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Transcript of Daniel O. Griffin, M.D., Ph.D.

Date: September 20, 2024
Case: BioNTech SE and Pfizer, Inc. -v- Moderna TX, Inc. (PTAB)

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Moderna 2253
BioNTech-Pfizer v. Moderna
IPR2023-01359

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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIONTECH SE AND PFIZER INC.,
Petitioner,
v.
MODERNA TX, INC.,
Patent Owner.

Case IPR2023-01358
U.S. Patent 10,702,600

Case IPR2023-01359
U.S. Patent 10,933,127

** CONFIDENTIAL **

DEPOSITION of DANIEL O. GRIFFIN, M.D., Ph.D.
New York, New York
Friday, September 20, 2024

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Pages 1 - 151
Reported by: Kristin Koch, RPR, RMR, CRR

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September 20, 2024
9:39 a.m.

Deposition of DANIEL O. GRIFFIN, M.D., Ph.D., held at the offices of Paul Hastings, LLP, 200 Park Avenue, New York, New York, before Kristin Koch, a Registered Professional Reporter, Registered Merit Reporter, Certified Realtime Reporter and Notary Public of the State of New York.

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A P P E A R A N C E S: (Continued)

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ALSO PRESENT:

JACOB MOORE, Esq., Moderna TX, Inc.
JESSICA MACKAY, Esq., BioNTech

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----------C O N T E N T S----------

WITNESS	EXAMINATION BY	PAGE
DANIEL O. GRIFFIN, M.D.	MR. PRUSSIA	8, 147
	MS. MAYS-WILLIAMS	144

----------EXHIBITS----------

(Attached)

NUMBER		PAGE
2252	Publication entitled Immunization with SARS Coronavirus Vaccines Leads to Pulmonary Immunopathology on Challenge with the SARS Virus	85

----------PREVIOUSLY MARKED EXHIBITS----------

(Attached)

NUMBER		PAGE
1010	International Application WO 2012/006369 A2	11
1159	Reply Declaration of Daniel O. Griffin, M.D., Ph.D.	10
1002	Declaration of Daniel O. Griffin, M.D., Ph.D.	33

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----------PREVIOUSLY MARKED EXHIBITS----------

(Attached)

NUMBER		PAGE
2199	Declaration of Deborah H. Fuller, Ph.D.	37
1104	Transcript of Deborah Fuller, Ph.D.	37
1011	article entitled: A DNA vaccine induces SARS coronavirus neutralization and protective immunity in mice	38
2005	article entitled: A Cationic Nanoemulsion for the Delivery of Next-generation RNA Vaccines	50
2021	article entitled: Nonviral delivery of self-amplifying RNA vaccines	72
2136	article entitled: Consensus summary report of CEPI/BC March 12-13, 2020 meeting: Assessment of risk of disease enhancement with COVID-19 vaccines	78

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----------PREVIOUSLY MARKED EXHIBITS----------

(Attached)

NUMBER		PAGE
1305	Daniel Griffin, M.D., Ph.D. Curriculum Vitae, IPR2023-01359 and IPR2023-01358, August 23, 2024	111
1003	Daniel Griffin, M.D., Ph.D. Curriculum Vitae, August 23, 2023	115
1001	United States Patent 10,933,127	134

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DANIEL O. GRIFFIN, M.D., Ph.D., called as a witness, having been duly sworn by a Notary Public, was examined and testified as follows:

EXAMINATION BY
MR. PRUSSIA:

Q. Good morning, Dr. Griffin.

A. Good morning.

Q. Since our last discussion in May, have you spoken with any non-lawyers about this proceeding?

A. So I have not discussed any of the substance of this proceeding with anyone who is not a lawyer.

Q. Okay. But just to be clear, have you had any conversations with Dr. Moon about this proceeding?

A. I have had no direct conversations with Dr. Moon.

Q. And just to be clear, have you spoken with any mRNA scientists in connection with forming your opinions in this proceeding?

9

1 MS. MAYS-WILLIAMS: Object to the form
2 of the question.
3 **A. Yeah, if you could ask that in a more**
4 **clear way. I'm not sure I understand.**
5 Q. Have you spoken with any mRNA
6 scientists in connection with forming your
7 opinions in these proceedings?
8 MS. MAYS-WILLIAMS: Object to the form
9 of the question.
10 **A. I'm not sure I understand the broad**
11 **question.**
12 Q. I am going to make it easier.
13 You haven't spoken with any non-lawyers
14 in connection with forming your opinions in this
15 proceeding; correct?
16 **A. In forming my opinions I used my**
17 **knowledge as a POSA. In preparing my declaration**
18 **I only spoke with counsel.**
19 Q. What is non-amplifying RNA?
20 **A. So as I lay out in my declaration,**
21 **RNA is a type of molecule that acts as an**
22 **intermediary between DNA and protein, and there**

10

1 **are two types of mRNA: One is self-amplifying**
2 **mRNA, which is a type of mRNA that has a**
3 **replicase, which can replicate, and then there are**
4 **replication-deficient non-self-amplifying mRNA**
5 **that does not have this replicase or the ability**
6 **to make a copy.**
7 Q. And in connection with providing that
8 answer, you were looking at your declaration.
9 Could you let us know what paragraph you are
10 looking at?
11 **A. So I have my declaration open to page 8**
12 **and 9.**
13 Q. And that's your second declaration or
14 your first declaration?
15 **A. This is my second declaration and it is**
16 **case IPR2023-01359, patent number 10,933,127.**
17 Q. Okay. So in your opinion,
18 non-amplifying mRNA is mRNA which cannot
19 replicate; correct?
20 **A. So non-self-amplifying mRNA would be**
21 **mRNA without a replicase, without the**
22 **self-amplifying property.**

11

1 Q. And non-amplifying mRNA encodes only
2 the antigen, do I understand that correctly?
3 **A. So non-amplifying mRNA encodes for only**
4 **the antigen.**
5 Q. So you have Exhibit 1010, which is the
6 Geall reference; right?
7 **A. I have Exhibit 1010 in front of me.**
8 Q. Now, does Geall enable a POSA to use
9 non-amplifying mRNA as a vaccine?
10 MS. MAYS-WILLIAMS: I object to the
11 form of the question.
12 **A. Yeah, so it's very broad, so if you**
13 **could just ask a more clear question, please.**
14 Q. Well, you are relying on Geall in
15 connection with your obviousness opinions in this
16 proceeding; right?
17 **A. So as I have walked through, I started**
18 **off by looking at Schrum, and then in Schrum I**
19 **learn about mRNA technology. I then am given LNPs**
20 **and then I get to paragraph 340, and so where**
21 **Geall is incorporated in its entirety, and then I**
22 **rely on Geall for the antigen.**

12

1 Q. And so just focusing on Geall, does it
2 contain enough teaching to allow a POSA to make
3 and use a non-amplifying mRNA vaccine?
4 MS. MAYS-WILLIAMS: Objection. Outside
5 the scope of his reply declaration.
6 **A. So in Geall they mention the S protein**
7 **in the coronavirus section and then there are**
8 **working examples. The working examples all**
9 **involve self-replicating mRNA.**
10 Q. And so in your opinion, do those
11 teachings in Geall allow a person of skill in the
12 art to make and use a non-amplifying mRNA vaccine?
13 MS. MAYS-WILLIAMS: I object to the
14 form of the question. Outside the scope of
15 his reply declaration.
16 **A. Yeah, so that does appear to be a**
17 **question outside of what I've been asked to opine**
18 **on.**
19 Q. So just to be clear, you did not
20 consider whether Geall allows a person of skill in
21 the art to make and use a non-amplifying mRNA
22 vaccine; right?

13

1 **A. So Geall specifically gives working**
2 **examples of non-replicating mRNA.**
3 Q. Okay. So I will ask my question again.
4 Does Geall allow a person of skill in
5 the art to make and use a non-amplifying mRNA
6 vaccine?
7 MS. MAYS-WILLIAMS: Objection. Scope.
8 **A. Yeah, so I'm aware that there are**
9 **working examples in Geall of self-replicating**
10 **mRNA, but I acknowledge that there is no examples**
11 **in Geall of non-self-amplifying mRNA.**
12 Q. So if a person of skill in the art just
13 had Geall, then we can agree that the person of
14 skill in the art would not be able to make and use
15 a non-amplifying mRNA vaccine; right?
16 MS. MAYS-WILLIAMS: I object to the
17 form of the question. Incomplete
18 hypothetical. Scope.
19 **A. Yeah, so as I walked through before, I**
20 **relied on Geall for the -- for the antigen. The**
21 **non-self-amplifying mRNA I was given by Schrum.**
22 **The LNP I was given by Schrum. I go to Geall for**

14

1 **the antigen and Geall only gives examples of**
2 **non-self-amplifying -- only gives examples of**
3 **self-amplifying mRNA. I see no working examples**
4 **of non-self-amplifying mRNA in Geall.**
5 Q. So focusing on the self-amplifying
6 mRNA, as you put it, does Geall contain enough
7 teaching to allow a person of skill in the art to
8 make and use a replicase mRNA vaccine for any
9 betacoronavirus?
10 MS. MAYS-WILLIAMS: Object to the form
11 of the question. Incomplete hypothetical.
12 **A. So I wasn't asked specifically to opine**
13 **on that question. You know, I -- as mentioned, I**
14 **go to Geall looking at it in its entirety for**
15 **the -- for the target, and then I acknowledge the**
16 **only examples are self-amplifying mRNA.**
17 Q. Okay. So just focusing on the
18 self-amplifying mRNA, does Geall contain enough
19 teaching to allow a person of skill in the art to
20 make and use a self-amplifying mRNA for SARS?
21 MS. MAYS-WILLIAMS: Object to the form
22 of the question.

15

1 **A. So I wasn't asked to specifically**
2 **comment on that, so it would be outside of the**
3 **scope of what I have thought about.**
4 Q. Okay. So you didn't consider whether
5 the teaching in Geall allows a person of skill in
6 the art to make and use a self-amplifying mRNA
7 vaccine for SARS?
8 MS. MAYS-WILLIAMS: Object to the form
9 of the question.
10 **A. So as I -- as I outlined, when I was**
11 **preparing for these proceedings, I was looking at**
12 **Schrum, getting mRNA, getting LNPs. I moved to**
13 **Geall for the antigen, and I acknowledge in Geall**
14 **I do not see examples of non-self-amplifying mRNA,**
15 **but those examples I'm getting from Schrum.**
16 Q. Could a person of skill in the art
17 based on the teachings in Geall make and use a
18 self-amplifying mRNA vaccine for SARS-CoV-2?
19 MS. MAYS-WILLIAMS: I object to the
20 form of the question. Asked and answered.
21 Incomplete hypothetical.
22 **A. Yeah, so I wasn't asked to specifically**

16

1 **weigh in on this question, but I did -- you know,**
2 **as I acknowledged, I look at Schrum for mRNA, I**
3 **get the LNPs. I see in Geall the antigen. I**
4 **acknowledge that the only examples in Geall are**
5 **self-amplifying mRNA, but that's okay, because I**
6 **only am relying on Geall for the antigen. I**
7 **already have the mRNA from Schrum.**
8 Q. Okay. No, I understand that. I am
9 just focusing on the antigen piece.
10 So with respect to developing a
11 self-amplifying mRNA vaccine for SARS-CoV-2, okay,
12 does Geall contain enough teaching to allow a
13 person of skill in the art to do that?
14 MS. MAYS-WILLIAMS: Object to the form
15 of the question.
16 **A. So I wasn't asked to specifically opine**
17 **on that, so -- yeah, if I was going to address**
18 **that question, I probably would need -- well, I**
19 **would need a lot of time to go through, consider**
20 **that carefully before giving a good reply.**
21 Q. So it's just fair to say it is not
22 something that you considered in connection with

17

1 forming your opinions; right?
2 **A. I was not asked to address that**
3 **specific question.**
4 Q. Okay. So the only coronavirus that's
5 specifically referenced in Geall is SARS; right?
6 Are you looking for page 19 or page 15
7 in Geall? Is that what you are looking for? 19.
8 **A. So Geall specifically calls out the**
9 **class coronavirus.**
10 Q. So just because it calls out the class
11 of coronavirus, in your view is that enough for
12 the person of skill in the art to make and use a
13 self-amplifying mRNA vaccine for all
14 coronaviruses?
15 **A. So that seems very similar to the**
16 **question I was asked before, and so it's really**
17 **the same response. I was not asked to**
18 **specifically opine on that line of thought. I go**
19 **to Geall after already getting mRNA, LNP**
20 **specifically for the immunogen, and here in Geall**
21 **we see a list of pathogens and we see this section**
22 **here, coronavirus, the coronavirus immunogen may**

18

1 **be a spike polypeptide.**
2 Q. Okay. So just focusing on the SARS
3 disclosure in Geall now, are you with me, doctor?
4 **A. Yes.**
5 Q. Okay. I just wanted to make sure,
6 because you were turning pages.
7 So just focusing on the SARS disclosure
8 in Geall, does the information in Geall allow a
9 person of skill in the art to make and use a
10 self-amplifying mRNA vaccine for SARS?
11 (Document review.)
12 **A. Can you ask that question again.**
13 Q. Sure. I will just reread it. Okay?
14 **A. Okay.**
15 Q. So just focusing on the SARS disclosure
16 in Geall, does the information in Geall allow a
17 person of skill in the art to make and use a
18 self-amplifying mRNA vaccine for SARS?
19 **A. So again, that seems like a question**
20 **I've already addressed, but with this sort of**
21 **added focus, I looked through and reinforced that**
22 **I was not actually asked to opine on that specific**

19

1 **question.**
2 Q. Okay. So just to be clear, it's not
3 something that you considered in connection with
4 forming your opinions in this proceeding; right?
5 **A. So your -- just because you are asking**
6 **multiple questions. So your original question,**
7 **can you just ask that again.**
8 Q. I am just saying your answer was -- I
9 am just going to read your answer.
10 **A. Okay. Perfect.**
11 Q. "So again, that seems like a question
12 I've already addressed, but with this sort of
13 added focus, I looked through and reinforced that
14 I was not actually asked to opine on that specific
15 question."
16 **A. Yes.**
17 Q. So I am just trying to understand that
18 answer. So my question in trying to understand
19 that answer is: It's not something that you
20 considered in connection with forming your
21 opinions in this proceeding?
22 MS. MAYS-WILLIAMS: Objection. Form.

20

1 **A. Yeah, so as I explained, when I go to**
2 **Geall in the context of looking at the limitations**
3 **of the '127 and the '600 Patent, I get mRNA from**
4 **Schrum, I get the LNP from Schrum, I'm directed to**
5 **go to Geall for the antigen. Right here at page**
6 **19 we have coronavirus called out, one of the top**
7 **pathogens of pandemic potential. I see the**
8 **coronavirus immunogen may be a spike polypeptide,**
9 **and then, as I acknowledged before, all the**
10 **working examples in Geall are with self-amplifying**
11 **mRNA.**
12 Q. Okay. Let's talk about the list of
13 immunogens in Geall that start at page 15 and, I
14 think, go through page 22.
15 **A. Okay.**
16 Q. It's a long list of immunogens, and you
17 are aware that at least some of those immunogens
18 were tested in non-amplifying mRNA vaccines prior
19 to October 2015; correct?
20 MS. MAYS-WILLIAMS: Objection. Form.
21 (Document review.)
22 **A. Okay. If you could ask again. I was**

21

1 **getting oriented.**
2 Q. Sure. I am going to rephrase, since
3 part of that was orienting you.
4 You are aware that at least some of the
5 immunogens listed in Geall had been tested in
6 non-amplifying mRNA vaccines as of October 2015?
7 **A. So I am aware that by 2015 vaccine**
8 **technologies that did not rely on self-amplifying**
9 **mRNA technology had been tested.**
10 Q. Sure. My question is specific with the
11 list of immunogens in Geall.
12 At least some of those immunogens had
13 been tested in non-amplifying mRNA vaccines as of
14 October 2015; correct?
15 Well, let me ask it -- let me withdraw
16 that and ask a different question.
17 Would a person of skill in the art
18 consider whether any of the antigens listed in
19 Geall had been tested in a non-amplifying mRNA
20 vaccine as of October 2015?
21 MS. MAYS-WILLIAMS: Objection to form.
22 **A. Yeah, I guess I'm missing the would**

22

1 **consider for what end, so I'm just not sure I**
2 **understand the full question.**
3 Q. The results of any testing that would
4 have been done with a non-amplifying mRNA vaccine
5 for one of the immunogens listed in Geall.
6 MS. MAYS-WILLIAMS: Objection. Form.
7 **A. So yeah, a POSA in 2015 would have been**
8 **aware of using antigens that are listed here in**
9 **Geall in the pursuit of vaccine science.**
10 Q. And would the results of any mRNA
11 vaccine that had been tested using one of the
12 immunogens listed in Geall be relevant to the
13 person of skill in the art?
14 **A. Yeah, I'm not sure what you mean by**
15 **"relevant."**
16 Q. Relevant in understanding the
17 usefulness of the technology disclosed in Geall.
18 **A. So I would say a POSA in 2015 would be**
19 **aware of and find informative research that used,**
20 **for instance, the S spike to generate an immune**
21 **response.**
22 Q. And so would the POSA be interested in

23

1 results with any other of the immunogens listed in
2 Geall, or would the POSA only be focused on the
3 spike polypeptide?
4 **A. So when a POSA reads Schrum, learns**
5 **about mRNA, learns about the LNP, is directed to**
6 **Geall for the -- incorporated in its entirety, one**
7 **runs into Geall where there is a list of different**
8 **pathogens. One is drawn to particular pathogens**
9 **in this list, in part because of the technology,**
10 **which is suggested to be something that could be**
11 **rapidly deployed. They are also drawn to specific**
12 **pathogens based upon sort of a priority list of**
13 **pathogens that we are interested in. So among**
14 **those priority pathogens, say flu, for instance,**
15 **coronavirus, for instance, one would then be given**
16 **here: The coronavirus immunogen may be a spike**
17 **polypeptide.**
18 Q. So would the POSA be interested in the
19 other -- strike that.
20 Would the POSA be interested in mRNA
21 vaccine results using immunogens other than the
22 spike polypeptide listed in Geall?

