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Transcript of Luwy K. Musey, M.D.

Date: July 23, 2026

Case: Pfizer, Inc. -v- Pogona, LLC (PTAB)

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1 UNITED STATES PATENT AND TRADEMARK OFFICE

2
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4
5 PFIZER INC.,
Petitioner,

6 V.

7 POGONA, LLC,
Patent Owner.

8
9 IPR2026-00189
10 Patent 11,058,757

11 -----
12 ORAL, REALTIMED DEPOSITION OF

13 LUWY K. MUSEY, M.D.

14 JULY 23, 2026

15 TAKEN VIA ZOOM VIDEOCONFERENCE
16 -----

17
18
19 JOB NO.: 642402

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22 ANNETTE PELTIER, CSR, CRR

1 ORAL AND REALTIMED DEPOSITION OF LUWY
2 K. MUSEY, M.D., produced as a witness at the
3 instance of the Patent Owner, and duly sworn,
4 was taken in the above-styled and numbered
5 cause on July 23, 2026, from 8:13 a.m. to
6 3:11 p.m. Central Time, before Annette
7 Peltier, CSR, Texas Certified Realtime
8 Reporter, in and for the State of Texas,
9 reported by machine shorthand pursuant to the
10 PTAB Rules of Civil Procedure and the
11 provisions stated on the record or attached
12 hereto.

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A P P E A R A N C E S

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Yujung Rho

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3 David Krinsky, Williams & Connolly
4 Julie Tavares, Williams & Connolly
Yujung Rho, Williams & Connolly

5 Connie Lee, O'Melveny & Myers
6 Aaron Clay, Merck

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* * * * *

1 LUWY MUSEY, M.D.,
2 Having been first duly sworn, testified upon
3 his oath as follows:

4 EXAMINATION

5 BY MS. SPIRES:

6 Q. All right. Thank you for coming
7 this morning, Dr. Musey.

8 A. Good morning.

9 Q. Good morning.

10 Have you been deposed before?

11 A. Yes.

12 Q. About how many times?

13 A. Yes. Twice before.

14 Q. Okay.

15 A. Two times.

16 Q. So the rules here should be, I
17 would think, the same, roughly, as the times
18 you've been deposed before, but I'll just go
19 through them briefly so that we're on the
20 same page.

21 So it's important that you give
22 verbal answers because the court reporter's

1 going to transcribe things, and it's very
2 hard to transcribe head nods and head shakes
3 and things like that.

4 It's important also that we try
5 not to talk over each other since the
6 reporter can only record what one person's
7 saying at a time. So I will do my absolute
8 best to let you finish your answers. If you
9 can try to let me finish my questions, that
10 will make things easier.

11 I know with the Zoom sometimes
12 there's a little bit of a lag and things
13 happen, but as long as we do our best, it
14 should go okay today.

15 So I'm obviously going to be
16 asking you some questions today, and so I'm
17 going to ask that if you don't understand my
18 question, please ask me to rephrase, say that
19 you don't understand, something to that
20 effect; otherwise, I will assume that you
21 understood what I asked; is that fair?

22 A. That's fair.

1 Q. If you need to take a break at
2 any time, let me know. I'm going to try to
3 take a break every hour. In all honesty, I'm
4 sometimes bad at watching the clock; so do
5 not feel bad about asking for a break if you
6 need one. All I ask is that if there's a
7 question pending, that you go ahead and
8 answer that before asking for a break; and
9 obviously, your counsel can ask for a break,
10 as well.

11 MR. KRINSKY: Appreciate that.

12 (BY MS. SPIRES)

13 Q. Or anyone else here.

14 Is there any reason you cannot
15 testify truthfully and honestly today?

16 A. There is no reason.

17 Q. Do you have any notes in front of
18 you today?

19 A. I only have the exhibits, as well
20 as my declaration and the patent.

21 Q. Okay. Are those all clean copies
22 that you have in front of you?

1 A. Yes, they're all clean copies.

2 Q. Okay. Did you do anything to
3 prepare for today's deposition?

4 A. I did consult with my -- the
5 lawyers to -- to understand what is at stake
6 and ask questions that I may have so that I
7 can be prepared for this testimony.

8 Q. Did you talk to anyone other than
9 your lawyers about today's deposition?

10 A. No.

11 Q. And when you say "your lawyers,"
12 are those the people that are in the room
13 with you today?

14 A. Yes.

15 Q. About how much time did you spend
16 consulting with your lawyers in preparing for
17 today's deposition?

18 A. So for today's deposition, I
19 can't remember how many hours I did spend,
20 but -- yeah. I have -- maybe the last two
21 days we're talking.

22 Q. In preparing for your deposition

1 today, did you review any documents?

2 A. I reviewed my declaration, and I
3 reviewed some of the references, as well.

4 Q. Those are the references that are
5 exhibits in your declaration? I'll rephrase.

6 Those are the references you
7 just -- those are the references you discuss
8 in your declaration?

9 A. The -- the references that I read
10 were -- those are the ones are part of my
11 declaration.

12 Q. Is this case the first time that
13 you have worked for Pfizer?

14 A. Yes.

15 Q. So you submitted a declaration in
16 this case, right?

17 A. Yes, I did.

18 Q. And that's related to U.S. Patent
19 Number 11,058,757; is that right?

20 A. The patent that I'm discussing
21 today is -- yes, it's 11,058,757.

22 Q. Is it okay with you if I call

1 that the "'757 patent" today?

2 A. That is fine.

3 Q. So for the declaration that you
4 submitted in this matter, how did you go
5 about preparing it?

6 MR. KRINSKY: Object to the
7 form.

8 You can answer.

9 A. Yeah. So it was a collaborative
10 effort between the lawyers and myself, and
11 ultimately it's my decision to sign on the --
12 on the declaration.

13 (BY MS. SPIRES)

14 Q. Did you have any discussions with
15 anyone other than your counsel relate --
16 regarding your declaration, as you were
17 preparing it?

18 A. No.

19 Q. Have you reviewed your
20 declaration since you submitted it?

21 A. I reviewed the last two days.

22 Q. In reviewing your declaration,

1 did you see anything that you felt needed to
2 be corrected?

3 A. Not to my knowledge.

4 Q. In your declaration, you provided
5 an opinion that the claims of the '757 would
6 have been either anticipated or obvious to a
7 person of ordinary skill in the art as of
8 March 31st, 2016; is that right?

9 A. Give me a minute. I can give you
10 my opinion.

11 So as I said in my declaration on
12 Page 9, paragraph 7, "I have been informed
13 that the person of ordinary skill in the art
14 is a hypothetical person who is presumed to
15 have known all the relevant art as of the
16 priority date of the '757 patent and is the
17 person to whom the subject matter of the '757
18 patent is directed."

19 And in -- "In my opinion, the
20 POSA that would include a research team with
21 one or more researchers" with different
22 degrees, in -- "in immunology, virology,

1 biochemistry, chemistry, and epidemiology,
2 clinical safety, or a related discipline, and
3 several years of work experience in
4 vaccinology and in such related fields, and
5 one or more individuals with an advanced
6 degree and experience in drug delivery of
7 vaccines."

8 Q. Okay. So the definition that you
9 just read from your declaration is the
10 definition that you have proposed for a POSA
11 as of March 31st, 2016; is that right?

12 A. So my opinion as to the
13 qualification of the POSA would not change if
14 the priority date of the '757 patent was
15 slightly different from March 31st, 2016 --
16 for instance, sometime in 2017 -- nor would
17 my opinion in this declaration change where I
18 (unintelligible) the POSA declaration --

19 THE COURT REPORTER: I'm sorry,
20 sir. I'm sorry, sir. I'm having trouble
21 understanding you. Can you slow down just a
22 little bit, please?

1 THE WITNESS: Okay. Thank you
2 very much.

3 THE COURT REPORTER: Yes, sir.

4 A. So I was just saying that my
5 opinion as to the qualification of the POSA
6 would not change if the priority date of the
7 '757 patent was slightly different from the
8 March 31st, 2016 -- for instance, sometime in
9 2017.

10 (BY MS. SPIRES)

11 Q. So the answer that you just gave,
12 you were reading from paragraph 11 in your
13 declaration; is that right?

14 A. It is my declaration in paragraph
15 11.

16 Q. So my question is, when you were
17 forming your opinions, did you put yourself
18 in the position of a POSA to -- to come up
19 with those opinions?

20 A. Can you please repeat your
21 question?

22 Q. Sure.

1 Did you -- strike that.

2 When you provided the opinions in
3 your declaration, did you provide those from
4 the standpoint of a POSA?

5 A. So "I have been asked to opine as
6 to the qualifications of the POSA to which
7 the claims of the '757 patent are directed.
8 For the purpose of rendering an opinion on
9 this question, I have further been instructed
10 to assume that the priority date of the...
11 patent is March 31st, 2016."

12 Q. Okay. And in answering my
13 question, you just read from paragraph 8 of
14 your declaration?

15 A. That is exact.

16 Q. Okay. My question is not about
17 the qualifications of a POSA. My question
18 right now is about your opinions in the
19 entirety of your declaration.

20 So in providing the opinions in
21 your declaration, did you provide those
22 opinions from the viewpoint of a POSA?

1 MR. KRINSKY: Objection to the
2 form of the question.

3 A. As I mentioned -- as I said
4 earlier, "In my opinion, the POSA would
5 include a research team with one or more
6 researchers with an M.D. or Ph.D. in
7 immunology, virology, biochemistry,
8 chemistry, epidemiology, clinical safety, or
9 a related discipline, and several years of
10 work experience in vaccinology and in such
11 related fields, and one or more individuals
12 with an advanced degree and experience in
13 drug delivery of vaccines."

14 So the POSA is a team of
15 individuals who are working together, and my
16 qualification is an M.D. with experience in
17 the field of pneumococcal disease and
18 vaccine, was -- provide a justification as --
19 as to my contribution to the POSA.

20 (BY MS. SPIRES)

21 Q. Okay. I think we're still kind
22 of ships passing in the night right here,

1 because I'm not asking about who a POSA is or
2 what the POSA's qualifications are.

3 I understand that you can read
4 that in your declaration. I can, as well.

5 I'm asking that when you provided
6 the opinions in your declaration, going well
7 past the paragraphs that you are reciting
8 right now, did you provide those opinions
9 from the viewpoint of a POSA?

10 A. So (as read) the opinion and
11 conclusion expressed herein are based on my
12 review of the materials cited here, as well
13 as my general knowledge of pneumococcal
14 conjugate vaccine and vaccine clinical
15 research and my experience and training as a
16 researcher in this field.

17 Q. Are you reading from your
18 declaration again?

19 A. I'm reading from my declaration
20 on Page 8.

21 Q. What paragraph?

22 A. Paragraph 4.

1 Q. Are you able to answer any
2 questions today without reading the answers
3 directly from your declaration?

4 MR. KRINSKY: Object to the
5 form of the question, argumentative.

6 A. I'm providing response to this
7 testimony to make sure that I'm not deviating
8 from my declaration, and that is why I want
9 to use the same term I'm using, for accuracy.

10 However, I will use my general
11 knowledge in pneumococcal conjugate vaccines
12 and vaccine clinical research and my
13 experience and training as a researcher to
14 answer any questions that has to do with this
15 particular field of pneumococcal disease and
16 pneumococcal vaccines that are pertaining
17 particularly to this patent.

18 (BY MS. SPIRES)

19 Q. Okay, because I -- I'm worried
20 that my question maybe cannot be answered by
21 reading directly from your declaration
22 because I still haven't gotten an answer to

1 my question, which is: When you provided the
2 opinions that you set forth in your
3 declaration, did you provide those opinions
4 from the viewpoint of a POSA?

5 MR. KRINSKY: Object to the
6 form.

7 A. I was informed that the person of
8 ordinary skill in the art, a POSA, is an
9 hypothetical person who is presumed to have
10 known all the relevant art as of the priority
11 date of the '757 patent and using my general
12 knowledge of pneumococcal conjugate vaccine
13 and vaccine clinical research, as well as my
14 experience and training as a researcher in
15 this field to provide the testimony that I'm
16 providing today.

17 So a POSA is somebody who have
18 some knowledge on the topic that we're
19 discussing today about pneumococcal vaccine,
20 and that's what I'm providing today as -- for
21 my testimony.

22 (BY MS. SPIRES)

1 Q. Okay. So I'm -- I'm not talking
2 about your testimony today or about who a
3 POSA is. I'm talking about your declaration
4 that you submitted.

5 When you submitted your
6 declaration in this case, you provided
7 certain opinions, correct?

8 A. As I mentioned, this declaration
9 that I'm providing is my understanding of the
10 patent that is -- I'm examining. There are
11 some legal terms that I had to be educated
12 with, and I've used my counsel to help me
13 understand the legal terms.

14 My real contribution here is my
15 scientific knowledge on the pneumococcal
16 conjugate vaccines and vaccine clinical
17 research, how vaccines are developed, and my
18 training -- experience and training as a
19 researcher in the field of pneumococcal
20 vaccine development.

21 Q. Okay. So I just asked you to
22 confirm that you provided certain opinions in

1 your declaration. Can -- strike that.

2 I need you to listen carefully to
3 my questions, because so far you haven't
4 answered any of them.

5 When you submitted your
6 declaration in this case, you provided
7 certain opinions; is that right?

8 A. As I said in -- as I just said,
9 the opinion and conclusion that I express in
10 this declaration, I expressed them -- are
11 based on my review of the material that we
12 cited, as well as my general knowledge of
13 pneumococcal conjugate vaccines and vaccine
14 clinical research and my experience and
15 training as a medical doctor, as a researcher
16 in the field of pneumococcal conjugate --
17 pneumococcal vaccines.

18 Q. Can you explain what general
19 knowledge of pneumococcal conjugate vaccines
20 and vaccine clinical research you used to
21 form your opinions in this matter?

22 MR. KRINSKY: Objection, vague.

1 A. So I -- I have a training in the
2 medical -- in medicine. I have a training in
3 immunology and I have a training in
4 microbiology and I have worked for several
5 years in vaccine research, more than 20 years
6 in vaccine research, and I understand how
7 vaccines are developed.

8 And so I bring here my 21 years
9 of experience in vaccine research and -- and
10 that is the expertise that I'm bringing to
11 the table; and I also have worked with teams,
12 multidisciplinary teams that are involved in
13 vaccine research. I have also interacted
14 with regulatory agencies about regulatory
15 expectations for vaccine licensure, so I
16 bring -- I'm -- my opinions that I'm
17 expressing here are based on not only what I
18 just said about the -- the material that I've
19 seen, that I've been asked to review, but
20 also that knowledge that I bring in the
21 medical -- in medicine, in vaccine
22 development.

1 (BY MS. SPIRES)

2 Q. So you said that you have 21
3 years of experience in vaccine research; is
4 that right?

5 A. I spent 21 years at -- vaccine
6 research and development at Merck; but before
7 that, I also worked indirectly in vaccine
8 development for HIV AIDS, but not really,
9 like, making a vaccine, but just thinking
10 about how one could develop a vaccine for HIV
11 AIDS in the '90s.

12 Q. So when you answered earlier that
13 you bring here your 21 years of experience in
14 vaccine research, were you referring to the
15 21 years that you spent in vaccine research
16 and development at Merck?

17 A. Yes, the 21 years that I'm
18 referring to is only for the 21 years I spent
19 doing vaccine research at Merck.

20 Q. And what were the dates of the 21
21 years that you spent doing vaccine research
22 at Merck?

1 A. As I provided in my resum[?], I
2 joined Merck in 2001, June of 2001; and I
3 retired from Merck in May or June of 2022.
4 That makes 21 years of research in vaccine at
5 Merck, and you can find that in my resum[?]
6 that I provided.

7 Q. So in forming the opinions that
8 you set forth in your declaration, you
9 applied the 21 years of vaccine research that
10 you spent at Merck, from June of 2001 through
11 June of 2022; is that right?

12 MR. KRINSKY: Object to the
13 form.

14 A. As I said, the opinion that I'm
15 providing here is not just about my 21 years
16 of Merck, it's also about my general
17 knowledge in medicine, immunology, as well as
18 microbiology, which precede my employment
19 with Merck.

20 (BY MS. SPIRES)

21 Q. So in forming your opinions that
22 you set forth in your declaration, you

1 applied the 21 years of vaccine research that
2 you spent at Merck, from June 2001 through
3 June of 2022, as well as your general
4 knowledge in medicine, immunology, and
5 microbiology that preceded your employment
6 with Merck; is that right?

7 A. That is correct.

8 Q. In forming your opinions that you
9 set forth in your declaration, based, in
10 part, on the 21 years of vaccine research
11 that you spent at Merck, from June 2001
12 through June of 2022, did you rely on any
13 information that is not known to the public,
14 or that is confidential?

15 A. Can you please clarify your
16 questions about what you mean by "any
17 information that is" not "confidential" -- or
18 "that is confidential," please?

19 Q. Sure.

20 So you said that you formed your
21 opinions in your declaration based, in part,
22 on the 21 years of vaccine research that you

1 spent at Merck, from June 2001 through June
2 of 2022, and I'm trying to understand whether
3 all of that research from your time at Merck
4 that you relied on is in the public domain or
5 whether some of that information that you
6 relied on from your time at Merck is still
7 confidential.

8 MR. KRINSKY: Object to the
9 form of the question, mischaracterizes
10 testimony, and lack of foundation.

11 Counsel, just to try to cut
12 through this, he didn't say that he was
13 relying on confidential information. You
14 asked him if he applied his expertise.

15 MS. SPIRES: Yes. I'm trying
16 to find out -- get there and see if he relied
17 on confidential information.

18 A. My declaration that I'm providing
19 does not take into consideration any
20 confidential information. It's solely based
21 on general knowledge of publicly-available
22 information about pneumococcal vaccine

1 development and the expectation from a POSA,
2 who would be a person that -- of ordinary
3 skill who would like to be part of a team
4 that will develop a vaccine for --
5 pneumococcal conjugate vaccine.

6 (BY MS. SPIRES)

7 Q. So when you said that you formed
8 your opinions in your declaration based, in
9 part, on the 21 years of vaccine research
10 that you spent at Merck, from June 2001
11 through June of 2022, is all of that vaccine
12 research that you did something that a POSA
13 would have been aware of?

14 MR. KRINSKY: Object to the
15 form.

16 A. The information I'm providing in
17 this declaration are all publicly-available
18 and they are not information that are
19 confidential. It's just information that I
20 am aware of, and I'm providing my opinion
21 based on that information, regardless of the
22 origin.

1 Some of the information could be,
2 you know, from a manuscript; some information
3 could be from a meeting that I attended to
4 sharpen my knowledge on pneumococcal disease
5 and vaccines and -- but as I said, most -- my
6 opinion here is solely based on
7 publicly-available information.

8 (BY MS. SPIRES)

9 Q. Are you aware that Merck has also
10 filed a different IPR petition against the
11 '757 patent?

12 A. I retired from Merck in 2022.
13 Since then, I was -- I have not been involved
14 in any work that Merck is doing, and I only
15 have contact with Ms. Connie Lee about this
16 particular IPR and I'm not involved in
17 anything else that is outside of this patent,
18 '757.

19 Q. Okay. So I am talking about the
20 '757 patent, and so my question is not
21 whether you worked on this other IPR, but
22 whether you are aware that Merck also filed a

1 different IPR petition against the '757
2 patent.

3 A. I don't remember whether somebody
4 told me that; but since I'm not really privy
5 to that, I cannot tell you whether somebody
6 mentioned that to me, so I'm -- I'm not
7 really -- cannot really comment on that
8 particular issue that you just mentioned.

9 Q. So the reason I bring this up is
10 because that IPR has a different "POSA"
11 definition, and so I'm going to just read to
12 you what that POSA definition is because I
13 want to know whether or not you agree with
14 that definition.

15 So in Merck's IPR petition,
16 Merck's expert defined a "POSA" as an
17 individual or a team with Ph.D. degrees in
18 the biological and chemical sciences and at
19 least two years of work experience, or an
20 M.D. degree with at least six years of work
21 experience developing conjugate vaccines,
22 including specifically growing sufficient

1 quantities of bacteria, extracting,
2 purifying, and analyzing bacterial
3 polysaccharides, conjugating polysaccharides
4 to a carrier.

5 A. Is it possible for me to see it
6 so I can read it, because I -- it's a long
7 definition, and I don't really know. So if I
8 can at least have that so I can read it, you
9 know, it would be very helpful.

10 Q. Sure.

11 MS. SPIRES: So if anyone is
12 able to turn real-time over to the doctor, he
13 can read it from that, or I can grab that
14 definition and put it into the chat. It's
15 not an exhibit in this IPR.

16 MR. KRINSKY: I mean, I think
17 if you want to show it to the witness, you're
18 going to have to mark it as an exhibit, but I
19 don't -- I don't have a copy of the Merck --

20 MS. SPIRES: Sure.

21 MR. KRINSKY: -- materials here.

22 MS. SPIRES: No problem. I

1 will grab it really quickly and throw it into
2 the chat. Okay. So much for having
3 everything marked.

4 This exhibit already has a
5 marking of Exhibit 1002. I do not want to
6 use that since that is the exhibit number for
7 Dr. Musey's declaration, so we will mark this
8 exhibit as Exhibit 2018.

9 (Whereupon Exhibit Number 2018
10 was marked for identification.)

11 MR. KRINSKY: And we can, I'm
12 sure, sort out the physical marking of the
13 PDF later.

14 But, Dr. Musey, if you click on
15 the chat icon, you should be able to see an
16 icon for Exhibit 1002, Kaspay or Kasper or
17 something like that. Do you see that?

18 THE WITNESS: Yes, I see.

19 MR. KRINSKY: I think if you
20 double-click on that, you'll be able to open
21 up the exhibit or -- it's trying to save it
22 somewhere, but save it and then you can open

1 it.

2 THE WITNESS: So if I do that,
3 but where can I find it then?

4 MR. KRINSKY: Just click on it
5 again.

6 THE WITNESS: But it asked me
7 to save it on the desktop.

8 MR. KRINSKY: That's fine.

9 THE WITNESS: Okay. Here.

10 (BY MS. SPIRES)

11 Q. No rush. Just tell me when you
12 have it and I'll direct you to where I'm
13 referring to.

14 A. Yeah, it's -- it's coming up.

15 MR. KRINSKY: Dr. Musey, just
16 let us know if you need help with it.

17 THE WITNESS: It's finding the
18 Adobe, so it's just like.... yeah. Okay. I
19 think I have it. It's very slow, I'm sorry.

