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

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MERCK SHARP & DOHME LLC,

Petitioner,

-against-

THE JOHNS HOPKINS UNIVERSITY,

Patent Owner.

CERTIFIED COPY

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CASE IPR2024-00240
U.S. Patent No. 11,591,393

STENOGRAPHIC DEPOSITION OF:
ALFRED I. NEUGUT, M.D., Ph.D., MPH
Thursday, August 8, 2024
7:31 a.m. - 3:31 p.m. | Pages 1 - 218
HYBRID DEPOSITION

Reported stenographically by:
Richard Germosen, FAPR, CA CSR No. 14391
RDR, CRR, CCR, CRCR, CSR-CA, NYACR, NYRCR
NCRA/NJ/NY/CA Certified Realtime Reporter
NCRA Realtime Systems Administrator
Job No. 140312
BILLING FR Ref. 52261-0005IP1

1 **STENOGRAPHIC DEPOSITION** on behalf of Patent Owner
2 of **ALFRED I. NEUGUT, M.D., Ph.D., MPH**, taken in the
3 above-entitled matter before **RICHARD GERMSEN**, Fellow of
4 the Academy of Professional Reporters, Certified Court
5 Reporter, (License No. 30XI00184700), Certified Realtime
6 Court Reporter-NJ, (License No. 30XR00016800),
7 California Certified Shorthand Reporter, (License No.
8 14391), NCRA/NY/CA Certified Realtime Reporter, NCRA
9 Registered Diplomate Reporter, New York Association
10 Certified Reporter, NCRA Realtime Systems Administrator,
11 taken at the offices of **PAUL HASTINGS LLP**, MetLife
12 Building, 200 Park Avenue, New York, New York 10166, on
13 Thursday, August 8, 2024, commencing at 7:31 a.m.

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23 **ALSO PRESENT:**

24 **KAREN MOREIRA, ESQ., Merck**

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I N D E X

WITNESS	EXAMINATION
ALFRED I. NEUGUT, M.D., Ph.D., MPH	
BY ATTORNEY MCCORMICK	8

E X H I B I T S

EXHIBIT NO.	DESCRIPTION	PAGE
Exhibit 2058	article in Frontiers in Oncology entitled Prognostic and therapeutic impact of the KRAS G12C mutation in colorectal cancer	44
Exhibit 2059	article in Journal of Oncology entitled Cost-effectiveness analysis in biomarker-guided treatment for metastatic gastric cancer in the second-line setting	50
Exhibit 1005	document previously marked Exhibit 1005	85
Exhibit 1057	document previously marked MERCK EX 1057	127

THE SULLIVAN GROUP OF COURT REPORTERS

1	E X H I B I T S (CONT'D.)		
2	EXHIBIT NO.	DESCRIPTION	PAGE
3	Exhibit 1006	document previously marked	149
4		MERCK EX1006	
5			
6	Exhibit 1008	document previously marked	164
7		MERCK EX1008	
8			
9	Exhibit 1009	document previously marked	165
10		MERCK EX1009	
11			
12	Exhibit 1010	document previously marked	169
13		MERCK EX1010	
14			
15	Exhibit 1011	document previously marked	171
16		MERCK EX1011	
17	**original exhibits returned with original transcript		
18	by SULLIVAN GROUP to FISH & RICHARDSON PC		
19	(exhibit index concluded)		
20	DIRECTION TO WITNESS NOT TO ANSWER		
21		Page Line	
22		213 12	
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P R O C E E D I N G S

7:31 a.m.

CERTIFIED STENOGRAPHER: On the
stenographic record at 7:31 a.m.

Good morning. My name is Rich
Germosen. I am a certified stenographic
reporter. My license is available for
inspection.

(Whereupon, the Certified
Stenographic Reporter administered the oath to
the witness.)

A L F R E D I. N E U G U T, M.D., Ph.D., MPH,
(witness produced a New Jersey driver's license),
585 West Englewood Avenue, Teaneck, New Jersey 07666,
having been first duly sworn or affirmed, was
examined and testified as follows:

EXAMINATION BY ATTORNEY McCORMICK:

BY ATTORNEY McCORMICK:

Q. Good morning, Dr. Neugut.

My name is Madelyn McCormick, and I
represent patent owner Johns Hopkins in this
proceeding, and I have some questions for you

1 today, okay?

2 A. Yes.

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

5 You understand that you are under
6 oath; correct?

7 A. Yes.

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

11 A. Sure.

12 Q. And you'll do that today; correct?

13 A. Yes.

14 Q. You also understand that the
15 testimony you give today is just as important
16 as if you were in a courtroom in front of a
17 judge; correct?

18 A. Yes.

19 Q. So you understand that you must
20 give truthful, complete, and accurate
21 testimony today; correct?

22 A. Yes.

23 Q. And you'll do that today; correct?

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

1 Q. You can answer it, Dr. Neugut.

2 A. Yes.

3 Q. If you don't understand my
4 question, please let me know, okay?

5 A. Yes.

6 Q. So if you answer a question, it's
7 fair for me to assume that you understood the
8 question; correct?

9 A. Yes.

10 Q. If you ever want to take back,
11 change, or modify an answer that you gave
12 today, please let me know, okay?

13 A. Yes.

14 Q. We'll take a break about every
15 hour, okay?

16 A. Okay.

17 Q. If you ever feel like you need to
18 take a break sooner, please let me know and
19 I'll let you take that break, okay?

20 A. Thank you.

21 Q. Is there any reason, medical or
22 otherwise, why you cannot give truthful,
23 complete, and accurate testimony today?

24 A. No.

25 Q. You requested that we start this

1 deposition early today; correct?

2 A. Yes.

3 Q. Why is that?

4 A. So I can get out early. No other
5 reason than that. I thought it was going to
6 run late.

7 Also, I don't want -- I won't
8 easily be available for another day, and if
9 you wanted to run over, it would be somewhat
10 difficult. I thought it would be difficult to
11 run to another day. Mr. Ratliff replied to me
12 that it was a possibility it might run to
13 another day. I don't know if you had more
14 questions or that was a possibility. The
15 truth is I could do another day, but it would
16 be difficult for me, and I didn't want -- I
17 wanted to minimize the possibility that we
18 would need an alternative day or a second day.

19 Q. Great. I appreciate that.

20 Just so you know, I hope to finish
21 today, so we'll do our best to do that.

22 A. That's fine.

23 Q. Did you also request not to be
24 video recorded today?

25 A. No.

1 Q. So just so we can establish some
2 common terminology today, if I use the term
3 "MSI," will you understand that I'm referring
4 to microsatellite instability?

5 A. Yes.

6 Q. What is microsatellite instability?

7 A. Microsatellite instability is a
8 marker that is present on tumors which
9 reflects an abnormality which stems from
10 what's called a mismatch repair and --

11 (Clarification requested by the
12 stenographer.)

13 A. Which stems from mismatch repair
14 and is present on a fraction of tumors.

15 Q. If I use the term "DMMR," will you
16 understand that I'm referring to mismatch
17 repair deficient?

18 A. Yes.

19 Q. And if I use the term "CRC," will
20 you understand I'm referring to colorectal
21 cancer?

22 A. Yes.

23 Q. And can we also agree for
24 efficiency sake that if I say MSI high, it
25 will encompass DMMR as well?

1 A. I will understand that the two
2 terms are for practical purposes synonymous.

3 Q. And if you ever want to distinguish
4 between the two, please let me know in my
5 question.

6 A. I would use the terms
7 interchangeably as well.

8 Q. Great.

9 Dr. Neugut, you're a clinical
10 oncologist; correct?

11 A. Yes.

12 Q. You're an epidemiologist as well?

13 A. Yes.

14 Q. You treat cancer patients; correct?

15 A. Yes.

16 Q. Do you treat CRC patients?

17 A. Yes.

18 Q. About how much of your practice
19 would you say is treating CRC patients versus
20 other types of cancer patients?

21 A. 80 to 90 percent.

22 Q. So most of the patients that you're
23 treating are CRC patients?

24 A. Yes.

25 Q. Do you treat patients with

1 metastatic CRC?

2 A. Yes.

3 Q. What does metastatic mean?

4 A. Metastatic means that the tumor has
5 spread from beyond the original site of origin
6 from the colon or the rectum and has spread to
7 distant organs, the liver, the lung, or other
8 sites in the body.

9 Q. And metastatic disease is something
10 different than measurable disease; is that
11 right?

12 A. Yes, they're different terms, yes.

13 Q. What is the difference between the
14 two terms "metastatic disease" and "measurable
15 disease"?

16 A. Well, the truth, they're -- it's
17 total different terms. I mean, measurable
18 means it's a term that's used -- metastatic I
19 already defined, and measurable means -- is a
20 term that's used for assessing the progress of
21 treatment for patients. If you want to know
22 how a patient is responding to therapy, then
23 we utilize -- we measure the tumors to see if
24 they've shrunk or if they've gotten larger,
25 and to do that we literally put calipers on

1 them or do something of similar sorts to see
2 if they've gotten bigger or smaller.

3 Not every tumor is measurable. We
4 have to have sort of a clear tumor, like a
5 lump, or on a radiograph, a tumor which is
6 circular, or something like that where it's
7 clearly outlined on the radiograph so that you
8 can measure it. Some forms of tumor are not
9 easily measurable. So although it's
10 measurable, although they may be metastatic
11 disease, they would not necessarily be
12 measurable, but that's what measurable means.

13 In the context of -- so in
14 day-to-day clinical oncology, we utilize
15 measurable disease in that fashion. It's
16 almost always a requirement in trials, because
17 in trials you want to assess progress of
18 treatment. It's almost always a criterion in
19 solid -- we're talking about solid tumor
20 oncology to determine how a patient is
21 responding to treatment.

22 Q. So is it true that measurable
23 cancer refers to a cancer that has a minimum
24 size?

25 ATTORNEY RATLIFF: I object to the form

1 of the question.

2 A. I don't know what minimum size
3 means.

4 Q. So there has to be some amount of
5 the cancer on the radiograph, for instance,
6 that you can measure in order for it to be
7 considered measurable disease; correct?

8 A. Yes, there has to be -- it has to
9 be visible, and as I said, it has to be
10 measurable. You can measure every -- not
11 every tumor is measurable.

12 Q. What do you mean by that? Can you
13 give me an example?

14 A. So if a patient has what's called a
15 pleural effusion, a pleural effusion is a
16 fluid around the lung. So that's
17 metastatic -- I'm talking about pleural, a
18 pleural effusion stemming from the tumor, so
19 that is -- that may be -- that's metastatic
20 disease. It's metastasized from the tumor,
21 and it would make a patient stage four or
22 metastatic disease, but you can't measure
23 fluid like that. You could not put calipers
24 on it and say how big it is and things like
25 that or measure its progression easily in a

1 quantitative way.

2 So that would not -- if that was
3 the only site of the disease a patient had, it
4 would not be possible to make a clear-cut
5 quantitative assessment to progress or
6 regression using that. You could say
7 something, I don't know, estimated, or you
8 could say, Well, it got a little better. It
9 got a little worse, but you could not make a
10 measurable assessment exactly how much bigger
11 or how much smaller it got. So that would be
12 an example of nonmeasurable metastatic
13 disease.

14 Q. Great. Thank you.

15 Dr. Neugut, have you ever conducted
16 a clinical trial for a cancer therapy?

17 A. I have participated in innumerable
18 clinical trials, either as putting patients
19 into them or as a co-investigator, but I can
20 only think of one or two where I've actually
21 been one of the PIs. It's not my primary area
22 of interest as a researcher. So I don't
23 normally -- I don't normally conduct clinical
24 trials as my main activity.

25 Q. What is your primary area of

1 interest for research?

2 A. I do two things. I do -- I'm a
3 cancer epidemiologist. So I do studies that
4 focus on cancer etiology and cancer
5 prevention, why you get cancer, causes of
6 cancer, and things like that, and then
7 stemming from that, how to prevent those
8 causes, and how to reduce cancer occurrence
9 related to that. So that has been, from the
10 start of my career, the main focus of my
11 research career.

12 For the last 20 years, I would say
13 I also have done what's called health outcomes
14 research. So health outcomes research is the
15 application of epidemiologic methodology to
16 clinical questions. So it uses the same
17 statistical and study design methods that we
18 use in epidemiology, but rather than
19 addressing ideologic questions, like is used
20 in classical epidemiology, it addresses
21 questions in clinical medicine.

22 So, for example, what I've studied
23 is quality of care in oncology. If someone is
24 supposed to get, for example, in stage three
25 colon cancer adjuvant therapy for their colon

1 cancer. Do people with stage three colon
2 cancer get the treatment they're supposed to
3 get. If they don't get it, why don't they get
4 it? Who doesn't get it? Is it because of
5 socioeconomic reasons, age, comorbidities,
6 race and ethnicity, where they live, access to
7 care, issues like those kind of questions,
8 again, addressing quality of care. I've been
9 very involved in questions like medication
10 adherence, who doesn't take their pills, you'd
11 be astounded at how big a problem medication
12 adherence is in general in medicine and in
13 oncology as well, and questions of that sort.

14 So that has been a major issue for
15 me or major area that I've addressed in
16 oncology. And, by the way, even with regard
17 to drugs, like pembrolizumab and
18 immunotherapy, I just had an editorial in JCO
19 which looked at the use of immunotherapy and
20 patients near the end of life and its use or
21 misuse and questions like that. So again,
22 questions addressing like that in quality of
23 care in oncology in particular. And more
24 recently, again, if you're asking what I do,
25 which I'm happy to talk about, I've been

1 mainly studying also cancer in Africa who gets
2 treated, how care is given in cancer in
3 Sub-Saharan Africa, particularly with regard
4 to HIV and HIV positive versus HIV negative
5 patients, how that affects care and questions
6 like that, so I've been doing that for about
7 15 years.

8 Q. It sounds like you do a lot of
9 important work, Dr. Neugut. Thank you for
10 that.

11 So I just want to make sure that I
12 understand.

13 A. Uh-huh.

14 Q. So one of your primary areas of
15 research interest is cancer epidemiology, so
16 prevention of cancer. Did I get that right?

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

19 A. Yes.

20 Q. And then another area of your
21 primary interests for research is researching
22 questions in clinical medicine regarding
23 quality of care; is that right?

24 A. Yes.

25 Q. And then another more recent,

1 although you've been doing it for 15 years,
2 primary area of research interest is studying
3 cancer in Africa; correct?

4 A. Yes.

5 Q. Any other primary research
6 interests?

7 A. If you look back over my 40-year
8 career, the answer is I did have a lot of
9 interest in what is called multiple primary
10 cancers, that is the occurrence of more than
11 one cancer in individuals, which is a major
12 occurrence, probably 15 percent of patients
13 get more than one cancer or something like
14 that. So I've studied that extensively as
15 well. I think I'd be considered a major
16 expert on that subject. I actually have a
17 book on it, it's on Amazon if you want to buy
18 a copy. So I would consider that another
19 major area of interest.

20 I've written over 800 papers, so
21 there is a lot sprinkled in there, where I've
22 had about 80 or 100 postdocs or graduate
23 students. So I've worked with them on a whole
24 range of topics. So again, I've been involved
25 in research on any number of things, which has

1 really been me collaborating with the fellows
2 and postdocs. So I have publications on any
3 number of other topics, which are different
4 from the three or four areas I've just
5 described as my -- I'll call my personal areas
6 of research interest.

7 Q. You said that you were a PI on one
8 or two clinical studies?

9 A. Uh-huh.

10 Q. Is that right?

11 A. Yes.

12 Q. And what do you mean by PI?

13 A. Principal investigator.

14 Q. And what's the role of a principal
15 investigator on a clinical study?

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

18 A. It's a person who is in charge of
19 it.

20 Q. Does the principal investigator
21 design the study?

22 A. Again, most studies that I
23 participate in are multiperson things, and so
24 it's hard to say sometimes who does what.

25 So these are group efforts, and so

1 who exactly to say design is a loaded word.
2 Let's say the person who may have had the
3 idea, the person who is the senior person and
4 is over the junior person who had the idea.
5 It's hard to say sometimes who is the -- who
6 is responsible and who is -- if you talk about
7 a PI and who is really doing what, it's
8 sometimes a little blurry or ambiguous, but
9 the PI, the principal investigator, is
10 generally the person who is responsible for --
11 overall for finances, for submitting the grant
12 for the contract or -- which is ultimately
13 generated for the grant, for the publications
14 that stem from it, for telling everybody what
15 to do and all of that. Their name is the one
16 that signs the proposal or the contract or the
17 grant or whatever. Again, exactly who really
18 does what? That's -- as I say, that may be a
19 little -- a little more difficult to discern,
20 but the PI is the one whose name is at the
21 bottom line overall and who is responsible.

22 Q. Those one or two clinical studies
23 where you had the in-charge role as PI, at a
24 high level, what were those studies about?

25 A. I did a randomized trial. I told

1 you one of my interests was medication
2 adherence. So I did a randomized trial at
3 SWOG. SWOG is -- many trials in oncology are
4 done in what are called cooperative groups. I
5 don't know if you're familiar with that or if
6 you need me to explain? Do you need me to
7 explain what a cooperative group is?

8 Q. No, that's fine. And I'm really
9 just asking like generally --

10 A. Okay.

11 Q. -- what those clinical studies --

12 A. Yeah.

13 Q. -- you're studying?

14 A. So it was a trial to see if sending
15 text messages to patients who were taking an
16 oral medication, sending them text messages
17 would enhance their adherence to the drug.
18 Tamoxifen, women take tamoxifen for breast
19 cancer for five years. It turns out more than
20 50 percent of women stopped taking the drug
21 along the way, which is real negative. It's a
22 very efficacious drug, so we did a randomized
23 trial to see if by sending them text messages
24 two or three times a week, that would enhance
25 the adherence of their compliance with taking

1 the medication.

2 They got a text message: Tamoxifen
3 is good for you. Keep taking it. Good
4 girl -- well, not girl. Good woman or
5 whatever. You know, and do that for -- and
6 then measuring their adherence to the drug to
7 see if it would help, and while the other was
8 a randomized trial, the second half of the
9 group -- second arm didn't get text messages,
10 and then after three years to see if there was
11 enhanced use of the tamoxifen in the text
12 message group.

13 Q. And did you know the outcome of
14 that trial before you got the results?

15 A. How would I know the outcome of the
16 trial before I got the results?

17 Q. So fair to say you didn't know the
18 outcome until you got the results; right?

19 A. Right.

20 Q. And then what was the other trial
21 that you were a PI for, just again at a high
22 level?

23 A. Oh. I'm not remembering it as I
24 sit here.

25 Q. Was it epidemiology-related?

1 A. Also prevention trial. So again,
2 we do prevention trials, but I'm not
3 remembering exactly what it was at the time.

4 Q. That's fine.

5 A. It's quite awhile ago.

6 Q. Great.

7 So have you ever designed a
8 clinical trial for testing a cancer therapy?

9 A. I haven't been the PI predominant.
10 I've helped some of my fellows or students
11 with writing the protocols for it, but I
12 haven't personally been the PI at such a
13 trial.

14 Q. So have you developed a method of
15 treatment for use in a clinical trial testing
16 a cancer therapy?

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

19 A. I don't know what the question
20 means.

21 Q. Fair enough.

22 I'm trying to ask if you have come
23 up with a novel method of treating cancer
24 before?

25 ATTORNEY RATLIFF: If that's the

1 question, I object to the form of the
2 question.

3 A. I can't recall ever doing that, no.

4 Q. In your experience, you're aware
5 that clinical -- cancer trials can fail;
6 correct?

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

9 A. I'm sorry, I'm aware that what?

10 Q. You're aware that clinical cancer
11 trials can fail?

12 ATTORNEY RATLIFF: I object to the form
13 of the question.

14 A. What do you mean by "fail"?

15 Q. So clinical cancer trials cannot
16 meet primary endpoints; correct?

17 A. Again, I'm not sure we're using
18 terminology in the same way. I mean, to me, a
19 trial is supposed to answer a question does a
20 drug reduce mortality. So if a trial is
21 conducted and the drug does not reduce
22 mortality, to me, that was a successful trial.

23 I don't know if you call that a
24 failure or if you don't call that a failure.
25 I call that a good trial because it answered

1 the question that the trial was designed to
2 answer. So I don't know if that answers your
3 question.

4 Q. So what do you call it, just
5 because you have the terminology obviously
6 that I do not, if a trial is conducted and the
7 drug does not reduce mortality, presumably
8 that didn't meet the primary endpoint if that
9 was the point of the study; correct?

10 ATTORNEY RATLIFF: I object to the form
11 of those questions.

12 A. Well, again, so if you ask me --
13 when you say a drug -- a trial failed, that
14 means to me that you tried to do a trial and
15 you were unsuccessful in being able to conduct
16 a trial.

17 So let's say when you do a trial,
18 you have a recruitment goal based on
19 statistical power and issues of that sort. So
20 let's say you wanted to recruit 100 patients
21 and randomize 50 to an arm, but for whatever
22 reason you couldn't find 100 patients who met
23 eligibility criteria and you only found 60, so
24 you had to discontinue the trial, you know,
25 halfway through or whatever it was, to me,

1 that was a failed trial, the trial failed. So
2 you couldn't finish it. So that to me is a
3 failed trial.

4 So when you ask the question,
5 that's what I saw as failure, but to me, when
6 you conduct a trial, you ask a question, Does
7 a drug improve mortality or does it not
8 improve mortality, in which you then recruit
9 100 patients, you randomize 50 to arm A and 50
10 to placebo, and then you conduct a trial, and
11 at the end you get a clear-cut answer, Yes, it
12 does improve mortality, or no, it does not
13 improve mortality. You've got an answer, a
14 clear answer. That was a great trial, and if
15 the answer was no, okay, tough, but -- and
16 maybe the drug company is not happy because
17 they wanted it to be positive, but at least
18 they got a good answer and now they can go on
19 and, you know, take the drug to some other
20 tumor or do something else with the drug or
21 not waste more money on developing the drug
22 further, but they got a clear answer and they
23 should be pleased -- in my mind, they should
24 be pleased with the trial and happy with it.

25 What's an unsuccessful trial is

1 either that you couldn't finish the trial or
2 you get an ambiguous answer where it's sort
3 of, Well, it got a trend to a positive answer.
4 That sometimes occurs. It was a .08, they'll
5 say, or this or that, and at the end, they'll
6 argue over whether it was positive or not. It
7 was positive in a subgroup or, you know,
8 things like that. So then you end up not
9 knowing what the result was, and that's --
10 that's to me, an unsuccessful trial and a
11 trial that gives difficulty to the
12 investigators and to the -- again, I'll say
13 the drug company, if we're talking about drug
14 company trials.

15 So that's when you do have a
16 problem, because then you don't know -- you
17 don't know what to do. Should we dump the
18 drug or should you exalt the drug. You don't
19 know what to do after that, and that's the
20 problem in a trial, not -- a good no is a good
21 no. That's great, you know.