24

1 **A. So a POSA in 2015 would be interested**
2 **in results that used other coronavirus immunogens.**
3 Q. So the POSA in 2015 would not consider
4 any of the other immunogens listed in Geall? I am
5 just trying to understand your testimony.
6 MS. MAYS-WILLIAMS: Objection.
7 Mischaracterizes testimony.
8 **A. One would have read Geall in its**
9 **entirety, as directed by Schrum, and would have**
10 **looked through the different pathogens and the**
11 **different immunogens.**
12 Q. And would the POSA have taken an
13 interest if in the prior art someone had used one
14 of those immunogens listed in Geall in connection
15 with an mRNA vaccine and had tested it to see if
16 it worked?
17 **A. So one more time. I am just trying to**
18 **follow the question.**
19 Q. I am going to have to rephrase the
20 question, because I can't follow the transcript.
21 Would a POSA have taken an interest in
22 whether someone had used one of the immunogens

25

1 listed in Geall and tested it in connection with
2 an mRNA vaccine?
3 **A. So a POSA in 2015, who was looking**
4 **through this list of viral immunogens or other**
5 **pathogen immunogens, would have found success**
6 **using mRNA expression of an antigen to be**
7 **informative.**
8 Q. You said "success." What about lack of
9 success, would the POSA have found lack of success
10 to have been informative?
11 **A. So by lack of success, if they tried to**
12 **use mRNA and failed to express the protein, then I**
13 **think that also would have been interesting to**
14 **understand why they were not able to express the**
15 **antigen.**
16 Q. Now, you understand that -- well, I
17 will just direct you to the cover of Geall, 1010.
18 The applicant is identified as Andrew Geall and he
19 was employed at Novartis, correct, at the time?
20 **A. It looks like that is the case here.**
21 Q. And Novartis is a pharmaceutical
22 company; right?

26

1 **A. Novartis is a pharmaceutical company.**
2 Q. And at the time, Novartis was working
3 on developing vaccines; right?
4 (Document review.)
5 **A. So I believe that Novartis was working**
6 **on vaccines in 2012, and I may have even**
7 **referenced that somewhere in my declaration.**
8 Q. Okay. And you are aware that Dr. Geall
9 and his team at Novartis never commercialized an
10 mRNA vaccine; right?
11 **A. So a POSA in 2015 would be aware that**
12 **there were no FDA-approved mRNA vaccines that**
13 **Geall or anyone else had produced.**
14 Q. And even as of today, as we sit here
15 today, Dr. Geall has never commercialized a
16 non-amplifying mRNA vaccine; right?
17 **A. So currently there are only three mRNA**
18 **vaccines for infectious diseases and all three,**
19 **the two by Moderna and the one by Pfizer BioNTech,**
20 **use non-self-amplifying mRNA.**
21 Q. I want to take a look at your
22 declaration, paragraph 22. For the record, I am

27

1 looking at Exhibit 1159.
2 MS. MAYS-WILLIAMS: Is that the '127?
3 MR. PRUSSIA: Yes, '127.
4 **A. Okay. I'm on page 9 and I am seeing**
5 **paragraph 22.**
6 Q. Okay. You have the first sentence
7 there and it states: "However, to the extent the
8 term 'mRNA' is construed to exclude
9 self-amplifying mRNA in the specific context of
10 the '127 patent, it would not affect the opinions
11 I have expressed with respect to the '127 patent."
12 Did I read that correctly?
13 **A. You read that correctly.**
14 Q. And in the next sentence you go on to
15 state that Schrum describes non-amplifying mRNA.
16 Do you see that?
17 **A. I see the next sentence where "as I**
18 **explain below in Section IV.B, Schrum describes**
19 **non-amplifying mRNA vaccines."**
20 Q. And so I just want to make sure I
21 understand this correctly, that you are relying on
22 Schrum and not Geall for teaching non-amplifying

28

1 mRNA; correct?
2 **A. So I am relying on Schrum for teaching**
3 **non-amplifying mRNA.**
4 Q. And so you are not offering the opinion
5 that Geall teaches non-amplifying mRNA; correct?
6 **A. I think that's different than what I am**
7 **saying here. What I am saying here is that Schrum**
8 **describes non-amplifying mRNA vaccines, and I go**
9 **on to say that Schrum is incorporating Geall and I**
10 **am relying on Geall solely for the antigen.**
11 Q. Yeah, I understand. I just want to be
12 very clear that you are not offering the opinion
13 that Geall teaches non-amplifying mRNA; right?
14 **A. So all the working examples in Geall**
15 **use non-amplifying mRNA, so I acknowledge that in**
16 **Geall I am not able to point to a working example**
17 **of a non-amplifying mRNA producing a protein.**
18 Q. So I think you may have misspoke. I
19 think you just said all the working examples in
20 Geall use non-amplifying-mRNA.
21 **A. Sorry. Thank you. So all the**
22 **working examples in Geall --**

29

1 Q. Let's just do a clean question and
2 answer. Okay?
3 **A. Sure.**
4 Q. So the question I asked was I just want
5 to be very clear that you are not offering the
6 opinion that Geall teaches non-amplifying mRNA;
7 right?
8 **A. So try to get it right this time. So**
9 **as I explained, I get the mRNA from Schrum, the**
10 **LNPs from Schrum. I go to Geall for the antigen,**
11 **and I acknowledge that all of the working examples**
12 **in Geall use self-amplifying mRNA, and I am not**
13 **able to point to a working example in Geall where**
14 **non-amplifying mRNA vaccines are used to produce a**
15 **protein.**
16 Q. Okay. And is the same true with
17 Altmeyer, that you are not offering the opinion
18 that Altmeyer teaches non-amplifying mRNA?
19 **A. So a very similar line of -- line of**
20 **thinking where Schrum gives us mRNA, Schrum gives**
21 **us LNP, and then I am only relying on Altmeyer for**
22 **the betacoronavirus S protein.**

30

1 Q. And that's because Altmeyer does not
2 contain any working examples of non-amplifying
3 mRNA; right?
4 (Document review.)
5 **A. So as I point out in my declaration,**
6 **when I go to Altmeyer, I am only relying on**
7 **Altmeyer for the antigen, and Altmeyer provides a**
8 **method of RNA and/or DNA vaccination against**
9 **SARS-CoV that includes administrating --**
10 **administering any combination of the nucleic acids**
11 **including spike polypeptides.**
12 Q. What paragraph were you just reading
13 from?
14 **A. So now I am on page 226, and I am**
15 **looking at section -- paragraph 389.**
16 Q. And in that paragraph you don't
17 disclose that Altmeyer -- strike that.
18 In that paragraph you don't describe
19 Altmeyer as disclosing working examples with
20 non-amplifying mRNA; correct?
21 **A. Yeah, so as -- you know, I can go**
22 **through the whole paragraph for clarity. So in**

31

1 **this paragraph, and I only read part of it the**
2 **first time, I start off by pointing out that the**
3 **reason I am going here is that Dr. Fuller also**
4 **asserts that Altmeyer does not disclose a spike**
5 **protein, so in particular Dr. Fuller states that**
6 **Altmeyer failed to specify whether the spike**
7 **protein is a full-length spike protein, and I**
8 **disagree with Dr. Fuller's assertion. Altmeyer**
9 **provides a method of RNA and/or DNA vaccination**
10 **against SARS-CoV that includes administering any**
11 **combination of the nucleic acids, including spike**
12 **protein. And then we go further, Example 5**
13 **reports that mice were immunized intramuscularly**
14 **with SFV, Simian Forest Virus, spike RNA, followed**
15 **by intraperitoneal injection of spike protein at**
16 **day 14 and day 35, and I explain so for reasons**
17 **explained in Section IV.B.1, a POSA would have**
18 **understood reference to a spike protein to mean a**
19 **full-length spike protein, and notably, Example 4**
20 **explains that the spike protein was expressed as a**
21 **full-length protein. The spike protein is**
22 **correctly folded, i.e., in its native**

32

1 **conformation.**
2 Q. Okay. And so my question is with
3 respect to the vaccine technology that's being
4 used in Altmeyer, you are not offering the opinion
5 that it involves non-amplifying mRNA; right?
6 **A. So as I explained, when I start off in**
7 **Schrum with mRNA, LNP, and then I go to Altmeyer,**
8 **I am going to Altmeyer specifically for the**
9 **antigen. So I comment here about the different**
10 **ways that the protein is presented to the immune**
11 **cells.**
12 Q. So I get all that.
13 So just like with respect to Geall, you
14 are relying on Altmeyer for the antigen; right?
15 **A. Just like Geall, I am relying on**
16 **Altmeyer for the antigen, but just to give that**
17 **context, a POSA by 2015 would already be well**
18 **aware of the literature surrounding spike protein**
19 **as the protein of most interest for**
20 **betacoronavirus vaccine antigens.**
21 Q. Okay. And you are not relying on
22 Altmeyer for vaccine technology?

33

A. In preparing this declaration, I was going to Altmeyer and relying on Altmeyer for the antigen.

Q. Okay. If you could go, please, to your first declaration, Exhibit 1002, and I am in the 1359 IPR, the '127 IPR.

A. Is this Exhibit 1002?

Q. Yes.

A. Okay.

Q. And I am going to ask you to, please, turn to page 23, paragraph 48. Are you there?

A. Page 23, paragraph 48. I am there.

Q. This is a section of your declaration where you discuss claim construction; is that right?

A. Section VI, Claim Construction.

Q. And in this section of your first declaration, you do not offer a claim construction for mRNA; right?

(Document review.)

A. So I am seeing here in Exhibit 1002 in Section VI, paragraphs 48 and 49 and 50 in that

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section, that I am laying out the claim constructions that I have been instructed for the purposes of forming my opinions.

Q. Okay. And mRNA is not one of the terms in that declaration; right?

A. In this section of my declaration on page 24, the term "betacoronavirus," "S protein" and "open reading frame" are put forward.

Q. Okay. If you turn to your second declaration --

A. Okay.

Q. -- and starting at paragraph 21. Are you there?

A. I am page 8, paragraph 21.

Q. And in paragraphs 21 and 22, you discuss mRNA; right? Well, let me withdraw and ask a different question.

There is -- right above paragraph 21 there is a subheading mRNA, do you see that?

A. I see that. "1. mRNA."

Q. And just to orient for the record, we are in the Claim Construction section of your

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declaration, second declaration; right?

A. So we are in the Claim Construction section of my second 2024 declaration.

Q. In these two paragraphs, 21 and 22, you respond to Dr. Fuller's opinions regarding the claim construction of mRNA in the context of the patents; right?

A. So here in paragraph 21 I respond to Dr. Fuller, who asserts that a POSA would have understood that the claimed mRNA of the '127 Patent does not include and is distinct from self-amplifying RNA, and to the extent that Dr. Fuller asserts that self-amplifying mRNA is not a type of mRNA as a scientific matter, I disagree. Self-amplifying mRNA is a specific type of mRNA that encodes for both the antigen as well as the proteins that form the replicon, whereas non-amplifying mRNA encodes for only the antigen. In both cases, however, the RNA acts as an intermediary between DNA and protein, and is involved in translating the DNA's genetic code into amino acids that form proteins. However, to

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the extent the term "mRNA" is construed -- is construed to exclude self-amplifying mRNA in the specific context of the '127 Patent, I point out it would not affect the opinions I have expressed with respect to the '127 Patent.

THE WITNESS: And always let me know if you need me to slow down.

Q. Okay. So just to be clear, you don't provide your own claim construction for the term "mRNA"; right?

MS. MAYS-WILLIAMS: Object to the form of the question.

(Document review.)

A. So in this section of my declaration, on page 8 I am outlining how a POSA would have understood the use of the term "mRNA."

MS. MAYS-WILLIAMS: Is now a good time for a break?

MR. PRUSSIA: We are going to give you the Fuller declaration, so we can take a break.

(Recess was taken from 10:32 to 10:47.)

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1 BY MR. PRUSSIA:
2 Q. So Dr. Griffin, you have been handed
3 Exhibits 2199 in both proceedings, as well as
4 Exhibit 1104 in both proceedings.
5 **A. Okay. I see 2199 is this large one and**
6 **1104 is this stapled one. Yes.**
7 Q. Okay. And those exhibits reflect
8 Dr. Fuller's declarations and her deposition
9 testimony; right?
10 **A. They do.**
11 Q. Okay. And I believe you reviewed her
12 declaration in connection with forming your
13 opinions in your reply declaration; right?
14 **A. So I reviewed her declaration and the**
15 **transcript of her deposition in preparing my reply**
16 **declaration.**
17 Q. Okay. Did you read the entire
18 deposition transcript?
19 **A. I read the entire transcript.**
20 Q. Okay. And you read the full
21 declaration too, I'm assuming?
22 **A. I read the entire declaration.**

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1 Q. Okay. And is it fair to say that your
2 reply declaration reflects your attempt to respond
3 to Dr. Fuller's opinions and her testimony?
4 **A. My declaration is a reply declaration.**
5 Q. And it's a reply to her opinions and
6 her testimony, is that fair?
7 **A. So my reply declaration has portions**
8 **where I respond to Dr. Fuller's opinions, but I**
9 **also have sections where, for instance, I reply to**
10 **Krause's opinions.**
11 Q. As you sit here today, is there
12 anything that you disagree with in Dr. Fuller's
13 testimony that you did not respond to in your
14 declaration?
15 **A. So my declaration includes specific**
16 **points where there were opinions by Dr. Fuller**
17 **that I responded to.**
18 Q. Okay. I am handing you what's been
19 identified as Exhibit 1011. This is the Yang
20 paper.
21 So Dr. Griffin, you have the Yang paper
22 in front of you; right?

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1 **A. I have the Yang paper in front of me**
2 **marked as Exhibit 1011.**
3 Q. And Yang makes reference to an S delta
4 TM and an S delta CD; right?
5 **A. The Yang paper includes an S delta CD,**
6 **an S protein with the cytoplasmic domain removed,**
7 **as an S delta TM, S protein with the transmembrane**
8 **and cytoplasmic domains removed.**
9 Q. Can we refer to those as truncated
10 spike proteins?
11 **A. It would be fair to describe the**
12 **S delta TM and the S delta CD as truncated**
13 **proteins.**
14 Q. If you could, please, turn to Figure 3,
15 which is on page 2 of the exhibit. It's internal
16 page 562 of Yang.
17 **A. All right. I am on page 562 of Letters**
18 **to Nature by Yang.**
19 Q. And focusing on Figure 3, it shows
20 protection against pulmonary SARS-CoV replication
21 following vaccination with a DNA vaccine encoding
22 truncated spike proteins; correct?

