UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARPE & DOHME LLC,

Petitioner,

vs.

THE JOHN HOPKINS UNIVERSITY,

Patent Owner.

_____

IPR2024-00622 (U.S. Patent No. 10,934,356)
IPR2024-00623 (U.S. Patent No. 11,325,974)
IPR2024-00624 (U.S. Patent No. 11,325,975)
IPR2024-00625 (U.S. Patent No. 11,339,219)
IPR2024-00648 (U.S. Patent No. 11,643,462)
IPR2024-00649 (U.S. Patent No. 11,629,187)
IPR2024-00647 (U.S. Patent No. 11,649,287)
IPR2024-00650 (U.S. Patent No. 11,634,491)

Job No.: 580483

Pages: 1 - 123

Stenographically Reported By:

Alison C. Webster, CSR, RPR, RMR, CRR, RDR

DEPOSITION OF DUNG LE, M.D.

Friday, April 18, 2025

Deposition of DUNG LE, M.D., produced as a witness atthe instance of the Petitioner, and duly sworn, was taken in the above-styled and numbered cause on Friday, April 18, 2025, from 9:07 a.m. to 12:14 p.m. Eastern Time, before Alison C. Webster, RPR, CRR, RMR, RDR, CSR-6266 (Michigan); License No. 14559 (California); License No. 084.004953 (Illinois); CSR-12432 (Texas), reported by stenographic method, via videoconference, pursuant to the Federal Rules of Civil Procedure and the provisions stated on the record or attached hereto.

A P P E A R A N C E S

ON BEHALF OF THE PETITIONER

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ALSO PRESENT:

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T A B L E O F C O N T E N T S

Witness Page

DUNG LE, M.D.

EXAMINATION

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EXAMINATION

BY MS. BROWN-MARSHALL: 104

RE-EXAMINATION

BY MR. RATLIFF: 117

E X H I B I T I N D E X

Exhibit Page

(Exhibit attached to transcript.)

EXHIBIT 1134 75

Keytruda labeling, IPR2024-00622

DEPOSITION OF DUNG LE, M.D.

Friday, April 18, 2025

STENOGRAPHER: The attorneys participating in this deposition and the witness have verified that she is Dung Le, M.D. In lieu of an oath administered in person, the witness will visually affirm her testimony in this matter is under penalty of perjury.

The parties and their counsel consent to this arrangement and waive any objections to this manner of reporting or admissibility of the transcript.

Would counsel please state their appearance and any objections to proceeding in this manner, starting with scheduling counsel. 09:07:41

MR. RATLIFF: This is Preston Ratliff from 09:07:41
the Paul Hastings law firm in New York on behalf of 09:07:47
petitioner. And I'm joined today by my colleagues 09:07:50
from Paul Hastings, Jessica Stauring and Jinny Lim, 09:07:54
and also I'm joined by in-house counsel Karen Moreira 09:07:58
and Mark Stewart. 09:08:02

MS. BROWN-MARSHALL: Christina 09:08:04

Brown-Marshall of Fish & Richardson. I'm here on behalf of patent owner Johns Hopkins University and Dr. Le. 09:08:06 09:08:10 09:08:12

STENOGRAPHER: Thank you.

Hearing no objections, Dr. Le, would you please raise your right hand?

Do you swear or affirm the testimony you are about to give in this matter will be the truth, the whole truth, and nothing but the truth?

DR. LE: I do.

STENOGRAPHER: Thank you.

You may proceed.

DUNG LE, M.D.,

was thereupon called as a witness herein, and after having first been duly sworn to testify to the truth, the whole truth and nothing but the truth, was examined and testified as follows: 09:08:28

EXAMINATION 09:08:28

BY MR. RATLIFF: 09:08:28

Q. Doctor, please state your full name for the record. 09:08:28

A. Dung T. Le. 09:08:32

Q. Please state your residence address. 09:08:36

A. 12 Laurel Circle, Lutherville, Maryland 21093. 09:08:39

Q. It's good to see you again, Doctor. I wish we could have been in person doing this today, but I understand that you have an issue that prevents that. Right? 09:08:44 09:08:49 09:08:51

A. Correct. 09:08:54

Q. And how are you feeling today? 09:08:54

A. I'm feeling okay today. Thank you. 09:08:58

Q. Do you understand that you are testifying under oath today? 09:08:59 09:09:03

A. Yes. 09:09:05

Q. Is there any reason you cannot testify truthfully today? 09:09:05 09:09:09

A. No. 09:09:09

Q. Now, the last time we spoke was on January 9, 2025, when you had your deposition taken in the IPR proceeding as to the '393 patent. 09:09:10 09:09:18 09:09:21

Are you still employed by the Johns Hopkins School of Medicine? 09:09:26 09:09:30

A. Yes. 09:09:31

Q. Now, since your deposition in the IPR proceeding as to the '393 patent, you signed eight additional IPR declarations on behalf of JHU. Right? 09:09:31 09:09:36 09:09:42

A. Yes. 09:09:46
Q. And you signed a declaration as to the '356 patent; is that right? 09:09:49 09:09:55
A. I don't have all the patent numbers in front of me. 09:09:58
Q. Do you have any documents with you or in front of you? 09:10:01
A. I do. 09:10:05
Q. Do you have a copy of your declarations in front of you? 09:10:06 09:10:09
A. That is what I do have a copy of. 09:10:10
Q. Okay. So let's take a look at your declarations and see if you can find a copy of a declaration that you signed as to the '356 patent. 09:10:13 09:10:18 09:10:22
A. I see one, yes. 09:10:38
Q. Okay. And you signed that declaration as to the '356 patent on January 12, 2025. Right? 09:10:39 09:10:42
A. That's the one I'm looking at, yes. It says January 12, 2025. 09:10:49 09:10:52
Q. Okay. And you signed a declaration as to the '974 patent on January 12, 2025. Right? 09:10:53 09:11:00
A. Yes. 09:11:08
Q. And you have a copy of that declaration with you? 09:11:08
A. I do. But you said '975? 09:11:11

Q. I said '974. 09:11:14
A. I'm sorry, '974. Yes. I'm looking at '974. 09:11:16
Q. Okay. So let's talk about '975. You signed a 09:11:20
declaration as to the '975 patent on January 12, 2025. 09:11:24
Right? 09:11:31
A. Yes. 09:11:38
Q. Do you have a copy of that declaration with you? 09:11:39
A. Yes. 09:11:42
Q. And you signed a declaration as to the '219 patent on 09:11:42
January 12, 2025. Right? 09:11:52
A. January 12, 2025. Yes. 09:12:05
Q. Okay. And you have a copy of that declaration with 09:12:07
you? 09:12:09
A. Yes. 09:12:10
Q. You signed a declaration as to the '287 patent on 09:12:10
January 22nd, 2025. Right? 09:12:18
A. '287... January -- wait, what's the date that you 09:12:28
said? 09:12:34
Q. January 22nd, 2025. 09:12:34
A. Yes, that one's dated January 22nd, 2025, yes. 09:12:37
Q. Do you have a copy of that declaration with you? 09:12:41
A. I do. 09:12:43

Q. You signed a declaration as to the '462 patent on January 22nd, 2025. Right? 09:12:43 09:12:53

A. '462... '462... January 22nd, 2025, yes. 09:12:58

Q. Do you have a copy of that declaration with you? 09:13:12

A. Yes. 09:13:14

Q. You signed a declaration as to the '187 patent on January 22nd, 2025. Right? 09:13:14 09:13:21

A. '187? 09:13:29

Q. '187. 09:13:31

A. '187... January 22nd, 2025. Yes. 09:13:33

Q. Do you have a copy of that declaration with you? 09:13:38

A. Yes. 09:13:41

Q. You signed a declaration as to the '491 patent on January 22nd, 2025. Right? 09:13:42 09:13:54

A. '491... January 22nd, 2025, yes. 09:13:55

Q. Do you have a copy of that declaration with you? 09:14:02

A. Yes. 09:14:04

Q. Now, have you read each of the eight patents that you mention in the declarations that we're discussing today? 09:14:04 09:14:10 09:14:13

A. I -- have I read them? I haven't read them in detail. 09:14:16 09:14:20

Q. Have you read them at all? 09:14:20
A. I don't recall reading the specific patents. 09:14:23
Q. Do you recall reading any of the eight patents that you mention in your declarations that we're discussing today? 09:14:26 09:14:29 09:14:33
A. I can't recall specifically if I read any of the eight patents. 09:14:34 09:14:38
Q. Do you have any general recollection of reading any of the eight patents that you mention in your declarations that we're discussing today? 09:14:39 09:14:42 09:14:45
A. I don't have a recollection of reading the patents. I certainly have read the declarations. 09:14:48 09:14:50
Q. Okay. Have you read any of the claims in each of the eight patents that you mention in your declarations that we're discussing today? 09:14:52 09:14:58 09:15:01
A. I don't recall specifically reading the claims. 09:15:04
Q. Do you have any general recollection whatsoever of ever looking at any of the claims of the eight patents that you mention in your declarations that we're discussing today? 09:15:07 09:15:11 09:15:15 09:15:19
A. I don't have a general recollection of reading specifically the claims. 09:15:21 09:15:23

Q. Sitting here today, do you know whether or not any of the claims in the eight patents that you mention in your declarations cover what you believe that you and the JHU scientists invented? 09:15:24 09:15:32 09:15:37 09:15:43

MS. BROWN-MARSHALL: Object to the form of the question. 09:15:48 09:15:48

BY MR. RATLIFF: 09:15:48

Q. You can answer, Doctor. 09:16:01

A. I'm sorry, can you repeat the question? 09:16:01

Q. Sure. Sitting here today, do you know whether any of the claims in the eight patents that you mention in your declarations that we're discussing today cover what you believe that you and the JHU scientists invented? 09:16:05 09:16:07 09:16:10 09:16:15 09:16:18

MS. BROWN-MARSHALL: Same objection. 09:16:19

A. I'm sorry, can you repeat the question again? 09:16:28

BY MR. RATLIFF: 09:16:30

Q. Maybe I won't repeat it because it sounds like you're having trouble with it. Maybe I'll try a different question. 09:16:30 09:16:33 09:16:36

Let's take, for example, the '356 patent. Do you know whether or not the '356 patent claims 09:16:36 09:16:39

cover what you believe that you and the JHU scientists invented? 09:16:45 09:16:49

MS. BROWN-MARSHALL: Object to the form of the question. 09:16:51 09:16:56

A. Do I believe these patents are associated with our claims? 09:16:56 09:17:00

BY MR. RATLIFF: 09:17:01

Q. No. I'm asking you a different question. 09:17:02

Do you believe that any of the eight patents cover what you think you and the JHU scientists invented? 09:17:04 09:17:06 09:17:13

MS. BROWN-MARSHALL: Object to the form of the question. 09:17:15 09:17:19

A. Do I believe that is associated with our claims? 09:17:19

BY MR. RATLIFF: 09:17:23

Q. I didn't say "associated." So my question is different. And let me try it again. 09:17:23 09:17:25

Do you have any understanding as to what is covered by the eight patents that you specifically mention in the eight declarations that you signed? 09:17:29 09:17:32 09:17:37

MS. BROWN-MARSHALL: Object to the form of the question. 09:17:45 09:17:48

A. I believe that they're associated with the declarations. 09:17:48 09:17:50

BY MR. RATLIFF: 09:17:53

Q. You believe they're associated with the declarations why? 09:17:54 09:17:56

MS. BROWN-MARSHALL: Object to the form of the question. 09:17:58 09:18:03

A. Because the topic of the discussion is the patents. 09:18:03

BY MR. RATLIFF: 09:18:09

Q. Okay. Do you discuss the patents in your declarations? 09:18:09 09:18:13

A. I discuss the fact that it's in relation to these patents. 09:18:14 09:18:20

Q. What's in relation to these patents? 09:18:22

A. It says I am one of the inventors of the United States patent, and then -- is the very first line of the declaration -- I mean, it's not the first line but one of the earlier lines of the declaration. 09:18:25 09:18:32 09:18:36 09:18:38

Q. Did you ever read any of the claims of the eight patents to confirm whether or not you believe that you invented the subject matter that's covered by the claims? 09:18:41 09:18:46 09:18:51 09:18:54

MS. BROWN-MARSHALL: Object to the form of the question. 09:18:55 09:18:58

A. Did I read the patent? 09:18:58

BY MR. RATLIFF: 09:19:06

Q. Did you ever read any of the claims of the eight patents to confirm whether or not you believe that you invented the subject matter that is covered by the claims? 09:19:06 09:19:11 09:19:15 09:19:18

MS. BROWN-MARSHALL: Object to the form of the question. 09:19:20 09:19:26

A. Did I ever read the patent. 09:19:26

BY MR. RATLIFF: 09:19:28

Q. No, I didn't say that. So here are the first couple of words. Did you ever read any of the claims of the eight patents. So keep that in mind. I'm going to say it again. 09:19:28 09:19:32 09:19:34 09:19:36

Did you ever read any of the claims of the eight patents to confirm what you believe that you invented is the subject matter that's covered by the claims? 09:19:37 09:19:40 09:19:44 09:19:48

MS. BROWN-MARSHALL: Object to the form of the question. 09:19:49 09:19:53

A. Did I ever read the claims. I don't recall if I read the claims specifically to these patents. 09:19:53 09:19:57

BY MR. RATLIFF: 09:19:57

Q. Sitting here today, do you know whether or not the claims cover what you believe you invented? 09:20:04 09:20:06

MS. BROWN-MARSHALL: Object to the form of the question. 09:20:14 09:20:16

A. I'm sorry, one more time? 09:20:16

BY MR. RATLIFF: 09:20:16

Q. Sitting here today, do you know whether or not the claims of the eight patents that you mention in your declarations cover what you believe you invented? 09:20:16 09:20:20 09:20:22

MS. BROWN-MARSHALL: Object to the form of the question. 09:20:27 09:20:28

A. Do I believe it? Do I believe the patents cover the claims? 09:20:28 09:20:34

BY MR. RATLIFF: 09:20:35

Q. No. Do you know whether or not the claims of the eight patents that you mention in your declarations cover what you believe you invented? 09:20:35 09:20:41 09:20:43

MS. BROWN-MARSHALL: Object to the form of the question. 09:20:45 09:20:53

A. Do I believe it -- do I believe the claims cover the... I'm sorry, I'm having trouble processing that. One more time? 09:20:53 09:20:56 09:21:00

