

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD
3

4 HOPEWELL PHARMA VENTURES, INC.,

5 Petitioner,

6 v.

7 MERCK SERONO S.A.,

8 Patent Owner.

9
10 IPR2023-00480 (Patent 7,713,947 B2)

11 IPR2023-00481 (Patent 8,377,903 B2)

12 * CONFIDENTIAL *

13 DEPOSITION OF

14 BERND MEIBOHM, PH.D.

15 New York, New York

16 Wednesday, March 6, 2024

17 9:02 a.m. EST
18

19 Job No.: 524918

20 Pages: 1 - 139

21 Reported by: Monique Vouthouris, CCR, RPR, CRR
22

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3 Deposition of BERND MEIBOHM, PH.D., held at
4 the offices of:

5
6
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14
15

16 Pursuant to notice, before Monique
17 Vouthouris, Certified Court Reporter, Register
18 Professional Reporter, Certified Realtime Reporter,
19 and Notary Public in and for the States of New York
20 and New Jersey.
21
22

1 A P P E A R A N C E S
2 ON BEHALF OF PETITIONER
3 HOPEWELL PHARMA VENTURES, INC.:
4 CHRISTINA E. DASHE, ESQ. (Via Zoom)
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1 ALSO PRESENT:

2 ALEJANDRO GOMEZ, Planet Depos Technician

3 RACHEL CARRICK, Remote Planet Depos Technician

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C O N T E N T S

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1 P R O C E E D I N G S

2

3 BERND MEIBOHM, PH.D.,

4 being first duly sworn or affirmed by the Notary,
5 testifies as follows:

6

7 MS. DASHE: Hello. I am Christina Dashe
8 from Sterne Kessler on behalf of petitioner Hopewell.
9 With me today remotely are Eldora Ellison and Olga
10 Partington, also Sterne Kessler. My colleague
11 Pratibha Khanduri of Sterne Kessler may also join
12 later remotely. And with me today in person with the
13 witness is my colleague Madeleine Bond, also with
14 Sterne Kessler.

15 MR. BASSETT: And I am Dave Bassett from
16 WilmerHale on behalf of the patent owner Merck Serono
17 and the Merck entities. I'm joined by my colleague
18 Mary Pheng, who is in person with Dr. Meibohm.

19

20 EXAMINATION

21 BY MS. DASHE:

22 Q Good morning, Dr. Meibohm.

1 Could you please state your name for the
2 record.

3 A Good morning. My name is Bernd Meibohm.

4 Q And you live in Tennessee; is that right?

5 A That is correct.

6 Q Have you ever been deposed before?

7 A Yes, I have.

8 Q About how many times?

9 A Twice.

10 Q And were any of those depositions in a case
11 or proceeding related to patents?

12 A No.

13 Q So then you have not had any depositions in
14 a proceeding before the Patent Office; is that right?

15 A That is correct.

16 Q Who were the parties in the cases where you
17 gave deposition testimony?

18 A I gave testimony for the University of
19 Tennessee.

20 Q Anyone else?

21 A Both cases were for the university; one was
22 a personnel issue and the other one was a contract

1 partner of the university.

2 Q Did you give testimony on behalf of the
3 University of Tennessee?

4 A That is correct.

5 Q So you have been deposed before, but I'll
6 go over some ground rules for today's deposition.

7 I will be asking you some questions and
8 your counsel may object. It is important for the
9 court reporter that we don't all talk over one
10 another.

11 Will you agree to that?

12 A I will do my best.

13 Q Similarly, the court reporter cannot take
14 down non-verbal answers like shaking your head or
15 saying "mm-hmm."

16 Can you agree to give only verbal answers
17 today?

18 A Yes.

19 Q Sometimes your counsel may object to my
20 questions but you still have to answer them unless
21 your counsel directs you not to answer them.

22 Will you agree to abide by this rule?

1 A Yes.

2 Q We will take breaks reasonably often, and
3 if at any point you need a break, please let me know
4 and I will try to accommodate, but I do ask that you
5 answer any pending questions before we take a break.

6 Will you agree to that?

7 A Yes.

8 Q If I ask a question you don't understand or
9 need further clarification, will you agree to let me
10 know and I can try to clarify or ask a better
11 question?

12 A Yes.

13 Q However, if you answer my question, I will
14 assume that you understood it.

15 Do you agree?

16 A I agree.

17 Q Because we are operating on a remote basis
18 for today's deposition, there may be some technical
19 difficulties. If anything happens that interferes
20 with your ability to hear or answer my questions,
21 will you agree to let me know?

22 A I will.

1 Q For example, it might happen that part of
2 my question gets cut off or garbled. If that
3 happens, will you agree to let me know?

4 A Yes, I will.

5 Q And will you agree to let me know even if
6 you think you generally understand what I'm asking?

7 A I will let you know if I think I do not
8 understand fully the question.

9 Q Now, the Patent Office rules require that I
10 tell you that during my questioning today you are not
11 permitted to discuss your testimony with counsel
12 unless you are discussing an issue related to
13 privilege.

14 Do you understand that rule?

15 A I do.

16 Q Will you agree to abide by the rule?

17 A I do.

18 Q Is there any reason you cannot give
19 truthful and accurate testimony today?

20 A No, not that I'm aware of.

21 Q Where are you located for today's
22 deposition?

1 A In New York City.

2 Q Besides counsel and the court reporter and
3 technicians, is there anyone else in the room with
4 you today?

5 A Your representative.

6 Q That would be a representative for
7 petitioner; is that right?

8 A That is correct.

9 Q Okay. Anyone else?

10 A No.

11 Q Whose computer are you using for today's
12 deposition, do you know?

13 A I do not know. I assume this is a computer
14 that belongs to WilmerHale.

15 Q So it's not your computer?

16 A It's not my computer.

17 Q Okay. Do you have any files or programs
18 open on the computer besides the deposition video
19 platform?

20 A I only see Zoom.

21 Q So you do not have any documents, PDFs,
22 email, web browsers open in front of you?

1 A No.

2 Q Do you have access to any files or
3 programs -- I'm sorry. Strike that.

4 Will you agree that you will not access any
5 documents, PDFs, emails, web browsers or the like
6 during today's deposition?

7 A I will.

8 Q Including during breaks?

9 A Yes.

10 Q Do you have any other electronic devices
11 with you today, such as cell phone, other laptops, or
12 a smart watch?

13 A Cell phone.

14 Q Will you agree that you will not access any
15 files, programs, or communications on that device?

16 A I agree.

17 Q So no text messages or phone calls?

18 A It's on flight mode. It's switched over
19 anyway.

20 Q So you will not be accessing your cell
21 phone during breaks; is that right?

22 A That is correct.

1 Q Okay. Did you bring anything else with you
2 to your deposition today?

3 A Not in this room, no. My reading glasses.

4 Q That's important.

5 What did you do to prepare for your
6 deposition today?

7 A I met with counsel the last two days.

8 Q Who specifically did you meet with?

9 A With Mary Pheng and Dave Bassett.

10 Q Anyone else?

11 A No.

12 Q Did you communicate with anyone else to
13 prepare for your deposition besides Mary and Dave?

14 A No.

15 Q And where did you meet?

16 A In the WilmerHale offices in New York City.

17 Q For approximately how long did you meet
18 with your counsel to prepare for today's deposition?

19 A Twice, half a day.

20 Q So you spent about one full day preparing
21 for today's --

22 A That's correct.

1 Q -- deposition; is that right?

2 A That's correct.

3 Q And during your preparation for today's
4 deposition, did you consider any documents not
5 mentioned in your declaration in this matter?

6 A No.

7 Q And have you communicated with anyone
8 besides counsel regarding the substance of your
9 deposition today?

10 A No.

11 MS. DASHE: Rachel, if you could please
12 introduce tab 1 onto the screen, which is the
13 declaration of Dr. Bernd Meibohm in Case IPR2023-480
14 and Case IPR2023-481.

15 And if you could also make Dr. Meibohm's
16 declaration available in the chat, that is Exhibit
17 2052.

18 Q So, Dr. Meibohm, on the screen, Exhibit
19 2052, this is your declaration that you submitted in
20 both Case IPR2023-480, as well as Case IPR2023-481?

21 A It is the first page of that declaration.

22 MS. DASHE: And, Rachel, if you could flip

1 through the document so that Dr. Meibohm can confirm
2 that this is, in fact, his full declaration and not
3 just the first page.

4 Q And, Dr. Meibohm, please let me know when
5 you agree this is your full declaration.

6 MR. BASSETT: And, Christina, I would just
7 offer we have a hard copy of his declaration with
8 attachments there and available for Dr. Meibohm to
9 also consult, in addition to the electronic copy.

10 MS. DASHE: Yes, if counsel -- do those
11 copies have any markings or other annotations or is
12 it just a clean copy?

13 MR. BASSETT: Just a clean copy.

14 MS. DASHE: If you would like to provide
15 the clean paper copy to the witness, that would be
16 helpful for all of us.

17 Rachel, I believe you can stop scrolling,
18 if you just want to go back to the first page. Thank
19 you.

20 BY MS. DASHE:

21 Q So, Dr. Meibohm, I will have your
22 declaration, Exhibit 2052, up on the screen in the

1 platform, but you can feel free to follow along in
2 your paper copy, if you would like.

3 A Yes.

4 Q So just to make the record clear, then,
5 Exhibit 2052 that's up on the screen, as well in
6 paper form in front of you, this is your declaration
7 that you submitted in both Case IPR2023-480, as well
8 as Case IPR2023-481; is that right?

9 A Yes, it is.

10 Q And if I refer to "this case" or "this
11 proceeding," will you understand that I am
12 collectively referring to both of these IPR
13 proceedings?

14 A Yes, that's understood.

15 Q And do you understand that unless I
16 specifically indicate, my questions today will relate
17 to both IPR proceedings?

18 A Yes.

19 Q If you could please go to page 41 of the
20 document PDF, it's after paragraph 96.

21 Dr. Meibohm, your declaration is signed and
22 dated December 21st, 2023?

1 MS. DASHE: Rachel, if you could scroll
2 back, please.

3 A Yes, it is. But it's page 40, not 41.

4 Q Right. On the PDF, I think that I'm
5 working off of the electronic copy. There we go.

6 So page 40 of your declaration, page 41 of
7 the PDF of Exhibit 2052, is that your signature?

8 A Yes, it is.

9 Q Dr. Meibohm, do you stand by your testimony
10 in your declaration in this case?

11 A Yes, I do.

12 Q When were you first approached to provide
13 your declaration in this case?

14 A Sometime in the I think summer or fall of
15 last year. I do not exactly recall.

16 Q That would be sometime in the summer or
17 fall of 2023?

18 A That is correct.

19 Q So sometime between roughly June of 2023 to
20 October, November of 2023. Does that sound about
21 right?

22 A I think so. Most of my interactions were

1 later, of course.

2 Q Who -- who first approached you to provide
3 your declaration in this case?

4 A I do not remember.

5 Q Was it someone from Merck or Merck's
6 counsel?

7 A No. It was someone from WilmerHale that
8 reached out to me.

9 Q And you understand that WilmerHale is
10 representing Merck in these proceedings?

11 A I do.

12 Q But you do not recall the specific name of
13 the person who reached out to you to provide your
14 declaration in this case?

15 A No. I would have to look at my records.

16 Q Okay. How much time did you spend
17 preparing your declaration?

18 A I worked through, I would say, approximately
19 15 to 20 hours.

20 Q Did you perform any literature searches in
21 preparing your declaration?

22 A I did one search.

1 Q And what did you search for?

2 A I searched for an example of an approved
3 drug that is dosed on a body weight-based dosing
4 regimen.

5 Q Was that limited to any specific condition
6 or treatment or was that any drug?

7 A That was any drug.

8 Q And what were the results of your search?

9 A Well, it was a directed search, because I
10 remembered from my professional background that low
11 molecular weight heparins are dosed based on body
12 weight, and I was looking for a publication that
13 would support that for one of the low molecular
14 weight heparins.

15 Q What is a low molecular weight heparin?

16 A A low molecular weight heparin is a
17 specific class of agents of drugs that are used to
18 produce or to reduce the coagulation of the blood.

19 Q Did you find any publications that
20 supported that low molecular weight heparins were
21 dosed based on body weight?

22 A Yes. I found a paper where I also knew

1 some of the authors, which basically made me believe
2 that this is a good quality publication to cite.

3 Q What was the date of the paper that you
4 found?

5 A I don't remember. I think it's in the --
6 in the -- in the appendix to my declaration.

7 Q Actually, if you want to turn to Appendix B
8 of your declaration, maybe we can find it. That
9 would be I think starting on page 135 of the PDF,
10 Rachel. And I think that's page 93 of 95 in the
11 appendices.

12 Let me know when you're there, Dr. Meibohm.

13 A Yes, I'm there. Second to last in the
14 list.

15 Q Okay. So if we flip to page 95 of 95, is
16 that the Hainer reference that you're referring to?

17 A That is correct.

18 Q And while we're on the subject of Appendix
19 B, in preparing your declaration in this case, you
20 reviewed and considered a number of documents that
21 are listed in Appendix B to your declaration, right?

22 A That is correct.

1 Q Does Appendix B contain a complete list of
2 documents that you considered in preparing your
3 declaration in this case?

4 A Yes.

5 Q And in forming your opinions in your
6 declaration, did you rely on any other documents that
7 are not cited in Appendix B?

8 A No.

9 Q And so besides the one literature search
10 that you referred to regarding heparins, did you
11 perform any other literature searches in preparing
12 your declaration in this case?

13 A No, I did not.

14 MS. DASHE: Rachel, you can take down
15 Exhibit 2052. Thank you.

16 Q Dr. Meibohm, do you know who else provided
17 a declaration in this case in support of Merck?

18 A I -- there is background noise. Sorry.

19 Q Yes, I was hearing that as well.

20 A Can you repeat the question, please.

21 Q Yes, yes. Do you know who else provided a
22 declaration in this case in support of Merck?

1 A I was told that there was an individual
2 that is referred to in the declaration as the person
3 of ordinary skill in the art that is a physician that
4 provided deposition.

