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Transcript of James E. Malackowski

Date: July 22, 2024

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

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

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Conducted on July 22, 2024

1 (1 to 4)

1 UNITED STATES PATENT AND TRADEMARK OFFICE 2 BEFORE THE PATENT TRIAL AND APPEAL BOARD 3 BIONTECH SE AND PFIZER INC. 4 Petitioners 5 v. 6 MODERNATX, INC. 7 Patent Owner 8 ----- 9 Case IPR2023-01358 10 Patent No. 10,702,600 11 ----- 12 Case IPR2023-01359 13 Patent No. 10,933,127 14 15 ** CONFIDENTIAL ** 16 DEPOSITION OF 17 JAMES E. MALACKOWSKI 18 July 22, 2024 19 Chicago, Illinois 20 21 Reported by: 22 Janice M. Kocek, CSR, CLR Job No. 546210	3 1 A P P E A R A N C E S: 2 ON BEHALF OF THE PETITIONER BIONTECH SE: 3 PAUL HASTINGS LLP 4 71 South Wacker Drive, Suite 4500 5 Chicago, Illinois 60606 6 312.499.6000 7 BY: DOUG SAWYER, ESQ. 8 dougsawyer@paulhastings.com 9 SUMMER STEVENS, ESQ. 10 summerstevens@paulhastings.com 11 12 ON BEHALF OF PETITIONER PFIZER INC.: 13 WILLIAMS & CONNOLLY LLP 14 680 Main Avenue SW 15 Washington, DC 20024 16 202.434.5000 17 BY: MICHAEL J. MESTITZ, ESQ. 18 mmestitz@wc.com 19 20 21 22
2 1 The deposition of JAMES E. MALACKOWSKI, 2 reported stenographically by Janice M. Kocek, 3 License No. 084-002871, Certified Shorthand 4 Reporter, Certified LiveNote Reporter, and Notary 5 Public for the State of Illinois, held at Ocean 6 Tomo, 200 West Madison Street, Chicago, Illinois, 7 commencing at the hour of 9:01 a.m. CST, on the 8 22nd day of July, 2024. 9 10 * * * 11 12 13 14 15 16 17 18 19 20 21 22	4 1 ON BEHALF OF THE PATENT OWNER MODERNATX, INC.: 2 WILMER CUTLER PICKERING HALE AND DORR LLP 3 60 State Street 4 Boston, Massachusetts 02109 5 617.526.6000 6 BY: ANNALEIGH E. CURTIS, ESQ. 7 annaleigh.curtis@wilmerhale.com 8 9 ALSO PRESENT: 10 JESSICA TYRUS MACKAY, ESQ. - BioNTech US Inc. 11 TOM PAPPALARDO, Ocean Tomo 12 JULIA ROWE, Charles River Associate 13 14 15 16 17 18 19 20 21 22

1 INDEX 2 3 TESTIMONY OF JAMES E. MALACKOWSKI PAGE 4 Examination by Mr. Sawyer 6 5 6 DEPOSITION EXHIBITS 7 NUMBER DESCRIPTION PAGE 8 Exhibit 1 Declaration of 13 9 James E. Malackowski 10 Exhibit 2 Moderna Science & Technology 70 11 Day, May 17th, 2022 12 13 14 15 16 17 18 19 20 21 22	7 1 this engagement? 2 A. Not recalling the specific rate because 3 it's changed recently. It's approximately 12- or 4 \$1,300 an hour. 5 Q. And would you characterize the rate 6 you're charging in this particular case 7 commensurate with what you typically charge other 8 clients? 9 A. Yes. I charge the same rate for all 10 matters for all clients. 11 Q. And as part of your engagement in this 12 PTAB action, did you work with a team at Ocean 13 Tomo? 14 A. I did. 15 I note we did not announce appearances 16 for the record. But Tom, who's sitting here, is 17 on my team. And I also worked with Robert 18 McSorley. 19 Q. Anyone else on your team besides Tom 20 and Robert? 21 A. Not to any meaningful degree. 22 Q. When were you first retained to work on
6 1 (Witness sworn.) 2 JAMES E. MALACKOWSKI, 3 called as a witness herein, having been first duly 4 sworn, was examined and testified as follows: 5 EXAMINATION 6 BY MR. SAWYER: 7 Q. Good morning, Mr. Malackowski. 8 A. Good morning, sir. 9 Q. I want to make sure I'm pronouncing 10 your name correctly. 11 Is it Malackowski? Is that correct? 12 A. Perfect. 13 Q. Great. 14 Can you state your full name, spell 15 your last name for the record? 16 A. James Edward Malackowski, 17 M-a-l-a-c-k-o-w-s-k-i. 18 Q. And who is your current employer? 19 A. Ocean Tomo, a part of J.S. Held. 20 Q. And what's your current position? 21 A. Senior managing director. 22 Q. And what was your hourly rate paid for	8 1 this particular report, the declaration of James 2 Malackowski, for the PTAB proceeding? 3 A. I don't recall a specific engagement 4 date for that proceeding as distinct from the 5 other work that we've done in the district court 6 litigation. But the focus of the report would 7 have been in the month prior to its issuance. 8 Q. And you mentioned your engagement with 9 the district court litigation. 10 Did you work with the same team for the 11 district court litigation as you did with the PTAB 12 declaration? 13 A. In addition to Tom and Robert, Liam 14 Howe also was involved in the district court 15 action. 16 Q. And is Liam Howell also a employee of 17 Ocean Tomo? 18 A. He was until quite recently. He's now 19 left to go work for a startup. 20 Q. You mentioned that you believe most of 21 -- or at least the beginning of your work on the 22 declaration for the PTAB action started about a

Conducted on July 22, 2024

1 month previous to the issuance of the report; is 2 that correct? 3 A. Within that month, yes, sir. 4 Q. And did you track how many hours you 5 personally spent on the declaration of James 6 Malackowski to support the PTAB action? 7 A. I don't track it specific to that 8 declaration from other work that I've done for 9 counsel for Moderna. But generally speaking, 10 would track my hours for Moderna. 11 Q. Do you recall how many hours you spent 12 writing the declaration for this IPR proceeding? 13 A. No. Your question uses the term 14 "writing." So to be transparent, consistent with 15 my track practice, most of the keys, the keyboard, 16 would have been Mr. McSorley, who's a managing 17 director on engagement in consultation and at my 18 direction. 19 Q. And Mr. McSorley, what's his position 20 at Ocean Tomo? 21 A. He is a managing director and has been 22 so for more than a decade.	11 1 Q. And how is speed to market related to 2 commercial success? 3 A. An ability to meet to market needs 4 sooner rather than later has both direct benefits 5 in terms of sales and profits, obviously. But it 6 also has indirect benefits as far as competitive 7 positioning, generally referred to as a first 8 mover advantage, for example. 9 Q. And is there a particular amount of 10 sales that's indicative of commercial success? 11 A. To my understanding, there is no 12 quantitative threshold required by the courts. 13 That it's contextual given the particular facts 14 and circumstances of the case. 15 Q. Would you characterize commercial 16 success as binary, either there is commercial 17 success or there is not commercial success? 18 A. In the end, I believe the conclusion, 19 as I understand it, that's important for the Court 20 is a binary conclusion. 21 From a business perspective, we also do 22 consider relative success among products. I
10 1 Q. And he's also working on the district 2 court litigation? 3 A. Yes, sir. 4 Q. And what's your understanding of the 5 analytical framework for determining commercial 6 success? 7 A. Well, that's a very general question. 8 I would direct to you my declaration specifically. 9 But generally speaking, it's looking to the 10 performance of the product that is found to embody 11 the technology, whether that be of the patent 12 owner, the infringer, or otherwise. And to look 13 to the significance of the intellectual property 14 at issue, vis-à-vis that product, typically 15 referred to as the nexus. 16 Q. And when you say "performance," what 17 are you referring to? 18 A. Again, defer to my declaration because 19 it's described. But it can include a variety of 20 things from level of sales, level of 21 profitability, speed to market. I believe all 22 those are relevant here.	12 1 believe that's also addressed within my report. 2 Q. So there's various levels of commercial 3 success? 4 A. Well, we need to be careful as to how 5 we think about that. From a legal perspective -- 6 and I'm not a lawyer. I'm not offering legal 7 opinions -- I believe it is binary. The trier of 8 fact will find there is commercial success or 9 there is not. 10 From a business perspective, you can 11 consider relative commercial success in the sense 12 you can compare one product, for example, and its 13 success to another product and its success. 14 Q. What if there's only one product on the 15 market? How would you determine commercial 16 success? 17 A. I don't believe one product would 18 change the analysis, in part because you would 19 still look to sales, profits, speed to market. 20 You could also still consider relative success in 21 that there may be other products that attempted to 22 come to market, but ultimately failed. And

Conducted on July 22, 2024

13 1 specifically, I think that's also addressed in my 2 declaration. 3 MR. SAWYER: I'm going to mark for 4 the record Malackowski PTAB Exhibit 1. 5 And for the record, Malackowski 6 PTAB Exhibit 1 is entitled Declaration of 7 James E. Malackowski and there's a 8 signature page on the back with 9 Mr. Malackowski's signature and the date is 10 May 29th, 2024. 11 (Malackowski PTAB Deposition Exhibit 1 12 was marked for identification.) 13 BY MR. SAWYER: 14 Q. Mr. Malackowski, do you have that 15 deposition, PTAB Exhibit 1, in front of you? 16 MS. CURTIS: Object to form. 17 THE WITNESS: I think you misspoke 18 and said "deposition." 19 BY MR. SAWYER: 20 Q. Sorry. 21 A. I think you mean exhibit. 22 But yes, I do have Exhibit 1.	15 1 speaking, it is evidence of the benefits of the 2 technology in a way that may have been surprising 3 or otherwise unknown to competitors in the market 4 because there was not success by them using the 5 same technology previously. 6 Q. Isn't the use or the benefits of a 7 technology being surprising a different objective 8 indicia of nonobviousness? 9 A. It may relate to other legal indicia. 10 But as it relates to commercial success, my 11 understanding is, as I provided to you, that 12 commercial success of a product demonstrates new 13 and novel introductions to the mark in some form 14 or fashion. 15 Q. You'd agree with me that economic 16 incentives to develop a product that practices the 17 alleged invention -- strike that. 18 Can you explain to me how economic 19 incentives to develop a product that practices the 20 alleged invention tell us anything about whether 21 the alleged invention was obvious? 22 MS. CURTIS: Object to form.
14 1 Q. Thank you. 2 And we have referred to a couple of 3 times, and you've referred me, as well, to a 4 declaration that you submitted in this particular 5 PTAB proceeding. 6 Is this the declaration you are 7 referring to? 8 A. It is. 9 And I would just note for the record 10 that I refer to it as a declaration or my report. 11 But in both cases, I was referring to this 12 exhibit. 13 Q. Mr. Malackowski, turn to paragraph 8 in 14 your report. 15 A. Yes, sir. 16 Q. And I'll just generally refer you to 17 that. 18 But my question is: What is your 19 understanding of why commercial success is an 20 objective indicia of nonobviousness? 21 A. Well, I believe that may also be 22 explained within the exhibit. But generally	16 1 THE WITNESS: I'm not sure that it 2 does in the sense your question describes 3 it. In every case there will be economic 4 incentives to develop a product, to provide 5 a return on the investment, to capture 6 sales, to capture profitability. Unless 7 you're talking about, you know, pure 8 research for academic purposes, there's 9 usually a business incentive behind it. 10 BY MR. SAWYER: 11 Q. So I think we agree that there are 12 usually economic incentives to develop a product, 13 correct? 14 A. Generally speaking. 15 Q. And the reason why commercial success 16 is an objective indicia of nonobviousness is 17 because the law presumes that an idea would have 18 been brought to market sooner in response to those 19 market forces had the idea been obvious, right? 20 A. I think generally that is what I 21 attempted to say a few moments ago. But 22 ultimately, that is a legal determination, and I'm

Conducted on July 22, 2024

17 1 not providing a legal opinion. But that's 2 consistent with my understanding. 3 Q. So for commercial success to be 4 relevant to the obviousness analysis, market 5 forces to produce a product embodying the 6 invention must necessarily be present at the time 7 of the invention, right? 8 A. I don't have that opinion. That seems 9 more like a legal opinion as to whether or not 10 commercial success can be found by the courts, or 11 in this case the PTAB, and outside the scope of 12 presenting the analysis within my declaration. 13 Q. But if there's no demand for a product 14 at a particular time, then there's no real market 15 incentive for others to be trying to develop that 16 particular invention, and therefore there's no 17 objective indicia of nonobviousness, right? 18 MS. CURTIS: Object to form. 19 THE WITNESS: That, again, sounds 20 like you're attempting to force a legal 21 standard of some sort into my analysis and 22 opinions, which I'm not providing a legal	19 1 report, I do evaluate demand for the patented 2 products, and I cite the results of that demand in 3 terms of a number of indicators. 4 Q. And that demand is viewed at the time 5 of the invention, right? 6 MS. CURTIS: Object to form. 7 THE WITNESS: I think the -- that is 8 also seeking a legal conclusion. I don't 9 deal with that specific issue within my 10 declaration. I show demand for the product 11 and the resultant success of that product. 12 I'm not speaking to the chronology that may 13 or may not have an issue with respect to 14 the validity of these patents. 15 BY MR. SAWYER: 16 Q. So your declaration doesn't disclose an 17 opinion for demand of either the '600 or the '127 18 patents in 2015, right? 19 MS. CURTIS: Object to form. 20 THE WITNESS: My opinion describes 21 the historical development of this 22 technology but doesn't seek to quantify
18 1 opinion. 2 That said, I disagree with the 3 premise. I think that there can be 4 commercial reasons to develop products in 5 anticipation of believed or likely future 6 demand. I think that happens all the time. 7 BY MR. SAWYER: 8 Q. That may be. But that isn't the proper 9 analytical framework to judge commercial success 10 for that -- for that particular product? 11 MS. CURTIS: Object to form. 12 THE WITNESS: That was a statement, 13 not a question. And the statement appeared 14 to be legal in nature, drawing -- asking 15 for a legal opinion. And I'm not providing 16 a legal opinion. 17 BY MR. SAWYER: 18 Q. So in your analytical framework to 19 develop -- to determine commercial success in this 20 particular project that you worked on, you weren't 21 evaluating demand? 22 A. I think that's not true. I think in my	20 1 sales and profits as of that time, again, 2 given specific facts, circumstances of this 3 product in this marketplace. 4 BY MR. SAWYER: 5 Q. So your declaration doesn't disclose -- 6 does not disclose an opinion as to the commercial 7 success of the '600 or '127 patent in 2015, 8 correct? 9 MS. CURTIS: Object to form. 10 THE WITNESS: My declaration 11 considers the commercial success of these 12 patents during their lifetime, including 13 the sales and profits that resulted. It 14 discusses the development of the technology 15 that ultimately became the patents, which 16 dates back several years prior. 17 But I don't present a chronology 18 by year or an opinion by year of commercial 19 success this year, not the prior year, or 20 not the following year, for example. 21 BY MR. SAWYER: 22 Q. So your declaration does not disclose

Conducted on July 22, 2024

21 1 an opinion that the '600 and '127 patents had 2 commercial success in 2015, correct? 3 MS. CURTIS: Objection. Asked and 4 answered. 5 THE WITNESS: Same answer. I'm not 6 providing year-by-year analysis. I do 7 provide a conclusion of commercial success 8 based upon the considerations that are in 9 my declaration for this technology covered 10 by these patents. 11 BY MR. SAWYER: 12 Q. Your declaration does not disclose an 13 opinion that the '600 and '127 patents had 14 commercial success in 2016, correct? 15 MS. CURTIS: Objection. 16 THE WITNESS: That's the same 17 question substituting the year. I would 18 have the same answer. 19 BY MR. SAWYER: 20 Q. And if I asked the same question 21 substituting the year of 2017, would your answer 22 be the same?	23 1 A. Fair. 2 Q. And so in 2021 -- late 2020, and early 3 2021, there were many market forces impacting the 4 use and development of vaccines to combat 5 COVID-19, correct? 6 MS. CURTIS: Object to form. 7 THE WITNESS: I'm not sure what you 8 mean by "many market forces." 9 Obviously, there was efforts to 10 produce a vaccine to address the pandemic. 11 That is true. 12 BY MR. SAWYER: 13 Q. And one such effort would be the impact 14 of at least the United States government and other 15 governments around the world investing hundreds of 16 millions of dollars, if not billions of dollars in 17 developing vaccines for COVID-19, correct? 18 A. I think factually, that is true. I 19 think that the efforts were across a number of 20 solutions. As I describe within my report, one of 21 the considerations that I do take into account is 22 that the patented vaccines were, in fact, the ones
22 1 A. Yes. 2 Q. If I asked you the same question, that 3 your declaration does not disclose an opinion that 4 the '600 and '127 patents had commercial success 5 in 2018, would your answer be the same? 6 A. My answer will be the same for any 7 specific isolated year because my analysis is 8 holistic to the technologies at issue and the 9 resultant commercial success. 10 Q. Your declaration does disclose that the 11 first sales of at least Moderna's Spikevax was in 12 either 2020 or -- December 2020 or January 2021, 13 correct? 14 A. It does report the actual sales 15 activity by year, that's true. 16 Q. And your declaration also does disclose 17 that the first sale of Comirnaty vaccine product 18 was also in December 2020 or January 2021, 19 correct? 20 A. I believe that's correct. 21 Q. And in late 2020 and early 2021, the 22 COVID pandemic was impacting the world, correct?	24 1 that were most successful and first successful. 2 Q. Your declaration did not specifically 3 evaluate the impact of the government investment 4 in the amount of sales that -- that may have 5 increased or decreased if that was not present, 6 correct? 7 A. I did not conduct an analysis of a 8 hypothetical world in which there was not 9 government investment, though, again, I do 10 consider the fact of that and other general market 11 forces, specifically with respect to the unique 12 performance of the patented products. 13 Q. And the other -- some other general 14 market forces impacting the development and sales 15 of vaccines for COVID-19 was the existence of very 16 large government contracts, correct? 17 A. Sure. Yes. 18 Q. And your declaration did not -- did not 19 specifically evaluate the impact on the 20 development and sales of COVID-19 vaccines in the 21 absence of those large government contracts? 22 A. Same answer as before. I have not

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BioNTech-Pfizer Exhibit 1157

BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Page 7 of 65

Conducted on July 22, 2024

25 1 specifically identified a hypothetical world where 2 those contracts did not exist, though I did 3 consider the relative performance of the patented 4 products versus others that, in my opinion, would 5 have also be subject to government contracts if 6 they had performed equally well. 7 Q. Do you know what other -- strike that. 8 Other market forces that were in 9 existence in the early 2021 are -- were guaranteed 10 sales of by purchasing government agencies that 11 exceeded the actual demand; is that right? 12 A. I don't specifically focus on that 13 issue within my report. But I do understand that 14 the government did seek to purchase a large 15 quantity that would exceed expected demand. 16 Q. And so your declaration did not 17 specifically evaluate the impact of that 18 purchasing of excess demand on the impact on 19 commercial success for particular vaccines 20 available at that time? 21 A. I disagree and would refer you back to 22 our prior discussion, that for each of these	27 1 when you ask me what is and isn't in my report, 2 let's just make clear, I defer to the context of 3 the report. I know it's not a memory test as to 4 each sentence within it. 5 Q. Okay. And I understand that. And 6 you're obviously free to look at your report any 7 time. And if I have not said that already, please 8 do. 9 I think one of my questions is I don't 10 see these things in your report, and so it's very 11 difficult for me to point you to your report to 12 point out something that's not in it. But if we 13 see it during questions and you want to point it 14 out later, please do. 15 Another market force impacting the 16 sales and development of COVID vaccines was the 17 government's requirement for individuals to get 18 vaccinated, correct? 19 A. Could you explain a little further what 20 you mean by the "government's requirement to get 21 vaccinated"? 22 Q. Sure.
26 1 market forces, although I have not conducted 2 unique hypothetical analysis in which a given 3 consideration was not present, I have considered 4 the relative performance of the patented vaccines 5 versus the alternatives that made it to market, as 6 well as the many alternatives that did not in 7 reaching my conclusion of commercial success. 8 Q. Is that analysis in your report? 9 A. I believe so. I believe 10 there's discussion of the failure of others, the 11 number of candidates that were originally advanced 12 by the parties in this case, the speed to market, 13 the efficacy. I believe that's all addressed. 14 Q. Okay. But the -- the market factor -- 15 the market force of guaranteed sales of amounts of 16 vaccine above actual demand is not specifically 17 addressed in your report? 18 A. I don't recall that that specific 19 consideration is called out within my report. But 20 I certainly believe that the analysis put forth in 21 the report would speak to that. 22 But, of course, in all these questions	28 1 Do you have an understanding that 2 during the pandemic to -- for certain government 3 positions, including the military and others, the 4 U.S. government, as being one example, required 5 individuals to be vaccinated to perform their job 6 duties? 7 A. I do understand that there were certain 8 governmental positions that had as part of their 9 job requirement vaccination. I don't believe 10 there was a general mandate that all citizens must 11 be vaccinated. 12 Q. Do you agree that the government 13 requirement for certain individuals to be 14 vaccinated impacted demand for Spikevax and 15 Comirnaty? 16 A. Well, I think as with the other factors 17 that we discussed, any sort of market force, and 18 that would be one, and we've now discussed 19 several, did have an effect on the marketplace. 20 But importantly, it would have had a 21 unique -- the same effect to any viable candidate, 22 if there -- if there was one. So I considered it

Conducted on July 22, 2024

29 1 from a relative perspective within my report. 2 Q. Do you agree that private requirements 3 for vaccination impacted demand for Spikevax and 4 Comirnaty? 5 A. Same as before. I believe it would be 6 a factor that would affect the demand for COVID 7 vaccines, but a factor that would span across all 8 effective and timely produced vaccines. 9 Q. Do you agree that the fact that the 10 vaccines were free to the consumer impacted the 11 demand for Spikevax and Comirnaty? 12 A. Same answer. 13 Q. Do you agree that the government 14 officials and government agencies promoting its 15 citizens to be vaccinated impacted demand for 16 Spikevax and Comirnaty? 17 A. Same answer. 18 Q. Do you agree that both branded and 19 unbranded advertisements for Comirnaty and 20 Spikevax impacted demand for Spikevax and 21 Comirnaty? 22 A. I have not specifically analyzed the	31 1 11. 2 A. Yes, sir. 3 Q. So in paragraph 11 -- please feel free 4 to read it -- but you make a statement that 5 (as read): The patentee is not required to 6 demonstrate that its claimed inventions are solely 7 responsible for the market success of the patented 8 product. 9 Do you see that? 10 A. Yes, sir. 11 Q. Okay. And if I didn't say it, that's 12 in demonstrating nexus, you don't have to 13 demonstrate that the claimed invention is solely 14 responsible for the market success of the patented 15 product, correct? 16 A. Yes, sir. 17 Q. Okay. How many nonclaim features or 18 aspects of the product may contribute to 19 commercial success in order to conclude that there 20 is no nexus? 21 A. To my knowledge, there is no 22 quantitative threshold in that regard. That it is
30 1 distinction between branded and unbranded 2 advertising. But I would agree that generally 3 speaking, market promotion of vaccines did have an 4 impact on adoption, but, again, would have had the 5 same impact with any available effective vaccine. 6 Q. So based on that, there are at least a 7 number of other market factors that influence the 8 demand for Spikevax and Comirnaty beyond the '600 9 and '127 patents? 10 MS. CURTIS: Object to form. 11 THE WITNESS: There are always 12 market conditions that affect the demand 13 for a product, in particular, the existence 14 of the pandemic. And so yes, they exist, 15 and yes, I've considered that, in 16 particular as it relates to the performance 17 of the patented products vis-à-vis others 18 in the market. 19 BY MR. SAWYER: 20 Q. Can you go back to your report, please? 21 A. Yes, sir. 22 Q. And I want to direct you to paragraph	32 1 contextual. I would direct you further to 2 paragraph 12, where I talk about the advice of the 3 federal circuit, and notes that in certain cases, 4 there can be nexus to the extent that the product 5 is the invention disclosed and claimed in the 6 patent. 7 Q. Is nexus binary, or do you agree that 8 there's -- in some cases there is a stronger nexus 9 to the patented features versus other cases where 10 it's less strong, or weaker? 11 A. I'm not aware of a gradient of nexus as 12 far as the conclusion of the courts. Obviously, 13 that's a legal question I'm not opining to. 14 But my understanding in the framework 15 for my analysis was that it's binary, that there 16 is a nexus or there is not. There may be nexus 17 with more than just the technology. But as long 18 as the technology is -- meets that threshold, then 19 it should be considered. 20 Q. And you didn't do the analysis to 21 determine whether there was nexus? 22 A. I rely upon Dr. Krause, as described in

