

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner

IPR2025-00246 (Patent 11,857,333 B1)
IPR2025-00247 (Patent 11,872,029 B1)

Record of Oral Hearing
Held: April 29, 2026

Before SHERIDAN K. SNEDDEN, NEIL T. POWELL, and CYNTHIA M.
HARDMAN, *Administrative Patent Judges*.

IPR2025-00246 (Patent 11,857,333 B1)

IPR2025-00247 (Patent 11,872,029 B1)

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1 P R O C E E D I N G S

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3 JUDGE POWELL: Good morning. Today, we are here to address
4 two inter partes reviews. Those include IPR 2025-00246, that involves U.S.
5 Patent number 11,857,333 B1. The other IPR is IPR2025-00247, and that
6 involves U.S. Patent number 11,872,029 B1. I'm Judge Powell and I am
7 joined by Judges Hardman and Snedden. Who do we have attending for
8 Petitioner today?

9 MS. NGUYEN: Good morning, Your Honor. This is Lisa Nguyen
10 of Paul Hastings for Petitioner ResMed Corp. With me is David Tennant.

11 JUDGE POWELL: And who do we have for Patent Owner?

12 MR. PRICE: Good morning, Your Honors. Jeffrey Price, on
13 behalf of Cleveland Medical Devices.

14 JUDGE POWELL: Thank you. So turning to the inter partes
15 reviews, I want to note that Patent Owner's motions to terminate the
16 proceedings are under consideration, and those will be decided in due
17 course. Today we're going to hear arguments regarding the patentability of
18 the challenged claims, as well as the merits of Patent Owner's motion to
19 amend in the 246 IPR.

20 Each party will have 75 minutes to argue. Petitioner will open and
21 may reserve rebuttal time. Patent Owner will then respond and may reserve
22 surrebuttal time. I will keep track of the time on the timer behind me, and I
23 plan to note when your time is running short. But I also encourage you to
24 keep track of your time in case I forget. When you present, please specify
25 which demonstratives, papers, and/or exhibits you're referencing, it's helpful

1 for the record as well as our remote judges.

2 Let me ask Patent Owner, do you have any questions or concerns
3 before we get started?

4 MR. PRICE: I don't have any questions. Or should I take your
5 opening to state that we should not be discussing the motion to terminate
6 today? Is that correct?

7 JUDGE POWELL: Well, I noted that you didn't have it in your
8 demonstratives. Let me confer briefly with my panel to see if they have any
9 thoughts on that matter. Yes, so I guess I think we were okay with it.

10 Does Petitioner have any problems with addressing the motions to
11 terminate today?

12 MS. NGUYEN: We don't have any issues either way.

13 JUDGE POWELL: Okay. Is that the only thing, Patent Owner?

14 MR. PRICE: The only other thing is the parties had discussed
15 before the hearing focusing on the 247 IPR first and then the 246, in that
16 order, but --

17 JUDGE POWELL: Sure. We can do that. Do you want to do all
18 of the 247 and then --

19 MR. PRICE: I don't think that's necessary.

20 JUDGE POWELL: Okay.

21 MR. PRICE: Originally, James Hannah was going to be here, and
22 he's not.

23 MR. TENNANT: And so when you say all of 247, do we reserve?

24 JUDGE POWELL: No, I think what he was saying -- I was trying
25 to get clarification. I think he just wants to start the presentations with the
26 247.

1 MR. PRICE: I think that's fine. When James was here, we I think
2 wanted to keep things more separate. But he's not here. We're fine.

3 MR. TENNANT: Do you want to do rebuttal, or should I do --

4 MR. PRICE: Do your two first and then I'll do --

5 MR. TENNANT: Okay.

6 JUDGE POWELL: Okay. And to close the loop then, we're all in
7 agreement it's fine to talk about the termination motions. That's fine also.
8 Well, does Petitioner have any questions or concerns with all that sorted?

9 Okay. My only other question then before I give Petitioner the
10 floor is, do you want to reserve some time?

11 MR. TENNANT: Yes, Your Honor.

12 JUDGE POWELL: How much?

13 MR. TENNANT: Twenty-five minutes.

14 JUDGE POWELL: Twenty-five minutes. Hopefully, this is
15 helpful, I'm going to change the clock to reflect 50 minutes so that you'll sort
16 of know when -- but as always, you're welcome to run into your reserve
17 time.

18 MR. TENNANT: And just so you know, I'm going to start with
19 the 247.

20 JUDGE POWELL: Okay.

21 MR. TENNANT: Then Lisa Nguyen will do 246. So we'll have a
22 change --

23 JUDGE POWELL: Okay.

24 MR. TENNANT: -- in argument.

25 JUDGE POWELL: Yes, that sounds good.

26 MR. TENNANT: Okay.

1 JUDGE POWELL: When you're ready.

2 MR. TENNANT: Good morning, Your Honors. My name is
3 David Tennant, on behalf of Petitioner ResMed Corp. So today we'll
4 demonstrate that the claims of the '029 Patent are unpatentable, as record
5 reflects. I'm going to go to Slide 2, which is the agenda. And I just want to
6 start by saying that this case is about the predictability of the integration of a
7 known PAP device with a standard telemedicine networking system. These
8 disputes shown on the slide will address airflow, measurement, severity
9 calculation, signal processing, retransmission, and sleep efficacy algorithm.

10 I'll go to Slide 4, and these are the grounds that Petitioner has
11 presented in this proceeding. Today I will discuss primarily Grounds 1 and
12 4. Ground 1 is the combination of Truitt in view of Kumar, and Ground 4
13 adds Mumford to that combination.

14 Going to Slide 5 briefly, the purported invention. It is a network
15 PAP system that transmits symptoms, severity, and usage data to a remote
16 internet site via a cell phone. And advancing the Slide 6, we see Figure 7 of
17 the '029 Patent. It is a known PAP system, and we'll get into more of these
18 specifics of Figure 7 and what the '029 Patent discloses at a later point.

19 I want to advance forward to Claim 16 -- Slide 16 and show you
20 Claim 1. Claim 1 is a rather lengthy claim. But notwithstanding the length
21 of it, there are very few issues in dispute. And you can break this claim into
22 three parts. The known PAP system, which is the middle element in the
23 claim spanning both columns. The known PAP system collects PAP data,
24 physiological symptom data from the patient that it's using the PAP device.
25 It provides that system or the PAP data to a cell phone.

26 On that cell phone you have software, and the cell phone then

1 transmits the PAP data to a remote internet site. And the claim only requires
2 that the remote internet site receive the PAP data. In the disclosure of the
3 '029 Patent, this is so a physician or another provider can view the PAP data
4 and function in a telemedicine type environment.

5 I want to go back to claim -- Slide 8. And I briefly want to discuss
6 the state of the art. So, by 2003 the industry had already moved on to auto
7 adjusting PAP devices. Auto adjusting PAP devices simply mean that
8 there's a controller on the PAP device. When the PAP is being used by a
9 patient and there's a need for increased pressure, it automatically increases
10 pressure. When the pressure is no longer needed, it decreases pressure. And
11 this improves comfort of the patient. And as you can see on the slide, Dr.
12 Kirkness has identified more than 10 known PAP devices that were in the
13 market by 2003.

14 Going to Slide 7, I'm getting into the telemedicine aspect of PAP
15 devices. And Toge and Wright, which are prior art in this proceeding, also
16 recognize the advancement of PAP devices and modifying PAP devices so
17 they can be -- function in a telemedicine environment. On the left-hand side
18 of the figure, we see Toge. Toge disclosed a transceiver in the PAP device
19 that would communicate PAP data externally. Wright also recognized that
20 PAP devices include wireless devices.

21 Our experts have likewise testified that it was common not only to
22 have wireless transceivers but wireless microphones in PAP devices. In
23 PAP devices, they are quite complex. There are many sensors, airflow
24 sensors, pressure sensors, wireless microphones. And all these sensors
25 together collect data on the patient, and it is applied to a controller. And the
26 controller can determine the appropriate response based on the symptoms

1 that the patient is exhibiting.

2 Going to Slide 10, this is also Toge. Toge has recognized early on
3 that PAP devices could be modified into a telemedicine environment. And
4 Toge disclosed that telemedicine functions well with PAP devices. And my
5 colleague, Lisa Nguyen, will discuss Toge later in the subsequent
6 proceeding. But we have discussed Toge before, it was -- it's related to PAP
7 devices and disclosed how to make a PAP device work in a telemedicine
8 environment. This was all prior to the effective date of the asserted patent
9 -- or challenge patent.

10 I want to move on to Slide 12. Slide 12 is Truitt. Truitt is the
11 primary reference that we're relying on here. And on the right-hand side of
12 the slide we can see Figure 1 and Figure 3. Figure 1 and Figure 3 show the
13 PAP device of Truitt. In Truitt, the PAP device had an airflow sensor. It
14 had a pressure transducer. Signals from those sensors were inputted to a
15 controller. That controller controls a blower. And so as I said earlier, the
16 pressure that is delivered to the patient is automatically adjusted based on
17 the symptoms that the patient is exhibiting.

18 In the middle, I want to point out that Figure 7 is not part of Truitt
19 -- in the middle. It's actually part of the '029 Patent. And as you can see
20 with Figure 7 of the '029 Patent, side by side with Figure 1 of Truitt patent,
21 the PAP devices are nearly identical, if not illustratively they are identical.

22 I'm moving on to Slide 13. Petitioner has combined Truitt with
23 Kumar. Kumar disclosed a -- discloses a network telemedicine system that
24 is generic to medical devices, but it has all of the components of the claim in
25 addition to the PAP device. And as you can see from Truitt on the left-hand
26 side, you have a medical instrument, one or two, which corresponds to a

1 PAP device. In the middle, highlighted in green, you have a computer
2 system 110 that corresponds to a cell phone and the remote internet sites,
3 which are highlighted or outlined in red, which is where the physician or
4 another provider can review the information received from the medical
5 instrument and provide treatment.

6 I want to move on to the disputed issues, and I'm advancing to
7 Slide 19. The first disputed issue concerns airflow sensor. The Claim 1
8 requires the airflow sensor be adapted to measure or derive the respiratory
9 airflow of a subject while using the PAP device. And this was known, and
10 Truitt expressly discloses this.

11 Moving on to Slide 20, we see Figure 3 of Truitt. And Truitt does
12 provide expressed disclosure of that airflow sensor. We have identified it as
13 the sensor system 782. That sensor system 782 includes many components,
14 which is why you see 782 with an arrow. As I briefly explained earlier, that
15 sensor system 782 will output a signal to controller 38. The pressure
16 transducer 22 also outputs a signal to 38. And 38 then measures or derives
17 respiratory airflow of the subject.

