1 UNITED STATES PATENT AND TRADEMARK OFFICE

2 _____

3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4 _____

5 MERCK SHARP & DOHME LLC,

6 Petitioner,

7 v.

8 THE JOHNS HOPKINS UNIVERSITY,

9 Patent Owner.

10 _____

11 IPR2024-00622, Patent No. 10,934,356;
IPR2024-00623, Patent No. 11,325,974;
12 IPR2024-00624, Patent No. 11,325,975;
IPR2024-00625, Patent No. 11,339,219;
13 IPR2024-00647, Patent No. 11,649,287;
IPR2024-00648, Patent No. 11,643,462;
14 IPR2024-00649, Patent No. 11,629,187;
IPR2024-00650, Patent No. 11,634,491.

15 _____

16 REMOTELY CONDUCTED DEPOSITION OF

17 JENNIFER NEWBERGER

18 THURSDAY, APRIL 10, 2025

19 10:00 A.M. EST

20 JOB NO.: 579965

21 PAGES: 1 - 69

22 REPORTED BY: KARISA EKENSEAIR, CCR RPR RMR

1 DEPOSITION OF JENNIFER NEWBERGER, CONDUCTED VIA
2 ZOOM VIDEOCONFERENCE.
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10 Pursuant to notice, before Karisa J.
11 Ekenseair, Certified Shorthand Reporter in and for
12 the States of Arkansas, Oklahoma, Missouri,
13 Illinois, Tennessee, Georgia, New Mexico,
14 Washington, and California; National Registered
15 Professional Reporter; National Registered Merit
16 Reporter; Notary Public.
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22

1 A P P E A R A N C E S
2 ON BEHALF OF THE PETITIONER MERCK SHARP & DOHME
3 (VIA ZOOM):
4 JESSICA M. STAURING, ESQUIRE
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10
11 ON BEHALF OF THE PATENT OWNER, THE JOHNS
12 HOPKINS UNIVERSITY, AND THE WITNESS, JENNIFER
13 NEWBERGER (VIA ZOOM):
14 CASEY KRANING, ESQUIRE
15 FISH & RICHARDSON
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18 302-652-5070
19
20 ALSO PRESENT:
21 KAREN MOREIRA, ESQUIRE, MERCK
22 KELLY WELCH, REMOTE TECHNICIAN

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13 (NONE MARKED)
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1 P R O C E E D I N G S
2 THE REPORTER: Good morning. We are the
3 record.
4 My name is Karisa Ekenseair. I am a
5 California Certified Shorthand Reporter, license
6 number 14546, and I will be handling the
7 transcript by code.
8 Today's date is April 10, 2025. Will
9 counsel please introduce themselves for the
10 record.
11 MS. STAURING: Good morning. My name is
12 Jessica Stauring with the Paul Hastings Law Firm
13 and I'm appearing on behalf of Petitioner Merck
14 today. I'm joined by Preston Ratliff, also with
15 the Paul Hastings Law Firm and appearing on behalf
16 of Petitioner Merck.
17 Additionally, Merck's in-house counsels
18 Karen Moreira and Mark Stewart are or are expected
19 to be on the line today.
20 MS. KRANING: And on behalf of Patent
21 Owner, the Johns Hopkins University, and the
22 witness, Casey Kraning from Fish & Richardson.

1 JENNIFER NEWBERGER
2 of lawful age, being first duly sworn, deposes and
3 says in reply to the questions propounded as
4 follows:
5 MS. STAURING: And, Karisa, before we
6 proceed, I don't believe that this deposition
7 should be recorded. There's no agreement to
8 record the deposition. And Kelly, I believe we
9 may have informed Planet Depos that this
10 deposition should not be recorded.
11 THE REPORTER: It's only being recorded
12 audio for backup purposes for my benefit should I
13 have some technical difficulty on my end. But my
14 understanding is that there's no video being
15 recorded; it's only audio.
16 MS. STAURING: Great. Thank you for that
17 clarification.
18 EXAMINATION
19 BY MS. STAURING:
20 Q Good morning, Ms. Newberger. Can you
21 please state your full name for the record?
22 A Jennifer Dianne Newberger.

1 Q Good to see you again, Ms. Newberger. How
2 are you feeling today?
3 A Doing well. Thank you. Good to see you
4 as well.
5 Q You understand that you're testifying
6 today under oath, correct?
7 A Correct.
8 Q Is there any reason that you cannot
9 testify truthfully today?
10 A No. There is not.
11 Q What is your standard current hourly rate
12 for your work as a lawyer?
13 A $950 an hour.
14 Q And this matter that we're discussing
15 today, you're being compensated at a rate of
16 $1,000 an hour; is that correct?
17 A That is correct.
18 Q Do you understand that your deposition
19 today concerns declarations that you prepared and
20 submitted in eight inter partes review
21 proceedings, correct?
22 A Correct.

1 Q And the eight inter partes review
2 proceedings that we're discussing today have case
3 numbers IPR2024-00622, 623, 624, 625, 647, 648,
4 649, and 650; is that correct?
5 A I do not know the numbers off the top of
6 my head.
7 Q Do you have your declarations before you
8 today?
9 A I do.
10 Q And the first page of your declarations
11 provides the case numbers, correct?
12 A Correct.
13 Q So I'll ask my question again, if you can
14 verify with your declarations the case numbers.
15 You understand today that your deposition
16 concerns eight declarations that you've prepared
17 and submitted in inter partes review procedures
18 having case numbers IPR2024-00622, 623, 624, 625,
19 647, 648, 649, and 650, correct?
20 MS. KRANING: Counsel, if it's helpful
21 we're willing to stipulate that those numbers are
22 correct.

1 Q Ms. Newberger, do you need me to ask the
2 question again?
3 A It's correct. My declarations have patent
4 numbers. I may not be looking at the right spot
5 but Counsel says we can stipulate that they're
6 correct so they're correct.
7 Q Ms. Newberger, the declarations that you
8 prepared in this proceeding, did you prepare a
9 declaration for Case No. IPR2024-00622?
10 A I am looking --
11 MS. KRANING: Her declaration doesn't have
12 the IPR numbers on it, Counsel. We stipulated you
13 have the numbers correct. Can we please move on?
14 Q Ms. Newberger, I'll ask my question with
15 respect to the patent numbers.
16 A Okay.
17 Q Did you prepare and submit a declaration
18 in connection with United States Patent No.
19 11,934,356?
20 A Yes.
21 Q Did you prepare and submit a declaration
22 in connection with United States Patent No.

