the '974 patent
25 declaration on March 4, 2024?

1 A. Yes, I did.

2 Q. And was your process for preparing
3 your '974 patent declaration any different than
4 what you previously described for preparing
5 your other declarations?

6 A. No, it was not.

7 Q. The claims of the '974 patent, those
8 are also claiming a method of treatment without
9 describing the cancer type, correct?

10 MR. RATLIFF: I object to the form
11 of the question.

12 THE WITNESS: That's correct.

13 BY MS. McCORMICK:

14 Q. Dr. Neugut, do you have the '975
15 patent declaration in front of you?

16 A. Yes.

17 Q. If you turn to page 74 of the '975
18 patent declaration, do you see your signature?

19 A. Yes.

20 Q. And you signed the '975 patent
21 declaration on March 4, 2024; is that right?

22 A. Yes.

23 Q. And did you do anything different
24 than what you previously described in preparing
25 your declaration for the '975 patent?

1 A. I don't believe that I did, no.

2 Q. And the '975 patent also claims
3 methods of treating cancer patients without
4 specifying the cancer type, correct?

5 MR. RATLIFF: I object to the form
6 of the question.

7 THE WITNESS: That's correct.

8 BY MS. McCORMICK:

9 Q. So, Dr. Neugut, we just reviewed the
10 '356 patent declaration, the '219 patent
11 declaration, the '974 patent declaration and
12 the '975 patent declaration.

13 If I refer to those as the cancer
14 agnostic group, will you know I'm referring to
15 those four patents?

16 MR. RATLIFF: I object to the form
17 of the question.

18 THE WITNESS: If you ask me to, I
19 will.

20 BY MS. McCORMICK:

21 Q. And you signed all four of those
22 declarations on the same day, correct?

23 A. Yes.

24 Q. Dr. Neugut, do you have the '187
25 patent declaration in front?

1 A. Yes.

2 Q. If you turn to page 75 of 84 of the
3 '187 patent declaration, do you see your
4 signature?

5 A. Yes.

6 Q. And you signed the '187 patent
7 declaration on March 13, 2024, correct?

8 A. Yes.

9 Q. Was your process for preparing the
10 '187 patent declaration any different than what
11 we've previously discussed?

12 A. No.

13 Q. The claims of the '187 patent
14 described methods of treating cancer where the
15 claims list out cancer types, correct?

16 MR. RATLIFF: I object to the form
17 of the question.

18 THE WITNESS: It lists certain
19 cancers, yes.

20 BY MS. McCORMICK:

21 Q. Let's actually look at the '187
22 patent if you have that in front of you. Do
23 you have the '187 patent in front of you, Dr.
24 Neugut?

25 A. Yes.

1 Q. We can look at claim 1. Claim 1
2 claims a method for treating a patient having a
3 solid tumor selected from the group consisting
4 of a list of cancers.

5 Do you see that?

6 A. Yes.

7 Q. And the list of cancers here in
8 claim 1 of the '187 patent does not include
9 colorectal cancer, correct?

10 A. Correct.

11 Q. If I refer to this method of
12 treating in the '187 patent as the list of
13 cancers, will you understand what I mean?

14 MR. RATLIFF: I object to the form
15 of the question.

16 THE WITNESS: You mean this
17 particular list of cancers?

18 MS. McCORMICK: Yes.

19 MR. RATLIFF: Same objection.

20 THE WITNESS: Okay.

21 MS. McCORMICK: I'm just trying to
22 establish some common terminology so that we
23 don't have to say every one of those cancers
24 every time we refer to the method of
25 treatment claimed here in the '187 patent.

1 MR. RATLIFF: If that's a question,
2 I object to the form of the question.

3 BY MS. McCORMICK:

4 Q. Does that work for you, Dr. Neugut?

5 A. If you wish, you can call it that,
6 yes.

7 Q. Perfect. As far as the sequence of
8 preparing your '187 patent declaration, do you
9 recall if you did this after the cancer
10 agnostic group of patents?

11 A. I have no recollection.

12 Q. Dr. Neugut, do you have the '462
13 patent declaration in front of you?

14 A. Did you say '462?

15 Q. I did. Do you have the '462 patent
16 declaration in front of you, Dr. Neugut?

17 A. Yes.

18 Q. If you could turn to page 76 of 85
19 of the '462 patent declaration, do you see your
20 signature?

21 A. Yes.

22 Q. And you signed the '462 patent
23 declaration on March 13, 2024, correct?

24 A. Yes.

25 Q. Did you do anything different than

1 what we've already discussed to prepare your
2 declaration for the '462 patent?

3 A. Not to my knowledge.

4 Q. The claim of the '462 patent claim a
5 method of treating a list of cancer -- claim a
6 method of treating cancers and list out cancer
7 types, correct?

8 MR. RATLIFF: I object to the form
9 of the question.

10 THE WITNESS: Yes.

11 BY MS. McCORMICK:

12 Q. And the list of cancer types in the
13 '462 patent, that's the same as the list of
14 cancer types in the '187 patent, right?

15 MR. RATLIFF: I object to the form
16 of the question.

17 THE WITNESS: I would have to check,
18 but it looked similar. It's probably
19 overlapping -- or it's probably identical,
20 but I didn't check it specifically.

21 BY MS. McCORMICK:

22 Q. Let's do that just to make sure
23 we're on the same page.

24 A. Which was the other one?

25 Q. The '187 patent compared to the '462

1 patent.

2 A. Okay. Okay.

3 Q. Are the list of cancers in the '187
4 patent claims the same as the list of cancers
5 in the '462 patent claims?

6 A. Yes.

7 Q. Dr. Neugut, do you have the '491
8 patent declaration in front of you?

9 A. Yes.

10 Q. If you turn to page 79 of 88 of the
11 '491 patent declaration, do you see your
12 signature?

13 A. Yes.

14 Q. You signed the '491 patent
15 declaration on March 13, 2024?

16 A. Yes.

17 Q. And the claims of the '491 patent
18 have the same list of cancers as the '462 and
19 '187 patents, correct?

20 MR. RATLIFF: I object to the form
21 of the question.

22 THE WITNESS: Yes.

23 BY MS. McCORMICK:

24 Q. Did you do anything different to
25 prepare the '491 patent declaration than what

1 we've already discussed?

2 A. No.

3 Q. Dr. Neugut, we just reviewed your
4 patent declarations for the '187 patent, the
5 '462 patent and the '491 patent, right?

6 MR. RATLIFF: I object to the form
7 of the question.

8 THE WITNESS: Yes.

9 BY MS. McCORMICK:

10 Q. And if I refer to the '187, '462 and
11 '491 patent declarations as -- let me start
12 again.

13 If I refer to the '187, '462 and
14 '491 patents as claiming a list of cancer
15 types, will you understand what I mean?

16 MR. RATLIFF: I object to the form
17 of the question.

18 THE WITNESS: Yes.

19 BY MS. McCORMICK:

20 Q. Just to establish some common
21 terminology, we have a group of patents that
22 you opined on that claim colorectal cancer,
23 correct?

24 A. Yes.

25 Q. And we have a group of patents that

1 you opined on that claim cancer generically or
2 agnostically.

3 MR. RATLIFF: I object to the form
4 of the question.

5 THE WITNESS: Yes.

6 BY MS. McCORMICK:

7 Q. And we have a third group of patents
8 that you opined on that refer to a list of
9 cancer types, correct?

10 MR. RATLIFF: I object to the form
11 of the question.

12 THE WITNESS: Yes.

13 BY MS. McCORMICK:

14 Q. Dr. Neugut, since we last spoke, has
15 anything changed with respect to your
16 relationship with Merck?

17 MR. RATLIFF: I object to the form
18 of the question.

19 THE WITNESS: My relationship with
20 Merck? Did I have any relationship before
21 with Merck?

22 BY MS. McCORMICK:

23 Q. Do you have any relationship with
24 Merck?

25 A. Well, I have a very distant

1 relationship that's totally irrelevant to what
2 we're doing today in the sense that I sit on
3 the DSMB of a study which involves I think one
4 of their drugs, which, again, has nothing to do
5 with what we're talking about, a diabetes -- I
6 think one of their drugs is involved, a
7 diabetes drug.

8 Q. What's DSMB?

9 A. A data safety monitoring board. In
10 other words, there's a class of drugs called
11 GLP-1 agonist. It's a class of drugs used for
12 diabetes, and there's a concern that they
13 increase the risk of thyroid cancer. And
14 Ozempic, for example, is one of them. And when
15 the drugs were approved by the FDA, the FDA
16 required that any company that makes one of
17 these drugs that there be a study to determine
18 if the rates of thyroid cancer are increased in
19 the United States. So there's a study to
20 follow the rates of thyroid cancer in the
21 United States. So any company that makes one
22 of these drugs has to participate in this
23 study, and I think Merck makes one of the
24 drugs. So it's sort of involved in that.

25 Q. Did Merck hire you to be on the --

1 A. No, it's done by a contract company.
2 They handle everything. There were five or six
3 or seven companies that contribute -- that pay
4 for this contract company to conduct the study
5 of thyroid cancer, and they hire the scientists
6 who are participating.

7 But that's a very peripheral thing.
8 I don't even know when Merck's participation
9 began because it would only have begun when
10 they started making one of these drugs that's
11 FDA approved. I think they recently starting
12 making one of these drugs. The study has been
13 going on for like ten years, but I think Merck
14 recently started making one of these drugs. So
15 they are sort of involved. But, again, it has
16 nothing to do with anything.