BY MR. RATLIFF: 09:21:01

Q. Do any of the claims of the '356 patent cover what you believe you invented? 09:21:06 09:21:10

MS. BROWN-MARSHALL: Object to the form of the question. 09:21:11 09:21:14

A. I cannot recall specifically the claims in these patents, so... 09:21:14 09:21:20

BY MR. RATLIFF: 09:21:26

Q. Do any of the claims of the '974 patent cover what you believe you invented? 09:21:26 09:21:31

MS. BROWN-MARSHALL: Object to the form of the question. 09:21:32 09:21:35

A. Do any of the claims... I cannot recall the specific claims in these patents. 09:21:35 09:21:40

BY MR. RATLIFF: 09:21:43

Q. Do any of the claims of the '975 patent cover what you believe you invented? 09:21:43 09:21:48

MS. BROWN-MARSHALL: Object to the form of the question. 09:21:49 09:21:54

A. I cannot recall the claims in the '974 patent. 09:21:54

BY MR. RATLIFF: 09:22:01

Q. Do any of the claims of the '219 patent cover what you believe you invented? 09:22:01 09:22:04

MS. BROWN-MARSHALL: Object to the form of the question. 09:22:07 09:22:09

A. I don't recall -- I can't recall any specific -- any of the specific claims in these patents. 09:22:09 09:22:16

BY MR. RATLIFF: 09:22:18

Q. Do any of the claims of the '287 patent cover what you believe you invented? 09:22:19 09:22:25

MS. BROWN-MARSHALL: Object to the form of the question. 09:22:26 09:22:31

A. I don't recall the specific claims in these patents. 09:22:31

BY MR. RATLIFF: 09:22:37

Q. Do any of the claims of the '462 patent cover what you believe you invented? 09:22:37 09:22:43

MS. BROWN-MARSHALL: Object to the form of the question. 09:22:44 09:22:50

A. I don't recall the claims specifically in the patent. 09:22:50

BY MR. RATLIFF: 09:22:54

Q. Do any of the claims of the '187 patent cover what you 09:22:54

believe you invented? 09:22:58

MS. BROWN-MARSHALL: Object to the form of the question. 09:22:59 09:23:04

A. I don't recall the specific claims in the -- I'm sorry, which patent was that, '187? 09:23:04 09:23:11

BY MR. RATLIFF: 09:23:15

Q. '187. 09:23:15

A. '187 patent. 09:23:16

Q. Do any of the claims of the '491 patent cover what you believe you invented? 09:23:18 09:23:22

MS. BROWN-MARSHALL: Object to the form of the question. 09:23:24 09:23:32

A. Will you repeat the question? Which patent? 09:23:32

BY MR. RATLIFF: 09:23:34

Q. Do any of the claims of the '491 patent cover what you believe you invented? 09:23:34 09:23:38

MS. BROWN-MARSHALL: Object to the form of the question. 09:23:41 09:23:42

A. I don't recall the specific claims in that patent. 09:23:42

BY MR. RATLIFF: 09:23:47

Q. And when you signed your eight declarations that we're discussing today, did you review the claims of any of 09:23:47 09:23:56

the eight patents mentioned in your declarations? 09:23:59
A. I did not specifically review the eight patents. 09:24:05
Q. Now, Doctor, in your view, are there any significant differences between your declaration in the IPR proceeding as to the '393 patent compared to the eight additional IPR declarations that you signed? 09:24:23 09:24:26 09:24:28 09:24:34
MS. BROWN-MARSHALL: Object to the form of the question. 09:24:37 09:24:45
A. Are there any significant changes from these declarations to the prior declarations? I -- would we be able to look at the two sets of declarations? 09:24:45 09:24:47 09:24:59
BY MR. RATLIFF: 09:25:05
Q. Let me ask my question a different way. 09:25:05
Sitting here today, in your view, are there any significant differences between your declaration and the IPR proceeding as to the '393 patent compared to the eight additional IPR declarations that you signed? 09:25:09 09:25:11 09:25:15 09:25:20 09:25:23
MS. BROWN-MARSHALL: Object to the form of the question. 09:25:28 09:25:33
A. Do I believe that there is... I know that there are differences. I don't know that they are particularly 09:25:33 09:25:37

significant, but I do know that there are differences. 09:25:40 09:25:43

BY MR. RATLIFF: 09:25:45

Q. Do you have an opinion one way or the other if the differences are significant, in your view? 09:25:45 09:25:49

A. I'd feel more comfortable just looking at them again to see what they are. 09:25:55 09:25:58

Q. Did you review your declarations in preparation for your deposition today? 09:26:00 09:26:08

A. I did. 09:26:09

Q. And when did you review your eight declarations in preparation for your deposition today? 09:26:11 09:26:14

A. Sometime this week. 09:26:17

Q. And sitting here today, are you aware of any differences between the declaration in the IPR proceedings as to the '393 patent compared to the eight additional IPR declarations that you signed? 09:26:18 09:26:24 09:26:28 09:26:31

A. I recall that there were differences. 09:26:33

Q. And do you recall any specific differences, sitting here today? 09:26:39 09:26:41

A. I'm always more comfortable looking at something rather than depending on my memory, but there were 09:26:41 09:26:44

differences.
Q. Okay. And I didn't ask you if you were more comfortable relying on your memory versus something else. It's a different question.
Just sitting here today right now, do you have any recollection whatsoever what were some of the differences between your declaration as to the '393 proceeding compared to the eight additional IPR declarations that you signed?
A. Can I take a look at my declarations just to jog my memory on the areas that were changed or added?
Q. We can do that. We can do that. But my question is different. I'm asking you, without taking a look, just sitting here today right now do you have any recollection whatsoever as to what differences there were that you made between your IPR declaration as to the '393 patent and the eight additional IPR declarations that you signed?
MS. BROWN-MARSHALL: Object to the form of the question.
A. Let me -- give me a second to think about it. I'm not the fastest on my feet.

The declarations... differences in the declarations... 09:28:08 09:28:14

I can remember a particular area. Can I just look at it since it's right next to me? 09:28:24 09:28:26

Q. Sure. Just let me know what you're looking at. 09:28:29

A. I'm just picking -- I'll just let you know. So I'll just look at the first one. The first one in my book is the '187. 09:28:39 09:28:43 09:28:47

I believe that -- again, without having the two sets of declarations in front of me, there was a little bit more about prescreening for Arm C in this declaration. 09:29:24 09:29:26 09:29:30 09:29:34

Q. And the declaration that you're looking at, are you referring to your declaration as to the '187 patent? 09:29:40 09:29:42

A. That's correct. 09:29:45

Q. And are you referring to what's written in paragraph 12? 09:29:47 09:29:56

A. That's correct. 09:29:57

Q. Why did you include paragraph 12 in this particular declaration? 09:30:09 09:30:13

MS. BROWN-MARSHALL: Object to the form of the question. 09:30:14 09:30:20

A. Paragraph 12 referenced Arm C of this study. 09:30:20

BY MR. RATLIFF: 09:30:36

Q. Okay, so my -- I'm asking you, why did you -- why did you include the text that we see in paragraph 12? I believe your prior declarations reference all arms of the study. 09:30:36 09:30:38 09:30:42 09:30:49

A. It just gave a little bit more detail about Arm C of the study. 09:30:50 09:30:53

Q. And why were you giving a little bit more detail about Arm C in this particular declaration? 09:30:53 09:31:01

A. It provides more information on selection for patients for Arm C of the study. 09:31:03 09:31:11

Q. Okay. Well, let's take a look at paragraph 12 in your declaration as to the '187 patent. And in the first sentence the text reads, "For Arm C, we did not specify which types of non-colorectal cancer we would include prior to the trial." 09:31:13 09:31:18 09:31:26 09:31:31 09:31:36

Do you see that? 09:31:38

A. Yes. 09:31:42

Q. And when you say "we did not specify," specify to who? Who are you referring to? 09:31:42 09:31:50

A. "We did not specify," referring to the -- anyone 09:31:53

who's reading the protocol. 09:32:07

Q. Okay. So this is a -- are you -- 09:32:10

A. Well, I guess any -- 09:32:12

[Simultaneous Speaking] 09:32:14

A. Say that one more time. 09:32:15

Q. I'm still asking for the who. 09:32:17

A. We did not specify which types... when we're writing the documents, we're not specifying which types. 09:32:19 09:32:24

Q. Which documents are you talking about? What did you mean -- when you signed off on this declaration, what did you mean by "we did not specify"? Who to? 09:32:27 09:32:29 09:32:37

MS. BROWN-MARSHALL: Object to the form of the questions. 09:32:40 09:32:44

A. We did not specify to anyone. 09:32:45

BY MR. RATLIFF: 09:32:54

Q. Okay. And you referenced documents, before, in your answer. What documents are you talking about? 09:32:54 09:32:56

A. Any documents when we're trying to put forth a study, we did not specify what types of non-colorectal cancer. 09:33:05 09:33:17 09:33:22

Q. What do you mean by "any documents when we're trying to put forth a study"? What documents are those? 09:33:22 09:33:26

MS. BROWN-MARSHALL: Objection. Asked and answered. 09:33:29 09:33:32

A. Which documents... specifically, they're -- there is not a document in which we specified which types of non-colorectal cancer we would include. 09:33:32 09:33:40 09:33:47

BY MR. RATLIFF: 09:34:00

Q. Okay. In the last sentence of this paragraph 12 you go on to write, "As part of a prescreening process for Arm C we consented patients to have their tumors tested for MSI and organized a research team to consent patients, retrieve archived samples and order testing." 09:34:00 09:34:02 09:34:09 09:34:12 09:34:15 09:34:23

Do you see that? 09:34:24

A. Yes. 09:34:24

Q. And is that a sentence that you wrote? 09:34:24

A. Yes. 09:34:27

Q. And this prescreening process that you refer to, is that something that was disclosed or mentioned in the New England Journal of Medicine article of which you are an author? 09:34:28 09:34:33 09:34:41 09:34:45

A. Prescreening process... I would have to look at it specifically again. 09:34:49 09:34:53

Q. We can take a look at it. 09:35:05

MR. RATLIFF: Let's put Exhibit 1031 in the Chat. 09:35:06 09:35:09

PLANET DEPOS TECH: Please stand by. 09:35:11

BY MR. RATLIFF: 09:35:37

Q. And let me know, Doctor, when you have Exhibit 1031, which is the New England Journal of Medicine article of which you are an author. 09:35:37 09:35:40 09:35:44

A. Yes, I have it in front of me. 09:35:48

Q. And my question is, this prescreening process for Arm C that you refer to in paragraph 12 of your declaration, is it included anywhere in the New England Journal of Medicine article? 09:35:50 09:35:56 09:36:01 09:36:09

A. Just a quick look at the study design, I do not see any words mentioned for prescreening. There is reference to a protocol, but I don't -- but the answer to your question is no. 09:36:59 09:37:02 09:37:05 09:37:11

Q. And I want to be sure I have an answer to my question because I'm asking you about the entire article. I know you referenced the study design. So let me just ask my question again so we're clear. 09:37:16 09:37:18 09:37:21 09:37:24

Is the prescreening process for Arm C that 09:37:30

you refer to in paragraph 12 of your declaration, is it included anywhere in the New England Journal of Medicine article, Exhibit 1031? 09:37:34 09:37:40 09:37:45

MS. BROWN-MARSHALL: Objection. Asked and answered. 09:37:51 09:37:52

A. I don't see it referenced in the article. 09:37:52

BY MR. RATLIFF: 09:38:11

Q. Now, in the patent specification for the eight patents that you mention in your declarations, you told the patent office that all patients underwent MSI status testing prior to enrollment. Right? 09:38:11 09:38:14 09:38:19 09:38:24

MS. BROWN-MARSHALL: Object to the form of the question. 09:38:29 09:38:31

A. I'm sorry, can you repeat the question? 09:38:31

BY MR. RATLIFF: 09:38:41

Q. In the patent specification for the eight patents that you mention in your declarations, you told the patent office that all patients underwent MSI status testing prior to enrollment. Right? 09:38:41 09:38:45 09:38:49 09:38:55

MS. BROWN-MARSHALL: Object to the form of the question. 09:38:57 09:38:57

A. I -- in -- I told the patent office? I -- again, I 09:39:00

don't know specifically what's in those patents. I'd have to look to see what it says. 09:39:04 09:39:11

BY MR. RATLIFF: 09:39:13

Q. Did you read the patents before they were applied for? 09:39:13

MS. BROWN-MARSHALL: Object to the form of the question. 09:39:23 09:39:27

A. I don't recall reading the patents specifically. 09:39:27

BY MR. RATLIFF: 09:39:32

Q. Okay. But is it your understanding that all patients underwent MSI status testing prior to enrollment? 09:39:33 09:39:36

MS. BROWN-MARSHALL: Object to the form of the question. 09:39:39 09:39:46

A. Did all patients undergo prior to enrollment... 09:39:46

Patients did undergo testing prior to treatment, so enrollment -- depends on what you mean by "enrollment." They have -- just depending on the study, it has different criteria. 09:39:56 09:40:05 09:40:09 09:40:14

But we did test patients after a prescreening consent for Arm C patients. 09:40:15 09:40:24

BY MR. RATLIFF: 09:40:34

Q. My question is about all patients. 09:40:34

A. Okay. 09:40:36

Q. Is it correct for the MSI-High study that's described in the MSI-High study record, this is Exhibit 1005 that you refer to in your declarations, that all patients for that study underwent MSI status testing prior to enrollment? 09:40:37 09:40:42 09:40:50 09:40:55 09:41:03

MS. BROWN-MARSHALL: Object to the form of the question. 09:41:04 09:41:08

A. Okay. So you're asking me about a study -- can you -- again, this is a study record that we talked about before? 09:41:08 09:41:15 09:41:17

BY MR. RATLIFF: 09:41:17

Q. I'm talking about the study record that you refer to in your declaration, Exhibit 1005. 09:41:27 09:41:29

A. Okay, can you show me that exhibit? 09:41:40

Q. Are you familiar with the study record for the trial with the identifier NCT02060188? 09:41:45 09:41:47

MS. BROWN-MARSHALL: Object to the form of the question. 09:41:54 09:41:56

A. Am I familiar with it? 09:41:56

BY MR. RATLIFF: 09:41:58

Q. Yes. 09:41:58

A. Yes, but I'd just like to look at it. I believe we 09:41:59

talked about it, the last declaration, but... 09:42:01

Q. And are you familiar with the study record for the trial NCT01876511? 09:42:04 09:42:06

MS. BROWN-MARSHALL: Object to the form of the question. 09:42:11 09:42:14

A. I don't remember the specific NCTs. I think you would have to show them -- the exhibit to me for that. 09:42:14 09:42:18 09:42:22

BY MR. RATLIFF: 09:42:22

Q. Are you familiar with the Phase 2 study of pembrolizumab in patients with microsatellite unstable MSI tumors? 09:42:22 09:42:26 09:42:29

MS. BROWN-MARSHALL: Object to the form of the question. 09:42:31 09:42:34

A. Am I familiar with the study... yes, I am familiar with the study. 09:42:34 09:42:38

BY MR. RATLIFF: 09:42:39

Q. Okay. And so my question is, in that particular study, is it correct that all patients underwent MSI status testing prior to enrollment? 09:42:40 09:42:43 09:42:46

MS. BROWN-MARSHALL: Object to the form of the question. 09:42:49 09:42:55

A. I think that -- you're asking me questions specifically to a study record. Could I see the study record? 09:42:55 09:42:57 09:43:00

BY MR. RATLIFF: 09:43:00

Q. No, I'm not asking you questions specific to a study record. We're talking about the study. 09:43:01 09:43:04

A. The clinical trial. 09:43:07

Q. That's what we're talking about. 09:43:09

A. The protocol. 09:43:10

Q. No, we're not talking about the protocol. We're talking about the clinical trial. Okay? So my question is -- 09:43:11 09:43:14 09:43:20

A. So what's the difference between the clinical trial and the protocol so that I just can just better answer the questions the best that I can? 09:43:21 09:43:23 09:43:27

Q. Let's try it this way because I don't think it's about a difference. I'm asking about the clinical trial. 09:43:29 09:43:32

You were -- maybe I have this wrong. You were the principal investigator for the Phase 2 study of pembrolizumab in patients with microsatellite unstable MSI tumors that was announced in a study record in June of 2013. Right? 09:43:36 09:43:44 09:43:49 09:43:52 09:43:59

A. Yes. 09:44:00
Q. That's you, right? 09:44:01
A. Yes. 09:44:04
Q. Okay. And for that trial, isn't it correct that all patients underwent MSI testing prior to enrollment? 09:44:04 09:44:12
A. For the clinical protocol, patients were tested prior to treatment. 09:44:19 09:44:25
Q. Okay. So all patients were tested prior to treatment. 09:44:33
A. Correct. 09:44:36
Q. Is it also correct that all patients underwent MSI status testing prior to enrollment? 09:44:37 09:44:44
MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 09:44:49 09:44:50
A. Yeah, I guess I'm stuck on this enrollment. We had a prescreening process where we signed consent and tested patients' tumors. 09:44:50 09:44:54 09:44:58
BY MR. RATLIFF: 09:45:03
Q. Okay. Let's take a look at the '356 patent that you refer to in one of your declarations. It's Exhibit 1001. 09:45:03 09:45:10 09:45:15
MR. RATLIFF: We can put that in the Chat. 09:45:19
BY MR. RATLIFF: 09:45:24