1 11,325,974?
2 A Yes.
3 Q Did you prepare and submit a declaration
4 in connection with United States Patent No.
5 11,325,975?
6 A Yes.
7 Q Did you prepare and submit a declaration
8 in connection with United States Patent No.
9 11,339,219?
10 A Yes.
11 Q Did you prepare and submit a declaration
12 in connection with United States Patent No.
13 11,634,491?
14 A Yes.
15 Q Did you prepare and submit a declaration
16 in connection with United States Patent No.
17 11,629,187?
18 A Yes.
19 Q Did you prepare and submit a declaration
20 in connection with United States Patent No.
21 11,643,462?
22 A Yes.

1 Q Did you prepare and submit a declaration
2 in connection with United States Patent No.
3 11,649,287?
4 A Yes.
5 Q Those eight declarations are the
6 declarations that we're discussing here today,
7 correct?
8 A Correct.
9 Q And these eight declarations that we're
10 discussing today have substantial similarity to
11 your declaration that you submitted -- excuse me,
12 that you signed on October 4th, 2024, and was
13 submitted in the '393 proceeding, correct?
14 A Correct.
15 Q Approximately how much time have you spent
16 working on these eight matters that we're
17 discussing today?
18 A The time spent for these eight matters was
19 tied in with the time spent for the prior matter.
20 Q Approximately how much time have you spent
21 working on the nine matters in total?
22 A As I stated in December, my estimate was

1 upwards of 30 and under 50. That hasn't changed.
2 Q So the eight declarations that we're
3 discussing here today, you prepared during the
4 same time that you prepared the declaration that
5 you signed on October 4th, 2024; is that correct?
6 A For the most part. I did make one
7 correction when an inadvertent omission was
8 brought to my attention. I made an error and I
9 fixed it. So I did spend time updating these
10 eight since we last spoke.
11 Q So since we last spoke at your deposition
12 on December 11th, 2024, how much time did you
13 spend working on these matters that we're
14 discussing today?
15 A Less than 10 hours.
16 Q Have you looked at the patents at issue in
17 these eight proceedings that we're discussing
18 today?
19 MS. KRANING: Objection, relevance.
20 A I have not looked at the patents.
21 Q Did you ask to review the eight patents
22 that we're discussing today?

1 MS. KRANING: Objection, relevance;
2 outside the scope.
3 MS. STAURING: Counsel, I'll note for the
4 record that as you're aware, speaking objections
5 are improper at the PTAB, so I'll ask that you
6 please refrain going forward.
7 MS. KRANING: Counsel, I'm allowed to
8 create my record and you're only allowed to
9 cross-examine her on the scope of her declaration.
10 I'm well within my rights to note when you're
11 outside the scope.
12 A I did not ask to review the patents, as I
13 stated in December.
14 Q So since the time of your deposition on
15 December 11th, 2024, you did not ask to review any
16 of the patents at issue in these proceedings; is
17 that correct?
18 MS. KRANING: Objection, outside the
19 scope.
20 A That is correct.
21 Q Did you consider asking to review the
22 patents at issue after your deposition on

1 December 11th, 2024?
2 MS. KRANING: Objection, outside the
3 scope.
4 A I -- I did not consider asking to review
5 the patents.
6 Q So to be clear, you did not review any of
7 the patents that are at issue in these IPR
8 proceedings; is that correct?
9 MS. KRANING: Objection, outside the
10 scope.
11 A That is correct.
12 Q Ms. Newberger, you're not an expert in
13 patent law, right?
14 A That is correct.
15 Q Do you consider yourself to have expertise
16 in the area of patent law?
17 MS. KRANING: Objection to form.
18 A I do not consider myself to have expertise
19 in the area of patent law.
20 Q You understand that the patent owner in
21 these eight IPR proceedings that we're discussing
22 today is JHU?

1 A Yes. I do understand that.
2 Q Since the time of your deposition on
3 December 11, 2024, other than your work on these
4 eight proceedings that we're discussing today,
5 have you done any work with JHU?
6 A I have not.
7 Q Since the time of your deposition on
8 December 11, 2024, other than your work on these
9 eight proceedings that we're discussing here
10 today, have you done any work with the Fish &
11 Richardson law firm?
12 A I have not.
13 Q You mentioned that you had your
14 declarations before you; is that correct?
15 A That is correct.
16 Q Do you have any other documents in the
17 room with you, whether in hard copy or loaded onto
18 your computer?
19 A Not with respect to this case. I'm on my
20 work computer, right. I have obviously other
21 matters.
22 Q So in front of you, you only have your

1 eight declarations that we're discussing today; is
2 that correct?
3 A That's correct. Well, and the -- yes, and
4 the exhibits to those declarations.
5 Q Let me break my question up.
6 Before you today, you have your eight
7 declarations that you submitted in this
8 proceeding, correct?
9 A Correct.
10 Q Are there any other documents that you
11 have before you today?
12 A I have the exhibits to those declarations.
13 Q Are there any markings on your
14 declarations or on the exhibits that you have
15 before you today?
16 A There are not.
17 Q Are there any tabs on the declarations or
18 the exhibits that you have before you today?
19 A The only tab that are between each exhibit
20 to separate the documents.
21 Q So you have a compilation of the exhibits
22 to your declaration that's separated by tabs

1 between each exhibit; is that correct?
2 A That is correct.
3 Q Are there any Post-it notes on the
4 documents that you have in front of you today?
5 A There are not.
6 Q Is there anything on the documents that
7 you have before you today that would turn your
8 documents into annotated versions?
9 A No.
10 MS. KRANING: Objection to form.
11 Q Sitting here today, are you familiar with
12 the declarations that you submitted in these eight
13 IPR proceedings?
14 MS. KRANING: Objection to form.
15 A Yes, I am.
16 Q Are you familiar with the exhibits that
17 you cite throughout your eight declarations that
18 we're discussing here today?
19 MS. KRANING: Objection to form.
20 A Yes, I am.
21 Q Are you familiar with the statutes that
22 you cite throughout your eight declarations that

1 we're discussing here today?
2 MS. KRANING: Objection to form.
3 A Yes.
4 Q And are you familiar with the regulations
5 that you cite throughout your eight declarations
6 that we're discussing here today?
7 MS. KRANING: Objection to form.
8 A Yes.
9 Q You're not confused by any statements that
10 you make in your eight declarations that we're
11 discussing here today, right?
12 MS. KRANING: Objection to form.
13 A Correct.
14 Q You're not confused by any opinions that
15 you include in your eight opinions that we're
16 discussing here today, right?
17 MS. KRANING: Objection to form.
18 A Right.
19 Q You're not confused by any conclusions
20 that you make in your eight declarations that
21 we're discussing here today, right?
22 MS. KRANING: Objection to form.

