

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

Case IPR2025-00246
U.S. Patent No. 11,857,333

**PATENT OWNER'S CONTINGENT MOTION TO AMEND AND
REQUEST FOR PRELIMINARY GUIDANCE**

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37 C.F.R. § 42.121	<i>passim</i>

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 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

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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 Exhibit H01 – List of Obviousness Combinations from Defendant’s Supplemental Invalidity Contentions, <i>ResMed Corp. v. Cleveland Med. Devices, Inc.</i> , No. 1:23-cv-02221-BMB (N.D. Ohio), served on January 9, 2025
2016	M.C. Bagnato, et al., “Comparison of AutoSet and polysomnography for the detection of apnea-hypopnea events,” <i>Braz. J. Med. Biol Res.</i> , vol. 33(5), May 2000

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Exhibit	Description
2017	Salmi, T., et al., "Evaluation of automatic analysis of SCSB, airflow and oxygen saturation signals in patients with sleep related apneas," Chest, vol. 96, no. 2, Aug. 1989, available at https://go.gale.com/ps/i.do?id=GALE%7CA12682650&sid=googleScholar&v=2.1&it=r&linkaccess=fulltext&issn=00123692&p=AONE&sw=w&userGr%E2%80%A6&userGr&userGroupName=anon%7E92eb47a3&aty=open-web-entry
2018	Kelly Pneumatics webpage - How Does a CPAP Machine Work? – printed on May 9, 2025
2019	Duan, Zhenhai, et al., "Push vs. Pull: Implications of Protocol Design on Controlling Unwanted Traffic" (USENIX July 7, 2005)
2020	Bunny webpage, "What is the Hypertext Transfer Protocol (HTTP)?" available at https://bunny.net/academy/http/what-is-http-hypertext-transfer-protocol/# , dated March 12, 2025
2021	Declaration of Jeffrey H. Price
2022	Declaration of Dr. David A. Borkholder in Support of Patent Owner's Response
2023	Transportation.gov webpage, "Continuous Positive Airway Pressure (CPAP) Machines," available at https://www.transportation.gov/resources/individuals/aviation-consumer-protection/assistive-device-guides/continuous-positive#:~:text=Basic , dated August 12, 2025
2024	Cleveland Clinic webpage, "CPAP Machine: What It Is, How It Works & Side Effects," available at https://my.clevelandclinic.org/health/treatments/22043-cpap-machine , dated October 24, 2025
2025	Apnea Hypopnea Index (AHI), dated December 23, 2023, available at https://www.resmed.co.in/blogs/apnea-hypopnea-index

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Exhibit	Description
2026	Declaration of Alan R. Schwartz, M.D., <i>ResMed Corp. v. Cleveland Medical Devices, Inc.</i> , No. PGR2024-00012, Ex. 1020 (P.T.A.B. Dec. 13, 2023)
2027	K. Sutherland, et al., "Efficacy versus Effectiveness in the Treatment of Obstructive Sleep Apnea: CPAP and Oral Appliances," <i>Journal of Dental Sleep Medicine</i> , Vol. 2, No. 4, 2015
2028	K. Abu, et al., "Obstructive sleep apnea diagnosis and beyond using portable monitors," <i>Sleep Medicine</i> , Vol. 113, 260-274, Jan. 2024
2029	N. Ghahjaverestan, et al., "Sleep apnea severity based on estimate tidal volume and snoring features from tracheal signals," <i>J. Sleep Res.</i> , Vol. 32, No. 2, Sept. 2021
2030	Cambridge Dictionary, Definition of "into" available at https://dictionary.cambridge.org/us/dictionary/english/into , dated October 24, 2025
2031	Merriam-Webster Dictionary, Definition of "into" available at https://www.merriam-webster.com/dictionary/into , dated October 24, 2025
2032	Declaration of Dr. Michael Goodrich in Support of Patent Owner's Contingent Motion to Amend and Request for Preliminary Guidance
2033	U.S Patent Application No. 11/266,899
2034	Online Learning Platform webpage, "What is single-tier, Two-tier and Three-tier Architecture of Software?" available at https://statlearner.org/what-is-single-tier-two-tier-and-three-tier-architecture-of-software , dated July 17, 2025
2035	AlgoMaster webpage, "Client-Server Architecture," by Ashish Singh, available at https://algomaster.io/learn/system-design/client-server-architecture , dated September 8, 2025

I. INTRODUCTION

Patent Owner (“CleveMed”) moves under 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121 to amend U.S. Pat. No. 11,857,333 (“the ’333 Patent”). CleveMed conferred with the Board as required by 37 C.F.R. § 42.121(a), and the Board authorized the filing of this motion on October 10, 2025.

