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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENE COMPANY PTY LTD.,

Petitioner,

v.

THE TRUSTEES OF COLUMBIA UNIVERSITY

IN THE CITY OF NEW YORK,

Patent Owner.

Case IPR2024-00313

Patent No. RE47,045

Tuesday, November 26, 2024

9:02 a.m.

****OUTSIDE COUNSEL'S EYES ONLY****

DEPOSITION OF LEONIDE SAAD, PhD

STENOGRAPHICALLY REPORTED BY:

Deanna J. Dean, RDR, CRR

Henderson Legal Services

202-220-4158

www.hendersonlegalservices.com

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Tuesday, November 26, 2024

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9:02 a.m.

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Deposition of LEONIDE SAAD, PhD, held at

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the law offices of Finnegan, Henderson, Farabow,

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Garrett & Dunner LLP, Two Seaport Lane, Boston,

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Massachusetts 02210, before Deanna J. Dean, a

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Registered Diplomate Reporter, Certified

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Realtime Reporter, and Notary Public of the

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State of Massachusetts.

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25

1 I N D E X

2

3 Examination Page

4 LEONIDE SAAD, PhD

5 By Attorney Mills 6, 227

6 By Attorney Feldstein 210

7

8

9 E X H I B I T S

10

11 Number Description Page

12 Exhibit 1071 Printed Pages from Alkeus 140

13 Pharmaceuticals Website

14 Titled "Transformation in

15 Sight"

16 Exhibit 1072 Printed Pages from Bain 162

17 Capital Private Equity

18 Website Titled "Current and

19 Former Portfolio Companies"

20 Exhibit 1073 Screenshots of Directors on 164

21 Alkeus Pharmaceuticals

22 Website

23 Exhibit 1074 LinkedIn Profile for Michael 183

24 Song

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1 E X H I B I T S (cont'd.)

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3 Number Description Page

4 Exhibit 1075 LinkedIn Profile for Monica 190

5 Hennessey

6 Exhibit 1076 LinkedIn Profile for 193

7 Christine Xu

8 Exhibit 1077 LinkedIn Profile for Cyriac 197

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10 Exhibit 1078 LinkedIn Profile for Runyao 200

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1 P R O C E E D I N G S

2 LEONIDE SAAD, PhD,

3 a witness called for examination by counsel for the
4 Petitioner, having been satisfactorily identified
5 by the production of his driver's license and being
6 first duly sworn by the Notary Public, was examined
7 and testified as follows:

8 EXAMINATION

9 BY ATTORNEY MILLS:

10 Q. Please state your name for the record.

11 A. **Leonide Saad.**

12 Q. And please provide your address.

13 A. **My office address?**

14 Q. The address at which you receive
15 correspondence.

16 A. [REDACTED]

17 Q. Have you ever been deposed before?

18 A. **I have not.**

19 Q. Okay. We're going to talk about some rules
20 of the deposition just to make things go smoothly.

21 The first rule of the deposition is that
22 everything that's said today is being taken down by
23 the court reporter.

24 Do you understand that?

25 A. **I do.**

1 Q. Okay. So what that means is that it's
2 very important that none of us talk at the same
3 time as the second person.

4 Do you understand that?

5 **A. I do.**

6 Q. So the attorneys will do our best to
7 follow that rule, and if you can do the same, that
8 would be great as well.

9 **A. Very good.**

10 Q. Okay. Because the official record of the
11 deposition is the transcript, it's important that
12 your answers to my questions be audible rather than
13 a gesture or a nod of the head.

14 Can you agree to do that?

15 **A. I agree.**

16 Q. Okay. At some points during the
17 deposition today, your attorney may lodge
18 objections. The objections are for the record.
19 They're not for you. Unless your attorney
20 instructs you not to answer the question, then you
21 still need to answer my question.

22 Do you understand that?

23 **A. I do.**

24 Q. Okay. If at any point you need to take a
25 break during the deposition, please let us know.

1 The one rule is that we ask you not to take a break
2 when a question has been asked but you haven't
3 given the answer yet.

4 Is that a rule that you can follow?

5 **A. I can.**

6 Q. Okay. Is there any reason that you can't
7 give your best truthful testimony today?

8 **A. I don't think so.**

9 Q. Okay. What did you do to prepare for your
10 deposition today?

11 ATTORNEY FELDSTEIN: And he's just asking,
12 I believe, generally. Don't disclose any
13 communications you had in preparation, please.

14 **A. I reread my declaration.**

15 Q. Other than reading your declaration, is
16 there anything else that you did to prepare for
17 your deposition today?

18 **A. Probably glanced at the -- some of the**
19 **exhibits to refresh my memory.**

20 Q. Which exhibits did you look at?

21 **A. I will not remember exactly which one, but**
22 **I probably glanced at -- rapidly at all of them.**

23 Q. Okay. In preparation for your deposition,
24 did you look at anything that is not cited in your
25 declaration?

1 **A. No.**

2 Q. Okay. Did you -- and I'm not asking you
3 to tell me what you talked about -- but did you
4 meet with the attorneys in preparing for your
5 deposition?

6 ATTORNEY FELDSTEIN: So he's just asking
7 yes or no.

8 **A. Yes.**

9 Q. When did you meet with the attorneys to
10 prepare for your deposition?

11 **A. I met in person yesterday.**

12 Q. And was that here in Finnegan's office?

13 **A. That is correct.**

14 Q. How long did you meet with the Finnegan
15 attorneys yesterday?

16 **A. I met till 5:00 p.m. or so from 9:00 a.m.**

17 Q. Who was present at that meeting?

18 **A. Mark Feldstein, Drew, and Caroline.**

19 Q. Is Caroline with Finnegan?

20 ATTORNEY FELDSTEIN: Yes.

21 Q. Other than the attorneys, was there
22 anybody else that was present at that meeting?

23 **A. Not in this room.**

24 Q. Was there anyone who participated in that
25 meeting in any way other than the three Finnegan

1 personnel you just named?

2 **A. I do not believe there was anyone else**
3 **present remotely.**

4 THE WITNESS: Right? There was no one?

5 ATTORNEY FELDSTEIN: You can't ask me.

6 Sorry.

7 **A. There was no one present.**

8 Q. And I should have mentioned when we were
9 talking about the rules. So the attorney can't
10 provide your answers for you. It has to be your
11 knowledge.

12 And also, if there's any time you don't
13 understand my question, go ahead and ask me for
14 clarification.

15 **A. Mm-hmm.**

16 Q. If I ask a question and you answer it, is
17 it fair to assume that you think you understood the
18 question?

19 ATTORNEY FELDSTEIN: Object to form.

20 **A. I will -- if I'm unable to answer a**
21 **question, I will ask you for a clarification.**

22 Q. Thank you.

23 Other than the meeting yesterday with the
24 Finnegan attorneys, did you have any other meetings
25 to prepare for your deposition?

1 **A. There were probably some other -- there**
2 **were some other phone calls with Finnegan as well.**

3 Q. And, again, without asking for the
4 contents of what you discussed, what was the most
5 immediately preceding meeting that you had with the
6 Finnegan attorneys to prepare for your deposition?

7 **A. That was the one yesterday.**

8 Q. And the most immediately preceding that?

9 **A. I believe it was on the -- it was on -- on**
10 **Saturday of last week.**

11 Q. Was that an in-person meeting?

12 **A. No.**

13 Q. How did that meeting take place?

14 **A. It was on Zoom.**

15 Q. How long was that meeting?

16 **A. Two to three hours.**

17 Q. Who was present at that meeting?

18 **A. Mark and Drew.**

19 Q. And other than Mark and Drew, no one else
20 was present or participated in that meeting.

21 Correct?

22 **A. That's correct. No one else was present**
23 **on the Zoom call.**

24 Q. Prior to that meeting, was there another
25 meeting to prepare?

1 **A.** Yes. I think there was one on -- on
2 either on Thursday or Friday. I don't recall.
3 That was a day -- one of the day before. It
4 lasted for approximately an hour. And Mark was
5 present for most of the call. I do not recall if
6 Drew was present.

7 Q. Other than Mark and Drew, was anyone else
8 present?

9 **A.** No.

10 Q. That was also a remote meeting?

11 **A.** That's correct.

12 Q. Okay. Before that, were there any
13 meetings?

14 **A.** There were probably other meetings, but
15 none in preparation for -- none specifically
16 directed to the preparation of this deposition.

17 Q. Okay. Those were meetings that took place
18 after you signed your declaration but before the
19 deposition. Is that correct?

20 ATTORNEY FELDSTEIN: I'm going to direct
21 you -- Dr. Saad, I'm going to direct you not to
22 answer about meetings that were in preparation
23 for the deposition.

24 **A.** I do not recall.

25 ATTORNEY FELDSTEIN: I'm directing you not

1 to answer. So when I direct you not to answer,
2 you should please not answer.

3 Q. In preparing for your deposition, did you
4 speak with anyone at Alkeus?

5 **A. No.**

6 Q. You have a document in front of you. Can
7 you tell us what it is?

8 **A. It's -- the document is the declaration**
9 **from myself in the IPR2024-00313 case.**

10 Q. And does it have an exhibit number on the
11 bottom right-hand corner?

12 **A. It's the Exhibit 2191.**

13 Q. Okay. So if we use the terminology "your
14 declaration," or if you were to say "my
15 declaration," we'll understand that to mean Exhibit
16 2191. Correct?

17 **A. I will, yes.**

18 Q. Okay.

19 When did you first see your declaration?

20 ATTORNEY FELDSTEIN: Object to form.

21 **A. I do not recall.**

22 Q. Go ahead and turn to page 19 of your
23 declaration and take a look at the date under the
24 signature line.

25 Do you see the September 22, 2024, date?

1 **A. I do.**

2 Q. Is that the day that you signed your
3 declaration?

4 **A. That is the date at which I signed -- I**
5 **indicate my -- my signature, yes.**

6 Q. And how did you sign the declaration?

7 **A. I signed it via online by typing the date**
8 **and typing my name.**

9 Q. You understood when you signed your
10 declaration that it's the same as swearing an oath
11 in court as to the truthfulness of it. Correct?

12 **A. I understood it based on the conclusion**
13 **of -- which is above on paragraph 56.**

14 Q. And you understand the same is true today
15 in the deposition; even though there's not a judge
16 here, it's the same as if you were in court in
17 front of a judge?

18 **A. I do.**

19 Q. Okay.

20 So that September 22nd date, when you
21 signed, how long before that did you first see your
22 declaration?

23 ATTORNEY FELDSTEIN: I'm going to direct
24 you not to answer in the preparation of your
25 declaration, Doctor.

1 So I'm directing you not to answer on the
2 grounds of work product.

3 Q. Did you request any changes be made to
4 your declaration?

5 ATTORNEY FELDSTEIN: I'm going to direct
6 you not to answer on -- as work product on any
7 information concerning the preparation of your
8 declaration.

9 Q. Before you signed your declaration on
10 September 22, 2024, did you have an adequate
11 opportunity to ensure that all of the information
12 contained therein is truthful and accurate?

13 **A. I believe so, yes.**

14 Q. Before you signed your declaration on
15 September 22, 2024, did you review each of the
16 exhibits that are cited in that declaration?

17 **A. I reviewed them, not necessarily in the**
18 **most ^ details.**

19 Q. What do you mean by that?

20 **A. I probably read them in a cursory manner.**

21 Q. When you reviewed them, did they have
22 exhibit numbers on the bottom of the page?

23 **A. I'm not sure.**

24 Q. Did you personally provide the documents
25 that are cited in your declaration to the

1 attorneys?

2 ATTORNEY FELDSTEIN: Object to form.

3 **A. Could you repeat the question?**

4 Q. Did you personally provide the documents
5 that are cited in your declaration to the
6 attorneys?

7 ATTORNEY FELDSTEIN: Object to form.

8 **A. Do you have a specific exhibit in mind?**

9 Q. Well, any of the ones that are cited there
10 that you said you reviewed before you signed your
11 declaration.

12 I'm just trying to find out if the way you
13 prepared your declaration was you handed them or
14 emailed them the documents and said, "Here are
15 these documents."

16 **A. Several of these documents were -- are --**

17 ATTORNEY FELDSTEIN: I'm sorry. What's
18 the question now?

19 ATTORNEY MILLS: Whether he personally
20 provided those to the attorneys.

21 ATTORNEY FELDSTEIN: Okay. Object to
22 form.

23 **A. Several --**

24 ATTORNEY FELDSTEIN: And, in fact, I'm
25 going to direct you not to answer on the grounds

1 of privilege in terms of -- on work product in
2 terms of preparation of your declaration.

3 So I'm directing you not to answer those,
4 Doctor.

5 Q. And I should have done this before. But
6 are you refusing to answer the question on the --
7 under the advice of the attorney?

8 **A. That's correct.**

9 Q. Is that -- that is also true with respect
10 to the other answers where you were instructed not
11 to answer? You're refusing to answer the questions
12 under the advice of the attorney. Is that correct?

13 ATTORNEY FELDSTEIN: Object to form.

14 **A. I am following my attorney's advice.**

15 Q. So you have a page open in your
16 declaration. Tell me what page you're at.

17 **A. I'm looking at page 2 and 3 right now.**

18 Q. And on pages 2 and 3, there's a list of
19 exhibits. Correct?

20 **A. I see a list of exhibits.**

21 Q. Okay. As you're sitting here today, you
22 can't tell me that you personally provided any of
23 those exhibits to counsel. Is that correct?

24 ATTORNEY FELDSTEIN: I'm going to direct
25 you not to answer, Doctor. That's your answer

1 is that I'm directing you not to answer.

2 Q. Are you refusing to answer the question on
3 the basis of counsel's instructions?

4 **A. That's correct.**

5 Q. Let's take a look at the table of contents
6 in your declaration. This is a Roman numeral II.
7 Correct?

8 **A. I see Roman numeral II.**

9 Q. So, in your declaration, you address your
10 personal background. Is that correct?

11 **A. Sorry. Could you repeat this?**

12 Q. In your declaration, you address your
13 personal background?

14 **A. Yes.**

15 Q. In your declaration, you address the
16 clinical development of ALK-001. Correct?

17 **A. That's correct.**

18 Q. In your declaration, you address Alkeus's
19 TEASE, T-E-A-S-E, and SAGA, S-A-G-A, studies.
20 Correct?

21 ATTORNEY FELDSTEIN: Object to form.

22 **A. In the declaration, we discuss -- with**
23 **respect to the TEASE and the SAGA studies, we**
24 **discuss here based on the table of contents study**
25 **design endpoints and analyses.**

1 Q. Thank you.

2 And when you say "analyses," that includes
3 statistical analyses?

4 ATTORNEY FELDSTEIN: Object to form.

5 **A. The document indicates statistical**
6 **analysis.**

7 Q. Please turn to paragraph -- well, page 1
8 of your declaration.

9 **A. Yes.**

10 Q. Do you see where you reference having
11 personal knowledge at the top of page 1 of your
12 declaration?

13 **A. Yes.**

14 Q. Do you have personal knowledge of the
15 study design for the TEASE studies?

16 **A. I believe I do. That is what is written,**
17 **yes.**

18 Q. And how many TEASE studies are there?

19 **A. There are four TEASE studies.**

20 Q. You have personal knowledge for all four
21 of the TEASE studies for their design. Is that
22 correct?

23 **A. I do. This particular declaration focuses**
24 **only on two of them.**

25 Q. Is it correct that this declaration

1 focuses on the TEASE-1 and the TEASE-3 studies but
2 has some discussion with regard to the TEASE-2 and
3 TEASE-4 studies?

4 ATTORNEY FELDSTEIN: Object to form.

5 **A. This declaration focuses on TEASE-1 and**
6 **TEASE-3. I do not recall if there is anything else**
7 **about the other two.**

8 Q. Do you have personal knowledge of the
9 study design for the SAGA study?

10 **A. I do.**

11 Q. Is there more than one SAGA study?

12 **A. No, there's only one.**

13 Q. Before you signed your declaration, had
14 you read the clinical trial protocols for the TEASE
15 studies?

16 **A. I do not believe so.**

17 Q. To the best of your knowledge, is there a
18 single clinical trial protocol for all four TEASE
19 studies?

20 **A. That is correct.**

21 Q. And you've never read the clinical trial
22 protocol for the TEASE studies. Is that correct?

23 **A. That's not correct.**

24 Q. You have read the clinical trial protocol
25 for the TEASE studies. Correct?

1 **A. Yes.**

2 Q. That clinical trial protocol encompasses
3 each of TEASE-1, 2, 3, and 4. Correct?

4 **A. Yes.**

5 Q. You've also read the clinical trial
6 protocol for the SAGA study?

7 **A. Yes.**

8 Q. With regard to the TEASE-1 study, were
9 there any amendments to the clinical trial protocol
10 after initiation of the study?

11 **A. Yes.**

12 Q. What amendments were made?

13 **A. I do not recall.**

14 Q. With regard to the TEASE-2 study, were
15 there any amendments made after initiation of the
16 study?

17 **A. It's possible.**

18 Q. Sitting here today, you don't know whether
19 or not any amendments were made to the clinical
20 trial protocol regarding the TEASE-2 study?

21 **A. That's correct.**

22 Q. Were there any amendments made to the
23 clinical trial protocol for the TEASE-3 study after
24 study initiation?

25 **A. It's possible.**

1 Q. You don't know one way or the other?

2 A. **That's correct.**

3 Q. Were there any amendments made to the
4 clinical trial protocol for the TEASE-4 study after
5 study initiation?

6 A. **That's possible.**

7 Q. You don't know one way or the other?

8 A. **That's correct.**

9 Q. Were there any amendments made to the
10 clinical trial protocol for the SAGA study after
11 study initiation?

12 A. **I'm not sure.**

13 Q. You don't know one way or the other?

14 A. **That's correct.**

15 Q. Do you have personal knowledge of how the
16 TEASE and SAGA studies were actually carried out?

17 A. **Define "carried out."**

18 Q. Conducted.

19 ATTORNEY FELDSTEIN: Object to form.

20 A. **Define "conducted."**

21 Q. Take a look at paragraph 14 of your
22 declaration.

23 A. **Mm-hmm.**

24 Q. In paragraph 14, it says you're the study
25 director for the TEASE trials and the SAGA trial.

1 Correct?

2 **A. That is correct.**

3 Q. It says as the study director, you have
4 been responsible for the TEASE and SAGA studies,
5 including designing the protocols, overseeing the
6 studies, assessing and reporting the results, and
7 drawing conclusions from the studies.

8 Do you see that?

9 **A. I see that.**

10 Q. So when you say "overseeing the studies,"
11 what does that mean?

12 **A. It mean providing oversight to the**
13 **studies.**

14 Q. Can you provide us with more detail as to
15 what that means?

16 ATTORNEY FELDSTEIN: Object to form.

17 **A. I mean essentially what it means.**
18 **Overseeing the studies, meaning you are not**
19 **conducting them, but you are overseeing the**
20 **studies.**

21 Q. Okay. Let's see if we can drill down and
22 understand this is a little bit better.

23 With regard to the SAGA study, what was
24 your role during -- well, let me withdraw that
25 question and start over.

1 So, first of all, the SAGA study is
2 completed at this point. Correct?

3 **A. The SAGA study is completed, yes.**

4 Q. With regard to the SAGA study, what was
5 your role in overseeing the SAGA study?

6 **A. The role of overseeing a study is**
7 **essentially to ensure that the various actors are**
8 **following good clinical practice in the protocol**
9 **and that the data that we obtain is reflecting the**
10 **data created by those actors.**

11 Q. So with regard to the SAGA trial, who are
12 those actors?

13 **A. The actors include all of the -- all the**
14 **parties that generate data.**

15 Q. So in the SAGA trial, who generated data?

16 **A. You have -- you have the clinical site.**
17 **The laboratories. The graders. The cardiologist.**
18 **That's -- that's about it.**

19 Q. What is the role of the cardiologist?

20 **A. The cardiologist assesses on behalf of the**
21 **clinical site the electrocardiogram traces.**

22 Q. For the patients?

23 **A. Of the patients, yes.**

24 Q. And what's the purpose of the
25 electrocardiograms from the patients?

1 **A. It's routine testing to verify heart**
2 **function.**

3 Q. Is there a single cardiologist or is there
4 more than one cardiologist for the SAGA study?

5 **A. I think I would not recall exactly. There**
6 **could be multiple.**

7 ATTORNEY FELDSTEIN: So, counsel, I'm
8 trying to be cognizant that presumably you're
9 delving into background, but this does seem
10 beyond the scope of what's covered in the
11 declaration, and I'm concerned that you
12 represent a competitor and are potentially using
13 this to develop information and get insights
14 into how -- irrelevant to this case -- insights
15 into how he has conducted protocols on behalf of
16 your client, a competitor.

17 And so I just want to put that on the
18 record, and ask you to stay focused on the
19 declaration and not delve into irrelevant
20 details of how they conducted clinical trials
21 that may be competitively sensitive.

22 ATTORNEY MILLS: So I disagree that a
23 witness who testified about clinical trials and
24 said that he has personal knowledge of the
25 clinical trials, that his knowledge of how the

1 clinical trials was conducted is irrelevant.

2 If you have concerns about competitive
3 information, the parties have agreed to a
4 protective order, and if there's information
5 that's discussed that ends up being
6 confidential, then there's a procedure for
7 dealing with that.

8 ATTORNEY FELDSTEIN: Just to be clear, I
9 don't disagree that some background is relevant,
10 but I can't see how a cardiologist and what
11 cardiologists are doing in this study is
12 particularly relevant. And so it makes me
13 wonder and concerned about trying to develop
14 information on behalf of a competitor.

15 ATTORNEY MILLS: Well, he mentioned a
16 cardiologist, and so I'm asking what the
17 relevance of the cardiologist is.

18 If there are concerns at any point about
19 confidentiality, then the remedy for that is to
20 designate the transcript confidential. So if we
21 reach that point, we can talk about it then.

22 ATTORNEY FELDSTEIN: That's fair. And I
23 want to put my concerns on the record. We don't
24 have to belabor it. But you're also
25 specifically beyond the scope of the

1 declaration, so the fact that you're trying
2 to -- it's not a remedy to seek confidential
3 information beyond the scope or beyond the
4 relevance of the declaration.

5 ATTORNEY MILLS: We're well within the
6 scope of the declaration.

7 BY ATTORNEY MILLS:

8 Q. We talked about the cardiologist. You
9 mentioned the graders. Tell me, what's the role of
10 the graders?

11 **A. The graders are grading retinal imaging of**
12 **the patient.**

13 Q. And you used the word "retinal imaging."
14 Can you tell me what that is?

15 **A. A retinal image is a photo of the back of**
16 **the eye.**

17 Q. The graders don't take the photo of the
18 eye, but they evaluate it. Is that correct?

19 **A. Sometimes the graders can be the same**
20 **person who takes photos.**

21 Q. In the SAGA study, were the graders
22 individuals who also took the photos?

23 **A. Could you repeat the question?**

24 Q. In the SAGA study, were the graders the
25 individuals who also took the photos?

1 **A. I believe there was a grading done at --**
2 **by the people taking the photos, and a grading done**
3 **by people not taking the photos.**

4 Q. And when you say that, are you saying
5 that, for an individual patient, one person would
6 take the photo and grade it, and then a second
7 person would look at the same photo and also grade
8 it?

9 **A. That's correct. And there could be even a**
10 **third person looking at the photo and grading.**

11 Q. When you say a third person, are you
12 testifying, in fact, that there were circumstances
13 where a third grader was grading the image?

14 **A. No. So, first of all, there -- it -- in**
15 **the SAGA study, there were multiple graders who are**
16 **not the people who take photos. So there were**
17 **indeed multiple people who grade the photos that**
18 **are not the people -- the one person who takes the**
19 **photo. And there was a person who takes the photo**
20 **who may or may not grade it.**

21 Q. Okay. So I'm trying to understand. Was
22 there -- is there like an official grader for this,
23 or one or more official graders for the study?

24 **A. I do not understand the word "official."**

25 Q. Well --

1 ATTORNEY FELDSTEIN: Give me a chance to
2 object.

3 Object to form.

4 Q. Yeah. What I'm trying to understand is,
5 ultimately, you're getting some sort of results
6 that you're recording out. Correct?

7 **A. In the end, you have a -- you generate a**
8 **data set.**

9 Q. Okay. So, I mean, maybe there's lots of
10 people looking at the image, but is there an
11 official grader whose grade counts?

12 ATTORNEY FELDSTEIN: Object to form.

13 **A. There is, in the end, a number that is**
14 **obtained from a combination of several graders.**
15 **That number is the one that ends up in the**
16 **database.**

17 Q. You used a word right before you said
18 "combination of" something.

19 "Several"? Did you say "several"?

20 **A. Yes.**

21 Q. So there are several graders, and then the
22 grades of those graders are combined in some
23 fashion to determine the final grade.

24 Am I correct so far?

25 **A. That's correct.**

1 Q. Okay. So for those initial graders, is
2 that a concrete set of individuals, or does it just
3 depend on who's there that day?

4 ATTORNEY FELDSTEIN: Object to form.

5 A. I would not even know the answer.

6 Q. And is that not information that is part
7 of the clinical trial protocol?

8 A. No, it's not. It's not actually extremely
9 important.

10 Q. Okay. It's not important who creates the
11 images?

12 ATTORNEY FELDSTEIN: Object to form.

13 A. I think that's a vague statement.

14 Q. I'm just trying to understand what you
15 meant. You said it's not actually extremely
16 important?

17 A. Yeah. I don't think it's extremely
18 important who grades, as long as I know that the
19 results are going to be accurate.

20 Q. I'm just trying to understand. Who's
21 responsible for grading the images in the SAGA
22 trial?

23 A. What do you mean by "responsible"?

24 Q. I mean, I haven't -- I haven't graded
25 retinal imaging. Right? So it's not something

1 I've done. But I have to imagine that you're not
2 walking through the hallway and asking random
3 people to look at it; that there's a set group of
4 people that are evaluating the images. But, like,
5 I don't know.

6 So I'm trying to get you to explain to me
7 how is it that -- is there a set of people that are
8 the people that are grading these images that your
9 data is based on?

10 **A. So grading images is an easy process that**
11 **requires delineating around an image areas of --**
12 **areas that are dark, essentially.**

13 Q. Okay. So --

14 **A. It can be done with extremely minimal**
15 **training.**

16 Q. Okay. So you said that grading is an easy
17 process. I'm still trying to understand, is
18 there -- in the SAGA study, is there a specific set
19 of people that are identified as the graders?

20 **A. There's a specific number of people that**
21 **are designated as graders.**

22 Q. Okay. In the SAGA trial, how many people
23 were designated as graders?

24 **A. I do not remember.**

25 Q. Is it more than two people?

1 **A. Yes.**

2 Q. Is it more than five people?

3 **A. I do not recall.**

4 Q. Is it more than 10 people?

5 **A. I do not recall.**

6 Q. Could it be more than 15 people?

7 **A. Unlikely so.**

8 Q. So your best estimate is it's somewhere
9 between 2 and 10 graders?

10 ATTORNEY FELDSTEIN: Object to form.

11 **A. It's -- it was at least three, and I know**
12 **it wasn't -- it wasn't 15 or 20.**

13 Q. So the graders for the SAGA trial, the
14 number of those graders is at least three but not
15 as many as 15. Is that your best estimate?

16 **A. That's basically what I said, yes.**

17 Q. And whether you can remember all of them
18 right now as you sit here, at some point did you
19 know who all of those graders were?

20 **A. No.**

21 Q. And why is that?

22 **A. Because it was not important.**

23 Q. Is there somebody else in the world who
24 would have known who the graders are?

25 ATTORNEY FELDSTEIN: Object to form.

1 **A. Yes. These people were known by -- these**
2 **people were known by someone.**

3 Q. Who would be the person who knew who the
4 graders were? If not the name, the role of the
5 individual who knew that.

6 **A. The -- the company we hired to do that job**
7 **would have known who these people are.**

8 Q. Okay. So there was a company that you
9 hired to perform the reading of the images?

10 **A. Yes.**

11 Q. Okay. And what is -- is there a term for
12 that function, the company that handles the reading
13 of the images?

14 **A. Yes.**

15 Q. What's that term?

16 **A. It's called a centralized reading center.**

17 Q. Okay. For the SAGA study, you employed a
18 centralized reading center. Is that correct?

19 **A. That's correct.**

20 Q. Do you know the name of the centralized
21 reading center?

22 **A. I -- I think it may be protected under**
23 **certain confidentiality.**

24 Q. So you know the name and you believe that
25 the name is protected under a confidentiality

1 agreement?

2 **A. I know the name, but I do not know any --**
3 **it may be protected under a confidentiality**
4 **agreement.**

5 Q. So go ahead and tell me the name, and if
6 we determine that it's protected by an agreement,
7 your counsel can designate the transcript
8 confidential.

9 ATTORNEY FELDSTEIN: Are you saying,
10 Dr. Saad, that you don't know whether you are
11 allowed to disclose it due to confidentiality
12 owed to third parties?

13 THE WITNESS: That's correct.

14 ATTORNEY FELDSTEIN: I'm going to advise
15 you in that case that you should be cautious of
16 your confidentiality and don't break
17 confidentiality because opposing counsel tells
18 you to break confidentiality.

