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PROTECTIVE ORDER MATERIAL

Transcript of Alain Munafò, Ph.D.

Date: June 7, 2024

Case: TWI Pharmaceuticals, Inc. -v- Merck Serono SA (PTAB)

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

EXHIBIT 1045, TWi
IPR2023-00049, -00050

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

4 TWI PHARMACEUTICALS, INC.

5 Petitioner,

6 v.

7 MERCK SERONO SA

8 Patent Owner.

9
10 IPR2023-00049 (Patent 7,713,947 B2)

11 IPR2023-00050 (Patent 8,377,903 B2)

12
13 PROTECTIVE ORDER MATERIAL

14 Deposition of

15 ALAIN MUNAFO, Ph.D.

16 Conducted Virtually

17 Friday, June 7, 2024

18 1:06 p.m. CEST

19
20 Job No.: 541019

21 Pages: 1 - 179

22 Reported by: Cassidy Western, RPR

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Conducted on June 7, 2024

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1 Deposition of ALAIN MUNAFO, Ph.D., conducted
2 virtually.

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8 Pursuant to notice, before Cassidy Western,
9 RPR, Notary Public in and for the Commonwealth of
10 Pennsylvania.

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A P P E A R A N C E S

ON BEHALF OF THE PETITIONER, TWI
PHARMACEUTICALS, INC.:

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Dr. Matthias Dotzauer
Willem de Weerd

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1 ALAIN MUNAFO, Ph.D.,
2 of lawful age, being first duly sworn or affirmed
3 to testify to the truth, the whole truth, and
4 nothing but the truth, was examined and testified
5 as follows:

6 EXAMINATION BY COUNSEL FOR THE PETITIONER,
7 TWI PHARMACEUTICALS, INC.

8 BY MR. SEGREST:

9 Q Good morning, Doctor. My name's Philip
10 Segrest, and I'm representing the party TWi
11 Pharmaceuticals in this case. I'm going to be
12 asking you some questions this morning.

13 My first question, how do I pronounce
14 your last name, please?

15 A Good morning, Counsel. My last name is
16 Munafo, M-u-n-a-f-o. Munafo.

17 Q Munafo. Munafo. Am I saying that
18 correctly?

19 A That's -- that's good enough. Thank
20 you.

21 Q Thank you, Doctor.
22 Would you --

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1 A I -- I would like just -- just before
2 starting, I would like to comment on one thing.
3 English is not at all my mother language. You can
4 see -- you can hear it from my accent. But also
5 in this case, I'm going to ask you to speak slowly
6 and intelligently so that I can make sure that I
7 understand what you are saying and be able to
8 address your question as -- as I should.

9 So please be -- be conscious that I need
10 you to speak slowly and make sure that I
11 understand. Thank you.

12 Q And if you have any questions about your
13 understanding, will you ask me for clarification?

14 A I will.

15 Q So if you don't ask me for
16 clarification, I'll assume that you understood my
17 question. Does that make sense?

18 A I will -- I may have to, you know,
19 iterate some question later on while I'm trying to
20 make up my mind that I do understand clearly what
21 you are asking for.

22 Q Now, Dr. Munafo, you understand that

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1 you're here today in connection with a declaration
2 that you submitted in a case that is brought by
3 TWi. Right?

4 A Yes, I do.

5 Q And you were previously deposed in
6 another case involving these same patents that was
7 brought by a company called Hopewell. Right?

8 A I had a deposition a couple of months
9 ago now in -- when -- in relation with an IPR
10 by -- with -- by Hopewell, yes.

11 Q Okay. And that was about March 27th
12 that you had that deposition?

13 A Sitting here today, I do not recall the
14 exact date, but it was a couple of months ago.

15 Q And just in terms of ground rules, we'll
16 be operating the same today. I'll ask questions,
17 I'll try to speak clearly and distinctly so that
18 you can understand. You'll need to give a verbal
19 response on the record so the court reporter can
20 write it down. There is a video recording being
21 made for backup, but the official record is the
22 written, stenographic record that the court

1 reporter provides. So it's very important to give
2 verbal answers, not just nod or shake your head.

3 Your counsel may object to some
4 questions, but unless you are given an instruction
5 not to answer, you'll need to go ahead and answer.
6 And there will be a ruling on any objections
7 later.

8 Do you have any questions about the
9 process this morning?

10 A No, I don't have any question at this
11 moment.

12 Q And where are you physically located for
13 your testimony this morning?

14 A So we are sitting here in a conference
15 room in a hotel in Divonne-les-Bains, which is in
16 France.

17 Q And you say "we are sitting here." Who
18 else is present with you?

19 A I am here together with Willem de Weerd,
20 who introduced himself --

21 Q And who is that?

22 A He introduced himself a moment ago. He

1 is working and representing Merck Serono and
2 RS Trading.

3 Q And I understand you have some copies of
4 exhibits there with you. Is that correct?

5 A This is correct.

6 Q What papers do you have with you?

7 A I have in front of me my declaration
8 with respect to TWi, Petitioner. I have the
9 so-called '947 patent. I have the so-called '903
10 patent. I have what we refer to as Bodor patent,
11 last three digit being '100 -- '101. I have the
12 product development and license agreement by and
13 between IVAX and RS Trading. I have the meeting
14 minutes of -- the minutes of the meeting hold in
15 August 2003 in Amsterdam, named Oral Cladribine
16 for MS Project. And I have the cladribine
17 briefing documents for review that's together with
18 the cover email, the cover email having a date of
19 December 17, 2003.

20 And this is all I have with me.

21 Q In preparing your declaration, did you
22 review any documents that are not cited in your

1 declaration?

2 MR. MCGUFFIN: I'm going to object to
3 privilege.

4 Dr. Munafo, to the extent you reviewed
5 anything by yourself, you can answer, but don't
6 reveal the contents of communications with
7 counsel.

8 THE WITNESS: So yes, I did.

9 BY MR. SEGREST:

10 Q And what documents did you review that
11 are not cited in your declaration?

12 MR. MCGUFFIN: I'm going to give the
13 same objection, the same instruction. You can
14 talk about anything you reviewed separately, but
15 you should not talk about what we -- what you
16 discussed with counsel.

17 MR. SEGREST: And I'll note for the
18 record that the witness is required to provide
19 whatever facts were sent by counsel. You can't
20 shield that as privileged. I'm not asking him
21 what you provided him, I'm not asking what he
22 provided himself. I'm asking him what he reviewed

1 and he's required to answer that.

2 MR. MCGUFFIN: So, Mr. Segrest, he is
3 definitely required to talk about the facts, but
4 asking specifically what documents he has looked
5 at could reveal communications with counsel. And
6 I'm just cautioning him not to reveal any
7 communications with counsel.

8 MR. SEGREST: But he has to say what
9 documents he's looked at without saying where he
10 got them from.

11 MR. MCGUFFIN: I don't necessarily
12 agree. I think anything that he reviewed himself
13 without counsel and anything that is cited in his
14 declaration, he can talk about. But I'm going to
15 instruct him not to reveal the contents of
16 communication with counsel.

17 BY MR. SEGREST:

18 Q You can answer the question, Doctor.

19 A I have reviewed a few documents, but
20 sitting here today, I'm not able to -- to give you
21 an exhaustive list.

22 Q Do you remember looking at any documents

1 that are not cited in your declaration?

2 MR. MCGUFFIN: I'm going to give the
3 same objection, the same instruction. Just don't
4 talk about the contents of communications with
5 counsel.

6 THE WITNESS: I have seen a few
7 documents, but sitting here today, I would not be
8 able to list exhaustively what I have seen or
9 reviewed.

10 BY MR. SEGREST:

11 Q So even if you can't give a complete
12 list, do you remember what any of those documents
13 are?

14 MR. MCGUFFIN: Same objection, same
15 instruction.

16 THE WITNESS: Sitting here today, I
17 would not be able to name precisely these
18 document. I would feel more at ease if you
19 present a document and ask me whether I have
20 reviewed or seen it before.

21 BY MR. SEGREST:

22 Q Yes. Doctor, I'm asking you about

1 things that were not cited in your declaration.

2 So I can't tell you what you didn't say.

3 Can you remember anything about those
4 documents that you did review that you chose not
5 to cite in your declaration?

6 MR. MCGUFFIN: Same objection, same
7 instruction.

8 THE WITNESS: Sitting here today, and
9 given the time lapse since I wrote this
10 declaration, I'm unsure of what I had seen by then
11 or after then. And I cannot give you -- cannot be
12 more specifically than that in total honesty and
13 being -- having sworn that I can tell the truth
14 and only the truth.

15 BY MR. SEGREST:

16 Q Other than your deposition for the
17 Hopewell IPRs, have you given any other testimony
18 about these patents? Given any other depositions
19 about these patents?

20 A I am going to ask you to repeat the
21 first part at least of your question to make sure
22 that I understand completely.

1 Q Yes. Other than your deposition in the
2 Hopewell IPRs, which we mentioned before, have you
3 given any other depositions about the '947 and
4 '903 patents?

5 A So yes, I have.

6 Q And when was that?

7 A Sitting here today, I am not able to
8 state the exact date, but this was within the last
9 few month.

10 Q And was that a deposition for a lawsuit
11 in federal district court in the United States?

12 MR. MCGUFFIN: Object to form.

13 THE WITNESS: Could you please repeat
14 your question?

15 BY MR. SEGREST:

16 Q Was that a deposition for a lawsuit
17 pending in federal district court in the United
18 States?

19 MR. MCGUFFIN: Object to form.

20 THE WITNESS: I'm not an expert in legal
21 terms, so I'm not sure how to address your
22 question precisely. Yet I have deposed in

1 relation with this case. And, again, excuse for
2 my naivete and lack of knowledge of legal terms,
3 but the terms "district court" was indeed
4 mentioned.

5 BY MR. SEGREST:

6 Q Let's turn to your declaration, which is
7 Exhibit 2053.

8 THE TECHNICIAN: Would you like that on
9 the screen, Counsel?

10 MR. SEGREST: I think the witness has a
11 copy of this. It may be useful to display a copy
12 so that we can make sure we're on the same page .

13 And let's go to page -- page number 25
14 at the bottom, but I think it's going to be the
15 26th page of the PDF. You're on the 27th page of
16 the PDF. That's page 25 at the bottom, 26th page.
17 Has paragraph 56 on it.

18 (MUNAFO Exhibit 2053 was marked for
19 identification.)

20 Q So, Dr. Munafo, are you at the page that
21 has the number 25 of your declaration?

22 A Yes, I see that.

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1 Q Is that your signature?

2 A Yes. This is -- this is my signature.

3 Q And where were you physically when you
4 signed this declaration?

5 MR. MCGUFFIN: Object to scope.

6 THE WITNESS: I was at home.

7 BY MR. SEGREST:

8 Q And where is home?

9 MR. MCGUFFIN: Object to scope.

10 THE WITNESS: I live in Switzerland. Do
11 you need the exact address?

12 BY MR. SEGREST:

13 Q No. So you were in Switzerland when you
14 signed this declaration. Is that correct?

15 MR. MCGUFFIN: Object to scope.

16 THE WITNESS: Yes, this is correct.

17 BY MR. SEGREST:

18 Q And just to be clear, you were outside
19 the United States when you signed this
20 declaration. Correct?

21 MR. MCGUFFIN: Objection; asked and
22 answered. Object to scope.

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1 THE WITNESS: I was in Switzerland.

2 BY MR. SEGREST:

3 Q Now, I'll direct you to paragraph 56,
4 the last paragraph of your declaration.

5 Do you see the first line there has a
6 statement that "all statements made herein of my
7 knowledge are true"?

8 A Yes, I do.

9 Q And then in the next line, you see
10 another clause and it says that "statements made
11 on information and belief are believed to be
12 true."

13 Do you see that?

14 MR. MCGUFFIN: Object to form.

15 THE WITNESS: I see the second line
16 reads, indeed, "and that all statements made on
17 information and belief are believed to be true."

18 And there's a continuation on that, yes,
19 I do.

20 BY MR. SEGREST:

21 Q Yes. So those statements made on
22 information and belief are not based on your

1 personal knowledge. Right?

2 MR. MCGUFFIN: Object to form.

3 THE WITNESS: Sitting here today, I am
4 not able to make a difference between information
5 that I have, belief that I have, and knowledge
6 that I have.

7 BY MR. SEGREST:

8 Q Let's go to paragraph 54 of your
9 declaration that begins on page 23.

10 Do you see this paragraph begins with
11 the phrase, "to the best of my knowledge"?

12 A I see on page 23 the paragraph 54
13 starting, "to the best of my knowledge," yes.

14 Q And the rest of this paragraph describes
15 work at IVAX. Right?

16 MR. MCGUFFIN: Object to form.

17 THE WITNESS: You are talking about the
18 rest of the whole paragraph 54?

19 BY MR. SEGREST:

20 Q Let's say the rest of that -- this
21 sentence. The rest of that first sentence is
22 about what IVAX did not design or develop. Right?

1 MR. MCGUFFIN: Object to form.

2 THE WITNESS: This whole sentence reads,
3 to make sure that I'm with you:

4 "To the best of my knowledge, IVAX did
5 not design or develop any regimen for treating MS
6 using cladribine, let alone the regimen of
7 administering 10-milligram of oral cladribine
8 tablets per day for five to seven days per month
9 for two months followed by a 10-month
10 cladribine-free period that I and my team at
11 Serono designed and communicated to IVAX before
12 February 2004."

13 BY MR. SEGREST:

14 Q All right. You did not work at IVAX.
15 Right?

16 MR. MCGUFFIN: Object to form.

17 THE WITNESS: I did not work at IVAX,
18 this is correct.

19 BY MR. SEGREST:

20 Q Now, you have information on which you
21 based a belief that this statement is true, but
22 you don't have personal knowledge of what IVAX did

1 and didn't develop. Right?

2 MR. MCGUFFIN: Object to form.

3 THE WITNESS: I do not have knowledge of
4 what IVAX was doing, but given the principle of
5 the collaboration, given what we shared at
6 meetings where IVAX was present, given the
7 agreed-upon distribution of responsibilities, and
8 given all what I understand and recall sitting
9 here today, it is my conviction that we at Serono
10 developed a dosing regimen, and that is mentioned
11 in this sentence. And that it was not developed
12 by IVAX.

13 BY MR. SEGREST:

14 Q You were in charge of a team of people
15 that were working at Serono. Right?

16 MR. MCGUFFIN: Object to form.

17 THE WITNESS: This is a vague question.
18 I would like you to clarify what you mean with --
19 whether this is in relationship with cladribine,
20 whether this is altogether my work at Serono, and
21 at what time you refer to.

22

1 BY MR. SEGREST:

2 Q In your work at Serono between 2001 and
3 2004, when it was developing a cladribine product,
4 you had a team that you worked with. Right?

5 A Between the period 2001 to 2004, I was
6 part of a team at Serono. A project team at
7 Serono that was working on developing oral
8 cladribine for the treatment of multiple
9 sclerosis.

10 Q Let me direct you to paragraph 18 of
11 your declaration on page 7.

12 That team at Serono included many people
13 other than the named inventors on the '947 and
14 '903 patents, didn't it?

15 MR. MCGUFFIN: Object to form.

16 THE WITNESS: The team at Serono
17 included experts and colleagues from various
18 expertise within Serono. And yes, it was larger
19 than the three co-inventors of the '947 and '903
20 patent.

21 BY MR. SEGREST:

22 Q Let me direct you to Exhibit 2049.

1 (MUNAFO Exhibit 2049 was marked for
2 identification.)

3 THE WITNESS: Can you let me know what
4 this is exhibit?

5 BY MR. SEGREST:

6 Q I think you referred to it as the
7 briefing document, and it's got a cover email.
8 It's the one displayed on the screen.

9 A I have it, yes, thank you.

10 Q And looking at this very first page,
11 which I think you've described as a cover email,
12 it has addresses for the sender, from, the
13 addressees, to, and the CC list for additional
14 recipients. Right?

15 MR. MCGUFFIN: Object to form.

16 THE WITNESS: This cover memo does,
17 indeed -- was initiated from Isabelle Emery and
18 lists a whole series of people either as
19 addressees or in CC, correct.

20 BY MR. SEGREST:

21 Q And Isabelle Emery was one of the people
22 on your team at Serono that you referenced in

1 paragraph 18 of your declaration. Right?

2 MR. MCGUFFIN: Object to form.

3 THE WITNESS: Sitting here today, I
4 cannot be sure of -- of the exact composition of
5 the team as it fluctuated to some extent along
6 the -- along the time. So being part of the team
7 is related to an exact time period. But, again,
8 sitting here today, I'm not able to address
9 formally your question.

10 BY MR. SEGREST:

11 Q Well, at the time of this email which
12 has a date of December 17th, 2003, 11:23:17 a.m.,
13 was Isabelle Emery on your team?

14 MR. MCGUFFIN: Object to form.

15 THE WITNESS: This is more than 20 years
16 ago, and sitting here today, I'm not able to say
17 exactly at what time Isabelle Emery or what month
18 Isabelle Emery was on the project team or not.

19 BY MR. SEGREST:

20 Q So is it your belief that this email was
21 distributed from and to people other than those
22 who were on that specific product team?

1 MR. MCGUFFIN: Object to form.

2 THE WITNESS: If I re- -- rephrase your
3 question to make sure I understand it correctly,
4 you are asking if all the addressees here, all the
5 people listed in the "to" or "CC" were part of the
6 Serono project team?

