UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

HOPEWELL PHARMA VENTURES, INC.

Petitioner,

v.

MERCK SERONO S.A.,

Patent Owner.

_____

IPR2023-00480 (Patent 7,713,947 B2)
IPR2023-00481 (Patent 8,377,903 B2)

_____

CONFIDENTIAL
VIDEOTAPED DEPOSITION OF
Nicholas Bodor, PhD, DSc, dhc, HoF

Pages 1 to 143

Thursday, February 15, 2024
9:34 a.m. - 2:03 p.m.

Bodor Laboratories
4400 Biscayne Boulevard
11th Floor
Miami, Florida

STENOGRAPHICALLY REPORTED BY:
NANCY E. PAULSEN, CRR, CRC, RPR

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I N D E X

E X H I B I T S

REMOTE ZOOM TECHNICIAN WHITE: Thank you to everyone for attending this proceeding remotely and in person. We anticipate things will run smoothly going forward. 09:32:33 09:32:33 09:32:36 09:32:41

Please remember to speak slowly and do your best not to talk over one another. Please be aware that we are recording this proceeding for backup purposes as well. 09:32:42 09:32:45 09:32:47 09:32:50

Any off-the-record discussion should be had away from the computer, and please remember to mute your mic for those conversations. 09:32:51 09:32:53 09:32:56

Please have your video enabled to help the reporter identify who is speaking, but if you are unable to connect video and you are connecting via phone, we just ask that you identify yourself each time before speaking. 09:32:58 09:33:01 09:33:04 09:33:07 09:33:09

I apologize in advance for any more technical-related interruptions. Thank you. 09:33:10 09:33:13

VIDEOGRAPHER ELMILKI: Here begins Media Number 1 in the videotape of Dr. Nicholas Bodor in the matter Hopewell Pharma Venture, Inc., versus Merck Serono, SA, in the Court of the United 09:33:20 09:33:23 09:33:26 09:33:33

States -- of the United States Patent and Trial Office, Case Number IPR2023-2 -- 00480 and IPR2023-00481. 09:33:38 09:33:41 09:33:53

Today is Thursday, February 15, 2024, and the time -- the time on the video monitor is 9:34 a.m. Eastern Time. The videographer for today is Lhassan Elmilki, representing Planet Depo, and the video deposition is taking place at 440 [sic] Biscayne Boulevard, Suite 980, Miami, Florida, ZIP Code is 33137. 09:33:55 09:34:01 09:34:04 09:34:10 09:34:13 09:34:17 09:34:22

Would the counsel please voice identify themselves and state whom them -- who -- who they represent. 09:34:23 09:34:26 09:34:29

MS. DASHE: I'm Christina Dashe from Sterne Kessler on behalf of Petitioner Hopewell. With me today remotely are Eldora Ellison, Olga Partington, and Tyler Lui, also of Sterne Kessler. And with me today in person with the witness is Madeleine Bond, also of Sterne Kessler. 09:34:29 09:34:32 09:34:36 09:34:43 09:34:45 09:34:48

MR. MLAVER: Good morning, this is David Mlaver of WilmerHale on behalf of the patent owner. With me are Asher McGuffin and by remote Willem de 09:34:50 09:34:52 09:34:56

Weerd of Merck KGaA. 09:35:03

THE COURT REPORTER: Doctor, would you raise your right hand, please. 09:35:18

Do you swear or affirm the testimony you are about to give will be the truth and nothing but the truth?

THE WITNESS: I do. 09:35:19

THE COURT REPORTER: Thank you.

THEREUPON,

NICHOLAS BODOR, PHD, DSC, DHC, HOF,

having been duly sworn to tell the truth, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. DASHE:

Q. Dr. Bodor, could you please state and spell your name for the record? 09:35:22 09:35:26

A. I am Nicholas Bodor, N-I-C-H-O-L-A-S, B-O-D-O-R. 09:35:27 09:35:34

Q. What is your address? 09:35:35

A. Home address is 10225 Collins Avenue, Apartment 1002, Bal Harbour, Florida, 33154. 09:35:36 09:35:41

Q. Have you ever been deposed before? 09:35:50

A. Not like this. 09:35:57

Q. ... this? 09:35:58

Have you ever sat for a deposition in any 09:36:02

capacity? 09:36:04

A. I have to ask opinion. About 40 years ago, I 09:36:05

was involved in a patent interference case and I was 09:36:14

deposed, but not like this, it was just the counsel on 09:36:20

both sides. 09:36:26

Q. The deposition 20 years ago -- or 40 years 09:36:26

ago, excuse me, in the patent interference case, have 09:36:35

you ever been deposed before? 09:36:39

A. No. 09:36:40

Q. Okay. I would like to go over some ground 09:36:40

rules for today's deposition. To start, I'll be asking 09:36:45

you some questions, and your counsel may object, but 09:36:47

it's important for the court reporter that we don't all 09:36:51

talk over one another today. 09:36:53

Is that all right? 09:36:56

A. Yes. 09:36:57

Q. And similarly, the court reporter cannot 09:36:58

really take down nonverbal answers, like shaking your 09:37:03

head or saying "um-hum." Can you please agree to give 09:37:06

verbal answers today? 09:37:11

A. Yes. 09:37:11

Q. Sometimes your counsel may object to my questions, but you still have to answer them unless counsel directs you not to answer them. Will you agree to abide by this rule? 09:37:12 09:37:16 09:37:19 09:37:22

A. Yes. 09:37:23

Q. Now, if at any point today you need a break, please let me know and I will try to accommodate, but the patent office rules require that you do answer any pending questions before we take a break. 09:37:23 09:37:29 09:37:32 09:37:35

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

A. Yes. 09:37:40

Q. If I ask a question today that you don't understand or need further clarification, will you agree to let me know, and I can try to clarify and ask a better question? 09:37:40 09:37:45 09:37:48 09:37:51

A. Yes. 09:37:52

Q. However, if you answer a question that I ask, I will assume that you understood it. Is that okay? 09:37:52 09:37:57

A. Yes. 09:38:01

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

basis for today's deposition, there might be some technical difficulties. If anything happens that interferes with your ability to understand or answer my questions, will you agree to let me know? 09:38:05 09:38:08 09:38:12 09:38:15

A. Yes. 09:38:16

Q. Now, the patent office rules require that I tell you that during my questioning today, you are not permitted to discuss your testimony with counsel unless you are discussing an issue relating to privilege. 09:38:20 09:38:23 09:38:26 09:38:31

Will you agree to abide by that rule? 09:38:32

A. Yes. 09:38:36

Q. ... why you cannot give truthful testimony today? 09:38:41 09:38:45

A. I -- I don't understand. 09:38:46

MR. MLAVER: Christina, the first few words of your question were cut off. 09:38:49 09:38:52

BY MS. DASHE: 09:38:53

Q. Is there any reason, Dr. Bodor, that you cannot give truthful testimony today? 09:38:54 09:38:57

A. No reason. 09:38:58

Q. Where are you located for today's deposition? 09:38:59

A. You mean the -- this room? It's -- 09:39:08

Q. Yes, please. 09:39:12

A. It's 4400 Biscayne Boulevard, on the 11th Floor, conference room. 09:39:13 09:39:18

Q. And besides the counsel and videographer and court reporter that already announced their presence on the record today, is there anyone else in the room with you? 09:39:21 09:39:26 09:39:28 09:39:31

A. No. 09:39:31

Q. Okay. Whose computer are you using for today's deposition? 09:39:32 09:39:36

A. I don't know. 09:39:38

Q. It's someone else's? 09:39:39

A. Yes. 09:39:42

Q. Do you have any files or programs open on your computer besides the deposition video platform? 09:39:42 09:39:49

A. I don't have any file with me. 09:39:53

Q. Do you have access to any other files or programs besides today's deposition video platform? 09:39:54 09:40:01

A. No. No. Not here. I don't have anything. 09:40:05

MR. MLAVER: Counsel, if it's helpful, we're using Planet Depo's computer. 09:40:08 09:40:11

MS. DASHE: Thank you. 09:40:15

BY MS. DASHE: 09:40:16

Q. Do you have any other electronic devices with you today, like a cell phone, things of that nature? 09:40:16 09:40:18

A. I have a cell phone. It was just put away by the counsel. 09:40:20 09:40:24

Q. You won't be accessing your cell phone to receive messages or phone calls during the deposition today? 09:40:25 09:40:29 09:40:31

A. I don't plan to, unless I am directed to do so. 09:40:31 09:40:40

But it is turned off, by the way. 09:40:40

Q. And including on breaks, you won't be accessing your cell phone for text messages, phone calls relating to the deposition today? 09:40:42 09:40:46 09:40:50

A. I don't plan to, no. 09:40:52

Q. Okay. Did you bring anything else with you to your deposition today? 09:40:54 09:41:00

A. No, just my medication if I need it. 09:41:01

MR. MLAVER: And, Counsel, we do have an otherwise unmarked copy of Dr. Bodor's declaration with us, if -- if that will assist. So we can provide that to him if -- if you need. 09:41:09 09:41:13 09:41:17 09:41:21

MS. DASHE: And, Counsel, that is unmarked, no notes or anything like that? 09:41:25 09:41:27

MR. MLAVER: That's correct. 09:41:28

MS. DASHE: Okay. 09:41:30

MR. MLAVER: And Ms. Bond has had an opportunity to inspect it and see if that's the case. 09:41:31 09:41:33 09:41:35

MS. DASHE: Okay. Thank you. 09:41:38

THE WITNESS: One more thing I want to ment- -- I don't know if my iWatch, it does matter? 09:41:39 09:41:41

MR. MLAVER: It -- not if you're not using it. 09:41:45

THE WITNESS: Okay. 09:41:48

BY MS. DASHE: 09:41:50

Q. To totally clarify, Dr. Bodor, will you agree not to access your cell phone, or your Apple watch, or any other electronic device to receive messages or discuss your deposition today? 09:41:51 09:41:55 09:41:57 09:42:00

A. Yes. 09:42:02

Q. Okay, thank you. 09:42:02

What did you do to prepare for this deposition? 09:42:09 09:42:11

A. I reviewed my deposition [sic] and my patent, 09:42:17

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

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

A. Yes, the Bodor PCT and the other two at-issue patents. 09:42:40 09:42:45

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

A. Yes. 09:42:47

Q. Yes? 09:42:47

A. Yes, patents which I am the sole inventor. Not with Dandiker. 09:42:57

Q. So you reviewed two issued US patents where you were the sole inventor? 09:42:57 09:43:03

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

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

A. No. 09:43:09

Q. You also said that you met with counsel yesterday. Who was that counsel? 09:43:09 09:43:18

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

Q. These patents that you reviewed, what were the titles of the patents that you reviewed? 09:43:33 09:43:35

A. I think it's "Cladribine Oral Formulation" or something like that. I don't know the exact title. 09:43:37 09:43:51

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

Q. Did you meet with your counsel yesterday? 09:43:55

A. Yes. 09:43:59

Q. I'm sorry, I talked over you. What did you say? 09:43:59 09:44:02

A. I think it was "Oral Formulation for Cladribine." 09:44:02 09:44:12

Q. For how long did you meet with counsel yesterday to prepare for today's deposition? 09:44:12 09:44:16

A. I would say it was about three to four hours. 09:44:19

Q. ... counsel, did you talk to anyone else regarding the substance of your deposition today? 09:44:22 09:44:31

A. No. 09:44:33

MS. DASHE: Emil, I would like you to introduce tab 1, which is the Bodor declaration, it's been marked as Exhibit 2054 in these proceedings. 09:44:44 09:44:46 09:44:49 09:44:53

REMOTE ZOOM TECHNICIAN WHITE: Stand by. 09:45:02

MR. MLAVER: Counsel, if we're going to ask questions about the declaration, is it all right if I hand him the paper copy of his declaration so he can refer to it? 09:45:03 09:45:05 09:45:07 09:45:10

MS. DASHE: That is just fine, Counsel. 09:45:11

MR. MLAVER: Thank you. 09:45:13

THE WITNESS: Thank you. 09:45:14

REMOTE ZOOM TECHNICIAN WHITE: Now showing what has been marked as Exhibit 2054. 09:45:19 09:45:20

BY MS. DASHE: 09:45:27

Q. Dr. Bodor, can you see the document on the screen as well? 09:45:28 09:45:30

A. Yes. 09:45:31

Q. And Exhibit 2054, this is your declaration that you submitted in Cases IPR2023-00480 and IPR2023-00481? 09:45:31 09:45:36 09:45:52

A. Yes. 09:45:52

Q. And if I refer to "this case" or "this proceeding," I will be collectively referring to both of these IPRs. Will you understand that? 09:45:53 09:45:55 09:45:59

A. Yes. 09:46:02

Q. If you could please turn to the last page of your declaration. 09:46:04 09:46:07

MS. DASHE: Which is page 13 of the PDF on the screen, Emil. 09:46:08 09:46:12

A. Yes. 09:46:15

BY MS. DASHE: 09:46:15

Q. Let me know when you're there. Okay. 09:46:15

And your declaration is signed and dated 09:46:19

December 21st, 2023? 09:46:24

A. Yes. 09:46:26

Q. That's your signature that we see on the page? 09:46:27

A. Yes. 09:46:30

Q. Do you stand by your testimony in your 09:46:31

declaration in this case? 09:46:38

A. Yes. 09:46:39

Q. You were asked to provide this declaration as 09:46:40

an inventor of the Bodor PCT patent application titled 09:46:43

"Oral Formulations to Cladribine"? 09:46:50

A. Yes. 09:46:53

Q. When were you first approached to provide your 09:46:54

declaration in this case? 09:46:56

A. I don't remember the exact date, but must have 09:47:00

been some -- sometime in December. 09:47:07

Late -- 09:47:08

Q. And that would be December 2023? 09:47:08

A. Yes. 09:47:11

Q. Who approached you to provide your declaration 09:47:11

in this case? 09:47:23

MR. MLAVER: If you recall who it was, you can answer, but I'll caution you not to reveal the substance of any communication with counsel. 09:47:23 09:47:25 09:47:27

A. I really don't remember with who. It was maybe my assistant who took the -- the message from the patent office -- I mean the law office. 09:47:30 09:47:35 09:47:43

BY MS. DASHE: 09:47:46

Q. So was it Merck or its counsel, then, that reached out to you to provide your declaration in this case? 09:47:46 09:47:51 09:47:53

Yes-or-no question. 09:47:53

A. I assume so. Yeah. 09:47:55

Q. So you have no reason to believe anybody besides Merck's counsel reached out to you to provide your declaration in this case; right? 09:48:01 09:48:04 09:48:08