22 Q. So I want to ask you about these
23 good no trials.

24 A. Uh-huh.

25 Q. How would you talk about those?

1 Like is there a phrase we can use for that
2 kind of trial?

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

5 A. Negative.

6 Q. Negative trial?

7 A. Not negative trial. Well, a trial
8 that got a negative result. I mean, you know,
9 trials either get a positive result or a
10 negative result. If the experimental drug,
11 the experimental arm, it could be a drug, it
12 could be a combination regimen, or whatever it
13 is, if the intervention, you know, the
14 experimental intervention, it can either be
15 positive in terms of say in comparison to the
16 comparison arm, if it improved the outcome,
17 whatever the outcome was. So that's a
18 positive result.

19 If it was negative, if it was
20 negative, now you can also get a null result.
21 So that -- so here actually there is ambiguity
22 in the way -- so we're talking about ambiguity
23 in the way people talk. People don't talk
24 correctly. I'm talking about my colleagues.
25 Everyone uses terms incorrectly, and I'm

1 talking about other oncologists.

2 So let us say arm A versus arm B,
3 the two arms have the same outcome in terms of
4 survival. So they'll call that a negative
5 study, and that has a negative result. That's
6 the incorrect term. It's not negative. It's
7 null. Again, speaking as an epidemiologist
8 and study design expert, I'll give myself that
9 designation, the truth is, but the correct
10 term is a null result, N-U-L-L.

11 A negative, a negative result
12 really means that arm B, the control arm, was
13 better than arm A, than the intervention arm,
14 because you can just as well -- if you're
15 comparing treatment A to treatment B, you can
16 just as well have treatment B be better than
17 arm A, and what are you going to call that?
18 The answer is that's a negative result, that
19 that's negative. That treatment B beat, if
20 you want to use that word, that treatment B
21 was better than arm A. That's a negative
22 result.

23 So when the two survival curves
24 overlap each other, that's a null result. The
25 truth is that in real life, in day-to-day

1 practice, at meetings, or whatever, if arm A
2 and arm B overlies each other and are the same,
3 everyone calls that negative in day-to-day
4 terminology or nomenclature, but technically
5 they're incorrect. It should be -- the
6 correct term should be null, and it's negative
7 when the other arm is better than -- you know,
8 improves survival compared to arm A, which can
9 happen, which can happen.

10 Q. Okay. Great.

11 So I want to make sure that we use
12 the correct terminology today. So a trial
13 with a negative result means that the control
14 arm did -- had better results than the
15 intervention arm?

16 ATTORNEY RATLIFF: Let the counsel
17 finish her question.

18 If you finished your question, I object
19 to the form of the question.

20 A. So a negative result means that,
21 yes, that the control arm improves survival,
22 let's say we're talking about survival as the
23 outcome, relative to the experimental one.

24 Q. And a null result from a clinical
25 trial is that the intervention arm and the

1 control arms perform the same?

2 ATTORNEY RATLIFF: I object to the form
3 of the question.

4 A. Yes.

5 Q. So clinical trials can have
6 negative results; correct?

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

9 A. Yes.

10 Q. And clinical trials in oncology can
11 have null results as well; right?

12 A. Yes. Again, I just want to make
13 clear that in real life, and I don't even know
14 how it's written in the actual articles, I
15 mean, if you read the articles, you know, the
16 descriptions of the trials in journals, I
17 don't know if you see the word "null"
18 utilized. They will refer to them as negative
19 results if the two arms overlap each other and
20 are similar.

21 Again, maybe I'm being overly
22 technical, you know, as an epidemiologist and
23 quasi statistician, but I'm simply saying that
24 that's -- those are the correct ways to
25 address it, because otherwise, what would a

1 clinical trialist say about if its control arm
2 beat out his experimental arm? How would he
3 refer to that? And the answer is that's so
4 far from his -- that's so far from his
5 thoughts, he doesn't anticipate it, so far out
6 of his way of thinking that he doesn't think
7 about it. So he doesn't care about it.

8 Q. In your experience, do clinical
9 trials in oncology get negative results often?

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

12 A. Not often, but occasionally, and
13 again, we would have to broaden our -- broaden
14 our universe of what we call "clinical trials
15 in oncology."

16 If you refer solely to drug trials,
17 then the answer is not that often, but if you
18 expand the definition, and I would, to, for
19 example, supportive care trials, let's say of
20 antiemetics or pain drugs or things like that
21 as opposed to purely therapeutic drugs, then
22 the answer is yes, then you start to see an
23 occasional comparison arm that goes the other
24 way.

25 Don't forget, there was controversy

1 over the use of the p-value -- of a two-sided
2 p-value, again, I don't know how much
3 statistics you know -- are you familiar with
4 statistics?

5 Q. Enough to know what a p-value is.

6 A. Well -- so there are p-values that
7 are two-sided as opposed to one-sided. Are
8 you familiar with that concept?

9 Q. (Indicating.)

10 A. Yeah. So not infrequently in the
11 past investigators tried -- did use and wanted
12 to use one-sided p-values, because by using
13 one-sided p-values they would get away with
14 using fewer subjects in their trials, so you
15 didn't have to utilize as many patients in a
16 trial.

17 The problem is if you use a
18 one-sided p-value, it eliminates the ability
19 to see if the comparison arm is better than
20 the experimental arm. So they would miss
21 occasionally seeing the ability of the
22 comparison arm to be better than the
23 experimental arm, and ultimately, the journal
24 editors and the powers that be decided that
25 this was not -- this was not a good way to do

1 trials.

2 So now, no one will allow a trial
3 to be conducted without having a two-sided
4 p-value, and if you have to then recruit more
5 subjects in order to fulfill the necessity of
6 having a two-sided p-value, tough on you, and
7 that's precisely because they wanted to allow
8 for the possibility that the comparison arm,
9 the control arm, would be better than the
10 experimental arm.

11 So that's why we have always now
12 two-sided p-values. I mean, we'll never see a
13 paper anymore, a study, or a trial without a
14 two-sided p-value exactly for that reason.

15 Q. You had mentioned experimental arm
16 and I wanted to ask you about that.

17 The clinical trials are
18 experiments; right?

19 A. Yes.

20 Q. Clinical trials are testing a
21 hypothesis about what might work?

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

24 A. They should be. I mean, so they
25 don't all, but it depends on what kind of a

1 clinical trial you have.

2 Q. So if you can help me just at a
3 very high level, what is a Phase I clinical
4 trial?

5 A. So a Phase I clinical trial does
6 not have a hypothesis. So it's not truly an
7 experiment, at least in the way I would define
8 an experiment, because it doesn't have an
9 a priori hypothesis.

10 The goal of a Phase I clinical
11 trial is not to tell us if the drug that's
12 being tested works, if it improves some
13 outcome for a disease, for some cancer.

14 A Phase I clinical trial is to
15 test -- to see -- so it's for a drug that's
16 not been used previously in humans. It's been
17 tested in animals or primates or whatever, and
18 now it's ready for humans, and so you take the
19 drug and you give it to humans for the first
20 time. The scientists at the drug company, at
21 Merck or wherever else, and you give it -- and
22 they've -- based on their testing, have come
23 up with a dose and a method of administration
24 for the drug, and now they start off at a dose
25 that they think will be safe, and they usually

1 start off lower than what they think will be
2 the ultimate successful dose, because again,
3 they don't want to knock anyone off, and they
4 started this lower dose. They give it to a
5 few patients and see how it goes and see what
6 adverse effects will occur.

7 So the purpose of a Phase I trial
8 is dose testing and the determination of, I'll
9 call them, common adverse effects, because
10 again, you're not giving it to a lot of
11 patients. So you want to see what side
12 effects are going to occur.

13 If you give it to, let's say, six,
14 seven, eight patients at a certain dose level
15 and nothing terrible happens, you know, you
16 don't get major toxicity, then they will move
17 on to a next prespecified dose level and give
18 it to another six, seven, eight patients, and
19 repeat again, see how they tolerate the drug
20 and see if any major side effects occur.

21 Now, occasionally, there will be a
22 major side effect that no one had anticipated,
23 or something bad will happen and the drug will
24 disappear from the market or something, you
25 know, bad will happen, but more commonly what

1 will happen is nothing bad will happen and
2 they'll move on to a third or fourth or fifth
3 dose level, and ultimately, they'll reach a
4 prespecified end, because usually it's from
5 end at which they'll stop, they won't go
6 higher than a certain level, and hopefully
7 there won't have been some terrible side
8 effect along the way which will have made them
9 stop along the way, and based on the Phase I
10 trial, they'll decide on what is the best dose
11 at which future testing will occur.

12 Because they're not testing for
13 effect, for efficacy, a Phase I trial will
14 usually use a mix of tumor sites. So it's not
15 going to be everybody with breast cancer or
16 everybody with colon cancer. It will have a
17 few breast cancer patients, a few colon cancer
18 patients, few lung cancer patients all mixed
19 together. So it's not homogeneous in terms of
20 tumor sites.

21 If you get some responses, any
22 responses in the Phase I trial, then that
23 is -- I would say everyone like raises a glass
24 of champagne, because that is really -- a
25 really good sign. If you get one or two or

1 three responses in a Phase I trial, because
2 that wasn't the goal, so if you do get a few
3 responses there, that is considered really
4 outstanding for the drug, and it's -- it -- it
5 presages that it will be an active drug going
6 forward, and whatever tumors it was, that
7 might be the first tumors, then go on to test
8 in a Phase II trial.

9 Q. So then what is a Phase II trial?

10 A. So a Phase II trial, now coming out
11 of the Phase I trial, you have a dose or a
12 method of administration that you have now
13 defined based on the Phase I trial, and then
14 the Phase II trial you're looking for
15 efficacy. So you'll give it to some number of
16 subjects with a specific cancer, breast,
17 colon, lung, whatever, so you may have
18 multiple Phase II trials, one for each -- one
19 for each cancer -- one for each cancer you
20 want to try, and you'll give the drug to them.
21 Now, you have to have measurable disease so
22 that you can determine if the tumor responds,
23 and you give it to 25, 30, whatever it is,
24 patients and then you see what happens.

25 And again, I would say that, again,

1 if you get one or two responses in 25 or 30
2 patients with metastatic, I don't know, colon
3 cancer or breast cancer, whatever it might be,
4 in a Phase II trial, again the drug is doing
5 pretty -- that's pretty good for a Phase II
6 trial, and you don't get that many positives.

7 I mean, speaking overall for
8 Phase II trials, you know, people think that
9 they do so well, but the truth is the overall
10 response rate in Phase II trials is, I don't
11 know, only a few percent. So they don't do
12 that well, but who knows. You never know.
13 You never know who is going to be the next big
14 winner, right?

15 Q. Do you know what a basket clinical
16 trial is?

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

19 A. A basket clinical trial is where
20 you treat subjects. It's sort of like, as I
21 said, a Phase II trial, as I just said, was
22 where you treat a homogeneous group of sites.
23 In a basket trial, you sort of -- like you
24 don't limit the Phase II trial to a specific
25 site.

1 Q. And are you familiar with
2 all-comers clinical trials?

3 A. I saw this term in Dr. Lonberg's
4 whatever it is, affidavit or whatever it's
5 called. I'm not sure it's actually a term
6 that's like technically used, but, I mean, I
7 can understand what it is. I assume it's a
8 trial where everyone at a given -- at a
9 participating institution is invited to
10 participate in a trial.

11 I mean, by that definition, I'd say
12 every trial is an all-comers trial to be
13 honest, so I -- I -- it doesn't have that much
14 meaning to me.

15 Q. How about biomarker stratified
16 clinical trial designs? Does that have
17 meaning for you?

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

20 A. Again, it has the meaning that it
21 says. I mean, it's a straightforward term. I
22 mean, are you -- subset the participants on
23 the basis of a biomarker as to whether they're
24 positive or negative or whatever on the basis
25 of a biomarker.

1 Q. Dr. Neugut, are you an inventor on
2 any patent?

3 A. No.

4 Q. You haven't filed a patent
5 application?

6 A. No.

7 Q. I think you said you'd authored
8 over 800 articles; is that right?

9 A. Yes.

10 Q. Let's look at one of them.

11 ATTORNEY McCORMICK: We'll mark this as
12 Exhibit 2058.

13 (Whereupon, article in Frontiers in
14 Oncology entitled Prognostic and therapeutic
15 impact of the KRAS G12C mutation in colorectal
16 cancer, is received and marked as Exhibit 2058
17 for Identification.)

18 CERTIFIED STENOGRAPHER: Number 2058.

19 ATTORNEY RATLIFF: And I'll just object
20 to Exhibit 2058 for the purposes of
21 authentication, foundation, and hearsay.

22 BY ATTORNEY McCORMICK:

23 Q. Dr. Neugut, do you have Exhibit
24 2058, which is an article titled: Prognostic
25 and therapeutic impact of KRAS G12C mutation

1 in colorectal cancer, in front of you?

2 ATTORNEY RATLIFF: You read that
3 incorrectly. I object to the form of the
4 question.

5 A. Yes.

6 ATTORNEY McCORMICK: I'm sorry,
7 counsel, how did I read that incorrectly?

8 ATTORNEY RATLIFF: You did not read all
9 the words that are in the title. You skipped
10 out words in the title and was representing
11 that that was the article and that's
12 incorrect.

13 Q. Dr. Neugut, is Exhibit 2058 titled:
14 Prognostic and Therapeutic Impact of the KRAS
15 G12C Mutation in Colorectal Cancer?

16 A. I have it.

17 Q. And the title I just read is the
18 title of the article number Exhibit 2058 that
19 you have in your hand?

20 A. Yes.

21 Q. Do you recognize Exhibit 2058?

22 A. Yes.

23 Q. And how do you recognize it?

24 A. What does that mean? What does
25 that mean?

1 Q. Are you an author of this article?

2 A. Yes.

3 Q. Do you recognize this article?

4 A. Yes.

5 Q. What was your contribution to this
6 article, Exhibit 2058?

7 A. The Journal Frontiers in Oncology
8 where this appeared was doing a special issue
9 on colon cancer and that was edited by Paul
10 Ruff, a colleague of mine, or you can see on
11 the title page his name, and he invited me to
12 submit a paper on biomarker -- on a biomarker
13 in colon cancer.

14 So actually I was the invitee for
15 this paper. So I thought about it and I knew
16 of work that my colleague, Dr. Herzberg, who
17 is another one of the authors, was doing on
18 the KRAS G12C mutation, and so I approached
19 him about doing the review article on that
20 subject.

21 Q. And this article published in
22 September 15, 2023; correct?

23 A. Yes.

24 Q. And this article discusses MSI and
25 DMMR; right?

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

3 A. I don't know. As I'm sitting here,
4 I don't have a recollection.

5 Q. Okay. If I can point you to page
6 three of Exhibit 2058, the second column under
7 the title: Genetic and Molecular Profile, and
8 the second paragraph down.

9 Do you see that?

10 A. Yes.

11 Q. And do you see there this article
12 that you authored, Exhibit 2058, mentions MSI
13 pathway?

14 A. Yes.

15 Q. And this article that you authored,
16 Exhibit 2058, mentions DMMR; right?

17 A. Yes.

18 Q. Have you written any other articles
19 that mention MSI or DMMR?

20 A. I'm sure.

21 Q. If we have your CV with your
22 articles in front of you, could you identify
23 them?

24 A. Probably, yes. I mean, it might
25 take me five minutes to identify them, but

1 yes, I could.

2 Q. Okay. You and your coauthors
3 sought to provide accurate information in this
4 article; right?

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

7 A. I object to the form of the
8 question also. I don't even understand it.
9 You mean did we put in inaccurate information?

10 Q. I'm not trying to ask you stupid
11 questions. Lawyers sometimes have to confirm
12 these sorts of things.

13 So is it fair if I ask you again?

14 A. Yes, we did provide accurate
15 information.

16 Q. So that same paragraph that I just
17 pointed you to on page three of Exhibit
18 2053 --

19 A. Uh-huh.

20 Q. -- second column, second paragraph,
21 you state in your article: MSI is caused by a
22 deficiency of mismatch repair, DMMR, and is
23 found in approximately 10 to 15 percent of
24 CRC; right?

25 A. Yes.

1 Q. And is that still your view today?

2 A. Yes.

3 ATTORNEY RATLIFF: I --

4 THE WITNESS: I'm sorry.

5 ATTORNEY RATLIFF: It's all right. You
6 already responded.

7 BY ATTORNEY McCORMICK:

8 Q. You can set that article aside,
9 Dr. Neugut.

10 ATTORNEY RATLIFF: Counsel, since you
11 seem to be switching to another exhibit and
12 it's been over an hour, let's take a break.

13 ATTORNEY McCORMICK: Okay. We can take
14 a break, if that's okay with you. Off the
15 record.

16 CERTIFIED STENOGRAPHER: Off the
17 stenographic record at 8:34 a.m.

18 (Whereupon, a recess is taken.)

19 CERTIFIED STENOGRAPHER: Back on the
20 stenographic record at 8:51 a.m.

21 BY ATTORNEY McCORMICK:

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

25 A. No.

1 Q. I'm going to hand you an exhibit
2 we'll mark Exhibit 2059.

3 (Whereupon, article in Journal of
4 Oncology entitled Cost-effectiveness analysis
5 in biomarker-guided treatment for metastatic
6 gastric cancer in the second-line setting, is
7 received and marked as Exhibit 2059 for
8 Identification.)

9 CERTIFIED STENOGRAPHER: Number 2059.

10 ATTORNEY McCORMICK: Correct.

11 ATTORNEY RATLIFF: And I'll just object
12 to Exhibit 2059 for purposes relating to
13 authentication, foundation, and hearsay.

14 BY ATTORNEY McCORMICK:

15 Q. Exhibit 2059 is titled:
16 Cost-Effectiveness Analysis of Biomarker
17 Guided Treatment for Metastatic Gastric Cancer
18 in the Second Line Setting.

19 Do you see that, Dr. Neugut?

20 A. Yes.

21 Q. Do you recognize Exhibit 2059?

22 A. Yes.

23 Q. Are you an author of the article
24 that is Exhibit 2059?

25 A. Yes.

1 Q. And what was your contribution to
2 this article?

3 A. As I sit here today, I don't have a
4 good recollection of what I did contribute.
5 I'm sure I read it at the time and reviewed it
6 and made corrections on it. I worked with
7 Dr. Hur, the senior author, and with the other
8 authors on the paper, but I don't recall what
9 else. You know, again, we work in groups and
10 this was a gastric cancer GI group and I was
11 one of the participants in it.

12 Q. And this article published in 2019;
13 is that right?

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

16 A. It was published in 2020.

17 Q. Yes. Thank you.

18 Article that is Exhibit 2059
19 published in 2020; right?

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

22 A. Yes, it was published in 2020.

23 Q. And this article, Exhibit 2059,
24 looks at the cost effectiveness of
25 pembrolizumab?

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

3 A. Yes.

4 Q. And if I could direct your
5 attention to the background section on the
6 first page of Exhibit 2059.

7 A. Where?

8 Q. The background section on the first
9 page of Exhibit 2059.

10 A. Okay.

11 Q. The second sentence on that
12 background section on the first page reads:
13 Pembrolizumab has shown particular efficacy
14 among patients with programmed death ligand-1,
15 PD-L1, expression, and high microsatellite
16 instability, MSI high.

17 Do you see that?

18 A. Yes.

19 Q. What does that mean?

20 A. It means that pembrolizumab has
21 some particular efficacy among patients with
22 PD-L1 expression and microsatellite
23 instability.

24 Q. So what do you mean by "particular
25 efficacy"?

1 ATTORNEY RATLIFF: I object to the form
2 of the question, as well as to the premise of
3 the question.

4 A. It means that's where it works.

5 Q. And if I could direct your
6 attention to the same section a few lines down
7 starting with "results," the sentence reads:
8 The most effective strategy was pembrolizumab
9 for MSI-H patients and ramucirumab/paclitaxel
10 for all other patients adding 3.8 months for
11 2.0 quality adjusted months compared to
12 paclitaxel.

13 Do you see that?

14 A. Yes.

15 Q. And I just want to focus your
16 attention on the most effective strategy was
17 pembrolizumab for MSI-H patients.

18 Do you see that?

19 A. Yes.

20 Q. And what does that mean?

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

23 A. This was what's called a Markov
24 model, M-A-R-K-O-V, in other words, this is
25 not a study where there was actually patients

1 or data, but this took publications from the
2 literature or data from the literature and
3 then did statistical analyses to generate
4 comparisons between different approaches to
5 the treatment of gastric cancer, and in doing
6 that what was found was that for patients that
7 were MSI high that giving pembrolizumab was
8 more -- even though it was a much more
9 expensive drug than conventional chemotherapy,
10 it was more cost effective than giving
11 conventional chemotherapy.

12 Q. And of all the uses that were
13 studied for this publication, Exhibit 2059, of
14 all the uses for pembrolizumab, the most
15 effective was for the treatment of MSI high
16 patients; is that right?

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

19 A. Yes.

20 Q. If you could turn to page two of
21 Exhibit 2059, the fourth paragraph down, the
22 first sentence of that fourth paragraph says:
23 The Cancer Genome Atlas Research Network,
24 TCGA, evaluated 295 primary gastric
25 adenocarcinomas for molecular characteristics

1 and found that 22 percent had high
2 microsatellite instability, MSI-H; is that
3 right?

4 A. Yes.

5 Q. What is the Cancer Genome Atlas
6 Research Network?

7 A. I don't want to guess. As I sit
8 here now, I would be speculating. I think I
9 know what it is, but I don't want to
10 speculate.

11 Q. Okay. For this article, Exhibit
12 2059, you relied on information from the
13 Cancer Genome Atlas Research Network; right?

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

16 A. That is correct.

17 Q. And in your experience, does the
18 Cancer Genome Atlas Research Network provide
19 accurate information?

20 A. I believe so, yes, uh-huh.

21 Q. So 22 percent of gastric cancers
22 have MSI high?

23 ATTORNEY RATLIFF: Are you asking about
24 today? What time frame are you talking about?

25 (No response.)

1 ATTORNEY RATLIFF: If you won't answer
2 my question, then I object to the form of your
3 question.

4 A. Again, you're talking about one
5 source of information according to them, yes,
6 but that would be one source. There are other
7 studies and other sources. So I don't know
8 how generalizable that figure would be. Even
9 the next sentence says: However, there is
10 variability based on other published
11 estimates, a recent review estimates that 10
12 to 39 percent of gastroesophageal cancers are
13 MSI high.

14 Q. Right. I see the rest of the
15 paragraph.

16 Gastroesophageal cancer is
17 different than a gastric adenocarcinoma;
18 right?

19 A. Upper GI cancers are frequently
20 lumped together in citing statistics.

21 Q. I'm sorry, how does that answer my
22 question? Gastroesophageal cancers are
23 different than gastric adenoma carcinomas;
24 right?

25 ATTORNEY RATLIFF: I object to the form

1 of the question, as well as to the premise of
2 the question.

