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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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PRESENT:

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ALSO PRESENT:

MR. JEREMY MANGAN, Videographer.

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I N D E X

WITNESS:

MAUREEN DONOVAN, Ph.D.

EXAMINATION BY:

PG LN

MS. ASCARRUNZ

5 10

MR. MATHAS

118 6

EXHIBITS:

DESCRIPTION

PG LN

None Marked

1 MAUREEN DONOVAN, Ph.D.

2 THE VIDEOGRAPHER: We are now on the record.

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

5 This deposition is taking place at
6 35 West Wacker Drive, Chicago, Illinois.

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

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

12 Today's witness is Maureen Donovan.

13 Will attorneys please identify
14 themselves.

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

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

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

1 MAUREEN DONOVAN, Ph.D.

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

4 (WHEREUPON, the witness was
5 duly sworn.)

6 MAUREEN DONOVAN, Ph.D.
7 called as a witness herein, having been first duly
8 sworn, was examined and testified as follows:

9 EXAMINATION

10 BY MS. ASCARRUNZ:

11 Q. Good morning, Dr. Donovan.

12 A. Good morning.

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

16 A. Correct.

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

19 A. Yes, I did.

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

22 A. Yes, I have.

23 Q. Recently?

24 A. Relatively recently, yes.

25 Q. Are you aware of any incorrect testimony

1 MAUREEN DONOVAN, Ph.D.

2 in that deposition?

3 A. No.

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

7 A. Correct. Yes.

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

12 A. That's fair.

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

17 A. Correct.

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

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

25 MR. MATHAS: We agree.

1 MAUREEN DONOVAN, Ph.D.

2 BY MS. ASCARRUNZ:

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

6 A. Yes.

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

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

12 A. That's fine.

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

16 A. Okay. Thanks. Yep.

17 Q. Thank you.

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

20 A. No.

21 Q. Do you know who Christopher Butler is?

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

24 Q. Okay. Have you ever spoken with him?

25 A. No.

1 MAUREEN DONOVAN, Ph.D.

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

5 A. Yes, I do.

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

8 A. Yes, I was.

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

11 A. Meaning relatively recently.

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

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

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

24 A. Not to my recollection.

25 Q. Have you reviewed a declaration from a

1 MAUREEN DONOVAN, Ph.D.

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

4 A. Yes, I've reviewed that declaration.

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

9 A. I'm not sure.

10 Q. Okay. Fair enough.

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

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

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

1 MAUREEN DONOVAN, Ph.D.

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

4 A. Okay.

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

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

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

14 Exhibit 1002 from IPR proceeding
15 2017-01622, entitled "Expert Declaration of Maureen
16 D. Donovan Ph.D."

17 BY MS. ASCARRUNZ:

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

22 A. I am, yes.

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

1 MAUREEN DONOVAN, Ph.D.

2 A. Yes.

3 Q. And in connection with the '507 patent
4 declaration you also rely on Combinations 1, 2, and
5 3?

6 A. Yes, I do.

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

10 A. Yes.

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

14 A. That's correct.

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

18 A. Yes, that's correct.

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

22 A. Yes.

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

1 MAUREEN DONOVAN, Ph.D.

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

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

8 A. Yes, I did.

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

13 A. Not distinctly, no.

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

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

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

22 A. Not in detail.

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

25 A. Not to my recollection.

1 MAUREEN DONOVAN, Ph.D.

2 Q. And you were not familiar from a
3 professional standpoint with treprostiniil before
4 these proceedings; correct?

5 A. Not in any specific research oriented
6 sense.

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

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

11 A. Yes, I do.

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

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

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

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

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

1 MAUREEN DONOVAN, Ph.D.

2 in this proceedings whether that is the case?

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

4 Q. Sure. Let me rephrase it.

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

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

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

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

1 MAUREEN DONOVAN, Ph.D.

2 differently. Each of those devices has different
3 capabilities.