19 **A. So I prefer not to disclose the name in**
20 **this case.**

21 Q. So you believe that there is a
22 confidentiality agreement to the centralized
23 reading center prohibiting you from disclosing that
24 they participated in the trial?

25 **A. I believe that there's -- that there's**

1 **confidentiality for all the parties we hire that**
2 **protects us or them with respect to the use of**
3 **names.**

4 Q. Okay. So there's an agreement between
5 Alkeus and the centralized reading center that you
6 think may have a confidentiality agreement in it.
7 Correct?

8 A. **That's correct.**

9 Q. And you believe that the centralized
10 reading center has prohibited Alkeus from
11 disclosing that they were performing the reads for
12 the SAGA clinical trial.

13 Is that your testimony?

14 A. **I'm not a lawyer, so -- but I know that**
15 **many of these agreements have non-use of names**
16 **restrictions in it.**

17 Q. So I asked a question that was specific to
18 the centralized reading center prohibiting you, and
19 you kind of answered in a passive way. Right? So
20 there may be restrictions, but they might be
21 restrictions that Alkeus imposed. Right?

22 So what I'm trying to find out is you
23 think that the centralized reading center is
24 prohibiting Alkeus from telling people that the
25 centralized reading center participated in the SAGA

1 trial?

2 **A. That's very possible.**

3 Q. So are there reasons that you're aware of
4 that a centralized reading center would not want to
5 be associated with Alkeus's SAGA trial?

6 ATTORNEY FELDSTEIN: I'm going to object.
7 It's beyond the scope of the declaration.

8 **A. The -- I do not know the answer to that**
9 **question.**

10 Q. Okay. So at a high level, what is the
11 role of the centralized reading center in the SAGA
12 trial?

13 **A. Grade the images.**

14 Q. Anything else?

15 **A. No.**

16 Q. Other than the centralized reading center,
17 is there anyone else that's involved in grading the
18 images for the SAGA trial?

19 **A. The -- as I mentioned, there were other**
20 **parties, including the photographer, the physician,**
21 **and people at Alkeus as well.**

22 Q. Okay. So I want to understand the
23 process.

24 So when you talk about the photographer
25 and the physician, are they also at the centralized

1 reading center?

2 **A. No.**

3 Q. Where are they?

4 **A. They are at the site, at the physician's**
5 **clinic.**

6 Q. Okay. And is there only one physician
7 clinic site or is there more than one physician
8 clinic site in the SAGA trial?

9 **A. This was a multisite trial with multiple**
10 **clinics.**

11 Q. How many clinics were there for the SAGA
12 trial?

13 **A. Between 20 and 25.**

14 Q. Was there a geographic concentration for
15 those sites?

16 ATTORNEY FELDSTEIN: I'm going to object
17 as beyond the scope of the declaration.

18 And, again, I think that, counsel, you're
19 trying to elicit information for a competitor
20 that's competitively sensitive and not pertinent
21 to the scope of the declaration.

22 ATTORNEY MILLS: So that's not correct.
23 We're actually entitled to all the underlying
24 data. You're not allowed to submit test results
25 without providing all of the underlying data,

1 and we're asking him questions about how the
2 study was conducted.

3 ATTORNEY FELDSTEIN: You're entitled to
4 ask within the scope of the declaration. You're
5 not entitled to elicit information that's going
6 to be competitively advantageous to your client
7 for the sake of doing that.

8 ATTORNEY MILLS: So this is all relevant
9 to the studies that he's submitted and the way
10 that the data was generated. If you have
11 concerns about competition issues, then that is
12 addressed --

13 ATTORNEY FELDSTEIN: I'm telling you them
14 right now, that we do have concerns. I've told
15 you twice already.

16 ATTORNEY MILLS: So if there is
17 confidential information that is elicited during
18 the deposition, then you can designate the
19 transcript confidential and you can file a
20 motion to seal.

21 ATTORNEY FELDSTEIN: If you stick to the
22 scope of the declaration, we won't need to worry
23 about you trying to elicit competitively
24 sensitive information.

25 ATTORNEY MILLS: The scope of the

1 declaration includes the underlying data and the
2 way the studies were performed.

3 ATTORNEY FELDSTEIN: It doesn't include
4 every detail about how a competitor of your
5 client set up his clinical trials. It doesn't
6 include the number of sites. It doesn't include
7 the geographic location or density of the sites.
8 That can't be relevant to the scope of the
9 declaration, whether there was a locus of where
10 the sites were concerted. That's what raises my
11 concern that you're trying to get competitive
12 information for your client.

13 ATTORNEY MILLS: So I very much disagree.
14 How the study is conducted goes to reliability
15 of the study. You're relying on the study. It
16 completely opens the door for us to ask all of
17 the details about how it's conducted. He said
18 he has personal knowledge of that. I'm allowed
19 to inquire into it.

20 ATTORNEY FELDSTEIN: And what is the
21 relevance, counsel, of where -- specifically
22 whether there is a geographic concentration for
23 the sites?

24 ATTORNEY MILLS: So, first of all, I don't
25 have to explain my thinking behind all of my

1 questions. But just so that we can put this to
2 bed, if all of his data is coming from one
3 place, one location, that may indicate that it's
4 not a representative sample. That's how science
5 works. I'm allowed to inquire as to how the
6 study was designed and implemented.

7 ATTORNEY FELDSTEIN: Okay. I think you're
8 going beyond the scope of the declaration, and I
9 think you're trying to elicit information for a
10 competitor.

11 ATTORNEY MILLS: So what I'm trying to do
12 is I'm trying to probe the underlying bases for
13 the studies that were submitted that were relied
14 on.

15 ATTORNEY FELDSTEIN: I think you're going
16 beyond that, counsel.

17 ATTORNEY MILLS: If you have concerns
18 about confidentiality, the remedy, rather than
19 interrupting the deposition, is to designate --
20 if there is confidential information, you can
21 designate it.

22 ATTORNEY FELDSTEIN: No. The remedy for
23 going beyond the scope of the declaration is to
24 stop the deposition.

25 ATTORNEY MILLS: So I haven't gone beyond

1 the scope of the declaration.

2 ATTORNEY FELDSTEIN: I worry that you
3 have. The concentration, the geographic
4 concentration of sites, seems so far beyond and
5 only relevant to competitors.

6 ATTORNEY MILLS: So it's not. It goes to
7 how the study was conducted and its reliability.

8 BY ATTORNEY MILLS:

9 Q. Can you answer the question?

10 **A. Could you repeat the question?**

11 Q. Was there a geographic concentration for
12 those sites?

13 ATTORNEY FELDSTEIN: Object to form.

14 **A. It's the very same question. Could you --**
15 **could you make the question a little more clear?**

16 Q. You said that there were 20 to 25 sites.
17 So I'm asking for information about whether those
18 sites were geographically concentrated.

19 **A. They were all in the United States.**

20 Q. Were they all in a particular state?

21 **A. No.**

22 Q. Okay.

23 Okay. So you were talking about what
24 happens at the physician site as opposed to what
25 happens at the grading site.

1 Do you recall that?

2 **A. Yes.**

3 Q. Okay. So walk me through what happens at
4 the physician site.

5 **A. I do not know. I was not present.**

6 Q. Okay. So during the SAGA study, you were
7 never present at the physician site. Is that
8 correct?

9 **A. No, that's not correct. I was present to
10 do training, to do oversight, but not for them
11 to -- in the day-to-day practice.**

12 Q. Okay. In the training or in the protocol,
13 were there instructions as to what is supposed to
14 happen at the clinical site?

15 **A. Yes.**

16 Q. Okay. So according to the protocol and
17 the training -- well, let me stop there.

18 You provided the training. Is that
19 correct?

20 **A. Not personally.**

21 Q. Okay. But you're familiar with the
22 training?

23 **A. I -- it will probably depend on the level
24 of detail.**

25 Q. Okay. So walk me through according to the

1 protocol and the training what is it that happens
2 at the clinical site?

3 ATTORNEY FELDSTEIN: Object to form.

4 **A. My understanding is that the photographer**
5 **takes the photo, looks at them. One or multiple**
6 **physicians or other photographers look at the**
7 **photo, and then they enroll the patients.**

8 Q. Okay. So that's at enrollment, which you
9 were talking about just now?

10 **A. That's part of the enrollment, yes.**

11 Q. After enrollment, does the patient return
12 to the clinical site?

13 **A. If the patient is randomized into the**
14 **trial, the patient returns multiple times.**

15 Q. Okay. And each time that the patient
16 returns to the clinical site, do they repeat the
17 process of having a photograph taken of their
18 retina?

19 **A. Yes.**

20 Q. And each time that photograph is taken,
21 the physician and potentially the photographer
22 would then look at that image. Is that correct?

23 **A. Yes.**

24 Q. Okay. So in that scenario, is the
25 physician a grader?

1 **A. You could call that a grader if you want,**
2 **yes. It's -- he's looking at the photo. Anyone**
3 **who looks at the photo performs some sort of**
4 **grading.**

5 Q. And then do you keep a record of that as
6 part of the trial?

7 **A. I believe so, yes.**

8 Q. Is that grade that that physician gives,
9 is that part of what goes into the data that you
10 end up creating for that patient?

11 **A. I think -- I think -- I'm not sure about**
12 **that.**

13 Q. Okay. And you also mentioned the
14 photographer may look at the image?

15 **A. Mm-hmm.**

16 Q. When the photographer looks at the image,
17 is that also a grading?

18 **A. It's -- it's -- they're also reviewing the**
19 **images.**

20 Q. Okay. Do they provide a grade for the
21 image?

22 **A. They may as well provide a grade to the**
23 **image.**

24 Q. And is that grade part of the data that
25 you take into account for your clinical trial?

1 **A. I'm not sure.**

2 Q. Okay. Other than the photographer and the
3 physician, is there anyone else at the clinical
4 site that would be grading the image?

5 **A. I do not know.**

6 Q. And then you mentioned the centralized
7 reading center. So at the centralized reading
8 center, was there a requirement in the protocol as
9 to a minimum number of graders at the centralized
10 reading center for each image?

11 **A. I believe each image was read at least two**
12 **times.**

13 Q. And when you say it was read at least two
14 times, would that be by a different grader each
15 time?

16 **A. Yes. Two times by two different graders.**

17 Q. Okay. If there was a disagreement between
18 the two graders at the centralized reading center,
19 was there a process in the protocol for that?

20 **A. Yes, there was a process.**

21 Q. What -- at a high level, what was that
22 process?

23 **A. Including another person to -- to**
24 **essentially determine what to do.**

25 Q. Would that third person be someone also

1 from the centralized reading center?

2 **A. It was someone also selected from -- by**
3 **the reading center. I do not know if they are a**
4 **part of it.**

5 Q. Would that -- and can we call that person
6 a tiebreaker? Or is there a different term that
7 you would use for that person?

8 **A. You can call it a tiebreaker if you want.**

9 Q. Would the tiebreaker ever come from
10 Alkeus?

11 **A. No. Not in the SAGA trial.**

12 Q. Okay. And why is that?

13 ATTORNEY FELDSTEIN: Object to form.

14 **A. No particular reason.**

15 Q. Okay. So once the -- would there ever be
16 a situation under the protocol where there would be
17 more than three readers at the centralized reading
18 center?

19 **A. I don't remember.**

20 Q. Okay. So in the scenario where you have
21 at least two and perhaps three readers at the
22 centralized reading center, are those two to three
23 reads the reads that become the official read for
24 that image in the trial?

25 **A. These are the reads that -- sorry. The**

1 **final read ends up in the database.**

2 Q. Okay. And when you say "the final read,"
3 what does that mean?

4 **A. It's one value provided by the reading**
5 **senior.**

6 Q. Okay. So the reading center either finds
7 agreement between the first two readers and
8 provides that as a final read, or based on the
9 input of the third reader, then they provide a
10 final read. Is that fair?

11 **A. Yes.**

12 Q. Okay. So in the SAGA trial, when the
13 final read was being determined, there's no role
14 for Alkeus in that read process. Is that correct?

15 **A. No. So we also receive/review the images**
16 **as well.**

17 Q. And in the SAGA trial, does Alkeus receive
18 and review the images prior to the final grading?

19 **A. Yes.**

20 Q. Okay. Does Alkeus provide its own grade
21 for the images?

22 **A. It's very possible.**

23 Q. So under the trial protocol, what happens
24 if Alkeus disagrees with the centralized reading
25 center read?

1 **A. We actually -- I don't remember.**

2 Q. And when you say you don't remember,
3 you're saying you don't remember what the protocol
4 requirement was?

5 **A. No. So usually when you hire the reading**
6 **center, you are going to use the reading center**
7 **values. So there's no necessary -- it doesn't even**
8 **matter if Alkeus agrees or disagrees.**

9 Q. Okay. So Alkeus gets the reads. They
10 might perform their own reads. But they're stuck
11 with what the reading center tells them?

12 **A. Okay.**

13 Q. And why is that?

14 ATTORNEY FELDSTEIN: Object to form.

15 **A. Again, when you hire the reading center,**
16 **you are going to use the data from the reading**
17 **center.**

18 Q. Just because you paid for it?

19 **A. Yes.**

20 Q. Okay. So even if you think your reads are
21 better, you're going to use the reading center's
22 reads because you paid for that?

23 ATTORNEY FELDSTEIN: So, counsel, asking
24 about these hypotheticals is just as beyond the
25 scope of the factual declaration.

1 Q. Can you answer the question?

2 ATTORNEY FELDSTEIN: I'll object beyond
3 the scope, I'll object to form, and I'll
4 reiterate my concern that you're trying to pump
5 confidential information from my client.

6 **A. Can you repeat the question?**

7 Q. So you said that if there's a difference
8 in opinion between the grading at Alkeus and the
9 grading at the centralized reading center, you're
10 going use the grading from the reading center,
11 because you've paid for it. And so I'm trying to
12 understand, is it really just, you know, it's -- my
13 money's down the drain so I'm stuck? Or is there
14 another reason? Even if you think your reads are
15 better, you still are going to use theirs just
16 because you paid for it, so now you're -- you're
17 stuck with it?

18 ATTORNEY FELDSTEIN: Object.

19 Q. Is that what you're saying?

20 ATTORNEY FELDSTEIN: Object to form.

21 **A. We've hired a reading center to provide us**
22 **data. We'll use their data.**

23 Q. Yeah. So I understand you're saying you
24 hired the reading center and so you will use their
25 data.

1 Does the protocol require that you use the
2 reading center's data instead of Alkeus's reading?

3 **A. I don't know.**

4 Q. Okay.

5 Okay. So this final read, what happens --
6 what's the next step in the process? What happens
7 with the final read in the SAGA trial?

8 **A. We perform statistical analyses on the**
9 **final read.**

10 Q. And when you say "we," who do you mean, in
11 the SAGA trial?

12 **A. So the -- in the -- during the blinded**
13 **portion, the data is sent to the statistics group**
14 **that performs statistical analyses on that.**

15 Q. Is the statistics group something that
16 exists at Alkeus?

17 **A. We have an internal statistics group.**

18 Q. Okay. And a moment ago, when you were
19 saying in the SAGA trial the data is sent to the
20 statistics group, were you referring to the
21 internal Alkeus statistics group?

22 **A. It's sent to the internal and the external**
23 **statistics group.**

24 Q. Okay. And are you in charge of the
25 internal statistics group at Alkeus for the SAGA

1 trial?

2 **A. I do not know what that mean, to be in**
3 **charge of. We're a small company.**

4 Q. Is there someone else at Alkeus that's in
5 charge of the internal statistics group for the
6 SAGA trial?

7 **A. We're a small company, so we're a -- it's**
8 **a -- we all relate and work together.**

9 Q. Since we're talking about titles -- so,
10 currently, what's your title at Alkeus?

11 **A. I'm the chief scientific officer.**

12 Q. And until June of this year, you were also
13 the president and CEO. Is that correct?

14 **A. That's correct.**

15 Q. Okay. So as the president and CEO of
16 Alkeus during the SAGA study, do you know who was
17 in charge of the internal statistics group?

18 ATTORNEY FELDSTEIN: Object to form.

19 **A. Again, I don't understand what "in charge"**
20 **means. We're a small company. Titles are titles,**
21 **but we all work together.**

22 Q. Okay. Well, as the CEO and president of
23 Alkeus, were you in charge of the company?

24 **A. I was president and CEO of the company.**

25 Q. And is the president and CEO of the

1 company in charge of the company?

2 **A. I believe the president and CEO runs the**
3 **company.**

4 Q. Okay. Who was running the internal
5 statistics group for the SAGA study?

6 **A. Again, I do not know what that means, to**
7 **run the statistics group.**

8 Q. Well, I was trying to use your language.

9 So I had asked if you were in charge of
10 the company as the president and CEO and you said,
11 "Well, I run the company as the president and CEO."

12 So I'm trying to use language that you're
13 comfortable with. If there's different language,
14 I'm just trying to understand whether that was part
15 of your role was to oversee the internal statistics
16 group at Alkeus for the SAGA study.

17 ATTORNEY FELDSTEIN: Object to form.

18 **A. The -- I communicate with the group.**

19 Q. Okay. And when you communicate with the
20 group, is there a list of people that you
21 communicate with?

22 **A. Our team is not -- yeah, I do. It's not**
23 **necessarily a list. There are people.**

24 Q. I just did not hear what you said. "It's
25 not necessarily a list"?

1 **A. There are people.**

2 Q. So did you say "it's not necessarily a
3 list; there are people"?

4 **A. Yeah. So meaning there are just a few**
5 **people.**

6 Q. Okay. So there's no more than five people
7 in the internal statistics group. Is that fair?

8 **A. Yes.**

9 Q. Is there somebody who is the head of the
10 internal statistics group?

11 **A. I do not believe so.**

12 Q. Okay. The internal statistics group,
13 these are employees at Alkeus?

14 **A. Correct.**

15 Q. And there's no person who's a supervisor
16 in the internal statistics group at Alkeus for the
17 SAGA trial. Correct?

18 **A. I'm not sure what that means, again, to be**
19 **supervisor.**

20 Q. Okay. So you were the CEO and president
21 of Alkeus, but you don't know what it means to be a
22 supervisor?

23 **A. That's correct.**

24 Q. Were you personally involved in doing the
25 statistics for the SAGA study?

1 **A. I was personally involved in preparing the**
2 **specific protocol for the statistical analysis.**

3 Q. Okay. So before the study, you weren't
4 involved in preparing the protocol for what
5 statistics would be done. Is that what you're
6 saying?

7 **A. Yes.**

8 Q. Okay. Once --

9 ATTORNEY FELDSTEIN: Can I -- counsel, can
10 you check your question that you asked it the
11 right way you meant it? I don't want to
12 direct --

13 Q. So the transcript is coming up you weren't
14 involved, but I meant to say -- so I'll ask the
15 question again.

16 Before the SAGA study, you were involved
17 in preparing the protocol for what statistics would
18 be done. Correct?

19 **A. Well, before the study, there's no --**
20 **there's no study. So you have to design the study.**
21 **So you prepare the only documentation required for**
22 **the performance of the study.**

23 Q. And for the SAGA study, you were
24 personally involved in preparing the protocol
25 details regarding the statistical analysis?

1 **A. The details of the statistics are**
2 **contained in our statistical analysis plan.**

3 Q. You were personally involved in preparing
4 the statistical analysis plan for the SAGA study.
5 Correct?

6 **A. Yes.**

7 Q. Okay. Were there other aspects of the
8 clinical trial protocol for the SAGA study in which
9 you were personally involved?

10 **A. That's a vague -- that's too vague of a**
11 **question. There's several aspects of it.**

12 Q. I'm asking about any of them. Were there
13 any other aspect -- well, I'll withdraw that
14 question. We can take it a step at a time.

15 So we talked about the statistical
16 analysis. Right?

17 **A. Yes.**

18 Q. Okay. You said there were several other
19 aspects to the trial protocol. So I just want to
20 know what the list is, and then I'll ask you about
21 them.

22 So in addition to the statistical analysis
23 plan, what other aspects of the protocol are there?

24 **A. I do not understand the question.**

25 Q. Okay. So a moment ago you said you were

1 personally involved in designing the statistical
2 analysis plan for the protocol for the SAGA study.
3 Correct?

4 **A. Yes.**

5 Q. I asked you if there were other aspects of
6 the clinical trial protocol that you were
7 personally involved in, and you said that there
8 were -- you didn't understand the question because
9 there were many different aspects of the protocol.

10 So I'm just trying to find out what you
11 meant when you said there's many different aspects
12 of the protocol, so that I can ask you if you were
13 personally involved in them.

14 **A. Yes.**

15 Q. So what are the other aspects of the
16 protocol?

17 **A. Well, they're not covered in my
18 declaration. So . . .**

19 Q. So your role in the SAGA trial was limited
20 to the statistical analysis plan?

21 **A. No. My role has including designing the
22 protocol, overseeing the studies, assessing and
23 reporting the results.**

24 Q. Right. So designing the protocol. So
25 what you've testified that part of what you did at

1 least in designing the protocol was designing the
2 statistical analysis plan?

3 **A. Yes.**

4 Q. I'm trying to understand -- when you say
5 that you designed the protocol or had a role in
6 designing the protocol, I'm trying to understand
7 what beyond the statistical analysis plan that
8 included?

9 **A. You can include the writing an informed**
10 **consent form. Working with the various parties**
11 **that include the cardiologist, the reading center,**
12 **and so forth. That's the oversight part.**

13 Q. Other than what you mentioned so far, is
14 there anything else that you were involved in in
15 designing the clinical trial protocol for the SAGA
16 study?

17 ATTORNEY FELDSTEIN: Object to form.

18 **A. I would add the selection of the clinical**
19 **laboratory, the centralized clinical laboratory.**

20 Q. Anything else?

21 **A. I cannot think of it now.**

22 Q. Okay. You had mentioned the clinical
23 laboratory before, and I wanted to follow up.
24 What -- we talked about the clinical site. We
25 talked about the reading center.

1 So in contrast to those two parts of the
2 study, what is the clinical laboratory?

3 **A. It's a facility that analyzes blood.**

4 Q. Okay. So that's maybe to look to make
5 sure the patients are safe and doing well.

6 Is that fair?

7 ATTORNEY FELDSTEIN: Object to form.

8 **A. They're analyzing blood and providing the**
9 **results.**

10 Q. Okay. When the clinical laboratory
11 analyzes the blood, do they know whose blood
12 they're analyzing?

13 **A. They know it's a patient in our clinical**
14 **trials.**

15 Q. Is that -- the identity of that patient
16 masked as to the clinical laboratory?

17 **A. I'm not sure.**

18 Q. Now I have the same question as to the
19 reading center.

20 **A. Oh, with the -- the same question with**
21 **respect to -- the same thing. They know it's a**
22 **patient in our clinical trials.**

23 Q. Okay. But does the reading center, are
24 they masked as to the identity of the patient from
25 whom the image came?

1 ATTORNEY FELDSTEIN: Object to form.

2 Sorry. Just give me a second.

3 Go ahead.

4 **A. They may or may not be.**

5 Q. Okay. And what do you mean when you say

6 "they may or may not be"?

7 **A. It means it's not an important parameter.**

8 Q. Okay. So in the SAGA study, masking
9 patient identity was not an important parameter.

10 Is that correct?

11 ATTORNEY FELDSTEIN: Object to form.

12 **A. I want to make sure you use the word**
13 **"masking" correctly, considering that our document**
14 **may have the word "masked." That's using a**
15 **different meaning than identity of a patient.**

16 Q. Go ahead and explain what you mean.

17 **A. In a clinical trial, masked or blinded is**
18 **not with respect to identity. It's with respect to**
19 **what treatment the patient is receiving.**

20 Q. Okay. So I think I understand what you're
21 saying now.

22 So in the SAGA trial, the independent
23 reading center was masked as to what treatment each
24 patient was receiving. Correct?

25 **A. Wait. First you used -- it's called a**

1 **centralized reading center.**

2 Q. Okay.

3 **A. So the centralized reading center may or**
4 **may not -- they're masked to the treatment**
5 **allocation of the patient, yes.**

6 Q. Okay. But they may or may not be masked
7 as to the identity of the patient?

8 **A. That's correct.**

9 Q. Okay. So it may have been possible for
10 the centralized reading center, when they're
11 looking at an image at year 2, for example, to
12 compare to the image of the same patient at study
13 entry. Is that correct?

14 ATTORNEY FELDSTEIN: Object. Object to
15 form.

16 **A. Could you repeat the question in a more**
17 **clear fashion?**

18 Q. So in a scenario where the identity of the
19 patient is not masked but the treatment group in
20 which the patient is is masked, the central reading
21 center has the ability to compare the images of the
22 retina at year 2 and compare them to the images of
23 the retina when the patient entered the study.

24 Correct?

25 ATTORNEY FELDSTEIN: Object. Object to

1 form.

2 **A. This is not in my declaration. So the --**
3 **I do not know exactly how the reading center would**
4 **be performing those analyses.**

5 Q. Okay. So as you sit here today, you can't
6 tell us that in the SAGA trial, the central reading
7 center -- one way or the other -- whether or not
8 they were comparing the images at year 2, for
9 example, to the images for the same patient at
10 study entrance? You just don't know. Is that
11 correct?

12 **A. Wait. I don't understand the question.**
13 **So the -- unless -- unless you -- it sound --**
14 **because it sounded different than the first one**
15 **you've been asking.**

16 **Are you saying that they are unable to**
17 **identify that it's the same patient?**

18 Q. Right. So my -- that's my question.
19 That's what I'm trying to get at.

20 **A. They know it's the same patient, yes.**

21 Q. Okay. So they know it's the same patient.
22 They have -- in a two-year period -- let me just
23 withdraw and start over.

24 In a two-year period, how many images
25 would there be involved?

1 **A. Several.**

2 Q. Maybe there's five images. Is that --

3 **A. There were five time points, I believe.**

4 Q. Okay. So when they're at the fifth time
5 point, the central reading center has at that point
6 five images for an individual patient.

7 Am I correct so far?

8 **A. Mm-hmm. Yes.**

9 Q. Okay. And so when they're grading image
10 number 5, they can look at image number 1 if they
11 want to?

12 ATTORNEY FELDSTEIN: Object to form.

13 **A. It would depend on the -- what the reading**
14 **center's usual practice is.**

15 Q. Okay. Sitting here right now, do you know
16 what the reading center's usual practice --

17 **A. I do not know.**

18 Q. -- was?

19 ATTORNEY FELDSTEIN: You have to let him
20 finish the question, and you have to give me a
21 second to object. Okay?

22 **A. Could you ask the question?**

23 Q. Sitting here today, you don't know what
24 the centralized reading center's usual practice was
25 in respect to reviewing earlier images from the

1 same patient while making a grade?

2 **A. That's correct.**

3 Q. Okay. In the SAGA study, would only a
4 single eye from an individual patient be looked at,
5 or both eyes?

6 **A. We looked at both eyes.**

7 Q. And would you keep records from each eye
8 for each patient?

9 **A. It would be -- the central reading center**
10 **takes care of that.**

11 Q. I just want to make sure I understand.

12 At all five of the time points, the
13 central reading center would have an image for each
14 eye for each patient. Is that correct?

15 **A. They would receive the images that are**
16 **being sent to them.**

17 Q. Okay. And, in general, those images would
18 include an image for each for each patient. Is
19 that fair?

20 **A. In general, the protocol indicates to take**
21 **a picture of both eyes.**

22 Q. Okay. In the protocol, do you then
23 combine together the data from the two eyes of the
24 patient at a given time point?

25 **A. What do you mean by "combine"?**

1 Q. Let me ask the question differently and
2 see if that's more clear.

3 In the SAGA study, was the evaluation for
4 each patient specific to individual eyes?

5 ATTORNEY FELDSTEIN: Object to form.

6 **A. I still don't -- I'm still unclear about**
7 **the meaning of the question.**

8 Q. Well, I'm trying to understand, because
9 you have images from both eyes, and then -- well,
10 let me -- let me back up a little bit.

11 So from those images, you're deriving some
12 measure. Correct? There's something that you're
13 measuring, that the reading center is measuring?

14 **A. That's the grade, yes.**

15 Q. Okay. So you have a grade for each eye.
16 Do you combine the grades in the SAGA study from
17 the two eyes for that individual?

18 **A. I do not know what "combine" means.**

19 Q. Well, is there any meaning of the word
20 "combine" that you understand in which the central
21 reading center would be combining the grade from
22 the individual eyes in the SAGA study?

23 **A. Not really.**

24 Q. Okay.

25 Okay. So you said the centralized reading

1 center is not masked as to the identity of the
2 patient, but is masked as to their treatment
3 status. Correct?

4 **A. That's not what I said.**

5 Q. Okay. Go ahead and fix it.

6 ATTORNEY FELDSTEIN: Object to form.

7 **A. What I said is that they may or may not be**
8 **masked --**

9 Q. Okay. Okay.

10 **A. -- to the identity.**

11 Q. Okay. Is the same true of the clinical
12 laboratory?

13 **A. It's a -- I believe it's the same.**

14 Q. Okay. Is the same true as to Alkeus?

15 **A. I believe it's the same.**

16 Q. Okay. So for all of the people that are
17 evaluating the data from a patient, they know which
18 patient -- or they may know which patient they're
19 dealing with; they just don't know whether that
20 patient is receiving treatment or placebo. Is that
21 fair?

