

PTAB Oral Argument

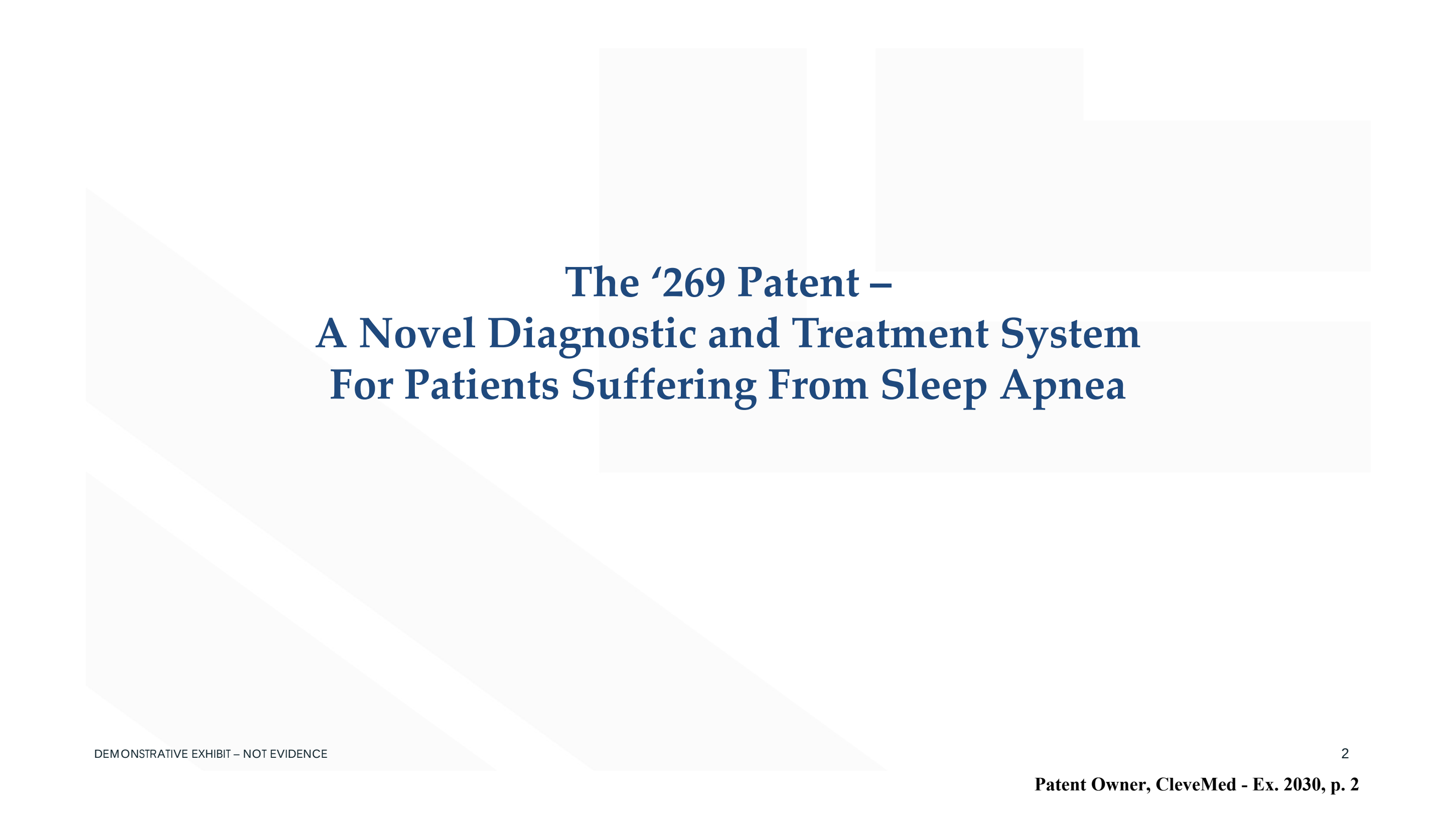
February 4, 2025

RESMED CORP.
PETITIONER

v.

CLEVELAND MEDICAL DEVICES, INC. (“CLEVEMED”)
PATENT OWNER

CASE NO.: IPR2023-00565
U.S.PATENT NO.: 10,076,269



The '269 Patent – A Novel Diagnostic and Treatment System For Patients Suffering From Sleep Apnea

The Claimed Invention

- Some key claimed features include, *inter alia*:
 1. An airflow sensor internal to the PAP device (“internal airflow sensor”) for measuring a patient’s respiratory airflow (claims 1 and 15);
 2. A base station that displays data to the patient and relays the data to a remote internet site (claim 15);
 3. Storing the data in nonvolatile memory before retransmitting to a remote location (claim 5); and
 4. A CPAP controller that administers a pharmaceutical agent based on the level of severity of the patient’s symptoms (claim 8).