17 Q. Other than your participation on
18 this DSMB, do you have any other relationship
19 with Merck?

20 A. No.

21 Q. Do you work with Merck's counsel,
22 Paul Hastings, for anything other than this
23 dispute?

24 A. No.

25 Q. Do you have any relationship with

1 Johns Hopkins?

2 A. I might have had some relation, you
3 know, 20 or 30 years ago, but I don't recall
4 anything recently.

5 Q. Have you ever worked with
6 researchers from Johns Hopkins?

7 A. I would think that I collaborated on
8 something or other 20 or 30 years ago, but
9 nothing in the recent past.

10 Q. How much have you been paid so far
11 for your work in connection with this case?

12 A. I would have to look in my records
13 to see. If you want the exact figure, I would
14 have to look in my records to see that.

15 Q. An estimate is fine.

16 A. I'm going to guess between 50- and
17 75,000.

18 Q. And can you estimate how many hours
19 you've spent working on this dispute?

20 A. No, I cannot. I would have to again
21 look in my records to let you know.

22 Q. Since we last spoke, have your
23 expert opinions been excluded from any case?

24 A. No.

25 Q. Since we last spoke, has your expert

1 testimony ever been excluded from a case?

2 A. No.

3 Q. Dr. Neugut, are you familiar with a
4 term objective indicia or secondary
5 considerations of nonobviousness?

6 A. No.

7 Q. If you're not familiar with the
8 term, is it fair to say you did not evaluate
9 objective indicia or secondary considerations
10 of nonobviousness as part of your opinions in
11 this case?

12 A. No, I did not do that.

13 Q. Dr. Neugut, you're a clinical
14 oncologist, correct?

15 A. Yes.

16 Q. You treat cancer patients?

17 A. Yes.

18 Q. What types of cancers do you treat?

19 A. I treat cancers of the GI tract and
20 primarily colorectal cancer and anal and
21 gastric cancer.

22 Q. Do you treat MSI high patients?

23 A. Yes.

24 Q. Do you test your patients for MSI
25 high status?

1 A. Yes.

2 Q. Do you order the test or does a
3 different person?

4 A. The testing of being MSI high is
5 generally now a reflexive test that's done as a
6 matter of routine on patients who undergo
7 surgery or biopsy. So by the time they get to
8 me, it's already -- I'll say 80 percent of the
9 time it's already been done, so I have the
10 result available to me. If a patient somehow
11 manages to get to me without the test having
12 been done, which happens not infrequently, then
13 I certainly order it. No patient gets by me
14 without having their MSI tested.

15 Q. And you said now it's a reflexive
16 test that you run.

17 When did that change?

18 A. That's a good question. I would say
19 it was a transitional thing that occurred. In
20 other words, it didn't happen all at once.
21 Sometime between 2010 and 2013 I would say it
22 was happening gradually. By 2013, 2014, I
23 would say everyone -- again, by then, at least
24 at a place like Columbia where I am, it was a
25 routine test. I don't know if I would say that

1 in the community at that point -- I don't
2 recall. I don't know if in the community it
3 was a routine test, but certainly at Columbia
4 it was. Now it's a routine test even in the
5 community, but even in the community I still
6 get patients who come and they haven't been
7 tested in the community. Particularly if the
8 biopsy is from a tumor which was not in the
9 colon, which someone has a metastasis in the
10 lung or somewhere else and then they get a
11 biopsy of the metastasis, then it may not be
12 tested for MSI. It happens.

13 Q. Why did this change in frequency of
14 MSI high testing happen?

15 A. I think it changed because -- it
16 didn't change because of the PD-1 inhibitors.
17 It changed I think initially because it had
18 prognostic significance, and it was an
19 important thing to know. It changed because it
20 was a genetic marker. You want to know if a
21 person might have lynch syndrome. So I think
22 it did change for those reasons. It changed
23 because it was a predictor of how the patient
24 would respond to treatment with a five
25 fluorouracil, one of the chemotherapy drugs.

1 So there were a number of reasons why you
2 wanted to know the MSI status of a colorectal
3 cancer patient.

4 Then once the PD-1 inhibitors came
5 along, that certainly became important. Of
6 course they were only important for metastatic
7 patients, which is only a small fraction --
8 well, a fraction of the patients. So it
9 wouldn't necessarily have made it reflexive for
10 everybody, but, nonetheless, you're either
11 metastatic in diagnosis or you have a risk of
12 becoming metastatic. So the information
13 wouldn't necessarily be important from the PD-1
14 inhibitor point of view.

15 MR. RATLIFF: We've been going for
16 an hour. Can we take a break?

17 MS. McCORMICK: Sure.

18 - - -

19 (Whereupon, a recess was held.)

20 - - -

21 BY MS. McCORMICK:

22 Q. Dr. Neugut, did you talk about the
23 substance of your testimony with counsel during
24 the break?

25 A. No.

1 Q. Before the break, we were talking
2 about testing for MSI status.

3 Do you recall that?

4 A. Yes.

5 Q. So now you test all the cancer
6 patients that you see for MSI status?

7 MR. RATLIFF: I object to the form
8 of the question.

9 THE WITNESS: At some point for
10 sure, yes.

11 BY MS. McCORMICK:

12 Q. But that hasn't always been the
13 case, right?

14 A. I don't know what always means.

15 Q. Before you didn't test all the
16 cancer patients you saw, right?

17 MR. RATLIFF: I object to the form
18 of the question.

19 THE WITNESS: I mean, certainly if
20 one goes way back to when the doesn't wasn't
21 done, it didn't exist.

22 BY MS. McCORMICK:

23 Q. If it helps, you said in 2010 to
24 2013, there was a gradual change in the
25 frequency of MSI testing, right?

1 MR. RATLIFF: I object to the form
2 of the question.

3 THE WITNESS: That's my
4 recollection. I mean, my choice of those
5 years is what my memory tells me. I may be
6 off a little bit, but that's my gestalt of
7 when it became I'll say normative to do MSI
8 testing. It might have been a little later.
9 It might have been a little earlier. But
10 that would be my time frame for when this
11 became commonplace.

12 BY MS. McCORMICK:

13 Q. And did it become normative to test
14 for MSI status before PD-1 inhibitors were
15 available for treatment?

16 A. As I was saying before, it became --
17 I would say it became common to do it
18 particularly at the more academic and
19 forward-looking institutions like my own. I
20 would probably say that if you went to a
21 Community Hospital or a city hospital or
22 something like that, it might not have been as
23 normal or as routinely done. It would have
24 only been done under certain circumstances.
25 But certainly at a place like Columbia or NYU

1 or Harvard or something like that, yes, it was
2 more routinely done. Even there it would be
3 missed occasionally, but it gradually became
4 more commonplace and routine.

5 Q. And before PD-1 inhibitors were
6 available for treating cancer patients, what
7 were the reasons you were testing cancer
8 patients for MSI status?

9 A. As I said, at some point it was
10 recognized that it was a good prognostic
11 indicator for colon cancer. If you were MSI
12 high, you had a better prognosis than if you
13 were MSI negative. So that was one reason. It
14 also predicted response to 5 fluorouracil.
15 That's the main drug we use, and if it turned
16 out you were not going to be very responsive to
17 that drug, that was important information to
18 know.

19 It also -- about a third of patients
20 who are MSI high turn out to have Lynch
21 syndrome, so it would also tell you or at least
22 it would give you an indication of whether you
23 should test someone for the germline presence
24 of mismatch repair genes in their genome.

25 Q. Are there any other reasons for

1 testing a cancer for MSI high status before
2 PD-1 inhibitors were available for treatment?

3 MR. RATLIFF: I object to the form
4 of the question.

5 THE WITNESS: As I'm sitting here, I
6 don't know offhand of any. Maybe there is,
7 but those are the ones I know.

8 BY MS. McCORMICK:

9 Q. Before PD-1 inhibitors were
10 available for treatment, did the MSI test
11 determine the treatment you would use for a
12 cancer patient?

13 MR. RATLIFF: I object to the form
14 of the question.

15 THE WITNESS: Under certain
16 circumstances.

17 BY MS. McCORMICK:

18 Q. What circumstances are those?

19 A. Well, as I said, you could not give
20 an MSI high patient 5 fluorouracil alone. It
21 would not be effective. So that was the main
22 one. You could only give FOLFOX or FOLFIRI
23 if the patient was MSI high. So that was an
24 important consideration for MSI high patients.
25 You can only give FOLFOX or FOLFIRI if someone

1 was MSI high.

2 Q. Were there any other
3 treatment-related decisions you would make
4 before PD-1 inhibitors were available for
5 treatment related to MSI high status?

6 MR. RATLIFF: I object to the form
7 of the question.

8 THE WITNESS: Again, I don't know if
9 this is called treatment. It would
10 determine whether you wanted to test someone
11 for Lynch syndrome. So of course if they
12 had Lynch syndrome, then you would be off on
13 that tangent dealing with that and treating
14 them appropriately for that condition. So
15 that was an important issue.

16 BY MS. McCORMICK:

17 Q. How do you deal with treating
18 someone with Lynch syndrome before PD-1
19 inhibitors were available?

20 MR. RATLIFF: I object to the form
21 of the question.

22 THE WITNESS: Well, there are
23 several considerations. One is, you want to
24 test their family members for the disease as
25 well, primarily their children or their

1 siblings, and see if they have Lynch
2 syndrome. So it's an important genetic
3 issue.

