1 UNITED STATES PATENT AND TRADEMARK OFFICE

2 BEFORE THE PATENT TRIAL AND APPEAL BOARD

3 - - - - - - - - - - - - - - -x

4 HOPEWELL PHARMA VENTURES, INC., : IPR2023-00480

5 Petitioner, : Patent 7,713,947

6 v. :

7 MERCK SERONO, S.A., : IPR2023-00481

8 Patent Owner. : Patent 8,377,903

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10

11 Remote and in-person deposition of

12 Fred David Lublin, M.D.

13 Boston, Massachusetts

14 March 5, 2024

15 8:08 a.m.

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19

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22 Reported By: Alan H. Brock, RDR, CRR

Hopewell EX1061
Hopewell v. Merck
IPR2023-00480

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1 I N D E X
2
3 EXAMINATIONS
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10 EXHIBITS MENTIONED

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1 March 5, 2024 8:08 a.m.
2 P R O C E E D I N G S
3 THE TECHNICIAN: Thank you to everyone for
4 attending this proceeding remotely, which we
5 anticipate will continue to run smoothly.
6 Please remember to speak slowly and do
7 your best not to talk over one another.
8 Please be aware that we're recording this
9 proceeding for backup purposes. Any off-the-record
10 discussions should be had away from the computer, and
11 please remember to mute your mike for those
12 conversations.
13 Please have your video enabled to help the
14 reporter identify who is speaking. If you are unable
15 to connect with video and you're connecting via phone,
16 we just ask that you identify yourself each time
17 before speaking.
18 We'll provide a complimentary unedited
19 recording of the deposition with the purchase of a
20 transcript. I apologize in advance for any technical-
21 related interruptions. Thank you.
22 * * *

1 FRED DAVID LUBLIN, M.D.,
2 being first duly sworn or affirmed to testify to the
3 truth, the whole truth, and nothing but the truth, was
4 examined and testified as follows:
5 MS. ELLISON: Good morning. We'll start
6 with the roll call this morning. I am Eldora Ellison,
7 from Sterne Kessler Goldstein & Fox, on behalf of
8 petitioner Hopewell Pharma Ventures, Inc. With me
9 today remotely are Olga Partington, Sarah Leesman, and
10 Pratibha Khanduri, also of Sterne Kessler. And then
11 in person today with the witness is Madeleine Bond,
12 also from Sterne Kessler.
13 Counsel will please introduce themselves
14 and the team, I'd appreciate it.
15 MS. WHELAN: Emily Whelan, of WilmerHale,
16 for patent owner, Merck Serono SA, and for the
17 witness, Dr. Lublin. With me is Cindy Kan, of
18 WilmerHale, and remotely Willem de Weerd, of Merck
19 KGaA.
20 EXAMINATION
21 BY MS. ELLISON:
22 Q. Dr. Lublin, will you please state your full

1 name and spell it for the record, please.
2 A. Fred David Lublin, L-u-b-l-i-n.
3 Q. And what is your address?
4 A. 40 East 94th Street, No. 4L, New York, New
5 York 10128.
6 Q. Thank you. Dr. Lublin, have you been deposed
7 before?
8 A. I have.
9 Q. Approximately how many times?
10 A. At least ten.
11 Q. And were any of those cases cases that
12 involved patents?
13 A. Yes.
14 Q. Of the cases in which you've been deposed
15 before, Dr. Lublin, how many of those cases involved
16 patents?
17 A. I believe three.
18 Q. And of those cases in which you've been
19 deposed that involve patents, who were the parties to
20 those cases?
21 A. One was Novartis. One was -- I'm blocking on
22 the company. They make Ampera. I don't recall the

1 name of the company. And one was a company called
2 Fast Forward.
3 Q. And for the case involving Novartis, did you
4 provide testimony on behalf of Novartis?
5 A. Yes.
6 Q. And on a high level, what was the subject
7 matter of that patent case?
8 A. It was a challenge to one of their patents on
9 the drug fingolimod.
10 Q. And for the second case that you mentioned,
11 on whose part did you provide testimony?
12 A. It was -- it wasn't as much a patent. It was
13 an arbitration issue over who deserved what, and I did
14 it for one of the parties. I'm just blocking on the
15 name of the company.
16 Q. Okay. And for the third case that you
17 mentioned, on behalf of which party did you provide
18 testimony?
19 A. The adverse party was Biogen. It was their
20 patent, and I was on the other side.
21 Q. Do you recall the name of the company for
22 whom you provided testimony in the Biogen case?

1 A. Yes, Forward Pharma.
2 Q. Thank you. And at a high level, what was the
3 subject matter of the Biogen versus Forward Pharma
4 case?
5 A. I think it was priority.
6 Q. And what was the technical subject matter of
7 the case?
8 A. I'm sorry, I couldn't hear you.
9 Q. What was the technical subject matter in that
10 case?
11 A. I don't recall.
12 Q. Have you provided testimony -- other than for
13 the proceeding that we're here for today, have you
14 provided testimony in any other proceedings in front
15 of the U.S. Patent and Trademark Office?
16 A. I believe just the ones I mentioned to you.
17 Those are the only ones I can recall.
18 Q. Dr. Lublin, for the three cases that you
19 mentioned, were all of those cases cases that were in
20 front of the U.S. Patent and Trademark Office?
21 A. No.
22 Q. Of the three cases that you mentioned,

1 Dr. Lublin, which ones were in front of the U.S.
2 Patent and Trademark Office?
3 A. I believe the Novartis -- part of the
4 Novartis was.
5 Q. Thank you. So Dr. Lublin, do you understand
6 that you have provided testimony in two inter partes
7 review proceedings?
8 A. Yes.
9 Q. So I may refer to these proceedings by the
10 abbreviations IPR or IPRs. Do you understand that?
11 A. Sure.
12 Q. And if I say "this case," will you understand
13 I'm referring to both IPR proceedings unless I
14 specifically state otherwise?
15 A. Okay.
16 Q. Dr. Lublin, do you understand that you're
17 here under oath and under penalty of perjury?
18 A. I do.
19 Q. And Dr. Lublin, do you understand that you're
20 here to testify truthfully and accurately today?
21 A. I do.
22 Q. Dr. Lublin, is there any reason that you

1 cannot testify truthfully and accurately today?
2 A. No.
3 Q. Dr. Lublin, are you taking any medications
4 that might preclude you from testifying truthfully and
5 accurately today?
6 A. No.
7 Q. Dr. Lublin, throughout the course of today's
8 deposition, if you do not understand the meaning of
9 any words or phrases that I use, please let me know,
10 and I will try my best to clarify my question. Okay?
11 A. Sure.
12 Q. And Dr. Lublin, we will take breaks
13 reasonably often. And if you need a break, please let
14 me know. But I would ask that you answer any pending
15 question before we break. Okay?
16 A. Okay.
17 Q. Dr. Lublin, as you can tell, there's a court
18 reporter who is transcribing what we are saying to
19 each other today, so I will do my best not to talk
20 over you, and I ask that you also do your best not to
21 talk over me. Okay?
22 A. Sure.

1 And the name of the company that I
2 couldn't remember was Acorda.
3 Q. Thank you. Also, Dr. Lublin, because there
4 is a court reporter transcribing today's deposition,
5 it's important that the answers to your questions,
6 it's important that they be vocal answers as opposed
7 to -- oral answers as opposed to "uh-huh" or shaking
8 your head or something. Understood?
9 A. Yes.
10 Q. Finally, under the rules of the Patent and
11 Trademark Office, I'm required to instruct you that
12 you are not permitted to speak with your counsel
13 during today's cross-examination regarding the
14 substance of your testimony. Do you understand that?
15 A. I do.
16 Q. And do you agree to abide by that rule?
17 A. I do.
18 Q. Did you bring anything with you to today's
19 deposition, like notes or files or anything like that?
20 A. The only thing I have here with me are my
21 declarations.
22 Q. And you're referring to your declarations

1 that have been marked as Exhibit -- let me start that
2 again. You're referring to your declarations that
3 have been marked as Exhibits 2051 in each of the two
4 IPRs; correct?
5 A. Correct.
6 Q. Thank you. Whose computer are you using for
7 today's remote deposition?
8 A. No idea.
9 Q. Was it provided to you by counsel?
10 A. I don't know whose computer this is.
11 Q. Fair enough. Other than the video platform
12 that we're speaking on right now for this deposition,
13 do you have any other computer programs open on the
14 computer that is in front of you?
15 A. Not that I'm aware of.
16 Q. Thank you. And you mentioned that you have
17 copies of your declarations. Are those clean copies
18 of your declarations?
19 A. Yes.
20 Q. So there are no notes or highlighting or
21 anything like that; correct?
22 A. That's correct.

1 Q. Also, do you currently have access to any
2 kind of electronic device other than the computer
3 that's in front of you -- for example, a phone or an
4 Apple Watch or anything like that?
5 A. There's a cell phone in my back pocket.
6 Q. I'm going to ask that during today's
7 deposition that you don't have access to that cell
8 phone regarding -- anything regarding the substance of
9 this deposition. Okay?
10 A. That's fine.
11 Q. What did you do to prepare for today's
12 deposition, Dr. Lublin?
13 A. I read over my declarations, over -- reviewed
14 some of the documents that are listed, and met with
15 counsel.
16 Q. And when did you meet with counsel?
17 A. I met with counsel for the deposition
18 remotely a little over a week ago, and then Sunday and
19 Monday of this week.
20 Q. And with whom did you meet, when you say you
21 met with counsel?
22 A. Ms. Kan and Ms. Whelan. Oh, and Mr. Geng.

1 Q. Thank you. And for how long did you meet
2 with counsel in preparation for today's deposition?
3 A. Those were full-day meetings, mostly.
4 Q. So you met approximately for three full days;
5 is that correct?
6 A. Maybe two and three quarters. The first day
7 wasn't a full day.
8 Q. Okay. And in your preparation for today's
9 deposition, did you consider any documents that are
10 not mentioned in your declaration?
11 A. No.
12 Q. Did you speak with anyone other than counsel
13 regarding the substance of your deposition today?
14 A. No.
15 Q. When were you first approached regarding the
16 possibility of providing testimony in these IPRs,
17 Dr. Lublin?
18 MS. WHELAN: I'm just going to object and
19 caution you not to reveal the substance of any
20 communications with attorneys, but you may answer a
21 date if you can.
22 A. I don't recall.

1 Q. And approximately when were you first
2 approached regarding possibly providing testimony in
3 these IPRs, Doctor?
4 A. Sometime in 2023, but I don't know the exact
5 date.
6 Q. Was it the summer of 2023?
7 A. I can't be more specific.
8 Q. Was it before the summer of 2023?
9 A. Again, I can't be more specific.
10 Q. Was it December of 2023?
11 MS. WHELAN: Object to form.
12 A. I just don't recall when.
13 Q. So you can't tell me whether you were first
14 approached to provide testimony in these IPRs in
15 December of 2023 versus January of 2023? Is that your
16 testimony, Dr. Lublin?
17 MS. WHELAN: Object to form.
18 A. My testimony is I don't recall when I was
19 approached to discuss these depositions.
20 Q. So I'm not asking you for an exact date. I'm
21 asking for an approximate time. So to the best of
22 your approximation, Dr. Lublin, are you unable to

1 recall whether you were approached in December of 2023
2 versus January of 2023?
3 A. Somewhere in between.
4 Q. So you already have copies of Exhibit 2051 in
5 front of you.
6 MS. ELLISON: Emil, will you provide
7 copies in the chat for anyone who may need them,
8 please.
9 THE TECHNICIAN: Stand by.
10 MS. BOND: May I inspect those copies as
11 we bring them up?
12 Q. Do you have your declarations in front of
13 you, Dr. Lublin, or is my colleague --
14 A. Your colleague's reviewing them.
15 Q. Just let me know when you have them back.
16 MS. ELLISON: Emil, do you have those
17 exhibits? I don't see them in the chat -- Exhibit
18 2051.
19 THE TECHNICIAN: I will create a folder in
20 the chat now for all marked exhibits.
21 MS. ELLISON: Thank you.
22 Q. Dr. Lublin, do you have your declarations

1 back in front of you yet?
2 A. Not yet.
3 MS. ELLISON: Madeleine, if you could hand
4 those back to Dr. Lublin.
5 A. Okay.
6 Q. And you have both of your declarations in
7 front of you; correct, Dr. Lublin?
8 A. Yes.
9 Q. Thank you. So Dr. Lublin, for the
10 declaration that has been provided as Exhibit 2051 in
11 IPR case 2023-00480, could you please turn to Page
12 137. Is that your signature that appears on Page 137.
13 Of the declaration provided as Exhibit 2051?
14 A. Yes.
15 Q. And you signed and dated that declaration on
16 December 21st, 2023; correct, Dr. Lublin?
17 A. That's correct.
18 Q. If you could look at the other declaration,
19 Dr. Lublin, which is Exhibit 2051 in IPR2023-00481.
20 If you could please turn to Page 136.
21 A. Okay.
22 Q. Is that your signature that appears on Page

1 136 of Exhibit 2051 in the 2023-00481 IPR?
2 A. Yes.
3 Q. And you signed and dated this declaration on
4 December 21st, 2023; correct, Dr. Lublin?
5 A. That's correct.
6 Q. For today's discussion, we're mostly going to
7 use Exhibit 2051 from IPR No. 2023-00480. I may refer
8 to the other one if needed, or may refer to the other
9 one if needed as well.
10 Given the overlapping exhibits and the
11 overlap in your testimony in these two IPRs, my
12 questions will apply to both IPRs unless you or I
13 specifically indicate otherwise. Is that okay?
14 A. Yes.
15 Q. Thank you. Do you know who else has provided
16 testimony in this case in support of Merck?
17 A. I know a pharmacologist, Dr. Meibohm, has.
18 Q. Are you aware of any other Merck witnesses in
19 these IPRs?
20 A. I'm not.
21 Q. Do you know who Dr. Nicholas Bodor is?
22 A. I don't know him.

1 Q. Do you know who he is?
2 A. I believe he's on the patent that's part of
3 this proceeding.
4 Q. Were you aware of Dr. Nicholas Bodor before
5 you became involved in these IPRs?
6 A. No.
7 Q. Are you familiar with Dr. Bodor's
8 professional background?
9 A. No.
10 Q. Are you familiar with Dr. Bodor's reputation
11 in the field?
12 A. No.
13 Q. You mentioned Dr. Bernd Meibohm; correct?
14 A. Correct.
15 Q. That's B-e-r-n-d M-e-i-b-o-h-m; correct?
16 A. Yes.
17 Q. When did you first learn of Dr. Meibohm?
18 A. Sometime last year.
19 Q. Was that before you were retained to provide
20 testimony in these IPRs?
21 A. No.
22 Q. Did you first learn of Dr. May in the context

1 of doing your work on these IPRs?
2 A. Yes.
3 Q. Have you ever met Dr. May?
4 A. No.
5 Q. Have you ever communicated with Dr. May?
6 A. No.
7 Q. Did Dr. Meibohm advise you when you were
8 preparing your declaration?
9 A. No.
10 Q. I understand that your current rate for
11 working on this IPR is $900 per hour; is that correct?
12 A. That's correct.
13 Q. And are you being compensated today in the
14 amount of $9,000 for your testimony today?
15 MS. WHELAN: Object to form.
16 A. I'm being paid $9,000 today for my time out
17 of office.
18 Q. And approximately how much have you billed in
19 this case so far for your time on these IPRs,
20 Dr. Lublin?
21 A. Well, I haven't billed all of it.
22 Q. Okay. Approximately how much time have you

1 spent working on these IPRs, Dr. Lublin, to date?
2 A. Probably about 30 hours.
3 Q. Other than for your work in connection with
4 these IPRs, have you ever received any compensation
5 from Merck for anything else?
6 A. There are other matters besides the IPRs.
7 Q. Are you saying you are a consultant to Merck
8 in other matters, other IPRs; correct?
9 A. Yes.
10 Q. Are those other legal matters?
11 A. Yes.
12 Q. Have you provided testimony in those other
13 matters, Dr. Lublin?
14 A. No.
15 Q. Approximately how many other matters, other
16 than the IPRs, are you working on for Merck?
17 A. At least one other.
18 Q. Is that a patent case, Dr. Lublin?
19 A. Yes.
20 Q. Does it relate to multiple sclerosis?
21 A. Yes.
22 Q. Which drug is involved in that other matter?

1 MS. WHELAN: I'm just going to object. I
2 think -- I don't think we should get into the
3 substance of other legal matters, other than what we
4 have at hand.
5 MS. ELLISON: So Ms. Whelan, as you
6 recall, the objections are intended to be limited to
7 one-word objections in IPRs.
8 MS. WHELAN: Right. I'm objecting --
9 MS. ELLISON: And I believe it's fair game
10 for us to have an understanding of the witness's
11 relationship with Merck. And this was not disclosed
12 in his declaration. And so I think it's fair game for
13 us to have an understanding of the witness's
14 relationship with Merck.
15 Q. Dr. Lublin, I'll ask you this question: Does
16 this other matter in which you are working with Merck,
17 does it involve the drug cladribine?
18 MS. WHELAN: I will allow you to answer
19 yes or no to that.
20 A. Yes.
21 Q. So I asked you earlier whether you have
22 received compensation from Merck on any matters other

1 than these IPRs. The next question is: Have you
2 received any compensation from any entities related to
3 Merck in matters other than these IPRs?
4 A. Yes.
5 Q. And which entity was that?
6 A. EMD Serono -- and possibly Merck as well;
7 some speaking I did in 2022.
8 Q. And when you say the speaking that you did in
9 2022, what was the subject matter of that speaking?
10 A. It was -- actually, it was a debate, and it
11 related to the clinical course of multiple sclerosis.
12 Q. You mentioned having received compensation
13 from EMD Serono. What was the reason that you
14 received compensation from EMD Serono?
15 A. It was the same.
16 Q. The same as what?
17 A. It was -- there were two debates at different
18 times, and one was in Europe, one was in the United
19 States, but the topic was the same.
20 Q. You're currently the director of the Corrine
21 Goldsmith Dickinson Center for Multiple Sclerosis at
22 the Icahn School of Medicine at Mount Sinai Hospital;

1 correct?
2 A. That's correct.
3 Q. Has the Corrine Goldsmith Dickinson Center
4 for Multiple Sclerosis ever received any compensation
5 from Merck or an entity related to Merck?
6 MS. WHELAN: Object to form.
7 A. Yes, I believe they provided some funds to
8 the institution to support fellowships.
9 Q. Approximately how much were those funds?
10 A. I'm going to say approximately 125,000.
11 Q. And when was that?
12 A. Last year.
13 Q. In the debate that you mentioned -- strike
14 that.
15 In the debates that you mentioned, who
16 were the parties to the debate?
17 A. I was debating another MS specialization
18 neurologist by the name of Gavin Giovannoni.
19 Q. Could you spell that, please?
20 A. Oh, boy. I can spell Gavin.
21 G-i-o-v-a-n-n-o-v-i, or something close to that.
22 Q. Thank you.