18 And we can see this on Slide 21, the expressed disclosure of Truitt
19 that describes that the controller receives the signals from the sensor system
20 782 from the pressure sensor 22, and they can distinguish between inhalation
21 or inhales and exhales of the patient. And because of that, when you can
22 distinguish between inhale and exhale of a patient, that is the respiratory
23 airflow of a subject. So when the PAP device can distinguish between the
24 two based -- at least on the airflow sensor signal does input to the controller,
25 it discloses measuring or deriving the respiratory airflow of a subject.

26 And this is not --

1 JUDGE HARDMAN: Counsel?

2 MR. TENNANT: Yes.

3 JUDGE HARDMAN: It's Judge Hardman. Could you show me in
4 your petition where exactly you talked about the pressure sensor being able
5 to distinguish between inspiratory and expiratory phases of the patient's
6 breathing cycle, please?

7 MR. TENNANT: Certainly. I believe that's at 14, if the citation
8 on my slide is correct.

9 JUDGE HARDMAN: Okay. Thank you.

10 MR. TENNANT: Yes, it is discussed in the paragraph on Page 14.
11 And it's also under the element, when we talk about this element, which I
12 believe is 1.b2. And it's saying this is not unlike the '029 Patent, which also
13 at the bottom of the slide discloses measuring the airflow based on
14 inhalation and exhalation of the patient.

15 JUDGE HARDMAN: As I understood the dispute raised by Patent
16 Owner around this limitation is that the petition really just talks about the
17 airflow that's delivered to the subject and doesn't account for the language of
18 the claim limitation itself that talks about deriving the airflow of the subject
19 itself, which is different than the airflow that goes into the patient. So there
20 seems to be a gap between the plain language and at least when you're
21 talking about the particular limitation, which I think is about on 27 and 28 of
22 the petition.

23 I don't see they're talking about how the Truitt airflow sensor
24 derives the airflow of the subject. So can you talk about -- a little bit about
25 how the petition really spans that gap between the airflow sensor and the
26 claimed language?

1 MR. TENNANT: So thank you, Your Honor. The claim
2 language, first of all, requires measuring or deriving, the airflow of a subject
3 while using the PAP device. And so we've applied measuring or deriving in
4 tandem. And I want to point out -- go back to Slide 20, and I'll point out in
5 the petition where this is discussed. But the airflow sensor 782 delivers air
6 via the blower. And also, the pressure transducer 22 monitors the volume of
7 the -- or the pressure of the air to the patient. And so with the airflow sensor
8 and the pressure transducer together, you're able to determine both the
9 direction of the airflow, if the patient is inhaling or exhaling, because the
10 pressure will change relative to an inspiration or an expiration of the subject.

11 And this is also further addressed by Dr. Kirkness when discussing
12 Truitt and reviewing Truitt. Truitt refers to the breathing gas of a system.
13 So a breathing gas, if it's going into the patient, it will only be the airflow
14 from the PAP. If it's a exhale, the breathing gas will include the gas from
15 the PAP but also the patient's breathe or air that the patient is breathing or
16 exhaling. So by Truitt monitoring the breathing gas, Truitt is necessarily
17 determining the airflow of a patient. And I'm on Slide 22 for that.

18 And at the bottom of the slide, we have cites to our petition which
19 is slide -- Page 14 and also 28. And to answer your specific question, the
20 discussion about the sensor system 782 operating within the device is
21 described on Page 28. And I believe that addresses the question of how the
22 device actually determines the airflow to the patient and out of the patient.
23 So it's from the patient.

24 JUDGE HARDMAN: And the citation in petition 28, was that in
25 connection with -- yes. Okay. I see that is your arguments for Claim 1.
26 Thank you.

1 MR. TENNANT: I'll move on issue two. Issue two is regarding
2 the second processor. And the second process is adapted to calculate the
3 data of a severity of a sleep disorder symptom of the subject and/or the
4 index. So to satisfy this claim, we only need to show one of the three
5 conditions that the second processor calculates. Truitt discloses at least two,
6 or at least -- Truitt discloses all three. We're addressing the remaining two,
7 romanette i and romanette iii, in this proceeding.

8 As for the first one, it's not in dispute that Truitt discloses a data of
9 a severity of a sleep disorder symptom. That corresponds to detecting an
10 apnea, a hypopnea, and the snore. And I'm on Slide 26. And as you can see
11 at the top of the slide, Truitt provides expressed disclosure of detecting these
12 three sleep disorder events or conditions. Patent Owner has also agreed in a
13 separate proceeding that detecting apnea and hypopnea events are
14 representative of data of a severity of a patient's sleep disorder symptom.

15 So the only issue that remains in dispute is whether calculation of
16 the -- of that data is disclosed. And Truitt provides expressed disclosure.
17 I'm moving on to Slide 27, Truitt discloses that the output of sensor 782
18 prime, which is part of these airflow sensor system 782 that we mapped to,
19 is provided to the controller. The controller calculates -- expressly
20 calculates the flow and/or volume of gas passing through the conduit 56.

21 So here we see an expressed disclosure that Truitt says it does
22 calculate the flow. And the flow is necessary for determining an apnea,
23 hypopnea, or a snore. And this provides expressed disclosure for that
24 limitation. Notwithstanding Dr. Kirkness, in his reply declaration, expanded
25 on this. And he observed that Truitt monitors the patient to determine these
26 sleep disorder events. And when monitoring the patient, you not only have

1 to take measurements of the patient airflow, it's also important to calculate
2 the number of disordered events.

3 For example, in a given period of time, if a patient snores not very
4 often compared to a patient that snores very often, the level of severity is
5 going to be much higher. So it's important to calculate the number of
6 disordered events that are occurring in a period of time. So even if Truitt
7 doesn't expressly disclose calculating, which it does, Dr. Kirkness had -- has
8 provided testimony that's necessary to calculate the number of disordered
9 events.

10 JUDGE HARDMAN: Can I just ask you a question about that,
11 Counsel? Are you saying it would just be merely obvious for Truitt to
12 calculate the number of events over time? Or are you saying that it does, in
13 fact, calculate events over time?

14 MR. TENNANT: It does calculate events over time. Because
15 when one of ordinary skill in the art reviews Truitt, they understand that
16 Truitt determines the number of events over a period of time. And that is
17 seen also -- I'm on the next slide, 28. When Truitt discloses that the
18 controller adjusts the pressure and the flow in a feedback fashion, a POSITA
19 understands in the feedback fashion you're looking at a prescribed period of
20 time, determining the severity of the symptoms that are occurring from the
21 patient because it's fed back to the system.

22 So based on that disclosure, Truitt provides -- according to a
23 POSITA's knowledge provides the expressed disclosure to determine the
24 number of events that are occurring. Also, the data calculation in PAP
25 devices were well-known. Dr. Kirkness testified to this fact in his
26 declaration of paragraph 169.

1 Regarding index, there is a expressed disclosure of index in Truitt.
2 And specifically, it refers to the -- when you're calculating the AHI or the
3 apnea hypopnea index. And this is an index that is widely published by the
4 -- and I'm on Slide 29. Here we see on Slide 29, at the top, the AASM
5 manual publishes the recommended indexes to observe. And for each index
6 you need to determine the quantity of a particular sleep disorder event.

7 JUDGE HARDMAN: And Counsel, you're not saying that Truitt
8 actually does this calculation of the AHI? I understand you'd instead be
9 saying that Truitt measures the data needed to go on and calculate this AHI;
10 is that accurate?

11 MR. TENNANT: Correct, Your Honor. A POSITA would have
12 known that when determining the AHI for a given patient, that includes the
13 calculation the number of events. Because AHI refers to the number of
14 events, as I've shown by the AASM manual. It's how I perceived to what I
15 understand this -- what this index means.

16 I want to go to dispute three briefly, Claims 8 and 11. And 8 and
17 11 concerns the signal processing techniques. And I'm on Slide 33. The
18 signal processing techniques include many techniques. Two of them are
19 Fast Fourier Transform, FFT, and Discrete Fourier Transform, DFT.

20 And I want to advance to Slide 36 briefly, Truitt expressly
21 discloses a PAP device, but -- and an controller of course. But it doesn't
22 precisely say the algorithms that the controller uses. Kumar, on the other
23 hand, discloses using FFT, Fast Fourier Transform, or DFT, Discrete Fourier
24 Transform to -- there's no methods when analyzing the sleep disorder
25 symptom of the patient. This is an obviousness challenge. In our petition,
26 we presented Truitt in view of Kumar. So the argument is that one of

1 ordinary skill in the art would have been motivated to modify Truitt and the
2 controller 38 to implement FFT and DFT on the controller.

3 This was raised in the petition. Going back to Slide 34, in POR,
4 Patent Owner did not dispute this disclosure or the combination, In the
5 reply, Petitioner merely referenced this argument in the petition. And Patent
6 Owner presented a new argument in the sur-reply.

7 And moving to Slide 35, we believe this new argument is waived.
8 Specifically, they argued that FFT and DFT in Kumar is on the server side.
9 And in Kumar, the controller's on the patient side. But as we argued in the
10 petition, this is a combination we're arguing that always been obvious to
11 implement FFT and DFT on the controller of Truitt. Notwithstanding this
12 argument the -- by Petitioner, we believe the argument has been waived by
13 Patent Owner and it should be disregarded.

14 I want to go to the next dispute, which is on Slide 38. It concerns
15 the remote internet site being adapted to retransmit data in whole or in part
16 to the cell phone. In whole or in part is important because in whole suggests
17 that the entire data from the PAP device is sent back to the cell phone. In
18 part also suggests that partial data is sent back to the cell phone, such as
19 when a physician or a provider reviews the data and sends back the
20 information to the cell phone.

21 And I'm on Slide 40. We argued obviousness for this limitation.
22 We believe it's very obvious to retransmit the data back to the cell phone. It
23 improves user experience. You improve the communication between the
24 base patient and the provider. Because when the provider is sending the data
25 back in part with comments, it betters communication with the provider.

26 And also, a big problem with PAP devices is patient compliance.

1 Patient compliance simply means it's uncomfortable and the patient tends to
2 take off the PAP device especially at night. When a provider can review the
3 information in how the patient is reacting to the PAP device and provide
4 -- and service the device remotely, that can improve patient compliance. So
5 there is very clear motivation to combine here and a need to retransmit the
6 PAP data back to the cell phone, especially after the provider reviews it.

7 Briefly, Mumford, Slide 42. Mumford is for Ground 4. And
8 Mumford provides expressed disclosure of the specific algorithms that
9 calculate the various symptoms. On the left-hand part of the slide these I, II,
10 and III part of the claim. And on the right-hand side, we have the disclosure
11 by Mumford. We believe the disclosure is clear. In the sur-reply, Patent
12 Owner argued that the Mumford sensors to check these conditions are not
13 internal airflow sensors.