To address the invalidity grounds set forth by Petitioner, CleveMed respectfully requests that the Board grant this contingent Motion to Amend (“Motion”). Specifically, CleveMed proposes cancelling the challenged claims 15-29 and substituting proposed claims 30-41 as set forth in the claim listing in Appendix A. As shown herein the Motion meets all the requirements of 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121. And although CleveMed does not bear the burden of either persuasion or production regarding the patentability of proposed substitute Claims 30-41, the Motion and supporting declaration of Dr. Goodrich demonstrate that the substitute claims are patentable over the references at issue in this proceeding. *See In re Aqua Prods., Inc.*, 872 F.3d 1290, 1295-96 (Fed. Cir. 2017).

II. STATEMENT OF THE RELIEF REQUESTED

CleveMed respectfully requests that the Board consider this Motion and grant entry of the following proposed amendments:

- Cancel claims 15-29; and

- Substitute canceled claims 15-16, 19, 21-29 with claims 30-41 as shown below (with the claimed dependencies shown in parentheses):

Original Claim	Substitute Claim
15	30
16	31
19	32 (30)
21	33 (30)
22	34 (30)
23	35 (34)
24	36 (34)
25	37 (30)
26	38 (30)
27	39 (30)
28	40 (30)
29	41 (30)

Pursuant to 37 C.F.R. § 42.121(b), a listing of the claims is attached hereto as Appendix A.

III. REQUEST FOR PRELIMINARY GUIDANCE FROM THE BOARD

Pursuant to 37 C.F.R. § 42.121(e), CleveMed requests the Board provide preliminary guidance on the Motion.

IV. THE SUBSTITUTE CLAIMS MEET THE PROCEDURAL REQUIREMENTS OF 37 C.F.R. § 42.121

Under *Lectrosonics, Inc. v. Zaxcom, Inc.*, No. IPR2018-01129, Paper 15 (P.T.A.B. Feb. 25, 2019) (precedential), the Board must determine whether “the motion to amend meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121.” *Id.* at 4. To meet these requirements, a patent owner’s motion must: (1) propose a reasonable number of substitute claims

(35 U.S.C. § 316(d)(1)(B); 37 C.F.R. § 42.121(a)(3)); (2) present substitute claims that do not enlarge claim scope (35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii)); (3) set forth written description support from the original disclosure (37 C.F.R. § 42.121(b)(1)-(2)); and (4) introduces amendments that respond to a ground of unpatentability involved in the trial (37 C.F.R. § 42.121(a)(2)(i)). *See Lectrosonics*, Paper 15 at 4-8.

As shown below, all statutory and regulatory requirements are met here.

A. The Number of Substitute Claims is Reasonable

Pursuant to 35 U.S.C. § 316(d)(1)(b), CleveMed's Motion proposes a reasonable number of substitute claims. "There is a rebuttable presumption that a reasonable number of substitute claims per challenged claim is one (1) substitute claim." *Lectrosonics*, Paper 15 at 4. CleveMed proposes a one-to-one substitution of claims by cancelling original claims 15-16, 19, 21-29 (**12 claims**) and substituting claims 30-41 (**12 claims**).

B. The Substitute Claims are Non-Broadening

Pursuant to § 316(d)(3) and § 42.121(a)(2)(ii), CleveMed's Motion presents substitute claims that do not enlarge the scope of the claims. "A substitute claim will meet [these requirements] if it narrows the scope of at least one claim of the patent" or if it "add[s] a novel and nonobvious feature or combination to avoid the prior art in an instituted ground of unpatentability." *Lectrosonics*, Paper 15 at 6-7.

The substitute claims do not enlarge the scope of the original claims. Substitute Independent Claim 30 narrows the scope of original Independent Claim 15 by adding claim features that avoid the prior art in Grounds 1-4, which is explained in detail in Section VI.C, *infra*. For example, substitute Independent Claim 30 adds a limitation establishing that the therapy administered by the PAP or CPAP device is configured to be adjusted by the subject's cell phone and the remote computer of a medical professional. *See* Appendix A.