40

1 **A. So Figure 3 shows data for reduced TCID**
2 **50 with both truncated S delta CD and S delta TM.**
3 Q. So in your opinion, does the figure
4 show that the DNA vaccine including the truncated
5 versions of spike protein resulted in protection
6 against the SARS-CoV virus?
7 **A. So the data here in Figure 3 does**
8 **support Yang's conclusion that injections of the**
9 **S delta TM and S delta CD expression vectors**
10 **induced a substantial and protective immune**
11 **response.**
12 Q. If you look at the text above Figure 3,
13 there is a paragraph that starts with: "Infection
14 of non-human primates." Do you see that
15 paragraph?
16 **A. Okay, I am oriented to that paragraph.**
17 Q. About two-thirds of the way down there
18 is a sentence that begins: "In this analysis."
19 Do you see that?
20 MS. MAYS-WILLIAMS: I actually don't.
21 Can you help?
22 MR. PRUSSIA: Sure. So I am looking at

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1 the right-hand column of the page right above
2 the figure, the paragraph that starts with
3 "infection of non-human primates," and then
4 about two-thirds of the way down there is a
5 sentence that starts about in the middle of
6 the page: "In this analysis, the most potent
7 immunogen." Do you see that?
8 MS. MAYS-WILLIAMS: Yes.
9 Q. Do you see that sentence?
10 **A. So I am oriented, yes.**
11 Q. So Yang discloses that the most potent
12 immunogen was one of the truncated spike proteins;
13 right?
14 **A. So we are seeing here -- and I can**
15 **just read, which is absolutely fine: In this**
16 **analysis, the most potent immunogen, SARS S delta**
17 **CD, led to greater than 10-to-the-6th-fold**
18 **reduction in viral load in the lungs compared with**
19 **a control group injected with the vector alone,**
20 **with mean viral titres of greater than**
21 **10-to-the-8th.**
22 Q. So Yang is disclosing that the most

42

1 potent immunogen was one of the truncated spike
2 proteins?
3 **A. So just to be exact in the language, as**
4 **he states here: In this analysis, the most potent**
5 **immunogen, SARS S delta CD, led to greater than**
6 **10-to-the-6th-fold reduction of viral load in the**
7 **lungs, but we also see data for nasal turbinate.**
8 **In the nasal turbinate you get an actually**
9 **slightly different result.**
10 Q. You can put that aside, and if we could
11 look to Dr. Fuller's declaration. I am going to
12 direct you to page 241, and specifically paragraph
13 566 on page 241. Are you there, doctor?
14 **A. I am on page 241, paragraph 566.**
15 Q. And I will just read the sentence, the
16 first sentence. "Research as of October 2015
17 showed that using the same vaccine technology
18 (e.g., DNA) but different protein choice also
19 resulted in different outcomes." Do you see that
20 sentence?
21 **A. Yes, I see that sentence.**
22 Q. My only question is do you agree or

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1 disagree with that sentence?
2 MS. MAYS-WILLIAMS: Object to the form
3 of the question. Just feel free to refer to
4 as much of the declaration as you need to
5 find the context that you may require to
6 answer the question.
7 (Document review.)
8 **A. So looking at page 241, this paragraph**
9 **566, I actually specifically addressed this in my**
10 **declaration where if we go to page 115, paragraph**
11 **202, and I will go through this very slowly: In**
12 **her declaration, Dr. Fuller attempts to dismiss**
13 **the wealth of literature showing that S**
14 **protein-based vaccines were protective as**
15 **irrelevant to the choice of immunogen for an mRNA**
16 **vaccine. For example, Dr. Fuller states in her**
17 declaration, "vaccine technology (e.g., DNA, viral
18 vectors, saRNA, mRNA) was not interchangeable --
19 success with one vaccine technology (e.g., saRNA)
20 did not mean that one could reasonably expect
21 success with a different vaccine technology
22 (example, mRNA). At her deposition, Dr. Fuller

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1 contradicted that opinion. She testified that,
2 not only was she aware of the significant
3 literature teaching the use of a betacoronavirus
4 S protein as a vaccine immunogen, but she relied
5 upon such previous data from other vaccine
6 modalities in selecting SARS-CoV2 S protein in
7 development of her own vaccine candidate.
8 Q. Okay. So you are reading from
9 paragraphs 202 and 203 of your reply declaration;
10 right?
11 **A. I am reading from page 115, paragraphs**
12 **202 and 203.**
13 Q. I understood your testimony there in
14 your declaration to be responding to Dr. Fuller's
15 opinions regarding interchangeability of vaccine
16 technology. Here in paragraph 566 I am focusing
17 on the sentence where she says -- the situation
18 where you hold the vaccine technology constant,
19 but you change the antigen protein choice. Are
20 you with me so far?
21 **A. Uh-huh. I am with you.**
22 Q. So my question is for that, for that

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1 statement, that using the same vaccine technology
2 but different protein choice, that it also results
3 in different outcomes, is that something that you
4 agree with or is that something that you disagree
5 with?
6 **A. If you chose a different protein to**
7 **produce, you would produce a different protein.**
8 Q. You can put that to the side. I am
9 going to ask you just some general questions, if I
10 can.
11 So do all mRNA vaccines work?
12 **A. It's kind of a vague question to**
13 **answer, because it ultimately comes down to what**
14 **one means by work and what defines something as a**
15 **vaccine.**
16 Q. Do all mRNA vaccines produce a
17 protective immune response?
18 **A. I think that's an easier question to**
19 **answer, and not all mRNA vaccine constructions**
20 **demonstrate a protective response.**
21 Q. What are the -- strike that.
22 What are the reasons that an mRNA

46

1 vaccine might fail to produce a protective immune
2 response?
3 MS. MAYS-WILLIAMS: Objection. Vague.
4 Incomplete hypothetical.
5 **A. So the success of any vaccine**
6 **technology would be based on several features.**
7 **One, as a POSA would be well aware in 2015,**
8 **protection would involve neutralizing antibodies,**
9 **so antibodies that neutralize the pathogen rather**
10 **than enhanced entry. It would also involve an**
11 **appropriate flavor of T cell response, so a**
12 **balance of Th-1, Th-2. And it also would require**
13 **a safety profile where the benefit was better than**
14 **any potential reactogenicity or adverse events.**
15 Q. Are there situations where the mRNA
16 vaccine would fail to produce neutralizing
17 antibodies?
18 MS. MAYS-WILLIAMS: Objection. Vague.
19 Incomplete hypothetical.
20 **A. If an mRNA vaccine construction failed**
21 **to produce a protein, one would not anticipate**
22 **production of neutralizing antibodies.**

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1 Q. And when you say fail to produce
2 protein, you are talking about expression?
3 **A. The way mRNA leads to protein is**
4 **through expression. RNA serves as a template for**
5 **the protein and then the protein is produced based**
6 **on that RNA.**
7 Q. So there are situations where the mRNA
8 vaccine could fail to express protein, do I
9 understand that correctly?
10 **A. If someone constructed an mRNA vaccine**
11 **in a way where the RNA was not translated into**
12 **protein, then there would be no protein**
13 **production.**
14 Q. Will there -- strike that.
15 Is expression of the protein by itself
16 sufficient to generate neutralizing antibodies?
17 **A. So expression of a protein by itself**
18 **does not necessarily lead to production of**
19 **neutralizing antibodies.**
20 Q. Why is that?
21 **A. So important for all vaccine**
22 **approaches, active vaccine approaches, is to not**

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1 **only produce a protein target, but to also trigger**
2 **a danger response from the immune system so the**
3 **immune system knows to target that antigen.**
4 Q. Are there situations where the protein
5 can be expressed but doesn't properly form?
6 **A. I certainly can imagine examples where**
7 **an RNA template is such that a produced protein**
8 **does not form as one might expect.**
9 Q. Does misfolding occur just in nature?
10 **A. In nature proteins can misfold.**
11 Q. So misfolding can occur in the context
12 of a synthetic mRNA vaccine?
13 **A. It seems rather hypothetical, but**
14 **depending upon the construction of the mRNA**
15 **technology, one could potentially end up with a**
16 **misfolded protein.**
17 Q. What role does delivery of the mRNA
18 play in whether the vaccine will generate a
19 protective immune response?
20 **A. So by 2015 a POSA or scientists in the**
21 **field would have long known that if mRNA was not**
22 **protected, it would potentially be degraded and**

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1 **not sufficiently circulate in the body.**
2 Q. Are there situations where the mRNA
3 could be protected by the delivery vehicle, but
4 still not work to provide a protective immune
5 response?
6 MS. MAYS-WILLIAMS: Object to the form
7 of the question. Incomplete hypothetical.
8 **A. Yeah, even if the mRNA was properly**
9 **encapsulated or properly protected, if the**
10 **sequence of the mRNA was not accurately achieved,**
11 **one could potentially end up with a misfolded**
12 **rather than a properly formed protein.**
13 Q. And even when the -- strike that.
14 And even in situations where the
15 protein is expressed and properly folds, are there
16 situations where the delivery vehicle just fails
17 to sufficiently deliver the payload?
18 **A. I think this specifically is addressed**
19 **in Schrum where, you know, after we learn about**
20 **mRNA, we are also taught about delivery vehicles,**
21 **specifically addressing the importance of choosing**
22 **the appropriate delivery vehicle to avoid**

50

1 **degradation and allowing for the mRNA to code for**
2 **a protein.**
3 Q. You recall in your declaration and
4 Dr. Fuller's declaration there was some
5 back-and-forth between you about the Brito paper,
6 do you recall that?
7 **A. I do recall that.**
8 Q. We can grab it and put it in front of
9 you.
10 Doctor, we have given you Exhibit 2005
11 in the proceedings, and this is the Brito paper
12 that we were just discussing; right?
13 **A. I see this here, Exhibit 2005, yes.**
14 **This is the Brito, et al., paper.**
15 Q. And Dr. Geall is one of the -- is the
16 senior author on the paper; right?
17 **A. Dr. Geall is the senior author on this**
18 **paper.**
19 Q. Let's look at Figure 2, which is on
20 page 2121 of the publication. Are you there,
21 doctor?
22 **A. So I'm here and maybe to save us, I**

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1 **know that I address these issues in my**
2 **declaration, so I could either kind of sort**
3 **through and find it, unless you specifically know**
4 **where it is, that would save us time.**
5 Q. I don't -- I think maybe it's around
6 paragraph 351, somewhere thereabouts there. Do
7 you see there is paragraphs before and after it
8 that discuss Brito? 351 of your second
9 declaration. Around page 210 and 211.
10 **A. Let's see. Okay. Thank you. Just to**
11 **save us all time.**
12 Q. Okay. No problem.
13 So you have your declaration in front
14 of you and you also have Figure 2 of Brito in
15 front of you, and in Figure 2 Brito compares three
16 different vaccines. There is an SAM, the mRNA and
17 the pDNA. Do you see that?
18 **A. I do. Just give me a second just to**
19 **get oriented here. Okay. All right. I'm there.**
20 **I'm on page 2121, molecular therapy.**
21 Q. Okay. And the SAM construct is the
22 self-amplifying RNA; right?

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1 **A. So as they describe back on the first**
2 **page of this publication, "we previously described**
3 **the SAM vaccine platform, in which delivery of a**
4 **self-amplifying mRNA was facilitated by a nonviral**
5 **lipid nanoparticle."**
6 Q. And what Geall and Brito refer to as
7 the mRNA is what you describe in your declaration
8 as being the non-amplifying mRNA; right?
9 **A. So the distinction they are making**
10 **in this paper between the self-amplifying mRNA,**
11 **and that's designated as SAM, and the**
12 **replication-deficient mRNA, which is just termed**
13 **mRNA.**
14 Q. Okay. Now, each one of these vaccines
15 were designed to express the RSV-F protein; right?
16 **A. That is correct, these -- these are**
17 **producing the RSV-F sub-unit antigen.**
18 Q. And I will just point you to your
19 declaration. 351, about halfway through, you do
20 agree with Dr. Fuller that the non-amplifying mRNA
21 did not elicit a measurable IgG titer; correct?
22 **A. So I see that sentence here in my**

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1 **declaration on page 211 where I start the**
2 **sentence: Although the non-self -- the**
3 **non-amplifying mRNA, non-self-amplifying mRNA did**
4 **not elicit a measurable IgG titer, Brito, however,**
5 **explains that it was perhaps due to the low dose**
6 **being tested here and previous reports with mRNA**
7 **have shown that much higher doses, about 80**
8 **micrograms of mRNA, have been used to generate**
9 **immune responses in mice.**
10 Q. Okay. So the construct that Geall and
11 Brito refer to as mRNA did not produce a
12 protective immune response; fair?
13 **A. Very similar to my last answer, what we**
14 **are seeing here in this data was that at this low**
15 **dose, the non-amplifying mRNA did not elicit a**
16 **measurable IgG titer, leading to speculation by**
17 **Brito based upon the other literature that would**
18 **be available to a POSA in 2015 that a higher dose**
19 **of mRNA would be required.**
20 Q. Yeah, I understand. I was just trying
21 to translate the IgG titer part. By that it's
22 reflecting that the mRNA vaccine did not produce a

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1 protective immune response; right?
2 **A. What we are looking at in Figure 2 is**
3 **on a log 10 scale, RSV neutralizing titers, so we**
4 **are looking at levels -- measurable levels of IgG**
5 **titers, so this is not showing, I think, anything**
6 **beyond that.**
7 Q. Let me ask it this way: You wouldn't
8 expect that that mRNA vaccine, the mRNA vaccine
9 that's described in Brito Figure 2, at that dose
10 to provide a protective immune response; correct?
11 **A. Just making this distinction, which I**
12 **think is important, between protective immune**
13 **response and neutralizing titers, because this is**
14 **specifically addressing a question, which is**
15 **important, which is at this particular dose are we**
16 **measuring RSV neutralizing titers after this**
17 **particular dose of mRNA.**
18 Q. Okay. Let's talk about the dose.
19 Why would a low dose lead to a
20 non-measurable antibody titer?
21 **A. So the advantage of self-amplifying**
22 **mRNA, and I don't think this is theoretical at**

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1 **this point, the actual advantage is that one can**
2 **use a lower dose of a self-amplifying mRNA**
3 **construct, because that initial dose of mRNA, that**
4 **initial amount of mRNA, will then be amplified**
5 **several fold leading to an ultimately higher level**
6 **of mRNA. If one was gonna put in mRNA that lacked**
7 **self-amplifying capacity, one would have to start**
8 **with that higher dose of mRNA.**
9 Q. Why is that an advantage of
10 self-amplifying RNA?
11 **A. The advantage of only needing to start**
12 **with a lower dose could have production**
13 **advantages. You don't need to make as much mRNA.**
14 **There are, of course, downsides, because the**
15 **molecule is larger and more complex because it has**
16 **to actually have a replicase attached to the mRNA**
17 **part.**
18 Q. What are the downsides of needing to
19 provide a higher dose of non-amplifying mRNA to
20 elicit an immune response?
21 **A. I think the biggest challenge with**
22 **needing a higher dose of mRNA using a**

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1 **non-replicating mRNA platform is just a production**
2 **issue, needing to produce that much more mRNA.**
3 Q. What do you mean by that, what's the
4 production issue?
5 **A. Well, as we see here, if 15 micrograms**
6 **wasn't enough and, for instance, one needed to use**
7 **80 micrograms, one would have to use five to six**
8 **times more mRNA, one would have to make five to**
9 **six times as much mRNA.**
10 Q. So with respect to the mRNA that Brito
11 tested at the doses that Brito tested, is it
12 possible that the -- strike that.
13 Do we know whether the mRNA vaccine
14 that Brito tested actually resulted in express
15 protein?
16 (Document review.)
17 MS. MAYS-WILLIAMS: Are you asking
18 about whether the non-self-amplifying mRNA
19 vaccine results in express protein?
20 MR. PRUSSIA: Brito just calls it mRNA.
21 I am just going by what Brito and Geall calls
22 it, but yes, to answer your question.