3 A. I'm saying when the sentence here
4 talks about gastroesophageal, it includes
5 gastric cancers in its statistical statement.
6 They didn't -- the paragraph, the sentence
7 didn't break down esophagus versus gastric,
8 but gave the statistic as this gastric
9 esophageal cancer together, but that's
10 frequently done --

11 Q. I've gotcha. Thank you.

12 So the 22 percent of gastric
13 adenocarcinomas with MSI high, those patients
14 respond best to pembrolizumab as compared to
15 other cancer type -- other cancer treatments;
16 correct?

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

19 A. This paper wasn't evaluating
20 response rates. This paper was assessing cost
21 effectiveness of pembrolizumab.

22 Q. So just turning back to that first
23 page that we looked at next to "results," when
24 it says: The most effective strategy, should
25 that say the most cost-effective strategy?

1 ATTORNEY RATLIFF: I object to the form
2 of the question, as well as to the premise of
3 the question.

4 A. I'm sorry, where were you reading
5 that?

6 Q. The first page of Exhibit 2059.

7 A. Yeah.

8 Q. About five lines up from the bottom
9 of that indented paragraph where it says
10 "results."

11 A. Yeah. I think they're talking
12 about most cost-effective strategy.

13 Q. Dr. Neugut, do you currently
14 prescribe pembrolizumab for your MSI high
15 patients?

16 A. Are you referring to colon cancer?

17 Q. Yes.

18 A. Yes, sometimes.

19 Q. Can you tell me more about when you
20 sometimes prescribe pembrolizumab?

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

23 A. I usually -- I usually prescribe
24 immunotherapy. Pembrolizumab is one option.
25 Now, there are other options available. So

1 sometimes I use pembrolizumab. Sometimes I
2 use other immunotherapeutic agents.

3 Q. What other immunotherapeutic agents
4 would you use for your MSI high colon cancer
5 patients?

6 A. Ipilimumab.

7 THE WITNESS: Good luck.

8 A. And nivolumab. There is also now a
9 new drug, dostarlinab. Under different
10 circumstances, any of those might be a
11 suitable immunotherapeutic agent, but I do
12 like pembro.

13 Q. Why do you like pembro?

14 A. It's easy to give and -- and I tend
15 to use it for older or more frail individuals
16 for those who are sicker. It has a good
17 toxicity profile. So I use it quite a bit
18 actually.

19 Q. So you prescribe ipilimumab for MSI
20 high colon cancer patients?

21 A. So there is a combination of
22 ipilimumab with nivolumab, a two-drug -- a
23 two-drug immunotherapy combination, which is
24 also recommended basically in the same context
25 for metastatic colorectal cancer.

1 Q. And you prescribe dostarlinab for
2 MSI high colon cancer patients?

3 A. Dostarlinab was reported in the
4 2023 ASCO meeting as being extremely
5 efficacious in the context of localized rectal
6 cancers. So I prescribed it in that context.

7 Q. So you don't prescribe dostarlinab
8 in the context of MSI high colon cancer
9 patients?

10 A. No.

11 Q. I think we've got a double negative
12 there, so I want to make sure I've got that
13 correct.

14 Do you prescribe dostarlinab in the
15 context of MSI high colon cancer patients?

16 A. Not for colon cancer.

17 Q. And when you use pembrolizumab for
18 your MSI high colon cancer patients, did you
19 first know that they have MSI high colon
20 cancer?

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

23 A. Sure.

24 Q. Why do you find that out first?

25 A. Number one, it would not be

1 efficacious in the absence of it being MSI
2 high, and number two, insurance wouldn't pay
3 for it.

4 Q. Dr. Neugut, I see you have
5 documents in front of you. Can you tell me
6 what those are, please?

7 A. I have my own declaration in this
8 case.

9 Q. And is there any markings on that
10 declaration that you have in front of you?

11 A. I don't have markings on anything.
12 I have the 2015 New England Journal
13 article from first author Le.

14 I have a paper by de la Chapelle on
15 microsatellite instability in colorectal
16 cancer.

17 A paper by Steinert. These are
18 included in the exhibits of my declaration.

19 A paper by Hamid, H-A-M-I-D, also
20 included in the exhibits.

21 A paper by Champiat, also included.

22 A paper by Salipante, also
23 included.

24 A paper by Pernot, also included.

25 I have the NCCN guidelines from

1 2014.

2 I have the 393 patent from -- the
3 '339 patent.

4 I have the MSI high study record.
5 That's it.

6 Q. And why do you have those with you?

7 A. I anticipated that reference would
8 be made to them during today's deposition. If
9 not, then they'll just sit here until I go
10 home.

11 Q. Okay. If we could look at your
12 declaration, which is Exhibit 1003, and if you
13 want to look at your copy, that's fine.

14 ATTORNEY McCORMICK: Sorry, counsel,
15 can I get one back of those so I can give it
16 to the court reporter? Thank you.

17 Q. Dr. Neugut, do you have Exhibit
18 1003 in front of you?

19 A. Yes.

20 Q. And is this your declaration that
21 you submitted in this IPR for the '393 patent?

22 A. I'm sorry, did you say IPR?

23 Q. (Indicating.)

24 A. I don't know what that is.

25 Q. So Exhibit 1003 was submitted to

1 the Patent Office in relation to the '393
2 patent.

3 Do you understand that?

4 A. Yes.

5 Q. And is this Exhibit 1003 that you
6 have in front of you your declaration?

7 A. Yes.

8 Q. And if you'd turn to page 88 of
9 Exhibit 1003, is that your signature,
10 Dr. Neugut?

11 A. Yes.

12 Q. If I could direct your attention to
13 paragraph 21, which is on page 20 of Exhibit
14 1003.

15 A. Paragraph 21?

16 Q. That's right. Are you there?

17 A. Yes.

18 Q. You state in paragraph 21 that you
19 understand that the terms must be interpreted
20 in light of the patent claims, the patent's
21 disclosure referred to as the specification,
22 and the prosecution history, the record of the
23 back-and-forth between the patent applicant
24 and the United States Patent and Trademark
25 Office during the process of obtaining

1 allowance of the patent's claims; is that
2 right?

3 A. Yes.

4 Q. What is the patent specification?

5 A. I'm not sure.

6 Q. I appreciate that you're not a
7 patent lawyer, Dr. Neugut.

8 The patent specification is the
9 disclosure in the '393 patent that you have in
10 front of you, that's Exhibit 1001, and it's
11 everything but the claims.

12 Do you understand that?

13 A. It's everything?

14 Q. But the claims.

15 A. I -- I -- I would have guessed
16 that, but I don't want to guess.

17 Q. I appreciate that. Thank you.

18 In preparing your declaration
19 that's here in Exhibit 1003, did you read the
20 patent specification of the '393 patent?

21 A. Yes.

22 Q. The prosecution history which you
23 have in paragraph 21 is the record of the
24 back-and-forth between the patent applicant
25 and the Patent Office.

1 Do you understand that?

2 A. Yes.

3 Q. Did you read the '393 patent
4 prosecution history as part of preparing your
5 declaration?

6 A. Yes.

7 Q. What does it mean to you to
8 interpret the terms in light of the patent
9 claims, the patent specification, and the
10 prosecution history?

11 A. That the terms are utilized in the
12 same way as they're used by the Patent Office
13 and by the litigants in this affair.

14 Q. So do you agree that patent claims
15 are typically given their ordinary and
16 customary meaning in their technological
17 field?

18 A. Yes.

19 Q. And did you review the words of
20 claim one of the '393 patent?

21 A. Yes.

22 Q. And did you understand those words?

23 A. Yes.

24 Q. Did any of the words of claim one
25 of the '393 patent strike you as ambiguous,

1 and I see that you're looking at the patent,
2 so we can look at that also.

3 A. Well, I want to look at it again
4 and see if ambiguous applies to any of the
5 words.

6 Q. That's great. Thank you.
7 And I'll hand counsel Exhibit 1001.

8 A. The answer is no.

9 Q. So none of the terms in claim one
10 of the '393 patent strike you as ambiguous?

11 A. Correct.

12 Q. Did you find anything in the '393
13 patent specification that redefined any of the
14 terms in claim one?

15 A. I don't understand the question.

16 Q. You reviewed -- sorry. You read
17 the '393 patent specification; right?

18 ATTORNEY RATLIFF: Objection. Asked
19 and answered.

20 A. Again, the specification is now --
21 it's the rest of the patent?

22 Q. That's right.

23 A. So I don't have a recollection
24 whether -- this was a long time ago, and as I
25 sit here now, I don't have a recollection if

1 there is anything in the specification then
2 which contradicts or is not consistent with
3 what's written in claim one.

4 Q. And if you had found something that
5 contradicts or is not consistent with what's
6 written in claim one, you would have put that
7 in your declaration; right?

8 A. I don't know because I -- I don't
9 know what it is. I don't know what I would
10 have done.

11 Q. Okay. So I have the same questions
12 related to the prosecution history. Did you
13 find anything in the '393 patent's prosecution
14 history that redefined any of the terms in
15 claim one?

16 A. I'll give the same answer. I have
17 no recollection.

18 Q. Did you review the words of claim
19 14 of the '393 patent?

20 A. Yes.

21 Q. Did you understand those words?

22 A. Yes.

23 Q. Did any of the words of claim 14
24 strike you as ambiguous?

25 A. No.

1 Q. Did you review the words of the
2 dependent claims of the '393 patent, so those
3 are the claims other than claims one and 14?

4 A. Yes.

5 Q. Did you understand the words of the
6 dependent claims?

7 A. Yes.

8 Q. Did any of the words of the
9 dependent claims of the '393 patent strike you
10 as ambiguous?

11 A. No.

12 Q. In paragraph 21 of your
13 declaration, you state that no reasonable
14 interpretation of the claim terms, however,
15 would alter your conclusions; is that right?

16 A. Yes.

17 Q. And did you consider any different
18 interpretations of the claim terms?

19 A. I did not or I don't have any other
20 alternative terms.

21 Q. And in your declaration, you did
22 not provide an analysis of the meaning of "in
23 response to" in your declaration; right?

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

1 A. You're talking about the first few
2 words in claim one where it says "in response
3 to determining"?

4 Q. That's right.

5 A. No, I did not.

6 ATTORNEY RATLIFF: I'm not sure what
7 the question is, but I'll just object to the
8 form of the question, as well as to the
9 premise of the question.

10 A. I'll ask for the question again
11 then.

12 Q. In your declaration, you did not
13 provide any analysis of the meaning of "in
14 response to"; right?

15 ATTORNEY RATLIFF: I object to the form
16 of the question, as well as to the premise of
17 the question.

18 A. I understood the words clearly.

19 Q. So, Dr. Neugut, you're aware that
20 this is a dispute between Merck and Hopkins;
21 correct?

22 A. Yes.

23 Q. And are you aware that Hopkins
24 argued that the phrase "in response to"
25 required no further interpretation?

1 A. As I said? You mean they interpret
2 "in response to" the same way I do?

3 Q. I'm not sure.

4 Dr. Neugut, it's just I'm just
5 asking if you're aware if Hopkins argued that
6 "in response to" required no further analysis
7 or interpretation?

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

10 A. I don't know what Hopkins argues.

11 Q. Are you aware that in front of the
12 Patent Office, Merck argued that the claim
13 term "in response to" required no further
14 interpretation?

15 ATTORNEY RATLIFF: I object to the form
16 of the question, as well as to the premise of
17 the question.

18 A. I -- I wouldn't know.

19 Q. In your declaration, did you
20 analyze how different interpretations of "in
21 response to" would affect your opinions?

22 ATTORNEY RATLIFF: I object to the form
23 of the question, as well as to the premise of
24 the question.

25 A. Never entered my mind that the

1 phrase "in response to" would have a meaning
2 different than what it says.

3 Q. Dr. Neugut, are you aware that
4 there is a District Court litigation between
5 Merck and Hopkins related to the '393 patent?

6 A. I'm aware that there is a district
7 litigation, a District Court litigation in
8 response to a contract between Merck and
9 Hopkins. I don't know how the patent
10 litigation plays into the contract litigation.
11 So if you're asking me if a patent is at play
12 in the litigation, I haven't a clue.

13 I think as I understand it, that
14 that was a contract litigation, and I don't
15 know the question as to who is the patent
16 holder or whatever is part of that litigation
17 or not. So I don't have any direct
18 understanding of that litigation.

19 Q. Okay. So if there was any claim
20 construction or claim interpretation that
21 happened as part of the District Court
22 litigation, you wouldn't be aware of it?

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

25 A. That's correct.

1 Q. Now, we talked earlier that you
2 treat metastatic CRC patients; right?

3 A. Yes.

4 Q. And you treated metastatic CRC
5 patients before 2015; right?

6 A. Did I treat metastatic colorectal
7 cancer before 2015?

8 Q. (Indicating.)

9 A. Yes.

10 Q. About how many metastatic CRC
11 patients did you see per week in 2015?

12 A. In 2015? 10 to 12.

13 Q. Do you see about the same 10 to 12
14 metastatic CRC patients per week now?

15 A. Yes.

16 Q. And in 2015, did you know at the
17 time you were treating those CRC patients that
18 they had MSI high status?

19 A. Or not.

20 Q. Or not?

21 A. Yes.

22 Q. And how did you know?

23 A. It was standard practice to do
24 testing on their tumor samples for MSI status.

25 Q. And why was it standard practice to

1 do MSI testing on tumor samples?

2 A. It was a recognized -- excuse me,
3 it was a recognized prognostic marker. So
4 it's helpful in that respect, and it also --
5 it also predicted response to 5-fluorouracil.

6 Q. And are there other reasons that
7 you would be testing CRC patients for MSI
8 status in 2015?

9 A. You're talking now, before it
10 became standard to give immunotherapy?

11 Q. I am.

12 ATTORNEY RATLIFF: I'm not sure what
13 the question is, but I object to the form of
14 the question.

15 A. Well, it was also a genetic marker.
16 So for the 10, 15 percent who turned out to be
17 MSI high, a substantial fraction of them may
18 have had Lynch syndrome, and if they were MSI
19 high, one would have made certain to refer
20 those patients on to the genetic counselors
21 for genetic testing.

22 Q. If you knew in 2015 that a CRC
23 patient was MSI high, did you have a specific
24 treatment for that patient?

25 ATTORNEY RATLIFF: I object to the form

1 of the question.

2 A. So in the context of metastatic
3 cancer, the answer is no. In the context of
4 localized cancer, it did affect
5 decision-making there, but I don't think it
6 affected a decision-making in
7 metastatic -- well, in metastatic cancer, you
8 could not give 5-fluorouracil alone without
9 oxalitlatin.

10 Q. Let's just focus on the metastatic
11 CRC patients in 2015.

12 A. Uh-huh.

13 Q. If those patients were MSI high,
14 what treatment options did you have for them?

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

17 A. They could get FOLFOX, which was
18 the standard chemotherapy regime that we
19 utilized and that we still utilize even now.
20 What the MSI status affected was that if you
21 were MSI high, it had the effect of -- let me
22 see how I can express this. In effect, if you
23 were MSI high, it was as if you were already
24 treated with 5FU, a patient who was MSI high
25 effectively as if they had been treated with

1 5FU alone, so you could not treat a patient
2 with 5FU alone. 5FU is probably the best
3 signal drug for colon cancer. Occasionally
4 you may want to treat someone with 5FU alone,
5 but if they were MSI high, you could not do
6 that.

7 So you could only give FOLFOX the
8 regime 5FU with oxaliplatin. So that was the
9 effect of being MSI high would have in the
10 context of colon cancer. That's still true
11 today. That will be still true now. I mean,
12 but that's still true today, although today
13 you would go first to immunotherapy, but after
14 the immunotherapy, when you shift to a
15 conventional chemotherapy, again, you would
16 still have to give FOLFOX as opposed to 5FU
17 alone. You could not give 5FU alone.

18 Q. And staying with the 2015 time
19 frame, what was the prognosis for MSI high
20 metastatic CRC patients?

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

23 A. So --

24 (Cell phone rings.)

25 A. Somewhat better than the patient

1 who is MSI negative, because as I would
2 express it, having the biological
3 characteristic of having been treated with
4 5FU, it's a good thing. So if biologically
5 you've been, in essence, treated with 5FU,
6 you've -- even though you haven't truly been,
7 it's better than not being treated with 5FU.
8 So they did better than the patients who were
9 MSI negative.

10 So if survival in 2015 on average
11 for all-comers was -- and I'm going to say in
12 the ballpark of approaching three years
13 average survival, so the MSI high patients
14 would have been on the upside of that, above
15 average, and the MSI negative patients would
16 be a little somewhat below that on the
17 downside.

18 Q. How did you do testing for MSI
19 status in 2015?

20 A. How did I do it?

21 Q. (Indicating.)

22 A. I sent it to the lab and said,
23 Please test this specimen for MSI status. How
24 they did it? I believe it was mostly done by
25 immunohistochemistry, although at some point

1 it was done more by PCR. I don't -- I
2 couldn't tell you exactly how they did it. I
3 just get back a lab report that gives a
4 result, and I don't really pay attention to
5 how it was done.

6 It was at our institution, so if
7 the patient was operated on or biopsied at our
8 institution, it was what we call a reflexive
9 test, meaning that every patient with
10 colorectal cancer, whether it's tumor tissue
11 from a colon cancer, is automatically tested
12 for it. If we had a patient from outside who
13 came for a second opinion or came from another
14 hospital and then came to us subsequently,
15 then we had to obtain tissue from the other
16 hospital and test it.

17 Q. Again, sticking with the 2015 time
18 frame, at that time did you know about
19 pembrolizumab?

20 A. I'm sure, yes.

21 Q. How would you have known about it?

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

24 A. Well, if we're talking mid-2015, I
25 would have known the paper, and I would have

1 known the presentation at ASCO that was done,
2 but, you know, those things are sort of --
3 there would have been talks about it. It
4 would have been described on the -- you know,
5 it would have been described on the grapevine.
6 You know, one would have heard these things.
7 I was already -- it would have been
8 well-known.

9 You know, so what I would have
10 known is that immuno -- I'm sorry, that
11 immunotherapy would have been effective. So
12 it would have been known also for nivolumab
13 and ipilimumab and all the other
14 immunotherapeutic agents.

15 I will say that I do not off the
16 top of my head remember from 2015 which agents
17 I would have necessarily have paid attention
18 to and at least until the New England Journal
19 paper or until the ASCO presentation.

20 Q. The New England paper that you're
21 referring to, is that the New England Journal
22 of Medicine article with Dr. Le as the first
23 author?

24 A. Yes.

25 Q. And the ASCO presentation you're

1 referring to, what's that?

2 A. So that would have come out roughly
3 the same time or a month or two earlier. It
4 was basically a presentation of the same thing
5 given at ASCO.

6 Q. Were you there for that 2015 as
7 co-presentation?

8 A. I was at the meeting. If you ask
9 me was I in the room? You know, the meetings
10 are huge. I never remember -- I don't
11 remember as I sit here if I was there. I
12 would bet I was because I don't think I would
13 have missed that, but I can't swear as I sit
14 here that I remember specifically hearing it,
15 but I was at the meeting, so I would have seen
16 the abstract -- you know, the written abstract
17 in the book for sure. That I definitely saw,
18 and I will -- I would bet that I was at the
19 presentation, but I can't swear to it.

20 Q. And why do you say that you
21 definitely remember seeing the ASCO abstract?

22 A. Because I always read through all
23 the GI -- the book is huge. There are, I
24 don't know, hundreds or thousands of
25 abstracts, but I go through the book, and I

1 certainly read all the colon and GI abstracts
2 and look at them. So without doubt I would
3 have seen them.

4 Q. And when did you first see the 2015
5 New England Journal of Medicine article?

6 A. Whenever it was published. I
7 always -- I get the New England Journal of
8 Medicine, so I -- I get the New England
9 Journal of Medicine, so I -- I would not have
10 missed it.

11 Q. What did you think when you first
12 saw the 2015 New England Journal of Medicine
13 article from Dr. Le?

14 ATTORNEY RATLIFF: I object to the form
15 of the question, as well as the premise of the
16 question.

17 A. In what spirit is the question
18 asked?

19 Q. I just kind of want to know what
20 your reaction to it was.

21 ATTORNEY RATLIFF: If that's a
22 question, I object to the form of the
23 question, as well as to the premise of the
24 question.

25 A. Well, you know, by then it was

1 already, I'll use the term, anticipated that
2 that was going to be the case, that
3 immunotherapy was going to work for MSI high
4 patients. I was impressed with the -- I mean,
5 if you look at survival curves, it really is a
6 pretty remarkable difference between the MSI
7 positive and MSI negative groups. You don't
8 frequently see in oncology that dramatic a
9 difference.

10 Q. Did you use pembrolizumab in your
11 practice in 2015?

12 A. After the paper.

13 Q. So before the 2015 paper, did you
14 use pembrolizumab in your practice?

15 A. So as I said, first of all, it
16 wasn't approved, and while it's true that you
17 can use drugs off-label, so it might have been
18 kosher to do that because the drug was
19 approved and on the market for -- again for
20 melanoma, I don't think it would have been
21 paid for by insurance and the drug is a
22 fortune. So it was impossible to use. The
23 answer is no.

24 Q. And then after the 2015 paper, you
25 used pembrolizumab in your practice; is that

1 right?

2 A. I used it as soon -- well, you had
3 to wait -- I don't know when it was FDA
4 approved. So I don't recall when that -- I
5 don't remember offhand when that occurred.
6 You really had to wait, because these drugs
7 are -- like I say, they're a fortune and no
8 patient can get these drugs without insurance
9 support, and that can take -- I don't know,
10 that can take a while. After it was FDA
11 approved, for sure.

12 Q. So the results from that --
13 published in that New England Journal of
14 Medicine article from 2015, they changed your
15 standard practice?

16 A. I'm sorry.

17 ATTORNEY RATLIFF: I -- hold on. If
18 you're finished with the question, I object to
19 the form of the question, as well as to the
20 premise of the question.

21 Q. After you saw the 2015 New England
22 Journal of Medicine article and once
23 pembrolizumab was approved for MSI high
24 colorectal cancer patients, you changed your
25 practice for those MSI high cancer patients?

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

3 A. That is correct.

4 Q. And why did you do that?

5 A. I mean, it's clear that -- well,
6 two reasons. One is the obvious efficacy of
7 the drug in that context, and the second is
8 it's actually a much more tolerable regime.
9 Patients are much happier getting an
10 immunotherapeutic agent than a conventional
11 chemotherapy.

12 Q. So we talked about the standard of
13 care kind of in 2015 for CRC patients with MSI
14 high tumors. How is that different from the
15 standard of care now for CRC MSI high --

16 ATTORNEY RATLIFF: I object to the --

17 Q. -- patients?

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

21 A. Well, now I am a first-line therapy
22 for a metastatic colorectal cancer patient who
23 is MSI high would need to give one of the
24 immunotherapeutic agents. Again, either
25 pembrolizumab or ipilimumab and nivolumab.