POR at 1-3; 269 Patent at Claims
1, 6, 8, 15

The Claimed Invention's Improvement Over the Art

- At the time of filing the claimed invention, traditional CPAP machines lacked key features.
- Dr. Patil, a medical doctor who practiced in the sleep-disordered breathing field at the time of the invention, explained that then traditional CPAP machines did **not**:

Offer data tracking abilities, as the data provided was directed to CPAP usage.

Provide real-time feedback of the patient's symptom data.

Measure and report the severity of a patient's sleep apnea events.

- Traditional CPAP machines measured respiratory airflow at the patient's mask because air leaks affected the accuracy of airflow measurements taken elsewhere in the system.

Ex. 2018 at ¶ 19

The Independent Claims:

'269 Patent, Claim 1:

1. A positive airway pressure (PAP) sleep disorder treatment system comprising:

a signal processing module comprising a first input adapted for connecting to a pulse oximeter sensor with a signal, electronics adapted for filtering and processing the signal, and an output adapted for outputting pulse oximetry sensor data;

a PAP device adapted for treating a subject's sleep disorder, the PAP device with a separate enclosure from the signal processing module further comprising:

a blower having an air output,

a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module,

an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject using the PAP device, and

a processor adapted for receiving the pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor and calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device;

a mask or a nasal cannula; and

a module transceiver adapted for receiving and transmitting the sleep disorder symptom data of the level of severity and/or the index of the level of severity of the subject's sleep disorder symptoms to a remote location.

'269 Patent, Claim 5:

5. A sleep disorder treatment system comprising:

a data acquisition system;

a positive airway pressure (PAP) device; and

a processor;

the data acquisition system consisting essentially of a data acquisition device having at least one first input adapted for receiving a first signal from a pulse oximeter sensor, an electronic component adapted for filtering and processing the first signal from the pulse oximeter sensor to remove artifacts, and a first output adapted for transmitting pulse oximeter sensor data based on the first signal from the pulse oximeter sensor to the PAP device;

the PAP device comprising:

a hose,

a blower,

an airflow sensor with a second signal adapted for measuring respiratory airflow of a subject,

a second input for receiving pulse oximetry sensor data from the data acquisition device; and

a mask or nasal cannula for treating a subject's sleep disorder symptoms; and

the processor adapted for receiving pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor, the processor further adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device, the processor adapted to be either part of or external to the PAP device and having a second output, the second output adapted for providing sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a nonvolatile memory to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location.

The Independent Claims:

'269 Patent, Claim 8:

8. A sleep disorder treatment system comprising:

a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the at least one physiological sensor; and

a positive airway pressure apparatus for providing pressurized air and dosing and chemically treating a subject's sleep disorder or symptoms with a pharmaceutical agent, the positive airway pressure apparatus comprising a controller adapted to adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject's sleep disorder from the data acquisition system.

'269 Patent, Claim 15:

15. A positive airway pressure (PAP) sleep disorder treatment system comprising:

a PAP device with an enclosure further comprising:

a blower having an air output,

an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data;

a processor adapted for receiving the airflow sensor data, and calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device;

a mask or a nasal cannula;

a first radio frequency wireless module transceiver; and

a base station, cellular phone, or PDA;

the first radio frequency wireless module transceiver adapted for receiving and transmitting the symptom data of the severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and the data of usage to the base station, cellular phone or PDA;

the base station, cellular phone, or PDA comprising a second radio frequency wireless module transceiver, a processor, a software, and a display, the base station, cellular phone, or PDA adapted to display the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms, and to retransmit the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms and the data of usage received from the PAP device to a remote internet site.

Summary of the Petition Grounds

Hindsight Combinations That Also Require Knowledge of a POSITA

Ground	Challenged Claims	Number of References	References
1	1-3, 5, 7	4 Plus Knowledge of a POSITA	Genger, Schmidt, Westbrook, Farrell, and knowledge of a POSITA.
2	4, 6	5 Plus Knowledge of a POSITA	Genger, Schmidt, Westbrook, Farrell, Paradiso, and knowledge of a POSITA.
3	8-11, 13	2 Plus Knowledge of a POSITA	Stahmann, Edgar, and knowledge of a POSITA.
4	12	3 Plus Knowledge of a POSITA	Stahmann, Edgar, Schmidt, and knowledge of a POSITA.
5	14	3 Plus Knowledge of a POSITA	Stahmann, Edgar, Paradiso, and knowledge of a POSITA.
6	15-16, 18-19	3 Plus Knowledge of a POSITA	Kocinski, Farrell, Bluetooth, and knowledge of a POSITA.
7	17	5 Plus Knowledge of a POSITA	Kocinski, Farrell, Bluetooth, Guillemineault-2004, Westbrook, and knowledge of a POSITA.
8	20	4 Plus Knowledge of a POSITA	Kocinski, Farrell, Bluetooth, Paradiso, and knowledge of a POSITA.

