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

WATSON LABORATORIES, INC.,)
Petitioner,)
vs.) IPR NO. 2017-01621
UNITED THERAPEUTICS CORP.,) IPR NO. 2017-01622
Patent Owner.)

The videotaped deposition of MAUREEN DONOVAN, Ph.D., called for examination, taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before Lynn A. McCauley, CSR No. 84-003268, RPR, a Certified Shorthand Reporter of the State of Illinois, at 35 West Wacker Drive, 47th Floor, Chicago, Illinois, on May 24, 2018, at 9:41 a.m.

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I N D E X

WITNESS:
MAUREEN DONOVAN, Ph.D.

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THE VIDEOGRAPHER: We are now on the record.

Today's date is May 24, 2018, and the time is now 9:41 a.m.

This deposition is taking place at 35 West Wacker Drive, Chicago, Illinois.

The caption of this case is Watson Laboratories, Inc. versus United Therapeutics.

This case is being held in the U.S. Patent and Trademark Office before the Patent and Trial Appeal Board.

Today's witness is Maureen Donovan.

Will attorneys please identify themselves.

MS. ASCARRUNZ: My name is Veronica Ascarrunz from the law firm of Wilson Sonsini Goodrich & Rosati in Washington, D.C. I'm here representing the patent owner. With me is my co-counsel from Foley & Lardner, Natasha Iyer, also in Washington, D.C.

MR. MATHAS: Good morning. Kurt Mathas from Winston & Strawn on behalf of the petitioner, Watson Laboratories, Inc. and Dr. Donovan.

And joining me this morning are two summer associates from our office, Jacob Wilbers and Joe Anderson.

MAUREEN DONOVAN, Ph.D.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness.

(WHEREUPON, the witness was duly sworn.)

MAUREEN DONOVAN, Ph.D.

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

EXAMINATION

BY MS. ASCARRUNZ:

Q. Good morning, Dr. Donovan.

A. Good morning.

Q. You recall your first deposition in connection with the two IPRs at issue was taken last month; correct?

A. Correct.

Q. And at that deposition you answered my questions truthfully; correct?

A. Yes, I did.

Q. And have you had an opportunity to review the transcript from that deposition?

A. Yes, I have.

Q. Recently?

A. Relatively recently, yes.

Q. Are you aware of any incorrect testimony

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in that deposition?

A. No.

Q. And, as with your earlier deposition in this matter, you understand that you are to answer my questions truthfully; correct?

A. Correct. Yes.

Q. And, as before, please let me know if you don't understand any of my questions; and if you answer, I'll assume that you have understood; is that fair?

A. That's fair.

Q. You understand that there are two proceedings before the Patent -- the Patent and Trademark Office regarding two separate patents; correct?

A. Correct.

MS. ASCARRUNZ: Okay. And since those weren't read into the caption at the beginning, just for the record, those are case IPR No. 2017-01621 and case IPR 2017-01622.

And, Kurt, as we did before, can we agree that this transcript will be used in connection with both of those proceedings.

MR. MATHAS: We agree.

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BY MS. ASCARRUNZ:

Q. Dr. Donovan, do you agree with me that your testimony in connection with both of those two cases is consistent?

A. Yes.

Q. And throughout the deposition today, as you heard, we'll be using this in connection with the two different patents.

I will try to make clear when my questions relate only to one; is that fair?

A. That's fine.

Q. And I'll ask that if your answers depend on which patent we're talking about, to please also make that clear?

A. Okay. Thanks. Yep.

Q. Thank you.

Have you spoken with anyone besides counsel in preparing for this deposition?

A. No.

Q. Do you know who Christopher Butler is?

A. I'm aware of a witness in this case who has been referred to as Mr. Butler.

Q. Okay. Have you ever spoken with him?

A. No.

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Q. And you recall that there is a district court litigation between the two parties concerning the same patents; correct?

A. Yes, I do.

Q. And you were deposed in that proceeding as well?

A. Yes, I was.

Q. Have you had the opportunity to review your deposition from that proceeding recently?

A. Meaning relatively recently.

Q. Okay. Have you reviewed the patent owner response filed in connection with these IPRs?

A. I reviewed something I recall being titled a patent owner response. There are a number of patent owner documents that I've seen that I -- you know, if there's a specific question or something, I don't remember which document is which, but I think I've seen something titled "The Patent Owner Response."

Q. Okay. And have you reviewed a declaration from a Dr. Aaron Waxman in connection with the two IPRs?

A. Not to my recollection.

Q. Have you reviewed a declaration from a

Dr. Richard Delvi (phonetic) in connection with the two declarations?

A. Yes, I've reviewed that declaration.

Q. Do you -- so there were two declarations by Dr. Delvi. I'm trying to understand which -- do you know if you've seen one or two of those declarations?

A. I'm not sure.

Q. Okay. Fair enough.

In the course of research in your professional capacity, do you regularly rely on research you perform in the European Union Community Register?

A. I more typically rely on information that's available from the FDA being a U.S.-based organization. I'm certainly aware of the European Union and the EMA and their methodologies for drug approving, and so I would know to go look there if what I was looking for wasn't currently available as information at the FDA.

Q. Okay. I know at the last deposition we covered a large volume of materials. I'm going to put some of those in front of you, not to sort of overwhelm you, but just so you have them in front of

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you if you need to reference them at any point, and you should be familiar with all of them so.

A. Okay.

MS. ASCARRUNZ: And, for the record, this will be Exhibit 1001 from Proceeding 2017-01621, which is U.S. Patent No. 9,358,240.

And then Exhibit 1001 from IPR Proceeding 2017-01622. This one is U.S. Patent No. 9,339,507.

And then Exhibit 1002 from IPR Proceeding 2017-01621, titled "Expert Declaration of Maureen D. Donovan Ph.D."

Exhibit 1002 from IPR proceeding 2017-01622, entitled "Expert Declaration of Maureen D. Donovan Ph.D."

BY MS. ASCARRUNZ:

Q. So I just want to make sure at the outset -- and you can take your time to glance through them -- you're familiar with these four documents; right?

A. I am, yes.

Q. And in your declarations, which are both Exhibits 1002 there, you refer to combinations 1, 2, and 3 for the '240 patent; correct?

A. Yes.

Q. And in connection with the '507 patent declaration you also rely on Combinations 1, 2, and 3?

A. Yes, I do.

Q. And in Combination 3 for each of the proceedings you rely on what you called the EU Community Register; right?

A. Yes.

Q. And in Combination 2 for each of the proceedings you rely on what you called the OptiNeb-ir user manual; right?

A. That's correct.

Q. And you're also an expert for Watson in the district court proceeding between the parties related to these same patents; correct?

A. Yes, that's correct.

Q. And in that proceeding you also offered opinions that the patents at issue here, which are Exhibits 1001 in front of you, are obvious; right?

A. Yes.

Q. And in that proceeding you also offered opinions based on the OptiNeb device as prior art; right?

A. I think -- and there's certainly discussion in that expert report about the OptiNeb device and some of the generations of OptiNeb.

Q. Okay. And in that proceeding you also offered opinions based on the Venta-Neb device; correct?

A. Yes, I did.

Q. And in your professional experience before you were engaged by Watson to opine on these patents, you were not familiar with Ventavis; correct?

A. Not distinctly, no.

Q. And you were not familiar with OptiNeb; correct?

A. Again, it was one of a number of devices. I probably was aware of it, but I didn't have any specific knowledge of it.

Q. Okay. And before these proceedings you never came to be familiar with the features of the OptiNeb devices; correct?

A. Not in detail.

Q. And you've never seen an OptiNeb or a Venta-Neb device in person; correct?

A. Not to my recollection.

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Q. And you were not familiar from a professional standpoint with treprostinil before these proceedings; correct?

A. Not in any specific research oriented sense.

Q. And I think you mentioned earlier in response to one of my questions.

You understand that there were multiple generations of OptiNeb device; correct?

A. Yes, I do.

Q. And you understand that there the multiple generations of the Venta-Neb device; correct?

A. I guess I'm less familiar with the generations of Venta-Neb device.

Q. Okay. And you don't have any specific knowledge of whether the OptiNeb-ir was a single device versus having multiple models that were termed OptiNeb-ir; correct?

A. Again, I would -- would need some further information to try to discern what -- what a brand name covered at any given time.

Q. And without seeing that further information, do you know in the course of your work

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in this proceedings whether that is the case?

A. I'm sorry. Can you repeat the question?

Q. Sure. Let me rephrase it.

Without further information do you have current knowledge of whether the OptiNeb-ir device encompasses a single device or multiple models?

A. Well, I think it comes down to what you -- what -- what I might define as a model difference and what the designer of that device might determine to be a -- you know, a change in the current model or what I might discern to be a simple change in the current model that the -- a slight change in the current model that the -- the manufacturer decided to rename as a -- as a next generation.

I think knowing what the changes were from the device from -- from known change to known change or discernable change to discernable change, I think is somewhat up to the person reviewing the change and the magnitude that that made a difference.

So I'm -- I'm aware that the Nebu-Tec company named their devices slightly

differently. Each of those devices has different capabilities.

What's really a model change or whatever, I -- I would need more information and probably a -- I -- I may or may not reserve my own opinion on whether that was really deserving of a model change or not.

Q. Are you aware of model numbers used by Nebu-Tec in connection with the OptiNeb-ir designation?

A. Not specific model numbers without, you know, some sort of context for reference.

Q. Okay. You reviewed and relied to some extent on the prosecution histories for these two patents in connection with your opinions; correct?

A. Yes, I did.

Q. And you are aware that during prosecution of the patents the examiner considered the Chaudry reference you rely on; correct?

A. Yes.

Q. And you are aware that during prosecution of the patents the examiner considered the Venta-Neb device and Ventavis; correct?

MR. MATHAS: Object to the form.

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BY THE WITNESS:

A. It's been quite awhile since I've reviewed the file history. I -- I just -- I don't remember.

BY MS. ASCARRUNZ:

Q. Okay. So is it fair to say you also don't remember whether the examiner actually cited this art against the applications during prosecution?

A. I guess I'd like to refer to the section where the examiner made comments about that art to refresh my memory.

Q. Okay. Did you take into consideration in forming your opinions what the examiner stated in connection with certain prior art references?

A. Oh, I certainly -- when I read the file histories, I certainly take into account what the examiner viewed, but the file histories represent a relatively reasonably long period of time with changes and so forth.

I -- there were other things probably that the examiner had in front of them that aren't necessarily directly part of the file history so -- so, yeah, I certainly consider the comments of the examiner, but they're performing a job in a way

that I'm unfamiliar with really what -- what the progress of that evaluation is, so I can't always say that at any given -- on any given page that what the examiner was determining at the time stays with me or really significantly informed my opinion.

Q. Okay. Are ultrasonic nebulizers preferable to the air jet nebulizers?

A. They're a different type of nebulizer.

The ultrasonic nebulizer has its own attributes that a jet nebulizer doesn't.

There are aspects of jet nebulizers that are distinct to what ultrasonic nebulizers are capable of.

So each one has some attributes, each has drawbacks.

There are -- there would be reasons why one would select an ultrasonic nebulizer. There would be reasons now post -- or now that there are availabilities of other types of nebulizers to select those.

It's very much a -- a -- it's a situational evaluation of whether one might be considered better than the other for a particular application.

Q. And in 2006 were ultrasonic nebulizers preferable to air jet nebulizers?

A. Again, I don't think that anybody would ever in a generalizable fashion say that they were always preferable over jet nebulizers. They had specific attributes to them. Many -- the portability of ultrasonic nebulizers compared to the portability of many of the jet nebulizers was a significant attribute, and patients appreciated that.

So there are times where if one could use an ultrasonic nebulizer, you'd select that just because you knew that your patient population would like the opportunity to have something that's slightly smaller and more portable to carry with them. But that wouldn't always -- it doesn't mean that it's always better.

Q. So based on your responses, is it fair to say that there would be times when jet nebulizers would be preferable over ultrasonic nebulizers under certain circumstances?

A. You know, it varied dependent on the circumstance which -- how you'd evaluate which nebulizer to select based on what performance criteria you desired.

