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Transcript of Nicholas Bodor, Ph.D., DSc, dhc, HoF

Date: February 15, 2024

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

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Merck 2041
TWi v Merck
IPR2023-00049

1 UNITED STATES PATENT AND TRADEMARK OFFICE

2 BEFORE THE PATENT TRIAL AND APPEAL BOARD

3
4 HOPEWELL PHARMA VENTURES, INC.

5 Petitioner,

6 v.

7 MERCK SERONO S.A.,

8 Patent Owner.

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

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

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12 VIDEOTAPED DEPOSITION OF
13 Nicholas Bodor, PhD, DSc, dhc, HoF

14 Pages 1 to 143

15 Thursday, February 15, 2024

16 9:34 a.m. - 2:03 p.m.

17 Bodor Laboratories
18 4400 Biscayne Boulevard
19 11th Floor
20 Miami, Florida

21 STENOGRAPHICALLY REPORTED BY:

22 NANCY E. PAULSEN, CRR, CRC, RPR

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Lhassan Elmilki, Videographer (In person)
Emil White, Remote Zoom Technician (via Zoom)
Michael Pietanza, In-room Zoom Technician

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1	REMOTE ZOOM TECHNICIAN WHITE: Thank you to	09:32:33
2	everyone for attending this proceeding remotely and	09:32:33
3	in person. We anticipate things will run smoothly	09:32:36
4	going forward.	09:32:41
5	Please remember to speak slowly and do your	09:32:42
6	best not to talk over one another. Please be aware	09:32:45
7	that we are recording this proceeding for backup	09:32:47
8	purposes as well.	09:32:50
9	Any off-the-record discussion should be had	09:32:51
10	away from the computer, and please remember to mute	09:32:53
11	your mic for those conversations.	09:32:56
12	Please have your video enabled to help the	09:32:58
13	reporter identify who is speaking, but if you are	09:33:01
14	unable to connect video and you are connecting via	09:33:04
15	phone, we just ask that you identify yourself each	09:33:07
16	time before speaking.	09:33:09
17	I apologize in advance for any more	09:33:10
18	technical-related interruptions. Thank you.	09:33:13
19	VIDEOGRAPHER ELMILKI: Here begins Media	09:33:20
20	Number 1 in the videotape of Dr. Nicholas Bodor in	09:33:23
21	the matter Hopewell Pharma Venture, Inc., versus	09:33:26
22	Merck Serono, SA, in the Court of the United	09:33:33

1	States -- of the United States Patent and Trial	09:33:38
2	Office, Case Number IPR2023-2 -- 00480 and	09:33:41
3	IPR2023-00481.	09:33:53
4	Today is Thursday, February 15, 2024, and the	09:33:55
5	time -- the time on the video monitor is 9:34 a.m.	09:34:01
6	Eastern Time. The videographer for today is	09:34:04
7	Lhassan Elmilki, representing Planet Depo, and the	09:34:10
8	video deposition is taking place at 440 [sic]	09:34:13
9	Biscayne Boulevard, Suite 980, Miami, Florida, ZIP	09:34:17
10	Code is 33137.	09:34:22
11	Would the counsel please voice identify	09:34:23
12	themselves and state whom they -- who -- who they	09:34:26
13	represent.	09:34:29
14	MS. DASHE: I'm Christina Dashe from Sterne	09:34:29
15	Kessler on behalf of Petitioner Hopewell. With me	09:34:32
16	today remotely are Eldora Ellison, Olga Partington,	09:34:36
17	and Tyler Lui, also of Sterne Kessler. And with me	09:34:43
18	today in person with the witness is Madeleine Bond,	09:34:45
19	also of Sterne Kessler.	09:34:48
20	MR. MLAYER: Good morning, this is David	09:34:50
21	Mlayer of WilmerHale on behalf of the patent owner.	09:34:52
22	With me are Asher McGuffin and by remote Willem de	09:34:56

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1	Weerd of Merck KGaA.	09:35:03
2	THE COURT REPORTER: Doctor, would you raise	09:35:18
3	your right hand, please.	
4	Do you swear or affirm the testimony you are	
5	about to give will be the truth and nothing but the	
6	truth?	
7	THE WITNESS: I do.	09:35:19
8	THE COURT REPORTER: Thank you.	
9	THEREUPON,	
10	NICHOLAS BODOR, PHD, DSC, DHC, HOF,	
11	having been duly sworn to tell the truth, was examined	
12	and testified as follows:	
13	DIRECT EXAMINATION	
14	BY MS. DASHE:	
15	Q. Dr. Bodor, could you please state and spell	09:35:22
16	your name for the record?	09:35:26
17	A. I am Nicholas Bodor, N-I-C-H-O-L-A-S,	09:35:27
18	B-O-D-O-R.	09:35:34
19	Q. What is your address?	09:35:35
20	A. Home address is 10225 Collins Avenue,	09:35:36
21	Apartment 1002, Bal Harbour, Florida, 33154.	09:35:41
22	Q. Have you ever been deposed before?	09:35:50

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1	A. Not like this.	09:35:57
2	Q. ... this?	09:35:58
3	Have you ever sat for a deposition in any	09:36:02
4	capacity?	09:36:04
5	A. I have to ask opinion. About 40 years ago, I	09:36:05
6	was involved in a patent interference case and I was	09:36:14
7	deposed, but not like this, it was just the counsel on	09:36:20
8	both sides.	09:36:26
9	Q. The deposition 20 years ago -- or 40 years	09:36:26
10	ago, excuse me, in the patent interference case, have	09:36:35
11	you ever been deposed before?	09:36:39
12	A. No.	09:36:40
13	Q. Okay. I would like to go over some ground	09:36:40
14	rules for today's deposition. To start, I'll be asking	09:36:45
15	you some questions, and your counsel may object, but	09:36:47
16	it's important for the court reporter that we don't all	09:36:51
17	talk over one another today.	09:36:53
18	Is that all right?	09:36:56
19	A. Yes.	09:36:57
20	Q. And similarly, the court reporter cannot	09:36:58
21	really take down nonverbal answers, like shaking your	09:37:03
22	head or saying "um-hum." Can you please agree to give	09:37:06

1 verbal answers today? 09:37:11

2 A. Yes. 09:37:11

3 Q. Sometimes your counsel may object to my 09:37:12

4 questions, but you still have to answer them unless 09:37:16

5 counsel directs you not to answer them. Will you agree 09:37:19

6 to abide by this rule? 09:37:22

7 A. Yes. 09:37:23

8 Q. Now, if at any point today you need a break, 09:37:23

9 please let me know and I will try to accommodate, but 09:37:29

10 the patent office rules require that you do answer any 09:37:32

11 pending questions before we take a break. 09:37:35

12 Will you agree to abide by this rule? 09:37:37

13 A. Yes. 09:37:40

14 Q. If I ask a question today that you don't 09:37:40

15 understand or need further clarification, will you agree 09:37:45

16 to let me know, and I can try to clarify and ask a 09:37:48

17 better question? 09:37:51

18 A. Yes. 09:37:52

19 Q. However, if you answer a question that I ask, 09:37:52

20 I will assume that you understood it. Is that okay? 09:37:57

21 A. Yes. 09:38:01

22 Q. Now, because we are operating on a remote 09:38:01

1	basis for today's deposition, there might be some	09:38:05
2	technical difficulties. If anything happens that	09:38:08
3	interferes with your ability to understand or answer my	09:38:12
4	questions, will you agree to let me know?	09:38:15
5	A. Yes.	09:38:16
6	Q. Now, the patent office rules require that I	09:38:20
7	tell you that during my questioning today, you are not	09:38:23
8	permitted to discuss your testimony with counsel unless	09:38:26
9	you are discussing an issue relating to privilege.	09:38:31
10	Will you agree to abide by that rule?	09:38:32
11	A. Yes.	09:38:36
12	Q. ... why you cannot give truthful testimony	09:38:41
13	today?	09:38:45
14	A. I -- I don't understand.	09:38:46
15	MR. MLAVER: Christina, the first few words of	09:38:49
16	your question were cut off.	09:38:52
17	BY MS. DASHE:	09:38:53
18	Q. Is there any reason, Dr. Bodor, that you	09:38:54
19	cannot give truthful testimony today?	09:38:57
20	A. No reason.	09:38:58
21	Q. Where are you located for today's deposition?	09:38:59
22	A. You mean the -- this room? It's --	09:39:08

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1	Q. Yes, please.	09:39:12
2	A. It's 4400 Biscayne Boulevard, on the 11th	09:39:13
3	Floor, conference room.	09:39:18
4	Q. And besides the counsel and videographer and	09:39:21
5	court reporter that already announced their presence on	09:39:26
6	the record today, is there anyone else in the room with	09:39:28
7	you?	09:39:31
8	A. No.	09:39:31
9	Q. Okay. Whose computer are you using for	09:39:32
10	today's deposition?	09:39:36
11	A. I don't know.	09:39:38
12	Q. It's someone else's?	09:39:39
13	A. Yes.	09:39:42
14	Q. Do you have any files or programs open on your	09:39:42
15	computer besides the deposition video platform?	09:39:49
16	A. I don't have any file with me.	09:39:53
17	Q. Do you have access to any other files or	09:39:54
18	programs besides today's deposition video platform?	09:40:01
19	A. No. No. Not here. I don't have anything.	09:40:05
20	MR. MLAYER: Counsel, if it's helpful, we're	09:40:08
21	using Planet Depo's computer.	09:40:11
22	MS. DASHE: Thank you.	09:40:15

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1	BY MS. DASHE:	09:40:16
2	Q. Do you have any other electronic devices with	09:40:16
3	you today, like a cell phone, things of that nature?	09:40:18
4	A. I have a cell phone. It was just put away by	09:40:20
5	the counsel.	09:40:24
6	Q. You won't be accessing your cell phone to	09:40:25
7	receive messages or phone calls during the deposition	09:40:29
8	today?	09:40:31
9	A. I don't plan to, unless I am directed to do	09:40:31
10	so.	09:40:40
11	But it is turned off, by the way.	09:40:40
12	Q. And including on breaks, you won't be	09:40:42
13	accessing your cell phone for text messages, phone calls	09:40:46
14	relating to the deposition today?	09:40:50
15	A. I don't plan to, no.	09:40:52
16	Q. Okay. Did you bring anything else with you to	09:40:54
17	your deposition today?	09:41:00
18	A. No, just my medication if I need it.	09:41:01
19	MR. MLAYER: And, Counsel, we do have an	09:41:09
20	otherwise unmarked copy of Dr. Bodor's declaration	09:41:13
21	with us, if -- if that will assist. So we can	09:41:17
22	provide that to him if -- if you need.	09:41:21

1 MS. DASHE: And, Counsel, that is unmarked, no 09:41:25
2 notes or anything like that? 09:41:27
3 MR. MLAYER: That's correct. 09:41:28
4 MS. DASHE: Okay. 09:41:30
5 MR. MLAYER: And Ms. Bond has had an 09:41:31
6 opportunity to inspect it and see if that's the 09:41:33
7 case. 09:41:35
8 MS. DASHE: Okay. Thank you. 09:41:38
9 THE WITNESS: One more thing I want to 09:41:39
10 ment- -- I don't know if my iWatch, it does matter? 09:41:41
11 MR. MLAYER: It -- not if you're not using it. 09:41:45
12 THE WITNESS: Okay. 09:41:48
13 BY MS. DASHE: 09:41:50
14 Q. To totally clarify, Dr. Bodor, will you agree 09:41:51
15 not to access your cell phone, or your Apple watch, or 09:41:55
16 any other electronic device to receive messages or 09:41:57
17 discuss your deposition today? 09:42:00
18 A. Yes. 09:42:02
19 Q. Okay, thank you. 09:42:02
20 What did you do to prepare for this 09:42:09
21 deposition? 09:42:11
22 A. I reviewed my deposition [sic] and my patent, 09:42:17

1 and I had discussion with my counsel yesterday. 09:42:21

2 Q. Patent, do you mean the Bodor PCT application? 09:42:32

3 A. Yes, the Bodor PCT and the other two at-issue 09:42:40

4 patents. 09:42:45

5 Q. US patents, like Bodor -- 09:42:45

6 A. Yes. 09:42:47

7 Q. Yes? 09:42:47

8 A. Yes, patents which I am the sole inventor.

9 Not with Dandiker. 09:42:57

10 Q. So you reviewed two issued US patents where 09:42:57

11 you were the sole inventor? 09:43:03

12 A. I think, yes. 09:43:05

13 Q. Do you recall what numbers those were? 09:43:06

14 A. No. 09:43:09

15 Q. You also said that you met with counsel 09:43:09

16 yesterday. Who was that counsel? 09:43:18

17 A. Next to me, David and Asher. 09:43:22

18 Q. These patents that you reviewed, what were the 09:43:33

19 titles of the patents that you reviewed? 09:43:35

20 A. I think it's "Cladribine Oral Formulation" or 09:43:37

21 something like that. I don't know the exact title. 09:43:51

22 It was "Oral formulation of cladribine" -- 09:43:55

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1	Q.	Did you meet with your counsel yesterday?	09:43:55
2	A.	Yes.	09:43:59
3	Q.	I'm sorry, I talked over you. What did you	09:43:59
4		say?	09:44:02
5	A.	I think it was "Oral Formulation for	09:44:02
6		Cladribine."	09:44:12
7	Q.	For how long did you meet with counsel	09:44:12
8		yesterday to prepare for today's deposition?	09:44:16
9	A.	I would say it was about three to four hours.	09:44:19
10	Q.	... counsel, did you talk to anyone else	09:44:22
11		regarding the substance of your deposition today?	09:44:31
12	A.	No.	09:44:33
13	MS. DASHE:	Emil, I would like you to	09:44:44
14		introduce tab 1, which is the Bodor declaration,	09:44:46
15		it's been marked as Exhibit 2054 in these	09:44:49
16		proceedings.	09:44:53
17	REMOTE ZOOM TECHNICIAN WHITE:	Stand by.	09:45:02
18	MR. MLAYER:	Counsel, if we're going to ask	09:45:03
19		questions about the declaration, is it all right if	09:45:05
20		I hand him the paper copy of his declaration so he	09:45:07
21		can refer to it?	09:45:10
22	MS. DASHE:	That is just fine, Counsel.	09:45:11

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1	MR. MLAYER: Thank you.	09:45:13
2	THE WITNESS: Thank you.	09:45:14
3	REMOTE ZOOM TECHNICIAN WHITE: Now showing	09:45:19
4	what has been marked as Exhibit 2054.	09:45:20
5	BY MS. DASHE:	09:45:27
6	Q. Dr. Bodor, can you see the document on the	09:45:28
7	screen as well?	09:45:30
8	A. Yes.	09:45:31
9	Q. And Exhibit 2054, this is your declaration	09:45:31
10	that you submitted in Cases IPR2023-00480 and	09:45:36
11	IPR2023-00481?	09:45:52
12	A. Yes.	09:45:52
13	Q. And if I refer to "this case" or "this	09:45:53
14	proceeding," I will be collectively referring to both of	09:45:55
15	these IPRs. Will you understand that?	09:45:59
16	A. Yes.	09:46:02
17	Q. If you could please turn to the last page of	09:46:04
18	your declaration.	09:46:07
19	MS. DASHE: Which is page 13 of the PDF on the	09:46:08
20	screen, Emil.	09:46:12
21	A. Yes.	09:46:15
22	BY MS. DASHE:	09:46:15

1	Q.	Let me know when you're there. Okay.	09:46:15
2		And your declaration is signed and dated	09:46:19
3		December 21st, 2023?	09:46:24
4	A.	Yes.	09:46:26
5	Q.	That's your signature that we see on the page?	09:46:27
6	A.	Yes.	09:46:30
7	Q.	Do you stand by your testimony in your	09:46:31
8		declaration in this case?	09:46:38
9	A.	Yes.	09:46:39
10	Q.	You were asked to provide this declaration as	09:46:40
11		an inventor of the Bodor PCT patent application titled	09:46:43
12		"Oral Formulations to Cladribine"?	09:46:50
13	A.	Yes.	09:46:53
14	Q.	When were you first approached to provide your	09:46:54
15		declaration in this case?	09:46:56
16	A.	I don't remember the exact date, but must have	09:47:00
17		been some -- sometime in December.	09:47:07
18		Late --	09:47:08
19	Q.	And that would be December 2023?	09:47:08
20	A.	Yes.	09:47:11
21	Q.	Who approached you to provide your declaration	09:47:11
22		in this case?	09:47:23

1 MR. MLAYER: If you recall who it was, you can 09:47:23
2 answer, but I'll caution you not to reveal the 09:47:25
3 substance of any communication with counsel. 09:47:27
4 A. I really don't remember with who. It was 09:47:30
5 maybe my assistant who took the -- the message from the 09:47:35
6 patent office -- I mean the law office. 09:47:43
7 BY MS. DASHE: 09:47:46
8 Q. So was it Merck or its counsel, then, that 09:47:46
9 reached out to you to provide your declaration in this 09:47:51
10 case? 09:47:53
11 Yes-or-no question. 09:47:53
12 A. I assume so. Yeah. 09:47:55
13 Q. So you have no reason to believe anybody 09:48:01
14 besides Merck's counsel reached out to you to provide 09:48:04
15 your declaration in this case; right? 09:48:08
16 A. No. 09:48:10
17 Q. How long did you spend preparing your 09:48:10
18 declaration? 09:48:16
19 A. I think about four or five hours. 09:48:19
20 Q. Was that over the course of multiple days? 09:48:20
21 A. Yes. 09:48:29
22 Q. Do you know who else provided a declaration in 09:48:29

1	this case?	09:48:35
2	A. I -- I just learned that I believe Yogesh	09:48:41
3	Dandiker did too, my coinventor.	09:48:47
4	Q. Just learned, how recently was that?	09:48:50
5	A. I think yesterday.	09:48:56
6	Q. And so you learned that from counsel?	09:48:57
7	A. Yes.	09:48:59
8	Q. And have you read Dr. Dandiker's declaration	09:49:00
9	in this case?	09:49:07
10	A. No.	09:49:08
11	Q. And are you aware of anyone else who provided	09:49:08
12	a declaration in this case?	09:49:16
13	A. No.	09:49:18
14	Q. And so because you just learned yesterday that	09:49:18
15	Dr. Dandiker provided a declaration, you did not assist	09:49:21
16	him in drafting his declaration; correct?	09:49:25
17	A. I didn't talk to Dr. Dandiker for 20 years.	09:49:28
18	Q. And so Dr. Dandiker also did not help you	09:49:38
19	draft or provide your declaration --	09:49:45
20	A. No.	
21	Q. -- in this case; correct?	09:49:46
22	A. No.	09:49:47

1	Q.	Besides counsel, did you communicate with	09:49:47
2		anyone else in order to create your declaration?	09:49:52
3	A.	My assistant in my office.	09:49:59
4	Q.	And do you know what the substance of	09:50:00
5		Dr. Dandiker's declaration is in this case?	09:50:07
6	A.	No.	09:50:10
7	Q.	So besides your assistants in your office and	09:50:10
8		counsel, you did not communicate with anyone else in	09:50:21
9		order to create your declaration in this case; right?	09:50:24
10	A.	To prepare the declaration?	09:50:26
11		I did ask my former director of research at	09:50:31
12		IVAX to send me files related to cladribine.	09:50:39
13	Q.	And -- and who -- what was that person's name?	09:50:49
14	A.	That is Dr. Peter Buchwald.	09:50:52
15	Q.	Could you spell that for the record, please?	09:50:55
16	A.	B-U-C-H-W-A-L-D.	09:50:58
17	Q.	... speak or communicate with Dr. Buchwald in	09:51:03
18		the presence of counsel?	09:51:11
19	A.	No.	09:51:12
20	Q.	So what did you speak with Dr. Buchwald about	09:51:12
21		specifically?	09:51:20
22	A.	Just to send me -- actually, my assistant	09:51:20

1	called him to send me the -- if he has any file on the	09:51:23
2	cladribine work we have done in the research institute	09:51:32
3	in Hungary.	09:51:39
4	Q. Did he send you any files?	09:51:40
5	A. Yes.	09:51:42
6	Q. What files did he send you?	09:51:43
7	A. Monthly reports.	09:51:45
8	Q. Monthly reports?	09:52:00
9	A. Yes.	09:52:01
10	And two annual reports too.	09:52:02
11	Q. How did Dr. Buchwald send you these reports?	09:52:05
12	Was it by email? Mail? Something else?	09:52:11
13	A. I think by email, and my assistant then made	09:52:14
14	copies.	09:52:18
15	Q. ... is Dr. Buchwald?	09:52:18
16	THE COURT REPORTER: Excuse me, you broke off.	
17	This is the court reporter.	
18	BY MS. DASHE:	09:52:18
19	Q. Where is Dr. Buchwald?	09:52:18
20	A. He is a professor at University of Miami.	09:52:37
21	Q. When you say University of Miami, that's in	09:52:42
22	Florida?	09:52:54