1 A Right.
2 Q You're not confused by any statements
3 contained in the exhibits that you cite throughout
4 your eight declarations that we're discussing here
5 today, right?
6 MS. KRANING: Objection to form.
7 A Right.
8 Q Is anyone with you in the room today?
9 A No.
10 Q Did you spend any time preparing for
11 today's deposition regarding the eight IPR
12 proceedings where you submitted declarations?
13 A Yes.
14 Q Approximately how much time did you spend
15 preparing for today's deposition?
16 A Less than 10 hours.
17 Q Other than the lawyers representing JHU,
18 did you speak with anyone in preparation for your
19 deposition today?
20 A No, I did not.
21 Q Ms. Newberger, did you hear my question?
22 A Yes. I responded. I said, "no, I did

1 not."
2 Q Did you speak with any other JHU
3 declarants for your work in connection with these
4 eight IPR proceedings?
5 A No, I did not.
6 Q Did you speak with anyone from JHU in
7 connection with your work on these eight IPR
8 proceedings?
9 A No, I did not.
10 Q In preparation for your deposition today,
11 did you review your eight declarations that you
12 submitted?
13 A Yes, I did.
14 Q And did you review the exhibits that you
15 cite throughout your eight declarations in
16 preparation for your deposition today?
17 A I did.
18 Q And did you review the statutes and
19 regulations that you cite throughout your
20 declarations in preparation for your deposition
21 today?
22 A I did.

1 Q Now, four of your declarations that we're
2 discussing here today you signed on January 7th,
3 2025; is that correct?
4 A I can look to check the date, but I -- I
5 will stipulate that that's correct.
6 Q Please take a look at the declarations
7 that you have in front of you and confirm that
8 four of the declarations you signed on January 7,
9 2025.
10 Ms. Newberger, I can take it one by one if
11 that would be easier.
12 A I see the four. Yeah. I flipped through
13 them.
14 Q So the four declarations that you signed
15 on January 7th, 2025, relate to patent numbers
16 that end in '356?
17 A Correct.
18 Q Patent number that ends in '974?
19 A Correct.
20 Q Patent number that ends in '975?
21 A Correct.
22 Q And patent number that ends in '219?

1 A Correct.
2 Q Your other four declarations that we're
3 discussing here today you signed on January 17th,
4 2025; is that correct?
5 A That's correct.
6 Q So the declaration that you submitted --
7 that you signed on January 17th, 2025, relates to
8 patent number that ends in '287, correct?
9 A Correct.
10 Q And patent number that ends in '491,
11 correct?
12 A Correct.
13 Q And patent number that ends in '462,
14 correct?
15 A Correct.
16 Q And patent number that ends in '187,
17 correct?
18 A Correct.
19 Q Now, prior to signing your eight
20 declarations, did you review your declarations
21 carefully?
22 MS. KRANING: Objection to form.

1 A I did.
2 Q And did you understand every statement
3 contained in your declarations before you signed?
4 MS. KRANING: Objection to form.
5 A Yes.
6 Q Are there any errors in any of the eight
7 declarations that we're discussing here today?
8 A Not to my knowledge.
9 Q And you reviewed those declarations
10 carefully before you signed them, right?
11 MS. KRANING: Objection to form.
12 A Right.
13 Q Now, your eight declarations that we're
14 discussing today all concern the June 10th, 2013,
15 ClinicalTrials.gov study record that is Exhibit
16 1005, right?
17 MS. KRANING: Objection to form.
18 A Correct.
19 Q And in your view, JHU registered with
20 ClinicalTrials.gov on June 10th, 2013, and
21 included only the information required by law,
22 right?

1 MS. KRANING: Objection to form.
2 A Yes. That is my view.
3 Q And in your view, every element that was
4 included in the June 10th, 2013, submission to
5 ClinicalTrials.gov was required by statute, right?
6 MS. KRANING: Objection to form.
7 A Yes. That is correct.
8 Q Since your December 11th, 2024,
9 deposition, did you review the submission that was
10 made to ClinicalTrials.gov on June 10th, 2013?
11 A I reviewed only what is publicly available
12 on the ClinicalTrials website.
13 Q So let me try my question again.
14 Since your December 11th, 2024 deposition,
15 did you review the submission that was made to
16 ClinicalTrials.gov on June 10th, 2013?
17 A I did not.
18 Q Did you ask to see a copy of the
19 submission that was made to ClinicalTrials.gov on
20 June 10th, 2013?
21 MS. KRANING: Objection to form.
22 A I did not.

1 Q Were you curious to see the submission
2 that was made to ClinicalTrials.gov on June 10th,
3 2013, after I asked you about it at your
4 December 11th, 2024 deposition?
5 MS. KRANING: Objection to form;
6 relevance.
7 A No, I was not.
8 Q You would agree that because you did not
9 see what was actually submitted to
10 ClinicalTrials.gov on June 10th, 2013, you do not
11 know whether the submission was made jointly by
12 Merck and JHU, right?
13 MS. KRANING: Objection to form; outside
14 the scope.
15 A As discussed in December and as I stated
16 then, I -- I do not know. All I know is that
17 Johns Hopkins is named as the responsible party.
18 This is what I stated in December and my opinion
19 has not changed.
20 Q So you do not know whether the submission
21 that was made to ClinicalTrials.gov on June 10th,
22 2013, was made jointly by Merck and JHU?

1 MS. KRANING: Objection to form; outside
2 the scope; asked and answered.
3 MS. STAURING: Counsel, I -- I'm just
4 going to note for the record that the Patent Trial
5 Practice Guide at page 128 specifically states
6 that the speaking objections you're reciting today
7 are improper. So I'll ask that you please refrain
8 as we move forward.
9 MS. KRANING: Counsel, I'm looking at the
10 same page of the Trial Practice Guide and it
11 specifically says I'm allowed to make short
12 objections with a single word or term. That's
13 what I'm doing. Thank you.
14 A As I previously answered, I did not see
15 the submission. I know only that Johns Hopkins is
16 named as the responsible party.
17 Q Let me try my question again.
18 You do not know whether the submission
19 that was made to ClinicalTrials.gov on June 10th,
20 2013, was made jointly by Merck and JHU because
21 you did not see the submission that was made on
22 June 10th, 2013, correct?

1 MS. KRANING: Objection to form; outside
2 the scope; asked and answered.
3 A I will answer as I previously did. I did
4 not see the submission. I know only what is
5 available on the public record.
6 Q And Merck is listed as a collaborator on
7 the June 10th, 2013 ClinicalTrials.gov study
8 record that is reflected as Exhibit 1005, right?
9 A Yes. That is correct.
10 Q And for your work on these matters, you
11 did not speak to anyone at Merck regarding the
12 submission to ClinicalTrials.gov on June 10th,
13 2013, right?
14 A That is correct.
15 Q And you do not know the level of Merck's
16 involvement in the study underlying the June 10th,
17 2013 ClinicalTrials.gov submission, right?
18 MS. KRANING: Objection to form.
19 A That is correct.
20 Q Now, Ms. Newberger, your declaration
21 submitted in the eight proceedings we're
22 discussing today reflect your opinion that certain

1 information is required to be submitted to
2 ClinicalTrials.gov, right?
3 MS. KRANING: Objection to form.
4 A Yes. That is correct.
5 Q And in your view, the information that's
6 required to be submitted to ClinicalTrials.gov is
7 set by 42 USC 282 (j)(2), right?
8 MS. KRANING: Objection to form.
9 A Yes. That is correct.
10 Q And in your view, the elements that are
11 required by 42 USC 282 (j)(2) to be included in
12 clinic -- submissions to ClinicalTrials.gov were
13 in effect in June of 2013; is that right?
14 MS. KRANING: Objection to form.
15 A They were in effect, yes.
16 Q The elements that are required by 42 USC
17 282(j)(2) to be included in submissions to
18 ClinicalTrials.gov were in effect in June of 2013,
19 right?
20 MS. KRANING: Objection to form; asked and
21 answered.
22 A Yes.

