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Transcript of Aaron E. Miller, M.D.

Date: December 12, 2023

Case: Hopewell Pharma Ventures, Inc. -v- Merck Serono, S.A. (PTAB)

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Merck 2009

Hopewell v Merck

IPR2023-00480

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

- - - - - x
HOPEWELL PHARMA VENTURES, :
INC., : Case IPR2023-00480
Petitioner, : (Patent 7,713,947 B2)
v. :
MERCK SERONO S.A., : Case IPR2023-00481
Patent Owner. : (Patent 8,377,903 B2)
- - - - - x

Deposition of AARON E. MILLER, M.D.
Washington, DC
Tuesday, December 12, 2023
8:10 a.m.

Job No. 512837
Pages: 1 - 147
Reported by: Janet A. Hamilton, RDR

1 Deposition of AARON E. MILLER, M.D., held
2 at the office of:

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5 Sterne, Kessler, Goldstein & Fox, P.L.L.C.
6 1101 K Street, NW
7 Washington, DC 20005
8 202.371.2600
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14 Pursuant to Notice, before Janet A.
15 Hamilton, Registered Diplomate Reporter and Notary
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1 A P P E A R A N C E S

2 ON BEHALF OF THE PETITIONER:

3 ELDORA L. ELLISON, Ph.D., ESQUIRE

4 OLGA A. PARTINGTON, Ph.D., ESQUIRE

5 STERNE KESSLER GOLDSTEIN & FOX, PLLC

6 1100 New York Avenue, NW

7 Washington, DC 20005

8 202.371.2600

9

10 ON BEHALF OF THE PATENT OWNER:

11 EMILY R. WHELAN, ESQUIRE

12 CINDY KAN, Ph.D., ESQUIRE

13 WILMER CUTLER PICKERING HALE AND DORR, LLP

14 60 State Street

15 Boston, Massachusetts 02109

16 617.526.6000

17

18 ALSO PRESENT:

19 WILLEM F.C. de WEERD, Corporate Patent

20 Counsel, Merck

21 DAVID B. BASSETT, ESQUIRE

22 WilmerHale (Via Zoom link)

1 ALSO PRESENT (CONTINUED) :

2 ANJA FUX, Sterne Kessler

3 SARAH LEESMAN, Sterne Kessler

4 AUSTIN COSTELLO, Planet Depos

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By Dr. Ellison	142

E X H I B I T S

(Attached to the transcript)

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Exhibit 2004 "Multiple Sclerosis: A Comprehensive Text"	22
Exhibit 2005 "Multiple Sclerosis: The Questions You Have -- The Answers You Need" Rosalind C. Kalb, Ph.D.	27
Exhibit 2006 "Immunotherapy of Multiple sclerosis - Current Practice And future directions" Mark J. Tullman, Fred Lublin and Aaron E. Miller, M.D.	80

E X H I B I T S C O N T I N U E D

Exhibit 2007	Thumb drive of video	128
	Presentation by Dr. Miller	
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PREVIOUSLY MARKED EXHIBITS

Exhibit 1002	Declaration of Dr. Miller	10
	Re: US Patent No. 7,713,947	
Exhibit 1013	"A pilot of cladribine (2-chlorodeoxyadenosine) in remitting- relapsing multiple sclerosis" Stelmasiak, et al.	29
Exhibit 1018	"Cladribine and progressive MS - Clinical and MRI outcomes of a multicenter controlled trial" Rice, et al.	20
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1	Exhibit 1031	"A Double-Blind, Placebo-	95
2		Controlled, Randomized Trial of	
3		Cladribine in Relapsing-Remitting	
4		Multiple Sclerosis"	
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1 P R O C E E D I N G S

2 -----

3 AARON E. MILLER, M.D.,
4 a witness herein, being duly sworn, testified as
5 follows:

6 EXAMINATION BY COUNSEL FOR THE PATENT OWNER
7 BY MS. WHELAN:

8 Q Good morning.

9 A Good morning.

10 Q Could you please state your name for the
11 record?

12 A Aaron E. Miller.

13 Q I'm Emily Whelan. I'm with the law firm
14 WilmerHale. I represent the patent owner, and
15 with me today is Cindy Kan, also of WilmerHale.
16 And joining by Zoom is Willem de Weerd of Merck
17 KGaA.

18 THE WITNESS: Good morning.

19 MR. DE WEERD: Good morning.

20 Q Doctor --

21 DR. ELLISON: Sorry, counsel. Oh, I was
22 just going to ask that the remote attendees turn

1 their cameras off. So thank you.

2 MS. WHELAN: Okay.

3 Q Is there any reason that you cannot
4 provide complete and accurate testimony here
5 today?

6 A No.

7 Q And you understand your testimony here
8 today is given under oath?

9 A Yes.

10 Q Have you ever been deposed before?

11 A Yes.

12 Q How many times?

13 A I don't know. No more than a few.

14 Q Have you testified in court before?

15 A Yes.

16 Q How many times?

17 A No more than a few.

18 Q And what sort of matters did you give
19 testimony in?

20 A Mostly medical malpractice cases.

21 Q Any patent cases?

22 A No.

1 Q Do you understand that today we're taking
2 your deposition for two IPR proceedings:
3 IPR2023-00480 and IPR2023-00481; correct?

4 A Yes.

5 Q Unless I note otherwise, all the exhibits
6 that we use today are being introduced with the
7 same exhibit number in both proceedings.

8 I see you've got some documents with you
9 there. Are those your declarations --

10 A Yes, they are.

11 Q -- in the IPR proceedings?

12 A Yes, they are.

13 Q Did you bring any other documents with you
14 today?

15 A No. No.

16 Q All right. So I want to turn first to
17 what has been marked Exhibit 1002 in
18 IPR2023-00480. We have copies here, but you can
19 refer to your own copy if you like.

20 DR. ELLISON: Thanks.

21 A Where did you want to go?

22 Q You're familiar with this declaration?

1 A Yes.

2 Q And this is your declaration providing
3 your opinions regarding US Patent 7,713,947?

4 A Yes, it is.

5 Q And I might refer to that as the '947
6 patent. Is that okay?

7 A That's fine.

8 Q Could you turn to page 94 of Exhibit 1002,
9 please, so all the way at the end?

10 A Yes.

11 Q Is that your signature on the declaration?

12 A Yes, it is.

13 Q And you stand by the opinions you provided
14 in your declaration?

15 A I stand by those opinions.

16 Q Could you turn to page 10 of Exhibit 1002,
17 please?

18 A Yes.

19 Q At paragraph 19 you say, "In formulating
20 my opinions I considered the following documents,"
21 and then you have a table of documents; correct?

22 A That's correct.

1 Q The table spanning pages 10 to 13?

2 A Correct.

3 Q Does this table identify all the materials
4 you considered in forming your opinions contained
5 in the declaration?

6 A Could you just repeat the question?

7 Q Does this table identify all the materials
8 you considered in forming your opinions contained
9 in the declaration?

10 A No.

11 Q What other materials did you consider?

12 A Well, over the years I've read many, many
13 articles about multiple sclerosis. So I've
14 considered that -- that fund of knowledge that I
15 have. I've also -- I've also reviewed the
16 prescribing information for Mavenclad, and I may
17 have reviewed some other articles that I don't
18 specifically recall.

19 Q In forming your opinions for the 480 IPR,
20 did you search for any literature yourself?

21 A Yes, I did.

22 Q Your opinion is that the challenged claims

1 of the '947 patent would have been obvious over
2 the Bodor and Stelmasiak references; correct?

3 A That's correct.

4 Q How did you become aware of Bodor and
5 Stelmasiak?

6 A I became aware of Bodor and Stelmasiak in
7 discussion with my attorneys.

8 Q Did you talk to anyone other than counsel
9 for Hopewell in forming the opinions that are in
10 your declaration for the 480 IPR?

11 A No.

12 Q Okay. I want to turn to your other
13 declaration, which is Exhibit 1002 in
14 IPR2023-00481; and I may refer to IPR 2023-00481
15 as the 481 IPR. Okay?

16 A Okay.

17 Q Do you recognize this declaration?

18 A Yes, I do.

19 Q And this is the declaration providing your
20 opinions regarding US Patent 8,377,903; correct?

21 A Yes.

22 Q And I may refer to this as the '903

1 patent. Okay?

2 A Yes.

3 Q Could you turn to page 94, please, the
4 very last page? Is that your signature on the
5 declaration?

6 A Yes, it is.

7 Q And you stand by the opinions you provided
8 in your declaration?

9 A Yes, I do.

10 Q Could you turn to page 10, please?

11 A Yes.

12 Q And at paragraph 19 you state, "In
13 formulating my opinions I considered the following
14 documents"; correct?

15 A Yes.

16 Q And then you have a table of documents?

17 A Yes.

18 Q Are the documents that you considered to
19 form your opinions in this 481 IPR the same as
20 what you considered to form your opinions in the
21 480 IPR?

22 DR. ELLISON: Objection. Form.

1 A Yes.

2 Q Did you talk to anyone other than counsel
3 for Hopewell in forming your opinions in your
4 declaration for the 481 IPR?

5 A No.

6 Q Did you do anything to prepare for today's
7 deposition?

8 DR. ELLISON: I'm going to caution the
9 witness not to divulge the substance of
10 communications with counsel, but subject to that
11 instruction, you can answer the question.

12 A Yes.

13 Q What did you do?

14 DR. ELLISON: Same caution.

15 A I reviewed my declarations. I reviewed
16 the patents. I reviewed many of the articles that
17 have been cited in the exhibits, and I met with --
18 I met with the attorneys.

19 Q How long did you meet with your attorneys?

20 A I would say roughly -- roughly 25 hours.

21 Q Did you communicate with anyone other than
22 your attorneys to prepare for this deposition?

1 A No.

2 Q Have you spoken with anyone other than
3 counsel about the IPR proceedings?

4 A No.

5 Q Could you please take your declaration for
6 the 480 IPR, the '947 patent, Exhibit 1002 in the
7 480 IPR, and I'd like you to turn to paragraph 49,
8 please. That's on page 35.

9 A I've got it.

10 Q So if you look about five lines from the
11 start of paragraph 49, you provide your opinion,
12 "As explained above, a POSA would have understood
13 that the patients in Rice's study exhibited a
14 positive response to cladribine therapy because
15 their enhancing lesions were eliminated"; correct?

16 A That's what it says, yes.

17 Q The enhancing lesions are identified by
18 MRI?

19 A Yes.

20 Q In your opinion does positive response
21 mean a therapeutic effect?

22 DR. ELLISON: Objection. Form.

1 Foundation.

2 A In the context of this sentence, yes.

3 Q Does a positive response mean the
4 patient's MS is being treated?

5 A Yes.

6 Q Does a positive response mean there is an
7 observed clinical benefit to the patient?

8 DR. ELLISON: Objection. Form.
9 Foundation.

10 A Not necessarily.

11 Q Let's turn to paragraph 27 of your
12 declaration for the 480 IPR.

13 A Okay.

14 Q In the last sentence of paragraph 27 you
15 provide your opinion that, "A POSA would have
16 understood that a reduction in the number or size
17 of these enhancing lesions were indicative of a
18 treatment response"; correct?

19 A Yes.

20 Q By treatment response did you mean a
21 therapeutic effect?

22 A In the context of this sentence it's

1 indicative of a treatment response, yes.

2 Q So in the sentence you use the word
3 "treatment response." By treatment response did
4 you mean a therapeutic effect?

5 A In the context of this sentence it means a
6 therapeutic effect, yes.

7 Q By treatment response did you mean there
8 is an observed clinical benefit to the patient?

9 A Not necessarily.

10 Q Okay. Could we go to paragraph 91, which
11 spans pages 61 to 62.

12 A Okay.

13 Q On page 62, in the first full sentence you
14 provide your opinion that, "Rice also observes
15 that cladribine-treated patients had a small dose-
16 dependent median percent decrease in T2 lesion
17 volume"; correct?

18 A That's what the sentence says, yes.

19 Q And that's your opinion?

20 A It's my opinion that that's what the
21 sentence says.

22 What are you asking me?

1 Q Well, this is your -- your sentence in
2 your declaration; right?

3 A Yes. Rice observed that, yes.

4 Q Is it your opinion that a decrease in T2
5 lesion volume is a positive response to cladribine
6 therapy?

7 A Yes.

8 Q Is it your opinion that a decrease in T2
9 lesion volume is a treatment response to
10 cladribine therapy?

11 A Could you repeat that question, please?

12 Q Is it your opinion that a decrease in T2
13 lesion volume is a treatment response to
14 cladribine therapy?

15 A Possibly.

16 Q And possibly not?

17 A And possibly not.

18 Q Okay. Let's go back to paragraph 49 of
19 your declaration on page 35.

20 If you look four lines up from the bottom
21 you note that, "Rice reported that no significant
22 treatment effects were found using EDSS scores as

1 an outcome measure"; correct?

2 A Yes.

3 Q Rice reported that clinical efficacy was
4 not shown in its trial; correct?

5 A Sorry. I lost my place. Where are you
6 reading?

7 Q So I'm asking you about the Rice reference
8 itself.

9 A Oh. So you're asking me about those.

10 Could you repeat the question, please?

11 Q Rice reported that clinical efficacy was
12 not shown in its trial; correct?

13 A No.

14 Q Okay. Why don't we go to Rice.

15 I'm going to hand you what has been
16 previously marked as Exhibit 1018.

17 Do you recognize this, Exhibit 1018, as
18 the Rice paper that you discussed in your
19 declaration?

20 A Yes, I do.

21 Q Can you turn to page 1153, please?

22 A Okay.

1 Q Okay. If we go on the left-hand column,
2 the first full paragraph, the first sentence.

3 Here Rice states, "Because clinical
4 efficacy was not shown in this trial, it is
5 necessary to scrutinize the Scripps study for
6 Type I errors (false positives)."

7 Do you see that?

8 A Yes. I see that.

9 Q So you agree that Rice reported clinical
10 efficacy was not shown in its trial; correct?

11 A Give me a moment to look at the paper.

12 Yes, I agree.

13 Q Do you agree that based on Rice there was
14 an enigmatic dissociation between positive effects
15 on MRI and unconvincing clinical benefit?

16 DR. ELLISON: Objection. Foundation.

17 A Well, I don't know how Rice interprets the
18 word "enigmatic." There was a dissociation
19 between the clinical findings and the MRI
20 findings.

21 Q In your opinion, was that dissociation
22 enigmatic?

1 A No. To me it's not enigmatic.

2 Q I'm going to mark Exhibit 2004, please.

3 (Miller Deposition Exhibit 2004 was marked
4 for identification.)

