of pulmonary delivery in particular, reproducibility was certainly important, and there's always a question about even what's -- what amount of drug emitted from any device what amount of that gets to the lungs. There's loss between the device, the mouth, and then subsequently the lungs, and many accept that the ability to accurately know the exact amount that got to the lungs is not something that we use to evaluate or derive dosing strategies or evaluate the particular system. It's the that it was presented in a fashion that it could have delivered the same amount each time the device was used.

Q. Is there a teaching in Patton on how long a patient needs to inhale after they know that the bolus of medicine is ready for inhalation?

A. My recollection is Patton doesn't describe the time, but the device is designed to contain -- the aerosol is emitted into a volume that is a volume that a typical user would be able to inhale under their use conditions with a single inhalation. It's

based on lung volume, in essence, but if for some patient it -- they weren't able to inhale that volume, that the opportunity to follow up with another breath is certainly part of the device design based on the valve system.

The speed with which the person inhales, you know, how fast they inhale, whatever isn't described, and this device is intended to potentially even limit some the needs to specify those additional requirements that were known as part of other devices at the time.

Q. Does Patton disclose an ultrasonic nebulizer?

A. It's not my recollection that Patton included ultrasonic nebulizers. It's certainly in his initial summary of the invention he describes using a predetermined volume of gas usually air as the material that aerosolizes the drug-containing formulation, but later in the patent I know that there is other discussion of other ways to accomplish some of the workings of the invention he is describing, and I just don't remember among all

of the possible alternatives and directional changes and so forth whether he opens or openly describes that this might be further modified for use with an ultrasonic system.

Q. Okay. My question might have been too broad to be fair. So why don't we do it this way.

If you could -- if I could direct your attention to paragraph 90 of your declaration. You state there that: "Patton teaches a system that generates aerosol using gas; i.e., a jet nebulizer."

So do you understand Patton to be discussing the use of a jet nebulizer?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, in the same way a jet nebulizer uses a gas to form the aerosol that's intended to be inhaled, Patton also primarily describes the formation of an aerosol brought forth by a volume of gas, usually a compressed gas. So there -- that's where they are similar.

The methodologies that

traditional jet nebulizers use to form aerosols are not the same methodologies that Patton's description uses to form the aerosol.

Q. I am not sure I understand.

So are you saying that Patton does not teach the use of a jet nebulizer?

A. No, I am saying that both jet nebulizers and Patton's invention description describe using a gas, typically a compressed gas to form the aerosol. That's their similarity. The mechanism by which a jet nebulizer -- the traditional jet nebulizers form that aerosol is different than the mechanism by which the aerosol is formed by the gas described in the invention described in Patton.

Q. Got it. Okay. And neither a traditional jet nebulizer or the device that's taught in Patton is an ultrasonic nebulizer, correct?

A. As described in this paragraph what I mean by jet nebulizer, no, there's not an ultrasonic source, a sound source that's forming the aerosol, nor in most of the

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description in Patton does he describe using an ultrasonic power or an ultrasonic energy source to form the aerosol.

Q. You said most of the description in Patton does not describe using an ultrasonic power energy source.

Is there any discussion in Patton that does talk about ultrasonic power?

A. Again, I don't recall all of the details regarding other aspects of the invention. So I just don't know whether the word ultrasonic or ultrasound appears anywhere in the patent document, but it's certainly not the original design of the invention that's being described primarily in the document.

Q. So we have been going 21 minutes since we last talked about breaking. Is this a good time to break?

A. It's a good time for me.

THE VIDEOGRAPHER: Going off the record. The time is 12:17 p.m.

(WHEREUPON, a recess was had at 12:17 p.m. until 1:23 p.m.)

THE VIDEOGRAPHER: Going on the

record. This marks the beginning of media number 3. The time is now 1:23 p.m.

BY MS. ASCARRUNZ:

Q. Dr. Donovan, when we were discussing Patton, I think we talked about the use of a compressor, correct?

A. We were talking about compressed air and jets, yes.

Q. Okay. And it's your opinion that Patton teaches the use of a light and sound that is -- that meets the claim limitation for an opto-acoustical trigger, correct?

A. Well, it has a light device, a sound device that signals the user. So, yes, it's an opto-acoustic device.

Q. Okay. And do you consider it to be an opto-acoustical trigger?

A. Well, it's a device that has a light and a sound. They have a meaning to the user based on the instructions, and so if you want to call that an opto-acoustic trigger, it can be viewed as an opto-acoustic trigger under that set of conditions.

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Q. Okay. I will come back to that.

The light and the sound comes on immediately after the operation of the compressor ceases, correct?

A. That's how it's described, yes.

Q. You agree with me that all of the claims of both patents require an opto-acoustical trigger, right?

A. Well, based in the description in claim 1 that describes a pulsed ultrasonic nebulizer that aerosolizes -- oh, next one second --

THE COURT REPORTER: Wait, I'm sorry.

BY THE WITNESS:

A. I'm sorry. Said pulsed ultrasonic nebulizer comprising an opto-acoustic trigger as stated in claim 1 of both patents, and the fact that all of the rest of the claims are dependent to claim 1, there's a requirement for an opto-acoustic trigger.

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BY MS. ASCARRUNZ:

Q. Okay. And that applies to both patents, correct?

A. It's my interpretation because of the dependency of the rest of the claims, yes.

Q. Do you agree with me that the word trigger must itself mean something in the claims?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't think so. I don't recall in the specification where trigger is specifically defined in the terminology of the patent writer.

