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

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

CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER

Remote and in-person deposition of Alain Munafo, Ph.D.
Boston, Massachusetts
March 27, 2024
9:10 a.m.

Job No.: 530267
Pages: 1 - 173
Reported By: Alan H. Brock, RDR, CRR

A P P E A R A N C E S

ON BEHALF OF PETITIONER:

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9 ALSO PRESENT:

10 Emil White, Technician (remotely)
11 Raechel Meyerowich, Technician
12
13
14
15
16
17
18
19
20
21
22

I N D E X

EXAMINATIONS

ALAIN MUNAFO, Ph.D.

MS. PARTINGTON

6

MS. FERRERA

154

Previously marked exhibits:

1022 144

2046 149

2049 137

2050 116

2053 19

March 27, 2024 9:10 a.m.

P R O C E E D I N G S

THE VIDEOGRAPHER: Here begins Media No. 1
in the videotaped deposition of Dr. Alain Munafo, in
the matter of Hopewell Pharma Ventures, Incorporated
versus Merck Serono S.A., in the United States Patent
and Trademark before the Patent Trial and Appeal
Board, Case No. IPR2023-00480 and IPR2023-00481.

Today's date is March 27th, 2024. The
time on the video monitor is 9:10. The videographer
today is Raechel Meyerowich, representing Planet
Depos, and this video deposition is taking place at 60
State Street, Boston, Massachusetts.

Would counsel please voice-identify
themselves and state whom they represent.

MS. PARTINGTON: Good morning. This is
Olga Partington. I'm here from Sterne Kessler, on
behalf of petitioner Hopewell.

MS. BOND: Madeleine Bond, on behalf of
petitioner.

MS. FERRERA: This is Vinita Ferrera, on
behalf of Merck and its affiliates; and I'm joined by

CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER

Transcript of Alain Munafo, Ph.D.

Conducted on March 27, 2024

6

1 my colleagues Mary Pheng and Asher McGuffin -- and

09:11:19

2 also on behalf of the witness.

09:11:22

3 THE VIDEOGRAPHER: The court reporter

09:11:25

4 today is Alan Brock, representing Planet Depos. The

09:11:26

5 witness will now be sworn.

09:11:28

6 ALAIN MUNAFO, PH.D.,

09:11:28

7 being first duly sworn or affirmed to testify to the

09:11:28

8 truth, the whole truth, and nothing but the truth, was

09:11:28

9 examined and testified as follows:

09:11:30

10 EXAMINATION

09:11:45

11 BY MS. PARTINGTON:

09:11:46

12 Q. All right. Good morning, Dr. Munafo.

09:11:49

13 A. Good morning.

09:11:53

14 Q. As I said, my name is Olga Partington, and I

09:11:54

15 should clarify for the record that I am here today

09:11:57

16 remotely with Ms. Eldora Ellison of Sterne Kessler as

09:12:00

17 well.

09:12:07

18 Could you please state and spell your name

09:12:07

19 for the record.

09:12:09

20 A. My name is Alain Munafo. First name is

09:12:10

21 Alain, A-l-a-i-n, last name is M-u-n-a-f-o.

09:12:15

22 Q. Thank you. And what is your address,

09:12:20

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CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER

Transcript of Alain Munafo, Ph.D.

Conducted on March 27, 2024

7

1	Dr. Munafo?	09:12:24
2	A. I live in Switzerland. My address is Rue des	09:12:25
3	Creuses No. 12 in Gilly, G-i-l-l-y, in Switzerland.	09:12:30
4	Q. I think you're going to have to probably	09:12:39
5	spell it for the court reporter. But we can do it	09:12:42
6	later.	09:12:46
7	Dr. Munafo, have you ever been deposed	09:12:47
8	before?	09:12:49
9	A. Yes, I have.	09:12:52
10	Q. How many times?	09:12:55
11	A. Once.	09:12:56
12	Q. Was the case related to a patent matter?	09:13:00
13	A. Yes, it was.	09:13:09
14	Q. Was the deposition in the case related to a	09:13:14
15	patent matter before the Patent Office?	09:13:17
16	A. The case -- the deposition was related to	09:13:23
17	litigation in Canada, and I do not know there how you	09:13:35
18	call the Patent Office. I'm sorry for not being in	09:13:39
19	this field at all.	09:13:42
20	Q. That's okay. So it was not in the United	09:13:43
21	States, it was in Canada?	09:13:46
22	A. It was in Switzerland -- it was in Serono, in	09:13:48

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1	France, just at the border of Switzerland, related to	09:13:52
2	a case in Canada.	09:13:57
3	Q. Got it. Do you remember who the parties	09:13:58
4	were?	09:13:59
5	A. Sitting here today, I'm not sure I can say	09:14:00
6	exactly who the deponent was -- who the parties were.	09:14:09
7	Sorry for my English.	09:14:13
8	Q. Okay. Do you remember what the subject	09:14:15
9	matter of the case was?	09:14:18
10	A. Yes.	09:14:21
11	MS. FERRERA: You may answer the question.	09:14:25
12	I'll just caution you not to disclose any	09:14:27
13	attorney-client communications. You can answer at a	09:14:28
14	high level.	09:14:31
15	A. This was a patent litigation regarding	09:14:33
16	cladribine.	09:14:40
17	Q. Regarding cladribine, you said?	09:14:40
18	A. Yes, I said.	09:14:42
19	Q. When was this deposition in that case?	09:14:44
20	A. It was -- the exact date I do not remember	09:14:56
21	sitting here today, but it was in spring -- this	09:14:59
22	winter, just beginning of spring. This year, but I do	09:15:03

1	not remember the exact date.	09:15:08
2	Q. So 2024, sometime January or February.	09:15:10
3	A. Correct.	09:15:16
4	Q. And whose side were you on in that case?	09:15:20
5	A. I was testifying as a witness as well as --	09:15:30
6	and excuse me if either term is not right -- but	09:15:39
7	representing corporate representative of Serono, of	09:15:42
8	Merck Serono.	09:15:46
9	Q. Merck Serono. Okay. And this was the only	09:15:49
10	deposition that you've ever been a part of?	09:15:54
11	A. Yes.	09:15:58
12	Q. Okay, excellent. Thank you for that.	09:16:01
13	I am going to go over some ground rules	09:16:07
14	for today's deposition. I will be asking you some	09:16:09
15	questions, and your counsel may object. It is	09:16:11
16	important for the court reporter that we don't talk	09:16:16
17	over one another. Okay?	09:16:18
18	A. Okay.	09:16:22
19	Q. And similarly, the court reporter can't	09:16:24
20	really take down nonverbal answers, so I'm going to	09:16:27
21	ask you to refrain from, you know, shaking your head	09:16:30
22	yes or no or responding "uh-huh." Can you agree to	09:16:35

CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER

Transcript of Alain Munafo, Ph.D.

Conducted on March 27, 2024

10

1	give only verbal answers?	09:16:40
2	A. I do.	09:16:42
3	Q. Thank you. And sometimes your counsel may	09:16:44
4	object to my questions, but you still have to answer	09:16:47
5	them unless counsel directs you not to answer them.	09:16:52
6	Will you agree to abide by this rule?	09:16:55
7	A. I do.	09:16:58
8	Q. Of course, if at any point you need a break,	09:17:01
9	please let me know, and, you know, we'll do our best	09:17:04
10	to give you a break.	09:17:09
11	I will ask you, however, that if there's a	09:17:10
12	question pending, that you answer the question first	09:17:13
13	before we take a break. Is that all right with you?	09:17:15
14	A. Yes, it is.	09:17:19
15	THE VIDEOGRAPHER: Would you like to go	09:17:24
16	off the record?	09:17:25
17	MS. FERRERA: Sure.	09:17:26
18	THE VIDEOGRAPHER: We are going off the	09:17:27
19	record. The time is 9:17.	09:17:28
20	(Recess taken.)	09:17:30
21	THE VIDEOGRAPHER: We are back on the	09:22:50
22	record. The time is 9:22.	09:22:54

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1 Q. Okay, thank you. I would just like to say 09:22:57
2 for the record, counsel: I don't think we've had a 09:23:00
3 single deposition in this case that did not go without 09:23:03
4 some sort of commotion. I just want to put this out 09:23:05
5 on the record. All right. 09:23:08

6 MS. FERRERA: Well, I need to respond to 09:23:10
7 that. This is not an issue of our making. The 09:23:11
8 witness is entitled to be able to examine the exhibits 09:23:16
9 carefully, to be able to see them. He needs to be 09:23:21
10 able to look at our portions of them if he needs to. 09:23:24

11 I don't know what exhibits you're planning 09:23:26
12 on using and whether they're ones that are available 09:23:28
13 in hard copy or not. So, you know, I think it's your 09:23:31
14 obligation to make sure the arrangements are such that 09:23:36
15 he can examine the exhibits. 09:23:38

16 MS. PARTINGTON: With all due respect, 09:23:41
17 this is your witness. You have arranged for the 09:23:42
18 Planet Depos to conduct this cross-examination. This 09:23:46
19 is not the first remote cross-examination in this 09:23:51
20 case. This is not the first time we're deposing your 09:23:53
21 witnesses remotely. 09:23:57

22 MS. FERRERA: I think we should just move 09:24:02

1 on. This is obviously not something that we had any
2 control over.

3 Q. Okay, let's just move on. Dr. Munafo, if I
4 ask you a question that you do not understand, could
5 you please let me know that you did not understand it,
6 and I will clarify it for you?

7 A. Thank you for proposing this. I was about to
8 say something similar. English is not my mother
9 language. I am usually okay with scientific terms,
10 not necessarily all terms either social or legal. And
11 I'd also like to apologize for my accent, which is
12 what it is, and for requesting that you speak loudly
13 and slowly, so that I can evaluate whether I
14 understand the question or not. Thank you.

15 Q. I will absolutely respect that request.
16 English is not my first language, either, so I
17 sympathize. And I will speak as slowly and loudly as
18 I can, and please let me know if you do not understand
19 something I say.

20 A. Thank you.

21 Q. However, if you do answer me, I will assume
22 that you understood my question. Is that fair?

1 A. If I do not ask specifically for 09:25:32

2 clarification, I would say so. 09:25:35

3 Q. That is correct. Now, because we are 09:25:37

4 operating on a remote basis for today's deposition, 09:25:42

5 there may be some technical difficulties, and if 09:25:45

6 anything happens that interferes with your ability to 09:25:51

7 understand or answer my questions, will you please 09:25:55

8 agree to let me know as well? 09:25:58

9 A. I will. 09:26:01

10 Q. The Patent Office rules require that I tell 09:26:06

11 you that during my questions today you are not 09:26:09

12 permitted to discuss your testimony with counsel 09:26:14

13 unless you're discussing an issue related to 09:26:18

14 privilege. Do you agree to abide by that rule? 09:26:21

15 A. I do. 09:26:25

16 Q. Any reason you cannot give truthful testimony 09:26:29

17 today? 09:26:31

18 A. I'm sorry, there was some noise around. Can 09:26:33

19 you repeat what you just said? 09:26:35

20 Q. Any reason that you cannot give a truthful 09:26:37

21 testimony today? 09:26:41

22 A. No. 09:26:45

1	Q.	Where are you located today?	09:26:48
2	A.	This is in Boston, in the offices of	09:26:50
3		WilmerHale, and it's 60 -- what is it? -- State	09:27:00
4		Street, I believe. The address I'm not totally sure,	09:27:05
5		but this is in the premises.	09:27:07
6	Q.	And, now, you're not using a laptop; correct?	09:27:14
7	A.	No, I'm not.	09:27:17
8	Q.	If they provide you with a laptop, I will ask	09:27:18
9		you some additional questions about it later, if	09:27:21
10		that's okay with you.	09:27:24
11		Let me ask you: Do you have any	09:27:28
12		electronic devices with you?	09:27:30
13	A.	No, I don't.	09:27:33
14	Q.	Did you bring anything to the deposition	09:27:37
15		today?	09:27:41
16	A.	No, I do not -- I did not.	09:27:42
17	Q.	I see that you have a binder in front of you.	09:27:44
18		Is that something you brought in?	09:27:49
19	A.	No. The binder was on the table when I	09:27:51
20		arrived.	09:27:53
21	Q.	You don't know what's in it?	09:27:54
22		MS. FERRERA: Counsel, I'll represent that	09:27:58

1 it's a copy of Dr. Munafo's -- a clean copy of his 09:27:59
2 declaration and supporting exhibits, and I believe 09:28:06
3 your colleague has already had a chance to examine it. 09:28:08

4 MS. PARTINGTON: Great. Thank you. 09:28:11

5 Q. Dr. Munafo, what did you do to prepare for 09:28:12
6 the deposition? 09:28:14

7 MS. FERRERA: And you may answer that 09:28:21
8 question, but I'll just caution you not to disclose 09:28:23
9 anything that you discussed with counsel. 09:28:25

10 A. So I -- we had several preparation meetings, 09:28:29
11 either by phones or in person in the last two days. 09:28:36
12 So it has been a process lasting for several months, 09:28:47
13 and I would ask for your clarification on what exactly 09:28:55
14 you need to know. 09:28:58

15 Q. Well, let's start with: Who did you meet 09:28:59
16 with? 09:29:02

17 A. As I said, there were remote meetings and 09:29:06
18 meetings in person. So in the remote meetings I had 09:29:10
19 discussion with the people from Wilmer that are around 09:29:22
20 the table today. And there was another person. I do 09:29:29
21 not recall the last name; the first name was Derek. 09:29:32
22 And there was also on occasions a person from 09:29:35

1 Switzerland, whose first name is Wilhelm, but I do not 09:29:41
2 remember either the last name. 09:29:47

3 And I'm not sure sitting here today 09:29:53
4 whether there were other people involved, but they 09:29:56
5 were all -- those that I remember were all either from 09:29:59
6 the firm -- the attorney firm here or the Wilhelm, who 09:30:03
7 is at Merck Serono in Switzerland. 09:30:13

8 Q. How many remote meetings would you say you 09:30:21
9 had with the team that you just mentioned? 09:30:26

10 A. Sitting here today I am not able to state the 09:30:33
11 exact number. There were a few -- several spread over 09:30:37
12 several months, but I did not count. 09:30:41

13 Q. At least five? 09:30:45

14 MS. FERRERA: Objection. 09:30:49

15 A. I did not record the number of meetings. 09:30:50

16 Q. Less than ten? 09:30:53

17 MS. FERRERA: Objection. 09:30:55

18 A. I did not record the number of the meetings. 09:30:56

19 Q. Less than 100? 09:31:00

20 MS. FERRERA: Objection. 09:31:01

21 A. Also I did not record the number of the 09:31:03
22 meetings. Yes, there was less than 100. 09:31:07

1 Q. Thank you. And how many in-person meetings 09:31:15
2 did you have with the team in preparation for the 09:31:17
3 deposition? 09:31:20

4 A. When you mean "in person," it means 09:31:21
5 physically present; right? Okay. 09:31:33

6 Q. Correct. 09:31:35

7 A. So yesterday and the day before. 09:31:35

8 Q. So two days. 09:31:39

9 A. Yes. 09:31:43

10 Q. And were these in-person meetings, were they 09:31:44
11 all-day-long meetings? 09:31:52

12 MS. FERRERA: Objection. 09:31:55

13 A. I did not record the duration of the 09:31:56
14 meetings. But I would like to clarify also that I had 09:32:00
15 some discussion earlier this morning with the counsel 09:32:02
16 as a preparation meeting in person. 09:32:06

17 Q. Thank you. Now, did you talk to anyone 09:32:09
18 besides counsel regarding the substance of your 09:32:18
19 deposition today? 09:32:20

20 A. In -- for the preparation and the deposition 09:32:24
21 for the Canada litigation, this was discussed at a 09:32:35
22 relatively high level. But besides that -- and it was 09:32:48

1 also with my attorneys there. But besides that, no, I 09:32:52
2 have not. 09:33:00

3 Q. And I just want to clarify for the record -- 09:33:00
4 and you kind of answered it -- that you talked to -- 09:33:02
5 strike that. 09:33:11

6 You discussed the substance -- or the 09:33:13
7 substance of your deposition with somebody other than 09:33:17
8 counsel? 09:33:20

9 A. No. 09:33:22

10 MS. FERRERA: Objection, mischaracterizes 09:33:23
11 the testimony. You may answer. 09:33:24

12 A. No, did I not discuss with anyone else. 09:33:32

13 Q. Okay. So you just only discussed at high 09:33:37
14 level with counsel. I just want to make it clear. 09:33:42

15 A. "High level" is a term that is a bit vague. 09:33:50
16 But I would say -- and I recognize that I used it. 09:33:53
17 But during the preparation of the meeting -- of the 09:33:59
18 deposition for the Canadian litigation case as well as 09:34:05
19 during the deposition itself, I've been asked whether 09:34:12
20 there was another similar case, and as I did today 09:34:17
21 with you, I did with them mention the other case 09:34:27
22 without giving any details in the substance. 09:34:30

1	MS. PARTINGTON: Okay, Emil, could you	09:34:38
2	please introduce Exhibit 2053.	09:34:42
3	THE TECHNICIAN: Stand by.	09:34:51
4	MS. PARTINGTON: Like I asked you before,	09:34:53
5	please also put a copy in the chat.	09:34:55
6	THE TECHNICIAN: It is now in the chat for	09:35:29
7	a download. Do parties need me to share this on the	09:35:36
8	Zoom screen?	09:35:40
9	MS. PARTINGTON: Yes, please.	09:35:41
10	THE TECHNICIAN: Now sharing the exhibit.	09:35:45
11	MS. PARTINGTON: Thank you.	09:35:52
12	Q. Dr. Munafo, this is your declaration that you	09:35:53
13	submitted in Cases IPR2023-00480 and IPR2023-00481;	09:35:57
14	correct?	09:36:14
15	A. Seeing only the first page, this is what it	09:36:14
16	says on this page. I do not know what you have in	09:36:17
17	your document there on screen.	09:36:20
18	MS. PARTINGTON: Emil, could you please	09:36:27
19	scroll down all the way through the exhibit.	09:36:28
20	Q. All right, Dr. Munafo, I'm going to ask you	09:38:22
21	again: Is this your declaration that you submitted in	09:38:24
22	Cases IPR2023-00480 and IPR2023-00481?	09:38:26

1	A.	Inasmuch as I can evaluate from the rapid	09:38:39
2		screen -- rapid screen, scan on the screen, I	09:38:43
3		recognize this document, yes.	09:38:48
4	Q.	Great. And you have a paper copy of this	09:38:51
5		declaration in front of you; correct?	09:38:55
6	A.	I do.	09:38:57
7	Q.	Now, I just read two case numbers for you,	09:39:04
8		and if I refer in our conversation today to "this	09:39:08
9		case" or "this proceeding," will you understand that	09:39:12
10		I'm collectively referring to the two IPR proceedings?	09:39:15
11	A.	Yes, that's okay. Thank you.	09:39:23
12	Q.	Sure. And the patents involved in these	09:39:26
13		proceedings are U.S. Patent No. 7,713,947 and	09:39:31
14		8,377,903; correct?	09:39:42
15	A.	To my understanding, yes.	09:39:44
16	Q.	If I need to refer to the individual patents,	09:39:49
17		I will use the shorthand of the either '947 patent or	09:39:54
18		the '903 patent; okay?	09:39:59
19	A.	That's fine.	09:40:04
20	Q.	Otherwise I will just refer to them as the	09:40:05
21		challenged patents; okay?	09:40:08
22	A.	That's fine.	09:40:13

1	Q. Okay. Can we please go to Page 25 of your	09:40:13
2	declaration. I believe it is Page 26 of the PDF.	09:40:17
3	Your declaration is signed and dated December 21,	09:40:32
4	2023; correct?	09:40:37
5	A. Yes, this is correct.	09:40:39
6	Q. And that is your signature?	09:40:41
7	A. Yes, it is.	09:40:44
8	Q. And Dr. Munafo, do you stand by your	09:40:47
9	testimony in your declaration in this case?	09:40:50
10	A. Yes, I do.	09:40:55
11	Q. Now, you provided this declaration as a	09:40:59
12	co-inventor of the '947 patent and the '903 patent	09:41:03
13	and, quote, "as someone knowledgeable about the	09:41:09
14	relationship and joint research and development	09:41:12
15	agreement between the team at Serono and IVAX," end	09:41:17
16	quote. And this is in Paragraph 5 of your	09:41:20
17	declaration.	09:41:24
18	A. This is a question? Can you repeat the	09:41:34
19	question?	09:41:35
20	Q. Yes. Sorry. The question is: You provided	09:41:36
21	the declaration as a co-inventor of the challenged	09:41:40
22	patents and as someone knowledgeable about the	09:41:43

1	relationship and joint research and development	09:41:45
2	agreement between the team at Serono and IVAX;	09:41:48
3	correct?	09:41:52
4	A. Yes, this is correct.	09:41:53
5	Q. When were you first approached to provide	09:41:56
6	your declaration in this case?	09:41:58
7	A. Sitting here today, I do not remember the	09:42:01
8	exact date. It was sometime in 2023. I'm not very	09:42:08
9	good with dates.	09:42:15
10	Q. Was it in the fall of 2023?	09:42:19
11	MS. FERRERA: Objection.	09:42:23
12	A. I do not recall the first time I was	09:42:24
13	approached for this.	09:42:29
14	Q. Do you recall what season it was that you	09:42:33
15	were approached about this?	09:42:36
16	MS. FERRERA: Objection.	09:42:40
17	A. As I said, I'm not good with dates. I do not	09:42:41
18	recall the exact date it was, neither the season. I	09:42:44
19	know it was last year, 2023.	09:42:48
20	Q. Do you recall if it was at the beginning of	09:42:53
21	2023 or the end of 2023?	09:42:55
22	MS. FERRERA: Objection.	09:42:56

1 A. I -- sitting here today, I'm not sure I can 09:42:58

2 answer this question with precision. 09:43:02

3 Q. I'm not asking you for precision. I'm just 09:43:04

4 asking you to tell me whether it was the very 09:43:07

5 beginning of 2023 or towards the end of 2023. 09:43:10

6 A. I swore to tell the truth and only the truth, 09:43:14

7 and the truth is that I do not remember the exact 09:43:17

8 dates. 09:43:19

9 Q. So you cannot tell the difference between a 09:43:21

10 January conversation and late-of-the-year 09:43:25

11 conversation. 09:43:30

12 MS. FERRERA: Objection. 09:43:30

13 A. I can certainly tell the difference between 09:43:34

14 January and late of 2023, yes. But what I cannot say 09:43:36

15 is when exactly I was first contacted on this topic. 09:43:40

16 Q. Okay. Who approached you in providing a 09:43:46

17 declaration for this case? 09:43:56

18 A. Inasmuch as I recall, sitting here today, I 09:44:03

19 was contacted by -- the first contact I think was the 09:44:23

20 firm, the attorney firm here, WilmerHale, but I do not 09:44:28

21 remember who did that. 09:44:36

22 Q. Okay. But at the time it was a counsel for 09:44:37

1	Merck; correct?	09:44:43
2	MS. FERRERA: Objection, mischaracterizes	09:44:44
3	the testimony.	09:44:45
4	MS. PARTINGTON: Counsel, I'm going to ask	09:44:54
5	you to stick to one-word objections as to the PTAB	09:44:55
6	rules.	09:44:59
7	A. Can you then repeat your question, because	09:45:00
8	I'm just distracted by this exchange.	09:45:01
9	Q. Sure, yes. So you mentioned that it was the	09:45:04
10	attorney from WilmerHale that approached you regarding	09:45:10
11	preparing a declaration in this case, and my question	09:45:15
12	was -- and maybe it wasn't very clear -- was the	09:45:18
13	attorney representing Merck?	09:45:23
14	A. As I said before, I do not remember precisely	09:45:30
15	who was the person who contacted me from the firm, but	09:45:34
16	I do remember that they introduced themselves as	09:45:39
17	representing -- and I would have to be careful in what	09:45:43
18	I'm saying here -- Merck Serono, EMD Serono, or	09:45:51
19	something similar. I'm not sure exactly, but it was	09:45:56
20	representing either EMD Serono or Merck Serono or	09:45:59
21	Merck.	09:46:04
22	Q. How long did you spend preparing your	09:46:08

1	declaration?	09:46:11
2	A. To make sure I understand your question, you	09:46:19
3	are talking about the written declaration here?	09:46:22
4	Q. That is correct.	09:46:24
5	A. The work was spread over several weeks, but I	09:46:29
6	have not recorded the duration of it.	09:46:38
7	Q. Do you recall approximately the number of	09:46:43
8	hours that you spent in preparing your declaration?	09:46:46
9	MS. FERRERA: Objection.	09:46:50
10	A. No, I do not.	09:46:52
11	Q. Do you recall if it was more than ten hours?	09:46:55
12	MS. FERRERA: Objection.	09:46:58
13	A. Sitting here today, I am not able to answer	09:46:58
14	this question.	09:47:04
15	Q. Do you recall if it was more than 30 hours?	09:47:08
16	MS. FERRERA: Objection.	09:47:11
17	A. Same reply as just before. Sitting here	09:47:13
18	today, I do not remember the duration.	09:47:18
19	Q. Could it have been more than 100 hours?	09:47:22
20	MS. FERRERA: Objection.	09:47:24
21	A. Also I did not record the hours, number of	09:47:29
22	hours. I would not evaluate this to exceed 100, no.	09:47:40