1 Q. We're using the molecule names for
2 the drugs when we say pembro. Do you
3 understand that's also called Keytruda?

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

6 A. Yes, we see it on commercials.

7 Q. So in order to give your metastatic
8 CRC patients Keytruda, do you test their
9 tumors to see if they're MSI high first?

10 A. Yes.

11 Q. And if the testing determines that
12 that patient has MSI high, you recommend
13 treating them with pembrolizumab?

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

16 A. I recommend immunotherapy. Whether
17 it's Keytruda or whether it's ipilimumab with
18 nivolumab vary depending on other issues.

19 ATTORNEY McCORMICK: We've been going
20 for about an hour. Is it all right if we take
21 a break?

22 THE WITNESS: Fine.

23 ATTORNEY McCORMICK: Perfect.

24 We can go off the record.

25 THE WITNESS: Uh-huh.

1 CERTIFIED STENOGRAPHER: Off the
2 stenographic record at 9:50 a.m.

3 (Whereupon, a recess is taken.)

4 CERTIFIED STENOGRAPHER: Back on the
5 stenographic record at 10:08 a.m.

6 BY ATTORNEY McCORMICK:

7 Q. Dr. Neugut, did you discuss the
8 substance of your testimony with counsel
9 during the break?

10 A. No.

11 Q. If I can point you to your
12 declaration, Exhibit 1003, at page 39,
13 paragraph 50. Let me know when you're there.

14 A. Okay.

15 Q. As part of your opinions in this
16 dispute, you allege that each and every
17 limitation of claims from the '393 patent,
18 which are here on page 39 of your declaration,
19 are found in the MSI study record; is that
20 right?

21 A. Yes.

22 (Whereupon, document previously
23 marked Exhibit 1005, is received and marked as
24 Exhibit 1005 for Identification.)

25

1 BY ATTORNEY MCCORMICK:

2 Q. And the MSI study record, that's
3 Exhibit 1005; correct?

4 A. Yes.

5 Q. Can you have Exhibit 5 in front of
6 you, please? 1005. Sorry.

7 A. Yes.

8 Q. Okay. And if we go in your
9 declaration, Exhibit 1003, to paragraph 59 on
10 page 44, can you let me know when you're
11 there?

12 A. We're now in my declaration?

13 Q. That's right.

14 A. Uh-huh. Okay, uh-huh.

15 Q. And paragraph 59. You're there?

16 A. Yeah.

17 Q. Okay. Great.

18 You state in paragraph 59: The MSI
19 high study record discusses treating a patient
20 with 10 mgs per kg of pembrolizumab every 14
21 days in response to a patient meeting the
22 eligibility criterion of having MSI high
23 colorectal cancer; is that right?

24 A. Yes.

25 Q. And in support for that sentence,

1 you point to Exhibit 1005, the eligibility
2 criteria and the arms and interventions; is
3 that right?

4 A. Yes.

5 Q. I appreciate your hesitation there.
6 You also point to additional
7 paragraphs in your declaration; correct?

8 A. Yes.

9 Q. If we could look at Exhibit 1005,
10 the MSI high study record.

11 A. Yes.

12 Q. So Exhibit 1005 is the MSI high
13 study record that you are relying on for the
14 "in response to" determining that colorectal
15 cancer is microsatellite instability high or
16 DNA mismatch repair deficient, treating the
17 patient with a therapeutically effective
18 amount of pembrolizumab; correct?

19 A. Yes.

20 Q. And I appreciate that there are
21 other versions of a clinical study record that
22 were published after the clinical study
23 records shown here in Exhibit 1050.

24 Do you understand that?

25 A. Yes.

1 Q. But when I'm referring to the MSI
2 high clinical study record, I'm only talking
3 about the one here in Exhibit 1005.

4 Do you understand that?

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

7 A. I understand that.

8 Q. And Exhibit 1005 here is the only
9 clinical study record that you are relying on
10 in your declaration; correct?

11 A. Yes.

12 Q. If you could turn to page two of
13 Exhibit 1005. Looking down almost to the
14 bottom of the page, the submitted date.

15 Do you see that?

16 A. Yes.

17 Q. And the date of this clinical --

18 A. Sorry.

19 Q. Are you okay, Dr. Neugut?

20 A. Yes, yes, I'm sorry.

21 Q. Can we get you some water?

22 A. No, I'm fine.

23 Q. Okay.

24 A. I'll try not to cough.

25 Yeah, so you said to look at the

1 submitted date, yes.

2 Q. Yes, and you see the date is June
3 10, 2013; correct?

4 A. Yes.

5 Q. So again, I'm just referring to
6 this version of the MSI high clinical study
7 record when talking about the MSI high
8 clinical study record, okay?

9 A. Yes.

10 Q. So looking on page four of Exhibit
11 1003, the arms and intervention section.

12 Do you see that?

13 A. Yes.

14 Q. And where does it say in the arms
15 and intervention section that you are to give
16 pembrolizumab to patients in response to
17 determining the MSI high status?

18 A. It says to give it for MSI positive
19 colorectal cancer and then to give MK3475 at
20 10 mgs per kg.

21 (Clarification requested by the
22 stenographer.)

23 A. MK3475 at 10 milligrams per
24 kilogram, and then it has MSI negative and to
25 give the same treatment. Likewise under the

1 inclusion criteria, it also in arm one has
2 patients with MSI positive colorectal cancer,
3 and in arm two patients with MSI negative
4 colorectal cancer. I think a POSA would have
5 understood that the drug was being given in
6 response to the biomarker and to being MSI
7 positive or being MSI negative.

8 Q. Is it possible that patients were
9 being given pembrolizumab if they had
10 colorectal cancer regardless of knowing their
11 MSI status at the time that they were given
12 the pembrolizumab?

13 ATTORNEY RATLIFF: I object to the form
14 of that hypothetical.

15 A. Then if that were the case, there
16 would have been no reason to do the biological
17 testing and to define who was MSI positive and
18 who was MSI negative, and I think logically
19 this would have been, I don't know, to me
20 silly, and I think a POSA would have
21 understood it that way.

22 The way the study was conducted,
23 that would not have been a logical way to
24 conduct a trial and to say otherwise is, I'll
25 use the word, absurd.

1 Q. So is it possible that patients
2 could have been enrolled in this study, been
3 given pembrolizumab, and then the doctors
4 would have determined the MSI high status?

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

7 A. Is it possible?

8 Q. (Indicating.)

9 A. I'm sorry, say it again.

10 Q. Is it possible that patients could
11 have been enrolled in this study without
12 knowing their MSI status, given pembrolizumab,
13 and then after that, determined the MSI status
14 for those patients?

15 ATTORNEY RATLIFF: I object to the form
16 of the question, as well as to the premise of
17 the question.

18 A. That's a hypothetical way to have
19 done it, and that would have been an entirely
20 different trial, but that's not the way this
21 trial was conducted. So the answer is no,
22 that is not possible, and if you actually read
23 the trial, that's not how it was done at all.
24 So the answer is no.

25 Now, someone else could have done a

1 trial that way if they wished to, but that's
2 not what was done in this particular trial.

3 Q. So you read how the clinical trial
4 was conducted?

5 A. Yes.

6 Q. When did you do that?

7 A. In 2015 and during the preparation
8 of these reports and proceedings and in
9 preparation for the deposition.

10 Q. And you know that this clinical
11 trial that's here in Exhibit 1005 was run in
12 the manner you described because you read the
13 clinical protocol?

14 ATTORNEY RATLIFF: I object to the form
15 of the question, as well as to the premise of
16 the question.

17 A. I read the actual protocol at one
18 point, and I also read the New England Journal
19 article.

20 Q. And because you read the New
21 England Journal article, you know that the
22 patients were tested for MSI status first and
23 then given pembrolizumab; is that right?

24 ATTORNEY RATLIFF: I object to the form
25 of the question, as well as to the premise of

1 the question.

2 A. Patients were recruited on the
3 basis of their MSI status and then recruited
4 on the basis of being MSI positive, that's how
5 they created the MSI positive cohort, and then
6 they recruited another cohort of colorectal
7 cancers and tested them for their MSI status,
8 and that's how they created the MSI negative
9 cohort.

10 Q. And is that recruitment method here
11 in Exhibit 1005?

12 A. It's -- I think it's clear that
13 that would have been how it would have had to
14 be conducted, because otherwise you would
15 never know who is MSI positive or MSI negative
16 without doing biological testing to determine
17 the MSI status, and again, anyone would have
18 known that or understood that to be the case.
19 It was mandatory.

20 Q. So regardless of MSI status, all of
21 the patients enrolled in the MSI clinical
22 study that's reflected here in Exhibit 1005
23 were given the same intervention; correct?

24 A. That's correct.

25 Q. So would it make sense that you

1 could enroll patients with colorectal cancer,
2 give them the drug, and then determine their
3 MSI status and assign them to a different arm?

4 ATTORNEY RATLIFF: Objection. Asked
5 and answered.

6 A. Say that again.

7 Q. So would it make sense because the
8 interventions are the same that you can enroll
9 colorectal cancer patients in the study here
10 reflected in Exhibit 1005, give them the drug,
11 and then determine MSI status to assign them
12 to the different arms?

13 ATTORNEY RATLIFF: Objection. Asked
14 and answered.

15 A. You mean determine the MSI status
16 after you've administered the pembrolizumab?

17 Q. Correct.

18 A. You could have done that, but
19 that's not what was done and it's not what's
20 implied. So the answer is no.

21 Q. And why do you say that's not
22 what's implied?

23 A. Because -- well, theoretically, it
24 is possible, then you would have had to treat
25 hundreds of patients in order to achieve -- in

1 order to achieve that, and so I guess
2 theoretically, it is possible, but I would say
3 that that would be an incredibly inefficient
4 way to do the study, and it would be -- the
5 rate of MSI in metastatic colorectal patients,
6 the patient population that's being entered in
7 this trial, the rate of MSI positivity in that
8 population is about 4 percent.

9 You know, while we talked about 10
10 to 15 percent of MSI in colorectal cancer
11 overall, that isn't true in the metastatic
12 setting. In the metastatic setting, the rate
13 of MSI positivity is 4 percent.

14 So if you had to find patients who
15 fit the eligibility criteria, metastatic
16 colorectal cancer, who had failed to prior
17 treatments and had measurable disease and you
18 wanted to find enough patients who are going
19 to be MSI positive, at 4 percent, 4 percent,
20 and you wanted to get -- let's say in this
21 case I got 10 patients who were MSI positive,
22 at 4 percent you'd need 400 patients, you'd
23 need to enter 400 to 500 patients, to find
24 them. That would be an incredible --
25 incredibly inefficient and stupid way to do

1 the trial. I guess theoretically, if you
2 wanted to, you could do it that way, but I
3 don't think a POSA or the Johns Hopkins group
4 or Merck would have been dumb enough to do
5 that, and they were not.

6 They did it in a correct way or in
7 a logical way or the efficient way. So you're
8 right. There could be a way to do it where
9 you put your arm around your head and put your
10 left elbow in your right ear, but that would
11 not be the smart way to do this, so that's my
12 answer.

13 Q. I appreciate that. Thank you.

14 And the only way you know for sure
15 how the clinical trial was actually performed
16 is because you read the New England Journal of
17 Medicine article discussing it; correct?

18 ATTORNEY RATLIFF: Objection. Asked
19 and answered.

20 A. Well, I think the protocol says how
21 it was done, although it doesn't give the
22 exact details as it was actually done in
23 the -- it tells it somewhat differently in the
24 study protocol as I recall and it was a
25 while --

1 (Clarification requested by the
2 stenographer.)

3 A. It tells it somewhat differently in
4 the study protocol than it does the actual New
5 England Journal article, but it's effectively
6 the same.

7 Q. We were talking a little bit ago
8 about the phrase "in response to."

9 Do you remember that?

10 A. I remember alluding to it. You
11 were talking about it.

12 Q. Fair enough.

13 Do you remember that I was talking
14 about the phrase "in response to"?

15 A. Yes.

16 Q. Do you agree that this phrase
17 requires a cause and effect?

18 A. Requires an exposure and an
19 outcome.

20 Q. Is that different than a cause and
21 effect?

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

24 A. You used the word "cause." I used
25 exposure, but okay.

1 Q. In the inclusion criteria section
2 of Exhibit 1005, is there anything in there
3 about requiring previous treatments?

4 A. Requiring? I'm sorry?

5 Q. Previous treatments?

6 ATTORNEY RATLIFF: Just so I'm
7 following along, what do you mean by
8 "inclusion criteria"?

9 (No response.)

10 ATTORNEY RATLIFF: If you don't want to
11 respond to my question, then I object to the
12 form of your question.

13 Q. Dr. Neugut, on page five of Exhibit
14 1005, somewhat near the middle it says:
15 Criteria, inclusion criteria.

16 Do you see that?

17 A. Yes.

18 Q. And under that heading there is
19 numbered sentences.

20 Do you see that?

21 A. Yes.

22 Q. And are any of those numbered
23 sentences about requiring previous treatments?

24 A. No, but I will say that it would
25 have been unethical and virtually impossible

1 for an experimental study of metastatic
2 colorectal cancer to put a patient on an
3 experimental drug in 2013 or '14 or '15
4 without having given -- without the patient
5 having received prior chemotherapy and having
6 progressed on it, that would have been
7 unethical and would never have been approved.

8 This is not a well-written -- I
9 think this is a very poorly written
10 experimental protocol. It leaves out a few
11 things, but that's left -- it should have been
12 written explicitly here.

13 Q. Why do you think the experimental
14 protocol written here in Exhibit 1005 is
15 poorly written?

16 A. Well, it leaves out exactly what I
17 just said, what you alluded to, which is that
18 the patients had to have previous treatment
19 and progressed on the previous treatment
20 before being allowed to be put on an
21 experimental drug.

22 Q. What else does this protocol here
23 in Exhibit 1005 leave out?

24 ATTORNEY RATLIFF: I object to the form
25 of the question, as well as to the premise of

1 the question.

2 A. Well, again, this is -- later on in
3 the claims alludes to giving the pembrolizumab
4 intravenously, and so it has to be given
5 intravenously. That was the only mode of
6 administration that was available, and so that
7 should have been said explicitly in the method
8 of administration. It does say they agree to
9 have a biopsy of their cancer. So that
10 already tells you they have to have a biopsy
11 of their cancer, so that is explicit. Okay.

12 Q. Anything else left out of Exhibit
13 1005 besides intravenous administration and
14 requiring previous treatments?

15 ATTORNEY RATLIFF: I object to the form
16 of the question, as well as to the premise of
17 the question.

18 A. Most protocols will have a demand
19 that the colorectal cancer be histologically
20 proven. Again, that may sound -- it's like
21 some of the other things. Every POA will
22 recognize and know that that's a given or an
23 obvious thing, and it would have been done and
24 it had to be done and it would have been done,
25 but it should say it explicitly, protocol

1 should be complete and list every requirement
2 openly, you know, and explicitly. It doesn't
3 say that anywhere here that I see, so it
4 should have said that as well, but it does
5 not.

6 Again, it leaves out certain
7 details. These details would never have been
8 missed in real life. You know, they would not
9 have been violated or missed in the conduct of
10 a real trial, but they should have been
11 explicitly written in the study record.

12 I mean, I can further say again
13 that -- I'm sorry, it's --

14 CERTIFIED STENOGRAPHER: I can't hear
15 you, Doctor.

16 A. It's in the -- there was something
17 else I thought of, but it's in the exclusion
18 criteria.

19 Q. So going back to --

20 A. I'm sorry?

21 Q. Going back to when one would test
22 the MSI status, testing could occur after a
23 patient was enrolled in the study; correct?

24 ATTORNEY RATLIFF: Which study are we
25 talking about?

1 (No response.)

2 ATTORNEY RATLIFF: If you don't want to
3 answer my question, I object to the form of
4 your question.

5 A. I don't understand the question.

6 Q. So patients would get enrolled into
7 the study that's reflected here in Exhibit
8 1005; correct?

9 A. Patient would be enrolled? What
10 patient would be enrolled? I'm sorry.
11 Someone who is at the entry criteria?

12 Q. Yeah, I'm asking a super basic
13 question.

14 A patient gets enrolled into the
15 study; correct?

16 ATTORNEY RATLIFF: I object to the form
17 of the question, as well as to the premise
18 that you're asking a super basic question.

19 A. Yes.

20 Q. And is there anything in this study
21 protocol that says a patient's MSI status
22 would need to be determined before enrollment?

23 A. "Before enrollment" being before
24 they were recruited into the study?

25 Q. (Indicating.)

1 A. No.

2 Q. Were you aware in 2015 that
3 nivolumab had been used to treat CRC patients?

4 ATTORNEY RATLIFF: I object to the form
5 of the question, as well as to the premise of
6 the question.

7 A. I don't think so.

8 Q. So is it fair to say that if you
9 weren't aware of nivolumab being used to treat
10 CRC patients, you didn't have an idea of the
11 results?

12 ATTORNEY RATLIFF: I object to the form
13 of the question, as well as to the premise of
14 the question.

15 A. I don't have a specific
16 recollection of nivolumab and treatment of
17 colon cancer at that time.

18 Q. I want to talk about ASCO again if
19 that's all right with you.

20 You refer to ASCO in your
21 declaration; correct?

22 A. Yes.

23 Q. And you write that: ASCO is an
24 annual meeting for oncologists which is
25 considered the Super Bowl of the cancer world

1 and attended by over 40,000 oncologist and
2 other -- others each year; correct?

3 A. Yes.

4 Q. You wrote that until 2020, you
5 regularly attended ASCO; right?

6 A. Well, I stopped going at the time
7 of the pandemic.

8 Q. And have you restarted going to
9 ASCO?

10 A. No.

11 Q. And why is that?

12 A. Personal reasons.

13 Q. When did you first go to ASCO?

14 A. When I was a fellow.

15 Q. And when was that?

16 A. I think my first meeting was in
17 1981.

18 Q. And why did you go to these
19 meetings?

20 ATTORNEY RATLIFF: Each and every one?

21 Wait. Hold on. Hold on.

22 I object to the form of the question.

23 A. It's a place to be. It's where
24 everyone is. First of all, to hear what's new
25 and exciting and also almost more importantly

1 to hobnob and interact with other oncologists
2 and meet the main players in oncology. So
3 it's the best way to network.

4 Later when I had fellows of my own,
5 I would go to make sure they would meet to
6 help them network with major players in the
7 field, and then also I present papers. I, as
8 well, lecture there as well. Give talks and
9 present posters and whatever and then also a
10 good place to pick up freebies and stuff like
11 that. So it was a good thing. It's usually
12 in a good place also. So an opportunity to
13 travel a bit.

14 The last, I don't know, 20 years
15 it's always been in the same -- they stopped
16 moving it, so it's always been in Chicago for
17 the last, I'm going to say, 20 years, so you
18 don't get to see other cities anymore, but it
19 used to be a good opportunity to see other
20 places.

21 Q. You said you had been invited to
22 give talks at ASCO. Have you ever given a
23 keynote address at ASCO?

24 A. I don't think so. I mean, I've
25 given certainly oral talks and, you know,

1 spoken in workshops and things like that, but
2 I don't think I ever gave one of the plenaries
3 or one of the main talks.

4 Q. In your opinion, is it an honor to
5 be invited to give a keynote address at ASCO?

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

8 A. I don't know what you mean by a
9 "keynote address." What exactly do you mean?
10 What do you mean by a "keynote address"?

11 Q. You referred to giving one of the
12 plenaries or one of the main talks.

13 A. Oh.

14 ATTORNEY RATLIFF: Wait, if that's a
15 question, which I don't understand what the
16 question is, I object to the form of the
17 question.

18 ATTORNEY McCORMICK: I wasn't done with
19 the question yet.

20 Q. So when I'm saying keynote address,
21 I think I mean the same thing as you do about
22 a plenary or one of the main talks.

23 ATTORNEY RATLIFF: If your question has
24 embedded something about you thinking you know
25 what he means, I object to the form of the

1 question.

2 A. Yeah, of course it's an honor to be
3 one of the plenary or main talks.

4 Q. Do you know why someone would be
5 selected to give one of the plenary or main
6 talks at ASCO?

7 A. Well, one of the plenary talks
8 would be because of the several thousand
9 papers would be considered one of the main --
10 one of the most important discoveries of the
11 year among all the abstracts that were
12 submitted.

13 The other -- I don't know, one of
14 the main -- other main talks would be because
15 someone was being honored. Sometimes there
16 were certain awards that are given out at
17 every meeting, you know, best basic scientist,
18 the best clinical scientist, things like that,
19 so if someone is given one of those awards,
20 then they're invited to give a talk about
21 their work or something like that, so they
22 give those talks.

23 Q. So you said you recall in 2015,
24 Dr. Le gave one of the main talks at the 2015
25 ASCO; right?

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

3 A. I don't -- as I sit here, I don't
4 recall or know, but --

5 Q. So you have no memory of whether
6 Dr. Le gave one of the main talks at the 2015
7 ASCO?

8 A. What does "one of the main talks"
9 mean?

10 Q. I thought we had established that
11 was one of the more important oral sessions at
12 ASCO.

13 ATTORNEY RATLIFF: I object to your
14 thought, if that's a question.

15 A. I didn't say that. If you tell me
16 that it was, I don't have a reason to
17 disbelieve you.

18 Are you saying it was a plenary
19 talk?

20 Q. Let me start again.

21 Do you recall Dr. Le's talk at the
22 2015 ASCO?

23 A. I already answered that. I do not
24 recall specifically hearing her talk. It
25 could have -- it probably would have been in

1 the colon cancer session as an oral talk, and
2 I probably would have gone to the colon cancer
3 early-on talks, and I probably would have
4 heard it, but I don't, as I sit here, have a
5 specific memory of hearing it.

6 Q. I recall you saying that you get
7 the New England Journal of Medicine; is that
8 right?

9 A. Yes.

10 ATTORNEY RATLIFF: You're asking --
11 it's okay.

12 Q. Why do you get the New England
13 Journal of Medicine?

14 A. Well, they send it to me for free,
15 and it is sort of the leading -- the most --
16 it has I guess the most -- I don't want to say
17 the most important, but certainly the
18 most -- well, I guess the most prominent
19 papers that are published in medicine.

20 Q. Are you a reviewer for the New
21 England Journal of Medicine?

22 A. I've reviewed a couple of times for
23 them.

24 Q. What's your view of the reputation
25 of the New England Journal of Medicine?

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

3 A. I mean, as I said, it's considered
4 the most prestigious journal.

5 Q. Have you written any papers that
6 were published in the New England Journal of
7 Medicine?

8 A. No.

9 Q. Did you read Dr. Le's New England
10 Journal of Medicine paper before you became
11 involved in this case?

12 ATTORNEY RATLIFF: I object to the form
13 of the question, as well as to the premise of
14 the question.

15 A. As I said, I read it in 2015.

16 Q. Okay. We can go back to your
17 declaration, Exhibit 1003, paragraph 108 on
18 page 61.

19 Are you there, Dr. Neugut?

20 A. Yes.

21 Q. Okay. Your opinion is that the
22 motivation to combine in an obviousness
23 analysis of the MSI high study record, which
24 is Exhibit 1005, and Pernot means a motivation
25 to carry out the clinical trial; is that

1 right?