22 **A. Everyone who deals with patient never**
23 **knows whether a patient is receiving treatment or**
24 **not receiving treatment.**

25 Q. Okay. But in the SAGA study, they might

1 know different pieces of data are trackable to a
2 single individual patient?

3 ATTORNEY FELDSTEIN: Object to form.

4 **A. There's a patient ID that shows you that**
5 **it is the same person.**

6 Q. Okay. We've been going about an hour.

7 **A. I'm good.**

8 Q. Do you want to keep going? Okay.

9 So we talked a little bit about your role
10 at Alkeus. Okay? Take a look at paragraph 13 of
11 your declaration.

12 So you've had a 14-year tenure at Alkeus.
13 Is that correct?

14 **A. A little over 14 years now. Close to 15.**

15 Q. Okay. So it says here that you led the
16 development of the ALK-001 for Stargardt disease
17 and age-related macular degeneration.

18 Do you see that?

19 **A. Yes, I do.**

20 Q. Okay. Then you say ALK-001 is a
21 formulation C20-D3-Vitamin A, more specifically
22 C20 deuterated retinyl acetate, also known as
23 gildeuretinol acetate.

24 Do you see that?

25 **A. I do.**

1 Q. When you wrote here ALK-001 is a
2 formulation of C20-D3-Vitamin A, what did you mean
3 by saying it's a formulation of C20-D3-Vitamin A?

4 **A. It means that it's a pill.**

5 Q. Okay. Do you know what the formulation of
6 the pill that was used in the SAGA study is?

7 **A. I would know it, yes.**

8 Q. Okay.

9 **A. In -- probably in vague terms. It's not**
10 **part of my declaration.**

11 Q. Well, I mean, your declaration has
12 testified that you led the development of ALK-001
13 and that ALK-001 is a formulation.

14 I'm not going to -- I'm not trying to
15 embarrass you about chemical details, but just at a
16 high level, what is the formulation of ALK-001 that
17 you're referring to in paragraph 13 of your
18 declaration?

19 **A. It's essentially a pill containing the**
20 **C20-D3-Vitamin A.**

21 Q. So it's a pretty conventional pill?

22 ATTORNEY FELDSTEIN: Object to form.

23 **A. I do not know what a conventional pill is.**
24 **But for a patient looking at it, it would look like**
25 **a conventional pill.**

1 Q. Okay. But do you yourself have personal
2 knowledge as to what the formulation of ALK-001 was
3 used in the SAGA study?

4 A. I have some knowledge of it.

5 Q. Is that formulation the same formulation
6 that was used in the TEASE-1 study?

7 A. That's correct. That would be the same
8 formulation.

9 Q. Is that the same formulation that was used
10 in the TEASE-2 study?

11 A. Yes. We have only used one formulation
12 from the beginning.

13 Q. Okay. So for all of the studies, the
14 formulation in the TEASE-1 through 4 and the SAGA
15 study, it's the same formulation of ALK-001.
16 Correct?

17 A. Yes.

18 Q. Okay. And you said you had some knowledge
19 as to what that formulation is.

20 Can you go ahead and tell me what it is
21 that you understand the formulation of ALK-001 is?

22 ATTORNEY FELDSTEIN: I'm going to stop, as
23 the formulation details are beyond the scope.

24 If you want to continue asking that, we're going
25 to have to stop the deposition.

1 ATTORNEY MILLS: So, counsel, it's -- you
2 can register your objection. It's not beyond
3 the scope. He's testified that he led the
4 development of ALK-001 and that ALK-001 is a
5 formulation. So I'm asking him what formulation
6 he led the development of.

7 ATTORNEY FELDSTEIN: Okay. And I'm
8 telling you we're going to stop the deposition
9 if you are going to continue asking.

10 ATTORNEY MILLS: So you don't get to stop
11 the deposition. It's not --

12 ATTORNEY FELDSTEIN: Okay. We'll stop the
13 deposition and we'll contact the board. I'm not
14 going to allow you to delve into his trade
15 secret information.

16 ATTORNEY MILLS: Are you instructing him
17 not to answer the question?

18 ATTORNEY FELDSTEIN: I'm telling you that
19 if you're asking the question, we're stopping
20 the deposition now. And if you're going to
21 press the question and we have to stop the
22 deposition now, we'll have to contact the board.

23 ATTORNEY MILLS: So you don't get to stop
24 the deposition. You don't get to threaten to
25 try and control my questions. You can instruct

1 him not to answer the question or you can not
2 instruct him not to answer the question.

3 ATTORNEY FELDSTEIN: What I'm going to do,
4 counsel, is if you press the question or require
5 the witness to answer, I'm going to stop the
6 deposition and we'll have to contact the board
7 for guidance.

8 ATTORNEY MILLS: Are you instructing him
9 not to answer the question?

10 ATTORNEY FELDSTEIN: Is the question still
11 on the table?

12 ATTORNEY MILLS: Are you instructing him
13 not to answer the question?

14 ATTORNEY FELDSTEIN: I've been clear. If
15 you're pressing the question, counsel, we're
16 going to contact the board and we'll get the
17 board's guidance.

18 I'm not telling Dr. Saad anything right
19 now. I'm telling you that if you press the
20 question or require an answer to his trade
21 secret formulation information, we're going to
22 contact the board for guidance.

23 Q. Are you refusing to answer the question?

24 ATTORNEY FELDSTEIN: Doctor, we're
25 stopping this deposition. We're not answering

1 any further questions.

2 Unless you withdraw the question, the
3 deposition is stopped until we get guidance from
4 the board.

5 ATTORNEY MILLS: So that's not how this
6 works.

7 ATTORNEY FELDSTEIN: Okay. It's how it's
8 working now. I'm not going to let you delve
9 into his trade secret information. If you want
10 to keep the question on the table, you're going
11 to have to hold it and wait until we get
12 guidance from the board.

13 ATTORNEY MILLS: So if you want to
14 instruct him not to answer the question, you can
15 instruct him not to answer the question.

16 ATTORNEY FELDSTEIN: I'm not doing that,
17 counsel. I'm telling that you can keep the
18 question on the table, but he's not answering
19 until we get guidance from the board.

20 BY ATTORNEY MILLS:

21 Q. Are you following counsel's instruction?

22 **A. I am following counsel's instruction.**

23 Q. Is it correct that you led the development
24 of the formulation of ALK-001 that was used in the
25 TEASE and SAGA studies?

1 **A. I led the development of ALK-001 for the**
2 **Stargardt disease and age-related macular**
3 **degeneration.**

4 Q. What was your role in leading the
5 development of the formulation of ALK-001 used in
6 the SAGA and TEASE studies?

7 **A. I did not say that I led the formulation.**
8 **I said I led the development of ALK-001.**

9 Q. And is ALK-001 a formulation or is it the
10 active ingredient?

11 **A. ALK-001 is a pill. So I think maybe**
12 **you're reading too much into the word**
13 **"formulation." It's a pill containing**
14 **C20-D3-Vitamin A.**

15 Q. Okay. And what is the amount of the
16 C20-D3-vitamin A in the ALK-001 pill?

17 **A. Let me check my exhibit here.**
18 **It's either 14 or 24 milligrams as shown**
19 **in paragraph 19.**

20 Q. Okay. So there's two different dosages of
21 ALK-001?

22 **A. The ones that are listed in my declaration**
23 **says 14 and 24 milligrams.**

24 Q. Okay. And in which studies was the
25 14-milligram dose used?

1 **A. The 14-milligram dose was used in -- in**
2 **all of the TEASE and the SAGA trial.**

3 Q. Okay. In all four TEASE studies and in
4 the SAGA trial, the 14-milligram dose was used.
5 Correct?

6 **A. Yes.**

7 Q. In which trials was 24-milligram dose
8 used?

9 **A. The 24-milligram dose was used in the**
10 **TEASE-1 clinical trial.**

11 Q. Was the 24-milligram dose used in any
12 other of the trials?

13 **A. I do not believe so.**

14 Q. Other than 14 milligrams and 24
15 milligrams, was there any other dose that was
16 administered in any of the five trials discussed in
17 your declaration?

18 **A. I believe so, yes.**

19 Q. And what doses were used?

20 **A. These doses have not been disclosed and**
21 **they're not part of my declaration.**

22 ATTORNEY FELDSTEIN: I think you two may
23 be miscommunicating.

24 Q. So I'm asking about the five trials
25 discussed in your declaration.

1 Do you understand that?

2 **A. Yes.**

3 Q. Okay. So in the five trials that are
4 discussed in your declaration, have any doses of
5 ALK-001 been administered other than the
6 14-milligram and the 24-milligram dose?

7 **A. Sorry. My declaration covers only two of**
8 **the -- sorry -- three clinical trials: TEASE-1,**
9 **TEASE-3, and SAGA. It does not cover the five**
10 **clinical trials. It covers three of them.**

11 Q. Can you take a look at paragraph 9 of your
12 declaration.

13 **A. Yes.**

14 Q. Paragraph 9 of your declaration discusses
15 four TEASE trials. Correct?

16 **A. Yes, in general terms.**

17 Q. So in any of the four TEASE trials
18 discussed in paragraph 9 of your declaration, is
19 there a dose of ALK-001 different than 14
20 milligrams or 24 milligrams used?

21 **A. Yes.**

22 Q. In which trial?

23 **A. In the TEASE-4 clinical trial.**

24 Q. Other than the TEASE-4 clinical trial, are
25 there any other doses that are -- any other trials

1 in which a dose different than 14 or 24 milligrams
2 is used?

3 **A. No.**

4 Q. In the SAGA trial?

5 **A. The SAGA trial used the 14-milligram dose.**

6 Q. Okay.

7 **A. The other dose, by the way, would be a**
8 **placebo, which is 0 milligram.**

9 Q. And I want to make sure I understand.

10 When you said that there was a different
11 dose used in the TEASE-4 trial, are you saying that
12 that was a placebo --

13 **A. No.**

14 Q. -- dose?

15 Okay.

16 **A. Inactive.**

17 ATTORNEY FELDSTEIN: Let him finish the
18 question. Let him fully ask the question before
19 you answer.

20 Q. Okay. So I'm just trying to make sure the
21 record is clear.

22 So in the TEASE-4 trial, there was an
23 ALK-001 dose different than 14 or 24 milligrams and
24 also not placebo. Correct?

25 **A. That's correct.**

1 Q. Okay. The -- while we're on paragraph 9,
2 the TEASE-4 trial is an ongoing study. Correct?

3 A. Yes.

4 Q. That's an extension study?

5 A. It's an open-label extension study.

6 Q. Open-label means that the participants
7 know what treatment they're receiving. Correct?

8 A. It means that the patient knows that they
9 are receiving ALK-001.

10 Q. So they may or may not know what dose
11 they're receiving?

12 A. They do not know what dose they're
13 receiving. They're unlikely to know.

14 Q. Do the study personnel, do they know what
15 dose the patient's receiving?

16 A. I'm not sure.

17 Q. Okay. And when it says "extension study,"
18 what does that mean?

19 A. It means it's a longer-term study that
20 several of the patients that are in TEASE-1, -2,
21 or -3 can get on, but brand-new patients can also
22 be involved.

23 Q. Okay. And there's an NCT number next to
24 your bullet point in paragraph 9 regarding TEASE-4.

25 Do you see that?

1 **A. Yes.**

2 Q. Is the NCT number that's on that line the
3 NCT number for all four TEASE studies?

4 **A. Could you repeat the question?**

5 Q. So do you see the NCT number that ends
6 with 660 in paragraph 9?

7 **A. Mm-hmm. Yes.**

8 Q. That's the NCT number for the TEASE-1
9 trial?

10 **A. Yes. And TEASE-2 and TEASE-3.**

11 Q. Okay. So TEASE-1 through 3 all share that
12 660 NCT number. Correct?

13 **A. Yes.**

14 Q. And TEASE-4 has its own NCT number?

15 **A. Yes.**

16 Q. Do you recall what that is?

17 **A. No.**

18 Q. Okay. TEASE-3 is also an ongoing open
19 label study. Correct?

20 **A. Yes.**

21 Q. Some of the literature you submitted
22 discussed the number of people enrolled in the
23 TEASE trial. I saw the number six. What I didn't
24 understand is, because that's a sibling trial, so I
25 didn't know if an enrollment of six meant three

1 younger siblings and three older siblings or
2 whether it meant six younger siblings.

3 Can you answer that question for me?

4 ATTORNEY FELDSTEIN: Object to form.

5 **A. I -- I do not know what document you're**
6 **talking about.**

7 Q. Okay.

8 Well, let's look at paragraph 33 of your
9 declaration.

10 **A. Mm-hmm.**

11 Q. It says, "The first three participants are
12 three patients (aged 13, 17, and 18)."

13 Do you see that?

14 **A. I do see that.**

15 Q. So is that an enrollment of three or an
16 enrollment of six?

17 ATTORNEY FELDSTEIN: Object to form.

18 **A. The specific sentence says, "The first**
19 **three participants are three patients (aged 13, 17,**
20 **and 18)."**

21 Q. Are you familiar with the clinical trial
22 design for the TEASE-3 study?

23 **A. I am familiar with the TEASE-3 trial**
24 **design, yes.**

25 Q. What is the total enrollment in the

1 clinical trial protocol for the TEASE-3 study?

2 ATTORNEY FELDSTEIN: Object to form.

3 **A. The protocol document -- document**
4 **indicates an enrollment of up to 10 patients.**

5 Q. So when it says up to 10 patients, is that
6 10 younger siblings or is that five younger
7 siblings and five older siblings?

8 ATTORNEY FELDSTEIN: Object to form.

9 **A. The -- the patient that is enrolled in**
10 **TEASE-3 is not -- if you read paragraph 32, it**
11 **evaluates this progression in the early stage**
12 **patients in comparison to their symptomatic sibling**
13 **when treated at the same age. The siblings are not**
14 **themselves in the TEASE-3 trial.**

15 Q. Okay. So I think that answers my
16 question.

17 In the TEASE-3 trial, is there also a
18 centralized reading center?

19 **A. The study is ongoing, so I'm not sure.**

20 Q. In the clinical trial protocol for the
21 TEASE-3 study, does it discuss a centralized
22 reading center?

23 **A. I do not believe so. The centralized**
24 **reading center can be placed at the end of this**
25 **trial or during the trial or at the beginning. Up**

1 **to the sponsor's discretion.**

2 Q. Okay. So going back to the SAGA trial,
3 then, was the centralized reading center in place
4 throughout the entirety of the SAGA trial?

5 **A. No.**

6 Q. At what point in the SAGA trial was the
7 centralized reading center employed?

8 **A. At the time that the images were ready for**
9 **analysis.**

10 Q. Are you testifying that in the SAGA study,
11 all of the images were collected and then a
12 centralized reading center was engaged to review
13 the entire collection of images?

14 **A. I do not recall the exact date at which**
15 **the reading center was retained.**

16 Q. To the best of your knowledge, was the
17 centralized reading center in the SAGA trial
18 retained when there were still additional images
19 that needed to be obtained?

20 ATTORNEY FELDSTEIN: Object to form.

21 **A. I do not recall.**

22 Q. In the TEASE-3 study, you don't know one
23 way or the other whether a centralized reading
24 center has been retained for that study --

25 **A. That is correct.**

1 Q. -- at this point?

2 ATTORNEY FELDSTEIN: You've still got to
3 let him finish the question. Okay?

4 Q. In the TEASE-3 study, do you know what is
5 being evaluated in the images of the patients?

6 ATTORNEY FELDSTEIN: Object to form.

7 **A. In the TEASE-3 study, we monitor disease**
8 **development using fundus autofluorescence and**
9 **optical coherence tomography as shown in**
10 **paragraph 35.**

11 Q. Would you spell those two for the court
12 reporter.

13 **A. Optical c-o-h-e-r-e-n-c-e**
14 **t-o-m-o-g-r-a-p-h-y, and f-u-n-d-u-s**
15 **a-u-t-o-f-l-u-o-r-e-s-c-e-n-c-e. FAF.**

16 Q. In the TEASE-3 study, is best visual
17 acuity measured?

18 **A. We are measuring something called best**
19 **corrected visual acuity.**

20 Q. Okay. Is that -- that's abbreviated BCVA?

21 **A. It's abbreviated BCVA.**

22 Q. And in the TEASE-3 study, how is BCVA
23 measured in the study patients?

24 **A. It's measured in a standardized fashion on**
25 **how BCVA is measured.**

1 Q. And what is the name for that standardized
2 measurement of BCVA?

3 A. It's -- there's no specific name. It's
4 called collecting BCVA using the standardized
5 protocol.

6 Q. Do you know what ETDRS is?

7 A. Yes. It means early treatment diabetes
8 retinopathy study.

9 Q. So is there such a thing as ETDRS BCVA?

10 A. ETDRS BCVA is one of the ways of measuring
11 BCVA.

12 Q. Is that the way that BCVA is measured in
13 the TEASE-3 study?

14 A. I'm not sure.

15 Q. What is Snellen acuity?

16 A. Snellen acuity is another way of measuring
17 visual acuity.

18 Q. Do you agree that the siblings of the
19 patients in the TEASE-3 studies were evaluated
20 using Snellen acuity rather than ETDRS BCVA?

21 A. I'm not sure if it's in my declaration.
22 The -- the siblings who were not enrolled would
23 have been -- would have been -- their visual acuity
24 would have been measured whichever way the
25 physician can decide, which can include ETDRS or

1 **Snellen, for example.**

2 Q. Okay. So in this study, the TEASE-3
3 study, you have a sibling that enters the study at
4 a particular age. Correct?

5 ATTORNEY FELDSTEIN: Object to form.

6 **A. I mean, every patient enter a trial at any**
7 **particular age.**

8 Q. And they're at least two years younger
9 than the sibling to whom they're being compared.
10 Correct?

11 **A. I think the age is not -- with respect to**
12 **the sibling is -- can vary.**

13 Q. Okay. But they're younger than the
14 sibling to whom they're being compared. Correct?

15 **A. I'm not sure. For these three patients, I**
16 **believe that they were younger. That's what it**
17 **says.**

18 Q. Okay. So when the siblings are being
19 measured, that is outside your study. Correct?

20 ATTORNEY FELDSTEIN: Object to form.

21 **A. When the siblings are measured, they --**
22 **they could be measured in a -- while enrolled in**
23 **one of our trials or they could be measured under**
24 **standard of care.**

25 Q. Okay. So the measurement that is used for

1 the siblings may vary, depending on who they happen
2 to be seeing when the data was collected. Is that
3 fair?

4 ATTORNEY FELDSTEIN: Object to form.

5 **A. Could you repeat the question?**

6 Q. The measurement that is used for the
7 siblings may vary, depending who they happen to be
8 seeing when the data was collected. Is that fair?

9 ATTORNEY FELDSTEIN: Object to form.

10 **A. I do not know what happens when -- when**
11 **specifically -- the patients who were not enrolled**
12 **would usually have a Snellen visual acuity taken.**

13 Q. Okay. And that's different than the
14 acronym that we were using?

15 **A. BCVA?**

16 Q. Yeah.

17 **A. Or ETDRS BCVA?**

18 **Not too different. Visual acuity is**
19 **inherently variable.**

20 Q. Okay.

21 **A. To give you an example, Snellen visual**
22 **acuity is what you take at your local optometrist.**
23 **So if you have glasses and you are satisfied with**
24 **them, they are acquired using Snellen.**

25 Q. Okay. Thank you. That's helpful.

1 We talked about in the SAGA study about
2 whether both eyes were measured. In the TEASE-3
3 study, do you know whether the protocol directs
4 that both eyes of the studies participants be
5 measured?

6 **A. Yes, I believe so.**

7 Q. In the TEASE-3 study protocol, is it
8 correct that the measurements from the two eyes of
9 the patient are combined?

10 ATTORNEY FELDSTEIN: Object to form.

11 **A. The study is ongoing. So the way that it**
12 **will be analyzed may be determined at the very end.**

13 Q. Is there no predetermined endpoint for the
14 TEASE-3 study?

15 **A. You can see them on -- in paragraph 35.**

16 Q. Okay. So where does paragraph 35 tell me
17 the predetermined endpoint for the TEASE-3 study?

18 **A. There's no one predetermined endpoint.**
19 **The study is an open-label trial.**

20 Q. Open-ended trial?

21 **A. Open-label. The study is an open-label**
22 **trial.**

23 Q. And why does that mean there isn't a
24 predetermined endpoint?

25 **A. Because the patients know what they are**

1 **taking.**

2 Q. Why does that prevent there from being a
3 predetermined study?

4 ATTORNEY FELDSTEIN: Object to form.

5 A. **It's not as important. You could set one**
6 **up, but it's not going to be as important as in a**
7 **randomized, double-masked, placebo-controlled**
8 **trial.**

9 Q. Why is it not as important?

10 A. **Because the -- again, the patients know**
11 **what they're taking.**

12 Q. Why does that make it not as important?

13 ATTORNEY FELDSTEIN: Object to form.

14 A. **The patient will know what they're taking.**

15 Q. Why does the patient knowing what they're
16 taking make it less important to have a
17 predetermined study endpoint?

18 ATTORNEY FELDSTEIN: Object to form.

19 A. **What we did was monitor using the multiple**
20 **endpoints. And so that's -- that's how it was**
21 **monitored, and that's how it would be analyzed.**

22 Q. My question is why does the patient
23 knowing what they're taking make it less important
24 to have a predetermined study endpoint?

25 ATTORNEY FELDSTEIN: Object to form.

1 **A. When you have a study that's open-label,**
2 **it is not a study that is going to be used for --**
3 **for what's called regulatory submission.**

4 Q. We were talking -- do you want to take a
5 break or keep going?

6 **A. Keep going.**

7 Q. We were talking about centralized reading
8 center with respect to the SAGA study and the
9 TEASE-3 study. In the SAGA study, you testified
10 that there was a centralized reading center that
11 was responsible for grading all of the images used
12 in the study. Correct?

13 **A. Yes.**

14 Q. In the TEASE-3 study, at this point you're
15 not certain that a centralized reading center has
16 been employed to review any of the images in the
17 study at this point. Is that correct?

18 **A. That's correct.**

19 Q. Okay. So now my question is about the
20 TEASE-1 study. Was a centralized reading center
21 employed for the images in the TEASE-1 study?

22 **A. Not at the time of the initial grading.**

23 Q. Okay. And when you say not at the time of
24 the initial grading, what do you mean by that?

25 **A. It means that the database was not**

1 **utilizing the central reading center.**

2 Q. And when you say the database, whose
3 database?

4 **A. The database that contains the data.**

5 Q. Is that an Alkeus database?

6 **A. It's always an Alkeus database. In SAGA**
7 **it's an Alkeus database, even using the centralized**
8 **reading center.**

9 Q. Okay. So for the TEASE-1 study, when
10 Alkeus received the data from the TEASE-1 trial, it
11 received grades from -- not from a centralized
12 reading center. Is that correct?

13 **A. No. We received the images, not the**
14 **grades.**

15 Q. Okay. So in the TEASE-1 study, the images
16 came directly from the clinical site to Alkeus. Is
17 that correct?

18 **A. That's correct.**

19 Q. Okay. Was the reading performed at the
20 clinical sites?

21 **A. The same way as in SAGA, some reading was**
22 **performed at the clinical site.**

23 Q. Was the grading performed at the clinical
24 sites in the TEASE-1 study?

25 **A. Not the grading that is in the database.**

1 Q. Okay.

2 A. Some grading may have been performed, and
3 some grading may not have been performed by all
4 sites.

5 Q. Okay. So the database for the TEASE-1
6 study, the grading that was performed there was
7 performed at Alkeus. Is that correct?

8 A. That's correct.

9 Q. Who at Alkeus performed the grading for
10 the TEASE-1 study?

11 A. I did, and one of my colleagues.

12 Q. And who was the colleague?

13 A. Her name is Gabrielle DeBartolomeo.

14 Q. What is Gabrielle's title at Alkeus?

15 A. Currently, she's a clinical trial lead.

16 Q. When the reading of the images in the
17 TEASE-1 study were performed, when was that reading
18 taking place?

19 A. I do not recall exactly.

20 Q. Can you recall what Gabrielle's title was
21 when she was performing the reading of the images
22 for the TEASE-1 study?

23 A. Yes. Gabrielle only had two titles, so
24 her title was clinical trial scientist.

25 Q. Do you know approximately when you hired

1 Gabrielle?

2 **A. I hired Gabrielle close to seven years**
3 **ago.**

4 Q. Around 2017 or 2018?

5 **A. Yes.**

6 Q. Were you personally involved in
7 Gabrielle's hiring?

8 **A. I was.**

9 Q. I'm not going to spend a lot of time on
10 this. I'll tell you what I'm interested in
11 knowing.

12 What were her qualifications for the job
13 when you were hiring her?

14 **A. Gabrielle was a graduate from Boston**
15 **College with a double major in economics and**
16 **biology, and a pre-med student.**

17 Q. Okay. So did she have a bachelor's of
18 science in biology?

19 **A. Probably. Either a Bachelor of Science or**
20 **Bachelor of Art. I don't know exactly the term.**

21 Q. Okay. She didn't have an advanced degree
22 in biology. Correct?

23 **A. Define "advanced."**

24 Q. Like postgraduate degree.

25 **A. What's a postgraduate degree?**

1 Q. After a bachelor's degree.

2 A. No, she did not have -- she had a bachelor
3 degree.

4 Q. Okay. And at the time that you hired her
5 in the 2017-2018 time frame, did she have prior
6 experience grading retinal images?

7 A. I do not believe so.

8 Q. And at that time -- this is -- maybe
9 sounds like a silly question, but she was not an
10 ophthalmologist. Correct?

11 A. She's not an ophthalmologist, that I know
12 of.

13 Q. So is it fair to say you provided
14 Gabrielle some sort of training as to how to grade
15 the images for the TEASE-1 study?

16 A. That's correct.

17 Q. What training did you provide to her?

18 A. The training involves essentially
19 delineating multiple images, verifying the
20 accuracy, and verifying the test-retest
21 variability.

22 THE REPORTER: The test variability?

23 THE WITNESS: Test-retest variability.

24 ATTORNEY FELDSTEIN: You said the test --

25 THE WITNESS: -- dash retest.

1 Q. Prior to your work at Alkeus, had you
2 graded retinal images?

3 A. No.

4 Q. Who trained you how to grade retinal
5 images?

6 A. I worked with Dr. Washington, the
7 cofounder of Alkeus.

8 Q. Was Dr. Washington involved in the grading
9 of images for the TEASE-1 study?

10 A. No.

11 Q. And then I'm -- just to clear it out, was
12 Dr. Washington involved in the grading of images
13 for any of the TEASE studies?

14 A. Not -- he's involved in the scientific
15 part. So not for, let's say, the database grading.
16 Will he be looking at an image, provide some
17 opinions? Yes. Will he be grading in a systematic
18 fashion over time? No.

19 Q. And that's true for which studies?

20 A. For all studies.

21 Q. Okay. So for all the studies, if you have
22 a question, or maybe if you and Gabrielle
23 disagreed, you'd have Dr. Washington look at it to
24 get his input?

25 A. Yeah. Absolutely.

1 Q. Okay. So is it correct that you also
2 graded images for the TEASE-2 study?

3 **A. The TEASE-2 study is ongoing.**

4 Q. So have you graded images for the TEASE-2
5 study?

6 ATTORNEY FELDSTEIN: I object as beyond
7 the scope of the declaration.

8 **A. It's beyond the scope. The study is**
9 **ongoing. There's no grading needed.**

10 Q. Okay. Have you graded images for the
11 TEASE-3 study?

12 **A. I did grade some images for the TEASE-3**
13 **study.**

14 Q. Did Gabrielle grade images for the TEASE-3
15 study?

16 **A. It's possible. The study is also ongoing,**
17 **so the results are interim at this point.**

18 Q. And just so I know whether to ask whether
19 you and Gabrielle graded images for TEASE-4, has
20 there been grading on TEASE-4 yet?

21 **A. I don't believe so.**

22 Q. Okay. For the SAGA study, did you grade
23 images for the SAGA study?

24 **A. I did.**

25 Q. Did Gabrielle grade images for the SAGA

1 study?

2 **A. I don't believe so.**

3 Q. Okay. So the results of the TEASE-1 study
4 which you discuss in your declaration, is it
5 correct that all of the grading for those results
6 was performed by you and Gabrielle with some input
7 from Dr. Washington?

8 **A. That's correct.**

9 ATTORNEY FELDSTEIN: Object to form.

10 **A. The -- the database, the results in the**
11 **database are the results from the grader of myself**
12 **and Gabrielle DeBartolomeo.**

13 Q. Okay. And I have to assume that there's a
14 cost advantage to doing the grading in-house as
15 opposed to the centralized reading center. Is that
16 fair?

17 ATTORNEY FELDSTEIN: Object to form.

18 **A. There -- doing it in-house allows you to**
19 **do it at your own pace; allows you to have**
20 **high-quality results, allows you to -- and has no**
21 **cost associated with it except that as of your own**
22 **employees' time.**

23 Q. And I know you have concerns about
24 confidentiality with the centralized reading
25 center. So instead of asking you about how much

1 the centralized reading center cost for SAGA, can
2 you just tell me in a ballpark fashion, for trials
3 of this nature, approximately how much does it cost
4 to use a centralized reading center?