1	Q. Do you know who else provided a declaration	09:47:49
2	for this case?	09:47:52
3	A. I have not seen with my eyes any other	09:48:03
4	declaration. What I have been told --	09:48:09
5	MS. FERRERA: And I caution you not to	09:48:13
6	disclose any communications with counsel, Dr. Munafo.	09:48:16
7	If you have knowledge other than what you've discussed	09:48:24
8	with counsel, you may answer.	09:48:27
9	A. So I have not seen any declaration by anyone	09:48:29
10	else.	09:48:36
11	Q. Do you know who else provided a declaration	09:48:39
12	in the case?	09:48:42
13	MS. FERRERA: You can answer yes or no.	09:48:43
14	A. No, I don't.	09:48:45
15	Q. Do you know who has been deposed in this case	09:49:00
16	so far?	09:49:04
17	MS. FERRERA: You may answer yes or no.	09:49:07
18	A. This is a term that I'm not sure I understand	09:49:11
19	what means, "being deposed." Can you please clarify?	09:49:14
20	Q. Sure. This is what's happening to you right	09:49:18
21	now. You are being deposed right now. So let me ask	09:49:20
22	you again:	09:49:24

1	Do you know who else has been deposed in	09:49:25
2	this case, if anyone else?	09:49:28
3	A. No, I do not.	09:49:31
4	Q. Besides counsel, did you communicate with	09:49:37
5	anyone in order to create your declaration?	09:49:40
6	A. I did attempt to retrieve a document with a	09:49:45
7	former colleague, but that was not possible, and I	09:50:18
8	never got it. And I did not -- and sorry, I would	09:50:24
9	like to clarify: And even then I did not disclose	09:50:30
10	anything about this presentation.	09:50:32
11	Q. Okay. Who was present for that communication	09:50:40
12	when you were trying to obtain a document from a	09:50:45
13	colleague?	09:50:49
14	A. No one was present. I just asked a former	09:50:51
15	colleague whether she had access to folders, archived	09:51:01
16	folders, of the beginning of 2000, and her response	09:51:14
17	was no, and that stopped.	09:51:18
18	Q. And was that colleague at Merck?	09:51:21
19	A. Yes.	09:51:25
20	Q. Was she still at Merck when you asked her to	09:51:27
21	retrieve the document?	09:51:30
22	A. Can you repeat your question?	09:51:34

1	MS. FERRERA: Objection.	09:51:36
2	A. I did not understand it fully.	09:51:37
3	Q. Sure. When you asked your colleague to	09:51:39
4	retrieve the document, was she still at Merck?	09:51:42
5	A. Yes, she was.	09:51:46
6	Q. What is the name of your colleague -- strike	09:51:52
7	that.	09:51:58
8	What is the name of your former colleague?	09:51:58
9	A. The name is Nadia Terranova.	09:52:03
10	Q. Could you please spell it for the record?	09:52:12
11	A. Nadia is Nadia; Terranova, T-e-r-r-a-n-o-v-a.	09:52:15
12	Q. As somebody with a Slavic background, I can	09:52:25
13	tell you that Nadia could be spelled with an i or with	09:52:30
14	a y. So how do you spell that, please?	09:52:34
15	A. N-a-d-i-a.	09:52:36
16	Q. Thank you. And what was her role at Merck at	09:52:38
17	the time you contacted her to retrieve the document?	09:52:45
18	A. She was working in the group that I was	09:53:00
19	working in, and I do not know her title by now, but	09:53:01
20	she was doing the same work as when I -- almost the	09:53:11
21	same work as when I left the company -- what is it? --	09:53:15
22	almost three years ago now.	09:53:22

1	Q. Let me make sure I understand. You don't	09:53:26
2	know what her role is right now, but three years ago,	09:53:30
3	when you were still at the company, you believe she	09:53:34
4	still had the same role that she has now?	09:53:37
5	MS. FERRERA: Objection.	09:53:42
6	A. I don't think this is what I said.	09:53:43
7	Q. It's possible that I misunderstood. That's	09:53:46
8	why I'm clarifying.	09:53:49
9	A. I said I do not know her title right now, but	09:53:53
10	the function she's in is a progression of what she was	09:54:05
11	doing when I was still in the company. More details I	09:54:19
12	would not be able to give.	09:54:24
13	Q. Was she a scientist?	09:54:27
14	A. Yes, she is.	09:54:31
15	Q. What kind of scientist is she?	09:54:34
16	A. She works -- she worked in my group in	09:54:36
17	clinical pharmacology, more specifically looking at	09:54:48
18	pharmacokinetics, modeling simulation and advanced	09:54:51
19	analytics, including incorporation of neural networks	09:54:58
20	in analysis.	09:55:06
21	Q. Now, you said that you asked to retrieve a	09:55:08
22	document of her. Which document was it, Dr. Munafo?	09:55:13

1	MS. FERRERA: Objection.	09:55:18
2	A. I didn't say that. I said I was interested	09:55:19
3	in trying to find a document, but what I asked her was	09:55:25
4	whether she had access to the archives.	09:55:30
5	Q. What document did you ask her -- strike that.	09:55:35
6	What document were you interested in?	09:55:41
7	A. I was interested in documents that would	09:55:43
8	allow me to refresh my memory in terms of timelines.	09:55:53
9	Q. Can you give me any more specifics about this	09:56:04
10	specific document that you were interested in that you	09:56:08
11	were hoping would refresh your memory?	09:56:10
12	MS. FERRERA: Objection. And I'll caution	09:56:12
13	you not to disclose any attorney-client	09:56:17
14	communications.	09:56:19
15	MS. PARTINGTON: Counsel, I'm not asking	09:56:20
16	anything privileged here.	09:56:22
17	MS. FERRERA: I don't know whether it	09:56:24
18	would call for privileged testimony. I'm just	09:56:26
19	cautioning him to avoid that.	09:56:28
20	MS. PARTINGTON: Well, from Dr. Munafo's	09:56:30
21	testimony, there were no attorneys present at that	09:56:32
22	communication, which was with his former colleague.	09:56:35

1	There's nothing privileged there.	09:56:41
2	MS. FERRERA: Counsel, I'm counseling him	09:56:41
3	to avoid attorney-client communications. I'm not	09:56:44
4	instructing him not to answer the question.	09:56:47
5	Q. You may answer.	09:56:52
6	A. I was trying to refresh my memory by looking	09:57:01
7	at a document that I had prepared or worked on at the	09:57:03
8	very beginning of this project.	09:57:09
9	Q. When you say "this project," what are you	09:57:12
10	referring to?	09:57:14
11	A. I'm referring to oral cladribine for the	09:57:21
12	treatment of multiple sclerosis.	09:57:29
13	Q. And was Nadia part of the team that worked on	09:57:32
14	oral cladribine for multiple sclerosis?	09:57:39
15	A. No, she was not.	09:57:43
16	Not -- I'd like to specify: not at that	09:58:00
17	time. She has worked later on, years later, together	09:58:03
18	with me on this project, but not at that time.	09:58:08
19	Q. And when you say "later," do you know	09:58:14
20	approximately the time?	09:58:16
21	MS. FERRERA: Objection.	09:58:19
22	A. Many years later.	09:58:22

1 Q. So did you obtain anything from Nadia in 09:58:26

2 response to the request? 09:58:29

3 A. No. I already replied to this question 09:58:32

4 earlier; and no, I have not got anything. 09:58:38

5 Q. Were you able to obtain the document that you 09:58:44

6 were interested in in some other way? 09:58:49

7 MS. FERRERA: Objection. 09:58:50

8 A. No, I have not. 09:58:54

9 Q. Did you actually search for the document 09:58:58

10 yourself? 09:59:00

11 A. I looked in my computer but had no record of 09:59:06

12 it. 09:59:11

13 Q. Do you know if Nadia searched for the 09:59:12

14 document? 09:59:15

15 A. I do not -- sitting here today, I don't know 09:59:22

16 the answer to this question. 09:59:26

17 Q. Now, you mentioned a word, "archives." Which 09:59:28

18 archives did you refer to? 09:59:41

19 MS. FERRERA: Objection. 09:59:42

20 A. Electronic archives. 09:59:43

21 Q. Electronic archives of Merck? 09:59:49

22 A. These archives were not at Merck at that 09:59:55

1 time. They were at Serono, before Merck was -- before 10:00:03
2 Serono was acquired by Merck. I do not know how to 10:00:07
3 answer your question whether this was Merck archives 10:00:13
4 or Serono archives. 10:00:16

5 Q. And why did you ask Nadia to see if she had 10:00:19
6 access to the archives? 10:00:24

7 MS. FERRERA: Well, again, I'll just 10:00:30
8 caution you not to disclose any attorney-client 10:00:32
9 communication. 10:00:34

10 A. The question that I asked Nadia was just 10:00:41
11 whether she has or she still had access to archives, 10:00:48
12 and Nadia is and was -- was a close collaborator to 10:00:56
13 me, with whom I kept some contact, and it appeared 10:01:02
14 normal to me to ask her whether these archives were 10:01:08
15 still available or not. 10:01:12

16 Q. Did you yourself not have the access to the 10:01:13
17 archives at the time you needed the document? 10:01:20

18 A. No. I left the company. 10:01:25

19 Q. And was Nadia responsible for maintaining the 10:01:28
20 archives? 10:01:34

21 A. No. 10:01:38

22 Q. Dr. Munafo, I'm just going to ask you this, 10:01:40

1	just to clear the record and for my own understanding:	10:01:46
2	What was specifically the document that you were	10:01:52
3	looking for?	10:01:54
4	MS. FERRERA: Objection.	10:01:55
5	A. This is -- this period is more than 20 years	10:02:03
6	ago, and I cannot, sitting here today, say	10:02:08
7	specifically what I was looking at. I was looking --	10:02:13
8	so I cannot say specifically what kind of document I	10:02:21
9	was looking at, the title of the document, or anything	10:02:24
10	more specific.	10:02:27
11	But I was looking at something, some	10:02:28
12	documents, some working documents, that could help me	10:02:32
13	refresh my memory.	10:02:40
14	Q. Were you able to refresh your memory in any	10:02:41
15	other way besides -- strike that.	10:02:50
16	You said you did not -- you were not able	10:02:54
17	to obtain the documents from Nadia, so my question for	10:02:58
18	you is: Were you able to refresh your memory in other	10:03:01
19	ways?	10:03:04
20	A. During the discussion with --	10:03:13
21	MS. FERRERA: And again just let me	10:03:15
22	caution you not to disclose any conversations with	10:03:17

1	counsel. But if you can answer the question without	10:03:19
2	doing so, you may.	10:03:21
3	A. I would request to have a discussion with my	10:03:35
4	adviser.	10:03:38
5	MS. FERRERA: Can we go off the record?	10:03:38
6	THE VIDEOGRAPHER: We are going off the	10:03:40
7	record. The time is 10:03.	10:03:41
8	(Discussion off the record.)	10:03:43
9	THE VIDEOGRAPHER: We are back on the	10:05:12
10	record. The time is 10:05.	10:05:17
11	MS. FERRERA: Could we just have the last	10:05:20
12	question read back for Dr. Munafo, please.	10:05:21
13	(Question read.)	10:05:24
14	MS. FERRERA: And that's actually a	10:05:44
15	yes-or-no question, Dr. Munafo.	10:05:45
16	A. Yes, I was.	10:05:48
17	Q. What was the memory -- strike that.	10:05:51
18	Memory about what?	10:05:56
19	A. I wanted, I had the hope, to be able to	10:06:09
20	reconstruct the timelines of the work that was done by	10:06:14
21	I and my team at Serono regarding the design of the	10:06:29
22	dosing regimen.	10:06:44

1	Q. The dosing regimen for cladribine?	10:06:46
2	A. The dosing regimen for cladribine, yes.	10:06:48
3	Q. And when did you make the request of Nadia of	10:06:53
4	whether she had access to archives?	10:06:57
5	A. Sitting here today, I do not recall the exact	10:07:02
6	dates.	10:07:13
7	Q. Dr. Munafo, is it fair to say that at the	10:07:38
8	time you contacted Nadia regarding whether she had	10:07:41
9	access to archives, you did not have an independent	10:07:45
10	memory of the timelines of the work that was done by	10:07:48
11	you and your team at Serono regarding the design of	10:07:52
12	the dosing regimen of cladribine?	10:07:56
13	MS. FERRERA: Objection.	10:07:57
14	A. Exact sequence of events more than 20 years	10:08:09
15	ago are not something easy to recall, and I was	10:08:12
16	looking for a way -- for ways to help my memory.	10:08:22
17	If I may: The screen is a bit fuzzy --	10:08:56
18	now it has been sharp. Thank you.	10:09:00
19	Q. The screen is fuzzy?	10:09:04
20	A. No, now it is good.	10:09:06
21	Q. Oh. Dr. Munafo, have you read any deposition	10:09:07
22	transcripts from this case?	10:09:16

1	A. No, I have not.	10:09:23
2	Q. Your current rate is 450 Swiss francs per	10:09:29
3	hour; correct?	10:09:36
4	A. You mean for this case, or do you mean --	10:09:41
5	Yes, for this case it is the case.	10:09:49
6	Q. How much have you billed so far in this case?	10:09:54
7	A. What do you mean with "billed"?	10:09:59
8	Q. So we just established that your rate is 450	10:10:05
9	Swiss francs per hour. So how much money -- or how	10:10:09
10	many hours have you worked so far in this case and you	10:10:17
11	have invoiced Merck for that work?	10:10:23
12	A. Sitting here today, I cannot answer this	10:10:29
13	question with precision. I did not record and I do	10:10:31
14	not have at hands my bills.	10:10:38
15	Q. Are you owed any additional money for this	10:10:44
16	case?	10:10:46
17	MS. FERRERA: Objection.	10:10:51
18	A. When you say "this case," you refer	10:10:52
19	specifically to the litigation in the U.S.?	10:10:58
20	Q. I'm referring to these proceedings, correct.	10:11:01
21	A. No, I have not -- no other financial	10:11:05
22	interest.	10:11:10

1	Q. That's not what I asked. My question was:	10:11:12
2	Are you owed any additional money for this case? Are	10:11:19
3	there any outstanding invoices?	10:11:25
4	A. Ah, sorry. No, no invoice outstanding at	10:11:28
5	present.	10:11:39
6	Q. Now, you said that for this case your rate is	10:11:40
7	450 Swiss francs hire hour. Is your rate different	10:11:44
8	for other cases?	10:11:48
9	MS. FERRERA: Objection.	10:11:54
10	A. My rates were the same with respect to the	10:11:57
11	Canadian litigation.	10:12:07
12	Q. Has Merck paid you anything yet for these	10:12:14
13	IPRs?	10:12:17
14	A. Sorry, can you repeat? There was a little	10:12:19
15	bit of noise.	10:12:21
16	Q. Has Merck paid you anything yet for these	10:12:22
17	IPRs?	10:12:26
18	A. I have received compensation -- I'm not sure	10:12:28
19	if the term "compensation" is correct. I have	10:12:40
20	received some money with respect to work that had been	10:12:44
21	done in preparation of the declaration and deposition.	10:12:46
22	This came from WilmerHale, and I am not aware of the	10:12:54

1	agreement between WilmerHale and Merck to answer	10:13:01
2	whether this is Merck who paid me or WilmerHale.	10:13:04
3	Q. Okay. Dr. Munafo --	10:13:07
4	Actually, let me, just for the record:	10:13:18
5	How much have they paid you so far?	10:13:21
6	A. Sitting here today, I am not able to answer	10:13:23
7	this question. I do not have my records with me.	10:13:27
8	Q. How about just approximately?	10:13:31
9	MS. FERRERA: Objection.	10:13:33
10	A. I do not have my records with me.	10:13:35
11	Q. A thousand dollars?	10:13:44
12	MS. FERRERA: Objection.	10:13:46
13	A. I do not have my records with me.	10:13:48
14	Q. Was it more than \$100,000?	10:13:53
15	MS. FERRERA: Objection.	10:13:56
16	A. No, it was not.	10:13:58
17	Q. Dr. Munafo, you joined Serono in 1992 and	10:14:03
18	worked there until Merck acquired Serono in 2006;	10:14:07
19	correct?	10:14:12
20	A. You said in 1992?	10:14:12
21	Q. Correct.	10:14:21
22	A. No, I joined Merck in 1993.	10:14:22

1	Q.	So you joined Serono in 1993 --	10:14:26
2	A.	Serono in '93, yes.	10:14:30
3	Q.	And then worked there until Merck acquired	10:14:32
4		Serono in 2006; correct?	10:14:35
5	A.	Yes, correct -- the dates....	10:14:38
6		I would have to go back to the exact date,	10:14:48
7		if that is important. But yes, I worked with Serono	10:14:53
8		until Merck acquired them, and then I continued to	10:14:56
9		work with Merck Serono after Merck acquired Serono.	10:14:59
10	Q.	And then you worked at Merck until your	10:15:05
11		retirement in 2021; correct?	10:15:10
12	A.	Yes, this is correct.	10:15:19
13	Q.	So you worked for Serono or Merck for nearly	10:15:21
14		30 years; correct?	10:15:24
15	A.	From '93 to -- until my age of 65, yes,	10:15:29
16		correct. This is not quite 30 years.	10:15:34
17	Q.	You mentioned in your declaration that Serono	10:15:41
18		entered into a joint research agreement with IVAX to	10:15:44
19		develop cladribine for treating MS; correct?	10:15:50
20	A.	To be specific on the word -- the beginning	10:15:53
21		of the sentence again?	10:15:57
22	Q.	You mentioned in your declaration that Serono	10:15:58

1	entered into a joint research agreement with IVAX to	10:16:04
2	develop cladribine for treating MS. And just for your	10:16:09
3	convenience, you can go to Paragraph 23 as well as 26	10:16:15
4	of your declaration.	10:16:21
5	A. That's my understanding, yes.	10:16:27
6	Q. When did you first learn of this agreement?	10:16:29
7	A. The first -- the exact dates of the first	10:16:45
8	time I heard about that, sitting here today, I cannot	10:16:48
9	recall.	10:16:54
10	What I do recall, however, that this was a	10:16:57
11	stepwise process, starting very early, and probably, I	10:17:03
12	think, in 2001, certainly in 2002.	10:17:09
13	Q. Were you involved in the decision to enter	10:17:14
14	into the agreement?	10:17:18
15	A. No, I was not.	10:17:23
16	Q. What do you mean by "stepwise process"?	10:17:25
17	A. I would ask for your indulgence in terms of	10:17:38
18	timelines. What I wanted to explain here -- or to	10:17:41
19	allude to by saying this is that it is a progressive	10:17:44
20	process in a company, and it was a progressive process	10:17:50
21	at Serono. When you are approached by your manager or	10:17:55
22	your -- yeah, your manager usually, asking whether you	10:18:04

1 would be okay to participate to a project, then you 10:18:09
2 get to know -- if you agree, to get a little bit more 10:18:16
3 of the project -- to get to know a little more of the 10:18:19
4 project, the topics, the general idea. 10:18:23

5 And in parallel to that, the company 10:18:26
6 pursues the legal aspect of the agreement, and that's 10:18:32
7 what I mean by "stepwise." It is not something -- it 10:18:34
8 is not something that I can give an exact date. 10:18:40

9 Q. Do you have any understanding as to why Merck 10:18:45
10 entered into the agreement? 10:18:48

11 A. It was not Merck; it was Serono. 10:18:49

12 Q. My apologies. Do you have any understanding 10:18:55
13 why Serono entered into the agreement? 10:18:59

14 A. My understanding is that Serono did a due 10:19:09
15 diligence in the pharma industry, with a due diligence 10:19:15
16 team, looking at some data and information provided 10:19:22
17 by, in that case it was IVAX to evaluate whether there 10:19:31
18 was an opportunity for Serono to enter into this 10:19:40
19 agreement. But not being part of the due diligence, I 10:19:45
20 do not know more about that. 10:19:52

21 Q. Who did the due diligence? 10:19:54

22 A. I was not part of this due diligence team, 10:20:02

1 and I do not know the name. This was a process at 10:20:04
2 Serono where a team was composed of experts from 10:20:09
3 various functions. But I was not part of it, so I do 10:20:13
4 not know, sitting here today, the name of the persons 10:20:21
5 who were part of this due diligence team. 10:20:25

6 Q. When you say "various functions," what do you 10:20:27
7 mean by that? 10:20:29

8 A. This may depend from project to project from 10:20:31
9 the states of the project, whether it is an early 10:20:43
10 phase -- early development phase project or late 10:20:47
11 development phase project. 10:20:50

12 In a case like cladribine, it would 10:20:54
13 certainly -- also, again, I was not part of the team, 10:20:59
14 and this is something that I am getting out of my 10:21:01
15 memory. It comprised people from clinical 10:21:07
16 development -- 10:21:19

17 I'm speaking way too fast. I understand. 10:21:20
18 Sorry. 10:21:22

19 -- from clinical development, from 10:21:22
20 preclinical development, from statistics, 10:21:26
21 formulations, and whatever functions is then relevant 10:21:41
22 to evaluate the opportunity. 10:21:44

1	I insist on the fact that I was not	10:21:52
2	present there -- I was not present in that team, and I	10:21:54
3	do not -- I cannot, sitting here today, say exactly	10:21:58
4	which functions were present in that team.	10:22:03
5	Q. Fair enough. Do you have an understanding of	10:22:08
6	what this opportunity was?	10:22:11
7	A. Yes. My understanding is that this was about	10:22:18
8	the development of oral -- of oral cladribine as a	10:22:23
9	treatment of multiple sclerosis.	10:22:28
10	Q. Now, you said that, you mentioned a manager,	10:22:34
11	I believe. So can we just go back to that for a	10:22:36
12	minute. Was there a manager of yours that came to you	10:22:40
13	about participating in this cladribine project?	10:22:45
14	A. I have -- I do not have today a crisp memory	10:23:02
15	of the exact first time I was exposed, if you wish, to	10:23:11
16	this potential project, so I can, sitting here today,	10:23:16
17	reply definitely.	10:23:26
18	Q. But just -- I'm just trying to understand:	10:23:32
19	Was there, you know, some sort of meeting or	10:23:38
20	correspondence where a team decides, "Okay, now we're	10:23:41
21	working on cladribine"? Like, how did it go? How	10:23:46
22	would it normally go in your company?	10:23:49

1	MS. FERRERA: Objection.	10:23:51
2	Q. Like, "Now we have a cladribine project."	10:23:52
3	A. "Normally" is a term too vague for me to	10:23:59
4	answer. And in the company I was an expert in my	10:24:03
5	field but not in the department looking for external	10:24:14
6	opportunities, and I cannot reply formally, sitting	10:24:20
7	here today, as -- on what was process to propose a	10:24:27
8	representative of the function into the project --	10:24:38
9	project team.	10:24:42
10	Q. Do you have an understanding of how a	10:24:49
11	decision was made to enter into cladribine	10:24:52
12	collaboration with IVAX?	10:24:55
13	A. I was not part of this decision. I was	10:24:57
14	informed that this project had been evaluated and that	10:25:11
15	the company had decided to go into it. But I cannot	10:25:17
16	answer definitely as of today on who, if there is one	10:25:27
17	single person or if it was at the level of an	10:25:35
18	executive committee or board. I cannot answer that.	10:25:39
19	Q. And who informed you of the decision to start	10:25:49
20	working on cladribine with IVAX?	10:25:53
21	A. Sitting here today, I do not recall who	10:26:03
22	informed me.	10:26:07

1	Q. Do you have an understanding of why Serono	10:26:13
2	entered into the agreement with IVAX?	10:26:16
3	MS. FERRERA: Objection.	10:26:19
4	A. Strategic decisions are way far away from my	10:26:20
5	domain of expertise, and I cannot answer this	10:26:37
6	question.	10:26:39
7	Q. Do you know if Serono were the ones that	10:26:41
8	approached IVAX?	10:26:45
9	A. Can you repeat your question? There was a	10:26:46
10	kind of noise.	10:26:48
11	Q. Do you know if Serono first approached IVAX?	10:26:50
12	A. Sitting here today, I am not sure and I	10:27:02
13	cannot answer who approached who.	10:27:28
14	MS. FERRERA: Counsel, we've been going	10:27:38
15	for a little over an hour. Could we take a short	10:27:39
16	break?	10:27:41
17	MS. PARTINGTON: Sure.	10:27:43
18	THE VIDEOGRAPHER: We are going off the	10:27:46
19	record. The time is 10:27.	10:27:47
20	(Recess taken.)	10:27:49
21	THE VIDEOGRAPHER: We are back on the	10:43:03
22	record. The time is 10:43.	10:43:10