20 MS. SPIRES: No problem.

21 THE WITNESS: It's just...

22 okay. So it's not really working. Can you

1 help, please?

2 MR. KRINSKY: I'm going to just
3 step over and help him.

4 MS. SPIRES: Sure.

5 (Discussion off the record,
6 trying to get the exhibit up.)

7 THE WITNESS: Yes, I can see it
8 now. Sorry.

9 (BY MS. SPIRES)

10 Q. No problem.

11 So the paragraph -- the "POSA"
12 definition that I read to you is in paragraph
13 20 of what is now exhibit -- what did I label
14 it as -- 2018.

15 You can look through any of the
16 declaration you'd like, but you'll see that
17 there is a heading on Page 6 that starts
18 "Level of Ordinary Skill in the Art." And so
19 that's the section that I'm asking you about
20 right now.

21 A. Yes, I can see it. Just give me
22 a few minutes to read it, please.

1 Q. Sure.

2 A. Okay. I've read the paragraph.

3 Q. Okay. So you've read --

4 A. So what is the question?

5 Q. You read the definition of a
6 "POSA" -- or they used the term "POSITA" --
7 that is set forth in paragraph 20 of the
8 Merck expert declaration; is that right?

9 A. I can see. Yes, I've read it.

10 Q. Do you agree with the definition
11 of a POSA that Merck's expert sets forth in
12 paragraph 20 of Exhibit 2018?

13 MR. KRINSKY: Objection,
14 outside the scope.

15 A. So is it -- you asked me if I
16 agree with the opinion formulated in
17 paragraph 18?

18 (BY MS. SPIRES)

19 Q. No. I'm asking if you agree with
20 the POSA definition in paragraph 20 of
21 Exhibit 2018.

22 MR. KRINSKY: Same objection,

1 outside the scope.

2 A. I cannot really -- I cannot
3 comment on what this statement here mentioned
4 because it's not my opinion, it's somebody
5 else opinion, and I cannot comment on that.

6 (BY MS. SPIRES)

7 Q. Well, you provided what you
8 believed was the definition of a POSA with
9 respect to the '757 patent, correct?

10 A. As I have indicated, my opinion
11 is what I provided in my declaration; and
12 that is my opinion when it comes to the
13 definition of POSA and I can only, you know,
14 comment on -- on what I provided in my -- in
15 my declaration.

16 Q. So you provided a definition of
17 what a POSA is with respect to the '757
18 patent, but paragraph 20 of Exhibit 2018 is a
19 different POSA definition with respect to the
20 '757 patent.

21 Do you see that?

22 A. I did not have the time to really

1 opine into what this document that you are
2 showing me really entails. I've not done any
3 in-depth analysis as to what is the
4 difference between what I've written in my
5 declaration and what is written in the
6 document that you have provided to me.

7 So I don't have any opinion on
8 the definition of the POSA that has been
9 provided in the document that you provided to
10 me.

11 Q. How did you come up with the
12 definition of a POSA that you included in
13 your declaration?

14 A. So I've been informed that the
15 person of ordinary skill in the art is an
16 hypothetical person who is presumed to have
17 known all the relevant art as of the priority
18 date of the '757 patent and is the person to
19 whom the subject matter of the '757 patent is
20 directed.

21 I'm -- it's the information
22 that I -- I was informed about what a POSA

1 is, and that is why I put it in my
2 declaration and guided me in the opinion that
3 I'm providing about this particular patent,
4 '757.

5 (BY MS. SPIRES)

6 Q. Did you come up with the POSA
7 definition you provided in paragraph 10 of
8 your declaration yourself?

9 MR. KRINSKY: Object to the
10 form.

11 A. As I mentioned earlier, this
12 declaration is a collaborative effort between
13 myself and the -- the team, or the counsel
14 that I was working -- I was working with in
15 drafting, altering this declaration.

16 There are a lot of legal terms
17 that needed to be clearly explained to me,
18 and I tried my best to provide my
19 understanding of those terms in this
20 document.

21 (BY MS. SPIRES)

22 Q. Well, I understand that the

1 declaration is a collaborative effort between
2 you and counsel. I'm asking about paragraph
3 10 in particular.

4 Was paragraph 10 also a
5 collaborative effort, or did you provide the
6 definition of the POSA that you provided in
7 paragraph 10?

8 MR. KRINSKY: Objection to
9 form.

10 A. As I said in my declaration on
11 paragraph 10, in my opinion, which means it's
12 myself, my opinion, Dr. Luwy Musey, that a
13 POSA would include a research team with one
14 or more researcher with an M.D. degree or
15 Ph.D. in immunology, virology, biochemistry,
16 chemistry, epidemiology, clinical safety, or
17 related discipline, and several years of work
18 experience in vaccinology and in such related
19 fields and one or more individual with
20 advanced degree and experience in drug
21 delivery of vaccines.

22 My opinion is based on my -- the

1 way I saw vaccine being developed, especially
2 pneumococcal conjugate vaccines, which
3 require a team of scientists to work together
4 and bring together those different knowledge
5 that contribute to a successful development
6 of -- of pneumococcal conjugate vaccine. So
7 that is my opinion, as I just mentioned, in
8 paragraph 10.

9 (BY MS. SPIRES)

10 Q. In paragraph 9, you refer to the
11 educational level of the inventor.

12 Do you have an understanding of
13 the educational level of the inventors of the
14 '757 patent?

15 A. Can you clarify your questions?

16 Q. Sure.

17 A. I don't understand what -- this
18 question.

19 Q. Sure.

20 If you look at paragraph 9 of
21 your declaration, you say, "I have been
22 informed that factors that may be considered

1 in determining the level of ordinary skill
2 may include," and the first factor you list
3 is the educational level of the inventor.

4 Do you see that?

5 A. Yes, I can see that.

6 Q. Do you have an understanding of
7 what the educational level of the inventors
8 of the '757 patent is?

9 A. The information that is in my --
10 in my -- my knowledge is that this particular
11 patent were provided or developed by --
12 trying to find what I -- the name of the
13 person.

14 Yes, the -- the patent is -- '757
15 lists Bruce D. Forrest and Jack D. Love as
16 named inventor. So that's the only
17 information I have.

18 And reading some papers, provide
19 that -- I don't remember, but one of them is
20 an M.D., but that's the information that I
21 have about the level of education.

22 Q. Why do you believe that a POSA

1 would need to have experience in drug
2 delivery of vaccines?

3 A. My opinion is solely based on the
4 patent '757, which discuss the development of
5 the pneumococcal conjugate vaccine.

6 In that spirit, it is important
7 for the POSA to understand how vaccines are
8 delivered because it's a very specialized
9 compound and need to be provided or delivered
10 in a certain way.

11 There are many differences --
12 different vaccines, and as I explain in my --
13 in the declaration, a vaccine can be
14 delivered different ways; and so knowing how
15 those vaccines can be delivered, it's
16 important.

17 And when you develop a vaccine,
18 you have knowledge of whether this vaccine is
19 going to be delivered in a certain fashion,
20 whether it's orally, intramuscularly,
21 intranasally, and so forth.

22 So that is my knowledge on

1 vaccine development and why drug delivery of
2 this vaccine is an important topic that the
3 person need to know.

4 Q. So you're talking about knowledge
5 of drug delivery, but your POSA definition
6 talks about experience in drug delivery of
7 vaccines.

8 Are you making a distinction
9 between those two?

10 MR. KRINSKY: Objection to
11 form, asked and answered.

12 A. Can you please explain the
13 difference that you are -- you want to make
14 here between "knowledge" and "experience,"
15 please?

16 (BY MS. SPIRES)

17 Q. In your opinion, would it be
18 sufficient for a POSA to have knowledge of
19 drug delivery of vaccines as opposed to
20 experience in drug delivery of vaccines?

21 MR. KRINSKY: Objection to
22 form.

1 A. I believe -- this is my own
2 opinion -- that to have experience, you need
3 to have knowledge. So you need to have that
4 knowledge, and then when you have -- you've
5 been exposed to that particular topic, you
6 acquire experience. The knowledge by itself
7 at one -- let's say in the first day of
8 reading a paper, you may have a knowledge of
9 a paper that you're reading. That doesn't
10 mean that you have experience on that.

11 So what I'm putting here is
12 "having experience in drug delivery of
13 vaccines," which implies that that person
14 also have knowledge.

15 (BY MS. SPIRES)

16 Q. I agree with you that someone
17 with experience in drug delivery of vaccines
18 would imply that they have knowledge of drug
19 delivery of vaccines, but my question is a
20 little different.

21 I'm asking whether it would be
22 sufficient for a POSA to have knowledge in

1 drug delivery of vaccines without also having
2 experience in drug delivery of vaccines.

3 MR. KRINSKY: Object to the
4 form of the question, outside the scope.

5 A. As I said, for a POSA, it's
6 important -- it would be preferred that that
7 person have not just the knowledge, but also
8 the experience in drug delivery of vaccines.

9 So the interpretation of
10 "knowledge" versus "experience," this is
11 something that -- I cannot comment on that
12 when it comes to what is -- exactly you're
13 trying to -- to distinguish between the two.

14 But here I'm talking about a
15 research team, and that research team will
16 have individuals with M.D. or Ph.D. degree in
17 different aspects of vaccine development,
18 including drug delivery of vaccine.

19 (BY MS. SPIRES)

20 Q. So you said that it would be
21 preferred that a POSA not -- have not just
22 knowledge, but also the experience in drug

1 delivery of vaccines.

2 Why is that important?

3 A. As I said, I give an example of
4 "knowledge" versus "experience." I may know
5 how, as a mechanic -- I may know -- as a
6 person, I may know that a car, you need to --
7 a car have certain features that are used
8 to -- used if I want to drive a car. I may
9 have that knowledge, or maybe just to say --
10 go back to the one example I said earlier.
11 You may have knowledge of a manuscript. I
12 can read a manuscript that talk about
13 navigations of how a boat goes into -- you
14 know, how a boat has to be -- goes from,
15 let's say, point A and point B, start the
16 engine and things like that.

17 But do I really have experience
18 piloting a boat? No. Because if you don't
19 have the experience, you may be going to a
20 situation on the boat, and you don't have
21 experience, you may not have used -- been
22 confronted -- experienced that situation.

1 So to me, it is -- knowledge is
2 one thing, but experience require knowledge
3 and some activities in that particular field.

4 Q. Do you believe that a research
5 team -- I'm looking at your POSA definition
6 again here.

7 Do you believe that a research
8 team with one or more researchers with an
9 M.D. or a Ph.D. in immunology, virology,
10 biochemistry, chemistry, or a related
11 discipline and several years of work
12 experience in vaccinology or related fields
13 would understand that a vaccine can be in the
14 form of, say, an intramuscularly-injectable
15 composition, an intradermally-injectable
16 composition, subcutaneously-injectable
17 composition, or an
18 intranasally-administratable composition?

19 MR. KRINSKY: Objection, vague,
20 outside the scope.

21 A. So as I said -- and it's provided
22 in my declaration on Page 10 -- in my

1 opinion, the POSA will include the research
2 team. There are a lot of contributors to the
3 development. Each one of them doesn't need
4 to know all the aspects. Each one of them
5 would contribute.

6 And, for example, I didn't
7 mention here -- I say what is discipline. I
8 didn't include do you need somebody to -- to
9 know what the policy is for that particular
10 field. We need to have somebody who will say
11 yes, this is -- this is the burden of
12 disease, the other medical needs, and then
13 how we can bring this particular vaccine to
14 the market that can be used, how it's going
15 to be used, which population, which
16 indication.

17 So there are a lot of different
18 members of that research team that make the
19 POSA, that each one of them would contribute
20 to -- contribute their knowledge and
21 experience to the development of the vaccine.
22 (BY MS. SPIRES)

1 Q. So in your opinion, the POSA
2 research team would include someone who knows
3 about the medical needs of the disease, how
4 you can bring the particular vaccine to the
5 market, how the vaccine's going to be used,
6 which population, and which indication for
7 the vaccine?

8 MR. KRINSKY: Objection to
9 form, compound, misstates testimony.

10 A. So as I said, in my opinion,
11 discussing vaccine development, it's -- it's
12 a multidisciplinary team of individuals with
13 different skills. They will come together to
14 bring their knowledge and expertise and
15 experience to look at all the different
16 aspects of the vaccine.

17 Some may be more important at the
18 beginning, some may be important in the
19 middle, some may be important at the end of
20 the process of developing the vaccine, but
21 it's really all those people coming together
22 to develop the vaccine.

1 So, in one way it's not a single
2 person, it's a group of persons.

3 And as I said, this particular
4 patent, what we're discussing today, it's a
5 POSA that will be -- have knowledge on what
6 is included in the patent. It's -- this
7 patent is not talking about which populations
8 of which countries or the marketing strategy,
9 so there are aspects that this patent is
10 talking about that is -- maybe one POSA will
11 have that knowledge and experience about what
12 is provided in the patent.

13 MR. KRINSKY: Counsel, we've
14 been going about an hour. Is this a good
15 time for a break?

16 MS. SPIRES: Sure, that's fine.

17 THE VIDEOGRAPHER: We're off
18 the record.

19 (Break taken from 9:15 a.m. to
20 9:26 a.m.)

21 (BY MS. SPIRES)

22 Q. Dr. Musey, if I refer to a "POSA"

1 or a "person of ordinary skill in the art"
2 today, can we agree that I'm referring to the
3 definition of a POSA that you set forth in
4 your declaration?

5 A. I think this is my opinion. So
6 if you agree to use that, that would be
7 helpful, but, you know, it's -- it's just my
8 opinion, so it's just what I feel and what I
9 think and it's not -- you may have a
10 different opinion, of course, like anybody
11 else, so -- but this is my opinion that I put
12 in my declaration.

13 Q. I just want us to be on the same
14 page when I use the term "POSA."

15 A. That would be helpful.

16 Q. So... okay.

17 In your declaration, you referred
18 to one prior art reference called Alexander,
19 right?

20 A. Yes.

21 Q. And for your reference, I believe
22 that's Exhibit 1008.

1 A. Let me make sure that I have
2 that.

3 MS. SPIRES: We can put it in
4 the chat if it's helpful.

5 MR. KRINSKY: And, Doctor, I
6 think you have 1008 in the big binder next to
7 you.

8 THE WITNESS: Okay. Give me
9 one second.

10 A. Yes.

11 (BY MS. SPIRES)

12 Q. Okay. So you've -- strike that.

13 In your declaration, you provided
14 certain opinions with respect to the
15 Alexander reference; is that right?

16 A. Yes, among many others, as well.

17 Q. Yes.

18 I'd like to direct you to
19 paragraph 55 of your declaration.

20 A. Can I have -- do you want me to
21 read that?

22 Q. Sure.

1 A. Okay. Thank you. I finished
2 reading paragraph 55.

3 Q. Yes. So in paragraph 55 of your
4 declaration, you state that, "Alexander
5 discloses a set of serotypes to select from
6 when formulating a vaccine composition,"
7 right?

8 A. That is the first sentence in
9 paragraph 55, yes.

10 Q. Right. And then you go on to
11 quote Alexander as explaining that, "In some
12 embodiments, the compositions of the
13 invention comprise a mixture of conjugates of
14 a separate pan DR peptide of the invention
15 with capsular polysaccharides from 2 up to 30
16 or more of the following serotypes," and then
17 you provide that list of serotypes; is that
18 right?

19 MR. KRINSKY: Objection to
20 form.

21 A. Let me see the reference that
22 I've included there. Give me one second.

1 Yes, I've read that.

2 Q. So that's correct, that's what
3 you provided in paragraph 55?

4 A. Yeah, it's taken from paragraph
5 63 of the Exhibit 1008 on Page 15.

6 Q. Right. And so when you say it's
7 taken from paragraph 63 of Exhibit 1008, are
8 you talking about that list of serotypes you
9 provided in paragraph 55 of your declaration?

10 A. That is correct.

11 Q. Did you count how many serotypes
12 are in that list you provided in paragraph 55
13 of your declaration?

14 A. No, I did not. I only know it
15 was some -- many of them.

16 Q. I will represent to you that
17 there are 53 serotypes in that list, but you
18 can also count that if you would like to.

19 A. Yeah, there appear to be 53
20 serotypes.

21 Q. Is there a reason that, prior to
22 just now, you had not counted the number of

1 serotypes in the list you provided in
2 paragraph 55?

3 MR. KRINSKY: Object to the
4 form.

5 A. I've been reading so many
6 documents, and those documents are listing
7 many serotypes. And in some of them, that --
8 I produced a small number, which is easy to
9 count, some of them a little bit more, and I
10 couldn't really tell you whether it was 45 or
11 53.

12 And so, you know, I just was
13 focusing on, you know, the information that
14 is provided and so -- so many listing
15 embodiment that I've seen in many documents.

16 (BY MS. SPIRES)

17 Q. Do you believe that the number of
18 serotypes listed in Alexander that you
19 provide in paragraph 55 of your declaration
20 is important to the opinions you provide?

21 MR. KRINSKY: Objection to
22 form, vague.

1 A. I'm trying to find what I quote
2 about that.

3 So my understanding as a POSA is
4 that Alexander disclosed the compositions of
5 the invention that comprised a mixture of
6 conjugate of a separate polypeptides of the
7 invention with capsular polysaccharide from 2
8 up to 30 or more of the following serotypes,
9 followed by a list of 53 serotypes that
10 include 23A, 23B, and 35.

11 Additionally, Alexander disclosed
12 independent claim that the invention
13 comprised serotype streptococcal pneumoniae
14 capsular polysaccharide from at least any
15 five of the following, including 23A, 23B,
16 and 35.

17 So that is a framework that
18 Alexander is providing about which serotype
19 can be included in the vaccine.

20 Q. All right. Let me reask my
21 question, because I don't think you answered
22 it.

1 Do you believe that the number of
2 serotypes listed in Alexander that you
3 provide in paragraph 55 of your declaration
4 is important to the opinions you provide in
5 your declaration?

6 MR. KRINSKY: Objection to
7 form, asked and answered and vague.

8 A. The information that I'm
9 providing in my opinion is based on the
10 listing of these serotypes and especially the
11 nature of those serotypes.

12 And as -- as Alexander has
13 indicated, it is in another section that
14 these are the serotypes that were not just
15 randomly listed, they had -- there was a
16 basis for why those serotypes were selected
17 in the list.

18 (BY MS. SPIRES)

19 Q. Can you point me to where in your
20 declaration you provide any other discussion
21 of a list of serotypes in Alexander?

22 A. Just give me one second.

1 MR. KRINSKY: Object to the
2 form.

3 A. In my declaration on Page 13,
4 paragraph 17, I mention the following, "To
5 date, researchers have identified more than
6 100 different pneumococcal serotypes of
7 streptococcus pneumoniae. Serotypes vary in
8 their prevalence and virulence across age
9 strata and geographical location. The
10 prevalence of different serotypes varies
11 geographically and temporally; a given
12 serotype may become unusually prevalent for a
13 period of time or in a particular region.
14 Monitoring pneumococcal serotype prevalence
15 and identifying newly emerging serotypes is
16 essential for designing new pneumococcal
17 vaccines. This is particularly important
18 after the introduction of a pneumococcal
19 vaccine to a population when the prevalence
20 of vaccine-type serotypes (i.e., serotypes
21 included in the vaccine) is reduced and there
22 is a corresponding increase in the prevalence

1 of" non-vaccine types, vaccine [sic] not
2 included in the vaccine.

3 "Epidemiological studies related
4 to the distribution of the circulating
5 pneumococcal serotypes in a given population
6 are based on the isolation of strains of the
7 streptococcal pneumoniae in individuals with
8 clinical systems suggestive of pneumococcal
9 disease as well as natural carriage of
10 streptococcal pneumoniae in the nasopharynx
11 from children and adults with or without
12 pneumococcal disease."

13 So this is really knowledge that
14 the serotype that are, you know, provided are
15 serotype that are associated with burden of
16 the pneumococcal disease.

17 So in paragraph 7 of -- paragraph
18 7 of the -- the patent -- which I did not
19 include the patent from Alexander, which I
20 did not include in my declaration -- it talk
21 about, you know, there are at least -- I can
22 read that if you want.

1 "There are at least 40
2 serogroups, some comprising multiple
3 serotypes that are immunologically" --

4 (Reporter clarification.)

5 A. So on paragraph 7, Page 2 of the
6 Exhibit 1008 -- I don't know if I quoted that
7 or I've provided that in my declaration, but
8 it says here, "There are at least 40
9 serogroups, some comprising multiple
10 serotypes that are immunologically
11 cross-reactive. Current pneumococcal vaccine
12 formulations are combination vaccines
13 containing a mixture of the capsular
14 polysaccharides from the more common
15 serotypes and are effective against invasive
16 disease in older children and adults."

17 So the -- that is common
18 knowledge in the field, that the serotype
19 that you'll be focusing on are serotypes that
20 are associated with the burden of
21 pneumococcal disease.

22 THE WITNESS: Do you want me to

1 repeat that?

2 THE COURT REPORTER: (Shakes
3 head.)

4 THE WITNESS: Okay.
5 (BY MS. SPIRES)

6 Q. So I'm going to go back and find
7 my question because it was a little
8 different. I guess I'll rephrase what I've
9 been asking to try and be a little clearer.

10 Do you believe that the -- strike
11 that.

12 Do you believe that it matters to
13 your opinion how many serotypes Alexander
14 lists that you provide in paragraph 55 of
15 your declaration?

16 A. Can you repeat that? I didn't
17 hear -- do I believe?

18 Q. Sure.

19 In paragraph 55 of your
20 declaration, you list 53 serotypes from
21 Alexander, right?

22 A. Yes.

1 Q. Do you believe that the size of
2 this list of serotypes matters to the
3 opinions you set forth in your declaration?

4 MR. KRINSKY: Objection, vague,
5 compound, asked and answered.

6 A. I don't know if I understand the
7 question on a scientific basis or not.

8 Are you telling me that 53
9 serotypes are all important? I don't
10 understand the question.

11 (BY MS. SPIRES)

12 Q. How about if I rephrase.

13 When you formed your opinions as
14 you set forth in your declaration, did you
15 consider the size -- strike that.

16 When you formed your opinions as
17 you set forth in your declaration, did you
18 consider the number of serotypes that you
19 list in paragraph 55 of your declaration?

20 MR. KRINSKY: Object to the
21 form.

22 A. What I did was to provide

1 Alexander's declarations -- Alexander's
2 viewpoint on the matter.

3 So I looked at what Alexander did
4 and what information he's providing, and I
5 based my opinion on what I've been asked to
6 assess as the patent '757 based on
7 information provided by Alexander, including
8 that particular list of 53 serotypes.