5 ATTORNEY FELDSTEIN: Object to form and
6 beyond the scope of the declaration.

7 **A. I would not know exactly a number.**

8 Q. Can you give me your best estimate?

9 ATTORNEY FELDSTEIN: Object to form.
10 Beyond the scope of the declaration.

11 **A. I think it would depend on the reading**
12 **center you are trying to hire. Some reading**
13 **centers will give you a very low cost, and some**
14 **reading centers may give you a very high cost. I**
15 **would not be very familiar with those numbers.**

16 Q. Were you involved in selecting the reading
17 center for the SAGA study?

18 **A. I was -- I was partly involved with**
19 **respect to the scientific part of it, yes.**

20 Q. Is it a good reading center?

21 **A. I do not know exactly what "good" would**
22 **mean. Until you hire someone, you -- we thought**
23 **the reading center would be good -- a good one.**

24 Q. Is it fair to estimate that it would cost
25 upwards of \$5 million to employ a reading center

1 for a study with a patient size of 300?

2 ATTORNEY FELDSTEIN: Object to form.

3 Beyond the scope of the declaration.

4 **A. I would say it's a -- I would say it's a**
5 **very expensive price.**

6 Q. The price I named is too expensive?

7 ATTORNEY FELDSTEIN: Object.

8 **A. I think it's a very expensive price, yes.**

9 Q. The price I supplied, you think is too
10 expensive?

11 **A. Yes.**

12 Q. Okay. So what's a better estimate of a
13 cost of a reading center?

14 **A. Again, I don't have a good estimate, but I**
15 **know what a number that is too high would look**
16 **like.**

17 Q. Okay. So 5 million is too high?

18 **A. Yes.**

19 Q. Is 1 million too high?

20 **A. 1 million would be borderline too high.**

21 Q. Okay. Whether the price is too high or
22 not, does that depend on the company that's
23 employing the reading center?

24 ATTORNEY FELDSTEIN: Object to form.

25 Beyond the scope of the declaration.

1 **A. I think that's kind of what I said.**

2 **Sorry. The company -- what do you mean by**
3 **"company"?**

4 Q. Well, what I mean is, are you saying it
5 would be too high for you because of your
6 particular company, or are you saying no one is
7 going to pay that much for a reading center?

8 ATTORNEY FELDSTEIN: Object to form.
9 Beyond the scope of the declaration.

10 **A. I do not know the answer to that question.**

11 Q. Okay. So you mentioned -- and are you
12 wanting a break now or are you --

13 **A. No.**

14 THE REPORTER: Can we -- can we --

15 ATTORNEY MILLS: The court reporter wants
16 a break. Okay.

17 Let's go off the record.

18 (Recess taken from 10:52 a.m.

19 to 10:59 a.m.)

20 BY ATTORNEY FELDSTEIN:

21 Q. Please take a look at paragraph 42 of your
22 declaration.

23 **A. Yes, paragraph 42.**

24 Q. In regard to the SAGA study, you say, "A
25 total of 198 patients were enrolled in the study."

1 Do you see that?

2 **A. I do see that.**

3 Q. So when I look at the NCT listing for the
4 SAGA study, which you also cite in your
5 declaration, it says that the estimated enrollment
6 is 300.

7 **A. Mm-hmm.**

8 Q. Do you recall that?

9 **A. I recall that.**

10 Q. So can you help me understand the
11 discrepancy in paragraph 42 that says less than 200
12 patients were enrolled but the estimated enrollment
13 was 300?

14 ATTORNEY FELDSTEIN: Object to form.

15 **A. We enrolled -- we stopped the enrollment**
16 **after approximately 200 patients were screened.**
17 **The enrollment period was during COVID.**

18 Q. Okay. So 200 patients were screened
19 total, and of those 200 patients, a certain number
20 of those were randomized to ALK-001 treatment of an
21 as-yet-undisclosed formulation. Correct?

22 ATTORNEY FELDSTEIN: Object to form.

23 **A. Could you repeat that -- a clearer**
24 **question?**

25 Q. Yeah.

1 So out of the 200 patients that were
2 screened, some percentage of those were given
3 ALK-001 treatment. Correct?

4 **A. It was a 2:1 randomization mentioned in**
5 **42.**

6 Q. Okay. In what favor?

7 **A. Two -- two for gildeuretinol 14**
8 **milligrams, and one for placebo.**

9 Q. Okay.

10 **A. So out of 198, that's probably 133**
11 **receiving gildeuretinol and 66 receiving placebo.**

12 Q. Okay. And the 100 and -- approximately
13 133, they're all receiving the 14-milligram dose.
14 Correct?

15 **A. That's correct.**

16 Q. And all of those 133 are receiving ALK-001
17 in the formulation that you don't want to disclose
18 to me during the deposition. Right?

19 ATTORNEY FELDSTEIN: Object to form.
20 Misstates the record.

21 **A. Well, everyone has -- and as discussed,**
22 **there's only one type of pill that we have used for**
23 **all of our clinical trials.**

24 Q. Okay. And I do want to ask, you've been
25 using the term "pill"?

1 **A. Mm-hmm.**

2 Q. In your declaration, I think it calls it a
3 capsule. Can you tell us whether it's a pill or a
4 capsule?

5 **A. Well, a capsule is a sort of pill.**

6 Q. Okay. So is it correct that in particular
7 it's a capsule?

8 **A. It has the shape of a capsule, yes.**

9 Q. Is it like a gel capsule that has things
10 filled into it, or is it a -- I'm just trying to
11 understand the terminology difference.

12 So when I take a Tylenol, it's, you know,
13 an elongated pill. Is that what you're telling me?
14 Or is it like a Benadryl where there's a --

15 **A. I'm not very familiar --**

16 ATTORNEY FELDSTEIN: Just a second. Just
17 a second.

18 Are you done with the question?

19 Q. Well, I guess let me withdraw that
20 question and try and ask a more clear question.

21 So when you use the word "capsule," what
22 do you mean by that?

23 **A. I mean a standardized gelatin capsule.**

24 Q. Okay. So does that mean that there's a
25 gelatin enclosure into which materials are placed?

1 **A. It's a gelatin cap that contains**
2 **ingredients.**

3 Q. So it's different than like a pressed
4 tablet. Is that right?

5 ATTORNEY FELDSTEIN: Object to form.

6 **A. I do not know what "different" means. It**
7 **doesn't look the same -- it doesn't look identical**
8 **as a pressed tablet.**

9 Q. Okay. Great.

10 And then with respect to the SAGA study,
11 so the patients that were enrolled in the study,
12 who makes that selection as to which patients are
13 enrolled in the study?

14 **A. The physician enrolls their own patients.**

15 Q. Okay. In the NCT listing that you cited
16 in your declaration --

17 **A. Are you talking about SAGA?**

18 Q. Yes, for SAGA.

19 So under "Locations," it lists one
20 location.

21 **A. Mm-hmm.**

22 ATTORNEY FELDSTEIN: He doesn't have a
23 copy of the document, counsel.

24 Q. Oh, okay.

25 You don't have it?

1 **A. I don't have any copies.**

2 Q. Do you want to see that document?

3 **A. It depends on your question. I will need**
4 **to see it.**

5 Q. Yeah. I'll ask the question, and then if
6 you want the document, I can give it to you.

7 So it says one location, Somerville,
8 Massachusetts, United States, and my question is
9 earlier you told me that there were multiple
10 clinical locations. So I'm just trying to
11 understand how to reconcile the single location NCT
12 listing with your testimony earlier that there were
13 multiple clinical sites.

14 ATTORNEY FELDSTEIN: Object to form.

15 **A. And what is the question?**

16 Q. So the NCT says there's one location in
17 Somerville. You said there's many locations.

18 So how can I reconcile those two things?

19 ATTORNEY FELDSTEIN: Object to form.

20 **A. There were multiple clinical trial sites**
21 **enrolling in the study.**

22 Q. So is Somerville just one example of
23 those?

24 **A. Can you show me the exhibit?**

25 Q. Sure.

1 So this is Exhibit 2099. I was looking on
2 page 3. Under "Contacts and Locations," it says
3 the study has one location.

4 **A. Yes. So it's listed as a coordinating**
5 **center, not as a clinical site.**

6 Q. So this NCT document does not provide a
7 list of the clinical sites. Correct?

8 **A. It does not list individual sites.**

9 Q. And I think your NCT for the TEASE study
10 does provide a list of clinical sites. Is that
11 correct?

12 ATTORNEY FELDSTEIN: Object to form.

13 **A. If you show it to me.**

14 **Yes, I believe that it does.**

15 Q. You can keep that in case you need it.

16 So this is Exhibit 2098.

17 ATTORNEY FELDSTEIN: It's in his
18 declaration.

19 **A. Yes. So it's a list of sites provided in**
20 **NCT of the TEASE trials.**

21 Q. Okay. And in the particular version that
22 you all submitted, it says the study has eight
23 locations.

24 Do you see that?

25 **A. I see that.**

1 Q. It's on page 4.

2 Do you see that?

3 A. I see that it says TEASE has eight
4 locations, yes.

5 Q. Okay. And there's a -- on the website,
6 presumably, we would have had to scroll down to see
7 the other seven because there's just one listed
8 here. Do you agree?

9 A. I do not know. I only see one listed
10 here.

11 Q. And the one that's listed here is UCLA?

12 A. It says University -- yeah, it says UCLA.

13 Q. Do you know the other seven locations that
14 are listed in the NCT document?

15 ATTORNEY FELDSTEIN: Object to form.

16 A. What do you want to know?

17 Q. Do you know what they are?

18 A. I need to recall them, but I -- in broad
19 strokes, I have an idea of what these sites are.

20 Q. Can you tell us any of the other seven
21 sites for the TEASE study that are provided in
22 this -- the online version of the TEASE -- of the
23 NCT document for the TEASE study?

24 A. You want one more?

25 Q. Let's do that.

1 **A. The Florida location would be in**
2 **Gainsville location.**

3 Q. Okay. Any others that you know?

4 **A. The Miami location. The New York.**
5 **Wisconsin. Utah.**

6 **Is that seven already or eight?**

7 Q. I think that's six.

8 **A. And Baltimore.**

9 Q. So I think there's one more, maybe.

10 So you have UCLA, Gainsville, Miami, New
11 York, Wisconsin, Utah, Baltimore.

12 **A. I do not know the eighth. The eighth one**
13 **is probably the coordinating center again.**

14 Q. Okay. But this is for the TEASE study?

15 **A. That's correct.**

16 Q. So are you saying there's a recording
17 center for the --

18 **A. Coordinating center.**

19 Q. -- for the TEASE study?

20 **A. Yeah.**

21 Q. So these eight locations, are they
22 locations for all of the TEASE studies?

23 **A. I do not believe so.**

24 Q. So, specifically, these are eight
25 locations for the TEASE-1 study. Is that correct?

1 **A. I believe the locations that I've given**
2 **you were the locations of the TEASE-1 trial.**

3 Q. The TEASE-3 study was not performed in any
4 locations. Correct?

5 **A. I do not know of -- any site that performs**
6 **TEASE can perform any of the TEASE studies. So**
7 **even all these eight locations and others, if you**
8 **can perform TEASE-1, you can perform 1, 2, 3, or 4.**

9 Q. Okay. And in the case of the TEASE-3
10 study, there's a total of six patients enrolled.
11 Correct?

12 **A. I do not know the exact number. Is it**
13 **mentioned in one of our exhibits?**

14 Q. I'm not sure. I'll look and we can check
15 later.

16 Okay. So these study locations in the NCT
17 listing for the TEASE-1 trial don't tell us whether
18 or not those are study locations for the SAGA
19 trial. Correct?

20 **A. There are different records. So in TEASE**
21 **you will have a potential list of sites. In SAGA**
22 **you'll have a potential list of sites. And these**
23 **sites are not always provided in the NCT.**

24 Q. Okay. And in the SAGA NCT, they were not
25 provided?

1 **A. That's correct.**

2 Q. I think you told me how many there were,
3 though?

4 **A. Between 20 and 25.**

5 Q. So you would agree, then, just based on
6 the number that there are clinical sites in the
7 SAGA study that were not in any of the TEASE
8 studies. Is that correct?

9 **A. It's very possible, yes.**

10 Q. Because in one there's eight, and in the
11 other there's 20 to 25. Right?

12 **A. Mm-hmm.**

13 Q. So there would have to be clinical sites
14 for SAGA that are not in TEASE. Do you agree?

15 **A. You have a degree in mathematics.**

16 Q. Right. Yeah.

17 Okay. So in the TEASE studies, the
18 clinicians selected which patients to enroll in the
19 study. Is that correct?

20 **A. Repeat that again.**

21 Q. The clinicians at the clinical site
22 decided which patients to enroll in the study.
23 Correct?

24 **A. The physician has that responsibility.**

25 Q. Does Alkeus have a veto power? If they

1 receive information from the clinician, can they
2 say no?

3 ATTORNEY FELDSTEIN: Object to form.

4 **A. I think, you know, there's a -- if a**
5 **patient is not going to meet eligibility criteria,**
6 **then our responsibility of oversight would lead us**
7 **to let them know that they should not enroll the**
8 **patient.**

9 Q. To the best of your knowledge, in your
10 role overseeing the TEASE studies, did Alkeus ever
11 reject any of the patients who were sent for
12 enrollment by the clinical site?

13 ATTORNEY FELDSTEIN: Object to form.

14 **A. I -- I do not recall.**

15 Q. Now, the same question for the SAGA trial.

16 ATTORNEY FELDSTEIN: Object to form.

17 **A. I do not recall.**

18 Q. Okay. So now my question is once the
19 patients are enrolled in the study, and let's start
20 first asking about TEASE-1.

21 So what is the process for randomizing the
22 patient between the placebo and the treatment arm?

23 **A. The physicians follow a randomization**
24 **list.**

25 Q. Okay. So it's the physicians at the

1 clinical site that make the randomization?

2 **A. No, they have a list. Think of it as a**
3 **list of envelopes where you pick a random envelope**
4 **and it tells you the number that -- of the**
5 **medication ID that they need to allocate to that**
6 **particular patient.**

7 Q. Okay. And is it physically an envelope or
8 is it a different --

9 **A. No, it's a list.**

10 ATTORNEY FELDSTEIN: You still have to let
11 him finish the question.

12 Q. Okay. So just depending on chance, at a
13 particular clinical site, you may have more people
14 in placebo versus treatment arm or vice versa. Is
15 that correct?

16 **A. Yes.**

17 Q. In the TEASE-1 study, there were 50
18 patients total enrolled in the study. Is that
19 correct?

20 **A. There were 50 patients randomized in the**
21 **study.**

22 Q. Okay. And I think I understand -- I said
23 "enrolled" and you said "randomized," so I think
24 the difference is there may have been patients that
25 were enrolled that were not randomized into a

1 treatment or a placebo group. Is that correct?

2 **A. That's correct.**

3 Q. Okay. Do you happen to know how many
4 patients were enrolled that were not randomized?

5 **A. It may be in one of the exhibits, but I**
6 **don't recall myself.**

7 Q. Okay. If we come across it at some point,
8 will you let me know?

9 **A. If we -- I will, if I remember.**

10 Q. Okay. Great.

11 So of those 50 patients, how many of those
12 patients were allocated to treatment?

13 **A. So the trial design is provided in the --**
14 **in paragraph -- well, here for the allocation**
15 **provided in paragraph 18 of my declaration.**

16 Q. So at initiation of study, how many
17 patients were randomized into treatment?

18 **A. So here, you can see on this graph, on**
19 **this illustration, that a total of 30 patients were**
20 **randomized to gildeuretinol.**

21 Q. And of those 15 were randomized to a
22 14-milligram dose and 15 patients were randomized
23 to a 24-milligram dose. Correct?

24 **A. That is correct.**

25 Q. I have a question about paragraph 19. It

1 says participants were randomized in a 1.5:1.5:1:1
2 ratio?

3 A. Mm-hmm.

4 Q. I wasn't sure how to reconcile that with
5 the schematic in paragraph 18. Is that second
6 column 1, is that a typo?

7 ATTORNEY FELDSTEIN: "Second colon."
8 Right?

9 ATTORNEY MILLS: Right.

10 A. So here, all it's trying to say is that --
11 and it's trying to say in a narrative format what
12 is inside the illustration -- that essentially 15
13 patients received the 14-milligram dose. 15
14 patients received the 24-milligram dose. 20
15 patients received placebo.

16 At the end of one year, of those 20
17 patients who received placebo, half of those were
18 to be randomly receiving gildeuretinol, and the
19 remaining half would continue on placebo.

20 Q. Okay. So the -- there are four things
21 being ratioed, separated by three colons. Correct?

22 A. Yes.

23 Q. Okay. And so it's intentional that it
24 says colon 1, colon 1. Correct?

25 A. I believe so, yes.

1 Q. And what that indicates is that 10
2 patients will have placebo throughout the two-year
3 period. That equates to one of the number 1s.
4 Correct?

5 **A. That's correct.**

6 Q. And the other number 1 equates that there
7 are 10 patients who will receive placebo and then
8 will be randomize -- will then receive ALK-001
9 treatment after one year. Correct?

10 **A. That is correct.**

11 Q. Okay. And then the 1.5s in that there is
12 15 patients in each of those treatment groups?

13 **A. The 1.5 corresponds to the 15 patients who**
14 **receive 14 and 15 patients who receive 24.**

15 Q. Okay. Thank you for helping me with that.

16 **A. You're welcome.**

17 Q. When the clinical trial protocol was
18 written -- well, let me first ask you, when was
19 that? When was it that you wrote the clinical
20 trial protocol for TEASE-1?

21 **A. I do not recall the exact date. I'm**
22 **sorry.**

23 Q. Can you tell me in general, within a year
24 or two time frame?

25 **A. The study TEASE-1 started in 2015.**

1 Q. Okay. Did it start in the first half of
2 the year or the second half of the year?

3 A. It started in August of 2015 as listed in
4 the exhibit.

5 Q. So is it fair to say that you prepared the
6 clinical trial protocol for TEASE-1 sometime in the
7 first half of 2015?

8 A. I prepared it before we started it. So
9 there was definitely some preparation involved
10 prior to the start of the TEASE-1 trial.

11 Q. And I'm just trying to understand your --
12 like if the study started in August 2015, do you
13 have a best estimate as to when you completed
14 preparing the protocol?

15 A. No. So I don't know what you mean by
16 completion of the preparation of the protocol.

17 Q. Well, at some point did you have to submit
18 the protocol to FDA?

19 A. Yes.

20 Q. Did you have to submit the protocol to FDA
21 prior to beginning the study?

22 A. Yes.

23 Q. Okay. So at that point was the protocol
24 completed?

25 A. That would be the -- one of the versions

1 of the protocol at that point. That is the one you
2 submit to the FDA. We submit it about 30 days or
3 at least 30 days prior to the enrollment of the
4 first patient.

5 Q. Okay. So sometime in June or July 2015,
6 you submitted the protocol to the FDA for the
7 TEASE-1 study. Correct?

8 A. I do not recall when the protocol was
9 submitted.

10 Q. But it was at least 30 days prior to the
11 August 2015 start?

12 A. It was at least 30 days, yes.

13 Q. All right. When you submitted the
14 protocol to FDA, did it specify which dose the 10
15 placebo patients would move on to at the end of the
16 first year?

17 A. Yes.

18 Q. What dose did it specify?

19 A. It is specified here that there is dose 1
20 or dose 2 in the illustration of -- of
21 paragraph 18.

22 Q. Okay. So the protocol said that the 10
23 patients in placebo group 1 would be split evenly
24 between the two treatment groups?

25 ATTORNEY FELDSTEIN: Object to form.

1 **A. It said that the randomization should be**
2 **according to the numbers shown here.**

3 Q. And those numbers happened to be even. Is
4 that correct?

5 **A. The -- so they're randomized. It depends**
6 **how many patients actually return at 12 month. But**
7 **if all the patients return, then it would be split**
8 **evenly.**

9 Q. Okay. And when you performed the study,
10 was that how the study was actually conducted?

11 **A. There was a prespecification also that if**
12 **the two dose levels have -- have shown equivalent**
13 **pharmacodynamics, then we would not use the higher**
14 **dose.**

15 Q. Is that in fact what happened?

16 **A. That's in fact what happened.**

17 Q. Okay. So in the implementation of the
18 TEASE-1 study, all 10 of the first placebo group
19 patients went into the 14-milligram treatment
20 group. Correct?

21 ATTORNEY FELDSTEIN: Object to form.

22 **A. That's correct.**

23 Q. So when you reported results from the
24 TEASE-1 study, did you separately report results
25 for the 24-milligram dose versus the 14-milligram

1 dose?

2 ATTORNEY FELDSTEIN: Object to form.

3 **A. With respect to the safety, we reported**
4 **them separately.**

5 Q. And with regard to activity?

6 **A. With respect to efficacy, we combined the**
7 **two dose levels.**

8 Q. Okay. So at the end of the TEASE-1 study,
9 there was 40 patients who had been treated --
10 actually, let me withdraw that question and start
11 over.

12 At any point did the patients on 24
13 milligrams go down to the 14-milligram dose?

14 **A. Yes.**

15 Q. When was that?

16 **A. At 12 months.**

17 Q. Okay. So at 12 months, beginning at
18 12 months, 40 of the 50 patients were receiving a
19 14-milligram dose of ALK-001. Correct?

20 **A. After 12 month, all patients receiving**
21 **active were to receive the 14-milligram dose. The**
22 **number will depend on how many patients actually**
23 **return for the 12-month visit.**

24 Q. Okay. And do you have a recollection as
25 to how many returned?

1 **A. I do not.**

2 Q. So it was, at most, 40 patients that
3 received --

4 **A. It was at most.**

5 Q. Okay.

6 ATTORNEY FELDSTEIN: You still have to let
7 him finish the question.

8 Q. It's harder than it looks, huh.

9 Okay. So at the 24-month time frame in
10 the TEASE-1 study, the size of the placebo group
11 was no larger than 10. Is that correct?

12 **A. Yes, it cannot be larger than 10.**

13 Q. Do you recall how many of those 10 people
14 showed up for the 24-month?

15 **A. I do not recall exactly.**

16 Q. Do you have a best estimate?

17 **A. No.**

18 Q. Okay. We were talking about the
19 randomization of the patients in the TEASE-1 study.

20 For the TEASE-3 study, there was no
21 randomization. Correct?

22 **A. For the TEASE-3 study, everyone received**
23 **the 14-milligram dose.**

24 Q. Okay. I have another question about
25 enrollment.

1 So in Exhibit 2098 -- you have that in
2 front of you -- it says, "Estimated enrollment:
3 140."

4 Do you see that?

5 **A. Yes, I do.**

6 Q. In paragraph 9 of your declaration, you
7 say that TEASE-1 had an enrollment of 50 and that
8 TEASE-2 had an enrollment of 80.

9 Do you see that?

10 **A. I see -- I see those numbers, yes.**

11 Q. So can you help me understand the
12 discrepancy between the NCT listing of 140 and the
13 numbers that are in your declaration?

14 ATTORNEY FELDSTEIN: Object to form.

15 **A. The T3 trial, if you remember, can enroll
16 up to 10 patients.**

17 Q. Okay. How -- what's the rest of the math
18 for getting to 140?

19 **A. 80 plus 50 plus 10 equal 140.**

20 Q. Okay.

21 ATTORNEY FELDSTEIN: A math degree.

22 **A. Now I'm the one with the math degree.**

23 Q. Okay. So the enrollment at 140, that's
24 for all three of TEASE-1 through 3. Is that
25 correct?

1 **A. Yes.**

2 Q. Does that also include TEASE-4?

3 **A. No. The TEASE-4 is in a separate entity.**

4 Q. And do you know the NCT number for
5 TEASE-4?

6 **A. I do not.**

7 Q. I'm going to do them in order.

8 50 plus 80 plus 10. Okay. So for the 50,
9 the 24-month mark, we have a placebo group of up to
10 10 and a treatment group of up to 40. Correct?

11 **A. I believe that are the numbers, yes, we**
12 **discussed.**

13 Q. And for the TEASE-3 study, there's 10
14 patients but they're all treatment. There's no
15 placebo. Correct?

16 ATTORNEY FELDSTEIN: Object to form.

17 **A. The goal is to enroll up to 10 patients,**
18 **and all of them would receive the drug open-label.**

19 Q. So in TEASE-3 there's no placebo group?

20 **A. There's no placebo group.**

21 Q. So in TEASE-2 where there's an enrollment
22 up to 80, up to how many of those can be in the
23 placebo group?

24 ATTORNEY FELDSTEIN: Object to form.

25 Beyond the scope of the declaration.

1 **A. Well, this is not in the declaration.**

2 Q. Let me start with do you know the answer
3 to the question?

4 **A. I do.**

5 Q. Okay. So the reason I'm asking is because
6 of this 140 number.

7 **A. Yes.**

8 Q. And so I'm trying to understand how many
9 of the 140 have been in a placebo group.

10 So can you tell me, out of the 80 in
11 TEASE-2, how many are in a placebo group?

12 ATTORNEY FELDSTEIN: Object to form.
13 Beyond the scope of the declaration.

14 **A. Yes. It's 40.**

15 Q. Okay. Now back to the SAGA trial.

16 The selection for enrollment takes place
17 by the physicians at the clinical site. Correct?

18 **A. The selection of patients is -- these are**
19 **all the physician's patients.**

20 Q. And the physicians decide that the
21 patients meet the criteria for inclusion in the
22 study and send the patients for enrollment in the
23 study. Correct?

24 ATTORNEY FELDSTEIN: Object to form.

25 **A. In broad strokes, that -- that would be**

1 **it.**

2 Q. In the SAGA trial, like in the TEASE-1
3 study, the patients are also randomized between
4 placebo and treatment at the clinical site?

5 ATTORNEY FELDSTEIN: Object to form.

6 **A. The patients are randomized between**
7 **gildeuretinol and placebo in the same way as they**
8 **were in the TEASE-1 trial.**

9 Q. Okay. And you said that that was -- it's
10 not literally an envelope, but it's a random draw
11 that happens at the clinical site. Is that
12 correct?

13 **A. Yes.**

14 Q. So of these seven clinical sites for the
15 TEASE-1 study, in your role overseeing the study,
16 did you ever visit those clinical sites?

17 **A. I did.**

18 Q. Did you visit all of the clinical sites?

19 **A. I did.**

20 Q. And what was your role in visiting those
21 clinical sites?

22 ATTORNEY FELDSTEIN: Object to form.

23 **A. Performing the oversight.**

24 Q. Tell me what that means.

25 ATTORNEY FELDSTEIN: Object to form.

1 **A. It means ensuring that the sites are and**
2 **the physician is following the protocol.**

3 Q. Okay. And how would how would you ensure
4 that the physicians were following the protocol?

5 ATTORNEY FELDSTEIN: Object to form.

6 **A. You verify the data. You verify the**
7 **documents.**

8 Q. What does it mean to verify the documents?

9 **A. You verify that documents are present, are**
10 **properly signed, properly dated, and that all the**
11 **documents are present.**

12 Q. What does it mean to verify the data?

13 **A. It means verifying that the data entered**
14 **into the database corresponds to the data that they**
15 **have in the paperwork.**

16 Q. And you did that personally for the
17 TEASE-1 study?

18 **A. I was one of the people involved.**

19 Q. Who else was involved in doing that?

20 **A. The -- first of all, Gabrielle**
21 **DeBartolomeo was involved.**

22 Q. Anyone else?

23 **A. And later on we've hired several other**
24 **staff members. I would not recall their names.**

25 Q. What approximate year did you hire an

1 additional staff member beyond you and Gabrielle to
2 make site visits?

3 **A. Over the past two years.**

4 Q. Okay. So prior to 2022 it was you and
5 Gabrielle that were making the site visits for the
6 TEASE-1 study. Is that correct?

7 **A. That would be correct.**

8 Q. Did you make site visits to the clinical
9 sites for the SAGA trial?

10 **A. I made some.**

11 Q. Of the 20 to 25 clinical sites in the SAGA
12 trial, how many of those did you personally visit?

13 **A. I do not recall. Probably less than half.**

14 Q. And for the other sites, would you send
15 Gabrielle to visit those sites?

16 **A. I would.**

17 Q. And just so that we have a better
18 understanding of the timeline, the site visits for
19 the TEASE-1 study, approximately what years would
20 those take place?

21 **A. The TEASE-1 study, until it's submitted,**
22 **is -- is still ongoing as part of the entire TEASE.**
23 **So it started in 2015.**

24 Q. And is there an end date for the TEASE-1
25 study as of today?

1 **A. No.**

2 Q. Okay. It's still ongoing today?

3 **A. Well, it's completed, but the data needs**
4 **to be -- needs to be verified before they submit it**
5 **to the FDA.**

6 Q. Okay. So you might still visit the
7 clinical site to compare the data at the clinical
8 site to make sure that it's what you have in the
9 database for the TEASE-1 study. Right?