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Q. But you're unwilling to say that ultrasonic nebulizers in 2006 were universally preferable to jet nebulizers?

A. I think there --

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I think there may be under certain criteria that nearly everybody would select a ultrasonic nebulizer.

So if your criteria was based on portability, for example, I think in 2006 probably everybody would recognize that an ultrasonic nebulizer was -- was slightly smaller and more portable.

It also was subject to more readily -- or it was more readily damaged by having it be portable, so there were some -- even some drawbacks with that.

But, you know, I don't think that there was a lot of controversy on that portion of the functionality.

But a number of the other aspects and, again, costs and ability to -- or the resistance to -- to mishap may have overweighed the portability

for a particular use.

Q. I'm sorry. What do you mean by resistance to mishap?

A. Well, knocking it off of a table and not have -- and having to immediately replace it because it no longer worked.

Q. In addition to portability, are there other considerations that would inform the selection of a jet versus ultrasonic nebulizer?

A. I mean certainly there are other considerations, but we very quickly get into considering -- you need to know something about the -- why you're either considering comparing those two, what -- what is your intended purpose, what are your -- what are your goals for comparing them.

So it's really hard just in the abstract to -- to say, well -- it's easy in the abstract to say, yes, you would compare them, but how you would compare them outside of a specific reason for comparing them is very difficult to do.

Q. Okay. Nevertheless I'm going to ask you some questions --

A. Okay.

Q. -- trying to compare them.

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Do ultrasonic nebulizers and air jet nebulizers differ in connection with considering output rate?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, they have different design specifications, and so in the world of jet nebulizers there's probably a range of outputs. It may be very different if you -- that range may be narrowed for pharmaceutical nebulizers compared to other reasons you'd use a jet compressed air what was -- what is essentially a nebulizer.

Same thing for ultrasonic nebulizers. So if you -- actually reask the question, and let me see if I can get to a more -- a more defined answer.

Q. Sure.

So the question was: Do ultrasonic nebulizers and air jet nebulizers differ in connection with considering output rate?

MR. MATHAS: Same objection.

BY THE WITNESS:

A. Yeah, again, I -- it's so dependent on their -- the design of the actual system and the

intended purpose for designing the system that they're pretty broad ranges that cover both of them regarding output rates.

BY MS. ASCARRUNZ:

Q. Are there differences in how ultrasonic nebulizers and air jet nebulizers affect particle size?

A. Well, they accomplish forming particles or droplets in different ways, so they -- like -- they -- as far as nebulizers and ultrasonic -- or as far as jet nebulizers and ultrasonic nebulizers used for pulmonary inhalation, there's a particular size range that is oftentimes a goal to achieve, and so the -- those pieces of -- or those devices are intentionally designed to maximize the droplet size in the range that's deemed to be beneficial for pulmonary delivery.

Whether they -- what the -- what the dist -- particle size distribution looks like and so forth around those is somewhat dependant on the actual type of nebulizer and how it was designed, so they -- they -- they differ in how each of them forms the droplets, so, therefore, there are different characteristics of those droplet particle size

distributions that's observed between them.

Q. Are you aware of any difficulties ultrasonic nebulizers face in aerosolizing certain types of formulations?

A. Yes, I am aware of situations where it would be less likely for the particle size -- the desired particle size or droplet size to be emitted from an ultrasonic nebulizer. Similar to there are different -- there are other situations where fluids used in jet nebulizers that I would anticipate they would have -- they would be more challenging potentially to be able to develop into the desired particle size range from -- for a pharmaceutical use.

Q. Are you aware of any situations with those challenges that are specific to ultrasonic nebulizers versus jet nebulizers?

A. I've been aware of them at times because I lecture on the differences. I just can't bring to mind what the specific differences are at this moment.

Q. Okay. In your opinion is pulse nebulization preferable to continuous nebulization?

A. Again, it depends on the use. It depends on the user. In -- I think in many situations the --

the ability not to have a -- a wasting of the aerosol being continuously produced to the environment or needing to add additional tubing or aspects to the device to capture that and redirect it back to the -- the -- the filled volume for nebulization is -- is certainly of benefit.

So you need -- you need to do more things to capture an aerosol. So if you -- than if you didn't have that aerosol being formed continuously.

So there are certainly -- there are certainly advantages both from a -- a device and environmental standpoint for having a -- a device that emits the desired aerosol when -- when you want it to and doesn't emit it when you're not able to use it.

Q. And in your opinion -- in -- it's your opinion that continuous nebulization is never preferable to pulsed nebulization; correct?

MR. MATHAS: Object to form.

BY THE WITNESS:

A. Yeah, I don't think it was never preferable.

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BY MS. ASCARRUNZ:

Q. In your opinion having a patient coordinate its breathing to the output and timing of a device is preferable to breath-actuated devices; right?

A. I don't know that I've ever expressed that opinion either, that -- there are virtues of both. The design aspects of one are different than the design aspects of the other, so they certainly contribute to cost and so forth, but being able to assure that the patient -- for a nebulizer, for example, being able to assure that the patient inhales the medication when the device is delivering the medication is the essential portion.

MS. ASCARRUNZ: Okay. I'm going to hand you another exhibit. And, for the record, this is Exhibit No. 1006 in both proceedings.

BY MS. ASCARRUNZ:

Q. And I see you're flipping through it, so I'll give you my question so you can keep it in mind when you flip.

Do you recognize this exhibit?

A. Yes, I do.

Q. What is it?

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A. This is a -- I believe this is a translation -- yes. This is a translation of the OptiNeb-ir operating instructions.

Q. Is this the reference you rely on for your Combination 2 as the OptiNeb-ir user manual?

A. Yes, it is.

Q. Did you locate this reference, or was it provided to you by counsel?

A. The -- the translation was provided to me by counsel.

Q. And was the original German version located by you, or was it provided to you by counsel?

A. That was also provided by counsel.

Q. You offer opinions about what this manual teaches a POSA; correct?

A. Yes, I do.

Q. So I understand that, but my question -- and my question is going to be are -- but you're not offering an expert opinion that this exhibit qualifies as prior art under the law; correct?

A. I don't know that I'm able to make that determination, but I am aware that -- that this device was available at the time that we're speaking, usually 2004, 2006 type dating; and so the device

was -- the device -- the OptiNeb device was being used. I know that the Nebu-Tec company was selling that device, was interested in having pharmaceutical companies and individuals use their devices; and so being able to obtain the user manual for a device that was commercially for sale, whether it was -- whether I accessed it, whether somebody accessed it, I didn't look for it in 2004, but it would have been easily obtainable.

MS. ASCARRUNZ: Okay. That wasn't my question.

And I move to strike it as not responsive.

BY MS. ASCARRUNZ:

Q. Dr. Donovan, in your declarations do you offer an expert opinion that the OptiNeb user manual meetings the legal requirements of public accessibility?

A. Well, in my opinion on Page -- or Paragraph 55 I believe --

Q. Which document are you looking at?

A. Oh, I'm sorry. I'm looking at my expert declaration in the '507 case.

So in Paragraph 55 I describe how

the -- the OptiNeb device is described in an abstract available publicly in the fall of 2000 -- and was presented in the fall of 2004 by a group of investigators, and then later in Paragraph 61 I describe that the OptiNeb device was detailed on the Nebu-Tec website by at least 2003 referring to a -- probably the same exhibit, different exhibit number, and I use the information provided to me by other witnesses who are able to assure that that information was available in that website in 2003.

Q. So your answer to the question I asked is, yes, in your declarations you offer an expert opinion that the OptiNeb user manual meets the legal requirements of public accessibility?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I mean there are -- there are descriptions in my expert declaration that state that the OptiNeb -- information about the OptiNeb device was available in 2004.

BY MS. ASCARRUNZ:

Q. So I'm not asking about the OptiNeb device. I'm asking about the OptiNeb user manual.

A. And my --

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MR. MATHAS: Object to the form. There's no question pending.

BY MS. ASCARRUNZ:

Q. So my question is, and was, for the third time: In your declarations you offer an expert opinion that the OptiNeb user manual meets the legal requirements of public accessibility; correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Again, I'm -- I'm not in a position to be able to discern whether it meets the legal requirements or not.

In my experience the -- I understand that the OptiNeb device was being used by investigators in 2004. There were user manuals associated with all of those devices as they were provided by the company.

And Nebu-Tec was interested in -- in providing their device for use, so being able to obtain the user manual would have been a simple activity requiring communication either with an investigator who was using it or the company who was supplying it.

I have provided a copy of the user

manual that was -- that was available on their website in 2004. I wasn't the one who obtained that from the website in 2004.

BY MS. ASCARRUNZ:

Q. Dr. Donovan, you are aware that there were multiple devices that were termed OptiNebs; correct?

A. Yeah, as they -- as a parent name, yes.

Q. And not all OptiNebs were pulsed nebulizers; correct?

A. Not all of the OptiNebs were only -- well, it's my recollection that the very earliest of OptiNeb devices was programmed to be a continuous delivery, but it could be operated in a pulsed fashion by -- by sort of a user interface if needed.

Q. And that's because it's your opinion that in a continuous device where the user can turn it on and turn it off, that is being used in a pulsed manner; correct?

A. That gives a pulsed dose, yes.

Q. You point to the manual or -- yeah, the user manual, Exhibit 1006, as demonstrating six different programs; right?

A. Yes, I do.

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Q. And the manual has very detailed information on the proper use and capabilities of those programs; right?

MR. MATHAS: Object to form.

BY THE WITNESS:

A. Well, it contains information about the different programs.

In a user manual it is written such that for the general user who doesn't have a scientific training or a training in device design or whatever that there are things that the user should be dissuaded from doing.

And so the instructions in a user manual don't necessarily limit a person with more experience from using that information and applying it in a different way than what -- what the manufacturer wants the users to use -- how they want the users to use them because that was the design, and used inappropriately the manufacturer doesn't have -- they -- they don't want to have the responsibility for an undesired effect when somebody used their device inappropriately.

BY MS. ASCARRUNZ:

Q. The question I asked was: The manual has

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detailed information on the proper use of those programs; correct?

MR. MATHAS: Object to the form. That's not precise question you asked.

BY THE WITNESS:

A. Well, the user manual contains descriptions, as they call them, and features of those programs.

That's the terminology being used in that section.

BY MS. ASCARRUNZ:

Q. Okay. Great. Thank you.

And the manual explains how those features can be implemented; right?

A. In a general sense, yes, they're trying to communicate what the features of those programs are and what their initial design -- or maybe not even initial, but under the -- the limitations of a user manual what -- how those features describe how the OptiNeb-ir is used or can be configured for that particular user.

MS. ASCARRUNZ: Okay. The next few questions I'm going to ask relate only to your declaration in connection with the '240 patent.

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MR. MATHAS: And, Veronica, you said the next few. Will you indicate when you are moving back to general questions.

MS. ASCARRUNZ: I will, yes.

MR. MATHAS: Thank you.

BY MS. ASCARRUNZ:

Q. And, in particular, so you know where I'm looking, I'm particularly focused on the discussion starting at Page 69 of that declaration entitled, "Combination 2" and the paragraphs that follow from that in that entire section.

A. Okay.

Q. So my question is: You are not relying on the OptiNeb-ir user manual for the additional limitations in Claims 2 -- well, let's do it one by one -- in Claim 2; correct?

A. Well, Claim 2 of the '240 patent reads: "The method of Claim 1, wherein the formulation comprises 600 micrograms per mil of the treprostinil or its pharmaceutically acceptable salt thereof.

And so Claim 2 refers back to Claim 1 as a dependent claim, and I believe in Claim 1 I am relying on the OptiNeb-ir user manual.

Well --

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Q. Sure. I under --

A. Yes.

Q. Are you done?

A. So -- so in my opinion about Claim 2, since Claim 2 relies -- or is dependent on Claim 1, the things I relied on for Claim 1 also would be relied opinion for Claim 2.

Q. Okay. Certainly. I understand that.

And that would be the case for all of the dependent claims as well; right, Claims 2 through 9?

A. Yes.

Q. Okay. The question I asked, and just to highlight the specific word that makes it a little bit different than the question you answered.