1 A. I guess o-n-i.
2 Q. Was that debate something that was open to
3 the public?
4 A. It was open to neurologists attending the
5 meetings where it was held.
6 Q. What were the meetings where it was held?
7 A. One was the European Charcot Foundation,
8 which was held in Italy. And one was the American
9 Academy of Neurology meeting that was held in the
10 United States, here in Boston.
11 Q. Thank you. You said the European, you say
12 Charcot?
13 A. Charcot.
14 Q. Thank you. What was the topic of the debate?
15 A. We were debating whether multiple sclerosis
16 was progressive from onset.
17 Q. And what was your viewpoint on that?
18 A. That it was not.
19 Q. And why was it your view that it's not
20 progressive from onset?
21 A. Because my view is that not all patients with
22 multiple sclerosis have a progressive form of the

1 illness. It's too variable a disease.
2 Q. If not all patients have a progressive form
3 from onset, then what form of MS do they have?
4 A. Relapsing-remitting.
5 Q. If you don't mind, explain the difference to
6 me, the difference between relapsing-remitting and
7 progressive forms of MS?
8 A. So relapsing-remitting is the commonest form
9 of MS, and it's the one that most people start with.
10 And that's having an acute attack of something
11 involving the central nervous system. It lasts for
12 days to weeks, and then it improves anywhere from zero
13 to 100 percent. But wherever it stops at, it stays
14 that way until the next attack.
15 The next attack can occur weeks, months,
16 years, or decades later, sometimes even never. And
17 that's what relapsing-remitting is.
18 Progressive MS is where, independent of
19 those relapses, there's gradual worsening over time.
20 Q. So when you say a relapse, what do you mean?
21 What is a relapse?
22 A. The terms interchangeably are relapse,

1 exacerbation, or attack. It's an acute onset of
2 something. It could be loss of vision in one eye. It
3 could be numbness, tingling, difficulty walking,
4 slurred speech, double vision. There's many, many
5 ways that it could present.
6 Q. What are some of the other ways?
7 A. Bladder dysfunction, cognitive dysfunction.
8 That covers most of it.
9 Q. What causes relapses?
10 MS. WHELAN: Object to form.
11 A. We don't know what causes most of them.
12 There's an increased risk of relapse after viral
13 infections, but most relapses aren't associated with
14 an infection. And there's an increased risk of
15 relapse in the three months after a woman delivers a
16 baby. But we don't know what the underlying cause is
17 of why it suddenly happens.
18 Q. How are relapses identified?
19 A. First with symptoms. The patient complains
20 of something. And then usually they're seen and
21 examined.
22 Q. Examined for what?

1 A. It's a neurological examination, so you
2 examine the whole nervous system.
3 Q. And how do you do that?
4 MS. WHELAN: Object to form.
5 A. You do a neurological examination.
6 Q. What is involved in doing a neurological
7 examination of a patient who may have experienced a
8 relapse?
9 A. So a neurological examination involves
10 examining of all brain functions, all spinal cord
11 functions, and all the functions of the peripheral
12 nerves and where they attach to muscles.
13 Q. How are brain functions examined?
14 MS. WHELAN: Object to form.
15 Q. How are brain functions examined in doing a
16 neurological examination of an MS patient?
17 MS. WHELAN: Object to form.
18 A. I could show you. I'm not sure I could tell
19 you how it's done. When we teach these, we teach it
20 by showing people how it's done.
21 Q. Can you show me today?
22 A. Sure, if you want to put a camera on someone

1 who's willing to have me examine them neurologically.
2 Q. Let's give it a try.
3 MS. ELLISON: Madeleine, you can be our
4 subject today. I don't know what's involved, so let's
5 give it a try.
6 MS. WHELAN: I'm just going to object to
7 this. This is not a verbal question and answer.
8 Q. Dr. Lublin, perhaps you can describe what
9 you're doing while you do it. If you could give us an
10 indication of how you would -- give us your best
11 explanation for how you would conduct a neurological
12 exam of a patient, I would appreciate your answering
13 the question.
14 MS. WHELAN: And I'm objecting to the
15 question and answer for the form.
16 Q. Please continue, Doctor.
17 THE WITNESS: First we would do a
18 cognitive assessment. So tell me today's date.
19 MS. BOND: March 5th, 2024.
20 THE WITNESS: And where are we?
21 MS. BOND: We're in Boston, WilmerHale.
22 THE WITNESS: And tell me something that's

1 been going on in the news.
2 MS. BOND: Oh, goodness. This is going to
3 be embarrassing. There's a storm going on in the
4 Sierra mountains that is affecting a lot of people
5 recently. It's taking a lot of lines out.
6 THE WITNESS: Anything else?
7 MS. BOND: There's always a lot going on
8 politically, but it's probably best not to get into.
9 THE WITNESS: What do you call this?
10 MS. BOND: A thumb.
11 THE WITNESS: And this?
12 MS. BOND: A mouth.
13 THE WITNESS: I want you to remember three
14 words for me: "river," "baseball," and "street."
15 MS. BOND: "Street"?
16 THE WITNESS: "Street." Can you say
17 those?
18 MS. BOND: "River," "baseball," "street."
19 THE WITNESS: Good. Keep them in mind.
20 And if I remember, I'll ask you to repeat them.
21 Spell the word "world" for me backwards.
22 MS. BOND: D-l-r-o-w.

1 THE WITNESS: Good.
2 Now, I want you to look right here at me.
3 Tell me which hand it is, left, right, or both?
4 MS. BOND: Your right or my right? Both.
5 THE WITNESS: Now.
6 MS. BOND: My left or right.
7 THE WITNESS: Good. Look right here.
8 Look way over here. Look way over here. Look up.
9 Down. Do you feel the same on both sides?
10 MS. BOND: Yes.
11 THE WITNESS: The same? Show me your
12 teeth. Stick your tongue out. Spread your fingers
13 apart. Hard, hard, hard. Harder, harder.
14 Arms up like there. Push against my arm.
15 Push them away. Touch your nose. Touch my finger.
16 Back and forth. This one. This one real fast likes
17 that. Great.
18 Lift this leg straight up right here.
19 Here. Bend your ankles up. Keep them up. Feel the
20 same on both sides?
21 Now let me see you walk from that wall to
22 that door.

1 Q. While she's doing that, Dr. Lublin, let me
2 just ask you this: Roughly how long does this exam
3 normally take?
4 A. I wasn't done with the walking through.
5 THE WITNESS: What I want you to do now
6 is -- I was going to have you walk on your heels.
7 MS. BOND: I don't know if that's
8 possible. I can do barefoot.
9 THE WITNESS: Can you do one foot in front
10 of the other? Come sit down.
11 A. There are some things I can't do, because I
12 don't have the tools to do them, like reflexes and a
13 tuning fork and a flashlight.
14 THE WITNESS: What were the three words I
15 asked you to remember?
16 MS. BOND: "River," "baseball," "street."
17 THE WITNESS: So you look fine.
18 MS. BOND: Glad to hear it.
19 Q. Thank you for that, Dr. Lublin. We
20 appreciate it.
21 Are there -- so in assessing whether a
22 patient has suffered a relapse, are there any

1 physiological measurements or assessments that are
2 done?
3 A. The main determinant of a relapse is what the
4 patient complains of; right? It always starts with a
5 complaint of some change in function.
6 It may or may not show up on the
7 examination, depending on how severe it is, and it may
8 or may not show up on an MRI scan.
9 Q. And in looking for -- looking at an MRI scan,
10 what would a physician be looking for?
11 MS. WHELAN: Object to form.
12 A. A new lesion somewhere in the nervous system
13 that corresponded with the complaint. And it may or
14 may not enhance when you give the radiologic dye
15 gadolinium.
16 Q. Dr. Lublin, how long have you been treating
17 MS patients?
18 A. About 48 years.
19 Q. And so you were treating MS patients in the
20 2004 time frame; is that correct?
21 A. That's correct.
22 Q. And do you have experience in clinical trials

1 involving therapies for multiple sclerosis?
2 A. I do.
3 Q. And do you have experience in using
4 cladribine in treating patients who have MS?
5 A. I do.
6 Q. I'm just going to ask you some questions,
7 some additional questions, about your understanding of
8 MS, and I'd like you to focus on the 2004 time frame,
9 unless I specifically say otherwise. Do you
10 understand?
11 A. Yes.
12 Q. So you were talking earlier about
13 neurological exams in the context of MS. What are the
14 signs and symptoms of multiple sclerosis?
15 A. Multiple sclerosis can affect any area of the
16 central nervous system. That's the brain, the spinal
17 cord, and the optic nerves. And so it can produce
18 signs and symptoms of dysfunction in any of those
19 areas.
20 Q. Can you give me examples of the signs and
21 symptoms of dysfunction in those areas?
22 A. Just what I described to you earlier.

1 Q. Can you think of any others?
2 A. I don't recall whether I mentioned walking
3 difficulty, gait problems, but....
4 I think I mentioned everything else. I
5 mentioned cognitive difficulties. I think I did.
6 Q. And when you say that multiple sclerosis can
7 affect any area of the central nervous system, what do
8 you mean by that?
9 A. I don't know how to say that any clearer. It
10 could affect any part of the brain, any part of the
11 spinal cord, and the optic nerves.
12 Q. Does inflammation play a role in multiple
13 sclerosis?
14 A. It does.
15 Q. In what way does inflammation play a role in
16 multiple sclerosis?
17 A. The acute attacks, the relapses, are
18 associated with inflammation in a localized area.
19 Q. When you say a localized area, meaning?
20 A. Meaning some part of the optic nerves, the
21 brain, or the spinal cord.
22 Q. Is it correct, then, that in relapses there's

1 inflammation in some part of the brain, the optic
2 nerves, or the spinal cord?
3 MS. WHELAN: Object to form.
4 A. Yes.
5 Q. Is inflammation in multiple sclerosis
6 mediated by lymphocytes?
7 MS. WHELAN: Object to form.
8 A. In part.
9 Q. And why do you say in part?
10 A. Because there's other cellular elements
11 involved.
12 Q. And what are those other cellular elements?
13 A. Other than white blood cells, monocytes,
14 macrophages.
15 Q. How do you know -- how does one know when a
16 patient has recovered from relapse?
17 MS. WHELAN: Object to form.
18 A. That's a little harder to assess, because it
19 can take weeks, months, sometimes up to a year to
20 fully recover. But it means they're no longer
21 improving from whatever got worse when they had the
22 attack.

1 Q. In considering patients who have relapses,
2 what is a relapse rate in the field of multiple
3 sclerosis treatments?
4 A. Relapse rate is the frequency of relapses
5 over a period of time.
6 Q. So how do you measure a relapse rate?
7 MS. WHELAN: Object to form.
8 A. You count the number of relapses and divide
9 it by the time period.
10 Q. And what time period typically is used in
11 measuring relapse rates?
12 A. Typically one year.
13 Q. Is measuring relapse rates something that
14 physicians commonly do, or measure, in treating
15 patients having MS?
16 MS. WHELAN: Object to form.
17 A. They may keep track of it, but usually not
18 formally. It's formally assessed in clinical trials.
19 Q. Is it routine to assess relapse rates in
20 clinical trials?
21 MS. WHELAN: Object to form.
22 A. It's common.

1 Q. It's common? Is it relatively
2 straightforward to assess relapse rates in clinical
3 trials?
4 MS. WHELAN: Object to form.
5 A. It depends on the design of the trial.
6 MS. WHELAN: Did you have a question,
7 counsel? We couldn't hear.
8 MS. ELLISON: Yes, I did.
9 Q. My question was: How so?
10 A. Oh. So sometimes it's hard to distinguish
11 between a relapse and what's called a pseudo-relapse.
12 A pseudo-relapse could be a worsening that's
13 associated with a fever, an infection, undue stress,
14 which can cause some symptoms, but it's a recurrence
15 of effects of an older lesion.
16 In addition, in clinical trials, each
17 clinical trial defines the specifications of the
18 relapse, and sometimes even utilizes what's called a
19 relapse adjudication committee, where the details of
20 the relapse are collected and the trial is sent
21 adjudication committee to determine whether it's a
22 relapse or not.

1 And the reason for doing that is that if,
2 for example, annualized relapse rate is your primary
3 outcome measure, then you want to be as strict as
4 possible in what you declare, what the investigator
5 declares, as the relapse. Other times, if the relapse
6 is not the primary outcome measure, then you may not
7 have as strict a definition.
8 Q. What do you mean by "primary outcome
9 measure"?
10 A. Whenever you do a clinical trial, you set one
11 metric as your primary outcome measure, and you design
12 your trial around that assessment, and then everything
13 else are secondary outcome measures or tertiary or
14 exploratory.
15 Q. What's the purpose of studying a secondary
16 outcome measure? Sorry, I'm not a physician, so
17 please explain?
18 A. When you design a clinical trial, you design
19 it around the outcome measure you're most interested
20 in, and that means that all the design, the statistics
21 and such, are set up to answer the question have you
22 met that primary outcome measure? Is drug A superior

1 to drug B? And basically, if you're on the relapse
2 rate, then you make the hypothesis as to how much it's
3 going to affect the relapse rate, and you use that
4 determine the number of individuals that you're going
5 to put in the study to give you enough of a sample
6 size to be able to answer the question.
7 Q. So is the primary outcome measure the measure
8 that's used to determine whether the drug being tested
9 in a clinical trial is effective?
10 MS. WHELAN: Object to form.
11 A. It is the measure that you use to determine
12 that. And so for that determination, you've got to
13 meet that primary outcome measure before you consider
14 any of the other outcomes.
15 Q. So why do clinical trials measure relapse
16 rates?
17 MS. WHELAN: Object to form.
18 A. Because it's important to decrease the number
19 of relapses. Patients don't like them. They cause
20 impairment. They cause time away from work. There's
21 potential suffering. And they may not fully recover
22 from the relapse. So it's an important metric.

1 We use it in clinical trials of
2 anti-inflammatory agents because usually there are
3 enough events, relapses that occur over the course of
4 the trial that you can measure the benefit of a given
5 agent -- that is, the difference between the agent
6 you're using and either placebo or some active
7 control.
8 Q. So the agent that's being used in the
9 clinical trial may decrease the relapse rate; correct?
10 A. That's the hypothesis of the study.
11 Q. Are relapses a measure of acute disease
12 activity in multiple sclerosis?
13 MS. WHELAN: Object to form.
14 A. They are a measure of acute disease activity,
15 yes.
16 Q. What other ways are there of measuring acute
17 disease activity in multiple sclerosis?
18 A. MRI scans.
19 Q. And in looking -- strike that.
20 In using MRI scans to measure acute
21 disease activity in the context of MS, what does one
22 look for on an MRI scan?

1 MS. WHELAN: Object to form.
2 A. A new lesion. And if you give the dye
3 gadolinium, you can look to see whether there are any
4 lesions that show that dye, what are called enhancing
5 lesions.
6 Q. Are there different types of enhancing
7 lesions?
8 A. No.
9 Q. Does the size of the lesion -- strike that.
10 Is the size of the lesion observed on an
11 MRI scan something that doctors measure and consider?
12 A. You might measure it.
13 Q. What does the size of a lesion tell a
14 physician regarding acute disease activity in a
15 patient?
16 MS. WHELAN: Object to form.
17 A. Not much. You just note it.
18 Q. Why do doctors measure the size of lesions of
19 MRI -- of lesions in MRI scans?
20 A. They don't always do it. Sometimes the
21 radiologist will do it just because the radiologist
22 may measure things.

1 Q. Do doctors count the number of lesions in MRI
2 scans of MS patients?
3 A. Yes.
4 Q. And Dr. Lublin, why do doctors count the
5 number of lesions in MRI scans of MS patients?
6 A. Well, A, so you know if there's any new
7 lesions on the next scan; but B, to some degree it's a
8 measure of severity. It's not a perfect measure, but
9 to a degree it is. And sometimes you use it for --
10 location more so, but in some of the diagnostic
11 criteria and number counted as well.
12 Q. You said to some degree it's a measure of
13 severity. The question is: Severity of what?
14 A. Of the illness.
15 Q. In this case multiple sclerosis?
16 A. Yes.
17 Q. What causes gadolinium-enhancing lesions?
18 MS. WHELAN: Object to form.
19 A. Gadolinium is a dye that's seen on MRI scans,
20 and under normal conditions it doesn't enter the
21 central nervous system -- the brain or the spinal cord
22 or the optic nerves.