1 Q As part of your analysis prior to signing
2 your eight declarations that we're discussing
3 today, you reviewed 42 USC 282(j)(2), right?
4 MS. KRANING: Objection to form.
5 A Yes.
6 Q And you cite that statute in your eight
7 declarations as Exhibit 2148, right?
8 A Yes. That is correct.
9 Q And you're not confused by anything that's
10 written in 42 USC 282(j)(2) that you cite
11 throughout your declarations, correct?
12 MS. KRANING: Objection to form.
13 A Correct.
14 Q At the time of the study records posting
15 in June 2013, was the element "brief title"
16 required in submissions to ClinicalTrials.gov for
17 applicable clinical trials?
18 MS. KRANING: Objection to form.
19 A Yes.
20 Q At the time of the study records posting
21 in June 2013, was the element "unique protocol
22 identification number" required in submissions to

1 ClinicalTrials.gov for applicable clinical trials?
2 MS. KRANING: Objection to form.
3 A Yes.
4 Q At the time of the study records posting
5 in June of 2013, was the element "official title"
6 required in submissions to ClinicalTrials.gov for
7 applicable clinical trials?
8 MS. KRANING: Objection to form.
9 A Yes.
10 Q At the time of the study records posting
11 in June of 2013, was the element "recruitment
12 status" required in submissions to
13 ClinicalTrials.gov for applicable clinical trials?
14 MS. KRANING: Objection to form.
15 A Yes. Yes. I responded. I don't know if
16 you heard me.
17 Q At the time of the study records posting
18 in June 2013, was the element "study start date"
19 required in submissions to ClinicalTrials.gov for
20 applicable clinical trials?
21 MS. KRANING: Objection to form.
22 A Yes.

1 Q At the time of the study records posting
2 in June of 2013, was the element "study completion
3 date" required in submissions to
4 ClinicalTrials.gov for applicable clinical trials?
5 MS. KRANING: Objection to form;
6 relevance.
7 A Yes.
8 Q At the time of the study records posting
9 in June of 2013, was the element "collaborator"
10 required in submissions to ClinicalTrials.gov for
11 an applicable clinical trial?
12 MS. KRANING: Objection to form.
13 A Yes.
14 Q At the time of the study records posting
15 in June of 2013, was the element "data monitoring"
16 required in submissions to ClinicalTrials.gov for
17 an applicable clinical trial?
18 MS. KRANING: Objection to form.
19 A Yes.
20 Q At the time of the study records posting
21 in June of 2013, was the element "primary purpose"
22 required in submissions to ClinicalTrials.gov for

1 an applicable clinical trial?
2 MS. KRANING: Objection to form.
3 A Yes.
4 Q Now, Ms. Newberger, you testified that at
5 the time of the study records posting in June of
6 2013, the element "collaborator" was required in
7 submissions to ClinicalTrials.gov.
8 Where in the statute that you cite as
9 Exhibit 2148 does it list the word "collaborator"?
10 MS. KRANING: Objection to form.
11 A Sorry. As I stated in December, the
12 statute provides high-level terminology. Under
13 each of those, there are a number of things that
14 would make up the content of each of those
15 requirements. A collaborator is part of the study
16 design to the extent that that collaborator is
17 involved in the study and it would be reasonable
18 to assume that it was -- it is a reasonable
19 interpretation that study design would require
20 inclusion of collaborator.
21 Q Let me try my question again.
22 You testified that at the time of the

1 study records posting, the element "collaborator"
2 was required in submissions to ClinicalTrials.gov
3 under the statute. Where in the statute that you
4 cite as Exhibit 2148 does it list the requirement
5 for collaborator?
6 MS. KRANING: Objection to form; asked and
7 answered.
8 A While I agree with you that the specific
9 word "collaborator" is not in the statute, that
10 does not mean that it is not part of one of the
11 required elements. In my view, in my expert
12 opinion, study design reasonably includes a
13 variety of things including collaborator.
14 Q So the element "collaborator" is not
15 listed in the Exhibit 2148 that you cite in your
16 declaration, correct?
17 A As I previously stated, the word
18 "collaborator", does not appear in the statute.
19 As I also stated, that is not the end of the
20 inquiry. The statute is high-level and does not
21 necessarily lay out every aspect that needs to be
22 included.

1 Q Ms. Newberger, the NIH provides guidance
2 on the protocol registration elements that you
3 discuss in your declaration which you cite as
4 Exhibit 2149, correct?
5 MS. KRANING: Objection to form.
6 A Correct.
7 Q And you're familiar with Exhibit 2149 that
8 you cite throughout your declarations, right?
9 MS. KRANING: Objection to form.
10 A Correct.
11 Q The NIH protocol registration description
12 that you cite in your declaration as Exhibit 2149
13 indicate that "collaborator" is an optional
14 element, right?
15 MS. KRANING: Objection to form.
16 A As I stated in December and we discussed
17 at length, NIH provides guidance. I use that
18 information as a guide to how NIH interprets the
19 elements. I am not aware whether that information
20 was available at the time. And I also noted
21 several times that at the top of the website, NIH
22 indicates it's only a guide and that the

1 responsible party must assess its own legal
2 requirements to ensure compliance with the
3 statute.
4 Q Let me try my question again because
5 I -- I don't think I got an answer to my question.
6 The NIH protocol registration description
7 that you cite in your declaration as Exhibit 2149
8 indicates that collaborator is an optional
9 element, right?
10 MS. KRANING: Objection to form; asked and
11 answered.
12 A I did answer the question. While the
13 guidance indicates "optional," I do not know if
14 that guidance was available at the time. I also
15 know that it is ultimately up to the responsible
16 party for them to determine whether they believe
17 something is required. The NIH page is guidance.
18 It is not law.
19 Q Did you ask anyone at JHU if they believed
20 listing "collaborator" was a required element?
21 A As I previously testified, I did not speak
22 to anyone at JHU.

