

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

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

PATENT OWNER'S SUR-REPLY

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I. INTRODUCTION

The Reply confirms the Petition's central problem: Petitioner never shows where the prior art teaches (1) an airflow sensor "adapted for measuring or deriving the respiratory airflow of a subject" while undergoing therapy; (2) a second processor that "calculat[es] the data of a severity" (and/or an index based in whole or in part on severity/usage) from that airflow sensor data; (3) for claims 8 and 11, that the PAP device's second processor applies the specified signal-processing techniques to the airflow sensor data; and (4) for claims 9 and 13, a remote internet site "adapted to retransmit" the claimed data/index to the cell phone. Ex. 1001 ("029 Patent") at Claims 1, 8, 11, 9, 13.

The Petition maps these elements by (i) conflating symptom detection (*e.g.*, snore/apnea/hypopnea detection) with calculating a level of severity of the subject's symptoms; (ii) invoking server-side analytics in Kumar to satisfy PAP device-side processing limits without establishing that a POSITA would have been motivated to perform those analytics on the PAP device; and (iii) misreading Kumar's storage/replay functionality as being relevant the claims' server to phone retransmission—all without identifying where the art actually discloses those features as claimed. Pet. at 17-21, 28-31, 48-52.

The Reply merely repeats these same misplaced arguments, so the Board should confirm the Challenged Claims.

II. THE CHALLENGED CLAIMS ARE PATENTABLE

A. Truitt Does Not Teach Measuring or Deriving the Patient's Respiratory Airflow for the Claim-Required Calculations

Claim 1 demands an airflow sensor “adapted for measuring or deriving the respiratory airflow of a subject” while using the PAP device. '029 Patent at Claim

1. Truitt's conduit measurements do not measure the subject's respiratory airflow, and Truitt does not disclose these assessments are made. Pet. at 28-29; Reply §II.A. Truitt measures system flow in the PAP's internal tortuous path and uses it for device operation/monitoring—not for computing a patient respiratory airflow signal used by the PAP processor to calculate severity. Ex. 1007 (“Truitt”) at 1:11-22; *id.* at 2:1-11.

Although Truitt discloses that pressure could be estimated at or near the patient (e.g., at a pick-off port), ResMed does not identify where Truitt discloses converting such data into a patient airflow signal and using it in an on-device calculation of the severity of the patient's symptoms. Truitt at 6:1-10 (pressure estimate at or near the patient); *id.* at 6:46-7:4 (flow/volume computation across ports 74/76); *see also* Reply at 1-2. By contrast, the '029 Patent itself describes ways for a POSITA to derive airflow at the patient (e.g., pneumotachograph; nasal/oral pressure transduction), underscoring that derivation differs from Truitt's conduit computations and that the claim requires using such derived airflow for a severity calculation on the device. '029 Patent at 7:43-59; *id.* at 8:10-28.

Furthermore, Petitioner's claim of Truitt measuring or deriving a patient's respiratory airflow "at the patient" relies upon additional sensors, which ResMed failed to identify in the Petition. *See* Reply at 1-2 (citing to Ex. 1071 at ¶¶4-7); Ex. 2036 ("Kirkness Tr.") at 15:4-21:24 (confirming that he has "not provided an opinion on the other sensors" referred to in Truitt). The Petition only identifies Truitt's flow sensing system 72 as the airflow sensor that is responsible for measuring or deriving the respiratory airflow of the patient, not an additional pressure sensor associated with the "pressure pick-off port in or near the patient interface device:"

Truitt also discloses the PAP device includes flow sensing system 72 within housing 58 (*airflow sensor being any type of sensor internal to the enclosure of the PAP device*), as shown in Figure 3, providing a signal to controller 38 for calculating gas flow and/or volume passing through conduit 56 and controlling operations of the PAP device, including operations of motor 54 and/or valve 40 that control air flow and pressure provided to the patient (*air flow sensor adapted for measuring or deriving the respiratory airflow of a subject while using the PAP device and outputting airflow sensor data*).

Pet. at 28 (citing Truitt at 6:1-5); *see also id.* at 27 (annotated image of Truitt, Fig. 3 showing the "airflow sensor" as component 72 and not connected to the pick-off point near the mask). In an IPR, the petition guides the life of the IPR by describing "each claim challenged" and "the grounds on which the challenge to each claim is

based”—and here, Petitioner specifically chose to rely only on the sensors in the flow sensing system 72 and no others. *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 364 (2018) (citation omitted); *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1335-36 (Fed. Cir. 2020) (citation omitted).

Therefore, Petitioner fails to show that Truitt invalidates this claim element.