4 In terms of the patient him or
5 herself, they're at risk for a number of
6 cancers in addition to the colon cancer that
7 they presumably already have. So you have
8 to screen them for the other cancers that
9 they're at risk of developing, notably
10 gastric cancer, endometrial cancer, small
11 bowel cancer, pancreas cancer, a few others.
12 So you have to basically do testing to make
13 sure that they don't have those conditions
14 as well. So they go for a whole panel of
15 tests. If it's a woman, she has to have a
16 hysterectomy, assuming she's already had her
17 children and things like that.

18 BY MS. McCORMICK:

19 Q. Anything else for treating Lynch
20 syndrome patients before PD-1 inhibitors were
21 available?

22 MR. RATLIFF: I object to the form
23 of the question.

24 THE WITNESS: Well, again, the
25 patient let's say who's already had a colon

1 cancer is at an increased risk for getting
2 another colon cancer, so you might consider
3 taking out what's left of their colon so
4 they don't get it. But it doesn't change
5 treatment in the sense of chemo or anything
6 like that.

7 BY MS. McCORMICK:

8 Q. You also said that it was common to
9 test for MSI before PD-1 inhibitors were
10 available because it was a prognostic
11 indicator.

12 What did you mean by that?

13 A. So after you tell someone that they
14 have cancer, whatever the cancer may be,
15 usually their next question is, "What are my
16 chances?" So we do like to be able to give
17 them some kind of answer to that question.
18 Staging is usually the best or the most
19 important part of the prognostic determination,
20 Stage 1, 2, 3, 4. But on top of that there are
21 other biological factors that will play into
22 your prognosis.

23 So MSI does give you a few points
24 one way or the other in terms of your
25 prognosis. So if you're MSI high, you'll

1 probably get a benefit of 3 to 5 percent in
2 terms of reduced risk of recurrence of the
3 tumor.

4 Q. And how has MSI testing changed now
5 that PD-1 inhibitors are available for
6 treatment?

7 A. Well, if you're MSI negative, it
8 hasn't done anything for you except given you
9 disappointment. If you're MSI high, it's a
10 major boom because what it does is it allows
11 you to be treated with one of the
12 immunotherapeutic agents as opposed to
13 conventional chemotherapy. So it depends if
14 we're talking about someone who's metastatic
15 and now it's already extended into neoadjuvant
16 therapy.

17 So the world is turning over. It's
18 like a whole -- I mean just the papers about
19 six months ago that's going to totally
20 revolutionize the treatment of colon cancer,
21 again only for those who are MSI high. If
22 you're not MSI high, you get nothing. But if
23 you are MSI high, it's a whole new world
24 because we'll be giving a PD-1 inhibitor prior
25 to surgery, and with that a tumor disappears a

1 large percentage of time. I think people are
2 not going to be getting surgery so much. It's
3 really remarkable. I mean, this is really very
4 new, in the last two years, but for rectal
5 cancer it's already normative, and for colon
6 cancer it's now just starting, but I think that
7 will -- it hasn't become routine yet, but I
8 think in the next year it will be routine to
9 give -- for those who are MSI high to give
10 nivolumab or pembrolizumab prior to surgery,
11 and that will really change how colon cancer is
12 treated. That's a very large part of the colon
13 cancer population.

14 Q. How large a portion of the colon
15 cancer population are the MSI high patients?

16 A. 15 to 20 percent. I mean, if you're
17 metastatic, the percentage is very small, but
18 if we're talking about the entire population of
19 colon cancer patients, it's 15 to 20 percent.

20 Q. Now that PD-1 inhibitors are
21 available for treatment, if you're MSI high,
22 it's a major boom because it allows you to be
23 treated with an immunotherapeutic agent like
24 pembrolizumab, right?

25 MR. RATLIFF: I object to the form

1 of the question.

2 THE WITNESS: Yeah, but now there's
3 a whole host of drugs that are available. I
4 mean, pembrolizumab is, I would say,
5 receding into the background a little bit
6 but still a major player. But there's
7 nivolumab, ipilimumab, and there's a drug
8 called dostarlimab. There's another drug
9 that's slipping my mind. There are other
10 competitors, and which one you should use
11 when, I mean, I guess the literature will
12 sort that out as time goes by.

13 BY MS. McCORMICK:

14 Q. You had mentioned that there was a
15 paper six months ago reporting something
16 interesting about treatment.

17 Do you recall that?

18 A. Yes.

19 Q. What journal were you reading that
20 in?

21 A. The New England Journal of Medicine.

22 Q. Do you read that journal, The New
23 England Journal of Medicine, often?

24 A. Regularly.

25 Q. Do you get a physical copy of it?

1 A. No, I don't get a physical copy of
2 anything anymore. I mean, it actually comes to
3 me in my mailbox, a paper copy, and I throw it
4 in the garbage. No, it comes online.

5 Q. Do you read the whole journal when
6 you get it online?

7 A. I go through the table of contents,
8 and I read the articles that are of interest to
9 me that are relevant. I mean, I don't read the
10 articles on Nile Valley fever or something like
11 that that are not appropriate to me.

12 Also, I always liked The New England
13 Journal, but they've become left-wing liberal.
14 Their articles now are a bit offbeat sometimes,
15 but most of their stuff is still -- the key
16 articles in treatment do end up published
17 there. You do have to look at The New England
18 Journal to know what's most important.

19 Q. Other than The New England Journal
20 of Medicine, what other journals do you read?

21 A. Well, again, if you say "read," I'm
22 talking about going through the table of
23 contents and looking at the articles that are
24 of interest and what I consider important.

25 So I look at the Journal of Clinical

1 Oncology, JAMA.

2 Q. What's JAMA?

3 A. Journal of the American Medical
4 Association. JAMA Oncology. So JAMA has a
5 family of subspecialty journals. So there's
6 JAMA Oncology, JAMA Surgery, JAMA Internal
7 Medicine, on and on and on. So they send
8 around the digest of all the articles on cancer
9 from all of their journals. So I look at the
10 JAMA cancer articles from all the JAMA network
11 journals. In other words, if there's a cancer
12 article in the JAMA Surgery, then I see that.
13 If JAMA Surgery has an article on how to do
14 better sutures in appendectomies, I don't
15 really care about that. But the cancer
16 articles from JAMA Surgery are important to me.
17 So they have a digest of all the cancer
18 articles that they send around, so that I look
19 at very carefully.

20 ASCO, the American Society of
21 Clinical Oncology, sends around a daily digest
22 called ASCO Communication, which is basically
23 all the key cancer articles or other
24 publications that goes around daily, not just
25 from cancer journals but from lay publications

1 as well. That is terrific. I mean, they'll
2 quote the New York Times. So that I find
3 extremely -- and they have an article today on
4 like -- the Times talking about alcohol, the
5 Surgeon General wanting to put alcohol
6 warnings on -- warnings about cancer on alcohol
7 bottles. They had an article about that. So
8 that's a very useful thing for me.

9 I also read the Journal of the
10 National Cancer Institute. That's a very
11 useful journal for me. Cancer Epidemiology,
12 Biomarkers & Prevention, a journal called The
13 Oncologist. And I read all the JCO family
14 journals. They have a whole family of journals
15 as well. So I see most of their journals,
16 Journal of Global Oncology, Journal of -- a few
17 others like that. That's it. I also look at
18 the Annals of Internal Medicine.

19 Q. Why do you read all of those
20 journals?

21 MR. RATLIFF: I object to the form
22 of the question.

23 THE WITNESS: So I can be educated
24 and stay up with my field. I want to know
25 what's going on. How else do you stay

1 current? It's a responsibility to your
2 patients and to yourself and also so some
3 resident doesn't show me up on rounds.

4 BY MS. McCORMICK:

5 Q. So the journals that you just
6 listed -- I think there were at least eight
7 plus The New England Journal of Medicine -- do
8 you read those routinely?

9 A. Yes.

10 Q. Are there any other journals that
11 you read routinely, other than the ones you
12 just listed?

13 A. Well, I mean, I get a lot of -- so
14 there are other journals that I see
15 intermittently. Breast Cancer Research and
16 Treatments I'd see occasionally. The Lancet.
17 There's a journal called Cancer. But I
18 don't -- I don't make it a routine to go out of
19 my way to look at them all the time.

20 And then there are digests that are
21 sent around, what we call throwaways, like
22 advertising things that send you information.
23 So they'll list articles that are published,
24 and sometimes I'll click on it and look at an
25 article that's in some obscure journal and look

1 at that but not that commonly.

2 Q. Do you read journal articles from
3 Cancer Genomics?

4 A. No.

5 Q. Do you read articles from The
6 Journal of Immunology?

7 A. No. I mean, I may read an
8 occasional one because it will come up in -- if
9 I'm writing a paper and something will come up
10 where I need a reference on something, so I may
11 see an occasional article from that journal,
12 but I don't routinely scan its website or its
13 table of contents to see all of the articles in
14 that journal.

15 Q. Do you routinely read articles in
16 The Journal of Immunotherapy?

17 A. No.

18 Q. Do you routinely read articles in
19 the World Journal of Gastroenterology?

20 A. Again, I don't make it my routine to
21 catch every issue, but now and then I'll see a
22 -- I'll catch it.

23 Q. When was the last time -- have you
24 ever cited an article from the World Journal of
25 Gastroenterology as part of your work as a

1 clinical oncologist?

2 A. Sure. I've published there. It's
3 actually not a bad journal.

4 Q. I hope there's not a lot of bad
5 journals.

6 MR. RATLIFF: If that's a question,
7 I object to the form of the question.

8 BY MS. McCORMICK:

9 Q. Do you routinely read from the
10 Journal of OncoImmunology?

11 A. No.

12 Q. Do you routinely read articles from
13 the Journal of Genome Research?

14 A. No.

15 Q. Have you heard of that journal
16 before?

17 A. Yes. Again, like I say, it may come
18 up if I'm writing about something and
19 particularly a specific article from there may
20 come across my vision, but I don't routinely
21 look at the journal.