Q. And let me know when you have it, Doctor. 09:45:25
A. Okay, United States Patent, Patent Number '356. 09:45:39
Q. You have the '356 patent, Doctor? 09:45:49
A. Yes. 09:45:51
Q. Okay. I'd like to turn your attention to column 9 of that patent. 09:45:51 09:46:01
A. Column 9. Is it on a particular page? 09:46:01
Q. It is on a particular page. 09:46:06
A. And which page would that be? 09:46:15
Q. I believe it's page 25. 09:46:17
A. Okay, I'm on page 25 of 31. 09:46:32
Q. Actually, go to page 22. 09:46:36
A. Okay. I see the number 9 up top. 09:46:44
Q. Okay. So that's -- now you're at column 9. 09:46:46
A. Yes. 09:46:48
Q. And then turn your attention to lines 49 through 50. Are you there? 09:46:50 09:47:15
A. Yes. 09:47:16
Q. Do you see where in the patent specification it's written, "All patients underwent MMR status testing prior to enrollment"? 09:47:16 09:47:20 09:47:26
A. Yes. 09:47:27

Q. You see that? 09:47:27
A. Yes. 09:47:29
Q. My question to you, is it correct that for the clinical trial that we've been discussing, all patients underwent MMR status testing prior to enrollment? 09:47:29 09:47:37 09:47:39 09:47:45
A. All patients underwent MMR testing prior to... patients underwent -- as far as I can remember, patients underwent MMR testing prior to treatment, which is, again, enrollment. There's different -- different definitions for enrollment. 09:47:52 09:47:59 09:48:00 09:48:03 09:48:07
Q. Okay. So the statement in the '356 patent that we're looking at, sitting here today, you don't know whether or not it's correct; is that fair? 09:48:09 09:48:18 09:48:24
MS. BROWN-MARSHALL: Object to the form of the question. 09:48:26 09:48:27
A. All patients underwent MMR testing prior to enrollment... I don't know specifically what we're referring to when we say "enrollment." 09:48:27 09:48:31 09:48:41
BY MR. RATLIFF: 09:48:53
Q. Okay. This part of the patent specification is not clear to you; is that fair? 09:48:54 09:48:56

MS. BROWN-MARSHALL: Object to the form of the question. 09:48:57 09:49:00

A. I don't recall specifically for every patient when they underwent their MMR testing. 09:49:00 09:49:10

BY MR. RATLIFF: 09:49:17

Q. That's a -- I'm not sure what you're answering because I didn't ask you whether or not you recall on what specific dates, for all patients, when they had their MSI status testing. That wasn't my question. 09:49:17 09:49:19 09:49:23 09:49:27

So my question is different. The statement in the '356 patent that we're looking at, column 9, lines 49 through 50, which states, quote, "All patients underwent MMR status testing prior to enrollment," end quote, sitting here today, you don't know whether that statement is true or untrue. Right? 09:49:32 09:49:42 09:49:49 09:49:57 09:50:03 09:50:12

MS. BROWN-MARSHALL: Object to the form of the question. 09:50:21 09:50:29

A. I don't recall specifically if all patients underwent MMR testing prior to enrollment. I can't tell you specifically that -- for an individual patient when they started -- when they had their MMR testing. 09:50:29 09:50:33 09:50:39 09:50:46

BY MR. RATLIFF: 09:50:52

Q. You recognize I'm not asking you for an individual patient, when that patient had their MSI status testing done. Do you recognize that? 09:50:53 09:50:56 09:50:59

A. Yes, but -- 09:51:01

MS. BROWN-MARSHALL: Objection. 09:51:02

Let me object. Object to the form of the question. 09:51:03 09:51:08

BY MR. RATLIFF: 09:51:08

Q. So is the statement at column 9, lines 49 through 50 of the '356 patent, is that a clear statement to you? Do you know what it means? 09:51:08 09:51:15 09:51:22

MS. BROWN-MARSHALL: Object to the form of the question. 09:51:22 09:51:28

A. Is the statement, "All patients underwent MMR [status] testing prior to enrollment," is that clear? Is that what you're asking me? 09:51:28 09:51:30 09:51:33

BY MR. RATLIFF: 09:51:34

Q. Yes. Is it clear to you? 09:51:35

A. I suppose it's not clear to me because I don't recall specifically what "enrollment" meant. 09:51:43 09:51:46

Q. Okay. And you were the principal investigator for this trial. Right? 09:51:48 09:51:55

MS. BROWN-MARSHALL: Objection. Asked and answered. 09:51:56 09:52:03

A. I was the principal investigator on this trial. 09:52:03

BY MR. RATLIFF: 09:52:05

Q. Okay. So let's go back to your declaration, paragraph 12. And I believe you were looking at your declaration as to the '187 patent. Let me know when you have it. 09:52:06 09:52:10 09:52:12 09:52:27

A. Yes. 09:52:30

Q. And looking again at that first sentence where the text says, "For Arm C, we did not specify which types of non-colorectal cancer we would include prior to the trial." 09:52:31 09:52:33 09:52:38 09:52:43

Do you have that? 09:52:43

A. Yes. 09:52:45

Q. Did there ever come a point in time when you specified the non-colorectal cancer patients? 09:52:45 09:52:57

A. The types? 09:53:01

Q. That's right. 09:53:02

A. They could have -- we didn't say that they had to have a specific histology. 09:53:05 09:53:09

Q. Okay. So was it the case that all non-colorectal 09:53:16

cancer patients were eligible for the trial so long as the non-colorectal cancer patients met the inclusion criteria and did not meet the exclusion criteria? 09:53:20 09:53:25 09:53:29

A. Did all -- I'm sorry, say that one more time. 09:53:40

Q. Is it correct that all non-colorectal cancer patients were eligible for the trial so long as they met the inclusion criteria for the trial and did not meet the exclusion criteria for the trial? 09:53:45 09:53:53 09:53:59 09:54:04

A. Were all non-colorectal -- were all non-colorectal cancer patients, if they met the inclusion and didn't meet exclusion... 09:54:10 09:54:16 09:54:24

So in that line we're talking about types of cancer, so we didn't exclude individual types of cancer. We didn't include -- we didn't exclude certain -- we didn't exclude cancers based on histology. 09:54:26 09:54:29 09:54:39 09:54:46 09:54:51

Q. So you did not exclude patients based upon the type of non-colorectal cancer that they had; is that right? 09:54:56 09:55:03

MS. BROWN-MARSHALL: Object to the form of the question. 09:55:08 09:55:12

A. We didn't exclude the patients... 09:55:12

So we allowed patients on cohort C or Arm C 09:55:14

with non-colorectal cancer. We didn't specify it had to be a particular type, a particular histology. 09:55:28 09:55:38

BY MR. RATLIFF: 09:55:47

Q. When you say "histology," are you referring to type of non-colorectal cancer? 09:55:47 09:55:50

A. No. When I say "histology," I'm referring to the type, yes, where the cancer originated. 09:55:52 09:56:00

Q. Okay. 09:56:05

A. The organ. 09:56:05

Q. Okay. So it's correct that all types of non-colorectal cancer patients were eligible for cohort C. Right? 09:56:13 09:56:15 09:56:21

A. I mean, there's a lot of different types of cancers. We may have excluded -- they might have been solid tumors. I just have to look more specifically at the language. 09:56:38 09:56:41 09:56:51 09:56:54

Q. The language of what? 09:56:59

A. You were referring to the clinical trial? 09:57:01

Q. You said you have to look at the language. What language do you have to look at? 09:57:09 09:57:11

A. Well, when I'm referring to types, without looking at the documents I can't recall specifically, but when 09:57:20 09:57:23

we're talking about types in general for this kind of protocol, we would specify solid tumors. But, again, I don't recall specifically the language in the protocol. 09:57:27 09:57:31 09:57:34 09:57:38

Q. Do you have any recollection whatsoever, sitting here today, that patients with certain types of non-colorectal cancer were not eligible for the clinical trial? 09:57:40 09:57:44 09:57:49 09:57:55

MS. BROWN-MARSHALL: Object to the form of the question. 09:57:56 09:58:05

A. Do I recall... I don't recall specifically excluding patients for the trial based on the type. 09:58:05 09:58:10

BY MR. RATLIFF: 09:58:25

Q. Now let's take a look at paragraph 13 of your declaration as to the '187 patent. Let me know when you have it. 09:58:25 09:58:29 09:58:32

A. I'm looking at it. 09:58:34

Q. And in paragraph 13 you have a reference to, quote, "our hypothesis," end quote. Do you see that? 09:58:39 09:58:43

A. Yes. 09:58:48

Q. And by "hypothesis," do you mean abstract theory? 09:58:49

MS. BROWN-MARSHALL: Object to the form of 09:58:54

the question. 09:58:57

A. By "hypothesis," do I mean abstract theory? 09:58:57

BY MR. RATLIFF: 09:59:05

Q. Yes, that's my question. 09:59:05

A. By "hypothesis," do I mean abstract theory... I don't know what that means. Is it abstract? I don't know what that means. 09:59:09 09:59:22 09:59:27

Q. So I guess I'm asking you the question, when you write "hypothesis," did you mean that to be taken as, quote, "an abstract theory"? 09:59:31 09:59:34 09:59:42

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 09:59:44 09:59:44

A. Can you define what "abstract theory" means? 09:59:50

BY MR. RATLIFF: 09:59:54

Q. Have you ever used that term, "abstract theory" before? 09:59:55 09:59:57

A. Not to my recollection. 09:59:57

Q. Have you ever thought about the clinical trial that's discussed in the MSI-High study record, again, Exhibit 1005, as an abstract theory? 10:00:00 10:00:03 10:00:07

MS. BROWN-MARSHALL: Object to the form of the question. 10:00:10 10:00:17

A. I don't -- I mean, I don't think so. I don't know what the definition of "abstract theory" is. 10:00:17 10:00:20

BY MR. RATLIFF: 10:00:22

Q. Is the term "abstract theory," as applied to a clinical trial, anything that you've ever used? 10:00:22 10:00:25

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 10:00:30 10:00:31

A. I do not recall using the terms "abstract theory." 10:00:33

BY MR. RATLIFF: 10:00:37

Q. Did you ever tell the FDA that the clinical trial that you were proposing -- and we're talking about the Phase 2 study of pembrolizumab in patients with microsatellite unstable tumors -- was an abstract theory? 10:00:58 10:01:02 10:01:11 10:01:13 10:01:18

MS. BROWN-MARSHALL: Object to the form of the question. 10:01:18 10:01:23

A. Did I... again, I don't -- I don't know what you mean by "abstract theory," so I don't recall telling the FDA this is an abstract theory. 10:01:23 10:01:25 10:01:28

BY MR. RATLIFF: 10:01:30

Q. Do you ever recall telling the FDA that the basis of which this trial you wanted to perform was based on an 10:01:31 10:01:35

abstract theory? 10:01:41
MS. BROWN-MARSHALL: Object to the form of 10:01:42
the question. 10:01:47
A. Do I recall... again, I don't -- I don't know what 10:01:47
you mean by "abstract theory." I don't recall 10:01:51
telling the FDA this is an abstract theory. 10:01:53
BY MR. RATLIFF: 10:01:56
Q. Right. Do you recall any of your co-inventors on any 10:01:56
of the eight patents that we're discussing today 10:02:01
referring to the clinical trial, the MSI-High clinical 10:02:04
trial, as an abstract theory? 10:02:11
MS. BROWN-MARSHALL: Object to the form of 10:02:12
the question. 10:02:15
A. Do I recall? I do not recall my co-inventors using 10:02:15
the terms "abstract theory." 10:02:22
BY MR. RATLIFF: 10:02:25
Q. Do you ever recall any of your co-inventors saying 10:02:25
that the clinical trial that was being proposed -- 10:02:27
and, again, this is the Phase 2 study of pembrolizumab 10:02:30
in patients with microsatellite unstable tumors -- as 10:02:36
being based on an abstract theory? 10:02:39
MS. BROWN-MARSHALL: Object to the form of 10:02:41

the question. 10:02:43
A. I don't recall them doing that. 10:02:43
BY MR. RATLIFF: 10:02:51
Q. And I just want to make sure I understand this. When you use the word "hypothesis" in your eight declarations, is that a synonym for abstract theory? 10:02:51 10:02:53 10:02:59
MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 10:03:03 10:03:10
A. I don't feel like I understand the definition of abstract theory. 10:03:10 10:03:13
BY MR. RATLIFF: 10:03:14
Q. Okay. So sitting here today, you wouldn't call it a synonym for hypothesis. Right? 10:03:14 10:03:23
MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 10:03:25 10:03:27
A. I don't understand the term "abstract theory." 10:03:30
BY MR. RATLIFF: 10:03:44
Q. Now, let's turn to paragraph 14 in your declaration. Again, we're looking at your declaration as to the '187 patent. 10:03:44 10:03:48 10:03:51
A. Yes. 10:03:56
Q. And as I understand it, you made a change from your 10:03:56

declaration as to the '393 patent compared to this '187 patent declaration where you change the word "dosing" to "dose scheduling." 10:04:05 10:04:12 10:04:23

Do you recall doing that? 10:04:25

A. Yes. 10:04:29

Q. Why did you make that change? 10:04:30

A. That is to dosing. I just thought it was more specific. 10:04:35 10:04:38

Q. And what do you mean by "dose scheduling"? 10:04:45

A. The frequency in which a treatment is given. 10:04:52

Q. And specifically what was this proposal that you're referring to in this paragraph? 10:05:07 10:05:10

A. The proposal? Our proposal with minor edits... okay. So the proposal to the study? The clinical protocol? 10:05:15 10:05:28 10:05:35

Q. It sounds like you're asking me a question. I'm asking you what -- what's the proposal as you wrote here. 10:05:36 10:05:38 10:05:43

A. Our proposal to study the MK-3475 in these specific patient populations. 10:05:43 10:05:54

Q. Okay. Are you certain about that? 10:05:56

A. Am I certain about what? 10:06:00

Q. That that's what's meant by "our proposal" and the text that's in paragraph 14 of your declaration. 10:06:02 10:06:05

A. Our proposal... 10:06:16

Q. I'm just asking because you sound unsure about what's -- what you intended or what's written here when it says "our proposal." 10:06:25 10:06:28 10:06:30

A. Right. So, again, there were some edits to the scheduling. 10:06:32 10:06:37

Q. I'm not asking about edits to the scheduling. I'm asking you a different question. 10:06:44 10:06:48

When it says "our proposal" in paragraph 14 of your declaration, what's that a reference to? What's being talked about? 10:06:49 10:06:52 10:06:57

MS. BROWN-MARSHALL: Objection. Asked and answered. 10:06:58 10:07:03

BY MR. RATLIFF: 10:07:03

Q. If you know. 10:07:03

A. I don't recall specifically which form of communication was about the scheduling. 10:07:06 10:07:15

Q. Okay, so let's try my question because I didn't ask about a form of communication. 10:07:25 10:07:27

In paragraph 14 it has the words, "our 10:07:32

proposal." And this is in your declaration as to the '187 patent. Right? Right? 10:07:35 10:07:39

A. Yes. 10:07:45

Q. So my question to you, what does "our proposal" refer to, if you know. 10:07:45 10:08:00

A. "Our proposal"... 10:08:01

MS. BROWN-MARSHALL: Objection to the form of the question. Asked and answered. 10:08:02 10:08:06

