

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,

Petitioner,

v.

CLEVELAND MEDICAL DEVICES INC.,

Patent Owner.

IPR2023-00565

Patent 10,076,269 B1

Record of Oral Hearing

Held: February 4, 2025

Before ULRIKE W. JENKS, SHERIDAN K. SNEDDEN, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

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The above-entitled matter came on for hearing on Tuesday, February 4, 2025, commencing at 1:00 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P R O C E E D I N G S

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USHER: All rise.

JUDGE SNEDDEN: Please be seated. Good afternoon. This is the final hearing in IPR2023-00565 involving U.S. Patent 10,076,269. I'm Judge Snedden and I'm joined by Judges Hardman and Jenks, who are with me remotely. We will begin with appearances, starting with Petitioner. Please stand, introduce yourself and who you have with you today.

MS. MILLER: Good morning, Your Honors. Tiffany Miller, on behalf of Petitioner ResMed. With me is my Co-Counsel, James Heintz. And also our representatives from the client, Eugene Kim and Rory Schermerhorn.

JUDGE SNEDDEN: Welcome. Patent Owner?

MR. HANNAH: Good afternoon, Your Honor, James Hannah on behalf of Cleveland Medical Devices, and with me is Jeffrey Price.

JUDGE SNEDDEN: Welcome. Per our order granting this oral hearing, each party is granted 60 minutes of total time to present its arguments. Petitioner will open the argument and may reserve up to 30 minutes rebuttal time. Patent Owner will then respond to Petitioner's arguments and may also reserve up to 30 minutes of sur-rebuttal time. Please note that this proceeding is being streamed online to enable public attendance. We remind everyone that the recording of any PTAB hearing is prohibited. The court reporter will provide a transcript of the hearing that the Board will enter into the record when it becomes available.

We have reviewed the briefs and evidence and we have that available to us on our computers along with the demonstratives. And so, you're

1 welcome to point us to any document in the record and we can move to that
2 as needed. For both the benefit of the transcript and the Judges appearing
3 remotely, please speak clearly and identify the slide numbers as you move
4 through your presentation. Does anyone have any questions?

5 MR. HANNAH: Can the Judges that are remote, can they actually
6 see this slide presentation or --

7 JUDGE SNEDDEN: I believe so. I'll let them answer for
8 themselves.

9 MR. HANNAH: Okay.

10 JUDGE SNEDDEN: And they also can see the courtroom.

11 MR. HANNAH: Okay, thank you.

12 JUDGE SNEDDEN: Okay, with that, Petitioner, would you -- Ms.
13 Miller?

14 MS. MILLER: Yes.

15 JUDGE SNEDDEN: Would you like to reserve any rebuttal time?

16 MS. MILLER: Yes, I'd like to reserve 25 minutes.

17 JUDGE SNEDDEN: Sure. Okay. When you're ready.

18 MS. MILLER: Thank you. Good morning, Your Honors. So, today
19 we're talking about the '269 Patent, which I may also refer to as the
20 Challenged Patent. Petitioner's demonstratives have a table of contents at
21 slide 2, and then at slide 3 we have claim 1 of the '269 Patent. So, as you
22 know, the '269 Patent has four independent claims. These are at slides 3
23 through 6. And all claims are directed to a positive airway pressure
24 treatment system.

25 Now, I'd like to just jump to, really, the dispute between the parties,
26 which is the main one is the air -- excuse me, really what was known in the

1 art. So, going to slide 12 we have figure 7 on the left in the Patentees
2 admission from the technical background section on the right. And the
3 Challenged Patent admits that systems like that shown in figure 7 were well
4 known. We see in the background section at column 2 line 17 through 25,
5 the patent admits that devices had been developed that adjusts CPAP
6 pressure through sensors built into the device for creating the positive gas
7 pressure which measures gas flow through the device. So, the patent itself
8 admits that actual PAP devices had been developed that have these internal
9 sensors that measure gas flow through the device. So, this was a
10 configuration well known in the arts.

11 Going to slide 13. I have figure 7 on the left and its corresponding
12 description from columns 22 and 23 on the right. So, this describes a
13 conventional pressure support system 310 shown in Figure 7. Continuing on
14 to column 23 lines 12 through 17 in the patent we're still talking about this
15 conventional pressure support system. This describes that conventional
16 system as including a flow sensor 320 pressure sensor 322, or both that
17 monitor the flow and or pressure gas passing in the subject circuit.

18 And the information from this flow sensor 320 and/or pressure sensor
19 is used to control the pressure or flow of gas provided to the subject, monitor
20 the condition of the subject, monitor the usage of pressure support device,
21 any combination thereof or the like. So, this is all conventional. And the
22 Patentee admits that this is description of the treatment systems that's recited
23 in the claims.

24 Going to slide 14. We also know the components and features of
25 figure 7 in its description are conventional because it was copied from this
26 prior art, Truitt patent, which is Exhibit 1026. I have figure 1 from Truitt on

1 the left and figure 7 from the Challenged Patent on the right. The Truitt
2 patent even labels this figure prior art. You can see Truitt shows the same
3 flow sensor labeled 20 on the left as this flow sensor 320 in the '269 Patent
4 on the right.

5 Truitt also illustrates this pressure sensor 22 internal to the PAP
6 enclosure with a pressure tap going to the hose. Notably, the pressure sensor
7 itself is within the enclosure, but the tap goes external and goes to the hose.
8 You can see that same configuration in figure 7. The '269 Patent's
9 description of figure 7 and the flow sensor that Patent Owner cites
10 throughout this proceeding is describing an airflow sensor adapted for
11 measuring the respiratory airflow of a subject. They point to that
12 consistently as being disclosed at column 23. But that's part of this
13 conventional pressure support system from figure 7, and that's from the prior
14 art and it was copied, that same description was copied from Truitt, Exhibit
15 1026 at column 2, lines 1 through 11.

16 Other aspects of the challenged claims were also disclosed in well-
17 known prior arts, including the Schmidt reference, which is part of the
18 grounds. Here on the left had the Schmidt patent, which is Exhibit 1006.
19 Now the Challenged Patents, figures 1 through 6 and almost 10 columns of
20 description were copied from Schmidt. So, you can see, for example at slide
21 17, figures 1 through 3 from Schmidt are the same as those in the '269
22 Patent. Slide 18, the same is true for figure 4. Slide 19, the same for figure
23 5. And slide 20, the same for figure 6. Even if you look at the text, the
24 description is the same in both the Schmidt patent and the '269 Patent. So,
25 column 8, line 57 from the '269 Patent, you can see it's describing figure 1
26 and all the way through column 18, line 50, that's all copied from Schmidt at

1 column 4, line 63 through 1454. The patent's reliance on the prior art does
2 not end there.

3 Turning to slide 22, on the top left, you can see from column 3, it
4 discloses that the treatment device can be any device known to those skilled
5 in the art. On the bottom quote from column 6, it relies on sensors which
6 can be used. Sensors which can be used are known to those skilled in the
7 art. On the top right, it also relies on algorithms known to those skilled in
8 the art. And it's going to use those known algorithms to quantify the level of
9 severity of the subject's sleeping disorder symptoms. And then on the
10 bottom right from column 20, the patent also relies on algorithms known to
11 those skilled in the art for the signal processing.

12 And finally, even the base station, if we turn to slide 23, the patent
13 relies on base stations which can be any device known to receive RF
14 transmissions. So, the point of all this being that the claims are directed to
15 prior art structures. To the extent the Patentee is reaching into the
16 specification to find some novelty, they're really just describing the prior art.

17 Turning to the airflow sensor limitation, specifically. So, this
18 limitation appears in claims 1, 5, and 15, and this is for grounds 1 and 6.
19 And so, I'll focus on the Genger and Farrell combination. So, looking at
20 slide 26, Genger in view of Farrell renders obvious the PAP device
21 comprising an internal airflow sensor adapted for measuring respiratory
22 airflow of a subject. The Patent Owner does not dispute that Genger
23 discloses an airflow sensor adapted for measuring the respiratory airflow of
24 a subject. Patent Owner admits that the only disclosure in the '269 Patent,
25 the Challenged Patent, of an internal respiratory airflow sensor is a

1 conventional PAP device. The Patent Owner does not dispute the
2 obviousness motivations identified in the petition.

3 So, looking at orienting ourselves with Genger, Genger discloses
4 three exemplary environments. We have the lab from figure 1. This is in
5 slide 27, the lab at figure 1, the domestic environment at figure 3, and the
6 combined environment at figure 8. You can see that domestic environment
7 is shown at the bottom of figure 8.

8 Genger, if we turn to slide 28, I have Genger's figure 1 on the left and
9 page 10 from Genger on the right. Genger describes a CPAP treatment
10 device having a compressor for multiple sensors, and going down to line 27,
11 Genger describes that these sensors include a flow sensor unit 12, which we
12 can see circled in red on the left. And that flow sensor will communicate via
13 radio back to the compressor module, which is identified as 4. So, the
14 relevant issue for the petition is where to put Genger's flow sensor unit. You
15 can put it at the mask, you can put it in the hose, or you can put it inside the
16 enclosure of the PAP device. And those are simply engineering design
17 choices as to where to put those in weighing different design considerations.

18 Turning to slide 29, Farrell discloses an airflow sensor internal to the
19 PAP device. The petition relies on Farrell for this internal flow sensor
20 limitation. Here I have Farrell's figure 1 on the slide, and you can see
21 outlined in purple the enclosure of the PAP device. You can even see it has
22 a handle that's illustrated in the figure and internal to that PAP device
23 enclosure is highlighted in red. That's the flow sensor 4f. So, we have the
24 flow sensor highlighted in red here illustrated internal to the enclosure of the
25 PAP device. This is not an issue whether the drawing is inaccurate or not

1 drawn to scale, you can clearly see the flow sensor illustrated internal to the
2 enclosure.

3 Turning to the text of Farrell on slide 30, on the left I have the
4 excerpt from page 5 of Farrell from lines 3 through 17, and figure 1 on the
5 right. So, consistent with other references in this proceeding, Farrell
6 describes the basic aspects of a PAP device. You have a blower 2, a mask 6,
7 and air delivery conduit 8. And turning to the disclosure starting at line 5,
8 Farrell describes that optionally a flow sensor 4f and/or pressure sensor 4p
9 may also be utilized, in which case mask flow may be measured using a
10 pneumotachograph and differential pressure transducer or similar device to
11 derive a flow signal $F(t)$.