1 Q So you did not ask anyone at JHU if they
2 believed listing collaborator was a required
3 element, correct?
4 MS. KRANING: Objection to form; asked and
5 answered.
6 A As I stated, I did not speak to anyone at
7 JHU so it would therefore have been impossible for
8 me to ask them this question because I did not
9 speak to anyone there about this case at all.
10 Q Did you ask anyone at Merck if it felt
11 that listing collaborator was a required element
12 under the statute?
13 MS. KRANING: Objection to form;
14 relevance.
15 A I would offer the same answer. Since I
16 previously testified that I spoke to no one at
17 Merck about any of this, I clearly did not speak
18 to anyone at Merck about whether collaborator was
19 required.
20 Q You testified that -- strike that.
21 You testified that at the time of the
22 study records posting, the element "data

1 monitoring" was required under the statute. Where
2 in the statute is "data monitoring" listed as a
3 required element?
4 MS. KRANING: Objection to form.
5 A Similar to my prior answer, while I
6 acknowledge that data monitoring, the words "data
7 monitoring" are not in the statute, data
8 monitoring is a critical part of any study design
9 and, again, would be a reasonable assumption for a
10 responsible party to draw the conclusion that they
11 should, in fact, indicate data monitoring.
12 Q In your declaration that you signed on
13 October 4th, 2024, and submitted in the '393 IPR
14 proceeding, you did not list data monitoring as a
15 required element, right?
16 A As I acknowledged earlier, it was an
17 inadvertent omission. I'm a big enough person to
18 accept when I make a mistake. I fixed it. I did
19 not intend to exclude it and that is why I updated
20 my declaration to include it.
21 Q The NIH guidance that you cite in your
22 declaration as Exhibit 2149 indicates that the

1 element "data monitoring" is an optional element
2 as well, correct?
3 MS. KRANING: Objection to form.
4 A As I stated earlier with respect to
5 "collaborator," the NIH guidance -- I will
6 acknowledge what the NIH guidance indicates that
7 it is optional, but it is guidance; it is not law.
8 And a responsible party may reasonably conclude,
9 as would I, that data monitoring is part of study
10 design and, therefore, should be indicated.
11 Q And sitting here today, you do not know if
12 JHU or Merck concluded that data monitoring was a
13 required element, right?
14 MS. KRANING: Objection to form; outside
15 the scope; relevance.
16 A It was included in the submission and I,
17 therefore, conclude that they determined that it
18 was, in fact, a required element.
19 Q But sitting here today, you do not know if
20 JHU or Merck concluded that data monitoring was a
21 required element at the time of the submission to
22 ClinicalTrials.gov in June of 2013, right?

1 MS. KRANING: Objection to form; outside
2 the scope; relevance.
3 A I answered the question. It was included
4 in the submission and, therefore, I -- I am
5 comfortable concluding that they deemed it a
6 required element.
7 Q But you did not speak with anyone at JHU
8 or Merck about why it was included in the
9 submission to ClinicalTrials.gov, right?
10 MS. KRANING: Objection to form; asked and
11 answered; outside the scope; relevance.
12 A As I have stated multiple times, I did not
13 speak with anyone at JHU or Merck.
14 Q I'm going to try my question again.
15 You did not speak with anyone at JHU or
16 Merck about why the element "data monitoring" was
17 included in the submission to ClinicalTrials.gov,
18 right?
19 MS. KRANING: Objection to form; asked and
20 answered; outside the scope.
21 A I will provide my answer again. I did not
22 speak to anyone at JHU or Merck about anything

1 related to this case, including their views on
2 data management.
3 Q Let me try my question one more time
4 because you said "data management," so I just want
5 to make sure that the testimony is clear.
6 You did not speak with anyone at JHU or
7 Merck about why the element "data monitoring" was
8 included in the submission to ClinicalTrials.gov,
9 right?
10 MS. KRANING: Objection to form; asked and
11 answered; outside the scope.
12 A My apologies. I said "management" instead
13 of "monitoring." My answer stands.
14 Q And you did not speak with anyone at JHU
15 or Merck about why the element "collaborator" was
16 included in the submission to ClinicalTrials.gov,
17 right?
18 MS. KRANING: Objection to form; asked and
19 answered; outside the scope.
20 A I have answered this question multiple
21 times. I did not speak with anyone at JHU or
22 Merck about anything, including why "collaborator"

1 was included.
2 Q Ms. Newberger, in your view, the
3 June 10th, 2013, ClinicalTrials.gov submission
4 included all of the elements required by 42 USC
5 282(j)(2)(A), correct?
6 MS. KRANING: Objection to form.
7 A Yes.
8 Q And the June 10, 2013, ClinicalTrials.gov
9 submission included the information that was
10 legally required and consistent with the NIH
11 guidance found on ClinicalTrials.gov, right?
12 MS. KRANING: Objection to form.
13 A Can you restate the question, please?
14 Q Sure. In your view, the June 10, 2013,
15 ClinicalTrials.gov submission included the
16 information that was legally required and
17 consistent with NIH guidance found on
18 ClinicalTrials.gov, right?
19 MS. KRANING: Objection to form.
20 A Right.
21 Q And you cite that NIH guidance in your
22 declaration as Exhibit 2149, correct?

1 A Yes.
2 Q Do you have any idea when the NIH guidance
3 that you cite in your declaration as Exhibit 2149
4 issued?
5 MS. KRANING: Objection to form.
6 A Because it references a date in, I
7 believe, 2017, it must have been after that. I
8 don't know more specifically.
9 Q So you don't know when the NIH guidance
10 that you cite in your declaration as Exhibit 2149
11 issued, correct?
12 MS. KRANING: Objection to form.
13 A I know only that it issued after
14 January 18th, 2017.
15 Q You cite this guidance in your
16 declarations in connection with the submission
17 made to ClinicalTrials.gov in June of 2013,
18 correct?
19 A I would modify that slightly. As I have
20 stated previously today and in December, I use it
21 for guidance as to how NIH thinks about these
22 terms today. But what I relied upon was the

1 statute with respect to whether the information
2 was legally required. The NIH page is guidance;
3 it is not law.
4 Q But you relied upon the NIH guidance to
5 describe what is legally required under the
6 statute, correct?
7 MS. KRANING: Objection to form.
8 A That is not correct. To determine whether
9 something was legally required, I relied on the
10 law, the statute. I used the NIH page as
11 guidance, as interpretation, but not to determine
12 whether something was legally required. That was
13 a statutory analysis.
14 Q Ms. Newberger, you state in your
15 declarations that the June 2013 submission
16 provided the information legally required and
17 consistent with NIH guidance, correct?
18 MS. KRANING: Objection to form; asked and
19 answered.
20 A Correct. And I previously stated
21 "correct" when you asked this question earlier.
22 Q And the NIH guidance that you cite in your

