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Transcript of James J. Moon, Ph.D.

Date: September 13, 2024

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

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Moderna 2254

BioNTech-Pfizer v. Moderna
IPR2023-01358

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Conducted on September 13, 2024

1 (1 to 4)

1	1	3
1	UNITED STATES PATENT AND TRADEMARK OFFICE	1
2	-----	2
3	BEFORE THE PATENT TRIAL AND APPEAL BOARD	3
4	-----	4
5	BIONTECH SE AND PFIZER INC.,	5
6	Petitioners,	6
7	v.	7
8	MODERNA TX, INC.,	8
9	Patent Owner.	9
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11	IPR2023-01359	11
12	U.S. Patent 10,933,127	12
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14	DEPOSITION OF JAMES J. MOON, PH.D.	14
15	Washington, D.C.	15
16	Friday, September 13, 2024	16
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18		18
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21	Pages 1 - 90	21
22	Reported by: Joan V. Cain	22
2	2	4
1	Deposition of JAMES J. MOON, PH.D., held at	1
2	the law offices of:	2
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15	District of Columbia.	15
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1 A P P E A R A N C E S C O N T I N U E D	1 E X H I B I T S C O N T I N U E D
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5 J a c o b D . M o o r e , P h . D . , E s q u i r e	5 J a m e s J . M o o n , P h . D . f o r
6 S e n i o r C o u n s e l , I n t e l l e c t u a l P r o p e r t y	6 U . S . P a t e n t N o .
7 M o d e r n a T X , I n c .	7 10,933,127, 8/30/24
8	8 E X H I B I T 1161 R e s p o n s i v e D e c l a r a t i o n o f 10
9	9 J a m e s J . M o o n , P h . D . f o r
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1 C O N T E N T S	1 E X H I B I T S C O N T I N U E D
2 E X A M I N A T I O N O F J A M E S J . M O O N , P H . D . P A G E	2 M O D E R N A P R E V I O U S L Y M A R K E D E X H I B I T S R E F E R E N C E D
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4	4 N o v e l , D i s r u p t i v e
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9 M o o n , P h . D . f o r U . S .	9 E X H I B I T 2077 S c h o l a r l y A r t i c l e : 79
10 P a t e n t N o . 10,933,127 ,	10 B i o m a t e r i a l s f o r
11 8/25/23	11 N a n o p a r t i c l e V a c c i n e
12 E X H I B I T 1004 D e c l a r a t i o n o f J a m e s J . 10	12 D e l i v e r y S y s t e m s , S a h d e v ,
13 M o o n , P h . D . f o r U . S .	13 e t a l . , 5/22/14
14 P a t e n t N o . 10,702,600 ,	14 E X H I B I T 2078 S c h o l a r l y A r t i c l e : 74
15 8/25/23	15 N o n - v i r a l C O V I D - 19 V a c c i n e
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18 2013/0266640 A1	18
19 E X H I B I T 1010 I n t e r n a t i o n a l P a t e n t 68	19
20 A p p l i c a t i o n N o . W O	20
21 2012/006369 A2, 1/12/12	21
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9 1 PROCEEDINGS 2 --- 3 9:05 a.m. EDT 4 September 13, 2024 5 --- 6 Whereupon, 7 JAMES J. MOON, PH.D., 8 having been duly sworn under penalties of perjury by 9 the Notary Public, was examined and did testify as 10 follows: 11 EXAMINATION BY COUNSEL FOR PATENT OWNER 12 MODERNA TX, INC. 13 BY MR. DANFORD: 14 Q Good morning. Could you please state your 15 name for the record. 16 A James Moon. 17 Q Dr. Moon, it's nice to meet you. My name's 18 Andrew Danford. I'm one of the lawyers representing 19 Moderna. 20 You understand that you're under oath? 21 A Yes. 22 Q And is there any reason that you cannot	11 1 submitting them, correct? 2 A Yes, I have reviewed them. 3 Q And you stand by what you said in your 4 August 2023 declarations for these proceedings? 5 A Yes. 6 Q Now, you previously gave a deposition in 7 this proceeding, correct? 8 A Yes, I have. 9 Q And have you reviewed the transcript of 10 your deposition testimony? 11 A Yes, I have. 12 Q And do you stand by what you said at your 13 prior deposition in this proceeding? 14 A Yes. 15 Q Okay. And now you've also submitted 16 responsive declarations in these proceedings, 17 correct? 18 A Yes. 19 Q And you stand by what you said in those 20 responsive declarations? 21 A Yes. 22 Q So let me direct your attention to your
10 1 provide complete and accurate testimony today? 2 A No. 3 Q I see you've brought some materials with 4 you. What did you bring with you today? 5 A These are declaration – the original 6 declaration for patent '127 and the responsive 7 declaration for the same patent. The original 8 declaration for '600 patent, as well as my 9 responsive declaration for the same. 10 Q Okay. And those are clean copies of those 11 declarations? 12 A Yes, they are. 13 Q Did you bring any other materials with you 14 today? 15 A No. 16 Q So let me start by asking about the 17 original declarations that you submitted. You 18 submitted those declarations back in August of 2023, 19 correct? 20 A Yes, they were submitted back in August of 21 2023. 22 Q You've reviewed those declarations since	12 1 responsive declaration and around paragraph 10. 2 A For which patent? 3 Q I think it doesn't matter. Whichever one 4 you have convenient to you. 5 A Okay. I'm looking at paragraph 10. 6 Q All right. And this is in a section of 7 your responsive declaration that discusses your 8 background and qualifications, correct? 9 A In this paragraph, I discuss my background 10 and expertise in delivery of nucleic acids. 11 Q And you specifically discuss your 12 postdoctoral work on the design and development of 13 nanoparticles for vaccine applications, correct? 14 A Yes. I stated here: "For example, during 15 my postdoctoral work, I focused primarily on the 16 design and development of nanoparticles for vaccine 17 applications." 18 Q What vaccines did your postdoctoral work 19 relate to? 20 A As I mentioned in the other sentence: "I 21 designed and developed various nanoparticles, 22 including lipid-based nanoparticles, to deliver

13 1 immunogens and immunostimulatory agents for 2 vaccination against the various pathogens (including 3 malaria sporozoites...HIV) and cancer. 4 Q And were any of those vaccines nucleic acid 5 vaccines? 6 A I've worked with nucleic acids during my 7 postdoctoral work, and that is one of the -- and 8 I've published on the use of nanoparticles for 9 delivering nucleic acids. 10 Q Sure. And just focusing on the vaccines, 11 and you mention them in paragraph 10, and you gave 12 some examples of what the targets for those vaccines 13 were. 14 Were any of those vaccines nucleic acid 15 vaccines? 16 A I worked on many different vaccine 17 formulations over the years, including peptides, 18 proteins, as well as nucleic acid-based vaccines. 19 Q Which nucleic acid-based vaccines have you 20 worked on? 21 A Could you specify your question? 22 Q Sure.	15 1 acid delivery technologies during my postdoctoral 2 work. 3 Q Okay. But those nucleic acid delivery 4 technologies were not in connection with a 5 particular vaccine project, correct? 6 MR. LIU: Objection. Form. 7 THE WITNESS: Over the years, I've worked 8 on lipid-based nanoparticles for delivering nucleic 9 acids as well. And they are targeted against 10 cancer, as well as other diseases. 11 BY MR. DANFORD: 12 Q When you described the vaccines against 13 cancer in paragraph 10, were you talking about 14 nucleic acid-based vaccines? 15 A Yes, I've worked on nucleic acid -- nucleic 16 acid-based nanoparticle vaccines for various 17 diseases, including cancer. 18 Q Okay. And what was your role with respect 19 to that research? 20 A I supervise my research lab as a principal 21 investigator. So, therefore, I oversee all aspects 22 of the research, including the design of the
14 1 You said that you've worked on nucleic acid 2 vaccines, correct? 3 A Yes, I've worked on nucleic acid vaccines. 4 Q What are those nucleic acid vaccines that 5 you've worked on? 6 A I've worked on nucleic acid vaccines, 7 including mRNA. 8 Q And what was the disease that was being 9 targeted by that nucleic acid vaccine that you 10 worked on? 11 A I've worked on nucleic acid vaccines for 12 cancer, as well as other diseases. 13 Q And when did you do that work on those 14 nucleic acid vaccines? 15 A I've worked on many different projects over 16 the years on many different vaccine areas, and, in 17 particular, against malaria sporozoites and HIV. 18 Q The malaria sporozoites and HIV vaccines 19 were nucleic acid vaccines? 20 A In particular, during my postdoctoral work, 21 we used peptides and proteins for malaria 22 sporozoites and HIV, but I also worked on nucleic	16 1 vaccines, in vitro work, in vivo work, as well as 2 interpretation of the data from those experiments. 3 Q Let me just try to get more specific. 4 How many nucleic acid vaccines have you 5 personally worked on? 6 A Could you specify your question? 7 Q Sure. 8 Did you have -- have you had personal 9 involvement in developing a nucleic acid vaccine? 10 A Yes. I have designed and directed my 11 research group to perform research on nucleic 12 acid-based vaccines. 13 Q And how many nucleic acid-based vaccines 14 have you personally been involved with the research 15 for? 16 A There are many different nucleic acid-based 17 formulations that I have worked on. I'm not able to 18 count all the numbers at this moment. 19 Q All right. But not focusing on the 20 formulations, but on specific vaccine candidates, 21 how many specific vaccine candidates using nucleic 22 acid technologies have you personally worked on?