5 Q Do you know who that individual is?

6 A I think the name was -- was mentioned to me
7 yesterday. I do not remember the name.

8 Q Before yesterday, did you know who that
9 individual --

10 A Sorry. It was on Monday, not yesterday.

11 Q Excuse me. So to clarify, before Monday,
12 did you know who that other individual who provided a
13 declaration in this case in support of Merck is?

14 A No.

15 Q So then you did not know who that
16 individual is before you signed your declaration in
17 this case, right?

18 A That is correct.

19 Q Okay. And so then it's fair to say that
20 you have not read that individual's declaration; is
21 that right?

22 A That is correct.

1 Q And you also have not communicated with
2 this other individual who provided the declaration in
3 this case on behalf of Merck; correct?

4 A That is correct.

5 Q Besides counsel, did you communicate with
6 anyone else in order to create your declaration in
7 this case?

8 A No, I did not.

9 Q Have you heard of Dr. Alain Munafo, spelled
10 A-l-a-i-n, M-u-n-a-f-o?

11 A Yes, I do.

12 Q How have you heard of Dr. Munafo?

13 A Dr. Munafo was an employee at Serono, that
14 then was acquired by Merck KGaA to become Merck
15 Serono in the, I think, early 2000s. And I did
16 consulting work for Merck Serono at that time and I
17 had interactions with Dr. Munafo.

18 Q And what were your interactions with
19 Dr. Munafo about?

20 A About development projects that Merck was
21 working on.

22 Q When were these interactions with

1 Dr. Munafo?

2 A They were in the early -- in the late
3 2000s. So I would say somewhere between 2005, 2006,
4 and probably 2014 or '15.

5 Q Were any of your interactions with
6 Dr. Munafo about cladribine?

7 A No.

8 Q When was the last time you interacted with
9 or communicated with Dr. Munafo?

10 A I do not recall. As I said, probably
11 around 2015 or 2016. I have met him afterwards at a
12 professional meeting, and I think I had an email
13 exchange with him a few years ago because he had
14 retired and I wished him well.

15 Q Your interactions with Dr. Munafo at Merck,
16 did any of them have any relation to multiple
17 sclerosis drugs or treatments?

18 A No.

19 Q So the last time you interacted with
20 Dr. Munafo with respect to Merck development products
21 was about eight years ago, but you've had two
22 interactions since then; is that right?

1 A I do not know whether I had two
2 interactions with him, but interactions with him that
3 were not related to Merck, that were related to --
4 well, scientific conferences and general scientific
5 exchange.

6 Q And the last time you interacted with
7 Dr. Munafo you said was about a couple years ago?

8 A I had my last consulting interactions with
9 Merck in 2017. After that, I had a training session
10 in 2022, but that was not related to consulting and
11 was a completely different group.

12 So the last that I had interacted with
13 Dr. Munafo was perhaps 2017, perhaps earlier than
14 that. I'm not sure if he was still at the company in
15 2017.

16 Q So then you've never interacted with
17 Dr. Munafo about cladribine or MS drugs or
18 treatments; is that right?

19 A That is correct.

20 Q Have you heard of Dr. Yogesh Dandiker?
21 Spelled Y-o-g-e-s-h, D-a-n-d-i-k-e-r.

22 A Not that I'm aware of.

1 Q And have you heard of Dr. Fred Lublin?
2 Spelled F-r-e-d, L-u-b-l-i-n.

3 A Not that I'm aware of.

4 Q Were you aware that Dr. Fred Lublin's
5 deposition was taken yesterday in this case?

6 A I think, as I said, someone else was
7 mentioned. I couldn't remember the name. If you
8 tell me so, yes, that's probably the name that was
9 mentioned to me.

10 Q Okay. And without revealing the contents
11 of any privileged communications, just did you learn
12 about this deposition from counsel?

13 A I was not -- I'm not sure that I knew that
14 until -- yes.

15 Q Just so the record is clear, you learned
16 about Dr. Fred Lublin's dep -- pardon me.

17 You learned about the deposition that
18 occurred yesterday from counsel; that's right?

19 A I think I did this morning.

20 Q Okay. And did you review the deposition
21 transcript from yesterday's deposition?

22 A No.

1 Q Are you aware of any of the questions that
2 were asked in yesterday's deposition?

3 A No.

4 Q And besides counsel, did you discuss
5 Dr. Lublin's deposition with anyone else in
6 preparation for your deposition today?

7 A No.

8 Q Were you aware that Dr. Yogesh Dandiker's
9 deposition was taken in this case last month?

10 A No.

11 Q Were you aware that Dr. Nicholas' -- strike
12 that.

13 Were you aware that Dr. Nicholas Bodor's
14 deposition was taken in this case last month?

15 A I think it was mentioned while we were
16 already online this morning.

17 Q And was that mentioned by counsel?

18 A I'm not sure who mentioned that. If
19 anybody can remember?

20 Q So you don't recall who mentioned that
21 Dr. Bodor was deposed earlier in this case?

22 A I think it was about the -- it may have

1 been you because it was about the -- the cut-off of
2 the -- of your questions, the technical difficulties
3 you had yesterday, you mentioned that when we were
4 starting.

5 Q Oh, okay. So you actually learned it
6 before today's deposition, when I mentioned that I
7 had deposed Dr. Bodor, that was the first time you
8 were aware that Dr. Bodor had been deposed in this
9 case?

10 A Yes.

11 Q Okay. I see what you're saying.

12 Dr. Meibohm, your current rate is \$600 an
13 hour; is that right?

14 A That is correct.

15 Q And how much have you billed for your work
16 so far in this case approximately?

17 A Approximately \$11,000.

18 Q Are you owed any other money for work that
19 you have performed in this case?

20 A Yes.

21 Q Approximately how much?

22 A Well, the time that I spent the last two

1 days.

2 Q So that would be about \$600 an hour times
3 roughly eight hours. Does that sound about right?

4 A That is about right.

5 Q Okay. Now, you mention in your
6 declaration, and earlier today as well, that you have
7 consulted for and been invited to present your
8 research by Merck.

9 So my question for you is when did you
10 first begin consulting with Merck or any related
11 entity?

12 A I started working with Merck in 1998.

13 Q And I believe you said both earlier in the
14 deposition, as well in your declaration, that your
15 last consulting work with Merck was in 2022.

16 But have you consulted with any other
17 entity related to Merck since 2022?

18 A No, I have not. And as I mentioned
19 earlier, my consulting work on development projects
20 really ended in 2017. In 2022, was a training
21 session for Merck scientists.

22 Q What was that training session about in

1 2022?

2 A About the general concepts of
3 pharmacokinetics and pharmacodynamics in the
4 development of therapeutic proteins.

5 Q So you've consulted for Merck for about 24
6 years. Does that sound right?

7 MR. BASSETT: Objection.

8 You may answer.

9 A Between '98 and 2017, so it is 19 years.

10 Q So you've consulted for Merck for about 19
11 years, plus the occasional additional work after
12 2017; is that right?

13 A That is correct.

14 Q How often have you been invited to present
15 your research by Merck or any related entity?

16 A I think, after going through my CV, that I
17 have been 14 or 15 times on the premises of Merck,
18 either in Europe or the U.S., and have given on those
19 occasions sometimes more than one presentation at one
20 visit.

21 Q Have you been invited to present your
22 research by Merck in any other location besides their

1 premises?

2 A Not that I remember. I think we were one
3 time in a hotel on Lake Geneva, but it was also a
4 Merck internal event.

5 Q And what were these invited presentations
6 at Merck generally about?

7 A They were either based on results from
8 consulting work where I did analysis for Merck and I
9 would present those results, or they were related to
10 general topics relevant in clinical pharmacology and
11 pharmacokinetics and pharmacodynamics of relevant to
12 clinical drug development.

13 Q What was your consulting work on behalf of
14 Merck generally about?

15 A About pharmacokinetic and
16 pharmacokinetic/pharmacodynamic analysis.

17 Q Have you worked on any specific drug
18 development projects on behalf of Merck?

19 A Yes, I did.

20 Q And what were those about?

21 A Can you be more specific?

22 Q What drug development projects did you work

1 on on behalf of Merck?

2 A There were multiple indications. Some of
3 the publicly-available results are, for example,
4 related to a glycoprotein IIb/IIIa inhibitor and the
5 name is Gantofiban.

6 Q Could you please spell that I think for us
7 spelling challenged folks on the record, that would
8 be helpful.

9 A If I remember correctly, it's
10 G-a-n-t-o-f-i-b-a-n.

11 Q Any other publicly-available projects that
12 you can list on behalf of Merck that you worked on?

13 A Yeah. We published on cetuximab which is a
14 monoclonal antibody.

15 Q Could you spell that?

16 A C-e-t-u-x-i-m-a-b.

17 And we may have worked and may have
18 published on other compounds that had EMD codes
19 rather than drug names. So developmental projects
20 that usually have a start with EMD and then a number
21 series.

22 Q The EMD code, is that internal to Merck?

1 A As far as I understand, yes.

2 Q Has any of your work on development
3 projects for Merck involved drugs or treatments for
4 multiple sclerosis or cladribine?

5 A No.

6 Q And have you received any financial
7 compensation from Merck for either your presentations
8 or your consulting work, or both?

9 A Yes.

10 Q Approximately how much?

11 A I don't know. Over 25 years, I really
12 don't know.

13 Q Can you give me a ballpark roughly?

14 A No.

15 Q Is it more than \$10,000?

16 A Over -- what did I say, 19 years? Over 19
17 years, yes, it's more than \$10,000.

18 Q Is it more than a hundred thousand dollars?

19 A I doubt it, but it could be.

20 Q So over the course of your consulting
21 relationship with Merck, you have received more than
22 \$10,000 in compensation with a ceiling of maybe

1 roughly \$100,000.

2 Does that sound right?

3 A Over the 17-year period, that may be right.

4 Q Approximately how much were you typically
5 paid for each consulting project that you worked on
6 on behalf of Merck?

7 MR. BASSETT: Objection.

8 A I was paid by hourly rates. The hourly
9 rates ranged from -- well, they obviously developed
10 over 17 years. I think they probably started around
11 \$200 per hour and may have topped at \$300 per hour.

12 Q And is your rate for your work in this --
13 these IPR proceedings of \$600 an hour, the same as
14 your consulting rate on behalf of Merck?

15 A I do not do consulting work for Merck
16 anymore, so I don't have the rate.

17 Q So let me rephrase the question.

18 Is your -- strike that.

19 Your rate of \$600 an hour for these IPR
20 proceedings, is that the same as the consulting rate
21 you had on behalf of Merck by the time you finished
22 consulting with them in the 2017 time frame?

1 A The rate of \$600 per hour is my standard
2 legal consulting fee for the last five years.

3 Q And is your standard legal consulting fee
4 different than what your standard consulting fee was
5 for Merck?

6 A The standard consulting fee for legal work
7 and the standard consulting fee for scientific work
8 is different.

9 Q Now, you are the proprietor of Meibohm
10 Consulting; is that right?

11 A LLC, yes.

12 Q And besides the financial compensation
13 we've already discussed today, has Meibohm Consulting
14 ever received any compensation from Merck or a
15 related entity?

16 A Beyond what we just discussed, no.

17 Q You are also the chair of the Department of
18 Pharmaceutical Sciences at University of Tennessee
19 Health Science Center; is that right?

20 A That's correct.

21 Q And has the Department of Pharmaceutical
22 Sciences at the University of Tennessee Health Center

1 ever received any compensation from Merck or any
2 related entity?

3 A I had development projects through the
4 university in the early 2000s, and -- yes, in the
5 early 2000s, we had joint projects that went through
6 the office of research at the university.

7 Q And what was the subject matter of those
8 joint projects?

9 A One was, I remember, was a populate
10 pharmacokinetic analysis for cetuximab.

11 Q Could you please spell that?

12 A Same as before, c-e-t-u-x-i-m-a-b.

13 And the second one was related to a general
14 review about the pharmacokinetics and
15 pharmacodynamics of phosphodiesterase V inhibitors.

16 Q Would you please spell that, too, for our
17 court reporter.

18 A P-h-o-s-p-h-o-d-i-e-s-t-e-r-a-s-e-s, and
19 then Roman V inhibitors.

20 Q So then the Department of Pharmaceutical
21 Sciences at University of Tennessee Health Science
22 Center received financial compensation from Merck for

1 these two projects; is that right?

2 A The university does, not the department.

3 Q Okay. Do you know approximately how much
4 compensation the university received from Merck?

5 A I would say combined, around \$20,000.

6 Q And are you aware of any other financial
7 compensation that the University of Tennessee has
8 received for work that you've done with Merck?

9 A No. Wait a second. There was one -- let
10 me think about this. No. No. I'm fine.

11 MS. DASHE: Now, Rachel, could you please
12 pull back up Exhibit 2052, Dr. Meibohm's declaration.

13 And, Dr. Meibohm, feel free to follow along
14 on the screen or your paper copy.

15 Rachel, could you please go to Appendix A
16 of Exhibit 2052. And then scroll down one more page
17 please, Rachel.

18 Thank you. You can stop there.

19 Q Dr. Meibohm, Appendix A of your
20 declaration, Exhibit 2052, is a copy of your CV?

21 A That is correct.

22 Q And it contains a full copy of your CV; is

1 that right?

2 A As far as I know, yes.

3 Q When did you last update this CV in
4 Appendix A?

5 A I think in October of 2023.

6 Q Does your CV accurately reflect your areas
7 of scientific expertise and credentials?

8 A I hope it does.

9 Q To the best of your knowledge it does?

10 A To the best of my knowledge it does.

11 Q Your CV provides a list of your
12 publications, right?

13 A That is correct.

14 Q Have you retracted any of the publications
15 listed in your CV?

16 A No.

17 Q Have you issued any corrections to any of
18 the publications listed in your CV?

19 A I don't think so. There are many -- to the
20 best of my knowledge, no.

21 MS. DASHE: Okay. Rachel, you can take
22 down Exhibit 2052 for now. Thank you.

1 Q Dr. Meibohm, you said in your declaration
2 that you are an expert in pharmaceuticals and clinical
3 pharmacology.

4 So my first question is, what is
5 pharmaceuticals?

6 A Pharmaceuticals is a discipline that
7 comprises topics related to formulation, drug dosing,
8 pharmacokinetics, biopharmaceuticals, pharmacodynamics,
9 that are related to the use of medications in
10 mammalian species or humans, usually humans.