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1 (Document review.)
2 **A. Do you have copies of the supplementary**
3 **figures? I'm just looking for data where I**
4 **actually see the protein production with the mRNA**
5 **platform. Can you get the supplement? I am just**
6 **looking for it. I don't know if it's in the**
7 **supplement or not. I wasn't asked previously to**
8 **look for the data on the protein production, but**
9 **if I could get the supplements, I could look**
10 **through and see if we have data on that.**
11 Q. But just based on the four corners of
12 what you see in Brito, do you have an opinion on
13 whether the mRNA vaccine that was tested actually
14 expressed protein?
15 MS. MAYS-WILLIAMS: Object to the form
16 of the question.
17 **A. Yeah, the Figure 6 is one figure where**
18 **they are using a luciferase assay, but as I will**
19 **point out, there is no western blot, there is no**
20 **quantification of the protein. This is using a**
21 **modified approach with luciferase, so I'd have to**
22 **probably look through the supplements and see if**

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1 **we have any data on whether or not this platform**
2 **actually resulted in measurable protein.**
3 Q. So at least with respect to the 15
4 microgram dose and the 1.5 microgram dose that was
5 tested of the mRNA RSV protein in Brito, we know
6 that it generated detectable IgG titers in the
7 SAM, but not -- SAM and the DNA, but not in the
8 mRNA; right?
9 **A. So as we see in Figure 2, at these**
10 **doses we are seeing measurable RSV neutralizing**
11 **titers not after the 0.015 micrograms of SAM, but**
12 **we are seeing them after the 0.15 microgram, we**
13 **are seeing them with the 1.5 microgram, and we are**
14 **seeing even higher on this log scale of the 15**
15 **micrograms using the SAM.**
16 Q. And at the same doses we are not seeing
17 detectable IgG titers in the mRNA construct;
18 right?
19 **A. As we are seeing in the data here, and**
20 **I will just walk through it just so everyone is on**
21 **the same page, we are -- we have got Figure 2a, we**
22 **have got Figure 2b. Right? So we are looking at**

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1 **neutralizing titers and we are looking at IgG**
2 **titers. We are being given the geometric means,**
3 **but we are also getting dots for individual**
4 **animals, in this case mice. So as we see looking**
5 **specifically at Figure 2b, we are seeing the**
6 **individual animals and the geometric means are**
7 **below level of detection. When we look at**
8 **F-specific IgG titers, even though we see our**
9 **geometric mean below this threshold, we are seeing**
10 **that individual animals did produce F-specific**
11 **IgG. But I don't think this, as I outline in my**
12 **declaration, would teach away from using an mRNA**
13 **vaccine technology. If anything, I would conclude**
14 **as Brito does, that previous reports have shown**
15 **that much higher doses, about 80 micrograms of**
16 **mRNA, are usually what would be required to**
17 **generate an immune response in mice.**
18 Q. Let's talk about the dose. So if you
19 turn to Brito page 2124, it's the left-hand
20 column, it's the paragraph that continues from the
21 preceding page, and that very last sentence says:
22 Previous reports with mRNA have shown that much

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1 higher doses (80 microgram) of mRNA have been used
2 to generate immune responses in mice. Do you see
3 that?
4 **A. Okay. Hold on a second. I think I see**
5 **it. Okay. I see that last sentence here where**
6 **page 2124, left column, it's in the partial top**
7 **paragraph: Previous reports with mRNA have shown**
8 that much higher doses (80 micrograms) of mRNA
9 have been used to generate immune responses in
10 mice.
11 Q. Okay. And this is the statement in
12 Brito that you were referring to earlier in your
13 declaration; right?
14 **A. So I directly quote this sentence in my**
15 **declaration.**
16 Q. And those prior reports that Brito is
17 referring to, what type of mRNA vaccine was at
18 issue?
19 **A. So the reference, number 6, is the**
20 **Petsch, et al., 2012 paper, looking at an mRNA**
21 **vaccine against influenza A.**
22 Q. What prior reports existed with mRNA in

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1 the context of -- strike that.
2 What prior reports existed as of 2015
3 with non-amplifying mRNA and RSV in terms of the
4 dose that had been used to generate an immune
5 response in mice or in any in vivo?
6 MS. MAYS-WILLIAMS: Objection to form.
7 **A. So ask that again.**
8 Q. What prior reports --
9 MS. MAYS-WILLIAMS: I think he was
10 about to testify --
11 **A. No, I said if you could ask that again.**
12 **I was trying to put the --**
13 Q. I will slightly rephrase it, but same
14 thing.
15 As of 2015, what prior reports existed
16 disclosing the dose that had been used in a
17 vaccine for RSV using non-amplifying mRNA?
18 (Document review.)
19 **A. So while a POSA in 2015 would have been**
20 **able to review the literature and look for that**
21 **information, right now I can't recall what papers**
22 **or publications would have given that information.**

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1 Q. As you sit here today, do you think
2 there were any?
3 **A. I don't know.**
4 Q. Do you think if there were, that
5 Dr. Brito and Dr. Geall would have cited that
6 instead of a reference to influenza A in
7 footnote 6?
8 MS. MAYS-WILLIAMS: Object to the form
9 of the question. Incomplete hypothetical.
10 Scope. Calls for speculation.
11 **A. Yeah, I don't -- I don't know.**
12 Q. Okay. Fair enough. Is it your
13 testimony -- strike that.
14 Is it your opinion that for any antigen
15 for which an mRNA vaccine is encoded for, that the
16 same dose would be required, or are different
17 doses found to be effective for different
18 antigens?
19 **A. So the amount of mRNA required for an**
20 **mRNA vaccine to produce a specific level of**
21 **protein would depend upon the formulation, the**
22 **encapsulation of the mRNA, as well as the specific**

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1 **protein being produced.**
2 Q. How does a person of skill in the art
3 determine the amount of mRNA that would be
4 required to generate a protective immune response
5 if that specific protein had never before been
6 tested in that mRNA construct?
7 **A. So there would be several steps to**
8 **answering the exact dose question. The first**
9 **would start with in vitro assays where the mRNA**
10 **was put in cells, and then ultimately one would**
11 **have to administer different doses in the target**
12 **organism to get the exact dose that correlates**
13 **with an exact level of protein production.**
14 Q. So would a person of skill in the art
15 be able to predict the effective amount that would
16 be required to generate a protective immune
17 response without doing that testing or if that
18 testing had not been done by others?
19 **A. So to know the exact level of protein**
20 **production, the exact level of antibody response,**
21 **a formulation would have to be administered**
22 **following the steps of first in vitro assays and**

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1 **ultimately given to a subject.**
2 Q. You can put that to the side, if you
3 haven't already. I am going to switch gears a
4 little bit.
5 **A. This is this publication I am putting**
6 **aside?**
7 Q. Yes, Brito.
8 **A. Thank you.**
9 Q. I am going to ask you a question.
10 If data were to show that an mRNA
11 vaccine encoding a full-length spike protein
12 resulted in neutralizing antibodies coupled with
13 protection from viral infection, could the POSA
14 infer that a spike protein had actually been
15 formed?
16 **A. This is very similar to one of the**
17 **questions when we actually were going through**
18 **Brito where what I was looking for, and I think**
19 **this would be applicable for scientific rigor, if**
20 **you deliver mRNA, it would be ideal to see western**
21 **blots measurement of the protein production.**
22 Q. Okay. If you could -- switch gears a

65

1 little bit. Turn to your declaration, paragraph
2 42. This is your second declaration.
3 **A. Second declaration, paragraph 42.**
4 Q. And about halfway through -- second
5 sentence. It's the sentence that starts "by the
6 priority date of the challenged patents."
7 **A. Okay. So we are on page 20, paragraph**
8 **42.**
9 Q. And I just want to make sure you are
10 with me. Are you with me?
11 **A. Yes, I am here on page 20, paragraph**
12 **42.**
13 Q. Okay. And the sentence starts or
14 reads: "By the priority date of the challenged
15 patents, it was well known 'the spikes of SARS-CoV
16 are composed of trimers of S protein' and that an
17 expressed S protein folds into the figurative
18 'spike' for which these proteins are named." Do
19 you see that?
20 **A. I see that sentence.**
21 Q. And you cite what I believe is Du for
22 that; right?

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1 **A. So I cite to Exhibit 1031. Is that Du?**
2 **I'm looking through my exhibits.**
3 Q. Yeah, and it's probably not so
4 important whether it's Du or not. Exhibit 1031.
5 The record knows what 1031 is.
6 But I guess the question I was really
7 getting at is -- since you have it, is it Du, just
8 so we are all on the same page?
9 **A. It is Du. Okay. So it's in my opening**
10 **declaration. Okay. This got to be pretty long.**
11 **Sorry.**
12 Q. It wasn't so important. But just to --
13 **A. Okay.**
14 Q. Here is the actual question that I
15 wanted to get at.
16 **A. Okay.**
17 Q. In that sentence you are describing the
18 viral spike protein; right?
19 **A. So yeah, I am specifically here**
20 **referring to the spikes of SARS-CoV.**
21 Q. And so you are referring to the virus
22 itself; right?

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1 **A. I mean, I am specifically referring to**
2 **the spikes of SARS-CoV.**
3 Q. Okay. Now, I think this is true, but I
4 just want to ask -- based on our earlier
5 discussion, but I just want to ask the question to
6 make sure we are on the same page.
7 You are not offering the opinion that
8 an expressed spike protein from an mRNA vaccine
9 will always properly fold and form into a spike;
10 right?
11 **A. So as I point out here, and it's the**
12 **absolute that might get one into trouble, the**
13 **spikes of SARS-CoV are composed of trimers of**
14 **S protein and that S protein folds into the**
15 **figurative spike of which these proteins are**
16 **named. Would some fraction of a percent not do**
17 **that? I think that would be quite the exception,**
18 **and then, you know, we would have an issue with it**
19 **being a spike polypeptide.**
20 Q. Right. So in the context of the
21 vaccine, it does that in terms of folding into a
22 spike when the vaccine actually works; right?

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1 **A. So if the mRNA codes for the S protein,**
2 **then the expressed S protein would fold into the**
3 **figurative spike.**
4 Q. So there is no -- strike that.
5 So earlier our discussion about
6 circumstances where, for example, a protein may
7 not express or not properly fold, are you saying
8 that doesn't happen in the context of SARS or any
9 betacoronavirus?
10 MS. MAYS-WILLIAMS: Object to the form
11 of the question.
12 **A. Yeah, with reference to our earlier**
13 **discussion, if one doesn't get the mRNA sequence**
14 **correct or one fails to actually get the protein**
15 **to express, well, then it wouldn't be able to, but**
16 **if the mRNA sequence is correct and the protein is**
17 **expressed, then the expressed S protein would fold**
18 **into the figurative spike for which these proteins**
19 **are named.**
20 Q. Okay. And how do you know if the mRNA
21 expresses, how does one determine that?
22 **A. The most compelling evidence would be**

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1 **to assay the level of protein produced.**
2 Q. And even if the spike protein
3 expresses, are there factors that may cause it to
4 not form a spike?
5 MS. MAYS-WILLIAMS: Objection. Vague.
6 Incomplete hypothetical.
7 **A. I'm not sure I can think of examples**
8 **where this would not occur, because it was well**
9 **known by 2015 that the S protein, when expressed,**
10 **would fold into figurative spikes.**
11 Q. Now, there is -- strike that.
12 MS. MAYS-WILLIAMS: If we are going to
13 move on, would now be a good time for a
14 break?
15 MR. PRUSSIA: We can take a break even
16 if I'm not moving on. I'm not saying I'm
17 moving on, but we could take a break.
18 (Recess was taken from 11:55 to 12:16.)
19 BY MR. PRUSSIA:
20 Q. So Dr. Griffin, could we go to
21 paragraph 44 of your second declaration.
22 **A. I am on page 21, paragraph 44.**

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1 Q. Okay. And in this paragraph you state
2 that you disagree with Dr. Fuller's opinion that
3 large proteins are difficult to express. Do you
4 see that?
5 **A. I see that sentence.**
6 Q. You state that you disagree with this
7 assertion because as by October 2015 it had
8 already been shown that betacoronavirus spike
9 proteins could be expressed using nucleic acid
10 vaccines to induce a protective immune response.
11 Do you see that?
12 **A. I see the sentence where I state that I**
13 **disagree with this assertion, as by October 2015**
14 **it had already been shown that betacoronavirus**
15 **spike proteins could be expressed using nucleic**
16 **acid vaccines to induce a protective immune**
17 **response.**
18 Q. And we know that with respect to those
19 nucleic acid vaccines, none of them involve
20 non-amplifying mRNA; right?
21 (Document review.)
22 **A. Okay. Can you ask that again.**

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1 Q. Sure. We know that with respect to
2 those nucleic acid vaccines, none of them involved
3 non-amplifying mRNA; right?
4 (Document review.)
5 **A. Ask it one more time. I am just trying**
6 **to piece together, because there is two parts to**
7 **it.**
8 Q. Okay. I will actually withdraw it.
9 I'm going to move on to something else.
10 Later in that paragraph you make
11 reference to a 9-10 kilobase nucleotide RNA
12 vaccine. Do you see that?
13 **A. I see that.**
14 Q. And you are referring to a
15 self-amplifying RNA; right?
16 **A. Actually, I am speaking here broadly**
17 **when I say: It was well-known by 2015 that "any**
18 **protein can be expressed from mRNA without the**
19 **need to adjust the production process," and that**
20 **9-10 kilobase nucleotide RNA vaccines could**
21 **express protective antigens in vivo to induce a**
22 protective immune response (around three-times the

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1 size of a betacoronavirus spike protein).
2 Q. And with respect to the 9 to 10
3 kilobase nucleotide RNA vaccine, my question is
4 you are referring to a self-amplifying RNA
5 vaccine; right?
6 **A. So here I see that I am referring to**
7 **Exhibit 2021 where it was an RNA vaccine delivered**
8 **via lipid nanoparticles used to induce immune**
9 **response against respiratory syncytial virus.**
10 Q. Do you need to see that reference to
11 know that it was a self-amplifying mRNA vaccine?
12 **A. That would be great, if you have the**
13 **reference, 2021.**
14 Q. Okay. So you have Exhibit 2021 and you
15 cite page 14604. So do you want to take a look at
16 that and refresh your recollection as to whether
17 the 9-10 kilobase nucleotide RNA vaccine you are
18 referring to in paragraph 44 is a self-amplifying
19 RNA vaccine?
20 **A. So here in Geall, et al., published in**
21 **2012, to which I reference in my declaration on**
22 **page 22, here they show that non-delivery of a 9**

73

1 **kilo -- 9 kb self-amplifying RNA encapsulated with**
2 **an LNP substantially increased immunogenicity**
3 **compared with delivery of unformulated RNA.**
4 Q. Okay. So just to be clear, in
5 paragraph 44 when you are referring to the 9-10
6 kilobase nucleotide RNA vaccine, you are referring
7 to the self-amplifying RNA vaccine that's
8 disclosed by Geall, right, in Exhibit 2021?
9 **A. So as I state in my declaration, it was**
10 **well known by 2015 that any protein can be**
11 **expressed from mRNA without the need to adjust the**
12 **production process, and that 9-10 kilobase**
13 **nucleotide RNA vaccines could express protective**
14 **antigens in vivo. I do cite to Geall where they**
15 **are describing here self-amplifying RNA, and they**
16 **are actually using a construct about three times**
17 **the size of the betacoronavirus spike protein, and**
18 **why do I say I am speaking broadly, because if**
19 **anything, the size of this and the formulation**
20 **would be even more complicated than an mRNA,**
21 **because the self-replicating would also involve**
22 **having a replicase portion of the RNA.**

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1 Q. The self-amplifying RNA contains genes
2 other than those for the viral protein of
3 interest; right?
4 **A. So the self-replicating mRNA is going**
5 **to contain a stretch that is the template for the**
6 **protein and a stretch that codes for the**
7 **replicase.**
8 Q. So the 9-10 kilobase that you refer to
9 in your declaration is with reference to the size
10 of the entire vaccine; right?
11 **A. It certainly refers to the size of the**
12 **entire self-amplifying RNA.**
13 Q. Now, the self-amplifying RNA vaccine at
14 issue in Geall in Exhibit 2021 is with respect to
15 RSV; right?
16 **A. So this specifically is looking at**
17 **encoding respiratory syncytial virus fusion**
18 **glycoprotein, so the RSV-F.**
19 Q. And the RSV-F protein, that's not three
20 times the size of a betacoronavirus spike protein,
21 is it?
22 **A. So the mRNA part of the self-amplifying**

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1 **RNA is only a portion of that 9 kilobases, so it**
2 **itself is smaller than the 9 kilobases.**
3 Q. It's about half the size, the RSV-F
4 protein as compared to the spike protein of a
5 betacoronavirus?
6 **A. Could you ask that question again.**
7 Q. The RSV-F protein is about half the
8 size of the full-length spike protein of a beta
9 coronavirus; right?
10 **A. I would have to look that up. I -- I**
11 **don't know, sitting here, the exact size.**
12 Q. Okay. But it's not three times the
13 size of a betacoronavirus spike protein; right?
14 MS. MAYS-WILLIAMS: Objection. Asked
15 and answered.
16 **A. So the 9 kilobase that I refer to is**
17 **the size of the RNA that can be delivered as a**
18 **payload with this technology.**
19 Q. You don't -- doctor, you don't cite any
20 reference prior to 2015 involving a nucleic acid
21 vaccine where the encoded antigen is three times
22 the size of a beta coronavirus spike protein, do

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1 you?
2 **A. So I'm specifically citing here in my**
3 **declaration to this 2012 publication.**
4 Q. And as you sit here today and you think
5 back to prior to 2015, are you aware of a nucleic
6 acid vaccine that existed at that time that had
7 successfully expressed an antigen larger than the
8 full-length betacoronavirus spike protein?
9 (Document review.)
10 **A. So I specifically cite this as an**
11 **example of the size of the RNA cargo that can be**
12 **delivered with this technology that was known to a**
13 **POSA of 2015. I would have to look through the**
14 **literature to find other examples looking**
15 **specifically at the mRNA portion of the**
16 **self-amplifying mRNA technology.**
17 Q. Okay. Fair enough. You could put that
18 to the side.
19 If a vaccine containing the gene for a
20 full-length S protein produced neutralizing
21 antibodies, would that be sufficient information
22 for a POSA to reasonably expect that the vaccine