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BioNTech-Pfizer Exhibit 1157

BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Page 9 of 65

Conducted on July 22, 2024

33 1 my report. 2 Q. So you don't have an opinion on whether 3 or not there's nexus? 4 A. I'm not offering that technical opinion 5 as to whether or not there's nexus or a legal 6 opinion. It is my understanding that there is 7 based upon the work with Dr. Krause. 8 Q. Can you have nexus in a commercial 9 success sense if there's no issued patent? 10 A. What would you -- nexus to what? 11 Q. To an application -- patent 12 application. 13 A. That sounds like a legal question I'm 14 not opining to. 15 Q. So you don't have an opinion one way or 16 the other? 17 A. No. That's a legal question, as I 18 understand it. 19 Q. You mentioned paragraph 12 of your 20 report, so maybe we can go there. 21 In paragraphs 12 you state (as read): 22 There is a presumption of -- there can be a	35 1 presumption of nexus? 2 A. I would defer to Dr. Krause's report. 3 I believe it is something that is considered and 4 discussed within the report, but I don't know that 5 it's relying solely upon such consideration. 6 Q. So your -- your report, in your 7 opinion, to demonstrate nexus is not based on some 8 other standard, like reasonable commensurate scope 9 of the claims? 10 MS. CURTIS: Object to form. 11 THE WITNESS: Again, that is part of 12 the background that may be considered in 13 deriving an opinion of nexus. But I would 14 refer you to Dr. Krause's report to address 15 that specific question. 16 BY MR. SAWYER: 17 Q. And you have no opinion one way or the 18 other that commercial success nexus is tied to any 19 unique feature of the alleged patented inventions? 20 A. Well, I have an understanding that it 21 is tied to the unique feature of these inventions 22 because that's what's described within
34 1 presumption of nexus under certain circumstances. 2 Do you see that? 3 A. Yes. 4 Q. And are any of your opinions in your 5 report which is exhibit Malackowski PTAB 1 based 6 on a presumption of nexus? 7 A. No. Because I'm drawing the conclusion 8 that there is nexus. I would defer to you 9 Dr. Krause for his discussion of presumption and 10 the coextensive nature of this technology to these 11 products. But that's not within the scope of my 12 assignment. 13 Q. So it is your understanding that your 14 report is not relying on any presumption of nexus? 15 MS. CURTIS: Object to form. 16 THE WITNESS: My report is relying 17 upon a finding of nexus. Whether that is a 18 finding that includes presumption or not is 19 not relevant to my work or conclusions. 20 BY MR. SAWYER: 21 Q. Do you have an understanding of whether 22 Dr. Krause was basing his opinion on nexus, on a	36 1 Dr. Krause's report. But the opinion that those 2 two are connected and linked is a technical 3 opinion that he provides. 4 Q. What is your understanding of the 5 unique patented features? 6 A. So as a layperson, my understanding 7 that that -- these patents do with a 8 betacoronavirus that has the spike protein above 9 betacoronavirus that's wrapped in an LNP. But for 10 that technical discussion, I would refer you to 11 Dr. Krause. 12 Q. Do you have an opinion on how -- strike 13 that. 14 Do you have an opinion on why the 15 patents that relate to a betacoronavirus that has 16 a spike protein after the betacoronavirus is 17 wrapped in an LNP contributes to commercial 18 success? 19 MS. CURTIS: Object to form. 20 THE WITNESS: That is a technical 21 question. But it's my understanding that 22 that invention allows for greater

Conducted on July 22, 2024

37 1 efficiency of response without creating a 2 viral incident that would cause the 3 recipient to have the disease. 4 BY MR. SAWYER: 5 Q. And from your lay perspective, does 6 that relate to modified mRNA? 7 A. My understanding is that it does. But 8 I'm not offering an opinion in that regard so I 9 would defer to Dr. Krause. 10 Q. Do you have an opinion as to whether it 11 relates to unmodified mRNA? 12 A. I do not. 13 Q. How about self-amplifying mRNA? 14 A. I don't have an opinion. 15 Q. Do you have an opinion on whether 16 there's a particular LNP that's required to 17 practice the inventions? 18 A. I do not. 19 Q. Do you have any opinion on the -- how 20 different LNPs impact the commercial success of 21 the -- of Comirnaty or Spikevax? 22 A. I have not studied or put forth an	39 1 the '127 or '600 patent, correct? 2 A. Correct. I'm assuming that there's use 3 of the technology within those products, but I'm 4 not offering a legal opinion in that regard. 5 Q. You're not an expert on vaccine 6 development, correct? 7 A. Correct. 8 Q. You're not an expert on the FDA 9 approval process? 10 A. I don't hold myself out as an expert in 11 that regard, no. 12 Q. You're not an expert on drug 13 development process, correct? 14 A. Same answer. 15 Q. You have no expertise on why drug 16 candidates fail in the development process, 17 correct? 18 A. I'm not offering any opinions in that 19 regard in conjunction with this case. I've had 20 business experience related to those issues and 21 several of the issues you've raised, but that's 22 outside the scope of my work here.
38 1 opinion in that regard. 2 Q. Mr. Malackowski, so you're not offering 3 any technical opinions, correct? 4 A. I'm not offering any technical or legal 5 opinions, correct. 6 Q. Okay. You're not an expert on mRNA, 7 correct? 8 A. Correct. 9 Q. You're not an expert on LNPs, correct? 10 A. Correct. Certainly not a technical 11 expert. 12 Q. Okay. And you have no opinions on what 13 the patents actually -- what the patent claims 14 actually cover, correct? 15 A. I'm not sure I understand the question. 16 I understand that there are others who have 17 described that in great detail. I've reviewed, 18 for example, Dr. Krause's report in that regard. 19 But I'm not offering a claim construction opinion. 20 Q. And you're also not offering a 21 technical opinion on whether or not Spikevax or 22 Comirnaty are covered by any particular claims of	40 1 Q. You have -- you're offering no opinion 2 on how many drug candidates failed during each 3 stage of the drug development process, correct? 4 A. Are you talking about generally 5 speaking? It is my understanding, and I believe 6 if not within this report, within the materials I 7 cite there is reference to the failure rate at 8 Phase I, Phase II, Phase III, for example. 9 Q. And where -- sorry. Strike that. 10 You're not offering an opinion on how 11 many drug candidates fail during each stage of the 12 drug development process specifically as it 13 relates to the COVID-19 development of vaccines, 14 are you? 15 A. I've not presented that quantitative 16 assessment. I believe there was reference to the 17 fact that there were several candidates that were 18 considered, and obviously I set forth a number 19 that have been approved. 20 Q. But you're not offering an expert 21 opinion on if that's a big number or small number 22 or how it relates to any other drug development or

Conducted on July 22, 2024

41 1 any other vaccine, correct? 2 A. That's a very general question. So I 3 would defer you to the context of my report as to 4 how that factual data is used within my work. But 5 I am not benchmarking the development here 6 quantitatively against the development of any 7 other specific vaccine or pharmaceutical. 8 Q. In your report, you didn't disclose 9 that you spoke to anyone to provide any technical 10 opinions; is that right? 11 A. Correct. 12 Q. Your report mentions that you read 13 Dr. Krause's declaration, and you've mentioned 14 that a couple of times in your deposition today, 15 correct? 16 A. Both are true. 17 Q. But you never actually talked to 18 Dr. Krause to prepare your report? 19 A. Correct. 20 Q. When did you first review Dr. Krause's 21 report? 22 A. I would have received the final report	43 1 something. So it's a lengthy document. And I 2 reviewed it more than once. I don't have a number 3 of hours for you. 4 Q. So it was maybe, like, a whole day? 5 A. I didn't sit down and spend a day, 6 start to finish, on the report. There are certain 7 portions that are more relevant to me. The end of 8 the report specifically deals with the issues that 9 I'm relying upon. I did also find it interesting 10 and helpful background. 11 I can't tell you, if you put all those 12 chunks together, if it would be more than a day or 13 not. I'd be speculating. 14 Q. Did you -- it sounds like the answer is 15 no, but I'll just ask it. 16 Did you review any draft reports of 17 Dr. Krause? 18 A. I did not. 19 Q. Did you review any of the materials he 20 relied on? 21 A. Not specifically. Though I can't tell 22 you as I sit here whether there wasn't some
42 1 of Dr. Krause the day it was produced. I had an 2 understanding of the opinions through my work with 3 my team shortly prior to that. 4 Q. Is it your understanding that the 5 report that you reviewed was the final report? 6 A. Yes. 7 Q. Do you know if anyone on your team 8 physically spoke with Dr. Krause prior to his 9 finalizing the report? 10 A. I don't. 11 Q. Do you know if anyone on your team 12 provided input that Dr. Krause included in his 13 report? 14 MS. CURTIS: And I'll just caution 15 you not to reveal the content of any 16 attorney-client communications. But if you 17 can answer without doing so, go ahead. 18 THE WITNESS: I don't. 19 BY MR. SAWYER: 20 Q. Do you recall how long you took to 21 review the report -- the Krause report? 22 A. I think it's, like, 150 pages or	44 1 overlap. I would have to simply go back and 2 investigate his materials considered list versus 3 my own. 4 Q. So you can take a look at your report, 5 but it doesn't appear that your report has a 6 materials considered list. It just has footnotes. 7 Do you -- are the footnotes all the 8 materials that you considered in drafting your 9 report? 10 A. I would say the footnotes represent all 11 of the third-party materials that I relied upon in 12 drafting my report. There may have been other 13 things that I reviewed as part of the research 14 process, but nothing that was meaningful or 15 material to the conclusions. 16 Q. So if it's not included in the report, 17 it wasn't material to your opinion, correct? 18 A. It was not a material basis for my 19 opinion, correct. 20 Q. You don't contend that the '600 patent 21 creates the sole basis for demand for Spikevax; do 22 you?

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BioNTech-Pfizer Exhibit 1157

BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Page 12 of 65

Conducted on July 22, 2024

45 1 A. That is not an opinion presented in my 2 report. 3 Q. You don't contend that the '600 patent 4 creates a sole basis for the demand for Comirnaty, 5 correct? 6 A. Same answer. 7 Q. You don't contend that the '127 patent 8 creates the sole basis for demand for Spikevax, 9 correct? 10 A. Same answer. 11 Q. You don't contend that the '127 patent 12 creates the sole basis for demand for Comirnaty, 13 correct? 14 A. Same answer. 15 Q. You don't contend that the combination 16 of the '127 and '600 patents create the sole basis 17 for the demand for Spikevax, correct? 18 A. Same answer. 19 Q. You don't contend that the combination 20 of the '127 and '600 patents create the sole basis 21 for the demand for Comirnaty, correct? 22 A. Same answer.	47 1 undefined technologies. So I would defer you to 2 my report, which focuses on the impact of the 3 technologies here based upon my work and reliance 4 upon Dr. Krause. 5 Q. So your opinion hasn't ruled out that 6 other technologies did, in fact, impact demand for 7 Spikevax, correct? 8 A. These are unnamed potential 9 technologies. I'd be speculating to say that 10 those unnamed things did or didn't impact demand 11 from my perspective because it's not required that 12 the technologies here be solely responsible. I 13 recognize that there may, in fact, be other 14 technologies, but I have not specifically seen or 15 identified them in my report. 16 Q. And since you haven't specifically seen 17 or identified in the report, you can't evaluate 18 one way or the other whether those technologies, 19 in fact, had greater impact on demand than the 20 alleged patented technologies? 21 MS. CURTIS: Object to form. 22 THE WITNESS: In a vacuum, it would
46 1 Q. And when you say "same answer," that's 2 yes, you're not contending that, correct? 3 A. That those opinions are not included 4 within the context of my report. 5 Q. You agree that other technologies 6 impacted the demand for Comirnaty, correct? 7 A. That's a very broad question. We'd 8 have to talk about the specific technologies. But 9 generally speaking, I'm not trying to limit the 10 impact of other technologies generally within my 11 report. 12 Q. And you agree that other technologies 13 impacted the demand for Spikevax, correct? 14 A. Same answer. 15 Q. When you say you're not trying to limit 16 the impact of other technologies generally in your 17 report, it means you agree with me that other 18 technologies impacted the demand for these 19 vaccines, meaning the increased demand for these 20 vaccines? 21 A. No. It means I haven't specifically 22 sought to identify and rule out other unnamed,	48 1 be very hard to say that because we don't 2 know what we're talking about generically. 3 But I do explain within my report the very 4 unique factors surrounding this technology. 5 In particular, the fact that it was 6 reflected in the two most successful, most 7 quickly introduced product when there were 8 many, many others who were trying. 9 So from a licensing perspective, 10 I can't imagine that there were others that 11 were more impactful because you would have 12 expected them to have succeeded in the 13 marketplace and they have not. 14 BY MR. SAWYER: 15 Q. What are the very unique factors 16 surrounding this technology? 17 A. Well, again, this is a technical 18 question so I defer to Dr. Krause. But it's my 19 understanding based upon my review of his report 20 that this technology speaks to the -- you know, 21 the essence of a vaccine, which is to stimulate an 22 immune response without creating a viral effect in

Conducted on July 22, 2024

49 1 the patient. 2 And that this -- that these -- this 3 technology had a very strong performance in that 4 regard and was able to be produced in a -- the 5 most timely way vis-à-vis other products. 6 So my understanding is this technology 7 is highly important to these products. 8 Q. Even if assuming it's highly important 9 to these products, you haven't evaluated one way 10 or the other whether or not there are other 11 technologies that had higher impact on commercial 12 success than the alleged patented features? 13 A. I'm not aware of those. So to that 14 extent, I haven't evaluated them. I don't know if 15 there are such things. But even if there are 16 theoretically such things, I don't believe there's 17 a requirement to say that the patented technology 18 here must be the most important or the most 19 impactful in order to meet the conditions of 20 commercial success. 21 Q. What happens if it's minimally 22 impactful? Does it still meet the definition of	51 1 the technology being considered for commercial 2 success must be the most impactful of all 3 technologies. 4 Q. Okay. And do you draw a line if it is 5 minimally impactful? Would you still form the 6 same opinion that a patented feature that is 7 minimally impactful demonstrates commercial 8 success in a nonobvious analytical framework? 9 A. Again, I believe that's ultimately a 10 legal question so I'm not opining to that. That 11 said, I don't believe that this is a case where 12 these inventions would be considered minimally 13 impactful so I have not specifically considered 14 that. 15 Q. And what's the basis for your view that 16 these are not viewed to be minimally impactful? 17 A. Largely, both the discussion of 18 Dr. Krause in describing the importance of these 19 technologies and the economic evidence that shows 20 they're a unique commercial success. 21 Q. When you say "they're a unique 22 commercial success," are you referring to unique
50 1 commercial success in your mind? 2 A. I think we'd have to look at the 3 specific facts and circumstances and try to define 4 what "minimally" means. That's not applicable to 5 the facts of this case so I haven't attempted to 6 do that. 7 Q. Well, what does "maximally impact" 8 mean, which is what you used to define the 9 patented features? 10 MS. CURTIS: Object to form. 11 THE WITNESS: I don't recall using 12 the phrase "maximally impacted," but maybe 13 you can refresh me. 14 BY MR. SAWYER: 15 Q. You said "most important" and "most 16 impactful." 17 A. Could you either reread the context of 18 that or -- 19 Q. Yeah. Well, I can just rephrase, too. 20 So in your mind, there's no requirement 21 that it be the most impactful, correct? 22 A. I'm aware of no legal requirement that	52 1 commercial success in the U.S. versus worldwide? 2 A. I believe there's a reference to both. 3 But my focus is on the actual sales as made, 4 regardless of the market or jurisdiction. 5 Q. Okay. And in order for something to 6 have commercial success in the U.S., would it have 7 to be FDA approved or receive an Emergency Use 8 Authorization? 9 A. I don't believe there's a requirement 10 that that be done in order to demonstrate 11 commercial success. 12 I do believe that in order to be able 13 to sell these products in the marketplace in the 14 United States, that is required. 15 Q. And isn't one of the primary factors 16 you're looking at to evaluate commercial success 17 the sales of the products in the U.S.? 18 A. That is an important factor, yes. 19 MR. SAWYER: Why don't we take a 20 little bit of a break. 21 MS. CURTIS: Sure. 22

Conducted on July 22, 2024

1 (Whereupon, a recess was taken 2 from 9:52 a.m. to 10:07 a.m.) 3 MR. SAWYER: Back on the record. 4 BY MR. SAWYER: 5 Q. Mr. Malackowski, could you turn back to 6 your report, which is Exhibit 1? 7 A. Yes, sir. 8 Q. I'll ask you to look at paragraph 17. 9 And specifically, sort of the last sentence there. 10 You state (as read): I understand from Dr. Krause 11 that the superior efficacy, safety, and rapid 12 development timelines for Spikevax and Comirnaty 13 are attributable to the technologies claimed in 14 the '600 and '127 patents. 15 Do you see that? 16 A. Yes, sir. 17 Q. You personally have no opinion on how 18 the '600 or '127 patents impact the efficacy, 19 safety, and rapid development timing for Spikevax 20 and Comirnaty, correct? 21 A. I'm offering no expert opinion. That's 22 a technical matter, as I understand it.	1 A. Other than my review of Dr. Krause's 2 report, which speaks to those issues. 3 Q. Your report did not disclose any 4 investigation by you into how much safer Spikevax 5 and Comirnaty are due to the '127 patent, correct? 6 A. Same answer. 7 Q. And when you say "same answer," that 8 means you did not disclose it. You're relying on 9 Dr. Krause? 10 A. Well, the safety issue is disclosed, 11 but it's disclosed relative to my reliance on 12 Dr. Krause. 13 Q. So you have no opinion on the impact 14 that the '127 patent has on the safety of Spikevax 15 and Comirnaty, correct? 16 A. Not other than what I rely upon from 17 Dr. Krause. And I do not offer a technical 18 opinion in that regard. 19 Q. Your report did not disclose any 20 investigation by you into how much slower or 21 faster the development of Spikevax or Comirnaty 22 was due to the '600 patent, correct?
1 Q. Okay. And you have no opinion on why 2 the '600 or '127 patents impact the efficacy, 3 safety, and rapid development timing for Spikevax 4 and Comirnaty, correct? 5 A. Same answer. 6 Q. Your report did not disclose any 7 investigation into how much more effective 8 Spikevax and/or Comirnaty are due to the '600 9 patent, correct? 10 A. Not other than the statements I cite to 11 Dr. Krause, correct. 12 Q. And your opinion did not disclose any 13 investigation by you into how much more effective 14 Spikevax and Comirnaty are due to the '127 patent, 15 correct? 16 A. Same answer. 17 Q. And your opinion does not disclose any 18 investigation by you into how much safer Spikevax 19 and Comirnaty are due to the '600 patent, correct? 20 A. Same answer. 21 Q. When you say "same answer," that is 22 yes, you did not disclose that?	1 A. Not specific to the patents at issue. 2 There is some general discussion of product 3 development time. And, again, I do refer back to 4 Dr. Krause's report. 5 Q. And your report does not disclose any 6 investigation into how much slower or faster the 7 development of Spikevax or Comirnaty was due to 8 the '127 patent, correct? 9 A. Same answer. 10 Q. And we discussed this generally, but 11 there are other factors that did impact the speed 12 in which at least Spikevax was developed, right? 13 MS. CURTIS: Object to form. 14 THE WITNESS: That's a very general 15 question. I don't know what you're 16 referring to by "other factors." So 17 perhaps you could be more specific or 18 rephrase. 19 BY MR. SAWYER: 20 Q. Well, certainly not the speed in which 21 Spikevax was developed was not solely due to the 22 '127 and '600 patents, right?

Conducted on July 22, 2024

57 1 A. I don't claim that to be the case, no. 2 Q. In fact, for example, government 3 funding that Moderna received likely had an impact 4 in the speed in which it was able to develop 5 Spikevax. 6 A. I'm not offering an opinion in that 7 regard. I'm not opining either way. 8 Q. You would agree with me that absent the 9 government funding, Spikevax would have likely 10 taken longer to develop? 11 A. That would be speculating. I don't 12 know. 13 Q. So you didn't factor that into your 14 opinion at all? 15 A. I did not factor into account the 16 incremental speed associated with governmental 17 funding aside from my understanding of the 18 technical attribution of these inventions 19 contributing to speed that is discussed within 20 Dr. Krause's report. 21 Q. Yeah. And, in fact, you didn't 22 actually take into the technical attribution of	59 1 could be countless other factors related to 2 employees or the like. I'm not aware of any other 3 factors cited in the record that has the 4 significance that Dr. Krause attributes to the 5 patented invention. 6 Q. You're not aware of them because you 7 didn't consider any others. 8 A. I considered them by looking to 9 understand if there was evidence in the record of 10 such, and I haven't seen it. 11 Q. And what record were you looking at? 12 A. All of the materials that are cited 13 within my report specifically. 14 Q. And you didn't look at the -- did you 15 look at the IPR filings and the related 16 declarations? 17 A. No, I don't believe I've looked at the 18 IPR file. 19 Q. So you've only looked at what's cited 20 in your report and Dr. Krause's final report, 21 correct? 22 A. True. But what's cited in my report
58 1 these inventions. You just relied on Dr. Krause. 2 MS. CURTIS: Object to form. 3 THE WITNESS: I don't know what you 4 mean by "take in," but I defer you to my 5 report where I cite to Dr. Krause and my 6 takings from Dr. Krause's report. 7 BY MR. SAWYER: 8 Q. So it was Dr. Krause that -- if there 9 is an opinion on how much the '600 and '127 10 patents affected the speed in which it was 11 developed, it was Dr. Krause's opinion and not 12 yours? 13 A. That's kind of an oddly worded phrase. 14 Let me just say that it's my 15 understanding that the two patents at issue did 16 contribute to the speed of development, and I 17 obtained that understanding from Dr. Krause. 18 Q. And in your opinion -- or in your 19 report, you didn't take into account other factors 20 that may also have impacted the speed at which the 21 Spikevax was developed? 22 A. That's an open-ended question. There	60 1 includes the public disclosures and filings of 2 these companies describing these products and 3 their success and the reasons for that. So I'm 4 not aware of anything that would suggest or 5 discount from Dr. Krause's conclusions. 6 Q. Having an emergency use authorization 7 as opposed to a typical FDA approval process 8 certainly sped up the development and launch of 9 Spikevax, right? 10 A. Certainly sped up the launch of the 11 products. I would agree with that. 12 Q. You'd also agree that it sped up the 13 development process, right? 14 A. I don't know what you mean by 15 "development." If you're including within 16 "development" the full FDA process, then yes. If 17 you're including something other than that, you 18 need to be more specific. 19 Q. Other COVID-19 vaccines were developed 20 just as quickly as Spikevax and Comirnaty, 21 correct? 22 MS. CURTIS: Object to form.