1 When there's a breakdown of something
2 called the blood-brain barrier, which can happen with
3 the acute lesions of multiple sclerosis, the
4 gadolinium can exit the bloodstream and into the
5 lesion and show up on the MRI scan.
6 Q. Earlier I believe you referred to progressive
7 forms of MS; correct?
8 A. Yes.
9 Q. In the context of MS, what causes disease
10 progression?
11 A. We don't know.
12 Q. Is disease progression the same thing as
13 disability progression in the context of MS?
14 MS. WHELAN: Object to form.
15 A. It can be.
16 Q. Is it always the same thing?
17 A. No. There's a problem with the term
18 "progression," that we've tried to clarify, that
19 there's worsening which includes progression, but
20 there's also worsening which can be disability caused
21 by the acute flare-ups, the exacerbations.
22 Q. When you say "exacerbations," that's the same

1 as relapse; correct?
2 A. Yes -- "relapse," "exacerbation," "attack"
3 all refer to the same process.
4 Q. Is the word "bout" another synonym for
5 relapse?
6 A. It could be.
7 Q. How is disability progression measured in the
8 context of multiple sclerosis?
9 A. There are multiple ways of measuring it. In
10 essence, you take the examination that I just did and
11 you look to see if it's changed. That's a measure.
12 You can measure how long it takes someone to walk a
13 distance. Any of the aspects of the exam that worsen
14 can be measures of disability.
15 There are more formal measures that are
16 done in clinical trials, sometimes even in practice,
17 like the EDSS -- initials -- and the multiple
18 sclerosis functional composite.
19 Q. How is the multiple sclerosis functional
20 composite measured, performed?
21 A. It's -- it involves three assessments. One
22 is the timed 25-foot walk. The second is the nine-

1 hole peg test. And the third is a short
2 neurocognitive assessment.
3 Q. And how is the EDSS test performed?
4 A. That involves doing the neurological
5 examination, and then there's a rater, a scoring
6 system, using something called functional systems.
7 And you add it up, and you come up with an EDSS score.
8 Q. What do you mean by "functional systems"?
9 A. Functional systems are, for example,
10 cognitive, visual, brain stem, cerebellar-slash-
11 coordination, motor function, sensory function, bowel
12 and bladder function, and an assessment of gait.
13 Q. In determining EDSS scores, do patients
14 report any of the information that's used to determine
15 EDSS scores?
16 A. The only patient input has to do with the
17 cognitive and mood assessment and the bladder
18 assessment.
19 Q. So the patients provide input regarding their
20 cognitive and mood assessment and the bladder
21 assessment; correct?
22 A. Correct.

1 Q. And what is that input that is provided by
2 the patients in those instances?
3 A. It's pretty short. "Are you depressed or not
4 depressed," in terms of mood? Cognitive is just
5 asking, "Have you had any difficulties with thinking,
6 calculating, et cetera?"
7 For bladder, you ask if there's any
8 alteration of bladder function, whether it be urgency,
9 frequency, hesitancy.
10 Q. Do EDSS scores -- strike that.
11 Is there a subjective element to EDSS
12 scores?
13 MS. WHELAN: Object to form.
14 A. Sort of. So certainly what you get from the
15 patient is subjective. But then in doing the
16 assessments, some of them call for a conclusion by the
17 examiner and grading. And so even though they're
18 objective tests, the assessment from one person to the
19 next may differ.
20 Q. Do EDSS scores change over time?
21 MS. WHELAN: Object to form.
22 A. They can.

1 Q. Is a higher score better or is a lower score
2 better on an EDSS score?
3 A. Zero is a perfectly normal exam, and ten is
4 death from MS, and everything in between.
5 Q. How are EDSS scores used in clinical trials?
6 A. They're one of the major tools used in
7 assessing disability, as residual impairment. So
8 they're commonly used in the clinical trials that have
9 occurred to date.
10 The best way to utilize them, because
11 there's some challenges with the EDSS, is to look for
12 a change -- a worsening, for example -- of one point,
13 that's then confirmed at a later time point; and even
14 better if it's sustained, meaning that it never
15 reverts back.
16 Q. You said there's some challenges with the
17 EDSS. What are the challenges with EDSS?
18 MS. WHELAN: Object to form.
19 A. The challenges are that it's dependent on the
20 examiner, and so there are intra- and inter-rater
21 variabilities can occur with EDSS.
22 Even more importantly, that scale from

1 zero to 10 is not linear, it's just ordinal -- one,
2 two, three, four, five, six. But going from a one to
3 a two is not the same as going from, say, a five to a
4 six. And that's why we don't use things like mean
5 EDSS any more -- like just adding up the EDSS scores
6 and looking for an average number -- which works
7 better for things that are linear. And so instead we
8 use what I mentioned to you, which is looking for a
9 fixed change -- for example, of one point -- that's
10 confirmed at least three or six months later, and even
11 more valuable if it's sustained through the entire
12 study.
13 Q. Is the time that it takes to see a change in
14 an EDSS score, is that something that doctors
15 consider?
16 A. I'm not sure I understand the question.
17 Q. Do doctors consider the time to a change in
18 an EDSS score?
19 A. They might.
20 Q. And why might a doctor consider the time to a
21 change in EDSS score?
22 A. Just to get an idea of the rate at which

1 someone's changing.
2 Q. So in a clinical trial, where one is
3 measuring EDSS scores, would one need to see a
4 reduction in EDSS scores in 100 percent of the
5 patients in that trial?
6 MS. WHELAN: Object to form.
7 A. When you say "a reduction," do you mean a
8 worsening?
9 Q. Let me ask again. To determine the clinical
10 efficacy of a drug, would one need to see a reduction
11 in EDSS scores of 100 percent of the patients in the
12 clinical trial?
13 MS. WHELAN: Object to form.
14 A. No.
15 Q. Does an EDSS score tell a doctor if a patient
16 is currently experiencing a relapse?
17 A. No. No, what is termed as a relapse, the
18 patient comes in and tells you something new has
19 happened to them. Now, they may do an EDSS at that
20 visit to formally measure what's going on, or they may
21 just do the neurological examination. But the EDSS
22 doesn't declare the exacerbation.

1 In some studies the definition of the
2 relapse requires a change in the EDSS.
3 MS. ELLISON: We've been going for about
4 an hour and 20 minutes. I think we're at a good point
5 for a break. So why don't we go off the record. Say,
6 ten minutes. Does that work for you, Dr. Lublin?
7 THE WITNESS: That's fine.
8 MS. ELLISON: Thank you.
9 (Recess taken.)
10 Q. Dr. Lublin, before the break we were talking
11 about relapse rates. The question for you is: Is it
12 desirable to reduce a patient's relapse rate in that
13 the patient's EDSS score doesn't change?
14 MS. WHELAN: Object to form.
15 A. Yes.
16 Q. Do you still have your declarations in front
17 of you, Dr. Lublin?
18 A. I do.
19 Q. In Paragraph 62 of your -- we're working
20 mostly with your declaration from IPR2023-00480. In
21 Paragraph 62 you use the term "clinical benefits." Do
22 you see that?

1 A. Can you point me to it?
2 Q. Do you see Paragraph 62? It's on Page 25.
3 A. Right.
4 Q. Do you see the word "clinical benefits" in
5 Paragraph 62 -- "clinical benefit"?
6 A. I see "unconvincing clinical benefit."
7 Q. Yes, and a couple of lines down you also use
8 the word "clinical benefit" again.
9 A. Okay.
10 Q. And it may appear elsewhere in that paragraph
11 as well.
12 My question for you is: In Paragraph 62
13 of your declaration, when you use the term "clinical
14 benefit," what do you mean by the term "clinical
15 benefit"?
16 MS. WHELAN: Object to form.
17 A. Improvement in some metric.
18 Q. Which metric?
19 A. It could be any clinical metric.
20 Q. Can you give me some examples of clinical
21 metrics that would be included when you use the term
22 "clinical benefit"?

1 A. Well, in a clinical trial it could be
2 reduction in relapse rate compared to something else.
3 It could be lessening the number of attacks or
4 lessening the severity of attacks, or improving
5 function that was impaired.
6 Q. Function of what?
7 A. Any function of the central nervous system.
8 Q. And also in Paragraph 62 you use the phrase
9 "clinical parameters." Do you see that? About
10 halfway down the paragraph of Paragraph 62.
11 A. Yes.
12 Q. What do you mean by the phrase "clinical
13 parameters" as you use that term in Paragraph 62 of
14 your declaration?
15 MS. WHELAN: Object to form.
16 A. Again, some metric of clinical function.
17 Q. Are you using the phrase "clinical
18 parameters" synonymously or interchangeably with the
19 phrase "clinical benefit"?
20 MS. WHELAN: Object to form.
21 A. Not exactly.
22 Q. What's the difference between "clinical

1 benefits" and "clinical parameters," as you use those
2 terms in your declaration?
3 MS. WHELAN: Object to form.
4 A. A clinical parameter is something you
5 measure. Clinical benefit is something that denotes
6 improvement.
7 Q. Is a reduction in brain lesions a clinical
8 benefit in the context of MS?
9 MS. WHELAN: Object to form.
10 A. No, it's a radiologic benefit.
11 Q. Is a reduction in brain lesions desirable in
12 the context of MS?
13 MS. WHELAN: Object to form.
14 A. Yes.
15 Q. In Paragraph 63 of your declaration,
16 Dr. Lublin, you use the phrase "clinical outcome." Do
17 you see that?
18 A. Yes.
19 Q. What do you mean by the phrase "clinical
20 outcomes," as you use that term in Paragraph 63 of
21 your declaration?
22 A. An outcome is the result of some activity.

1 Q. I didn't quite understand your answer. What
2 do you mean it's the result of some activity?
3 A. Just that: It's an outcome. So you assess
4 something, and the outcome is the result.
5 Q. What are examples of "clinical outcomes," as
6 you use that phrase in Paragraph 63 of your
7 declaration?
8 A. Well, reduction in relapse rate could be one.
9 Change in EDSS could be one. Change in the timed
10 25-foot walk could be one.
11 Q. Can you tell me what a disease-modifying
12 treatment is in the context of MS?
13 A. Disease-modifying treatments, therapies,
14 agents alter the course of the disease, as opposed to
15 treating symptoms of the disease.
16 Q. And what do you mean by they alter the course
17 of the disease?
18 A. They affect the clinical course of the
19 illness by improving something.
20 Q. In the context of MS, how do disease-
21 modifying treatments improve something, to use your
22 words?

1 MS. WHELAN: Object to form.
2 A. So the commonest is reduction in annualized
3 relapse rate. There also could be decreased worsening
4 of the EDSS, less worsening of the timed 25-foot walk
5 or the nine-hole peg test.
6 Q. Are the words "disease-modifying treatments,"
7 "disease-modifying therapies," and "disease-modifying
8 agents" used synonymously?
9 A. Yes.
10 Q. You mentioned there could be decreased
11 worsening of the EDSS. What do you mean by "decreased
12 worsening"?
13 A. Well, if you're comparing, let's say, an
14 agent to a placebo and you're monitoring people over
15 time, the EDSS, depending on the population that
16 you've put into the clinical trial, the EDSS could
17 worsen. That's part of the clinical course of
18 multiple sclerosis.
19 And if your agent slows that worsening,
20 then that's a therapeutic effect.
21 Q. How do disease-modifying treatments alter the
22 course of the disease in the context of multiple

1 sclerosis?
2 MS. WHELAN: Object to form.
3 A. Well, we mostly don't know. The mechanism of
4 action is -- to be certain about the mechanism of
5 action is very difficult for almost all the disease-
6 modifying therapies.
7 Q. Do disease-modifying therapies reduce
8 inflammation in patients having MS?
9 MS. WHELAN: Object to form.
10 A. The currently approved disease-modifying
11 therapies do, yes.
12 Q. I think we earlier briefly touched on
13 different types of MS. Again, I'm not a physician.
14 So if you don't mind, could you explain to me the
15 different clinical subtypes of multiple sclerosis?
16 MS. WHELAN: Object to form.
17 A. As of 2004?
18 Q. Yes.
19 A. So in 2004 there were four subtypes of MS.
20 There was relapsing-remitting, primary progressive,
21 secondary progressive, and progressive relapsing.
22 As I mentioned earlier, relapsing-

1 remitting is where you have acute attack and then a
2 period of stability and then another acute attack that
3 could be in weeks, months, years, decades later. But
4 in between attacks you don't change.
5 In secondary progressive MS you start out
6 as relapsing-remitting, but then at some point you
7 transition into secondary progressive MS, where you
8 gradually worsen in between attacks or independent of
9 attacks. Attacks still may occur, but it's worsening
10 that's independent of that attack.
11 In primary progressive MS, that's
12 progressive from onset. So instead of starting with
13 an acute attack, they start with a gradual worsening
14 over time.
15 And progressive relapsing is a primary
16 progressive patient who then subsequently has acute
17 attacks.
18 Q. Thank you for that. Does the use of DMTs,
19 disease-modifying therapies, depend on the clinical
20 subtype of MS?
21 MS. WHELAN: Object to form.
22 A. The disease-modifying therapies are approved

1 for use in the type of MS they were studied in.
2 Q. Does the use of DMTs, then, depend upon the
3 clinical subtype of MS?
4 MS. WHELAN: Object to form.
5 A. Yes.
6 Q. Are DMTs used primarily for a certain subtype
7 of MS versus other subtypes?
8 MS. WHELAN: Object to form.
9 A. In 2004?
10 Q. Yes, sir.
11 A. Yes.
12 Q. And which subtypes were DMTs primarily used
13 for in 2004?
14 A. So in 2004 they were all approved for
15 relapsing-remitting MS, and one was approved for --
16 this is in the United States -- for secondary
17 progressive MS.
18 Q. In 2004 were DMTs approved for PPMS?
19 A. No.
20 Q. Does relapsing-remitting MS have higher
21 inflammatory activity than progressive forms of MS?
22 A. Generally so.

1 Q. It sounds like the DMTs were approved for
2 relapsing-remitting MS rather than the progressive
3 forms of MS?
4 MS. WHELAN: Object to form and
5 foundation.
6 A. That's a little difficult to answer.
7 Progressive MS is more difficult to treat.
8 Q. Progressive forms of MS were more difficult
9 to treat than what?
10 A. Than relapsing-remitting MS.
11 Q. In the 2004 time frame, how were clinical
12 benefits measured when assessing a drug-modifying --
13 sorry, disease-modifying therapy in the context of MS?
14 MS. WHELAN: Object to form.
15 A. The assessment differed as to where the drug
16 was along the development pathway. If you're talking
17 about getting an agent approved for use, then the
18 commonest assessment was the annualized relapse rate.
19 Q. And what assessments were used at other
20 stages along the drug-development pathway?
21 MS. WHELAN: Object to form.
22 A. When you're looking at proof-of-principle

1 studies, earlier-phase studies, you may use MRI as
2 your primary outcome measure.
3 Q. What does MRI measure in those instances?
4 A. You're looking for a reduction in the number
5 of new lesions over a period of time.
6 Q. And in assessing DMTs, how would one assess
7 whether a patient is responding to the DMT?
8 MS. WHELAN: Object to form.
9 A. No way to know for certain, because MS is an
10 extremely variable disease. It's just not
11 predictable. So even if someone coming into a study,
12 for example, had had a lot of relapses in the prior
13 year or two, they may not have any more over the
14 course of your study -- or they may. Again, perfectly
15 variable. Same thing with, to some degree, measures
16 of disability or impairment.
17 And so once you start someone on the
18 medication, you don't know how they would have done
19 had they not been on the medication. And so we do not
20 have any guidance on determining a responder to the
21 drug or a nonresponder to the drug. It doesn't exist.
22 If someone continues to have really a lot

1 of activity after starting on a medication, you may
2 say, well, this medication may not be working for
3 them, or it just may be that disease is really bad.
4 So the short answer is we do not have
5 individual responder metrics.
6 Q. In the context of assessing DMTs as potential
7 therapies for treating MS, what metrics would one use
8 to assess the clinical benefits of that DMT in
9 patients?
10 MS. WHELAN: Object to form.
11 A. Group response. So you take a group of
12 individuals that gets the drug and a group of
13 individuals that gets the placebo, or whatever you're
14 controlling with. And then you follow them over a
15 period of time and assess, say, the annualized relapse
16 rate in each group for the group.
17 Q. Do DMTs cause suppression of lymphocyte
18 counts?
19 A. Some do.
20 Q. Do DMTs target inflammation?
21 MS. WHELAN: Object to form.
22 A. The DMTs that were available in 2004

1 putatively targeted inflammation.
2 Q. We talked earlier about gadolinium-enhancing
3 T1 lesions. My question for you is: Are gadolinium-
4 enhancing T1 lesions a sign of inflammation?
5 MS. WHELAN: Object to form.
6 A. They can be.
7 Q. In the context of MS, are gadolinium-
8 enhancing T1 lesions a sign of inflammation?
9 MS. WHELAN: Object to form.
10 A. Usually.
11 Q. Do you know what T2 lesions are?
12 A. Yes.
13 Q. I would hope so. Can you please tell me what
14 T2 lesions are?
15 A. T2 lesions are an MRI -- there are MRI
16 sequences where the lesions of MS show up bright, and
17 that's called a T2 lesion.
18 Q. So how do T2 lesions differ from T1 lesions?
19 A. T1 lesions are a different sequence of MRI
20 scanning. And there the lesions of MS, when you don't
21 get gadolinium, either don't show up at all or show up
22 hypointense, dark.

1 Q. So what do you mean by "dark"?
2 A. They're dark. So you have the context of the
3 brain, and then you have a circle that's darker than
4 the area around it.
5 Q. And what does that darkness represent?
6 A. It represents the damage that was done by the
7 lesion.
8 Q. What causes the darkness in that situation?
9 A. Underlying tissue destruction.
10 Q. How is that tissue destroyed?
11 A. By the MS process.
12 Q. What do you mean by "the MS process"?
13 A. It could be inflammation. It could be
14 underlying neurodegeneration. But it's the scar of
15 MS.
16 Q. What causes neurodegeneration?
17 A. That's a little harder to know, so I don't
18 have a good answer for you. But part of the concern
19 in MS is that, in addition to the inflammatory aspect,
20 there's a separate neurodegenerative aspect, with
21 underlying tissue damage.
22 Q. And when you say "inflammatory aspect," what

1 do you mean by that?
2 A. The inflammation we've been talking about.
3 Q. Earlier you referred to some lesions as
4 showing up bright. What do you mean by "bright" in
5 this context?
6 A. It depends on the sequence. So the MRI
7 sequences that are T1, where you give gadolinium and
8 you have an acute lesion, it may show up bright,
9 because it takes up the dye of the gadolinium.
10 On the T2 scans, independent of
11 gadolinium, because gadolinium doesn't really affect
12 the T2 scans, the bright lesions are the scars of MS.
13 Q. Can you tell me what a T2 lesion load is?
14 A. A T2 lesion load would be the number and/or
15 volume of T2 lesions.
16 Q. Does a reduction in gadolinium-enhancing
17 lesions inform a doctor about a patient's response to
18 a drug?
19 MS. WHELAN: Object to form.
20 A. An individual patient? It could over time.
21 Q. Does a reduction in gadolinium-enhancing
22 lesions inform a doctor about a group of patients'

1 response to a drug?
2 MS. WHELAN: Object to form.
3 A. In a clinical trial it could.
4 Q. How so?
5 A. You can use it, as I had mentioned earlier,
6 as a metric in earlier-phase studies. And it could be
7 a secondary-outcome measure in more pivotal studies.
8 Q. When you say "pivotal study," what do you
9 mean by that?
10 A. A pivotal study is a Phase III study -- that
11 is, a study that, if you succeed, you can take those
12 results to a regulator and request licensing of your
13 agent.
14 Q. And when you say "secondary outcome measure,"
15 what do you mean by that?
16 A. I mentioned that earlier, that when you
17 design a clinical trial, you design it around your
18 primary-outcome measure, and that's what you most want
19 to succeed in. And then you have additional measures
20 that you utilize to provide more information on the
21 effect of the agent.
22 Q. Does a reduction in the number of lesions

1 suggest a decrease in inflammation?
2 MS. WHELAN: Object to form.
3 A. It could.
4 Q. Does a reduction in the volume of lesions
5 suggest a decrease in inflammation?
6 MS. WHELAN: Object to form.
7 A. It could.
8 Q. You still have your declaration in front of
9 you; correct, Dr. Lublin?
10 A. Yes.
11 Q. Appendix B to your declaration is a copy of
12 your CV; correct?
13 A. Yes.
14 Q. When was your CV last updated prior to the
15 signing of your declaration?
16 A. Prior to? Not the date that's at the end of
17 the CV. So it was updated more recently. I just
18 didn't change the date at the end. I think, if I
19 remember correctly, it says May 20, 2023. Yeah.
20 But I had updated it probably later in
21 2023. And even now it's accurate except for maybe one
22 or two other publications.

