

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner

Case No. IPR2025-00247
U.S. Patent No. 11,872,029

**DECLARATION OF JASON KIRKNESS, PH.D. IN SUPPORT OF
PETITIONER'S REPLY TO PATENT OWNER RESPONSE**

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I, Jason Kirkness, Ph.D., declare as follows:

I. INTRODUCTION

1. I have been retained as an independent expert consultant in this proceeding regarding U.S. Patent No. 11,872,029 (“the ’029 patent”) (EX1001).

2. My experience and qualifications and my status as an independent expert were summarized in paragraphs 4-30 of the Declaration of Dr. Jason Kirkness in Support of Petition for Inter Partes Review of 11,872,029 (“the ’029 patent”) (EX1003, “Kirkness”) and, further, in my curriculum vitae (CV) (EX1004).

3. I have reviewed PO’s Response (“POR”) and the Declaration of Dr. David A. Borkholder submitted in support (EX2019, “Borkholder”), and provide below my opinions to certain arguments made in those documents.

III. OBVIOUSNESS

A. **Truitt discloses a PAP device with an airflow sensor “adapted for measuring or deriving the respiratory airflow of a subject”**

4. Dr. Borkholder states that Truitt “does not disclose or imply that the system derives respiratory airflow” since “measur[ing] the airflow being provided *to the patient* within the device” “does not provide the necessary airflow sensor data of the subject needed to ‘derive the [subject’s] respiratory airflow.’” Borkholder ¶¶ 47-48 (emphasis in original). I disagree. Truitt is not limited to measuring the provided airflow; it clearly describes both “measuring” and “deriving” a patient’s

respiratory airflow. EX1001, claim 1. Moreover, a POSITA at the time would have well-known how to derive a patient's "respiratory airflow" from the airflow provided to the patient, which is confirmed by the '029 patent itself. *See* discussion ¶6 *infra*.

5. Truitt describes a pressure sensor that "measur[es] the pressure at the patient" "by providing a pressure pick-off port in or near the patient interface device," e.g., a port on the patient's mask assembly. EX1007, 6:2-5. A POSITA would understand that air pressure measured at a "pick-off port" to be indicative of the patient's respiratory airflow. Truitt also details that the airflow pressure that can be "used to estimate the pressure at the patient" (i.e., derive the patient's airflow) "within [the] patient interface device." *Id.*, 6:1-2. The claims themselves also make clear that Truitt's device measures the patient's respiratory airflow. For instance, claims 2 and 12 recite a processing unit that, based on the measured airflow, determines "a flow of the ***breathing*** [sic] [gas] within the conduit, a volume of breathing gas passing through the conduit, or both." *Id.*, claims 2, 12; *see also* EX1007, 7:65-8:2 ("flow/volume sensing assembly" placed in-line between "an end of second conduit 64 and a corresponding end of patient circuit 14" that measures the instantaneous flow of breathing gas going into the patient circuit). "Breathing gas," a mixture of the supplied air and the patient's breath, includes the patient's respiratory airflow.

6. Moreover, a POSITA could have derived a patient's respiratory airflow based on the airflow measured in the Truitt circuit. Thus, in a PAP/CPAP device (including the Truitt device), the breathing tube connected to the CPAP provides a constant (prescribed) air pressure that varies because of the patient's respiration ("respiratory airflow"). An airflow sensor or differential pressure transducer is used to measure and quantify the amount of gas/air flow through the tubing. The difference in the provided air pressure and the measured air pressure is the patient's "respiratory airflow." The calculation of the patient's respiratory airflow is a basic calculation that would have been well-known to a POSITA in the field with knowledge of PAP/CPAP devices.¹ And the method to "derive" respiratory airflow is described in the '029 patent itself. *See* EX1001, 8:12-22 ("The nasal cannula or facemask can be used to measure ***the subject's respiratory airflow***" using a pressure transducer, whereby "[a]irflow can be estimated by measuring nasal or oral airway pressure that decreases during inspiration and increases during expiration. ***Inspiration and expiration produce fluctuations on the pressure transducer's signal that is proportional to airflow***") (emphasis added). Because Truitt's CPAP provides for pressure sensor 22 to measure the pressure of gas passing through

¹ I note that Dr. Borkholder does not appear to have any experience with PAP/CPAP devices, nor in the sleep disorder field in general. *See* Borkholder ¶¶2-16.

patient circuit 14 (*see, e.g.*, Kirkness ¶¶114, 168; EX1007, 5:60-6:10, 6:49-59), a patient's respiratory airflow could easily have been derived from those measurements as explained above.