A. "Our proposal" refers to our proposed study. Clinical trial. 10:08:08 10:08:15

BY MR. RATLIFF: 10:08:20

Q. Okay. And you're sure about that? 10:08:20

MS. BROWN-MARSHALL: Objection. Asked and answered. 10:08:22 10:08:32

A. Yes, our proposed trial. 10:08:32

BY MR. RATLIFF: 10:08:43

Q. All right, let's turn to paragraph 20 of your declaration as to the '187 patent. Let me know when you're there. 10:08:43 10:08:53 10:08:56

A. Yes, I'm there. 10:08:56

Q. Okay. Now, paragraph 20, this reflects changes that you made to your declaration as to the '393 patent 10:09:01 10:09:26

when you had your deposition taken last. Right? 10:09:36

MS. BROWN-MARSHALL: Object to the form of 10:09:39

the question. 10:09:47

A. Yes. 10:09:47

BY MR. RATLIFF: 10:09:53

Q. And let's turn to paragraph 29 of your declaration as 10:09:54

to the '187 patent. Let me know when you're there. 10:10:00

A. Okay. 10:10:07

Q. In paragraph 29, in the second sentence, there is a 10:10:07

reference to, quote, "the initial phase of our small 10:10:19

study," end quote. Do you see that? 10:10:27

A. Uh-huh. 10:10:29

Q. What is meant by "the initial phase of our small 10:10:29

study"? 10:10:35

A. Initial phase of our small study... the beginning, 10:10:38

the initial part. 10:10:42

Q. And what's the beginning? Is the beginning days? Is 10:10:45

it months? What's the timing for the beginning? 10:10:49

MS. BROWN-MARSHALL: Object to the form of 10:10:51

the question. 10:10:57

A. I don't have a specific time, just the beginning. 10:10:57

BY MR. RATLIFF: 10:11:05

Q. Okay. So when it refers to "the initial phase of our small study," this is not a reference to any specific time; is that fair? 10:11:05 10:11:08 10:11:13

A. Yes, that's fair. 10:11:18

Q. And can we turn to paragraph 35 of your declaration as to the '187 patent? Let me know when you're there. 10:11:21 10:11:26

A. Yes. 10:11:34

Q. And in that paragraph do you see the reference to, quote, "the initial phase of our study," end quote? 10:11:35 10:11:37

A. Say that one more time. On page -- yes, the final sentence. "While Merck had not agreed to provide financial support for the initial phase of our study." Correct. 10:11:43 10:11:48 10:11:52 10:11:55

Q. And when you -- and when the text here says, "the initial phase of our study," is that just like paragraph 29 of your declaration, that it doesn't have any specific time in mind? 10:12:00 10:12:01 10:12:09 10:12:11

A. It would be towards the beginning, initial. 10:12:24

Q. And what do you mean by "towards the beginning"? Is that days? Weeks? Months? What's the time frame that's meant here? 10:12:26 10:12:28 10:12:31

A. I don't remember the specifics. I mean, "initial" is 10:12:36

towards the beginning. 10:12:39

Q. Do you have any more detail by what you mean, "towards the beginning"? 10:12:42 10:12:45

A. In terms of not agreeing to financial support? 10:12:51

Q. No, in terms of "the initial phase of our study," what's written there. Do you have any more details as to what you mean by "in the beginning"? 10:12:54 10:12:58 10:13:04

A. Just the earlier parts of the study. 10:13:08

Q. And when you say "the earlier parts," can you describe that in terms of hours, days, weeks? What period are you talking about? 10:13:10 10:13:12 10:13:20

A. I can't give you a specific period. Those -- when we're talking about the initial phase is really the beginning, when it was, you know, started and then initiated through some period. I don't know -- I don't have a specific -- I wasn't referring to something specific, I was just referring to in the beginning. 10:13:24 10:13:28 10:13:32 10:13:40 10:13:45 10:13:49 10:13:51

Q. Can you give me any more information as to what you mean by "in the beginning"? 10:13:51 10:13:56

A. When we initiate a study and started it and -- started treating patients, the -- do you -- okay. 10:14:01 10:14:12

Yeah. So -- yes, initial. 10:14:22

Q. And what time frame is that, when you started it and started treating patients? 10:14:27 10:14:30

MS. BROWN-MARSHALL: Object to the form of the question. 10:14:32 10:14:34

A. What time frame? You mean the initial -- what was the initial period? 10:14:34 10:14:41

BY MR. RATLIFF: 10:14:41

Q. You testified that by "in the beginning," you meant when we initiated a study and started it -- started treating patients. 10:14:58 10:15:03 10:15:06

So I'm asking you, what time frame do you mean when you say you initiated the study and started treating patients? 10:15:07 10:15:12 10:15:15

MS. BROWN-MARSHALL: Object to the form of the question. 10:15:15 10:15:22

A. When I'm referring to "initial phase" of our study, I'm referring to the earlier parts of the study rather than the later parts. 10:15:22 10:15:26 10:15:32

BY MR. RATLIFF: 10:15:36

Q. And what are the earlier parts of the study? 10:15:36

A. The process of the study in terms of the initial part 10:15:52

of the study. Different things, like you have to come up with the idea. You have to make proposals. You have to put the teams together to start the study. You have to submit the studies to the regulatory authorities. You have to get everything set up to start the patients. You have to start treating patients. 10:15:56 10:15:59 10:16:03 10:16:10 10:16:17 10:16:19 10:16:22

So there's -- so I was only referring to the initial phases. And then there's later phases of the study. 10:16:23 10:16:26 10:16:30

Q. And about what time frame did this earlier phase of the study, as you view it, end? 10:16:33 10:16:37

MS. BROWN-MARSHALL: Object to the form of the question. 10:16:44 10:16:46

A. When did it... I don't think I was referring to anything specific when I was saying "initial" other than the beginning phases rather than later. 10:16:46 10:16:48 10:16:53

BY MR. RATLIFF: 10:17:01

Q. And can you provide me with any more detail as to what you meant by the "beginning phases" of the study in terms of timing? 10:17:01 10:17:03 10:17:10

MS. BROWN-MARSHALL: Objection. Asked and 10:17:11

answered. 10:17:14

A. Yeah, it's -- I don't have a specific time. 10:17:14

BY MR. RATLIFF: 10:17:29

Q. Okay. 10:17:30

MS. BROWN-MARSHALL: Counsel, we've been going for well over an hour. Is now a good time to take a break? 10:17:31 10:17:33 10:17:36

MR. RATLIFF: Dr. Le, would you like to take a break now? 10:17:37 10:17:40

THE WITNESS: I'd like to run to the bathroom. 10:17:41 10:17:43

MR. RATLIFF: Let's take a break. 10:17:43

(Off the record at 10:17 a.m.) 10:17:45

(Back on the record at 10:30 a.m.) 10:30:14

BY MR. RATLIFF: 10:30:17

Q. Doctor, during the break did you speak with anyone? 10:30:17

A. No. 10:30:19

Q. Doctor, do you believe that you or any of your colleagues at JHU invented a method for treating cancer in a patient where the patient has been determined to be MSI-High by administering any amount of anti-PD-1 antibody to a patient? 10:30:20 10:30:32 10:30:35 10:30:37 10:30:42

MS. BROWN-MARSHALL: Object to the form of the question. 10:30:47 10:30:54

A. Do I -- can you repeat the question? 10:30:54

BY MR. RATLIFF: 10:30:57

Q. Try it this way. Do you believe that you or any of your colleagues at JHU invented a method for treating cancer in a patient where the patient has been determined to be MSI-High by administering an effective amount of any anti-PD-1 antibody to a patient? 10:30:58 10:31:03 10:31:06 10:31:10 10:31:14 10:31:19

MS. BROWN-MARSHALL: Object to the form of the question. 10:31:19 10:31:19

A. Do I believe that we invented a method... 10:31:29

I believe that patients with MSI-High cancers, I believe that we invented the concept of testing -- of treating MSI-High cancer patients with anti-PD-1 therapy. 10:31:38 10:32:01 10:32:10 10:32:19

BY MR. RATLIFF: 10:32:23

Q. Okay, so let me try my question again. 10:32:24

Do you believe that you or any of your colleagues at JHU invented a method for treating cancer in a patient where the patient has been 10:32:26 10:32:29 10:32:32

determined to be MSI-High by administering an effective amount of any anti-PD-1 antibody to a patient? 10:32:35 10:32:41 10:32:46

MS. BROWN-MARSHALL: Object to the form of the question. 10:32:47 10:32:48

A. Do I believe that we invented a method... 10:32:48

I believe that we invented a method of identifying patients for treatment with anti-PD-1 therapy. 10:32:58 10:33:10 10:33:13

BY MR. RATLIFF: 10:33:21

Q. And is that the complete response that you have to my question? 10:33:21 10:33:23

MS. BROWN-MARSHALL: Object to the form of the question. 10:33:23 10:33:29

A. Yes. 10:33:29

BY MR. RATLIFF: 10:33:31

Q. Okay. Would you agree that BMS was the first group to conduct a Phase 2 study in MSI-High patients with the anti-PD-1 antibody nivolumab? 10:33:31 10:33:44 10:33:51

MS. BROWN-MARSHALL: Object to the form of the question. 10:33:57 10:33:58

A. Would I agree that BMS -- can you repeat the 10:33:58

question? 10:34:03

BY MR. RATLIFF: 10:34:04

Q. Would you agree that BMS was the first group to conduct a Phase 2 study in MSI-High patients with the anti-PD-1 antibody nivolumab? 10:34:07 10:34:11 10:34:17

MS. BROWN-MARSHALL: Object to the form of the question. 10:34:20 10:34:23

A. Would I agree that they're the first to test anti-PD-1 in MSI-High patients? 10:34:23 10:34:30

BY MR. RATLIFF: 10:34:34

Q. Do you think that's what I said? 10:34:35

A. I would not agree that BMS is the first -- I mean, as far as my knowledge, that they did not design a study to treat MSI-High patients with PD-1 therapy. 10:34:37 10:34:43 10:34:48

Q. Okay, so let's go back to my question. 10:34:57

Would you agree that BMS was the first group to conduct a Phase 2 study in MSI-High patients with the anti-PD-1 antibody nivolumab? 10:35:01 10:35:03 10:35:07

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 10:35:13 10:35:13

A. I would not agree. 10:35:20

BY MR. RATLIFF: 10:35:26

Q. Who, to your knowledge, conducted a Phase 2 study in MSI-High patients with the anti-PD-1 antibody nivolumab? 10:35:26 10:35:31 10:35:39

A. Who to my knowledge -- 10:35:42

Q. Correct. 10:35:43

A. -- has studied nivolumab in MSI? 10:35:43

Q. Who, to your knowledge, was the first group to conduct a Phase 2 study in MSI-High patients with the anti-PD-1 antibody nivolumab? 10:35:48 10:35:52 10:35:59

MS. BROWN-MARSHALL: Object to the form of the question. 10:36:01 10:36:03

A. Who, to my knowledge, was the first to conduct a Phase 2 study... okay, one more time. 10:36:03 10:36:06

BY MR. RATLIFF: 10:36:19

Q. Who, to your knowledge, was the first group to conduct a Phase 2 study in MSI-High patients with the anti-PD-1 antibody nivolumab? 10:36:24 10:36:26 10:36:34

MS. BROWN-MARSHALL: Object to the form of the question. 10:36:35 10:36:41

A. When you say -- I can't -- I can't remember what phases they called what in terms of when you're -- if you're referring to a specific phase of a study, and 10:36:41 10:36:46 10:36:49

then you say MSI-High cancers. I can tell you what I know, but I'm not sure -- are you asking me if I know if BMS conducted a study of nivolumab in MSI-High cancer? 10:36:55 10:37:01 10:37:13 10:37:21

BY MR. RATLIFF: 10:37:23

Q. No. You heard my question. Right? My question didn't say anything about BMS. 10:37:29 10:37:31

A. Oh, you said nivolumab. I'm sorry. Yeah, you said nivolumab. Okay. 10:37:33 10:37:37

Who conducted a study of nivolumab? 10:37:37

Q. Let me try my question again. 10:37:41

A. Okay. I'm sorry. 10:37:43

Q. Who, to your knowledge, was the first group to conduct a Phase 2 study in MSI-High patients with the anti-PD-1 antibody nivolumab? 10:37:45 10:37:51 10:37:59

MS. BROWN-MARSHALL: Object to the form of the question. 10:38:00 10:38:03

A. Who to my knowledge would be the first to conduct a Phase 2 study of nivolumab in MSI-High patients. Again, I don't recall specifically phases. Is there a particular study you're referring to? 10:38:03 10:38:08 10:38:19 10:38:28

BY MR. RATLIFF: 10:38:31

Q. Do you know who was the first group to conduct a Phase 2 study in MSI-High patients with the anti-PD-1 antibody nivolumab? 10:38:35 10:38:37 10:38:43

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 10:38:45 10:38:46

A. Do I know... 10:38:47

I don't know specifically who was the first to study nivolumab in MSI-High patients. 10:39:02 10:39:08

BY MR. RATLIFF: 10:39:14

Q. Okay. But you are familiar with a clinical -- let me start that again. 10:39:14 10:39:20

You are familiar with a Phase 2 clinical trial that BMS conducted to study MSI-High patients with the anti-PD-1 antibody nivolumab. Right? 10:39:20 10:39:23 10:39:33

MS. BROWN-MARSHALL: Object to the form of the question. 10:39:37 10:39:39

A. I think I -- I am familiar with nivolumab studies by BMS, but I guess I would need to see which study you're specifically referring to. 10:39:39 10:39:46 10:39:49

BY MR. RATLIFF: 10:39:52

Q. Well, you already said you were familiar with the study NCT02060188. Right? 10:39:52 10:39:55

A. I would -- if you could show me which study. I'm probably getting -- I can't keep the numbers straight for the NCTs. 10:40:00 10:40:04 10:40:07

Q. Well, you already answered my question. You said you were familiar with that study. 10:40:09 10:40:11

MS. BROWN-MARSHALL: Object to the form of the question. 10:40:12 10:40:13

A. Yeah, but -- 10:40:13

MS. BROWN-MARSHALL: Hold on, Dr. Le. Object to the form of the question. 10:40:14 10:40:15

A. I would feel more comfortable looking specifically at which NCT study you are referring to. 10:40:18 10:40:23

BY MR. RATLIFF: 10:40:26

Q. More comfortable for what purpose? 10:40:26

A. To make sure I'm referring to the right study. I don't -- when you say "Phase 2 study," I mean, they're -- I don't know specifically which Phase 2 study. So I would be more comfortable just actually looking at it when you're referencing a specific study. 10:40:28 10:40:31 10:40:33 10:40:36 10:40:40 10:40:42

Q. Okay, but you've already answered my -- you already said that you're familiar with that study. We're on 10:40:42 10:40:47

to a different question. All right? So let me try my question. 10:40:49 10:40:52

You are aware that BMS conducted a study of nivolumab and nivolumab plus ipilumumab in recurrent and metastatic colon cancer. Right? 10:40:52 10:41:19 10:41:27

MS. BROWN-MARSHALL: Object to the form of the question. 10:41:30 10:41:31

A. Am I aware that they conducted a study... yes. 10:41:31

BY MR. RATLIFF: 10:41:35

Q. And you are aware that they announced that study before the July 10, 2015, alleged invention date of the eight patents that you mention in your declarations. Right? 10:41:36 10:41:40 10:41:54 10:41:56

MS. BROWN-MARSHALL: Object to the -- 10:41:57

A. I -- 10:42:00

MS. BROWN-MARSHALL: Object to the form of the question. 10:42:00 10:42:01

A. I don't recall specifically the dates. 10:42:01

BY MR. RATLIFF: 10:42:06

Q. Do you have any general recollection that BMS announced their study of nivolumab and nivolumab plus ipilumumab in recurrent and metastatic colon cancer 10:42:06 10:42:11 10:42:19

patients before the July 10, 2015, alleged invention date of the eight patents that you mention in your declarations? 10:42:23 10:42:30 10:42:33