14 First of all, we're not bodily incorporating Mumford into Truitt.
15 We are relying on the algorithms of Truitt to be implemented in the
16 controller 38 of Truitt. Notwithstanding, this is a very narrow reading of
17 Claim 1, nothing in Claim 1 requires that the airflow sensor be the exclusive
18 means to detect these conditions. As I showed you earlier in this
19 proceeding, the pressure transducer 22, I believe, in the airflow sensor and
20 other sensors in combination are used to detect the various -- or used to
21 calculate the various conditions of a patient.

22 And moving to Slide 43, more broadly, Mumford identifies that a
23 oximeter, a pressure transducer can also detect sleep apnea. And Truitt also
24 has ports 74 and 76 that incorporate electronic sensing elements mounted on
25 the circuit board. The point being is that a POSITA understands that you
26 have to use a large array of sensors, including the airflow sensor, to detect

1 the various conditions of a patient.

2 And moving this Slide 45, this is also recognized by the '029
3 Patent when it states that although -- it says that one sensor 14 is shown, but
4 it can accept many other sensors. A POSITA very well understands that
5 many sensors are required in PAP devices for detecting and calculating sleep
6 disorder events.

7 JUDGE HARDMAN: Counsel, do you have any disclosure in
8 your petition about the sensors in Truitt that would operate with Mumford's
9 sleep algorithm?

10 MR. TENNANT: Yes, Your Honor. The airflow sensor system
11 782 would operate with Mumford's algorithms. But that's the only sensor
12 that is required of the claim. There may be more sensors that can be added
13 on. But at a minimum, the airflow sensor system 782 in Truitt is required.
14 That determines the flow of the of the air to the patient. And at a minimum,
15 that sensor is required, and Truitt does disclose it.

16 JUDGE HARDMAN: And would Mumford's sleep algorithm be
17 useful if it was only fed by signals from the airflow sensor? Or do you need
18 -- in fact need additional sensors to get any utility out of that algorithm?

19 MR. TENNANT: I'm not aware of -- so at a minimum, you need
20 an airflow sensor to determine these conditions. '029 Patent discloses you
21 use other sensors, such as a pressure transducer. A pressure transducer
22 doesn't detect the flow. It's the pressure on the tube. So you can tell if the
23 patient is inhaling or exhaling. That connected with the flow, you're able to
24 diagnose certain obstructions: if it's apnea, a complete obstruction, or a
25 hypopnea, a partial obstruction, or a snore. Just a very limited obstruction of
26 the airway. So at a minimum, the claim requires an airflow sensor. And in

1 all of the algorithms by Mumford, at least an airflow sensor is required.

2 Given the time, I'm going to turn it over to my colleague.

3 MS. NGUYEN: Good morning, Your Honors. Lisa Nguyen, on
4 behalf of ResMed Corp. I'll be addressing the issues in the 246 proceeding
5 on the '333 Patent. Let's go ahead and start with Slide 2. And on Slide 2 we
6 talk about -- we identify the disputes with respect to the original claims, with
7 respect to the '333 Patent. And the main thing to note with respect to the
8 '333 Patent original claims is that there really are very few disputes.

9 With respects to Ground 1 and 3, on the combination of Toge and
10 Kumar, only dispute is whether or not Toge discloses quantified level of
11 severity data. And then with respect to Grounds 2 and 4, that is not an issue.
12 There is no dispute that quantified level of severity data is disclosed.
13 Instead, Patent Owner disputes whether or not integrated into is actually
14 disclosed. But the thing to note with respect to Patent Owner's argument is
15 that Patent Owner is not actually addressing the combination as disclosed in
16 the petition.

17 In the combination that is in the petition, Petitioner basically has
18 the Norman algorithm and takes it and integrates it as part of Toge's
19 processor. So you're still using Toge's processor, which is in fact integrated
20 into the CPAP machine. Regardless of whether or not you want to argue
21 that it's inside or not, that is not disputed. And so the only final dispute with
22 respect to that combination is really whether or not there is a motivation to
23 combine. And there, Patent Owner argues that Petitioner only provides
24 generic motivation to combine.

25 But this is not a situation where we say Toge, Norman are in the
26 same field, therefore there's motivation to combine. We provide specific

1 cites to both Toge and Norman as to why you would want to combine both
2 of them. And our expert explains why efficiency, accuracy, compliance are
3 all motivations to combine the Norman algorithm as part of Toge's
4 processor.

5 And so let's actually just go ahead and jump to the first dispute,
6 which is the actual construction and limitation of quantified level of severity
7 data. And let's go to Slide 21. So in Claim 15, it provides a method that
8 includes the step of analyzing with a processor the collected data to
9 determine a quantified level of severity data based on the subject's sleep
10 apnea symptoms. And we are specifically discussing whether or not this
11 value indicates how dire patients with a snore are. But what Patent Owner is
12 really trying to exclude is this tidal volume disclosed by Toge.

13 And actually, let's look at what Toge states about tidal volume.
14 And let's go to Slide 28. So tidal volume is volume. Patent Owner
15 repeatedly says it's airflow. But it's not. Actually, airflow, flow is very
16 different from volume. And Toge specifically states that you do have to
17 calculate tidal volume. And you see that formula in paragraph 35 of Toge.
18 In paragraph 39 of Toge, it states, by transmitting the tidal volume of P
19 almost in real time on regular intervals, the physicians can remotely monitor
20 patient's condition."

21 So we are specifically talking about what the severity of those
22 symptoms are. And in fact, Toge expressly says that a decreasing trend in
23 tidal volume can provide emergency measures for adjusting the prescribed
24 pressure to higher level remotely. And again, they're looking just at tidal
25 volume.

26 So going to Patent Owner's own evidence -- so for example, let's

1 go to Slide 25 where Patent Owner talks about its own experts description of
2 what quantified level of severity means. Patent Owner's expert says, a
3 clinician would understand it represents how dire a patient's calculated
4 senses data may be. And if Toge is saying the physician is seeing that the
5 tidal volume is extremely low, that those symptoms are very severe, and
6 therefore, must have increased pressure.

7 So this is exactly what Patent Owner's own expert is saying. It
8 represents how dire a patient's calculated symptom data is. And so we can
9 also see that in Patent Owner's own evidence. If you look at Slide 27, Patent
10 Owner repeatedly cites to Exhibit 2028 to say that this is simply just a
11 measurement, tidal volume is simply just a measurement. But if you look at
12 the complete document, even Patent Owner's own evidence shows that tidal
13 volume also shows severity based off of whether or not the patient is having
14 a hypopnea event or an apnea event.

15 Hypopnea event is only a partial reduction of airflow versus an
16 apnea event is a complete reduction. And so if there is an absence of tidal
17 volume for at least 10 seconds, according to Patent Owner's own evidence
18 then does show that there is a more severe symptom occurring and apnea is
19 occurring as opposed to hypopnea event.

20 And even going back to Claim 15, the language itself, if we go to
21 then Slide 21, to determine a quantified level of severe data based on the
22 subject's sleep apnea symptoms. Subject's sleep apnea symptoms, and so
23 we are looking at whether or not the patient is actually having partial
24 obstruction or full obstructions which can be represented in the form of tidal
25 volume. And so it goes back to Toge does disclose that limitation of
26 quantified level of severity data.

1 Now let's go to the next dispute with respect to the parties, which
2 is the integrated into limitation. And let's go to Slide 30. So a processor,
3 both which are integrated into a PAP or CPAP device. Again, with respect
4 to Toge, Toge does disclose basically the same thing as Patent Owner, which
5 is you have your processor which is in the same device as your CPAP
6 device that provides the airflow and pressurized air for the patient.

7 But even assuming that Patent Owner is correct and we were
8 somehow arguing that it should be Norman's processor. Norman itself also
9 expressly says that the type -- that the titration device, the CPAP device
10 itself, may be combined with the processing arrangement. So going to Slide
11 35 of Petitioner's demonstratives, you see in paragraph 23 of Norman, it
12 expressly says that the titration device may be built into system one, which it
13 explains to be a titration device 26 may be combined with the processing
14 arrangement 24.

15 Now Patent Owner does try to say that we're arguing system versus
16 device and making some sort of distinction about that. But the question is
17 whether or not the CPAP device and the processes processor are together,
18 regardless of whether or not you call that a system or device. And Norman
19 expressly establishes that the titration device may be combined with the
20 processing arrangement. So with respect to that dispute, again, Toge
21 discloses processor integrated into the CPAP device, but so does Norman,
22 even assuming Patent Owner's characterization of Petitioner's combination is
23 correct.

24 Now the final dispute with respect to the original claims is
25 motivation to define. And if we go to Slide 37, we go through a number of
26 different motivations to combine. Again, Patent Owner says this is generic.

1 But this is far from generic. Again, there are specific citations that our
2 expert relied on to review and assess why a person of ordinary skill in the art
3 would have been motivated to integrate Norman's automated titration system
4 with the Toge and Kumar system.

5 And accuracy and efficiency was certainly one of those. Because
6 if you're auto titrating, it's much more efficient because the physician doesn't
7 constantly need to be monitoring the patient. And it can be more accurate as
8 well because it ultimately looks at, for example, the data collected as
9 Norman has expressly taught. So Norman teaches multiple types of data
10 collected over the course of multiple nights, which can enhance the accuracy
11 of the treatment. So in Norman's algorithm, if you see a certain pattern, you
12 can automatically adjust the pressure to address that certain pattern quickly
13 and efficiently and more accurately.

14 On top of that, because compliance is an important issue, as my
15 colleague mentioned before, this really helps with patient compliance. One
16 of the huge issues with respect to CPAP machines is that patients just don't
17 want to use CPAP machines because they're uncomfortable, many times
18 because the pressure is too high. And so if the system of Norman can be
19 more accurate and more efficiently adjust the pressure, that is going to
20 increase patient compliance.

21 Because the more accurate the pressure, as stated in Norman -- the
22 more accurate the pressure is applied to a particular patient, the more likely
23 the patient will regularly make use of this patent therapy. So again, far from
24 being generic, these are very specific motivations to combine based in part
25 in disclosures in both Toge and Norman. And so a POSITA would certainly
26 have motivation to combine. And Patent Owner's characterization that these

1 are generic is just plainly incorrect.

2 Now if we go to Slide 3, we have the disputes with respect to the
3 substitute claims. So there's a written description dispute whether or not the
4 written description supports substitute claims. And then there are three
5 disputes with respect to whether or not the subject's cell phone receives and
6 displays data, whether the cell phone adjusts PAP therapy, and then the
7 familiar remote internet site dispute that we had from the prior proceedings
8 in 159 and 160 proceedings as to whether or not a person of ordinary skill in
9 the art would have been motivated to take Toge's physician-side computer,
10 which is really just a collection of computers, not something like a personal
11 computer and turn that into a remote internet side.

