

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

Case IPR2025-00158
U.S. Patent No. 11,690,512

PATENT OWNER'S RESPONSE

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PATENT OWNER'S EXHIBIT LIST

Exhibit	Description
2001	Intentionally Omitted
2002	Intentionally Omitted
2003	Intentionally Omitted
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	Excerpts of Defendant ResMed Inc.'s Initial Invalidity Contentions cover pleading from <i>Cleveland Med. Devices, Inc. v. ResMed, Inc.</i> , No. 22-cv-00794-JLH (D. Del.) (the "Delaware Case"), served on February 21, 2023
2006	Excerpts of Plaintiff ResMed Corp.'s Response and Affirmative Defenses to Defendant's Counterclaims for Patent Infringement, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 23-cv-02221-BMB, Dkt. No. 66 (N.D. Ohio), filed on March 18, 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 or 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	<i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB, Dkt. No. 87-6, Excerpts of Petitioner's parent company's (ResMed) Q4 FY2024 Earnings call (N.D. Ohio), filed on August 21, 2024
2013	Declaration of Timothy Layden in Support of Unopposed Motion for <i>Pro Hac Vice</i> Admission
2014	Declaration of Dr. Michael T. Goodrich in Support of Patent Owner's Response
2015	Declaration of Dr. David A. Borkholder in Support of Patent Owner's Response
2016	Deposition Transcript of Jason Paul Kirkness, Ph.D., <i>ResMed Corp. v. Cleveland Medical Devices, Inc.</i> , Case No. IPR2025-00158, taken on August 27, 2025
2017	Deposition Transcript of Sandeep Chatterjee, Ph.D., <i>ResMed Corp. v. Cleveland Medical Devices, Inc.</i> , Case No. IPR2025-00158, taken on September 5, 2025
2018	"Mobile Medical Applications – Guidance for Industry and Food and Drug Administration Staff," U.S. Dept. of Health and Human Services Food and Drug Administration, dated September 25, 2013
2019	"Information Consumer Technologies 2010," Perceptions of Libraries, 2010: Context and Community

Exhibit	Description
2020	Explain that Stuff webpage, “How do cellphones work?” by Chris Woodford, dated February 20, 2025, available at https://www.explainthatstuff.com/cellphones.html
2021	Lydia Saad, “Gallup Vault: Misjudging Cellphone Adoption,” dated February 16, 2018, available at https://news.gallup.com/vault/227810/gallup-vault-misjudging-cellphone-adoption.aspx

I. INTRODUCTION

The Board should confirm that the Challenged Claims are patentable because Petitioner's proposed combination of Ciulla and Orbach does not teach a computer (or processor) that receives sleep data over cell towers from cell phone/PDA and executes software to analyze and display the sleep data for diagnosis, as recited in Independent Claim 1.¹ See '512 Patent, Claim 1 (claim limitations [1.d]-[1.g]). Petitioner relies on Orbach for these limitations, but to the extent that the limitations are taught they are split between Orbach's remote server and viewing station computer. See Pet. at 48-49, 49-52, 52-54; Ex. 1008 ("Orbach") at 3:19-4:3, 13:21-14:2. Petitioner also does not argue that a POSITA would have had a reason to configure Orbach such that one computer (or processor) performs the claimed functions.

A POSITA also would not have been motivated to combine Ciulla's system with Orbach's communication technique (*i.e.* a "cell phone to wirelessly collect and transmit sleep sensor data to a remote computer") because Ciulla does not have a problem that required solving with such technique. Pet. at 10. Thus, while Petitioner alleges that a POSITA would have added Orbach's communication technique to

¹ The Petition challenges Claims 1-20 (the "Challenged Claims") of U.S. Patent No. 11,690,512 (Ex. 1001, the "'512 Patent").

provide real-time, continuous health data (*see id.* at 12), that problem does not exist in Ciulla. Ciulla already provides real-time continuous health data—without the need for a cell phone—because its system includes an LCD screen for display and can directly transmit reports to healthcare providers, including over a Wide Area Network (“WAN”) like a mobile communications network or the Internet. *See, e.g.*, Ex. 1007 (“Ciulla”) at ¶¶ [0076], [0103], [0125], [0214].

