

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 PRELIMINARY RESPONSE
UNDER 37 C.F.R. § 42.107**

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PATENT OWNER'S EXHIBIT LIST

Exhibit	Description
2001	Response to Non-Final Rejection from File History of U.S. Patent No. 12,213,775, filed August 28, 2024
2002	Non-Final Rejection from File History of U.S. Patent No. 12,213,775, filed May 30, 2024
2003	Notice of Allowance from File History of U.S. Patent No. 12,213,775, filed September 24, 2024
2004	Excerpts of Plaintiff and Counterclaim Defendant ResMed Corp.'s Initial Invalidity and Unenforceability Contentions cover pleading, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-02221-BMB (N.D. Ohio), served on July 15, 2024
2005	Intentionally Omitted
2006	Excerpts of Plaintiff ResMed Corp.'s Response and Affirmative Defenses to Defendant's Second Amended Counterclaims for Patent Infringement, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 75 (N.D. Ohio), filed on April 25, 2024
2007	Excerpts of Declaration of James Hannah in Support of Defendant CleveMed's Opposition to Plaintiff ResMed's Motion for Temporary Stay Pending Mediation, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-02221-BMB, Dkt. No. 87-1 (N.D. Ohio), filed on August 21, 2024
2008	Excerpts of Declaration of Lisa Kobialka in Support of Defendant CleveMed's Opposition to Plaintiff ResMed's Motion to Stay, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-02221-BMB, Dkt. No. 100-1 (N.D. Ohio), filed on January 24, 2025
2009	Excerpts of ResMed Corp.'s Reply in Support of its Motion to Stay, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-02221-BMB, Dkt. No. 101 (N.D. Ohio), filed on January 31, 2025

Exhibit	Description
2010	Excerpts of Defendant Cleveland Medical Devices, Inc.'s Memorandum in Support of its Motion to Dismiss Plaintiff's Complaint for Declaratory Judgment of Noninfringement, or to the Extent Not Granted, to Transfer, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-00500-TWR-JLB, Dkt. No. 10-1 (S.D. Cal.), filed on June 5, 2023
2011	<i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 87-5, Declaration of Hani Kayyali in Support of Patent Owner's Opposition to Motion to Stay Pending Mediation (N.D. Ohio), filed on August 21, 2024
2012	Excerpts of Petitioner's parent company's (ResMed) Q4 FY2024 Earnings call, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 87-6 (N.D. Ohio), filed on August 21, 2024
2013	Excerpts of Defendants' Initial Validity and Enforceability Contentions Pursuant to L.P.R. 3.7, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB (N.D. Ohio), served on August 5, 2024
2014	Case Management Order, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 54 (N.D. Ohio), filed on January 10, 2024
2015	Excerpts of Defendant ResMed Inc.'s Third Amended Initial Invalidity Contentions cover pleading from <i>Cleveland Med. Devices, Inc. v. ResMed, Inc.</i> , No. 22-cv-00794-GBW-CJB (D. Del.), served on November 10, 2023
2016	Excerpts of Non-Final Office Action from the File History of U.S. Patent 11,602,284 filed on September 13, 2022
2017	National Library of Medicine, National Center for Biotechnology Information webpage –Physiological Feedback, printed on May 8, 2025
2018	Declaration of Jeffrey H. Price

I. INTRODUCTION

The '029 Patent is patentable on the merits because the prior art of record does not disclose key aspects of the claimed invention, and Petitioner's experts do not credibly fill those gaps.

With respect to Grounds 1-3, Petitioner fails to demonstrate that Truitt and Kumar disclose a Positive Air Pressure ("PAP") device that sends any patient data to a cell phone *and* to a remote internet site via a radio frequency wireless transceiver. In Kumar's system, patient data is always routed through the computing device that it likens to the claimed cell phone, so the PAP device does not communicate with any remote internet site via a wireless transceiver.

Grounds 1-3 are also meritless because Truitt does not disclose an internal airflow sensor that measures a patient's respiratory airflow, as claimed. At best, Truitt's sensor measures the airflow provided *to the patient*. Nor does Truitt's PAP device calculate any "data of a severity of the sleep disorder symptoms of the subject." Indeed, a POSITA would recognize that if such data were to be calculated anywhere, given the combined teachings of Truitt and Kumar, it would be calculated at Kumar's computing device (the alleged cell phone), which is configured to receive and analyze raw data from medical devices.

In an attempt to cure Truitt's deficiencies with respect to calculating severity data, Petitioner proposes modifying Truitt to perform Mumford's sleep efficacy

algorithm in Grounds 4-6. However, Petitioner fails to show that Mumford's algorithm would be functional in Truitt's system without the existence of the multiplicity of sensors and signals that are fed into Mumford's algorithm. Petitioner's oversimplified reading of Mumford's algorithm fails to demonstrate that a POSITA would have had a reasonable expectation of success when only receiving information from a single airflow sensor.

For these reasons, and those discussed in detail below, Patent Owner respectfully requests that the Board deny institution of *inter partes* review.