BY MS. ASCARRUNZ:

Q. Okay. So let me ask it this way.

Let's look at the '507 patent, and you see that claim 1 claims a kit for treating pulmonary hypertension comprising, and then has several paragraphs following?

A. Okay.

Q. The section labeled Romanette

ii reads: "A pulsed ultrasonic nebulizer comprising an opto-acoustical trigger."

Do you agree with me that claim 1 and, therefore, all claims of this patent by dependency require a pulsed ultrasonic nebulizer comprising an opto-acoustical trigger?

A. I agree that that's what's stated in claim 1, Roman Numeral II.

Q. The word trigger in that claim language, what does that mean to a person of ordinary skill in the art?

A. I think the best synonym for that for a POSA would be the word indicator.

Q. And it's your opinion that Patton expressly teaches the need and function of an opto-acoustical trigger, right?

A. Well, Patton describes the usage of an opto-acoustic indicator in the device that he has designed as a way of demonstrating that the aerosol containing the medicament has been placed into the chamber.

Q. The word trigger doesn't carry a specific -- it's not a term of art that's

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used in the art of inhalation therapies, correct?

A. Not in the art that I am most familiar, no.

Q. Okay. And it's your opinion that, as used in the claims, the word trigger is synonymous with indicator?

A. That's the way -- that's the synonym I use for that word, and I anticipate a number of other POSAs would use that term also or use that synonym also.

Q. So in your opinion is any signal that would demonstrate to the patient that a device is ready for the patient to inhale is a trigger within the meaning of the claims?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. That can either -- restate that. I am going to have to ask you to break that down.

BY MS. ASCARRUNZ:

Q. Okay. In your opinion is a -- is an indicator that demonstrates to the

patient that a device is ready for the patient to inhale is a trigger within the meaning of the claims?

MR. MATHAS: Same objection.

BY THE WITNESS:

A. Well, I think, as I stated, when I read the descriptor for Roman Numeral II, my interpretation of the meaning of that is I could substitute the word indicator for trigger. That that was the intended meaning and no further meaning implied to some term the word used trigger.

BY MS. ASCARRUNZ:

Q. Okay. Since we were focusing on the '507 patent, can I ask is it also your opinion with respect to the word trigger in the '240 patent that you could substitute the word trigger for indicator and that would cover the intended meaning of the word?

A. The phrase in the '240 patent is different than the phrase in the '507. So in this case said pulsed ultrasonic nebulizer comprising an opto-acoustic trigger which allows said human to synchronize each breath to

each pulse, and in the case of this phrase within this claim, yes, as a POSA, my equal interpretation to the word trigger is indicator.

Q. Okay. In paragraph 125 of your '240 declaration, you state that: "A POSA would be motivated to combine Voswinckel's teaching of a therapeutically efficacious treatment using a pulse nebulizer with Patton's teachings on reliability, precision, and efficiency."

Do you see that?

A. Yes.

Q. Why would a POSA be motivated to combine those two references in that way?

A. Well, because at the time it was well known in the art that there were human factors involved in the therapeutic efficacy of inhaled dosage forms, and there was a motivation to try to make the devices that were being used as -- as obvious and easy for patients to use them correctly as possible. And so including additional indicators that allowed the patient to use the device as

designed was a motivation for everybody involved in pulmonary device development at the time.

Q. Okay. Is there any statement in Voswinckel itself that provides a specific motivation to modify the nebulizer disclosed?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, there's nothing specific in the Circulation abstract, but even comparing the European Heart Journal abstract to the Circulation abstract, it's obvious that the -- that Voswinckel changed nebulizers. So he was certainly aware that one could select a different nebulizer for whatever purpose one needed to during a -- you know, during a series of investigations.

So it doesn't expressly state that, but I think there's a clear indication that by just comparing those two abstracts, that Voswinckel and certainly others in the art were open to selecting a device where they were confident that that device was accomplishing what they desired for patient treatment.

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BY MS. ASCARRUNZ:

Q. Okay. So you referred to the European Heart Journal abstract, and what I am trying to do is focus just on your statement in paragraph 125 about a motivation to combine Voswinckel's teachings with Patton's teachings.

So -- and I understand your testimony that you believe there are human factor considerations that a POSA would consider that would guide the motivation to combine those teachings in particular ways. Did I understand your testimony correctly?

A. Yes.

Q. What I am trying to understand is is there a statement in either of those two references explicitly in Voswinckel or in Patton that motivates a person of ordinary skill in the art to modify one or the other to arrive at the invention that is claimed in the patents at issue?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, again, a POSA is -- is aware of the activities surrounding device

development for inhalation delivery, and certainly understood the teachings of Patton and some of the -- both the technology to form the aerosol and other portions of the device that Patton describes and their attributes and understands the attributes of other devices, some of which were more readily available potentially in particular regions.

And as a result, there's a motivation from the POSA to always try to -- try to identify some of the best qualities of the art at the time and include them in a next stage in this case we are talking about devices.

BY MS. ASCARRUNZ:

Q. Okay. So I understand you said there's a motivation from the POSA to always try to identify the best qualities of the art at the time, but my question is you don't identify an explicit statement in either of Voswinckel or Patton that directly invites a POSA to modify the teachings to combine them; is that right?

MR. MATHAS: Object to the form.

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BY THE WITNESS:

A. Well, the POSA would realize that the OptiNeb nebulizer family already had the physical capabilities to have an opto-acoustic trigger, and the device described in Patton describes that as a component of the device. And the POSA essentially is learning from Patton that -- and knew this likely even before Patton described it in the specific -- in the specific patent based on the fact that there were other devices available that used -- used lights, used sounds, used other things to indicate to patients how to use the device appropriately.