7 BY MR. SEGREST:

8 Q Okay. Let me ask a different question.
9 Looking at the email addresses, you can
10 see that some of them are listing Serono as the
11 organization for that person. Right?

12 MR. MCGUFFIN: Object to form.

13 THE WITNESS: In the list of people in
14 the "to," there -- and in the "CC," there are
15 several people listed with a Serono address.

16 BY MR. SEGREST:

17 Q Okay. And there are others like Yogesh
18 Dandiker in the recipient list who were at
19 different organizations. Right?

20 MR. MCGUFFIN: Object to form.

21 THE WITNESS: Yogesh Dandiker is listed
22 with a IVAX address.

1 BY MR. SEGREST:

2 Q Okay. Would this email have been sent
3 to people at Serono who were not on the team that
4 you describe in your declaration?

5 MR. MCGUFFIN: Object to form,
6 foundation.

7 THE WITNESS: This email was distributed
8 to the people listed in "to" and "CC." I am not
9 able to say here whether this has been distributed
10 to other people or seen by other people.

11 BY MR. SEGREST:

12 Q Are there people on the "to" and "CC"
13 list in the Serono organization that were not on
14 your team in December of 2003?

15 MR. MCGUFFIN: Object to form.

16 THE WITNESS: If I understand your
17 question, whether in the list of "to" and "CC"
18 people, there are people from Serono that are not
19 on the project team, I am not able, sitting here
20 today, to reply definitely because I do not
21 recall, as of today, who was on the team by that
22 date of December 2003.

1 BY MR. SEGREST:

2 Q So looking at the -- starting with the
3 "to" list of addressees, was Gordon Francis on the
4 team that you referred to?

5 A Inasmuch as I recall sitting here today,
6 Gordon Francis was involved in this -- in many
7 discussions that we had with this development
8 program. But, again, sitting here today, I do not
9 recall whether he was formally on the team or not.

10 Q Was Maria Lopez-Bresnahan on the team
11 that you testified about?

12 A Sitting here today I had -- I know that
13 Maria Lopez-Bresnahan has been working extensively
14 on this project, and I have collaborated with her,
15 but I am not able to say whether she was formally
16 part of the team or not.

17 Q Was Samir Shah on this team that you
18 testified about?

19 A Samir Shah was working on the cladribine
20 oral for treatment of MS, but sitting here today,
21 I'm not able to state whether he was formally on
22 the team at the date of December 2003.

1 Q Was Alain Micaleff on the team that you
2 testified about?

3 A Alain Micaleff has contributed and
4 worked on the project of development of oral
5 cladribine for the treatment of MS, but sitting
6 here today, I am not able to recall whether he was
7 formally on the product team as of the date of
8 December 2003.

9 Q Would your answer that you don't recall
10 if the person was on the product team at that time
11 be the same for the other email recipients listed
12 with a Serono email address?

13 MR. MCGUFFIN: Object to form.

14 THE WITNESS: Sitting here today more
15 than 20 years later, I do not recall, remember,
16 who was formally on the product team by that date.

17 BY MR. SEGREST:

18 Q And sitting here today, if you don't
19 remember who was on the team, you also don't
20 personally remember who made exactly what
21 contributions on the team. Right?

22 MR. MCGUFFIN: Object to form.

1 Objection; mischaracterizes testimony. Objection;
2 argumentative.

3 THE WITNESS: I'm sorry. I'm going to
4 ask my advise -- my counsel to repeat his
5 objection.

6 BY MR. SEGREST:

7 Q His objection should not affect your
8 answer, sir.

9 A I -- I just want to make sure that I
10 understand everything that is said during this
11 deposition please.

12 MR. MCGUFFIN: Yeah, Mr. Segrest is
13 right. You should answer. My objections are just
14 to note my objections on the record.

15 THE WITNESS: Okay. So excuse me for
16 this diversion. Could you please repeat your
17 question?

18 BY MR. SEGREST:

19 Q Sure. And I'm trying to read it from
20 the realtime.

21 And sitting here today, if you don't
22 remember who was on the team, you also don't

1 personally remember who made exactly what
2 contributions to the team. Right?

3 MR. MCGUFFIN: Same objections.

4 THE WITNESS: Sitting here today, I have
5 a good recollection of contribution I had with
6 several colleague at Serono. But I cannot list
7 exhaustively all the contribution that all
8 colleagues have had on this project.

9 BY MR. SEGREST:

10 Q Let's turn to the Exhibit 1001.

11 Dr. Munafo, the Exhibit 1001 is the '947
12 patent. Do you have that in front of you now?

13 A I have the -- a reprint of the '947
14 patent in front of me, yes. And I can see it on
15 screen.

16 (MUNAFO Exhibit 1001 was marked for
17 identification.)

18 Q And you're listed as the third-named
19 inventor on this patent. Right?

20 A The inventors are four, Giampiero De
21 Luca, Arnaud Ythier, myself, and Maria
22 Lopez-Bresnahan. I'm not aware whether the number

1 is relative or not.

2 Q And the first name on that list,
3 Giampiero De Luca, he's the chief intellectual
4 property counsel at Serono. Right?

5 MR. MCGUFFIN: Object to form.

6 THE WITNESS: Sitting here today and
7 more than 20 years later, I do not recall his
8 title at the company at that time.

9 BY MR. SEGREST:

10 Q Let's go back to your declaration,
11 Exhibit 2053. Go to paragraph 21 of your
12 declaration.

13 A Yes.

14 Q And here you testify that Dr. De Luca
15 was Serono's chief intellectual property counsel.
16 Did you not have a recollection of what his
17 position was when you gave this testimony?

18 MR. MCGUFFIN: Object to form.

19 THE WITNESS: My memory had been -- my
20 recollection has been refreshed by the time I
21 wrote this -- this declaration. And now that I
22 read what I wrote, I can positively answer your

1 previous question that, indeed, at that time
2 Giampiero De Luca was Serono's chief intellectual
3 property counsel.

4 BY MR. SEGREST:

5 Q And at the time you wrote your
6 declaration, what refreshed your recollection
7 about Dr. De Luca's title at Serono?

8 MR. MCGUFFIN: I'm just going to caution
9 you not to reveal the contents of communication
10 with counsel. If you recall a particular document
11 that refreshed your recollection, you can identify
12 it.

13 MR. SEGREST: And I'm going to state our
14 position that's an improper instruction because
15 refreshed recollection can't be privileged. But
16 we'll address that in the motions that are --
17 we'll be filing.

18 MR. MCGUFFIN: I think my instruction
19 was pretty clear. Just don't reveal the contents
20 of communication with counsel. But if you recall
21 any document that refreshed your recollection, you
22 can identify it.

1 THE WITNESS: Beside discussion with my
2 counsel, I do not recall of any document that
3 helped me refresh my memory.

4 BY MR. SEGREST:

5 Q So was that fact about what Dr. De
6 Luca's position was something that was
7 communicated to you by counsel?

8 MR. MCGUFFIN: Object; privileged.

9 I'm going to instruct you not to reveal
10 the contents of any communication with counsel.
11 Again, if you -- if you recall any document that
12 refreshed your recollection, you can identify it.

13 THE WITNESS: Sitting here today, I do
14 not recall any other document.

15 BY MR. SEGREST:

16 Q We can go back to Exhibit 1001 now, the
17 '947 patent. And we'll go to the second page of
18 this document, page 2 of 13. And I'm looking at
19 the column on the left under the heading "Other
20 Publications."

21 At the bottom of that column on the
22 left, do you see a publication of Rice from 2000?

1 A I see a publication authored by G. Rice,
2 et al., named Cladribine and progressive MS
3 clinical and MRI outcomes of a multicenter
4 controlled trial in "Neurology," March 2000,
5 page 1145 to 1155, Volume 54. Yes.

6 Q Let's go to Column 2 of the patent,
7 Line 45.

8 A So the page -- are you referring, sorry,
9 for the page -- page number, number 3?

10 Q It is page 3 of 13. And I'm referring
11 to Column 2, Line 45 and continuing from there.

12 A Yeah, I see this line.

13 Q And does this part of the specification
14 of your patent cite that Rice 2000 article?

15 A This sentence, Line 43 to 45, reads:

16 "In addition, placebo controlled phase
17 III study was conducted in patients with primary
18 progressive or secondary progressive multiple
19 sclerosis, Rice, et al., 2000, 'Neurology' 54, 5,
20 1145 to 1155."

21 Q And that's that Rice 2000 article that
22 was listed in the other publications we looked at.

1 Right?

2 A This -- this is the way we refer to a
3 publication. And yes, I understand it to be the
4 one we mentioned in the other publications on
5 page 2.

6 Q And then does the rest of that paragraph
7 indicate that in the Rice 2000 study, both patient
8 groups received a cladribine dose of
9 0.07 milligrams per kilogram per day repeated for
10 either two months or six months?

11 MR. MCGUFFIN: Object to form.

12 THE WITNESS: I'd like to read the exact
13 sentence. It says:

14 "In this study both patient groups
15 received cladribine by subcutaneous injection at a
16 dose of 0.07-milligram per kilogram per day. The
17 treatment was repeated for either two months or
18 six months."

19 BY MR. SEGREST:

20 Q And looking at the last sentence of the
21 next paragraph, which is Lines 56 through 58, this
22 again cites Rice 2000. Right?

1 MR. MCGUFFIN: Object to form.

2 THE WITNESS: The last sentence reads:

3 "Phase II study results were positive on
4 the significant reduction of MRI-measured brain
5 lesions, in parentheses, Rice, et al., 2000,
6 above, close parentheses."

7 BY MR. SEGREST:

8 Q Let's go to Exhibit 1008 please.

9 (MUNAFO Exhibit 1008 was marked for
10 identification.)

11 MR. MCGUFFIN: Object to scope. I don't
12 believe this was cited in Dr. Munafo's
13 declaration. Was it?

14 MR. SEGREST: It may not have been.

15 THE WITNESS: I don't think --

16 BY MR. SEGREST:

17 Q And, Doctor, I think you may not have a
18 copy of this in front of you, but do you see the
19 one that's displayed on the screen there?

20 A I see a -- the top of a page 1 of what
21 appears to be a publication by George P.A. Rice
22 and others. Name, "Cladribine and Progressive MS,

1 Clinical and MRI Outcomes of a Multicenter
2 Controlled Trial." And after the end of the
3 abstract, it says that this is published or
4 appears to be published in "Neurology" 2000,
5 Volume 54 page 1145 to 1155.

6 MR. MCGUFFIN: I'm going to renew my
7 objection to scope.

8 BY MR. SEGREST:

9 Q And this is the article cited in the
10 specification of your patent. Right?

11 MR. MCGUFFIN: Object to form; scope,
12 foundation.

13 THE WITNESS: I have not seen the whole
14 paper. I'm just here on the top of the first
15 page. But the reference seems to correspond to
16 the reference we quote in the patent '947.

17 MR. SEGREST: Can you show us the full
18 first page? Just the first page is fine.

19 Q And you can see this is marked as
20 Exhibit 1008. Right?

21 A I do not see this on the screen.

22 Q Do you see the bottom right hand of the

1 screen, it says EX1008?

2 A No, I do not see the bottom of the
3 screen.

4 Now I see it. I see there that it says
5 "Petitioner TWi Pharms, Inc. EX1008, page 1 of
6 11."

7 MR. SEGREST: If the technician could
8 put the full first page on the screen again for me
9 please.

10 Q Dr. Munafo, on your screen, what's the
11 lowest line in this document that you can see on
12 your screen?

13 A It's very small and I'm not sure I can
14 read it properly, but it seems to be partial line
15 received June 10 I think with a date I'm not sure
16 I can read and accepted in final form, November 1
17 with a date that is too small to be read fully.

18 Q Okay. So that'll give us an idea for
19 the technician of how much we need to zoom in for
20 you to be able to see a full page. Thank you.

21 I want to look now up in the abstract,
22 about the fifth line.

1 Do you see the line in the abstract that
2 the first characters on the left are "0.07"?

3 A I see this starting -- a line starting
4 by this, but I'm going to ask you to allow me just
5 a minute to put this in context and read quickly
6 the abstract.

7 Q Okay.

8 A Okay. I have read the -- the article
9 abstract and I'm ready to take your question
10 regarding the line starting with 0.07-milligram
11 per kilo per day.

12 Q Right. So is this describing two
13 cladribine arms of the Rice 2000 study, one with a
14 total dose of 0.7 milligrams per kilogram and
15 another with a total dose of 2.1 milligrams per
16 kilogram?

17 MR. MCGUFFIN: Object to form; scope,
18 foundation.

19 THE WITNESS: This is describing a study
20 with apparently three arms: One of a placebo, and
21 two arms with a dose of 0.7-milligram per kilo and
22 2.1-milligram per kilo, respectively.

1 BY MR. SEGREST:

2 Q And does it indicate that it achieves
3 the 0.7 milligrams per kilo and the 2.1 milligrams
4 per kilo by dosing for either two or six cycles,
5 respectively?

6 MR. MCGUFFIN: Object to form; scope,
7 foundation.

8 THE WITNESS: Other than interpreting
9 what it says, I'm going to read it again.

10 It says that the patient "were randomly
11 assigned to receive placebo or cladribine
12 0.07-milligram per kilo per day for five
13 consecutive days every four weeks for either two
14 or six cycles."

15 BY MR. SEGREST:

16 Q Every four weeks would be every 28 days.
17 Right?

18 A I would have to go through the detail of
19 the methodology in the paper to confirm whether in
20 this study, they considered a week of seven days
21 or some variance of it.

22 Q Let's turn to the second page of the

1 document. In the right-hand column, the paragraph
2 at the top of the page, this is the second full
3 sentence, which begins with the words "patients
4 were assigned."

5 Do you see that sentence, Doctor?

6 A I only see the second column to a part
7 of the word by "subcutaneou-" (ph.) And then I
8 have the screen with the video that hides -- okay.

9 MR. MCGUFFIN: And I'll renew my
10 objection to scope.

11 BY MR. SEGREST:

12 Q And do you now see the sentence that
13 begins with the words "patients were assigned"?

14 MR. MCGUFFIN: Objection to scope.

15 THE WITNESS: Are you referring to
16 the -- make sure I am with you -- to the sentence
17 on the sixth line of the column to the right?

18 BY MR. SEGREST:

19 Q Yes.

20 A Okay. So I read this sentence to make
21 sure.

22 "Patients were assigned to one of three

1 parallel treatment groups, in parentheses,
2 cladribine, 2.1mg per kilo, cladribine, 0.7mg per
3 kilo or placebo according to a computer-generated
4 randomization schedule stratified by baseline
5 disease severity and site."

6 Q Okay. Let's go to the last paragraph on
7 this column.

8 Do you see this paragraph with the
9 heading "study medications and dosage"?

10 MR. MCGUFFIN: Object to scope.

11 THE WITNESS: I can read a part of the
12 paragraph to the bottom of the page, which is
13 named in italics "study medications and dosage."

14 BY MR. SEGREST:

15 Q And does the second sentence indicate
16 that the total dose of 2.1 milligrams per kilo was
17 achieved by administering --

18 A Sorry. Can you point me again exactly
19 to where you want me to look at?

20 Q Yeah. I'm looking at the sentence that
21 begins "patients received six courses of
22 cladribine."

1 Do you see that sentence?

2 MR. MCGUFFIN: Object to scope.

3 THE WITNESS: I will read it for the
4 sake of making sure we are on the same one.

5 "Patients received six courses of
6 cladribine 0.07mg per kg per day SC for five
7 consecutive days, in parentheses, total dose 2.1mg
8 per kg, close parentheses, followed by two courses
9 of placebo or two courses of cladribine 0.07mg per
10 kg per day SC for five consecutive days,
11 parentheses, total dose, 0.7mg per kg, close
12 parentheses, followed by six courses of placebo or
13 eight courses of placebo SC for five consecutive
14 days."

15 Q Okay. And does that indicate that the
16 total 2.1mg per kilo was achieved by patients
17 receiving six courses of cladribine of 0.07mg per
18 kilogram per day for five consecutive days?

19 MR. MCGUFFIN: Object to form, scope and
20 foundation.

21 THE WITNESS: It reads what it reads,
22 that the author claimed that patient received six

1 courses of cladribine 0.07 manages per kilo per
2 day for five consecutive days subcutaneously with
3 a total dose being 2.1mgs per kilo. This is,
4 indeed, the author's claim.

5 BY MR. SEGREST:

6 Q Okay. And 0.07 times 5 times 6 is 2.1.
7 Right?

8 MR. MCGUFFIN: Object to scope.

9 THE WITNESS: I'm not able to do the
10 arithmetic by my head like this in such an
11 important instance.

12 BY MR. SEGREST:

13 Q Okay. Does it also indicate that the
14 total dose of 0.7mg per kilogram was administered
15 as two courses of cladribine 0.07 milligrams per
16 kilogram per day for five consecutive days?

17 MR. MCGUFFIN: Object to form, scope,
18 foundation.

19 THE WITNESS: The sentence says, "and
20 the author claimed that the patient received two
21 courses of -- in the -- in the second group, the
22 patient received two courses of cladribine 0.07mgs

1 per day SC for five consecutive dose -- five
2 consecutive days, in parentheses, total dose being
3 0.7mgs per kgs."