11 Q What is clinical pharmacology?

12 A Clinical pharmacology is a subdiscipline of
13 pharmacology that is focused on the actions of
14 medications in humans and to quantify the processes
15 that ultimately produce these actions in a
16 qualitative, as well as quantitative manner.

17 Q Now, you mentioned pharmacokinetics. To
18 start, is that sometimes referred to as PK?

19 A That is usually abbreviated as PK.

20 Q And what is pharmacokinetics?

21 A Pharmacokinetics is a discipline that tries
22 to characterize the relationship between the

1 administration of an amount of drug to a patient in a
2 dose or dosing regimen and the resulting time
3 profiles of concentrations in different organs,
4 tissues, and body fluids.

5 It also entails what the body does to the
6 drug with regard to breaking it down, metabolizing
7 it, or potentially excreting it.

8 Q Are there different pharmacokinetic or PK
9 properties for a drug?

10 A I do not understand the question fully.
11 Can you rephrase it, please.

12 Q Well, in your declaration you discuss
13 pharmacokinetic properties. So what do you mean by
14 that?

15 A Pharmacokinetic properties are related to
16 the behavior of a drug with regard to time courses in
17 different organs and tissues in the body after
18 administration by a specific route of administration,
19 and whether this changes for a drug in usually
20 pharmacokinetic properties are a fixed for a specific
21 drug in a specific dosage form, in a specific
22 patient.

1 So there's variability or there can be
2 changes in PK parameters between different dosage
3 forms between different routes of administration and
4 between different patients.

5 Q So there could be variable -- strike that.
6 There can be variation in the
7 pharmacokinetic properties for a drug formulation
8 between different patients; is that right?

9 A There can be variability in a patient
10 population with regard to pharmacokinetic properties.

11 Q And the pharmacokinetic properties can vary
12 between different dosage forms of the same drug; is
13 that right?

14 A That is correct as well.

15 Q And just to make sure we're on the same
16 page, so I've -- in your declaration sometimes you
17 said "drug," sometimes you said "formulation."

18 To start, is there a difference between a
19 drug and formulation?

20 A Drug usually colloquially refers to the
21 drug substance or also called API. A drug substance
22 can be in different formulations.

1 Q What is a formulation?

2 A A formulation is a pharmaceutical
3 preparation of a drug substance in a specific carrier
4 designed to allow application of the drug to a
5 patient to be treated.

6 Q Is bioavailability a pharmacokinetic
7 property?

8 A Bioavailability is usually a
9 pharmacokinetic property that's specific for a
10 formulation.

11 Q What is a dosage form?

12 A A dosage form is similar to a formulation,
13 but not the same. A dosage form is a summary of
14 different formulations that basically constitute the
15 same principle.

16 For example, a dosage form would be a
17 tablet. There may be many different formulations for
18 a drug in a tablet dosage form.

19 Q So would a tablet and an oral solution,
20 would those be two different examples of dosage
21 forms?

22 A An oral solution and a tablet are two

1 different dosage forms.

2 Q Besides bioavailability, are there other
3 pharmacokinetic properties for a drug formulation?

4 A Yes.

5 Q What are they?

6 A Can you be more specific?

7 Q Well, just could you provide some examples
8 of other pharmacokinetic properties besides
9 bioavailability for drug formulations?

10 A That is specific for a formulation?

11 Q Yes.

12 A For example, the absorption rate constant.

13 Q What is the absorption rate constant?

14 A The absorption rate constant is a
15 mathematical expression that describes a first order
16 absorption process.

17 Q What is a first order absorption process?

18 A A first order process, we can start there,
19 a first order process is a process where the rate of
20 change in the amount that's taken up is a function of
21 the amount that is present at the absorption site and
22 the absorption rate constant.

1 Q Besides the absorption rate constant and
2 bioavailability, are there any other examples of
3 pharmacokinetic properties for drug formulations?

4 A For example, the time to reach the maximum
5 concentration, also referred to as T_{max} . So that's T
6 with a subscript m-a-x.

7 Q Is that maximum concentration of the drug
8 also a pharmacokinetic property?

9 A The maximum concentration is also -- that
10 is achieved, is to some degrees also a
11 pharmacokinetic property of a formulation.

12 Q Is that sometimes referred to as C_{max} , with
13 max in a subscript?

14 A That is correct.

15 Q This variation you discuss in
16 pharmacokinetic properties between patients taking a
17 drug formulation, is that itself a pharmacokinetic
18 property?

19 A Sorry, I couldn't follow. Can you -- can
20 you --

21 Q Yes.

22 A -- ask again, please.

1 Q Right. You mentioned earlier that the
2 pharmacokinetic properties for a drug formulation can
3 vary between different patients. And is that
4 variation itself a pharmacokinetic property of a drug
5 formulation?

6 A It is not often used as a specific
7 property, but it can be -- is obviously a part of the
8 overall pharmacokinetic characteristics of a
9 formulation.

10 Q And is the variation that you discuss, is
11 that sometimes referred to as interpatient
12 variability?

13 A Interpatient variability is something very
14 specific and would obviously be considered as part of
15 a wide variability because it obviously specifies a
16 certain usually fraction of variability.

17 Q So what specifically is interpatient
18 variability?

19 A Well, interpatient variability is part of
20 the overall variability that you have, for example,
21 in the pharmacokinetic parameter that can be
22 attributed to differences in individual patients.

1 Q So can there be interpatient variability,
2 for example, of the bioavailability of a drug
3 formulation?

4 A There is usually interpatient variability
5 for the bioavailability of a drug formulation.

6 Q Now, you've mentioned dosing regimens a bit
7 earlier, as well as in your declaration.

8 What is a dosing regimen?

9 A A dosing regimen is the combination of how
10 much of a drug is taken at a specific occasion, how
11 it is delivered, so the administration route, as well
12 as how frequently it is administered.

13 Q Going back briefly to interpatient
14 variability, is interpatient variability formulation
15 dependent?

16 A Interpatient variability can have multiple
17 sources. Interpatient variability in pharmacokinetic
18 parameters can have multiple sources, some of them
19 may be inherent to patient-specific properties and
20 some of them may be related to how a specific dosage
21 form behaves in a specific patient.

22 Q So is the drug formulation one of the

1 sources of interpatient variability?

2 A No, it is not the formulation itself. It's
3 the formulation in interaction with the patient.

4 Q Okay. So to clarify, then, is the drug
5 formulation in interaction with the patient one of
6 the sources of interpatient variability?

7 A Interpatient variability in what?

8 Q Pharmacokinetic properties.

9 A In general terms, pharmacokinetic
10 properties, yes.

11 Q So just so the record is clear, I'm just
12 going to ask this all at once, just to make sure that
13 we're all on the same page here.

14 Is the drug formulation in interaction with
15 the patient one of the sources of interpatient
16 variability of pharmacokinetic properties?

17 A Yes, potentially.

18 Q In your declaration you mentioned that when
19 designing a -- well, actually, let me back up.

20 You say in your declaration that you,
21 yourself, have worked on designing dosing regimens;
22 is that right?

1 A I have worked on designing or helping to
2 design dosing regimens, yes.

3 Q And has any of that dosing regimen work
4 involved cladribine or treatments for multiple
5 sclerosis?

6 A No.

7 Q Now, in your declaration you mentioned that
8 when designing a dosing regimen, one consideration is
9 a drug's bioavailability.

10 But my question for you is are there other
11 considerations when designing a dosing regimen
12 besides bioavailability?

13 A Yes.

14 Q And what are examples of that?

15 A Route of administration, clearance,
16 half-life. Just to name a few.

17 Q Well, to start, you mention route of
18 administration. What is a route of administration?

19 A It is the way how a drug is introduced into
20 the body.

21 Q For example, there could be an injectable
22 route of administration or an oral route of

1 administration?

2 A Was there a question? There was some noise
3 in between. I didn't know whether that was an
4 objection or not.

5 Q Yeah. I think there was -- I heard some
6 interference, but I'll just re-ask.

7 For example, there could be an injectable
8 route of administration or an oral route of
9 administration. Does that sound right?

10 A No.

11 Q Is the -- what are examples of routes of
12 administration?

13 A Intravenous administration, subcutaneous
14 administration, peroral administration or oral
15 administration.

16 Q Are intravenous and subcutaneous routes of
17 administration sometimes referred to as injectables?

18 A The dosage forms that are used are
19 injectables, but the route of administration is
20 either intravenous or subcutaneous. Whether it's
21 injected or not is secondary.

22 Q I see. Thanks. Learning today.

1 And how -- strike that.

2 Why is it that the route of administration
3 is a consideration in developing a dosing regimen?

4 A It may determine the bioavailability, as
5 well as how rapidly a drug is available in the
6 systemic circulation.

7 Q Is there any other reason that you would
8 take the route of administration into consideration
9 when developing a dosing regimen; for example,
10 administration convenience?

11 A That is a consideration, but a secondary
12 one.

13 Q And why is it that administration
14 convenience is a consideration when developing a
15 dosing regimen?

16 A Because acceptance of a dosing regimen in
17 the target patient population is obviously important,
18 and if a route of administration is used that is
19 challenging for the patient or difficult to use, then
20 that may affect the acceptance. But ultimately, the
21 criterion is always trumped by the safety and
22 efficacy of the drug.

1 Q You say "acceptance." Is that sometimes
2 referred to as patient compliance?

3 A Compliance is an obsolete expression.
4 Should be adherence.

5 Q So what is patient adherence?

6 A Patient adherence means that the patient
7 adheres to the described dosing regimen.

8 Q And is patient adherence a consideration
9 when designing a dosing regimen?

10 A As I said, it is a secondary consideration
11 that is always trumped by efficacy and safety.

12 Q But all other things being equal, would
13 convenience or patient adherence be a consideration
14 in developing a dosing regimen?

15 A With all other factors being equal, it
16 would.

17 Q But does the dosage form, is that a
18 consideration in developing a dosing regimen?

19 A Yes.

20 Q Why is that?

21 A Because some dosage forms are easier to use
22 than others.

1 Q And forgive me if this is a stupid
2 question, but why is it that some dosage forms are
3 easier to use than others?

4 A If I have a subcutaneous injection that
5 requires training by the patient, if it's
6 self-administered, an intravenous administration
7 would require a visit to a healthcare provider;
8 whereas, an oral administration of a tablet is done
9 by the patient themselves.

10 Q And is the stability of a dosage form a
11 consideration when developing a dosing regimen?

12 A There are defined criteria for dosage forms
13 to have a certain stability to be useful in use in a
14 patient population.

15 Q Why are there defined criteria for dosage
16 forms to have a certain stability to be useful for
17 use in a patient population?

18 A To ensure that within the time period that
19 has been defined as where the dosage form is stable,
20 that during this time period, the dosage form
21 performs consistently with regard to, for example,
22 the content of the drug or the active pharmaceutical

1 ingredient, the API, and its release from the dosage
2 form and uptake into the body.

3 Q Are there any specific types of dosage
4 forms that tend to be more stable than other types of
5 dosage forms?

6 MR. BASSETT: Objection.

7 A Not necessarily.

8 Q But is it ever the case that some dosage
9 forms tend to be more stable than others?

10 MR. BASSETT: Objection. Vague.

11 A I think you cannot generalize this.

12 Q Is the interpatient variability in
13 pharmacokinetic properties that we discussed earlier,
14 can that be a consideration when developing a dosing
15 regimen?

16 A That could be a consideration.

17 Q And why is that?

18 A If the patient -- if interpatient
19 variability is related to variability or to -- can
20 you please repeat the question? Sorry, I lost --

21 Q Yes, of course. Of course.

22 Why is it that interpatient variability of

1 pharmacokinetic properties is a consideration when
2 developing a dosing regimen?

3 A A dosing regimen is usually designed to
4 produce, at least within a certain range, similar
5 exposures in the systemic circulation of patients,
6 and the higher interpatient variability would be, the
7 more variability in that exposure you would expect.

8 Q And is it generally a negative thing if
9 there's a high interpatient variability for a drug
10 formulation?

11 MR. BASSETT: Objection.

12 A Interpatient variability for a drug
13 formulation, I do not understand what you mean by
14 that.

15 Q So we have been discussing interpatient
16 variability of pharmacokinetic properties in a drug
17 formulation.

18 A Okay.

19 Q And for a drug formulation, if there's a
20 high level of that interpatient variability, is that
21 generally considered to be a negative thing?

22 MR. BASSETT: Objection. Vague.

1 A That depends on the specific drug and its
2 pharmacologic properties.

3 Q Is a high degree of interpatient
4 variability in pharmacokinetic properties of a drug
5 formulation undesirable?

6 MR. BASSETT: Objection.

7 A It, again, depends on the pharmacologic
8 properties of the drug. For some drugs, it may be
9 undesirable; for others, it doesn't play a role.

10 Q So for some drugs, it is undesirable to
11 have a high degree of interpatient variability of
12 pharmacokinetic properties; is that right?

13 A I think that's different from what you
14 asked earlier. Can you please restate this --
15 this -- it's very general.

16 Q For some drugs, it is undesirable to have a
17 high degree of interpatient variability of
18 pharmacokinetic properties; is that right?

19 A If you refer --

20 MR. BASSETT: Objection. Sorry, I waited
21 too long. Objection.

22 A If you refer to this as pharmacokinetic

1 parameters that are related to the dosage form, then
2 in some instances, high between patient variability
3 in those parameters may be undesired for specific
4 drugs.