12 Now, a few things to point out here. First, as we just saw and you
13 can see on the right hand of this slide, Farrell illustrates the flow sensor
14 internal to the enclosure of the PAP device. So, this is internal to the PAP
15 device. You can see it with its output to the controller there. Second,
16 nothing in Farrell says the flow sensor is positioned at the mask and solely at
17 the mask. It says you can measure mask flow as one way to derive the flow
18 signal, but it does not limit the location of the flow sensor to the mask. On
19 the contrary, it illustrates it within the enclosure of the PAP device.

20 Third, the text of Farrell describes this pneumotachograph which
21 Patent Owner really zeroes in on and focuses on this pneumotachograph.
22 But it describes that the pneumotachograph and the differential pressure
23 transducer are examples of what can be used for this flow sensor. You can
24 see there that it says mask flow may be measured using this
25 pneumotachograph and the differential pressure transducer, or you could use

1 a similar device. So, those are in the alternative. So, Farrell's disclosure is
2 not limited to a pneumotachograph.

3 Farrell also acknowledges, but it was known in the art how to
4 measure flow. You can see down at line 10 it says it is understood that those
5 skilled in the art would understand how to measure flow and pressure. So,
6 Farrell doesn't have to be specific about where in the airflow path this flow
7 sensor is located. A person of ordinary skill would know where to put this
8 flow sensor. You could measure mask flow, or you could use a similar
9 device to derive a flow signal $F(t)$. A person of ordinary skill would know
10 how to do that.

11 Turning to slide 31, Patent Owner argues that locating the airflow
12 sensor internal to the PAP device enclosure was not common. That's merely
13 an attorney argument and it's contrary to the record. Patent Owner's
14 arguments on this issue actually included admission and repeated emphasis
15 that the Challenged Patent's figure 7 in its corresponding description
16 disclosed the claimed internal airflow sensor adapted for measuring the
17 respiratory airflow of a subject. Patent Owner says figure 7 in its description
18 disclosed the claimed internal airflow sensor. But the patent admits, as we
19 saw at slide 12, that this is a conventional system, and that description is
20 from the prior art Truitt patents. Also, notably the '269 Patent relies on the
21 drawing, not the text, to show placement inside the enclosure. And that's
22 just like the disclosure that Farrell provides.

23 Moving to slide 32, I have the '269 Patent on the left with the PAP
24 device enclosure highlighted in purple. I have the Farrell figure 1 on the
25 right with the PAP enclosure shown in purple as well. So, in the same way
26 that the '269 Patent relies on its illustration to show that the flow sensor is

1 internal to the PAP device enclosure, Farrell provides the same disclosure
2 illustrating the flow sensor internal to the PAP device. So, if there are no
3 questions --

4 JUDGE JENKS: I have a quick --

5 MS. MILLER: Yeah.

6 JUDGE JENKS: I'm sorry, I do have a -- can you go back one slide
7 that you were just on? Yes. So, number 14 on Farrell, that takes us from the
8 mask all the way into, I guess, to the sensor which is inside the device. That
9 is basically telling me that what's in the mask is just a tube to give us the
10 oxygen levels?

11 MS. MILLER: It says --

12 JUDGE JENKS: A hollow tube possibly? I don't --

13 MS. MILLER: Yes, it's just --

14 JUDGE JENKS: Or a sensor?

15 MS. MILLER: That is just a hollow tube. And it's described in
16 Farrell as, I believe it says, measured at a pressure tap and it uses a pressure
17 transducer. So, the pressure transducer itself is within the enclosure and
18 then it has just this little tube that goes to the mask. And so, the sensor itself
19 is within the enclosure. And actually Dr. Borkholder, Patent Owner's expert
20 confirmed this in his deposition, that the actual sensor is inside the
21 enclosure. So, again that's just a tube going from the mask back to the
22 enclosure. And you can see the same concept in the figure on the left that
23 was copied from Truitt. You have the sensor itself within the enclosure.
24 Then you have just a tube going to the hose. So, that's very common in the
25 prior arts.

1 JUDGE JENKS: And then one more thing, the -- hold on. Farrell
2 references the -- what is it? BJ patent. Let me get you to, on that. And so,
3 the Berthon-Jones patent --

4 MS. MILLER: Mm-hmm.

5 JUDGE JENKS: -- which is, I believe, in the record as Exhibit 2015.
6 And there it's telling us this air pressure, this alternative arrangement. Can
7 you talk a little bit more about that? How you figured that gives you a
8 reason to move it anywhere along the hose? I believe you had in your
9 petition --

10 MS. MILLER: Right. So --

11 JUDGE JENKS: -- this?

12 MS. MILLER: Yep. Berthon-Jones is relied on by Dr. Sharony,
13 Petitioner's expert, to corroborate his opinions that you could put this flow
14 sensor anywhere in the airflow path. That that was common. So, Berthon-
15 Jones confirms that it may not be convenient. This is just a simple
16 engineering design choice to mount the flow transducer at or near the mask.
17 And that an alternative arrangement is to put the flow and pressure
18 transducers mounted at or near the air pressure generator. And the
19 embodiment being the turbine shown in figure 3 in Berthon-Jones.

20 JUDGE JENKS: Mm-hmm.

21 MS. MILLER: And in particular, they described that the flow
22 through tubing 32, excuse me, is measured with the flow sensor 72 provided
23 at the output of the turbine. And so, here Patent Owner's expert Dr.
24 Borkholder also agreed that this turbine, the blower, is internal to the PAP
25 device. So, when Berthon-Jones is talking about putting this flow sensor at

1 the output of the blower or the turbine, that's still going to be internal to the
2 PAP device.

3 JUDGE JENKS: Thank you.

4 JUDGE HARDMAN: Counsel, it's Judge Hardman. I have a
5 question about, it seems that Berthon-Jones and Truitt, neither of those
6 references were discussed in the petition, but did feature in the reply. Do we
7 have to worry about, sort of, any concerns about backfilling the petition
8 here? I'm not sure why they came up first on reply and weren't in the
9 petition itself.

10 MS. MILLER: Right. So, Truitt came up for the first time in the
11 reply because Patent Owner really emphasized that its figure 7 provided
12 some novelty, and that's just not true. After the petition was filed, we
13 discovered that that section of the Challenged Patent figure 7 in its
14 description was copied from this prior art reference. So, that's why Truitt
15 makes its appearance. It's because Patent Owner brought that up on their
16 Patent Owner response. So, that's why it only came up in Petitioner's reply.
17 Berthon-Jones was not relied on as a ground in the petition. It was relied on
18 by the expert to corroborate his opinions, to support his opinions, relying on
19 art rather than just his plain opinions. And then Patent Owner challenged
20 the relevance of that in its response. And so, that's why we respond to it for
21 the first time in our reply.

22 JUDGE HARDMAN: Thank you.

23 MS. MILLER: So, so speaking of these motivations to locate
24 Genger's flow sensor internally, the petition identifies motivations including
25 avoiding the need to transmit the airflow data from an external sensor or
26 change external sensor batteries. And this is at slide 33, and Patent Owner

1 does not challenge these. This is basic engineering. If you put the sensor at
2 the mask, you've got to get that sensor signal back to the controller that's in
3 the PAP device. So, you're going to do that by a cable, which has design
4 challenges in the home environment. You don't want the user dealing with
5 cables. Or if you use a radio module like that in Genger, you've got to
6 change the batteries in that radio module. And even Genger confirms this,
7 because it talks about figure 2 in the domestic environment. This is at page
8 12, here, preferably no radio connected sensors are used to avoid changing
9 or recharging the batteries in the radio module. Dr. Sharony also articulated
10 additional motivations to position the airflow sensor internally. Again, these
11 are just design choices. It's a matter of engineering. If you don't put the
12 sensor in tubing because it's flexible and it can crack, can break and it's also
13 replaceable, so you wouldn't want to be replacing the sensor so it's more
14 secure to put it inside the mask, but that's also replaceable. And you have
15 this issue about getting that signal back to the controller or you can place it
16 inside the device. So, these are just engineering design choices.

17 If there are no additional questions about the airflow sensor, I'll move
18 on.

19 JUDGE JENKS: I don't have any additional questions about the
20 airflow sensor, but I do have a question that, before you move on to claim
21 15, is, in claim 1, I read the PAP device as it's been pointed out by Patent
22 Owner as not encompassing the mask. However, claim 5 appears to
23 encompass the mask as part of the PAP device. Is my reading of those two
24 claims correct?

25 MS. MILLER: We agree with that reading, Your Honor.

26 JUDGE JENKS: Thank you so much.

1 MS. MILLER: So, I'll just note that for ground 6, claim 15 and the
2 airflow sensor limitation in Patent Owner's response, they relied on their
3 same arguments for Genger and Farrell. However, in their sur-reply they
4 raised new arguments. But as we know from the scheduling order at paper
5 24 at 9, any arguments that were not raised in the Patent Owner response are
6 waived. So, I'll reserve my responses to those.

7 Turning now to non-volatile memory, which is an additional
8 limitation of claim 5. I'm not really sure why we're arguing about this, that
9 nonvolatile memory somehow provides some kind of novelty. The '269
10 Patent didn't even bother to disclose this. So, they seem to concede that this
11 was an obvious part of this PAP system. So, unless there are any questions,
12 I'll reserve any response on that for rebuttal.

13 Turning to claim 15, and in particular, Patent Owner does not dispute
14 for claim 15 that Kocinski discloses a base station or that alternatively
15 Farrell discloses the claim PDA. And I'm on slide 45. Patent Owner also
16 does not dispute that Kocinski and Farrell disclose symptom data. Patent
17 Owner disputes whether Kocinski and Farrell disclose transmitting and
18 retransmitting symptom data. Patent Owner's arguments ignore the Kocinski
19 and Farrell disclosures. Patent Owner also disputes whether Kocinski and
20 Farrell disclose displaying symptom data. But Patent Owner's arguments
21 here again mischaracterize the petition in the prior art.