9 (BY MS. SPIRES)

10 Q. If a POSA wanted to create a
11 pneumococcal vaccine using from 2 to 30 or
12 more of these 53 serotypes that you list from
13 Alexander in paragraph 55 of your
14 declaration, do you know how many possible
15 combinations of serotypes the POSA could come
16 up with?

17 A. No. I did not calculate the
18 number of permutations or combinations.

19 Q. Do you have an understanding as
20 to whether the size of the list of serotypes
21 you provide in paragraph 55 of your
22 declaration from Alexander has any relevance

1 to your anticipation analysis?

2 MR. KRINSKY: Object to the
3 form of the question, calls for a legal
4 conclusion.

5 A. As I indicated, and what
6 Alexander did mention in what I just read in
7 paragraph 7 of the -- the -- Alexander's
8 patent, there are many, many pneumococcal
9 serotypes.

10 And as I said, the -- the field
11 knowledge at the time of this '757 patent was
12 based on common knowledge in the field of
13 pneumococcal vaccine development.

14 So the first licensed
15 pneumococcal conjugate vaccines that included
16 multiple serotypes was Prevnar, which is the
17 pneumococcal -- 7-valent pneumococcal
18 conjugate vaccine manufactured by Wyeth,
19 which was later acquired by Pfizer, the
20 petitioner, in 2009.

21 So Prevnar contained seven
22 serotypes of streptococcal pneumoniae,

1 serotype 4, 6B, 9V, 14, 18C, 19, and 23F, and
2 they were conjugated to a toxoid derived from
3 diphtheria CRM 197 protein.

4 So the seven serotypes included
5 in Prevnar accounted for 80 percent of all
6 invasive pneumococcal disease cases among
7 U.S. children less than five years of age
8 before the 7-valent vaccine was licensed in
9 the United States in 2000.

10 After that, the development --
11 the implementation of Prevnar, cases of
12 pneumococcal disease and hospitalization due
13 to the specific serotype in Prevnar decreased
14 in children immunized with Prevnar and other
15 age group that did not receive Prevnar,
16 including the elderly, which is defined in
17 the field as indirect protection.

18 After the introduction of
19 Prevnar, there was an increase in
20 pneumococcal diseases caused by the
21 non-Prevnar serotypes a few years after the
22 vaccine implementation. That's -- this led

1 to the development of Prevnar 13, a 13-valent
2 vaccine which was licensed in the United
3 States in 2010.

4 "Prevnar 13 was introduced to
5 cover all seven serotypes in Prevnar as well
6 as six of the most prevalent streptococcal
7 pneumoniae serotypes that were not included
8 in Prevnar." And the list is known as
9 serotype 1, serotype 3, serotype 4, so -- so
10 serotype 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F
11 and 23 [sic].

12 And so the new six serotypes were
13 serotype 1, 3, 5, 6A, 7F, and 19A. So after
14 implementation of Prevnar 13, the
15 pneumococcal disease rate from these new
16 serotypes also dropped. So the mind -- the
17 way that vaccine developers in the field of
18 pneumococcal vaccine do, they looked at all
19 the most prevalent serotype-causing disease,
20 they select those that can be put into a
21 vaccine to cover maximum -- the disease
22 burden.

1 And so some may decide to include
2 7, like Wyeth did in 2000; others, later on,
3 based on the change in epidemiology, included
4 13.

5 So the list that Alexander
6 provide is a framework from which a POSA who
7 has knowledge on the epidemiology would
8 select a serotype that they would include in
9 their vaccine.

10 There are other considerations as
11 to how this selection is done, and this is
12 really a work that all the scientists need to
13 do to really select the most important
14 serotype to include in a vaccine.

15 (BY MS. SPIRES)

16 Q. Do you agree that a POSA would
17 not have tried to create a vaccine utilizing
18 all 53 serotypes listed in Alexander that you
19 provided in paragraph 55 of your declaration,
20 correct?

21 MR. KRINSKY: Object to the
22 form.

1 A. At the time of this priority date
2 of 2016, March 2016, there were two -- three
3 vaccines that were developed for pneumococcal
4 disease. One is a 23-valent pneumococcal
5 polysaccharide vaccine that has 23 serotypes.
6 They were the Prevnar 7, which is the
7 conjugate vaccine 7, and then the Prevnar 13
8 with 13 conjugate -- 13 serotypes.

9 So at that time the -- the -- the
10 knowledge that we have is to include 13
11 serotypes among the most frequent serotypes,
12 and that's the -- what is the state of the
13 art at that time.

14 (BY MS. SPIRES)

15 Q. So is that a yes, you agree that
16 a POSA in 2016 would not have tried to create
17 a vaccine utilizing all 53 serotypes that
18 Alexander lists?

19 MR. KRINSKY: Objection, asked
20 and answered.

21 A. I'm not aware of any vaccines
22 that contain more than 23 polysaccharide --

1 capsular polysaccharide serotypes,
2 pneumococcal vaccine at that time. I'm not
3 knowledgeable -- I don't know about that.
4 That's the only thing I can say, based on my
5 knowledge.

6 (BY MS. SPIRES)

7 Q. And are you aware of any vaccines
8 that contain more than 13 conjugated
9 pneumococcal serotypes as of 2016?

10 A. In retrospect, the information
11 you're asking me is whether I knew people
12 working on a vaccine that has more than 13
13 serotypes? That is the question?

14 Q. No. I asked, are you aware of
15 any vaccines that contain more than 13
16 conjugated pneumococcal serotypes as of 2016.

17 A. There was no licensed vaccine
18 that contained more than 13 serotypes by
19 March 31st, 2016.

20 Q. Are you aware of any nonlicensed
21 vaccine that was known to the public that
22 contained more than 13 serotypes by

1 March 31st, 2016?

2 MR. KRINSKY: Object to the
3 form.

4 A. I am... I cannot speak to that
5 because I do not know if the information
6 that -- provided to me was confidential or
7 not at that time.

8 (BY MS. SPIRES)

9 Q. The information that you have in
10 mind that you don't know whether it was
11 confidential or not at the time, is that
12 something that you relied on in forming your
13 opinions set forth in your declaration?

14 A. If -- if you go to my declaration
15 and -- you'll see as Exhibit 1050, it says,
16 "A Study to Evaluate the Safety,
17 Tolerability, and Immunogenicity of V114 in
18 Healthy Adults and Infants," V114 protocol 5.
19 That is a 15-valent vaccine.

20 Q. In Exhibit 1050?

21 A. Yes.

22 Q. Can you point me to where in

1 Exhibit 1050 you're referring to?

2 THE WITNESS: Can we show that
3 to -- to her?

4 MS. SPIRES: I've got it up if
5 you --

6 A. It's a posting of
7 ClinicalTrials.gov.

8 MS. SPIRES: Okay.

9 A. And I don't know if you can see
10 it.

11 (BY MS. SPIRES)

12 Q. Yes, I can now.

13 A. Okay. So that particular posting
14 was done on -- around August of 2015; and if
15 you looked at Page 7 of the posting, there is
16 information about biological -- on the right
17 column of the "Assignment Interventions,"
18 "Biological: V114 medium dose."

19 And it says, "Pneumococcal
20 capsular polysaccharide serotypes 1, 3, 4, 5,
21 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F," 3 --
22 "23F, 33F," and 6B.

1 So if you count the number of
2 serotypes that are listed there, it's 15
3 serotypes.

4 Q. So based on your Exhibit 1050, it
5 looks like Merck started studying a 15-valent
6 conjugated pneumococcal vaccine in September
7 of 2015 and completed this study around
8 September of 2017; is that right?

9 MR. KRINSKY: Object to the
10 form.

11 And, counsel, maybe to stave
12 off a problem, I don't think you're asking or
13 intend to be asking when confidentially Merck
14 began working on this, but your question
15 could be interpreted that way. So I don't
16 know if you want to rephrase just to avoid an
17 issue.

18 MS. SPIRES: Sure. I'm just
19 looking at the study start and estimated
20 completion dates on Page 4.

21 MR. KRINSKY: Of this study?

22 MS. SPIRES: Yes.

1 MR. KRINSKY: Okay. Thank you
2 for the clarification.

3 A. So if you go to Page 5 -- Page --
4 Page 5 talk about first posted date, which is
5 2015-08-24. That is the timing that this
6 particular study was posted in
7 ClinicalTrials.gov.

8 (BY MS. SPIRES)

9 Q. And I see on Page 1 of
10 Exhibit 1050 that it says last update was
11 posted April of 2019. Do you see that?

12 A. On Page 1?

13 Q. Yes.

14 A. "Last update posted," yeah.
15 April 2nd of 2019, correct.

16 Q. Do you have an understanding as
17 to which information in Exhibit 1050 would
18 have been available to a POSA as of March
19 of 2016?

20 A. So as I mentioned, in 2015,
21 information of the first posting was
22 available. I don't have with me the

1 information to really speculate on what
2 information was provided in 2015 in the first
3 posting, but it is customary that the
4 interventions could have been provided. So
5 that's the only information I can provide to
6 you at this point.

7 Q. Of the 15 serotypes listed in
8 Exhibit 1050, none of these serotypes are the
9 ones listed in Claim 1 of the '757 patent; is
10 that right?

11 A. Just give me a second to look at
12 Claim 1.

13 Claim 1 says, "A pharmaceutical
14 composition comprising a plurality of at
15 least two unique immunogenic
16 saccharide-polypeptide conjugates, each
17 comprising individually a capsular
18 polysaccharides conjugated to a polypeptide,
19 wherein each of the capsular polysaccharides
20 is from a streptococcus pneumoniae serotype
21 selected from a group consisting of 23A, 23B,
22 and 35B."

1 When we talk about the plurality
2 of serotypes, it -- comprising the plurality
3 of serotypes, it's an open list of different
4 serotypes.

5 Q. Okay. You would agree that the
6 list of serotypes in Merck's experimental
7 conjugated pneumococcal vaccine described in
8 Exhibit 1050 does not include any of
9 serotypes 23A, 23B, or 35B; is that correct?

10 A. As I've indicated, the
11 information provided by Alexander is giving
12 framework to the vaccine researcher to use
13 the scientific knowledge/judgment to include
14 serotypes that are mostly causing disease in
15 the population of interest.

16 And so at the time of -- the
17 Merck vaccine was -- this is called protocol
18 5. It doesn't really -- and it doesn't
19 really tell us what was included in the
20 selection of those serotypes; if not, just
21 the fact that it's -- a POSA with knowledge
22 and expertise and experience would have

1 selected the most -- serotype causing most of
2 the disease at that time.

3 Q. Okay. I didn't ask about
4 Alexander, so I'm going to repeat my
5 question.

6 You would agree that the list of
7 serotypes in Merck's experimental conjugated
8 pneumococcal vaccine described in
9 Exhibit 1050 does not include any of
10 serotypes 23A, 23B, or 35B; is that correct?

11 A. What I'm trying to answer to your
12 questions is that what you're saying --
13 making a statement is correct, that 23A, 23B,
14 and 35B I can read as not included, but you
15 are missing a very important point, which is
16 we don't know when that particular vaccine
17 was initiated and where -- an element we
18 used.

19 So we are not clear view to
20 elements that were use to select those 15
21 serotypes, so we cannot just look at the
22 prior art in 2015 or 2016 and say -- I don't

1 know when this particular product -- vaccine
2 was designed, whether 23A, 23B was among the
3 most permanent vaccines -- serotypes that are
4 causing disease.

5 And the other thing I want to
6 mention, too, is that as I just mentioned --
7 put that in my declaration, it is common
8 knowledge in the field of pneumococcal
9 vaccine that if you have a Pevnar 7 vaccine
10 with those 7 serotypes and you see these
11 serotypes were causing more than 80 percent
12 of the disease and then you see emergence of
13 the 6 additional serotypes that I just
14 mentioned, Pevnar 13, you cannot just make a
15 vaccine that does not include those 7 or 13
16 serotypes.

17 Experience have shown in -- in
18 some countries that if you have a vaccine
19 that does not include all the serotypes that
20 are in Pevnar 13, it -- the disease caused
21 by those serotypes would come back. So it is
22 common knowledge in the field of pneumococcal

1 vaccination that you need to build from the
2 original 7 or 13 serotypes that are in
3 Prevnar 7, Prevnar 13.

4 Q. And a POSA would have understood
5 that you have to build on the original 7 or
6 13 serotypes that are in Prevnar 7 or Prevnar
7 13, slowly adding one or two serotypes at a
8 time, correct?

9 MR. KRINSKY: Object to the
10 form, vague, outside the scope.

11 A. Yeah. So the common knowledge
12 for pediatric vaccines, pneumococcal
13 pediatric vaccines, is that you need to
14 maintain the suppression of the disease
15 caused by those 13 serotypes. You need to do
16 that. If you don't do that, those disease
17 will come back.

18 And so in the pediatric
19 population, it is common knowledge from
20 vaccine researcher and vaccine experts that
21 those serotypes are so important and need to
22 be maintained in that population that receive

1 the pediatric vaccines.

2 (BY MS. SPIRES)

3 Q. Understood, but my question is --
4 for instance, we see Exhibit 1050. It adds
5 two serotypes to Prevnar 13; is that right?

6 A. It is correct.

7 Q. And that's consistent with what a
8 POSA would expect, that a new vaccine built
9 on Prevnar 13 would be built in such a way to
10 add one or two serotypes at a time to Prevnar
11 13; is that right?

12 MR. KRINSKY: Object to the
13 form.

14 A. I did not -- I did not say that.
15 I just said you need to select serotypes that
16 are causing disease. And a POSA from one
17 company may decide to add one, a POSA from
18 another company may say, let's add two,
19 another group may decide to add ten or --
20 or -- it's all depend on many factors,
21 including how much disease you want to cover,
22 can that be, you know, technically feasible,

1 and so forth.

2 So my response to that is just if
3 you go back to Pevnar 7 and you see Pevnar
4 13 follow, they did not remove those 7
5 serotypes in Pevnar 7.

6 To the contrary, they maintained
7 them, for the reasons that I just mentioned,
8 that the disease would come back; and so when
9 you go from 13 to 15, what Merck did was to
10 add 2 new serotypes.

11 It's a decision that was made at
12 the time. I'm assuming that it was based on
13 scientific evidence, but I -- I -- I cannot
14 say like you are stating, that you add one
15 serotype or two serotypes or -- or something
16 like that.

17 Does that make sense?

18 (BY MS. SPIRES)

19 Q. Yes.

20 You would probably agree that a
21 POSA would not have developed a vaccine based
22 on Pevnar 13 that would have added all 53

1 serotypes listed in Alexander, correct?

2 MR. KRINSKY: Object to the
3 form.

4 A. You're asking my opinion on
5 making a 53-valent vaccine?

6 (BY MS. SPIRES)

7 Q. Yes, 53 added on to Prevnar 13.

8 A. I would just maybe remind you
9 that in the list that are provided in
10 paragraph 55, you do have serotype 1,
11 serotype 3, serotype 4, serotype 5, 6B, 7F,
12 14, 18C, 19A, 19F, and 6A, which are all
13 present in Prevnar 13.

14 So you already have 13 of them
15 that are on the list of Alexander that are
16 already in Prevnar 13.

17 Q. Okay. So my question, I believe,
18 is the same. You would agree that a POSA
19 would not have developed a vaccine based on
20 Prevnar 13 that would have included all 53
21 serotypes listed in Alexander, correct?

22 A. This is pure speculation. I'm

1 not -- I'm not privy to the -- the technology
2 that was available in some companies or some
3 laboratory or some universities where they
4 could do that, so I cannot -- if -- my
5 interpretation would just be pure
6 speculation.

7 Q. Well, I'm not asking you about
8 technology that was available in some
9 companies or some laboratory or some
10 universities. I'm asking you from the
11 perspective of a POSA, which would be
12 information that was publicly-available.

13 So I'll repeat my question, which
14 is: Wouldn't you agree that a POSA would not
15 have developed a vaccine based on Prevnar 13
16 that would have included all 53 serotypes
17 listed in Alexander in 2016?

18 A. Exact -- what I'm trying to say
19 is there are different factors that need to
20 be taken into consideration when making a
21 vaccine: The age of the subject -- I know
22 you may be not -- you're not familiar with

1 this, but in -- infants is -- receive already
2 many, many vaccines at birth and at two
3 months. They have a limited, immature even,
4 system; cannot be compared to an adult.

5 The technology that existed in
6 2015 maybe, or '16 maybe in some, you know,
7 area, they were -- I'm not aware of that, but
8 I cannot speculate on that.

9 So asking me to say whether a
10 15 -- a 53-valent vaccine, conjugated
11 pneumococcal vaccine was feasible or not in
12 2016 would be just as -- pure speculation on
13 my part.

14 Q. As of -- well, strike that.

15 The conjugation of the PPSV23
16 vaccine serotypes that led to 12 of the 13
17 serotypes in Prevnar 13 was based, in part,
18 on making the vaccine more immunogenic to
19 infants, or at least to children under two;
20 is that correct?

21 MR. KRINSKY: Object to the
22 form.

1 A. Can you repeat when you talk
2 about the 23-valent vaccine, please?

3 (BY MS. SPIRES)

4 Q. You agree that the first
5 pneumococcal vaccine was PPSV23, right?

6 A. No, I don't agree.

7 Q. You don't?

8 A. I disagree. I disagree.

9 Q. Okay.

10 A. My knowledge is that the first
11 pneumococcal polysaccharide vaccine was a
12 14-valent vaccine, and later, in -- in the --
13 in the -- in the 70s and then later on they
14 were adding more serotypes and then in 20 --
15 in 1983, the 23-valent was licensed. The
16 first was not a 23-valent pneumococcal
17 polysaccharide vaccine.

18 Q. Okay. You will agree that the
19 23-valent pneumococcal vaccine was not a
20 conjugated vaccine, correct?

21 MR. KRINSKY: Object to the
22 form, vague.

1 A. It is correct.

2 (BY MS. SPIRES)

3 Q. And are you comfortable if I call
4 this 23-valent pneumococcal vaccine PPSV23?

5 A. That is fine.

6 Q. Would you agree that after
7 PPSV23, the next pneumococcal vaccine was
8 PCV7?

9 MR. KRINSKY: Object to the
10 form, outside the scope.

11 A. I want to make a clear
12 difference. We're talking about two
13 different populations. PPSV23 was for
14 children two years and older and adults.
15 PCV7 was for children starting at two months
16 of age.

17 If we can agree on that, then we
18 can say on the market there were two
19 different vaccines, but PPSV23 did not
20 disappear because PCV7 was licensed.

21 (BY MS. SPIRES)

22 Q. Correct. So PCV7 and then later

1 PCV13 were specifically directed to children
2 starting at two months of age and in this
3 children two and under population, correct?

4 A. I would not say the word
5 "specifically." I will say the word
6 "primarily" directed to children below the
7 age of two.

8 Q. And so earlier you mentioned that
9 children below the age of two have already
10 received many vaccines and have an immature
11 immune system compared to an adult; is that
12 right?

13 A. What I stated was children at the
14 age of two months receive several pediatric
15 vaccines. That was well-known, and so there
16 are a lot of pressure on -- they have an
17 immature immune system by the age of two
18 months, and so there was common knowledge
19 about how much those babies -- how they
20 process antigen, given the fact that they
21 have an immature immune system.

22 Q. And what is this common

1 knowledge?

2 A. The common knowledge about
3 immaturity or common knowledge about vaccine
4 in the pediatric?

5 I don't understand the question.

6 Q. You said that there was a common
7 knowledge around how much those babies, how
8 they process antigen, given the fact that
9 they have an immature immune system; and so
10 I'm asking what that common knowledge was.

11 A. The common knowledge is certain
12 vaccines, like PPSV23, if you give that to a
13 baby that is below the age of two, they don't
14 mount -- they mount an immune response, but
15 it's not optimal, and therefore, they -- that
16 is why PPSV23 was not given to the kid -- to
17 the children below the age of two years of
18 age.

19 Q. Does Alexander provide any
20 guidance within that document for a POSA as
21 to which of its 53 serotypes would be the
22 most preferable to select when creating a new

1 vaccine?

2 A. Can you tell me if you're asking
3 me a question that has -- I'm assuming that
4 it has to do with this -- the scope of the
5 patent that I'm -- I've been asked to
6 discuss, correct, or you're asking me a
7 general scientific question?

8 Q. I'm asking about the Alexander
9 reference that you discuss in your
10 declaration. In paragraph 55 of your
11 declaration, you quoted from Alexander a list
12 of 55 serotypes; and so I'm asking, does
13 Alexander provide any guidance for a POSA as
14 to which of these 53 serotypes would be the
15 most preferable to select when creating a
16 vaccine?

17 A. Just give me one second.

18 So Alexander required no further
19 step on the part of the POSA to make an
20 anticipating embodiment. All the POSA needs
21 to do is select two or more serotypes, up to
22 30 or more, for a vaccine composition that

1 include any two of the serotypes that are in
2 the claim.

3 So it's really -- Alexander
4 disclosure would enable the POSA to envision
5 how to make a good multitude of anticipated
6 combination. So it's a framework about these
7 are the serotypes that you could use to make
8 your -- your vaccine based on the one that
9 are the most common serotype causing disease.

10 Q. Okay. That was not my question.

11 My question is, in paragraph 55
12 of your declaration, you quoted from
13 Alexander a list of 55 [sic] serotypes.

14 Does Alexander provide any
15 guidance for a POSA as to which of these 53
16 serotypes would be the most preferable to
17 select when creating a vaccine?

18 MR. KRINSKY: Objection, asked
19 and answered.

20 You can answer if you're able.

21 A. Can you clarify that? Sometime
22 you speak about 55 serotypes, sometime you

1 talk about 53 serotypes, and we're talking
2 about paragraph 55. So sometimes it's a
3 little bit confusing. So I understand that,
4 but I just want Annette to be understanding
5 that, you know, when she talk about paragraph
6 55 in my declaration, the number of serotypes
7 that I list is 53.

8 (BY MS. SPIRES)

9 Q. Correct, I misspoke. So I will
10 try to not transpose "55" and "53" in my
11 question. I'll repeat the question.

12 My question is: In paragraph 55
13 of your declaration, you quoted from
14 Alexander a list of 53 serotypes. Does
15 Alexander provide any guidance for a POSA as
16 to which of these 53 serotypes would be the
17 most preferable to select when creating a
18 vaccine?