2 ATTORNEY RATLIFF: I object to the form
3 of the question, as well as to the premise of
4 the question.

5 A. I think Pernot, yeah, gives an
6 increased enthusiasm to conduct the trial.

7 Q. And if we could look at paragraph
8 112, which is on page 63, which is still in
9 the same section as paragraph 108.

10 Do you see that?

11 A. Yes.

12 Q. Okay. And your opinion is that a
13 motivation to combine means a motivation to
14 obtain the data from the results of carrying
15 out the MSI high study record; right?

16 ATTORNEY RATLIFF: I object to the form
17 of the question, as well as to the premise of
18 the question.

19 A. Yes, I agree.

20 Q. And a POSA wouldn't know the
21 results from carrying out the protocol
22 disclosed in MSI high study record until they
23 ran the trial; right?

24 A. They wouldn't know the results, the
25 exact results, until they did the trial, but I

1 think they would have anticipated that there
2 would have been a positive outcome.

3 Q. And is it your opinion that if the
4 results naturally flow from the clinical study
5 protocol, the results of that study protocol
6 are disclosed?

7 A. I don't know what "disclosed"
8 means.

9 Q. You don't know what discloses
10 means?

11 A. Disclosed to whom?

12 Q. To anyone?

13 A. Could you repeat the question?

14 Q. So is it your opinion that if the
15 results from the MSI high study record are
16 carried out and those results naturally flow
17 from -- sorry. Let me start again; is that
18 okay with you?

19 A. (Indicating.)

20 Q. Is that a yes?

21 A. Yes.

22 Q. Is it your opinion that if the
23 results naturally flow from carrying out the
24 MSI high study record protocol, then the
25 results of that study protocol are disclosed

1 to a POSA?

2 A. Again, I am unclear as to what you
3 mean by the word "disclosed." You mean that
4 somewhere down the road, that these were done
5 and that it's kept as a secret, but the POSA
6 is told the results in some secret way? Is
7 this a legal term?

8 Q. I'm using the word "disclosed" in
9 the way that anyone would. Like I mean --

10 ATTORNEY RATLIFF: Hold on. I would
11 definitely object to that, because how you're
12 using it is not how I would use it, so that's
13 invalid.

14 What's the question pending?

15 THE WITNESS: Yeah?

16 ATTORNEY RATLIFF: Hold on. There is
17 no question pending.

18 THE WITNESS: Okay.

19 ATTORNEY McCORMICK: Counsel, you don't
20 need to make a speaking objection.

21 ATTORNEY RATLIFF: It's not a speaking
22 objection. There is no question pending
23 then --

24 A. I'm not trying to be difficult. I
25 really don't understand the word.

1 BY ATTORNEY MCCORMICK:

2 Q. I'm trying to understand in
3 paragraph 112 of your report or your
4 declaration the last sentence: As a result of
5 carrying out the methods in the MSI high study
6 record of treating MSI high colorectal
7 patients with pembrolizumab at the dosage that
8 was applied in the clinical study, the person
9 of ordinary skill would have seen the results
10 that naturally flow from those methods.

11 Do you see that?

12 A. Yes.

13 Q. What do you mean by that?

14 A. I mean that the -- as I said
15 previously, the POSA would have anticipated
16 that by carrying out the MSI -- the study
17 that's described in the MSI study record, that
18 there would have been a positive outcome from
19 the conduct of the study and would have gotten
20 a positive result as was obtained in the
21 ultimate conduct of the clinical trial.

22 Again, what the exact number would
23 have been, okay, that, you know, you can't
24 anticipate exactly, but the POSA would have
25 anticipated that there would have been -- that

1 the drug would have been efficacious in the
2 context of MSI high colorectal cancer and not
3 efficacious in the context of MSI negative
4 colorectal cancer.

5 Q. I want to focus on the word "seen"
6 that you use here in that last sentence of
7 paragraph 112 of your declaration.

8 A. Yeah.

9 Q. Where would the POSA have seen the
10 results that naturally flow from those methods
11 disclosed in the MSI high study record?

12 ATTORNEY RATLIFF: I object to the form
13 of the question.

14 A. Okay. So perhaps the word "seen"
15 should not be taken literally as seen or have
16 those results to hand, but would have, as I
17 say -- would have anticipated seeing the
18 results might be a better way to phrase my
19 intent.

20 Q. And your opinion is that based on
21 the MSI high study record, a POSA would have
22 anticipated seeing positive results from
23 carrying out the MSI high study record?

24 A. Precisely.

25 Q. A POSA would not have known the

1 results from carrying out the methods of the
2 MSI high study record until it was carried
3 out; correct?

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

6 A. A POSA would not have known the
7 exact numbers, of course.

8 Q. Do you understand that's part of an
9 obviousness analysis, it has to be based on
10 what is in the prior art?

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

13 A. Yes.

14 Q. I want to point you to page 62,
15 your footnote seven.

16 A. 62?

17 Q. Yeah.

18 Do you see that?

19 A. Yeah.

20 Q. If information is not found in the
21 prior art, that would affect your obviousness
22 analysis; correct?

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

25 A. I'm sorry, what's your question?

1 Q. If information is not found in the
2 prior art, that would affect an obviousness
3 analysis; correct?

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

6 A. To be honest, I don't know the
7 legal implications or how that would affect
8 things.

9 Q. Fair enough.
10 I think you have the patent in
11 front of you; is that right? The '393 patent,
12 Exhibit 1001?

13 A. Yeah.

14 Q. I just want to focus on the
15 inventor section there.

16 Do you see that on the first page
17 of Exhibit 1001? It's at the top.

18 A. On the cover page?

19 Q. That's right.

20 A. Yes.

21 Q. Do you know any of these inventors?

22 A. When you use the term "know," do
23 you mean do I know them by reputation or do
24 you mean do I play stickball with them?

25 Q. By reputation is fine, although I

1 do want to know if you play stickball with any
2 of them?

3 A. No, I certainly know a few of them
4 by reputation, but I don't -- I don't
5 believe -- I don't know them personally. I
6 probably -- I met a couple of them like in the
7 sense of at a meeting and you shook hands with
8 them at a poster or something like that, but
9 we're not -- we're not friendly. But I don't
10 think I've had dinner with any of them or
11 anything like that.

12 Q. You said you know a few of them by
13 reputation. Which few?

14 A. Well, certainly Vogelstein.

15 Q. And why do you say that?

16 A. He is, you know, world famous, and
17 Kinzler and Papadopoulos and Pardoll.

18 Q. Anyone else you know by reputation?

19 A. No.

20 Q. And how do you know Dr. Kinzler by
21 reputation?

22 A. Kinzler I believe was a fellow in
23 Vogelstein's lab, and so Vogelstein is famous
24 for the Vogelgram.

25 Q. The what?

1 A. Vogelgram. That's -- published in
2 1990, a genetic sequence for colorectal
3 cancer. So that's like a very important
4 finding. Basically showed the sequence of
5 molecular changes that take place in the
6 progression of colon cancer from the normal
7 cell to the cancer cell. So that is an
8 extremely important discovery.

9 Kinzler I believe did the same
10 thing in his lab as his postdoc for a
11 different tumor. So I don't remember which
12 tumor he did. He had several postdocs who
13 basically did the Vogelgram for other tumors,
14 like the pancreas cancer or for head and neck
15 cancer or for other cancers. I don't remember
16 which one Kinzler did. So he did the same
17 thing.

18 I don't remember how Papadopoulos
19 plays into that, but somewhere, but I've seen
20 his name on some of the papers as well, and
21 likewise Pardoll also did something similar,
22 so they were all involved in this and they're
23 all on multiple papers together, but mostly,
24 again, in this molecular genetic series of
25 studies on colon cancer or pancreas or other

1 cancers. Nothing to do with what we're
2 talking about today.

3 THE WITNESS: Sorry.

4 Q. MSI is a molecular genetic marker;
5 correct?

6 A. MSI is a? A molecular genetic
7 marker? Yes.

8 Q. Are you aware of Dr. Luis Diaz's
9 reputation at all?

10 A. Only insofar as he was involved
11 with this 2015 paper, but beyond that, I don't
12 really know.

13 Q. Is that the same for Dr. Le?

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

16 A. Dr. Le I don't know at all.
17 Dr. Diaz I think I've heard a couple of times
18 in terms of treatment of colorectal cancer,
19 but Dr. Le I don't know at all.

20 Q. And do you know the reputation of
21 Dr. Topalian at all?

22 A. No.

23 Q. I just want to look at paragraph 15
24 of your declaration. Let me know when you're
25 there.

1 A. Okay.

2 Q. And in paragraph 15, you say that
3 in forming your opinions expressed in your
4 declaration, you reviewed the following
5 documents and materials, and there is a list
6 that goes onto the next page; is that right?

7 A. Yes, yes.

8 Q. And what do you mean by "reviewed"?

9 A. I read them. I'll say some of them
10 I didn't read quite as thoroughly as some of
11 the others, but I certainly looked at all of
12 them.

13 Q. Are there any that you read more
14 thoroughly than others?

15 A. I guess the ones that are listed
16 were read more thoroughly than some of the
17 ones that aren't listed.

18 Q. By "some of the ones that aren't
19 listed," are you talking about the materials
20 in appendix A that's at the end of the list
21 here in paragraph 15?

22 A. Yes.

23 Q. And I think we can turn to the
24 appendix A so we're all talking about the same
25 thing, so on page 89 of your declaration or

1 page 90 of the exhibit.

2 A. Okay.

3 Q. So did you read all of the
4 materials listed here in appendix A?

5 A. Well, again, I certainly looked at
6 everything that was in Exhibit A, but some of
7 these things I didn't read in depth or, you
8 know, study closely.

9 Q. Did you review or rely on anything
10 that isn't in paragraph 15 and appendix A in
11 forming your opinions for this case?

12 A. I may or may not have.
13 Occasionally I might have Googled something
14 just to fill in a blank on something where I
15 didn't remember a word or fill in some fact,
16 just because my memory doesn't remember or
17 just to make sure I knew what the word meant
18 or needed to look up exactly what an acronym
19 stood for or something like that, but beyond
20 doing something like that, no.

21 (Clarification requested by the
22 stenographer.)

23 A. Beyond that, the answer is no.

24 Q. Do you remember off the top of your
25 head what you had to like Google?

1 A. Not off the top of my head, no. I
2 do like to look things up to make sure I
3 refresh myself on things that I don't know,
4 and I don't remember everything of course. So
5 I do -- I do that a fair amount, but will look
6 in -- I don't know if you're familiar with
7 UpToDate. So I look things up there
8 occasionally.

9 (Clarification requested by the
10 stenographer.)

11 THE WITNESS: I'm sorry.

12 A. I look in UpToDate occasionally to
13 refresh myself on clinical things, but I don't
14 think I had to do that very much here.

15 Q. What's UpToDate?

16 A. UpToDate is an online, I'll use the
17 word, textbook of medicine. No one buys
18 textbooks anymore. I don't think I've bought
19 a textbook in 10 or 12 years, but everything
20 is in -- UpToDate is everything in medicine
21 that you want to know, and if you bring it up,
22 you know, if you go to its site and put in the
23 search term, whatever disease it is or
24 something like that, it will bring up the
25 item, and then if you read there, it has

1 almost everything in it up-to-date, more or
2 less, plus any references that you may want to
3 know. It's really remarkable how good it is,
4 and all of my colleagues I think use it as
5 their main source of information on clinical
6 matters.

7 Q. Which of the documents here in
8 paragraph 15 did you identify yourself?

9 A. In the paragraph we were just in?

10 Q. (Indicating.)

11 A. I don't believe any of them.

12 Q. Who provided you with the documents
13 listed in paragraph 15 in appendix A?

14 A. The attorneys in the case.

15 ATTORNEY McCORMICK: I think it's a
16 good time for another break, if that's all
17 right with you?

18 Okay. We can go off the record.

19 CERTIFIED STENOGRAPHER: Off the
20 stenographic record at 11:13 a.m.

21 (Whereupon, a recess is taken.)

22 CERTIFIED STENOGRAPHER: Back on the
23 stenographic record at 11:33 a.m.

24 BY ATTORNEY McCORMICK:

25 Q. Dr. Neugut, did you discuss the

1 substance of your testimony with counsel
2 during the break?

3 A. No.

4 Q. And I have heard you coughing
5 during this deposition. I want to make sure
6 you're still okay to give truthful, complete,
7 and accurate testimony today?

8 A. I'm fine. The coughing is I don't
9 know what. It has nothing to do with
10 anything.

11 Q. Okay. Good to hear.
12 I want to talk about clinical
13 trials again, okay?

14 A. Okay.

15 Q. A skilled artisan would understand
16 that just because a therapy resulted in a
17 positive outcome in one clinical trial, does
18 not mean it will result in a positive outcome
19 in subsequent trials; right?

20 ATTORNEY RATLIFF: What time frame are
21 we talking?

22 (No response.)

23 ATTORNEY RATLIFF: If you're not going
24 to answer my question, I object to the form of
25 your question.

1 A. That is true.

2 Q. Dr. Neugut, do you agree that prior
3 to the clinical trial described in MSI high
4 study record, only one patient had responded
5 to a PD-1 blocker?

6 ATTORNEY RATLIFF: I object to the form
7 of the question, as well as to the premise of
8 the question.

9 A. I don't know how many patients had
10 responded previously to PD-1 blockers.

11 Q. Are you aware of any patients that
12 had responded to PD-1 blockers before the MSI
13 high study record?

14 A. Well, there is the one case that
15 they reference in their paper and that's been
16 sort of talked about all the time, the one guy
17 who had a complete response and a prolonged
18 complete response to the drug. I don't know
19 if there were others and either they weren't
20 written up or they were in other papers or
21 whatnot. I don't even know.

22 Q. So you're aware of one patient that
23 responded to a PD-1 blocker before the MSI
24 high study record; correct?

25 A. Yes.

1 Q. And you are not aware of any other
2 patients that responded to a PD-1 blocker
3 before the MSI high study record?

4 A. You mean it was published, so
5 correct.

6 Q. So I want to look at that
7 publication regarding the one PD-1 -- the one
8 patient that responded to the PD-1 inhibitor,
9 okay?

10 A. Okay.

11 Q. So I'm going to hand you Exhibit
12 1057.

13 (Whereupon, document previously
14 marked MERCK EX 1057, is received and marked
15 as Exhibit 1057 for Identification.)

16 BY ATTORNEY MCCORMICK:

17 Q. Dr. Neugut, do you recognize
18 Exhibit 1057?

19 A. Yes.

20 Q. Exhibit 1057 is an article titled:
21 Durable Cancer Regression Off-Treatment and
22 Effective Reinduction Therapy with an
23 Anti-PD-1 Antibody; is that right?

24 A. Yes.

25 Q. And the first author of Exhibit

1 1057 is Evan Lipson.

2 Do you see that?

3 A. Yes.

4 Q. So if I refer to this as the Lipson
5 article, will you understand I mean Exhibit
6 1057?

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

9 A. Yes.

10 Q. Do you see in the author's section
11 of Exhibit 1057 Drew Pardoll and Suzanne
12 Topalian?

13 A. Yes.

14 Q. And, Dr. Neugut, Pardoll and
15 Topalian are inventors of the '393 patent
16 claims; correct?

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

19 A. Yes.

20 Q. And is the Lipson article -- does
21 it reflect the one cancer patient that you're
22 aware of that responded to PD-1 inhibitors?

23 A. Yes.

24 Q. And if we could turn to page two of
25 the Lipson article.

1 Down at the very bottom on the
2 second column, under the heading: Durable
3 complete response in colorectal cancer.

4 Do you see that?

5 A. Yes.

6 Q. And it does mention there in the
7 very bottom of the second column of page two:
8 Microsatellite instability, MSI, high
9 genotype.

10 Do you see that?

11 A. Yes.

12 Q. Nowhere in this section or anywhere
13 in this Lipson article does it say that the
14 patient responded because of their MSI high
15 status; does it?

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

18 A. I'm not understanding the question.
19 It says he's MSI high, but it doesn't say he
20 responded because he was MSI high. Is that
21 the question?

22 Q. (Indicating.)

23 ATTORNEY RATLIFF: Wait. If that's the
24 question, then I object to the form of the
25 question.

1 A. Well, you wouldn't write that here
2 anyway. You would put that in the discussion
3 I assume. So do you want to look at the
4 discussion?

5 Q. Sure. We can look at the
6 discussion.

7 ATTORNEY RATLIFF: For what purpose are
8 we looking at the discussion?

9 (No response.)

10 ATTORNEY RATLIFF: If there is a
11 question pending, I object to the form of the
12 question.

13 Q. Dr. Neugut, I just want to clarify,
14 the Lipson paper is talking about one MSI high
15 CRC patient who was treated with a PD-1
16 blocker before the MSI high study record; is
17 that your understanding?

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

20 A. I don't know when the patient was.
21 I didn't see the date. Was it before the MSI
22 high study record?

23 Q. So Exhibit 1057, the Lipson paper,
24 was published January 15, 2013.

25 Do you see that? I'm sorry, it was

1 published online first, November 20, 2012.

2 A. Yeah.

3 Q. Do you see that?

4 A. Uh-huh, yes, uh-huh. Okay.

5 Q. And reported in the Lipson article
6 is one CRC patient who was treated with a PD-1
7 inhibitor and had a durable complete response;
8 correct?

9 A. Yes.

10 Q. And we were looking at the
11 discussion section to see if anything in the
12 discussion section mentions that that one CRC
13 patient treated with a PD-1 inhibitor
14 responded because they were MSI high?

15 A. Yes.

16 ATTORNEY RATLIFF: If -- okay.

17 Is there a question pending?

18 ATTORNEY McCORMICK: I'm giving
19 Dr. Neugut a chance to read the discussion
20 section so he can answer my question.

21 ATTORNEY RATLIFF: I don't know what
22 the question is. So I object to the form of
23 the question.

24 A. All right.

25

1 BY ATTORNEY MCCORMICK:

2 Q. Did you finish reading the
3 discussion section of the Lipson article?

4 A. Yes.

5 Q. And do you see anything in there
6 about the one CRC patient who was treated with
7 a PD-1 blocker responding because of their MSI
8 high status?

9 A. No, it makes no reference to it.

10 Q. And is it true that in 2012, when
11 this article published, testing for MSI high
12 status was routine?

13 A. Was what?

14 Q. Routine?

15 A. I'm going to have to say I don't
16 recall that far back if it was or wasn't. It
17 might have been. I don't recall.

18 Q. This morning we were talking about
19 testing for MSI high status in 2015.

20 Do you recall that?

21 A. Yes.

22 Q. And one of the reasons that you
23 might have tested for MSI high status was to
24 know if the patient had Lynch syndrome; is
25 that right?

1 A. Yes.

2 Q. So is it possible that this CRC
3 patient referred to in the Lipson article was
4 tested for MSI status in order to understand
5 their Lynch syndrome status?

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

8 A. It's possible.

9 Q. The Lipson article evaluates the
10 PD-1 status of the tumor; correct?

11 A. Yes.

12 Q. And looking at page three of the
13 exhibit, the second column at the very top.

14 A. Yes?

15 Q. The authors are -- the authors
16 state: We have previously reported
17 preliminary evidence for a correlation between
18 tumor cell membranous PD-L1 expression and the
19 likelihood of response to anti-PD-1 therapy;
20 is that right?

21 A. Yes.

22 Q. And in that discussion that I just
23 read, the authors aren't talking about MSI
24 status; right?

25 ATTORNEY RATLIFF: I object to the form

1 of the question.

2 A. Correct.

3 Q. And in the Lipson article, that
4 patient that was treated with an anti-PD-1
5 inhibitor, it's not pembrolizumab that they
6 were given; right?

7 A. Correct.

8 Q. Do you know which drug they were
9 given?

10 A. I believe it's nivolumab, but I'm
11 not 100 percent sure.

12 Q. In 2012, at the time of the Lipson
13 article, a POSA didn't know that pembrolizumab
14 had treated MSI high cancers; correct?

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

17 A. In 2012? I don't know if he would
18 have known about pembrolizumab. Might have
19 had some inkling of -- he, I think, would have
20 thought that immunotherapy might do it, but
21 not necessarily pembrolizumab.

22 Q. And why would a POSA have some
23 inkling that immunotherapy might treat MSI
24 high cancers?

25 A. I think some of the articles that I

1 reference in my declaration alluded to that.

2 Q. Which articles?

3 A. Pernot and the MSI high study
4 record itself would have implied it.

5 There was a press release from
6 Galactica that I reference in 1084 that refers
7 to several trials going on at the time that
8 referred it, that's not in 2012, but it's
9 still prior to the relevant time frame that
10 we're talking about of the patent. So I think
11 there you have a few examples of publications
12 or documents that would have told the POSA and
13 from which the POSA could have inferred or
14 learned that the use of PD-1 inhibitors in
15 immunotherapy would have been effective in MSI
16 high patients.

17 Q. So those are a few examples, the
18 Pernot article, MSI high study record, and the
19 press release. Are there any others from
20 which a POSA would have learned or expected
21 that a PD-1 inhibitor would be effective in
22 MSI high patients?

23 A. Tougeron.

24 Q. Is there an exhibit number for that
25 one?

1 A. 1036.

2 Q. Thank you.

3 A. That's about it.

4 Q. Perfect. Thank you.

5 Dr. Neugut, I'd like to go back to
6 the MSI high study record, Exhibit 1005.

7 ATTORNEY RATLIFF: I've got it.

8 Q. Do you have Exhibit 1005 in front
9 of you?

10 A. Yep.

11 Q. The MSI high study record is a
12 clinical study announcement. It's not a
13 clinical study report; correct?

14 A. Yes.

15 Q. And the MSI high study record in
16 Exhibit 1005 is a protocol posting; right?

17 A. Yes.

18 Q. The MSI high study record in
19 Exhibit 1005 reflects a hypothesis to be
20 tested?

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

23 A. Yes.

24 Q. And at the time the MSI high study
25 record in Exhibit 1005 was posted, the

1 protocol had not been performed; correct?

2 A. Had not been performed, no.

3 Q. At the time the MSI high study
4 record in Exhibit 1005 was posted, the
5 protocol had not been performed; correct?

6 A. Correct.

7 ATTORNEY RATLIFF: I --

8 Q. At the time the MSI high study
9 record was first posted, oncologists could not
10 know the results; right?

11 A. Well, we've discussed this a little
12 bit. They could not know the exact results,
13 but as I said, they could anticipate that
14 there would be -- that the drug would be
15 efficacious.