II. OVERVIEW OF THE '029 PATENT AND PRIOR ART

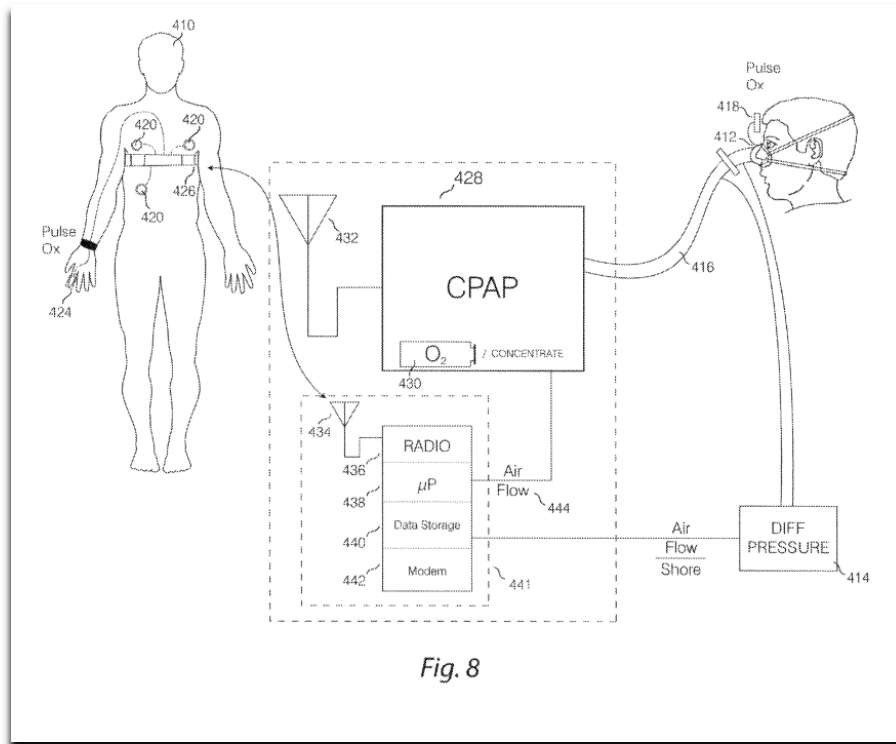
A. The '029 Patent (Ex. 1001)

The '029 Patent relates to a novel integrated sleep diagnosis and treatment device for patients suffering from sleep apnea. '029 Patent at Abstract, 1:31-35. The device (1) analyzes the patient's breathing metrics, including parameters related to a patient's breath, such as respiratory airflow and effort, and blood oxygenation levels, and (2) adjusts the treatment based, at least in part, on this analysis. *Id.* at 2:49-56, 3:21-56.

The claimed invention uses a positive airway pressure ("PAP") device with internal airflow sensors that detect the patient's respiratory airflow data. *Id.* at 7:36-8:41. The readings from airflow sensors are collected and processed by the PAP's device processor(s) to indicate the data of severity of a patient's sleep disorder

symptoms (*e.g.*, respiratory effort, respiration rate, respiratory airflow), that is used along with the usage of the PAP device to generate an index (*e.g.*, respiratory disturbance index (RDI), apnea-hypopnea-index (AHI)), related to the patient's treatment and the treatment's efficacy, which are transferred to a remote internet site and a cell phone for display. *See id.* at Claim 1. The PAP device may distinguish between, and calculate the severity of, obstructive and central apneas and then be adjusted remotely based on the data sent to the remote internet site. *See id.* at Claims 12, 18.

An exemplary embodiment of the PAP device, shown below, includes a pressure generator, a blower with an air output, a mask or nasal cannula, a flow sensor, and a pressure sensor, with a microprocessor 438 for processing the data or signals from the flow sensor to determine the data of severity of the patient's sleep disorder symptoms and/or index related to the treatment's efficacy:



'029 Patent at FIG. 8, 23:31-54. The calculated information is used to control the pressure or flow of gas provided to the subject, initiate a medicinal intervention, monitor the condition of the subject, and/or monitor the usage of the pressure support device. *Id.* at 23:20-30, Claims 6, 12, 14, 18.

B. Truitt (Ex. 1007)

Truitt discloses a flow assembly for a conventional PAP device with no disclosed ability to integrate the PAP device with other devices. The Truitt invention “pertains to a technique for measuring gas flow and/or volume in a pressure support system” so that its signal “can be used in the same manner” as those sensors used in conventional PAP devices. Truitt at 1:12-13, 3:41-46, 3:66-4:1.

The claims of the '029 Patent require a PAP device that measures a subject's respiratory airflow and calculates symptom severity data. '029 Patent, Claim 1. On the other hand, Truitt's invention seeks to measure the airflow provided to the patient, like conventional PAP devices, but without the flow sensors found on those conventional PAP devices. Truitt at 3:66-4:3, 5:35-38, 6:38-60. Thus, rather than disclose any new functionalities, Truitt discloses conventional functions, such as monitoring the pressure of gas delivered to the patient, adjusting the pressure or flow in a feedback fashion to meet the desired prescription pressure level, and adjusting pressure based on the breathing cycle. *Id.* at 2:60-3:4. Measurements of the airflow delivered to the patient do not represent the patient's respiratory airflow, they represent the airflow provided to the patient.

Further Truitt describes a conventional auto-titration mode, "where the flow of breathing gas and the pressure level thereof is controlled based on the conditions of the patient, these pressure and flow sensors, or other sensors, such as a microphone, are used to detect snoring, apneas, hypopneas, etc." *Id.* at 3:4-9; *id.* at 1:35-43 (describing the same known CPAP therapy, which changes pressure based on the detection of snoring or upper airway resistance). However, the feedback loop is not based on physiological data or symptom severity data but rather just whether an abnormal pressure or flow level is detected within the device. That this event

may be assigned as an apnea does not show that the subject's symptom severity is quantified and used to adjust the PAP device.

As was known at the time, the determinations made by Truitt were highly inaccurate and not suitable for patient monitoring because conventional PAP devices were not controlled by physiological feedback and supplied air at different periods that were not always beneficial to the patient. *Id.* at 3:21-36; *see also* Ex. 1002 at 160 (citing Geva ¶ [0299]: “[c]onventional CPAP systems . . . have several drawbacks: (1) apnea events may return whenever the CPAP is used improperly, which is normally the case because conventional CPAP systems are poorly controlled, or not controlled at all, by physiological feedback. Therefore, these systems output a constant continuous pressure, or vary the pressure to coincide with the person's breathing pattern, or start with low pressure, after which the pressure is gradually increased From technical point of view conventional CPAP systems are inefficient, because they supply, at different periods, air that is not beneficial to the patient.”). As shown by the National Library of Medicine, “[p]hysiological feedback is mediated through extensive feedback mechanisms that use physiological cues as feedback loop signals to control other systems.” Ex. 2017 at 1.