5 Q Do you recognize Exhibit 2004 as a book
6 chapter that you co-authored in Multiple
7 Sclerosis: A Comprehensive Text?

8 And you co-authored chapter 22, "Escape
9 therapies and management of multiple sclerosis."

10 A So this was written many years ago. So I
11 didn't immediately recognize the text, but I
12 recognize that I've written the chapter.

13 Q This is a book chapter that you
14 co-authored in 2008; correct?

15 A Well, the book was published in 2008.
16 Probably well before that.

17 Q And you wrote this book chapter with a
18 Dr. El-Moslimany?

19 A Halima El-Moslimany, yes.

20 Q Okay. Please turn to page 341 of your
21 book chapter.

22 A Okay.

1 Q Here you provide a review of cladribine;
2 correct?

3 A Yes.

4 Q In the left column, the second full
5 paragraph, you wrote, "In one study, 51 patients
6 with MS (mostly secondary progressive) were
7 randomized to cladribine treatment consisting of
8 four monthly, seven-day infusions (0.1 milligrams
9 per kilogram per day) or placebo"; correct?

10 A Yes.

11 Q And you cite to reference 147.

12 A Yes.

13 Q Okay. So if you look on page 350,
14 reference 147 is Sipe, Romine, Koziol, et al.,
15 "Development of cladribine treatment in multiple
16 sclerosis," Multiple Sclerosis, 1996, 1:343 to
17 347; correct?

18 A Yes.

19 Q This is the cite reference from 1996?

20 A Yes.

21 Q Okay. Let's go back to page 341. In the
22 left column, the fourth full paragraph you wrote,

1 "In a subsequent multicenter, double-blind
2 placebo-controlled trial done to evaluate the
3 safety and efficacy of cladribine in progressive
4 MS no significant treatment effects were found for
5 cladribine using the expanded disability status
6 scale scores"; correct?

7 A Yes. Yes.

8 Q And here you cite reference 148?

9 A Yes.

10 Q So we go back to page 350, reference 148
11 is Rice, Filippi and Comi, "Cladribine and
12 progressive MS: Clinical and MRI outcomes of a
13 multicenter controlled trial," Neurology, 2000,
14 54:1145 to 1155; correct?

15 A Yes.

16 Q This is the same Rice study, Exhibit 1018,
17 that you discussed in your declaration; correct?

18 A Yes.

19 Q Now, on page 341 of your book chapter,
20 Exhibit 2004, you did not include any other
21 citations to cladribine studies in the cladribine
22 section that makes up the first four paragraphs of

1 the left column; correct?

2 A That's correct.

3 Q Okay. Now, let's look at the summary and
4 recommendations section beginning at the bottom of
5 the left column of page 341.

6 Here you state, "Initial trials with
7 cladribine showed promise in the treatment of
8 SPMS, but these results were not seen in the
9 subsequent blinded randomized placebo-controlled
10 trial"; correct?

11 A Yes.

12 Q Now, this statement that "initial trials
13 with cladribine showed promise in treatment of
14 SPMS," was referring to the Sipe study; correct?

15 A Yes.

16 Q And your conclusion that these results
17 were not seen in the subsequent blinded randomized
18 placebo-controlled trial is based on the Rice
19 study; correct?

20 A Yes.

21 Q In the next sentence you wrote,
22 "Furthermore, studies of cladribine continue to

1 show an enigmatic dissociation between positive
2 effects on MRI and unconvincing clinical benefit";
3 correct?

4 A Yes. That's stated.

5 Q And your statement in 2008 about the
6 enigmatic dissociation and unconvincing clinical
7 benefit of cladribine was based on the Rice study;
8 correct?

9 A The statement was based on the Rice study,
10 yes.

11 Q Enigmatic means "difficult to interpret or
12 understand, mysterious"; correct?

13 A That's the -- I would say that's the
14 general use of the term in the English language.

15 Q Okay. Please look at the first paragraph
16 at the top of the right column on page 341 of your
17 2008 book chapter.

18 Here you wrote, about four lines down, "At
19 this point it seems prudent to await the results
20 of a prospective randomized blinded trial of oral
21 cladribine before recommending its use in patients
22 with MS"; correct?

1 A That's what's written.

2 Q When you wrote your 2008 book chapter, you
3 were not ready to recommend oral cladribine for
4 use in patients with MS; correct?

5 A Well, based on that sentence I would -- I
6 would say it would be preferable or prudent to
7 await the results of -- of the prospective trial,
8 yes.

9 Q Your statement there was based on your
10 review of the Sipe and Rice studies that you
11 cited; correct?

12 A Yes.

13 Q And you did not cite anything else in
14 support of that statement; correct?

15 A I did not in that chapter cite other
16 things.

17 Q Do you agree that as of the year 2000
18 recently completed trials of cladribine found that
19 cladribine was not to be of benefit for MS?

20 A No, I would not agree.

21 Q I'm going to mark Exhibit 2005, please.

22 (Miller Deposition Exhibit 2005 was marked

1 for identification.)

2 Q Do you recognize Exhibit 2005 as a book
3 chapter that you published in 2000 in the book
4 Multiple Sclerosis, the Questions You Have, the
5 Answers You Need, and your chapter was chapter 3,
6 Treatment Issues?

7 A Yes. That's what I'm looking at.

8 Yes. I recognize the book and the
9 chapter.

10 Q And you authored this chapter?

11 A Yes, I did.

12 Q Could you please turn to page 45?

13 A All right.

14 Q The second full paragraph, second
15 sentence, you wrote, "In recently completed trials
16 of oral myelin cladribine and sulfasalazine, these
17 agents were found not to be of benefit"; correct?

18 A I'm referring here to the cladribine trial
19 in progressive forms of MS, yes.

20 Q And your statement is that in recently
21 completed trials cladribine was found not to be of
22 benefit; correct?

1 A Yes.

2 Q Okay. Let's go back to your declaration
3 for the 480 IPR, Exhibit 1002. Could you turn to
4 paragraph 16, please?

5 A 16?

6 Q 16, on page 7.

7 A All right.

8 Q Four lines from the bottom of paragraph
9 16, you provide your opinion that "During
10 treatment, neurologists commonly assess the
11 therapeutic effect of cladribine by monitoring a
12 patient's lymphocyte count with the sustained
13 reduction of lymphocytes, e.g., below 1,000 per
14 microliter being characteristic of a treatment
15 response"; correct?

16 A Yes.

17 Q For this opinion you cite Exhibit 1018 at
18 page 1146, Exhibit 1013 at page 5, and Exhibit
19 1014 at page 1717; correct?

20 A That is correct.

21 Q And those exhibits are Stelmasiak, Beutler
22 and Rice; correct?

1 A Yes.

2 Q 1013 is Stelmasiak?

3 A Yes.

4 Q 1014 is Beutler?

5 A Yes.

6 Q And 1018 is Rice; correct?

7 A Correct.

8 Q In your opinion a patient's lymphocyte
9 count is a measure of cladribine's therapeutic
10 effect; correct?

11 A It's one measure, yes.

12 Q In your opinion a sustained reduction of
13 lymphocytes below 1,000 cells per microliter
14 indicate the treatment response to cladribine;
15 correct?

16 A Yes.

17 Q In your opinion here in paragraph 16, by
18 treatment response, you meant the same thing as
19 therapeutic effect; correct?

20 DR. ELLISON: Objection. Foundation.

21 A In this instance I mean the same thing,
22 treatment effect and therapeutic effect. It's an

1 effect of the therapy.

2 Q In this sentence we just looked at in
3 paragraph 16, you meant the same thing by
4 treatment response and therapeutic effect?

5 DR. ELLISON: Objection. Foundation.

6 A Yes. I mean the same thing between the
7 treatment effect and a therapeutic effect.

8 Q Your words here are treatment response and
9 therapeutic effect; right?

10 DR. ELLISON: Objection. Form.

11 Q In the last sentence of paragraph 16?

12 DR. ELLISON: Objection. Form.

13 A Yes. I'm using -- the treatment response
14 here is an effect of the therapy. It is a
15 therapeutic effect.

16 Q In your opinion a lymphocyte level of
17 1,000 cells per microliter is within the normal
18 range of lymphocytes; correct?

19 A 1,000 is usually given as the lower limit
20 of normal.

21 Q Is it your opinion that a lymphocyte level
22 below the normal range constitutes suppression?

1 A Constitutes?

2 Q Suppression?

3 A Well, not necessarily. Depends whether
4 something was given.

5 Q Whether a drug was given?

6 A Whether a treatment is given. Some people
7 might naturally have a somewhat lower than 1,000
8 lymphocyte count.

9 Q So if a treatment is given and then the
10 lymphocyte level is below normal range, that
11 constitutes suppression in your opinion?

12 A Yes.

13 Q I wanted to go back to Rice that was
14 Exhibit 1018. Have it?

15 Okay. Could you go to page 1146, please?

16 A All right.

17 Q Could you go to the right column, the
18 first full paragraph, the second sentence. Do you
19 see Rice says, "During the one-year double-blind
20 phase, patients were evaluated monthly for vital
21 signs, adverse events and a complete blood count,
22 CBC, that was obtained just before the monthly

1 visit"; correct?

2 A Yes.

3 Q And the paragraph goes on to say,
4 "Neurologic status was evaluated bimonthly by
5 assessment of EDSS and Scripps Neurologic Rating
6 Scale, SNRS, scores." And then further, "Brain
7 MRI scans were obtained at baseline among 6 and 12
8 as were total lymphocyte count and lymphocyte
9 subset counts, and physical examinations were
10 performed."

11 Do you see that?

12 A Yes, I do.

13 Q In this reference to lymphocyte counts,
14 Rice did not state that the lymphocyte counts are
15 measured to assess therapeutic efficacy; correct?

16 A Rice doesn't talk about anything that he's
17 measuring as a measure of efficacy in this
18 particular paragraph or sentence.

19 Q Rice does not state that patients'
20 lymphocyte counts are measured to assess a
21 therapeutic effect; correct?

22 A Rice does not talk about measurements of

1 therapeutic effects in this paragraph. Simply
2 talking about what was done.

3 Q Now, please go to paragraph 11 -- sorry,
4 page 1152 of Rice.

5 A Okay.

6 Q Do you see in the right column figure 4 at
7 the top?

8 A Yes, I do.

9 Q And this is plotting lymphocyte count over
10 time?

11 A Yes.

12 Q Rice does not demonstrate that a
13 lymphocyte level below the normal range is linked
14 to any clinical benefit; correct?

15 A You're speaking of figure 4?

16 Q And Rice generally.

17 A I don't see a discussion here in Rice of
18 an examination of the effect of lymphocyte counts
19 on clinical or MRI outcomes.

20 Q Now, please turn to page 1151 of Rice. In
21 the right-hand column about halfway down, you see
22 the words Safety Evaluation in italics?

1 A Yes.

2 Q And then the first subsection under Safety
3 Evaluation is titled Adverse Events.

4 Do you see that?

5 A Yes.

6 Q Rice discusses adverse events as a
7 subsection of the safety evaluation; correct?

8 A Yes.

9 Q Now, if we go to the next subsection under
10 Safety Evaluation, that's Clinical Laboratory
11 Analytes on the next page; correct?

12 A Yes.

13 Q And Clinical Laboratory Analytes is also a
14 subtopic of the safety evaluation; correct?

15 A Yes.

16 Q And here in the Clinical Laboratory
17 Analytes section, Rice says, "At the final
18 evaluation of the double-blind period,
19 dose-related decreases in mean leukocyte count,
20 absolute lymphocyte count, absolute neutrophil
21 count, absolute monocyte count, platelet count,
22 hemoglobin and hematocrit were observed in

1 cladribine-treated patients compared with small
2 increases or no change in the mean values of the
3 analytes in the placebo group"; correct?

4 A Yes.

5 Q Okay. And if you look in the following
6 paragraph, the bottom of the left column of page
7 1152, Rice says, "Lymphocyte subset analyses
8 showed cladribine treatment to be associated with
9 dose-dependent decreases in mean levels of CD4
10 positive, CD3 positive, CD8 positive and to a
11 lesser degree CD19 positive lymphocytes"; correct?

12 A Yes.

13 Q Rice is discussing lymphocyte levels in
14 the context of the safety evaluation; correct?

15 A Yes.

16 Q I'm going to hand you what's been
17 previously marked as Exhibit 1013. Do you
18 recognize Exhibit 1013 as the Stelmasiak article
19 that you relied on for your obviousness opinions?

20 A Yes.

21 Q Can you turn to page 5 of Stelmasiak,
22 please? I'm using the numbers in the bottom right

1 corner. So it's the second page of the document.

2 A I've got it.

3 Q Do you see in the right-hand column under
4 results Stelmasiak states, "Compliance of
5 patients' intolerance of therapy was good, and
6 hematological side effects were mild. Granulocyte
7 counts remained relatively constant at about 4,000
8 per microliter on average. Platelet counts
9 dropped only slightly to approximately 200,000 on
10 average and not in a single case below 100,000 per
11 microliter. Lymphocyte counts dropped from the
12 initial count of 2336 plus or minus 595 per
13 microliter, mean plus or minus SD, to 968 plus or
14 minus 229 per microliter at 6 months and remained
15 at approximately 1,000 per microliter for the next
16 15 months."

17 Did I read that right?

18 A Yes.

19 Q You agree that Stelmasiak discusses
20 lymphocyte counts here together with granulocyte
21 counts and platelet counts; right?

22 A Stelmasiak is reporting the counts, the

1 mean counts of all of those types of -- of
2 hematological cells.

3 Q Lymphocytes, granulocytes and platelets
4 are all components of blood; correct?

5 A Yes.

6 Q And the context that Stelmasiak provides
7 in discussing these counts is that hematological
8 side effects were mild; correct?

9 A Yes.

10 Q This paragraph does not refer to measuring
11 lymphocyte counts to assess the therapeutic
12 effect; correct?

13 DR. ELLISON: Objection. Form.

14 A All of the results reported in this
15 paragraph relate to therapeutic effects. They're
16 results seen in the context of the therapy.

17 Q This discussion is the -- in the context
18 of hematological side effects; right?

19 DR. ELLISON: Objection. Form.

20 A That sentence refers -- that first
21 sentence refers to hematological side effects, but
22 the counts are a result of the therapeutic

1 administration of cladribine.

2 Q And they are a hematological side effect;
3 correct?

4 DR. ELLISON: Objection. Form.

5 A These counts are a result of the
6 administration of cladribine.

7 Q And Stelmasiak refers to them in the
8 context of hematological side effects; correct?

9 DR. ELLISON: Objection. Form.

10 A Stelmasiak's first sentence in this
11 paragraph refers to hematological side effects
12 were mild, and he then reports the counts that
13 resulted from the therapeutic administration of
14 cladribine.