1	Q. Dr. Munafo, welcome back. Did you have any	10:43:17
2	discussions with counsel about the substance of your	10:43:20
3	deposition during the break?	10:43:22
4	A. No, we did not.	10:43:25
5	Q. Thank you. Are you receiving any retirement	10:43:27
6	compensation from Merck or any Merck-related entity?	10:43:34
7	A. I am receiving, according to Swiss law, two	10:43:41
8	pensions. One is from the state. One is from the	10:43:51
9	pension fund that was built with Serono and thereafter	10:43:55
10	Merck Serono. But my understanding, according to	10:44:00
11	Swiss law, is that the money does not come from Serono	10:44:06
12	or Merck Serono but from the pension fund.	10:44:09
13	Q. Do you have any stock or ownership shares of	10:44:13
14	Merck or any Merck-related entity?	10:44:17
15	A. No, I do not.	10:44:19
16	Q. Are you under any contractual obligation with	10:44:24
17	Merck or any Merck-related entity to assist in legal	10:44:28
18	matters?	10:44:31
19	A. These are legal terms that I'm not sure I	10:44:36
20	completely understand. What I -- I am under the terms	10:44:39
21	of the Swiss law when someone leaves a company, but	10:44:53
22	nothing more specific than that.	10:44:59

1 Q. Do you know if there's a contract that you 10:45:07
2 signed that requires that you testify on behalf of 10:45:10
3 Merck in any legal matters? 10:45:16

4 MS. FERRERA: Objection. 10:45:21

5 A. There is no contract besides the -- besides 10:45:24
6 what was signed for this case. I'm not sure I 10:45:53
7 understand -- address your question. But there is no 10:46:02
8 other contract signed. 10:46:04

9 Q. So there's no contract that requires you to 10:46:06
10 participate on behalf of Merck in legal proceedings; 10:46:10
11 correct? 10:46:16

12 MS. FERRERA: Objection. 10:46:16

13 A. I need to discuss with my attorney on that. 10:46:19
14 It will be quick. 10:46:23

15 Q. That's okay. I withdraw my question. Strike 10:46:27
16 that. 10:46:29

17 Okay, Dr. Munafo, you are a co-inventor of 10:46:30
18 the '947 and '903 patents; correct? 10:46:39

19 A. This is correct. 10:46:43

20 Q. And those patents are now assigned to Merck; 10:46:44
21 correct? 10:46:52

22 A. I -- sitting here today, I do not know the 10:46:52

1 background of that and the owner of the patent, so I 10:46:58

2 cannot answer this legal aspects of them, I'm sorry. 10:47:04

3 Q. At the time that Serono or Merck filed for 10:47:10
4 the patents, do you remember assigning your rights to 10:47:17
5 Merck or Serono to this invention? 10:47:20

6 A. I do remember some documents that I signed 10:47:24
7 and were related to this patent. But sitting here 10:47:43
8 today, I do not recall the text in them. 10:47:48

9 Q. Do you remember receiving any compensation 10:47:58
10 from Merck or related entities for the '947 and '903 10:48:08
11 patents? 10:48:19

12 A. No, I do not. 10:48:22

13 MS. PARTINGTON: Okay, Emil, can we put 10:48:31
14 the Exhibit 2053 back up, please, Dr. Munafo's 10:48:36
15 declaration, and if you could go to Appendix A, Page 10:48:47
16 27. And if you can just scroll through the appendix, 10:48:50
17 please. 10:49:11

18 Thank you. 10:49:43

19 Q. Is this your CV, Dr. Munafo? 10:49:44

20 A. Again, scrolling through it as much as I can, 10:49:46
21 yes, it is. 10:49:50

22 Q. And you have it in front of you as well; 10:49:54

1	correct?	10:49:57
2	A. I have the CV as an appendix of my	10:49:57
3	declaration in front of me.	10:50:01
4	Q. When was the last time you updated your CV?	10:50:03
5	A. The last update is, at the bottom of the last	10:50:09
6	page, and you have on the screen right now, it was in	10:50:14
7	June 2020, 11th.	10:50:17
8	Q. Does your CV accurately reflect your areas of	10:50:25
9	scientific expertise and credentials?	10:50:28
10	A. Yes.	10:50:41
11	Q. Now I'm going to ask you some questions	10:50:45
12	regarding your career and scientific background, and I	10:50:48
13	would like you to focus on the 2004 time frame unless	10:50:51
14	I specifically say otherwise. Okay?	10:50:55
15	A. Okay.	10:51:02
16	Q. Dr. Munafo, you use the term, or rather the	10:51:05
17	word, "formulation" -- strike that. I'm going to	10:51:09
18	start over.	10:51:12
19	Dr. Munafo, you use the word "formulation"	10:51:13
20	a number of times in your declaration. My question	10:51:20
21	for you is: What is a formulation?	10:51:22
22	MS. FERRERA: Objection.	10:51:26

1	A.	Within the pharmaceutical industry, this is a	10:51:35
2		term that is used to describe the components and	10:51:38
3		strengths of those components of a pharmaceutical	10:52:03
4		preparation.	10:52:12
5		Having said that, we may want to go place	10:52:14
6		by place where I use this word if you need more	10:52:27
7		explanation of what I meant at a certain moment.	10:52:33
8	Q.	I think this should suffice for now. Thank	10:52:37
9		you.	10:52:40
10		Is the formulation the same as a dosage	10:52:41
11		form?	10:52:43
12	MS. FERRERA:	Objection.	10:52:44
13	A.	No, it is not exactly the same, in the sense	10:52:45
14		that a dosage form is the physical form that is used,	10:53:05
15		while the formulation also refers to its composition.	10:53:16
16	Q.	Could you explain what you mean by "the	10:53:26
17		physical form that is used"?	10:53:31
18	A.	A dosage form could be a capsule, gel form, a	10:53:34
19		suppository; in my understanding, also could be an	10:53:44
20		injection. This is a dosage form, the physical nature	10:53:52
21		of what is intended to be administered.	10:54:00
22	Q.	Is there a difference between a drug and a	10:54:06

1	formulation?	10:54:09
2	MS. FERRERA: Objection.	10:54:14
3	A. Yes. "Drug" is a very general term that can	10:54:15
4	have various meanings in various contexts.	10:54:21
5	In the pharmaceutical understanding, the	10:54:30
6	drug is --	10:54:36
7	It is a generic term, "drug," like "Food	10:54:43
8	and Drug Administration" at the FDA. And it does not	10:54:59
9	have the specificity of form or formulation, and it	10:55:00
10	can refer to a variety of things, including the active	10:55:04
11	component, but also, as in "FDA," the final	10:55:09
12	administration form. It's a term that is quite vague.	10:55:18
13	Q. An active component -- is cladribine an	10:55:24
14	example of an active component?	10:55:29
15	A. In cladribine oral administration, cladribine	10:55:40
16	is the active component, yes.	10:55:44
17	Q. If I use the term "drug formulation," do you	10:55:45
18	understand what I mean by that term?	10:55:54
19	A. I would appreciate if you share your meaning	10:55:55
20	so that we are totally aligned.	10:56:05
21	Q. Do you have an understanding of what "drug	10:56:06
22	formulation" means?	10:56:08

1 A. In my understanding, I think I do. But
2 again, given that, as I said, "drug" is quite vague,
3 "formulation" is a bit more specific, so when and if
4 you have some question, I would like you to be very
5 specific on that.

6 Q. What is your understanding of the term "drug
7 formulation"?

8 A. My understanding is that it is the -- the
9 ensemble of -- this is not an easy definition.

10 It is what has -- or what is prepared,
11 assembled, and, as we say, formulated, and in order to
12 deliver the drug in the way it is intended to be
13 delivered -- in the way and by the rules it is
14 intended to be delivered.

15 Q. Have you ever designed a drug formulation?

16 A. During my pharmacy studies we did -- yes, we
17 did some preparations, as well as when I was working
18 for a certain time in a pharmacy as part of my
19 pharmaceutical studies, one of the aspects of
20 pharmaceutical development was to prepare, so
21 preparation, of a drug for appropriate delivery, which
22 encompassed the formulation.

1 Now, when you say "developed" a 10:58:44
2 formulation, do you mean prepare a drug for delivery, 10:58:48
3 or do you mean invent a formulation? 10:58:54

4 Q. So I asked if you've ever designed a drug 10:58:57
5 formulation that's prepared or developed, so I'm going 10:59:00
6 to ask you: Have you ever designed a drug 10:59:05
7 formulation? 10:59:08

8 A. I have in pharmaceutical studies elaborated a 10:59:17
9 formula for -- and I give you an example -- the 10:59:23
10 preparation of a tablet, where as students we were in 10:59:28
11 charge of calculating the amount of each excipient, if 10:59:34
12 this is a term that I can use, as well as the amount 10:59:41
13 of -- to allow for the final capsule, tablets -- in 10:59:46
14 that case it was tablets, if I recall -- to have a 10:59:54
15 certain ratio of excipients to active principle. 10:59:58

16 And whether this is what you mean with 11:00:06
17 "design," I would answer yes. If you mean something 11:00:09
18 else, you will have to specify. 11:00:14

19 Q. And this example you just gave, this was part 11:00:20
20 of your university or postgraduate studies; correct? 11:00:23

21 A. Correct. 11:00:27

22 Q. Have you ever designed a drug formulation in 11:00:29

1	your professional role?	11:00:31
2	MS. FERRERA: Objection.	11:00:40
3	A. What do you mean with "professional role"?	11:00:41
4	You mean my time at Merck Serono?	11:00:43
5	Q. Well, yeah, let me clarify the question.	11:00:47
6	Have you ever designed a drug formulation -- strike	11:00:52
7	that.	11:00:57
8	Have you ever designed a cladribine	11:00:58
9	formulation?	11:00:59
10	A. No, I have not.	11:01:03
11	Q. Dr. Munafo, you used the term "dosing	11:01:09
12	regimen" multiple times in your declaration. My	11:01:12
13	question for you is: What is a dosing regimen?	11:01:16
14	A. It is the -- it is a description of when and	11:01:33
15	how much and to which frequency and for how long and	11:01:46
16	at which dose a drug has to be or is planned to be	11:01:52
17	administered to, in this case, a patient.	11:02:02
18	Q. Okay, just to make sure I understand: You	11:02:09
19	said it's a description of when, No. 1; two, how much;	11:02:12
20	three, to which frequency; and four, for how long; and	11:02:20
21	five, at which dose a drug has to be or is planned to	11:02:25
22	be administered. Correct? Did I count correct, that	11:02:28

1 there are five features, if you will, of a dosing 11:02:32

2 regimen? 11:02:35

3 MS. FERRERA: Objection. 11:02:36

4 A. You may want to go back to what exactly I 11:02:51

5 said if you want to be specific. It is a description 11:02:54

6 of how, when, which dose, how long, which frequency, 11:03:04

7 and all these aspects that surround the recommendation 11:03:20

8 for the administration and -- for the administration 11:03:28

9 of the drug. 11:03:31

10 I am not sure I can say it is only five, 11:03:33

11 and it may depend on the case and circumstances. 11:03:39

12 Also, that's a generalization that I would not make. 11:03:47

13 Q. Okay. Can we just take each of them at a 11:03:55

14 time, please. So the first one is when. What does 11:04:01

15 that mean? 11:04:05

16 MS. FERRERA: Objection. 11:04:13

17 A. When relates to time, and this is a 11:04:27

18 description of the time when the drug should be taken. 11:04:37

19 It is, again, not in my intent to make a 11:04:43

20 generalization, but it can and it could include 11:04:48

21 elements such as whether the drug should be 11:04:55

22 administered once a day or together with meal or after 11:05:06

1 meal, for example, and this kind of element. This is

11:05:18

2 what I had in mind with talking about time.

11:05:21

3 But again, we are here in a very general

11:05:30

4 situation, and I would like to refrain from being

11:05:38

5 positive that the when is only in this aspect. It

11:05:50

6 could be more, it could be less, depending on the

11:05:57

7 circumstances of the drug, the prescriber, the

11:05:59

8 situation that's at hand.

11:06:06

9 Q. Okay. And in the design of a dosing regimen,

11:06:07

10 does it matter when a drug is taken?

11:06:11

11 MS. FERRERA: Objection.

11:06:15

12 A. This is also a very general question, and

11:06:15

13 depending on the circumstances, it may matter, yes.

11:06:28

14 Q. Why might it matter, Dr. Munafo?

11:06:36

15 MS. FERRERA: Objection.

11:06:42

16 A. I'd like you to repeat your question. Why?

11:06:42

17 Q. You said that depending on the circumstances,

11:06:45

18 it may matter, and my question for you is: Why?

11:06:50

19 MS. FERRERA: Objection.

11:06:57

20 A. We are at a very general level here; and if

11:06:58

21 you want a specific answer related to cladribine,

11:07:06

22 please be specific, or otherwise tell me that you want

11:07:09

1 to have a very general answer, please. 11:07:17

2 Q. I'm just trying to understand your testimony, 11:07:23

3 Dr. Munafo. You said it might matter, and I'm just 11:07:25

4 trying to understand why it might matter when you 11:07:31

5 administer a drug. 11:07:34

6 MS. FERRERA: Objection. 11:07:37

7 A. I think you're asking for an expert opinion 11:07:39

8 here. Is that your question? Is that your point? 11:07:51

9 Q. I'm just trying to clarify what you meant by 11:07:59

10 in some circumstances it might matter when you 11:08:04

11 administer the drug. 11:08:09

12 A. I will give you a very -- 11:08:14

13 MS. FERRERA: Sorry, I don't think you've 11:08:15

14 actually asked a question. 11:08:17

15 MS. PARTINGTON: Dr. Munafo said "may 11:08:38

16 matter," not "might matter." I quoted him 11:08:41

17 incorrectly. 11:08:45

18 MS. FERRERA: So what is the question? 11:08:45

19 Q. My question for you is: Why might it matter 11:08:47

20 when the drug is administered, Dr. Munafo? 11:08:54

21 MS. FERRERA: Objection. 11:08:56

22 A. If you allow me to give you an example to 11:08:58

1 show why it might or it may matter: If you decide to 11:09:17
2 take a sleeping pill, you will take it before you 11:09:21
3 intend to go to sleep and not before you want to go to 11:09:27
4 the office. In this sense the time, or when, may 11:09:31
5 matter when you consider a dosing regimen. 11:09:45

6 Q. Thank you. Now, you also said that a dosing 11:09:48
7 regimen includes how the drug is administered. What 11:09:51
8 do you mean by that? 11:09:53

9 A. "How" referred in what I was saying to the 11:10:07
10 administration route, whether you take the drug by 11:10:10
11 mouth, suppository, or any other route. That's one 11:10:16
12 aspect of the how. 11:10:25

13 Other aspects of the how that you can see 11:10:29
14 in drug labels, for example -- and again, I'm giving 11:10:35
15 examples to clarify this, and this is general issues. 11:10:39
16 It may be recommended to administer a pill with a 11:10:47
17 glass of water. That would be part of the how. 11:10:53

18 Q. In designing a dosing regimen, does it matter 11:10:57
19 how a drug is taken? 11:11:01

20 MS. FERRERA: Objection. 11:11:05

21 A. The route of administration does matter, yes. 11:11:08

22 Q. And why is that? 11:11:12

1	MS. FERRERA: Objection.	11:11:19
2	A. Why it matters?	11:11:20
3	Q. That is correct.	11:11:24
4	A. That is your question?	11:11:26
5	Q. Correct.	11:11:27
6	A. Because the route of administration and the	11:11:28
7	formulation are interlinked. And again an example:	11:11:52
8	It would not be the same -- you would define the route	11:12:06
9	of administration in a dosing regimen differently if	11:12:11
10	it is to be taken orally or as a suppository. You	11:12:17
11	may -- you would say -- the terms would be different.	11:12:26
12	You would use the term "suppository" or "pill" in your	11:12:34
13	description.	11:12:41
14	Q. You mentioned the word "interlinked." What	11:12:44
15	do you mean by "interlinked"?	11:12:51
16	Let me read you what you said. You said,	11:12:53
17	"Because the route of administration and the	11:12:56
18	formulation are interlinked." My question is: What	11:12:58
19	do you mean by "interlinked"?	11:13:03
20	A. I mean that the formulation would not be the	11:13:05
21	same if the intent is to administer orally or by	11:13:10
22	another route.	11:13:16

1	Q.	Does the route of administration depend on	11:13:42
2		the formulation?	11:13:44
3		MS. FERRERA: Objection.	11:13:45
4	A.	This is a question?	11:13:57
5	Q.	That is the question. Does the route of	11:14:04
6		administration depend on the formulation?	11:14:07
7	A.	You said does the route of administration	11:14:09
8		depend on the formulation?	11:14:11
9	Q.	Yes.	11:14:13
10	A.	A formulation is designed for a certain	11:14:13
11		route. So I'm not sure the dependency is in one	11:14:26
12		direction or the other, but one, it is designed for	11:14:33
13		the other, to design a formulation for oral	11:14:37
14		formulation -- for oral administration.	11:14:40
15	Q.	And does the dosing regimen depend on the	11:14:43
16		formulation?	11:14:46
17		MS. FERRERA: Objection.	11:14:52
18	A.	Are you again in a very general	11:14:58
19		pharmaceutical discussion, or are you specific to my	11:15:02
20		declaration?	11:15:06
21	Q.	I'm just trying to understand whether a --	11:15:12
22		what your understanding is about a dosing regimen	11:15:17

1 depending on the formulation. 11:15:23

2 A. So your question was does the dosing regimen 11:15:39
3 depend on the formulation? 11:15:43

4 Q. Yes. To your understanding, does the dosing 11:15:44
5 regimen depend on the formulation? 11:15:46

6 MS. FERRERA: Objection. 11:15:49

7 A. Specifically in the case of cladribine oral 11:15:49
8 administration or generally speaking in the 11:15:52
9 pharmaceutical industry? 11:15:56

10 Q. Why don't we start with generally speaking. 11:15:57

11 MS. FERRERA: Objection. 11:16:10

12 A. There is a huge diversity in the formulation 11:16:11
13 developed in the pharmaceutical industry, and I can 11:16:18
14 give one example of where it would be relevant. And 11:16:30
15 this is, for example -- again, this is an example -- 11:16:34
16 if a drug was developed in a sustained-release form, 11:16:41
17 then this would have to be accounted for in in the 11:16:53
18 recommended dosing regimen. 11:16:58

19 Q. Okay. And what about for cladribine 11:17:02
20 specifically? To your understanding, does the dosing 11:17:05
21 regimen depend on the cladribine formulation? 11:17:09

22 A. Formulation is one of the numerous aspects 11:17:16

1 that leads to designing a dosing regimen, among them 11:17:27
2 convenience to the patient, the possible interactions 11:17:51
3 that a drug has with food or with other medications, 11:17:55
4 the course of the disease -- a number of aspects that 11:18:02
5 come into -- that needs to be considered when 11:18:12
6 designing a dosing regimen, and formulation is one of 11:18:17
7 these aspects. 11:18:23

8 Q. Go back to the dosing regimen. You mentioned 11:18:26
9 frequency of administration. What is frequency of 11:18:30
10 administration? 11:18:35

11 MS. FERRERA: Objection. 11:18:38

12 A. "Frequency" is a term that relates to 11:18:59
13 scientifically the inverse of time. This means that, 11:19:05
14 in the design of a dosing regimen, "frequency" means 11:19:13
15 how often the drug is intended to be administered. 11:19:21
16 And again, as an example, it could be once a day. 11:19:33

17 Q. And in the design of a dosing regimen, does 11:19:39
18 the frequency of administration matter? 11:19:42

19 MS. FERRERA: Objection. 11:19:45

20 A. Frequency of administration is a component of 11:19:47
21 a dosing regimen. It is an integral part of it. 11:19:58

22 Q. How integral? 11:20:15

1	MS. FERRERA: Objection.	11:20:18
2	A. Is this a question? Can you....	11:20:18
3	Q. Yeah, let me -- let me strike my previous	11:20:25
4	question and ask you: Why is it integral?	11:20:28
5	A. A dosing regimen defines various elements	11:20:32
6	that we discussed -- and the list was possibly not	11:21:06
7	comprehensive, but you know the five points, if I	11:21:12
8	recall well. And frequency is one aspect of it. When	11:21:15
9	I was mentioning that the when and the duration and	11:21:29
10	the frequency matter, that's what I intended to -- one	11:21:33
11	of the aspects that I was mentioning.	11:21:42
12	So maybe if I may ask you what -- to be	11:21:44
13	more specific in your question or what has not been	11:21:52
14	addressed before, it would help me answer.	11:21:55
15	Q. Well, I was just trying to understand what	11:22:00
16	you meant by frequency being an integral part of the	11:22:02
17	regimen.	11:22:05
18	A. Maybe this is due to my English. What I	11:22:10
19	meant there is that it is -- it is part of -- it is	11:22:17
20	part of it. I think I can strike the word "integral."	11:22:29
21	It is part of the dosing regimen.	11:22:33
22	Q. Okay. And then you also mentioned how much	11:22:40

1 of the drug, so my question is: In designing a dosing 11:22:47

2 regimen, does the how much of the drug matter? 11:22:53

3 MS. FERRERA: Objection. 11:22:59

4 A. Yes, it does matter. 11:23:00

5 Q. And why is that? 11:23:14

6 A. Dosing regimen is about administering a drug 11:23:20

7 in a formulation, and in this context the amount of 11:23:45

8 the drug that is included in the formulation is part 11:23:52

9 of this dosing regimen. Yes, it is part of the dosing 11:24:10

10 regimen. 11:24:21

11 Q. Okay. Dr. Munafo, you said in your 11:24:27

12 declaration that during your time at Serono you worked 11:24:40

13 as a member of several drug development project teams, 11:24:44

14 including cladribine in treating multiple sclerosis. 11:24:51

15 So my question for you is: Did your role in 11:24:54

16 cladribine include designing cladribine formulations? 11:24:57

17 A. My role in the Serono project team was to 11:25:11

18 provide expert's input in aspects related to my 11:25:28

19 function, and this included designing or contributing 11:25:41

20 to the design of the dosing regimen. 11:25:47

21 Q. In your declaration you mentioned that when 11:26:03

22 you were at Serono -- you mentioned in your 11:26:05

1	declaration that when you were at Serono you	11:26:20
2	researched and investigated the pharmacokinetics of	11:26:24
3	cladribine with the goal of developing dosing regimens	11:26:28
4	that would be safe and effective. So my question for	11:26:31
5	you is: What do you mean when you say	11:26:34
6	"pharmacokinetics of cladribine"?	11:26:37
7	MS. FERRERA: Are you referring to a	11:26:43
8	particular statement in Dr. Munafo's declaration?	11:26:44
9	MS. PARTINGTON: Counsel, the question is	11:26:48
10	still pending. I ask you not to interrupt and	11:26:50
11	interject with the question is pending.	11:26:53
12	Q. Dr. Munafo, what do you mean when you say	11:26:55
13	"pharmacokinetics of cladribine"?	11:26:58
14	MS. FERRERA: Objection.	11:27:00
15	A. It would help me if you could point me to	11:27:00
16	this exact sentence so that I can answer very	11:27:04
17	specifically.	11:27:10
18	Q. It's in Paragraph 19.	11:27:10
19	A. Okay, I have the sentence in front of me. So	11:27:27
20	your question is: What is meant by the term	11:27:31
21	"pharmacokinetics"?	11:27:36
22	Q. My question for you is: What do you mean	11:27:37

1	when you say "pharmacokinetics of cladribine"?	11:27:39
2	A. "Pharmacokinetics" is a term that is used to	11:27:52
3	describe -- again, that is -- sorry to interrupt my	11:28:04
4	response. I need to contextualize this.	11:28:17
5	"Pharmacokinetics" is a term that has been	11:28:21
6	used for probably 50 years now, with books and books	11:28:24
7	and books written on that. And I'm really trying my	11:28:28
8	best here to explain what is meant -- what I meant	11:28:35
9	here, with the caveat that I hope I'm not too	11:28:38
10	restrictive, and I will try to explain within this	11:28:47
11	environment.	11:28:54
12	Pharmacokinetics of cladribine was	11:28:55
13	investigated to understand the time profile of the	11:28:59
14	concentration in the body following administration of	11:29:09
15	cladribine to living systems -- and I mean here --	11:29:27
16	what I meant with that is that it could encompass	11:29:32
17	animals as well as humans as well as -- or animals,	11:29:35
18	and so living organisms -- looking at concentration	11:29:41
19	and how it evolves with time, and including metrics	11:29:47
20	of -- that characterize this time profile, as well as	11:30:00
21	the variability around these metrics.	11:30:07
22	Q. When you say "pharmacokinetics of	11:30:16