7. In view of the foregoing, Truitt discloses a PAP device with an airflow sensor "adapted for measuring or deriving the respiratory airflow of a subject." EX1001, claim 1.

B. Truitt in view of Kumar renders obvious "calculating the data of a severity of the sleep disorder symptoms of the subject"

8. Dr. Borkholder contends that Truitt does not disclose "calculating the data of a severity of the sleep disorder symptoms of the subject" as recited in claim 1, for reasons primarily dependent on limiting the phrase to a 'quantitative' measurement. *See* Borkholder ¶¶54-63. I disagree with Dr. Borkholder's reasoning and address his arguments in turn below.

1. The apneas, hypopneas, and snores detected in Truitt represent "data of a severity"

9. Dr. Borkholder alleges that "merely identifying symptoms, like snores, apneas, and hypopneas is not tantamount to calculating 'data of a *severity* of the symptoms of the subject.'" Borkholder ¶55 (emphasis in original). I disagree—detecting an airflow event as a snore, apnea or hypopnea indicates symptom severity. *See, e.g.*, EX1070, 9 (listing respiratory events to be measured and reported during a comprehensive overnight sleep study (polysomnography)). 'Apnea' is defined by

a severity in airflow reduction- it is essentially a near complete drop in the patient's airflow over a period of time, generally defined as a $\geq 90\%$ drop in airflow for ≥ 10 seconds. *See* EX1070, 62. In contrast, a hypopnea is only a partial reduction in airflow, commonly understood to be a $\geq 30\%$ reduction in airflow for ≥ 10 seconds. *Id.*, 63. Snoring is similarly a sleep-time severity measure, as it indicates an airflow limitation due to upper airway narrowing. A PAP/CPAP device measures the change/reduction in airflow, detects whether a snore, apnea, or hypopnea has occurred,² and adjusts the air pressure delivered to the patient in manner that alleviates the level of severity of the airflow obstruction, i.e., the symptom severity, accordingly. Thus, the terms 'apnea,' 'hypopnea,' and 'snore' characterize the severity of a patient's reduction in airflow. As such, a POSITA would understand that measuring/detecting the events represents "calculating the data of a severity of the sleep disorder symptoms." EX1001, claim 1.

2. Truitt discloses "quantitatively" "calculating the data of

² Typically, the quantification of how far the airflow drops from the patient's baseline and/or how obstructed the airflow waveform or snore intensity is, over a short window of time.

severity of the sleep disorder symptoms”

10. Dr. Borkholder states that, in his opinion, “Truitt does not disclose a PAP device with a processor that receives airflow sensor data and calculates data indicative of the severity of the patient’s symptoms” because “monitoring ... snoring, apneas, and hypopneas” is not “quantitatively” “calculating the data of severity of sleep disorder symptoms.” Borkholder ¶¶52-55, 63. I disagree.

11. To begin with, I find nothing in the patent or claims that limits “calculating the data of severity of the sleep disorder symptoms” to a “quantitative” assessment. The claims do not recite “quantitative,” and the patent discloses numerous examples, only a few of which describe a “quantitative” determination of symptom severity. EX1001, claim 1, 4:3-59, 3:41-43.

12. Moreover, I have previously discussed how Truitt does, in fact, disclose “calculating the data of a severity of sleep disorder symptoms” “quantitatively.” See Kirkness ¶¶172-178. (explaining that measuring snores, apneas, and hypopneas “represent[s] data of severity of the patient’s sleep disorder symptoms.”) (citing EX1010,³ 27); *see also* Pet., 17-18. Truitt’s monitoring of a patient’s condition for sleep disorder events like snores, apneas, and hypopneas (i.e., “data of severity”)

³ *Resmed Corp. v. Cleveland Medical Devices, Inc.*, Case PGR2024-00012, Patent Owner’s Preliminary Response, Paper 6 (PTAB Mar. 29, 2024)

requires both measurement of the patient's airflow and a calculation of the number of disordered events, which is "quantitatively" "calculating the data of severity of sleep disorder symptoms." Truitt's utilization of sensor (e.g., airflow) data over time "in a feedback fashion" to adjust PAP/CPAP pressure as needed would have also involved evaluating the number of sleep disorder events (e.g., apneas, hypopneas). *See* EX1070, 9 (listing the "[n]umber of obstructive apneas" and "[n]umber of hypopneas" to determine sleep symptom severity); *see also* Kirkness ¶¶182-183. And as I have already discussed (Kirkness ¶181), producing an index (e.g., an "apnea hypopnea index" (AHI)) to aggregate the number of a patient's disordered sleeping events over time would have been yet another method by which a POSITA would have used Truitt's apneas, hypopneas, and snores to quantify severity symptom data. *See* EX1070, 9 ("Apnea index," "[h]ypopnea index," and "AHI" calculated using the "number" of apneas and hypopneas to assess sleep symptom severity).