19 MR. KRINSKY: Objection, asked
20 and answered.

21 A. As I say in paragraph 107 in my
22 declaration, Alexander requires "no further

1 step on the part of the POSA to make an
2 anticipating embodiment. All the POSA needs
3 to do is select two or more serotypes, up to
4 30 or more serotypes, for a vaccine
5 composition that includes any two of the
6 three serotypes recited in limitation 1.c."

7 So "Alexander's disclosure would
8 enable the POSA to envision how to make a
9 great multitude of anticipating
10 combinations." So it gives the POSA a
11 framework.

12 And as I said at the beginning,
13 this decision about which serotype to include
14 would be based on several factors that the
15 POSA would need to select and decide, but
16 that is just a framework.

17 MR. KRINSKY: Counsel, it's
18 been about an hour. I don't know if this is
19 time for another break.

20 MS. SPIRES: Just let me get a
21 question or two, and then we'll be there.

22 MR. KRINSKY: Sounds good.

1 (BY MS. SPIRES)

2 Q. Does Alexander provide any of
3 these factors that a POSA would need to
4 select and decide how to make a vaccine based
5 on -- strike that.

6 So you said that a POSA would
7 need to select and decide which serotypes to
8 make based on Alexander's framework. And
9 what I want to know is whether Alexander
10 provided any information other than the list
11 of 53 serotypes to guide the POSA in
12 selecting and deciding which serotypes to
13 use.

14 MR. KRINSKY: Objection, asked
15 and answered.

16 A. As I mention in paragraph 107,
17 Alexander require "no further step on the
18 part of the POSA to make an anticipating
19 embodiment."

20 And if we go back to the -- the
21 time of the -- the Alexander, you know,
22 patent, 2005, at that time, even though that

1 document, that patent, was available, the
2 next vaccine that was developed was
3 Prevnar 13; and that vaccine, as I said,
4 contained 13 of the 53 serotypes that are
5 listed in Alexander.

6 So Alexander did not require the
7 POSA to -- specifically which serotype to
8 select. It's up to the judgment of the POSA
9 to decide, based on multiple factors, which
10 one to be included in the -- in the vaccine.
11 (BY MS. SPIRES)

12 Q. And what are those factors?

13 A. So different -- as I said,
14 different POSA and different expert will give
15 you the factor, but what we have seen is
16 most -- the first most important one is
17 serotypes that are contributing to the burden
18 of disease.

19 So you may have 100 serotypes, as
20 I mentioned, in paragraph -- in paragraph --
21 in paragraph 25, Page 16 of my declaration.

22 "Because streptococcal pneumoniae

1 has many serotype, pneumococcal vaccines are
2 generally multivalent, containing purified
3 forms of capsular polysaccharides for
4 multiple serotypes."

5 And it's common -- what we've
6 seen in the field -- and I give the example
7 in paragraph 26 of Prevnar 7, which was based
8 on selecting the seven serotypes that account
9 for the most commonly reported disease in
10 infants, and those serotypes cover 80 percent
11 of the disease that was prevalent in the
12 United States prior to the licensure of
13 Prevnar 7 in 2000.

14 So one factor is how many
15 serotypes you can put together, conjugate --
16 in the -- in the conjugated vaccine. They
17 will cover a certain -- the majority of the
18 disease that you have. That is one factor.

19 There are other factors that --
20 that will be too long for us to discuss that
21 comes in play about you -- which area, which
22 geographical area, because some countries

1 have different profile, maybe a little bit of
2 one serotype being different, one serotype
3 being more prominent in another country.

4 There are -- the technology is
5 also a factor that you need to keep in mind.
6 So there are a lot of different factors that
7 one will take into consideration as you
8 select your serotypes to include in your
9 vaccine.

10 MS. SPIRES: Okay. I think
11 this is a good time for a break.

12 MR. KRINSKY: Okay. Sounds
13 good.

14 (Break taken from 10:32 a.m. to
15 10:43 a.m.)

16 (BY MS. SPIRES)

17 Q. Dr. Musey, I'd like to switch
18 over to the Gu reference that you referred to
19 in your declaration.

20 Do you remember that one?

21 A. Yes.

22 Q. And it's Exhibit 1009, if that's

1 helpful.

2 A. Yes, I found it.

3 Q. In paragraph 59 of your
4 declaration, you discuss a list of eight
5 serotypes from Gu.

6 Do you see that?

7 A. Yes, I can see that.

8 Q. Does Gu provide any guidance for
9 a POSA as to which of these eight serotypes
10 would be the most preferable to select for a
11 new pneumococcal vaccine?

12 A. Yeah, Gu does not provide any --
13 he just provide the framework about which
14 serotype to be included and provided three
15 different type of embodiment that one could
16 consider in the selection of the serotypes.

17 Q. And the three different types of
18 embodiments that one consider -- could
19 consider in the selection of the serotypes,
20 does Gu provide any guidance as to which of
21 these eight serotypes the POSA should select?

22 MR. KRINSKY: Object to the

1 form of the question.

2 A. So if you read this particular
3 paragraph, the -- Page 11, where this
4 information is taken from, Exhibit 1009,
5 Page 11, in this particular -- it is the
6 third paragraph starting on line 17, in this
7 particular paragraph, going to line 25, Gu
8 provides two different embodiments.

9 The first one is -- contain more
10 than 20 serotypes, the second one contain
11 about approximately 20 serotypes, and the
12 third one contain about 8 serotypes. So what
13 we can conclude from that is that if you
14 looked at these three -- these three
15 different embodiments -- as I said earlier,
16 Gu is just providing a framework of serotype
17 that the POSA could drive its selection of
18 which one to include in the potential
19 vaccine.

20 (BY MS. SPIRES)

21 Q. So Gu is providing a framework,
22 along with a list of potential serotypes to

1 select, but does not provide any further
2 guidance as to which, from the list of
3 serotypes, a POSA should select; is that
4 correct?

5 MR. KRINSKY: Objection to
6 form, asked and answered.

7 A. So as I said, if Gu -- as
8 Alexander -- both of them provide a framework
9 on which serotype could be included in a
10 vaccine.

11 They do not provide any
12 additional requirement from the POSA to -- in
13 the way of serotype selection to be included
14 in the vaccine.

15 (BY MS. SPIRES)

16 Q. Not only is there not a
17 requirement from the POSA about serotype
18 selection, there is no guidance in either
19 Alexander or Gu as to which serotype a POSA
20 should select from among the list they
21 provide; is that correct?

22 MR. KRINSKY: Objection to

1 form, compound, vague, asked and answered.

2 A. So what I've been indicating is
3 that both Alexander and Gu provide framework,
4 and the POSA need to use their own knowledge,
5 different factors, to make a decision on
6 which one to apply in the vaccine.

7 And the POSA at the time of that
8 decision would not rely solely on the -- the
9 Alexander or the Gu. There are also
10 additional publications, priority
11 art article, that shows the serotype that
12 could be included in -- would be beneficial
13 to include in pneumococcal conjugated
14 vaccines.

15 And I rely on such article, as
16 well as another patent application, to really
17 provide my understanding of how these
18 particular selections could be made.

19 (BY MS. SPIRES)

20 Q. Do you rely on these additional
21 publications and prior art articles for how
22 these selections of serotypes in Alexander

1 and Gu could be made for your anticipation
2 analysis and for your obviousness analysis?

3 A. So as I said earlier, "for many
4 years leading up to the priority date of
5 March 2016, the epidemiological data
6 regarding widely circulating streptococcal
7 pneumoniae serotypes had been compiled and
8 published by public health agencies,
9 particularly by Centers for Disease Control
10 and Prevention (CDC) in the U.S., the
11 European Centre for Disease Control and
12 Prevention (ECDC), and the Public Health
13 Agency of Canada," as well as the UK, would
14 have been known to the POSA.

15 "Because" of the "naturally" --
16 "of interest to vaccine developers to provide
17 protection against common serotypes of
18 streptococcal pneumoniae, such information
19 played an important role in vaccine
20 development."

21 So "as those references describe,
22 the successful immunization of significant

1 portions of the population using earlier
2 generation of pneumococcal conjugate
3 vaccines," like Prevnar 7, and later on
4 Prevnar 13, "caused the prevalence of
5 serotypes covered by those vaccines to
6 diminish and the prevalence of other
7 serotypes (not covered by those vaccines) to
8 increase."

9 So "I rely on several references
10 that address common serotypes of
11 streptococcal pneumoniae in different
12 geographical areas in the period leading up
13 to the priority date."

14 Q. And you were just reading from
15 paragraph 60 of your declaration; is that
16 right?

17 A. Yes.

18 Q. Did you rely on the references
19 you describe in paragraph 60 for your
20 anticipation opinions in your declaration?

21 A. So as I've read that's provided
22 in my declaration, "Kaplan specifically

1 highlights" these three serotype, 23A, 23B,
2 and 35 "among the top ten most common
3 non-PCV13... isolated from children in the
4 'PCV13 era' from 2011 to 2013."

5 And so that is important
6 information that was available at the time
7 prior to the priority date.

8 Q. So were you relying on the
9 references you describe in paragraph 60
10 through 64 in your -- for your
11 anticipations -- strike that.

12 Were you relying on the
13 references you describe in paragraph 60
14 through 64 for your anticipation opinions in
15 your declaration?

16 MR. KRINSKY: Object to the
17 form of the question, calls for a legal
18 conclusion.

19 A. Can you -- can you repeat the
20 question, please?

21 (BY MS. SPIRES)

22 Q. Sure.

1 Were you relying on the
2 references you describe in paragraphs 60
3 through 64 for your anticipation opinions
4 that you provided in your declaration?

5 A. So what I just mentioned is
6 the -- the information that I relied on in
7 the declaration for anticipation really is
8 relying on Alexander and Gu, but I also
9 mentioned that there are other information
10 that was -- that I've -- I rely on that
11 really support what Gu and Alexander was
12 making -- was stating in the -- in the claim
13 as well.

14 Q. So I'm unclear by that answer.

15 Are you or are you not relying on
16 the references described in paragraph 60 to
17 64 for your anticipation opinions in your
18 declaration?

19 MR. KRINSKY: Objection, asked
20 and answered.

21 A. So my understanding of
22 anticipation -- my understanding of

1 anticipation is that "I have been informed
2 that a claim is invalid as anticipated if a
3 single prior art reference discloses every
4 limitation of the claim, either expressly or
5 inherently, as arranged in the claim. I also
6 understand that a reference can anticipate if
7 it discloses a sufficiently small group of
8 possible options for a parameter that the
9 POSA could at once envisage the claimed
10 invention from within that group. I have
11 been informed that, for a reference to
12 anticipate a claim, the reference must
13 provide disclosure sufficient for the POSA to
14 practice the relevant disclosure without
15 undue experimentation. I understand,
16 however, that a reference does not need to
17 disclose what is already known to the POSA.
18 Moreover, I understand that a prior art
19 reference should be considered for all that
20 it teaches, and not just limited to a
21 particular embodiment or the" claim -- "or
22 the claimed invention of the prior art."

1 So as I've been -- I just stated,
2 the anticipation of this claim was really
3 based on Gu and Alexander.

4 (BY MS. SPIRES)

5 Q. So if that is the case, then a
6 POSA looking at Gu or Alexander would not
7 have any guidance as to which serotypes to
8 select from among the lists provided by Gu
9 and Alexander respectively; is that right?

10 A. "As I have explained, the leading
11 serotypes causing invasive... diseases are
12 provided regularly in disease surveillance
13 reports from many countries.

14 So you have the Gu, you have the
15 Alexander that give you a list of serotypes,
16 but they are also -- the POSA would have
17 access to all the information when deciding
18 that.

19 So "an analysis of the
20 pneumococcal serotype distribution causing
21 invasive and non-invasive pneumococcal
22 diseases over a period of multiple years

1 would have given the POSA a good insight
2 about trends, persistence, antibiotic
3 resistance, and the importance of some
4 serotypes compared to others in their
5 contribution to the burden of pneumococcal
6 disease, and thus support their inclusion in"
7 the "pneumococcal conjugate vaccines."

8 So -- so I have provided serotype
9 prevalence references like the one that we
10 discussed, Kaplan, and as -- others that
11 provide such information "and individually
12 and collectively would have given the POSA
13 reasons to select the particular"
14 serotypes -- "additional serotypes that are
15 recited" in all the different claims.

16 Q. So I'm a little confused because
17 I thought you just said that, for your
18 anticipation analysis, you relied on Gu or
19 Alexander, depending on which ground we're
20 talking about, and did not rely on the Kaplan
21 reference; is that right?

22 MR. KRINSKY: Object to the

1 form of the question, mischaracterizes
2 testimony.

3 A. So as I understand the legal
4 definition of "anticipation," this
5 anticipation was solely based on Gu and
6 Alexander; and as I said, there was
7 additional information that I provided in
8 view of that that makes these particular
9 references provide obviousness as to what
10 are -- been claimed here.

11 So the anticipation is solely
12 based on Alexander and Gu.

13 (BY MS. SPIRES)

14 Q. Okay. So for the anticipation
15 references that are based solely on Alexander
16 and Gu, a POSA who only has Alexander or Gu
17 to go on would not have any guidance as to
18 which serotypes among the lists provided by
19 Alexander and Gu, respectively, would be
20 preferable for the POSA to select; is that
21 right?

22 A. So I -- I -- I'm trying to

1 understand whether we -- we all agree on what
2 the POSA used to make the selection of the
3 serotype. As I said, Gu and Alexander just
4 give the framework. They did not provide any
5 requirement, with the exception of the list
6 that they're providing is a list of the
7 common serotypes that are causing disease.
8 As I said, a POSA will have other elements as
9 they make the decision.

10 Q. And the other elements that a
11 POSA would have used to make a decision about
12 the serotype selection the POSA would have
13 found outside of Gu and Alexander; is that
14 right?

15 A. The only information that I found
16 in Alexander, as I said earlier, is just the
17 common serotype. Keep in mind, as we
18 discussed, there's more than 100 serotypes
19 and Gu -- Alexander just provided a few of
20 them, a subset of those. Even though it's 53
21 serotypes, it's not 100. So he did
22 characterize which serotype to include in the

1 list, and those are the most common
2 serotypes. So that's a really important
3 element that the POSA will include in the --
4 in that selection.

5 Q. And is that the same for Gu, that
6 the only information you found in Gu is the
7 list of the eight common serotypes without
8 any further guidance about serotype
9 selection?

10 MR. KRINSKY: Object to the
11 form of the question, mischaracterizes
12 testimony.

13 A. I would have to read the document
14 in the entirety again to try to see if that
15 information is there. In my recollection,
16 that's the only thing I can say at this
17 point.

18 (BY MS. SPIRES)

19 Q. Do you agree that a composition
20 with multiple glycoconjugates can refer to
21 multiple serotypes conjugated to multiple
22 carrier proteins?

1 A. Can you repeat your question,
2 please?

3 Q. Sure.

4 Do you agree that a composition
5 with multiple glycoconjugates can refer to
6 multiple serotypes conjugated to multiple
7 carrier proteins?

8 A. So "the POSA would also have
9 reason to adopt this interpretation" of what
10 you just mentioned "based on their background
11 knowledge of vaccine development. The POSA
12 would understand that the inclusion of
13 multiple distinct carrier proteins" can be
14 beneficial and increase the immunogenicity
15 for vaccine composition.

16 So that's the information that I
17 can provide.

18 Q. I'm not sure if you agree with my
19 statement or not, so I'm just going to ask
20 again because I'm a little unclear.

21 Do you agree that a composition
22 that has multiple glycoconjugates can refer

1 to a composition with multiple serotypes
2 conjugated to multiple carrier proteins?

3 MR. KRINSKY: Objection, asked
4 and answered.

5 A. What I'm providing is the opinion
6 I provided in my declaration, that "the POSA
7 would have reason to adopt this
8 interpretation based on their background
9 knowledge of vaccine development," because
10 they "would understand that the inclusion of
11 multiple distinct carrier proteins can
12 increase the immunogenicity of a vaccine
13 composition."

14 So there are reason to believe
15 that -- sorry, excuse me -- that -- that the
16 use of multiple carrier protein could be --
17 could be considered.

18 (BY MS. SPIRES)

19 Q. Okay. So I think you just said
20 that the -- you referred -- strike that.

21 You talked about multiple carrier
22 proteins -- or strike that again.

1 Yeah, I think you said that a
2 composition with multiple carrier proteins
3 can be referred to as a composition with
4 multiple glycoconjugates; is that right?

5 MR. KRINSKY: Object to the
6 form, mischaracterizes testimony.

7 A. So I don't know if I understand
8 your question, whether you're talking about a
9 vaccine that contains multiple carrier
10 protein conjugated to different serotypes or
11 whether you're talking about a vaccine that
12 just have carrier proteins.

13 Is -- what exactly are you
14 asking?

15 (BY MS. SPIRES)

16 Q. So the -- I changed my question
17 because you gave me the same answer. I think
18 you're reading from somewhere, but it -- your
19 answer didn't really respond to my question.

20 So I'm trying to figure out what
21 your answer is saying, because you said, I
22 have -- well, "The POSA will have reason to

1 adopt this interpretation," and I'm not sure
2 what interpretation you're talking about.

3 And then you went on to talk
4 about multiple distinct carrier proteins, And
5 so that's why I was focusing on the carrier
6 proteins portion of your answer; but I'll ask
7 my question again and see if we can come to
8 some understanding.

9 So I'm asking, if you've got a
10 composition that has multiple serotypes
11 conjugated to multiple carrier proteins,
12 would you agree that that could be considered
13 a composition with multiple glycoconjugates?

14 MR. KRINSKY: Objection, asked
15 and answered. Objection to form,
16 argumentative.

17 A. So I think that is why I'm
18 confused. You know, multiple glycoconjugate
19 could mean different things. It could mean
20 that you can have the same carrier proteins
21 with different -- different polysaccharides,
22 capsular polysaccharides.

1 The example is Prevnar 7, which
2 are seven different serotypes, each one of
3 them conjugated with CRM 197.

4 The other one, the different --
5 maybe that's where you're going to -- is you
6 have multiple serotypes. Some serotypes are
7 conjugated with one specific carrier protein,
8 other serotypes are conjugated with a
9 different carrier protein.

10 If that is what you are
11 mentioning, if that is possible, I would say
12 yes, that example is the PCV10 -- 10 from
13 Glaxo Smith Klein, where you have ten
14 serotype, eight conjugated with protein D of
15 non-typeable haemophilus influenzae, 118C,
16 conjugated with --

17 THE COURT REPORTER: I'm sorry,
18 with what?

19 THE WITNESS: So let me go
20 back.

21 A. So the 10-valent from Glaxo Smith
22 Klein, GSK, contains ten serotypes. Eight

1 serotypes are conjugated with protein D of
2 the non-typeable haemophilus influenzae --
3 haemophilus influenzae.

4 It's -- let's say -- how can I
5 say that? Maybe my -- the way I say it is
6 incorrect.

7 So haemophilus influenzae is a
8 bacteria, and so one of the carrier proteins
9 is coming from that particular bacteria
10 called protein D.

11 So let's just say, Annette, for
12 simplicity, that eight serotype are
13 conjugated with protein D; one serotype,
14 which is 18C, is conjugated with tetanus
15 toxoid; and then one serotype, 19F, is
16 conjugated with diphtheria toxoid.

17 So in this particular vaccine
18 with ten serotype, they use three different
19 carrier proteins.

20 THE WITNESS: Do you want me to
21 repeat, Annette?

22 THE COURT REPORTER: No, sir.

1 I'll just have to go do some research.

2 A. Sarah, do you see what I'm
3 saying?

4 (BY MS. SPIRES)

5 Q. Yes.

6 A. It's an example of what Sarah
7 was -- one of the examples that I think Sarah
8 was talking about, you know, of a vaccine
9 with glycoconjugate because a glycoconjugate
10 is just like a protein and -- and a
11 polysaccharide, but it doesn't tell you if --
12 in a mixture of plurality, where you have
13 multiple serotypes that are conjugated to the
14 same carrier protein or they're conjugated to
15 different carrier protein.

16 MR. KRINSKY: And, Dr. Musey,
17 just as a reminder, not to minimize Annette's
18 interest in the science, but if she asks for
19 a clarification, she probably just didn't
20 hear you and would like you to try to repeat
21 what you said before rather than give further
22 explanation, so...

1 THE WITNESS: Okay.

2 (BY MS. SPIRES)

3 Q. And I appreciate that. That did
4 make sense.

5 So do you also agree that a
6 composition that has a single serotype
7 conjugated to multiple carrier proteins can
8 also be referred to as a composition with
9 multiple glycoconjugates?

10 MR. KRINSKY: Object to the
11 form.

12 A. Can I just clarify? Are you
13 talking about technically, or are you talking
14 about whether a vaccine that has one single
15 serotype conjugated with multiple carrier
16 protein will be something that could be, you
17 know, valuable in -- in -- in the field? So
18 I don't understand the -- the -- the
19 rationale from asking that question.

20 (BY MS. SPIRES)

21 Q. I'm just asking right now about
22 the terminology. If you see a reference

1 that's talking about conjugating a single
2 serotype to multiple carrier proteins, would
3 you consider that to be a composition with
4 multiple glycoconjugates?

5 A. I'm trying to see how I can
6 answer this question because in order to go
7 into the field of pneumococcal vaccines that
8 were developed -- you know, developed
9 prior -- and due to the prior art and before
10 March of 2016, it was understanding --
11 understood by vaccine developers and
12 researchers that one of the paradigms that
13 they were using is a vaccine that contained
14 multiple serotypes, and so -- just to be able
15 to cover the disease. That is why I gave you
16 the example of PCV7 and then PCV13.

17 So technically, can you make a
18 glycoconjugate or several glycoconjugates
19 that have -- using the same serotypes but
20 multiple carrier protein? Technically, yeah,
21 it can be feasible.

22 Q. I know we've said that there are

1 roughly 100 serotypes -- or strike that.

2 By 2016, March of 2016,
3 approximately how many pneumococcal serotypes
4 would have been known to a POSA?

5 A. I cannot give you the precise
6 number, but I will say -- I don't know. I
7 would say more than 90, I would say; but I
8 cannot give you an exact number.

9 Q. By March of 2016, would a POSA
10 have been aware of any prior art references
11 disclosing actual PCVs that included serotype
12 23A?

13 A. Are you talking about licensed
14 vaccines?

15 Q. I am talking about any vaccine,
16 licensed or unlicensed, that a POSA would
17 have been aware of in March of 2016. So
18 something that was publicly known.