15 Q In your opinion the result of the
16 therapeutic administration of cladribine includes
17 its side effects?

18 A Can you rephrase -- repeat or rephrase the
19 question?

20 Q In your opinion the result of the
21 therapeutic administration of cladribine includes
22 its side effects; is that correct?

1 DR. ELLISON: Objection. Form.

2 A The results of the therapeutic effect do
3 include side effects.

4 Q Can we go to page 6 of Stelmasiak, please.
5 The 6 in the bottom left. In the right-hand
6 column, second full paragraph, do you see where
7 Stelmasiak states, "Further inspection of the data
8 revealed that from the point of view of the
9 apparent efficacy of the treatment, the group
10 under study can be divided into two subgroups, the
11 responders and the non-responders"; correct?

12 A Yes.

13 Q So Stelmasiak divided the patients into
14 two groups based on the efficacy of the cladribine
15 treatment; correct?

16 A In this particular paragraph, yes.

17 Q And if we keep going in that paragraph
18 Stelmasiak states, "The responders subgroup
19 consisted of seven patients who reported a total
20 of 29 relapses during the two preceding years
21 (average relapse rate 2.07 per patient per year)
22 and a total of 6 relapses during the two-year

1 study period (average relapse rate 0.43 per
2 patient per year)"; correct?

3 A Yes.

4 Q According to Stelmasiak, the responders
5 had a reduction in relapse rate; correct?

6 A Yes.

7 Q And Stelmasiak continues by stating, "The
8 non-responder subgroup consisted of three patients
9 whose relapse rate was the same during the
10 two-year period prior to and after the initiation
11 of the therapy (total of nine relapses, average
12 relapse rate 1.5 per patient per year)"; correct?

13 A Yes.

14 Q According to Stelmasiak, the
15 non-responders did not have a reduction in relapse
16 rate; correct?

17 A Yes.

18 Q In evaluating efficacy Stelmasiak divided
19 the patients into groups based on whether a
20 patient's relapse rate improved; correct?

21 A Yes.

22 Q In evaluating efficacy Stelmasiak did not

1 group the patients by lymphocyte count; correct?

2 DR. ELLISON: Objection. Form.

3 Foundation.

4 A Could you please repeat the question?

5 Q In evaluating efficacy Stelmasiak did not
6 group the patients by lymphocyte count; correct?

7 A Correct.

8 Q Stelmasiak did not identify lymphocyte
9 count as a measure of cladribine efficacy;
10 correct?

11 DR. ELLISON: Objection. Form.

12 A He did not.

13 Q If we continue in the same paragraph,
14 Stelmasiak states, "One patient who did not
15 respond to treatment displayed only a slight and
16 transient reduction in lymphocyte count during the
17 treatment, but the other two showed the reduction
18 of approximately the same magnitude as in some
19 responders"; correct?

20 A Yes.

21 Q Stelmasiak reports here that two
22 non-responders showed a reduction in lymphocytes

1 of approximately the same magnitude of some of the
2 responders; correct?

3 A Yes.

4 Q These non-responders in Stelmasiak's study
5 had a reduction in lymphocytes of approximately
6 the same magnitude as some responders but did not
7 have an improvement in relapse rate; correct?

8 DR. ELLISON: Objection. Form.
9 Foundation.

10 A Please repeat the question.

11 Q These non-responders in Stelmasiak's study
12 had a reduction in lymphocytes of approximately
13 the same magnitude as some responders but did not
14 have an improvement in relapse rate; correct?

15 DR. ELLISON: Objection. Form.
16 Foundation.

17 A Yes.

18 Q Why don't we take a short break.

19 A Okay.

20 DR. ELLISON: That's fine. Go off the
21 record.

22 (A recess was taken.)

1 BY MS. WHELAN:

2 Q Back on the record. Could we turn back to
3 Stelmasiak, please, Exhibit 1013. Can you go on
4 to page 5, please, figure 1?

5 A Yes.

6 Q That shows average lymphocyte counts
7 during and after treatment with cladribine;
8 correct?

9 A Yes.

10 Q In the paragraph above figure 1,
11 Stelmasiak says, "Lymphocyte counts dropped from
12 the initial count of 2336 plus or minus 595 per
13 microliter, mean plus or minus SD, to 968 plus or
14 minus 229 per microliter at six months and
15 remained at approximately 1,000 per microliter for
16 the next 15 months."

17 Do you see that?

18 A Yes.

19 Q Stelmasiak indicates that lymphocyte
20 counts remained at approximately 1,000 cells per
21 microliter for month six through month 21;
22 correct?

1 A Yes.

2 Q In the last sentence of page 5 and
3 continuing on to page 6, Stelmasiak states, "A
4 tendency toward normalization of lymphocyte counts
5 became evident only at the end of the two-year
6 observation period (Fig. 1)"; correct?

7 A Yes.

8 Q Lymphocyte levels at month 24 continue to
9 be suppressed as compared to lymphocyte levels at
10 month zero; correct?

11 DR. ELLISON: Objection. Form.
12 Foundation.

13 A Yes.

14 Q Now, please turn on page 6 of Stelmasiak
15 to the left column, table 1.

16 Do you see that?

17 A Yes.

18 Q And that shows average EDSS scores during
19 and after the treatment; correct?

20 A Yes.

21 Q Table 1 shows the baseline EDSS score at
22 month zero is 4.3 plus or minus 1.8; correct?

1 A Yes.

2 Q And table 1 shows the EDSS score at month
3 24 is 4.3 plus or minus 2.0; correct?

4 A Yes.

5 Q Even though lymphocyte levels continue to
6 be suppressed at month 24, there was no
7 improvement in EDSS scores compared to baseline at
8 month 24; correct?

9 A These are means over -- over all the
10 patients.

11 Q And for means over all the patients, even
12 though lymphocyte levels continue to be suppressed
13 at month 24, there was no improvement in EDSS
14 scores compared to baseline at month 24; correct?

15 A The means of all the patients' EDSS scores
16 were not changed, and the means of all the
17 lymphocyte counts were still suppressed.

18 Q I'm going to hand you what has previously
19 been marked as Exhibit 1014. Do you recognize
20 Exhibit 1014 as the Beutler reference you
21 discussed in your declaration?

22 A Yes.

1 Q Please turn to page 1717.

2 A 1717?

3 Q On the right-hand column, first full
4 paragraph. Do you see the heading for
5 Hematological Evaluation?

6 A I do.

7 Q In the last sentence this paragraph
8 states, "Lymphocyte subset evaluation was done
9 monthly during the course of drug administration
10 and less frequently thereafter"; correct?

11 A Yes.

12 Q Beutler's discussion of lymphocyte subset
13 evaluation is in the context of hematological
14 evaluation; correct?

15 A Yes.

16 Q This paragraph doesn't say anything about
17 measuring lymphocyte counts to assess a
18 therapeutic effect; correct?

19 A This paragraph is simply talking about --
20 about blood counts.

21 Q Please turn to page 1719 of Exhibit 1014.

22 A All right.

1 Q In the left-hand column, first full
2 paragraph, do you see where it starts with the
3 heading Toxicity and Adverse Events?

4 A Yes.

5 Q The last two sentences of this paragraph
6 state, "Changes in lymphocyte subsets are depicted
7 in Fig 3. There was marked depletion of CD4 cells
8 with both the high- and low-dose schedule";
9 correct?

10 A That's what it says, yes.

11 Q Beutler is discussing changes in
12 lymphocyte subsets in the Toxicity and Adverse
13 Events section; correct?

14 A Yes.

15 Q When treating a patient with cladribine in
16 the Beutler study, lymphocyte counts were
17 monitored for safety purposes; correct?

18 DR. ELLISON: Objection. Form.
19 Foundation.

20 A Lymphocyte counts were monitored by
21 Beutler in this study. He doesn't say why they
22 monitored.

1 Q And he discusses them in the Toxicity and
2 Adverse Events section; correct?

3 A He does.

4 Q Please go back to your declaration for the
5 480 IPR, Exhibit 1002, and turn to paragraph 52.

6 Are you there?

7 A Mm-hmm. Yes.

8 Q Here you provide your opinion that "In
9 light of the potential side effects of
10 immunosuppression it was routine in the art to
11 monitor a patient's lymphocyte counts when
12 treating a patient with certain immunosuppressants
13 such as cladribine"; correct?

14 A Yes.

15 Q "Potential side effects of suppressing a
16 patient's immune system include an increased risk
17 of infection"; correct?

18 A Yes.

19 Q Your opinion is that because of the
20 increased risk of infection a patient being
21 treated with cladribine would have had their
22 lymphocyte counts monitored; correct?

1 DR. ELLISON: Objection. Form.

2 Foundation.

3 A Would you repeat the question, please?

4 Q Your opinion is that because of the
5 increased risk of infection a patient being
6 treated with cladribine would have had their
7 lymphocyte counts monitored; correct?

8 DR. ELLISON: Objection. Form.

9 Foundation.

10 A That's one -- that's one reason why
11 lymphocyte counts would be monitored.

12 DR. ELLISON: Go off the record for a
13 minute.

14 (A discussion was held off the record.)

15 MS. WHELAN: Back on the record.

16 Q Could you please turn to paragraph 91 of
17 your declaration, page 61?

18 A Okay.

19 Q In the third sentence you provide your
20 opinion that a POSA would have known that
21 monitoring a patient's lymphocyte counts was
22 necessary because cladribine causes prolonged

1 profound suppression of lymphocyte counts;
2 correct?

3 A Yes, that's correct.

4 Q That's still your opinion?

5 A Yes.

6 Q Do you agree that a drawback to the use of
7 cladribine is the profound and very long-lasting
8 lymphopenia induced by the drug?

9 DR. ELLISON: Objection. Foundation.

10 A I don't agree with this statement.

11 Q Can you go back to your 2008 book chapter?
12 We had marked that Exhibit 2004. At page 341, do
13 you see your statement in 2008 beginning at the
14 very bottom of the left-hand column, "Another
15 drawback to the use of cladribine is the profound
16 and very long-lasting lymphopenia induced by the
17 drug"? That's what you wrote in 2008; correct?

18 A I'm just having trouble finding where
19 you're reading. Yes. I see the sentence.

20 Q So in 2008 you wrote that another drawback
21 to the use of cladribine is the profound and very
22 long-lasting lymphopenia induced by the drug;

1 correct?

2 A That's what I wrote in 2008, yes, maybe
3 2007.

4 Q Do you agree that as of 2004 the mechanism
5 of action of cladribine was not entirely
6 understood?

7 DR. ELLISON: Objection. Form.
8 Foundation.

9 A Please repeat the question.

10 Q Do you agree that as of 2004 the mechanism
11 of action of cladribine was not entirely
12 understood?

13 DR. ELLISON: Objection. Form.
14 Foundation.

15 A Well, "entirely" is a pretty broad word.
16 I think in 2004 we had a pretty good idea of how
17 cladribine worked.

18 Q So if you go back to your book chapter in
19 2008, possibly written in 2007, Exhibit 2004, will
20 you look at page 341, the top of the left-hand
21 column, third sentence. In 2007 or 2008 you wrote
22 that cladribine's mechanism of action is not

1 entirely understood; correct?

2 A Yes. I wrote that citing the reference in
3 the literature.

4 Q You're aware that Mavenclad was approved
5 for multiple sclerosis by the FDA in 2019;
6 correct?

7 A Yes.

8 Q Do you agree that at that time the
9 mechanism by which cladribine exerts its
10 therapeutic effects in patients with multiple
11 sclerosis had not been fully elucidated?

12 DR. ELLISON: Objection. Form.
13 Foundation.

14 A Well, although the mechanism of action may
15 not have been fully elucidated, it was pretty
16 clear what its main effect was.

17 Q Do you agree that in 2019 the mechanism by
18 which cladribine exerts its therapeutic effects in
19 patients with multiple sclerosis had not been
20 fully elucidated?

21 DR. ELLISON: Objection. Form.
22 Foundation.

1 A Although the mechanism may not have been
2 fully elucidated, there was a clearly known
3 mechanism of action that had been elucidated that
4 had an impact on lymphocyte counts.

5 Q But you agree that in 2019 cladribine's
6 mechanism of action in MS had not been fully
7 elucidated; correct?

8 DR. ELLISON: Objection. Form.
9 Foundation.

10 A There's virtually no drug whose mechanism
11 of action is fully elucidated. There are always
12 things we may not know, but we can see a clear
13 mechanism of action for cladribine in multiple
14 sclerosis.

15 Q You said that you reviewed the Mavenclad
16 prescribing information in preparing for this
17 deposition; correct?

18 A Yes.

19 Q Let's look at that which has previously
20 been marked Exhibit 2001. Could you go to page 20
21 of Exhibit 2001, please?

22 A Yes.

1 Q In section 12.1, Mechanism of Action?

2 A Yes.

3 Q The FDA approved prescribing information
4 for Mavenclad states that "the mechanism by which
5 cladribine exerts its therapeutic effect in
6 patients with multiple sclerosis has not been
7 fully elucidated"; correct?

8 A That's an incomplete statement. It adds,
9 "But is thought to involve cytotoxic effects on B
10 and T lymphocytes..."

11 THE REPORTER: Sorry, sir. Please speak
12 up.

13 A I'm sorry. You didn't read the complete
14 sentence. It says, "Has not been fully elucidated
15 but is thought to involve cytotoxic effects on B
16 and T lymphocytes through impairment of DNA
17 synthesis resulting in depletion of lymphocytes."

18 Q Do you agree with this statement in the
19 Mavenclad prescribing information about the
20 mechanism of action of cladribine?

21 A I agree with that statement.

22 Q I'm going to hand you what has been marked

1 Exhibit 1048. Do you recognize Exhibit 1048 as a
2 publication by Liliemark that you discussed in
3 your declaration?

4 A Yes.

5 Q Please turn to page 122 of Exhibit 1048.

6 A Yes.

7 Q In the left column under 2.1, Oral
8 Administration, second sentence, Liliemark says,
9 "The oral bioavailability in these trials varies
10 from 37 to 51 percent when the saline solution for
11 intravenous administration is given to patients to
12 drink"; correct?

13 A Yes.

14 Q And the next sentence says, "Thus when
15 administered orally at about twice the intravenous
16 dose, the areas under the concentration-time
17 curve, AUC, are similar, fig 2"; correct?

18 A Yes.

19 Q When Liliemark states that the areas under
20 the concentration-time curve, AUC, are similar,
21 Liliemark is referring to the AUC curves for an
22 intravenous dose and an oral dose; correct?