16 Q. And that's the opinion that you're
17 giving as part of this; right?

18 A. Yes.

19 Q. Is there anything in the MSI high
20 study record in Exhibit 1005 that tells a POSA
21 that the protocol will be successful or have a
22 positive outcome?

23 A. No.

24 Q. If the clinical trial posted in the
25 MSI high study record had been halted once it

1 started, oncologists would have no way of
2 knowing whether the treatment would have a
3 positive outcome; correct?

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

6 A. You mean if it had been halted
7 before it was completed, then they would not
8 have known the exact results of the outcome,
9 right.

10 Well, I suppose if it had been
11 halted before any data was collected, then
12 yes. I suppose if they have partial data,
13 they might have known something. So I don't
14 know exactly what they would have known.

15 Q. Do you understand that FDA requires
16 posting protocols on ClinicalTrials.gov before
17 researchers can run a human clinical trial?

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

21 A. Yes.

22 Q. And this MSI high clinical study
23 record in Exhibit 1005 was posted on
24 ClinicalTrials.gov; correct?

25 A. Yes.

1 Q. And Hopkins was required by FDA to
2 post the MSI high study record on
3 ClinicalTrials.gov before conducting the
4 protocol; right?

5 ATTORNEY RATLIFF: Wait. You're asking
6 about Hopkins and Merck or Hopkins alone?

7 I object to the form of the question.

8 A. I'll agree to that point, that it
9 was really Hopkins and Merck together who
10 posted it.

11 Q. How do you know that?

12 A. They collaborated in the trial.

13 Q. So if you turn to page three of
14 Exhibit 1005 under the section sponsor
15 collaborators.

16 A. Yep.

17 Q. The sponsor is Sidney Kimmel
18 Comprehensive Cancer Center at Johns Hopkins;
19 correct?

20 A. Yes.

21 Q. And the responsible party here is
22 the sponsor?

23 A. Yeah.

24 Q. Meaning Johns Hopkins; correct?

25 A. Correct, and the collaborator was

1 Merck Sharp & Dohme.

2 Q. And if you go to the last page of
3 the MSI high study record, contacts and
4 locations.

5 Do you see that?

6 A. Yes.

7 Q. And the principal investigator for
8 the study protocol shown here in the MSI high
9 clinical study record is Dr. Dung Le; right?

10 A. Yes.

11 Q. And Dr. Dung Le is at the Sidney
12 Kimmel Comprehensive Cancer Center at Johns
13 Hopkins; correct?

14 ATTORNEY RATLIFF: I object to the form
15 of the question. You keep saying Young Le.

16 A. Yes. It's Dung Le, right.

17 Q. She says it Young.

18 A. Oh, she does?

19 Q. She does.

20 A. I guess there is good reason for
21 that.

22 Q. What's your understanding of
23 Merck's contribution to the study here in the
24 MSI high clinical study record?

25 A. I don't have any knowledge of

1 exactly how the collaboration was conducted.
2 As I said in an earlier answer to another
3 question, most studies, most trials nowadays
4 involve a number of collaborators.

5 Obviously, Dr. Le was the principal
6 investigator and had overall responsibility
7 for the conduct of the study, but then there
8 are multiple people who are listed as
9 collaborators or investigators on the study,
10 and exactly what each one contributed or what
11 each one did, I have no way of being able to
12 describe or to be aware of.

13 Q. So FDA required Hopkins and Merck
14 to post the clinical study protocols shown
15 here in the MSI high clinical study record
16 before they could run the study; correct?

17 A. To post it on ClinicalTrials.gov,
18 yes.

19 Q. Is it your understanding that it's
20 necessary to post the study announcement on
21 ClinicalTrials.gov to get human clinical data?

22 A. To get human clinical data?

23 Q. (Indicating.)

24 A. To be honest, I don't know what you
25 mean by that.

1 Q. To run a clinical trial in humans,
2 is it your understanding that you have to post
3 the protocol that you're going to run on
4 ClinicalTrials.gov before you run the clinical
5 trial?

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

8 A. Well, as you said, the FDA demands
9 it. So it's required that you do it. That's,
10 I don't want to say, the law, but that's
11 required. I think they want the public to be
12 aware of all the trials, and they also don't
13 want -- they don't want -- they don't want
14 redundancy in trials. So that's a reason why
15 it's done as well. So this way everyone knows
16 here is a trial of, in this case, for example,
17 MSI high colon cancer, and so if someone else
18 were planning such a study, they would or they
19 should look at the website and see that such a
20 study is planned, here is how it's going to be
21 done, and they shouldn't exactly do the same
22 thing or whatever or at least they should be
23 aware of it so they don't recapitulate it
24 exactly or trip over each other's feet and
25 stuff like that.

1 I mean, also the other reason the
2 FDA requires it is so that patients can be
3 aware of it, so that if there is someone in
4 Chicago who is looking for a trial because
5 they had metastatic colon cancer and they're
6 desperate, so they go to ClinicalTrials.gov
7 and look around for trials on the website.

8 If they put in their
9 characteristics, they'll find out in Baltimore
10 there is a trial going on and they can travel
11 to Baltimore and call Dr. Le or whatever and
12 try to get into the trial, if they want to do
13 that.

14 Q. Do you know if it's required to
15 post a protocol on ClinicalTrials.gov before
16 running a clinical trial?

17 A. I'm sorry, have you not asked me
18 that now three times?

19 ATTORNEY RATLIFF: I'll just note for
20 the record that counsel is shaking her head
21 that to your question about if she's asked you
22 the question three times.

23 A. I mean, wasn't this the same
24 question you asked me a minute or two ago?

25 Q. Yes. Dr. Neugut, I'm trying to

1 make sure that I understand your testimony
2 clearly and also that the judges in this case
3 understand your testimony clearly.

4 A. So the answer is, yes, it is
5 required by the FDA that all clinical
6 protocols for trials be posted on
7 ClinicalTrials.gov, and the patent board
8 should be aware of that. It wasn't posted
9 frivolously, and I don't know if they were
10 planning not to post it and to keep it secret
11 otherwise, but yes, it is required that it be
12 posted.

13 Q. And if Hopkins or Merck wanted to
14 keep a clinical study secret, they could do
15 that; right?

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

18 A. If that's your point, yes, you're
19 correct. They could not -- they could not
20 keep a trial secret. I mean, if putting it on
21 ClinicalTrials.gov means not keeping it
22 secret, you're right, they could not keep it
23 secret. They would have to post it on
24 ClinicalTrials.gov, so anyone who wanted to,
25 could look it up or find out about it and know

1 about it.

2 Q. Thank you.

3 Now, clinical study protocols
4 outline an experiment; right?

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

7 A. I'm sorry, I didn't hear the
8 question clearly.

9 Q. Clinical study protocols outline an
10 experiment; correct?

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

13 A. Yes, they do.

14 Q. The MSI high study record in
15 Exhibit 1005 does not disclose how the MSI
16 high status will be tested; is that right?

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

19 A. It doesn't state exactly what
20 methodology should be utilized as I've said
21 now once or twice. It does imply that it has
22 to be tested, otherwise you wouldn't know who
23 was MSI high and who was MSI negative, but it
24 does not explicitly state what was required to
25 be done in order to make that determination.

1 Q. So the MSI high study record does
2 not disclose having carried out an
3 immunohistochemistry test on the patient
4 sample?

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

7 A. No, it does not explicitly say that
8 they have to have immunohistochemistry. They
9 could have PTR. They could have next
10 generation sequencing. They could have
11 another method done.

12 Q. Those other methods that you
13 mentioned, that PCR or next gen sequencing,
14 those are not disclosed in the MSI high
15 clinical study record; right?

16 A. None of them are disclosed, but any
17 of them would fulfill the requirement of
18 determining the MSI status of the patient
19 before they undergo pembrolizumab therapy.

20 Q. And the MSI high study record does
21 not disclose that the biological sample being
22 tested for MSI high status is a body fluid
23 from the patient; right?

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

1 A. It does not disclose that, but also
2 it could just as well be a body fluid and the
3 POSA would have totally appreciated that, that
4 would be just as well as having a tumor
5 specimen or not. Either one would be suitable
6 or adequate for doing whatever test was
7 necessary in order to determine MSI status.

8 Q. The MSI high study record does not
9 disclose that the protocol results in being
10 effective in promoting progression-free
11 survival in multiple human subjects whose
12 colorectal cancer is MSI high or mismatch
13 repair deficient; right?

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

16 A. I'm sorry, you lost me on that
17 question.

18 Q. The MSI high study record does not
19 disclose any results from carrying out the
20 protocol; correct?

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

23 A. No, it does not.

24 Q. And the MSI high study record does
25 not disclose any preclinical results, like

1 animal testing or in vitro testing; right?

2 A. No, it does not.

3 Q. Are you aware of any animal methods
4 that could be used to test PD-1 inhibitors for
5 MSI high tumors?

6 A. No, I'm not familiar with them.

7 Q. You said that you reviewed the
8 prosecution history for the '393 patent;
9 right?

10 A. Yes.

11 Q. Are you aware that the Patent
12 Office considered the clinical study record as
13 part of the -- part of evaluating the
14 patentability of the '393 patent?

15 ATTORNEY RATLIFF: I object to the form
16 of the question, as well as to the premise of
17 the question.

18 A. Could you repeat the question?

19 Q. Are you aware that the Patent
20 Office considered the MSI high clinical study
21 record as part of evaluating the patentability
22 of the '393 patent claims?

23 ATTORNEY RATLIFF: I object to the form
24 of the question, as well as to the premise of
25 the question.

1 A. Yes.

2 Q. And you think the Patent Office got
3 it wrong?

4 A. Yes.

5 (Whereupon, document previously
6 marked MERCK EX1006, is received and marked as
7 Exhibit 1006 for Identification.)

8 BY ATTORNEY McCORMICK:

9 Q. Do you have Pernot Exhibit 1006 in
10 front of you?

11 A. (No response.)

12 Q. Do you have Pernot Exhibit 1006 in
13 front of you, Dr. Neugut?

14 A. Yes.

15 Q. Let's look at that.

16 Do you know what a claim limitation
17 is, Dr. Neugut?

18 A. Could you repeat the question?

19 Q. Do you know what a claim limitation
20 is?

21 A. It's -- yes, I do know, but I have
22 to recollect. It's a part -- it's like you
23 have separate paragraphs.

24 Q. Perfect. I will use that same
25 understanding of what a claim limitation is

1 when we talk, okay?

2 You're not relying on Pernot,
3 Exhibit 1006, for disclosing the "in response
4 to" claim limitation; correct?

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

7 A. I don't believe so.

8 Q. And just so we're all on the same
9 page somewhat literally, you could have the
10 '393 patent in front of you on the very last
11 page looking at the claims.

12 A. On the very last page?

13 Q. That's right. Second-to-last page,
14 sorry.

15 A. Second-to-last page. Yeah.

16 Q. And when I'm referring to the "in
17 response to" limitation, I'm talking about the
18 very last phrase of claim one and claim 14
19 where it says: In response to determining
20 that the colorectal cancer is microsatellite
21 instability high or DNA mismatch repair
22 deficient, comma, treating the patient with a
23 therapeutically effective amount of
24 pembrolizumab.

25 Do you see that?

1 A. Yes.

2 Q. So if I refer to that as the "in
3 response to" limitation, will you understand
4 what I just read is what I'm referring to?

5 A. Yes.

6 Q. And you are not relying on Pernot
7 for disclosing the "in response to" claim
8 limitation; right?

9 A. Correct.

10 Q. You are only relying on Pernot for
11 the testing limitation; correct?

12 ATTORNEY RATLIFF: I object to the form
13 of the question, as well as to the premise of
14 the question.

15 A. I'm sorry, could you repeat your
16 question?

17 Q. You are only relying on Pernot for
18 the testing claim limitation; correct?

19 ATTORNEY RATLIFF: I object to the form
20 of the question, as well as to the premise of
21 the question.

22 And, Dr. Neugut, I know that you're
23 coughing, so you could take your time.

24 THE WITNESS: No, no, I'm fine.

25 A. I would say that I'm relying on

1 Pernot for the conduct of the clinical trial,
2 which would involve both testing and then
3 following up the testing with giving
4 pembrolizumab in response to the results of
5 the testing. I don't think it's limited to
6 the testing.

7 Q. Is there anything else from Pernot
8 that you're relying on --

9 A. No.

10 Q. -- for your opinions in this case?

11 A. No.

12 Q. Pernot does not disclose anti-PD-1
13 therapies; right?

14 A. No, correct.

15 Q. Pernot does not disclose that MSI
16 high CRC patients would be promising
17 candidates for PD-1 checkpoint blockade
18 therapy; correct?

19 ATTORNEY RATLIFF: I object to the form
20 of the question, as well as to the premise of
21 the question.

22 A. No, he does not.

23 Q. And Pernot does not disclose any
24 relationship between MSI high CRC patients and
25 their likelihood of responding to PD-1

1 checkpoint blockade therapy; right?

2 ATTORNEY RATLIFF: I object to the form
3 of the question, as well as to the premise of
4 the question.

5 A. No, he doesn't make reference to
6 it.

7 Q. And if I could direct your
8 attention to page four of Pernot, the second
9 column under the heading: Microsatellite
10 Instability CRC is Associated with Immunogenic
11 TAAs.

12 Do you see that?

13 A. Yes.

14 Q. And the Pernot article states that:
15 Microsatellite instability MSI is associated
16 with CRC in patients with Lynch syndrome, but
17 also with sporadic cancer, in particular in
18 elderly patients, and is observed in 5 percent
19 of 25 percent of CRC patients depending on
20 tumor stage.

21 Did I read that right?

22 A. Yes.

23 Q. And do you agree with that?

24 A. Yes.

25 Q. You can set that one aside.

1 **ATTORNEY RATLIFF:** Counsel, since
2 you're switching gears and we're close to an
3 hour, let's take our lunch break now.

4 **ATTORNEY McCORMICK:** That sounds good.
5 We can go off the record.

6 **CERTIFIED STENOGRAPHER:** Off the
7 stenographic record at 12:26 p.m.

8 (Whereupon, a luncheon recess is
9 taken at 12:26 p.m.)

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1 A F T E R N O O N S E S S I O N

2 (1:06 p.m.)

3 CERTIFIED STENOGRAPHER: Back on the
4 stenographic record at 1:06 p.m.

5 BY ATTORNEY MCCORMICK:

6 Q. Dr. Neugut, did you talk about the
7 substance of your testimony during the lunch
8 break?

9 A. No.

10 Q. Do you have Exhibit 1007, Chapelle,
11 in front of you?

12 A. I'm sorry, which? Oh, 1007?

13 Q. Yes.

14 A. Yes.

15 Q. As part of your opinions for this
16 case, you're only relying on Chapelle, Exhibit
17 1007, for disclosing testing of a biological
18 sample; is that right?

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

21 A. I don't recall what exactly I said
22 about it, but I don't know if there was
23 anything else in the article that was
24 important.

25 Q. You are relying on Chapelle for

1 disclosing testing a biological sample; right?

2 A. Yes.

3 Q. And you're not relying on Chapelle
4 for disclosing the "in response to" claim
5 limitation; right?

6 A. That's correct. I am not.

7 Q. And Chapelle did not suggest giving
8 a patient pembrolizumab in response to
9 determining a patient's tumor as MSI high;
10 correct?

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

13 A. The truth is that he does not
14 discuss the use of immunotherapy in the
15 context of MSI colorectal cancer.

16 Q. And if I could point your attention
17 to kind of the middle of the abstract, seven
18 lines down the sentence: Of all colorectal
19 cancers, CRCs, 15 percent to 20 percent
20 display MSI or abnormal IHC, often referred to
21 as a -- as microsatellite instability MIN
22 pathway.

23 Do you see that?

24 A. Yes.

25 Q. And do you agree with that?

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

3 A. Yes. As I said, since we're
4 talking primarily about metastatic colorectal
5 cancer, that percentage actually does not
6 apply to metastatic colon cancer. That
7 percentage is for all colorectal cancer, and
8 that number has been repeated several times
9 now, and it's really not accurate. Well, it's
10 accurate for what it is accurate for, but it's
11 not accurate for metastatic colorectal cancer.
12 The number is significantly smaller.

13 If this is relevant or important to
14 us, the number is significantly smaller for
15 metastatic colorectal cancer for various
16 reasons.

17 Q. And you said that MSI high for
18 metastatic colorectal cancers is 4 percent;
19 right?

20 A. 4 percent, 4 to 6 percent. I --
21 I -- I guess it depends on the study you read,
22 but the number in my head is 4 to 6 percent.

23 Q. And if I can direct your attention
24 to page three of Exhibit 1007, under the
25 subheading: Clinical significance of MSI L --

1 A. I'm sorry, what page are you on?

2 Q. Page three.

3 A. Three?

4 Q. Correct.

5 A. Uh-huh.

6 Q. The very first sentence under the
7 subheading: Clinical significance of MSI L --

8 A. Uh-huh.

9 Q. -- says: Around 15 percent of
10 unselected CRC tumors are MSI high, MSI-H.
11 Did I read that correctly?

12 A. Yes.

13 Q. What does unselected CRC tumors
14 mean?

15 A. I think that's what I was alluding
16 to before. Unselected meaning all-comers, if
17 you take all colorectal cancer then 15 percent
18 are MSI high, but that would be like all
19 stages, all colorectal cancers, everybody, but
20 then subgroups you'll get different
21 percentages depending on the subgroup you look
22 at.

23 Q. If I could turn your attention to
24 page five of Exhibit 1007, under the
25 subheading: MSI M CRC prognosis.

1 Are you there?

2 A. Okay.

3 Q. And that second paragraph right at
4 the very bottom of the second column on page
5 five of Exhibit 1007, the first sentence says:
6 Some recent studies have not found a better
7 prognosis for patients with MSI CRCs.

8 Do you see that?

9 A. Yes.

10 Q. Okay. And this Chapelle article
11 was published in 2010; right?

12 A. Yes.

13 Q. And do you agree with that
14 statement, that some recent studies in 2010
15 have not found a better prognosis for patients
16 with MSI CRCs?

17 A. I wouldn't be able to address that.
18 I mean, he makes a reference to publications
19 which I guess I would have to -- yeah, I guess
20 I would have to read the two papers he
21 references, and I don't know in general what
22 he's talking about or what he's referring to.
23 Even if two papers didn't find a similar
24 prognosis for MSI high patients, that would go
25 against I would say the bulk of studies.

1 Q. On the next page, page six of
2 Exhibit 1007, under the subtitle: MSI and CRC
3 Treatment, Chapelle discusses in the second
4 paragraph: The first major study indicating
5 that patients with stage two or stage three
6 MSI CRCs did not benefit from FU-based
7 adjuvant therapy, while patients with stage
8 two or stage three MSS or MSIL CRC did was
9 Redick, et al., in 2003.

10 Did I read that right?

11 A. Yes.

12 Q. And he goes on to report that:
13 This study indicated that the overall survival
14 for patients with MSI tumors who received FU
15 was worse than for those who did not; correct?

16 A. Yes.

17 Q. Is Chapelle reporting that the MSI
18 high patients had a worst outcome on the FU
19 treatment?

20 A. I don't know. I would have to read
21 the paper. As I said, patients who are MSI
22 high don't benefit from 5FU. The truth is the
23 tumor is biologically as if it already got
24 5FU, so that's why it has a better prognosis.
25 It's as if it already got 5FU, so overall it's

1 better off. The prognosis is superior for MSI
2 high patients, but it does not -- so getting
3 5FU is a negative. You're being treated for
4 no purpose and you're getting the side effects
5 of 5FU. So I suspect that's what really goes
6 on in this context.

7 Q. And if the stage two or stage three
8 MSI patients don't benefit from getting FU,
9 what other treatment option did they have
10 before 2015?

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

13 A. We discussed this in the morning.
14 They could get a full FOLFOX. So the common
15 regime, the standard regime for colon cancer
16 is a regimen called FOLFOX, which is a
17 combination of two drugs, 5FU and oxalitlatin.
18 So 5FU is the main drug in that combination.

19 Theoretically under some
20 circumstances, you might get 5FU alone without
21 the oxalitlatin, and the oxalitlatin, 75
22 percent of the benefit of FOLFOX comes from
23 the 5FU, so under some circumstances you could
24 get the 5FU without the oxalitlatin, if you
25 had reason to, but in the context of -- we've

1 been saying of MSI positive colon cancer, you
2 wouldn't get any benefit from 5FU alone, but
3 if you give the 5FU with oxalitlatin, then
4 you've got a good regime.

5 Again, you sort of restored --
6 you've got a good regime again so you can give
7 the full regime, but you can't give 5FU alone.
8 So if there were a reason why you didn't want
9 to give oxalitlatin in the context of a
10 patient who is MSI high, it forces your hand
11 to give the full regime even if you didn't
12 want to.

13 So, for example, sometimes in an
14 elderly patient, oxalitlatin has a lot of side
15 effects, so I might not want to give
16 oxalitlatin to an 80-year old lady. So I
17 might want to give just 5FU alone and let her
18 have 75 percent benefit without getting the
19 side effect of oxalitlatin, but if you were
20 MSI high, I would feel compelled to give her
21 full the FOLFOX regime and let -- let her
22 hazard the side effects of the oxalitlatin and
23 have to, you know, take her chances with the
24 full regime.

25 Q. Was there any other treatment

1 option for metastatic MSI CRC patients besides
2 the FOLFOX?

3 A. Oh. Well, nowadays, again,
4 depending on other tumor markers, there are
5 other treatments that you might be sensitive
6 to if you have other markers. So that's a
7 possibility, and there are two or three new
8 oral -- and again, now we're talking about in
9 2024 --

10 Q. And I -- and if I may --

11 ATTORNEY RATLIFF: Wait. Wait. Wait.
12 Don't cut him off.

13 A. So in 2024, there are new oral
14 agencies, wouldn't have been around, you know,
15 Chapelle's time or -- you know, but so, yeah,
16 now there are new oral drugs you could give
17 patients, but again, back to classical, you
18 know, real chemotherapy, most chemotherapy
19 depends on 5FU so --

20 Q. So in 2015, were there any other
21 treatment options for metastatic MSI CRC
22 patients besides FOLFOX?

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

25 A. There were others, but they were

1 all 5FU dependent. So, in other words, 5FU
2 was always the core. So there are other
3 regimes, because you could add other drugs
4 besides oxalitlatin to them, but always it
5 would be with 5FU, plus something else.

6 Q. Okay. You can set Chappelle aside.

7 (Whereupon, document previously
8 marked MERCK EX1008, is received and marked as
9 Exhibit 1008 for Identification.)