C. Kumar (Ex. 1008)

Kumar discloses a system and method for network-based monitoring of physiological data. Kumar at Abstract. Kumar's patient-side device 102 transmits

signal data to computing device 110, which forwards that data to central server 106, from which it is sent to a medical provider. The signal data transmitted from the patient-side device is received and analyzed using computing device 110's data interpretation and analysis module 114. Kumar at ¶ [0075] (“data interpretation and analysis module 114 [that] 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”).

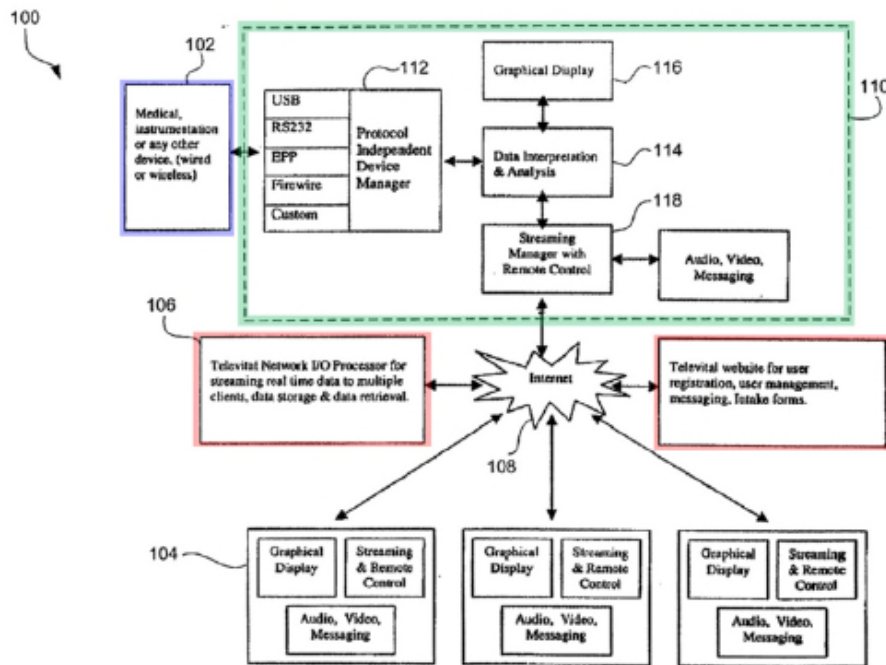


Fig. 1A

Pet. at 23 (citing Kumar, Fig. 1A) (annotated); *see also* Kumar at ¶ [0067] (“[T]he system includes one or more patient-side devices 102 for collecting data from a

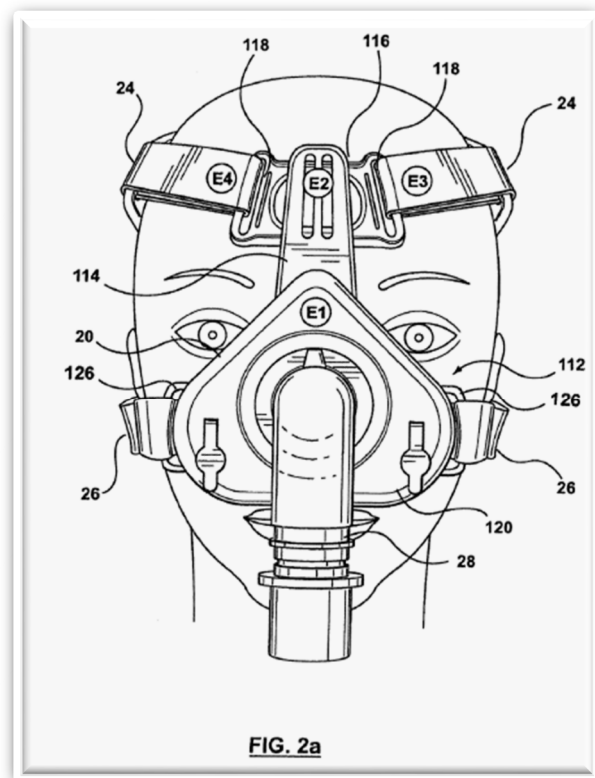
patient/client, one or more provider-side devices 104, and an engine implemented on a central server 106.”); Kumar at Fig. 5, ¶¶ [0078]-[0083], [0091]-[0092].

A POSITA would understand, based on the type of sensors and devices described in Kumar, that its interpretation and analysis module can receive, process, and analyze raw data from the connected device. *Id.* at ¶ [0071] (describing the different patient-side devices Kumar is intended to receive data from); *id.* at ¶ [0179] (“Data collected by the unit is processed by the system to provide real-time medical monitoring, summary reports, statistical calculations, and visual displays, which can further be tailored for the healthcare provider’s particular needs, and can each be tailored for a particular protocol.”); *see also id.* at ¶¶ [0010, 0081, 0179, 0192], and Claim 6 (“The system as recited in claim 5, wherein the computing device processes the data prior to receipt of the data by the engine.”).

Finally, in regards to Kumar’s use for “Sleep Apnea-Hypopnea Syndrome,” Kumar discloses that its system is intended for monitoring devices used in traditional in-home sleep testing, using polysomnography and oximetry, and in standard in-laboratory polysomnography and breathing monitoring, using thermocouples or thermistors, thoracic EMG or inductive plethysmography, and oximetry. *Id.* at ¶¶ [0239]-[0241].