5 Q And when you say those pharmacokinetic
6 parameters, are there any pharmacokinetic parameters
7 you're referring to specifically?

8 A I think you referred to pharmacokinetic
9 parameters, not me.

10 Q Well, so, for example, for some drugs, it
11 is undesirable to have a high degree of interpatient
12 variability in bioavailability; is that right?

13 A That is in -- generally correct.

14 Q And so all else being equal, would it ever
15 be desirable to have a high degree of interpatient
16 variability of pharmacokinetic properties for a drug
17 formulation?

18 A I think it would for -- as I pointed out
19 before, for certain drugs it doesn't matter.

20 Q But setting aside whether or not it
21 matters, my specific question is, all else being
22 equal, would it ever be desirable to have a high

1 degree of interpatient variability of pharmacokinetic
2 properties for a drug formulation?

3 A I do not think that it is desirable. I
4 think what is desirable is less relevant than what is
5 actually needed for a specific drug and a specific
6 formulation.

7 Q So these various considerations that we've
8 just been discussing when developing a dosing
9 regimen, were these all considerations as of the 2004
10 time frame?

11 MR. BASSETT: Objection. Vague.

12 A Which considerations? Can you specify?

13 Q The specific ones that we discussed earlier
14 today. So that would be interpatient variability,
15 route of administration, dosage form, patient
16 adherence, stability.

17 Would those all have been considerations in
18 developing a dosing regimen as of the 2004 time
19 frame?

20 MR. BASSETT: Objection.

21 A Yes.

22 MR. BASSETT: Christina, we've been going

1 about an hour 15, hour and 20 minutes, if you could
2 at some point --

3 MS. DASHE: You read my mind, actually. I
4 was just going to suggest that we all take a break,
5 so we're all on the page here.

6 MR. BASSETT: Excellent.

7 MS. DASHE: Thank you.

8 MR. BASSETT: How long? Five minutes? Ten
9 minutes?

10 MS. DASHE: Let's do 10 minutes.

11 MR. BASSETT: Great. Okay. Talk to you
12 soon.

13 (Recess 10:18 a.m. - 10:32 a.m.)

14 BY MS. DASHE:

15 Q Welcome back, Dr. Meibohm.

16 During the break did you discuss the
17 substance of your testimony with anyone?

18 A No.

19 Q Did you access any information regarding
20 the substance of your testimony during the break?

21 A No.

22 Q So before the break we were talking about

1 various pharmacokinetic properties, including
2 bioavailability.

3 And my question for you, is there any
4 threshold or minimum bioavailability that a drug
5 formulation needs to have in order for it to have a
6 pharmacologic or therapeutic effect?

7 MR. BASSETT: Vague. Objection.

8 A Well, the absolute minimum would obviously
9 be more than zero. If there's no bioavailability,
10 there's no drug.

11 Q Is there any other threshold or minimum
12 bioavailability that's needed above zero?

13 A No. There are examples of approved drugs
14 with a bioavailability of 1 to 2 percent.

15 Q Now, in your career have you been involved
16 in any clinical trials?

17 A As a patient?

18 Q Let me clarify. In your career, as part of
19 your work on drug development, have you been involved
20 in any clinical trials?

21 A "Involved" is pretty unspecific. Can you
22 be more specific what that means?

1 Q Have you ever worked on a clinical trial?

2 A Yes.

3 Q And approximately how many?

4 A I don't know. It depends on what you
5 define "worked."

6 Q More than five?

7 A No. Again, I do not understand what you
8 mean with "worked." Worked can be anything from
9 planning to executing to being part of collecting
10 data, assembling data, storing data, analyzing data,
11 interpreting data. If all that is including work,
12 then I would say several dozen.

13 Q So you've had some sort of role that you
14 just mentioned in several dozen clinical trials over
15 your career; is that right?

16 A In the definition that I said, yes.

17 Q And have any of those clinical trials been
18 for treatments for multiple sclerosis?

19 A No.

20 Q Have any of them -- strike that.

21 Have any of those clinical trials been for
22 treatments for autoimmune disorders or any

1 neurological conditions?

2 A In the widest sense, autoimmune disorders.

3 Q So yes, you've had some role under your
4 definition in clinical trials for autoimmune
5 disorders?

6 A Yes.

7 Q Which autoimmune disorders are you
8 referring to?

9 A Rheumatoid arthritis, Crohn's disease,
10 colitis. So basically chronic inflammatory
11 conditions.

12 Q And approximately how many clinical trials
13 that you've had some sort of role in, under your
14 definition, have involved autoimmune disorders?

15 A Hard to say. So I interpreted data that
16 may be of multiple studies.

17 Q Would it be more or less than five?

18 A Perhaps.

19 Q So it's possible that you have had some
20 role in clinical trials regarding autoimmune
21 disorders of more than five trials; is that right?

22 MR. BASSETT: Objection.

1 A If you consider interpreting data that have
2 been generated in those trials, then probably.

3 Q And what sorts of data were you
4 interpreting?

5 MR. BASSETT: Objection. Compound. Vague.

6 A Usually PK and PK/PD data.

7 Q "PK" being pharmacokinetic, "PD" being
8 pharmacodynamic; is that right?

9 A That is correct.

10 Q And did you play any other role in those
11 autoimmune clinical trials besides interpreting PK
12 and PD data?

13 A No.

14 Q Do you recall what specific drugs were
15 being studied in those clinical trials regarding
16 autoimmune disorders that you had a role in?

17 MR. BASSETT: Objection.

18 A I think I'm not privileged to share those
19 information.

20 Q Are there any currently approved drugs that
21 you recall?

22 A As I said, I think I cannot -- these are

1 confidential work that I've done, so I cannot
2 disclose which drugs were affected.

3 Q And we are -- we can mark this transcript
4 confidential so that it will not be disclosed.

5 So with the transcript being confidential,
6 could you answer my question?

7 A I could answer your question saying that
8 these were antibody-based drugs.

9 Q Were they all antibody-based drugs, these
10 clinical trials for autoimmune disorders that you
11 referred to?

12 A Yes.

13 Q And what companies were these clinical
14 trials on behalf of?

15 A I cannot disclose that information either.

16 Q Are those clinical trials on your CV?

17 A The trials are not on the CV. The
18 companies are on my CV, yes.

19 Q And you provide a list of companies that
20 you consulted for on your CV, right?

21 A That is correct.

22 Q So these clinical trials regarding

1 autoimmune disorders were -- that you were involved
2 in, had a role in, were on behalf of at least some of
3 the companies that are listed on your CV that you
4 provided consulting work for; is that right?

5 A That is correct.

6 Q And was Merck one of those companies that
7 you performed clinical trials for autoimmune
8 disorders for?

9 A No.

10 MR. BASSETT: Objection. Objection.
11 Mischaracterizes his testimony.

12 You may answer.

13 A No.

14 MS. DASHE: And, Counsel, I would like to
15 remind you that under the PTAB rules that it is one
16 word objections.

17 MR. BASSETT: I'm going to object as
18 appropriate, Christina. I have been very -- I
19 haven't interrupted you. But when you
20 mischaracterize his testimony, I'm going to say so,
21 and you can take it up with the Board if you want.

22 Please proceed.

1 MS. DASHE: I would just like to note for
2 the record that that is outside of the rules. But I
3 can proceed.

4 BY MS. DASHE:

5 Q Have you, Dr. Meibohm, ever designed a
6 clinical trial for autoimmune disorder treatments?

7 A No.

8 Q Now, you worked with the United States Food
9 and Drug Administration on an advisory committee for
10 pharmaceutical sciences and clinical pharmacology; is
11 that right?

12 A That is correct.

13 Q And did any of your work at the FDA involve
14 clinical trials?

15 A In the broadest sense, yes.

16 Q Okay. And how is that?

17 A Well, the discussions that were at those
18 advisory -- at the advisory board, were related to --
19 if I remember correctly, it's already long ago --
20 were related to study designs for different --
21 different dosage forms. So ultimately, that is
22 obviously related to clinical studies.

1 Q Did any of your work at the FDA involve
2 cladribine or treatments for multiple sclerosis?

3 A No, not that I'm aware of.

4 Q Now, the FDA requires that clinical trials
5 have certain clinical efficacy endpoints, right?

6 A That depends on the purpose of the trial.

7 Q Yeah. Actually, I understand what you're
8 saying, so let me rephrase my question to be more
9 clear.

10 For clinical efficacy trials for a specific
11 drug, the FDA requires the clinical trial have
12 certain clinical efficacy endpoints, correct?

13 A That is correct.

14 Q And those clinical efficacy endpoints are
15 specified in advance of the trial, right?

16 A Yes, they are.

17 Q And the FDA also requires that clinical
18 trials related to clinical efficacy of drugs have a
19 certain patient population size. It has to be more
20 than one patient, right?

21 A That depends on the objectives of the
22 trial.

1 Q For those clinical trials where an
2 objective is assessing clinical efficacy of a drug
3 formulation, the FDA requires that the clinical trial
4 have a certain patient population size that is more
5 than one patient, right?

6 A That is what you would expect a trial that
7 is designed to show efficacy of a specific drug
8 formulation would be designed to have a certain
9 statistical chance of finding a predefined treatment
10 difference.

11 Q And that requires more than one patient to
12 perform that statistical analysis, right?

13 A Usually it does.

14 Q Okay. Have you ever seen a clinical trial
15 where there has only been one patient?

16 A A trial, yes, but not an efficacy trial.

17 Q So just let me just clarify the question.
18 Have you ever seen a clinical efficacy
19 trial with only one patient?

20 A No.

21 Q Now, during your career, have you ever
22 worked with cyclodextrins?

1 A Not personally.

2 Q What do you mean by "not personally"?

3 A I did not work on any specific project that
4 entailed cyclodextrins. I've read and I've seen
5 colleagues have worked on cyclodextrins, but I
6 personally have not.

7 Q Have you read or seen colleagues having
8 used cyclodextrins to increase the solubility of a
9 drug?

10 A Yes, I have.

11 Q And have you read or seen colleagues having
12 used cyclodextrins to increase the bioavailability of
13 a drug?

14 A Yes, I have.

15 Q And approximately when -- when did you see
16 that?

17 MR. BASSETT: Objection.

18 A I would say I knew about it in the last
19 century.

20 Q So "the last century" meaning in the 1990s?

21 A The 1990s.

22 Q How is it that cyclodextrins work to

1 increase solubility?

2 MR. BASSETT: Objection. Vague.

3 Objection.

4 A Well, that is not my expertise. But as far
5 as I understand, there are molecular interactions
6 between cyclodextrins and molecules of an active
7 pharmaceutical ingredient, or API, that may stabilize
8 those APIs, and by that, increase the solubility.

9 Q And I realize that -- well, strike that.

10 Now, how is it exactly that cyclodextrins
11 work to increase bioavailability of a drug?

12 MR. BASSETT: Objection.

13 A As far as I understand, cyclodextrins
14 solely increase -- get more drug into solution, and
15 by that, as a secondary effect, increase
16 bioavailability.

17 Q And this understanding regarding
18 cyclodextrins and their role in solubility and
19 bioavailability, is that something you were aware of
20 in the 1990s?

21 A Yes.

22 Q Now, you say that you are not an expert in

1 cyclodextrins. Is there anybody you would consider
2 an expert in cyclodextrins specifically?

3 MR. BASSETT: Objection.

4 A I do not know personally.

5 Q Now, in your declaration you mention that
6 over the course of your career you have interacted
7 with various experts and inventors in pharmaceuticals,
8 including Dr. Nicholas Bodor.

9 And my question for you is, what were your
10 interactions with Dr. Nicholas Bodor?

11 MR. BASSETT: Objection. Compound.

12 A Dr. Bodor was a faculty member at the
13 University of Florida College of Pharmacy when I
14 spent there two years as a postdoctoral research
15 fellow from 1995 to 1997.

16 During that time and prior to that time, as
17 far as I know, my research advisor at the University
18 of Florida had interacted with Dr. Bodor and he was
19 the chair of the department that Dr. Bodor was in.

20 So I had seen Dr. Bodor at that time. I
21 saw presentations, research presentations of some of
22 his staff.

1 Q What was the subject matter of the research
2 presentation that you saw -- presentations that you
3 saw of Dr. Bodor or his staff?

4 A I think --

5 MR. BASSETT: Objection.

6 A I think most of it was related -- the topic
7 that I remember was related to a concept that's
8 called retro-metabolism.

9 Q What is retro-metabolism?

10 A As far as I understand it, it is a concept
11 where drugs are specifically designed to be rapidly
12 metabolized, and by that, have very little systemic
13 exposure while they may have, for example, topical
14 exposure.

15 The prime example was a compound developed
16 by Dr. Bodor that's used as an anti-inflammatory in
17 the eye, where whenever the drug gets into the
18 systemic circulation, it's very rapidly removed.

19 Q When was the last time that you interacted
20 with Dr. Bodor?

21 A I interacted with him indirectly through
22 his -- his assistant or secretary, I don't remember

1 what the role of that individual was, probably around
2 2017, 2018 when he asked me for a letter of support
3 for nominating my research advisor at the time from
4 the University of Florida for a -- for an
5 international award.

6 Q Besides that interaction -- strike that.

7 Besides the interaction in the 2017, 2018
8 time frame, when was the last time you interacted
9 with Dr. Bodor?

10 A I do not think I saw him after I left the
11 University of Florida, that was in 1997.

12 Q So you considered Dr. Bodor to be an expert
13 and an inventor in pharmaceuticals; is that right?

14 A That was how he was always characterized to
15 me.

16 Q And who is he -- strike that.

17 You say that Dr. Bodor was characterized as
18 an expert and an inventor in pharmaceuticals by others
19 presumably.

20 Who are those others?

21 A Well, my research advisor at the time,
22 Dr. Hartmut Derendorf. Hartmut, H-a-r-t-m-u-t. Last

1 name, D-e-r-e-n-d-o-r-f.