22 So, looking to Kocinski, just to orient everyone again about the
23 structure of this system, I have figure 1 on the left side of slide 46 and
24 paragraph 35 on the right. Paragraph 35 describes that the IPS collects
25 compliance data and other parametric data from the CPAP apparatus 11 in
26 the patient's home 14, transmits the data to a central database server 15, and

1 makes the data available to the medical professional 17, the medical
2 equipment provider 18, and the reimbursement organization 19, via the
3 Internet connection 16. So, you can see those entities 17 through 19 on the
4 right that receive this data over that Internet connection 16.

5 Now, claim 15 requires a base station, cell phone, or PDA. Figure 1
6 in paragraph 35, excuse me, I have figure 1, an annotated version of figure 1
7 on the left of slide 47, and I have paragraph 49 on the right. Kocinski
8 discloses a specific embodiment in paragraph 49 that's illustrated with the
9 annotation on the left from Petitioner's -- from the petition at 70, page 70.
10 And you can see that Kocinski describes that the CPAP apparatus 11 can
11 optionally be connected directly to a computer, which is not shown in this
12 original figure. This computer can communicate with the central database
13 server 15 via the modem 12 or can have the same software as the central
14 database server 15 and thus function as a central database server 15 and
15 bypass the modem 12. So, Patent Owner does not dispute that this computer
16 discloses a base station. Patent Owner also does not dispute that it would
17 have been obvious for the CPAP device that you see on the left to
18 communicate with the base station computer via Bluetooth. So, that's the
19 configuration, if you can picture it, that applies to claim 15, which is we
20 have a CPAP device that communicates via Bluetooth to the base station
21 computer, and that base station computer communicates over the Internet
22 connection 16 still to these entities on the right of the figure 17, 18, and 19.

23 Turning to slide 48, Patent Owner disputes what type of data is
24 transmitted and retransmitted. We saw on slide 46, paragraph 35 discloses
25 that parametric data is transmitted from the CPAP device. Here on slide 48,
26 I have paragraph 28, and it describes that different amounts of data may be

1 collected and transferred to the central database server 15 from the CPAP
2 apparatus. If you look at the first arrow in blue, the data sent from the CPAP
3 apparatus to the base station computer includes information regarding the
4 frequency and nature of events detected while the patient sleeps, such as
5 apnea events. So, that's the transmission from the CPAP apparatus to the
6 base station computer.

7 Second blue arrow on the right. If we look down at the bottom of
8 paragraph 28, Kocinski also discloses, for example, that sleep event such as
9 apnea events are made available to the medical professional, and the medical
10 professional only receives this information over that Internet connection 16.
11 So this means the base station computer had retransmitted those apnea
12 events to the medical professional over the Internet connection.

13 Kocinski also provides as an additional example, in addition to these
14 two disclosures of transmitting and retransmitting symptom data, of the
15 ability of the PAP device to send a message if the number of apnea events
16 per hour exceeds a program threshold. And that's kind of in the middle of
17 this paragraph 28 that's described. And the Patent Owner here really takes
18 an unduly narrow of what that message could be. Even if merely an alarm
19 indicating a threshold was exceeded, if the medical professional set that
20 threshold when it receives the message, it will know that that certain number
21 of apnea events was exceeded. So, if it was five apnea events, the medical
22 professional knows that the patient had experienced five apnea events and
23 that's information about their symptoms. This also ignores that the message
24 could include the specific number of apnea events exceeded to provide the
25 medical professional with useful information. That's just common sense that
26 the message might include that information. And that's actually confirmed

1 in Kocinski, because Kocinski says the medical professional could set
2 multiple thresholds. So, it would be important for the medical professional
3 to know which of those thresholds was exceeded. And therefore, it would be
4 at least obvious, if not inherent, that this information that's sent to the
5 medical professional in connection with this threshold embodiment, that it
6 would provide information about how many apnea events the patient has
7 experienced.

8 Turning to this display issue part of the claim, Patent Owner also
9 disputes that Kocinski discloses displaying the symptom data, the base
10 station computer. Here, Kocinski discloses that the software includes the
11 ability to display reports such as that shown in figure 10 on the left side of
12 slide 49, and I've blown up the tabs from that figure on the left. And the
13 patent describes -- excuse me, Kocinski describes at paragraph 45 that you
14 could use these tabs to move between reports. And it only makes common --
15 it's just common sense. The patent is, Kocinski is talking about transmitting
16 data, including sleep events and other parametric data. It just makes sense
17 that you would -- this is what would be displayed at that daily summary tab.
18 And if it's not disclosed explicitly by Kocinski, it would have been obvious,
19 because this is information that, for example, a patient, the home caregiver,
20 or a visiting medical professional would want to see in one of those reports
21 when it visits the patient and views this information on the base station
22 computer.

23 Kocinski also makes clear that the reports are not limited to a medical
24 base professional. It just describes that you could provide authorized users
25 and viewers, and that the user rights, such as permission to view reports, is
26 managed by the software. So, it doesn't limit those reports from being

1 viewed by only the medical professional. Patent Owner, actually, argues,
2 they focus in on this statement at the bottom of paragraph 28 that I have on
3 slide 48, where it says the pressure and sleep events may be made available
4 only to the medical professional. But that's just an example. It says it may
5 be made available only to the medical professional. And that's because it's
6 really talking about here, earlier in that sentence, you wouldn't send this to
7 the equipment provider. The equipment provider doesn't need to know how
8 many apnea events the patient has experienced. But if that medical
9 professional is visiting that patient, they would want to know how many
10 apnea events they're experiencing. So, they would look at this daily
11 summary tab in the reports at that base station computer in the patient's
12 home.

13 The petition also has an alternative attack on claim 15 in the base
14 station cell phone and PDA limitation. So, if the term base station is
15 interpreted to not include Kocinski's base station computer, it would have
16 been obvious to implement that base station computer with the PDA that
17 Farrell discloses. And I want to point out here that Patent Owner really
18 takes a different view or casts the petition's embodiment here. And they say
19 that you would replace that medical professional element 17 from Kocinski
20 with the PDA. But that's not the combination that Petitioner is relying on.
21 Petitioner's assertion is that you would replace that base station computer
22 with the PDA disclosed by Farrell.

23 Any questions about claim 15? Moving to slide 8 or excuse me,
24 claim 8, slide 55. So, claim 8 is quite a bit different from the other claims.
25 The petition relies on the Stahmann reference, which is very dense. But the
26 Institution Decisions seem to have really the right grasp on that reference.

1 So, I won't spend too much time here. Ultimately, Stahmann discloses a
2 drug therapy may be used to treat disordered breathing. And that's exactly
3 what the claim is talking about. We have a drug that's the pharmaceutical
4 agent in red. We have treating. That's the therapy may also be used to treat.
5 That's in blue. And we have the disordered breathing that's the subject's
6 sleep disorder.

7 Stahmann also describes automatically controllable drug delivery.
8 And when it's talking about this drug delivery, excuse me, the drug therapy.
9 If we go to slide 56, it would have been obvious to the extent it's not explicit,
10 which I think it is in Stahmann, that this drug therapy would be used in
11 combination with the feedback system which is shown in figures 54, for
12 example, in Stahmann. And here it's talking about you're determining these
13 characteristics of sleep disorder breathing events such as severity, frequency,
14 and or duration, determining those and then you're using this feedback to
15 adjust the therapy. And then Stahmann also describes at page 47, this is in
16 Petitioner's reply at 21, that you could use the respiratory part of the system
17 to control another part of the system which would be understood to include
18 the drug therapy. And as you're adjusting the drug therapy, you're
19 automatically addressing the drug. Adjusting the drug. That's the whole
20 point of adjusting the therapy.

21 JUDGE JENKS: I have a question here, just so I'm clear on it. The
22 apnea/hypoxia index, the AHI is what you equate as the level of severity.
23 That is a measure of the level of severity of somebody's symptoms. Is my
24 understanding correct on that?

25 MS. MILLER: Yes, that's what Patent Owner, I believe, stated in the
26 parent application. They conceded that AHI is a level of severity.

1 JUDGE JENKS: Thank you so much.

2 MS. MILLER: Now the Board does not have to reach --

3 JUDGE SNEDDEN: Ms. Miller, just letting you know that you are
4 entering into your rebuttal time.

5 MS. MILLER: Okay, thank you. Actually, I'll stop there. Thank
6 you.

7 JUDGE SNEDDEN: Mr. Hannah, would you like to reserve any
8 rebuttal time?

9 MR. HANNAH: Yes, please, 15 minutes. If I can have a second just
10 to switch this over.

11 JUDGE SNEDDEN: Sure. Take your time and when you're ready,
12 you can begin.

13 MR. HANNAH: All right. Good afternoon, Your Honor. Good
14 afternoon, good morning, Your Honors, based on your location. First of all,
15 I want to thank you on behalf of Cleveland Medical Devices, we call them
16 CleveMed, for your time. We do appreciate your time in analyzing the prior
17 art, taking a fresh look at the record. It is important to my client. My client,
18 CleveMed, is a small, smallish medical device company based in Cleveland.
19 They have provided sleep apnea devices web-based services for a number of
20 years that are both FDA approved and in the process of an FDA clearance.
21 But what they're really known for is their innovation. They have a robust
22 patent portfolio, they're constantly innovating with their technology in order
23 to come out with a new technology to help support the market, in particular
24 with sleep apnea.

25 Now, here we're dealing with the '269 Patent. And the '269 Patent --
26 and I'm showing slide 2. Can you see my slides, Your Honors, that are

1 remote? Thank you. This is a diagnostic treatment system for forced sleep
2 apnea. And as we'll dive right into, there's a number of claimed features that
3 are just simply not taught in the prior art. The first that we'll go through is
4 the airflow sensor that's internal to the PAP device. This is in claims 1 and
5 15. And the prior art simply does not disclose an airflow sensor that is
6 internal to that PAP device. As we see in Genger and Farrell, the airflow
7 sensor is located at the mask. This was actually acknowledged by the
8 Institution Decision from Your Honors in which they said the sensors for
9 Farrell, which is supposed to provide the motivation, is at the mask. And
10 we'll see as we look into the diagrams or whatnot that any of those symbols
11 that are shown in Farrell are merely symbolic and in fact cannot be the
12 airflow sensor because they're not in the path of the airflow from the patient
13 to the device.