1	A. Yes.	09:52:54
2	Q. And did you provide these monthly reports and	09:52:54
3	annual reports Dr. Buchwald sent you to counsel?	09:53:07
4	A. Yes.	09:53:10
5	Q. And so -- and Dr. Buchwald, did he work with	09:53:10
6	you on the cladribine project at IVAX?	09:53:28
7	A. No. No, he did not.	09:53:33
8	Q. How would Dr. Buchwald have had these files,	09:53:34
9	then?	09:53:39
10	A. Because he was my assistant at IVAX. He had	09:53:39
11	the position of assistant director of research. And so	09:53:46
12	he was contact in between the researchers in Budapest	09:53:52
13	and me and my assistants. So he was part of my team,	09:53:59
14	but he did not work on cladribine here, I don't believe	09:54:03
15	he had any involvement of any kind.	09:54:09
16	Q. ... a cladribine team at IVAX?	09:54:13
17	A. Yes, well, there was not really a team, but	09:54:21
18	most of the work was done, actually, at Budapest, at the	09:54:30
19	research institute, where they developed the analytical	09:54:36
20	methods and then the pharmacokinetic and bioavailability	09:54:39
21	studies.	09:54:48
22	But Buchwald was not part of it.	09:54:50

1	Q. ... talk to Dr. Buchwald about your	09:54:51
2	cladribine --	09:54:55
3	A. He was not part of this.	09:54:55
4	Q. Okay. So Dr. -- so Dr. Buchwald was not part	09:54:56
5	of the actual cladribine research?	09:54:59
6	A. Right.	09:55:01
7	Q. He was part of --	09:55:02
8	A. Correct.	09:55:04
9	Q. Okay. And when you reached out to	09:55:04
10	Dr. Buchwald about your cladribine files, did you	09:55:07
11	discuss those files with him at all?	09:55:12
12	A. No.	09:55:19
13	Q. Their substance?	09:55:20
14	A. No.	09:55:22
15	Q. And before you reached out to Dr. Buchwald	09:55:22
16	about these documents, when was the last time you had	09:55:25
17	spoken with him?	09:55:28
18	A. Last fall sometime. His father, who was my	09:55:29
19	best friend at the university, passed away, and then we	09:55:43
20	talked about his memories and...	09:55:50
21	Q. I'm sorry to hear that.	09:55:57
22	Besides reaching out to Dr. Buchwald about his	09:55:58

1 father, when was the last time you had spoken with him 09:56:02
2 before that? 09:56:06

3 A. We spoke in -- occasionally last year, because 09:56:06
4 I nominated him to be member of the Florida Academia of 09:56:12
5 Sciences, and so I needed update his CV. 09:56:22

6 But I talked to him on the phone. I -- I 09:56:29
7 don't remember when I met him in person. 09:56:32

8 Q. And so do you know if Merck provided these 09:56:33
9 documents you received from Dr. Buchwald to Hopewell? 09:56:42

10 A. I'm sorry, can I have -- you ask again? 09:56:45

11 Q. Yeah. 09:56:50
12 Do you know if Merck provided these -- 09:56:51

13 A. Merck. Yeah. 09:56:53

14 Q. -- documents to Hopewell? 09:56:55

15 A. No. No. These were our files in my I- -- in 09:56:57
16 IVAX office. 09:57:06

17 Q. And did you provide all of the files you 09:57:09
18 received from Dr. Buchwald to Merck's counsel? 09:57:12

19 A. Yes. 09:57:15

20 Q. Do you recall -- is it that you don't know 09:57:15
21 whether or not Merck provided the documents to Hopewell? 09:57:25
22 Or Merck did not provide the documents to Hopewell? 09:57:29

1 A. I really don't know if Merck had these 09:57:34
2 reports, because these were in Hungarian, internal 09:57:42
3 reports of the Hungarian research institute, which I was 09:57:46
4 director of, and which they did the analytical and 09:57:50
5 pharmacokinetic development. 09:57:56

6 Q. ... was a little bit different. 09:57:58

7 My question was did Merck not provide these 09:58:03
8 documents from Dr. Buchwald to Hopewell? Or do you not 09:58:07
9 know whether or not Merck provided these documents to 09:58:12
10 Hopewell? 09:58:14

11 A. I -- again, I said I don't know if Merck had 09:58:22
12 these reports, because these were Hungarian reports 09:58:23
13 internal to the institute. So I don't think Merck had 09:58:27
14 these reports. 09:58:31

15 Q. ... one way or another whether or not Merck 09:58:32
16 provided these reports from Dr. Buchwald to Hopewell; 09:58:34
17 correct? 09:58:38

18 A. I don't know. 09:58:38

19 Q. Okay. But Merck's counsel has these reports 09:58:42
20 from Dr. Buchwald at this point in time; correct? 09:58:47

21 A. Yes. 09:58:51

22 Q. Okay. Do you know what the substance of these 09:58:52

1	reports are from Dr. Buchwald?	09:58:58
2	A. Yes.	09:59:00
3	Q. And what is that?	09:59:00
4	MR. MLAYER: Objection, form.	09:59:03
5	You can answer.	09:59:07
6	A. I mentioned before that the bioavailability	09:59:08
7	and pharmacokinetic studies were done by the research	09:59:16
8	institute in Hungary. And these monthly and then annual	09:59:24
9	report related to the findings of animal and then human	09:59:27
10	studies of the very formulation which we developed in	09:59:34
11	my -- in our patent.	09:59:45
12	BY MS. DASHE:	09:59:46
13	Q. That formulation you're referring to in your	09:59:46
14	patent in your declaration is the complex --	09:59:49
15	A. Complex --	
16	Q. -- cladribine-cyclodextrin complex; correct?	09:59:55
17	A. Yes.	09:59:59
18	Q. Okay. And that's the formu- -- that --	09:59:59
19	scratch that.	10:00:02
20	The complex cladribine-cyclodextrin complex	10:00:02
21	described in your Bodor PCT application and your	10:00:09
22	declaration, that's your invention; right?	10:00:12

1 A. That's my invention and Dr. Dandiker's 10:00:15

2 invention. 10:00:21

3 Q. And you just referred to bioavailability and 10:00:21

4 pharmacokinetic studies related to the findings of 10:00:29

5 animal and human studies. What were those findings? 10:00:34

6 A. Well, actually, all of those findings or 10:00:37

7 almost all you can find in our patents, in the PCT 10:00:39

8 patent. 10:00:47

9 Q. The reports you received from Dr. Buchwald 10:00:48

10 contain study results that were ultimately disclosed in 10:00:53

11 your Bodor PCT application? 10:00:58

12 A. Correct. 10:01:01

13 Q. And when were these reports prepared? 10:01:01

14 A. As I remember, it was in 2003, '4, '5. Mostly 10:01:05

15 '4. 10:01:14

16 Q. And how many documents did you receive from 10:01:15

17 Dr. Buchwald? 10:01:24

18 A. As I remember, about five or six monthly 10:01:26

19 reports, or -- monthly, and two annual reports in 10:01:40

20 English. 10:01:42

21 Q. How many pages are the reports apiece? 10:01:43

22 A. I would estimate about six or seven pages. 10:01:48

1 Q. Five to six reports that you received total 10:01:53
2 about 30 to 40 pages? Is that right? 10:02:01

3 A. Yes. 10:02:04

4 Q. And you said that almost all of the findings 10:02:04
5 for your bioavailability and pharmacokinetic studies are 10:02:14
6 in the Bodor PC- -- Bodor PCT. Are there any findings 10:02:19
7 in these reports that are not reported in your Bodor PCT 10:02:26
8 application? 10:02:32

9 A. Yes. 10:02:35

10 Q. What findings are those? 10:02:35

11 A. If I may disclose, they were some attempts to 10:02:39
12 modify cladribine structure. [REDACTED] 10:02:45
13 [REDACTED] 10:02:50

14 Q. ... modify the cladribine structure? 10:02:51

15 A. Modify, yes. 10:02:57

16 Q. But what would -- I'm sorry, I'm not a 10:02:59
17 scientist, so -- but what do you mean by modify the 10:03:01
18 cladribine structure? 10:03:05

19 A. To make a derivative of cladribine. 10:03:05

20 Q. What is a derivative of cladribine? 10:03:09

21 A. To have a substituent introduced into the 10:03:14
22 molecule. 10:03:20

1 Q. Why were you trying to modify the cladribine 10:03:21
2 structure? 10:03:25

3 A. Maybe to find a different drug. That was our 10:03:27
4 main business, drug research. 10:03:35

5 Q. You said a derivative of cladribine is a 10:03:45
6 substituent to introduce into the molecule; is that 10:03:53
7 right? 10:03:55

8 A. Yes. 10:03:55

9 Q. And which substituent was that? 10:03:56

10 MR. MLAYER: I'm going to object on scope and 10:04:00
11 relevance. This has nothing to do with the 10:04:04
12 substance of Dr. Bodor's testimony. 10:04:07

13 THE WITNESS: But I -- 10:04:13

14 MS. DASHE: And Dr. Bodor provided testimony 10:04:14
15 in his declaration regarding the formulation of the 10:04:17
16 cladribine complex. This is directly relevant to 10:04:21
17 that. 10:04:24

18 And so, Dr. Bodor, I will continue asking my 10:04:25
19 questions. 10:04:31

20 And, Counsel, I would like to remind you that 10:04:32
21 the rules at the PTO are one-word objections, so. 10:04:34

22 BY MS. DASHE: 10:04:38

1 Q. Dr. Bodor, just to reask my question here for 10:04:39
2 the record, what substituent were you trying to 10:04:44
3 introduce into cladribine? 10:04:46
4 MR. MLAYER: Objection, scope. Objection, 10:04:48
5 relevance. 10:04:49
6 THE WITNESS: But I can answer? 10:04:50
7 MR. MLAYER: You can answer. 10:04:51
8 A. [REDACTED] 10:04:52
9 [REDACTED] 10:05:01
10 [REDACTED] 10:05:06
11 [REDACTED] --
12 BY MS. DASHE: 10:05:09
13 Q. Attempts related to -- 10:05:09
14 A. [REDACTED] 10:05:11
15 Q. I'm sorry, could you repeat that, Dr. Bodor? 10:05:16
16 I did not mean to talk over you. 10:05:19
17 A. [REDACTED] 10:05:20
18 [REDACTED] 10:05:23
19 [REDACTED] 10:05:31
20 Q. And what indication -- scratch that. 10:05:33
21 This formulation you were trying to make, was 10:05:36
22 this for treating multiple sclerosis? 10:05:39

1 A. That was not -- it simply modified cladribine 10:05:44
2 molecule. And while the cladribine is effective, maybe 10:05:51
3 the activity will be modified. 10:05:57

4 But it was not directed to multiple sclerosis 10:06:00
5 or anything, it's just try to modify the cladribine 10:06:03
6 molecule. 10:06:07

7 [REDACTED] 10:06:07

8 [REDACTED] 10:06:10

9 Q. [REDACTED] 10:06:18

10 MR. MLAYER: Objection, scope. Objection, 10:06:20
11 relevance and form. 10:06:23

12 A. [REDACTED] 10:06:25

13 [REDACTED] 10:06:31

14 [REDACTED] 10:06:38

15 BY MS. DASHE. 10:06:39

16 Q. ... Dr. Buchwald and counsel, did you talk to 10:06:53
17 anyone else in order to create your declaration in this 10:06:58
18 case? 10:07:02

19 A. No. 10:07:02

20 But I didn't talk to Buchwald about 10:07:07
21 declaration. 10:07:12

22 Q. You talked to him about the reports. 10:07:12

1 A. I did not talk about anything, just had him 10:07:15

2 send the -- everything he had on -- on the cladribine. 10:07:18

3 Q. And did you communicate -- scratch that. 10:07:22

4 Did you otherwise communicate with anyone in 10:07:31

5 order to create your declaration besides counsel and 10:07:33

6 your discussions, communications with Buchwald to get 10:07:36

7 the reports? 10:07:41

8 A. No. 10:07:41

9 Q. Have you heard of Dr. Alain Munafo? 10:07:42

10 A. No. 10:07:54

11 Q. Have you heard of Dr. Bernd Meibohm? 10:07:55

12 A. No. 10:07:59

13 Q. Have you heard of Dr. Fred Lublin? 10:08:04

14 A. No. 10:08:07

15 Q. And just in case I'm mispronouncing these 10:08:07

16 names, I'll just go through those questions again, but 10:08:29

17 I'll spell the names for you in case -- to clarify 10:08:32

18 anything. 10:08:33

19 So have you heard of Dr. Alain Munafo, spelled 10:08:33

20 A-L-A-I-N, space, M-U-N-A-F-O? 10:08:37

21 A. Still no. 10:08:45

22 Q. And have you heard of Dr. Bernd Meibohm, 10:08:46

1 spelled B-E-R-N-D, space, M-E-I-B-O-H-M? 10:08:51

2 A. No. 10:09:01

3 Q. Have you heard of Dr. Fred Lublin, spelled 10:09:01

4 F-R-E-D, space, L-U-B-L-I-N? 10:09:07

5 A. No -- no. 10:09:11

6 Just for curiosity, -- 10:09:13

7 Q. Were -- 10:09:15

8 A. -- why should I know about them? 10:09:15

9 Q. I was just asking, so. 10:09:18

10 Your current billing rate is \$1,250 an hour? 10:09:22

11 A. Yes. 10:09:27

12 Q. And how much have you billed so far in this 10:09:27

13 case? 10:09:33

14 A. I would have to ask my assistant, but I guess 10:09:36

15 maybe five or six hours. 10:09:39

16 Q. So the amount of money that you are either 10:09:47

17 owed or have received for your work on this case is five 10:09:50

18 or six hours times \$1,250 an hour, roughly? 10:09:52

19 A. Yes. 10:09:57

20 Q. Are you owed any additional money for this 10:09:58

21 case? 10:10:09

22 A. I feel I am, based on yesterday and today. 10:10:09

1 Q. Do you know approximately how much money that 10:10:13

2 will be? 10:10:16

3 A. It depends on you very much. 10:10:16

4 Q. But I think you said you spent a few hours 10:10:21

5 yesterday with counsel and then you've spent however 10:10:26

6 many hours today on your deposition. 10:10:29

7 Is the amount of money you will be owed just 10:10:31

8 the number of hours that you spent preparing and sitting 10:10:33

9 for this deposition times your current rate of \$1,250 an 10:10:35

10 hour? 10:10:40

11 A. Yes. 10:10:40

12 Q. Have you ever received any other compensation 10:10:41

13 from Merck or related entity? 10:10:48

14 A. No. 10:10:50

15 Well, I shouldn't say -- 10:10:50

16 Q. Have you -- 10:10:50

17 A. No, no. In 2008, the very patent was 10:10:55

18 defended, I went to the patent office, had an interview 10:11:04

19 with the patent examiner with the counsel, which 10:11:09

20 ultimately led to the allowance of the patent. 10:11:13

21 So at that time, I was also compensated. I 10:11:16

22 don't remember what was that time my hourly rate. 10:11:20

1 Q. When you say the patent, do you mean the 10:11:26

2 Bodor -- the Bodor PCT patent? 10:11:31

3 A. Yes. 10:11:34

4 Q. What patent office was that in front of? 10:11:34

5 A. The US patent office in Washington. 10:11:36

6 Q. Do you recall how much time you spent on 10:11:39

7 defending the Bodor PCT application in front of the 10:11:49

8 patent office? 10:11:52

9 A. I don't know, but all in all, going there and 10:11:53

10 talking and then -- probably there is a couple of days. 10:11:56

11 Q. What was discussed during your interview with 10:11:58

12 the patent office in 2008 about your Bodor PCT? 10:12:07

13 A. Well, as I remember, it's really essence of 10:12:13

14 the patent that is a combination of two types of 10:12:16

15 complexes, inclusion and noninclusion complexes, and 10:12:22

16 this forms a unique complex complex. And that was 10:12:28

17 really the essence of the discussions. 10:12:34

18 Q. Was your complex complex in your Bodor PCT -- 10:12:38

19 actually, scratch that. 10:12:50

20 The complex complex you are referring to is 10:12:51

21 the complex cladribine-cyclodextrin complex; right? 10:12:52

22 A. Yes. 10:12:58

1 Q. And why was that complex complex unique? Or 10:12:58
2 what did you tell the patent office as to why it was 10:13:03
3 unique? 10:13:06

4 A. Cyclodextrins were known then, and I had a 10:13:10
5 long time working on cyclodextrins. Cyclodextrins are 10:13:14
6 known to form inclusion complexes in which a molecule or 10:13:20
7 part of a molecule is incorporated into the middle of 10:13:26
8 the cyclodextrin by van der Waals forces. And that was 10:13:34
9 well-known. And we have done that before. 10:13:39

10 But as it turns out, certain conditions, 10:13:51
11 temperature and time, you can increase the cyclodextrin 10:13:54
12 or incorporate the cladribine incorporation into 10:14:00
13 cyclodextrin. But, of course, this will not be 10:14:03
14 inclusion complex, this additional one, because that is 10:14:08
15 limited and that was determined by the phase solubility 10:14:13
16 diagram. 10:14:17

17 So the ideal component is now hydrogen-bonded, 10:14:21
18 different type of complex, hydrogen-bonded complex, 10:14:25
19 which is in addition to the inclusion complex, and that 10:14:30
20 together is forming the complex complex, which is the 10:14:35
21 Merck or our PCT patent. 10:14:40

22 It almost tripled the amount of cladribine 10:14:48

1 which can be incorporated in -- in cyclodextrin in this 10:14:53

2 way. 10:14:58

3 Q. Did you want to increase the amount of 10:15:00

4 cladribine in your complex? 10:15:04

5 A. Yes. Yeah, because the molecule are very 10:15:06

6 difference, and more the ratio of the incorporation 10:15:13

7 would require large amounts of cyclodextrin if that 10:15:18

8 would be -- if the inclusion complex would be the only 10:15:23

9 one. 10:15:27

10 Q. ... something about requiring large amounts of 10:15:28

11 cyclodextrin. 10:15:41

12 Just so that I understand, were you trying to 10:15:43

13 increase or decrease the amount of cyclodextrin in your 10:15:48

14 formulation? 10:15:54

15 A. Yeah, the latter, to the cladribine ratio want 10:15:54

16 to decrease so you won't have a gigantic pill to take. 10:15:58

17 Q. Why would you want to decrease the relative 10:16:05

18 amount of cyclodextrin in your formulation? 10:16:08

19 A. There are several reasons, but one of the main 10:16:13

20 reason would be to make a saturated complex in which the 10:16:15

21 cladribine is in the highest thermodynamic activity 10:16:26

22 stage, so when taken as a pill and gets in contact with 10:16:32

1 the mucosa, the fact that it's in the highest 10:16:39
2 thermodynamic activity stage would allow the dilution to 10:16:45
3 drive the drug to the mucosa, so facilitate absorption. 10:16:50
4 Q. Why would you want a high thermodynamic state 10:16:56
5 for the cladribine? 10:17:01
6 MR. MLAYER: Objection to scope and relevance. 10:17:03
7 You can answer. 10:17:08
8 A. Well, just, as I said before, to optimize 10:17:08
9 absorption to the mucosa, intestinal mucosa. 10:17:17
10 BY MS. DASHE. 10:17:22
11 Q. ... optimizing the absorption of cladribine to 10:17:22
12 the intestinal mucosa do? Like, why do you want to do 10:17:30
13 that? 10:17:35
14 MR. MLAYER: Objection to scope and relevance 10:17:35
15 and also to the extent this calls for expert 10:17:37
16 testimony. 10:17:40
17 MS. DASHE: And, Counsel, again, "calls for 10:17:40
18 expert testimony" is not permitted under the PTO 10:17:43
19 rules. So single-word objections. 10:17:46
20 BY MS. DASHE: 10:17:49
21 Q. But, Dr. Bodor, if you would like me to repeat 10:17:49
22 my question, I can. 10:17:54

1 A. Yeah, I think the answer is obvious. I mean, 10:17:55
2 the main reason to do this kind of complex, number one, 10:17:59
3 to protect cy- -- cladribine from the acidity in the 10:18:08
4 symptom, and number two, to allow oral absorption. And 10:18:12
5 that was the objective of the whole project, and that 10:18:16
6 was the objective of making the complex complex. 10:18:22

7 Q. Why does absorption matter for the cladribine 10:18:25
8 formulation you were developing? 10:18:39

9 MR. MLAYER: Objection, scope, relevance, 10:18:40
10 foundation, form. 10:18:42

11 A. Again, that's obvious. We are comparing it to 10:18:42
12 injectable forms. When you inject something in 10:18:49
13 the circulatory system, it's there, you cannot remove. 10:18:57

14 What you want to achieve, a high blood levels 10:18:59
15 from an oral formulation. That's the basis of the -- 10:19:03
16 the whole exercise. 10:19:09