3. The "data of a severity of the sleep disorder symptoms of the subject" does not mean "the degree of deviation from the baseline characteristics of a patient without sleep disorder symptoms"

13. Agreeing with the statement of another expert in a different litigation (Dr. Roozbeh Jafari (EX2020)), Dr. Borkholder states that "a POSITA would readily understand that "data of a severity" for the subject's symptoms indicates "the degree of deviation from the baseline characteristics of a patient without sleep disorder

symptoms.” Borkholder ¶53. It is unclear why Dr. Borkholder believes “data of severity” need be defined in this manner, even to support his erroneous claim construction (discussed above); regardless, I disagree with this definition of “data of severity.”⁴ To assess and treat a particular patient’s sleep disorder symptoms, a POSITA would typically use that patient as their own baseline. In other words, a POSITA would compare the non-disordered sleep patterns of the patient (e.g., awake-state breathing patterns) with their disordered sleep breathing patterns to best determine treatment. The “baseline characteristics of a [generic] patient without sleep disorder symptoms” would be irrelevant to any particular patient with their own unique breathing patterns and sleep disorder symptoms. Borkholder ¶53. At any rate, even if “data of a severity” was so limited, it would still encompass Truitt’s detection of sleep disorder symptoms like apneas, hypopneas, and (excessive)

⁴ Dr. Borkholder also alleges, without evidence, that “‘data of a severity’ is a ‘term[] of art’ that has ‘known algorithms’ to ‘determine the level of severity of the patient’s sleep breathing disorder symptoms associated with those events.’” Borkholder ¶53. To my knowledge, “data of a severity” is not a term of art. As a sleep disorder specialist who has worked in the field for over 27 years, I have never encountered the term, nor a POSITA who used it. Relatedly, there is not, to my knowledge, any “known algorithm” associated with “data of a severity.”

snores, because the number of events would be higher in a patient being treated (e.g., sleep apnea patients) compared to someone “without sleep disorder symptoms.” *Id.* Accordingly, Dr. Borkholder's definition is incorrect and irrelevant.

4. Truitt discloses an “index based in whole or in part on” “the data of a severity of the sleep disorder symptoms of the subject” and/or “the data of usage of the PAP device”

14. Dr. Borkholder also states that Truitt “does not disclose calculating indices like AHI, which represent the severity of the patient's symptoms” because Truitt's CPAP uses “auto-titration” “which responds immediately to changes in pressure” so “cannot be based on any index calculated over time.” Borkholder ¶¶59-60. I disagree. Dr. Borkholder's characterization of Truitt's device is inaccurate, and whether Truitt calculates AHI is irrelevant to the claims.

15. To begin with, I note that Truitt's device is not limited to operating in a “CPAP, bi-level, or auto-titration type of pressure support mode”; instead, the “sensing assembly can be used in conjunction with any type of pressure support or ventilatory system where the flow and/or volume of fluid is to be measured.” EX1007, 8:18-24.

16. But in the event Truitt's CPAP is used in a bi-level or auto-titration mode (e.g., “real time” mode), a POSITA would have still utilized Truitt's severity and usage device data to calculate an index. Real time intervention does not preclude the use of an index calculated over time. A controller can compute a running severity

indicator (e.g., a rolling event burden or rolling flow-limitation severity) that updates continuously and still drives immediate changes in therapy.

17. I have explained that because Truitt's CPAP uses data signals from the pressure/flow sensors to adjust the CPAP system to treat/prevent sleep disorder symptoms of varying severity, a POSITA would have understood that in addition to auto-titration in real time, the overall effectiveness of the CPAP therapy would have been determined based on data of symptom severity and/or CPAP usage. Kirkness ¶¶179-80. As I detailed, such a determination would have represented an “index based in whole or in part” on that data, including, for instance, the “apnea hypopnea index” (AHI), which is calculated based on the number of apneas and hypopneas the CPAP detects. *Id.*, ¶¶179-181. Thus, a POSITA would have understood that the sensor data would have been used **both** to change pressure in response to a patient's severity symptoms in real time and to calculate an index aggregating the data over time. Such an index would have been used by a POSITA to change, for example, a patient's initial prescription pressure to prevent disordered breathing symptoms.

18. Dr. Borkholder complains that Truitt “does not disclose calculating indices like AHI” (Borkholder ¶59), but, as I discussed previously and above (*see* ¶¶16-17 *supra*), a POSITA would have used the PAP/CPAP data to do so. I note that nothing in the '029 patent defines an “index,” explains an exclusive method for its calculation, or explicitly discloses AHI.