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 10:42:34 10:42:36

A. I don't recall specifically when BMS released their study for colon cancer. 10:42:38 10:42:50

BY MR. RATLIFF: 10:42:51

Q. Okay. So let's try my question because I didn't ask you if you recall specifically when they released their study. It was nothing about releasing the study. It's about announcing the study. 10:42:56 10:42:58 10:43:01 10:43:03

A. Okay. 10:43:06

Q. Okay? So we're gonna work with announcing the study. BMS's study in MSI-High patients with colon cancer. Okay? Are you with me? 10:43:06 10:43:12 10:43:18

A. Yes. 10:43:20

Q. Is it your understanding that BMS announced that study before the July 10, 2015, alleged invention date of the eight patents that you refer to in your declarations? 10:43:26 10:43:31 10:43:39 10:43:42

MS. BROWN-MARSHALL: Object to the form of 10:43:43

the question. Asked and answered. 10:43:47

A. Do I recall the announcement... no, I don't recall the announcement. 10:43:50 10:43:53

BY MR. RATLIFF: 10:43:57

Q. I didn't ask if you recall the announcement. 10:43:57

Do you believe that I asked you if you recalled the announcement? 10:44:17 10:44:19

MS. BROWN-MARSHALL: Object to the form of the question. 10:44:20 10:44:26

A. Do I believe... you asked me -- I believe you asked me if I remember the announcement and the date. 10:44:26 10:44:29

BY MR. RATLIFF: 10:44:46

Q. Okay, let me try my question again because I didn't ask that. 10:44:47 10:44:49

A. Okay. 10:44:49

Q. Is it your understanding that BMS announced its study in MSI-High patients with nivolumab before the July 10, 2015, alleged invention date of the eight patents that you refer to in your declarations? 10:44:50 10:44:58 10:45:00 10:45:07

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered several times. 10:45:09 10:45:10

A. I do not recall. 10:45:15

BY MR. RATLIFF: 10:45:16

Q. So you don't know if BMS announced their study before or after the July 10, 2015, alleged invention dates of the eight patents that you refer to in your declarations? 10:45:16 10:45:27 10:45:30 10:45:31

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered multiple times. 10:45:32 10:45:34

A. I don't recall when BMS announced their study in colon cancer. 10:45:38 10:45:45

BY MR. RATLIFF: 10:45:49

Q. That's a different question. 10:45:49

MR. RATLIFF: Let's take a look at Exhibit 1053. And we can put that in the Chat. 10:45:52 10:45:53

PLANET DEPOS TECH: Please stand by. 10:46:00

BY MR. RATLIFF: 10:46:22

Q. Let me know when you have it, Doctor. 10:46:22

A. Yes. 10:46:25

Q. And do you see here that the first version of the study record for BMS's study in MSI-High patients using the drug nivolumab was in February of 2014? 10:46:41 10:46:46 10:46:54

A. I see the document has a little dot on February 10th, 2014, for recurrent and metastatic colon cancer. 10:47:02 10:47:14

Q. So do you see that the first version of the study record for BMS's study in MSI-High patients using the drug nivolumab was in February of 2014? 10:47:18 10:47:20 10:47:25

MS. BROWN-MARSHALL: Object to the form of the question. 10:47:30 10:47:31

A. I see the document that you put in front of me, yes. 10:47:31

BY MR. RATLIFF: 10:47:35

Q. I didn't ask you -- I already know you have the document. I know that. My question is different. 10:47:36 10:47:38

A. Do I see the date? Yes, I see the date. 10:47:42

Q. Nope, that's not my question. 10:47:46

Do you see that the first version of the study record for BMS's study in MSI-High patients using the drug nivolumab was in February of 2014? 10:47:48 10:47:50 10:47:54

MS. BROWN-MARSHALL: Object to the form of the question. 10:48:00 10:48:01

A. Yes, I see that there -- the study record is dated 2014. I... yeah. This study record that you put in front of me is dated 2014. 10:48:01 10:48:09 10:48:17

BY MR. RATLIFF: 10:48:19

Q. But you would agree that BMS announced their study in MSI-High patients using an anti-PD-1 antibody before 10:48:19 10:48:28

the July 10, 2015, alleged invention date of the eight patents that you mention in your declarations. Right? 10:48:37 10:48:42

MS. BROWN-MARSHALL: Object to the form of the question. 10:48:46 10:48:50

A. Looking at this document that you gave me, I see that it included patients -- actually, the inclusion doesn't actually say what kinds of cancers. It says... oh, confirmed colorectal cancer. 10:48:50 10:48:55 10:49:04 10:49:10

And it says that the inclusion criteria that they require testing for MSI-High status, but that doesn't really tell us much about that. I don't really know what -- when and -- when they required testing, but I see it required colon cancer and required testing for MSI status. 10:49:13 10:49:20 10:49:26 10:49:29 10:49:32 10:49:35

BY MR. RATLIFF: 10:49:39

Q. Are you finished with your response? 10:49:44

A. Yes. 10:49:47

Q. Okay. So let's go back to my question. 10:49:47

Would you agree that BMS announced their study in MSI-High patients using an anti-PD-1 antibody before the July 10, 2015, alleged invention date of the eight patents that you mention in your 10:49:51 10:49:54 10:49:59 10:50:04

declarations? 10:50:06

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 10:50:08 10:50:09

A. I'd have to look at this closer. I can agree that there is a February 2014 study record and they listed inclusion for the study to have confirmed colorectal cancer and that they would need testing for MSI to be included. 10:50:16 10:50:20 10:50:26 10:50:32 10:50:38

BY MR. RATLIFF: 10:50:39

Q. So you don't -- sitting here today, you don't know the answer to my question? 10:50:44 10:50:46

A. I -- the answer to the question is what you put in front of me. I can -- I can tell you that there is a document from February of 2014 that says there is a study that includes colorectal cancer patients and it -- and it just says inclusion criteria is testing for MSI status. Those are the inclusion. 10:50:50 10:50:53 10:50:57 10:51:02 10:51:05 10:51:09

Q. I didn't ask what the inclusion criteria was. Let me try my question one more time. 10:51:13 10:51:17

Would you agree that BMS announced their study in MSI-High patients using an anti-PD-1 antibody before the July 10, 2015, alleged invention date of 10:51:19 10:51:22 10:51:28

the eight patents that you mentioned in your declaration? 10:51:35 10:51:37

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered several times. 10:51:39 10:51:41

A. I can agree that in this 2014 announcement that they have a study in colon cancer and the included criteria include testing for MSI status. 10:51:54 10:51:58 10:52:03

BY MR. RATLIFF: 10:52:15

Q. Is that your response to my question? 10:52:15

A. That is. 10:52:17

Q. That's a complete response, in your view? 10:52:18

A. Yes. 10:52:20

Q. Is it your understanding that this -- in this BMS study in MSI-High patients, BMS were giving the patients an anti-PD-1 antibody? 10:52:21 10:52:31 10:52:35

A. Is it my understanding that in this study the plan was to give them an anti-PD-1 antibody? 10:52:38 10:52:40

Q. That's right. 10:52:44

A. It does appear that the treatment is nivolumab and then nivolumab and ipilumumab, and that the patients have to have colorectal cancer and the patients have to have MSI testing. 10:52:44 10:52:59 10:53:06 10:53:09

Q. Doctor, you're familiar with this study. Right? 10:53:15
A. I am familiar with -- 10:53:19
MS. BROWN-MARSHALL: Wait. Object to the form of the question. Asked and answered. 10:53:21 10:53:23
A. You -- yeah. I'm familiar with some of the study results. Yes. 10:53:24 10:53:31
BY MR. RATLIFF: 10:53:36
Q. I wasn't -- I didn't ask if you were familiar with some of the study results, but thank you for that. 10:53:36 10:53:39
You're familiar with the study. Right? 10:53:41
MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 10:53:43 10:53:44
A. I am familiar with the study. 10:53:46
BY MR. RATLIFF: 10:54:22
Q. Doctor, do you have a copy of your declaration as to the '356 patent? 10:54:22 10:54:26
A. Yes. 10:54:29
Q. Can you turn your attention to paragraph 25 of that declaration? 10:54:30 10:54:36
A. Yes. 10:54:44
Q. And in paragraph 25, you comment about the PD-L1 biomarker. Right? 10:54:45 10:54:52

A. Correct. 10:54:54

Q. And you write, "Thus, even though using the PD-L1 biomarker seemed like a promising approach, Merck's clinical testing showed that it did not work." 10:54:59 10:55:04 10:55:07

Do you see that? 10:55:10

A. Yes. 10:55:21

Q. To be clear, you're not taking the position in these IPR proceedings that the PD-L1 biomarker has never been a promising approach for treatment of various cancer patients using pembrolizumab. Right? 10:55:21 10:55:28 10:55:32 10:55:35

A. Am I saying it has never been used? I'm not saying it's never been used. 10:55:41 10:55:44

Q. You're not taking the position in these cases that the PD-L1 biomarker has never been a promising approach for treatment of various cancer patients using pembrolizumab. Right? 10:55:48 10:55:52 10:55:58 10:56:01

MS. BROWN-MARSHALL: Object to the form of the question. 10:56:03 10:56:06

A. I'm not taking -- I'm not saying that PD-L1 biomarker has not been used in others cancers. 10:56:06 10:56:14

BY MR. RATLIFF: 10:56:21

Q. Okay. So let's try my question because I'm asking you 10:56:21

about this terminology that you use in your declaration, "promising approach." And I want to be sure that's part of your response because that's what I'm asking about. 10:56:23 10:56:25 10:56:29 10:56:31

So here's my question. To be clear, you're not taking the position in these IPR cases that the PD-L1 biomarker has never been a promising approach for treatment of various cancer patients using pembrolizumab. Right? 10:56:33 10:56:39 10:56:44 10:56:50 10:56:54

MS. BROWN-MARSHALL: Object to the form of the question. 10:56:55 10:56:57

A. I am not taking that position. 10:56:57

BY MR. RATLIFF: 10:57:03

Q. You would agree that Merck's clinical work using the PD-L1 biomarker has resulted in multiple FDA approvals for treating various forms of cancer with pembrolizumab. Right? 10:57:04 10:57:07 10:57:12 10:57:16

A. I'm sorry, can you repeat the question? 10:57:22

Q. You would agree that Merck's clinical work using the PD-L1 biomarker has resulted in multiple FDA approvals for treating various forms of cancer with pembrolizumab. Right? 10:57:34 10:57:38 10:57:43 10:57:47

A. Would I agree... I would agree that there have been PD-L1 -- PD-L1 has been used as a biomarker for some FDA approvals. I haven't kept up with -- I don't know what still can use PD-L1 as a biomarker. It's -- I don't know. The field's evolved over these years, so... but not specific to colon cancer. 10:57:51 10:57:59 10:58:07 10:58:14 10:58:20 10:58:23

Q. Sitting here today, what FDA approvals are you aware of that the PD-L1 biomarker has been used for pembrolizumab? 10:58:34 10:58:48 10:58:58

A. Sitting here today, I can't specifically tell you what indications Merck has for PD-L1 biomarker for patients for FDA -- 10:59:01 10:59:07 10:59:15

Q. Sitting here today, do you have any understanding of any indication where the PD-L1 biomarker is part of an FDA-approved indication for pembrolizumab? 10:59:18 10:59:20 10:59:35

A. Sitting here today... I would have to look at all the different studies. I do get them mixed up on which ones are still potentially approved for which disease. 10:59:50 10:59:56 11:00:03 11:00:13

Q. So sitting here today right now, do you know? 11:00:17

A. Sitting here today, I would have to look at the label, today's label. 11:00:20 11:00:23

MR. RATLIFF: Well, let's put in the Chat a new exhibit, Exhibit 1134. And this is a new exhibit for all eight IPR proceedings. 11:00:31 11:00:32 11:00:39

PLANET DEPOS TECH: Please stand by. 11:00:43

MARKED FOR IDENTIFICATION: 11:00:49

EXHIBIT 1134 11:00:49

11:00 a.m. 11:01:10

BY MR. RATLIFF: 11:01:10

Q. And let me know when you have it, Doctor. 11:01:11

A. Yes. 11:01:23

Q. Okay. So I can represent to you that new Exhibit 1134 is a copy of the prescribing information or package insert for Keytruda as revised December 2024. 11:01:23 11:01:28 11:01:36

And I want to turn your attention to the first page of the labeling. 11:01:44 11:01:47

A. Okay. 11:01:53

MS. BROWN-MARSHALL: And, Doctor, feel free to review the exhibit if you need to in order to answer counsel's questions. 11:01:54 11:02:01 11:02:03

BY MR. RATLIFF: 11:02:05

Q. And do you see here, as reflected on the first page of the labeling, FDA approvals for pembrolizumab using 11:02:05 11:02:10

the PD-L1 biomarker? 11:02:18

A. Are you referring to a specific line or are you just referring to page 1? 11:02:25 11:02:29

Q. I'm just referring to page 1. 11:02:31

A. Okay. Do I see reference to PD-L1? 11:02:33

Q. No. Different question. Very different question. 11:02:38

So let me try it this way. Do you see in the Indication and Usage section of the Keytruda package insert, indications approved by the FDA for pembrolizumab using the PD-L1 biomarker? 11:02:40 11:02:44 11:02:50 11:02:59

A. I see an approval for single agent for the first-line treatment of patients with non-small cell lung cancer expressing PD-L1. I'd have to -- I mean, I see -- yes. 11:03:16 11:03:23 11:03:26 11:03:33

Q. Do you see any others? 11:03:33

A. Outside of lung cancer? As a single agent for the first-line treatment of patients with head and neck cancer with a PD-L1 of greater than 1. 11:03:37 11:03:47 11:03:50

Q. Do you see any others? 11:03:57

A. In combination with trastuzumab, fluoropyrimidine, and platinum in HER2-positive gastric whose PD-L1 is greater than 1. 11:03:57 11:04:32 11:04:38

Q. So that's a use of the PD-L1 biomarker in gastric cancer for pembrolizumab. Correct? 11:04:40 11:04:49

A. Correct. 11:04:56

Q. Do you see any other FDA approvals in the Indication and Usage section of the Keytruda package insert using the PD-L1 biomarker? 11:04:56 11:05:01 11:05:05

A. In a single agent after one or more prior lines of therapy for squamous histology that express PD-L1 as greater than 10. 11:05:19 11:05:22 11:05:28

Q. And that's an approval with respect to esophageal cancer. Correct? 11:05:36 11:05:42

A. Correct. 11:05:43

Q. Do you see any others? 11:05:43

A. In cervical cancer, in combination with chemo with or without bevacizumab, in the treatment of patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 -- greater than 1. 11:05:52 11:05:56 11:06:01 11:06:06

Q. And if you could turn to the next page, that also includes the Indication and Usage section of the Keytruda package insert, do you see the FDA approval using the PD-L1 biomarker with respect to triple-negative breast cancer? 11:06:12 11:06:17 11:06:21 11:06:23 11:06:28

A. Yes, in combination with chemotherapy for the treatment of patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1, CPS greater than 10, yes. 11:06:35 11:06:39 11:06:42 11:06:48

Q. Now, Doctor, would you agree that for Merck, the PD-L1 biomarker has been shown to be a proven approach for treating various forms of cancer? 11:06:50 11:06:54 11:06:59

