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

BIONTECH SE AND PFIZER INC.
Petitioners
v.
MODERNATX, INC.
Patent Owner

Case IPR2023-01358
Patent No. 10,702,600

Case IPR2023-01359
Patent No. 10,933,127

** CONFIDENTIAL **

DEPOSITION OF
JAMES E. MALACKOWSKI
July 22, 2024
Chicago, Illinois

Reported by:
Janice M. Kocek, CSR, CLR
Job No. 546210

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The deposition of JAMES E. MALACKOWSKI, reported stenographically by Janice M. Kocek, License No. 084-002871, Certified Shorthand Reporter, Certified LiveNote Reporter, and Notary Public for the State of Illinois, held at Ocean Tomo, 200 West Madison Street, Chicago, Illinois, commencing at the hour of 9:01 a.m. CST, on the 22nd day of July, 2024.

* * *

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(Witness sworn.)

JAMES E. MALACKOWSKI,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. SAWYER:

Q. Good morning, Mr. Malackowski.

A. Good morning, sir.

Q. I want to make sure I'm pronouncing your name correctly.

Is it Malackowski? Is that correct?

A. Perfect.

Q. Great.

Can you state your full name, spell your last name for the record?

A. James Edward Malackowski, M-a-l-a-c-k-o-w-s-k-i.

Q. And who is your current employer?

A. Ocean Tomo, a part of J.S. Held.

Q. And what's your current position?

A. Senior managing director.

Q. And what was your hourly rate paid for this engagement?

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A. Not recalling the specific rate because it's changed recently. It's approximately 12- or $1,300 an hour.

Q. And would you characterize the rate you're charging in this particular case commensurate with what you typically charge other clients?

A. Yes. I charge the same rate for all matters for all clients.

Q. And as part of your engagement in this PTAB action, did you work with a team at Ocean Tomo?

A. I did.

I note we did not announce appearances for the record. But Tom, who's sitting here, is on my team. And I also worked with Robert McSorley.

Q. Anyone else on your team besides Tom and Robert?

A. Not to any meaningful degree.

Q. When were you first retained to work on this particular report, the declaration of James Malackowski, for the PTAB proceeding?

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A. I don't recall a specific engagement date for that proceeding as distinct from the other work that we've done in the district court litigation. But the focus of the report would have been in the month prior to its issuance.

Q. And you mentioned your engagement with the district court litigation.

Did you work with the same team for the district court litigation as you did with the PTAB declaration?

A. In addition to Tom and Robert, Liam Howe also was involved in the district court action.

Q. And is Liam Howell also a employee of Ocean Tomo?

A. He was until quite recently. He's now left to go work for a startup.

Q. You mentioned that you believe most of -- or at least the beginning of your work on the declaration for the PTAB action started about a

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month previous to the issuance of the report; is that correct?

A. Within that month, yes, sir.

Q. And did you track how many hours you personally spent on the declaration of James Malackowski to support the PTAB action?

A. I don't track it specific to that declaration from other work that I've done for counsel for Moderna. But generally speaking, would track my hours for Moderna.

Q. Do you recall how many hours you spent writing the declaration for this IPR proceeding?

A. No. Your question uses the term "writing." So to be transparent, consistent with my track practice, most of the keys, the keyboard, would have been Mr. McSorley, who's a managing director on engagement in consultation and at my direction.

Q. And Mr. McSorley, what's his position at Ocean Tomo?

A. He is a managing director and has been so for more than a decade.

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Q. And he's also working on the district court litigation?

A. Yes, sir.

Q. And what's your understanding of the analytical framework for determining commercial success?

A. Well, that's a very general question. I would direct to you my declaration specifically. But generally speaking, it's looking to the performance of the product that is found to embody the technology, whether that be of the patent owner, the infringer, or otherwise. And to look to the significance of the intellectual property at issue, vis-à-vis that product, typically referred to as the nexus.

Q. And when you say "performance," what are you referring to?

A. Again, defer to my declaration because it's described. But it can include a variety of things from level of sales, level of profitability, speed to market. I believe all those are relevant here.

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Q. And how is speed to market related to commercial success?

A. An ability to meet to market needs sooner rather than later has both direct benefits in terms of sales and profits, obviously. But it also has indirect benefits as far as competitive positioning, generally referred to as a first mover advantage, for example.

Q. And is there a particular amount of sales that's indicative of commercial success?

A. To my understanding, there is no quantitative threshold required by the courts. That it's contextual given the particular facts and circumstances of the case.

Q. Would you characterize commercial success as binary, either there is commercial success or there is not commercial success?

A. In the end, I believe the conclusion, as I understand it, that's important for the Court is a binary conclusion.

From a business perspective, we also do consider relative success among products. I

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believe that's also addressed within my report.

Q. So there's various levels of commercial success?

A. Well, we need to be careful as to how we think about that. From a legal perspective -- and I'm not a lawyer. I'm not offering legal opinions -- I believe it is binary. The trier of fact will find there is commercial success or there is not.

From a business perspective, you can consider relative commercial success in the sense you can compare one product, for example, and its success to another product and its success.

Q. What if there's only one product on the market? How would you determine commercial success?

A. I don't believe one product would change the analysis, in part because you would still look to sales, profits, speed to market. You could also still consider relative success in that there may be other products that attempted to come to market, but ultimately failed. And

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specifically, I think that's also addressed in my declaration.

MR. SAWYER: I'm going to mark for the record Malackowski PTAB Exhibit 1.

And for the record, Malackowski PTAB Exhibit 1 is entitled Declaration of James E. Malackowski and there's a signature page on the back with Mr. Malackowski's signature and the date is May 29th, 2024.

(Malackowski PTAB Deposition Exhibit 1 was marked for identification.)

BY MR SAWYER:

Q. Mr. Malackowski, do you have that deposition, PTAB Exhibit 1, in front of you?

MS. CURTIS: Object to form.

THE WITNESS: I think you misspoke and said "deposition."

BY MR. SAWYER:

Q. Sorry.

A. I think you mean exhibit.

But yes, I do have Exhibit 1.

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Q. Thank you.

And we have referred to a couple of times, and you've referred me, as well, to a declaration that you submitted in this particular PTAB proceeding.

Is this the declaration you are referring to?

A. It is.

And I would just note for the record that I refer to it as a declaration or my report. But in both cases, I was referring to this exhibit.

Q. Mr. Malackowski, turn to paragraph 8 in your report.

A. Yes, sir.

Q. And I'll just generally refer you to that.

But my question is: What is your understanding of why commercial success is an objective indicia of nonobviousness?

A. Well, I believe that may also be explained within the exhibit. But generally

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speaking, it is evidence of the benefits of the technology in a way that may have been surprising or otherwise unknown to competitors in the market because there was not success by them using the same technology previously.

Q. Isn't the use or the benefits of a technology being surprising a different objective indicia of nonobviousness?

A. It may relate to other legal indicia. But as it relates to commercial success, my understanding is, as I provided to you, that commercial success of a product demonstrates new and novel introductions to the mark in some form or fashion.

Q. You'd agree with me that economic incentives to develop a product that practices the alleged invention -- strike that.

Can you explain to me how economic incentives to develop a product that practices the alleged invention tell us anything about whether the alleged invention was obvious?

MS. CURTIS: Object to form.

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THE WITNESS: I'm not sure that it does in the sense your question describes it. In every case there will be economic incentives to develop a product, to provide a return on the investment, to capture sales, to capture profitability. Unless you're talking about, you know, pure research for academic purposes, there's usually a business incentive behind it.

BY MR. SAWYER:

Q. So I think we agree that there are usually economic incentives to develop a product, correct?

A. Generally speaking.

Q. And the reason why commercial success is an objective indicia of nonobviousness is because the law presumes that an idea would have been brought to market sooner in response to those market forces had the idea been obvious, right?

A. I think generally that is what I attempted to say a few moments ago. But ultimately, that is a legal determination, and I'm

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not providing a legal opinion. But that's consistent with my understanding.

Q. So for commercial success to be relevant to the obviousness analysis, market forces to produce a product embodying the invention must necessarily be present at the time of the invention, right?

A. I don't have that opinion. That seems more like a legal opinion as to whether or not commercial success can be found by the courts, or in this case the PTAB, and outside the scope of presenting the analysis within my declaration.

Q. But if there's no demand for a product at a particular time, then there's no real market incentive for others to be trying to develop that particular invention, and therefore there's no objective indicia of nonobviousness, right?

MS. CURTIS: Object to form.

THE WITNESS: That, again, sounds like you're attempting to force a legal standard of some sort into my analysis and opinions, which I'm not providing a legal

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opinion.

That said, I disagree with the premise. I think that there can be commercial reasons to develop products in anticipation of believed or likely future demand. I think that happens all the time.

BY MR. SAWYER:

Q. That may be. But that isn't the proper analytical framework to judge commercial success for that -- for that particular product?

MS. CURTIS: Object to form.

THE WITNESS: That was a statement, not a question. And the statement appeared to be legal in nature, drawing -- asking for a legal opinion. And I'm not providing a legal opinion.

BY MR. SAWYER:

Q. So in your analytical framework to develop -- to determine commercial success in this particular project that you worked on, you weren't evaluating demand?

A. I think that's not true. I think in my

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report, I do evaluate demand for the patented products, and I cite the results of that demand in terms of a number of indicators.

Q. And that demand is viewed at the time of the invention, right?

MS. CURTIS: Object to form.

THE WITNESS: I think the -- that is also seeking a legal conclusion. I don't deal with that specific issue within my declaration. I show demand for the product and the resultant success of that product. I'm not speaking to the chronology that may or may not have an issue with respect to the validity of these patents.

BY MR. SAWYER:

Q. So your declaration doesn't disclose an opinion for demand of either the '600 or the '127 patents in 2015, right?

MS. CURTIS: Object to form.