So the motivation is that Patton describes using light and sound to indicate something about the dose being ready for the patient, and that's easily transferable to a different device that is easily capable of using those same sensory readouts to improve the ability of a patient to use that device correctly.

BY MS. ASCARRUNZ:

Q. I understand your testimony.

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I do. But that wasn't the question that I asked. So let me go about it this way.

Can you point to a statement in the Voswinckel reference that invites a POSA to modify the device used in that reference in any way?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Again, the Voswinckel Circulation abstract is merely an abstract. It's a very abbreviated form of information that's being presented, but even in its very abbreviated form when I compare it to a similar abstract by a similar group of investigators, I already see that they have changed the nebulizer from a continuous nebulizer to a pulse nebulizer.

It tells me that they are open to the opportunity of improvements or changes in a nebulizer to advantage some characteristics of those nebulizers for improved patient therapy, and knowing that there are other improvements from a human factors standpoint that could yet again improve

the usefulness, the ability of patients to use the nebulizers correctly in an outpatient setting, not in the acute care setting that was described in the Voswinckel Circulation abstract, certainly there's a motivation to provide the -- the invention or the -- provide the best possible characteristics in any nebulizer to provide to a set of patients who are in need of a reproducible, accurate, at-home nebulizer system for an important therapy.

BY MS. ASCARRUNZ:

Q. Is that motivation made explicit in the text of Voswinckel?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Again, a POSA doesn't need a specific text to direct them to --

BY MS. ASCARRUNZ:

Q. And that wasn't my question. My question was --

MR. MATHAS: Veronica, you have to let her answer. Then you can ask your question again if you don't like her answer.

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BY THE WITNESS:

A. So, again, a POSA doesn't need specific direction to take known information in the art and utilize it and combine it, and whether there's something actually specifically in an abstract an abbreviated description of a body of work that suggests that or not, that -- a POSA doesn't need that.

BY MS. ASCARRUNZ:

Q. I understand that. I'm asking the question whether -- so I understand that it's your testimony that a POSA did have a motivation to combine those two references as you have indicated, and you've testified at length as to where you believe that motivation would reside in the considerations of a POSA.

Is that a fair characterization of your testimony?

A. Yes.

Q. Okay. All I am trying to establish is that that motivation was in the mind-set and considerations of a POSA and not in a sentence in one of these references. So I am asking you to identify is there a sentence

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in Voswinckel that provides a motivation to modify the device used in Voswinckel?

MR. MATHAS: Asked and answered.

BY THE WITNESS:

A. There's not a specific sentence that -- in the Voswinckel Circulation abstract that describes anything about needing or desiring to change the device in their future studies. It doesn't necessarily mean that they -- they hadn't or another POSA wouldn't contemplate doing that.

BY MS. ASCARRUNZ:

Q. Okay. Is there a specific statement or sentence in the Patton reference that invites a POSA to use the features described for the treatment of pulmonary hypertension?

A. Well, again, Patton is open to the use of the device described in the '951 patent application or however we want to refer to that. That his device provides a method to deliver a medicament by inhalation to reach the lungs of the patient which means that to a POSA that any treatment that a POSA would need to

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reach the lungs to achieve the treatment goal that the Patton device is capable of being utilized to do that.

(Reporter Clarification.)

BY MS. ASCARRUNZ:

Q. Earlier in your discussion of a POSA being motivated to modify the device used in Voswinckel, you referred to the Voswinckel Exhibit 1047 reference.

Do you recall that discussion?

A. I think I need to be reminded what the Voswinckel 1047 reference is.

Q. Sometimes we refer to it as Voswinckel II, but it's the European Heart Journal.

A. Okay. Can I take a look at that reference?

MR. MATHAS: 1046?

BY MS. ASCARRUNZ:

Q. Did I -- sorry, 1046.

A. So it's European Heart Journal abstract.

Q. Yes.

A. Okay. Yes. All right.

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Q. So when I asked you about the motivation in Voswinckel to modify the device, you told -- you referred me to this other Voswinckel reference and said that it tells you that they are open to the opportunity of improvements or changes in a nebulizer to advantage some characteristics of those nebulizers for improved patient therapy.

Do you recall that testimony?

A. Yes.

Q. What does this reference which I will start referring to as Voswinckel II just for clarity of the record, tell you about the willingness of the investigators to improve -- to make improvements or changes to the nebulizer?

A. Well, the Voswinckel II abstract describes the use of an OptiNeb ultrasound nebulizer and a six-minute inhalation exposure, and the Voswinckel American Heart Association abstract describes using three single breaths from a pulsed OptiNeb ultrasonic nebulizer, and it was certainly very well known in the field for

nebulizer therapy that reducing the amount of time to achieve the dose needed for a patient was an important aspect of nebulizer therapy and patient adherence to nebulizer therapy.

So moving from a six-minute nebulization to a three inhalation therapy whether that was accomplished exactly by a change in nebulizer or accomplished by other activities in addition was certainly something that Voswinckel demonstrates that groups were aware of and were in relatively similar timeframes evaluating the opportunity to use a device that provided a better user experience.

Q. Okay. Now, you are aware that the single ground that the Board instituted for decision in this trial was the question -- speaking just to the '240 patent, was limited to the question of obviousness over Voswinckel in view of Patton and Ghofrani, correct?

A. In the '240 patent, yes.

Q. But it's your opinion that in part a motivation to combine those references is evidenced by Voswinckel II, correct?

A. No, I don't need Voswinckel

II, but you were asking directly about specific statements in Voswinckel I, and because it's an abstract, it's a very short description of work conducted and has often times very little description about what other information the authors are thinking, and so I look to other evidence even from the same group to demonstrate that, yes, those other -- those investigators were thinking about other things to improve this therapy beyond just the mere words that are included in the written description in the abstract.