1 cladribine," do you mean pharmacokinetics of the 11:30:18

2 active cladribine itself or the pharmacokinetics of 11:30:21

3 the specific cladribine formulation? 11:30:27

4 A. The pharmacokinetics is the study of the 11:30:41

5 relationship between dose and concentration and time. 11:30:49

6 So it does include the relationship, as I just said, 11:30:55

7 between dose and concentration. So to this respect it 11:31:01

8 includes aspects -- it includes, not aspects, but 11:31:09

9 includes, for example, the route of administration, 11:31:15

10 would be an element that we consider when we 11:31:22

11 investigate the pharmacokinetics. 11:31:24

12 Does this address your question? 11:31:27

13 Q. When you were investigating the 11:31:29

14 pharmacokinetics of cladribine, were you working with 11:31:31

15 a specific formulation of cladribine? 11:31:37

16 MS. FERRERA: Objection. 11:31:46

17 A. By the time we were developing the dosing 11:31:48

18 regimen, we were looking at all available information. 11:32:02

19 So having contextualized this, your question was we 11:32:17

20 looked at a specific formulation, if I got that right. 11:32:25

21 The answer to this is no, we looked at every available 11:32:28

22 information that we could get. 11:32:31

1 Q. What do you mean, "every available 11:32:40

2 information we could get"? 11:32:44

3 A. There were both nonconfidential, publicly 11:32:46

4 available information and some information that we 11:32:55

5 were gathering confidentially from previous trials. 11:33:02

6 Sitting here today, I am not able to say or to label 11:33:09

7 each of them as such. But this was the panel of 11:33:16

8 information that we could gather either, as I said -- 11:33:27

9 not "either," but also that we could get in this 11:33:34

10 research. 11:33:41

11 Q. When did you develop the dosing regimen for 11:33:49

12 cladribine? 11:33:52

13 A. When did we develop the dosing regimen, is 11:33:55

14 your question? 11:33:59

15 Q. That is correct. 11:33:59

16 MS. FERRERA: Objection. 11:34:00

17 A. Development of a dosing regimen is a lengthy 11:34:01

18 process that can spread and did spread over several 11:34:10

19 months. So sitting here today, I cannot answer 11:34:19

20 precisely a date. 11:34:23

21 Q. When did it start? Strike that. 11:34:28

22 When did you start developing the dosing 11:34:34

1	regimen of cladribine?	11:34:39
2	MS. FERRERA: Objection.	11:34:40
3	A. Sitting here today, I cannot give you a	11:34:44
4	precise date of the start, as it was an iterative	11:34:53
5	process, and I do not recall sitting here today the	11:35:02
6	exact start date.	11:35:08
7	Q. Do you know if it was before Serono entered	11:35:11
8	into the joint research agreement with IVAX?	11:35:14
9	A. I would not be able, sitting here today, to	11:35:32
10	say the exact date with respect to the signature of	11:35:36
11	the agreements. What I can, however, reply is that it	11:35:40
12	was not before I was made aware and started to	11:35:45
13	contribute to the project team.	11:35:52
14	Q. Do you remember approximately which year it	11:35:54
15	was? I'm not asking you for an exact date.	11:36:06
16	MS. FERRERA: Objection.	11:36:12
17	A. I do not recall, as I said, the exact date.	11:36:26
18	In terms of the year, it was --	11:36:31
19	Again, it was in the frame of 2003,	11:36:41
20	perhaps before, before -- a little bit before, but in	11:36:48
21	that time frame. And please excuse me, more than 20	11:36:52
22	years later, if I do not recall the exact dates.	11:37:00

1	And with this, may I ask for a short	11:37:07
2	break?	11:37:10
3	Q. Of course.	11:37:12
4	THE VIDEOGRAPHER: We are going off the	11:37:13
5	record. The time is 11:37.	11:37:14
6	(Recess taken.)	11:37:16
7	THE VIDEOGRAPHER: We are back on the	11:48:56
8	record. The time is 11:48.	11:49:00
9	Q. Thank you. Dr. Munafo, did you have any	11:49:10
10	discussions with counsel about the substance of the	11:49:12
11	deposition during the break?	11:49:14
12	A. No, I have not.	11:49:16
13	Q. Dr. Munafo, are the pharmacokinetic	11:49:19
14	properties of a drug formulation a consideration when	11:49:24
15	developing its dosing regimen?	11:49:29
16	MS. FERRERA: Objection.	11:49:30
17	A. You're asking in general terms whether the	11:49:33
18	pharmacokinetics are an important element in	11:49:37
19	consideration --	11:49:41
20	Q. I'm going to ask again.	11:49:43
21	A. Yes, please.	11:49:44
22	Q. Are the pharmacokinetic properties of a drug	11:49:46

1 formulation a consideration when developing a dosing
2 regimen?

11:49:51

11:49:58

3 MS. FERRERA: Objection.

11:49:58

4 A. This is a general statement, and I would like
5 to request some clarification whether you want to have
6 this as a general lecture on pharmacokinetics or if
7 you want to speak specifically on the case of
8 cladribine formulation, please.

11:50:05

11:50:16

11:50:21

11:50:25

11:50:28

9 Q. In your experience, are the pharmacokinetic
10 properties of a drug formulation a consideration when
11 developing a dosing regimen?

11:50:30

11:50:34

11:50:37

12 MS. FERRERA: Objection.

11:50:38

13 A. In general terms, if I understand now your
14 question, yes, formulation -- pharmacokinetics are an
15 important element to take into consideration.

11:50:39

11:50:45

11:50:52

16 Q. And why is that?

11:50:57

17 A. Pharmacokinetics characterize the
18 relationship between dose, concentration, and time, as
19 I was mentioning earlier. So given that the dosing
20 regimen includes elements of dose and time, yes,
21 pharmacokinetics is -- is to be considered in the
22 design of a dosing regimen.

11:50:58

11:51:06

11:51:14

11:51:27

11:51:34

11:51:47

1 Q. Does the specific formulation of a drug
2 affect its pharmacokinetic properties?

3 MS. FERRERA: Objection.

4 A. If we are still in the very general term --
5 general domain, I gave you an example early on that
6 the formulation can affect the pharmacokinetics, when
7 I was giving the example of a sustained-release
8 formulation. So in some circumstances, yes.

9 Q. Does the specific formulation of cladribine
10 affect its pharmacokinetic properties?

11 A. There are in the case of cladribine various
12 aspects. One of them is --

13 Step back just one second.
14 Pharmacokinetics is the relationship between dose,
15 concentration, and time. So in the sense that the
16 relationship between dose and concentration is part of
17 this, one of the aspects of cladribine formulation
18 being the amount of drug that is delivered to the
19 systemic concentration -- to the systemic circulation,
20 yes, this has to be accounted for.

21 Other elements of the formulation have
22 potentially impact. And to put this in context: IVAX

1 designed a first trial that was aimed at looking at 11:54:04
2 the concentration of cladribine following 11:54:08
3 administration of a few and viable -- a few different 11:54:12
4 formulations. And this has indeed shown that there 11:54:21
5 could be and there were some differences in the pharma 11:54:30
6 signatures following these different formulations. 11:54:37

7 Q. So you said IVAX designed a few different 11:54:50
8 formulations. My question is: What were -- do you 11:54:55
9 have any knowledge of what those formulations were? 11:55:01

10 A. Sitting here today, I would not be able to 11:55:04
11 give a precise response to this. But if you need to 11:55:11
12 have something more specific, perhaps we can go to 11:55:24
13 some minutes where the formulations were described or 11:55:32
14 when the results of the so-called 101 trial, which is 11:55:41
15 how IVAX named their trial investigating a few 11:55:55
16 formulations, and the formulations were described 11:56:03
17 there. 11:56:09

18 Q. And do you know if IVAX designed those 11:56:16
19 formulations before Merck -- rather, before Serono 11:56:26
20 started developing a cladribine dosing regimen? 11:56:39

21 A. I am not -- I was not an employee in IVAX, 11:56:46
22 and I do not know when they started to work on 11:56:52

1 potential formulations. 11:56:56

2 Q. Do you have any knowledge of whether -- 11:57:00

3 strike that. 11:57:08

4 Do you know if Serono approached IVAX 11:57:09

5 because of the formulations that IVAX had of 11:57:30

6 cladribine? 11:57:34

7 A. Sitting here today, I do not know if it is 11:57:38

8 Serono who approached IVAX or IVAX who approached 11:57:41

9 Serono. 11:57:43

10 Q. Do you know if the joint research agreement 11:57:50

11 was entered after -- strike that. 11:57:57

12 Do you know if IVAX had designed their 11:58:02

13 formulations before the joint research agreement was 11:58:07

14 entered into by the two parties? 11:58:11

15 A. Sitting here today, I have no recollection of 11:58:17

16 any information on when they started to work on the 11:58:25

17 formulation. 11:58:28

18 Q. When you joined the cladribine team in 11:58:31

19 Serono, Dr. Munafo, did you have IVAX's formulations 11:58:45

20 available to you? 11:58:57

21 A. I'd like to paraphrase your question, to make 11:59:04

22 sure I understand it well. You're asking when I 11:59:07

1	joined the project team whether I had available -- and	11:59:09
2	maybe I'd like you to characterize what you mean with	11:59:18
3	"available" the formulations? Do you mean whether I	11:59:21
4	knew what they intended to do or what they had done?	11:59:25
5	Q. My question is: Do you know if IVAX had	11:59:32
6	already designed their formulations at the time that	11:59:39
7	you joined the Serono cladribine team?	11:59:43
8	A. I do not know when exactly they -- IVAX, I	11:59:54
9	mean -- started to work on the various formulations.	12:00:02
10	What I do recall is that in meetings that	12:00:10
11	we had together with them either in person or by	12:00:17
12	teleconference, and repeatedly so over several	12:00:23
13	years -- over, at least, a certain time -- I remember	12:00:28
14	having seen some proposals and -- yes, some proposals,	12:00:32
15	but I do not know when they started to work on them.	12:00:49
16	Q. So, Dr. Munafo, I'm not asking you when --	12:00:51
17	whether you have any knowledge of the start date of	12:00:56
18	designing the formulation from IVAX. My question was:	12:01:04
19	When you joined the Serono cladribine team, do you	12:01:10
20	know whether the formulations had already been	12:01:17
21	designed by IVAX?	12:01:19
22	MS. FERRERA: Objection.	12:01:25

1	A. I do not know, sitting here today, whether	12:01:34
2	IVAX had started -- or had worked already on the	12:01:38
3	formulation at the time I joined the Serono team.	12:01:44
4	Q. Do you know whether IVAX had developed their	12:02:06
5	formulations before Serono started developing their	12:02:14
6	dosing regimen for cladribine?	12:02:19
7	A. The start date of their development at IVAX	12:02:35
8	sitting here today I cannot answer, and the start date	12:02:43
9	of the dosing regimen, as I said earlier today, I do	12:02:47
10	not recall the exact dates, either. So for me, I	12:02:57
11	cannot average one against the other.	12:03:04
12	Q. Dr. Munafo, I'm not asking for an exact date.	12:03:05
13	I'm trying to understand the sequence of events that	12:03:09
14	took place. You have testified in your declaration	12:03:12
15	that IVAX designed a formulation, or several	12:03:17
16	formulations, of cladribine, and according to your	12:03:23
17	testimony, the Serono team designed a dosing regimen	12:03:26
18	for cladribine. I'm just trying to understand the	12:03:31
19	sequence of events between these two events: design	12:03:35
20	of the formulation and the design of the dosing	12:03:44
21	regimen. So let me ask you again: Did IVAX design --	12:03:46
22	strike that.	12:03:56

1	Do you have a recollection of whether IVAX	12:03:58
2	had designed their formulation before Serono started	12:04:07
3	working on their dosing regimen?	12:04:11
4	MS. FERRERA: Objection.	12:04:15
5	A. Also you are not asking for a precise date;	12:04:16
6	you are asking for a sequence. And in order for me to	12:04:29
7	answer the sequence, I would have to know the dates,	12:04:32
8	which I repeat, I do not recall sitting here today.	12:04:35
9	What I can say is that this process, as	12:04:38
10	illustrated by minutes, were run in parallel in the	12:04:43
11	two companies. IVAX was in charge of developing the	12:04:49
12	formulation. Serono was in charge of taking this	12:04:51
13	formulation and making a clinical development,	12:04:56
14	registration, and commercialization. That was a	12:05:06
15	high-level understanding of mine of the roles and	12:05:15
16	responsibilities in these agreements.	12:05:17
17	And as I said also earlier, I recall at	12:05:22
18	meetings IVAX presenting progress on their formulation	12:05:28
19	development and Serono presenting progress on the	12:05:34
20	design of the clinical development plan and including	12:05:44
21	the first clinical Phase III study, which included the	12:05:50
22	dosing regimen, or at least a draft of it.	12:05:55

1 So these processes were run essentially in 12:05:58
2 parallel, and I cannot be more specific on that with 12:06:02
3 respect to the exact sequence. 12:06:08

4 Q. Okay. And did Serono design the dosing 12:06:12
5 regimen having the IVAX's formulation in mind? 12:06:16

6 A. I am not sure what you mean, "having the 12:06:24
7 formulation in mind." Can you perhaps explain? 12:06:27

8 Q. Did Serono design the dosing regimen in view 12:06:39
9 of IVAX's formulation? 12:06:42

10 A. Given that, as I said earlier, the 12:06:56
11 formulation is part of the elements that you consider 12:06:59
12 in designing a dosing regimen, it became part of -- I 12:07:02
13 mean, it became an element that we were considering 12:07:10
14 when designing this dosing regimen. 12:07:13

15 I gave you an example earlier of sustained 12:07:20
16 release. If IVAX had -- and it is totally 12:07:27
17 hypothetical, but just to explain it. If IVAX had 12:07:31
18 ever thought of designing a sustained release or 12:07:34
19 something similar, that might have had -- that would 12:07:38
20 have had an effect on what we would have designed as a 12:07:44
21 dosing regimen. 12:07:51

22 So, yes, elements like that, which is 12:07:51

1	immediate-release oral administration, have to be	12:07:55
2	considered when you design -- when one designs a	12:07:59
3	dosing regimen. So if that is what you mean with	12:08:06
4	"having in mind," the answer would be yes.	12:08:10
5	MS. PARTINGTON: Okay, I think we can take	12:08:19
6	lunch now, counsel, if that's all right with you.	12:08:22
7	THE VIDEOGRAPHER: We are going off the	12:08:25
8	record. The time is 12:08.	12:08:26
9	(Recess for lunch.)	12:08:29
10	THE VIDEOGRAPHER: We are back on the	13:01:37
11	record. The time is 13:01.	13:01:39
12	MS. PARTINGTON: Thank you.	13:01:45
13	Q. Dr. Munafo, welcome back. Did you have any	13:01:45
14	discussions with counsel regarding the substance of	13:01:47
15	the deposition during your lunch break?	13:01:51
16	A. No, I did not.	13:01:53
17	Q. Thank you. Dr. Munafo, you have testified	13:01:55
18	that you and your team at Serono developed a	13:02:00
19	cladribine dosing regimen described in the Bodor PCT	13:02:05
20	Application No. 2004/087101. And my question for you	13:02:14
21	is: What did you specifically contribute	13:02:21
22	intellectually to the development of this regimen?	13:02:28

1	A. I will address your question, but the	13:02:35
2	beginning, you were referring to a special text of my	13:02:37
3	declaration. Just to make sure that I get exactly, do	13:02:41
4	you want to point me to the paragraph, please?	13:02:46
5	Q. I have a couple of paragraphs here that you	13:02:49
6	can look at: Paragraph 7, Paragraph 50, Paragraph 53.	13:02:51
7	A. Okay, 50 and 53 I'm with you. But on the	13:03:26
8	first one you said 7, and 17 is not -- is the Bodor	13:03:29
9	text; right?	13:03:37
10	Q. That's right.	13:03:38
11	A. So I'm with you.	13:03:41
12	Q. Paragraph 6 is the Bodor PCT number, for your	13:03:43
13	reference.	13:03:52
14	A. Thank you. So would you mind, please,	13:03:53
15	repeating your question?	13:03:55
16	Q. Sure. What did you specifically contribute	13:03:56
17	intellectually to the development of the dosing	13:03:59
18	regimen described in the Bodor PCT?	13:04:05
19	A. The design of such a dosing regimen is a	13:04:07
20	complex process, in which many -- several, if not	13:04:22
21	many, expertises are engaged -- namely, the clinical	13:04:28
22	experts, those with experience on the clinical fields,	13:04:36

1 elements regarding feasibility of a protocol, elements 13:04:43

2 regarding logistics, et cetera. 13:04:50

3 And my contribution -- my and my team's 13:04:52

4 contribution to the dosing regimen was to elaborate a 13:04:55

5 dosing regimen, as we defined "dosing regimen" earlier 13:05:08

6 this morning, that would allow to deliver cladribine 13:05:12

7 to patients in a trial with expectation that it would 13:05:18

8 be safe and efficacious. 13:05:28

9 "Intellectual contribution" is a bit of a 13:05:30

10 term that I would like you to have better defined what 13:05:34

11 you mean with "intellectual" in that case. 13:05:37

12 Q. Okay. First of all, my question was about 13:05:40

13 you specifically, not your team, so let me repeat it 13:05:46

14 again. 13:05:49

15 What did you specifically contribute 13:05:51

16 intellectually to the development of the Bodor PCT 13:05:53

17 regimen? 13:05:57

18 A. I personally -- 13:05:58

19 MS. FERRERA: Objection. I'll just 13:06:07

20 interject an objection. 13:06:08

21 Sorry. Go ahead. 13:06:09

22 A. I personally -- 13:06:11

1 Well, I'd like to step back to what I was 13:06:18
2 just saying. First, everything, as I said, is a 13:06:20
3 joint -- is a team effort and joint expertise. So it 13:06:27
4 is not necessarily appropriate to extract a single one 13:06:35
5 contribution. 13:06:40

6 But having said that, my intellectual 13:06:41
7 contribution into that was to translate our knowledge 13:06:46
8 on the disease -- the pharmacokinetics of cladribine 13:06:57
9 and integrate claim elements that came from the other 13:07:09
10 team members into that dosing regimen. 13:07:12

11 So I was really for that part of the 13:07:15
12 dosing regimen translating all of this together with 13:07:25
13 my knowledge and my expertise into something that is, 13:07:27
14 first of all, acceptable and has -- and was aimed at 13:07:32
15 attaining efficacy with acceptable variability. 13:07:41

16 Q. You said it was a joint team effort. Who was 13:07:55
17 it joint with? 13:07:59

18 A. There were contributors from the clinical 13:08:01
19 expertise at Serono, and this is represented in our 13:08:12
20 patent by Maria Lopez-Bresnahan. You have this name? 13:08:18

21 Q. You might have to spell it now for the court 13:08:27
22 interpreter. 13:08:30

1 THE REPORTER: Actually, you don't. 13:08:31

2 THE WITNESS: Okay, thank you. 13:08:35

3 A. So there were other members, and sitting here 13:08:44

4 today, I would not be able to name the other members 13:08:45

5 of the clinical team. But it was more than Maria 13:08:49

6 Lopez. We had discussion with the expert within 13:08:57

7 Serono on feasibility of clinical trials with the 13:09:07

8 drug. 13:09:16

9 You know, at Serono we had a really long 13:09:17

10 and extensive experience in multiple sclerosis. We 13:09:19

11 had developed drugs for this, and we had a 13:09:25

12 long-lasting experience with one of them, which is 13:09:28

13 called Rebif, R-e-b-i-f, interferon beta -- for which 13:09:31

14 we had done several trials in multiple sclerosis. We 13:09:41

15 had a team of statisticians who have worked on Rebif 13:09:46

16 and trials of it and know the disease of multiple 13:09:55

17 sclerosis and its specificities in terms of clinical 13:10:03

18 trial and disease progression very well. We had -- I 13:10:09

19 said operations already. We had statisticians. We 13:10:16

20 had clinicians. We had experts in various fields. 13:10:20

21 And all of this was coming into -- and 13:10:24

22 Arnaud Ythier. The last name is Ythier, and the first 13:10:32

1 name is Arnaud, A-r-n-a-u-d. 13:10:40

2 So a lot of discussions, a lot of 13:10:49
3 exchange, a lot of things to integrate into the 13:10:52
4 reasoning to arrive together with all the information 13:10:55
5 we gathered, being confidential and nonconfidential, 13:11:00
6 being elements of the discussion that we could gather 13:11:08
7 at any places. All of this is integrated into a 13:11:11
8 conceptualization of a dosing regimen. 13:11:16

9 So when you ask me to be specific of my 13:11:21
10 contribution, for the dosing regimen I was probably 13:11:24
11 central into bringing this information, taking into 13:11:33
12 account the pharmacokinetics of cladribine and all the 13:11:38
13 information we had to design this dosing regimen, 13:11:40
14 unique dosing regimen, and innovative, by and large. 13:11:45

15 Q. You mentioned an expert at Serono with whom 13:11:56
16 you had discussions regarding feasibility of clinical 13:11:58
17 study. My question is: Who was that expert at 13:12:02
18 Serono? 13:12:06

19 A. I mentioned experts, plural, and I said that 13:12:06
20 Serono has a long experience with clinical trials, in 13:12:13
21 particular in multiple sclerosis. Sitting here today, 13:12:21
22 and besides Maria Lopez-Bresnahan, I'm not able to 13:12:26

1 cite a name, but the expertise was in house. 13:12:35

2 Q. The expertise regarding the feasibility of 13:12:59

3 clinical trials: Was it important for designing the 13:13:01

4 dosing regimen in the Bodor PCT? 13:13:05

5 MS. FERRERA: Objection. 13:13:09

6 A. All expertise have a certain level of 13:13:23

7 importance. That's the definition of "expertise," in 13:13:26

8 my understanding. 13:13:29

9 In practical terms, there is a back-and- 13:13:35

10 forth between a proposal, and then we had a group of 13:13:39

11 people that has worked with multiple sclerosis 13:13:46

12 patients, multiple sclerosis trials, that told us 13:13:52

13 whether our proposal would be feasible or totally 13:13:58

14 unfeasible; and I do not recall, sitting here today, 13:14:02

15 that they came with any -- any objection to what we 13:14:08

16 were proposing. 13:14:17

17 Q. Okay. When did Dr. Lopez-Bresnahan join the 13:14:29

18 cladribine team at Serono? 13:14:35

19 A. Sitting here today, I'm unable to remember 13:14:37

20 that. 13:14:39

21 Q. Do you know if she intellectually contributed 13:14:47

22 to the development of the regimen described in the 13:14:49

1	Bodor PCT?	13:14:53
2	MS. FERRERA: Objection.	13:14:54
3	Q. Let me clarify the question. Do you know if	13:14:58
4	Dr. Lopez-Bresnahan intellectually contributed to the	13:15:01
5	development of the oral cladribine regimen described	13:15:04
6	in the Bodor PCT?	13:15:08
7	MS. FERRERA: Objection.	13:15:10
8	A. Yeah, the dose regimen that is described in	13:15:18
9	the Bodor PC -- Bodor patent, in my conviction, comes	13:15:22
10	from what we have presented to them on various	13:15:28
11	occasions, meaning in meetings or by teleconference.	13:15:32
12	So Maria Lopez contributed to the elaboration of the	13:15:43
13	design of the dosing regimen that we elaborated at	13:15:48
14	Serono and, to my understanding and recollection and	13:15:50
15	conviction, not directly to -- what is in Bodor's is	13:15:59
16	in direct consequence of that. It means that what is	13:16:07
17	in Bodor comes from our dosing regimen, and Maria	13:16:11
18	Lopez contributed to our dosing regimen.	13:16:17
19	What I mean with "our" is the one that we	13:16:24
20	have proposed, described, presented in various	13:16:30
21	meetings where IVAX were present and that we have	13:16:34
22	nailed down to a certain detail in the briefing	13:16:39

1 document that we had prepared for the Swedish health 13:16:43
2 authorities, that IVAX also had an opportunity to 13:16:49
3 review. And this is what I mean with "our" proposal. 13:16:55

4 Q. What do you mean by "we," Dr. Munafo? 13:16:58

5 A. I mean by "we" that it is Serono. "We" 13:17:05
6 globally can be understood as Serono. This is an 13:17:16
7 entity, a project team, and a proposal is a joint 13:17:19
8 effort. So "we" means Serono -- we at Serono. 13:17:24

9 Q. And who specifically at Serono, Dr. Munafo? 13:17:28

10 MS. FERRERA: Objection. 13:17:39

11 A. The efforts of developing a dosing regimen is 13:17:41
12 a long-lasting, iterative process. There were 13:17:51
13 expertise from the various fields that I have 13:17:58
14 mentioned, and the list is probably not exhaustive 13:18:00
15 that I mentioned just a few minutes ago. And I am not 13:18:04
16 able sitting here today to name all the persons, 13:18:07
17 period. 13:18:19

18 Q. Let's go back to Dr. Lopez-Bresnahan, please. 13:18:19
19 What did she specifically contribute to the 13:18:22
20 development of the regimen described in the Bodor PCT 13:18:25
21 application? 13:18:29

22 MS. FERRERA: Objection. 13:18:30

1 A. I already said that asking specifically for 13:18:37
2 an input is a task that is not feasible, in the sense 13:18:40
3 that -- in the sense that this is a joint effort and 13:18:51
4 where expertise from everyone involved can be engaged 13:19:01
5 and used. 13:19:15