THE WITNESS: My opinion describes the historical development of this technology but doesn't seek to quantify

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sales and profits as of that time, again, given specific facts, circumstances of this product in this marketplace.

BY MR. SAWYER:

Q. So your declaration doesn't disclose -- does not disclose an opinion as to the commercial success of the '600 or '127 patent in 2015, correct?

MS. CURTIS: Object to form.

THE WITNESS: My declaration considers the commercial success of these patents during their lifetime, including the sales and profits that resulted. It discusses the development of the technology that ultimately became the patents, which dates back several years prior.

But I don't present a chronology by year or an opinion by year of commercial success this year, not the prior year, or not the following year, for example.

BY MR. SAWYER:

Q. So your declaration does not disclose

BioNTech-Pfizer Exhibit 1157
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an opinion that the '600 and '127 patents had commercial success in 2015, correct?
MS. CURTIS: Objection. Asked and answered.
THE WITNESS: Same answer. I'm not providing year-by-year analysis. I do provide a conclusion of commercial success based upon the considerations that are in my declaration for this technology covered by these patents.
BY MR. SAWYER:
Q. Your declaration does not disclose an opinion that the '600 and '127 patents had commercial success in 2016, correct?
MS. CURTIS: Objection.
THE WITNESS: That's the same question substituting the year. I would have the same answer.
BY MR. SAWYER:
Q. And if I asked the same question substituting the year of 2017, would your answer be the same?

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A. Yes.
Q. If I asked you the same question, that your declaration does not disclose an opinion that the '600 and '127 patents had commercial success in 2018, would your answer be the same?
A. My answer will be the same for any specific isolated year because my analysis is holistic to the technologies at issue and the resultant commercial success.
Q. Your declaration does disclose that the first sales of at least Moderna's Spikevax was in either 2020 or -- December 2020 or January 2021, correct?
A. It does report the actual sales activity by year, that's true.
Q. And your declaration also does disclose that the first sale of Comirnaty vaccine product was also in December 2020 or January 2021, correct?
A. I believe that's correct.
Q. And in late 2020 and early 2021, the COVID pandemic was impacting the world, correct?

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A. Fair.
Q. And so in 2021 -- late 2020, and early 2021, there were many market forces impacting the use and development of vaccines to combat COVID-19, correct?
MS. CURTIS: Object to form.
THE WITNESS: I'm not sure what you mean by "many market forces."
Obviously, there was efforts to produce a vaccine to address the pandemic. That is true.
BY MR. SAWYER:
Q. And one such effort would be the impact of at least the United States government and other governments around the world investing hundreds of millions of dollars, if not billions of dollars in developing vaccines for COVID-19, correct?
A. I think factually, that is true. I think that the efforts were across a number of solutions. As I describe within my report, one of the considerations that I do take into account is that the patented vaccines were, in fact, the ones

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that were most successful and first successful.
Q. Your declaration did not specifically evaluate the impact of the government investment in the amount of sales that -- that may have increased or decreased if that was not present, correct?
A. I did not conduct an analysis of a hypothetical world in which there was not government investment, though, again, I do consider the fact of that and other general market forces, specifically with respect to the unique performance of the patented products.
Q. And the other -- some other general market forces impacting the development and sales of vaccines for COVID-19 was the existence of very large government contracts, correct?
A. Sure. Yes.
Q. And your declaration did not -- did not specifically evaluate the impact on the development and sales of COVID-19 vaccines in the absence of those large government contracts?
A. Same answer as before. I have not

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specifically identified a hypothetical world where those contracts did not exist, though I did consider the relative performance of the patented products versus others that, in my opinion, would have also be subject to government contracts if they had performed equally well.

Q. Do you know what other -- strike that.

Other market forces that were in existence in the early 2021 are -- were guaranteed sales of by purchasing government agencies that exceeded the actual demand; is that right?

A. I don't specifically focus on that issue within my report. But I do understand that the government did seek to purchase a large quantity that would exceed expected demand.

Q. And so your declaration did not specifically evaluate the impact of that purchasing of excess demand on the impact on commercial success for particular vaccines available at that time?

A. I disagree and would refer you back to our prior discussion, that for each of these

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market forces, although I have not conducted unique hypothetical analysis in which a given consideration was not present, I have considered the relative performance of the patented vaccines versus the alternatives that made it to market, as well as the many alternatives that did not in reaching my conclusion of commercial success.

Q. Is that analysis in your report?

A. I believe so. I believe there's discussion of the failure of others, the number of candidates that were originally advanced by the parties in this case, the speed to market, the efficacy. I believe that's all addressed.

Q. Okay. But the -- the market factor -- the market force of guaranteed sales of amounts of vaccine above actual demand is not specifically addressed in your report?

A. I don't recall that that specific consideration is called out within my report. But I certainly believe that the analysis put forth in the report would speak to that.

But, of course, in all these questions

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when you ask me what is and isn't in my report, let's just make clear, I defer to the context of the report. I know it's not a memory test as to each sentence within it.

Q. Okay. And I understand that. And you're obviously free to look at your report any time. And if I have not said that already, please do.

I think one of my questions is I don't see these things in your report, and so it's very difficult for me to point you to your report to point out something that's not in it. But if we see it during questions and you want to point it out later, please do.

Another market force impacting the sales and development of COVID vaccines was the government's requirement for individuals to get vaccinated, correct?

A. Could you explain a little further what you mean by the "government's requirement to get vaccinated"?

Q. Sure.

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Do you have an understanding that during the pandemic to -- for certain government positions, including the military and others, the U.S. government, as being one example, required individuals to be vaccinated to perform their job duties?

A. I do understand that there were certain governmental positions that had as part of their job requirement vaccination. I don't believe there was a general mandate that all citizens must be vaccinated.

Q. Do you agree that the government requirement for certain individuals to be vaccinated impacted demand for Spikevax and Comirnaty?

A. Well, I think as with the other factors that we discussed, any sort of market force, and that would be one, and we've now discussed several, did have an effect on the marketplace.

But importantly, it would have had a unique -- the same effect to any viable candidate, if there -- if there was one. So I considered it

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from a relative perspective within my report.
Q. Do you agree that private requirements for vaccination impacted demand for Spikevax and Comirnaty?
A. Same as before. I believe it would be a factor that would affect the demand for COVID vaccines, but a factor that would span across all effective and timely produced vaccines.
Q. Do you agree that the fact that the vaccines were free to the consumer impacted the demand for Spikevax and Comirnaty?
A. Same answer.
Q. Do you agree that the government officials and government agencies promoting its citizens to be vaccinated impacted demand for Spikevax and Comirnaty?
A. Same answer.
Q. Do you agree that both branded and unbranded advertisements for Comirnaty and Spikevax impacted demand for Spikevax and Comirnaty?
A. I have not specifically analyzed the

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distinction between branded and unbranded advertising. But I would agree that generally speaking, market promotion of vaccines did have an impact on adoption, but, again, would have had the same impact with any available effective vaccine.
Q. So based on that, there are at least a number of other market factors that influence the demand for Spikevax and Comirnaty beyond the '600 and '127 patents?
MS. CURTIS: Object to form.
THE WITNESS: There are always market conditions that affect the demand for a product, in particular, the existence of the pandemic. And so yes, they exist, and yes, I've considered that, in particular as it relates to the performance of the patented products vis-à-vis others in the market.
BY MR. SAWYER:
Q. Can you go back to your report, please?
A. Yes, sir.
Q. And I want to direct you to paragraph

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11.
A. Yes, sir.
Q. So in paragraph 11 -- please feel free to read it -- but you make a statement that (as read): The patentee is not required to demonstrate that its claimed inventions are solely responsible for the market success of the patented product.
Do you see that?
A. Yes, sir.
Q. Okay. And if I didn't say it, that's in demonstrating nexus, you don't have to demonstrate that the claimed invention is solely responsible for the market success of the patented product, correct?
A. Yes, sir.
Q. Okay. How many nonclaim features or aspects of the product may contribute to commercial success in order to conclude that there is no nexus?
A. To my knowledge, there is no quantitative threshold in that regard. That it is

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contextual. I would direct you further to paragraph 12, where I talk about the advice of the federal circuit, and notes that in certain cases, there can be nexus to the extent that the product is the invention disclosed and claimed in the patent.
Q. Is nexus binary, or do you agree that there's -- in some cases there is a stronger nexus to the patented features versus other cases where it's less strong, or weaker?
A. I'm not aware of a gradient of nexus as far as the conclusion of the courts. Obviously, that's a legal question I'm not opining to.
But my understanding in the framework for my analysis was that it's binary, that there is a nexus or there is not. There may be nexus with more than just the technology. But as long as the technology is -- meets that threshold, then it should be considered.
Q. And you didn't do the analysis to determine whether there was nexus?
A. I rely upon Dr. Krause, as described in

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my report.
Q. So you don't have an opinion on whether or not there's nexus?
A. I'm not offering that technical opinion as to whether or not there's nexus or a legal opinion. It is my understanding that there is based upon the work with Dr. Krause.
Q. Can you have nexus in a commercial success sense if there's no issued patent?
A. What would you -- nexus to what?
Q. To an application -- patent application.
A. That sounds like a legal question I'm not opining to.
Q. So you don't have an opinion one way or the other?
A. No. That's a legal question, as I understand it.
Q. You mentioned paragraph 12 of your report, so maybe we can go there.
In paragraphs 12 you state (as read): There is a presumption of -- there can be a