I asked whether you are relying on the OptiNeb-ir user manual for the additional limitation in Claim 2?

A. And so --

Q. Understanding, of course, that you are relying on what's brought in from independent Claim 1?

A. Okay. So the limitation regarding the specific concentration of treprostinil or its

pharmaceutically acceptable salt?

Q. Yes. The 600 microgram per mil.

A. Okay. And, no, I'm not relying the OptiNeb-ir user manual to describe the 600 microgram per mil concentration of treprostinil.

Q. Okay. And are you relying on the OptiNeb-ir user manual for the additional limitation in claims -- in Claim 7?

A. The -- so I -- the additional limitation I assume that -- or I understand you to mean is the single event dose is inhaled at 3 to 18 breaths by the human.

And the OptiNeb-ir user manual allows for a variety of numbers of breaths that a user would be able to -- to use as a single event dose, so a -- whatever the -- or the OptiNeb-ir user manual doesn't direct that specific subset but that specific subset is certainly within all of the information encompassed in the OptiNeb-ir user manual regarding the use of -- of the OptiNeb-ir nebulizer.

Now, the one thing to note about this particular user manual is it's directed at using the OptiNeb-ir for ventilation, so it's -- it has some additional information about how to -- how to

set up the ventilators and so forth.

So it's less likely that this version would speak to specific numbers of breaths, but a similar user manual for the same nebulizer used for -- for non-ventilation purposes would, again, leave open the possibility to however many breaths a user and their physician or -- or someone who was directing them how to use that.

3 to 18 is just a subset of the possibilities.

Q. Nowhere in your declaration do you address the limitation of Claim 7 in connection with the OptiNeb-ir user manual; correct?

MR. MATHAS: Object to the form.

THE WITNESS: Can you restate that question, please?

BY MS. ASCARRUNZ:

Q. Nowhere in your declaration do you address the additional limitation of Claim 7 in connection with the OptiNeb-ir user manual; correct?

MR. MATHAS: Same objection.

BY THE WITNESS:

A. Well, in Paragraph 80 where I'm talking about the additional limitations of Claims 2, 7, and

8, that paragraph describes that Voswinckel is sufficient to teach that, and a POSA would understand that the OptiNeb device is certainly capable of meeting the description of the number of breaths in that claim.

MR. MATHAS: Dr. Donovan, I believe in your answer you said Paragraph 80, but I believe you might be looking at something different.

THE WITNESS: Oh, I did. I was looking at Paragraph 180. Sorry if I misspoke.

BY MS. ASCARRUNZ:

Q. Nowhere in your declaration do you express what you just stated.

That a POSA would understand the OptiNeb device is certainly capable of meeting the description of the number of breaths in that claim; correct?

A. My -- my declaration does not contain that explicit statement, and there -- I don't speak directly to what a POSA would recognize regarding the OptiNeb-ir device being able to be configured so that an individual could breathe -- take 18 breaths or however many breaths was desired from that -- from that nebulizer, but it was well-known that nebulizers

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are designed to be used with a variety of different breath numbers.

MS. ASCARRUNZ: I move to strike the latter part of that answer as not responsive.

BY MS. ASCARRUNZ:

Q. Dr. Donovan, in connection with dependent Claim 8, nowhere in your declaration do you express an opinion that the OptiNeb-ir user manual discloses the additional limitation of dependent Claim 8; correct?

A. Again, in a similar manner in Paragraph 180 I describe how in the context of using Voswinckel, Patton, and Opti-Neb -- the OptiNeb-ir user manual, that Voswinckel sufficiently describes Claim 8, yet a POSA would understand that the OptiNeb-ir, based on the user manual, just based on an understanding of nebulizers, was able to be used with a variety of different breath numbers.

MS. ASCARRUNZ: I, again, move to the strike the latter part of that answer as not responsive.

BY MS. ASCARRUNZ:

Q. Dr. Donovan, you've referred to Paragraph 180 a few times now, and in its entirety it states: "As explained in connection with Combination 1,

Voswinckel alone teaches the required additional limitations of Claims 2, 7, and 8"; correct?

A. That's what it states, yes.

Q. It doesn't say anything there about a POSA and the OptiNeb-ir user manual; correct?

A. That -- that paragraph does not explicitly have words including statements about the OptiNeb-ir user manual, yet the entire description is under the subheading of being -- using the combination of Voswinckel, Patton, and the OptiNeb-ir user manual.

Q. Okay. And in the entire subheading of the -- Subsection B, including Paragraphs 180, 181, 182, you don't mention the OptiNeb-ir user manual in any of those paragraphs; correct?

A. I do not mention the OptiNeb-ir user manual specifically in any of those numbered paragraphs, yet in the context of Point B where the combination makes those obvious, the POSA certainly has a knowledge of the OptiNeb-ir user manual in that evaluation.

Q. So since a POSA has knowledge of the OptiNeb-ir user manual in the evaluation of dependent Claims 2, 7, and 8, it is your opinion that a POSA

would consider the OptiNeb-ir user manual in assessing what you call Combination 2; correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, again, as I stated before, the -- the POSA would certainly be well aware that the OptiNeb-ir, based on the user manual, or based on just knowledge of nebulizers and ultrasonic nebulizers, that -- that those nebulizers are designed to be used to -- to deliver multiple doses, multiple breaths; and so that -- any of the statements regarding the dependent claims are made in context with that. It's in perfect keeping with what a POSA understands about an ultrasonic nebulizer and the OptiNeb-ir nebulizer in particular.

BY MS. ASCARRUNZ:

Q. Let me direct your attention to Paragraph 170.

A. 170?

Q. Yes.

A. In my '240 declaration?

Q. Correct.

A. Right.

Q. In there you state that: "The preamble

and Limitations A, B, B1, and C" -- of Claim 1 -- "would have been obvious over Voswinckel in view of Patton"; correct?

A. That's what it states, yes.

Q. And in the following paragraph you indicate that you have been asked to alternately consider whether Limitation D would have been obvious in reference to the OptiNeb-ir user manual in place of Ghofrani; correct?

A. That's what it states.

Q. And you continue that you explain below that the Limitation D would have been obvious over Voswinckel in view of Patton and the OptiNeb-ir user manual; correct?

A. That's what it states.

Q. That paragraph does not purport to state that you were asked to consider whether anything other than Limitation D would have been obvious in view of the OptiNeb-ir user manual; correct?

A. Well, Paragraph 171 describes a specific aspect that I was asked to consider, but it doesn't mean that there was a lack of consideration of the OptiNeb-ir capabilities with reflection to the rest of this specific claim or the other claims presented.

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As -- as -- as a POSA the -- the claims have to -- I have to be -- well, the -- the claims descriptions themselves and specific pieces of art that I -- I use to describe what was known in the art doesn't mean that I've evacuated my brain from consideration of anything else during that particular evaluation, so, again, in 171 I was certainly asked to consider this directly, but it doesn't mean I was absent of consideration or thought about the OptiNeb-ir during the rest of my evaluation of the '240 or the '507 patent claims.

Q. Okay. So I'm not asking what is in your brain. I'm asking what did you express to the Patent Board, and my question is -- well, are you saying then that you have considered certain things in forming your opinion that are not expressed in this declaration?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. That's not specifically what I'm saying. I mean there's many things that I -- I have thought regarding these claims and so forth, not all of which are recorded because it's -- it would be impossible to do that; but in the case of Paragraph 171, that

was a succinct description of a particular combination of pieces of art that I used to -- to evaluate Claim 1 of the 240 patent, and that was -- to make that statement that is -- that -- even though I was aware of other art, those pieces of art were sufficient to describe the art known regarding Claim 1.

BY MS. ASCARRUNZ:

Q. Okay. And in this section talking about Claim 1 of the '240 patent in connection with Combination 2, the only subsection is in connection with Limitation D; correct?

A. As -- as this -- as I designed this report, yes, in this particular section I simply highlighted the difference regarding the limitation -- limitation -- or the Limitation D of Claim 1, yet all of the description previously in the report regarding Claim 1 and some of the other references -- or the other art that was evaluated is part of -- is part of this discussion, too. It's already been -- but it's already been described, so it wasn't repeated.

Q. Okay. So my question is only about the OptiNeb-ir user manual.

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In your report do you express a specific opinion that the OptiNeb-ir user manual teaches any limitation of Claim 1 that is not Limitation D?

A. Can you reask the question?

Q. Yes.

In your report do you express a specific opinion that the OptiNeb-ir user manual teaches any limitation of Claim 1 that is not Limitation D?

And, I'm sorry. Let me rephrase that because I said report instead of declaration.

In your declaration do you express a specific opinion that the OptiNeb-ir user manual teaches any limitation of Claim 1 that is not Limitation D?

A. Well, I certainly don't remember every instance of my descriptions of the OptiNeb user manual throughout my declaration, so I could go back and look for all of those, but in keeping with this particular Combination 2, my -- my approach is that the combi -- the combination of Voswinckel, Patton, and the OptiNeb user manual make -- are all -- those pieces of prior art make Claim 1 obvious.

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Now, I specifically made a point about Limitation D and the relationship to what one would learn from the OptiNeb-ir user manual for Limitation D, but it's -- this section, again, speaks to the combination of those references, so whether explicitly stated or not, that combination of references is being evaluated in terms of these claims.

Q. So you're saying you implicitly considered the OptiNeb-ir user manual in connection with Limitations A, B, B1, and C?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, I'm saying as a POSA I know what the information is in the OptiNeb-ir user manual, and it's nearly impossible for me to not have that be the -- be contextual information regarding my opinions, and how I have stated information in this expert declaration of how I've arrived at using specific pieces of art in combinations to arrive at those opinions.

BY MS. ASCARRUNZ:

Q. You said that in this section you specifically made a point about Limitation D.

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In this section you did not specifically make a point about Limitations A, B, B1, and C in connection with the OptiNeb-ir user manual; correct?

A. Not specifically in this section; but, again, this section is a subsection of Point No. 2, which is speaking to the combination of Voswinckel in view of Patton and the OptiNeb-ir user manual.

Q. Okay. And where in Section 2 where you discuss Combination 2 do you address Limitations A, B, B1, and C?

A. Okay. Again, in -- in an effort to keep the number of pages to -- or the -- or the succinctness of this report that A, B -- oh, let me use the letters -- let me see if I can -- A, B, B1, and C and my evaluation of A, B, B1, and C regarding their obviousness specifically with Voswinckel and Patton as pieces of prior art was described completely in Combination 1, and it's still the same description. I just didn't cut and paste that entire description and put it in Combination 2.

Q. Okay. And the OptiNeb-ir user manual is not a component of Combination 1; correct?

A. That's correct. The OptiNeb user -- ir

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user manual is -- is not a specific piece of prior art that was used in my evaluation of Combination 1.

MS. ASCARRUNZ: We've been going for a little over -- well, a bit over an hour, so this is a good time to break if you'd like one.

THE WITNESS: Sure.

THE VIDEOGRAPHER: Going off the record at 10:49 a.m.

(WHEREUPON, a recess was had.)

THE VIDEOGRAPHER: Going on the record. This marks the beginning of Media No. 2.

The time is now 11:07 a.m.

BY MS. ASCARRUNZ:

Q. Okay. Dr. Donovan, I promised I would tell you when we stopped talking about '240 declaration, and now we're going to talk about just the '507 declaration.

A. Okay. I'll switch.

Q. And if it's helpful to you, I'm looking at Paragraph 182 and 183; but, of course, you're free to look wherever you need to to answer my questions.

A. Okay.

Q. So in connection with this '507

declaration, you are relying on the OptiNeb-ir user manual for Limitations B and C; correct?

A. I'm going to try to get my bearings on where I am first.

Q. Sure. Take as long as you need to answer.

A. Okay. Can you state the question, please?

Q. Sure.

In connection with this '507 declaration, you are relying on the OptiNeb-ir user manual as disclosing or making obvious Limitations B and C; correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, again, the -- the prior paragraphs describe some of the considerations of the OptiNeb and of the user manual in my considerations, so in Paragraph 182, while it may not be explicitly stated, and certainly Limitations A and D could have been evaluated and found to be obvious with just Voswinckel and Chaudry, again, there's -- this is -- Voswinckel, Chaudry, Patton, and OptiNeb-ir is the combination that's being described in this section.