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1 did not cause enhanced disease?
2 (Document review.)
3 **A. So the issue of enhanced disease a POSA**
4 **in 2015 would have understood involved several**
5 **components. One would have been the ability to**
6 **raise sufficient levels of neutralizing antibodies**
7 **against the target as opposed to non-neutralizing**
8 **antibodies that would, rather than neutralize,**
9 **facilitate pathogen entry. That would not be**
10 **sufficient, because one would also want**
11 **information about the flavor of the T cell**
12 **response, the balance between Th-1 and Th-2, and**
13 **by 2015 a POSA would already have understanding**
14 **that nucleic acid vaccines in general drove a**
15 **Th-1-type immune response.**
16 Q. So the presence -- are you done?
17 Sorry. Are you done?
18 So the presence of neutralizing
19 antibodies in and of itself is not enough to rule
20 out the possibility of enhanced disease?
21 **A. The concerns about antibody-dependent**
22 **enhancement are very much tied to levels of**

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1 **neutralizing antibodies, but levels of**
2 **neutralizing antibodies alone don't fully address**
3 **vaccine-associated or vaccine-associated disease**
4 **enhancement.**
5 Q. Doctor, you have Exhibit 2136?
6 **A. I have Exhibit Moderna 2136.**
7 Q. And that is a journal article titled:
8 Consensus summary report for CEPI/BC March 12-13,
9 2020 meeting: Assessment of risk of disease
10 enhancement with COVID-19 vaccines. Do you see
11 that?
12 **A. I see that.**
13 Q. If you could, please, turn to page 4785
14 of the article. You will see a Table 1.
15 **A. I see Table 1.**
16 Q. And Table 1 is titled: Evidence of
17 enhanced disease in SARS-CoV-1 vaccine candidates.
18 Do you see that?
19 **A. I see here Table 1 entitled: Evidence**
20 **of enhanced disease in SARS-CoV-1 vaccine**
21 **candidates.**
22 Q. And if you look at the fifth entry

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1 down, there is a reference Tseng, T-S-E-N-G, 2012.
2 Do you see that?
3 **A. Tseng 2012, yes.**
4 Q. And if you look at the end notes, the
5 references, there is a reference 32. Do you see
6 that?
7 **A. I see that here, reference 32, Tseng CT**
8 **et al., immunization with SARS coronavirus**
9 **vaccines leads to pulmonary immunopathology on**
10 **challenge with the SARS virus. PLoS ONE.**
11 Q. So you have tab 20, and does tab 20
12 appear to be the Tseng reference in Exhibit 2136?
13 MS. MAYS-WILLIAMS: I just want to --
14 before we get into this want to object to
15 this exhibit as outside the scope of the
16 declaration of the witness. Hearsay. It's
17 not a pre-marked exhibit, so it's a little
18 bit late in the game to be using this
19 exhibit. I also want to object on the basis
20 of relevance.
21 Q. So I will just reask my question and
22 her objections will carry over.

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1 So you have tab 20, and does tab 20
2 appear to be the same reference in Exhibit 2136?
3 MS. MAYS-WILLIAMS: Same objections.
4 **A. So this appears to be the reference**
5 **that was cited in this original Moderna 2136**
6 **paper.**
7 Q. And if you look at the Abstract under
8 Design, the first sentence, it makes reference to
9 four candidate vaccines. Do you see that?
10 **A. I see here: "Design: Four candidate**
11 **vaccines for humans with or without alum adjuvant**
12 **were evaluated in a mouse model of SARS, a VLP**
13 **vaccine, the vaccine given to ferrets and NHP,**
14 **another whole virus vaccine and an rDNA-produced S**
15 **protein."**
16 MS. MAYS-WILLIAMS: I don't want to
17 interrupt you, but I do want to just make a
18 standing objection to every line of questions
19 that relate to this exhibit, but I don't want
20 to be disruptive.
21 Q. If you turn to page 2, do you see a
22 section -- subsection under Materials and Methods

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1 titled Vaccines?
2 **A. So on page 2 and I see the subsection**
3 **Vaccines.**
4 Q. And about halfway through that
5 paragraph you will see that, as you noted a minute
6 ago, one of vaccines that were evaluated was a
7 recombinant DNA spike S protein vaccine; right?
8 **A. So I see here on page 2, we are in the**
9 **vaccine paragraph, in the Materials and Methods**
10 **section, where a recombinant DNA spike S protein**
11 vaccine (SV) was produced in insect cells and
12 purified by column chromatography was tested with
13 and without alum adjuvant.
14 Q. And if you turn back to the abstract
15 under Results, the first sentence, the report is
16 that all vaccines induced serum neutralizing
17 antibody with increasing dosages, and it goes on.
18 Do you see that?
19 **A. I see the Results section of the**
20 **abstract and that sentence that you just read.**
21 Q. So the results of the study showed that
22 the S protein vaccine produced neutralizing

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1 antibodies; right?
2 **A. To be completely fair, this is the**
3 **first time that I'm seeing this article. I am**
4 **actually not sure that I've seen it before. So**
5 **I -- I can read the sentence with you, but I**
6 **haven't actually looked through all the data.**
7 Q. Okay. Did I read the sentence
8 correctly?
9 **A. You read the sentence correctly.**
10 Q. And it reports that the S protein
11 vaccine induced neutralizing antibodies; right?
12 **A. Just like you, I see the sentence here,**
13 **the first line of Results, where the authors**
14 **write: "All vaccines induced serum neutralizing**
15 **antibody."**
16 Q. The abstract goes on to say, if you see
17 the second to last sentence --
18 **A. Is this "histopathology seen in**
19 **animals," that sentence?**
20 Q. Yes. "Histopathology seen in animals
21 given one of the SARS-CoV vaccines was uniformly a
22 Th2-type immunopathology with prominent eosinophil

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1 infiltration, confirmed with special eosinophil
2 stains." Do you see that?
3 **A. So I see here the sentence:**
4 **"Histopathology seen in animals given one of the**
5 **SARS-CoV vaccines was uniformly a Th2-type**
6 **immunopathology with prominent eosinophil**
7 **infiltration, confirmed with special eosinophil**
8 **stains."**
9 Q. And I believe you testified to this
10 earlier, that the Th-2-type immunopathology is
11 associated with disease enhancement following
12 vaccination; right?
13 **A. So specifically a balance with more of**
14 **a Th-1-type response is associated with a lower**
15 **concern for disease enhancement.**
16 Q. If you turn to page 11 of the
17 reference, it's the right-hand column is the
18 paragraph beginning "because of well documented
19 severity." Are you there?
20 **A. So I am here on page 11, second**
21 **paragraph down I see "because of well documented**
22 **severity."**

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1 Q. About two-thirds of the way down there
2 is a sentence that starts in the right margin:
3 "The finding of a Th-2-type pathology." Do you
4 see that?
5 **A. Okay. So I am here "because of well**
6 **documented severity" -- how far down?**
7 Q. About two-thirds of the way down.
8 There is a sentence that starts with the word
9 "the." "The" is sort of close to the right
10 margin. It goes "the finding of a Th-2" --
11 **A. Okay. I see. I am oriented. So "the**
12 **finding of a Th-2-type pathology."**
13 Q. So the complete sentence reads: "The
14 finding of a Th-2-type pathology in our studies in
15 animals immunized with an rDNA-produced S protein
16 is unequivocal." Do you see that?
17 **A. I see that.**
18 Q. So the prior art reports that an S
19 protein vaccine producing neutralizing antibodies
20 but also caused Th-2 mediated pathology; right?
21 THE COURT REPORTER: Can you repeat
22 that.

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1 Q. The prior art reports that an S protein
2 vaccine produced neutralizing antibodies, but also
3 caused Th-2 mediated pathology; correct?
4 **A. I certainly can read these sentences**
5 **out of context, but as mentioned, this is the**
6 **first time I am seeing this publication, so I have**
7 **not had the time to read it completely through.**
8 MR. PRUSSIA: So we are actually going
9 to mark this as Exhibit 2252.
10 MS. MAYS-WILLIAMS: I object to marking
11 this as an exhibit. Too late to introduce a
12 new exhibit.
13 (Exhibit 2252, publication entitled
14 Immunization with SARS Coronavirus Vaccines
15 Leads to Pulmonary Immunopathology on
16 Challenge with the SARS Virus, marked for
17 identification.)
18 Q. Let's talk some more about the RSV
19 protein if we can, doctor.
20 And just to take a step back, what is
21 the F protein of RSV?
22 **A. So the F protein is the surface protein**

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1 **on the RSV, respiratory syncytial virus, that is**
2 **specifically involved in binding to the receptor.**
3 Q. And was the F protein a known target
4 for an RSV vaccine as of 2015?
5 **A. So in 2015 a POSA would have been well**
6 **aware of the RSV F protein and not only its**
7 **potential role as a vaccine target, but the whole**
8 **history of vaccine-associated disease enhancement**
9 **associated with the work of Barney Graham and**
10 **others on trying to use that.**
11 Q. And at a high level, the F protein has
12 multiple domains; right?
13 **A. So the F protein, like all surface**
14 **proteins, has multiple domains.**
15 Q. So, for example, like it has a
16 transmembrane domain like the S protein does;
17 right?
18 **A. So the F protein has a transmembrane**
19 **domain.**
20 Q. Now, would you consider the -- strike
21 that.
22 As of 2015, did you consider that the

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1 F protein, the full length, that it was the main
2 target for RSV?
3 MS. MAYS-WILLIAMS: Object to the form
4 of the question.
5 Q. For an RSV vaccine.
6 MS. MAYS-WILLIAMS: I object to the
7 form of the question.
8 **A. So I didn't previous to today sit back**
9 **and put myself in the role of a POSA in 2015 to**
10 **consider that issue.**
11 Q. As you sit here today thinking back to
12 2015, based on your experience, was it the main
13 target for an RSV vaccine?
14 **A. So a POSA in 2015, even whether or not**
15 **they were specifically working on RSV, would have**
16 **been aware of the original work, Barney -- by**
17 **Barney Graham and others looking at RSV as a**
18 **target for vaccine development and all the**
19 **information that followed from that regarding**
20 **vaccine-associated disease enhancement.**
21 Q. Okay. So you could have a full-length
22 RSV F protein, but you could also have a truncated

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1 RSV F protein, am I understanding that right?
2 **A. So just like every protein, you can**
3 **have the entire protein or you can truncate a**
4 **protein.**
5 Q. So if we go to Geall, Exhibit 1010.
6 **A. I probably have Geall somewhere here,**
7 **right? Okay. So I have Geall and where am I**
8 **going?**
9 Q. You are going to go to page 29.
10 **A. Internal pagination or the bottom left**
11 **pagination?**
12 Q. It's the -- page 30 of the exhibit, 29
13 of the internal pagination. It's under Modes For
14 Carrying Out the Invention. Are you there?
15 **A. I am. I am there at page 29, Modes For**
16 **Carrying Out the Invention.**
17 Q. And then if you go to line 12, you see
18 a reference to a full-length RSV F protein, do you
19 see that?
20 **A. I see full-length RSV F protein.**
21 Q. So here Geall specifically mentions a
22 full-length RSV F protein; right?

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1 **A. I see here the specific mention of the**
2 **full-length RSV F protein.**
3 Q. And let me ask you this: Do you agree
4 or disagree with the following statement: When
5 the patent intends to refer to a full-length
6 protein, it expressly does so by referring to it
7 as a full-length protein?
8 **A. And by "the patent" you are referring**
9 **to Geall, so you are saying in the Geall patent,**
10 **is that --**
11 Q. That's right.
12 **A. Okay.**
13 (Document review.)
14 **A. So I definitely see here that Geall is**
15 **using the termination full-length -- term --**
16 **terminology -- terminology full-length RSV F**
17 **protein, but it's really a broader question of**
18 **whether every single time Geall is referring to**
19 **RSV F protein whether or not full length is being**
20 **specified or not.**
21 Q. Okay. If you could turn to page 34.
22 **A. We are doing internal pagination?**

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1 Q. Yes. Sorry. Page 34, and for the
2 reference -- for the record, it's page 35 of the
3 exhibit number. And starting at line 11. And it
4 says "to assess" -- are you there, sir?
5 **A. So I'm on page 34, line 11, yes.**
6 Q. And it says: "To assess in vivo
7 immunogenicity a replicon was constructed to
8 express full-length F protein from respiratory
9 syncytial virus (RSV)." Do you see that?
10 **A. Syncytial.**
11 Q. Syncytial virus. Do you see that?
12 **A. Yes, I see that.**
13 Q. And so again, Geall refers to it as a
14 full-length protein; right?
15 **A. So I see here, same sentence that you**
16 **just read: "To assess in vivo immunogenicity a**
17 **replicon was constructed to express full-length**
18 F protein from respiratory syncytial virus (RSV)."
19 Q. If you go to page -- internal page 40,
20 page 41 of the exhibit.
21 **A. 40 or 41?**
22 Q. 40.

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1 **A. Okay. I'm on 40.**
2 Q. Under Large Mammal Study at about line
3 15, do you see the reference again to full-length
4 RSV F protein?
5 **A. I see that here, yes.**
6 Q. So Geall makes multiple references to a
7 full-length protein; right?
8 MS. MAYS-WILLIAMS: Objection. Vague.
9 **A. So this same paragraph, just to put it**
10 **in context, starts off by saying: A large-animal**
11 study was performed in cattle. Calves (4-6 six
12 weeks old, approximately 60 to 80 kilograms, 5 per
13 group) were immunized with 66 micrograms of
14 replicon vA317 encoding full-length RSV F protein
15 on days 0, 21, 86 and 146.
16 It then goes on to say: All calves
17 received 15 micrograms F protein adjuvanted with
18 the MF59 emulsion on day 146.
19 So we are seeing, just for context,
20 full-length RSV F protein, and then we are also
21 seeing just F protein.
22 Q. Okay. And so if you want to go to

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1 paragraph -- you can keep that open, but if you
2 also want to go to paragraph 24 of your
3 declaration. And you state -- are you there, sir?
4 **A. I am there. Page 10 of mine and**
5 **paragraph 24.**
6 Q. You state about halfway down: "These
7 passages indicate that when the patent intends to
8 refer to a full-length spike protein, it expressly
9 does so -- by referring to it as a 'full-length'
10 spike protein." Do you see that?
11 **A. So I see that sentence in my**
12 **declaration.**
13 Q. And you stand by that statement; right,
14 sir?
15 **A. So as I say here, I am specifically**
16 **talking about the -- Dr. Fuller's comments**
17 **regarding the '127 Patent, and: Dr. Fuller cites,**
18 **without explanation, to several sections of the**
19 **'127 patent expressly referring to a full-length**
20 **Spike protein. For example, Dr. Fuller refers to**
21 **how the '127 patent describes a coronavirus mRNA**
22 **vaccine encoding the MERS -- so it's capital**

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1 **MERS-CoV full-length Spike protein. In my**
2 **opinion, these passages do not support**
3 **Dr. Fuller's proposed construction. In these --**
4 **instead, these passages indicate that when the**
5 **patent intends to refer to full-length spike**
6 **protein, it expressly does so -- by referring to**
7 **it as a "full-length" spike protein.**
8 Q. So when the patent intends to refer to
9 the protein as full length, it uses those words,
10 that's your opinion, right, sir?
11 MS. MAYS-WILLIAMS: Sorry. Just so the
12 record is clear, when you are referring to
13 the patent, which patent are you referring to
14 now, the '127 Patent or the Geall reference
15 which you also referred to as a patent
16 earlier? I just want to make sure I
17 understand and the record is clear.
18 MR. PRUSSIA: My question stands.
19 MS. MAYS-WILLIAMS: I don't think the
20 record is clear, so I object to the form of
21 that question as incredibly vague.
22 **A. So in my declaration here I am**

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1 **commenting on the '127 Patent.**
2 Q. And my question is do you agree or
3 disagree with the following statement: When the
4 patent intends to refer to a full-length protein,
5 it expressly does so by referring to it as a
6 full-length protein?
7 MS. MAYS-WILLIAMS: I object to the
8 form of the question. It's a vague question.
9 The record is unclear as to the question
10 that's actually pending.
11 **A. I am still not clear on which patent.**
12 **When you say "the patent," I don't know which**
13 **patent you are referring to.**
14 Q. Well, let's start with the '127 Patent.
15 **A. Okay. So question about the '127**
16 **Patent.**
17 Q. Same question. Do you agree or
18 disagree with the following statement: When the
19 patent intends to refer to a full-length protein,
20 it expressly does so by referring to it as a
21 full-length protein?
22 **A. So in the '127 Patent a POSA would have**