10 BY ATTORNEY McCORMICK:

11 Q. And do you have Exhibit 1008,
12 Steinert, in front of you?

13 A. If you'd give me a moment.

14 Q. Of course.

15 A. Okay.

16 Q. You have Steinert in front of you?

17 A. Yes.

18 Q. As part of your opinions for this
19 case, you rely on Steinert for disclosing
20 testing body fluid; correct?

21 A. Yes.

22 ATTORNEY RATLIFF: And, Counsel, do you
23 have a copy of Steinert for us?

24 ATTORNEY McCORMICK: Apologies.

25 ATTORNEY RATLIFF: No worries.

1 **ATTORNEY McCORMICK:** For you, Mr. Court
2 Reporter.

3 **BY ATTORNEY McCORMICK:**

4 **Q.** As part of your opinions for this
5 case, you do not rely on Steinert for the "in
6 response to" claim limitation; correct?

7 **A.** No.

8 **Q.** And Steinert does not suggest
9 giving a patient pembrolizumab in response to
10 determining the patient's tumor is MSI high;
11 correct?

12 **A.** Doesn't refer to that, no.

13 **Q.** Steinert is about characterizing
14 circulating tumor cells in colorectal cancer
15 patients; right?

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

18 **A.** That's correct.

19 **Q.** All right. We can set Exhibit 1008
20 to the side.

21 (Whereupon, document previously
22 marked MERCK EX1009, is received and marked as
23 Exhibit 1009 for Identification.)

24 **BY ATTORNEY McCORMICK:**

25 **Q.** And as you might have guessed,

1 let's look at Exhibit 1009, Benson.

2 Do you have that in front of you?

3 A. Yes.

4 ATTORNEY McCORMICK: Sorry, counsel.

5 I'm looking for a copy. Oh, hiding.

6 Q. Dr. Neugut, you have Exhibit 1009,
7 the article by Benson in front of you?

8 A. Yes.

9 Q. What is this Benson publication?

10 A. These are what are called the NCCN
11 guidelines from 2014.

12 Q. And are these guidelines you would
13 review in the normal course of your practice?

14 A. Yes. They're guidelines that are
15 widely utilized within oncology for clinical
16 decision-making.

17 Q. And as part of your opinions for
18 this case, you rely on the Benson publication
19 for two points; correct?

20 A. For what?

21 Q. Two points?

22 A. I don't recall where I referred to
23 it. I don't recall where I referred to it. I
24 would have to look it up.

25 Q. And you're looking in your

1 declaration?

2 A. Yes.

3 Q. Okay. Let me know when you're
4 ready.

5 A. Thank you. Okay.

6 Q. As part of your opinions for this
7 case, you relied on Benson for disclosing the
8 patient's cancer having progressed following
9 different cancer therapy; correct?

10 A. Yes.

11 Q. And you also relied on Benson for
12 disclosing the patient's cancer being
13 metastatic or metastatic colorectal cancer;
14 correct?

15 A. Yes, we sort of reviewed this
16 briefly this morning, that the POSA would have
17 understood and no one would have thought
18 otherwise that in order to be in a clinical
19 trial, a patient with advanced colon cancer
20 would have been both metastatic and would have
21 had to have progressed on two prior
22 treatments, one of which would have been
23 FOLFOX and another one is known as FOLFIRI.

24 Q. Pembrolizumab is not recommended as
25 a treatment for colon cancer anywhere in

1 Benson; right?

2 A. That's correct.

3 Q. As a part of your opinions for this
4 case, you do not rely on Benson for your
5 opinions regarding claim -- patent claims 37,
6 39, and 41; correct?

7 ATTORNEY RATLIFF: I object to the form
8 of the question, as well as to the premise of
9 the question.

10 A. Could you repeat the question?

11 Q. As part of your opinions for this
12 case, you do not rely on Benson for your
13 opinions regarding claims 37, 39, and 41;
14 correct?

15 ATTORNEY RATLIFF: I object to the form
16 of the question, as well as to the premise of
17 the question.

18 A. I believe it also refers to those
19 claims.

20 Q. And can you point me where in your
21 declaration you see that?

22 A. On page 70 under .5, each and every
23 limitation of claim seven, 20, 29, 30, 32, 34,
24 and 36 to 42 found in the MSI high study
25 record or the MSI high study record in view of

1 Pernot in combination with Benson.

2 Q. Benson does not disclose any
3 results from giving pembrolizumab to the
4 metastatic CRC patients; correct?

5 A. No, it does not. You know, the
6 NCCN guidelines are like -- they're vanilla.
7 You know, they are exactly what the
8 straightforward practice is at the time that
9 they're being written. So they would not
10 deviate from the straight and narrow, and at
11 that time giving pembrolizumab would have
12 been -- it wasn't FDA approved. It wasn't
13 tested. It wasn't anything.

14 Q. That context is helpful. Thank
15 you.

16 (Whereupon, document previously
17 marked MERCK EX1010, is received and marked as
18 Exhibit 1010 for Identification.)

19 BY ATTORNEY McCORMICK:

20 Q. Do you have Salipante, Exhibit
21 1010, in front of you?

22 A. I will get it.

23 Q. Okay. Great. Let me know when
24 you've got it.

25 A. Okay. I have it.

1 Q. And as part of your opinions for
2 this case, you're relying on Exhibit 1010 for
3 disclosing methods of testing for MSI status;
4 right?

5 A. Yes.

6 ATTORNEY RATLIFF: And, counsel, do you
7 have a copy of Salipante for us?

8 ATTORNEY McCORMICK: I do.

9 Q. And you rely on Salipante for your
10 opinions in this case for disclosing methods
11 of testing MSI status because those methods
12 aren't disclosed in the MSI study record;
13 right?

14 ATTORNEY RATLIFF: I object to the form
15 of the question, as well as to the premise of
16 the question.

17 A. Well, again, the MSI study record
18 does not disclose explicitly the methods by
19 which one could test or for the -- for MSI,
20 but again, the POSA would have understood that
21 one had to test, and the exact method or which
22 precise method one used really doesn't matter.
23 One could have used the immunohistochemistry
24 on tumor specimen or one could have done PCR
25 or one could have used body fluid for the

1 POSA, and for clinical practice it really
2 makes no difference which one of those you
3 use, and Salipante at least describes the
4 method -- two of the methods that could be
5 used as alternatives to tumor specimen
6 analysis and the POSA would have been aware of
7 it.

8 Q. And you're not relying on Salipante
9 for disclosing the "in response to" claim
10 limitation; correct?

11 A. No.

12 Q. "No" meaning correct?

13 A. Meaning correct. While it is true
14 that the therapeutic use of or the use of
15 pembrolizumab would have been in response to
16 the testing that Salipante describes according
17 to the MSI study record, Salipante himself
18 does not make any illusions to the use of
19 immunochemistry -- immunotherapy or to
20 pembrolizumab specifically.

21 (Whereupon, document previously
22 marked MERCK EX1011, is received and marked as
23 Exhibit 1011 for Identification.)

24 BY ATTORNEY MCCORMICK:

25 Q. Do you have Hamid, Exhibit 1011, in

1 front of you?

2 A. I'm sorry, which paper is that?

3 Q. Hamid.

4 A. Oh, Hamid.

5 Q. The Exhibit 1011.

6 A. I have it.

7 Q. And as part of your opinions in
8 this case, you rely on Hamid only for the
9 claim limitation of administering
10 pembrolizumab intravenously; correct?

11 ATTORNEY RATLIFF: I object. Sorry,
12 you were coughing, Doctor. I object to the
13 form of the question, as well as to the
14 premise of the question.

15 A. Well, in this case, I think -- I'm
16 sorry, can you repeat the question?

17 Q. As part of your opinions for this
18 case, you rely on Hamid only for the claim
19 limitation of administering pembrolizumab
20 intravenously; right?

21 ATTORNEY RATLIFF: I object to the form
22 of the question, as well as to the premise of
23 the question.

24 A. I think there are two aspects to
25 Hamid. One is what you said, which is that it

1 indicates that pembrolizumab is given
2 intravenously or would be given intravenously,
3 which, again, everyone already knew that at
4 the time. The POSA would know that as well,
5 but in addition, it talks about the use of
6 pembrolizumab for melanoma and it's
7 successfully used for melanoma, and I think
8 that would have been an encouragement to the
9 POSA, to the conduct of the trial, in the
10 context of MSI high colorectal cancer, because
11 there is transitions or there is transference
12 of drug from one tumor to another. So the
13 fact that immunotherapy was positive or useful
14 in one context, would have been certainly
15 encouraging for its use in different context.

16 Q. And when you say it would have been
17 encouraging for use in a different context, do
18 you mean any different tumor type or
19 colorectal cancer specifically?

20 A. Well, certainly if one were
21 entertaining the use -- if one were setting up
22 a trial to utilize it in MSI colorectal
23 cancer, then I think any investigator or
24 anyone looking at that would have felt, Oh,
25 look, it was used in melanoma successfully.

1 The odds or the probability that it would be
2 successful or efficacious in our context as
3 well is more likely because of that. If the
4 drug had never been useful in any cancer, the
5 odds out of the blue that it's going to be
6 successful in MSI colorectal cancer would
7 certainly be much lower. So the fact that it
8 had been used in melanoma with great success
9 was certainly a very positive sign or a very
10 positive signal to the investigators I think
11 for the MSI colon cancer and it would have
12 been to a POSA as well.

13 Q. Hamid doesn't talk about MSI high
14 status; right?

15 A. I don't believe that it does, no.

16 Q. And Hamid doesn't talk about
17 colorectal cancer; correct?

18 A. No, it does not.

19 Q. The only dependent claims, patent
20 claims that you rely on for Hamid are the ones
21 that have the IV administration limitation;
22 correct?

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

25 A. To be honest, I don't really

1 understand that, because -- why it is that
2 way, because isn't it given intravenously in
3 all the claims? So why it's limited to those
4 in particular I don't know, but that's true,
5 the way I have it written here, but it's
6 always given intravenously, so -- but yes,
7 according to the way that my declaration is
8 written.

9 Q. Okay. Thank you.

10 Dr. Neugut, do you agree that Merck
11 did not invent pembrolizumab?

12 ATTORNEY RATLIFF: I object to the form
13 of the question, as well as to the premise of
14 the question.

15 A. I have no idea who invented
16 pembrolizumab.

17 Q. The FDA approval for Keytruda for
18 MSI high cancers was the first approval based
19 on a biomarker; right?

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

22 A. The first approval of what for a
23 biomarker?

24 Q. FDA approval for Keytruda, for MSI
25 high cancers was the first approval of a

1 cancer drug that was based on a biomarker
2 instead of the site of the cancer; is that
3 right?

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

6 A. No.

7 Q. Why do you say that?

8 A. Because it's not true.

9 Q. Please tell me more about why
10 that's not true.

11 A. Or at least not how I would
12 understand this, but maybe I'm -- give
13 tamoxifen for estrogen receptor positive
14 breast cancer, to me that's a biomarker being
15 given for -- a drug being given for a
16 biomarker.

17 Q. Okay. Are you familiar with the
18 term "tumor agnostic"?

19 A. Yes.

20 Q. What does that mean to you?

21 A. Oh, okay. If you're going to use
22 the term that way, tumor agnostic means that
23 we're giving a drug purely on the basis of a
24 marker and not on the basis of the site of the
25 disease.

1 There are other drugs that are
2 tumor agnostic, but I don't know which is the
3 first. If MSI is the first, then okay. I
4 don't know that -- I don't know if that's the
5 first one, but yes, it is, or it's become
6 tumor agnostic.

7 There are others that are also
8 tumor agnostic, but so I don't know which is
9 the first, but I don't know the answer to your
10 question.

11 (Clarification requested by the
12 stenographer.)

13 ATTORNEY RATLIFF: But I don't know the
14 answer to --

15 A. I don't know -- that's the first
16 one. So I didn't know exactly that's the
17 first, but it is tumor agnostic.

18 Q. So Keytruda has a tumor agnostic
19 indication for MSI cancer, MSI high cancers;
20 correct?

21 A. Yes. I don't know if that was the
22 way the original approval was given, but at
23 this point it is.

24 Q. When the MSI high clinical study
25 record was published, which was 2013, were you

1 aware that pembrolizumab had not been approved
2 by FDA for any indication?

3 A. Yes.

4 Q. Are you aware that Keytruda has
5 cured patients with advanced stage MSI high
6 CRC?

7 A. I cure them all the time.

8 Q. You have seen advanced stage MSI
9 high CRC patients cured with Keytruda?

10 A. Uh-huh. I'm sorry?

11 Q. Are you asking me to repeat the
12 question?

13 A. Did you ask me a question?

14 Q. You have seen advanced stage MSI
15 high CRC patients cured with Keytruda; right?

16 A. Yes.

17 Q. And those patients you've seen who
18 have been cured with Keytruda, what do they
19 think about Keytruda?

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

22 A. I don't know. I don't do -- we
23 don't fill out surveys like that. I don't ask
24 them questions like that. I -- I know that
25 they like me, so I have no idea what they say

1 about the drug, but I assume they like it.

2 Q. Fair enough. Thank you.

3 Have you seen the Keytruda
4 prescribing information?

5 ATTORNEY RATLIFF: I object to the form
6 of the question, as well to the premise of the
7 question.

8 A. I've never read the package insert,
9 if that's what you're asking me.

10 Q. That is what I'm asking you.

11 How do you know how you can
12 prescribe Keytruda if you haven't read the
13 package insert?

14 A. So as to many cancer centers, we
15 use computerized prescribing or chemotherapy
16 order, order programs, software programs so
17 that we don't screw up and kill someone. To
18 be honest, you know, you don't want to screw
19 up ordering chemotherapy. So everything we do
20 is carefully preprogrammed.

21 So we -- to minimize the risk of
22 misordering the wrong dose or never so -- so I
23 just go to the correct website and put in the
24 patient's -- you know, put the patient in and
25 put it in for the right day and whatever and

1 then pull up -- and then when I tell the
2 computer that I'm giving the patient chemo
3 starting on a certain day, it asks which
4 chemotherapy regime do you want to do, and
5 then I go down to P and pull up pembrolizumab,
6 and then it offers me a menu of exactly when I
7 want it, and it has the dose and
8 administration information already
9 preprogrammed based on the patient's weight
10 and height, and I can alter it, but the
11 default is already in, and then I can review
12 it, which I do carefully, of course, and then
13 I sign off on it.

14 That may sound simplistic, but
15 believe me, it's -- you can save a lot of
16 lives.

17 Q. So in the system that you use, when
18 you're prescribing Keytruda for patients, do
19 you indicate that the patient is getting
20 Keytruda because of their MSI high status?

21 A. It does ask the patient's
22 diagnosis. So I don't know if it asks -- I do
23 put in colon cancer. I don't know if I put in
24 MSI high colon cancer.

25 The insurance company will ask, you

1 know, they have to get preauthorization for
2 chemotherapy because otherwise they don't get
3 paid and nothing happens without the
4 insurance. So I am certain that that gets
5 indicated and then forwarded to the patient's
6 insurance company and authorized, and it would
7 not get authorized if it wasn't -- and they
8 check if it's MSI high as opposed to MSI
9 negative. It would never be paid if it were
10 not MSI high.

11 Q. You said that you cure people all
12 the time with MSI high --

13 A. All right. Maybe that was an
14 exaggeration.

15 Q. I appreciate that. You cure people
16 using Keytruda, the MSI high CRC patients.

17 Before you had Keytruda, were you
18 curing MSI high CRC patients?

19 A. Curing a patient with a metastatic
20 solid tumor, it's a very rare phenomenon. I
21 would say in my career, which stretches back
22 40 years and encompasses thousands of
23 patients, I've cured seven. And with Keytruda
24 and MSI high colon cancer, I've probably cured
25 another seven in the last five years.

1 Q. That's great.

2 Is that computer system that you
3 use for prescribing drugs set up to prescribe
4 according to the prescribing information for
5 the drug?

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

8 A. I assume they used the recommended
9 dosing. Again, I -- I don't know if they're
10 copying it off the label or where they're
11 getting it from, but I know dosing --
12 sometimes I will use Google to check the
13 dosing myself because I want to be sure also
14 that it's right. I'm responsible, you know,
15 and I do modify the doses on occasion, but I
16 couldn't tell you -- I mean, a chief of
17 pharmacy who puts the dosing in and it's all
18 checked when we put it in the drug, you know,
19 when we -- when a drug is entered into the
20 system, it's very carefully done and everyone
21 signs off on it, etc. So I couldn't tell you
22 where the initial doses come from, but I
23 assume they come off the prescribing
24 information provided by the company.

25 Q. Were you aware that the FDA awarded

1 Keytruda a breakthrough therapy designation
2 for using Keytruda to treat MSI high CRC
3 patients?

4 A. No. I'm not surprised.

5 Q. Why do you say that?

6 A. Well, the survival benefit is
7 impressive, I'm sure there was pressure on the
8 FDA to give it what they call a fast track
9 designation.

10 Q. Are you familiar with the
11 breakthrough therapy designation the FDA gives
12 drugs?

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

15 A. I didn't know there were
16 breakthrough. I've always heard it called the
17 fast track designation, but I assume it's the
18 same thing, yes.

19 Q. Why would FDA feel pressure to give
20 Keytruda the fast track designation for MSI
21 high colorectal patients?

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

24 A. Normal time frame for getting the
25 drug approved by the FDA is on the order of

1 years. So let us say you wait two years to
2 get a drug approved, the number of patients
3 who are not going to be treated and suffer
4 during that time is certainly in the hundreds,
5 and the drug, which has such a dramatic
6 benefit, would really be unethical to -- or it
7 would be detrimental to not fast track it and
8 do something more rapidly. It's not done
9 except in such dramatic circumstances.

10 Q. Dr. Neugut, are you aware that
11 Keytruda has made Merck a lot of money?

12 ATTORNEY RATLIFF: I object to the form
13 of the question, as well as to the premise of
14 the question.

15 A. Yes.

16 Q. Are you aware that Keytruda is the
17 world's best selling drug?

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

21 A. I'm aware that it was at one time.
22 I don't know if it still is, but I know that
23 there was a time when it was the number one
24 selling drug.

25 Number one in revenue. I don't

1 know if it's number one in the number of
2 patients who are receiving it, but there are
3 different ways to measure number one.

4 Q. I hear you.

5 Would you agree that some
6 percentage of the Keytruda sales are going to
7 patients with MSI high tumors?

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

10 A. I would not know how to break down
11 Merck's revenues.

12 Q. Are you aware that Hopkins receives
13 no money from Merck for Keytruda sales?

14 ATTORNEY RATLIFF: Are you representing
15 that?

16 (No response.)

17 ATTORNEY RATLIFF: If you won't answer
18 my question, I object to the form of your
19 question.

20 A. I have no idea how much Merck --
21 how much Hopkins made or did not make on this.

22 Q. Part of your opinions for this case
23 are that the posting of the MSI high study
24 record invalidates these patent claims; is
25 that right?

1 A. Yes.

2 Q. So is it your opinion that if you
3 post a clinical study protocol, you can't get
4 patent claims for that method of treatment?

5 A. I don't know. That's a legal
6 question and I'm not a lawyer. So that's
7 something you would have to ask the Paul
8 Hastings' attorneys. I don't have a legal
9 opinion in this case.

10 ATTORNEY RATLIFF: And, counsel, I
11 would think whenever you're at a question,
12 we've been going about an hour, so let's take
13 a break.

14 ATTORNEY McCORMICK: I'm happy for a
15 break.

16 We can go off the record.

17 CERTIFIED STENOGRAPHER: Off the
18 stenographic record at 2:08 p.m.

19 (Whereupon, a recess is taken.)

20 CERTIFIED STENOGRAPHER: Back on the
21 stenographic record at 2:28 p.m.

22 BY ATTORNEY McCORMICK:

23 Q. Dr. Neugut, did you discuss the
24 substance of your testimony during the break
25 with counsel?

1 A. No.

2 Q. I want to talk about clinical
3 trials again with you, okay?

4 A. Whatever you'd like.

5 Q. Oncology clinical trials, they can
6 take a long time to complete; correct?

7 A. Yes.

8 Q. Why is that?

9 A. Usually it's because the endpoint
10 is -- the usual endpoint is survival and it
11 takes a long time for people to die.

12 Q. And patients enrolled in oncology
13 clinical trials, they don't pay to be enrolled
14 in those clinical trials; right?

15 ATTORNEY RATLIFF: Wait. Every single
16 clinical trial that ever existed, is that what
17 your question is about?

18 (No response.)

19 ATTORNEY RATLIFF: If you're not going
20 to answer my question, I object to the form of
21 the question.

22 A. The point is accurate. There may
23 be some trials where people actually pay, but
24 generally speaking, trials are funded by
25 someone or other, like a drug company or

1 government, and so they're usually done gratis
2 to the patients. Very occasionally an
3 insurance company will pay, but that's -- no,
4 actually not infrequently, an insurance
5 company will pay too.

6 Q. So generally speaking for oncology
7 clinical trials, patients aren't paying to
8 participate in the clinical trial?

9 ATTORNEY RATLIFF: Objection. Asked
10 and answered.

11 A. I'm sorry, I didn't hear the
12 question.

13 Q. Generally speaking for oncology
14 clinical trials, patients are not paying to
15 participate in the clinical trial?

16 ATTORNEY RATLIFF: Objection. Asked
17 and answered.

18 A. That is correct. Patients do not
19 usually pay to be in a trial, although, again,
20 that is not -- it really depends on the
21 circumstances. There may be clinical trials
22 where patients are paying -- where the
23 clinical trial is sort of in the normal course
24 of clinical events, and under those
25 circumstances, they may pay in the same way

1 that they would pay for any other clinical
2 therapy. That occurs.

3 Q. As far as you're aware, FDA does
4 not pay companies to publish results from
5 oncology clinical studies?

6 A. The FDA?

7 Q. (Indicating.)

8 A. I think the FDA expects
9 investigators to publish their studies or the
10 results of their studies, but it doesn't pay
11 them to do it.

12 Whatever funding paid for the trial
13 will usually have funding in it to pay for the
14 publication and will expect the publication to
15 emanate as an end product of the conduct of
16 the trial.

17 Q. Is it your understanding that
18 clinical trial data is kept confidential until
19 publication?

20 ATTORNEY RATLIFF: Is your question as
21 to every possible clinical trial that's ever
22 been done?

23 (No response.)

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

1 A. It really depends on what data
2 you're talking about. I mean, patient data
3 is -- first of all, it's always confidential
4 in the sense of being anonymized. So to that
5 degree, it's, I don't know, confidential, but
6 no, nowadays actually data is public and
7 expected to be made available to other
8 investigators to be able to utilize it for
9 study.

10 There may be a delay time which
11 gives the initial investigators a chance to
12 get their data out and publish it first, but
13 ultimately, I think they expect that data will
14 be made available to other investigators so
15 they can analyze it also.

16 Q. While -- generally speaking, while
17 a clinical trial is ongoing, is it fair to say
18 that only a limited number of people would
19 have access to the data generated from that
20 clinical trial?

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

23 A. Yes.

24 Q. Generally speaking, the sponsor of
25 an oncology clinical trial keeps the records

1 resulting from that clinical trial; right?