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Q. My question again is: In connection with this '507 declaration, you are relying on the OptiNeb-ir user manual as disclosing or making obvious Limitations B and C; correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, in Paragraph 183 I certainly state that in specific reference to the OptiNeb-ir user manual regarding Limitations B and C, that it's -- that B and C are -- are obvious over Voswinckel in view of Chaudry, Patton, and the OptiNeb-ir user manual.

BY MS. ASCARRUNZ:

Q. So, yes, in connection with the '507 patent, you are relying on the OptiNeb-ir user manual as making obvious Limitations B and C; correct?

A. And, again, as I stated before, this entire section is about the combination of Voswinckel, Chaudry, Patton, and the OptiNeb user manual; and in Paragraph 183 I explicitly state that the OptiNeb user manual contributes to concluding that the Limitations B and C are obvious.

Q. Okay. Fair enough.

So in connection with the

'507 patent, you rely on the OptiNeb-ir user manual as making -- strike that. Start over.

In connection with the '507 patent, it is your opinion that Limitations B and C are obvious over Voswinckel in view of Chaudry, Patton, and the OptiNeb-ir user manual; correct?

A. Can you ask that again, please?

Q. In connection with the '507 patent, it is your opinion that Limitations B and C are obvious over Voswinckel in view of Chaudry, Patton, and the OptiNeb-ir user manual; correct?

A. Yes, as stated in the last sentence of Paragraph 183.

Q. You do not rely on the OptiNeb-ir user manual as making obvious or teaching Limitations A and D; correct?

A. Again, in Paragraph 182 I specifically point to the Limitations A and D were obvious simply looking at Voswinckel and Chaudry; but, again, the combination being described in this section is Voswinckel, Chaudry, Patton, and the OptiNeb-ir user manual, and -- and their -- that -- and it's the combination of information, while explicitly A and D could be viewed as obvious, only if one chose to only

look at Voswinckel and Chaudry.

Q. So are you saying that you do rely on the OptiNeb-ir user manual as making obvious or teaching Limitations A and D?

A. No. What I'm saying is that, again, this -- the combination being described in this section is Voswinckel, Chaudry, Patton, and the OptiNeb-ir user manual and how that combination makes Claims 1 through 9 obvious.

But specifically in Paragraph 182 if one wanted to take a limited subset of that combination, which there's no reason one would have to, that simply Voswinckel and Chaudry are sufficient to demonstrate that Sections A and D of Claim 1 are obvious.

Q. In your declaration do you rely on the OptiNeb-ir user manual as making obvious or teaching Limitation A?

A. Because I use the OptiNeb-ir user manual in combination with the other references described in Combination 2 to describe Claims 1 through 9 as being invalid as obvious, there -- it's -- a knowledge of the OptiNeb-ir user manual can contribute to the evaluation of Limitations A and D, but I specifically

used Voswinckel and Chaudry as examples of sufficient art to demonstrate that those two limitations of Claim 1 are obvious.

Q. Dr. Donovan, are you able to answer my question of whether or not in your declaration do you rely on the OptiNeb-ir user manual as making obvious or teaching Limitation A --

MR. MATHAS: Objection.

BY MS. ASCARRUNZ:

Q. -- in your declaration?

MR. MATHAS: Object to the form. It's been asked and answered many times.

BY THE WITNESS:

A. While in Paragraph 182 of my declaration I don't specifically include the OptiNeb-ir user manual, in that description it's the -- that section is a subsection of the Combination 2 section, which uses Voswinckel, Chaudry, Patton, and the OptiNeb-ir user manual; and there are times where various subsets of those four are sufficient to demonstrate obviousness, but I'm not limiting my evaluation to subsets of those four as I evaluated the obviousness based on that combination.

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BY MS. ASCARRUNZ:

Q. So, yes, in your declaration you do rely on the OptiNeb-ir user manual as making obvious or teaching Limitation A?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Again, I use Voswinckel in view of Chaudry, Patton, and the OptiNeb user manual as Combination 2 to -- for my opinion that Claims 1 through 9 are invalid.

The -- and that Voswinckel and Chaudry alone are sufficient to evaluate Limitations A and D of Claim 1 as being obvious, but one wouldn't necessarily need to select a subset of those five -- one, two, three, four pieces of art that were -- are being used in combination.

BY MS. ASCARRUNZ:

Q. Dr. Donovan, in your declaration on the '507 patent do you rely on the OptiNeb-ir user manual as teaching or making obvious Limitation D?

A. The OptiNeb-ir user manual is considered along with Voswinckel, Chaudry, and Patton to evaluate Claims 1 through 9, and my opinion is that those are -- those claims are obvious over those

references; and Limitation D can be obvious in view of Voswinckel and Chaudry; and I would need to spend a few moments thinking about whether there would be a subset of -- of these four references using the OptiNeb-ir user manual that I would want to add as an addition in that paragraph; but I didn't see the need to do that.

Q. Do you rely on the OptiNeb-ir user manual in connection with the '507 patent -- strike that.

In your declaration concerning the '507 patent, do you rely on the OptiNeb-ir user manual as disclosing or making obvious any of the additional limitations of the dependent claims?

A. I -- I don't think I understand your question. In fact, I know I don't understand your question.

Q. Is there a particular part of it that was confusing?

A. Yes. If you would repeat the question, I will tell you what's confusing to me.

Q. In your declaration concerning the '507 patent, do you rely on the OptiNeb-ir user manual as disclosing or making obvious any of the additional limitations of the dependent claims?

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A. And -- and it's in the terminology of the additional limitations of the dependent claims that I'm not sure what you're -- what you're specifically asking about.

Q. Okay. Let's pin that down.

So you understand that there are dependent Claims 2 through 9 in the '507 patent; correct?

A. Yes, I understand that.

Q. And I think we both understand that those dependent claims encompass and incorporate the limitations of Claim 1; correct?

A. Yes.

Q. Okay. So setting aside those limitations that are incorporated by reference to Claim 1, there are additional limitations specified in each of Claims 2 through 9; correct?

A. Yes, that's my understanding.

Q. And are those additional limitations in dependent Claims 2 through 9 taught or rendered obvious by the OptiNeb-ir user manual in your declaration?

MR. MATHAS: Object to the form.

MS. ASCARRUNZ: That's a good objection.

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Let me rephrase that.

BY MS. ASCARRUNZ:

Q. In your declaration do you express an opinion that those additional limitations in dependent Claims 2 through 9 are taught or rendered obvious by the OptiNeb-ir user manual?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, throughout Paragraphs -- and what I'm looking at is Paragraphs 205 through 212 where there's specific description of Claims 2 through 9 and a bit of additional information about Claim 5 and Claim 6.

All of them indicate that I have -- my opinion is that those claims would have been obvious over Voswinckel in view of Chaudry, Patton, and the OptiNeb user manual.

Now, whether -- so, for example, in Paragraph 205 I provide additional information about my opinion that even Voswinckel alone I wouldn't necessarily need to use the combination to -- to evaluate the additional limitations of Claims 2, 7, and 8 as being obvious.

That doesn't prohibit or limit me

because -- or -- or and I'm not trying to communicate that I didn't continue to evaluate the combination of Voswinckel, Chaudry, Patton, and the OptiNeb-ir user manual.

It's simply a brief statement of a simplification of that grouping of -- of prior art describing the obviousness of Claims 2 through 9.

BY MS. ASCARRUNZ:

Q. All right. So you stated that you're not trying to communicate that you didn't continue to evaluate the combination of Voswinckel, Chaudry, Patton, and the OptiNeb-ir user manual.

Did you, in fact, continue to evaluate the combination of Voswinckel, Chaudry, Patton, and the OptiNeb-ir user manual in connection with dependent Claims 2 through 9?

A. Again, I evaluated all of those as I was forming my opinions about Claims 2 through 9; and the information provided in Paragraphs 205, 206, and 207 are sort of the -- a succinct summary of some of the key combinations and information that support my opinion that those claims were made obvious.

Q. Do you agree with me that the OptiNeb-ir user manual does not expressly teach an

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opto-acoustical trigger?

A. I believe my recollection of the OptiNeb-ir user manual is they do not expressly use the phrase optico-acoustic trigger anywhere in the user manual.

Q. Okay. Apart from using the phrase directly, do you agree with me that the OptiNeb-ir user manual does not expressly teach an opto-acoustical trigger within the meaning of the claims?

MS. ASCARRUNZ: Let me withdraw that question and rephrase it so it doesn't have a negative in it.

BY MS. ASCARRUNZ:

Q. Is it your opinion that the OptiNeb-ir user manual expressly teaches an opto-acoustical trigger within the meaning of the claims?

A. Well, the -- OptiNeb-ir user manual -- and I'm looking at Section 7 on Page 16 -- describes lights that are provided through primarily the A -- it's the A17 denotation or the multifunction lamp, and there is information also about auditory signals provided. I'm trying to find that.

Oh, I should have not skimmed, and I should have read closer. So in Section 7 it's

describing the lighting system that's available in the OptiNeb-ir and in 7.0.3 it's describing an auditory or acoustic signal that's also available in the OptiNeb-ir nebulizer, and these are optical and acoustic signals.

Q. Let me ask my question again.

Is it your opinion that the OptiNeb-ir user manual expressly teaches an opto-acoustical trigger within the meaning of the claims?

A. Well, the -- the OptiNeb-ir user manual describes components of the OptiNeb nebulizer that function as optical and acoustic signals, and in -- and the user manual and the knowledge of a POSA regarding how those optical and acoustic signals can be used to communicate things about the device function to the user indicates that a -- that the -- the -- the lights and sound, along with the knowledge of -- knowledge of the POSA, knowledge of the prior art, that using those to be able to signal the user or to communicate with the user something about the operation is -- is in keeping with being an optical acoustic, and we can call that a trigger if we want.

Q. Okay. You understand that the claims of

the '507 patent require an opto-acoustical trigger; correct?

A. They use the term opto-acoustic trigger, yes.

Q. Okay. Does the OptiNeb-ir user manual expressly teach that limitation?

A. In -- the OptiNeb-ir user manual does not use that phrasing, and the '507 patent doesn't specifically define or limit what an opto-acoustical trigger is, and as a result there are optical properties or signals provided by the OptiNeb-ir, and there are acoustic signals provided by the OptiNeb-ir.

And user knowledge, POSA knowledge would allow individuals to use those light and sound signals or know that one could adapt that -- that nebulizer to provide what triggers it is, if one wants to use the term trigger or signal or communication, about the operation of the device if they so chose.

Q. Okay. I'm quoting your words verbatim here. It is your opinion that the '507 patent does not specifically define or limit what an opto-acoustical trigger is; correct?

A. Well, I understand that there's probably a different definition to limit legally than what I use, so we'll just say define.

That it doesn't define what it -- what the specific limitations to the optical acoustical trigger is in the claim.

So it's a -- something that involves -- or my understanding and recollection of the construction of that claim is that this is -- it's something that involves an optical and an acoustic signal, and I'm choosing to use the term to communicate something about the device operation.

Q. In the Section 7.0.3 on Page 16 of Exhibit 1006 that you referred to in a recent answer, the light that you referred to is just to signal through a color change whether the nebulization process is on or off; correct?

A. Well, in the particular configuration being described in this user manual, that -- that is the description that's being provided for this specific use, but a POSA would understand that if they had a potentially different use for that light and that -- and later that sound, that the device could likely be configured to also have other

information communicated about the operation of the device from the lights or the sounds.

MS. ASCARRUNZ: Okay. In my question I didn't ask anything about what a POSA would understand, so I move to strike everything after but as not responsive in that previous answer.

BY MS. ASCARRUNZ:

Q. The sound that you referred to in the OptiNeb-ir user manual is only to indicate when the device is switched off; correct?

A. In the configuration described in this ventilator user manual it indicates that the sound is initiated when the nebulizer is switched off, but there's nothing that implies that that's the only potential use for that sound.