19 A. The POSA would know there was no
20 licensed vaccine that would contain -- that
21 contained those serotypes, but I cannot
22 speculate into whether there was other

1 vaccines that were under development that --
2 that may contain those serotypes.

3 The reason I'm saying that is
4 that there are so many people working on
5 different types of vaccine. Sometimes they
6 have meetings that some vaccines are
7 provided, composition, but I'm always not
8 aware -- I'm not privy to that information.

9 Q. Okay. To your knowledge, by
10 March of 2016, were there any publicly-known
11 vaccines, licensed or unlicensed, that -- PCV
12 vaccines that included serotype 23A?

13 A. So from my knowledge, again,
14 looking at the information I'm sharing with
15 you, there are composition of vaccine
16 embodiments that are provided in Alexander
17 and Gu that contain those -- those serotypes.

18 Q. Are you testifying that the
19 vaccine embodiments provided in Alexander and
20 Gu containing serotype 23A actually existed
21 by March of 2016 as PCV vaccines?

22 MR. KRINSKY: Object to the

1 form of the question, asked and answered.

2 A. I'm not privy to what exactly --
3 what vaccine composition that Alexander and
4 Gu used in support of the patents. I'm not
5 aware of that.

6 What they provided is a
7 framework, and those framework is -- is --
8 should be supported by data that shows that
9 these particular -- those vaccines were
10 tested.

11 So I'm not privy to that
12 information. I cannot -- I'm not privy to
13 that information from Alexander in details.

14 (BY MS. SPIRES)

15 Q. It's your understanding that a
16 POSA would have viewed Alexander as being
17 supported by data testing vaccines at all 53
18 PCV serotypes disclosed -- or strike that --
19 all 53 pneumococcal serotypes disclosed in
20 Alexander?

21 MR. KRINSKY: Objection,
22 mischaracterizes testimony.

1 A. Can you repeat your question,
2 please? I want you to clarify what you
3 exact -- asked me exactly.

4 (BY MS. SPIRES)

5 Q. So you said that Alexander's
6 framework should be supported by data that
7 shows that the particular vaccines were
8 tested.

9 And so I'm asking, are you saying
10 a POSA would expect Alexander to have been
11 supported by data testing vaccines using all
12 53 pneumococcal serotypes that Alexander
13 discloses?

14 A. I'm not privy to that
15 information. I cannot tell you which vaccine
16 Alexander tested in the experiments that
17 they've done, so I cannot really comment on
18 that.

19 Q. Does Alexander provide data
20 disclosing that it did any testing on PCV
21 vaccines or on pneumococcal vaccines?

22 A. I'm looking at that information

1 from the patent, so give me a few minutes.

2 If you go to Page 36 of

3 Alexander --

4 THE COURT REPORTER: 36, sir?

5 THE WITNESS: Yes, please.

6 A. Page 36, paragraph -- starting
7 paragraph 125 -- let me know when you get
8 there.

9 (BY MS. SPIRES)

10 Q. I'm there.

11 A. So Alexander provided an example
12 as a "way of illustration and not by way of
13 limitation."

14 And if you follow the paragraph
15 that follow after that, he explained some of
16 the experiment that he has done and -- and
17 the result that they found by way of
18 illustration, not limitation.

19 So he does provide an example of
20 vaccine that he has made to support what he
21 was talking about.

22 Q. Right, but Alexander does not

1 provide any data with respect to the
2 serotypes 23A, 23B, or 35B, correct?

3 A. So as I just mentioned, what
4 Alexander provide is example by way of
5 illustration and not by way of limitation,
6 which means that he gave an example of some
7 of the work that he has done.

8 And as a POSA, one would expect
9 that a polysaccharide vaccine, a
10 polysaccharide conjugate vaccine would behave
11 the same way whether you're using serotype 4
12 or you're using serotype 23A, that when you
13 inject a foreign agent in a person or in an
14 animal, that that particular serotype
15 polysaccharide will behave the same way.

16 So he gave good examples, but
17 it's not a limitation on his part.

18 Q. So it is your testimony that a
19 POSA in March of 2016 would have believed
20 that a polysaccharide conjugate vaccine that
21 works for one serotype would work for all
22 known serotypes?

1 A. My testimony is that -- and based
2 on experience with the 23-valent
3 polysaccharide vaccine, the -- the -- the
4 7-valent pneumococcal conjugate vaccine, the
5 13-valent pneumococcal conjugate vaccine,
6 that if you replace one of the serotypes with
7 another serotype and the POSA that -- knows
8 how to make those conjugates, there was -- I
9 do not anticipate -- I do not expect that
10 there would be a difference, that these
11 particular conjugates will provide some type
12 of immunoresponse.

13 Q. Is it your testimony that
14 replacing a -- one of the serotypes in
15 Prevnar 13 -- or strike that.

16 Is it your testimony that
17 replacing one of the serotypes in Prevnar 7
18 with serotype 3C would function just as --
19 strike that.

20 Is it your testimony that
21 replacing serotype 3C with one of the
22 serotypes in Prevnar 13 would create a

1 vaccine with a -- an immunogenic 3C response?

2 MR. KRINSKY: Objection,
3 outside the scope; objection to the form.

4 A. I'm not aware of serotype 3C. I
5 know serotype 3, but 3C, I specifically -- I
6 don't know.

7 Can you explain to me what is
8 serotype 3C?

9 (BY MS. SPIRES)

10 Q. Well, let's switch my question to
11 3, then.

12 Is it your testimony that
13 replacing one of the serotypes in Prevnar 7
14 with serotype 3 would create an immunogenic
15 serotype 3 vaccine?

16 A. Based on my knowledge on the
17 pneumococcal conjugate vaccine, replacing one
18 of the serotype in Prevnar 7 or even adding
19 serotype 3 to Prevnar 7 does -- would have
20 provided immunoresponse to serotype 3.

21 Q. And what is the standard you're
22 using for measuring an immunoresponse?

1 MR. KRINSKY: Object to the
2 form of the question, outside the scope.

3 A. My standard of knowledge is that
4 if you have a foreign agent, like a
5 polysaccharide, or you conjugate the
6 polysaccharide that you inject in an animal
7 or a human, that that person will react, will
8 produce antibodies; and depending on the
9 technique, laboratory technique or testing
10 technique that you're using, what is known by
11 the priority date, you should be able to
12 detect antibodies that are produced against
13 that particular foreign agent, which could be
14 a polysaccharide.

15 (BY MS. SPIRES)

16 Q. You would want for an
17 immunoresponse, the response to be greater
18 than it would by just injecting the -- the
19 composition without the serotype, correct?

20 MR. KRINSKY: Objection,
21 incomplete hypothetical, lack of foundation,
22 outside the scope.

1 A. The response to your question,
2 the scientific knowledge, it's all depend on
3 whether you are talking about the naive
4 animals and naive humans, which means that
5 that person has never seen that particular
6 antigen versus a person who have already seen
7 that particular antigen, their response to
8 that particular antigen may differ.

9 But to -- this is what maybe I
10 think you're saying. Tell me if I'm really
11 understanding what you're saying. Do you
12 mean a person who has never seen this antigen
13 and is vaccinated, he will have more antibody
14 than prior to being exposed? Is that what
15 you're asking in the naive individuals?

16 (BY MS. SPIRES)

17 Q. What I'm asking is, anything that
18 you inject is going to get a response,
19 correct?

20 MR. KRINSKY: Object to the
21 form, vague, outside the scope, and
22 incomplete hypothetical.

1 A. The question that you're asking
2 is unclear because how are you defining
3 "response"? Is it a response like a safety
4 response, or is it like immunological
5 response? And how do you measure that? What
6 technique are you using?

7 So there are a lot of factors. I
8 don't know if I understand your question, the
9 scope of your question, when it comes to how
10 somebody will respond.

11 (BY MS. SPIRES)

12 Q. All right. I'll come back to
13 this one in a bit.

14 MR. KRINSKY: Counsel, we've
15 been going about another hour. I don't
16 know I know you're in a different time zone
17 from where we are, but I don't know if we
18 want to take a lunch break.

19 MS. SPIRES: Sure. So yeah, my
20 calculation, we're only about 48 minutes.

21 MR. KRINSKY: We can go a
22 little longer. I'm sorry, I may not have

1 noted down the time right.

2 MS. SPIRES: I had that we
3 ended at 10:32 and started at 10:43, but
4 if -- I mean, if you're ready for a lunch
5 break, we can do that now, too. I am at a
6 point that I can stop. Whatever makes you
7 happy.

8 MR. KRINSKY: You'd like to
9 keep going, Dr. Musey?

10 THE WITNESS: We can continue.

11 MR. KRINSKY: Let's keep going.
12 That's fine.

13 MS. SPIRES: Okay. But
14 whenever you are ready for a lunch break,
15 please stop me; and if that's now, that's
16 fine too.

17 MR. KRINSKY: Let's go a little
18 longer. I thought we had gone longer on the
19 record.

20 (BY MS. SPIRES)

21 Q. So earlier we were talking about
22 how there can be variance in emerging

1 serotypes based on, kind of, different
2 factors. You'd agree, I think, that the
3 emerging serotypes can be age dependent, so
4 different in children or adults or adults
5 over 65; is that right?

6 MR. KRINSKY: Object to the
7 form.

8 A. I don't know if I would
9 characterize that that way. When you say
10 "difference," what do you mean?

11 (BY MS. SPIRES)

12 Q. I mean that if you look at a
13 chart of, say, the top 10, 15, 20 emerging
14 serotypes, that those serotypes may differ if
15 you're looking at children versus adults; is
16 that right?

17 A. I would rather say that the --
18 the frequency or the rates of some of those
19 serotypes may be different between adults and
20 children, but I would not go to the point of
21 saying they're different when it comes to --
22 an example, do I see serotype A and not see

1 it -- in infant and not see it in adults? A
2 may still be in adult, maybe ranked a little
3 bit lower or a little bit higher. Some may
4 not be there, but sometimes it's just a
5 ranking issue.

6 Q. That makes sense.

7 And this is the same for looking
8 at serotype prevalence based on geographic
9 region, as well, right, that the rate of
10 different serotypes can vary based on
11 geographic region; is that right?

12 A. As I said in my declaration on
13 Page 13, paragraph 17, "To date, researchers
14 have identified more than 100 different
15 pneumococcal serotype of streptococcus
16 pneumoniae. Serotypes vary in their
17 prevalence and virulence across age strata
18 and geographical location. The prevalence of
19 different serotypes varies both
20 geographically and temporally; a given
21 serotype may become unusually prevalent for a
22 period of time or in a particular region.

1 Monitoring pneumococcal serotype prevalence
2 and identifying newly emerging serotypes is
3 essential for designing new pneumococcal
4 vaccines."

5 And I will add, it's also depend
6 on the source of your data. Is the serotype
7 coming from carriage? Is the serotype coming
8 from invasive disease?

9 So that is so important after the
10 introduction of pneumococcal vaccine to a
11 population when the prevalence of vaccine
12 type, that's the serotype included in the
13 vaccine, is reduced, and there was a
14 corresponding increase in the prevalence of a
15 nonvaccine type, those that are not included
16 in the vaccine.

17 And so as I said in paragraph 18,
18 "Epidemiological studies related to the
19 distribution of the circulating pneumococcal
20 serotypes in a given population are based on
21 the isolation of strains of streptococcus
22 pneumoniae in individuals with clinical

1 symptoms suggestive of pneumococcal disease
2 as well as natural carriage of streptococcal
3 pneumoniae in the pharynx [sic] from children
4 and adults with or without pneumococcal
5 disease."

6 And I will add to that that they
7 also depend on which population you are
8 looking at, whether there are people with
9 certain medical conditions, like chronic lung
10 and chronic heart disease, or people who are
11 immunosuppressed because they have HIV or
12 other immunosuppressive conditions.

13 So there are a lot of factors
14 that one needs to look into other than just
15 saying, here's the picture. This data just
16 showed this. It's a different characteristic
17 that you need to put into -- a factor that
18 you need to take into consideration.

19 Q. Okay. So you said, "Serotypes
20 vary in their prevalence and virulence across
21 age strata and" geographic locations. Those
22 are the two that we just talked about.

1 And I think the other one that
2 you said -- I want to make sure I got it --
3 is that it's based on the -- a variance can
4 be based on the site.

5 So is it -- I think this is,
6 like, IPD versus pneumonia or carriage versus
7 mastoid versus otitis media; is that right?

8 A. It is. So what I'm saying is
9 when you have data on certain distribution,
10 you need to look at -- examine, analyze those
11 data and understanding how those data were
12 collected and the populations and the site,
13 whatever you name it, and the underlying
14 medical conditions and so forth. So you need
15 to take into consideration all those factors
16 when you analyze your data.

17 Q. Would the serotype prevalence and
18 virulence also potentially differ depending
19 on whether a population has been vaccinated
20 with a PCV or not?

21 A. As I mentioned earlier, after the
22 introduction of Prevnar 7 and depending on

1 which country or which place that this
2 particular vaccine was used and at what level
3 you have a good vaccine uptake, but data from
4 many countries where this vaccine was used
5 have shown that widespread use of Prevnar 7
6 led to the reduction or the decrease of the
7 disease caused by those serotypes within
8 Prevnar in that particular population of --
9 that were targeted by the vaccine and all the
10 age group that did not receive Prevnar,
11 including the elderly.

12 And this is -- in my declaration
13 it's paragraph 26 that I'm providing.

14 Q. So was that a yes, then, that
15 serotype prevalence can vary depending on
16 whether the population has been vaccinated
17 with a PCV?

18 MR. KRINSKY: Objection, asked
19 and answered.

20 A. Again, it -- it's -- it's depend
21 on -- it's depend on where the study's done
22 and the vaccine uptake.

1 So what I'm saying, in other
2 words, is this vaccine has been very
3 successful. So the disease caused by those
4 serotypes in the country where it was high
5 coverage of the vaccine, those serotypes were
6 significantly reduced.

7 Are they still there? Some of
8 them are.

9 Would that be different in a
10 population that did not -- where the vaccine
11 is not available? Possibly, but it's -- it's
12 something that, when you develop a vaccine,
13 you need to think about the population that's
14 going to be vaccinated.

15 Q. Would serotype prevalence
16 potentially vary based on whether there is a
17 local or regional outbreak at the time?

18 A. Are you talking about outbreak in
19 the vaccinated population or outbreaks in --
20 because pneumococcal is -- is there. It
21 doesn't go away. It's there. You may need
22 the reservoir. So there may be some

1 outbreaks in there with specific serotypes,
2 in one region, but that -- I don't know how
3 that -- your question -- what -- what do you
4 mean by -- by what is serotype -- I don't
5 know -- can you clarify your question or
6 repeat your question, please?

7 Q. I think you answered it, but
8 yeah. My question was that -- you were
9 talking about the ways in which -- or the
10 factors that can cause serotype prevalence to
11 vary, and another would -- I believe, would
12 be that if there is a regional or a local
13 outbreak and there's testing in the side of
14 -- or in the region where there's that
15 outbreak, there could be a serotype outbreak
16 that causes a serotype to spike for a while
17 during that outbreak; is that right?

18 A. Like for any infectious disease,
19 outbreak can occur.

20 Q. And if outbreak occurs, then the
21 serotype prevalence of whatever the outbreak
22 is would spike in the region where there's

1 the outbreak, right?

2 MR. KRINSKY: Object to the
3 form.

4 A. I believe that's the definition
5 of an "outbreak."

6 (BY MS. SPIRES)

7 Q. Can serotype variant -- strike
8 that.

9 Can serotype prevalence also vary
10 depending on capsular switching events?

11 A. I'm trying to understand the
12 relevance of this question with the patent
13 that we're talking about. We are not
14 basically talking about capsular switching,
15 and so I don't know how that is relevant to
16 the discussion we have today, sincerely.

17 Q. Okay. But humor me, because
18 relevance isn't really a reason to not answer
19 a question in a deposition; so regardless of
20 whether you think it's relevant, as --
21 sitting here today as Pfizer's expert, can
22 you tell me whether a POSA in 2016 would

1 understand that serotype prevalence can vary
2 based on capsular switching events?

3 MR. KRINSKY: Objection,
4 outside the scope and incomplete
5 hypothetical.

6 A. I need to think hard about that
7 because it's not a -- there is no simple
8 answer to your question, and I don't want to
9 go into a tirade of scientific discussion, so
10 I don't know. I need to give you a short
11 answer. Let me think about it.

12 So you're asking me, if I
13 understand correctly, whether capsular
14 switching occurs, correct?

15 (BY MS. SPIRES)

16 Q. I'm asking whether capsular
17 switching can result in the variance of
18 serotype prevalence.

19 A. I don't know if you're familiar
20 with capsular switching, because capsular
21 switching could affect a given serotype. So
22 you can have 19F, have a capsular switching

1 that only affect 19F, but capsular switching
2 could come from 19F switching to -- being
3 acquired by other serotypes.

4 So when we talk about capsular
5 switching, it's important to understand what
6 exactly we are discussing and what the
7 capsular switching really entailed.

8 What I mean by that is that you
9 may find capsular switching, but does that
10 mean that the prevalence of that particular
11 serotype would increase? I don't know. It's
12 not always true.

13 Does that mean that the switching
14 would make the -- the serotype to be more
15 virulent? Sometimes yes, sometimes no.

16 So there are a lot of -- a lot of
17 things that could happen with the capsular
18 switching that I think it's -- it's -- it's a
19 very complex, really, topic that -- for
20 discussion.

21 Q. So what I heard was that capsular
22 switching events sometimes could affect

1 serotype prevalence and sometimes might not;
2 isn't that right?

3 MR. KRINSKY: Objection to
4 form, mischaracterizes testimony, asked and
5 answered.

6 A. Based on my knowledge -- and I
7 will say that capsular switching is a
8 phenomenon that can occur with pneumococcal
9 capsular polysaccharides; however, the
10 consequences of that capsular switching is
11 not well-defined or clearly predictable. So
12 that's what I can say. I cannot say whether
13 it's one or the other.

14 MS. SPIRES: Okay. I'm about
15 to move to a new exhibit, so we can keep
16 going or take a lunch break now, whatever
17 makes --

18 MR. KRINSKY: We've been going
19 over an hour, and it's pushing 1:00 p.m.
20 here; so why don't we do a lunch break.

21 MS. SPIRES: Sounds good.

22 (Break taken from 11:48 a.m. to

1 12:27 p.m.)

2 (BY MS. SPIRES)

3 Q. All right. If you could pull up
4 Exhibit 1045. And I can put it into the chat
5 if that's helpful.

6 MR. KRINSKY: Probably makes
7 sense to put it there for the court reporter.
8 He has it in paper form.

9 MS. SPIRES: Yes, go ahead, if
10 y'all can -- so Exhibit 1045 into the chat,
11 that would be amazing.

12 THE COURT REPORTER: Can I make
13 a clarification? When you bring these up, do
14 you want them attached to the transcript as
15 an exhibit when you're referencing them?

16 MR. KRINSKY: Speaking for
17 Pfizer, I don't think we need any of these
18 ones that have been previously marked. I
19 don't know, Sarah, if you agree with that.

20 MS. SPIRES: Completely agree.

21 MR. KRINSKY: So thus far we
22 have only one new exhibit, and I defer to

1 Ms. Spires about what we do with it.

2 THE COURT REPORTER: Thank you.

3 MS. SPIRES: I don't honestly
4 care if it's attached. It's public record
5 what it is, so... but I'll say this, if
6 you-all want that one attached, we can do
7 that.

8 MR. KRINSKY: Well, why don't
9 you just submit it with -- when you submit
10 the transcript.

11 MS. SPIRES: Yeah, that's fine.

12 THE COURT REPORTER: Okay.
13 Thank you.

14 MS. SPIRES: Brian, are you
15 able to get that Exhibit 1045 into the chat?

16 MR. KRINSKY: I don't think we
17 need it to proceed. I just want to make sure
18 Annette has it later if she needs it.

19 MS. SPIRES: Yes.

20 (Whereupon Exhibit Number 1045

21 was shown.)

22 (BY MS. SPIRES)

1 Q. Okay. Dr. Musey, do you recall
2 reviewing Exhibit 1045 as part of the work
3 you did in your declaration?

4 A. So it's the paper by Calvin
5 Daniels --

6 Q. Yes.

7 A. -- "A Review of Pneumococcal
8 Vaccines"?

9 Q. Yes.

10 A. Okay. I have it.

11 Q. Okay. Do you remember reviewing
12 this as part of the work you did in drafting
13 your declaration?

14 A. I did include it as a reference.

15 Q. You said you did include it?

16 A. Yes.

17 Q. Okay. If I could have you look
18 at the second page of this document, the --
19 I'm looking at the very first paragraph, not
20 even the first full paragraph, just the first
21 paragraph on the top left.

22 There's a sentence about halfway

1 down of that paragraph that says, "The
2 prevalence of particular capsular serotypes
3 can vary greatly among continents, providing
4 differing levels of protection for vaccinated
5 individuals depending on their location."

6 Do you see that?

7 A. Yes, I can see that.

8 Q. Do you agree with this statement
9 in Exhibit 1045 that I just read?

10 MR. KRINSKY: Objection,
11 outside the scope.

12 A. I'm trying to look at the
13 reference that you pulled, that statement.

14 Yeah, I think the reference -- I
15 didn't read that reference, Bogaert, but I'm
16 assuming that whatever they -- whatever
17 Calvin is providing here reflects what
18 Bogaert's indicated in that reference.

19 (BY MS. SPIRES)

20 Q. What are you referring to with
21 "Bogaert"?

22 A. So the sentence that you are --

1 you have indicated, "The prevalence of
2 particular capsular" poly -- "serotypes can
3 vary greatly among continents..."

4 And then it goes to the next
5 sentence. There is a reference there. This
6 is reference number 4 for that paper, and
7 that reference is from Bogaert in -- trying
8 to see -- Bogaert and -- in Vaccine 2004.

9 What I'm saying, I'm assuming
10 that Daniel -- Daniels -- Daniels accurately,
11 you know, reflect what Bogaert's -- the
12 reference, as mentioned.

13 Q. So you have no reason to
14 disagree, at least with the statement in
15 Daniels that, "The prevalence of particular
16 capsular serotypes can vary greatly among
17 continents, providing differing levels of
18 protection for vaccinated individuals
19 depending on their location," right?

20 MR. KRINSKY: Objection,
21 outside the scope, asked and answered.

22 A. My knowledge is that even in a

1 given continent, you may have different --
2 different prevalence or capsular
3 polysaccharides, capsular serotypes, even
4 within the same continent.