17 1 A It's too many to count because, in my 2 research, we begin the study by screening different 3 nucleic acid-based formulations for subsequent in 4 vivo and in vitro work. So we screen many different 5 candidates and then select them for subsequent 6 animal studies. 7 Q What type of nucleic acids have you -- 8 strike that. 9 When you've personally been involved in the 10 work on a nucleic acid vaccine, what type of nucleic 11 acids were used with those vaccines? 12 A I have used mRNA-based vaccines 13 encapsulated in lipid-based nanoparticles for 14 various biomedical applications, including vaccines. 15 Q Besides mRNA, have you had experience 16 personally working on any other -- vaccines using 17 other nucleic acid technologies? 18 A I've worked on siRNA-based systems, but the 19 target application was very broad, not necessarily 20 solely focused on vaccines. 21 Q Is siRNA used for vaccination? 22 A In general, siRNA is not widely used for	19 1 When did you do that work? 2 A During my postdoctoral work, one of the 3 projects were using DNA-based nanoparticles for 4 transfection. 5 Q Besides that work, have you ever personally 6 conducted research on a DNA-based vaccine? 7 A Yes, we have designed other lipid-based 8 nanoparticles and tested them using DNA plasmid as a 9 potential vaccine candidates. 10 Q Now, you also mentioned saRNA. Do you 11 recall that? 12 A Yes, I mentioned self-amplifying RNA was 13 one of the candidates for vaccine applications as of 14 2015. 15 Q And have you personally worked on an saRNA 16 vaccine? 17 A I have not worked on saRNA vaccine. 18 Q Are you familiar with what saRNA is? 19 A I'm familiar with what saRNA is. 20 Q What is saRNA? 21 A As the name suggests, self-amplifying RNA 22 is able to replicate itself within cells, producing
18 1 vaccination, but we were developing a platform -- 2 lipid-based nanoparticles, as well as other 3 nanoparticles for delivering siRNA. 4 Q As of 2015, what types of nucleic acids 5 were being studied for use as vaccines? 6 A I know at least self-amplifying RNA, as 7 well as mRNA were candidates that we examined for 8 vaccine applications as of 2015. 9 Q What about DNA? Was DNA being studied for 10 use as a vaccine as of 2015? 11 A Yes. DNA-based vaccines were one of the 12 candidates for vaccine applications as of 2015. 13 Q Can you think of any other type of nucleic 14 acid that would have been studied as of 2015 as a 15 vaccine candidate? 16 A I think those three are the most prominent 17 nucleic acid-based vaccine candidates as of 2015. 18 Q And have you ever personally worked on a 19 DNA vaccine? 20 A Yes, I've worked on DNA-based vaccine 21 platforms. 22 Q What was the -- strike that.	20 1 proteins as a result of transfection. 2 Q How is saRNA different from mRNA? 3 A saRNA is a type of mRNA. 4 Q Does saRNA function differently from mRNA? 5 MR. LIU: Objection. Foundation. Form. 6 THE WITNESS: As I mentioned, saRNA is a 7 type of mRNA, and I described what saRNA does. So 8 saRNA is, yeah, a type of mRNA. 9 BY MR. DANFORD: 10 Q And when you -- you were talking about mRNA 11 vaccines that you've done in your own research, 12 correct? You said that you had worked on mRNA 13 vaccines? 14 A Yes, I've worked on mRNA vaccines. 15 Q Okay. And those mRNA vaccines didn't have 16 the self-replication feature of saRNA, correct? 17 A The mRNA candidates that I've worked on did 18 not have self-amplifying function of saRNA. 19 Q Now, in paragraph 12 of your responsive 20 declaration, you mention work on Simian 21 Immunodeficiency Virus. 22 Do you see that?

21 1 A Yes, I see that. 2 Q And that was another vaccine candidate that 3 you worked on? 4 A Yes, that was another candidate that my lab 5 has worked on. 6 Q And was the Simian Immunodeficiency Virus a 7 nucleic acid vaccine? 8 A No, it was not nucleic acid-based vaccine. 9 Q What was the technology used in the Simian 10 Immunodeficiency Virus vaccine? 11 A It was a peptide-based vaccine delivery 12 platform based on lipid nanoparticles. 13 Q Now, you provided a technology overview in 14 your original declaration submitted in this 15 proceeding, correct? 16 A Yes, I have provided technology overview in 17 the original report. 18 Q Okay. And that technology overview 19 addressed lipid nanoparticle delivery technologies, 20 correct? 21 A Yes, I discussed lipid-based nanoparticles 22 in the technology overview section of my original	23 1 THE WITNESS: In paragraph 24 I mention 2 SNALPs, solid nucleic acid lipid particles, which 3 were a family of LNPs, and I also mention liposomes, 4 which are lipid-based nanoparticles, and liposomes 5 and LNPs are terminologies that have been used 6 interchangeably in the past. 7 I also mentioned, in paragraph 25, 8 nanostructured lipid carriers, NLCs, and cubosomes. 9 Once again, LNPs were one of the most prominent 10 technologies for delivering nucleic acid as of 2015. 11 So that's reason why I covered LNPs in my report. 12 BY MR. DANFORD: 13 Q Now, in 2015, a person of ordinary skill in 14 the art would have been aware of other delivery 15 technologies for nucleic acids besides lipid 16 nanoparticles, correct? 17 A A POSA, as of 2015, would have understood 18 that there are various candidates for delivery of 19 nucleic acids. 20 Q Okay. What were some of those other 21 candidates that were not lipid nanoparticle 22 technologies that would have been available to a
22 1 report. 2 Q Why did your technology overview address 3 lipid nanoparticle technology? 4 A Lipid nanoparticles are promising 5 candidates for vaccine applications, including for 6 nucleic acid-based vaccines; therefore, I covered 7 this technology in my technology overview section. 8 Q Now, were lipid nanoparticles, as of 2015, 9 the only delivery technology for nucleic acids that 10 was known? 11 A There were other candidates for delivery of 12 nucleic acids as of 2015. 13 Q And you did not discuss any of those other 14 delivery technologies in your original declaration, 15 correct? 16 A As of 2015, lipid-based nanoparticle was 17 one of the most prominent candidate for nucleic acid 18 delivery, so I covered LNPs in my original report. 19 Q And you did not discuss any other delivery 20 technologies that were known as of 2015 for nucleic 21 acids, correct? 22 MR. LIU: Objection. Asked and answered.	24 1 person of ordinary skill in the art as of 2015? 2 A There were research groups that are using 3 other polymer systems for delivering nucleic acids. 4 Q Is PLGA an example of a polymer system for 5 delivering nucleic acids? 6 A There were some groups using PLGA as a 7 delivery of drug delivery applications. A subset of 8 the groups may have used PLGA for delivering nucleic 9 acids. But what I meant by polymer systems were 10 more general than PLGA. There are many groups that 11 are using cationic polymers, positively charged 12 polymers, to deliver nucleic acids. 13 Q And as of 2015, those polymer-based 14 technologies were being studied by many groups, 15 correct? 16 A There were research groups that were using 17 polymer-based systems for delivering nucleic acids 18 as of 2015. 19 Q Okay. And besides those polymer-based 20 technologies, what other delivery technologies for 21 nucleic acids would have been known to a person of 22 ordinary skill in the art in 2015?

25 1 A Some research groups were using cationic 2 peptides to deliver nucleic acids. Some were using 3 protamine for delivering nucleic acids as of 2015. 4 Q Is protamine a cationic peptide? 5 A Protamine is a cationic peptide-based 6 polymer that have been used for delivering primarily 7 DNA. 8 Q And those cationic peptide-based delivery 9 systems would have been known as a potential 10 technology for delivering nucleic acids to a person 11 of ordinary skill in 2015, correct? 12 MR. LIU: Objection. Form. 13 THE WITNESS: As I mentioned, as a POSA 14 back in 2015, you'd have understood that there were 15 many candidates for delivering nucleic acids, 16 including those candidates that I mentioned, but LNP 17 was one of the most prominent technologies among 18 them. 19 BY MR. DANFORD: 20 Q Why didn't you discuss those other delivery 21 technologies that would have been known to a person 22 of ordinary skill in the art in your technology	27 1 Q So you focused on lipid nanoparticle 2 technology because that was what was disclosed in 3 the '127 patent? 4 MR. LIU: Objection. Mischaracterizes the 5 witness's testimony. 6 THE WITNESS: "This section is not intended 7 to be technically comprehensive..." and I covered 8 LNP because it's -- it was considered one of the 9 most prominent technologies for nucleic acid 10 delivery. 11 BY MR. DANFORD: 12 Q Now, if we could go back to your reply 13 declaration, and specifically I'm looking at 14 paragraph 21. 15 A Okay. 16 Q In paragraph 21 you respond to the opinions 17 that were offered by Dr. Warren Chan in these 18 proceedings, correct? 19 A Here in this paragraph, I provided my 20 assessment of Dr. Chan's focus on other delivery 21 technologies. 22 Q And it's your opinion that those other
26 1 overview? 2 A As I wrote in paragraph 19 of my original 3 report, when I presented the lipid nanoparticle 4 technologies, I stated that: "This section is not 5 intended to be technically comprehensive, but rather 6 provide a foundation for the [sic] better 7 understanding of [sic] disclosures related to the 8 [sic] lipid delivery systems in the '127 patent and 9 prior art, including certain terminology." 10 Q Did you not think that it would be 11 important to discuss all of the options that would 12 have been available to a person of ordinary skill in 13 the art as of 2015? 14 MR. LIU: Objection. Objection, form. 15 Asked and answered. 16 THE WITNESS: As I wrote here: "This 17 section is not intended to be technically 18 comprehensive, but rather provide a foundation for 19 better understanding the disclosures related to 20 lipid delivery systems in the '127 patent and prior 21 art, including certain terminology." 22 BY MR. DANFORD:	28 1 delivery technologies are not relevant to whether 2 Schrum discloses a lipid nanoparticle mRNA vaccine, 3 correct? 4 A Schrum disclosed a lipid-based 5 nanoparticles for our mRNA vaccine. 6 Q And it's your opinion that those other 7 delivery technologies that were known in the field 8 are not relevant, correct? 9 MR. LIU: Objection. Mischaracterizes the 10 document. 11 THE WITNESS: "As discussed in my original 12 declaration and below, Schrum expressly instructs 13 the POSA to use lipid nanoparticles as a delivery 14 vehicle for mRNA vaccines." 15 BY MR. DANFORD: 16 Q And it's your opinion that the availability 17 of other delivery technologies is not relevant to 18 whether Schrum discloses a lipid nanoparticle mRNA 19 vaccine, correct? 20 A As it relates to patent '127, it is my 21 opinion that Schrum already disclosed lipid 22 nanoparticles for mRNA-based vaccines.