A. No. 09:48:10

Q. How long did you spend preparing your declaration? 09:48:10 09:48:16

A. I think about four or five hours. 09:48:19

Q. Was that over the course of multiple days? 09:48:20

A. Yes. 09:48:29

Q. Do you know who else provided a declaration in 09:48:29

this case? 09:48:35

A. I -- I just learned that I believe Yogesh Dandiker did too, my coinventor. 09:48:41 09:48:47

Q. Just learned, how recently was that? 09:48:50

A. I think yesterday. 09:48:56

Q. And so you learned that from counsel? 09:48:57

A. Yes. 09:48:59

Q. And have you read Dr. Dandiker's declaration in this case? 09:49:00 09:49:07

A. No. 09:49:08

Q. And are you aware of anyone else who provided a declaration in this case? 09:49:08 09:49:16

A. No. 09:49:18

Q. And so because you just learned yesterday that Dr. Dandiker provided a declaration, you did not assist him in drafting his declaration; correct? 09:49:18 09:49:21 09:49:25

A. I didn't talk to Dr. Dandiker for 20 years. 09:49:28

Q. And so Dr. Dandiker also did not help you draft or provide your declaration -- 09:49:38 09:49:45

A. No.

Q. -- in this case; correct? 09:49:46

A. No. 09:49:47

Q. Besides counsel, did you communicate with anyone else in order to create your declaration? 09:49:47 09:49:52

A. My assistant in my office. 09:49:59

Q. And do you know what the substance of Dr. Dandiker's declaration is in this case? 09:50:00 09:50:07

A. No. 09:50:10

Q. So besides your assistants in your office and counsel, you did not communicate with anyone else in order to create your declaration in this case; right? 09:50:10 09:50:21 09:50:24

A. To prepare the declaration? 09:50:26

I did ask my former director of research at IVAX to send me files related to cladribine. 09:50:31 09:50:39

Q. And -- and who -- what was that person's name? 09:50:49

A. That is Dr. Peter Buchwald. 09:50:52

Q. Could you spell that for the record, please? 09:50:55

A. B-U-C-H-W-A-L-D. 09:50:58

Q. ... speak or communicate with Dr. Buchwald in the presence of counsel? 09:51:03 09:51:11

A. No. 09:51:12

Q. So what did you speak with Dr. Buchwald about specifically? 09:51:12 09:51:20

A. Just to send me -- actually, my assistant 09:51:20

called him to send me the -- if he has any file on the cladribine work we have done in the research institute in Hungary. 09:51:23 09:51:32 09:51:39

Q. Did he send you any files? 09:51:40

A. Yes. 09:51:42

Q. What files did he send you? 09:51:43

A. Monthly reports. 09:51:45

Q. Monthly reports? 09:52:00

A. Yes. 09:52:01

And two annual reports too. 09:52:02

Q. How did Dr. Buchwald send you these reports? Was it by email? Mail? Something else? 09:52:05 09:52:11

A. I think by email, and my assistant then made copies. 09:52:14 09:52:18

Q. ... is Dr. Buchwald? 09:52:18

THE COURT REPORTER: Excuse me, you broke off. This is the court reporter.

BY MS. DASHE: 09:52:18

Q. Where is Dr. Buchwald? 09:52:18

A. He is a professor at University of Miami. 09:52:37

Q. When you say University of Miami, that's in Florida? 09:52:42 09:52:54

A. Yes. 09:52:54

Q. And did you provide these monthly reports and annual reports Dr. Buchwald sent you to counsel? 09:52:54 09:53:07

A. Yes. 09:53:10

Q. And so -- and Dr. Buchwald, did he work with you on the cladribine project at IVAX? 09:53:10 09:53:28

A. No. No, he did not. 09:53:33

Q. How would Dr. Buchwald have had these files, then? 09:53:34 09:53:39

A. Because he was my assistant at IVAX. He had the position of assistant director of research. And so he was contact in between the researchers in Budapest and me and my assistants. So he was part of my team, but he did not work on cladribine here, I don't believe he had any involvement of any kind. 09:53:39 09:53:46 09:53:52 09:53:59 09:54:03 09:54:09

Q. ... a cladribine team at IVAX? 09:54:13

A. Yes, well, there was not really a team, but most of the work was done, actually, at Budapest, at the research institute, where they developed the analytical methods and then the pharmacokinetic and bioavailability studies. 09:54:21 09:54:30 09:54:36 09:54:39 09:54:48

But Buchwald was not part of it. 09:54:50

Q. ... talk to Dr. Buchwald about your cladribine -- 09:54:51 09:54:55

A. He was not part of this. 09:54:55

Q. Okay. So Dr. -- so Dr. Buchwald was not part of the actual cladribine research? 09:54:56 09:54:59

A. Right. 09:55:01

Q. He was part of -- 09:55:02

A. Correct. 09:55:04

Q. Okay. And when you reached out to Dr. Buchwald about your cladribine files, did you discuss those files with him at all? 09:55:04 09:55:07 09:55:12

A. No. 09:55:19

Q. Their substance? 09:55:20

A. No. 09:55:22

Q. And before you reached out to Dr. Buchwald about these documents, when was the last time you had spoken with him? 09:55:22 09:55:25 09:55:28

A. Last fall sometime. His father, who was my best friend at the university, passed away, and then we talked about his memories and... 09:55:29 09:55:43 09:55:50

Q. I'm sorry to hear that. 09:55:57

Besides reaching out to Dr. Buchwald about his 09:55:58

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

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

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

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

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

Q. Yeah. 09:56:50

Do you know if Merck provided these -- 09:56:51

A. Merck. Yeah. 09:56:53

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

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

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

A. Yes. 09:57:15

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

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

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

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

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

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

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

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

A. Yes. 09:58:51

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

reports are from Dr. Buchwald? 09:58:58

A. Yes. 09:59:00

Q. And what is that? 09:59:00

MR. MLAVER: Objection, form. 09:59:03

You can answer. 09:59:07

A. I mentioned before that the bioavailability and pharmacokinetic studies were done by the research institute in Hungary. And these monthly and then annual report related to the findings of animal and then human studies of the very formulation which we developed in my -- in our patent. 09:59:08 09:59:16 09:59:24 09:59:27 09:59:34 09:59:45

BY MS. DASHE: 09:59:46

Q. That formulation you're referring to in your patent in your declaration is the complex -- 09:59:46 09:59:49

A. Complex --

Q. -- cladribine-cyclodextrin complex; correct? 09:59:55

A. Yes. 09:59:59

Q. Okay. And that's the formu- -- that -- scratch that. 09:59:59 10:00:02

The complex cladribine-cyclodextrin complex described in your Bodor PCT application and your declaration, that's your invention; right? 10:00:02 10:00:09 10:00:12

A. That's my invention and Dr. Dandiker's invention. 10:00:15 10:00:21

Q. And you just referred to bioavailability and pharmacokinetic studies related to the findings of animal and human studies. What were those findings? 10:00:21 10:00:29 10:00:34

A. Well, actually, all of those findings or almost all you can find in our patents, in the PCT patent. 10:00:37 10:00:39 10:00:47

Q. The reports you received from Dr. Buchwald contain study results that were ultimately disclosed in your Bodor PCT application? 10:00:48 10:00:53 10:00:58

A. Correct. 10:01:01

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

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

Q. And how many documents did you receive from Dr. Buchwald? 10:01:15 10:01:24

A. As I remember, about five or six monthly reports, or -- monthly, and two annual reports in English. 10:01:26 10:01:40 10:01:42

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

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

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

A. Yes. 10:02:04

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

A. Yes. 10:02:35

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

A. If I may disclose, they were some attempts to modify cladribine structure. [redacted] 10:02:39 10:02:45

[redacted] 10:02:50

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

A. Modify, yes. 10:02:57

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

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

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

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

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

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

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

A. Yes. 10:03:55

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

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

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

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

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

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

BY MS. DASHE: 10:04:38

Q. Dr. Bodor, just to reask my question here for the record, what substituent were you trying to introduce into cladribine? 10:04:39 10:04:44 10:04:46

MR. MLAVER: Objection, scope. Objection, relevance. 10:04:48 10:04:49

THE WITNESS: But I can answer? 10:04:50

MR. MLAVER: You can answer. 10:04:51

A. [redacted] 10:04:52 10:05:01 10:05:06

[redacted] --

BY MS. DASHE: 10:05:09

Q. Attempts related to -- 10:05:09

A. [redacted] 10:05:11

Q. I'm sorry, could you repeat that, Dr. Bodor? I did not mean to talk over you. 10:05:16 10:05:19

A. [redacted] 10:05:20 10:05:23 10:05:31

Q. And what indication -- scratch that. 10:05:33

This formulation you were trying to make, was this for treating multiple sclerosis? 10:05:36 10:05:39

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

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

[redacted] 10:06:07

[redacted] 10:06:10

Q. [redacted] 10:06:18

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

A. [redacted] 10:06:25

[redacted] 10:06:31

[redacted] 10:06:38

BY MS. DASHE. 10:06:39

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

A. No. 10:07:02

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

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

A. I did not talk about anything, just had him send the -- everything he had on -- on the cladribine. 10:07:15 10:07:18

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

Did you otherwise communicate with anyone in order to create your declaration besides counsel and your discussions, communications with Buchwald to get the reports? 10:07:31 10:07:33 10:07:36 10:07:41

A. No. 10:07:41

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

A. No. 10:07:54

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

A. No. 10:07:59

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

A. No. 10:08:07

Q. And just in case I'm mispronouncing these names, I'll just go through those questions again, but I'll spell the names for you in case -- to clarify anything. 10:08:07 10:08:29 10:08:32 10:08:33

So have you heard of Dr. Alain Munafo, spelled A-L-A-I-N, space, M-U-N-A-F-O? 10:08:33 10:08:37

A. Still no. 10:08:45

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

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

A. No. 10:09:01

Q. Have you heard of Dr. Fred Lublin, spelled F-R-E-D, space, L-U-B-L-I-N? 10:09:01

10:09:07

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

Just for curiosity, -- 10:09:13

Q. Were -- 10:09:15

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

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

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

A. Yes. 10:09:27

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

10:09:33

A. I would have to ask my assistant, but I guess maybe five or six hours. 10:09:36

10:09:39

Q. So the amount of money that you are either owed or have received for your work on this case is five or six hours times $1,250 an hour, roughly? 10:09:47

10:09:50

10:09:52

A. Yes. 10:09:57

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

10:10:09

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

Q. Do you know approximately how much money that will be? 10:10:13 10:10:16

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

Q. But I think you said you spent a few hours yesterday with counsel and then you've spent however many hours today on your deposition. 10:10:21 10:10:26 10:10:29

Is the amount of money you will be owed just the number of hours that you spent preparing and sitting for this deposition times your current rate of $1,250 an hour? 10:10:31 10:10:33 10:10:35 10:10:40

A. Yes. 10:10:40

Q. Have you ever received any other compensation from Merck or related entity? 10:10:41 10:10:48

A. No. 10:10:50

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

Q. Have you -- 10:10:50

A. No, no. In 2008, the very patent was defended, I went to the patent office, had an interview with the patent examiner with the counsel, which ultimately led to the allowance of the patent. 10:10:55 10:11:04 10:11:09 10:11:13

So at that time, I was also compensated. I don't remember what was that time my hourly rate. 10:11:16 10:11:20

Q. When you say the patent, do you mean the Bodor -- the Bodor PCT patent? 10:11:26 10:11:31

A. Yes. 10:11:34

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

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

Q. Do you recall how much time you spent on defending the Bodor PCT application in front of the patent office? 10:11:39 10:11:49 10:11:52

A. I don't know, but all in all, going there and talking and then -- probably there is a couple of days. 10:11:53 10:11:56

Q. What was discussed during your interview with the patent office in 2008 about your Bodor PCT? 10:11:58 10:12:07

A. Well, as I remember, it's really essence of the patent that is a combination of two types of complexes, inclusion and noninclusion complexes, and this forms a unique complex complex. And that was really the essence of the discussions. 10:12:13 10:12:16 10:12:22 10:12:28 10:12:34

Q. Was your complex complex in your Bodor PCT -- actually, scratch that. 10:12:38 10:12:50

The complex complex you are referring to is the complex cladribine-cyclodextrin complex; right? 10:12:51 10:12:52

A. Yes. 10:12:58

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

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

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

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

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

which can be incorporated in -- in cyclodextrin in this way. 10:14:53 10:14:58

Q. Did you want to increase the amount of cladribine in your complex? 10:15:00 10:15:04

A. Yes. Yeah, because the molecule are very difference, and more the ratio of the incorporation would require large amounts of cyclodextrin if that would be -- if the inclusion complex would be the only one. 10:15:06 10:15:13 10:15:18 10:15:23 10:15:27

Q. ... something about requiring large amounts of cyclodextrin. 10:15:28 10:15:41

Just so that I understand, were you trying to increase or decrease the amount of cyclodextrin in your formulation? 10:15:43 10:15:48 10:15:54

A. Yeah, the latter, to the cladribine ratio want to decrease so you won't have a gigantic pill to take. 10:15:54 10:15:58

Q. Why would you want to decrease the relative amount of cyclodextrin in your formulation? 10:16:05 10:16:08

A. There are several reasons, but one of the main reason would be to make a saturated complex in which the cladribine is in the highest thermodynamic activity stage, so when taken as a pill and gets in contact with 10:16:13 10:16:15 10:16:26 10:16:32

the mucosa, the fact that it's in the highest thermodynamic activity stage would allow the dilution to drive the drug to the mucosa, so facilitate absorption. 10:16:39 10:16:45 10:16:50

Q. Why would you want a high thermodynamic state for the cladribine? 10:16:56 10:17:01

MR. MLAVER: Objection to scope and relevance. You can answer. 10:17:03 10:17:08

A. Well, just, as I said before, to optimize absorption to the mucosa, intestinal mucosa. 10:17:08 10:17:17

BY MS. DASHE. 10:17:22

Q. ... optimizing the absorption of cladribine to the intestinal mucosa do? Like, why do you want to do that? 10:17:22 10:17:30 10:17:35

MR. MLAVER: Objection to scope and relevance and also to the extent this calls for expert testimony. 10:17:35 10:17:37 10:17:40

MS. DASHE: And, Counsel, again, "calls for expert testimony" is not permitted under the PTO rules. So single-word objections. 10:17:40 10:17:43 10:17:46

BY MS. DASHE: 10:17:49

Q. But, Dr. Bodor, if you would like me to repeat my question, I can. 10:17:49 10:17:54

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

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

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

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

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

BY MS. DASHE: 10:19:10

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

MR. MLAVER: Objection, form. 10:19:28

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

results compared to injectable forms. You can achieve more than 30 percent, that was the objective, to achieve more than 30 percent bioavailability, and you -- we can read the report, something like 39 or so percent. 10:19:33 10:19:38 10:19:41 10:19:48

BY MS. DASHE: 10:19:51

Q. ... objective to achieve 30 percent bioavailability? 10:19:51 10:19:56

A. More than 30 percent I say. That was the objective. 10:19:57 10:20:01

Q. And why was the objective to achieve more than 35 -- or, excuse me, scratch that. 10:20:01 10:20:04

Why was the objective to achieve more than 30 percent bioavailability? 10:20:06 10:20:10