2 Q You're anticipating my spelling questions
3 at this point.

4 And was Dr. Bodor characterized as an
5 expert and inventor in pharmaceuticals as of the 2004
6 time frame?

7 A Well, he was characterized in 1997, so I
8 assume that continued. But that's an assumption.

9 Q And do you have any reason to disagree with
10 the characterization of Dr. Nicholas Bodor as an
11 inventor in pharmaceuticals -- strike that.

12 Do you have any reason to disagree with the
13 characterization of Dr. Nicholas Bodor as an expert
14 and inventor in pharmaceuticals?

15 A No.

16 Q Was Dr. Bodor ever characterized as an
17 expert and inventor in the field of cyclodextrins
18 specifically?

19 MR. BASSETT: Objection. Vague.

20 A Not that I'm aware of.

21 Q Do you have your own view of Dr. Bodor?

22 A Yes.

1 Q And what is that?

2 A What is --

3 MR. BASSETT: Objection.

4 A It's very vague. I don't know what to
5 answer.

6 Q What is your professional opinion of
7 Dr. Bodor?

8 A I think he is an accomplished scientist.

9 Q And did you think that back in 2004?

10 A I don't know. That question was not asked
11 to me in 2004.

12 Q You do not have an MD or are not a medical
13 doctor, right?

14 A That is correct.

15 Q Have you ever yourself treated a patient?

16 A I'm a licensed pharmacist in Germany. I
17 worked as a licensed pharmacist over there, so I have
18 given medications to patients. I have counseled
19 non-prescription medications to patients. But
20 obviously, all prescription medications would have
21 been prescribed by a licensed healthcare provider
22 that can prescribe. At the time when I practiced, it

1 was only physicians.

2 Q So you, yourself, have never prescribed a
3 medication to a patient; is that right?

4 A That is correct.

5 Q Okay. And when you say you've given
6 medications to patients, do you mean -- just mean
7 dispense the medication to the patient?

8 A Well, that means dispense for medications
9 that are prescription medications, but also give
10 medications to patients that are non-prescription
11 medications.

12 Q But you, yourself, have never actually
13 administered a medication to a patient; is that
14 right?

15 A That is correct.

16 Q Have you ever diagnosed a patient with a
17 disease or a condition?

18 A No.

19 Q So then you've never diagnosed a patient
20 with multiple sclerosis, right?

21 A That is correct.

22 Q And you, yourself, have never written a

1 prescription for a treatment for multiple sclerosis,
2 correct?

3 A That is correct.

4 Q Nor have you administered a treatment for
5 multiple sclerosis to a patient, right?

6 A That is correct as well.

7 Q Do you have any education or training in
8 multiple sclerosis?

9 A No, I do not, beyond my general pharmacy
10 degree.

11 Q Have you ever developed a drug formulation
12 or a dosing regimen for treating multiple sclerosis?

13 A No, I did not.

14 Q Besides your specific work on this case,
15 have you ever done any work with cladribine?

16 A No, I did not.

17 Q Have you ever worked with the drug brand
18 name Tysabri or natalizumab?

19 And I'll spell that. Tysabri,
20 T-y-s-a-b-r-i. And then natalizumab,
21 n-a-t-a-l-i-z-u-m-a-b.

22 Have you ever worked with those drugs?

1 A There's only one, I think, right?

2 Q Yeah. With that single drug with the brand
3 name being Tysabri?

4 A No.

5 Q Have you ever worked with the drug
6 glatiramer acetate, brand name Copaxone? Spelled
7 g-l-a-t-i-r-a-m-e-r a-c-e-t-a-t-e. Copaxone spelled
8 C-o-p-a-x-o-n-e.

9 A Yes.

10 Q And when was that?

11 A I think around 2009 or 2010.

12 Q And what specifically was your work on
13 Copaxone, glatiramer acetate?

14 A There were questions about -- sorry, I was
15 distracted.

16 There were questions about the emergence of
17 generic Copaxone drugs at the time.

18 Q What were those questions?

19 A I do not remember the details, and I think
20 I cannot even disclose much further about those
21 details because they are confidential.

22 Q You did not work on Copaxone or glatiramer

1 acetate before 2004, right?

2 A No.

3 Q Have you ever performed a study
4 investigating different dosing regimens for treating
5 MS?

6 A No.

7 Q Have you ever advised a physician or
8 medical doctor regarding the treatment of multiple
9 sclerosis?

10 A No.

11 Q And have you ever advised a physician or
12 medical doctor regarding selecting a drug formulation
13 or a dosing regimen for treating a patient with MS?

14 A No.

15 Q Now, just to circle back on the Copaxone
16 front, I realize that I don't think I was clear.

17 So you did not work on Copaxone, glatiramer
18 acetate, before 2004, correct?

19 A Correct.

20 Q Now I'm going to ask you some questions
21 regarding multiple sclerosis, multiple sclerosis
22 treatments, and I want to focus on the 2004 time

1 frame, unless I specifically say otherwise. Is that
2 understood?

3 A Understood.

4 Q Okay. How would you assess whether a
5 particular drug formulation or dosing regimen for
6 treating multiple sclerosis has demonstrated clinical
7 efficacy?

8 MR. BASSETT: Objection.

9 A Clinical efficacy would be assessed in
10 usually double blind-randomized clinical studies with
11 predefined primary and secondary endpoints.

12 Q And what would those predefined primary and
13 secondary endpoints be?

14 MR. BASSETT: Objection. Vague.

15 A That is outside my expertise.

16 Q So you do not know what the predefined
17 primary and secondary endpoints for assessing
18 clinical efficacy of a multiple sclerosis treatment
19 would be, correct?

20 A Correct.

21 Q You also say that clinical efficacy would
22 usually be assessed with a double-blind, randomized

1 clinical study with predefined primary and secondary
2 endpoints.

3 Are there other ways to assess clinical
4 efficacy of an MS treatment?

5 MR. BASSETT: Objection. Foundation.

6 A The question is for what purpose you try to
7 determine efficacy. If you determine it for
8 regulatory approval, I think you would have to have
9 the double-blind, randomized, placebo-controlled, or
10 at least standard of care controlled clinical study.

11 Q But is there a difference in assessing
12 clinical efficacy for regulatory approval for an MS
13 treatment versus assessing clinical efficacy in some
14 other context?

15 A For exploratory studies, obviously other
16 study designs could potentially be used.

17 Q What is an exploratory study?

18 A An exploratory study would be a study where
19 a drug developer will -- ultimately would like to get
20 some indication of efficacy and/or safety without
21 necessarily having the statistical rigor of a study
22 design that can be submitted for regulatory approval.

1 Q So you mentioned other study designs for
2 exploratory studies. What other study designs were
3 you thinking of?

4 A It could be a single-arm study, it could be
5 a dose-ranging study.

6 Q What's a single-arm study?

7 A Single-arm study would be that you just
8 treat one group of patients and you try to see
9 whether some efficacy and/or safety signals can be
10 followed.

11 Q What's a dose-ranging study?

12 A A dose-ranging study would usually evaluate
13 multiple different dose levels or dosing regimens of
14 a drug to explore which of them may provide the
15 desired efficacy and/or safety.

16 Q Now, does a dose-ranging study for an
17 exploratory study, is that less time and energy
18 involved than a full clinical trial for the FDA or
19 other regulatory body?

20 MR. BASSETT: Objection.

21 A Usually exploratory studies are -- have
22 smaller patient numbers and are shorter in duration.

1 Q Now, you mentioned something called EDSS
2 scores in your declaration.

3 My question for you is, what is an EDSS
4 score?

5 A Can I see where I mention this in my
6 declaration?

7 Q Yeah. You know, for example, you mention
8 it a number of places. So I'll just pick an example.
9 Paragraph 53.

10 MS. DASHE: Rachel, if you want to put up
11 Exhibit 2052, Dr. Meibohm's declaration, paragraph
12 53.

13 And, Dr. Meibohm, feel free to follow along
14 on the screen or on paper.

15 A Okay.

16 Q So you refer to EDSS scores. So my
17 question is, what is an EDSS score?

18 A Yes. So I refer to EDSS score as it is
19 mentioned in the Stelmasiak paper. It seems to be a
20 disease-specific outcome score, similar to outcome
21 scores in other disease conditions that ultimately
22 are composed of either some objective measures of --

1 of disease activity, and sometimes also included some
2 more functional or subjective measures, depending on
3 patient symptoms and functionality.

4 Q What does EDSS stand for?

5 A I don't remember.

6 Q Do you know how the EDSS scores are
7 measured?

8 A As far as I mentioned, as I just said, I
9 think it's a score that comprises a variety of
10 different assessments and is disease specific for
11 multiple sclerosis.

12 Q But do you know what that variety of
13 different assessments is for the -- determining an
14 EDSS score?

15 A As far as I vaguely remember, it includes,
16 as I mentioned, functional measures, patient
17 abilities to perform certain -- certain activities,
18 as well as objective disease progression measures, I
19 assume, assessed by some imaging technique.

20 Q So do you know what those functional
21 measures of patient abilities are?

22 A I think it's related to walk tests or

1 something like that, but I don't know more details.

2 Q So you don't know specific details
3 regarding what the functional measurements of patient
4 abilities are in determining an EDSS score; is that
5 right?

6 A That is correct.

7 Q Do you know how to -- strike that.

8 Do you know any other specific details
9 regarding how to make an assessment of an EDSS score
10 in a multiple sclerosis patient?

11 A Not --

12 MR. BASSETT: Objection.

13 A Not beyond what I have just said.

14 Q And do EDSS scores change?

15 A As far as --

16 MR. BASSETT: Objection.

17 A As far as I understand, they change over
18 time depending on disease activity and -- yeah,
19 disease activity.

20 Q What does a change in EDSS score mean?

21 A Well, as far as --

22 MR. BASSETT: I'm sorry. Objection.

1 Please go ahead.

2 A As far as I understand, the EDSS score is a
3 scale from 0 to 10 or 1 to 10, where the highest
4 scores relate to more advanced disease severity.

5 Q Have you ever measured or determined a
6 patient's EDSS score?

7 A No.

8 Q Have you ever been involved in any capacity
9 in a clinical study or trial that measured EDSS
10 scores?

11 A Not that I'm aware.

12 Q Have you ever analyzed EDSS scores in your
13 career, besides your work on this case?

14 A No.

15 Q You also mention changes in relapse rates
16 in your declaration -- do you see that again on the
17 screen in paragraph 53? -- as an example.

18 My question for you is, what is a relapse?

19 A To my understanding, some forms of multiple
20 sclerosis have a discontinuous disease progression,
21 where you have periods of active disease that are
22 followed by periods of relative limited disease

1 activity, and then periods of recurrent active
2 disease, and the recurrent active disease periods are
3 then termed "relapses."

4 Q So your understanding is that relapses are
5 a period of active disease in a multiple sclerosis
6 patient?

7 A Yes.

8 Q And what happens during a patient's
9 relapse, like clinically?

10 A I'm not a clinician. Beyond my expertise.

11 Q So you do not know what happens during a
12 patient's relapse clinically, correct?

13 A I think that's what I just said.

14 Q How do you determine or assess whether or
15 not a patient has had a relapse?

16 MR. BASSETT: Objection. Foundation.

17 A Again, outside my expertise. Would be done
18 by a clinician that works with that patient.

19 Q So you do not know how to determine or
20 assess whether a patient with MS has had a relapse,
21 right?

22 A No.

1 Q How do you determine or assess whether a
2 patient with MS has recovered from a relapse?

3 MR. BASSETT: Objection. Foundation.

4 A Well, again, outside my expertise.

5 Q So you do not know how to determine or
6 assess whether a patient with MS has recovered from a
7 relapse?

8 A Correct.

9 Q What is a relapse rate?

10 A A relapse rate, according to my
11 understanding, is that the number of relapse events
12 in a certain time period.

13 Q And do you know what that certain time
14 period is?

15 MR. BASSETT: Objection.

16 A That time period could be anything that you
17 define as a period. Could be a year, could be two
18 years. Usually it's probably something that's very
19 easy and -- to assess in order to compare results.
20 But theoretically, a rate is always a defined time
21 period -- or, sorry, a rate of something is the
22 number of occurrences in a predefined time period.

1 Q Do you know what the time period for
2 assessing relapse rate in multiple sclerosis
3 typically is?

4 A No.

5 MR. BASSETT: Objection.

6 A No.

7 Q Have you ever assessed relapse rate in
8 multiple sclerosis?

9 A I think you asked me that before. The
10 answer is no.

11 Q And what does a change in relapse rate for
12 a multiple sclerosis patient show?

13 MR. BASSETT: Objection. Foundation.

14 A To my limited understanding, a reduction in
15 relapse rate for multiple sclerosis patient would
16 potentially indicate a beneficial effect with regard
17 to the disease progression severity.

18 Q Have you ever -- pardon me. Strike that.
19 Have you ever been involved in a clinical
20 study or trial that has assessed changes in relapse
21 rate in patients with multiple sclerosis?

22 A No.

1 Q All right. You we can see mentioned in
2 your declaration in the next paragraph down,
3 paragraph 54, lymphocyte counts.

4 And so my first question for you is, what
5 is a lymphocyte?

6 A A lymphocyte is a group of white blood
7 cells.

8 Q Do you have an understanding of
9 lymphocytes' role in the MS disease process?

10 A Very vaguely.

11 Q And what is your understanding?

12 A Well, lymphocytes are part of the immune
13 system. Lymphocyte activity, increased lymphocyte
14 activity seems to be, to my understanding, related to
15 some of the chronic inflammatory conditions that
16 are -- that are part of multiple sclerosis, and as
17 such, are part of the driving force of the disease
18 process in MS.

19 MS. DASHE: Rachel, could you take down
20 Dr. Meibohm's declaration, just so we can all see
21 each other a little better here.

22 Thank you.

1 Q You mentioned inflammatory conditions part
2 of the MS disease process.

3 Do you have any understanding of the role
4 of inflammation in the MS disease process?

5 MR. BASSETT: Objection.

6 A That's, again, very vague. I would say
7 yes.

8 Q What is your understanding of the role of
9 inflammation in the MS disease process?

10 A I think inflammatory processes in the brain
11 ultimately lead to damage of neurons that are
12 basically triggered through a continuous or an
13 ongoing inflammatory process in the brain, and that
14 is usually modulated with immunomodulatory agents to
15 basically reduce that undesired chronic inflammatory
16 process.

