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

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TWI PHARMACEUTICALS, INC., :

Petitioner : Case IPR2023-00049

v. : (Patent 7,713,947 B2)

MERCK SERONO S.A., : Case IPR2023-00050

Patent Owner. : (Patent 8,377,903 B2)

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\*\*\* CONFIDENTIAL \*\*\*

DEPOSITION OF  
YOGESH DANDIKER, Ph.D.  
Minneapolis, MN  
Friday, May 24, 2024  
9:30 a.m.

Reported Stenographically By:  
Amy L. Larson, RPR, CCR, CSR  
Job No. 538879

1 Deposition of YOGESH DANDIKER, Ph.D., held at the  
2 office of:

3

4 Fabyanske, Westra, Hart & Thomson, P.A.,

5 80 South Eighth Street

6 Suite 1900

7 Minneapolis, MN 55402

8

9 Pursuant to Notice, before Amy L. Larson,

10 Registered Professional Reporter, Certified

11 Court Reporter, Certified Shorthand Reporter, and

12 Notary Public in and for the States of Minnesota

13 and Wisconsin.

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1 A P P E A R A N C E S :

2 O N B E H A L F O F T H E P E T I T I O N E R :

3 P H I L I P S E G R E S T , E S Q U I R E

4 H U S C H B L A C K W E L L , L L P

5 120 South Riverside Plaza

6 Suite 2200

7 Chicago, IL 60606

8

9 O N B E H A L F O F Y O G E S H D A N D I K E R , P H . D . , A N D T H E

10 P A T E N T O W N E R :

11 M A R Y P H E N G , E S Q U I R E

12 A S H E R M C G U F F I N , E S Q U I R E ( B o s t o n ) ( v i a Z o o m )

13 W I L M E R C U T L E R P I C K E R I N G H A L E A N D D O R R , L L P

14 7 World Trade Center

15 250 Greenwich Street

16 New York, NY 10007

17

18 A L S O P R E S E N T :

19 M a l c o l m C o o k e , T e c h n i c i a n

20 R a c h e l C a r r i c k , T e c h n i c i a n ( v i a Z o o m )

21

22

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P R O C E E D I N G S

YOGESH DANDIKER, Ph.D.,  
after having been first duly sworn to  
tell the truth, the whole truth and  
nothing but the truth, was examined and  
testified as follows:

EXAMINATION

BY MR. SEGREST:

Q. Good morning, Dr. Dandiker. My name is  
Philip Segrest. I'll be asking you some  
questions this morning.

You've been deposed previously,  
right?

A. Yes.

Q. So it's the same type of setup. I'll ask  
questions, you'll answer questions. If for  
some reason your attorney objects to a  
question, which they may need to do, you  
should still answer unless you're  
specifically instructed by your attorney not

1 to answer.

2 If at any point you need to take a  
3 break, then let me know --

4 A. Okay.

5 Q. -- we can take a break. I'll probably ask  
6 you to answer any pending question --

7 A. Sure.

8 Q. -- before a break, but it's not meant to be  
9 an endurance test.

10 A. Yeah.

11 Q. We've got the court reporter here, who is  
12 taking down everything I say, everything you  
13 say. We need to try to not to speak over  
14 each other.

15 A. Okay.

16 Q. You need to give verbal answers, "yes" or  
17 "no," not nodding or shaking your head.

18 A. Sure.

19 Q. Do you have any questions about the  
20 deposition process?

21 A. Not -- not at this stage, no.

22 Q. Is there any reason you could not testify

1 fully and accurately today?

2 A. No.

3 Q. You're not on any kind of medication that  
4 could affect your testimony or anything like  
5 that?

6 A. No.

7 Q. Okay. Now, are you familiar with the IPR  
8 cases in which you submitted a declaration,  
9 the reason we're here today?

10 A. Yes. To some extent, yes.

11 Q. And how many times have you been deposed  
12 before overall?

13 A. Before this, twice before.

14 Q. Okay. Once of those was in another IPR on  
15 these same patents, right?

16 A. Sorry, let me just qualify that. So that is  
17 twice before any -- any cases related to this  
18 particular issue.

19 Q. Okay.

20 A. So they were on different products.

21 Q. And have you ever testified at trial?

22 A. I have not.

1 Q. What was the first time you were deposed?

2 A. You mean in terms of time?

3 Q. Yeah. When was it?

4 A. It must have been about five years ago, I  
5 guess.

6 Q. And what was that about?

7 A. It was about a product I developed.

8 Q. Is that product public at this point?

9 A. Yeah, it was -- it was a deposition related  
10 to venlafaxine.

11 Q. And when was the next time you were deposed?

12 A. So I think it was after -- about a year after  
13 that.

14 Q. And what was that deposition about?

15 A. It was similar. I can't really recall the  
16 product, but venlafaxine was part of that  
17 deposition.

18 Q. And then were you also deposed in February of  
19 this year by Hopewell about these same  
20 patents?

21 A. Yes.

22 Q. And that's another proceeding, but you also



1 submitted a declaration in that proceeding,  
2 right?

3 A. Yes.

4 Q. Have you been deposed in any district court  
5 litigations about cladribine or about these  
6 patents?

7 A. No. The only thing -- again, it's only the  
8 depositions which are related to these IPR  
9 cases. So when you say district court,  
10 I'm -- it was two depositions.

11 Q. Okay. But these IPR proceedings are in front  
12 of the United States Patent and Trademark  
13 Office. You can also have lawsuits about  
14 patents, and there are some lawsuits pending  
15 in various courts about these patents.

16 But you haven't been deposed in those  
17 lawsuits, right?

18 A. No, I've just had two depositions so far, and  
19 this is the third one.

20 Q. Have you been asked to collect any documents  
21 or have you turned over any documents to  
22 attorneys that you may have related to these

1 patents?

2 MS. PHENG: Objection. I just  
3 want to caution the witness to not reveal the  
4 substance of any attorney/client  
5 communications, but you may answer.

6 MR. SEGREST: And just for the  
7 record, I'll point out this is a third-party  
8 witness. And there may be some issues  
9 about -- about privilege, but I think you can  
10 answer this question without --

11 THE WITNESS: Yeah, no, I don't  
12 have any documents.

13 BY MR. SEGREST:

14 Q. Okay. What did you do to prepare for your  
15 testimony today?

16 A. So I had -- you know, I had, you know, some  
17 practice sessions with my counsel.

18 Q. When were those practice sessions?

19 A. It was yesterday.

20 Q. And how long did that take?

21 A. Oh, that was about, I don't know, four hours.

22 Q. With whom did you meet?

1 A. Sorry?

2 Q. With whom, the names of the people that you  
3 were doing a practice session with?

4 A. The attorney sitting here, and online with  
5 Asher McGuffin, who is connected.

6 Q. And did you review any documents during that  
7 preparation time?

8 A. Only what we had reviewed before.

9 Q. And so does that include the declaration you  
10 submitted in this IPR?

11 A. The focus really much more was on, you know,  
12 some of the other documents which had been  
13 provided to me previously by counsel.

14 Q. Okay. Did you review any documents that are  
15 not cited in your declaration that you  
16 submitted?

17 A. I did not, no.

18 Q. I'm handing you what's been previously marked  
19 as Merck 20 --

20 THE COURT REPORTER: I'm sorry,  
21 2025?

22 MR. SEGREST: 2055.

1 BY MR. SEGREST:

2 Q. And let me direct you to the page labeled  
3 number 13 at the bottom.

4 So is this your signature on page 13?

5 A. Yes.

6 Q. And then turning back to the cover, is this  
7 declaration you signed one that was filed in  
8 IPR 2023-00049?

9 A. Yes.

10 Q. Okay. And if I call this Exhibit 2055, or  
11 2055, you'll know what I'm referring to,  
12 right?

13 A. Yeah.

14 Q. And do you understand that IPR 2023-00049  
15 concerns U.S. Patent Number 7,713,947?

16 A. Yeah.

17 Q. Now, if I call those the '049 IPR and  
18 the '947 patent, will you understand what I'm  
19 referring to?

20 A. Yeah.

21 Q. Okay. Now, you see in the middle on the  
22 cover here that it also lists IPR 2023-00050?

1 A. Yes.

2 Q. Okay. And did you sign just this one  
3 declaration that was filed in both of the  
4 IPRs?

5 A. I would say that I signed two declarations,  
6 and there are some changes, be it minor, in  
7 this one.

8 Q. Okay. So the two declarations, was one of  
9 those for the IPRs for which you were deposed  
10 back in February?

11 A. Yes.

12 Q. Okay. And then the IPR that you're being  
13 deposed on today, that was the second  
14 declaration?

15 A. Yes.

16 Q. And that's this Exhibit 2055 that we're  
17 looking at here?

18 A. Yeah.

19 Q. Okay. And that's the -- that same  
20 declaration was filed both in IPR 2023-00049  
21 and IPR 2023-00050; is that correct?

22 MS. PHENG: Objection to form.

1 THE WITNESS: For this particular  
2 event, yes.

3 BY MR. SEGREST:

4 Q. Okay. And you understand IPR 2023-00050  
5 concerns U.S. Patent Number 8,377,903?

6 A. Yes.

7 Q. So if I call that the '050 IPR and the '903  
8 patent, will you understand what I'm talking  
9 about?

10 A. Yeah.

11 MR. SEGREST: Are you able to hear  
12 the witness okay?

13 THE COURT REPORTER: (Nods head.)

14 MR. SEGREST: Okay.

15 BY MR. SEGREST:

16 Q. Let's turn to page 13 again in Exhibit 2055.  
17 And let me direct you to paragraph 31 right  
18 above your signature there.

19 Do you see that?

20 A. Right.

21 Q. Now, does the first clause in that sentence  
22 say that, "The statements made herein of my

1 knowledge are true"?

2 A. Yes.

3 Q. Okay. And then there's the second clause  
4 here, right, that says, "Statements made on  
5 information and belief are believed to be  
6 true," right?

7 A. Yes.

8 Q. So does that mean that some of the statements  
9 in this declaration are based on information  
10 believed and not your personal knowledge?

11 MS. PHENG: Objection to form.

12 THE WITNESS: Yes, I would say  
13 that.

14 BY MR. SEGREST:

15 Q. Okay. Let's go back to paragraph 4 on  
16 page 1.

17 You're being paid \$800 an hour --

18 A. Right.

19 Q. -- on this case, right?

20 A. Yes.

21 Q. And how much have you been paid so far?

22 A. Oh, I would say -- I don't know. It must be

1 10, 15,000, something like that. I really  
2 don't know.

3 Q. Okay. And is that just for this case or is  
4 that for this and the other two IPRs?

5 A. Oh, it is for everything.

6 Q. Okay. About how many hours did you spend on  
7 this declaration that is Exhibit 2055 before  
8 it was filed?

9 A. Well, this was a little easier, because I had  
10 already done one declaration. So it is  
11 really going through the previous one and  
12 seeing whether, you know, changes need to be  
13 made. So I would say three, four hours.

14 Q. And how long did you spend on the previous  
15 one?

16 A. It was several days, because there were a  
17 number of iterations.

18 Q. Do you have an idea how many hours you spent  
19 on it?

20 A. By "several days," I mean over several days.  
21 How many hours? I'd say three, four hours.

22 Q. Okay. And were you also paid for your time



1 preparing for and testifying for that  
2 previous deposition?

3 A. Yes.

4 Q. And you'll be paid for your time preparing  
5 for and testifying today, right?

6 A. Yes.

7 Q. About how much time did you spend on the  
8 preparation and testimony for that last  
9 deposition?

10 A. Sorry, for the last deposition?

11 Q. Yeah.

12 A. So I just want to be clear, so this -- the  
13 first one was related to IPR, then there was  
14 a district court one, and then there is this  
15 one.

16 Q. Okay.

17 A. So are you referring to a district court one  
18 or --

19 Q. No, I'm referring to the IPR one.

20 A. Yeah, that was actually, I would say, I don't  
21 know, maybe 15 hours or so.

22 Q. Okay. Were you also deposed in the district

1 court matter?

2 A. Yes.

3 Q. Okay. And when was that deposition?

4 A. That was -- I can't remember the exact date,  
5 but I would say, I don't know, a couple of  
6 months ago.

7 Q. Okay. And were you paid at this same \$800 an  
8 hour for that?

9 A. Yes.

10 Q. And about how many hours did you spend in  
11 your preparation for and testimony for that  
12 district court deposition?

13 A. That was fairly short, I would say, and it  
14 was remote. So it was -- wasn't as much  
15 time, really. So there was five, six hours  
16 really, so less.

17 Q. Were you asked about any documents during  
18 that deposition?

19 MS. PHENG: Objection. I just  
20 want to caution the witness not to reveal the  
21 substance of any attorney/client  
22 communications.

1 THE WITNESS: May I answer or --

2 BY MR. SEGREST:

3 Q. Yes.

4 A. Yes, we did -- well, let me just again  
5 clarify --

6 MS. PHENG: And, Dr. Dandiker, as  
7 well, that proceeding was sealed. So you may  
8 answer whether you were asked about  
9 documents, but please don't reveal the  
10 contents of any documents.

11 THE WITNESS: Okay.

12 Documents were referred to.

13 BY MR. SEGREST:

14 Q. Okay. So and without telling me the  
15 contents, what documents were you asked  
16 about?

17 A. I think they were the same as the IPR.

18 Q. Were you asked in that district court  
19 deposition about any documents that are not  
20 cited in your IPR declarations?

21 A. No.

22 Q. Other than the time relating to your

1           declarations and the district court matter,  
2           have you been compensated for any other  
3           consulting work in relation to the  
4           litigations concerning these patents?

5       A.   No.

6       Q.   Have you been paid by Merck Serono for any  
7           other sort of consulting or other work that  
8           you've done for them?

9       A.   No.

10      Q.   Let's turn to paragraph 9 in your deposition  
11          just for reference, 9 and 10 on page 3.

12                   MS. PHENG:  Sorry, Counsel, did  
13                   you mean declaration?

14                   MR. SEGREST:  Yes.  I'm sorry.  
15                   What did I say?

16                   MS. PHENG:  I heard "deposition."

17                   MR. SEGREST:  I definitely meant  
18                   declaration, if I misspoke.

19      BY MR. SEGREST:

20      Q.   So paragraphs 9 and 10 of your declaration,  
21          page 3.

22      A.   Thank you.

1 Q. So did you work at IVAX from 2001 to 2004?

2 A. Yes, I did.

3 Q. And was your job at IVAX director of research  
4 and development?

5 A. Yes.

6 Q. Now, in paragraph -- let's turn to  
7 paragraph 14. Here you refer to a joint  
8 development agreement, right?

9 A. Yes.

10 Q. Okay. And it's called a product development  
11 and license agreement, right?

12 A. Yeah.

13 Q. Now, in paragraph 14 you don't cite to a copy  
14 of that agreement, do you?

15 A. I don't.

16 Q. Okay. Were you asked to review a copy of  
17 that agreement?

18 A. No.

19 Q. Do you have a copy of that agreement?

20 A. I have seen it, but I -- I wasn't a party to  
21 any discussions regarding that document  
22 when -- when the agreement was made.