22 There are -- there must be 20,000
23 journals, and there's probably a million or
24 more articles published a year in the
25 biomedical world. So one doesn't expect to see

1 or keep track of all of them. I'm only talking
2 about those that are published in English. So
3 you do have to pick and choose a little bit.

4 Q. How did you identify the references
5 that you rely on in your declarations?

6 A. Most of them were chosen by the
7 attorneys.

8 Q. Are there any that you chose?

9 A. As I'm sitting here, I don't recall,
10 but there may be one or two.

11 Q. Did you look for references as part
12 of preparing your opinions for this case?

13 A. No.

14 Q. Why not?

15 A. The attorneys did it for me. Again,
16 the articles that were articles I would have
17 read I had read already and were already
18 included. I mean, I read, for example, the
19 actual trial so that I had seen and read. I
20 mean, if you want to say I generated that,
21 you're welcome to say that, but that
22 publication I knew.

23 Q. And the trial you're referring to is
24 the -- what trial are you referring to?

25 A. The paper in 2015 of the

1 pembrolizumab by Merck and Hopkins.

2 Q. The paper in 2015 that was published
3 in The New England Journal of Medicine, you had
4 reviewed that previously to working on this
5 case?

6 A. Yes. I mean, my point is that some
7 of the papers that the attorneys provided I had
8 already seen in the normal course of life.

9 Q. Just to go back to the testing for a
10 moment, Dr. Neugut, before PD-1 inhibitors were
11 available for treatment, what cancers were
12 being tested for MSI status?

13 MR. RATLIFF: I object to the form
14 of the question.

15 THE WITNESS: To my knowledge -- and
16 I may not be totally familiar with this,
17 but, to my knowledge, it would have been
18 tumors that are associated with Lynch
19 syndrome. So it would have been colorectal
20 cancer, small bowel cancer and -- it depends
21 what you mean by being tested.

22 Are you talking about routinely
23 tested or tested once in a blue moon?

24 I mean, small bowel cancer and
25 colorectal cancer would have been tested --

1 again, if we're in the 2010 to 2015 time
2 frame, I believe they would have been tested
3 then reflexively or routinely, whatever term
4 you would care to use. Beyond that, I would
5 not say anything else was tested as
6 routinely. Once in a while perhaps a
7 gastric cancer was tested.

8 Around that time, there was also the
9 gradual increase in a procedure called NGS,
10 next genome sequencing. That was already
11 going on. That's like where they're doing
12 testing of the DNA in tumors to look for
13 anything, any kind of marker that would
14 possibly be useful in treating cancers
15 across the board. This was an outgrowth of
16 the precision medicine movement that was
17 arising in oncology. So in the consequence
18 of next genome sequencing, they would have
19 been testing for MSI, I suppose, in many
20 different cancers as just kind of a routine.

21 I don't know what year NGS sort of
22 became a commonplace or a routine test. I
23 don't know if it goes back as far as 2011,
24 2012, 2013. Maybe it did.

25 BY MS. McCORMICK:

1 Q. NGS testing is not testing for MSI
2 specifically; it's testing for a lot of things,
3 correct?

4 A. Yeah. If you're asking what would
5 have been test -- in what tumor would you have
6 tested consciously for MSI? I would say
7 colorectal cancer and small bowel. Other than
8 those two, anything else would have been
9 catch-as-catch can. It would have been if you
10 had a reason or if someone had a tumor and you
11 wondered if they had Lynch syndrome for some
12 reason, if you had a family history of -- if
13 someone had endometrial cancer and they had a
14 relative who had colon cancer, then you might
15 have tested the endometrial cancer for MSI
16 also. I think it would have been more random,
17 not routine.

18 Q. Has MSI testing for these other
19 cancers, aside from CRC and small bowel,
20 changed -- the frequency of that testing
21 changed now that PD-1 inhibitors are available?

22 MR. RATLIFF: I object to the form
23 of the question.

24 THE WITNESS: Yes.

25 BY MS. McCORMICK:

1 Q. How has it changed?

2 A. More frequent.

3 Q. And why is that?

4 A. Because we look for -- it's more
5 common now to treat tumors I guess you would
6 use the term agnostically without regard to
7 site and with regard to the biomarker that the
8 tumor exhibits and hoping that you find
9 something and give it to the patient.

10 Personally, I don't find it actually
11 all that helpful. Maybe I've just had not that
12 much of a positive experience from it or maybe
13 some of my colleagues have had more benefit
14 from it than I have.

15 Q. What do you mean that you haven't
16 had that much of a positive experience from it.
17 What "it" are you talking about?

18 A. I don't find we need, for example,
19 next genome sequencing and just randomly look
20 for any biomarker and you find in a tumor a
21 biomarker that you don't normally see in a
22 given tumor. That's what the theory is. It
23 doesn't matter what the tumor is. If you just
24 find the biomarker, you can treat it. So then
25 you find it and you give the drug that's

1 targeted to that biomarker. So when I've done
2 that in my colon cancer patients, I don't find
3 that I get such dramatic results or benefits
4 out of it. Maybe you get a couple of months,
5 but I don't find that it's really all that --
6 you know, it's touted as being terrific, but I
7 don't find -- maybe there are other tumors
8 where that works.

9 Q. Are you thinking about MSI when
10 you're talking about this?

11 A. MSI is one of them. MSI in colon
12 cancer I don't have to worry about that because
13 I always have that. I'm talking about finding
14 biomarkers that we don't normally test for and
15 we don't normally treat in colon cancer but
16 that have -- that are treatable, what we call
17 druggable biomarkers, which there were a whole
18 slew of them. So we randomly test for them,
19 and you turn up one, and then you use that drug
20 which you normally would never think to use,
21 and you use it because a particular tumor
22 happens to have that marker in it.

23 I have to tell you, when I've done
24 that, I don't find that I get particularly
25 positive results out of it. Again, maybe I'm

1 just unlucky or patients I have are unlucky in
2 that regard, and maybe it works for others
3 better. If you read the literature, like some
4 of the keynote studies, they'll get 4 out of 15
5 patients responded. Maybe they do better than
6 I do.

7 Q. Do you treat patients with
8 endometrial cancer?

9 A. No, that's a gynecologic cancer. At
10 my institution the gynecologists treat the
11 gynecologic cancers and not the medical
12 oncologists.

13 Q. So you do not treat patients with
14 endometrial cancer?

15 A. No.

16 Q. Do you treat patients with small
17 bowel cancer?

18 A. Yes.

19 Q. And you treat patients with gastric
20 cancer?

21 A. Yes.

22 Q. Do you treat patients with ampullary
23 cancer?

24 A. Not a lot, but occasionally, yes.

25 Q. Do you treat patients with

1 cholangiocarcinoma?

2 A. Again, not commonly, but
3 occasionally.

4 Q. Do you treat patients with
5 pancreatic cancer?

6 A. I haven't done it in a while. I
7 used to be the main pancreas doctor, but in our
8 institution, we sub -- when you go to the major
9 cancer centers, everyone sub subspecializes. I
10 think it's a good thing because then everyone
11 gets really good at what they do. You know, if
12 you treat right-sided breast cancer, someone
13 else treats left-sided breast cancer. So
14 someone else treats pancreas, but I used to be
15 the pancreas person.

16 Q. When were you the pancreas person?

17 A. Six, seven years ago, eight years
18 ago. I don't remember exactly.

19 Q. When you were the person treating
20 pancreas cancer, were you testing pancreas
21 cancer for MSI status routinely?

22 A. My recollection is that when I was
23 the pancreas person, MSI status wasn't routine.

24 Q. Do you treat patients with prostate
25 cancer?

1 A. I don't -- it's not my area of
2 expertise, but the truth is that everyone has
3 prostate cancers. It's so common that a large
4 fraction of my patients happen to have prostate
5 cancer. So I see a lot of it even though I
6 don't particularly specialize in it.

7 Q. Do you treat patients with breast
8 cancer?

9 A. No.

10 Q. Do you treat patients with
11 esophageal cancer?

12 A. No.

13 Q. Do you treat patients with cervical
14 cancer?

15 A. No.

16 Q. Do you treat patients with ovarian
17 cancer?

18 A. No.

19 Q. Do you treat patients with uterine
20 cancer?

21 A. No.

22 Q. Do you treat patients with bladder
23 cancer?

24 A. No.

25 Q. Do you treat patients with

1 testicular cancer?

2 A. No.

3 Q. Do you treat patients with oral
4 cancer?

5 A. No. I mean, I'm trained to treat
6 all of them and I'm familiar with all of them
7 to a greater or lesser degree, but I don't on a
8 daily basis or as a routine now deal with them.

9 Q. In preparing your declarations for
10 this case, did you review any articles or
11 references that you did not cite in your
12 declarations?

13 A. I would say probably yes.

14 Q. And why is that?

15 A. Whenever I prepare documents,
16 reports, legal documents, publications within
17 academics, I want to be 100 percent accurate
18 and knowledgeable, and so I'll look things up
19 just to fill in gaps in my information or in my
20 memory. You know, basic things. Sometimes I
21 may have forgotten the most fundamental thing.
22 Even when I treat people, I'll use Google to
23 look up a dose of a drug or to make sure I have
24 it right. I don't want to have one of you guys
25 come after me because I screwed up something.