12 But first, let's go to Slide 42 to talk about written description
13 support for the substitute claims. So on Slide 42, we see the priority change
14 seen for the '333 Patent. And the issue, besides the identified support that
15 Patent Owner cited to in its briefing, is that Patent Owner doesn't even try to
16 address two of the applications and whether or not that provides written
17 description support. So already, at that point, there's no written description
18 to support because Patent Owner has not addressed those two applications in
19 the chain.

20 But regardless, let's go to Slide 43 and talk about the standard with
21 respect to written description support. Because what Patent Owner is really
22 trying to do is take a bunch of various different citations and passages and
23 say, oh, well, a person of ordinary skill in the art would have basically found
24 that obvious. But that's completely different from the standard for written
25 description, which is does this inventor actually possess the invention.

26 And strangely enough, this actually conflicts with Patent Owner's

1 position that the combination does not disclose it. Because again, for
2 obviousness, it's what a person of ordinary in the art looking at all these
3 teachings would have been motivated to combine and whether or not they
4 would have ended up with that combination. But with description, you have
5 to teach the POSITA that you are actually in possession of the invention.
6 And that's just not the case with respect to the citations that Patent Owner
7 provides.

8 So if we go to Slide 44 with respect to the 715 citations, there are
9 various different citations. But the main thing that is missing is there is no
10 citation of a subject's cell phone that actually adjusts the PAP therapy.
11 There's citations here and there about PAP therapy being adjusted. There's
12 citations here and there about cell phones. But there's nothing putting those
13 together. So a person of ordinary skill in the art reading this would not have
14 found that inventors actually possess the invention because they were never
15 together. These citations were never together or discussed so that the cell
16 phone was actually adjusting to PAP therapy to show a person of ordinary
17 skill in the art that the inventor was in possession of the invention.

18 And that similarly goes to the 819 citations. If we go to Slide 45,
19 again, there is nothing that actually connects the patient's cell phone to
20 actually adjusting that PAP therapy. So we're really left with -- again, on
21 Slide 46, pointing to amalgam of disclosures from which an artisan could
22 have created the claim invention but did not. Again, this is different from
23 obviousness. For obviousness, you can look a bunch of different teachings
24 and then figure it out. That's not what you can do for written description.

25 So let's go to the actual disputes once again, and let's go to Slide
26 50. So Kumar discloses a patient cell phone that receives and displays PAP

1 data. And let's think about this combination again. We're talking about
2 taking Kumar, which is just a reference that talks about, hey, we can have a
3 telemedicine system where the patient can actually download software and
4 monitor and do things with that cell phone. And we have Toge, which
5 already teaches that a physician can modify or adjust the therapy, the
6 treatment from a cell phone.

7 So a person of ordinary skill in the art during this time period
8 could just understand, okay, well, Kumar teaches, hey, why don't we give it
9 to this -- to a patient as well. And since the cell phone in Toge already has
10 that functionality, it would have been obvious, would have been easy for a
11 person of ordinary skill in the art to do. Now Patent Owner discusses a lot
12 about how just that wouldn't have been capable at the time. But --

13 If we go to Slide 52, in 1999 there were already references
14 disclosing using a consumer web-enabled cell phone in telehealth systems.
15 We saw that again in 2002 for Toge and Kumar and even 2005 with Orbach.
16 There's multiple references that teach using cellular phones as part of a
17 network telemedicine system, including Kumar's client cell phone as part of
18 that. And so it would have been obvious to do that at the time.

19 And just to end things very quickly, going back to remote internet
20 site, we've heard these arguments before about whether or not implementing
21 Toge's physician computer would have made sense. Because Patent Owner
22 says there might be security issues or performance issues. Again, it just goes
23 back to what the law says, which is it doesn't have to be the preferred
24 combination, the best combination.

25 If you go to Slide 71 or Slide 72, there's going to be advantages
26 and disadvantages of different combinations. But that does not mean that

1 was not obvious. And it would have been obvious as Toge and Kumar
2 taught have a -- well for Toge, you already have a physician-side computer.
3 And again, a physician-side computer can be multiple computers that's
4 collecting data. And it would have been obvious to make that accessible, as
5 Kumar teaches to multiple people, and making it available remotely by
6 making that physician-side computer available through web servers and web
7 applications.

8 And unless there are any questions, I'll take the rest of the time for
9 rebuttal.

10 JUDGE POWELL: Thank you. So you'll have 23, roughly.
11 Would Patent Owner that like to reserve some time?

12 MR. PRICE: I will also reserve 20 minutes.

13 JUDGE POWELL: Twenty minutes. Okay. I'll begin with 55 on
14 the clock, so you know that.

15 MR. PRICE: Good morning, Your Honors, may it please Board.
16 As we discussed, I will start with the 00247 proceeding concerning the '029
17 Patent on Claim 2, which just has an overview of the grounds. As Counsel
18 did during the opening, I'll be focusing mostly on Grounds 1 and 4 today.

19 And here's a summary of the arguments that I'll be running through
20 today. Number one is measuring the airflow provided to the patient is not
21 the same as measuring or deriving the patient's respiratory airflow.
22 Similarly, detection of an event related to a breathing metric like Truitt's
23 data is not the same as performing a calculation of the data of the severity of
24 the patient's symptoms.

25 As we'll see, the breathing metrics that are determined in both
26 Truitt for the 247 and Toge for the 246 proceeding, these are breathing

1 metrics that can be used to first determine whether or not a symptom has
2 happened. But then in order to determine the data of the severity of the
3 systems, you need to actually analyze those symptoms. So these breathing
4 metrics that are measured in Truitt and in Toge are at least two steps
5 removed from the symptoms. They tell you nothing about the data, the
6 severity of those symptoms, which have to be calculated based on detected
7 symptoms.

8 JUDGE HARDMAN: Counsel, for tidal volume, if you have a
9 tidal volume of zero, that is already -- you know that it's a severe issue. So
10 isn't it kind of one and the same for some of these symptoms?

11 MR. PRICE: No, Your Honor. So as the patents state, the -- a
12 breathing-related symptom might be an apnea event, which is -- when you
13 have a tidal volume that reaches zero, you can then use that to infer an apnea
14 event. It tells you nothing about the severity of the patent -- the patient's
15 apnea symptoms. So just because you can use this measured data, again
16 -- and Truitt doesn't actually say this. But just because you can use that tidal
17 volume in order to calculate when an event has occurred, such as an apnea or
18 hypopnea -- that's one thing. And then you need to determine the severity of
19 those symptoms to get what's actually claimed.

20 So again, the breathing metrics, the airflow sense values, they are
21 at least two steps removed from the data of the severity of these symptoms.
22 And it's the data of the severity of the symptoms, which is plural. So just the
23 idea that you can detect that the patient's airflow has gone to zero is not the
24 data -- any data reflecting the severity of the symptoms. It's data that may be
25 used to infer that a symptom has occurred.

26 With respect to Claims 8 and 11, we will talk about why the Truitt

1 system does not do the calculations on the device that are necessary in the
2 first place, which was what was focused on in the Patent Owner response
3 and then the response to the arguments made in the reply, wherein Kumar
4 was brought in for these certain algorithms, and why we believe that there
5 was no showing that that would occur or it would have been obvious for that
6 to occur on the device itself.

7 And then finally, I will touch on Claims 9 and 13, which require an
8 internet site adapted to retransmit data back to the cell phone. Now this is
9 not disclosed in Kumar. ResMed makes an obviousness argument that it
10 would have been obvious to retransmit data back to the cell phone.

11 However, in Kumar system, once data is at the remote internet site, it can be
12 downloaded by physicians is what's disclosed. There is no disclosure in
13 Kumar of sending it back to the cell phone. And we'll see, the cell phone in
14 Kumar sends the data to the remote internet site. It already has the data.
15 And there is no disclosure of sending it back. There's no motivation to make
16 that modification to reach these claims.

17 And finally, I will just talk briefly about the motivation to combine
18 Mumford and Truitt and how Mumford has many, many sensors that it uses
19 to calculate the calculations that Petitioner relies on it for. But Truitt is
20 specifically about reducing the number of sensors in the device. Therefore,
21 not only are Mumford's algorithms require input from data -- from sensors
22 that are not the internal airflow sensor, but adding all of these extra sensors
23 to Truitt's system would destroy core -- Truitt's core objective, which is to
24 reduce the number and types of sensors in the system.

25 Just an overview of claim, one of the '029 Patent, I'm on Page 5, it
26 requires an airflow sensor internal to the PAP device that measures the

1 subject's respiratory airflow. A second processor within the PAP device that
2 receives that airflow sensor and calculates the severity of the sleep disorder
3 symptoms, an index based on the severity and/or usage data. And then it
4 also transmits that data to a remote internet site and to a cell phone.

5 So one of the key features of the '029 Patent is that you will be
6 detecting the severity of the patient's symptoms and not merely reacting in
7 real time to two events, which is what Truitt discloses. This feedback
8 system that Truitt discloses is the very, very type of PAP device that was
9 distinguished in the '029 Patent, these types of systems that measure one
10 value and immediately provide a feedback based on that. That's auto
11 titration. I think Truitt also has a bi-level auto titration. That's very different
12 from deriving severity of the sleep disorder symptoms and then -- and then
13 using that for control.

14 So, onto Page 6, this is what I was talking about, there's the
15 pressure that's delivered to the patient and it adjusts immediately in a
16 feedback fashion to meet the desired prescription level. So if the air
17 pressure drops to zero, it will increase the pressure until the patient starts
18 breathing again. These type of auto titration devices are exactly what the
19 '029 Patent distinguished in their background. Truitt does not measure the
20 patient's respiratory airflow, it does not quantitatively determine the severity
21 of the symptoms, and it does not transmit diagnostic data to a remote
22 internet site.

23 JUDGE HARDMAN: Counsel, can I ask you there about -- you
24 said Truitt does not measure the patient's respiratory airflow. What about
25 what we talked about with Petitioner's counsel where it can distinguish
26 between the inspiratory and expiratory phases of breathing?

1 MR. PRICE: Sure. And that's all it can do, it can distinguish when
2 the patient is breathing in, when the cycles begin, and when it ends. But it
3 tells you nothing more about the actual airflow. It doesn't tell you the
4 volume of the airflow. It doesn't tell you how much airflow. It can only
5 sense that there has been a change that indicates that the patient has moved
6 on to an inspiratory cycle or an expiratory cycle. So --

7 JUDGE HARDMAN: Doesn't that fit the claim language, though,
8 because the claim says, "deriving -- measuring or deriving the respiratory
9 airflow"? And it doesn't say much more, so why wouldn't -- just knowing
10 inspiration versus exploration, why isn't that enough for this broad claim
11 language?