29 1 Q And why is it that you say -- why is it 2 that you qualified your answer as it relates to the 3 '127 patent? 4 A As I wrote in my report -- original report, 5 paragraph 19, I intended to provide a foundation for 6 better understanding the disclosures related to 7 lipid delivery systems in the '127 patent and prior 8 art, including certain terminology. 9 Q So your review of the prior art focused on 10 what the '127 patent disclosed, correct? 11 MR. LIU: Objection. Form. 12 Mischaracterized the witness's testimony. 13 THE WITNESS: I reviewed LNPs because LNPs 14 were considered most prominent drug delivery 15 platform for mRNA as of 2015. 16 BY MR. DANFORD: 17 Q Now, you agree that Schrum discloses 18 delivery technologies other than lipid 19 nanoparticles, correct? 20 A Schrum discloses other technologies other 21 than LNPs. 22 Q And a person of ordinary skill in the art	31 1 BY MR. DANFORD: 2 Q Is it your opinion that the only delivery 3 technology that a person of ordinary skill in the 4 art would have considered for an mRNA vaccine was 5 lipid nanoparticles? 6 A As I mentioned, there are other drug 7 delivery technologies other than LNPs that were 8 considered for nucleic acid delivery applications. 9 Q So you wouldn't agree that lipid 10 nanoparticles were the only delivery technology that 11 a person of ordinary skill in the art would have 12 considered as of 2015, correct? 13 MR. LIU: Objection. Form. 14 THE WITNESS: As of 2015, a POSA would 15 consider various technologies, including LNP, for 16 delivering nucleic acids. 17 BY MR. DANFORD: 18 Q So nucleic acids would be among the things 19 that a person of ordinary skill would have 20 considered, but they would not have been the only 21 thing that a person of ordinary skill in the art 22 would have considered, correct?
30 1 reading Schrum would have to choose between the 2 different delivery technologies that are disclosed 3 in that reference, correct? 4 A A POSA reading Schrum would have understood 5 LNPs are prominently featured and discussed in the 6 examples in Schrum, but there are other technologies 7 that are disclosed in Schrum. 8 Q And a person of ordinary skill in the art 9 would consider the entirety of Schrum's disclosure, 10 correct? 11 A A POSA would read entirety of Schrum to 12 understand what's being disclosed. 13 Q And upon reading the entirety of Schrum, a 14 person of ordinary skill in the art would have to 15 choose among the different delivery technologies 16 that are disclosed within that reference, correct? 17 MR. LIU: Objection. Asked and answered. 18 THE WITNESS: Yeah, a POSA would read 19 entirety of Schrum and understand there are 20 different technologies disclosed in Schrum, but it's 21 my opinion that LNP was one of -- the most prominent 22 technology discussed in Schrum.	32 1 MR. LIU: Objection. Form. 2 THE WITNESS: Could you repeat the 3 question? 4 BY MR. DANFORD: 5 Q LNPs would have been among the delivery 6 technologies that a person of ordinary skill in the 7 art would have considered as of 2015, but LNPs would 8 not have been the only delivery technology that a 9 person of skill in the art would have considered at 10 that time, correct? 11 A As I mentioned, there were technologies -- 12 various technologies that had been considered for 13 nucleic acid delivery, but LNP was considered one of 14 the top candidates as of 2015. 15 Q Are you familiar with sustained-release 16 formulations? 17 A Yes, I'm familiar with sustained-release 18 formulations. 19 Q What is a sustained-release formulation? 20 A As the name suggests, those technologies 21 aim to prolong the release of drugs over long period 22 of time.

33 1 Q Are lipid nanoparticles a sustained release 2 technology for mRNA? 3 A Sustained-release formulations usually 4 refer to polymer-based formulations, and as for 5 whether LNP fits into that category, I'll have to 6 look at exact composition of matter for the LNPs. 7 But, in general, LNPs are not considered 8 sustained-release formulations. 9 Q Why don't I put the Schrum reference -- 10 I've handed you what's been previously marked in 11 these proceedings as Exhibit 1009. 12 Do you have Exhibit 1009 before you? 13 A Yes, I see Exhibit 1009. 14 Q Exhibit 1009 is the Schrum reference, 15 correct? 16 A Yes, I see Schrum in Exhibit 1009. 17 Q And this is one of the references that you 18 reviewed in connection with your work for this case? 19 A Yes, I reviewed this in preparation for my 20 report. 21 Q And you reviewed the Schrum reference in 22 its entirety, correct?	35 1 modified nucleic acid, or mmRNA)." 2 Do you see that? 3 A Yes, I see that. 4 Q And that goal of obtaining sustained or 5 delayed release is not something that you could 6 achieve with a lipid nanoparticle delivery system, 7 correct? 8 A Could you repeat the question again? 9 Q Sure. 10 The goal of obtaining sustained or delayed 11 release is not something that you could achieve with 12 a lipid nanoparticle delivery system, correct? 13 A That's pretty broad statement, and before 14 making my opinion, I'd like to review the data. 15 Q Are you aware of any example of a sustained 16 or delayed release formulation using lipid 17 nanoparticles? 18 A One can imagine LNPs could be designed to 19 achieve sustained or delayed release, and some 20 research groups are trying to achieve sustained or 21 delayed release using mRNA. 22 Q In your declaration, you discuss a
34 1 A Yes, I reviewed the entire document 2 provided here. 3 Q I want to direct your attention to 4 paragraph 363. If you're looking at the numbers at 5 the top, it's 70. If you're looking at the bottom, 6 it's page 74 of 363. 7 A Three hundred? 8 Q 363. 9 A Okay. 10 Q And this is a section of the Schrum patent 11 under the heading "Formulations," correct? 12 A Yes, I see heading "Formulations." 13 Q And the first sentence of that paragraph 14 states: "The modified nucleic acid, and mmRNA of 15 the invention can be formulated using one or more 16 excipients to" -- there's a colon and then a list of 17 objectives of the formulation. 18 Do you see that? 19 A Yes, I see that. 20 Q All right. And the third objective that's 21 listed is to: "Permit the sustained or delayed 22 release (e.g., form a depot formulation of the	36 1 four-component lipid nanoparticle system, correct? 2 A Yes, I discuss four-lipid component LNPs. 3 Q Are you aware of anyone who's ever used one 4 of those four-component lipid nanoparticle delivery 5 systems for a sustained-release formulation? 6 A I attend many conferences and read papers, 7 and I may have come across mRNA-based systems that 8 sustain or delay release, but as for which 9 technology, I'll need to review the reference to 10 give you the answer for whether LNPs were used to 11 achieve sustained or delayed release of mRNA. 12 Q Are you familiar with the term "synthetic 13 nanocarrier"? 14 A Yes, I'm familiar with the term "synthetic 15 nanocarrier." 16 Q What is a synthetic nanocarrier? 17 A That refers to nanoparticles that are 18 synthesized and designed for delivering drugs. 19 Q Can synthetic nanocarriers be used with 20 mRNA? 21 A Yes, synthetic nanocarriers could be used 22 with mRNA.