Independent claims are bolded.

Paper 1 (“Pet.”) at 3-4

The Deficiencies of the Petition Grounds

Ground	Challenged Claims	Number of References	Deficiencies
1	1-3, 5, 7	4 Plus Knowledge of a POSITA	Does not teach (1) internal airflow sensor limitation, and (2) nonvolatile memory limitation.
2	4, 6	5 Plus Knowledge of a POSITA	Does not teach (1) internal airflow sensor limitation, and (2) nonvolatile memory limitation.
3	8-11, 13	2 Plus Knowledge of a POSITA	Does not teach a CPAP controller administering a pharmaceutical agent based on the level of severity.
4	12	3 Plus Knowledge of a POSITA	Does not teach a CPAP controller administering a pharmaceutical agent based on the level of severity.
5	14	3 Plus Knowledge of a POSITA	Does not teach a CPAP controller administering a pharmaceutical agent based on the level of severity.
6	15-16, 18-19	3 Plus Knowledge of a POSITA	Does not teach (1) internal airflow sensor limitation, and (2) base station that displays and retransmits data.
7	17	5 Plus Knowledge of a POSITA	Does not teach the (1) internal airflow sensor limitation, and (2) base station that displays and retransmits data limitation.
8	20	4 Plus Knowledge of a POSITA	Does not teach the (1) internal airflow sensor limitation, and (2) base station that displays and retransmits data limitation.

Independent claims are bolded.

The Genger Combinations (Grounds 1-2) Do Not Teach the Internal Airflow Sensor and Nonvolatile Memory Limitations

The Claim Limitations at Issue:

'269 Patent, Claim 1:

1. A positive airway pressure (PAP) sleep disorder treatment system comprising:

a signal processing module comprising a first input adapted for connecting to a pulse oximeter sensor with a signal, electronics adapted for filtering and processing the signal, and an output adapted for outputting pulse oximetry sensor data;

a PAP device adapted for treating a subject's sleep disorder, the PAP device with a separate enclosure from the signal processing module further comprising:

a blower having an air output,

a second input adapted for receiving the pulse oximetry sensor data from the output of the signal processing module,

an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject using the PAP device, and

a processor adapted for receiving the pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor and calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity of the subject's sleep disorder symptoms measured during use of the PAP device;

a mask or a nasal cannula; and

a module transceiver adapted for receiving and transmitting the sleep disorder symptom data of the level of severity and/or the index of the level of severity of the subject's sleep disorder symptoms to a remote location.

'269 Patent, Claim 5:

5. A sleep disorder treatment system comprising:

a data acquisition system;

a positive airway pressure (PAP) device; and

a processor;

the data acquisition system consisting essentially of a data acquisition device having at least one first input adapted for receiving a first signal from a pulse oximeter sensor, an electronic component adapted for filtering and processing the first signal from the pulse oximeter sensor to remove artifacts, and a first output adapted for transmitting pulse oximeter sensor data based on the first signal from the pulse oximeter sensor to the PAP device;

the PAP device comprising:

a hose,

a blower,

an airflow sensor with a second signal adapted for measuring respiratory airflow of a subject,

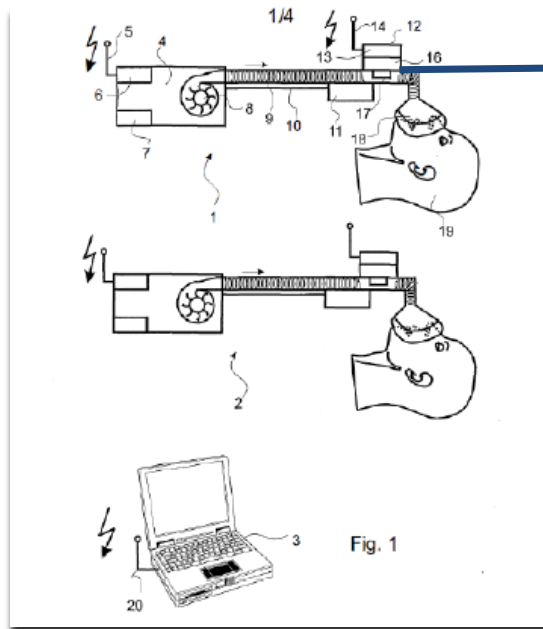
a second input for receiving pulse oximetry sensor data from the data acquisition device; and

a mask or nasal cannula for treating a subject's sleep disorder symptoms; and

the processor adapted for receiving pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor, the processor further adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device, the processor adapted to be either part of or external to the PAP device and having a second output, the second output adapted for providing sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a nonvolatile memory to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location.