4 BY MR. SEGREST:

5 Q And 0.07 times 5 times 2 is 0.7. Right?

6 MR. MCGUFFIN: Object to scope.

7 THE WITNESS: Arithmetically, 0.07 times
8 5 times 2 equals 0.7. 0.07 times 5 times 2 equals
9 0.7.

10 BY MR. SEGREST:

11 Q And then one of those five-day cycles of
12 0.07 milligrams per kilograms per day, a patient
13 would receive 0.35 milligrams of cladribine.
14 Right?

15 MR. MCGUFFIN: Object to form, scope,
16 foundation.

17 THE WITNESS: Arithmetically, 0.07 times
18 5 is indeed equal to 0.35. Understanding
19 everything here for the arithmetic. For the rest
20 of the sentence, I'm not sure I got it totally.

21 BY MR. SEGREST:

22 Q Let's look at page 9. Scratch that.

1 We can set that one aside and go to
2 Exhibit 2050 now.

3 MR. MCGUFFIN: Yes.

4 (MUNAFO Exhibit 2050 was marked for
5 identification.)

6 BY MR. SEGREST:

7 Q I think you referred to these as the
8 August meeting notes.

9 MR. MCGUFFIN: Mr. Segrest, if you're
10 switching documents, would this be a good time for
11 a short break?

12 MR. SEGREST: Yeah, we can do that.
13 Five minutes? 10 minutes?

14 MR. MCGUFFIN: Five would be enough for
15 us.

16 Dr. Munafo, do you think five is enough?

17 THE WITNESS: Yeah, I think eight
18 minutes so I have time to go to the restroom.

19 MR. SEGREST: Let's say 10 to make it
20 easy.

21 THE WITNESS: Okay. Thank you.

22 MR. MCGUFFIN: See you back here at

1 8:20 Eastern.

2 (Whereupon, there was a recess in the
3 proceedings.)

4 BY MR. SEGREST:

5 Q Doctor, I want to direct you now to
6 Exhibit 2050, which I think you had referred to as
7 the "meeting minutes."

8 A I see on screen the document that I have
9 in front of me, yes. Thank you.

10 Q And does this document purport to be
11 minutes of a meeting held August 27th, 2003 in
12 Amsterdam?

13 MR. MCGUFFIN: Object to form.

14 THE WITNESS: The front page here is
15 named "Oral Cladribine for MS Project, meeting on
16 27 August 2003, Amsterdam." And the bottom says
17 that these are draft minutes.

18 BY MR. SEGREST:

19 Q Were you one of the Serono participants
20 in this meeting?

21 A In the meeting of August 2003, 27, in
22 Amsterdam, I am indeed listed as a participant.

1 Q And so are you basing your testimony on
2 seeing yourself listed as a participant in this
3 document? Is that how you know that you were a
4 participant in this meeting?

5 A No. I'm just confirming that I'm listed
6 as a participant, and I have no reason to believe
7 that that is in any way not representing the
8 truth.

9 Q But you're testifying about what's
10 printed on the document. You don't have any
11 present recollection of this meeting. Right?

12 MR. MCGUFFIN: Object to form.
13 Objection; mischaracterizes testimony.

14 THE WITNESS: You are speaking a little
15 fast. Can I ask you to please repeat your
16 question?

17 BY MR. SEGREST:

18 Q Yes. My question was, but you're
19 testifying about what's printed on the document.
20 And you don't have any present recollection of
21 this meeting. Right?

22 MR. MCGUFFIN: Object to form.

1 Objection; mischaracterizes testimony.

2 THE WITNESS: This is not what I was
3 saying. I was just confirming that I am listed as
4 a participant. I did not say that I do not recall
5 being present at that meeting.

6 BY MR. SEGREST:

7 Q Do you have a present recollection of
8 the meeting?

9 A Sitting here today and more than
10 20 years later, I have a partial recollection of
11 that meeting.

12 Q Looking at the document again, [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 MR. MCGUFFIN: Object to form.

17 Objection; asked and answered.

18 THE WITNESS: [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22

1 BY MR. SEGREST:

2 Q [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 MR. MCGUFFIN: Object to form.

6 THE WITNESS: To make sure I understand
7 completely your question, could you point me to
8 the paragraph you are -- you would be referring to
9 here?

10 BY MR. SEGREST:

11 Q Well, first, I'm asking about your
12 recollection of this -- what was happening at this
13 time. And if we need to, I can point you to
14 something later, but I want to get your answer
15 about your recollection.

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 MR. MCGUFFIN: Object to form.

21 THE WITNESS: [REDACTED]

22 [REDACTED]

1

[REDACTED]

2

[REDACTED]

3

[REDACTED]

4

[REDACTED]

5

BY MR. SEGREST:

6

Q Well, now let me direct you to page 4 of
7 this document, and we'll look at the paragraph
8 beginning at the top of the page there. [REDACTED]

9

[REDACTED]

10

[REDACTED]

11

A I'm with you on the top of the
12 page number 4 of the draft minutes.

13

Q [REDACTED]

14

[REDACTED]

15

[REDACTED]

16

MR. MCGUFFIN: Object to form.

17

Objection; mischaracterizes document.

18

THE WITNESS: [REDACTED]

19

[REDACTED]

20

[REDACTED]

21

[REDACTED]

22

1 BY MR. SEGREST:

2 Q Does that refresh your recollection that
3 at the time of this meeting in August 2003, [REDACTED]

4 [REDACTED]
5 [REDACTED]

6 MR. MCGUFFIN: Object to form.

7 THE WITNESS: [REDACTED]

8 [REDACTED]
9 [REDACTED]

10 BY MR. SEGREST:

11 Q Well, as you sit here today, do you
12 remember that yourself? Or are you just relying
13 on what the document says?

14 A As I said, [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]

21 Q And that sentence also indicates that [REDACTED]

22 [REDACTED]

1

[REDACTED]

2

[REDACTED] Right?

3

MR. McGUFFIN: Object to form.

4

THE WITNESS: [REDACTED]

5

[REDACTED]

6

[REDACTED]

7

[REDACTED]

8

BY MR. SEGREST:

9

Q And Yogesh is Yogesh Dandiker from IVAX.

10

Right?

11

A This is my understanding.

12

Q [REDACTED]

13

[REDACTED]

14

[REDACTED]

15

MR. McGUFFIN: Object to form.

16

THE WITNESS: [REDACTED]

17

[REDACTED]

18

BY MR. SEGREST:

19

Q [REDACTED]

20

[REDACTED]

21

[REDACTED]

22

MR. McGUFFIN: Object to form.

1 THE WITNESS: IVAX, according to the
2 license agreement, was in charge of developing a
3 formulation for oral administration of cladribine.
4 They have investigated various formulations and
5 strengths. [REDACTED]

6 [REDACTED]
7 [REDACTED]
8 [REDACTED]

9 BY MR. SEGREST:

10 Q [REDACTED]
11 [REDACTED]
12 [REDACTED]

13 MR. MCGUFFIN: Object to form.

14 THE WITNESS: I do not agree with this
15 statement. [REDACTED]

16 [REDACTED]

17 BY MR. SEGREST:

18 Q What's your understanding of the
19 difference between referring to strength and
20 referring to dose?

21 A The strength is, in my understanding,
22 relates to the amount of active ingredient in a

1 certain pharmaceutical form, while the dose is
2 what is administered or to be administered to a
3 patient in that case.

4 Q On that same page 4 of the document,
5 scroll down to about halfway down the page, and
6 you can look on the paper there.

7 Do you see a heading, "Expert Panel and
8 Phase III Design"?

9 A I see what is on screen and I have it in
10 front of me.

11 Q [REDACTED]
12 [REDACTED]

13 MR. MCGUFFIN: Object to form;
14 foundation.

15 THE WITNESS: [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]

20 BY MR. SEGREST:

21 Q [REDACTED]
22 [REDACTED]

1 A Sitting here today, I remember having
2 participated to that meeting, but the exact -- I
3 would not be able to give an exhaustive list of
4 everything that has been discussed.

5 Q [REDACTED]
6 [REDACTED]
7 [REDACTED]

8 MR. MCGUFFIN: Object to form.

9 THE WITNESS: [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]

13 BY MR. SEGREST:

14 Q And do you agree that that sentence is
15 accurate, that that's what happened at that expert
16 panel?

17 A To the best of my recollection, sitting
18 here today, more than 20 years later, I have no
19 reason to believe that this is not reflecting what
20 has indeed happened.

21 Q But sitting here today, more than
22 20 years later, [REDACTED]

1

[REDACTED]

2

[REDACTED]

3

[REDACTED]

4

MR. MCGUFFIN: Object to form; calls for
an opinion.

5

6

THE WITNESS: Sitting here today, more
than 20 years later, [REDACTED]

7

8

[REDACTED]

9

[REDACTED]

10

[REDACTED]

11

[REDACTED]

12

[REDACTED]

13

[REDACTED]

14

[REDACTED]

15

[REDACTED]

16

BY MR. SEGREST:

17

Q Could there be --

18

A But (indiscernible) were discussed.

19

Sorry.

20

Q I didn't mean to interrupt you, sir.

21

A (Indiscernible) --

22

Q Could there have been other things that

1 were discussed that you don't recall currently?

2 MR. MCGUFFIN: Sorry. I want to be
3 clear. It sounded like you accidentally cut off
4 Dr. Munafo again.

5 Did you have more to say, Dr. Munafo, or
6 were you done?

7 THE WITNESS: I would have to go back to
8 what I was saying before to -- to say definitely
9 whether I was done or not because my attention was
10 captured by the next question of the counsel.

11 BY MR. SEGREST:

12 Q Why don't I go ahead and ask you the
13 next question again.

14 So sitting here today, more than
15 20 years later, could there have been other things
16 discussed at that expert panel [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 MR. MCGUFFIN: Object to form; calls for
20 speculation.

21 THE WITNESS: I have difficulty to
22 answer a question if I recall what I do not

1 recall. Maybe you can rephrase your question.

2 BY MR. SEGREST:

3 Q [REDACTED]
4 [REDACTED]
5 [REDACTED]

6 A Yes, this is correct.

7 Q Those [REDACTED] experts are not Serono
8 employees. Right?

9 MR. MCGUFFIN: Object to form,
10 foundation.

11 THE WITNESS: To the best of my
12 recollection sitting here today, they were experts
13 and not employee by Serono.

14 BY MR. SEGREST:

15 Q And sitting here today, do you agree
16 that you can't recall everything that was
17 discussed at that expert panel?

18 MR. MCGUFFIN: Object to form.

19 THE WITNESS: Sitting here today, I
20 recall several point that were discussed. [REDACTED]

21 [REDACTED]
22 [REDACTED]

1

[REDACTED]

2

[REDACTED]

3

[REDACTED]

4

[REDACTED]

5

[REDACTED]

6

[REDACTED]

7

[REDACTED]

8

But it is true that more than 20 years

9

later, I cannot swear that I remember everything

10

that has been discussed or not discussed.

11

BY MR. SEGREST:

12

Q And after that paragraph, [REDACTED]

13

[REDACTED]

14

[REDACTED]

15

MR. MCGUFFIN: Object to form.

16

THE WITNESS: On page 4 of these minutes

17

under the paragraph [REDACTED]

18

[REDACTED]

19

[REDACTED]

20

[REDACTED]

21

[REDACTED]

22

1 BY MR. SEGREST:

2 Q And that first primary phase III study
3 suggestions has a row with the heading "Arms."

4 Right?

5 A I can see this -- this row, yes.

6 Q [REDACTED]

7 [REDACTED]

8 MR. MCGUFFIN: Object to form.

9 THE WITNESS: [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 The dose that are mentioned here as
16 0.7mgs per kilo and 2.1mgs per kilo were
17 targets -- were to be considered as target
18 exposure that we wanted to have for the patient in
19 the two -- in the two arms.

20 BY MR. SEGREST:

21 Q Right. And you wanted the cumulative
22 dose in each of those arms to approximate those

1 target exposures. Right?

2 MR. MCGUFFIN: Object to form.

3 THE WITNESS: When you say "you wanted,"
4 I'd like to clarify that these are -- this is a
5 summary of the presentation made in that meeting.
6 And when you say "you," I should specify that this
7 is not necessarily me that you refer to. Is this
8 correct?

9 BY MR. SEGREST:

10 Q Yes, that's correct. I'm asking you
11 what was intended in this description of the arms?
12 Was it intended that the cumulative dose
13 approximating 0.7 milligrams per kilogram would be
14 the target exposure in one arm?

15 MR. MCGUFFIN: Object to form.

16 THE WITNESS: In one arm, the target
17 exposure would accumulate to 0.7mgs per kilo as
18 0.35mgs per kilo times 5 days times 2 months.

19 BY MR. SEGREST:

20 Q But it says approximating 0.7 milligrams
21 per kilo. Right?

22 A It reads what it reads. I can read

1 it -- I can read approximating as well.

2 Q Okay. And it also -- in the other arm
3 or in the other cladribine arm, it says cumulative
4 dose again is approximating 2.1mgs per kilo.
5 Right?

6 MR. MCGUFFIN: Object to form.

7 THE WITNESS: Sitting here today, I do
8 not -- I'm not able to recall what -- what's the
9 meaning and intent between -- behind the word
10 "approximating" here. But it reads what it reads.

11 BY MR. SEGREST:

12 Q And 0.7mgs per kilo and 2.1mgs per kilo,
13 those are the total doses in each of those arms,
14 respectively, that are being approximated. Right?

15 MR. MCGUFFIN: Object to form.

16 THE WITNESS: I am not sure what your
17 use of the word that had been approximated. What
18 I'm reading here is that this cumulative dose
19 approximating 0.7mgs per kilo and 2.1mgs per kilo
20 were the two active treatment arms in addition to
21 the placebo arm.

22

1 BY MR. SEGREST:

2 Q And in each of those active treatment
3 arms, it wants to -- it says that it's going to
4 approximate those total doses. Right?

5 MR. MCGUFFIN: Object to form.

6 THE WITNESS: Again, the use of the term
7 "approximating" here, I am not able to recall,
8 sitting here today, what was the intent or meaning
9 of "it." But I'm not reading it in exact same
10 wording as you are using in your last sentence.
11 I'm reading it as really it reads here, that the
12 cumulative dose approximating 0.7mgs per kilo and
13 2.1mgs per kilo were the two active treatment arms
14 doses.

15 BY MR. SEGREST:

16 Q And a total dose of 0.7mgs per kilo is
17 the same total dose as in one of the arms of that
18 Rice 2000 study we looked at, isn't it?

19 MR. MCGUFFIN: Object to form; scope,
20 foundation.

21 THE WITNESS: Would you specify what you
22 mean with same dose here?

1 BY MR. SEGREST:

2 Q Well, one of the arms of the Rice 2000
3 study we looked at was 0.7mgs per kilo achieved by
4 two cycles of five days administration. Right?

5 MR. MCGUFFIN: Object to form; scope,
6 foundation.

7 THE WITNESS: I -- in what you call the
8 Rice paper, there was indeed a mention of -- of
9 such a dose and such doses in the study that they
10 report.

11 BY MR. SEGREST:

12 Q And the other cladribine arm in the Rice
13 2000 paper was a total dose of 2.1mgs per kilo
14 achieved by six cycles of five days. Right?

15 MR. MCGUFFIN: Objection; form, scope,
16 foundation.

17 THE WITNESS: In the Rice -- what you
18 call the Rice paper in "Neurology" 2000, there was
19 indeed an arm in the study that they report
20 communicating that dose of 2.1mgs per kilo
21 cumulative.

22

1 BY MR. SEGREST:

2 Q [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 MR. McGUFFIN: Object to form;
6 mischaracterizes testimony.

7 THE WITNESS: [REDACTED]

8 [REDACTED] Is it my
9 understanding of your question?

10 BY MR. SEGREST:

11 Q [REDACTED]

12 [REDACTED]

13 [REDACTED] Right?

14 MR. McGUFFIN: Object to form;
15 mischaracterizes testimony.

16 THE WITNESS: The process of designing
17 the clinical trial and its dosing regimen and the
18 process of -- and this -- this part was Serono
19 responsibility. And the process of developing a
20 formulation for oral cladribine, which was the
21 responsibility of IVAX, were two process that were
22 developed in parallel with a strong

1 superimposition of the timetable.

2 So IVAX was, at that time, developing
3 cladribine oral formulation in various strengths,
4 formulations and -- and, yes, strengths and
5 formulations and even pharmaceutical form, while
6 we at Serono were developing a clinical trial and
7 development plan.

8 BY MR. SEGREST:

9 Q Was --

10 A There is --

11 Q I'm sorry. I didn't mean to interrupt.

12 A There is a superimposition of the two
13 processes, but I do not recall, sitting here
14 today, that there has been -- that there was the
15 intention to use all formulation developed by
16 IVAX, but rather to select one to go into a
17 clinical trial and clinical development.

18 Q [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]

1 A Yes. I'm with you. [REDACTED]

2 [REDACTED]

3 Q [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 A It reads what you just said, yes.

7 Q Right. [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 MR. MCGUFFIN: Object to form.

13 THE WITNESS: In -- yes, my

14 understanding is that we -- [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

1

2 BY MR. SEGREST:

3 Q Okay. Let's go back to page 4 and the
4 arms again.

5 MR. SEGREST: Okay. So we're under
6 suggestions for primary phase III study, and the
7 third item on there says "Arms." Can you get us
8 to that?