**B. The “Data of a Severity of the Sleep Disorder Symptoms”
Requires A Calculation Based on Symptom Data, Not Mere
Identification of Symptoms**

Petitioner repeatedly treats mere symptom detection (e.g., identification of individual snores, apneas, and hypopneas) as if it were the “calculating [of] the data of a severity” required by Claim 1. Pet. at 17-21, 28-29 (equating Truitt’s event detection/feedback to severity calculation); Reply §II.B.1. That overbroad interpretation misreads the plain language of the claims.

As recited in Independent Claim 1, the PAP device’s processor must calculate “the data of a severity of the sleep disorder symptoms of the subject,” not just identify sleep disorder symptoms. ’029 Patent at Claim 1. The specification likewise teaches processing of sensor signals, including airflow, to determine the level of severity of a subject’s disorder or symptoms. ’029 Patent at 3:4-20 (integrated diagnosis/treatment device); *id.* at 8:10-28 (deriving/processing signals, including airflow, to determine severity and adjust therapy). Thus, the claim

requires a calculation of the severity of the subject's symptoms, not mere detection of those symptoms. POR at 14-21.

Truitt's controller, by contrast, detects symptoms and reacts (e.g., increases pressure) in a closed feedback loop in real time. Truitt at 2:57-3:11 (detect snore/apnea/hypopnea and control pressure); *id.* at 6:11-17. Truitt does not disclose calculating the *severity* of any sleep disorder symptoms, let alone using such a calculated value to adjust pressure in the PAP device. Petitioner points to Truitt's auto-titration and bi-level control, which are react in real-time to detect breathing disorder events and do not involve any calculation of the severity of the subject's symptoms. Pet. at 18, 20-21; POR at 18-19; Reply §II.B.

Finally, Truitt contradicts ResMed's unsubstantiated allegation that "[a] POSITA would have understood Truitt's PAP device to calculate the quantity (e.g., the number of) snores and apnea." Reply at 8. As just discussed, Truitt discloses reacting in real-time to individual breathing events rather than calculating or adjusting PAP therapy in response to data indicating the severity of the subject's symptoms. Truitt at 2:57-3:11 (detect snore/apnea/hypopnea and control pressure); *id.* at 6:11-17. If Truitt's system detects an apnea event, it will increase the pressure delivered to the subject in real-time without ever calculating the number of events over time. *Id.* ResMed's attempt to bridge the gap between the prior art and the claimed invention with nothing more than its expert's conclusory testimony must be

rejected. *Xerox Corp. v. Bytemark, Inc.*, No. IPR2022-00624, Paper 12 at 5 (Vidal, Feb. 10, 2023).

C. Claims 8 and 11: The Petition Does Not Place the Specified Signal-Processing on the PAP Device's Second Processor Operating on Airflow Sensor Data

Claims 8 and 11 require that “the airflow sensor data is processed by the second processor, at least in part using” one or more specified techniques (e.g., standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis, and a wavelet analysis). '029 Patent at Claims 8 and 11. Petitioner cites Kumar for this limitation, but the calculations in question are not alleged to be performed with PAP device's processor using the airflow sensor data, as claimed. Pet. at 48-50 (citing Ex. 1008 (“Kumar”) at ¶ [0075]); Reply §II.D.

Kumar's “FFT/DFT” analysis is performed in a server-side data interpretation and analysis module, not on the PAP device. Kumar at ¶ [0075] (“The data interpretation and analysis module 114 is used to interpret the data Stream from the client-side device, perform mathematical analysis on the data using FFT, DFT, etc., and generate statistics.”); *id.* at Fig. 1A. The Petition and Reply identify no disclosure that relocates these techniques into the PAP device to operate on the airflow signal for the claimed calculation, because they cannot. Pet. at 48-50; Reply

§II.D. Instead, as Kumar shows, prior to the '029 Patent, such calculations were not conducted by monitoring devices, let alone PAP devices. Kumar at ¶ [0075].

Therefore, Petitioner fails to show that Truitt and Kumar meet these claims.

D. Claims 9 and 13: The Petition Does Not Disclose a Remote Internet Site “Adapted to Retransmit” to the Cell Phone

Claims 9 and 13 require a remote internet site “adapted to retransmit to the first radio frequency wireless transceiver on the cell phone” the claimed data/index. Petitioner argues that Kumar contemplates storing, later access, and replay, and suggests “retransmit[ting]” would have been obvious. Pet. at 50-52; Reply §II.E. But Kumar does not disclose a server-initiated retransmission back to the patient’s phone (the very client that uplinked the data). Instead, it describes central storage and the ability to access or replay. Kumar at ¶¶ [0016]-[0017], [0077].

The claim elements use of “in whole or in part” does not provide the missing directionality; nor do the Petition/Reply articulate a contemporaneous reason to implement a redundant return path to the phone given Kumar’s client–server architecture. Pet. at 50-52; Reply at 19-20. Kumar shows that real-time alerts may be forwarded to the patient when in an emergency, but Kumar does not disclose that any data received by the server is or would be sent back to the patient. Kumar at ¶ [0016]. There is no argument or disclosure that sending an alert to an undisclosed device equates retransmitting data of severity, data of usage, and/or an index to the patient’s cell phone.