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1 **understood that the patent uses the term "spike**
2 **protein" broadly.**
3 Q. With respect to my question, you can
4 keep in your mind the context of the '127 Patent,
5 but do you agree or disagree with the statement.
6 I will read it again from the transcript.
7 When the patent intends to refer to a
8 full-length protein, it expressly does so by
9 referring to it as a full-length protein?
10 MS. MAYS-WILLIAMS: I object to the
11 form of the question. Asked and answered.
12 **A. So speaking specifically about the '127**
13 **Patent, unlike Dr. Fuller, I did not take issue**
14 **with the court's definition, and a POSA and I**
15 **understood that the patent, the '127 Patent, uses**
16 **the term "spike protein" broadly.**
17 Q. So am I to take that to mean that you
18 agree with my question with respect to the '127
19 Patent?
20 MS. MAYS-WILLIAMS: I object to the
21 form of the question. Asked and answered.
22 Q. Let me ask it this way: Do you agree

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1 that when the patent refers to a full-length
2 protein, it expressly does so by referring to it
3 as a full-length protein?
4 MS. MAYS-WILLIAMS: Asked and answered.
5 **A. So I cover this in depth in my**
6 **declaration, so I will walk through it and**
7 **hopefully this will be very clear. So on page 9**
8 **in my declaration I have a section S Protein, it's**
9 **paragraph 23, and "Dr. Fuller contends that the 'S**
10 **Protein' term of the '127 patent claims**
11 **necessarily refers to a full-length spike protein.**
12 **Dr. Fuller's opinion is not the same language as**
13 **Patent Owner advanced before the District Court,**
14 which I understood adopted (at Patent Owner's
15 urging) the definition that I identified in my
16 opening declaration: 'S protein' means a 'spike
17 protein,' which 'is a structural protein forming a
18 spike'."
19 "In her declaration, Dr. Fuller cites,
20 without explanation, to several sections of the
21 '127 patent expressly referring to a full-length
22 Spike protein. For example, Dr. Fuller refers to

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1 how the '127 patent describes a 'betacoronavirus
2 mRNA vaccine encoding the MERS-CoV full-length
3 Spike protein.' In my opinion, those passages do
4 not support Dr. Fuller's proposed construction.
5 Instead, these passages indicate that when the
6 patent intends to refer to a full-length spike
7 protein, it expressly does so -- by referring to
8 it as a 'full-length' spike protein."
9 A POSA, as I have stated before, would
10 therefore have understood that the patent uses the
11 term "spike protein" more broadly, but in any
12 event, even limiting the S protein to a
13 full-length spike protein, this would not affect
14 my opinion that the challenged claims of the '127
15 patent were already disclosed in the prior art by
16 October 2015.
17 Q. Okay. So I am just going to ask you,
18 are you able to answer the following question yes
19 or no: With respect to the '127 Patent, do you
20 agree that when the patent intends to refer to a
21 full-length spike protein, it expressly does so by
22 referring to it as a full-length spike protein?

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1 MS. MAYS-WILLIAMS: Object to the form
2 of the question. Asked and answered.
3 Q. Are you able to answer that question
4 yes or no?
5 **A. So as I --**
6 MS. MAYS-WILLIAMS: Give me time to
7 object, just for the courtesy of the court
8 reporter. I object to the form of the
9 question. Asked and answered.
10 And I also want to let you know you can
11 use whatever language you feel necessary to
12 provide any context that you think is
13 important in order to provide a fulsome
14 answer.
15 Q. That's all fair, but my question is can
16 you answer it yes or no? That's the only question
17 that's pending right now, can you answer yes or
18 no. And if the answer is no, that's fine, but can
19 you answer it yes or no?
20 **A. So the answer is a full-length**
21 **betacoronavirus spike protein is simply the**
22 **normal, default version of a betacoronavirus spike**

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1 **protein.**
2 Q. So you couldn't answer it yes or no.
3 Let me ask it with respect to the Geall patent.
4 Do you agree that when the patent
5 refers to a full-length protein, it expressly does
6 so by referring to it as a full-length protein?
7 **A. So now we are looking at the Geall**
8 **patent?**
9 Q. Sure.
10 **A. Okay. So as an example, I am here on**
11 **internal pagination 19 of the Geall patent. It's**
12 **in the Coronavirus section. And here we see:**
13 **"The coronavirus immunogen may be a spike**
14 **polypeptide." And as I mentioned, a full-length**
15 **betacoronavirus spike protein is simply the**
16 **normal, default version of a betacoronavirus spike**
17 **protein.**
18 Q. So Geall uses the term "full-length"
19 with respect to an RSV F protein, we looked at
20 that earlier; right?
21 **A. We looked at that terminology earlier.**
22 Q. And Geall never uses the term

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1 "full-length" with respect to a spike polypeptide;
2 correct?
3 **A. I'd have to look through Geall to**
4 **verify that.**
5 Q. As you sit here right now, you can't
6 identify one, can you, a single reference to a
7 full-length spike polypeptide in Geall? I'll
8 withdraw the question. Just in the interests of
9 us getting to our weekend sooner than later. If
10 it's there, it's there. It speaks for itself.
11 Let's shift gears. Okay?
12 MS. MAYS-WILLIAMS: Actually, if we are
13 going to shift gears, how about we take a
14 break?
15 MR. PRUSSIA: Okay. That's fine.
16 (Lunch recess was taken from 1:13 to
17 2:03.)
18 BY MR. PRUSSIA:
19 Q. Okay, doctor. Let's turn to paragraph
20 434 of your second declaration. It's on page 245.
21 **A. Okay. So I am on 245 of my second**
22 **declaration.**

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1 Q. And in that first sentence you make
2 reference to there being no nexus between Spikevax
3 and Comirnaty and the claims of the '127 patent.
4 Do you see that?
5 **A. So here on page 244 I see where I use**
6 **the term "nexus."**
7 Q. Okay. And I'm not asking you for your
8 opinions. I am just going to ask you what do you
9 understand nexus to require in the context of the
10 analysis that you did?
11 **A. So I actually wrote it out to make sure**
12 **I would have this well understood. So as I write**
13 **out here: "In other words, there must be a causal**
14 **correlation," that's the nexus, "between what is**
15 **claimed in the patent and the secondary factors."**
16 **So I understand that to establish this nexus, the**
17 **Patent Owner must show that the claims are**
18 **co-extensive, so they actually are a match with**
19 **the relevant product, and that the evidence of**
20 **secondary considerations is commensurate in scope**
21 **with the claims of the patent.**
22 Q. Okay. And that's the standards you

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1 applied in conducting your analysis, is that -- do
2 I understand that right?
3 **A. So this is the standard, as I outline**
4 **in paragraph 432, that I applied.**
5 Q. And in paragraph 435, in the first
6 sentence you state that you disagree with
7 Dr. Krause's assertion that Spikevax and Comirnaty
8 embody the challenged claims. Do you see that?
9 **A. So I see right here, paragraph 435: "I**
10 **disagree with Dr. Krause's assertion that Spikevax**
11 **and Comirnaty embody the challenged claims."**
12 Q. And I am not asking for you to recite
13 your whole opinion, but just I am asking you
14 specifically with respect to the word "embody,"
15 what do you understand that to require?
16 **A. So much like I lay out in paragraph**
17 **432, that I am disagreeing with Dr. Krause's**
18 **assertion that Spikevax and Comirnaty are**
19 **co-extensive with the patent.**
20 Q. Okay. And with respect to whether they
21 embody the claims, do you have the opinion that
22 any of the limitations -- strike that.

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1 With respect to whether they embody the
2 claims, I didn't see that you offered the opinion
3 that there are claimed limitations that are not
4 present in Spikevax and Comirnaty?
5 MS. MAYS-WILLIAMS: I object to the
6 form of the question. Lacks foundation.
7 **A. Yeah, so as I go through here, I point**
8 **out -- there is sort of two parts to this, but**
9 **Dr. Krause fails to recognize that the claims of**
10 **the '127 are broad, but they are also unbounded.**
11 Q. And you will recall that Dr. Krause
12 included with his declaration a number of
13 appendices that identified claim charts, do you
14 remember that?
15 **A. I remember looking over Dr. Krause's**
16 **material, but yeah, I'd have to reacquaint myself**
17 **with that.**
18 Q. Okay. You didn't prepare any claim
19 charts of your own in response to Dr. Krause;
20 right?
21 **A. I did not prepare any claim charts.**
22 Q. And you don't identify any claimed

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1 limitations that are not present in Spikevax and
2 Comirnaty; right?
3 **A. So as I point out here, I talk about a**
4 **number of the aspects of the mRNA technology such**
5 **as the 2-proline modification and the specific**
6 **mRNA structural features.**
7 Q. And you describe those as unclaimed
8 aspects; right? I am looking at 435. The
9 question is you describe those as unclaimed
10 aspects; right?
11 MS. MAYS-WILLIAMS: Just a reminder,
12 you can look at any part of the declaration
13 you need to look at.
14 **A. I do here very clearly write out:**
15 **"Dr. Krause ignores the numerous unclaimed aspects**
16 of the vaccines' mRNA technology, including (1)
17 the 2-proline modification, (2) specific mRNA
18 structural features, and (3) the lipid
19 nanoparticle composition."
20 Q. And with respect to the claimed aspects
21 of the challenged claims, you don't disagree that
22 they are present in Comirnaty and Spikevax; right?

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1 **A. So I think my wording is a little and**
2 **subtly and importantly different. Here I am**
3 **pointing out unclaimed aspects of the vaccine's**
4 **mRNA technology.**
5 Q. Right. And my question is with respect
6 to the claimed aspects. Okay? Are you with me so
7 far, the claimed aspects?
8 MS. MAYS-WILLIAMS: Objection. Scope.
9 **A. Yeah, I might be missing your question.**
10 Q. I just want to orient that I am not
11 talking about unclaimed aspects, I am talking
12 about claimed aspects. Then I will ask my
13 question. Are you with me that I am talking about
14 claimed aspects so far?
15 **A. Not completely, so -- yeah, but ask**
16 **another question and I will try to follow you.**
17 Q. Okay. With respect to the claimed
18 aspects of the challenged claims, you don't
19 identify any limitation that's not present in
20 Spikevax and Comirnaty; right?
21 (Document review.)
22 **A. So I don't know if this -- if this**

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1 **makes my response a little more clear, but I go on**
2 **to talk about other elements of the vaccine's mRNA**
3 **technology that affect protein translation and**
4 **immunogenicity not claimed in the '127 Patent. I**
5 **also talk about codon optimization.**
6 Q. Okay. As of October 2015, was there a
7 need for a betacoronavirus vaccine?
8 **A. So I address this question on page 258**
9 **in my declaration where I am disagreeing with**
10 **Dr. Krause's opinion that the alleged invention in**
11 **the '127 Patent satisfied a long-felt need. As I**
12 **first explain in Section VIII.A.1-2, Spikevax and**
13 **Comirnaty do not embody the challenged claims, and**
14 **have features that were known in the prior art**
15 **including, for example, the 1-methylpseudouridine**
16 **modification, the full-length spike protein, and**
17 **the lipid nanoparticle composition. Thus, there**
18 **is no nexus between the patents and any**
19 **satisfaction of long-felt need.**
20 **Additionally, there was a need for a**
21 **safe and effective COVID-19 vaccine that first**
22 **arose not in 2015, but with the outbreak of the**

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1 **pandemic in early 2020, and the mRNA vaccines were**
2 **not the only vaccines that met this need. Other**
3 **vaccines became available in response to the**
4 **pandemic as well with comparable efficiency and**
5 **safety. For example, the Spikevax and Comirnaty**
6 **vaccines had comparable efficacy and safety to the**
7 **protein subunit vaccine developed by Novavax, and**
8 **I go into detail. Specifically by June 2021,**
9 **Novavax demonstrated that its vaccine had a**
10 **favorable safety profile and an overall efficacy**
11 **rate of 90.4% at preventing COVID-19, which is**
12 **comparable to Spikevax's efficiency rate of 94.1,**
13 **and Pfizer/BioNTech's efficacy rate of 95%.**
14 **Further, the Novavax impressively was**
15 **shown to be a hundred percent effective at**
16 **preventing moderate to severe disease, 93%**
17 **effective against predominantly circulating**
18 **variants of concern and variants of interest, and**
19 **91% effective in high-risk populations.**
20 **This actually led to on December 20th,**
21 **2021, the European Medicines Agency granting**
22 **conditional marketing authorization for Novavax's**

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1 **vaccine, and on July 13, 2022, the FDA issuing an**
2 **EUA for Novavax's vaccine for individuals 18 years**
3 **and older.**
4 Q. Okay. So you were reading from
5 paragraphs 455 and 456 of your second declaration;
6 right?
7 **A. Yes. I was reading from -- in my**
8 **declaration 258, mostly 455, 456, with slight**
9 **modifications of the text.**
10 Q. Okay. And is that your best answer to
11 my question as to whether there was a need for a
12 betacoronavirus vaccine as of October 2015?
13 **A. That was my best answer.**
14 Q. Okay. Please turn to paragraph 11,
15 page 4.
16 **A. So I'm on page 11.**
17 Q. And you say in this paragraph that you
18 acquired your Ph.D. in molecular medicine in 2012.
19 Do you see that?
20 **A. I might not be on the right page.**
21 **Where are we?**
22 Q. I'm sorry. Paragraph 11, page 4.

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1 **A. I'm on page 4, section 11.**
2 Q. Okay. And you say that your "degree
3 involved drug delivery of nucleic acid drugs
4 (including lipid-based drug delivery systems),
5 vaccines, virology, molecular medicine, and
6 infectious diseases." Did I read that correctly?
7 **A. You read that correctly.**
8 Q. And you prepared a thesis in connection
9 with your degree; right?
10 **A. I prepared a thesis in connection with**
11 **my degree, which focused on the phenotype of human**
12 **B1 cells.**
13 Q. Did your thesis include the delivery of
14 any nucleic acid vaccine?
15 **A. My thesis did not include the delivery**
16 **of any nucleic acid vaccine.**
17 Q. Now, you -- did your counsel tell you
18 that Moderna asked for you to provide your Ph.D.
19 in connection with these proceedings -- I mean
20 your thesis in connection with these proceedings?
21 MS. MAYS-WILLIAMS: Objection to the
22 form of the question.

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1 I just want to caution the witness that
2 you are permitted to provide facts that were
3 given to you in forming the opinions in this
4 declaration, but I caution you otherwise not
5 to reveal the substance of any communications
6 that you had with us in preparing for this.
7 MR. PRUSSIA: Let me ask a different
8 question. Withdrawn.
9 Q. Do you know where your dissertation is?
10 **A. I do not know where a final copy of my**
11 **dissertation is.**
12 Q. Do you have copies other than your
13 final copy?
14 **A. I have drafts of my thesis.**
15 Q. Do you recall the last time you read
16 your thesis?
17 **A. It's been years since I last read my**
18 **thesis.**
19 Q. If you look at paragraph 12, you state
20 in the first sentence: "I have extensive research
21 experience involving nucleic acids, including mRNA
22 specifically." Do you see that?

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1 **A. I see page 4, paragraph 12: "I have**
2 **extensive research experience involving nucleic**
3 **acids, including mRNA specifically."**
4 Q. Then on the next page you identify
5 six -- strike that. You identify five abstracts
6 and a presentation that reflect your work; right?
7 **A. I see here in page 4 and page 5 my**
8 **referencing to a number of presentations.**
9 Q. You refer to a 2014 Infectious Disease
10 Society of New York Annual Meeting, as well as
11 2017, 2018 and 2019 Cold Spring Harbor meetings,
12 as well as presentations in 2014 and 2018 at
13 Columbia University; right?
14 **A. Yes, I see those here in my**
15 **declaration.**
16 Q. Now, did any of those -- strike that.
17 Did any of that work include testing of
18 a nucleic acid vaccine?
19 **A. So none of this work involved testing**
20 **of a nucleic acid vaccine.**
21 Q. Now, at the end of paragraph 12, you
22 cite footnote 8, which is Exhibit 1305. Do you

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1 see that?
2 **A. I see that.**
3 Q. And Exhibit 1305 is a CV that you
4 submitted in connection with your second
5 declaration; right? I can give it to you.
6 **A. I see that 1305 exhibit is an updated**
7 **curriculum vitae. I have two.**
8 Q. There is one in each proceeding.
9 MS. GREENBERG: It's marked with a
10 different IPR proceeding number, but they
11 should be the same.
12 **A. Are they exactly the same? Are they**
13 **exactly the same?**
14 Q. I don't know. You gave them to us.
15 But I guess my question is going to be --
16 **A. They look to be exactly the same.**
17 Q. Okay. You said a minute ago that
18 you -- that they were -- that it's an updated CV.
19 And what do you mean by that?
20 **A. So this CV was prepared August 23rd,**
21 **2024. And so I periodically update my CV. For**
22 **instance, I published another article this week,**

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so when I get a chance, I will update my CV and include the accepted publication in my list of publications.