17 Q Now, are lymphocyte counts used in the
18 context of MS treatment, do you know?

19 A I do not know whether they are used in the
20 context. I obviously infer that from the fact that
21 they are used and presented as an accepted biomarker
22 in the Stelmasiak paper.

1 Q But you, yourself, do not know why
2 lymphocyte counts are used in the context of MS
3 treatment; is that right?

4 A No. I think, again, lymphocyte counts --
5 we have worked extensively with lymphocyte counts in
6 the late '90s with regard to corticosteroid therapy,
7 and obviously lymphocyte counts can be used as a
8 potential biomarker for drug effects that are
9 modulating the immune system.

10 Q Aside from your work in this case, have you
11 ever assessed lymphocyte count data in the context of
12 MS treatments?

13 A Not in the context of MS treatment.

14 Q And getting back to relapse rate really
15 quickly, just circle back on that, have you ever
16 interpreted relapse rate data in the context of MS
17 treatments?

18 A I think you asked me that question before.
19 The answer is no.

20 Q Now, you reviewed and considered the U.S.
21 Patent Numbers 713 -- strike that.

22 You reviewed and considered U.S. Patent

1 Numbers 7,713,947 and 8,377,903 in order to provide
2 your declaration in this case, correct?

3 A That is correct.

4 Q All right. And you understand that they
5 are sometimes referred to as the '947 or '903
6 patents?

7 A That is correct.

8 Q And you understand that the challenged
9 claims of the '947 patent are claims 36, 38, 39, and
10 41 to 46. I can direct you to paragraph 19 of your
11 declaration if -- to refresh your recollection.

12 A Could I look at the patent? Could I look
13 at the patent --

14 Q Yes, certainly.

15 MS. DASHE: Rachel, could you please pull
16 up first tab 2, which is the '947 patent, and put it
17 in the chat, and it is Exhibit 1001 in IPR2023-00480.

18 Q Dr. Meibohm, can you see the cover page of
19 the '947 patent, Exhibit 1001, on your screen?

20 A Yes, I can.

21 Q And if we can go to the claims
22 specifically, if you would like.

1 A That would be great.

2 Q Let me figure out what page number I would
3 like to show.

4 MS. DASHE: So that would be, Rachel, page
5 -- starting on page 10 of the PDF, please, of Exhibit
6 1001, the '947 patent.

7 THE WITNESS: Yes.

8 MS. DASHE: And if you scroll down, Rachel.

9 Q You see where it says "The invention
10 claimed is:" Do you see that, Dr. Meibohm?

11 A Yes, I do.

12 Q Okay. And you say in your declaration that
13 the challenged claims of the '947 patent are claims
14 36, 38, 39, 41, 46, right?

15 And I'll show you those in just a second.

16 A Yes.

17 MS. DASHE: And, Rachel, could you please
18 scroll down to claim 36.

19 Q So, Dr. Meibohm, you see here on page 12 of
20 the PDF of Exhibit 1001, the '947 patent, you see the
21 challenged claims listed here, correct?

22 A Correct.

1 Q Okay. And these are -- the '947 patent
2 claims 36, 38, 39, 41 to 46, those are the claims
3 that are the challenged one in this proceeding and
4 that you have reviewed, correct?

5 A Correct.

6 MS. DASHE: Okay. Let's just do this for
7 the '903 patent, just to make sure everybody is on
8 the same page.

9 Rachel, if you could take down Exhibit
10 1001, the '947 patent, and pull up -- and put in the
11 chat tab 3, which is, unfortunately, also Exhibit
12 1001, but in IPR2023-00481.

13 Q Dr. Meibohm, do you see the '903 patent
14 cover page on your screen?

15 A Yes, I do.

16 MS. DASHE: Okay. And if we could, Rachel,
17 scroll to the claims of the '903 patent here, that
18 would start on page 10 of the PDF.

19 Scroll down a bit to where it says "We
20 claim".

21 Q Do you see that, Dr. Meibohm?

22 A Yes, I do.

1 MS. DASHE: Rachel, if you could scroll to
2 the next page, such that claim 17 is being depicted.

3 Q Okay. So, Dr. Meibohm, in paragraph 19 of
4 your declaration, you say that you understand that
5 the challenged claims of the '903 patent are claims
6 17, 19, 20 and 22 through 27, correct?

7 A Correct.

8 Q And we see here --

9 MS. DASHE: Rachel, I think if you just
10 zoom out just a teeny.

11 Q Dr. Meibohm, you see claim 17, 19, 20, 22
12 through 27 of the '903 patent on your screen here,
13 correct?

14 A That is correct.

15 Q Do you know what the file history of a
16 patent is, Dr. Meibohm?

17 A No, I do not.

18 Q So then do you know whether or not you
19 reviewed the file history for the '947 and '903
20 patents in preparing your declaration in this case?

21 A I don't recall whether I did or did not.

22 Q I'll represent to you that the file history

1 -- actually, strike that.

2 Have you ever heard of the term
3 "prosecution history"?

4 A No, sir.

5 Q I'll represent to you that a file history
6 or a prosecution history of a patent is a collation
7 of the communications between the Patent Office and a
8 patent applicant.

9 In preparing your declaration for this
10 case, have you seen or reviewed the file history for
11 the '903 or '947 patents?

12 A Not that I'm aware of.

13 MS. DASHE: Rachel, you can take that down
14 for now, just so that we can all see each other
15 better.

16 Q But, Dr. Meibohm, if at any point you would
17 like me to bring back up the patents, I'm more than
18 happy to do so.

19 Now, you mention in your declaration,
20 Dr. Meibohm, that the '947 and '903 patents are
21 directed to methods of treating certain forms of
22 multiple sclerosis. And my question for you is, what

1 is a form of multiple sclerosis?

2 A I would see this as a subclass of the
3 overall disease process. So, for example, multiple
4 sclerosis is probably an overarching ICD code and
5 there are certain subclassifications within this
6 disease. And I think the one that I think I have
7 read about is obviously the -- if I can find my
8 footing here -- is obviously the relapsing remitting
9 multiple sclerosis.

10 Q Besides relapsing remitting multiple
11 sclerosis, are you aware of any of the other forms of
12 multiple sclerosis?

13 A No.

14 Q Do you have any awareness of what
15 differences, if any, there are between the different
16 forms of multiple sclerosis?

17 A No.

18 Q And do you have any awareness of whether or
19 not there are different considerations for developing
20 a treatment for one form of multiple sclerosis versus
21 another?

22 A No.

1 Q Which forms of multiple sclerosis are
2 covered by the challenged claims, do you know?

3 A I think the '903 patent is covering the
4 relapsing remitting multiple sclerosis; whereas, the
5 '947 patent just claims multiple sclerosis in
6 general.

7 Q Now, do the challenged claims of the '947
8 and '903 patents contain any EDSS score requirements?

9 A Not that I'm aware.

10 Q And do the challenged claims of the '947
11 and '903 patents contain any requirements regarding a
12 reduction in relapse rate?

13 MR. BASSETT: Objection.

14 A Not that I'm aware of.

15 Q And do the challenged claims contain any
16 requirements regarding an effect on lymphocyte count?

17 MR. BASSETT: Objection.

18 A Not that I'm aware of.

19 Q Do the challenged claims of the '947 and
20 '903 patents contain any requirements regarding
21 treating a certain patient population size?

22 MR. BASSETT: Objection.

1 A You mean with size, a number of patients?

2 Q Correct.

3 A No.

4 Q In your view, must one know a patient's
5 weight before administering cladribine according to
6 the methods claimed in the challenged claims of the
7 '947 and '903 patents?

8 MR. BASSETT: Objection.

9 A In order to treat a patient based on the
10 treatment schedules or treatment regimens in those
11 two patents, it would be necessary to measure body
12 weight in order to devise the individual dose for the
13 individual patient.

14 Q Do the challenged claims of the '947 and
15 '903 patents require knowing a patient's body weight
16 before the cladribine is administered?

17 MR. BASSETT: Objection.

18 A They do not say that. But you cannot dose
19 cladribine in the described doses if you do not know
20 the body weight of the patient.

21 Q In forming your opinions in your
22 declaration, did you construe the challenged claims

1 of the '947 and '903 patents?

2 MR. BASSETT: Objection. Vague.
3 Foundation.

4 A I do not know what you mean with
5 "construe." Can you rephrase that question for me,
6 please?

7 Q Well, first let me just ask, do you have an
8 understanding of what the word "construe" means?

9 A Not fully, and that's why I asked you to
10 rephrase the question, please.

11 Q Do you have any understanding of the legal
12 requirements for claim construction of patents
13 claims?

14 A No.

15 MS. DASHE: You know, we have been going
16 for about an hour, if you would like to take a
17 10-minute break.

18 MR. BASSETT: Sure.

19 THE WITNESS: That would be good.

20 MS. DASHE: Okay. See you in 10 minutes.

21 MR. BASSETT: Okay. Thanks.

22 (Recess 11:34 a.m. - 11:48 a.m.)

1 BY MS. DASHE:

2 Q Welcome back, Dr. Meibohm.

3 Did you discuss the substance of your
4 testimony during the break?

5 A No.

6 Q Did you access information regarding the
7 substance of your testimony during the break?

8 A No.

9 Q Before the break we were talking a little
10 bit -- actually, one last thing.

11 During the break did you speak with
12 counsel?

13 A Yes.

14 Q What about?

15 MR. BASSETT: Objection.

16 Instruct the witness not to answer.

17 Q Without revealing the contents of
18 privileged communications --

19 MS. DASHE: Well, Counsel, we are entitled
20 to know what Dr. Meibohm may have discussed with
21 counsel during the break.

22 Q But yes or no, did your discussion with

1 counsel relate to the deposition at all?

2 A The deposition at all, yes.

3 Q Did it relate to the substance of the
4 deposition?

5 A No.

6 Q Did it relate to the logistics of the
7 deposition?

8 A Yes.

9 Q And those logistics being timing,
10 et cetera; is that right?

11 A Yes.

12 Q Okay. Now, did you -- strike that.

13 In forming the opinions set forth in your
14 declaration for this case, did you interpret the
15 challenged claims of the '947 and '903 patents?

16 MR. BASSETT: Objection.

17 A I'm not sure what you mean with
18 "interpret." Can you be more specific, please.

19 Q What is your understanding of the meaning
20 of "interpret"?

21 A In general terms?

22 Q Yes.

1 A Probably should look in the dictionary. I
2 would basically say form an opinion on a presented
3 subject matter.

4 Q And did you form -- strike that.

5 In forming the opinions set forth in your
6 declaration in this case, did you form an opinion
7 regarding the meaning of any of the challenged claim
8 terms?

9 MR. BASSETT: Objection. Vague.

10 A I think I read the claim terms and I tried
11 to interpret the words that are written.

12 Q And did you use any particular process to
13 interpret the words that are written in the
14 challenged claims besides simply reading those
15 claims?

16 A Well, trying to process them with --
17 together with my general knowledge base in clinical
18 pharmacology and pharmacokinetics.

19 Q What information did you consider in
20 interpreting the meaning of the challenged claim
21 terms?

22 MR. BASSETT: Objection.

1 A I used my understanding of medical
2 practice, my understanding of dosing regimen, and the
3 application in patient populations.

4 Q Did you consider any other information?

5 MR. BASSETT: Objection. Vague.

6 A I'm not sure what other information. My
7 general knowledge base, yes.

8 Q So besides your general knowledge base, did
9 you consider any other information in interpreting
10 the meaning of the challenged claim terms?

11 A In addition to my general knowledge base
12 and my specific knowledge in clinical pharmacology
13 and pharmacokinetics and pharmacy-related topics, no.

14 Q And did you determine or interpret the
15 meaning of any particular terms within the challenged
16 claims in providing your declaration in this case?

17 MR. BASSETT: Objection.

18 A I'm not sure what you're asking me.

19 Q Well, the challenged claims are made up of
20 a number of words, correct?

21 A Yes.

22 Q Okay. So did you determine the meaning of

1 any particular word or words appearing in the
2 challenged claims in providing your opinions in your
3 declaration?

4 MR. BASSETT: Objection. Vague.

5 A I have no clue what you're asking me,
6 sorry.

7 Q Well, sometimes -- all right.

8 So in forming the opinions set forth in
9 your declaration --

10 A Right.

11 Q -- did you interpret the meaning of any of
12 the words, the specific words appearing in the
13 challenged claims?

14 MR. BASSETT: Objection. Vague.

15 A Yes, I obviously had to know what a month
16 is. I had to know what a milligram is, yes. So I
17 made certain interpretations with regard to that.

18 Q Did you interpret any other words besides
19 month or milligram?

20 A Probably all of them, otherwise I wouldn't
21 understand it.

22 Q Now, you say in your declaration, in

1 paragraph 19, that you are aware that the petitioner
2 has alleged the challenged claims of the '947 and
3 '903 are obvious --

4 A May I interrupt you. Can I read this?
5 Where is this? Where are you --

6 Q Paragraph 19 of your declaration.

7 MS. DASHE: Rachel, if you would like to
8 put it up on the screen.

9 A Yeah, I still have it here, so -- okay.

10 Q Okay. So just to rewind that, you're on
11 paragraph 19.

12 Dr. Meibohm, you say in your declaration
13 that you are aware that petitioner has alleged that
14 the challenged claims of the '947 and '903 patents
15 are obvious in view of Bodor and Stelmasiak, and it's
16 your understanding that a POSA would not be motivated
17 to combine or modify Bodor and Stelmasiak.

18 And so my question for you is, did you
19 conclude that the challenged claims are not obvious?

20 MR. BASSETT: Objection.

21 A No, I did not make that claim. I was -- I
22 was told that this is the matter of the patent

1 dispute. What I basically commented on was matters
2 related to dosing and to pharmacokinetics,
3 specifically bioavailability.