1 A An oral saline solution.

2 Q So when Liliemark states that the areas
3 under the concentration-time curve, AUC, are
4 similar, Liliemark is referring to the AUC curves
5 for an intravenous dose and an oral saline
6 solution dose; correct?

7 A Yes.

8 Q And the oral saline solution dose is twice
9 that of the intravenous dose; correct?

10 A About -- about twice the intravenous dose.

11 Q Do you agree that Liliemark is conveying
12 that bioavailability can be measured based on AUC
13 values?

14 A Yes.

15 Q Okay. I want to focus on Liliemark's
16 statement that "When administered orally at about
17 twice the intravenous dose, the areas under the
18 concentration time curve, AUC, are similar."

19 Do you have that?

20 A I see that sentence, yes.

21 Q "This means that Liliemark's oral
22 cladribine saline solution has about 50 percent

1 bioavailability"; correct?

2 A Please repeat the question.

3 Q So we're focusing on the statement by
4 Liliemark, "When administered orally at about
5 twice the intravenous dose, the areas under the
6 concentration-time curve, AUC, are similar." This
7 means Liliemark's oral cladribine saline solution
8 has about 50 percent bioavailability; correct?

9 DR. ELLISON: Objection. Form.
10 Foundation.

11 A Yes.

12 Q You agree that Liliemark disclosed the
13 same oral cladribine saline solution dosage form
14 as Stelmasiak; correct?

15 A He indicated a saline -- a saline
16 solution, and Stelmasiak indicated a saline
17 solution. I can't know if they're exactly the
18 same.

19 Q Okay. Let's go to paragraph 110 of your
20 declaration. And you see about six lines down in
21 paragraph 110 you say, "Stelmasiak discloses
22 administering oral cladribine prepared as a

1 sterile solution in isotonic saline which a POSA
2 would have understood was the same dosage form
3 disclosed by Liliemark"; correct?

4 A Yes.

5 Q Do you stand by that opinion?

6 A Yes, I stand by the opinion.

7 Q Now, still in paragraph 110 of your
8 declaration, three lines up from the bottom of
9 page 76, you provide your opinion that "Bodor
10 teaches that its oral cladribine tablet
11 formulation increases or enhances the oral
12 bioavailability of cladribine"; correct?

13 A Correct.

14 Q "Bodor provides bioavailability and
15 pharmacokinetic data for oral cladribine compared
16 to subcutaneous cladribine"; correct?

17 A Correct.

18 Q Let's look at Bodor. I'm going to hand
19 you what has been marked as Exhibit 1022. Do you
20 recognize Exhibit 1022 as the Bodor reference that
21 you discussed in your declaration?

22 A Yes, I do.

1 Q Would you go to page 36, please. On page
2 36 do you see example 5, Clinical Study: Dose
3 Response and Absolute Bioavailability?

4 A I'm sorry. You're using Bodor's numbers.

5 Q Yes, numbers at the top of the page.

6 A Yeah.

7 Q Okay. So you see example 5, Clinical
8 Study: Dose Response and Absolute
9 Bioavailability?

10 A Yes.

11 Q You reviewed example 5 of Bodor; correct?

12 A Yes.

13 Q Now, here Bodor states, "The objective of
14 the study was to assess the systemic availability
15 of cladribine after oral administration in two
16 different fixed oral doses, in comparison with one
17 fixed intravenous administration (reference
18 formulation) in patients with MS (multiple
19 sclerosis)"; correct?

20 A Yes.

21 Q And the two different fixed oral doses of
22 cladribine that Bodor studied were 3 milligram and

1 10 milligram tablets; correct?

2 A Yes.

3 Q Can you go to table 8 of Bodor? It's on
4 page 38.

5 A Yes.

6 Q Table 8 provides ratios of oral to IV
7 pharmacokinetic parameters; correct?

8 Do you have the question?

9 A Please repeat it.

10 Q Table 8 of Bodor provides ratios of oral
11 to IV pharmacokinetic parameters; correct?

12 A Yes.

13 Q And here the bioavailability that Bodor
14 reports for its 10 milligram tablets is 39.1 or
15 39.4 percent; correct?

16 A In -- in this particular -- in this
17 particular example and study, that's what he
18 reports.

19 Q And for the 3 milligram tablet, Bodor
20 reports 34.5 or 34.0 percent; correct?

21 A Although he reports that, a POSA would
22 have understood from many sources that the

1 bioavailability is about 50 percent.

2 Q But what Bodor reports for Bodor's tablets
3 is 39.1 and 39.4 percent for the 10 milligram
4 tablet; correct?

5 A That's what Bodor reported in this
6 particular single example.

7 Q And for the 3 milligram tablet, Bodor
8 reported 34.5 or 34.0 percent bioavailability;
9 correct?

10 A In this particular example.

11 Q Correct for this particular example;
12 right?

13 A Correct for this particular example.

14 Q Can we go to paragraph 110 of your
15 declaration, please. In the second sentence you
16 provide your opinion, "The general knowledge in
17 the art demonstrated the oral bioavailability of
18 cladribine varies from 37 to 51 percent when the
19 saline solution for intravenous administration is
20 given to patients to drink."

21 That's your opinion; correct?

22 A Yes.

1 Q And that is the general knowledge in the
2 art that you were referring to when you said that
3 a POSA would have understood from many sources
4 that the bioavailability is about 50 percent?

5 A This is only one of several, several
6 sources on which I would have made that statement.

7 Q And the one of several that you're talking
8 about is Exhibit 1048 that you cited in paragraph
9 110? That's the Liliemark that we just looked at.

10 A Well, Liliemark says that when the drug is
11 administered in this oral saline solution at about
12 twice the intravenous dose, it has the same
13 concentration curve as the intravenous dose.

14 Q And Liliemark is what you cited in
15 paragraph 110 of your declaration when you talked
16 about general knowledge in the art regarding oral
17 bioavailability of cladribine; correct?

18 A Could you repeat that question?

19 Q Liliemark is what you cited in paragraph
20 110 of your declaration when you talked about
21 general knowledge in the art regarding oral
22 bioavailability of cladribine; correct?

1 A That's one of -- that's one of the
2 sources.

3 Q That's the source that you cited; correct?

4 DR. ELLISON: Objection. Form.

5 A That's the source that I cited for the
6 statement about the general knowledge in the art.

7 Q I wanted to go back to Bodor, please,
8 Exhibit 1022. And go to page 33, please. Do you
9 see example 4, Clinical Study: Relative
10 Bioavailability?

11 A Yes.

12 Q At line 24 Bodor says, "This study was a
13 two center, open-label, randomized, four-way,
14 crossover single dose study using 12 patients with
15 MS. Patients received randomly three different
16 fixed oral doses, 3.0 milligrams, and a fixed
17 subcutaneous dose of 3.0 milligrams"; correct?

18 A Yes.

19 Q This study in example 4 of Bodor involved
20 giving patients fixed oral doses; correct?

21 A Yes.

22 Q This study in example 4 of Bodor also

1 involved giving patients fixed subcutaneous doses;
2 correct?

3 A Yes.

4 Q Every patient receiving oral doses
5 received the same dose amount; correct?

6 A Yes.

7 Q The fixed oral dose was not based on a
8 patient's weight; correct?

9 DR. ELLISON: Objection. Form.
10 Foundation.

11 A I have no idea at this point on what basis
12 he chose the 3 milligram dose.

13 Q Patients of different weights did not
14 receive different doses; correct?

15 A I don't know the weights of the patients
16 in the study.

17 Q But every patient received the same dose
18 amount; correct?

19 A Correct.

20 Q And every patient receiving subcutaneous
21 doses received the same dose amount; correct?

22 A Correct.

1 Q Could you go to page 36, please, and now
2 we're back at Bodor's example 5, Clinical Study:
3 Dose Response and Absolute Bioavailability.

4 You see it?

5 A Yes.

6 Q At line 17 Bodor says, "This study was a
7 three center, open-label, randomized, three-way,
8 crossover single dose study using 26 patients with
9 MS. Patients received randomly two different
10 fixed oral doses and a fixed IV dose of 3
11 milligrams administered as a one-hour infusion";
12 correct?

13 A Yes.

14 Q In the study described in Bodor example 5,
15 patients were given fixed oral doses; correct?

16 A Yes.

17 Q And in the study described in Bodor
18 example 5, patients were given fixed intravenous
19 doses; correct?

20 A Yes.

21 Q Every patient receiving oral doses
22 received the same dose amount; correct?

1 A That depends what time period you're
2 talking about.

3 Q Well, Bodor says patients received
4 randomly two different fixed oral doses, 3
5 milligrams and 10 milligrams; correct?

6 A That's what Bodor says, yes.

7 Q So the patients in the 3 milligram group
8 all received the same 3 milligram dose; correct?

9 A I don't see any reference here to a 3
10 milligram group.

11 Q Well, you see that it says, "Patients
12 received randomly two different fixed oral doses,
13 3 milligrams and 10 milligrams"; correct?

14 A Yes, I see that.

15 Q So the patients who randomly received 3
16 milligrams all received that same 3 milligram
17 dose; correct?

18 A Well, of course, all patients who received
19 the 3 milligram dose received the 3 milligram
20 dose.

21 Q So even if the patients had different
22 weights, they still received the 3 milligram dose;

1 correct?

2 A I don't know anything about the weights of
3 the patients.

4 Q But the 3 milligram dose was the same
5 regardless of patient weight; correct?

6 A 3 milligram dose was the same regardless
7 of the patient's weight.

8 Q And the 10 milligram dose was also the
9 same regardless of patient weight; correct?

10 A Yes.

11 Q And the 3 milligram intravenous dose was
12 also the same regardless of patient weight;
13 correct?

14 A Yes.

15 Q Let's go back to your declaration, please,
16 paragraph 115. If you look at the top of page 80,
17 about four lines down, yeah, can you go on to page
18 80?

19 A Yeah, but I'm not going to read it out of
20 context. I'm going to read the whole paragraph.

21 Q So on page 80, four lines down from the
22 top, you provide your opinion, "Thus, because oral

1 cladribine has been previously shown to have
2 clinical efficacy in patients with MS using
3 cyclical treatment/no treatment regimens, a POSA
4 would have had a reasonable expectation of
5 successfully treating MS by orally administering
6 Bodor's improved oral dosage form of cladribine
7 following the claimed steps of an induction
8 period, cladribine-free period, a maintenance
9 period and a cladribine-free period"; correct?

10 A Yes.

11 Q And for this opinion you cite Exhibit 1013
12 at page 7 and Exhibit 1022 at page 23, lines 15 to
13 20; correct?

14 A Yes.

15 Q Now, Exhibit 1013 is Stelmasiak; correct?

16 A Yes.

17 Q And Exhibit 1022 is Bodor?

18 A Yes.

19 Q Let's look at the next paragraph in your
20 declaration, paragraph 116. You provide your
21 opinion that "A POSA would have reasonably
22 expected Bodor's induction dose to have efficacy

1 in treating MS because Bodor expressly instructs
2 that the dose is suitable for the treatment of
3 multiple sclerosis"; correct?

4 A Yes.

5 Q And for that opinion you also cite Exhibit
6 1022 at page 23, lines 15 to 16; correct?

7 A Yes.

8 Q Exhibit 1022 is Bodor?

9 A Yes.

10 Q So let's go back to Bodor, Exhibit 1022 at
11 page 23, lines 15 to 20. Bodor does not provide
12 any efficacy data at page 23, lines 15 through 20;
13 correct?

14 A He does not provide efficacy data in those
15 lines.

16 Q Bodor does not provide efficacy data
17 anywhere; correct?

18 A A POSA would have understood that the
19 doses of cladribine that Bodor was -- recommended
20 were in a range that would have been consistent
21 with other -- with other studies showing efficacy.

22 Q But Bodor does not provide any efficacy

1 data; correct?

2 A A POSA would have understood that Bodor
3 used doses of cladribine that were consistent with
4 efficacy data from other studies.

5 Q I understand you have that opinion, but my
6 question is Bodor does not provide any efficacy
7 data; correct?

8 A A POSA would have understood from Bodor's
9 doses that these were consistent with efficacy
10 data from other studies.

11 Q I understand that's your opinion. Are you
12 able to answer my question which is Bodor does not
13 provide any efficacy data; correct?

14 A I stand by the opinion I've stated.

15 Q Can you answer the question whether Bodor
16 provides any efficacy data?

17 A Although Bodor doesn't himself provide
18 efficacy data, a POSA would understand that the
19 doses Bodor uses were consistent with efficacy
20 data from other studies.

21 Q Bodor teaches that administration of
22 cladribine may be accompanied by administration of

1 one or more additional active ingredients for
2 treating multiple sclerosis; correct?

3 A Could you tell me where you're reading?

4 Q Look at Bodor page 24, lines 10 to 13.

5 And my question was, Bodor teaches that
6 administration of cladribine may be accompanied by
7 administration of one or more additional active
8 ingredients for treating multiple sclerosis;
9 correct?

10 A Well, he refers to in this paragraph
11 treating the cladribine-responsive condition.

12 Q And the cladribine-responsive condition
13 includes MS; correct?

14 A Yes.

15 Q So you agree that Bodor teaches
16 administration of cladribine may be accompanied by
17 administration of one or more additional active
18 ingredients for treating multiple sclerosis;
19 correct?

20 A I agree that Bodor says the invention may
21 be accompanied by administration of one or more
22 additional active ingredients for treating the

1 cladribine-responsive condition.

2 Q And the cladribine-responsive condition
3 includes multiple sclerosis; correct?

4 A Yes, it does include the multiple
5 sclerosis.

6 Q And Bodor says that in the treatment of
7 multiple sclerosis other useful drugs include
8 interferon beta, glatiramer acetate and
9 natalizumab; correct?

10 A He says that, but there's an error in --
11 in this sentence.

12 Q Is it a true statement that in the
13 treatment of multiple sclerosis other useful drugs
14 include interferon beta, glatiramer acetate and
15 natalizumab?

16 A That part's true, but all of those
17 preparations of interferon beta that he lists are
18 not identical to naturally occurring protein
19 found in the --

20 (Reporter clarification.)

21 THE WITNESS: I said that Ms. Whelan's
22 statement was correct about those drugs, but that

1 Bodor's statement that Rebif, Betaseron/Betaferon
2 and Avonex are identical to the naturally
3 occurring protein found in the human body is not
4 correct.

5 Q So Bodor teaches that administration of
6 cladribine may be accompanied by administration of
7 interferon beta, glatiramer acetate or natalizumab
8 for treating multiple sclerosis; correct?

9 A This -- this is not an accurate statement.

10 Q You agree that Bodor teaches that
11 administration of cladribine can be accompanied by
12 administration of one or more additional active
13 ingredients for treating the cladribine-responsive
14 condition which includes MS; correct?