5 So it's -- it's -- it's a
6 statement that is really broad, I would say.
7 (BY MS. SPIRES)

8 Q. So, true, but broad, and there
9 can be more variance of capsular serotypes
10 even than the statement indicates; is that
11 correct?

12 MR. KRINSKY: Objection,
13 outside the scope, asked and answered.

14 A. What I'm stating is that there
15 are certainly differences in the prevalence
16 of particular capsular serotypes among
17 continents, but it's a very broad one that
18 they may be, even within the continent --
19 let's give an example: Two different
20 continents -- I can take two countries,
21 maybe -- I don't know, I've never looked at
22 the data, but to -- to confirm that, but I'm

1 just saying, the viability is not just about
2 continent. It can be different -- some --
3 there are other things that could -- they
4 could come up with.

5 (BY MS. SPIRES)

6 Q. Would you agree that, as of March
7 2016, PPSV23 was the most widely used
8 pneumococcal vaccine in the world?

9 MR. KRINSKY: Objection,
10 outside the scope.

11 A. As of March 2016, I -- PPSV22
12 [sic] was the most widely used pneumococcal
13 vaccine in the world? That's what you're
14 saying?

15 (BY MS. SPIRES)

16 Q. No.

17 Would you agree that as of
18 March 2016, PPSV23 was the most widely used
19 pneumococcal vaccine in the world?

20 A. I'm not so sure I would make -- I
21 would make that statement because I don't
22 know.

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

3 A. There are a lot of factors. I'm
4 not a commercial person to tell you how those
5 vaccines are distributed worldwide. Keep in
6 mind that you have -- in 2016 you have also
7 Pevnar 13 and you have PCV10 from Glaxo, and
8 so I cannot tell you whether your statement
9 is accurate.

10 Q. Do you agree that for individuals
11 greater than two years old, PPSV23 was
12 regarded as effective at preventing IPD?

13 A. I think this is also a very broad
14 statement because the vaccine PPSV23
15 indication vary between the age, and those
16 are between 2 and 64. It's only those who
17 have medical conditions associated with high
18 risk for pneumococcal disease, those are 65
19 and older, because, age being a factor, they
20 are vaccinated.

21 And there are studies that were
22 done for PPSV23 -- were done in the 80s, and

1 so those data -- those studies were done in
2 the 80s, and those studies shows that PPSV22
3 was efficacious, or effective, I will say, in
4 protection against pneumococcal disease.

5 Q. Did you say PVS -- it came up on
6 the transcript "PPSV32." Were you talking
7 about PPSV --

8 A. 23.

9 Q. Okay.

10 A. 23, sorry.

11 Q. I'm doing it, too, so no worries.

12 A. Yeah, that's okay.

13 Q. Do you agree that PPSV23 was
14 widely recommended by authorities such as the
15 Advisory Committee on Immunization Practice
16 for use in adults 65 and older and adults
17 that were high risk individuals as of
18 March 2016?

19 A. So I -- I don't know how many
20 individual below the age of 65 have used
21 pneumo vax 23, PPSV23; but most of the data
22 that I'm aware of are really in adults --

1 adults 65 years and older.

2 So I don't know if that is what
3 you're referring to.

4 Q. So I am asking whether PPSV was
5 widely recommended by authorities, and
6 includes ACIP, other similar authorities, for
7 use in adults 65 years and older, as well as
8 adults that were high risk individuals.

9 A. So the recommendation from the
10 FDA is that PPSV23 should be given to all
11 adults 60 years of age and older, and it's
12 also recommended for those who have increased
13 risk, that have that -- those conditions; so
14 adult -- children and adult 5 to 64 years of
15 age are recommended to use PPSV23.

16 Q. Are you aware of whether any
17 authorities outside of the United States also
18 recommended PPSV23 for their populations?

19 MR. KRINSKY: Objection,
20 outside the scope.

21 A. So vaccine recommendation could
22 change over time.

1 Can you tell me what time period
2 are you talking about?

3 (BY MS. SPIRES)

4 Q. March of 2016.

5 A. March of 2016. I'm just thinking
6 about countries where I could say for sure
7 that the product was recommended. 2016.

8 Japan, Germany -- I don't have
9 the list on top of my head, but there are
10 probably people that have that list of where
11 PPSV23 was recommended worldwide, but for
12 sure, if my recollection is correct, Germany
13 and -- and Japan were two countries that I
14 think were -- I remember that they were --
15 that PPSV23 was recommended to be given in
16 adults.

17 Q. So PPS -- sorry, strike that.

18 PCV13 is a conjugated version of
19 12 of the PPSV23 serotypes plus one
20 additional serotype that wasn't in PPSV23; is
21 that right?

22 MR. KRINSKY: Object to the

1 form, outside the scope.

2 A. Yeah. On Page 17 of my
3 declaration, I do provide the list of the
4 serotypes that I included in Prevnar 13, and
5 that lists are -- does include the serotype
6 that you just mentioned, which 12 of them
7 being in PPSV23 and one, 6A, being a new
8 serotype.

9 (BY MS. SPIRES)

10 Q. Would you agree that if a POSA
11 were to create a new conjugated version of
12 PPSV23 -- so all 23 serotypes conjugated --
13 that would provide the broader vaccine
14 coverage than PCV13 in March of 2016?

15 MR. KRINSKY: Objection,
16 incomplete hypothetical, outside the scope.

17 A. I think you need to look at the
18 burden of disease in that particular country
19 you're talking about, look at the list, and
20 what are the contribution of each serotype
21 because the contribution can be different,
22 and therefore, one should expect that the

1 more serotype you're adding, you expect to
2 see more disease coverage, but the difference
3 could vary between region and region --
4 between region or location or countries.

5 (BY MS. SPIRES)

6 Q. So if a POSA were looking to
7 expand the coverage of PCV13, what region or
8 country would they look to?

9 MR. KRINSKY: Objection,
10 outside the scope, objection to form.

11 A. A POSA living in China in 2016
12 may have a different view about which
13 serotype to include in their vaccine than a
14 POSA who's living in the United States that
15 already have a PCV13 on the market.

16 So what I'm trying to indicate
17 here is the POSA need to look at the most
18 frequent serotype causing disease, and
19 therefore, that doesn't mean that because
20 there is a PCV13 in country A, that the
21 country B will also use PCV13. I'll give you
22 an example.

1 PCV13 was available in 2010 or
2 2013. Some scientists in India did develop a
3 vaccine. It was a PCV10 with no -- a
4 small -- a few number of serotypes.

5 So I think the -- it's up to the
6 POSA to really examine/analyze the disease
7 burden, and that is also a way to decide
8 which serotype to include in the vaccine to
9 address the disease burden in that country.

10 (BY MS. SPIRES)

11 Q. I'd like to look at Exhibit 1018.

12 A. Can you confirm that is the
13 exhibit "Surveillance of Invasive Bacterial
14 Diseases in Europe" from 2012 -- published in
15 2012?

16 Q. Yes, that's right.

17 A. Okay.

18 Q. Okay. So I am looking at what
19 is -- there are a whole bunch of page
20 numbering systems here, so... it is labeled
21 on the bottom right "Page 24 of 99."

22 A. Do you mean 24 of 62?

1 Q. No.

2 A. Sorry, sorry, sorry.

3 MR. KRINSKY: I think that's
4 the wrong exhibit, Dr. Musey.

5 A. I went to the next one. Sorry.

6 MR. KRINSKY: Yeah.

7 A. Yes, I see "24 of 99."

8 (BY MS. SPIRES)

9 Q. Okay. And just to confirm,
10 Exhibit 1018 is an exhibit you discussed in
11 your declaration, right?

12 A. Yes.

13 Q. So I am looking at Table 1.3
14 that's on that Page 24 of 99.

15 Do you see that?

16 A. Table 1.3. Yes, I can see that.

17 Q. And the table is captioned, "The
18 10 most common IPD serotypes reported in
19 2012, EU/EEA countries," right?

20 A. Yes.

21 Q. Okay. So this ECDC report that's
22 Exhibit 1018 shows in Table 1.3 that PPSV23

1 covered 8 of the top 10 most common IPD
2 serotypes overall; is that right?

3 MR. KRINSKY: Object to the
4 form of the question.

5 A. I don't know top of my head which
6 serotype exactly are you calling PPSV23, by
7 head. So I don't know. I'm -- I cannot -- I
8 need to look at the list of the serotype in
9 PPV23 [sic]. I don't want to be misquoting
10 something here.

11 So what is the question, please?

12 (BY MS. SPIRES)

13 Q. Do you have a list of the PPV23
14 serotypes -- or PPSV23 serotypes?

15 A. No, I don't have that here.

16 Q. I thought you had it in your
17 declaration, so I was looking for it; but it
18 may not be there.

19 A. Let me see.

20 Q. That's okay.

21 A. I cannot find it. Can you direct
22 me to that place that I provided --

1 Q. No. I was saying -- sorry, I was
2 saying I thought it was in your declaration,
3 but I'm not seeing it, so I won't worry about
4 it.

5 A. I'm sorry.

6 Q. I'm sure it's in all the
7 documents we have here somewhere, but we can
8 move on and I'll come back to that if I find
9 it.

10 So let's look at the next page of
11 Exhibit 1018, Figure 1.5. This figure
12 provides an -- kind of key as to which
13 serotype was in which vaccine, and so has, it
14 looks like, four different key indicators
15 saying that that serotype was covered by
16 PPV23.

17 Do I have that right?

18 MR. KRINSKY: Object to the
19 form of the question, outside the scope.

20 A. I can see there Figure 1.5.

21 (BY MS. SPIRES)

22 Q. Okay. So would you agree from

1 Figure 1.5 of the ECDC report, Exhibit 1018,
2 that PPSV23 covered 17 of the top 25 most
3 common IPD serotypes overall?

4 MR. KRINSKY: Object to the
5 form, outside the scope.

6 A. I did not calculate how many of
7 them were covered by PPSV23, so I can trust
8 that what you say is correct.

9 (BY MS. SPIRES)

10 Q. Okay. Okay. So on page -- or
11 Page 27 of 99, in Exhibit 1018, can I have
12 you turn there?

13 A. Page 27?

14 Q. Yes.

15 A. Okay. I can see it.

16 Q. So -- are you there?

17 A. Yeah, I'm here. I'm there.

18 Q. Okay. So under the heading
19 "Serotype and Vaccines," it lists the
20 percentage of IPD cases due to serotypes
21 included in PCV7, PCV10, PCV13, and PPV23.

22 Do you see that?

1 A. So the first paragraph only talk
2 about PCV7, PCV10, and PCV13, correct?

3 Q. Yes, the first paragraph; and
4 then the second paragraph, I believe, talks
5 about PPV23, right?

6 A. Only for certain age range.

7 Q. Right. The second paragraph only
8 discusses the 15 to 64 year age range and
9 then also the 65 and over age range for
10 PPV23, right?

11 A. Yes.

12 Q. So based on the ECDC report,
13 would you agree that PPSV23 had the highest
14 vaccine coverage of the -- any of the
15 available vaccines that were discussed here?

16 A. It's not that simple. If you
17 read the first paragraph underneath "Serotype
18 and Vaccines," all the information for the
19 PCV talk about children under the -- one year
20 of age and then talk about the coverage of
21 PCV13 in all age groups compared to the
22 coverage of PCV7.

1 But the PPV23 discussion is not
2 in children under the age of one year, it's
3 on the adults 15 to 64 and those 65 and
4 older. So I think it's -- as I said, which
5 we've been discussing, this is not a fair
6 comparison of the two based on the
7 information that is provided.

8 Q. So the PCV vaccines all have all
9 age group data, right, not just under one
10 year of age?

11 A. No. If you read -- if you read
12 that first paragraph, it says that, "Across
13 all age... 13 percent of IPD cases were due
14 to serotypes included in PCV7, 31 percent
15 were due to serotypes included in PCV10, and
16 51 percent" due to "serotypes covered by
17 PCV13, Table 1.5."

18 And then when you talk about the
19 PCV13, "could have potentially prevented
20 about 50 percent of the cases in children"
21 one year -- "under one year of age."

22 What I'm saying is the -- the --

1 all age that you have in the first column is
2 different from the information provided in
3 the second paragraph, which talk about 15 to
4 64 and then 65 and older.

5 So it's not the same population
6 that you have in both paragraph.

7 Q. Right, but PCV13, the next
8 sentence, that you didn't read, does give the
9 all age coverage for PCV13, as well, right?

10 A. I understand that, but what I'm
11 saying is that the second paragraph of that
12 section talk about 15 to 64, 84 percent for
13 PCV23 [sic] and those 65 and older would have
14 done that.

15 So what I'm saying, it's the
16 compare- -- it -- using the information in
17 the first paragraph and comparing that with
18 the second paragraph and making that --
19 assuming that it's the same -- the
20 denominator is not fair. That's what I'm
21 trying to be cautious about, making a
22 conclusion based on the denominator in the

1 two not being the same when it comes to the
2 population.

3 Q. Table 1.6, though, does have the
4 all age percent -- the all age percentage for
5 the PPV23 serotypes, right?

6 MR. KRINSKY: Object to the
7 form, outside the scope.

8 A. So if you read that second
9 paragraph, it just tell you that, the first
10 sentence, in the 15 to 65 [sic] years of age,
11 "84 percent of the reported cases would have
12 been covered by PPV23; among confirmed"
13 case -- "IPD cases aged" 60 [sic] and older,
14 PPV22 [sic] "would have covered 70 percent.
15 Overall, serotypes included in the PPV23
16 vaccine were responsible for 79 percent of
17 cases for which information on serotype and
18 age was available."

19 So we don't know. Table -- which
20 is referred to in Table 1.6. We don't know
21 if Table 1.6 really have children below the
22 age of -- of 15 and how many of them were

1 below the age of one, and so it's very
2 difficult to really make that conclusion; and
3 that's what I'm trying to convey. It's --
4 it's -- it's not the same denominator.

5 (BY MS. SPIRES)

6 Q. But it says in Table 1.6 all age
7 groups, right, and the "N" is significantly
8 larger in all age groups than adding the "N"
9 of the 15 to 64 and the 65 and over, right?

10 A. But...

11 MR. KRINSKY: Sorry, object to
12 the form, outside the scope.

13 A. So what I'm trying to convey is,
14 in Table 1.6 you have 527 15 to 64, 237 65
15 and older. Even if you say that the third
16 column with all age is 1,008 greater than the
17 two column that we just mentioned, it doesn't
18 tell us whether that particular -- the
19 remaining subjects that are not in the first
20 two column were below the age of five and how
21 many were below the age of one because
22 whatever analysis they were doing for the

1 PCV7, PCV10, and PCV13, does include children
2 below the age of one year, and -- and so
3 it's -- it's a very -- I -- I have found it
4 difficult to make that conclusion. I feel
5 like the denominator is different.

6 I don't have information to say
7 that all age have the same representation
8 than the data that they're providing for PCV7
9 and PCV10 and PCV13, so I'm having a hard
10 time making that jump that you're making and
11 say, based on that data, PC -- PPV23 has a
12 broader coverage.

13 (BY MS. SPIRES)

14 Q. But you see that the total
15 denominator is identical for the PPV23
16 analysis as for the PCV analysis and that
17 it's out of 12,992 people. So it's the same
18 12,992 people that were analyzed, right, in
19 Table 1.6 and Table 1.5?

20 A. As you can see, there's an
21 asterisk next to the number; so even though
22 the total number of people that were

1 evaluated may be the same, the distribution
2 of age may not be the same between the two
3 data because the analysis --

4 Q. If it's the same people -- sorry,
5 go ahead.

6 A. No, but the analysis in Table
7 1.5, if you look carefully, is really
8 focusing on those below the age of 1, 1 to
9 14, and greater than 15.

10 And so if you use the same
11 analysis, you will think that it's the same
12 total of 12, 2, 1992, that is true, but I'm
13 -- I'm just having a hard time putting these
14 two together and say that, based on those
15 data, that your conclusion is accurate.

16 I don't -- I don't want to go
17 there. I'm -- I'm not comfortable doing it.
18 That's the only thing I'm saying.

19 Q. So you're saying you think it's a
20 coincidence that the number -- the total "N"
21 in Table 1.5 and Table 1.6 is identical for
22 every serotype that overlaps between the two?

1 A. What I'm saying is not that.
2 What I'm saying is when they do their
3 analysis on the serotype by age, the age is a
4 different factor that you need to take into
5 consideration, even if the total is -- like,
6 you have the United States population, and
7 then you have those who are below the age of
8 65, those who are greater than 65. It's
9 difficult to really -- I'm just not
10 comfortable making that -- that conclusion
11 that you're making, based on this data.

12 Q. So you would agree that PCVs such
13 as PCV13 are serotype-specific vaccines,
14 right?

15 MR. KRINSKY: Object to the
16 form of the question.

17 A. What do you mean by being
18 serotype-specific?
19 (BY MS. SPIRES)

20 Q. I mean that they only provide an
21 immunological response against these specific
22 serotypes in that vaccine, plus potentially

1 other cross-reacting serotypes within
2 possibly the same sero group.

3 A. So you're basically saying that
4 they are not serotype-specific, correct,
5 because you say that they may cross-react
6 with other serotypes that are not in the
7 vaccine.

8 Q. If they are within their same
9 sero group.

10 A. Okay.

11 Q. Did you -- I don't know, did you
12 respond to that? I didn't catch it if you
13 did.

14 A. I'm trying to -- to understand.
15 So you're saying, if I understand
16 correctly, that PCV13 end use immunoresponse
17 to the serotype that's in the vaccine and
18 also other serotype for which there was a
19 cross-reactivity?

20 Q. I am -- okay. Let's strike that.

21 You would agree that PCV13
22 provides an immunological response against

1 the specific serotypes that are in that
2 vaccine, right?

3 A. Yes.

4 Q. Do you believe that PCV13
5 provides an immunological response against
6 serotypes that are not in that vaccine?

7 MR. KRINSKY: Objection,
8 outside the scope.

9 A. There is a cross-reactivity that
10 occur and have been demonstrated that a
11 serotype -- that PCV13 will induce an
12 immunoresponse to serotypes that are not --
13 that are not in the vaccine.

14 (BY MS. SPIRES)

15 Q. And is that cross-reactivity to
16 serotypes that are within the same sero group
17 of serotypes that are in the PCV13 vaccine?

18 MR. KRINSKY: Objection,
19 outside the scope.

20 A. I will qualify that you will see
21 cross-reactivity to a certain degree to some
22 of the serotypes that have -- that are from

1 the same sero group, but not all of them
2 necessarily.

3 (BY MS. SPIRES)

4 Q. Okay. So if we put that
5 together, I think we're in agreement that
6 PCV13 provides an immunological response
7 against the specific serotypes in that
8 vaccine, plus some, but not all serotypes
9 that are within the same sero group of the
10 serotypes within PCV13 where there's
11 cross-reactivity; is that right?

12 MR. KRINSKY: Objection,
13 mischaracterizes testimony, outside the
14 scope.

15 A. I'm trying not to generalize what
16 you said because, as I said, depending on the
17 assay you're using -- so cross-reactivity to
18 certain serotypes from the same sero group
19 has been observed, yes.

20 (BY MS. SPIRES)

21 Q. Okay. Would you agree that PCV13
22 does not provide an immunological response

1 against any serotypes that are not in the
2 PCV -- strike that. I will start over and
3 make this better.

4 Would you agree that PCV13 does
5 not provide an immunological response against
6 any serotypes that are not within the same
7 sero groups as those that are included in
8 PCV13?

9 MR. KRINSKY: Objection to
10 form; objection, outside the scope.

11 A. I have not done the experiments.
12 I cannot tell you that.

13 (BY MS. SPIRES)

14 Q. Would a POSA in 2016 have had a
15 belief as to the truth or not of that
16 statement?

17 MR. KRINSKY: Objection to
18 form; objection, outside the scope.

19 A. As you have indicated earlier,
20 pneumococcal conjugate vaccine are really
21 based on capsular polysaccharides, and they
22 do mount an immunoresponse, and -- to the

1 serotype, not including the vaccine.

2 However, when you talk about an
3 immunoresponse to the un- -- to the serotypes
4 that are not from the same sero group -- you
5 know, if it's just an immunoresponse, I'm
6 not -- I cannot comment on that for the
7 simple reason that it's depend on many
8 factors.

9 And you can imagine, too, that
10 there was a -- a common capsular moiety
11 that -- or antigen that is present to all the
12 different -- the different pneumococcal
13 polysaccharides.

14 So it's -- we need to think about
15 what exactly you're measuring, and it's
16 really -- it's not easy to say that you're
17 never going to find antibody to that
18 unrelated serotype.

19 (BY MS. SPIRES)

20 Q. Would you agree that a
21 non-serotype-based PCV would cover most, if
22 not all, of the roughly 100 pneumococcal

1 serotypes?

2 MR. KRINSKY: Object to the
3 form of the question, outside the scope, and
4 incomplete hypothetical.

5 A. I think what you're trying to
6 express here is what I call the holy grail.
7 If somebody can find it -- I think that
8 people are looking for it. Have they found
9 it? By 2016 they have not found it, so I --
10 I cannot speculate on that particular
11 statement.

12 (BY MS. SPIRES)

13 Q. By 2016 would a POSA have been
14 looking for what you call the holy grail of a
15 non-serotype-based PCV?

16 MR. KRINSKY: Object to the
17 form, outside the scope.

18 A. Yeah.

19 My simple question would be --
20 it's a different paradigm. It's a very
21 different paradigm to what the field was --
22 knew about effective, efficacious

1 pneumococcal conjugated vaccines, a different
2 paradigm.

3 (BY MS. SPIRES)

4 Q. My question is different, and
5 it's rather -- by 2016, do you believe a POSA
6 would have been researching a
7 non-serotype-based PCV?

8 MR. KRINSKY: Objection, asked
9 and answered.

10 A. My recollection is that there
11 were some efforts in that particular, you
12 know, research topic at that time.

13 (BY MS. SPIRES)

14 Q. Do you know whether a
15 non-serotype-based PCV would cover emerging
16 serotypes?

17 A. What do you mean by "cover"? How
18 do you define "cover"?

19 Q. Would a non-serotype-based PCV
20 provide an immunological response to emerging
21 serotypes?

22 A. It's depend on what you are

1 measuring.

2 Are you measuring the capsular
3 polysaccharide antibodies? Are you measuring
4 something else? That antigen that you talk
5 about, which is the non-serotype antigens --
6 I don't know what you mean by "response."
7 What exactly do you want to talk about, the
8 "response"?