9 THE WITNESS: Yes, I'm with you.

10 BY MR. SEGREST:

11 Q Okay. Now, the parentheses after 0.7mgs
12 per kilo says, ".35mgs per kilo multiplied by five
13 days multiplied by two months." Right?

14 A Right.

15 Q So there are two multiplication symbols
16 in that parenthetical. Right?

17 A There is mention of times 5 days times
18 2 month.

19 Q Okay. And after the 2.1mgs per kilo,
20 there's a parentheses that says, ".35mgs per kilo
21 multiplied by five days multiplied by six months."
22 Right?

1 A I can read it.

2 Q And that's correct. Right?

3 A Yeah, I can read what you said.

4 Q Okay.

5 MR. MCGUFFIN: Object to form.

6 BY MR. SEGREST:

7 Q And, again, there's two multiplication
8 symbols in that second parenthetical. Right?

9 A This parentheses says, ".35mgs per kilo
10 times 5 days times 6 months."

11 Q Okay. So looking back at the first
12 parenthetical, though, if you multiple .35 times
13 5 times 2, that would be 3.5mgs per kilo. Right?
14 Not 0.7mgs per kilo?

15 A .35 times 10 is 3.5. I think there is
16 a -- a mistake in this, the way it has been
17 written here.

18 Q Okay. And for the second one, if you
19 multiple .35 times 5 times 6, that would be
20 10.5mgs per kilo, not 2.1mgs per kilo. Right?

21 A I think that as in the first
22 parentheses, there have been a mistake in the way

1 the sign times -- the sign "X" has been used.

2 Q [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 A This sentence reports the exposure and
6 so the -- the dose as you put it, and not the
7 strengths.

8 Q [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 A I'm asking you to please repeat your
12 question. There is a bit of background noise
13 here.

14 THE WITNESS: Can we close the window --

15 BY MR. SEGREST:

16 Q Yes. [REDACTED]

17 [REDACTED]

18 [REDACTED] Right?

19 A This line on the paragraph mention the
20 dose, not the strengths.

21 Q Okay. [REDACTED]

22 [REDACTED]

1

[REDACTED]

2 A This line on the arms report the dose,
3 not the strengths.

4

Q Right. [REDACTED]

5

6

7 A Same response. The line on the arms
8 mention the dose, not the strengths.

9

10

11

12

13

Q So we've been looking at this language
under the heading "Expert Panel and Phase III
Design." Was the section before that which begins
on page 3 under the heading "Formulation progress
and patent issues"?

14

15

A So you are on page 3 of the draft
minutes?

16

Q Yes.

17

A Okay.

18

19

20

Q I just want to make the record clear
about what part we're looking at. This is
"Formulation progress and patent issues." Right?

21

A I can read this title bold, yes.

22

Q Okay. And this is the part that has the

1 language I was asking you about earlier about the

2 [REDACTED]
3 Right? It's on the next -- I'm not sure what's on
4 the screen now. I was on page -- yeah, [REDACTED]

5 [REDACTED]
6 [REDACTED] Right?

7 MR. MCGUFFIN: Object to form.

8 THE WITNESS: On the next page, there
9 are mention of -- [REDACTED]

10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]

19 Is this what you are referring to?

20 Q Yes.

21 A Thank you.

22 Q And then below that, you see a list of

1

[REDACTED]

2

A Yes.

3

Q Now, the last [REDACTED]

4

[REDACTED]

5

A [REDACTED]

6

[REDACTED]

7

[REDACTED]

8

[REDACTED]

9

[REDACTED]

10

Q Okay. [REDACTED]

11

[REDACTED]

12

[REDACTED]

13

[REDACTED]

14

MR. MCGUFFIN: Object to form.

15

THE WITNESS: [REDACTED]

16

[REDACTED]

17

[REDACTED]

18

[REDACTED]

19

[REDACTED]

20

That's what it reads.

21

BY MR. SEGREST:

22

Q And that language about [REDACTED]

1

[REDACTED]

2

[REDACTED]

Right?

3

A Yeah.

[REDACTED]

4

Q

[REDACTED]

5

[REDACTED]

6

A Sitting here today, I do not know.

7

Q Let's go back to the cover of the

8

document.

9

Do you see a blue stamp on this first

10

page that says "Serono International SA Corporate

11

IP Department"?

12

A I see a stamp with Serono International

13

SA with a date of 09 October 2003, and in small,

14

"Corporate IP Dept".

15

Q Do you know if there was somebody in the

16

corporate IP department

[REDACTED]

17

[REDACTED]

18

[REDACTED]

19

MR. MCGUFFIN: Object to form.

20

THE WITNESS: Sitting here today, no, I

21

do not know.

22

MR. MCGUFFIN: I'm about to move onto a

1 new document if y'all want to take another short
2 break now.

3 THE WITNESS: Yes, please. I would
4 appreciate.

5 (Whereupon, there was a recess in the
6 proceedings.)

7 BY MR. SEGREST:

8 Q So I want to turn now to Exhibit 2049,
9 which we looked at briefly earlier, which is what
10 you called the briefing document, I believe.

11 MR. MCGUFFIN: I don't think we looked
12 at that earlier, Counsel.

13 Oh, no. We did look at the first page.
14 Sorry.

15 BY MR. SEGREST:

16 Q Dr. Munafo, do you have that document?

17 A I have -- the document that is on screen
18 now, I have in front of me. Just to confirm, the
19 bottom says Merck 2049. Is that correct?

20 Q That's correct. Thank you.

21 A Yes. Then I have it in front of me.

22 Q Now, is this document from

1 December 2003?

2 A The date on the front page is 17 of
3 December, 2003.

4 Q Do you remember this document being from
5 December 2003?

6 A Sorry. Sitting here today, I do not
7 remember when I saw this document for the first
8 time, but I have seen it, and my memory has been
9 refreshed on it.

10 Q So in December 2003, clinical studies on
11 pharmacokinetics and bioavailability of the
12 contemplated oral dosage forms were still
13 underway. Right?

14 MR. MCGUFFIN: Object to form.

15 THE WITNESS: When you -- when you refer
16 to studies on bioavailability and the rest of your
17 sentence, could you please be more specific to
18 which one you are referring to?

19 BY MR. SEGREST:

20 Q I'll direct you to page 9 of 59 on this
21 document. And just for clarification, in the top
22 center, you'll see an indication of page 9 of 59.

1 There may be other page numbers at the bottom, but
2 I'm referring to those page numbers at the top.

3 And you see the fifth paragraph that
4 starts with the words "Serono partnered with
5 IVAX"?

6 A I see a paragraph starting like this.

7 Q And then in the second sentence, do you
8 see where it says that "two clinical studies to
9 study the pharmacokinetics and bioavailability of
10 three tablet and capsule oral formulations of
11 cladribine are currently being conducted in MS
12 patients"?

13 A I see -- I can read what you just read,
14 yes.

15 Q Okay. That's what I'm referring to when
16 I ask you: In December of 2003, do you recall
17 that studies on the pharmacokinetics and
18 bioavailability of the contemplated oral dosage
19 forms were still being conducted?

20 MR. MCGUFFIN: Object to form.

21 THE WITNESS: Sitting here today, that
22 long after, I recall that these studies were

1 conducted by IVAX. I do not have the precise
2 timetable of these two studies in mind. But the
3 sentence reads that they are currently being
4 conducted, referring to December 2003.

5 BY MR. SEGREST:

6 Q And you agree that the -- the oral
7 formulation of cladribine to be used in the
8 proposed phase III study in MS patients would be
9 selected based on the results of those trials?

10 MR. MCGUFFIN: Object to form.

11 THE WITNESS: These trials were designed
12 to inform on the characteristics of the -- of
13 various formulation and pharmaceutical form that
14 IVAX was developing. And provided that one would
15 meet -- that -- that -- no. Sorry. I strike
16 this.

17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]

1 BY MR. SEGREST:

2 Q The formulations that were being studied
3 included at least three different tablets in the
4 capsule oral formulation. Right?

5 A That sentence reads -- refer to three
6 tablet and capsule oral formulations of
7 cladribine.

8 Q Let's turn to the next page. This is
9 page 10 of 59. And I'm looking at the first full
10 paragraph on that page, the paragraph that starts
11 with [REDACTED]

12 [REDACTED]
13 [REDACTED]
14 [REDACTED]

15 A The whole sentence reads:

16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]

1 Q Let's turn to page 13 of 59.

2 Now, Doctor, [REDACTED]

3 [REDACTED]

4 MR. MCGUFFIN: Object to form.

5 THE WITNESS: This page on screen,

6 page 13 of 59, is [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED] the composition of various tablets
10 in a capsule.

11 BY MR. SEGREST:

12 Q [REDACTED]

13 [REDACTED] Right?

14 A [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 Q [REDACTED]

21 [REDACTED] Right?

22 A [REDACTED]

1

[REDACTED]

2

[REDACTED]

3

Q Right.

[REDACTED]

4

[REDACTED]

5

[REDACTED]

Right?

6

A

[REDACTED]

7

[REDACTED]

8

[REDACTED]

9

[REDACTED]

10

[REDACTED]

11

Q Let's turn to page 17 of 59. I'm

12

looking at the bottom of the page on this one.

13

[REDACTED]

14

[REDACTED]

15

[REDACTED]

16

MR. MCGUFFIN: Object to form.

17

THE WITNESS:

[REDACTED]

18

[REDACTED]

19

[REDACTED]

20

BY MR. SEGREST:

21

Q

[REDACTED]

22

[REDACTED]

1 [REDACTED] Right?

2 MR. MCGUFFIN: Objection; relevance.

3 THE WITNESS: Last paragraph on page 17
4 of 59 starts by mentioning [REDACTED]

5 [REDACTED] Yes, it mentions this.

6 BY MR. SEGREST:

7 Q And it refers [REDACTED]

8 [REDACTED]

9 [REDACTED] Right?

10 A [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 Q And you read the question mark that's in
17 parentheses. [REDACTED]

18 [REDACTED]

19 A Can you repeat your question?

20 Q Yes. [REDACTED]

21 [REDACTED]

22 [REDACTED]

1

[REDACTED]

2

[REDACTED]

3

[REDACTED]

4

A Sitting here today, I do not know. I do not recall why this was included, and I'm not the author of this section at least.

5

6

7

Q

[REDACTED]

8

[REDACTED]

9

[REDACTED]

10

[REDACTED]

11

A I see that on the screen, not on my print. But I see that on the screen.

12

13

Q That's not on your printed version?

14

A On the printed version, it is only in black-and-white, so there is something in gray, but I cannot tell you whether it is yellow or not.

15

16

17

Q

[REDACTED]

18

[REDACTED]

19

A I -- sitting here today, I can only comment that this was a document sent for review, and the various reviewers are listed on the second page of the cover letter. So it would be an

20

21

22

1 assumption, but I assume -- and, again, it is a
2 speculation. I insist on that. And I assume that
3 these are -- would mean that this was a point to
4 be reviewed.

5 Q Let's turn to page 25 of 59.

6 A I'm with you.

7 Q [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 MR. MCGUFFIN: Object to form.

11 THE WITNESS: [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 BY MR. SEGREST:

16 Q Right. [REDACTED]

17 [REDACTED]

18 [REDACTED] Right?

19 A I would not say that this is a
20 description because a description of a study is
21 much more complete and comprehensive than what is
22 mentioned here. This is a mention of other

1 trials.

2 Q Okay. [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED] Right?

8 MR. MCGUFFIN: Object to form.

9 THE WITNESS: Sentence -- you're
10 speaking fast, so I'm reading the sentence to make
11 sure we are on the same -- on the same page.

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 BY MR. SEGREST:

20 Q [REDACTED]

21 [REDACTED]

22 [REDACTED]

1 MR. MCGUFFIN: Object to form.

2 THE WITNESS: The first sentence of the
3 next paragraph reads:

4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]

9 BY MR. SEGREST:

10 Q [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]

16 [REDACTED] Right?

17 MR. MCGUFFIN: Object to form.

18 THE WITNESS: This is part of the
19 sentence.

20 [REDACTED]
21 [REDACTED]
22 [REDACTED]

1

[REDACTED]

2

[REDACTED]

3

BY MR. SEGREST:

4

Q

[REDACTED]

5

[REDACTED]

6

[REDACTED]

7

[REDACTED]

8

[REDACTED]

Right?

9

MR. MCGUFFIN: Object to form; scope,

10

foundation, mischaracterizes testimony.

11

THE WITNESS: When you say -- you ask

12

about was it the same regimen?

13

BY MR. SEGREST:

14

Q

Yes.

15

A

I am -- I am not sure the Rice paper

16

refers to both studies.

[REDACTED]

17

[REDACTED]

18

[REDACTED]

19

[REDACTED]

20

[REDACTED]

21

[REDACTED]

22

Q

Right. And Rice 2000 also was 0.07mgs

1 per kilo per day. Right?

2 MR. MCGUFFIN: Objection; form, scope,
3 foundation.

4 THE WITNESS: I -- is it possible to
5 quickly go back to the Rice paper --

6 BY MR. SEGREST:

7 Q Sure.

8 A -- to make sure that this is exactly it?

9 Q This is Exhibit 1008. It's the one that
10 you don't have there. And I think we can go to
11 the abstract again.

12 THE TECHNICIAN: Which page is that,
13 Counsel? Sorry.

14 MR. SEGREST: The first page. The
15 abstract.

16 Q And the fourth line, you see this is
17 also 0.07mgs per kilo per day?

18 A So here, to be precise, there is
19 reference of 0.07mgs per kilo per day for five
20 consecutive day every four weeks for either two or
21 six cycle, [REDACTED]

22 [REDACTED]

1

[REDACTED]

2

[REDACTED]

3

[REDACTED]

4

Q Right.

[REDACTED]

5

Rice 2000 also refers to administering this

6

0.07 milligrams per kilogram per day for five days

7

in each cycle. Right?

8

MR. MCGUFFIN: Objection; form, scope,

9

foundation.

10

THE WITNESS:

[REDACTED]

11

[REDACTED]

12

[REDACTED]

13

[REDACTED] the document of the

14

so-called Rice publication mention 0.07mgs per

15

kilo per day for five consecutive days every four

16

weeks for either two or six cycles followed by

17

placebo.

18

BY MR. SEGREST:

19

Q And both Rice 2000

[REDACTED]

20

[REDACTED]

21

[REDACTED]

22

[REDACTED] Right?

1 MR. MCGUFFIN: Objection; form, scope,
2 foundation.

3 THE WITNESS: [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED] And Rice arrives to a total dose of
8 0.7mgs per kgs or 2.1mgs per kilo, respectively.

9 BY MR. SEGREST:

10 Q Right. [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED] Right?

14 MR. MCGUFFIN: Objection; form, scope,
15 foundation.

16 THE WITNESS: The -- in the Rice paper,
17 there is the word "respectively," which is used to
18 demonstrate to -- to clarify that 0.7mgs per kg or
19 2.1mgs per kg refer to two cycle for the first one
20 and six cycle for the second one. [REDACTED]

21 [REDACTED]

22 [REDACTED]

1

[REDACTED]

2

[REDACTED]

3

[REDACTED]

4

[REDACTED]

5

BY MR. SEGREST:

6

Q Let's turn to page 35 of 59.

7

[REDACTED]

8

[REDACTED]

9

[REDACTED]

10

A I'm with you.

11

Q Okay. And there are three groups in

12

that study. Right?

13

MR. MCGUFFIN: Object to form.

14

THE WITNESS: [REDACTED]

15

[REDACTED]

16

[REDACTED]

17

[REDACTED]

18

BY MR. SEGREST:

19

Q [REDACTED]

20

[REDACTED]

21

Right?

22

MR. MCGUFFIN: Objection; form, scope,

1 foundation.

2 THE WITNESS: [REDACTED]

3 BY MR. SEGREST:

4 Q [REDACTED]

5 A [REDACTED]

6 Q Let me repeat the question for you.

7 A Yes, please.

8 Q [REDACTED]

9 [REDACTED]

10 [REDACTED] Right?

11 MR. MCGUFFIN: Objection; form, scope,
12 foundation.

13 THE WITNESS: [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 BY MR. SEGREST:

20 Q Right. [REDACTED]

21 [REDACTED]

22 [REDACTED]

1 [REDACTED] Right?

2 MR. MCGUFFIN: Objection; form, scope,
3 foundation.

4 THE WITNESS: [REDACTED]

5 [REDACTED]
6 [REDACTED] Could you go back to the Rice paper?
7 Because if it is -- they mention four weeks or 28
8 days. I don't remember.

9 Four weeks. So in Rice, it is four
10 weeks. [REDACTED]

11 [REDACTED]
12 [REDACTED]
13 MR. MCGUFFIN: I just want to note for
14 the record that halfway through that answer, the
15 tech switched to Exhibit 1008. And I want to note
16 for the record now we're looking at 2059. Excuse
17 me, 2049.

18 BY MR. SEGREST:

19 Q [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]

1

[REDACTED]

2

[REDACTED] Right?

3

MR. MCGUFFIN: Object to form; scope,
4 foundation, calls for an opinion.

5

THE WITNESS: The same response to what
6 I just gave on the previous statement.

7

BY MR. SEGREST:

8

Q The next page, [REDACTED]

9

[REDACTED]

10

[REDACTED]

11

Do you see that?