15 DR. ELLISON: Objection. Form.
16 Foundation.

17 A I agree that Bodor says the administration
18 of cladribine may include one or more additional
19 active ingredients.

20 Q For treating the cladribine-responsive
21 condition; correct?

22 A Yes.

1 Q And Bodor then says two sentences later
2 that, for example, in treating multiple sclerosis,
3 other useful drugs include interferon beta,
4 glatiramer acetate and natalizumab; correct?

5 DR. ELLISON: Objection. Form.
6 Foundation.

7 A I agree that he states that, and I agree
8 that those are other useful drugs for treating
9 multiple sclerosis.

10 Q And Bodor also teaches -- if you look at
11 page 25, line 20, Bodor also teaches that,
12 "Generally speaking, those drugs which work by a
13 mechanism different from that of cladribine are
14 particularly useful for concomitant therapy with
15 the cladribine composition described herein";
16 correct?

17 A Bodor is speculating there.

18 Q You agree that the statement I read is
19 what Bodor says; correct?

20 A Can you read the statement again?

21 Q Bodor teaches that, "Generally speaking,
22 those drugs which work by a mechanism different

1 from that of cladribine are particularly useful
2 for concomitant therapy with the cladribine
3 composition described herein"?

4 DR. ELLISON: Objection. Form.

5 Q Correct?

6 DR. ELLISON: Objection. Form.

7 A I'd agree that that's what Bodor says.

8 Q Interferon beta works by a mechanism
9 that's different from cladribine's mechanism;
10 correct?

11 A Yes.

12 Q And glatiramer acetate works by a
13 mechanism that's different than cladribine's
14 mechanism; correct?

15 A Yes.

16 Q Natalizumab works by a mechanism different
17 from cladribine's mechanism; correct?

18 A Yes.

19 Q What FDA-approved drugs were you
20 prescribing to your multiple sclerosis patients in
21 2004?

22 A I prescribed them interferon beta-1b which

1 is Betaseron. I prescribed interferon beta-1a in
2 the form of Avonex. I prescribed
3 interferon beta-1a in the form of Rebif. I
4 prescribed interferon beta 1 -- I'm sorry. I
5 prescribed glatiramer acetate. You asked about
6 2004, correct?

7 Q Correct.

8 A So I probably had not prescribed
9 natalizumab. Natalizumab, I believe, was approved
10 by the FDA in -- I think in November of 2004 and
11 was removed from the market, I believe, in
12 February of 2005. So I'm not sure whether I would
13 have prescribed natalizumab in 2004.

14 Q Glatiramer acetate is marketed as
15 Copaxone; correct?

16 A In 2004 it was marketed as Copaxone.

17 Q Copaxone is dosed 20 milligrams per day;
18 correct?

19 A In 2004 it was dosed 20 milligrams per
20 day.

21 Q And today there's another dose available;
22 correct?

1 A Correct.

2 Q What's that?

3 A 40 milligrams, three times --

4 (Reporter clarification.)

5 THE WITNESS: 40 milligrams, three times a
6 week.

7 Q Betaseron was administered 0.25 milligrams
8 every other day; correct?

9 A Correct.

10 Q Avonex was administered 30 micrograms per
11 week; correct?

12 A Correct.

13 Q And Rebif was administered 44 micrograms
14 three times a week; correct?

15 A I believe that there was also a 22
16 micrograms, three times a week preparation of
17 Rebif. I don't believe that I ever used it, and
18 it wasn't widely used. Most people used 44
19 micrograms, three times per week.

20 Q Administration of glatiramer acetate did
21 not involve administering a therapy for a period
22 of time, stopping the therapy for a period of

1 time, and retreating for a period of time;
2 correct?

3 DR. ELLISON: Objection. Form.
4 Foundation.

5 A Well, in 2000 -- in 2004 Copaxone was
6 administered on a daily basis. It was not
7 stopped.

8 Q So my statement was correct?

9 A Yes.

10 Q And in 2004 administration of beta
11 interferon did not involve administering a therapy
12 for a period of time, stopping the therapy for a
13 period of time, and retreating for a period of
14 time; correct?

15 A That's correct.

16 Q Beta interferon is a disease-modifying
17 therapy; correct?

18 A That's correct.

19 Q And Copaxone is also a disease-modifying
20 therapy; correct?

21 A Correct.

22 Q Do you agree that disease-modifying

1 therapies alter the long-term course of multiple
2 sclerosis?

3 DR. ELLISON: Objection. Form.
4 Foundation.

5 A The response to disease-modifying
6 therapies is variable.

7 Q Is the purpose of disease-modifying
8 therapies to alter the long-term course of
9 multiple sclerosis?

10 A The purpose of disease-modifying therapy
11 is to alter the behavior of the multiple
12 sclerosis.

13 Q Is the behavior of the multiple sclerosis
14 different from the long-term course of multiple
15 sclerosis?

16 A You'd have to define what you meant by
17 long-term course of multiple sclerosis.

18 Q I'm going to mark Exhibit 2006.

19 (Miller Deposition Exhibit 2006 was marked
20 for identification.)

21 Q Do you recognize Exhibit 2006 as an
22 article that you published with Mark Tullman and

1 Fred Lublin titled, "Immunotherapy of multiple
2 sclerosis--current practice and future directions"
3 in the Journal of Rehabilitation Research and
4 Development, volume 39, number 2, March-April
5 2002, pages 273 to 286?

6 A So I've written many -- authored or
7 co-authored many articles. So I don't necessarily
8 have independent recollection of every one of them
9 as I sit here. I accept that this is an article
10 that I wrote based on what you've handed me.

11 Q You recognize this as an article that you
12 published in 2002; correct?

13 A Yes.

14 Q Okay. On page 273, right-hand column, the
15 first full paragraph. It's the first page of the
16 article.

17 A The first page?

18 Q First page.

19 A Yeah. Sorry.

20 Q Right column, first full paragraph. Here
21 you wrote, "Therapy for MS generally involves
22 either disease-modifying agents, DMA, i.e., those

1 that alter the long-term course of MS, treatments
2 of acute exacerbations or symptomatic therapies."

3 That's what you wrote --

4 A Yes.

5 Q -- in 2002; correct?

6 A Yes.

7 Q So you described disease-modifying agents
8 as those that alter the long-term course of MS;
9 correct?

10 A As I understand what's meant by the
11 long-term course of MS.

12 Q And in this statement about
13 disease-modifying agent, what did you mean by the
14 long-term course of MS?

15 A I mean, I meant -- I understand it as how
16 the disease is behaving over many years.

17 Q And is that how a person of ordinary skill
18 in the art understands the long-term course of MS?

19 A I believe the person of ordinary skill in
20 the art would understand long-term course of MS
21 to encompass how the disease was behaving over
22 many years.

1 Q So the person of ordinary skill would have
2 the same understanding as you of the long-term
3 course of MS; correct, according to your opinion?

4 DR. ELLISON: Objection. Form.
5 Foundation.

6 A A person of ordinary skill in the art
7 would have an understanding of -- of what he or
8 she meant by long-term course of disease. I am
9 not a person of ordinary skill in the art so I
10 might have some additional information and
11 knowledge.

12 Q So you're not -- strike that.

13 So do you stand by your prior written
14 statement that disease-modifying agents alter the
15 long-term course of MS?

16 A Where are you reading?

17 Q We were in your article from 2002, Exhibit
18 2006, page 273, right-hand column, first full
19 paragraph, and my question is, do you stand by
20 your prior statement that disease-modifying agents
21 are those that alter the long-term course of MS?

22 A I stand by my statement that

1 disease-modifying agents are meant to be those
2 that alter the long-term course of MS in my
3 understanding of what's encompassed by the
4 long-term course of MS.

5 Q Disease-modifying therapies do not work by
6 making multiple sclerosis patients feel better;
7 correct?

8 DR. ELLISON: Objection. Form.
9 Foundation.

10 A I can't answer that question as asked.

11 Q Let's go to Exhibit 2005 which was your
12 book chapter from 2000 --

13 A The Kalb?

14 Q -- 2005 -- Kalb, yes.

15 So please go to page 59.

16 A Okay.

17 Q Do you see about halfway down the page you
18 wrote, "In the clinical trials of interferon
19 beta-1b, Betaseron, interferon beta-1a, Avonex,
20 and Rebif and glatiramer acetate, Copaxone, there
21 was no evidence that the drugs made the treatment
22 groups feel better"?

1 A Yes. That's what I wrote.

2 Q Okay. So with that statement in mind, do
3 you agree that disease-modifying therapies do not
4 work by making multiple sclerosis patients feel
5 better?

6 DR. ELLISON: Objection. Form.

7 A I can't answer that question as stated.

8 Q Is it a true statement that in the
9 clinical trials of interferon beta-1b, interferon
10 beta-1a and glatiramer acetate, there was no
11 evidence that the drugs made the treatment groups
12 feel better?

13 A That's a true statement.

14 Q Patients taking a disease-modifying
15 therapy like Copaxone can still experience
16 attacks; correct?

17 A Correct.

18 Q To treat such attacks, patients could be
19 administered intravenous steroids; correct?

20 A Correct.

21 Q And patients who experience attacks while
22 taking a disease-modifying therapy can still be

1 treated with intravenous steroids; correct?

2 A That's correct.

3 Q Have you ever prescribed corticosteroids
4 to your multiple sclerosis patients?

5 A Yes.

6 Q Before 2004, did you prescribe
7 corticosteroids to your multiple sclerosis
8 patients?

9 A Yes.

10 Q Corticosteroids are not a
11 disease-modifying therapy; correct?

12 A That may or may not be correct.

13 Q Corticosteroids are only used to treat
14 acute attacks; correct?

15 A That may or may not be correct.

16 Q You agree that corticosteroids are used to
17 treat acute attacks; correct?

18 A I do agree that corticosteroids can be
19 used to treat attacks and are used to treat
20 attacks.

21 Q You cannot predict when an MS patient will
22 suffer an attack; correct?

1 DR. ELLISON: Objection. Form.

2 A I cannot -- I cannot reliably predict when
3 a patient is going to have an attack, correct.

4 Q And a person of ordinary skill in the art
5 also cannot predict when an MS patient will suffer
6 an attack; correct?

7 DR. ELLISON: Objection. Form.
8 Foundation.

9 A A person of ordinary skill in the art
10 might know that -- that during a particular time
11 frame a patient with MS may be more likely to
12 incur -- to experience an attack, but a person of
13 ordinary skill in the art would not be able to
14 accurately predict in the short term when an
15 attack might occur.

16 Q Could you turn back to Exhibit 2005?

17 A Still Kalb?

18 Q Still Kalb. Your book chapter from 2000.

19 If you look in the bottom paragraph --
20 one, two, three, four, five -- six lines down.

21 A Give me the page number, please.

22 Q Page 61.

1 A And where am I going?

2 Q Bottom paragraph. And then about six
3 lines into that paragraph.

4 A Okay.

5 Q You stated, "Although people who are
6 feeling and doing relatively well may see little
7 reason to begin one of these medications, the fact
8 is that multiple sclerosis is a very unpredictable
9 disease."

10 That's a true statement; correct?

11 DR. ELLISON: Objection. Form.

12 A So this is a book written by -- written
13 for lay people, and so when -- when one is
14 writing, or at least when I'm writing for lay
15 people, one wants to give accurate but general --
16 general statements.

17 So in general for an individual patient,
18 as I've said, the course is unpredictable but
19 they're -- overall, one who has skill in the art
20 can have some sense of how -- how a disease is
21 likely to behave. One can never be 100 percent
22 sure.

1 Q So your accurate statement in 2000 was
2 that "multiple sclerosis is a very unpredictable
3 disease"; correct?

4 DR. ELLISON: Objection. Form.
5 Foundation.

6 A My -- my statement when I would be
7 addressing an individual patient, which is how
8 this book is written, answers questions that an
9 individual patient might pose to a physician. I
10 would say -- I would stand by this, that the
11 disease is unpredictable.

12 DR. ELLISON: Counsel, are you close to
13 taking a break? We've been going about an hour
14 and a half now.

15 MS. WHELAN: We can take a break.

16 DR. ELLISON: How long?

17 MS. WHELAN: Why don't we go off the
18 record.

19 (A discussion was held off the record.)

20 (A recess was taken.)

21 BY MS. WHELAN:

22 Q Have you ever prescribed corticosteroids

1 to an MS patient who was not experiencing an
2 attack?

3 A Yes.

4 Q You agree that before 2004 continuous
5 administration of steroids had never been shown to
6 provide long-term benefits for people with MS;
7 correct?

8 DR. ELLISON: Objection. Form.

9 A I don't know what you mean by "continuous
10 administration of steroid."

11 Q Okay. Let's go back to Exhibit 2005.
12 This is your 2000 book chapter. And, please, go
13 to page 48.

14 A Page 48.

15 Q So Exhibit 2005 has this Kalb book with
16 your chapter.

17 A 48?

18 Q And go to page 48, please.

19 Okay. The first sentence on page 48 says,
20 "Continuous administration of steroids has never
21 been shown to provide long-term benefits for
22 people with MS."

1 That's a true statement that you wrote in
2 your 2000 book chapter; correct?

3 A Yes.

4 Q Do you agree that continuous
5 administration of steroids has not been
6 established as effective therapy for the
7 prevention of clinical worsening in MS?

8 A Well, the term "continuous" could be --
9 could be interpreted in -- in different ways, and
10 I'm not precisely sure, actually, how I was using
11 that term back in 2000.

12 Q Are you familiar with regularly scheduled
13 intermittent doses of pulse steroids?

14 A Yes.

15 Q Do you agree that administration of
16 regularly scheduled intermittent doses of pulse
17 steroids has not been established as effective
18 therapy for the prevention of clinical worsening
19 in MS?

20 A There are some -- some papers that have
21 suggested that there is a benefit. I don't think
22 it's firmly established whether or not there is a

1 benefit.

2 Q As of 2008, was it a true statement that
3 administration of regularly scheduled intermittent
4 doses of pulse steroids had not been established
5 as effective therapy for the prevention of
6 clinical worsening in MS?

7 A I think that requires some interpretation
8 of what the word "established" means.

9 There were some references that had found
10 some benefit in some forms of progressive MS. I
11 would say it was not definitively established that
12 they had a benefit.

13 Q All right. I want to go to your 2008 book
14 chapter, which was Exhibit 2004.

15 Would you please go to page 342?

16 A Okay.

17 Q And you see the "Summary and
18 recommendations" section?

19 Are you there?

20 A Yes. I'm reading it.

21 Q Okay. So your second sentence in that
22 "Summary and recommendations" section in your 2008

1 book chapter you wrote, "Administration of
2 regularly scheduled intermittent doses of pulse
3 steroids has not been established as effective
4 therapy for the prevention of clinical worsening
5 in MS."