II. OVERVIEW OF THE '512 PATENT AND ASSERTED ART

A. The '512 Patent

The '512 Patent discloses and claims a sleep diagnostic test system that transfers data over cellular towers to one or more remote computers that execute software to analyze and display the data. *See* '512 Patent at Claim 1. The sleep diagnostic test system includes sensors that record physiological data while the subject sleeps and a data acquisition system that sends the recorded data to a cellular device. *Id.* at 10:24-50. The cellular device then transfers this data over cell towers to a remote computer for medical analysis and display. Ex. 2014 (“Goodrich Decl.”) at ¶¶ 30-32.

The '512 Patent also discloses a portable patient interface box worn by the patient during the sleep test. The interface box connects to one or more physiological data sensors, which may include, for example, a pulse oximeter, which measures the level of blood oxygenation, a pneumotachograph, which converts a measured

pressure into an electrical signal to quantify respiratory airflow, and/or other physiological sensors. '512 Patent at 9:27-39, 9:57-10:4; Goodrich Decl. at ¶ 31.

The wearable patient interface box processes the collected sensor data and transmits the patient data to a cell phone or PDA. See '512 Patent at 15:33-44. The cell phone or PDA then transmits the data to a remote computer for further analysis and display of the data so that a health care provider can diagnose the patient's sleep disorder and/or modify the PAP device treatment. '512 Patent, Claim 1; Goodrich Decl. at ¶ 32.

B. Ciulla

Ciulla discloses a sleep disordered breathing (SDB) treatment device. See Ciulla at Abstract, ¶¶ [0095], [0129]-[0132]. The SBD treatment device generates and provides reports to the patient's LCD screen or directly to the healthcare provider for review. See, *e.g.*, *id.* at ¶¶ [0103], [0214]; Goodrich Decl. at ¶ 33.

C. Orbach

Unlike the claimed invention, where a computer receives sleep data over cellular towers and executes software to analyze and display the sleep data for diagnosis and the modification of treatment, Orbach's system is configured with two computers that execute their own distinct software. Orbach's system includes a remote server that receives physiological data from a cell phone. See Orbach at Abstract, 13:14-14:2. Orbach's system also includes a viewing station computer that

is transmitted the data from the remote server (via WAN, for example) for further analysis by an expert. See Orbach at 8:11-15, 13:14-14:2, Claims 27 and 28; Goodrich Decl. at ¶ 34.

III. LEVEL OF ORDINARY SKILL IN THE ART

Patent Owner applies Petitioner's proposed definition of a POSITA in 2006, as someone with "at least a bachelor's degree in mechanical engineering, electrical engineering, computer science, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience working with diagnostic sensor systems and network data systems. Additional experience could substitute for less education, and additional education could likewise substitute for less experience." Pet. at 8-9; Goodrich Decl. at ¶¶ 35-37.

IV. CLAIM CONSTRUCTION

No express construction is necessary for the Board to resolve the instant dispute and affirm patentability. See *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that "we need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

V. THE CHALLENGED CLAIMS ARE PATENTABLE OVER THE CIULLA-ORBACH COMBINATION²

A. Orbach Does Not Disclose a Computer that Receives Sleep Data Over Cell Towers from a Cell Phone/PDA and Executes Software to Analyze and Display Data for Diagnosis and Treatment Modification (Claim Limitations [1.d]-[1.g])

Orbach³ does not disclose a computer that (1) receives sleep data over cell towers from a cell phone/PDA and (2) executes second software that analyzes and displays the sleep data for diagnosing and providing the basis for treatment modification, as required by the Challenged Claims. *See* '512 Patent at Claim 1 (claim limitations [1.d]-[1.g]). To the extent that Orbach discloses these limitations at all, they are performed at two different devices: the remote server and viewing

² Petition Grounds 1 and 2 challenge the only independent claim based on the Ciulla-Orbach combination. While Ground 2 additionally relies on Nagai (Ex. 1010), it is only for claim limitation of “hardwiring or releasably connect[ing] a pulse oximeter for [1.b.iii.C] and [1.c.iii].” *Pet.* at 67 (emphasis omitted). Accordingly, the incorporation of Nagai does not change the Ciulla-Orbach combination as it relates to the unnecessary introduction of Orbach’s communication technique. Therefore, all grounds fail for the reasons discussed herein.