Q. Did you do anything more than just add new publications?

A. I actually went through the entire CV, a lot of like spelling and making sure that it was correct and a little more thorough.

Q. And among the things you did was add descriptions to some of the abstracts and presentations; right?

A. I did go ahead and expand adding descriptions to a number of the presentations, and also I think I expanded on some of the work I had done.

Q. Why did you do that?

A. I felt that by -- rather than just presenting titles, if I expanded and explained a little more about what I was working on, that the CV would be more instructive, more informative.

Q. Okay. With respect to the six -- strike that.

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With respect to the abstracts and the presentations that you describe in paragraph 12, why didn't you just cite to those directly in your declaration as opposed to citing to the description of them that's in your updated CV?

MS. MAYS-WILLIAMS: Objection. Vague.

A. It seemed like a very clear way to reference this material without having to put in every single reference.

Q. Okay. Let's look at page 19 of your CV.

A. I'm on page 19. The Case Reports and Abstracts sections.

Q. Okay. And under the Abstracts section, there are the three -- the first three that are listed are the three from the Cold Spring Harbor meeting that you describe in paragraph 12 of your declaration; right?

A. Yes, I see these first three abstracts.

Q. And we also see as number 4 the 2014 Infectious Disease Society of New York Annual Meeting abstract that you describe in paragraph 12 of your declaration; right?

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A. Yes, I also see here it's number 4, 2014 Infectious Disease Society of New York Annual Meeting.

Q. Then we also see the 2014 Columbia University Stem Cell Initiative abstract that's described in paragraph 12 of your declaration; right?

A. I see here number 5.

Q. Number 5. Thank you. You can turn a couple pages over to 21. Entry 28 is the presentation that you -- the 2018 presentation that you describe in paragraph 12 of your declaration; right?

A. Yes, I see here 28 under Presentations.

Q. Okay. So you have your original CV that you submitted with your first declaration in front of you; is that right, sir?

A. So I have here in front of me Exhibit 1003, which is my CV preparation dated a year before, August 23rd, 2023.

Q. I noticed that myself too.

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Coincidental. The only thing I am asking you to do is in the original CV -- strike that.

The descriptions that you added in your new CV were not included in your original CV with respect to the abstracts and the presentations that we just looked at; right?

A. Yeah, in my original CV, this is Exhibit 1003, prepared August 23rd, 2023, under my abstracts I merely mention the conference and the titles, but no explanation regarding what I was presenting.

Q. Okay. And the descriptions that are in the new CV, the updated CV, you added those descriptions; right?

A. I added the descriptions in my new CV.

Q. And do those descriptions accurately describe your work as reflected in the underlying abstracts and presentations?

A. These do accurately describe.

Q. I am going to focus on the abstract that's listed as entry 1 in your updated CV. 2019 Cold Spring Harbor abstract poster. Do you see

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1 that?
2 **A. So we are in the 2024, we are in which**
3 **section?**
4 Q. It's the Abstracts section that starts
5 at page 19.
6 **A. Okay. So here I am, I am on page 19 of**
7 **24 of the 2024, and I have 2019.**
8 Q. And this is the 2019 Cold Spring Harbor
9 Retroviruses Meeting Abstract/Poster; right?
10 **A. This was an abstract and a poster, yes.**
11 Q. Now, this abstract does not describe
12 introducing mRNA into cells; right?
13 **A. So at the 2019 Cold Spring Harbor**
14 **Retrovirus Meeting, my poster discussion I shared**
15 **the results of introduction of mRNA and siRNA**
16 **using electroporation introduction into primary**
17 **hematopoietic human stem and hematopoietic**
18 **progenitor cells on expression levels and**
19 **lentiviral nuclear entry.**
20 Q. And you just read from the description
21 that's written in your updated CV; right?
22 **A. This is the description in my 2024**

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1 **updated CV.**
2 Q. But I am asking you the abstract
3 itself, it does not disclose introducing mRNA into
4 cells, does it?
5 **A. I'd have to look at the abstract and**
6 **the poster, as well as reference the discussion of**
7 **the 2019 meeting.**
8 Q. (Handing.)
9 MS. MAYS-WILLIAMS: Again, this is an
10 exhibit that has not been previously marked
11 and so I am going to object as hearsay and on
12 the basis of relevance.
13 Q. So this is --
14 MS. MAYS-WILLIAMS: And outside the
15 scope of the opinions offered in the reply
16 declaration.
17 Q. So this is the 2019 abstract that's
18 referenced in your CV; right?
19 MS. MAYS-WILLIAMS: Sorry, and to
20 further avoid continuing to interrupt the
21 questioning attorney, I will just make a
22 standing objection as to every question

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1 regarding this document.
2 Q. I will restate my question. The
3 objection will carry.
4 This is the 2019 abstract that's
5 referenced in -- as number 1 in your CV; right?
6 **A. So the bottom part of this abstract is**
7 **where I reference the further experiments are**
8 **currently underway to determine specific points in**
9 **the retroviral life cycle that are affected by**
10 **electroporation to give a more detailed view into**
11 **this poorly understood phenomenon, and then this**
12 **work actually later results in a publication.**
13 Q. Okay. Focusing on this abstract, it
14 describes transfection of cells with DNA via
15 electroporation; right?
16 **A. This research does involve**
17 **electroporation.**
18 Q. There is no mention of mRNA anywhere in
19 the abstract; right?
20 **A. So as I pointed out, the further**
21 **experiments that I am referring to are the ones**
22 **where we are looking at introduction of mRNA and**

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1 **siRNA.**
2 Q. Okay. I am focusing, sir, on this
3 abstract. This abstract there is no mention of
4 mRNA anywhere in it; right?
5 **A. I think the subtle difference between**
6 **what you are suggesting and what I am pointing out**
7 **is I don't use the word mRNA or siRNA, but I refer**
8 **here to the further experiments, which involved**
9 **mRNA and siRNA.**
10 Q. Okay. The abstract does not disclose
11 the delivery of mRNA into cells; right?
12 **A. The abstract does not disclose, but it**
13 **does refer to experiments that involve the**
14 **delivery of mRNA into cells.**
15 Q. Now, if you go to entry 28 of your CV,
16 this is the presentation that we looked at
17 earlier, on the page 20 I think it is.
18 **A. Okay.**
19 Q. Page 21. Sorry.
20 **A. And which number?**
21 Q. Entry 28.
22 **A. Yes, here is 28.**

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1 Q. This is the 2018 presentation to the
2 Columbia University Stem Cell Initiative; right?
3 **A. I see that here.**
4 Q. Does this presentation include some of
5 the later work that you were just referring to in
6 your testimony?
7 MS. MAYS-WILLIAMS: Objection. Vague.
8 **A. So this work presented here precedes**
9 **the work that was presented in 2019. This**
10 **presentation was given in the spring of 2018.**
11 Q. Okay. So as of 2015, you hadn't done
12 that work?
13 **A. So the work that I did in 2018 I had**
14 **not done prior to 2015.**
15 Q. Now, in the work described in the 2018
16 presentation that's identified here as number 28,
17 you did not actually introduce mRNA into the
18 cells, you don't disclose that in your
19 presentation; right?
20 **A. So at this presentation I did share**
21 **preliminary data regarding the introduction of**
22 **mRNA and siRNA into primary hematopoietic human**

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1 **stem and progenitor cells and discussed the impact**
2 **on expression levels and lentiviral nuclear entry.**
3 Q. The date -- the presentation, it shows
4 testing of RNA expression levels in the cell;
5 right?
6 **A. So in this presentation I shared the**
7 **results of an RNAseq screen which looked at mRNA**
8 **levels of cytoskeletal proteins.**
9 Q. But you didn't actually introduce mRNA
10 expressing whatever the host proteins were into
11 the cell; isn't that right?
12 **A. So when I presented this work in**
13 **4/2018, I had already performed experiments**
14 **looking at introduction of mRNA and siRNA into**
15 **human primary cells, I had done those experiments,**
16 **and I did discuss and share the impact on these**
17 **primary cells.**
18 Q. You weren't -- strike that.
19 You weren't testing delivery of an mRNA
20 encoding a foreign antigen; right?
21 **A. So maybe to help answer this, it's**
22 **probably helpful to give the context in which this**

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1 **work was done so I don't have to spend the entire**
2 **afternoon, and so just to give the context and**
3 **maybe this is helpful, I feel like it will be,**
4 **when I finished my Ph.D., 2012, I had identified a**
5 **phenotype of the human B1 cell. The human B1 cell**
6 **is the source of the broadly neutralizing**
7 **antibody, sort of the Holy Grail of vaccine**
8 **science. At that point there really were two**
9 **avenues of research: Can one present an antigen**
10 **in such a way to get the B cells to make those**
11 **broadly neutralizing antibodies, or does someone**
12 **have to rely on monoclonal antibody technology.**
13 **So what is an infectious disease-focused person**
14 **interested in B cell biology with training in**
15 **molecular biology doing working with lentiviral**
16 **factors? And to give this context, I'm looking at**
17 **moving away from just providing passive**
18 **vaccination with monoclonal antibodies to**
19 **different ways of delivering nucleic acids to**
20 **promote protein production, and as we can see**
21 **here, I am demonstrating repeatedly the challenges**
22 **of DNA-based introduction, showing that it is**

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1 **quite different in human cells than mouse cells,**
2 **demonstrating that there are major challenges in**
3 **trafficking. It's easy to get into the cytoplasm,**
4 **but in the human system the major challenge to DNA**
5 **approaches is nuclear entry. So a lot of this**
6 **work I discuss in the context of my declaration**
7 **why in 2015 we were already aware of and building**
8 **on concerns about trying to use DNA rather than**
9 **RNA to produce proteins for our vaccine**
10 **strategies.**
11 Q. Done with your answer? Okay.
12 So you were studying the expression
13 levels of the host cell's endogenous mRNA?
14 **A. So I think as I laid out here, I had**
15 **hoped it was very clear, in looking at different**
16 **ways of producing protein using nucleic acid**
17 **technology, I had actually developed a tracking**
18 **system to look at where those nucleic acids were**
19 **being delivered, showing that it was easy to**
20 **deliver nucleic acids to the cytoplasm, and here I**
21 **am actually using a lentivirus, which is an RNA**
22 **virus, so I am delivering RNA to the cytoplasm,**

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1 **and then I am showing the challenges of getting**
2 **that into the nucleus. And I do several things**
3 **with RNA. One is I have introduced it to the**
4 **cytoplasm in the context of the lentiviral vector.**
5 **Then I am looking at why it's not trafficking to**
6 **the nucleus, what are the challenges. I am**
7 **looking at levels of RNA in a screen, and then I**
8 **am introducing mRNA to over-express and siRNA to**
9 **downregulate RNA.**
10 Q. So none of the work that you just
11 described involved testing any nucleic acid
12 vaccine containing genes for a viral protein of
13 interest; right?
14 **A. So none of this research specifically**
15 **involved testing of an mRNA vaccine construct or**
16 **nucleic acid vaccine construct.**
17 Q. And it didn't involve extrapolating
18 results from DNA to make predictions regarding
19 results that you would expect to see with
20 non-replicating mRNA; right?
21 MS. MAYS-WILLIAMS: Object to the form
22 of the question. Vague. Are you just

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1 referring to the references that you are
2 discussing now or his experience more
3 generally?
4 MR. PRUSSIA: The abstracts and
5 presentations we have been talking about for
6 the past ten minutes.
7 **A. So the research that we are focusing on**
8 **specifically speaks to the challenges of using**
9 **different types of nucleic acid modalities to**
10 **express proteins and, as we have discussed before,**
11 **critical to any active vaccination strategy, as**
12 **opposed to a passive vaccination strategy,**
13 **particularly if it's nucleic acid based, is to get**
14 **the nucleic acid to the right location for protein**
15 **production.**
16 Q. You weren't making predictions for mRNA
17 based on results you saw with DNA or any other
18 nucleic acid technology; right?
19 (Document review.)
20 **A. So this research that I am discussing**
21 **specifically speaks to my comments that unlike DNA**
22 **vaccines, mRNA vaccines do not need to be**

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1 **transported across the nuclear membrane, but can**
2 **be translated to protein in the cytosol of the**
3 **cell, so really demonstrating the challenges with**
4 **DNA where the field is particularly excited about**
5 **mRNA vaccines because they don't require**
6 **transporting the cargo nucleic acid across the**
7 **nuclear membrane. You can see this is a critical**
8 **issue in vaccine development that I have actually**
9 **developed and I am sharing at meetings, abstracts**
10 **and publications the challenges with getting DNA**
11 **into the nucleus for expression, and here I am**
12 **using a lentiviral vector, so actually starting**
13 **with RNA, getting that into the cytoplasm, and**
14 **then showing these challenges which were really**
15 **what a POSA in 2015 would be thinking about when**
16 **they were considering DNA vaccines versus mRNA**
17 **vaccines.**
18 MR. PRUSSIA: Strike that -- move to
19 strike as not responsive.
20 Q. Just to be clear, the six references we
21 have been talking about, none of them are
22 printed -- strike that.

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1 The six references we have been talking
2 about, none of them appeared in a peer-reviewed
3 publication; right?
4 MS. MAYS-WILLIAMS: Objection. Lacks
5 foundation.
6 **A. So much of the work discussed in these**
7 **abstracts and presentations actually led to the**
8 **publication that I list in my CV on page 16, and**
9 **this is 22 where I publish Successfully**
10 **Transfected Primary Peripherally Mobilized Human**
11 **CD34 Positive Hematopoietic Stem and Progenitor**
12 Cells (HSPCs) Demonstrate Increased Susceptibility
13 to Retroviral Infection. So really adding another
14 potential wrinkle and concern to DNA vaccine
15 technology where showing that if you actually
16 successfully introduce the DNA into the nucleus,
17 in addition to all the other concerns, you have
18 actually now seen and associate with increased
19 susceptibility to retroviral infection.
20 Q. Which publication are you referring to
21 there?
22 **A. So this is page 16 of 24, and this is**

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1 **publication 22, and this was published in the**
2 **Virology Journal.**
3 Q. What's the date?
4 **A. This was published in 2020.**
5 Q. Okay. You can put that to the side.
6 What does cellular immune response
7 refer to?
8 **A. So an immunologist in general would**
9 **make a distinction between a humoral immune**
10 **response, which refers to antibodies in general,**
11 **but probably also includes complement, and**
12 **cellular, which is mainly focused on T cells, but**
13 **I will say that is very simplified.**
14 Q. And do all vaccines elicit the same
15 type of immune response?
16 **A. Different vaccines can produce**
17 **different immune responses.**
18 Q. For vaccines against infectious agents,
19 what type of immune response is most important?
20 **A. So it would depend upon which pathogen**
21 **we were targeting what type and what part of the**
22 **immune system was most important.**

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1 Q. Generally as between the humoral immune
2 response and the cellular immune response, which
3 is more important for vaccines against infectious
4 agents?
5 **A. It ultimately comes down to each**
6 **specific pathogen. So for instance, if you were**
7 **developing a hookworm or an intestinal parasite**
8 **platform, you would want the generation of**
9 **humoral, and particularly secretory IgA responses.**
10 Q. For cancer vaccines, what type of
11 immune response is generally considered most
12 important?
13 **A. Sort of vague, because in general sort**
14 **of sounds like we are looking for a, you know,**
15 **what do a lot of people think, so a very general**
16 **question.**
17 Q. You can't answer that question?
18 **A. Can you ask a more specific, is there a**
19 **specific cancer you were interested?**
20 Q. So no, actually, there is no specific
21 cancer I am interested in. So I am asking you as
22 someone who holds himself out as a POSA, whether

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1 as of 2015 it was known that there was a certain
2 type of immune response that was considered most
3 important for cancer vaccines?
4 MS. MAYS-WILLIAMS: Objection. Vague.
5 **A. It's very vague, but I can speak as a**
6 **POSA. There was a paradigm introduced in the**
7 **1980s talking about particular types of T cell**
8 **responses, Th-1, Th-2. Since, the paradigm has**
9 **become much more sophisticated, but among these**
10 **responses, part of a Th-1-type response is the**
11 **production of cytotoxic T cells. Certain people**
12 **consider the cytotoxic T cell response to be the**
13 **most critical, but there is a growing amount of**
14 **information that the humoral response and**
15 **particularly the targeting of tumor neoantigens**
16 **with antibodies may actually turn out to be a**
17 **successful approach.**
18 Q. When you say "a growing amount of
19 information," as of when?
20 **A. So the paradigm started back in 1986 as**
21 **described, but already a conference I attended in**
22 **Cuba, much of the focus of that discussion was on**