14 Number two is the base station. It's a base station that displays data
15 to the patient and it relays it to a remote site. Again, the Institution Decision
16 and the Patent Owner, in fact, acknowledge that the display is not taught.
17 It's simply not taught, and it's not needed in the prior art. And in fact, it
18 would require a reconfiguration of the entire system in order to include a
19 display of the device. And there's no need to do that because the medical
20 professional can already see it on their own devices such as a PDA, after it
21 goes through the entire system.

22 Number three is storing the data in nonvolatile memory. Petitioner,
23 during her opening remarks and even in the papers, gave short shrift to this
24 limitation. But this limitation is important because it involves storing this
25 data for later retransmission. And the reason that they pay such small
26 attention to it is because it is not taught in the prior art. You do not -- you

1 would not put volatile memory in a modem. It simply would not work. The
2 whole point of a modem, remember modem is modulation and
3 demodulation. That's what modem stands for, is to transmit data
4 immediately as it receives. It would be impossible to have volatile memory
5 to store all of the data that you would have for the modem to transmit. It
6 simply wouldn't be possible. And no one with skill in the art would design a
7 modem in that way. And that's why they always gloss over this limitation.
8 It's an important limitation.

9 And number four is the CPAP controller that administers this
10 pharmaceutical agent based on the level of severity. And this is for
11 treatment. The claim specifically says that you're going to administer this
12 pharmaceutical agent to treat the sleeping disorder. And as we see in
13 Stahmann and as we see in Edgar, you would not use the doxepin in order to
14 treat sleep apnea. That's for insomnia. If you gave doxepin to a patient that
15 had a breathing irregularity, and you gave that every time during the middle
16 of the night as they're having trouble breathing, you may kill the patient with
17 doxepin. Doxepin is well known to not treat insomnia -- I mean, it is only
18 used to treat insomnia. It is not used to treat sleep apnea. And in fact, if you
19 look, look at the warning labels for doxepin, it specifically says that it may
20 promote trouble breathing and you should not use it for sleep apnea.

21 So, turning to slide 4, we have, at the time of the invention, a new
22 device that can offer this data tracking capability, measure and report the
23 severity, provide this real time feedback of the patient's symptom data in
24 order to adjust pharmaceutical agents. And another theme that we'll be
25 hitting on here is that Patent Owner is the only party in this case that has
26 offered evidence from a person of ordinary skill in the art. Dr. Sharony, by

1 his own admission, is not a person of ordinary skill in the art. This is a trial.
2 We look at the federal rules of evidence. As such, we look at the record as it
3 stands. And if you have -- we have two unrebutted declarations that the
4 Patent Owner submitted supporting that the prior does not teach. We do not
5 have any evidence in the record from a person of ordinary skill to counter
6 that, and that's important.

7 JUDGE JENKS: I'm sorry. I'm sorry. Let's go back to your person
8 of ordinary skill in the art here.

9 MR. HANNAH: Yes.

10 JUDGE JENKS: I believe -- let me find the petition, what it says
11 there. Hold on. Level of ordinary skill in the art. And Patent Owner agreed
12 to this definition, I believe, in your Patent Owner response.

13 MR. HANNAH: Absolutely, Your Honor.

14 JUDGE JENKS: And it says would have had a bachelor's degree in
15 mechanical engineering, electrical engineering, computer science, or an
16 equivalent field. And two years of industry experience working with
17 diagnostic sensor systems and network data systems.

18 MR. HANNAH: Yep. Yes, Your Honor.

19 JUDGE JENKS: An increase in experience could compensate for
20 less education and vice versa. So, I looked at Dr. Sharony's CV, and he
21 seems to have a PhD in electrical engineering, so he certainly meets our
22 education requirement. He also has several years of industry experience in
23 working with sensors as well, and certainly network data systems. So, I'm
24 not understanding why you keep referencing that he doesn't have experience
25 in this particular device, the CPAP device, when that is not part of our
26 definition.

1 MR. HANNAH: The diagnostic sensor, Your Honor. He does not
2 have any experience in diagnostic sensor devices. You have to have -- and
3 that was -- that's his definition that we agreed with. And the case law that
4 we've cited is explicit on this, saying that if you do not have the requisite
5 experience, you are not a person of ordinary skill in the art. And he admitted
6 he does not have any experience in diagnostic sensors or devices with
7 diagnostic systems. He has no experience in medical devices. Dr.
8 Borkholder, on the other hand, decades of experience. Dr. Patil, a medical
9 doctor who specializes in sleep apnea. That's the issue, Your Honor. That's
10 where we come down to --

11 JUDGE JENKS: But --

12 MR. HANNAH: -- a 702 issue in that the Federal Circuit will come -
13 - the Federal Circuit has come down on several occasions, and this is -- we
14 can turn to slide 32, but you have to be qualified in the art in order to
15 provide an expert opinion under 702. And Dr. Sharony doesn't have it. So,
16 that's the issue that we have, Your Honor.

17 JUDGE JENKS: Okay. I'm just looking at Dr. Sharony's CV again.
18 Just a second.

19 MR. HANNAH: You can even look at, I mean, if you want to help
20 shortcut it, you can look at slide 23 of our slide deck. He has no knowledge
21 of the -- he has no knowledge of ever treating a patient experiencing
22 diagnostic sleep disorders. Treating sleep disorders. Any experience
23 operating a CPAP machine. None of that.

24 JUDGE HARDMAN: Counsel, I think you said Dr. Sharony
25 admitted he didn't have any experience with diagnostic sensors. Could you
26 point us to that admission, please?

1 MR. HANNAH: Well, here's some of it, Your Honor, I'll do it on the
2 -- in my rebuttal to find the specific -- but -- the specific attributes. But here
3 he
4 says --

5 JUDGE HARDMAN: This looks more directed toward medical
6 treatment. So, I'm asking about diagnostic sensors. So, if you have that
7 citation, I'd appreciate that.

8 MR. HANNAH: Okay, of course, Your Honor. I mean, but I guess,
9 but slide 23, showing on the screen is showing that he doesn't have -- the
10 diagnostic sensors is dealing with medical devices. That's what we're talking
11 about here. We're talking about medical devices that are doing diagnostics.
12 And he never had any of that experience. His focus is on wireless
13 communications. That's what his focus is on. He often --

14 JUDGE JENKS: I'm sorry, where do we have the definition of
15 diagnostic sensors? Because to me, a diagnostic sensor could be just a
16 temperature probe. And I can have a temperature probe to measure a
17 person's temperature, but I can also have a temperature probe to measure the
18 temperature in my engine. So, it's a diagnostic sensor in that sense.

19 MR. HANNAH: Well, it says --

20 JUDGE JENKS: So --

21 MR. HANNAH: -- a diagnostic sensor for systems.

22 JUDGE JENKS: Sensor systems.

23 MR. HANNAH: Yeah, for sensor systems.

24 JUDGE JENKS: Sensor systems and network data systems.

25 MR. HANNAH: Well, Your Honor I mean, we have to look at the
26 context here. So, if -- I'm at a loss for words, if we can say that someone

1 who deals with cars is qualified to deal with medical devices. I mean, I
2 mean, I'm at a loss. I can't --

3 JUDGE JENKS: So --

4 MR. HANNAH: -- this is --

5 JUDGE JENKS: I'm sorry. An electrical engineer takes information.
6 They gather information from whatever. Again, I'll go back to my
7 temperature probe. And that transmits in zeros and ones to your network
8 data systems. And it has to be translated back into something that I can use
9 on my screen. That's what an electrical engineer does. Sure, I mean, does it
10 matter that he's working on a CPAP device or on a car? I'm not so sure. I
11 think they could work on both, because they know how the information gets
12 transported and how sensors work.

13 MR. HANNAH: Well, if we were talking -- if we were only talking
14 about data and data transfer, then maybe you can get an electrical engineer.
15 But we're talking about a CPAP machine that has to go through FDA
16 clearance that has very specific requirements. And the Federal Circuit,
17 again, has said that FDA approval is a factor in determining obviousness.
18 And so, when you have someone who has zero medical experience, and
19 when they said in their POSITA definition that you have to have that type of
20 experience, that's a 702 issue. That's black and white. It's 702. The Federal
21 Circuit will kick that every day, because they have to have the requisite
22 experience that they even say that is required. And so, anytime -- and this is
23 the part is Dr. Sharony could not rebut Dr. Patil. In several instances, he
24 said they couldn't rebut anything about the FDA.

25 JUDGE JENKS: I'm sorry, Dr. Patil is a medical doctor. Did he also
26 have an electrical engineering degree in his background that I missed?

1 MR. HANNAH: No, he did not. But what he does have --

2 JUDGE JENKS: He, too, would not meet the definition of one of
3 ordinary skill in the art under the definition set out in the petition.

4 MR. HANNAH: Your Honor, yes, he does not have -- well, it says
5 or similar education. But if you're saying that a doctor that deals with sleep
6 apnea devices on a daily basis does not have the requisite experience and or
7 education to talk about CPAP machines, I mean, that's a tough pill to
8 swallow. I mean, and --

9 JUDGE JENKS: Well, he certainly doesn't fit this definition. And I
10 will grant you that, you know, he can tell me about medicines that are used
11 for treating sleep apnea that Dr. Sharony certainly could provide us with
12 information on. But my level of ordinary skill in the arts says mechanical
13 engineering, electrical engineering, computer science, or equivalent field.

14 MR. HANNAH: I agree. That's what it says, Your Honors, and
15 that's -- the point is having both experts is because that's the evidence in the
16 record, right? And so, we have a combination of both of those and they
17 support each other. And on the other side, the Petitioner lacks the evidence.
18 It is their burden. It's their burden to provide this evidence. And if they
19 can't facially meet their burden because they don't have a POSITA to support
20 their opinion, their case falls. It would fall in any court, including this court.
21 And from Patent Owner side, we have both. We have someone who can talk
22 about the electronics, who's been with medical devices for decades, and a
23 doctor who can talk about the FDA, the treating of sleep apnea, et cetera.