1 I will look up things just to fill in the hole.
2 I won't remember what an acronym stands for,
3 and then I'll look it up and then refresh my
4 memory as to what it is. I look up PCR, how is
5 it done? Do I remember that? Sure, I learned
6 it. But could I tell you now what it is? I
7 would have to look it up again.

8 Q. Can you tell me something that you
9 looked up that you didn't cite in your
10 declarations that you prepared for this case?

11 A. Not as I sit here right now. I
12 would look up a general textbook. I'm talking
13 about things like a textbook equivalent. I'm
14 not talking about a journal article
15 necessarily. We're not talking about that
16 level of detail. I might want to know what's
17 the percent of -- well, you asked me earlier
18 the percent of patients who are MSI high. I
19 vaguely know what that is sort of on a
20 day-to-day basis, but I don't know the number
21 at my fingertips. I might have looked that up
22 and found a journal article on that to just
23 make sure I had it right in my head so that I
24 could deal with that. So that I might have
25 looked up. I wouldn't have necessarily put the

1 reference into any of these articles. There
2 was no need to do that.

3 Q. Dr. Neugut, do you have the MSI high
4 study record in front of you? That's
5 Exhibit 1005.

6 A. Give me a moment.

7 Q. Let's actually come back to that one
8 because I don't have a copy of it in front of
9 me. We'll come back to it.

10 Do you have a copy of Exhibit 1034
11 in front of you? That's an article by Brown.

12 A. Yes.

13 Q. And you're looking in one of your
14 declarations?

15 A. Yes.

16 Q. Are you looking at something
17 specific?

18 A. I wanted to see what I said about
19 Brown.

20 Q. Have you found it?

21 A. I found one paragraph about it. I
22 don't know if I quoted it somewhere else.

23 Q. Does Exhibit 1034 look familiar to
24 you?

25 A. Yes.

1 Q. This is one of the articles counsel
2 found for you?

3 A. Yes.

4 Q. And in this article, Exhibit 1034,
5 there's one mention of MSI, correct?

6 MR. RATLIFF: I object to the form
7 of the question.

8 BY MS. McCORMICK:

9 Q. I can point you to page 5 of 8 in
10 Exhibit 1034 at the bottom of the second
11 column.

12 MR. RATLIFF: Is there a question
13 pending?

14 BY MS. McCORMICK:

15 Q. Dr. Neugut, do you see the mention
16 of microsatellite instability at the bottom of
17 page 5 of Exhibit 1034?

18 A. No. Where it talks about being MSI
19 high?

20 Q. No, at the -- do you see a point
21 where it says MSI high?

22 A. You said it was MSI high, mentioned
23 being MSI high. I don't see it.

24 Q. At the bottom of page 5 of
25 Exhibit 1034, the bottom of that first column.

1 A. Oh, the first column.

2 Q. "In patients with hereditary
3 nonpolyposis colorectal cancer, microsatellite
4 instability is a major determinant of dense
5 tumor infiltration by activated CD8+ T cells."

6 Do you see that?

7 A. Yes.

8 Q. That's the only mention of
9 microsatellite instability in this article,
10 right?

11 MR. RATLIFF: I object to the form
12 of the question as well as the premise of
13 the question.

14 THE WITNESS: I don't know if that's
15 the only mention of it. I would have to
16 re-read the article to determine that.

17 BY MS. McCORMICK:

18 Q. What is hereditary nonpolyposis?

19 A. Lynch syndrome.

20 Q. Am I saying nonpolyposis correctly?

21 A. Yes.

22 Q. And what does it mean that
23 microsatellite instability is the major
24 determinant of dense tumor infiltration by
25 activated CD8+ T cells?

1 A. I think what he is saying is that in
2 Lynch syndrome in which you're MSI high, you
3 have -- in those tumors you have -- the tumors
4 are infiltrated with a high concentration of
5 immunoreactive T cells.

6 Q. And why is that important?

7 A. He's suggesting that patients who
8 are MSI high or that have this condition have a
9 more internal immune response.

10 Q. And what do you mean by more
11 internal immune response?

12 A. These are cells which are likely to
13 have the ability to fight against the tumor
14 cells. There are more of them. And it's what
15 suggests that if there were a drug like a PD-1
16 inhibitor that these cells would then become
17 more activated and able to fight against the
18 tumor. That's the whole underlying hypothesis
19 or premise of why the PD-1 inhibitors are
20 active in the MSI high colorectal cancers as
21 opposed to the negative colorectal cancers.

22 Q. On page 2 --

23 A. And just to finish that, I wrote in
24 -- I said in the declaration -- I just pulled
25 out any declaration. I found in '462 I quote

1 Brown and say he concludes that patients with
2 tumors showing naturally immunogenic mutations,
3 which this is, and associated tumor
4 infiltrating lymphocytes, which is what we're
5 talking about here, are potential candidates
6 for treatment with immune modulators such as
7 PD-1 targeted antibody.

8 Brown also discusses that its
9 findings suggest that the abundance of
10 predicted immunogenic mutations may be useful
11 for identifying patients likely to benefit from
12 checkpoint blockade and related
13 immunotherapies.

14 So that's why Brown is an
15 interesting paper.

16 Q. There are other targets besides PD-1
17 listed in Brown, right?

18 A. Targets?

19 Q. In talking about PD-1 or PDCD1
20 targeted antibodies, Brown is also talking
21 about CTLA4 targeted antibodies, correct?

22 A. Yeah, so that's the target for
23 nivolumab, which is another immunotherapeutic
24 agent or checkpoint blockade agent. So it's a
25 similar analogous mechanism and would have the

1 same benefit and would have the same rationale
2 for why MSI high would respond to -- I would
3 say more broadly than saying PD-1 inhibitors,
4 one should say checkpoint blockade inhibitors
5 or immunotherapeutic agents.

6 Q. And a drug that targets CTLA4 would
7 be an option for targeting the immune
8 checkpoint blockade, right?

9 MR. RATLIFF: I object to the form
10 of the question.

11 THE WITNESS: That's correct.

12 BY MS. McCORMICK:

13 Q. In the middle of the first column on
14 page 5 of Exhibit 1034, the last sentence in
15 the middle of the page there, "A comprehensive
16 evaluation of immunogenic mutations specific to
17 individual cancer types remains an important
18 topic for future study."

19 Do you see that?

20 A. Yes.

21 Q. Why is it important to study based
22 on cancer types?

23 A. I can't read Brown's mind, but as I
24 would see it, mutations vary, at least to our
25 knowledge -- or at least that mutations varied

1 by cancer subtype. So that's what he's
2 building off of or reacting to. I think the
3 idea that you shouldn't think about the subtype
4 is a later concept.

5 Q. Tumor biology is different across
6 different organs; is that right?

7 A. I would think so.

8 MS. McCORMICK: I think we can put
9 Brown to the side.

10 I don't know what time we started.

11 MR. RATLIFF: We've been going for
12 about an hour.

13 MS. McCORMICK: Let's take a break.

14 - - -

15 (Whereupon, a recess was held.)

16 - - -

17 BY MS. McCORMICK:

18 Q. Dr. Neugut, let's talk about
19 Exhibit 1005, which I'll refer to as the MSI
20 high study record.

21 Do you have that in front of you?

22 A. Yes.

23 Q. And is there any markings or
24 highlighting on this Exhibit 1005 in front of
25 you?

1 A. No.

2 Q. Now, the MSI high study record
3 doesn't have any results from a clinical study
4 in it, right?

5 A. Correct.

6 Q. So the MSI high study records
7 doesn't have in it observing an objective
8 response rate of about 12 percent to 96 percent
9 in the population of cancer patients after
10 administration of pembrolizumab; is that right?

11 MR. RATLIFF: I object to the form
12 of the question.

13 THE WITNESS: That's correct.

14 BY MS. McCORMICK:

15 Q. And the MSI high study record does
16 not talk about treating patients with
17 endometrial cancer, right?

18 MR. RATLIFF: I object to the form
19 of the question.

20 THE WITNESS: It talks about
21 treating patients with non-colorectal
22 cancer. To that degree, I would guess
23 endometrial cancer would be subsumed under
24 that categorization.

25 BY MS. McCORMICK:

1 Q. How many non-colorectal cancers are
2 there?

3 A. Are you asking that as a general
4 question in the universe of oncology?

5 Q. Yes.

6 A. That's a difficult question to ask
7 because it depends on how finely you want to
8 slice the number of sites and the number of
9 histologies, but there's certainly a few
10 hundred.

11 Q. Is non-Hodgkin's lymphoma is not
12 colorectal cancer, right?

13 A. Correct.

14 Q. Do you treat non-Hodgkin's lymphoma?

15 A. It's not a disease I see regularly,
16 no. I mean, I have treated it in the past but
17 not recently.

18 Q. Is it similar to colorectal cancer?

19 A. No.

20 Q. Why not?

21 A. It falls into the category of
22 hematologic malignancies. In the world of
23 oncology, if there is a compartmentalization,
24 probably it falls along the categorization of
25 hematology versus non-hematology, and

1 non-Hodgkin's lymphoma falls into the category
2 of hematologic malignancy.

3 Q. Are solid tumors hematologic
4 cancers?

5 A. That's a funny question. The truth
6 is, they are solid, if you go by the fact that
7 they're solid, but when we talk about solid
8 tumors, we're not usually including lymphomas
9 into that terminology. Solid tumors are the
10 opposite of hematologic malignancies.