And so I don't need to rely on Voswinckel II to come to the -- to come to the opinions that I did in the matter of the '507 or '240 patents. Merely use that as an obvious example of even whether it's -- whether something is actually stated clearly in an abstract. It was clear that even that same research group understood that that was a consideration and a motivation.

Q. Okay. So because Voswinckel I is an abstract and it's a very short description of work conducted and has often

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times very little description about what other information the authors are thinking, you looked to Voswinckel II to supplement that understanding, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. No, that's not correct. I didn't need to look to Voswinckel II. We started discussing Voswinckel II because I was answering questions you were asking about specific statements included in the Voswinckel I abstract that would have described the author's thoughts, desires, I don't remember the wording about the nebulizer, and I provided you with actual evidence of what would be clear to a POSA that there -- that those investigators must have been thinking about issues regarding modifying the nebulizers being used because they demonstrated that they even did that in order to modify the dosing regimen that they used that was different between those two, but I don't need to rely on Voswinckel II for that. I was using that as an example to answer your questions.

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BY MS. ASCARRUNZ:

Q. Do you need to refer to Voswinckel II to understand the motivation of the Voswinckel I authors to modify the device disclosed therein?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. No. Again, a POSA understood that certainly at the time of the priority date of the '240 and the '507 patents it was well known that in evaluating human factors and improving the human interface with devices was an important thing to do in order to improve user -- improve the use of the device, improve the adherence to the design dosing strategies and so forth.

It was -- POSA's were well aware of those issues and were motivated to try to find ways to improve devices to address human factors issues and improve patient interactions with devices.

BY MS. ASCARRUNZ:

Q. Okay. Where in Voswinckel I is it said that three breaths are delivered in

less than six minutes?

A. It doesn't -- let's see. Voswinckel I doesn't specifically indicate the timeframe over which the three breaths were taken, but a POSA reading this and, again, if it was -- if the occurrence or the description -- start over.

If the methodology used by the investigators was going to differ significantly from what a reader of this abstract would be expected to understand, the authors typically make additional -- put in additional information into the abstract. So those methods are clear.

So not having additional information indicates that a POSA is free to believe that this medication was dosed in the same way you would dose other medications with the OptiNeb ultrasound nebulizer which means three single breaths receiving the dose over a relatively short interval of time, certainly far less than six minutes.

Q. Okay. We were talking about paragraph 125, and the last sentence there you

indicate: "A POSA would have a reasonable expectation of success with such a combination," which refers to the combination of Voswinckel and Patton, "because it simply seeks to improve upon the successful treatment already achieved."

Do you see that?

A. I see that.

Q. Why would a POSA seek to improve a treatment that is already successful?

A. Because while the treatment was therapeutically successful, the future of the treatment was having patients be able to use that treatment in -- and, you know, not have it be a lifestyle interference. So in addition to being able to demonstrate that it was a successful treatment in the acute study or even with the two patients who were using it for compassionate use, there's a -- there's a motivation to make improvements so that when that is sent out into patients using it in their homes and other situations, that again it's as easy as possible for them to adhere to

the therapeutic regimen. And for the alterations to -- and the need to take Patton's teaching about an optical and sound based indicator and combine that, a POSA wouldn't -- would have every expectation that that could be achieved.

Q. You reviewed the file histories of both patents at issue, correct?

A. I did quite a while ago, yes.

Q. Do you recall reviewing the declarations of -- of a Dr. Rubin?

A. I -- only vaguely. I know I speak to it in my report, but I would need to see that declaration again to remind myself what it said.

Q. Do you recall reviewing the declaration of a Dr. Zamanian?

A. Again, I think I recall. I mean, I know there was something about material provided by Dr. Zamanian, but I don't recall in what aspects.

Q. Okay. Do you recall reviewing a declaration of a Dr. Elder?

A. I'm not sure. It's been a

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very long time since I have looked at those file histories.

Q. And you recalled that you may have discussed Dr. Rubin's declaration somewhere in your declaration, correct?

A. I thought that I did. Yes, in paragraph 210 in the '240 declaration, I mention what I understood Dr. Rubin's declaration to communicate.

Q. And what did you understand that to be?

A. Well, Dr. Rubin was -- I think it's -- I can only summarize essentially what's in this paragraph. I think -- I am sure there's more in the declaration I should speak to. So I would like to review it briefly.

Q. In the course of forming your opinions in this case, did you at any point form an opinion that Dr. Rubin's declaration and the file histories was not credible?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Again, it's been a long time since I have reviewed the file history or the

declarations. So I would need to refresh my memory about what that specific declaration said and whether there were other things I evaluated as I read that.

BY MS. ASCARRUNZ:

Q. Well, certainly nowhere in your declaration did you articulate an opinion that Dr. Rubin is not credible, correct?

A. No, I did not communicate that in my declaration.

Q. Did you communicate anywhere in your declaration that Dr. Zamanian is not credible?

A. I don't know that I recall that there's a description of Dr. Zamanian's declarations in this report.

Q. Okay. Are you aware that both Drs. Rubin and Dr. Zamanian are medical doctors with an expertise in treating patients with pulmonary hypertension?

A. I think people have told me that that's their background.

Q. You don't claim to know more than Dr. Rubin or Dr. Zamanian regarding the

medical treatment of pulmonary hypertension, correct?