1 Q. When have you seen that agreement?

2 A. I may have seen it certainly through my time  
3 at IVAX, but also more recently, you know,  
4 during preparation with counsel.

5 Q. Okay. So you did see that agreement during  
6 your preparation with counsel?

7 A. I think I may have seen it.

8 Q. Okay. That agreement is not cited anywhere  
9 in your declaration, is it?

10 A. No.

11 Q. Okay. Are there any other documents that you  
12 have seen in connection with this matter that  
13 are not cited in your declaration?

14 MS. PHENG: Objection. I caution  
15 the witness not to reveal the substance of  
16 any attorney/client communication, and I'm  
17 going to instruct you not to answer.

18 THE WITNESS: I have to go by what  
19 my counsel says.

20 MR. SEGREST: So you're  
21 instructing him not to tell me whether he's  
22 seen any other documents that weren't cited?

1 MS. PHENG: I'm instructing him  
2 not to provide any privileged communications  
3 and reveal any attorney/client  
4 communications, so, yes.

5 MR. SEGREST: Okay. And the  
6 question didn't ask for him to identify the  
7 documents. You just -- you consider whether  
8 he's reviewed documents to be privileged?

9 MS. PHENG: If you want to reask  
10 your question, then we can reevaluate it.

11 BY MR. SEGREST:

12 Q. Did you communicate any confidential  
13 information to any attorneys about those  
14 other documents you may have reviewed?

15 MS. PHENG: Objection to form.

16 THE WITNESS: Can you rephrase the  
17 question?

18 MR. SEGREST: No.

19 THE WITNESS: Can you repeat it?

20 MR. SEGREST: Yes.

21 BY MR. SEGREST:

22 Q. Did you reveal any confidential information

1 to attorneys about any of those other  
2 documents you might have reviewed?

3 MS. PHENG: Objection to form.

4 And same caution, please don't reveal  
5 the substance of any communications with  
6 counsel.

7 THE WITNESS: I don't have any  
8 confidential information.

9 BY MR. SEGREST:

10 Q. Okay. Did you request any legal advice from  
11 attorneys about any of those other documents  
12 that you may have reviewed?

13 MS. PHENG: Objection to form.  
14 Objection; privileged.

15 Please don't reveal the substance of  
16 any communications with counsel. And I will  
17 instruct you not to answer.

18 MR. SEGREST: So you understand  
19 this is the foundation for privilege? If he  
20 hasn't communicated confidential information  
21 or received a legal opinion, there is no  
22 privilege.



1 MS. PHENG: Counsel, I --

2 MR. SEGREST: I'm entitled to ask  
3 about that.

4 MS. PHENG: Counsel, I think that  
5 you're pushing the boundaries here, and I  
6 think you're aware of our privilege  
7 objections in this case, and I'm going to  
8 instruct him not to answer.

9 MR. SEGREST: Okay. I think we've  
10 got a call scheduled with the Board on  
11 Tuesday, so we'll probably want to get an  
12 expedited transcript and we'll raise it with  
13 them then.

14 BY MR. SEGREST:

15 Q. Getting back to that product development and  
16 license agreement, you didn't sign that on  
17 behalf of IVAX, right?

18 A. No.

19 Q. Do you know who did sign it?

20 A. No.

21 Q. And none of your testimony in this  
22 declaration, Exhibit 2055, cites to any

1 term -- or quotes any terms from that  
2 document, right?

3 A. I mean, again, to be clear, that is a  
4 business transaction, and I was aware of the  
5 transaction, but the substance or the content  
6 is really, you know, not my area.

7 Q. Okay. So it's not your area. And with  
8 reference to your declaration, Exhibit 2055,  
9 none of your testimony in this quotes from  
10 that document, right?

11 A. Yes.

12 Q. And you don't specify any clauses in that  
13 document that identify particular roles for  
14 IVAX and Serono at that time, right?

15 A. I -- yes, that is correct, I don't reference  
16 to that document for any roles.

17 Q. Now, in paragraph 14, the last sentence --

18 A. Right.

19 Q. -- you say Serono's role was to design and  
20 develop a dosing regimen for treating MS with  
21 cladribine, right?

22 A. Right.

1 Q. Now, did you supervise the people at Serono  
2 who were developing that dosing regimen?

3 A. No, they're a different company.

4 Q. So do you have any personal knowledge of what  
5 specific individual contributed what to the  
6 development of any dosing regimen at Serono?

7 A. I would -- I would hesitate to answer that.  
8 It's -- Serono is a large company. And,  
9 again, just to clarify things, IVAX  
10 predominantly was a -- company --

11 THE COURT REPORTER: A generic  
12 company?

13 THE WITNESS: A generic company,  
14 and so they developed generic products. And  
15 my responsibility was largely developing  
16 generic products.

17 Cladribine is -- you know, was really  
18 a one-off. And IVAX had the expertise to  
19 develop generic products, but really did not  
20 have the capability to develop cladribine.  
21 As a result, IVAX searched for partners with  
22 expertise in that area, and Serono was -- was

1 deemed to be that partner. Serono had a  
2 product already in multiple sclerosis on the  
3 market and, you know, they were the experts.

4 So when it came to responsibilities,  
5 our responsibilities were more -- certainly,  
6 mine was to develop a formulation. And for  
7 IVAX as a whole is to, you know, conduct some  
8 of the early pharmacokinetic studies to prove  
9 that our formulation worked or formulations  
10 worked. And so we looked at a number of  
11 options.

12 But when it came to developing the  
13 clinical protocols, the clinical regimen,  
14 the -- you know, doing, let's say, phase II,  
15 phase III trials, that was not our  
16 responsibility, that was Serono's, as well as  
17 the other aspects, which is, you know,  
18 regulatory, marketing, commercialization.

19 And, you know, so that -- that is how  
20 the project came into being. And my  
21 particular role was really to develop a  
22 formulation, but also to see whether it could

1 even be developed as an -- product.

2 THE COURT REPORTER: A what  
3 product?

4 THE WITNESS: Oral.

5 THE COURT REPORTER: Oral?

6 THE WITNESS: Yeah.

7 So, effectively, that's how  
8 responsibilities were divided.

9 BY MR. SEGREST:

10 Q. Okay. Thank you for that background and  
11 explanation.

12 Does that mean that, in answer to my  
13 question that I asked, that you don't know  
14 what particular individuals over at Serono  
15 contributed what particular details to any  
16 given dosing regimen?

17 MS. PHENG: Objection to form.

18 THE WITNESS: Yeah, I would agree  
19 to that to some extent, but I would qualify  
20 that by saying that drug development is a  
21 team sport. Often, there's no one individual  
22 who says, Look, this is how it is, and the

1 whole company -- and this is a company of,  
2 you know, several thousand people -- who  
3 would say, Yes, sir. Right? There's a lot  
4 of back and forth and a lot of discussion  
5 before something is arrived at.

6 So when you ask the question, you  
7 know, who is that person responsible for, it  
8 is usually not a person, it is a team and a  
9 team of experts. And I think it's rightly so  
10 that people have different views and express  
11 differing opinions before we come with a  
12 better solution.

13 So when you ask the question, you  
14 know, was there one single individual, I  
15 would say there was a team at Serono who came  
16 up with -- you know, with a dosing regimen,  
17 as with other things, you know.

18 For instance, the dosing regimen is  
19 only one part of a clinical protocol, and  
20 that takes a lot of work and a lot of time  
21 and a lot of input from a lot of people.  
22 Some are clinical and some are also not

1 clinical. So that does not mean that it's  
2 come from one person.

3 BY MR. SEGREST:

4 Q. Okay. And on the whole team that's working  
5 on that dosing regimen over at Serono, you  
6 wouldn't know what individuals contributed  
7 what information to that, right?

8 MS. PHENG: Objection to form.

9 THE WITNESS: I did interact with  
10 people at Serono and -- you know, and  
11 particularly a couple of people. And most of  
12 those interactions were about, you know, our  
13 work. And it was important for both  
14 organizations to know exactly what was  
15 happening, because one company's work  
16 determined, you know, the outcome for the  
17 other company.

18 So, yeah, for instance, when we were  
19 developing the formulations, I had a number  
20 of calls with Serono, you know, this -- I was  
21 calling, This is working, this is not  
22 working, you know, this is the kind of

1 timeline we are looking for, looking at.

2 And, you know, and they were saying, Look,

3 this is -- these are our needs.

4 So those kind of discussions, you  
5 know, were occurring all the time.

6 BY MR. SEGREST:

7 Q. Okay. And so are those kinds of discussions  
8 both Serono and IVAX keeping each other  
9 abreast of their project -- of their progress  
10 on the project?

11 A. Yeah.

12 Q. Okay. But that doesn't include necessarily  
13 knowing what particular individual came up  
14 with some particular idea that's included,  
15 right?

16 A. It's --

17 MS. PHENG: Objection to form.

18 THE WITNESS: Sorry.

19 It's -- in normal course of work, and  
20 particularly, you know, I'm a scientist, and  
21 within companies you never -- certainly, in  
22 my experience, you don't say -- point the



1 finger to one person and say, Look, this is  
2 all one person's work, because then you  
3 wouldn't need anybody, right, you just say,  
4 Look, that person develop it so nobody needs  
5 to get involved. That is really not the  
6 case.

7 BY MR. SEGREST:

8 Q. I want to circle back to the --

9 A. Sure.

10 Q. -- explanation you gave earlier.

11 You said that IVAX was mainly a  
12 generic company?

13 A. Yes.

14 Q. Do you mean that they mainly worked on  
15 developing generic pharmaceuticals?

16 A. Yes.

17 Q. And so just to understand, generic  
18 pharmaceuticals, does that mean developing a  
19 generic version of something that some other  
20 company had previously developed and brought  
21 to market?

22 A. Yes.

1 Q. And so we can -- can we call that earlier  
2 version the brand version?

3 A. Yes.

4 Q. So when you're developing a generic version,  
5 you don't have to do all of these same  
6 phase I, phase II, phase III trials, right?

7 A. Yes. So the -- what you have to do is you  
8 have to have a bioequivalent product, which  
9 the context of a -- product is --

10 THE COURT REPORTER: Did you say  
11 brown product?

12 THE WITNESS: Brand.

13 THE COURT REPORTER: Brand?

14 THE WITNESS: Yeah. And in the  
15 context of a brand product, it is -- you  
16 know, it's construed as phase I for a brand.

17 For a generic, you know, often that  
18 is the only study you have to do to show your  
19 product is bioequivalent.

20 BY MR. SEGREST:

21 Q. And is -- so the fact that you -- that IVAX  
22 was doing generics, is that why they didn't

1 really have the expertise on phase III  
2 clinical trials and all of that stuff to  
3 develop a brand product?

4 A. Yes. Yeah, I would say that.

5 And the other -- other thing to  
6 really consider here is that when you're a  
7 generic company, you're developing a lot of  
8 generic company -- generic products. When  
9 you're doing the brand, you are really  
10 specialized, and that specialist knowledge  
11 is -- is, you know, vested in some companies,  
12 some individuals, but not in all.

13 So, for instance, a company  
14 developing a multiple sclerosis product may  
15 not be able to develop an oncology product  
16 because they just don't have -- have the  
17 expertise and the background. And then, you  
18 know, a generic company is really one further  
19 rung down really.

20 Q. So that would sort of depend on the size of  
21 the company though, wouldn't it?

22 MS. PHENG: Objection to form.

1 THE WITNESS: Not necessarily. So  
2 every company, even branded companies, have  
3 their own specialized areas. I mean, I've  
4 worked in a number of brand companies, and  
5 there are things we would never do because,  
6 you know, to develop that expertise has  
7 been -- usually it's developed over decades.

8 BY MR. SEGREST:

9 Q. Aren't there some fairly large brand  
10 companies that have different teams that work  
11 in different areas?

12 A. Sure.

13 MS. PHENG: Objection to form.  
14 Objection to relevance. Objection to scope.

15 THE WITNESS: Yeah, sure. But  
16 there are many other companies which focus on  
17 areas where they feel they can succeed. And  
18 if anything, that makes Serono actually quite  
19 special, because in the multiple sclerosis  
20 area, there are not many people.

21 BY MR. SEGREST:

22 Q. I want to direct you to paragraph 16 in your

1 declaration.

2 A. Sure.

3 Q. Here you refer to minutes of a meeting that  
4 was held in August 2003 in Amsterdam?

5 A. Yes.

6 Q. And you cite those meeting minutes as  
7 Exhibit 2050, right?

8 A. Sorry, what was the question?

9 Q. The question was: And you cite those meeting  
10 minutes as Exhibit 2050, right?

11 A. Yes.

12 Q. Okay. I'm going to hand you a document  
13 that's been previously marked as  
14 Exhibit 2050.

15 Now, you did not prepare these  
16 minutes, right?

17 A. Yes, that's correct.

18 Q. And these minutes did not come from your  
19 files, right?

20 A. Yes.

21 Q. Now, looking back at paragraph 16 in your  
22 declaration again, the last sentence there

1           you say, "It appears to me that those minutes  
2           accurately summarize the meeting"?

3           A. Yes.

4           Q. Okay. And there you don't say that you have  
5           any present recollection now of everything  
6           that happened in that meeting more than  
7           20 years ago, right?

8                           MS. PHENG: Objection to form.

9                           THE WITNESS: I do remember the  
10          meeting.

11         BY MR. SEGREST:

12         Q. So you remember the meeting. Do you remember  
13         today everything that's in these meeting  
14         minutes?

15         A. I mean, having read the minutes again, I  
16         mean, you know, I do recollect --

17         Q. Okay.

18         A. -- some things, which if I hadn't seen the  
19         meeting minutes, I wouldn't have gone back  
20         and said, Look here, you know, this is what  
21         they exactly meant.

22         Q. Okay. Did those -- did these meeting minutes

1 refresh your recollection of what happened at  
2 the meeting?