4 Q Do you have any understanding of the legal
5 requirements for obviousness?

6 A Not in this jurisdiction.

7 Q "This jurisdiction" being in front of the
8 Patent Office, is that what you mean?

9 A Correct.

10 Q Do you have the understanding -- strike
11 that.

12 Do you have any understanding of the legal
13 requirements for obviousness in any other
14 jurisdiction?

15 A Yes.

16 Q What jurisdiction is that?

17 A The England and Wales.

18 Q So just to make sure that the record is
19 clear, do you have any understanding of the legal
20 requirements for obviousness under United States law?

21 A No.

22 Q So then you -- strike that.

1 Do you have any understanding of the legal
2 requirements for secondary considerations or
3 objective indicia of nonobviousness under United
4 States law?

5 A I do not even understand the question.

6 Q So then you do not know what the legal
7 standards are then?

8 MR. BASSETT: Objection.

9 A So since I do not understand your question,
10 I assume that I do not know anything about it.

11 Q Have you ever heard the term "secondary
12 considerations" or "objective indicia of
13 nonobviousness"?

14 A No.

15 Q Now, do you have any understanding of the
16 legal requirements for motivation to combine under
17 United States law?

18 A No.

19 Q Do you have any understanding of the legal
20 requirements for a reasonable expectation of success
21 under United States law?

22 A No.

1 Q Sorry. Fiddling with my notes here.

2 Okay. Now, Dr. Meibohm, weight-based
3 dosing for cladribine for the treatment of multiple
4 sclerosis was known in the prior art, correct?

5 A Not that I'm aware of.

6 Q I would like to -- let's look at paragraph
7 69 of your declaration.

8 MS. DASHE: Rachel, if you want to put that
9 up on the screen so we can all follow along, please.
10 And that would be Exhibit 2052.

11 Could you scroll down, Rachel, to the top
12 of page 30 to have that at the top of the screen
13 here. Okay.

14 Q Dr. Meibohm, do you see the sentence [As
15 read]: "It is my opinion that a pharmacologist would
16 have understood that despite acknowledging
17 weight-based cladribine doses in the prior art...
18 Bodor nevertheless," do you see that sentence?

19 A Yes.

20 Q So then Bodor acknowledges weight-based
21 cladribine doses in the prior art, right?

22 A Well, the prior art that's cited here is

1 the patents, right?

2 Q Well, just let me -- let me read the
3 sentence and make sure we're on the same page.

4 So it says, "It is my opinion" -- on
5 paragraph 69 -- "that a pharmacologist would have
6 understood that despite acknowledging weight-based
7 cladribine doses in the prior art... Bodor
8 nonetheless specifically chose to describe a
9 theoretical flat, fixed dosing regimen for use
10 with" --

11 (Court Reporter clarification.)

12 THE WITNESS: Sorry. The court reporter
13 couldn't follow.

14 Q I'm sorry.

15 The last sentence of paragraph 69,
16 Dr. Meibohm, that sentence refers to the Bodor prior
17 art reference, right?

18 A It relates to what the patents are
19 referencing as prior art.

20 Q What do you mean by "the patents"?

21 A Well, the two references that I pointed to
22 is the '480 and the '481 -- sorry. I need to -- I

1 need to look where that is.

2 Q Actually, so I think I can help you here.

3 So it says '480 and '481, do you see the
4 top of the page where it says IPR2023 --

5 A Yes.

6 Q So that's IPR -- so that's IPR 480, Exhibit
7 1022 --

8 A Oh, sorry. Yes, sorry. I got confused.

9 Q Okay. So now that we're all on the same
10 page.

11 A Okay. Good. Okay.

12 Q Got it. Got it. I do see the confusion
13 here. It's unfortunate that patents are referred to
14 by their last three numbers as well.

15 So the last sentence of paragraph 69 of
16 your declaration refers to the Bodor prior art
17 reference, right?

18 A Yes.

19 Q Okay. And the Bodor prior art reference
20 acknowledges that weight-based cladribine doses were
21 in the prior art, correct?

22 A I'm not sure if he says this anywhere.

1 Q Well, you say that Bodor --

2 A Oh, it -- would have understood that
3 despite acknowledging weight-based -- sorry.

4 (Court Reporter clarification.)

5 THE WITNESS: I apologize. I was loud
6 reading. I should have read without speaking.

7 Okay. Can we reset?

8 Q Yes. So in your declaration, paragraph 69,
9 the last sentence, you say that Bodor acknowledges
10 weight-based cladribine doses in the prior art,
11 right?

12 A Yes.

13 Q Okay. And in addition to weight-based
14 dosing, the prior art also discloses flat, fixed
15 cladribine dosing for treating multiple sclerosis,
16 correct?

17 A That's my understanding.

18 Q Okay. Have you identified any study or
19 publication that specifically compares administering
20 cladribine in a flat, fixed dose versus administering
21 cladribine in a weight-based dose for treating
22 multiple sclerosis?

1 A No.

2 MS. DASHE: So I know we have only been
3 going for a half an hour, but I believe lunch might
4 be here, and I don't want to make the witness answer
5 questions hungry. So if lunch is here, I'm happy to
6 take the lunch break.

7 MR. BASSETT: That's fine with us, assuming
8 the food is there. How long do you want to break?

9 MS. DASHE: Well, first of all, Rachel, can
10 you take down the exhibit here so I can see
11 everybody's faces.

12 Well, actually, can we go off the record
13 and we can decide the logistics.

14 THE COURT REPORTER: Off the record, 12:04.

15 (Recess 12:04 p.m. - 12:51 p.m.)

16 BY MS. DASHE:

17 Q Welcome back, Dr. Meibohm.

18 During the lunch break did you discuss the
19 substance of your testimony today?

20 A No, I did not.

21 Q Did you access information regarding the
22 substance of your testimony during the lunch break?

1 A No, I did not.

2 Q Now, Dr. Meibohm, I would like to pull up
3 paragraph 48 of your declaration, Exhibit 2052.

4 MS. DASHE: And, Rachel, if you could put
5 that up on the screen, paragraph 48.

6 Q Feel free to follow along in your paper
7 copy, Dr. Meibohm.

8 A I will.

9 Q And let me know when you see paragraph 48,
10 Dr. Meibohm.

11 A I can.

12 Q And in paragraph 48 of your declaration,
13 Exhibit 2052, you have a quote from the Bodor
14 reference. Do you see that?

15 A I do.

16 Q And that quote is of Bodor's, in your
17 words, theoretical treatment regimen. Do you see
18 that?

19 A Yes.

20 Q And so you are quoting, in your words, the
21 Bodor's theoretical treatment regimen, which is
22 administering for the treatment of multiple sclerosis

1 10 milligrams of cladribine in a solid dosage form,
2 once per day for a period of five to seven days in
3 the first month, repeated for another period of five
4 to seven days in the second month, followed by ten
5 months of no treatment, correct?

6 A Correct.

7 Q And if you just want to keep that treatment
8 regimen handy in front of you in the paper copy, I'm
9 just going to ask Rachel to pull down the document so
10 we can all see each other.

11 But I'm going to ask you some questions
12 about this regimen in Bodor, so feel free to keep
13 this quote handy. And there will be some math
14 involved in my questions, and so I'm going to ask my
15 colleague Madeline Bond to hand you a calculator just
16 so that this doesn't turn into a math test.

17 And specifically, I am going to ask you
18 some questions about a patient weighing 70 kilograms,
19 who receives this regimen described in Bodor.

20 Are you with me?

21 A Yes, I do.

22 Q Okay. So in the first month of this

1 regimen in Bodor, the 70 kilogram patient would
2 receive 50 to 70 milligrams of cladribine total,
3 right?

4 A That is correct.

5 Q Okay. And that's because 10 milligrams per
6 day times five to seven days is 5270 milligrams,
7 correct?

8 A Correct. Any patient would get that.

9 Q Okay. And, therefore, when expressed in
10 terms of milligrams per kilogram of body weight, this
11 70 kilogram patient would receive approximately .7 to
12 1.0 milligrams per kilogram in the first months.

13 Is that math right?

14 MR. BASSETT: Objection.

15 A Let me try to operate the calculator.

16 So your question is -- can you restate it?

17 Q So we've already established that a 70
18 kilogram patient is receiving 50 to 70 milligrams
19 cladribine in the first month, which means that when
20 we express that dose in the terms of milligrams per
21 kilogram of body weight, the patient will receive
22 approximately 0.7 to 1.0 milligrams per kilogram.

1 Is my math right?

2 MR. BASSETT: Objection.

3 A Based on the dosing regimen that is
4 described by Bodor and that I cite, the milligram per
5 kilogram dose for the first month for a patient that
6 weighs 70 kilogram would be between .7 and 1
7 milligram per kilogram.

8 Q And that's because 50 milligrams cladribine
9 divided by 70 kilograms is about .7, and 70
10 milligrams divided by 70 kilograms is 1, correct?

11 A Correct.

12 Q And then the second month of Bodor's
13 regimen, that 70 kilogram patient receives the same
14 amount of cladribine as they received in the first
15 month, correct?

16 A Correct.

17 Q Which means that overall, at the end of the
18 two-month treatment period, the 70 kilogram patient
19 would receive approximately -- let me strike that to
20 make sure it's clear.

21 So which means that overall, when expressed
22 in terms of milligrams per kilogram of body weight,

1 the 70 kilogram patient receiving Bodor's treatment
2 regimen, would receive approximately 1.4 to 2.0
3 milligrams per kilogram by the end of the two-month
4 treatment period; is that right?

5 MR. BASSETT: Objection.

6 A Based on Bodor's dosing regimen, that would
7 be correct.

8 Q And that's because .7 times 2 is 1.4, and 1
9 times 2 is 2, right?

10 A And the weight is 70 kilogram.

11 Q Right. Thank you for clarifying.

12 Now, Bodor reported that the
13 bioavailability for its oral cladribine tablets
14 administered in this regimen was about 40 percent as
15 compared to subcutaneous administration of
16 cladribine, right?

17 A For the 10-milligram tablet that he tested,
18 he reported those numbers, yes.

19 Q Okay. So we already established that for
20 70-kilogram patients receiving Bodor's regimen, they
21 would receive 1.4 to 2 milligrams per kilogram at the
22 end of the two-month treatment period, and we can

1 then determine what that oral -- sorry, this is
2 getting messy. I'm sorry.

3 So when expressed in milligrams per
4 kilogram of body weight, the 70 kilogram patient
5 receiving Bodor's regimen would receive a cladribine
6 dose orally that would be roughly equivalent to about
7 .56 to .8 milligrams per kilogram of a subcutaneous
8 cladribine dose; is that right?

9 MR. BASSETT: Objection.

10 A Can I have a pen?

11 Q Yes.

12 A Otherwise I cannot remember those numbers.

13 Q That's just fine. And if you need me to
14 repeat any numbers that we've already gone through,
15 I'd be happy to do so.

16 A So can you repeat the numbers for the
17 monthly doses?

18 Q Right. So we established in the 70
19 kilogram patient receiving Bodor's treatment regimen
20 would overall receive approximately 1.4 to 2
21 milligrams per kilogram cladribine when expressed in
22 terms of milligrams per kilogram of body weight.

1 A Per?

2 Q For the 70 kilogram patient.

3 A For which treatment period?

4 Q The total two-month treatment period.

5 A Two-month period, okay. Okay.

6 Q So my question is with what -- with the 40
7 percent bioavailability number in mind --

8 A Right.

9 Q -- and subcutaneous, what would be the
10 roughly equivalent dose of cladribine subcutaneously
11 that that 70 kilogram patient would receive?

12 MR. BASSETT: Objection.

13 A Okay. So what was the question now?

14 Q Okay. So with the 40 percent
15 bioavailability of oral cladribine in Bodor's tablet
16 compared to subcutaneously-administrated cladribine,
17 what would be the approximate dose of cladribine
18 subcutaneously administered to that patient weighing
19 70 kilograms?

20 MR. BASSETT: Objection.

21 A The question is what is the dose if you
22 give subcutaneously. So the -- if you ask what would

1 it take to get to the same systemic availability of
2 drug, then that can be said, but not what would be
3 the subcutaneous dose because, obviously, you give
4 the subcutaneous dosage form. So you have to have
5 something in mind to do that. I think you're --

6 Q You're calling out the mistake in my
7 question. So let me make sure we're all operating on
8 the same page here.

9 So I am asking you what it would take to
10 get the same systemic availability of the drug.

11 So, to clarify, Bodor discloses that its
12 10-milligram tablet has 40 percent bioavailability as
13 compared to subcutaneously-administered cladribine,
14 right?

15 A Right.

16 Q Okay. And so I'm trying to determine the
17 approximate amount of subcutaneous cladribine that it
18 would take to get the same systemic availability as
19 the orally administered 10-milligram tablet expressed
20 in terms of milligram per kilogram of body weight.

21 A Yeah.

22 MR. BASSETT: Objection.

1 A So if you would give -- if you wanted to
2 give a subcutaneous dosage form that produces the
3 same systemic availability as Bodor's oral dosage
4 form that has a bioavailability of 39 percent, then
5 instead of giving a dose of 100 milligram and -- 100
6 to 140 milligram, you would have to give a dose of 39
7 to 55 milligram.

8 And if you adjust this for a 70 kilogram
9 person -- if you adjust this for a 70 kilogram
10 person, then the milligram per kilogram would be .55
11 to .78 milligram per kilogram.

12 Q All right. And so for the 70 kilogram
13 patient receiving Bodor's oral cladribine dose for
14 the two-month treatment period, what's the
15 bioavailable amount that that 70 kilogram patient
16 would get?

17 MR. BASSETT: Objection.

18 A Based on the reported bioavailability of 39
19 percent, in the 10-milligram oral dose that's given
20 twice for five consecutive days, that would end up to
21 39 milligrams if it's given for five days, and if
22 it's -- and if it's given for seven days, then

1 obviously it would be 55 milligrams.