9 Q. Well, let's take it in parts; so
10 first, the capsular polysaccharide
11 antibodies.

12 MR. KRINSKY: Objection to
13 form, incomplete hypothetical.

14 A. Yeah, I think the question is a
15 little bit, I will say, not what the common
16 POSA will think about because typically you
17 induce immunoresponse, the product that you
18 are injecting, so -- or you are providing to
19 the person.

20 So if you are injecting product
21 A, I'm not expecting to show a response that
22 is directed at product B. So that's the

1 basic -- the basic assumption that is very
2 specific to that, so I cannot answer that
3 question.

4 Can we stop for a minute and take
5 a break for five minutes?

6 MS. SPIRES: Sure, it's a good
7 time.

8 MR. KRINSKY: Yeah.

9 (Break taken from 1:22 p.m. to
10 1:31 p.m.)

11 (BY MS. SPIRES)

12 Q. Okay. If I could have you look
13 back at Exhibit 1045 that we were looking at
14 earlier...

15 A. I can see it.

16 Q. Okay. If you can turn to the
17 fifth page of that document, so Page 5 of 9.

18 A. Yes.

19 Q. Under the heading "New" -- sorry?

20 A. I'm there.

21 Q. Okay. Do you see the heading
22 "New Vaccine Antigens"?

1 A. Yes.

2 Q. Okay. So under that heading, it
3 says: "The incidence of serotype replacement
4 in both carriage and infection isolates after
5 implementation of conjugate vaccines and the
6 increase in antibiotic resistance among
7 serotype replacement strains stress the need
8 for pneumococcal vaccines with broader
9 coverage against pneumococci. Due to the
10 large diverse pool of capsular polysaccharide
11 serotypes that pneumococci can express,
12 researcher has focused on finding a more
13 conserved protein-based antigen that could
14 offer protection against pneumococcal
15 disease."

16 Do you see that?

17 A. Yes.

18 Q. Would this be an example of the
19 non-serotype-based PCV that we were talking
20 about earlier?

21 MR. KRINSKY: Object to the
22 form of the question, outside the scope of

1 the report.

2 A. I'm reading what it says about
3 those proteins, so give me one -- a few
4 minutes, please.

5 (BY MS. SPIRES)

6 Q. Okay.

7 A. So can you repeat the question,
8 please?

9 Q. How about, do you have an
10 understanding of what this author is talking
11 about under this "New Vaccine Antigens"
12 paragraph in Exhibit 1045?

13 A. Yes.

14 Q. What is that?

15 A. I do know about, as I said, the
16 holy grail, those, you know, antigen --
17 common antigens to pneumococcus that people
18 were pursuing with the hope that they can
19 really solve the problem of the multitude of
20 serotypes, capsular polysaccharides.

21 Q. So this is discussing research
22 into a PCV that is not based on serotype or

1 is not serotype-specific; is that right?

2 A. I would not go and just say PCV,
3 because if these particular proteins are
4 designed on their own, they are not
5 conjugated to anything. I would not define
6 them as being conjugate.

7 If they are bound to -- linked to
8 something else, then I would call that a
9 conjugate. So it's -- it's depend on which
10 approach you're talking about.

11 Q. Okay. So would it be fair to say
12 that Exhibit 1045 is talking here about
13 research into a pneumococcal vaccine that is
14 not based on serotype? Is that right?

15 A. So as I said earlier, this
16 particular approach, as I've said, is a
17 different paradigm that is not -- mechanism
18 of action is not targeting the capsular
19 polysaccharides of the pneumococci.

20 Q. So does that mean that it is not
21 targeting specific serotypes?

22 A. So if you read those -- what are

1 those antigens you just mentioned, the first
2 one, "Pneumococcal Surface Protein A," it
3 says it's -- allows surface protein attached
4 to -- "attached non-covalently via binding to
5 choline residues in lipoteichoic acid and
6 cell wall teichoic acid on the pneumococcal
7 surface."

8 So the already particular antigen
9 is targeting a different antigen than the --
10 the current vaccine that we have on the
11 market, which are, like, PCV7, PCV13. It's a
12 different part of -- a different approach.

13 Q. So it's targeting something that
14 is not serotype-specific; is that right?

15 A. It's targeting a region of the
16 pneumococcus; and that region, we would hope
17 that the majority of the pneumococcal strain
18 have that so that you can induce
19 immunoresponse and that will neutralize or --
20 really neutralize the -- prevent the growth
21 of the bacteria.

22 Q. That makes sense.

1 Do you agree that it was known to
2 a POSA in March of 2016 that immune
3 interference could occur with PCVs?

4 MR. KRINSKY: Object to the
5 form of the question, outside the scope of
6 the declaration.

7 A. I've seen a lot of paper talking
8 about immune interference, but I don't
9 know -- when you say "immune interference,"
10 what do you mean?

11 (BY MS. SPIRES)

12 Q. Well, what is your understanding
13 of what "immune interference" is with respect
14 to PCVs?

15 MR. KRINSKY: Objection,
16 outside the scope.

17 A. So I'm not trying to put you on
18 the spot, but I said I've seen papers talking
19 about immune interference; and for this
20 particular opinion I'm providing, I did not
21 research that to tell you exactly what
22 those -- those individual -- how -- why --

1 what is the definition of "immune
2 interference," so I was hoping that when you
3 talk to me about the immune interference,
4 that you will be more specific about what you
5 mean by "immune interference."

6 (BY MS. SPIRES)

7 Q. Okay. So if I talk about
8 antigenic interference as opposed to immune
9 interference, does that clarify things for
10 you?

11 MR. KRINSKY: Objection,
12 outside the scope, vague.

13 A. I really -- I mean, are you -- I
14 don't know how you define that "antigen
15 interference" because I -- it's -- a human
16 body can -- can really process many things,
17 how the human body part decides which one to
18 process more than the other, it's something
19 that vary between individuals, vary between
20 the antigens and the age.

21 There are a lot of things that
22 could come to see how antigen can compete

1 with what immunologists call
2 antigen-presenting cells. Is it what you
3 were referring to?

4 (BY MS. SPIRES)

5 Q. Right.

6 So I'm talking about the fact
7 that you would agree, I think -- or tell me
8 if I'm wrong, but do you agree that a POSA
9 would have been concerned that adding more
10 and more additional serotype-specific
11 polysaccharide conjugates to an existing PCV
12 could reduce the immune response and vaccine
13 efficacy to one or more individual serotypes
14 within the vaccine?

15 MR. KRINSKY: Object to the
16 form of the question, outside the scope.

17 A. Give me one minute, please.

18 So your question -- can you
19 repeat your question, please, so I can really
20 try to answer that?

21 (BY MS. SPIRES)

22 Q. Sure.

1 I asked, "Do you agree that a
2 POSA in March of 2016 would have been
3 concerned that adding more and more
4 additional serotype-specific polysaccharide
5 conjugates to an existing PCV could reduce
6 the immune response and vaccine efficacy to
7 one or more individual serotypes within the
8 vaccine?"

9 MR. KRINSKY: Objection,
10 incomplete hypothetical, objection to form,
11 outside the scope.

12 A. Yes, yeah. It's -- it's a tricky
13 question because -- you talk about concern.
14 They're a different level of concern, and so
15 whether you observe a reduction in the immune
16 response, does that raise a concern or not?
17 It's going to depend on the data that you
18 have in front of you.

19 Q. Okay. Then let me change the
20 wording.

21 Do you agree that a POSA in March
22 of 2016 would have believed that adding more

1 and more additional serotype-specific
2 polysaccharide conjugates to an existing PCV
3 could reduce the immune response and vaccine
4 efficacy to one or more individual serotypes
5 within the vaccine?

6 MR. KRINSKY: Objection to
7 form, incomplete hypothetical, outside the
8 scope.

9 A. Again you're mixing two different
10 topic in the same question. You talk about
11 immune response, and you talk about efficacy.
12 So, you know, it's -- it's -- they don't
13 go -- I mean, it's -- like, the concern is --
14 is -- the concern is -- it's -- it's -- are
15 you talking about the immune response that
16 is -- can be reduced, or are you talking
17 about the efficacy? Because a reduction on
18 the immune response may not imply a reduction
19 in efficacy. So I don't know, really, the
20 question that you're trying to -- I'm trying
21 to understand. If you can clarify that, it
22 would be helpful.

1 (BY MS. SPIRES)

2 Q. Okay. I'll split it into two.

3 Do you agree that a POSA in March of 2016
4 would have believed that adding more and more
5 serotype-specific polysaccharide conjugates
6 to an existing PCV could reduce the immune
7 response to one or more individual serotypes
8 within the vaccine?

9 MR. KRINSKY: Objection to
10 form, incomplete hypothetical, outside the
11 scope.

12 A. If you go to my Exhibit 1024,
13 it's a manuscript reference that -- the title
14 is "Immunogenicity and Safety of 13-Valent
15 Pneumococcal Conjugate Vaccine in Infants and
16 Toddlers."

17 So here we're just talking about
18 infants and toddlers, and I will not explain
19 whether that can be applied to all the
20 population. I'm just going to talk about
21 this particular reference that I did include
22 in my declaration.

1 So if you go to Page 6 of 14 of
2 the document, there was four different time
3 mirrors that has been analyzed, the first one
4 being proportion of responders according to
5 antipolysaccharide IgG.

6 And they explain in the footnote
7 this is a concentration equal or greater than
8 0.35 microgram per mL.

9 The second is antipolysaccharide
10 IgG geometric mean concentration.

11 The third is OPA titers, percent
12 with titer greater than one to eight.

13 And then the last one is OPA GMT,
14 which is OPA geometric mean titers, so the
15 overall titers.

16 Do you see that?

17 Q. Yes.

18 A. So if I just go to the one in the
19 middle, antipolysaccharide IgG geometric mean
20 concentration in microgram per mL, the first
21 row is Prevnar 13, the second row is Prevnar
22 7, and the last row is a ratio.

1 What you can see here in those
2 infants -- because this is after the infant
3 vaccination series. So you have a reduction,
4 slight reduction in IgG concentration in
5 Prevnar 13 recipients compared to the Prevnar
6 7 for those 7 serotype in common.

7 This is what you're trying to
8 convey to me?

9 Q. Yes.

10 A. But my question to you is you
11 need to read those data in the context of
12 those infants, and you cannot extrapolate and
13 say if I go to the adult, will I see the same
14 thing.

15 (Reporter clarification.)

16 You cannot extrapolate the
17 information that we just discussed -- that
18 is, data from infants to adults. So this is
19 data from infants, and I would not -- I would
20 be cautious about saying that if I was using
21 adults, I would see the same thing.

22 Does that make sense?

1 Q. Yes.

2 Would a POSA in March of 2016
3 have believed that there would not be a
4 reduction in antipolysaccharide IgG in
5 adults, like we see with respect to infants
6 here?

7 MR. KRINSKY: Objection,
8 outside the scope, calls for speculation.

9 A. I'm trying to provide an accurate
10 response to your question.

11 The information we just discussed
12 is really solely based on these particular
13 vaccines that we have here with the
14 technology that was used for this vaccine and
15 in infants.

16 So depending on the technology, I
17 would not be inclined to assume that a
18 different vaccine or even the same vaccine
19 that is here -- if used in adults, I would
20 expect to see also the same production as I
21 see in the infants. That was pure
22 speculation on my part.

1 (BY MS. SPIRES)

2 Q. So you don't know one way or the
3 other whether the reduction in IgG that we
4 see by adding serotypes to the PCV in infants
5 would also occur when adding the same
6 serotypes to a PCV in adults?

7 MR. KRINSKY: Objection,
8 mischaracterizes testimony, asked and
9 answered.

10 A. I believe that what we see here
11 is the same population, of infants, and you
12 see something, a reduction in the antibodies
13 for the shared serotypes.

14 You can do -- I'm not aware of a
15 study that compare the same two vaccines here
16 into adults and -- as to whether the
17 reduction that I see here in the infants, I
18 would see the same in the adults.

19 So I'm not familiar with that,
20 and I cannot speculate on that.

21 (BY MS. SPIRES)

22 Q. So sticking with infants, then,

1 would a POSA in March of 2016 believe that
2 increasing the valency of a new pneumococcal
3 vaccine could decrease the antipolysaccharide
4 IgG seen in infants, among the shared
5 serotypes?

6 A. My personal opinion is -- again,
7 depending on the technology that you're
8 using; depend also on the amount of antigen
9 you have in your -- in your vaccine, and I --
10 I can only speak for the data that are in
11 front of me by 2016 that shows a comparison
12 of the immune response between a 7-valent
13 vaccine and a 13-valent vaccine made a
14 certain way.

15 And I -- I don't -- I'm not privy
16 either whether there was some modification --
17 I don't know, some -- but dramatic,
18 significant modification were done going from
19 PCV7 to PCV13.

20 The only one that I know about is
21 that PCV7 has 2 microgram of each of the
22 serotype, except 6B at 4 microgram and PCV13

1 has 2.2 micrograms, slightly 10 percent
2 increase.

3 So I don't know more than that
4 about the difference in the manufacturing
5 process between 7 and 13.

6 Q. Okay. So my question wasn't
7 about 7 and 13 in particular.

8 I'm asking, based on the data
9 you've seen, Exhibit 1024, any other data a
10 POSA would be aware of in March of 2016,
11 would a POSA believe, at least with respect
12 to infants, that increasing the valency of a
13 new PCV vaccine could decrease the
14 antipolysaccharide IgG seen in infants among
15 the shared serotypes?

16 MR. KRINSKY: Objection to
17 form, outside the scope of the declaration,
18 calls for speculation.

19 A. At the time of the priority date,
20 the only data that were available were data
21 that we are provided. Some of the data we
22 provided -- like this one here from Yeh and

1 another one that is the Vesikari, which is a
2 different vaccine compared to Prevnar 7,
3 which was the GSK PCV 2010 -- and so those
4 data seems to indicate that the -- for PCV7
5 and PCV13, that there is a reduction for the
6 shared serotypes.

7 Regarding the other one -- trying
8 to see if I can find it, I can show you. I
9 don't know if we provide -- I think we
10 provided it. It's 1023, which is before
11 that. It's Exhibit 1023, with the title
12 "Immunogenicity of the 10-Valent Pneumococcal
13 Non-Typeable Haemophilus Influenzae Protein D
14 Conjugate Vaccine Compared to the Licensed
15 7-valent CRM Vaccine."

16 Do you see that?

17 Q. Yes.

18 A. So if you go to Page 5 of the
19 document, on Table 2 -- you can see Table
20 2 -- are you there?

21 Q. Yes.

22 A. You can see the comparison. On

1 the first column you have the vaccine
2 serotypes.

3 The second column you have
4 response based on cutoff of 0.20 microgram
5 per mL.

6 The third column in response
7 rates based on equal or greater than 0.35,
8 and then you have the GMC for the first
9 vaccine, the 10-valent; and then to the
10 right, you have the same parameters being
11 analyzed for the 7-valent vaccine. Okay.

12 First of all, the two vaccines
13 are manufactured differently. Second, the
14 sample size are different. You have 1,000
15 subjects -- 1107 subjects in the PCV10, and
16 only 375 in the 7-valent.

17 The serotype here, as shown --
18 but let's just focus on some of the serotypes
19 that are common to these two vaccines, like
20 serotype 4.

21 The GMC on PCV10 is 1.45 compared
22 to 2.78; 6B, 0.33 compared to 0.59; 9V, 1.32

1 versus 2.68; 14, 2.90 versus 4.49; 18C, 1.66
2 versus 2.46; 19F, 1.84 versus 3.42; and 23F,
3 0.5 versus 1.34. Okay?

4 If you read that, you will say,
5 yeah, the results are the same as the system
6 reduction like we saw for the paper we just
7 discussed, Exhibit 1025; however, the amount
8 of antigen in these two vaccines are
9 different.

10 Most of the serotypes in PCV10
11 contain 1 microgram of the capsular
12 polysaccharide; and as I said earlier, for
13 the 7-valent vaccine, it's 2 micrograms.

14 So when you look at the data --
15 you look at the data, it's very -- we have to
16 be careful about reaching a conclusion just
17 looking at the numbers that you see.

18 Does that make sense?

19 Q. Yes.

20 Would a POSA have reason to
21 decrease the amount of antigen when -- per
22 serotype when increasing the valency of a

1 vaccine?

2 MR. KRINSKY: Objection,
3 incomplete hypothetical, outside the scope.

4 A. I think that decision lies with
5 the POSA and -- based on what they knew about
6 their product, how the product behave in
7 pre-clinical animal studies and so forth.

8 So here I give an example of 1024
9 were -- went from 2 micrograms to 2.2, a
10 10 percent increase; and I show you another
11 one where they looked at the -- they did a
12 vaccine that has for most serotypes, a
13 reduction on the amount of antigen.

14 So different POSA will have
15 different, you know, choice, and it's not --
16 I'm not here to give a judgment as to which
17 one is right, which one is wrong.

18 (BY MS. SPIRES)

19 Q. Was there a concern among POSAs
20 in March of 2016 about the amount of antigen
21 given in infant vaccines?

22 MR. KRINSKY: Objection, asked

1 and answered.

2 A. It's -- it's a -- it's a very
3 difficult question to answer for multiple
4 reasons, and the most important one is if I
5 gave you an antigen of polysaccharides versus
6 giving you an antigen of something that is
7 toxic, it doesn't matter whether I give you 5
8 microgram of the polysaccharide versus .1
9 microgram of the something that is toxic.

10 At the end of the day, there are
11 many factors that you need to take into
12 consideration as you make that decision. For
13 pneumococcal vaccine, you need to think about
14 how do you make your polysaccharides, how do
15 you make your conjugation, and how does your
16 vaccine perform as you think about increasing
17 or decreasing the antigen in your -- in
18 your -- in your vaccine.

19 (BY MS. SPIRES)

20 Q. But there were papers on or
21 before March of 2016 worried about the amount
22 of antigen being given to infants through

1 vaccines, correct?

2 MR. KRINSKY: Objection to
3 form, vague, outside the scope.

4 A. My assessment to that question,
5 your comment, is what are those concerns that
6 those individual was sent, because people
7 have -- may have different concerns of --
8 than others. So I don't know what the
9 concern was that you -- you want us to
10 discuss.

11 (BY MS. SPIRES)

12 Q. Let's see. Exhibit 1010, the
13 Porro reference that you cite, for one
14 example.

15 A. I found it.

16 Q. This reference beginning on
17 Page 3 -- actually, it kind of starts on
18 Page 2, but the top of Page 3 [sic] is
19 talking about "the possibility to reduce the
20 amount of carrier protein in the whole
21 conjugate formulations is becoming a
22 prioritary issue.

1 "In fact, one must consider that
2 a child undertaking immunization with" --

3 A. Can I ask a question?

4 Q. Yes.

5 A. Sorry to interrupt.

6 I don't know, is the beginning of
7 Page 3 or the middle of Page 3?

8 Q. This is the top of Page 3 [sic].

9 A. Okay.

10 MR. KRINSKY: And, Counsel, are
11 we talking about the internal page numbering
12 or 3 of 102?

13 MS. SPIRES: 3 of 102 [sic],
14 but it's the same.

15 MR. KRINSKY: Wait.

16 MS. SPIRES: No, sorry. It's 4
17 of 102.

18 THE WITNESS: Okay.

19 MS. SPIRES: Internal 3.

20 MR. KRINSKY: We are all on the
21 same page, as it were.

22 Why don't you repeat your

1 question? I'm not sure I know what question
2 is pending.

3 MS. SPIRES: No problem.

4 (BY MS. SPIRES)

5 Q. So on the top of Page 4 of 102 is
6 kind of where this all starts. It's a very
7 long paragraph that that's a part of, but it
8 talks about the possibility of reducing the
9 amount of carrier protein in the whole
10 conjugate formulations becoming a prioritary
11 -- I don't know if that's a word -- issue,
12 and then it talks about, in the next
13 paragraph, the first whole paragraph of
14 Page 4 of 102, that one must consider a child
15 undertaking immunization.

16 And it lists a whole series of
17 vaccines and all of the doses that are given
18 to a child to confer full protection the
19 first two years, and so it talks about the
20 whole amount of carrier protein injected in a
21 child easily may reach doses of .2 mg and
22 with an obvious stress on the immune system,

1 and it goes on.

2 But you -- you asked for an
3 example of papers that talked about a concern
4 about the amount of antigen being given in
5 the infant vaccine series, and so I'm giving
6 you exhibit Porro to your declaration as an
7 example of that.

8 So take whatever time you need to
9 review Porro, but my question is: Would a
10 POSA in 2016, March of 2016, have been aware
11 of concerns on the amount of antigen being
12 given in childhood vaccines in the first two
13 years of age?

14 MR. KRINSKY: Objection to
15 form, vague, outside the scope.

16 A. I believe anything that you give
17 to somebody carry a risk, anything that you
18 give to a person, even when intended --
19 intended, like a vaccine; therefore, one need
20 to really evaluate the benefit/risk of
21 vaccination. And I think there are people
22 that are experts that -- in policy that

1 really examine those particular concern all
2 the time; however, as you were reading that
3 particular paragraph, if you go a little bit
4 down there, on line 23, it says, "All
5 considered, the whole amount of carrier
6 protein injected in a child, easily may reach
7 doses of about .2 milligram, at least in the
8 case of the protein CRM197, with an obvious
9 stress of the immune system which, however,
10 so far seem to well tolerate such an amount
11 of protein carrier for conferring helper
12 T-cell dependency to the host."

13 So -- and then it continues to
14 say that we still need to be looking at that
15 very carefully.

16 So "by continuously upgrading the
17 formulation of polyvalent vaccines like the
18 one for prevention of" pneumococcal --
19 "streptococcal pneumoniae infections, the
20 amount of serotype polysaccharide, ergo of
21 carrier protein, is destined to climb over
22 time."

1 So there is a balance here that I
2 see in Porro, which is there is a concern.
3 The benefit/risk is there, and therefore, we
4 just have to be careful about what we're
5 doing.

6 I don't know if that answered
7 your question.

8 (BY MS. SPIRES)

9 Q. Yes.

10 Do you agree that PCV13 was FDA
11 approved only based on immunological testing
12 and not clinical efficacy data?

13 MR. KRINSKY: Objection to
14 form, outside the scope.

15 A. PCV13 was approved in infants
16 based on immunogenicity data comparing PCV7
17 and PCV13. It was a well-accepted threshold
18 of antibody for comparison.