3 A. They do.

4 Q. Did you review a copy of these meeting  
5 minutes after that meeting?

6 A. I recall having been sent the meeting  
7 minutes.

8 Q. But this version is not -- this document that  
9 we have, that's not from whatever you were  
10 sent, right --

11 MS. PHENG: Objection --

12 BY MR. SEGREST:

13 Q. -- this is something that was provided to  
14 you?

15 MS. PHENG: Objection to form.

16 THE WITNESS: What was provided to  
17 me was -- was not redacted.

18 BY MR. SEGREST:

19 Q. Okay. And there's also -- I'm sorry, this is  
20 a black and white copy.

21 Do you see some highlighting on  
22 page 2?

1 A. Yes.

2 Q. And that's in color on the PDF original. It  
3 looks sort of gray here. Did what you get  
4 before have that highlighting in it?

5 A. To me it feels like, you know, the  
6 highlighting has been done by somebody else  
7 or maybe somebody's copy. I mean, I would  
8 have seen a clean copy.

9 Q. So in your declaration, let's turn to  
10 paragraph 28. So here in the first sentence  
11 of this paragraph, do you say that these  
12 meeting minutes, Exhibit 2050, describe a  
13 certain dosing regimen from the Bodor  
14 disclosures?

15 MS. PHENG: Objection to form.

16 THE WITNESS: Yeah.

17 BY MR. SEGREST:

18 Q. Okay. And the second sentence here, you list  
19 three different things that you say that's  
20 disclosed in two documents, one of which is  
21 Exhibit 2050, right?

22 A. Yep.



1 Q. So in Exhibit 2050, you see in the bottom  
2 right-hand corner where it says, "Draft  
3 minutes," page something of 8?

4 MS. PHENG: Objection to form.

5 THE WITNESS: Yeah.

6 BY MR. SEGREST:

7 Q. Okay. So I'm looking at page 4 of 8.

8 A. Okay.

9 Q. And about halfway down, do you see the  
10 heading, Expert Panel and Phase III Design?

11 A. Yeah.

12 Q. Is this the portion of the meeting minutes  
13 that you're referring to as disclosing that  
14 information in paragraph 28 of your  
15 declaration?

16 A. Well, actually, when I look at the  
17 declaration, it is referring to the '247  
18 provisional Bodor PCT.

19 Q. Right. So then the second sentence, we agree  
20 that there you identify three things that you  
21 say are disclosed in two documents, one of  
22 which is Exhibit 2050, right?

1 A. Right.

2 Q. Okay. And right after that you cite  
3 Exhibit 2050, 4, right?

4 A. Sorry, could you just read that again?

5 Q. Yes. Right after that second sentence, you  
6 cite to Exhibit 2050 --

7 A. Right.

8 Q. -- comma 4, right?

9 A. Yeah.

10 Q. And so that cites to page 4 of this  
11 Exhibit 2050, right?

12 A. Right.

13 Q. And that's the page we're looking at now,  
14 right --

15 A. Okay.

16 Q. -- page 4 of Exhibit 2050?

17 A. Okay.

18 Q. So is this information under the heading,  
19 Expert Panel and Phase III Design, is that  
20 what you're citing to that you believe  
21 discloses these three items that are listed  
22 in the second sentence of paragraph 28 of

1 your declaration?

2 A. Yeah.

3 Q. And underneath that there's a heading,  
4 Suggestions for Primary Phase III Study and  
5 PB-Controlled -- or Study, parenthesis,  
6 PB-Controlled. And under that there's  
7 something that says, "Arms."

8 Do you see that?

9 A. So we're still on the same page, right?

10 Q. We're still on the same page, page 4 of 8 in  
11 Exhibit 2050.

12 A. Yeah.

13 Q. And right after, "Arms," there, does it say,  
14 "Cumulative dose approximating 0.7  
15 milligrams/kilograms" --

16 A. Right.

17 Q. -- "(.35 milligrams per kilogram times 5 days  
18 times 2 months)" --

19 A. Yeah.

20 Q. -- and, "2.1 milligrams per kilogram  
21 (.35 milligrams per kilogram times 5 days  
22 times 6 months), and placebo"?

1 A. Uh-huh. Yeah.

2 Q. Okay. Is that text what you believe  
3 discloses the three different things that you  
4 list in the second sentence of paragraph 28  
5 in your declaration?

6 MS. PHENG: Objection to form.

7 THE WITNESS: Well, the -- the  
8 minutes actually are slightly different. For  
9 instance, the declaration said the yearly  
10 dosing regimen including --

11 THE COURT REPORTER: I'm sorry,  
12 can you speak up?

13 THE WITNESS: Yeah. A yearly  
14 dosing regimen including a six-month dosing  
15 phase and six dosing cycles, and so I think  
16 it was a little different.

17 BY MR. SEGREST:

18 Q. Okay. So and you're telling me there's some  
19 differences between that and paragraph 28 of  
20 your declaration and this text I'm pointing  
21 you to?

22 A. Yes.

1 Q. And I appreciate that.

2 So but my question is: Is this text  
3 that I'm pointing you to, is that the part of  
4 these meeting minutes that you're referring  
5 to when you cited this document in the second  
6 sentence of your declaration saying that it  
7 disclosed these things?

8 MS. PHENG: Objection to form.

9 THE WITNESS: Yes. But to qualify  
10 that again, now when I read it, it's not an  
11 accurate reflection.

12 BY MR. SEGREST:

13 Q. Okay. Is there any other text in these  
14 meeting minutes that you're referring to in  
15 this citation as disclosing that information?

16 A. No, I think that -- the meeting minutes,  
17 that's the only -- only section.

18 Q. Okay. So looking then now at the items you  
19 listed, do you think that this text discloses  
20 the first one of low dose arm with a dosing  
21 regimen of 10 milligram cladribine tablets  
22 each day for five consecutive days in two

1 months?

2 MS. PHENG: Objection to form.

3 THE WITNESS: Well, that's what it  
4 says.

5 BY MR. SEGREST:

6 Q. Okay. It doesn't mention 10-milligram  
7 tablets in this text, does it?

8 A. Exactly.

9 Q. Okay.

10 A. So my point was it's as it's written, but  
11 it's not exactly the same.

12 Q. Okay. And as you look at it now, do you  
13 think that it discloses a second thing, "A  
14 yearly dosing regimen including a six-month  
15 dosing phase with six-dosing cycles (one each  
16 month) and a six-month nontreatment period"?

17 A. I would hesitate to speculate on that. I  
18 wouldn't -- you know, I think it's -- I would  
19 hesitate to speculate on that.

20 Q. Okay. So you can't really say that it  
21 discloses that as you sit here today, right?

22 MS. PHENG: Objection to form.

1 THE WITNESS: If I just read that,  
2 then that would not -- that would not give me  
3 enough information to do -- to do what was  
4 done in the clinical study.

5 BY MR. SEGREST:

6 Q. And then now that you're looking at it today,  
7 do you think it discloses a third item, a six  
8 monthly dosing cycle that administers a low  
9 dose arm through two months of cladribine  
10 followed by four months of placebos to, "Fill  
11 out high dose cycles"?

12 MS. PHENG: Objection to form.

13 THE WITNESS: Are we still looking  
14 at --

15 BY MR. SEGREST:

16 Q. Yes, I'm comparing the third item in the  
17 second sentence --

18 A. Right.

19 Q. -- of paragraph 28 of your declaration --

20 A. Okay.

21 Q. -- with this specific text --

22 A. Okay.

1 Q. -- that we've identified in Exhibit 2050.

2 A. Okay. So one of the things which kind of,  
3 you know, sticks out to me is that somebody  
4 reading this, in the first instance, would  
5 really not know what a dosing cycle is,  
6 because it is not specified in the meeting  
7 minutes.

8 Q. Okay.

9 A. Whereas in the PCT it says, you know,  
10 six-month dosing cycle, and a dosing cycle  
11 has a specific definition.

12 Q. And this text in Exhibit 2050 doesn't say  
13 anything about four months placebo to fill  
14 out a cycle, does it?

15 MS. PHENG: Objection to form.

16 THE WITNESS: Well, it says  
17 placebo, but it doesn't say what you just  
18 said.

19 BY MR. SEGREST:

20 Q. Right. And placebo, as it's used in  
21 Exhibit 2050, that refers to one of the arms  
22 of the clinical trial, right? There's the



1 placebo arm, and that's compared to the arms  
2 that are actually getting treatment?

3 MS. PHENG: Objection to form.

4 THE WITNESS: I -- I don't believe  
5 that is really the case here, because, you  
6 know, multiple sclerosis is a devastating  
7 disease and you cannot take patients and put  
8 them on placebo for a number of months or  
9 even longer. You'd be doing them a  
10 disservice. So that is not how this study  
11 was actually done. And that's not what it  
12 says anyway.

13 BY MR. SEGREST:

14 Q. Okay. How does -- what does this text in  
15 Exhibit 2050 say about how the placebo is  
16 used?

17 A. Yeah, so the active is given and then, you  
18 know, there is a break and a placebo is  
19 given, right? It's -- but you -- you know, I  
20 think what you mentioned earlier, where you  
21 have people on the drug and people on  
22 placebo, that is not the case here.



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[REDACTED]

[REDACTED]

A. [REDACTED]. And as I say, I am going by what is in the minutes. I was not present at this discussion.

Q. When you say you weren't present at this discussion, do you mean you weren't present at the panel of experts discussion?

A. Yes.

Q. But you were present during the meeting where there was a discussion about the panel of experts discussion, right?

A. Yes, but then the kind of -- the discussion -- so, again, to clarify, the expert panel discussion was [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

And so, you know, a summary of that would have been presented. But when somebody says -- when one says that was there a

1 discussion of that, you know, there was  
2 probably a summary presented and then a view  
3 of what Serono thought should be done.

4 So generally speaking, in clinical  
5 development, you do speak to the experts, but  
6 that does not mean that you do everything  
7 they tell you, because often it may not be  
8 practical, it may be too long, it may not be  
9 safe.

10 But more critically, it may not take  
11 into account what the regulators are  
12 thinking. And by "regulators," I mean people  
13 who approve the drug.

14 Q. So let's get back to what's in the document.  
15 Does the next sentence after the one you were  
16 just saying, does it start out saying that,

17 [REDACTED]

18 [REDACTED]

19 MS. PHENG: Objection to form.

20 THE WITNESS: Well, that is what  
21 this document says.

22 BY MR. SEGREST:

1 Q. Okay. And they give [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]

6 A. Yes.

7 Q. Okay. And then doesn't this document say  
8 that, [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]

12 A. Yes, it is an opinion. It is an opinion. I  
13 mean, what I don't see is somebody saying  
14 [REDACTED]

15 Q. Okay. But they do say it would be [REDACTED]  
16 [REDACTED], right?

17 A. But that does not mean that it is -- it will  
18 be.

19 Q. Okay.

20 A. I have been in many situations where, you  
21 know, people have gone into FDA and said,  
22 Look, this is really going to work, and then

1           they throw -- you know, throw something else  
2           at you. So it -- until -- until you get a  
3           definitive yes from them, you never know.

4       Q.   And it's the people -- it's the team from  
5           Serono with the expertise in these clinical  
6           trials that's saying [REDACTED]

7           [REDACTED]

8           [REDACTED], right?

9           MS. PHENG:  Objection to form.

10          THE WITNESS:  It is an opinion.

11          MR. SEGREST:  Okay.

12          THE WITNESS:  Because at the end  
13           of the day -- and, again, just to put this  
14           into bigger picture, if it was that easy,  
15           Serono would have got approval a long time  
16           ago.  It took them a long time to get  
17           approval for the product.  And so it was not  
18           that the -- that they were incapable of doing  
19           the clinical studies.  [REDACTED]

20          [REDACTED]

21          [REDACTED]

22          [REDACTED] they would have had

1 an approval a long time ago.

2 Q. But we can tell from this that at this  
3 time --

4 A. Yeah, that's what people thought.

5 Q. Okay. So Serono then thought that [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED], right?

9 A. That's what --

10 MS. PHENG: Objection to form.

11 THE WITNESS: That's what they  
12 thought. But, you know, this was back in  
13 2003. They got approval in 2019.

14 BY MR. SEGREST:

15 Q. Let's turn back to your declaration.

16 MS. PHENG: Counsel, before we  
17 move forward, we've been going for about an  
18 hour, do you mind if we take a break soon?

19 MR. SEGREST: No, we can take a  
20 break now.

21 MS. PHENG: Okay. Do you want to  
22 instruct to go off the record?

1 MR. SEGREST: We can go off the  
2 record now.

3 (Recess.)

4 BY MR. SEGREST:

5 Q. So let me direct you to paragraph 17 in your  
6 declaration, Exhibit 2055.

7 A. Right. Yeah.

8 Q. Now, in the -- the fourth sentence here, you  
9 indicate that Dr. Maria Lopez-Bresnahan from  
10 Serono presented this phase III study design?

11 A. Yeah.

12 Q. Did I pronounce her name correctly?

13 A. Maria Lopez-Bresnahan.

14 Q. Bresnahan?

15 A. Yeah. But I always used to call her  
16 Maria Lopez. It's easier for me.

17 Q. And you also say someone else from Serono  
18 presented on the regulatory strategy, right?

19 A. Yes.

20 Q. So turning back to Exhibit 2050 on page 5, do  
21 you see the heading down here, Regulatory  
22 Strategy?



1 A. Yeah.

2 Q. Is that what you're referring to, the person  
3 that presented on regulatory strategy?

4 A. Yes.

5 Q. And the parts on page 5 that are above that  
6 heading, that's still referring to the  
7 phase III design, right?

8 A. Sorry, this --

9 Q. I'll repeat it.

10 So on page 5, the parts of page 5  
11 that are above that heading, Regulatory  
12 Strategy --

13 A. Right.

14 Q. -- the parts that are above that are still  
15 referring to phase III design, right?

16 A. Yes.

17 Q. So, like, at the top there's a subheading,  
18 Phase III Design Issues Need to be  
19 Fine-Tuned, right?

20 A. Yes.

21 Q. And it's one of those Efficacy Endpoints?

22 A. Yeah.

1 Q. And so in that do you see the second sentence  
2 starts out, "Secondary endpoints discussed,"  
3 and a colon?

4 A. Yeah.

5 Q. And then does it say, "MRI endpoints to be  
6 determined with suggestion that majority of  
7 sites perform MRI at baseline, 12 and  
8 24 months, with a subset of 5 doing frequent  
9 MRI (baseline, 9, 10, 11, 12, 21, 22, 23 &  
10 24 months)"?