10 ATTORNEY FELDSTEIN: Object to form.
11 Beyond the scope.

12 **A. Beyond the scope. But I believe that**
13 **the -- these activities are now completed.**

14 Q. Okay. So sometime recently, the
15 verification finished for TEASE-1?

16 **A. Define "recently." Over the past several**
17 **months, this activity was completed, yes.**

18 Q. Okay. So the past several months in 2024
19 is when that was completed?

20 **A. That's correct.**

21 Q. Okay. Now, can you give me a timeline for
22 the SAGA study?

23 ATTORNEY FELDSTEIN: Again, object.
24 Beyond the scope.

25 **A. The SAGA study started in 2019 and data**

1 **was -- results were announced. Initial results**
2 **were announced during the AAO 2024 conference as in**
3 **one of the exhibits.**

4 Q. Is the SAGA study still ongoing as of
5 today?

6 A. **So similar to TEASE, so it's completed,**
7 **and I do not know the status specifically of the**
8 **database itself.**

9 Q. So it's possible that they're still doing
10 the verification for SAGA?

11 ATTORNEY FELDSTEIN: Object to form.

12 Beyond the scope.

13 A. **I -- I do not know.**

14 Q. Related to that, in your declaration you
15 have a list of abstracts relating to these studies?

16 A. **Yes.**

17 Q. So if we look at pages 2 to 3 of your
18 declaration, you see the list of exhibits?

19 A. **I see the list.**

20 Q. Do you know what a peer-reviewed
21 publication is?

22 ATTORNEY FELDSTEIN: Object to form.

23 A. **It's a -- it's a paper that's being**
24 **reviewed prior to being presented.**

25 Q. Reviewed by whom?

1 ATTORNEY FELDSTEIN: Object to form.

2 Q. Just in general. I'm not asking for
3 specific people's names. But --

4 ATTORNEY FELDSTEIN: Just a second.

5 Object to form. Beyond the scope of the
6 declaration.

7 **A. I believe that it would be reviewed by a**
8 **panel of specialists selected by the organization**
9 **to whom you are submitting that specific**
10 **information.**

11 Q. You were involved in the preparation and
12 submission of the exhibits listed on pages 2
13 through 4 of your declaration. Correct?

14 **A. I was involved, yes.**

15 Q. Did you submit Exhibit 2086 for peer
16 review?

17 **A. I do not recall if I'm -- what do you mean**
18 **by "submitting"?**

19 Q. Do you have an understanding as to what it
20 means to submit a publication for peer review?

21 ATTORNEY FELDSTEIN: Object to form.

22 **A. I was listed as an author. So I reviewed;**
23 **I wrote. I do not know who submitted it.**

24 Q. Is the answer the same for Exhibit 2087?

25 ATTORNEY FELDSTEIN: Object to form.

1 **A. It's the same for 2087.**

2 Q. Is the answer the same for Exhibit 2088?

3 ATTORNEY FELDSTEIN: Object to form.

4 **A. It's the same for 2088.**

5 Q. Is the answer the same for Exhibit 2089?

6 ATTORNEY FELDSTEIN: Object to form.

7 **A. It's the same for 2089.**

8 Q. Is the answer the same for Exhibit 2090?

9 ATTORNEY FELDSTEIN: Object to form.

10 **A. Same answer.**

11 Q. Is the answer the same for Exhibit 2091?

12 ATTORNEY FELDSTEIN: Object to form.

13 **A. Same answer.**

14 Q. Is the answer the same for Exhibit 2092?

15 ATTORNEY FELDSTEIN: Object to form.

16 **A. 2092 is a press release. A press release**
17 **would have been not peer-reviewed.**

18 Q. You do not know who submitted Exhibit

19 2093. Correct?

20 ATTORNEY FELDSTEIN: Object to form.

21 **A. 2093 is a press release. I do not know**
22 **who submitted it.**

23 Q. And you agree that neither Exhibit 2092 or

24 2093 are peer-reviewed publications. Correct?

25 ATTORNEY FELDSTEIN: Object to form.

1 **A. 2092 and 2093 are press releases. They're**
2 **not peer-reviewed.**

3 Q. And you don't know who submitted either
4 one of those. Correct?

5 ATTORNEY FELDSTEIN: Object to form.

6 **A. I do not know who submitted them.**

7 Q. You don't know who submitted Exhibit 2094?

8 ATTORNEY FELDSTEIN: Object to form.

9 **A. Same answer. I do not know.**

10 Q. You don't know who submitted Exhibit 2095?

11 ATTORNEY FELDSTEIN: Object to form.

12 **A. That one's a press release and not**
13 **peer-reviewed.**

14 Q. You don't know who submitted Exhibit 2096?

15 ATTORNEY FELDSTEIN: Object to form.

16 **A. This one, I did submit.**

17 Q. Exhibit 2096 is a press release that you
18 did submit?

19 **A. Yes.**

20 Q. You don't know who submitted Exhibit 2097?

21 ATTORNEY FELDSTEIN: Object to form.

22 **A. 2097?**

23 Q. Yes.

24 **A. I may be the one, or maybe not. So I'm**
25 **not too sure.**

1 Q. Take a look at paragraph 53 of your
2 declaration.

3 **A. Yes.**

4 Q. So the very last sentence in paragraph 53
5 on page 17, you talk about the press releases and
6 on your website to inform the public regarding your
7 work and Alkeus's business progress.

8 Do you see that?

9 **A. I see the sentence, yes.**

10 Q. So do you agree that when you issued the
11 press releases, at least Exhibit 2096, that you
12 intended to inform the public regarding your work
13 through those press releases?

14 **A. That is the objective of a press release.**

15 Q. And you understood that the public might
16 rely on the information you provided in those press
17 releases?

18 ATTORNEY FELDSTEIN: Object to form.

19 **A. I'm not sure what you mean by "rely."
20 These press releases were submitted to inform the
21 public regarding our work.**

22 Q. I have a question about the inclusion and
23 exclusion criteria for the studies.

24 So if you have those NCT documents, so
25 Exhibits 2098 and 2099 -- do you still have those

1 in front of you?

2 **A. I do.**

3 Q. Can you point us to the inclusion -- the
4 location of the inclusion criteria for the TEASE
5 studies?

6 **A. For the TEASE study on page 5 is what is**
7 **listed in the NCT page for the simplified inclusion**
8 **and the main exclusion criteria.**

9 Q. So the very first of the inclusion
10 criteria says male or female between 8 and 70 years
11 old inclusive.

12 Do you see that?

13 **A. I see that.**

14 Q. In some of the documents for the TEASE
15 study, I saw a range of 8 to 60 years old.

16 Can you tell me what the age range in the
17 inclusion criteria for the TEASE studies is?

18 **A. Well, for the -- at least what's currently**
19 **in the NCT is a male or female between 8 and 70**
20 **years old inclusive.**

21 Q. Is that the inclusion criteria that were
22 actually filed during the conduct of the TEASE
23 studies?

24 **A. The -- each TEASE study may have had**
25 **different age of enrollment, where overall 8 to 70**

1 **would be over -- encompassing everybody.**

2 Q. And when you say may have had different
3 enrollment, does that just depend on who shows up?
4 Or are you talking about a difference in the
5 inclusion criteria?

6 **A. I do not recall.**

7 Q. So it might be the case, for instance,
8 that the age inclusion criteria for TEASE-2 might
9 be different than for TEASE-1?

10 ATTORNEY FELDSTEIN: Objection. Form.
11 Beyond the scope of the declaration.

12 **A. I do not recall the answer.**

13 Q. In the second bullet point, do you see
14 that it says, "Has a clinical diagnosis of typical
15 autosomal recessive Stargardt macular dystrophy
16 (STGD1)"?

17 **A. I do see that.**

18 Q. Is -- and that's Stargardt 1?

19 **A. STGD1 would stand for Stargardt 1.**

20 Q. So that's a particular type of Stargardt?

21 **A. Stargardt 1 is a particular type of**
22 **Stargardt, yes.**

23 Q. The third bullet point, it says, "When
24 only one ABCA4 disease causing mutation is
25 reported, sponsor's permission will be required."

1 Do you see that?

2 **A. I see that.**

3 Q. To your knowledge as the director of the
4 TEASE studies, was the sponsor's permission ever
5 requested to enroll a patient with only a single
6 ABCA4 disease causing mutation?

7 **A. I do not recall, but I know that some**
8 **patients only had one mutation.**

9 Q. Okay. So some of the patients enrolled in
10 the study only had one mutation?

11 **A. Yes.**

12 Q. And is that true with respect to the
13 TEASE-1 study?

14 **A. This is true with respect to any TEASE.**

15 Q. So is it your testimony that in the
16 TEASE-3 study, some of the patients were
17 heterozygous with respect to their ABCA4 disease
18 causing mutations?

19 **A. I do not know the answer.**

20 Q. Okay. You're saying it's possible that
21 there could have been some?

22 ATTORNEY FELDSTEIN: Object to form.

23 **A. I'm not sure, actually.**

24 Q. Same question with respect to TEASE-2.

25 ATTORNEY FELDSTEIN: Object to form and --

1 **A. I'm not sure.**

2 ATTORNEY FELDSTEIN: -- beyond the
3 scope -- sorry.

4 Object to form and beyond the scope of the
5 declaration.

6 Q. And same question with respect to TEASE-1?

7 **A. I'm not sure.**

8 Q. So you don't know one way or the other
9 whether this exception for individuals with only
10 one ABCA4 disease causing mutation was ever
11 implemented in any of the TEASE studies. Correct?

12 ATTORNEY FELDSTEIN: Object to form.

13 **A. I do not recall. Every single patient was**
14 **diagnosed with Stargardt disease, a clinical**
15 **diagnosis.**

16 Q. Okay. I'm going to ask you now about the
17 main exclusion criteria.

18 Under the first bullet point, there's a
19 list of disallowed items over the past 30 days.

20 Do you see that?

21 **A. I see that.**

22 Q. So in the TEASE studies, the patients were
23 excluded from the trial if 30 days prior to
24 enrollment they had taken a supplement containing
25 vitamin A or beta-carotene. Is that correct?

1 **A. That's -- it is listed as one of the main**
2 **exclusion criteria.**

3 Q. Okay. So let's open Exhibit 2099.
4 Can you identify the page of Exhibit 2099
5 where the main exclusion criteria are listed?

6 **A. On page 4 of 9.**

7 Q. Okay. Under -- on page 4 of 9 of Exhibit
8 2099, there's a single major exclusion criteria
9 listed. Correct?

10 **A. I see one listed, correct.**

11 Q. Okay. And the listed exclusion criteria
12 in Exhibit 2099 does not mention disallowing
13 patients who had used a supplement containing
14 vitamin A or beta-carotene over the past 30 days.
15 Correct?

16 ATTORNEY FELDSTEIN: Object to form.

17 **A. This bullet does not appear.**

18 Q. So there is a bullet that appears on
19 page 4. Correct?

20 ATTORNEY FELDSTEIN: Object to form.

21 **A. What do you mean by that?**

22 Q. So there is a major exclusion criteria
23 that's listed on page 4 of Exhibit 2099. Correct?

24 **A. One bullet is listed under major exclusion**
25 **criteria.**

1 Q. Okay. And there's one and only one
2 bullet. Correct?

3 **A. I can see one and only one bullet here.**

4 Q. And I just want to make sure. That bullet
5 does not mention supplements containing vitamin A
6 or beta-carotene over the past 30 days. Correct?

7 **A. It does not.**

8 Q. Okay. Thank you.

9 In Exhibit 2099, please take a look at
10 page 2 of the document. At the top of the page,
11 this is a continuation of the detailed description
12 of the study overview. Correct?

13 **A. It is in the detailed description section.**

14 Q. Did you have a role in preparing this NCT
15 submission?

16 **A. I believe yes.**

17 Q. What was your role?

18 **A. Preparing the submission.**

19 Q. Okay. So you wrote the study overview.
20 Is that correct?

21 **A. I do not exactly recall if I wrote every
22 single word of it.**

23 Q. So you reviewed and approved the study
24 overview prior to submission. Correct?

25 **A. Yes.**

1 Q. Okay. So on page 2, the study overview
2 for the SAGA study says, "ALK-001, the study drug,
3 is a modified form of vitamin A."

4 Do you see that?

5 **A. I see that.**

6 Q. The next sentence, it says, "When taken
7 once a day as a capsule, it replaces natural
8 vitamin A in the body with one that forms vitamin A
9 dimers more slowly." Correct?

10 **A. That's what it says.**

11 Q. Okay. Thank you. You can set that aside.

12 So if you still have Exhibit 2098, on
13 page 7 there's a description of intervention.

14 Do you see that?

15 **A. I see that.**

16 Q. And it says daily oral administration for
17 24 months?

18 **A. Yes.**

19 Q. Okay. So is that the intervention in all
20 three of the TEASE-1 through the TEASE-3 studies?

21 ATTORNEY FELDSTEIN: Object to form.

22 Beyond the scope.

23 **A. That's what's listed in this document.**

24 Q. And is that accurate?

25 ATTORNEY FELDSTEIN: Object to form.

1 Beyond the scope.

2 **A. I believe that it is.**

3 Q. Does that intervention differ from the
4 intervention that was employed in the SAGA study?

5 ATTORNEY FELDSTEIN: Object to form.

6 **A. What do you mean?**

7 Q. Is there a difference between the
8 intervention that is employed in the TEASE studies
9 as compared to the SAGA study?

10 ATTORNEY FELDSTEIN: Object to form.

11 **A. What do you mean by "the intervention"?**

12 Q. So on page 7 of Exhibit 2098, do you see
13 that it -- there's a heading in the box that says
14 "Intervention"?

15 **A. I do.**

16 Q. So this is a document that you prepared or
17 approved prior to submission. Correct?

18 **A. Yes.**

19 Q. Okay. So when you approved this document,
20 you had an understanding as to what the box meant
21 when it said "Intervention." Correct?

22 **A. Yes.**

23 Q. So my question is whether the
24 intervention, the experimental intervention in the
25 TEASE studies, is that the same or different than

1 the experimental intervention in the SAGA study?

2 ATTORNEY FELDSTEIN: Object to form.

3 **A. We discussed that it was the same pill**
4 **across all studies.**

5 Q. Is there any other difference between the
6 interventions?

7 ATTORNEY FELDSTEIN: Object to form.

8 **A. There may be minor differences such as the**
9 **color of the capsule.**

10 Q. I think you told me before that the dosage
11 is the same. Correct?

12 ATTORNEY FELDSTEIN: Object to form.

13 **A. Except for the 24 milligrams. The 14**
14 **milligrams were the same.**

15 Q. And I think you said that the formulation
16 is the same. Correct?

17 **A. The ingredients were all the same.**

18 Q. Was the amount of the ingredients all the
19 same between the TEASE and the SAGA study?

20 **A. I believe so.**

21 Q. Was the daily oral administration the same
22 between the TEASE and the SAGA study?

23 **A. Patients were instructed to take the pill**
24 **once a day.**

25 Q. In all of the studies?

1 **A. Yes.**

2 ATTORNEY FELDSTEIN: Object to form.

3 Q. Okay. And in the TEASE as well as the
4 SAGA study, there was an instruction to take the
5 pill orally once a day for 24 months. Is that
6 correct?

7 **A. Could you repeat that?**

8 Q. In the TEASE as well as the SAGA study,
9 there was an instruction to take the pill orally
10 once a day for 24 months. Correct?

11 **A. That is correct.**

12 Q. Does the TEASE-1 study include a natural
13 history comparison group?

14 **A. The natural history, yes, it does.**

15 Q. So what does that mean?

16 **A. It means that additional cases of**
17 **untreated Stargardt patients were pooled with the**
18 **placebo arm in the primary prespecified analysis.**

19 Q. Okay. So in your -- in your study, at
20 24 months there was 40 treatment patients and 10
21 placebo patients. Correct?

22 ATTORNEY FELDSTEIN: Object to form.

23 **A. Randomized. Randomized.**

24 Q. Let me ask the question again just to try
25 to get it correct.

1 In the TEASE-1 study, at 24 months there
2 were 40 patients randomized to treatment and 10
3 patients randomized to placebo. Correct?

4 **A. At the end of TEASE-1, yes.**

5 Q. Separate from those 50 randomized
6 patients, your analysis for the TEASE-1 study
7 includes data from different patients other than
8 those 50 randomized patients. Correct?

9 **A. That's correct.**

10 Q. So on your website, for instance, there's
11 a graph of TEASE-1 data.

12 Do you know what I'm talking about?

13 **A. No.**

14 Q. Okay. I'll see if I can find it and share
15 it with you.

16 Okay. We're going to need to mark an
17 exhibit. Can we mark this as 1071.

18 (Exhibit 1071 is marked for
19 identification.)

20 ATTORNEY FELDSTEIN: I object to new
21 Exhibit 1071 summarily at least on completeness
22 and authenticity.

23 Q. So, Doctor, please take a moment to look
24 through Exhibit 1071, and my question to you will
25 be whether you recognize what's depicted in Exhibit

1 1071.

2 **A. Okay. I thumbed through it.**

3 Q. Do you recognize this document?

4 **A. It's a printout of what looks to be**
5 **something -- of our website.**

6 Q. So in the upper left-hand corner, there's
7 the logo for Alkeus Pharmaceuticals. Correct?

8 **A. I see a logo, yeah.**

9 Q. And in the bottom left-hand corner,
10 there's a website that says Alkeuspharma.com.

11 Do you see that?

12 **A. I see that.**

13 Q. And that is the Alkeus website. Is that
14 correct?

15 ATTORNEY FELDSTEIN: Object to form.

16 **A. I'm not -- I'm not most familiar with our**
17 **website, but it looks essentially like something**
18 **I've seen before.**

19 Q. If you were meeting with a business
20 colleague and they wanted to know what you were
21 working on, you might direct them to this website
22 to understand what your business is. Right?

23 ATTORNEY FELDSTEIN: Object to form.

24 Beyond the scope of the declaration.

25 Hypothetical.

1 **A. I -- I don't know. Most of the time I**
2 **don't even direct them to a website, no.**

3 Q. Okay. In your declaration, you referred
4 to putting the press releases on the Alkeus
5 website. Do you recall that?

6 **A. Yes.**

7 Q. So this is the website where someone would
8 go to get the Alkeus press releases. Correct?

9 ATTORNEY FELDSTEIN: Object to form.

10 **A. Well, press releases are sent to a wire,**
11 **and the wire then describes those press releases.**
12 **Usually -- and I'm not in charge of that -- but the**
13 **press release is also placed on our website.**

14 Q. Okay. So I was asking you a question
15 about the natural history group. So I have a
16 question about page 12 of 30 of Exhibit 1071.

17 **A. Okay.**

18 Q. So do you recognize the graph on page 12
19 of Exhibit 1071?

20 **A. Yes, I do.**

21 Q. Okay. So my question is whether the black
22 dotted line is the untreated control for this data.

23 **A. Yes, it is.**

24 Q. And that untreated control includes both
25 the measurements of the placebo patients from the

1 TEASE-1 study as well as some number of additional
2 natural history patients. Correct?

3 **A. That's what it says, yes.**

4 Q. So if we look at the two-year data point
5 on the far right, at that point the number of
6 placebo patients is up to 10. Correct?

7 **A. At the two-year mark, there were at most
8 10 patients who are receiving the placebo.**

9 Q. And up to how many natural history
10 patients are included in that data point?

11 **A. I do not recall the exact number, but I
12 believe it was around 50 or greater.**

13 Q. Were the natural history patients included
14 in the untreated control data point at the 1.5-year
15 mark?

16 ATTORNEY FELDSTEIN: Object to form.

17 Beyond the scope of the declaration.

18 **A. I -- I do not recall. We included all
19 measurements of the natural history as if they were
20 part of a clinical trial. So they were treated
21 exactly the same.**

22 Q. So the natural history patients would have
23 been included on the data point at year 1.5. Is
24 that correct?

25 ATTORNEY FELDSTEIN: Object to form.

1 Beyond the scope of the declaration.

2 **A. It's a -- it's a -- we included -- again,**
3 **I'm going to repeat because that's the correct**
4 **answer. Every data point of the natural history**
5 **between 0 and 2 years were included. All available**
6 **data were included for the generation of this**
7 **analysis.**

8 Q. So are you saying it's possible that there
9 were not natural history patient data at the
10 1.5-year mark to include?

11 ATTORNEY FELDSTEIN: Object to form.
12 Misstates the testimony. Beyond the scope of
13 the declaration.

14 **A. It's -- it's -- again, I'm going to**
15 **repeat. There were -- every single data point that**
16 **were included were included for the performance of**
17 **and the estimation of the slope that you see.**

18 Q. Right. So I'm just trying to understand
19 whether the natural history patients were included
20 at every single data point.

21 ATTORNEY FELDSTEIN: Object to form.
22 Beyond the scope of the declaration.

23 **A. Again, every single data point that we had**
24 **with respect to the natural history was included in**
25 **the model.**

1 Q. So I understand that whatever you had, you
2 included it.

3 Do you know whether you had natural
4 history data for the 1.5-year mark?

5 **A. So it's irrelevant.**

6 Q. Well, that's not a responsive answer. But
7 my question right now is do you know the answer to
8 that question, whether there was untreated control
9 data at -- for the 1.5-year mark?

10 ATTORNEY FELDSTEIN: Object to form.
11 Beyond the scope.

12 **A. I -- I believe that it's irrelevant.**

13 Q. Well, whether you think it's irrelevant or
14 not doesn't really matter. The question is whether
15 you know that or not.

16 **A. So when you plot a graph like that, what
17 you're actually plotting are slopes. The point at
18 each time point here is not relevant. That's why
19 the question itself is not relevant.**

20 Q. Are you saying you don't understand the
21 question?

22 **A. I'm saying the question is not -- is not
23 mathematically correct.**

24 Q. Okay. So are you saying that there was
25 not -- there was not data that was specific to the

1 1.5-year mark from the natural history group?

2 **A. I'm saying that whether there is or not is**
3 **irrelevant with respect to the -- to the**
4 **computation leading to the slope.**

5 Q. Okay. So you're saying that you could and
6 did calculate a slope regardless of whether you had
7 data at the 1.5 mark?

8 **A. What I'm saying is that we calculated a**
9 **slope based on all the available data point that we**
10 **had for the natural history patients and the**
11 **placebo patients. That's how we computed the**
12 **slope.**

13 Q. Right. And I'm just trying to understand
14 whether you know whether the data that you used to
15 compute the slope included data at a 1.5-year mark.

16 ATTORNEY FELDSTEIN: Objection. Beyond
17 the --

18 **A. I'm going to --**

19 ATTORNEY FELDSTEIN: Sorry.

20 Objection. Beyond the scope. Object to
21 form.

22 **A. I'm going to give you my same answer which**
23 **is the one that I've provided with respect to how**
24 **the slope is computed, which is what we report, and**
25 **to the fact that we've used all available data for**

1 **these patients.**

2 Q. So your answer doesn't really answer my
3 question, because my question is whether you know
4 whether the natural history patient group had data
5 for the 1.5-year mark.

6 ATTORNEY FELDSTEIN: Object to form and
7 beyond the scope of the declaration.

8 **A. I think it does answer your question,**
9 **respectfully.**

10 Q. So do you know whether there was data in
11 the natural history group for the 1.5 mark?

12 ATTORNEY FELDSTEIN: Objection. Beyond
13 the scope of the declaration.

14 **A. I have given you my answer already.**

15 Q. You haven't. You haven't answered whether
16 you know whether there was data in the natural
17 history group for the 1.5-year mark.

18 ATTORNEY FELDSTEIN: Object to form.
19 Beyond the scope.

20 **A. Again, we compute a slope, and that's the**
21 **slope that we're providing.**

22 Q. So when you calculated the slope, did you
23 use data from the natural history group for the
24 1.5 -year mark?

25 ATTORNEY FELDSTEIN: Objection. Beyond

1 the scope of the declaration.

2 **A. The reason why it's irrelevant is because**
3 **the 1.5-year mark is -- seems like a precise value.**
4 **There is no one that comes exactly on 1.5. Not a**
5 **single patient.**

6 **When you represent this like this, there's**
7 **always a -- a range of dates. It's represented**
8 **here for simplicity. The real value you need to**
9 **look at is the slope itself, which is one number.**

10 Q. Okay. Let's switch gears a little bit.

11 So you mentioned Gabrielle, who you hired
12 at Alkeus in -- I think you said the 2017-2018 time
13 frame. Is that right?

14 **A. Yes.**

15 Q. At that time was anybody else working with
16 you at Alkeus?

17 **A. In 2000 -- at the time that I hired**
18 **Gabrielle, I hired also two additional personnel.**

19 Q. What were their roles?

20 **A. They were similar to that of Gabrielle.**

21 Q. Okay. Did they have similar
22 qualifications to Gabrielle?

23 **A. That's correct.**

24 ATTORNEY FELDSTEIN: Objection. Beyond
25 the scope of the declaration.

1 Q. In that 2017 to 2018 time frame, to whom
2 did you report?

3 ATTORNEY FELDSTEIN: Objection. Beyond
4 the scope of the declaration.

5 Objection to form also.

6 **A. I don't know what that means, to whom do I**
7 **report.**

8 Q. Was there anyone at Alkeus that you
9 reported to --

10 ATTORNEY FELDSTEIN: Objection.

11 Q. -- in 2017 through 2018 time frame?

12 ATTORNEY FELDSTEIN: I'm sorry.

13 Objection to form, and objection as beyond
14 the scope of the declaration.

15 **A. In 2017 to 2018 I was the president and**
16 **CEO.**

17 Q. Because you were the president and CEO,
18 everyone at the company ultimately reported to you.
19 Is that fair?

20 ATTORNEY FELDSTEIN: Objection. Beyond
21 the scope. Objection to form.

22 **A. I was the president and CEO at Alkeus.**

23 Q. Because you were the president and CEO at
24 Alkeus, everyone at Alkeus ultimately reported to
25 you. Correct?

1 ATTORNEY FELDSTEIN: Objection to form.

2 Objection to beyond the scope of the

3 declaration.

4 **A. I was the president and CEO.**

5 Q. So you've told me that there were four

6 people at Alkeus at the time. Is that correct?

7 **A. At the time there were four full-time**

8 **employees.**

9 Q. Okay. And you were the boss of all of the

10 four full-time employees. Correct?

11 **A. I was their boss, yes.**

12 Q. Okay. And if there were any part-time

13 employees, you were also their boss. Correct?

14 ATTORNEY FELDSTEIN: Objection to form,

15 and objection, beyond the scope.

16 **A. I would have been the president and CEO.**

17 Q. You mentioned full-time employees. Were

18 there part-time employees at Alkeus?

19 ATTORNEY FELDSTEIN: Objection. Beyond

20 the scope of the declaration.

21 **A. I don't recall. There might have been.**

22 Q. As you sit here today, you don't recall

23 any part-time employees of Alkeus in the 2017-2018

24 time frame?

25 ATTORNEY FELDSTEIN: Objection. Beyond

1 the scope of the declaration.

2 **A. Not directly. You know, it's been a long**
3 **time.**

4 Q. Aside from full-time employees and
5 part-time employees, were there any other
6 categories of personnel that were assisting you in
7 performing the work at Alkeus in that 2017-2018
8 time frame?

9 ATTORNEY FELDSTEIN: Objection to form.
10 Objection. Beyond the scope of the declaration.

11 **A. I don't know what "assist" means. But**
12 **it's a -- we work with physicians. We work with**
13 **Dr. Washington. There's a -- it's a broad field.**

14 Q. Okay. So the physicians were not internal
15 to Alkeus. Correct?

16 **A. The physicians are not internal to Alkeus.**

17 Q. Dr. Washington was internal to Alkeus in
18 this time frame?

19 ATTORNEY FELDSTEIN: Objection. Beyond
20 the scope.

21 **A. Define "internal."**

22 Q. He was a cofounder. Correct?

23 **A. Dr. Washington is a cofounder of Alkeus,**
24 **yes.**

25 Q. So in the 2017-2018 time frame, you and

1 Dr. Washington were the two cofounders of the
2 company. Correct?

3 **A. Yes. And we still remain the two**
4 **cofounders.**

5 Q. And in 2017 to 2018 time frame, both you
6 and Dr. Washington had an insider role in Alkeus.
7 Correct?

8 ATTORNEY FELDSTEIN: Objection to form.
9 Objection. Beyond the scope.

10 **A. I don't know what you mean, "insider**
11 **role." We were both founders.**

12 Q. So you were both part of the company.
13 Correct?

14 **A. We were both founders. I don't know what**
15 **"part" means. But we were founders of the company.**

16 ATTORNEY FELDSTEIN: Counsel, this is
17 again straying way beyond what what's his
18 declaration, and I think again trying to get
19 into internal company information that is
20 potentially competitively sensitive for your
21 client. And I object to that. And if you
22 continue with things beyond the scope of the
23 declaration, we'll stop and get board advice as
24 needed.

25 ATTORNEY MILLS: So the questioning is not

1 beyond the scope of the declaration. His
2 declaration discusses his roles and
3 responsibilities over his 14-year tenure. It
4 discusses the studies. The individuals that he
5 selected and used to prepare and accomplish
6 those study work is relevant to his testimony.

7 And so you can lodge your objections. If
8 you have concerns about confidentiality, the
9 remedy is a designation of confidentiality.