1 declarations states that "collaborator" and "data
2 monitoring" are optional elements, right?
3 MS. KRANING: Objection to form; asked and
4 answered.
5 A I have answered this question multiple
6 times. The NIH guidance indicates that they are
7 optional. The NIH guidance is not the legal
8 requirement. It is helpful. It is guidance. It
9 is not -- it does not set forth the legal
10 requirements. The statute sets forth the legal
11 requirements.
12 Q But you rely on the NIH guidance that you
13 cite in your declaration as Exhibit 2149 to form
14 your opinions expressed in those declarations,
15 right?
16 MS. KRANING: Objection to form; asked and
17 answered.
18 A I have -- I have answered this question.
19 I use it as guidance. My opinions as to whether
20 something was legally required was formed based
21 upon the statute.
22 Q Let me try my question again and I'll

1 rephrase my question.
2 You rely upon and cite Exhibit 2149 in
3 your declaration to form your opinions, correct?
4 MS. KRANING: Objection to form; asked and
5 answered.
6 A I do not rely upon it to say whether
7 something is legally required. I used it as
8 guidance for how NIH interprets the criteria on
9 ClinicalTrials.gov.
10 Q That's not quite what I asked so let me
11 try my question again.
12 You rely upon and cite Exhibit 2149 in
13 your declaration to form your opinions, correct?
14 MS. KRANING: Objection to form; asked and
15 answered.
16 A I cannot answer this any differently than
17 I have. My opinions as to whether something was
18 legally required is based upon the statute. I
19 used the NIH guidance as guidance, as helpful
20 interpretation.
21 Q I'm not sure that that's an answer to my
22 question but I'll move on.

1 You include Table 1 in the eight
2 declarations that we're discussing here today to
3 reflect all posted elements that you believe were
4 legally required at the time of the study records
5 posting in June of 2013, right?
6 MS. KRANING: Objection to form.
7 A Yes.
8 Q And the Table 1 that's included in your
9 eight declarations that we're discussing today,
10 you prepared carefully, right?
11 MS. KRANING: Objection to form.
12 A Yes.
13 Q And Table 1 that's included in your eight
14 declarations that we're discussing here today
15 reflects every element that's included in the
16 posted June 10th, 2013, study record that you
17 believe is legally required, right?
18 MS. KRANING: Objection to form.
19 A I believe that to be correct.
20 Q You didn't omit anything that was legally
21 required at the time of the study records posting
22 in June of 2013, from Table 1 in your

1 declarations, right?
2 MS. KRANING: Objection to form.
3 A Not to my knowledge.
4 Q You mentioned earlier that Table 1 that's
5 included in your eight declarations that we're
6 discussing today is slightly different from Table
7 1 that's included in your declaration that you
8 signed on October 4th, 2024, right?
9 A Yes. That is correct.
10 Q Your declaration that you signed on
11 October 4th, 2024, in the '393 proceeding, you did
12 not include the posted element "collaborator,"
13 right?
14 A That is correct. It was an inadvertent
15 omission.
16 Q And in your view, you did not omit any
17 posted elements from Table 1 that's included in
18 your eight declarations that we're discussing here
19 today, correct?
20 MS. KRANING: Objection to form; asked and
21 answered.
22 A I am not aware of any omissions.

1 Q You previously represented that your
2 declaration that you signed on October 4th, 2024,
3 in the '393 proceeding did not have any legally
4 required elements missing from Table 1 included in
5 that declaration, right?
6 MS. KRANING: Objection to form.
7 A At the time of that declaration, I
8 believed that to be true. I later learned that I
9 had omitted two legally required elements. I
10 accept that I made an error which I have now
11 corrected.
12 Q And you learned that you omitted the
13 element "collaborator" during your deposition on
14 December 11th, 2024, right?
15 A Yes. That is correct.
16 Q So the posted element "collaborator" was
17 added to your declaration submitted in the eight
18 proceedings that we're discussing here today after
19 your December 11th, 2024, deposition; is that
20 correct?
21 MS. KRANING: Objection to form; asked and
22 answered.

1 A As I previously stated, yes.
2 Q Your view now is that the posted element
3 "collaborator" was a legally required element,
4 right?
5 MS. KRANING: Objection to form.
6 A Yes. It was -- it would always have been
7 my position. I made an error and did not include
8 it in the table. That was not intentional.
9 Q The NIH guidance that you cite in your
10 declaration states that "collaborator" is an
11 optional element, right?
12 MS. KRANING: Objection to form; asked and
13 answered.
14 A I -- I have answered this question easily
15 half a dozen times. I cannot answer it any
16 differently. The NIH guidance is guidance. I
17 acknowledge that it indicates it is optional.
18 However, the statute says study design which is
19 very broad. It is my view that collaborator is
20 reasonably part of study design. That is the
21 basis for my legal opinion.
22 Q When you added "collaborator" to the

1 declarations that we're discussing here today, you
2 also added "data monitoring"; is that correct?
3 MS. KRANING: Objection to form.
4 A That is correct.
5 Q Now, the Table 1 that's included in your
6 declarations here today, you reviewed that in
7 preparation for your deposition today, right?
8 A Yes.
9 Q You testified earlier today that the
10 element "brief summary" is a legally required
11 element for submissions to ClinicalTrials.gov
12 under 42 USC 282(j)(2), correct?
13 MS. KRANING: Objection to form to the
14 extent it mischaracterizes her testimony.
15 A Correct. And this was also discussed in
16 December.
17 Q And the June 10th, 2013,
18 ClinicalTrials.gov submission includes the brief
19 summary of the clinical study, correct?
20 A It does.
21 Q But you do not include the element "brief
22 summary" in Table 1 in your declarations that you

1 prepared and submitted in the proceedings relating
2 to patent numbers that end in '974, '975, '219,
3 '287, '187, '462, and '491, right?
4 MS. KRANING: Objection to form to the
5 extent it mischaracterizes the document.
6 Q Ms. Newberger, I can break those up into
7 separate questions if that would be easier for
8 you. So let me start again.
9 You do not include the element "brief
10 summary" in Table 1 of your declaration that you
11 prepared and submitted in connection with the
12 patent proceeding that ends in '974, correct?
13 MS. KRANING: Objection to form and to the
14 extent it mischaracterizes the document.
15 A One moment, please.
16 Q Ms. Newberger, let's take a look at your
17 declaration that on the first page has patent
18 number ending in '974.
19 A Okay.
20 Q And if you turn to the first page of your
21 Table 1 which begins at page 16 of your
22 declaration, do you have that before you?