11 A. Yeah.

12 MS. PHENG: So just let me object,  
13 please.

14 Objection to form. Objection to  
15 scope.

16 And sorry to interrupt, I'm getting  
17 feedback that Dr. Dandiker is not that loud  
18 on the feed. Could we bring him closer or  
19 bring the mic closer?

20 MR. SEGREST: We can go off the  
21 record if we need to make technical  
22 adjustments.

1 (Recess.)

2 BY MR. SEGREST:

3 Q. So we're back on the record now. I was  
4 asking about the top half of page 5 in  
5 Exhibit 2050.

6 A. Right.

7 Q. So after that part we were talking about, is  
8 there also a section labeled, [REDACTED] ?

9 A. Yes.

10 Q. And does that list below the heading,

11 [REDACTED]  
12 [REDACTED]

13 A. Yes.

14 Q. [REDACTED]  
15 [REDACTED]  
16 [REDACTED] ?

17 MS. PHENG: Objection to form.  
18 Objection to relevance and scope.

19 THE WITNESS: [REDACTED]  
20 [REDACTED].

21 BY MR. SEGREST:

22 Q. [REDACTED]

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[REDACTED]

A. [REDACTED]

Q. [REDACTED] And I think if we look at the front of this memo, it lists him as a Serono participant, right?

A. Right.

Q. And who is D. Frank?

A. Actually, I can't recall who D. Frank is.

Q. And then there's another person in that list identified as G. Francis, right?

A. Yeah, that's Gordon Francis.

Q. Okay. Gordon Francis.

And the front page of the memo also identifies him as a Serono participant, right?

A. Yes.

Q. [REDACTED]

[REDACTED]

MS. PHENG: Objection to form.

THE WITNESS: [REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

BY MR. SEGREST:

Q. Okay. And then there's a person identified as A. Jaber, right?

A. Yes.

Q. And the front also lists A. Jaber as a Serono participant, right?

A. Yes.

Q. Who was A. Jaber?

A. I had not come across A. Jaber until this meeting.

Q. [REDACTED]  
[REDACTED]

MS. PHENG: Objection to form.

THE WITNESS: But I -- when I kind of read the minutes, to me it actually was a little different, which is that within [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED] I [REDACTED]  
[REDACTED]  
[REDACTED]

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[REDACTED]  
BY MR. SEGREST:  
Q. Well, [REDACTED]  
[REDACTED]  
[REDACTED]?

MS. PHENG: Objection to form,  
relevance and scope.

THE WITNESS: Yeah.

BY MR. SEGREST:  
Q. Okay. And what is that referring to?  
A. [REDACTED]  
[REDACTED]  
[REDACTED].  
Q. [REDACTED]?

A. Right.  
Q. Now, it -- [REDACTED]  
[REDACTED], right?

A. Yes.  
Q. Okay. [REDACTED] ?  
A. I have no idea. [REDACTED]  
[REDACTED]  
[REDACTED]

1 Q. [REDACTED] ?

2 A. Yes.

3 Q. Okay. Let's turn now to paragraph 18 in your  
4 declaration.

5 A. Yeah.

6 Q. Now, here in paragraph 18 are you describing  
7 a draft regulatory briefing document from  
8 December 2003, this Exhibit 2049?

9 A. Yes.

10 Q. Now, you were provided Exhibit 2049 by  
11 counsel, right?

12 A. Yes.

13 Q. Have you kept a copy of the documents you  
14 received in December 2003?

15 A. No, I -- I didn't keep any documents when I  
16 left IVAX.

17 Q. In the last sentence of this paragraph you  
18 say it appears to be the document that you  
19 received in December 2003, right?

20 MS. PHENG: Objection to form.

21 THE WITNESS: Yeah.

22 BY MR. SEGREST:

1 Q. Okay. So you say, "It appears to be." Is  
2 that -- is this another one of those  
3 statements it's not personal knowledge, but  
4 it's based on information and belief in this  
5 declaration?

6 A. It is going back to my recollection 20 years  
7 ago. And, again, to clarify, I did not keep  
8 any documents when I left IVAX. And so  
9 20 years later when somebody shows me a  
10 document, you say, yeah, maybe it is the same  
11 document.

12 Q. So let's turn now to Exhibit 2049. I'm  
13 handing you a copy of it.

14 Are the first three pages of this  
15 Exhibit 2049 a cover email?

16 A. Yes.

17 Q. Okay. And that cover email is from somebody  
18 called Isabelle Emery at Serono, right?

19 A. Yes.

20 Q. And then there's a fairly long To list and cc  
21 list, right?

22 A. Uh-huh. Yes.



1 Q. And you're one of the people it was sent to,  
2 right?

3 A. Yeah.

4 Q. Now, the way this is formatted, the email  
5 addresses actually tell us which organization  
6 that recipient is at, right?

7 A. Yes.

8 Q. Like, your email address is [REDACTED],  
9 right?

10 A. Yes.

11 Q. But there's others who were [REDACTED],  
12 right?

13 A. Yes.

14 Q. Now, this email had two attachments, right?

15 A. I'm not sure. But, I mean, it has an  
16 attachment.

17 Q. Okay. Well, on the second page, the line at  
18 the top, the row, table, row at the top of  
19 the second page here --

20 A. Right.

21 Q. -- do you see it says, "Cladribine Briefing  
22 Document, 17 December 20"?

1 A. Yeah.

2 Q. -- "2003" --

3 A. That's right.

4 Q. -- ".doc"?

5 A. Yeah.

6 Q. And so that's one attachment, right?

7 A. Which is that one.

8 Q. And then on the next page, the last row of  
9 this cell, do you see something called,

10 "████████████████████"?

11 A. Yeah.

12 Q. Okay. So that's a second attachment, right?

13 A. Yeah.

14 Q. And the rest of this Exhibit 2049 is that  
15 first attachment, right?

16 A. Yes.

17 Q. On the exhibit, do you see the legend at the  
18 top of the page says page -- well, for  
19 example, the page we were just looking at  
20 says page 3 of 59?

21 A. Yes.

22 Q. Okay. And I'll direct you to where it says

1 page 4 of 59.

2 A. Yeah.

3 Q. Is that the cover page of that briefing  
4 document attachment?

5 A. Yes.

6 Q. So let's look at paragraph 28 again in your  
7 declaration. And, again, in the first  
8 sentence here of paragraph 28 you say that  
9 this December 2003 briefing document that's  
10 Exhibit 2049, also describes dosing regimens  
11 that are substantially the same as in --

12 A. Right.

13 Q. -- the patent you're named as an inventor,  
14 right?

15 A. Right.

16 Q. We're stepping on each other a little bit,  
17 but you're agreeing with me, right?

18 A. Yeah, it is kind of similar.

19 Q. Okay. And then the second sentence, which we  
20 looked at before, you cite after that second  
21 sentence, Exhibit 2049, 47-51, right?

22 A. Yeah.

1 Q. Okay. So let's turn to page 47 of 59 in  
2 Exhibit 2049. And so are you with me where  
3 it says page 47 of 59 at the top?

4 A. Yes.

5 Q. And you see at the bottom it says page 43,  
6 right?

7 A. Yes.

8 Q. So in paragraph 28 of your declaration where  
9 you have that citation, are you referring to  
10 the page numbers at the top or the bottom?

11 A. Sorry, can you repeat that again?

12 Q. Yes. In paragraph 28 --

13 A. Yes.

14 Q. -- we had a citation to Exhibit 2049, 47  
15 through 51. Are you citing to the page  
16 numbers at the top of the document or at the  
17 bottom of the page in the document?

18 A. It would be top of the document.

19 Q. Okay. So on this page 47 of 59 in  
20 Exhibit 2049, do you see the heading, 5.1,  
21 Phase III: Oral Cladribine in the Treatment  
22 of Relapsing Forms of MS?

1 A. Yes.

2 Q. And is this the part of this document,  
3 Exhibit 2049, that you're referring to with  
4 your citation in paragraph 28 of your  
5 declaration?

6 MS. PHENG: Objection to form.

7 THE WITNESS: Yeah, so what the  
8 declaration says is what's actually in the  
9 Bodor PCT, which is, if anything, a summary.  
10 What the briefing document actually shows is  
11 a lot more detail.

12 BY MR. SEGREST:

13 Q. Okay. So the second sentence of paragraph 28  
14 in your declaration, it says that these  
15 documents include the disclosure of certain  
16 things, right?

17 MS. PHENG: Objection to form.

18 MR. SEGREST: Well, strike that.

19 BY MR. SEGREST:

20 Q. It says that those documents include the  
21 disclosure of certain things, right?

22 MS. PHENG: Same objection.

1 THE WITNESS: Right.

2 BY MR. SEGREST:

3 Q. Okay. And by, "Those documents," it's  
4 referring to the August 2003 meeting minutes,  
5 Exhibit 2050, and the December 2003 briefing  
6 document, right?

7 A. Yes.

8 Q. Okay. And the part of the December 2003  
9 briefing document that you are pointing to as  
10 disclosing the three things listed, that's  
11 the part below that heading that I pointed  
12 you to, right?

13 MS. PHENG: Objection to form.

14 THE WITNESS: Yes.

15 BY MR. SEGREST:

16 Q. Okay. And there's a table there, right,  
17 Table 5.1-1 called Synopsis of Proposed  
18 Phase III Study?

19 A. Yes.

20 Q. So on this same page, the last row of that  
21 table, continuing on to the next page, 28 of  
22 59, do you see it's -- the left-hand column

1 calls this the Study Design?

2 A. Yes.

3 Q. And is that Study Design row part of what  
4 you're identifying as disclosing the three  
5 things that you list in the second sentence  
6 of paragraph 28 in your declaration?

7 MS. PHENG: Objection to form.

8 THE WITNESS: Yes, it's a summary.

9 BY MR. SEGREST:

10 Q. Okay. And also on page 49 of 59, do you see  
11 a row in the label -- in the table called,  
12 The Study Treatment?

13 A. Page 49 to?

14 Q. Page 49 of 59 --

15 A. Yes.

16 Q. -- in Exhibit 2049.

17 A. Yeah.

18 Q. Do you see a row on this page called,  
19 Study Treatment?

20 A. Yes.

21 Q. Okay. And is this row with the label,  
22 Study Treatment in the left-hand column, also

1 part of what you are identifying as  
2 disclosing the three items you list in the  
3 second sentence of paragraph 28 in your  
4 declaration?

5 MS. PHENG: Objection to form.

6 THE WITNESS: Yes, as I say, it is  
7 a summary.

8 MR. SEGREST: Okay.

9 THE WITNESS: This is more  
10 detailed.

11 BY MR. SEGREST:

12 Q. Is there any other text in this document,  
13 Exhibit 2049, that you identify as disclosing  
14 the three items listed in the second sentence  
15 of paragraph 28 of your declaration?

16 A. Not that I am aware of.

17 Q. Okay.

18 A. Again, I would just like to kind of clarify  
19 that this document, 2049, and the clinical  
20 proposal for phase III study, is actually a  
21 proposal put together by Serono. So the  
22 synopsis for the phase III study, as we



1 discussed before, is put together by Serono.

2 Q. Okay.

3 A. And so there is nobody at IVAX, not me or  
4 Dr. Bodor were working on the clinical design  
5 or the clinical regimen for this study.

6 Q. So, again, let's look at the three things you  
7 identify in that second sentence as being  
8 disclosed.

9 What particular text in those two  
10 rows from the table discloses, quote, "A low  
11 dose arm with a dosing regimen of  
12 10 milligram cladribine tablets each day for  
13 five consecutive days each month for two  
14 months"?

15 A. Yeah, so I think if you go back to page 47 --  
16 so, sorry, top of page 48, first phase, six  
17 cycles, high, low placebo. Second phase,  
18 retreatment, six cycles, low, low placebo.  
19 Third phase, retreatment, six cycles, low,  
20 low, low. One cycle equals 5-day course of  
21 treatment during a 28-day period.

22 Q. So this refers to a 28-day period instead of

1           one month, right?

2           A. Yes.

3                           MS. PHENG: I just want to be  
4           clear, objection to form.

5           BY MR. SEGREST:

6           Q. And this language you pointed to doesn't  
7           mention a 10-milligram tablet, does it?

8           A. Sorry, the -- the 20 -- you mean 2049?

9           Q. The language you just read in 2049 doesn't  
10          refer to a 10-milligram tablet, right?

11          A. No, it does not.

12          Q. So this refers to three different phases,  
13          right?

14          A. Yes.

15          Q. And in each of those there's a parenthesis  
16          with three words separated by slashes, right?

17          A. Yes.

18          Q. Are each of those three words separated by  
19          slashes referring to an arm of the proposed  
20          study?

21          A. Yes.

22          Q. Okay. So in the first phase there's a high

1 arm, a low arm, and a placebo arm, right?

2 A. Yes.

3 Q. And in the second phase there's a low arm, a  
4 low arm, and a placebo arm, right?

5 A. Yes.

6 Q. And then in the third phase there's a low  
7 arm, a low arm, and a low arm, right?

8 A. Yes.

9 Q. Okay. So what language in Exhibit 2049 do  
10 you identify as disclosing the second item  
11 here, "A yearly dosing regimen including a  
12 six-month dosing phase with six dosing  
13 cycles, one each month, and a six-month  
14 nontreatment period"?

15 MS. PHENG: Objection to form.

16 THE WITNESS: Yeah, so I think you  
17 have to read the full, kind of, document.  
18 But so the first -- let me just start step by  
19 step.

20 The first phase is six cycles, high,  
21 low placebo. Each cycle is a five -- course  
22 of treatment --

1 THE COURT REPORTER: Five --

2 THE WITNESS: Day.

3 THE COURT REPORTER: Day?

4 THE WITNESS: Yeah. So,

5 basically, one cycle is five days of

6 treatment during, for sake or argument, one

7 month.

8 BY MR. SEGREST:

9 Q. It doesn't say one month, does it? It  
10 says --

11 A. Twenty-eight days. Okay. To be specific,  
12 let's say 28 days and not one month. And so  
13 there are six cycles. So that is 28 times 6  
14 days, right? So that is first phase.

15 Your second phase is retreatment, is  
16 six cycles again, so that approximates to six  
17 months, but to be specific, 28 times 6. And  
18 that is low, low placebo.

19 And your third phase is retreatment,  
20 is again another six months. And then one  
21 cycle -- it says there, you know, one cycle  
22 equals five days.