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BioNTech-Pfizer Exhibit 1157

BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Page 16 of 65

Conducted on July 22, 2024

61 1 THE WITNESS: Other vaccines may 2 have developed within a similar period of 3 time but not with the same effectiveness. 4 BY MR. SAWYER: 5 Q. My question is: Were other COVID-19 6 vaccines developed in roughly the same period of 7 time as Spikevax and Comirnaty? 8 A. Other unsuccessful vaccines were. I 9 believe that's true. 10 Q. And by "other," what you're classifying 11 as unsuccessful, would you classify AstraZeneca's 12 Vaxzevria unsuccessful? 13 A. "Unsuccessful" is a term that we also 14 have to put some definition around it because I've 15 not considered it from a commercial success point 16 of view in the nexus of success to successful. 17 But it was not as effective as the products at 18 issue, though it did receive authorization in a 19 similar time frame. 20 Q. And do you have an expert opinion on 21 effectiveness of vaccines against COVID-19? 22 A. Very general question. Within my	63 1 time. For example, the AstraZeneca product was 2 given authorization in February of 2021 as 3 compared to December 2020 or January 2021 for the 4 patented products. 5 Q. And the J&J as well, J&J vaccine, 6 similar time frame? 7 A. Yes. 8 Q. And neither the AstraZeneca or the J&J 9 vaccine are alleged to practice the '127 patent, 10 right? 11 A. Neither of the patents-in-suit is my 12 understanding. 13 Q. Okay. So that includes the '600 patent 14 as well? 15 A. Yes. 16 Q. You're not offering an opinion on what 17 the '600 patent covers, right? 18 A. That, to me, is a technical and/or 19 legal question. I'm not offering that opinion. I 20 describe my understanding of it, and I'm making 21 the assumption that it is infringed by the 22 Pfizer-BioNTech vaccines.
62 1 report you'll see data regarding the 2 effectiveness. I believe within the record you'll 3 hear expectations of effectiveness prior to 4 development targeting governmental satisfaction, 5 if it got to be over 50 percent. And that there 6 was surprise and delight when the patented 7 vaccines exceeded 90 percent. 8 Q. So you don't have an expert opinion on 9 what constitutes effectiveness? 10 A. As far as a threshold? No, I'm not 11 offering an opinion that above a certain 12 percentage would be deemed effective by the 13 industry. 14 I do have an understanding that 15 relatively speaking, the patented vaccines are 16 among the most effective and, in fact, are the 17 most effective that were introduced to the market. 18 Q. So going back to my earlier question, 19 there were other COVID-19 vaccines that were 20 developed as quickly as Spikevax and Comirnaty, 21 right? 22 A. Within a reasonable approximation of	64 1 Q. Do you know if the '600 patent covers 2 any mRNA vaccine formulated in a lipid 3 nanoparticle? 4 A. Technical question. Outside my scope. 5 I don't have an opinion. 6 Q. Do you have any understanding if there 7 is any requirement for the lipid nanoparticle -- 8 strike that. 9 Do you have any understanding of the 10 technical requirements of the NLP, or nano lipid 11 particle, in order to practice the '600 patent? 12 MS. CURTIS: Object to form. 13 THE WITNESS: I'm not offering an 14 opinion in that regard, if there even are 15 such requirements. 16 BY MR. SAWYER: 17 Q. Have you read the '600 patent? 18 A. Yes. 19 Q. Do you know about how long it is? 20 A. How many pages? It's quite lengthy. I 21 don't recall. 22 Q. When you say "quite lengthy," what do

Conducted on July 22, 2024

1 you think? 2 A. I don't have an estimate for you. 3 Q. Half an inch thick? 4 A. I don't have an estimate for you. 5 Q. Did you read it in paper form or did 6 you read it online? 7 A. Both. I have abstracts in paper, and 8 then I reviewed it online. 9 Q. Do you know if it's possible for 10 unmodified RNA vaccines to practice the '600 11 patent? 12 A. Outside my scope. I don't have an 13 opinion. 14 Q. Is it also outside the scope of your 15 opinion whether or not self-amplifying RNA 16 practices the '600 patent? 17 A. Correct. Yes. 18 Q. Do you think the commercial success of 19 Spikevax would be reduced if it did not practice 20 the '600 patent? 21 A. I suppose that depends upon what it did 22 practice instead. That would be a hypothetical	1 A. I consider that within the question of 2 distribute. But I'm not specifically offering 3 that. I have considered the issue of the 4 contribution of the distribution network and the 5 temperature control required thereto. But I've 6 not presented that here as an additional reason 7 for commercial success. 8 Q. But the ability to do that does 9 contribute to the commercial success or at least 10 the amount of sales? 11 A. With any product the ability to 12 actually deliver it to customers will be a factor 13 that affects sales, profits, and other metrics 14 that are commonly used in assessing commercial 15 success. 16 Q. You're not offering an opinion on what 17 the '127 patent covers, right? 18 A. I thought you already asked me that. I 19 am not offering a legal or claim construction 20 opinion. 21 I have an understanding that it covers 22 the products at issue here.
1 I've not considered. 2 Q. Do you think that the commercial 3 success of Comirnaty would be reduced if it didn't 4 practice the '600 patent? 5 A. Same answer. I'm not aware of any 6 commercially acceptable noninfringing 7 alternatives. But that analysis is outside the 8 scope of this report. 9 Q. Do you agree that the '600 patent 10 doesn't relate to the ability to manufacture a 11 vaccine? 12 A. I'm not offering any opinion in that 13 regard. I've not studied that issue. 14 Q. Okay. Do you agree that the '600 15 patent does not relate to having any benefits -- 16 any ability to distribute a vaccine? 17 A. Same answer. 18 Q. You're not offering an opinion on that? 19 A. Correct. 20 Q. You would agree with me that the '600 21 patent does not relate to having any benefits to 22 the ability to transport a vaccine?	1 Q. I asked you about the '600. But I 2 understand that. I just wanted to make sure that 3 your answer would be similar to the '127. 4 A. It would be. 5 Q. How do you distinguish between the '127 6 patent and the '600 patent in your analysis of 7 commercial success? 8 A. There is no specific identification of 9 one versus the other. 10 It's my understanding that there are 11 certain composition versus method claims that are 12 distinct between the two patents. But that I 13 looked at them assuming they are both infringed 14 and assess them jointly. 15 Q. Would your opinion change as to nexus 16 if the '127 patent wasn't part of the analysis? 17 A. It would not change my opinions 18 regarding the '600 so long as the opinions of 19 Dr. Krause did not change. 20 Q. Would your opinions change if the '600 21 were no longer part of the analysis? 22 A. An analogous response, that it would

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BioNTech-Pfizer Exhibit 1157

BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Page 18 of 65

Conducted on July 22, 2024

69 1 depend upon whether or not that had a bearing or 2 impact on Dr. Krause's conclusions. 3 Q. Do you agree that the '127 patent 4 doesn't claim any benefit to the ability to 5 manufacture a vaccine? 6 A. I'm not speaking to that issue. One 7 would need to look to the patent and apply the 8 Court's -- any claim construction and assess it 9 from a technical point of view. 10 Q. Would you agree that the '127 patent 11 does not claim having any benefit to the ability 12 to distribute a vaccine? 13 A. Same answer. That's a technical 14 question. I'm not claiming distribution benefits 15 within the context of my report. 16 Q. Okay. And how about the '127 having an 17 impact on -- or a benefit to the transportation of 18 a vaccine? 19 A. Same. Same answer. 20 MR. SAWYER: I'm going to mark 21 another exhibit, Malackowski PTAB 2. 22	71 1 documents. Do you recognize this as a document 2 that likely was put together by Moderna? 3 MS. CURTIS: Object to form. 4 THE WITNESS: I can only read the 5 document as shown to me. It's titled 6 Moderna, Moderna Science & Technology Day, 7 and contains disclaimers noting that it's 8 based upon Moderna's expectations. So I 9 can make that assumption, if you'd like. 10 BY MR. SAWYER: 11 Q. All right. Well, you've said you've 12 seen at least similar documents to this. And I'm 13 going to direct you to slide 16. 14 A. Slide 16 of 135. Yes, I have it. 15 Q. Okay. Great. 16 And you can see there the title of that 17 slide says (as read): Moderna combines mRNA 18 engineering, delivery system discovery, and 19 clinical manufacturing platforms within a single, 20 fully integrated organization. 21 Do you see that? 22 A. I do.
70 1 (Malackowski PTAB Deposition Exhibit 2 2 was marked for identification.) 3 BY MR. SAWYER: 4 Q. Mr. Malackowski, I've handed you a 5 document that I've printed off the internet, and 6 it is entitled Moderna Science & Technology Day, 7 May 17th, 2022. 8 Have you ever seen this document 9 before? 10 A. I have seen documents similar to this. 11 I can't tell you from memory if I've seen this 12 exact document. It doesn't bear a Bates stamp so 13 I don't know if it's something that was produced 14 in conjunction with this matter or not. But I 15 have seen similar Moderna presentations. 16 Q. I will represent to you it has not been 17 produced as part this matter or -- and I don't 18 know if it's been produced as part of a previous 19 district court litigation. But it is publicly 20 available. 21 A. Thank you. 22 Q. And so you said you've seen similar	72 1 Q. Okay. And so Moderna, at least 2 publicly here, has stated that there are at least 3 sort of three different processes here when it's 4 developing its vaccines. The sort of mRNA, which 5 is kind of in those red boxes; the delivery, which 6 is in the blue boxes; and the manufacturing in the 7 green boxes. 8 Do you see that? 9 MS. CURTIS: Object to form. 10 Foundation. 11 THE WITNESS: So it does appear to 12 make distinction of three different 13 groupings of engineering. I agree with 14 that. 15 BY MR. SAWYER: 16 Q. And if you flip to slide 19. 17 A. Yes. 18 Q. You can see that, again, Moderna here 19 sort of lays out what is -- what's required in an 20 mRNA formulation into lipid nanoparticles, and it 21 lists off a number of different sort of 22 technologies. It's got "mRNA," you see that?

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BioNTech-Pfizer Exhibit 1157

BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Page 19 of 65

Conducted on July 22, 2024

73 1 It's at the top. The ionizable lipid, which is 2 the second one down; the phospholipid, third one 3 down; Sterol; and the PEG lipid. 4 Do you see that? 5 MS. CURTIS: Object to form. 6 Foundation. 7 THE WITNESS: I see what you're 8 reading on the chart. Your question 9 implied that all of these are required. I 10 don't read the chart to say that. But 11 short of that, yes, I can read the data. 12 BY MR. SAWYER: 13 Q. Is it your understanding that a -- 14 like, Spikevax, for instance, which is a COVID-19 15 vaccine, is made up of multiple parts of 16 technology? 17 MS. CURTIS: Object to form. 18 THE WITNESS: I wouldn't view it as 19 multiple parts or components of technology. 20 I do understand that there was engineering 21 related to the development of the product 22 that spanned a number of technologies. I	75 1 BY MR SAWYER: 2 Q. When you were doing your analysis, did 3 you presume that the '600 and '127 patents covered 4 each and every component of the vaccine? 5 MS. CURTIS: Object to form. 6 Foundation. 7 THE WITNESS: The answer to your 8 question is no. Because I don't view this 9 as a componentized product. I don't recall 10 seeing within my review of the patents the 11 phrase "components." But perhaps I've 12 forgotten that, and you can point that out 13 to me. 14 BY MR. SAWYER: 15 Q. Well, when were you doing your 16 evaluation, what -- did you -- did you view that 17 the patents covered the sum and total part of the 18 vaccine? 19 A. I don't know what you mean by "sum and 20 total part." I understand that the patents cover 21 the vaccines, that as these vaccines are produced, 22 the patented technology can't be separated. But
74 1 think that's fair. 2 BY MR. SAWYER: 3 Q. Would you consider Spikevax a 4 multicomponent in nature -- a multicomponent 5 vaccine in nature? 6 A. I would not. Not from a business 7 perspective. That phrase "multicomponent" might 8 have legal meaning outside of my scope. But from 9 a business licensing point of view, I would not 10 consider this a multicomponent product. I would 11 reserve that for something more akin to a 12 computer, a smartphone, a car. 13 Q. And so you would consider the lipid 14 nanoparticle as being the same component as the 15 mRNA strain? 16 MS. CURTIS: Object to form. 17 THE WITNESS: I wouldn't view either 18 of them as components. I would view the 19 vaccine as a product, which is based on a 20 formulation or certain engineering. But I 21 don't see this as a componentized product. 22	76 1 ultimately, that's more of a technical question 2 for Dr. Krause. 3 Q. So your evaluation assume that in order 4 to produce the vaccine, you couldn't separate out 5 the patented aspects? 6 A. For the commercially -- for the 7 commercial product as delivered, I don't believe 8 that that can be separated out, certainly, and 9 maintain the same degree of success. But from a 10 technical separation point of view, I would defer 11 to Dr. Krause. 12 Q. You understand from your work on this 13 -- this case and reviewing Dr. Krause's report 14 that there are other patents that also cover the 15 Spikevax protein -- the Spikevax vaccine, correct? 16 A. Yes, sir. 17 Q. Okay. And you understand that there 18 are other patents that cover the Comirnaty 19 vaccine, correct? 20 MS. CURTIS: Object to form. 21 Foundation. 22 THE WITNESS: I'm not aware of any

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BioNTech-Pfizer Exhibit 1157

BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Page 20 of 65

Conducted on July 22, 2024

77 1 other patents that are so marked that would 2 claim coverage. But I'm not disputing it. 3 It simply is outside my scope. 4 BY MR. SAWYER: 5 Q. So do you agree with me that Spikevax 6 and Comirnaty are complex and multicomponent in 7 nature? 8 MS. CURTIS: Object to form. 9 THE WITNESS: You're asking me, 10 again, the same question you asked me 11 before about components which I've already 12 disclaimed my under- -- my view of. So do 13 I agree they're complex technologies? I 14 don't have a problem with that. 15 BY MR. SAWYER: 16 Q. You don't agree that they're 17 multicomponent in nature? 18 A. I'm not offering that opinion. I 19 understand that it has certain legal 20 ramifications. That's outside my scope. From a 21 licensing perspective, I would not consider this a 22 multicomponent product for the reasons I	79 1 A. Not for its intended purpose unless you 2 can easily supplement it with another processor. 3 Q. Okay. So why is that a separable 4 component and, for instance, a patent or a 5 component that works in conjunction in the vaccine 6 not a separable component? 7 A. I think largely based upon the market 8 characteristics wherein those processors are often 9 developed by third parties, sold separately, 10 marketed separately with competitive elements. 11 Q. So if a component is developed by a 12 third party and then implemented in, it would be a 13 separable component? 14 MS. CURTIS: Object to form. 15 THE WITNESS: Again, you would have 16 to look to the characteristics of it. To 17 some extent, once you -- once you combine 18 certain elements, they become nonseparable. 19 But I don't think that's true of the 20 processor in a computer. 21 BY MR. SAWYER: 22 Q. And your report in this case didn't do
78 1 described. 2 Q. What are the reasons you described? 3 A. That from a licensing perspective, I 4 would look to products that have separable 5 elements, such as the laptop, the smartphone, the 6 automobile. 7 Q. And your current understanding of, for 8 example, Spikevax, they don't have any separable 9 components? 10 A. From a business perspective, I'm not 11 aware of any separable components that would allow 12 for the essence of the product providing the same 13 commercial success. But to the extent there are 14 from a technical perspective, I would defer to 15 Dr. Krause. 16 Q. Okay. And would you compare -- like, 17 drawing your analysis a little bit further, is the 18 processor of a computer, is that a separable 19 component? 20 A. Yes, I would think so. 21 Q. Okay. Does the computer work without 22 the processor?	80 1 that analysis? 2 A. "That analysis" being trying to 3 separate out elements of the vaccine? 4 Q. Or even consider that they could be 5 separated. 6 A. I did not present that analysis. From 7 my perspective, the assignment was to determine 8 whether or not the vaccine as produced and alleged 9 to infringe was commercially successful, not to 10 consider a theoretical list of potential 11 design-arounds. I'm not aware of any commercial 12 successful noninfringing design-arounds. 13 Q. Well, we weren't really talking about 14 commercially successful design-arounds. We were 15 talking about separable components. And you 16 mentioned that some separable components, if 17 they're designed and developed by a third party, 18 you would consider that as a separable component. 19 MS. CURTIS: Object to form. 20 THE WITNESS: In the analogy that 21 we're speaking to, which is from a 22 licensing perspective, products more like

Conducted on July 22, 2024

81 1 computers are viewed to have separable 2 components as opposed to vaccines. 3 But I'm not providing an opinion 4 that there are components. I don't 5 understand there to be. I do understand 6 that there may be certain legal parameters 7 around that term. That's outside my scope. 8 BY MR. SAWYER: 9 Q. And if there were separable components, 10 it would change your analysis? 11 A. I don't believe that it would because I 12 think the analysis is still whether or not the 13 products as offered and sold were commercially 14 successful. 15 Q. Except that the commercial success has 16 to be tied to the patented components? 17 A. I don't recall the language of "tied to 18 components." Again, maybe you're speaking to the 19 legal requirements. There certainly has to be a 20 nexus of the invention to the commercial success, 21 which I believe we clearly have here. 22 Q. You're correct. I meant nexus. So	83 1 Q. And so this was a chart that was 2 already prepared and that you included, or is this 3 a chart that you put together and created for your 4 -- for this particular document? 5 A. This is a chart that I prepared from a 6 variety of sources that's reflected in Appendix B of 7 Exhibit 1. 8 Q. So it's something you prepared? 9 A. Yes, sir. 10 Q. Okay. And why did you choose to only 11 include these vaccines? 12 A. My research would suggest that these 13 are the vaccines that received the FDA or WHO 14 within this period of time. I'm not aware of 15 others as I sit here. To the extent there are, 16 I'd certainly consider including them. 17 Q. And did you -- was there a reason you 18 limited it to the FDA and WHO? 19 A. Well, the FDA, of course, has the U.S.A 20 authority, and the WHO is representative of a 21 global perspective. There may in other select 22 markets, China or otherwise, approval of certain
82 1 thank you for correcting me. 2 So there would have to be a nexus to 3 the patented component? 4 MS. CURTIS: Object to form. 5 THE WITNESS: Again, you're throwing 6 the word "component" into your question. 7 Perhaps for you that has some significant 8 legal meaning. For me, it does not. 9 I do not view these as 10 multicomponent products. But I do agree 11 that there must be a nexus between the 12 invention and the commercial success. 13 BY MR. SAWYER: 14 Q. Can you go back to Exhibit 1, please. 15 A. Yes, sir. 16 Q. Great. I'm going to ask you to turn to 17 Figure 1, which is on page 8. 18 A. Yes, sir. 19 Q. You've included a table of vaccines 20 that were approved by the FDA and the WHO. 21 Do you see that? 22 A. Yes, sir.	84 1 domestics vaccines, and I would be happy to 2 acknowledge that. 3 Q. Okay. Would you consider FDA approval 4 an intangible asset? 5 A. It depends how you're using that 6 phrase. But I would have no objection to that. 7 Q. There's definitely a value that can be 8 placed on FDA approval? 9 A. Yes, that's true. 10 Q. Have you ever evaluated that -- that 11 value in any of your work? 12 A. Most likely, yes. There are certain 13 cases where we've attempted to value vouchers 14 which would accelerate FDA review, which I think 15 is, you know, closely tied to this question. 16 Q. And FDA approval or WHO -- WHO approval 17 can impact your evaluation of commercial success? 18 A. Well, that's facts and circumstances of 19 a given situation. Obviously, here we are 20 considering the products that have FDA or WHO 21 approval. 22 Q. And if you look at the AstraZeneca

85 1 vaccine, again, that was developed at about the 2 same pace as Spikevax, right? 3 A. It was approved at about the same time. 4 I don't recall when they began their work as 5 opposed to Spikevax. But in response to COVID, by 6 definition it would have been relatively within 7 the same time frame. 8 Q. And the AstraZeneca vaccine is approved 9 in even more countries than Spikevax. 10 A. I don't cite that within my report. 11 But my recollection is that may very well be true, 12 yes. 13 Q. And the AstraZeneca vaccine does not 14 practice either the '600 or '127 patent? 15 A. That is my understanding. 16 Q. And the AstraZeneca vaccine, a least by 17 WHO standards, is considered safe and effective? 18 MS. CURTIS: Object to form. 19 Foundation. 20 THE WITNESS: "Safe and effective." 21 At least effectiveness has a relative term. 22 But I would generally believe that they	87 1 the pandemic was global and, therefore, 2 widespread. 3 BY MR. SAWYER: 4 Q. Despite maybe disagreeing with my 5 terms, you're not disagreeing with that concept, 6 right? I mean, I think everyone that lived 7 through it was very -- we're all very familiar 8 with the demand for the vaccine and the impact 9 that COVID had on all of our daily lives, right? 10 MS. CURTIS: Object to form. 11 THE WITNESS: I think people are 12 generally familiar with the impact of 13 COVID, and for many, their demand for the 14 vaccine -- a vaccine. 15 BY MR. SAWYER: 16 Q. When Spikevax and Comirnaty first 17 became available in the U.S. in December 2020 or 18 January 2021, the U.S. government was the sole 19 purchaser of the vaccine for doses distributed in 20 the U.S.; is that right? 21 A. I believe that the government had 22 actually purchased or made purchase commitments in
86 1 would not have granted authorization if 2 they did not consider it safe and 3 effective, though I'm not an expert on WHO 4 approval process. 5 BY MR. SAWYER: 6 Q. So do you have an understanding that 7 the -- the WHO declared sort of a worldwide health 8 emergency in or around January 31st, 2020? 9 A. I am somewhat aware of WHO declarations 10 in that regard, both as to beginning and ending 11 parameters for the pandemic, though those issues 12 are not core to my analysis here. 13 Q. Okay. And you would agree that the 14 demand for COVID-19 vaccines was extremely high in 15 the, you know, 2020, 2021 time frame because the 16 pandemic was raging worldwide? 17 MS. CURTIS: Object to form. 18 THE WITNESS: General question. 19 Undefined terms as to what's "extremely 20 high" or "raging." But I think it's common 21 sense that, yes, there was a demand for the 22 vaccine as a result of the pandemic, and	88 1 advance, and that the private payer commitments 2 came later. I don't disagree with that. 3 Q. The government being the sole purchaser 4 meant that the market for vaccine doses was 5 different from sort of a traditional commercial 6 market; is that right? 7 A. I don't necessarily agree. It's 8 different, but every market is unique. I don't 9 draw any huge distinction, especially for product 10 responding to a pandemic. Maybe you can rephrase 11 or ask a more specific question. 12 Q. There was only a single buyer, right? 13 A. I don't understand that question. At 14 one point, there's going to be a first buyer. At 15 the point of first purchase, they would be the 16 single buyer. But it was never envisioned, I 17 don't believe, that there would only be a single 18 buyer for the COVID vaccines. 19 Q. But there was, indeed, only a single 20 buyer for the first year and a half or two years 21 in which Comirnaty and Spikevax were available, 22 right?

Conducted on July 22, 2024

89 1 MS. CURTIS: Object to form. 2 THE WITNESS: I haven't put a 3 particular time frame or studied that 4 uniquely. I'm happy to accept it for 5 purposes of your question. I don't think 6 it's relevant to the scope of my work. 7 The government was interested in 8 purchasing quantities of vaccine based upon 9 the safety and efficacy. I don't think it 10 has any bearing to the commercial success 11 question here. 12 BY MR. SAWYER: 13 Q. But the U.S. government was 100 percent 14 of the U.S. market demand in January of 2021? 15 A. Same answer. I don't recall from 16 memory that that was the case, but I'll accept it. 17 I don't think it's relevant to the considerations 18 said here. 19 Q. The U.S. government was the only entity 20 determining the amount of vaccine being purchased 21 in the U.S. in January 2021? 22 A. I don't know that that's true. Even if	91 1 full premise of your question. I do agree 2 they were looking to multiple suppliers. I 3 think they were looking to protect -- the 4 U.S. government was looking to protect not 5 only the American public but had 6 considerations for the rest of the world 7 given the ability for citizens outside of 8 the United States to travel and affect the 9 pandemic management here. 10 But I don't think they were 11 looking to buy as much as they possibly 12 could because they certainly had targets 13 and quantities that they were considering. 14 BY MR. SAWYER: 15 Q. They were looking to buy at least more 16 doses than they expected to need in the U.S.? 17 A. Before our first break, you and I 18 talked about the fact that they sought to buy some 19 surplus. I agree with that. 20 Q. Okay. And when the government, after 21 they purchased the vaccines, they were 22 distributing to the American public for free,
90 1 they were the only one purchasing at the time, I 2 do believe that the industry generally was looking 3 or considering the rollout of vaccines and the 4 distribution of those, including purchase 5 decisions. 6 Q. Do you have an understanding if the 7 U.S. government was pursuing a strategy of, like 8 you said, contracting for vaccines, even before 9 they were available, so that they could stockpile 10 and then distribute the vaccine? 11 A. I believe the government was 12 introducing that through -- with multiple 13 suppliers. Of course, dependent upon the approval 14 and success of the products when they matured. 15 Q. And in fact, they were actively -- the 16 U.S. government was actively seeking multiple 17 suppliers so that they could execute on that 18 strategy, which is to contract and buy as much as 19 they could so they could stockpile and distribute, 20 right? 21 MS. CURTIS: Object to form. 22 THE WITNESS: I don't agree with the	92 1 right? 2 A. Generally, there was distribution that 3 was at no cost to the American public. I haven't 4 undertaken the studies to whether that was solely 5 subsidized by the government or otherwise and at 6 what point that transitioned. I don't believe 7 that's a relevant factor in consideration of 8 commercial success by these patents. 9 Q. Well, the availability of a free 10 vaccine would increase demand in such that not 11 having to pay for something typically increases 12 demand, right? If something was expensive or 13 couldn't buy it, that may decrease demand? 14 MS. CURTIS: Object to form. 15 THE WITNESS: I acknowledge price 16 elasticity as a concept. But my 17 understanding was that the government and 18 industry generally were looking to purchase 19 safe and effective vaccines in that the 20 availability in terms of speed to market 21 and safety and effectiveness were all 22 considerations.