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

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

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

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

17 A. Yes, I did.

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

21 A. Yes.

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

25 MR. MATHAS: Object to the form.

1 MAUREEN DONOVAN, Ph.D.

2 BY THE WITNESS:

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

6 BY MS. ASCARRUNZ:

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

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

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

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

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

1 MAUREEN DONOVAN, Ph.D.

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

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

9 A. They're a different type of nebulizer.

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

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

15 So each one has some attributes,
16 each has drawbacks.

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

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

1 MAUREEN DONOVAN, Ph.D.

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

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

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

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

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

1 MAUREEN DONOVAN, Ph.D.

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

5 A. I think there --

6 MR. MATHAS: Object to the form.

7 BY THE WITNESS:

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

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

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

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

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

1 MAUREEN DONOVAN, Ph.D.

2 for a particular use.

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

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

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

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

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

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

24 A. Okay.

25 Q. -- trying to compare them.

1 MAUREEN DONOVAN, Ph.D.

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

5 MR. MATHAS: Object to the form.

6 BY THE WITNESS:

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

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

18 Q. Sure.

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

22 MR. MATHAS: Same objection.

23 BY THE WITNESS:

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

1 MAUREEN DONOVAN, Ph.D.

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

5 BY MS. ASCARRUNZ:

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

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

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

1 MAUREEN DONOVAN, Ph.D.

2 distributions that's observed between them.

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

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

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

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

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

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

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MAUREEN DONOVAN, Ph.D.

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.

1 MAUREEN DONOVAN, Ph.D.

2 BY MS. ASCARRUNZ:

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

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

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

19 BY MS. ASCARRUNZ:

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

23 Do you recognize this exhibit?

24 A. Yes, I do.

25 Q. What is it?

1 MAUREEN DONOVAN, Ph.D.

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

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

7 A. Yes, it is.

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

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

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

14 A. That was also provided by counsel.

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

17 A. Yes, I do.

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

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

1 MAUREEN DONOVAN, Ph.D.
2 was -- the device -- the OptiNeb device was being
3 used. I know that the Nebu-Tec company was selling
4 that device, was interested in having pharmaceutical
5 companies and individuals use their devices; and so
6 being able to obtain the user manual for a device
7 that was commercially for sale, whether it was --
8 whether I accessed it, whether somebody accessed it,
9 I didn't look for it in 2004, but it would have been
10 easily obtainable.

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

13 And I move to strike it as not
14 responsive.

15 BY MS. ASCARRUNZ:

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

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

22 Q. Which document are you looking at?

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

25 So in Paragraph 55 I describe how

1 MAUREEN DONOVAN, Ph.D.
2 the -- the OptiNeb device is described in an abstract
3 available publicly in the fall of 2000 -- and was
4 presented in the fall of 2004 by a group of
5 investigators, and then later in Paragraph 61 I
6 describe that the OptiNeb device was detailed on the
7 Nebu-Tec website by at least 2003 referring to a --
8 probably the same exhibit, different exhibit number,
9 and I use the information provided to me by other
10 witnesses who are able to assure that that
11 information was available in that website in 2003.

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

16 MR. MATHAS: Object to the form.

17 BY THE WITNESS:

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

22 BY MS. ASCARRUNZ:

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

25 A. And my --

1 MAUREEN DONOVAN, Ph.D.

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

4 BY MS. ASCARRUNZ:

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

9 MR. MATHAS: Object to the form.

10 BY THE WITNESS:

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

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

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

25 I have provided a copy of the user

1 MAUREEN DONOVAN, Ph.D.

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

5 BY MS. ASCARRUNZ:

6 Q. Dr. Donovan, you are aware that there
7 were multiple devices that were termed OptiNeb;
8 correct?

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

10 Q. And not all OptiNeb were pulsed
11 nebulizers; correct?

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

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

21 A. That gives a pulsed dose, yes.

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

25 A. Yes, I do.

1 MAUREEN DONOVAN, Ph.D.

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

5 MR. MATHAS: Object to form.

6 BY THE WITNESS:

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

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

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

24 BY MS. ASCARRUNZ:

25 Q. The question I asked was: The manual has

1 MAUREEN DONOVAN, Ph.D.

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

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

6 BY THE WITNESS:

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

10 That's the terminology being used in
11 that section.

12 BY MS. ASCARRUNZ:

13 Q. Okay. Great. Thank you.

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

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

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

1 MAUREEN DONOVAN, Ph.D.

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

5 MS. ASCARRUNZ: I will, yes.

6 MR. MATHAS: Thank you.

7 BY MS. ASCARRUNZ:

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

13 A. Okay.

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

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

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

25 Well --

1 MAUREEN DONOVAN, Ph.D.

2 Q. Sure. I under --

3 A. Yes.

4 Q. Are you done?

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

9 Q. Okay. Certainly. I understand that.

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

13 A. Yes.

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

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

20 A. And so --

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

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

1 MAUREEN DONOVAN, Ph.D.

2 pharmaceutically acceptable salt?