Genger in View of Farrell Does Not Teach the Internal Airflow Sensor Limitation (Claims 1-3)

- Genger and Farrell disclose mask-based pneumotachographs that **directly** measure a patient's respiratory airflow.
- Genger's mask-based pneumotachograph (flow sensor unit 12) is depicted below:



- The pneumotachograph “quantitatively and directly” measures a patient’s airflow.
- The location of the pneumotachograph at or near the mask is most convenient because it “can be flexibly added or omitted, depending on the clinical condition of patient.”

Paper 32 (“Sur-Reply”) at 6; *id.* at 8 (citing Paper 31 (“Reply”) at 12)

- As the Board recognized at institution, Farrell “incorporate[s] sensors into the mask.” Paper 23 at 30-31.

POR at 2, 13, 20-21; Sur-Reply at 5-6, 7

Genger in View of Farrell Does Not Teach the Internal Airflow Sensor Limitation (Claims 1-3)

- Petitioner does not establish that a POSITA would have had a reasonable expectation of success replacing Genger's pneumotachograph with an internal airflow sensor ***because:***
 1. Pneumotachographs ***directly*** measure respiratory airflow.
 - Petitioner has not alleged or established that a POSITA would have had a reasonable expectation of success replacing a mask-based pneumotachograph with an internal airflow sensor that measures airflow ***indirectly***.
 - Petitioner has not established that its measurements would be sufficiently accurate to calculate the level of severity of a patient's sleep disorder symptoms.
 2. Dr. Patil's un rebutted testimony establishes that such relocation would result in substantial changes and significant costs that would weigh against the proposed modification:
 - The significant amount of time and expense required to receive FDA approval for the redesign of Genger's medical device would discourage a POSITA from seeking modifications absent a strong motivation. Ex. 2018 at ¶¶ 23-25.
 - No motivation exists in any event because the proposed modification would make measurements less accurate and remove the ability to manipulate the pneumotachograph as desired.

POR at 13, 21-22, Sur-Reply at 5-10

Genger in View of Farrell Does Not Teach the Internal Airflow Sensor Limitation (Claims 1-3)

23. The Federal Food, Drug, and Cosmetic Act (FDCA) defines a medical

“device” as follows:

(1) The term “device” (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term “device” does not include software functions excluded pursuant to section 360j(o) of this title.

21 U.S.C. § 321(h).

24. Some high-risk devices require premarket approval before they can be legally marketed. FDCA Section 515. Examples of high-risk devices include implantable pacemakers, neurostimulators, long-term ventilators. For medium-risk devices, like CPAP devices, a product may be cleared using the relatively fast and inexpensive 510(k) process, but only if the new device is “substantially equivalent” to an already cleared device. Ex. 2027. Accordingly, medical device manufacturers are not motivated to consider substantial changes to an existing design absent a very compelling reason to make the modification.

Ex. 2018 at ¶¶ 23-24

Genger Does Not Disclose the Nonvolatile Memory Limitation (Claims 5-7)

- The claimed invention requires that the “PAP device” include a “second output adapted for providing sleep disorder system data and/or the index . . . to a nonvolatile memory to be used for later transmission.”
- Petitioner acknowledges that Genger does not disclose a “nonvolatile memory.” Pet. at 46.

Genger Does Not Disclose the Nonvolatile Memory Limitation (Claims 5-7)

- A POSITA would **not** have found it obvious to put nonvolatile memory in Genger's modem for the later transmission of "data, AHI, and alarms." Pet. at 46; Sur-Reply at 10.
 1. Modems convert data from one form to another to **immediately** pass the converted data through a network. The data is temporarily stored in volatile buffer memory.
 2. Genger immediately transmits the relevant data given to ensure prompt medical care, including the dispatch of an ambulance in case of emergency. Genger at 18:27-39.
 - The data is **not** stored in nonvolatile memory at the modem and at some later time transmitted to medical professionals for analysis and assessment of whether medical care is needed, as Petitioner contends.
 3. The medical professional's server stores Genger's data long term, so there is no independent need for long term storage at the base station that relays this data to the medical professional.

Sur-Reply at 10-13; POR at 23-24; Reply at 16-18

The Stahmann Combinations (Grounds 3-5) Do Not Teach a CPAP Controller Administering a Pharmaceutical Agent Based on the Level of Severity Limitation

Claim Limitations at Issue:

'269 Patent, Claim 8:

8. A sleep disorder treatment system comprising:

a data acquisition system, the data acquisition system comprising a data acquisition device having inputs for receiving signals from at least one physiological sensor, the data acquisition system for creating an output of the level of severity of a subject's sleep disorder or symptoms based in part on the signals from the at least one physiological sensor; and

a positive airway pressure apparatus for providing pressurized air and dosing and chemically treating a subject's sleep disorder or symptoms with a pharmaceutical agent, the positive airway pressure apparatus comprising a controller adapted to adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject's sleep disorder from the data acquisition system.