93 1 BY MR SAWYER: 2 Q. Your report doesn't disclose how many 3 fewer vaccine doses would have been administered 4 if the vaccine were not free? 5 A. True, I did not undertake that 6 hypothetical analysis. 7 Q. And so your report did not disclose the 8 impact of the doses that were administered for 9 free as separate and apart from the impact of the 10 '600 and '127 patents, right? 11 A. I'm not sure I understand your question 12 there. My report does take into account market 13 conditions generally, and in particular, speaking 14 to the relative success of the products at issue 15 versus other products, all of whom would have had 16 the same access to those types of benefits. 17 So, again, I don't believe that those 18 macroeconomic factors detract in any way from the 19 conclusion of commercial success here. 20 Q. Paragraph 19 in your report, and 21 paragraph 20 because we kind of look at them, 22 they're both -- both 19 and 20 appear to list out	95 1 record at 11:19. 2 BY MR. SAWYER: 3 Q. Welcome back, Mr. Malackowski. 4 Have you ever opined that there was no 5 nexus to a patent in a commercial success report? 6 MS. CURTIS: Object to form. 7 THE WITNESS: I don't recall doing 8 so for the purpose of invalidity. But as 9 you may know, within traditional patent 10 litigation one of the Georgia-Pacific 11 factors speaks to commercial success and 12 the contributions of the invention. And so 13 I have critiqued that countless times. 14 But I don't have a specificity 15 as to whether I said in a binary way there 16 was no commercial success associated with 17 the patent. 18 BY MR. SAWYER: 19 Q. Do you remember what the -- what some 20 of the reasons were why you previously critiqued a 21 nexus in a commercial success analysis? 22 A. Not as I sit here, no.
94 1 some financial numbers for Moderna, Pfizer, and 2 BioNTech. 3 Do you see that? 4 A. Yes, sir. 5 Q. And you'd agree with me that the 6 majority of demand or the majority of sales for 7 both Spikevax and Comirnaty were between January 8 2021 and, say, May 2023? 9 MS. CURTIS: Object to form. 10 THE WITNESS: I believe my analysis 11 goes through all of 2023, so I wouldn't 12 want to speculate sitting here that May was 13 a particularly relevant cutoff. But that 14 said, the majority of sales as reflected in 15 my chart does occur in 2021 through 2023. 16 Can we take a two-minute break? 17 MR. SAWYER: Absolutely. 18 THE STENOGRAPHER: We're off the 19 record at 10:57. 20 (Whereupon, a recess was taken 21 from 10:57 a.m. to 11:19 a.m.) 22 THE STENOGRAPHER: Back on the	96 1 Q. Did you ever do so in a complex, 2 multicomponent product? 3 A. I don't recall. 4 Q. When's the last time you gave an 5 opinion on commercial success? 6 A. In a damages context, it would have 7 been the last case that I testified in at trial, 8 which would probably be earlier this year. In an 9 IPR context, I don't recall. 10 Q. Okay. And in the last context when you 11 testified at trial, were you giving an opinion 12 that there was commercial success and a nexus to a 13 patented feature or that it was absent? 14 A. My recollection would be in the last 15 case I testified on trial -- or the last couple, 16 that there would have been an evaluation of 17 commercial success under the Georgia-Pacific 18 factors. I don't recall giving any opinion that 19 there was complete absence of nexus. 20 Q. When you say you "don't recall giving 21 an opinion that there was complete absence of 22 nexus," what do you mean by a "complete absence"?

Conducted on July 22, 2024

97 1 Is it binary, meaning is it -- was your 2 opinion that there was a slight nexus, or was your 3 opinion there was nexus and there was -- sorry. 4 That was not a very clear question. 5 But when you say "the complete absence 6 of nexus," I'm wondering what you meant by that. 7 A. I had thought that you had started this 8 line of questioning about asking if I've ever 9 opined to there being no nexus, and so I was 10 simply trying to address it in that context. 11 I don't recall providing an opinion in 12 any matter that there was no nexus, meaning a 13 binary zero. But I've testified in many cases, 14 and perhaps over the decades that's happened. I 15 just don't recall it. 16 Q. Do you recall whether or not you 17 testified that if there was some slight nexus, 18 that commercial success shouldn't be considered? 19 A. No. Because in most cases, a damages 20 perspective is a more relative concept than a 21 binary concept in that you are apportioning for 22 numeric reasons the contribution of an invention	99 1 involving a pharmaceutical API, but that the 2 patent had nothing to do with the drug, per se, 3 but had to do with some ancillary distribution or 4 something else. And I don't recall the specifics. 5 But I suspect there have been cases 6 where I've testified that there -- in that case, 7 that there was no specific nexus. 8 Q. You have a general understanding of 9 what an API is? 10 A. Yeah, an active pharmaceutical 11 ingredient into a drug. 12 Q. So you said that you have a vague 13 recollection of a case involving a pharmaceutical 14 API, but that the patent had nothing to do with 15 the drug, per se. 16 Do you see that? Do you recall saying 17 that? 18 A. Yes, sir. 19 Q. Okay. So do you recall what the patent 20 was related to, if it wasn't related to the drug? 21 A. My recollection is it was some form of 22 packaging. But I don't recall the specifics.
98 1 versus others. That quantitative apportionment 2 isn't applicable, as I understand it, when you're 3 dealing with the secondary considerations of 4 nonobviousness. 5 Q. So sitting here today, you don't recall 6 doing -- sorry. 7 So sitting here today, you don't recall 8 offering an opinion as to commercial success to 9 support nonobviousness? 10 A. No, I didn't say that. 11 I don't recall offering an opinion of 12 no nexus to the commercial success as I sit here 13 today. Not to say that I haven't done that, but I 14 hadn't thought about it prior to sitting here, and 15 I don't recall such. 16 Q. In a similar situation, whether it be a 17 district court litigation or an IPR setting, have 18 you offered an opinion where you determined that 19 the patented features of a patent did not have a 20 nexus such that there was no commercial success? 21 A. I suspect that I have. The vague 22 recollection that's coming to mind is a case	100 1 Q. And when you say "packaging," you're 2 not talking about, like, the pill bottle it was 3 in, right? 4 A. I think I might be talking about the 5 syringe packaging, but essentially, yes. 6 Q. In your report, you did not 7 specifically consider -- strike that. 8 In your report, did you specifically 9 consider other technologies that might have 10 impacted the demand and, therefore, commercial 11 success of Comirnaty and Spikevax? 12 A. Yes. At a general level, including, as 13 for example, what's reflected in the table you and 14 I were looking at earlier today shown in Appendix 15 B. And noting that there were other vaccines that 16 went to market that used different technologies 17 but that were not as successful or as effective. 18 Q. You have an understanding that Moderna 19 has claimed that U.S. Patent Number 10,898,574 is 20 also practiced by Spikevax and Comirnaty, correct? 21 A. I understand that from the district 22 court litigation, yes.

Conducted on July 22, 2024

101 1 Q. Did you evaluate that technology and 2 how it impacts demand and commercial success for 3 your report in this case? 4 A. Not as identified here in this case. 5 This case stands alone based upon the two patents 6 that are asserted. 7 Q. So does the '574 patent impact demand 8 and, therefore, commercial success of Spikevax and 9 Comirnaty? 10 MS. CURTIS: Object to form. 11 THE WITNESS: That is outside the 12 scope of what I have done here. I'm not 13 presenting a conclusion on the commercial 14 success for purposes of nonobviousness as 15 it relates to that patent. And I haven't 16 prepared such analysis. 17 BY MR. SAWYER: 18 Q. So you haven't considered it one way or 19 the other? 20 MS. CURTIS: Object to form. 21 THE WITNESS: I understand that it's 22 within the products -- that it's asserted	103 1 Q. So you couldn't do the relatively -- 2 relative weighting of the '600 and '127 patent 3 versus the '574 patent? 4 MS. CURTIS: Object to form. 5 THE WITNESS: I don't know that I 6 couldn't do it. I would tell you that I 7 haven't done it because it's not necessary. 8 BY MR. SAWYER: 9 Q. Why isn't it necessary? 10 A. Because as I understand the legal 11 requirements, one need not show that the 12 technology here is solely responsible or a 13 majority responsible for the product. The 14 standards are as I've described them within my 15 report, and I believe that including the 16 consideration of Dr. Krause's report, these two 17 patents meet the standard for a conclusion of 18 commercial success. 19 Q. Have you ever done a relative analysis 20 or weighting of the '600 and '127 patent versus 21 the '574 patent? 22 MS. CURTIS: Object to form.
102 1 to be within the products that are at issue 2 here. I don't dispute that it has 3 contribution to nexus and commercial 4 success. But as I understand the legal 5 test for what's at issue in this case, the 6 fact that there may be a third Moderna 7 patent that is also responsible for success 8 does not diminish the conclusions that I've 9 reached. 10 BY MR. SAWYER: 11 Q. Does the -- is your opinion that the 12 '600 and '127 patent account for the majority of 13 demand and nexus for the commercial success of 14 Comirnaty and Spikevax? 15 A. I don't offer that opinion. I don't 16 believe it's necessary to do that qualitative 17 ranking. 18 That said, what you're really asking is 19 more of a technical question. To the extent that 20 any relative weighting would be necessary, that it 21 would be more within the purview of 22 Dr. Krause.	104 1 THE WITNESS: Not specifically. I 2 don't believe so, no. 3 BY MR. SAWYER: 4 Q. So you have no opinion on whether or 5 not the '574 patent is more important to the 6 commercial success of Comirnaty and Spikevax 7 versus the '600 and '127 patent? 8 MS. CURTIS: Object to form. 9 THE WITNESS: That's the question 10 you asked me a few minutes ago. I have not 11 rank ordered or weighted them. I haven't 12 specifically opined as to the commercial 13 success for purposes of nonobviousness as 14 it relates to the third patent. 15 I don't dispute that it is a 16 contributor. But its relative impact 17 vis-à-vis the two patents at issue here is 18 a better question for Dr. Krause. 19 BY MR. SAWYER: 20 Q. So just like other technology that you 21 haven't evaluated, you don't know one way or the 22 other whether or not the '574 patent impacts

Conducted on July 22, 2024

105 1 commercial success for Spikevax and Comirnaty? 2 MS. CURTIS: Object to form. 3 Foundation. 4 THE WITNESS: I haven't conducted 5 that study. 6 I do understand that the '574 7 patent is asserted to be within the two 8 products at issue in this case, i.e., 9 infringed. But I haven't conducted a 10 relative assessment of their impact on 11 commercial success. I don't believe that's 12 necessary. 13 BY MR. SAWYER: 14 Q. So you would agree that the '574 15 patent, because it's Moderna saying it covers the 16 Comirnaty and Spikevax, does impact commercial 17 success, though, correct? 18 MS. CURTIS: Object to form. 19 THE WITNESS: No. You're just 20 asking if I had any assessment of that 21 patent vis-à-vis this undefined list of 22 other technologies. And I would note that	107 1 go back and, for the purposes of 2 nonobviousness, consider that issue. 3 BY MR. SAWYER: 4 Q. And so based on that, your report 5 doesn't include an analysis of the '574 patent and 6 how it impacts commercial success, right? 7 A. Well, my report doesn't include an 8 analysis of the '574 patent largely because it was 9 outside the scope. And such an analysis is not 10 necessary to reach the conclusions that I was 11 presenting. 12 Q. So you don't have -- you don't know one 13 way or the other whether or not the '574 patent is 14 the main reason for any commercial success of 15 Comirnaty and Spikevax? 16 MS. CURTIS: Object to form. 17 THE WITNESS: I haven't assessed 18 whether or not it is, quote/unquote, "the 19 main reason." 20 BY MR. SAWYER: 21 Q. Okay. 22 A. "Okay" meaning you're done?
106 1 as compared to an undefined list of other 2 technologies, one thing I do know is that 3 it's been asserted as embodied within the 4 two products at issue. 5 BY MR. SAWYER: 6 Q. So because it's been asserted and 7 because it's defined, then you do know that it 8 does have an impact on commercial success that's 9 unrelated to the '600 and '127, correct? 10 MS. CURTIS: Object to form. 11 THE WITNESS: Not correct. That's 12 not what I said. I haven't studied it. So 13 it would be premature for me to draw that 14 conclusion. 15 BY MR. SAWYER: 16 Q. So you have no opinion one way or the 17 other whether or not the '574 patent impacts 18 commercial success? 19 MS. CURTIS: Object to form. 20 THE WITNESS: I haven't studied 21 that. I understand that it's embodied 22 within these products. But I would have to	108 1 Q. No. I'm sorry. 2 MR. MESTITZ: The question of an 3 optimist. 4 MR. SAWYER: Yeah. 5 BY MR. SAWYER: 6 Q. You're aware that both Moderna and 7 BioNTech have a license from CELLSRIPT, right? 8 A. Yes. 9 Q. And you understand that the license 10 from CELLSRIPT relates to work that 11 Dr. Kariko and Dr. Weismann performed at 12 University of Pennsylvania? 13 MS. CURTIS: Object to form. 14 Foundation. 15 THE WITNESS: I haven't reviewed 16 that license to memorize the innovators. 17 But I'm happy to accept that. 18 BY MR. SAWYER: 19 Q. Do you know if that license relates to 20 modified RNA technology? 21 A. I don't recall from sitting here. And 22 I wouldn't want to speculate without reviewing the

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BioNTech-Pfizer Exhibit 1157

BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Page 28 of 65

Conducted on July 22, 2024

109 1 license and related documents. 2 Q. Do you recall whether or not the -- do 3 you recall if the '574 patent relates to modified 4 RNA technology? 5 A. Same answer. I haven't gone back and 6 reviewed that. I believe that's an issue in the 7 district court case, not something that's dealt 8 with in the scope of my report here. 9 Q. Do you have understanding that Moderna 10 has paid CELLSCRIPT royalties under the CELLSCRIPT 11 license agreement? 12 A. That, I believe, is true. 13 Q. And do you have an understanding that 14 BioNTech has also paid CELLSCRIPT royalties under 15 the license agreement for sales of Comirnaty? 16 A. I think that's true as well. 17 Q. In your report, you didn't evaluate the 18 impact of the CELLSCRIPT patents to the commercial 19 success of Comirnaty in comparison to any page 20 impact of the '600 and '127 patents, correct? 21 A. Correct. 22 Q. In your report, you didn't evaluate the	111 1 Acuitas? 2 A. Yes. 3 Q. Okay. Do you have an understanding if 4 BioNTech has a license to Acuitas patents that it 5 pays a royalty to Acuitas for Comirnaty? 6 A. I have reviewed that as part of the 7 district court action. I don't recall from 8 memory, but my presumption is that is true. 9 Q. Do you know if Moderna has a license 10 with Acuitas? 11 A. I don't recall. 12 Q. Do you have an understanding that the 13 Acuitas patent and technology relate to LNPs, 14 lipid nanoparticles? 15 MS. CURTIS: Object to form. 16 THE WITNESS: That sounds familiar. 17 But I haven't studied that specifically for 18 purposes of my work here so I don't want to 19 speculate. 20 BY MR. SAWYER: 21 Q. Well, do you have understanding that 22 BioNTech uses Acuitas LNPs in its Comirnaty
110 1 impact of CELLSCRIPT patents to the commercial 2 success of Spikevax in comparison to any impact of 3 the '600 and '127 patents, correct? 4 A. Correct. 5 Q. In fact, you can't provide an opinion 6 on that because -- strike that. 7 Therefore, you can't provide an opinion 8 on whether the CELLSCRIPT patents have a greater 9 technical impact on the safety, efficacy, or speed 10 to market vis-à-vis the '600 and '127 patents? 11 MS. CURTIS: Object to form. 12 THE WITNESS: So I'm not providing 13 an opinion in that regard for many reasons, 14 including it requires a technical 15 assessment that's outside my scope, and 16 it's not necessary for purposes of my 17 assignment here. 18 But as you asked me a few 19 minutes ago, it's not contained within the 20 scope of Exhibit 1. 21 BY MR. SAWYER: 22 Q. Have you heard of a company called	112 1 vaccine? 2 A. I'm not offering an opinion in that 3 regard so I don't know. It's outside my scope. 4 Q. In your report, you did not evaluate 5 the impact of the Acuitas patents to the 6 commercial success of Comirnaty in comparison to 7 any impact by the '600 and '127 patents, right? 8 A. Correct. 9 Q. Therefore, you can't provide an opinion 10 on whether the Acuitas patents had a greater 11 technical impact on safety, efficacy, or speed to 12 market vis-à-vis the '600 or '127 patents? 13 MS. CURTIS: Object to form. 14 THE WITNESS: I'm not providing such 15 an opinion. 16 It's my understanding such would 17 require a technical expertise, which I do 18 not have, and that such would not be 19 necessary to reach the conclusions in 20 Exhibit 1. 21 BY MR. SAWYER: 22 Q. You have an understanding that both

Conducted on July 22, 2024

1 Moderna and BioNTech have a license with the NIH 2 related to the Spike protein? 3 A. Again, it sounds familiar from my work 4 in the district court case, but I haven't 5 specifically examined that for my work here. But 6 I'm happy to accept that. 7 Q. Okay. In your report, you didn't 8 evaluate the impact of the NIH patents to the 9 commercial success of Comirnaty in comparison to 10 any impact the '600 or '127 patents might have 11 had? 12 (Stenographer clarification.) 13 BY MR SAWYER: 14 Q. In your report, you did not evaluate 15 the impact of the NIH patents to the commercial 16 success of Comirnaty in comparison to any impact 17 by the '600 or '127 patents? 18 A. Correct. For the reasons we've 19 discussed previously. A, it would be a technical 20 assessment; B, it's not necessary for purposes of 21 my work here. 22 Q. And in your report, you did not	113 1 Q. Your report does not disclose any 2 evaluation of the impact of other Moderna 3 technology, whether it be patented or unpatented, 4 on the commercial success of Spikevax? 5 A. Not specifically, no. Certainly not in 6 comparison to the two patents that are at issue. 7 Q. Your declaration did not evaluate the 8 impact of BioNTech's, whether it be patented 9 technology or unpatented technology, on the 10 commercial success of Comirnaty as compared to the 11 '600 and '127 patent? 12 A. Not specifically in comparison. I 13 believe that would be a technical assessment. 14 Q. Your opinion does not -- did not 15 evaluate the impact of Pfizer's technology on the 16 commercial success of Comirnaty as compared to any 17 commercial success contributed by the '600 and 18 '127 patent, correct? 19 A. Well, certainly not from a technical 20 perspective. I defer to my report for general 21 business conditions and promotion by Pfizer. But 22 I don't believe that any such conditions would
114 1 evaluate the impact of the NIH patents to the 2 commercial success of Spikevax in comparison to 3 any impact by the '600 or '127 patents? 4 A. Same answer. 5 Q. Meaning you did not do that evaluation? 6 A. For the reasons I described, correct. 7 Q. Therefore, you can't provide an opinion 8 on whether the NIH patents have a greater 9 technical impact on efficacy, safety, or time to 10 market vis-à-vis the '600 or '127 patents? 11 MS. CURTIS: Object to form. 12 THE WITNESS: I'm not providing that 13 opinion for the same two reasons I've 14 addressed. 15 It's technical and not necessary 16 for the purposes of my work. 17 BY MR. SAWYER: 18 Q. Your report does not disclose any 19 evaluation of the impact of any other Moderna 20 patents on the commercial success of Spikevax, 21 right, besides the '600 and '127 patent? 22 A. Correct.	115 1 affect my conclusions. 2 Q. Did Moderna's MERS vaccine practice the 3 '600 and '127 patent? 4 MS. CURTIS: Object to form. 5 Foundation. 6 THE WITNESS: I'm not offering an 7 opinion in that regard. I believe there's 8 some discussion in the record about that, 9 though, that any need to introduce the 10 vaccine was stayed as a result of the 11 reduced risk associated with MERS. 12 MR. SAWYER: Why don't we take a 13 break. 14 MS. CURTIS: Sure. Ten minutes? 15 MR. SAWYER: Yeah, ten minutes is 16 great. 17 THE STENOGRAPHER: Off the record at 18 11:42. 19 (Whereupon, a recess was taken 20 from 11:42 a.m. to 11:51 a.m.) 21 THE STENOGRAPHER: Back on the 22 record at 11:51.

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BioNTech-Pfizer Exhibit 1157

BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Page 30 of 65

Conducted on July 22, 2024

117 1 BY MR. SAWYER: 2 Q. Mr. Malackowski, do you know if the 3 '600 or '127 patents have been licensed by 4 Moderna? 5 A. Not to my knowledge. 6 MR. SAWYER: I have nothing further. 7 THE WITNESS: Thank you. Very 8 professional. 9 MS. CURTIS: Nothing from me. 10 MR. MESTITZ: Nothing from Pfizer. 11 MS. CURTIS: Okay. Yeah, nothing 12 from me. 13 Do we need to designate this as 14 confidential? I don't think so. 15 MR. MESTITZ: I don't think so. 16 MS. CURTIS: There was some of the 17 stuff about licenses that I thought was -- 18 MR. SAWYER: Close? 19 MS. CURTIS: -- I was getting ready, 20 but I don't think we got there so I think 21 we're good. But just wanted to check 22 before we go off the record.	119 1 ACKNOWLEDGMENT OF DEPONENT 2 3 I, JAMES E. MALACKOWSKI, do hereby 4 acknowledge that I have read and examined the 5 foregoing testimony, and the same is a true, 6 correct and complete transcription of the 7 testimony given by me, and any corrections appear 8 on the attached errata sheet signed by me. 9 10 11 12 _____ 13 (DATE) (SIGNATURE) 14 15 16 17 18 19 20 21 22
118 1 MR. SAWYER: Can we go ahead and 2 let's mark it confidential? And I don't 3 think it needs to be marked highly 4 confidential, but confidential, and we'll 5 evaluate. 6 MS. CURTIS: Okay. Seems sensible. 7 (Time concluded: 11:51 a.m.) 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	120 1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC 2 3 I, JANICE M. KOCEK, Certified Reporter, 4 Certified LiveNote Reporter and Notary Public 5 within and for the State of Illinois do hereby 6 certify: 7 That JAMES E. MALACKOWSKI, the witness 8 whose deposition is hereinbefore set forth, was 9 duly sworn by me before the commencement of such 10 deposition and that such deposition was taken 11 before me and is a true record of the testimony 12 given by such witness. 13 I further certify that present on behalf 14 of Petitioners were Doug Sawyer and Summer Stevens 15 of the law firm Paul Hastings LLP, and Michael J. 16 Mestitz of the law firm Williams & Connolly; and 17 present on behalf of the patent owner was 18 Annaleigh E. Curtis of the law firm Wilmer Cutler 19 Pickering Hale and Dorr LLP. 20 I further certify that the deposition of 21 JAMES E. MALACKOWSKI, occurred at the offices 22 of Ocean Tomo, 200 West Madison, Chicago, Illinois,

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BioNTech-Pfizer Exhibit 1157

BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Page 31 of 65

Conducted on July 22, 2024

121

1 on Monday, the 22nd of July, 2024, commencing at
2 9:01 a.m. to 11:51 a.m.

3 I further certify that I am not related
4 to any of the parties to this action by blood or
5 marriage, I am not employed by or an attorney to
6 any of the parties to this action, and that I am
7 in no way interested, financially or otherwise, in
8 the outcome of this matter.