10 ATTORNEY FELDSTEIN: I've already
11 explained to you that at some point we're going
12 to stop the declaration -- excuse me -- stop the
13 deposition until we can get board advice on
14 going beyond the scope of the declaration.

15 ATTORNEY MILLS: Your behavior obstructing
16 the deposition is inappropriate. If you have
17 objections, you should lodge your objections.
18 But it's inappropriate for you to threaten to
19 stop the deposition because you don't like the
20 questions.

21 ATTORNEY FELDSTEIN: I'm not threaten --
22 well, I am telling you that that's what we'll
23 do, and I'm trying to make the deposition
24 actually work effectively by warning you that we
25 will need to stop if you continue to go beyond

1 the scope of the declaration so that we can get
2 board counsel.

3 If you want to continue discussing it with
4 me, that's fine. I've advised you my position.
5 I'm just repeating it now. So the only reason
6 I'm repeating it is because you keep asking.

7 ATTORNEY MILLS: I haven't asked any
8 questions that are beyond the scope of the
9 deposition.

10 ATTORNEY FELDSTEIN: Well, we disagree
11 with that.

12 BY ATTORNEY MILLS:

13 Q. Dr. Saad, would you please take a look at
14 paragraph 2 of your declaration.

15 **A. Yes.**

16 Q. So in here you discuss your educational
17 background. Correct?

18 **A. Yes.**

19 Q. You have a degree in mechanical
20 engineering. Correct?

21 **A. I have two degrees in mechanical**
22 **engineering.**

23 Q. What is mechanical engineering?

24 **A. It's what it says. It's mechanical**
25 **engineering.**

1 Q. So can you give me a brief description of
2 what that means without just using the words again?

3 ATTORNEY FELDSTEIN: Object to form.

4 A. **Mechanical engineering is very broad. It**
5 **involves essentially creation of anything.**

6 Q. Okay. You have a degree in regenerative
7 medicine?

8 A. **No. My research was in tissue engineering**
9 **and regenerative medicine.**

10 Q. What is regenerative medicine?

11 A. **It involves the regeneration of tissues in**
12 **the body.**

13 Q. And more specifically, how are the tissues
14 of the body regenerated?

15 A. **Usually you use stem cells or other kinds**
16 **of cells or mixed with other materials.**

17 Q. And you discuss in your declaration your
18 experience with tissue engineering?

19 A. **I do not know if I am describing this, no.**

20 Q. You said, "The focus of my PhD was tissue
21 engineering"?

22 A. **Yeah. Tissue engineering and regenerative**
23 **medicine.**

24 Q. What is tissue engineering?

25 A. **Tissue engineering is a creation of**

1 **tissues using engineering methods.**

2 Q. You do not have an advanced degree in
3 chemistry or biochemistry. Correct?

4 **A. My -- my graduate degree from Ecole**
5 **Polytechnique in France had a concentration in**
6 **organic chemistry and physics.**

7 Q. So in your declaration you say you are a
8 graduate of the Polytechnique in France?

9 **A. Yes.**

10 Q. So is that a graduate degree?

11 **A. It's a master of science.**

12 Q. Okay. So you're saying you have a master
13 of science in which you had a concentration in
14 organic chemistry and physics?

15 **A. That's correct.**

16 Q. You are not a physician. Correct?

17 **A. I am not a physician.**

18 Q. You don't have a degree in pharmaceutical
19 science?

20 **A. I do not have a degree in pharmaceutical**
21 **science.**

22 Q. You're not an ophthalmologist?

23 **A. I'm not an ophthalmologist.**

24 Q. You are not the chief medical officer at
25 Alkeus. Correct?

1 **A. I am not.**

2 Q. Who is?

3 **A. Currently, our chief medical officer is**
4 **Seemi Kahn.**

5 Q. Dr. Kahn is not an ophthalmologist.
6 Correct?

7 ATTORNEY FELDSTEIN: Object to form.
8 Beyond the scope of the declaration.

9 **A. Dr. Kahn is not an ophthalmologist.**

10 Q. You're not testifying in this case as an
11 expert witness. Correct?

12 ATTORNEY FELDSTEIN: Object to form.

13 **A. It's not in the declaration. I would not**
14 **even know what that means.**

15 Q. You didn't submit a CV?

16 **A. I did not submit a CV.**

17 Q. You did not submit a publications list.
18 Correct?

19 **A. I did not.**

20 Q. And sitting here today, you can't point me
21 to any pre-2007 publications that you have authored
22 involving lipofuscin. Correct?

23 **A. That's correct.**

24 Q. Sitting here today, you can't point me to
25 any pre-2007 publications that you authored on the

1 biosynthesis and structure of retinoids. Correct?

2 **A. That's correct.**

3 Q. Please take a look at paragraph 3 of your
4 declaration.

5 **A. Yes.**

6 Q. Have you had a chance to read that to
7 yourself?

8 **A. Okay.**

9 Q. So in paragraph 3 of your declaration, you
10 say that you understand that the real
11 parties-in-interest in IPR2024-00313 are the
12 Trustees of Columbia University in the City of New
13 York and the owner of the '045 patent -- sorry. I
14 misspoke.

15 You identified in paragraph 3 of your
16 declaration the Trustees of Columbia University in
17 the City of New York and Alkeus Pharmaceuticals as
18 the real parties-in-interest in IPR2024-00313.
19 Correct?

20 ATTORNEY FELDSTEIN: Object to form.

21 **A. I'm saying that I understand that these**
22 **real parties of interest are the Trustees of**
23 **Columbia University in the City of New York as well**
24 **as Alkeus Pharmaceuticals, which is the exclusive**
25 **licensee of the '045 patent.**

1 Q. And what is your basis for your statement
2 in paragraph 3 as to your understanding regarding
3 the real parties-in-interest?

4 A. We are the exclusive licensee of the
5 patent that is owned by the Trustees of Columbia
6 University.

7 Q. When you wrote this sentence in
8 paragraph 3 of your declaration, were you aware
9 that Andrew Hack was a member of the board of
10 directors of Alkeus?

11 A. I am.

12 Q. You're aware that he's affiliated with
13 Bain Capital?

14 A. I am.

15 Q. When you wrote this paragraph in your
16 declaration, you were aware that Ian Smith is a
17 director on the board of directors for Alkeus?

18 A. I am.

19 Q. You're aware that he's affiliated with
20 Bain Capital?

21 A. Define "affiliated."

22 Q. Were you aware that he had an association
23 of some kind with Bain Capital?

24 A. What's an association of some kind?

25 Q. Of any kind.

1 **A. Excuse me?**

2 Q. Of any kind.

3 **A. Well, I do have an association of any kind**
4 **with Bain Capital as one of our investors.**

5 Q. Okay. Are you aware that Ian Smith that a
6 preexisting relationship with Bain Capital prior to
7 serving on the board of Alkeus?

8 **A. Ian Smith was introduced to us by Bain**
9 **Capital. I assume that this is what you're looking**
10 **for?**

11 Q. Okay. Yes.

12 Of the nonmanagement members of the board
13 of Alkeus, how many of them have a relationship
14 with Bain Capital?

15 ATTORNEY FELDSTEIN: Objection. Beyond
16 the scope of the declaration.

17 Again, it seems that you're trying to get
18 commercially sensitive information as a
19 representative of a competitor.

20 Q. Can you answer the question?

21 **A. Can you repeat the question specifically?**

22 Q. When you signed your declaration,
23 including paragraph 3 of your declaration, were you
24 aware that the majority of the nonmanagement
25 directors of the Alkeus board have an affiliation

1 or relationship with Bain Capital?

2 ATTORNEY FELDSTEIN: Objection. Beyond
3 the scope of the declaration. Objection. Form.

4 **A. The nonmanagement, can you -- if you name**
5 **them -- you used the word "majority." You used the**
6 **word "nonmanagement." It would be easier if you**
7 **give me names --**

8 Q. Okay.

9 **A. -- and count yourself.**

10 Q. Okay.

11 So we discussed Andrew Hack. Yes?

12 **A. We discussed Andrew Hack affiliation with**
13 **Bain Capital.**

14 Q. Ian Smith?

15 **A. Yes.**

16 ATTORNEY FELDSTEIN: Objection. Beyond
17 the scope.

18 Q. You understand that Joshua Boger has a
19 relationship with Bain Capital?

20 ATTORNEY FELDSTEIN: Objection. Form.
21 Beyond the scope.

22 **A. I do not understand what the relationship**
23 **again means.**

24 Q. Do you understand that Joshua Boger ran
25 Vertex Pharmaceuticals?

1 ATTORNEY FELDSTEIN: Objection. Beyond
2 the scope. Objection to form.

3 **A. Joshua Boger was a CEO of Vertex.**

4 Q. Do you understand that Vertex
5 Pharmaceuticals was a Bain Capital company?

6 ATTORNEY FELDSTEIN: Objection. Form.
7 Objection. Beyond the scope.

8 **A. I have no idea about that.**

9 Q. Joshua Boger introduced you to the
10 individuals at Bain Capital. Correct?

11 **A. That's not correct.**

12 ATTORNEY FELDSTEIN: Objection to form.
13 Beyond the scope.

14 You have to give me a chance to object.

15 (Exhibit 1072 is marked for
16 identification.)

17 ATTORNEY FELDSTEIN: I object to Exhibit
18 1072, at least on authenticity, relevance, and
19 completeness.

20 Q. Go ahead and take a look at Exhibit 1072.

21 ATTORNEY FELDSTEIN: Also beyond the
22 scope.

23 **A. Yes, I have it.**

24 Q. Exhibit 1072 is entitled "Current and
25 Former Portfolio Companies." Correct?

1 ATTORNEY FELDSTEIN: Objection to form,
2 foundation, and beyond the scope.

3 **A. It says -- the document in front of me**
4 **says "Current and Former Portfolio Companies" as**
5 **the title.**

6 Q. And the website at the bottom of the page
7 is Baincapitalprivateequity.com. Correct?

8 ATTORNEY FELDSTEIN: Objection to form,
9 foundation, and beyond the scope.

10 **A. The -- the -- at the bottom of the page it**
11 **says -- it says "Baincapitalprivateequity.com."**

12 Q. Please take a look at page 8 of the
13 document.

14 **A. The document pages are not listed.**

15 Q. It's the page that faces, so it's opposite
16 the one at the end that has the Bain Capital LP
17 message.

18 Do you see that?

19 **A. I see that.**

20 Q. So the page immediately preceding that.
21 The third entity up from the bottom, it says
22 "Vertex." Correct?

23 ATTORNEY FELDSTEIN: Objection to form,
24 foundation, and beyond the scope.

25 **A. I see -- I see it's written.**

1 Q. Okay. Thank you.

2 **A. I don't see Alkeus on this.**

3 Q. You should talk to them about that.

4 ATTORNEY FELDSTEIN: You should wait for a
5 question also.

6 (Exhibit 1073 is marked for
7 identification.)

8 ATTORNEY FELDSTEIN: I object to Exhibit
9 1073 at least on relevance, foundation --
10 relevance, completeness, and authenticity.

11 Q. Go ahead and take a look at Exhibit 1073.

12 **A. I see that.**

13 Q. If it helps, if you look at Exhibit
14 1071 --

15 **A. Which one was 1071?**

16 Q. [Indicating.]

17 So starting on page 25 of Exhibit 1071,
18 there's the photo of Andrew Hack?

19 **A. I see that.**

20 Q. Okay. And that's the same fellow that's
21 on the page -- the first page of Exhibit 1073.
22 Correct?

23 ATTORNEY FELDSTEIN: Objection to form,
24 foundation, and beyond the scope.

25 **A. One is smaller than the other, but looks**

1 **like the same person.**

2 Q. Okay. And in Exhibit 1073, the web
3 address is Alkeuspharma.com. Correct?

4 ATTORNEY FELDSTEIN: Objection to form.
5 Foundation. Beyond the scope.

6 **A. It says that on the print.**

7 Q. Andrew Hack is a director on the board of
8 directors for Alkeus Pharma. Correct?

9 ATTORNEY FELDSTEIN: Objection to beyond
10 the scope of the declaration.

11 **A. Andrew Hack is a director at Alkeus, yes.**

12 Q. The very first line of his bio on the
13 Alkeus website says, "Dr. Hack is a partner of Bain
14 Capital Life Sciences LP"?

15 ATTORNEY FELDSTEIN: Objection to
16 foundation. Beyond the scope.

17 **A. That's what it says.**

18 Q. Okay. Take a look at the second page of
19 Exhibit 1073. This is the same picture for Ian
20 Smith on page 26 of Exhibit 1071. Correct?

21 ATTORNEY FELDSTEIN: Objection to form.
22 Foundation. Beyond the scope.

23 **A. What is the question?**

24 Q. It's the same -- a picture of the same guy
25 in Exhibit 1071 and 1073. Correct?

1 ATTORNEY FELDSTEIN: Objection to form.

2 Foundation. Beyond the scope.

3 **A. It's a good-looking picture.**

4 Q. And it's the same guy. Right?

5 ATTORNEY FELDSTEIN: Objection to form.

6 Foundation. Beyond the scope.

7 **A. It looks like the same person.**

8 Q. And they're both from Alkeuspharma.com.

9 Correct?

10 ATTORNEY FELDSTEIN: Objection to form.

11 Foundation. Beyond the scope.

12 **A. Same answer.**

13 Q. Sorry. What's the answer?

14 **A. That Alkeus Pharma is listed on top.**

15 Q. And here, it's not the very first line,
16 but the second sentence says he currently serves as
17 a senior advisor to Bain Capital Life Sciences.

18 Correct?

19 ATTORNEY FELDSTEIN: Objection to form.

20 Foundation. Beyond the scope.

21 **A. I see that listed on the document.**

22 Q. Okay. Ian Smith also is a director on the
23 board of directors for Alkeus. Correct?

24 ATTORNEY FELDSTEIN: Objection. Beyond
25 the scope.

1 **A. Ian Smith is listed as a director, and he**
2 **is a director at Alkeus Pharmaceuticals, yes.**

3 Q. Okay. The third page of Exhibit 1073 is
4 for Chen Yu.

5 Do you see that?

6 ATTORNEY FELDSTEIN: Objection. Form.
7 Foundation. Beyond the scope.

8 **A. I see a photo of Chen Yu, yes.**

9 Q. Chen Yu also shows up on page 27 of
10 Exhibit 1071. Correct?

11 ATTORNEY FELDSTEIN: Objection. Form.
12 Foundation. Beyond the scope.

13 **A. Yes, he does.**

14 Q. And it identifies Chen Yu as the founder
15 and managing partner of TCGX. Correct?

16 ATTORNEY FELDSTEIN: Objection to form.
17 Foundation. Beyond the scope.

18 **A. That's what it says.**

19 Q. And in the press releases that you discuss
20 in your declaration, you identify TCGX as one of
21 the investors who invested in Alkeus in the funding
22 led by Bain Capital. Correct?

23 ATTORNEY FELDSTEIN: Objection to form.
24 Foundation.

25 **A. I believe that it's indeed what we have in**

1 **one of the press releases that was given as an**
2 **exhibit.**

3 Q. So when you signed your declaration,
4 including paragraph 3 of your declaration
5 discussing the real parties-in-interest, you were
6 aware that these individuals that we've been
7 discussing today, who are on the board of directors
8 for Alkeus, have affiliations with Bain and TCGX.
9 Correct?

10 ATTORNEY FELDSTEIN: Objection. Form.
11 Foundation. Beyond the scope.

12 **A. And which people are affiliation with**
13 **Bain?**

14 Q. So we've talked about Andrew Hack?

15 **A. Yes.**

16 Q. You agree that he has an affiliation with
17 Bain?

18 ATTORNEY FELDSTEIN: Objection to form and
19 foundation. Beyond the scope.

20 **A. Andrew Hack is a managing partner at Bain.**

21 Q. We talked about Ian Smith. He also has an
22 affiliation with Bain. Correct?

23 **A. At least in the document you provided,**
24 **he's listed as a senior advisor.**

25 Q. And you agree that Dr. Yu has an

1 affiliation with TCGX, one of the investors who
2 invested in Alkeus through the Bain-led financing.
3 Correct?

4 ATTORNEY FELDSTEIN: Objection. Objection
5 to form. Foundation. Beyond the scope.

6 **A. I don't know if that means they're**
7 **affiliated with Bain. It just means that they**
8 **coinvested.**

9 Q. And you agree that TCGX is one of the
10 investors in Alkeus. Correct?

11 ATTORNEY FELDSTEIN: Objection to form.
12 Foundation. Beyond the scope.

13 **A. Yes.**

14 Q. You agree that Bain Capital is a major
15 investor in Alkeus?

16 ATTORNEY FELDSTEIN: Objection to form.
17 Foundation. Beyond the scope.

18 **A. I do not know whether it's a major**
19 **investor. Bain Capital is an investor.**

20 Q. So you're not sure whether or not you
21 would agree that Bain Capital is a major investor
22 in Alkeus?

23 ATTORNEY FELDSTEIN: Objection to form.

24 **A. Again, I don't know what "major investor"**
25 **meant. It's one of our four institutional**

1 **investors.**

2 Q. And who are the other investors?

3 ATTORNEY FELDSTEIN: Objection. Beyond
4 the scope.

5 **A. They're listed in the exhibit provided to**
6 **you in the press release.**

7 Q. Bain Capital is the largest of the four.
8 Correct?

9 ATTORNEY FELDSTEIN: Objection. Beyond
10 the scope.

11 **A. I -- Bain Capital was the lead investor**
12 **and probably was the one that invested the highest**
13 **amount.**

14 Q. You were aware of that when you failed to
15 identify Bain Capital as a real party-in-interest
16 when you signed your declaration. Correct?

17 ATTORNEY FELDSTEIN: Objection to form.
18 Foundation.

19 **A. I -- my understanding was that Bain**
20 **Capital is not a real party-in-interest. But I am**
21 **not a lawyer, and if I made a mistake or if it is a**
22 **mistake, then I would need to check with counsel**
23 **what specifically needs to be listed as real party**
24 **of interest.**

25 Q. And my question is, when you were listing

1 the real parties-in-interest and not listing Bain
2 Capital, you were aware that there was -- that Bain
3 Capital was the largest of the four investors and
4 that there was board members on Alkeus who were
5 affiliated with Bain Capital. Correct?

6 ATTORNEY FELDSTEIN: Objection to form,
7 and beyond the scope.

8 **A. Again, I think we've already covered these**
9 **questions.**

10 Q. And the answer -- yes. Those are things
11 that you knew when you signed the declaration.
12 Correct?

13 ATTORNEY FELDSTEIN: Objection to form and
14 beyond the scope.

15 **A. These parties are affiliated, or the**
16 **investor from Bain Capital is Andrew Hack, and it**
17 **looks like Ian Smith is a senior advisor for Bain**
18 **Capital.**

19 Q. And you knew about the overlapping board
20 positions when you signed your declaration.
21 Correct?

22 ATTORNEY FELDSTEIN: Objection to form.
23 Foundation. Beyond the scope.

24 **A. I don't know what you mean by**
25 **"overlapping."**

1 Q. You knew that three of the directors on
2 the Alkeus board are from the venture investment in
3 Alkeus from either Bain or from TCGX. Right?

4 ATTORNEY FELDSTEIN: Objection to form.
5 Foundation. Beyond the scope.

6 **A. Yeah, these are the three -- three parties**
7 **associated with the investors.**

8 Q. Okay. And you knew at the time you signed
9 your declaration, when you decided not to identify
10 Bain as a real party-in-interest, you knew about
11 those directors' affiliations with those investors.
12 Correct?

13 ATTORNEY FELDSTEIN: Objection to form.
14 Misstates the document. Calls for a legal
15 conclusion. Beyond the scope.

16 **A. Again, I'm not a lawyer. The**
17 **identification and -- was provided to me by counsel**
18 **in terms of who are the real parties-in-interest.**
19 **I would not be able to determine who is a real**
20 **party of interest. That was my understanding,**
21 **which was provided to me by counsel.**

22 Q. My question is about the facts. So the
23 facts about these Alkeus board members being
24 affiliated with these investors that you did not
25 name as real parties-in-interest, I just want to

1 know, those are facts that you knew when you signed
2 your declaration. Correct?

3 ATTORNEY FELDSTEIN: Objection to form.
4 Foundation -- oh, excuse me. Objection to form
5 and beyond the scope.

6 **A. Again, we've -- we've discussed who these**
7 **three board members are: one who is a managing**
8 **partner at Bain, one who is a senior -- listed as a**
9 **senior advisor, and one who is a separate investor**
10 **from a firm called TCG Crossover.**

11 Q. And you knew about those relationships
12 when you signed your declaration. Correct?

13 ATTORNEY FELDSTEIN: Objection to form and
14 beyond the scope.

15 **A. I do not know what you mean by**
16 **"relationship."**

17 Q. So you just summarized for us the
18 relationships of those three board members with the
19 Alkeus investors.

20 Do you recall that?

21 ATTORNEY FELDSTEIN: Objection to form.

22 **A. The three individuals are affiliated with**
23 **the parties that they've been affiliated, since**
24 **they were affiliated with those.**

25 Q. And you were aware of those affiliations

1 at the time that you signed your declaration.

2 Correct?

3 ATTORNEY FELDSTEIN: Objection. Beyond
4 the scope.

5 **A. I believe that I was.**

6 Q. Thank you.

7 Would you like to take a break?

8 **A. No.**

9 THE REPORTER: I would.

10 ATTORNEY FELDSTEIN: The court reporter is
11 asking for a break.

12 Is that okay, Mark?

13 ATTORNEY MILLS: Yes.

14 ATTORNEY FELDSTEIN: Okay.

15 (Lunch recess taken from 12:42 p.m.
16 to 1:15 p.m.)

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1 A F T E R N O O N S E S S I O N

2 BY ATTORNEY FELDSTEIN:

3 Q. Dr. Saad, during the break, did you have
4 any discussions with counsel relating in any way to
5 this case?

6 A. I did not.

7 Q. I'm handing you what has previously been
8 marked as Exhibit 2093.

9 Do you recognize as a January 10th Alkeus
10 press release?

11 A. Yes, I do.

12 Q. On the second page of the press release,
13 I'm going to ask you questions under the heading
14 about gildeuretinol (ALK-001).

15 A. I see that.

16 Q. The very first sentence says,
17 "Gildeuretinol acetate (ALK-001) is a novel
18 molecule."

19 Do you see that?

20 A. I see that.

21 Q. Were you involved in the creation of this
22 January 10, 2024, press release?

23 A. I may or may not have been involved, yes.

24 It's a company press release, so I might have read
25 it.

1 Q. Okay. You're aware that this case that
2 we're dealing with now was filed before January 10,
3 2024. Correct?

4 ATTORNEY FELDSTEIN: Object to form.

5 **A. Yes.**

6 Q. So before this press release issued on
7 January 10, 2024, you had an opportunity to
8 evaluate whether it was true that gildeuretinol
9 acetate is a novel molecule. Correct?

10 ATTORNEY FELDSTEIN: Object to form.

11 Beyond the scope.

12 **A. I do not know the answer to the question.**

13 Q. I hand you Exhibit 2092.

14 Do you recognize this as a July 18, 2024,
15 Alkeus press release?

16 **A. Yes.**

17 Q. Were you involved in the preparation or
18 approval of this press release?

19 ATTORNEY FELDSTEIN: Object to form.

20 Beyond the scope.

21 **A. Again, I might have read it. And, indeed,
22 I might have read it before it came out.**

23 Q. Do you see under the heading on page 2
24 about gildeuretinol acetate that in July of 2024
25 Alkeus was still claiming that gildeuretinol

1 acetate is a novel molecule?

2 ATTORNEY FELDSTEIN: Object to form.

3 Beyond the scope.

4 **A. It says that gildeuretinol acetate is a**
5 **novel molecule created as a specialized form of**
6 **deuterated vitamin A designed to reduce the**
7 **dimerization of vitamin A without disrupting**
8 **vision.**

9 Q. I'm handing you Exhibit 2094. Do you
10 recognize this document?

11 **A. Yes.**

12 Q. This is an August 6, 2024, submission by
13 Alkeus to the AAO Retina Subspecialty Day.
14 Correct?

15 **A. I'm not sure if it's the August 4th --**
16 **August 6th is the abstract deadline.**

17 Q. Oh, okay.

18 So do you know when this was submitted?

19 **A. I do not.**

20 Q. Okay. To the best of your knowledge, was
21 it submitted on or around August 6th?

22 **A. I believe it had to be submitted before.**

23 Q. Do you see under "Purpose," the document
24 describes gildeuretinol acetate as a novel
25 deuterated vitamin A?

1 **A. I see that.**

2 Q. So as of approximately August 6, 2024,
3 Alkeus was still claiming that gildeuretinol
4 acetate is a novel molecule. Correct?

5 ATTORNEY FELDSTEIN: Object to form.

6 Beyond the scope. Misrepresents the document.

7 **A. This document is an abstract submitted on**
8 **behalf of the authors by Dr. Boyer.**

9 Q. You're saying that Exhibit 2094 is not a
10 document that Alkeus is responsible for?

11 ATTORNEY FELDSTEIN: Objection to form.

12 Foundation. Beyond the scope.

13 **A. This document again was submitted by**
14 **Dr. Boyer.**

15 Q. So let me ask you a different question.

16 Before this document was submitted, did
17 you review it?

18 ATTORNEY FELDSTEIN: Objection to form and
19 beyond the scope.

20 **A. I do not recall.**

21 Q. You can set it aside.

22 I'm handing you what has been premarked as
23 Exhibit 2095. You recognize this as a
24 September 17, 2024, Alkeus press release. Correct?

25 **A. That's what it says, yes.**

1 Q. Did you have an opportunity to review this
2 document before it was issued?

3 ATTORNEY FELDSTEIN: Object. Beyond the
4 scope. Form.

5 A. I might have read it before it was
6 submitted.

7 Q. Looking at page 2, do you see that as of
8 September 17, 2024, Alkeus was still claiming to
9 the public that gildeuretinol acetate is a novel
10 molecule?

11 ATTORNEY FELDSTEIN: Object to form.
12 Foundation. Beyond the scope.

13 A. In this press release, it simply says that
14 gildeuretinol acetate -- with the same sentence
15 that I've read before.

16 Q. Go ahead and read the sentence.

17 A. "Gildeuretinol acetate is a novel molecule
18 created as a specialized form of deuterated vitamin
19 A designed to reduce the dimerization of vitamin A
20 without disrupting vision."

21 Q. You agree that Alkeus was making that
22 claim publicly as of September 17, 2024. Correct?

23 ATTORNEY FELDSTEIN: Object to form.
24 Foundation. Beyond the scope.

25 A. This is written in a press release issued

1 **by Alkeus Pharmaceuticals.**

2 Q. The press release was issued for the
3 public to see. Is that correct?

4 ATTORNEY FELDSTEIN: Object to form.
5 Foundation. Beyond the scope.

6 **A. The press release is a -- is sent to the**
7 **wire.**

8 Q. You're aware that subsequent to this
9 September 17, 2024, press release, that Alkeus
10 informed the board that they were not going to
11 defend their patent covering gildeuretinol acetate
12 as a novel molecule?

13 ATTORNEY FELDSTEIN: Object to form.
14 Foundation. Beyond the scope.

15 **A. I --**

16 ATTORNEY FELDSTEIN: Misrepresents the
17 record. Excuse me.

18 THE WITNESS: It's what?

19 ATTORNEY FELDSTEIN: Misrepresents the
20 record.

21 **A. I'm not very familiar with this, no.**

22 Q. Is it correct to say that you have not
23 issued a press release informing the public of
24 Alkeus's decision not to defend the patent covering
25 gildeuretinol acetate as a novel molecule?

1 ATTORNEY FELDSTEIN: Objection to form.
2 Foundation. Beyond the scope. Misstates the
3 record.

4 **A. The -- we have not issued any press**
5 **release related to any of the -- these specific IPR**
6 **proceedings.**

7 Q. So I want to go back to your oversight of
8 the gildeuretinol acetate clinical trials.

9 Have you utilized any interns to
10 facilitate your work on any of the gildeuretinol
11 acetate trials?

12 ATTORNEY FELDSTEIN: Counsel, I'm
13 concerned again that you're going beyond the
14 scope of the declaration and seeking
15 commercially sensitive information.

16 I'm also concerned that you may be relying
17 on misappropriated confidential information.

18 Can you represent that none of this is
19 based on information you've learned from someone
20 who may have had a duty of confidentiality to
21 Alkeus?

22 ATTORNEY MILLS: I have a stack of public
23 documents right here that we can go through.

24 ATTORNEY FELDSTEIN: Are you representing
25 that none of the foundation for your questions

1 secured today are based on confidential
2 information from someone who at one point owes a
3 duty of confidentiality to Alkeus?

