

1 MAUREEN DONOVAN, Ph.D.

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

5 (Reporter Clarification.)

6 BY MS. ASCARRUNZ:

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

11 Do you recall that discussion?

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

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

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

19 MR. MATHAS: 1046?

20 BY MS. ASCARRUNZ:

21 Q. Did I -- sorry, 1046.

22 A. So it's European Heart Journal
23 abstract.

24 Q. Yes.

25 A. Okay. Yes. All right.

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

10 Do you recall that testimony?

11 A. Yes.

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

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

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

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

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

21 A. In the '240 patent, yes.

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

25 A. No, I don't need Voswinckel

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

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

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

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

6 MR. MATHAS: Object to the form.

7 BY THE WITNESS:

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

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2 BY MS. ASCARRUNZ:

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

7 MR. MATHAS: Object to the form.

8 BY THE WITNESS:

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

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

23 BY MS. ASCARRUNZ:

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

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2 less than six minutes?

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

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

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

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

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

8 Do you see that?

9 A. I see that.

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

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

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

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

10 A. I did quite a while ago, yes.

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

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

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

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

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

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

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

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

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

11 Q. And what did you understand
12 that to be?

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

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

22 MR. MATHAS: Object to the form.

23 BY THE WITNESS:

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

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

6 BY MS. ASCARRUNZ:

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

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

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

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

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

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

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

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2 medical treatment of pulmonary hypertension,
3 correct?

4 A. That's correct.

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

10 A. Clinically observable patient
11 responses?

12 Q. Yes.

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

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

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

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

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

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2 had been in shortage or not available.

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

9 MR. MATHAS: Object to the form.

10 BY THE WITNESS:

11 A. Can you restate that question?

12 BY MS. ASCARRUNZ:

13 Q. Yes.

14 A. Or at least reread it.

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

20 MR. MATHAS: Same objection.

21 BY THE WITNESS:

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

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

12 Q. Let me ask you about paragraph
13 213 of your '240 declaration. The first
14 sentence of paragraph 213 you state: "I
15 understand that the examiner rejected each and
16 every one of these secondary consideration
17 arguments, and I agree especially in light of
18 the teachings of Voswinckel and Ghofrani."

19 Do you see that?

20 A. I see that.

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

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

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

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

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

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

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

25 A. I have no recollection on the

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

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

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

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

15 MR. MATHAS: Object to the form.

16 BY THE WITNESS:

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

21 BY MS. ASCARRUNZ:

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

25 MR. MATHAS: Same objection.

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2 BY THE WITNESS:

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

5 BY MS. ASCARRUNZ:

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

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

15 A. Yes, in both claim 1 -- claim
16 1 in both the '240 and the '507 include the
17 phrase pulsed ultrasonic nebulizer, and a POSA
18 would understand that term to mean an
19 ultrasonic nebulizer that's capable of
20 delivering the aerosols in a pulsed manner.

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

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2 aerosols in a pulsed manner, correct?

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

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

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

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

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

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

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

1 MAUREEN DONOVAN, Ph.D.

2 BY MS. ASCARRUNZ:

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

8 MR. MATHAS: Same objection.

9 BY THE WITNESS:

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

18 BY MS. ASCARRUNZ:

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

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

25 Q. Is it your opinion that an

1 MAUREEN DONOVAN, Ph.D.

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

5 MR. MATHAS: Object to the form.

6 BY THE WITNESS:

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

13 BY MS. ASCARRUNZ:

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

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

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

1 MAUREEN DONOVAN, Ph.D.

2 the terminology in the claims?