6 The question, if I rephrase it in my 13:19:18
7 understanding, is what was Maria's contribution to the 13:19:21
8 dosing regimen that we proposed. She brought a very 13:19:26
9 significant expertise in clinical development. She 13:19:33
10 is -- she was, but I think she still is -- a medical 13:19:43
11 doctor. She knows and she knew about multiple 13:19:47
12 sclerosis. She knew about feasibility of clinical 13:19:51
13 trials in that setting. And again, she was working in 13:19:54
14 a department, a clinical department, at Serono with a 13:20:03
15 huge expertise in neurology and in particular in 13:20:09
16 multiple sclerosis. 13:20:13

17 Q. But can you identify for me any specific 13:20:13
18 intellectual contributions that she made to the 13:20:31
19 cladribine regimen? 13:20:34

20 MS. FERRERA: Objection. 13:20:35

21 A. I think I replied to that just in the 13:20:43
22 previous response, that her contribution was input 13:20:45

1	of -- was related to -- or was -- her contribution was	13:20:51
2	based on her expertise in the clinical development, in	13:20:56
3	multiple sclerosis, and together with her -- other	13:21:02
4	representatives of her department. More detail, more	13:21:06
5	specificity, more than 20 years ago, I cannot give	13:21:09
6	today.	13:21:14
7	Q. Have you ever met Dr. Lopez-Bresnahan?	13:21:17
8	A. By "ever" you mean at any time?	13:21:22
9	Q. Yes.	13:21:26
10	A. Yes.	13:21:27
11	Q. Have you ever communicated with	13:21:27
12	Dr. Lopez-Bresnahan?	13:21:36
13	A. Yes.	13:21:42
14	Q. When is the last time you communicated with	13:21:43
15	Dr. Lopez-Bresnahan?	13:21:45
16	A. I do not remember, sitting here today, in	13:21:48
17	detail, but it was several years ago.	13:21:51
18	Q. Who else participated in that communication	13:21:55
19	between you and Dr. Lopez-Bresnahan?	13:22:02
20	MS. FERRERA: Objection.	13:22:08
21	A. To the best of my recollection as of today,	13:22:13
22	this was an informal, "Hey, how are you," several	13:22:17

1	years ago, with no one else that I can recall as of	13:22:22
2	today being with us.	13:22:24
3	Q. Do you know where Dr. Lopez-Bresnahan is now?	13:22:30
4	A. Sitting here today, I do not recall.	13:22:33
5	Q. You mentioned Dr. Ythier, Y-t-h-i-e-r. Can	13:22:35
6	you identify his contribution to the cladribine dosing	13:22:54
7	regimen in Bodor?	13:22:59
8	A. I'd like to -- I'd like to set the scene.	13:23:07
9	Dr. Ythier and myself have worked together for many	13:23:13
10	years at Serono, and he is, or was -- because I think	13:23:18
11	he's retired now -- a medical doctor with expertise	13:23:31
12	also in early clinical developments, including	13:23:35
13	clinical pharmacology. And I have reported to him	13:23:42
14	twice in my career at Serono. There was a period --	13:23:46
15	an intermittent period where the line management had	13:23:52
16	changed for a couple of years. I do not have the	13:23:56
17	dates at hand, sitting here today, to tell you when it	13:24:00
18	was exactly.	13:24:07
19	But what I can tell is that, regarding the	13:24:08
20	cladribine project that is in question today, we had	13:24:13
21	several discussions about how to translate the	13:24:17
22	information that I was referring to a few minutes	13:24:26

1 ago -- how to translate this whole set of information 13:24:31
2 and knowledge into the dosing regimen that I and my -- 13:24:36
3 that I and my colleagues proposed. 13:24:45

4 Q. Were those discussions with Dr. Ythier in 13:24:50
5 person? 13:24:54

6 MS. FERRERA: Objection. 13:24:58

7 A. The discussions with Dr. Ythier were both in 13:24:58
8 person and in writing and in regular discussion that 13:25:09
9 employees have together. Whether there were other 13:25:24
10 persons present or not I am not able, sitting here 13:25:29
11 today, to respond. 13:25:33

12 Q. Was there anybody else present for those 13:25:35
13 discussions between you and Dr. Ythier? 13:25:40

14 MS. FERRERA: Objection. 13:25:44

15 A. I think I just said that, that I'm not able, 13:25:44
16 sitting here today, to address this. 13:25:49

17 Q. So I'm going to ask you again to identify 13:25:51
18 specific intellectual contributions from Dr. Ythier to 13:26:01
19 the dosing regimen in Bodor. Could you do that for 13:26:06
20 me, please? 13:26:10

21 MS. FERRERA: Objection. 13:26:10

22 A. Dr. Ythier has been working for Serono for 13:26:15

1 very long, has acquired significant experience and 13:26:23
2 expertise in many aspects of early clinical 13:26:29
3 development. And we had discussions and, if you wish 13:26:33
4 me to say this, mutual challenges on the line of 13:26:47
5 thought that we were developing as employees 13:26:55
6 participating to a project or team have in such 13:27:00
7 setting of both hierarchy and -- hierarchical and 13:27:08
8 project matrix structure. 13:27:14

9 So I do recall discussions. I do recall 13:27:24
10 presentations that I made to him that he challenged 13:27:29
11 me. I do recall such aspects, but I'm not able to 13:27:34
12 nail down and put a precise definition of his 13:27:38
13 intellectual contribution besides what I just said. 13:27:49

14 Q. When was the last time you communicated with 13:27:55
15 Dr. Ythier? 13:27:58

16 A. The last time was that he commented in 13:28:10
17 WhatsApp on a picture that I placed in my profile, and 13:28:15
18 that's the very last time I heard about him -- and 13:28:18
19 this was just a couple of weeks ago. 13:28:24

20 Q. And do you know where Dr. Ythier is now? 13:28:25

21 A. I have not discussed this with him. But I 13:28:35
22 heard from a third person that he is in a village not 13:28:42

1	very far to where I live.	13:28:45
2	Q. It sounds lovely.	13:28:53
3	A. It is.	13:28:55
4	Q. Dr. Munafo, you have also mentioned in your	13:28:55
5	declaration Dr. Giampiero De Luca. So my question for	13:28:59
6	you is: What did Dr. De Luca contribute	13:29:10
7	intellectually to the development of the cladribine	13:29:18
8	regimen in Bodor?	13:29:20
9	MS. FERRERA: Objection.	13:29:22
10	A. Dr. De Luca has been working with the	13:29:29
11	company, Serono, for very long as well, but in a	13:29:34
12	department which was remote to mine, and I am not able	13:29:38
13	to say in detail what his contribution was, except	13:29:50
14	that he was also represented in --	13:29:58
15	MS. FERRERA: Sorry, I don't mean to	13:30:00
16	interrupt your answer, Dr. Munafo, but I do just want	13:30:01
17	to counsel you --	13:30:04
18	MS. PARTINGTON: Counsel, the witness is	13:30:06
19	answering the question. You cannot interject like	13:30:08
20	this. I'm sorry.	13:30:10
21	MS. FERRERA: Counsel, I just want to	13:30:11
22	caution Dr. Munafo not to disclose any attorney-client	13:30:13

1	communications, because Dr. De Luca was an attorney.	13:30:15
2	You may answer the question.	13:30:19
3	A. So to continue what I was saying: As I said,	13:30:23
4	his department was remote to mine, and I'm not aware	13:30:28
5	of his, how you call it, personal intellectual	13:30:38
6	contribution. I cannot give details on that, besides	13:30:42
7	the fact that his department was also represented in	13:30:48
8	the project team.	13:30:51
9	Q. Do you know Dr. Lopez-Bresnahan provided a	13:30:54
10	declaration in this case?	13:30:58
11	A. I do not know that, sitting here today. I'm	13:31:01
12	not surprised, however. But I do not know. I do not	13:31:08
13	know this for sure.	13:31:14
14	Q. I'm sorry, for the clarity of the record,	13:31:15
15	when you say you're not surprised, however, could you	13:31:17
16	clarify what you mean by that, please?	13:31:20
17	A. Yes, I can, in the sense that Dr. Maria	13:31:24
18	Lopez-Bresnahan is named as a co-author of this -- of	13:31:30
19	our patent. I am not surprised that she has been	13:31:40
20	approached. Besides that, I do not know if she has	13:31:46
21	made a declaration or a deposition.	13:31:51
22	Q. But you do know that she was approached?	13:32:02

1	MS. FERRERA: Objection.	13:32:04
2	A. I said I would not be surprised that she has	13:32:08
3	been, but I do not know if she has been.	13:32:11
4	Q. Do you know if Dr. Ythier provided a	13:32:17
5	declaration in this case?	13:32:19
6	A. I do not know, sitting here today.	13:32:23
7	Q. Do you know if Dr. De Luca provided a	13:32:27
8	declaration in this case?	13:32:30
9	A. Sitting here today, I do not know.	13:32:32
10	Q. Now, you mentioned in your declaration that	13:32:38
11	Dr. Lopez-Bresnahan had her own team working on	13:32:40
12	designing a dosing regimen. My question for you is:	13:32:45
13	How many people were on Dr. Lopez-Bresnahan's team?	13:32:48
14	A. Sitting here today, I'm not able to state a	13:32:51
15	number. There were numerous people in clinical	13:32:55
16	development and in the -- the department she was in	13:32:57
17	that --	13:33:07
18	There were numerous people, but I cannot	13:33:08
19	give a number.	13:33:10
20	Q. Do you remember anybody's names on that team?	13:33:11
21	A. Sitting here today, the names are not	13:33:20
22	something that I remember with certainty.	13:33:27

1 Q. Do you have any knowledge as to their 13:33:35
2 roles -- strike that. 13:33:40

3 Do you have any knowledge as to the roles 13:33:40
4 of any of the people on Dr. Lopez-Bresnahan's team in 13:33:42
5 developing cladribine oral dosing regimen? 13:33:49

6 A. Let me rephrase. Do I have any knowledge of 13:34:05
7 people in her -- on what other people on her team 13:34:11
8 contributed to the design of the dosing regimen? 13:34:18

9 Q. That is correct. 13:34:22

10 A. Sitting here today, I cannot reply this with 13:34:25
11 certainty. 13:34:30

12 Q. Did you ever communicate with anybody on 13:34:30
13 Dr. Lopez-Bresnahan's team besides Dr. Lopez- 13:34:37
14 Bresnahan? 13:34:47

15 A. The team at Serono was composed of many 13:34:47
16 people of various functions, and also I will not be 13:34:52
17 able to cite names. There were other people joining 13:35:06
18 or providing some contribution from time to time from 13:35:23
19 her team, from her department. 13:35:29

20 Q. Do you know roughly how many people were on 13:35:33
21 that team? 13:35:37

22 MS. FERRERA: Objection. 13:35:37

1	A. I am not able to state a number.	13:35:38
2	Q. Were all the members of the team on	13:35:40
3	Dr. Lopez-Bresnahan's team in the same building?	13:35:48
4	Strike that.	13:35:54
5	Were all the people on Dr. Bresnahan's	13:35:54
6	team working in the same building?	13:35:59
7	A. At that time we had a group of people working	13:36:07
8	in Geneva and a group of people working in the U.S. I	13:36:12
9	do not recall today in which site in the U.S. Maria	13:36:20
10	was working, but I do recall that there were also	13:36:27
11	clinical development people in Geneva. So I cannot	13:36:32
12	say that they were all in the same building.	13:36:39
13	Q. Were all the team members -- strike that.	13:36:51
14	Were all the cladribine team members working on the	13:36:55
15	same site?	13:37:01
16	A. No. We had people in the U.S., and we had	13:37:10
17	people in Switzerland. Sitting here today, I do not	13:37:14
18	recall if there were people from other regions or	13:37:18
19	countries, but at least these two.	13:37:20
20	Q. Okay. In the U.S. were there multiple sites	13:37:22
21	for the place of work for the cladribine team?	13:37:30
22	A. In the U.S. there were multiple sites	13:37:34

1 belonging to Serono, but sitting here today, I am not 13:37:38

2 able to say who was on which site. 13:37:45

3 Q. What about in Switzerland? Were there 13:37:48

4 multiple sites where people on the cladribine team 13:37:51

5 worked at? 13:37:56

6 A. In Switzerland, too, we have -- we have 13:37:57

7 multiple sites. But to the best of my recollection as 13:38:06

8 of today, at that time those working on cladribine 13:38:11

9 were in Geneva. 13:38:16

10 But thank you for bringing this to my 13:38:20

11 attention, because I -- you refreshed my memory by 13:38:22

12 saying this, that we had also people from preclinical 13:38:29

13 development who were coming from a site in Italy. 13:38:33

14 Q. They were also employed at Serono, those 13:38:41

15 people coming from Italy? 13:38:43

16 A. They were employed by a subsidiary of Serono. 13:38:45

17 Q. And did those people from Italy, from the 13:39:03

18 preclinical development, did they contribute to the 13:39:07

19 development of the oral cladribine regimen? 13:39:10

20 MS. FERRERA: Objection. 13:39:14

21 Q. In Bodor. 13:39:22

22 MS. FERRERA: Objection. 13:39:23

1 A. Sorry. You added "in Bodor"? 13:39:24

2 Q. Yeah. Let me ask again. Did those people 13:39:26
3 from Italy, from the preclinical development, did they 13:39:31
4 contribute to the development of the oral cladribine 13:39:36
5 regimen in Bodor? 13:39:39

6 MS. FERRERA: Objection. 13:39:40

7 A. To rephrase one thing that I said already: 13:39:45
8 It is my conviction that the regimen that is in Bodor 13:39:50
9 was in fact an extract, an incomplete extract, of what 13:40:01
10 we presented in various meetings. And here again, 13:40:06
11 what I mean with "we" is we at Serono. So that is 13:40:11
12 something that I want to emphasize and repeat. 13:40:24

13 Having said that: To the best of my 13:40:26
14 recollection as of today, my former colleagues, part 13:40:31
15 of the preclinical teams in Italy, did not contribute 13:40:35
16 significantly to the proposed dosing regimen. 13:40:39

17 Q. Do you know who Gordon Francis is? I will 13:40:49
18 spell it for you: G-o-r-d-o-n, last name 13:40:55
19 F-r-a-n-c-i-s. 13:41:01

20 A. Well, thank you for refreshing my memory on 13:41:03
21 one of the names that I was not able to remember 13:41:06
22 earlier. Gordon Francis has been an employee of 13:41:10

1	Serono, and I do remember him, yes.	13:41:20
2	Q. Was he part of the Serono cladribine team?	13:41:27
3	A. At a certain moment, I am sure about it.	13:41:38
4	What I do not know is at what time he started to be on	13:41:41
5	the team.	13:41:44
6	Q. Do you know what his role on the team was?	13:41:50
7	A. Gordon was an expert in neurology, and in	13:42:06
8	multiple sclerosis in particular. I am not sure as of	13:42:10
9	today of his hierarchical role in the company in that	13:42:18
10	clinical development, nor do I remember precisely	13:42:25
11	whether he was -- what role exactly he was playing in	13:42:33
12	the Serono project team.	13:42:40
13	Q. Okay, I would like to go back to the	13:42:42
14	collaboration with IVAX. And you mentioned Drs.	13:43:16
15	Nicholas Bodor and Yogesh, Y-o-g-e-s-h, last name	13:43:25
16	D-a-n-d-i-k-e-r.	13:43:46
17	A. Could you point me to the first instance	13:43:58
18	where you saw these names in the declaration, to help	13:44:01
19	me?	13:44:03
20	Q. Why don't you try Paragraph 26.	13:44:04
21	A. You said 26; correct?	13:44:25
22	Q. That is correct.	13:44:27

1 A. Okay, I am with you, yes. 13:44:36

2 Q. Do you know what, if anything, Dr. Bodor 13:44:37
3 contributed to the joint research between IVAX and 13:44:45
4 Serono on cladribine? 13:44:48

5 MS. FERRERA: Objection. 13:44:54

6 A. I was not part of IVAX and do not know and do 13:44:54
7 not remember at least as of today what his 13:45:02
8 contribution was in any detail. 13:45:05

9 Q. Have you ever communicated with Dr. Bodor 13:45:08
10 regarding cladribine? 13:45:13

11 A. Communications between IVAX team and Serono 13:45:14
12 were frequent, encouraged. They were both by means of 13:45:22
13 direct, face-to-face meetings, as well as 13:45:31
14 teleconferences and email exchanges. And my memory 13:45:34
15 has been refreshed by reading minutes, that we have 13:45:42
16 both been present to the same meetings. So we have 13:45:47
17 been present to the same meetings, but sitting here 13:45:51
18 today, I cannot point to any direct discussion that I 13:45:55
19 had with him. 13:45:58

20 Q. Do you have any recollections of the meetings 13:45:59
21 beyond what's memorialized in meeting minutes? 13:46:22

22 MS. FERRERA: Objection. 13:46:30

1 A. There have been a significant number of 13:46:39
2 meetings along the years, and my memory was refreshed 13:46:47
3 by way of minutes for only a few of them. So I 13:46:52
4 cannot, sitting here today, be more specific on this. 13:47:02

5 But I would like to mention that, as an 13:47:08
6 example, I flew over all the way to IVAX headquarters 13:47:15
7 in Miami personally to sit with their pharmacokinetics 13:47:23
8 expert there to review the data of the second trial 13:47:34
9 that they did, to go into the detail of the 13:47:39
10 pharmacokinetic calculations, statistic calculations, 13:47:44
11 the inference on bioavailability and viability around 13:47:48
12 it. 13:47:52

13 So this is an example of a meeting, you 13:47:55
14 asked for, which my recollection is independent of any 13:47:59
15 minutes. 13:48:03

16 Q. Who was the pharmacokinetic expert in IVAX 13:48:08
17 headquarters with whom you met in Miami? 13:48:18

18 A. The primary person there is Dan Weiner, 13:48:29
19 W-e-i-n-e-r, at that time when I went there. 13:48:38

20 Q. And do you know what his role was at IVAX at 13:48:53
21 the time? 13:49:01

22 A. I was not an employee of IVAX and did not 13:49:04

1 know the titles and roles of every employees. Yet 13:49:09
2 with respect to Dan Weiner, he's the one with whom I 13:49:16
3 interacted to review the pharmacokinetic data of the 13:49:22
4 102 trial. 13:49:29

5 Q. I'm sorry, could you please remind me what 13:49:41
6 the 102 trial is? 13:49:44

7 A. In my recollection, IVAX ran two trials to 13:49:46
8 characterize the formulation that they developed. The 13:49:54
9 first one was a trial they called 101, which we 13:49:59
10 discussed this morning, when they tested a few 13:50:07
11 formulations. And the second trial, which, I recall 13:50:13
12 well, the name 102, in short, was the trial in which 13:50:20
13 the pharmacokinetics of the retained formulation in 13:50:29
14 patients, and in comparison to IV routes, in order to 13:50:39
15 characterize the pharmacokinetics, the bioavailability 13:50:53
16 and the variability around it. 13:51:04

17 Q. Could you explain to me what "the retained 13:51:10
18 formulation" means? 13:51:13

19 A. What I mean by "retained" is the formation 13:51:20
20 that was chosen out of the various candidates to be 13:51:32
21 pursued for this second trial and was eventually also 13:51:40
22 retained for the clinical development that we ran at 13:51:47

1	Serono.	13:51:57
2	Q. Is this the formulation that forms the	13:52:01
3	product Mavenclad?	13:52:08
4	MS. FERRERA: Objection.	13:52:12
5	A. Sitting here today, I would have to compare	13:52:13
6	the detail of the two formulations to be able to	13:52:15
7	answer this question, as of the product that is on the	13:52:18
8	market now, if you name it Mavenclad -- I assume this	13:52:27
9	is what you mean.	13:52:34
10	So I cannot confirm for sure that this is	13:52:39
11	the case. But it is the case that this is a	13:52:41
12	formulation that we used in the clinical development,	13:52:44
13	in the early phases of clinical development, yes.	13:52:49
14	Q. Was this formulation a complex	13:52:52
15	cladribine-cyclodextrin complex?	13:53:01
16	A. It is my understanding, from having been	13:53:03
17	presented the so-called Bodor patent, that this is the	13:53:09
18	way they call it.	13:53:13
19	Q. And when exactly did you meet with Dan	13:53:19
20	Weiner?	13:53:22
21	MS. FERRERA: Objection.	13:53:24
22	A. I'm not able, sitting here today, to remember	13:53:25

1 the date. What I can say is that this was just after 13:53:30
2 the results of the 102 trials became available, in 13:53:38
3 order to agree with him on the pharmacokinetic and 13:53:49
4 statistical calculations. 13:53:52

5 Q. Do you remember approximately when that was? 13:53:58

6 MS. FERRERA: Objection. 13:54:02

7 A. Sitting here today, I cannot remember when 13:54:04
8 this was exactly. I cannot remember the dates. I 13:54:06
9 remember the sequence, as I just explained, but not 13:54:12
10 the date. 13:54:15

11 Q. How about approximate year? 13:54:16

12 A. I would not be able, sitting here today, to 13:54:19
13 state the year, neither the months. I would have to 13:54:31
14 refresh my memory on this. And honestly, I don't 13:54:40
15 think I have this information in front of me. 13:54:48

16 Q. Dr. Munafo, when was the last time you 13:55:18
17 communicated with Dr. Dandiker? 13:55:20

18 A. A long time ago, but I do not remember, 13:55:31
19 sitting here today, when it was, but many years ago. 13:55:34

20 Q. Was anyone else present during that 13:55:39
21 communication? 13:55:46

22 MS. FERRERA: Objection. 13:55:48

1	A.	I'm not able, sitting here today, to say this	13:55:53
2		because I do not remember any detail about this	13:55:55
3		discussion.	13:55:58
4	Q.	Do you know where Dr. Dandiker is now?	13:56:07
5	A.	No, I do not.	13:56:10
6	Q.	Do you know where Dan Weiner is now?	13:56:15
7	A.	I know where he was a few months or year ago.	13:56:21
8		I do not know where he is now.	13:56:27
9	Q.	And where was he a few month or a year ago?	13:56:30
10	A.	To the best of my knowledge, he was with a	13:56:35
11		company called Pharsight, P-h-a-r-s-i-g-h-t. It was	13:56:38
12		in the U.S., but I do not know -- I do not remember	13:56:52
13		with more detail today where it was.	13:56:58
14	Q.	And what is the basis of your knowledge	13:57:02
15		regarding Dr. Weiner being at the company called	13:57:04
16		Pharsight?	13:57:09
17	A.	Could you repeat your question? I'm not sure	13:57:14
18		I understood the beginning.	13:57:16
19	Q.	What is the basis of your knowledge regarding	13:57:17
20		Dr. Weiner being at the company called Pharsight?	13:57:21
21	A.	Pharsight is a company that specialized in	13:57:32
22		modeling and simulation, which is a field in which me	13:57:38

1 and my people at Serono and thereafter Merck Serono 13:57:48
2 and thereafter Merck were deeply involved. So I got 13:57:54
3 to know that he went there and was there for long, 13:58:03
4 given the knowledge that we had on considering 13:58:11
5 companies in the world. 13:58:17

6 Q. You also mention in your declaration 13:58:25
7 Dr. Steve Marcus at IVAX, so my question for you is: 13:58:30
8 Was Dr. Marcus also part of the IVAX team that 13:58:34
9 collaborated with your team at Serono on cladribine? 13:58:38

10 A. It is my understanding, sitting here today, 13:58:47
11 that, yes, he was part of that team. And his name 13:58:49
12 appears on minutes and emails that I have been shown. 13:58:59

13 Q. Do you know what, if anything, Dr. Marcus 13:59:11
14 contributed to the joint research between IVAX and 13:59:14
15 Serono on cladribine? 13:59:16

16 MS. FERRERA: Objection. 13:59:17

17 A. I was not part of IVAX company. I do not 13:59:20
18 know in detail. I do know that he has been present in 13:59:25
19 many, if not all -- in many of our meetings, and 13:59:29
20 always -- "always" is perhaps not a word -- but I have 13:59:37
21 seen his name on numerous emails. 13:59:42

22 Q. Did you ever communicate with Dr. Marcus 13:59:47

1	regarding cladribine?	13:59:49
2	A. "Ever" means at any time?	13:59:53
3	Q. Sure.	13:59:57
4	A. So given that we both attended the same	14:00:00
5	meetings and the conference as I was mentioning	14:00:05
6	earlier, yes, communication between him and myself	14:00:19
7	occurred.	14:00:22
8	Q. And what were those communications	14:00:27
9	specifically about?	14:00:28
10	A. Specifically today, I cannot -- sitting here	14:00:36
11	today, I cannot remember the specificity of the	14:00:39
12	communication. My memory again has been refreshed by	14:00:42
13	exchanges and minutes, and I saw that his name was on	14:00:51
14	these -- on these minutes or list of attendees or	14:01:02
15	action points. But more specific than that I cannot	14:01:08
16	be, sitting here today.	14:01:11
17	Q. And when was the last time you communicated	14:01:16
18	with Dr. Marcus?	14:01:17
19	A. Sitting here today, I do not remember the	14:01:31
20	exact time, but it is many years ago.	14:01:33
21	Q. And just for clarity of record, did you ever	14:01:35
22	communicate with Dr. Dandiker regarding cladribine?	14:01:42

1 A. Dr. Dandiker's name is also appearing on 14:01:57
2 minutes, and I do recall that we visited -- when I say 14:02:03
3 "we," it was at least members of the project team -- 14:02:18
4 we visited a lab belonging to IVAX in Ireland, where 14:02:24
5 Dr. Dandiker was present. So, yes, there had been 14:02:31
6 communication with him. 14:02:34
7 Q. And who else was there? 14:02:40
8 A. There was a team of people from Serono and 14:02:48
9 from IVAX, but sitting here today, I cannot name the 14:02:53
10 persons, besides him, that I do recall myself, as I 14:02:57
11 was there. 14:03:05
12 Q. And do you know what Dr. Marcus's role was on 14:03:12
13 the cladribine team? 14:03:20
14 MS. FERRERA: Objection. 14:03:29
15 A. I think this is a question that you asked 14:03:29
16 already, but maybe I misunderstood it. Can you 14:03:32
17 perhaps repeat if it is different to what I replied 14:03:36
18 already? 14:03:39
19 Q. Sure. What was Dr. Marcus's role on the 14:03:40
20 cladribine team? 14:03:46
21 A. I was not an employee of IVAX, and I cannot 14:03:50
22 say, sitting here today, anything about his role on 14:04:00

1 the IVAX parts of the project team.