19. Dr. Borkholder also states that even if “a POSITA *could have* calculated the patient’s AHI using data generated at Truitt’s CPAP machine [it] does not establish that a POSITA *would have* been motivated to do so” because it would not “provide any known benefit” “in the context of Truitt’s real-time treatment device.” Borkholder ¶60 (emphasis in original). For the reasons I discussed above (e.g., determining device effectiveness, changing overall prescription pressure) (*see* ¶¶16-17 *supra*), I disagree that a POSITA would not have been motivated to use an index with an auto-titrating PAP/CPAP device.

5. Truitt’s PAP system is encompassed by the claims

20. Dr. Borkholder alleges that PAP machines such as those disclosed in Truitt were “distinguished” in the ’029 patent specification. Borkholder ¶¶38, 56-57. I disagree. As I stated previously, “Truitt’s PAP system operates in a way that is substantially similar to that of the ’029 patent.” Kirkness ¶182; *see also* Pet., 15. I do not find anywhere in the patent where it “distinguishe[s]” a device like the PAP disclosed in Truitt. Although Dr. Borkholder states that PAP devices like Truitt’s were “expensive and largely ineffective” and “basic” (Borkholder ¶56), that is untrue. The Truitt PAP was designed to decrease the “complexity and cost of the device” while “allow[ing] for a relatively accurate flow or volume measurement of the gas,” solving the problems of prior devices that Truitt *similarly* distinguishes his invention from. EX1007, 3:21-23; 42-45. Moreover, the Truitt PAP device was not

merely a “basic adjustable device.” Borkholder ¶56. Truitt repeatedly describes sensor-driven control and patient-condition monitoring that went beyond basic adjustability. *See, e.g.*, EX1007; 5:60-6:63.

21. Regardless, I find that the claims of the '029 patent, which broadly recite the “standard components of a CPAP device” encompass the PAP device disclosed in Truitt. *See* Kirkness ¶¶218-225; Pet., 27-29.

C. A POSITA would have been motivated to combine Truitt's PAP with Kumar's networked telemedicine system

22. Dr. Borkholder disparages a number of the reasons that a POSITA at the time would have been motivated to combine Truitt's CPAP with Kumar's networking system for the remote treatment and monitoring of sleep disordered events. *See* Borkholder ¶¶65-74. I disagree with Dr. Borkholder's assertions, which I address in turn below.

23. For one, Dr. Borkholder categorically states that “at-home CPAP therapy is prescribed in situations where the patient does not require live monitoring.” Borkholder ¶67. Not only is this statement untrue, it also does not address the knowledge of a POSITA presented with the possibility of in-home sleep monitoring in view of networking advances. A POSITA would have understood and recognized the advantages of remotely monitoring and treating a patient in their own home as opposed to in a sleep laboratory or hospital. A POSITA would have well-

known that a person would not sleep the same in a hospital/lab as they would in their regular sleeping location in their home, as the lab or hospital setting was unfamiliar, uncomfortable, and prone to disruptions not present in their normal sleeping environment. The foregoing resulted in sleep data that was likely nonrepresentative of a patient's actual sleep disorder symptoms. *See* Kirkness ¶¶143-145. It is ludicrous to suggest that a POSITA would not have been excited by the possibility of addressing the biggest limitations of monitoring sleep in the hospital or laboratory through the creation of a networked PAP/CPAP that would allow a patient to be monitored and treated in their home, including in real-time.

24. And contrary to Dr. Borkholder's suggestion (*see* Borkholder ¶¶65, 67), patient monitoring and treatment using conventional, non-networked PAP devices in-home did not solve all the problems of patient monitoring and treatment in a hospital or laboratory setting. Dr. Borkholder opines that "neither Petitioner nor its experts identify any issue with the monitoring methods known at the time." Borkholder ¶67. This is patently untrue. I identified numerous pieces of literature detailing how those in the sleep therapy field had been looking for solutions to in-lab and conventional in-home PAP usage for decades and had been advancing those solutions with the advancement of technology. *See* Kirkness ¶¶93-100. For instance, at-home CPAP machines available at the time were inefficient for patient monitoring (e.g., data collection with "USB connection or SD Card") (Borkholder ¶66),

inconvenient for further patient treatment (e.g., lengthy wait times for appointments), time-consuming for patient therapy (e.g., requirement for patient to travel to the doctor for assessment and adjustments, limited patient appointments and limited number of patients able to be treated), and, further, did not allow for monitoring or therapy in real-time. *See id.*; 146-149.