24 And so, for those reasons, that's why we have submitted the motion
25 to exclude and believe there's numerous holes in the Petitioner's case and Dr.
26 Sharony's opinion. We kind of jumped to my last slides here. I'm going to

1 go back to the actual limitations in the art unless Your Honors have any
2 further questions.

3 JUDGE SNEDDEN: Go ahead.

4 MR. HANNAH: So, let's move to slide 8. Now, we put in slide 8
5 just because it gives me a little pause. Anytime, if we just look at ground 1,
6 that you have to have four references plus the knowledge of one of the skill
7 in order to say that something's obvious that has to give us pause. It's a --

8 JUDGE JENKS: I'm sorry, I think you -- just move on to the next
9 point you want to make. This is not going to convince me one way or
10 another.

11 MR. HANNAH: All right.

12 JUDGE JENKS: So, I need to see what's missing and where
13 Petitioner failed to show something.

14 MR. HANNAH: Sure. So, let's move on to the airflow sensor. So,
15 where Petitioner failed here is that they have not shown an airflow sensor
16 that is actually in the in the device, in the enclosure. And this is for claims 1
17 through 3. Genger is admittedly outside the disclosure and in the mask. So,
18 what do they rely on? They rely on Farrell. Farrell, as the Board has
19 already recognized, teaches that the sensor is at or near the mask. That was
20 actually in the Institution Decision itself. And so, based on that alone --
21 that's page 31 of the Institution Decision. Based on that alone, Petitioner has
22 not met this burden of proof.

23 Now, Your Honor referenced the tube in Farrell which is sense tube
24 14 --

25 JUDGE JENKS: Mm-hmm?

1 MR. HANNAH: -- in the graph. Now if you look at sense tube 14,
2 and this is on pages 5 and 6 of the reference, that is not for an airflow sensor.
3 That is for the pressure transducer. If you look at the bottom of page five, it
4 says there is a sense tube 14 connected to the main housing of the blower to
5 the mask that allows the apparatus to sense oxygen concentration and
6 pressure levels in the mask 6. The claims and the specification of the '269
7 separate out the pressure transducer and the airflow sensor. As Your Honors
8 know, the airflow sensor needs to be within the flow of the air from the
9 patient's mouth. And that little tube that goes down in Farrell is not it that
10 measures the pressure. And that makes sense because it can't measure the
11 flow as it goes through.

12 Now, the Petitioner constantly points to these little figures with the
13 colors on it and looks at 4 and says oh, this is the airflow sensor that's being
14 shown. Well, if you look at that, first of all, the specification says that this is
15 symbolic. It's not the actual representation. And the reason it says that is
16 because that airflow sensor is not connected in any way to the tube to
17 measure airflow. That's why it says it's symbolic, because the airflow sensor
18 as disclosed in Farrell is at or near the mask. And so, that disclosure is
19 missing from the Genger and the Farrell reference. So, that's one limitation
20 that's missing.

21 JUDGE JENKS: Now, just going back to my airflow sensor being in
22 the mask.

23 MR. HANNAH: Yes.

24 JUDGE JENKS: That would be okay for claim 5. The only thing
25 you have at issue with claim 5 is the nonvolatile memory. Is my
26 understanding correct on that?

1 MR. HANNAH: Yeah, I'd have to double check that. But that does
2 sound right, Your Honor, that it is a different disclosure for that one.

3 JUDGE JENKS: Okay. Thank you.

4 MR. HANNAH: So, with regard to additional evidence that was
5 un rebutted, and we touched on this a little bit earlier, and I'm looking at slide
6 13. Dr. Patil did provide un rebutted testimony that the relocation of the
7 sensor in Genger and in Farrell would require additional FDA clearance and
8 approval. As Your Honors know, I know you've all dealt with medical
9 devices and are familiar with the field, but that's an extensive process. This
10 is a Class 2 device that has to undergo FDA approval in order to be marketed
11 to the public. And Dr. Patil explains in his declaration at Exhibit 2018, 23
12 through 25, that changing the location would require additional FDA
13 approval. And as we've seen from the case law, the case law from the
14 Federal Circuit says explicitly that FDA approval is a consideration for
15 obviousness. This is additional evidence that was un rebutted and could not
16 be rebutted as Dr. Sharony admitted that he has not dealt with FDA
17 compliant medical devices. So, that's an --

18 JUDGE HARDMAN: Counsel, it's Judge Hardman.

19 MR. HANNAH: Yes, Your Honor.

20 JUDGE HARDMAN: What is the Federal Circuit case that you're
21 referring to?

22 MR. HANNAH: Well, there's numerous that are cited in both our
23 Patent Owner response, and our reply, and our sur-reply. One that I have --
24 well, I would say even -- if Your Honor doesn't mind, I'll get that on my sur-
25 reply just to cite it. But it's cited in our case. There's at least two cases, I

1 believe, is the -- well, we're looking it up, but I believe there's multiple cases
2 that say that FDA approval is a consideration for obviousness.

3 JUDGE HARDMAN: Okay, when you get those cites, just let us
4 know, please. Thank you.

5 MR. HANNAH: So, moving on from the airflow sensor. I'd like to
6 move on from the airflow sensor as long as, but I want to see if there's any
7 additional questions. All right.

8 JUDGE JENKS: I don't have any. Thank you.

9 MR. HANNAH: All right, thank you. Thank you, Your Honors. All
10 right, let's turn to the nonvolatile memory limitation. As I indicated earlier,
11 this is an important limitation. This is a limitation that's going to actually
12 store this data for later transmission. This is claims 5 through 7. It's in
13 independent claim 5. And again, we're dealing with the evidence that has
14 been presented by the Petitioner in this trial.

15 First, the Petitioner admits that volatile memory -- nonvolatile
16 memory, is not disclosed. But then it makes this statement that it would
17 have been obvious to put nonvolatile memory in a modem. The way that a
18 modem works is that it is designed in order to modulate and demodulate the
19 signal. If you can just imagine all the information that could come into a
20 modem from a variety of devices, and if you actually stored that data, you
21 would break the system. The modem is not designed to do that. The modem
22 is designed in order to have a buffer in order to immediately convert that
23 data and send it on to its next destination, which in this reference was over a
24 phone line. And so, what they point to, it just doesn't work. And this is
25 from an electrical engineer perspective, Your Honor, is that if you have
26 volatile memory in a modem, it just wouldn't work in terms of the

1 transmission. So, this is important limitation, even though that the Petitioner
2 skipped over it.

3 JUDGE JENKS: Mm-hmm?

4 MR. HANNAH: I'd like to turn to grounds three through five and
5 talk about the CPAP controller that administers this pharmaceutical agent.
6 So, I'm showing claim -- slide 18 on the screen, and here are the limitations
7 that are in dispute. I'd actually increase this box a little bit on the bottom to
8 say that it has to be the positive airway pressure apparatus that provides the
9 pressurized air and dosing and chemical treating the sleep disorders or
10 symptoms with the pharmaceutical agent, because the prior art simply does
11 not disclose that. And it doesn't disclose adjusting the pharmaceutical agent
12 based on the severity of the subject's sleep disorder.

13 Now, with the Petitioner points to for this limitation is Stahmann.
14 Stahmann, as Counsel pointed out, is a long reference and it has numerous
15 disclosures, but there are numerous disclosures that are distinct from each
16 other. So, what the Petitioner points to with regard to adjusting the
17 pharmaceutical agent based on the AHI, the only thing in that disclosure of
18 Stahmann is breathing therapy. And the breathing therapy is adjusted using
19 this breathing therapy pressure, the CO2, and has no disclosure of using drug
20 therapy at all.

21 Now, when Stahmann --

22 JUDGE JENKS: So, here, I mean, what I'm understanding you
23 saying is that Stahmann has a lot of disclosures. I mean, there's 300, 400
24 pages, around. I don't know, lots of pages in this reference. But your point
25 is that they have multiple distinct disclosures. It's not, in essence, an
26 anticipatory reference, but this is also not an anticipatory ground that the

1 Petitioner is presenting as I understand it. But it does talk about, I'll give
2 you this, Stahmann produces, tells me no drugs. They just talk about drug
3 therapy generically or generally. And they're saying that -- and I'm on page
4 236 of the Stahmann reference where it says, drug therapy may be used to
5 treat disordered breathing, drugs may be delivered to the patient through one
6 or more automatically controllable drug delivery devices, (inaudible),
7 controllable nebulizer, or electrically activated drug patch. Those are.
8 They're just saying you can treat this disordered breathing, which I believe
9 apnea is a disordered breathing as well. Is my understanding correct on
10 that? Sleep apnea is a type of disordered breathing. And they're just saying
11 disordered breathing generically can be treated with drugs.

12 MR. HANNAH: Well, I'm not sure it says that it can be treated with
13 drugs there. It says it can be treated with the nebulizer agent and things of
14 that order. But the thing that's missing, Your Honor, is that it's not based on
15 the AHI levels. There's nothing in that disclosure that says that you're going
16 to automatically adjust any drugs of any kind based on AHI.

17 Now, what the Petitioner pointed to for that was page 302. This is
18 what they pointed to for the drug therapy. When you look at page 302, that
19 is the cardio pacing therapy that Stahmann discloses. That's looking for
20 your cardiopulmonary status in order to provide any type of drug therapy.
21 One of skill in the art, looking at a completely different field in terms of
22 what is required, and it also talks about this being implanted into the patient
23 in some circumstances.

24 But in any case, the cardio pacing therapy is completely distinct from
25 the sleep apnea, any sleep apnea discussion in Stahmann. And so, what the
26 Petitioner had to point to was Edgar and saying that Edgar discloses

1 doxepin, which is going to be given to the patient. And they said it would
2 have been obvious to give doxepin to the patient response to a high AHI.