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presumption of nexus under certain circumstances.
Do you see that?
A. Yes.
Q. And are any of your opinions in your report which is exhibit Malackowski PTAB 1 based on a presumption of nexus?
A. No. Because I'm drawing the conclusion that there is nexus. I would defer to you Dr. Krause for his discussion of presumption and the coextensive nature of this technology to these products. But that's not within the scope of my assignment.
Q. So it is your understanding that your report is not relying on any presumption of nexus?
MS. CURTIS: Object to form.
THE WITNESS: My report is relying upon a finding of nexus. Whether that is a finding that includes presumption or not is not relevant to my work or conclusions.
BY MR. SAWYER:
Q. Do you have an understanding of whether Dr. Krause was basing his opinion on nexus, on a

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presumption of nexus?
A. I would defer to Dr. Krause's report. I believe it is something that is considered and discussed within the report, but I don't know that it's relying solely upon such consideration.
Q. So your -- your report, in your opinion, to demonstrate nexus is not based on some other standard, like reasonable commensurate scope of the claims?
MS. CURTIS: Object to form.
THE WITNESS: Again, that is part of the background that may be considered in deriving an opinion of nexus. But I would refer you to Dr. Krause's report to address that specific question.
BY MR. SAWYER:
Q. And you have no opinion one way or the other that commercial success nexus is tied to any unique feature of the alleged patented inventions?
A. Well, I have an understanding that it is tied to the unique feature of these inventions because that's what's described within

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Dr. Krause's report. But the opinion that those two are connected and linked is a technical opinion that he provides.
Q. What is your understanding of the unique patented features?
A. So as a layperson, my understanding that that -- these patents do with a betacoronavirus that has the spike protein above betacoronavirus that's wrapped in an LNP. But for that technical discussion, I would refer you to Dr. Krause.
Q. Do you have an opinion on how -- strike that.
Do you have an opinion on why the patents that relate to a betacoronavirus that has a spike protein after the betacoronavirus is wrapped in an LNP contributes to commercial success?
MS. CURTIS: Object to form.
THE WITNESS: That is a technical question. But it's my understanding that that invention allows for greater

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efficiency of response without creating a viral incident that would cause the recipient to have the disease.
BY MR. SAWYER:
Q. And from your lay perspective, does that relate to modified mRNA?
A. My understanding is that it does. But I'm not offering an opinion in that regard so I would defer to Dr. Krause.
Q. Do you have an opinion as to whether it relates to unmodified mRNA?
A. I do not.
Q. How about self-amplifying mRNA?
A. I don't have an opinion.
Q. Do you have an opinion on whether there's a particular LNP that's required to practice the inventions?
A. I do not.
Q. Do you have any opinion on the -- how different LNPs impact the commercial success of the -- of Comirnaty or Spikevax?
A. I have not studied or put forth an

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opinion in that regard.
Q. Mr. Malackowski, so you're not offering any technical opinions, correct?
A. I'm not offering any technical or legal opinions, correct.
Q. Okay. You're not an expert on mRNA, correct?
A. Correct.
Q. You're not an expert on LNPs, correct?
A. Correct. Certainly not a technical expert.
Q. Okay. And you have no opinions on what the patents actually -- what the patent claims actually cover, correct?
A. I'm not sure I understand the question. I understand that there are others who have described that in great detail. I've reviewed, for example, Dr. Krause's report in that regard. But I'm not offering a claim construction opinion.
Q. And you're also not offering a technical opinion on whether or not Spikevax or Comirnaty are covered by any particular claims of

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the '127 or '600 patent, correct?
A. Correct. I'm assuming that there's use of the technology within those products, but I'm not offering a legal opinion in that regard.
Q. You're not an expert on vaccine development, correct?
A. Correct.
Q. You're not an expert on the FDA approval process?
A. I don't hold myself out as an expert in that regard, no.
Q. You're not an expert on drug development process, correct?
A. Same answer.
Q. You have no expertise on why drug candidates fail in the development process, correct?
A. I'm not offering any opinions in that regard in conjunction with this case. I've had business experience related to those issues and several of the issues you've raised, but that's outside the scope of my work here.

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Q. You have -- you're offering no opinion on how many drug candidates failed during each stage of the drug development process, correct?
A. Are you talking about generally speaking? It is my understanding, and I believe if not within this report, within the materials I cite there is reference to the failure rate at Phase I, Phase II, Phase III, for example.
Q. And where -- sorry. Strike that.
You're not offering an opinion on how many drug candidates fail during each stage of the drug development process specifically as it relates to the COVID-19 development of vaccines, are you?
A. I've not presented that quantitative assessment. I believe there was reference to the fact that there were several candidates that were considered, and obviously I set forth a number that have been approved.
Q. But you're not offering an expert opinion on if that's a big number or small number or how it relates to any other drug development or

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any other vaccine, correct?
A. That's a very general question. So I would defer you to the context of my report as to how that factual data is used within my work. But I am not benchmarking the development here quantitatively against the development of any other specific vaccine or pharmaceutical.
Q. In your report, you didn't disclose that you spoke to anyone to provide any technical opinions; is that right?
A. Correct.
Q. Your report mentions that you read Dr. Krause's declaration, and you've mentioned that a couple of times in your deposition today, correct?
A. Both are true.
Q. But you never actually talked to Dr. Krause to prepare your report?
A. Correct.
Q. When did you first review Dr. Krause's report?
A. I would have received the final report

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of Dr. Krause the day it was produced. I had an understanding of the opinions through my work with my team shortly prior to that.
Q. Is it your understanding that the report that you reviewed was the final report?
A. Yes.
Q. Do you know if anyone on your team physically spoke with Dr. Krause prior to his finalizing the report?
A. I don't.
Q. Do you know if anyone on your team provided input that Dr. Krause included in his report?
MS. CURTIS: And I'll just caution you not to reveal the content of any attorney-client communications. But if you can answer without doing so, go ahead.
THE WITNESS: I don't.
BY MR. SAWYER:
Q. Do you recall how long you took to review the report -- the Krause report?
A. I think it's, like, 150 pages or

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something. So it's a lengthy document. And I reviewed it more than once. I don't have a number of hours for you.
Q. So it was maybe, like, a whole day?
A. I didn't sit down and spend a day, start to finish, on the report. There are certain portions that are more relevant to me. The end of the report specifically deals with the issues that I'm relying upon. I did also find it interesting and helpful background.
I can't tell you, if you put all those chunks together, if it would be more than a day or not. I'd be speculating.
Q. Did you -- it sounds like the answer is no, but I'll just ask it.
Did you review any draft reports of Dr. Krause?
A. I did not.
Q. Did you review any of the materials he relied on?
A. Not specifically. Though I can't tell you as I sit here whether there wasn't some

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overlap. I would have to simply go back and investigate his materials considered list versus my own.
Q. So you can take a look at your report, but it doesn't appear that your report has a materials considered list. It just has footnotes.
Do you -- are the footnotes all the materials that you considered in drafting your report?
A. I would say the footnotes represent all of the third-party materials that I relied upon in drafting my report. There may have been other things that I reviewed as part of the research process, but nothing that was meaningful or material to the conclusions.
Q. So if it's not included in the report, it wasn't material to your opinion, correct?
A. It was not a material basis for my opinion, correct.
Q. You don't contend that the '600 patent creates the sole basis for demand for Spikevax; do you?

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A. That is not an opinion presented in my report.
Q. You don't contend that the '600 patent creates a sole basis for the demand for Comirnaty, correct?
A. Same answer.
Q. You don't contend that the '127 patent creates the sole basis for demand for Spikevax, correct?
A. Same answer.
Q. You don't contend that the '127 patent creates the sole basis for demand for Comirnaty, correct?
A. Same answer.
Q. You don't contend that the combination of the '127 and '600 patents create the sole basis for the demand for Spikevax, correct?
A. Same answer.
Q. You don't contend that the combination of the '127 and '600 patents create the sole basis for the demand for Comirnaty, correct?
A. Same answer.

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Q. And when you say "same answer," that's yes, you're not contending that, correct?
A. That those opinions are not included within the context of my report.
Q. You agree that other technologies impacted the demand for Comirnaty, correct?
A. That's a very broad question. We'd have to talk about the specific technologies. But generally speaking, I'm not trying to limit the impact of other technologies generally within my report.
Q. And you agree that other technologies impacted the demand for Spikevax, correct?
A. Same answer.
Q. When you say you're not trying to limit the impact of other technologies generally in your report, it means you agree with me that other technologies impacted the demand for these vaccines, meaning the increased demand for these vaccines?
A. No. It means I haven't specifically sought to identify and rule out other unnamed, undefined technologies. So I would defer you to my report, which focuses on the impact of the technologies here based upon my work and reliance upon Dr. Krause.