37 1 Q Okay. And the four-component lipid 2 nanoparticle system that you discuss in your 3 declaration does not involve any synthetic 4 nanocarriers, correct? 5 A Synthetic nanocarrier is a very broad term 6 that describes any nanostructures for drug delivery 7 applications. So it's hard to say LNP does not fall 8 into synthetic nanocarriers. 9 Q The Schrum reference discusses synthetic 10 nanocarriers, correct? 11 A Could you point me to the exact place? 12 Q Sure. 13 Why don't you turn to paragraph 432. 14 A Okay. 15 Q And do you see the paragraph 432 discusses 16 synthetic nanocarriers? 17 A Yes. 18 Q And the Schrum reference cites other patent 19 publications describing synthetic nanocarriers, 20 correct? 21 A Yeah, I see that they cited other 22 references.	39 1 as synthetic nanocarrier. 2 Q And the first sentence of paragraph 432 of 3 Schrum states that: "...the synthetic nanocarrier 4 may be formulated for use as a vaccine," correct? 5 A I see that sentence. 6 Q And you agree that a person of ordinary 7 skill in the art could follow the teachings of 8 Schrum to develop a vaccine using a synthetic 9 nanocarrier, correct? 10 A Reading the sentence, POSA would understand 11 that synthetic nanocarriers, including LNPs and 12 PLGA, may be formulated for use as a vaccine. 13 Q Now, you're familiar with the 14 term "encapsulation" in the context of drug 15 delivery, correct? 16 A Yes, I'm familiar with the term 17 "encapsulation." 18 Q What does encapsulation refer to? 19 A Encapsulation usually refers to loading 20 drugs within the formulations. 21 Q Are you familiar with the term 22 "encapsulation efficiency"?
38 1 Q Have you gone to look to see what those 2 other cited references disclose? 3 A I don't recall whether I went to check all 4 these references, but in reviewing Schrum, I 5 reviewed references. 6 Q Okay. And do you know whether any of the 7 references in this paragraph refer to lipid 8 nanoparticles? 9 A I don't remember whether these exact 10 references refer to LNPs, but it's clear Schrum 11 mentions LNPs in other sections. 12 Q Okay. And you agree that Schrum discloses 13 delivery technologies other than lipid 14 nanoparticles, correct? 15 MR. LIU: Objection. Asked and answered. 16 THE WITNESS: Schrum discloses LNPs 17 prominently, as well as other drug delivery 18 technologies, including PLGA microspheres. 19 BY MR. DANFORD: 20 Q Are PLGA microspheres an example of a 21 synthetic nanocarrier? 22 A Yes, PLGA nanoparticles would be classified	40 1 A Yes, I'm familiar with the 2 term "encapsulation efficiency." 3 Q What is encapsulation efficiency? 4 A That term usually quantifies percent of the 5 drug that's loaded or encapsulated into the carrier. 6 Q Is loading efficiency another term for the 7 same concept? 8 A Yes, those are sometimes used 9 interchangeably. 10 Q Did you review what the Schrum reference 11 disclosed regarding encapsulation of mRNA using 12 PLGA? 13 A I reviewed sections in Schrum where they -- 14 where they described using PLGA for mRNA delivery. 15 Q Why don't we look at one of those sections. 16 If you could turn to paragraph 973 of Schrum. 17 MR. LIU: I don't know how long this is 18 going to take, but I just wanted to see if there's a 19 good point for a break. 20 MR. DANFORD: Yeah, let me just finish this 21 up. Because then we can put the reference aside. 22 THE WITNESS: Okay. 973.

41 1 BY MR. DANFORD: 2 Q This is example 15 in the Schrum reference, 3 correct? 4 A Yes. 5 Q And the title of that example is "PLGA 6 Microsphere Formulations," correct? 7 A Correct. 8 Q And this example in the Schrum reference 9 relates to PLGA microspheres, correct? 10 A Yes, I see the title "PLGA Microspheres." 11 Q And this example doesn't involve lipid 12 nanoparticle formulations of mRNA, correct? 13 A I'll have to read the whole section to 14 answer that question. 15 Q Why don't you familiarize yourself with 16 example 15, and then we can talk about it. 17 A Okay. 18 Okay. 19 Q Example 15 does not involve lipid 20 nanoparticle formulations, correct? 21 A I didn't see lipid nanoparticles in example 22 15.	43 1 THE WITNESS: A POSA reading this would 2 have understood how to use PLGA to load mRNA. 3 MR. DANFORD: We can take a break. 4 (Recessed at 10:18 a.m.) 5 (Reconvened at 10:34 a.m.) 6 BY MR. DANFORD: 7 Q Dr. Moon, I just want to come back to your 8 background. We talked earlier about your research 9 on nucleic acid vaccines. 10 Do you recall that? 11 A Yes, I recall that. 12 Q Has any of your research on nucleic acid 13 vaccines resulted in publications? 14 A There are many projects that are ongoing in 15 my lab that uses nucleic acids for vaccine 16 applications, including mRNA, and we are getting 17 ready to publish them soon. 18 As for other past projects, whether I 19 published them or not, I'll have to review my 20 publications. But there are certainly at least 21 several manuscripts that we are working on now. 22 Q And those would be manuscripts relating to
42 1 Q Okay. Now, if you turn to paragraph 982, 2 this section of Schrum discloses the encapsulation 3 efficiency for PLGA formulations of mRNA, correct? 4 A It discusses loading and encapsulation 5 efficiency. 6 Q And Table 23 beneath that paragraph 7 provides some data on encapsulation efficiency for 8 those PLGA formulations, correct? 9 A I see encapsulation efficiency reported in 10 Table 23. 11 Q Okay. And Table 23 shows that formulation 12 A achieved encapsulation efficiency of 97.1 percent, 13 correct? 14 A I see 97.1 percent reported in row A. 15 Q Schrum discloses that it's possible to 16 encapsulate mRNA using PLGA, correct? 17 A Schrum shows that PLGA can be used to load 18 mRNA. 19 Q And you agree that a person of ordinary 20 skill in the art would be able to apply Schrum's 21 teachings with respect to PLGA, correct? 22 MR. LIU: Objection, form.	44 1 ongoing work in your lab, correct? 2 A Those are ongoing work in my lab. 3 Q And -- 4 A As for prior work, I'll have to review my 5 publications to see if we published nucleic 6 acid-based vaccines in the past. 7 Q Do you consider yourself to be an expert in 8 immunology? 9 A In my lab, we study vaccines and vaccine 10 delivery systems. 11 Q Have you ever measured the immune response 12 to a vaccine? 13 A Yes. We routinely measure vaccine response 14 using animal models. 15 Q And how do you measure the immune response 16 to a vaccine? 17 A We immunize animals, for example, collect 18 their blood, and analyze their immune cells using 19 flow cytometry. We also analyze serum for antibody 20 titers, and we also dissect animals and analyze 21 various lymphatic tissues for immune activation 22 signal.

45 1 Q And when doing those analyses, what are you 2 looking for? 3 A We are looking for signs of innate immune 4 activation, activation of T-cells and B-cells in 5 general. 6 Q Are there different types of immune 7 responses that a vaccine can induce? 8 A Could you specify? 9 Q Sure. 10 You mentioned that you're looking for 11 innate immune activation. What is that? 12 MR. LIU: I'll object to this line of 13 questions as outside the scope of his responsive 14 declaration. 15 THE WITNESS: So vaccines needs to activate 16 innate immune cells for mounting strong immune 17 response, and activation of innate immune activation 18 generally leads to strong T-cell and B-cell 19 activation. So in vaccine studies, we study all of 20 these holistically. 21 BY MR. DANFORD: 22 Q And it's possible that you would see innate	47 1 causes inflammation? 2 A Yes, we have done that. 3 Q And what do you look for to determine 4 whether a vaccine causes inflammation? 5 A For example, in animal studies, you can 6 examine the injection sites for any signs of 7 swelling, redness. You can also section tissues and 8 study immune cell infiltrates into skin. You could 9 also collect blood and analyze for markers of 10 inflammation. 11 Q And is inflammation an immune response? 12 A Inflammation is generally thought to be 13 driven by post-immune response. 14 Q And you could observe inflammation without 15 activating T-cells or B-cells, correct? 16 MR. LIU: Objection. Asked and answered. 17 Outside the scope. 18 THE WITNESS: That's a very general 19 statement that I need to review data for. 20 BY MR. DANFORD: 21 Q Okay. But as a general proposition, that 22 is possible, that you could see one type of immune
46 1 immune activation without seeing a response in 2 T-cells or B-cells, correct? 3 MR. LIU: Same objection. Outside the 4 scope. 5 THE WITNESS: I guess it depends on the 6 vaccine type, but it's certainly feasible that you 7 get innate immune activation without T-cell 8 activation. 9 BY MR. DANFORD: 10 Q Is inflammation an immune response? 11 A Inflammation is usually our body's response 12 to -- immunological response to external stimuli. 13 Q And when doing these -- when measuring the 14 immune response to a vaccine, do you look to see 15 whether the vaccine causes inflammation? 16 A In that context of a vaccine development, 17 you'd examine innate immune activation, T-cell 18 activation, B-cell activation, and when -- 19 generally, when you refer to inflammation, that's 20 side effects in the studying of vaccines. 21 Q In the studies that you've done, have you 22 done any testing to determine whether the vaccine	48 1 response without observing another, correct? 2 MR. LIU: Objection. Asked and answered. 3 Outside the scope. 4 THE WITNESS: I assume some vaccines could 5 elicit various immune responses, yeah. 6 BY MR. DANFORD: 7 Q Now, let's come back to talk about some of 8 the delivery technologies we've been talking about. 9 One that you mentioned earlier is protamine, 10 correct? 11 A Yes, I mentioned protamine. 12 Q Okay. And protamine is a different 13 delivery technology from lipid nanoparticles, 14 correct? 15 A Protamine is a different drug delivery 16 platform than LNPs. 17 Q And by 2015, protamine had been used to 18 formulate mRNA vaccines for infectious disease, 19 correct? 20 A I'll have to check references on that, but 21 I know protamine had been used to deliver DNA by 22 2025 -- I mean 2015.