11 Q. Are there non-hematologic cancers
12 that aren't solid cancers?

13 A. Yes.

14 Q. Like what?

15 A. Leukemia.

16 Q. Leukemia is not a hematologic
17 cancer?

18 A. Yes, it is. Hematologic
19 malignancies are mainly leukemia and lymphoma.

20 Q. And do you treat leukemia?

21 A. No.

22 Q. Are you familiar with how one treats
23 leukemia just in a general sense?

24 MR. RATLIFF: I object to the form
25 of the question.

1 THE WITNESS: Yes.

2 BY MS. McCORMICK:

3 Q. And is it different than how you
4 treat a solid tumor?

5 A. There are some similarities and some
6 major differences.

7 Q. What are some of the major
8 differences?

9 A. The major difference is that solid
10 tumors when it's possible can be treated with
11 surgery or with localized forms of treatment
12 like radiation. Leukemia is a systemic
13 disease, so you can never treat it or almost
14 never treat it with a localized therapy like
15 surgery or radiation. From the get-go, you
16 have to treat it with chemotherapy.

17 Q. Is there anything in the MSI high
18 study record that eliminates treating patients
19 with hemological cancers?

20 MR. RATLIFF: I object to the form
21 of the question.

22 THE WITNESS: Can you ask the
23 question again?

24 BY MS. McCORMICK:

25 Q. Sure. Is there anything in the MSI

1 high study record, Exhibit 1005, that
2 eliminates from the patient population being
3 treated hematological cancers?

4 MR. RATLIFF: I object to the form
5 of the question.

6 THE WITNESS: I never thought about
7 that. I would have to look at it for a
8 moment.

9 I would say two things do. First,
10 it requires measurable disease and -- so
11 three things.

12 It requires measurable disease and
13 related to that that one of the outcomes is
14 an objective response rate which is related
15 to measurable disease. You could not have
16 that with leukemia. So per se, that would
17 exclude leukemia and I would say for the
18 most part lymphoma as well.

19 And, secondly, I would think that a
20 POSA would understand that the way this is
21 intended or constructed that it would be
22 illogical to include leukemia and lymphoma
23 in a category of non-colorectal cancer when
24 you're talking about MSI high where it says
25 MSI negative, solid tumors, and it would not

1 be logical to also put in a hematological
2 malignancy with it. I guess it would not be
3 impossible, but...

4 BY MS. McCORMICK:

5 Q. Why would it be illogical to include
6 lymphoma or leukemia in the non-colorectal
7 cancer group?

8 A. It just wouldn't follow along in the
9 same ballpark. It's not the same animal. It
10 would be illogical and not of the same
11 category.

12 Any solid tumor could fit into, I
13 think, the third category of the arms, but
14 leukemia and lymphoma really are of a whole
15 other world. You know, the world of oncology
16 really does dichotomize into hematologic versus
17 non-hematologic malignancies. So lumping in
18 leukemia and lymphoma with the other tumors
19 would be very unorthodox.

20 Q. Would neuroendocrine cancer fit into
21 the non-colorectal MSI positive arm of the MSI
22 study record?

23 MR. RATLIFF: I object to the form
24 of the question.

25 THE WITNESS: I suppose the way it

1 is written and the way it's instructed, the
2 answer is yes. I'll say yes.

3 BY MS. McCORMICK:

4 Q. Same question about thyroid cancer;
5 does that fit into the MSI positive
6 non-colorectal cancer arm of the MSI study
7 record?

8 MR. RATLIFF: I object to the form
9 of the question.

10 THE WITNESS: I would say the way
11 it's written, yes.

12 BY MS. McCORMICK:

13 Q. Does the MSI high study record call
14 out any specific cancer type besides colorectal
15 cancer?

16 MR. RATLIFF: I object to the form
17 of the question.

18 THE WITNESS: I don't understand
19 what your question is asking.

20 BY MS. McCORMICK:

21 Q. Where in a MSI high study record
22 does it give instruction as to what kind of
23 patients could be included in the study?

24 A. Well, the eligibility criteria.

25 Q. Anywhere else?

1 A. I would say no, but, again, I think
2 a POSA would have applied a certain degree of
3 logic and intelligence to being able to define
4 who would fall into the various categories but
5 constitute these three arms in the study.
6 That's what I meant when I said that I don't
7 think that anyone rational doing this study --
8 by rational I mean anyone who is doing a
9 normative study like this would have under
10 normal circumstances have included a
11 hematologic malignancy in the third arm. It
12 would be apples and oranges, and they would
13 appreciate that.

14 Neuroendocrine tumors are close in
15 terms of being on the border of whether you
16 would include them or not. If I were the PI of
17 the study and I was called up and someone said,
18 "Hey, Dr. Le, I have a patient who's otherwise
19 eligible and I want to put him in the study
20 under arm three and he's got a neuroendocrine
21 tumor. Can I?" I would have said no. If he
22 would have said yes, I wouldn't have said it
23 was the most ridiculous thing on Earth. You
24 could go either way on the neuroendocrine
25 tumor.

1 I'll tell you because -- I mean, the
2 question is whether you're really restricting
3 it to carcinomas. The question is, where does
4 neuroendocrine tumor fit into the world of
5 carcinomas? And that's a little bit of a
6 question. I think you could have gone either
7 way.

8 Q. An adenocarcinoma, does that mean
9 it's a solid tumor?

10 A. Yes.

11 Q. In the eligibility criteria of a MSI
12 study record, there's no other cancer type
13 listed except for colorectal cancer, correct?

14 MR. RATLIFF: I object to the form
15 of the question.

16 THE WITNESS: Well, that's what I
17 was just saying. There's no other tumor
18 that is specifically by name specified. But
19 as I say, I think by logic or by -- some
20 other tumors would have been excluded, even
21 aside from the ones I just said.

22 I mean aside from hematologic
23 malignancies, you would have had a tough
24 time putting a brain tumor, for example,
25 into this study. Again, I'm not looking at

1 a list of who's in this, who actually they
2 would have put into the study, but I would
3 have been surprised if they put in a brain
4 tumor in. Again, if someone called me and
5 said, "I have a brain tumor patient. Can I
6 put him in?" I would have been very
7 negative. I can't believe they would have
8 put in a brain tumor patient.

9 But that still falls -- you know, if
10 you say a non-colorectal cancer, it's a
11 non-colorectal cancer, but it's really a
12 horse of a different color.

13 BY MS. McCORMICK:

14 Q. The MSI high study record doesn't
15 specifically call out, for instance, an anal
16 cancer, right?

17 A. What do you mean by "call out"?

18 Q. Sorry, mention an anal cancer?

19 MR. RATLIFF: I object to the form
20 of the question.

21 THE WITNESS: No.

22 BY MS. McCORMICK:

23 Q. But the anal cancer could fall into
24 the arm three patients with MSI positive
25 non-colorectal cancer?

1 A. Yes.

2 Q. Dr. Neugut, can you look at
3 Exhibit 1063?

4 A. Okay.

5 Q. It's an article by DiMasi.

6 A. Okay.

7 Q. You have Exhibit 1063 in front of
8 you?

9 A. Uh-huh.

10 Q. You relied on Exhibit 1063 in
11 preparing your declarations for this case,
12 right?

13 A. I believe so, yes.

14 Q. The data recorded in Exhibit 1063 is
15 reliable, as far as you're concerned?

16 A. I imagine so, yes.

17 Q. Do you disagree with any of the
18 statements in DiMasi?

19 A. I haven't read it in a while, so as
20 I sit here at this moment I'm not able to vouch
21 for every word in here.

22 Q. When you read it before, do you
23 remember if there was anything you disagreed
24 with in Exhibit 1063?

25 A. I don't have a memory of it.

1 Q. How many indications did Merck
2 pursue with pembrolizumab before that MSI high
3 clinical study?

4 MR. RATLIFF: I object to the form
5 of the question.

6 THE WITNESS: You're asking me how
7 many indications Merck had for pembrolizumab
8 before MSI high colorectal cancer?

9 BY MS. McCORMICK:

10 Q. Almost. How many indications had
11 Merck pursued for pembrolizumab before the MSI
12 high study?

13 MR. RATLIFF: I object to the form
14 of the question.

15 THE WITNESS: Did I put that in one
16 of my declarations?

17 BY MS. McCORMICK:

18 Q. It's fine if you don't know.

19 A. So I don't know.

20 Q. Was the MSI clinical study the first
21 clinical study with pembrolizumab?

22 A. No.

23 Q. Do you know if it was the second
24 clinical study with pembrolizumab?

25 A. For colorectal cancer?

1 Q. For any cancer.

2 A. No, I don't think so.

3 Q. How many indications for
4 pembrolizumab had failed to achieve FDA
5 approval?

6 MR. RATLIFF: I object to the form
7 of the question.

8 THE WITNESS: I don't know.

9 BY MS. MCCORMICK:

10 Q. We can put DiMasi aside.

11 If you can get Exhibit 1049 in front
12 of you and let me know when you've got it.
13 It's an article by Alexios Matikas.

14 A. Okay.

15 Q. Do you recognize Exhibit 1049?

16 A. I have to say that as I look at it
17 as I'm sitting here, I don't recall it, but
18 feel free to ask me a question about it, and
19 I'll take a quick look at it.

20 Q. You cited Exhibit 1049 in your
21 declarations, right?

22 A. Yes.

23 Q. And if you could turn to page 6 of
24 Exhibit 1049 under the heading Novel
25 Approaches. Let me know when you're there.

1 A. Yup.

2 Q. And under the heading Novel
3 Approaches in Exhibit 1049, the authors discuss
4 immune checkpoint blockade with monoclonal
5 antibodies.