12 MR. PRICE: Because it tells you nothing about the flow. And I
13 would dispute that it's broad claim language. The airflow is the amount of
14 air flowing. So just because you can distinguish when the patient is
15 breathing out and when the patient is breathing in doesn't mean that you
16 have any information about how much. And that's what flow is. Flow is
17 how much air is being inhaled or exhaled. So just the basic ability to
18 distinguish between inspiration and expiration doesn't give you the airflow.

19 And the '029 Patent gives you -- unlike Truitt, it gives you ways to
20 either measure directly or infer -- estimate from the internal airflow sensor,
21 the actual airflow of the patient. So, I'm on Page 7, and that had the material
22 about Truitt. It's not measuring the airflow of the subject.

23 JUDGE HARDMAN: And where do we find the citations to -- I
24 think you said that the '029 Patent tells you how to derive the airflow of the
25 subject. Do you have citations for that?

26 MR. PRICE: I can get you those citations, sure, if I don't get there

1 during this proceeding.

2 Moving on to page -- Slide 8, Truitt does not disclose, as I alluded
3 to earlier, determining the data of a severity of the patient's symptoms. The
4 data of severity measures the degree of deviation from the baseline
5 characteristics of patient without sleep disorder systems -- symptoms. It's
6 also been described as determining how dire the patient's symptoms are.
7 And like I said earlier, just detecting that airflow has -- to the patient has
8 exceeded or gone below a certain value doesn't tell you anything about the
9 data of the severity of the patient's symptoms overall. It may help you
10 identify those symptoms in the first place.

11 And again, we spoke earlier about Truitt's feedback loop. How
12 that works is as soon as an event is detected, the system itself increases the
13 pressure to alleviate that symptom. That's what the feedback loop is.
14 There's no idea of measuring the symptoms over time, determining how dire
15 the symptoms are, or taking any actions based on that. Again, the Truitt
16 feedback loop is immediate based on what's sensed directly on the device.
17 And again, that is exactly the type of system that was distinguished in the
18 '029 Patent. Are there any other questions on those matters?

19 So just briefly I'll touch on the motivation to combine Truitt into a
20 networked PAP system based on Kumar. So again, because Truitt is an auto
21 titrating device, a lot of the reasons for combining with a network device
22 like Kumar just really don't make sense. Again, unlike the '029 Patent where
23 this there's this idea of calculating the data of severity, showing it to the
24 patient, showing it to the physician to make certain changes, Truitt's device
25 is self-contained and auto titrating. So it's not even clear what the physician
26 having this data would do in order to improve Truitt's system.

1 Moving on to Claims 8 and 11, so in the Patent Owner response we
2 focused on the fact that Truitt doesn't do any kind of calculations based on
3 its airflow measurements. All it does is infer what the tidal volume is. And
4 it doesn't do any calculations. It doesn't use FFT, DFT, RMACs in order to
5 analyze this data because it has no use for that type of analyzed data.

6 In the reply, I know Petitioner focused heavily on Kumar provide
7 doing these kind of calculations at the server. And in the sur-reply, we only
8 pointed out that there's no motivation -- there was no argument or motivation
9 to actually do that type of analysis on the PAP device, which is what the
10 claims require.

11 And getting to Claims 9 and 13, Kumar does not disclose
12 retransmitting data back to the cell phone. Both of these claims require that
13 the remote internet site be adapted to retransmit the first radio frequency
14 transceiver on the cell phone, which includes the severity usage and/or index
15 data. Kumar just doesn't disclose this.

16 Kumar discloses a system where the data goes from the client
17 device to a computing device 110, which I understand Petitioner refers to as
18 the cell phone, and then into a server for analysis and storage. And then that
19 data can be accessed by physicians. There is no disclosure of it being
20 retransmitted back to the cell phone. And I would say that all of the
21 motivations that Petitioners come up with are all based in hindsight. There's
22 just no disclosure there.

23 Okay. Moving on to Ground 4 with Mumford. Again, Mumford
24 teaches analysis, but it teaches analysis, again, of signals outside of the PAP
25 device. And Petitioner has not provided any motivation to use Mumford's
26 algorithms within Truitt's PAP device. Again, Truitt doesn't disclose doing

1 any kind of -- this analysis on the system. And I would say it's also -- there's
2 no reason to be doing this kind of calculation on Truitt system, which again
3 is a auto titrating system which works on a on a feedback loop based on
4 signals that's collected on the device. So that's the one thing.

5 And then Mumford also does not -- is in conflict with Truitt's
6 desire to eliminate the extra sensors that are required to perform Mumford's
7 sleep efficiency algorithm. So the idea that you would take a device like
8 Truitt, auto titrating, self-contained, works on feedback loops based on
9 sensors that are calculating data on the device, and you're going to modify it
10 with -- to calculate, these sleep efficiency algorithms from Mumford, both
11 -- there's no disclosure of that.

12 There's no motivation for moving the calculations to the device.
13 And doing so, in order to get the benefits of Mumford's algorithm, you
14 would have to add in all of the sensors that Truitt says we don't want to
15 have. So in our view, a person of ordinary skill in the art would not have
16 been motivated to modify Truitt with Mumford, as expressed in the petition
17 and reply.

18 So moving on to Slide 15, the person of ordinary skill in the art
19 would not have -- even had reasonable expectation of success. Mumford's
20 algorithm requires these multiple electrode sensors to calculate it to run its
21 algorithm. But Truitt only has this flow sensing assembly. And Petitioner
22 has not explained how a person of ordinary skill in the art would have been
23 able to calculate Mumford's algorithms with only the sensors that are
24 available in Truitt's PAP device. Your Honors have any other questions
25 about the '029?

26 Okay. I switched over to the slides for the 00246 proceeding,

1 about the '333 Patent. Similar to the previous proceeding and consistent
2 with the type of PAP devices that were available at the time of the invention,
3 Toge does not teach a PAP device that calculates a quantified level of
4 severity. Kumar is not relied on for that limitation. And Toge in view of
5 Kumar and Norman would not render obvious the limitation that requires
6 determining the quantified level of severity data using a processor integrated
7 into the PAP or CPAP device, because Norman's processor is not integrated
8 into the CPAP device.

9 And Petitioner's motivation to combine Norman and Toge does not
10 have anything to do with moving the calculations being done outside of the
11 PAP device to a processor inside the PAP device. I know I heard a lot of
12 arguments about why the reason it's not generic. Whatever specific
13 motivations there are for combining Norman and Toge have nothing to do
14 with moving it to where they're -- where it's required to be, the calculations
15 being done on a processor of the PAP device.

16 Okay. So moving on to Slide 5, we know the Petitioner argues that
17 Toge's tidal volume is a quantified level of severity data, but it just isn't. It is
18 the amount of air that the patient is breathing. But again, that's a breathing
19 metric. And we know from Petitioner's experts that breathing metrics like
20 this are not a quantified level of severe -- severity data. Again, you're going
21 to be at least two steps removed from that quantified level of severity data.
22 You need to take the tidal volume, analyze it to recognize a symptom, then
23 you have to analyze the symptoms to determine the quantified level of
24 severity of those symptoms. And that's just not what the tidal volume is.

25 So, moving on to Page 6, just outlining the claim construction
26 dispute here. Both parties believe that their interpretation of quantified level

1 of severity data represents the plain and ordinary meaning. As far as
2 CleveMed, our position is that the plain and ordinary meaning of this term is
3 that it's a calculated value that represents how dire the patient's symptoms
4 are. That's just what it means to a person of ordinary skill in the art.
5 Petitioner doesn't have an explanation of what their plain and ordinary
6 meaning is. They leave it vague and undefined, and then just claim that the
7 title volume meets that construction, whatever it is.

8 So, on Page 8, I have ResMed's expert, Dr. Schwartz, who's
9 testified in a related proceeding that the level of severity is not mere
10 statistics of measured conditions. Okay. So a person of ordinary skill in the
11 art -- and he's actually looking at statements made during the prosecution
12 history of one of CleveMed's patents, based on the statements that Patent
13 Owner made that the level of severity and an index of the level of severity
14 are not merely statistics of a measured conditions alone, such as pressure
15 leak, airflow, pulse rate, or oxygen saturation that could be used to
16 determine events.

17 So this is saying that the measured statistic of tidal volume is not a
18 level of severity. It is a measured condition, but it does not -- it's not the
19 level of severity of the patient's symptoms.

20 JUDGE HARDMAN: Counsel -- oh, go ahead, Judge Powell.

21 JUDGE POWELL: Thank you. Sorry. He doesn't mention tidal
22 volume. He mentions airflow pressure. Is it possible that tidal volume is
23 something that could be calculated based on pressure and airflow and
24 therefore is not excluded by Dr. Schwartz as a level of severity?

25 MR. PRICE: Well, again, I think they are two different things.
26 The tidal volume is the total airflow measured. It's the airflow into the

1 system into a patient. When you determine how much of that air went in,
2 that is the tidal volume. And this is measured in the system. Usually it's
3 measured at the mask to actually determine the airflow. But again, just
4 because you have the tidal volume, again, you're two steps removed from the
5 data of severity of the symptoms. You can use the tidal volume to detect a
6 symptom, then you can analyze those symptoms to get to the level of
7 severity of those symptoms. But the tidal volume is just the patient's
8 airflow.

9 JUDGE POWELL: So you would submit that because he said
10 airflow is not a measure of severity, that we should interpret that as meaning
11 tidal volume is not a measure -- as him saying tidal volume is not a measure
12 of severity?

13 MR. PRICE: Well, even if you didn't equate airflow and tidal
14 volume -- these are examples. Tidal volume is certainly a measured
15 condition. Okay. These are examples. So pressure leak airflow, again, the
16 point here is that the data that you use, these breathing metric data that you
17 use to identify symptoms in the first place, are not a level of severity of
18 those symptoms. And so whether or not airflow is identical to tidal volume,
19 these are just examples. And tidal volume is a measured condition.

20 JUDGE POWELL: Okay. I should let Judge Hardman get her
21 question.

22 JUDGE HARDMAN: I'm just curious what patent Dr. Schwartz is
23 talking about here and if it's in the same family as the challenged patent in
24 this case?

25 MR. PRICE: I will get you that answer on rebuttal.

26 JUDGE HARDMAN: Okay. Thanks.

1 MR. PRICE: Page 9, more on this, so Petitioner is arguing that the
2 tidal volume is a quantified level of severity because it represents the level
3 of the airway obstruction. But again, the level of severity is not a mere
4 statistic of the measured condition. It's actually determining how bad the
5 symptoms are. Anything else before I move on to Ground 2?

6 So neither Truitt nor Norman discloses a processor integrated to a
7 PAP or CPAP device that determines a quantified level of severity. For
8 Ground 1 we talked about how tidal volume is not a quantified level of
9 severity data. And Norman does not disclose a processor that's integrated
10 into the PAP device that performs this analysis.