17 BY MS. DASHE: 10:19:10

18 Q. Did you achieve the high blood levels of 10:19:10
19 cladribine with your complex cladribine-cyclodextrin 10:19:16
20 complex described in your Bodor PCT application? 10:19:23

21 MR. MLAYER: Objection, form. 10:19:28

22 A. Well, it is in the patent, so you can see the 10:19:29

1 results compared to injectable forms. You can achieve 10:19:33
2 more than 30 percent, that was the objective, to achieve 10:19:38
3 more than 30 percent bioavailability, and you -- we can 10:19:41
4 read the report, something like 39 or so percent. 10:19:48
5 BY MS. DASHE: 10:19:51
6 Q. ... objective to achieve 30 percent 10:19:51
7 bioavailability? 10:19:56
8 A. More than 30 percent I say. That was the 10:19:57
9 objective. 10:20:01
10 Q. And why was the objective to achieve more than 10:20:01
11 35 -- or, excuse me, scratch that. 10:20:04
12 Why was the objective to achieve more than 30 10:20:06
13 percent bioavailability? 10:20:10
14 MR. MLAYER: Objection to scope and relevance. 10:20:13
15 A. Because that would make it practical to have 10:20:16
16 a -- an oral formulation. Because below that, they have 10:20:20
17 a 10 percent or so percentage of bioavailability, 10:20:23
18 that's -- and it cannot be a successful drug. 10:20:29
19 BY MS. DASHE: 10:20:32
20 Q. ... successful drug? 10:20:36
21 A. Successful. 10:20:37
22 Q. Yeah, what do you mean by successful drug? 10:20:38

1 A. To be used in any kind of treatment. To 10:20:44
2 replace injectable forms by oral formulation, that's a 10:20:50
3 successful drug. 10:20:56

4 Q. Your complex cladribine-cyclodextrin complex 10:20:56
5 as described in your Bodor PCT application, you 10:21:07
6 described that in the application that it is a 10:21:12
7 successful drug? 10:21:16

8 A. Yes. 10:21:16

9 Q. Because it -- okay. 10:21:17

10 And what was the basis for the 30 percent 10:21:18
11 bioavailability complex -- excuse me, strike that. 10:21:22

12 What was the basis for the 30 percent cutoff 10:21:25
13 for the bioavailability? 10:21:28

14 A. I don't know exactly. That's just generally 10:21:30
15 in the field, you think achieve at least 30 percent 10:21:35
16 bioavailability. And that's one thing. The other thing 10:21:43
17 is reproducibility and reduced interpatient variation. 10:21:47

18 Q. ... by reduced interpatient variation? 10:21:54

19 A. Yes. 10:22:03

20 Q. I'm sorry, I don't -- just -- I'm asking 10:22:03
21 what -- when you say reduced interpatient variation, 10:22:05
22 what do you mean by that? 10:22:09

1 A. That one patient shows 10 percent, the other 10:22:13
2 50 percent. That cannot be a successful drug because 10:22:16
3 the variability by this patient who is treated is too 10:22:19
4 much, you cannot assure the desired blood concentration. 10:22:25
5 Q. Complex cladribine-cyclodextrin complex 10:22:33
6 described in your Bodor PCT application, you described 10:22:39
7 that as achieving reduced interpatient variation and 10:22:42
8 that's a successful drug; right? 10:22:52
9 A. Yes. 10:22:53
10 MR. MLAYER: Objection to -- 10:22:54
11 Just let me put in my object and then you can 10:22:54
12 answer. 10:22:55
13 Objection to form, scope, relevance. 10:22:56
14 You can answer. 10:23:01
15 A. Yes. 10:23:02
16 And if you look in the patent, we have done a 10:23:02
17 very important demonstration of the reduction of the 10:23:08
18 interpatient variation, it's called crossover 10:23:11
19 pharmacokinetic studies, which means a group of patients 10:23:19
20 who are treated the different oral formulations and the 10:23:30
21 IV, so the very patients could serve as its own control. 10:23:34
22 Then you can compare the interpatient and inpatient 10:23:40

1 variations. 10:23:45

2 So that was what demonstrated the value of the 10:23:47

3 formu- -- of the complex. 10:23:52

4 BY MS. DASHE: 10:23:57

5 Q. And that was described in the Bodor PCT 10:23:57

6 application; right? 10:23:57

7 A. Yes. Yes. 10:23:57

8 Q. Okay. Now, besides the desired blood level 10:23:58

9 concentrations and this reduction in interpatient 10:24:01

10 variation, are there any other reasons to increase the 10:24:04

11 absorption of cladribine? 10:24:08

12 MR. MLAYER: Objection, scope, foundation. 10:24:10

13 You can answer. 10:24:15

14 A. I don't know what the reason. As I say, it's 10:24:16

15 obvious that what the objective is to develop an oral 10:24:22

16 formulation of an active drug, in this case cladribine. 10:24:28

17 BY MS. DASHE. 10:24:31

18 Q. ... want to reduce the interpatient variation 10:24:34

19 of the drug? 10:24:37

20 A. Well, I already addressed this, but I don't 10:24:42

21 like to repeat myself. 10:24:48

22 The interpatient variations means that 10:24:50

1 depending on the individual, the absorption is 10:24:52
2 different. Now, if you have a form of the cladribine 10:24:55
3 which does not depend on individual stomach content, 10:25:02
4 et cetera, but in all cases gives about the same blood 10:25:07
5 levels, then you are on the right way to develop a 10:25:15
6 successful drug. 10:25:19

7 Q. Interpatient variation in the cladribine 10:25:20
8 absorption, would that affect the therapeutic efficacy 10:25:30
9 between patients of the cladribine? 10:25:35

10 A. Of course. 10:25:36

11 MR. MLAYER: Objection, form, scope, 10:25:37
12 relevance. 10:25:39

13 You can answer. 10:25:41

14 A. Of course. 10:25:41

15 BY MS. DASHE: 10:25:42

16 Q. Now, you've said that it was obvious to try to 10:25:49
17 reduce the interpatient variation and increase the 10:25:56
18 cladribine absorption. To whom are you referring -- 10:26:02
19 like, it was obvious to whom? Like, obviously, it's not 10:26:05
20 obvious to me because I'm a lawyer. But who would it be 10:26:08
21 obvious to? 10:26:10

22 MR. MLAYER: Objection, form, scope, 10:26:12

1 foundation. 10:26:14

2 A. I didn't say it's obvious to reduce the 10:26:14

3 interpatient variation. 10:26:21

4 I mean, in drug discovery or drug development, 10:26:23

5 your objective is to have a drug which is equally or 10:26:26

6 close to equally effective in different patients, so 10:26:31

7 somebody who has blue eyes is not more sensitive to the 10:26:35

8 tablet what you give than the others. 10:26:44

9 BY MS. DASHE: 10:26:46

10 Q. Dr. Bodor, you are the founder and CEO of 10:26:53

11 Bodor Laboratories? 10:26:57

12 A. Yes. 10:26:58

13 Q. And has Bodor Laboratories ever received any 10:26:59

14 compensation from Merck or any related entity? 10:27:03

15 A. I don't believe so. No. 10:27:06

16 Q. You are also the executive director of the 10:27:11

17 University of Florida Center for Drug Discovery? 10:27:17

18 A. Well, I was. I was. I retired from that. 10:27:20

19 But I am graduate research professor emeritus, and I am 10:27:28

20 involved in some activities at the University. There is 10:27:32

21 a Nicholas Bodor Distinguished Lectureship Award given 10:27:38

22 at the University every year, which will be in April of 10:27:46

1 this year. And also there is a Nicholas Bodor 10:27:49
2 Distinguished Chair in drug discovery. 10:27:54

3 Q. The University of Florida for Drug -- Center 10:28:02
4 for Drug Discovery or the distinguished lectureship or 10:28:08
5 the distinguished chair received any compensation from 10:28:11
6 Merck or any other related entity? 10:28:14

7 A. Not as I know. 10:28:16

8 Q. Now, Dr. Bodor, I know you have a copy, a 10:28:17
9 paper copy of your declaration in front of you, but does 10:28:25
10 it have your Appendix A with your CV attached to it? 10:28:28

11 A. Not here, no. But I understand that's how -- 10:28:31

12 Q. Okay. 10:28:38

13 A. -- you received it or... 10:28:38

14 Q. Okay. Then I'll just have -- 10:28:41

15 MS. DASHE: Emil, could you please pull up 10:28:44
16 Appendix A of Dr. Bodor's CV, Exhibit 2054. It 10:28:46
17 should be page 14 of the PDF. 10:28:52

18 REMOTE ZOOM TECHNICIAN WHITE: 54 or 2045? 10:29:11

19 MS. DASHE: 2054. It was the tab 1 that I had 10:29:14
20 you introduce earlier today. 10:29:17

21 Yes. Okay. 10:29:26

22 And, Emil, could you scroll to the next page? 10:29:28

1 And maybe make that full-sized? It's kind of 10:29:35
2 cutting off the top and the bottom. Or, rather, 10:29:37
3 shrink it so that the whole page shows up on the 10:29:40
4 screen? Thank you. 10:29:43
5 BY MS. DASHE:
6 Q. And, Dr. Bodor, this Appendix A, this is your 10:29:45
7 CV? 10:29:48
8 A. Yes. It looks like it. 10:29:51
9 Q. And your CV has, we see, 144 pages? 10:29:53
10 A. I understand, yes. 10:30:01
11 Q. Okay. And when did you last update this CV? 10:30:02
12 A. I don't believe I know, but my assistant 10:30:08
13 always puts on the new publications or patents or awards 10:30:16
14 or whatever happens. Anytime some important event 10:30:21
15 happens, she updates it. 10:30:27
16 Q. Has this CV -- or scratch that. 10:30:29
17 Was this CV updated before December 2023, when 10:30:38
18 you started working on your declaration? 10:30:42
19 MR. MLAYER: Objection, form. 10:30:44
20 You can answer. 10:30:50
21 A. I don't know when was the last time updated. 10:30:51
22 MS. DASHE: Emil, could you please go to page 10:31:00

1 131 of the PDF? Still on your CV. 10:31:04

2 And you could -- yeah. Thank you. 10:31:10

3 BY MS. DASHE: 10:31:12

4 Q. So, Dr. Bodor, this is a list of your 10:31:12

5 publications and your CV. Do you see where it says last 10:31:15

6 update, April 21, 2023? 10:31:19

7 A. Yes. 10:31:21

8 Q. Does that help you recall when your CV was 10:31:22

9 last updated? 10:31:30

10 A. Well, no, not really. That just means the 10:31:30

11 list of publications updated. Some other things could 10:31:33

12 have happened, I don't remember. 10:31:46

13 I think I achieved my lifetime achievement 10:31:46

14 award last May, so that's included somewhere. 10:31:50

15 But this update is mainly for the list of 10:31:53

16 publication. 10:31:55

17 Q. Was your CV -- was this CV updated before 10:31:56

18 December of 2023? 10:32:09

19 MR. MLAYER: Objection, form. 10:32:10

20 BY MS. DASHE: 10:32:11

21 Q. Scratch that. 10:32:12

22 Was this CV last updated before December 2023? 10:32:12

1 A. Yeah, I told you, I don't remember, I have 10:32:15
2 to -- to look. But this is -- when the list was 10:32:17
3 updated, the list of the publications, is April, but 10:32:23
4 not -- something must have -- or could have been added, 10:32:26
5 I don't know. 10:32:28

6 Again, my assistant takes care of -- 10:32:29

7 Q. Did... 10:32:31

8 A. But it is irrelevant. 10:32:37

9 Q. Does your CV -- I was trying to get the -- 10:32:39
10 does your CV accurately reflect your areas of scientific 10:32:45
11 expertise and credentials? 10:32:48

12 A. I would say yes. 10:32:50

13 MS. DASHE: So, Emil, could you please go to 10:32:58
14 page 57 of the PDF. 10:33:02

15 This will be page 43 of your CV, Dr. Bodor. 10:33:03

16 If you could, Emil, kind of let the whole 10:33:12
17 thing be on the page. 10:33:17

18 So -- thank you. 10:33:18

19 BY MS. DASHE: 10:33:20

20 Q. Dr. Bodor, your CV, provided as a part of 10:33:21
21 Exhibit 2054, your declaration, it contains a list of 10:33:24
22 the patents you've had issued -- 10:33:28

1 A. Yes. 10:33:29

2 Q. -- here? 10:33:29

3 A. Yes. 10:33:33

4 Q. And I believe you're the named inventor on 10:33:33

5 over 300 patents; is that right? 10:33:36

6 A. Yes. 10:33:37

7 MS. DASHE: Emil, could you please go to page 10:33:41

8 73 of the PDF, we'll still be on the list of 10:33:48

9 patents. 10:33:51

10 BY MS. DASHE: 10:34:02

11 Q. Okay. And do you see item 228, "N. Bodor, Y. 10:34:03

12 Dandiker, 'Oral Formulations of Cladribine,' US Patent 10:34:08

13 7,888,328"? Do you see that? 10:34:12

14 A. Yes. 10:34:16

15 Q. And if I refer to this as the `328 patent, 10:34:16

16 you'll know what I'm referring to? 10:34:26

17 A. Yes. 10:34:28

18 Q. And is this `328 patent -- you refer to this 10:34:28

19 patent in your declaration; right? 10:34:33

20 A. Yes. 10:34:34

21 MS. DASHE: So then if we flip to the next 10:34:35

22 page, Emil, please. 10:34:37

1 BY MS. DASHE: 10:34:44

2 Q. So this would be page 60 of your CV. If we go 10:34:44

3 to item 252, towards the bottom of the page there, do 10:34:49

4 you see, Dr. Bodor, "N. Bodor and Y. Dandiker, 'Oral 10:34:56

5 Formulations of Cladribine,' US Patent 8,785,415"? 10:35:00

6 A. Yes. 10:35:06

7 Q. Okay. If I refer to this patent as the '415 10:35:09

8 patent, you'll know what I'm referring to? 10:35:15

9 A. Yes. Yeah. 10:35:21

10 Q. If you need it bigger, please let me know. 10:35:21

11 MR. MLAYER: Yeah, it would be helpful. The 10:35:24

12 screen is -- is maybe 3 feet away from Dr. Bodor, 10:35:25

13 so it's -- 10:35:29

14 MS. DASHE: Got it. 10:35:29

15 MR. MLAYER: It would be helpful if we could 10:35:30

16 zoom in on the things we're -- we're talking about. 10:35:32

17 MS. DASHE: Yes. 10:35:33

18 Emil, could you go -- have it zoomed in on 10:35:35

19 item 252? 10:35:41

20 Thank you.

21 BY MS. DASHE:

22 Q. All right. Is that better, Dr. Bodor? 10:35:42

1	A.	Not yet.	10:35:44
2	Q.	Okay.	10:35:45
3	A.	Okay.	10:35:45
4	Q.	Oops. Well, that's a little much. There we	10:35:46
5		go.	10:35:52
6		Okay, so this `415 patent on item 252, that's	10:35:52
7		the `415 patent that you refer to in your declaration;	10:35:57
8		right?	10:36:01
9	A.	Yes.	10:36:01
10	Q.	Okay.	10:36:06
11		MS. DASHE: Emil, could we please go to page	10:36:06
12		81 of the PDF of Exhibit 2054.	10:36:10
13		BY MS. DASHE:	
14	Q.	And so, Dr. Bodor, again, this is still part	10:36:18
15		of your CV in Exhibit 2054. You provide a list of all	10:36:21
16		of your publications; right?	10:36:31
17	A.	Yeah. Yes.	10:36:33
18	Q.	And I believe you have more than 500; is that	10:36:34
19		right?	10:36:37
20	A.	Yes.	10:36:37
21	Q.	Have you retracted any of the publications	10:36:37
22		listed in your CV?	10:36:41

1	A. No.	10:36:42
2	Q. And have you issued any corrections?	10:36:43
3	A. No.	10:36:46
4	Q. Okay.	10:36:46
5	MS. DASHE: And could we also, Emil, please go	10:36:49
6	to page 26 of the PDF, still in Dr. Bodor's CV, of	10:36:54
7	Exhibit 2054.	10:37:02
8	So -- and if -- Emil, could you just have the	10:37:05
9	whole paper so we can see it so it's not so zoomed	10:37:10
10	in? We can zoom back in, but...	10:37:13
11	And Emil, if you could flip through, the	10:37:16
12	witness --	
13	BY MS. DASHE:	
14	Q. Page 12, 13, and 14 of your CV provides a	10:37:20
15	summary of your scientific interests and achievements;	10:37:24
16	right?	10:37:27
17	A. Yes.	10:37:27
18	Q. Okay.	10:37:31
19	MS. DASHE: And, Emil, could you please go to	10:37:33
20	page 14 of this section to page 28 of the PDF. And	10:37:38
21	could you zoom in, Emil, on the top paragraph so	10:37:42
22	everybody can see?	10:37:48

1 BY MS. DASHE: 10:37:53

2 Q. Dr. Bodor, can you see that text on the top 10:37:54

3 paragraph all right? 10:37:56

4 A. Yes. 10:37:56

5 Q. Okay. Do you see in the middle "Dr. Bodor's 10:37:58

6 US, and associated European and US, patents, 'Oral 10:38:04

7 Formulations of Cladribine'"? Do you see that? 10:38:09

8 MS. DASHE: Emil, if you could highlight that 10:38:16

9 for the -- for the witness. 10:38:17

10 A. Yes. Yes. 10:38:18

11 MS. DASHE: "Dr. Bodor's US" -- 10:38:19

12 A. Yes. 10:38:20

13 BY MS. DASHE: 10:38:21

14 Q. Okay, you can see that. 10:38:21

15 Okay. And so the -- your US patents entitled 10:38:22

16 "Oral Formulations of Cladribine" referred to here are 10:38:26

17 those two patents we just looked at in your CV, the `328 10:38:30

18 and `415 patent; correct? 10:38:33

19 A. I assume so, except European patents mentioned 10:38:38

20 also here. 10:38:45

21 Q. Right. But the specific US patents referred 10:38:45

22 to here -- 10:38:47

1 A. Yes. 10:38:48

2 Q. -- are the `328 and `415 patent? 10:38:49

3 A. Yeah. 10:38:51

4 Q. Okay.

5 MS. DASHE: You can take that down, Emil. 10:38:55

6 Actually, we've been going for about an hour, 10:38:58

7 Dr. Bodor, if you would like to take a brief break. 10:39:01

8 THE WITNESS: I appreciate it. 10:39:04

9 MS. DASHE: Okay. I think we can take a 10:39:05

10 ten-minute break. 10:39:08

11 MR. MLAYER: Okay. 10:39:10

12 VIDEOGRAPHER ELMILKI: Okay. We off of the 10:39:10

13 record, the time now is 10:39 a.m. 10:39:12

14 (Recess taken.) 10:39:17

15 VIDEOGRAPHER ELMILKI: We are back on the 10:51:33

16 record, and the time now is 10:51 a.m. 10:51:43

17 BY MS. DASHE: 10:51:48

18 Q. Welcome back, Dr. Bodor. 10:51:48

19 A. Yes. 10:51:49

20 Q. During your -- during the break, did you speak 10:51:50

21 with counsel about the substance of your testimony? 10:51:53

22 A. No. 10:51:54

1 Q. Okay. Now, Dr. Bodor, I'm going to ask you 10:51:55
2 some questions regarding your career and scientific 10:52:01
3 background. And I would like you to focus on the 2004 10:52:04
4 time frame unless I specifically say otherwise. Do you 10:52:08
5 understand that? 10:52:12

6 A. Yes. 10:52:12

7 Q. Okay. Now, you developed a number of drug 10:52:13
8 formulations; right? 10:52:17

9 MR. MLAYER: Objection, form. 10:52:19

10 A. I don't -- I wouldn't call that I developed 10:52:24
11 formulations. I invented some new drugs, yes, new 10:52:28
12 chemicals. 10:52:35

13 BY MS. DASHE: 10:52:36

14 Q. What's a formulation? 10:52:39

15 A. Like you take cladribine, which is a chemical, 10:52:41
16 and you formulate into a tablet. Or formulate 10:52:45
17 prednisolone into a liquid formulation or topical. 10:52:53
18 Those are formulations. 10:52:57

19 You make a drug accessible to the body. So 10:53:00
20 you modify the -- the drug substance surrounding to make 10:53:07
21 it another as a useful drug. 10:53:16