1                   Now, I think there's some other  
2                   detail in this document, and I'm just going  
3                   back to study treatment. The study  
4                   treatment, which is page 49, does specify  
5                   the .3 and the 10 milligrams, which the top  
6                   of page 48 does not.

7                   So the low dose -- you know, you can  
8                   infer from that low dose is .3 -- or, sorry,  
9                   is 3 milligrams, and the high dose is  
10                  10 milligrams, 0 is placebo. So I think you  
11                  have to start kind of putting all of those  
12                  things together.

13                  And then treatment regimens, which  
14                  is, again, page 49, talks about three phases,  
15                  so, you know, within 28-day cycles, times 6  
16                  cycles per phase. So I think it's -- the  
17                  duration of the study is 36 months. So I  
18                  think when you kind of put it all together,  
19                  that's -- it does actually come to that.

20                  Q. And there's also the statements in your  
21                  declaration about a six-month nontreatment  
22                  period, right?

1 A. Yes.

2 Q. So looking on page 48 of 59, do you see that  
3 next paragraph, Duration of Study?

4 A. Yes.

5 Q. And is that telling you when each phase  
6 occurs?

7 A. I mean, if I was kind of looking at this, I'd  
8 take a piece of paper and write it down,  
9 because there's pieces of information  
10 different places and you have to kind of do  
11 that. So when you say strength zero, which  
12 is placebo, that is your nontreatment period.

13 Q. Well, is it the language in this Duration of  
14 Study paragraph that you think shows the --  
15 that you're identifying as disclosing the six  
16 months with no treatment?

17 MS. PHENG: Objection to form.

18 THE WITNESS: Yeah, so, again,  
19 when I go back to -- let us again look at  
20 page 48, top of page 48. You know, when --  
21 when you put down placebo, you know, it is  
22 basically -- you know, people are not

1 receiving the drug.

2 BY MR. SEGREST:

3 Q. So what is the language in these sections  
4 that you identify as disclosing this third  
5 item, which is a six monthly dosing cycle  
6 that administers the low dose arm for two  
7 months of cladribine followed by four months  
8 of placebos to, quote, "Fill out high dose  
9 cycles"?

10 A. Yeah, I think that may have come from --

11 MS. PHENG: Objection to form.

12 THE WITNESS: Part of that may  
13 have come from this kind of document, which  
14 is 2050.

15 BY MR. SEGREST:

16 Q. Okay. So what in Exhibit 2050 shows that  
17 third item, a six monthly dosing cycle that  
18 administers the low dose arm through two  
19 months of cladribine followed by four months  
20 of placebos to, quote, "Fill out high dose  
21 cycles"?

22 A. So let me kind of maybe stop there and just

1 clarify one or two things. As I mentioned  
2 earlier, the dosing cycle and dosing regimen  
3 has come from Serono.

4 Let me also say that what is in that  
5 PCT, Bodor PCT, is not something I recall  
6 putting myself in. So when I'm commenting,  
7 I'm actually interpreting, you know, what is  
8 in front of me, but it is not something I  
9 have --

10 THE COURT REPORTER: I'm sorry,  
11 have -- I didn't hear that.

12 THE WITNESS: Put into the PCT.  
13 So, you know, I can kind of go through the  
14 interpretation, but that doesn't take away  
15 the point that I did not put it into the PCT.

16 BY MR. SEGREST:

17 Q. Okay. Your third item here, you just told me  
18 that you thought that that third item, the  
19 six monthly dosing cycle that administers the  
20 low dose arm through two months of cladribine  
21 followed by four months of placebo to, "Fill  
22 out high dose cycles," you said you thought



1           that was in Exhibit 2050.

2           A. Yeah, it is --

3                           MS. PHENG: Objection to form.

4           BY MR. SEGREST:

5           Q. So where in Exhibit 2050 do you identify that  
6           disclosure?

7           A. Let me go back and look at this.

8           Q. Just for the record, I think the witness is  
9           examining Exhibit 2049 right now.

10          A. Yeah. (Reviews document.)

11                          Okay. Actually, I misspoke. It is  
12          in 2050. So --

13          Q. Are you looking at 2049 or 2050?

14          A. I'm looking -- sorry, 2049.

15          Q. Okay.

16          A. Yeah, 49. So I'm looking at, Assignment of  
17          Treatment Groups, and it says, "Blinding,"  
18          Serono's patients received placebo -- I'm  
19          reading the last sentence there, "Receive  
20          placebo to fill out high dose cycles." I  
21          don't know whether that's what you're  
22          referring to. "Any decrease in active

1 treatment dose is replaced with placebo, and  
2 any patient who does not qualify for  
3 retreatment will receive placebo."

4 Q. So this is on page 49 of 59 in Exhibit 2049,  
5 right?

6 A. Yes.

7 Q. And it's the row in the table that's labeled,  
8 Assignment to Treatment Groups, right?

9 A. Yes.

10 Q. And the part you're reading is from the --  
11 the paragraph that's labeled, Blinding,  
12 right?

13 A. Yes. Yeah.

14 Q. And what it says there is that, "The  
15 double-blind, central MRI blinded to  
16 treatment assignment," right?

17 A. What it says there, "Double-blind, central  
18 MRI blinded to treatment," that is how it  
19 starts --

20 Q. Okay.

21 A. -- but then it says, "i.e."

22 Q. It doesn't have the "i.e." there, that --

1           those letters don't appear, right?

2           A. Sorry, I didn't --

3           Q. I'm sorry, I thought you said there's an i.e.  
4           there, and it doesn't say i.e., right?

5           A. In parenthesis it says, "i.e., low dose  
6           patients receive placebo to fill out high  
7           dose cycles."

8           Q. But you skipped ahead of me. Because before  
9           it gets to that, the next part of the  
10          sentence says, "All patients receive the same  
11          number of tabs," right?

12          A. Yeah.

13          Q. Okay. And where does it say two months and  
14          four months?

15                        MS. PHENG: Objection to form.

16                        THE WITNESS: So if you go back to  
17          2050, and this is -- again, to be clear, this  
18          is an ongoing discussion, right, this is not  
19          final final.

20                        So when you go back to page 4 of 8,  
21          Arms: Cumulative dose approximately .7  
22          milligrams per kilograms, .35 milligrams per

1 kilogram times 5 days times 2 months, and  
2 2.5 milligrams per kilogram, .35 milligrams  
3 for 5 days times 6 months.

4 BY MR. SEGREST:

5 Q. Yes, but in Exhibit 2049, in this briefing  
6 document, isn't the low dose a 3-milligram  
7 dose?

8 A. Yeah.

9 MS. PHENG: Objection to form.

10 BY MR. SEGREST:

11 Q. And isn't the high dose a 10-milligram dose?

12 MS. PHENG: Objection to form.

13 THE WITNESS: Yes.

14 BY MR. SEGREST:

15 Q. So there's two different tablets that you get  
16 for low dose and high dose, right?

17 A. Yeah.

18 Q. So they don't have to follow what they were  
19 talking -- proposed last August, where you do  
20 it for a shorter time period and then four  
21 months of placebo, right?

22 MS. PHENG: Objection to form.

1 BY MR. SEGREST:

2 Q. They just -- for the low dose, they just give  
3 the 3-milligram tablet, right?

4 MS. PHENG: Objection to form.

5 THE WITNESS: Can you say that  
6 again?

7 BY MR. SEGREST:

8 Q. Yes. 2050, which you turned back to, was  
9 giving the same dose for different durations  
10 for a low arm and a high arm, right?

11 MS. PHENG: Objection to form.

12 THE WITNESS: Yeah.

13 BY MR. SEGREST:

14 Q. Right. But 2049 is different, right?

15 A. It is different.

16 Q. It's got a 3-milligram low dose and a  
17 10-milligram high dose that are separate  
18 doses, right?

19 MS. PHENG: Objection to form.

20 THE WITNESS: They are separate  
21 arms, yes. Well, separate part of arms.

22 BY MR. SEGREST:

1 Q. So let's look back a minute at the top of  
2 page 48 of 59.

3 A. Right.

4 Q. And I think you agreed with me before, didn't  
5 you, that the third arm here is placebo in  
6 the first phase, placebo in the second phase,  
7 and low in the third phase, right?

8 MS. PHENG: Objection to form.

9 THE WITNESS: Yes.

10 BY MR. SEGREST:

11 Q. So isn't that what it means on page 49 of 59  
12 when it says that, "Low dose patients receive  
13 placebo to fill out high dose cycles"?

14 MS. PHENG: Same objection.

15 THE WITNESS: Yeah. Yes, that's  
16 probably what it means.

17 BY MR. SEGREST:

18 Q. Okay. So where does it show two months --  
19 where does it show on Exhibit 2049 two months  
20 of cladribine followed by four months of  
21 placebos?

22 A. I'm not able to find that at the moment.

1 Q. Okay. The next sentence in paragraph 28 of  
2 your declaration, it says, "In particular,  
3 the December 2003 briefing document discloses  
4 a regimen including 2 months of cladribine, 4  
5 months of placebos, then 6 months where no  
6 pills were administered, i.e., a 2-month  
7 cladribine dosing period followed by 10-month  
8 cladribine-free period."

9 You see that, right?

10 A. Yeah.

11 Q. That's what you're not able to find right now  
12 as being disclosed, right?

13 A. Yeah. But I wrote it down, that's how I  
14 understood it.

15 Q. Okay.

16 A. So I actually -- when I read this, I wrote  
17 down the dosing regimen and that's what I  
18 understood it as.

19 Q. And one more and then we can take a break if  
20 you all want.

21 On page -- Exhibit 2049, page 39 of  
22 59, do you see a section here that's [REDACTED]

1 [REDACTED] ?

2 A. Yes.

3 Q. [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED] ?

10 A. Yes.

11 Q. Okay. And as of December 2003 when this  
12 document was prepared, that's the language  
13 that Serono and IVAX were planning to submit  
14 to the regulators, because this is a draft  
15 regulatory briefing document, right?

16 MS. PHENG: Objection to form,  
17 foundation, scope.

18 THE WITNESS: This is a draft  
19 regulator document with Serono we're  
20 submitting to the regulators.

21 MR. SEGREST: Okay. I'm going to  
22 move to a different subject, if you want to



1 take a break now.

2 MS. PHENG: Yeah, that would be  
3 nice for me. I appreciate it.

4 MR. SEGREST: We can go off the  
5 record.

6 (Recess.)

7 BY MR. SEGREST:

8 Q. Dr. Dandiker, let me direct you now to your  
9 declaration again, Exhibit 2055,  
10 paragraph 24.

11 Now, does the last sentence in this  
12 paragraph 24 -- I'm sorry, strike that.

13 Does this paragraph 24 refer to a  
14 U.S. Provisional Application 60/541,247?

15 A. Yes.

16 Q. And is that provisional application  
17 Exhibit 2046?

18 A. I don't have it in front of me, so I --

19 Q. Well, look at the last sentence in  
20 paragraph 24. Does that quote language from  
21 the provisional application?

22 A. Yes.

1 Q. And does it cite Exhibit 2046?

2 A. I can't see 2046.

3 Q. Go to the last words on page 10,  
4 paragraph 24.

5 A. Oh, yeah. Yeah.

6 Q. And that says Exhibit 2046, 20:6-10, right?

7 A. Right.

8 Q. And that's your citation for this block quote  
9 that's immediately before it, right?

10 A. Yeah.

11 Q. And that block quote you say is -- the '247  
12 provisional contains similar language, right?

13 A. Right.

14 Q. Okay. And so this is Exhibit 2046.

15 (Hands document.) It's been previously  
16 marked.

17 Now, you're not identified as an  
18 inventor on this provisional application,  
19 right?

20 A. Yes, that's correct.

21 Q. Okay. This one is the one that only  
22 identifies Dr. Bodor as an inventor, right?

1 A. Yes.

2 Q. And this is again serial number 60/541,247,  
3 right, as Exhibit 2046?

4 A. Yeah.

5 Q. Okay. Let me hand you -- this has been  
6 previously marked as Exhibit 1007, but it  
7 looks like the bottom of the page cut off on  
8 this printout. I'm not sure why. So it's --  
9 I think all that's cut off is the exhibit  
10 number.

11 MS. PHENG: Counsel, do you mind  
12 if I just write 1007 so that Dr. Dandiker  
13 doesn't get confused?

14 MR. SEGREST: Sure, that's fine.

15 THE WITNESS: (Hands document.)

16 MS. PHENG: This is -- that's  
17 2046.

18 THE WITNESS: (Hands document.)

19 MS. PHENG: Okay.

20 BY MR. SEGREST:

21 Q. And this Exhibit 1007 is your PCT application  
22 WO 2004/087101, right?

1 A. Yes.

2 Q. Now, you are named as one of the co-inventors  
3 on this PCT application, right?

4 A. Yes.

5 Q. Okay. And it claims priority to three  
6 different provisional applications, right?

7 A. Yes.

8 Q. Okay. You see that under the item 30 on the  
9 bibliographic page where it has, Priority  
10 Date, and there's three different  
11 provisionals listed there?

12 A. Yeah.

13 Q. Okay. And one of those is the provision we  
14 were just looking at as Exhibit 2046, right,  
15 60/541,247?

16 A. Yes.

17 Q. Okay. And then I want to turn to -- I don't  
18 know why this did not scale properly, but  
19 I -- this is Exhibit 1029. And it again  
20 looks like that exhibit number got cut off.  
21 It is -- for identification, it's U.S. Patent  
22 Number 7,888,328. But if you want to write

1 1029 on it, that's the exhibit number.

2 A. (Complies.)

3 Q. And this -- does this 1029 -- or does this  
4 Exhibit 1029, which is the '328 patent, did  
5 that issue from an application that was the  
6 national stage entry of the PCT application  
7 that is Exhibit 2046?

8 MS. PHENG: Objection to form.

9 BY MR. SEGREST:

10 Q. I'm sorry, Exhibit 1007.

11 A. I'm just going by the publication dates  
12 there.

13 Q. Well, on the bibliographic page, the front  
14 page of the patent, let me direct you to the  
15 left-hand column, item 86.

16 Do you see it lists a PCT number?

17 A. Yes.

18 Q. And that's the PCT number of your PCT  
19 application, Exhibit 1007, right?

20 A. Yes.

21 Q. Okay. And then, again, let me direct you to  
22 column 1 of the '328 patent, Exhibit 1029.

1 A. Yeah.

2 Q. And in that column, at the very beginning, a  
3 cross-reference to earlier applications, do  
4 you see, "This application is the U.S.  
5 national stage of application number," and  
6 then it gives the number of your PCT  
7 application?