C. The Substitute Claims Have Written Description Support

Pursuant to § 42.121(b)(1)-(2), CleveMed's Motion sets forth written description support from the original disclosure. *Lectrosonics*, Paper 15 at 7 (explaining that the "original disclosure" is "the application as originally filed").

The substitute claims are supported by U.S. Patent App. No. 15/641,715 (the "'715 Application," Ex. 1002), which issued as the '333 Patent, filed on July 5, 2017, and U.S Patent App. No. 11/266,899 (the "'899 Application"), which is the first non-provisional application in the chain of priority, filed on November 4, 2005.¹

The '715 and '899 Applications disclose the Amended Independent Claim 30's requirements that a subject's cell phone and remote internet site receive the

¹ The '333 Patent is a continuation-in-part of the '899 Application. *See* '333 Patent at (63).

subject's sleep data . *See, e.g.*, Ex. 1002 at 29:13-31:12 (disclosing the transmission of the subject's sleep data to a cell phone and a remote internet site), 72:25-73:18 (disclosing the transmission of the subject's sleep data to a remote internet site hosted on a server); Ex. 2033 at 34:9-21 (disclosing a "remote internet site for analysis"). Those applications also disclose the additional requirement that the patient's cell phone and medical provider's remote computer contain software configured to adjust the therapy administered by the PAP or CPAP device. *See* Ex. 1002 at 34:20-24 (disclosing that the clinician or the subject can adjust the therapy administered by the PAP device based on the diagnostic device's output data), 5:2-12 (disclosing that the diagnostic device transmits output data to intermediary devices such as a cell phone, modem, or router); Ex. 2033 at 38:24-39:28.

The table below shows for substitute Independent Claim 30 written description support from the '715 and '899 Applications and for the substitute dependent claims written description support from at least the '715 Application.

Claim Limitation	Support for Substitute Claims 30-41 in the '715 Application	Support for Substitute Claims 30-41 in the '899 Application
Claim 30 (Substituting for Claim 15) A method of treating a subject's sleep apnea comprising steps of:	Ex. 1002 at 3:9-19, 6:25-9:8, 12:2-6, 87 (Abstract)	Ex. 2033 at 3:19-26, 39:19-40:19
providing a therapy to a subject using a PAP or CPAP device while sleeping, the PAP or	Ex. 1002 at 3:9-19, 4:5-19, 5:29-12:1, 15:3-17, 20:16-24, 92-93 (Figs. 7-8)	Ex. 2033 at 3:19-29, 4:19-5:5, 5:20-7:27, Figs. 7-8

Claim Limitation	Support for Substitute Claims 30-41 in the '715 Application	Support for Substitute Claims 30-41 in the '899 Application
CPAP comprising a flow or pressure sensor, and a processor both which are integrated into the PAP or CPAP device;		
collecting data with the PAP or CPAP device from the flow or pressure sensor during a time period of the therapy;	Ex. 1002 at 5:13-28, 9:25-10:30 15:3-17, 20:16-21:29	Ex. 2033 at 14:16-16:25
analyzing with the processor the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy;	Ex. 1002 at 12:2-6, 30:5-32:1	Ex. 2033 at 33:4-35:15
transmitting, in either order, both 1) the collected data and/or the quantified level of severity data to a subject's cellular phone with downloadable first software via a radio frequency wireless link; and 2) the collected data and/or the quantified level of severity data to a remote internet site hosted on at least one server from either a) the PAP or CPAP device via a cellular system, or b) the subject's cellular	Ex. 1002 at 5:2-12, 10:1-13, 29:13-31:12, 72:25-73:18, 95 (depicting Fig. 10)	Ex. 2033 at 34:9-21

Claim Limitation	Support for Substitute Claims 30-41 in the '715 Application	Support for Substitute Claims 30-41 in the '899 Application
<p>phone to the remote internet site via the cellular system or Internet for further analysis with a second processor on the at least one server and review of the collected data, the quantified level of severity and/or this analysis by a clinician, technician or physician at a remote computer;</p>		
<p>further determining therapy efficacy data with either the processor of the PAP or CPAP device, the second processor configured with a second software stored on a computer readable medium at the at least one server or the subject's cellular phone using the first software further provided to receive and display the quantified level of severity data and/or therapy efficacy data to the subject and</p>	<p>Ex. 1002 at 12:2-6, 20:3-10, 29:13-32:1, 42:9-18, 72:25-73:18, 95 (depicting Fig. 10)</p>	<p>Ex. 2033 at 5:6-7:14, 34:9-21</p>
<p>wherein the therapy administered by the PAP or CPAP device is configured to be adjusted by the first software on the subject's</p>	<p>Ex. 1002 at 5:2-12, 11:17-12:1, 34:20-24, 72:25-73:18</p>	<p>Ex. 2033 at 34:9-21, 38:24-39:28</p>