Q. Is there anything that implies additional uses for that sound?

A. Well, those additional uses could be just based in what a POSA determines they would like that nebulizer to be able to accomplish that are beyond what the user manual for the OptiNeb-ir and its ventilation function is being communicated to the users.

Q. Within this OptiNeb-ir user manual is

there a location that describes a light and a sound simultaneously signaling a patient to synchronize each breath to each pulse?

A. Well, again, this -- this user manual specifically provides information to users who are using the OptiNeb-ir in -- in conjunction with a ventilator, but the OptiNeb-ir was able to be used for non-ventilator based purposes, and a POSA or a user or a prescriber could attribute additional meaning outside of what's specified in this particular user manual to those lights or sounds.

Q. I understand that you have several opinions about what a POSA or a user would have in their minds, and my question is to what is explicitly described in this user manual, and I want to ask:

Do you disagree with me when I say that the OptiNeb-ir user manual nowhere describes a light and a sound simultaneously signaling a patient to synchronize each breath to each pulse?

A. And, again, the version of the OptiNeb-ir user manual that is expressly describing the use of the OptiNeb-ir in conjunction with a ventilator doesn't contain specific information about the use of lights and sounds and individual breaths of a user,

but there -- there -- the knowledge of what the OptiNeb-ir device capabilities are are not subject or is not -- that knowledge is beyond what the specific information in a user manual for a specific configuration of the device is intended to be.

Q. I'm going to ask my question again because I don't think you answered it.

Do you disagree with me, yes or no, when I say that the OptiNeb-ir user manual nowhere describes a light and a sound simultaneously signaling a patient to synchronize each breath to each pulse?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. The OptiNeb-ir is a nebulizer that's able to be used in a number of different configurations.

The user manual that we are looking at right now that is a user manual describing the use of the OptiNeb-ir configured to be used with a ventilator does not address the OptiNeb-ir being used for patients who are able to take distinct breaths directly from the nebulizer.

BY MS. ASCARRUNZ:

Q. I'm sorry.

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Does that mean, yes, you agree with me?

A. My answer stands.

Q. Are you unable to answer the question, yes or no, whether you agree with me that the OptiNeb-ir user manual nowhere describes a light and a sound simultaneously signaling a patient to synchronize each breath to each pulse?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. The OptiNeb user -- ir user manual that is described by this -- by Exhibit No. 1006 is a user manual describing the OptiNeb-ir under its artificial respiration or ventilation configuration, and in that specific user manual it does not describe the use of -- and I'll try to paraphrase what you asked -- lights or sounds synchronized to the breaths of the individual.

BY MS. ASCARRUNZ:

Q. The light on the OptiNeb-ir as described in the OptiNeb-ir user manual is located on the front of the device; correct?

A. Let's -- do we want to use the picture on the cover and define front and back?

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Q. Well, let me rephrase it this way.

Where on the device is the light located? If we're looking at Page 1 of Exhibit 1006, where is the light that you referenced located?

A. The light is in the -- the area of the device that also contains the start and stop button and the on and off button and information from an LED display, and I believe that -- it has -- that LED display provides multiple different forms of information to the users.

Q. Okay. In one of your previous answers you indicated that a POSA would understand -- and let me just -- so you -- so you know where I'm quoting from you -- that, quote, "A POSA would understand that if they had a potentially different use for that light and that -- and later that sound, that the device could likely be configured to also have other information communicated about the operation of the device from the lights or the sounds."

Do you recall that testimony?

A. Yes.

Q. Okay. When you say, "could likely be configured," is it your opinion that the OptiNeb-ir as described in this manual could be configured to

have a light and a sound simultaneously signal a user to synchronize each breath to each pulse?

A. Well, as a POSA, I'm aware that there -- there were devices that did that very thing.

This device, as described in this manual, may not distinctly be set up to do that in its default programming; but since it contains a light and contains -- and has the ability to produce a sound, it would be -- or I'd have every expectation that it could be configured to use those sounds and that light in other manners beyond simply what they're being used for in -- as described in this specific use in this user manual.

Q. And what would a POSA have to do to configure the device to be used in the other manners that you described?

A. Well, I -- I really haven't spent very much time thinking about the details of what -- how one might be able to do that, but it provides -- there -- there are built-in capabilities for light and sound in this device, and I'd have every expectation that those lights -- that light and sound capability could be configured to communicate things in addition to what they currently communicate.

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Q. In the Page 1 image that we were looking at, you identified the lights being on the same side of the device or where the start and stop buttons are.

Do you recall that?

A. Yes, I'm using the diagram on Page 16 to help me with that. It indicates that the multifunction lamp, which is A17 when described, as having -- well, it has -- it can light up yellow.

And -- let's see. And apparently, according to 7.0.2, can light up green, so is changes color, but it's present next to the LED panel.

Q. And in the image shown on Page 1 of the manual, on the image on the left, the upper most blue portion, what is that?

A. That's the mouth piece for the device.

Q. So that's where the patient would put his mouth?

A. Yes.

Q. And when the patient has his mouth on the device, can he see the light that is on the device?

A. I'm -- potentially. I'm not sure.

Q. Does this manual teach a person how to reconfigure the lights and sounds for other purposes?

A. Well, that's not the intent of the user manual or operating instruction manual for a specific configuration.

Q. In your declaration for the '507 patent still, your Ground 2 -- sorry -- your Combination 2 includes the references Voswinckel, Chaudry, Patton, and the OptiNeb-ir user manual; correct?

A. So -- so that you don't have to repeat your question, Combination 2, as described right above Paragraph 179, include "Voswinckel in view of Chaudry, Patton, and the OptiNeb-ir user manual."

Q. Okay. It is your position that Voswinckel teaches a therapeutically efficacious treatment; right?

A. Voswinckel describes the use of treprostinil to a group of patients.

I'd have to look at that abstract again to remember exactly the cross section of patients, but the summary communication of that abstract is that the pulmonary administration of treprostinil demonstrated reductions in pulmonary -- I have to remember exactly what they measured -- but they decreased the pulmonary pressure.

And in a group of patients on

longer-term use they also saw good -- what they -- what would be considered efficacy or therapeutic effect in a small number of patients.

Q. So, yes, it is your position that the Voswinckel reference teaches the therapeutically efficacious treatment; correct?

A. I guess I'd like to take a look at the Voswinckel reference to refresh my memory to make sure that I'm answering your question accurately.

Q. Okay. Let me direct you to Paragraph 186. The first sentence there states: "Since Voswinckel teaches that a therapeutically efficacious treatment was obtained using the OptiNeb ultrasonic nebulizer..." And then the sentence continues.

Do you see that?

A. Yes.

Q. So is it your opinion that Voswinckel teaches a therapeutically efficacious treatment using the OptiNeb ultrasonic nebulizer?

A. Yes, it is.

Q. Okay. So now I'm going to switch back to questions that address both declarations.

A. Okay.

Q. So, again, if for whatever reason one of

my questions requires a different answer depending on which patent we're talking about, please let me know, and we can try to parse it out.

A. Yes. Okay.

MS. ASCARRUNZ: All right. I'm handing you Exhibit 1003 in both proceedings.

BY MS. ASCARRUNZ:

Q. Dr. Donovan, do you know what this exhibit is?

A. This is a copy of the abstract that we've been referring to in shorthand as Voswinckel in the last couple of questions, and the pages prior to that are information about where that abstract came from, so the print copy of the journal that the abstract appeared in following its presentation at the Scientific Session of the American Heart Association in 2004.

Q. And this is the same Voswinckel that you refer to in your Grounds 2 and 3; right?

A. Let me just make sure, but -- yes.

Q. You rely on the fact that Voswinckel discloses a "pulse OptiNeb ultrasound nebulizer"; correct?

A. Yes.

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Q. What model of OptiNeb was used in Voswinckel?

A. The abstract doesn't specifically say which model number, but it was a model that was able to be used in a pulsed fashion.

Q. Well, in your opinion all OptiNebs are able to be used in a pulse fashion; correct?

A. I think there are ways of configuring nebulizers to be used in a pulsed fashion whether they're commercially labeled or described as pulsed or not. As a individual is trying to communicate what they did in an abstract, the -- the -- one of the general objectives is to be as clear as possible and in as few of words as possible.

So if they -- if Voswinckel is describing a pulsed OptiNeb ultrasound nebulizer, a POSA would view that as an OptiNeb nebulizer that was commonly known to be able to be used in a pulsed manner.

Q. Would that include a nebulizer that works exclusively in a continuous fashion with an on-off switch?

A. Again, the -- the very limited number of words that a scientist can put into an abstract.

They are going to communicate as accurately as possible the -- the methods they used and the conclusions they drew and the experiments they conducted.

So by describing a pulsed OptiNeb ultrasound nebulizer in the abstract, a POSA would recognize that these individuals used an OptiNeb nebulizer that had or that was -- that was designed or the -- the manufacturer had built in a methodology that was clearly understood by users to be -- how it could be used in a pulsed manner.

Q. Let me direct your attention to Paragraph 179 of your declaration in the '240 patent.

A. Okay. 179 in the 240?

Q. Yes.

A. Okay.

Q. It is your opinion that a POSA would look to the specific OptiNeb-ir user manual, that is Exhibit 1006, because Voswinckel discloses the use of an OptiNeb; correct?

MR. MATHAS: Object to the form.

THE WITNESS: Will you repeat the question, please?

MAUREEN DONOVAN, Ph.D.

BY MS. ASCARRUNZ:

Q. It is your opinion that a POSA would look to the specific OptiNeb-ir user manual, that is Exhibit 1006, because Voswinckel discloses the use of an OptiNeb; correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. No. The statement that I put in my -- my expert declaration is that a POSA would be motivated to look at the specifications of the device to help them understand how that device operated so that they would have a better understanding beyond the few words that Voswinckel was able to include in his abstract regarding how that device produced the therapeutically effective aerosol of treprostinil.

Q. Okay. And when you say the specifications of that device, what device are you talking about?

A. Of the pulsed ultra -- OptiNeb nebulizer described in the Voswinckel abstract.

Q. And it's your opinion that the OptiNeb-ir user manual contains the specifications of the device that was used in Voswinckel?

A. I'm saying that the Opti -- the

specifications of the OptiNeb-ir, be it it's described in the user manual that we've been discussing as Exhibit 1006, has -- contains some specifications.

Other specifications, if they're not contained in that user manual, would be readily accessible from -- from the Nebu-Tec company, the manufacturer of that nebulizer, if they were contacted, and a specification that they actually had measured and wasn't proprietary for some reason, those specifications are readily shared among scientists, users, anybody else.

So if -- there are some specifications in the user manual, but not all of the specifications for the device, but those other specifications, again, are easily available, either from the manufacturer or potentially from other sources.

Q. Okay. And those other specifications that are easily available from the manufacturer or potentially from other sources, are they part of your Combination 2?

A. Well, the OptiNeb-ir user manual and other information known about the OptiNeb-ir user --

ir nebulizer from the prior art are -- are what I've used to form the basis of my opinion.

MS. ASCARRUNZ: Do you still have Voswinckel in front of you?

BY MS. ASCARRUNZ:

Q. Do you agree with me that Voswinckel does not expressly state the dose that was delivered?

A. Voswinckel does not describe a specific number of milligrams of treprostinil that each patient received as a distinct description within the abstract.

Q. Okay. But it's your opinion that such information could be derived by combining the information from Voswinckel and the information from the OptiNeb-ir user manual; correct?

A. Yes, that's my opinion, that knowledge about the operation of the OptiNeb-ir and the information provided in the Voswinckel abstract would allow a POSA to -- to determine within -- to determine a likely dose that the individuals received.

Q. Is the nebulization rate of an OptiNeb the same when it is switched from a continuous mode to a pulsed mode?

A. I believe it's certainly possible to have them be the same. I'd have to have some further information regarding the -- the differences between the configurations to be sure that the -- that the same capabilities under all circumstances existed in both, but it would be my anticipation that the -- well, I don't -- I'm not -- between generations there may have been additional enhancements in the -- the output rates that were being evaluated in some of those -- in some of the generations of OptiNebs.