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Q. So your opinion hasn't ruled out that other technologies did, in fact, impact demand for Spikevax, correct?
A. These are unnamed potential technologies. I'd be speculating to say that those unnamed things did or didn't impact demand from my perspective because it's not required that the technologies here be solely responsible. I recognize that there may, in fact, be other technologies, but I have not specifically seen or identified them in my report.
Q. And since you haven't specifically seen or identified in the report, you can't evaluate one way or the other whether those technologies, in fact, had greater impact on demand than the alleged patented technologies?
MS. CURTIS: Object to form.
THE WITNESS: In a vacuum, it would

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be very hard to say that because we don't know what we're talking about generically. But I do explain within my report the very unique factors surrounding this technology. In particular, the fact that it was reflected in the two most successful, most quickly introduced product when there were many, many others who were trying.
So from a licensing perspective, I can't imagine that there were others that were more impactful because you would have expected them to have succeeded in the marketplace and they have not.
BY MR. SAWYER:
Q. What are the very unique factors surrounding this technology?
A. Well, again, this is a technical question so I defer to Dr. Krause. But it's my understanding based upon my review of his report that this technology speaks to the -- you know, the essence of a vaccine, which is to stimulate an immune response without creating a viral effect in

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the patient.
And that this -- that these -- this technology had a very strong performance in that regard and was able to be produced in a -- the most timely way vis-à-vis other products.
So my understanding is this technology is highly important to these products.
Q. Even if assuming it's highly important to these products, you haven't evaluated one way or the other whether or not there are other technologies that had higher impact on commercial success than the alleged patented features?
A. I'm not aware of those. So to that extent, I haven't evaluated them. I don't know if there are such things. But even if there are theoretically such things, I don't believe there's a requirement to say that the patented technology here must be the most important or the most impactful in order to meet the conditions of commercial success.
Q. What happens if it's minimally impactful? Does it still meet the definition of

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commercial success in your mind?
A. I think we'd have to look at the specific facts and circumstances and try to define what "minimally" means. That's not applicable to the facts of this case so I haven't attempted to do that.
Q. Well, what does "maximally impact" mean, which is what you used to define the patented features?
MS. CURTIS: Object to form.
THE WITNESS: I don't recall using the phrase "maximally impacted," but maybe you can refresh me.
BY MR. SAWYER:
Q. You said "most important" and "most impactful."
A. Could you either reread the context of that or --
Q. Yeah. Well, I can just rephrase, too.
So in your mind, there's no requirement that it be the most impactful, correct?
A. I'm aware of no legal requirement that

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the technology being considered for commercial success must be the most impactful of all technologies.
Q. Okay. And do you draw a line if it is minimally impactful? Would you still form the same opinion that a patented feature that is minimally impactful demonstrates commercial success in a nonobvious analytical framework?
A. Again, I believe that's ultimately a legal question so I'm not opining to that. That said, I don't believe that this is a case where these inventions would be considered minimally impactful so I have not specifically considered that.
Q. And what's the basis for your view that these are not viewed to be minimally impactful?
A. Largely, both the discussion of Dr. Krause in describing the importance of these technologies and the economic evidence that shows they're a unique commercial success.
Q. When you say "they're a unique commercial success," are you referring to unique

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commercial success in the U.S. versus worldwide?
A. I believe there's a reference to both. But my focus is on the actual sales as made, regardless of the market or jurisdiction.
Q. Okay. And in order for something to have commercial success in the U.S., would it have to be FDA approved or receive an Emergency Use Authorization?
A. I don't believe there's a requirement that that be done in order to demonstrate commercial success.
I do believe that in order to be able to sell these products in the marketplace in the United States, that is required.
Q. And isn't one of the primary factors you're looking at to evaluate commercial success the sales of the products in the U.S.?
A. That is an important factor, yes.
MR. SAWYER: Why don't we take a little bit of a break.
MS. CURTIS: Sure.

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(Whereupon, a recess was taken from 9:52 a.m. to 10:07 a.m.)
MR. SAWYER: Back on the record.
BY MR. SAWYER:
Q. Mr. Malackowski, could you turn back to your report, which is Exhibit 1?
A. Yes, sir.
Q. I'll ask you to look at paragraph 17. And specifically, sort of the last sentence there. You state (as read): I understand from Dr. Krause that the superior efficacy, safety, and rapid development timelines for Spikevax and Comirnaty are attributable to the technologies claimed in the '600 and '127 patents.
Do you see that?
A. Yes, sir.
Q. You personally have no opinion on how the '600 or '127 patents impact the efficacy, safety, and rapid development timing for Spikevax and Comirnaty, correct?
A. I'm offering no expert opinion. That's a technical matter, as I understand it.

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Q. Okay. And you have no opinion on why the '600 or '127 patents impact the efficacy, safety, and rapid development timing for Spikevax and Comirnaty, correct?
A. Same answer.
Q. Your report did not disclose any investigation into how much more effective Spikevax and/or Comirnaty are due to the '600 patent, correct?
A. Not other than the statements I cite to Dr. Krause, correct.
Q. And your opinion did not disclose any investigation by you into how much more effective Spikevax and Comirnaty are due to the '127 patent, correct?
A. Same answer.
Q. And your opinion does not disclose any investigation by you into how much safer Spikevax and Comirnaty are due to the '600 patent, correct?
A. Same answer.
Q. When you say "same answer," that is yes, you did not disclose that?

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A. Other than my review of Dr. Krause's report, which speaks to those issues.
Q. Your report did not disclose any investigation by you into how much safer Spikevax and Comirnaty are due to the '127 patent, correct?
A. Same answer.
Q. And when you say "same answer," that means you did not disclose it. You're relying on Dr. Krause?
A. Well, the safety issue is disclosed, but it's disclosed relative to my reliance on Dr. Krause.
Q. So you have no opinion on the impact that the '127 patent has on the safety of Spikevax and Comirnaty, correct?
A. Not other than what I rely upon from Dr. Krause. And I do not offer a technical opinion in that regard.
Q. Your report did not disclose any investigation by you into how much slower or faster the development of Spikevax or Comirnaty was due to the '600 patent, correct?

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A. Not specific to the patents at issue. There is some general discussion of product development time. And, again, I do refer back to Dr. Krause's report.
Q. And your report does not disclose any investigation into how much slower or faster the development of Spikevax or Comirnaty was due to the '127 patent, correct?
A. Same answer.
Q. And we discussed this generally, but there are other factors that did impact the speed in which at least Spikevax was developed, right?
MS. CURTIS: Object to form.
THE WITNESS: That's a very general question. I don't know what you're referring to by "other factors." So perhaps you could be more specific or rephrase.
BY MR. SAWYER:
Q. Well, certainly not the speed in which Spikevax was developed was not solely due to the '127 and '600 patents, right?

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A. I don't claim that to be the case, no.
Q. In fact, for example, government funding that Moderna received likely had an impact in the speed in which it was able to develop Spikevax.
A. I'm not offering an opinion in that regard. I'm not opining either way.
Q. You would agree with me that absent the government funding, Spikevax would have likely taken longer to develop?
A. That would be speculating. I don't know.
Q. So you didn't factor that into your opinion at all?
A. I did not factor into account the incremental speed associated with governmental funding aside from my understanding of the technical attribution of these inventions contributing to speed that is discussed within Dr. Krause's report.
Q. Yeah. And, in fact, you didn't actually take into the technical attribution of

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these inventions. You just relied on Dr. Krause.
MS. CURTIS: Object to form.
THE WITNESS: I don't known what you mean by "take in," but I defer you to my report where I cite to Dr. Krause and my takings from Dr. Krause's report.
BY MR. SAWYER:
Q. So it was Dr. Krause that -- if there is an opinion on how much the '600 and '127 patents affected the speed in which it was developed, it was Dr. Krause's opinion and not yours?
A. That's kind of an oddly worded phrase. Let me just say that it's my understanding that the two patents at issue did contribute to the speed of development, and I obtained that understanding from Dr. Krause.
Q. And in your opinion -- or in your report, you didn't take into account other factors that may also have impacted the speed at which the Spikevax was developed?
A. That's an open-ended question. There

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could be countless other factors related to employees or the like. I'm not aware of any other factors cited in the record that has the significance that Dr. Krause attributes to the patented invention.
Q. You're not aware of them because you didn't consider any others.
A. I considered them by looking to understand if there was evidence in the record of such, and I haven't seen it.
Q. And what record were you looking at?
A. All of the materials that are cited within my report specifically.
Q. And you didn't look at the -- did you look at the IPR filings and the related declarations?
A. No, I don't believe I've looked at the IPR file.
Q. So you've only looked at what's cited in your report and Dr. Krause's final report, correct?
A. True. But what's cited in my report

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includes the public disclosures and filings of these companies describing these products and their success and the reasons for that. So I'm not aware of anything that would suggest or discount from Dr. Krause's conclusions.
Q. Having an emergency use authorization as opposed to a typical FDA approval process certainly sped up the development and launch of Spikevax, right?
A. Certainly sped up the launch of the products. I would agree with that.
Q. You'd also agree that it sped up the development process, right?
A. I don't know what you mean by "development." If you're including within "development" the full FDA process, then yes. If you're including something other than that, you need to be more specific.
Q. Other COVID-19 vaccines were developed just as quickly as Spikevax and Comirnaty, correct?
MS. CURTIS: Object to form.

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THE WITNESS: Other vaccines may have developed within a similar period of time but not with the same effectiveness.
BY MR. SAWYER:
Q. My question is: Were other COVID-19 vaccines developed in roughly the same period of time as Spikevax and Comirnaty?
A. Other unsuccessful vaccines were. I believe that's true.
Q. And by "other," what you're classifying as unsuccessful, would you classify AstraZeneca's Vaxzevria unsuccessful?
A. "Unsuccessful" is a term that we also have to put some definition around it because I've not considered it from a commercial success point of view in the nexus of success to successful. But it was not as effective as the products at issue, though it did receive authorization in a similar time frame.
Q. And do you have an expert opinion on effectiveness of vaccines against COVID-19?
A. Very general question. Within my

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report you'll see data regarding the effectiveness. I believe within the record you'll hear expectations of effectiveness prior to development targeting governmental satisfaction, if it got to be over 50 percent. And that there was surprise and delight when the patented vaccines exceeded 90 percent.
Q. So you don't have an expert opinion on what constitutes effectiveness?
A. As far as a threshold? No, I'm not offering an opinion that above a certain percentage would be deemed effective by the industry.
I do have an understanding that relatively speaking, the patented vaccines are among the most effective and, in fact, are the most effective that were introduced to the market.
Q. So going back to my earlier question, there were other COVID-19 vaccines that were developed as quickly as Spikevax and Comirnaty, right?
A. Within a reasonable approximation of

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time. For example, the AstraZeneca product was given authorization in February of 2021 as compared to December 2020 or January 2021 for the patented products.
Q. And the J&J as well, J&J vaccine, similar time frame?
A. Yes.
Q. And neither the AstraZeneca or the J&J vaccine are alleged to practice the '127 patent, right?
A. Neither of the patents-in-suit is my understanding.
Q. Okay. So that includes the '600 patent as well?
A. Yes.
Q. You're not offering an opinion on what the '600 patent covers, right?
A. That, to me, is a technical and/or legal question. I'm not offering that opinion. I describe my understanding of it, and I'm making the assumption that it is infringed by the Pfizer-BioNTech vaccines.