49 1 Q 2015. 2 A Yeah. 3 Q I'll just hand you this document, which has 4 been previously marked as Exhibit 2024 in these 5 proceedings. 6 Do you recognize Exhibit 2024? 7 A I see this is a research article from 8 CureVac. 9 Q The date of this article is October 2013, 10 correct? 11 A This was published in October 2013. 12 Q And the title of the article is "A Novel, 13 Disruptive Vaccination Technology," correct? 14 A I see that as a title. 15 Q And if you look at the Abstract, the 16 Abstract describes the vaccine that they had 17 developed at CureVac, correct? 18 A I see they report a vaccine candidate in 19 the Abstract. 20 Q Okay. And the article describes the 21 vaccine candidate as having mRNA that's complexed 22 with protamine, correct?	51 1 enticing, could you refer me to their reports where 2 they say that? 3 Q Well, let me just ask you this: A person 4 of ordinary skill in the art would have been aware 5 of the work done by CureVac to develop an mRNA 6 vaccine using protamine-based technology, correct? 7 A Yeah, a POSA would have been aware of this 8 technology for mRNA delivery. 9 Q If we could go back to your reply 10 declaration, and I'd like to direct your attention 11 to paragraph 67, please. 12 A Okay. 13 Q And in this paragraph, you respond to 14 Dr. Chan's opinions regarding motivation to combine 15 and reasonable expectation of success, correct? 16 A In this paragraph, I'm stating that a POSA 17 would have good reason to formulate mRNA in LNP. 18 Q And at the end of the paragraph, you state 19 that: "...a POSA would reasonably expect to 20 successfully encapsulate the immunogen-encoding mRNA 21 in a lipid nanoparticle system and to use such a 22 formulation for vaccine applications to induce an
50 1 A The Abstract says they are complexed with a 2 protamine. 3 Q And you understand that that's describing a 4 protamine-based delivery system, correct? 5 A I have to review the whole document, but it 6 seems to suggest that they are using protamine to 7 complex with mRNA. 8 Q And this mRNA vaccine was for influenza, 9 correct? 10 A I see they tested this in influenza models, 11 in preclinical models. 12 Q And this article refers to the vaccine that 13 CureVac was working on as: "...an enticing novel 14 approach to vaccination," correct? 15 A Where does it say that? 16 Q In the first sentence of the Abstract. 17 A I think they're just generally saying 18 nucleotide-based vaccines are enticing vaccine 19 candidates. 20 Q And that would include the vaccine 21 candidate that CureVac had developed here, correct? 22 A As to whether their exact formulation is	52 1 immune response," correct? 2 A Yes, I stated that in paragraph 67. 3 Q And what do you mean when you say that the 4 formulation would induce an immune response? 5 A A POSA would have understood that when you 6 use lipid nanoparticles encapsulating mRNA-encoding 7 immunogen, that such platform would induce an immune 8 response and that could be measured in, for example, 9 animal studies where you collect their blood and 10 analyze antibody responses or T-cell responses. 11 Q Are you aware of any published data as of 12 2015 showing the immune response to a 13 betacoronavirus spike protein encoded by an mRNA 14 vaccine? 15 A I don't recall any particular paper 16 mentioning such results against betacoronavirus as 17 of 2015, but I can also say that Schrum used mRNA 18 LNPs to successfully translate proteins, and in 19 animals, and Schrum also discloses that such system 20 can be used for vaccination in Schrum document. 21 Q There's no data in Schrum showing the 22 immune response to a betacoronavirus spike protein,

53 1 correct? 2 A In disclosure -- well, in paragraph 397 3 Schrum says LNPs loaded with mRNA-encoding immunogen 4 could be used for vaccines, and as for whether they 5 provided data for that, I don't recall examples 6 where they report that. 7 Q If we could turn to paragraph 98 of your 8 responsive declaration. 9 A Okay. 10 Q And this is another paragraph in which you 11 discuss a reasonable expectation of success, 12 correct? 13 A Yes, I discuss reasonable expectation of 14 success. 15 Q Now, reasonable expectation of success was 16 not an issue that you addressed in your original 17 declaration, correct? 18 MR. LIU: Objection. Mischaracterizes the 19 witness's testimony. 20 THE WITNESS: In my original report, I 21 cited Schrum, as well as Geall, and stated that a 22 POSA reading those documents would have understood	55 1 success," correct? 2 A As to whether I used the exact 3 word "expectation of success" in my original report, 4 I didn't use that word in that paragraph, but 5 overall, I was stating that looking at Schrum, a 6 POSA would understand that Schrum is teaching a POSA 7 how to use lipid nanoparticles formulated for use in 8 a vaccine, such as, but not limited to, against a 9 pathogen as taught in paragraph 397. 10 Q So let's come back to your reply 11 declaration, paragraph 98, where you say that a POSA 12 would reasonably expect that administration of such 13 a composition would result in expression of the 14 betacoronavirus spike protein which would induce 15 some level of an immune response to that encoded 16 immunogen. 17 Do you see that? 18 A In paragraph 98, I said: "Instead, a POSA 19 would have reasonably expected to induce some level 20 of immune response using an mRNA vaccine formulated 21 in a lipid nanoparticle system." 22 MR. LIU: Slow down for the court reporter.
54 1 that LNP delivering nucleic acids could be used as 2 vaccines. 3 BY MR. DANFORD: 4 Q You didn't provide any opinion in your 5 original report that a person of ordinary skill in 6 the art would have had a reasonable expectation of 7 success in producing an immune response, correct? 8 MR. LIU: Same objection. 9 THE WITNESS: As I wrote in paragraph 51 of 10 my original report: "Schrum discloses compositions 11 comprising modified nucleic acids encoding a protein 12 formulated in and delivered via a nanoparticle. 13 Specifically, Schrum teaches that '[t]he modified 14 nucleic acid molecules and mmRNA...of the invention 15 can be formulated using one or more...lipid 16 nanoparticles.' Schrum further teaches that 'the 17 lipid nanoparticle may be formulated for use in a 18 vaccine such as, but not limited to, against a 19 pathogen,'" paragraph 397. 20 BY MR. DANFORD: 21 Q Paragraph 51 of your original report 22 doesn't use the words "reasonable expectation of	56 1 THE WITNESS: Okay. 2 BY MR. DANFORD: 3 Q What do you mean when you say, would induce 4 some level of an immune response to that encoded 5 immunogen? 6 A Immune response could be measured by 7 various means, for example, antibody responses 8 against a vaccine candidate or T-cell activation or 9 other combinations. 10 Q And you don't specify in your declaration 11 what that immune response would be, correct? 12 A On immune response, this, again, can be any 13 of these, including antibody responses, T-cell 14 activation, and/or B-cell activation, and if you get 15 any of these, you could say you get immune response. 16 Q Is it your opinion that simply expressing 17 an immunogen will always result in a protected 18 immune response? 19 A Could you define "protected immune 20 response"? 21 Q Sure. 22 When developing a vaccine, what type of

57 1 immune response are you looking for? 2 A In general, any immune activation, 3 including B-cells, antibody response, or T-cells, 4 would be considered immune response after 5 vaccination. 6 Q And which of those immune responses provide 7 protection against the disease? 8 MR. LIU: Objection. Form. 9 THE WITNESS: It depends on the pathogens, 10 but in general, if you get any of those responses, 11 you'd say that's a vaccine candidate. 12 BY MR. DANFORD: 13 Q And is it your opinion that simply 14 expressing an antigen will always result in inducing 15 either an antibody response, a T-cell response, or a 16 B-cell response? 17 A As I wrote below in that paragraph, 18 Dr. Fuller stated that: "It's just basic 19 fundamental nucleic acid vaccine biology that when 20 you have a DNA or an RNA vaccine...you could 21 validate that it expresses a protein in vitro, then 22 the hypothesis is that if you inject that DNA or RNA	59 1 an antigen, then you expect to get some kind of 2 immune response in vivo in animals. 3 Q Putting aside Dr. Fuller's testimony, are 4 you aware of any disclosure in the prior art that 5 supports that opinion? 6 A I'm aware of at least Geall, where they 7 used LNPs delivering nucleic acids and they elicited 8 immune responses in vivo. 9 Q Besides Geall, are you aware of any other 10 disclosure in the prior art supporting that opinion? 11 A I'm aware of at least the Geall that 12 supports that. There may be other references, but 13 I'm at least aware of Geall's statement. 14 Q Why don't you turn to paragraph 44 of your 15 reply declaration. 16 In paragraph 44 you discuss Schrum's 17 working examples, correct? 18 A Okay. Yeah, we are discussing Schrum's 19 working examples in paragraph 44. 20 Q And you reviewed all of the working 21 examples in Schrum, correct? 22 A I reviewed all working examples in Schrum.
58 1 vaccine into an animal, the muscle cell, or in the 2 case of gene gun delivery, the skin cell, will 3 express that antigen. You can give that antigen to 4 express in animal, and the hypothesis is that it 5 will elicit an immune response." 6 Q Is it your opinion that a hypothesis is the 7 same as a reasonable expectation of success? 8 A A POSA would expect to get immune response 9 using mRNA that expresses antigen. 10 Q Is it your opinion that delivering mRNA 11 that expresses antigen will always result in an 12 immune response? 13 A A POSA would have reasonable expectation of 14 success that when they used mRNA that encodes 15 antigens and if they used that to vaccinate or treat 16 animals, you'd expect some kind of immune response. 17 Q And what is that opinion based on? What 18 disclosure in the art as of 2015 are you basing that 19 statement on? 20 A As Dr. Fuller mentions here, it's just the 21 basic fundamental nucleic acid vaccine biology that 22 when you have DNA or RNA vaccine that could express	60 1 Q None of the working examples in Schrum 2 describe a vaccine, correct? 3 A Schrum's working examples are focused on 4 LNPs delivering mRNA, resulting in strong protein 5 expression in vitro and in vivo, and in paragraph 6 397, Schrum teaches that the same formulation can be 7 used to deliver immunogen-encoding mRNA for vaccine 8 applications. 9 Q So focusing just on the working examples, 10 none of those actually involve a vaccine, correct? 11 MR. LIU: Objection. Asked and answered. 12 THE WITNESS: Schrum is using mRNA encoding 13 various proteins in their working examples, and a 14 POSA reading that would have understood that mRNA 15 encoding immunogen could be used for vaccine 16 applications, and paragraph 397 further highlights 17 that. 18 BY MR. DANFORD: 19 Q Is it your opinion that the delivery of 20 mRNA for therapeutic uses and vaccine uses is 21 identical in all respects? 22 A Looking at Schrum, a POSA would have