11 And Petitioner is not has established that it would have been
12 obvious to move Norman's calculations into a processor that's integrated into
13 a PAP device. Again, all of the devices that we've seen at this time do this
14 kind of analysis, which is more heavy data analysis outside of the PAP
15 device itself.

16 And I think I'm moving on to Slide 13, which I think is the critical
17 slide here. Now I heard during the opening that Petitioner's relying on the
18 Norman's disclosure of integrating the titration device 26 with the processing
19 arrangement 24 and indicating that that somehow teaches a processor
20 integrated into the PAP device that would perform these calculations.
21 However, as we can see in the figure of Norman here on this slide, the
22 processing arrangement 24 is outside of the PAP device, which is numbers
23 22 and 25. The titration device 26 is also outside of the PAP device.

24 So even if you integrate the titration device and the processing
25 arrangement, that still results in a processor that's outside of the PAP device.

26 So --

1 JUDGE HARDMAN: Isn't the argument there that you take
2 Norman's functionality and put it on Toge's processor which is admittedly in
3 the PAP device?

4 MR. PRICE: So I think that that's one argument. I think they are
5 also trying to rely on an expressed disclosure argument that Norman actually
6 teaches doing this calculation on a processor inside a PAP device. So
7 certainly, on the expressed disclosure it's not there. Norman very clearly
8 teaches doing the processing -- or the processing arrangement outside of the
9 PAP device. I think I heard Counsel saying that the titration device is the
10 PAP device, which is not true. The titration device is the device that
11 measures the amount of pressure that it will inform the PAP device to
12 provide, but it's not integrated into the PAP device.

13 And then so --

14 JUDGE HARDMAN: What's the basis for -- on this Slide 13, such
15 a literal view of the blue is the only part that's the PAP device, whereas the
16 other elements are thus outside of the PAP device. That seems like a pretty
17 literal conception of that figure that I'm not sure is based in Norman itself.

18 MR. PRICE: So this is Norman, this is Norman's disclosure.
19 Norman has a disclosure of the system that indicates that the PAP device,
20 which is -- we've highlighted here in 22 and 26 -- 22 and 25 is connected via
21 wires versus via -- or some communications system to the processing
22 arrangement and titration device. And I didn't spend much time on it, but
23 there is -- we do have a claim construction argument about the -- integrated
24 into the PAP device means that it's inside the PAP device.

25 What we see Petitioner doing is allowing for the term integrated
26 into the PAP device being broad enough to encompass a processing

1 arrangement anywhere in the system. They can correct me if I'm wrong, but
2 I don't believe Petitioner actually makes an argument that Norman teaches or
3 even suggests that the processing arrangement and the titration device
4 -- and/or the titration device would be integrated into the PAP device.

5 And then moving on to the motivation to amend, there is no
6 motivation indicated in the patent for why you would take this processing
7 arrangement where all of these systems at the time of the invention, when
8 you were analyzing this breathing metric data, would be done outside. None
9 of the motivations to combine actually relate to why you would want to do it
10 on the PAP device instead. So we have made the point that these motivation
11 to combine motivations are generic, and none of them point to a system
12 where these things would be done on a processor integrated into the PAP
13 device itself. Any further questions there?

14 Okay. So I will move on to Patent Owner's contingent motion to
15 amend. So there is written description support for a patient cell phone
16 adjusting the PAP, CPAP therapy. Toge and Kumar do not disclose such a
17 feature. And with respect to the other limitation that was added about
18 transmitting data to a remote internet site, we have two different arguments
19 from Petitioner, one in which Kumar's browser side engine would be
20 implemented on the physician's computer. Which I think we've gone over in
21 fairly deep detail in some of the other cases, but I'll touch on it today.

22 There's a new argument in this proceeding about how Kumar's
23 server could be implemented anywhere in the system. And I would say that
24 in that case the Petitioner has not actually identified how the system would
25 be implemented in order to reach all of the client limitations.

26 Okay. So, we're in description support for the subject accessing

1 the PAP device on Page 20. First, I just want to touch on the issue of
2 whether or not the disclosure in the first 899 application has carried through
3 all the applications. I think that's not relevant to the questions that we have
4 in this case. So in this case, we need to know whether or not there's written
5 description support in the most recent application. It's a written description
6 argument.

7 We haven't attempted to show priority all the way back to the first
8 application in the priority chain, which would then require us to also show
9 that the intervening applications also carried through the same disclosures
10 that we were relying on. They did, but it's not necessary for Your Honors to
11 find that in order to find that there is written description for this limitation in
12 the 715 application itself which issued us the '333 Patent.

13 JUDGE HARDMAN: You're saying that the 715 application has
14 all of the disclosure you need for written description support for the added
15 limitations?

16 MR. PRICE: That's correct. Okay. And here's the reason, so the
17 715 application discloses that a subject, a physician -- a subject or a
18 physician, or it can be done automatically, can alter the -- can adjust the
19 device based on the output of the level of severity. So the 715 patent is
20 expressed -- expressly says that, that the subject can adjust it based on that
21 information. Then the patent also -- the application also talks about
22 numerous places about how the adjustments actually happen. And they can
23 happen from a cell phone. They can happen from a processor, a base station,
24 a PDA. Any of these devices are capable of adjusting the pressure based on
25 the level of severity data.

26 So taking just these two disclosures together that you can -- the

1 patient is allowed to adjust the pressure based on the level of severity and
2 umpteen disclosures in the patent about what devices are capable of and how
3 the devices are capable of making that adjustment, a person of ordinary skill
4 in the art understands that one of the ways to do that is with the patient's cell
5 phone. It's unclear how else the patient would be able to adjust it based on
6 the level of severity which is output and displayed if it's not, for example,
7 done with the patient's cell phone.

8 So just at a high level, we have the disclosure of the subject being
9 able to make these adjustments. And we have disclosures up and down
10 about what devices are capable of making these adjustments. So taken
11 together, they inform a POSITA that the inventors had the idea of a patient
12 adjusting the PAP device with their cell phone.

13 JUDGE HARDMAN: Can you show me the clearest disclosure
14 that a cell phone, whether it's the patient's or the physician's, can be used to
15 adjust the device? I see that the cell phone receives data, but what I'm
16 failing to see is that the cell phone does the adjustment.

17 MR. PRICE: Yes. So here, I'm on Slide 20, there's the first bullet
18 point in the lower box. It discloses that the output is provided -- and the
19 output being the level of severity data -- which is then used by a clinician or
20 the subject to adjust the device. In that same box, the 715 application also
21 clarifies that a device can remotely program the therapy of the PAP or CPAP
22 device and is not limited in any way.

23 Certainly, the applicant thought that that's what they were
24 disclosing here. So, I'm on Page 21. And this is statements that the
25 inventors made during prosecution, that the invention allows not only the
26 patient but their clinicians to be aware of the efficacy of the patient's

1 therapy, as precedent -- presently configured, and to adjust or titrate the
2 therapy efficiently, quickly, and remotely.

3 In terms of Petitioner's challenge, we think that they are reading
4 the applications too narrowly. They're looking at things in isolation and
5 looking for expressed disclosure that says that the device that's making these
6 changes is the patient's cell phone. That's not the standard for written
7 description. The written description is -- doesn't require inaccurate support,
8 but it's based on what the disclosure as a whole conveys to a person of
9 ordinary skill in the art.

10 And certainly, a disclosure of being able to adjust the pressure
11 remotely via any device and the disclosure that the subject is able to adjust
12 the pressure based on the output which is the level of severity data, those
13 two disclosures taken together sufficient to provide a written description.

14 Okay. So in terms of the obviousness case, Kumar does not
15 disclose the subject adjusting PAP therapy at all. So this idea that there's
16 some sort of admission based on our analysis of the written description
17 issue, that it would also have been obvious to do this in the system of
18 Kumar, it's not. Because the key difference is the '029 Patent -- or the '333
19 Patent actually discloses the subject making adjustments to the PAP device
20 where Kumar doesn't right.

21 So this is a missing limitation, even in their combination of Toge
22 and Kumar. And moreover, it's a -- there's a missing limitation that
23 Petitioner just tries to gap fill with expert testimony. And we think, first of
24 all, that this -- at a high level, this is conclusory expert testimony that cannot
25 be used to supply a limitation to begin with. But also, moving on to Page
26 26, we believe that the director's enforcement and non-waiver of 37 CFR

1 42.104 before applies here. Because Petitioner had the opportunity to bring
2 in additional evidence to show that this limitation was known, and instead
3 they are trying to rely on general knowledge and conclusory expert
4 testimony.

5 I think this is probably an issue of first impression as to whether
6 this should apply in a motion to amend context. But we believe that that it
7 absolutely should because Petitioner had the opportunity to come in with
8 evidence to show that this was actually known, and that evidence did not
9 come forth. But again, I'm here on Page 27, regardless of whether or not
10 that memo should apply to this motion to amend proceeding, Petitioner's
11 expert really does just conclusionary state that it would have been obvious to
12 do this thing as a wholesale substitute for recent analysis and evidentiary
13 support.

14 Moving on to the second limitation at issue here in the motion to
15 amend context, the subject cell phone must -- so the data must be transmitted
16 to both the subject's cell phone and to a remote internet site hosted on at
17 least one server. So Toge doesn't disclose a remote internet site. Toge
18 discloses a system where data from a PAP device is sent to a physician's side
19 computer and potentially also to a mobile device operated by the physician.

20 So Petitioner proposes two different combinations of Kumar with
21 Toge. The first one is new, at least it didn't come up in any of the prior
22 proceedings that had similar limitations. And that's this idea that Kumar's
23 web server could be implemented at various locations. So in terms of this
24 configuration, we don't know what Petitioner is actually envisioning, how
25 they're planning to combine the systems of Toge and Kumar and whether
26 -- or I should say or whether the system that's envisioned -- the combined

1 system that's envisioned of Toge and Kumar would actually read on all of
2 the limitations of the claims.

3 Now there is a very specific implementation that Petitioner argues
4 would be obvious, and that's where Toge's physician-side computer actually
5 runs a web server in addition to being a client, which I think we've discussed
6 ad nauseam in some other proceedings. But there's no disclosure of doing
7 that. And it doesn't make sense because you would not be able to run the
8 type of web server that -- of Toge's physician-side computer.

9 Moving on to Page 32, a browser-based engine at various
10 locations, it doesn't show why a POSITA would have implemented it at any
11 one of those locations or how it would have read on the claims. So they
12 might want to implement reasons for that. But from the response to the
13 motion to amend, we don't even know what this various sites combination
14 looks like.

15 And in terms of the other where you would actually put it on
16 Toge's physician-side computer, we know that a web server and a client on
17 the same machine has to run or the motivations that would have given a
18 POSITA to -- the reason to try to implement the remote internet site
19 somewhere in Toge's system. There are fundamental security problems and
20 fundamental performance problems and fundamentally no teaching of
21 implementing a web server on a client device like Toge's physician-side
22 computer.