3 A. Can you repeat that, please?

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

8 MR. MATHAS: Object to the form.

9 BY THE WITNESS:

10 A. I am still confused. One more
11 time.

12 BY MS. ASCARRUNZ:

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

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

20 MR. MATHAS: Object to the form.

21 BY THE WITNESS:

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

25

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2 BY MS. ASCARRUNZ:

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

9 MR. MATHAS: Object to the form.

10 BY THE WITNESS:

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

19 BY MS. ASCARRUNZ:

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

23 A. Yes, I am.

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

1 MAUREEN DONOVAN, Ph.D.

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

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

8 MR. MATHAS: Object to the form.

9 BY THE WITNESS:

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

16 BY MS. ASCARRUNZ:

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

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

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

25 A. That's very dependent on

1 MAUREEN DONOVAN, Ph.D.

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

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

9 MR. MATHAS: Object to the form.

10 BY THE WITNESS:

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

18 BY MS. ASCARRUNZ:

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

21 MR. MATHAS: Object to the form.

22 BY THE WITNESS:

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

1 MAUREEN DONOVAN, Ph.D.

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

5 BY MS. ASCARRUNZ:

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

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

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

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

20 A. I see where it says that, yes.

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

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

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

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

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

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

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

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

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

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

8 A. Yes, that's what they say.

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

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

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

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

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

7 THE COURT REPORTER: Wait. One
8 would anticipate?

9 BY THE WITNESS:

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

18 BY MS. ASCARRUNZ:

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

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

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

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

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

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

16 Q. Is it affected by drug
17 concentration or volume?

18 A. That depends on the site of
19 administration.

20 Q. So we are talking about
21 inhalation administration.

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

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

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

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

17 Q. Okay.

18 A. -- on that.

19 Q. In the context of inhaled
20 treprostiniil, does the time to peak plasma
21 concentration depend on the number of breaths?

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

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

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

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

17 MR. MATHAS: Object to the form.

18 BY THE WITNESS:

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

22 BY MS. ASCARRUNZ:

23 Q. What do you mean?

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

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2 is being inhaled? A number of other things.

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

8 A. Well, there's certainly the
9 chance that they could under the conditions
10 that are being described in the '240 and the
11 '507 patent. If we contain ourselves to that
12 specific -- those specific ranges for
13 treprostinil and the use of the ultrasonic
14 nebulizers and the assumption that those are
15 providing the appropriate particle size for
16 inhalation delivery which is built into all of
17 these claims, that the 10 to 15 minute --
18 that's the timeframe -- 10 to 15 minute
19 timeframe for the Tmax is in keeping with the
20 expectation of a POSA for the system that's
21 described by the claims in the '507 and '240
22 patents.

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

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2 treprostiniil per breath?

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

7 Q. Does -- in the context of the
8 administration of treprostiniil under the
9 claims, does the droplet size affect what the
10 micrograms per breath would be, or can the
11 droplet size affect what the micrograms per
12 breath would be?

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

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

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

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

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

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

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

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

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

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

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

14 (WHEREUPON, a recess was had at
15 2:46 p.m. until 3:05 p.m.)

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

19 BY MS. ASCARRUNZ:

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

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

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

13 Q. Okay. Fair enough.

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

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

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

4 EXAMINATION

5 BY MR. MATHAS:

6 Q. Just a couple questions.

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

12 Do you recall those?

13 A. Yes.

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

16 Do you recall that?

17 A. Yes.

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

22 MS. ASCARRUNZ: Objection to form.

23 BY THE WITNESS:

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

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

7 THE COURT REPORTER: I'm sorry.

8 BY THE WITNESS:

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

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

23 BY MR. MATHAS:

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

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2 research at a conference?

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

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

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2 same things, lots of other reasons why.

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

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

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

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

24 THE WITNESS: Okay. Thanks.

25 MS. ASCARRUNZ: No questions from

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me. Thank you for your time.
THE VIDEOGRAPHER: Going off the
record. The time is 3:12 p.m.
(WHEREUPON, the deposition was
concluded at 3:12 p.m.)

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

MAUREEN DONOVAN, Ph.D.

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

Notary Public

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I, ANDREA L. KIM, a State of Illinois
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concerning the matters herein;

That the foregoing deposition
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That I am not a relative or
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such attorney or counsel for any of the parties
hereto, nor am I interested directly or
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IN WITNESS WHEREOF, I do
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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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