MS. BROWN-MARSHALL: Object to the form of the question. 11:07:02 11:07:07

A. Do I agree that PD-L1 has been helpful to Merck? 11:07:07

BY MR. RATLIFF: 11:07:12

Q. No, I didn't say "helpful." Did you hear me say "helpful"? 11:07:12 11:07:15

A. No, I'm sorry, what was your question? 11:07:16

Q. Okay. So let me try my question again. 11:07:18

Would you agree that, for Merck, the PD-L1 biomarker has been shown to be a proven approach for treating various forms of cancer? 11:07:20 11:07:26 11:07:32

MS. BROWN-MARSHALL: Object to the form of the question. 11:07:36 11:07:39

A. Would I believe. I believe that excluding patients with low PD-L1 is helpful to determine patients who 11:07:39 11:07:47

are not going to respond to therapy by Merck. 11:07:58

BY MR. RATLIFF: 11:08:04

Q. Are you finished with your response? 11:08:04

A. Yes. 11:08:07

Q. Okay. So let's get back to my question. 11:08:07

Would you agree that, for Merck, the PD-L1 biomarker has been shown to be a proven approach for treating non-small cell lung cancer? 11:08:10 11:08:13 11:08:16

MS. BROWN-MARSHALL: Object to the form of the question. 11:08:22 11:08:37

A. I believe that Merck has approvals for use of pembrolizumab in certain -- in non-small cell lung cancers as long as they don't have low levels of PD-L1. 11:08:37 11:08:43 11:08:49 11:08:53

BY MR. RATLIFF: 11:08:55

Q. Would you agree that, for Merck, the PD-L1 biomarker has been shown to be a proven approach for treating non-small cell lung cancer? 11:09:07 11:09:11 11:09:15

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 11:09:17 11:09:20

BY MR. RATLIFF: 11:09:21

Q. Yes-or-no, do you agree? 11:09:22

A. I agree that in non-small cell lung cancer, Merck's approval limits the use if the patient has low PD-L1. 11:09:24 11:09:32

Q. Okay. Do you recognize I wasn't asking if anything limits the use? You recognize that. Right? 11:09:42 11:09:46

MS. BROWN-MARSHALL: Object to the form of the question. 11:09:50 11:09:54

BY MR. RATLIFF: 11:09:54

Q. Do you know what I asked you? 11:09:54

MS. BROWN-MARSHALL: Object to the form of the question. Badgering the witness. 11:09:56 11:09:57

A. You're welcome to repeat the question. 11:10:06

BY MR. RATLIFF: 11:10:08

Q. Doctor, do you know what my question was? 11:10:08

MS. BROWN-MARSHALL: Object to the form of the question. 11:10:13 11:10:15

A. You asked if Merck has proven -- successfully used PD-L1 as a biomarker. Is that what you asked? 11:10:15 11:10:25

BY MR. RATLIFF: 11:10:31

Q. No. Let's try it again. 11:10:31

Would you agree that, for Merck, the PD-L1 biomarker has been shown to be a proven approach for treating non-small cell lung cancer? 11:10:34 11:10:37 11:10:40

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered several times. 11:10:43 11:10:44

A. I think -- I don't know what you mean by "proven approach." I do see that they have an FDA approval that requires that the patient not have low PD-L1. 11:10:49 11:10:52 11:10:56

BY MR. RATLIFF: 11:11:08

Q. You don't know what a "proven approach" means? 11:11:08

MS. BROWN-MARSHALL: Object to the form of the question. 11:11:11 11:11:12

A. It is a proven approach in that it did lead to an FDA approval; that if they have a low PD-L1 status, that they cannot receive the single agent treatment. 11:11:12 11:11:16 11:11:19

BY MR. RATLIFF: 11:11:25

Q. Do you agree that the PD-L1 biomarker has been shown to be a proven approach with respect to non-small cell lung cancer, head and neck cell cancer, gastric cancer, esophageal cancer, cervical cancer, and triple-negative breast cancer with respect to pembrolizumab? 11:11:25 11:11:30 11:11:37 11:11:42 11:11:48 11:11:51

MS. BROWN-MARSHALL: Object to the form of the question. 11:11:53 11:11:54

A. I believe that the PD-L1 biomarker has been -- well, 11:11:54

I guess pembro has actually been approved. 11:12:02

Well, that -- in these indications, that if you have a low PD-L1, that you are unlikely to respond to pembrolizumab. I guess proven -- I don't -- it isn't an approved approach to limit its use in patients who have low PD-L1. 11:12:07 11:12:10 11:12:15 11:12:23 11:12:33

BY MR. RATLIFF: 11:12:44

Q. Do you agree that the PD-L1 biomarker has been shown to be an FDA approved approach with respect to non-small cell lung cancer, head and neck cell cancer, gastric cancer, esophageal cancer, cervical cancer, and triple negative breast cancer with respect to pembrolizumab? 11:12:45 11:12:48 11:12:54 11:12:58 11:13:04 11:13:07

MS. BROWN-MARSHALL: Object to the form of the question. 11:13:10 11:13:13

A. I believe that PD-L1 is an approved approach to limit the use of pembrolizumab based on the biomarker. 11:13:13 11:13:24

BY MR. RATLIFF: 11:13:42

Q. Are you finished with your response? 11:13:43

A. Yes. 11:13:45

Q. I'm going to try my question one more time because I don't think you've answered it. 11:13:48 11:13:54

Do you agree that the PD-L1 biomarker has been shown to be an FDA-approved approach with respect to non-small cell lung cancer, head and neck cancer, gastric cancer, esophageal cancer, cervical cancer, and triple-negative breast cancer with respect to pembrolizumab? 11:14:00 11:14:02 11:14:06 11:14:10 11:14:15 11:14:17

MS. BROWN-MARSHALL: Object to the form of the question. 11:14:20 11:14:22

A. I believe that the PD-L1 biomarker is part of the FDA approval for those cancers to help select for patients who will not respond to pembrolizumab or pembrolizumab in combination, depending on the study. 11:14:22 11:14:32 11:14:39 11:14:44

BY MR. RATLIFF: 11:14:48

Q. Doctor, do you have a copy of your declaration as to the '356 patent? 11:14:53 11:14:56

A. Yes. 11:15:04

Q. Can you turn to paragraph 50 in that declaration? 11:15:04

A. Paragraph 50. 11:15:29

Q. Do you have it? 11:15:34

A. Yes, yes, yes. 11:15:35

Q. And in paragraph 50 you make reference to an ASCO GI Cancers Symposium -- 11:15:37 11:15:43

A. Yes. 11:15:46
Q. -- in January of 2016; is that right? 11:15:47
A. Yes. 11:15:49
Q. And the text says here that you remember that during this presentation an audience member stood up during the question-and-answer session. 11:15:49 11:15:56 11:16:01
You see that? 11:16:06
A. Yes. 11:16:06
Q. Do you know the name of that audience member? 11:16:07
A. I don't. 11:16:12
Q. Other than your eight declarations, have you ever published or spoke about, publicly, this audience member? 11:16:13 11:16:27 11:16:36
A. I don't recall speaking publicly about the audience member. 11:16:39 11:16:42
Q. And do you know what affiliation this audience member had? 11:16:43 11:16:54
MS. BROWN-MARSHALL: Object to the form of the question. 11:16:55 11:16:57
A. No, I don't. 11:16:57
BY MR. RATLIFF: 11:17:01
Q. And according to you, this audience member was a male? 11:17:02

A. I don't know if that's what I put, but I recall he was a male, yes. 11:17:05 11:17:08

Q. And what did this male look like, that this was an audience member that is referred to in paragraph 50 of your declaration? 11:17:11 11:17:17 11:17:20

A. I can't remember the details. It was a long time ago, and when you're on a stage you have bright lights in your eyes. 11:17:24 11:17:26 11:17:29

Q. So the bright lights prevented you from having any understanding of what this person looked like; is that right? 11:17:35 11:17:39 11:17:42

MS. BROWN-MARSHALL: Object to the form of the question. 11:17:43 11:17:47

A. I don't remember what the patient -- I'm sorry, person, not patient, I don't remember what the person looked like. 11:17:47 11:17:49 11:17:50

BY MR. RATLIFF: 11:17:51

Q. Okay. And sitting here today, you have -- you can't tell me any characteristics of what this supposed audience member looked like; is that right? 11:17:53 11:17:55 11:18:00

MS. BROWN-MARSHALL: Object to the form of the question. 11:18:02 11:18:08

A. I don't remember any details of what the person looked like. 11:18:08 11:18:12

BY MR. RATLIFF: 11:18:12

Q. Okay. Do you think if you were in a room with this person, you would recognize who that person was? 11:18:12 11:18:16

MS. BROWN-MARSHALL: Object to the form of the question. 11:18:21 11:18:23

A. I do not feel like I could recognize the person. 11:18:23

BY MR. RATLIFF: 11:18:25

Q. Okay. And you say that this audience member expresses views that it was too early for you to be presenting our data. Do you see that? 11:18:28 11:18:32 11:18:36

A. Yes. 11:18:39

Q. And what specifically did this audience member say during the question-and-answer session? 11:18:39 11:18:44

A. I can't remember exactly the words. 11:18:51

Q. So give us your general recollection of what this audience member said during the question-and-answer session. 11:18:57 11:19:01 11:19:03

A. The general recollection was that there were -- it was early in terms of, you know, small numbers. 11:19:06 11:19:15

Q. So the audience member said it was early? 11:19:21

A. I don't remember the details specifically. 11:19:25
Q. Can you give us any more information as to what this audience member said, even if it's a general recollection? 11:19:30 11:19:34 11:19:39
MS. BROWN-MARSHALL: Object to the form of the question. 11:19:42 11:19:42
A. I can't remember any details. It was just a general recollection that it was early to be presenting the data. 11:19:42 11:19:46 11:19:49
BY MR. RATLIFF: 11:19:50
Q. Did the audience member ask a question during the question-and-answer session? 11:19:50 11:19:54
A. I don't recall if he just had comments or questions. I don't recall. 11:19:55 11:19:58
Q. How long did this audience member speak during the question-and-answer session? 11:19:59 11:20:09
A. I don't recall how long they spoke, but it went in -- I mean, question -- they're not long sessions, so... 11:20:14 11:20:19
Q. What's not a long session? 11:20:21
A. The question-and-answer session. We're not talking, like, hours. It's, you know, a few minutes after each presentation. 11:20:24 11:20:27 11:20:31

Q. Can you give us any more information as to how long this audience member supposedly expressed a comment or what this audience member looked like? 11:20:33 11:20:41 11:20:51

MS. BROWN-MARSHALL: Object to the form of the question. 11:20:53 11:20:56

A. Can I give you more details on how long? Again, it would not have been many minutes, it's just one I can recall that it's very short and I don't -- I cannot recall what the person looked like. 11:20:56 11:21:00 11:21:07 11:21:09

BY MR. RATLIFF: 11:21:13

Q. Did you ever ask the audience member what the comment that the member made meant? 11:21:19 11:21:24

A. Did I ask them? No, I did not ask them. 11:21:29

Q. And in your declaration it's written that you took the comment to mean something. But to be clear, did you ever ask the audience member what they actually meant by the comment? 11:21:35 11:21:39 11:21:45 11:21:48

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 11:21:51 11:21:51

A. I did not ask the audience member what he meant. 11:21:54

BY MR. RATLIFF: 11:21:58

Q. Now, Doctor, providing your responses to the questions 11:22:15

that I have asked so far, you didn't intend to put any hidden or ambiguous meanings in your responses. Right? 11:22:18 11:22:23 11:22:26

MS. BROWN-MARSHALL: Object to the form of the question. 11:22:26 11:22:29

A. Did I intend to? 11:22:29

BY MR. RATLIFF: 11:22:34

Q. That was my question. 11:22:34

A. I didn't intend to. 11:22:35

Q. Okay. And in providing responses to the questions I have asked so far, you tried to be as clear as possible. Right? 11:22:40 11:22:44 11:22:48

A. Did I try to be as clear as possible? I believe I did. 11:22:52 11:22:56

Q. And in providing responses to the questions that I've asked so far, you tried to be as complete as possible to the best of your ability. Right? 11:22:58 11:23:01 11:23:07

A. I believe I did. 11:23:11

Q. And right now, are you aware of any responses that you gave to me that were unclear or wrong? 11:23:13 11:23:18

A. Well, I did note that in the beginning you talked about a bunch of NCTs, and as I realized that you 11:23:25 11:23:29

were talking about multiple studies, I asked for a clarification. And I can't keep the numbers straight, so there -- that's just a clarification for the NCTs that you were referring to. 11:23:34 11:23:36 11:23:39 11:23:41

Q. Anything else? 11:23:46

A. Off the top of my head, that was the one where I realized that you were asking about multiple NCTs. 11:23:49 11:23:56

Q. So is there anything else? 11:24:04

A. Not that -- not that I can recall off the top of my head right this minute. 11:24:10 11:24:14

Q. Okay. So let's take a look again at Exhibit 1053. This would have been a document that was put in the Chat. 11:24:16 11:24:22 11:24:27

A. Yeah, I've got it open. 11:24:29

Q. And this is the study record for NCT02060188. Right? 11:24:30

A. Correct. And I believe that perhaps you had mentioned this in the beginning and I didn't realize you were talking about this study. 11:24:42 11:24:45 11:24:47

Q. Right. But you're familiar with this study. Right? 11:24:49

A. I'm not familiar with this particular study record in front of me, but I am familiar with the CheckMate 142 study. 11:24:53 11:24:55 11:25:01

Q. Okay. So let me ask my question again. I want to be sure we're clear. I didn't ask if you were familiar with this study record. 11:25:06 11:25:10 11:25:12

A. Okay. 11:25:14

Q. You're familiar with the study NCT02060188. Right? 11:25:17

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 11:25:27 11:25:28

A. I am familiar with CheckMate 142. 11:25:29

BY MR. RATLIFF: 11:25:33

Q. Is CheckMate 142 different from NCT02060188? Are those two different studies or the same? 11:25:34 11:25:40

A. It's referring -- CheckMate 142 is the BMS -- what they called their protocol, CheckMate 142. The NCT refers to the number that was given to it in the system. 11:25:48 11:25:56 11:26:01 11:26:06

Q. So are you familiar with the study that has the clinical trial number NCT02060188? 11:26:11 11:26:16

MS. BROWN-MARSHALL: Object to the form of the question -- 11:26:21 11:26:24

A. Yes, I'm familiar -- 11:26:24

MS. BROWN-MARSHALL: Doctor, let me finish my objections. 11:26:25 11:26:28

Object to the form of the question. Asked and answered. 11:26:30

A. I am familiar with CheckMate 142. 11:26:30

BY MR. RATLIFF: 11:26:39

Q. Let me ask my question again. Are you familiar with the study that has the clinical trial number NCT02060188? 11:26:44

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 11:26:56

A. I am familiar with CheckMate 142, and if CheckMate 142 is the study in NCT06 -- I'm sorry, NCT02060188, then I am familiar with the clinical trial in that study record. 11:27:05

BY MR. RATLIFF: 11:27:23

Q. Okay, so let's take a look at the copy of the 97 patent -- '975 patent. 11:27:26

A. Okay. 11:27:35

MS. BROWN-MARSHALL: Counsel, are we talking about the patent or the declaration? 11:27:50