14:04:04

2 I know he was present and presenting
3 frequently, but I am, sitting here today, unable to
4 state his role with precision.

14:04:11

14:04:19

14:04:25

5 Q. Do you know what his job was at IVAX?

14:04:29

6 A. Sitting here today, I am not able to remember
7 his function at IVAX.

14:04:37

14:04:42

8 Q. You also mentioned a D. Emma at IVAX in your
9 declaration. And my question for you is: Was D. Emma
10 also part of the IVAX team collaborated with your team
11 at Serono on cladribine?

14:04:59

14:05:09

14:05:13

14:05:20

12 MS. FERRERA: Objection. And I'll just
13 caution you, Dr. Munafo, not to reveal the content of
14 any attorney-client communications involving Mr. Emma.

14:05:20

14:05:21

14:05:25

15 A. The name of D. Emma appeared to me when my
16 memory was refreshed, but I do not remember anything
17 about this person.

14:05:35

14:05:47

14:05:50

18 Q. When was your memory about Mr. Emma
19 refreshed?

14:06:00

14:06:06

20 A. When I was shown the minutes that are
21 reported in my declaration in Paragraph 28, and this
22 is where I saw what I wrote here, "Dr. Dandiker, a

14:06:14

14:06:16

14:06:25

1 co-inventor of the Bodor PCT, and D. Emma (also of
2 IVAX) presented on formulation progress for soft gel,
3 hard gel, and tablet formulations of cladribine. Id.,
4 3-4."

14:06:33

14:06:49

14:06:52

14:06:58

5 Q. Do you know what, if anything, D. Emma
6 contributed to the joint research between IVAX,
7 Serono, on cladribine?

14:07:04

14:07:07

14:07:12

8 MS. FERRERA: I'll just give you the same
9 caution, but you may answer the question.

14:07:14

14:07:17

10 A. Sitting here today, I do not know.

14:07:19

11 Q. Besides -- strike that.

14:07:41

12 Without disclosing anything specific about
13 the communication, have you ever communicated with D.
14 Emma regarding cladribine?

14:07:48

14:07:50

14:07:54

15 A. Sitting here today, I do not recall of any
16 direct discussion with D. Emma.

14:07:58

14:08:02

17 Q. Besides Dr. Dandiker, Marcus, and Weiner, did
18 you collaborate with anyone else on the IVAX
19 cladribine team?

14:08:05

14:08:33

14:08:36

20 A. To specify your question: you mean at IVAX?

14:08:41

21 MS. FERRERA: Objection.

14:08:47

22 Q. The question is whether you have ever

14:08:47

1	communicated with anyone else on IVAX's cladribine	14:08:50
2	team.	14:08:54
3	MS. FERRERA: Objection.	14:08:57
4	A. Sitting here today, I would not be able to	14:08:58
5	state with confidence whether or not I had any other	14:09:02
6	communication.	14:09:05
7	Q. You also mentioned that the joint research	14:09:16
8	agreement established a joint development committee	14:09:34
9	comprising at least two representatives from each of	14:09:38
10	Serono and IVAX and that met regularly through 2003	14:09:42
11	and 2004. So my question for you is: Were you part	14:09:47
12	of the joint development committee?	14:09:52
13	A. I was part of the project team but not part	14:09:54
14	of the higher committee.	14:10:06
15	Q. Do you know who was part of the committee?	14:10:12
16	A. Sitting here today, I'm unable to give names.	14:10:22
17	Q. You said that the committee met regularly	14:10:26
18	through 2003 and 2004. What do you mean by you "met	14:10:35
19	regularly"?	14:10:43
20	A. My memory was refreshed by my the attorneys	14:10:44
21	showing me an edited version of the contract that was	14:11:07
22	between IVAX and Serono; and there was definition of	14:11:19

1 the roles and responsibilities of the two companies as 14:11:28
2 well as of these supervisory committees and potential 14:11:31
3 escalation process. 14:11:45

4 And were these committees to meet 14:11:47
5 regularly? Sitting here today, I'm not able to state 14:11:59
6 what the frequency of this "regularly" meant. 14:12:02

7 Q. Did you see the contract before being 14:12:05
8 retained for these IPRs? 14:12:08

9 A. No, I did not. 14:12:10

10 Q. Let me just ask this question again for 14:12:24
11 clarity of the record: Have you seen -- strike that. 14:12:27
12 Did you see the joint research agreement before you 14:12:35
13 were retained on these IPRs? 14:12:40

14 MS. FERRERA: Objection. 14:12:42

15 A. The agreement I did not see. However, to be 14:12:44
16 complete, I would like to add that I had been informed 14:12:55
17 about it and the principle, the guiding principle, of 14:13:00
18 it had been exposed to us in the project team. But to 14:13:10
19 your response, whether I have seen the agreement, the 14:13:15
20 response is no. 14:13:27

21 Q. Dr. Munafo, have you ever had any discussions 14:13:34
22 with IVAX's legal team? 14:13:37

1	MS. FERRERA: You may answer yes or no.	14:13:44
2	A. No.	14:13:47
3	Q. Have you had any communications with IVAX's	14:14:05
4	legal team?	14:14:08
5	MS. FERRERA: Again, you may answer yes or	14:14:09
6	no.	14:14:11
7	A. I will answer, but I want to specify that,	14:14:13
8	sitting here today, I don't know -- I don't recall	14:14:19
9	what you mean, the IVAX legal team. I do not recall	14:14:24
10	the persons in the IVAX legal team. So perhaps if you	14:14:28
11	give me names, I would be more able to answer.	14:14:32
12	Q. Let me define the legal team for you: Anyone	14:14:48
13	at IVAX who worked on legal matters. So my question	14:15:11
14	then, is: Have you communicated anybody -- I'm sorry,	14:15:15
15	strike that. Have you communicated with anybody at	14:15:20
16	IVAX who worked on legal matters?	14:15:22
17	MS. FERRERA: Objection.	14:15:27
18	A. Sitting here today, I'm not able to say if	14:15:27
19	anyone with whom I have communicated at IVAX was part	14:15:48
20	of the legal team.	14:15:54
21	MS. PARTINGTON: How about a break,	14:16:00
22	counsel?	14:16:02

1	MS. FERRERA: Ten minutes?	14:16:02
2	MS. PARTINGTON: Yeah. Let's go off the	14:16:09
3	record. Let's take a ten-minute break.	14:16:11
4	THE VIDEOGRAPHER: We are going off the	14:16:13
5	record. The time is 14:16.	14:16:14
6	(Recess taken.)	14:16:28
7	THE VIDEOGRAPHER: We are back on the	14:29:15
8	record. The time is 14:29.	14:29:27
9	Q. Welcome back, Dr. Munafo. Did you have any	14:29:30
10	discussions with counsel regarding the subject of the	14:29:35
11	deposition during the break?	14:29:41
12	A. No, I did not.	14:29:43
13	MS. PARTINGTON: Emil, can you please	14:29:47
14	bring up Exhibit 2050.	14:29:50
15	Q. Dr. Munafo, here on the screen you see	14:30:26
16	Exhibit 2050, which is called Meeting on 27 August	14:30:28
17	2003 in Amsterdam. Do you see that?	14:30:34
18	A. I see the first page, yes.	14:30:37
19	MS. PARTINGTON: Emil, could you please	14:30:41
20	scroll through the document. Thank you.	14:30:43
21	Emil, did you put the copy of this exhibit	14:31:13
22	in the chat? Thank you.	14:31:15

1	Q. Dr. Munafo, do you have a copy, a paper copy,	14:31:18
2	of Exhibit 2050 in front of you as well?	14:31:23
3	A. Yes, I do.	14:31:27
4	Q. Great.	14:31:29
5	A. Yes. This is the last page. Thank you.	14:31:33
6	Q. Dr. Munafo, do you recognize this exhibit?	14:31:36
7	A. Yes. This is, reading, Oral Cladribine for	14:31:44
8	MS Project Meeting on 27 August 2003 in Amsterdam.	14:31:49
9	And I see my name on the participant list.	14:31:54
10	Q. When was the first time you saw this	14:31:57
11	document?	14:32:00
12	A. Sitting here today, I am not able to remember	14:32:00
13	when I saw this document that was dated 2003. This is	14:32:10
14	more than 20 years ago.	14:32:14
15	Q. Have you seen this document before you were	14:32:27
16	retained for these proceedings?	14:32:28
17	A. I'm on the participant list, so --	14:32:41
18	Also, I do not -- I cannot, sitting here	14:32:49
19	today, confirm definitely that I read it. But I am on	14:32:52
20	the list, so -- again, I cannot confirm that I saw it	14:32:58
21	at the time. But being on the list, I would be	14:33:12
22	surprised if I did not.	14:33:14

1 Q. Did you review a draft of this document? 14:33:18

2 A. I note that the bottom says "draft minutes." 14:33:25

3 So I do not recall as of today whether this was in 14:33:37

4 fact unchanged draft, final draft, or that the word 14:33:46

5 "draft" had been forgotten, and I cannot be more 14:33:50

6 certain than that with respect to your question. 14:33:53

7 Q. When was the last time you saw this document 14:33:58

8 before you prepared your declaration in this case? 14:34:00

9 A. When you mean I prepared my deposition in the 14:34:12

10 States, do you mean being physically present in the 14:34:20

11 States or the declaration in the States? 14:34:22

12 Q. Let me rephrase. When is the last time you 14:34:24

13 saw this document before you were retained in this 14:34:27

14 case? 14:34:30

15 A. Sitting here today, I do not have -- I do not 14:34:33

16 remember having seen this document since many, many 14:34:36

17 years, and I do not recall when it was the last time. 14:34:41

18 Q. What was the purpose of this document? 14:34:46

19 A. This document lists -- summarizes a project 14:35:06

20 meeting that was held in Amsterdam where we had 14:35:14

21 participants from Serono -- the list is on the first 14:35:18

22 page -- as well as from IVAX. The list is on the 14:35:22

1	first page, adding D. Emma by phone.	14:35:27
2	So these are minutes of such -- of this	14:35:32
3	meeting.	14:35:36
4	Q. Do you know who wrote this document?	14:35:39
5	A. The author I think is not mentioned here, and	14:35:53
6	I do not recall, sitting here today, who wrote this.	14:36:04
7	Q. Could you please repeat your answer, because	14:36:15
8	your answer is unclear right now. You say "the order	14:36:19
9	I think is not mentioned." So let me just ask you	14:36:23
10	again: Do you know who wrote this document?	14:36:25
11	A. This is what I meant with "author." And no,	14:36:27
12	I do not know, sitting here today -- I do not recall	14:36:32
13	who wrote this document.	14:36:35
14	Q. Got it. Does this document disclose a flat	14:36:40
15	cladribine dosing regimen?	14:36:45
16	A. I'm not sure I got the beginning of the	14:36:46
17	question. Can you please repeat?	14:36:48
18	Q. Sure. Does this document disclose a flat	14:36:50
19	cladribine dosing regimen?	14:36:55
20	MS. FERRERA: Objection.	14:36:58
21	A. Can you for the purposes of clarity explain	14:37:19
22	what you mean with "flat"?	14:37:23

1 Q. Do you have an understanding of what "flat
2 dosing regimen" is?

3 MS. FERRERA: Objection.

4 A. My understanding of what we call a flat
5 dosing regimen is a dosing regimen that is not
6 adjusted for any body-size metrics.

7 Q. So using your understanding of "flat dosing
8 regimen," does Exhibit 2050 disclose a flat cladribine
9 dosing regimen?

10 A. When I go specifically to Page 4, there are
11 suggestions for Phase III studies, and the dosing
12 regimens that are described here are not flat, they
13 are reported per kilo, which is a body-size metric.

14 Whether there are other places of this
15 document, in this document, where the flat dosing is
16 mentioned, I would have to read line by line again.
17 Perhaps you can help me point to it, if this is to
18 another place to the one I just mentioned.

19 Q. How about Page 5? Could you read Page 5, and
20 let me know if Page 5 discloses a flat cladribine
21 dosing regimen, the way you define "flat."

22 A. I do not see upon this quick reading any

1	mention of a flat dosing regimen on Page 5.	14:41:18
2	Q. Okay.	14:41:24
3	MS. PARTINGTON: Emil, could we please go	14:41:31
4	to Page 2 of the document.	14:41:33
5	Q. Dr. Munafo, do you see that there are	14:41:42
6	markings and highlightings on this document on Page 2?	14:41:44
7	A. In pink color? Is that what you refer to?	14:41:52
8	Q. Yeah. I'm talking about the highlights and	14:41:59
9	the markings on Page 2 of Exhibit 2050.	14:42:02
10	A. To make sure I read the same, this sentence	14:42:07
11	says, [REDACTED]	14:42:11
12	something. That sentence, you mean?	14:42:15
13	Q. Right now I'm just asking you if you see the	14:42:20
14	black markings and the highlights on Page 2 of Exhibit	14:42:22
15	2050.	14:42:26
16	A. I see this on screen, and I have in front of	14:42:28
17	me. I just ask you to specify whether the highlight	14:42:31
18	you mention is the one in pink or is there anything	14:42:36
19	else that I am missing?	14:42:39
20	Q. That's one of them. But do you see the	14:42:40
21	black --	14:42:43
22	A. Yes.	14:42:44

1	Q. -- blocks?	14:42:44
2	A. I do.	14:42:48
3	Q. Do you know who made these blocks and	14:42:53
4	highlights?	14:42:56
5	A. I received this document from my attorneys,	14:43:02
6	and I do not know who made these black -- and I'm	14:43:09
7	sorry, I do not know the name in English for this --	14:43:18
8	the black marks here.	14:43:22
9	Q. Do you know who provided this document to the	14:43:28
10	attorneys?	14:43:30
11	A. Ah. Sitting here today, I do not.	14:43:34
12	MS. PARTINGTON: Emil, can you please go	14:43:41
13	to Page 3 of the document.	14:43:42
14	Q. Dr. Munafo, do you see the black redactions	14:43:47
15	on this document on Page 3 of Exhibit 2050?	14:43:49
16	A. I see on screen the first one, and there is a	14:43:59
17	second one in the bottom of the page. Yes, I see	14:44:02
18	that.	14:44:05
19	Q. Do you know who made these redactions on Page	14:44:06
20	3 of Document 2050?	14:44:09
21	A. I received this document from my attorneys,	14:44:13
22	and I do not know who made this redaction.	14:44:16

1	MS. PARTINGTON: Emil, could you please go	14:44:20
2	to the next page, Page 4.	14:44:22
3	Q. Dr. Munafo, do you see pink highlights on	14:44:27
4	Page 4 of Exhibit 2050?	14:44:29
5	A. Yes, I do.	14:44:33
6	Q. Do you know who made these highlights?	14:44:36
7	A. I received this document from my attorney. I	14:44:40
8	do not know who made these highlights.	14:44:43
9	MS. PARTINGTON: Emil, please go to Page 6	14:44:47
10	of this document.	14:44:49
11	Q. Dr. Munafo, do you see pink highlights on	14:44:54
12	Page 6 of Exhibit 2050?	14:44:57
13	A. Yes, I do.	14:45:00
14	Q. Dr. Munafo, do you know who made these	14:45:03
15	highlights on Page 6 of Exhibit 2050?	14:45:05
16	A. I received this document from my attorneys,	14:45:09
17	and I do not know who made these highlights.	14:45:11
18	Q. So we've identified a couple of spaces that	14:45:15
19	have been redacted in this document. My question for	14:45:17
20	you is: Do you know what was redacted from this	14:45:20
21	document?	14:45:26
22	MS. FERRERA: You can answer that yes or	14:45:29

1	no.	14:45:31
2	A. No, I don't.	14:45:31
3	Q. Dr. Munafo, what is the first time the IVAX	14:45:45
4	and Serono team met in person as part of their joint	14:45:49
5	work on cladribine?	14:45:54
6	MS. FERRERA: Objection.	14:45:55
7	A. Sitting here today, I do not remember the	14:45:58
8	chronology of the meeting that IVAX and Serono had. I	14:46:00
9	cannot answer this question with certainty.	14:46:04
10	Q. Okay. Let's go back to Page 1 of Exhibit	14:46:17
11	2050, please. Dr. Munafo, do you see it says up there	14:46:26
12	Serono Participants: I. Emery, G. Francis, D. Frank,	14:46:41
13	M. Lopez-Bresnahan, A. Munafo, A. Ythier, A. Jaber, by	14:46:45
14	phone N. Ammoury, J. Hillier?	14:46:54
15	A. Yes, I do.	14:46:59
16	Q. Anyone else participated in the meeting on	14:47:00
17	August 27, 2003, from Serono, not listed here? Let me	14:47:05
18	ask again. That was terrible.	14:47:12
19	Besides people listed on Page 1 on Exhibit	14:47:14
20	2050 under the Serono Participants, did anyone else	14:47:24
21	participate in this meeting of the 27th of 2023 in	14:47:28
22	Amsterdam?	14:47:34

1	A.	Anyone else from Serono?	14:47:38
2	Q.	That is correct.	14:47:40
3	A.	Sitting here today and reviewing these	14:47:53
4		minutes, I have no information that anyone else	14:47:55
5		attended or did not attend this meeting.	14:47:59
6	Q.	And do you see under IVAX Participants there	14:48:02
7		are also people listed: S. Marcus, Y. Dandiker, D.	14:48:08
8		Weiner, by phone D. Emma?	14:48:13
9	A.	I do.	14:48:17
10	Q.	Besides people listed on Page 1 of Exhibit	14:48:18
11		2050 under the IVAX participants, did anyone else	14:48:20
12		participate in this meeting on the 27th of 2023 in	14:48:23
13		Amsterdam (sic)?	14:48:30
14	A.	Sitting here today, I cannot reply, I do not	14:48:32
15		remember, and I was not at IVAX.	14:48:35
16	Q.	Dr. Munafo, what was the purpose of the	14:48:45
17		August 23 meeting in Amsterdam? I'm sorry, let me	14:48:46
18		strike that.	14:48:52
19		What was the purpose of the 27th-of-August	14:48:52
20		2003 meeting in Amsterdam?	14:48:57
21	A.	To me, sitting here today, this was a meeting	14:49:00
22		presenting the progress of the two parties to each	14:49:13

1	other.	14:49:18
2	Q. If you go to Page 2 of the document, please.	14:49:28
3	Under "Phase I Studies, Discussion leader S. Marcus,"	14:49:33
4	do you see where it says, [REDACTED]	14:49:38
5	[REDACTED]	14:49:40
6	[REDACTED]	14:49:45
7	[REDACTED]	14:49:47
8	A. I see that.	14:49:59
9	Q. Did you or the Serono team participate in	14:50:01
10	these Phase I studies?	14:50:04
11	MS. FERRERA: Objection.	14:50:08
12	A. I can speak for myself, and the answer would	14:50:10
13	be no. For the rest of Serono people, sitting here	14:50:13
14	today, I cannot reply.	14:50:20
15	Q. Did you or the Serono team provide any input	14:50:21
16	on the Phase I study that Dr. Marcus presented on?	14:50:24
17	A. Sitting here today, I do not recall the	14:50:46
18	detail of this. But I do recall that this study had	14:50:48
19	been -- the design or principle of the study had been	14:50:54
20	shown to us, but I do not recall whether we had any	14:50:57
21	input on it.	14:51:05
22	Q. Now, if you go to a third paragraph --	14:51:08

1 A. Sorry, if I go to which paragraph? 14:51:15

2 Q. Third, third paragraph, that starts with [REDACTED] 14:51:17

3 [REDACTED] Do you see that? 14:51:20

4 A. Yes. 14:51:24

5 Q. So it says, [REDACTED] 14:51:26

6 [REDACTED] 14:51:28

7 [REDACTED] 14:51:31

8 [REDACTED] 14:51:35

9 [REDACTED] 14:51:40

10 [REDACTED] 14:51:46

11 Now, my question is: Do you know what is 14:51:49

12 meant by the term "team" here? 14:51:55

13 MS. FERRERA: Objection. 14:51:59

14 A. Well, sitting here today, and having not been 14:52:02

15 the author of these minutes, I cannot be positive in 14:52:11

16 what "the team" is meaning in these minutes. 14:52:15

17 Q. Do you know what was [REDACTED] 14:52:21

18 [REDACTED] 14:52:30

19 MS. FERRERA: Objection. 14:52:31

20 A. Do I know, was this a [REDACTED] what? Sorry, 14:52:32

21 I did not understand that word. 14:52:34

22 Q. Sure. Let me repeat. Do you know what was 14:52:36

1 [REDACTED] referred to here? See how it 14:52:39
2 says, [REDACTED] 14:52:47
3 [REDACTED] 14:52:52
4 [REDACTED] 14:52:54
5 So my question for you is: What was [REDACTED] 14:52:57
6 [REDACTED] referred to here? 14:53:00
7 MS. FERRERA: Objection. 14:53:06
8 A. I recall that IVAX had [REDACTED] 14:53:17
9 but I cannot be any more specific on what the word 14:53:20
10 [REDACTED] means here. I do not know, sitting here 14:53:26
11 today. 14:53:29
12 Q. Do you know if [REDACTED] 14:53:30
13 [REDACTED] 14:53:35
14 MS. FERRERA: Objection. 14:53:42
15 A. It is my reading that [REDACTED] is 14:54:02
16 mentioned on a few occasions in this discussion led by 14:54:04
17 Dr. Marcus. But just reading those minutes, I 14:54:10
18 cannot -- I cannot go beyond speculations in whether 14:54:28
19 it was or not included. 14:54:35
20 Q. Now, when this document says [REDACTED] 14:54:36
21 [REDACTED] 14:54:52
22 [REDACTED] do you know what it means to be [REDACTED] 14:54:55

1	[REDACTED] in this context?	14:55:03
2	MS. FERRERA: Objection.	14:55:04
3	A. I do not know in details, but I can give	14:55:18
4	context, in which [REDACTED]	14:55:23
5	[REDACTED]	14:55:31
6	[REDACTED]	14:55:34
7	[REDACTED]	14:55:37
8	[REDACTED]	14:55:43
9	[REDACTED]	14:55:48
10	[REDACTED] And my reading in terms of [REDACTED] is not	14:55:50
11	totally clear of what is meant by [REDACTED] It would	14:56:01
12	be --	14:56:12
13	I wouldn't be able to swear what the	14:56:12
14	meaning of [REDACTED] is here.	14:56:16
15	Q. Do you know who determined [REDACTED]	14:56:18
16	[REDACTED]	14:56:20
17	A. Sitting here today I do not remember of the	14:56:27
18	decision process.	14:56:29
19	Q. And why did the team -- strike that. And do	14:56:31
20	you know why [REDACTED]	14:56:50
21	[REDACTED]	14:56:52
22	[REDACTED]	14:56:56

1 A. Sitting here today, I can only say that, in
2 the interests of developing a compound for the
3 treatment of multiple sclerosis to patients, it was a
4 fair statement that [REDACTED]

5 [REDACTED]

6 Now, as I said, the definition of [REDACTED]
7 is beyond my ability to swear today.

8 Q. Okay, now, you say "developing a compound for
9 the treatment of multiple sclerosis to patients." I
10 just want to clarify: The compound -- by "compound"
11 you mean cladribine; correct?

12 A. You are right in correcting me, and I should
13 have said, going back to the discussion we had this
14 morning, developing cladribine for multiple
15 sclerosis -- developing oral cladribine for multiple
16 sclerosis.