6 Do you see that?

7 A. Yes.

8 Q. There are at least two targets
9 listed there.

10 Do you see that?

11 A. Yes.

12 Q. Those two at CTLA-4, PD-1 and its
13 ligand PD-L1.

14 Do you see that?

15 A. Yes.

16 Q. This article was published in 2015,
17 right?

18 A. Yes.

19 Q. What other immunotherapies were
20 available in 2015?

21 A. Interferon, interleukin.

22 Q. Dr. Neugut, let me stop you so I can
23 be a little more specific.

24 MR. RATLIFF: You can't stop him.

25 He's answering the question. You can

1 withdraw your question.

2 THE WITNESS: Interleukin 2. There
3 were all sorts of experimental approaches,
4 but if you're asking what was in I'll say
5 common use at the time, those are two that
6 come to mind to me, and I don't know offhand
7 what else was being used in -- oh, well
8 there was BCG, Bacillus Calmette-Guerin.

9 BY MS. McCORMICK:

10 Q. The authors of Exhibit 1049 list
11 some immune checkpoint blockade monoclonal
12 antibodies: ipilimumab, nivolumab and
13 pembrolizumab.

14 Do you see that?

15 A. Yes.

16 Q. Were there other immune checkpoint
17 blockade monoclonal antibodies available in
18 2015?

19 A. I believe these were the first, but
20 maybe I'm missing one. To my knowledge, these
21 were the first.

22 Q. And interferon, interleukin and BCG,
23 those are immunotherapies, right?

24 A. Again, I use the term immunotherapy
25 to refer to treatment that somehow utilizes the

1 body's immune system to act against cancer
2 cells. So, yes, those are treatments to do
3 that.

4 Q. And in 2015, were there other
5 immunotherapies besides these monoclonal
6 antibodies, interferon, interleukin and BCG?

7 MR. RATLIFF: I object to the form
8 of the question.

9 THE WITNESS: There were
10 experimental methods. People were trying
11 vaccines, tumor vaccines. I don't have a
12 recollection that any of them worked or
13 worked well enough that it became FDA
14 approved or effective therapy, but at least
15 it was being tried.

16 There may have been other methods
17 being used to stimulate the immune system to
18 function against cancer, but I don't know --
19 as I'm sitting here, I don't recall what
20 else was being tried.

21 BY MS. McCORMICK:

22 Q. So some other approaches for
23 treating cancer listed under novel approaches
24 of Exhibit 1049, cancer vaccine?

25 A. I just mentioned that.

1 Q. You did just mention that.

2 And then also oncolytic viruses, do
3 you see that a little bit further down in the
4 paragraph?

5 A. I mean, that's -- I don't know much
6 about that. That's an oddball one. That's
7 another one that never made it big. I don't
8 know anything about that.

9 Q. And the same paragraph under the
10 heading Novel Approaches mentions that
11 pembrolizumab is being tested in metastatic
12 tumors with microsatellite instability,
13 including colorectal.

14 But there's no results from this
15 clinical study being mentioned reported in
16 Exhibit 1049, right?

17 A. No, but I don't know when in 2015
18 this article was published.

19 Q. But regardless of when it's
20 published, there are no results from the
21 pembrolizumab trial reported in Exhibit 1049,
22 right?

23 A. Yes.

24 Q. And that same sentence that I just
25 read from also reports on a study that's

1 testing a combo of nivolumab and ipilimumab
2 being tested in metastatic colorectal cancer
3 patients, right?

4 A. Yes.

5 Q. And this paragraph concludes whether
6 any of these novel treatments prove to improve
7 outcomes in randomized trials in patients with
8 mCRC remains to be seen.

9 Do you see that?

10 A. Yes.

11 Q. And do you agree with that at the
12 time in 2015?

13 MR. RATLIFF: I object to the form
14 of the question.

15 THE WITNESS: Well, agree with what?
16 I mean, the author hadn't yet seen the
17 results of those trials. They were
18 published around that time or shortly
19 thereafter.

20 MS. McCORMICK: You can set that
21 article aside, and if you can get
22 Exhibit 1006, an article by Pernot.

23 BY MS. McCORMICK:

24 Q. Dr. Neugut, do you recognize
25 Exhibit 1006?

1 A. You're talking about the article by
2 Pernot, right?

3 Q. Yes.

4 A. Yes.

5 Q. If you could turn to the end of the
6 article, on page 10 of Exhibit 1006, there's a
7 table there.

8 A. What page?

9 Q. Page 10 of Exhibit 1006.

10 A. Yes.

11 Q. Do you see table 1?

12 A. Yes.

13 Q. Table 1 is titled Ongoing Clinical
14 Trials, According to National Cancer Institute
15 registration, using Immunotherapy, according to
16 strategy; is that right?

17 A. Yes.

18 Q. Do you know the outcome of any of
19 these trials?

20 A. No.

21 Q. If you wanted to know the outcome of
22 these trials, how would you do it?

23 A. I guess you could look on the
24 clinicaltrials.gov and check it out.

25 Q. Do you know if any of the trials

1 listed here in table 1 made it to the next
2 phase of clinical study?

3 A. By the "next phase," do you mean
4 phase 3 --

5 Q. Correct.

6 A. -- or whatever?

7 MR. RATLIFF: I object to the form
8 of the question.

9 THE WITNESS: No. If I knew that,
10 I -- no.

11 BY MS. McCORMICK:

12 Q. Do you know if any of the studies
13 listed here in table 1 of Exhibit 1006 resulted
14 in FDA approved indications?

15 A. The truth is, I don't know any of
16 these treatments, so I'm going to assume at
17 least -- well, I shouldn't assume. I have no
18 idea.

19 MS. McCORMICK: You can set
20 Exhibit 1006 to the side.

21 If you could find Exhibit 1009 and
22 Exhibit 1095.

23 BY MS. McCORMICK:

24 Q. We can start with Exhibit 1095. Do
25 you recognize this exhibit, Dr. Neugut?

1 MR. RATLIFF: I object to the form
2 of the question.

3 THE WITNESS: I recognize it in one
4 sense.

5 BY MS. MCCORMICK:

6 Q. What sense is that?

7 A. I know what it is.

8 Q. What is it?

9 A. It's the NCCN guidelines for --
10 well, this one is for uterine tumors.

11 Q. Uterine tumors, that category, does
12 that include endometrial cancer?

13 A. Yes. It's primarily endometrial
14 cancer.

15 Q. And what are the NCCN guidelines?

16 A. Some time ago there was a bunch of
17 cancer centers who got together and decided
18 that they would -- that what they did in terms
19 of treatment was good, and they, therefore,
20 decided that they would be the arbiters of what
21 should be appropriate therapy for cancer. So
22 they put out guidelines tumor by tumor. They
23 met on a regular basis and began publishing and
24 promulgating guidelines on the tumor-by-tumor
25 basis for how to manage each type of

1 malignancy.

2 The reality is that they do a pretty
3 good job of giving general guidelines on how to
4 manage each clinical setting for each cancer
5 and what to do, and they give mostly a good
6 rationale as the basis for their recommendation
7 for each tumor.

8 I would say when there's no
9 randomized trial or no published basis for the
10 situation they're addressing, then their
11 recommendation is usually a bit more shaky,
12 but, in general, their recommendations are
13 pretty good. They're widely utilized. That is
14 very often the case that clinicians or fellows
15 will often refer to their guidelines in given
16 situations to see what they recommendation and
17 then decide what to do based on that.

18 Q. Do you rely on the NCCN guidelines?

19 A. No. Well, I don't want to say no.
20 Once in a while I look them up, but mostly no.

21 Q. In forming your opinions for this
22 case, did you consult with anyone other than
23 Merck's counsel?

24 A. No.

25 Q. Dr. Neugut, what did you do to

1 prepare to give testimony today?

2 A. What did I do for what?

3 Q. To prepare to give testimony today.

4 A. I met several times with the
5 attorneys from Paul Hastings to review the
6 declarations and to prepare for the deposition.
7 I re-read all the patents and the declarations.
8 I re-read all the publications that we're
9 discussing that are included in the discussion.

10 Q. Anything else?

11 A. I'm thinking. I tried to get a good
12 night's rest. That's all I can think of.

13 Q. To prepare to give testimony today,
14 how long did you meet with the attorneys from
15 Paul Hastings?

16 A. Cumulative you mean?

17 Q. Yes.

18 A. It's a ballpark estimate, 25 to
19 28 hours.

20 Q. Dr. Neugut, when we were talking
21 earlier, we were talking about MSI being a
22 prognostic indicator for CRC cancers before
23 PD-1 inhibitors were available for treatment.

24 Do you recall that?

25 A. Yes.

1 Q. Before PD-1 inhibitors were
2 available for treatments, was MSI a prognostic
3 indicator for any other cancer type?

4 MR. RATLIFF: I object to the form
5 of the question.

6 THE WITNESS: So small bowel cancers
7 parallel colorectal cancer in most ways, so
8 the answer is that it would be a prognostic
9 indicator for that as well.

10 It's funny, I don't know the answer
11 to that. I should. It's a good question.
12 I should know the answer and I don't. I
13 only know my own cancer. I don't know the
14 prognostic indicator for other tumors.

15 MS. McCORMICK: If we could just
16 take a quick break, and then we might be
17 done.

18 - - -

19 (Whereupon, a recess was held.)