A. We're talking about the declaration. Right? 11:27:51

BY MR. RATLIFF: 11:27:54

Q. We're talking about the patent. 11:27:56

A. Oh. 11:27:56
Q. So if you don't have the patent, we can pull that up and put it in the Chat. It should be Exhibit 1001. 11:27:57 11:28:00
PLANET DEPOS TECH: It should be in the Chat now. 11:28:05 11:28:09
BY MR. RATLIFF: 11:28:09
Q. And let me know when you have it, Doctor. 11:28:09
A. Okay, patent '975. 11:28:20
Q. And the '975 patent, this is a patent that you say that you're one of the named inventors. Right? 11:28:27 11:28:31
A. Yes. 11:28:35
Q. And you understand that in this patent there are a number of cited references. Right? 11:28:35 11:28:43
A. Yes. 11:28:50
Q. And you understand that in this patent there are references to the clinical trial with the identifier NCT2060188. Right? 11:28:50 11:28:59 11:29:06
A. I don't recall. 11:29:14
MS. BROWN-MARSHALL: I was just going to say, Dr. Le, feel free to review the exhibit if you need to to answer counsel's questions. 11:29:14 11:29:15 11:29:19
THE WITNESS: Yeah. 11:29:24

BY MR. RATLIFF: 11:29:24

Q. You don't recall? 11:29:25

A. I don't recall. 11:29:25

Q. Okay. Can you turn to page 4 of the patent? And you're looking for page 4 at the top. Let me know when you have it. 11:29:26 11:29:30 11:29:33

A. Okay. 11:29:34

Q. Do you have it? 11:29:38

A. Uh-huh. 11:29:39

Q. And do you see in the right-hand column the many references to the clinical trial identifier NCT2060188? 11:29:39 11:29:43 11:29:50

A. In the right-hand column? You said the NCT2060188, do I see those references? Yes. 11:29:52 11:30:05

Q. And the first reference related to the clinical trial NCT2060188 is the first study record, Version 1, for BMS's Phase 2 clinical trial of nivolumab and nivolumab plus ipilimumab in recurrent and metastatic microsatellite high colon cancer. Right? 11:30:10 11:30:14 11:30:28 11:30:31 11:30:37

A. Wait, I'm sorry... what was the question? Is that -- yeah, I see the clinical trial identifier NCT2060188. Yes. 11:30:41 11:30:44 11:30:55

Q. So my question is that the first reference related to the clinical trial NCT2060188 is the study record Version Number 1 for BMS's Phase 2 clinical trial nivolumab in MSI-High colorectal cancer patients. Right? 11:30:57 11:31:03 11:31:14 11:31:21 11:31:24

A. I can see the clinical trials identifier and the date February 10th, 2014. 11:31:24 11:31:28

Q. Okay, so can we focus on my question? 11:31:38

A. Yes. 11:31:40

Q. Do you see the very first study record for BMS's clinical trial in MSI-High patients using nivolumab referred to on page 4 of the patent in which you are a named inventor? 11:31:41 11:31:45 11:31:54 11:31:58

A. I see the reference to NCT2060188 version dated February 10th, 2014, which is the exhibit you showed me previously where they included patients with colon cancer and they had to have MSI testing. 11:31:59 11:32:09 11:32:12 11:32:18

Q. And that's the first version of the study record. Right? 11:32:24 11:32:28

MS. BROWN-MARSHALL: Object to the form of the question. 11:32:30 11:32:32

A. As far as I know. That's what you showed me. 11:32:32

BY MR. RATLIFF: 11:32:37
Q. As far as you know, that's the first version. Right? 11:32:38
A. I just know what you showed me. 11:32:43
Q. Well, doesn't the patent refer to it as Version 1? 11:32:46
A. It refers to this as Version 1, yes. 11:32:53
Q. And this is a patent in which you are a named inventor. Right? 11:32:56 11:33:01
A. Yes. 11:33:01
MS. BROWN-MARSHALL: Objection. Asked and answered. 11:33:02 11:33:06
BY MR. RATLIFF: 11:33:06
Q. And, in fact, there's several references to the BMS clinical study in your patent. Right? 11:33:06 11:33:12
MS. BROWN-MARSHALL: Object to the form of the question. 11:33:16 11:33:20
A. Are there several references... 11:33:20
Yes, there are several references to that NCT2060188. 11:33:23 11:33:33
BY MR. RATLIFF: 11:33:38
Q. And there's several references to the various study record versions for that trial. Correct? 11:33:38 11:33:41
A. Correct. 11:33:47

Q. And there are 32 study record versions for that trial that are cited in your patent. Right? 11:33:47 11:33:55

A. I don't know. I would have to count them. 11:33:59

Q. Do you see at least 32 versions referred to? 11:34:03

A. Okay, you said at least 32? 11:35:02

Q. That's what I said. 11:35:06

A. Okay. There are at least 32. 11:35:07

Q. And have you read the study record versions on the BMS trial that were available and announced prior to the July 10, 2015, alleged invention date for the eight patents referred to in your declarations? 11:35:12 11:35:19 11:35:25 11:35:32

MS. BROWN-MARSHALL: Object to the form of the question. 11:35:36 11:35:38

A. I'm sorry, can you repeat the question? 11:35:38

BY MR. RATLIFF: 11:35:41

Q. Have you read the study record versions of the BMS trial that were available and announced prior to the July 10, 2015, alleged invention date for the eight patents referred to in your declarations? 11:35:42 11:35:47 11:35:49 11:35:54

MS. BROWN-MARSHALL: Object to the form of the question. 11:35:56 11:35:59

A. I don't recall reading -- I don't recall reading the 11:35:59

study record prior to July 10th. 11:36:06

BY MR. RATLIFF: 11:36:14

Q. 2015. 11:36:15

A. 2015. 11:36:16

Q. Do you know why the study record versions are included in the patent? 11:36:17 11:36:25

A. I don't know why. 11:36:27

Q. In your view, does the work that BMS was doing with respect to nivolumab have anything to do with the work that you and other scientists were doing for the MSI-High study that's discussed in your eight declarations? 11:36:30 11:36:35 11:36:41 11:36:49 11:36:53

MS. BROWN-MARSHALL: Object to the form of the question. 11:36:55 11:36:57

A. Can you repeat the question? 11:36:57

BY MR. RATLIFF: 11:37:00

Q. In your view, does the work that BMS was doing with respect to nivolumab have anything to do with the work that you and other scientists were doing with the MSI-High study that's discussed in your eight declarations? 11:37:01 11:37:05 11:37:08 11:37:11 11:37:14

A. I can't -- 11:37:15

MS. BROWN-MARSHALL: Object to the form of the question. 11:37:15 11:37:17

A. I can't tell you what was happening at BMS. 11:37:17

BY MR. RATLIFF: 11:37:22

Q. And I'm not asking you to tell me what was happening at BMS. It's a different question. You're familiar with what you say is the trial CheckMate 142. Right? 11:37:27 11:37:29 11:37:33

A. Yes. 11:37:39

Q. In your view, does the science involved with CheckMate 142 have any relationship to the science involved with the MSI-High study that's discussed in your eight declarations? 11:37:46 11:37:49 11:37:57 11:38:03

MS. BROWN-MARSHALL: Object to the form of the question. 11:38:05 11:38:09

A. Do I -- in my view, does BMS's study have anything to do with our study? 11:38:09 11:38:16

BY MR. RATLIFF: 11:38:20

Q. Do you think that's what I asked you? 11:38:20

MS. BROWN-MARSHALL: Object to the form of the question. Badgering the witness. 11:38:22 11:38:23

A. Can you just repeat the question? 11:38:26

BY MR. RATLIFF: 11:38:29

Q. In your view, does the science involved with the BMS study NCT02060188 have any relationship to the science involved with the MSI-High study that's discussed in your eight declarations, NCT number 01876511? 11:38:29 11:38:40 11:38:50 11:38:56

MS. BROWN-MARSHALL: Object to the form of the question. 11:39:06 11:39:12

A. NCT, does it have any relationship to the science. I'd have to look closer at that study because it's very old. 11:39:12 11:39:28 11:39:35

BY MR. RATLIFF: 11:39:38

Q. Which study is very old? 11:39:38

A. All of them. And I don't remember -- I mean, I wasn't involved in them, so I can't really say. 11:39:40 11:39:44

Q. You weren't involved in either study that we're discussing? 11:39:48 11:39:50

A. I wasn't involved in the BMS study. 11:39:52

Q. But you're familiar with the BMS study. Right? 11:39:56

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 11:40:00 11:40:02

A. I am familiar with the BMS study. 11:40:04

BY MR. RATLIFF: 11:40:07

Q. In your view, is the hypothesis of the BMS study -- 11:40:10

strike that.

In your view, is the science behind the BMS study the same as the science behind the MSI-High study that's discussed in your eight declarations?

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered several times.

A. In my view, this study record is for patients with colorectal cancer and they had to have testing for MSI-High status. That's all I can tell you based on the study record.

I -- the study -- the NCT -- I would have to look at the protocol. I don't know. There's just a lot of different -- I think CheckMate 142 was actually a lot more complicated as far as I remember, but... in terms of what they were studying, but I don't know. I don't -- I can't -- I didn't -- I wasn't an investigator on the trial, so I don't know all the details.

BY MR. RATLIFF:

Q. Is the science behind the BMS study the same science behind the MSI-High study that's discussed in your eight declarations?

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered multiple times. 11:41:38 11:41:38

A. Again, I don't have the information to be able to -- I would have to look at the actual study to be able to tell you what I think. 11:41:42 11:41:49 11:41:53

BY MR. RATLIFF: 11:42:03

Q. Sitting here today, you have no idea one way or another; is that fair? 11:42:03 11:42:06

MS. BROWN-MARSHALL: Object to the form of the question. 11:42:06 11:42:11

A. Sitting here today, I would need more information on what was in the actual study. 11:42:11 11:42:20

BY MR. RATLIFF: 11:42:23

Q. To be clear, what study? 11:42:23

A. The protocol. 11:42:28

Q. Is it the study? You need more information on the study or the protocol? Which is it? 11:42:33 11:42:36

A. Well, you asked me about the science, so I would need to look at the study protocol and... 11:42:38 11:42:41

Q. You would need to look at the study protocol for what? 11:42:49

A. For CheckMate 142, where it would talk about the science. 11:42:53 11:43:04

Q. And so is it your testimony from looking at the study record that we saw earlier today, you have no idea if the science behind the BMS study is the same as the science behind the MSI-High study that's discussed in your eight declarations? 11:43:10 11:43:14 11:43:21 11:43:24 11:43:27

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered multiple times. 11:43:28 11:43:30

A. I would need to look at the science in the study to be able to answer that. 11:43:35 11:43:40

BY MR. RATLIFF: 11:43:47

Q. So I'm asking you, take a look at Exhibit 1053 -- 11:43:48

A. Yes, I'm looking at 1053. 11:43:53

Q. -- the BMS study record. 11:43:55

A. Uh-huh. 11:43:57

Q. And looking at that, do you have any opinion whatsoever whether or not the science behind the BMS study is the same as the science behind the MSI-High study as discussed in your eight declarations? 11:44:01 11:44:07 11:44:11 11:44:18

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered multiple times. 11:44:21 11:44:22

A. Based on this record, I cannot comment specifically on the science behind their study, the design. 11:44:26 11:44:33

BY MR. RATLIFF: 11:44:46

Q. And why can't you comment? 11:44:46

A. Because I would need to see their -- the 11:44:48
scientific -- the -- in the -- there's more 11:44:53
information in the protocol on the science and the 11:44:56
design. 11:44:59

MR. RATLIFF: All right, Doctor, I have no 11:45:07
further questions for you at this time but I may have 11:45:09
questions if your counsel has questions for you. 11:45:13

MS. BROWN-MARSHALL: Can we take a 11:45:14
ten-minute break? We'll come back and see if we have 11:45:15
any questions. 11:45:19

MR. RATLIFF: Sure. 11:45:20

(Off the record at 11:45 a.m.) 11:45:24

(Back on the record at 11:56 a.m.) 11:56:11

MS. BROWN-MARSHALL: Dr. Le, I have just a 11:56:12
few questions for you. 11:56:14

EXAMINATION 11:56:14

BY MS. BROWN-MARSHALL: 11:56:14

Q. Do you remember when counsel asked you about the 11:56:17
prescreening process discussed in paragraph 12 of your 11:56:23
declaration? 11:56:26

A. Yes. 11:56:29

Q. Okay. Was that prescreening process described in paragraph 12 limited to Arm C of the JHU clinical trial? 11:56:29 11:56:33 11:56:37

MR. RATLIFF: Objection. Beyond the scope. 11:56:38

BY MS. BROWN-MARSHALL: 11:56:42

Q. You can answer, Dr. Le. 11:56:42

A. I'm sorry, can you repeat the question? 11:56:44

Q. Was that -- was that prescreening process described in paragraph 12 of your declarations limited to Arm C of the JHU clinical trial? 11:56:47 11:56:51 11:56:54

MR. RATLIFF: Objection. Beyond the scope. 11:56:58

A. Was that limited to Arm C... that is my recollection, but I honestly would have to go back and review all the documents to see if there was any other situation where we could use it, but the purpose was to find patients with non-colorectal cancer. 11:57:03 11:57:20 11:57:23 11:57:28 11:57:32

BY MS. BROWN-MARSHALL: 11:57:35

Q. Dr. Le, if you would bring up Exhibit 1053. You remember counsel asked you several questions about Exhibit 1053 and clinical trial CheckMate 142. Right? 11:57:37 11:57:44 11:57:48

A. Yes. 11:57:55

Q. Okay. And the title for CheckMate 142 is A Study of Nivolumab and Nivolumab Plus Ipilimumab in Recurrent and Metastatic Colorectal Cancer. Correct? 11:57:55 11:58:01 11:58:12

MR. RATLIFF: Objection. Leading. 11:58:15

BY MS. BROWN-MARSHALL: 11:58:16

Q. You can answer, Dr. Le. 11:58:17

A. Yes. The title is A Study of Nivolumab and Nivolumab Plus Ipilimumab in Recurrent and Metastatic Colon Cancer (Checkmate 142). 11:58:17 11:58:17 11:58:17

Q. And what is ipilimumab? 11:58:17

A. It's a CTLA-4 antagonist. 11:58:29

Q. So is ipilimumab an anti-PD-1 therapy? 11:58:30

MR. RATLIFF: Objection. Beyond the scope. 11:58:35

A. Ipilimumab is not an anti-PD-1 therapy. 11:58:36

BY MS. BROWN-MARSHALL: 11:58:41

Q. And, Dr. Le, does Exhibit 1053 list the conditions that are to be studied in this clinical trial? 11:58:41 11:58:50

MR. RATLIFF: Objection. Beyond the scope. 11:58:53

A. The -- in the inclusion criteria in the exhibit, it says patients with confirmed colon cancer, that they have to have confirmed colon cancer. 11:58:55 11:59:04 11:59:09

BY MS. BROWN-MARSHALL: 11:59:12

Q. And is there a specific condition section in Exhibit 1053? 11:59:12 11:59:16

MR. RATLIFF: Objection. Beyond the scope. 11:59:17

A. I don't see a section other than what's in the inclusion criteria. 11:59:27 11:59:28

BY MS. BROWN-MARSHALL: 11:59:29

Q. If you would go to page 6 of Exhibit 1053. 11:59:30

A. Page 6. And that is the page, okay, that starts with "Responsible Party: Sponsor"? 11:59:35 11:59:42

Q. Yes. And on page 6 -- does page 6 identify the conditions to be studied in this clinical trial? 11:59:43 11:59:46

MR. RATLIFF: Objection. Beyond the scope. 11:59:55

A. Does it -- what it says under Study Description is patients with recurrent and metastatic colon cancer. 11:59:57 12:00:03

BY MS. BROWN-MARSHALL: 12:00:12

Q. Does page 6 identify MSI-High negative colorectal cancer as a condition to be studied? 12:00:12 12:00:17

MR. RATLIFF: Objection. Beyond the scope. 12:00:17

A. I'm sorry. There is a section under Conditions that says "MSI Positive Colorectal Cancer, MSI Negative Colorectal Cancer." 12:00:19 12:00:21 12:00:26