So I can't say specifically. I'd need some further information to determine, but in --

Q. I'm sorry. Are you done?

A. In most cases I would expect the -- the -- the user-based ranges to be quite similar; and, again, a POSA could easily get that information from Nebu-Tec or from other sources that had those specifications to confirm that they were the same.

Q. In the user manual do you know what the ir in the designation OptiNeb-ir means?

A. I knew at one time. I'm not sure that it actually says specifically in English what the ir means.

And I'm nearly certain that the I

stands for intermittent, but I can't place what the R stands for in my memory.

Q. Okay. The OptiNeb-ir that is described in this manual has a way of ensuring that the inhalation is not longer than the exhalation; right?

A. That's my understanding based on -- there's a section in here -- on Page 21 it describes that the active phase cannot be greater or longer than the passive phase.

Q. Okay. Could you direct me to where it says that?

A. On Page 21, the very top paragraph.

Q. Got it.

In Paragraph 174 of your declaration -- actually strike that -- Paragraph 175 of your declaration -- actually strike that again -- 174 of your declaration, and I'm talking about the '240 declaration.

Although this questioning I believe applies universally to both patents, so, again, we're in that universe of talking about both of them, so if you disagree with me and think that your answers differ, again, please let me know.

A. Okay.

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Q. In that paragraph you conclude -- well, that a patient may inhale from somewhere between two to three seconds.

Do you see that?

A. Yes, as an estimate. Yes, I see that.

Q. And where do you get the three seconds from in that sentence?

A. Well, I think the -- the three is included because when you -- when you do the -- the math around 12 times per minute and 15 times per minute and give an equal amount of time to inhalation and exhalation, you end up with some decimals, so I was just giving what would be a physically possible range because you can't have a decimal of a -- of a breath and this -- these are just general estimates of a -- the duration of time for an inhalation. They're not meant to be it either has to be two seconds or it has to be three seconds.

Q. Got it.

But in -- so understanding you can't have a decimal of a breath, you can certainly have decimals of seconds; right?

A. Yes.

Q. And if we were to be more precise, the

three seconds would actually be two and a half; right?

A. Given the structure of this -- of the introductory limiting to the inhalation, exhalation cycle taking somewhere between four seconds and five seconds, yes, then the inhalation representing 50 percent of that time would have been two and a half.

Q. Okay. And is it possible that a patient would inhale for one second?

A. Yes, it is possible that patients could inhale for one second.

Q. So I'd like to look at your calculations in Paragraph 175, and there you note that the OptiNeb, quote, could be configured to generate an output of 0.173 mils per min.

Do you see that?

A. Yes.

Q. And then you include two bullets to calculate the micrograms per breath in that scenario; right?

A. That's correct.

Q. I'd like to look at the first bullet where you have the 3.46 micrograms per breath number.

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Do you see that?

A. Yes.

Q. If you were to administer that amount across three breaths, that yields a 10.38 microgram total dose; right?

A. In the time I've spent looking back and forth across these I could have probably done the multiplication in my head, but, yes.

Q. Okay. So this 10.38 micrograms is a total dose that one could get using the information from the OptiNeb manual and Voswinckel; right?

A. If the -- if the OptiNeb device was -- was being operated at a unusually low flow rate, then these would be the dose values calculated based on Voswinckel's three breaths, three-breath dose and 600 microgram per mil fill volume; but, again, the -- the output velocity of 0.173 mills per minute is a very slow output velocity. Patients don't like excessively slow outputs because it makes their nebulization periods longer; and since Voswinckel doesn't say anything about operating that pulsed ultrasonic nebulizer at a much slower rate than is typically used or desired by -- by the users, which, again, would -- especially in an earlier report

knowing that you had to administer it slowly, would be an important thing to include, even in an abstract, that a POSA would -- would not necessarily initially select the .0173 [sic] mills per minute to make their estimate of the dose that Voswinckel delivered.

Q. Dr. Donovan, in Paragraph 175 of your declaration you state that: "The Nebu-Tec website also reported that an earlier OptiNeb device could nebulize at a rate of up to 0.6 mils per min, but could be configured to generate an output of 0.173 mils per min"; right?

A. Yes, that's what it states.

Q. And for that reason you included the calculations shown in that paragraph; right?

A. That's correct.

Q. In my previous question did you understand me to ask any questions about excessively slow rates?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. You may not have asked the question specifically, but to give context to these isolated paragraphs, I thought it necessary to include that

information.

Q. Okay. In your discussion in your declaration as it was submitted to the Patent Trial Appeal Board, did you find it necessary at that point to discuss at any time excessively slow flow rates?

A. No, I was trying to communicate to the Patent Trial Board that these things were known about the OptiNeb device, and it allowed a POSA to calculate the -- the likely range of doses that patients being -- that patients described in the Voswinckel abstract were likely to have received.

MR. MATHAS: Veronica, if you're at a -- close to or at a good stopping point, may we take a break.

MS. ASCARRUNZ: I may be at a minute or two, but not right now.

MR. MATHAS: Okay.

BY MS. ASCARRUNZ:

Q. Okay. I see. So in this part of your declaration you were attempting to describe the likely range of doses that patients might have received?

A. Well, since Voswinckel didn't describe in specific detail the number of micrograms that those

patients received, and if that information had been desired by a POSA, I'm demonstrating that a POSA, knowing about the OptiNeb devices and simply being able to do algebra, could estimate what likely ranges of treprostinil those patients received and thus which -- what received doses were efficacious in the patients studied and described in the Voswinckel abstract.

Q. You actually have no direct knowledge what the flow rate used in Voswinckel was; right?

A. Voswinckel doesn't directly include that or specifically include that information in his abstract; and, again, abstracts have a limited number of words that a -- that can be included, and unless an investigator does something to alter the typical use of a device or an instrument, they're using in measurement or using in experimental sense, they typically don't communicate that they're using the device as would normally be used.

They communicate when they have changed the device from how it would normally be used in an abstract so it's clear how they conducted the work; but, again, given the limited number of words they can use, verifying that they used the devices or

did the experiments in the typical way is not included in those abstracts.

Q. You've mentioned a couple of times the limited number of words one can use in an abstract.

Is there a word limit that is placed on abstracts?

A. It depends on where you're submitting the abstract to. Every abstract I've -- nearly every abstract I've submitted, some of the regional meetings I've presented at don't have word limits, but near -- I can't think of a national meeting that I have presented an abstract at that didn't limit -- didn't tell me what the word count limit was, and in some cases we get down to space count limits for the abstract.

Q. So is it your opinion that the calculation you have at the top of Page 74 that includes a 10.38 microgram per three breath, that that couldn't have been a result of combining Voswinckel and OptiNeb?

A. No, if -- if Voswinckel had used a output rate that was likely to be provided by the OptiNeb, that patients with two second breaths would likely receive a dose within that range.

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Q. So in your calculations on these pages at Paragraph 175 one of the alternative possibilities for the different parameters that could be combined of the OptiNeb and Voswinckel you have there as the first bullet point a possibility of 3.46 micrograms per breath; correct?

A. Yes, the -- the first bullet point communicates that at the slowest flow rate that I was able to identify the OptiNeb device worked at that each breath would -- or each two second breath would provide a dose of 3.46 micrograms of treprostinil.

Q. And I think earlier you said it was possible that a one second breath could also happen.

In that case the micrograms per dose -- sorry -- micrograms per breath would be 1.73 micrograms; correct?

A. Yes, that's correct.

MS. ASCARRUNZ: Okay. This is a good time for a break.

THE VIDEOGRAPHER: Going off the record. 12:28 p.m.

(WHEREUPON, a lunch recess was had.)

THE VIDEOGRAPHER: Going on the record. This

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marks the beginning of Media No. 3. The time is now 1:20 p.m.

MS. ASCARRUNZ: Welcome back, Dr. Donovan.

THE WITNESS: Thank you.

MS. ASCARRUNZ: For certainly at least the next little while I'm going to be talking about your ground -- or Combination 3, and this is discussion is going, again, talk about both patents, so if you feel the need to identify one particular patent over the other in your answers, just please let me know.

THE WITNESS: Okay.

BY MS. ASCARRUNZ:

Q. So in your declaration you -- for both patents you rely on a Combination No. 3; right?

A. I describe a Combination No. 3, yes.

Q. And that relies on what you call the EU Community Register; right?

A. Yes.

Q. What precise exhibit numbers is -- or number or numbers is the EU Community Register?

A. Well, let me see -- let me find the combination as I'm describing it and see if I can help you with that.

All right. Well, what I'm using

to -- what I'm using a shorthand to describe the EU Community Register starts being described about Paragraph 101 in the 507 declaration that I've provided.

Q. Uh-huh.

My question was what exhibit number do you mean by EU Community Register?

A. Well, the -- the EU Community Register contains a number of documents about medications that are available and approved by the European Union, contains information about a lot of other European Union activities.

The Community Register of Medicinal Products is the area that I was looking at.

On pages following I provide URLs to the specific pages where you can find information about Ventavis, and there are exhibit numbers -- 144 -- or I guess 1043. I'm sorry. I was looking at the footnote numbers, but 1043, 1051, which I believe are printed pages from pages that are available from the website, so the European -- the EU Community Register really is not a printed document since the EU was -- was formed and continues to operate as -- as a -- as an entity. They formed when it was --

communication via computers and websites was actually faster and potentially more important than print versions of their work, so I believe most of -- most of the information that goes on at the EU is website available rather than hard publication available.

So the -- when I'm describing EU Community Register and provided a couple of examples of the -- the specific Web pages where that information is -- is available, that's the best way to provide that information because download -- printing out the entire contents of the website from the European Community -- EU Community Register would probably be excessive and difficult to wade through.

Q. In your Combination 3 in connection with both patents, when you say, "EU Community Register," you're saying that is not contained in the exhibits to your declaration?

A. Well, if I could --

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. If I could take a look at those specific exhibits, I could tell you what's -- what their -- what they are or what they contain, what they were intended to communicate.

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My recollection is that -- that those exhibits don't contain all of the possible documents specifically about Ventavis available at the time on the -- on the -- the EU Community Register websites, but that the exhibits that I provided give the English translations of a number of the key documents that I used in my opinion.

Q. Okay. So in your Combination 3 when you talk about the EU Community Register, are you saying that that might encompass some documents that were not printed -- that were not printed?

A. I don't --

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Again, I don't remember exactly what Exhibit 1053, 1043, and other exhibits, 1003, where I'm using those to describe the EU Community Register.

So until I could take a look at those and tell you what -- what they -- what those exhibits specifically are, I can maybe tell you if there's -- there is other information that was directly used to form my opinion.

Q. So then are you saying that when you talk

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about the EU Community Register as part of Combination 3, you're not referring to one single document exhibit number in this proceeding?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I'm -- I used documents available from the EU Community Register, specifically documents about the Ventavis product that was available in Europe to -- to form my opinions about the obviousness of the claims in these patents.

I need to look at the specific exhibits to remind myself what those exhibits are and what they communicate to be able to answer your questions.

BY MS. ASCARRUNZ:

Q. Okay. So until you look at the specific exhibit numbers, you cannot answer the question of whether the EU Community Register, as part of your Combination 3, is a specific exhibit number in this proceeding?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't recall the -- the exhibit number designations of the materials that I used to form my

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opinion regarding -- and used and called the EU Community Register.

BY MS. ASCARRUNZ:

Q. Okay. What exhibits do you need to look at to answer my question?

A. Well, we'll look at the exhibits that I've footnoted to start with, so 1043, 1051, 1053, 1043.

Q. Okay. I'm handing you an exhibit marked IPR Exhibit 1053.

Is this a component of the EU Community Register of Combination 3?

A. Yes, this page was -- was used to -- to find or be able to request the document described as Commission Decision 592005 Amending Marketing Authorization for Ventavis Iloprost, as a -- a medicinal product for human use granted by Decision 3/2003/33448.

Q. I'm handing you Exhibit 1051.

Is this a component the EU Community Register of Combination 3?

A. Again, this is a page from the website that is essentially part of the pathway to get to the Commission decision document I believe was the

pathway for this one. Unfortunately the URLs aren't printed on these pages that correspond to the URLs in my report, so I can't place exactly which one corresponds to which of those.