³ Petitioner relies on Orbach’s disclosure for these claim limitations. *See Pet.* at 48-49, 49-51, 52-54.

station, respectively. The Challenged Claims are patentable, therefore, because Petitioner neither establishes that the claim language is broad enough to encompass Orbach's technique nor argues that it would have been obvious to consolidate Orbach's remote server and viewing station at all, let alone in a way that reaches the claimed invention. See Goodrich Decl. at ¶ 38.

Orbach does not teach or suggest these limitations at least because two different computers execute their own distinct software, and Petitioner fails to demonstrate why a POSITA would have combined different server and viewing station embodiment components into one to arrive at the claimed invention. See *In re Stepan Co.*, 868 F.3d 1342, 1345-46, n.1 (Fed. Cir. 2017) ("Whether a rejection is based on combining disclosures from multiple references, combining multiple embodiments from a single reference, or selecting from large lists of elements in a single reference, there must be a motivation to make the combination . . .").

Orbach discloses a remote server and viewing station, which are both computers, as Petitioner's own analysis confirms, and which execute their own software having differing functionality. Pet. at 48 ("The remote server with a viewing station (*either being the computer*")) (emphasis modified). Specifically, Orbach's describes a configuration in which the **remote server** receives data from a cell phone and retransmits the data (for example, via WAN (Internet)) to the separate

viewing station computer where the data is displayed and expert analysis is performed. See Orbach at 3:19-4:3, 13:21-14:2; see also *id.* at Abstract, 8:13-15.



Goodrich Decl. at ¶ 39 (illustration of Orbach's remote server 140 (**left**) transferring data via a WAN to the viewing station computer 150 (**right**) (citing Orbach at Fig. 1, 13:21-14:2).

Neither computer receives sleep data over cell towers from a cell phone and executes second software directed to the analysis and display of data for diagnosis and providing the basis for modification of treatment. For receiving sleep data over cell towers, Petitioner relies on Orbach's **remote server**. Pet. at 51 ("As explained for [1.a], Orbach's phone uses its communication means . . . to 'communicate with . . . **remote server**.'" (emphasis added). However, the remote server does not execute second software that displays data for diagnosis and provides a basis for the modification of sleep treatment. Goodrich Decl. at ¶ 40.

Rather, as discussed above, the remote server transmits the data to the viewing station computer, for example via the Internet (WAN). See Orbach at 13:28-14:2; 8:13-15 (disclosing the viewing station as including "a remote call center and an interactive expert system"). Accordingly, for analysis and display of data, Petitioner

turns to Orbach's **viewing station**. See Pet. at 53 ("POSITA would have understood, analyzing the sleep data at the remote site would have means that the **viewing station** would have also displayed the analyzed sleep data, to allow the expert to efficiently interpret the data.") (emphasis modified). However, the viewing station computer (and executed software) does not receive data from a cell phone's/PDA's wireless transceiver that is over cell towers. See Goodrich Decl. at ¶ 41.

Petitioner combines the viewing station computer's software functionality (and even Ciulla's technical trial version) with the remote server to try to arrive at the claim limitations. Pet. at 51 (alleging that the "remote server, viewing station, and processor [are the] (**computer and second processor**)") (emphasis added); *id.* at 52 (same), 53 (same), 53-54 (Ciulla discloses a "clinical trial version" that allegedly allows for sleep treatment adjustment). But they are separate computers executing their own distinct software, and Petitioner does not provide a basis as to why these distinct embodiment components would be combined. *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) ("[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications.").