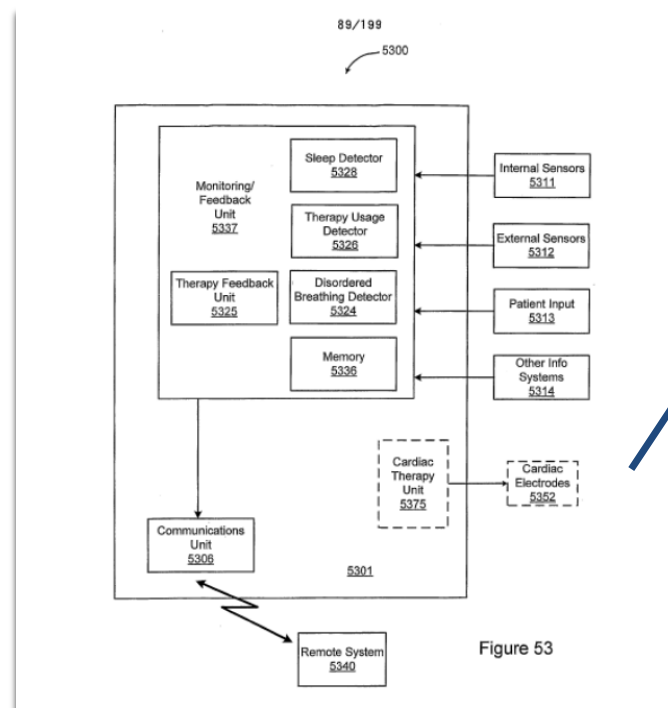
'269 Patent at Claim 8

Stahmann in View of Edgar Does Not Teach the CPAP Controller Administering a Pharmaceutical Agent Based on the Level of Severity (Claims 8-14)

- Petitioner admits that Stahmann does not disclose a CPAP device that adjusts a pharmaceutical agent based on a level of severity (alleged as “AHI”).
 - Petitioner presents no reason why a POSITA would have modified Stahmann’s disclosure to adjust a pharmaceutical agent based on a patient’s AHI. Sur-Reply at 13-17.
 - Instead, Petitioner concludes with no other analysis or evidence, a POSITA would have been motivated to “adjust drug therapy . . . based on AHI” that because drug therapies and AHI are both disclosed in Stahmann. Reply at 20; see also Pet. at 53.

Stahmann in View of Edgar Does Not Teach the CPAP Controller Administering a Pharmaceutical Agent Based on the Level of Severity (Claims 8-14)

- Stahmann discloses calculating AHI, but it does not disclose adjusting any pharmaceutical treatments based on AHI.



Stahmann at Fig. 53

- The only therapy adjusted is “breathing therapy pressure” (e.g., CO₂), not drug therapy.*
- There is no pharmaceutical agent adjustment, let alone based on AHI.

*During prosecution, CO₂ was distinguished from a pharmaceutical agent. POR at 33 (citing Ex. 1002 at 283).

Sur-Reply at 14-16 (citing Stahmann at 244-4-11, Figs. 53, 54A-54F, 79)

**Stahmann in View of Edgar Does Not Teach the CPAP
Controller Administering a Pharmaceutical Agent Based on
the Level of Severity (Claims 8-14)**

- None of the pharmaceutical agents identified in the Petition are, or would be, adjusted based on AHI.
- The pharmaceutical agents cited in the petition are unrelated to AHI because:
 - **(1)** they are given when a patient is awake, and/or
 - **(2)** treat non-sleep-related breathing disorders, like asthma:

Reference	Agent	Treatment For
Stahmann	Nebulizer agent	Asthma: a non-sleep disordered breathing event, occurring when patient is awake.
Edgar	Doxepin	Insomnia: a patient's inability to sleep, occurring when patient is awake.

- Because asthmatic and insomnia events do not occur while a patient is sleeping and the treatments do not affect sleep disorders, AHI would not be used to adjust Stahmann's nebulizer agent or Edgar's Doxepin.

Sur-Reply at 17-18

Stahmann in View of Edgar Does Not Teach the CPAP Controller Administering a Pharmaceutical Agent Based on the Level of Severity (Claims 8-14)

- Dr. Patil, a medical doctor who used CPAPs at the time of the invention, confirms that Doxepin would not be adjusted based on AHI:



A medical professional would understand that Edgar primarily addresses a different problem than the one solved by the claimed invention—namely, that patients would often remove the CPAP device while sleeping due to discomfort. As Edgar teaches, doxepin could be administered to improve the likelihood that the patient kept the mask on all night. *See* Edgar at Paragraphs 0406-0408. In this case, the treatment for the patient's sleep disorder or symptoms was the positive pressure provided by the CPAP, not the doxepin.