Q. Can you answer the question of whether or not Exhibit 1051 is a component of the EU Community Register of Combination 3?

A. I can answer that this page was a page I arrived at to get to the information that I used about Ventavis to form my opinion, but exactly which page it is that I've described in my -- in my declaration, I -- without the URL or without being able to find -- or to use the Web to -- to verify which one of those it is, I can't comment on which one it is, but it's a -- it's a pathfinding page.

Q. Okay. So third time I'm asking.

Can you answer -- is Exhibit 1051 a component of the EU Community Register of Combination 3?

A. Well, again, the -- Exhibit 1051 is a Web page that as a POSA, if I'm looking for information about Ventavis that's in or that's part of the EU Community Register, I would -- would likely get to this page to be able to access the documents that I'm

looking for, so it's -- it's merely an access page to get the specific documents that a POSA is -- will look to about Ventavis for information about that product approved in the European Union.

Q. Okay. So, no, Exhibit 1051 is not a component of the EU Community Register of Combination 3?

A. Exhibit 1051 is part of the -- the European Commission, and the European -- the EU Community Register is -- my recollection is the European -- the EU Community Register resides within the European Commission document database.

Q. So are you saying that in Combination 3 when you talk about the EU Community Register, you're referring to the entirety of the database?

A. No, as described in Paragraph 101 at the end, I'm using the EU Community Register of Medicinal Products to locate information about the Ventavis label and other information about the Ventavis approval in -- that was available in the European Union.

Q. I'm handing you Exhibit 1043.

Is Exhibit 1043 a component of the EU Community Register of Combination 3?

A. Exhibit 1043 are the -- I seem to recall I think these are sort of the opening pages when you arrive at the information lodged on the European Commission about Ventavis as part of the Community Register of Medicinal Products, this is the -- the sort of Ventavis home page, and it contains summary information, and it contains links to other documents that describe the history of the European -- the -- the EMA and other -- I guess we'll stick with EMA -- EMA primarily decisions regarding Ventavis.

Q. Dr. Donovan, I didn't ask you what your thinking was on everything about Exhibit 1043. I asked you whether Exhibit 1043 is a component of what you mean when you say EU Community Register in Combination 3?

A. Well, again, Exhibit 1043 is a printout of the -- the Ventavis home page -- as a lack of a better term -- to describe where a POSA would find the information about Ventavis that is available on the website from the European Commission.

Q. Are you refusing to answer my question of whether or not Exhibit 1043 is a component of what you mean when you say EU Community Register in talking about Combination 3?

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MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, again, to get the information about Ventavis that I looked at through the European Commission, I went through the URLs that are described in my report, arrived at this Web page or what's printed here as a portion of the Web page.

There are links within -- or that -- that are listed below, each of those downward carrots have links along with them. There is information within those links that I also considered as part of my -- in forming my opinion.

BY MS. ASCARRUNZ:

Q. Let me ask you to turn in your declaration to Paragraph 213.

A. And this is my 507 declaration?

Q. Yes.

A. 213?

Q. Yes.

Do you see where it says: "I have also found that Claims 1 through 9 are obvious over Voswinckel in view of Chaudry, Ghofrani, and the EU Community Register.

Do you see that?

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A. I see that.

Q. When you use the term EU Community Register, what exhibit numbers are you referring to?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Again, I refer you back to the portion of my expert declaration where I describe the EU Community Register as -- I think it's in the section of prior art, but I can't remember what that section -- what I named that section -- scope and content of prior art, and there's a description of the EU Community Register and how I used the EU Community Register to form my opinions which are described in more specific detail in Combination 3, which is described starting with Paragraph 213.

Q. And when you talk about the EU Community Register, what exhibits are you talking about?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Both the exhibits that -- that you've presented to me, the contents that are available from links through those exhibits, some of which are -- are at least named or described or, you know, so, for example, the Ventavis label is available through one

of the links on Exhibit 1043 I believe, and label changes, label updates are available through those links.

So that's what I'm using to refer -- that's what I'm referring to as the EU Community Register.

Q. You just referred to the Ventavis label.

In Paragraph 101 I believe of your declaration you indicate that: "I understand that this label was made publicly available by being published by the European Union's EU regulatory agencies"; is that correct?

A. That's what it states, yes.

Q. And is that your understanding?

A. That is my understanding.

Q. Is that -- are you presenting an expert opinion of that. Or is that an assumption you were given by counsel?

A. No, I'm understanding that based in what I -- what I know about how the European Union handles drug approvals and what -- how regulatory bodies make labels available for -- for public access, and so the -- the European Union -- one of the European Union's methodologies of communicating label

information is through the community register.

Q. When was the community register first available online?

A. After the European Union formed and certainly before 2005.

Q. You're expressing an expert opinion that the European Union Community Register was available online before 2005?

A. I -- I can't express that opinion as an expert. I express it as I certainly know many documents from the -- and, again, being U.S. based I refer to the FDA more frequently than I refer to documents available from the EU or other counties, and -- and so I know about things that were available online in around 2004 and 2005 from the FDA or U.S.-based organizations.

I would as a POSA certainly anticipate that the EU used the same forms of communication as the pharmaceutical industry, in particularly regarding pharmaceuticals, was globalized significantly by 2005, so to be able to communicate that information to individuals whether they be part of the European Union or whether they be outside the European Union, one of the most expedient

ways of doing that was via the Web, and in 2000 -- so I'm -- I'm basing my opinion on -- as a -- as my judgment of data basis that were easily available in the early 2000s and the preference for communication using Web-based materials by regulatory bodies.

I -- I don't have specific knowledge of this being available online, but I don't have any reason to believe it wasn't.

Q. In Paragraph 106 you indicate that you searched the European Commission's Register of Commission Documents.

Do you see that?

A. Yes, I see that.

Q. And then you have a URL in that paragraph?

A. Yes.

Q. And you cite to -- in Footnote 147 Exhibit 1051?

A. Yes.

Q. Is Exhibit 1051 the URL?

A. I don't know that it's the specific printout of that URL. It refers to the European Commission where the footnote is placed.

Q. Okay. You indicated that you searched

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for Ventavis on that website; correct?

A. Correct.

Q. And when you searched for Ventavis -- did you do this personally or?

A. I did this, yeah.

Q. And when you searched for Ventavis, there was an option for full text search; correct?

A. You know, I'd have to have the website in front of me to remember the choices, but there were -- there were options for, as I -- as I state here, so that it was clearly understood which selections I made, that there were -- there were version selections, and I selected the all versions.

MS. ASCARRUNZ: Can we go off the record for a second.

THE VIDEOGRAPHER: Off the record at 1:45 p.m.

(WHEREUPON, a discussion was had off the record.)

THE VIDEOGRAPHER: Going on the record. The time is 1:47 p.m.

BY MS. ASCARRUNZ:

Q. So, Dr. Donovan, looking again at Paragraph 106, there's a URL that's included there

that I've typed into my iPad, and I will hand to you so you can walk us through what it is that you did.

A. Okay.

Q. So you indicate in your paragraph that, "Using the document search feature I searched for Ventavis and selected the radio button to search all versions."

A. So I'm on essentially the home page, which is Exhibit 1051, and I'm going to choose document search, and then I'm going to type Ventavis I believe into -- all versions -- okay.

So the URL must have already gotten me to the Ventavis stuff I hope.

Q. Could you talk us through what you see and what you're clicking on?

A. I'm in -- I'm not clicking on very many things here. I'm in the section that says, "Title," and because I can't type very well, it just took me away from the page.

So the section that says, "Title" I'm typing Ventavis into words in the title because, as I described, I came in to this site having already I think typed in Ventavis, and now I'm choosing where the language of the "Title" is "All."

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There's one word at least and "sort order by document date descending."

And I reach a page that looks like this that has a lot of document titles on it in many languages.

Q. And in your paragraph you said that you reached a page from which a POSA could request the commission decision, including a September 5, 2005 decision.

Do you see that on the Web page?

A. Well, I think there's -- I have to make a selection from among the documents that show up here, and I'm going to potentially reconsider my "all languages criteria."

No, I'm not. Maybe not. I'm clicking through to find years that are approximately 2005 to shorten up what I need to look at.

Okay. And on Page 3 of the 4 that were linked to my previous search I come to a title that is "Commission Decision of 5/9/2005. Amending the Marketing Authorization for Ventavis-Iloprost a Medicinal Product for Use Granted by Decision C\2003\3348."

Q. And what happens when you click on that?

A. I click on "document request," and it asks me to fill out a form to request that document.

Q. It doesn't take you to the document; correct?

A. It does not.

Q. And did you previously fill out that form yourself personally?

A. I did not fill it out personally, but I have seen hard copies of the document.

Q. So since you did not fill it out personally, do you know how long it took to receive the document after that form was filled out?

A. I don't have any information about that.

Q. So you're unaware that when you click on that document request it advises you that you have to wait 30 days to receive the document; correct?

A. I'll believe you, sure.

Q. And you're unaware that when you receive an e-mail confirmation of the request form it indicates you have to wait at least 15 days to receive the document; correct?

A. I have to believe you. I didn't go through those steps.

Q. Okay.

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A. Do you want this back?

Q. Yeah, thank you.

Dr. Donovan, what devices was Ventavis approved with?

A. It depends on the time period that you're asking about.

Q. Let's say before May of 2006.

A. I guess I'd like the opportunity to take a look at the Ventavis label to remind myself, but there were several devices at that time that Ventavis was approved for use.

Q. In the United States how many devices were approved for use with Ventavis?

A. Again, I need to see the Ventavis label for that period of time to be able to refresh myself about how many devices were approved for use.

Q. You provide opinions in your declarations about the Venta-Neb device; correct?

A. Yes, I do.

Q. And the Venta-Neb device is one that you identify as having been approved for use with Ventavis in Europe; correct?

A. Correct.

Q. So you know that at least the Venta-Neb

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device was approved for use with Ventavis prior to May of 2006; correct?

A. That is correct, yes.

Q. Was the Venta-Neb device approved for use in the United States with Ventavis?

A. Before May 2006?

Q. Ever.

A. I'd have to take a look at the -- the Ventavis label for -- from the FDA to refresh my memory about that.

Q. Okay. I have the paragraph number in your '240 declaration, so I'm going to ask you to look at that one, and specifically Paragraph 198.

Why did you include the discussion in Paragraph 198?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Give me a minute to find out where I am here.

BY MS. ASCARRUNZ:

Q. I just want to make sure we're looking at the same thing because I see you looking for the patent, and I'm not quite sure why.

Are you looking at Paragraph 198

that starts: "As I explained above"?

A. Yeah.

Q. Okay.

A. But I mean we just started discussing a paragraph in the middle of the context, and what I paged back to find was Combination 3, and -- and so Paragraph 198 actually is a discussion of limitation B1 of claims -- of Claim 1 I believe, and I wanted to refresh myself on what Claim B1 that we refer to in my report is, which is why I went to look at the '240 patent.

Q. Okay.

A. So now that I have put myself in place where we -- where I am in my report, the information in Paragraph 198 was -- is in this report to explain how users may interact with a nebulizer device and the advantages of having each pulse be represented as a fixed amount of drug being delivered, so that if change -- if -- if things happen, which things happen, during a nebulization treatment and the patient wants to receive the intended dose that they can -- that one of the advantages of using a fixed dose per pulse or a per breath or inspiration from the nebulizer, is -- is that if you have to stop for

some reason, you can restart and still receive the total dose that was intended, and it would be relatively easy for the user to adjust to that interruption in their -- in that particular nebulization opportunity.

Q. Is it your opinion that a POSA would have a motivation to modify a device to deliver a fixed amount per pulse at least in part because a POSA would want to have a mechanism to allow the patient to generate pulses if they are interrupted by a fit of coughing or an urgent phone call?

A. Again, one of the advantages of using a fixed amount per pulse is that it's -- a user can understand how to still complete their intended dosing regimen. It's easy to communicate to the user how it is they need to -- to utilize their nebulization dosing regimen. It potentially can make designing individualized dosing regimens that are, again, easy for the user to adhere to.