22 So formulation is a -- is a combination of the 10:53:20

1 drug, active drug and many other things. 10:53:23

2 Q. ... you said drug substances? 10:53:27

3 A. Drug substance. 10:53:37

4 Q. What's a drug substance? 10:53:38

5 A. For example, cladribine is a drug substance, a 10:53:39

6 chemical. 10:53:43

7 They call it anything -- 10:53:43

8 Q. ... of formulations because your complex 10:53:43

9 cladribine-cyclodextrin complex, that's a formulation; 10:53:58

10 right? 10:53:59

11 A. That's a formulation, yes. 10:53:59

12 Q. Okay. And have you developed formulations or 10:54:01

13 drug substances for different routes of administration? 10:54:07

14 A. Yes, for a number of my new chemical drugs, I 10:54:10

15 did develop some formulations, yes. 10:54:15

16 Q. What routes of administration did you develop 10:54:17

17 for formulations? 10:54:24

18 MR. MLAYER: Objection, form. 10:54:25

19 You can answer. 10:54:33

20 A. Yeah, for example, ophthalmic drugs, developed 10:54:34

21 eyedrops to be suspension, or gels for topical use on 10:54:37

22 the skin, or brain-targeted drugs using the redox system 10:54:47

1 and -- so variety. I was involved in a large number of 10:54:54
2 different fields using in my retrometabolic drug design 10:54:57
3 concept. 10:55:05

4 BY MS. DASHE. 10:55:07

5 Q. ... oral routes of administration for 10:55:08
6 formulations; right? 10:55:10

7 A. Oral -- 10:55:11

8 MR. MLAYER: Counsel, I think the first words 10:55:12
9 of your questions may be getting cut off by the 10:55:14
10 audio, because we keep getting, kind of, sentence 10:55:17
11 fragments. And I -- 10:55:23

12 MS. DASHE: Okay. Okay, I'll -- I'll -- I'll 10:55:24
13 reask the question. 10:55:26

14 BY MS. DASHE: 10:55:28

15 Q. So you developed formulations for oral route 10:55:29
16 of administration; right? 10:55:33

17 A. I wouldn't say -- my -- it's not my main field 10:55:34
18 to develop formulations, that is defined on the adaptive 10:55:42
19 mean, but, yes, we developed a number of formulations of 10:55:48
20 the drugs, I invented. 10:55:53

21 Q. Were oral -- sorry, let me just rephrase, I'm 10:55:58
22 not trying to be confusing, and I think my question came 10:56:11

1 out confusing. 10:56:13

2 So you have developed drugs for the oral route 10:56:16

3 of administration; correct? 10:56:21

4 A. As well. Not -- that wasn't -- 10:56:22

5 Q. Okay.

6 A. That wasn't my prime interest. 10:56:24

7 Q. What was your prime interest or main field in 10:56:26

8 your career? 10:56:30

9 A. There are several of them, but I say 10:56:31

10 brain-targeting drugs, ophthalmic drugs, and then 10:56:33

11 topical to be dermatological, like my most recent one is 10:56:39

12 for hyperhidrosis, and that's a topical use. 10:56:46

13 Q. And you developed the drug substances -- 10:56:54

14 scratch that. 10:56:59

15 Your focus was on developing the drug 10:56:59

16 substances, not as much developing the drug 10:57:01

17 formulations; right? 10:57:05

18 A. My prime -- yes. My prime objective is to 10:57:06

19 develop a reactive new chemical entity for a specify 10:57:09

20 disease. And then, of course, you have to develop 10:57:14

21 formulation to be used for that particular reason. 10:57:17

22 Q. Now, there is other routes to administration, 10:57:21

1 right? Like injectables or -- 10:57:27

2 A. Yes. Yes. 10:57:28

3 Q. -- inhaled drugs? 10:57:29

4 A. Yes. 10:57:31

5 Q. Have you -- what is the parenteral route to 10:57:32

6 administration? 10:57:38

7 A. Parenteral is different injectable, you know, 10:57:38

8 subQ or intravenous, intramuscular. 10:57:44

9 Q. Are there any benefits of the oral route of 10:57:51

10 administration over an injectable or parenteral route? 10:57:55

11 MR. MLAYER: Objection to scope, form, 10:58:00

12 foundation. 10:58:04

13 A. I say convenience. 10:58:05

14 BY MS. DASHE: 10:58:06

15 Q. What do you mean by convenience? 10:58:10

16 A. People rather take a pill than get injected. 10:58:11

17 Q. And does that increase patient compliance with 10:58:20

18 taking their medications? 10:58:23

19 A. Yes. 10:58:25

20 MR. MLAYER: Objection to scope and foundation 10:58:25

21 and form. 10:58:27

22 You can answer. 10:58:30

1 A. Yes. Yes. Of course. 10:58:30

2 BY MS. DASHE: 10:58:33

3 Q. Are there any cost savings for the oral route 10:58:35

4 of administration over injectables or parenterals? 10:58:39

5 MR. MLAYER: Objection to scope, form, and 10:58:45

6 foundation. 10:58:47

7 A. Yes. 10:58:47

8 BY MS. DASHE: 10:58:48

9 Q. And would the oral route of administration be 10:58:54

10 less painful or less uncomfortable than an injectable or 10:58:57

11 parenteral medication? 10:59:03

12 MR. MLAYER: Objection to scope, form, and 10:59:05

13 foundation. 10:59:07

14 A. Generally, yes. 10:59:07

15 BY MS. DASHE: 10:59:08

16 Q. Now, the oral medicines can be given in a slow 10:59:08

17 or extended-release form; right? 10:59:17

18 A. Yes. 10:59:18

19 Q. Is that possible with an injectable or 10:59:19

20 parenteral medication? 10:59:26

21 A. Yes. 10:59:27

22 Q. But is it more common to have an oral 10:59:27

1	formulation that is	10:59:33
2	MR. MLAYER: Objection.	10:59:35
3	BY MS. DASHE:	10:59:35
4	Q. a slow or extended release than an	10:59:35
5	injectable?	10:59:38
6	MR. MLAYER: Objection to form, scope,	10:59:39
7	relevance, and foundation.	10:59:40
8	A. Well, both are possible.	10:59:43
9	BY MS. DASHE:	10:59:47
10	Q. Now, you referred to oral dosage form a number	10:59:49
11	of times in your declaration. What do you mean by an	10:59:53
12	oral dosage form?	10:59:56
13	A. Those are oral, normally pills or can be,	10:59:59
14	well, a solution too. Oral, whatever you take it, by	11:00:05
15	mouth.	11:00:13
16	Q. Pills, could that be a tablet?	11:00:13
17	A. Yes.	11:00:19
18	Q. Is there any reason a drug developer might	11:00:19
19	prefer to use a solid tablet over an oral liquid?	11:00:26
20	MR. MLAYER: Objection to form, scope,	11:00:30
21	foundation.	11:00:32
22	A. Well, there could be many reasons. Again,	11:00:33

1 convenience, or cost, or compliance, stability. 11:00:39

2 Stability. 11:00:49

3 BY MS. DASHE. 11:00:52

4 Q. ... stability? 11:00:55

5 MR. MLAYER: I'm sorry, I think your question 11:00:58

6 was cut off again. 11:00:59

7 MS. DASHE: Oh, I'm sorry. 11:01:01

8 BY MS. DASHE: 11:01:02

9 Q. You refer to stability. What is stability? 11:01:02

10 A. A molecule, which is a drug, can undergo 11:01:05

11 degradation. And if it's in a solution, it's more 11:01:13

12 likely to degrade than if it's in a solid form. In a 11:01:22

13 solid form, it's more stable. 11:01:31

14 So the shelf life is different. 11:01:33

15 Q. ... specific formulation of a drug impact its 11:01:36

16 stability? 11:01:43

17 A. Yes. 11:01:43

18 Q. How so? 11:01:44

19 MR. MLAYER: Objection to scope, foundation, 11:01:47

20 form. 11:01:51

21 A. If you have a drug which is an ester, I am 11:01:51

22 specifically thinking of something, which would be 11:01:57

1 hydrolyzed in water, if you make an aqueous solution, 11:02:00
2 you let it sit, the drug will degrade within a given 11:02:06
3 time, days or weeks, who knows. 11:02:12

4 So, of course, the formulation affects 11:02:17
5 stability. 11:02:20

6 BY MS. DASHE. 11:02:21

7 Q. .. -er stability better than a lower stability 11:02:24
8 for a drug formulation? 11:02:25

9 MR. MLAYER: Objection to scope. 11:02:26

10 A. Well, you always go for high stability, 11:02:28
11 otherwise you have to throw -- throw out your drug after 11:02:34
12 a month or so. 11:02:40

13 BY MS. DASHE: 11:02:42

14 Q. Any other reasons besides the ones we've just 11:02:42
15 discussed as to why a drug formulation -- formulator 11:02:44
16 might prefer to use a solid tablet over an oral liquid? 11:02:48

17 MR. MLAYER: Objection to scope, foundation, 11:02:51
18 relevance. 11:02:53

19 A. There are many reasons, but I think it's 11:02:54
20 outside of our current interest. 11:03:00

21 BY MS. DASHE: 11:03:03

22 Q. But do you -- do you have any of those other 11:03:05

1 reasons in mind right now? 11:03:07

2 MR. MLAYER: Objection to scope, relevance, to 11:03:08

3 form. 11:03:12

4 A. The primary is really convenience and the 11:03:12

5 stability. You know, if it's a liquid formulation, it 11:03:20

6 has to be sterile. If it's a tablet, it doesn't have to 11:03:23

7 be sterile, you have -- you can handle it by hand. 11:03:29

8 BY MS. DASHE. 11:03:32

9 Q. ... reasons known in 2004? 11:03:39

10 A. Oh, yes. 11:03:41

11 MR. MLAYER: Objection to scope, relevance, 11:03:42

12 form. 11:03:44

13 You can answer. 11:03:46

14 A. Yes. These are all known in 2004. 11:03:47

15 BY MS. DASHE: 11:03:53

16 Q. You referred -- okay. 11:03:54

17 You referred to dosing regimen a number of 11:03:55

18 times in your declaration. What do you mean by dosing 11:04:00

19 regimen? 11:04:04

20 A. Well, dosing regimen in general, I say it's 11:04:04

21 the frequency of taking the -- a pill, or an injection, 11:04:10

22 or eyedrops, or whatever, that is the dosing regimen. 11:04:21

1 Q. ... or days you might have to take the 11:04:26

2 formulation, something like that? 11:04:34

3 A. Yes. 11:04:35

4 Q. Okay. Does the number of days you have to 11:04:35

5 take the drug in a dosing regimen matter? 11:04:40

6 MR. MLAYER: Objection to form, foundation, 11:04:44

7 scope. 11:04:47

8 A. It depends on the drug. 11:04:47

9 BY MS. DASHE: 11:04:51

10 Q. Well, what about for cladribine, does the 11:05:02

11 number of days you would take cladribine in a dosing 11:05:07

12 regimen matter? 11:05:09

13 MR. MLAYER: Objection to form, foundation, 11:05:10

14 scope. 11:05:12

15 A. Well, let me tell you something about this, 11:05:13

16 treatment, medical treatment and dosing regimen is 11:05:21

17 really not my field. And I don't have the expertise to 11:05:24

18 comment on the value or variation of dose regimens. 11:05:32

19 I was never involved in any of this. 11:05:44

20 BY MS. DASHE: 11:05:47

21 Q. Do you know if it can matter, the number of 11:05:49

22 days that one takes the cladribine in a dosing regimen? 11:05:51

1 MR. MLAYER: Objection to form, foundation, 11:05:56
2 scope. 11:05:57
3 A. I didn't understand the question. Can you 11:05:58
4 repeat the question? 11:06:03
5 BY MS. DASHE:
6 Q. Of course. 11:06:05
7 Do you know if it can matter, the number of 11:06:06
8 days that one takes cladribine in a dosing regimen? 11:06:09
9 MR. MLAYER: Same objections. 11:06:12
10 A. Again, as I said, I don't know, but if you are 11:06:13
11 thinking about 2004, I didn't have any knowledge of 11:06:22
12 cladribine use and -- and certainly regimen and 11:06:26
13 whatever. 11:06:35
14 BY MS. DASHE: 11:06:35
15 Q. Now, you joined IVAX in 2000; right? 11:06:36
16 A. Um-hum (affirmative). 11:06:42
17 Q. And you left in 2006; right? 11:06:42
18 A. Yes. 11:06:44
19 Q. And after you left IVAX, excluding the 11:06:44
20 discussions with Dr. Buchwald we already talked about 11:06:51
21 today, did you have access to your documents and 11:06:53
22 communications from IVAX at any point after you left the 11:06:56

1	company?	11:07:00
2	MR. MLAYER: Objection to form.	11:07:00
3	You can answer.	11:07:06
4	A. I think, you know, I licensed at the beginning	11:07:09
5	to IVAX a new steroid, which was developed to some	11:07:17
6	extent, and after I left, I regained ownership, and so a	11:07:25
7	lot of documents, files, were transferred back to me.	11:07:39
8	BY MS. DASHE:	11:07:45
9	Q. Let me get to the relevant question here, I	11:07:45
10	guess, which is after you left IVAX in 2006, aside from	11:07:47
11	our discussions of Dr. Buchwald, did you have access to	11:07:52
12	your cladribine-related documents and communications at	11:07:56
13	IVAX at any point after you left the company?	11:08:00
14	A. No.	11:08:02
15	MR. MLAYER: Objection to form.	11:08:03
16	A. No.	11:08:04
17	BY MS. DASHE:	11:08:05
18	Q. Okay. Now, when you were at IVAX, you served	11:08:07
19	in various managing capacities, including chief	11:08:11
20	scientific officer?	11:08:16
21	A. Yes.	11:08:16
22	Q. How many people worked under you when you were	11:08:16

1 at IVAX? Approximately. 11:08:21

2 A. My main role was to drive the research 11:08:23

3 institute in Hungary, which at some point I had like 400 11:08:33

4 people. 11:08:37

5 In my office here in Miami, it was limited to 11:08:41

6 a few, like Peter Buchwald; my assistant, Mrs. Guy; and 11:08:46

7 there was another senior director, John Howes, who was 11:08:58

8 under me. 11:09:04

9 Q. Chief scientific officer, you were an officer 11:09:04

10 of the company? 11:09:11

11 A. Yes. 11:09:12

12 Q. Okay. And when you were at IVAX, were you 11:09:13

13 physically located in Hungary or Miami? 11:09:21

14 A. I was located in -- in Miami, and I usually 11:09:25

15 went for a week a month to Hungary. 11:09:30

16 Q. Primary office was in Miami, but the 400 11:09:36

17 people that worked under you were in Hungary; -- 11:09:43

18 A. Yes. 11:09:47

19 Q. -- is that right? 11:09:48

20 A. Right. 11:09:48

21 Q. Okay. Now, you say in your declaration that 11:09:49

22 you were on a team at IVAX. How many overall teams were 11:09:57

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1 there at IVAX when you were at the company? 11:10:01

2 A. I cannot tell. IVAX was a large corporation, 11:10:07

3 like 12,500 people, located in different part of the 11:10:12

4 world. And each site, like the UK, Hungary, so on, had 11:10:16

5 all kinds of teams based on the project they were 11:10:28

6 working on. 11:10:32

7 Q. chief scientific officer for other IVAX 11:10:32

8 locations outside of Hungary in the United States? 11:10:42

9 A. Well, in principle, yes, but I did not have, 11:10:47

10 like, for example, in the UK team report to me or the 11:10:53

11 team from Czechoslovakia or Chile or whatever. I mean, 11:10:58

12 I had meetings and discussions of -- scientific 11:11:08

13 meetings, but it's not direct reporting, no. The direct 11:11:11

14 reporting was the institute in Budapest. 11:11:15

15 Q. ... a number of different places that IVAX had 11:11:22

16 offices. Where were all those places? 11:11:25

17 A. As I mentioned, as I remember, the UK, 11:11:28

18 Ireland, Czechoslovakia, Chile. I don't know. 11:11:37

19 Q. Obviously Hungary and the United States -- 11:11:48

20 A. Yes.

21 Q. -- as well? 11:11:51

22 A. Yeah. 11:11:51

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1 Q. Okay. And I know -- you said your primary 11:11:52
2 office was in the United States and you visited Hungary 11:11:58
3 about, I think you said, once a month; is that right? 11:12:02
4 A. Yeah, one week, 12 months, yeah. 11:12:04
5 Q. Okay. How often would you visit IVAX's other 11:12:07
6 offices in person? 11:12:14
7 A. I did not. 11:12:15
8 Q. Okay. 11:12:15
9 A. I mean, maybe once or twice I was in -- in 11:12:20
10 London and talked to the vice-chairman who was there, I 11:12:25
11 forgot his name. But I never had been to their offices 11:12:29
12 in Chile -- in -- in Czechoslovakia or Chile. 11:12:37
13 Q. ... visits to Hungary that you mentioned, were 11:12:47
14 these visits happening in 2004? 11:12:52
15 A. I don't get -- I didn't get that question. In 11:13:00
16 2004 -- 11:13:04
17 Q. Did you -- go ahead. 11:13:05
18 A. Yeah, in 2004, I was -- 11:13:07
19 Q. Well, let me re- -- let me rephrase. 11:13:10
20 I just -- the once-a-month visits to Hungary, 11:13:12
21 were you doing those once-a-month visits in 2004? 11:13:16
22 A. Yes. Yeah. 11:13:21

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1 Q. Okay. And all of these other locations for 11:13:21
2 IVAX that you mentioned around the world, were they 11:13:26
3 doing research and development on drugs as well? 11:13:30
4 A. Yes. I would say mostly -- 11:13:32
5 Q. And -- 11:13:36
6 A. -- development -- not basic research, but many 11:13:37
7 of them were just commercial sites. 11:13:41
8 Q. What offices were doing drug developments -- 11:13:45
9 MR. MLAYER: Objection -- 11:13:58
10 BY MS. DASHE: 11:13:58
11 Q. -- at IVAX when you were there? 11:13:59
12 MR. MLAYER: -- to form and relevance. 11:14:02
13 A. To my knowledge, the UK; in Ireland, 11:14:04
14 Waterford; Czech -- the Czech Republic, Czechoslovakia 11:14:18
15 was then, site or something. 11:14:27
16 BY MS. DASHE: 11:14:29
17 Q. The visits that you did to Hungary, did you 11:14:29
18 also make those visits in 2003? 11:14:33
19 A. Yes, I -- after I became director, managing 11:14:37
20 director, which was in November 1999, I often visited 11:14:42
21 the research institute. That was the main research 11:14:51
22 institute of IVAX. 11:14:55

1 Q. During your time at IVAX from 2000 to 2006, 11:15:02
2 the offices that were doing drug development were the 11:15:07
3 United States, Hungary, the United Kingdom, Ireland, and 11:15:12
4 the Czech Republic; right? 11:15:20

5 A. Yes. 11:15:23

6 MR. MLAYER: Umm -- that's fine, just go ahead 11:15:24
7 and answer. 11:15:26

8 A. Yes. 11:15:27

9 Maybe more, maybe I don't remember some, you 11:15:28
10 know, but... 11:15:31

11 BY MS. DASHE: 11:15:35

12 Q. So there could have been more beyond what I 11:15:35
13 just listed, but you just don't recall at this time; -- 11:15:37

14 A. Yes. 11:15:41

15 Q. -- is that right? 11:15:42

16 A. Right. 11:15:43

17 Q. Now, approximately how many drug development 11:15:43
18 projects would a team at IVAX work on? 11:15:50

19 A. Well, if the question is -- is -- my main job 11:15:55
20 was new drug discovery and development. There were many 11:16:04
21 other groups and sites who worked on the OTC drugs or -- 11:16:09
22 but the new drug development and discovery was my field. 11:16:22

1 And as I remember, at a given point, we had 11:16:27
2 like 12 or 13 active projects of different kinds, 11:16:30
3 epilepsy, inflammation, all kinds. 11:16:38
4 Q. ... teen active projects that you recall, 11:16:42
5 were those active in the 2003, 2004 time frame? 11:16:51
6 A. Yes. 11:16:54
7 Q. Did you have any role at IVAX for deciding 11:16:55
8 what to patent? 11:17:06
9 A. No. 11:17:08
10 Q. Do you know what the process was at IVAX for 11:17:09
11 deciding what to patent? 11:17:18
12 MR. MLAYER: Objection, privilege. 11:17:20
13 I'll -- you can answer yes or no. 11:17:22
14 A. I don't know. I can only talk about my own 11:17:27
15 intellectual topic.
16 BY MS. DASHE: 11:17:36
17 Q. Did you have any role in deciding whether to 11:17:36
18 file your Bodor PCT application? 11:17:42
19 MR. MLAYER: I'll give you the same caution. 11:17:47
20 You can answer yes or no. 11:17:49
21 A. Well, not really. I mean, the filing was 11:17:50
22 decided by the patent office -- I mean the IVAX patent 11:17:57