3 So, a high AHI means that I'm having an apnea event while I'm
4 sleeping. And according to the Petitioner's logic, the pharmaceutical agent
5 would be given to the patient while they're sleeping. I don't think anyone
6 that is skilled in the art, in this art, with medical devices and dealing with
7 pharmaceutical treatments, is going to give a patient doxepin while they're
8 sleeping if they have trouble breathing. I think it might be fatal to the
9 patient if they were constantly given doxepin as they were having an apnea
10 event. And that's why Dr. Patil comes and he's very clear. Doxepin is for
11 insomnia. You take it when you're awake so that you can fall asleep.
12 Doxepin would not be given to a patient who's already sleeping in response
13 to some type of event, some type of breathing, some type of breathing event.
14 It just wouldn't happen.

15 And so, again, we point to the Petitioner's evidence here, and it just
16 simply falls apart. And when you look at the real reason that Edgar is
17 disclosing doxepin, we point this out in our briefing. It's because people
18 have trouble wearing masks, especially back in this time period. Masks
19 were bulky. They sat on the face, sometimes in a weird manner. Dr. Patil
20 lays this all out in his declaration. And so, sometimes it might be helpful
21 while the patient's awake to give them doxepin in order to have them fall
22 asleep. But you would never give a patient doxepin while they're sleeping.
23 It simply wouldn't happen.

24 And so, because of that, and just to go directly to what Your Honor
25 said, you know, identify the points that are missing. The points here that are
26 missing is that there is no disclosure of a treatment. Remember, the claim

1 requires that you have to treat the sleeping disorder. There's no disclosure of
2 a treatment for the sleeping disorder and adjusting the pharmaceutical agent
3 based on the level of severity. And I think that that's the important missing
4 portion of Stahmann and Edgar, because you simply would not treat a
5 patient with doxepin.

6 So, moving on to slide 21. And this kind of just reiterates the points
7 that I was making about the pharmaceutical agents that are referred to in the
8 petition and why they wouldn't work. Slide 22. Again, I foreshadowed this
9 already, but this is Dr. Patil's opinion here. It's in the surrounding opinions
10 from 28 to 31 as well. But as he says here, that a medical professional
11 would not understand to give doxepin to a patient in order to treat sleep
12 apnea. The actual treatment that would be given for the sleep apnea in the
13 traditional sense would be the CPAP device. And that's the part that's
14 missing. We don't have that automatic adjustment of the pharmaceutical
15 agent. And again, this was unrebutted. Dr. Sharony said he couldn't talk
16 about this stuff because he's not a medical professional. And we talked
17 about this earlier when we had our discussion. But on slide 23, this is the
18 admissions when he said that he didn't have the requisite experience to talk
19 about any type of medical treatments.

20 Do Your Honors have any questions about that limitation? If not, I
21 can move on to the missing limitation for the Kocinski reference. So, for
22 this reference, we're primarily talking about the airflow sensor that again is
23 internal to the PAP device. And we're talking here, as well, about the
24 display, having a display on the base station. And that, what's important,
25 though, is that base station cellular phone PDA has to also be able to
26 retransmit the information to a remote site. As Your Honors know, in the

1 Institution Decision based on the limited record, Your Honors instituted on
2 this claim as well, but did indicate that there was no display in the
3 references. And based on a full record, it became clear that there is no
4 display and there's no reason for a display.

5 Now, we're looking here, this is slide 26. We're looking at figure 1 of
6 the Kocinski reference. And the way that this figure works is you have this
7 information from the CPAP device given to the modem that goes to the
8 central database, the central database server. Then a medical professional
9 may receive that information on a device such as a PDA. It's undisputed that
10 that information that's shown on the PDA is not going to be retransmitted
11 from the PDA. The medical professional's device is not a base station that
12 can receive, display, and retransmit data to the remote site. It's the endpoint
13 for the communications.

14 And the Board recognized this. The Board recognized that any
15 device doesn't have an on-site display at the base station. And that's on slide
16 27. So, what does a Petitioner point to? The Petitioner says that it just
17 would have been obvious to put a display anywhere and in fact said that it
18 was necessary -- Petitioner says that data would be necessarily present in the
19 home. And this is at the reply at 29. The Petitioner can't back that up,
20 doesn't back it up with any evidence. And the reason is, is because that is
21 raw data that is actually in the home that's going to be transmitted. There's
22 no presentation which would require a user interface, a total reconfiguration
23 of the system in order to display that data at the home and retransmit that
24 data. That's a completely different system.

25 You have to render it. First, you have to make sure that it's -- you
26 have to validate it. You'd have to authenticate it. Then you'd have to render

1 it and make sure that it is accurate. And then you'd have to decompose that
2 data and then send it on. And the disclosures are simply lacking for any of
3 that. They said that -- Petitioner also said that you may want to do that so
4 the medical device professional could come to the patient's home. This is an
5 argument that was raised a minute ago. Could come to the patient's home so
6 they could analyze the data with the patient. Well, there's no need to have
7 that either. The medical professional can pull out the PDA and show it to
8 the patient. Why would there need to be a second display in the home if the
9 medical professional already has it and has it on their PDA? The evidence
10 isn't there and the motivation doesn't exist.

11 And this was a problem that CleveMed solved. Having the display,
12 being able to render, make that data available based on their innovations
13 became very valuable. And this was recognized by ResMed. We put in, and
14 this is slide 29, this evidence that respiratory compliance was hovering
15 around 50 percent. They released these systems that allowed for self-
16 monitoring so that a patient could actually see the device. They
17 reconfigured their systems in order to have this type of information available
18 to the patient and they went up to more than an 87 percent adherence. That
19 is evidence that a display was not obvious at the time and is extremely
20 important today for the sleep apnea community and the market in general.

21 And it kind of comes back to what did the prior art say? On the
22 arguments a minute ago, Counsel said that it's that the disclosures in
23 Kocinski don't say that it can only go to the professional. I want to read the
24 whole quote and it's actually not even shown on this slide on 28. It actually
25 goes a little bit farther. Because it teaches that the data is made available
26 only to the medical professional, and this is in paragraph 28, since others do

1 not need this information. That's what Kocinski says. It says nobody else
2 needs this information except the medical professional. And if the only
3 person that needs that information is the medical professional, they already
4 have it in their pocket. They have it on their PDA. They can see it on their
5 PDA. There is no reason to have a second display in the home. The only
6 reason to do that is if you're looking through the eyes of hindsight bias in
7 order to try to fill in these gaps. Any disclosure or motivation is just simply
8 lacking.

9 Now, the final point with regard to the limitations that are missing
10 Your Honors is that the Petitioner, again, this is the internal airflow sensor
11 but with regard to claims 15 through 20. They point to the pressure
12 transducer. And I think it became clear throughout these proceedings that a
13 pressure transducer is not an airflow sensor. It measures the pressure that's
14 applied to the patient. And so, again, what do they point to? They point to
15 Farrell. And as we had a long discussion earlier, Farrell does not disclose an
16 airflow sensor that's going to be internal to the PAP device. It discloses the
17 traditional airflow sensor that's at the mask.

18 My final point during this presentation was Dr. Sharony's declaration.
19 But I think that -- and whether or not he should be excluded under Rule 702.
20 I think we already covered those grounds, Your Honor, with our back and
21 forth. But just to point you to slide 32, that lays out the requirements under
22 the federal rules of evidence, which we're all governed by here. And that it
23 requires this knowledge. And the only case that they point to was
24 Medtronic. And Medtronic actually, as we put in our recent papers, I
25 believe was last week, Medtronic actually didn't talk about the, or challenge
26 whether the expert was one of skill in the art. And they also used the word -

1 - and it's important, they used the word education could substitute for
2 experience. In our case, it says that you have to have education and, and
3 experience which is not present for Dr. Sharony.

4 With that, Your Honor, I'll reserve my last minute for the rebuttal
5 time, if that's all right. Unless you have any questions.

6 JUDGE JENKS: I do not have any questions at this time. Thank you
7 so much.

8 MR. HANNAH: Thank you very much.

9 JUDGE SNEDDEN: Thank you, Mr. Hannah. I'll reserve 16
10 minutes for rebuttal.

11 MR. HANNAH: Thank you. Appreciate it.

12 JUDGE SNEDDEN: Ms. Miller, whenever you're ready, you may
13 begin.

14 MS. MILLER: Counsel, could you disconnect?

15 MR. HANNAH: Oh. Sure. There you go.

16 MS. MILLER: Thank you. I'm ready, Your Honor. Excuse me. So,
17 I just want to start to note Patent Owner showed you that slide 30, and it was
18 talking about those arguments with regard to Kocinski and the airflow
19 sensor. That's an example of the arguments that only first appeared in Patent
20 Owner's sur-reply. So, those were not in the Patent Owner response. I'm
21 happy to address any questions the Board has about that, but my
22 understanding is those arguments are waived.

23 Now, I'll start by addressing substantively about Patent Owner's
24 arguments for Farrell's closed sensor. Your honor, I don't know if you were
25 going to start the timer.

26 JUDGE SNEDDEN: Oh, thank you.

1 MS. MILLER: Keep me honest here.

2 JUDGE SNEDDEN: Appreciate the reminder.

3 MS. MILLER: So, Patent Owner really relied heavily on this word
4 symbolic in Farrell's disclosure. I have slide 32 from Petitioner's
5 demonstratives up. And really this comment about how these that the
6 sensors are only shown symbolically. First of all, this doesn't retract from
7 the actual illustration shown. It's shown inside the internal to the enclosure
8 of the PAP device in exactly the same manner that the patent itself describes
9 this. It's also shown symbolically simply as a box. That's what the
10 disclosure means. It's just shown as a box. So, you're not drawing any
11 particular structure around how that flow sensor is specifically implemented.
12 So, unless the Board has any more questions about the flow sensor, I think
13 we've covered that one.

14 I want to talk about Dr. Patil's declaration. If we could look at Dr.
15 Patil's declaration. Patent Owner makes some obviousness arguments in
16 particular -- actually, I don't think we need to look at it, based on this whole
17 FDA approval. But this is just a sideshow because Petitioner's reply at page
18 15 cited the Allergan v. Sandoz case, which directly refutes Patent Owner's
19 argument about getting FDA approval. So, Patent Owner also does not
20 argue there is any evidence indicating the FDA would not approve a PAP
21 device with an internal airflow sensor or this modification from Genger. It's
22 just speculation from Dr. Patil. And actually, Dr. Patil admits, if we look at
23 paragraph 25 of Dr. Patil's declaration, which is Exhibit 2018, he describes
24 this issue about where to locate the airflow sensor as a fundamental technical
25 problem. A technical problem. That's a problem for an engineer, not a

1 medical doctor. So, Dr. Patil even admits that where you locate this sensor
2 is an engineering question for someone like Dr. Sharony.