D. Mumford (Ex. 1009)

Mumford is directed to “a mask assembly with integrated sensors for sensing the efficacy of treatment of medical conditions.” Mumford at 1:20-22. “The mask assembly 12 further includes sensors (e.g., electrodes E1, E2, E3, E4 and E5 of FIGS. 2a and 2b) positioned on the nasal mask 12, the straps 24 and 26”



Id. at FIGS. 2a-b, 7:22-25, 9:40-10:24. The mask sensors are connected to the monitoring unit and include electrodes for detecting EEG, EMG, EOG, and sensors for detecting blood oximetry, body position, and pressure. *Id.* at 7:25-33. The sensors are integrated directly into the inner surface of the mask so that the electrodes rest against the skin of the wearer. *Id.* at 7:58-60, 8:24-27, 8:40-45 (providing

examples of the sensors that are preferable because they require minimal preparation of the skin of the CPAP wearer), 8:46-67 (discussing metal, saline, disk, and peel and stick electrodes that may directly integrated into the mask and require additional preparation prior to use), 9:2-6 (discussion how it is beneficial for the wearer to prepare their skin in the locations where the electrodes are used).

These electrodes are “located at predetermined locations on the face and head of the wearer 18 in order to obtain good signal quality and different types of physiological data with a minimal number of electrodes.” *Id.* at 9:17-39 (discussing the physiological data collected from the electrodes providing data related to the CPAP wearer’s brainwaves, facial muscle tone and eye movements). Mumford also discloses that other electrode locations can be used, such as “below and beside one eye” or vertically flipping the location of electrode E1 with respect to electrodes E3 and E4. *Id.* at 10:25-50. The E1-E5 electrodes can be used in different combinations but in each instance, Mumford discloses using multiple sensors for gathering physiological information. *Id.* at 10:51-11:48. Thus, Mumford directs a POSITA that multiple sensor electrodes are needed to supply multiple channels of physiological information that are collected for sleep stage determination. *Id.* at 10:66-11:16.

Mumford has an alternative mask assembly embodiment with an integrated oximeter and pressure and position sensors. *Id.* at 11:66-12:21. In that embodiment,

the pressure transducer is disposed within the nasal cavity of the mask so that it is in close proximity to the gas inlet. *Id.* The pressure transducer is used to detect the pressure within the mask for deriving the breathing rate of the wearer in order to provide an indication of apnea and hypopnea events. *Id.* at 12:42-46. The electrodes and sensors are connected to a monitoring unit that contains mask interface 602 module, which connects the sensors on the mask assembly to the monitoring unit. *Id.* at 14:65-66. The physiological information provided by the sensors is processed by the monitoring unit according to a sleep efficacy algorithm that determines the sleep stage of the wearer and how many arousals they experienced. *Id.* at 7:34-42. Mumford also discloses using these parameters to control the CPAP. *Id.* at 7:46-51.

The sleep efficacy algorithm uses “a frontal staging algorithm, ***based on at least the electrode signals***, to determine which stage of sleep the wearer 18 is in.” *Id.* at 15:39-16:3 (emphasis added). A POSITA would understand that it is important for Mumford's sleep efficacy algorithm to rely on information from a combination of signals from the integrated electrodes as the inputs to its algorithm. *Id.* at 15:42-46. Thus, without at least a combination of electrodes being used, Mumford's sleep efficacy algorithm would be useless. *See id.* at Claims 1, 17-19, 24 (Mumford independent claims all claiming multiple sensors and electrodes used within the mask assembly).

III. THE CHALLENGED CLAIMS ARE PATENTABLE

Patent Owner further respectfully requests that the Board deny *inter partes* review because Petitioner has not shown a reasonable likelihood that any Challenged Claim is obvious.

A. Grounds 1-3: The Challenged Claims are Patentable Over Truitt and Kumar

1. Truitt in View of Kumar Does Not Disclose a PAP Transmitting Severity Data to a Cell Phone and Remote Internet Site

The Challenged Claims are patentable because Truitt in view of Kumar does not disclose transmitting any¹ data to a cell phone **and** to a remote internet site via the PAP's wireless transceiver, as claimed. Petitioner's arguments for the cell phone and remote internet site limitations only focus on Kumar. Pet. at 29-40.

Petitioner alleges that the remote internet site is hosted at Kumar's central server 106, which is accessible to patient-side device 102 over WAN 108 (*e.g.*, the Internet). *Id.* at 34-40. As shown in FIG. 1A, the connection between the patient-side device 102 and central server 106 always traverses computing device 110

¹ As discussed below, Truitt and Kumar also do not disclose measuring a patient's respiratory airflow, calculating severity data at a PAP device, or transmitting severity data from a PAP device to a cell phone or remote internet site. See § III, *infra*.

(which is alleged to be the claimed “cell phone”), so there is no disclosure in Kumar of separately sending the data of severity of the subject’s symptoms and/or an index based in whole or in part on the subject’s symptom severity data generated and transmitted by the PAP device to a cell phone and a remote internet site, as claimed:

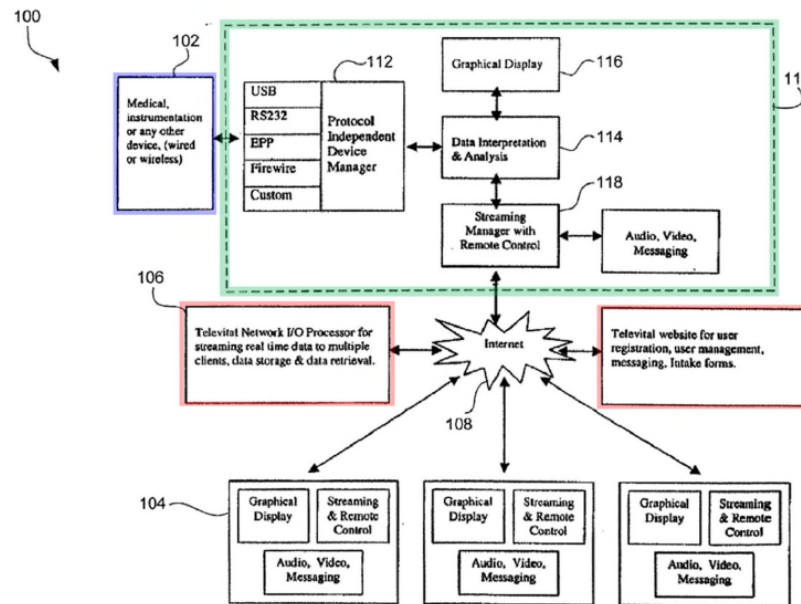


Fig. 1A

EX1008, FIG. 1A

Pet. at 35.