Instead, Petitioner relies on its experts who allege that it would have been obvious for the remote server to include the viewing station configuration because "such software was standard, fundamental, and well-known to operate." Ex. 1003

(“Kirkness”) at ¶ 177; Ex. 2016 (“Kirkness Tr.”) at 81:4-11 (“So in the - - 177, my opinion is that it would be obvious for the server to include the second software”); *see also id.* at 81:20-82:14, 87:21-89:23; *see also* Ex. 1005 (“Chatterjee”) at ¶¶ 88, 160-161, 173; Ex. 2017 (“Chatterjee Tr.”) at 9:19-10:2, 10:13-11:23. But the mere fact that other configurations were known does not provide a reason that a POSITA would have combined Orbach’s viewing station computer and remote server configurations onto one device. *Virtek Vision Int’l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 886-88 (Fed. Cir. 2024) (reversing the Board’s obviousness determination because the Board’s reliance on the fact that other “possible arrangements existed in the prior art” did not provide a reason that a POSITA “would have been motivated to use the 3D coordinate system” instead of “the angular direction system” embodiment).

Viewing each computer and its functionality individually, as opposed to combined as Petitioner erroneously does, Orbach does not disclose a computer that receives sleep data over cell towers from a cell phone/PDA’s wireless transceiver and either it or its processor executes software that analyzes and displays data for diagnosis and providing the basis for modification of the subject’s sleep treatment as recited in claim limitations [1.d]-[1.g]. Therefore, the Ciulla-Orbach combination does not disclose the claimed invention. Goodrich Decl. at ¶¶ 42-43.

B. A POSITA Would Not Have Been Motivated to Transfer Sleep Data from a Wearable Device to a Cell Phone/PDA, and from Cell Phone/PDA to Remote Site Via Cell Towers

The Challenged Claims are also patentable because a POSITA would not have been motivated to combine Ciulla's wearable sleep data acquisition system with Orbach's communication technique (*i.e.* a "cell phone to wirelessly collect and transmit sleep sensor data to a remote computer"). *See* Pet. at 9-10; Goodrich Decl. at ¶ 44; Ex. 2015 ("Borkholder Decl.") at ¶¶ 43-53.

Petitioner creates a problem within Ciulla's system that does not exist—continuous, real-time data, tracking and reporting, and patient engagement—to justify why its proposed combination would have solved the issues in Ciulla's system. Pet. at 12 (alleging patient health data benefits of "continuous, real-time data communication, allowing more personalized and timely interventions for users," "track and report health data . . . improv[ing] early detection of health issues" and "greater patient engagement"); Goodrich Decl. at ¶¶ 45-48; Borkholder Decl. at ¶¶ 43-45. Where an issue is predicated on a problem already addressed in the art, there is no motivation to combine. *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 (Fed. Cir. 2000) (affirming a finding of no motivation to combine because there was no apparent problem with the existing prior art mechanism); *Runway Safe LLC v. Engineered Arresting Sys.*, No. IPR2015-01921, Paper 9 at 6-

8, 10-11 (P.T.A.B. Feb. 29, 2016) (finding no motivation to combine because a POSITA would have had no reason to solve a problem that does not exist).

Because Petitioner's rationale, *i.e.* real-time data, tracking and reporting health data, and patient engagement, is predicated on solving a problem that does not exist in Ciulla, there is no motivation to combine Orbach's features with Ciulla. Ciulla's system offers these health data benefits as it includes features that provide continuous, real-time health data (*see* Ciulla, ¶ [0125]); generate messages to encourage the patient (¶¶ [0103], [0192]); and analyze and report health data (¶ [0192]). Goodrich Decl. at ¶ 48; Borkholder Decl. at ¶ 45.

Ciulla's system includes an LCD that displays health data in real-time and messages of encouragement, therefore providing "continuous, real-time data communication . . . [for] timely interventions" and "greater patient engagement" capabilities (Pet. at 12):

The LCD display screen 62 may be similar to a PDA, insofar as the screen may be a touch screen so that the screen 62 also serves as an input device [T]he LCD display screen can include ***things such [as] messages of encouragement (good job)***, messages regarding the user's weight, along with various menu items (e.g. program outputs, ***display results***).

Ciulla at ¶ [0103] (emphasis added).

[The] data [sic] could be reported ***in real time and displayed in real time*** at a location spatially removed from the main back module, such as in a room next door from the room in which the patient is sleeping.