1 office, the chairman, president, and they maybe asked me 11:18:04
2 sometimes, but I don't recall except my own patents. 11:18:14
3 BY MS. DASHE: 11:18:19
4 Q. You mentioned an IVAX patent office. Do you 11:18:24
5 know how big the IVAX patent office was? 11:18:27
6 A. I really don't -- 11:18:30
7 Q. Like how many people, I mean? 11:18:32
8 A. Depends on time. I mean, we are talking about 11:18:33
9 six years. But most of the time, it was one or two 11:18:41
10 lawyer and then patent assistant. 11:18:45
11 I'd say the office was maybe four or five 11:18:54
12 people. 11:18:56
13 Q. The 2003, 2004 time frame? 11:18:56
14 A. That's what I remember, yes. 11:19:04
15 Q. And do you recall any of the names of the 11:19:06
16 people in the IVAX patent department? 11:19:14
17 A. I remember just one, who was head for quite 11:19:17
18 some time, I don't know when did she start. Her name 11:19:23
19 was Simona Levi-Minzi. 11:19:26
20 Q. Can you spell that for us spelling-challenged 11:19:30
21 folks on the record? 11:19:35
22 A. Simona, S-I-M-O-N-A, L-E-V-I dash M-I-N-Z-I. 11:19:35

1 Q. Was she at IVAX in the 2003, 2004 time frame? 11:19:45

2 A. I think so, yes. Not a hundred percent 11:19:56

3 positive, but that's what I remember. 11:19:59

4 Q. Do you know if Simona is at -- still at IVAX 11:20:03

5 as a part of Teva now, or has she left? 11:20:10

6 A. Well, IVAX doesn't exist anymore after 2006. 11:20:13

7 And I don't know if Simona stayed with Teva or not. I 11:20:22

8 lost -- I don't know --

9 Q. So you don't recall -- 11:20:37

10 A. I don't know where she is. 11:20:30

11 Q. Okay. So you don't recall -- or, excuse me. 11:20:38

12 Do you recall the last time you spoke with Simona? 11:20:39

13 A. Probably in 2006. 11:20:42

14 Q. ... have any role in drafting your Bodor PCT 11:20:43

15 application? 11:21:01

16 MR. MLAYER: Objection, privilege. 11:21:01

17 You can answer yes or no. 11:21:02

18 A. Not as I know. 11:21:04

19 BY MS. DASHE: 11:21:12

20 Q. And did you communicate with Simona about your 11:21:12

21 Bodor PCT application? 11:21:18

22 A. Maybe some -- to some extent, but the patent 11:21:22

1 was worked by an outside firm, patent -- what was 11:21:28
2 it -- Buckingham -- 11:21:40
3 Q. Sorry. 11:21:41
4 A. Buchanan Inger- -- 11:21:42
5 Q. Do you recall -- 11:21:44
6 A. Buchanan Inger- --
7 Q. I keep talking over you. I'm sorry. 11:21:45
8 A. Buchanan -- 11:21:46
9 Q. Just so the record is clear because I keep, 11:21:48
10 kind of, heading in and out, so who was the outside firm 11:21:50
11 responsible for your Bodor PCT? 11:21:56
12 A. Buchanan Inger- -- something like that. 11:22:02
13 Q. Buchanan Ingersoll, does that ring a bell? 11:22:05
14 A. Yes. 11:22:10
15 Q. Okay. So -- okay. Did you communicate within 11:22:10
16 Buchanan Ingersoll lawyers about your Bodor -- or 11:22:15
17 scratch that. 11:22:22
18 Did you communicate with the Buchanan 11:22:23
19 Ingersoll lawyers when they submitted your PCT 11:22:25
20 application to the patent office? 11:22:30
21 MR. MLAYER: Objection to privilege, I'll 11:22:32
22 caution you, but you can answer yes or no. 11:22:34

1 A. Well, certainly I communicated with them, but 11:22:37
2 I don't know who filed the patent ultimately. The -- if 11:22:40
3 you look at the patent issued, well, two different 11:22:49
4 patents, I have either Dentson [sic] or Buchanan. 11:22:52

5 What -- both represented -- I worked with a 11:23:00
6 patent agent, Mary Katherine Baumeister, for many, many 11:23:02
7 years. So any patent which I worked on during my IVAX 11:23:10
8 time, I -- although we had a patent office, I did use 11:23:20
9 from Denton or -- or the other firm because of -- of 11:23:29
10 Baumeis- -- Kathy Baumeister. 11:23:07

11 Q. ... patent agent's name, but I missed it. Who 11:23:39
12 was this patent agent that you communicated with? 11:23:44

13 A. Mary Katherine Baumeister. B-A-U-M-E -- 11:23:45

14 Q. Could you spell that? 11:23:51

15 A. B-A-U-M-E-I-S-T-E-R. 11:23:53

16 And before that, there was Norman Stepno. But 11:24:06
17 unfortunately, both of them are dead. 11:24:10

18 Q. Well, that takes care of my next question, so. 11:24:14

19 When was the last time you spoke with either 11:24:17
20 Mary or Norman? 11:24:19

21 A. I talked to Kathy maybe two years ago, she was 11:24:22
22 working on a patent for me. 11:24:29

1 Q. That had nothing... 11:24:31

2 A. Didn't get any -- 11:24:39

3 MR. MCGUFFIN: Did -- 11:24:43

4 BY MS. DASHE: 11:24:45

5 Q. Correct. 11:24:45

6 So when was the last time you communicated 11:24:45

7 with -- with Norman? 11:24:48

8 A. Oh, it must have been six, seven years. I 11:24:52

9 don't remember when he passed. 11:24:57

10 Q. Have you -- had you communicated with Mary or 11:25:06

11 Norman about your Bodor PCT or related US patents after 11:25:10

12 you left IVAX? 11:25:15

13 A. Yes, Mary -- or Kathy, we called her Kathy, I 11:25:16

14 actually didn't use the "Mary." 11:25:25

15 Kathy was with me, I said before, at the 11:25:27

16 patent office interview for the very application in 11:25:29

17 2008. And she was in contact with Merck people. 11:25:38

18 Q. And besides the 2008 patent office interview, 11:25:45

19 did you have any role in communicating with the patent 11:25:52

20 office about either your Bodor PCT or issued US patents, 11:25:57

21 the `328 and `415 patent? 11:26:05

22 A. No. 11:26:08

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Conducted on February 15, 2024

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1	Q. Okay. Did you ever review IVAX's SEC or	11:26:08
2	Securities and Exchange Commission filings when you were	11:26:28
3	at the company?	11:26:29
4	A. No.	11:26:30
5	Q. Have you ever seen IVAX's SEC filings?	11:26:30
6	A. I don't believe so. I don't know.	11:26:40
7	Q. So you don't know if you've ever seen, for	11:26:43
8	example, a 10-K or an annual report for IVAX?	11:26:48
9	A. That's right, I don't know. I was not	11:26:53
10	involved in the financial part, although I was an	11:26:55
11	officer, but I was not involved in the finances.	11:27:01
12	Q. Okay.	11:27:10
13	MS. DASHE: Emil, could you please pull up tab	11:27:14
14	11, which is the IVAX Corporation's Form 10-K to	11:27:19
15	the SEC for fiscal year 2003, and mark that as	11:27:27
16	Hopewell's Exhibit 1055, please.	11:27:32
17	MR. MLAYER: I'm going to object to the	11:27:35
18	introduction of a document that hasn't been	11:27:37
19	previously produced and to the extent any new	11:27:42
20	argument is based on that and to foundation.	11:27:44
21	MS. DASHE: Emil, could you please zoom in on	11:28:03
22	the address under IVAX Corporation for Dr. Bodor?	11:28:06

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1 BY MS. DASHE: 11:28:20

2 Q. Dr. Bodor, do you see it lists this 10-K, 11:28:20

3 Exhibit 1055, for IVAX Corporation? 11:28:23

4 A. Um-hum (affirmative). 11:28:29

5 Q. Do you see where it says 4400 Biscayne 11:28:29

6 Boulevard, Miami, Florida 33137? 11:28:32

7 A. Yes. 11:28:36

8 Q. And was that the address, the US address for 11:28:36

9 IVAX in 2003? 11:28:44

10 A. Yes. 11:28:45

11 Q. Okay. And so you have not previously seen 11:28:45

12 this 10-K? 11:28:51

13 A. I don't think I have seen any 10-Ks or looked 11:28:52

14 at it or -- I don't think so. 11:28:58

15 Q. Do you have any reason to believe that this 11:29:00

16 SEC filing for IVAX has any errors in it? 11:29:07

17 MR. MLAYER: Objection, foundation. 11:29:14

18 A. I have no reason one way or another. 11:29:16

19 MS. DASHE: Go to page 19 of the PDF for 11:29:23

20 Exhibit 1055, please. 11:29:25

21 And scroll to where it says "employees." 11:29:37

22 Go back up. You scrolled past it. 11:29:43

1	"Employees." There you go. Thank you.	11:29:47
2	BY MS. DASHE:	11:29:50
3	Q. And, Dr. Bodor, do you see where it says,	11:29:50
4	Exhibit 1055, the 2003 10-K for IVAX, --	11:29:55
5	A. Yes.	11:30:00
6	Q. -- "As of December 31, 2003, we had	11:30:00
7	approximately 8,719 employees worldwide"?	11:30:04
8	A. Yes.	11:30:07
9	Q. Do you see that? Okay.	11:30:08
10	A. Yeah.	11:30:13
11	Q. And is that number of employees that IVAX	11:30:14
12	listed here consistent with your recollection of the	11:30:18
13	number of employees that IVAX had in 2003?	11:30:19
14	A. I -- I don't have any recollection, really. I	11:30:21
15	said before 12,000, but I don't know when was it. You	11:30:28
16	know, at some point, IVAX was the largest generic firm	11:30:30
17	in the world. And so I don't know.	11:30:36
18	I don't have any reason to doubt that this	11:30:38
19	is -- this number is right.	11:30:41
20	MS. DASHE: Emil, turn to page 13 -- back to	11:30:49
21	page 13 of the PDF of Exhibit 1055, the 2003 10-K,	11:30:53
22	please.	11:31:03

1 And if you could scroll down to "Patents and 11:31:04

2 proprietary rights" on this page for the witness. 11:31:07

3 And, Emil, if you could zoom in on the "We 11:31:20

4 hold approximately" paragraph so the witness could 11:31:24

5 see it. 11:31:27

6 BY MS. DASHE: 11:31:34

7 Q. And so, Dr. Bodor, do you see here page 10 of 11:31:34

8 the 10-K, page 13 of Exhibit 1055, it says for IVAX 11:31:39

9 "Patents and proprietary rights," and "We hold 11:31:46

10 approximately 1,026 United States and foreign patents 11:31:49

11 and have filed several hundred United States and foreign 11:31:54

12 patent applications," do you see that? 11:31:59

13 A. Yes. 11:32:01

14 Q. And my question for you, is that number of 11:32:01

15 patents and patent applications consistent with your 11:32:06

16 recollection of the number IVAX had in 2003? 11:32:11

17 A. I have no recollection. I didn't know number 11:32:13

18 of -- 11:32:16

19 Q. Do you have any reason to believe this is 11:32:17

20 inaccurate? 11:32:19

21 MR. MLAYER: Objection to foundation. 11:32:20

22 A. I believe it is accurate. I don't see any 11:32:22

1 reason why they didn't report accurately. 11:32:25

2 MS. DASHE: You can take Exhibit 1055 down. 11:32:36

3 And could you please open tab 14, which will 11:32:38

4 be IVAX's -- IVAX Corporation's Form 10-K to the 11:32:51

5 SEC for fiscal year ending in December 31, 2004. 11:32:55

6 And that will be Exhibit 1056. 11:33:00

7 MR. MLAYER: And I'll object again to the 11:33:03

8 introduction of a new document and to any new 11:33:05

9 argument as well as to foundation. 11:33:08

10 REMOTE ZOOM TECHNICIAN WHITE: You said that's 11:33:25

11 the IVAX 2001? 11:33:27

12 MS. DASHE: No. So this will be tab 14, which 11:33:29

13 should be the IVAX 2004 10-K. 11:33:35

14 REMOTE ZOOM TECHNICIAN WHITE: My apologies. 11:33:44

15 MS. DASHE: No problem. 11:33:47

16 BY MS. DASHE: 11:34:00

17 Q. Okay. So -- 11:34:00

18 MS. DASHE: Oh, Emil, that will be 11:34:04

19 Exhibit 1056, please. 11:34:08

20 BY MS. DASHE: 11:34:08

21 Q. Dr. Bodor, you can see Exhibit 1056 on the 11:34:20

22 screen? 11:34:23

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Transcript of Nicholas Bodor, Ph.D., DSc, dhc, HoF

Conducted on February 15, 2024

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1 A. It's too small. 11:34:23

2 MS. DASHE: Emil, maybe if you could zoom in a 11:34:25

3 little bit on the first page, yeah. 11:34:29

4 BY MS. DASHE: 11:34:33

5 Q. Okay. So, Dr. Bodor, I'm showing you 11:34:34

6 Exhibit 1056 in this case, which is IVAX Corporation's 11:34:38

7 Form 10-K for the fiscal year ended December 31st, 2004. 11:34:43

8 And do you see in the middle there, it says 11:34:48

9 "4400 Biscayne Boulevard, Miami, Florida 33137"? 11:34:51

10 A. Yes. 11:34:57

11 Q. And again, that is the correct address for the 11:34:58

12 IVAX Corporation in the United States? 11:35:06

13 A. It was, yes. 11:35:08

14 Q. And do you have -- have you ever seen this 11:35:09

15 Form 10-K before? 11:35:17

16 A. Maybe. I don't know. 11:35:22

17 I was never party to any -- 11:35:25

18 Q. Reason to --

19 A. -- interested in looking at 10-Ks. 11:35:27

20 Q. Okay. But do you have any reason to believe 11:35:30

21 that IVAX's filing with the Securities and Exchange 11:35:32

22 Commission that we see here was -- has any errors in it? 11:35:38

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1 MR. MLAYER: Objection, foundation. 11:35:43

2 A. I have no -- no reason to think. 11:35:45

3 MS. DASHE: Turn -- Emil, if you could please 11:35:50

4 turn to page 21 of the PDF, that will be page 16 of 11:35:53

5 the 10-K. 11:35:59

6 MR. MLAYER: While that's happening, I would 11:36:02

7 also like to object to this exhibit and the 11:36:03

8 previous exhibit as hearsay as well. 11:36:05

9 BY MS. DASHE: 11:36:14

10 Q. Okay. And, Dr. Bodor, could you -- do you see 11:36:14

11 "employees," kind of in the middle of the page? 11:36:17

12 MS. DASHE: Emil, if you could zoom in a 11:36:20

13 little bit. 11:36:22

14 A. Yes. It's a little too small, but I think 11:36:22

15 it's... 11:36:26

16 BY MS. DASHE: 11:36:33

17 Q. Yeah. There we go. 11:36:35

18 A. 10 -- 10,100. 11:36:36

19 Q. Right. So my question for you is IVAX's 10-K, 11:36:38

20 Exhibit 1056, says that as of December 31st, 2004, "We 11:36:43

21 had approximately 10,100 employees worldwide." 11:36:47

22 My question for you, is that number of 11:36:52

1 employees at IVAX shown here consistent with your 11:36:55
2 recollection of the ballpark number of employees IVAX 11:36:58
3 had in 2004? 11:37:02
4 MR. MLAYER: Objection to the form, hearsay, 11:37:03
5 scope, and relevance. 11:37:05
6 A. As I said before, I don't recall, and I don't 11:37:06
7 think I ever was particularly interested to -- to know 11:37:11
8 the total number of employees. 11:37:16
9 BY MS. DASHE. 11:37:20
10 Q. ... to doubt that IVAX had 10,100 employees as 11:37:25
11 of December 31, 2004? 11:37:32
12 A. No, I don't doubt. 11:37:33
13 Q. Okay. And so similarly, you have no reason to 11:37:38
14 doubt that during your time at IVAX, there were roughly 11:37:40
15 between 8 to 10,000 employees at the company? 11:37:42
16 A. Yes. You know, when I see the numbers, I 11:37:47
17 believe them. 11:37:51
18 Q. Okay. Excuse me, I'm dropping my papers here. 11:37:51
19 Just one second. 11:38:07
20 MS. DASHE: All right. Emil, if we could 11:38:23
21 please go to page 13 of the PDF for Exhibit 1056. 11:38:26
22 BY MS. DASHE: 11:38:39

1 Q. And do you see where it says "Patents and 11:38:39
2 proprietary rights"? 11:38:41
3 MS. DASHE: That's perfect, Emil, thank you. 11:38:43
4 BY MS. DASHE: 11:38:46
5 Q. Do you see that, Dr. Bodor? 11:38:46
6 A. No. I saw it before. 11:38:47
7 MS. DASHE: Emil, if you could zoom back in, 11:38:51
8 that was -- yeah. 11:38:54
9 A little bit more, Emil, please. 11:38:56
10 Thank you. That's great, right there. 11:38:58
11 BY MS. DASHE: 11:39:00
12 Q. Do you see now, Dr. Bodor, -- 11:39:00
13 A. Yes. 11:39:02
14 Q. -- where it says "Patents and proprietary 11:39:02
15 rights"? 11:39:05
16 A. Um-hum (affirmative). 11:39:05
17 Q. Okay. And do you see in the second paragraph 11:39:05
18 under that subheader -- 11:39:09
19 A. Yes. 11:39:11
20 Q. -- "We hold approximately 1,490 US and foreign 11:39:11
21 patents and have filed several hundred US and foreign 11:39:15
22 applications," do you see that? 11:39:20

1 A. Yes. 11:39:21

2 MR. MLAYER: Objection to hearsay. 11:39:22

3 BY MS. DASHE: 11:39:23

4 Q. Okay. And my question for you, is that number 11:39:23

5 of patents and patent applications consistent with your 11:39:26

6 recollection of the number IVAX had in 2004? 11:39:29

7 MR. MLAYER: Objection, foundation. 11:39:34

8 A. Well, as I said before, I have no recollection 11:39:35

9 how many patents that IVAX had. It was not my business. 11:39:39

10 BY MS. DASHE: 11:39:51

11 Q. Okay. But you have no reason to disbelieve 11:39:51

12 IVAX's SEC filing here that said the company holds 11:39:54

13 approximately 1,490 US and foreign patents and has 11:39:58

14 several hundred more applications? 11:40:03

15 MR. MLAYER: Objection, hearsay, foundation, 11:40:05

16 scope, relevance. 11:40:07

17 A. Yeah, I have no doubt -- or no reason to 11:40:08

18 doubt. 11:40:10

19 BY MS. DASHE: 11:40:19

20 Q. Your cladribine team at IVAX, that included, I 11:40:20

21 believe you mentioned, Dr. Yogesh Dandiker? 11:40:24

22 A. Yes. 11:40:33

1 MS. DASHE: Emil, you can take down 11:40:33
2 Exhibit 1056. 11:40:37
3 Thank you. 11:40:37
4 BY MS. DASHE: 11:40:38
5 Q. When did Dr. Dandiker join the cladribine team 11:40:38
6 at IVAX? 11:40:43
7 A. I really don't remember. I mean, I met 11:40:44
8 Dr. Dandiker once in my life, when we discussed his 11:40:52
9 findings about making the complex complex. And that 11:40:56
10 must have been sometime in 2003, but I don't know. I 11:41:03
11 don't remember. 11:41:07
12 Q. Okay. 11:41:07
13 A. I don't know when he got employed, when he 11:41:09
14 left. 11:41:13
15 Q. What office was Dr. Dandiker at in IVAX? 11:41:18
16 A. I thought he was working in Waterford, 11:41:24
17 Northern Ireland. Is that Northern? Or just Ireland? 11:41:29
18 But I -- 11:41:36
19 Q. You met Dr. Dandiker once in your life? 11:41:37
20 A. Yes, in my office here in Miami. 11:41:40
21 Q. That -- when you -- the one time you met 11:41:42
22 Dr. -- scratch that. 11:41:55

1 Aside from meeting in person in your that 11:41:55
2 one time in Miami, how many times did you communicate 11:41:58
3 with Dr. Dandiker during your time at IVAX on 11:42:02
4 cladribine? 11:42:07
5 MR. MLAYER: Objection to form. 11:42:12
6 A. I really don't remember. Not many times. I 11:42:13
7 mean, the issue related to the patent was done by some 11:42:19
8 other people who talked to us separate, not -- I didn't 11:42:24
9 talk to him. 11:42:29
10 Maybe some of my other people contacted him 11:42:39
11 for some material, but I didn't talk to him. Don't 11:42:41
12 remember talking -- talking to him after. 11:42:46
13 BY MS. DASHE: 11:42:55
14 Q. Would you communicate with Dr. Dandiker via 11:42:55
15 email? 11:43:01
16 A. I don't recall any email communication. I 11:43:01
17 communi- -- I talked to him in person when he came to my 11:43:11
18 office. 11:43:13
19 Q. Communication in person in your office in 11:43:14
20 Miami in roughly 2003, was that the only communication 11:43:23
21 that you had with Dr. Dandiker at IVAX regarding 11:43:28
22 cladribine? 11:43:30