Accordingly, Petitioner does not identify where Kumar teaches “a remote internet site, the remote internet site adapted for receiving [i) the subject’s symptom severity data and ii) data of usage,] or [i)the subject’s symptom severity data, ii) data of usage, and iii) an index based in whole or in part on either the subject’s symptom severity data and/or data of usage,] related to the subject’s treatment and the

treatment's efficacy, in whole or part, ***generated by the PAP device and transmitted via the at least one second radio frequency wireless transceiver.*** '029 Patent at Claim 1 (emphasis added).

For at least the foregoing reasons, Patent Owner respectfully requests that the Board deny institution.

2. Truitt Does Not Disclose Measuring or Deriving the Respiratory Airflow of a Subject while using the PAP or Outputting Airflow Sensor Data

The Board should deny institution because Petitioner fails to demonstrate that Truitt discloses an internal airflow sensor is adapted for measuring or deriving the respiratory airflow of a subject. Pet. at 27-29.

It is the petitioner's burden to explain with particularity why the challenged claims are unpatentable. *See Nichia Corp. v. Document Sec. Sys., Inc.*, No. 2020-2261, 2022 WL 1218036, at *4 (Fed. Cir. Apr. 26, 2022) ("The patent challenger must provide an understandable explanation of the element-by-element specifics of its unpatentability contentions, identifying supporting disclosures from the asserted prior art." (citing 35 U.S.C. § 312(a)(3)); *see also Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). Thus, a petition must specify where each element of the claim is found in the relied-on prior art. 37 C.F.R. § 42.104(b); *see also* 37 C.F.R. § 42.22(a)(2) (a petition must include "a detailed explanation of the

significance of the evidence including material facts, and the governing law, rules, and precedent.”).

Petitioner argues that Truitt discloses measuring the airflow “provided to the patient,” but Petitioner fails to explain how measuring the airflow provided to the patient is either a measurement or derivation of the *patient*’s respiratory airflow. Pet. at 28. Indeed, Petitioner’s experts provide no analysis to explain how measuring airflow within the device is representative of a measurement of a subject’s respiration. See Ex. 1003 at ¶ 219 (opining that the airflow “signal that controller 38 uses to calculate gas flow and/or volume passing through conduit 56” is used to control “the operations of blower assembly 52 . . . and/or the operation of valve 40 that controls air flow and pressure provided to the patient”); Ex. 1005 at ¶ 106 (“flow sensing assembly 72 . . . measures the pressure differential that can be used for calculating the flow of gas”). Although Truitt’s system may detect certain symptoms, like snores, apneas, and hypopneas, it does not disclose detecting these symptoms as a function of the patient’s respiratory airflow *or* how to derive the patient’s respiratory airflow from the measurements that its system does take. Truitt at 2:57-60, 6:39-48.

For at least the foregoing reasons, Patent Owner respectfully submits that Truitt does not disclose “an airflow sensor internal to the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP.”

Patent Owner respectfully requests, therefore, that the Board deny institution of *inter partes* review.

3. Truitt in View of Kumar Does Not Disclose Transmitting Severity Data From the PAP to a Cell Phone

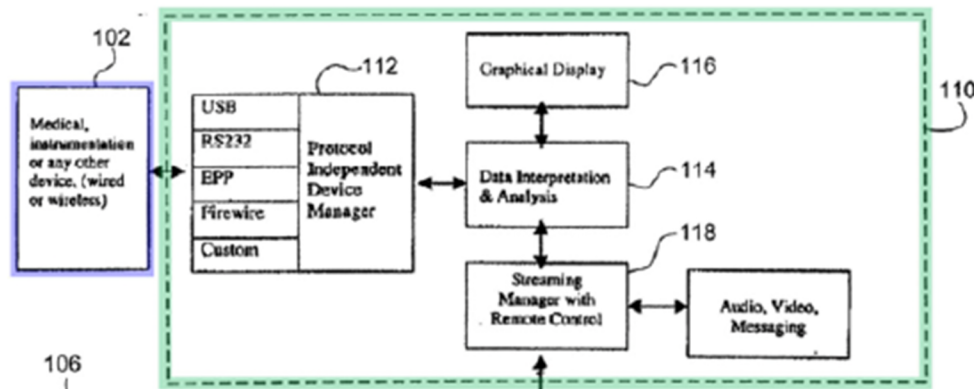
The Boards should also deny institution because Truitt and Kumar do not disclose transmitting severity data from a PAP device to a cell phone.

Since Truitt does not disclose or suggest transmitting data anywhere outside of its device, Petitioner relies upon Kumar to fill the void for this limitation. Pet. at 29-34 (“[A] POSITA would have been motivated to combine teachings of Truitt and Kumar such that the PAP device would wirelessly transmit to a patient’s cell phone”).

Because neither reference discloses calculating such data at the PAP device, and Kumar is built to analyze the type of raw data that Truitt’s PAP device **does** generate, Petitioner’s proposal that a POSITA would have calculated severity data at the PAP device is the product of hindsight. *WL Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983) (“To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.”). The Examiner reached the same conclusion

when considering the substantially similar combination of Farrell and Geva during prosecution of the '029 Patent and the related '775 Patent. See Paper 6 at § V.A.