Therefore, Petitioner fails to show that Truitt and Kumar meet these claims.

E. Petitioner's Mumford Add-On (Grounds 4–6) Still Does Not Cure the Defects

Mumford does not cure the deficiencies of Truitt and Kumar. Although Petitioner argues that a POSITA would have been motivated to perform Mumford's algorithm in the context of Truitt's PAP therapy device, Mumford's algorithm requires mask-integrated, multi-channel sensors that incorporate electrodes to assess sleep stage and arousals for computing a test score to control therapy. Ex. 1009 ("Mumford") at Abstract, 7:34-57, 11:44-48, 16:8-13. None of these sensors, which are necessary for Mumford's algorithm are internal airflow sensors, and ResMed has not demonstrated that a POSITA would have had a reasonable expectation of success implementing Mumford's algorithm with Truitt's sensor.

Petitioner is explicit that it is incorporating Mumford's sleep efficacy algorithm into the Truitt/Kumar combination and nothing else. Reply at 20-21; Pet. at 64. However, in Reply, Petitioner argues that the inputs used in the algorithm and its determinations are "not for the detection of sleep disordered events." Reply at 21. This assertion is flatly inconsistent with Mumford's disclosure, which uses an array of sensors other than an internal airflow sensor to provide input to the very algorithm that ResMed relies on. Mumford at 7:37-57 ("The sleep efficacy algorithm 36 monitors the quality of sleep for the wearer 18."); *id.* at 14:29-31 ("The sleep efficacy algorithm 26 may employ a frontal staging algorithm to calculate the

sleep profile of the CPAP wearer 18.”); *id.* at 15:39-16:13; *id.* at Claim 15 (“The mask assembly of claim 14, wherein the remote processing unit includes a sleep efficacy algorithm for processing the physiological information and generating a sleep information profile for the wearer.”). Indeed, Petitioner admits that additional sensors are needed by Mumford to identify apneas. Reply at 21-22.

Petitioner identifies no disclosure in Mumford where its sleep efficacy algorithm is reliant upon an internal airflow signal, nor does the Petition describe incorporating any additional sensors, from Mumford or any other reference. Even Petitioner's expert states that he would need additional sensor data to make the claimed severity calculation, but what those sensors are and how they are incorporated in the combinations is never described or discussed. Ex. 2036 at 32:16-34:4.

Therefore, Petitioner fails to show that the combination of Truitt, Kumar, and Mumford meet any of the claims.

F. There is No Motivation to Combine Petitioner's References

Petitioner invokes home representativeness, convenience/efficiency, access expansion, and IoT/mobile trends as alleged motivations to combine the references. Pet. at 7-11, 64, 66; Reply §II.C and §III.B. These generic motivations do not explain why a POSITA, at the time, would (1) derive patient respiratory airflow in the PAP device; (2) perform an on-device severity calculation from that airflow

using the specified transforms; and (3) build a server to cell phone retransmission pathway. Furthermore, Petitioner's motivations create a problem where one does not exist. *Motorola Mobility LLC v. Largan Precision Co.*, No. 2024-1414, 2025 WL 2642194, at *1, *3 (Fed. Cir. Sept. 15, 2025) (nonprecedential) (affirming finding in an IPR that claims to an "optical lens assembly comprising five lens elements" were not proven obvious over a prior art combination since "the mere fact that a combination is possible does not establish that a skilled artisan would be motivated to pursue it").

Dr. Kirkness' testimony strikes at the Petition's motivations to combine regarding the need to obtain more representative data from the patients home and physician convenience. Pet. at 7-8; POR at 22-23. Dr. Kirkness confirmed that CPAPs were used by patients at home and that physicians were obtaining the data from them since the 90's without issue. Ex. 2036 at 38:5-40:9.

The Petition's argument that motivation comes from increasing health access to more people also fall by Dr. Kirkness' words. Pet. at 9. Contrary to the Petition's motivation, Dr. Kirkness confirmed that in order to receive access to CPAP therapy, a patient would need to first receive a physician recommendation for a diagnostic sleep test and then upon completion of that test, CPAP treatment may be prescribed. Kirkness Tr. at 40:20-41:17. Thus, "the only way to increase access to CPAP

therapy is by way of a home sleep test” not incorporating a CPAP into a network. POR at 25-26.

Finally, neither “advances in mobile computing and wireless communications” nor the “general [IoT] market trend” provide motivation to combine the references to meet the Challenged Claims. Pet. at 9-10; POR at 26-27. Truitt provides no disclosure showing how data could be sent from its device and Kumar describes a server-centric diagnostic system (with FFT/DFT done at the server), not a PAP device that internalizes the analytics and pushes a return link to the phone. Kumar at ¶¶ [0007], [0010], [0075].