Reply at 19 (citing Ex. 2018 at ¶ 31)

- Thus, while Doxepin can be used alongside CPAP treatment to reduce the likelihood that a patient would remove their mask (Edgar ¶¶ [0407]-[0409]), it would not be used in the treatment of the sleep-related breathing based on AHI.

Petitioner's Expert, Dr. Sharony, Lacks the Experience to Opine on Medical Treatments

Dr. Sharony testified about alleged obviousness in modifying medical treatments without any relevant knowledge or experience in treating sleep-disordered breathing. As he admitted on cross-examination:

Q. Have you ever treated a patient for any disease?

A. No. I'm not a medical practitioner. But this patent is about the system. It's – there is nothing about medical here. . . .

Q. Do you have any experience diagnosing sleep disorders?

A. I'm not a medical professional.

Q. Do you have any experience treating sleep disorders?

A: Same answer. I'm not a medical professional.

Q. Do you have any experience operating a CPAP machine?

A: I'm not a medical practitioner; so . . .

Q. Do you have any experience designing a CPAP machine?

A. I haven't designed CPAP machine

Ex. 2016 at 24:9-22; POR at 11-12; Sur-Reply at 19-20

The Kocinski Combinations (Grounds 6-8) Do Not Teach the Internal Airflow Sensor and Base Station that Displays and Retransmits Data Limitations

Claim Limitations at Issue:

'269 Patent, Claim 15:

15. A positive airway pressure (PAP) sleep disorder treatment system comprising:

a PAP device with an enclosure further comprising:

a blower having an air output,

an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data;

a processor adapted for receiving the airflow sensor data, and calculating both symptom data of a severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and data of usage of the PAP device;

a mask or a nasal cannula;

a first radio frequency wireless module transceiver; and

a base station, cellular phone, or PDA;

the first radio frequency wireless module transceiver adapted for receiving and transmitting the symptom data of the severity of the subject's sleep disorder symptoms and/or an index of a subject's symptoms measured during use of the PAP device and the data of usage to the base station, cellular phone or PDA;

the base station, cellular phone, or PDA comprising a second radio frequency wireless module transceiver, a processor, a software, and a

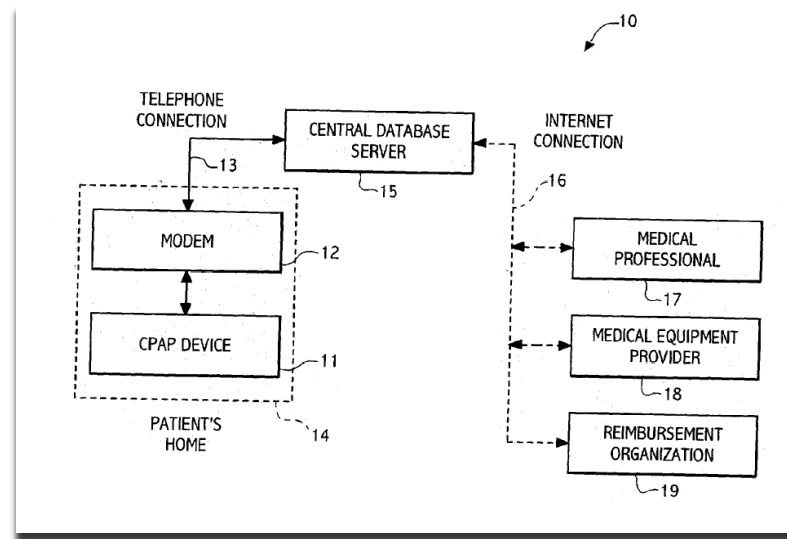
display, the base station, cellular phone, or PDA adapted to display the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms, and to retransmit the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms and the data of usage received from the PAP device to a remote internet site.

'269 Patent at Claim 15

Kocinski in View of Farrell Does Not Teach the Base Station that Displays and Retransmits Data Limitation (Claims 15-20)

- The data illustrated in Kocinski figure 10 is **not** displayed by an on-site device (PDA or base station) that retransmits the data to a remote internet site, as Petitioner suggests. Sur-Reply at 20-23.
- **Instead** the data is transmitted to a server, where it is accessed by and displayed on a medical professional's device. Sur-Reply at 21 (citing Kocinski at ¶¶ [0028], [0031], [0045], Fig. 10).

Data is transferred to the server.



Kocinski at Fig. 1 (annotated)

A medical professional's device receives the data.

- The medical professional's device is not a base station that receives, displays, and retransmits the data to a remote internet site. It is the endpoint for such communications.