3 Q. Yes. The 600 microgram per mil.

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

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

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

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

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

1 MAUREEN DONOVAN, Ph.D.

2 set up the ventilators and so forth.

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

10 3 to 18 is just a subset of the
11 possibilities.

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

15 MR. MATHAS: Object to the form.

16 THE WITNESS: Can you restate that question,
17 please?

18 BY MS. ASCARRUNZ:

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

22 MR. MATHAS: Same objection.

23 BY THE WITNESS:

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

1 MAUREEN DONOVAN, Ph.D.

2 8, that paragraph describes that Voswinckel is
3 sufficient to teach that, and a POSA would understand
4 that the OptiNeb device is certainly capable of
5 meeting the description of the number of breaths in
6 that claim.

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

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

12 BY MS. ASCARRUNZ:

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

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

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

1 MAUREEN DONOVAN, Ph.D.

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

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

6 BY MS. ASCARRUNZ:

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

12 A. Again, in a similar manner in Paragraph
13 180 I describe how in the context of using
14 Voswinckel, Patton, and Opti-Neb -- the OptiNeb-ir
15 user manual, that Voswinckel sufficiently describes
16 Claim 8, yet a POSA would understand that the
17 OptiNeb-ir, based on the user manual, just based on
18 an understanding of nebulizers, was able to be used
19 with a variety of different breath numbers.

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

22 BY MS. ASCARRUNZ:

23 Q. Dr. Donovan, you've referred to Paragraph
24 180 a few times now, and in its entirety it states:
25 "As explained in connection with Combination 1,

1 MAUREEN DONOVAN, Ph.D.

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

4 A. That's what it states, yes.

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

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

13 Q. Okay. And in the entire subheading
14 of the -- Subsection B, including Paragraphs 180,
15 181, 182, you don't mention the OptiNeb-ir user
16 manual in any of those paragraphs; correct?

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

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

1 MAUREEN DONOVAN, Ph.D.

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

4 MR. MATHAS: Object to the form.

5 BY THE WITNESS:

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

17 BY MS. ASCARRUNZ:

18 Q. Let me direct your attention to
19 Paragraph 170.

20 A. 170?

21 Q. Yes.

22 A. In my '240 declaration?

23 Q. Correct.

24 A. Right.

25 Q. In there you state that: "The preamble

1 MAUREEN DONOVAN, Ph.D.

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

5 A. That's what it states, yes.

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

11 A. That's what it states.

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

16 A. That's what it states.

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

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

1 MAUREEN DONOVAN, Ph.D.

2 As -- as -- as a POSA the -- the
3 claims have to -- I have to be -- well, the -- the
4 claims descriptions themselves and specific pieces of
5 art that I -- I use to describe what was known in the
6 art doesn't mean that I've evacuated my brain from
7 consideration of anything else during that particular
8 evaluation, so, again, in 171 I was certainly asked
9 to consider this directly, but it doesn't mean I was
10 absent of consideration or thought about the
11 OptiNeb-ir during the rest of my evaluation of the
12 '240 or the '507 patent claims.

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

19 MR. MATHAS: Object to the form.

20 BY THE WITNESS:

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

1 MAUREEN DONOVAN, Ph.D.
2 was a succinct description of a particular
3 combination of pieces of art that I used to -- to
4 evaluate Claim 1 of the 240 patent, and that was --
5 to make that statement that is -- that -- even though
6 I was aware of other art, those pieces of art were
7 sufficient to describe the art known regarding
8 Claim 1.