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Q. Do you know if the '600 patent covers any mRNA vaccine formulated in a lipid nanoparticle?
A. Technical question. Outside my scope. I don't have an opinion.
Q. Do you have any understanding if there is any requirement for the lipid nanoparticle -- strike that.
Do you have any understanding of the technical requirements of the NLP, or nano lipid particle, in order to practice the '600 patent?
MS. CURTIS: Object to form.
THE WITNESS: I'm not offering an opinion in that regard, if there even are such requirements.
BY MR. SAWYER:
Q. Have you read the '600 patent?
A. Yes.
Q. Do you know about how long it is?
A. How many pages? It's quite lengthy. I don't recall.
Q. When you say "quite lengthy," what do

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you think?
A. I don't have an estimate for you.
Q. Half an inch thick?
A. I don't have an estimate for you.
Q. Did you read it in paper form or did you read it online?
A. Both. I have abstracts in paper, and then I reviewed it online.
Q. Do you know if it's possible for unmodified RNA vaccines to practice the '600 patent?
A. Outside my scope. I don't have an opinion.
Q. Is it also outside the scope of your opinion whether or not self-amplifying RNA practices the '600 patent?
A. Correct. Yes.
Q. Do you think the commercial success of Spikevax would be reduced if it did not practice the '600 patent?
A. I suppose that depends upon what it did practice instead. That would be a hypothetical

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I've not considered.
Q. Do you think that the commercial success of Comirnaty would be reduced if it didn't practice the '600 patent?
A. Same answer. I'm not aware of any commercially acceptable noninfringing alternatives. But that analysis is outside the scope of this report.
Q. Do you agree that the '600 patent doesn't relate to the ability to manufacture a vaccine?
A. I'm not offering any opinion in that regard. I've not studied that issue.
Q. Okay. Do you agree that the '600 patent does not relate to having any benefits -- any ability to distribute a vaccine?
A. Same answer.
Q. You're not offering an opinion on that?
A. Correct.
Q. You would agree with me that the '600 patent does not relate to having any benefits to the ability to transport a vaccine?

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A. I consider that within the question of distribute. But I'm not specifically offering that. I have considered the issue of the contribution of the distribution network and the temperature control required thereto. But I've not presented that here as an additional reason for commercial success.
Q. But the ability to do that does contribute to the commercial success or at least the amount of sales?
A. With any product the ability to actually deliver it to customers will be a factor that affects sales, profits, and other metrics that are commonly used in assessing commercial success.
Q. You're not offering an opinion on what the '127 patent covers, right?
A. I thought you already asked me that. I am not offering a legal or claim construction opinion.
I have an understanding that it covers the products at issue here.

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Q. I asked you about the '600. But I understand that. I just wanted to make sure that your answer would be similar to the '127.
A. It would be.
Q. How do you distinguish between the '127 patent and the '600 patent in your analysis of commercial success?
A. There is no specific identification of one versus the other.
It's my understanding that there are certain composition versus method claims that are distinct between the two patents. But that I looked at them assuming they are both infringed and assess them jointly.
Q. Would your opinion change as to nexus if the '127 patent wasn't part of the analysis?
A. It would not change my opinions regarding the '600 so long as the opinions of Dr. Krause did not change.
Q. Would your opinions change if the '600 were no longer part of the analysis?
A. An analogous response, that it would

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depend upon whether or not that had a bearing or impact on Dr. Krause's conclusions.

Q. Do you agree that the '127 patent doesn't claim any benefit to the ability to manufacture a vaccine?

A. I'm not speaking to that issue. One would need to look to the patent and apply the Court's -- any claim construction and assess it from a technical point of view.

Q. Would you agree that the '127 patent does not claim having any benefit to the ability to distribute a vaccine?

A. Same answer. That's a technical question. I'm not claiming distribution benefits within the context of my report.

Q. Okay. And how about the '127 having an impact on -- or a benefit to the transportation of a vaccine?

A. Same. Same answer.

MR. SAWYER: I'm going to mark another exhibit, Malackowski PTAB 2.

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(Malackowski PTAB Deposition Exhibit 2 was marked for identification.)

BY MR. SAWYER:

Q. Mr. Malackowski, I've handed you a document that I've printed off the internet, and it is entitled Moderna Science & Technology Day, May 17th, 2022.

Have you ever seen this document before?

A. I have seen documents similar to this. I can't tell you from memory if I've seen this exact document. It doesn't bear a Bates stamp so I don't know if it's something that was produced in conjunction with this matter or not. But I have seen similar Moderna presentations.

Q. I will represent to you it has not been produced as part this matter or -- and I don't know if it's been produced as part of a previous district court litigation. But it is publicly available.

A. Thank you.

Q. And so you said you've seen similar documents. Do you recognize this as a document that likely was put together by Moderna?

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MS. CURTIS: Object to form.

THE WITNESS: I can only read the document as shown to me. It's titled Moderna, Moderna Science & Technology Day, and contains disclaimers noting that it's based upon Moderna's expectations. So I can make that assumption, if you'd like.

BY MR. SAWYER:

Q. All right. Well, you've said you've seen at least similar documents to this. And I'm going to direct you to slide 16.

A. Slide 16 of 135. Yes, I have it.

Q. Okay. Great.

And you can see there the title of that slide says (as read): Moderna combines mRNA engineering, delivery system discovery, and clinical manufacturing platforms within a single, fully integrated organization.

Do you see that?

A. I do.

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Q. Okay. And so Moderna, at least publicly here, has stated that there are at least sort of three different processes here when it's developing its vaccines. The sort of mRNA, which is kind of in those red boxes; the delivery, which is in the blue boxes; and the manufacturing in the green boxes.

Do you see that?

MS. CURTIS: Object to form. Foundation.

THE WITNESS: So it does appear to make distinction of three different groupings of engineering. I agree with that.

BY MR. SAWYER:

Q. And if you flip to slide 19.

A. Yes.

Q. You can see that, again, Moderna here sort of lays out what is -- what's required in an mRNA formulation into lipid nanoparticles, and it lists off a number of different sort of technologies. It's got "mRNA," you see that?

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It's at the top. The ionizable lipid, which is the second one down; the phospholipid, third one down; Sterol; and the PEG lipid.

Do you see that?

MS. CURTIS: Object to form. Foundation.

THE WITNESS: I see what you're reading on the chart. Your question implied that all of these are required. I don't read the chart to say that. But short of that, yes, I can read the data.

BY MR. SAWYER:

Q. Is it your understanding that a -- like, Spikevax, for instance, which is a COVID-19 vaccine, is made up of multiple parts of technology?

MS. CURTIS: Object to form.

THE WITNESS: I wouldn't view it as multiple parts or components of technology. I do understand that there was engineering related to the development of the product that spanned a number of technologies. I

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think that's fair.

BY MR. SAWYER:

Q. Would you consider Spikevax a multicomponent in nature -- a multicomponent vaccine in nature?

A. I would not. Not from a business perspective. That phrase "multicomponent" might have legal meaning outside of my scope. But from a business licensing point of view, I would not consider this a multicomponent product. I would reserve that for something more akin to a computer, a smartphone, a car.

Q. And so you would consider the lipid nanoparticle as being the same component as the mRNA strain?

MS. CURTIS: Object to form.

THE WITNESS: I wouldn't view either of them as components. I would view the vaccine as a product, which is based on a formulation or certain engineering. But I don't see this as a componentized product.

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BY MR SAWYER:

Q. When you were doing your analysis, did you presume that the '600 and '127 patents covered each and every component of the vaccine?

MS. CURTIS: Object to form. Foundation.

THE WITNESS: The answer to your question is no. Because I don't view this as a componentized product. I don't recall seeing within my review of the patents the phrase "components." But perhaps I've forgotten that, and you can point that out to me.

BY MR. SAWYER:

Q. Well, when were you doing your evaluation, what -- did you -- did you view that the patents covered the sum and total part of the vaccine?

A. I don't know what you mean by "sum and total part." I understand that the patents cover the vaccines, that as these vaccines are produced, the patented technology can't be separated. But

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ultimately, that's more of a technical question for Dr. Krause.

Q. So your evaluation assume that in order to produce the vaccine, you couldn't separate out the patented aspects?

A. For the commercially -- for the commercial product as delivered, I don't believe that that can be separated out, certainly, and maintain the same degree of success. But from a technical separation point of view, I would defer to Dr. Krause.

Q. You understand from your work on this -- this case and reviewing Dr. Krause's report that there are other patents that also cover the Spikevax protein -- the Spikevax vaccine, correct?

A. Yes, sir.

Q. Okay. And you understand that there are other patents that cover the Comirnaty vaccine, correct?

MS. CURTIS: Object to form. Foundation.