3 I also want to point out paragraph 25 is also cited by Patent Owner to
4 argue that Dr. Patil is talking about accuracy and airflow sensor
5 measurements. But Dr. Patil is not talking about airflow. He's talking about
6 pressure measurements, which we already described -- we already addressed
7 that airflow measurements are different from pressure measurements. You
8 can see this if you go back to paragraph 18 in Dr. Patil's declaration. This is
9 also relied on by Patent Owner to argue about accuracy, I believe, in airflow
10 sensor measurements. But Dr. Patil here is talking about pressure
11 measurement. He's talking about exactly what we saw before, which is
12 measuring pressure at the mask because the pressure at the mask is
13 important. The whole point is you want to deliver a particular pressure to
14 the patient. So, that's why you have that little tube going specifically to the
15 mask. And so, that's what Dr. Patil is describing at paragraph 18. He's
16 talking about that specific pressure sensor limitation. Excuse me, that
17 pressure sensor and the pressure tap going to the mask. He's not talking
18 about airflow or accuracy of airflow measurements.

19 Going back to Patent Owner's arguments about this FDA approval,
20 even if moving Genger's flow sensor was a substantial change, which there's
21 no evidence there is. Dr. Patil is speculating, and he admits that that's an
22 engineering question. The precedent is clear that just because a better
23 alternative may exist, whether that was a substantial change, whether a better
24 alternative exists in the prior art, does not mean that an inferior combination
25 is inapt for obviousness purposes.

1 So, that was expressed in *Dome Patent L.P. v. Lee*, 799 F.3d 1372, at
2 1381 and also recently emphasized again in *USAA v. PNC Bank*, which is
3 an appeal from IPR2022-76. There, the Panel stated that we have repeatedly
4 held that a combination need not be the best solution for obviousness
5 purposes. And we also know from *Par Pharma Inc. v. TWi Pharms*, which is
6 at 773 F.3d 1186, at 1197 through 98. Precedent does not require that the
7 motivation be the best option, only that it be a suitable option from which
8 the prior art did not teach away. So, that's sufficient for the KSR analysis
9 here that's provided in Petitioner's papers that even if you were to move
10 Genger's airflow sensor internal to the PAP device and there were, for
11 example, reasons why you may not do that, there are plenty of reasons why
12 you would, and that's sufficient to find obvious.

13 Moving to Petitioner's slide 43 in this issue for claim 5 in nonvolatile
14 memory. So, the reason that Petitioner gives this short shrift is because the
15 Challenged Patent doesn't even bother to mention it. Patent Owner argues
16 that this is not taught in the prior art. That's false. The petition relies on the
17 disclosure in Westbrook that describes, as you can see in slide 43, that this
18 microcontroller has an associated flash memory, and you're going to use that
19 to store 40 hours of sleep data, and then you're going to use this high-speed
20 transfer connection to transfer that data. So, Patent Owner also argues that
21 this disclosure is somehow limited to the flash card you have to physically
22 transfer. That's incorrect. That's a complete mischaracterization of the
23 Westbrook disclosure.

24 The other thing about the nonvolatile memory limitation is that
25 Patent Owner severely limits the disclosure in Genger. They really focus on
26 the modem, but that's not the structure that's being represented in Genger in

1 the combination between Genger and Westbrook. Because Genger describes
2 that you're going to collect this trend data, and a person of ordinary skill
3 would know where do you collect that trend data. You collect that in
4 memory associated with the controller. It's not being collected in memory
5 for the modem. So, their emphasis on the modem is a complete misdirection
6 and it's not relevant to the combination that the petition relies on.

7 Turning to claim 8 and the Stahmann disclosure. Again, Patent
8 Owner attempts to misdirect the Board away from the relevant disclosures in
9 Stahmann. So, Stahmann discloses adjustment of drug therapy based on
10 feedback from other components of the system, including this respiratory
11 airflow. If we could look at, actually, slide 56, it talks about combining
12 these drug therapy and also the respiratory feedback system. So, that is
13 specifically disclosed in Stahmann. As I stated in my opening argument,
14 Patent Owner, here, goes very deep into the alleged danger of using doxepin,
15 but this is absolutely unsupported by the record. You could even see, in
16 Patent Owner slide 22, that the expert declaration that they provide Dr. Patil
17 never provided support for such statements.

18 Also, here we're talking about treating for example insomnia. As the
19 Institution Decision recognized, the claim is talking about treating
20 symptoms. It says, treating a subject's sleep disorder or symptoms with a
21 pharmaceutical agent. So, the patent claim is not limited to respiratory sleep
22 disorders. So, treatment of insomnia is completely within the scope of the
23 claim. And also as the Institution Decision recognized, Edgar talks about
24 improving sleep which is also a component of symptoms of a sleeping
25 disorder. If a person has daytime sleepiness, it means they're not sleeping
26 well. And that's what Edgar describes addressing.

1 Turning up to claim 15. Patent Owner made an argument with regard
2 to Kocinski, which I have not seen support for, where they allege that the
3 data being transferred from the CPAP to the central database is raw data.
4 But that's not supported anywhere, and I haven't seen a citation for that. And
5 in fact, in the base station computer embodiment, which is at slide 47 of
6 Petitioner's demonstratives, the base station computer includes the software
7 which implements the central database service -- server, excuse me, and then
8 that component will transmit data to the medical professional. So, in this
9 implementation, this configuration, that Petitioners rely on this computer
10 embodiment, which Patent Owners completely ignore, that software will be
11 provided at the space station computer at the patient's location. And the
12 Kocinski disclosure shows that this software includes these reports. It has
13 displays. It has a user interface. This software is provided in that base
14 station computer. And these reports include these tabs, including a daily
15 summary, which you would expect to include information about, if we go
16 back to paragraph 28, the frequency and nature of events detected while the
17 patient sleeps, such as apnea events. So, that's what you would expect to see
18 in these reports, and that would be at the computer base station
19 embodiments.

20 JUDGE JENKS: So, your position, as Kocinski said, already makes
21 these calculations before it sends it out over the Internet to be displayed on
22 the medical professional's handheld device. Is that it?

23 MS. MILLER: Yes.

24 JUDGE JENKS: Okay.

25 MS. MILLER: And that's also confirmed, for example, by this. For
26 example, it says the CPAP apparatus can provide these alarms. So, it's

1 already determining that an apnea has occurred before it even transmits the
2 data. So, this is not raw flow data or raw pressure data. These are events.

3 JUDGE JENKS: Okay.

4 MS. MILLER: And I think I already addressed the argument from
5 Patent Owner that the data is only made available to the medical equipment
6 provider. The full quote, actually, at the bottom of Petitioner's slide 48 is
7 that the maintenance warnings may be made available only to the medical
8 equipment provider in the pressure and sleep events may be made available
9 only to the medical professional 17 since others do not need this
10 information. So, I believe Patent Owner dropped that may be made
11 available from their quotes. And here, as I explained before, this is really
12 just talking about, oh, you wouldn't send sleep events to the medical
13 equipment provider, but it would be pertinent for the patient or a home
14 caregiver to have that information. So, it's complete common sense that that
15 would be displayed at the base station computer at the patient's location.

16 If there's no other questions on that, I'll turn to the challenges to Dr.
17 Sharony. So, Patent Owner challenges Petitioner's expert, Dr. Sharony,
18 whose declaration is at Exhibit 1004. And I have his, excuse me, I have the
19 definition of a POSITA at the last slide of Petitioner's demonstratives. But
20 as Your Honors seemed to key in on before, Dr. Sharony's education meets
21 the definition of a person of ordinary skill, Patent Owner does not dispute
22 that.

23 I'm almost there.

24 JUDGE JENKS: So, can you talk a little bit more about this
25 diagnostic sensor thing? I mean I have a diagnostic sensor in my car. Why
26 should I interpret diagnostic sensor as being a medical device? Is that --

1 MS. MILLER: Right. So, I kind of agree with --

2 JUDGE JENKS: It didn't seem quite right to me. So, that's what I'm
3 saying.

4 MS. MILLER: Yeah. I'm also kind of at a loss as to how Patent
5 Owner is trying to twist this concept of a diagnostic sensor to somehow
6 require medical experience. That's really what they're saying, that you have
7 to be a medical doctor. And they're simply using this diagnostic sensor part
8 of the definition of a person of ordinary skill to try and exclude, wholly
9 exclude Dr. Sharony's testimony. And that just has no basis in the art.
10 They've never proposed a definition of diagnostic sensor. They've also not
11 disputed that experience with physiological sensors is experience with
12 diagnostic sensors. In Dr. Sharony's declaration, I think at paragraphs 10,
13 we've cited this in our papers, paragraphs 10, 14, and 16, he talks about his
14 experience with physiological sensors. So, Patent Owner has never
15 expressed some special definition of diagnostic sensors that we've had an
16 opportunity to respond to. They seem to be twisting this to somehow require
17 some medical experience, which is just not in the plain words of the
18 definition of a person of ordinary skill, here.

19 The evidence and issues in this proceeding are also basic engineering
20 concepts as we've already addressed. We're talking about the placement of
21 an airflow sensor, whether you would include nonvolatile memory. That's
22 completely reflected in the definition of a person of ordinary skill in this
23 educational background and experience. And Patent Owner argues that, for
24 some reason, that education could not compensate for lack of experience.
25 But that's exactly what that last sentence in the definition of a person of
26 ordinary skill says, increase in experience could compensate for less

1 education and vice versa. So, I'm not sure what they think that word "and"
2 what's that importing there, but it seems pretty clear to me. We also have
3 Dr. Patil who as the Board recognized does not meet the definition of a
4 person of ordinary skill. And even he admits that the location of a flow
5 sensor is a technical problem. It's not a medical issue; it's a technical
6 problem. And that's reflected in the definition of a person of ordinary skill,
7 here.