12

A [REDACTED]

13

[REDACTED] Yes.

14

Q [REDACTED]

15

[REDACTED]

16

[REDACTED]

17

[REDACTED] Right?

18

MR. MCGUFFIN: Objection; form, scope,
19 foundation.

20

THE WITNESS: When you say "also," can
21 you refer -- can you specify to what your "also"
22 refers to please?

1 BY MR. SEGREST:

2 Q [REDACTED]

3 [REDACTED]

4 Right?

5 MR. MCGUFFIN: Objection; form, scope,
6 foundation.

7 THE WITNESS: [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED] Sorry. Forget about.

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 BY MR. SEGREST:

15 Q Let's turn to page 47 of 59.

16 Now, is this where the draft begins to
17 address the phase III clinical trials that Serono
18 was considering?

19 MR. MCGUFFIN: Object to form.

20 THE WITNESS: The draft document that we
21 have in front of us here does have a Table 5.1-1
22 that is labeled -- named Synopsis of the Proposed

1 Phase III Design [sic].

2 BY MR. SEGREST:

3 Q And the last row on the page for that
4 Table 5.1-1, do you see that row has the title of
5 "Study Design"?

6 A Yes, I see that.

7 Q Okay. And does it indicate that the
8 treatment groups have two doses, high and low,
9 approximating cumulative doses of 2.1mgs per kilo
10 and 0.7mgs per kilo?

11 A I can read this -- this sentence for the
12 treatment groups.

13 Q And that's the same cumulative dose that
14 we saw in those other studies we looked at,
15 MS-001, Scripps-B, and Rice 2000. Right?

16 A Numerically, the numbers of 0.7mgs per
17 kg and 2.1mgs per kg as we saw in the previous
18 page on the screen. So just numerically, yes, now
19 I read that this is high and low approximating
20 cumulative doses of 2.1 and --

21 MR. MCGUFFIN: And I want to note
22 objection --

1 THE WITNESS: -- 0.7.

2 MR. MCGUFFIN: Sorry. I didn't mean to
3 cut you off. I just was noting objections to
4 form, scope, foundation.

5 BY MR. SEGREST:

6 Q And this entry in the table continues on
7 the next page, page 48 of 59. Do you see the
8 heading "Duration of treatment"?

9 A I read that.

10 Q And does this indicate for the duration
11 of treatment that there are three phases?

12 MR. MCGUFFIN: Object to form.

13 THE WITNESS: Definition of "phase"
14 being vague, I will just read what is written
15 here.

16 Duration of treatment, first phase,
17 dash, six cycles, in parentheses,
18 high/low/placebo, period. Second phase, slash,
19 re-treatment, dash, six cycles, parentheses,
20 low/low/placebo, period. Third phase, slash,
21 re-treatment, dash, six cycles, low/low/low.

22

1 BY MR. SEGREST:

2 Q So that lists three phases. Right?

3 A Yes. I just said definition of "phase"
4 is vague. But three -- there are three phases as
5 described here that are mentioned in this duration
6 of treatment.

7 Q And it also describes three arms in each
8 of those three phases. Right?

9 MR. MCGUFFIN: Object to form.

10 THE WITNESS: The cycles are mentioned
11 as being six cycle, and a parentheses
12 high/low/placebo for the first phase.
13 Low/low/placebo for the second phase. And
14 low/low/low for the third phase.

15 BY MR. SEGREST:

16 Q So all three phases say that it's six
17 cycles. Right? That's the same for all three
18 phases?

19 MR. MCGUFFIN: Object to form.

20 THE WITNESS: Six cycles are mentioned
21 for each phase with a definition of a cycle being
22 five-day course of treatment during a 28-day

1 period.

2 BY MR. SEGREST:

3 Q Okay. And in the first phase, the six
4 cycles have a high arm, a low arm, and a placebo
5 arm. Right?

6 MR. MCGUFFIN: Object to form.

7 THE WITNESS: This is what it -- it
8 reads.

9 BY MR. SEGREST:

10 Q And then in the second phase, the first
11 arm changes from high to low, the second arm is
12 still low, and the third arm is still placebo.
13 Right?

14 MR. MCGUFFIN: Object to form.

15 THE WITNESS: This is what it -- it
16 reads. But I would like to comment here and put
17 in context that when we have six cycle mentioned
18 here, and I take the example of first phase, my
19 recollection is that this was six cycles of active
20 drug for the high, it was two cycles of active
21 drug and four cycles of placebo for the low, and
22 six cycle of placebo for the placebo.

1 BY MR. SEGREST:

2 Q It doesn't say that here, does it?

3 A It may not say it here, but it is my
4 recollection.

5 Q And then for the third arm, the third
6 phase --

7 A Sorry. Sorry. Sorry. I was not
8 finished. I was not finished.

9 It doesn't say here, but this is my
10 recollection. And on page 49 on the blinding, it
11 says -- so "assignment to treatment groups" row,
12 "blinding" in the parentheses, it does say that
13 low-dose patient receive placebo to fill out a
14 high-dose cycle.

15 So it may not be said on page 48 under
16 duration of treatment, but this is clearly
17 designed -- clearly described on page 49 on the
18 blinding.

19 Q Okay. Now --

20 A And it is --

21 Q You need to answer my questions instead
22 of volunteering other information. We're going to

1 get to that --

2 MR. MCGUFFIN: Mr. Segrest, he was --

3 BY MR. SEGREST:

4 Q -- discussion of blinding.

5 A No. I was finishing my answer.

6 MR. MCGUFFIN: Mr. Segrest, he was
7 answering your question. You interrupted him.

8 MR. SEGREST: With respect, Asher, he
9 was not. He had answered my question and then
10 said, "I want to make an additional comment,"
11 which is not appropriate on cross-examination.

12 MR. MCGUFFIN: Mr. Segrest, just because
13 he paused and you may or may not have liked what
14 he said does not mean he was done answering. I
15 think the record is extremely clear that he wanted
16 to add context and felt it was important to
17 understand his answer, and I don't appreciate you
18 trying to cut my witness off.

19 MR. SEGREST: I don't appreciate --

20 MR. MCGUFFIN: And I would ask --

21 MR. SEGREST: -- your witness trying to
22 say I want to add an additional comment that's not

1 responsive to the question. We can move on. We
2 are going to talk about all of that.

3 MR. MCGUFFIN: Excuse me. That was
4 clearly responsive. And it is the witness's right
5 to give as clear an answer as he wants to. I
6 don't appreciate you interrupting him when he
7 paused. And if you want to ask another question
8 now, you're free to do so.

9 BY MR. SEGREST:

10 Q So this description "duration of
11 treatment," it doesn't say anything here about
12 using placebos during the low cycle. Right?

13 MR. MCGUFFIN: Objection.

14 THE WITNESS: The section on duration of
15 treatment is part of a synopsis that is almost
16 four pages long and has to be seen in the
17 entirety. And I'm not willing to extract a single
18 word when, in fact, it is described elsewhere in
19 complement to -- and it has to be seen in its
20 totality.

21 BY MR. SEGREST:

22 Q So, again, my question is there's

1 nothing in this duration of treatment portion that
2 we're looking at that talks about administering a
3 placebo during the low-dose cycle, is there?

4 MR. MCGUFFIN: Objection; asked and
5 answered.

6 THE WITNESS: There is nothing in that
7 row, but it is clearly mentioned in another row of
8 the same table on the synopsis of the proposed
9 phase III study.

10 BY MR. SEGREST:

11 Q Let's turn to page 49 of 59.

12 Do you see the row labeled "Study
13 Treatment"?

14 A Yes, I'm with you.

15 Q And do you see the line that says
16 "strength"?

17 A Yes, I'm with you.

18 Q And it gives three different strengths,
19 right? 0, 3 and 10 milligrams. Right?

20 A At the time of this draft for proposed
21 phase III study, the various strengths or the
22 strengths to be used had not been defined yet, and

1 there are indeed on this line reporting strengths
2 the possibility of 0 and 10-milligram of active
3 treatment dose -- strength. Sorry.

4 Q It doesn't say 0, 3, or 10 milligrams.
5 It says 0, 3, and 10 milligrams, doesn't it?

6 MR. MCGUFFIN: Object to form.

7 THE WITNESS: [REDACTED]

8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]

15 BY MR. SEGREST:

16 Q Do you think that you didn't know if you
17 were going to use a 0 or a 3 or a 10? Is that
18 your testimony today?

19 MR. MCGUFFIN: Object to form.

20 THE WITNESS: So 0 is placebo. Whether
21 we were going to use 3 and/or 10-milligram, to the
22 best of my recollection at the time of that and

1 sitting here today, I do not recall that the
2 decision had been taken.

3 BY MR. SEGREST:

4 Q [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED] Right?

9 MR. MCGUFFIN: Object to form.

10 THE WITNESS: [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 BY MR. SEGREST:

15 Q [REDACTED]

16 [REDACTED] the next line says it's going to have
17 a 0-milligram, a 3-milligram, and a 10-milligram
18 strength, doesn't it?

19 MR. MCGUFFIN: Object to form;
20 mischaracterizes document.

21 THE WITNESS: The 0-milligram is
22 referring to the placebo, and then the 3 and the

1 10 milligrams are two strengths that IVAX was
2 investigating at that time and of which decision
3 had not been taken which one to pursue for
4 clinical development and clinical trial.

5 BY MR. SEGREST:

6 Q But this lists two different strengths
7 that are going to be used in addition to the
8 placebo in a clinical trial which corresponds to a
9 high and low-dose in the two arms, doesn't it?

10 MR. MCGUFFIN: Object to form;
11 mischaracterizes testimony and document.

12 And I think this has been asked and
13 answered, Philip.

14 MR. SEGREST: I don't think this one
15 has.

16 THE WITNESS: According to my reading of
17 this -- of this, and, again, I'm -- I have
18 attempted through this discussion to differentiate
19 dose and strength, which in my understanding of
20 your question, you put together.

21 So can you perhaps repeat your question?
22

1 BY MR. SEGREST:

2 Q 0 milligrams is the placebo. Right?

3 A I understand it this way.

4 Q And 3 milligrams would be a lower dosage
5 strength than 10 milligrams. Right?

6 MR. MCGUFFIN: Object to form.

7 THE WITNESS: The strength is
8 3-milligram for the 3-milligram, 10-milligram for
9 the 10-milligram. That arithmetically 3 is less
10 than 10, I agree.

11 BY MR. SEGREST:

12 Q And 3 milligrams administered in five
13 days for six cycles would be a lower cumulative
14 dose than 10 milligrams administered in five days
15 for six cycles. Right?

16 MR. MCGUFFIN: Object to form.

17 THE WITNESS: My understanding and
18 recollection of the design we proposed there was
19 that as described in the "duration of treatment"
20 as well as in the "blinding" section, the low-dose
21 and the high-dose were differentiated by the
22 number of cycle, not by the strengths of the

1 medication.

2 BY MR. SEGREST:

3 Q And that does not answer my question.

4 My question was, 3 milligrams dosage
5 strength administered in five days for six cycles
6 would be a lower cumulative dose than
7 10 milligrams dosage strength administered in five
8 days for six cycles. Right?

9 MR. MCGUFFIN: Object to form; scope,
10 relevance.

11 You're right he didn't answer your
12 question. But I think your question seems
13 irrelevant in view of his answer.

14 MR. SEGREST: Well, objection's noted,
15 but let's not make longer speaking objections.

16 Q You can answer my question now.

17 A Arithmetically, you want to make a
18 calculation, and your calculation is correct in
19 terms of, again, arithmetic. But not in terms of
20 the definition that we had for low and high dose
21 in that synopsis.

22 Q So the -- where are -- are you -- back

1 up.

2 There's nothing supporting your
3 definition of low and high dose in the portion of
4 the synopsis labeled "Study Design." Right?

5 MR. MCGUFFIN: Object to form; asked and
6 answered.

7 THE WITNESS: I need you to please
8 repeat your question. You were speaking a little
9 bit --

10 BY MR. SEGREST:

11 Q Yeah. There's --

12 A -- fast.

13 Q -- nothing supporting your definition of
14 low and high dose in the portion of the synopsis
15 that is the study design, is there?

16 MR. MCGUFFIN: Object to form; asked and
17 answered.

18 THE WITNESS: I have addressed my
19 position on that earlier, that synopsis has to
20 look -- to be looked in its totality. This is
21 four pages here, and even if it is not mentioned
22 in the row on "Study Design," it is mentioned in

1 the row on assignment to treatment group under
2 blinding.

3 BY MR. SEGREST:

4 Q Well, let's look at that row,
5 "assignment to treatment group." The first line
6 there is assignment of subject ID numbers. Right?

7 A First line is assignment of subject ID
8 numbers, central randomization.

9 Q And central randomization, assignment of
10 subject ID numbers has nothing to do with the
11 treatment regimen. Right?

12 MR. MCGUFFIN: Object to form; scope,
13 relevance.

14 THE WITNESS: I cannot agree to this
15 statement. Randomization to a ID number links
16 directly to -- to the treatment groups. So I
17 cannot agree with what you were saying.

18 BY MR. SEGREST:

19 Q But it doesn't affect the definition of
20 the treatment regimens for each arm, does it?

21 MR. MCGUFFIN: Object to form.

22 THE WITNESS: Randomization is a

1 procedure of assignment of the study ID number and
2 does not have -- and refers to the patient group
3 in this sense. The treatment group.

4 As you will see from the second bullet
5 that randomization should ensure equal
6 distribution to all treatment groups.

7 BY MR. SEGREST:

8 Q And isn't blinding how the study
9 prevents the subjects from knowing to which
10 treatment group they are assigned?

11 MR. MCGUFFIN: Object to form; scope,
12 foundation.

13 THE WITNESS: Blinding is an element of
14 relevance to ensure that neither the patient know
15 the treating physician, as in this case it is
16 double blinding, would know which treatment the
17 patient was assigned to.

18 BY MR. SEGREST:

19 Q And the blinding process as described of
20 filling out high-dose cycles is in part how
21 blinding was achieved in studies like Rice 2000.
22 Right?

1 MR. MCGUFFIN: Objection; form, scope,
2 foundation.

3 THE WITNESS: This synopsis, the design
4 of the clinical trial, the dosing regimen, was a
5 comprehensive process encompassing knowledge and
6 expertise from within the company from information
7 that was obtained either publicly or
8 confidentially of knowledge about the disease,
9 knowledge about the clinical trial in multiple
10 sclerosis, about its feasibility, about potential
11 recruitments, about -- knowledge about the
12 pharmacokinetics, the pharmacodynamics, the course
13 of the disease, relationship between endpoints.

14 And the list is not exhaustive, but it
15 does include information that was gathered, as I
16 said, either from publication or confidentially.
17 And to this sense, the -- the dose -- dosing
18 regimen that you mention and keep referring to in
19 the Rice paper were part of this -- I would not
20 accept to say the word "relying on," but part of
21 the elements that we considered in designing the
22 dosing -- the study in its totality is reflected

1 into the four pages that you have here on the
2 synopsis of the phase III design -- on the
3 proposed phase III design.

4 BY MR. SEGREST:

5 Q The Rice 2000 study indicated that each
6 arm included eight cycles. Right?

7 MR. MCGUFFIN: Objection; form, scope,
8 foundation.

9 THE WITNESS: What you call the Rice
10 paper 2000 mention indeed doses, total doses, and
11 principle of cycles. And it -- as I said, this
12 was part of the elements, among many others, that
13 we have used in designing this trial and the
14 dosing regimen.

15 BY MR. SEGREST:

16 Q And in Rice 2000, and in Scripps-B, and
17 in MS-001, all of those, it said that it achieved
18 the 2.1 milligrams per kilo total dose by
19 administering the dose for six cycles of the
20 active dose. Right?

21 MR. MCGUFFIN: Objection; form, scope,
22 foundation.

1 THE WITNESS: It says that the dose --
2 the total dose was achieved by giving cladribine
3 parenterally for the duration and repetition of
4 cycles. This is true. Yet as I said, this is
5 only one of the elements, given that confidential
6 and publicly available information were all looked
7 together to develop our proposal.

8 BY MR. SEGREST:

9 Q And in Rice 2000 and in Scripps-B, it
10 expressly says that the lower cumulative dose
11 comes from two cycles of administering the active
12 ingredient. Right?

13 MR. MCGUFFIN: Object to form; scope,
14 foundation.

15 THE WITNESS: I would have to go back to
16 the exact text of Rice and Scripps study. But the
17 principle of achieving the total dose by
18 administering the dose for a certain duration
19 repeated 28 days or one month later, depending
20 where it comes from, is what could be read in the
21 reference you mentioned.

22

1 BY MR. SEGREST:

2 Q And --

3 A But -- but this is not the only element
4 that we took into consideration when designing
5 this dosing regimen for our proposed development
6 and clinical study.

7 Q And neither Rice 2000 nor Scripps-B, nor
8 MS-001 included three different strengths for
9 their dosage, did they?

10 MR. MCGUFFIN: Objection; form, scope,
11 foundation.

12 THE WITNESS: Sitting here today, I do
13 not recall the detail of the strengths that were
14 used in Rice, Scripps studies, given the
15 formulation that they had used.

16 BY MR. SEGREST:

17 Q Okay. In this four-page synopsis,
18 Table 5.1-1, there is nowhere that says the low
19 dosage arm is two months of active ingredient, is
20 there?