MR. MLAVER: Objection to scope and relevance. 10:20:13

A. Because that would make it practical to have a -- an oral formulation. Because below that, they have a 10 percent or so percentage of bioavailability, that's -- and it cannot be a successful drug. 10:20:16 10:20:20 10:20:23 10:20:29

BY MS. DASHE: 10:20:32

Q. ... successful drug? 10:20:36

A. Successful. 10:20:37

Q. Yeah, what do you mean by successful drug? 10:20:38

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

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

A. Yes. 10:21:16

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

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

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

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

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

A. Yes. 10:22:03

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

A. That one patient shows 10 percent, the other 50 percent. That cannot be a successful drug because the variability by this patient who is treated is too much, you cannot assure the desired blood concentration. 10:22:13 10:22:16 10:22:19 10:22:25

Q. Complex cladribine-cyclodextrin complex described in your Bodor PCT application, you described that as achieving reduced interpatient variation and that's a successful drug; right? 10:22:33 10:22:39 10:22:42 10:22:52

A. Yes. 10:22:53

MR. MLAVER: Objection to --

Just let me put in my object and then you can answer. 10:22:54 10:22:54 10:22:55

Objection to form, scope, relevance. 10:22:56

You can answer. 10:23:01

A. Yes. 10:23:02

And if you look in the patent, we have done a very important demonstration of the reduction of the interpatient variation, it's called crossover pharmacokinetic studies, which means a group of patients who are treated the different oral formulations and the IV, so the very patients could serve as its own control. Then you can compare the interpatient and intrapatient 10:23:02 10:23:08 10:23:11 10:23:19 10:23:30 10:23:34 10:23:40

variations. 10:23:45

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

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

BY MS. DASHE: 10:23:57

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

application; right? 10:23:57

A. Yes. Yes. 10:23:57

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

concentrations and this reduction in interpatient 10:24:01

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

absorption of cladribine? 10:24:08

MR. MLAVER: Objection, scope, foundation. 10:24:10

You can answer. 10:24:15

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

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

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

BY MS. DASHE. 10:24:31

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

of the drug? 10:24:37

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

like to repeat myself. 10:24:48

The interpatient variations means that 10:24:50

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

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

A. Of course. 10:25:36

MR. MLAVER: Objection, form, scope, relevance. 10:25:37 10:25:39

You can answer. 10:25:41

A. Of course. 10:25:41

BY MS. DASHE: 10:25:42

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

MR. MLAVER: Objection, form, scope, 10:26:12

foundation. 10:26:14

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

interpatient variation. 10:26:21

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

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

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

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

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

BY MS. DASHE: 10:26:46

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

Bodor Laboratories? 10:26:57

A. Yes. 10:26:58

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Q. Okay. 10:28:38

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

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

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

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

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

Yes. Okay. 10:29:26

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

And maybe make that full-sized? It's kind of cutting off the top and the bottom. Or, rather, shrink it so that the whole page shows up on the screen? Thank you. 10:29:35 10:29:37 10:29:40 10:29:43

BY MS. DASHE:

Q. And, Dr. Bodor, this Appendix A, this is your CV? 10:29:45 10:29:48

A. Yes. It looks like it. 10:29:51

Q. And your CV has, we see, 144 pages? 10:29:53

A. I understand, yes. 10:30:01

Q. Okay. And when did you last update this CV? 10:30:02

A. I don't believe I know, but my assistant always puts on the new publications or patents or awards or whatever happens. Anytime some important event happens, she updates it. 10:30:08 10:30:16 10:30:21 10:30:27

Q. Has this CV -- or scratch that. 10:30:29

Was this CV updated before December 2023, when you started working on your declaration? 10:30:38 10:30:42

MR. MLAVER: Objection, form. 10:30:44

You can answer. 10:30:50

A. I don't know when was the last time updated. 10:30:51

MS. DASHE: Emil, could you please go to page 10:31:00

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

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

BY MS. DASHE: 10:31:12

Q. So, Dr. Bodor, this is a list of your publications and your CV. Do you see where it says last update, April 21, 2023? 10:31:12 10:31:15 10:31:19

A. Yes. 10:31:21

Q. Does that help you recall when your CV was last updated? 10:31:22 10:31:30

A. Well, no, not really. That just means the list of publications updated. Some other things could have happened, I don't remember. 10:31:30 10:31:33 10:31:46

I think I achieved my lifetime achievement award last May, so that's included somewhere. 10:31:46 10:31:50

But this update is mainly for the list of publication. 10:31:53 10:31:55

Q. Was your CV -- was this CV updated before December of 2023? 10:31:56 10:32:09

MR. MLAVER: Objection, form. 10:32:10

BY MS. DASHE: 10:32:11

Q. Scratch that. 10:32:12

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

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

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

Q. Did... 10:32:31

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

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

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

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

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

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

So -- thank you. 10:33:18

BY MS. DASHE: 10:33:20

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

A. Yes. 10:33:29
Q. -- here? 10:33:29
A. Yes. 10:33:33
Q. And I believe you're the named inventor on 10:33:33
over 300 patents; is that right? 10:33:36
A. Yes. 10:33:37
MS. DASHE: Emil, could you please go to page 10:33:41
73 of the PDF, we'll still be on the list of 10:33:48
patents. 10:33:51
BY MS. DASHE: 10:34:02
Q. Okay. And do you see item 228, "N. Bodor, Y. 10:34:03
Dandiker, 'Oral Formulations of Cladribine,' US Patent 10:34:08
7,888,328"? Do you see that? 10:34:12
A. Yes. 10:34:16
Q. And if I refer to this as the `328 patent, 10:34:16
you'll know what I'm referring to? 10:34:26
A. Yes. 10:34:28
Q. And is this `328 patent -- you refer to this 10:34:28
patent in your declaration; right? 10:34:33
A. Yes. 10:34:34
MS. DASHE: So then if we flip to the next 10:34:35
page, Emil, please. 10:34:37

BY MS. DASHE: 10:34:44

Q. So this would be page 60 of your CV. If we go to item 252, towards the bottom of the page there, do you see, Dr. Bodor, "N. Bodor and Y. Dandiker, 'Oral Formulations of Cladribine,' US Patent 8,785,415"? 10:34:44 10:34:49 10:34:56 10:35:00

A. Yes. 10:35:06

Q. Okay. If I refer to this patent as the `415 patent, you'll know what I'm referring to? 10:35:09 10:35:15

A. Yes. Yeah. 10:35:21

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

MR. MLAVER: Yeah, it would be helpful. The screen is -- is maybe 3 feet away from Dr. Bodor, so it's -- 10:35:24 10:35:25 10:35:29

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

MR. MLAVER: It would be helpful if we could zoom in on the things we're -- we're talking about. 10:35:30 10:35:32

MS. DASHE: Yes. 10:35:33

Emil, could you go -- have it zoomed in on item 252? 10:35:35 10:35:41

Thank you.

BY MS. DASHE:

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

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

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

BY MS. DASHE: 10:37:53

Q. Dr. Bodor, can you see that text on the top paragraph all right? 10:37:54 10:37:56

A. Yes. 10:37:56

Q. Okay. Do you see in the middle "Dr. Bodor's US, and associated European and US, patents, 'Oral Formulations of Cladribine'"? Do you see that? 10:37:58 10:38:04 10:38:09

MS. DASHE: Emil, if you could highlight that for the -- for the witness. 10:38:16 10:38:17

A. Yes. Yes. 10:38:18

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

A. Yes. 10:38:20

BY MS. DASHE: 10:38:21

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

Okay. And so the -- your US patents entitled "Oral Formulations of Cladribine" referred to here are those two patents we just looked at in your CV, the `328 and `415 patent; correct? 10:38:22 10:38:26 10:38:30 10:38:33

A. I assume so, except European patents mentioned also here. 10:38:38 10:38:45

Q. Right. But the specific US patents referred to here -- 10:38:45 10:38:47

A. Yes. 10:38:48
Q. -- are the `328 and `415 patent? 10:38:49
A. Yeah. 10:38:51
Q. Okay.
MS. DASHE: You can take that down, Emil. 10:38:55
Actually, we've been going for about an hour, 10:38:58
Dr. Bodor, if you would like to take a brief break. 10:39:01
THE WITNESS: I appreciate it. 10:39:04
MS. DASHE: Okay. I think we can take a 10:39:05
ten-minute break. 10:39:08
MR. MLAVER: Okay. 10:39:10
VIDEOGRAPHER ELMILKI: Okay. We off of the 10:39:10
record, the time now is 10:39 a.m. 10:39:12
(Recess taken.) 10:39:17
VIDEOGRAPHER ELMILKI: We are back on the 10:51:33
record, and the time now is 10:51 a.m. 10:51:43
BY MS. DASHE: 10:51:48
Q. Welcome back, Dr. Bodor. 10:51:48
A. Yes. 10:51:49
Q. During your -- during the break, did you speak 10:51:50
with counsel about the substance of your testimony? 10:51:53
A. No. 10:51:54

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

A. Yes. 10:52:12

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

MR. MLAVER: Objection, form. 10:52:19

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

BY MS. DASHE: 10:52:36

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

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

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

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

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

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

A. Drug substance. 10:53:37

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

A. For example, cladribine is a drug substance, a chemical. 10:53:39 10:53:43

They call it anything -- 10:53:43

Q. ... of formulations because your complex cladribine-cyclodextrin complex, that's a formulation; right? 10:53:43 10:53:58 10:53:59

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

Q. Okay. And have you developed formulations or drug substances for different routes of administration? 10:54:01 10:54:07

A. Yes, for a number of my new chemical drugs, I did develop some formulations, yes. 10:54:10 10:54:15

Q. What routes of administration did you develop for formulations? 10:54:17 10:54:24

MR. MLAVER: Objection, form. 10:54:25

You can answer. 10:54:33

A. Yeah, for example, ophthalmic drugs, developed eyedrops to be suspension, or gels for topical use on the skin, or brain-targeted drugs using the redox system 10:54:34 10:54:37 10:54:47

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

BY MS. DASHE. 10:55:07

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

A. Oral -- 10:55:11

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

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

BY MS. DASHE: 10:55:28

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

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

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

out confusing. 10:56:13

So you have developed drugs for the oral route of administration; correct? 10:56:16 10:56:21

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

Q. Okay.

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

Q. What was your prime interest or main field in your career? 10:56:26 10:56:30

A. There are several of them, but I say brain-targeting drugs, ophthalmic drugs, and then topical to be dermatological, like my most recent one is for hyperhidrosis, and that's a topical use. 10:56:31 10:56:33 10:56:39 10:56:46

Q. And you developed the drug substances -- scratch that. 10:56:54 10:56:59

Your focus was on developing the drug substances, not as much developing the drug formulations; right? 10:56:59 10:57:01 10:57:05

A. My prime -- yes. My prime objective is to develop a reactive new chemical entity for a specify disease. And then, of course, you have to develop formulation to be used for that particular reason. 10:57:06 10:57:09 10:57:14 10:57:17

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

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

A. Yes. Yes. 10:57:28

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

A. Yes. 10:57:31

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

A. Parenteral is different injectable, you know, subQ or intravenous, intramuscular. 10:57:38

Q. Are there any benefits of the oral route of administration over an injectable or parenteral route? 10:57:44

MR. MLAVER: Objection to scope, form, foundation. 10:57:51

A. I say convenience. 10:58:00

BY MS. DASHE: 10:58:04

Q. What do you mean by convenience? 10:58:05

A. People rather take a pill than get injected. 10:58:06

Q. And does that increase patient compliance with taking their medications? 10:58:10

A. Yes. 10:58:11

MR. MLAVER: Objection to scope and foundation and form. 10:58:20

You can answer. 10:58:23

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

BY MS. DASHE: 10:58:33

Q. Are there any cost savings for the oral route of administration over injectables or parenterals? 10:58:35 10:58:39

MR. MLAVER: Objection to scope, form, and foundation. 10:58:45 10:58:47

A. Yes. 10:58:47

BY MS. DASHE: 10:58:48

Q. And would the oral route of administration be less painful or less uncomfortable than an injectable or parenteral medication? 10:58:54 10:58:57 10:59:03

MR. MLAVER: Objection to scope, form, and foundation. 10:59:05 10:59:07

A. Generally, yes. 10:59:07

BY MS. DASHE: 10:59:08

Q. Now, the oral medicines can be given in a slow or extended-release form; right? 10:59:08 10:59:17

A. Yes. 10:59:18

Q. Is that possible with an injectable or parenteral medication? 10:59:19 10:59:26

A. Yes. 10:59:27

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

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

convenience, or cost, or compliance, stability. 11:00:39
Stability. 11:00:49
BY MS. DASHE. 11:00:52
Q. ... stability? 11:00:55
MR. MLAVER: I'm sorry, I think your question 11:00:58
was cut off again. 11:00:59
MS. DASHE: Oh, I'm sorry. 11:01:01
BY MS. DASHE: 11:01:02
Q. You refer to stability. What is stability? 11:01:02
A. A molecule, which is a drug, can undergo 11:01:05
degradation. And if it's in a solution, it's more 11:01:13
likely to degrade than if it's in a solid form. In a 11:01:22
solid form, it's more stable. 11:01:31
So the shelf life is different. 11:01:33
Q. ... specific formulation of a drug impact its 11:01:36
stability? 11:01:43
A. Yes. 11:01:43
Q. How so? 11:01:44
MR. MLAVER: Objection to scope, foundation, 11:01:47
form. 11:01:51
A. If you have a drug which is an ester, I am 11:01:51
specifically thinking of something, which would be 11:01:57

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

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

BY MS. DASHE. 11:02:21

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

MR. MLAVER: Objection to scope. 11:02:26

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

BY MS. DASHE: 11:02:42

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

MR. MLAVER: Objection to scope, foundation, relevance. 11:02:51 11:02:53

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

BY MS. DASHE: 11:03:03

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

reasons in mind right now? 11:03:07

MR. MLAVER: Objection to scope, relevance, to form. 11:03:08 11:03:12

A. The primary is really convenience and the stability. You know, if it's a liquid formulation, it has to be sterile. If it's a tablet, it doesn't have to be sterile, you have -- you can handle it by hand. 11:03:12 11:03:20 11:03:23 11:03:29

BY MS. DASHE. 11:03:32

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

A. Oh, yes. 11:03:41

MR. MLAVER: Objection to scope, relevance, form. 11:03:42 11:03:44

You can answer. 11:03:46

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

BY MS. DASHE: 11:03:53

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

You referred to dosing regimen a number of times in your declaration. What do you mean by dosing regimen? 11:03:55 11:04:00 11:04:04

A. Well, dosing regimen in general, I say it's the frequency of taking the -- a pill, or an injection, or eyedrops, or whatever, that is the dosing regimen. 11:04:04 11:04:10 11:04:21