1 Q. To the best of your recollection, when was
2 your CV that's provided as Appendix B to your
3 declaration last updated?
4 A. Probably last fall.
5 Q. Does your CV that was provided as Appendix B
6 to your declaration accurately summarize your
7 experience and credentials?
8 A. Yes.
9 Q. Does your CV that's provided as Appendix B to
10 your declaration accurately reflect your areas of
11 scientific expertise?
12 A. Yes.
13 Q. Now, you list a number of publications on
14 your CV; correct?
15 A. Yes.
16 Q. Have you retracted any of the publications
17 that are listed on your CV?
18 A. No.
19 Q. Have you issued any corrections to any of the
20 publications that are listed on your CV?
21 A. No.
22 Q. Thank you. In Paragraph 74 of your

1 declaration you stated that -- I'll wait until you get
2 there.
3 Do you have Paragraph 74, Dr. Lublin?
4 Dr. Lublin?
5 A. Yes.
6 Q. Are you at Paragraph 74?
7 A. I am.
8 Q. My question is: In Paragraph 74 of your
9 declaration you stated that before 2004 it was known
10 that cladribine induces a reduction in lymphocyte
11 count as a pharmacological effect. My question is:
12 What was the mechanism by which cladribine lowered
13 lymphocyte counts?
14 MS. WHELAN: Object to form.
15 A. Cladribine is a purine analog, and it
16 interfered with the cell's function, the lymphocyte
17 function.
18 Q. How did it interfere with the lymphocyte
19 function?
20 MS. WHELAN: Object to form.
21 A. It interfered with the DNA of the
22 lymphocytes, but I don't know the exact mechanism

1 underlying that.
2 Q. Before 2004 was cladribine known to kill
3 lymphocytes by apoptosis?
4 MS. WHELAN: Object to form.
5 A. I don't know whether it was apoptosis or not.
6 Q. Before 2004 was the lymphocyte-lowering
7 activity of cladribine thought to be permanent?
8 A. I don't know what you mean by that question.
9 Q. Did cladribine cause a permanent reduction in
10 lymphocyte counts in patients?
11 A. No.
12 Q. So the lymphocyte counts would rebound after
13 cessation of cladribine treatment; is that correct?
14 MS. WHELAN: Object to form.
15 A. The lymphocyte counts would return at some
16 point after the cessation of cladribine treatment.
17 Q. What caused the lymphocyte count to return
18 after the cessation of cladribine treatment?
19 MS. WHELAN: Object to form.
20 A. New lymphocytes coming out of the bone marrow
21 that weren't subjected to the cladribine.
22 Q. Can one confirm the pharmacological effect of

1 cladribine by measuring lymphocyte count before and
2 after cladribine administration?
3 MS. WHELAN: Object to form.
4 A. Can I hear that again?
5 Q. Sure. By way of background: You had stated
6 that cladribine introduces -- sorry, you had said
7 cladribine induces a reduction in lymphocyte count as
8 a pharmacological effect. My question is: Can one
9 confirm the pharmacological effect of cladribine by
10 measuring lymphocyte count before and after cladribine
11 administration?
12 MS. WHELAN: Object to form.
13 A. Yes.
14 MS. ELLISON: Let's go off the record
15 really briefly. I just need like a one-minute break.
16 (Recess taken.)
17 MS. ELLISON: We can go back on the
18 record.
19 Q. Dr. Lublin, does the pharmacological effect
20 depend on the dose of cladribine that's administered?
21 MS. WHELAN: Object to form.
22 A. It can.

1 Q. Why do you say it can?
2 A. Yes.
3 Q. Just so the record's clear: Does the
4 pharmacological effect depend on the dose of
5 cladribine?
6 MS. WHELAN: Object to form.
7 A. It can.
8 Q. Why do you say it can? Are you using the
9 words "it can" synonymously with an answer of "yes"?
10 A. No. It can because it doesn't necessarily
11 have to be linear, and you can have floor and ceiling
12 effects.
13 Q. What's a ceiling effect?
14 A. It means that you get to a point where you
15 can't reduce any further.
16 Q. And what's a floor?
17 A. Just the opposite. In other words, if you
18 think of the boundaries of something, you can't
19 reasonably go above it or go below it because you're
20 not measuring anything -- or you're unable to
21 measure -- or the agent's unable to change more than
22 that.

1 Q. And in between the floor and the ceiling, is
2 the pharmacological effect dependent upon the dose of
3 cladribine administered?
4 MS. WHELAN: Object to form.
5 A. It might.
6 Q. Why do you say it might?
7 A. I can't answer it definitively for you.
8 Q. So you don't know one way or the other?
9 A. I just can't answer definitively on what
10 you're saying. It would depend on the agent and the
11 pharmacokinetics and pharmacodynamics of that agent.
12 Q. Well, we're referring to cladribine.
13 A. Even with cladribine, it was variable, and
14 the reduction wasn't always related to dose.
15 Q. So in the context of cladribine, when one is
16 in between a floor and a ceiling, to use your terms,
17 can the pharmacological effect of cladribine be
18 dependent on the dose of cladribine administered?
19 MS. WHELAN: Object to form.
20 A. So you said "can," and therefore my answer is
21 yes.
22 MS. ELLISON: Emil, can you put up Exhibit

1018, and also put a copy in the chat, please.

THE TECHNICIAN: Stand by.

MS. ELLISON: Emil, can you enlarge that, please.

Q. So Dr. Lublin, I understand you have a paper copy of Exhibit 1018 in front of you; is that correct?

A. That's correct.

Q. And do you recognize Exhibit 1018 as a copy of a publication or paper from Rice?

A. I do.

Q. I'm going to ask you to turn to Page 1152, and Dr. Lublin, I'll ask you to do the same.

A. I see it.

MS. ELLISON: Emil, if you can give me control. We're trying to get to Figure 4.

Q. Dr. Lublin, you have Exhibit 1018 in front of you. We're looking at Figure 4, which appears on Page 1152.

In the Rice publication, as shown in Figure 4, Rice administered two different doses of cladribine; correct?

A. Yes.

1 Q. And one cohort of patients received six
2 courses of 0.07 milligrams per kilogram per day for
3 five days; correct?
4 A. Yes.
5 Q. And those same patients received a total of
6 2.1 milligrams per kilogram; correct?
7 A. I'm sorry, say that again.
8 Q. Those same patients received a total of 2.1
9 milligrams per kilogram; correct?
10 A. Sorry, which same patients?
11 Q. I'll start again, Dr. Lublin. And
12 Dr. Lublin, you have reviewed the Rice publication
13 before; correct?
14 A. Yes.
15 Q. This is one of the exhibits cited in your
16 declaration; correct?
17 A. Yes.
18 Q. So Rice administered two different cladribine
19 doses; correct?
20 A. Yes.
21 Q. One cohort of patients received six courses
22 of 0.07 milligrams per kilogram per day for five days,

1 for a total of 2.1 milligrams per kilogram; correct?
2 A. Yes.
3 Q. And another cohort of patients received two
4 courses of 0.07 milligrams per kilogram per day for
5 five days, for a total of 0.7 milligrams per kilogram;
6 correct?
7 A. Yes.
8 Q. Within Figure 4 Rice plots the lymphocyte
9 counts for the two different treatment arms and the
10 placebo arm of the study; correct?
11 A. Yes.
12 Q. Can you estimate from Figure 4 what the
13 baseline lymphocyte counts are for both cladribine
14 treatment groups and the placebo group?
15 MS. WHELAN: Object to form and
16 foundation.
17 A. About 1.7.
18 Q. Is that your answer for all three groups?
19 A. Well, let's see. It was 1.5 for it looks
20 like the lower-dose cladribine, 1.7 for the
21 higher-dose cladribine, and something in between,
22 maybe 1.6, for the placebo.

1 Q. Thank you. And can you estimate from Figure
2 4 what the nadir lymphocyte counts are for the
3 0.7-milligram-per-kilogram treatment group?
4 A. About .95.
5 Q. And can you estimate in Figure 4 what the
6 nadir lymphocyte counts are for the 2.1-milligram-
7 per-kilogram treatment group?
8 A. 0.5.
9 Q. And can you estimate what the nadir
10 lymphocyte counts are for the placebo group?
11 A. They're at their lowest -- well, final.
12 It doesn't change very much. But it's at
13 its lowest point at baseline, so maybe instead of 1.6
14 it's 1.7.
15 Q. Would you agree that the lymphocyte levels
16 for the two treatment arms are similar at two months?
17 MS. WHELAN: Object to form.
18 A. Yes.
19 Q. And after two months the lymphocyte level in
20 the 2.1-milligram-per-kilogram arm continues to
21 decrease, while the lymphocyte level in the
22 0.7-milligram-per-kilogram treatment arm is around

1 1,000 lymphocytes per microliter; correct?
2 MS. WHELAN: Object to form and
3 foundation.
4 A. Yes.
5 Q. So the higher dose of cladribine in this
6 instance caused a larger decrease in lymphocyte counts
7 than did the lower dose; correct?
8 MS. WHELAN: Object to form.
9 A. Not exactly. To be able to say a higher dose
10 caused more lymphocyte suppression than the lower
11 dose, you would have had to continue at a lower dose
12 at the same time points. And here, in the 2.1
13 milligram, they're still getting dosed, whereas the .7
14 is no longer being dosed.
15 Q. At the end of the study was the lymphocyte
16 level in the 2.1-milligram-per-kilogram arm lower than
17 the lymphocyte level in the 0.7-milligram-per-kilogram
18 arm?
19 A. Yes.
20 Q. You can put that exhibit away.
21 MS. ELLISON: And Emil, will you please
22 pull out Exhibit 1022 and put a copy in the chat and

1 up on the screen.
2 Q. Dr. Lublin, do you have a copy of Exhibit
3 1022, which is the Bodor reference?
4 A. I do.
5 MS. ELLISON: Emil, if you can go to Page
6 22 of that, please.
7 A. Top or bottom?
8 Q. I heard your question. Let me tell you in
9 just a second.
10 It's going to be about, well, in the
11 middle of the page.
12 MS. ELLISON: I'm sorry, just a second.
13 Actually, if you can go to the page that's
14 numbered at the top of the page -- that's numbered 23
15 at the top of the page, and scroll to about Line 15 on
16 the left side. Yes, right there.
17 Q. Dr. Lublin, you've read the Bodor reference
18 that's provided as Exhibit 1022; correct?
19 A. Yes.
20 Q. We're looking at the page that has a native
21 page numbering of Page 23, and about the middle of the
22 page it says, "At the present time, it is envisioned

1 that, for the treatment of multiple sclerosis, 10
2 milligrams of cladribine in the instant complex
3 (cladribine-cyclodextrin complex) in the instant solid
4 dosage form would be administered once per day for a
5 period of five to seven days in the first month,
6 repeated for another period of five to seven days in
7 the second month, followed by ten months of no
8 treatment." Do you see that?
9 A. I do.
10 Q. So the Bodor reference tells one to
11 administer cladribine for a discrete period of time;
12 correct?
13 MS. WHELAN: Object to form.
14 A. That's correct.
15 Q. And in Bodor's proposed method, lymphocytes
16 are killed as a result of treatment with cladribine;
17 correct?
18 MS. WHELAN: Object to form.
19 A. I don't think Bodor discusses killing
20 lymphocytes.
21 Q. But Bodor suggests using cladribine; correct?
22 A. Yes.

1 Q. And you testified that cladribine kills
2 lymphocytes; correct?
3 A. It's one of its mechanisms of action.
4 Q. Thank you. Let's look at -- just one second.
5 You can put that reference away.
6 MS. ELLISON: Let's pull out Exhibit 1013,
7 which is Stelmasiak.
8 Emil, if you could put Exhibit 1013 on the
9 screen, we'd appreciate it. And if you could scroll
10 to the second page, about where it says Materials and
11 Methods. Zoom in. And we're going to look at the
12 right-hand column.
13 Q. Dr. Lublin, you've read the Stelmasiak
14 reference before; correct?
15 A. Yes.
16 Q. When is the last time you read the Stelmasiak
17 reference?
18 A. Sometime in the past week.
19 Q. Thank you.
20 MS. ELLISON: Actually, Emil, let's first
21 go to the summary that appears on the first page.
22 Q. Dr. Lublin, my question for you is:

1 Stelmasiak administered cladribine to patients having
2 a relapsing-remitting MS; correct?
3 A. Yes.
4 Q. And in the cladribine arms of this study,
5 patients received six monthly courses of cladribine
6 orally or subcutaneously, followed by two additional
7 courses at nine months and 12 or 15 months; correct?
8 A. We're not in the summary any longer. But
9 yes.
10 Q. Yes. You can look wherever you like to
11 answer these questions.
12 A. The answer was yes.
13 Q. Thank you. And if you look -- if you turn to
14 the Materials and Methods, on the second page,
15 Stelmasiak describes taking blood counts and
16 conducting neurological examinations of its patients;
17 correct?
18 A. Yes.
19 Q. If you turn to -- go to the Results, which
20 are further down on the second page of Stelmasiak.
21 The question for you is: What type of blood counts
22 did Stelmasiak take?

1 A. It looks like he did what was called a CBC, a
2 complete blood count.
3 Q. What types of blood cells are measured in a
4 complete blood count?
5 A. Red blood cells, white blood cells, and
6 platelets.
7 Q. So in this instance Stelmasiak measured
8 granulocyte counts; correct?
9 A. Yes.
10 Q. And Stelmasiak measured platelet counts;
11 correct?
12 A. Yes.
13 Q. And Stelmasiak measured lymphocyte counts;
14 correct?
15 A. Yes.
16 Q. What metrics did Stelmasiak use to assess
17 clinical efficacy of cladribine?
18 A. It looks like he used relapses and EDSS
19 scores.
20 Q. Did Stelmasiak measure average relapse rate
21 to assess clinical efficacy of cladribine?
22 A. Yes.

1 Q. Turn to native page number 5, with bold page
2 numbered 2; look at Figure 1.
3 MS. ELLISON: You just scrolled past it,
4 Emil. Right there. Figure 1.
5 Q. Do you see Figure 1, Dr. Lublin?
6 A. I do.
7 Q. Figure 1 of the Stelmasiak reference is a
8 plot of the average lymphocyte counts of the patients
9 that received cladribine therapy; correct?
10 A. Yes.
11 Q. And in Figure 1 of Stelmasiak, what is the
12 average lymphocyte count at baseline?
13 MS. WHELAN: Object to form.
14 A. About 2400.
15 Q. If you look at the text just above Figure 1,
16 can you answer my question with any more precision:
17 What was the lymphocyte -- average lymphocyte count at
18 baseline in Stelmasiak, Figure 1?
19 A. 2,336.
20 Q. Thank you. What is the lowest average
21 lymphocyte count achieved with cladribine therapy, as
22 discussed in Stelmasiak, Exhibit 1013, Figure 1?

1 MS. WHELAN: Object to form.
2 A. 968.
3 Q. And what is the total reduction of the
4 average lymphocyte count achieved with cladribine in
5 Stelmasiak's Figure 1?
6 MS. WHELAN: Object to form.
7 A. Could I hear the question again?
8 Q. What was the total reduction of the average
9 lymphocyte count achieved with cladribine in
10 Stelmasiak's Figure 1?
11 MS. WHELAN: Object to form.
12 A. I don't see an average number here. Perhaps
13 you could point me to it?
14 Q. I think this was really just a math exercise,
15 Dr. Lublin. If the average lymphocyte count at
16 baseline was 2,336, as you said, and the lowest
17 average lymphocyte count achieved with cladribine
18 therapy was 968, my question is: What is the total
19 reduction of the average lymphocyte count achieved
20 with cladribine?
21 A. I don't have a calculator with me.
22 MS. BOND: Would you like one?

1 Q. My colleague, Madeleine, can give you a
2 calculator.
3 A. Okay.
4 So about 59 percent.
5 Q. And how did you arrive at the number of 59
6 percent?
7 A. I divided 968 by 2,336 and took the inverse.
8 Q. Why did you divide 968 by 2,336 and take the
9 inverse?
10 A. Because that's the ratio.
11 Q. So is it your testimony that in Stelmasiak's
12 Figure 1 the average lymphocyte count --
13 A. Let me look at this again and see if that
14 makes sense.
15 No, maybe it's the 41. It's the 41
16 percent.
17 Q. Is it your testimony that in Stelmasiak's
18 Figure 1 the average lymphocyte count decreased by 41
19 percent from baseline to the lowest average lymphocyte
20 count?
21 A. Yes.
22 Q. Is it fair to say that the average lymphocyte

1 count in Stelmasiak's Figure 1 decreased from 2336 at
2 baseline by 1300 lymphocytes to the lowest average
3 lymphocyte count of 968?
4 A. Yes.
5 Q. In looking at Stelmasiak's Figure 1, does the
6 lymphocyte count begin to rebound between Months 21
7 and 24?
8 MS. WHELAN: Object to form.
9 A. Yes.
10 Q. And is that because new lymphocytes are
11 formed?
12 MS. WHELAN: Object to form and
13 foundation.
14 Q. Is the rebound because new lymphocytes are
15 formed?
16 MS. WHELAN: Object to form and
17 foundation.
18 A. Yeah, probably.
19 Q. Okay.
20 MS. ELLISON: I think we can take a short
21 break at this point. Let's go off the record.
22 (Recess taken.)