21 MR. MCGUFFIN: Object to form; asked and
22 answered.

1 THE WITNESS: I disagree. In page 49 of
2 59, "assignment to treatment group, blinding,
3 parentheses, low-dose patient received placebo to
4 fill out high-dose cycle."

5 So it is clearly said.

6 BY MR. SEGREST:

7 Q Where does it say "two months" in what
8 you just read to me?

9 MR. MCGUFFIN: Object to form.

10 BY MR. SEGREST:

11 Q I mean, we can have the tech give you
12 control of the screen if you want to highlight
13 where it says "two months."

14 A It is my reading and understanding and
15 recollection that when we say -- we said in this
16 synopsis, which, again, has to be seen in its
17 totality, that we define six cycle
18 high/low/placebo, second phase of six cycle,
19 low/low/placebo. And then we say in the blinding
20 that low-dose patients receive placebo to fill out
21 high-dose cycles.

22 And then it says in the treatment

1 regimen, three phases -- next row, three phases,
2 five-day consecutive dosing within 28-day cycles
3 for six-cycle phase. That this is indeed exactly
4 what we had proposed and -- and designed
5 thereafter in -- in -- in our development plan and
6 clinical study.

7 So, again, I have to look into this in
8 its totality and not just one line by one line to
9 say that I confirm that this is what we had
10 proposed and shared with -- within the company at
11 meetings where IVAX representatives were present.

12 Q Okay. Looking at the synopsis as a
13 whole -- I don't think you answered my question --
14 where does this synopsis say that a low dose is
15 two months administering the active ingredient?
16 Point me to the words "two months."

17 MR. MCGUFFIN: Objection; form, asked
18 and answered.

19 MR. SEGREST: It's been asked. It
20 hasn't been answered.

21 THE WITNESS: I don't see how I can
22 answer your question better than what I just did,

1 so I will -- I will not repeat my -- my exact
2 answer. But I repeat the principle of it.

3 It is my recollection that in the
4 synopsis that we have in front of us that was
5 shared with IVAX that we planned to send to the
6 health authority, we have here it's written, but
7 it has been discussed orally at meetings, the
8 principle of this is that low treatment were to
9 receive two cycles followed by -- of treatment of
10 active medication followed by four cycles of
11 placebo, while the high-dose patient were to
12 receive six cycle of active treatment and the
13 placebo were to receive six cycles of placebo.

14 This is what we have described by the
15 five-day consecutive dosing within 28-day cycles
16 for six cycles, what we have described in saying
17 that the low-dose patient receive placebo to fill
18 out high-dose cycles, and when we describe the --
19 the six-cycle phase in the duration of treatment
20 that I have read already several times.

21 BY MR. SEGREST:

22 Q Right. And none of that that you have

1 read includes the words "two months," does it?

2 MR. MCGUFFIN: Objection; form, asked
3 and answered.

4 THE WITNESS: I think, with all due
5 respect, that I have already answered this
6 question twice.

7 BY MR. SEGREST:

8 Q Well, the words "two months" do not
9 appear in this synopsis, do they?

10 MR. MCGUFFIN: Object to form.

11 Mr. Segrest, I think the document speaks
12 for itself. I think the --

13 MR. SEGREST: Don't make a speaking
14 objection.

15 THE WITNESS: Although the words "two
16 months" may not appear in the synopsis as written
17 in this briefing document, it has been shown to
18 the project team and to the Joint Development
19 Committee and that the principle by which we
20 wanted to differentiate the low-dose and the
21 high-dose was that the low-dose were to get two
22 successive months of treatment followed by four

1 months of placebo, while the high-dose were to
2 receive six cycles of active treatment.

3 BY MR. SEGREST:

4 Q Now, two months of active treatment
5 followed by four months of placebo is the same as
6 those other studies we've looked at. Right?
7 Rice 2000, Scripps-B?

8 MR. MCGUFFIN: Objection; form, scope,
9 foundation.

10 THE WITNESS: The word "same" is -- if
11 the word "same" is referring to the arithmetic,
12 I -- I would not object. But the regimen that we
13 have designed here included much more than just
14 consideration of the Rice paper.

15 BY MR. SEGREST:

16 Q Sure. I mean, there's more to it. But
17 two months of active ingredient and four months of
18 placebo is not a part that you invented. Right?
19 That was something that was already disclosed in
20 Rice, in Scripps, and in other references?

21 MR. MCGUFFIN: Objection; form, scope,
22 foundation, calls for an opinion and a legal

1 conclusion.

2 THE WITNESS: The invention on the
3 dosing regimen is -- is described in the -- in our
4 patents, and includes all the aspects that -- that
5 are mentioned there, including the dose, the
6 duration, the frequency, and the repetition of --
7 on the second year. All of this is part of the
8 invention altogether, and I cannot comment on Rice
9 elements, but only on the totality.

10 This was a process that required a lot
11 of experience, expertise, integration of knowledge
12 from -- from our understanding of the course of
13 the disease, our understanding of the patient
14 suffering from MS, our understanding of the
15 pharmacokinetic, of the pharmacodynamic, of the
16 intermediate endpoints, and ultimately, of the
17 clinical endpoints as well and integrating
18 information that we got both from
19 publicly-available sources like the publication
20 you keep mentioning, but also from confidential
21 information that we received. And all of this
22 contributed to the invention, and not a factor in

1 isolation.

2 BY MR. SEGREST:

3 Q Looking at your declaration in
4 Exhibit 2053. Do paragraphs 39 through 49 of your
5 declaration concern this Exhibit 2049 that we've
6 been looking at?

7 MR. MCGUFFIN: Object to form.

8 THE WITNESS: So I'm with you on my
9 declaration, page 17, with the header starting B,
10 December 2003 Briefing Document.

11 BY MR. SEGREST:

12 Q Do any of these paragraphs, 39 through
13 49, discuss the 3-milligram dosage strength that's
14 described in the briefing document, Exhibit 2049?

15 A Sorry. I think I misunderstood --
16 misunderstand what you just said. Are you talking
17 that it refers to the 3-milligram?

18 Q Yes. Is there any testimony in
19 paragraphs 39 through 49 about the 3-milligram
20 dosage strength that's recited in the briefing
21 document, Exhibit 2049?

22 MR. MCGUFFIN: Object to form.

1 THE WITNESS: I -- I can -- I can read
2 again these numerous pages that you referred to.
3 But I am requiring you to confirm that you
4 strictly want me to comment on referring to
5 3-milligram strengths?

6 BY MR. SEGREST:

7 Q Yes. I don't know of anything in this
8 section that refers to the 3-milligram strengths,
9 do you?

10 MR. MCGUFFIN: Object to form.

11 THE WITNESS: So in my declaration,
12 paragraph 39 to 49, I do not mention the
13 3-milligram strengths.

14 MR. SEGREST: Okay. We can take another
15 short break if y'all want to.

16 MR. MCGUFFIN: That works well for us.
17 Five minutes?

18 MR. SEGREST: Sure.

19 (Whereupon, there was a recess in the
20 proceedings.)

21 BY MR. SEGREST:

22 Q Dr. Munafo, let's look back at your

1 declaration again. That's Exhibit 2053.

2 And does paragraph 6 of your declaration
3 refer to the Bodor PCT application?

4 A Yes.

5 Q And is the Bodor PCT application
6 WO 2004/087101?

7 A When I -- I'm referring to the Bodor
8 application, it has indeed 2004/0871002A2 as an
9 application number.

10 Q You said 1002 with A2 as the number. I
11 believe it does say WO 2004/87101 for the Bodor
12 PCT?

13 A Yes. And then it has a label A2 which
14 I -- this is why I said A2 at the end.

15 But yes, it is '101.

16 Q And looking at paragraph 7, does this
17 paragraph quote some language from Bodor that
18 appears in both another disclosure document and
19 you say the Bodor PCT contains the same language?

20 MR. MCGUFFIN: Object to form.

21 THE WITNESS: Can you please repeat your
22 question? I've lost --

1 BY MR. SEGREST:

2 Q Yeah. Sorry. You see the block quote
3 in paragraph 7 of your declaration?

4 A Yes.

5 Q And in the sentence after that, you say
6 the Bodor PCT contains that same language that's
7 in your block quote?

8 MR. MCGUFFIN: Object to form.

9 THE WITNESS: I am in the paragraph 7
10 says Bodor 328 includes the following disclosure
11 of a regimen for treating multiple sclerosis using
12 cladribine.

13 Is that what you're referring to?

14 BY MR. SEGREST:

15 Q No, sir. I was asking about actually
16 the Bodor PCT which you mention in the sentence
17 after the block quote.

18 Doesn't that sentence after the block
19 quote say "the Bodor PCT contains the same
20 language"?

21 A Can you point this on the screen? It
22 will help me, because I'm not with you.

1 Q So the -- after the --

2 A After that.

3 Q -- block quote, do you see the sentence,
4 "The Bodor PCT contains the same language"?

5 A Yes, I see that sentence.

6 Q Okay. And in the Bodor PCT, it cites
7 page 23, lines 15 through 20. Right?

8 A This is what it reads here, so I would
9 have to go back to the -- to the initial document.

10 Q Okay. Let's go to Exhibit 1001, the
11 '947 patent.

12 I'll direct you to Column 6, Line 24.
13 In Column 6, Line 24, do you see the citation to
14 WO 2004/87101?

15 A I'm sorry. I'm not used to this
16 numbering. So I need to go very slowly. And if
17 you want to highlight something very specific, you
18 need to let me know. Because as I said I'm --
19 first, you start to speak a bit fast again, and
20 then I'm not used to this numbering. So.

21 Q Yes, sir. So I'm on Column 6.

22 A Yes.

1 Q Are you at Column 6?

2 And the line numbers are down the middle
3 of the page there. So I'm looking at Line 24 of
4 Column 6.

5 A Yes.

6 Q And do you see the citation to WO 0 --
7 I'm sorry -- WO 2004/087101?

8 A I do.

9 Q And that is the Bodor PCT application
10 from paragraphs 6 and 7 of your declaration.
11 Right?

12 A Yes, it is.

13 Q So you and your co-inventors were aware
14 of the Bodor PCT application when you filed this
15 application. Right?

16 A Sorry. You went fast at the beginning
17 of your sentence. I'm sorry. I'm --

18 Q I'll try to speak more clearly.

19 A Thank you.

20 Q You and your co-inventors were aware of
21 the Bodor PCT application when you filed the
22 application for this patent. Right?

1 MR. MCGUFFIN: Object to form.

2 THE WITNESS: I -- sitting here today, I
3 cannot speak for my co-inventors. [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 BY MR. SEGREST:

8 Q But you cited to it here in your patent
9 application. Right?

10 MR. MCGUFFIN: Object to form.

11 THE WITNESS: This -- I'm sorry to --
12 just I have to inform you that we have a
13 technician entering into the room, so I hold my
14 response by just a few seconds.

15 Okay. Technician is -- is away now.

16 So I can see that in our patent
17 application, the so-called Bodor patent is
18 mentioned, but I did not write every single
19 paragraph of our patent. And I particularly did
20 not write this section here.

21 BY MR. SEGREST:

22 Q I'm going to direct you to Column 12,

1 Line 9.

2 Sorry. And at Column 12, Line 9 of
3 Exhibit 101 --

4 A Yes.

5 Q Or 1001, the '947 patent. Here again
6 you cite the Bodor patent. Right?

7 MR. MCGUFFIN: Object to form.

8 THE WITNESS: In Line 9 of Column 12 of
9 our -- of the '947, I can indeed see the number of
10 WO 2004/087101.

11 BY MR. SEGREST:

12 Q And in Column 14, Line 44, you again
13 cite to the Bodor PCT application. Right?

14 A On Line 44 on --

15 Q Column 14?

16 A Column 14?

17 Q Column 14. Yes, sir.

18 A Sorry? What did you say?

19 Q Column 14, Line 44, you again cite to
20 the Bodor PCT application. Right?

21 A This is what I was about to reply. On
22 Line 44 of Column 14 of the '947, indeed we

1 mention again the Bodor application.

2 MR. MCGUFFIN: And just object to form.

3 BY MR. SEGREST:

4 Q And in that same -- and in that same
5 column down at Line 62, this is in a little bit
6 smaller script, it's right below Table 2. But you
7 again cite to the Bodor PCT application. Right?

8 A When you say "you," do you mean me
9 personally or do you mean it is cited in this
10 application? Because I did not write that part.

11 MR. MCGUFFIN: Object to form.

12 BY MR. SEGREST:

13 Q I mean you and your co-inventors. You
14 read the application that was filed. Right?

15 MR. MCGUFFIN: Object to form.

16 THE WITNESS: [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 BY MR. SEGREST:

21 Q But somebody who wrote this patent
22 clearly had seen it. Right?

1 MR. MCGUFFIN: Object to form.

2 BY MR. SEGREST:

3 Q Because they cite to it?

4 A I cannot speak for the other author. 

5 

6 Q And you understand that as one of the
7 inventors, you're responsible for reading your
8 specification and you submit an oath that refers
9 to that. Right?

10 A I'm sorry. You speak --

11 MR. MCGUFFIN: Object to form.

12 THE WITNESS: -- too fast again.

13 BY MR. SEGREST:

14 Q Sure. You understand that as one of the
15 named inventors, you're responsible for the
16 specification of your patent, and you submit an
17 oath including a statement that you're -- you've
18 read it?

19 MR. MCGUFFIN: Object to form.

20 THE WITNESS: I understand that this
21 patent has been written by colleagues and
22 co-inventors at Serono. I cannot comment, sitting

1 here today, on who wrote which section and who
2 reviewed what application. I can only comment
3 that I did not by that time.

4 BY MR. SEGREST:

5 Q Let's open up Exhibit 1003.

6 (MUNAFO Exhibit 1003 was marked for
7 identification.)

8 MR. MCGUFFIN: Object to scope. I don't
9 believe Exhibit 1003 is cited in Dr. Munafo's
10 declaration.

11 BY MR. SEGREST:

12 Q Dr. Munafo, do you see on the cover that
13 this document is a file wrapper and contents of
14 application for Patent Number 7,713,947?

15 A I -- I'm not familiar with this kind of
16 document, not at all. So I am seeing an
17 application number, patent number, issue date.

18 So what is your question?

19 Q Well, that patent number on the cover is
20 for the '947 patent. Right? It's for the patent
21 that's Exhibit 1001?

22 A The patent number that is here on the

1 front page corresponds to the -- our U.S. Patent
2 '947, yes.

3 Q Okay. And let's turn to page 16 of 822
4 in the document.

5 MR. MCGUFFIN: Object to scope.

6 BY MR. SEGREST:

7 Q And Dr. Munafo, do you see that on this
8 information disclosure statement by applicant,
9 citation F1, down under the foreign patent
10 documents, is the Bodor PCT application. Right?

11 A I'm --

12 MR. MCGUFFIN: Object to scope.

13 THE WITNESS: Not with you. Information
14 disclosure and statement by applicant. I see a
15 write up which says "complete if known." Then
16 there is another box which is U.S. Patent
17 documents, which is essentially empty. And
18 foreign patent document? This is what you refer
19 to?

20 BY MR. SEGREST:

21 Q Yes, sir.

22 A So yes, I see -- I see that there is

1 reference to the '101 patent.

2 Q Let's go to page 385 out of 822.

3 MR. MCGUFFIN: Object to scope.

4 THE WITNESS: I'm sorry. I need
5 clarification. What -- what is the document that
6 we look at? Because I only saw the -- the first
7 page and I don't know what it is in here, and I
8 have seen pages out of -- out of the blue. I
9 don't know what -- what is this document. Can you
10 clarify for me please?

11 BY MR. SEGREST:

12 Q So let's go back to the cover page. So
13 you see that sentence there:

14 "This is to certify that annexed is a
15 true copy from the records of this office of the
16 file wrapper and contents of," and then it gives
17 the application number, filing date, patent
18 number, and issue date?

19 A I can see this, but, as I said, I'm not
20 at all familiar with -- with this kind of
21 document.

22 Q Yes, sir.

1 A So this is -- I saw that there are
2 several hundred pages long. That is correct?

3 Q That's correct. So what this document
4 is is a certified copy from the Patent Office of
5 the whole history of the correspondence between
6 the applicants, including you, your legal
7 representative, and the Patent Office, that led to
8 the issue in this patent.

9 And, like I said, there's hundreds of
10 pages, there's lots of stuff in it. I've just got
11 a few parts that I'm going to ask you about.

12 A Thank you for the clarification.

13 Q So I think I directed us to page 385 of
14 822.

15 Now, have you seen this kind of document
16 before?

17 A You mean about this -- this -- this --

18 Q This page.

19 A -- this very long document here --

20 Q I mean this page.

21 A -- or this page? This page?

22 Q This kind of correspondence from the

1 Patent Office?

2 MR. MCGUFFIN: Object to scope and form.

3 THE WITNESS: To the best of my
4 recollection, if I have seen it, I don't remember
5 it. This is very unfamiliar to me.

6 BY MR. SEGREST:

7 Q Okay. Let's flip over to page 388 out
8 of 822. This is authored by the examiner. Do you
9 see that item 6 there cites to the Bodor PCT
10 application?

11 MR. MCGUFFIN: Object to form; scope.

12 THE WITNESS: This is a page I have no
13 idea where it comes from. You are -- and I don't
14 know what it refers. This is a communication of
15 Serono with the Patent Office? Or vice versa?