Q. ... or days you might have to take the formulation, something like that? 11:04:26 11:04:34

A. Yes. 11:04:35

Q. Okay. Does the number of days you have to take the drug in a dosing regimen matter? 11:04:35 11:04:40

MR. MLAVER: Objection to form, foundation, scope. 11:04:44 11:04:47

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

BY MS. DASHE: 11:04:51

Q. Well, what about for cladribine, does the number of days you would take cladribine in a dosing regimen matter? 11:05:02 11:05:07 11:05:09

MR. MLAVER: Objection to form, foundation, scope. 11:05:10 11:05:12

A. Well, let me tell you something about this, treatment, medical treatment and dosing regimen is really not my field. And I don't have the expertise to comment on the value or variation of dose regimens. 11:05:13 11:05:21 11:05:24 11:05:32

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

BY MS. DASHE: 11:05:47

Q. Do you know if it can matter, the number of days that one takes the cladribine in a dosing regimen? 11:05:49 11:05:51

MR. MLAVER: Objection to form, foundation, scope. 11:05:56 11:05:57

A. I didn't understand the question. Can you repeat the question? 11:05:58 11:06:03

BY MS. DASHE:

Q. Of course. 11:06:05

Do you know if it can matter, the number of days that one takes cladribine in a dosing regimen? 11:06:06 11:06:09

MR. MLAVER: Same objections. 11:06:12

A. Again, as I said, I don't know, but if you are thinking about 2004, I didn't have any knowledge of cladribine use and -- and certainly regimen and whatever. 11:06:13 11:06:22 11:06:26 11:06:35

BY MS. DASHE: 11:06:35

Q. Now, you joined IVAX in 2000; right? 11:06:36

A. Um-hum (affirmative). 11:06:42

Q. And you left in 2006; right? 11:06:42

A. Yes. 11:06:44

Q. And after you left IVAX, excluding the discussions with Dr. Buchwald we already talked about today, did you have access to your documents and communications from IVAX at any point after you left the 11:06:44 11:06:51 11:06:53 11:06:56

company? 11:07:00

MR. MLAVER: Objection to form. 11:07:00

You can answer. 11:07:06

A. I think, you know, I licensed at the beginning to IVAX a new steroid, which was developed to some extent, and after I left, I regained ownership, and so a lot of documents, files, were transferred back to me. 11:07:09 11:07:17 11:07:25 11:07:39

BY MS. DASHE: 11:07:45

Q. Let me get to the relevant question here, I guess, which is after you left IVAX in 2006, aside from our discussions of Dr. Buchwald, did you have access to your cladribine-related documents and communications at IVAX at any point after you left the company? 11:07:45 11:07:47 11:07:52 11:07:56 11:08:00

A. No. 11:08:02

MR. MLAVER: Objection to form. 11:08:03

A. No. 11:08:04

BY MS. DASHE: 11:08:05

Q. Okay. Now, when you were at IVAX, you served in various managing capacities, including chief scientific officer? 11:08:07 11:08:11 11:08:16

A. Yes. 11:08:16

Q. How many people worked under you when you were 11:08:16

at IVAX? Approximately. 11:08:21

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

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

people. 11:08:37

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

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

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

under me. 11:09:04

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

of the company? 11:09:11

A. Yes. 11:09:12

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

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

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

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

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

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

A. Yes. 11:09:47

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

A. Right. 11:09:48

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

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

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

A. I cannot tell. IVAX was a large corporation, 11:10:07
like 12,500 people, located in different part of the 11:10:12
world. And each site, like the UK, Hungary, so on, had 11:10:16
all kinds of teams based on the project they were 11:10:28
working on. 11:10:32

Q. .... chief scientific officer for other IVAX 11:10:32
locations outside of Hungary in the United States? 11:10:42

A. Well, in principle, yes, but I did not have, 11:10:47
like, for example, in the UK team report to me or the 11:10:53
team from Czechoslovakia or Chile or whatever. I mean, 11:10:58
I had meetings and discussions of -- scientific 11:11:08
meetings, but it's not direct reporting, no. The direct 11:11:11
reporting was the institute in Budapest. 11:11:15

Q. ... a number of different places that IVAX had 11:11:22
offices. Where were all those places? 11:11:25

A. As I mentioned, as I remember, the UK, 11:11:28
Ireland, Czechoslovakia, Chile. I don't know. 11:11:37

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

A. Yes.

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

A. Yeah. 11:11:51

Q. Okay. And I know -- you said your primary office was in the United States and you visited Hungary about, I think you said, once a month; is that right? 11:11:52 11:11:58 11:12:02

A. Yeah, one week, 12 months, yeah. 11:12:04

Q. Okay. How often would you visit IVAX's other offices in person? 11:12:07 11:12:14

A. I did not. 11:12:15

Q. Okay. 11:12:15

A. I mean, maybe once or twice I was in -- in London and talked to the vice-chairman who was there, I forgot his name. But I never had been to their offices in Chile -- in -- in Czechoslovakia or Chile. 11:12:20 11:12:25 11:12:29 11:12:37

Q. ... visits to Hungary that you mentioned, were these visits happening in 2004? 11:12:47 11:12:52

A. I don't get -- I didn't get that question. In 2004 -- 11:13:00 11:13:04

Q. Did you -- go ahead. 11:13:05

A. Yeah, in 2004, I was -- 11:13:07

Q. Well, let me re- -- let me rephrase. 11:13:10

I just -- the once-a-month visits to Hungary, were you doing those once-a-month visits in 2004? 11:13:12 11:13:16

A. Yes. Yeah. 11:13:21

Q. Okay. And all of these other locations for IVAX that you mentioned around the world, were they doing research and development on drugs as well? 11:13:21 11:13:26 11:13:30

A. Yes. I would say mostly -- 11:13:32

Q. And -- 11:13:36

A. -- development -- not basic research, but many of them were just commercial sites. 11:13:37 11:13:41

Q. What offices were doing drug developments -- 11:13:45

MR. MLAVER: Objection -- 11:13:58

BY MS. DASHE: 11:13:58

Q. -- at IVAX when you were there? 11:13:59

MR. MLAVER: -- to form and relevance. 11:14:02

A. To my knowledge, the UK; in Ireland, Waterford; Czech -- the Czech Republic, Czechoslovakia was then, site or something. 11:14:04 11:14:18 11:14:27

BY MS. DASHE: 11:14:29

Q. The visits that you did to Hungary, did you also make those visits in 2003? 11:14:29 11:14:33

A. Yes, I -- after I became director, managing director, which was in November 1999, I often visited the research institute. That was the main research institute of IVAX. 11:14:37 11:14:42 11:14:51 11:14:55

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

A. Yes. 11:15:23

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

A. Yes. 11:15:27

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

BY MS. DASHE: 11:15:35

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

A. Yes. 11:15:41

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

A. Right. 11:15:43

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

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

And as I remember, at a given point, we had like 12 or 13 active projects of different kinds, epilepsy, inflammation, all kinds. 11:16:27 11:16:30 11:16:38

Q. ... teen active projects that you recall, were those active in the 2003, 2004 time frame? 11:16:42 11:16:51

A. Yes. 11:16:54

Q. Did you have any role at IVAX for deciding what to patent? 11:16:55 11:17:06

A. No. 11:17:08

Q. Do you know what the process was at IVAX for deciding what to patent? 11:17:09 11:17:18

MR. MLAVER: Objection, privilege. 11:17:20

I'll -- you can answer yes or no. 11:17:22

A. I don't know. I can only talk about my own intellectual topic. 11:17:27

BY MS. DASHE: 11:17:36

Q. Did you have any role in deciding whether to file your Bodor PCT application? 11:17:36 11:17:42

MR. MLAVER: I'll give you the same caution. 11:17:47

You can answer yes or no. 11:17:49

A. Well, not really. I mean, the filing was decided by the patent office -- I mean the IVAX patent 11:17:50 11:17:57

office, the chairman, president, and they maybe asked me sometimes, but I don't recall except my own patents. 11:18:04 11:18:14

BY MS. DASHE: 11:18:19

Q. You mentioned an IVAX patent office. Do you know how big the IVAX patent office was? 11:18:24 11:18:27

A. I really don't -- 11:18:30

Q. Like how many people, I mean? 11:18:32

A. Depends on time. I mean, we are talking about six years. But most of the time, it was one or two lawyer and then patent assistant. 11:18:33 11:18:41 11:18:45

I'd say the office was maybe four or five people. 11:18:54 11:18:56

Q. The 2003, 2004 time frame? 11:18:56

A. That's what I remember, yes. 11:19:04

Q. And do you recall any of the names of the people in the IVAX patent department? 11:19:06 11:19:14

A. I remember just one, who was head for quite some time, I don't know when did she start. Her name was Simona Levi-Minzi. 11:19:17 11:19:23 11:19:26

Q. Can you spell that for us spelling-challenged folks on the record? 11:19:30 11:19:35

A. Simona, S-I-M-O-N-A, L-E-V-I dash M-I-N-Z-I. 11:19:35

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

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

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

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

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

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

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

lost -- I don't know --

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

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

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

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

A. Probably in 2006. 11:20:42

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

application? 11:21:01

MR. MLAVER: Objection, privilege. 11:21:01

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

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

BY MS. DASHE: 11:21:12

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

Bodor PCT application? 11:21:18

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

was worked by an outside firm, patent -- what was it -- Buckingham -- 11:21:28 11:21:40

Q. Sorry. 11:21:41

A. Buchanan Inger- -- 11:21:42

Q. Do you recall -- 11:21:44

A. Buchanan Inger- --

Q. I keep talking over you. I'm sorry. 11:21:45

A. Buchanan -- 11:21:46

Q. Just so the record is clear because I keep, kind of, heading in and out, so who was the outside firm responsible for your Bodor PCT? 11:21:48 11:21:50 11:21:56

A. Buchanan Inger- -- something like that. 11:22:02

Q. Buchanan Ingersoll, does that ring a bell? 11:22:05

A. Yes. 11:22:10

Q. Okay. So -- okay. Did you communicate within Buchanan Ingersoll lawyers about your Bodor -- or scratch that. 11:22:10 11:22:15 11:22:22

Did you communicate with the Buchanan Ingersoll lawyers when they submitted your PCT application to the patent office? 11:22:23 11:22:25 11:22:30

MR. MLAVER: Objection to privilege, I'll caution you, but you can answer yes or no. 11:22:32 11:22:34

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

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

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

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

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

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

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

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

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

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

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

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

MR. McGUFFIN: Did -- 11:24:43

BY MS. DASHE: 11:24:45

Q. Correct. 11:24:45

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

with -- with Norman? 11:24:48

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

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

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

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

you left IVAX? 11:25:15

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

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

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

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

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

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

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

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

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

A. No. 11:26:08

Q. Okay. Did you ever review IVAX's SEC or Securities and Exchange Commission filings when you were at the company? 11:26:08 11:26:28 11:26:29

A. No. 11:26:30

Q. Have you ever seen IVAX's SEC filings? 11:26:30

A. I don't believe so. I don't know. 11:26:40

Q. So you don't know if you've ever seen, for example, a 10-K or an annual report for IVAX? 11:26:43 11:26:48

A. That's right, I don't know. I was not involved in the financial part, although I was an officer, but I was not involved in the finances. 11:26:53 11:26:55 11:27:01

Q. Okay. 11:27:10

MS. DASHE: Emil, could you please pull up tab 11, which is the IVAX Corporation's Form 10-K to the SEC for fiscal year 2003, and mark that as Hopewell's Exhibit 1055, please. 11:27:14 11:27:19 11:27:27 11:27:32

MR. MLAVER: I'm going to object to the introduction of a document that hasn't been previously produced and to the extent any new argument is based on that and to foundation. 11:27:35 11:27:37 11:27:42 11:27:44

MS. DASHE: Emil, could you please zoom in on the address under IVAX Corporation for Dr. Bodor? 11:28:03 11:28:06

BY MS. DASHE: 11:28:20

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

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

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

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

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

A. Yes. 11:28:36

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

IVAX in 2003? 11:28:44

A. Yes. 11:28:45

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

this 10-K? 11:28:51

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

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

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

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

MR. MLAVER: Objection, foundation. 11:29:14

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

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

Exhibit 1055, please. 11:29:25

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

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

"Employees." There you go. Thank you. 11:29:47

BY MS. DASHE: 11:29:50

Q. And, Dr. Bodor, do you see where it says, 11:29:50

Exhibit 1055, the 2003 10-K for IVAX, -- 11:29:55

A. Yes. 11:30:00

Q. -- "As of December 31, 2003, we had 11:30:00

approximately 8,719 employees worldwide"? 11:30:04

A. Yes. 11:30:07

Q. Do you see that? Okay. 11:30:08

A. Yeah. 11:30:13

Q. And is that number of employees that IVAX 11:30:14

listed here consistent with your recollection of the 11:30:18

number of employees that IVAX had in 2003? 11:30:19

A. I -- I don't have any recollection, really. I 11:30:21

said before 12,000, but I don't know when was it. You 11:30:28

know, at some point, IVAX was the largest generic firm 11:30:30

in the world. And so I don't know. 11:30:36

I don't have any reason to doubt that this 11:30:38

is -- this number is right. 11:30:41

MS. DASHE: Emil, turn to page 13 -- back to 11:30:49

page 13 of the PDF of Exhibit 1055, the 2003 10-K, 11:30:53

please. 11:31:03

And if you could scroll down to "Patents and proprietary rights" on this page for the witness. 11:31:04 11:31:07

And, Emil, if you could zoom in on the "We hold approximately" paragraph so the witness could see it. 11:31:20 11:31:24 11:31:27

BY MS. DASHE: 11:31:34

Q. And so, Dr. Bodor, do you see here page 10 of the 10-K, page 13 of Exhibit 1055, it says for IVAX "Patents and proprietary rights," and "We hold approximately 1,026 United States and foreign patents and have filed several hundred United States and foreign patent applications," do you see that? 11:31:34 11:31:39 11:31:46 11:31:49 11:31:54 11:31:59

A. Yes. 11:32:01

Q. And my question for you, is that number of patents and patent applications consistent with your recollection of the number IVAX had in 2003? 11:32:01 11:32:06 11:32:11

A. I have no recollection. I didn't know number of -- 11:32:13 11:32:16

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

MR. MLAVER: Objection to foundation. 11:32:20

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

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

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

And could you please open tab 14, which will be IVAX's -- IVAX Corporation's Form 10-K to the SEC for fiscal year ending in December 31, 2004. 11:32:38 11:32:51 11:32:55

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

MR. MLAVER: And I'll object again to the introduction of a new document and to any new argument as well as to foundation. 11:33:03 11:33:05 11:33:08

REMOTE ZOOM TECHNICIAN WHITE: You said that's the IVAX 2001? 11:33:25 11:33:27

MS. DASHE: No. So this will be tab 14, which should be the IVAX 2004 10-K. 11:33:29 11:33:35

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

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

BY MS. DASHE: 11:34:00

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

MS. DASHE: Oh, Emil, that will be Exhibit 1056, please. 11:34:04 11:34:08

BY MS. DASHE: 11:34:08

Q. Dr. Bodor, you can see Exhibit 1056 on the screen? 11:34:20 11:34:23

A. It's too small.

MS. DASHE: Emil, maybe if you could zoom in a little bit on the first page, yeah.