1 A. Yes. 11:43:30

2 Q. And you said you communicated with 11:43:31

3 Dr. Dandiker regarding, I want to make sure I get your 11:43:43

4 wording right here, "his findings about making the 11:43:48

5 complex complex." 11:43:51

6 A. Yes. 11:43:53

7 Q. What do you mean by that? 11:43:53

8 A. Well, he found, as I said before, that raising 11:43:56

9 the temperature and extending the time of combining 11:44:04

10 cladribine and hydroxypropyl beta cyclodextrin leads to 11:44:13

11 an increased incorporation of cladribine into the 11:44:21

12 cyclodextrin, which was an unusual finding, and I 11:44:27

13 discussed with him, because the inclusion complex 11:44:33

14 formation is actually decreasing with the increasing 11:44:38

15 temperature. 11:44:43

16 However, since cladribine is a complex 11:44:44

17 molecule which has this sugar relate -- part, then it 11:44:50

18 became obvious that that is contributing to a different 11:44:54

19 type of interaction with the 11:45:01

20 hydroxypropyl-beta-cyclodextrin. 11:45:04

21 And so that's what I described many times led 11:45:06

22 to this complex complex concept in actuality. 11:45:09

1 Q. Oh, go ahead. 11:45:16

2 And did you work together with Dr. Dandiker on 11:45:20

3 developing the complex cladribine-cyclodextrin complex? 11:45:23

4 A. Well, if the -- this is how we worked 11:45:31

5 together, that we discussed it in my office and we 11:45:34

6 agreed that -- 11:45:43

7 Q. Work with -- together with Dr. Dandiker on 11:45:43

8 cladribine at IVAX involved the one meeting that you had 11:45:48

9 in your office in Miami in roughly 2003; is that right? 11:45:53

10 A. Yes. 11:45:56

11 Q. Now, you mentioned you had some other team 11:45:57

12 members at IVAX. Who were they? 11:46:06

13 A. Not the cladribine team, if that's what you 11:46:15

14 mean. In the cladribine team at IVAX I considered was 11:46:17

15 Dr. Steve Marcus. 11:46:23

16 Q. I meant -- I should have said about the 11:46:25

17 cladribine team. So let me just rephrase to make sure 11:46:32

18 we're all on the same page. 11:46:35

19 So the members of your cladribine team at IVAX 11:46:36

20 were Dr. Dandiker and Dr. Steve Marcus; is that right? 11:46:40

21 A. And a large number of researchers in the 11:46:47

22 research institute in Hungary who did the actual -- 11:46:52

1 Q. What were their names? 11:47:00

2 A. -- work on the pharmacokinetic and 11:47:02

3 bioavailability studies. 11:47:08

4 Oh, Dandiker, I am sure he had other people 11:47:08

5 working with him. They made the complex complex, which 11:47:11

6 was then provided to Hungary for the studies. 11:47:15

7 Q. Other people were on the cladribine team at 11:47:17

8 IVAX that you mentioned? 11:47:27

9 A. Yes. I told you about the people at the 11:47:32

10 research -- research institute in Budapest. But again, 11:47:39

11 I am sure that there were others in Waterford working 11:47:41

12 with Dr. Dandiker. 11:47:49

13 Q. ... figure out is what number of people at 11:47:50

14 IVAX worked on the cladribine project. 11:47:55

15 A. Well, besides these whom I mentioned, only the 11:48:01

16 people in Hungary. There were quite a number, five or 11:48:05

17 six involved development of the analytical technique, 11:48:11

18 and then receiving the blood samples from different 11:48:15

19 sites in Europe and also the dog studies which were 11:48:22

20 performed at the Budapest institute. 11:48:32

21 But these are, again -- 11:48:43

22 Q. Besides Dr. Dandiker -- Dr. Dandiker and 11:48:45

1 Dr. Steve Marcus, you don't recall the specific names of 11:48:58
2 the other IVAX people who worked on cladribine; is that 11:49:02
3 right? 11:49:05
4 A. That's right. 11:49:05
5 Q. All right. So we discussed Dr. Dandiker and 11:49:05
6 his role on the cladribine project. What was Dr. Steve 11:49:20
7 Marcus' role on the cladribine project at IVAX? 11:49:27
8 A. Well, all I can tell you, that Steve was the 11:49:30
9 originator in 2000 sometime, I was fairly new and he was 11:49:34
10 fairly new, he was the vice president of clinical 11:49:43
11 affairs, he came to my office and talked about 11:49:45
12 cladribine. 11:49:54
13 So he introduced to me, he said that there is 11:49:55
14 an interest in cladribine if I could find a way to make 11:49:58
15 it orally bioavailable. And I looked at the structure 11:50:03
16 and I said I think there should be a way complexing with 11:50:11
17 cyclodextrins. 11:50:15
18 After that, I really don't -- didn't have 11:50:19
19 any -- much interaction with Steve about the cladribine. 11:50:22
20 Q. ... by something you -- 11:50:31
21 A. I had many interactions otherwise. 11:50:32
22 Q. Go ahead. 11:50:36

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Transcript of Nicholas Bodor, Ph.D., DSc, dhc, HoF

Conducted on February 15, 2024

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1 A. But not about cladribine. 11:50:37

2 Q. And you said that -- okay. You said that 11:50:39
3 Steve came into your office in 2000 and said that there 11:50:42
4 was an interest in cladribine if you could find a way to 11:50:46
5 make it orally bioavailable? 11:50:51

6 A. Yes. Yeah, he told me that he had contacts 11:50:55
7 for -- in the -- at Scripp, and Scripp has developed 11:51:05
8 cladribine, I think they developed for using in areas 11:51:10
9 leukemia. And Steve knew about it because he was 11:51:17
10 basically an oncologist. 11:51:21

11 So that's where it started, he knew about 11:51:25
12 cladribine and he came to me and asked me if I could 11:51:27
13 look a way to make it orally bioavailable. He told me 11:51:30
14 that it's -- as it's sensitive, fairly low solubility. 11:51:37

15 Q. That was Scripps' institute that Dr. Marcus 11:51:42
16 told you had developed cladribine? 11:51:52

17 A. Yes. 11:51:54

18 Q. Is that right? 11:51:54

19 A. Yeah. 11:51:54

20 Q. Okay. And so you told Dr. Marcus that you 11:52:03
21 thought you could create cladribine-cyclodextrin 11:52:08
22 complex. 11:52:13

1 A. Yes. 11:52:13

2 Q. When did you first make your complex 11:52:13
3 cladribine-cyclodextrin complex? 11:52:20

4 A. I honestly don't remember, but it relates to 11:52:20
5 the other two patents, the applications, which I am the 11:52:23
6 sole inventor. And I must have -- some people I 11:52:30
7 instructed to do the study and how to do it, but I don't 11:52:34
8 remember whom and where. But the phase solubility 11:52:38
9 diagrams are included in those applications. 11:52:47

10 And then it ended up I guess somehow in -- 11:52:49
11 with Dandiker, and Dandiker changed the conditions, and 11:52:53
12 that's how we arrived to the complex complex. 11:52:59

13 Q. What conditions did Dandiker change? 11:53:10

14 A. I mentioned that before. He looked -- 11:53:13
15 extended the time of the mixing and raised the 11:53:17
16 temperature. And as I talked to him, that was our 11:53:20
17 discussion main focus. That was against the concept of 11:53:26
18 inclusion complex, but it became evident that there is 11:53:32
19 something that is going on that is the hydrogen-bonded 11:53:35
20 complex. 11:53:41

21 Q. ... sometime in 2003 you said? 11:53:41

22 MR. MLAYER: I'm sorry, your question was cut 11:53:49

1	off again.	11:53:58
2	MS. DASHE: Oh.	11:53:58
3	BY MS. DASHE:	
4	Q. This discussion with Dr. Dandiker, that was	11:53:58
5	sometime in 2003 you said; right?	11:54:00
6	A. Well, I don't remember the date. But it must	11:54:09
7	have been before we filed the patent application.	11:54:16
8	Q. ... charged with keeping your complex	11:54:18
9	cladribine-cyclodextrin complex confidential before you	11:54:25
10	filed your Bodor PCT application?	11:54:30
11	MR. MLAYER: Objection, form.	11:54:36
12	A. Would you repeat that question?	11:54:37
13	BY MS. DASHE:	
14	Q. Yes.	11:54:40
15	Were you -- were you -- strike that.	11:54:42
16	Were you and your team at IVAX charged with	11:54:45
17	keeping your complex cladribine-cyclodextrin complex	11:54:50
18	confidential before you filed your Bodor PCT	11:54:55
19	application?	11:54:59
20	MR. MLAYER: Objection, form.	11:55:01
21	A. Well, of course, any work done at IVAX we kept	11:55:02
22	confidential. We never published.	11:55:07

1 BY MS. DASHE: 11:55:12

2 Q. Before you filed your Bodor PCT application, 11:55:20

3 you kept your complex cladribine-cyclodextrin complex 11:55:24

4 confidential; is that right? 11:55:31

5 A. Confidential from whom? 11:55:31

6 Of course. It was the company 11:55:35

7 confidentiality. We didn't talk about internal work 11:55:39

8 with outsiders. 11:55:46

9 Q. So you didn't talk about your complex 11:55:47

10 cladribine-cyclodextrin -- excuse me, let me rephrase 11:55:57

11 that. 11:56:00

12 So did IVAX as a company keep your complex 11:56:00

13 cladribine-cyclodextrin complex confidential from the 11:56:09

14 public before you filed your Bodor PCT application? 11:56:12

15 MR. MLAYER: Objection, form, foundation, 11:56:18

16 scope, relevance. 11:56:21

17 A. I assume so. I mean, I have no reason to 11:56:22

18 believe that IVAX went and advertised our work. 11:56:24

19 BY MS. DASHE: 11:56:27

20 Q. So this initial conversation with Dr. Marcus, 11:56:33

21 you said it happened in 2000. Do you recall when in 11:56:40

22 2000 that would have been? 11:56:43

1 MR. MLAYER: Objection to form. 11:56:43

2 A. I assume it was in 2000 because it was early 11:56:44

3 my position at IVAX. And Steve Marcus just joined also 11:56:52

4 IVAX not long before me. 11:57:02

5 And so we are both early. I was new coming 11:57:04

6 from university. So Steve came to my office and talked 11:57:09

7 about cladribine. 11:57:16

8 I -- 11:57:21

9 BY MS. DASHE: 11:57:22

10 Q. That -- and forgive me if I've already covered 11:57:23

11 this, I just want to make it clear. 11:57:25

12 After that initial conversation with Dr. Steve 11:57:26

13 Marcus about cladribine, did you have any other 11:57:28

14 communications with Dr. Marcus about cladribine at IVAX? 11:57:32

15 A. I am sure that I told him later, after we have 11:57:36

16 succeeded to make complex, the results. I don't know 11:57:41

17 what -- don't remember what his reaction was. These -- 11:57:47

18 these are the complexes in -- included in the other 11:57:52

19 patents which were never used. 11:57:58

20 But you have to understand, if I may say, 11:58:10

21 cladribine, on the larger scale for me in my position, 11:58:14

22 was a very minor issue, it was not a main thing. So I 11:58:18

1 don't remember too much about it. It became more 11:58:23
2 important after the patent examiner in 2008 finally 11:58:29
3 allowed it. 11:58:38

4 Q. What was Dr. Marcus' role on the cladribine 11:58:39
5 project at IVAX? Aside from that one conversation you 11:58:54
6 had with him, what was his role? 11:58:58

7 A. I don't know. I mean, with me, we were just 11:58:59
8 communicating about this complexation. If he talked to 11:59:05
9 others -- I know he talked to the president, Dr. Frost, 11:59:11
10 because he told me that he -- Dr. Frost is interested. 11:59:16
11 And, you know, he probably talked to other people, I 11:59:19
12 don't know. 11:59:23

13 Q. Cladribine was somewhat of a minor project for 11:59:23
14 you -- 11:59:33

15 A. Yes. 11:59:33

16 Q. -- at the time at IVAX and it happened a long 11:59:33
17 time ago, -- 11:59:36

18 A. Yes. 11:59:37

19 Q. -- you just don't really recall the details of 11:59:37
20 folks' roles? 11:59:40

21 A. That's correct. 11:59:41

22 Q. Okay. 11:59:42

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Transcript of Nicholas Bodor, Ph.D., DSc, dhc, HoF

Conducted on February 15, 2024

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1 MS. DASHE: You know, we've been going for 11:59:44
2 about an hour, so I'm happy to take a break if you 11:59:45
3 would like to, Dr. Bodor. 11:59:48
4 THE WITNESS: I appreciate it. 11:59:50
5 VIDEOGRAPHER ELMILKI: Okay. We are off the 11:59:52
6 record, and the time now is 11:59. 11:59:54
7 (Recess taken.) 11:59:59
8 VIDEOGRAPHER ELMILKI: We are back on the 12:46:54
9 record, and the time now is 12:46 p.m. 12:46:56
10 BY MS. DASHE: 12:47:02
11 Q. Welcome back, Dr. Bodor. During the break, 12:47:02
12 did you speak with your counsel about your testimony at 12:47:05
13 all? 12:47:08
14 A. No. 12:47:08
15 Q. We've been talking a bit about the Bodor PCT 12:47:08
16 today, so let's actually pull that up. That would be 12:47:19
17 tab 2, Exhibit 1022 in this case. 12:47:23
18 MR. MLAYER: Is that supposed to appear on the 12:47:40
19 screen? 12:47:42
20 Oh, sorry. We see it now. 12:47:43
21 BY MS. DASHE: 12:47:49
22 Q. Okay. And we are looking at Exhibit 1022 in 12:47:49

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1 this case, the Bodor PCT application. 12:48:00

2 MS. DASHE: Emil, could you zoom in on item 12:48:05

3 75, where it says "Inventors/applicants"? 12:48:08

4 BY MS. DASHE: 12:48:27

5 Q. And, Dr. Bodor, do you see the that PCT 12:48:27

6 application lists you and Dr. Dandiker as inventors? 12:48:30

7 A. Yes. 12:48:33

8 Q. Did you read the Bodor PCT application before 12:48:34

9 it was filed? 12:48:48

10 A. Most of it, I guess, yes. 12:48:49

11 THE COURT REPORTER: Could you repeat that? 12:48:55

12 THE WITNESS: Most of it. 12:48:57

13 THE COURT REPORTER: Thank you.

14 A. I mean, many times I read these things, just 12:48:58

15 focusing on the important things, what I see in the 12:49:01

16 examples and the claims. The preliminaries don't matter 12:49:06

17 that much. 12:49:13

18 BY MS. DASHE. 12:49:15

19 Q. ... stand by the disclosures within the Bodor 12:49:15

20 PCT application? 12:49:18

21 MR. MLAYER: So I think the -- the first words 12:49:19

22 of your question were cut off there. 12:49:21

1 MS. DASHE: Oh, no. Okay. 12:49:23

2 BY MS. DASHE: 12:49:25

3 Q. Dr. Bodor, do you stand by the disclosures of 12:49:25

4 your Bodor PCT application? 12:49:30

5 A. Yes. 12:49:36

6 Yes. Yes. 12:49:36

7 Q. What was your specific contribution to the 12:49:37

8 complex cladribine-cyclodextrin complex disclosed in the 12:49:45

9 Bodor PCT? 12:49:54

10 A. Well, I described before, first the concept of 12:49:54

11 using cyclodextrins and using hydroxypropyl-beta- 12:49:58

12 cyclodextrin, which is one of my favorites for many 12:50:07

13 years, then doing the actual phase solubility diagram in 12:50:09

14 the interpretation, and talking to Yogesh Dandiker about 12:50:20

15 his finding, then I give an explanation of the happening 12:50:29

16 why this complex complex is not just a simple inclusion 12:50:34

17 process of a cyclodextrin. 12:50:45

18 Q. You mentioned hydroxy something, I missed the 12:50:50

19 word. 12:50:52

20 A. Hydroxypropyl. 12:50:53

21 Q. What was that word and how do you spell it? 12:50:53

22 A. Hydroxypropyl. Hydroxy, and propyl, 12:50:55

1	P-R-O-P-Y-L.	12:51:00
2	Important thing, the hydroxypropyl-beta-	12:51:03
3	cyclodextrin is a intrinsically amorphous material,	12:51:11
4	because it's a mixture of a variety of isomers, and that	12:51:15
5	makes it very water soluble.	12:51:20
6	It has a lot of advantages.	12:51:33
7	Q. ... those advantages?	12:51:36
8	MR. MLAYER: Sorry, we only got the last two	12:51:38
9	words of your question.	12:51:40
10	BY MS. DASHE:	12:51:41
11	Q. What are some of those advantages you just	12:51:42
12	mentioned, Dr. Bodor?	12:51:44
13	A. I just said the high water solubility and the	12:51:47
14	safety, it was tested in people in many different	12:51:50
15	conditions, even intravenous administration, it's very	12:51:58
16	safe.	12:52:01
17	Q. The findings that Dr. Dandiker communicated to	12:52:07
18	you in that one in-person meeting, what else did he	12:52:10
19	specifically contribute to the complex	12:52:15
20	cladribine-cyclodextrin complex disclosed in the Bodor	12:52:21
21	PCT?	12:52:25
22	MR. MLAYER: Objection to form.	12:52:25

1 A. Well, first I want to clarify one thing. To 12:52:32
2 my knowledge, the inventorship is decided by the patent 12:52:34
3 lawyer. So it's not up to me to judge what Yogesh's 12:52:38
4 contribution was. 12:52:52

5 But, of course, he is the one who -- who found 12:52:52
6 that you can increase the certain conditions, the 12:52:58
7 incorporation of cladribine in cyclodextrin, in this 12:53:01
8 cyclodextrin only, and then we figured out the 12:53:07
9 conditions to optimize formulation of the complex 12:53:11
10 complex. 12:53:19

11 BY MS. DASHE: 12:53:20

12 Q. Just to make sure that I was clear, because I 12:53:20
13 don't want to muck anything up here, I was simply asking 12:53:23
14 what were Dr. Dandiker's scientific contributions to the 12:53:27
15 complex cladribine-cyclodextrin complex disclosed in the 12:53:34
16 Bodor PCT? 12:53:39

17 A. And I said, he found that you can increase the 12:53:40
18 incorporation of cladribine in the cyclodextrin under 12:53:48
19 certain conditions. Because before that, we always just 12:53:58
20 made the -- the -- the inclusion complex, which is 12:53:58
21 probably 30 to 40 percent of the total product. 12:54:05

22 Q. So the inventorship thing. 12:54:10

1 You said that -- well, let me scratch that. 12:54:16

2 What is your under- -- or scratch that again. 12:54:22

3 Do you have an understanding of the legal 12:54:25

4 requirements for inventorship? 12:54:28

5 MR. MLAYER: Objection to scope and 12:54:30

6 foundation. 12:54:36

7 A. My understanding is that somebody has to be 12:54:36

8 responsible at least for one of the claims or invented 12:54:40

9 one of the claims to be a potential inventor. 12:54:47

10 But again, that is decided by the patent 12:54:51

11 lawyer. 12:54:53

12 BY MS. DASHE. 12:54:54

13 Q. ... responsible for? 12:55:01

14 THE COURT REPORTER: We lost the beginning of 12:55:04

15 your question. 12:55:06

16 BY MS. DASHE: 12:55:07

17 Q. You said "My understanding is someone has to 12:55:10

18 be responsible for at least one of the claims." 12:55:13

19 A. Yes. 12:55:16

20 Q. My question to you is what do you mean by 12:55:16

21 "responsible for"? 12:55:20

22 A. That his contribution is that that specific 12:55:22

1 claim was his idea or the result of his work or 12:55:27
2 whatever. 12:55:36
3 Q. Do you have any understanding of the legal 12:55:36
4 requirements for conception? 12:55:44
5 A. For what? 12:55:49
6 Q. Conception. 12:55:50
7 A. Confection? 12:55:54
8 Q. Conception, C-O-N- -- 12:55:56
9 A. Conception, yeah.
10 Q. -- C-E-P-T-I-O-N. 12:55:59
11 A. I am not a lawyer, so I -- I -- I cannot 12:56:01
12 really define you. 12:56:05
13 And again, if we -- we are talking -- 12:56:10
14 Q. And similarly -- oh, go ahead. 12:56:11
15 A. If you are talking about inventorship again, I 12:56:13
16 rely on whatever the patent lawyer decided who is that 12:56:19
17 inventor. It's not up to me. 12:56:26
18 Q. ... of any understanding of the difference or 12:56:28
19 any differences between conception and inventorship? 12:56:36
20 MR. MLAYER: Objection, foundation and form. 12:56:46
21 A. I -- I don't know. 12:56:47
22 I mean, the concept can be an invention. 12:56:56