8 A. Yes.

9 Q. Okay. Let's go back to Exhibit 2050 for a  
10 minute, the meeting minutes. I'll direct you  
11 to page 3.

12 A. Yep.

13 Q. And do you see the heading, Formulation  
14 Progress and Patent Issues?

15 A. Yes.

16 Q. Okay. And underneath that it says that you  
17 discussed the formulation progress [REDACTED]

18 [REDACTED]

19 [REDACTED] ?

20 A. Well, it says [REDACTED]

21 [REDACTED] --

22 Q. Okay.

1 A. -- by --

2 Q. So let's be accurate. It says, "Yogesh

3 discussed formulation progress [REDACTED]

4 [REDACTED], "

5 right?

6 A. Yes.

7 Q. Who is Dennis?

8 A. He was a patent attorney.

9 Q. Okay.

10 A. I believe it's Dennis Emma, and I believe he

11 joined remotely.

12 Q. And then at the bottom of page 3 continuing

13 over onto page 4 -- I think there's only one

14 word on page 3, but it says, [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED] "

18 right?

19 A. Yeah.

20 Q. And then at the end of that same paragraph,

21 or at the top of the fourth page of

22 Exhibit 2050, the last sentence in that

1 paragraph says, [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]"

5 A. Yes.

6 Q. So [REDACTED]  
7 [REDACTED]; is that right?

8 MS. PHENG: Objection to form.

9 THE WITNESS: Sorry, can you  
10 repeat that again?

11 BY MR. SEGREST:

12 Q. Yeah. [REDACTED]  
13 [REDACTED]

14 A. [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED].

21 Q. Okay. And still on page 4 --

22 A. Right.



1 Q. -- of Exhibit 2050, right below where we were  
2 just looking at, you see [REDACTED]  
3 [REDACTED], right?

4 A. Yes.

5 Q. And these are [REDACTED]  
6 [REDACTED]  
7 right?

8 A. Yes.

9 Q. And is [REDACTED]  
10 [REDACTED]  
11 [REDACTED] ?

12 A. Yes.

13 Q. Okay. And then is it also [REDACTED]  
14 [REDACTED]  
15 [REDACTED]

16 A. Yes.

17 Q. Is that referring to [REDACTED]  
18 [REDACTED]  
19 [REDACTED]

20 MS. PHENG: Objection to form,  
21 relevance, scope.

22 THE WITNESS: I can't exactly

1 recall at the moment what it referred to.  
2 But my supposition is that it could have  
3 been, you know, [REDACTED].

4 BY MR. SEGREST:

5 Q. Okay. Well, there are three provisional  
6 applications --

7 A. Yeah.

8 Q. -- that are relied upon in that PCT  
9 application, right?

10 A. Right.

11 Q. Now, this is before that third provisional  
12 application was filed in February of 2004,  
13 right?

14 A. Right.

15 Q. But two provisionals had already been filed,  
16 right?

17 A. Right.

18 Q. And you're named as a coinventor on those two  
19 provisionals, aren't you?

20 A. Yes.

21 Q. [REDACTED]  
22 [REDACTED]

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22

[REDACTED]

A. [REDACTED]

Q. Okay.

A. Because those are the -- you know, [REDACTED]

[REDACTED] But  
prior to this, there were applications filed  
by Dr. Bodor as part of --

THE COURT REPORTER: I'm sorry, I  
didn't hear that.

THE WITNESS: Dr. Bodor,  
B-O-D-O-R.

THE COURT REPORTER: As part of --

THE WITNESS: The same project.

BY MR. SEGREST:

Q. When you say the application by Dr. Bodor, is  
that Exhibit 2046 that we were looking at?

A. 2046?

Q. I'm sorry. Yeah, 2046.

A. Yeah, so Dr. Bodor was working on cladribine  
before I was.

1 Q. That application that's just Dr. Bodor,  
2 that's actually later, right?

3 MS. PHENG: Objection --

4 BY MR. SEGREST:

5 Q. That's February of 2004?

6 MS. PHENG: Objection to form.

7 THE WITNESS: I mean, by date,  
8 yes. But in practice, he was working before  
9 I was.

10 BY MR. SEGREST:

11 Q. I'm going to hand you a document that was  
12 marked as Exhibit 1040.

13 A. Okay.

14 Q. And if you look at the second page of it --

15 A. Yes.

16 Q. -- is that your signature?

17 A. It is.

18 Q. So this document is an inventor's oath or  
19 declaration for a U.S. utility patent, right?

20 A. Yes.

21 Q. And if we look on the first page, it says  
22 it's for the specification which was filed as

1 PCT international application number, and  
2 then it gives your PCT application number,  
3 right?

4 A. Yes.

5 MS. PHENG: Objection to form.

6 BY MR. SEGREST:

7 Q. And right below that box that's checked  
8 there, do you see that the paragraph says, "I  
9 hereby state I have reviewed and understand  
10 the contents of the above-identified  
11 specification, including the claims, as  
12 amended by the amendment referred to above"?

13 A. Yes.

14 Q. Right? So you were submitting your  
15 inventor's oath that you had reviewed the  
16 specification and understood it, right?

17 A. I recall having reviewed the claims.

18 Q. Okay.

19 A. I can't recall having reviewed the  
20 specification. By this time I had left the  
21 company.

22 Q. Okay. Was this -- the statement where you

1 say, "I have reviewed and understand the  
2 contents of the above-identified  
3 specification," was that statement false?

4 A. I may have scanned it, but I think -- I mean,  
5 usually when I look at patents, my focus is  
6 always on the claims.

7 Q. Okay. Did you read the oath before you  
8 signed it?

9 A. I signed many oaths, so...

10 Q. Okay.

11 A. But I certainly recall reading the claims.

12 Q. Okay. So this PC -- or this patent  
13 application, the PCT application,  
14 Exhibit 1007, I think --

15 A. Yeah.

16 Q. I've got too many papers here. Oh.

17 MS. PHENG: It's the second one,  
18 if that helps.

19 BY MR. SEGREST:

20 Q. Does this application disclose any  
21 confidential information of Serono that -- or  
22 Serono, that IVAX was not authorized to

1 disclose?

2 MS. PHENG: Objection to form,  
3 relevance, scope, foundation.

4 THE WITNESS: That is really  
5 for -- not for me to comment. It's -- the  
6 PCT application is put together by a patent  
7 attorney. So the way it worked is you  
8 provided the information to the patent  
9 attorney to put together.

10 BY MR. SEGREST:

11 Q. Okay. And so you're providing the  
12 information to the patent attorney, right?

13 A. Yes.

14 Q. And did you provide to the patent attorney,  
15 did the patent attorney include in the  
16 application as published here, any  
17 confidential information of Serono that IVAX  
18 was not authorized to disclose?

19 MS. PHENG: Objection to form,  
20 relevance, scope and foundation.

21 And I caution the witness not to  
22 reveal the substance of any communications

1 with counsel.

2 THE WITNESS: Again, I provided my  
3 information, and that's all I can say.

4 BY MR. SEGREST:

5 Q. Okay. Did you provide any confidential  
6 information of Serono that IVAX was not  
7 authorized to disclose?

8 MS. PHENG: Same objections.

9 THE WITNESS: I provided  
10 information which belonged to IVAX to be  
11 included in the application.

12 BY MR. SEGREST:

13 Q. And so did you believe that all the  
14 information to be included in the application  
15 was information that IVAX was authorized to  
16 provide to the patent attorney, authorized to  
17 disclose?

18 MS. PHENG: Same objections.

19 THE WITNESS: To me it -- the  
20 question never occurred.

21 BY MR. SEGREST:

22 Q. Did you or anyone else at Serono -- I'm



1           sorry. Scratch that. Start over.

2                       Did you or anyone else at IVAX  
3           conceal from Serono that IVAX was filing this  
4           patent application, your PCT application,  
5           listing you and Dr. Bodor as inventors?

6                       MS. PHENG: Objection to form,  
7           relevance, scope and foundation.

8                       THE WITNESS: I think there's no  
9           reason for us to conceal anything from  
10          Serono.

11   BY MR. SEGREST:

12   Q. Okay. So there's no reason to conceal it.  
13   And, in fact, you didn't conceal it, did you?

14                       MS. PHENG: Same objections.

15                       THE WITNESS: I think I would kind  
16   of rephrase that to say our objective was  
17   that we came up with a workable formulation  
18   which would be, and is still to this day, the  
19   only oral treatment for multiple sclerosis.  
20   And that is what our focus was on, to, you  
21   know, file a patent application --

22                       MR. SEGREST: Well --

1 THE WITNESS: -- to protect that  
2 invention. And I -- in many ways, it's a  
3 joint collaboration. It kind of -- to me, it  
4 never occurred, the question you are asking,  
5 which is, you know, did you conceal anything.  
6 There's no reason to.

7 BY MR. SEGREST:

8 Q. So in Exhibit 2050 that we were just looking  
9 at, there was an action item there we looked  
10 at, right, that was about you forwarding to  
11 Serono copies of patent applications, right?

12 A. Yeah.

13 Q. At some point did you forward to Serono a  
14 copy of this PCT application?

15 A. Frankly speaking, I can't --

16 MS. PHENG: Objection -- hold on,  
17 please. Let me object.

18 THE WITNESS: Sure.

19 MS. PHENG: Objection to form,  
20 relevance, scope and foundation. And just  
21 let me reread the question. And I will  
22 object on the basis of privilege.

1 I'll instruct the witness not to  
2 reveal the substance of any communications  
3 with counsel, including any common interest  
4 privilege with respect to their patent  
5 applications.

6 THE WITNESS: So do I answer or  
7 not?

8 BY MR. SEGREST:

9 Q. Yes, you can answer.

10 MS. PHENG: I'll instruct you not  
11 to answer.

12 MR. SEGREST: So you're  
13 instructing him not to answer my question of  
14 whether they forwarded this application  
15 that's published to Serono?

16 MS. PHENG: You asked, "At some  
17 point did you forward to Serono a copy of  
18 this PCT application," and I'm instructing  
19 him not to answer.

20 BY MR. SEGREST:

21 Q. After this PCT application was published, did  
22 you send a copy of it to the people at

1 Serono?

2 MS. PHENG: Sorry, I just -- same  
3 objections.

4 THE WITNESS: I think I have to go  
5 by what counsel says.

6 BY MR. SEGREST:

7 Q. So you weren't instructed not to answer  
8 there.

9 A. Yeah.

10 Q. So you can answer.

11 MS. PHENG: So to be clear, same  
12 objections. I'm going to instruct you not to  
13 answer. It's the same question.

14 BY MR. SEGREST:

15 Q. I'm going to hand you a copy of 1001 in this  
16 case. It's U.S. Patent 7,713,947.

17 A. One thousand --

18 MS. PHENG: 1001.

19 BY MR. SEGREST:

20 Q. I'll direct you to column 6, line 24. So  
21 does this '947 patent, Exhibit 1001, in  
22 column 6, line 24, cite to your PCT

1 application?

2 A. Sorry, did you say column --

3 Q. Column 6, line 24.

4 MS. PHENG: Objection to form.

5 THE WITNESS: So, sorry, what is  
6 the question again?

7 BY MR. SEGREST:

8 Q. Yes. Does this '947 patent, Exhibit 1001, at  
9 column 6, line 24, cite your PCT application?

10 MS. PHENG: Same objection.

11 THE WITNESS: Yes, it appears to.

12 BY MR. SEGREST:

13 Q. Okay. And is it cited again at column 12,  
14 line 9?

15 A. Yeah. Yes, it is.

16 Q. And it's cited again at column 14, line 44?

17 A. Yes.

18 Q. And then again, that same column 14 at  
19 line 62, this is smaller print, under  
20 table 2?

21 A. Yeah.

22 Q. Now, you're named as an inventor on multiple

1 patents, right?

2 A. Yes.

3 Q. Okay. And so you understand, from having  
4 participated in that, that a patent applicant  
5 has a duty of candor to disclose to the  
6 patent office any prior art they know about?

7 MS. PHENG: Objection to form,  
8 relevance, scope.

9 THE WITNESS: Yes.

10 BY MR. SEGREST:

11 Q. Okay. And you understand that an applicant  
12 can disclose that prior art on something  
13 that's called an Information Disclosure  
14 Statement, right?

15 MS. PHENG: Same objections.

16 THE WITNESS: Yes.

17 BY MR. SEGREST:

18 Q. I'll hand you what's --

19 MR. MCGUFFIN: Sorry, I don't mean  
20 to interrupt. Planet Depos has informed us  
21 that the reporter has shared the transcript  
22 of this with counsel for another case. Can

1 we have that reporter please change their  
2 credentials so that we don't share any more  
3 confidential information with anyone  
4 unrelated to this case?

5 MR. SEGREST: Let's go off record  
6 and fix --

7 MS. PHENG: Yeah, let's go off the  
8 record.

9 MR. SEGREST: -- whatever issue  
10 we've got.

11 (Lunch recess.)

12 MR. SEGREST: We can go back on  
13 the record.

14 BY MR. SEGREST:

15 Q. Dr. Dandiker, I have here what's previously  
16 marked as Exhibit 1003 in this case. It's a  
17 fairly thick document, so I did not make as  
18 many copies of this one. I think I can work  
19 from my electronic version here so you and  
20 counsel can each have one of the physical  
21 copies.

22 Looking at the cover of this

1 document, the front page, if you can fold it  
2 back over and look at the front page for me,  
3 please.

4 A. (Complies.)

5 Q. There you go.

6 Do you see on the cover that this  
7 document is the file wrapper of the '947  
8 patent?

9 A. Yeah.

10 Q. Okay. And let me direct you to pages 15 and  
11 16.

12 MS. PHENG: Counsel, I know you  
13 haven't asked a specific question about the  
14 document yet, but I will object to the use of  
15 the document as beyond the -- beyond the  
16 scope of Dr. Dandiker's direct -- sorry,  
17 direct testimony.

18 BY MR. SEGREST:

19 Q. I'll direct you to pages 15 and 16, please.

20 A. And, again, to be clear, this is the first  
21 time I'm seeing this document.

22 Q. Okay.



1 Do you see the numbering in the  
2 bottom right-hand corner --

3 A. Yes.

4 Q. -- page 15 of 822 and page 16 of 822?

5 And do these pages appear to be an  
6 Information Disclosure Statement?

7 A. Is there a question?

8 Q. Yes. Do these pages appear to be an  
9 Information Disclosure Statement?

10 A. Yeah.

11 Q. And you're familiar, in general, with  
12 Information Disclosure Statements from your  
13 own patent applications, right?