9 BY MS. ASCARRUNZ:

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

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

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

1 MAUREEN DONOVAN, Ph.D.

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

6 A. Can you reask the question?

7 Q. Yes.

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

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

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

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

1 MAUREEN DONOVAN, Ph.D.

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

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

13 MR. MATHAS: Object to the form.

14 BY THE WITNESS:

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

23 BY MS. ASCARRUNZ:

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

1 MAUREEN DONOVAN, Ph.D.

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

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

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

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

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

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

1 MAUREEN DONOVAN, Ph.D.

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

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

7 THE WITNESS: Sure.

8 THE VIDEOGRAPHER: Going off the record at
9 10:49 a.m.

10 (WHEREUPON, a recess was
11 had.)

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

14 The time is now 11:07 a.m.

15 BY MS. ASCARRUNZ:

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

20 A. Okay. I'll switch.

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

24 A. Okay.

25 Q. So in connection with this '507

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

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

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

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

10 Q. Sure.

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

15 MR. MATHAS: Object to the form.

16 BY THE WITNESS:

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

1 MAUREEN DONOVAN, Ph.D.

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

6 MR. MATHAS: Object to the form.

7 BY THE WITNESS:

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

14 BY MS. ASCARRUNZ:

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

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

24 Q. Okay. Fair enough.

25 So in connection with the

1 MAUREEN DONOVAN, Ph.D.

2 '507 patent, you rely on the OptiNeb-ir user manual
3 as making -- strike that. Start over.

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

8 A. Can you ask that again, please?

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

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

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

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

1 MAUREEN DONOVAN, Ph.D.

2 look at Voswinckel and Chaudry.

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

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

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

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

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

1 MAUREEN DONOVAN, Ph.D.

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

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

9 MR. MATHAS: Objection.

10 BY MS. ASCARRUNZ:

11 Q. -- in your declaration?

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

14 BY THE WITNESS:

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

25

1 MAUREEN DONOVAN, Ph.D.

2 BY MS. ASCARRUNZ:

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

6 MR. MATHAS: Object to the form.

7 BY THE WITNESS:

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

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

18 BY MS. ASCARRUNZ:

19 Q. Dr. Donovan, in your declaration on the
20 '507 patent do you rely on the OptiNeb-ir user manual
21 as teaching or making obvious Limitation D?

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

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

6 Q. Okay. Let's pin that down.

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

10 A. Yes, I understand that.

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

14 A. Yes.

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

19 A. Yes, that's my understanding.

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

24 MR. MATHAS: Object to the form.

25 MS. ASCARRUNZ: That's a good objection.

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2 Let me rephrase that.

3 BY MS. ASCARRUNZ:

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

8 MR. MATHAS: Object to the form.

9 BY THE WITNESS:

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

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

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

25 That doesn't prohibit or limit me

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

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

9 BY MS. ASCARRUNZ:

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

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

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

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

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2 opto-acoustical trigger?

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

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

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

14 BY MS. ASCARRUNZ:

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

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

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

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

7 Q. Let me ask my question again.

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

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

25 Q. Okay. You understand that the claims of

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

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

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

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

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

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

1 MAUREEN DONOVAN, Ph.D.

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

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

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

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

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

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

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

8 BY MS. ASCARRUNZ:

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

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

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

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

25 Q. Within this OptiNeb-ir user manual is

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

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

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

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

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

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

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

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

14 MR. MATHAS: Object to the form.

15 BY THE WITNESS:

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

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

24 BY MS. ASCARRUNZ:

25 Q. I'm sorry.

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2 Does that mean, yes, you agree with
3 me?

4 A. My answer stands.

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

10 MR. MATHAS: Object to the form.

11 BY THE WITNESS:

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

20 BY MS. ASCARRUNZ:

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

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

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2 Q. Well, let me rephrase it this way.

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

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

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

21 Do you recall that testimony?

22 A. Yes.

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

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

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

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

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

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

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

6 Do you recall that?

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

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

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

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

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

20 A. Yes.

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

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

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

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

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

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

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

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

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

25 And in a group of patients on

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

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

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

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

16 Do you see that?

17 A. Yes.

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

21 A. Yes, it is.

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

24 A. Okay.

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

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

5 A. Yes. Okay.

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

8 BY MS. ASCARRUNZ:

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

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

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

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

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

25 A. Yes.

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2 Q. What model of OptiNeb was used in
3 Voswinckel?