9

10 IN WITNESS WHEREOF, I have hereunto set
11 my hand this 24th day of July, 2024.

12

13 *Janice M. Koczek*

14

15 CERTIFIED SHORTHAND REPORTER

16 CERTIFIED LIVENOTE REPORTER

17 LICENSE NO. 0084-008271

18 NOTARY PUBLIC FOR THE STATE OF ILLINOIS

19

20

21

22

A			
ability	account	advance	69:3, 69:10,
11:3, 66:10,	23:21, 57:15,	88:1	72:13, 77:5,
66:16, 66:22,	58:19, 93:12,	advanced	77:13, 77:16,
67:8, 67:11,	102:12	26:11	82:10, 86:13,
69:4, 69:11,	acknowledge	advantage	88:7, 90:22,
91:7	84:2, 92:15,	11:8	91:1, 91:19,
able	119:4	advertisements	94:5, 105:14
49:4, 52:12,	acknowledgment	29:19	agreement
57:4	119:1	advertising	109:11, 109:15
about	across	30:2	ahead
8:22, 12:5,	23:19, 29:7	advice	42:17, 118:1
15:20, 16:7,	action	32:2	akin
32:2, 37:13,	7:12, 8:15,	affect	74:11
40:4, 46:8,	8:22, 9:6,	29:6, 30:12,	all
48:2, 64:19,	111:7, 121:4,	91:8, 116:1	7:9, 7:10,
68:1, 69:16,	121:6	affected	10:21, 18:6,
77:11, 80:13,	active	58:10	26:13, 26:22,
80:15, 85:1,	99:10	affects	28:10, 29:7,
85:3, 91:18,	actively	67:13	43:11, 44:7,
97:8, 98:14,	90:15, 90:16	after	44:10, 51:2,
100:2, 100:4,	activity	36:16, 91:20	57:14, 59:12,
116:8, 117:17	22:15	again	71:11, 73:9,
above	actual	10:18, 17:19,	87:7, 87:9,
26:16, 36:8,	22:14, 25:11,	20:1, 24:9,	92:21, 93:15,
62:11	26:16, 52:3	30:4, 35:11,	94:11
absence	actually	48:17, 51:9,	alleged
24:21, 96:19,	38:13, 38:14,	56:3, 72:18,	15:17, 15:20,
96:21, 96:22,	41:17, 57:22,	77:10, 79:15,	15:21, 35:19,
97:5	67:12, 87:22	81:18, 82:5,	47:20, 49:12,
absent	acuitas	85:1, 93:17,	63:9, 80:8
57:8, 96:13	111:1, 111:4,	113:3	allow
absolutely	111:5, 111:10,	against	78:11
94:17	111:13, 111:22,	41:6, 61:21	allows
abstracts	112:5, 112:10	agencies	36:22
65:7	addition	25:10, 29:14	alone
academic	8:13	ago	101:5
16:8	additional	16:21, 104:10,	already
accelerate	67:6	110:19	27:7, 67:18,
84:14	address	agree	77:11, 83:2
accept	23:10, 35:14,	15:15, 16:11,	also
89:4, 89:16,	97:10	28:12, 29:2,	4:9, 7:17,
108:17, 113:6	addressed	29:9, 29:13,	8:14, 8:16,
acceptable	12:1, 13:1,	29:18, 30:2,	10:1, 11:6,
66:6	26:13, 26:17,	32:7, 46:5,	11:21, 12:1,
access	114:14	46:12, 46:17,	12:20, 13:1,
93:16	administered	57:8, 60:11,	14:21, 19:8,
	93:3, 93:8	60:12, 66:9,	22:16, 22:18,
	adoption	66:14, 66:20,	25:5, 38:20,
	30:4		

43:9, 58:20, 60:12, 61:13, 65:14, 76:14, 100:20, 102:7, 109:14 alternatives 26:5, 26:6, 66:7 although 26:1 always 30:11 american 91:5, 91:22, 92:3 among 11:22, 62:16 amount 11:9, 24:4, 67:10, 89:20 amounts 26:15 analogous 68:22 analogy 80:20 analysis 12:18, 17:4, 17:12, 17:21, 21:6, 22:7, 24:7, 26:2, 26:8, 26:20, 32:15, 32:20, 66:7, 68:6, 68:16, 68:21, 75:2, 78:17, 80:1, 80:2, 80:6, 81:10, 81:12, 86:12, 93:6, 94:10, 95:21, 101:16, 103:19, 107:5, 107:8, 107:9 analytical 10:5, 18:9, 18:18, 51:8 analyzed 29:22	ancillary 99:3 annaleigh 4:6, 4:7, 120:18 announce 7:15 another 12:13, 27:15, 69:21, 79:2 answer 21:5, 21:18, 21:21, 22:5, 22:6, 24:22, 29:12, 29:17, 39:14, 42:17, 43:14, 45:6, 45:10, 45:14, 45:18, 45:22, 46:1, 46:14, 54:5, 54:16, 54:20, 54:21, 55:6, 55:7, 56:9, 66:5, 66:17, 68:3, 69:13, 69:19, 75:7, 89:15, 109:5, 114:4 answered 21:4 anticipation 18:5 any 7:21, 22:6, 27:6, 28:17, 28:21, 30:5, 34:4, 34:14, 35:18, 37:19, 38:3, 38:4, 38:22, 39:18, 40:22, 41:1, 41:6, 41:9, 42:15, 43:16, 43:19, 54:6, 54:12, 54:17, 55:3, 55:19, 56:5, 59:2, 59:7, 64:2,	64:6, 64:7, 64:9, 66:5, 66:12, 66:15, 66:16, 66:21, 67:11, 69:4, 69:8, 69:11, 76:22, 78:8, 78:11, 80:11, 84:11, 88:9, 89:10, 93:18, 96:18, 97:12, 102:20, 105:20, 107:14, 109:19, 110:2, 112:7, 113:10, 113:16, 114:3, 114:18, 114:19, 115:1, 115:16, 115:22, 116:9, 119:7, 121:4, 121:6 anyone 7:19, 41:9, 42:7, 42:11 anything 15:20, 60:4 apart 93:9 api 99:1, 99:9, 99:14 appeal 1:2 appear 44:5, 72:11, 93:22, 119:7 appearances 7:15 appeared 18:13 appendix 83:6, 100:14 applicable 50:4, 98:2 application 33:11, 33:12 apply 69:7 apportioning 97:21	apportionment 98:1 approval 39:9, 60:7, 83:22, 84:3, 84:8, 84:16, 84:21, 86:4, 90:13 approved 40:19, 52:7, 82:20, 85:3, 85:8 approximately 7:3 approximation 62:22 around 23:15, 61:14, 81:7, 86:8 aside 57:17 asked 21:3, 21:20, 22:2, 67:18, 68:1, 77:10, 104:10, 110:18 asking 18:14, 77:9, 97:8, 102:18, 105:20 aspects 31:18, 76:5 asserted 101:6, 101:22, 105:7, 106:3, 106:6 assess 68:14, 69:8 assessed 107:17 assessing 67:14 assessment 40:16, 105:10, 105:20, 110:15, 113:20, 115:13 asset 84:4
---	--	---	---

assignment 34:12, 80:7, 110:17	available 25:20, 30:5, 70:20, 87:17, 88:21, 90:9	became 20:15, 87:17	believe 8:20, 10:21, 11:18, 12:1, 12:7, 12:17, 14:21, 22:20, 26:9, 26:13, 26:20, 28:9, 29:5, 35:3, 40:5, 40:16, 49:16, 51:9, 51:11, 52:2, 52:9, 52:12, 59:17, 61:9, 62:2, 76:7, 81:11, 81:21, 85:22, 87:21, 88:17, 90:2, 90:11, 92:6, 93:17, 94:10, 102:16, 103:15, 104:2, 105:11, 109:6, 109:12, 115:13, 115:22, 116:7
associate 4:12	avenue 3:14	because 7:2, 10:18, 12:18, 15:4, 16:17, 22:7, 34:7, 35:22, 47:11, 48:1, 48:11, 59:6, 61:14, 75:8, 81:11, 86:15, 91:12, 93:21, 97:19, 103:7, 103:10, 105:15, 106:6, 106:7, 107:8, 110:6	believed 18:5
associated 57:16, 95:16, 116:11	aware 32:11, 49:13, 50:22, 59:2, 59:6, 60:4, 66:5, 76:22, 78:11, 80:11, 83:14, 86:9, 108:6	become 79:18	benchmarking 41:5
assume 76:3	B	been 6:3, 8:7, 9:16, 9:21, 15:2, 16:18, 16:19, 40:19, 44:12, 70:16, 70:18, 85:6, 93:3, 96:7, 96:16, 99:5, 106:3, 106:6, 117:3	benefit 69:4, 69:11, 69:17
assuming 39:2, 49:8, 68:13	back 13:8, 20:16, 25:21, 30:20, 44:1, 53:3, 53:5, 56:3, 62:18, 82:14, 94:22, 95:3, 107:1, 109:5, 116:21	before 1:2, 24:22, 29:5, 70:9, 77:11, 90:8, 91:17, 117:22, 120:9, 120:11	benefits 11:4, 11:6, 15:1, 15:6, 66:15, 66:21, 69:14, 93:16
assumption 63:21, 71:9	background 35:12, 43:10	began 85:4	besides 7:19, 114:21
astrazeneca 63:1, 63:8, 84:22, 85:8, 85:13, 85:16	based 21:8, 30:6, 33:7, 34:5, 35:7, 47:3, 48:19, 71:8, 74:19, 79:7, 89:8, 101:5, 107:4	beginning 8:21, 86:10	betacoronavirus 36:8, 36:9, 36:15, 36:16
astrazeneca's 61:11	basis 44:18, 44:21, 45:4, 45:8, 45:12, 45:16, 45:20, 51:15	behalf 3:2, 3:12, 4:1, 120:13, 120:17	better 104:18
attached 119:8	bates 70:12	behind 16:9	being 15:7, 28:4, 51:1, 74:14, 80:2, 88:3, 89:20, 97:9
attempted 12:21, 16:21, 50:5, 84:13	bearing 69:1, 89:10		between 30:1, 68:5, 68:12, 82:11, 94:7
attempting 17:20			beyond 30:8
attorney 121:5			
attorney-client 42:16			
attributable 53:13			
attributes 59:4			
attribution 57:18, 57:22			
authority 83:20			
authorization 52:8, 60:6, 61:18, 63:2, 86:1			
automobile 78:6			
availability 92:9, 92:20			

big 40:21 billions 23:16 binary 11:16, 11:20, 12:7, 32:7, 32:15, 95:15, 97:1, 97:13, 97:21 biontech 1:4, 3:2, 4:10, 94:2, 108:7, 109:14, 111:4, 111:22, 113:1 biontech's 115:8 bit 52:20, 78:17 blood 121:4 blue 72:6 board 1:2 boston 4:4 both 11:4, 14:11, 29:18, 41:16, 51:17, 52:2, 65:7, 68:13, 86:10, 93:22, 94:7, 108:6, 112:22 bottle 100:2 boxes 72:5, 72:6, 72:7 branded 29:18, 30:1 break 52:20, 91:17, 94:16, 116:13 broad 46:7 brought 16:18	business 11:21, 12:10, 16:9, 39:20, 74:6, 74:9, 78:10, 115:21 buy 90:18, 91:11, 91:15, 91:18, 92:13 buyer 88:12, 88:14, 88:16, 88:18, 88:20 C called 6:3, 26:19, 110:22 came 88:2 can't 43:11, 43:21, 47:17, 48:10, 70:11, 75:22, 110:5, 110:7, 112:9, 114:7 candidate 28:21 candidates 26:11, 39:16, 40:2, 40:11, 40:17 capture 16:5, 16:6 car 74:12 careful 12:4 case 1:14, 1:18, 7:6, 11:14, 16:3, 17:11, 26:12, 39:19, 50:5, 51:11, 57:1, 76:13, 79:22, 89:16, 96:7, 96:15, 98:22, 99:6,	99:13, 101:3, 101:4, 101:5, 102:5, 105:8, 109:7, 113:4 cases 14:11, 32:3, 32:8, 32:9, 84:13, 97:13, 97:19, 99:5 cause 37:2 caution 42:14 cellscript 108:7, 108:10, 109:10, 109:14, 109:18, 110:1, 110:8 certain 28:2, 28:7, 28:13, 32:3, 34:1, 43:6, 62:11, 68:11, 74:20, 77:19, 79:18, 81:6, 83:22, 84:12 certainly 26:20, 38:10, 56:20, 60:8, 60:10, 76:8, 81:19, 83:16, 91:12, 115:5, 115:19 certificate 120:1 certified 2:3, 2:4, 120:3, 120:4, 121:15, 121:16 certify 120:6, 120:13, 120:20, 121:3 change 12:18, 68:15, 68:17, 68:19, 68:20, 81:10 changed 7:3	characteristics 79:8, 79:16 characterize 7:5, 11:15 charge 7:7, 7:9 charging 7:6 charles 4:12 chart 73:8, 73:10, 83:1, 83:3, 83:5, 94:15 check 117:21 chicago 1:28, 2:6, 3:5, 120:22 china 83:22 choose 83:10 chronology 19:12, 20:17 chunks 43:12 circuit 32:3 circumstances 11:14, 20:2, 34:1, 50:3, 84:18 cite 19:2, 40:7, 54:10, 58:5, 85:10 cited 59:3, 59:12, 59:19, 59:22 citizens 28:10, 29:15, 91:7 claim 38:19, 57:1, 67:19, 69:4, 69:8, 69:11, 77:2
--	---	---	---

claimed 31:6, 31:13, 32:5, 53:13, 100:19 claiming 69:14 claims 35:9, 38:13, 38:22, 68:11 clarification 113:12 classify 61:11 classifying 61:10 clear 27:2, 97:4 clearly 81:21 clients 7:8, 7:10 clinical 71:19 close 117:18 closely 84:15 clr 1:31 coextensive 34:10 com 3:8, 3:10, 3:18, 4:7 combat 23:4 combination 45:15, 45:19 combine 79:17 combines 71:17 come 12:22 coming 98:22 comirnaty 22:17, 28:15,	29:4, 29:11, 29:16, 29:19, 29:21, 30:8, 37:21, 38:22, 45:4, 45:12, 45:21, 46:6, 53:12, 53:20, 54:4, 54:8, 54:14, 54:19, 55:5, 55:15, 55:21, 56:7, 60:20, 61:7, 62:20, 66:3, 76:18, 77:6, 87:16, 88:21, 94:7, 100:11, 100:20, 101:9, 102:14, 104:6, 105:1, 105:16, 107:15, 109:15, 109:19, 111:5, 111:22, 112:6, 113:9, 113:16, 115:10, 115:16 commencement 120:9 commencing 2:7, 121:1 commensurate 7:7, 35:8 commercially 66:6, 76:6, 80:9, 80:14, 81:13 commitments 87:22, 88:1 common 86:20 commonly 67:14 communications 42:16 companies 60:2 company 110:22 compare 12:12, 78:16	compared 63:3, 106:1, 115:10, 115:16 comparison 109:19, 110:2, 112:6, 113:9, 113:16, 114:2, 115:6, 115:12 competitive 11:6, 79:10 competitors 15:3 complete 96:19, 96:21, 96:22, 97:5, 119:6 complex 77:6, 77:13, 96:1 component 74:14, 75:4, 78:19, 79:4, 79:5, 79:6, 79:11, 79:13, 80:18, 82:3, 82:6 componentized 74:21, 75:9 components 73:19, 74:18, 75:11, 77:11, 78:9, 78:11, 80:15, 80:16, 81:2, 81:4, 81:9, 81:16, 81:18 composition 68:11 computer 74:12, 78:18, 78:21, 79:20 computers 81:1 concept 87:5, 92:16, 97:20, 97:21 conclude 31:19	concluded 118:7 conclusion 11:18, 11:20, 19:8, 21:7, 26:7, 32:12, 34:7, 93:19, 101:13, 103:17, 106:14 conclusions 34:19, 44:15, 60:5, 69:2, 102:8, 107:10, 112:19, 116:1 conditions 30:12, 49:19, 93:13, 115:21, 115:22 conduct 24:7 conducted 26:1, 105:4, 105:9 confidential 1:23, 117:14, 118:2, 118:4 conjunction 39:19, 70:14, 79:5 connected 36:2 connolly 3:13, 120:16 consider 11:22, 12:11, 12:20, 24:10, 25:3, 59:7, 67:1, 74:3, 74:10, 74:13, 77:21, 80:4, 80:10, 80:18, 83:16, 84:3, 86:2, 100:7, 100:9, 107:2 consideration 26:3, 26:19, 35:5, 92:7, 103:16
--	---	--	---

considerations 21:8, 23:21, 89:17, 91:6, 92:22, 98:3 considered 26:3, 28:22, 30:15, 32:19, 35:3, 35:12, 40:18, 44:2, 44:6, 44:8, 51:1, 51:12, 51:13, 59:8, 61:15, 66:1, 67:3, 85:17, 97:18, 101:18 considering 84:20, 90:3, 91:13 considers 20:11 consistent 9:14, 17:2 constitutes 62:9 construction 38:19, 67:19, 69:8 consultation 9:17 consumer 29:10 contained 110:19 contains 71:7 contend 44:20, 45:3, 45:7, 45:11, 45:15, 45:19 contending 46:2 content 42:15 context 27:2, 41:3, 46:4, 50:17, 69:15, 96:6, 96:9, 96:10,	97:10 contextual 11:13, 32:1 contract 90:18 contracting 90:8 contracts 24:16, 24:21, 25:2, 25:5 contribute 31:18, 58:16, 67:9 contributed 115:17 contributes 36:17 contributing 57:19 contribution 67:4, 97:22, 102:3 contributions 95:12 contributor 104:16 control 67:5 core 86:12 correct 6:11, 9:2, 16:13, 20:8, 21:2, 21:14, 22:13, 22:19, 22:20, 22:22, 23:5, 23:17, 24:6, 24:16, 27:18, 31:15, 38:3, 38:5, 38:7, 38:8, 38:9, 38:10, 38:14, 39:1, 39:2, 39:6, 39:7, 39:13, 39:17, 40:3, 41:1, 41:11, 41:15, 41:19,	44:17, 44:19, 45:5, 45:9, 45:13, 45:17, 45:21, 46:2, 46:6, 46:13, 47:7, 50:21, 53:20, 54:4, 54:9, 54:11, 54:15, 54:19, 55:5, 55:15, 55:22, 56:8, 59:21, 60:21, 65:17, 66:19, 76:15, 76:19, 81:22, 100:20, 105:17, 106:9, 106:11, 109:20, 109:21, 110:3, 110:4, 112:8, 113:18, 114:6, 114:22, 115:18, 119:6 correcting 82:1 corrections 119:7 correctly 6:10 cost 92:3 could 12:20, 27:19, 50:17, 53:5, 56:17, 59:1, 80:4, 90:9, 90:17, 90:19, 91:12 couldn't 76:4, 92:13, 103:1, 103:6 counsel 9:9 countless 59:1, 95:13 countries 85:9 couple 14:2, 41:14,	96:15 course 26:22, 83:19, 90:13 court 8:5, 8:9, 8:11, 8:14, 10:2, 11:19, 70:19, 98:17, 100:22, 109:7, 111:7, 113:4 court's 69:8 courts 11:12, 17:10, 32:12 cover 38:14, 75:20, 76:14, 76:18 coverage 77:2 covered 21:9, 38:22, 75:3, 75:17 covers 63:17, 64:1, 67:17, 67:21, 105:15 covid 22:22, 23:5, 23:17, 24:15, 24:20, 27:16, 29:6, 40:13, 60:19, 61:5, 61:21, 62:19, 73:14, 85:5, 86:14, 87:9, 87:13, 88:18 create 45:16, 45:20 created 83:3 creates 44:21, 45:4, 45:8, 45:12 creating 37:1, 48:22 critiqued 95:13, 95:20
--	---	--	---

CONFIDENTIAL

Transcript of James E. Malackowski

Conducted on July 22, 2024

38

csr	D		
1:31	daily	20:10, 20:22,	25:18, 26:16,
cst	87:9	21:9, 21:12,	28:14, 29:3,
2:7	damages	22:3, 22:10,	29:6, 29:11,
current	96:6, 97:19	22:16, 24:2,	29:15, 29:20,
6:18, 6:20,	data	24:18, 25:16,	30:8, 30:12,
78:7	41:4, 62:1,	41:13, 115:7	44:21, 45:4,
curtis	73:11	declarations	45:8, 45:12,
4:6, 13:16,	date	59:16, 86:9	45:17, 45:21,
15:22, 17:18,	8:4, 13:9,	declared	46:6, 46:13,
18:11, 19:6,	119:13	86:7	46:18, 46:19,
19:19, 20:9,	dates	decrease	47:6, 47:10,
21:3, 21:15,	20:16	92:13	47:19, 86:14,
23:6, 30:10,	day	decreased	86:21, 87:8,
34:15, 35:10,	2:8, 5:11,	24:5	87:13, 89:14,
36:19, 42:14,	42:1, 43:4,	deemed	92:10, 92:12,
47:21, 50:10,	43:5, 43:12,	62:12	92:13, 94:6,
52:21, 56:13,	70:6, 71:6,	defer	100:10, 101:2,
58:2, 60:22,	121:11	10:18, 27:2,	101:7, 102:13
64:12, 71:3,	dc	34:8, 35:2,	demonstrate
72:9, 73:5,	3:15	37:9, 41:3,	31:6, 31:13,
73:17, 74:16,	deal	47:1, 48:18,	35:7, 52:10
75:5, 76:20,	19:9	58:4, 76:10,	demonstrates
77:8, 79:14,	dealing	78:14, 115:20	15:12, 51:7
80:19, 82:4,	98:3	define	demonstrating
85:18, 86:17,	deals	50:3, 50:8	31:12
87:10, 89:1,	43:8	defined	depend
90:21, 92:14,	dealt	106:7	69:1
94:9, 95:6,	109:7	definitely	dependent
101:10, 101:20,	decade	84:7	90:13
103:4, 103:22,	9:22	definition	depends
104:8, 105:2,	decades	49:22, 61:14,	65:21, 84:5
105:18, 106:10,	97:14	85:6	deponent
106:19, 107:16,	december	degree	119:1
108:13, 110:11,	22:12, 22:18,	7:21, 76:9	deposition
111:15, 112:13,	63:3, 87:17	delight	1:25, 2:1, 5:6,
114:11, 116:4,	decisions	62:6	13:11, 13:15,
116:14, 117:9,	90:5	deliver	13:18, 41:14,
117:11, 117:16,	declaration	67:12	70:1, 120:8,
117:19, 118:6,	5:8, 8:1, 8:12,	delivered	120:10, 120:20
120:18	8:22, 9:5, 9:8,	76:7	deriving
curtis@wilmerhale	9:12, 10:8,	delivery	35:13
4:7	10:18, 13:2,	71:18, 72:5	describe
customers	13:6, 14:4,	demand	23:20, 63:20
67:12	14:6, 14:10,	17:13, 18:6,	described
cutler	17:12, 19:10,	18:21, 19:1,	10:19, 32:22,
4:2, 120:18	19:16, 20:5,	19:2, 19:4,	35:22, 38:17,
cutoff		19:10, 19:17,	78:1, 78:2,
94:13		25:11, 25:15,	103:14, 114:6

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BioNTech-Pfizer Exhibit 1157

BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Page 39 of 65

describes 16:2, 19:20 describing 51:18, 60:2 description 5:7 design-arounds 80:11, 80:12, 80:14 designate 117:13 designed 80:17 despite 87:4 detail 38:17 determination 16:22 determine 12:15, 18:19, 32:21, 80:7 determined 98:18 determining 10:5, 89:20 detract 93:18 develop 15:16, 15:19, 16:4, 16:12, 17:15, 18:4, 18:19, 57:4, 57:10 developed 56:12, 56:21, 58:11, 58:21, 60:19, 61:2, 61:6, 62:20, 79:9, 79:11, 80:17, 85:1 developing 23:17, 72:4 development 19:21, 20:14, 23:4, 24:14, 24:20, 27:16, 39:6, 39:13,	39:16, 40:3, 40:12, 40:13, 40:22, 41:5, 41:6, 53:12, 53:19, 54:3, 55:21, 56:3, 56:7, 58:16, 60:8, 60:13, 60:15, 60:16, 62:4, 73:21 different 15:7, 37:20, 72:3, 72:12, 72:21, 88:5, 88:8, 100:16 difficult 27:11 diminish 102:8 direct 10:8, 11:4, 30:22, 32:1, 71:13 direction 9:18 director 6:21, 9:17, 9:21 disagree 18:2, 25:21, 88:2 disagreeing 87:4, 87:5 disclaimed 77:12 disclaimers 71:7 disclose 19:16, 20:5, 20:6, 20:22, 21:12, 22:3, 22:10, 22:16, 41:8, 54:6, 54:12, 54:17, 54:22, 55:3, 55:8, 55:19, 56:5, 93:2, 93:7, 114:18,	115:1 disclosed 32:5, 55:10, 55:11 disclosures 60:1 discount 60:5 discovery 71:18 discussed 28:17, 28:18, 35:4, 56:10, 57:19, 113:19 discusses 20:14 discussion 25:22, 26:10, 34:9, 36:10, 51:17, 56:2, 116:8 disease 37:3 dispute 102:2, 104:15 disputing 77:2 distinct 8:4, 68:12 distinction 30:1, 72:12, 88:9 distinguish 68:5 distribute 66:16, 67:2, 69:12, 90:10, 90:19 distributed 87:19 distributing 91:22 distribution 67:4, 69:14, 90:4, 92:2, 99:3 district 8:5, 8:9, 8:11, 8:14, 10:1,	70:19, 98:17, 100:21, 109:7, 111:7, 113:4 document 43:1, 70:5, 70:8, 70:12, 71:1, 71:5, 83:4 documents 70:10, 71:1, 71:12, 109:1 doing 42:17, 75:2, 75:15, 95:7, 98:6 dollars 23:16 domestics 84:1 done 8:5, 9:8, 52:10, 98:13, 101:12, 103:7, 103:19, 107:22 dorr 4:2, 120:19 doses 87:19, 88:4, 91:16, 93:3, 93:8 doug 3:7, 120:14 dougsawyer@paulh-astings 3:8 down 43:5, 73:2, 73:3 dr 32:22, 33:7, 34:9, 34:22, 35:2, 35:14, 36:1, 36:11, 37:9, 38:18, 41:13, 41:18, 41:20, 42:1, 42:8, 42:12, 43:17, 47:4, 48:18, 51:18,
---	--	--	--

53:10, 54:11, 55:1, 55:9, 55:12, 55:17, 56:4, 57:20, 58:1, 58:5, 58:6, 58:8, 58:11, 58:17, 59:4, 59:20, 60:5, 68:19, 69:2, 76:2, 76:11, 76:13, 78:15, 102:22, 103:16, 104:18, 108:11 draft 43:16 drafting 44:8, 44:12 draw 51:4, 88:9, 106:13 drawing 18:14, 34:7, 78:17 drive 3:4 drug 39:12, 39:15, 40:2, 40:3, 40:11, 40:12, 40:22, 99:2, 99:11, 99:15, 99:20 due 54:8, 54:14, 54:19, 55:5, 55:22, 56:7, 56:21 duly 6:3, 120:9 during 20:12, 27:13, 28:2, 40:2, 40:11 duties 28:6	40:2, 40:11, 75:4 earlier 62:18, 96:8, 100:14 early 22:21, 23:2, 25:9 easily 79:2 economic 15:15, 15:18, 16:3, 16:12, 51:19 edward 6:16 effect 28:19, 28:21, 48:22 effective 29:8, 30:5, 54:7, 54:13, 61:17, 62:12, 62:16, 62:17, 85:17, 85:20, 86:3, 92:19, 100:17 effectiveness 61:3, 61:21, 62:2, 62:3, 62:9, 85:21, 92:21 efficacy 26:13, 53:11, 53:18, 54:2, 89:9, 110:9, 112:11, 114:9 efficiency 37:1 effort 23:13 efforts 23:9, 23:19 either 11:16, 19:17, 22:12, 50:17, 57:7, 74:17, 85:14	elasticity 92:16 elements 78:5, 79:10, 79:18, 80:3 else 7:19, 99:4 embodied 106:3, 106:21 embody 10:10 embodying 17:5 emergency 52:7, 60:6, 86:8 employed 121:5 employee 8:16 employees 59:2 employer 6:18 end 11:18, 43:7 ending 86:10 engagement 7:1, 7:11, 8:3, 8:8, 9:17 engineering 71:18, 72:13, 73:20, 74:20 entitled 13:6, 70:6 entity 89:19 envisioned 88:16 equally 25:6 errata 119:8 especially 88:9 esq 3:7, 3:9, 3:17,	4:6, 4:10 essence 48:21, 78:12 essentially 100:5 estimate 65:2, 65:4 evaluate 19:1, 24:3, 24:19, 25:17, 47:17, 52:16, 101:1, 109:17, 109:22, 112:4, 113:8, 113:14, 114:1, 115:7, 115:15, 118:5 evaluated 49:9, 49:14, 84:10, 104:21 evaluating 18:21 evaluation 75:16, 76:3, 84:17, 96:16, 114:5, 114:19, 115:2 even 49:8, 49:15, 64:14, 80:4, 85:9, 89:22, 90:8 ever 70:8, 84:10, 95:4, 96:1, 97:8, 103:19 every 16:3, 75:4, 88:8 everyone 87:6 evidence 15:1, 51:19, 59:9 exact 70:12 examination 5:4, 6:5 examined 6:4, 113:5,
E			
each 25:22, 27:4,			

119:4 example 11:8, 12:12, 20:20, 28:4, 38:18, 40:8, 57:2, 63:1, 78:8, 100:13 exceed 25:15 exceeded 25:11, 62:7 except 81:15 excess 25:18 execute 90:17 exhibit 5:8, 5:10, 13:4, 13:6, 13:11, 13:15, 13:21, 13:22, 14:12, 14:22, 34:5, 53:6, 69:21, 70:1, 82:14, 83:7, 110:20, 112:20 exhibits 5:6 exist 25:2, 30:14 existence 24:15, 25:9, 30:13 expectations 62:3, 71:8 expected 25:15, 48:12, 91:16 expensive 92:12 experience 39:20 expert 38:6, 38:9, 38:11, 39:5, 39:8, 39:10, 39:12, 40:20,	53:21, 61:20, 62:8, 86:3 expertise 39:15, 112:17 explain 15:18, 27:19, 48:3 explained 14:22 extent 32:4, 49:14, 78:13, 79:17, 83:15, 102:19 extremely 86:14, 86:19 F fact 12:8, 23:22, 24:10, 29:9, 40:17, 47:6, 47:13, 47:19, 48:5, 57:2, 57:21, 62:16, 90:15, 91:18, 102:6, 110:5 factor 26:14, 29:6, 29:7, 52:18, 57:13, 57:15, 67:12, 92:7 factors 28:16, 30:7, 48:4, 48:15, 52:15, 56:11, 56:16, 58:19, 59:1, 59:3, 93:18, 95:11, 96:18 facts 11:13, 20:2, 50:3, 50:5, 84:18 factual 41:4 factually 23:18 fail 39:16, 40:11	failed 12:22, 40:2 failure 26:10, 40:7 fair 23:1, 74:1 familiar 87:7, 87:12, 111:16, 113:3 far 11:6, 32:12, 62:10 fashion 15:14 faster 55:21, 56:6 fda 39:8, 52:7, 60:7, 60:16, 82:20, 83:13, 83:18, 83:19, 84:3, 84:8, 84:14, 84:16, 84:20 feature 35:19, 35:21, 51:6, 96:13 features 31:17, 32:9, 36:5, 49:12, 50:9, 98:19 february 63:2 federal 32:3 feel 31:3 few 16:21, 104:10, 110:18 fewer 93:3 figure 82:17 file 59:18 filings 59:15, 60:1	final 41:22, 42:5, 59:20 finalizing 42:9 financial 94:1 financially 121:7 find 12:8, 43:9 finding 34:17, 34:18 finish 43:6 firm 120:15, 120:16, 120:18 first 6:3, 7:22, 11:7, 22:11, 22:17, 24:1, 41:20, 87:16, 88:14, 88:15, 88:20, 91:17 flip 72:16 focus 8:6, 25:12, 52:3 focuses 47:2 following 20:20 follows 6:4 footnotes 44:6, 44:7, 44:10 force 17:20, 26:15, 27:15, 28:17 forces 16:19, 17:5, 23:3, 23:8, 24:11, 24:14, 25:8, 26:1 foregoing 119:5
--	---	---	---

forgotten 75:12 form 13:16, 15:13, 15:22, 17:18, 18:11, 19:6, 19:19, 20:9, 23:6, 30:10, 34:15, 35:10, 36:19, 47:21, 50:10, 51:5, 56:13, 58:2, 60:22, 64:12, 65:5, 71:3, 72:9, 73:5, 73:17, 74:16, 75:5, 76:20, 77:8, 79:14, 80:19, 82:4, 85:18, 86:17, 87:10, 89:1, 90:21, 92:14, 94:9, 95:6, 99:21, 101:10, 101:20, 103:4, 103:22, 104:8, 105:2, 105:18, 106:10, 106:19, 107:16, 108:13, 110:11, 111:15, 112:13, 114:11, 116:4 formulated 64:2 formulation 72:20, 74:20 forth 26:20, 37:22, 40:18, 120:8 found 10:10, 17:10 foundation 72:10, 73:6, 75:6, 76:21, 85:19, 105:3, 108:14, 116:5 frame 61:19, 63:6,	85:7, 86:15, 89:3 framework 10:5, 18:9, 18:18, 32:14, 51:8 free 27:6, 29:10, 31:3, 91:22, 92:9, 93:4, 93:9 front 13:15 full 6:14, 60:16, 91:1 fully 71:20 funding 57:3, 57:9, 57:17 further 27:19, 32:1, 78:17, 117:6, 120:13, 120:20, 121:3 future 18:5 G gave 96:4 general 10:7, 24:10, 24:13, 28:10, 41:2, 56:2, 56:14, 61:22, 86:18, 99:8, 100:12, 115:20 generally 9:9, 10:9, 11:7, 14:16, 14:22, 16:14, 16:20, 30:2, 40:4, 46:9, 46:10, 46:16, 56:10, 85:22, 87:12, 90:2, 92:2, 92:18,	93:13 generically 48:2 georgia-pacific 95:10, 96:17 getting 117:19 given 11:13, 20:2, 26:2, 63:2, 84:19, 91:7, 119:7, 120:12 giving 96:11, 96:18, 96:20 global 83:21, 87:1 go 8:19, 30:20, 33:20, 42:17, 44:1, 82:14, 107:1, 117:22, 118:1 goes 94:11 going 13:3, 62:18, 69:20, 71:13, 82:16, 88:14 gone 109:5 good 6:7, 6:8, 117:21 government 23:14, 24:3, 24:9, 24:16, 24:21, 25:5, 25:10, 25:14, 28:2, 28:4, 28:12, 29:13, 29:14, 57:2, 57:9, 87:18, 87:21, 88:3, 89:7, 89:13, 89:19, 90:7, 90:11, 90:16, 91:4, 91:20,	92:5, 92:17 government's 27:17, 27:20 governmental 28:8, 57:16, 62:4 governments 23:15 gradient 32:11 granted 86:1 great 6:13, 38:17, 71:15, 82:16, 116:16 greater 36:22, 47:19, 110:8, 112:10, 114:8 green 72:7 groupings 72:13 guaranteed 25:9, 26:15 H hale 4:2, 120:19 half 65:3, 88:20 hand 121:11 handed 70:4 happened 97:14 happens 18:6, 49:21 happy 84:1, 89:4, 108:17, 113:6 hard 48:1 hastings 3:3, 120:15 health 86:7
---	--	---	---

hear 62:3 heard 110:22 held 2:5, 6:19 helpful 43:10 here 7:16, 10:22, 39:22, 41:5, 43:22, 47:3, 47:12, 49:18, 67:6, 67:22, 72:2, 72:3, 72:18, 81:21, 83:15, 84:19, 86:12, 89:11, 89:18, 91:9, 93:19, 94:12, 95:22, 98:5, 98:7, 98:12, 98:14, 101:4, 101:12, 102:2, 103:12, 104:17, 108:21, 109:8, 110:17, 111:18, 113:5, 113:21 hereby 119:3, 120:5 herein 6:3 hereinbefore 120:8 hereunto 121:10 high 86:14, 86:20 higher 49:11 highly 49:7, 49:8, 118:3 historical 19:21 hold 39:10 holistic 22:8	hour 2:7, 7:4 hourly 6:22 hours 9:4, 9:10, 9:11, 43:3 howe 8:14 howell 8:16 huge 88:9 hundreds 23:15 hypothetical 24:8, 25:1, 26:2, 65:22, 93:6 I idea 16:17, 16:19 identification 13:12, 68:8, 70:2 identified 25:1, 47:15, 47:17, 101:4 identify 46:22 ii 40:8 iii 40:8 illinois 1:28, 2:5, 2:6, 3:5, 120:5, 120:22, 121:18 imagine 48:10 immune 48:22 impact 23:13, 24:3, 24:19, 25:17, 25:18, 30:4, 30:5, 37:20,	46:10, 46:16, 47:2, 47:6, 47:10, 47:19, 49:11, 50:7, 53:18, 54:2, 55:13, 56:11, 57:3, 69:2, 69:17, 84:17, 87:8, 87:12, 93:8, 93:9, 101:7, 104:16, 105:10, 105:16, 106:8, 109:18, 109:20, 110:1, 110:2, 110:9, 112:5, 112:7, 112:11, 113:8, 113:10, 113:15, 113:16, 114:1, 114:3, 114:9, 114:19, 115:2, 115:8, 115:15 impacted 28:14, 29:3, 29:10, 29:15, 29:20, 46:6, 46:13, 46:18, 50:12, 58:20, 100:10 impactful 48:11, 49:19, 49:22, 50:16, 50:21, 51:2, 51:5, 51:7, 51:13, 51:16 impacting 22:22, 23:3, 24:14, 27:15 impacts 101:2, 104:22, 106:17, 107:6 implemented 79:12 implied 73:9 importance 51:18 important 11:19, 49:7,	49:8, 49:18, 50:15, 52:18, 104:5 importantly 28:20 inc 1:4, 1:10, 3:12, 4:1, 4:10 incentive 16:9, 17:15 incentives 15:16, 15:19, 16:4, 16:12 inch 65:3 incident 37:2 include 10:19, 83:11, 107:5, 107:7 included 42:12, 44:16, 46:3, 82:19, 83:2 includes 34:18, 60:1, 63:13 including 20:12, 28:3, 60:15, 60:17, 83:16, 90:4, 100:12, 103:15, 110:14 increase 92:10 increased 24:5, 46:19 increases 92:11 incremental 57:16 indeed 88:19 index 5:1 indicative 11:10 indicators 19:3
---	--	---	---

indicia 14:20, 15:8, 15:9, 16:16, 17:17	introducing 90:12	19:13, 22:8, 25:13, 55:10, 56:1, 58:15, 61:18, 66:13, 67:3, 67:22, 69:6, 93:14, 102:1, 102:5, 104:17, 105:8, 106:4, 107:2, 109:6, 115:6	jurisdiction 52:4
indirect 11:6	introductions 15:13		K
individuals 27:17, 28:5, 28:13	invalidity 95:8		kariko 108:11
industry 62:13, 90:2, 92:18	invention 15:17, 15:20, 15:21, 17:6, 17:7, 17:16, 19:5, 31:13, 32:5, 36:22, 59:5, 81:20, 82:12, 95:12, 97:22	issued 33:9	keyboard 9:15
influence 30:7	inventions 31:6, 35:19, 35:21, 37:17, 51:12, 57:18, 58:1	issues 39:20, 39:21, 43:8, 55:2, 86:11	keys 9:15
infringe 80:9		J	kind 58:13, 72:5, 93:21
infringed 63:21, 68:13, 105:9	investigate 44:2	j&j 63:5, 63:8	know 16:7, 25:7, 27:3, 35:4, 42:7, 42:11, 48:2, 48:20, 49:14, 56:15, 57:12, 60:14, 64:1, 64:19, 65:9, 70:13, 70:18, 75:19, 84:15, 86:15, 89:22, 95:9, 103:5, 104:21, 106:2, 106:7, 107:12, 108:19, 111:9, 112:3, 117:2
infringer 10:12	investigation 54:7, 54:13, 54:18, 55:4, 55:20, 56:6	james 1:26, 2:1, 5:3, 5:9, 6:2, 6:16, 8:1, 9:5, 13:7, 119:3, 120:7, 120:21	knowledge 31:21, 117:5
ingredient 99:11	investing 23:15	janice 1:31, 2:2, 120:3	known 58:3
innovators 108:16	investment 16:5, 24:3, 24:9	january 22:12, 22:18, 63:3, 86:8, 87:18, 89:14, 89:21, 94:7	kocek 1:31, 2:2, 120:3
input 42:12	involved 8:14	jessica 4:10	krause 32:22, 33:7, 34:9, 34:22, 36:11, 37:9, 41:18, 42:1, 42:8, 42:12, 42:21, 43:17, 47:4, 48:18, 51:18, 53:10, 54:11, 55:9, 55:12, 55:17,
instance 73:14, 79:4	involving 99:1, 99:13	job 1:32, 28:5, 28:9	
instead 65:22	ionizable 73:1	jointly 68:14	
intangible 84:4	ipr 1:14, 1:18, 9:12, 59:15, 59:18, 96:9, 98:17	judge 18:9	
integrated 71:20	isolated 22:7	julia 4:12	
intellectual 10:13	issuance 8:7, 9:1	july 1:27, 2:8, 121:1, 121:11	
intended 79:1	issue 10:14, 19:9,		
interested 89:7, 121:7			
interesting 43:9			
internet 70:5			
introduce 116:9			
introduced 48:7, 62:17			

58:1, 58:5, 58:8, 58:17, 59:4, 68:19, 76:2, 76:11, 78:15, 102:22, 104:18 krause's 35:2, 35:14, 36:1, 38:18, 41:13, 41:20, 55:1, 56:4, 57:20, 58:6, 58:11, 59:20, 60:5, 69:2, 76:13, 103:16 L language 81:17 laptop 78:5 large 24:16, 24:21, 25:14 largely 51:17, 79:7, 107:8 last 6:15, 53:9, 96:4, 96:7, 96:10, 96:14, 96:15 late 22:21, 23:2 later 11:4, 27:14, 88:2 launch 60:8, 60:10 law 16:17, 120:15, 120:16, 120:18 lawyer 12:6 lay 37:5 layperson 36:6	lays 72:19 least 8:21, 22:11, 23:14, 30:6, 56:12, 67:9, 71:12, 72:1, 72:2, 85:16, 85:21, 91:15 left 8:19 legal 12:5, 12:6, 15:9, 16:22, 17:1, 17:9, 17:20, 17:22, 18:14, 18:15, 18:16, 19:8, 32:13, 33:5, 33:13, 33:17, 38:4, 39:4, 50:22, 51:10, 63:19, 67:19, 74:8, 77:19, 81:6, 81:19, 82:8, 102:4, 103:10 lengthy 43:1, 64:20, 64:22 less 32:10 let's 27:2, 118:2 level 10:20, 100:12 levels 12:2 liam 8:13, 8:16 license 2:3, 108:7, 108:9, 108:16, 108:19, 109:1, 109:11, 109:15, 111:4, 111:9, 113:1, 121:17 licensed 117:3	licenses 117:17 licensing 48:9, 74:9, 77:21, 78:3, 80:22 lifetime 20:12 likely 18:5, 57:3, 57:9, 71:2, 84:12 limit 46:9, 46:15 limited 83:18 line 51:4, 97:8 linked 36:2 lipid 64:2, 64:7, 64:10, 72:20, 73:1, 73:3, 74:13, 111:14 list 44:2, 44:6, 80:10, 93:22, 105:21, 106:1 lists 72:21 litigation 8:6, 8:9, 8:11, 10:2, 70:19, 95:10, 98:17, 100:22 little 27:19, 52:20, 78:17 lived 87:6 livenote 2:4, 120:4, 121:16 lives 87:9 llp 3:3, 3:13, 4:2,	120:15, 120:19 lnp 36:9, 36:17, 37:16 lnps 37:20, 38:9, 111:13, 111:22 long 32:17, 42:20, 64:19, 68:18 longer 57:10, 68:21 look 10:12, 12:19, 27:6, 44:4, 50:2, 53:8, 59:14, 59:15, 69:7, 78:4, 79:16, 84:22, 93:21 looked 59:17, 59:19, 68:13 looking 10:9, 52:16, 59:8, 59:11, 90:2, 91:2, 91:3, 91:4, 91:11, 91:15, 92:18, 100:14 M m-a-l-a-c-k-o-w-- s-k-i 6:17 mackay 4:10 macroeconomic 93:18 made 26:5, 52:3, 73:15, 87:22 madison 2:6, 120:22 main 3:14, 107:14, 107:19 maintain 76:9
---	--	---	--

majority 94:6, 94:14, 102:12, 103:13 make 6:9, 27:2, 31:4, 68:2, 71:9, 72:12 making 63:20 malackowski 1:26, 2:1, 5:3, 5:9, 6:2, 6:7, 6:11, 6:16, 8:2, 9:6, 13:4, 13:5, 13:7, 13:11, 13:14, 14:13, 34:5, 38:2, 53:5, 69:21, 70:1, 70:4, 95:3, 117:2, 119:3, 120:7, 120:21 malackowski's 13:9 management 91:9 managing 6:21, 9:16, 9:21 mandate 28:10 manufacture 66:10, 69:5 manufacturing 71:19, 72:6 many 9:4, 9:11, 23:3, 23:8, 26:6, 31:17, 40:2, 40:11, 48:8, 64:20, 87:13, 93:2, 97:13, 110:13 mark 13:3, 15:13, 69:20, 118:2 marked 13:12, 70:2,	77:1, 118:3 market 10:21, 11:1, 11:3, 12:15, 12:19, 12:22, 15:3, 16:18, 16:19, 17:4, 17:14, 23:3, 23:8, 24:10, 24:14, 25:8, 26:1, 26:5, 26:12, 26:14, 26:15, 27:15, 28:17, 30:3, 30:7, 30:12, 30:18, 31:7, 31:14, 52:4, 62:17, 79:7, 88:4, 88:6, 88:8, 89:14, 92:20, 93:12, 100:16, 110:10, 112:12, 114:10 marketed 79:10 marketplace 20:3, 28:19, 48:13, 52:13 markets 83:22 marriage 121:5 massachusetts 4:4 material 44:15, 44:17, 44:18 materials 40:6, 43:19, 44:2, 44:6, 44:8, 44:11, 59:12 matter 53:22, 70:14, 70:17, 97:12, 121:8 matters 7:10	matured 90:14 maximally 50:7, 50:12 maybe 33:20, 43:4, 50:12, 81:18, 87:4, 88:10 mcsorley 7:18, 9:16, 9:19 mean 13:21, 23:8, 27:20, 50:8, 58:4, 60:14, 75:19, 87:6, 96:22 meaning 46:19, 74:8, 82:8, 97:1, 97:12, 107:22, 114:5 meaningful 7:21, 44:14 means 46:17, 46:21, 50:4, 55:8 meant 81:22, 88:4, 97:6 meet 11:3, 49:19, 49:22, 103:17 meets 32:18 memorize 108:16 memory 27:3, 70:11, 89:16, 111:8 mentioned 8:8, 8:20, 33:19, 41:13, 80:16 mentions 41:12 mers 116:2, 116:11	mestitz 3:17, 108:2, 117:10, 117:15, 120:16 method 68:11 metrics 67:13 michael 3:17, 120:15 might 74:7, 100:4, 100:9, 113:10 military 28:3 millions 23:16 mind 50:1, 50:20, 98:22 minimally 49:21, 50:4, 51:5, 51:7, 51:12, 51:16 minutes 104:10, 110:19, 116:14, 116:15 misspoke 13:17 mmestitz@wc 3:18 moderna 5:10, 9:9, 9:10, 57:3, 70:6, 70:15, 71:2, 71:6, 71:17, 72:1, 72:18, 94:1, 100:18, 102:6, 105:15, 108:6, 109:9, 111:9, 113:1, 114:19, 115:2, 117:4 moderna's 22:11, 71:8, 116:2 modernatx 1:10, 4:1
--	--	--	---

modified 37:6, 108:20, 109:3 moments 16:21 monday 121:1 month 8:7, 9:1, 9:3 more 9:22, 17:9, 32:17, 43:2, 43:7, 43:12, 48:11, 54:7, 54:13, 56:17, 60:18, 74:11, 76:1, 80:22, 85:9, 88:11, 91:15, 97:20, 102:19, 102:21, 104:5 morning 6:7, 6:8 most 8:20, 9:15, 24:1, 48:6, 49:5, 49:18, 50:15, 50:21, 51:2, 62:16, 62:17, 84:12, 97:19 mover 11:8 mrna 37:6, 37:11, 37:13, 38:6, 64:2, 71:17, 72:4, 72:20, 72:22, 74:15 much 54:7, 54:13, 54:18, 55:4, 55:20, 56:6, 58:9, 90:18, 91:11 multicomponent 74:4, 74:7, 74:10, 77:6,	77:17, 77:22, 82:10, 96:2 multiple 73:15, 73:19, 90:12, 90:16, 91:2 must 17:6, 28:10, 49:18, 51:2, 82:11 myself 39:10 N name 6:10, 6:14, 6:15 nano 64:10 nanoparticle 64:3, 64:7, 74:14 nanoparticles 72:20, 111:14 nature 18:14, 34:10, 74:4, 74:5, 77:7, 77:17 nd 2:8, 121:1 necessarily 17:6, 88:7 necessary 102:16, 102:20, 103:7, 103:9, 105:12, 107:10, 110:16, 112:19, 113:20, 114:15 need 12:4, 60:18, 69:7, 91:16, 103:11, 116:9, 117:13 needs 11:3, 118:3 neither 63:8, 63:11 network 67:4	never 41:17, 88:16 new 15:12 nexus 10:15, 31:12, 31:20, 32:4, 32:7, 32:8, 32:11, 32:16, 32:21, 33:3, 33:5, 33:8, 33:10, 34:1, 34:6, 34:8, 34:14, 34:17, 34:22, 35:1, 35:7, 35:13, 35:18, 61:16, 68:15, 81:20, 81:22, 82:2, 82:11, 95:5, 95:21, 96:12, 96:19, 96:22, 97:2, 97:3, 97:6, 97:9, 97:12, 97:17, 98:12, 98:20, 99:7, 102:3, 102:13 nih 113:1, 113:8, 113:15, 114:1, 114:8 nlp 64:10 nonclaim 31:17 noninfringing 66:6, 80:12 nonobvious 51:8 nonobviousness 14:20, 15:8, 16:16, 17:17, 98:4, 98:9, 101:14, 104:13, 107:2 nonseparable 79:18	notary 2:4, 120:1, 120:4, 121:18 note 7:15, 14:9, 105:22 notes 32:3 nothing 44:14, 99:2, 99:14, 117:6, 117:9, 117:10, 117:11 noting 71:7, 100:15 novel 15:13 number 5:7, 19:3, 23:19, 26:11, 30:7, 40:18, 40:21, 43:2, 72:21, 73:22, 100:19 numbers 94:1 numeric 97:22 O object 13:16, 15:22, 17:18, 18:11, 19:6, 19:19, 20:9, 23:6, 30:10, 34:15, 35:10, 36:19, 47:21, 50:10, 56:13, 58:2, 60:22, 64:12, 71:3, 72:9, 73:5, 73:17, 74:16, 75:5, 76:20, 77:8, 79:14, 80:19, 82:4, 85:18, 86:17, 87:10, 89:1, 90:21,
---	---	---	--