6 That was an accurate statement when you
7 wrote that in 2007 or 2008; correct?

8 A As I previously stated, it depends on the
9 use of the term "established." And that sentence
10 is followed by reference to some studies which
11 have suggested a benefit. I stand by the fact
12 that it's not firmly established is effective in
13 progressive MS.

14 THE REPORTER: I'm sorry?

15 THE WITNESS: I stand by the sentence that
16 it's not firmly established is effective in
17 progressive MS, but it is used.

18 Q You didn't use the word "firmly" in your
19 sentence in 2008; correct?

20 A That's correct, that I didn't use the word
21 "firmly."

22 Q You agree that if a patient experiences

1 attacks while taking a disease-modifying therapy,
2 they can still be treated with intravenous
3 steroids; correct?

4 A I agree.

5 Q And as an alternative, the patient could
6 also switch to a different MS drug; correct?

7 A That's apples and oranges.

8 Q Do you agree that many people with MS
9 start on a medication and then need to change
10 medication, at some point, for one reason or
11 another?

12 A I --

13 DR. ELLISON: Objection. Form.
14 Foundation.

15 A I agree.

16 Q Do you agree that there is a certain
17 period of time required for any treatment to take
18 effect in an MS patient's body?

19 DR. ELLISON: Objection. Form.
20 Foundation.

21 A Well, there's always a certain period of
22 time; could be seconds, could be minutes, could be

1 hours, could be days, could be weeks, could be
2 months.

3 Q I'm going to hand you what's been marked
4 as Exhibit 1031.

5 Do you recognize Exhibit 1031 as a 1999
6 publication by Romine, et al., that you discussed
7 in your declaration?

8 A Yes, I do.

9 Q Please turn to page 43.

10 A Yes.

11 Q Okay. On the right-hand column, about
12 nine lines down, Romine says, "24 patients from
13 our initial study of cladribine in chronic
14 progressive MS have been retreated (0.07
15 milligrams per kilograms) by five days by four
16 courses because of a recurrence of disease
17 worsening"; correct?

18 A That's correct, what it says. Yes.

19 Q Romine selected patients for retreatment
20 with cladribine because they had a recurrence of
21 disease worsening; correct?

22 A Yes.

1 Q Now, I want to go back to Rice,
2 Exhibit 1018.

3 Could you please go to page 1146 of Rice?

4 A Yes.

5 Q Please look in the right-hand column, the
6 last paragraph, at the heading "Study medications
7 and dosage."

8 Here Rice says, "Patients who met the
9 protocol specified entry criteria were randomized
10 in approximately equal numbers to receive eight
11 monthly courses of therapy. Patients received six
12 courses of cladribine, 0.07 milligrams per
13 kilogram per day, SC for five consecutive days
14 (total dose 2.1 milligrams per kilogram), followed
15 by two courses of placebo or two courses of
16 cladribine 0.07 milligrams per kilogram per day,
17 SC for five consecutive days (total dose 0.7
18 milligrams per kilogram) followed by six courses
19 of placebo or eight courses of placebo SC for five
20 consecutive days"; correct?

21 A Correct.

22 Q "Patients in one arm re" --

1 A Where are you reading?

2 Q Now, I just want to talk -- oh, actually
3 let's just look at the next sentence from what we
4 were looking at.

5 "Patients in one arm received six courses
6 of cladribine, 0.07 milligrams per kilogram per
7 day SC, for five consecutive days, total dose 2.1
8 milligrams per kilogram followed by two courses of
9 placebo"; correct?

10 A Yes.

11 Q Patients in this arm had a two-month
12 cladribine-free period; correct?

13 A Well -- I can't answer the question as is.

14 Q During the two months when patients in
15 this arm received courses of placebo, patients in
16 this arm were cladribine-free; correct?

17 DR. ELLISON: Objection. Form.

18 A Patients in the study receiving that dose
19 of cladribine did not get cladribine in the
20 subsequent two months. I don't know what they got
21 after that.

22 Q So patients in the arm we're talking about

1 got six monthly courses of cladribine followed by
2 two monthly courses of placebo; correct?

3 A They got the two months treatment of
4 placebo. I don't know what they got after that.

5 Q But during the two months when the
6 patients in this arm received placebo, they were
7 cladribine-free; correct?

8 A That is correct.

9 Q "Patients in the other arm received two
10 courses of cladribine, .07 milligrams per kilogram
11 per day, SC, for five consecutive days (total dose
12 0.7 milligrams per kilogram) followed by six
13 courses of placebo"; correct?

14 A That's correct.

15 Q So patients in this arm got two monthly
16 courses of cladribine and then six monthly courses
17 of placebo; correct?

18 A That is correct.

19 Q And during the six months when the
20 patients in this arm received the placebo courses,
21 those patients were cladribine-free; correct?

22 A I don't know how long they were free of

1 cladribine, but they were free of cladribine
2 during those six months.

3 Q Okay. So now I'm back on page 1146 of
4 Rice. I want to look at the paragraph above Study
5 Medications and Dosage.

6 A Okay.

7 Q Okay. So three sentences into that
8 paragraph, it says, "After all patients at a study
9 site completed the 12-month, double-blind phase,
10 the blind was broken and patients who fulfilled
11 the hematologic dosing criteria were permitted to
12 receive open-label cladribine treatment during the
13 long-term extension phase of the study provided at
14 least 12 months had elapsed since the last dose of
15 cladribine and there was evidence of disease
16 progression"; correct?

17 A Correct.

18 Q Rice describes several criteria for
19 retreatment with cladribine; correct?

20 A I'd have to look and see where his
21 criteria are.

22 Q Well, I'm talking about the sentence that

1 we just looked at.

2 DR. ELLISON: Objection. Form.

3 Foundation.

4 A Point me back to where we were.

5 Q Okay. So we were in -- on page 1146.

6 A Oh, yeah.

7 Q Paragraph above Study Medications and
8 Dosage, third sentence, it talks about which
9 patients were permitted to receive open-label
10 cladribine treatment during the long-term
11 extension phase; correct?

12 A Yes.

13 Q And that's retreatment; correct?

14 A That is retreatment, yes.

15 Q And Rice describes several criteria for
16 that retreatment; right?

17 A Yes.

18 Q And the criteria for cladribine
19 retreatment include evidence of disease
20 progression; correct?

21 A Yes. That's what he says.

22 Q And the criteria for cladribine

1 retreatment include fulfilling the hematologic
2 dosing criteria; correct?

3 A That's what he says.

4 Q And the criteria for cladribine
5 retreatment include having at least 12 months
6 elapsed since the last dose of cladribine;
7 correct?

8 A Yes.

9 Q For the patients who received six courses
10 of cladribine followed by two courses of placebo,
11 they could not receive cladribine retreatment
12 until at least 12 months had elapsed since their
13 last dose of cladribine; correct?

14 A Yes.

15 Q And that would not be until month 18 at
16 the earliest; correct?

17 A Could you repeat that question, please?

18 Q Okay. So we're focusing on the patients
19 who received six courses of cladribine followed by
20 two courses of placebo.

21 Do you have that in mind?

22 A Mm-hmm.

1 Q Those patients could not receive
2 cladribine retreatment until month 18 at the
3 earliest; correct?

4 A Not necessarily correct.

5 Q Well, they had to wait 12 months from
6 their last dose of cladribine before getting
7 retreatment; correct?

8 A They had to get -- they had to wait 12
9 months, yes.

10 Q And their last dose of cladribine was at
11 month six; correct?

12 A Not necessarily.

13 Q They received six monthly courses of
14 cladribine; correct?

15 A Not necessarily.

16 Q We're talking about the patient arm who
17 received six monthly courses of cladribine.

18 A Yes. That's what you're talking about.

19 Q Yes. So those patients received
20 cladribine for the first six months; correct?

21 A Not necessarily.

22 Q But you agree they received six monthly

1 courses of cladribine?

2 A Not necessarily.

3 Q The patients who received six monthly
4 courses of cladribine, you disagree that they
5 received six monthly courses of cladribine?

6 A What is your question?

7 Q Well, I'm talk -- we're talking about the
8 patients who received six courses of cladribine.

9 DR. ELLISON: Objection. Form.

10 A You're talking about patients in the group
11 that were assigned to receive six months of
12 cladribine.

13 Q Patients -- do you agree that there was a
14 group of patients who received six courses of
15 cladribine followed by two courses of placebo;
16 correct?

17 A There were -- there was a group of
18 patients who were assigned to receive six monthly
19 doses of cladribine.

20 Q Okay. So for the patients who were
21 assigned to receive six monthly doses of
22 cladribine and who, in fact, received six monthly

1 doses of cladribine, those patients could not
2 receive retreatment until month 18 at the
3 earliest; correct?

4 A That's correct.

5 Q For the patients who were assigned to
6 receive two courses of cladribine followed by six
7 courses of placebo and who, in fact, received two
8 courses of cladribine followed by six courses of
9 placebo, those patients could not be retreated
10 until month 14 at the earliest; correct?

11 A That's correct.

12 DR. ELLISON: Objection.

13 A That's correct.

14 Q Could we go back to your declaration,
15 please, for the 480 IPR, Exhibit 1002?

16 A Yes.

17 Q Please go to paragraph 30.

18 A 30?

19 Q Mm-hmm. It's on page 23.

20 A Yes.

21 Q Now, in the second sentence of paragraph
22 30, you provide your opinion that, in fact, the

1 most common therapeutic approach to MS before
2 December 2004 was with immunosuppressive drugs;
3 correct?

4 A Yes.

5 Q Is that still your opinion?

6 A That's my opinion.

7 Q And you cite for that opinion Exhibit 1013
8 at page 4 and Exhibit 1007 at page 131; correct?

9 A That's correct.

10 Q Immunomodulatory drugs are different from
11 immunosuppressive drugs; correct?

12 A Those terms have been used in different
13 ways at different times and by different people.

14 Q Not all immunomodulatory drugs are
15 immunosuppressants; correct?

16 A That's how many people understand them.

17 Q That's how a person of ordinary skill in
18 the art would understand it; correct?

19 A Person of ordinary skill in the art would
20 likely understand that an immunomodulatory drug is
21 not felt to be an immunosuppressant drug. Yes.

22 Q Do you agree that in 2004 the best study

1 agents for MS had been immunomodulatory?

2 A It all depends what you mean by "best
3 study."

4 Q Go to Exhibit 2006.

5 Can you pull out 2006? That was your 2002
6 article "Immunotherapy of multiple sclerosis."

7 A That's the Mark Tullman and Fred Lublin
8 article?

9 Q Correct.

10 A Okay.

11 Q Okay. Please go to page 278. Sorry, 273.

12 A 273?

13 Q Yeah.

14 Okay. Do you see the paragraph that
15 starts, "Therapy for MS generally involves either
16 disease-modifying agents," and then it goes on?

17 A Yes.

18 Q Okay. In the last sentence you say,
19 "Currently the best study agents have been
20 immunomodulatory."

21 That was a true statement in your article
22 in 2002; correct?

1 A Reflecting my opinion on what best studies
2 are, yes.

3 Q Let's go back to your declaration,
4 Exhibit 1002, paragraph 30.

5 Can you take a look at the last sentence
6 on page 23?

7 Here you provide your opinion, "For
8 example, Weiner states that a number of clinical
9 trials designed to suppress the immune system or
10 to restore immune balance in multiple sclerosis
11 have been attempted"; correct?

12 A That's correct that Weiner stated that,
13 yes.

14 Q Are agents that restore immune balance
15 immunomodulatory agents?

16 A They might be.

17 Q And if you go to the page -- the top of
18 page 24, that first full sentence. Here you say,
19 "Weiner explains that many MS immunotherapies are
20 designed to alter or suppress the immune
21 response"; correct?

22 A Correct.

1 Q Are MS immunotherapies that are designed
2 to alter the immune response immunomodulatory
3 agents?

4 A They might be.

5 Q Some MS immunotherapies designed to alter
6 the immune response are immunomodulatory agents?

7 A Some are immunomodulatory agents.

8 Q And some agents that restore immune
9 balance are immunomodulatory agents?

10 A Some are immunomodulatory agents.

11 Q And then back on page 24 of your
12 declaration, second full sentence you say,
13 "Whitaker also teaches that a first line of MS
14 therapy may be directed at limiting demyelination
15 through systematic immunomodulation with
16 therapeutic agents that attempt to alter the
17 immune system such as immunosuppressants."

18 A That's what Whitaker wrote.

19 Q In your opinion, do agents that attempt to
20 alter the immune system include immunomodulatory
21 agents?

22 A So I think you can see from this Whitaker

1 statement that there's confusion about the use of
2 those terms because in one phrase he says
3 "limiting demyelination through systemic
4 immunomodulation." And then he says, "with
5 therapeutic agents that attempt to alter the
6 immune system, such as immunosuppressants."

7 Q In your opinion, do agents that attempt to
8 alter the immune system include immunomodulatory
9 agents?

10 A Yes. In my opinion agents which are
11 designed to alter the immune system may include
12 immunomodulatory agents.

13 Q Some agents that attempt to alter the
14 immune system are immunomodulatory agents?

15 A Yes.

16 Q And then in your declaration, paragraph
17 30, the second-to-last sentence of paragraph 30,
18 you provide your opinion that "Before December
19 2004, immunosuppressive agents, such as
20 cladribine, mitoxantrone, azathioprine, and
21 cyclophosphamide were used to treat MS"; correct?

22 A Yes.

1 Q Is it your opinion that use of
2 cyclophosphamide before 2004 would have motivated
3 a POSA to use cladribine to treat MS?

4 A It's my opinion that immunosuppressive
5 agents used before 2004, including
6 cyclophosphamide, would have motivated a POSA to
7 try to use a different immunosuppressive agent.

8 Q Do you agree that cyclophosphamide proved
9 too toxic for widespread acceptance by physicians
10 for their patients?

11 A I would -- I would only agree in the sense
12 that cyclophosphamide in the way it was used in
13 studies in MS would not have been accepted as a --
14 as a -- as a generally useful drug because of its
15 toxicity in those studies.

16 Q Okay. Let's go back to Exhibit 2005,
17 which was your 2000 book chapter. And could you
18 turn to page 68, please?

19 A What page?

20 Q 68.

21 A I'm at page numbers in the 300s, so...

22 Q Can you make sure you're at 2005? It's

1 this other document here.

2 A Oh, Kalb. Sorry.

3 68?

4 Q Yeah. Exhibit 2005, page 68.

5 A Okay.

6 Q If you look at the second full paragraph,
7 seven lines down, you wrote, "Cyclophosphamide
8 proved too toxic for widespread acceptance by
9 physicians for their patients."