1 MS. ELLISON: We can go back on the
2 record.
3 Q. Dr. Lublin, during either of our breaks, have
4 you spoken with anyone regarding the substance of your
5 testimony?
6 A. No.
7 Q. During our breaks have you accessed any
8 information on your phone relating to the substance of
9 your testimony?
10 A. No.
11 Q. Thank you. Let's look at Exhibit 1022,
12 Bodor.
13 MS. ELLISON: Emil, if you could, please
14 put that back on the screen. We'll go to Page 23,
15 based on the native page numbering.
16 Q. Dr. Lublin, you still have a copy of Exhibit
17 1022 in front of you; correct?
18 A. I do.
19 Q. Great. At Page 23, based on the native page
20 numbering --
21 A. I'm sorry, would you tell me what you mean by
22 "native page number"?

1 Q. My apologies. The page numbering at the top
2 of the page is No. 23. At the bottom it's No. 25.
3 23's the native page number.
4 MS. ELLISON: Emil, if you could scroll
5 down to roughly Lines 15 to 20 --
6 Q. Where is I would like you to focus your
7 attention, or where you may want to focus your
8 attention to answer my questions, Dr. Lublin.
9 At Page 23 of Bodor, which is Exhibit
10 1022, Bodor states, quote, "At the present time, it is
11 envisioned that, for the treatment of multiple
12 sclerosis, 10 milligrams of cladribine in the instant
13 complex cladribine-cyclodextrin complex in the instant
14 solid dosage form would be administered once per day
15 for a period of five to seven days in the first month,
16 repeated for another period of five to seven days in
17 the second month, followed by ten months of no
18 treatment." Do you see that, Dr. Lublin?
19 A. I do.
20 Q. What is the total dose of cladribine that
21 Bodor teaches to administer over the two-month period?
22 MS. WHELAN: Object to form.

1 A. I believe it would be 100 to 140 milligrams.
2 Q. Thank you. Also, do you still have the
3 calculator that Madeleine handed to you earlier?
4 A. I do now.
5 Q. Does Bodor teach that the dose of cladribine
6 described in Bodor is not suitable for patients of a
7 certain weight?
8 MS. WHELAN: Object to form and
9 foundation.
10 A. Not that I'm aware of.
11 Q. If you look at Paragraph 89 of your
12 declaration. Let me know when you're there.
13 A. I'm there.
14 Q. You stated in Paragraph 89 that a patient
15 weighing 70 kilograms would receive a total dose of
16 about 1.4 milligrams per kilogram to 2 milligrams per
17 kilogram, according to Bodor's regimen; right?
18 MS. WHELAN: Object to form.
19 A. No. I say that Dr. Miller opined that.
20 Q. Would a patient being treated according to
21 Bodor's regimen who weighs 70 kilograms receive a
22 total dose of about 1.4 milligrams per kilogram to 2

1 milligrams per kilogram?
2 MS. WHELAN: Object to form and
3 foundation.
4 A. I believe so.
5 Q. If you'll indulge me, I'm going to ask you to
6 do a little math again, and you're welcome to use the
7 calculator that Madeleine handed to you.
8 My question is: How much cladribine would
9 a patient weighing 52 kilograms receive in following
10 Bodor's regimen that's disclosed on Page 23, that we
11 just looked at?
12 MS. WHELAN: Object to form and
13 foundation.
14 A. I believe it would be 2 milligrams per
15 kilogram.
16 Q. Can you tell me how you did that calculation?
17 A. I took 100 milligrams and divided it by 50
18 kilograms.
19 Q. And why did you divide it by 50 kilograms,
20 when my question was about a patient weighing 52
21 kilograms?
22 A. I'm sorry, I heard you wrong.

1 Q. Okay. So let me repeat my question. How
2 much cladribine would a patient weighing 52 kilograms
3 receive following Bodor's regimen disclosed on Page 23
4 of Bodor?
5 MS. WHELAN: Object to form, foundation.
6 A. I believe it would be -- well, wait a
7 minute -- 1.4 to 2.6.
8 Q. And can you tell me how you did that
9 calculation?
10 A. I took 100 and divided it by 52 and 140 and
11 divided it by 52.
12 Q. If you take 100 and divide it by 52, what
13 number would you get?
14 A. 1.9.
15 Q. And if you take 140 and divide by 52, what
16 number do you get?
17 A. 2.69.
18 Q. So let me ask you again: How much cladribine
19 would a patient weighing 52 kilograms receive
20 following Bodor's regimen that's disclosed on Page 23
21 of Bodor?
22 MS. WHELAN: Object to form and

1 foundation.
2 A. Let me hear the question again, please.
3 Q. How much cladribine would a patient weighing
4 52 kilograms receive when following Bodor's regimen
5 that's disclosed on Page 23 of Bodor?
6 MS. WHELAN: Object to form and
7 foundation.
8 A. Oh, okay. 100 to 140 milligrams.
9 Q. And in terms of milligrams per kilogram, how
10 much cladribine would a patient weighing 52 kilograms
11 receive when following Bodor's regimen as disclosed on
12 Page 23 of Bodor?
13 MS. WHELAN: Object to form, foundation.
14 A. I gave you my calculation on that already.
15 Q. I'd like the answer to my question, please,
16 Dr. Lublin.
17 A. 2.69 to 1.92.
18 Q. Thank you. So for a patient weighing 75
19 kilograms, how much cladribine would a patient
20 weighing 75 kilograms receive in terms of milligrams
21 per kilogram when following Bodor's regimen disclosed
22 on Page 23?

1 MS. WHELAN: Object to form, foundation.
2 A. You want milligrams per kilogram?
3 Q. Yes, sir, please.
4 A. Lower limit would be 1.3. Upper limit would
5 be 1.866 -- 1.87.
6 Q. And can you please tell me how you did that
7 calculation?
8 A. I divided 100 and 140 into the 75 kilograms.
9 Q. So Dr. Lublin, if I could have you turn to
10 Page 150 -- sorry, Paragraph 150 of your declaration,
11 towards the end. It appears on Page 75.
12 At the end of Paragraph 150 you testified
13 that the bioavailability of cladribine according to
14 Bodor is 39 to 43 percent; correct?
15 A. I'm sorry, where are we?
16 Q. Paragraph 150 of your declaration. If you
17 look at the end of Paragraph 150 of your declaration.
18 At the end of Paragraph 150 of your declaration you
19 state that the bioavailability reported in Bodor is 39
20 to 43 percent; correct?
21 A. Yes.
22 Q. So for a 70-kilogram patient who is treated

1 according to Bodor's dosing regimen disclosed on Page
2 23 of Bodor, if you factor in the bioavailability
3 range recorded in Bodor of 39 to 43 percent, what is
4 the bioavailable amount of cladribine that a
5 70-kilogram patient would receive?
6 A. I have no idea.
7 Q. Do you know how one would calculate the
8 bioavailable amount of cladribine that a patient would
9 receive according to Bodor's dosing regimen disclosed
10 on Page 23?
11 MS. WHELAN: Object to form.
12 Q. Of cladribine?
13 A. I haven't thought about it.
14 Q. You can put that exhibit away, if you'd like.
15 A. Go ahead.
16 Q. Sorry, I didn't mean to interrupt you.
17 A. That's okay.
18 Q. Let's turn to Exhibit 1013, Stelmasiak. Do
19 you still have that in front of you?
20 A. Yes.
21 Q. I'll also direct your attention to, let's
22 look at Paragraph 124 of your declaration. It appears

1 on Page 59.
2 A. Are we done with Stelmasiak?
3 Q. You might want to keep it handy.
4 A. And what paragraph is that?
5 Q. 124 of your declaration.
6 A. Okay.
7 Q. Now, you testified that Stelmasiak teaches
8 administering 300 milligrams of oral cladribine during
9 the initial treatment period of six months, followed
10 by additional 50-milligram doses; correct?
11 A. Yes.
12 Q. If you'd turn to Paragraph 77 of your
13 declaration, please. Paragraph 77 spans Pages 32 to
14 33.
15 A. Okay.
16 Q. You also testified that 300 milligrams of
17 oral cladribine in Stelmasiak's study is equivalent to
18 150 milligrams of subcutaneous cladribine; correct?
19 A. Yes.
20 Q. My question for you is: How much cladribine
21 would a patient who weighs 70 kilograms receive when
22 following Stelmasiak's oral cladribine administration

1 after six months?
2 MS. WHELAN: Object to form.
3 A. I haven't considered that. I've only
4 considered the actual dosage given.
5 Q. Are you able to answer my question? I
6 understand that you haven't yet considered it, but can
7 you answer the question that I'm asking?
8 A. No.
9 Q. Are you unable to answer the question that
10 I'm asking?
11 A. I don't understand what you're asking me, in
12 terms of dosing. And so, no, I'm not able to answer
13 the question.
14 Q. Okay. So my question is: How much
15 cladribine would a patient weighing 70 kilograms
16 receive following Stelmasiak's oral cladribine dosing
17 regimen after six months of treatment?
18 MS. WHELAN: Object to form.
19 A. Let me hear it again, please.
20 MS. ELLISON: Could the court reporter
21 read back the question, please.
22 (Question read.)

1 MS. WHELAN: Object to form.
2 A. That was oral; right?
3 Q. Correct.
4 A. 300 milligrams.
5 Q. And how much bioavailable cladribine would a
6 patient receive following Stelmasiak's oral cladribine
7 dosing regimen after six months of treatment?
8 MS. WHELAN: Object to form.
9 A. Half that; 150 milligrams.
10 Q. Okay, you can put that exhibit away, if you'd
11 like.
12 Let's look at Exhibit 1018, which is Rice.
13 A. Okay.
14 Q. I'm waiting for Emil to pull it up and put a
15 copy in the chat.
16 MS. ELLISON: Emil, if you could please go
17 to Page 1153. Right there is good. Zoom in a little
18 bit.
19 Q. So, Dr. Lublin, you've read the Rice exhibit
20 that's provided as Exhibit 1018; correct?
21 A. Yes.
22 Q. We're looking at Page 1153, and I'd like to

1 direct your attention to the left-hand column, which
2 states, "Long-term follow-up through month 24 showed a
3 trend toward beneficial cladribine effect in the SPMS
4 subgroup of both the 0.7- and 2.1-milligram-per-
5 kilogram doses."
6 My question for you is: One of the
7 cladribine arms in Rice's study received 0.7
8 milligrams per kilogram; correct?
9 A. Yes.
10 MS. ELLISON: Now if you'd scroll down a
11 little bit on the same page. Keep scrolling, keep
12 scrolling. There you go. That's good.
13 Q. Dr. Lublin, you see on the left-hand side
14 Rice states, "Both the 0.7-milligram-per-kilogram and
15 2.1-milligram-per-kilogram doses were significantly
16 superior to placebo with respect to the proportion of
17 patients having detectable enhanced T1 lesions as well
18 as to the mean volume and number of such lesions at
19 six months and final evaluation." Do you see that?
20 A. I do.
21 Q. What does "significantly superior to placebo
22 with respect to the proportion of patients having

1 detectable enhanced T1 lesions" mean?
2 MS. WHELAN: Object to form.
3 A. It means that there were statistically
4 significantly fewer lesions in the treatment groups
5 than in the placebo group.
6 Q. And in Rice's study were these lesions
7 measured by MRI?
8 A. Yes.
9 Q. And Rice reported that -- Rice reported
10 examining both the mean number -- sorry, please strike
11 that.
12 Rice reported examining both the mean
13 volume and number of such lesions; correct?
14 A. Correct.
15 Q. And Rice reported that both the mean volume
16 and the number of such lesions were significantly
17 superior to placebo with respect to the proportion of
18 patients having detectable enhanced T1 lesions;
19 correct?
20 A. Can I hear that again?
21 Q. I'll rephrase the question. Rice reported
22 that the 0.7-milligram-per-kilogram and the

1 2.1-milligram-per-kilogram cladribine doses were
2 significantly superior to placebo with respect to both
3 the mean volume and the number of detectable enhanced
4 T1 lesions; correct?
5 A. Yes.
6 Q. And the volume of lesions was measured by
7 MRI; correct?
8 A. Yes.
9 Q. Let's go to Page 1148 of Rice and look at
10 Table 1.
11 A. Okay.
12 MS. ELLISON: Emil, if you could please
13 scroll to Page 1148, Table 1. Thank you. That's
14 good.
15 Q. Dr. Lublin, looking at Rice, Page 1148, Table
16 1, do you see on the left-hand column it says
17 Characteristic? Do you see that?
18 A. Yes.
19 Q. And then on the right-hand side there are
20 three columns. Do you see that?
21 A. Yes.
22 Q. And under Placebo, Rice states n equals 54.

1 Do you see that?
2 A. Yes.
3 Q. Under cladribine 0.7 milligrams per kilogram,
4 Rice states n equals 53; correct?
5 A. Yes.
6 Q. And under cladribine 2.1 milligrams per
7 kilogram, Rice states n equals 52; correct?
8 A. Yes.
9 Q. In Table 1 of Rice what does n equals 53
10 mean?
11 A. Number of subjects in that group.
12 Q. In Table 1 of Rice, what does n equals 52
13 mean?
14 A. Number of subjects in that group.
15 Q. We can turn to Page 1153 of Rice, please.
16 I'm going to direct your attention to the right-hand
17 column of Rice, that says, "Cladribine doses of 0.7
18 milligrams per kilogram and 2.1 milligrams per
19 kilogram were well tolerated. The most common adverse
20 events were related to the patients' underlying
21 disease or to SC administration of the study drug.
22 They were mild or moderate in severity, not treatment

1 limiting, and were judged by the investigator to be
2 unrelated to the study drug therapy." Do you see
3 that, Dr. Lublin?
4 A. Yes.
5 Q. So Rice reported mild or moderate-in-
6 severity -- strike that.
7 Rice reported that adverse events were
8 mild or moderate in severity, not treatment-limiting,
9 and were judged by the investigator to be unrelated to
10 the study drug therapy; correct?
11 MS. WHELAN: Object to form.
12 A. Yes.
13 Q. You can put that exhibit away.
14 MS. ELLISON: Emil, if you could please
15 pull up Exhibit 1031, which is Romine.
16 Q. Do you have a copy of Exhibit 1031,
17 Dr. Lublin?
18 A. Yes.
19 Q. I'm going to focus on the abstract, when it's
20 up on the screen or in chat, for anyone who needs it.
21 MS. ELLISON: If you could focus on the
22 abstract, which appears at the beginning, I'd

1 appreciate it. If you could zoom in just a little
2 bit, please. Thank you.
3 Q. Dr. Lublin, you've read the Romine reference
4 that's provided as Exhibit 1031; correct?
5 A. Yes.
6 Q. The question for you is: Romine reported
7 that mild segmental herpes zoster occurred in two
8 cladribine-treated patients and one patient receiving
9 placebo; correct?
10 A. Yes.
11 Q. And Romine reported that otherwise there were
12 no side effects or adverse events; correct?
13 A. Yes.
14 Q. Let me rephrase that last question.
15 Otherwise there were no side effects or adverse events
16 following cladribine treatment; correct?
17 MS. WHELAN: Object to form.
18 A. Well, it was otherwise there were no side
19 effects or adverse events, period.
20 Q. Do you understand Rice to be reporting that,
21 other than mild segmental herpes zoster occurring in
22 two cladribine-treated patients, there were otherwise

1 no side effects or adverse events following treatment?
2 MS. WHELAN: Object to form.
3 A. Two problems. One, it doesn't say following
4 treatment. And second, it's not Rice, it's Romine.
5 Q. Yes, I realized my own mistake, so let me
6 correct my question.
7 Is it your understanding that Romine
8 treated patients with cladribine?
9 A. Yes.
10 Q. And is it your understanding that following
11 treatment with cladribine, Romine -- strike that
12 question.
13 Is it your understanding that Romine
14 assessed side effects and adverse events?
15 A. Yes.
16 Q. And is it your understanding that, other than
17 mild segmental herpes zoster occurring in cladribine-
18 treated patients and one patient receiving placebo,
19 Romine observed no side effects or adverse events in
20 the cladribine-treated patients?
21 MS. WHELAN: Object to form and
22 foundation.

1 A. I've looked this over and now I can answer
2 the question, if you'd repeat it.
3 Q. Is it your understanding that, other than
4 mild segmental herpes zoster occurring in two
5 cladribine-treated patients and one patient receiving
6 placebo, Romine observed no side effects or adverse
7 events in the cladribine-treated patients?
8 MS. WHELAN: Object to form.
9 A. That's what he reports.
10 Q. Do you know what mild segmental herpes zoster
11 is?
12 A. I think it's a mischaracterization.
13 Q. My question is: Do you know what mild
14 segmental herpes zoster is?
15 A. Well, I don't know what he means by mild
16 segmental herpes zoster. But no herpes zoster is
17 mild, and these cases require treatment.
18 Q. What is herpes zoster?
19 A. It's commonly called shingles.
20 Q. What is segmental herpes zoster?
21 A. It means it occurs over a segment of the
22 body -- for example, the upper part of the face or

1 across the body in a nerve distribution.
2 Q. Okay, thank you. You can put that exhibit
3 away, if you'd like.
4 Dr. Lublin, do you have an understanding
5 of the legal requirements for demonstrating unexpected
6 results?
7 MS. WHELAN: Object to form.
8 A. I can give you my understanding.
9 Q. Please do.
10 A. Okay. I understand that unexpected results
11 also weigh in favor of the non-obviousness of a
12 claimed invention.
13 Q. Is that your complete understanding of the
14 legal requirements of what is needed to demonstrate
15 unexpected results?
16 A. No.
17 MS. WHELAN: Object to form.
18 A. I don't know all the legal requirements.
19 Q. Do you know any of the legal requirements of
20 what is needed to demonstrate unexpected results?
21 MS. WHELAN: Object to form.
22 A. I assume one of them is that it's unexpected.