1	Maybe not all inventions are concepts, I don't know.	12:57:00
2	This is semantics.	12:57:05
3	BY MS. DASHE:	12:57:06
4	Q. And do you have any understanding of any	12:57:06
5	differences between reduction to practice and	12:57:10
6	inventorship?	12:57:15
7	MR. MLAYER: Objection, form, foundation.	12:57:15
8	A. Yes, I do. Reduction to practice is to	12:57:17
9	practically demonstrate the concept or the invention.	12:57:26
10	BY MS. DASHE:	12:57:33
11	Q. And did you read the Bodor PCT application	12:57:42
12	before you signed your declaration in this case?	12:57:46
13	MR. MLAYER: Objection, form, asked and	12:57:49
14	answered.	12:57:53
15	A. Yes. I said that before, it was.	12:57:54
16	BY MS. DASHE:	12:58:01
17	Q. And when was the last time that you read the	12:58:05
18	Bodor PCT application?	12:58:08
19	A. Maybe before I signed this declaration or	12:58:10
20	deposition.	12:58:24
21	MS. DASHE: And so, Emil, you can take down	12:58:31
22	Exhibit 1022.	12:58:36

1 And could you please pull up tab 6, which has 12:58:38
2 already been marked as Exhibit 2069 in these 12:58:43
3 proceedings, and it's US Patent Number 7,888,328. 12:58:47

4 And, Emil, could you zoom in a little bit on 12:59:08
5 the top of the -- of Exhibit 2069 so Dr. Bodor can 12:59:11
6 see? Thank you. 12:59:17

7 BY MS. DASHE: 12:59:19

8 Q. So, Dr. Bodor, Exhibit 2069 on the screen 12:59:19
9 here, this is the `328 patent that you referred to in 12:59:25
10 your declaration; right? 12:59:32

11 A. Yes. 12:59:33

12 Q. And it names you and Dr. Dandiker as 12:59:33
13 inventors? 12:59:36

14 A. Yes. 12:59:36

15 Q. And did you read the `328 patent before it was 12:59:37
16 filed? 12:59:42

17 MR. MLAYER: Objection, scope. 12:59:44

18 A. I would say yes. 12:59:45

19 BY MS. DASHE: 12:59:47

20 Q. Okay. Do you stand by the disclosures of your 12:59:47
21 `328 patent? 12:59:52

22 A. Yes. 12:59:55

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Transcript of Nicholas Bodor, Ph.D., DSc, dhc, HoF

Conducted on February 15, 2024

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1	Q.	And we see here that the 32 patent is assigned	12:59:55
2		to Ares Trading SA. Do you see that?	13:00:03
3	A.	Yes.	13:00:07
4	Q.	Did you receive any sort of compensation for	13:00:07
5		this assignment?	13:00:11
6	A.	No.	13:00:12
7	Q.	Did you receive any awards or accolades,	13:00:12
8		plaques on the wall, anything like that?	13:00:17
9	A.	No.	13:00:19
10	Q.	Did Dr. Dandiker?	13:00:21
11	A.	I don't know.	13:00:22
12	Q.	And did you read the `328 patent,	13:00:23
13		Exhibit 2069, before you signed your declaration in this	13:00:37
14		case?	13:00:45
15	A.	Yes.	13:00:45
16	Q.	When was the last time you read the `328	13:00:46
17		patent?	13:00:49
18	A.	Maybe a few days ago. I didn't read --	13:00:49
19		MS. DASHE: Emil --	13:00:56
20		BY MS. DASHE:	
21	Q.	Oh, go on.	13:00:57
22	A.	I didn't read it all. I mean, it's a long	13:00:58

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1 patent, a lot of introductory statements, which I -- I 13:01:00

2 just glanced to, is a... 13:01:12

3 Q. ... last time you read the '328 patent before 13:01:12

4 you signed your declaration in this case? 13:01:15

5 A. Yes. 13:01:18

6 Q. Oh, I think my question might have been cut 13:01:26

7 off. 13:01:28

8 My question was when was the last time you 13:01:28

9 read the '328 patent before you signed your declaration 13:01:32

10 in this case? 13:01:35

11 MR. MLAYER: Objection to form. 13:01:37

12 A. Maybe sometime in December. Was it -- 13:01:41

13 BY MS. DASHE:

14 Q. 2023? 13:01:47

15 A. Yes. 13:01:47

16 MS. DASHE: All right, Emil, you can take down 13:01:53

17 Exhibit 2069. 13:01:56

18 And could you please introduce tab 10. And 13:01:59

19 this will be Exhibit 1057 in these proceedings. 13:02:05

20 And this is the full file history for US Patent 13:02:09

21 Number 7,888,328. 13:02:16

22 MR. MLAYER: I want to object again to a new 13:02:20

1 document to the extent any new argument is 13:02:23
2 introduced. 13:02:26

3 BY MS. DASHE: 13:02:43

4 Q. All right. Dr. Bodor, for one thing, have you 13:02:43
5 seen the whole prosecution history for your `328 patent 13:02:49
6 before? 13:02:53

7 A. I don't know. Probably. 13:03:02
8 I mean, this was a long time ago. 13:03:09

9 Q. ... read through the whole -- have you ever 13:03:12
10 read through the whole thing? 13:03:14

11 A. Yes, I did. At that time, I guess. I don't 13:03:19
12 know when. See, again, this goes back to 2008 or 13:03:21
13 before. 13:03:32

14 Q. Anticipated my next question. 13:03:37
15 When was the last time you read through the 13:03:38
16 prosecution history for the `328 patent? 13:03:41

17 A. I don't remember. I guess that was -- 13:03:51

18 Q. Did you -- 13:03:56

19 A. -- before my interview at the patent office. 13:03:57

20 Q. So that would have been sometime in the 2008 13:04:03
21 time frame? 13:04:10

22 A. Yes. 13:04:10

1 MS. DASHE: Emil, if you could please go to 13:04:15

2 page 159 of the PDF of Exhibit 1057, please. 13:04:17

3 And, Emil, if you could zoom in about the top 13:04:31

4 third of the document so everybody can see. 13:04:35

5 Maybe zoom out just a little bit. 13:04:38

6 Thank you. That's great. 13:04:40

7 BY MS. DASHE:

8 Q. Now, Dr. Bodor, we see here a declaration from 13:04:48

9 the below-named inventors of the `328 patent. Do you 13:04:53

10 see that? 13:04:58

11 A. Um-hum (affirmative). Yes. 13:04:58

12 Q. Okay. 13:05:03

13 MS. DASHE: And, Emil, if you could flip to 13:05:04

14 the next page of Exhibit 1057. 13:05:09

15 And, Emil, do you see how there is a table? 13:05:13

16 Could you center around the table? 13:05:15

17 Thank you.

18 BY MS. DASHE:

19 Q. And so, Dr. Bodor, do you see on page 160 of 13:05:25

20 the PDF of Exhibit 1057 a table of the inventors of the 13:05:28

21 `328 patent? 13:05:35

22 A. Yes. 13:05:36

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Transcript of Nicholas Bodor, Ph.D., DSc, dhc, HoF

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1	Q.	And it shows your name in that table?	13:05:36
2	A.	Yes.	13:05:40
3	Q.	That is your signature in the table?	13:05:46
4	A.	Yes.	13:05:47
5	Q.	And it also shows Dr. Dandiker's name and	13:05:51
6		signature below that; right?	13:05:54
7	A.	Yes.	13:05:55
8		MS. DASHE: Okay, Emil, you can take down	13:05:55
9		Exhibit 1057.	13:05:57
10		And could you please pull up tab 3,	13:06:00
11		Exhibit 2029 in these proceedings, which is US	13:06:09
12		Patent Number 8,785,415.	13:06:13
13		Thank you.	13:06:25
14		And again, Emil, if you could zoom in maybe on	13:06:31
15		the top third of the page.	13:06:33
16		BY MS. DASHE:	
17	Q.	Dr. Bodor, this Exhibit 2029, that is the `415	13:06:43
18		patent that you have referred to in your declaration;	13:06:48
19		right?	13:06:50
20	A.	Yes.	13:06:50
21	Q.	And again, it names you and Dr. Dandiker as an	13:06:51
22		inventor?	13:06:58

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Transcript of Nicholas Bodor, Ph.D., DSc, dhc, HoF

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1	A. Yes.	13:06:59
2	Q. Did you read the `415 patent before it was	13:06:59
3	filed?	13:07:10
4	A. Yes.	13:07:10
5	Q. And do you stand by the disclosures of your	13:07:11
6	`415 patent?	13:07:21
7	A. Yes.	13:07:24
8	Q. And again we see the `415 patent is assigned	13:07:25
9	to Ares Trading, SA, do you see that?	13:07:33
10	A. Yes.	13:07:36
11	Q. Did you receive any compensation or awards or	13:07:37
12	accolades for this assignment?	13:07:39
13	A. No.	13:07:41
14	Q. Did Dr. Dandiker?	13:07:43
15	A. I don't know.	13:07:44
16	Q. Did you read the `415 patent, Exhibit 2029,	13:07:54
17	before you signed your declaration in this case?	13:08:01
18	A. Most of it. I didn't read the whole patent	13:08:08
19	because it's long and verbose. I didn't read the whole	13:08:11
20	thing in order to sign the affidavit.	13:08:17
21	Q. When was the last time you read the `415	13:08:19
22	patent?	13:08:27

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1	A. In full?	13:08:27
2	Q. Well, how about let's start with at all. When	13:08:31
3	was the last time you read any part of the `415 patent?	13:08:34
4	A. It was, I said, before the patent office	13:08:37
5	interview.	13:08:45
6	Q. When was the last time you read the `415	13:08:45
7	patent before signing your declaration in this case?	13:09:01
8	A. I'd say December '23.	13:09:02
9	MS. DASHE: Okay, Emil, you can take down	13:09:11
10	Exhibit 2029.	13:09:15
11	And could you please pull up tab 4, which will	13:09:19
12	be marked as Exhibit 1058 in these proceedings, and	13:09:21
13	that will be the file history for US Patent Number	13:09:24
14	8,785,415.	13:09:29
15	MR. MLAYER: And same objection to a new	13:09:31
16	document.	13:09:34
17	I'll also note that we haven't been served	13:09:34
18	copies of these exhibits, so, you know, reserve the	13:09:37
19	right to make any objection that may be necessary	13:09:43
20	to the contents that we aren't literally looking	13:09:46
21	at.	13:09:49
22	BY MS. DASHE:	13:10:19

1 Q. So in front of you is Exhibit 1058 in these 13:10:19
2 proceedings, which is the full file history for your 13:10:28
3 `415 patent. 13:10:34

4 My question for you is have you ever seen the 13:10:36
5 full prosecution history for your `415 patent before? 13:10:38

6 A. Not as I recall. I am sure the patent lawyer 13:10:44
7 who handled it did it, but she never showed it to me. I 13:10:48
8 don't recall seeing the full file. 13:10:57

9 MS. DASHE: And, Counsel, before I move on, 13:11:09
10 with respect to the new documents, you're being 13:11:12
11 provided with copies during the deposition, and we 13:11:14
12 agreed to remote, and you have the download link, 13:11:18
13 so you have access to the documents during the 13:11:21
14 deposition today. 13:11:23

15 BY MS. DASHE: 13:11:29

16 Q. And, Dr. Bodor, when was -- or have you 13:11:29
17 ever -- scratch that. 13:11:37

18 And for -- I apologize if I covered this 13:11:38
19 before, but I just want to make sure that the record is 13:11:40
20 clear. 13:11:43

21 Have you ever read through the whole 13:11:43
22 prosecution history for the `415 patent? 13:11:45

1	A. Not as I recall.	13:11:49
2	MS. DASHE: Emil, could you please go to page	13:11:51
3	9 of the PDF of Exhibit 1058?	13:12:05
4	BY MS. DASHE:	
5	Q. Okay. And again, Dr. Bodor, here we see a	13:12:16
6	declaration from the below-named inventors, the '415	13:12:20
7	patent, do you see that?	13:12:25
8	A. Yes.	13:12:27
9	Q. Okay. And you also see in the third paragraph	13:12:27
10	down, it says "I believe I am the original first and	13:12:33
11	either sole inventor or joint inventor of the subject	13:12:36
12	matter which is claimed and for which a patent is	13:12:41
13	sought"?	13:12:45
14	A. Yes.	13:12:45
15	MS. DASHE: Emil, could you please flip to the	13:12:46
16	next page and again center on the table that you	13:12:48
17	see?	13:12:52
18	BY MS. DASHE:	13:13:00
19	Q. So, Dr. Dandiker, do you see the table listing	13:13:00
20	inventors on page 10 of the PDF of Exhibit 1058?	13:13:04
21	A. I am not Dandiker.	13:13:14
22	You called me Dr. Dandiker.	13:13:17

1 Q. I was looking at "Dandiker" on the page. 13:13:19

2 Dr. Bodor, do you see the table listing the 13:13:23

3 inventors of the '415 patent -- 13:13:27

4 A. Yes. 13:13:31

5 Q. -- on page 10 of the PDF? 13:13:31

6 A. Yes.

7 Q. Okay. I apologize for that.

8 And so it shows that -- it shows your name at 13:13:31

9 the top of the table; right? 13:13:32

10 A. Yes. 13:13:34

11 Q. And that's your signature right underneath? 13:13:34

12 A. Yes. 13:13:36

13 Q. Okay. And then again it shows Dr. Dandiker's 13:13:37

14 name and signature? 13:13:41

15 A. Yes. 13:13:42

16 Q. Okay. 13:13:47

17 MS. DASHE: Okay, Emil, you can take down 13:13:47

18 Exhibit 1058. 13:13:49

19 And could you actually bring up, Emil, 13:13:53

20 Exhibit 1022 that we've already introduced, which 13:13:56

21 would be the Bodor PCT. 13:13:58

22 MR. MLAYER: I just wanted to say at the next 13:14:09

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1 break, would it be okay to email us that download 13:14:12
2 link? We're not sure we have it. 13:14:16
3 MS. DASHE: Chat, I believe, on the Zoom link. 13:14:18
4 MR. MLAYER: Oh. I am not in the Zoom because 13:14:21
5 I am here. So if you could just -- 13:14:23
6 MS. DASHE: Oh. 13:14:26
7 MR. MLAYER: -- send an email, that would be 13:14:26
8 great. 13:14:28
9 MS. DASHE: Emil -- Emil, is that possible, to 13:14:30
10 send that link to opposing counsel via their email? 13:14:33
11 REMOTE ZOOM TECHNICIAN WHITE: Yes, I can -- 13:14:39
12 excuse me, my apologies. Yes, I can -- I can 13:14:40
13 forward that to you, Counsel. 13:14:44
14 MS. DASHE: Thank you very much, Emil. 13:14:46
15 BY MS. DASHE: 13:14:48
16 Q. Okay. Dr. Bodor, we have your Bodor PCT up on 13:14:48
17 the screen. Do you see that? 13:14:56
18 A. Yes. Sort of. 13:14:57
19 Q. Okay. Sort of. Yeah. 13:15:00
20 MS. DASHE: Emil, could you just zoom into the 13:15:08
21 top part so Dr. Bodor can be sure that he's looking 13:15:10
22 at the right thing? 13:15:12

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1 BY MS. DASHE: 13:15:19

2 Q. You got your Bodor PCT, you can see it, 13:15:20

3 Dr. Bodor? 13:15:24

4 A. Yes. 13:15:24

5 Q. Okay. 13:15:24

6 MS. DASHE: And, Emil, could you please go to 13:15:29

7 page 25 of the PDF of Exhibit 1022? 13:15:31

8 And this is actually page 23 of the actual 13:15:36

9 Bodor PCT application. 13:15:41

10 Emil, could you please go down to the bottom 13:15:44

11 third of this page? 13:15:46

12 All right. Yeah. And then just zoom in on -- 13:15:55

13 starting on line 26, just kind of zoom in on that 13:15:58

14 bottom part so it's centered and everybody can see. 13:16:01

15 Okay. 13:16:05

16 BY MS. DASHE: 13:16:06

17 Q. And, Dr. Bodor, do you see starting page 23 of 13:16:06

18 your reference, 25 of the PDF, -- 13:16:09

19 A. Um-hum (affirmative). 13:16:13

20 Q. -- starting on line 24, it mentions two US 13:16:13

21 provisional patent applications, both entitled 13:16:20

22 "Cladribine Regimen for Treating Multiple Sclerosis," 13:16:24

1 filed on March 25th, 2004, and incorporated by reference 13:16:28
2 into the Bodor PCT, do you see that? 13:16:34
3 A. Yes. 13:16:36
4 Q. And you see that the specific application 13:16:37
5 numbers are left blank? 13:16:41
6 A. Yes. 13:16:42
7 Q. But in the brackets next to the blank space, 13:16:43
8 do you see some attorney docket numbers? 13:16:52
9 A. Yes. 13:16:54
10 Q. Those are IVAX attorney docket numbers? 13:16:54
11 A. I don't know. 13:17:02
12 Q. They do say IVAX, though; right? 13:17:03
13 A. Well, it starts with IVAXX0022 [sic]. So it 13:17:11
14 may be IVAX docket number. 13:17:18
15 Q. Before you filed your Bodor PCT application, 13:17:19
16 did you read those two provisional applications 13:17:32
17 referenced here? 13:17:37
18 A. No. 13:17:37
19 Q. And before you filed your Bodor PCT 13:17:37
20 application, did you have any understanding of the 13:17:44
21 contents or the subject matter of the two provisional 13:17:48
22 applications? 13:17:52

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1	MR. MLAYER: Looks like we're all back.	
2	MS. DASHE: Can people hear me?	13:19:12
3	THE WITNESS: Yes.	13:19:13
4	MR. MLAYER: Yes.	13:19:13
5	MS. DASHE: I cannot hear them.	13:19:13
6	MR. MLAYER: Yes, you --	
7	MS. DASHE: Ah, here we go.	13:19:15
8	MR. MLAYER: You disappeared for a minute	13:19:16
9	there, so.	13:19:17
10	MS. DASHE: Okay.	13:19:25
11	BY MS. DASHE:	13:19:25
12	Q. Let me -- let me repeat my question, then.	13:19:25
13	So do you know who wrote on page 23 of your	13:19:31
14	Bodor PCT application, lines 24 to the end of the	13:19:41
15	page, --	13:19:47
16	A. No, I don't.	13:19:48
17	Q. -- that we see here on the screen?	13:19:48
18	A. I don't.	13:19:50
19	Q. But it would have been one of the lawyers;	13:19:51
20	right?	13:20:00
21	A. Yes, it would have been one of the lawyers at	13:20:00
22	IVAX.	13:20:06

1 Q. Okay. Do you know who wrote any part of the 13:20:07
2 Bodor PCT application? 13:20:19
3 MR. MLAYER: Objection to form. 13:20:19
4 A. I really don't. 13:20:22
5 MS. DASHE: Emil, could you please go to the 13:20:38
6 first page of Exhibit 1022, please. 13:20:40
7 BY MS. DASHE: 13:20:51
8 Q. And, Dr. Bodor, do you see where it says 13:20:51
9 agents, Norman Stepno, for Burns, Doane or Doane or 13:20:55
10 however you pronounce that? 13:21:00
11 A. Yes. 13:21:02
12 Q. Did you communicate with Norman Stepno about 13:21:02
13 the Bodor PCT application? 13:21:07
14 MR. MLAYER: Objection, privileged. 13:21:10
15 I'll instruct the witness to answer a limited 13:21:12
16 answer to yes or no. 13:21:15
17 A. No. 13:21:18
18 MS. DASHE: Okay, Emil, you can take down 13:21:24
19 Exhibit 1022, please. 13:21:28
20 Thank you. 13:21:36
21 BY MS. DASHE: 13:21:37
22 Q. So, Dr. Bodor, in 2002, IVAX entered into an 13:21:38

1 agreement with Serono for the development of an oral 13:21:42
2 formulation of cladribine for the treatment of MS; 13:21:44
3 right? 13:21:47
4 A. I -- I don't know that for a fact until fairly 13:21:47
5 recently. I was not part of that kind of agreement. 13:21:56
6 Q. So just so the record is clear, then, and 13:22:04
7 because your audio broke up a little bit, you were not 13:22:07
8 personally involved with the agreement between IVAX and 13:22:11
9 Serono; is that right? 13:22:14
10 A. That's right. 13:22:16
11 Q. Okay. Do you at all know how the agreement 13:22:16
12 between IVAX and Serono came about? 13:22:27
13 A. I don't know. 13:22:30
14 Q. Okay. Now, as a part of IVAX and Serono 13:22:30
15 having an agreement, Serono also had a team that worked 13:22:41
16 on cladribine; right? 13:22:47
17 A. I assume so. I -- I don't know. 13:22:48
18 I mean, it was -- 13:22:49
19 Q. Did you ever communicate with -- oh, go ahead. 13:22:51
20 A. That was clearly part of the IVAX/Serono 13:22:53
21 agreement, which I was not part of. 13:22:58
22 Q. Okay. Did you ever communicate with anybody 13:22:59