19 And I don't want to go into the
20 detail as to why they did that; however,
21 PCV13 was also approved in the adults, and
22 that particular indication in adults was

1 confirmed by an efficacy trial.

2 (BY MS. SPIRES)

3 Q. So, for infants, you agree that
4 no data were available that PCV13
5 demonstrated equal clinical effectiveness
6 compared to PCV7 for the 7 shared serotypes,
7 right?

8 MR. KRINSKY: Object to the
9 form, mischaracterizes testimony, outside the
10 scope.

11 A. I'm not a regulator; and I think
12 that in the field, we understand that
13 regulatory agencies like the FDA may approve
14 a product like Prevnar 13 in infants based on
15 immunogenicity endpoint, but they are likely
16 to require that some post-licensure
17 effectiveness study be conducted to confirm
18 the vaccine impact on the burden of disease.

19 And there are numerous studies
20 that were conducted after Prevnar 13 was
21 licensed that clearly shows that the vaccine
22 was very effective.

1 So I don't know if that also
2 answer your question. It's -- the reason for
3 why it was an immunological problem is
4 something that, you know, it's going to be
5 too long to explain.

6 (BY MS. SPIRES)

7 Q. And I think your answer is that,
8 at approval, there was not data available on
9 the clinical effectiveness of PCV13 versus
10 PCV7 for the 7 shared serotypes, but that
11 that data was produced or developed after
12 approval; is that right?

13 MR. KRINSKY: Objection to
14 form, mischaracterizes testimony.

15 A. I would not characterize that
16 that way for -- the simple reason is that
17 after Prevnar 7 was licensed and before
18 Prevnar 13 was licensed, most of the disease
19 caused by the 7 shared serotypes were gone,
20 in the United States, at least, where there
21 was a high percentage of babies being given
22 Prevnar 7.

1 So there was no way that one will
2 -- looked at efficacy against those 7
3 serotypes, even doing an effectiveness. The
4 only thing that you can do is to make sure
5 that with the use of Pevnar 13, the level of
6 disease control, I would say, was maintained
7 so that it was not a surge on disease caused
8 by those 7 serotypes in Pevnar 7. They will
9 peak or would increase after Pevnar 13 was
10 licensed.

11 (BY MS. SPIRES)

12 Q. Sorry for the pause.

13 You've just answered -- already
14 answered some of the things on my outline, so
15 I'm trying to skip things to get us through
16 this instead of reasking.

17 I want to look back at
18 Exhibit 1024 that you were talking about
19 earlier.

20 A. Okay.

21 Q. So we talked about the IgG rows
22 of Table 2, right?

1 A. Yeah, I'm there.

2 Q. Okay. So looking back at Table
3 2, would you agree that the PCV7
4 immunogenicity data in children demonstrated
5 that different serotypes demonstrated
6 differing serum concentrations of the
7 serotype-specific serum IgG antibody?

8 MR. KRINSKY: Objection to
9 form, mischaracterizes the document, outside
10 the scope.

11 A. I can see that the concentration
12 is not exactly the same for all the
13 serotypes. Some of them are close to each
14 other, like 23F and serotype 4, but some of
15 them are a little bit lower, some of them are
16 a little bit higher. So there is some
17 variability between serotypes.

18 (BY MS. SPIRES)

19 Q. So from this, would a POSA
20 believe that the PCV7 immunogenicity data in
21 children demonstrated that different
22 serotypes required differing serum

1 concentrations of serotype-specific serum IgG
2 antibody to provide clinical protection from
3 IPD?

4 MR. KRINSKY: Object to the
5 form, outside the scope.

6 A. I'm trying to see if there is any
7 data by 2016. The data that I have in my
8 head, I'm not so sure that it was published
9 before 2016. There is another piece of data
10 that I remember is not part of my assessment
11 here. I want to make sure that we're not
12 talking about my declaration here, we're just
13 talking about my general knowledge on
14 pneumococcal vaccines.

15 There was one paper by Joe
16 Seibert. I don't know which year it was, but
17 that is the paper that was the basis for
18 using this 0.35 microgram per mL as a
19 threshold.

20 In that paper they took -- this
21 was based on Prevnar 7. They took studies
22 across different geographical areas, one in

1 the U.S., one in South Africa, and another
2 one somewhere else; I don't remember.

3 But they looked at efficacy
4 across -- the vaccine efficacy against the
5 serotypes that are in the vaccine, and they
6 find differences in the antibody
7 concentration between children in the U.S.
8 and children in South Africa for the same
9 serotypes, with the same vaccine, even though
10 I think that the one in South Africa, some of
11 the children were given the PCV9, not the
12 PCV7, if I remember correctly.

13 So there are geographical
14 differences, as well, in the amount of
15 antibodies for some serotypes that you'll see
16 with the same vaccine.

17 Having said that, what you're
18 asking, it's a very difficult questions
19 because, even today, there is not a -- a
20 well-established threshold to say, This is
21 what you need to be protected against disease
22 caused by given serotypes. People believe

1 that that concentration could vary between
2 serotypes, could vary between region for the
3 same serotype, could vary between individuals
4 with underlying medical conditions; so there
5 are a lot of factors that one needs to
6 consider in trying to establish the threshold
7 of the antibody concentration that is
8 required for protection.

9 And I will add that last, but not
10 the least, that when people looked at vaccine
11 efficacy, like PCV7, it was not on a serotype
12 basis, but it was for all the serotype that
13 were included in the vaccine, all taken
14 together.

15 When you start looking at each
16 individual serotypes, your sample size is too
17 small, and you cannot make a good assessment.

18 (BY MS. SPIRES)

19 Q. So we talked earlier about the
20 IgG rows of Table 2 in Yeh. For the -- the
21 OPA responses were also higher for PCV7 than
22 PCV13 for serotypes 4, 6B, 14, 18C, and 23F,

1 right?

2 A. Can you repeat which type you're
3 mentioning?

4 Q. Yes. 4, 6B, 14, 18C, and 23F.

5 A. And your question is? It's just
6 an observation you're making, or there was a
7 question?

8 Q. I just wanted to know if you
9 agreed with me that PCV7 demonstrated higher
10 OPA responses than PCV13 versus for serotypes
11 for 6B, 14, 18C, and 23F.

12 MR. KRINSKY: Object to the
13 form of the question, compound, outside the
14 scope.

15 A. One of the dangers that
16 scientists always face is to make a statement
17 or conclusion based on numerical differences
18 between two groups.

19 So I'll give you an example. You
20 see serotype 4 was higher in PCV7 recipient
21 than PCV13. At the point estimate, it is
22 true, 3.59 versus 5.36.

1 But if you look at the confidence
2 interval, they do overlap, so -- and you go
3 to serotype 6B, the same; serotype 14 that
4 you just mentioned is also overlapping.

5 So we -- we always -- we're
6 always very cautious to make that
7 interpretation that the difference that we
8 see in the point estimate can be translated
9 into saying that there was a difference.

10 And I'm not a statistician to
11 give you that analysis, but I will be very
12 cautious by implying that the difference that
13 I see here, number one, is that statistically
14 significant; number two, even more
15 importantly, it's clinically significant. So
16 that is the thing that -- the comments that I
17 will add to that observation.

18 (BY MS. SPIRES)

19 Q. With the comment added, you agree
20 with the observation from my question,
21 though?

22 MR. KRINSKY: Objection, asked

1 and answered.

2 A. I can see in the table that there
3 are numerical differences on the point
4 estimate. I think it's there, but I'm just
5 saying you have to be cautious about making
6 conclusion based on that.

7 (BY MS. SPIRES)

8 Q. Based on Table 2, can a POSA draw
9 any conclusions regarding the
10 serotype-specific serum IgG antibody
11 concentration for any serotypes not included
12 in Table 2 to provide protection against IPD
13 in children?

14 MR. KRINSKY: Sorry. Object to
15 the form, incomplete hypothetical, outside
16 the scope.

17 A. So are you talking about
18 information on Page 8, Table 3 after the
19 infant immunization, or are you talking about
20 information in Page 4, on the toddler dose?

21 (BY MS. SPIRES)

22 Q. I was talking about -- well,

1 let's just say Yeh in general. Does Yeh
2 provide any data for a POSA regarding the
3 serotype-specific serum IgG antibody
4 concentration for serotype 23A needed to
5 provide protection against IPD in children?

6 MR. KRINSKY: Object to the
7 form of the question, incomplete
8 hypothetical, outside the scope.

9 A. The article that I shared with
10 you does not provide information about
11 results of immune response to serotype 23A,
12 and that's the only conclusion I can make
13 without knowing the extent of the testing
14 that they did.

15 And I don't see any scientific
16 reason for disclosing it in this particular
17 document, paper, unless there is something
18 that will indicate that, you know, there's a
19 need to do that.

20 (BY MS. SPIRES)

21 Q. Does Exhibit 1024 provide
22 information about results of immunoresponse

1 to serotype 23B?

2 MR. KRINSKY: Object to the
3 form, incomplete hypothetical, outside the
4 scope.

5 A. The same response can be applied
6 for 23B as I've provided for 23A, which means
7 that the results that are provided in this
8 particular manuscript does not mention
9 serotype 23A or serotype 23B, and I'm not
10 aware of the scope of the testing that they
11 did.

12 Keep in mind, too, that babies
13 are small and they have limited volume of
14 blood; and depending on the technique of the
15 assay you are conducting, you may not have
16 enough blood or serum to test for everything
17 that you want. So we have to be careful
18 about what did they do and what they didn't
19 do it.

20 (BY MS. SPIRES)

21 Q. And same question for serotype
22 35B. Does Exhibit 1024 provide information

1 about results of immunoresponse to serotype
2 35B?

3 MR. KRINSKY: Object to the
4 form, incomplete hypothetical, outside the
5 scope.

6 A. I'll answer the same way. The
7 manuscript does not provide information about
8 serotype 35B, and I'm not privy to the scope
9 of the testing for this particular serotype
10 by Yeh and this colleague.

11 But if you go to scope to -- the
12 Exhibit 1 -- 1023 that we also discussed and
13 if you can go to Page 5, Table 2, you'll see
14 that in this particular manuscript, Table 2
15 -- are you there?

16 (BY MS. SPIRES)

17 Q. Yes.

18 A. You'll see that the top list of
19 serotypes include those serotypes that are in
20 common between the PCV10, which is the
21 PHiD-CV and the 7VCRM, but at the bottom they
22 provide information about serotype that are

1 not in PCV10 but are -- that are not in PCV10
2 and also are not in Prevnar 7.

3 So what I mean by that is some
4 will test against additional serotype, some
5 won't. Those who test for those additional
6 serotype will provide the rationale as to why
7 they did that. So I think that my
8 knowledge -- or my comment can only be based
9 on information that's available to me.

10 MR. KRINSKY: Counsel, we've
11 been going over an hour. Should we take a
12 break?

13 MS. SPIRES: Let's do it.

14 (Break taken from 2:36 p.m. to
15 2:46 p.m.)

16 (BY MS. SPIRES)

17 Q. All right. If we could keep
18 looking at Yeh, Exhibit 1024, but turn to
19 Table 4 on Page 8 of 14.

20 A. I'm there.

21 Q. Okay. Do you see in Table 4 of
22 Yeh that the results demonstrate that both

1 before and after the toddler dose, PCV13
2 demonstrated a much lower antipolysaccharide
3 IgG GMC versus serotype 3 compared to
4 serotypes 1, 5, 6A, 7F, and 19A?

5 MR. KRINSKY: Objection to
6 form, mischaracterizes, outside the scope.

7 A. So we're looking at the bottom
8 serotype -- serotype at the bottom of the
9 table, correct?

10 (BY MS. SPIRES)

11 Q. Yes.

12 A. Yes. What is the question?

13 Q. Do you agree that in this bottom
14 table, on Table 4 of Yeh, that serotype 3
15 demonstrates a much lower antipolysaccharide
16 IgG GMC both before and after the toddler
17 dose compared to any of the other additional
18 serotypes in the table?

19 MR. KRINSKY: Objection to
20 form, mischaracterizes the document, outside
21 the scope.

22 A. I'm assuming that you are

1 referring to recipient of Prevnar 13,
2 correct?

3 (BY MS. SPIRES)

4 Q. Yes.

5 A. So before, it was expected,
6 because at that time they have not received
7 that particular serotype -- oh, no, sorry,
8 you're right. So before -- before the
9 toddler dose -- so this is after -- after the
10 primary series and after the toddler dose,
11 the antibody concentration for serotype 3 is
12 numerically lower than the antibodies to the
13 other serotypes.

14 Q. Do you agree that it was
15 well-known to a POSA that serotype 3 was one
16 of the most virulent pneumococcal serotypes?

17 MR. KRINSKY: Object to the
18 form, outside the scope.

19 You can answer.

20 A. Serotype 3 really emerged after
21 Prevnar 7 was licensed, and it was among the
22 most prevalent serotype. That is why it was

1 included in Prevnar 13.

2 Does that answer your question?

3 (BY MS. SPIRES)

4 Q. Yes.

5 And serotype 3, do you agree that
6 it was associated with invasive pneumococcal
7 disease as well as severe pneumonia and
8 pyemia and septic shock?

9 A. The data I have in my head is
10 really for IPD. For the other one, pyemia
11 and others, I have to look at the data.

12 And we're talking about infants,
13 correct, or children; or we're talking in
14 general?

15 Q. In general, or you can limit it,
16 whatever makes -- whatever data you happen to
17 know, if you know any of it.

18 A. Yeah, the data I know is about
19 IPD in both infants and adults.

20 Q. So at least for IPD, you know --
21 you agree that serotype was associated with
22 IPD in both infants and adults, right?

1 MR. KRINSKY: Object to the
2 form, outside the scope.

3 A. That's the data that I remember.
4 (BY MS. SPIRES)

5 Q. Were you -- would a -- I guess,
6 would a POSA have been aware that serotype 3
7 was associated with a higher risk of death
8 compared to the other known pneumococcal
9 serotypes in March of 2016?

10 MR. KRINSKY: Object to the
11 form, outside the scope.

12 A. I -- the way I understand your
13 question -- can you clarify, because you -- I
14 don't know if I understand that question
15 correctly.

16 (BY MS. SPIRES)

17 Q. Okay. Are you aware of whether
18 a -- whether serotype 3 is associated with a
19 higher risk of death than other pneumococcal
20 serotypes in March of 2016?

21 MR. KRINSKY: Object to the
22 form, asked and answered.

1 MS. SPIRES: He didn't answer,
2 he asked me to clarify.

3 A. No, no, no, sorry.

4 MR. KRINSKY: Sorry. Also
5 outside the scope.

6 But you can answer to the
7 extent you're able.

8 THE WITNESS: Yeah.

9 A. I know that serotype 3 was
10 associated with IPD, but I cannot confirm
11 that serotype 3 was the highest -- it was a
12 serotype that was associated with the highest
13 mortality rate. That -- I'm not -- I cannot
14 confirm that.

15 (BY MS. SPIRES)

16 Q. You can't confirm or deny, you
17 just don't know?

18 A. I don't know. I don't have the
19 data in front of me, so I cannot really
20 comment on that.

21 Q. Would a POSA in 2016 have known
22 that serotype 3 had a very thick

1 polysaccharide capsule, thicker than other
2 serotypes?

3 MR. KRINSKY: Objection,
4 outside the scope.

5 A. A POSA would have known that
6 serotype 3 has a thick wall, but I don't know
7 personally whether this wall is the thickest
8 among all serotypes or most serotypes or
9 certain serotypes. I cannot rank it among
10 the -- the different serotypes.

11 (BY MS. SPIRES)

12 Q. Would you agree that the
13 immunogenicity data for serotype 3 was poorer
14 than other serotypes contained within PCV13?

15 MR. KRINSKY: Objection,
16 outside the scope.

17 A. So this question that you are
18 asking about serotype 3 is not -- I think you
19 need to ask the -- I mean, my information --
20 my knowledge is -- first of all, I would not
21 say it's the poorest. I don't know how you
22 define "poor." I think the data is showing

1 that it's lower, but I also -- I don't have
2 the data because it's out of the scope. I
3 didn't really go back to those data.

4 But what I also remember is that,
5 depending on the population, the response
6 could vary; and so the population were -- the
7 response to serotype 3 was higher than what
8 we see here in this particular study, if my
9 memory is correct, yes.

10 So I think that the population in
11 China, for example, if I remember
12 correctly -- but those are really coming
13 after this particular priority date. So at
14 the time that the data were collected, there
15 were some data, but I'm not familiar with
16 those data. I don't remember those data.

17 (BY MS. SPIRES)

18 Q. So, in your opinion, the
19 immunogenicity data versus serotype 3 was
20 lower than for the other PCV13 serotypes as
21 of March 2016, at least in the data provided
22 in Yeh; is that right?

1 MR. KRINSKY: Object to the
2 form of the question, outside the scope.

3 A. I'm -- I'm looking at the data
4 from Yeh, and give me a minute to examine the
5 data for serotype 3.

6 So the data that we see here in
7 Yeh show that the IgG concentration for
8 serotype 3 after the infant vaccination
9 series and after the toddler dose were
10 numerically lower than the point estimate for
11 the other serotypes in Prevnar 13.

12 (BY MS. SPIRES)

13 Q. Are you aware of whether the
14 clinical effectiveness of serotype 3 was
15 lower than the other -- for the other
16 serotypes of PCV13 as of March 2016?

17 MR. KRINSKY: Object to the
18 form, outside the scope.

19 A. Trying to remember -- there was
20 one paper published by the CDC. I -- in
21 Lancet Infectious Disease. I don't know if
22 it was prior to the priority date or not; but

1 assuming that it was not, I think that the
2 impact of the vaccine in the disease, as I
3 said, is really taken into the context of all
4 the entire vaccine.

5 When data provide -- are provided
6 by the CDC about the trend over time about
7 how the -- the disease caused by a certain
8 serotype are being evaluated, the data by
9 serotype depend on what is -- the level of
10 infection by that serotype was before and
11 after and depending on the magnitude that
12 the -- the number of cases, it's very
13 difficult to -- to really make that case. I
14 think some serotypes, clearly, they were
15 coming very high and they were very -- went
16 way down, and some serotype, the reduction
17 was a bit -- was not as significant as
18 others.

19 I don't remember exactly those
20 data from 2015 or 2016, looking at four years
21 after Prevnar 13.

22 And I will also add that

1 sometimes it takes longer to see the effect
2 of the vaccine for some serotypes, and so
3 vaccine penetration is also something that is
4 important to see effect on the disease.

5 So I don't remember the data from
6 2015 about serotype 3, but I'm just saying
7 that without those data in front of me and
8 looking at those data in the context, I
9 cannot really say that -- make too much about
10 the difference in the decrease between some
11 different serotypes.

12 (BY MS. SPIRES)

13 Q. Would a POSA in March of 2016
14 have recognized that there was a need -- a
15 need to improve vaccine immunogenicity
16 against serotype 3?

17 MR. KRINSKY: Object to the
18 form of the question, outside the scope.

19 A. I think we need to be careful
20 about making that statement because it's --
21 it's -- it's -- you are talking about
22 serotype 3 but another person may talk about

1 another serotype, and so whatever you need to
2 improve a serotype immunogenicity and how
3 that would translate into better or greater
4 effectiveness, there are two different --
5 many, many things that would make me very
6 cautious about saying let's improve that.

7 And I will say this, that
8 depending on the population, depending on the
9 burden of disease, depending on the vaccine
10 impact, one may make that decision or one may
11 feel like even though the immunogenicity is
12 low, it may having an impact on the disease
13 in that population; so it's very difficult to
14 make that jump by just looking at the
15 immunogenicity here and say, because it has a
16 lower IgG GMCs, that more need to be done for
17 this particular serotype compared to another
18 serotype.

19 (BY MS. SPIRES)

20 Q. And you said you don't recall the
21 effectiveness data of serotype 3 versus the
22 other PCV serotypes in March of 2016. Was

1 that right?

2 MR. KRINSKY: Objection, asked
3 and answered.

4 A. What I'm saying is the one --
5 there are -- there are different papers. I
6 don't recollect which one, but the one I was
7 thinking was Matthew Moore, but I'm not so
8 sure whether it was prior to the priority
9 date or not, and so I cannot comment on that.

10 Q. Do you recall the author or no?

11 A. Matthew Moore, Matthew M-O-O-R-E,
12 from the CDC.

13 Q. All right. Probably last
14 question: During your break today or any
15 other time, did you talk to your counsel
16 about the substance of your testimony?

17 A. Can you repeat the question,
18 please?

19 Q. During your breaks today or at
20 any other time since your deposition started
21 today, did you talk to your counsel about the
22 substance of your testimony?

1 A. No.

2 Q. Okay. I have no further
3 questions.

4 MR. KRINSKY: All right. Let's
5 go off the record just for a minute.

6 MS. SPIRES: Sure.

7 (Break taken from 3:06 p.m. to
8 3:10 p.m.)

9 MR. KRINSKY: I don't know how
10 you want to mark this on the record, Annette,
11 but we have no questions. Happy to close the
12 deposition.

13 MS. SPIRES: Good for me.

14 THE COURT REPORTER: Ms. Lee,
15 do you need a rough draft?

16 MS. LEE: No.

17 (Discussion about orders.)

18 MR. KRINSKY: I mean, whatever
19 they send me because I've logged into the
20 real-time -- we can just do a regular order.
21 No rough.

22 (Deposition concluded at 3:11 p.m.)

1 Certificate of Shorthand Reporter

2

3 I, Annette Peltier, CSR, Texas

4 Certified Realtime Reporter in and for the

5 State of Texas do hereby certify:

6 That Luwy K. Musey, M.D., the witness
7 whose deposition is herein before set forth,
8 was duly sworn before the commencement of
9 such deposition and that such deposition was
10 taken before me and is a true record of the
11 testimony given by such witness.

12 I further certify that the adverse
13 party, Pfizer Inc., was represented by
14 counsel at the deposition.

15 I further certify that the deposition
16 of Luwy K. Musey, M.D., occurred via Zoom
17 teleconference on July 23, 2026, commencing
18 at 8:13 a.m. to 3:11 p.m. Central time.

19 I further certify that I am not related
20 to any of the parties to this action by blood
21 or marriage, I am not employed by or an
22 attorney to any of the parties to this

1 action, and that I am in no way interested,
2 financially or otherwise, in the outcome of
3 this matter.

4 IN WITNESS WHEREOF, I have hereunto set
5 my hand this 28th day of July, 2026.

6
7 
8 Annette Peltier, Texas CSR 3253
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22

Transcript of Luwy K. Musey, M.D.
Conducted on July 23, 2026

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