23 34, this is just the evidence about why web servers on a client are
24 not suitable for web applications. As far as I can tell, this is not -- there's no
25 counterevidence here. So for this reason, a person of ordinary skills in the
26 art would not have been motivated to implement a web server on a client

1 device like Toge's physician-side computer. We have security reasons why
2 you would separate the web server from clients, and also performance
3 reasons why a web server would be separated from a client in a web
4 application. Now Petitioner didn't depose Dr. Goodrich. There's no
5 evidence counteracting this evidence. So as far as we can tell, this is
6 unrebutted.

7 And I think the last thing here on page -- Slide 37, we heard this
8 alternative theory that Toge's physician-side computer could be a distributed
9 system. Again, first of all, it wasn't set forth in the petition. But also, Toge
10 doesn't teach that its physician-side computer is a distributed system, nor is
11 there any explanation of when -- if this physician-side computer was actually
12 implemented as a distributed system, what the combination would actually
13 look like.

14 And it's just not about bottling incorporation or anything like that,
15 it's what would a person of ordinary skill in the art have understood and
16 done with the teachings of these references, and does that combination read
17 on the claims. Now there are certain limitations that require certain
18 communications with client device, certain communications between the
19 client device and a remote internet site.

20 If they're distributed, I think the idea is to say that, well, then the
21 distributed computer could then still be considered a client device in the web
22 server because it's somehow distributed. But again, these theories are not set
23 forth in anywhere near the kind of detail that would allow us to understand
24 what's actually being suggested in the combination or how it would read on
25 the claims.

26 If there are no questions from the panel, I'll save the rest of my

1 time for rebuttal.

2 MR. TENNANT: Thank you, Your Honors. I'll be quick. I'll
3 address the '029 Patent first, and then my colleague will address the '333
4 Patent. Mr. Price raised arguments regarding the airflow, and I want to
5 address -- let me go to Slide 19 and just emphasize that the airflow sensor
6 -- all that the claim requires is the airflow sensor is adapted for measuring or
7 deriving the respiratory airflow of a subject.

8 And what does the '029 Patent disclose for that? We see this on
9 Slide 21, in the bottom paragraph, it indicates the airflow can be estimated
10 by measuring various passageways to determine an inspiration or an
11 expiration. This is precisely what Petitioner identified as measuring the
12 airflow in the petition. And we also address this in the reply.

13 And Judge Hardman asked the question where it's cited in the
14 petition, before this argument I confirmed that the citations in the lower left-
15 hand corner of Slide 21 are indeed accurate. The petition at 14 talks about
16 the inspiration and expiration in the context of the preamble of Claim 1.
17 And then Page 28 again cites the same paragraph when discussing this
18 element. We believe it is clear that Truitt discloses the airflow sensor of
19 Claim 1.

20 Let me go to the second dispute, I'm Slide 24. I'll advance from
21 that. Actually, Slide 25 is better. This second dispute is what is calculating
22 the data of a severity of a sleep disorder symptom of a subject.

23 And advancing the Slide 26, it's undisputed that Truitt can detect a
24 snore, can't detect an apnea, can detect hypopnea. And each of these
25 conditions are different sleep disorder events. In a PAP system, when you
26 calculate a sleep disorder, you're not necessarily doing a quantitative

1 analysis. You're comparing it to a baseline. How do you determine if there's
2 a complete obstruction such as an apnea compared to a baseline? How do
3 you determine if there's a hypopnea? You compare it to a baseline.

4 And with respect to these arguments that Patent Owner has raised,
5 they've been addressed concretely in the reply at 9 when talked about
6 calculation not necessarily being limited to a quantitative analysis that Patent
7 Owner argues. And I want to point out and go back to Slide 25, nothing in
8 Claim 1 requires calculating being limited to a quantitative analysis. It's just
9 not required in these PAP systems. You can do a quantitative analysis, but
10 there are other ways to calculate, such as we argued in the reply of
11 comparing to a baseline event; such as if a patient doesn't snore, what does
12 baseline indicate compared to when a patient does snore.

13 And the difference in the level of severity that Patent Owner
14 argued is really the difference between determining an apnea has occurred
15 compared to a hypopnea compared to a snore. There are different levels of
16 obstruction going from a complete obstruction to a not a complete
17 obstruction with a snore. And furthermore, Patent owner has already
18 recognized that distinguishing between apnea and hypopnea, such as
19 indicated on Slide 26, in a different proceeding represents the data of a
20 severity of a patient's sleep disorder symptom. So these PAP systems are
21 quite smart. They're able to detect and determine the difference between
22 these various symptoms.

23 With respect to quantitative, I do want to point out -- and I want to
24 go to Slide 30. Even the '029 Patent indicates that it's preferable to do a
25 quantitative analysis. But that doesn't mean it's required to do a quantitative
26 analysis. So when you're trying to determine what does calculating include,

1 it can include quantitative. But it certainly include other methods for
2 determining the level of severity.

3 And going back to -- I just want to point out again, going back to
4 Slide 26, Petitioner believes that detecting snoring, apneas, and hypopneas is
5 the way to calculate the level of severity. And I want to emphasize too on
6 Slide 27 that there is expressed disclosure of calculating. He uses the same
7 words as the claim to calculate the flow to the patient. And this flow to the
8 patient is used to determine -- along with other sensor inputs, it's used to
9 determine the severity of the sleep disorder symptom.

10 Next, I want to talk about Mumford. And I'll go to -- sorry, I think
11 Slide 36, and I'll just speak to this issue primarily. Patent Owner has argued
12 that Mumford tries to limit the sensors. And this argument was made in the
13 briefing papers. They've argued that Truitt is trying to limit the number of
14 sensors. It needs to be clear that Truitt is not necessarily limiting the
15 sensors. Truitt actually has an airflow sensor. It has a pressure sensor.

16 And if you read our reply, we've responded to this argument at our
17 reply at the paragraph spanning PAGEs 23 and 24. And we identify the
18 large number of sensors that Truitt recognizes needs to output signals to the
19 controller to control the PAP according to the calculated or detected sleep
20 disorder symptom. And this is in a reply on Page 24. But I do want to read
21 one sentence from Truitt, paragraph -- actually, column 6, line 60, the
22 sentence, and this is quoted in a reply. This is after the paragraph where it
23 talks about you need the airflow sensor and the pressure transducer input
24 into the controller to determine the severity of the symptom.

25 And it also indicates that it is to be understood that other sensors
26 can be provided to provide additional information to the controller. So when

1 a skilled in the art is looking at Mumford, and Mumford refers to other
2 sensors -- actually, go to Slide 43. When Mumford refers to other sensors, it
3 is expressly recognized in Truitt that additional sensors may be required and
4 put to the controller. So when you combine Mumford's algorithms with
5 Truitt, a POSITA would understand that additional sensors may be necessary
6 to carry out the algorithms. At bottom, at least an airflow sensor is
7 necessary or a flow sensor. And Truitt provides the expressed disclosure of
8 the flow sensor inputted to the controller.

9 I want to talk about motivation to combine briefly, and I'll go to
10 Slide 48. And this has been addressed in our in our papers. There is quite
11 extensive motivation to combine Truitt with Kumar. Truitt it is a single
12 CPAP device. Kumar teaches to make it into a CPAP device that works in
13 telemedicine network environment. We have very expressed cites, clear
14 cites, detailed sites cites in the record to why this would have been obvious.

15 Now Slide 48, we've identified five of the -- at least five of the
16 reasons why one would be motivated to combine. In their sur-reply, it's
17 -- Patent Owner has tried to narrow the motivation to combine. They argue
18 that there needs to be motivation to combine to measure or derive airflow on
19 the device. But Truitt expressly discloses this. They argue that that needs to
20 be motivation to combine to perform severity calculations. True, it
21 expressly discloses this. So in their sur-reply, the -- what they allege we
22 need to show for motivation to combine, Truitt actually expressly discloses
23 those things.

24 A third thing they argue in their sur-reply, that there needs to be a
25 motivation to combine to build a server to a phone return path, referring to
26 the retransmission argument. Again, that's -- not again, but that's not a

1 requirement of the claim. There's no requirement of the claim of a server;
2 and moreover, a phone to server return path. There would not be need to be
3 a motivation to combine for that element as well.

4 I'm addressing Mumford, I'm moving to Slide 50. We provide
5 clear motivation why one would have combined Mumford with Truitt and
6 Kumar. The combination improves the performance. And the modification
7 would have been advantageous to minimize pressure applied, increase
8 comfort, and therefore improve compliance. If there's no further questions,
9 I'll turn it over to my colleague. Thank you.

10 MS. NGUYEN: Patent Owner had many arguments, so I'll try to
11 be brief in responding since we have limited time. But I wanted to go back
12 to the claim construction that Patent Owner provides for the quantified level
13 of severity of data. It's a calculated value that indicates how dire patients
14 symptoms are. And one of the things that Patent Owner said was that this
15 information the tidal volume does infer that a symptom has occurred. Now
16 he stated this with respect to the '029 Patent. But it still applies here that
17 even if you're admitting that it infers that a system symptom has occurred,
18 you are still calculating a value that indicates how dire patient's symptoms
19 are.

20 And if we go to Slide 26 once again, Patent Owner repeatedly talks
21 about how it can't just be a measured value but never addresses the fact that
22 Toge actually does calculate it. So this isn't just a measured value. This is a
23 value that is determined using a formula that Toge teaches in paragraph 38,
24 as you see in Slide 26. And I actually did want to go to Patent Owner's Slide
25 8 with respect to what Patent Owner says is an admission by Petitioner's
26 expert with respect to a measurement or statistic just being not a quantitative

1 level of severity data.

2 But I believe Judge Hardman asked if this is from a related patent.

3 It's not. But I think the larger issue is that if you look right after the

4 highlighted language, it says that could be used to determine stroke related

5 parameters. So again, this goes back to the fact that you can't use a random

6 declaration related to random patent to take a statement out of context

7 without really understanding what it means. And this is applying it to a

8 completely different reference, a completely different patent, and discussing

9 different issues. And so you can't take this as a statement that the level of

10 severity excludes tidal volume, particularly when tidal volume is not even

11 used in the cited declaration.

12 With respect to integrated into on -- I believe Patent Owner

13 discussed motivation to combine and said there's no motivation to combine

14 Norman's -- even if it was integrated, Norman's integrated processor into

15 Toge. But again, we're not talking about changing Toge in that way. And

16 there is no dispute that Toge actually discloses a processor that's integrated

17 with the CPAP device.

18 Now with respect to Patent Owner's arguments on the fact that

19 Norman, even -- again, frankly, Norman is really irrelevant because that is

20 not part of the combination. But if we go to Slide 35 once again, the passage

21 in the specification in Norman that describes Figure 6 and the different

22 components of the Norman system says alternatively. So the Figure 6 is not

23 supposed to represent all disclosures in Norman.