17 Q. Would it be fair to say that it's developing
18 oral dosing regimen of cladribine for multiple
19 sclerosis --

20 MS. FERRERA: Objection.

21 Q. -- in this context?

22 A. That would be a restriction of what I was

1 saying. Development of oral cladribine goes far 14:58:43
2 beyond the development of the dosing regimen. 14:58:47

3 Q. Okay, I'm going to go back to your answer, 14:58:49
4 and I'm going to read it. You said, "You are right in 14:59:08
5 correcting me." 14:59:20

6 I'm sorry, I'm having technical 14:59:39
7 difficulties here. Just one second, please. 14:59:41

8 You said, "You are right in correcting me, 15:00:25
9 and I should have said, going back to the discussion 15:00:28
10 we had this morning, developing cladribine for 15:00:30
11 multiple sclerosis -- developing oral cladribine for 15:00:34
12 multiple sclerosis." 15:00:37

13 And my question for you here is: Is it 15:00:39
14 fair to say that in the context of Exhibit 2050, Page 15:00:42
15 2, Paragraph 3, it is development of the oral dosing 15:00:53
16 regimen of cladribine for multiple sclerosis? 15:00:59

17 MS. FERRERA: Objection. 15:01:01

18 A. No, I think that this is not what I am 15:01:04
19 reading. This paragraph refers to the development of 15:01:17
20 oral cladribine, and not only of its dosing regimen, 15:01:23
21 in my answer. 15:01:31

22 Q. Moving on: Do you see the highlighted 15:01:32

1 portion on Page 2 of Exhibit 2050? It says 15:01:48

2 [REDACTED] 15:01:52

3 redacted, [REDACTED] 15:02:01

4 [REDACTED] Do you see that, Dr. Munafo? 15:02:04

5 A. I do. 15:02:07

6 Q. Do you have any understanding what [REDACTED] means? 15:02:08

7 A. In this context [REDACTED] 15:02:15

8 [REDACTED] 15:02:20

9 Q. And what does it mean? 15:02:22

10 MS. FERRERA: Objection. 15:02:24

11 A. [REDACTED] 15:02:42

12 [REDACTED] 15:02:48

13 [REDACTED] 15:02:57

14 [REDACTED] 15:03:06

15 Q. And what was [REDACTED] 15:03:15

16 [REDACTED] Dr. Munafo? 15:03:18

17 A. Oh, sitting here today, I am not able to 15:03:20

18 remember the [REDACTED] that we had there. 15:03:23

19 Q. And why did the team consider [REDACTED] 15:03:36

20 [REDACTED] 15:03:40

21 [REDACTED] 15:03:42

22 A. Sitting here today, as I said, I cannot 15:03:52

1	comment on the [REDACTED] not recalling its content. But	15:03:55
2	I'm happy to talk about [REDACTED]	15:04:02
3	[REDACTED] if that is your question.	15:04:05
4	Q. Sure. Why did the team consider [REDACTED]	15:04:07
5	[REDACTED]	15:04:12
6	[REDACTED]	15:04:18
7	[REDACTED]	15:04:26
8	[REDACTED]	15:04:36
9	[REDACTED]	15:04:49
10	[REDACTED]	15:04:56
11	[REDACTED]	15:05:11
12	[REDACTED]	15:05:13
13	[REDACTED]	15:05:18
14	[REDACTED]	15:05:24
15	[REDACTED]	15:05:29
16	[REDACTED]	15:05:34
17	[REDACTED]	15:05:47
18	[REDACTED]	15:05:53
19	[REDACTED]	15:05:59
20	[REDACTED]	15:06:05
21	[REDACTED]	15:06:15
22	[REDACTED]	15:06:18

1	[REDACTED]	15:06:25
2	[REDACTED]	15:06:27
3	[REDACTED]	15:06:37
4	[REDACTED]	15:06:41
5	[REDACTED]	15:06:49
6	[REDACTED]	15:07:04
7	Q. And the cyclodextrin formulation described on	15:07:08
8	Page 3 -- strike that.	15:07:16
9	And the cyclodextrin formulation described	15:07:19
10	on Page 2 of Exhibit 2050 met at least [REDACTED]	15:07:22
11	[REDACTED]	15:07:28
12	MS. FERRERA: Objection.	15:07:31
13	Q. Right?	15:07:33
14	A. These minutes, as I can see here, are a	15:07:34
15	snapshot after [REDACTED]	15:07:50
16	[REDACTED]	15:07:58
17	[REDACTED]	15:08:04
18	[REDACTED]	15:08:13
19	Q. And who requested [REDACTED]	15:08:26
20	[REDACTED]	15:08:31
21	A. As you can read in the first paragraph, [REDACTED]	15:08:39
22	[REDACTED]	15:08:42

1 [REDACTED] and screening is not -- a 15:08:47
2 screening study is not statistically powered to have 15:09:04
3 enough confidence about these statistics. 15:09:11
4 Q. Okay. Let's go to Page 4 of Exhibit 2050. 15:09:29
5 Do you see, Dr. Munafo, where it says, [REDACTED] 15:09:48
6 [REDACTED] 15:09:54
7 [REDACTED] Do you see that? 15:10:04
8 A. Yes, I do. 15:10:07
9 Q. Do you know who proposed that [REDACTED] 15:10:08
10 [REDACTED] 15:10:11
11 A. Sitting here today and reading these minutes, 15:10:19
12 I do not recall who precisely made this proposal. But 15:10:21
13 again, reading that, it was [REDACTED] 15:10:30
14 [REDACTED] 15:10:37
15 Q. Now, do you see further down on Page 4 it 15:10:48
16 says Presentation M. Lopez-Bresnahan, regarding the 15:10:51
17 [REDACTED] and Phase III Design? 15:11:02
18 A. Yes. 15:11:06
19 Q. So am I correct in understanding that 15:11:10
20 Dr. Lopez-Bresnahan presented on the Phase III design 15:11:15
21 in this meeting that is described in Exhibit 2050? 15:11:19
22 A. The minutes say that Maria Lopez presented on 15:11:26

1 [REDACTED] and Phase III design. So this included 15:11:36

2 Phase III design, yes. 15:11:39

3 Q. Did anyone else at Serono assist in the 15:11:41

4 presentation on the Phase III design? 15:11:44

5 A. I would like to ask for clarification. Do 15:11:53

6 you mean anyone else than the Serono participants? 15:11:56

7 Q. No. My question is: Did anyone else at 15:11:59

8 Serono besides Dr. Lopez-Bresnahan make a 15:12:04

9 presentation? 15:12:11

10 A. Reading the minutes, the presentation was 15:12:20

11 made by her. But sitting here today, I cannot state 15:12:22

12 formally whether she was the only one who has prepared 15:12:29

13 it or -- and/or whether there have been interventions 15:12:32

14 during her presentation by other members of -- other 15:12:45

15 members present. 15:12:50

16 Q. Did anyone from the IVAX team provide any 15:12:51

17 input on the Phase III study design presented by 15:12:54

18 Dr. Lopez-Bresnahan? 15:12:59

19 A. Sitting here today, I do not recall of any 15:13:01

20 such things. 15:13:10

21 Q. So staying on Page 4, under the "Suggestions 15:13:17

22 for primary Phase III study," it says "Arms." Do you 15:13:44

1	see that, where it says "Arms"?	15:13:54
2	A. Yes, I do.	15:13:57
3	Q. And do you see where it says, "Cumulative	15:13:58
4	dose approximating .7 mgs per kg and 2.5 mgs per kg	15:14:01
5	and placebo"?	15:14:09
6	A. No, I see "2.1 mgs per kg and placebo."	15:14:11
7	Q. Oh. Thank you for correcting me.	15:14:15
8	And you have referred to these two dosing	15:14:19
9	regimens and the low-dose and high-dose regimens in	15:14:22
10	your declaration; correct?	15:14:29
11	A. With respect to the low-dose, yes. With	15:14:30
12	respect to the high-dose, at that time, yes, this is	15:14:32
13	the one that was referred to.	15:14:36
14	Q. And these regimens were to be administered in	15:14:41
15	five-day courses of treatment each month; correct?	15:14:54
16	A. In this proposal, yes, five days for two	15:15:03
17	months for the 0.7 milligrams per kilo group and five	15:15:13
18	days for six months for the 2.1 milligrams per	15:15:20
19	kilogram dose.	15:15:27
20	MS. PARTINGTON: Emil, can you please	15:15:41
21	bring up Exhibit 2049.	15:15:42
22	And I just want to confirm, Emil, that you	15:16:19

1	put a copy of this in the chat as well.	15:16:21
2	THE TECHNICIAN: Yes, counsel, it's in the	15:16:28
3	chat.	15:16:30
4	MS. PARTINGTON: Thank you.	15:16:33
5	Q. Dr. Munafo, is this a briefing document,	15:16:34
6	December 17, 2003 you referred to in your declaration?	15:16:36
7	A. This is indeed the document that I refer in	15:16:52
8	my declaration.	15:17:10
9	Q. Dr. Munafo, when was the first time you saw	15:17:12
10	Exhibit 2049?	15:17:19
11	A. That is not an easy -- easily answerable	15:17:37
12	question, because I have in part contributed to this	15:17:47
13	document in various -- at various times. So I do	15:17:51
14	not -- I can't --	15:17:57
15	You're asking when I saw it in this form	15:17:58
16	for the first time or when I saw the briefing document	15:18:00
17	for the first time?	15:18:04
18	Q. When did you see the document that has been	15:18:09
19	provided as Exhibit 2049 for the first time?	15:18:11
20	A. This document was provided by my advisers as	15:18:19
21	part of those to refresh my memory during and -- for	15:18:25
22	the preparation of this and my declaration.	15:18:32

1 Q. And when you say "advisers," do you mean 15:18:36

2 attorneys from WilmerHale? 15:18:39

3 A. Yes. Excuse me for my language. 15:18:41

4 Q. That is not a problem. 15:18:55

5 Dr. Munafo, when was the first time you 15:18:58

6 saw the briefing document? 15:19:10

7 A. The briefing document that is in this exhibit 15:19:26

8 is a document that appears to be in a draft form. 15:19:32

9 There are still edits to be made. And I cannot reply, 15:19:39

10 sitting here today, the contact dates when I saw it 15:19:44

11 for the first time. 15:19:47

12 Q. And what was the purpose of the document that 15:19:51

13 later became Exhibit 2049? 15:19:54

14 A. The purpose of the -- to clarify your 15:20:02

15 question: What was the purpose of the briefing 15:20:04

16 document, or what was the purpose of the cover letter? 15:20:07

17 Q. Let's start with the briefing document. What 15:20:14

18 was the purpose of the briefing document that later 15:20:18

19 became Exhibit 2049? 15:20:21

20 A. To the best of my recollection as of today, 15:20:26

21 this was aimed to provide -- to be provided to health 15:20:28

22 authorities for discussion of the development plan for 15:20:37

1	oral cladribine in MS.	15:20:49
2	Q. And what was the purpose of the cover letter	15:20:53
3	that is included in Exhibit 2049, Pages 1 through 3?	15:20:57
4	A. This cover letter, which contains names both	15:21:09
5	from Serono and from IVAX, was intended, in my reading	15:21:14
6	of it, for a distribution for review and inputs from	15:21:24
7	the various parties. This can be seen in an Under	15:21:37
8	Review brief, where various reviewers are named, and	15:21:54
9	function, for the various sections to be reviewed.	15:22:02
10	Q. Which page are you on, Dr. Munafo?	15:22:09
11	A. On Page 2 of the exhibit. But it started,	15:22:11
12	first line, in fact, at the bottom of Page 1.	15:22:18
13	Q. And do you know who wrote the cover letter	15:22:30
14	that is included on Exhibit 2049?	15:22:34
15	A. It is signed and was sent by Isabelle Emery.	15:22:38
16	Q. Would you please go to Page 41 of Exhibit	15:22:55
17	2049 -- I'm sorry, 47 of Exhibit 2049.	15:22:57
18	A. Do you refer to the top or the bottom	15:23:02
19	numbering?	15:23:04
20	Q. That's a good question. I'll tell you in a	15:23:09
21	minute.	15:23:11
22	Top numbering, please.	15:23:17

1	Let me know when you're there.	15:23:36
2	A. I am on Page 47.	15:23:38
3	Q. Does this page of Exhibit 2049 disclose flat	15:23:40
4	cladribine dosing regimen?	15:23:47
5	MS. FERRERA: Objection.	15:23:50
6	A. If I refer to your definition -- to the	15:23:53
7	definition we discussed earlier of "flat," being not	15:23:55
8	adjusted for any body-size metric, then no. My	15:24:03
9	reading of this describes treatment group where	15:24:10
10	cumulative dose is expressed per kilo.	15:24:13
11	Q. Let's go to Page 48 of Exhibit 2049. Does	15:24:18
12	Page 48 of Exhibit 2049 disclose flat cladribine	15:24:27
13	dosing regimen?	15:24:32
14	MS. FERRERA: Objection.	15:24:32
15	A. Perhaps you can help me. I cannot spot	15:24:33
16	quickly any mention of the dose on Page 48.	15:24:58
17	Q. So does Page 48 of Exhibit 2049 disclose flat	15:25:02
18	cladribine dosing regimen?	15:25:06
19	A. After reading this page, admittedly quite	15:25:16
20	quickly, I do not see mention of flat dosing regimen.	15:25:34
21	Q. Okay. Let's go to Page 49 of Exhibit 2049.	15:25:39
22	Dr. Munafo, does Page 49 of Exhibit 2049 disclose a	15:25:52

1	flat cladribine dosing regimen?	15:25:57
2	MS. FERRERA: Objection.	15:26:02
3	A. Under the definition of flat that we said --	15:26:10
4	that we used minutes ago, and upon quick review of	15:26:13
5	this Page 49, I do not see mention of a flat dosing	15:26:16
6	regimen.	15:26:28
7	Q. Let's go to Page 50 of Exhibit 2049. Does	15:26:28
8	Page 50 of Exhibit 2049 disclose a flat cladribine	15:26:36
9	dosing regimen?	15:26:39
10	MS. FERRERA: Objection.	15:26:53
11	A. Under the definition that we used minutes	15:27:00
12	ago, and upon quick reading of the page, I do not see	15:27:03
13	mention of a flat dosing regimen.	15:27:06
14	Q. Let's go to Page 51 of Exhibit 2049, please.	15:27:09
15	Dr. Munafo, does Page 51 of Exhibit 2049 disclose a	15:27:18
16	flat cladribine dosing regimen?	15:27:23
17	MS. FERRERA: Objection.	15:27:25
18	A. Under the same definition of "flat" that we	15:27:26
19	used recently, and upon quick reading of Page 51, I do	15:27:45
20	not see mention of a flat dosing regimen.	15:27:49
21	Q. Let's go to Page 2 of Exhibit 2049, please.	15:27:54
22	Do you see where it says "Reviewers 3," and it lists	15:28:05

1	Alain Munafo and Steve Marcus?	15:28:11
2	A. I do.	15:28:19
3	Q. Why was Dr. Marcus asked to provide any	15:28:20
4	feedback on this document?	15:28:22
5	MS. FERRERA: Objection.	15:28:30
6	A. I'm not the one who assigned the reviewers of	15:28:43
7	this document and cannot -- cannot stand for Isabelle	15:28:48
8	Emery in this respect.	15:28:57
9	Yet I would like to add that the	15:28:59
10	collaboration with IVAX was -- we were instructed that	15:29:06
11	this collaboration was a co-development and that there	15:29:11
12	should be no restriction on our side on sharing	15:29:16
13	information, and that Steve Marcus reviewed -- as a	15:29:20
14	representative from IVAX, reviewed this section, goes	15:29:32
15	along the collaboration that Serono intended to have	15:29:40
16	with IVAX.	15:29:44
17	Q. Let's go to Page 9 of Exhibit 2049, please.	15:29:47
18	A. Yeah.	15:30:08
19	Q. Just a minute, please.	15:30:09
20	I just want to clarify something for the	15:30:37
21	record. Dr. Munafo, you said, "We were instructed	15:30:39
22	that this collaboration was a code development." I	15:30:43

1	just want to clarify that you meant "co-development."	15:30:49
2	A. Excuse me for my pronunciation. Yes, I meant	15:30:53
3	"co-development."	15:31:00
4	Q. Actually, let's be done with this exhibit for	15:31:27
5	now.	15:31:30
6	MS. PARTINGTON: And Emil, can we please	15:31:31
7	go to Exhibit 1022. And as always, Emil, please put	15:31:33
8	Exhibit 1022 in the chat as well.	15:31:54
9	THE TECHNICIAN: I can confirm that it is	15:32:00
10	now in the chat, and I'm now showing it on the screen.	15:32:02
11	Q. Dr. Munafo, do you recognize this document?	15:32:06
12	A. This is a document that I have in front of	15:32:14
13	me.	15:32:16
14	Q. And this is the Bodor PCT that you cited in	15:32:23
15	your declaration; correct?	15:32:27
16	A. This is what we called the Bodor PCT, yes.	15:32:28
17	Q. Dr. Munafo, do you know who drafted the Bodor	15:32:35
18	PCT that became Exhibit 1022?	15:32:38
19	A. I was not an IVAX employee, and I do not	15:32:45
20	know, sitting here today, who drafted that. Just	15:32:49
21	reading at the front page, it says "inventors," but I	15:32:55
22	do not know who drafted it.	15:33:00

1 Q. And did you review a copy of the Bodor PCT in 15:33:02

2 providing your declaration for this case? 15:33:05

3 A. In the preparation of the declaration, this 15:33:14

4 was brought to my attention by my counsels, my 15:33:18

5 attorneys. So I read this document. 15:33:23

6 Q. And when did you read the Bodor PCT 15:33:32

7 application? 15:33:35

8 A. I do not remember the exact date, sitting 15:33:42

9 here today, but it was before I wrote my declaration. 15:33:44

10 Q. And had you seen the Bodor PCT before you 15:33:50

11 were retained for these proceedings? 15:33:54

12 A. No, I did not. 15:34:00

13 MS. PARTINGTON: Let's go to Page 23 of 15:34:04

14 Bodor, please. 15:34:08

15 A. Again, do you mean top or bottom numbering? 15:34:11

16 Q. Top, please. 15:34:15

17 A. Thank you. 15:34:17

18 Q. And I would like to direct your attention to 15:34:17

19 lines 15 through 20. Now, these are the lines you've 15:34:27

20 cited in your declaration, Dr. Munafo; correct? 15:34:31

21 A. I cited to instances in lines 15 to 20 and 20 15:34:40

22 to -- I don't remember exactly where I stopped. But 15:34:49

1	yes.	15:34:51
2	Maybe I have to go back to my declaration	15:34:56
3	to see what exactly I cited, if you --	15:34:59
4	Q. Sure. How about you try Paragraph 7 of your	15:35:03
5	declaration.	15:35:06
6	A. Thank you. Yes, thank you. So yes, I	15:35:22
7	confirm that what is in my declaration is an extract	15:35:25
8	of this Bodor PCT.	15:35:30
9	Q. And do the lines 15 to 20 on Page 23 of	15:35:34
10	Exhibit 1022 disclose a weight-based cladribine	15:35:40
11	regimen?	15:35:47
12	MS. FERRERA: Objection.	15:35:51
13	A. These lines read, "At the present time, it is	15:36:02
14	envisioned that, for the treatment of multiple	15:36:06
15	sclerosis, 10 milligrams of cladribine in the instant	15:36:09
16	complex cladribine-cyclodextrin complex in the instant	15:36:13
17	solid dosage form would be administered once per day	15:36:18
18	for a period of five to seven days in the first month,	15:36:23
19	repeated for another period of five to seven days in	15:36:27
20	the second month, followed by ten months of no	15:36:31
21	treatment."	15:36:35
22	So answer to your question: -- you	15:36:38

1	answered if I remember well whether it was	15:36:46
2	weight-based. Am I correct?	15:36:49
3	Q. My question for you was: Do the lines 15	15:36:50
4	through 20 disclose a weight-based cladribine dosing	15:36:54
5	regimen?	15:36:58
6	A. No, they do not.	15:36:59
7	Q. Now, you mentioned in your declaration that	15:37:05
8	the Bodor PCT application includes a reference to two	15:37:07
9	provisional applications apparently filed by IVAX;	15:37:10
10	correct?	15:37:22
11	A. Correct, and this is an extract from the same	15:37:27
12	page of the PCT, line 24 to the bottom of the page.	15:37:31
13	Q. Did you ever review the two provisional	15:37:40
14	applications that are quoted on Page 23 of Exhibit	15:37:44
15	1022?	15:37:52
16	MS. FERRERA: Objection.	15:37:55
17	A. No, I have never reviewed these documents.	15:37:57
18	Q. Do you have an understanding of the contents	15:38:05
19	of the two provisional applications referred to on	15:38:08
20	Page 23 of Exhibit 1022?	15:38:11
21	A. I have never reviewed nor have any idea of	15:38:15
22	the content of these provisional applications.	15:38:20

1 Q. Do you know who would know about these two 15:38:26

2 provisional applications? 15:38:29

3 MS. FERRERA: Objection. 15:38:30

4 A. Sitting here today, I would not. 15:38:32

5 Q. To the best of your knowledge, do you know if 15:38:36

6 these applications were filed by IVAX? 15:38:38

7 MS. FERRERA: Objection. 15:38:44

8 A. I'd like to have a discussion with my 15:38:46

9 adviser -- with my attorney on that. 15:38:49

10 THE VIDEOGRAPHER: We are going off the 15:38:54

11 record. The time is 15:38. 15:38:55

12 (Recess taken.) 15:38:59

13 THE VIDEOGRAPHER: We are back on the 15:49:42

14 record. The time is 15:49. 15:49:43

15 Q. Welcome back, Dr. Munafo. During the break 15:49:47

16 did you discuss the substance of your deposition with 15:49:50

17 your counsel, besides the questions for which we 15:49:52

18 broke? 15:49:58

19 A. Thank you for clarifying. 15:49:59

20 No, besides this question, no. 15:50:00

21 Q. So let me ask my question again: To the best 15:50:04

22 of your knowledge, do you know if the two provisional 15:50:08

1	applications that are referenced on Page 23 of Exhibit	15:50:12
2	1022 were filed by IVAX?	15:50:16
3	MS. FERRERA: Objection.	15:50:21
4	A. Sitting here today, I do not know.	15:50:22
5	MS. PARTINGTON: Emil, could you please	15:50:29
6	bring up Exhibit 2046. And as always, please put it	15:50:32
7	in the chat as well.	15:50:51
8	THE TECHNICIAN: It has been uploaded to	15:50:58
9	the chat.	15:51:01
10	Q. And Dr. Munafo, do you have a paper copy of	15:51:01
11	Exhibit 2046?	15:51:04
12	A. I do not see this in my binder.	15:51:07
13	Q. Okay, so we're just going to have to work	15:51:13
14	with the electronic copy, then.	15:51:16
15	A. Is there any possibility that I could have it	15:51:19
16	on the computer that is in front of me? Because on	15:51:23
17	the screen it's pretty far and not easy to read or	15:51:28
18	follow.	15:51:30
19	MS. PARTINGTON: Counsel, do you have a	15:51:33
20	laptop that Dr. Munafo can borrow?	15:51:34
21	MR. MCGUFFIN: Yes. It will take a moment	15:51:45
22	to log into Zoom.	15:51:48

1	MS. PARTINGTON: Sure. And while they're	15:51:50
2	getting situated, Emil, will you please give	15:51:52
3	Dr. Munafo control of the document.	15:51:56
4	THE TECHNICIAN: Counsel, it looks like	15:52:11
5	their system doesn't allow for remote control, but I	15:52:13
6	will do my best to navigate for the doctor.	15:52:17
7	THE VIDEOGRAPHER: If you just give me one	15:52:21
8	moment, you might be able to do it for the new	15:52:23
9	addition.	15:52:27
10	MS. PARTINGTON: Sure.	15:52:28
11	THE VIDEOGRAPHER: All right, Emil, you	15:53:19
12	should see the new addition to the Zoom chat under the	15:53:22
13	Wilmer heading. Maybe we can hand control over to	15:53:25
14	him.	15:53:29
15	THE TECHNICIAN: There we go. You have	15:53:33
16	control. If you just click the mouse or click the	15:53:35
17	trackpad and move, you should be able to navigate.	15:53:40
18	A. I'm on the first page of the document that is	15:54:00
19	also on screen.	15:54:06
20	Q. Do you recognize this document, Dr. Munafo?	15:54:12
21	A. Sitting here today, I do not remember having	15:54:15
22	ever seen this document.	15:54:35

CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER

Transcript of Alain Munafo, Ph.D.