61 1 understood that LNP that works well for 2 protein-encoding mRNA could be readily used for 3 vaccine applications, and POSA would have gone to 4 the same LNP formulation disclosed in Schrum to test 5 vaccines, as taught by paragraph 397. 6 Q So it's your opinion that the use of mRNA 7 for therapeutic purposes is completely the same as 8 using mRNA for a vaccine? 9 MR. LIU: Objection. Asked and answered. 10 Mischaracterized the witness's testimony. 11 THE WITNESS: A POSA would have understood 12 that LNP that works well for protein-encoding mRNA 13 would be also good candidate for vaccine 14 applications using immunogen-encoding mRNA. 15 BY MR. DANFORD: 16 Q Okay. And, respectfully, my question was: 17 It's your opinion that the delivery of mRNA for a 18 therapeutic use is completely the same as the 19 delivery of mRNA for a vaccine. Is that your 20 opinion? 21 MR. LIU: Objection. Asked and answered. 22 Mischaracterized the witness's testimony.	63 1 A A POSA would have used LNP as working well 2 for protein delivery applications to test vaccine 3 candidates and with the reasonable expectation of 4 success that you'd get immune response. You can do 5 further studies from there to make it better by 6 making tweaks, but a POSA would have started out 7 with the same LNP formulations. 8 Q And let me just ask you this: For a 9 vaccine use of mRNA, the goal is to induce an immune 10 response, correct? 11 A For vaccines you'd need to induce immune 12 response. 13 Q For a therapeutic use of mRNA, the goal is 14 not to induce an immune response, correct? 15 A For therapeutic use of mRNA, you want to 16 have good protein expression. 17 Q An immune response against the therapeutic 18 would be problematic, correct? 19 A In general, you don't want strong immune 20 responses to a protein you're trying to express, 21 but, once again, the same LNP that works well for 22 protein therapeutics would be a good candidate for a
62 1 THE WITNESS: As I mentioned, a POSA would 2 have used the same lipid nanoparticles that works 3 well for protein-encoding mRNA as a starting point 4 to test vaccine encoding mRNA. There may be 5 additional tweaks the POSA would make to vaccines 6 work better, but a starting point would be the same 7 LNP because it works well for protein-encoding mRNA. 8 BY MR. DANFORD: 9 Q Are there differences between delivering 10 mRNA for a therapeutic use versus a vaccine? 11 MR. LIU: Objection. Form. 12 THE WITNESS: The top criteria -- one of 13 the criteria for successful mRNA-based applications 14 would be good protein expression, and if LNP that 15 works well for one form of mRNA-encoding protein, 16 that will give a reasonable expectation of success 17 for POSA looking for mRNA that works well for 18 vaccine applications. 19 BY MR. DANFORD: 20 Q But you agree that there are differences 21 between a therapeutic use and a vaccine use of mRNA, 22 correct?	64 1 POSA to test as a platform for vaccine delivery 2 applications, and that's what Schrum teaches in 3 paragraph 397. 4 Q Let me direct you to paragraph 72 of your 5 reply declaration. 6 In this paragraph, you discuss increased 7 protein expression that Schrum showed for mRNA 8 formulated in LNPs versus lipoplexes, correct? 9 A Here I discuss Schrum's example where they 10 use LNP and compare that to lipoplex. 11 Q What is a lipoplex? 12 A Lipoplex usually refers to lipid vesicles 13 that are complexed with mRNA or other nucleic acids. 14 Q How is a lipoplex different from a lipid 15 nanoparticle? 16 A A lipoplex does not usually have the four 17 lipid components that go into LNPs. 18 Q Now, you state that: "A POSA would readily 19 recognize that achieving such an increase in the 20 protein expression achieved by mRNA administration 21 would be a significant benefit, as increased 22 immunogen expression could, in turn, improve vaccine

65 1 performance," correct? 2 A Yes, I stated that there. 3 Q And what do you mean when you say that: 4 "...increased immunogen expression could, in turn, 5 improve vaccine performance"? 6 A For successful mRNA vaccine, you want mRNA 7 that encodes an immunogen and leads to strong 8 antigen expression as a first criterion for antigen 9 delivery in vivo. And in this example, Schrum is 10 teaching that LNP encapsulating mRNA results in very 11 strong protein production in vivo; therefore, a POSA 12 would readily recognize that achieving such an 13 increase in the protein expression achieved by mRNA 14 administration would be a significant benefit 15 because increased immunogen expression could, in 16 turn, improve vaccine performance by inducing immune 17 responses. 18 Q How does increased immunogen expression 19 improve vaccine performance? 20 MR. LIU: Objection. Asked and answered. 21 THE WITNESS: When immunogen is expressed, 22 our immune cells will recognize the antigen and then	67 1 PLGA for mRNA delivery in paragraph 86. 2 Q Okay. And you don't cite any prior art 3 references describing those challenges, correct? 4 A While I did not cite specific references in 5 paragraph 86, these are common knowledge among POSA 6 working on PLGA drug delivery fields. 7 Q If you'd go to paragraph 88, you address 8 chitosan, correct? 9 A Yes, I discuss chitosan. 10 Q Okay. And you state that chitosan has 11 several major limitations when it comes to mRNA 12 delivery, correct? 13 A Yes, I highlight several limitations. 14 Q And you didn't cite any prior art 15 disclosing those limitations, correct? 16 A I didn't cite references in this paragraph, 17 but it's widely known that chitosan has limitations 18 when it comes to delivering mRNA in the field of 19 drug delivery. 20 Q In paragraph 89, you discuss protamine 21 delivery systems for mRNA, correct? 22 A Yes, I discuss protamine.
66 1 mount immune response. So for any vaccine 2 candidates, you want to expose immune cells to 3 immunogen so that you can mount immune responses. 4 And what this is teaching is that when you 5 use LNP encapsulating mRNA, you'd get very strong 6 protein production in vivo. Therefore, a POSA would 7 have understood that such LNP resulting in very 8 strong immunogen expression could be a good platform 9 for vaccine applications. 10 BY MR. DANFORD: 11 Q A person of ordinary skill in the art would 12 have been motivated to increase protein production 13 in order to improve vaccine performance, correct? 14 A A POSA would have used technology that 15 results in strong immunogen expression as a basis to 16 develop vaccines. 17 Q If we could turn to paragraph 86 of your 18 reply declaration. 19 In paragraph 86, you address what you 20 perceive to be several challenges for RNA delivery 21 applications using PLGA, correct? 22 A I discuss challenges associated with the	68 1 Q And you offer the opinion that there are 2 several disadvantages for the use of protamine 3 delivery for mRNA, correct? 4 A Yes, I discuss limitations of protamine in 5 paragraph 89. 6 Q You did not cite any prior art in paragraph 7 89 disclosing those disadvantages, correct? 8 A Yeah, I didn't cite any particular 9 reference in paragraph 89 regarding protamine, but 10 these are widely known facts among drug delivery 11 scientists. 12 MR. DANFORD: Why don't we take a break 13 before shifting topics here. 14 (Recessed at 11:31 a.m.) 15 (Reconvened at 11:46 a.m.) 16 BY MR. DANFORD: 17 Q Dr. Moon, I've handed you Exhibit 1010. Do 18 you recognize Exhibit 1010? 19 A Yes, I recognize this document. 20 Q What is Exhibit 1010? 21 A It's an international patent application by 22 Geall.