1 A I do.
2 Q Table 1 included in your declaration
3 relating to the '974 patent does not include the
4 element "brief summary," right?
5 MS. KRANING: Objection to form. Counsel,
6 that appears on page 18 in the document.
7 Q Ms. Newberger, do you need me to repeat my
8 question?
9 A No, I do not. I don't see it.
10 Q Okay. So let's put that declaration aside
11 and look at your declaration submitted in
12 connection with the '975 patent. And if you turn
13 to the first page of your Table 1 on page 16 and
14 you take a look at Table 1, this declaration does
15 not include the element "brief summary," right?
16 A The same table was used for all of them.
17 I'm willing to acknowledge that.
18 Q So Ms. Newberger, if you look at Table 1
19 in your declaration in the '97 -- in connection
20 with the '975 patent, Table 1 does not include the
21 element "brief summary," correct?
22 A That's correct.

1 Q So let's take a look at your declaration
2 that's submitted in connection with the '219
3 patent. And if you turn to Table 1 that begins on
4 page 16, Table 1 does not include the element
5 "brief summary" for your declaration in the '219
6 patent proceeding, right?
7 A It does not have that header, no.
8 Q "Brief summary" is not included as a
9 posted element, correct?
10 A It is not included.
11 Q Let's take a look at your declarations
12 submitted in connection with the '462 patent. And
13 if we turn to Table 1 which begins on page 16 of
14 your declaration, Table 1 does not include the
15 element "brief summary," correct?
16 A Correct.
17 Q Let's take a look at Table 1 in your
18 declaration submitted in connection with the '187
19 patent. That begins on page 16. Table 1 --
20 A Yeah.
21 Q -- does not include the element "brief
22 summary," correct?

1 A It does not.
2 Q Let's take a look at your declaration
3 submitted in connection with the '491 patent.
4 Turning to Table 1 that begins on page 16 of your
5 declaration, Table 1 does not include the element
6 "brief summary"; is that correct?
7 A Correct. Correct. I responded.
8 Q Now, according to your declarations that
9 you signed in those seven proceedings, in your
10 view, you included in Table 1 everything that was
11 required by statute, right?
12 MS. KRANING: Objection to form.
13 A Correct.
14 Q And you did not include the element "brief
15 summary" in Table 1 in your declarations in
16 connection with the seven patents that we just
17 discussed, right?
18 A I did not. I should have.
19 Q You can set those aside, Ms. Newberger.
20 In your view, the failure to submit
21 required information to ClinicalTrials.gov results
22 in civil monetary penalties, right?

1 MS. KRANING: Objection to form.
2 A As discussed at length in December, the
3 statute gives the right to the agency to issue
4 civil money -- civil monetary penalties for the
5 failure to comply. It's certainly not an
6 obligation, but that authority exists.
7 Q You'd agree that prior to 2021, the FDA
8 had never previously issued a notice of
9 noncompliance, right?
10 MS. KRANING: Objection to form;
11 relevance.
12 A We discussed this at length in December.
13 Prior to 2021, they had not issued a notice of
14 noncompliance, but as I stated in December and as
15 I will state again today, that does not mean that
16 the legal authority for penalties did not exist.
17 It did.
18 Q Ms. Newberger, I know that you have
19 positions and at the end of today, your counsel
20 may ask you questions. But I'll ask that you
21 please keep your responses focused to the question
22 that I'm ask -- asking today. So let me just try

1 my question one more time.
2 You'd agree that prior to 2021, the FDA
3 had never previously issued a notice of
4 noncompliance, right?
5 MS. KRANING: Objection to form; asked and
6 answered.
7 A I will answer as I did previously because
8 I believe that it requires more than a yes or no.
9 I agree with you that no notice of
10 nonconformity had been issued prior to 2021. That
11 is correct. However, there was legal authority in
12 the statute to enforce for failure to not comply.
13 Q Do you know if as of today the FDA has
14 ever subjected a responsible party to civil money
15 penalties in connection with a notice of
16 noncompliance?
17 MS. KRANING: Objection to form; outside
18 the scope; relevance.
19 A I am not aware of FDA doing so. They give
20 parties an opportunity to come into compliance.
21 Q As of today, how many notices of
22 noncompliance issued by the FDA are you aware of?

1 MS. KRANING: Objection to form; outside
2 the scope; relevance.
3 A I am aware of six notices of
4 noncompliance. However, there are hundreds of
5 pre-notices that come the step before the notice
6 of noncompliance.
7 Q And has the FDA ever subjected a party to
8 civil -- civil money penalties in connection with
9 a notice of noncompliance for postings to
10 ClinicalTrials.gov?
11 MS. KRANING: Objection to form; outside
12 the scope; asked and answered; relevance.
13 A As I previously stated, not to my
14 knowledge.
15 Q The notices of noncompliance that you
16 mentioned just a moment ago, what is the time
17 frame that these notices of noncompliance were
18 issued within that you're aware of?
19 MS. KRANING: Objection to form; outside
20 the scope; relevance.
21 A Can you reframe the question, please?
22 Q Sure. The six notices of noncompliance

1 that you mentioned just a moment ago, what is the
2 time frame for when they were issued by the FDA?
3 MS. KRANING: Objection to form; outside
4 the scope; relevance.
5 A As we just discussed, I believe the first
6 was issued in 2021.
7 Q So the other five notices were issued
8 after 2021?
9 MS. KRANING: Objection to form; outside
10 the scope; relevance.
11 A I believe that is true. I don't, however,
12 know when the first pre-notice was issued. I
13 don't recall that off the top of my head.
14 Q And Ms. Newberger, I'm not -- I'm not
15 asking about any pre-notices. I'm asking about
16 notices of noncompliance issued by the FDA and the
17 six that you mentioned earlier.
18 And so when after 2021, did the other five
19 notices of noncompliance issue by the FDA?
20 MS. KRANING: Objection to form; outside
21 the scope; relevance.
22 A I do not recall with specificity all six

1 notices of noncompliances and the dates on which
2 they were issued.
3 Q Do you know if any issued in 2022?
4 MS. KRANING: Objection to form;
5 relevance; outside the scope.
6 A I do not know. So it's not something that
7 I was asked to look at as part of my testimony.
8 Q But you discuss in your declarations civil
9 money penalties in connection with notices of
10 noncompliance by the FDA, right?
11 MS. KRANING: Objection to form.
12 A Certainly because that enforcement
13 mechanism was in place when the rest of this
14 statute went into place in 2007.
15 Q So how many of the six notices of
16 noncompliance that you mention that you're aware
17 of issued in 2022?
18 MS. KRANING: Objection to form; outside
19 the scope; relevance.
20 A I -- I just answered that I do not know
21 the answer to that question. I do not know the
22 dates of each of the six notices of

1 nonconformance.
2 Q Do you know how many issued in 2023, if
3 any?
4 MS. KRANING: Objection to form; outside
5 the scope; relevance; asked and answered.
6 A As I stated, I do not know the dates of
7 issuance. I, therefore, do not know how many were
8 issued in 2023, or 2022, or any other year.
9 Q Do you know if any issued in 2024?
10 MS. KRANING: Objection to form; outside
11 -- outside the scope; relevance; asked and
12 answered. Please move on, Counsel.
13 A I do not know if any notices of
14 nonconformance were issued in 2024. I know I was
15 looking at pre-notices for another matter and
16 there were over 50 of those issued in 2024.
17 That's the step before the notice of
18 nonconformance.
19 Q And I'm only asking about notices of
20 noncompliance.
21 And so do you know if any notices of
22 noncompliance issued this year in 2025?