1 Q. Is that the entirety of your -- strike that.
2 Do you have any further understanding of
3 the legal requirements of what is needed to
4 demonstrate unexpected results?
5 MS. WHELAN: Object to form.
6 A. No.
7 Q. When you say that you assume that one of the
8 legal requirements is that it's unexpected, my
9 question is: Is -- in determining whether the results
10 are unexpected, is that a relative term, as you
11 understand it?
12 MS. WHELAN: Object to form.
13 A. It could be relative.
14 Q. You say it could be. Is it your
15 understanding that unexpected results must be relative
16 to something else?
17 MS. WHELAN: Object to form.
18 A. I don't understand that question.
19 Q. In your understanding, how does one determine
20 whether the results are unexpected in demonstrating
21 unexpected results under the law?
22 MS. WHELAN: Object to form.

1 A. I can't give you the legal definition because
2 I haven't had legal training. I can tell you what
3 "unexpected" would mean to a person of ordinary skill.
4 Q. What is your understanding of what is needed
5 to demonstrate unexpected results as you have used
6 that phrase in your declaration?
7 MS. WHELAN: Object to form.
8 A. For my purposes, something that would be
9 unexpected to a person of skill.
10 Q. And as you use the phrase "unexpected
11 results" in your declaration, how did you determine
12 whether something would be unexpected to a person of
13 skill?
14 A. From my knowledge of the field.
15 Q. And how did you determine whether something
16 would have been unexpected versus expected to a person
17 of skill, as you use the phrase "unexpected results"
18 in your declaration?
19 MS. WHELAN: Object to form.
20 A. I'm afraid I don't understand that question.
21 Q. You used the phrase "unexpected results" in
22 your declaration; correct?

1 A. Yes.
2 Q. So I'm trying to understand how you
3 determined whether results were unexpected.
4 MS. WHELAN: Object to form.
5 A. So unexpected results are results that you
6 didn't expect. I don't know how I could clarify it
7 beyond that.
8 Q. What information did you take into
9 consideration in -- strike that.
10 Beyond determining that results are
11 results that you didn't expect, did you consider any
12 other information in reaching the opinions in your
13 declaration regarding unexpected results?
14 MS. WHELAN: Object to form.
15 A. I don't know how to answer that question.
16 Q. You stated earlier that you used the phrase
17 "unexpected results" in your declaration by
18 determining whether something would be unexpected to a
19 person of skill; correct?
20 A. Yes.
21 Q. Beyond determining whether something would be
22 unexpected to a person of skill, did you consider any

1 other factors in assessing the legal concept of
2 unexpected results in your declaration?
3 MS. WHELAN: Object to form.
4 A. I can't comment on legal definitions.
5 Q. I'm just trying to make sure I understand the
6 entirety of how you carried out your analysis
7 regarding unexpected results. What I understood you
8 to say thus far is that you determined whether it
9 would be something that would be unexpected to a
10 person of skill. Is there any other analysis that you
11 did to determine the existence or lack of existence of
12 unexpected results as summarized in your declaration?
13 MS. WHELAN: Object to form.
14 A. You look at a result such as what I refer to
15 here in Paragraph 200, and you make a determination as
16 to whether you expected that or did not. In this
17 case, it was unexpected.
18 Q. In forming the opinions in your declaration
19 regarding unexpected results, did you determine what
20 is the closest prior art?
21 MS. WHELAN: Object to form.
22 Q. Let me back up. Dr. Lublin, do you

1 understand the term "prior art" as it's used in patent
2 law?
3 A. I do.
4 Q. What is your understanding of the meaning of
5 the term "prior art" as it's used in patent law?
6 MS. WHELAN: Object to form.
7 A. Information that's available to a person of
8 skill prior to whatever you're referring to.
9 Q. In forming the opinions in your declaration
10 regarding unexpected results, did you determine what
11 is the closest prior art?
12 MS. WHELAN: Object to form.
13 A. I considered all of the prior art.
14 Q. That's not my question. My question was: In
15 forming the opinions in your declaration regarding
16 unexpected results, did you determine what is the
17 closest prior art?
18 MS. WHELAN: Object to form, asked and
19 answered.
20 MS. ELLISON: That's coaching the witness,
21 and I'm going to tell you to keep it to a one-word
22 objection, per the IPR PTAB rules, and only one word.

1 A. So I was aware of all the prior art. I
2 cannot tell you what you're referring to as the
3 closest prior art.
4 Q. Do you have any concept of the phrase
5 "closest prior art"?
6 MS. WHELAN: Object to form.
7 Q. Strike that question. I'll ask a better
8 question.
9 Do you have an understanding of the legal
10 requirements for determining the closest prior art?
11 MS. WHELAN: Object to form.
12 A. No.
13 Q. In forming the opinions in your declaration
14 regarding unexpected results, did you make any
15 assumptions regarding what is the closest prior art?
16 MS. WHELAN: Object to form.
17 A. I don't know, because I don't understand the
18 term, as you're using it.
19 Q. You don't understand the term "closest prior
20 art"; correct?
21 A. In the legal --
22 MS. WHELAN: Object to form.

1 A. In the legal setting.
2 Q. Do you have an understanding of the term
3 "closest prior art" in any other setting?
4 MS. WHELAN: Object to form.
5 Q. Strike that. Do you have an understanding of
6 the phrase "closest prior art" in any setting?
7 MS. WHELAN: Object to form.
8 A. I would assume the plain and ordinary meaning
9 of the words.
10 Q. And what's your understanding of the phrase
11 "closest prior art" when you assume the plain and
12 ordinary meaning of the words?
13 MS. WHELAN: Object to form.
14 A. Something that was available for review or
15 information right before the event you're discussing.
16 Q. In forming the opinions in your declaration
17 regarding unexpected results, did you make any
18 assumptions regarding what is the closest prior art?
19 MS. WHELAN: Object to form.
20 A. No.
21 Q. In forming the opinions set forth in your
22 declaration regarding unexpected results, did you make

1 any comparisons with the closest prior art?
2 MS. WHELAN: Object to form.
3 A. I compared it to all the prior art.
4 Q. In forming the opinions set forth in your
5 declaration regarding unexpected results, did you --
6 strike that.
7 Do you have an understanding of the legal
8 requirements to demonstrate skepticism in the context
9 of assessing obviousness?
10 MS. WHELAN: Object to form.
11 A. Yes.
12 Q. What is your understanding of the legal
13 requirements for demonstrating skepticism in the
14 context of assessing obviousness?
15 A. My understanding is that I understand that
16 evidence of skepticism of a claimed invention can
17 weigh in favor of the nonobviousness of an invention.
18 This is because doubt or disbelief by skilled artisans
19 about the likely success of a solution suggests that
20 they would not have combined or modified references to
21 achieve the claimed invention.
22 Q. Is the testimony that you just provided the

1 entirety of your understanding regarding the legal
2 requirements for demonstrating skepticism in the
3 context of assessing obviousness?
4 MS. WHELAN: Object to form.
5 A. Yes.
6 Q. Let's look at Exhibit 2005, which is a
7 publication from Miller, 2000.
8 MS. ELLISON: Emil, if you could please
9 bring it up to the screen.
10 Emil, if you could please turn to -- first
11 let me ask this:
12 Q. Dr. Lublin, do you recognize Exhibit 2005?
13 A. I do.
14 Q. What is it?
15 A. It's a text. Rosalind Kalb is the editor,
16 and it's called Multiple Sclerosis: The Questions You
17 Have - the Answers You Need.
18 Q. And you've seen Exhibit 2005 before; correct?
19 A. Yes.
20 MS. ELLISON: Emil, could you please turn
21 to Page 25.
22 A. What page?

1 Q. 25.
2 A. Did you say two five? I don't have a 25.
3 Q. With the native page numbering.
4 A. I don't have native pages.
5 Q. Bear with me for a second, please.
6 My apologies. If you could please turn to
7 native Page No. 45.
8 MS. ELLISON: Keep scrolling. That's
9 good.
10 Q. Dr. Lublin, have you previously read Page 45
11 of Exhibit 2005?
12 A. Yes.
13 Q. And what is generally -- let me ask this:
14 Does Page 45 report -- does Page 45 of
15 Exhibit 2005 include a report from Dr. Aaron Miller
16 regarding cladribine?
17 MS. WHELAN: Object to form.
18 A. Aaron Miller and Robert Herndon.
19 Q. On Page 45 of Exhibit 2005, Dr. Miller and
20 his co-author state, quote, "In recently completed
21 trials of oral myelin, cladribine, and sulfasalazine,
22 these agents were found not to be of benefit." Do you

1 see that?
2 A. I do.
3 Q. Do Dr. Miller and his co-author cite the
4 Stelmasiak paper we have discussed during this, which
5 is Exhibit 1013?
6 A. I don't see references.
7 Q. In Exhibit 2005 did Dr. Miller and his
8 co-author cite Romine's 1999 paper that we have
9 discussed in this deposition, which is Exhibit 1031?
10 MS. WHELAN: Object to form.
11 A. I don't see any citations in this document.
12 Q. In Exhibit 2005 does Dr. Miller discuss oral
13 administration of cladribine?
14 MS. WHELAN: Object to form.
15 A. It just says cladribine.
16 Q. In Exhibit 2005 does Dr. Miller discuss any
17 particular dosing regimen for administering
18 cladribine?
19 MS. WHELAN: Object to form.
20 A. No.
21 Q. Let's also look at Page 67 of Exhibit 2005.
22 MS. ELLISON: Emil, if you could please

1 scroll to Page 67. Scroll down just a little bit,
2 just before the paragraph that starts "Thus." Keep
3 scrolling. There you go.
4 Q. Dr. Lublin, on Page 67 of Exhibit 2005 Dr.
5 Miller states, "A trial of cladribine failed to show
6 benefit in progressive disease." Do you see that?
7 A. I do.
8 Q. Here does Dr. Miller cite the Stelmasiak
9 reference you've been discussing during this
10 deposition, which is Exhibit 1013?
11 MS. WHELAN: Object to form.
12 A. There are no citations in this document.
13 Q. Okay. And so Dr. Miller also does not cite
14 Romine's 1999 paper that is Exhibit 1031 in this case;
15 correct?
16 MS. WHELAN: Object to form and
17 foundation.
18 A. There are no citations in this document.
19 Q. On Page 67 of Exhibit 2005 does Dr. Miller
20 discuss oral administration of cladribine?
21 MS. WHELAN: Object to form.
22 A. It says, "A trial of cladribine failed to

1 show benefit in progressive disease." That's the
2 extent of what's mentioned of cladribine.
3 Q. So it doesn't mention oral administration;
4 correct?
5 A. Correct.
6 Q. At Page 67 does Dr. Miller discuss any
7 particular dosing regimen for administering
8 cladribine?
9 MS. WHELAN: Object to form.
10 A. No.
11 Q. You can put that exhibit away, if you'd like.
12 MS. ELLISON: Emil, can you pull out
13 Exhibit 2004, which is from El-Moslimany, please.
14 Q. Dr. Lublin, do you recognize Exhibit 2004?
15 A. Yes.
16 Q. And what is it?
17 A. It's from a text called Multiple Sclerosis:
18 A Comprehensive Text.
19 Q. When was it published?
20 A. 2008.
21 Q. If we could turn to Page 341, please.
22 A. Okay.

1 MS. ELLISON: Emil, if you could zoom in,
2 because I surely cannot read that, please. We're
3 looking for the language that starts -- paragraph that
4 starts, "In one study, 51 patients." I think it's on
5 the left there. If you can zoom in a little further.
6 Q. Okay, so Dr. Lublin, we're looking at Exhibit
7 2004, the El-Moslimany reference from 2008, looking at
8 Page 341.
9 Do you see on the left-hand column the
10 author writes, "In one study, 51 patients with MS
11 (mostly secondary progressive) were randomized to
12 cladribine treatment consisting of four monthly, 7-day
13 infusions (0.1 milligrams per kilogram per day) or
14 placebo"? Citation 147. Do you see that?
15 A. I do.
16 MS. ELLISON: If you could scroll down.
17 There's a paragraph that begins, "In a subsequent
18 multicenter." Right there.
19 Q. So farther down on Page 341, Dr. Lublin, do
20 you see the paragraph that begins, "In a subsequent
21 multicenter, double blind, placebo-controlled trial
22 done to evaluate the safety and efficacy of cladribine

1 in progressive MS," citation 148, "no significant
2 treatment effects were found for cladribine using the
3 Expanded Disability Status Scale scores"? Do you see
4 that?
5 A. I do.
6 Q. Does the El-Moslimany paper that's provided
7 as Exhibit 2004 cite to the Stelmasiak paper we've
8 discussed, which is Exhibit 1013?
9 A. No.
10 Q. Does El-Moslimany cite Romine's 1999 paper
11 that we've looked at, which is Exhibit 1031?
12 MS. WHELAN: Object to form.
13 A. Not directly.
14 Q. Does El-Moslimany discuss administering
15 cladribine orally?
16 MS. WHELAN: Object to form.
17 A. No.
18 Q. Does the El-Moslimany reference that's
19 provided as Exhibit 2004 discuss any particular dosing
20 regimen for administering cladribine?
21 MS. WHELAN: Object to form.
22 A. Yes.

1 Q. Where do you see El-Moslimany discussing a
2 particular dosing regimen for administering
3 cladribine?
4 A. In the studies that were discussed in some
5 detail.
6 Q. And does the El-Moslimany reference express
7 skepticism about administering cladribine with any
8 particular dosing regimen?
9 MS. WHELAN: Object to form.
10 A. Can I hear the question again?
11 Q. Does the El-Moslimany reference that we
12 provided as Exhibit 2004 express skepticism regarding
13 any particular dosing regimen for administering
14 cladribine?
15 MS. WHELAN: Object to form.
16 A. It provides skepticism for all of the
17 cladribine studies to date.
18 Q. You can set that reference aside, if you'd
19 like.
20 MS. ELLISON: Emil, can you please pull up
21 Exhibit 2031.
22 Q. Dr. Lublin, do you have a copy of Exhibit

1 2031?
2 A. I do now.
3 Q. Dr. Lublin, do you recognize Exhibit 2031?
4 A. I do.
5 Q. What is it?
6 A. Sorry?
7 Q. What is it? What is Exhibit 2031?
8 A. This is part of a text from the McAlpine's
9 Multiple Sclerosis text.
10 Q. And have you previously read Exhibit 2031?
11 A. I have.
12 Q. When was the text that's provided as Exhibit
13 2031 published?
14 A. 2006.
15 Q. Where on Exhibit 2031 do you see a 2006
16 publication date?
17 A. On the second page, at the top.
18 MS. ELLISON: Could you Zoom in, please,
19 Emil.
20 Q. And when was the text that's provided as
21 Exhibit 2031 first published?
22 A. It says first published December, 2005, and

1 the copyright is 2006.
2 Q. If we could please turn to Page 753.
3 Dr. Lublin, Exhibit 2031 is a publication by
4 Noseworthy; correct?
5 A. I didn't get there yet.
6 The authors are Noseworthy, Miller, and
7 Compston. And what page are we going to?
8 Q. 753. On Page 753 Noseworthy discusses
9 several cladribine clinical studies; correct?
10 A. Yes.
11 Q. Noseworthy discusses a clinical study by Sipe
12 et al. in 1994 -- correct? -- on Page 753?
13 A. Yes.
14 Q. And on Page 753 Noseworthy also discusses a
15 clinical study by Beutler et al., 1976; correct?
16 A. Yes.
17 Q. And on Page 753 Noseworthy also discusses a
18 clinical study by Romine et al., 1999; correct?
19 A. Yes.
20 Q. And at Page 753 Noseworthy discusses a
21 clinical study by Rice et al. in 2000; correct?
22 A. Yes.

1 Q. In Exhibit 2031 does Noseworthy cite the
2 Stelmasiak reference we've discussed today, that's
3 provided as Exhibit 1015?
4 A. No.
5 Q. In Exhibit 2031 does Noseworthy express
6 skepticism about administering cladribine orally?
7 MS. WHELAN: Object to form.
8 A. I don't see oral called out specifically.
9 Q. In Exhibit 2031 does Noseworthy express
10 skepticism about administering cladribine according to
11 any particular dosing regimen?
12 MS. WHELAN: Object to form.
13 A. No.
14 Q. Thank you. You can set that reference aside
15 for now, if you'd like. And let's turn to Exhibit
16 2011.
17 MS. ELLISON: Emil, could you please put
18 that up on the screen.
19 MS. WHELAN: Counsel, we've been going
20 quite a while now. Is it a good time for a lunch
21 break soon?
22 MS. ELLISON: Yeah. We can either take a

1 break now, or it might take me ten more minutes to get
2 through the rest of this section. Your choice.
3 Q. Do you have a preference, Dr. Lublin?
4 A. I don't.
5 MS. ELLISON: Let's take a break now,
6 since you asked for it. Let's go off the record.
7 (Recess for lunch.)
8 MS. ELLISON: Let's go back on the record.
9 Q. Dr. Lublin, during the break did you speak
10 with anyone regarding the substance of your testimony
11 today?
12 A. No.
13 Q. And during the break, Dr. Lublin, did you
14 access any information regarding the deposition other
15 than the exhibits that have been presented during this
16 deposition?
17 A. No.
18 Q. Thanks. Dr. Lublin, do you have an
19 understanding of the legal requirements for
20 demonstrating long-felt need in the context of
21 obviousness?
22 MS. WHELAN: Object to form.