BY MS. BROWN-MARSHALL: 12:00:27

Q. Thank you. You can put that exhibit aside. 12:00:28
If you could go back to your declaration, 12:00:33
and paragraph 35. 12:00:35
A. I'm sorry, which one? 12:00:42
Q. This was the '187 that you were asked about, 12:00:43
paragraph 35. 12:00:46
A. '187, 35. Okay. 12:00:53
Q. Okay. And do you remember counsel asking you 12:00:55
questions about the phrase "initial phase" in the last 12:00:57
sentence of paragraph 35? 12:01:00
A. Yes. 12:01:07
Q. Okay. Would you please read that entire sentence? 12:01:07
A. While Merck not had -- "while Merck had not agreed to 12:01:11
provide financial support for the initial phase of 12:01:14
our study, after seeing our preliminary results, 12:01:16
Merck agreed to provide our team funding to enroll 12:01:19
additional patients and to collect additional data." 12:01:22
Q. After reading the full sentence, do you have a better 12:01:26
understanding of what you meant by "initial phase of 12:01:29
our study" in that sentence? 12:01:31
MR. RATLIFF: Objection. Form. 12:01:35
A. "Initial phase of our study." Again, I just mean the 12:01:38

initial parts of the study. 12:01:46

BY MS. BROWN-MARSHALL: 12:01:50

Q. And what did you mean when you said, "Merck had not agreed to provide financial support for the initial phase of our study"? 12:01:50 12:01:53 12:01:55

MR. RATLIFF: Objection. Beyond the scope. 12:01:57

A. So because it was our study, we had to find other resources to pay for the study. So they didn't provide any financial support for the study, the initial phase of the study. 12:02:02 12:02:04 12:02:12 12:02:14

BY MS. BROWN-MARSHALL: 12:02:16

Q. And you also write that, "after seeing our preliminary results, Merck agreed to provide our team funding to enroll additional patients and to collect additional data." Correct? 12:02:16 12:02:19 12:02:21 12:02:23

A. Correct. 12:02:24

Q. Okay. What preliminary results are you referring to in that sentence? 12:02:25 12:02:28

MR. RATLIFF: Objection. Beyond the scope. 12:02:30

A. The results of the earliest patients in the study, they provided funding later. 12:02:33 12:02:37

BY MS. BROWN-MARSHALL: 12:02:39

Q. And do you have an idea when they provided that funding? 12:02:40 12:02:43

A. I can't remember the -- 12:02:44

MR. RATLIFF: Objection. Beyond the scope. 12:02:44

A. I can't remember the exact dates, but it was later we started the study on our own. 12:02:46 12:02:53

BY MS. BROWN-MARSHALL: 12:02:55

Q. Okay. If you would, go to Exhibit 1031, please. 12:02:55

A. 1031, okay. Yes. 12:03:05

Q. And you are -- you were the principal investigator on the clinical trial that's described in the New England Journal of Medicine article, Exhibit 1031. Correct? 12:03:09 12:03:15 12:03:24

A. Correct. 12:03:26

Q. And you're also the first author on this paper. Correct? 12:03:26 12:03:28

A. That is correct. 12:03:28

Q. Okay. Were you involved in drafting this article that was published in the New England Journal of Medicine? 12:03:29 12:03:33

MR. RATLIFF: Objection. Beyond the scope. 12:03:36

A. Yes, I was involved in drafting. 12:03:38

BY MS. BROWN-MARSHALL: 12:03:40

Q. Okay. And as an author on the New England Journal of 12:03:40

Medicine paper, were you required to list funding support for the clinical trial described in the paper? 12:03:47 12:03:49

MR. RATLIFF: Objection. Beyond the scope. 12:03:52

A. Yes. 12:03:55

BY MS. BROWN-MARSHALL: 12:03:56

Q. Okay. And is that funding support described in Exhibit 1031? 12:03:56 12:04:02

MR. RATLIFF: Objection. Beyond the scope. 12:04:03

A. Yes. 12:04:12

BY MS. BROWN-MARSHALL: 12:04:12

Q. Okay. Where is that described in Exhibit 1031? 12:04:12

MR. RATLIFF: Objection. Beyond the scope. 12:04:15

A. There is one section that says "funded by Johns Hopkins and others" on page 1, and then on page 10 there is a listing of support at the bottom before the appendix. 12:04:20 12:04:26 12:04:34 12:04:37

BY MS. BROWN-MARSHALL: 12:04:39

Q. Okay. And what sources are listed in that list of support on page 10 above the appendix? 12:04:39 12:04:42

MR. RATLIFF: Objection. Beyond the scope. 12:04:45

A. Supported by Swim Across America Lab at John Hopkins University, the Banyan Gate Foundation, the 12:04:50 12:04:54

Lustgarten Foundation, the Commonwealth Fund, the Ludwig Fund, the Sol Goldman Pancreatic Cancer Research, the GI SPORE, and grants from NIH. 12:04:57 12:04:59 12:05:03

BY MS. BROWN-MARSHALL: 12:05:13

Q. Is Merck listed in that page of support on page 10 of Exhibit 1031? 12:05:14 12:05:17

MR. RATLIFF: Objection. Beyond the scope. 12:05:18

A. Merck is not listed under funders on this study. 12:05:21

BY MS. BROWN-MARSHALL: 12:05:25

Q. So in your understanding, as of the publication of Exhibit 1031, the New England Journal of Medicine article, Merck had not provided support for the clinical trial. Correct? 12:05:26 12:05:29 12:05:31 12:05:34

MR. RATLIFF: Objection. Beyond the scope. Objection. Leading. 12:05:36 12:05:38

A. That is my understanding. 12:05:41

BY MS. BROWN-MARSHALL: 12:05:44

Q. Okay. If you would go to the top of this -- page 1 of Exhibit 1031. 12:05:44 12:06:03

A. The top of... okay. 12:06:09

Q. And is there a list of authors at the top of page 1 of 1031? 12:06:10 12:06:15

A. Yes. 12:06:16
Q. Okay. And you are the first author on this paper. 12:06:16
Correct? 12:06:20
A. Yes. 12:06:21
Q. And the author list also includes D.M. Pardoll. Do 12:06:21
you see that? 12:06:28
MR. RATLIFF: Objection. Beyond the scope. 12:06:29
A. Yes. 12:06:31
BY MS. BROWN-MARSHALL: 12:06:32
Q. And is that Dr. Drew Pardoll? 12:06:32
A. Yes. 12:06:35
MR. RATLIFF: Objection. Beyond the scope. 12:06:35
BY MS. BROWN-MARSHALL: 12:06:36
Q. And is Dr. Pardoll an inventor on the eight patents at 12:06:37
issue in these IPRs that we've discussed today? 12:06:40
MR. RATLIFF: Objection. Beyond the scope. 12:06:43
A. Yes. 12:06:46
BY MS. BROWN-MARSHALL: 12:06:48
Q. Okay. And next is N. Papadopoulos. Is that Dr. Nick 12:06:48
Papadopoulos? 12:06:53
MR. RATLIFF: Objection. Beyond the scope. 12:06:54
A. Yes. 12:06:56

BY MS. BROWN-MARSHALL: 12:06:57
Q. Okay. And was Dr. Papadopoulos one of the inventors on the eight patents that we discussed today? 12:06:57 12:07:00
MR. RATLIFF: Objection. Beyond the scope. 12:07:03
A. Yes. 12:07:04
BY MS. BROWN-MARSHALL: 12:07:05
Q. Okay. And the next author listed is K.W. Kinzler. Is that Dr. Ken Kinzler? 12:07:06 12:07:11
A. Yes. 12:07:18
Q. Okay. And is Dr. Ken -- is Dr. Kinzler one of the inventors on the eight patents we've discussed today? 12:07:18 12:07:22
MR. RATLIFF: Objection. Beyond the scope. 12:07:25
A. Yes. 12:07:26
BY MS. BROWN-MARSHALL: 12:07:27
Q. Okay. And then you see the next-to-last author is Dr. -- is B. Vogelstein. Do you see that? 12:07:27 12:07:34
A. Yes. 12:07:37
Q. Is that Dr. Burt Vogelstein? 12:07:37
A. Yes. 12:07:40
Q. And is he one of the inventors on the eight patents we've discussed today? 12:07:40 12:07:44
MR. RATLIFF: Objection. Beyond the scope. 12:07:45

A. Yes. I'm sorry. 12:07:46
BY MS. BROWN-MARSHALL: 12:07:47
Q. Okay. And then the last author is L.A. Diaz, Jr. Is that Dr. Luis Diaz? 12:07:47 12:07:52
MR. RATLIFF: Objection. Beyond the scope. 12:07:55
A. Yes. 12:07:56
BY MS. BROWN-MARSHALL: 12:07:57
Q. And was he one of the inventors on the eight patents that we've discussed today? 12:07:57 12:08:02
A. Yes. 12:08:04
Q. Okay. 12:08:04
MR. RATLIFF: Objection. Beyond the scope. 12:08:05
BY MS. BROWN-MARSHALL: 12:08:07
Q. Okay. So other than you and the other inventors that we've identified in this list, there are several other authors that are listed as authors of this paper. Correct? 12:08:07 12:08:12 12:08:16 12:08:18
MR. RATLIFF: Objection. Beyond the scope. 12:08:19
A. Yes, that is correct. 12:08:24
BY MS. BROWN-MARSHALL: 12:08:26
Q. Okay. Were any of those other non-inventor authors involved in designing the treatment strategy used in 12:08:26 12:08:30

the study? 12:08:33

MR. RATLIFF: Objection. Beyond the scope. 12:08:35

A. Can you repeat that question? 12:08:38

BY MS. BROWN-MARSHALL: 12:08:39

Q. I said, were any of the other authors, excluding the inventors, involved in designing the treatment strategy used in this study? 12:08:40 12:08:44 12:08:47

MR. RATLIFF: Objection. Beyond the scope. 12:08:54

A. Can you define "design the treatment strategy"? 12:08:57

BY MS. BROWN-MARSHALL: 12:09:02

Q. So the clinical trial described in Exhibit 1031 involved three arms. Correct? 12:09:03 12:09:11

MR. RATLIFF: Objection. Beyond the scope. 12:09:15

Objection. Leading. 12:09:16

A. Correct. 12:09:20

BY MS. BROWN-MARSHALL: 12:09:21

Q. Okay. And part of the clinical trial involved treating the patients in those three arms with pembrolizumab. Correct? 12:09:21 12:09:26 12:09:30

MR. RATLIFF: Objection. Beyond the scope. 12:09:33

Objection. Leading. 12:09:34

A. Correct. 12:09:36

BY MS. BROWN-MARSHALL: 12:09:37

Q. Okay. Were any of the authors listed on Exhibit 1031, other than the inventors, involved in designing that treatment strategy used in the study? 12:09:37 12:09:44 12:09:48

MR. RATLIFF: Objection. Beyond the scope. 12:09:51

A. Not in the treatment strategy. 12:09:57

MS. BROWN-MARSHALL: No further questions. 12:10:05

MR. RATLIFF: Doctor, I have a few questions for you. 12:10:06 12:10:08

THE WITNESS: Okay. 12:10:11

RE-EXAMINATION 12:10:11

BY MR. RATLIFF: 12:10:11

Q. Doctor, is it your testimony that everyone that was involved in designing the so-called treatment strategy used in the study in which you are listed as an author? And we're talking about Exhibit 1031. 12:10:12 12:10:28 12:10:32 12:10:34

A. Say that one more time? 12:10:40

Q. Is it your testimony that everyone that was involved in designing the so-called treatment strategy used in the study listed in Exhibit 1031 appears as an author of the article? 12:10:42 12:10:47 12:10:54 12:11:09

MS. BROWN-MARSHALL: Object to the form of 12:11:10

the question. 12:11:13

A. Is it my testimony that everybody on this article... 12:11:13

no, that's not my testimony. 12:11:23

BY MR. RATLIFF: 12:11:30

Q. Now, you understand that Dr. Topalian is listed as an 12:11:30

inventor on the eight patents that you discuss in your 12:11:41

declarations. Right? 12:11:43

A. Yes. 12:11:49

Q. And Dr. Topalian is not listed as an author of the New 12:11:49

England Journal of Medicine article, Exhibit 1031. 12:11:54

Right? 12:11:56

A. Yes. 12:11:59

Q. Yes, she's not listed. Right? 12:12:00

A. Correct. 12:12:02

Q. And, Doctor, before your counsel asked you questions 12:12:02

did you have a conversation with anyone? 12:12:11

A. My daughter. 12:12:14

Q. Did you have a -- 12:12:17

A. That's it. 12:12:18

Q. Did you -- go ahead. You can finish. 12:12:20

A. Just my daughter. 12:12:22

Q. Did you have a conversation with counsel? 12:12:23

A. Before she -- like in the -- during this break? 12:12:26
Q. Did you have a conversation with counsel during any of the breaks today? 12:12:32 12:12:34
A. No, I did not. 12:12:35
Q. And during my questioning, before your counsel asked you questions, did I ask you any questions about the authors that are listed in the New England Journal of Medicine article at Exhibit 1031? 12:12:40 12:12:45 12:12:53 12:12:59
A. I don't recall that you did. 12:13:04
Q. And during my questioning to you before your counsel asked you questions, did I ask you any questions about statements concerning funding in Exhibit 1031, which is the New England Journal of Medicine article? 12:13:05 12:13:13 12:13:18 12:13:25
A. Okay, I'm sorry, you -- you're talking about the New England Journal article specifically. 12:13:29 12:13:35
Q. That's right. 12:13:36
A. Okay. I think the funding came from the reference to the declaration about the term "initial phase of the study," and we were talking about funding by Merck. I think that was the line of rationale with the funding. 12:13:37 12:13:43 12:13:48 12:13:51 12:13:55
Q. So my question to you is, when I was asking you 12:13:55

questions before your counsel asked questions, did I refer you at all to any statements about funding in the Merck Exhibit 1031, which is the New England Journal of Medicine article? 12:13:58 12:14:02 12:14:08 12:14:13

MS. BROWN-MARSHALL: Object to the form of the question. Asked and answered. 12:14:13 12:14:15

A. I don't recall you specifically referring to the New England Journal article when it referred to funding. 12:14:16 12:14:21

MR. RATLIFF: I have no further questions for you, Doctor. 12:14:30 12:14:31

MS. BROWN-MARSHALL: I have no further questions. 12:14:32 12:14:34

Thank you for your time, Dr. Le. 12:14:34

MR. RATLIFF: Thank you. We are done. 12:14:38

(Proceedings concluded at 12:14 p.m.

CERTIFICATE OF NOTARY

STATE OF MICHIGAN)
) SS
COUNTY OF OAKLAND)

I, ALISON WEBSTER, stenographic reporter and notary public in and for the state of Michigan do hereby certify:

That the deposition of DUNG LE, M.D. was taken before me via videoconference on the date hereinbefore set forth; that the foregoing questions and answers were recorded by me stenographically and reduced to computer transcription; that this is a true, full, and correct transcript of my stenographic notes so taken; and that I am not related to, nor of counsel to, either party nor interested in the event of this cause.

I further certify that the adverse party was represented by counsel at the deposition.

I further certify that the deposition of DUNG LE, M.D., occurred via Zoom videoconference on Friday, April 18, 2025, commencing at 9:07 a.m., and ending at 12:14 p.m.

Alison C. Webster

ALISON C. WEBSTER, CSR-6266, RPR, RMR, CRR, RDR
Notary Public, Oakland County, Michigan
My commission expires: May 1, 2029

ACKNOWLEDGMENT OF DEPONENT

I, DUNG LE, M.D., do hereby acknowledge that I have read and examined the foregoing testimony and the same is a true, correct, and complete transcription of the testimony given by me and any corrections appear on the attached errata sheet signed by me.

_____ _____

(SIGNATURE) (DATE)