4 ATTORNEY MILLS: I have no idea what
5 you're talking about. My questions are based on
6 public documents.

7 BY ATTORNEY MILLS:

8 Q. Can you answer the question?

9 **A. Could you repeat the question?**

10 Q. I'm going to ask specifically with
11 regard -- well, I'll repeat the question.

12 Have you utilized any interns to
13 facilitate your work on any of the gildeuretinol
14 acetate trials?

15 ATTORNEY FELDSTEIN: Objection to form.
16 Beyond the scope.

17 **A. I do not know what "facilitate" means.**
18 **Alkeus has hired interns over the years.**

19 Q. Have you interacted with any of those
20 interns?

21 ATTORNEY FELDSTEIN: Objection to form and
22 beyond the scope.

23 **A. What do you mean by "interacted"?**

24 Q. Have you had any interactions with any of
25 the interns at Alkeus over the years?

1 ATTORNEY FELDSTEIN: Objection to form and
2 beyond the scope.

3 **A. I hired several of these interns.**

4 Q. Do you know who Michael Song is, S-o-n-g?

5 ATTORNEY FELDSTEIN: Objection to beyond
6 the scope.

7 **A. Michael Song was one of our interns.**

8 Q. Were you involved in hiring Michael Song?

9 ATTORNEY FELDSTEIN: Objection. Beyond
10 the scope.

11 **A. I do not remember if I'm the one who**
12 **signed his offer letter.**

13 Q. Were you involved in approving the
14 decision to hire Michael Song as an intern?

15 ATTORNEY FELDSTEIN: Objection. Beyond
16 the scope.

17 **A. I do not remember.**

18 **(Exhibit 1074 is marked for**
19 **identification.)**

20 ATTORNEY FELDSTEIN: I'm going to object
21 to Exhibit 1074 for authenticity, relevance,
22 completeness, beyond the scope of the
23 declaration.

24 Is this one of the documents you're
25 representing is public about interns, counsel?

1 ATTORNEY MILLS: Yes. This is a publicly
2 available LinkedIn profile for Michael Song.

3 ATTORNEY FELDSTEIN: It describes him as
4 an intern at Alkeus?

5 ATTORNEY MILLS: Yes.

6 Q. If you look at the second-to-last -- well,
7 we'll get to that. That's counsel's question. But
8 let's just figure out what we're looking at first.

9 So Exhibit 1074, on the bottom left-hand
10 side, do you see a LinkedIn.com web address?

11 **A. I see it.**

12 ATTORNEY FELDSTEIN: Objection to
13 foundation. Beyond the scope.

14 **A. I see that.**

15 Q. Okay. And do you see a picture of an
16 individual above the name Michael Song?

17 ATTORNEY FELDSTEIN: Objection to
18 foundation. Beyond the scope.

19 **A. I see a picture.**

20 Q. Do you recognize the image of the person
21 in the picture as someone that you've seen in the
22 past?

23 ATTORNEY FELDSTEIN: Objection. Beyond
24 the scope.

25 **A. I think so.**

1 Q. And who do you recognize that picture as?

2 A. It looks like --

3 ATTORNEY FELDSTEIN: Objection. Beyond
4 the scope.

5 A. Looks like a photo of Michael Song.

6 Q. Okay. And Michael Song is the intern that
7 was hired at Alkeus under your tenure. Correct?

8 ATTORNEY FELDSTEIN: Objection. Beyond
9 the scope. Form.

10 A. Michael Song was an intern at Alkeus
11 Pharmaceuticals.

12 Q. If you look at the second-to-last page of
13 the stapled document.

14 A. Is it numbered?

15 Q. The numbering is a little bit weird,
16 because when you print from LinkedIn, sometimes it
17 puts objects in front of some of the entries and
18 it's hard to read. So it's actually printed twice
19 to make sure everything's visible.

20 A. Yeah.

21 Q. The page I'm talking about says 2 of 4 at
22 the bottom of it.

23 A. Yes.

24 Q. Okay. Do you see the entry that says
25 "Clinical operations intern"?

1 **A. I see that.**

2 Q. It says "Clinical operations intern at
3 Alkeus Pharmaceuticals Inc., part-time."

4 Do you see that?

5 ATTORNEY FELDSTEIN: Objection. Form --
6 excuse me. Objection. Foundation. Beyond the
7 scope.

8 **A. I see that.**

9 Q. And the dates are August 2020 through
10 February 2022. Is that correct?

11 ATTORNEY FELDSTEIN: Objection.
12 Foundation. Beyond the scope.

13 **A. That's what it says.**

14 Q. Do you dispute that Michael Song was a
15 clinical operations intern at Alkeus
16 Pharmaceuticals part-time from August 2000 to
17 February of 2002 -- '22?

18 ATTORNEY FELDSTEIN: Objection.
19 Excuse me. Objection. Foundation.
20 Beyond the scope.

21 **A. I do not know at all what was his title
22 except for the fact that he was an intern.**

23 Q. Do you dispute the timeline?

24 ATTORNEY FELDSTEIN: Objection.
25 Foundation. Beyond the scope.

1 **A. I do not know or recall the timeline.**

2 **This could be right; this could be wrong.**

3 Q. Okay. You're not disputing or agreeing
4 with it. Right?

5 ATTORNEY FELDSTEIN: Objection.

6 Foundation. Beyond the scope.

7 **A. That's correct.**

8 Q. Okay. The description, the first sentence
9 says, "Aided in the development of novel therapies
10 for dry, age-related macular degeneration,
11 Stargardt disease, and other rare genetic
12 ophthalmic diseases with clinical trials of
13 gildeuretinol (ALK-001)." Correct?

14 ATTORNEY FELDSTEIN: Objection.

15 Foundation. Beyond the scope.

16 **A. Again, that's what's written in that**
17 **document.**

18 Q. The next sentence says, "Performed
19 independent data entry and verification, reviewed
20 ocular imagery, prepared narrative literature
21 reviews and briefs, as well as systematically
22 organized TEASE and SAGA study data." Correct?

23 ATTORNEY FELDSTEIN: Objection.

24 Foundation. Beyond the scope.

25 **A. This is what's written on this.**

1 Q. Okay. Looking back on the first page,
2 under the "About" section, it says, "Michael Song,
3 D2 at Tufts University School of Dental Medicine."

4 Do you see that?

5 ATTORNEY FELDSTEIN: Objection.

6 Foundation. Beyond the scope.

7 **A. I see that written.**

8 Q. Do you have an understanding as to what D2
9 means in relation to Tufts University School of
10 Dental Medicine?

11 ATTORNEY FELDSTEIN: Objection.

12 Foundation. Beyond the scope.

13 **A. I don't.**

14 Q. Okay. Take a look at the next page,
15 please. Actually, so it's page 3 of 10 at the
16 bottom.

17 Do you see under "Education" --

18 **A. Mm-hmm.**

19 Q. -- there are two entries for Tufts
20 University.

21 Do you see that?

22 ATTORNEY FELDSTEIN: Objection.

23 Foundation. Beyond the scope.

24 **A. I see that.**

25 Q. The first most recent entry says "Doctor

1 of Dental Medicine (DMD), Dentistry," with the
2 dates 2023 to 2027.

3 Do you see that?

4 ATTORNEY FELDSTEIN: Objection. Beyond
5 the scope. Foundation.

6 **A. I see -- I see these words written.**

7 Q. The entry under that says "Tufts
8 University Bachelor of Science, BS, Biology,
9 General" between the years of 2019 and 2023.

10 Do you see that?

11 ATTORNEY FELDSTEIN: Objection. Beyond
12 the scope. Foundation.

13 **A. I see those words written.**

14 Q. When Michael Song was hired at Alkeus, did
15 you know that he was an undergraduate student at
16 Tufts University?

17 ATTORNEY FELDSTEIN: Objection. Beyond
18 the scope.

19 **A. When we hire interns, they are usually
20 students in universities.**

21 Q. And in the case of Michael Song in
22 particular, were you aware when he was hired at
23 Alkeus that he was an undergraduate student at
24 Tufts University?

25 ATTORNEY FELDSTEIN: Objection. Beyond

1 the scope. Sorry.

2 **A. I do not recall.**

3 Q. You can set that document aside.

4 **A. The next intern. There's going to be a**
5 **lot.**

6 ATTORNEY FELDSTEIN: Just wait for a
7 question, Doctor.

8 (Exhibit 1075 is marked for
9 identification.)

10 ATTORNEY FELDSTEIN: I object to Exhibit
11 1075 as to authenticity, completeness,
12 relevance, hearsay.

13 Q. So, Dr. Saad, on the first page of Exhibit
14 1075, do you see the LinkedIn.com address for
15 Monica Hennessey at the bottom of the page?

16 **A. I see that.**

17 Q. Okay. And do you see a picture above the
18 name Monica Hennessey on the first page?

19 **A. I do.**

20 Q. Have you ever met a Monica Hennessey that
21 worked at Alkeus?

22 **A. I have.**

23 Q. Do you recognize the photo on the first
24 page of Exhibit 1075 as a photograph of the Monica
25 Hennessey that worked at Alkeus?

1 **A. It looks like Monica Hennessey who worked**
2 **at Alkeus.**

3 Q. On the first page, do you see that there's
4 an entry under "Experience" entitled "Alkeus
5 Pharmaceuticals Inc."?

6 ATTORNEY FELDSTEIN: Objection.
7 Foundation. Beyond the scope.

8 **A. I see that.**

9 Q. The most recent title says "Clinical trial
10 associate" beginning in September 2023. Correct?

11 ATTORNEY FELDSTEIN: Objection.
12 Foundation. Beyond the scope.

13 **A. That's what's written on the document.**

14 Q. Is that consistent with your knowledge as
15 to when Monica Hennessey became a clinical trial
16 associate at Alkeus?

17 ATTORNEY FELDSTEIN: Objection. Beyond
18 the scope.

19 **A. I do not recall.**

20 Q. Do you see the next entry to the page says
21 "Clinical trial associate intern"?

22 ATTORNEY FELDSTEIN: Objection.
23 Foundation. Beyond the scope.

24 **A. I see that written.**

25 Q. And it says that the internship began in

1 February of 2023.

2 Do you see that?

3 ATTORNEY FELDSTEIN: Objection.

4 Foundation. Beyond the scope.

5 **A. I see February 2023 written on it as the**
6 **potential beginning of the internship.**

7 Q. Do you have any basis to disagree that
8 Monica Hennessey began a clinical associate
9 internship at Alkeus in February 2023?

10 ATTORNEY FELDSTEIN: Objection. Beyond
11 the scope. Foundation.

12 **A. I have no idea of when specifically Monica**
13 **Hennessey started.**

14 Q. Do you see the first entry says "Perform
15 statistical analyses on trial data to assist in
16 planning future trials"?

17 ATTORNEY FELDSTEIN: Objection.
18 Foundation. Beyond the scope.

19 **A. I see those words written.**

20 Q. Do you see that the second entry says
21 "Perform site closeout activities including SDV and
22 source document review"?

23 ATTORNEY FELDSTEIN: Objection.
24 Foundation. Beyond the scope.

25 **A. I see those words written.**

1 Q. Do you have an understanding as to what
2 SDV means?

3 ATTORNEY FELDSTEIN: Objection.
4 Foundation. Beyond the scope.

5 **A. Yes.**

6 Q. What is that?

7 **A. Source data verification.**

8 Q. Do you see the third line says "Monitored
9 data in EDC"?

10 ATTORNEY FELDSTEIN: Objection.
11 Foundation. Beyond the scope. Incomplete.

12 **A. I see -- I see these words.**

13 Q. Do you have an understanding what is meant
14 by EDC?

15 **A. Yes.**

16 Q. What is that?

17 **A. Electronic data capture.**

18 Q. Thank you. You can set that document
19 aside.

20 (Exhibit 1076 is marked for
21 identification.)

22 ATTORNEY FELDSTEIN: I'm going to object
23 to Exhibit 1076 for relevance, completeness,
24 authenticity.

25 Q. Dr. Saad, on the first page of Exhibit

1 1076, in the lower left-hand corner there's the
2 LinkedIn.com address for first name Christine, last
3 name X-u. Is that correct?

4 ATTORNEY FELDSTEIN: Objection.
5 Foundation. Beyond the scope.

6 **A. I see that written.**

7 Q. Can you help me with the pronunciation of
8 the last name?

9 **A. It would be pronounced "shoe."**

10 Q. Okay. And do you know a Christine Xu?

11 **A. Do I know a Christine Xu? Yes, I do.**

12 Q. Okay. Christine Xu is an individual who
13 you worked with at Alkeus. Is that correct?

14 ATTORNEY FELDSTEIN: Objection. Beyond
15 the scope.

16 **A. Christine Xu was never an employee of**
17 **Alkeus Pharmaceuticals.**

18 Q. Is it correct that you know Christine Xu
19 in relation to Alkeus Pharmaceuticals?

20 ATTORNEY FELDSTEIN: Objection. Beyond
21 the scope.

22 **A. In connection, yes.**

23 Q. There's a picture above the name Christine
24 Xu in Exhibit 1076. Correct?

25 ATTORNEY FELDSTEIN: Objection.

1 Foundation. Beyond the scope.

2 **A. Yes.**

3 Q. Do you recognize that picture on the front
4 page of Exhibit 1076 as the Christine Xu who you
5 know in relation to Alkeus Pharmaceuticals?

6 ATTORNEY FELDSTEIN: Objection. Beyond
7 the scope.

8 **A. It looks like Christine Xu.**

9 Q. There's an entry for Christine Xu on
10 page 3 of 8 of Exhibit 1076.

11 ATTORNEY FELDSTEIN: Objection.

12 Foundation. Beyond the scope.

13 Q. Do you see that?

14 **A. I do.**

15 Q. The entry has the job title "Clinical
16 research coordinator, Alkeus Pharmaceuticals Inc."
17 Correct?

18 ATTORNEY FELDSTEIN: Objection.

19 Foundation. Beyond the scope.

20 **A. That's what the document says.**

21 Q. Do you disagree that Christine Xu was
22 clinical research coordinator at Alkeus
23 Pharmaceuticals Inc. --

24 ATTORNEY FELDSTEIN: Objection.

25 Q. -- from May 2017 through June 2018?

1 ATTORNEY FELDSTEIN: Objection. Beyond
2 the scope.

3 **A. I do.**

4 Q. Do you see under the entry for Christine
5 Xu for Alkeus Pharmaceuticals, the second sentence
6 says, "Tasks included acquiring all endpoints for
7 patients enrolled at Columbia Harkness Eye
8 Institute"?

9 ATTORNEY FELDSTEIN: Objection.
10 Foundation. Beyond the scope.

11 **A. That's what it says.**

12 Q. Do you disagree with that sentence?

13 ATTORNEY FELDSTEIN: Objection.
14 Foundation. Beyond the scope.

15 **A. Again, I do not know. Christine Xu was**
16 **not an employee of Alkeus Pharmaceuticals.**

17 Q. So do you agree that -- do you disagree
18 that Christine Xu acquired all endpoints for
19 patients enrolled at Columbia's Harkness Eye
20 Institute?

21 ATTORNEY FELDSTEIN: Objection. Beyond
22 the scope.

23 **A. I do not have an opinion.**

24 Q. What was your interaction with Christine
25 Xu in relation to Alkeus?

1 ATTORNEY FELDSTEIN: Objection. Beyond
2 the scope.

3 **A. Christine was one of the research**
4 **coordinators working under Dr. Tsang.**

5 Q. Who is Dr. Tsang?

6 **A. One of the research principal**
7 **investigators.**

8 Q. You can set that document aside.
9 (Exhibit 1077 is marked for
10 identification.)

11 ATTORNEY FELDSTEIN: I'm going to object
12 to Exhibit 1077. Relevance, completeness,
13 authenticity.

14 Q. So, Dr. Saad, do you see in the bottom
15 left-hand corner of the first page of Exhibit 1077
16 there's the Linkedin.com address for Cyriac Joyce?

17 ATTORNEY FELDSTEIN: Objection.
18 Foundation. Beyond the scope.

19 **A. I see those words.**

20 Q. Do you see also on the first page, there
21 is a picture above the name Cyriac Joyce?

22 ATTORNEY FELDSTEIN: Objection.
23 Foundation. Beyond the scope.

24 **A. I see that.**

25 Q. Do you recognize that individual?

1 **A. It looks like Cyriac Joyce.**

2 Q. How do you know Cyriac Joyce?

3 **A. Cyriac Joyce was one of our interns.**

4 Q. Please take a look at the page that says 2
5 of 5 of Exhibit 1077.

6 Do you see an entry there that says
7 "Clinical operations intern, Alkeus Pharmaceuticals
8 Inc. internship"?

9 ATTORNEY FELDSTEIN: Objection.
10 Foundation. Beyond the scope.

11 **A. I see those words.**

12 Q. Do you disagree with that description?

13 ATTORNEY FELDSTEIN: Objection.
14 Foundation. Beyond the scope.

15 **A. Again, interns are hired as interns. I**
16 **would not know specifically if he was a clinical**
17 **operations intern.**

18 Q. Do you see the dates July 2022 through
19 December 2022?

20 ATTORNEY FELDSTEIN: Objection.
21 Foundation. Beyond the scope.

22 **A. I see those dates.**

23 Q. Do you have any disagreement that Cyriac
24 Joyce was an intern at Alkeus Pharmaceuticals from
25 approximately July 2022 through December 2022?

1 ATTORNEY FELDSTEIN: Objection. Form.

2 Foundation. Beyond the scope.

3 **A. I do not recall at all the dates that**
4 **Cyriac Joyce was an intern.**

5 Q. The first line of the entry lists
6 "Participated in management of ongoing clinical
7 trials."

8 Do you see that?

9 ATTORNEY FELDSTEIN: Objection.
10 Foundation. Beyond the scope.

11 **A. I see those words.**

12 Q. The second entry says, "Verified clinical
13 trial data quality in real time. "

14 Do you see that?

15 ATTORNEY FELDSTEIN: Objection.
16 Foundation. Beyond the scope.

17 **A. I see those words.**

18 Q. The third entry says, "Tracked patient
19 recruitment and progress."

20 Do you see that?

21 ATTORNEY FELDSTEIN: Objection.
22 Foundation. Beyond the scope.

23 **A. I see that. It's also missing a semicolon**
24 **at the end.**

25 Q. The fourth line says, "Assisted in

1 performing remote monitoring of clinical data and
2 regulatory documents."

3 Do you see that?

4 ATTORNEY FELDSTEIN: Objection.

5 Foundation. Beyond the scope.

6 **A. I see that.**

7 Q. The next line says, "Reviewed, maintained,
8 and tracked clinical trial regulatory documents."

9 Do you see that?

10 ATTORNEY FELDSTEIN: Objection.

11 Foundation. Beyond the scope.

12 **A. I see the words.**

13 Q. The next line says, "Assisted in clinical
14 or preclinical data collection and analysis."

15 Do you see that?

16 ATTORNEY FELDSTEIN: Objection.

17 Foundation. Beyond the scope.

18 **A. I see that.**

19 Q. You can set that document aside.

20 (Exhibit 1078 is marked for
21 identification.)

22 ATTORNEY FELDSTEIN: I'm going to object
23 to Exhibit 1078 for authenticity, relevance, and
24 completeness.

25 Q. Looking at page 1 of Exhibit 1078, in the

1 bottom left-hand corner, you see the Linkedin.com
2 web address for Runyao Tong. Correct?

3 ATTORNEY FELDSTEIN: Objection.
4 Foundation. Beyond the scope.

5 **A. I see something that say "Tong" at the**
6 **bottom of the page.**

7 Q. And you see the name on the firsthand page
8 that says Runyao, R-u-n-y-a-o?

9 **A. I see that.**

10 Q. Do you know a Runyao Tong?

11 **A. I believe so, yes.**

12 Q. Runyao Tong was an intern at Alkeus.
13 Correct?

14 ATTORNEY FELDSTEIN: Objection. Beyond
15 the scope.

16 **A. I believe so.**

17 Q. And the picture that's on the first page
18 of Exhibit 1078, you recognize that as an image of
19 Runyao Tong, the Alkeus intern. Correct?

20 **A. It looks like it.**

21 Q. Please take a look at page 2 of the
22 document. Do you see an entry at Alkeus
23 Pharmaceuticals Inc., part-time as an intern?

24 ATTORNEY FELDSTEIN: Objection. Beyond
25 the scope. Foundation.

1 **A. I see that.**

2 Q. Do you see it says that Runyao Tong was an
3 intern at Alkeus from January 2023 through May
4 2023?

5 ATTORNEY FELDSTEIN: Objection.

6 Foundation. Beyond the scope.

7 **A. That's what the -- that's what the date --**
8 **that's the dates that are indicated.**

9 Q. Do you dispute those dates?

10 ATTORNEY FELDSTEIN: Objection.

11 Foundation. Beyond the scope.

12 **A. I do not remember the exact dates that he**
13 **was an intern.**

14 Q. The first bullet point says, "Verified the
15 clinical trial data in 30 sites and examined their
16 quality."

17 Do you see that?

18 ATTORNEY FELDSTEIN: Objection.

19 Foundation. Beyond the scope.

20 **A. I see those words.**

21 Q. The second line says, "Assist the
22 scientists in performing remote monitoring of
23 clinical data and regulatory documents."

24 Do you see that?

25 ATTORNEY FELDSTEIN: Objection.

1 Foundation. Beyond the scope.

2 **A. I see those words.**

3 Q. And all the way at the bottom of the
4 entry, the second-to-last entry, do you see where
5 it says, "Assist the scientists in clinical data
6 collection and analysis"?

7 ATTORNEY FELDSTEIN: Objection,
8 foundation, and beyond the scope.

9 **A. I see those words.**

10 Q. On the bottom of page 3 of 8 of Exhibit
11 1078, do you see an entry under "Education" at
12 Boston College?

13 ATTORNEY FELDSTEIN: Objection.
14 Foundation. Beyond the scope.

15 **A. I see an entry, yes.**

16 Q. The entry indicates that Runyao Tong was
17 an undergraduate student between 2020 and 2024.
18 Correct?

19 ATTORNEY FELDSTEIN: Objection.
20 Foundation. Beyond the scope.

21 **A. That's what the entry seems to say.**

22 Q. Do you dispute that Runyao Tong was an
23 undergraduate student when he was hired at Alkeus
24 as an intern?

25 ATTORNEY FELDSTEIN: Objection. Beyond

1 the scope.

2 **A. I cannot confirm or -- or not confirm.**

3 Q. You can set that document aside.

4 Please take a look at paragraph 7 of your
5 declaration.

6 **A. Which one?**

7 Q. Paragraph 7.

8 **A. 7. Yeah.**

9 Q. In the second sentence, you state that you
10 cofounded Alkeus in 2010 together with Ilyas
11 Washington, PhD, the inventor of the '045 patent.

12 Do you see that?

13 **A. I see that.**

14 Q. When you decided to found Alkeus with
15 Ilyas Washington, were you familiar with his
16 qualifications?

17 ATTORNEY FELDSTEIN: Objection. Beyond
18 the scope. Form.

19 **A. I'm not sure what you mean by**
20 **"qualifications." I knew he was a professor at**
21 **Columbia University.**

22 Q. Other than being a professor at
23 qualification -- withdrawn. Let me start over.

24 Other than being professor at Columbia
25 University, did you know anything else about his

1 qualifications?

2 ATTORNEY FELDSTEIN: Objection. Form.

3 And beyond the scope.

4 **A. I had never met Dr. Washington prior to me**
5 **becoming familiar with his research and deciding**
6 **together to cofound Alkeus.**

7 Q. So when you were deciding to cofound
8 Alkeus with him, did you investigate his research?

9 ATTORNEY FELDSTEIN: Objection. Beyond
10 the scope. Form.

11 **A. I do not know what "investigate" means.**

12 Q. Okay. So just a moment ago, you said you
13 had never met Dr. Washington prior to becoming
14 familiar with his research and deciding together to
15 cofound Alkeus?

16 **A. That's correct.**

17 Q. Okay. So my question is what did you do
18 to become familiar with his research before
19 deciding to cofound Alkeus with him?

20 ATTORNEY FELDSTEIN: Counsel, this is also
21 beyond the scope of his declaration. It has
22 nothing to do with his declaration. Either
23 withdraw the question or we'll stop here and
24 contact the board.

25 Q. Are you going to answer the question?

1 ATTORNEY FELDSTEIN: He -- we're going to
2 wait for board direction unless you withdraw the
3 question. I'll stop the deposition. We'll
4 contact the board. You've gone really, really
5 far -- way beyond his declaration. What
6 research and investigation he did in founding
7 Alkeus is beyond the scope of this deposition.
8 If you don't withdraw the question, we need to
9 stop the deposition now and contact the board
10 for guidance.

11 ATTORNEY MILLS: Sir, that's not correct,
12 counsel. You have been obstructing the
13 deposition the entire day. He testified about
14 his founding of Alkeus with Ilyas Washington.
15 You have put at issue the founding of the
16 company as well as his conduct, Dr. Saad, in
17 running the company. And you can't pick and
18 choose which questions you're going to let him
19 answer. If you want to issue an instruction, it
20 would be improper, but at least then there would
21 be an instruction.

22 ATTORNEY FELDSTEIN: I'm not picking and
23 choosing. We're going to let the board resolve
24 it. You and I disagree here, and we'll let the
25 board resolve it, because we could do that

1 before the questions are answered.

2 ATTORNEY MILLS: So are you refusing to
3 let him answer the question?

4 ATTORNEY FELDSTEIN: I'm saying if you
5 don't withdraw the question, we need the board
6 guidance.

7 ATTORNEY MILLS: So you're refusing to let
8 him answer the question?

9 ATTORNEY FELDSTEIN: Without board
10 guidance, correct.

11 Q. Okay. Are you following counsel's
12 instruction?

13 A. I am.

14 Q. Okay.

15 ATTORNEY FELDSTEIN: And I take it you
16 don't want board guidance?

17 ATTORNEY MILLS: Your instruction's
18 improper.

19 ATTORNEY FELDSTEIN: I didn't, in fact,
20 instruct the witness. But the record is what it
21 is.

22 Q. You agree that Ilyas Washington is not an
23 ophthalmologist?

24 ATTORNEY FELDSTEIN: Objection. Beyond
25 the scope.

1 **A. Ilyas Washington is not an**
2 **ophthalmologist.**

3 Q. Thank you.

4 As part of your job responsibilities at
5 Alkeus regarding the development of gildeuretinol
6 acetate, do you give interviews to the press?

7 ATTORNEY FELDSTEIN: Objection. Beyond
8 the scope.

9 **A. I have given interviews with the press.**

10 Q. Do you recall giving an interview to the
11 Boston Business Journal?

12 ATTORNEY FELDSTEIN: Objection. Beyond
13 the scope.

14 **A. I do not recall.**

15 Q. Do you recall telling Rowan Walrath at the
16 Boston Business Journal in June 2023 that Mr. Boger
17 left Alkeus Pharmaceuticals because you told him
18 that you wanted to wait to build the company until
19 there were clinical results?

20 ATTORNEY FELDSTEIN: Objection.
21 Foundation. Beyond the scope.

22 **A. I do not recall.**

23 Q. Do you recall giving an interview to Ben
24 Fiddler at Biopharma Dive on or about June 5, 2023?

25 ATTORNEY FELDSTEIN: Objection. Beyond

1 the scope.

2 **A. I do not recall.**

3 Q. Do you recall telling Mr. Fiddler that you
4 largely stayed away from venture funding for Alkeus
5 Pharmaceuticals because you were reluctant to
6 relinquish control over the company?

7 ATTORNEY FELDSTEIN: Objection. Beyond
8 the scope. Foundation.

9 **A. I do not remember those words.**

10 ATTORNEY MILLS: No further questions.

11 ATTORNEY FELDSTEIN: Okay. We'll take a
12 break and we'll be back.

13 (Recess taken from 2:02 p.m.
14 to 2:39 p.m.)

15 ATTORNEY FELDSTEIN: We can go back on.

16 Let me first say you brought up, Jad, a
17 number of times about potential necessity to
18 address confidentiality. We'd like to have the
19 transcript marked as outside counsel's eyes only
20 for now until we can work out an appropriate
21 protective order for the board.

22 ATTORNEY MILLS: For the benefit of both
23 parties and the board, we would ask you to -- as
24 quickly as you can to go through and narrow what
25 you are designating, so that we can have a

1 redacted public transcript as quickly as
2 possible that minimizes the amount that we would
3 then have to redact our briefing it, sir.

4 ATTORNEY FELDSTEIN: And let me ask you
5 some questions now, Doctor.

6 EXAMINATION

7 BY ATTORNEY FELDSTEIN:

8 Q. Do you have your declaration, Exhibit
9 2191?

10 A. I may not have all the exhibits.

11 Q. Just your declaration, sir.

12 A. On which page?

13 Q. Paragraph 4 of Exhibit 2191.

14 A. Yes.

15 Q. The first dark bullet are exhibits related
16 to TEASE-1. Correct?

17 A. Yes.

18 Q. And is it correct that 2086, 2087, 2088,
19 2089, and 2090 are all abstracts related to
20 TEASE-1?

21 ATTORNEY MILLS: Objection to form.

22 A. Each of these exhibits correspond to
23 documents submitted to IOVS or to the American
24 Academy of Ophthalmologists.

25 Q. I'm sorry. What is IOVS?

1 **A. Investigative Ophthalmology and Vision**
2 **Science.**

3 Q. Okay. To your understanding, are the IOVS
4 abstracts peer-reviewed?

5 ATTORNEY MILLS: Objection to form.
6 Foundation. To the extent it calls for
7 speculation.

8 **A. The -- when submitting an abstract, IOVS,**
9 **I believe that these abstracts are indeed**
10 **peer-reviewed by the IOVS specialists.**

11 Q. And what's the basis for that
12 understanding?

13 **A. I had seen that on their website.**

14 Q. Okay. And the abstracts submitted to
15 American Academy of Ophthalmology, to your
16 understanding, are those peer-reviewed?