16 BY MR. SEGREST:

17 Q This is a communication -- this
18 particular document is a communication from the
19 Patent Office to Serono or to your legal
20 representative that was handling this patent.

21 And my question is you see that on this
22 page, right there, item 6, it cites to the Bodor

1 PCT application?

2 MR. MCGUFFIN: Object to scope, form.

3 THE WITNESS: I can -- yeah, I can see
4 reference to Bodor application in this paragraph
5 starting number 6.

6 BY MR. SEGREST:

7 Q Okay. And on the next page, there's a
8 sentence that starts "alternatively." No, sorry.
9 The -- the third line, it says "in particular."

10 And it -- there's a sentence there after
11 the words "in particular" that the examiner writes
12 down something that he says "Bodor teaches."
13 Right?

14 MR. MCGUFFIN: Object to form; scope,
15 foundation.

16 THE WITNESS: I'm seeing on the screen a
17 four-line sentence starting by in particular,
18 Bodor teaches, et cetera, all the way to followed
19 by 10 months of no treatment.

20 That's the sentence you want to refer
21 to?

22 Q Uh-huh.

1 A So I can see it.

2 Q And then further down on that page --

3 A Sorry?

4 Q Further down on that page, the ninth
5 line, you see cites to page 23, lines 7 through
6 24?

7 MR. MCGUFFIN: Objection; scope.

8 THE WITNESS: You need to point me to
9 where you're looking at. Because I'm lost.

10 Q Sure. Can you see the parentheses?

11 A And it's very small on my screen.
12 Sorry.

13 Q Sorry. I'm trying to direct you to what
14 I'm looking at.

15 Do you see the parentheses on -- I think
16 it's the ninth line.

17 A Okay.

18 Q And --

19 A There's a parentheses saying "see
20 page 23, lines 7 through 24."

21 Q Right.

22 A Okay.

1 Q So you see it's citing to the Bodor PCT
2 application page 23, lines 7 through 24. Right?

3 MR. MCGUFFIN: Objection; form, scope,
4 foundation.

5 THE WITNESS: I see a whole sentence
6 saying that, "Alternatively, the patient may be
7 treated with 10 milligrams of cladribine in the
8 dosage form once per day for a period of five to
9 seven days per month for a total of six months,
10 followed by eighteen months of no treatment, see
11 page 23, lines 7 through 24."

12 BY MR. SEGREST:

13 Q And that citation, page 23, lines 7
14 through 24 of the Bodor PCT, includes the same
15 passage that you quote from in paragraph 7 of your
16 declaration. Right?

17 MR. MCGUFFIN: Objection; form, scope.

18 THE WITNESS: This is referring to
19 the -- to the '101 patent, so let me just check on
20 page 23.

21 BY MR. SEGREST:

22 Q No, sir. The page 23, lines 7 through

1 24 is referring to the -- the Bodor PCT
2 application, not the '947 patent. So I don't want
3 you to be confused there. You're not going to
4 find --

5 A Oh, the '101?

6 Q You're not going to find this in -- yes,
7 the '101, which is, I think is Exhibit 1007.

8 But what I'm asking you really is this
9 citation, page 23, lines 7 through 24. Doesn't
10 that cover the same citation you have in
11 paragraph 7 of your declaration for the language
12 you quote from the Bodor PCT application?

13 MR. MCGUFFIN: Object to form.

14 BY MR. SEGREST:

15 Q Which was page 23, lines 15 through 20?

16 MR. MCGUFFIN: Object to form; scope.

17 THE WITNESS: I'm a bit lost with all
18 this references. So.

19 BY MR. SEGREST:

20 Q Let me see if I can simplify it some.
21 Have you got your declaration there?

22 A Yes.

1 Q The paper copy of it?

2 A Yes.

3 Q And if you can go to the sentence after
4 paragraph 7, the one I pointed you to, the one
5 that says "the Bodor PCT contains the same
6 language"?

7 A On page 7, you said?

8 Q It's paragraph 7, it's on page 3.

9 A Ah, sorry. Sorry.

10 Bodor PCT contains the same language.

11 Just before paragraph 8, right?

12 Q Right.

13 A Okay.

14 Q And you see it cites to page 23,
15 lines 15 through 20?

16 A Yeah.

17 Q So that citation is included within this
18 citation to page 23, lines 7 through 24 in
19 Exhibit 1003 on page 389 of 822. Right?

20 MR. MCGUFFIN: Object to form; scope.

21 THE WITNESS: So just to make sure, this
22 reference on screen, page 23, lines 7 to 24, is

1 the -- the -- is the -- the Bodor PCT is the same
2 as the Exhibit 1007 that we have in -- in my
3 declaration?

4 BY MR. SEGREST:

5 Q Yes, and that's why I was asking you
6 about the citations to -- do you want to go back
7 to the previous page where it says WO 2004/087101?

8 A Okay. So you are asking whether the
9 number 15 to 20 are included in the range 7 to 24?

10 Q Yes, sir.

11 A Arithmetically, yes.

12 MR. MCGUFFIN: Object to scope.

13 BY MR. SEGREST:

14 Q Let's go to page 405 out of 822.

15 Doctor, have you seen examples of
16 responses to office actions that gets filed in the
17 U.S. Patent Office like this one?

18 MR. MCGUFFIN: Objection to form, scope.

19 THE WITNESS: You speak -- you speak too
20 fast and not directly --

21 BY MR. SEGREST:

22 Q I apologize.

1 Doctor, have you ever seen before
2 examples of responses to office actions like this
3 one that get filed in the U.S. Patent Office?

4 MR. MCGUFFIN: Object to form; scope.

5 THE WITNESS: Again, this is one page,
6 and I don't know if it is the first page or
7 something else in this 822 pages. But I am not
8 familiar with this kind of document.

9 BY MR. SEGREST:

10 Q Let's go to page 415 of 822.

11 And in the -- not the quote at the top
12 of the page, but the paragraph that starts "with
13 regard."

14 A What --

15 Q Last two lines of it.

16 A Yeah, I can see that paragraph, but I
17 have no idea where we stand in context of this
18 paragraph, so you need -- this is page 11 of a
19 document that I -- I don't know what it is about.

20 Q Okay.

21 MR. MCGUFFIN: And object to scope.

22

1 BY MR. SEGREST:

2 Q Okay. But you see that it says that:

3 "Bodor fails to teach a cladribine-free
4 period of between 8 and 10 months followed by a,
5 quote, maintenance period, close quote, during
6 which a cladribine formulation is administered
7 such that the total dose administered in the,
8 quote, maintenance period, close quote, is lower
9 than the total dose first administered to the
10 patient which is then followed by another
11 cladribine-free period."

12 Do you see that?

13 MR. MCGUFFIN: Object to form; scope,
14 foundation.

15 THE WITNESS: I -- I mean, I -- I can
16 read what you just read.

17 BY MR. SEGREST:

18 Q Okay. As far as you know, during the
19 prosecution that issued as the '947 patent,
20 neither you nor any of the other applicants ever
21 argued to the Patent Office that you were the
22 source of this disclosure in Bodor. Right?

1 MR. MCGUFFIN: Object to form; scope,
2 foundation, relevance.

3 THE WITNESS: I -- sitting here today, I
4 can only speak for myself, not for anyone else.
5 And for my -- and myself, I have not been involved
6 in any discussion, argumentation with -- with the
7 Patent Office.

8 BY MR. SEGREST:

9 Q Okay.

10 We can close that and go back to
11 document 2053, your declaration.

12 I'm looking at paragraph 3 on page 1.
13 So, Doctor, are you being paid for your time on
14 this case at a rate of 450 Swiss francs per hour?

15 A If your question is whether I'm
16 compensated for the time in preparing this
17 declaration and being here today at 450 Swiss
18 francs per hour, my response is yes, this is
19 correct.

20 Q And how much have you been paid in that
21 compensation?

22 MR. MCGUFFIN: Object to form.

1 THE WITNESS: As you asked the question
2 earlier today, I have been deposing on several
3 instances. And I have not kept records of the
4 time spent on any of -- of this. And in
5 particular, not on that one.

6 BY MR. SEGREST:

7 Q Do you know the total amount you've been
8 paid?

9 A No --

10 MR. MCGUFFIN: Object to form.

11 THE WITNESS: -- I have not -- I have
12 not kept such records.

13 BY MR. SEGREST:

14 Q Were you being paid at the same rate on
15 those other two proceedings as you are here?
16 450 Swiss francs per hour?

17 MR. MCGUFFIN: Object to form.

18 THE WITNESS: Yes, I have.

19 BY MR. SEGREST:

20 Q How many hours did you spend preparing
21 your declaration in this case?

22 MR. MCGUFFIN: Object to form.

1 THE WITNESS: The process of writing
2 this declaration spread over a certain duration,
3 time duration. And I have not kept records on the
4 specificities of neither the amount nor the time
5 spent on this specific declaration.

6 BY MR. SEGREST:

7 Q Did you submit an invoice that indicated
8 how many hours you had spent in preparing your
9 declaration in order to be paid?

10 MR. MCGUFFIN: Object to form.

11 THE WITNESS: I have submitted invoices,
12 yes. But sitting here today, I am not able to
13 describe on which topic I have invoiced in any
14 detail.

15 BY MR. SEGREST:

16 Q Okay. But it would be true that you
17 have made records of it, but you don't remember
18 today what the amounts are. Right?

19 MR. MCGUFFIN: Object to form.

20 THE WITNESS: I made invoices stating
21 the duration of my time spent on the case
22 altogether, not necessarily separated by one IPR

1 or the other.

2 BY MR. SEGREST:

3 Q Look at paragraph 32 of your
4 declaration.

5 And that first sentence, do you see the
6 testimony that your team at Serono and the team at
7 IVAX exchanged numerous emails and documents?

8 A I can read that the sentence says, "In
9 addition to formal meetings of the Joint
10 Development Committee, my team at Serono and the
11 team at IVAX exchanged numerous emails and
12 documents." Yes.

13 Q Have you retained copies of any of those
14 emails and documents that were exchanged?

15 A No, I have not.

16 Q Okay. Other than Exhibits 2048, 49, and
17 50, did you look at any such emails and documents
18 that were exchanged in the process of preparing
19 your declaration?

20 MR. MCGUFFIN: Object to privilege.

21 I'm going to instruct you not to discuss
22 the contents of any communications with counsel.

1 To the extent you looked at any documents not with
2 counsel, you can answer.

3 THE WITNESS: Can you then repeat your
4 question?

5 BY MR. SEGREST:

6 Q Other than Exhibits 2048, 49, and 50,
7 did you look at any such emails and documents that
8 were exchanged in the process of preparing your
9 declaration?

10 MR. MCGUFFIN: Object; privileged.

11 I'm going to instruct you not to discuss
12 the contents of any communications with counsel.
13 To the extent you looked at any documents
14 separately from counsel, you can answer.

15 THE WITNESS: I have not reviewed any
16 document outside of discussion with my counsel --
17 with my counsels.

18 BY MR. SEGREST:

19 Q Let's look at paragraph 53.

20 Do you see it says that communications
21 from your team at Serono included but were not
22 limited to these two documented communications,

1 referring to Exhibit 2049 and 2050?

2 A I can read paragraph 53, yes.

3 Q Okay. Now, you haven't cited to or
4 otherwise provided any copies of those other
5 communications. Right?

6 MR. MCGUFFIN: Object to form.

7 THE WITNESS: I did not get the first
8 word of your sentence. Excuse me.

9 BY MR. SEGREST:

10 Q Sorry.

11 You say these other communications are
12 there, but you don't discuss those in your
13 declaration, do you?

14 MR. MCGUFFIN: Object to form.

15 THE WITNESS: I'm sorry. I must get
16 tired. I'm going to have to request to repeat
17 again your question. I'm sorry.

18 BY MR. SEGREST:

19 Q Sure.

20 This part of your testimony refers to
21 other communications other than Exhibits 2049 and
22 2050, but you don't cite to those other

1 communications anywhere in your declaration, do
2 you?

3 MR. MCGUFFIN: Object to form.

4 THE WITNESS: The communication with --
5 within Serono and with IVAX was inquest to be open
6 and free. This was -- we were instructed that
7 this was a co-development between Serono and --
8 and IVAX. So the flow of information and -- that
9 we exchanged with -- with -- with the other party
10 was not restricted.

11 And sitting here today, I can't list all
12 of them. What I remember is that we had free
13 exchange and presented our design, for example,
14 freely to -- to meetings where IVAX
15 representatives were present either in person or
16 remotely that we shared as you have seen in the --
17 we shared the briefing document with them. We had
18 an open mindset in terms of collaboration and
19 co-development.

20 But to be specific to your question, I
21 cannot recall, sitting here today, of a specific
22 slide deck or something like that. I can recall

1 me going, for example, to IVAX in January 2004 to
2 discuss face-to-face on the same table with Dan
3 Weiner there to review some -- some data.

4 I can recall also of some other meetings
5 like we had in IVAX manufacturing. I think it was
6 in Ireland. I can recall of various instances
7 where we -- we shared information and opinions and
8 ideas, but I don't have a track record of this.

9 BY MR. SEGREST:

10 Q And did you review any of those other
11 communications from back then when you were
12 preparing your declaration?

13 MR. MCGUFFIN: Object to form.

14 THE WITNESS: Not other than what has
15 been discussed with my counsel.

16 BY MR. SEGREST:

17 Q I'm not asking about what you discussed
18 with your counsel. But did you review any of
19 those other communications from back then when you
20 were preparing your declaration?

21 MR. MCGUFFIN: Object to form.

22 THE WITNESS: I -- sitting here today, I

1 don't -- I don't recall of having seen anything
2 specific, and especially not outside of any
3 discussion with my counsel.

4 BY MR. SEGREST:

5 Q [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 MR. MCGUFFIN: Object to form.

9 THE WITNESS: [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 BY MR. SEGREST:

14 Q Okay.

15 MR. SEGREST: If we can take a -- really
16 only a couple-minutes break. I want to look
17 through my outline and see if I've missed
18 anything.

19 MR. MCGUFFIN: That's fine.

20 (Brief pause off the record.)

21 MR. SEGREST: I don't have any further
22 questions subject to the dispute we've got about

1 some privilege instructions.

2 MR. McGUFFIN: Okay. Why don't we take
3 another break just while I get my thoughts in
4 order. I think we'll have a couple questions just
5 to clarify the testimony.

6 (Whereupon, there was a recess in the
7 proceedings.)

8 EXAMINATION BY COUNSEL FOR THE PATENT OWNER,
9 MERCK SERONO SA

10 BY MR. McGUFFIN:

11 Q Dr. Munafo, I do want to ask a couple of
12 questions to clarify some of your testimony.

13 And to start, can you please pull up
14 Exhibit 2050? This is the August meeting minutes,
15 Dr. Munafo. Can you go to page 4?

16 Right under the heading in the middle of
17 the page, you were asked earlier by Counsel about
18 the [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

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A

Q

A

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1

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3

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5

6

Q And then moving further down

7

Exhibit 2050, in the section, Suggestions for

8

Primary Phase III Study, Counsel asked you earlier

9

about the third line which starts with "Arms."

10

And specifically about the parentheses,

11

.35 milligrams per kilogram times 5 days times

12

2 months and .35 milligrams per kilograms times

13

5 days times 6 months.

14

Do you see those?

15

A Yes, I do.

16

Q And you testified that there was a

17

mistake in these parentheses. Do you remember

18

that?

19

A When I read this again today, I realize

20

that -- and, again, these are draft minutes. I'm

21

not sure how it was in the final minutes.

22

But I realized that the mathematic that

1 the counsel was pointing to should have read
2 differently in the sense that it should have
3 been -- I think I would have to redo the
4 mathematic. But .35 mgs per kilo over 5 days
5 times 2 months rather than times 5 days times
6 2 months.

7 Q Thank you.

8 So you were asked some questions about
9 an exhibit called 1008, which was a paper by Rice.
10 Do you remember that?

11 A I see it on the screen right now for the
12 record, yes.

13 Q So you were asked to compare a lot of
14 numbers in this exhibit to numbers in regimens
15 Serono had proposed. Do you remember that?

16 A Uh-huh. Yes. Sorry.

17 Q In your answers, you testified that they
18 were numerically the same. What did you mean by
19 "numerically the same"?

20 A I just see that 0.7 is 0.7 and 2.1 is
21 2.1. That's what I mean with "numerically."

22 Q And why is it important that they were

1 the same numerically as opposed to the same in any
2 other way?

3 A Because a -- a dosing regimen includes
4 many more elements than just the dose. It
5 includes how often it is administered, to which
6 frequency, to which interval. It includes also
7 the fact that here it was parenteral formulation
8 while our -- while we were looking at
9 orally-administered drug.

10 And, again, a dosing regimen is much
11 more than just comparing the total dose.

12 Q Is the regimen that Counsel read to you
13 from Exhibit 1008 the same regimen you proposed to
14 IVAX?

15 MR. SEGREST: Objection; leading.

16 THE WITNESS: No. Again, a regimen
17 is -- is not just the dose. A regimen includes
18 the whole set of -- of elements that come into it
19 like -- like the -- not only the dose, but also
20 the -- the frequency, the route of administration,
21 the duration. Also, the fact that we have this
22 unique retreatment on the second year.