BY MS. DASHE:

Q. Okay. So, Dr. Bodor, I'm showing you Exhibit 1056 in this case, which is IVAX Corporation's Form 10-K for the fiscal year ended December 31st, 2004.

And do you see in the middle there, it says "4400 Biscayne Boulevard, Miami, Florida 33137"?

A. Yes.

Q. And again, that is the correct address for the IVAX Corporation in the United States?

A. It was, yes.

Q. And do you have -- have you ever seen this Form 10-K before?

A. Maybe. I don't know.

I was never party to any --

Q. Reason to --

A. -- interested in looking at 10-Ks.

Q. Okay. But do you have any reason to believe that IVAX's filing with the Securities and Exchange Commission that we see here was -- has any errors in it?

MR. MLAVER: Objection, foundation. 11:35:43

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

MS. DASHE: Turn -- Emil, if you could please turn to page 21 of the PDF, that will be page 16 of the 10-K. 11:35:50 11:35:53 11:35:59

MR. MLAVER: While that's happening, I would also like to object to this exhibit and the previous exhibit as hearsay as well. 11:36:02 11:36:03 11:36:05

BY MS. DASHE: 11:36:14

Q. Okay. And, Dr. Bodor, could you -- do you see "employees," kind of in the middle of the page? 11:36:14 11:36:17

MS. DASHE: Emil, if you could zoom in a little bit. 11:36:20 11:36:22

A. Yes. It's a little too small, but I think it's... 11:36:22 11:36:26

BY MS. DASHE: 11:36:33

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

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

Q. Right. So my question for you is IVAX's 10-K, Exhibit 1056, says that as of December 31st, 2004, "We had approximately 10,100 employees worldwide." 11:36:38 11:36:43 11:36:47

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

employees at IVAX shown here consistent with your recollection of the ballpark number of employees IVAX had in 2004? 11:36:55 11:36:58 11:37:02

MR. MLAVER: Objection to the form, hearsay, scope, and relevance. 11:37:03 11:37:05

A. As I said before, I don't recall, and I don't think I ever was particularly interested to -- to know the total number of employees. 11:37:06 11:37:11 11:37:16

BY MS. DASHE. 11:37:20

Q. ... to doubt that IVAX had 10,100 employees as of December 31, 2004? 11:37:25 11:37:32

A. No, I don't doubt. 11:37:33

Q. Okay. And so similarly, you have no reason to doubt that during your time at IVAX, there were roughly between 8 to 10,000 employees at the company? 11:37:38 11:37:40 11:37:42

A. Yes. You know, when I see the numbers, I believe them. 11:37:47 11:37:51

Q. Okay. Excuse me, I'm dropping my papers here. Just one second. 11:37:51 11:38:07

MS. DASHE: All right. Emil, if we could please go to page 13 of the PDF for Exhibit 1056. 11:38:23 11:38:26

BY MS. DASHE: 11:38:39

Q. And do you see where it says "Patents and proprietary rights"? 11:38:39 11:38:41

MS. DASHE: That's perfect, Emil, thank you. 11:38:43

BY MS. DASHE: 11:38:46

Q. Do you see that, Dr. Bodor? 11:38:46

A. No. I saw it before. 11:38:47

MS. DASHE: Emil, if you could zoom back in, that was -- yeah. 11:38:51 11:38:54

A little bit more, Emil, please. 11:38:56

Thank you. That's great, right there. 11:38:58

BY MS. DASHE: 11:39:00

Q. Do you see now, Dr. Bodor, -- 11:39:00

A. Yes. 11:39:02

Q. -- where it says "Patents and proprietary rights"? 11:39:02 11:39:05

A. Um-hum (affirmative). 11:39:05

Q. Okay. And do you see in the second paragraph under that subheader -- 11:39:05 11:39:09

A. Yes. 11:39:11

Q. -- "We hold approximately 1,490 US and foreign patents and have filed several hundred US and foreign applications," do you see that? 11:39:11 11:39:15 11:39:20

A. Yes. 11:39:21

MR. MLAVER: Objection to hearsay. 11:39:22

BY MS. DASHE: 11:39:23

Q. Okay. And my question for you, is that number of patents and patent applications consistent with your recollection of the number IVAX had in 2004? 11:39:23 11:39:26 11:39:29

MR. MLAVER: Objection, foundation. 11:39:34

A. Well, as I said before, I have no recollection how many patents that IVAX had. It was not my business. 11:39:35 11:39:39

BY MS. DASHE: 11:39:51

Q. Okay. But you have no reason to disbelieve IVAX's SEC filing here that said the company holds approximately 1,490 US and foreign patents and has several hundred more applications? 11:39:51 11:39:54 11:39:58 11:40:03

MR. MLAVER: Objection, hearsay, foundation, scope, relevance. 11:40:05 11:40:07

A. Yeah, I have no doubt -- or no reason to doubt. 11:40:08 11:40:10

BY MS. DASHE: 11:40:19

Q. Your cladribine team at IVAX, that included, I believe you mentioned, Dr. Yogesh Dandiker? 11:40:20 11:40:24

A. Yes. 11:40:33

MS. DASHE: Emil, you can take down Exhibit 1056. Thank you. 11:40:33 11:40:37 11:40:37

BY MS. DASHE: 11:40:38

Q. When did Dr. Dandiker join the cladribine team at IVAX? 11:40:38 11:40:43

A. I really don't remember. I mean, I met Dr. Dandiker once in my life, when we discussed his findings about making the complex complex. And that must have been sometime in 2003, but I don't know. I don't remember. 11:40:44 11:40:52 11:40:56 11:41:03 11:41:07

Q. Okay. 11:41:07

A. I don't know when he got employed, when he left. 11:41:09 11:41:13

Q. What office was Dr. Dandiker at in IVAX? 11:41:18

A. I thought he was working in Waterford, Northern Ireland. Is that Northern? Or just Ireland? 11:41:24 11:41:29

But I -- 11:41:36

Q. You met Dr. Dandiker once in your life? 11:41:37

A. Yes, in my office here in Miami. 11:41:40

Q. That -- when you -- the one time you met Dr. -- scratch that. 11:41:42 11:41:55

Aside from meeting in person in your that one time in Miami, how many times did you communicate with Dr. Dandiker during your time at IVAX on cladribine? 11:41:55 11:41:58 11:42:02 11:42:07

MR. MLAVER: Objection to form. 11:42:12

A. I really don't remember. Not many times. I mean, the issue related to the patent was done by some other people who talked to us separate, not -- I didn't talk to him. 11:42:13 11:42:19 11:42:24 11:42:29

Maybe some of my other people contacted him for some material, but I didn't talk to him. Don't remember talking -- talking to him after. 11:42:39 11:42:41 11:42:46

BY MS. DASHE: 11:42:55

Q. Would you communicate with Dr. Dandiker via email? 11:42:55 11:43:01

A. I don't recall any email communication. I communi- -- I talked to him in person when he came to my office. 11:43:01 11:43:11 11:43:13

Q. Communication in person in your office in Miami in roughly 2003, was that the only communication that you had with Dr. Dandiker at IVAX regarding cladribine? 11:43:14 11:43:23 11:43:28 11:43:30

A. Yes. 11:43:30

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

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

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

complex complex." 11:43:51

A. Yes. 11:43:53

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

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

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

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

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

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

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

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

temperature. 11:44:43

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

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

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

type of interaction with the 11:45:01

hydroxypropyl-beta-cyclodextrin. 11:45:04

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

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

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

And did you work together with Dr. Dandiker on developing the complex cladribine-cyclodextrin complex? 11:45:20 11:45:23

A. Well, if the -- this is how we worked together, that we discussed it in my office and we agreed that -- 11:45:31 11:45:34 11:45:43

Q. Work with -- together with Dr. Dandiker on cladribine at IVAX involved the one meeting that you had in your office in Miami in roughly 2003; is that right? 11:45:43 11:45:48 11:45:53

A. Yes. 11:45:56

Q. Now, you mentioned you had some other team members at IVAX. Who were they? 11:45:57 11:46:06

A. Not the cladribine team, if that's what you mean. In the cladribine team at IVAX I considered was Dr. Steve Marcus. 11:46:15 11:46:17 11:46:23

Q. I meant -- I should have said about the cladribine team. So let me just rephrase to make sure we're all on the same page. 11:46:25 11:46:32 11:46:35

So the members of your cladribine team at IVAX were Dr. Dandiker and Dr. Steve Marcus; is that right? 11:46:36 11:46:40

A. And a large number of researchers in the research institute in Hungary who did the actual -- 11:46:47 11:46:52

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

A. -- work on the pharmacokinetic and bioavailability studies. 11:47:02 11:47:08

Oh, Dandiker, I am sure he had other people working with him. They made the complex complex, which was then provided to Hungary for the studies. 11:47:08 11:47:11 11:47:15

Q. Other people were on the cladribine team at IVAX that you mentioned? 11:47:17 11:47:27

A. Yes. I told you about the people at the research -- research institute in Budapest. But again, I am sure that there were others in Waterford working with Dr. Dandiker. 11:47:32 11:47:39 11:47:41 11:47:49

Q. ... figure out is what number of people at IVAX worked on the cladribine project. 11:47:50 11:47:55

A. Well, besides these whom I mentioned, only the people in Hungary. There were quite a number, five or six involved development of the analytical technique, and then receiving the blood samples from different sites in Europe and also the dog studies which were performed at the Budapest institute. 11:48:01 11:48:05 11:48:11 11:48:15 11:48:22 11:48:32

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

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

Dr. Steve Marcus, you don't recall the specific names of the other IVAX people who worked on cladribine; is that right? 11:48:58 11:49:02 11:49:05

A. That's right. 11:49:05

Q. All right. So we discussed Dr. Dandiker and his role on the cladribine project. What was Dr. Steve Marcus' role on the cladribine project at IVAX? 11:49:05 11:49:20 11:49:27

A. Well, all I can tell you, that Steve was the originator in 2000 sometime, I was fairly new and he was fairly new, he was the vice president of clinical affairs, he came to my office and talked about cladribine. 11:49:30 11:49:34 11:49:43 11:49:45 11:49:54

So he introduced to me, he said that there is an interest in cladribine if I could find a way to make it orally bioavailable. And I looked at the structure and I said I think there should be a way complexing with cyclodextrins. 11:49:55 11:49:58 11:50:03 11:50:11 11:50:15

After that, I really don't -- didn't have any -- much interaction with Steve about the cladribine. 11:50:19 11:50:22

Q. ... by something you -- 11:50:31

A. I had many interactions otherwise. 11:50:32

Q. Go ahead. 11:50:36

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

Q. And you said that -- okay. You said that 11:50:39

Steve came into your office in 2000 and said that there 11:50:42

was an interest in cladribine if you could find a way to 11:50:46

make it orally bioavailable? 11:50:51

A. Yes. Yeah, he told me that he had contacts 11:50:55

for -- in the -- at Scripp, and Scripp has developed 11:51:05

cladribine, I think they developed for using in areas 11:51:10

leukemia. And Steve knew about it because he was 11:51:17

basically an oncologist. 11:51:21

So that's where it started, he knew about 11:51:25

cladribine and he came to me and asked me if I could 11:51:27

look a way to make it orally bioavailable. He told me 11:51:30

that it's -- as it's sensitive, fairly low solubility. 11:51:37

Q. That was Scripps' institute that Dr. Marcus 11:51:42

told you had developed cladribine? 11:51:52

A. Yes. 11:51:54

Q. Is that right? 11:51:54

A. Yeah. 11:51:54

Q. Okay. And so you told Dr. Marcus that you 11:52:03

thought you could create cladribine-cyclodextrin 11:52:08

complex. 11:52:13

A. Yes. 11:52:13

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

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

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

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

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

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

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

off again. 11:53:58

MS. DASHE: Oh. 11:53:58

BY MS. DASHE:

Q. This discussion with Dr. Dandiker, that was 11:53:58

sometime in 2003 you said; right? 11:54:00

A. Well, I don't remember the date. But it must 11:54:09

have been before we filed the patent application. 11:54:16

Q. ... charged with keeping your complex 11:54:18

cladribine-cyclodextrin complex confidential before you 11:54:25

filed your Bodor PCT application? 11:54:30

MR. MLAVER: Objection, form. 11:54:36

A. Would you repeat that question? 11:54:37

BY MS. DASHE:

Q. Yes. 11:54:40

Were you -- were you -- strike that. 11:54:42

Were you and your team at IVAX charged with 11:54:45

keeping your complex cladribine-cyclodextrin complex 11:54:50

confidential before you filed your Bodor PCT 11:54:55

application? 11:54:59

MR. MLAVER: Objection, form. 11:55:01

A. Well, of course, any work done at IVAX we kept 11:55:02

confidential. We never published. 11:55:07

BY MS. DASHE: 11:55:12

Q. Before you filed your Bodor PCT application, you kept your complex cladribine-cyclodextrin complex confidential; is that right? 11:55:20 11:55:24 11:55:31

A. Confidential from whom? 11:55:31

Of course. It was the company confidentiality. We didn't talk about internal work with outsiders. 11:55:35 11:55:39 11:55:46

Q. So you didn't talk about your complex cladribine-cyclodextrin -- excuse me, let me rephrase that. 11:55:47 11:55:57 11:56:00

So did IVAX as a company keep your complex cladribine-cyclodextrin complex confidential from the public before you filed your Bodor PCT application? 11:56:00 11:56:09 11:56:12

MR. MLAVER: Objection, form, foundation, scope, relevance. 11:56:18 11:56:21

A. I assume so. I mean, I have no reason to believe that IVAX went and advertised our work. 11:56:22 11:56:24

BY MS. DASHE: 11:56:27

Q. So this initial conversation with Dr. Marcus, you said it happened in 2000. Do you recall when in 2000 that would have been? 11:56:33 11:56:40 11:56:43

MR. MLAVER: Objection to form. 11:56:43

A. I assume it was in 2000 because it was early 11:56:44
my position at IVAX. And Steve Marcus just joined also 11:56:52
IVAX not long before me. 11:57:02

And so we are both early. I was new coming 11:57:04
from university. So Steve came to my office and talked 11:57:09
about cladribine. 11:57:16

I -- 11:57:21

BY MS. DASHE: 11:57:22

Q. That -- and forgive me if I've already covered 11:57:23
this, I just want to make it clear. 11:57:25

After that initial conversation with Dr. Steve 11:57:26
Marcus about cladribine, did you have any other 11:57:28
communications with Dr. Marcus about cladribine at IVAX? 11:57:32