20 - - -

21 BY MS. McCORMICK:

22 Q. Dr. Neugut, before July 10, 2015,
23 did oncologists routinely test endometrial
24 cancer for MSI status?

25 A. I don't know. Not to my knowledge.

1 Q. Before July 10, 2015, did
2 oncologists routinely test ampullary cancer for
3 MSI status?

4 A. I don't think so.

5 Q. Before July 10, 2015, did
6 oncologists routinely test cholangiocarcinoma
7 carcinoma for MSI status?

8 A. Well, again, let me reiterate from
9 my earlier testimony that while there was -- I
10 don't believe there was routine testing
11 specifically for MSI status, there was
12 frequently the next genome sequencing, which
13 was a broad-spectrum test of biomarkers. So in
14 the course of doing that, you would determine
15 that someone was MSI high or not, but the
16 testing wasn't specifically for MSI. Did they
17 do MSI testing just to do MSI testing? I don't
18 think it was done routinely as it was for
19 colorectal cancer.

20 Q. Before July 10, 2015, was NGS
21 testing routinely done?

22 A. It was done very frequently. Not on
23 everybody, but it was done a lot. I don't know
24 what year it became kind of a common practice.
25 It was done frequently, particularly at the

1 better centers, but even in the community, yes.

2 Q. And was the NGS testing done for
3 specific cancer types?

4 MR. RATLIFF: I object to the form
5 of the question.

6 THE WITNESS: It's done for most of
7 the solid tumors, many of the solid tumors.

8 BY MS. McCORMICK:

9 Q. Before July 10, 2015, did
10 oncologists routinely test prostate cancer for
11 MSI status?

12 A. I don't think so.

13 Q. Before July 10, 2015, did
14 oncologists routinely test breast cancer for
15 MSI status?

16 A. I don't know.

17 Q. Before July 10, 2015, did
18 oncologists routinely test esophageal cancer
19 for MSI status?

20 A. I don't know. I don't think so.

21 Q. Before July 10, 2015, did
22 oncologists routinely test liver cancer for MSI
23 status?

24 A. I don't believe so.

25 Q. Before July 10, 2015, did

1 oncologists routinely test ovarian cancer for
2 MSI status?

3 A. I don't think so.

4 Q. Before July 10, 2015, did
5 oncologists routinely test uterine cancer for
6 MSI status?

7 A. That I don't know because, again,
8 that's part of Lynch syndrome. I don't know.
9 I didn't see endometrial cancer.

10 Q. Before July 10, 2015, did
11 oncologists routinely test cervical cancer for
12 MSI status?

13 A. I don't think so.

14 Q. Before July 10, 2015, did
15 oncologists routinely test bladder cancer for
16 MSI status?

17 A. I don't think so.

18 Q. Before July 10, 2015, did
19 oncologists routinely test bladder cancer for
20 MSI status?

21 A. I don't think so.

22 Q. Before July 10, 2015, did
23 oncologists routinely test oral cancer for MSI
24 status?

25 A. I don't know.

1 Q. Before July 10, 2015, did
2 oncologists routinely test small bowel cancer
3 for MSI status?

4 A. Yes.

5 Q. And before July 10, 2015, did
6 oncologists routinely test gastric cancer for
7 MSI status?

8 A. Yes.

9 Q. Before July 10, 2015, did
10 oncologists routinely test ampullary cancer for
11 MSI status?

12 A. I don't know.

13 Q. And before July 10, 2015, did
14 oncologists routinely test cholangiocarcinoma
15 for MSI status?

16 A. I don't know.

17 Q. Dr. Neugut, are any of the other
18 documents in front of you highlighted besides
19 the '356 patent?

20 A. I'm sorry?

21 Q. Are any of the other documents in
22 front of you highlighted besides the '356
23 patent?

24 A. No.

25 MS. McCORMICK: We would ask that

1 the copy of the document in front of Dr.
2 Neugut be made an exhibit to this
3 deposition, including a copy of that Post-it
4 note that's on Exhibit 1005 in front of Dr.
5 Neugut.

6 MR. RATLIFF: Sure.

7 BY MS. McCORMICK:

8 Q. Before July 10, 2015, routine
9 testing for small bowel cancer and gastric
10 cancer was for Lynch syndrome, correct?

11 MR. RATLIFF: I object to the form
12 of the question.

13 THE WITNESS: I mean, I think the
14 information had applications beyond Lynch
15 syndrome, but that's why those two cancers
16 were particularly tested.

17 BY MS. McCORMICK:

18 Q. The applications beyond Lynch
19 syndrome related to MSI testing of small bowel
20 and gastric cancers, were those the ones we
21 previously discussed in relation to colorectal
22 cancer?

23 A. Yes.

24 MR. RATLIFF: I object to the form
25 of the question.

1 THE WITNESS: Yes.

2 MS. McCORMICK: I have no further
3 questions for you, Dr. Neugut. I appreciate
4 your time.

5 MR. RATLIFF: Let's take a break to
6 see if I have any questions for Dr. Neugut.

7 - - -

8 (Whereupon, a recess was held.)

9 - - -

10 MR. RATLIFF: Dr. Neugut, I do not
11 have any questions for you today. I'd like
12 to thank you for your time. I'd like to
13 also thank the court reporter for her time
14 today.

15 I would like the transcript
16 designated highly confidential under the
17 proposed protective order for these matters.
18 To the extent you want to do any redaction,
19 we can work that out.

20 MS. McCORMICK: What's the reason
21 for the designation?

22 MR. RATLIFF: Given the subject
23 matter that Dr. Neugut talked about
24 involving some of his work on a board.

25 MS. McCORMICK: I understand.

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(Whereupon, the documents were
marked, for identification purposes, as
Exhibit 2041 and Exhibit 2042.)

- - -

(Witness excused.)

- - -

(Deposition concluded at 11:13 a.m.)

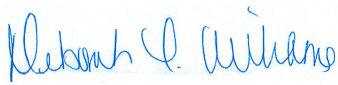
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C E R T I F I C A T E

I do hereby certify that I am a Notary Public in good standing, that the aforesaid testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my supervision with computer-aided transcription; that the deposition is a true and correct record of the testimony given by the witness; and that I am neither of counsel nor kin to any party in said action, nor interested in the outcome thereof.

WITNESS my hand and official seal this 7th day of January, 2025.


Deborah L. Williams, CCR, CLR
Notary Public

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby
certify that I have read the foregoing pages ____
to ____ and that the same is a correct
transcription of the answers given by me to the
questions therein propounded, except for the
corrections or changes in form or substance, if
any, noted in the attached Errata Sheet.

DATE

SIGNATURE

Subscribed and sworn to before me
this
_____ day of _____, 2025.

My commission expires:

Notary Public

<div> <div>Exhibits</div> <div> Neugut Exhibit 2041 4:13 107:4 Neugut Exhibit 2042 4:14 107:4 </div> </div> <div>1</div> <div> 1 10:8,15 13:9 14:20,22 15:8 30:1,8 49:20 95:11,13 96:1,13 10 8:22 95:6,9 100:22 101:1,5,20 102:9,13,17, 21,25 103:4,10,14,18, 22 104:1,5,9,13 105:8 10,934,356 12:17 100 12:8 68:17 1001 10:24 13:4,7 1002 10:20,25 1003 11:12,13,17,21 12:10 24:5 1005 70:5 76:19,24 81:1 105:4 1006 94:22,25 95:6,9 96:13, 20 1009 96:21 1034 70:10,23 71:4,10,17,25 75:14 1049 89:11,15,20,24 90:3 91:10 92:24 93:16,21 1063 87:3,7,10,14,24 1095 96:22,24 </div>	<div> 11:13 107:8 12 14:13 77:8 13 29:7 31:23 33:15 15 51:16,19 65:4 187 8:14 28:24 29:3,6,10, 13,21,23 30:8,12,25 31:8 32:14,25 33:3,19 34:4,10,13 </div> <div>2</div> <div> 2 10:19 49:20 73:22 91:2 20 38:3,8 51:16,19 20,000 58:22 2010 40:21 43:23 61:1 2011 61:23 2012 61:24 2013 40:21,22 43:24 61:24 2014 40:22 2015 8:22 59:25 60:2 61:1 90:16,20 91:18 92:4 93:17 94:12 100:22 101:1,5,20 102:9,13,17, 21,25 103:4,10,14,18, 22 104:1,5,9,13 105:8 2024 12:13 24:14 26:25 27:21 29:7 31:23 33:15 2041 107:4 2042 107:4 </div>	<div> 219 8:14 23:24 24:2,6,10, 13,16 25:5,21 26:13 28:10 23 13:24 14:2,17 15:8 25 13:19 22:4 99:18 28 99:19 287 8:15 9:21 </div> <div>3</div> <div> 3 49:20 50:1 96:4 30 13:7,12 38:3,8 31 13:12 356 8:15 11:8,11,17,21 12:10,19 13:3,8,12 15:12 17:4,7 18:8 24:24 25:12 28:10 104:19,22 393 19:23 21:18 </div> <div>4</div> <div> 4 12:13 24:14 26:25 27:21 49:20 65:4 462 8:13,14 31:12,14,15,19, 22 32:2,4,13,25 33:5,18 34:5,10,13 73:25 491 8:14 33:7,11,14,17,25 34:5,11,14 </div> <div>5</div> <div> 5 45:14 46:20 50:1 71:9, 17,24 75:14 50- 38:16 </div>	<div>6</div> <div> 6 89:23 66 24:9 </div> <div>7</div> <div> 72 26:19 74 27:17 75 24:9 29:2 75,000 38:17 76 31:18 79 33:10 </div> <div>8</div> <div> 8 71:9 80 40:8 81 26:19 84 29:2 85 31:18 88 33:10 </div> <div>9</div> <div> 90 11:20 12:3,9 96 14:13 77:8 974 8:15 26:16,20,24 27:3,7 28:11 </div>
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