As a preliminary matter, Patent Owner does not concede that Kumar discloses calculating severity data or that it would have been obvious to calculate severity data missing from Truitt at Kumar's computing device. But more fundamentally, neither reference discloses or suggests calculating this data at the PAP device, and Kumar's system is purpose-built to analyze raw data from patient devices. Pet. at 17-24.



Id. at 35 (Petitioner's annotated FIG. 1A from Kumar showing computing device 110 containing Data Interpretation & Analysis module 114). Computing device 110 contains "data interpretation and analysis module 114 [that] 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." Kumar at ¶ [0075].

A POSITA would recognize, therefore, that Kumar's computing device is intended to receive multiple streams of data from the patient's device and analyze that data before sending it to a remote site. *Id.* at Claim 6 ("The system as recited in

claim 5, wherein the computing device processes the data prior to receipt of the data by the engine.”); *id.* at ¶ [0071] (describing the different patient-side devices Kumar is intended to receive data from); *id.* at ¶ [0179] (“Data collected by the unit is processed by the system to provide real-time medical monitoring, summary reports, statistical calculations, and visual displays, which can further be tailored for the healthcare provider’s particular needs, and can each be tailored for a particular protocol.”).

Accordingly, since neither Truitt nor Kumar suggests calculating severity or index data at a PAP device, a POSITA reading Kumar and Truitt would not be motivated to add that functionality to Truitt’s PAP device, particularly because Kumar’s computing device already has the necessary computational resources. Patent Owner, therefore, respectfully requests that the Board deny institution.

4. Truitt and Kumar Do Not Disclose a Processor Within the PAP Device that Receives Airflow Sensor Data and Calculates Data Indicative of the Severity of the Patient’s Symptoms

Independent Claim 1 is also patentable because Truitt does not disclose a PAP device with a processor that receives airflow sensor data and data indicative of the severity of the patient’s symptoms, and Petitioner does not suggest that Kumar cures Truitt’s deficiencies. Pet. at 17-21, 28-29.

Truitt does not disclose or suggest equipping a PAP device with a processor that receives a subject’s respiratory airflow data and calculates data indicating the

severity of the patient's symptoms. Petitioner's suggestion that Truitt discloses this limitation "because it discloses monitoring the patient's condition, and specifically detecting snoring, apneas, and hypopneas," relies on an unsupported and overly broad (and unsupported) interpretation of the term "data of a severity of the symptoms of the subject." Pet. at 17-18; 37 C.F.R § 42.104(b)(4).

Data of the severity of the subject's symptoms are quantitative determinations or estimations of the patient's condition based on data from one or more sensors fed into one or more algorithms. '029 Patent at 19:61-20:23. As the Board determined for a parent of the '029 Patent, patient monitoring requires disclosure of a quantitative determination of the severity of the symptoms, not mere identification of an event. *ResMed Corp. v. Cleveland Med. Devices, Inc.*, No. PGR2024-00012, Paper 7 at 16 (P.T.A.B. June 24, 2024) ("Based on the above disclosures in the specification, we agree with Patent Owner that the specification discloses that the gathered information is processed to monitor the condition of the subject (i.e., the system quantitatively estimates or determines the 'severity of sleep disorder symptoms') and how much pressure / flow of gas is to be provided to the subject (i.e., the system calculates the 'usage of the PAP device by the subject')."). Accordingly, while detected snoring, apnea, and hypopnea events may represent detected *symptoms*, they are not "data of a *severity* of the symptoms of the subject," as claimed.

The Board should also reject Petitioner's reasoning on this point because it wrongly assumes that all ways of monitoring a patient's condition involve "calculating 'data of severity of sleep disorder symptoms.'" Pet. at 17. While calculating severity data is one way to monitor a patient's condition, the opposite is not true: there are boundless ways to monitor a patient's condition (taking the patient's temperature, pulse, blood pressure, etc.) that are entirely unrelated to calculating the severity of a patient's symptoms. See Truitt at 3:4-9 (disclosing that in auto-titration mode, "other sensors, such as a microphone, are used to detect snoring, apneas, hypopneas, etc." in addition to pressure and flow sensors). Accordingly, there is no basis for Petitioner's conclusion that Truitt teaches calculating severity data from airflow sensor data merely because it discloses monitoring the patient's condition. *Id.*

Truitt discloses that its conventional PAP device merely receives flow and/or pressure signals and adjusts the internal flow or pressure "in a feedback fashion," but that does not disclose or imply that the system calculates symptom severity:

Controller 38 receives the signals output from sensors 20 and 22 and controls the operation of valve 40, pressure generator 12, or a combination thereof in a feedback fashion based on these received signals. For example, in a simple CPAP device, controller 38 monitors the pressure or flow of breathing gas delivered to the patient and adjusts the pressure or flow in a feedback fashion to meet the desired prescription pressure level.

Truitt at 2:57-64. Using this feedback technique, conventional PAP devices could measure the airflow being provided **to the patient** within the device and (1) provide bi-level pressure support, “where the pressure is greater during inspiration than during expiration,” or (2) auto-titrate pressure to counteract or prevent “snoring, apneas, hypopneas, etc.” *Id.* at 2:64-3:11.

One known measure of severity is the apnea-hypopnea-index (AHI), but Truitt does not teach determining such an index based on its sensor data. Instead, Truitt teaches a feedback loop based upon its internal airflow system readings to adjust the blower to meet the pre-programmed, prescribed pressure level. *See id.* at 5:35-6:10 (describing pressure and motor control), 6:38-53 (describing the controller for calculating the flow and/or volume of gas passing through the conduit for control of the motor), 6:60-62 (describing that “other sensors” are needed “to provide additional information to the controller”). Thus, this measurement of airflow **to the patient** is not a measurement of the patient’s respiratory airflow, and Truitt does not teach or suggest **deriving** the patient’s respiratory airflow for **calculating** symptom severity from this data.