69 1 Q And Exhibit 1010 is one of the references 2 that you considered for this case, correct? 3 A Yes. 4 Q If you'd turn to page 31 of Exhibit 1010, 5 at line 3, do you see that there's a heading: 6 "Liposomal encapsulation"? 7 A Could you repeat the page? 8 Q It's 31 of the document. I guess it's 32 9 of 57, if you look at the bottom numbers. 10 A Okay. 11 Q Are you with me? 12 A Yes. 13 Q Okay. And there's a heading: "Liposomal 14 encapsulation," at line 3? 15 A Yes. 16 Q And the paragraph under that heading 17 describes liposomes made with four components, 18 correct? 19 A I see four components listed here. 20 Q What are the four components of the 21 liposome described in that paragraph? 22 A So these four lipid components are	71 1 Q Is it your opinion that every lipid 2 delivery technology with the same four components, 3 the ionizable lipid, the neutral lipid, cholesterol, 4 and PEG lipid made using a T mixer, is also a lipid 5 nanoparticle? 6 A I'd have to review the exact formulation 7 you are referring to, but, in general, lipid 8 nanoparticles nowadays refer to those four lipid 9 components leading to nanoparticle system, and that 10 can be used for mRNA delivery. 11 Q Your opinion is that the liposomes 12 disclosed in Geall are the same as the lipid 13 nanoparticles disclosed in the '600 and '127 14 patents, correct? 15 A So Schrum is using the same lipid 16 nanoparticles that are in '127 and '600 patents. 17 And in this particular example provided by Geall, 18 they are using the same four lipid components to 19 formulate RNA into their lipid nanoparticles. 20 Q So the answer is, yes, your opinion is that 21 the liposomes disclosed in Geall are the same as the 22 lipid nanoparticles disclosed in the '600 and '127
70 1 ionizable lipids, neutral lipid, cholesterol, and 2 PEGylated lipid. 3 Q And you consider that four-component 4 liposome to be a lipid nanoparticle, correct? 5 A So the term "liposomes" and "lipid 6 nanoparticles" have been used interchangeably over 7 the years, and looking at these four lipid 8 components, it seems they're describing lipid 9 nanoparticles -- what we now call as lipid 10 nanoparticles. 11 Q So your opinion is that the Geall reference 12 discloses lipid nanoparticles, correct? 13 A In this example, they are using lipid 14 nanoparticles. 15 Q And what are the reasons that you consider 16 the liposomes disclosed in Geall to be lipid 17 nanoparticles? 18 A In this paragraph shown in page 31, they 19 are using four lipid components: ionizable lipid, 20 neutral lipid, cholesterol, and PEG lipid to 21 encapsulate RNA using T mixer, and that's how, 22 generally, LNPs are used to formulate with RNA.	72 1 patents, correct? 2 A The four lipid components used in this 3 particular example shown in Geall falls within the 4 specifications that is listed in '127 and '600 5 patents. In that patent, they describe four lipid 6 components that go into formulations of LNP and 7 their ratios, and in this particular example from 8 Geall, they are using LNP formulations that fall 9 within the specifications of that listed in '127 and 10 '600. 11 Q Now, Pfizer and BioNTech's COVID-19 vaccine 12 uses a four-component LNP, correct? 13 A Pfizer and BioNTech's COVID-19 vaccine uses 14 four lipid components. 15 Q And those four lipid components are 16 ionizable lipid, a neutral lipid, cholesterol, and a 17 PEGylated lipid, correct? 18 A The LNP in Pfizer and BioNTech vaccines use 19 ionizable lipids, neutral lipids, cholesterol, and 20 PEGylated lipid. 21 Q Pfizer and BioNTech's COVID-19 vaccine uses 22 the same four components as the liposomes disclosed

73 1 in Geall, correct? 2 MR. LIU: Objection. Form. Foundation. 3 THE WITNESS: They are not the same. 4 BY MR. DANFORD: 5 Q Meaning, the individual lipids are 6 different, but the categories are the same? 7 A Pfizer vaccine does not use the same LNP 8 formulation listed here in Geall reference. 9 Q The Pfizer vaccine uses a cationic lipid, 10 correct? 11 A My understanding is Pfizer vaccine uses an 12 ionizable lipid in their LNP. 13 Q And the Pfizer vaccine uses a neutral lipid 14 in its LNP, correct? 15 MR. LIU: I'm just going to object to this 16 line of questions as outside the scope of his 17 responsive declaration. 18 THE WITNESS: Yeah, I was not asked to 19 review exact compositions of Pfizer vaccine's LNP. 20 BY MR. DANFORD: 21 Q But you are familiar with the composition 22 of Pfizer's COVID-19 vaccine LNP, correct?	75 1 A Yes, I'm a senior author in this article. 2 Q And this is the review article that you 3 were just speaking about? 4 A Yes, this is a review article that I was 5 referring to. 6 Q And if you'd turn to page 142 of the review 7 article, there's a figure 3 at the top of the page. 8 Do you see that? 9 A Yes, I see that. 10 Q And the figure illustrates the components 11 of lipid nanoparticles used in COVID-19 vaccines, 12 correct? 13 A This is showing various potential 14 candidates for COVID-19 vaccine. 15 Q Okay. And the lipid nanoparticle shown on 16 this -- in this figure contains four components, 17 correct? 18 A We showed four lipid components in the top 19 panel of this figure. 20 Q And those four lipid -- those four 21 components are the same as the four components from 22 the Geall liposomes that we were just looking at,
74 1 A I have not been asked to look at individual 2 components that go into LNPs within Pfizer vaccine. 3 Q But you are familiar, through your work in 4 the field, with the components of Pfizer's LNP, 5 correct? 6 A I have a general understanding of Pfizer's 7 LNP, but as to exact composition and the ratios of 8 each components and et cetera, I'll have to review 9 the relevant references on that. 10 Q You've published papers describing the 11 composition of Pfizer's LNP, correct? 12 A I have published many papers. In one of 13 the review articles we may have covered LNP 14 technology in Pfizer's vaccine, but as to specific 15 compositions and ratios, I'll need to rereview my 16 earlier work. 17 Q Why don't I give you this. This has been 18 marked previously as Exhibit 2078. 19 Do you recognize Exhibit 2078? 20 A Yes. 21 Q And Exhibit 2078 is a review article on 22 which you are named as an author, correct?	76 1 correct? 2 MR. LIU: Objection. Asked and answered. 3 THE WITNESS: So this is showing four 4 general categories of lipids that go into LNP 5 formulations. 6 BY MR. DANFORD: 7 Q And those four components are the 8 components that are used in Pfizer's LNP for its 9 COVID-19 vaccine, correct? 10 MR. LIU: Objection. Form. Foundation. 11 THE WITNESS: This is a general schematic 12 showing four lipid components that go into LNPs, but 13 as to what exactly Pfizer COVID-19 vaccine is 14 composed of, this figure is not intended to depict 15 that. 16 BY MR. DANFORD: 17 Q Do you agree that Geall discloses lipid 18 nanoparticles as used in Pfizer and BioNTech's 19 COVID-19 vaccine? 20 A Geall is not using the exact same 21 formulation that is in Pfizer's COVID-19 vaccine. 22 Q And what do you mean by that?

77 1 A The identity of the four lipid components 2 may be different. The composition ratios of each 3 component may be different between Geall and Pfizer 4 LNP vaccines. 5 Q Putting aside the ratios and the exact 6 identity of the components, do you agree that Geall 7 discloses that the nanoparticles is used in Pfizer 8 and BioNTech's COVID-19 vaccine? 9 MR. LIU: Objection. Asked and answered. 10 Outside the scope. 11 THE WITNESS: I have not been asked to 12 review what goes into the composition of LNP in 13 Pfizer vaccine, so without reviewing further 14 documents, I'm not able to answer that question. 15 BY MR. DANFORD: 16 Q If someone had said that Geall does not 17 disclose lipid nanoparticles as used in Pfizer and 18 BioNTech's COVID-19 vaccine, would you have any 19 basis to disagree with that statement? 20 A Could you repeat the question? 21 Q Yeah. 22 If someone had said Geall does not disclose	79 1 A As I mentioned, many research groups were 2 examining chitosan for various biomedical 3 applications, including vaccines. 4 Q If someone had said, "Chitosan has great 5 potential for vaccine delivery," would you have 6 disagreed with them and said, "No, that's not right. 7 It doesn't have any potential"? 8 MR. LIU: Objection. Form. 9 THE WITNESS: As I mentioned, there were 10 many -- there are still many research groups using 11 chitosan for various biomedical applications, 12 including vaccines. 13 BY MR. DANFORD: 14 Q As of 2015, PLGA was a promising vaccine 15 delivery candidate, correct? 16 A Similar to chitosan, as of 2015, many 17 research groups were examining PLGA for various drug 18 delivery applications, including vaccines. 19 Q Let me hand you a document that's 20 previously been marked as Exhibit 2077. 21 Do you recognize Exhibit 2077? 22 A Yes. It's a review article from my
78 1 lipid nanoparticles as used in Pfizer and BioNTech's 2 COVID-19 vaccine, would you have any basis to 3 disagree with that statement? 4 A As I mentioned, LNP described in the Geall 5 is not the same as what's in Pfizer vaccine. 6 Q Now, we talked about chitosan earlier. Do 7 you recall that? 8 A Yes, I recall that. 9 Q And would you agree that chitosan had great 10 potential for vaccine delivery as of 2015? 11 A There were a number of groups that were 12 examining chitosan for vaccine delivery 13 applications, including peptides or proteins as an 14 immunogen. So chitosan was one of the classes of 15 vaccine delivery platforms as of 2015. 16 Q Chitosan had been studied for use of 17 delivery of nucleic acids -- correct? -- as of 2015? 18 A There were research groups studying 19 chitosan for various drug delivery applications, 20 including nucleic acids as of 2015. 21 Q Would you agree that chitosan, as of 2015, 22 had great potential for vaccine delivery?	80 1 laboratory. 2 Q And you're one of the authors on this 3 review article, correct? 4 A Yes. 5 Q And this review article was published in 6 2014, correct? 7 A Yes, this was published in 2014. 8 Q And this review article is an accurate 9 assessment of the state of the art for vaccine 10 delivery in 2014, correct? 11 A Yes, this is an accurate overview of the 12 review -- overview of the vaccine delivery field, 13 focusing on nanoparticles. 14 Q And in 2014 this review article that you 15 published discussed many different vaccine delivery 16 technologies, correct? 17 A Yes, we discussed the various vaccine 18 delivery platforms in this review article. 19 Q Why did you discuss the different delivery 20 platforms in this article that you published in 21 2014? 22 A We provided an overview of various drug