10 This was a true statement when you wrote
11 it in your book chapter; correct?

12 A Yes.

13 Q And then if you look at the bottom of that
14 paragraph you wrote, "There is some evidence that
15 azathioprine may slow progression in MS, but the
16 effect, if it exists, is small and somewhat
17 controversial."

18 That was a true statement when you wrote
19 it in your book chapter; correct?

20 A That was my opinion when I wrote it.

21 Q In your own clinical practice, have you
22 ever optimized the dose of a multiple sclerosis

1 drug for any of your patients?

2 DR. ELLISON: Objection. Form.
3 Foundation.

4 A Yes.

5 Q In your own clinical practice, have you
6 ever optimized the dose of a multiple sclerosis
7 drug for a patient by adjusting the daily dose?

8 A Yes.

9 Q And was the drug for which you optimized
10 the dose a disease-modifying therapy?

11 A I need you to -- to re-ask the question
12 because I don't know the context or the time frame
13 in which you're talking about.

14 Q Well, I'm talking about your last two
15 responses when you said, yes, you had optimized
16 the dose. And so I'm asking if the drug for which
17 you said you optimized the dose was a
18 disease-modifying therapy.

19 A You've asked me -- I believe you -- can
20 you read back her previous questions?

21 THE REPORTER: Questions plural?

22 THE WITNESS: The last three questions,

1 please.

2 (The Reporter read from the record as
3 requested.)

4 THE WITNESS: Thank you.

5 A So you're asking about my practice, and
6 many MS medications are not administered on a
7 daily basis. So not all the drugs for which I've
8 optimized the dosage or the frequency of
9 administration have been administered on a daily
10 basis.

11 Q I'm asking about the drug for which you
12 said you optimized the dose.

13 Was it a disease-modifying therapy?

14 A I've opt --

15 DR. ELLISON: Objection. Form.

16 A I've optimized the dose for a number of
17 drugs.

18 Q Was any of those drugs a disease-modifying
19 therapy?

20 A Yes.

21 Q Do you agree that multiple sclerosis is a
22 disease that progresses quite slowly?

1 DR. ELLISON: Objection. Form.
2 Foundation.

3 A MS is a disease that is extremely
4 variable. Sometimes it progresses slowly.

5 Q Do you agree that for patients with MS
6 symptoms and disease progression are highly
7 variable from one patient to the next?

8 A I would agree that -- I would agree with
9 that statement.

10 Q And do you agree that the clinical course
11 of multiple sclerosis may follow a variable
12 pattern over time?

13 A Different patients with MS may have a
14 different course over time.

15 Q So you agree that the clinical course of
16 MS may follow a variable pattern over time?

17 A Comparing one patient to another, yes.

18 Q Trials -- clinical trials for multiple
19 sclerosis drugs take many months to a year or
20 longer to complete because of the variable nature
21 of MS; correct?

22 A Can you repeat the question, please?

1 Q Clinical trials for multiple sclerosis
2 drugs take many months to a year or longer to
3 complete because of the variable nature of MS;
4 correct?

5 A Some trials take that period of time.

6 Q Let's look, again, at your Kalb book
7 chapter, Exhibit 2005. Please go to page 49.

8 A All right.

9 Q In the first full paragraph on page 49,
10 about six lines down, you refer to an "open trial
11 in a few patients with known disease."

12 Do you see that?

13 A Yes.

14 Q And you say, "These trials are typically
15 of much shorter duration than later studies but
16 still take many months to a year or longer because
17 of the variable nature of MS."

18 That's a true statement in your book
19 chapter; correct?

20 A I said they're typically much shorter
21 duration. Not all trials of drugs for MS are of
22 much shorter -- of much shorter duration.

1 Q And here you were talking about an open
2 trial in a few patients with known disease;
3 correct?

4 A Yes.

5 Q And you said, "These trials are typically
6 of a much shorter duration than later studies but
7 still take many months to a year or longer because
8 of the variable nature of MS."

9 That is a true statement in your book
10 chapter; correct?

11 A Clinical trials have a variety of designs.
12 Typically these trials are of much shorter
13 duration, but still may take months to a year or
14 longer. But there are exceptions.

15 Q Do you stand by the statement in your book
16 chapter?

17 A I stand by the statement, yes.

18 Q Do you agree that disease-modifying drugs
19 are designed to slow disease progression over the
20 long term?

21 A I don't agree with that statement.

22 Q Still in Exhibit 2005, please go to page

1 61. In the last paragraph you see about --
2 actually so right above this paragraph at the
3 bottom of page 61, there's a bold question, "I
4 have recently been diagnosed with MS and have no
5 apparent symptoms at this time. Should I start
6 taking Betaseron, Avonex, Copaxone or Rebif not
7 available in US right away?"

8 Do you see that?

9 A Mm-hmm.

10 Q Okay. So this paragraph at the bottom of
11 page 61 is talking about these medications that
12 were just listed; correct?

13 A Yes.

14 Q So then if we go in this paragraph on the
15 bottom of page 61 about ten lines down, nine or
16 ten, you wrote, "These medications are designed to
17 reduce the number and severity of attacks in the
18 hope that they will slow disease progression over
19 the long term."

20 Is that a true statement in your book
21 chapter?

22 A Yes.

1 Q Do you agree that because
2 disease-modifying drugs are designed to work over
3 the long term it is not possible to evaluate the
4 extent to which a disease-modifying drug is
5 working for any one individual at a particular
6 point in time?

7 DR. ELLISON: Objection. Form.
8 Foundation.

9 A I don't agree with the statement.

10 Q Still in Exhibit 2005, your book chapter.

11 A Yes.

12 Q Please go to page 60. Do you see the
13 first full paragraph starts, "Since it is not
14 possible"?

15 A Yes.

16 Q So here you said, "Since it is not
17 possible to evaluate the extent to which any of
18 these drugs is working for any one individual at
19 any particular point in time, it is advisable for
20 you to remain on the drug unless you are having
21 frequent attacks, rapid disease progression or
22 severe side effects."

1 Is that a true statement in your book
2 chapter?

3 A Yes.

4 Q And if we go back on to page 59, this
5 statement that we just looked at is talking about
6 disease-modifying agents as mentioned in the
7 question on page 59; correct?

8 A Yes.

9 Q In your opinion cladribine is a
10 disease-modifying drug; correct?

11 A Yes.

12 Q Why don't we take a break.

13 MS. WHELAN: Go off the record, please.

14 (A recess was taken.)

15 BY MS. WHELAN:

16 Q Good afternoon, Dr. Miller.

17 A Good afternoon.

18 Q During the break, did you have a chance to
19 discuss the substance of your testimony with your
20 counsel?

21 A No.

22 Q Can you please go to your declaration in

1 the 480 IPR, Exhibit 1002? Please turn to
2 paragraph 35.

3 A Okay.

4 Q In the second sentence of paragraph 35,
5 you provide your opinion that these studies before
6 December 2004 demonstrated a treatment response in
7 patients with different forms of MS as measured by
8 lymphocyte suppression, a decrease in EDSS scores,
9 a reduction in relapse rate and/or a decrease in
10 enhancing lesions on MRI scans; correct?

11 A Yes.

12 Q In your opinion a decrease in EDSS scores
13 is a measure of cladribine's treatment response;
14 correct?

15 A It would be one measure of -- one
16 potential measure of a treatment response.

17 Q In your opinion a decrease in EDSS scores
18 is a measure of cladribine's therapeutic efficacy;
19 correct?

20 A Can be one measure of cladribine's
21 therapeutic efficacy.

22 Q In your opinion a reduction in relapse

1 rate is a measure of cladribine's treatment
2 response; correct?

3 A Can be one measure of cladribine's
4 treatment response.

5 Q And in your opinion a reduction in relapse
6 rate is a measure of cladribine's therapeutic
7 efficacy; correct?

8 A It's one measure of therapeutic efficacy.

9 Q In your opinion, lymphocyte suppression is
10 a measure of cladribine's treatment response;
11 correct?

12 A It's one measure of cladribine's treatment
13 response.

14 Q And in your opinion lymphocyte suppression
15 is a measure of cladribine's therapeutic efficacy;
16 correct?

17 A Lymphocyte suppression is not a measure of
18 efficacy.

19 Q Is it your opinion that the term
20 therapeutic effect includes side effects?

21 DR. ELLISON: Objection to form.
22 Foundation.

1 A In my view therapeutic effects do include
2 side effects.

3 Q Do you prescribe Mavenclad to your
4 patients?

5 A Sometimes.

6 Q You're familiar with the dosing regimen of
7 Mavenclad?

8 A Yes.

9 Q Okay. I think in your pile you have
10 Exhibit 2001 which is the Mavenclad prescribing
11 information?

12 A Okay.

13 Q On the first page of the Mavenclad
14 prescribing information, under Dosage and
15 Administration, it says that "The dosage is a
16 cumulative dosage of 3.5 milligrams per kilogram
17 administered orally and divided into two treatment
18 courses (1.75 milligrams per kilogram per
19 treatment course)"; correct?

20 A Yes.

21 Q The dosing of Mavenclad is weight based;
22 correct?

1 A Yes.

2 Q You agree the dose of Mavenclad is
3 dependent on an individual's weight?

4 A Yes.

5 Q And we discussed FDA-approved Mavenclad in
6 2019; right?

7 A Yes.

8 Q In 2019 when FDA approved Mavenclad, there
9 were no other approved multiple sclerosis drugs
10 that were dosed by kilogram of body weight;
11 correct?

12 A I believe that's correct, yes.

13 Q And we discussed that you're familiar with
14 glatiramer acetate for treating MS; correct?

15 A Correct.

16 Q You've been involved in clinical studies
17 of glatiramer acetate?

18 A Yes.

19 Q By 2004 glatiramer acetate was approved as
20 Copaxone; correct?

21 A Yes.

22 Q And we discussed that Copaxone has two

1 approved doses: 20 milligrams once a day and 40
2 milligrams three times a week; right?

3 DR. ELLISON: Objection. Form.

4 A You didn't ask the question.

5 THE REPORTER: I'm sorry?

6 A You didn't ask the question.

7 Q Is it correct that Copaxone has two
8 approved doses: 20 milligrams once a day and 40
9 milligrams three times a week?

10 A Yes.

11 Q Copaxone's dose of 20 milligrams per day
12 is flat-fixed dosing; correct?

13 A That is correct.

14 Q Every patient gets the same 20-milligram
15 daily dose?

16 A That is correct.

17 Q And the dose does not vary --

18 A Oh, that is every patient's getting 20
19 milligrams daily rather than 40 milligrams, three
20 times a week.

21 Q The dose of Copaxone administered does not
22 vary depending upon the patient's weight; correct?

1 A That's correct.

2 Q You agree Copaxone's dosing regimen is
3 different from Mavenclad's dosing regimen;
4 correct?

5 A Well, of course, it's correct. The dosing
6 regimen is different. It's a different drug.

7 Q The dose of Mavenclad is dependent on an
8 individual's weight; correct?

9 DR. ELLISON: Objection. Form.
10 Foundation.

11 A The dose of Mavenclad as FDA approved is
12 dependent on a patient's weight.

13 Q And weight-based dosing is different from
14 flat fixed dosing; correct?

15 DR. ELLISON: Objection. Form.
16 Foundation.

17 A While it's nominally different, a POSA
18 would understand that there is some weight-based
19 consideration in the development of a flat dose.

20 Q With fixed flat dosing, every patient gets
21 the same dose; correct?

22 A That is correct.

1 Q And with weight-based dosing, the dose
2 varies depending on the patient's weight; correct?

3 A That is correct.

4 Q So weight-based dosing and flat-fixed
5 dosing differ in that respect; correct?

6 DR. ELLISON: Objection. Form.
7 Foundation.

8 A Could you please repeat that question?

9 Q You agreed that with fixed-flat dosing
10 every patient gets the same dose; correct?

11 A That is correct.

12 Q And with weight-based dosing, the dose
13 varies depending on the patient's weight; correct?

14 A Yes.

15 Q So weight-based dosing and flat-fixed
16 dosing differ in that respect; correct?

17 DR. ELLISON: Objection. Form.
18 Foundation.

19 A While fixed dose -- while fixed-dose
20 dosing -- fixed-dose dosing and weight-based
21 dosing do differ for an individual patient, the
22 fixed dose is predicated on some understanding of

1 weight.

2 Q Do you agree that Mavenclad's treatment
3 regimen is unique?

4 A I don't agree that it's unique.

5 Q Do you agree that Mavenclad's treatment
6 regimen was unique as of 2019?

7 A I mean, it's unique in some sense that it
8 differs from certain other approved drugs.

9 Q And that was true in 2019 and today?

10 A Yes.

11 Q When FDA approved Mavenclad, there were no
12 other multiple sclerosis drugs that were dosed by
13 kilogram of body weight; correct?

14 A To the best of my knowledge, yes.

15 Q And when Mavenclad was approved, it was
16 the only multiple sclerosis medicine that's not
17 given in a fixed dose but rather the dose is
18 determined by how much the individual weighs;
19 correct?

20 A Yes, that's correct.

21 Q We're going to show a video. I'm going to
22 mark the video as Exhibit 2007.

1 MS. WHELAN: Could you put a sticker on
2 that drive, 2007.

3 DR. ELLISON: Counsel, we're not going to
4 be able to access a video off of a flash drive
5 that you provided to us because it's a security
6 risk for our firm, but if you could upload this to
7 some website or submit that, we would request that
8 -- later, I'm not -- I don't mean today, but I'm
9 going to object to your submission of the flash
10 drive as an exhibit.

11 MS. WHELAN: Okay. Understood. We can --
12 we can work out providing it in an additional
13 format.

14 We do have it uploaded with Planet Depos,
15 so I don't think it should be a problem to provide
16 it as a link. But why don't we just still put a
17 2007 sticker on the flash drive.

18 DR. ELLISON: So just to be clear, I'm
19 objecting to submission of 2007 as being in a --
20 at a minimum as being an unacceptable format.

21 (Miller Deposition Exhibit 2007 was marked
22 for identification.)

1 MS. WHELAN: So can we play just about the
2 first 30 seconds of the video, please. And I
3 think -- it's going to play on the Zoom.

4 THE TECHNICIAN: Yes. It will play on
5 that monitor, and it will also --

6 MS. WHELAN: So it will be up here, too?

7 THE TECHNICIAN: Yes, that's correct.

8 MS. WHELAN: And it will be on this one,
9 too?

10 THE TECHNICIAN: Yes, that's correct.

11 (Video being played from laptop.)