Kocinski in View of Farrell Does Not Teach the Base Station that Displays and Retransmits Data Limitation (Claims 15-20)

- The Board recognized that Kocinski's system transmits the relevant data to a server without an on-site base station display:

Kocinski teaches “[t]wo-way communication between the CPAP apparatus 11 and the central database server 15 is accomplished via an internet processing system (IPS). The IPS collects compliance data and other parametric data from the CPAP apparatus 11 in the patient’s home 14, *transmits the data to a central database server 15, . . . and makes the data available to the medical professional 17.*” *Id.* ¶ 35.

Paper 23 at 47-48 (emphasis added)

Kocinski in View of Farrell Does Not Teach the Base Station that Displays and Retransmits Data Limitation (Claims 15-20)

- Farrell does not cure Kocinski's deficiencies because it also discloses transmitting data to a medical professional's device displaying the data, with no display and retransmission by an on-site device and no re-transmission from the medical professional's device. Sur-Reply at 22 (citing Farrell at 6:20-32).
- It would **not** have been obvious to display data, such as patient-specific data, on-site by a device that also does the retransmission because Kocinski "expressly teaches that such data is 'made available **only to the medical professional.**'"

Sur-Reply at 22 (citing Kocinski at ¶ [0028], [0039], [0045])

Kocinski in View of Farrell Does Not Teach the Base Station that Displays and Retransmits Data Limitation (Claims 15-20)

- Objective indicia also supports nonobviousness because it satisfied a long-felt need and achieved unexpected results:

Respiratory companies have been struggling with this challenge for many years. Designers and developers have made both iterative and innovative improvements, without demonstrably moving the needle on changing patient behavior. For the most part, compliance rates hover around 50%.

- ResMed's CEO expressly credited its "remote and self-monitoring" technology with increasing patient compliance from 50 to 87%:

And it appears to work. A November 2017 study of 128,000 patients published in the journal CHEST showed that sleep apnea therapy users whose nightly use was remotely and self-monitored via ResMed's AirView and myAir platforms, respectively, were more than 87% adherent on therapy.

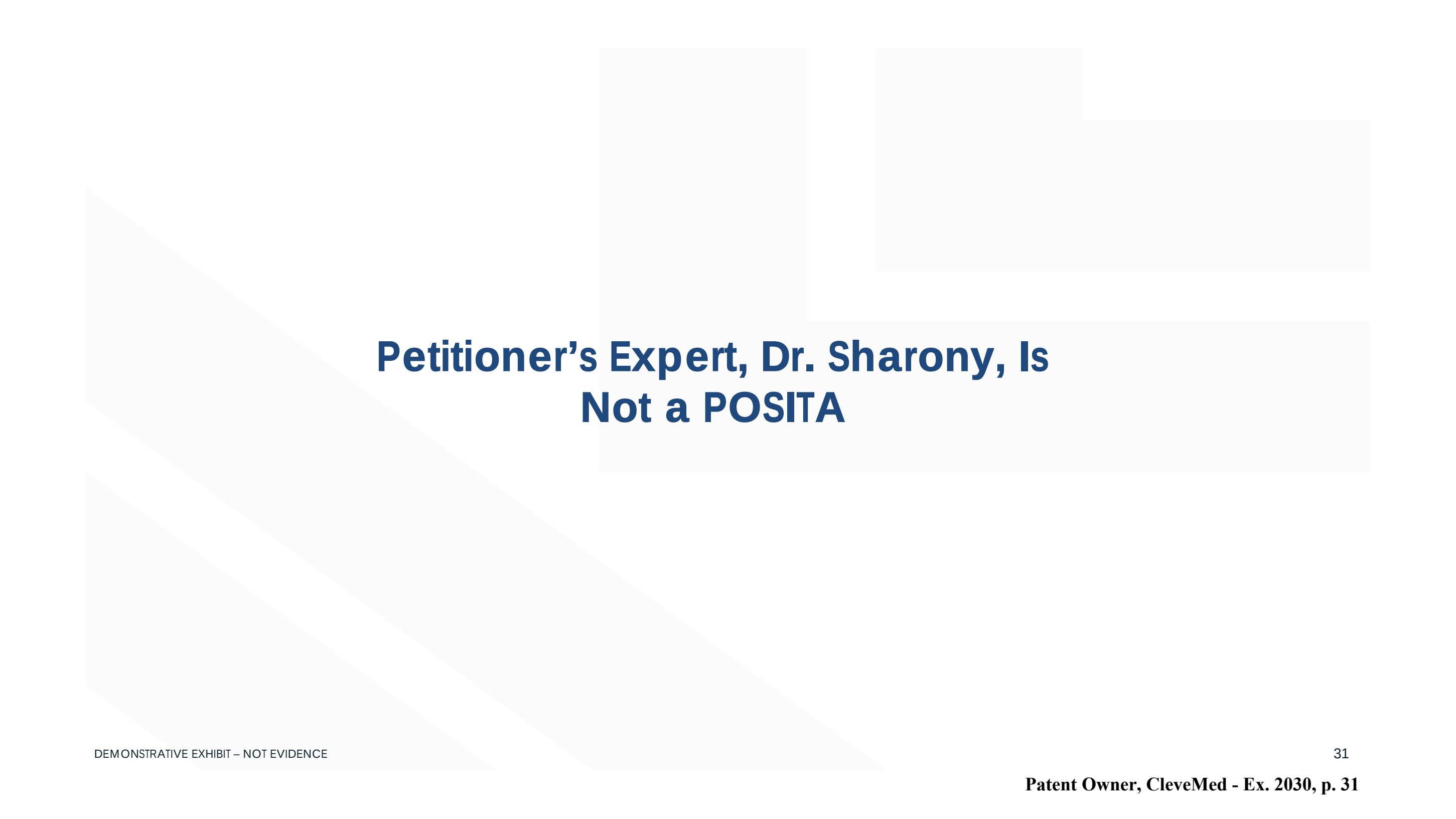
In re: Soni, 54 F.3d 746, 750 (Fed. Cir. 1995) (unexpected results based on a significant increase in performance).