Because it's a -- it's a discreet countable unit, and users and prescribers are -- are used to thinking in terms of distinct units that total up to the total dose.

Q. I'm handing you Exhibit 1009.

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This is a document you refer to in your declaration; yes?

A. I'll take a look at it, but.

Okay. And -- and, yes, this is -- these are the annex materials to the --

Q. Dr. Donovan, I apologize for interrupting, but this has continued throughout the day. I asked you whether this is a document you referred to in your declaration, not what it is or what you think about it.

MR. MATHAS: Well, I'm going to object to the form. The witness can answer the question as posed without your commentary. That has also continued throughout the day.

BY THE WITNESS:

A. Well, there's -- there's no date on this document, there's no title on this document. There is an indication that it was supplied by Watson, but I don't have recollection of every document that was supplied by Watson in this IPR, and I wanted to point out that similar annex documents were available from the European Commission Web pages that I looked at when I searched for Ventavis.

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BY MS. ASCARRUNZ:

Q. Okay. In this document what is the concentration of the nebulizer solution used for Ventavis?

A. On Page 2 of Exhibit 10 -- 1009 it indicates that Ventavis is a 10 microgram per mil nebulizer solution.

Q. And in the claims of the patents at issue in these proceedings, the concentration of treprostinil in the claims is 600 micrograms per mil; correct?

A. That's my recollection, yes.

Q. So the claims require a concentration 60 times that found in this reference; correct?

A. It's getting late in the day, so, yes.

Q. And what is the total dosage that this reference teaches with respect to Ventavis?

A. Well, the -- this reference describes three different methodologies of administering -- or three different nebulizers to administer Ventavis, and for each of those nebulizers it describes a 2.5 microgram dose and a 5 microgram dose.

Q. And the concentration of treprostinil in the claims is 15 to 90 micrograms; correct? I'm

sorry. Let me make that clear.

The concentration of treprostinil in the claims of the patents at issues in these proceedings is 15 to 90 micrograms; correct?

A. No, the amount in the claims is 15 to 90 micrograms.

Q. Thank you. I used the wrong words.

So the total dosage of treprostinil in the claims at issue in the proceedings is 15 to 90 micrograms; correct?

A. The therapeutically effective single event dose is comprised from 15 micrograms to 90 micrograms of treprostinil is what Claim 1 describes.

Q. Okay. So the claims of the patents require a dosage of no less than three times that reflected in this Exhibit 1009; correct?

A. If you're comparing the 5 microgram dose of Ventavis to the 15 microgram dose of the -- described in the claim, yes, that's a three times difference.

Q. And up to potentially 36 times difference; correct?

A. I'd have to actually do that calculation. Let's see. 36 times. Gosh, I can't even multiply in

my head right now.

Q. Okay. Do you agree 90 divided by two and a half?

A. Again, I'd like to have a calculator.

Q. Okay.

A. I'm not in the mood to do math in my head -- or a piece of paper and a pencil. I would be happy to do that, too.

Q. Okay. That's fine. We'll go on.

Does this document state that the Venta-Neb device was a pulsed ultrasonic nebulizer?

A. In this particular document it doesn't use the word pulsed ultrasonic nebulizer, but for any -- but it describes a nebulization scheme that includes a integer number of inhalation cycles; and if one was not familiar with the Venta-Neb that was approved for use with Ventavis, that information would be readily available to anyone interested to identify that it was a pulsed ultrasonic nebulizer.

Q. Where would that information be readily available?

A. You can -- that information is available in the scientific discussion of the approval.

You can look at the Venta-Neb user

manual. It also describes it as a -- that comes with the Venta-Neb device administered with Iloprost.

It describes it as a -- or it's understandable that that is a pulsed ultrasonic nebulizer.

Q. Does anywhere in the European Community Register indicate that the Venta-Neb was a pulsed ultrasonic nebulizer?

A. I don't recall all of the details that I read, so I don't know.

Q. This document, 1009, that you have in front of you also teaches to jet nebulizer systems; right?

A. The HaloLite and the Prodose nebulizer were compressed air nebulizer systems.

Q. Okay. And they are also dosimetric systems; correct?

A. That's how they're described in the paragraph on Page 2.

Q. And they are governed by the patient's breathing pattern; correct?

A. That's the general understanding for the HaloLite and Prodose how they -- how they dose or administer their doses of Ventavis.

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Q. And with respect to the HaloLite and Prodose, the dose is given as a measure of time and not numbers of breaths; correct?

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

Q. And that's, again, because it's a dosimetric system; right?

A. Well, I'm not sure that that's --

Q. Okay. Fair enough.

Is there a statement in this reference anywhere that suggests that the Venta-Neb nebulizer is preferred over the two compressed air nebulizer systems?

A. I'd have to read the entire document, but it's not my recollection there is a statement that says one of these is preferred over the other.

Q. Are you aware that the Venta-Neb device in Europe was approved with an additional nebulizer before May 2006, and specifically I'm talking about the I-Neb vibrating mesh nebulizer?

A. In some of the documents I've seen regarding Ventavis I've seen the I-Neb referred to, but I don't have an understanding of the timeframes of when it was approved in the European Union or any place else.

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Q. Okay. But you are aware that the Venta-Neb device was never approved in the United States for use with Ventavis; correct?

A. I don't know that I'm specifically aware of that, no.

Q. So you're not aware -- strike that.

In this Document 1009, at the top of Page 3 there's a discussion that says, "For a dose of 5 micrograms Iloprost at mouth piece it is recommended to complete two inhalation cycles with 2.5 microgram preset dose program with a filling of one 2 mil ampoule."

Do you see that?

A. I see that.

Q. When it refers to an inhalation cycle there, it's referring to the time it takes to deliver the two-and-a-half preset dose; correct?

A. I suppose that that's how I would interpret that, yes.

Q. In your declaration you refer to certain claim limitations by a letter in brackets; correct?

So like --

(WHEREUPON, there was simultaneous speaking.)

A. Especially for Claim 1?

I'm sorry, but are you referring to the letters that we used -- that I've used to describe the subsections of Claim 1?

Q. Yes. So, for example, Limitation C?

A. Yes.

Q. Okay. Do you agree with me that Limitation C requires a pulsed ultrasonic nebulizer? And, I'm sorry. I'm referring to Limitation C in the '240.

A. Yes. As I've described in Paragraph 126 in my --

Q. And you -- sorry. Were you done?

A. That -- I was -- well, that -- I was just going to repeat that it says, "Said pulsed ultrasonic nebulizer comprising an opto-acoustical trigger which allows said human to synchronize each breath to each pulse."

Q. Okay. So you agree with me that Limitation C requires that the pulsed ultrasonic nebulizer have an opto-acoustical trigger; yes?

A. Well, it's -- it's -- the limitation states that it's a pulsed ultrasonic nebulizer with -- comprising an opto-acoustical trigger.

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Q. And the limitation also requires that the optical -- that the opto-acoustical trigger must allow the human to synchronize each breath to each pulse; correct?

A. That's what the claims states, yes.

MR. MATHAS: And, Veronica, I believe we're at the seven hours on the record mark.

MS. ASCARRUNZ: Okay. I will state for the record and on the record that I don't think we're limited to the seven hours given the SAS order that instituted the additional grounds, but we will stop at this point.

MR. MATHAS: Okay. Because I -- wait. For the record, I also have an e-mail from your team indicating that you would complete your examination within the 3 hours and 20 minutes remaining on the record.

Let's take a break, go off the record. I'm going to have some questions.

THE VIDEOGRAPHER: Off the record at 2:14 p.m.

(WHEREUPON, a recess was had.)

THE VIDEOGRAPHER: Going on the record.

MAUREEN DONOVAN, Ph.D.
The time is 2:36 p.m.
MR. MATHAS: Dr. Donovan, I have just a few questions for you.
EXAMINATION
BY MR. MATHAS:
Q. I believe counsel directed you to Paragraph 213 of your declaration in the '507 patent case. If you could hold that up.
Are you there?
A. Yes.
Q. What is -- what section begins with Paragraph 213?
A. That's -- that section is describing Combination 3, so the combination of prior art that I reviewed and used to -- to determine that Claims 1 through 9 were obvious.
Q. All right. And in that -- in that discussion in Paragraphs 213 through 236 what references are you relying on?
A. I'm relying on Voswinckel, Chaudry, Ghofrani, any the EU Community Register.
Q. And in Paragraph 220 you talk about some information that the community register provides about Ventavis.

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Do you see that?

A. Yes.

Q. And what reference are you relying on there?

MS. ASCARRUNZ: Objection. Leading.

BY THE WITNESS:

A. Well, in Paragraph 220 I'm describing things about the EU Community Register and the Ventavis information there, and there's a footnote that cites to Exhibit 1009.

Q. What is Exhibit 1009?

A. Exhibit 1009 was -- we were discussing previously, and it's the -- it's annex documents on the community register describing Ventavis and essentially the -- Annex 1 is the summary of product characteristics, and Annex 2 is the labeling and package leaflet, and Annex 3 is the labeling for Ventavis.

Q. All right. In -- counsel also asked you some questions about some calculations related to the OptiNeb user manual.

Do you recall those?

A. Yes.

Q. And one of the -- there was a calculation

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or a discussion in that section about using a nebulization rate of .173.

Do you recall that?

A. I do. I'm just trying to get to --

Q. I'm sorry. Paragraph 200 and 201 I believe in the -- in the '507 declaration.

A. All right. I'm there, yes.

Q. Okay. And the -- the -- the OptiNeb-ir user manual that you used in connection with Ground 2, did it include the .173 metric?

A. No, that metric was from other information about OptiNeb. The specifications in the user manual that's Exhibit 1006 only list the output as 0.6 mils per minute.

Q. And what -- and that's in 1006 at what page?

A. Page 28.

Q. Okay. In counsel's questioning about the .173 limitation, she asked some questions about if you used the 1 point -- I'm sorry -- the .173 metric with a 1 second breath.

Do you recall that?

A. I do, yeah.

Q. And she had you do the math for her as to

what the output of that dosing would be; right?

A. For -- I -- I think I agreed with the math that she presented, but, yes.

Q. Okay. And if we go back to Paragraph 200, in Paragraph 200 you're using the .6 milliliter per minute -- what did you refer that to, a speed?

A. The output rate.

Q. Output rate. Output rate.

Okay. So Paragraph 200, .6 milliliter per minute output rate; right?

A. Yes.

Q. And the calculations you did there were at two and three seconds; correct?

MS. ASCARRUNZ: Objection. Leading.

BY THE WITNESS:

A. That's --

MR. MATHAS: Let me ask that differently.

BY MR. MATHAS:

Q. What calculations did you perform in Paragraph 200?

A. I performed estimates of the dose if an individual was inhaling for two seconds and a second calculation if they happened to be inhaling for three

seconds.

Q. And if you use counsel's assumption in her questions earlier about one second, what would that result in using a .6 milliliter per minute output speed?

A. At the 600 microgram per mil concentration that would result in a six microgram dose per one second inhalation.

Q. And if you used a one second breath in that calculation using the .6 output speed and the 600 microgram per milliliter solution, would that change your opinions with respect to the obviousness over Ground 2?

A. No, it wouldn't.

Q. Why not?

A. Well, because with -- let me look at a specific to make sure that we're talking about the range here.

So we're describing a range -- a dose range of 15 micrograms to 90 micrograms and a six microgram dose per one second inhalation, and that given over three breaths or three inhalations is 18 micrograms, which is within the -- the limitation describing 15 micrograms to 90 micrograms as a dose.

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MR. MATHAS: All right. I have no further questions.

We will read and sign the transcript.

THE VIDEOGRAPHER: Going off the record.

The time is 2:44 p.m.

MS. REPORTER: Are you ordering the transcript at this time?

MS. ASCARRUNZ: Yes.

MS. REPORTER: Would you like a copy?

MR. MATHAS: Yes. Just regular delivery for us.

(Whereupon, at 2:44 p.m. the deposition was concluded.)

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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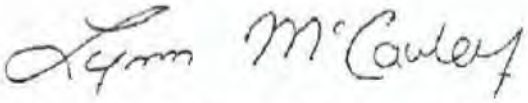

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