81 1 delivery nanoparticles that could be used for 2 vaccine applications in this review article. 3 Q And a person of ordinary skill in the art 4 in 2015 would have been aware of all of the delivery 5 technologies that you discuss in your review 6 article, correct? 7 A A POSA would have understood various 8 technologies are there, and in this review article, 9 we aimed to showcase some of those lipid 10 nanoparticle systems for vaccine applications. 11 Q And you discussed more than lipid 12 nanoparticle delivery systems, correct? 13 A In addition to lipid nanoparticle systems, 14 we discussed other biomaterials, including chitosan 15 and other polymers. 16 Q And in 2014 you stated that chitosan had 17 great potential for vaccine delivery, correct? 18 A Could you point me to the exact place? 19 Q Yeah. I'm on page 2570 -- 20 A Okay. 21 Q -- the right-hand column, last full 22 paragraph on the page.	83 1 the right column, last sentence, it says: "We 2 expect that future studies focused on addressing low 3 aqueous solubility at physiological conditions, 4 irregular particle size distribution, and low target 5 specificity can lead to highly effective vaccine 6 formulations," basically, outlining what the 7 remaining challenges are for chitosan-based 8 vaccines. 9 And also, this is an overview review 10 article that summarizes use of chitosan for various 11 vaccine delivery applications, not limited to mRNA. 12 Q Is it your opinion that those other vaccine 13 delivery applications besides mRNA would have been 14 irrelevant to a person of ordinary skill in the art 15 seeking to deliver mRNA? 16 A A POSA as of 2015 would have understood 17 that chitosan has pros and cons for vaccine delivery 18 applications, and when it comes to mRNA delivery, 19 chitosan has challenges, as I outlined in paragraph 20 88, and it was clear from prior art and others by 21 2015 that LNPs are very attractive drug delivery 22 platforms for nucleic acids, including mRNA.
82 1 A The last paragraph of page 2570? 2 Q Correct. 3 A There we said: "These studies suggest 4 great potential of chitosan based nano/micro 5 particles for vaccine delivery." 6 Q And that was an accurate assessment of the 7 state of the art at the time, correct? 8 A Yes, as of 2014 people were looking at 9 chitosan as a vaccine delivery platform, and they 10 had great potential. 11 Q And that remained true as of 2015, correct? 12 A That is true as of 2015. 13 Q Now, in your reply declaration, we looked 14 at a discussion that you provided earlier about some 15 of the downsides of chitosan-based delivery, 16 correct? 17 A Yes. In paragraph 88 I outlined challenges 18 associated with chitosan-based mRNA delivery. 19 Q Your 2014 review article does not describe 20 any of those supposed challenges with chitosan-based 21 delivery, correct? 22 A In the last sentence of that page, 2570, on	84 1 Q Now, this review article you published in 2 2014 also discusses PLGA, correct? 3 A Yes, we covered PLGA as a potential vaccine 4 delivery platform. 5 Q And you stated at the time that: "PLGA 6 based micro/nanoparticles have emerged as promising 7 vaccine delivery candidates due to their current 8 clinical usage, biodegradable nature, ability to 9 prolong antigen release and co-encapsulate antigen 10 and immunopotentiator," correct? 11 A I stand by that statement saying PLGA is a 12 promising vaccine delivery candidate, but the focus 13 of this review was using PLGA for peptide and 14 protein-based vaccines, not mRNA-based vaccines. 15 Q Is it your opinion that protein-based 16 vaccines are irrelevant to mRNA-based vaccines? 17 MR. LIU: Objection. Form. 18 THE WITNESS: A POSA reading this review 19 article, as well as the state of art as of 2015, 20 would have understood PLGA has certain pros and cons 21 in terms of mRNA delivery, and the limitations of 22 PLGA for mRNA delivery are listed in my report,

85 1 paragraph 86. 2 BY MR. DANFORD: 3 Q You didn't describe any of the limitations 4 of PLGA delivery from paragraph 86 in this 2014 5 review article, correct? 6 A The focus of this review article, 7 especially on PLGA, was to provide overview of PLGA 8 for delivering peptide and protein antigens. 9 MR. DANFORD: All right. Could we just 10 take a short break? 11 MR. LIU: Sure. We can go off the record. 12 (Recessed at 12:29 p.m.) 13 (Reconvened at 12:32 p.m.) 14 BY MR. DANFORD: 15 Q If you could pull out Exhibit 2077 again, 16 that we were looking at just before we took a break, 17 and if you'd go to page 2566, do you see that 18 there's a heading: "Lipid-Based Delivery Vehicles"? 19 A Yes. 20 Q And beneath that heading, you have a 21 smaller heading for: "Liposomes"? 22 A Yes.	87 1 term "lipid nanoparticles." Some used "lipid-based 2 nanoparticles." 3 So these are terms that have been used 4 interchangeably over the years. 5 Q And if they're interchangeable, why did you 6 have them as two separate sections in this 2014 7 review article? 8 A As to why we exactly divided it up into 9 these, I don't recall the exact reason. But what I 10 can tell you is some groups used liposomes and lipid 11 nanoparticles interchangeably. So one needs to look 12 at the lipid components, as well as the way they are 13 formulated, to understand what they're referring to 14 is LNPs nowadays. 15 Q Okay. I don't have anything further. 16 MR. LIU: We don't have any questions for 17 you either, Dr. Moon. 18 THE COURT REPORTER: Mr. Liu, are you 19 purchasing the final transcript and a rough draft? 20 MR. LIU: Yes and regular on the final. 21 THE COURT REPORTER: And for you? 22 MR. MEUTH: Same.
86 1 Q And then if you'd turn to the next page, 2 there, at the bottom of the page, is a smaller 3 heading for: "Lipid-Based Nanoparticles." 4 Do you see that? 5 A Yes. 6 Q Why do you have liposomes and lipid-based 7 nanoparticles as two separate headings in this 8 article? 9 A Okay. So liposomes and lipid-based 10 nanoparticles are terms that have been used 11 interchangeably over the years, and their 12 definitions have evolved over the years. And what 13 we call nowadays as lipid nanoparticles, usually 14 refers to those four lipid components that go into 15 using mRNA delivery. 16 Q As of 2015, would a person of ordinary 17 skill in the art have understood that there was any 18 difference between liposomes and lipid 19 nanoparticles? 20 A Once again, these were terms that were used 21 interchangeably by various scientists in the field. 22 Some used the term "liposomes." Some used the	88 1 THE COURT REPORTER: So regular and a 2 rough? 3 MR. MEUTH: Yes, please. 4 (Signature having not been discussed, 5 the deposition of James J. Moon, Ph.D. was concluded 6 at 12:40 p.m. EDT.) 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22

Transcript of James J. Moon, Ph.D.
Conducted on September 13, 2024

23 (89 to 92)

89 1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC 2 3 I, JOAN V. CAIN, court reporter and Notary 4 Public within and for the District of Columbia do 5 hereby certify: 6 7 That JAMES J. MOON, PH.D., the 8 witness whose deposition is hereinbefore set forth, 9 was duly sworn by me before the commencement of such 10 deposition and that such deposition was taken before 11 me and is a true record of the testimony given by 12 such witness. 13 14 I further certify that the adverse 15 parties, PETITIONERS BIONTECH SE AND PFIZER INC., 16 were represented by counsel at the deposition. 17 18 I further certify that the deposition of 19 JAMES J. MOON, PH.D., occurred at the offices of 20 WILLIAMS & CONNOLLY LLP, 680 MAINE AVE SOUTHWEST, 21 WASHINGTON, D.C. 20024, on FRIDAY, 22 SEPTEMBER 13, 2024, commencing at 9:05 A.M. to 12:40	
90 1 P.M. EDT. 2 3 I further certify that I am not related to 4 any of the parties to this action by blood or 5 marriage, I am not employed by or an attorney to any 6 of the parties to this action, and that I am in no 7 way interested, financially or otherwise, in the 8 outcome of this matter. 9 10 IN WITNESS WHEREOF, I have hereunto set 11 my hand and affixed my notarial seal this 18th day 12 of September 2024. 13 14 My Commission Expires: July 31, 2029 15 16 17  18 _____ 19 NOTARY PUBLIC IN AND FOR 20 THE DISTRICT OF COLUMBIA 21 22	

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Transcript of James J. Moon, Ph.D.
Conducted on September 13, 2024

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Williams & Connolly LLP (DC)
680 Maine Avenue, SW
Washington, DC 20024

Re: Deposition of **James J. Moon, Ph.D.**

Date: 9/13/2024

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

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Re: Deposition of **James J. Moon, Ph.D.**

Date: 9/13/2024

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ACKNOWLEDGMENT OF DEPONENT

I, James J. Moon, Ph.D., do hereby
acknowledge that I have read and examined the
foregoing testimony, and the same is a true, correct
and complete transcription of the testimony given by
me and any corrections appear on the attached Errata
sheet signed by me.

Oct 7, 2024

(Date)

Jack Moon

(Signature)