14 A. Yeah.

15 Q. And then looking at page 16 of 822, is one of  
16 the items disclosed your PCT application as  
17 number F1?

18 A. Yeah.

19 Q. Okay. Now let's go to page 385 of 822.

20 MS. PHENG: Sorry, what page was  
21 that?

22 MR. SEGREST: 385 of 822.

1 THE WITNESS: All right.

2 BY MR. SEGREST:

3 Q. And does this page appear to be the first  
4 page of an office action dated August 3rd,  
5 2009?

6 A. Yes, it appears to be so.

7 Q. Okay. Let's go to page 288. And in point 6  
8 here on page 388 --

9 A. Yeah.

10 Q. -- does it appear to cite your PCT  
11 application as prior art against this  
12 application?

13 MS. PHENG: Objection to form,  
14 relevance, scope, foundation.

15 THE WITNESS: It mentions it.

16 BY MR. SEGREST:

17 Q. Yeah. In fact, it has a sentence here, do  
18 you see, that says, "In particular" -- let me  
19 make sure I'm at the right spot here. Yeah.

20 On page 389, the second line on the  
21 page, do you see it says, "In particular,  
22 Bodor teaches that for the treatment of

1 multiple sclerosis, 10 milligrams of  
2 cladribine in solid dosage form is to be  
3 administered orally once per day for a period  
4 of five to seven days in the first month,  
5 repeated for another period of five to  
6 seven days in the second month, followed by  
7 ten months of no treatment"?

8 MS. PHENG: Objection to form,  
9 relevance, scope and foundation.

10 THE WITNESS: That's what it says.

11 BY MR. SEGREST:

12 Q. Okay. Well, let's look at your declaration,  
13 Exhibit 2055, paragraph 24.

14 A. Sorry, say that again.

15 Q. Your declaration, Exhibit 2055, paragraph 24.

16 A. All right. So what about it?

17 Q. So the disclosure you quote in paragraph 24  
18 here, that's the same disclosure that the  
19 examiner is citing in that office action,  
20 right?

21 A. Right.

22 MS. PHENG: Objection to form,

1 relevance, scope and foundation.

2 BY MR. SEGREST:

3 Q. In the next few months after this office  
4 action, from August until December of 2009,  
5 did anyone contact you about this office  
6 action?

7 A. No.

8 Q. Did anyone contact you at that time about  
9 this passage in your PCT application that you  
10 discussed in paragraph 24 of your  
11 declaration?

12 A. No.

13 MS. PHENG: Objection to form,  
14 relevance, scope and foundation.

15 Please just give me an opportunity to  
16 object, Doctor.

17 BY MR. SEGREST:

18 Q. You can set that big one aside.

19 This is Exhibit 1004. And this one  
20 is slightly less thick. But, again, I've  
21 only got the two physical copies.

22 Now, let's look at the cover page

1 first, please. So looking at that cover, do  
2 you see this is the file wrapper for the '903  
3 patent?

4 A. Right.

5 Q. Let me direct you now to page 98 of 207.  
6 Again, the page numbers are in the bottom  
7 right.

8 I apologize. Let's first back up to  
9 page 3 of 207.

10 A. Yeah.

11 Q. Okay. Does this page appear to be an  
12 Information Disclosure Statement again?

13 A. Yeah.

14 MS. PHENG: And just, again,  
15 before you go any further, Counsel, same  
16 objections as to the Exhibit 1003 [sic].  
17 It's beyond the scope of Dr. Dandiker's  
18 declaration.

19 BY MR. SEGREST:

20 Q. And turn to page 5 of 207. Does the  
21 Information Disclosure Statement cite your  
22 PCT application as prior art, item F1?

1 MS. PHENG: Objection to form,  
2 relevance, scope and foundation.

3 THE WITNESS: It does.

4 BY MR. SEGREST:

5 Q. Now let's go to page 98 of 207, please.

6 A. 98?

7 Q. 98, yes.

8 Does this appear to be an office  
9 action dated December 19th, 2011?

10 A. Yes.

11 MS. PHENG: Same objections.

12 BY MR. SEGREST:

13 Q. And turning to page 103 of 207, in point 8 on  
14 page 3 of 207, is the examiner citing your  
15 PCT application against the claims that were  
16 then pending?

17 MS. PHENG: Same objection to  
18 form, relevance, scope and foundation.

19 THE WITNESS: Yes.

20 BY MR. SEGREST:

21 Q. And looking on the next page, 104 of 207, do  
22 you see the sentence says, "This dose is

1           taught to be administered for five to seven  
2           days per month which meets the limitation of  
3           claims 13 and 27, i.e., the formulation is  
4           orally administered one to seven days per  
5           month during the induction period"?

6                       Do you see that sentence?

7                       MS. PHENG: Objection to form,  
8           relevance, scope and foundation.

9                       THE WITNESS: Sorry, so what is  
10          the question?

11       BY MR. SEGREST:

12       Q. I'm just making sure that you see the  
13          sentence, you agree that's in there.

14                       MS. PHENG: Same objections.

15                       THE WITNESS: It is in there,  
16          but --

17       BY MR. SEGREST:

18       Q. Okay. And that's referring to the same  
19          disclosure again from your PCT application  
20          that you discussed in paragraph 24 of your  
21          declaration, right?

22                       MS. PHENG: Same objections.

1 THE WITNESS: It is -- it's one  
2 part of --

3 THE COURT REPORTER: I'm sorry, I  
4 didn't hear that.

5 THE WITNESS: Sorry. It is one  
6 aspect of it or one part of it.

7 BY MR. SEGREST:

8 Q. So in the next few months after this from  
9 December 2011 through March 2012, did anyone  
10 contact you about this office action?

11 A. No.

12 Q. Did anyone contact you about the passage from  
13 your PCT application then that's now  
14 discussed in paragraph 24 of your  
15 declaration?

16 A. No.

17 Q. So your declaration, Exhibit 2055, is dated  
18 February 22nd, 2024.

19 When did anybody first contact you  
20 about this passage in your declaration --  
21 passage in your patent application as it  
22 relates to the '947 and '903 patents?



1 MS. PHENG: Objection to form,  
2 scope, relevance.

3 THE WITNESS: So let me maybe  
4 clarify things. So I left IVAX in 2004. And  
5 as I mentioned earlier, I did not have any  
6 information with me related to IVAX.

7 The next time anybody contacted me  
8 with respect to this patent application was  
9 in -- was by counsel from WilmerHale, and I  
10 think, I believe it was November of last  
11 year, 2023. So I think it's after a passage  
12 of 20 years.

13 BY MR. SEGREST:

14 Q. Let's go back to your declaration,  
15 Exhibit 2055. And looking at paragraph 27,  
16 it spans pages 11 and 12. I want to look in  
17 particular at the phrase at the very bottom  
18 of page 11, the last three words. Do you see  
19 it says, "I believe that"?

20 A. Yeah.

21 Q. Okay. Is this statement another one of those  
22 in your declaration that's based on

1 information and belief and not on personal  
2 knowledge?

3 MS. PHENG: Objection to form.

4 THE WITNESS: As I said, these are  
5 related to events 20 years ago, so I have to  
6 say that that's what I believe.

7 BY MR. SEGREST:

8 Q. Okay. I'll direct you to paragraph 29. You  
9 say here that you believe the Serono team  
10 communicated additional details about their  
11 dosing regimen to you and the rest of the  
12 IVAX team in additional other meetings and  
13 emails?

14 A. Yeah.

15 Q. Would those meetings have had meeting minutes  
16 like the ones we saw in Exhibit 2050?

17 A. Not necessarily. My recollection is that  
18 more so the communication with Serono was  
19 over the phone, so it would be one-to-one  
20 conversations. And they were important,  
21 because, you know, [REDACTED]

22 [REDACTED]

1

[REDACTED]

2

[REDACTED]

3

[REDACTED]

4

[REDACTED]

5

[REDACTED]

6

[REDACTED]

7

[REDACTED]

8

So that communication was essential,

9

because what we discussed, let's say, in the

10

August Amsterdam meeting, is not the final --

11

final dosing regimen, it's not the final

12

formulation. Patent applications had been

13

filed, but not --

14

THE COURT REPORTER: But not --

15

THE WITNESS: Had been filed for

16

some, but not by everything by then. So it's

17

an ongoing development. So as a -- you know,

18

as a consequence of that or as a result of

19

that, that communication is ongoing all the

20

time. And so beyond this document, there

21

were certainly phone calls.

22

[REDACTED]

1

[REDACTED]

2

[REDACTED]

3

[REDACTED]

4

[REDACTED]

5

And for Serono, it was also important

6

to know what we were doing so that they could

7

plan whether we'd have a viable product. [REDACTED]

8

[REDACTED]

9

[REDACTED]

10

So everybody is working with the

11

assumption that everything is going to work

12

out. And so I would say some of the

13

communication is there, but it may not be

14

final. But that's the nature of work, right,

15

it's the nature of how things develop.

16

BY MR. SEGREST:

17

Q. So it's your belief that there's other

18

emails, meetings maybe with minutes,

19

communications between Serono and IVAX about

20

the dosing regimen, right?

21

MS. PHENG: Objection to form.

22

THE WITNESS: No, that's not my

1 belief.

2 BY MR. SEGREST:

3 Q. You don't think there are other  
4 communications?

5 A. So what I -- what I believe is that there  
6 were phone calls and emails, but I only  
7 remember -- I only recall attending the  
8 Amsterdam meeting, right, where there were  
9 minutes. There were -- there were  
10 discussions, and there were discussions all  
11 the time.

12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]

20 Q. And there may not be more meeting minutes,  
21 but you do think there were other meetings,  
22 and there are emails that discuss the dosing

1           regimen, right?

2       A.   Yes, I --

3                               (Phone interruption.)

4                               MR. SEGREST:   Sorry.

5                               THE WITNESS:   Yes.   But

6           specifically not with me, because I -- I only

7           remember that Amsterdam meeting.   I mean,

8           certainly I did speak with, you know,

9           Maria Lopez and Dr. Munafo, you know, have

10          conversations, but there were not -- I can't

11          recall any meeting minutes from that.

12       BY MR. SEGREST:

13       Q.   Were you provided with any of these other

14          emails or other documents to review when you

15          were preparing your declaration?

16                               MS. PHENG:   Objection; calls for

17          privileged information.   I'm going to

18          instruct the witness not to answer.

19                               MR. SEGREST:   That's all I have at

20          this time.

21                               Did you have any redirect?

22                               MS. PHENG:   I think I -- we'll

1 take a brief break and take look and see if I  
2 have any.

3 MR. SEGREST: Okay.

4 (Recess.)

5

6 EXAMINATION

7 BY MS. PHENG:

8 Q. Thank you, Dr. Dandiker. So I'm just going  
9 to ask you a few quick questions as well.

10 You were asked earlier today whether  
11 any statements in your declaration were made  
12 on information and belief.

13 Do you recall that?

14 A. Yeah.

15 Q. And do you have personal knowledge about the  
16 work you did at IVAX from 2001 and 2004?

17 A. Yes, I was there, yep.

18 Q. And to be -- I just want the record to be  
19 clear. You have personal knowledge of the  
20 work that you performed at IVAX between the  
21 years 2001 and 2004?

22 A. I have, of course, knowledge of the work I

1 performed.

2 Q. And you have knowledge of the work that you  
3 performed at IVAX from 2001 to 2004 with  
4 respect to the cladribine project; is that  
5 right?

6 A. The work I performed, yes.

7 Q. And as part of your work at IVAX, do you have  
8 personal knowledge of the respective roles of  
9 IVAX and Serono as it related to the  
10 cladribine project?

11 A. Yes.

12 Q. And do you have personal knowledge about the  
13 communications between you and members of the  
14 Serono team as it relates to the cladribine  
15 project?

16 MR. SEGREST: Objection to form.

17 THE WITNESS: Communication  
18 related to my interactions. I can't speak to  
19 other people at IVAX who may have also  
20 communicated with Serono.

21 BY MS. PHENG:

22 Q. And is the testimony in your declaration



1 about your work between 2001 and 2004 based  
2 on all of that personal knowledge you just  
3 testified to?

4 A. Yes.

5 Q. And is your testimony in your declaration  
6 about your communications between 2001 and  
7 2004 with members of the Serono team, based  
8 on that personal knowledge?

9 A. Yeah.

10 Q. And does your testimony in your declaration  
11 reflect your understanding in 2003 of what  
12 Serono had disclosed to IVAX, including to  
13 you?

14 MR. SEGREST: Objection to form.

15 THE WITNESS: Can you repeat that?

16 BY MS. PHENG:

17 Q. Does your testimony in your declaration  
18 reflect your understanding of what Serono had  
19 disclosed to IVAX, including yourself, in  
20 2003?

21 A. So --

22 MR. SEGREST: Same objection.

1 THE WITNESS: So I would say that  
2 is documented in the minutes of the Amsterdam  
3 meeting.

4 BY MS. PHENG:

5 Q. So I just want to be -- make sure that I  
6 understand and we're being clear.

7 Does your declaration reflect your  
8 understanding of what Serono had disclosed to  
9 you in 2003?

10 MR. SEGREST: Object to form.

11 THE WITNESS: Yes.

12 BY MS. PHENG:

13 Q. And do you stand by your description --  
14 strike that.

15 Do you stand by the contents of your  
16 declaration?

17 A. Yes, I do.

18 Q. Okay. Now, you were also asked today about  
19 some sections of Exhibit 2049, which I  
20 believe is the December 2003 briefing  
21 document.

22 A. Yes.

1 Q. And you were asked earlier about what the  
2 high and low doses meant in this exhibit.

3 Do you recall that?

4 A. Yes.

5 Q. Do you have Exhibit 2049 in front of you,  
6 Dr. Dandiker?

7 A. Yeah.

8 Q. And can I ask you to turn to page 47 of  
9 Exhibit 2049?

10 A. Yeah.

11 Q. Okay. And can I ask you to turn your  
12 attention to the row that says, "Study  
13 Design"?

14 A. Okay.

15 Q. And that's at the bottom of page 47.

16 Do you see that?

17 A. Yeah.

18 Q. And you were asked some questions earlier  
19 about the section that says, "Treatment  
20 Groups."

21 Do you remember that?

22 A. Yeah.

1 Q. Exhibit 2049 says here, "Treatment Groups:  
2 Two doses, high and low approximating  
3 cumulative doses of 2.1 milligrams per  
4 kilogram and 0.7 milligrams per kilogram."