A. I am sure that I told him later, after we have 11:57:36
succeeded to make complex, the results. I don't know 11:57:41
what -- don't remember what his reaction was. These -- 11:57:47
these are the complexes in -- included in the other 11:57:52
patents which were never used. 11:57:58

But you have to understand, if I may say, 11:58:10
cladribine, on the larger scale for me in my position, 11:58:14
was a very minor issue, it was not a main thing. So I 11:58:18

don't remember too much about it. It became more important after the patent examiner in 2008 finally allowed it. 11:58:23 11:58:29 11:58:38

Q. What was Dr. Marcus' role on the cladribine project at IVAX? Aside from that one conversation you had with him, what was his role? 11:58:39 11:58:54 11:58:58

A. I don't know. I mean, with me, we were just communicating about this complexation. If he talked to others -- I know he talked to the president, Dr. Frost, because he told me that he -- Dr. Frost is interested. And, you know, he probably talked to other people, I don't know. 11:58:59 11:59:05 11:59:11 11:59:16 11:59:19 11:59:23

Q. Cladribine was somewhat of a minor project for you -- 11:59:23 11:59:33

A. Yes. 11:59:33

Q. -- at the time at IVAX and it happened a long time ago, -- 11:59:33 11:59:36

A. Yes. 11:59:37

Q. -- you just don't really recall the details of folks' roles? 11:59:37 11:59:40

A. That's correct. 11:59:41

Q. Okay. 11:59:42

MS. DASHE: You know, we've been going for about an hour, so I'm happy to take a break if you would like to, Dr. Bodor. 11:59:44 11:59:45 11:59:48

THE WITNESS: I appreciate it. 11:59:50

VIDEOGRAPHER ELMILKI: Okay. We are off the record, and the time now is 11:59. 11:59:52 11:59:54

(Recess taken.) 11:59:59

VIDEOGRAPHER ELMILKI: We are back on the record, and the time now is 12:46 p.m. 12:46:54 12:46:56

BY MS. DASHE: 12:47:02

Q. Welcome back, Dr. Bodor. During the break, did you speak with your counsel about your testimony at all? 12:47:02 12:47:05 12:47:08

A. No. 12:47:08

Q. We've been talking a bit about the Bodor PCT today, so let's actually pull that up. That would be tab 2, Exhibit 1022 in this case. 12:47:08 12:47:19 12:47:23

MR. MLAVER: Is that supposed to appear on the screen? 12:47:40 12:47:42

Oh, sorry. We see it now. 12:47:43

BY MS. DASHE: 12:47:49

Q. Okay. And we are looking at Exhibit 1022 in 12:47:49

this case, the Bodor PCT application. 12:48:00

MS. DASHE: Emil, could you zoom in on item 75, where it says "Inventors/applicants"? 12:48:05 12:48:08

BY MS. DASHE: 12:48:27

Q. And, Dr. Bodor, do you see the that PCT application lists you and Dr. Dandiker as inventors? 12:48:27 12:48:30

A. Yes. 12:48:33

Q. Did you read the Bodor PCT application before it was filed? 12:48:34 12:48:48

A. Most of it, I guess, yes. 12:48:49

THE COURT REPORTER: Could you repeat that? 12:48:55

THE WITNESS: Most of it. 12:48:57

THE COURT REPORTER: Thank you.

A. I mean, many times I read these things, just focusing on the important things, what I see in the examples and the claims. The preliminaries don't matter that much. 12:48:58 12:49:01 12:49:06 12:49:13

BY MS. DASHE. 12:49:15

Q. ... stand by the disclosures within the Bodor PCT application? 12:49:15 12:49:18

MR. MLAVER: So I think the -- the first words of your question were cut off there. 12:49:19 12:49:21

MS. DASHE: Oh, no. Okay. 12:49:23

BY MS. DASHE: 12:49:25

Q. Dr. Bodor, do you stand by the disclosures of your Bodor PCT application? 12:49:25 12:49:30

A. Yes. 12:49:36

Yes. Yes. 12:49:36

Q. What was your specific contribution to the complex cladribine-cyclodextrin complex disclosed in the Bodor PCT? 12:49:37 12:49:45 12:49:54

A. Well, I described before, first the concept of using cyclodextrins and using hydroxypropyl-beta-cyclodextrin, which is one of my favorites for many years, then doing the actual phase solubility diagram in the interpretation, and talking to Yogesh Dandiker about his finding, then I give an explanation of the happening why this complex complex is not just a simple inclusion process of a cyclodextrin. 12:49:54 12:49:58 12:50:07 12:50:09 12:50:20 12:50:29 12:50:34 12:50:45

Q. You mentioned hydroxy something, I missed the word. 12:50:50 12:50:52

A. Hydroxypropyl.

Q. What was that word and how do you spell it? 12:50:53

A. Hydroxypropyl. Hydroxy, and propyl, 12:50:55

P-R-O-P-Y-L. 12:51:00

Important thing, the hydroxypropyl-beta-cyclodextrin is a intrinsically amorphous material, because it's a mixture of a variety of isomers, and that makes it very water soluble. 12:51:03 12:51:11 12:51:15 12:51:20

It has a lot of advantages. 12:51:33

Q. ... those advantages? 12:51:36

MR. MLAVER: Sorry, we only got the last two words of your question. 12:51:38 12:51:40

BY MS. DASHE: 12:51:41

Q. What are some of those advantages you just mentioned, Dr. Bodor? 12:51:42 12:51:44

A. I just said the high water solubility and the safety, it was tested in people in many different conditions, even intravenous administration, it's very safe. 12:51:47 12:51:50 12:51:58 12:52:01

Q. The findings that Dr. Dandiker communicated to you in that one in-person meeting, what else did he specifically contribute to the complex cladribine-cyclodextrin complex disclosed in the Bodor PCT? 12:52:07 12:52:10 12:52:15 12:52:21 12:52:25

MR. MLAVER: Objection to form. 12:52:25

A. Well, first I want to clarify one thing. To my knowledge, the inventorship is decided by the patent lawyer. So it's not up to me to judge what Yogesh's contribution was. 12:52:32 12:52:34 12:52:38 12:52:52

But, of course, he is the one who -- who found that you can increase the certain conditions, the incorporation of cladribine in cyclodextrin, in this cyclodextrin only, and then we figured out the conditions to optimize formulation of the complex complex. 12:52:52 12:52:58 12:53:01 12:53:07 12:53:11 12:53:19

BY MS. DASHE: 12:53:20

Q. Just to make sure that I was clear, because I don't want to muck anything up here, I was simply asking what were Dr. Dandiker's scientific contributions to the complex cladribine-cyclodextrin complex disclosed in the Bodor PCT? 12:53:20 12:53:23 12:53:27 12:53:34 12:53:39

A. And I said, he found that you can increase the incorporation of cladribine in the cyclodextrin under certain conditions. Because before that, we always just made the -- the -- the inclusion complex, which is probably 30 to 40 percent of the total product. 12:53:40 12:53:48 12:53:58 12:53:58 12:54:05

Q. So the inventorship thing. 12:54:10

You said that -- well, let me scratch that. 12:54:16

What is your under- -- or scratch that again. 12:54:22

Do you have an understanding of the legal 12:54:25

requirements for inventorship? 12:54:28

MR. MLAVER: Objection to scope and 12:54:30

foundation. 12:54:36

A. My understanding is that somebody has to be 12:54:36

responsible at least for one of the claims or invented 12:54:40

one of the claims to be a potential inventor. 12:54:47

But again, that is decided by the patent 12:54:51

lawyer. 12:54:53

BY MS. DASHE. 12:54:54

Q. ... responsible for? 12:55:01

THE COURT REPORTER: We lost the beginning of 12:55:04

your question. 12:55:06

BY MS. DASHE: 12:55:07

Q. You said "My understanding is someone has to 12:55:10

be responsible for at least one of the claims." 12:55:13

A. Yes. 12:55:16

Q. My question to you is what do you mean by 12:55:16

"responsible for"? 12:55:20

A. That his contribution is that that specific 12:55:22

claim was his idea or the result of his work or whatever. 12:55:27 12:55:36

Q. Do you have any understanding of the legal requirements for conception? 12:55:36 12:55:44

A. For what? 12:55:49

Q. Conception. 12:55:50

A. Confection? 12:55:54

Q. Conception, C-O-N- -- 12:55:56

A. Conception, yeah.

Q. -- C-E-P-T-I-O-N. 12:55:59

A. I am not a lawyer, so I -- I -- I cannot really define you. 12:56:01 12:56:05

And again, if we -- we are talking -- 12:56:10

Q. And similarly -- oh, go ahead. 12:56:11

A. If you are talking about inventorship again, I rely on whatever the patent lawyer decided who is that inventor. It's not up to me. 12:56:13 12:56:19 12:56:26

Q. ... of any understanding of the difference or any differences between conception and inventorship? 12:56:28 12:56:36

MR. MLAVER: Objection, foundation and form. 12:56:46

A. I -- I don't know. 12:56:47

I mean, the concept can be an invention. 12:56:56

Maybe not all inventions are concepts, I don't know. This is semantics. 12:57:00 12:57:05

BY MS. DASHE: 12:57:06

Q. And do you have any understanding of any differences between reduction to practice and inventorship? 12:57:06 12:57:10 12:57:15

MR. MLAVER: Objection, form, foundation. 12:57:15

A. Yes, I do. Reduction to practice is to practically demonstrate the concept or the invention. 12:57:17 12:57:26

BY MS. DASHE: 12:57:33

Q. And did you read the Bodor PCT application before you signed your declaration in this case? 12:57:42 12:57:46

MR. MLAVER: Objection, form, asked and answered. 12:57:49 12:57:53

A. Yes. I said that before, it was. 12:57:54

BY MS. DASHE: 12:58:01

Q. And when was the last time that you read the Bodor PCT application? 12:58:05 12:58:08

A. Maybe before I signed this declaration or deposition. 12:58:10 12:58:24

MS. DASHE: And so, Emil, you can take down Exhibit 1022. 12:58:31 12:58:36

And could you please pull up tab 6, which has already been marked as Exhibit 2069 in these proceedings, and it's US Patent Number 7,888,328. 12:58:38 12:58:43 12:58:47

And, Emil, could you zoom in a little bit on the top of the -- of Exhibit 2069 so Dr. Bodor can see? Thank you. 12:59:08 12:59:11 12:59:17

BY MS. DASHE: 12:59:19

Q. So, Dr. Bodor, Exhibit 2069 on the screen here, this is the `328 patent that you referred to in your declaration; right? 12:59:19 12:59:25 12:59:32

A. Yes. 12:59:33

Q. And it names you and Dr. Dandiker as inventors? 12:59:33 12:59:36

A. Yes. 12:59:36

Q. And did you read the `328 patent before it was filed? 12:59:37 12:59:42

MR. MLAVER: Objection, scope. 12:59:44

A. I would say yes. 12:59:45

BY MS. DASHE: 12:59:47

Q. Okay. Do you stand by the disclosures of your `328 patent? 12:59:47 12:59:52

A. Yes. 12:59:55

Q. And we see here that the 32 patent is assigned to Ares Trading SA. Do you see that? 12:59:55 13:00:03

A. Yes. 13:00:07

Q. Did you receive any sort of compensation for this assignment? 13:00:07 13:00:11

A. No. 13:00:12

Q. Did you receive any awards or accolades, plaques on the wall, anything like that? 13:00:12 13:00:17

A. No. 13:00:19

Q. Did Dr. Dandiker? 13:00:21

A. I don't know. 13:00:22

Q. And did you read the `328 patent, Exhibit 2069, before you signed your declaration in this case? 13:00:23 13:00:37 13:00:45

A. Yes. 13:00:45

Q. When was the last time you read the `328 patent? 13:00:46 13:00:49

A. Maybe a few days ago. I didn't read -- 13:00:49

MS. DASHE: Emil -- 13:00:56

BY MS. DASHE:

Q. Oh, go on. 13:00:57

A. I didn't read it all. I mean, it's a long 13:00:58

patent, a lot of introductory statements, which I -- I just glanced to, is a... 13:01:00 13:01:12

Q. ... last time you read the `328 patent before you signed your declaration in this case? 13:01:12 13:01:15

A. Yes. 13:01:18

Q. Oh, I think my question might have been cut off. 13:01:26 13:01:28

My question was when was the last time you read the `328 patent before you signed your declaration in this case? 13:01:28 13:01:32 13:01:35

MR. MLAVER: Objection to form. 13:01:37

A. Maybe sometime in December. Was it -- 13:01:41

BY MS. DASHE:

Q. 2023? 13:01:47

A. Yes. 13:01:47

MS. DASHE: All right, Emil, you can take down Exhibit 2069. 13:01:53 13:01:56

And could you please introduce tab 10. And this will be Exhibit 1057 in these proceedings. 13:01:59 13:02:05

And this is the full file history for US Patent Number 7,888,328. 13:02:09 13:02:16

MR. MLAVER: I want to object again to a new 13:02:20

document to the extent any new argument is introduced. 13:02:23 13:02:26

BY MS. DASHE: 13:02:43

Q. All right. Dr. Bodor, for one thing, have you seen the whole prosecution history for your `328 patent before? 13:02:43 13:02:49 13:02:53

A. I don't know. Probably. 13:03:02

I mean, this was a long time ago. 13:03:09

Q. ... read through the whole -- have you ever read through the whole thing? 13:03:12 13:03:14

A. Yes, I did. At that time, I guess. I don't know when. See, again, this goes back to 2008 or before. 13:03:19 13:03:21 13:03:32

Q. Anticipated my next question. 13:03:37

When was the last time you read through the prosecution history for the `328 patent? 13:03:38 13:03:41

A. I don't remember. I guess that was -- 13:03:51

Q. Did you -- 13:03:56

A. -- before my interview at the patent office. 13:03:57

Q. So that would have been sometime in the 2008 time frame? 13:04:03 13:04:10

A. Yes. 13:04:10

MS. DASHE: Emil, if you could please go to page 159 of the PDF of Exhibit 1057, please. 13:04:15 13:04:17

And, Emil, if you could zoom in about the top third of the document so everybody can see. 13:04:31 13:04:35

Maybe zoom out just a little bit. 13:04:38

Thank you. That's great. 13:04:40

BY MS. DASHE:

Q. Now, Dr. Bodor, we see here a declaration from the below-named inventors of the `328 patent. Do you see that? 13:04:48 13:04:53 13:04:58

A. Um-hum (affirmative). Yes. 13:04:58

Q. Okay. 13:05:03

MS. DASHE: And, Emil, if you could flip to the next page of Exhibit 1057. 13:05:04 13:05:09

And, Emil, do you see how there is a table? Could you center around the table? 13:05:13 13:05:15

Thank you.