Sur-Reply at 22-23; Ex. 2011 at 1-3

Kocinski in View of Farrell Does Not Teach the Internal Airflow Sensor Limitation (Claims 15-20)

- Petitioner’s obviousness theory for this limitation fails for the following two reasons:
 1. Kocinski’s pressure transducer is **not** an “airflow sensor” that measures the respiratory airflow of the patient. It measures the pressure applied to the patient.
Sur-Reply at 24 (citing Kocinski at ¶¶ [0010], [0046]); Reply at 23.
 2. Petitioner also fails to show that the Kocinski-Farrell combination provides a sensor “adapted for measuring the respiratory airflow of a subject.”
 - As Petitioner acknowledges, Farrell’s sensor measures “airflow to the patient,” not the patient’s respiratory airflow. Reply at 23.
 - Even if such a sensor *could* measure the patient’s respiratory airflow, Petitioner does not demonstrate that a POSITA would have “adapted” the sensor to perform this function.
 - *In re Giannelli*, 739 F.3d 1375, 1379-80 (Fed. Cir. 2014) (finding that the Board’s conclusion that a function could be performed using the prior art was insufficient, the correct inquiry was whether it would have been obvious to modify the prior art to contain a structure “adapted to” or configured to perform the function).

Sur-Reply at 23-26



Petitioner's Expert, Dr. Sharony, Is Not a POSITA

Dr. Sharony's Declaration (Ex. 1003) Should be Excluded Under FRE 702 Because He is Not a Qualified Expert

- FRE 702 governs the admissibility of expert witness testimony.
- FRE 702 requires that a witness be “qualified in the pertinent art” to testify as an expert.
Paper 35 at 1 (citing *HVLPO2, LLC v. Oxygen Frog, LLC*, 949 F.3d 685, 689 (Fed. Cir. 2020)).
 - FRE 702 states that a witness “is qualified as an expert by knowledge, skill, experience, training, or education.”
- Dr. Sharony has no experience or knowledge in the pertinent art: diagnostic sensor systems for the diagnosis and treatment of sleep-disordered breathing.
- Dr. Sharony's experience is in a different industry, namely wireless communications nothing like Dr. Patil, who was a practicing medical doctor using CPAPs at the time of the invention. Ex. 1003 at ¶ 16 (“data capture devices” include digital imagers (bar code readers) and wireless communication devices).

Reversible Error To Consider Dr. Sharony's Hindsight Analysis Based on Numerous References

- Dr. Sharony's general experience with "data capture devices" (e.g. wireless communications) ***does not*** suffice with experience and skills in diagnostic sensor systems in the medical field and leads to the use of hindsight.
 - *Extreme Networks, Inc. v. Enterasys Networks, Inc.*, 395 F. App'x 709, 715 (Fed. Cir. 2010) ("General experience in a related field may not suffice when experience and skill in specific product design are necessary to resolve patent issues.").
 - *Seaman v. Seacor Marine L.L.C.*, 326 F. App'x 721, 725 (5th Cir. 2009) (affirming the district court's exclusion of an oncologist's testimony concerning the cause of the plaintiff's bladder cancer because the oncologist had no "particular expertise in bladder cancer and its causes").
- Dr. Sharony also has no knowledge or experience in diagnosing or treating sleep-disordered breathing. On cross-examination, he admitted that he has never "treated a patient" and has no "experience diagnosing sleep disorders." Ex. 2016 at 24: 9-25:22.

Paper 35 at 2-6; Sur-Reply at 3-5; POR at 8-11