THE WITNESS: I'm not aware of any

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other patents that are so marked that would claim coverage. But I'm not disputing it. It simply is outside my scope.
BY MR. SAWYER:
Q. So do you agree with me that Spikevax and Comirnaty are complex and multicomponent in nature?
MS. CURTIS: Object to form.
THE WITNESS: You're asking me, again, the same question you asked me before about components which I've already disclaimed my under- -- my view of. So do I agree they're complex technologies? I don't have a problem with that.
BY MR. SAWYER:
Q. You don't agree that they're multicomponent in nature?
A. I'm not offering that opinion. I understand that it has certain legal ramifications. That's outside my scope. From a licensing perspective, I would not consider this a multicomponent product for the reasons I

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described.
Q. What are the reasons you described?
A. That from a licensing perspective, I would look to products that have separable elements, such as the laptop, the smartphone, the automobile.
Q. And your current understanding of, for example, Spikevax, they don't have any separable components?
A. From a business perspective, I'm not aware of any separable components that would allow for the essence of the product providing the same commercial success. But to the extent there are from a technical perspective, I would defer to Dr. Krause.
Q. Okay. And would you compare -- like, drawing your analysis a little bit further, is the processor of a computer, is that a separable component?
A. Yes, I would think so.
Q. Okay. Does the computer work without the processor?

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A. Not for its intended purpose unless you can easily supplement it with another processor.
Q. Okay. So why is that a separable component and, for instance, a patent or a component that works in conjunction in the vaccine not a separable component?
A. I think largely based upon the market characteristics wherein those processors are often developed by third parties, sold separately, marketed separately with competitive elements.
Q. So if a component is developed by a third party and then implemented in, it would be a separable component?
MS. CURTIS: Object to form.
THE WITNESS: Again, you would have to look to the characteristics of it. To some extent, once you -- once you combine certain elements, they become nonseparable. But I don't think that's true of the processor in a computer.
BY MR. SAWYER:
Q. And your report in this case didn't do

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that analysis?
A. "That analysis" being trying to separate out elements of the vaccine?
Q. Or even consider that they could be separated.
A. I did not present that analysis. From my perspective, the assignment was to determine whether or not the vaccine as produced and alleged to infringe was commercially successful, not to consider a theoretical list of potential design-arounds. I'm not aware of any commercial successful noninfringing design-arounds.
Q. Well, we weren't really talking about commercially successful design-arounds. We were talking about separable components. And you mentioned that some separable components, if they're designed and developed by a third party, you would consider that as a separable component.
MS. CURTIS: Object to form.
THE WITNESS: In the analogy that we're speaking to, which is from a licensing perspective, products more like

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computers are viewed to have separable components as opposed to vaccines.

But I'm not providing an opinion that there are components. I don't understand there to be. I do understand that there may be certain legal parameters around that term. That's outside my scope.

BY MR. SAWYER:

Q. And if there were separable components, it would change your analysis?

A. I don't believe that it would because I think the analysis is still whether or not the products as offered and sold were commercially successful.

Q. Except that the commercial success has to be tied to the patented components?

A. I don't recall the language of "tied to components." Again, maybe you're speaking to the legal requirements. There certainly has to be a nexus of the invention to the commercial success, which I believe we clearly have here.

Q. You're correct. I meant nexus. So

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thank you for correcting me.

So there would have to be a nexus to the patented component?

MS. CURTIS: Object to form.

THE WITNESS: Again, you're throwing the word "component" into your question. Perhaps for you that has some significant legal meaning. For me, it does not.

I do not view these as multicomponent products. But I do agree that there must be a nexus between the invention and the commercial success.

BY MR. SAWYER:

Q. Can you go back to Exhibit 1, please.

A. Yes, sir.

Q. Great. I'm going to ask you to turn to Figure 1, which is on page 8.

A. Yes, sir.

Q. You've included a table of vaccines that were approved by the FDA and the WHO.

Do you see that?

A. Yes, sir.

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Q. And so this was a chart that was already prepared and that you included, or is this a chart that you put together and created for your -- for this particular document?

A. This is a chart that I prepared from a variety of sources that's reflected in Appendix B of Exhibit 1.

Q. So it's something you prepared?

A. Yes, sir.

Q. Okay. And why did you choose to only include these vaccines?

A. My research would suggest that these are the vaccines that received the FDA or WHO within this period of time. I'm not aware of others as I sit here. To the extent there are, I'd certainly consider including them.

Q. And did you -- was there a reason you limited it to the FDA and WHO?

A. Well, the FDA, of course, has the U.S.A authority, and the WHO is representative of a global perspective. There may in other select markets, China or otherwise, approval of certain

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domestics vaccines, and I would be happy to acknowledge that.

Q. Okay. Would you consider FDA approval an intangible asset?

A. It depends how you're using that phrase. But I would have no objection to that.

Q. There's definitely a value that can be placed on FDA approval?

A. Yes, that's true.

Q. Have you ever evaluated that -- that value in any of your work?

A. Most likely, yes. There are certain cases where we've attempted to value vouchers which would accelerate FDA review, which I think is, you know, closely tied to this question.

Q. And FDA approval or WHO -- WHO approval can impact your evaluation of commercial success?

A. Well, that's facts and circumstances of a given situation. Obviously, here we are considering the products that have FDA or WHO approval.

Q. And if you look at the AstraZeneca

BioNTech-Pfizer Exhibit 1157
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01358

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vaccine, again, that was developed at about the same pace as Spikevax, right?

A. It was approved at about the same time. I don't recall when they began their work as opposed to Spikevax. But in response to COVID, by definition it would have been relatively within the same time frame.

Q. And the AstraZeneca vaccine is approved in even more countries than Spikevax.

A. I don't cite that within my report. But my recollection is that may very well be true, yes.

Q. And the AstraZeneca vaccine does not practice either the '600 or '127 patent?

A. That is my understanding.

Q. And the AstraZeneca vaccine, a least by WHO standards, is considered safe and effective?

MS. CURTIS: Object to form. Foundation.

THE WITNESS: "Safe and effective." At least effectiveness has a relative term. But I would generally believe that they

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would not have granted authorization if they did not consider it safe and effective, though I'm not an expert on WHO approval process.

BY MR. SAWYER:

Q. So do you have an understanding that the -- the WHO declared sort of a worldwide health emergency in or around January 31st, 2020?

A. I am somewhat aware of WHO declarations in that regard, both as to beginning and ending parameters for the pandemic, though those issues are not core to my analysis here.

Q. Okay. And you would agree that the demand for COVID-19 vaccines was extremely high in the, you know, 2020, 2021 time frame because the pandemic was raging worldwide?

MS. CURTIS: Object to form.

THE WITNESS: General question. Undefined terms as to what's "extremely high" or "raging." But I think it's common sense that, yes, there was a demand for the vaccine as a result of the pandemic, and

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the pandemic was global and, therefore, widespread.

BY MR. SAWYER:

Q. Despite maybe disagreeing with my terms, you're not disagreeing with that concept, right? I mean, I think everyone that lived through it was very -- we're all very familiar with the demand for the vaccine and the impact that COVID had on all of our daily lives, right?

MS. CURTIS: Object to form.

THE WITNESS: I think people are generally familiar with the impact of COVID, and for many, their demand for the vaccine -- a vaccine.

BY MR. SAWYER:

Q. When Spikevax and Comirnaty first became available in the U.S. in December 2020 or January 2021, the U.S. government was the sole purchaser of the vaccine for doses distributed in the U.S.; is that right?

A. I believe that the government had actually purchased or made purchase commitments in

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advance, and that the private payer commitments came later. I don't disagree with that.

Q. The government being the sole purchaser meant that the market for vaccine doses was different from sort of a traditional commercial market; is that right?

A. I don't necessarily agree. It's different, but every market is unique. I don't draw any huge distinction, especially for product responding to a pandemic. Maybe you can rephrase or ask a more specific question.

Q. There was only a single buyer, right?

A. I don't understand that question. At one point, there's going to be a first buyer. At the point of first purchase, they would be the single buyer. But it was never envisioned, I don't believe, that there would only be a single buyer for the COVID vaccines.

Q. But there was, indeed, only a single buyer for the first year and a half or two years in which Comirnaty and Spikevax were available, right?

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MS. CURTIS: Object to form.
THE WITNESS: I haven't put a particular time frame or studied that uniquely. I'm happy to accept it for purposes of your question. I don't think it's relevant to the scope of my work.
The government was interested in purchasing quantities of vaccine based upon the safety and efficacy. I don't think it has any bearing to the commercial success question here.
BY MR. SAWYER:
Q. But the U.S. government was 100 percent of the U.S. market demand in January of 2021?
A. Same answer. I don't recall from memory that that was the case, but I'll accept it. I don't think it's relevant to the considerations said here.
Q. The U.S. government was the only entity determining the amount of vaccine being purchased in the U.S. in January 2021?
A. I don't know that that's true. Even if

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they were the only one purchasing at the time, I do believe that the industry generally was looking or considering the rollout of vaccines and the distribution of those, including purchase decisions.
Q. Do you have an understanding if the U.S. government was pursuing a strategy of, like you said, contracting for vaccines, even before they were available, so that they could stockpile and then distribute the vaccine?
A. I believe the government was introducing that through -- with multiple suppliers. Of course, dependent upon the approval and success of the products when they matured.
Q. And in fact, they were actively -- the U.S. government was actively seeking multiple suppliers so that they could execute on that strategy, which is to contract and buy as much as they could so they could stockpile and distribute, right?
MS. CURTIS: Object to form.
THE WITNESS: I don't agree with the

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full premise of your question. I do agree they were looking to multiple suppliers. I think they were looking to protect -- the U.S. government was looking to protect not only the American public but had considerations for the rest of the world given the ability for citizens outside of the United States to travel and affect the pandemic management here.
But I don't think they were looking to buy as much as they possibly could because they certainly had targets and quantities that they were considering.
BY MR. SAWYER:
Q. They were looking to buy at least more doses than they expected to need in the U.S.?
A. Before our first break, you and I talked about the fact that they sought to buy some surplus. I agree with that.
Q. Okay. And when the government, after they purchased the vaccines, they were distributing to the American public for free,

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right?
A. Generally, there was distribution that was at no cost to the American public. I haven't undertaken the studies to whether that was solely subsidized by the government or otherwise and at what point that transitioned. I don't believe that's a relevant factor in consideration of commercial success by these patents.
Q. Well, the availability of a free vaccine would increase demand in such that not having to pay for something typically increases demand, right? If something was expensive or couldn't buy it, that may decrease demand?
MS. CURTIS: Object to form.
THE WITNESS: I acknowledge price elasticity as a concept. But my understanding was that the government and industry generally were looking to purchase safe and effective vaccines in that the availability in terms of speed to market and safety and effectiveness were all considerations.