1 A. The extent of my understanding is -- I
2 understand that evidence of a long-felt but unresolved
3 need can weigh in favor of the nonobviousness of the
4 claimed invention. This is because a long-felt need
5 reasonably would have been resolved if its solution
6 were obvious.
7 Q. Do you have any additional understanding of
8 the legal requirements for demonstrating long-felt
9 need?
10 MS. WHELAN: Object to form.
11 A. No.
12 Q. Can a long-felt need be satisfied without FDA
13 approval of a therapy?
14 MS. WHELAN: Object to form.
15 A. I'm not sure.
16 MS. ELLISON: Emil, can you pull up
17 Exhibit 2038, please.
18 Q. Dr. Lublin, do you have a copy of Exhibit
19 2038?
20 A. Coming.
21 I do now.
22 Q. We also have Exhibit 2038 on the screen, and

1 I believe it has been shared in chat.
2 Dr. Lublin, are you familiar with Exhibit
3 2038?
4 A. I am.
5 Q. What is Exhibit 2038?
6 A. It's a news blurb from Fierce Biotech, which
7 is a news service that tends to follow pharmaceutical
8 news.
9 Q. And Exhibit 2038 is titled Merck Receives
10 Complete Response Letter From FDA on Cladribine
11 Tablets New Drug Application. Correct?
12 A. Yes.
13 Q. Does Exhibit 2038 identify any safety
14 concerns that the FDA had with Merck's cladribine
15 tablets?
16 MS. WHELAN: Object to form.
17 A. Can I hear the question again?
18 Q. Does Exhibit 2038 identify any safety
19 concerns that the FDA had with Merck's cladribine
20 tablets?
21 MS. WHELAN: Object to form.
22 A. What it says is, "The FDA has requested the

1 company provide an improved understanding of safety
2 risks and overall benefit/risk profile."
3 Q. Does Exhibit 2038 identify any particular
4 safety concerns that the FDA had regarding Merck's
5 cladribine tablets?
6 MS. WHELAN: Object to form.
7 A. I don't see a specific concern.
8 Q. Do you know how -- strike that.
9 Do you know whether Merck addressed any
10 safety concerns from the FDA?
11 MS. WHELAN: Object to form.
12 A. Well, they must have.
13 Q. Do you know whether Merck made any changes --
14 strike that.
15 Is it your understanding that Exhibit 2038
16 relates to Merck's drug product known as Mavenclad?
17 MS. WHELAN: Object to form.
18 A. Let me hear the question again.
19 Q. Is it your understanding that Exhibit 2038
20 relates to Merck's drug product known as Mavenclad?
21 MS. WHELAN: Object to form.
22 A. Yes.

1 Q. In response to the FDA's complete response
2 letter that is mentioned in Exhibit 2038, did Merck
3 make any changes to Merck's Mavenclad dosing regimen?
4 A. Not that I'm aware of.
5 Q. You can set that exhibit aside, if you'd
6 like.
7 MS. ELLISON: Emil, could you please put
8 Exhibit 1001 from each of the two proceedings in the
9 chat.
10 Q. And Dr. Lublin, these are the '947, '903
11 issues that are at issue in this proceeding. Does
12 counsel have copies of those for you?
13 MS. WHELAN: We only have paper copies of
14 the '947.
15 MS. ELLISON: You don't have a paper copy
16 of the '903; is that correct?
17 MS. WHELAN: That is correct.
18 Q. We can start looking at '947.
19 MS. ELLISON: Emil, if you could please
20 put a copy of the '947 patent, which is Exhibit 1001
21 from IPR2023-00480, if you could put that in the chat
22 and pull it up on the screen, please.

1 Great. And Emil, if you could please
2 scroll to the end. Scroll up a little. Sorry. Thank
3 you. Scroll up a little bit now, please.
4 Actually, can I take control of this
5 exhibit, please? Thank you.
6 Q. Dr. Lublin, you have a paper copy of U.S.
7 Patent No. 7,713,947, which is Exhibit 1001, in front
8 of you; correct?
9 A. I do.
10 Q. And I'm going to refer to this most likely as
11 the '947 patent. Do you understand that?
12 A. I do.
13 Q. Great. Before signing your declaration in
14 these IPRs, did you read the '947 patent?
15 A. I did.
16 Q. And before signing your declaration, did you
17 read the claims of the '947 patent?
18 A. I did.
19 Q. Is it your understanding that claims 36, 38,
20 39, and 41 to 46 of the '947 patent are at issue in
21 IPR2023-00480?
22 A. This is the wrong one.

1 My understanding of the challenges are to
2 claims 36, 38, 39, and 41 to 46 of the '947 patent.
3 Q. Thank you. We have those same claims on the
4 screen right now, in case you would prefer to refer to
5 the screen instead of your paper copy. But it's your
6 choice.
7 So Dr. Lublin, I'm going to ask you some
8 questions regarding the claims of the '947 patent
9 that's been provided as Exhibit 1001 in this
10 proceeding. But when I refer to the claims, I'm
11 referring only to the claims that are at issue in this
12 proceeding, namely claims 36, 38, 39, and 41 to 46.
13 Do you understand that?
14 A. I do.
15 Q. Thank you. Do you have an understanding of
16 what is claimed in the '947 patent?
17 A. My understanding is what's written here.
18 Q. Do the claims of the '947 patent require
19 administering cladribine to a patient having a
20 particular weight?
21 MS. WHELAN: Object to form.
22 A. Let me hear the question again.

1 Q. Do the claims of the '947 patent require
2 administering cladribine to a patient having a
3 particular weight?
4 MS. WHELAN: Object to form.
5 A. Not that I see.
6 Q. Do the claims of the '947 patent exclude
7 administering cladribine to a patient of a particular
8 weight?
9 MS. WHELAN: Object to form.
10 A. I don't see a weight exclusion.
11 Q. Do the claims of the '947 patent require any
12 particular degree of efficacy in its methods of
13 treating multiple sclerosis?
14 MS. WHELAN: Object to form.
15 A. Can I hear that question again?
16 Q. Do the claims of the '947 patent require any
17 particular degree of efficacy in its methods of
18 treating multiple sclerosis?
19 MS. WHELAN: Object to form, calls for a
20 legal conclusion.
21 MS. ELLISON: Emily, one-word objections.
22 That's what the rules require. You know that.

1 A. Well, the claim calls for treating multiple
2 sclerosis.
3 Q. That's not my question. My question is: Do
4 the claims of the '947 patent require any particular
5 degree of efficacy in its methods of treating multiple
6 sclerosis?
7 MS. WHELAN: Same objections.
8 A. No, not that I see.
9 Q. Do the claims of the '947 patent require that
10 the effects of cladribine be related to the dose of
11 cladribine per kilogram of body weight?
12 MS. WHELAN: Same objections.
13 A. Let me hear it again, please.
14 Q. Do the claims of the '947 patent require that
15 the effects of cladribine be related to the dose of
16 cladribine per kilogram of body weight?
17 MS. WHELAN: Same objections.
18 A. No.
19 Q. You can set the '947 patent aside.
20 MS. ELLISON: Emil, if you could take down
21 the '947 patent and bring up Exhibit 1001 from
22 IPR2023-00481.

1 Q. Dr. Lublin, we're going to look at the '903
2 patent.
3 A. I have it.
4 MS. WHELAN: We've got a paper copy.
5 Q. So you have a paper copy of the '903 patent
6 in front of you, and we'll just give Emil a minute to
7 put Exhibit 1001 up on the screen.
8 MS. ELLISON: Thank you, Emil. If you'd
9 give me control, I'd appreciate it. Thank you.
10 Q. Dr. Lublin, do you recognize Exhibit 1001
11 from IPR2023-00481?
12 A. I do.
13 Q. And this exhibit is a copy of U.S. Patent No.
14 8,377,903; correct?
15 A. Yes.
16 Q. And Dr. Lublin, is it your understanding that
17 claims 19, 20, 22 through 27 of the '903 patent are at
18 issue in IPR2023-00481?
19 A. I have also included claim 17.
20 Q. Thank you.
21 A. Do you?
22 Q. I get to ask the questions today, Dr. Lublin.

1 My apologies. I'm tired, too.
2 I get to ask the questions today,
3 Dr. Lublin.
4 So Dr. Lublin, I'm going to ask you some
5 questions about the claims of the '903 patent, and
6 when I refer to the claims, I'm only going to refer to
7 the claims that are at issue in this proceeding. Do
8 you understand that?
9 A. Well, I'm not sure I understand which claims
10 are at issue.
11 Q. Okay. I'm going to ask you questions today,
12 Dr. Lublin, and I'm going to refer to claims 17, 19,
13 20, and 22 through 27 of the '903 patent. Do you
14 understand that?
15 A. I do.
16 Q. So when I refer to the claims, I'm referring
17 to claims 19, 20 -- let me try that again. When I
18 refer to the claims, I'm referring to claims 17, 19,
19 20, and 22 through 27 of the '903 patent. Okay?
20 A. Okay.
21 Q. Dr. Lublin, do you have an understanding of
22 what is claimed in the '903 patent?

1 A. Yes.
2 Q. Do the claims of the '903 patent require
3 administering cladribine to a patient having a
4 particular weight?
5 MS. WHELAN: Object to form.
6 A. No.
7 Q. Do the claims of the '903 patent exclude
8 administering cladribine to a patient of a particular
9 weight?
10 MS. WHELAN: Object to form.
11 A. Not that I'm aware of.
12 Q. Do the claims of the '903 patent -- sorry,
13 and I'll scroll on the screen to the claims, so you
14 maybe can look at this. My apologies.
15 Do the claims of the '903 patent require
16 any particular degree of efficacy in its methods of
17 treating multiple sclerosis?
18 MS. WHELAN: Object to form.
19 A. Not that I see.
20 Q. Do the claims of the '903 patent require that
21 the effects of cladribine be related to its dose per
22 kilogram of body weight?

1 MS. WHELAN: Object to form.
2 A. Not that I see.
3 Q. Do the claims of the '903 patent require any
4 particular dosage form of cladribine?
5 MS. WHELAN: Object to form.
6 A. What do you mean by "dosage form"?
7 Q. Dr. Lublin, do you have an understanding of
8 what a dosage form is?
9 A. I want to know what you're referring to as a
10 dosage form.
11 Q. That wasn't my question. My question is: Do
12 you have an understanding of what a dosage form is?
13 A. Yeah, the formulation or form in which the
14 dose is given.
15 Q. So let me ask this question again, or a
16 slightly different question. Do the claims of the
17 '903 patent require any particular oral dosage form of
18 cladribine?
19 MS. WHELAN: Object to form.
20 A. They require an oral dosage.
21 Q. Beyond requiring an oral dosage form, do the
22 claims of the '903 patent require any particular oral

1 dosage form of cladribine?
2 MS. WHELAN: Object to form.
3 A. It just says "oral administration of a
4 formulation comprising cladribine."
5 Q. So my question is: Do the claims of the '903
6 patent require any particular oral dosage form of
7 cladribine?
8 MS. WHELAN: Object to form.
9 A. I can't answer that question because I don't
10 understand it.
11 Q. What don't understand about the question,
12 Dr. Lublin?
13 A. I don't understand what you're asking me.
14 Q. Do you understand what an oral dosage form
15 is?
16 A. Yeah, it's something that you take by mouth.
17 Q. In 2004 were you aware of various oral dosage
18 forms?
19 A. Again, I don't know what you're -- what that
20 means.
21 Q. Are you aware of various oral dosage forms of
22 cladribine that existed in 2004?

1 MS. WHELAN: Object to form.
2 A. I don't know that I would know the full range
3 of what was orally available in 2004.
4 Q. Are oral solutions of cladribine an oral
5 dosage form of cladribine?
6 A. Yes.
7 Q. Are oral suspensions of cladribine an oral
8 dosage form of cladribine?
9 A. Yeah, I think so.
10 Q. Are oral tablets an oral dosage form of
11 cladribine?
12 A. Yes.
13 Q. Are oral capsules an oral dosage form of
14 cladribine?
15 A. Yes.
16 Q. Are oral mucoadhesive tablets an oral dosage
17 form of cladribine?
18 A. I suppose so. Yeah, it goes into the mouth;
19 it's oral.
20 MS. ELLISON: Something just happened on
21 the screen. Thank you.
22 Q. Do the claims of the '903 patent require any

1 of the oral dosage forms we just -- strike that.
2 So we just discussed various oral dosage
3 forms of cladribine; correct, Dr. Lublin?
4 A. Yes.
5 Q. The question is: Do the claims of the '903
6 patent require any particular oral dosage form of
7 cladribine?
8 MS. WHELAN: Object to form.
9 A. No particular form is called out.
10 Q. And do you still have the '947 patent in
11 front of you, or near you?
12 A. I do.
13 Q. Do the claims of the '947 patent require any
14 particular oral dosage form of cladribine?
15 MS. WHELAN: Object to form.
16 A. Not that I see.
17 Q. You still have the '947 in front of you;
18 correct?
19 A. Yes.
20 Q. Do the claims of the '947 patent require any
21 particular metric for assessing clinical efficacy of
22 the claimed treatment methods?

1 MS. WHELAN: Object to form.
2 A. You're asking me if the claims define a
3 metric?
4 Q. Do the claims of the '947 patent require any
5 particular metric for assessing clinical efficacy of
6 the claimed treatment method?
7 MS. WHELAN: Object to form.
8 A. Not that I see.
9 Q. And if you could turn back to the '903
10 patent, please. Dr. Lublin, do the claims of the '903
11 patent require any particular metric for assessing
12 clinical efficacy of the claimed treatment method?
13 MS. WHELAN: Object to form.
14 A. Not that I see.
15 Q. You can set that aside for now.
16 Dr. Miller -- I apologize. Dr. Lublin, do
17 you still have the '947 patent near you, please? I'm
18 going to ask another question.
19 A. Okay.
20 Q. Looking at the '947 patent claims,
21 Dr. Lublin: In your view, must one know a patient's
22 weight before administering cladribine according to

1 the methods claimed in the '947 patent?
2 MS. WHELAN: Object to form.
3 A. Yes.
4 Q. In your view, do the claims of the '947
5 patent require knowing a patient's weight before
6 cladribine is administered?
7 MS. WHELAN: Object to form.
8 A. Yes.
9 Q. And if you could turn to the '903 patent,
10 please, Dr. Lublin.
11 A. I have it.
12 Q. Great. Dr. Lublin, in your view, do the
13 claims of the '903 patent require knowing a patient's
14 weight before cladribine is administered to the
15 patient?
16 MS. WHELAN: Object to form.
17 A. Yes.
18 Q. Looking at the '903 patent claims,
19 Dr. Lublin: Are the claims of the '903 patent limited
20 to administering two treatment courses with
21 cladribine?
22 MS. WHELAN: Object to form.

1 A. The claims describe the induction period and
2 a maintenance period. So that's two courses.
3 Q. Do the claims of the '903 patent encompass
4 administering more than two treatment courses with
5 cladribine?
6 MS. WHELAN: Object to form.
7 A. Not that I see.
8 Well, hold on a second.
9 Let me hear the question again.
10 Q. Do the claims of the '903 patent encompass
11 administering more than two treatment courses of
12 cladribine?
13 MS. WHELAN: Object to form.
14 A. Yes.
15 Q. Let's look at the '947 patent claims.
16 A. Okay.
17 Q. Do the claims of the '947 patent encompass
18 administering more than two treatment courses of
19 cladribine?
20 MS. WHELAN: Object to form.
21 A. Yes.
22 Q. You have the '903 and '947 patents in front

1 of you; right, Dr. Lublin?
2 A. Yes.
3 Q. The claims of the '903 patent and the '947
4 patent are almost identical; right?
5 MS. WHELAN: Object to form.
6 A. They're very similar.
7 Q. They recite the same cladribine dosing
8 regimen; right?
9 MS. WHELAN: Object to form.
10 A. Yes.
11 Q. And the only difference between the claims of
12 the '947 patent and the '903 patent is that the '903
13 claims recite a method of treating RRMS or early SPMS
14 with the dosing regimen, whereas the '947 patent
15 recites a method of treating MS more generally with
16 that same dosing regimen; correct?
17 MS. WHELAN: Object to form.
18 A. Those two characterizations are correct.
19 Q. So in 2004, when you went about treating --
20 strike that.
21 So in 2004 if one knew about the method of
22 treating RRMS and ESPMS using the dosing regimen

1 recited in the '903 patent claims, would it have been
2 obvious to use that same treatment method to treat MS
3 more generally?
4 MS. WHELAN: Object to form and
5 foundation.
6 A. Let me hear that again.
7 Q. In 2004 if one knew about the method of
8 treating RRMS and ESPMS using the dosing regimen
9 that's recited in the '903 patent claims, would it
10 have been obvious for them to use that same treatment
11 regimen to treat MS more generally?
12 MS. WHELAN: Object to form and foundation
13 and scope.
14 A. No.
15 Q. Do you agree that the single largest unmet
16 need in treating multiple sclerosis is the treatment
17 of progressive disease?
18 MS. WHELAN: Object to form and
19 foundation.
20 A. At what time point?
21 Q. Start with now.
22 A. Now?

1 Q. Yes, sir.
2 A. Yes. Now, treating progressive disease is a
3 significant challenge, and an important one.
4 Q. Was this also true in 2004?
5 MS. WHELAN: Object to form.
6 A. It was true in 2004, but there were also
7 pressing needs for relapsing-remitting disease as
8 well.
9 Q. And was it true in 2016 that the single
10 largest unmet need in treating multiple sclerosis was
11 the treatment of progressive disease?
12 MS. WHELAN: Object to form and
13 foundation.
14 A. In the year 2016, yeah, progressive disease
15 was an important unmet need.
16 Q. If a treatment is shown to work in treating
17 relapsing disease in multiple sclerosis, would you
18 expect it to work in treating progressive disease?
19 MS. WHELAN: Object to form.
20 A. You wouldn't know how to answer that until
21 you actually studied it in both forms of the disease.
22 Q. Does the '947 patent include a study

1 assessing cladribine for the treatment of progressive
2 disease in MS?
3 MS. WHELAN: Object to form.
4 A. Could I hear the question again?
5 Q. Does the '947 patent include a study that
6 assessed cladribine for the treatment of progressive
7 disease in multiple sclerosis?
8 MS. WHELAN: Object to form.
9 A. You said progressive disease; right?
10 Q. Yes, sir.
11 A. And can I assume you're not discussing the
12 progressive studies that are referenced in the
13 patent -- prior studies?
14 Q. You can answer the question both ways, then,
15 please.
16 A. Well, there's a discussion of some prior
17 studies in progressive disease. And there -- I'm
18 sorry?
19 Q. I was just going to ask to what are you
20 referring specifically?
21 A. Column 2 on page 3.
22 Q. What line -- column 2, what line?

1 A. Multiple lines, I guess starting at 30.
2 Q. And ending where?
3 A. Page 3, line 2.
4 Q. So earlier I asked does the '947 patent
5 include a study that assessed cladribine for the
6 treatment of progressive disease in multiple
7 sclerosis. In answering that question, do you wish to
8 direct me to anywhere else in the '947 patent?
9 MS. WHELAN: Object to form.
10 A. Yes.
11 Q. Where else?
12 A. I'm working on it.
13 Okay, page 6, paragraph 8, line 16 -- 17.
14 Q. Sorry, if you don't mind, could you refer to
15 the column number and the line number?
16 A. Page 6, column 8, line 17.
17 Q. Just line 17 or any additional lines?
18 A. Well, it runs from line 17, line 18.
19 Q. Anywhere else in the patent?
20 A. I think that's all I can find.
21 Q. Dr. Lublin, I'm going to ask you to turn to
22 the examples that are provided in the '947 patent.