Id. at ¶ [0125] (emphasis added); *see also id.* Fig. 3 (depicting the LCD screen as receiving data via a data transmitter). Accordingly, Ciulla's LCD screen feature enables the patient to "navigate through the operation of the device" to be alerted of potential health issues while also receiving encouraging messages. *Id.* at ¶ [0103]; *see also id.* at ¶ [0192] ("LCD display . . . [that] displays alerts of poorer sleep and breathing, and/or positive statements when the data analysis shows improvements."); Goodrich Decl. at ¶ 49; Borkholder Decl. at ¶ 46.

Ciulla's system also includes "track[ing] and report[ing] health data . . . improv[ing] early detection of health issues" capabilities that Petitioner looks to Orbach for. Pet. at 12. The main module 44 of Ciulla's system executes algorithms that detect and respond to sleep disordered breathing events. *See* Ciulla at ¶¶ [0095], [0101], [0129]-[0132], [0139], Fig. 3. Ciulla's system also provides analysis reports to the LCD screen and/or a healthcare provider. *Id.* at ¶ [0076] ("the display screen can be used as a device for displaying reports"), ¶ [0214] ("In the preferred embodiment of the system the microprocessor will either store its analysis reports . . . or directly transmit these reports by IT to the therapist's computer . . ."); ¶ [0230] ("The system is [] designed to permit total monitoring, control, and analyses to be performed in a different location . . . by being capable of transmitting data it obtains

at any distance, either wirelessly or by modem.”). For example, a transmitter (e.g., RF transmitter) would be attached to the medical device and wirelessly transmit the information to a web server where the physician's device can access the data. See Ciulla at ¶ [0102]; *Resmed Corp. v. Cleveland Med. Devices, Inc.*, IPR2025-00159, Ex. 1003 (Kirkness) at ¶¶ 100-101 (citing IPR2025-00159, Ex. 1043); Kirkness Tr. at 100:12-16; Chatterjee Tr. at 28:5-29:1. Accordingly, the patient's health data is “track[ed]” and “report[ed]” by Ciulla's system—without the need for an intermediate cell phone/PDA. Pet. at 12; Goodrich Decl. at ¶ 50; Borkholder Decl. at ¶¶ 47-53.

In fact, the addition of Orbach's communication technique (*i.e.* a “cell phone to wirelessly collect and transmit sleep sensor data to a remote computer”) would be completely unnecessary. Pet. at 10. Ciulla's system uses a CAST algorithm on its main module in lieu of a PDA program running on a PDA, with the system transmitting the analysis reports to the patient/healthcare provider (as discussed above). Ciulla at ¶ [0139] (“Several different CASTs will be programmed into the main processor (CPU) of the device for the CPU to use, as it will act like a PDA program.”); Goodrich Decl. at ¶ 51. Given that Ciulla already includes PDA like functionality and a transmitter, the addition of a PDA/cell phone would be completely unnecessary and introduce unwanted cost and complexity. See *In re Schweickert*, 676 F. App'x 988, 995 (Fed. Cir. 2017) (remanding the Board's

obviousness determination because the proposed modification was “unnecessary” because the prior art system “already” performed the function and the additional feature “would do little more than add unwanted cost and complexity to the system”).

Because Ciulla's system already addresses the issues that Petitioner's proposed combination with Orbach sought to solve, a POSITA would not have been motivated to add Orbach's communication technique to Ciulla's system, absent hindsight bias. Goodrich Decl. at ¶ 52.

VI. CONCLUSION

For at least the foregoing reasons, the Board should hold patentable the Challenged Claims.

Respectfully submitted,

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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 RESPONSE** specified in 37 C.F.R. § 42.24 has 3,035 words in compliance with the 14,000 word limit set forth in 37 C.F.R. § 42.24(b)(2). This word count was prepared using the Microsoft Word word-processing system used to prepare this paper.

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CERTIFICATE OF SERVICE

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

<i>Date of service</i>	September 16, 2025
<i>Manner of service</i>	Electronic Filing and Electronic Mail (PH-ResMed-CleveMed@paulhastings.com)
<i>Documents served</i>	PATENT OWNER'S RESPONSE
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