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BY MR SAWYER:
Q. Your report doesn't disclose how many fewer vaccine doses would have been administered if the vaccine were not free?
A. True, I did not undertake that hypothetical analysis.
Q. And so your report did not disclose the impact of the doses that were administered for free as separate and apart from the impact of the '600 and '127 patents, right?
A. I'm not sure I understand your question there. My report does take into account market conditions generally, and in particular, speaking to the relative success of the products at issue versus other products, all of whom would have had the same access to those types of benefits.
So, again, I don't believe that those macroeconomic factors detract in any way from the conclusion of commercial success here.
Q. Paragraph 19 in your report, and paragraph 20 because we kind of look at them, they're both -- both 19 and 20 appear to list out

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some financial numbers for Moderna, Pfizer, and BioNTech.
Do you see that?
A. Yes, sir.
Q. And you'd agree with me that the majority of demand or the majority of sales for both Spikevax and Comirnaty were between January 2021 and, say, May 2023?
MS. CURTIS: Object to form.
THE WITNESS: I believe my analysis goes through all of 2023, so I wouldn't want to speculate sitting here that May was a particularly relevant cutoff. But that said, the majority of sales as reflected in my chart does occur in 2021 through 2023.
Can we take a two-minute break?
MR. SAWYER: Absolutely.
THE STENOGRAPHER: We're off the record at 10:57.
(Whereupon, a recess was taken from 10:57 a.m. to 11:19 a.m.)
THE STENOGRAPHER: Back on the

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record at 11:19.
BY MR. SAWYER:
Q. Welcome back, Mr. Malackowski.
Have you ever opined that there was no nexus to a patent in a commercial success report?
MS. CURTIS: Object to form.
THE WITNESS: I don't recall doing so for the purpose of invalidity. But as you may know, within traditional patent litigation one of the Georgia-Pacific factors speaks to commercial success and the contributions of the invention. And so I have critiqued that countless times.
But I don't have a specificity as to whether I said in a binary way there was no commercial success associated with the patent.
BY MR. SAWYER:
Q. Do you remember what the -- what some of the reasons were why you previously critiqued a nexus in a commercial success analysis?
A. Not as I sit here, no.

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Q. Did you ever do so in a complex, multicomponent product?
A. I don't recall.
Q. When's the last time you gave an opinion on commercial success?
A. In a damages context, it would have been the last case that I testified in at trial, which would probably be earlier this year. In an IPR context, I don't recall.
Q. Okay. And in the last context when you testified at trial, were you giving an opinion that there was commercial success and a nexus to a patented feature or that it was absent?
A. My recollection would be in the last case I testified on trial -- or the last couple, that there would have been an evaluation of commercial success under the Georgia-Pacific factors. I don't recall giving any opinion that there was complete absence of nexus.
Q. When you say you "don't recall giving an opinion that there was complete absence of nexus," what do you mean by a "complete absence"?

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Is it binary, meaning is it -- was your opinion that there was a slight nexus, or was your opinion there was nexus and there was -- sorry. That was not a very clear question.

But when you say "the complete absence of nexus," I'm wondering what you meant by that.

A. I had thought that you had started this line of questioning about asking if I've ever opined to there being no nexus, and so I was simply trying to address it in that context.

I don't recall providing an opinion in any matter that there was no nexus, meaning a binary zero. But I've testified in many cases, and perhaps over the decades that's happened. I just don't recall it.

Q. Do you recall whether or not you testified that if there was some slight nexus, that commercial success shouldn't be considered?

A. No. Because in most cases, a damages perspective is a more relative concept than a binary concept in that you are apportioning for numeric reasons the contribution of an invention

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versus others. That quantitative apportionment isn't applicable, as I understand it, when you're dealing with the secondary considerations of nonobviousness.

Q. So sitting here today, you don't recall doing -- sorry.

So sitting here today, you don't recall offering an opinion as to commercial success to support nonobviousness?

A. No, I didn't say that.

I don't recall offering an opinion of no nexus to the commercial success as I sit here today. Not to say that I haven't done that, but I hadn't thought about it prior to sitting here, and I don't recall such.

Q. In a similar situation, whether it be a district court litigation or an IPR setting, have you offered an opinion where you determined that the patented features of a patent did not have a nexus such that there was no commercial success?

A. I suspect that I have. The vague recollection that's coming to mind is a case

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involving a pharmaceutical API, but that the patent had nothing to do with the drug, per se, but had to do with some ancillary distribution or something else. And I don't recall the specifics.

But I suspect there have been cases where I've testified that there -- in that case, that there was no specific nexus.

Q. You have a general understanding of what an API is?

A. Yeah, an active pharmaceutical ingredient into a drug.

Q. So you said that you have a vague recollection of a case involving a pharmaceutical API, but that the patent had nothing to do with the drug, per se.

Do you see that? Do you recall saying that?

A. Yes, sir.

Q. Okay. So do you recall what the patent was related to, if it wasn't related to the drug?

A. My recollection is it was some form of packaging. But I don't recall the specifics.

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Q. And when you say "packaging," you're not talking about, like, the pill bottle it was in, right?

A. I think I might be talking about the syringe packaging, but essentially, yes.

Q. In your report, you did not specifically consider -- strike that.

In your report, did you specifically consider other technologies that might have impacted the demand and, therefore, commercial success of Comirnaty and Spikevax?

A. Yes. At a general level, including, as for example, what's reflected in the table you and I were looking at earlier today shown in Appendix B. And noting that there were other vaccines that went to market that used different technologies but that were not as successful or as effective.

Q. You have an understanding that Moderna has claimed that U.S. Patent Number 10,898,574 is also practiced by Spikevax and Comirnaty, correct?

A. I understand that from the district court litigation, yes.

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Q. Did you evaluate that technology and how it impacts demand and commercial success for your report in this case?

A. Not as identified here in this case. This case stands alone based upon the two patents that are asserted.

Q. So does the '574 patent impact demand and, therefore, commercial success of Spikevax and Comirnaty?

MS. CURTIS: Object to form.

THE WITNESS: That is outside the scope of what I have done here. I'm not presenting a conclusion on the commercial success for purposes of nonobviousness as it relates to that patent. And I haven't prepared such analysis.

BY MR. SAWYER:

Q. So you haven't considered it one way or the other?

MS. CURTIS: Object to form.

THE WITNESS: I understand that it's within the products -- that it's asserted

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to be within the products that are at issue here. I don't dispute that it has contribution to nexus and commercial success. But as I understand the legal test for what's at issue in this case, the fact that there may be a third Moderna patent that is also responsible for success does not diminish the conclusions that I've reached.

BY MR. SAWYER:

Q. Does the -- is your opinion that the '600 and '127 patent account for the majority of demand and nexus for the commercial success of Comirnaty and Spikevax?

A. I don't offer that opinion. I don't believe it's necessary to do that qualitative ranking.

That said, what you're really asking is more of a technical question. To the extent that any relative weighting would be necessary, that it would be more within the purview of Dr. Krause.

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Q. So you couldn't do the relatively -- relative weighting of the '600 and '127 patent versus the '574 patent?

MS. CURTIS: Object to form.

THE WITNESS: I don't know that I couldn't do it. I would tell you that I haven't done it because it's not necessary.

BY MR. SAWYER:

Q. Why isn't it necessary?

A. Because as I understand the legal requirements, one need not show that the technology here is solely responsible or a majority responsible for the product. The standards are as I've described them within my report, and I believe that including the consideration of Dr. Krause's report, these two patents meet the standard for a conclusion of commercial success.

Q. Have you ever done a relative analysis or weighting of the '600 and '127 patent versus the '574 patent?

MS. CURTIS: Object to form.

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THE WITNESS: Not specifically. I don't believe so, no.

BY MR. SAWYER:

Q. So you have no opinion on whether or not the '574 patent is more important to the commercial success of Comirnaty and Spikevax versus the '600 and '127 patent?

MS. CURTIS: Object to form.

THE WITNESS: That's the question you asked me a few minutes ago. I have not rank ordered or weighted them. I haven't specifically opined as to the commercial success for purposes of nonobviousness as it relates to the third patent.

I don't dispute that it is a contributor. But its relative impact vis-à-vis the two patents at issue here is a better question for Dr. Krause.

BY MR. SAWYER:

Q. So just like other technology that you haven't evaluated, you don't know one way or the other whether or not the '574 patent impacts

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commercial success for Spikevax and Comirnaty?
MS. CURTIS: Object to form.
Foundation.
THE WITNESS: I haven't conducted that study.
I do understand that the '574 patent is asserted to be within the two products at issue in this case, i.e., infringed. But I haven't conducted a relative assessment of their impact on commercial success. I don't believe that's necessary.
BY MR. SAWYER:
Q. So you would agree that the '574 patent, because it's Moderna saying it covers the Comirnaty and Spikevax, does impact commercial success, though, correct?
MS. CURTIS: Object to form.
THE WITNESS: No. You're just asking if I had any assessment of that patent vis-à-vis this undefined list of other technologies. And I would note that

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as compared to an undefined list of other technologies, one thing I do know is that it's been asserted as embodied within the two products at issue.
BY MR. SAWYER:
Q. So because it's been asserted and because it's defined, then you do know that it does have an impact on commercial success that's unrelated to the '600 and '127, correct?
MS. CURTIS: Object to form.
THE WITNESS: Not correct. That's not what I said. I haven't studied it. So it would be premature for me to draw that conclusion.
BY MR. SAWYER:
Q. So you have no opinion one way or the other whether or not the '574 patent impacts commercial success?
MS. CURTIS: Object to form.
THE WITNESS: I haven't studied that. I understand that it's embodied within these products. But I would have to

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go back and, for the purposes of nonobviousness, consider that issue.
BY MR. SAWYER:
Q. And so based on that, your report doesn't include an analysis of the '574 patent and how it impacts commercial success, right?
A. Well, my report doesn't include an analysis of the '574 patent largely because it was outside the scope. And such an analysis is not necessary to reach the conclusions that I was presenting.
Q. So you don't have -- you don't know one way or the other whether or not the '574 patent is the main reason for any commercial success of Comirnaty and Spikevax?
MS. CURTIS: Object to form.
THE WITNESS: I haven't assessed whether or not it is, quote/unquote, "the main reason."
BY MR. SAWYER:
Q. Okay.
A. "Okay" meaning you're done?