A. That's correct.

Q. And you don't claim to know more than Dr. Rubin or Dr. Zamanian regarding patient responses to the treatment of pulmonary hypertension with inhaled treprostinil, correct?

A. Clinically observable patient responses?

Q. Yes.

A. No, I don't know more than those two physicians, no.

Q. You are aware that there's a consideration in this case as one of the objective indicia as to whether or not TYVASO is commercially successful, correct?

A. I understand that that's certainly part of the case, yes.

Q. And you are aware that TYVASO has been sold on the market since its approval by the FDA, correct?

A. That's -- I mean, that's my assumption. I haven't tracked any time that it

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had been in shortage or not available.

Q. Okay. And you agree that the attributes of TYVASO that drive its sales include the frequency of its administration, its shorter duration of treatment time as compared to Ventavis, and its efficacy, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Can you restate that question?

BY MS. ASCARRUNZ:

Q. Yes.

A. Or at least reread it.

Q. Do you agree that the attributes of TYVASO that drive its sales include the frequency of its administration, its shorter duration treatment time as compared to Ventavis, and its efficacy?

MR. MATHAS: Same objection.

BY THE WITNESS:

A. Well, I understand that there are differences between TYVASO and other pulmonary inhalation products for pulmonary hypertension that allow TYVASO to have

administration characteristics that might be preferred by patient users. It is well known that treprostinil was particularly pulmonary selective. The half life of TYVASO provides or -- provides the opportunity to have a longer duration between administrations. The ability of -- to formulate TYVASO or treprostinil at a concentration that allows a reduced number of inhalations allow the product known as TYVASO to have the characteristics it has.

Q. Let me ask you about paragraph 213 of your '240 declaration. The first sentence of paragraph 213 you state: "I understand that the examiner rejected each and every one of these secondary consideration arguments, and I agree especially in light of the teachings of Voswinckel and Ghofrani."

Do you see that?

A. I see that.

Q. And you don't cite any particular portion of the file history for that statement, correct?

A. I didn't cite it in this particular paragraph, no.

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Q. Did you have in mind when you wrote this sentence where the examiner rejected each and every one of the patent owner's secondary consideration arguments?

A. Again, I don't recall a specific section because, again, it's been a really long time since I looked at the file histories. I don't remember the sequence of rejections and responses and final determinations.

Q. Okay. But do you stand by the statement that the examiner rejected each and every one of the patent owner's secondary consideration arguments?

A. In the absence of being able to review the file history, yes. I believe that my understanding of the record as I read it and wrote my report is that the examiner rejected each and every one of the secondary considerations arguments.

Q. And do you know with respect to what claims the examiner rejected such arguments?

A. I have no recollection on the

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details of the -- again, the rejections and the responses and the rejections and the responses that are part of the file histories.

Q. You are obviously aware that some claims issued in both of the patents that are at issue in this case in the IPR proceedings, correct?

A. Well, that there are claims issued for the '507 patent and the '240 patent. So, yes, some claims issued.

Q. And that necessarily means the examiner found those claims to be non-obvious, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Again, those claims issued, but exactly what the patent examiner evaluated, how they made their determination to issue those is beyond my ability to comment on.

BY MS. ASCARRUNZ:

Q. And that includes the examiner's opinions with respect to objective indicia, correct?

MR. MATHAS: Same objection.

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BY THE WITNESS:

A. The claims issued. That's what I understand.

BY MS. ASCARRUNZ:

Q. I want to go back to our discussion about the word pulsed, and before we do that, let's maybe set the context and have both of the two patents at issue in front of you.

And looking to the '240 patent -- the '240 patent, do you agree with me that a requirement of the claims includes the use of a quote "pulsed ultrasonic nebulizer"?

A. Yes, in both claim 1 -- claim 1 in both the '240 and the '507 include the phrase pulsed ultrasonic nebulizer, and a POSA would understand that term to mean an ultrasonic nebulizer that's capable of delivering the aerosols in a pulsed manner.

Q. So your understanding of the word pulsed in the context of the claims of both patents is that it is -- that the phrase pulsed ultrasonic nebulizer means an ultrasonic nebulizer that is capable of delivering the

aerosols in a pulsed manner, correct?

A. Well, as I -- you know, as we read the remaining description about the pulsed ultrasonic nebulizer in claim 1, and I am looking at the '240 patent, it's requiring it to be able to deliver a fixed amount of treprostinil or pharmaceutically acceptable salt. So that fixed amount indicates that it's being delivered as a pulse where there's a pause in time where there's not delivery happening.

Q. In your reading of the claim, does it indicate how long that period of time is when there is a pause in time when there is not delivery happening?

A. No, I don't read anything into the claim regarding the amount of -- the length of the time interval.

Q. And there's nothing else in the claim that describes to you the length of the time interval?

A. Well, later in the claim it describes the number of breaths that might be used to administer a particular mass of the

drug treprostinil, and depending on what sequence of breaths somebody wanted to take, that indicates a possible amount of time that the total administration might take, but there's nothing within the claim that describes the specific length of time of the pulse.

Q. Okay. Focusing again on the use of the word pulse in the claims and not just speaking in the abstract general English terminology, but focusing on the use of the word pulsed in the claims, is it your opinion that an ultrasonic nebulizer with a constant output that has a switch you can use to turn the device on and off can be a pulsed ultrasonic nebulizer within the meaning of the claims?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I believe that an ultrasonic nebulizer that's capable of administering a fixed amount of the drug and then not -- not continue to aerosolized could be viewed as a pulsed ultrasonic nebulizer.