1 And all of these aspects make it that
2 the word "same," which is vague, does not really
3 apply to -- to comparing to dosing regimen, no.

4 BY MR. MCGUFFIN:

5 Q And was the regimen that Counsel read to
6 you from Exhibit 1008 the same regimen claimed in
7 the '947 and '903 patents?

8 MR. SEGREST: Objection; form, calls for
9 expert opinion.

10 THE WITNESS: I -- when you say
11 exhibit -- can you -- can you tell me what you
12 mean with this exhibit, Counsel?

13 BY MR. MCGUFFIN:

14 Q So I'm referring to Exhibit 1001 in each
15 of the IPRs, which are the challenged patents, the
16 '947 and '903 patents.

17 A So exhibit?

18 Q 1001.

19 A So this is the '947. Right?

20 Q Yes, this is the '947 patent.

21 A Okay. And your question is?

22 MR. MCGUFFIN: Can we go to the claim at

1 the end? Which I think -- let's go to Claim 36,
2 which I think is on the last page. It's on the
3 second-to-last page. I forgot about the
4 certificate.

5 So it's the bottom of Column 19.

6 Q So looking at the claim of this patent,
7 is the regimen that Counsel read to you from
8 Exhibit 1008 the same regimen claimed in the '947
9 patent?

10 A I am not a specialist of legal terms and
11 the implication. The regimen that we have in the
12 patent '947 is -- is elaborated for treating
13 multiple sclerosis, which is already a difference
14 with -- with respect to the other Rice paper.

15 And we have oral administration, which
16 is not the case there. We have a clear
17 description of an induction -- what was called at
18 that time an induction period and a
19 cladribine-free period. And then we have a
20 maintenance or re-treatment period as we call it
21 sometimes and then, again, a cladribine-free
22 period.

1 So the articulation of the regimen is
2 more specific and aimed at achieving the corridor
3 of efficacy and safety in multiple -- in treating
4 multiple sclerosis patient with -- with -- with
5 cladribine being administered orally. All of this
6 does not qualify to say that it is the same as --
7 as the one mentioned in -- in Rice or in former
8 studies.

9 Q Thank you.

10 MR. MCGUFFIN: We can take this exhibit
11 down.

12 Q So Counsel also asked you questions
13 about Exhibit 2049, which is the December briefing
14 document. Do you remember Counsel asked you where
15 on pages 47 to 51 it described two months of
16 dosing for the low-dose arm followed by four
17 months of placebo?

18 A Yes.

19 Q And in some of your answers, you said
20 that in addition to your understanding of the
21 document, this is what we had proposed and shared
22 with -- within the company at meetings where IVAX

1 representatives were present.

2 So just to be clear, what are you saying
3 that you proposed at meetings where
4 representatives from IVAX were present?

5 MR. SEGREST: Objection; scope.

6 THE WITNESS: The collaboration of the
7 dosing regimen is not only a complex process
8 engaging many, many expertise, knowledge, and --
9 and internal know-how, but it is also lengthy and
10 iterative. And that meeting internally and where
11 we had IVAX representatives present, we shared
12 freely the elaboration of our thoughts towards the
13 dosing regimen and the design of the trial.
14 And -- and for the dosing regimen, the fact of --
15 of dosing as described, in fact, in the briefing
16 document that we -- we sent -- we prepared for
17 sending to the health authority.

18 This elaborated -- this was an
19 elaboration of thoughts and refinement of thoughts
20 over several months. I'm not able, sitting here
21 today, to say at what meeting we presented which
22 level, but during the whole -- not the whole. But

1 at least the second half of the year 2003, this
2 started to -- to concretize, to be more specific
3 in terms of our proposal.

4 In particular, the dosing per kilo -- I
5 should -- even when using strengths of
6 10-milligram, we wanted to still stay with the
7 concept of dosing per kilo as well as introducing
8 the -- the fact that we wanted to re-treat
9 after -- in the second year.

10 BY MR. MCGUFFIN:

11 Q And did communications at meetings where
12 IVAX representatives were present include the
13 proposal to treat the low-dose arm with two months
14 of active treatment followed by four months of
15 placebos?

16 A This is part of the concept that we
17 elaborated from -- from early on. So yes, it was
18 presented this way, that the low-dose would be two
19 consecutive cycles. Then the high-dose would be
20 six consecutive cycles. And in order to maintain
21 blinding in the -- in the low-dose group, the next
22 four cycles would be placebo so that the patient

1 nor the -- the treating physician would know in
2 which group the patient was -- in which treatment
3 group the patient was.

4 Q Now, you mentioned that -- excuse me.
5 Let me clear my throat. Excuse me.

6 You mentioned that some of those
7 meetings were in person. Were there any meetings
8 by phone?

9 A Yes. There were. Sitting here today,
10 I -- I am not able to remember all the meetings,
11 the frequency, the number. But there were
12 frequent -- this is a general term. There were
13 meetings on -- on -- several meetings during the
14 year, being either in person or in -- or remote
15 by -- by phone.

16 And in addition, there was some email
17 exchange, and there were, as -- as you said, I
18 myself have been to -- to visit IVAX in the U.S.
19 to discuss specifically the results.

20 And I speak only for me, but, again,
21 the -- the organization was interested to have a
22 total free flow of information, so this was both

1 frequent and intense.

2 Q Were there written records of every
3 in-person meeting?

4 A Sitting here today, I'm not able to
5 answer this question. There were some minutes for
6 sure on -- of some meetings, but I am not sure
7 that there were records of -- or minutes of every
8 meeting.

9 Q And were there written records of every
10 phone meeting?

11 A Sitting here today, I do not remember
12 this. But I may not have the full picture here.
13 I was not in -- in the group looking at project
14 managements or the like.

15 Q Do you personally recall any meetings,
16 either in-person or over the phone, with IVAX
17 between August 2003 and the end of January 2004?
18 And I don't -- I'm not asking if you recall the
19 details of every meeting. I'm just asking if you
20 recall some details of some meetings.

21 MR. SEGREST: Objection; form.

22 THE WITNESS: I recall, as I said, that

1 I went to Miami in January 2004. I -- I recall of
2 a meeting, but I do not remember the date, where
3 Serono team went to Ireland to visit IVAX
4 facility. I am not 100 percent sure, but I think
5 that we had another meeting in Miami, but this is
6 really long ago, so I'm not confident in -- in
7 saying that I recall all or any with respect to
8 the exact dates beside what I just cited.

9 BY MR. MCGUFFIN:

10 Q Yeah. Can you turn to Exhibit 2053,
11 which is your declaration, and go to paragraph 47
12 on page 21? That's 22 of the PDF.

13 A I am on the -- yeah, I am there.

14 Q Do you see the second sentence starts,
15 "The Serono inventors discussed, e.g. during joint
16 meetings that IVAX attended"? Do you see that?

17 A Yeah. The sentence reads: "Serono
18 inventors discussed, e.g. during joint meetings
19 that IVAX attended, that certain parameters in the
20 study protocol, such as the number of days of
21 cladribine dosing each month, might need minor
22 adjustment, e.g., to six or seven days per month."

1 Q Now, do you recall whether there were
2 written records of the meetings you're referring
3 to in this paragraph?

4 A I -- sitting here today, I cannot recall
5 precisely at which meeting this was discussed and
6 whether there are minutes or there were minutes of
7 it. But this is a topic that has been discussed
8 when I -- I was alluding to earlier to the
9 iterative refinements of the dosing regimen in
10 that -- in that time frame.

11 Q Just one moment.

12 MR. MCGUFFIN: Yeah. I have no further
13 questions, Dr. Munafo.

14 MR. SEGREST: Just a couple on recross.
15 FURTHER EXAMINATION BY COUNSEL FOR THE PETITIONER,
16 TWI PHARMACEUTICALS, INC.

17 BY MR. SEGREST:

18 Q Have you still got Exhibit 2049 there?

19 A What is 2049?

20 Q 2049 is what you've referred to as the
21 briefing document. Go to page 49 of 59.

22 I want to look at the study treatment.

1 So on redirect, Dr. Munafo, you were asked some
2 questions about this regimen. Right?

3 A Sorry. I really need to ask you to
4 speak louder.

5 Q Yes, sir.

6 A I apologize for this.

7 Q My apologies.

8 On redirect, you were asked some
9 questions about the dose -- the treatment regimens
10 in the study treatment. Right?

11 A The elaboration of the dosing regimen,
12 which includes aspects like the dose, total dose,
13 dose per day, frequency, duration, re-treatment,
14 et cetera, has been a subject of discussion and
15 adjustments over time. And this is what we
16 presented in December 2003, given the dates.

17 I cannot comment, sitting here today,
18 with certainty, whether we continued to discuss
19 the duration after this briefing -- after this
20 draft briefing document or not.

21 Q Okay. I want to ask you again about the
22 strength 0, 3, and 10 milligrams. Do you see that

1 line?

2 A On the same -- are you on the same
3 page 49 of the -- the briefing document?

4 Q Yes, sir. Page 49 of 59, "Study
5 Treatment."

6 A Yes.

7 Q You've got formulation and you've got
8 strength. Do you see strength 0, 3, and a
9 10-milligram?

10 A Yeah. There is not a second comma, but
11 yes.

12 Q Oh, thank you.

13 And 10 milligrams, a 10-milligram
14 tablet, for five consecutive days per cycle, per
15 six cycles, is what would get you the high dosing
16 arm in this study. Right?

17 MR. MCGUFFIN: Object to form.

18 THE WITNESS: The dose was to be
19 adjusted by kilo, and here you're talking about
20 the strengths of 10-milligram, which is not the
21 dose.

22

1 BY MR. SEGREST:

2 Q Would the high dosing arm require
3 administration of the 10-milligram dosing strength
4 for six cycles?

5 A The high dosing regimen was focusing on
6 getting a total dose. And inasmuch as I recall
7 sitting here today, at that time, we had not yet
8 decided which strengths we would use to arrive to
9 this dose.

10 Q Well, the high dosing regimen has the
11 total dose of 2.1 milligrams per kilogram. Right?

12 A Total dose in the high -- high-dose
13 treatment group was said to approximating
14 cumulative dose of 2.1mgs per kilo.

15 Q Well, I thought you were saying that the
16 high-dose was six cycles of 10 milligrams, and the
17 low-dose was two cycles with the 10-milligram,
18 filled out by a placebo. Was I wrong about that?

19 A I don't recall having said today that
20 the strength at that time was fixed at
21 10-milligram, [REDACTED]

22 [REDACTED]

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[REDACTED]

[REDACTED]

So the high-dose arm was designed to have or was -- was proposed to have, indeed, six cycle, the low-dose arm to have two cycle. And the target exposure that we wanted to have was defined, [REDACTED]

[REDACTED]

Q If you took six cycles of the 10-milligram dose to meet the total dose of the high dosing arm, then six cycles of the 3-milligram strength dose would not have been sufficient for the high dosing arm, would it?

A I did not --

MR. MCGUFFIN: (Indiscernible.)

THE WITNESS: It would not have been what? Sorry.

BY MR. SEGREST:

Q It would not have been sufficient to reach the dose on the high dosing arm, would it?

MR. MCGUFFIN: Can I ask you to pause before you answer, Dr. Munafo?

1 I object to form.

2 THE WITNESS: Yeah, I'm -- I don't
3 understand the question, so can you perhaps
4 rephrase it?

5 BY MR. SEGREST:

6 Q In your testimony, you've said that the
7 target of 2.1 milligrams per kilogram would be six
8 cycles of the 10-milligram dose strength, and that
9 the target of .7 milligrams per kilogram would be
10 two cycles of the 10-milligram dose strength.

11 Isn't that what you've said?

12 A I -- I --

13 MR. MCGUFFIN: Object to form.

14 THE WITNESS: I don't recall having
15 mentioned the strengths in that discussion, have
16 I?

17 BY MR. SEGREST:

18 Q The total dose for administering
19 10 milligrams is going to be higher than the total
20 dose for administering 3 milligrams on the same
21 schedule, isn't it?

22 MR. MCGUFFIN: Object to form.

1 THE WITNESS: I think you -- you made a
2 hypothetical calculation using 10-milligram that I
3 agreed on the arithmetic. But I don't think I
4 have, and I would not have -- I should not have
5 agreed on the strengths at this moment.

6 BY MR. SEGREST:

7 Q Well, you see for treatment regimen,
8 this says five-day consecutive dosing within 28
9 cycles times six cycles per phase. Right?

10 A I'm getting tired. The -- the high
11 dose --

12 Q No, it's the treatment regimen.

13 A Consisted.

14 Q You see it says five-day consecutive
15 dosing within 28-day cycles times six cycles per
16 phase?

17 A Which dosing regimen are you referring
18 to here? The one in the briefing document, the
19 cladribine one, the clarity one, the --

20 Q I'm referring to the page we're looking
21 at, the briefing document, Exhibit 2049. The cell
22 we're looking at on the study treatment --

1 A Okay.

2 Q -- and the underscore heading there,
3 "treatment regimens."

4 A Yes.

5 Q Doesn't that say 5-day consecutive
6 dosing within 28-day cycles times 6 cycles per
7 phase?

8 A This is what it reads in this draft
9 briefing document dated December 2003. But as I
10 have already said, there have been discussions
11 whether -- regarding the -- the number of
12 consecutive days. And sitting here today, more
13 than 20 years later, I cannot tell you whether
14 this discussion of five, six, or seven had come to
15 the conclusion this -- to conclusion, period.

16 This is a snapshot of what we had in
17 December 2003 as a proposal to be submitted to the
18 health authority in Sweden for their feedback.

19 Q So if you use the treating -- treatment
20 regimen exactly as written here, 5-day consecutive
21 dosing within a 28-day cycle times 6 cycles per
22 phase, if you did that in one group with

1 10-milligram, following that same schedule with
2 3-milligram dosing strength, it's going to give
3 you a much lower total dose, isn't it?

4 MR. MCGUFFIN: Object to form. And
5 also, this is well beyond the scope of the
6 redirect examination.

7 You can answer --

8 MR. SEGREST: You can object to scope.

9 MR. MCGUFFIN: -- Dr. Munafo. But --

10 MR. SEGREST: You can object to scope,
11 but don't make a speaking objection on it.

12 THE WITNESS: I cannot object on the --
13 on the arithmetic of your calculation, but this
14 was not what we had planned, what we had proposed,
15 what we have discussed and shared with IVAX in --
16 or had shared in meeting where IVAX was present.

17 And the low-dose was -- was defined by
18 two cycle, the high-dose by six cycle, and the
19 strengths was not part of the discussion inasmuch
20 as I remember sitting here today.

21 It was not part of the -- of the
22 discussion or the argumentation with respect to

1 the low-dose or high-dose arm.

2 BY MR. SEGREST:

3 Q Five-day consecutive dosing within
4 28-day cycles for six cycles with a 3-milligram
5 dosage strength oral formulation would only be
6 about 30 percent of the total dose you would get
7 with 5-day consecutive dosing within a 28-day
8 cycle times 6 cycles per phase for a 10-milligram
9 tablet. Right?

10 MR. MCGUFFIN: Object to form; scope,
11 asked and answered.

12 THE WITNESS: This is a hypothetical
13 scenario that you present and was not part of our
14 concept inasmuch as I remember sitting here today.

15 MR. SEGREST: Okay. That's all I've
16 got.

17 MR. MCGUFFIN: We have no further
18 questions, Dr. Munafo. Thank you so much for your
19 time today.

20 MR. SEGREST: Thank you, sir.

21 And as I said before, I think we've got
22 an issue about privilege, but that's being

1 addressed separately. So that's all we've got for
2 today.

3 MR. MCGUFFIN: Yep.

4 MR. SEGREST: We can go off the record
5 unless you've got something for the record.

6 MR. MCGUFFIN: Before we go off the
7 record, Merck designates the record protective
8 order material under the Board's default
9 protective order.

10 And I also just want to be -- make sure
11 that the appearances at the start are correct,
12 that I'm Asher S. McGuffin on behalf of both
13 Dr. Munafo and Merck Group, the Patent Owner.

14 (Off the record at 6:29 p.m.)
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Transcript of Alain Munafo, Ph.D.

Conducted on June 7, 2024

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1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

2 I, CASSIDY WESTERN, RPR, Certified

3 Reporter and Notary Public within and for the

4 Commonwealth of Pennsylvania, do hereby certify:

5 That ALAIN MUNAFO, Ph.D., the witness

6 whose deposition is hereinbefore set forth was

7 duly sworn by me before the commencement of such

8 deposition and that such deposition was taken

9 before me and is a true record of the testimony

10 given by such witness.

11 I further certify that the adverse

12 party, MERCK SERONO SA, was represented by counsel

13 at the deposition.

14 I further certify that the deposition of

15 ALAIN MUNAFO, Ph.D., occurred via videoconference

16 on Friday, the 7th of June, 2024, commencing at

17 1:06 p.m. CEST to 6:29 p.m. CEST.

18 I further certify that I am not related

19 to any of the parties to this action by blood or

20 marriage, I am not employed by or an attorney to

21 any of the parties to this action, and that I am

22 in no way interested, financially or otherwise, in

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IPR2023-00049, -00050

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1 the outcome of this matter.

2 IN WITNESS WHEREOF, I have hereunto set
3 my hand this 10th day of June, 2024.

4 My commission expires August 4, 2025.

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Cassidy Western, RPR

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