5 A. Yes.

6 Q. Is the low dose in that sentence referring to  
7 a cumulative dose of 0.7 milligrams per  
8 kilogram?

9 MR. SEGREST: Objection; leading.

10 THE WITNESS: Yes.

11 BY MS. PHENG:

12 Q. And is the high dose in that sentence  
13 referring to a cumulative dose of  
14 2.1 milligrams per kilogram?

15 A. Yes.

16 MR. SEGREST: Same objection.

17 BY MS. PHENG:

18 Q. Is 0.7 milligrams per kilogram one-third of  
19 2.1 milligrams per kilogram?

20 A. Yes.

21 MR. SEGREST: Same objection.

22 BY MS. PHENG:

1 Q. So in order to reach 2.1 milligrams per  
2 kilogram, you would have to take three times  
3 the dosage of .7 milligrams per kilogram; is  
4 that right?

5 MR. SEGREST: Same objection.

6 THE WITNESS: Yeah, that's  
7 correct.

8 BY MS. PHENG:

9 Q. And you testified earlier that Exhibit 2049  
10 disclosed that the high dose was administered  
11 through six monthly cycles, and that patients  
12 in the low dose cycle received placebos to  
13 fill out high dose cycles.

14 Do you recall that?

15 MR. SEGREST: Objection to the  
16 characterization of prior testimony.  
17 Objection to form.

18 THE WITNESS: Yes.

19 BY MS. PHENG:

20 Q. Is two months one-third of six months?

21 A. Yep.

22 MR. SEGREST: Objection to form.

1           Objection; leading.

2           BY MS. PHENG:

3           Q.   Dr. Dandiker, you can -- actually, you can  
4           keep Exhibit 2049 in front of you for the  
5           moment.

6                       Earlier you had also testified that  
7           one document described what a dosage cycle  
8           meant in the context of Serono's disclosures.

9                       Do you recall that?

10          A.   Yeah.

11          Q.   And you were also -- strike that.

12                       Could I ask you to turn to page 48 of  
13          Exhibit 2049?

14          A.   Yeah.

15          Q.   And earlier today you had read for counsel  
16          the sentence here, "One cycle equals 5-day  
17          course of treatment during a 28-day period"?

18          A.   Right. Yes.

19          Q.   Is this what you were referring to when you  
20          testified a document described what dosage  
21          cycle meant?

22                       MR. SEGREST:  Objection; leading.

1 THE WITNESS: A five-day course of  
2 treatment is one cycle.

3 BY MS. PHENG:

4 Q. Okay. So I just want to make sure that the  
5 testimony -- that the testimony in the record  
6 is clear.

7 Is this what you were referring to  
8 when you testified a document described what  
9 dosage cycle meant?

10 MR. SEGREST: Objection; leading.  
11 Objection to the characterization of prior  
12 testimony.

13 THE WITNESS: Yes.

14 BY MS. PHENG:

15 Q. And you were also asked some questions today  
16 about provisional applications.

17 A. Right.

18 Q. I want to take you to paragraph 19 of your  
19 declaration.

20 Do you have your declaration in front  
21 of you, Dr. Dandiker?

22 A. Yes. Yep.

1 Q. And can you let me know when you get to  
2 paragraph 19?

3 A. Yep. Okay. I'm at paragraph 19.

4 Q. Okay. Earlier today counsel had asked you  
5 about provisional applications referenced in  
6 Exhibit 2050.

7 Do you recall that?

8 A. Yes.

9 Q. And in your declaration at paragraph 19 here,  
10 you testified that IVAX had filed U.S.  
11 Provisional Application Numbers 60/458,922,  
12 60/484,756, and 60/541,247, between  
13 March 24th, 2003, and February 4th, 2004?

14 A. Yes.

15 Q. [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 MR. SEGREST: Objection to form.

19 THE WITNESS: [REDACTED]

20 [REDACTED]

21 BY MS. PHENG:

22 Q. And you had testified -- strike that. I --



1 MS. PHENG: Counsel, I'm just  
2 going to hand you what -- I only have one  
3 copy, but I'm going to hand you what was  
4 previously marked as Exhibit 24, if you want  
5 to examine before I bring it to the witness.

6 MR. SEGREST: I think you just  
7 said Exhibit 24. This is --

8 MS. PHENG: 2044.

9 MR. SEGREST: 2044?

10 MS. PHENG: Yes. Thank you. I  
11 don't know if you have a copy.

12 MR. SEGREST: I think I may have a  
13 copy of that one. Let me look.

14 Yeah. Here are copies, multiple  
15 copies of Exhibit 2044.

16 MS. PHENG: And if you have 2045  
17 as well. I know you handed us 2046 earlier.

18 MR. SEGREST: I did. So here are  
19 more copies of 2044.

20 MS. PHENG: Thank you.

21 MR. SEGREST: And more copies of  
22 2045.

1 MS. PHENG: Much appreciated,  
2 Counsel. Thank you. And excuse my tenuous  
3 reach over the table.

4 BY MS. PHENG:

5 Q. Dr. Dandiker, I'm just going to hand those to  
6 you so you have those at your hands, two  
7 exhibits that have been previously marked as  
8 Exhibit 2044 and Exhibit 2045. And these two  
9 exhibits, they were referenced here in  
10 paragraph 19 of your declaration; is that  
11 correct?

12 A. Yeah.

13 Q. If you could take Exhibit 2044 in hand and  
14 just let me know when you have it. I  
15 recognize you have many documents in front of  
16 you.

17 A. Yep.

18 Q. Okay. And if you could turn to what is the  
19 third page of Exhibit 2044 --

20 A. Yes.

21 Q. -- where it says, "Provisional Application  
22 for Patent Cover Sheet, Large Entity," at the

1 top.

2 A. Yeah.

3 Q. Do you see below that where it identifies  
4 inventors and applicants?

5 A. Yep.

6 Q. And are you a named inventor on Exhibit 2044?

7 A. No.

8 Q. And Exhibit 2044 is the Provisional  
9 Application Number 60/458,922?

10 If you turn to the first page. And  
11 I'll ask again, Exhibit 2044 is the  
12 Provisional Application Number 60/458,922?

13 A. Yeah, it is.

14 Q. And you can put Exhibit 2044 down.

15 And if I could turn you now to  
16 Exhibit 2045.

17 A. Yeah.

18 Q. And is Exhibit 2045 referenced in  
19 paragraph 19 of your declaration?

20 A. Yep, it is.

21 Q. And Exhibit 2045 is Provisional Application  
22 Number 60/484,756?

1 A. Yes.

2 Q. And if I can turn you to the fourth page of  
3 Exhibit 2045, can you let me know when you're  
4 there?

5 A. Yep.

6 Q. And it says, "Provisional Application Cover  
7 Sheet," on the top?

8 A. It does, yeah.

9 Q. And beneath that it identifies inventors and  
10 applicants?

11 A. Yeah.

12 Q. Are you listed as a named inventor on  
13 Exhibit 2045?

14 A. I am not.

15 Q. Okay. You can put Exhibit 2045 down.

16 And earlier counsel had given you  
17 Exhibit 2046. I don't know if you can -- if  
18 you have that copy in front of you still.

19 A. Yeah, I do.

20 Q. And Exhibit 2046 is also referenced --

21 A. Yes.

22 Q. -- in paragraph 19 of your declaration?

1 A. Yes.

2 Q. And Exhibit 2046 is Provisional Application  
3 Number 60/541,247?

4 A. Yes.

5 Q. And, Dr. Dandiker, if I can have you turn to  
6 page 3 of Exhibit 2046 --

7 A. Yes.

8 Q. -- where it says at the top, "Provisional  
9 Application for Patent Cover Sheet."

10 A. Yes.

11 Q. And beneath that it identifies the inventors  
12 for Exhibit 2046.

13 A. Yep.

14 Q. Are you with me?

15 A. Yep.

16 Q. And are you listed as a named inventor for  
17 Exhibit 26 -- 2046?

18 A. I am not.

19 Q. Okay. And so I just want the record to be  
20 clear. Were you named as an inventor on any  
21 of the provisional applications that we just  
22 discussed described in paragraph 19 of your

1 declaration?

2 A. No, I was not.

3 MS. PHENG: Pending any additional  
4 questions from counsel, I don't have any  
5 further questions for you, Dr. Dandiker.

6 MR. SEGREST: Just a few  
7 questions.

8

9

FURTHER EXAMINATION

10 BY MR. SEGREST:

11 Q. During our break did you discuss your  
12 testimony with counsel?

13 A. No.

14 Q. Okay. Let's go back to Exhibit 2049 again.  
15 And I believe you were looking at page 47 of  
16 59.

17 MS. PHENG: Just to help, that  
18 would be the briefing document, right,  
19 Counsel?

20 MR. SEGREST: Yes, that's correct.

21 THE WITNESS: Yeah.

22 BY MR. SEGREST:

1 Q. Page 47 of 59, I think we were looking at the  
2 row in the table called, Study Design, right?

3 A. Yeah.

4 Q. So it says there's two doses, right?

5 A. Right.

6 Q. And there's another word in there,  
7 "Approximating."

8 Do you see that word?

9 A. Yeah.

10 Q. So your two doses are approximating these  
11 cumulative doses of 2.1 milligrams per  
12 kilogram and 0.7 milligrams per kilogram,  
13 right?

14 MS. PHENG: Objection to form.

15 THE WITNESS: Yes.

16 BY MR. SEGREST:

17 Q. Now, 2.1 milligrams per kilogram and  
18 0.7 milligrams per kilogram, those are doses  
19 that were, in previous studies, done  
20 intravenously, right?

21 A. I believe so.

22 Q. And your dose that --

1 MS. PHENG: Sorry. Objection to  
2 form.

3 BY MR. SEGREST:

4 Q. Your dose that approximates the  
5 0.7 milligrams per kilogram intravenously, is  
6 that 3-milligram tablet, right?

7 MS. PHENG: Objection to form.

8 THE WITNESS: Yes.

9 BY MR. SEGREST:

10 Q. And your dose that approximates the  
11 2.1 milligrams per kilogram intravenously, is  
12 that 10-milligram tablet, right?

13 MS. PHENG: Objection to form.

14 THE WITNESS: Yes. I would  
15 hesitate to say "my dose."

16 BY MR. SEGREST:

17 Q. The dose described in these documents, the  
18 3-milligram and 10-milligram tablets, right?

19 A. Yeah.

20 Q. Okay.

21 MR. SEGREST: I don't have any  
22 further questions.



1           We've got an open issue as to some  
2           assertions of privilege. As I said before,  
3           we're reserving the right, we may have to  
4           bring that before the Board on Wednesday,  
5           asking for an expedited transcript on that  
6           basis, and holding the deposition open  
7           pending resolution of that issue.

8           MS. PHENG: So we don't agree to  
9           hold the deposition open. We understand that  
10          we have a pending issue before the Board. I  
11          do not think those current issues with  
12          respect to, I presume you're alluding to  
13          those discovery requests, will require us to  
14          keep this deposition open.

15          MR. SEGREST: The assertions of  
16          privilege also.

17          MS. PHENG: I still disagree that  
18          this requires the deposition to be kept open,  
19          so we don't agree to that.

20          But we have no objections to ordering  
21          an expedited transcript so that we can  
22          resolve this issue.

1 MR. SEGREST: Okay.

2 MS. PHENG: I do want to take just  
3 one moment, and we can go off the record, I  
4 just want to take one moment to see if I have  
5 any further questions.

6 (Recess.)

7 MS. PHENG: We can go back on the  
8 record.

9 I don't have any further questions  
10 for you, Dr. Dandiker. Thank you for your  
11 time.

12 I would like to, while we're on the  
13 record, provisionally designate this under  
14 the default protective order as confidential.  
15 We'll follow the procedures in the protective  
16 order and provide any redactions for a public  
17 copy as needed.

18 MR. SEGREST: Okay.

19 THE COURT REPORTER: And, Counsel,  
20 can I get the transcript orders on the  
21 record, please.

22 MS. PHENG: Expedited for both

1 parties, I believe.

2 THE COURT REPORTER: And expedited  
3 what date?

4 MS. PHENG: We have the hearings  
5 coming up -- or not the hearing.

6 MR. SEGREST: If we can get it  
7 before -- if we can get it by Tuesday. I  
8 understand it's Memorial Day weekend, so I  
9 don't know what your resources are going to  
10 be. But as soon as possible. If we could  
11 get it by Tuesday, that would be great.

12 MS. PHENG: Yeah.

13 THE COURT REPORTER: Okay. And do  
14 you need a rough draft?

15 MS. PHENG: Yeah, same-day rough,  
16 if possible.

17 MR. SEGREST: Yes.

18 THE COURT REPORTER: Okay. Thank  
19 you.

20 (Time noted: 1:56 p.m.)

21

22

1 CERTIFICATE OF SHORTHAND REPORTER-NOTARY PUBLIC

2 I, Amy L. Larson, Registered Professional  
3 Reporter, Certified Shorthand Reporter, Certified  
4 Court Reporter, and Notary Public within and for  
5 the States of Minnesota and Wisconsin, do hereby  
6 certify:

7 That YOGESH DANDIKER, Ph.D., the witness  
8 whose deposition is hereinbefore set forth, was  
9 duly sworn by me before the commencement of such  
10 deposition and that such deposition was taken  
11 before me and is a true record of the testimony  
12 given by such witness.

13 I further certify that the adverse party,  
14 TWI PHARMACEUTICALS, was represented by counsel at  
15 the deposition.

16 I further certify that the deposition of  
17 YOGESH DANDIKER, Ph.D., occurred at the offices  
18 of Fabyanske, Westra, Hart & Thomson, P.A.,  
19 80 South Eighth Street, Suite 1900, Minneapolis,  
20 Minnesota, on Friday, May 24, 2024, commencing at  
21 9:30 a.m. to 1:56 p.m.

22 I further certify that I am not related to

1 any of the parties to this action by blood or  
2 marriage, I am not employed by or an attorney to  
3 any of the parties to this action, and that I am  
4 in no way interested, financially or otherwise, in  
5 the outcome of this matter.

6

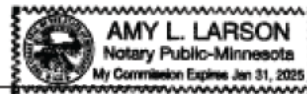
7

8 IN WITNESS WHEREOF, I have hereunto set my  
9 hand this 28th day of May, 2024.

10

11

*Amy L. Larson*



12

Amy L. Larson, RPR, CCR, CSR

13

My commission expires January 31, 2025

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