12 MS. WHELAN: Pause the video, please.

13 DR. ELLISON: I'm also going to object to
14 any questions you ask based on showing what
15 appears to be merely a portion of the video to the
16 witness, and providing merely a portion of it to
17 counsel during this deposition.

18 Q Dr. Miller, do you recognize this video,
19 which we're calling Exhibit 2007, as a video
20 presentation by you?

21 A I thought you were going to show me
22 something from Saturday Night Live, but I do

1 recognize it.

2 Q This is a video presentation by you;
3 correct?

4 A Yes.

5 Q And this is a recorded video called "What
6 you need to know, Mavenclad cladribine"; right?

7 A Yes.

8 Q You prepared this video about Mavenclad in
9 the summer of 2019 for the National Multiple
10 Sclerosis Society; correct?

11 A Well, I don't have any recollection as I
12 sit here as exactly when I prepared it, but I did
13 prepare it for the National MS Society.

14 Q The statements you made in this video
15 presentation were intended for MS physicians and
16 patients?

17 A Yes.

18 Q And the statements you made in this video
19 are your opinions; correct?

20 A They were my opinions as of the time I
21 made the video.

22 Q And the video is after the approval of

1 Mavenclad; correct?

2 A I believe so, as again I said -- I believe
3 it was after FDA approval.

4 Q You were being truthful when you made the
5 statements in the video; correct?

6 A To the best of my ability at the time.

7 Q And you understand this video of your
8 presentation is now available on the National
9 Multiple Sclerosis Society website?

10 A I believe it is. I haven't looked at the
11 website recently.

12 Q I'm going to mark as Exhibit 2008 a
13 transcript of the video, "What you need to know
14 about Mavenclad."

15 (Miller Deposition Exhibit 2008 was marked
16 for identification.)

17 DR. ELLISON: Exhibit number?

18 MS. WHELAN: 2008.

19 DR. ELLISON: I'm going to object to
20 Exhibit 2008 for lack of authentication.

21 Q Exhibit 2008 is a transcript prepared of
22 the video that we just looked at and which was

1 prepared by Planet Depos, which is the court
2 reporting service that is also transcribing
3 today's deposition.

4 Can you turn, please, to page 4 of the
5 transcript of your video, Exhibit 2008, starting
6 at line 17.

7 And as reflected in the transcript you
8 stated, "The treatment regimen for Mavenclad is
9 rather unique. So Mavenclad is a tablet. It
10 comes as a 10-milligram tablet, and the dose of
11 Mavenclad is dependent on an individual's weight.
12 This is the only MS medicine that we have that is
13 not given in a fixed dose, but rather the dose is
14 determined by how much the individual weight is";
15 correct?

16 A That's correct.

17 Q And sitting here today, do you have any
18 reason to doubt that this is a fair and accurate
19 transcription of your statement in the video?

20 A Well, I haven't re-listened to the video,
21 but I don't have any reason to doubt that the
22 transcription was correct.

1 Q Okay. Well, we can show the video.

2 MS. WHELAN: If you could please play the
3 video at 3 minutes and 53 seconds. And we'll play
4 up to 4 minutes 18 seconds, please.

5 (Video being played.)

6 Q So you agree the excerpt that we just
7 watched on the video matches the transcript,
8 Exhibit 2008; correct?

9 A Yes.

10 Q And according to your statement in the
11 video, Mavenclad's dosing regimen is unique;
12 correct?

13 DR. ELLISON: Objection. Form.
14 Foundation.

15 A I use the term "unique" in this video in
16 the sense that it -- that it differs from the way
17 other medications are administered.

18 Q You agree that Mavenclad's dosing regimen
19 is unique because in 2019 when FDA approved
20 Mavenclad there were no other multiple sclerosis
21 drugs that were dosed by kilogram of body weight;
22 correct?

1 A In 2019 there were no other MS drugs that
2 were dosed by body weight. Correct.

3 Q And Mavenclad's dosing regimen is unique
4 for that reason; correct?

5 DR. ELLISON: Objection. Form.

6 A A POSA would have understood in 2019 that
7 Mavenclad was being administered based on the
8 actual weight of a patient, but that other drugs
9 and other regimens would also have considered
10 weight in developing those regimens.

11 Q But you stated in your video that "the
12 treatment regimen for Mavenclad is rather unique";
13 correct?

14 A I do.

15 Q And that was a true statement; correct?

16 A That is a true statement.

17 Q Do you agree that for safety reasons a
18 patient would not have been treated with
19 cladribine if their lymphocyte count was below
20 1,000?

21 A You have to ask -- you have to ask me that
22 question in a context. I don't agree with -- I

1 don't agree with the question as you stated it.

2 Q Can we go to your video transcript,
3 Exhibit 2008, at page 12, please.

4 So do you see in the second line of
5 page 12 in your video transcript it says, "Now, in
6 the case of Mavenclad that the main circumstance
7 here would be that we need to have the lymphocyte
8 count be up to 1,000, and some of the drugs that
9 we -- that the person might have been on before
10 Mavenclad may have suppressed the lymphocyte count
11 and so we may need to wait to get that lymphocyte
12 count back into the safe range for Mavenclad."

13 That's what --

14 A I see that it says that, yes.

15 Q Okay. And that's your statement in your
16 video; correct?

17 A Yes.

18 Q So do you agree in the context of your
19 statement that for safety reasons a patient would
20 not have been treated with cladribine if their
21 lymphocyte count was below 1,000?

22 DR. ELLISON: Objection. Form.

1 Foundation.

2 A I don't agree with the statement.

3 Q And your statement in your video was that,
4 "In the case of Mavenclad the main circumstance
5 would be that we need to have the lymphocyte count
6 be up to 1,000"; correct?

7 DR. ELLISON: Objection. Form.
8 Foundation.

9 A Please repeat the question.

10 Q Your statement reflected in your video
11 transcript, Exhibit 2008, is that in the case of
12 Mavenclad the main circumstance would be that we
13 need to have the lymphocyte count be up to 1,000;
14 correct?

15 DR. ELLISON: Objection. Form.
16 Foundation.

17 A My -- my sense is correct, emphasizing the
18 main circumstance and not implying that invariably
19 it would be a thousand.

20 Q And in the main circumstance, the reason
21 that it would need to be at a thousand is for
22 safety reasons; correct?

1 A Yes. That's correct.

2 Q Do you agree that cladribine doses for
3 treating MS should both demonstrate a treatment
4 effect and have a satisfactory safety profile?

5 DR. ELLISON: Objection. Form.
6 Foundation.

7 A Yes, I agree.

8 Q Can we go off the record, please?

9 (A recess was taken.)

10 BY MS. WHELAN:

11 Q So we want to circle back to your video,
12 Dr. Miller, and I just wanted to note that in the
13 transcript of the video that we introduced as
14 Exhibit 2008, the first page is the title,
15 Recorded Video: What You Need to Know About
16 Mavenclad, and then there is the URL which is
17 [https://www.NationalMSSociety.org/treating-MS/](https://www.NationalMSSociety.org/treating-MS/medication/Mavenclad)
18 medication/Mavenclad. And that is where the video
19 can be found on the National MS Society website,
20 and we are also going to make the video available
21 in the chat for the Zoom link of the deposition.

22 MS. WHELAN: And can you please let us

1 know when that's available? The technician will
2 make it available.

3 THE TECHNICIAN: I have it.

4 DR. ELLISON: And, counsel, for the
5 record. We're here in person. We don't have
6 access to the Zoom link. I don't think we
7 actually ever received that information. We
8 certainly don't have that open and available since
9 we're here in person. So your providing that
10 video via Zoom link does not provide that video to
11 us as counsel.

12 MS. WHELAN: All right. Well, why don't
13 we go off the record for a minute, and we can have
14 you log in to the Zoom link.

15 Okay. Are we off the record?

16 DR. ELLISON: Is there -- well, just stay
17 on the record for a second.

18 Is there a folder within Planet Depos
19 where that video that you uploaded will be
20 available after this deposition?

21 MS. WHELAN: Can the technician confirm if
22 that's the case?

1 THE TECHNICIAN: Yes. Where you uploaded
2 that video, there is a subsequent download folder
3 where everything that has been uploaded to that
4 specific folder can be seen. A separate link can
5 also be made to put in chat with specifically just
6 that video if other files intend to be added into
7 that upload link that was provided to you.

8 DR. ELLISON: Yeah, in the interest of
9 time, what I'm saying is that I've had other cases
10 that where we've used the same court reporting
11 service, there's been a shared exhibit folder that
12 we could access even after the video -- or excuse
13 me -- even after the deposition.

14 If you make the video available in some
15 shared folder on the Planet Depos website such
16 that we can access it after the video -- again
17 apologies -- so we can access it after this
18 deposition, that should be sufficient for making
19 it available to us.

20 MS. WHELAN: Okay. Thank you. We will
21 plan to do that.

22 DR. ELLISON: As long as we have some kind

1 of assurance that it is exactly what you've
2 uploaded today.

3 MS. WHELAN: Yes. We will do that, and
4 Planet Depos has a record of what's been uploaded
5 and used as the file that's played at the video --
6 at the deposition. So we will have the same thing
7 that's available to you.

8 DR. ELLISON: Okay.

9 MS. WHELAN: Okay. However, it's still
10 not clear to me that counsel's objections about
11 authentication of the video have been resolved.
12 So we are going to play the whole video, and then
13 ask Dr. Miller to confirm that this is, in fact,
14 the video he prepared for the National MS Society.

15 So could the technician please play the
16 video that's Exhibit 2007 starting from the
17 beginning?

18 THE TECHNICIAN: One moment.

19 (Video being played.)

20 BY MS. WHELAN:

21 Q Dr. Miller, you've now had the opportunity
22 to watch the entire video that we marked as

1 Exhibit 2007 with the transcript as Exhibit 2008.

2 Can you please confirm for the record that
3 Exhibit 2007, the video we just watched, is a
4 video presentation by you called What You Need to
5 Know, Mavenclad Cladribine; correct?

6 A Yes.

7 Q And you prepared this video about
8 Mavenclad for the National Multiple Sclerosis
9 Society; correct?

10 A Yes.

11 Q And your understanding is that this video
12 is available on the National MS Society website;
13 correct?

14 A I believe so, but I haven't looked on the
15 website recently.

16 Q The statements you made in this video,
17 Exhibit 2007, are your opinions; correct?

18 A They reflected my opinions as of 2019.

19 Q And you were being truthful when you made
20 the statements in your video, Exhibit 2007;
21 correct?

22 A I was.

1 Q Okay.

2 MS. WHELAN: I have no further questions.

3 DR. ELLISON: Thank you. Let's go off the
4 record.

5 (A recess was taken.)

6 DR. ELLISON: Let's go back on the record.

7 EXAMINATION BY COUNSEL FOR THE PETITIONER
8 BY DR. ELLISON:

9 Q Dr. Miller, I have a couple questions for
10 you.

11 Earlier today you were asked questions
12 regarding Bodor and bioavailability. My question
13 for you is, what does Bodor postulate regarding
14 absorption of Bodor's cyclodextrin cladribine
15 formulation in comparison with previously known
16 oral solutions of cladribine?

17 MS. WHELAN: Objection. Form and
18 foundation.

19 A Could you please repeat the question?

20 Q Sure. Earlier today you were asked
21 questions regarding Bodor and bioavailability;
22 correct?

1 A Yes.

2 Q What -- my question is, what does Bodor
3 postulate regarding absorption of Bodor's
4 cyclodextrin cladribine formulation in comparison
5 with previously known oral solutions of
6 cladribine?

7 MS. WHELAN: Objection. Form and
8 foundation.

9 A According to Bodor, cladribine's
10 formulated into the prescribed solid oral dosage
11 form, is in a high thermodynamic state which
12 results in improved cladribine absorption as
13 reflected by higher bioavailability and/or lower
14 interpatient variation.

15 Q And so what does Bodor suggest to a person
16 of ordinary skill in the art regarding Bodor's
17 cyclodextrin cladribine formulation in comparison
18 with previously known oral solutions of
19 cladribine?

20 MS. WHELAN: Objection. Form and leading.

21 Q You can answer.

22 A Bodor states that this form of cladribine

1 would have better oral absorption and, therefore,
2 would have better bioavailability --
3 bioavailability than previously used oral
4 preparations which were saline solutions.

5 Q Thank you. Today, Dr. Miller, you've been
6 shown various documents, including your own
7 publications, and my question to you is, to what
8 extent, if any, do the documents shown to you
9 today impact your opinions as set forth in your
10 declaration?

11 MS. WHELAN: Objection. Form.

12 A The documents shown to me don't in any way
13 alter my declaration. I stand by the statements
14 in my declaration.

15 Q Thank you.

16 DR. ELLISON: I have no further questions.

17 MS. WHELAN: Could we go off the record,
18 please.

19 (A discussion was held off the record.)

20 MS. WHELAN: Thank you, Dr. Miller. I
21 have no further questions.

22 DR. ELLISON: Thank you, Dr. Miller.

1 Thank you, everyone else.

2 MS. WHELAN: Thank you, everyone.

3 (A discussion was held off the record.)

4 THE REPORTER: I wanted to get your
5 transcript orders.

6 DR. ELLISON: Whatever. Standard should
7 be fine.

8 THE REPORTER: Do you want a rough?

9 DR. ELLISON: Yes, please.

10 (Off the record at 3:10 p.m.)

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1 CERTIFICATE OF SHORTHAND REPORTER-NOTARY PUBLIC

2 I, Janet A. Hamilton, Certified Reporter and
3 Notary Public within and for the District of
4 Columbia do hereby certify:

5 That AARON E. MILLER, M.D, the witness whose
6 deposition is hereinbefore set forth, was duly
7 sworn by me before the commencement of such
8 deposition and that such deposition was taken
9 before me and is a true record of the testimony
10 given by such witness.

11 I further certify that the adverse party,
12 HOPEWELL PHARMA VENTURES, INC., was represented
13 by counsel at the deposition.

14 I further certify that the deposition of
15 AARON E. MILLER, M.D, occurred at the offices
16 of Sterne, Kessler, Goldstein & Fox, P.L.L.C.,
17 1101 K Street, NW, Washington, DC 20005
18 on Tuesday, December 12, 2023, commencing at
19 8:10 a.m. to 3:10 p.m..

20 I further certify that I am not related to
21 any of the parties to this action by blood or
22 marriage, I am not employed by or an attorney to any

1 of the parties to this action, and that I am in no way
2 interested, financially or otherwise, in the outcome
3 of this matter.

4
5
6 IN WITNESS WHEREOF, I have hereunto set my hand
7 this 15th day of December, 2023.

8
9
10 *Janet A. Steyer*



11
12 Registered Diplomat Reporter
13 My commission expires
14 March 31, 2028
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