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Q. No. I'm sorry.
MR. MESTITZ: The question of an optimist.
MR. SAWYER: Yeah.
BY MR. SAWYER:
Q. You're aware that both Moderna and BioNTech have a license from CELLSCRIPT, right?
A. Yes.
Q. And you understand that the license from CELLSCRIPT relates to work that Dr. Kariko and Dr. Weismann performed at University of Pennsylvania?
MS. CURTIS: Object to form.
Foundation.
THE WITNESS: I haven't reviewed that license to memorize the innovators.
But I'm happy to accept that.
BY MR. SAWYER:
Q. Do you know if that license relates to modified RNA technology?
A. I don't recall from sitting here. And I wouldn't want to speculate without reviewing the

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license and related documents.
Q. Do you recall whether or not the -- do you recall if the '574 patent relates to modified RNA technology?
A. Same answer. I haven't gone back and reviewed that. I believe that's an issue in the district court case, not something that's dealt with in the scope of my report here.
Q. Do you have understanding that Moderna has paid CELLSCRIPT royalties under the CELLSCRIPT license agreement?
A. That, I believe, is true.
Q. And do you have an understanding that BioNTech has also paid CELLSCRIPT royalties under the license agreement for sales of Comirnaty?
A. I think that's true as well.
Q. In your report, you didn't evaluate the impact of the CELLSCRIPT patents to the commercial success of Comirnaty in comparison to any page impact of the '600 and '127 patents, correct?
A. Correct.
Q. In your report, you didn't evaluate the

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impact of CELLSCRIPT patents to the commercial success of Spikevax in comparison to any impact of the '600 and '127 patents, correct?
A. Correct.
Q. In fact, you can't provide an opinion on that because -- strike that.
Therefore, you can't provide an opinion on whether the CELLSCRIPT patents have a greater technical impact on the safety, efficacy, or speed to market vis-à-vis the '600 and '127 patents?
MS. CURTIS: Object to form.
THE WITNESS: So I'm not providing an opinion in that regard for many reasons, including it requires a technical assessment that's outside my scope, and it's not necessary for purposes of my assignment here.
But as you asked me a few minutes ago, it's not contained within the scope of Exhibit 1.
BY MR. SAWYER:
Q. Have you heard of a company called

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Acuitas?
A. Yes.
Q. Okay. Do you have an understanding if BioNTech has a license to Acuitas patents that it pays a royalty to Acuitas for Comirnaty?
A. I have reviewed that as part of the district court action. I don't recall from memory, but my presumption is that is true.
Q. Do you know if Moderna has a license with Acuitas?
A. I don't recall.
Q. Do you have an understanding that the Acuitas patent and technology relate to LNPs, lipid nanoparticles?
MS. CURTIS: Object to form.
THE WITNESS: That sounds familiar. But I haven't studied that specifically for purposes of my work here so I don't want to speculate.
BY MR SAWYER:
Q. Well, do you have understanding that BioNTech uses Acuitas LNPs in its Comirnaty

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vaccine?
A. I'm not offering an opinion in that regard so I don't know. It's outside my scope.
Q. In your report, you did not evaluate the impact of the Acuitas patents to the commercial success of Comirnaty in comparison to any impact by the '600 and '127 patents, right?
A. Correct.
Q. Therefore, you can't provide an opinion on whether the Acuitas patents had a greater technical impact on safety, efficacy, or speed to market vis-à-vis the '600 or '127 patents?
MS. CURTIS: Object to form.
THE WITNESS: I'm not providing such an opinion.
It's my understanding such would require a technical expertise, which I do not have, and that such would not be necessary to reach the conclusions in Exhibit 1.
BY MR. SAWYER:
Q. You have an understanding that both

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Moderna and BioNTech have a license with the NIH related to the Spike protein?

A. Again, it sounds familiar from my work in the district court case, but I haven't specifically examined that for my work here. But I'm happy to accept that.

Q. Okay. In your report, you didn't evaluate the impact of the NIH patents to the commercial success of Comirnaty in comparison to any impact the '600 or '127 patents might have had?

(Stenographer clarification.)

BY MR SAWYER:

Q. In your report, you did not evaluate the impact of the NIH patents to the commercial success of Comirnaty in comparison to any impact by the '600 or '127 patents?

A. Correct. For the reasons we've discussed previously. A, it would be a technical assessment; B, it's not necessary for purposes of my work here.

Q. And in your report, you did not

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evaluate the impact of the NIH patents to the commercial success of Spikevax in comparison to any impact by the '600 or '127 patents?

A. Same answer.

Q. Meaning you did not do that evaluation?

A. For the reasons I described, correct.

Q. Therefore, you can't provide an opinion on whether the NIH patents have a greater technical impact on efficacy, safety, or time to market vis-à-vis the '600 or '127 patents?

MS. CURTIS: Object to form.

THE WITNESS: I'm not providing that opinion for the same two reasons I've addressed.

It's technical and not necessary for the purposes of my work.

BY MR. SAWYER:

Q. Your report does not disclose any evaluation of the impact of any other Moderna patents on the commercial success of Spikevax, right, besides the '600 and '127 patent?

A. Correct.

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Q. Your report does not disclose any evaluation of the impact of other Moderna technology, whether it be patented or unpatented, on the commercial success of Spikevax?

A. Not specifically, no. Certainly not in comparison to the two patents that are at issue.

Q. Your declaration did not evaluate the impact of BioNTech's, whether it be patented technology or unpatented technology, on the commercial success of Comirnaty as compared to the '600 and '127 patent?

A. Not specifically in comparison. I believe that would be a technical assessment.

Q. Your opinion does not -- did not evaluate the impact of Pfizer's technology on the commercial success of Comirnaty as compared to any commercial success contributed by the '600 and '127 patent, correct?

A. Well, certainly not from a technical perspective. I defer to my report for general business conditions and promotion by Pfizer. But I don't believe that any such conditions would

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affect my conclusions.

Q. Did Moderna's MERS vaccine practice the '600 and '127 patent?

MS. CURTIS: Object to form. Foundation.

THE WITNESS: I'm not offering an opinion in that regard. I believe there's some discussion in the record about that, though, that any need to introduce the vaccine was stayed as a result of the reduced risk associated with MERS.

MR. SAWYER: Why don't we take a break.

MS. CURTIS: Sure. Ten minutes?

MR. SAWYER: Yeah, ten minutes is great.

THE STENOGRAPHER: Off the record at 11:42.

(Whereupon, a recess was taken from 11:42 a.m. to 11:51 a.m.)

THE STENOGRAPHER: Back on the record at 11:51.

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BY MR. SAWYER:
Q. Mr. Malackowski, do you know if the '600 or '127 patents have been licensed by Moderna?
A. Not to my knowledge.
MR. SAWYER: I have nothing further.
THE WITNESS: Thank you. Very professional.
MS. CURTIS: Nothing from me.
MR. MESTITZ: Nothing from Pfizer.
MS. CURTIS: Okay. Yeah, nothing from me.
Do we need to designate this as confidential? I don't think so.
MR. MESTITZ: I don't think so.
MS. CURTIS: There was some of the stuff about licenses that I thought was --
MR. SAWYER: Close?
MS. CURTIS: -- I was getting ready, but I don't think we got there so I think we're good. But just wanted to check before we go off the record.

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MR. SAWYER: Can we go ahead and let's mark it confidential? And I don't think it needs to be marked highly confidential, but confidential, and we'll evaluate.
MS. CURTIS: Okay. Seems sensible.
(Time concluded: 11:51 a.m.)

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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.

_____ _____
(DATE) (SIGNATURE)

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CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, JANICE M. KOCEK, Certified Reporter, Certified LiveNote Reporter and Notary Public within and for the State of Illinois do hereby certify:
That JAMES E. MALACKOWSKI, the witness whose deposition is hereinbefore set forth, was duly sworn by me before the commencement of such deposition and that such deposition was taken before me and is a true record of the testimony given by such witness.
I further certify that present on behalf of Petitioners were Doug Sawyer and Summer Stevens of the law firm Paul Hastings LLP, and Michael J. Mestitz of the law firm Williams & Connolly; and present on behalf of the patent owner was Annaleigh E. Curtis of the law firm Wilmer Cutler Pickering Hale and Dorr LLP.
I further certify that the deposition of JAMES E. MALACKOWSKI, occurred at the offices of Ocean Tomo, 200 West Madison, Chicago, Illinois,

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

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

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

Janice M. Kocek

_____

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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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Page	Line	Correction/Change and Reason
11	3	"An ability to meet to market needs." Delete "to"

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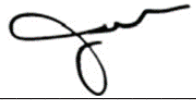

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I, James E. Malackowski, do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me and any corrections appear on the attached Errata sheet signed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

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