92:14, 94:9, 95:6, 101:10, 101:20, 103:4, 103:22, 104:8, 105:2, 105:18, 106:10, 106:19, 107:16, 108:13, 110:11, 111:15, 112:13, 114:11, 116:4 objection 21:3, 21:15, 84:6 objective 14:20, 15:7, 16:16, 17:17 obtained 58:17 obvious 15:21, 16:19 obviously 11:5, 23:9, 27:6, 32:12, 40:18, 84:19 obviousness 17:4 occur 94:15 occurred 120:21 ocean 2:5, 4:11, 6:19, 7:12, 8:17, 9:20, 120:22 oddly 58:13 offer 55:17, 102:15 offered 81:13, 98:18 offering 12:6, 33:4, 37:8, 38:2, 38:4, 38:19, 38:20, 39:4, 39:18, 40:1, 40:10, 40:20,	53:21, 57:6, 62:11, 63:16, 63:19, 64:13, 66:12, 66:18, 67:2, 67:16, 67:19, 77:18, 98:8, 98:11, 112:2, 116:6 office 1:1 offices 120:21 officials 29:14 often 79:8 okay 26:14, 27:5, 31:11, 31:17, 38:6, 38:12, 51:4, 52:5, 54:1, 63:13, 66:14, 69:16, 71:15, 72:1, 76:17, 78:16, 78:21, 79:3, 83:10, 84:3, 86:13, 91:20, 96:10, 99:19, 107:21, 107:22, 111:3, 113:7, 117:11, 118:6 once 43:2, 79:17 one 12:12, 12:14, 12:17, 23:13, 23:20, 27:9, 28:4, 28:18, 28:22, 33:15, 35:17, 47:18, 49:9, 52:15, 68:9, 69:6, 73:2, 88:14, 90:1, 95:10, 101:18, 103:11, 104:21, 106:2, 106:16, 107:12	ones 23:22 online 65:6, 65:8 only 12:14, 59:19, 71:4, 83:10, 88:12, 88:17, 88:19, 89:19, 90:1, 91:5 open-ended 58:22 opined 95:4, 97:9, 104:12 opining 32:13, 33:14, 51:10, 57:7 opinion 17:1, 17:8, 17:9, 18:1, 18:15, 18:16, 19:17, 19:20, 20:6, 20:18, 21:1, 21:13, 22:3, 25:4, 33:2, 33:4, 33:6, 33:15, 34:22, 35:7, 35:13, 35:17, 36:1, 36:3, 36:12, 36:14, 37:8, 37:10, 37:14, 37:15, 37:19, 38:1, 38:19, 38:21, 39:4, 40:1, 40:10, 40:21, 44:17, 44:19, 45:1, 47:5, 51:6, 53:17, 53:21, 54:1, 54:12, 54:17, 55:13, 55:18, 57:6, 57:14, 58:9, 58:11, 58:18, 61:20, 62:8, 62:11,	63:16, 63:19, 64:5, 64:14, 65:13, 65:15, 66:12, 66:18, 67:16, 67:20, 68:15, 77:18, 81:3, 96:5, 96:11, 96:18, 96:21, 97:2, 97:3, 97:11, 98:8, 98:11, 98:18, 102:11, 102:15, 104:4, 106:16, 110:5, 110:7, 110:13, 112:2, 112:9, 112:15, 114:7, 114:13, 115:14, 116:7 opinions 12:7, 17:22, 34:4, 38:3, 38:5, 38:12, 39:18, 41:10, 42:2, 46:3, 68:17, 68:18, 68:20 opposed 60:7, 81:2, 85:5 optimist 108:3 order 31:19, 49:19, 52:5, 52:10, 52:12, 64:11, 76:3 ordered 104:11 organization 71:20 originally 26:11 other 7:7, 8:5, 9:8, 12:21, 15:9, 23:14, 24:10, 24:13, 25:7,
---	---	---	--

25:8, 28:16, 30:7, 32:9, 33:16, 35:8, 35:18, 40:22, 41:1, 41:7, 44:12, 46:5, 46:10, 46:12, 46:16, 46:17, 46:22, 47:6, 47:13, 47:18, 49:5, 49:10, 54:10, 55:1, 55:16, 56:11, 56:16, 58:19, 59:1, 59:2, 60:17, 60:19, 61:1, 61:5, 61:8, 61:10, 62:19, 67:13, 68:9, 76:14, 76:18, 77:1, 83:21, 93:15, 100:9, 100:15, 101:19, 104:20, 104:22, 105:22, 106:1, 106:17, 107:13, 114:19, 115:2 others 17:15, 25:4, 26:10, 28:3, 30:17, 38:16, 48:8, 48:10, 59:7, 83:15, 98:1 otherwise 10:12, 15:3, 83:22, 92:5, 121:7 out 26:19, 27:12, 27:14, 39:10, 46:22, 47:5, 72:19, 75:12, 76:4, 76:8, 80:3, 93:22 outcome 121:8	outside 17:11, 39:22, 64:4, 65:12, 65:14, 66:7, 74:8, 77:3, 77:20, 81:7, 91:7, 101:11, 107:9, 110:15, 112:3 over 62:5, 97:14 overlap 44:1 own 44:3 owner 1:12, 4:1, 10:12, 120:17 P pace 85:2 packaging 99:22, 100:1, 100:5 page 5:3, 5:7, 13:8, 82:17, 109:19 pages 42:22, 64:20 paid 6:22, 109:10, 109:14 pandemic 22:22, 23:10, 28:2, 30:14, 86:11, 86:16, 86:22, 87:1, 88:10, 91:9 paper 65:5, 65:7 pappalardo 4:11 paragraph 14:13, 30:22, 31:3, 32:2, 33:19, 53:8, 93:20, 93:21	paragraphs 33:21 parameters 81:6, 86:11 part 6:19, 7:11, 12:18, 28:8, 35:11, 44:13, 68:16, 68:21, 70:17, 70:18, 75:17, 75:20, 111:6 particle 64:11 particular 7:6, 8:1, 11:9, 11:13, 14:4, 17:14, 17:16, 18:10, 18:20, 25:19, 30:13, 30:16, 37:16, 38:22, 48:5, 83:4, 89:3, 93:13 particularly 94:13 parties 26:12, 79:9, 121:4, 121:6 parts 73:15, 73:19 party 79:12, 80:17 patent 1:1, 1:2, 1:12, 1:15, 1:20, 4:1, 10:11, 20:7, 32:6, 33:9, 33:11, 38:13, 39:1, 44:20, 45:3, 45:7, 45:11, 54:9, 54:14, 54:19, 55:5, 55:14, 55:22, 56:8, 63:9, 63:13, 63:17, 64:1, 64:11, 64:17,	65:11, 65:16, 65:20, 66:4, 66:9, 66:15, 66:21, 67:17, 68:6, 68:16, 69:3, 69:7, 69:10, 79:4, 85:14, 95:5, 95:9, 95:17, 98:19, 99:2, 99:14, 99:19, 100:19, 101:7, 101:15, 102:7, 102:12, 103:2, 103:3, 103:20, 103:21, 104:5, 104:7, 104:14, 104:22, 105:7, 105:15, 105:21, 106:17, 107:5, 107:8, 107:13, 109:3, 111:13, 114:21, 115:11, 115:18, 116:3, 120:17 patented 19:1, 23:22, 24:12, 25:3, 26:4, 30:17, 31:7, 31:14, 32:9, 35:19, 36:5, 47:20, 49:12, 49:17, 50:9, 51:6, 59:5, 62:6, 62:15, 63:4, 75:22, 76:5, 81:16, 82:3, 96:13, 98:19, 115:3, 115:8 patentee 31:5 patents 19:14, 19:18, 20:12, 20:15, 21:1, 21:10, 21:13, 22:4, 30:9, 36:7,
--	--	--	---

36:15, 38:13, 45:16, 45:20, 53:14, 53:18, 54:2, 56:1, 56:22, 58:10, 58:15, 68:12, 75:3, 75:10, 75:17, 75:20, 76:14, 76:18, 77:1, 92:8, 93:10, 101:5, 103:17, 104:17, 109:18, 109:20, 110:1, 110:3, 110:8, 110:10, 111:4, 112:5, 112:7, 112:10, 112:12, 113:8, 113:10, 113:15, 113:17, 114:1, 114:3, 114:8, 114:10, 114:20, 115:6, 117:3 patents-in-suit 63:11 patient 49:1 paul 3:3, 120:15 pay 92:11 payer 88:1 pays 111:5 peg 73:3 pennsylvania 108:12 people 87:11 percent 62:5, 62:7, 89:13 percentage 62:12 perfect 6:12	perform 28:5 performance 10:10, 10:16, 24:12, 25:3, 26:4, 30:16, 49:3 performed 25:6, 108:11 perhaps 56:17, 75:11, 82:7, 97:14 period 61:2, 61:6, 83:14 personally 9:5, 53:17 perspective 11:21, 12:5, 12:10, 29:1, 37:5, 47:11, 48:9, 74:7, 77:21, 78:3, 78:10, 78:14, 80:7, 80:22, 83:21, 97:20, 115:20 petitioner 3:2, 3:12 petitioners 1:6, 120:14 pfizer 1:4, 3:12, 94:1, 115:21, 117:10 pfizer's 115:15 pfizer-biontech 63:22 pharmaceutical 41:7, 99:1, 99:10, 99:13 phase 40:8 phospholipid 73:2 phrase 50:12, 58:13,	74:7, 75:11, 84:6 physically 42:8 pickering 4:2, 120:19 pill 100:2 placed 84:8 platforms 71:19 please 27:7, 27:14, 30:20, 31:3, 82:14 point 27:11, 27:12, 27:13, 61:15, 69:9, 74:9, 75:12, 76:10, 88:14, 88:15, 92:6 portions 43:7 position 6:20, 9:19 positioning 11:7 positions 28:3, 28:8 possible 65:9 possibly 91:11 potential 47:8, 80:10 practice 9:15, 37:17, 63:9, 64:11, 65:10, 65:19, 65:22, 66:4, 85:14, 116:2 practiced 100:20 practices 15:16, 15:19, 65:16	premature 106:13 premise 18:3, 91:1 prepare 41:18 prepared 83:2, 83:5, 83:8, 101:16 present 4:9, 17:6, 20:17, 24:5, 26:3, 80:6, 120:13, 120:17 presentations 70:15 presented 40:15, 45:1, 67:6 presenting 17:12, 101:13, 107:11 presume 75:3 presumes 16:17 presumption 33:22, 34:1, 34:6, 34:9, 34:14, 34:18, 35:1, 111:8 previous 9:1, 70:18 previously 15:5, 95:20, 113:19 price 92:15 primary 52:15 printed 70:5 prior 8:7, 20:16, 20:19, 25:22, 42:3, 42:8, 62:3, 98:14 private 29:2, 88:1
--	--	---	---

probably 96:8 problem 77:14 proceeding 8:2, 8:4, 9:12, 14:5 process 39:9, 39:13, 39:16, 40:3, 40:12, 44:14, 60:7, 60:13, 60:16, 86:4 processes 72:3 processor 78:18, 78:22, 79:2, 79:20 processors 79:8 produce 17:5, 23:10, 76:4 produced 29:8, 42:1, 49:4, 70:13, 70:17, 70:18, 75:21, 80:8 product 10:10, 10:14, 12:12, 12:13, 12:14, 12:17, 15:12, 15:16, 15:19, 16:4, 16:12, 17:5, 17:13, 18:10, 19:10, 19:11, 20:3, 22:17, 30:13, 31:8, 31:15, 31:18, 32:4, 48:7, 56:2, 63:1, 67:11, 73:21, 74:10, 74:19, 74:21, 75:9, 76:7, 77:22, 78:12, 88:9, 96:2, 103:13	products 11:22, 12:21, 18:4, 19:2, 24:12, 25:4, 30:17, 34:11, 39:3, 49:5, 49:7, 49:9, 52:13, 52:17, 60:2, 60:11, 61:17, 63:4, 67:22, 78:4, 80:22, 81:13, 82:10, 84:20, 90:14, 93:14, 93:15, 101:22, 102:1, 105:8, 106:4, 106:22 professional 117:8 profitability 10:21, 16:6 profits 11:5, 12:19, 20:1, 20:13, 67:13 project 18:20 promoting 29:14 promotion 30:3, 115:21 pronouncing 6:9 proper 18:8 property 10:13 protect 91:3, 91:4 protein 36:8, 36:16, 76:15, 113:2 provide 16:4, 21:7, 41:9, 110:5, 110:7, 112:9, 114:7 provided 15:11, 42:12	provides 36:3 providing 17:1, 17:22, 18:15, 21:6, 78:12, 81:3, 97:11, 110:12, 112:14, 114:12 ptab 7:12, 8:2, 8:11, 8:22, 9:6, 13:4, 13:6, 13:11, 13:15, 14:5, 17:11, 34:5, 69:21, 70:1 public 2:5, 60:1, 91:5, 91:22, 92:3, 120:1, 120:4, 121:18 publicly 70:19, 72:2 purchase 25:14, 87:22, 88:15, 90:4, 92:18 purchased 87:22, 89:20, 91:21 purchaser 87:19, 88:3 purchasing 25:10, 25:18, 89:8, 90:1 pure 16:7 purpose 79:1, 95:8 purposes 16:8, 89:5, 101:14, 104:13, 107:1, 110:16, 111:18, 113:20, 114:16 pursuing 90:7 purview 102:21	put 26:20, 37:22, 43:11, 61:14, 71:2, 83:3, 89:2 Q qualitative 102:16 quantify 19:22 quantitative 11:12, 31:22, 40:15, 98:1 quantitatively 41:6 quantities 89:8, 91:13 quantity 25:15 question 9:13, 10:7, 14:18, 16:2, 18:13, 21:17, 21:20, 22:2, 32:13, 33:13, 33:17, 35:15, 36:21, 38:15, 41:2, 46:7, 48:18, 51:10, 56:15, 58:22, 61:5, 61:22, 62:18, 63:19, 64:4, 67:1, 69:14, 73:8, 75:8, 76:1, 77:10, 82:6, 84:15, 86:18, 88:11, 88:13, 89:5, 89:11, 91:1, 93:11, 97:4, 102:19, 104:9, 104:18, 108:2 questioning 97:8 questions 26:22, 27:9, 27:13
---	--	--	--

quickly 48:7, 60:20, 62:20 quite 8:18, 64:20, 64:22 quote 107:18 R raging 86:16, 86:20 raised 39:21 ramifications 77:20 rank 104:11 ranking 102:17 rapid 53:11, 53:19, 54:3 rate 6:22, 7:2, 7:5, 7:9, 40:7 rather 11:4 reach 107:10, 112:19 reached 102:9 reaching 26:7 read 31:4, 31:5, 33:21, 41:12, 53:10, 64:17, 65:5, 65:6, 71:4, 71:17, 73:10, 73:11, 119:4 reading 73:8 ready 117:19 real 17:14	really 80:13, 102:18 reason 16:15, 67:6, 83:17, 107:14, 107:19 reasonable 35:8, 62:22 reasons 18:4, 60:3, 77:22, 78:2, 95:20, 97:22, 110:13, 113:18, 114:6, 114:13 recall 8:3, 9:11, 26:18, 42:20, 50:11, 64:21, 75:9, 81:17, 85:4, 89:15, 95:7, 96:3, 96:9, 96:18, 96:20, 97:11, 97:15, 97:16, 98:5, 98:7, 98:11, 98:15, 99:4, 99:16, 99:19, 99:22, 108:21, 109:2, 109:3, 111:7, 111:11 recalling 7:2 receive 52:7, 61:18 received 41:22, 57:3, 83:13 recently 7:3, 8:18 recess 53:1, 94:20, 116:19 recipient 37:3 recognize 47:13, 71:1 recollection 85:11, 96:14, 98:22, 99:13, 99:21 record 6:15, 7:16, 13:4, 13:5, 14:9, 53:3, 59:3, 59:9, 59:11, 62:2, 94:19, 95:1, 116:8, 116:17, 116:22, 117:22, 120:11 red 72:5 reduced 65:19, 66:3, 116:11 refer 14:10, 14:16, 25:21, 35:14, 36:10, 56:3 reference 40:7, 40:16, 52:2 referred 10:15, 11:7, 14:2, 14:3 referring 10:17, 14:7, 14:11, 51:22, 56:16 reflected 48:6, 83:6, 94:14, 100:13 refresh 50:13 regard 31:22, 37:8, 38:1, 38:18, 39:4, 39:11, 39:19, 49:4, 55:18, 57:7, 64:14, 66:13, 86:10, 110:13, 112:3, 116:7 regarding 62:1, 68:18 regardless 52:4	relate 15:9, 36:15, 37:6, 66:10, 66:15, 66:21, 111:13 related 11:1, 39:20, 59:1, 59:15, 73:21, 99:20, 109:1, 113:2, 121:3 relates 15:10, 30:16, 37:11, 40:13, 40:22, 101:15, 104:14, 108:10, 108:19, 109:3 relative 11:22, 12:11, 12:20, 25:3, 26:4, 29:1, 55:11, 85:21, 93:14, 97:20, 102:20, 103:2, 103:19, 104:16, 105:10 relatively 62:15, 85:6, 103:1 relevant 10:22, 17:4, 34:19, 43:7, 89:6, 89:17, 92:7, 94:13 reliance 47:3, 55:11 relied 43:20, 44:11, 58:1 rely 32:22, 55:16 relying 34:14, 34:16, 35:5, 43:9, 55:8 remember 95:19 rephrase 50:19, 56:18,
---	--	---

88:10 reported 1:30, 2:2 reporter 2:4, 120:1, 120:3, 120:4, 121:15, 121:16 reports 43:16 represent 44:10, 70:16 representative 83:20 require 112:17 required 11:12, 28:4, 31:5, 37:16, 47:11, 52:14, 67:5, 72:19, 73:9 requirement 27:17, 27:20, 28:9, 28:13, 49:17, 50:20, 50:22, 52:9, 64:7 requirements 29:2, 64:10, 64:15, 81:19, 103:11 requires 110:14 reread 50:17 research 16:8, 44:13, 83:12 reserve 74:11 respect 19:13, 24:11 responding 88:10 response 16:18, 37:1, 48:22, 68:22, 85:5	responsible 31:7, 31:14, 47:12, 102:7, 103:12, 103:13 rest 91:6 result 86:22, 116:10 resultant 19:11, 22:9 resulted 20:13 results 19:2 retained 7:22 return 16:5 reveal 42:15 review 41:20, 42:21, 43:16, 43:19, 48:19, 55:1, 75:10, 84:14 reviewed 38:17, 42:5, 43:2, 44:13, 65:8, 108:15, 109:6, 111:6 reviewing 76:13, 108:22 right 16:19, 17:7, 17:17, 19:5, 19:18, 25:11, 41:10, 56:12, 56:22, 60:9, 60:13, 62:21, 63:10, 63:17, 67:17, 71:11, 85:2, 87:6, 87:9, 87:20, 88:6, 88:12, 88:22, 90:20, 92:1, 92:12, 93:10, 100:3, 107:6, 108:7,	112:7, 114:21 risk 116:11 river 4:12 rna 65:10, 65:15, 108:20, 109:4 robert 7:17, 7:20, 8:13 rollout 90:3 roughly 61:6 rowe 4:12 royalties 109:10, 109:14 royalty 111:5 rule 46:22 ruled 47:5 S s 3:1 safe 85:17, 85:20, 86:2, 92:19 safer 54:18, 55:4 safety 53:11, 53:19, 54:3, 55:10, 55:14, 89:9, 92:21, 110:9, 112:11, 114:9 said 13:18, 18:2, 27:7, 50:15, 51:11, 70:22, 71:11, 89:18, 90:8, 94:14, 95:15, 99:12, 102:18, 106:12	sale 22:17 sales 10:20, 11:5, 11:10, 12:19, 16:6, 20:1, 20:13, 22:11, 22:14, 24:4, 24:14, 24:20, 25:10, 26:15, 27:16, 52:3, 52:17, 67:10, 67:13, 94:6, 94:14, 109:15 same 7:9, 8:10, 15:5, 21:5, 21:16, 21:18, 21:20, 21:22, 22:2, 22:5, 22:6, 24:22, 28:21, 29:5, 29:12, 29:17, 30:5, 39:14, 45:6, 45:10, 45:14, 45:18, 45:22, 46:1, 46:14, 51:6, 54:5, 54:16, 54:20, 54:21, 55:6, 55:7, 56:9, 61:3, 61:6, 66:5, 66:17, 69:13, 69:19, 74:14, 76:9, 77:10, 78:12, 85:2, 85:3, 85:7, 89:15, 93:16, 109:5, 114:4, 114:13, 119:5 satisfaction 62:4 sawyer 3:7, 5:4, 6:6, 13:3, 13:13, 13:19, 16:10, 18:7, 18:17,
---	--	--	---