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

7 Q. Well, in your opinion all OptiNeb's are
8 able to be used in a pulse fashion; correct?

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

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

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

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

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

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

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

15 A. Okay. 179 in the 240?

16 Q. Yes.

17 A. Okay.

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

22 MR. MATHAS: Object to the form.

23 THE WITNESS: Will you repeat the question,
24 please?

25

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2 BY MS. ASCARRUNZ:

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

7 MR. MATHAS: Object to the form.

8 BY THE WITNESS:

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

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

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

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

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

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

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

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

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

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

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

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

6 BY MS. ASCARRUNZ:

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

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

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

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

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

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

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

14 Q. I'm sorry. Are you done?

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

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

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

25 And I'm nearly certain that the I

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

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

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

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

13 A. On Page 21, the very top paragraph.

14 Q. Got it.

15 In Paragraph 174 of your
16 declaration -- actually strike that -- Paragraph
17 175 of your declaration -- actually strike that
18 again -- 174 of your declaration, and I'm talking
19 about the '240 declaration.

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

25 A. Okay.

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

5 Do you see that?

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

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

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

20 Q. Got it.

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

24 A. Yes.

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

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

4 A. Given the structure of this -- of the
5 introductory limiting to the inhalation, exhalation
6 cycle taking somewhere between four seconds and
7 five seconds, yes, then the inhalation representing
8 50 percent of that time would have been two and a
9 half.

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

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

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

18 Do you see that?

19 A. Yes.

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

23 A. That's correct.

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

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2 Do you see that?

3 A. Yes.

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

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

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

13 A. If the -- if the OptiNeb device was --
14 was being operated at a unusually low flow rate, then
15 these would be the dose values calculated based on
16 Voswinckel's three breaths, three-breath dose and
17 600 microgram per mil fill volume; but, again, the --
18 the output velocity of 0.173 mills per minute is a
19 very slow output velocity. Patients don't like
20 excessively slow outputs because it makes their
21 nebulization periods longer; and since Voswinckel
22 doesn't say anything about operating that pulsed
23 ultrasonic nebulizer at a much slower rate than is
24 typically used or desired by -- by the users, which,
25 again, would -- especially in an earlier report

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

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

14 A. Yes, that's what it states.

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

17 A. That's correct.

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

21 MR. MATHAS: Object to the form.

22 BY THE WITNESS:

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

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2 information.

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

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

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

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

18 MR. MATHAS: Okay.

19 BY MS. ASCARRUNZ:

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

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

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

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

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

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

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

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

6 Is there a word limit that is placed
7 on abstracts?

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

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

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

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

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

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

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

18 A. Yes, that's correct.

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

21 THE VIDEOGRAPHER: Going off the record.

22 12:28 p.m.

23 (WHEREUPON, a lunch recess
24 was had.)

25 THE VIDEOGRAPHER: Going on the record. This

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

4 MS. ASCARRUNZ: Welcome back, Dr. Donovan.

5 THE WITNESS: Thank you.

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

12 THE WITNESS: Okay.

13 BY MS. ASCARRUNZ:

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

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

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

19 A. Yes.

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

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

25 All right. Well, what I'm using

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

6 Q. Uh-huh.

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

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

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

16 On pages following I provide URLs to
17 the specific pages where you can find information
18 about Ventavis, and there are exhibit numbers --
19 144 -- or I guess 1043. I'm sorry. I was looking at
20 the footnote numbers, but 1043, 1051, which I believe
21 are printed pages from pages that are available from
22 the website, so the European -- the EU Community
23 Register really is not a printed document since the
24 EU was -- was formed and continues to operate as --
25 as a -- as an entity. They formed when it was --

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

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

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

19 A. Well, if I could --

20 MR. MATHAS: Object to the form.

21 BY THE WITNESS:

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

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

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

13 A. I don't --

14 MR. MATHAS: Object to the form.

15 BY THE WITNESS:

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

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

25 Q. So then are you saying that when you talk

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

5 MR. MATHAS: Object to the form.

6 BY THE WITNESS:

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

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

16 BY MS. ASCARRUNZ:

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

22 MR. MATHAS: Object to the form.

23 BY THE WITNESS:

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

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

4 BY MS. ASCARRUNZ:

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

7 A. Well, we'll look at the exhibits that
8 I've footnoted to start with, so 1043, 1051, 1053,
9 1043.

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

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

14 A. Yes, this page was -- was used to -- to
15 find or be able to request the document described as
16 Commission Decision 592005 Amending Marketing
17 Authorization for Ventavis Iloprost, as a -- a
18 medicinal product for human use granted by Decision
19 3/2003/33448.