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BY MS. ASCARRUNZ:

Q. Is it your opinion that an ultrasonic nebulizer with a constant output that has a switch you can use to turn the device on and off can be a pulsed ultrasonic nebulizer within the meaning of the claims?

MR. MATHAS: Same objection.

BY THE WITNESS:

A. That same -- if the turning the switch off can discontinue the aerosol production and then switching the -- switching the nebulizer back on in whatever timeframe it is that is desired or required that delivers two pulses or if you switch it off again, it will deliver -- and switch it back on again, it will deliver three pulses of the medication.

BY MS. ASCARRUNZ:

Q. And in that instance then that would fall within the meaning of pulsed ultrasonic nebulizer in the claims?

A. Well, because it's aerosolizing a fixed amount of treprostinil, yes.

Q. Is it your opinion that an

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ultrasonic nebulizer with a timed uninterrupted stream of aerosol that lasts for ten seconds is a pulsed ultrasonic nebulizer?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. As long as the amount of aerosol is reproducible during the time that the aerosol is being produced and that there's a period of time where the aerosol is not being produced, that could be considered a pulsed delivery.

BY MS. ASCARRUNZ:

Q. Can a pulse within the meaning of the claims last more than one breath?

A. I don't see anything in the claims that indicates that there's a time duration requirement for the time between pulses. So there could be -- there could be other breaths between the breaths being used to inhale the aerosol.

Q. Okay. If a device has intermittent periods of aerosol generation and no aerosol generation, would this be pulsed according to your understanding of the use of

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the terminology in the claims?

A. Can you repeat that, please?

Q. Sure. If a device has intermittent periods of aerosol generation and no aerosol generation, would this be pulsed within the meaning of the claims?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I am still confused. One more time.

BY MS. ASCARRUNZ:

Q. Would it be considered pulsed within the meaning of the claims if a device were to have intermittent periods of aerosol generation and no aerosol generation?

So it switches back and forth from aerosol generation, no aerosol generation, aerosol generation, no aerosol generation.

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Yes, I believe that is within the definition of pulsed delivery from an ultrasonic nebulizer.

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BY MS. ASCARRUNZ:

Q. Okay. If a device is turned on to generate aerosol, turned off to cease the aerosol generation, put down, and then turned on again after a period of time to generate aerosol, would this be pulsed according to the meaning of the claims?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. It -- I would certainly consider it could be. There -- there are a number of different ways that someone might configure an ultrasonic nebulizer and a solution of drug and the need of a particular patient or group of patients or whatever that conceivably might include a longer non-aerosol generation period.

BY MS. ASCARRUNZ:

Q. Are you familiar with the term breath actuated in the art of inhalation therapy?

A. Yes, I am.

Q. If a device generates aerosol -- okay. In a breath-actuated device

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where the device delivers aerosol to the patient due to the patient's breathing -- I'm sorry. Let me start all over.

Can a breath-actuated device be a pulsed device within the meaning of the claims?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. It depends. If that breath actuated device is capable of or is designed to deliver that fixed amount regardless of the other factors in the patient inhalation, yes, it could be considered if it uses ultrasonic -- a pulsed ultrasonic device.

BY MS. ASCARRUNZ:

Q. And when you say regardless of the other factors in the patient inhalation, did you have specific factors in mind?

A. That most obvious is for how long does the patient inhale and how is the aerosol being formed during that time.

Q. Is the inspiratory flow of the patient also a factor?

A. That's very dependent on

the -- what's being emitted from the nebulizer whether the inspiratory flow add additional effects.

Q. In your mind or in your opinion, does the requirement in the claims of a pulsed device require that the pulse equates to one breath?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I think you could certainly be -- there are -- would be circumstances where, yes, it could equate to one breath and each breath is a breath that is utilized to inhale the aerosol, and I think there could conceivably be breaths where they were part of the pause.

BY MS. ASCARRUNZ:

Q. Okay. And could there also conceivably be more than one breath per pulse?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, if the pulsed ultrasonic nebulizer was configured as a breath-actuated nebulizer, there could be the possibility, but,

again, there's some additional requirements that aren't really clearly specified in the claim so.

BY MS. ASCARRUNZ:

Q. Okay. If I were to take a sort of standard asthma inhaler and take a puff and then wait a few seconds and then take another puff, is that pulse delivery?

A. Under sort of the POSA's understanding of pulse delivery versus multiple dose delivery, yes.

Q. Let me turn your attention to paragraphs 126 -- 126 of your '240 declaration -- '507 declaration. Thank you.

Do you see where you discuss that the primary purpose of using a pulsed nebulizer is to avoid wasting the drug that gets aerosolized while the patient is exhaling?

A. I see where it says that, yes.

Q. Is this the only possible purpose for using a pulsed nebulizer?

A. There are probably others, but this again is one of the key purposes for designing pulsed nebulizers or nebulizers that

pause when the patient is not breathing and the aerosol that's being formed.

Q. And how did you determine that this is the primary purpose?

A. It's based on my experiences and teaching and understanding of the field of nebulized drug delivery.

Q. Let me ask you to look at paragraphs 37 and 38.

Do you consider the HaloLite's device to being a pulsed nebulizer?

A. It's a breath-actuated or signaled-type nebulizer. I would have to look at the details I think again about the HaloLite to find out whether there's anything else beyond my description in this paragraph to make sure that it doesn't do something else that I wouldn't consider it being a pulsed nebulizer, but it has pause periods and periods that it produces aerosol or at least directs aerosol out the mouthpiece.

Q. Unfortunately, we don't have this one printed so let me ask you to get out the two patents again.

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Both patents contain a dependent claim limitation, and I will direct you to claim 4 of both patents where the single event dose produces a peak plasma concentration of treprostinil about 10 to 15 minutes after the single event dose, right?