8 That's the end of my presentation. I'm happy to address any
9 questions.

10 JUDGE JENKS: I do not have any further questions.

11 MS. MILLER: Thank you.

12 JUDGE SNEDDEN Thank you so much.

13 MS. MILLER: Thank you.

14 MR. HANNAH: Actually, could you, I'm going to put back the
15 figure. Can you leave yours on? I'm just going to put on the --

16 MS. MILLER: The definition?

17 MR. HANNAH: Just go a little bit back, the Farrell one. Go back to
18 Farrell.

19 MS. MILLER: If I go too fast, it freaks out.

20 MR. HANNAH: There you go. Right there. Perfect.

21 JUDGE SNEDDEN: Mr. Hannah, when you're ready, you will have
22 16 minutes.

23 MR. HANNAH: All right. Thank you, Your Honor. So, first, I
24 wanted to talk about the case, Your Honor, you asked for the case site.
25 That's in the record. So, the case that the Petitioner actually raised was the
26 Allergan v. Sandoz case. And that's at 726 F.3d 1286. And what it says

1 here is that for -- this is at page 1291. This is a Federal Circuit case. It says,
2 we have previously noted that FDA approval may be relevant to the
3 obviousness inquiry. And it cites the Knoll Pharm case v. Teva Pharma, and
4 that's 367 F.3d 1381. And it says the potential for FDA approval also may
5 be probably be considered as it was here, in determining whether one of
6 ordinary skill in the art would be motivated to develop a drug product and
7 whether there was skepticism regarding the efficiency -- efficacy of the
8 product.

9 So, that is from the Petitioner themselves in this case citing that FDA
10 approval is relevant to the obviousness inquiry. And the entire point that we
11 are trying to make is not one of Dr. Patil giving speculation. That's
12 evidence. It's his opinion regarding that moving the airflow sensor would
13 require additional FDA approval that would be a lack of motivation for one
14 of skill in the art.

15 And the other point is that this evidence is unrebutted. Again, we're
16 dealing with the record here and what we have in the record. And because
17 FDA approval is in consideration for obviousness and because we have Dr.
18 Patil who says that FDA -- this would require substantial change and that
19 one or skill in the art would not be motivated to do that change. That's all
20 evidence that we must consider here.

21 Now, I heard Counsel, you know, talk about arguments that may or
22 may not have been waived. I know that there was a lot of discussion of Dr.
23 Patil, here. None of that was in the briefings. But I would like to make the
24 point that if there was something in the sur-reply that they believed should
25 not have been there, there's a process for that, an objection, a filing, in order
26 to have that evidence and bring that before the Board and we had none of

1 that before today. We had no objections, nothing of that nature. And the
2 reason for that is because everything in the sur-reply was responsive to
3 arguments that were made in the reply.

4 Now, one thing that we never saw and we never saw any evidence is
5 that there was no reasonable expectation to move the airflow sensor. This
6 was a point that was made in our Patent Owner response and it was not
7 addressed in the reply. And we had it again in our in our sur-reply, because
8 they needed to show that expectation of success. And based on the
9 disclosures it's not there.

10 Now, when -- I've put up, and thank you, Counsel. I've put up on the
11 screen Counsel's demonstrative and this is for the Farrell and there's a lot of
12 argument saying that this f3 is the same as 320 that's shown on the right.
13 Well, let me just point out the Most obvious difference. F3 is not in the
14 airflow path between the patient and the device; 320 is in the airflow path.
15 As you can see the tube, and I know you can't see this Your Honors that are
16 remote, but if you see the tube that goes from the patient's nose all the way
17 into the enclosure within the PAP device, 320 is within the device and is in
18 that airflow path, 4f is not. And the reason it's not is because that's a
19 symbolic representation of the airflow sensor. And Farrell specifically says
20 that that airflow sensor is near the mask. It is not in the device. What's
21 being shown here is data that's going to be, if you look at the disclosure, data
22 that's going to be going into the controller, into the microcontroller, and it
23 shows all those different boxes, shows the switches on the left and it shows
24 these different attributes of information that's going to be fed into the
25 controller. This is not a disclosure of an airflow sensor that's internal to the
26 device, especially in light of the disclosure referral.

1 Moving on to the memory and please interrupt me with any questions
2 at any time. But moving on to the memory. Counsel stated repeatedly that
3 the memory aspect is not disclosed in the patent. Well, if we go to column
4 three of the patent, and if we go to line 42 it says, alternatively, the signals
5 from the sensors can be saved on a medium in order to be retrieved and
6 analyzed at a later date. Media on which data can be saved includes but are
7 not limited to chart recorders, hard drive, floppy disk, computer networks,
8 optimal storage, solid state memory, magnetic tapes, punch cards. A hard
9 drive is an example of the nonvolatile memory. And so, when Counsel says
10 that there's no disclosure of that in the specification, I beg to differ with
11 regard to column three, lines 42 through 47.

12 Counsel also seem to pivot on where this memory needs to be. The
13 only -- if you look at the petition, they admit that there is no nonvolatile
14 memory disclosed. The only thing that they show, then, with regard to claim
15 5 is the modem and they point to a flash, you know, this flash memory from
16 Westbrook. If you gave a POSITA a modem and some flash memory, I
17 guarantee they're not going to have some motivation to combine those in
18 order to store data that's going to be transmitted through the modem.
19 They're simply not going to do it. They're going to be, thanks for that
20 equipment, let's figure out what you want to do with it. The only way that
21 you can come back to integrating that memory in either the CPAP, if we go
22 with the pivot or the modem is through hindsight bias because the references
23 are completely silent as to that and the only memory disclosed in that
24 combination would have to be the buffers that are within the modem.

25 Counsel also talked a bit about the display and the information that's
26 going to be shown to the medical professional. As I talked about on my

1 opening remarks, there is no motivation to create a second display in the
2 patient's home because the medical professional already has it on their PDA.
3 They don't need two of them. If, following Petitioner's logic, a medical
4 professional is going to go to the house and show them the data, they're
5 going to take their PDA with them.

6 She also talked a little bit about the data that's going to be sent and
7 one of skill in the art might know to display this data. That's a complete
8 reconfiguration of the system. What the prior art discloses is raw data that's
9 being sent up through the modem into a central server. That's raw data.
10 You have to have some type of computer, you have to have some algorithm,
11 something that's going to be used to be able to render and have that
12 information available. And it's not available to be rendered until it's passed
13 to the PDA for the medical professional. There's simply, there is no
14 disclosure, as we know, for a display in the home or at the base station.
15 There's certainly no motivation given the disclosures of the prior art, because
16 the prior art specifically says, I can put it on the PDA. If I show that to one
17 of skill in the art, and I have, I've got the data in my pocket, and I go to a
18 patient's home, they're going to say, why would I want it? Why would I
19 want it in the home? Only if I'm trying to fill in the holes of the claim. And
20 that's hindsight.

21 And the thing that she did not address was the secondary
22 considerations. I call them objective addition by obviousness because I don't
23 think that they're secondary. But that was not addressed. It went from a 50
24 percent rate to over 87 percent. And it came from the CEO of ResMed.
25 And that was because they reconfigured the system to be able to display it to
26 the patient.

1 Finally, I'd like to talk about the evidence and the opinion of Dr.
2 Sharony, and Dr. Patil, Dr. Borkholder. In the end, Your Honors, it's your
3 job to weigh the evidence. You're the finders of fact. You have to weigh the
4 evidence. And so, if you have an opinion from someone that has zero
5 medical experience dealing with CPAP devices, I don't care if they have
6 sensors on their car. Set that aside. I don't care about the explicit definition
7 that's provided. Let's just take a step back. Weighing the evidence. You
8 have on one side, someone that specializes in wireless communications and
9 they offer an opinion that is directly contrary to a doctor who deals with
10 sleep apnea and someone with decades of medical device experience. That's
11 what you have to weigh. You have to weigh the evidence just like any other
12 fact finder. I don't think there's any other way, when you weigh that
13 evidence, to find that a doctor who deals with sleep apnea every day,
14 someone with medical devices, that evidence absolutely outweighs someone
15 that has some sensor experience in wireless communications or otherwise.

16 JUDGE SNEDDEN: In your Patent Owner response, you agreed to
17 the definition of a POSITA that was presented by the Petitioner. Are you
18 now turning that around?

19 MR. HANNAH: No.

20 JUDGE SNEDDEN: No?

21 MR. HANNAH: No, no, not at all, Your Honor. I still
22 wholeheartedly believe that Dr. Sharony does not have the requisite
23 experience. I think you have to look at the word diagnostic sensor systems
24 in context. And in context with this patent, which is dealing with sleep
25 apnea. My point, Your Honor, is that in the end, whether you believe that
26 Dr. Sharony is a POSITA under that definition or not, if you want to say,

1 technically, sensors in a car, and he has tons of sensors in the car, he still, he
2 qualifies under that definition. In the end, it doesn't matter because you have
3 to weigh the evidence.

4 JUDGE SNEDDEN: Okay.

5 MR. HANNAH: And you've got the testimony from someone who
6 has -- two people who have a ton of experience dealing with CPAP
7 machines versus someone who doesn't.

8 JUDGE SNEDDEN: Under that definition, does Dr. Patil qualify as
9 a POSITA?

10 MR. HANNAH: Dr. Patil does not have the engineering
11 requirements, but that's why we have both experts in there. And also, again,
12 it comes down to weighing the evidence, so.

13 JUDGE SNEDDEN: I understand your argument. Thank you.

14 MR. HANNAH: Yeah. Any questions, Your Honors? If not, then
15 thank you for your time again. Thank you for taking a fresh look at the
16 record. Now that we've had a full record in this case.

17 JUDGE JENKS: I do not have any further questions. Thank you so
18 much for coming today and presenting your side.

19 MR. HANNAH: Thank you, Your Honor.

20 JUDGE SNEDDEN: That will conclude our hearing today. Thank
21 you all for your helpful arguments. The Panel will take this matter under
22 advisement and issue our final written decision in due course. If you could
23 just stay behind and answer any questions that the court reporter may have
24 for you regarding spellings or anything else. We are adjourned. Thank you.

25 (Whereupon, the proceedings at 2:58 p.m. were concluded.)

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Patent 10,076,269 B1

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