BY MS. DASHE:

Q. And so, Dr. Bodor, do you see on page 160 of the PDF of Exhibit 1057 a table of the inventors of the `328 patent? 13:05:25 13:05:28 13:05:35

A. Yes. 13:05:36

Q. And it shows your name in that table? 13:05:36
A. Yes. 13:05:40
Q. That is your signature in the table? 13:05:46
A. Yes. 13:05:47
Q. And it also shows Dr. Dandiker's name and signature below that; right? 13:05:51 13:05:54
A. Yes. 13:05:55
MS. DASHE: Okay, Emil, you can take down Exhibit 1057. 13:05:55 13:05:57
And could you please pull up tab 3, Exhibit 2029 in these proceedings, which is US Patent Number 8,785,415. 13:06:00 13:06:09 13:06:13
Thank you. 13:06:25
And again, Emil, if you could zoom in maybe on the top third of the page. 13:06:31 13:06:33
BY MS. DASHE:
Q. Dr. Bodor, this Exhibit 2029, that is the `415 patent that you have referred to in your declaration; right? 13:06:43 13:06:48 13:06:50
A. Yes. 13:06:50
Q. And again, it names you and Dr. Dandiker as an inventor? 13:06:51 13:06:58

A. Yes. 13:06:59

Q. Did you read the `415 patent before it was filed? 13:06:59 13:07:10

A. Yes. 13:07:10

Q. And do you stand by the disclosures of your `415 patent? 13:07:11 13:07:21

A. Yes. 13:07:24

Q. And again we see the `415 patent is assigned to Ares Trading, SA, do you see that? 13:07:25 13:07:33

A. Yes. 13:07:36

Q. Did you receive any compensation or awards or accolades for this assignment? 13:07:37 13:07:39

A. No. 13:07:41

Q. Did Dr. Dandiker? 13:07:43

A. I don't know. 13:07:44

Q. Did you read the `415 patent, Exhibit 2029, before you signed your declaration in this case? 13:07:54 13:08:01

A. Most of it. I didn't read the whole patent because it's long and verbose. I didn't read the whole thing in order to sign the affidavit. 13:08:08 13:08:11 13:08:17

Q. When was the last time you read the `415 patent? 13:08:19 13:08:27

A. In full?
Q. Well, how about let's start with at all. When was the last time you read any part of the `415 patent? 13:08:27 13:08:31 13:08:34
A. It was, I said, before the patent office interview. 13:08:37 13:08:45
Q. When was the last time you read the `415 patent before signing your declaration in this case? 13:08:45 13:09:01
A. I'd say December '23. 13:09:02
MS. DASHE: Okay, Emil, you can take down Exhibit 2029. 13:09:11 13:09:15
And could you please pull up tab 4, which will be marked as Exhibit 1058 in these proceedings, and that will be the file history for US Patent Number 8,785,415. 13:09:19 13:09:21 13:09:24 13:09:29
MR. MLAVER: And same objection to a new document. 13:09:31 13:09:34
I'll also note that we haven't been served copies of these exhibits, so, you know, reserve the right to make any objection that may be necessary to the contents that we aren't literally looking at. 13:09:34 13:09:37 13:09:43 13:09:46 13:09:49
BY MS. DASHE: 13:10:19

Q. So in front of you is Exhibit 1058 in these proceedings, which is the full file history for your `415 patent. 13:10:19 13:10:28 13:10:34

My question for you is have you ever seen the full prosecution history for your `415 patent before? 13:10:36 13:10:38

A. Not as I recall. I am sure the patent lawyer who handled it did it, but she never showed it to me. I don't recall seeing the full file. 13:10:44 13:10:48 13:10:57

MS. DASHE: And, Counsel, before I move on, with respect to the new documents, you're being provided with copies during the deposition, and we agreed to remote, and you have the download link, so you have access to the documents during the deposition today. 13:11:09 13:11:12 13:11:14 13:11:18 13:11:21 13:11:23

BY MS. DASHE: 13:11:29

Q. And, Dr. Bodor, when was -- or have you ever -- scratch that. 13:11:29 13:11:37

And for -- I apologize if I covered this before, but I just want to make sure that the record is clear. 13:11:38 13:11:40 13:11:43

Have you ever read through the whole prosecution history for the `415 patent? 13:11:43 13:11:45

A. Not as I recall. 13:11:49

MS. DASHE: Emil, could you please go to page 9 of the PDF of Exhibit 1058? 13:11:51 13:12:05

BY MS. DASHE:

Q. Okay. And again, Dr. Bodor, here we see a declaration from the below-named inventors, the `415 patent, do you see that? 13:12:16 13:12:20 13:12:25

A. Yes. 13:12:27

Q. Okay. And you also see in the third paragraph down, it says "I believe I am the original first and either sole inventor or joint inventor of the subject matter which is claimed and for which a patent is sought"? 13:12:27 13:12:33 13:12:36 13:12:41 13:12:45

A. Yes. 13:12:45

MS. DASHE: Emil, could you please flip to the next page and again center on the table that you see? 13:12:46 13:12:48 13:12:52

BY MS. DASHE: 13:13:00

Q. So, Dr. Dandiker, do you see the table listing inventors on page 10 of the PDF of Exhibit 1058? 13:13:00 13:13:04

A. I am not Dandiker. 13:13:14

You called me Dr. Dandiker. 13:13:17

Q. I was looking at "Dandiker" on the page. 13:13:19

Dr. Bodor, do you see the table listing the 13:13:23

inventors of the `415 patent -- 13:13:27

A. Yes. 13:13:31

Q. -- on page 10 of the PDF? 13:13:31

A. Yes.

Q. Okay. I apologize for that.

And so it shows that -- it shows your name at 13:13:31

the top of the table; right? 13:13:32

A. Yes. 13:13:34

Q. And that's your signature right underneath? 13:13:34

A. Yes. 13:13:36

Q. Okay. And then again it shows Dr. Dandiker's 13:13:37

name and signature? 13:13:41

A. Yes. 13:13:42

Q. Okay. 13:13:47

MS. DASHE: Okay, Emil, you can take down 13:13:47

Exhibit 1058. 13:13:49

And could you actually bring up, Emil, 13:13:53

Exhibit 1022 that we've already introduced, which 13:13:56

would be the Bodor PCT. 13:13:58

MR. MLAVER: I just wanted to say at the next 13:14:09

break, would it be okay to email us that download link? We're not sure we have it. 13:14:12 13:14:16

MS. DASHE: Chat, I believe, on the Zoom link. 13:14:18

MR. MLAVER: Oh. I am not in the Zoom because I am here. So if you could just -- 13:14:21 13:14:23

MS. DASHE: Oh. 13:14:26

MR. MLAVER: -- send an email, that would be great. 13:14:26 13:14:28

MS. DASHE: Emil -- Emil, is that possible, to send that link to opposing counsel via their email? 13:14:30 13:14:33

REMOTE ZOOM TECHNICIAN WHITE: Yes, I can -- excuse me, my apologies. Yes, I can -- I can forward that to you, Counsel. 13:14:39 13:14:40 13:14:44

MS. DASHE: Thank you very much, Emil. 13:14:46

BY MS. DASHE: 13:14:48

Q. Okay. Dr. Bodor, we have your Bodor PCT up on the screen. Do you see that? 13:14:48 13:14:56

A. Yes. Sort of. 13:14:57

Q. Okay. Sort of. Yeah. 13:15:00

MS. DASHE: Emil, could you just zoom into the top part so Dr. Bodor can be sure that he's looking at the right thing? 13:15:08 13:15:10 13:15:12

BY MS. DASHE: 13:15:19

Q. You got your Bodor PCT, you can see it, 13:15:20

Dr. Bodor? 13:15:24

A. Yes. 13:15:24

Q. Okay. 13:15:24

MS. DASHE: And, Emil, could you please go to 13:15:29

page 25 of the PDF of Exhibit 1022? 13:15:31

And this is actually page 23 of the actual 13:15:36

Bodor PCT application. 13:15:41

Emil, could you please go down to the bottom 13:15:44

third of this page? 13:15:46

All right. Yeah. And then just zoom in on -- 13:15:55

starting on line 26, just kind of zoom in on that 13:15:58

bottom part so it's centered and everybody can see. 13:16:01

Okay. 13:16:05

BY MS. DASHE: 13:16:06

Q. And, Dr. Bodor, do you see starting page 23 of 13:16:06

your reference, 25 of the PDF, -- 13:16:09

A. Um-hum (affirmative). 13:16:13

Q. -- starting on line 24, it mentions two US 13:16:13

provisional patent applications, both entitled 13:16:20

"Cladribine Regimen for Treating Multiple Sclerosis," 13:16:24

filed on March 25th, 2004, and incorporated by reference into the Bodor PCT, do you see that? 13:16:28 13:16:34

A. Yes. 13:16:36

Q. And you see that the specific application numbers are left blank? 13:16:37 13:16:41

A. Yes. 13:16:42

Q. But in the brackets next to the blank space, do you see some attorney docket numbers? 13:16:43 13:16:52

A. Yes. 13:16:54

Q. Those are IVAX attorney docket numbers? 13:16:54

A. I don't know. 13:17:02

Q. They do say IVAX, though; right? 13:17:03

A. Well, it starts with IVAXX0022 [sic]. So it may be IVAX docket number. 13:17:11 13:17:18

Q. Before you filed your Bodor PCT application, did you read those two provisional applications referenced here? 13:17:19 13:17:32 13:17:37

A. No. 13:17:37

Q. And before you filed your Bodor PCT application, did you have any understanding of the contents or the subject matter of the two provisional applications? 13:17:37 13:17:44 13:17:48 13:17:52

A. No. 13:17:52

Excuse me. I did not put in -- I mean, you 13:17:54

understand that this was written by one of the patent 13:17:57

lawyers, and, I mean, I -- I don't remember reading any 13:18:02

of this. 13:18:09

Q. Who would know about these two provisional 13:18:09

applications if -- on page 23 of your Bodor PCT 13:18:18

reference? 13:18:22

A. Whoever filed. I don't know. 13:18:22

Q. Do you know their names? 13:18:32

A. Of the lawyers? 13:18:33

Q. Let me -- let me just rephrase. 13:18:35

Do you know the... 13:18:37

IN-ROOM ZOOM TECHNICIAN PIETANZA: We lost 13:18:47

connection. 13:18:48

MR. MLAVER: Can you just let Christina know 13:18:49

that the Zoom is -- 13:18:52

MS. BOND: Yeah, okay. 13:18:55

IN-ROOM ZOOM TECHNICIAN PIETANZA: I'm 13:18:55

messaging our tech right now.

MR. MLAVER: The Zoom has died. 13:19:11

MS. DASHE: Progress. 13:19:11

MR. MLAVER: Looks like we're all back.
MS. DASHE: Can people hear me? 13:19:12
THE WITNESS: Yes. 13:19:13
MR. MLAVER: Yes. 13:19:13
MS. DASHE: I cannot hear them. 13:19:13
MR. MLAVER: Yes, you --
MS. DASHE: Ah, here we go. 13:19:15
MR. MLAVER: You disappeared for a minute 13:19:16
there, so. 13:19:17
MS. DASHE: Okay. 13:19:25
BY MS. DASHE: 13:19:25
Q. Let me -- let me repeat my question, then. 13:19:25
So do you know who wrote on page 23 of your 13:19:31
Bodor PCT application, lines 24 to the end of the 13:19:41
page, -- 13:19:47
A. No, I don't. 13:19:48
Q. -- that we see here on the screen? 13:19:48
A. I don't. 13:19:50
Q. But it would have been one of the lawyers; 13:19:51
right? 13:20:00
A. Yes, it would have been one of the lawyers at 13:20:00
IVAX. 13:20:06

Q. Okay. Do you know who wrote any part of the Bodor PCT application? 13:20:07 13:20:19

MR. MLAVER: Objection to form. 13:20:19

A. I really don't. 13:20:22

MS. DASHE: Emil, could you please go to the first page of Exhibit 1022, please. 13:20:38 13:20:40

BY MS. DASHE: 13:20:51

Q. And, Dr. Bodor, do you see where it says agents, Norman Stepno, for Burns, Doane or Doane or however you pronounce that? 13:20:51 13:20:55 13:21:00

A. Yes. 13:21:02

Q. Did you communicate with Norman Stepno about the Bodor PCT application? 13:21:02 13:21:07

MR. MLAVER: Objection, privileged. 13:21:10

I'll instruct the witness to answer a limited answer to yes or no. 13:21:12 13:21:15

A. No. 13:21:18

MS. DASHE: Okay, Emil, you can take down Exhibit 1022, please. 13:21:24 13:21:28

Thank you. 13:21:36

BY MS. DASHE: 13:21:37

Q. So, Dr. Bodor, in 2002, IVAX entered into an 13:21:38

agreement with Serono for the development of an oral formulation of cladribine for the treatment of MS; right? 13:21:42 13:21:44 13:21:47

A. I -- I don't know that for a fact until fairly recently. I was not part of that kind of agreement. 13:21:47 13:21:56

Q. So just so the record is clear, then, and because your audio broke up a little bit, you were not personally involved with the agreement between IVAX and Serono; is that right? 13:22:04 13:22:07 13:22:11 13:22:14

A. That's right. 13:22:16

Q. Okay. Do you at all know how the agreement between IVAX and Serono came about? 13:22:16 13:22:27

A. I don't know. 13:22:30

Q. Okay. Now, as a part of IVAX and Serono having an agreement, Serono also had a team that worked on cladribine; right? 13:22:30 13:22:41 13:22:47

A. I assume so. I -- I don't know. 13:22:48

I mean, it was -- 13:22:49

Q. Did you ever communicate with -- oh, go ahead. 13:22:51

A. That was clearly part of the IVAX/Serono agreement, which I was not part of. 13:22:53 13:22:58

Q. Okay. Did you ever communicate with anybody 13:22:59

about cladribine at Serono? 13:23:03

A. No. 13:23:07

Q. Okay. And do you have any knowledge of what individuals at Serono worked on cladribine? 13:23:07 13:23:12

A. Well, I do, because I saw the publication, the paper, the study about this complex complex. 13:23:18 13:23:24

But I 13:23:33

Q. So aside from your thirdhand knowledge of a public paper -- 13:23:33 13:23:38

A. Yes. 13:23:40

Q. Go ahead. 13:23:40

A. Yeah, I didn't have any other -- 13:23:41

Q. So aside -- oh, yeah. 13:23:43

Okay, I talked over you, so I'm just going to reask my question so it's clear. And I'm sorry for doing that, sir. So let me just ask one more time. 13:23:46 13:23:48 13:23:51

So aside from your thirdhand knowledge from a public paper, did you have any other knowledge of who at Serono worked on the cladribine project? 13:23:53 13:23:58 13:23:59

A. No. 13:24:02

MR. MLAVER: Objection to form. 13:24:03

BY MS. DASHE: 13:24:12

Q. And do you have any knowledge of the joint work allocation between IVAX and Serono beyond what's in the agreement between the two parties? 13:24:13 13:24:16 13:24:20