20 Q. I'm handing you Exhibit 1051.

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

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

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

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

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

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

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

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

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

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

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

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

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

23 Q. I'm handing you Exhibit 1043.

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

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

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

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

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

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2 MR. MATHAS: Object to the form.

3 BY THE WITNESS:

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

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

14 BY MS. ASCARRUNZ:

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

17 A. And this is my 507 declaration?

18 Q. Yes.

19 A. 213?

20 Q. Yes.

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

25 Do you see that?

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2 A. I see that.

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

5 MR. MATHAS: Object to the form.

6 BY THE WITNESS:

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

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

19 MR. MATHAS: Object to the form.

20 BY THE WITNESS:

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

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

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

8 Q. You just referred to the Ventavis label.

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

14 A. That's what it states, yes.

15 Q. And is that your understanding?

16 A. That is my understanding.

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

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

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2 information is through the community register.

3 Q. When was the community register first
4 available online?

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

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

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

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

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

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

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

13 Do you see that?

14 A. Yes, I see that.

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

17 A. Yes.

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

20 A. Yes.

21 Q. Is Exhibit 1051 the URL?

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

25 Q. Okay. You indicated that you searched

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2 for Ventavis on that website; correct?

3 A. Correct.

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

6 A. I did this, yeah.

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

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

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

17 THE VIDEOGRAPHER: Off the record at
18 1:45 p.m.

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

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

23 BY MS. ASCARRUNZ:

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

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

4 A. Okay.

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

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

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

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

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

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

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

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

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

11 Do you see that on the Web page?

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

16 No, I'm not. Maybe not. I'm
17 clicking through to find years that are approximately
18 2005 to shorten up what I need to look at.

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

25 Q. And what happens when you click on that?

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

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

6 A. It does not.

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

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

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

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

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

18 A. I'll believe you, sure.

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

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

25 Q. Okay.

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2 A. Do you want this back?

3 Q. Yeah, thank you.

4 Dr. Donovan, what devices was
5 Ventavis approved with?

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

8 Q. Let's say before May of 2006.

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

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

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

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

20 A. Yes, I do.

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

24 A. Correct.

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

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

4 A. That is correct, yes.

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

7 A. Before May 2006?

8 Q. Ever.

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

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

15 Why did you include the discussion
16 in Paragraph 198?

17 MR. MATHAS: Object to the form.

18 BY THE WITNESS:

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

21 BY MS. ASCARRUNZ:

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

25 Are you looking at Paragraph 198

1 MAUREEN DONOVAN, Ph.D.

2 that starts: "As I explained above"?

3 A. Yeah.

4 Q. Okay.

5 A. But I mean we just started discussing a
6 paragraph in the middle of the context, and what I
7 paged back to find was Combination 3, and -- and so
8 Paragraph 198 actually is a discussion of limitation
9 B1 of claims -- of Claim 1 I believe, and I wanted to
10 refresh myself on what Claim B1 that we refer to in
11 my report is, which is why I went to look at the
12 '240 patent.

13 Q. Okay.

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

1 MAUREEN DONOVAN, Ph.D.

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

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

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

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

25 Q. I'm handing you Exhibit 1009.

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

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

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

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

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

16 BY THE WITNESS:

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

25

1 MAUREEN DONOVAN, Ph.D.

2 BY MS. ASCARRUNZ:

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

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

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

13 A. That's my recollection, yes.

14 Q. So the claims require a concentration
15 60 times that found in this reference; correct?

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

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

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

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

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2 sorry. Let me make that clear.

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

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

8 Q. Thank you. I used the wrong words.

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

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

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

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

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

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

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2 my head right now.