1 A. Okay.
2 Q. Did the examples that are provided in the
3 '947 patent include a study that assessed cladribine
4 for the treatment of progressive disease in multiple
5 sclerosis?
6 MS. WHELAN: Object to form.
7 A. Yes.
8 Q. Which example in the '947 patent included a
9 study that assessed cladribine for the treatment of
10 progressive disease in multiple sclerosis?
11 A. Page 9, column 14, line 24 -- either 24 or
12 23.
13 Q. We have up on the screen the '947 patent,
14 column 14, page 9. Which line are you referring to,
15 24, 23, what is the language?
16 A. "A study of sixty patients."
17 Q. So my question -- so you're referring to the
18 line which says, "A study of sixty patients with
19 relapsing forms of clinically definite multiple
20 sclerosis is undertaken"? Is that correct?
21 A. Yes.
22 Q. My question was: Do the examples in the '947

1 patent include a study that assessed cladribine for
2 the treatment of progressive disease in multiple
3 sclerosis?
4 MS. WHELAN: Object to form.
5 A. Secondary progressive multiple sclerosis is a
6 relapsing form of multiple sclerosis, so it's included
7 in that group.
8 Q. Does the '947 patent provide any clinical
9 data for treating progressive disease in multiple
10 sclerosis?
11 MS. WHELAN: Object to form.
12 A. I'm sorry, what do you mean by "clinical
13 data"?
14 Q. Do you have an understanding of what clinical
15 data are?
16 A. There are thousands of clinical datas, maybe
17 millions. You need to be more specific. Clinical
18 data includes the demographics, and it includes
19 baseline, includes results. So perhaps you could help
20 me.
21 Q. Does the '947 patent include any results of
22 using cladribine for treating progressive forms of

1 multiple sclerosis?
2 MS. WHELAN: Object to form.
3 A. It does have some clinical results.
4 Q. Where does the '947 patent describe clinical
5 results in patients having progressive forms of
6 multiple sclerosis?
7 A. As I mentioned earlier, some progressive
8 patients fit into the characterization of this study,
9 which was relapsing forms of MS. And then on page 10,
10 paragraph 16, line 23, "patients in Groups 2 and 3
11 have a decrease in brain lesions." And then going
12 down, "The data show that the two CDA regimen
13 consisting of a succession of an induction treatment
14 and maintenance treatment is efficient in decreasing
15 brain lesions, and no severe adverse effects
16 observed."
17 Q. When you said paragraph 16, you're referring
18 to column 16; correct?
19 A. If I said paragraph, I'm sorry. It's column.
20 Q. Where in column 16 does the '947 patent say
21 that the patients in Groups 2 and 3 had progressive
22 forms of MS?

1 A. It doesn't. They're included in the
2 inclusion criteria for the study.
3 Q. If a certain category of patients are
4 included in inclusion criteria for the study, does
5 that necessarily mean that those patients necessarily
6 actually were included?
7 MS. WHELAN: Object to form.
8 A. I can't answer that.
9 Q. So if inclusion criteria are open to
10 including patients having progressive forms of MS, do
11 those inclusion criteria mean that patients having
12 progressive forms of MS necessarily were included in
13 the study?
14 MS. WHELAN: Object to form.
15 A. It's not an answerable question.
16 Q. Why not?
17 A. We don't have the data.
18 Q. So without the data, you can't be certain
19 that the patients included in the study had
20 progressive forms of MS; correct?
21 MS. WHELAN: Object to form.
22 A. That's correct.

1 Q. Does the '947 patent include any results of
2 using cladribine for treating primary progressive MS?
3 A. No.
4 Q. Let's look at the '903 patent claims. The
5 '903 patent claims provided a method of treating RRMS
6 or early secondary progressive MS; correct?
7 A. Yes.
8 Q. In the '903 patent it states that four
9 courses -- strike that.
10 The '903 patent refers to four courses of
11 multiple sclerosis; correct?
12 MS. WHELAN: Object to form.
13 A. Can you point me to where you're seeing that?
14 Q. Let's look at column 1, lines 48 to 50.
15 A. Okay.
16 Q. Let's look at column 1. Just a second.
17 So in column 1 -- let me start over.
18 The '903 patent refers to four courses of
19 multiple sclerosis that are individualized -- namely,
20 relapsing-remitting, secondary progressive, primary
21 progressive, and progressive relapsing multiple
22 sclerosis; correct?

1 A. Yes.
2 Q. Early secondary progressive MS is not one of
3 the four enumerated courses of multiple sclerosis
4 discussed in the '903 patent; correct?
5 MS. WHELAN: Object to form.
6 A. It's not mentioned in this particular
7 paragraph.
8 Q. And if you look at the '903 patent at column
9 1, lines 50 to 65, the patent discusses the four
10 courses of MS -- namely, relapsing-remitting,
11 secondary progressive, primary progressive, and
12 progressive relapsing MS. Correct?
13 MS. WHELAN: Object to form.
14 A. Isn't that what we just established?
15 Q. I was just looking at additional text. I was
16 directing your attention to column 1, lines 50 to 65.
17 A. But the four courses start above that.
18 Q. Yes. So in column 1 the '903 patent refers
19 to four courses of MS -- namely, relapsing-remitting,
20 secondary progressive, primary progressive, and
21 progressive relapsing multiple sclerosis. Correct?
22 A. Yes.

1 Q. And column 1 does not refer to early
2 secondary progressive MS; correct?
3 MS. WHELAN: Object to form.
4 A. Correct.
5 Q. Does the '903 patent define what early
6 secondary progressive MS is?
7 MS. WHELAN: Object to form.
8 A. I don't see a definition.
9 Q. Let's look at the '947 patent again. If you
10 could turn to column 1, the first column in the '947.
11 Dr. Lublin, the '947 patent also states that four
12 courses of MS are individualized -- namely,
13 relapsing-remitting, secondary progressive, primary
14 progressive, and progressive relapsing multiple
15 sclerosis; correct?
16 A. Those are the four courses listed.
17 Q. And early secondary progressive MS is not one
18 of the enumerated courses of MS in the '947 patent;
19 correct?
20 MS. WHELAN: Object to form.
21 A. Correct.
22 Q. Does the '947 patent define what early

1 secondary progressive MS is?
2 MS. WHELAN: Object to form.
3 A. I don't see one.
4 Q. You can set those patents aside, if you'd
5 like, and let's turn back to your declaration. I'm
6 looking at, again, in your declaration from
7 IPR2023-00480, Exhibit 2051.
8 Beginning on Page 15, you provide a
9 discussion of MS clinical course and diagnosis. Do
10 you see that?
11 A. Yes.
12 Q. And in Paragraph 42 of your declaration,
13 which appears on Page 16, you provide a discussion of
14 the different clinical subtypes of MS; correct?
15 A. Yes.
16 Q. And you list four clinical subtypes of MS as
17 of 2004 -- namely, relapsing-remitting MS, secondary
18 progressive MS, primary progressive MS, and
19 progressive relapsing MS. Correct?
20 A. Yes.
21 Q. And your declaration does not identify early
22 secondary progressive MS as one of the clinical

1 subtypes of MS; correct?
2 MS. WHELAN: Object to form.
3 A. Correct.
4 Q. And when you use the phrase "clinical
5 subtypes of MS," are you using that phrase
6 interchangeably with the term "courses of MS"?
7 MS. WHELAN: Object to form.
8 A. Yes.
9 Q. Does your declaration provide a definition of
10 what "early secondary progressive MS" is?
11 MS. WHELAN: Object to form.
12 A. I don't believe so.
13 Q. Can you point me to a definition of "early
14 secondary progressive MS" in your declaration?
15 A. I said I don't believe there is a definition
16 in this declaration.
17 Q. So you cannot point me to a definition of
18 "early secondary progressive MS" in your declaration;
19 correct?
20 MS. WHELAN: Object to form.
21 A. Correct.
22 MS. ELLISON: Let's go off the record,

take a short break.

(Recess taken.)

MS. ELLISON: Let's go back on the record.

Q. Dr. Lublin, do you know what a prosecution history of a patent is?

A. Isn't it a detailed list of what's been submitted? Or at least that's the extent of my understanding.

Q. Do you know what the file history of a patent is?

A. I would have thought that's the same thing, so maybe not.

Q. I'll use the terms "prosecution history" and "file history" interchangeably.

And when you say "submitted," are you referring to documents that have been submitted to the U.S. Patent and Trademark Office?

A. I guess, or other offices as well.

Q. I'll use the terms "prosecution history" and "file history" to refer to documents that have been submitted by a patent applicant to the Patent Office during the process of seeking a patent, as well as

1 referring to documents that the Patent Office sent
2 back to the applicant. Do you understand that?
3 A. Sure.
4 Q. In preparing your declaration regarding the
5 '947 patent, did you review the prosecution history
6 for the '947 patent?
7 A. I don't see it here. Maybe I'm missing it.
8 Let me look again.
9 I don't see it on the list of items
10 reviewed.
11 Q. In preparing the declaration regarding the
12 '947 patent, did you review the prosecution history
13 for the '947 patent?
14 A. I don't believe so.
15 Q. In reviewing -- strike that.
16 In preparing your declaration regarding
17 the '903 patent, did you review the prosecution
18 history for the '903 patent?
19 A. No.
20 Q. In formulating the opinions set forth in your
21 declarations for the '903 and '947 patent, did you
22 construe the claims of the '903 or '947 patents?

1 MS. WHELAN: Object to form.
2 Q. Let me just break that into two parts.
3 In forming the opinions set forth in your
4 declaration on the '947 patent, did you construe the
5 claims of the '947 patent?
6 MS. WHELAN: Object to form.
7 A. I read and reviewed the claims. I'm not sure
8 what you mean by "construed."
9 Q. Do you have an understanding of what the word
10 "construe" means?
11 A. No.
12 Q. In forming the opinions set forth in your
13 declaration on the '947 patent, did you interpret the
14 claims of the '947 patent?
15 MS. WHELAN: Object to form.
16 A. So I know what "interpret" means, but I don't
17 know what the question means.
18 Q. Why do you not know what the question means,
19 if you understand what the word "interpret" means?
20 A. I don't know what you mean by "interpret." I
21 read the claims. I understand the claims.
22 Q. In forming the opinions set forth in your

1 declaration regarding the '947 patent, did you
2 determine what the scope of the '947 patent claims
3 are?
4 MS. WHELAN: Object to form.
5 A. Yes.
6 Q. How did you determine the scope of the '947?
7 A. By reading it.
8 Q. Did you apply any particular standard to
9 assess the scope of the '947 patent claims?
10 A. Just what was written in the document.
11 Q. For the '903 patent, in forming the opinions
12 set forth in your declaration regarding the '903
13 patent, did you construe the claims of the '903
14 patent?
15 MS. WHELAN: Object to form.
16 A. If we take "construe" to mean interpret and
17 understand, yes.
18 Q. And did you use any particular standard to
19 determine -- strike that.
20 What process, if any, did you use to
21 interpret the claims of the '903 patent?
22 MS. WHELAN: Object to form.

1 A. I have no idea what that question means.
2 Q. How did you interpret the claims of the '903
3 patent?
4 MS. WHELAN: Object to form.
5 A. I read them.
6 Q. And how did you understand -- how did you
7 come to an understanding of the scope of the '903
8 patent claims?
9 MS. WHELAN: Object to form.
10 A. I understood the scope of the claims as a
11 POSA would.
12 Q. What information did you consider in
13 assessing the scope of the '903 patent claims?
14 MS. WHELAN: Object to form.
15 A. Everything that's in the patent document and
16 my understanding of the area.
17 Q. What standard did you use, if any, to
18 understand the scope of the '903 patent claims?
19 MS. WHELAN: Object to form.
20 A. I guess the standard of a person of ordinary
21 skill.
22 Q. What standard, if any, did you use to

1 determine the scope of the '947 patent claims?
2 MS. WHELAN: Object to form.
3 A. The same.
4 Q. During any of our breaks today have you
5 spoken with anyone regarding the substance of your
6 testimony?
7 A. No.
8 Q. During any of our breaks today have you
9 accessed any information relevant to your testimony
10 during any of the breaks?
11 A. I have not.
12 Q. Let me just clarify that last question.
13 During any of our breaks today have you accessed any
14 information that I have not presented to you regarding
15 your testimony today?
16 A. I haven't accessed any information relative
17 to this matter.
18 Q. So, for example, when you were looking at
19 your cell phone today, you were not accessing
20 information relevant to these IPR proceedings; is that
21 correct?
22 A. Yeah. Flight schedules.

1 Q. Fair enough. Dr. Lublin, at this time I have
2 no further questions for you, so I'll pass the
3 witness. Thank you.
4 MS. WHELAN: Let's go off the record and
5 take a break, please.
6 (Recess taken.)
7 MS. WHELAN: Can we go back on the record
8 on the record, please.
9 EXAMINATION
10 BY MS. WHELAN:
11 Q. I just have a couple of questions for you,
12 Dr. Lublin.
13 Could you please take your declaration.
14 And in your declaration in the 480 IPR, please turn to
15 Section 5 on Page 12. Do you see the section with a
16 Roman Numeral V?
17 A. Yes.
18 Q. Could you read the title of that section
19 aloud?
20 A. Legal Standards.
21 Q. And did you apply the legal standards in
22 Section V in forming your opinions in the 480 and 481

1 IPRs?
2 MS. ELLISON: Objection, leading.
3 A. Yes.
4 Q. And can you turn to Paragraph 37, please,
5 under the heading Claim Construction. Could you
6 please read Paragraphs 37 and 38 out loud.
7 MS. ELLISON: Objection, leading.
8 A. "I understand that each term of the claims of
9 the patent should be interpreted according to its
10 plain and ordinary meaning to a POSA at the time of
11 the invention in the context of the patent. I've
12 reviewed the decision on institution and understand
13 that in its preliminary findings the Board found the
14 challenged claims do not require that the total
15 maintenance dose be lower than the total induction
16 dose.
17 "Additionally, the Board found the
18 challenged claims cover embodiments in which the same
19 total dose (about 1.7 milligrams per kilogram) is used
20 for both the induction and the maintenance periods."
21 Q. Did you apply this understanding in
22 Paragraphs 37 and 38 in forming your opinions in the

1 480 and 481 IPRs?
2 A. Yes.
3 MS. ELLISON: Objection, leading, scope.
4 Q. Could you turn to Paragraph 44 of your
5 declaration, please.
6 A. Okay.
7 Q. In Paragraph 44 do you discuss early SPMS?
8 MS. ELLISON: Objection, leading.
9 A. Yes.
10 Q. And what do you say about early SPMS in this
11 paragraph of your declaration?
12 A. The paragraph reads, "The RRMS disease course
13 can be followed by disease progression with or without
14 relapses, leading to SPMS. An initial, transitional
15 stage of SPMS can be referred to as early SPMS. As
16 shown in the following graph of a disease course for
17 SPMS, progression worsens and includes occasional
18 relapses and minor remissions."
19 Q. And you cite a couple of exhibits in that
20 Paragraph 44; correct?
21 MS. ELLISON: Objection, leading.
22 A. Yes.

1 Q. And which exhibits do you cite?
2 MS. ELLISON: Objection, leading, scope.
3 A. Exhibits 1038 and 1037.
4 Q. Thank you, Dr. Lublin. I have nothing
5 further.
6 MS. ELLISON: Can we go off the record and
7 take a break, probably five to ten minutes.
8 (Recess taken.)
9 MS. ELLISON: Let's go back on the record.
10 RE-EXAMINATION
11 BY MS. ELLISON:
12 Q. Dr. Lublin, if you could turn to your '947
13 declaration, Page 12, Section V, on legal standards.
14 A. Okay.
15 Q. In Paragraph 33 you state, "This section sets
16 forth certain legal standards that have been provided
17 to me by attorneys for Patent Owner, Merck Serono SA."
18 Do you see that?
19 A. Yes.
20 Q. At the time you signed your declaration, did
21 you have any understanding of the legal standards
22 relating to obviousness or claim construction beyond

1 the description of the legal standards set forth in
2 Section V of your declaration?
3 MS. WHELAN: Object to form and beyond the
4 scope of the redirect.
5 A. Let me hear the question again, please.
6 Q. At the time you signed your declaration, did
7 you have any understanding of the legal standards for
8 obviousness and claim construction beyond what's
9 written in Section V of your declarations?
10 MS. WHELAN: Same objections.
11 A. No.
12 Q. Dr. Lublin, I have no further questions for
13 you. Thank you very much for your time today. Have a
14 safe flight home, or wherever.
15 A. Thank you.
16 MS. WHELAN: No further questions.
17 MS. ELLISON: We can go off the record.
18 (The deposition concluded at 3:16 p.m.)
19
20
21
22

1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC.
2 I, Alan H. Brock, Certified Reporter and
3 notary public within and for the Commonwealth of
4 Massachusetts, do hereby certify:
5 That Fred David Lublin, M.D., the witness
6 whose deposition is hereinbefore set forth, was duly
7 sworn by me before the commencement of such deposition
8 and that such deposition was taken before me and is a
9 true record of the testimony given by such witness.
10 I further certify that the adverse party,
11 Merck Serono, S.A., was represented by counsel at the
12 deposition.
13 I further certify that the deposition of
14 Fred David Lublin, M.D. occurred at the offices of
15 Wilmer Cutler Pickering Hale and Dorr LLP, 60 State
16 Street, on Tuesday, March 5, 2024, commencing at 8:08
17 a.m. to 3:16 p.m.
18 I further certify that I am not related to
19 any of the parties to this action by blood or
20 marriage, I am not employed by or an attorney to any
21 of the parties to this action, and that I am in no way
22 interested, financially or otherwise, in the outcome

1 of this matter.
2 IN WITNESS WHEREOF, I have hereunto
3 set my hand this 5th day of March, 2024.
4
5 My commission expires:
6 March 25, 2027.
7
8
9 _____
10 Alan H. Brock, RDR, CRR
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