17 **A. It is also my understanding that the**
18 **American Academy of Ophthalmology abstracts are**
19 **peer-reviewed prior to being accepted for**
20 **presentation at the conference.**

21 ATTORNEY MILLS: I object to the question
22 on the basis of form, and lack of foundation to
23 the extent it calls for speculation.

24 Q. What's the basis of your understanding,
25 Doctor?

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1 **A. I have seen that on their website as well.**

2 Q. Okay.

3 Also, still in paragraph 4 of the second
4 black bullet is for TEASE-3. Correct?

5 **A. Yes.**

6 Q. And Exhibit 2091 is also submitted to
7 IOVS. Correct?

8 **A. Yes, it is.**

9 Q. To your understanding, was Exhibit 2091
10 peer-reviewed?

11 ATTORNEY MILLS: Objection to form.
12 Foundation. To the extent it calls for
13 speculation.

14 **A. I believe that 2091 followed the same**
15 **review process as the other exhibits submitted to**
16 **IOVS.**

17 Q. Go down to SAGA, Exhibit 2094.

18 Is Exhibit 2094 a SAGA abstract submitted
19 to American Academy of Ophthalmology?

20 **A. Yes.**

21 Q. To your understanding, was that
22 peer-reviewed?

23 ATTORNEY MILLS: Objection. Form.
24 Foundation. To the extent it calls for
25 speculation.

1 **A. Same thing. So I believe that any**
2 **document submitted to American Academy of**
3 **Ophthalmology for admitting is also peer-reviewed.**

4 Q. In your cross-examination, there was some
5 discussion of image reading for TEASE-1.

6 Do you recall that?

7 **A. Yes, I recall that.**

8 Q. Okay. Was there a centralized reading
9 center for the image reading for TEASE-1?

10 ATTORNEY MILLS: Objection to form.

11 **A. So in TEASE-1, the image were read**
12 **centralized by -- the primary read of our images**
13 **was done centralized by myself and Gabrielle**
14 **DeBartolomeo. So we acted as some sort of**
15 **centralized reading center as well.**

16 Q. Do you have an understanding of why, if at
17 all, a centralized reading center is important in
18 such image reading?

19 ATTORNEY MILLS: Objection to form.

20 **A. I believe that centralized reading leads**
21 **to more consistent results.**

22 Q. What is your basis for that belief?

23 **A. Because the graders can be adequately --**
24 **well, have the right amount of time to spend on the**
25 **grading, and are also trained to verify the**

1 **test-retest variability.**

2 Q. Were -- was Alkeus blinded when it was
3 grading the images for TEASE-1?

4 ATTORNEY MILLS: Objection. Form.

5 **A. So the -- the -- myself and Gabrielle**
6 **DeBartolomeo, we were fully blinded to treatment**
7 **allocation during the grading of all images of**
8 **TEASE-1.**

9 Q. And what does it mean that you were fully
10 blinded to treatment allocation during the grading
11 of all images of TEASE-1?

12 **A. It means that for the randomized patients,**
13 **we had no knowledge as to whether a patient**
14 **received a drug or a placebo.**

15 Q. So was it the case that when you and your
16 colleague were creating images from TEASE-1, that
17 you didn't know and couldn't know if an image was
18 from a patient on placebo versus an actual drug?

19 ATTORNEY MILLS: Objection. Form.

20 **A. We had no way of knowing.**

21 Q. Okay. Can you explain just generally what
22 grading and image in this context entails?

23 ATTORNEY MILLS: Objection to form to the
24 extent it calls for a narrative, which is
25 outside the scope of redirect.

1 **A. Well, it involves opening an image,**
2 **delineating the size of a lesion, in order to**
3 **obtain a number which is essentially the size of**
4 **the retinal atrophic lesions.**

5 Q. And how does one delineate the size of a
6 lesion in an image?

7 **A. You --**

8 ATTORNEY MILLS: Objection to form,
9 foundation, and to the extent it calls for
10 speculation.

11 **A. You take a mouse and you essentially**
12 **delineate around a dark region of the retina, which**
13 **is relatively easy to do.**

14 Q. Okay. To your understanding, are there
15 any regulatory or professional certifications
16 related to this type of image reading?

17 ATTORNEY MILLS: Objection to form.
18 Foundation. To the extent it calls for
19 speculation. Outside the scope of redirect.

20 **A. I believe that I've never seen any**
21 **specific degrees or national or even local**
22 **certification for -- for that, except maybe at the**
23 **level itself of a reading center. But there's**
24 **nothing that's accredited to be a grader in a**
25 **reading center.**

1 Q. Was your grading -- let me start again.

2 Was the grading of images conducted by
3 Alkeus during TEASE-1, was that ever checked or
4 validated by an outside reading center?

5 ATTORNEY MILLS: Objection to form.

6 Foundation. To the extent it calls for
7 speculation. Outside the scope of redirect.

8 A. Yes.

9 Q. Can you explain what was done?

10 A. Alkeus has hired an external central
11 reading center to perform grading in the same
12 blinded fashion of the images of TEASE-1.

13 Q. They were taking the same data that Alkeus
14 had reviewed and reviewing it independently? Is
15 that what you're explaining?

16 ATTORNEY MILLS: Objection. Form. The
17 question is leading, which is improper on
18 redirect. It's outside of the scope of redirect
19 to lead the witness.

20 A. No. They actually -- that's not correct.
21 They actually received -- the centralized reading
22 center received blinded images exactly as they were
23 received by the sites in order for them to be
24 performing grading in a blinded fashion.

25 Q. And what, if any, was determined by the

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1 external centralized reading center with respect to
2 the TEASE-1 data as compared to the grading that
3 was done internally by Alkeus?

4 ATTORNEY MILLS: Objection to form.

5 Leading, which is outside the scope of direct.
6 The question asks for facts that were not
7 provided in Dr. Saad's declaration that were
8 withheld along with all of the other information
9 that was withheld, which you prevented us from
10 inquiring into repeatedly today. And it's
11 improper for you to try to introduce new
12 evidence now on redirect.

13 Q. Do you need the question read back,
14 Doctor?

15 A. No, I understand the question.

16 The -- the -- that external verification
17 essentially -- and indicated -- so, essentially,
18 what you obtained from the centralized reading
19 center is a new data set, and you compare this data
20 set to our data set, the one that was graded by
21 myself and Gabrielle DeBartolomeo. The results
22 indicated a correlation of results of 99.9 percent
23 between what we had done and what the centralized
24 reading center had done.

25 Q. And by "correlation," is that another way

1 of referring to accuracy?

2 ATTORNEY MILLS: Objection to form. The
3 question is leading, which is improper on
4 redirect.

5 A. Well, it indicates that there's a --
6 there's a very strong correlation between the two,
7 meaning that the results that were obtained
8 originally were most likely accurate, at least
9 compared to the other reading center.

10 Q. The data for TEASE-1, have you ever
11 submitted that to the FDA?

12 ATTORNEY MILLS: Objection to form. This
13 is outside the scope. This is very much outside
14 the scope.

15 A. The --

16 ATTORNEY MILLS: So, counsel, you can't
17 preclude me from asking questions throughout the
18 deposition and then elicit completely new
19 testimony on a different subject matter on
20 redirect. It's improper.

21 Q. Can you answer the question, Doctor?

22 ATTORNEY MILLS: So we're going to have to
23 call the board.

24 ATTORNEY FELDSTEIN: Okay. Call the
25 board.

1 (Discussion off the record.)

2 BY ATTORNEY FELDSTEIN:

3 Q. Did you come to the understanding, at all,
4 Doctor, whether opposing counsel was challenging
5 the validity of the TEASE-1 data?

6 ATTORNEY MILLS: Objection to form.

7 **A. Could you repeat the question?**

8 Q. During your cross-examination by opposing
9 counsel, did you come to the understanding on
10 whether opposing counsel was challenging the
11 validity of the TEASE-1 data?

12 ATTORNEY MILLS: Objection to form.

13 Foundation. The witness has no basis to testify
14 as to what's in counsel's mind or counsel's
15 legal strategy.

16 **A. I do not have anything in counsel's mind
17 or strategy, but it was a feeling that I generally
18 had.**

19 Q. Okay. Did you have bases to -- has the
20 TEASE-1 data been -- well, let me do it this way.

21 Let's go to Exhibit 2089. I believe it
22 was something that hopefully is in your pile.

23 Do you have 2089?

24 **A. No.**

25 Q. It looks like this.

1 **A. I do not have this one in my pile.**

2 ATTORNEY MILLS: All right. So --

3 ATTORNEY FELDSTEIN: We won't do it that
4 way, then.

5 ATTORNEY MILLS: Yeah.

6 ATTORNEY FELDSTEIN: Save your objection,
7 Jad.

8 Q. You discussed -- do you recall discussing
9 the clinical trial protocols in your
10 cross-examination earlier, Doctor?

11 ATTORNEY MILLS: Objection. Form.

12 **A. I believe we discussed several protocols.**

13 Q. And the protocol for TEASE-1 was one of
14 the clinical trial protocols that you discussed on
15 cross-examination. Is that correct?

16 **A. Yes, we discussed the TEASE-1 clinical**
17 **trial.**

18 Q. And I believe you testified that you were
19 involved in the preparation of the TEASE-1 clinical
20 trial protocol. Is that correct?

21 **A. Yes, I was.**

22 Q. Other than you, were there others who
23 reviewed the TEASE-1 clinical trial protocol before
24 it was run?

25 ATTORNEY MILLS: Objection to form and to

1 scope. You impeded my questioning as to
2 personnel at Alkeus who were involved in the
3 preparation of the trial other than Dr. Saad,
4 and it's improper for you now to elicit
5 additional testimony about additional viewers at
6 this time.

7 Q. Can you answer the question, Doctor?

8 **A. Clinical trial protocols are usually**
9 **reviewed by more than just the company developing**
10 **the trial. So, for example, the TEASE protocol was**
11 **reviewed by the clinical investigators, which are**
12 **all the physicians contributed to the TEASE-1**
13 **protocol. This was before its implementation and**
14 **finalization.**

15 After that, this protocol was submitted
16 for a review by institutional review boards at each
17 of the clinic that were performing for review.
18 And, finally, the protocol was -- and it may have
19 been said before, but -- last but not least, the
20 protocol is submitted to the FDA for review and --
21 and authorization to proceed.

22 ATTORNEY MILLS: I object to the question
23 as narrative.

24 Q. The clinicians, you said they're all
25 physicians. Were they ophthalmologists?

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1 **A. All of the -- all of the physicians were**
2 **ophthalmologists, yes.**

3 Q. Do you recall discussing natural history
4 patients as part of TEASE-1?

5 **A. Could you repeat the question?**

6 Q. Do you recall on cross-examination
7 discussing the inclusion of natural history patient
8 data as part of TEASE-1?

9 **A. Yes, I do recall that.**

10 Q. When was the inclusion of natural history
11 patients included as part of the TEASE-1 protocol?

12 ATTORNEY MILLS: Objection to form.

13 **A. We included these patients during the**
14 **blinded portion of the TEASE-1 trial.**

15 Q. Has Alkeus evaluated the data without --
16 let me start again.

17 Has Alkeus evaluated the TEASE-1 data
18 without the natural history patient contribution?

19 ATTORNEY MILLS: Objection to form.

20 Outside the scope. Foundation.

21 **A. Yes, we did.**

22 Q. And how did the results from TEASE-1
23 without natural history patients compare to the
24 data with the natural history patients for the
25 protocol?

1 ATTORNEY MILLS: So I'm going to object to
2 the question as outside the scope of the
3 redirect. The board rules require that you
4 provide the data underlying these studies that
5 you want to rely upon. You withheld that data.
6 You failed to produce it. You failed -- or you
7 refused to let me inquire as to Dr. Saad
8 regarding the details of the study throughout
9 the deposition. And after sandbagging me for
10 hours, you're now eliciting new testimony from
11 Dr. Saad regarding new data that you had not
12 previously provided.

13 And so I object to the question. This
14 entire line of questioning is inappropriate.

15 Q. Do you need the question back, Doctor?

16 A. No, I don't.

17 **The -- the -- with or without the use of**
18 **natural history, the results continued to remain**
19 **statistically significant with a very low p-value**
20 **indicating the statistical significance of those**
21 **results. These results have been presented at**
22 **several conferences now at this point.**

23 Q. Do you recall discussing on
24 cross-examination questions about references to
25 gildeuretinol as a, quote, novel molecule?

1 **A. I do recall.**

2 Q. What is your understanding of what it
3 means to be a novel molecule?

4 **A. Well, in the pharmaceutical setting, a**
5 **novel molecule is a molecule that has never been**
6 **FDA-approved. It's essentially a new chemical or a**
7 **new molecular entity.**

8 Q. In that context, is it correct to describe
9 gildeuretinol as a novel molecule?

10 ATTORNEY MILLS: Objection to form.

11 Foundation. The witness has testified that he's
12 not an attorney.

13 **A. It is -- it is a, like I said, a new**
14 **chemical entity or a new molecular entity with**
15 **respect to pharmaceutical jargon. It may not be**
16 **a -- what, let's say, a patent or other -- other**
17 **industries would characterize it.**

18 Q. Let me ask you about that.

19 Do you have a legal understanding of the
20 term "novelty" in the context of patent law?

21 **A. I do not have a legal understanding of**
22 **"novelty." All I know is that if a patent is**
23 **issued, I understand that it needs to be -- that**
24 **it's because the US Patent Office has deemed it to**
25 **be novel.**

1 Q. Have you used -- have you -- let me start
2 again.

3 Have you used -- let me start for the
4 third time.

5 Have you in -- fourth time.

6 Are you aware of Alkeus using the term
7 "novel" with respect to gildeuretinol in a patent
8 law context?

9 ATTORNEY MILLS: Objection to form,
10 foundation, and outside the scope.

11 **A. I do not think so, no.**

12 Q. Do you recall discussing centralized
13 reading centers on your cross-examination?

14 **A. I do.**

15 Q. Do you recall discussions of whether the
16 TEASE-1 centralized reading center had access to
17 patient-identifying code numbers?

18 **A. I remember we had a discussion on that**
19 **topic.**

20 Q. Do you recall discussions of whether the
21 TEASE-1 centralized reading center had access to
22 temporal information for image sequence?

23 **A. I think we discussed that.**

24 Q. Why did the centralized reading center
25 have access to both patient-identifying codes and

1 temporal information for image sequences?

2 ATTORNEY MILLS: Objection to form.

3 Outside the scope.

4 A. Well, you need a patient ID in order to be
5 able to understand that this is coming from a
6 specific -- a given patient. And the temporal
7 information is usually built into the images.

8 Q. Did you have an understanding of whether
9 the centralized reading center had a standard
10 protocol with respect to the inclusion of
11 patient-identifying codes and temporal sequence
12 information?

13 ATTORNEY MILLS: Objection to form, and to
14 the extent it calls for speculation.

15 A. The -- at the very least, after reviewing
16 or discussing with several centralized reading
17 centers, it is my understanding that they follow
18 very similar standard operating procedure that does
19 include knowing the temporal information and
20 knowing the patient ID of each of the grader.

21 Q. Have each of the centralized reading
22 centers that Alkeus has used, to your knowledge,
23 been fully blinded to randomization on drug or
24 placebo?

25 A. So, for example, in -- so in the case of

1 **TEASE-1, Alkeus personnel was blinded to drug and**
2 **placebo. We graded in a very similar fashion as**
3 **any other centralized reading center would have**
4 **done, including the one that we sent it for**
5 **verification. In all the centralized reading**
6 **centers that have discussed or interviewed, the**
7 **standard operating procedures with respect to this**
8 **grading was very similar. It doesn't mean that one**
9 **could not use a bespoke approach and change that if**
10 **they wanted to.**

11 ATTORNEY FELDSTEIN: Okay. No further
12 questions, Doctor.

13 EXAMINATION

14 BY ATTORNEY MILLS:

15 Q. Dr. Saad, when I stopped asking you
16 questions, the time was 2:02 p.m. Eastern time, and
17 when you walked back into the room, it was 40
18 minutes later.

19 Do you disagree with that?

20 **A. I do not remember the times. I didn't**
21 **check it.**

22 Q. Okay. So you left the room with counsel
23 for 40 minutes, and then you came in and provided
24 the testimony that was just elicited during
25 redirect. Is that correct?

1 ATTORNEY FELDSTEIN: Object to form and
2 foundation.

3 **A. When I returned, I provided answers to the**
4 **questions that were asked.**

5 Q. After spending 40 minutes outside the
6 deposition room, having left with counsel?

7 ATTORNEY FELDSTEIN: Object to form and
8 foundation.

9 **A. After -- after being outside of this room,**
10 **in a break room.**

11 Q. During the redirect, you were asked
12 questions about peer review of the Alkeus clinical
13 trial abstracts.

14 Do you recall that?

15 **A. I do.**

16 Q. You testified that you've seen on the
17 websites of those journals information about peer
18 review of abstracts. Is that correct?

19 **A. That's what I said.**

20 Q. Okay. Did you personally engage in any
21 correspondence with those journals regarding peer
22 review of those specific Alkeus abstracts?

23 ATTORNEY FELDSTEIN: Object to form.

24 **A. I -- can you rephrase? I'm not sure what**
25 **you mean by "correspondence."**

1 Q. Were you personally involved in
2 corresponding with those journals during a
3 peer-review process?

4 ATTORNEY FELDSTEIN: Object to form.

5 **A. No. I was not the one submitting them, so**
6 **I would not be the one doing any of the**
7 **correspondence.**

8 Q. And here at the deposition today -- well,
9 let me start over with a different question.

10 In your declaration, you don't cite any
11 documents from any source discussing or detailing a
12 peer-review process for any of the Alkeus
13 abstracts. Correct?

14 ATTORNEY FELDSTEIN: Object to form and
15 foundation.

16 **A. In my declaration, I neither mention**
17 **whether they are or whether they are not**
18 **peer-reviewed.**

19 Q. When you showed up at the deposition, you
20 did not bring with you documents providing a
21 peer-review correspondence between Alkeus and any
22 of those journals. Correct?

23 ATTORNEY FELDSTEIN: Object to form.
24 Foundation.

25 **A. I did not bring any of the documentation**

1 **indicating that they're -- the peer review or**
2 **non-peer-review process of these journals.**

3 Q. Do you know who Luke Timmerman is?

4 ATTORNEY FELDSTEIN: Object to form.

5 Foundation. Beyond the scope of the redirect.

6 **A. Luke Timmerman is a journalist.**

7 Q. And he writes something called "The
8 Timmerman Report"?

9 ATTORNEY FELDSTEIN: Objection. Form.

10 Foundation. Beyond the scope of the redirect.

11 **A. I've heard of this.**

12 Q. Sometime around the 5th of June 2023, you
13 and Mr. Boger gave an interview to Luke Timmerman
14 regarding Bain Capital's decision to provide the
15 Series B financing to Alkeus. Correct?

16 ATTORNEY FELDSTEIN: Objection to form,
17 foundation, and beyond the scope of the
18 redirect.

19 **A. I don't remember very clearly, no.**

20 Q. You don't remember Luke Timmerman
21 describing ALK-001 as your, quote/unquote,
22 "obsession"?

23 ATTORNEY FELDSTEIN: Objection. Form.

24 Foundation. Beyond the scope.

25 **A. "Obsession" is a word that I very rarely**

1 **use, so I would remember. But I don't remember**
2 **that -- that one.**

3 Q. And with regard to the TEASE-1 data, you
4 don't recall telling Luke Timmerman that the data
5 haven't yet been published in a peer-reviewed
6 medical journal?

7 ATTORNEY FELDSTEIN: Objection. Form.
8 Foundation. Beyond the scope of the redirect.

9 **A. I do not remember, no.**

10 Q. You mentioned the reading centers that you
11 spoke to. So is the reading center that you used
12 in the SAGA trial the same reading center that you
13 used to double-check your reading for the TEASE-1
14 trial?

15 **A. I believe that it's the same.**

16 Q. How many other reading centers did you
17 speak to for the Alkeus clinical trials?

18 **A. The question is vague. Can you make it**
19 **clearer?**

20 Q. Well, you were offering a lot of testimony
21 about standard operating procedures at reading
22 centers, and so I want to know what the N-value
23 is --

24 **A. Yeah.**

25 Q. -- for your sample.

1 **A. I would say approximately five or six.**

2 Q. Okay. Tell me the names of the reading
3 centers that you're including within your data set
4 for reading center standard operating procedures.

5 **A. I think again that would be something**
6 **privileged, and I'm not -- I'm not in a position to**
7 **disclose these names.**

8 Q. So counsel hasn't objected on the basis of
9 privilege. You have put it at issue by testifying
10 about it, and so now you need to tell me the
11 identities of the data set that you're using for
12 the testimony that you offered.

13 ATTORNEY FELDSTEIN: If you have
14 confidentiality, Doctor, you should consider
15 those and not be bullied by counsel.

16 **A. I believe that I do have confidentiality**
17 **obligations, and, unfortunately, I'll have to**
18 **follow them.**

19 Q. So your counsel has designated the
20 transcript as confidential, which means that
21 nothing will be shared until counsel has the
22 opportunity to enforce any confidentiality
23 obligations that you have.

24 So confidentiality is no excuse to hide
25 relevant information from the PTAB judges who are

1 tasked by Congress with evaluating and adjudicating
2 this case.

3 **A. Same answer. I think I have my**
4 **obligations with respect to the confidentiality.**
5 **If you want to find reading centers, you can Google**
6 **them and you'll find a list of reading centers.**

7 Q. So you are refusing to identify the list
8 of reading centers that you're including in the
9 data set that you used to make generalizations
10 about standard operating procedures. Correct?

11 **A. None of these are included in our data**
12 **set.**

13 Q. You made generalizations about standard
14 operating procedures at data reading centers based
15 your conversations with specific reading centers
16 that you considered for the Alkeus clinical trials.
17 Do you recall that testimony?

18 **A. Yes.**

19 Q. So I'm asking you to tell me the
20 identities of the reading centers that you are
21 including within your testimony about standard
22 operating procedures.

23 **A. And I'll have to respectfully decline to**
24 **disclose these names due to those possible**
25 **confidentiality obligations.**

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1 Q. You're refusing to answer the question?

2 A. **This would be my answer.**

3 Q. So we reserve the right to move on that.

4 You talked about reading center

5 accreditation certificates. Do you recall that

6 testimony?

7 A. **I recall having used those two words.**

8 Q. Okay. I think this goes without saying,

9 but I just want to be clear. Neither you nor the

10 Alkeus employee Gabrielle were awarded a reading

11 center accreditation prior to beginning your work

12 as graders for the Alkeus clinical trials.

13 Correct?

14 A. **I have never heard of an accreditation of**
15 **a reading center.**

16 Q. And you haven't received any. Is that

17 correct?

18 A. **I have not received an accreditation that**
19 **I don't believe exists.**

20 Q. Okay. When you were talking about this

21 post hoc comparison that was performed between your

22 grading and the reading center that you had hired

23 to do the SAGA study in relation to the TEASE-1

24 data, you used the words "you compare."

25 So you said when you get the grades, you

1 compare them together, and you discussed a
2 90-something percent correlation. Do you recall
3 that testimony?

4 ATTORNEY FELDSTEIN: Object to form.

5 **A. I do not remember unless you show me the**
6 **exact sentence.**

7 Q. Okay. So my question is about the subject
8 of that sentence.

9 So you, Dr. Saad, performed a comparison
10 between the image grading at the reading center and
11 your own grading. Is that correct?

12 **A. That's not correct.**

13 Q. So you never performed that comparison.
14 Is that correct?

15 **A. That's correct.**

16 Q. So when you testified that there is a
17 90-something percent correlation between your
18 grading and the reading center's grading, you don't
19 have personal knowledge as to that correlation
20 because you did not make that comparison
21 personally. Correct?

22 ATTORNEY FELDSTEIN: Object to form.

23 **A. That comparison was done by an external**
24 **statistician.**

25 Q. And so it's not a comparison that you

1 performed. Correct?

2 **A. I may have performed it. The data that I**
3 **gave you is a data provided by an external**
4 **statistician.**

5 Q. So, before, you told me you didn't make
6 the comparison. Now you're telling me you may have
7 made the comparison?

8 **A. I did not do the comparisons that I gave**
9 **you the data of.**

10 Q. So you may have made a different
11 comparison?

12 **A. I may or I may not. I don't recall.**

13 Q. Sitting here today, you don't recall
14 whether you had personal knowledge as to comparing
15 the data from when you did the grading as compared
16 to the post hoc analysis that you had performed by
17 the reading center after the fact. Correct?

18 ATTORNEY FELDSTEIN: Object to form.

19 Misstates the testimony.

20 **A. I look at what the graders -- or the**
21 **gradings provided by the reading center. Looked at**
22 **them, found there was an incredible correlation**
23 **between the two, and that the statistician did**
24 **their job to do the computation.**

25 Q. Okay. So you did perform the comparison

1 yourself. Correct?

2 **A. I did look at the images.**

3 Q. In your declaration -- and you can take a
4 moment to look through it if you need to -- but in
5 your declaration, you don't disclose that the
6 control group for the TEASE-1 study data that
7 you're discussing includes natural history patients
8 that were not patients that were randomized as part
9 of your clinical trial. Correct?

10 ATTORNEY FELDSTEIN: Object to form.

11 Beyond the scope of the redirect.

12 **A. It is not mentioned inside the**
13 **declaration.**

14 Q. You were asked questions during redirect
15 about the lack of blinding for the reading of the
16 images in the clinical trials with regard to
17 temporal information.

18 Do you recall that?

19 **A. I do.**

20 Q. Okay. Because of that lack of blinding as
21 to the temporal information from the images, when a
22 grader is evaluating the 24-month time point, for
23 instance, by looking at the image, they know or can
24 know that that image corresponds to the same
25 patient who had a grade at the previous time point.

1 Correct?

2 ATTORNEY FELDSTEIN: Object to form and
3 foundation.

4 **A. It's common practice.**

5 Q. So my question wasn't about common
6 practice. My question is about the implication of
7 it.

8 So you said there were five time points.
9 Correct?

10 **A. There are five time points, yes. Six time**
11 **points, actually.**

12 Q. Okay. Before the trial begins, and then
13 five time points in treatment. Is that what you're
14 saying?

15 **A. No. It depends on the study.**

16 Q. Okay. So if we're looking at the very
17 last time point, when that reader is grading that
18 very last time point, they very well may be doing
19 it with the bias of knowing what the grades were
20 for the prior time points for that patient.

21 Correct?

22 ATTORNEY FELDSTEIN: Object to form.
23 Foundation. Beyond the scope. Misstates the
24 record.

25 **A. I do not know that there was any specific**

1 **bias.**

2 ATTORNEY MILLS: So I'm going to stop
3 asking questions at this time. We're holding
4 the deposition open because of the many
5 questions that Dr. Saad refused to answer, and
6 we reserve all rights.

7 ATTORNEY FELDSTEIN: Yeah. Obviously, we
8 disagree with your proposal to hold it open.
9 And -- give me one second here.

10 Okay. No questions from us, Doctor.
11 We'll close the deposition here.

12 ATTORNEY MILLS: We can go off the record.
13 (Witness excused and deposition concluded
14 at 3:25 p.m.)

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1 J U R A T

2

3 I, Leonide Saad, PhD, do hereby certify
4 that I have read the foregoing transcript of my
5 testimony, and is an accurate record of said
6 testimony (except
7 for the following corrections listed below):

8 Page Line Correction

9

10

11

12

13

14

15

16

17

18 LEONIDE SAAD, PhD

19

20 Sworn to and subscribed before me this _____

21 day of _____, 2024.

22

23

24 Notary Public/Justice of the Peace

25 My commission expires:

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Gene Company Exhibit 1079, Page 240 of 284

Gene Company Pty Ltd v. The Trustees of Columbia Univ - IPR2024-00313

1 CERTIFICATE OF REPORTER

2 I, Deanna J. Dean, Registered Diplomate
3 Reporter, Certified Realtime Reporter, and
4 Massachusetts Notary Public, the officer before
5 whom the proceedings were taken, do hereby certify
6 that the foregoing transcript is a true and
7 accurate record of these proceedings; that said
8 proceedings were taken in Stenotype note by me on
9 November 26, 2024, commencing at 9:02 a.m. and
10 ending at 3:25 p.m.

11 I further certify that present on behalf of
12 Party Gene Company Pty Ltd. was Jad Mills of Wilson
13 Sonsini and on behalf of Party The Trustees of
14 Columbia University in the City of New York was
15 Mark J. Feldstein, of Finnegan, Henderson, Farabow,
16 Garrett & Dunner LLP.

17 I further certify that I am not related to, nor
18 associated with any of the parties or their
19 attorneys, nor do I have any disqualifying interest,
20 personal or financial, in the actions within.

21 Dated this 9th day of December, 2024, at Suffolk
22 County in the Commonwealth of Massachusetts.

23
24 

25 My commission expires December 26, 2025

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