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1	about cladribine at Serono?	13:23:03
2	A. No.	13:23:07
3	Q. Okay. And do you have any knowledge of what	13:23:07
4	individuals at Serono worked on cladribine?	13:23:12
5	A. Well, I do, because I saw the publication, the	13:23:18
6	paper, the study about this complex complex.	13:23:24
7	But I	13:23:33
8	Q. So aside from your thirdhand knowledge of a	13:23:33
9	public paper --	13:23:38
10	A. Yes.	13:23:40
11	Q. Go ahead.	13:23:40
12	A. Yeah, I didn't have any other --	13:23:41
13	Q. So aside -- oh, yeah.	13:23:43
14	Okay, I talked over you, so I'm just going to	13:23:46
15	reask my question so it's clear. And I'm sorry for	13:23:48
16	doing that, sir. So let me just ask one more time.	13:23:51
17	So aside from your thirdhand knowledge from a	13:23:53
18	public paper, did you have any other knowledge of who at	13:23:58
19	Serono worked on the cladribine project?	13:23:59
20	A. No.	13:24:02
21	MR. MLAYER: Objection to form.	13:24:03
22	BY MS. DASHE:	13:24:12

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1 Q. And do you have any knowledge of the joint 13:24:13
2 work allocation between IVAX and Serono beyond what's in 13:24:16
3 the agreement between the two parties? 13:24:20

4 MR. MLAYER: Objection to form. 13:24:24

5 A. Again, I don't know about the agreement. 13:24:25

6 In -- in 2004, when I was director of the 13:24:30
7 institute, indirectly some came through because -- it 13:24:38
8 must have been based on the agreement, how they have 13:24:42
9 done some clinical studies in Europe, but the blood 13:24:45
10 samples from the patients were sent to the institute to 13:24:54
11 be analyzed. 13:24:58

12 So I knew that there must be some kind of 13:25:02
13 bio- -- bioavailability study ongoing, but I didn't know 13:25:09
14 that it -- that it was an IVAX/Serono joint or whatever. 13:25:11

15 BY MS. DASHE: 13:25:21

16 Q. Some came through regarding clinical studies. 13:25:24
17 I'm not -- I guess I'm not quite following what you were 13:25:27
18 saying. Could you just maybe repeat that and explain 13:25:29
19 yourself a little bit more? 13:25:33

20 MR. MLAYER: Objection to form. 13:25:34

21 A. As I have seen in the reports given to me on 13:25:34
22 the cladribine project at the institute, it was clear 13:25:48

1 that four or three or four different clinical sites in 13:25:54
2 Europe were used to study single doses of complex 13:26:01
3 complex, and blood level -- blood samples were collected 13:26:09
4 and sent to the institute to be analyzed. 13:26:14

5 And this was the basis of the disclosures in 13:26:22
6 our patent. 13:26:27

7 BY MS. DASHE: 13:26:27

8 Q. Studies on single doses of the complex complex 13:26:27
9 and the blood samples, these were studies that were done 13:26:38
10 at IVAX? 13:26:42

11 A. No. These studies, as I said, I don't know 13:26:42
12 the sites, but it indicated in the report that sites in 13:26:45
13 Europe, in Belgium, in Poland, and I don't remember 13:26:51
14 where, but I don't know where sites and who all was 13:26:56
15 conducting the studies, who was the involved physician 13:26:59
16 and who was from part of IVAX or Serono, whoever. 13:27:03

17 So that -- I tell you what I know. 13:27:10

18 Q. ... have any first -- you don't have any 13:27:11
19 firsthand knowledge of the division of labor between 13:27:17
20 IVAX and Serono pursuant to the agreement between the 13:27:20
21 two companies; is that right? 13:27:23

22 A. I have -- no, I have no idea, because I didn't 13:27:25

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1 even know about the agreement. 13:27:27

2 Q. Okay. And so, then, you don't have any 13:27:32

3 specific recollection of anyone at Serono communicating 13:27:36

4 any dosing regimens for cladribine directly to you; 13:27:40

5 right? 13:27:44

6 A. Actually, I don't even know anybody from 13:27:44

7 Serono. I don't remember ever meeting anybody. 13:27:47

8 Q. You don't remember anybody from Serono 13:27:52

9 indicating a dosing regimen to you; right? 13:28:01

10 A. Or any, anything. I had no connection with 13:28:04

11 Serono. 13:28:10

12 MS. DASHE: A quick five-minute break or -- 13:28:14

13 Dr. Bodor, is that -- is that all right? 13:28:18

14 THE WITNESS: Sure. That's fine. 13:28:20

15 MR. MLAVER: Okay. We'll be back on at 1:33. 13:28:21

16 VIDEOGRAPHER ELMILKI: Okay. We are off the 13:28:24

17 record, and the time now is 1:28 p.m. 13:28:26

18 (Recess taken.) 13:28:29

19 VIDEOGRAPHER ELMILKI: We are back on the 13:45:25

20 record, and the time is now 1:45 p.m. 13:45:26

21 BY MS. DASHE: 13:45:30

22 Q. Dr. Bodor, did you discuss the substance of 13:45:32

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1 your testimony during the breaks today? 13:45:35

2 A. No. 13:45:36

3 Q. Okay. Now, going back to my line of 13:45:37

4 questioning before we broke, I just want to clean up a 13:45:42

5 few things here with the timelines, I'm a little bit 13:45:45

6 fuzzy on that. 13:45:49

7 Now, before 2004, were you aware of the 13:45:50

8 existence of any joint work between Serono and IVAX on 13:45:55

9 cladribine at that time? 13:46:01

10 A. No. 13:46:01

11 Q. And so then before you filed your Bodor PCT 13:46:01

12 application, were you aware of the existence of any 13:46:09

13 joint work between Serono and IVAX on cladribine at that 13:46:12

14 time? 13:46:17

15 A. No. 13:46:17

16 MR. MLAYER: Objection to form. 13:46:18

17 BY MS. DASHE: 13:46:18

18 Q. When did you first become aware that IVAX and 13:46:22

19 Serono had entered into a joint research agreement? 13:46:29

20 A. That's a good question. I don't think I ever 13:46:47

21 knew that there is an agreement. I was not involved. 13:46:49

22 So even though I -- I cannot say that I was ever aware 13:46:54

1 of the agreement until I read some publication 13:46:57

2 somewhere, press release or something like that. 13:47:06

3 Q. So the first time you became knowledgeable of 13:47:09

4 the specific agreement between IVAX and Serono was when 13:47:15

5 Merck approached you to write your declaration in this 13:47:20

6 case? 13:47:23

7 A. No, not really. I mean, as I said before, I 13:47:24

8 just assumed that there was an agreement because 13:47:30

9 somebody said, oh, no, IVAX sent the samples to be 13:47:36

10 analyzed at the institute of the -- that the 13:47:40

11 bioavailability clinical trials. 13:47:48

12 So I assumed that it was somebody from Serono 13:47:52

13 who was involved in sending the material, but I'm not 13:47:54

14 sure. It might -- 13:47:58

15 Q. And approximately when was that? 13:47:59

16 A. That was in 2003 sometime. 13:48:00

17 Q. Let -- well, hold on. So you -- you were not 13:48:13

18 aware of -- strike that. 13:48:18

19 When did you become aware specifically of the 13:48:23

20 joint research agreement between Serono and IVAX? 13:48:28

21 A. I never really saw a specific agreement. So 13:48:35

22 I -- 13:48:43

1 Q. My question is a little different, it's not 13:48:43
2 when did you see the agreement, it's when did you first 13:48:45
3 become aware that there -- of the existence of an 13:48:48
4 agreement between IVAX and Serono regarding cladribine? 13:48:51
5 A. It could be before the patent office interview 13:48:59
6 in 2008. 13:49:06
7 Q. But would it have been much before that? 2008 13:49:07
8 would be roughly the time that you first became aware 13:49:16
9 that -- 13:49:19
10 A. You see, I don't know about the agreement, 13:49:20
11 didn't know about the agreement, but could be that 13:49:23
12 somebody from Serono was involved with IVAX for the -- 13:49:27
13 for people and organized these clinical trials, which 13:49:35
14 was analyzed at the institute, but I was not in the know 13:49:41
15 about the agreement or kind of agreement. I still don't 13:49:48
16 know. I don't know what was -- 13:49:51
17 Q. So -- 13:49:54
18 A. -- what was the subject, -- 13:49:55
19 Q. So then -- 13:49:56
20 A. -- what was the conditions, what was the 13:49:57
21 terms, I don't know. 13:49:59
22 Q. Okay. So then the first time you became aware 13:49:59

1 of the existence of an agreement between IVAX and Serono 13:50:04
2 regarding cladribine was roughly in the 2008 time frame; 13:50:10
3 is that right? 13:50:16

4 A. Well, it -- yes. And if I think back, see, it 13:50:16
5 is the patent which we filed in 2004 ultimately was 13:50:22
6 assigned to R. Arens. So that's -- I think that is part 13:50:27
7 of the Serono or something like that. 13:50:33

8 But again, it is something that is not clear 13:50:38
9 to me, I was not involved in. 13:50:40

10 Q. So when did you first become aware -- strike 13:50:46
11 that.

12 What was -- when did you first become aware of 13:50:56
13 any existence of any joint cladribine work between IVAX 13:51:02
14 and Serono? 13:51:08

15 A. We are going back and forth on the same issue. 13:51:22

16 I did not know about IVAX/Serono agreement 13:51:24
17 whenever that happened, I don't know, 2003, '4. I 13:51:27
18 assume within that period there was some kind of 13:51:35
19 agreement because the material studied in Europe and the 13:51:37
20 material was sent to IVAX in Budapest for analysis, and 13:51:45
21 that's what was in my patent. 13:51:53

22 So that -- that shows the flavor, except I did 13:51:55

1 not know what was said on those involvement. I never 13:52:00
2 have met -- the Serono people never came to visit 13:52:04
3 Budapest and -- and that's all I can say. 13:52:10

4 Q. What material -- excuse me. 13:52:15

5 You referenced material that was sent to IVAX 13:52:21
6 in Budapest for analysis. What material was that? 13:52:26

7 A. I mentioned before, the blood samples drawn 13:52:28
8 from patients, in the hundreds of blood samples, based 13:52:33
9 on these crossover studies comparing various oral 13:52:37
10 formulation and subcutaneous or inter- -- intervenous, 13:52:45
11 which are in the patent. 13:52:51

12 Q. And who sent this material? 13:52:53

13 A. The clinical sites from Poland and whatever, I 13:53:01
14 don't know, they sent to the institute. Who organized 13:53:07
15 it and collect it, I don't know. I assume that my -- 13:53:13

16 Q. Okay, so you don't -- 13:53:16

17 A. My deputy director at the institute and the 13:53:17
18 clinical director, they knew where the samples come 13:53:22
19 from, but I never knew, it really didn't matter, it was 13:53:29
20 just one of the jobs they did. 13:53:34

21 Q. So you do not know who organized, collected, 13:53:38
22 and sent these blood sample materials to IVAX; is that 13:53:41

1 right? 13:53:47

2 A. Yes. That's correct. 13:53:48

3 Q. And so then do you know why these materials 13:53:50

4 were sent to IVAX? 13:53:58

5 A. They were sent for analysis. I told you I 13:53:59

6 knew about -- 13:54:03

7 Q. Well, what sort -- 13:54:03

8 A. Analytical methods were developed for 13:54:05

9 cyclodextrin from blood samples at the institute, and 13:54:17

10 then the samples were received and analyzed. 13:54:20

11 Q. But you don't know -- I'm just trying to -- to 13:54:23

12 get a frame of reference here. 13:54:27

13 These weren't samples that were being sent 13:54:32

14 from Serono? Or do you know? 13:54:34

15 A. I don't think it was Serono. It was the 13:54:35

16 clinical sites where the studies were done. Who 13:54:40

17 organized these clinical studies, I don't know, I just 13:54:43

18 assumed was done by IVAX with Serono or alone, but 13:54:47

19 primarily IVAX because the samples came to the IVAX 13:54:58

20 institute in Budapest. 13:55:05

21 Q. So does any of this have anything to do with 13:55:05

22 Serono's work on cladribine? 13:55:07

1 A. What work are you related -- the published 13:55:09
2 one? 13:55:16
3 The published work had important -- 13:55:16
4 Q. I'm just saying -- I guess I'm a little bit 13:55:18
5 confused is -- is all. 13:55:23
6 So this discussion we're having about samples 13:55:25
7 and analysis, does this relate to Serono's work on 13:55:27
8 cladribine at all, setting aside any publications or 13:55:31
9 anything like that? 13:55:35
10 MR. MLAYER: Objection, foundation. 13:55:36
11 A. Yeah, I don't know. You are assuming things 13:55:39
12 which I -- I don't know. Maybe these IVAX study of 13:55:41
13 the -- which entered in my patent, maybe those studies 13:55:50
14 were shared with Serono or they knew about it, I don't 13:55:54
15 know. But again, I was not involved with the 13:56:01
16 Serono/IVAX interaction. 13:56:05
17 MS. DASHE: Counsel, could we take a -- a 13:56:39
18 quick break? We're almost done, I just want to 13:56:41
19 make -- consolidate my notes and make sure we can 13:56:43
20 bring this home quickly. 13:56:46
21 MR. MCGUFFIN: That would be great. 13:56:48
22 MR. MLAYER: Let's go ahead and go off the 13:56:49

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1	record.	13:56:52
2	MS. DASHE: Okay.	13:56:52
3	VIDEOGRAPHER ELMILKI: Off the record, and the	13:56:53
4	time now is 1:56 p.m.	13:56:54
5	(Recess taken.)	13:57:06
6	VIDEOGRAPHER ELMILKI: We are back on the	14:00:38
7	record, and the time now is 2:00 p.m.	14:00:44
8	MS. DASHE: Good afternoon, Dr. Bodor. I have	14:00:49
9	no further questions for you.	14:00:51
10	THE WITNESS: Great.	14:00:54
11	Thank you.	14:01:00
12	MR. MLAVER: No questions for me. Let's go	14:01:02
13	off the record.	14:01:05
14	MS. DASHE: Thank you.	14:01:06
15	All right, thank you very much. Thank you for	14:01:06
16	your time, Dr. Bodor, I really appreciate it.	14:01:08
17	THE WITNESS: Thank you.	14:01:11
18	VIDEOGRAPHER ELMILKI: Wait. Wait.	14:01:12
19	We are off the record, and the time now is	14:01:13
20	2:01 p.m.	14:01:15
21	THE COURT REPORTER: Let me check, I don't	
22	have it in front of me, but I know someone is	

1 getting a rough draft. Is that both sides or is it
2 just -- 14:01:38

3 MR. MCGUFFIN: I mean, I don't think we've put 14:01:38
4 in our order. It would be great if we can get a 14:01:40
5 rough. 14:01:41

6 THE COURT REPORTER: Okay. This evening.
7 Okay.

8 MR. MCGUFFIN: Yeah. 14:01:42

9 MS. DASHE: Yes, us too as well, please, for 14:01:42
10 the Hopewell team. 14:01:45

11 THE COURT REPORTER: Okay. And regular time 14:01:48
12 on the transcript delivery? 14:01:49

13 MS. DASHE: Oh, regular versus expedited. 14:02:09

14 THE COURT REPORTER: Yes.

15 MS. DASHE: Is what you're saying?

16 THE COURT REPORTER: Yes.

17 MS. DASHE: Let me quickly confer with my team 14:02:22
18 here. 14:02:23

19 Expedited, please. Thank you. 14:02:30

20 THE COURT REPORTER: When would you like it? 14:02:32

21 MS. DASHE: Sometime today would be great if 14:02:36
22 you could. 14:02:44

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1 (Off the record from 2:03 p.m. to 2:03 p.m.) 14:03:00

2 THE COURT REPORTER: I could have it probably
3 in 24 hours.

4 (Off the record from 2:03 p.m. to 2:03 p.m.)

5 MS. DASHE: Final as soon as possible, please.
6 Expedited on the -- 24 hours on the full, nice,
7 pretty copy is wonderful.

8 THE COURT REPORTER: Good. Yes. I will have
9 you the draft before too long.

10 And would y'all like a copy -- expedited copy? 14:03:13

11 MR. MCGUFFIN: We'll take the same, yeah, 14:03:13

12 rough when it's ready, expedited when it's ready. 14:03:15

13 (Off the record from 2:03 p.m. to 2:03 p.m.) 14:03:33

14 MR. MLAYER: And I just forgot to say on the 14:03:34

15 record that we would like to designate the 14:03:35

16 transcript confidential under the protective order. 14:03:38

17 If you could have it marked that way. And that's 14:03:43

18 all for me. 14:03:45

19 (This deposition was concluded at 2:03 p.m.)

20

21

22

CERTIFICATE OF REPORTER - NOTARY PUBLIC

STATE OF FLORIDA)
COUNTY OF SARASOTA)

I, Nancy E. Paulsen, CRR, CRC, RPR, RSA certify
that I was authorized to and did stenographically report
the deposition of Nicholas Bodor, PhD, DSc, dhc, HoF and
that the foregoing pages are a true and complete record
of my stenographic notes taken during said deposition.

I, Nancy E. Paulsen, CRR, CRC, RPR, RSA
Notary Public within and for the State of Florida
do hereby certify:

That Nicholas Bodor, PhD, DSc, dhc, HoF, the
witness whose deposition is hereinbefore set forth,
was duly sworn by me before the commencement of such
deposition and that such deposition was taken before
me and is a true record of the testimony given by such
witness.

I further certify that the adverse party,
MERCK SERONO S.A., was represented by counsel at the

1 deposition.

2 I further certify that the deposition of
3 Nicholas Bodor, PhD, DSc, dhc, HoF, occurred at the
4 offices of Bodor Laboratories, 4400 Biscayne Boulevard,
5 11th Floor, Miami, Florida, 33137, on Thursday,
6 February 15, 2024, 9:34 a.m. to 2:03 p.m.

7 I further certify that I am not related to
8 any of the parties to this action by blood or
9 marriage, I am not employed by or an attorney to any
10 of the parties to this action, and that I am in no way
11 interested, financially or otherwise, in the outcome
12 of this matter.

13
14 Dated this 16th day of February, 2024.

15
16 

17 _____
18 NANCY E. PAULSEN, CRR, CRC, RPR, FPR

19 CERTIFICATE OF OATH
20
21
22

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Transcript of Nicholas Bodor, Ph.D., DSc, dhc, HoF
Conducted on February 15, 2024

1 STATE OF FLORIDA)

2 COUNTY OF SARASOTA)

3

4 I, the undersigned authority, certify that

5 Nicholas Bodor, PhD, DSc, dhc, HoF, personally appeared

6 before me on February 15, 2024, produced a Florida

7 driver's license for identification, and was duly sworn.

8

9 WITNESS my hand and official seal this 16th day of

10 February, 2024.

11

12

13

14



15

Nancy E. Paulsen, CRR, CRC, RPR

16

Notary Public

17

State of Florida at Large

18

My Commission Number: HH421500

19

Expires: September 17, 2027

20

21

22

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CONFIDENTIAL

Transcript of Nicholas Bodor, Ph.D., DSc, dhc, HoF

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Transcript of Nicholas Bodor, Ph.D., DSc, dhc, HoF

Conducted on February 15, 2024

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Transcript of Nicholas Bodor, Ph.D., DSc, dhc, HoF

Conducted on February 15, 2024

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Date: 2/15/2024


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

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Page	Line	Correction/Change and Reason
5	8	Typo. Address should read as "4400"
23	4	Typo. Replace "Academia" with "Academy"
23	5	Typo. Should read, "and so I needed an updated CV."
36	5-6	Typo. Should read, "because the molecules are very different,"
37	9	Typo. Delete "to"; replace with "through"
37	11	Typo. Delete "to"; replace with "through"
38	3	Typo. Delete "cy- --"
57	2	Typo. Delete "in"
58	19	Typo. Delete "a reactive"; Replace with "an active"
59	8	Clarification. "Sub-Q" is short for "subcutaneous"
76	15	Typo. Should read "did you communicate with"
77	4	Typo. Delete "Dentson" and replace with "Dentons"
84	17	Typo. Should read "I was never particularly"
91	17	Typo. Delete "relate --"; Replace with "related"
92	14	Typo. Should read "The only cladribine team at Ivax, I consider, was"
92	22	typo. Delete "--"; Replace with "work"
95	7	Misspoke. "Scripps"
95	8-9	Typo. Should read "for use in hairy-cell leukemia"
95	14	Typo. Delete "-- as it's"; Replace with "acid"
96	10	Typo. Delete "--"; Replace with "Waterford"
96	14-15	Typo. Should read "He looked at extending"

March 11, 2024

(Date)



(Signature)

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Date: 2/15/2024

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ACKNOWLEDGMENT OF DEPONENT

I, Nicholas Bodor, Ph.D., DSc, dhc, HoF, do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me and any corrections appear on the attached Errata sheet signed by me.

March 11, 2024

(Date)

Nicholas Bodor

(Signature)