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

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

6 Q. Okay.

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

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

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

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

21 Q. Where would that information be readily
22 available?

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

25 You can look at the Venta-Neb user

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

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

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

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

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

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

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

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

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

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

1 MAUREEN DONOVAN, Ph.D.

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

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

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

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

9 Q. Okay. Fair enough.

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

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

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

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

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

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

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

8 In this Document 1009, at the top of
9 Page 3 there's a discussion that says, "For a dose of
10 5 micrograms Iloprost at mouth piece it is
11 recommended to complete two inhalation cycles with
12 2.5 microgram preset dose program with a filling of
13 one 2 mil ampoule."

14 Do you see that?

15 A. I see that.

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

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

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

23 So like --

24 (WHEREUPON, there was
25 simultaneous speaking.)

1 MAUREEN DONOVAN, Ph.D.

2 A. Especially for Claim 1?

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

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

7 A. Yes.

8 Q. Okay. Do you agree with me that
9 Limitation C requires a pulsed ultrasonic nebulizer?
10 And, I'm sorry. I'm referring to Limitation C in the
11 '240.

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

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

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

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

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

1 MAUREEN DONOVAN, Ph.D.

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

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

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

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

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

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

21 THE VIDEOGRAPHER: Off the record at
22 2:14 p.m.

23 (WHEREUPON, a recess was
24 had.)

25 THE VIDEOGRAPHER: Going on the record.

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2 The time is 2:36 p.m.

3 MR. MATHAS: Dr. Donovan, I have just a few
4 questions for you.

5 EXAMINATION

6 BY MR. MATHAS:

7 Q. I believe counsel directed you to
8 Paragraph 213 of your declaration in the '507 patent
9 case. If you could hold that up.

10 Are you there?

11 A. Yes.

12 Q. What is -- what section begins with
13 Paragraph 213?

14 A. That's -- that section is describing
15 Combination 3, so the combination of prior art that I
16 reviewed and used to -- to determine that Claims 1
17 through 9 were obvious.

18 Q. All right. And in that -- in that
19 discussion in Paragraphs 213 through 236 what
20 references are you relying on?

21 A. I'm relying on Voswinckel, Chaudry,
22 Ghofrani, any the EU Community Register.

23 Q. And in Paragraph 220 you talk about some
24 information that the community register provides
25 about Ventavis.

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2 Do you see that?

3 A. Yes.

4 Q. And what reference are you relying on
5 there?

6 MS. ASCARRUNZ: Objection. Leading.

7 BY THE WITNESS:

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

12 Q. What is Exhibit 1009?

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

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

23 Do you recall those?

24 A. Yes.

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

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

4 Do you recall that?

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

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

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

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

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

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

18 A. Page 28.

19 Q. Okay. In counsel's questioning about the
20 .173 limitation, she asked some questions about if
21 you used the 1 point -- I'm sorry -- the .173 metric
22 with a 1 second breath.

23 Do you recall that?

24 A. I do, yeah.

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

1 MAUREEN DONOVAN, Ph.D.

2 what the output of that dosing would be; right?

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

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

9 A. The output rate.

10 Q. Output rate. Output rate.

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

13 A. Yes.

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

16 MS. ASCARRUNZ: Objection. Leading.

17 BY THE WITNESS:

18 A. That's --

19 MR. MATHAS: Let me ask that differently.

20 BY MR. MATHAS:

21 Q. What calculations did you perform in
22 Paragraph 200?

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

1 MAUREEN DONOVAN, Ph.D.

2 seconds.

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

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

10 Q. And if you used a one second breath in
11 that calculation using the .6 output speed and the
12 600 microgram per milliliter solution, would that
13 change your opinions with respect to the obviousness
14 over Ground 2?

15 A. No, it wouldn't.

16 Q. Why not?

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

20 So we're describing a range -- a
21 dose range of 15 micrograms to 90 micrograms and a
22 six microgram dose per one second inhalation, and
23 that given over three breaths or three inhalations is
24 18 micrograms, which is within the -- the limitation
25 describing 15 micrograms to 90 micrograms as a dose.

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MAUREEN DONOVAN, Ph.D.

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.)

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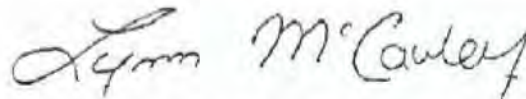
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this action.

IN WITNESS WHEREOF, I do hereunto set my
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After doing so, please sign the errata sheet and date it.

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and
(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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