1 MS. KRANING: Objection to form; outside
2 the scope; relevance; asked and answered.
3 A I recognize you are asking about notices
4 of noncompliance and what I'm saying is that
5 there's a pre-notice that also can be issued.
6 There were over 50 of those issued in 2024. I do
7 not know whether the notices of noncompliance were
8 issued in 2024 or 2025.
9 Q For those six notices of noncompliance
10 that you mentioned, were any civil money penalties
11 assessed in connection with those notices of
12 noncompliance?
13 MS. KRANING: Objection to form; outside
14 the scope; relevance.
15 A I am not aware of any civil money
16 penalties being issued, being enforced. My
17 report, however, talks about what were the
18 possible enforcement mechanisms in place in 2013.
19 Civil money penalties were one such enforcement
20 mechanism.
21 Q Of the six notices of noncompliance that
22 you mentioned, were any of those notices issued

1 based on a concern for failure to list a
2 collaborator?
3 MS. KRANING: Objection to form; outside
4 the scope; relevance.
5 A I have not reviewed them. It was not
6 relevant to my report.
7 Q So Ms. Newberger, the six notices of
8 noncompliance that you testified about today, you
9 did not review those; is that correct?
10 MS. KRANING: Objection to form; outside
11 the scope; relevance.
12 A I did not review them for purposes of my
13 report. I am answering your questions. I am
14 aware that they exist, but I did not read each and
15 every letter from the agency.
16 Q And how did you learn of the existence of
17 the six notices of noncompliance that you
18 testified about today?
19 MS. KRANING: Objection to form; outside
20 the scope; relevance.
21 A I was looking into them for another matter
22 that had nothing to do with this.

1 Q So you did not read the six letters that
2 were issued by the FDA, correct?
3 MS. KRANING: Objection to form; outside
4 the scope; relevance; asked and answered.
5 A I had no reason to.
6 Q So just to be clear, you did not read the
7 six letters that were issued by the FDA, correct?
8 MS. KRANING: Objection to form; outside
9 the scope; relevance; asked and answered.
10 A I'm not sure how I can be any more clear
11 in my response. I had no reason to read them.
12 They were not relevant for purposes of my report.
13 I did not read them.
14 MS. STAURING: Counsel, I think it might
15 be a good time to take a break.
16 MS. KRANING: Okay.
17 (Whereupon a break was had.)
18 MS. STAURING: Ms. Newberger, I don't have
19 any additional questions for you at this
20 particular time. Your counsel may have questions
21 for you and then I may have some after, but at
22 this time I have no further questions.

1 MS. KRANING: I do have a couple of brief
2 follow-up questions.
3 EXAMINATION
4 BY MS. KRANING:
5 Q Ms. Newberger, you testified today about
6 the differences in your declaration you submitted
7 in relation to the '393 patent versus the eight
8 declarations that we've been discussing today.
9 Do you remember that?
10 A Yes, I do.
11 Q And specifically, you testified about two
12 elements that you added to Table 1 in your
13 declarations?
14 A Correct.
15 Q And those two elements were "collaborator"
16 and "data monitoring," correct?
17 A Correct.
18 Q Did the inclusion of the two elements of
19 "collaborator" and "data monitoring" in any way
20 impact your conclusions in your declarations?
21 A No. They did not.
22 Q And Ms. Newberger, can you please turn to

1 your declaration that you submitted in connection
2 with the '356 patent?
3 A Okay.
4 Q And do you recall earlier counsel was
5 asking you about the element "brief summary" in
6 connection with Table 1 in your declaration?
7 A I do.
8 Q And can you please turn to Table 1 in your
9 declaration that was submitted in connection with
10 the '356 patent?
11 A Yes.
12 Q And is the element --
13 MS. STAURING: Objection. Counsel, this
14 is beyond the scope.
15 MS. KRANING: This is well within the
16 scope, Counsel.
17 Q Ms. Newberger, is the element "brief
18 summary" included in Table 1 of your declaration
19 submitted in connection with the '356 patent?
20 MS. STAURING: Objection. Counsel, beyond
21 the scope. I did not ask Ms. Newberger about her
22 '356 declaration.

1 A Yes. I see that on page 19.
2 Q To the best of your recollection, is there
3 any reason that "brief summary" was not included
4 in the declaration submitted in connection with
5 the other seven patents?
6 MS. STAURING: Objection, beyond the
7 scope.
8 A No. I'm not sure why that would be.
9 Q And does the omission of "brief summary"
10 from Table 1 in your declaration submitted in
11 connection with the other seven patents affect
12 your conclusions in those declarations?
13 A No, it does not.
14 MS. KRANING: Thank you, Ms. Newberger. I
15 have no further questions for you.
16 MS. STAURING: Ms. Newberger, I have no
17 further questions for you today. Just want to
18 thank you for your time and thank the court
19 reporter as well as the remote technician for your
20 time today.
21 THE REPORTER: Counsel, I do have standing
22 orders for you, Ms. Stauring.

1 Ms. Kraning, I don't believe I have orders
2 for you.
3 MS. KRANING: Okay. We can follow up
4 afterward with that.
5 (Whereupon the proceedings were concluded at
6 11:44 a.m. EST)
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1 CERTIFICATE OF SHORTHAND REPORTER
2 I, Karisa Ekenseair, Certified Reporter and
3 Notary Public within and for the State of Arkansas
4 do hereby certify: That JENNIFER NEWBERGER,
5 the witness whose deposition is hereinbefore set
6 forth, was duly sworn by me before the
7 commencement of such deposition and that such
8 deposition was taken before me and is a true
9 record of the testimony given by such witness.
10 I further certify that the adverse party,
11 PATENT OWNER, was represented by counsel at
12 the deposition.
13 I further certify that the deposition of
14 JENNIFER NEWBERGER, occurred virtually on
15 April 10, 2025, commencing at 10:00 A.M. EST to
16 11:44 a.m.
17 I further certify that I am not related
18 to any of the parties to this action by blood
19 or marriage, I am not employed by or an attorney
20 to any of the parties to this action, and that I
21 am in no way interested, financially or otherwise,
22 in the outcome of this matter.

1 IN WITNESS WHEREOF, I have hereunto set my hand
2 and affixed my seal this 14th day of April 2025.
3 My commission expires: 6-18-2028
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5
6 Karisa Ekenseair, CCR RPR RMR LS #802
7 Notary Public in and for
8 Pulaski County, Arkansas
9 Commission No. 12704567
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