2 Q And is that because the 70 kilogram patient
3 is receiving 100 milligrams to 140 milligrams total
4 in that two months, and those two numbers multiplied
5 by 39 percent are 39 milligrams and 55 milligrams; is
6 that correct?

7 A That is correct.

8 Q Okay. Thank you for bearing with me.

9 Now I'm going to ask you some of the same
10 questions about a 52 kilogram patient receiving
11 Bodor's treatment regimen that you have quoted on
12 paragraph 48 of your declaration.

13 So 52 -- 52 kilogram patient. Are you with
14 me?

15 A Yes.

16 Q Okay. And so in the first month of this
17 regimen in Bodor, that 52 kilogram patient, like the
18 70 kilogram patient, would receive 50 to 70
19 milligrams of cladribine, correct?

20 A Correct.

21 Q And that's because 10 milligrams a day
22 times five or seven days is 50 to 70 milligrams

1 total, right?

2 A That's correct.

3 Q Okay. And so for the 52 kilogram patient,
4 when expressed in terms of milligram per kilogram of
5 body weight, that patient receives approximately 0.9
6 to 1.3 milligrams per kilogram in the first month of
7 Bodor's regimen, right?

8 MR. BASSETT: Objection.

9 A .96 to 1.35.

10 Q And that's -- sorry, go ahead.

11 A I cannot remember what you said.

12 Q Okay. So for -- so the 52 kilogram patient
13 has received 50 to 70 milligrams total by the end of
14 the month.

15 So for that patient, when expressed in the
16 terms of milligram per kilogram of body weight, the
17 52 kilogram patient receives approximately 0.9 to 1.3
18 milligrams per kilogram of their body weight of
19 cladribine, correct?

20 A In the first month of treatment --

21 MR. BASSETT: Objection. Objection.

22 Go ahead.

1 A In the first month of treatment, correct.

2 Q And that's because 50 milligrams divided by
3 52 kilograms is about .9, and 70 milligrams divided
4 by 52 kilograms is about 1.3, right?

5 A That is correct.

6 Q Okay. And then in the second month of
7 Bodor's treatment regimen, that 52 kilogram patient
8 would receive the same amount of cladribine as in the
9 first month, correct?

10 A Correct.

11 Q So that means that when expressed in terms
12 of milligrams per kilogram of body weight, the 52
13 kilogram patient would receive approximately 1.8 to
14 2.6 milligrams per kilogram overall in the two-month
15 treatment period, correct?

16 MR. BASSETT: Objection.

17 A The first one was .96 to 1.35, then the
18 second one which should be 1.92 to 2.7 milligram per
19 kilogram.

20 Q So when expressed in terms of milligrams
21 per kilogram of body weight, the 52 kilogram patient
22 receiving Bodor's treatment regimen would receive

1 1.92 to 2.7 milligrams per kilogram cladribine in the
2 two-month treatment period, correct?

3 A Correct.

4 MR. BASSETT: Objection.

5 Q Okay. And that's because .96 times 2 and
6 1.35 times 2 is 1.92 and 2.7, right?

7 A That is correct.

8 Q Again, thank you for bearing with me.

9 Now I'm going to ask you some of these same
10 questions about a patient weighing 75 kilograms
11 receiving Bodor's treatment regimen described in
12 paragraph 48 of your declaration.

13 Are you with me, 75 kilograms?

14 A 75 kilograms, yes.

15 Q And again, in the first month of Bodor's
16 regimen, that patient will receive 50 to 70
17 milligrams of cladribine, right?

18 A That is correct.

19 Q Okay. Which means that when expressed in
20 terms of milligram per kilogram of body weight, that
21 75-kilogram patient receives approximately 0.6 to 0.9
22 milligrams per kilogram in the first month, correct?

1 MR. BASSETT: Objection.

2 A The patient would receive 0.67 to -- sorry.
3 The patient would receive 0.67 to 0.93 milligram per
4 kilogram body weight.

5 Q And that's because 50 milligrams divided by
6 75 kilograms of body weight is 0.67, and 70
7 milligrams divided by 75 kilograms of body weight is
8 0.93, correct?

9 A Correct.

10 Q And then again, in the second month of
11 Bodor's regimen, that 75-kilogram patient would
12 receive the same amount of cladribine as they
13 received in the first treatment month, correct?

14 A Correct.

15 Q So that means overall, when expressed in
16 terms of milligrams per kilogram of body weight, the
17 75-kilogram patient would receive approximately 1.3
18 to 1.8 milligrams per kilogram of cladribine in the
19 two-month treatment period, right?

20 MR. BASSETT: Objection.

21 A The patient would receive 1.33 to 1.86
22 milligram per kilogram.

1 Q And that's because .67 milligrams per
2 kilogram times 2 is 1.33, and .93 milligrams per
3 kilogram times 2 is 1.86, right?

4 A That's correct.

5 Q Now, how much -- so for the -- strike that.
6 For the patient weighing 70 kilograms that
7 we discussed earlier, approximately how many pounds
8 is that?

9 MR. BASSETT: Objection.

10 A 154.

11 Q And is that because there are about 2.2
12 pounds to every kilogram? Is that the conversion you
13 used?

14 A I used the conversion that one pound is 454
15 grams.

16 Q So you converted the kilograms to grams, I
17 see what you did. Okay.

18 And then the patient weighing 52 kilograms
19 that I asked you about earlier, how much would they
20 weigh in pounds using that same conversion factor?

21 MR. BASSETT: Objection.

22 A 115 pounds.

1 Q And finally, for the 75-kilogram patient I
2 asked you about earlier, how much would they weigh in
3 pounds using the same conversion factor as before?

4 MR. BASSETT: Objection.

5 A 165 pounds.

6 Q Okay. You also talk about the Stelmasiak
7 paper and how those subjects received a 300-milligram
8 cumulative oral dose of cladribine.

9 Do you recall that?

10 A Yes, I do.

11 Q And you also say in your declaration that
12 Stelmasiak reports a bioavailability of about 50
13 percent for its oral cladribine solution compared to
14 subcutaneous injection, right?

15 A That is correct.

16 Q So for -- I'm going to ask you about a 70
17 kilogram patient receiving Stelmasiak's 300-milligram
18 cumulative oral dose of cladribine.

19 So are you with me? Stelmasiak's
20 300-milligram dose given to 70 kilogram patient.

21 A Which dosage form?

22 Q This is his -- Stelmasiak's oral solution

1 administered in the 300-milligram cumulative dose.

2 A That has a bioavailability of 50 percent?

3 Q That's what I believe you said in your
4 declaration, but correct me if I'm wrong.

5 A I would have to look that up in my
6 declaration.

7 Q Well, for example, I believe paragraph 57
8 you say Stelmasiak --

9 A Approximately 50 percent, yes.

10 Q Yeah, okay. Great. Trying to make sure
11 we're not using different numbers here.

12 Okay. So for the 70 kilogram patient
13 receiving Stelmasiak's 300-milligram cumulative dose
14 of the oral cladribine solution, what is the
15 bioavailable amount of that 300-milligram dose?

16 MR. BASSETT: Objection.

17 A So the 300-milligram dose is given, that
18 you referred to, I think is given over six months
19 period. Yeah.

20 Q So I guess I'm not sure how that relates to
21 my question --

22 A No, it just relates to my understanding.

1 Q Got it. Got it. Okay. Okay.

2 A When you said 300 milligram, we previously
3 talked about doses that were given, cumulative doses
4 given within one month or two months.

5 Now you're switching to a six-month period,
6 correct?

7 Q Correct. So I'm talking about
8 Stelmasiak -- Stelmasiak's cumulative 300-milligram
9 dose administered to a 70 kilogram patient. What is
10 the bioavailable amount of cladribine administered
11 pursuant to Stelmasiak's oral dose?

12 MR. BASSETT: Objection.

13 A Assuming the bioavailability of
14 Stelmasiak's dosage form in the oral solution, the
15 amount would be 150 milligrams given over six months.

16 Q And so then when expressed in terms of
17 milligrams per kilogram of body weight, the 70
18 kilogram patient receiving Stelmasiak's oral dosage
19 300 milligrams -- strike that. I made a word salad.

20 And so when expressed in terms of
21 milligrams per kilogram of body weight for the 70
22 kilogram patient, that 150 milligrams would be

1 approximately 2.14 milligrams per kilogram for the 70
2 kilogram patient receiving Stelmasiak's 300-milligram
3 dose?

4 MR. BASSETT: Objection.

5 A Can you repeat the number, please.

6 Q Yes. I'll just repeat the whole question.

7 When expressed in terms of milligrams per
8 kilogram of body weight for the 70 kilogram patient,
9 that 150 milligrams of bioavailable dose would be
10 approximately 2.14 milligrams per kilogram, correct?

11 MR. BASSETT: Objection.

12 A The cumulative dose given over six months
13 would be 2.14 milligram per kilogram for a 70
14 kilogram person.

15 Q And just to be clear, that 70 kilogram
16 person is receiving Stelmasiak's oral solution,
17 correct?

18 A Correct.

19 MS. DASHE: Could we take a five-minute
20 break?

21 MR. BASSETT: Sure.

22 THE COURT REPORTER: We're off the record.

1 (Recess 1:25 p.m. - 1:31 p.m.)

2 MS. DASHE: Dr. Meibohm, I have no further
3 questions for you.

4 THE WITNESS: Thank you.

5 MR. BASSETT: Can we have a five-minute
6 break ourselves and then we'll come back and let you
7 know whether we have any redirect.

8 MS. DASHE: Great. Thank you.

9 MR. BASSETT: Thank you.

10 (Recess 1:31 p.m. - 1:37 p.m.)

11 EXAMINATION

12 BY MR. BASSETT:

13 Q Dr. Meibohm, I just have a few questions
14 for you on redirect.

15 First, earlier this morning counsel asked
16 you about your consulting activities with Merck over
17 a period of about 17 or 19 years.

18 Do you recall that testimony?

19 A Yes, I do.

20 Q In the course of your career, Doctor, have
21 you consulted with any other pharmaceutical companies
22 other than Merck?

1 A Yes, with a variety of them. I want to say
2 between 30 and 40.

3 Q And were you paid for the consulting work
4 you did for the other 30 or 40 pharmaceutical
5 companies?

6 A Yes, I was.

7 Q And did the other pharmaceutical companies
8 pay you your regular hourly rate for those
9 consultations?

10 MS. DASHE: Objection. Form.

11 A They paid for the hourly rates that were
12 agreed upon usually around my scientific consulting
13 rate that I had mentioned earlier this morning; of
14 course, changing over time over a period of 17 years.

15 Q And just before the break, Doctor, counsel
16 asked you a series of hypotheticals about various
17 body weight patients using the Bodor dosing regimen.

18 Do you recall that?

19 A Yes --

20 MS. DASHE: Objection. Form.

21 A Yes, I do.

22 Q Doctor, does -- does Dr. Bodor report a

1 body weight of any patients in the document counsel
2 referred you to?

3 MS. DASHE: Objection. Form.

4 A In the Bodor document that is part of these
5 proceedings, I do not recall to see any specific
6 patient weights.

7 Q And does that Bodor document report varying
8 the dosage of cladribine for any patient by body
9 weight?

10 MS. DASHE: Objection. Form.

11 A The Bodor document lists -- may I see the
12 Bodor document?

13 Sorry, no, it's fine. I can just look at
14 my -- at my testimony, my declaration. Just find the
15 relevant part.

16 Yeah. Okay. Can you ask the question
17 again, please?

18 Q Sure. Does the Bodor document report the
19 variability of the dosage for cladribine for any
20 patient by body weight?

21 MS. DASHE: Objection. Form.

22 A No.

1 Q And counsel asked you some questions about
2 the Stelmasiak document.

3 Do you remember -- recall that?

4 A I do.

5 Q Does Stelmasiak report a 70 kilogram
6 patient?

7 MS. DASHE: Objection. Form.

8 A Not that I'm aware.

9 Q And does Stelmasiak report varying the
10 dosage of cladribine for any patient by body weight?

11 MS. DASHE: Objection. Form.

12 A No.

13 MR. BASSETT: I have no further questions.
14 Thank you.

15 MS. DASHE: Counsel, could we take a brief
16 break? Five minutes?

17 MR. BASSETT: Yeah.

18 MS. DASHE: Thank you.

19 (Recess 1:42 p.m. - 1:48 p.m.)

20 MS. DASHE: Welcome back, Dr. Meibohm.

21 I have no further questions for you, and I
22 believe that means you are dismissed for the day.

1 THE WITNESS: Thank you.

2 MS. DASHE: Thank you for your time. I
3 really appreciate it.

4 MR. BASSETT: Thank you. Thanks everyone,
5 the reporter and everyone else, thank you.

6 MS. DASHE: Yes, agreed. Thank you.

7 (Time noted: 1:49 p.m.)

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1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER

2 NOTARY PUBLIC

3 I, MONIQUE VOUTHOURIS, Certified Court Reporter
4 and Notary Public within and for the State of New
5 York, do hereby certify:

6 That BERND MEIBOHM, PH.D., the witness whose
7 deposition is hereinbefore set forth, was duly sworn
8 by me before the commencement of such deposition, and
9 that such deposition was taken before me and is a
10 true record of the testimony given by such witness.

11 I further certify that the adverse party, MERCK
12 SERONO S.A., was represented by counsel at the deposition.

13 I further certify that the deposition of BERND
14 MEIBOHM, PH.D. occurred at WilmerHale, 250 Greenwich
15 Street, New York, New York, on Wednesday, March 6,
16 2024, commencing at 9:02 a.m. to 1:49 p.m.

17 I further certify that I am not related to any
18 of the parties to this action by blood or marriage, I
19 am not employed by or an attorney to any of the
20 parties to this action, and that I am in no way
21 interested, financially or otherwise, in the outcome
22 of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand
this 7th day of March 2024.

Monique Vouthounis

Monique Vouthouris, CCR, RPR, CRR

Notary Public of the State of New York

My commission expires: December 1, 2027

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