Conducted on March 27, 2024

151

1	Q. Okay. This is a U.S. Application	15:54:51
2	No. 60/541,247, and I will refer to this as the '247	15:55:01
3	application. Okay?	15:55:07
4	A. Okay. Yeah, okay.	15:55:22
5	Q. Could we please go to Page 20 of Exhibit	15:55:27
6	2046, please?	15:55:32
7	A. Having not seen this document before, or at	15:55:38
8	least recollecting of it, I don't even know neither	15:55:42
9	its intent nor its content. And even so, I have the	15:55:49
10	rights to go through it and act on it. If there is	15:55:52
11	anything specific, I would request to have the time to	15:56:05
12	read it. That's completely new to me, and I do not	15:56:08
13	know who filed it.	15:56:12
14	Q. Let me --	15:56:16
15	MS. PARTINGTON: Let's go off the record	15:56:18
16	for just a couple of minutes.	15:56:21
17	THE VIDEOGRAPHER: We are going off the	15:56:22
18	record. The time on the monitor is 15:56.	15:56:23
19	(Recess taken.)	15:56:29
20	THE VIDEOGRAPHER: We are back on the	15:59:50
21	record. The time is 15:59.	15:59:54
22	Q. Thank you. Dr. Munafo, did you discuss the	15:59:59

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1	substance of your deposition with counsel during the	16:00:01
2	break?	16:00:04
3	A. No, I did not.	16:00:06
4	Q. Thank you. Can we please go back to Exhibit	16:00:08
5	2046, Page 20 of Exhibit 2046, please.	16:00:12
6	A. I repeat what I was saying just before the	16:00:24
7	break: This is the first time that I see, to the best	16:00:26
8	of my recollection, these documents. And if there	16:00:31
9	is -- I got a printed copy during the break.	16:00:34
10	Q. Okay.	16:00:39
11	A. If you have any question that requires --	16:00:42
12	that requires some context, I would kindly ask you to	16:00:45
13	have the time to quickly go through the document.	16:00:49
14	Q. Okay. Well, why don't I ask you the	16:00:52
15	question, and then you can tell me if you would like	16:00:55
16	to go through the document. Okay?	16:00:57
17	A. Okay.	16:01:02
18	Q. So let's go to Page 20, please, Line 6, that	16:01:03
19	starts with "At the present time." Let me know when	16:01:08
20	you are there, Dr. Munafo.	16:01:12
21	A. I am there.	16:01:14
22	Q. Could you please read into the record from	16:01:16

1	the "At the present time" until the word	16:01:21
2	"alternatively."	16:01:26
3	A. "At the present time, it is envisioned that,	16:01:29
4	for the treatment of multiple sclerosis, 10 milligrams	16:01:32
5	of cladribine in the instant complex cladribine-	16:01:36
6	cyclodextrin complex in the instant solid dosage form	16:01:40
7	would be administered once per day for one week in the	16:01:44
8	first month, repeated for another week in the second	16:01:49
9	month, followed by ten months of no treatment."	16:01:54
10	Q. Thank you. Dr. Munafo, do these lines that	16:01:59
11	you just read on Page 20 of Exhibit 2046 disclose a	16:02:02
12	weight-based cladribine dosing regimen?	16:02:10
13	A. On this line there is no mention on weight-	16:02:24
14	based dosing.	16:02:32
15	Q. Okay, Dr. Munafo, we have no further	16:02:40
16	questions. Thank you for your time today.	16:02:44
17	MS. FERRERA: Can we take a five-minute	16:02:46
18	break, just for us to check our notes?	16:02:48
19	MS. PARTINGTON: Sure. Off the record.	16:02:50
20	THE VIDEOGRAPHER: We are going off the	16:02:52
21	record. The time is 16:02.	16:02:53
22	(Recess taken.)	16:02:58

1	THE VIDEOGRAPHER: We are back on the	16:17:39
2	record. The time is 16:17.	16:17:43
3	EXAMINATION	16:17:47
4	BY MS. FERRERA:	16:17:47
5	Q. Dr. Munafo, I have a few followup questions	16:17:49
6	for you. You were asked earlier today about your	16:17:51
7	memory of the timeline of events relating to the	16:17:55
8	development of a dosing regimen for oral cladribine.	16:17:59
9	Do you recall those questions?	16:18:03
10	A. I do.	16:18:07
11	Q. Did you have any memory of those events prior	16:18:09
12	to being contacted by WilmerHale in connection with	16:18:12
13	this proceeding?	16:18:16
14	A. Could you repeat the question, please?	16:18:17
15	MS. PARTINGTON: Objection, leading.	16:18:19
16	Q. Did you have any memory of those events prior	16:18:21
17	to being contacted by WilmerHale in connection with	16:18:24
18	this proceeding?	16:18:27
19	MS. PARTINGTON: Objection, leading.	16:18:28
20	A. This is more than 20 years ago, and during	16:18:37
21	these 20 years I have worked for many years -- many,	16:18:45
22	many years, from -- I'll start again.	16:18:50

1 I have been working for many, many years 16:19:06
2 on cladribine up to the first submission and 16:19:10
3 thereafter again after the second submission, approval 16:19:17
4 in Europe, approval in the U.S., and in other 16:19:24
5 countries. During these years, yes, the fact that I 16:19:29
6 had worked on the formulation came from time to time. 16:19:42
7 For example, I received on occasion some letters from 16:19:50
8 the patent department. To be honest, I did not go 16:19:54
9 into detail in that. But yes, there were other 16:20:01
10 elements during these 20-plus years which contributed 16:20:03
11 to building a memory. 16:20:12

12 Q. And in the course of working on your 16:20:13
13 declaration that is Exhibit 2053 in this proceeding, 16:20:15
14 were you able to refresh your memory about some 16:20:21
15 aspects of the timeline of that development? 16:20:25

16 MS. PARTINGTON: Objection, leading. 16:20:30

17 A. Yes. For example, the minutes, the meetings, 16:20:34
18 and the briefing document that we discussed just a 16:20:42
19 moment ago, they are dated. This contributes to 16:20:50
20 building the memory of the timelines. 16:20:53

21 Q. In fact, if I could have you turn to your 16:20:59
22 declaration, Exhibit 2053, and in particular, if you 16:21:02

1	would turn to Paragraph 17 in your declaration. And	16:21:12
2	let me know when you're there.	16:21:23
3	A. I am there. I need just to read it.	16:21:25
4	Q. Sure.	16:21:28
5	A. I have read 17.	16:21:54
6	Q. And at the top of Page 7 you have a sentence	16:21:56
7	that says, "My team at Serono started investigating	16:21:59
8	whether cladribine could be used to treat multiple	16:22:02
9	sclerosis in 2001." Do you see that sentence?	16:22:05
10	A. I do.	16:22:10
11	Q. And then if you turn to Paragraph 23, on the	16:22:11
12	next page.	16:22:14
13	A. Yes.	16:22:14
14	Q. In the first sentence in Paragraph 23 you	16:22:26
15	say, "In October, 2002, Serono partnered with IVAX to	16:22:28
16	develop an oral formulation of cladribine." Did I	16:22:32
17	read that correctly?	16:22:35
18	A. Yes, you do.	16:22:37
19	Q. So was Serono investigating cladribine for	16:22:38
20	the treatment of multiple sclerosis prior to entering	16:22:42
21	into the agreement with IVAX?	16:22:46
22	MS. PARTINGTON: Objection, leading.	16:22:50

1	A. The question -- can you repeat it again?	16:22:54
2	Because I was distracted.	16:22:57
3	Q. Sure. Was Serono investigating cladribine	16:22:59
4	for treatment of multiple sclerosis prior to entering	16:23:06
5	into the agreement with IVAX?	16:23:08
6	MS. PARTINGTON: Objection, leading.	16:23:14
7	A. The date of October 2002 that you referred to	16:23:15
8	on Paragraph 23 is the date of, if I get it right, of	16:23:18
9	the signature of the agreements. However, and in	16:23:25
10	response to your question, some work in the company	16:23:32
11	starts before that, in order to be prepared at the	16:23:36
12	time of the agreements. So yes, we started before	16:23:40
13	that to start to elaborate ideas and concepts on how	16:23:44
14	cladribine oral -- oral cladribine could be developed	16:23:54
15	for the treatment of MS.	16:23:59
16	Q. Okay. Counsel asked you some questions about	16:24:01
17	whether IVAX designed its formulations before you and	16:24:04
18	the Serono team began working on dosing regimens. Do	16:24:12
19	you recall that?	16:24:17
20	A. Yes, I do.	16:24:18
21	Q. Could I have you turn to Exhibit 2049.	16:24:20
22	A. Yes.	16:24:33

1	Q.	And 2049 is the cover email dated December	16:24:36
2		17th, 2003, attaching a briefing document for the	16:24:41
3		Swedish authorities; correct?	16:24:48
4	A.	Correct.	16:24:49
5	Q.	And if you would turn to Page 47, referring	16:24:50
6		to the pages numbers at the top.	16:25:00
7	A.	Uh-huh.	16:25:10
8	Q.	Starting at Page 47 and continuing to Page	16:25:11
9		51, there's a Table 5.1.1. Do you see that?	16:25:14
10	A.	Yes.	16:25:17
11	Q.	And the title of that table is Synopsis of	16:25:18
12		Proposed Phase 3 study. Do you see that?	16:25:22
13	A.	Yes, I do.	16:25:25
14	Q.	Does this synopsis describe proposed dosing	16:25:26
15		regimens for oral cladribine for multiple sclerosis?	16:25:30
16		MS. PARTINGTON: Objection, leading.	16:25:34
17	A.	In various places in this document there is	16:25:45
18		indeed mention of the dosing regimen for the Phase III	16:25:47
19		study, yes.	16:25:53
20	Q.	And who developed the dosing regimens that	16:25:54
21		are described in Table 5.1.1?	16:25:59
22	A.	In accordance with the distribution of work	16:26:08

1 between IVAX and Serono, it was Serono's

16:26:10

2 responsibility and engagement to develop this

16:26:13

3 synopsis.

16:26:16

4 Q. And did Serono provide this December 17th,

16:26:26

5 2003 briefing document, or draft of a briefing

16:26:33

6 document, to IVAX under the terms of the agreement?

16:26:38

7 A. The cover letter mentioned that this was sent

16:26:48

8 by Isabelle Emery, signed by Isabelle Emery. And in

16:26:53

9 the distribution list there are indeed representatives

16:27:00

10 from IVAX -- and I can quickly point to Yogesh

16:27:05

11 Dandiker and Steve Marcus.

16:27:10

12 So to answer your question, yes, this

16:27:14

13 document, being attached to the memo, was sent to

16:27:18

14 them.

16:27:24

15 Q. And the date of this email is December 17th,

16:27:25

16 2003. Do you see that?

16:27:31

17 A. Yes, this is correct.

16:27:33

18 Q. So had Serono developed -- strike that. Had

16:27:35

19 Serono disclosed to IVAX its proposed dosing regimens

16:27:40

20 as of December 17th, 2003?

16:27:48

21 MS. PARTINGTON: Objection, leading.

16:27:53

22 A. When you mean as of December 17, I want to be

16:27:56

1 sure I understand your question correctly. Are you 16:28:08
2 asking whether I can confirm that this briefing 16:28:11
3 document disclosing the full-seen dosing regimen was 16:28:16
4 distributed to IVAX on the 17th of December, or are 16:28:23
5 you asking whether it has been set before? 16:28:27

6 Q. On. 16:28:30

7 A. On. Yes, it is disclosed -- it is an 16:28:31
8 attachment to this document. 16:28:33

9 Q. Now would you turn, please, to Page -- 16:28:38
10 starting at Page 26. 16:28:44

11 A. Of this document? 16:28:46

12 Q. In Exhibit 2049. And starting on Page 26 and 16:28:47
13 continuing to Page 28 there is a Table 4.2.1. Do you 16:28:57
14 see that? 16:29:05

15 A. Yes, I do. 16:29:06

16 Q. And the title of that table is Clinical 16:29:07
17 Pharmacology Studies: Completed and Ongoing. Did I 16:29:09
18 read that correctly? 16:29:14

19 A. I read the same. 16:29:14

20 MS. PARTINGTON: Objection, scope. 16:29:16

21 Q. If you go down to Page -- if you look at Page 16:29:17
22 27, there's a subheading Ongoing Studies. Do you see 16:29:21

1 that? 16:29:25

2 MS. PARTINGTON: Objection, scope. 16:29:26

3 A. Yes, I do. 16:29:32

4 Q. And there are [REDACTED] in that 16:29:33

5 section. 16:29:35

6 MS. PARTINGTON: Objection, scope. 16:29:39

7 Q. Do you see that? 16:29:40

8 A. Yes, I do. 16:29:40

9 Q. Are the studies listed there the 101 and 102 16:29:41

10 studies that you testified about earlier today? 16:29:44

11 A. Yes, they are. 16:29:47

12 Q. And for the 101 study do you see in the 16:29:49

13 column, the last two columns, it indicates [REDACTED] 16:29:56

14 MS. PARTINGTON: Objection, scope. 16:30:04

15 A. I see that the label of the column is 16:30:05

16 [REDACTED] 16:30:16

17 [REDACTED] 16:30:24

18 Q. [REDACTED] 16:30:30

19 [REDACTED] 16:30:34

20 MS. PARTINGTON: Objection, leading. 16:30:36

21 A. Sitting here today, I can only comment on the 16:30:44

22 [REDACTED], and not basing on my 16:30:48

1	recollection. [REDACTED]	16:30:55
2	[REDACTED]	16:30:57
3	Q. And similarly, [REDACTED]	16:30:58
4	[REDACTED]	16:31:04
5	MS. PARTINGTON: Objection, leading.	16:31:07
6	A. The same response to the previous one: [REDACTED]	16:31:08
7	[REDACTED]	16:31:13
8	[REDACTED]	16:31:21
9	Q. [REDACTED]	16:31:24
10	[REDACTED]	16:31:29
11	[REDACTED]	16:31:34
12	[REDACTED]	16:31:41
13	[REDACTED]	16:31:45
14	[REDACTED]	16:31:50
15	A. [REDACTED]	16:32:10
16	[REDACTED]	16:32:17
17	[REDACTED]	16:32:27
18	[REDACTED]	16:32:34
19	[REDACTED]	16:32:37
20	MS. PARTINGTON: Objection, leading.	16:32:39
21	A. If you'll allow me to scroll through the	16:32:48
22	documents?	16:32:50

1 Q. Sure. Let me ask you another -- or direct 16:32:51
2 you to a portion of the document, Dr. Munafo. If 16:33:24
3 you'd turn to Page 9. 16:33:27
4 A. We are still on the briefing? 16:33:31
5 Q. Yes. 16:33:32
6 A. Yes. 16:33:37
7 Q. You see there's an introduction? 16:33:37
8 A. Yes. 16:33:39
9 Q. The fifth paragraph of the introduction 16:33:42
10 starts [REDACTED] 16:33:45
11 A. Right. 16:33:48
12 Q. And in the second sentence it says, [REDACTED] 16:33:49
13 [REDACTED] 16:33:53
14 [REDACTED] 16:33:55
15 [REDACTED] 16:33:58
16 [REDACTED] Do you see that? 16:33:59
17 A. I see that. 16:34:03
18 MS. PARTINGTON: Objection, scope. 16:34:08
19 Q. Do you see that statement, Dr. Munafo? 16:34:14
20 A. Yes. 16:34:16
21 Q. Based on that, do you believe that you had 16:34:16
22 data regarding the bioavailability and 16:34:24

1 pharmacokinetics of IVAX's formulation as of the date 16:34:28
2 of this document? 16:34:34

3 MS. PARTINGTON: Objection, leading. 16:34:38

4 A. Sitting here today, I cannot say what I saw 16:35:07
5 or had not seen by the time of the briefing documents. 16:35:15
6 And I want to say that this is because saying that [REDACTED] 16:35:24

7 [REDACTED] 16:35:29

8 [REDACTED] So I 16:35:34
9 cannot state with certainty that I had not seen some 16:35:43
10 PK data. 16:35:48

11 Q. Had you and your team at Serono begun work on 16:35:56
12 your proposed dosing regimens before becoming -- 16:36:00
13 before obtaining PK data for the IVAX formulations? 16:36:08

14 MS. PARTINGTON: Objection, leading. 16:36:15

15 A. The start of the thought process is a date 16:36:18
16 very difficult to assess, and sitting here today, I'm 16:36:32
17 not able, neither was I this morning, to state the 16:36:37
18 exact date of the start of the process. 16:36:40

19 However, as I am -- as I'd like to 16:36:44
20 explain, the definition of the dosing regimen is a 16:36:51
21 long, iterative process, which started early into the 16:36:54
22 project team discussion with the various partners. 16:37:02

1 Also, I cannot state the date, the exact
2 date; but given that it is a long process, I can
3 affirm that it started early. The exact date with
4 respect to first seeing PK data I cannot say with
5 confidence.

6 Q. [REDACTED]

7 [REDACTED]
8 [REDACTED]
9 MS. PARTINGTON: Objection, leading.

10 A. [REDACTED]

11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 Q. Now, in your declaration you discuss certain
16 communications and meetings that occurred between IVAX
17 and Serono. Do you recall that?

18 A. What do you mean with "certain"?

19 Q. In your declaration you discuss examples of
20 meetings and communications that Serono had with IVAX.
21 Do you recall that?

22 A. Correct. Yes, I do.

1	Q. Were there or were there not other meetings	16:39:02
2	and communications between IVAX and Serono besides the	16:39:06
3	ones that you describe in your declaration?	16:39:11
4	A. Yes, there were.	16:39:15
5	Q. And what type of information did Serono	16:39:17
6	communicate to IVAX in those various meetings and	16:39:20
7	communications?	16:39:23
8	MS. PARTINGTON: Objection, leading.	16:39:30
9	A. Sitting here today, I cannot say with -- I do	16:39:32
10	not recall the detail of what was communicated. But	16:39:35
11	to put this in context, we were open in everything	16:39:39
12	that we communicated to IVAX, and certainly the	16:39:45
13	projects -- or the initial concepts of the Phase III	16:39:57
14	study were discussed on an ongoing basis with IVAX.	16:40:06
15	And what I mean with "ongoing" is that during the team	16:40:12
16	meetings in person, by teleconference, or by other	16:40:19
17	routes this was freely discussed with IVAX.	16:40:26
18	Q. Would you turn to Exhibit 2050. And Exhibit	16:40:36
19	2050 are the minutes of the August 27th, 2003 meeting	16:40:56
20	that counsel showed you earlier today. Do you see	16:41:00
21	that?	16:41:02
22	A. I see the document.	16:41:03

1 Q. And if you turn to Page 2 of the document,
2 under the Phase I Studies section there's reference to

3 [REDACTED] Do you see that? For example --

4 A. There are several instances of [REDACTED] in
5 this section.

6 Q. Right. And I think you said earlier today
7 that [REDACTED]; is that
8 right?

9 A. This is correct.

10 Q. Did you play any role in helping to define
11 [REDACTED] for oral cladribine?

12 MS. PARTINGTON: Objection, leading.

13 A. I -- sitting here today, I do not recall all
14 of the components of [REDACTED]. I
15 contributed, however, to [REDACTED]

16 [REDACTED]
17 [REDACTED] But to be clear, I do not recall whether
18 these elements were part of [REDACTED] or not.

19 Q. If I could then have you turn to Exhibit
20 1022. That's the Bodor PCT, Tab 4, I think.

21 A. Yes.

22 Q. Sorry; Tab 4, I think.

1	A. Sorry.	16:42:57
2	Q. And do you recognize that as the Bodor PCT	16:42:58
3	application that counsel showed you earlier?	16:43:00
4	A. Yes.	16:43:03
5	Q. And counsel asked you about the dosing	16:43:03
6	regimen that's described on Page 23 of that	16:43:07
7	application. Do you recall that?	16:43:13
8	A. I do.	16:43:14
9	Q. And I think she asked you whether or not that	16:43:14
10	discloses a flat dosing regimen or a weight-based	16:43:17
11	dosing regimen. Do you recall that?	16:43:21
12	A. I recall that she asked me whether there was	16:43:24
13	a weight-based indication here.	16:43:27
14	MS. PARTINGTON: Objection.	16:43:31
15	Q. And am I correct that in your view this does	16:43:32
16	not disclose a weight-based dosing regimen?	16:43:35
17	MS. PARTINGTON: Objection, leading.	16:43:39
18	A. In my view, it does not. It is referring to	16:43:40
19	a dose -- a fixed dose of 10 milligrams of cladribine.	16:43:49
20	It does not mention weight adjustment, and it does not	16:43:54
21	mention either a re-treatment phase one year later.	16:44:00
22	So this is an abrogated, incomplete dosing regimen in	16:44:14

1 comparing to what we have proposed. 16:44:24

2 Q. Given that, why do you believe that Dr. Bodor 16:44:26
3 and Dr. Dandiker obtained the dosing regimen that is 16:44:31
4 disclosed in their PCT from you and your team at 16:44:40
5 Serono? 16:44:42

6 MS. PARTINGTON: Objection, leading, 16:44:44
7 scope. 16:44:45

8 A. I need you to rephrase your question. Why 16:44:49
9 did they obtain it? 16:44:52

10 Q. Why do you believe that the dosing regimen 16:44:54
11 that is disclosed in the Bodor PCT application on Page 16:45:01
12 23, starting at line 15, comes from information that 16:45:03
13 you and your team at Serono disclosed to IVAX? 16:45:07

14 MS. PARTINGTON: Objection, leading, 16:45:11
15 scope. 16:45:12

16 A. It is my conviction that this example -- and 16:45:14
17 I really do understand this in the Bodor as example -- 16:45:24
18 comes from an understanding -- incidentally, not 16:45:36
19 totally correct -- of what we presented to them during 16:45:42
20 the year before, before they filed this application. 16:45:46

21 Q. And what is the basis for that belief, that 16:45:51
22 conviction? 16:45:55

1 MS. PARTINGTON: Objection, leading. 16:45:58

2 A. It was us at Serono, me and my team, and no 16:46:01
3 one at IVAX, which was in charge of developing a 16:46:11
4 dosing regimen, and we presented what we had in mind 16:46:15
5 to IVAX. I'm not aware of any work that IVAX has 16:46:19
6 performed independently in attempting to define a 16:46:26
7 dosing regimen. 16:46:29

8 Q. In any of the meetings and communications 16:46:31
9 that you had with IVAX during the development process, 16:46:33
10 did IVAX describe any -- did they or did not describe 16:46:39
11 any dosing regimens for oral cladribine to Serono? 16:46:45

12 MS. PARTINGTON: Objection, leading. 16:46:49

13 A. Sitting here today, I do not recall of any 16:46:51
14 such allusion. 16:46:53

15 MS. FERRERA: Thank you. I have no more 16:47:00
16 questions. 16:47:02

17 MS. PARTINGTON: May we please go off 16:47:17
18 record for a minute and take a five-minute break. 16:47:19

19 THE VIDEOGRAPHER: We are going off the 16:47:22
20 record at 16:47. 16:47:23

21 (Recess taken.) 16:47:25

22 THE VIDEOGRAPHER: We are back on the 17:02:32

CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER

Transcript of Alain Munafo, Ph.D.

Conducted on March 27, 2024

171

1	record. The time is 17:02.	17:02:35
2	MS. PARTINGTON: Dr. Munafo, we have no	17:02:41
3	further questions. Thank you for your time today.	17:02:44
4	THE WITNESS: Thank you.	17:02:46
5	THE VIDEOGRAPHER: This marks the end of	17:02:47
6	the deposition of Dr. Alain Munafo. We are going off	17:02:48
7	the record at 17:02.	17:02:52
8	(Discussion off the record.)	17:03:02
9	THE VIDEOGRAPHER: We are back on the	17:03:08
10	record. The time is 17:03.	17:03:16
11	MS. FERRERA: Sorry, I just want to make	17:03:19
12	clear that we would like to designate the transcript	17:03:21
13	as confidential information subject to the protective	17:03:23
14	order in this matter.	17:03:29
15	MS. PARTINGTON: Okay.	17:03:31
16	THE VIDEOGRAPHER: This marks the end of	17:03:32
17	the deposition of Dr. Alain Munafo. We are going off	17:03:36
18	the record at 17:03.	17:03:40
19	(The deposition concluded at 5:03 p.m.)	17:03:42
20		
21		
22		

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1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC.

2 I, Alan H. Brock, Certified Reporter and
3 notary public within and for the Commonwealth of
4 Massachusetts, do hereby certify:

5 That Alain Munafo, Ph.D., the witness
6 whose deposition is hereinbefore set forth, was duly
7 sworn by me before the commencement of such deposition
8 and that such deposition was taken before me and is a
9 true record of the testimony given by such witness.

10 I further certify that the adverse party,
11 Merck Serono, S.A., was represented by counsel at the
12 deposition.

13 I further certify that the deposition of
14 Alain Munafo, Ph.D. occurred at the offices of
15 Wilmer Cutler Pickering Hale and Dorr LLP, 60 State
16 Street, on Wednesday, March 27, 2024, commencing at 9:10
17 a.m. to 5:03 p.m.

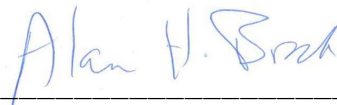
18 I further certify that I am not related to
19 any of the parties to this action by blood or
20 marriage, I am not employed by or an attorney to any
21 of the parties to this action, and that I am in no way
22 interested, financially or otherwise, in the outcome

1 of this matter.

2 IN WITNESS WHEREOF, I have hereunto
3 set my hand this 27th day of March, 2024.

4
5 My commission expires:

6 March 25, 2027.

7
8 
9

10 Alan H. Brock, RDR, CRR
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