2 ATTORNEY RATLIFF: I object to the form
3 of the question.

4 A. I'm sorry, who did you say keeps
5 the data?

6 Q. The sponsor of the clinical trial?

7 ATTORNEY RATLIFF: The same objection.

8 A. No.

9 Q. Why do you say that?

10 A. Because it's not true.

11 Q. Who keeps the study records then?

12 ATTORNEY RATLIFF: I object to the form
13 of the question, as well as to the premise of
14 the question.

15 A. Those who are conducting the trial
16 keep the data.

17 Q. So those who are conducting a
18 clinical trial keep the records from that
19 clinical trial?

20 A. Yes. I mean, I should say that it
21 really depends on the circumstances. Also, if
22 it's under, for example, the NIH or something
23 like that, then they may -- they have the
24 right to monitor that and to come in and do
25 audits and to do -- make sure that the data is

1 being kept correctly and ethically and there
2 aren't any oversights, errors, etc.

3 Likewise, I mentioned earlier
4 cooperative groups do many, many of the trials
5 in the United States, and so cooperative
6 groups have oversight over trials oftentimes
7 and the drug companies have oversight over
8 their own trials. If an institution, like a
9 university, is conducting a trial under the --
10 in collaboration with a drug company, then the
11 drug company certainly would have oversight or
12 access to the data or to be able to audit the
13 data as well.

14 Q. So clinical -- oncology clinical
15 trial can take time to get enough eligible
16 patients enrolled to power the study
17 sufficiently; is that right?

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

20 A. Depends on the nature of the study.
21 Sometimes as you say recruitment can be what
22 delays or what takes time. Sometimes, as I
23 said, it's waiting for the endpoint to occur,
24 like waiting for people to die.

25 Q. And because it can take time to

1 recruit enough patients to carry out the
2 clinical study, that can lead to additional
3 time before results are reported; right?

4 ATTORNEY RATLIFF: I object to the form
5 of the question, as well as to the premise of
6 the question.

7 A. Again, all these things take time.
8 Everything -- all of these things can get --
9 getting an IRB approval can take time. You
10 know, each thing adds its own layer of delay
11 into the conduct and completion of the trial.

12 Q. And even after, generally speaking,
13 a clinical trial is completed, researchers
14 will continue to monitor clinical trial
15 patients; right?

16 A. That will vary from trial to trial,
17 but oftentimes, yes, and occasionally, no. It
18 really depends on the nature of the trial.
19 That question is not answerable as a
20 general -- there is no hard and fast rule.

21 Q. You had mentioned that one of the
22 endpoints you might be monitoring for an
23 oncology clinical trial is how long it takes
24 the person to die; right?

25 A. Yes.

1 Q. And that's a measure that endpoint,
2 it can take some time; correct?

3 A. Yeah. Well, nowadays that's often
4 not used anymore as a -- as an endpoint
5 because it takes so long. So most studies now
6 use an endpoint called progression free
7 survival as the main endpoint and, in fact, I
8 think this trial did as well.

9 Q. All right.
10 Dr. Neugut, I want to talk to you
11 about your role in this case and preparing
12 your declaration, okay?

13 A. Whatever you'd like.

14 Q. When were you first contacted about
15 this case?

16 A. I don't recall.

17 Q. Was it in the last year?

18 A. I think more than a year.

19 Q. More than two years?

20 A. I don't think so. I would say if
21 that's my -- if that's the time -- the choice,
22 I would say probably in one to two years.

23 Q. Who first contacted you about this
24 case?

25 A. I don't know who actually sent me

1 the first email, but I ended up talking to a
2 Ms. Dana Weir.

3 Q. Were you first contacted about this
4 case via email?

5 A. I'm pretty sure at least the
6 initial contact. I mean, I ended up pretty
7 soon thereafter having a Zoom call or
8 something like that to discuss issues or
9 whatever. You know, whatever, if I was
10 suitable or whatever they needed.

11 Q. And what was your first impression
12 on hearing about this case for the first time?

13 A. By "impression," what do you mean?

14 Q. What did you think about this case
15 when you heard about it for the first time?

16 A. I didn't have an impression. I
17 mean, my impression of my -- the issue for me
18 was did I have the wherewithal and expertise
19 to be able to competently and effectively
20 fulfill the role that the law firm needed in
21 dealing with this.

22 My second thought was patent case.
23 Who the hell understands patent law anyway.
24 It's all totally off the wall, and I'll never
25 understand what's going on here, and after I

1 dealt with those two issues, then it was
2 pretty straightforward.

3 Q. When did you start working on your
4 declaration for this case?

5 A. That would be -- it depends on what
6 you mean by "working on." I mean, I started
7 early on reading various documents that were
8 germane to the case, so that took place from
9 early after coming in contact or after signing
10 on as an expert in the case. So I would
11 include that as part of the preparation of the
12 declaration.

13 So that -- let's assume for the
14 moment that this all took shape two years ago,
15 which is possible, it's probably a little less
16 than that, but if we talk about the actual
17 preparation of the written document, I'm going
18 to guess or believe that that was -- if I
19 signed this in November, then the preparation
20 of the declaration would have been early in
21 the fall. So that would have been not a year
22 ago, but a little less than a year ago.

23 Q. And once you started preparing your
24 declaration, how much time did you spend on
25 it?

1 A. I can't -- I can't estimate the
2 hours.

3 Q. Do you have a ballpark estimate of
4 the hours you spent on the declaration?

5 A. Again, if we include the reading of
6 the documents and things of that sort, then
7 we're talking -- and the various meetings with
8 the lawyers, then we're talking 50 to 75
9 hours.

10 Q. In preparing your declaration for
11 this case, did you look for articles that
12 expressed a view contrary to yours?

13 ATTORNEY RATLIFF: I object to the form
14 of the question, as well as to the premise of
15 the question.

16 A. As I said before, the lawyers
17 obtained the articles for me. I did not
18 personally do a literature search on the
19 subject, but I am not sure what a negative
20 article would have said. Would it have said
21 that MSI high colorectal cancer is not treated
22 by immunotherapy? I suppose there are some
23 articles that do say that, but -- and then I
24 don't know that that is an important -- in its
25 context that that's really an important

1 counterargument here. We're not really
2 arguing about whether immunotherapy is -- or
3 at least I'm not arguing about whether
4 immunotherapy is effective in MSI high
5 colorectal cancer. So I'm not looking to
6 rebut that.

7 I did not look for articles that
8 looked at the role of Hopkins versus the role
9 of Merck, if that's what you're referring to.
10 And so -- and I did not look into the
11 legalities of the issue because that's not my
12 role and not my expertise.

13 So again, I don't know what -- if
14 you say did I look for articles that were
15 negative or opposed the views of these
16 articles, I don't know what -- did I look for
17 an article that said you don't give
18 pembrolizumab intravenously? No, that would
19 have been silly, but so there was no counter
20 to these articles in my -- to look for.

21 Q. In preparing your declaration for
22 this case, did you look for articles that
23 discussed the importance of Hopkins'
24 contributions to cancer treatment by
25 demonstrating the efficacy of treating MSI

1 high cancer patients with pembrolizumab?

2 ATTORNEY RATLIFF: I object to the form
3 of the question, as well as to the premise
4 embedded in the question.

5 A. As I said, I did not address the
6 relative contributions of Hopkins versus Merck
7 or the -- if you'd like, the actual
8 nitty-gritty of the various litigation claims
9 that are either in the district litigation or
10 in the District Court litigation or in the
11 patent litigation, except insofar as they're
12 addressed in the declaration with regard to
13 the obviousness or anticipation of the patent
14 itself.

15 Q. Are you aware that there are
16 articles discussing the importance of Hopkins'
17 contribution to cancer treatment by
18 demonstrating the efficacy of treating MSI
19 high cancer patients?

20 ATTORNEY RATLIFF: Are you representing
21 that to be true?

22 (No response.)

23 ATTORNEY RATLIFF: Okay. If you're not
24 going to answer my question, I object to the
25 form of your question, as well as to the

1 premise of your question.

2 A. I imagine there are articles that
3 give the story one way or the other, but I
4 don't know one way or the other what it is,
5 and it's not my job and it's not my role and I
6 don't really care one way or the other what
7 they would say.

8 Again, my only claim here is that
9 the MSI high study record has all the
10 information in it that's ultimately addressed
11 in the claim. So they're reported in the
12 patent, and that again, a POSA would have seen
13 that and it would have been anticipated or
14 obvious prior to the patent and that the
15 patent board should be aware of that, etc.

16 Q. Do you teach oncology medical
17 students?

18 A. I used -- if you're saying directly
19 to medical students, I used to participate in
20 the second-year medical student course. I
21 haven't done that in a while. To be honest,
22 I'm above that, but I do teach third-year
23 students -- well, okay, they're students too,
24 and I mostly teach on the fellow level. I
25 teach fellows.

1 Q. Do you teach oncology fellows to
2 treat MSI high cancer with pembrolizumab?

3 A. I use the term "immunotherapy,"
4 yes, including pembrolizumab.

5 Q. And what was the process like for
6 creating your declaration? And I don't want
7 to know any conversations between you and your
8 attorneys in doing this, but just the
9 mechanics of how it worked?

10 A. As I said, I had long preliminary
11 discussions with the various attorneys. I
12 read various documents and exhibits that are
13 included in the list of exhibits and so that I
14 understood all those issues involved, as well
15 as the MSI high study record itself and the
16 patent, etc., and the claims. I was sort of
17 educated about the patent law process enough
18 so I could appreciate what a POSA was and
19 those sorts of patent law issues, at least on
20 a pretty decent level, so I was not totally
21 out of the loop and being able to think about
22 such things.

23 Ultimately, I discussed these
24 issues and the key points that are in the
25 declaration with the attorneys. I, myself,

1 did not actually write the initial document.
2 That was written by the attorneys and a draft
3 was given to me. I went over it very
4 carefully and made significant amendments that
5 went back and forth for a while and then came
6 up with the final document.

7 Q. In forming your opinions for this
8 case that are reflected in your declaration,
9 did you consult with anyone other than the
10 lawyers?

11 A. I did speak to my wife. She did
12 not understand one word -- she's a lawyer, but
13 she did not understand one word of the patent
14 law issues. So I gave that up and she wished
15 me the best of luck, but aside from that, I
16 haven't spoken to anyone about it.

17 Q. In paragraph 16 of your
18 declaration, you state that you were asked to
19 assume that the relevant time period could
20 also be November 13, 2014, but none of your
21 opinions would change in view of that date,
22 and if you want to get to it, let me know when
23 you're there.

24 A. Yeah, give me a second.

25 Q. Sure.

1 Paragraph 16.

2 A. Uh-huh. I'm sorry, what's your
3 question?

4 Q. So in paragraph 16 of your
5 declaration, you state that you were asked to
6 assume that the relevant time period could
7 also be November 13, 2014, but none of your
8 opinions would change in view of that date; is
9 that correct?

10 A. Yes.

11 Q. What did you do to assess whether
12 your opinions would change in light of the
13 November 2014 date versus the July 2015 date?

14 A. What was I asked to do if -- what
15 did I do to consider November 13, 2014?

16 Q. I'm asking specifically about that
17 phrase in your paragraph 16.

18 A. Right. I understand.

19 Q. And what did you do to assess
20 whether your opinions would change in light of
21 the November 2014 date versus the July 2015
22 date?

23 A. I didn't do anything.

24 Q. Dr. Neugut, have you served as an
25 expert in any capacity for Merck other than

1 for this dispute?

2 A. I've -- I've consulted for Merck in
3 the past in unrelated circumstances. So it
4 would not be relevant to anything we're
5 talking about today.

6 Q. I'll come to the consulting in a
7 minute, but have you served as an expert for
8 Merck other than for this litigation?

9 A. I don't believe so.

10 Q. You said you've done consulting for
11 Merck unrelated to what we're talking about
12 here. When was that?

13 A. I don't recall exactly. I do
14 pharmacoepidemiology consulting. So I
15 consulted for Merck in the past on issues
16 related to their drugs and their clinical
17 trials.

18 Right now I serve on a DSMB for
19 drugs, for certain diabetes drugs which are
20 being evaluated, which are being monitored,
21 and, again, it has nothing to do with
22 anything, but I think it involves several drug
23 companies that have diabetes drugs of a
24 certain class, and I think one of the
25 companies was Merck, but again, it has nothing

1 to do with anything we're talking about today,
2 but if you're asking, I'm telling.

3 Q. Have you collaborated with any
4 research -- on any research projects with
5 Merck?

6 A. Not to my -- not to my
7 recollection. The former CEO of Merck hangs
8 out at Columbia a lot. So I've been to dinner
9 with him a couple of times, but I don't think
10 that counts as anything.

11 Q. Who is that former CEO of Merck
12 you're referring to?

13 A. His name is Vagelos.

14 THE WITNESS: Vagelos, V-A-G-E-L-O-S.

15 Q. Have you worked with Merck's
16 counsel before, which is Paul Hastings?

17 A. No.

18 Q. I asked you a few questions ago
19 about your work relating to this litigation.
20 Is it your understanding that this litigation
21 includes the District Court litigation or just
22 the dispute in front of the Patent Office?

23 A. The one we're discussing today is
24 distinct from the District Court litigation,
25 and I understood that that litigation was

1 suspended or I don't know what word is used
2 legally, but it's in abeyance until this
3 patent issue is resolved.

4 Q. Have you ever consulted for Johns
5 Hopkins?

6 A. I don't recall consulting for them.

7 Q. Have you ever worked with any
8 researchers from Johns Hopkins?

9 A. I'm sure that I have, but as I sit
10 here, I don't recall any.

11 Q. Do you consider Johns Hopkins to be
12 a good research university?

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

15 A. Yes.

16 Q. How much have you been paid for
17 your work in connection with this case?

18 A. I get 650 an hour.

19 Q. And do you know how much you have
20 earned to date for your work on this case?

21 A. As I'm sitting here, I don't know
22 offhand, but I'm going to guess in the
23 ballpark of or estimate in the ballpark of
24 \$40,000.

25 Q. You've served as an expert witness

1 in a litigation before; right?

2 A. In a litigation?

3 Q. (Indicating.)

4 A. I do a fair amount of litigation
5 consulting.

6 Q. And are you aware if any of your
7 testimony has been excluded as part of your
8 work doing litigation consulting?

9 A. Am I aware if any of my --

10 Q. Testimony has been excluded?

11 A. Once, uh-huh.

12 Q. When was that?

13 A. I'm not sure exactly legally what
14 it was, but it was around 2017.

15 Q. And why was your testimony
16 excluded?

17 A. To be honest, I'm not exactly sure
18 what the legal basis was. I think it was a
19 misunderstanding by the judge, but there is a
20 big -- there is a big litigation or a big --
21 there is a lot of litigation going on with
22 regard to an herbicide called Roundup going
23 on. So I was the -- or I am one of the main
24 plaintiff witnesses with regard to the
25 relationship between Roundup and non-Hodgkin's

1 lymphoma.

2 So when the case was initially in
3 litigation, there was, I think what you call,
4 an MDL, I don't know what the letters stand
5 for, but so there was a Daubert hearing on the
6 subject, and the judge who heard the case,
7 this was in some Federal Court in
8 California -- I mean, the testimony went on
9 for hours and the judge said I contradicted
10 myself in the testimony. I was asked a few
11 times the same question back and forth. It
12 was on technical points, but I didn't. I
13 mean, he didn't understand it. The truth is
14 there were two different answers to the same
15 question, but whatever. So he said because I
16 contradicted myself that -- or this is how I
17 understood what happened, that my testimony
18 wasn't reliable, and he excluded me from
19 testifying further in, I guess, some federal
20 cases with regard to Roundup.

21 Q. How many cases have you been an
22 expert witness for?

23 A. I testify a lot. I would have
24 trouble quantifying that. I probably -- I
25 don't testify very much, but I review a lot of

1 cases.

2 Q. How much time would you say you
3 spend serving as an expert witness for
4 litigations?

5 A. Well, I have two aspects to my
6 litigation consulting. I do malpractice
7 reviews and I do mass tort reviews, because,
8 again, I'm an epidemiologist, so I do a lot
9 of, you know, drug epidemiology. I testify
10 against drug companies. So -- or whoever, so
11 I would say I do about -- I do one to two
12 malpractice cases a month to review, but
13 again, they never -- they hardly go to court.
14 They all settle or they have no basis, so they
15 review them and that's the end of the case.

16 In the mass tort area, I do, I
17 don't know, two or three cases a year. Again,
18 Roundup has been like the big -- a big thing
19 for me because that seems to go on forever.
20 It's a case of all time, but I haven't had
21 that many. You know, maybe I do two Roundups
22 a year or I've been doing two Roundups a year
23 since 2017, but always in state court. And
24 then I've had a couple of -- a few other mass
25 tort cases. So that's been that.

1 Q. And have you served as an expert
2 witness in a patent case before?

3 A. Once.

4 Q. What case was that?

5 A. There was a case against Genentech.
6 I was on the plaintiff -- I was the expert
7 witness on the plaintiff side. It was for a
8 drug called Avastin, also a colon cancer -- a
9 very commonly used colon cancer drug. The
10 issue there was that Genentech had a
11 long-standing patent on the drug, and the
12 plaintiff was a company -- a generic company
13 that wanted to, I guess, make the drug and
14 wanted to -- I don't know what you'd call it,
15 wanted to get around the patent and then have
16 permission to make the drug or to be able to
17 produce it and stop the patent and argue that
18 whatever the basis was, Genentech had for
19 lengthening out, they kept lengthening out the
20 patent, whatever the argument they were making
21 for lengthening the patent another two or
22 three years or however they were doing it, but
23 the basis for the patent extension was not
24 legitimate.

25 Q. So in that Genentech patent

1 litigation, you served as an expert witness
2 for Genentech?

3 A. For the generic firm.

4 Q. Have you been engaged by Merck as
5 an expert for the District Court litigation
6 against Hopkins?

7 A. Not to my knowledge.

8 Q. And I would hope you would know.

9 A. Huh?

10 Q. I would hope you would know if
11 you've been engaged.

12 All right.

13 Dr. Neugut, what did you do to
14 prepare to give testimony today?

15 A. I have met with the attorneys
16 multiple times and I have reread all these
17 documents and I have reread my declaration any
18 number of times and I got a good night's
19 sleep.

20 Q. When you say you met with the
21 attorneys to prepare to give testimony today,
22 how many times did you meet?

23 A. The meetings varied in length and
24 intensity, but if you add them all up, I would
25 say seven or eight times.

1 Q. And I want to make sure that you
2 understand I'm just talking about preparing
3 for the deposition, not also your declaration.
4 Is that your understanding?

5 A. Yes.

6 Q. Okay. So you met seven or eight
7 times to prepare to give testimony today;
8 right?

9 A. But as I say, some of the meetings
10 were an hour or two.

11 Q. And who did you meet with?

12 A. The occasions varied and the
13 granatis personi varied from meeting to
14 meeting and depending on the occasion involved
15 Mr. Ratliff, Mr. Feigenbaum, Daniel, whose
16 last name I can't remember as I'm sitting
17 here. Ms. Moreira, that Dana Weir, who is not
18 here. Another Merck attorney whose name I
19 also cannot recall, and there was someone else
20 I'm not remembering.

21 Q. And during those seven to eight
22 meetings with attorneys that have varying
23 lengths, did you review any documents?

24 ATTORNEY RATLIFF: Doctor, I instruct
25 you not to answer that question.

1 ATTORNEY KRANING: He can't.

2 ATTORNEY McCORMICK: He can't answer a
3 yes-or-no question about whether he reviewed
4 documents?

5 ATTORNEY RATLIFF: One, you didn't say
6 it's a yes-or-no question. Two, I don't
7 believe there is such thing as a yes-or-no
8 question. Three, it seems like you're seeking
9 privileged information.

10 (Direction not to answer the
11 question.)

12 BY ATTORNEY McCORMICK:

13 Q. Dr. Neugut, if you can answer yes
14 or no, please, as part of the meetings to
15 prepare for your testimony today, did you
16 review any documents?

17 A. I don't want to answer based on
18 Mr. Ratliff saying I shouldn't answer.

19 Q. Dr. Neugut, if we get the chance to
20 depose you again, do you have any general
21 objection to being videotaped?

22 ATTORNEY RATLIFF: I object to the form
23 of the question, and, Doctor, I instruct you
24 not to answer that question.

25 (Direction not to answer the

1 question.)

2 ATTORNEY McCORMICK: On what basis?

3 ATTORNEY RATLIFF: On a privilege
4 basis.

5 ATTORNEY McCORMICK: It's privileged
6 whether he's okay being videotaped?

7 ATTORNEY RATLIFF: Yeah. Counsel,
8 you're rolling your eyes?

9 ATTORNEY McCORMICK: I did not roll my
10 eyes, Preston.

11 ATTORNEY RATLIFF: Counsel, I'm looking
12 directly at you, that's what you're doing.

13 BY ATTORNEY McCORMICK:

14 Q. Dr. Neugut, are you going to follow
15 Mr. Ratliff's instruction not to answer my
16 question about not being videotaped?

17 A. Of course.

18 Q. All right.

19 ATTORNEY McCORMICK: If we can just
20 take a short break, I think we can be done.

21 We can go off the record.

22 CERTIFIED STENOGRAPHER: Off the
23 stenographic record at 3:18 p.m.

24 (Whereupon, a recess is taken.)

25 CERTIFIED STENOGRAPHER: Back on the

1 stenographic record at 3:30 p.m.

2 BY ATTORNEY McCORMICK:

3 Q. Dr. Neugut, did you discuss the
4 substance of your testimony with counsel
5 during the break?

6 A. No.

7 ATTORNEY McCORMICK: Dr. Neugut, I have
8 no further questions for you today. Thank you
9 very much.

10 ATTORNEY RATLIFF: And, Dr. Neugut, on
11 behalf of the petitioner here, I have no
12 questions for you. We're done.

13 ATTORNEY McCORMICK: We can go off the
14 record.

15 CERTIFIED STENOGRAPHER: Off the
16 stenographic record at 3:30 p.m.

17 (Time noted: 3:31 p.m.)

18

19 ALFRED I. NEUGUT, M.D., Ph.D., MPH

20

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C E R T I F I C A T E

I, RICHARD GERMOSEN, Fellow of the Academy of Professional Reporters, stenographic New Jersey Certified Court Reporter, New Jersey Certified Realtime Court Reporter, California Certified Shorthand Reporter, California Certified Realtime Reporter, NCRA Registered Diplomate Reporter, and NCRA Certified Realtime Reporter, do hereby certify:

That ALFRED I. NEUGUT, M.D., Ph.D., MPH, the witness whose deposition is hereinbefore set forth, having been duly sworn, and that such deposition is a true record of the testimony of said witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 12th day of August 2024.



RICHARD GERMOSEN,
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NYACR, NYRCR
LICENSE NO. 30XI00184700
LICENSE NO. 30XR00016800
California CSR No. 14391
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