19:15, 20:4, 20:21, 21:11, 21:19, 23:12, 30:19, 34:20, 35:16, 37:4, 42:19, 48:14, 50:14, 52:19, 53:3, 53:4, 56:19, 58:7, 61:4, 64:16, 69:20, 70:3, 71:10, 72:15, 73:12, 74:2, 75:1, 75:14, 77:4, 77:15, 79:21, 81:8, 82:13, 86:5, 87:3, 87:15, 89:12, 91:14, 93:1, 94:17, 95:2, 95:18, 101:17, 102:10, 103:8, 104:3, 104:19, 105:13, 106:5, 106:15, 107:3, 107:20, 108:4, 108:5, 108:18, 110:21, 111:20, 112:21, 113:13, 114:17, 116:12, 116:15, 117:1, 117:6, 117:18, 118:1, 120:14 say 10:16, 16:21, 31:11, 44:10, 46:1, 46:15, 47:9, 48:1, 49:17, 51:21, 54:21, 55:7, 58:14, 64:22, 73:10, 94:8, 96:20, 97:5, 98:10, 98:13, 100:1 saying 99:16, 105:15	says 71:17 science 5:10, 70:6, 71:6 scope 17:11, 34:11, 35:8, 39:22, 64:4, 65:12, 65:14, 66:8, 74:8, 77:3, 77:20, 81:7, 89:6, 101:12, 107:9, 109:8, 110:15, 110:20, 112:3 se 1:4, 3:2, 99:2, 99:15 second 73:2 secondary 98:3 see 27:10, 27:13, 31:9, 34:2, 53:15, 62:1, 71:16, 71:21, 72:8, 72:18, 72:22, 73:4, 73:7, 74:21, 82:21, 94:3, 99:16 seeing 75:10 seek 19:22, 25:14 seeking 19:8, 90:16 seems 17:8, 118:6 seen 47:14, 47:16, 59:10, 70:8, 70:10, 70:11, 70:15, 70:22, 71:12 select 83:21	self-amplifying 37:13, 65:15 sell 52:13 senior 6:21 sense 12:11, 16:2, 33:9, 86:21 sensible 118:6 sentence 27:4, 53:9 separable 78:4, 78:8, 78:11, 78:18, 79:3, 79:6, 79:13, 80:15, 80:16, 80:18, 81:1, 81:9 separate 76:4, 80:3, 93:9 separated 75:22, 76:8, 80:5 separately 79:9, 79:10 separation 76:10 set 40:18, 120:8, 121:10 setting 98:17 several 20:16, 28:19, 39:21, 40:17 sheet 119:8 short 73:11 shorthand 2:3, 120:1, 121:15 shortly 42:3 should 32:19	shouldn't 97:18 show 19:10, 103:11 shown 71:5, 100:14 shows 51:19 signature 13:8, 13:9, 119:13 signature-b7fzp 121:13 signed 119:8 significance 10:13, 59:4 significant 82:7 similar 61:2, 61:19, 63:6, 68:3, 70:10, 70:15, 70:22, 71:12, 98:16 simply 44:1, 77:3, 97:10 since 47:16 single 71:19, 88:12, 88:16, 88:17, 88:19 sir 6:8, 9:3, 10:3, 14:15, 30:21, 31:2, 31:10, 31:16, 53:7, 53:16, 76:16, 82:15, 82:18, 82:22, 83:9, 94:4, 99:18 sit 43:5, 43:22, 83:15, 95:22, 98:12 sitting 7:16, 94:12,
--	---	--	--

98:5, 98:7, 98:14, 108:21 situation 84:19, 98:16 slide 71:13, 71:14, 71:17, 72:16 slight 97:2, 97:17 slower 55:20, 56:6 small 40:21 smartphone 74:12, 78:5 sold 79:9, 81:13 sole 44:21, 45:4, 45:8, 45:12, 45:16, 45:20, 87:18, 88:3 solely 31:6, 31:13, 35:5, 47:12, 56:21, 92:4, 103:12 solutions 23:20 some 15:13, 17:21, 24:13, 32:8, 35:7, 43:22, 56:2, 61:14, 79:17, 80:16, 82:7, 91:18, 94:1, 95:19, 97:17, 99:3, 99:21, 116:8, 117:16 something 27:12, 35:3, 43:1, 52:5, 60:17, 70:13, 74:11, 83:8, 92:11, 92:12, 99:4, 109:7 somewhat 86:9	sooner 11:4, 16:18 sorry 13:20, 40:9, 97:3, 98:6, 108:1 sort 17:21, 28:17, 53:9, 72:3, 72:4, 72:19, 72:21, 86:7, 88:5 sought 46:22, 91:18 sounds 17:19, 33:13, 43:14, 111:16, 113:3 sources 83:6 south 3:4 span 29:7 spanned 73:22 speak 26:21 speaking 9:9, 10:9, 15:1, 16:14, 19:12, 30:3, 40:5, 46:9, 62:15, 69:6, 80:21, 81:18, 93:13 speaks 48:20, 55:2, 95:11 specific 7:2, 8:3, 9:7, 19:9, 20:2, 22:7, 26:18, 35:15, 41:7, 46:8, 50:3, 56:1, 56:17, 60:18, 68:8, 88:11, 99:7	specifically 10:8, 13:1, 24:2, 24:11, 24:19, 25:1, 25:12, 25:17, 26:16, 29:22, 40:12, 43:8, 43:21, 46:21, 47:14, 47:16, 51:13, 53:9, 59:13, 67:2, 100:7, 100:8, 104:1, 104:12, 111:17, 113:5, 115:5, 115:12 specificity 95:14 specifics 99:4, 99:22 speculate 94:12, 108:22, 111:19 speculating 43:13, 47:9, 57:11 sped 60:8, 60:10, 60:12 speed 10:21, 11:1, 12:19, 26:12, 56:11, 56:20, 57:4, 57:16, 57:19, 58:10, 58:16, 58:20, 92:20, 110:9, 112:11 spell 6:14 spend 43:5 spent 9:5, 9:11 spike 36:8, 36:16, 113:2 spikevax 22:11, 28:14,	29:3, 29:11, 29:16, 29:20, 30:8, 37:21, 38:21, 44:21, 45:8, 45:17, 46:13, 47:7, 53:12, 53:19, 54:3, 54:8, 54:14, 54:18, 55:4, 55:14, 55:21, 56:7, 56:12, 56:21, 57:5, 57:9, 58:21, 60:9, 60:20, 61:7, 62:20, 65:19, 73:14, 74:3, 76:15, 77:5, 78:8, 85:2, 85:5, 85:9, 87:16, 88:21, 94:7, 100:11, 100:20, 101:8, 102:14, 104:6, 105:1, 105:16, 107:15, 110:2, 114:2, 114:20, 115:4 spoke 41:9, 42:8 st 86:8 stage 40:3, 40:11 stamp 70:12 standard 17:21, 35:8, 103:17 standards 85:17, 103:14 stands 101:5 start 43:6 started 8:22, 97:7 startup 8:19
--	---	--	--

state 2:5, 4:3, 6:14, 33:21, 53:10, 120:5, 121:18 stated 72:2 statement 18:12, 18:13, 31:4 statements 54:10 states 1:1, 23:14, 52:14, 91:8 stayed 116:10 stenographer 94:18, 94:22, 113:12, 116:17, 116:21 stenographically 2:2 sterol 73:3 stevens 3:9, 120:14 still 12:19, 12:20, 49:22, 51:5, 81:12 stimulate 48:21 stockpile 90:9, 90:19 strain 74:15 strategy 90:7, 90:18 street 2:6, 4:3 strike 15:17, 25:7, 36:12, 40:9, 64:8, 100:7, 110:6 strong 32:10, 49:3 stronger 32:8	studied 37:22, 66:13, 89:3, 106:12, 106:20, 111:17 studies 92:4 study 105:5 stuff 117:17 subject 25:5 submitted 14:4 subsidized 92:5 substituting 21:17, 21:21 succeeded 48:12 successful 24:1, 48:6, 61:16, 80:9, 80:12, 80:14, 81:14, 100:17 suggest 60:4, 83:12 suite 3:4 sum 75:17, 75:19 summer 3:9, 120:14 summerstevens@pa- ulhastings 3:10 superior 53:11 supplement 79:2 suppliers 90:13, 90:17, 91:2 support 9:6, 98:9 suppose 65:21 sure 6:9, 16:1,	23:7, 24:17, 27:22, 38:15, 52:21, 68:2, 93:11, 116:14 surplus 91:19 surprise 62:6 surprising 15:2, 15:7 surrounding 48:4, 48:16 suspect 98:21, 99:5 sw 3:14 sworn 6:1, 6:4, 120:9 syringe 100:5 system 71:18 T table 82:19, 100:13 take 23:21, 44:4, 52:19, 57:22, 58:4, 58:19, 93:12, 94:16, 116:12 taken 53:1, 57:10, 94:20, 116:19, 120:10 takings 58:6 talk 32:2, 46:8 talked 41:17, 91:18 talking 16:7, 40:4, 48:2, 80:13, 80:15, 100:2, 100:4 targeting 62:4	targets 91:12 team 7:12, 7:17, 7:19, 8:10, 42:3, 42:7, 42:11 technical 33:4, 36:2, 36:10, 36:20, 38:3, 38:4, 38:10, 38:21, 41:9, 48:17, 53:22, 55:17, 57:18, 57:22, 63:18, 64:4, 64:10, 69:9, 69:13, 76:1, 76:10, 78:14, 102:19, 110:9, 110:14, 112:11, 112:17, 113:19, 114:9, 114:15, 115:13, 115:19 technologies 22:8, 46:5, 46:8, 46:10, 46:12, 46:16, 46:18, 47:1, 47:3, 47:6, 47:9, 47:12, 47:14, 47:18, 47:20, 49:11, 51:3, 51:19, 53:13, 72:22, 73:22, 77:13, 100:9, 100:16, 105:22, 106:2 technology 5:10, 10:11, 15:2, 15:5, 15:7, 19:22, 20:14, 21:9, 32:17, 32:18, 34:10, 39:3, 48:4, 48:16, 48:20, 49:3, 49:6, 49:17,
--	--	---	---

51:1, 70:6, 71:6, 73:16, 73:19, 75:22, 101:1, 103:12, 104:20, 108:20, 109:4, 111:13, 115:3, 115:9, 115:15 tell 15:20, 43:11, 43:21, 70:11, 103:6 temperature 67:5 ten 116:14, 116:15 term 9:13, 61:13, 81:7, 85:21 terms 11:5, 19:3, 86:19, 87:5, 92:20 test 27:3, 102:5 testified 6:4, 96:7, 96:11, 96:15, 97:13, 97:17, 99:6 testimony 5:3, 119:5, 119:7, 120:11 th 5:11, 13:10, 70:7, 121:11 thank 14:1, 70:21, 82:1, 117:7 theoretical 80:10 theoretically 49:16 therefore 17:16, 87:1, 100:10, 101:8, 110:7, 112:9, 114:7	thereto 67:5 thick 65:3 thing 106:2 things 10:20, 27:10, 44:13, 47:10, 49:15, 49:16 think 12:5, 13:1, 13:17, 13:21, 16:11, 16:20, 18:3, 18:6, 18:22, 19:7, 23:18, 23:19, 27:9, 28:16, 42:22, 50:2, 65:1, 65:18, 66:2, 74:1, 78:20, 79:7, 79:19, 81:12, 84:14, 86:20, 87:6, 87:11, 89:5, 89:9, 89:17, 91:3, 91:10, 100:4, 109:16, 117:14, 117:15, 117:20, 118:3 third 73:2, 79:9, 79:12, 80:17, 102:6, 104:14 third-party 44:11 thought 67:18, 97:7, 98:14, 117:17 three 72:3, 72:12 threshold 11:12, 31:22, 32:18, 62:10 through 42:2, 87:7, 90:12, 94:11,	94:15 throwing 82:5 tied 35:18, 35:21, 81:16, 81:17, 84:15 time 17:6, 17:14, 18:6, 19:4, 20:1, 25:20, 27:7, 56:3, 61:3, 61:7, 61:19, 63:1, 63:6, 83:14, 85:3, 85:7, 86:15, 89:3, 90:1, 96:4, 114:9, 118:7 timelines 53:12 timely 29:8, 49:5 times 14:3, 41:14, 95:13 timing 53:19, 54:3 title 71:16 titled 71:5 today 41:14, 98:5, 98:7, 98:13, 100:14 together 43:12, 71:2, 83:3 tom 4:11, 7:16, 7:19, 8:13 tomo 2:6, 4:11, 6:19, 7:13, 8:17, 9:20, 120:22 took 42:20	top 73:1 total 75:17, 75:20 track 9:4, 9:7, 9:10, 9:15 trademark 1:1 traditional 88:5, 95:9 transcription 119:6 transitioned 92:6 transparent 9:14 transport 66:22 transportation 69:17 travel 91:8 trial 1:2, 96:7, 96:11, 96:15 trier 12:7 true 18:22, 22:15, 23:11, 23:18, 41:16, 59:22, 61:9, 79:19, 84:9, 85:11, 89:22, 93:5, 109:12, 109:16, 111:8, 119:5, 120:11 try 50:3 trying 17:15, 46:9, 46:15, 48:8, 80:2, 97:10 turn 14:13, 53:5, 82:16 two 36:2, 48:6,
--	--	--	---

58:15, 68:12, 88:20, 101:5, 103:16, 104:17, 105:7, 106:4, 114:13, 115:6 two-minute 94:16 types 93:16 typical 60:7 typically 7:7, 10:14, 92:11 tyrus 4:10	14:19, 15:11, 17:2, 28:1, 32:14, 33:6, 34:13, 34:21, 35:20, 36:4, 36:6, 36:21, 37:7, 40:5, 42:2, 42:4, 48:19, 49:6, 57:17, 58:15, 58:17, 62:14, 63:12, 63:20, 64:6, 64:9, 67:21, 68:10, 73:13, 78:7, 85:15, 86:6, 90:6, 92:17, 99:8, 100:18, 109:9, 109:13, 111:3, 111:12, 111:21, 112:16, 112:22 undertake 93:5 undertaken 92:4 unique 24:11, 26:2, 28:21, 35:19, 35:21, 36:5, 48:4, 48:15, 51:20, 51:21, 51:22, 88:8 uniquely 89:4 united 1:1, 23:14, 52:14, 91:8 university 108:12 unknown 15:3 unless 16:6, 79:1 unmodified 37:11, 65:10 unnamed 46:22, 47:8,	47:10 unpatented 115:3, 115:9 unquote 107:18 unrelated 106:9 unsuccessful 61:8, 61:11, 61:12, 61:13 until 8:18 use 15:6, 23:4, 39:2, 52:7, 60:6 uses 9:13, 111:22 using 15:4, 50:11, 84:5 usually 16:9, 16:12	87:14, 87:19, 88:4, 89:8, 89:20, 90:10, 92:10, 93:3, 93:4, 112:1, 116:2, 116:10 vaccines 23:4, 23:17, 23:22, 24:15, 24:20, 25:19, 26:4, 27:16, 29:7, 29:8, 29:10, 30:3, 40:13, 46:19, 46:20, 60:19, 61:1, 61:6, 61:8, 61:21, 62:7, 62:15, 62:19, 63:22, 65:10, 72:4, 75:21, 81:2, 82:19, 83:11, 83:13, 84:1, 86:14, 88:18, 90:3, 90:8, 91:21, 92:19, 100:15 vacuum 47:22 vague 98:21, 99:12 validity 19:14 value 84:7, 84:11, 84:13 variety 10:19, 83:6 various 12:2 vaxzevria 61:12 versus 25:4, 26:5, 32:9, 44:2, 52:1, 68:9, 68:11, 93:15, 98:1, 103:3,
U		V	
ultimately 12:22, 16:22, 20:15, 51:9, 76:1 unbranded 29:19, 30:1 undefined 47:1, 86:19, 105:21, 106:1 under 34:1, 77:12, 96:17, 109:10, 109:14 understand 11:19, 25:13, 27:5, 28:7, 33:18, 38:15, 38:16, 53:10, 53:22, 59:9, 68:2, 73:20, 75:20, 76:12, 76:17, 77:19, 81:5, 88:13, 93:11, 98:2, 100:21, 101:21, 102:4, 103:10, 105:6, 106:21, 108:9 understanding 10:4, 11:11,			

103:20, 104:7 viable 28:21 view 51:15, 61:16, 69:9, 73:18, 74:9, 74:17, 74:18, 75:8, 75:16, 76:10, 77:12, 82:9 viewed 19:4, 51:16, 81:1 viral 37:2, 48:22 vis-à-vis 10:14, 30:17, 49:5, 104:17, 105:21, 110:10, 112:12, 114:10 vouchers 84:13	we've 8:5, 28:18, 84:13, 113:18 weaker 32:10 weighted 104:11 weighting 102:20, 103:2, 103:20 weismann 108:11 welcome 95:3 went 100:16 weren't 18:20, 80:13 west 2:6, 120:22 when's 96:4 wherein 79:8 whereof 121:10 whereupon 53:1, 94:20, 116:19 whether 10:11, 15:20, 17:9, 32:21, 33:2, 33:5, 34:17, 34:21, 37:10, 37:15, 38:21, 43:22, 47:18, 49:10, 65:15, 69:1, 80:8, 81:12, 92:4, 95:15, 97:16, 98:16, 104:4, 104:22, 106:17, 107:13, 107:18, 109:2, 110:8, 112:10, 114:8, 115:3, 115:8 whole 43:4	widespread 87:2 williams 3:13, 120:16 wilmer 4:2, 120:18 within 9:3, 12:1, 14:22, 17:12, 19:9, 23:20, 25:13, 26:19, 27:4, 29:1, 34:11, 35:4, 35:22, 39:3, 40:6, 41:4, 46:4, 46:10, 48:3, 57:19, 59:13, 60:15, 61:2, 61:22, 62:2, 62:22, 67:1, 69:15, 71:19, 75:10, 83:14, 85:6, 85:10, 95:9, 101:22, 102:1, 102:21, 103:14, 105:7, 106:3, 106:22, 110:19, 120:5 without 37:1, 42:17, 48:22, 78:21, 108:22 witness 6:1, 6:3, 13:17, 16:1, 17:19, 18:12, 19:7, 19:20, 20:10, 21:5, 21:16, 23:7, 30:11, 34:16, 35:11, 36:20, 42:18, 47:22, 50:11, 56:14, 58:3, 61:1, 64:13, 71:4, 72:11, 73:7, 73:18, 74:17,	75:7, 76:22, 77:9, 79:15, 80:20, 82:5, 85:20, 86:18, 87:11, 89:2, 90:22, 92:15, 94:10, 95:7, 101:11, 101:21, 103:5, 104:1, 104:9, 105:4, 105:19, 106:11, 106:20, 107:17, 108:15, 110:12, 111:16, 112:14, 114:12, 116:6, 117:7, 120:7, 120:12, 121:10 wondering 97:6 word 82:6 worded 58:13 work 7:12, 7:22, 8:5, 8:10, 8:19, 8:21, 9:8, 33:7, 34:19, 39:22, 41:4, 42:2, 47:3, 76:12, 78:21, 84:11, 85:4, 89:6, 108:10, 111:18, 113:3, 113:5, 113:21, 114:16 worked 7:17, 18:20 working 10:1 works 79:5 world 22:22, 23:15, 24:8, 25:1, 91:6 worldwide 52:1, 86:7, 86:16 wouldn't 73:18, 74:17,
W			
wacker 3:4 want 6:9, 27:13, 30:22, 94:12, 108:22, 111:18 wanted 68:2, 117:21 washington 3:15 way 15:2, 33:15, 35:17, 47:18, 49:5, 49:9, 57:7, 93:18, 95:15, 101:18, 104:21, 106:16, 107:13, 121:7 we'll 118:4 we're 48:2, 80:21, 87:7, 94:18, 117:21			

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Transcript of James E. Malackowski

Conducted on July 22, 2024

60

94:11, 108:22 wrapped 36:9, 36:17 writing 9:12, 9:14	02109 4:4 07 53:2 084 2:3	110:10, 112:7, 112:12, 113:10, 113:17, 114:3, 114:10, 114:21, 115:11, 115:18, 116:3, 117:3	22:21, 23:2, 63:3, 86:8, 86:15, 87:17
Y	1	13 5:8 135 71:14 150 42:22 16 71:13, 71:14 17 5:11, 53:8, 70:7 19 23:5, 23:17, 24:15, 24:20, 40:13, 60:19, 61:5, 61:21, 62:19, 72:16, 73:14, 86:14, 93:20, 93:22, 94:21, 95:1	2021 22:12, 22:18, 22:21, 23:2, 23:3, 25:9, 63:2, 63:3, 86:15, 87:18, 89:14, 89:21, 94:8, 94:15 2022 5:11, 70:7 2023 1:14, 1:18, 94:8, 94:11, 94:15 2024 1:27, 2:8, 13:10, 121:1, 121:11 22 1:27, 2:8, 121:1 24 121:11 29 13:10
yeah 50:19, 57:21, 99:10, 108:4, 116:15, 117:11 year 20:18, 20:19, 20:20, 21:17, 21:21, 22:7, 22:15, 88:20, 96:8 year-by-year 21:6 years 20:16, 88:20	10 53:2, 94:19, 94:21 10,702,600 1:15 10,898,574 100:19 10,933,127 1:20 100 89:13 11 31:1, 31:3, 94:21, 95:1, 116:18, 116:20, 116:22, 118:7, 121:2 12 7:3, 32:2, 33:19, 33:21 127 19:17, 20:7, 21:1, 21:13, 22:4, 30:9, 39:1, 45:7, 45:11, 45:16, 45:20, 53:14, 53:18, 54:2, 54:14, 55:5, 55:14, 56:8, 56:22, 58:9, 63:9, 67:17, 68:3, 68:5, 68:16, 69:3, 69:10, 69:16, 75:3, 85:14, 93:10, 102:12, 103:2, 103:20, 104:7, 106:9, 109:20, 110:3,	2 20 93:21, 93:22, 121:11 200 2:6, 120:22 20024 3:15 2015 19:18, 20:7, 21:2 2016 21:14 2017 21:21 2018 22:5 202.434 3:16 2020 22:12, 22:18,	22 1:27, 2:8, 121:1 24 121:11 29 13:10 3 31 86:8 312.499 3:6 4 42 116:18, 116:20 4500 3:4 5 50 62:5 51 116:20, 116:22, 118:7, 121:2 52 53:2
Z			
zero 97:13			
\$			
\$1,300 7:4			
.			
.5000 3:16 .6000 3:6, 4:5			
0			
002871 2:3 008271 121:17 0084 121:17 01 2:7, 121:2 01358 1:14 01359 1:18			

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61

546210 1:32 57 94:19, 94:21 574 101:7, 103:3, 103:21, 104:5, 104:22, 105:6, 105:14, 106:17, 107:5, 107:8, 107:13, 109:3 6 60 4:3 600 19:17, 20:7, 21:1, 21:13, 22:4, 30:8, 39:1, 44:20, 45:3, 45:16, 45:20, 53:14, 53:18, 54:2, 54:8, 54:19, 55:22, 56:22, 58:9, 63:13, 63:17, 64:1, 64:11, 64:17, 65:10, 65:16, 65:20, 66:4, 66:9, 66:14, 66:20, 68:1, 68:6, 68:18, 68:20, 75:3, 85:14, 93:10, 102:12, 103:2, 103:20, 104:7, 106:9, 109:20, 110:3, 110:10, 112:7, 112:12, 113:10, 113:17, 114:3, 114:10, 114:21, 115:11, 115:17, 116:3, 117:3 60606 3:5 617.526 4:5	680 3:14 7 70 5:10 71 3:4 9 9 2:7, 53:2, 121:2 90 62:7	
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BioNTech-Pfizer Exhibit 1157

BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Page 62 of 65



Annaleigh Curtis, Esquire
Wilmer Cutler Pickering Hale and Dorr LLP (Boston)
60 State Street
Boston, MA 02109

Re: Deposition of **James E. Malackowski**

Date: 7/22/2024

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

Dear Sir/Madam,

Attached please find the above-referenced deposition transcript. If applicable, signature is required within 30 days from the date of receipt of this letter.

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

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ACKNOWLEDGMENT OF DEPONENT

I, James E. Malackowski, 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.

8/27/2024

(Date)



(Signature)