25. Dr. Borkholder also contends that a Truitt-Kumar CPAP system would not have increased patient accessibility “because the only way to increase the access to CPAP therapy is by making home sleep testing more available and getting more patients diagnosed with sleep apnea and prescribed a CPAP,” but that “a CPAP would not be used in the diagnosis of patents [sic] for sleep apnea.” Borkholder ¶¶70-71. I disagree. A POSITA would use a CPAP in the further diagnosis of prospective patients to detect and modify any sleep disorder events and would do so based on that person’s *probability* of having sleep apnea. As with the diagnosis of any disease or disorder, a POSITA would have been able to determine whether a person had a high probability of sleep apnea by, for example, taking that person’s history of clinical features of sleep apnea like persistent day time fatigue and sleepiness, obesity, age, and other observed events by, for instance, family (e.g., loud snoring, pauses in breathing). These are the very characteristics that would have brought a prospective patient to a clinician in the first instance. The presence of these clinical features would have indicated a possible sleep disorder, and a POSITA

likely would have deployed an in-home CPAP for the patient for further monitoring and eventual clinical diagnosis.

26. Dr. Borkholder also attempts to discredit Kumar's sleep apnea related disclosures, stating that "its application regarding sleep apnea is focused upon replacing the in-lab monitoring of sleep apnea diagnostic tests," using "polysomnography and oximetry" and "not [on] sleep apnea therapies." Borkholder ¶68. For the reasons I have described above (*see* ¶¶23-25 *supra*), a POSITA of just ordinary inventiveness would have envisioned employing a networked PAP, like Truitt's CPAP, for the full panoply of sleep disorder monitoring and treatment, and not just the uses discussed in Kumar.⁵

⁵ Dr. Borkholder also states that the "Petition does not argue that the inclusion of polysomnography and oximetry is necessary to complete their [sic] combination," which would have required additional "sensors" and "wireless data communication techniques between CPAPs and a distributed computing system." Borkholder ¶69. I see nothing in the claims that requires patient monitoring through either polysomnography or oximetry and, moreover, disagree that any particular "wireless data communication techniques" or "distributed computing systems" would have been necessary to do so.

D. Truitt and Kumar in further view of Mumford render obvious calculating “data of usage of the PAP device by the subject,” “data of severity of sleep disorder symptoms of the subject,” and/or “the index” of treatment efficacy data (together “therapy efficacy data”)

27. Dr. Borkholder states unequivocally that to implement Mumford's therapy efficacy algorithm, a POSITA “would have [had] to include a combination of electrodes and pressure transducers integrated into the mask.” Borkholder ¶98. But implementation of Mumford's sleep efficacy algorithm does not require the use of electrode sensors. In disclosing several sensors for use with its algorithm, Mumford clearly illustrates this point. *See* EX1009, 12:2-46. In fact, Dr. Borkholder agrees that Mumford does so. *See* Borkholder ¶94 (describing in Mumford a pressure transducer used in combination with a “pulse oximeter or position sensor” or “other sensors”).

28. Dr. Borkholder's further suggestion that electrode sensors would not be incorporated into Truitt's CPAP because it is “only equipped with an internal airflow sensor” (Borkholder ¶91), is incorrect for at least a couple of reasons. First, Truitt discloses the use of more than one sensor in its CPAP system. *See* EX1007, 5:60-67, 6:1-10 (pressure sensor 22); *id.*, 6:39-41 (pressure sensor 32); *id.*, 6:43-46 (flow sensor 32'); *id.*, 6:53-58 (in bi-level operation mode, pressure sensor 22 and pressure sensor 32 (in sensing assembly 72)); *id.*, 7:39-42, 7:49-54 (pressure sensor or flow sensor); 6:60-63 (any “other sensors”). Second, electric sensing elements were, in

fact, incorporated into Truitt's CPAP system at ports 74 and 76, and these elements are equivalent to Mumford's electrodes. *See, e.g.*, EX1007, 7:39-43 ("a pressure sensor or sidestream flow sensor is connected to ports **74** and **76**" with the "sensors [] [preferably] mounted ***on a circuit board***") (emphasis added and in original); *see also* Figs. 4 and 5 (showing ports 74 and 75). Contrary to Dr. Borkholder's assertion (Borkholder ¶¶91-93), then, Truitt's CPAP is not solely a mechanical device that determines air flow with just one flow sensor. Thus, even if Mumford's sleep efficacy algorithm required electrode sensing elements (which it does not), it could have still been implemented with Truitt's CPAP to determine therapy efficacy data.

IV. CONCLUSION

29. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: January 14, 2026

By: 

Jason Kirkness