MR. MLAVER: Objection to form. 13:24:24

A. Again, I don't know about the agreement. 13:24:25

In -- in 2004, when I was director of the institute, indirectly some came through because -- it must have been based on the agreement, how they have done some clinical studies in Europe, but the blood samples from the patients were sent to the institute to be analyzed. 13:24:30 13:24:38 13:24:42 13:24:45 13:24:54 13:24:58

So I knew that there must be some kind of bio- -- bioavailability study ongoing, but I didn't know that it -- that it was an IVAX/Serono joint or whatever. 13:25:02 13:25:09 13:25:11

BY MS. DASHE: 13:25:21

Q. Some came through regarding clinical studies. I'm not -- I guess I'm not quite following what you were saying. Could you just maybe repeat that and explain yourself a little bit more? 13:25:24 13:25:27 13:25:29 13:25:33

MR. MLAVER: Objection to form. 13:25:34

A. As I have seen in the reports given to me on the cladribine project at the institute, it was clear 13:25:34 13:25:48

that four or three or four different clinical sites in Europe were used to study single doses of complex complex, and blood level -- blood samples were collected and sent to the institute to be analyzed. 13:25:54 13:26:01 13:26:09 13:26:14

And this was the basis of the disclosures in our patent. 13:26:22 13:26:27

BY MS. DASHE: 13:26:27

Q. Studies on single doses of the complex complex and the blood samples, these were studies that were done at IVAX? 13:26:27 13:26:38 13:26:42

A. No. These studies, as I said, I don't know the sites, but it indicated in the report that sites in Europe, in Belgium, in Poland, and I don't remember where, but I don't know where sites and who all was conducting the studies, who was the involved physician and who was from part of IVAX or Serono, whoever. 13:26:42 13:26:45 13:26:51 13:26:56 13:26:59 13:27:03

So that -- I tell you what I know. 13:27:10

Q. ... have any first -- you don't have any firsthand knowledge of the division of labor between IVAX and Serono pursuant to the agreement between the two companies; is that right? 13:27:11 13:27:17 13:27:20 13:27:23

A. I have -- no, I have no idea, because I didn't 13:27:25

even know about the agreement. 13:27:27

Q. Okay. And so, then, you don't have any 13:27:32

specific recollection of anyone at Serono communicating 13:27:36

any dosing regimens for cladribine directly to you; 13:27:40

right? 13:27:44

A. Actually, I don't even know anybody from 13:27:44

Serono. I don't remember ever meeting anybody. 13:27:47

Q. You don't remember anybody from Serono 13:27:52

indicating a dosing regimen to you; right? 13:28:01

A. Or any, anything. I had no connection with 13:28:04

Serono. 13:28:10

MS. DASHE: A quick five-minute break or -- 13:28:14

Dr. Bodor, is that -- is that all right? 13:28:18

THE WITNESS: Sure. That's fine. 13:28:20

MR. MLAVER: Okay. We'll be back on at 1:33. 13:28:21

VIDEOGRAPHER ELMILKI: Okay. We are off the 13:28:24

record, and the time now is 1:28 p.m. 13:28:26

(Recess taken.) 13:28:29

VIDEOGRAPHER ELMILKI: We are back on the 13:45:25

record, and the time is now 1:45 p.m. 13:45:26

BY MS. DASHE: 13:45:30

Q. Dr. Bodor, did you discuss the substance of 13:45:32

your testimony during the breaks today? 13:45:35

A. No. 13:45:36

Q. Okay. Now, going back to my line of questioning before we broke, I just want to clean up a few things here with the timelines, I'm a little bit fuzzy on that. 13:45:37 13:45:42 13:45:45 13:45:49

Now, before 2004, were you aware of the existence of any joint work between Serono and IVAX on cladribine at that time? 13:45:50 13:45:55 13:46:01

A. No. 13:46:01

Q. And so then before you filed your Bodor PCT application, were you aware of the existence of any joint work between Serono and IVAX on cladribine at that time? 13:46:01 13:46:09 13:46:12 13:46:17

A. No. 13:46:17

MR. MLAVER: Objection to form. 13:46:18

BY MS. DASHE: 13:46:18

Q. When did you first become aware that IVAX and Serono had entered into a joint research agreement? 13:46:22 13:46:29

A. That's a good question. I don't think I ever knew that there is an agreement. I was not involved. So even though I -- I cannot say that I was ever aware 13:46:47 13:46:49 13:46:54

of the agreement until I read some publication somewhere, press release or something like that. 13:46:57 13:47:06

Q. So the first time you became knowledgeable of the specific agreement between IVAX and Serono was when Merck approached you to write your declaration in this case? 13:47:09 13:47:15 13:47:20 13:47:23

A. No, not really. I mean, as I said before, I just assumed that there was an agreement because somebody said, oh, no, IVAX sent the samples to be analyzed at the institute of the -- that the bioavailability clinical trials. 13:47:24 13:47:30 13:47:36 13:47:40 13:47:48

So I assumed that it was somebody from Serono who was involved in sending the material, but I'm not sure. It might -- 13:47:52 13:47:54 13:47:58

Q. And approximately when was that? 13:47:59

A. That was in 2003 sometime. 13:48:00

Q. Let -- well, hold on. So you -- you were not aware of -- strike that. 13:48:13 13:48:18

When did you become aware specifically of the joint research agreement between Serono and IVAX? 13:48:23 13:48:28

A. I never really saw a specific agreement. So I -- 13:48:35 13:48:43

Q. My question is a little different, it's not when did you see the agreement, it's when did you first become aware that there -- of the existence of an agreement between IVAX and Serono regarding cladribine? 13:48:43 13:48:45 13:48:48 13:48:51

A. It could be before the patent office interview in 2008. 13:48:59 13:49:06

Q. But would it have been much before that? 2008 would be roughly the time that you first became aware that -- 13:49:07 13:49:16 13:49:19

A. You see, I don't know about the agreement, didn't know about the agreement, but could be that somebody from Serono was involved with IVAX for the -- for people and organized these clinical trials, which was analyzed at the institute, but I was not in the know about the agreement or kind of agreement. I still don't know. I don't know what was -- 13:49:20 13:49:23 13:49:27 13:49:35 13:49:41 13:49:48 13:49:51

Q. So -- 13:49:54

A. -- what was the subject, -- 13:49:55

Q. So then -- 13:49:56

A. -- what was the conditions, what was the terms, I don't know. 13:49:57 13:49:59

Q. Okay. So then the first time you became aware 13:49:59

of the existence of an agreement between IVAX and Serono regarding cladribine was roughly in the 2008 time frame; is that right? 13:50:04 13:50:10 13:50:16

A. Well, it -- yes. And if I think back, see, it is the patent which we filed in 2004 ultimately was assigned to R. Arens. So that's -- I think that is part of the Serono or something like that. 13:50:16 13:50:22 13:50:27 13:50:33

But again, it is something that is not clear to me, I was not involved in. 13:50:38 13:50:40

Q. So when did you first become aware -- strike that. 13:50:46

What was -- when did you first become aware of any existence of any joint cladribine work between IVAX and Serono? 13:50:56 13:51:02 13:51:08

A. We are going back and forth on the same issue. 13:51:22

I did not know about IVAX/Serono agreement whenever that happened, I don't know, 2003, '4. I assume within that period there was some kind of agreement because the material studied in Europe and the material was sent to IVAX in Budapest for analysis, and that's what was in my patent. 13:51:24 13:51:27 13:51:35 13:51:37 13:51:45 13:51:53

So that -- that shows the flavor, except I did 13:51:55

not know what was said on those involvement. I never have met -- the Serono people never came to visit Budapest and -- and that's all I can say. 13:52:00 13:52:04 13:52:10

Q. What material -- excuse me. 13:52:15

You referenced material that was sent to IVAX in Budapest for analysis. What material was that? 13:52:21 13:52:26

A. I mentioned before, the blood samples drawn from patients, in the hundreds of blood samples, based on these crossover studies comparing various oral formulation and subcutaneous or inter- -- intervenous, which are in the patent. 13:52:28 13:52:33 13:52:37 13:52:45 13:52:51

Q. And who sent this material? 13:52:53

A. The clinical sites from Poland and whatever, I don't know, they sent to the institute. Who organized it and collect it, I don't know. I assume that my -- 13:53:01 13:53:07 13:53:13

Q. Okay, so you don't -- 13:53:16

A. My deputy director at the institute and the clinical director, they knew where the samples come from, but I never knew, it really didn't matter, it was just one of the jobs they did. 13:53:17 13:53:22 13:53:29 13:53:34

Q. So you do not know who organized, collected, and sent these blood sample materials to IVAX; is that 13:53:38 13:53:41

right? 13:53:47

A. Yes. That's correct. 13:53:48

Q. And so then do you know why these materials were sent to IVAX? 13:53:50 13:53:58

A. They were sent for analysis. I told you I knew about -- 13:53:59 13:54:03

Q. Well, what sort -- 13:54:03

A. Analytical methods were developed for cyclodextrin from blood samples at the institute, and then the samples were received and analyzed. 13:54:05 13:54:17 13:54:20

Q. But you don't know -- I'm just trying to -- to get a frame of reference here. 13:54:23 13:54:27

These weren't samples that were being sent from Serono? Or do you know? 13:54:32 13:54:34

A. I don't think it was Serono. It was the clinical sites where the studies were done. Who organized these clinical studies, I don't know, I just assumed was done by IVAX with Serono or alone, but primarily IVAX because the samples came to the IVAX institute in Budapest. 13:54:35 13:54:40 13:54:43 13:54:47 13:54:58 13:55:05

Q. So does any of this have anything to do with Serono's work on cladribine? 13:55:05 13:55:07

A. What work are you related -- the published one? 13:55:09 13:55:16

The published work had important -- 13:55:16

Q. I'm just saying -- I guess I'm a little bit confused is -- is all. 13:55:18 13:55:23

So this discussion we're having about samples and analysis, does this relate to Serono's work on cladribine at all, setting aside any publications or anything like that? 13:55:25 13:55:27 13:55:31 13:55:35

MR. MLAVER: Objection, foundation. 13:55:36

A. Yeah, I don't know. You are assuming things which I -- I don't know. Maybe these IVAX study of the -- which entered in my patent, maybe those studies were shared with Serono or they knew about it, I don't know. But again, I was not involved with the Serono/IVAX interaction. 13:55:39 13:55:41 13:55:50 13:55:54 13:56:01 13:56:05

MS. DASHE: Counsel, could we take a -- a quick break? We're almost done, I just want to make -- consolidate my notes and make sure we can bring this home quickly. 13:56:39 13:56:41 13:56:43 13:56:46

MR. McGUFFIN: That would be great. 13:56:48

MR. MLAVER: Let's go ahead and go off the 13:56:49

record. 13:56:52
MS. DASHE: Okay. 13:56:52
VIDEOGRAPHER ELMILKI: Off the record, and the 13:56:53
time now is 1:56 p.m. 13:56:54
(Recess taken.) 13:57:06
VIDEOGRAPHER ELMILKI: We are back on the 14:00:38
record, and the time now is 2:00 p.m. 14:00:44
MS. DASHE: Good afternoon, Dr. Bodor. I have 14:00:49
no further questions for you. 14:00:51
THE WITNESS: Great. 14:00:54
Thank you. 14:01:00
MR. MLAVER: No questions for me. Let's go 14:01:02
off the record. 14:01:05
MS. DASHE: Thank you. 14:01:06
All right, thank you very much. Thank you for 14:01:06
your time, Dr. Bodor, I really appreciate it. 14:01:08
THE WITNESS: Thank you. 14:01:11
VIDEOGRAPHER ELMILKI: Wait. Wait. 14:01:12
We are off the record, and the time now is 14:01:13
2:01 p.m. 14:01:15
THE COURT REPORTER: Let me check, I don't
have it in front of me, but I know someone is

getting a rough draft. Is that both sides or is it just -- 14:01:38

MR. McGUFFIN: I mean, I don't think we've put in our order. It would be great if we can get a rough. 14:01:38 14:01:40 14:01:41

THE COURT REPORTER: Okay. This evening. Okay.

MR. McGUFFIN: Yeah. 14:01:42

MS. DASHE: Yes, us too as well, please, for the Hopewell team. 14:01:42 14:01:45

THE COURT REPORTER: Okay. And regular time on the transcript delivery? 14:01:48 14:01:49

MS. DASHE: Oh, regular versus expedited. 14:02:09

THE COURT REPORTER: Yes.

MS. DASHE: Is what you're saying?

THE COURT REPORTER: Yes.

MS. DASHE: Let me quickly confer with my team here. 14:02:22 14:02:23

Expedited, please. Thank you. 14:02:30

THE COURT REPORTER: When would you like it? 14:02:32

MS. DASHE: Sometime today would be great if you could. 14:02:36 14:02:44

(Off the record from 2:03 p.m. to 2:03 p.m.) 14:03:00

THE COURT REPORTER: I could have it probably in 24 hours.

(Off the record from 2:03 p.m. to 2:03 p.m.)

MS. DASHE: Final as soon as possible, please. Expedited on the -- 24 hours on the full, nice, pretty copy is wonderful.

THE COURT REPORTER: Good. Yes. I will have you the draft before too long.

And would y'all like a copy -- expedited copy? 14:03:13

MR. McGUFFIN: We'll take the same, yeah, 14:03:13
rough when it's ready, expedited when it's ready. 14:03:15

(Off the record from 2:03 p.m. to 2:03 p.m.) 14:03:33

MR. MLAVER: And I just forgot to say on the 14:03:34
record that we would like to designate the 14:03:35
transcript confidential under the protective order. 14:03:38
If you could have it marked that way. And that's 14:03:43
all for me. 14:03:45

(This deposition was concluded at 2:03 p.m.)

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

deposition.

I further certify that the deposition of Nicholas Bodor, PhD, DSc, dhc, HoF, occurred at the offices of Bodor Laboratories, 4400 Biscayne Boulevard, 11th Floor, Miami, Florida, 33137, on Thursday, February 15, 2024, 9:34 a.m. to 2:03 p.m.

I further certify that I am not related to any of the parties to this action by blood or marriage, I am not employed by or an attorney to any of the parties to this action, and that I am in no way interested, financially or otherwise, in the outcome of this matter.

Dated this 16th day of February, 2024.

NANCY E. PAULSEN, CRR, CRC, RPR, FPR

CERTIFICATE OF OATH

STATE OF FLORIDA)

COUNTY OF SARASOTA)

I, the undersigned authority, certify that Nicholas Bodor, PhD, DSc, dhc, HoF, personally appeared before me on February 15, 2024, produced a Florida driver's license for identification, and was duly sworn.

WITNESS my hand and official seal this 16th day of February, 2024.

Nancy E. Paulsen, CRR, CRC, RPR
Notary Public
State of Florida at Large
My Commission Number: HH421500
Expires: September 17, 2027

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