Truitt also fails to disclose calculating an “index based in part on data of severity of sleep disorder symptoms” at least because its processor does not calculate severity data. Although Petitioner’s argument is that “Truitt’s PAP system operates in the materially same way as the ’029 patent,” Petitioner points to no disclosure in

Truitt supporting this. Pet. at 18-21. Rather, Petitioner improperly analogizes Truitt's detection of individual snores, apneas and hypopneas with the '029 Patent's identification and calculation of symptom severity data without any reasoned or evidentiary basis for the comparison.

Furthermore, the '029 Patent claims a PAP device that identifies different types of apneas with different symptoms that require different treatments. *See, e.g.*, '029 Patent at Claim 12 (“the second processor of the PAP is configured to distinguish between and calculate the severity of both obstructive apneas and central apneas of the subject”);

There are three different types of sleep apnea: obstructive sleep apnea (OSA), central sleep apnea (CSA), and mixed sleep apnea (MSA). Of these three, OSA is the most common; CSA is rare; mixed sleep apnea is a combination of the previous two with treatment being the same as OSA. Treatment of OSA and CSA vary substantially which makes a proper diagnosis of the correct type of sleep apnea (OSA or CSA) critical for an effective treatment.

id. at 5:57-65 (emphasis added);

Central Sleep Apnea is defined as a neurological condition causing cessation of all respiratory effort during sleep, usually with corresponding decreases in blood oxygen saturation. The brainstem center controlling breathing shuts down there's no respiratory effort and no breathing. This is in contrast with OSA where there is respiratory effort from the brain stem but a physical blockage prevents inhalation

of oxygen. The subject is aroused from sleep by an automatic breathing reflex, so the subject may end up getting very little sleep at all. CSA, which is a neuroglial disorder, is very different in cause than OSA, which is a physical blockage though the effects are highly similar.

Id. at 5:65-6:24 (emphasis added).

Petitioner's expert agrees that the symptoms present in central apnea and obstructive apnea is "the presence or absence of respiratory effort, with obstructive events involving persistent effort and central events showing none." Ex. 1003 at ¶ 68; *id.* at ¶ 301 ("Central apnea is not caused by the collapse of the upper airway, but by the nervous system, and therefore the treatment is not the same."). Because the symptoms are substantially different, conventional PAP devices had to be operated in different modes where the device either identifies and treats obstructive apnea or central apnea, not both. *Id.* at ¶ 133 (discussing the CPAP state of the art and Wright).

Truitt discloses a conventional CPAP device that "suppl[ies] a constant positive pressure to the airway of a patient to treat **obstructive sleep apnea (OSA)** as well as other disorders." Truitt at 1:26-30 (emphasis added). As made clear by the '029 Patent, this supply of constant pressure is only suitable for the treatment of OSA and maybe mixed apneas, not central apneas, which the claimed invention identifies and treats. '029 Patent at 5:66-6:24. Truitt provides no disclosure of a device capable of distinguishing the symptom severity of a patient experiencing

individual bouts of obstructive and central apnea symptoms, it merely provides “a pressure support system that allows for a relatively accurate flow or volume measurement of the gas passing therethrough, without the need for a dedicated flow element.” Truitt at 3:42-46. Accordingly, Truitt discloses the type of “basic adjustable [PAP] devices” that the '029 Patent distinguishes because they were “expensive and largely ineffective.” '029 Patent at 2:36-37.

For at least the foregoing reasons, Truitt does not disclose a “processor adapted for receiving the airflow sensor data, for calculating the data of a severity of the symptoms of the subject and/or the index.” And as discussed below, it would not have been obvious to modify Truitt with Mumford to reach this limitation because Mumford's algorithm is incompatible with the design and intended purpose of Truitt.

B. Grounds 4-6: The Challenged Claims are Patentable Over Truitt in View of Kumar and in Further View of Mumford

Petitioner recognizes Truitt's inability to calculate the claimed symptom severity data and seeks to fill the gap using Mumford sleep efficacy algorithm. Pet. at 64-71. However, a POSITA would not be motivated to modify Truitt's PAP device with Mumford's sleep efficacy algorithm absent of hindsight because Mumford's sleep efficacy algorithm relies upon sensor inputs not present in Truitt, and Mumford's algorithm detection of apneas provides the same functionality already present in Kumar's external computing device. *Id.* at 64-66.

1. Mumford's Sleep Efficacy Algorithm Relies On Electrodes Not Present in Truitt

Mumford's sleep efficacy algorithm is "based on at least the electrode signals" received from the sensors and electrodes integrated into its mask assembly. *See* § II.D, *supra*. The sleep efficacy algorithm uses "a frontal staging algorithm, based on at least the electrode signals, to determine which stage of sleep the wearer 18 is in," which indicates that the primary inputs used in the algorithm come from the electrode signals located in the mask. Mumford at 15:39-16:3. Further, Mumford makes clear that "[t]he information provided by the electrodes is important since it is well known that some sleep apnea events occur more frequently in some of the sleep stages rather than others." *Id.* at 15:42-45. It goes on to disclose three physiological signals, EEG, EOG, and EMG used to score sleep stages and that arousals due to upper airway resistance (i.e. apneas) may be detected from a shift in the frequency EEG and/or EOG signal as well as a decrease in blood oxygenation levels. *Id.* at 1:56-2:12.