1. The Petition’s “Could Have” Does Not Establish “Would Have” With Expectation of Success

The Petition and Reply assert that a POSITA could calculate AHI, could retransmit, could apply the claimed signal processing techniques, and could integrate Mumford. Pet. at 18-21, 48-52, 64-71; Reply at 10-12, 16-22. But obviousness requires showing why a POSITA at the time would have implemented these claim-specific choices—including the on-PAP device calculation of severity from patient airflow using the specified transforms, and the server to cell phone retransmission—with a reasonable expectation of success. *Intell. Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (instructing that having a reasonable expectation of success, i.e., that one of skill in the art would have the capability to make the combination, is not sufficient to show obviousness).

That a POSITA could have combined the references cited here does not imply that a POSITA would have been motivated to make combine the specific teachings of those references to reach the claimed invention. *See Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) (“The obviousness inquiry does not merely ask whether a skilled artisan could combine the references, but instead asks whether ‘they would have been motivated to do so.’”). Truitt’s tortuous-path flow measurement was meant to eliminate the need for the type of dedicated flow elements (e.g., mask-integrated sensors) needed to perform Mumford algorithm, and Kumar’s architecture does not supply the claimed retransmission nor relocate the calculative analytics to the PAP device. Truitt at 3:39-46, 5:1-6:62; Kumar at ¶¶ [0014]-[0017], [0072]-[0075]; Mumford at 7:34-10:65. Thus, just because the references could possibly be integrated with one another to some successful degree does not show that the Petition’s generic motivations would lead a POSITA to the claimed invention.

III. CONCLUSION

For all of these reasons, Patent Owner accordingly requests that the Board find the Challenged Claims of the '029 Patent patentable.

Respectfully submitted,

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/James Hannah/

James Hannah (Reg. No. 56,369)
HERBERT SMITH FREEHILLS
KRAMER (US) LLP
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065
Telephone: (650) 752-1700
Facsimile: (650) 752-1800
james.hannah@hsfkramer.com

Jeffrey H. Price (Reg. No. 69,141)
Jenna Fuller (Reg. No. 74,212)
Jeffrey Eng (Reg. No. 63,189)
HERBERT SMITH FREEHILLS
KRAMER (US) LLP
1177 Avenue of the Americas
New York, NY 10036
Telephone: (212) 715-9100
Facsimile: (212) 715-8000
jeffrey.price@hsfkramer.com
jenna.fuller@hsfkramer.com
jeffrey.eng@hsfkramer.com

(Case No. IPR2025-000247)

Attorneys for Patent Owner
Cleveland Medical Devices, Inc.

CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

The undersigned hereby certifies that the portions of the above-captioned **PATENT OWNER'S SUR-REPLY** specified in 37 C.F.R. § 42.24 has 2,769 words in compliance with the 5,600 word limit set forth in 37 C.F.R. § 42.24(c)(4). This word count was prepared using the Microsoft Word word-processing system used to prepare this paper.

Dated: February 25, 2026

/James Hannah/
James Hannah (Reg. No. 56,369)
HERBERT SMITH FREEHILLS
KRAMER (US) LLP
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065
Telephone: (650) 752-1700
Facsimile: (650) 752-1800
james.hannah@hsfkramer.com

Jeffrey H. Price (Reg. No. 69,141)
Jenna Fuller (Reg. No. 74,212)
Jeffrey Eng (Reg. No. 63,189)
HERBERT SMITH FREEHILLS
KRAMER (US) LLP
1177 Avenue of the Americas
New York, NY 10036
Telephone: (212) 715-9100
Facsimile: (212) 715-8000
jeffrey.price@hsfkramer.com
jenna.fuller@hsfkramer.com
jeffrey.eng@hsfkramer.com

(Case No. IPR2025-000247)

Attorneys for Patent Owner
Cleveland Medical Devices, Inc.

CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. § 42.6(e), and pursuant to agreement by the parties that filing with the Board through the P-TACTS constitutes electronic service if Patent Owner provides the foregoing document (excluding exhibits), that service was made on the Petitioner as detailed below.

<i>Date of service</i>	February 25, 2026
<i>Manner of service</i>	Electronic Filing and Electronic Mail (PH-ResMed-CleveMed@paulhastings.com)
<i>Documents served</i>	PATENT OWNER'S SUR-REPLY
<i>Persons Served</i>	Paul Hastings LLP Lisa K. Nguyen David M. Tennant Eric E. Lancaster Grace Wang Howard Herr Kamilah Alexander Rachel Wu Hankinson

/James Hannah/
James Hannah
Registration No. 56,369
Lead Counsel for Patent Owner