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1 **antibody, human B1 cell derived antibodies for**
2 **tumor therapeutics.**
3 Q. To achieve successful immunization
4 against cancer or against an infectious disease,
5 would a POSA seek to elicit different types of
6 immune responses for each?
7 MS. MAYS-WILLIAMS: Objection. Vague.
8 **A. So again, as I point out, the type of**
9 **immune response would depend upon the type of**
10 **pathogen or the type of cancer. And just to give**
11 **this context, getting us prior to 2015, in my CV,**
12 **this is the updated 2024 version, I actually refer**
13 **to -- this is page 20, this is in the abstract --**
14 **to an abstract presentation in 2012 in Havana,**
15 **Cuba where the conference is actually based on**
16 **looking at natural antibodies, and this conference**
17 **specifically looked at cancer immunotherapies. So**
18 **in certain cancers, and this goes back to 2012,**
19 **one would be interested in producing particularly**
20 **broad neutralizing natural antibodies.**
21 Q. Would an mRNA encoding a cancer protein
22 be expected to elicit the same type of immune

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1 response as an mRNA encoding a viral protein?
2 MS. MAYS-WILLIAMS: Objection. Vague.
3 **A. Only at a very broad level. One would**
4 **expect -- by 2015 a POSA would expect a particular**
5 **Th-1 skew to using nucleic acid technology for the**
6 **delivery, and then you would produce a different**
7 **antigen depending upon which antigen your mRNA was**
8 **coded for.**
9 Q. Shift gears a little bit.
10 Are you familiar with the term
11 "prophetic example"?
12 **A. I don't know if I am. It sounds**
13 **familiar, but I am not sure I am fully versed in**
14 **it.**
15 Q. Fair enough. If you want to take a
16 look at the -- let's give him 5.
17 THE WITNESS: Is this a good time for a
18 break?
19 MR. PRUSSIA: Sure.
20 (Recess was taken from 2:59 to 3:13.)
21 BY MR. PRUSSIA:
22 Q. We gave you both patents just to sort

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1 of offload our weight going back, but you can
2 focus on the '127 and I am going to ask you to
3 turn to Example 20.
4 **A. Do you want to give me a page number?**
5 Q. I don't remember. You think we would
6 all memorize it by now, but it's in the 200s.
7 **A. Whoever finds it first, let me know.**
8 MR. MEUTH: 213 is what's coming to
9 mind.
10 THE WITNESS: Page 213?
11 MS. GREENBERG: Column.
12 **A. So what example are we looking at?**
13 Q. 20.
14 **A. Example 20. Okay. So I am here. It's**
15 **Column 216, I have Example 20, Betacoronavirus**
16 **Immunogenicity Study.**
17 Q. Okay. And you can take a moment to
18 read it to yourself and just let me know when you
19 are done.
20 (Document review.)
21 **A. Okay. So I have read this Example 20.**
22 Q. Okay. So my question is does Example

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1 20 of the patent, the '127 Patent, disclose an
2 mRNA vaccine for a betacoronavirus that a POSA
3 would reasonably expect would provide protective
4 immunity?
5 (Document review.)
6 **A. I am seeing here the description of a**
7 **study to test the immunogenicity of candidate**
8 **betacoronavirus vaccines comprising an mRNA**
9 **polynucleotide including the spike protein, and I**
10 **am also seeing a mention of lipid nanoparticles.**
11 Q. And so my question is does the
12 disclosure in Example 20 provide a reasonable
13 expectation for a POSA that the mRNA vaccine would
14 provide protective immunity?
15 **A. We are not getting a lot of**
16 **information, we are just getting a study design**
17 **here, so as mentioned, this is a study designed to**
18 **test the immunogenicity in rabbits of a candidate**
19 **betacoronavirus encoding the spike protein, the S1**
20 **subunit of the spike protein or the S2 subunit of**
21 **the spike protein.**
22 Q. So does it provide a reasonable

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1 expectation to the POSA that it would work to
2 provide protective immunity when administered?
3 (Document review.)
4 **A. I am still left in the same situation**
5 **where I am seeing here that Column 216, Example**
6 **20, is describing the design of an experiment.**
7 Q. So is there more that you would need to
8 know whether what's disclosed here would provide a
9 reasonable expectation to the POSA?
10 **A. I'd say even as someone designing an**
11 **experiment, it would be nice to have a little more**
12 **detail of the methods.**
13 Q. What additional information would you
14 need?
15 **A. So for instance, here they talk about**
16 **the vaccine comprising mRNA polynucleotide, but we**
17 **are not getting a lot of detail about that**
18 **construction.**
19 Q. What do you mean by that?
20 **A. So really what I am going back to is**
21 **this is really just describing we are going to do**
22 **an experiment.**

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1 Q. So what additional information --
2 strike that.
3 Would a person of skill in the art need
4 additional information to know whether what's
5 disclosed in Example 20 would provide a reasonable
6 expectation that the mRNA vaccine would provide
7 protective immunity?
8 **A. So I think there is several aspects of**
9 **your question. I will break them down and**
10 **hopefully this answers. So they start by talking**
11 **about mRNA and they start by coding -- encoding a**
12 **spike protein. So -- well, no, and I am just**
13 **going to use 2015, which is fine. When was this**
14 **put out? 2021. So well before 2021, so we will**
15 **say 2015 is fine, because much of my declaration**
16 **focuses on that. There is a number of things that**
17 **they are talking about that are already known at**
18 **this point. So reading this, even if we read it**
19 **back in 2015, they start off by talking about**
20 **using mRNA, and we have a lot of information about**
21 **how to create that mRNA. They next talk about**
22 **spike protein, and well before 2021 known in the**

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1 **art by 2015 a POSA would have reasonably expected**
2 **to synthesize mRNA encoding for a betacoronavirus**
3 **S protein using methods well known in the art by**
4 **2015, and a POSA would have had reason -- would**
5 **have been reasonably expected to induce immune**
6 **response using an mRNA vaccine encoding for a**
7 **betacoronavirus S protein.**
8 Q. Are you done with your answer?
9 **A. Uh-huh.**
10 Q. Okay. So I'm not sure I understand.
11 I'm not sure I know if you actually answered my
12 question.
13 So my question was just based on
14 Example 20, would the POSA have a reasonable
15 expectation that the mRNA vaccine would work to
16 provide a protective immune response?
17 MS. MAYS-WILLIAMS: Objection. Asked
18 and answered.
19 **A. Yeah, as I -- as I explained, reading**
20 **this even as far back as 2015, they are basically**
21 **describing things that were known, they are**
22 **describing that they have an mRNA nucleotide**

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1 **encoding a spike protein, so a POSA would**
2 **reasonably have expected to synthesize or be able**
3 **to synthesize an mRNA encoding for a**
4 **betacoronavirus S protein. Methods were well**
5 **known as far back as 2015. We also knew that this**
6 **approach would produce an immune response.**
7 **So I would say before reading this in**
8 **2021 a person would -- a POSA would already**
9 **understand that if you synthesized an mRNA**
10 **encoding for a betacoronavirus S protein, a POSA**
11 **would have reasonably expected to induce an immune**
12 **response using an mRNA vaccine as described here.**
13 Q. Okay. You said an immune response.
14 Would the POSA have a reasonable
15 expectation that it would generate a protective
16 immune response?
17 **A. I think the only lack of clarity would**
18 **be how protective. We knew at this point that**
19 **S RNA from the betacoronavirus, the spike protein,**
20 **was the best target. We knew that nucleic**
21 **acid-based vaccines could provoke an appropriate**
22 **Th-1, Th-2 skewed immune response. So one would**

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1 **expect an immune response. And then it would be**
2 **just a question of what dosing and what level of**
3 **protection.**
4 Q. Okay. What is your understanding of
5 what is required to show a reasonable expectation
6 of success in the context of obviousness?
7 (Document review.)
8 **A. Okay. If you could ask that question**
9 **again.**
10 Q. What is your understanding of what is
11 required to show a reasonable expectation of
12 success in the context of obviousness?
13 (Document review.)
14 **A. So my understanding is that reading**
15 **through, a person of skill in the art would have**
16 **seen the components so arranged so that they would**
17 **have the ability to view with optimism the success**
18 **of creating the said item and then the item**
19 **actually resulting in some sort of impact.**
20 Q. What do you mean when you say "the item
21 actually resulting in some sort of impact"?
22 **A. So particularly with claim to the '127**

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1 **Patent versus the '600 Patent, it's any amount of**
2 **immune response.**
3 Q. Does having a hypothesis that the
4 vaccine may elicit any amount of immune response
5 equate to a reasonable expectation that the
6 vaccine will do so in your mind?
7 (Document review.)
8 **A. So I think as we read through, Schrum,**
9 **for instance, gives us mRNA and a POSA in 2015 is**
10 **familiar with what we know about mRNA and its**
11 **ability to express protein. If we are given the**
12 **lipid nanoparticle, if we are given the antigen,**
13 **as we are from Geall, I don't believe that a**
14 **working example of that specific complex is**
15 **required.**
16 Q. Okay. Is that your best answer to my
17 question?
18 **A. That's my best answer.**
19 Q. In your opinion, do the claims --
20 strike that.
21 When you conducted your analysis for
22 whether there was a reasonable expectation of

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1 success, did you interpret the claims to allow for
2 any immune response or for -- or require a
3 protective immune response?
4 **A. I felt that based on Schrum's**
5 **disclosure, a POSA would understand the spike**
6 **protein to induce an immune response specific to**
7 **the beta-CoV S protein.**
8 Q. Is that your best answer to my
9 question?
10 **A. That is my best answer to your**
11 **question.**
12 Q. All right. Just a few more questions.
13 First, before I ask those questions,
14 before I forget, because it's on my mind, did you
15 during any of the breaks today, did you talk to
16 counsel about the subject matter of your
17 testimony?
18 **A. I did not.**
19 Q. Let me ask you this: I think -- so
20 prior to 2015, can we agree that there was no
21 non-replicating mRNA vaccine for betacoronavirus
22 that was known to have been tested in the prior

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1 art?
2 **A. So when I went through as a POSA in**
3 **2015 and looked at different vaccine formulations,**
4 **I only cited of the mRNA vaccines the**
5 **self-replicating.**
6 Q. Okay. So prior to 2015, you weren't
7 able to identify prior to 2015 a non-replicating
8 mRNA vaccine that had been tested for
9 betacoronavirus; right?
10 **A. So I would have to review my lengthy**
11 **declaration, but I do not, sitting here, recall**
12 **referencing a non-self-replicating mRNA vaccine.**
13 Q. Okay. And that is with respect to
14 either in vivo testing or otherwise; right?
15 **A. So I think it's the same answer. When**
16 **I was preparing this declaration, putting myself**
17 **in the position of a POSA in 2015, I do not recall**
18 **referencing any non-replicating mRNA vaccines in**
19 **my declaration.**
20 Q. And so the effective amount of mRNA
21 that would be required to generate a protective
22 immune response to a betacoronavirus, that was not

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1 something that had been tested and determined as
2 of 2015; right?
3 **A. So in 2015 a POSA would not have known**
4 **the exact mRNA content required to produce a**
5 **specific SARS coronavirus immune response.**
6 MR. PRUSSIA: Okay. I just need to
7 designate the transcript under the protective
8 order because of the fact that materials that
9 were discussed were under seal. We will
10 pass.
11 MS. MAYS-WILLIAMS: Take a quick break.
12 (Recess was taken from 3:40 to 4:02.)
13 MS. MAYS-WILLIAMS: I do have a couple
14 of questions for you, Dr. Griffin.
15 EXAMINATION BY
16 MS. MAYS-WILLIAMS:
17 Q. Do you recall being asked before the
18 break about the effective amount of mRNA that
19 would be required to generate a protective immune
20 response to a betacoronavirus?
21 **A. I remember being asked that question**
22 **before the break.**

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1 Q. In 2015, would a POSA have expected to
2 be able to express the S protein with an mRNA
3 construct?
4 **A. In 2015, a POSA would have had the**
5 **reasonable expectation that they could use an mRNA**
6 **construct to express the S protein.**
7 Q. You just used the phrase "reasonable
8 expectation." Would a POSA have a reasonable
9 expectation that mRNA construct expressing the S
10 protein to have generated some level of
11 neutralizing antibodies?
12 **A. Yes, a POSA would have.**
13 Q. Why?
14 **A. So as I outline in my declaration, in**
15 **2015 a POSA would have been well aware of the**
16 **advances in mRNA and they would have reasonably**
17 **expected to synthesize an mRNA encoding a**
18 **betacoronavirus S protein using methods known in**
19 **the art by 2015, and again, as I outline in my**
20 **declaration, a POSA would have reasonably expected**
21 **to induce an immune response using an mRNA vaccine**
22 **encoding for a betacoronavirus S protein.**

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1 Q. Would a POSA have been able to
2 determine the effective amount required to
3 generate that immune response through routine
4 experimentation?
5 MR. PRUSSIA: Objection. Asked and
6 answered.
7 **A. So that's -- you are asking a slightly**
8 **different question. And as I responded before,**
9 **in 2015 a POSA did not -- would not know the**
10 **exact microgram amount of mRNA to use and would**
11 **actually be required to perform routine**
12 **experiments to determine the appropriate amount**
13 **of RNA payload.**
14 Q. You mentioned requiring performance of
15 routine experimentation; correct?
16 **A. I did.**
17 Q. Would a POSA have known how to perform
18 these routine experiments that you mentioned in
19 2015?
20 **A. In 2015 a POSA would have known how to**
21 **perform those routine experiments.**
22 MS. MAYS-WILLIAMS: Pass the witness.

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1 FURTHER EXAMINATION BY
2 MR. PRUSSIA:
3 Q. So the experiments that you just
4 testified to -- strike that.
5 The experiments that you just testified
6 to, there was no such testing disclosed in the
7 prior art; correct?
8 **A. That is correct, no such specific**
9 **dosing experiments were disclosed in the prior**
10 **art.**
11 Q. And in the about 25-minute break that
12 you took with counsel, did you have a conversation
13 with counsel about your redirect?
14 **A. So we, again, followed the rules, did**
15 **not discuss any of the content of my testimony.**
16 Q. Did counsel tell you that she was going
17 to do a redirect?
18 **A. She did tell me she was going to do a**
19 **redirect, which I was not happy about, but...**
20 Q. Fair enough. I just have to ask: Did
21 she tell you what she was going to ask you about?
22 MS. MAYS-WILLIAMS: I am going to

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1 actually instruct the witness not to answer
2 that question.
3 MR. PRUSSIA: Okay.
4 Q. Are you going to follow your counsel's
5 instruction?
6 **A. I will follow my counsel's instruction.**
7 Q. Okay. Did you practice any questions
8 during the 25-minute break?
9 MS. MAYS-WILLIAMS: I am going to
10 instruct the witness not to answer that
11 question.
12 Q. Are you going to follow your counsel's
13 instruction?
14 **A. I will follow my counsel's instruction.**
15 MR. PRUSSIA: I'm done. I think that's
16 it.
17 MS. MAYS-WILLIAMS: Take a very brief
18 break. I think I am done.
19 MR. PRUSSIA: I think actually you are
20 done, because under the rules it's just
21 cross, redirect, re-cross. I think it's like
22 7, 4, 1, or something like that, that's all

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1 you are allowed to do. 7, 4, 2. I mean, I
2 don't want to be a jerk, but I
3 think that's --
4 MS. MAYS-WILLIAMS: It's fine. Off the
5 record.
6 (Time noted: 4:08 p.m.)
7
8
9 ----------
10 DANIEL O. GRIFFIN, M.D., Ph.D.
11
12
13 Subscribed and sworn to before me
14 this day of 2024.
15
16 ----------
17
18
19
20
21
22

150

1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC
2
3 I, Kristin Koch, Court Reporter and
4 Notary Public within and for the State of New
5 York do hereby certify:
6 That Daniel O. Griffin, M.D. Ph.D., the
7 witness whose deposition is hereinbefore set
8 forth, was duly sworn by me before the
9 commencement of such deposition and that such
10 deposition was taken before me and is a true
11 record of the testimony given by such
12 witness.
13 I further certify that the adverse
14 parties, BioNTech SE and Pfizer Inc., were
15 represented by counsel at the deposition.
16 I further certify that the deposition
17 of Daniel O. Griffin, M.D. Ph.D. occurred at
18 the offices of Paul Hastings, LLP, 200 Park
19 Avenue, New York, New York, on Friday,
20 September 20, 2024, commencing at 9:39 a.m.
21 to 4:08 p.m.
22 I further certify that I am not related

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1 to any of the parties to this action by blood
2 or marriage, I am not employed by or an
3 attorney to any of the parties to this
4 action, and that I am in no way interested,
5 financially or otherwise, in the outcome of
6 this matter.
7 IN WITNESS WHEREOF, I have hereunto set
8 my hand this 28th day of September, 2024.
9
10 Kristin Koch
11 Notary Public in and for the State of
12 New York.
13
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