On the other hand, Truitt discloses a CPAP with an internal flow sensing assembly that sends signals to its controller used in determining the flow or volume of gas in the system. *See* § III.A.1, *supra*. There is no motivation provided in Mumford to use its sleep efficacy algorithm with a PAP device like Truitt's, where its only input to the algorithm would be from its flow sensing assembly. Mumford at 10:66-11:16 (emphasis added) (discussing why it is "preferable, and more robust

. . . to use a subset of electrodes that contains ***at least three electrodes***. However, in some cases it may be possible to use only two electrodes.”). For each embodiment in Mumford, the pressure transducer is never used as the sole provider of information for determining either the wearer’s sleep stage or arousals. *Id.* at 4:24-35 (pressure transducer in combination with a pulse oximeter or position sensor), 12:62-13:22 (pressure transducer is optionally used in combination with the electrodes and other sensors), Claims 10, 13 (pressure transducer used in combination with electrodes and other sensors).

Petitioner’s argument that Mumford furthers the objective and purpose of Truitt, ignores that Mumford defeats Truitt’s purpose of providing an “accurate flow or volume measurement of the gas passing therethrough, without the need for a dedicated flow element.” Truitt at 3:42-46; *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (finding nonobviousness where proposed combination “destroy[s] the basic objective” of the primary reference); *see also Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, 4 F.4th 1370, 1376 (Fed. Cir. 2021) (reversing the Board’s obviousness determination because the Board failed to explain why a POSITA would have “alter[ed] the inventive concept”). This is because in order to implement Mumford’s sleep efficacy algorithm, one of ordinary skill would have to include a combination of electrodes and pressure transducers integrated into the mask. Pet. at 64-66; Mumford at 12:14-16 (“The ***pressure transducer 316*** is

disposed within the nasal mask 20 preferably in close proximity to the gas inlet 28.”); *id.* at 12:42-44 (“The pressure transducer 316 is used to ***detect the pressure within the cavity of the nasal mask 20 . . .***”) (emphases added). Thus, a POSITA would not look to Mumford’s algorithm when attempting to interpret Truitt’s internal flow or volume reading sent from its flow-sensing assembly found within the PAP device.

Further, neither Petitioner nor their experts demonstrate how Mumford’s algorithms would need to be modified in order to be successfully operational with Truitt’s PAP device and the data it measures. Pet. at 66-71; *see also Sprint Spectrum L.P. v. Intellectual Ventures II LLC*, No. IPR2018-01765, Paper 11 at 25 (P.T.A.B. May 6, 2019) (denying institution because the petitioner failed to demonstrate how a reference’s algorithms would be modified to serve the purpose of the proposed combination) (citing *Pers. Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017)).

2. A POSITA Would Not Be Motivated to Use Mumford’s Sleep Efficacy Algorithm in Truitt

Petitioner alleges that only Mumford’s sleep efficacy algorithm would be incorporated into Truitt, not the entire mask assembly with its integrated sensors and its algorithm. Pet. at 64-70. However, Mumford’s sleep efficacy algorithm determines two things: (1) the present sleep stage of the wearer and (2) how many arousals they experienced. Mumford at 7:34-42. As disclosed in Mumford, each of

these calculations requires multiple data streams as inputs because the “information is weak” and the “signals are more difficult to detect because they do not originate in the frontal lobes of the brain.” *Id.* at 10:66-11:16. Thus, a POSITA considering Mumford's sleep efficacy algorithm must use it in conjunction with the electrodes integrated into Mumford's mask assembly, a point ignored by Petitioner.

Mumford discloses that to determine the wearer's sleep stage, signals from the EEG (brain activity), EOG (eye movement), EMG (muscle tone) sensors are used together in the assessment. *Id.* at 1:56-2:3, 11:17-21. Further, arousals due to upper airway resistance are detected by Mumford from the shift in the patient's EEG and/or EOG accompanied with a decrease in blood oxygen levels. *Id.* at 2:4-6. The pressure transducer is never used alone when determining either the wearer's sleep stage or arousals. *Id.* at 4:24-35 (pressure transducer in combination with a pulse oximeter or position sensor), 12:62-13:22 (pressure transducer is optionally used in combination with the electrodes and other sensors), Claims 10, 13 (pressure transducer used in combination with electrodes and other sensors).

Furthermore, a POSITA would not be motivated to use Mumford's algorithm without modification when considering using it with a device that only has a flow/pressure sensor within the device and not the mask. Mumford's pressure transducer is found integrated within the mask worn by the patient, not within the CPAP device. *Id.* at 11:66-12:17. Truitt discloses that the flow and pressure sensors

can be used to detect apneas which provides substantially the same functionality disclosed for Mumford's algorithm when its only input is from the pressure sensor. *Id.* at 12:42-47. Thus, a POSITA would not be motivated to use Mumford's sleep efficacy algorithm in Truitt because the sleep efficacy algorithm would not provide any capability not already found within Truitt. Truitt can detect apneas and control the operation of the device the same as Mumford when the additional electrode inputs are removed. Thus, the Petition fails to show motivation for combining Mumford with Truitt.

IV. CONCLUSION

For all of these reasons, Patent Owner accordingly requests that the Board deny institution of *inter partes* review of the Challenged Claims of the '029 Patent.

Patent Owner's Preliminary Response
IPR2025-00247 (U.S. Patent No. 11,872,029)

Respectfully submitted,

Dated: May 12, 2025

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

The undersigned hereby certifies that the portions of the above-captioned **PATENT OWNER'S PRELIMINARY RESPONSE** specified in 37 C.F.R. § 42.24 has 6,097 words in compliance with the 14,000 word limit set forth in 37 C.F.R. § 42.24(b)(1). This word count was prepared using the Microsoft Word word-processing system used to prepare this paper.

Dated: May 12, 2025

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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>	May 12, 2025
<i>Manner of service</i>	Electronic Filing and Electronic Mail (PH-ResMed-CleveMed@paulhastings.com)
<i>Documents served</i>	PATENT OWNER'S PRELIMINARY RESPONSE
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