A. Yes, that's what they say.

Q. What factors impact when the peak -- the time to peak plasma concentration will be?

A. The time to peak plasma concentration is highly dependent on the absorption rate of the drug at the site of administration, and the time indicated here is certainly in keeping with the times and the absorption rates known to occur in pulmonary delivery.

Q. Are time to peak plasma concentrations similar across all known inhalation therapies, or do they differ? Just leave it at that.

A. Well, they would differ between a material being administered as a suspension as compared to a material being

administered as a solution. As long as the material that was undissolved in the suspension actually continues to dissolve and be absorbed in the lungs, one would anticipate a different Tmax than --

THE COURT REPORTER: Wait. One would anticipate?

BY THE WITNESS:

A. A different Tmax, sorry, time to peak plasma concentration than -- I'm sorry, now let me -- so with a suspension formulation, one would anticipate as long as there was continued dissolution and then absorption of the drug that was delivered as the suspension, that that would have a longer Tmax than the same drug administered entirely in solution.

BY MS. ASCARRUNZ:

Q. So does the solubility of the drug impact the Tmax?

A. To be absorbed, the drug has to have been in solution, and the Tmax is affected by the absorption rate. So if there's continued dissolution and continued absorption, that will affect the Tmax because there's a

time lag for all of the drug to go into solution.

If the drug is presented in solution, it's there immediately and available for absorption. So the Tmax between those two situations would be anticipated to be different as long, again, as the drug that was administered in the insoluble form actually did continue to dissolve and be absorbed.

Q. So that's a, yes, the Tmax is affected by solubility?

A. No, it's not. It's affected by how you -- how you present the material that you are intending to be absorbed.

Q. Is it affected by drug concentration or volume?

A. That depends on the site of administration.

Q. So we are talking about inhalation administration.

A. Okay. And the Tmax might be affected by the -- more the volume of the aerosol than the volume of the aerosol droplets. It depends on the surface area

that's exposed that's available or that's able to absorb the drug, and the surface area that's exposed is another -- has other factors that influence it. The concentration of the drug. The concentration will affect the Cmax, the peak plasma concentration more than it's going to affect the Tmax.

Q. Is the time to peak plasma concentration affected by number of breaths?

A. Again, it -- that starts to become very dependent on the characteristics of the material that are being absorbed. So I would have to contemplate a specific material and characteristics and absorption rate to be able to draw some sort of estimate --

Q. Okay.

A. -- on that.

Q. In the context of inhaled treprostinil, does the time to peak plasma concentration depend on the number of breaths?

A. Well, I think I am going to have to think about that more. I really -- I don't know that I was -- I know I didn't provide an opinion on alterations in Tmax in my

declaration, and there are just a number of things that need to be held constant in essence for me to be able to answer that question. I'd have to think about what those all are and articulate them. I'd have to take some time to be able to identify that list.

Q. Okay. So based on that, I think I know the answer to my question, but I still need to ask it.

Sitting here right now without the benefit of that additional analysis that you said would prefer to do, are you able to articulate any factors that would affect the time to peak plasma concentration in the context of inhaled treprostinil?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I think I need a more specific question than that especially regarding what inhaled treprostinil are we talking about.

BY MS. ASCARRUNZ:

Q. What do you mean?

A. What concentration of solution are we -- is being inhaled? What particle size

is being inhaled? A number of other things.

Q. So would the concentration, particle size, dosage, a number of breaths, timing between breaths, would all of those factors affect the time to peak plasma concentration of inhaled treprostinil?

A. Well, there's certainly the chance that they could under the conditions that are being described in the '240 and the '507 patent. If we contain ourselves to that specific -- those specific ranges for treprostinil and the use of the ultrasonic nebulizers and the assumption that those are providing the appropriate particle size for inhalation delivery which is built into all of these claims, that the 10 to 15 minute -- that's the timeframe -- 10 to 15 minute timeframe for the Tmax is in keeping with the expectation of a POSA for the system that's described by the claims in the '507 and '240 patents.

Q. Okay. Do you agree with me that certain of the dependent claims in the patents relate to the micrograms of

treprostinil per breath?

A. Yes. For example, claim 6 in the '240 as a dependent claim describes at least 5 micrograms of treprostinil or its pharmaceutically acceptable salt.

Q. Does -- in the context of the administration of treprostinil under the claims, does the droplet size affect what the micrograms per breath would be, or can the droplet size affect what the micrograms per breath would be?

A. Only indirectly. The number of micrograms per breath is determined by the volume of aerosol emitted, and the actual deposition into the respiratory tract is certainly dependent on particle size. So indirectly, yes, but the direct delivery from the device is a function of the concentration of the fluid that's being aerosolized and the volume of -- the total volume of aerosol formed able to be inhaled.

Q. Does the microgram per breath inhaled by the human also depend on that person's breathing capacity?

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A. Depending on how the aerosol is -- how it forms, what its characteristics are, there certainly are characteristics of the aerosol that will be dependent on patient inhalation conditions. There are also characteristics of aerosols where the patient conditions are certainly significantly blunted. That they are not significantly dependent or that they don't offer -- or they don't result in a significant difference in the delivery. So it's again a more of a slightly more complicated interface between the aerosol being produced and the user.

Q. We talked about the two patients in Voswinckel that were treated for a longer term.

Are those two patients part of the 17, or is it 17 plus two patients that were treated in total in that study?

A. Based on the notation that the two patients who received the compassionate use treatment received it after the acute test, they would have been part of the 17 patients that underwent the acute test.