24 And ultimately, Norman does provide other disclosures that says

25 this is all part of system one, that even if you're saying that -- I'm not sure

26 what Patent Owner is saying is part of the CPAP device. But if you're

1 saying it's 22, 25, 20, 23 and everything else, it's all part of system one. And
2 so again, alternatively it can all be built into system one. And regardless,
3 again, Toge discloses it anyway.

4 With respect to the arguments with respect to written description, I
5 am a bit confused as to what Patent Owner is stating with respect to the
6 ancestral applications and whether or not Patent Owner is just basically
7 saying that we don't want to claim priority all the way to the original
8 application but just to the original - or just to the 715 application with
9 respect to the 211, which was -- sorry, filed in 2011.

10 So Patent Owner is just saying, okay, we're only going to try to
11 claim priority to 2011. But let's talk about, again, the disclosures there and
12 go actually to Patent Owner's Slide 20 in their deck, in Patent Owner's deck.
13 And Patent Owner say you have to believe because of the last citation, that it
14 needs to be the patient's cell phone that is actually adjusting the CPAP
15 therapy. But again, nowhere in these disclosures even talks about the
16 patient's cell phone, and certainly not together in context.

17 So there are certainly different ways the clinician or the patient can
18 adjust the device. They can do it manually. And so the mere fact that it's an
19 option, again, it doesn't tell you that the inventors were actually in
20 possession of a patient cell phone that actually adjusts the patient's CPAP
21 therapy.

22 JUDGE HARDMAN: Counsel, on that, what about this last
23 citation on this slide, the right column, last bullet that says that the 715
24 application clarifies that the device can remotely program the therapy of the
25 PAP device? The first instance of device in that sentence, does that refer to
26 or include a cell phone?

1 MS. NGUYEN: So it's unclear again. But even if it did include a
2 cell phone, it could be the clinician's cell phone just like in Toge. And so
3 this goes back to Patent Owner's real intention that they're saying, okay, for
4 written description, we want you to -- a person of ordinary skill in the art to
5 just put this all together, even though they're not related. When this case law
6 says you have to look at the disclosure as a whole, they're talking about
7 looking at everything in context and making sure that when you are referring
8 to the device, you are referring to the patient's cell phone and not just any
9 cell phone.

10 And that goes back to -- this is just an amalgam of different
11 citations that doesn't tell you that the patient's cell phone is the one that is
12 adjusting the CPAP therapy versus manually adjusting the CPAP therapy by
13 the patient or having the clinician remotely adjust the CPAP therapy. So
14 again, there's nothing in the citations that fixes that lack of connection
15 between adjusting CPAP therapy and a patient's cell phone.

16 Now Patent Owner also discussed -- saying that Petitioner is gap
17 filling because of -- there is no teaching in Kumar that the patient's cell
18 phone adjusts the CPAP therapy. But there is a teaching, again, in Toge,
19 that the patient is adjusting the CPAP therapy. And so it goes back to
20 everything is in Toge except patient cell phone. So we are not doing any
21 gap filling. It just goes back to, okay, Toge already teaches patients
22 adjusting CPAP therapy.

23 And you can see that on Slide 59 that Toge is teaching that patient
24 itself, him or herself, can adjust the CPAP therapy. Toge also teaches that
25 the physician has a cell phone that can adjust the CPAP therapy. And so a
26 person of ordinary skill in the art looking at Kumar's additional teaching of,

1 hey, let's give a patient a cell phone also, would take all those teachings:
2 Kumar's teaching of a cell phone, Toge's teaching of a patient adjusting
3 CPAP therapy, and Toge's teaching of a phone -- cell phone that can adjust
4 CPAP therapy and improve upon the system of Toge where the patient is
5 adjusting the cell phone remotely.

6 Now with respect to the two configurations, with respect to the
7 remote internet site, this has come up repeatedly. With respect to the first
8 one when Patent Owner says, okay, yes, somebody would be motivated to
9 actually have a remote internet site, but I don't know where that remote
10 internet site is. . There is nothing in the claims that actually require it to be
11 at a specific location. So if you wanted to implement a remote internet site
12 on a web server, in the hospital, next to the physician-side computer, you
13 could do that. There's no requirement, and so it doesn't matter that it can be
14 located in various locations. Only that person would be motivated to do that.

15 And Patent Owner said something about the distributed systems
16 argument not making any sense because it wasn't in the petition. But again,
17 these are substitute claims, it would not have been in the petition. Thank
18 you.

19 JUDGE POWELL: Thank you. When you're ready.

20 MR. PRICE: Okay. Thank you, Your Honor. So I just wanted to
21 first answer the questions I said I would come back to, questions about how
22 to measure airflow and determine the data of severity of the patient's
23 symptoms based on the airflow. There's about six columns worth of very,
24 very detailed embodiments from column 1866 through 2354 which talks all
25 about how to do that, what algorithms are used, and how it's used to
26 determine the level of severity data.

1 The other question was which patent was being referred to on Slide
2 8, this testimony from Dr. Schwartz. This is CleveMed's '284 Patent, which
3 was the subject of an IPR and PGR petitions, both of which were denied.
4 And this testimony, both parties believe that this term has a plain and
5 ordinary meaning, quantified level of severity data. And that's what exactly
6 what Dr. Schwartz was testifying about here. Whether or not it was in a
7 patent that's -- that was in the same priority chain as the '333 Patent, it's very
8 clearly related information and very clearly the same term.

9 Petitioner is not saying that the '284 Patent is so different from the
10 '333 Patent that his -- that their expert's explanation as to why a measured
11 statistic like tidal volume would not be considered a level of severity, it
12 applies in either case because we're just talking about a plain and ordinary
13 meaning.

14 JUDGE POWELL: I'm going to interrupt there and say that I sort
15 of read that declaration from the PGR as indicating that it was prosecution
16 history that drove his interpretation of the limitation as excluding certain
17 baseline data. So the fact that there may be a connection between the
18 terminology in -- I'm not sure if these are related or not. But apart from the
19 prosecution history of some, according to Petitioner, unrelated application, it
20 didn't seem to me as though Schwartz was necessarily saying that airflow
21 couldn't be used as an indication of symptom severity.

22 And in fact, it seemed to -- I don't mean to waylay you here. I
23 think I saw some merit in what Petitioner said that paragraph 46 of that
24 declaration seemed to say -- Schwartz seemed to say that in, a general sense,
25 severity of symptom data is pretty broad. But in the case of the 116
26 application, which was a parent or grandparent or something like that of the

1 '284 Patent, the Patent Owner had argued in a way that would have narrowed
2 the claimed language.

3 MR. PRICE: Yes, Your Honor. And I'm not sure, honestly,
4 whether or not the application that these statements were made in were part
5 of the '333 Patent's priority chain. I just don't know.

6 JUDGE POWELL: That's fair. But would you agree -- well,
7 anyway, I suppose it's more of a comment than a question. But I guess how
8 would you respond if I said that I don't think the -- I'm not sure Schwartz's
9 statement was about the plain and ordinary meaning of the claimed language
10 severity data but more so about prosecution history interpretation that had
11 happened at some point in Patent Owner's suite of applications?

12 MR. PRICE: And what I would say, Your Honor, is the Patent
13 Owner made this statement about what does and does not qualify as level of
14 severity data. At least in this proceeding, this expert relied on that to
15 distinguish the level of severity data from breathing metrics. We also think
16 that separate and apart from the prosecution history, we don't think you need
17 to rely on that. Just the plain and ordinary meaning of data of severity of the
18 patient's symptoms cannot rely to the input data that allows you to identify
19 those symptoms to begin with.

20 So we think that his analysis here is correct. We think that he's
21 properly reading the prosecution history and CleveMed's statements about
22 what a level of severity data is and isn't. And it's also consistent with the
23 plain and ordinary meaning.

24 JUDGE POWELL: Okay. Thank you.

25 MR. PRICE: You're welcome. We'll just jump back to the '029. I
26 believe that there was question about whether or not data of severity requires

1 a quantitative determination. We believe that it does, and I know there are
2 other patents that actually say quantitative. But regardless, it does require it
3 to be calculated. And it does require it to represent the severity of the
4 patient's symptoms and not just a measured value that would go in to
5 determine whether or not a symptom has occurred in the first place.

6 So whether or not it requires a quantitative determination that says,
7 okay, this is at a level 100 or this is at a level red, which would be this data
8 of severity but is not quantitative, either way, that data needs to be calculated
9 based on the symptoms and tell you something about how severe the
10 symptoms are and not just that the symptoms -- there were symptoms
11 detected.

12 In terms of the combination of Toge and Norman, I think what I
13 heard during the rebuttal period is that they don't have motivation to
14 implement Norman's calculations in an integrated PAP device. They're
15 relying on Toge for actually doing this on the PAP device. They're relying
16 on expressed disclosure in Toge of calculating the quantified level of
17 severity data on the PAP device. That's Ground 1. If it's expressly
18 disclosed, Your Honors can find that it's expressly disclosed in Norman and
19 Toge. There is no motivation provided to move Norman's external
20 calculation onto the internal -- onto an internal PAP processor.

21 Moving to the motion to amend and the written description issue, a
22 person of ordinary skill in the art reading this patent -- reading the
23 application that led to this patent sees a disclosure that a PAP device can be
24 remotely programmed. It can be adjusted from an external device based on
25 the output, the level of severity, and that the physician or the subject can
26 make those adjustments. So reading those two things together, I think again

1 during the rebuttal period there was a lot of focus on whether or not there
2 was in haec verba support for this as opposed to a person of ordinary skill in
3 the art reading the specification as an integrated document.

4 So we believe that there is written description support for that.
5 And no disclosure in Toge or Kumar of a patient, one, adjusting it from the
6 cell phone or, even more broadly, adjusting it from -- based on the level of
7 severity data. Neither Toge nor Kumar discloses that, and that's part of the
8 claim.

9 I don't have anything else, Your Honors, but I'm happy to answer
10 any questions you may have.

11 JUDGE HARDMAN: If you wouldn't mind, just give me a
12 moment. Ok, nothing for me. Thank you.

13 MR. PRICE: Okay. Thank you, Your Honors.

14 JUDGE POWELL: Judge Snedden?

15 JUDGE SNEDDEN: Nothing further from me. Thank you.

16 JUDGE POWELL: Okay. Well, thank you both for helping us
17 further understand the issues of these cases. They are submitted. And let's
18 go off the record and give the court reporter an opportunity to ask any
19 questions about spelling or such.

20 (Whereupon, the above-entitled matter went off the record at 11:27
21 a.m.)

IPR2025-00246 (Patent 11,857,333 B1)

IPR2025-00247 (Patent 11,872,029 B1)

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