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Q. Okay. Let me ask you to turn to paragraph 126 of the '240 declaration.

MR. MATHAS: Veronica, when you get a chance, maybe we can take another or an afternoon break.

MS. ASCARRUNZ: Yeah, this is a great time actually. Are you ready to take a break?

THE WITNESS: Yes. That would be appreciate, thank you.

THE VIDEOGRAPHER: Going off the record. The time is 2:46 p.m.

(WHEREUPON, a recess was had at 2:46 p.m. until 3:05 p.m.)

THE VIDEOGRAPHER: Going on the record. This marks the beginning of media number 4. The time is now 3:05 p.m.

BY MS. ASCARRUNZ:

Q. Dr. Donovan, can you give me an example of an inhalation device that does not use pulsed delivery, and I should clarify within the meaning of the claims?

A. So ultrasonic nebulizers that couldn't be configured for pulsed delivery.

I'm -- I'm sure there is a nebulizer in a system. I would suspect that in particular if the formulation viscosity was somewhat higher than -- than water, the traditional formulations that are currently used, that the response time for the nebulizer might be such that it really wouldn't be effective in pulsed delivery. So that it would have to have a different sort of delivery time relationship, but, you know, it's not something I have spent any time thinking about.

Q. Okay. Fair enough.

In the course of our discussion today and in the course of your preparation for today, did you identify any portions of your declaration that are incorrect?

A. I continue to find typos that make me wonder why I hadn't seen them before or, you know, a word choice or something, but there's nothing of substance in my declarations that I have found that I no longer agree with or think need to be communicated in a different way.

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MS. ASCARRUNZ: Okay. I have no further questions at this time.

EXAMINATION

BY MR. MATHAS:

Q. Just a couple questions.

Dr. Donovan, early in your deposition, counsel for the patent owner asked you some questions about how you would go about researching a particular -- a scientific area of interest.

Do you recall those?

A. Yes.

Q. And you mentioned using some online databases and running searches.

Do you recall that?

A. Yes.

Q. How, if at all, would you have used information if you knew a particular researcher or group of researchers was interested in the topic of interest?

MS. ASCARRUNZ: Objection to form.

BY THE WITNESS:

A. Okay. You know, it's sort of the same process. Most of the databases that I

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mentioned so Web of Science, PubMed, International Pharmaceutical Abstracts, and chem abstracts for lack of a better phrase for what they are called, offers you the opportunity to search the authors. So I can --

THE COURT REPORTER: I'm sorry.

BY THE WITNESS:

A. I'm sorry. Offers the opportunity to search authors. So if there's a particular research group that I am interested in, I will just search based on the author, and that's the advantage of using Web of Science even is it gives -- it both gives the publications the author is named in, and it also gives easy access to all the people who have cited those same publications.

So you can expand your family of people of interest pretty rapidly. So just searching based on a particular group that I was interested in, knew that they were doing work is just as easy as doing a topic search.

BY MR. MATHAS:

Q. In your experience, Dr. Donovan, why do researchers present their

research at a conference?

A. They both want to demonstrate the things that they are doing that are -- and usually they're novel and hope people are interested in them and most of the time no people are interested in them because they are choosing topics that they know are pertinent to the particular group that they are presenting in front of, and they want to be able to describe the work they are doing before perhaps they even have enough data to completely write a manuscript and have that go through review and be published and so forth.

Now it's not quite as bad. Back in the day, manuscript writing to actual hard copy publication time might be a year and a half or longer when you got into the queue for particular journals. Now with electronic access that becomes less of an issue, but it became a -- that's why you present so that people understood what you were doing in realtime almost versus, you know, two years previous. It also allows you to find collaborators, people who are interested in the

same things, lots of other reasons why.

Q. And in your experience why, Dr. Donovan, are abstracts of presentations published?

A. Because they describe bodies of knowledge and bodies of work that people have been accomplishing. They are just not in the format for complete publication. When things are presented at meetings, there's a whole group of interested scientists who don't attend that meeting.

So you have the ability then as -- you know, with a published abstract to also inform others who weren't physically present at a meeting what took part, what was the latest information being presented, who is doing things in a similar area that people look at but just can't afford the time or the money to attend every meeting that something might be presented at.

MR. MATHAS: Thank you, Doctor. I have no further questions?

THE WITNESS: Okay. Thanks.

MS. ASCARRUNZ: No questions from

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me. Thank you for your time.

THE VIDEOGRAPHER: Going off the record. The time is 3:12 p.m.

(WHEREUPON, the deposition was concluded at 3:12 p.m.)

STATE OF _____)
) :ss
COUNTY OF _____)

I, MAUREEN DONOVAN, Ph.D., the witness herein, having read the foregoing testimony of the pages of this deposition, do hereby certify it to be a true and correct transcript, subject to the corrections, if any, shown on the attached page.

_____
MAUREEN DONOVAN, Ph.D.

Sworn and subscribed to before me,
this _____ day of _____, 2018.

_____
Notary Public

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OF

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That the foregoing deposition transcript was reported stenographically by me, was thereafter reduced to typewriting under my personal direction and constitutes a true and accurate record of the testimony given and the proceedings had at the aforesaid deposition;

That the said deposition was taken before me at the time and place specified;

That I am not a relative or employee or attorney or counsel for any of the parties herein, nor a relative or employee of

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IN WITNESS WHEREOF, I do hereunto set my hand and affix my seal of office at Chicago, Illinois, this 5th day of April, 2018.

Andrea L. Kim

ANDREA L. KIM, CSR
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After doing so, please sign the errata sheet and date it.

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