Claim Limitation	Support for Substitute Claims 30-41 in the '715 Application	Support for Substitute Claims 30-41 in the '899 Application
<p>cell phone and the remote computer of the clinician, technician, or physician based on the wirelessly transmitted collected data, quantified level of severity data, or the therapy efficacy data.</p>		
<p>Claim 31 (Substituting for Claim 16) The method of claim 30, wherein the subject's cellular phone and the PAP or CPAP device each have a Bluetooth standard wireless RF connection and can communicate directly with each other through the wireless connection in real time.</p>	<p>Ex. 1002 at 21:14-18, 27:28-28-3, 28:19-28</p>	<p>Ex. 2033 at 15:3-4</p>
<p>Claim 32 (Substituting for Claim 19) The method of claim 30, wherein the steps of the method can be used to train the PAP or CPAP to adjust or titrate itself to better identify and distinguish between obstructive, central and complex sleep apneas during a second time period with data from the first sensor.</p>	<p>Ex. 1002 at 34:25-35:12, 38:17-23</p>	

Claim Limitation	Support for Substitute Claims 30-41 in the '715 Application	Support for Substitute Claims 30-41 in the '899 Application
<p>Claim 33 (Substituting for Claim 21) The method of claim 30, wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician from the remote computer.</p>	<p>Ex. 1002 at 31:13-26</p>	<p>Ex. 2033 at 34:22-35:9</p>
<p>Claim 34 (Substituting for Claim 22) The method of claim 30, including the step of storing the collected data, the quantified level of severity data from either the PAP or CPAP device transmitted to the remote internet site, and/or data based on the transferred data on a database with similar data from treatments of many other subjects.</p>	<p>Ex. 1002 at 29:22-26, 65:3-9, 72:25-73:18</p>	<p>Ex. 2033 at 34:9-21</p>
<p>Claim 35 (Substituting for Claim 23) The method of claim 34, wherein the database is stored on the at least one server, which consists of either a central server or a group of servers remote to the test location, the central server or the group of servers and upon which the second software is</p>	<p>Ex. 1002 at 29:22-26, 65:3-9 72:25-73:18</p>	<p>Ex. 2033 at 34:9-21</p>

Claim Limitation	Support for Substitute Claims 30-41 in the '715 Application	Support for Substitute Claims 30-41 in the '899 Application
<p>stored on a computer readable medium and executed by the central server or the group of servers.</p>		
<p>Claim 36 (Substituting for Claim 24) The method of claim 34, including the step of analyzing the data on the database with a relationship algorithm or a neural network to determine an optimal treatment for the subject.</p>	<p>Ex. 1002 at 5:25-28, 29:22-26, 35:3-12, 36:26-37:2, 72:25-73:18</p>	
<p>Claim 37 (Substituting for Claim 25) The method of claim 30, wherein the PAP or CPAP device, the software on the subject's cellular phone or the remote internet site determines a total sleep time.</p>	<p>Ex. 1002 at 20:3-15, 38:24-39:8</p>	
<p>Claim 38 (Substituting for Claim 26) The method of claim 30, wherein the processor of the PAP or CPAP device analyzes the collected data, in part, using one or more of a Short-Time Fourier Transform, a Discrete Fourier Transform, a Fast Fourier Transform,</p>	<p>Ex. 1002 at 32:2-16, 33:19-23</p>	<p>Ex. 2033 at 35:23-36:4, 37:15-19</p>

Claim Limitation	Support for Substitute Claims 30-41 in the '715 Application	Support for Substitute Claims 30-41 in the '899 Application
<p>a recursively identified system model, a standard deviation technique, a time-frequency signal analysis and/or a Wavelet signal analysis to determine the quantified level of severity data.</p>		
<p>Claim 39 (Substituting for Claim 27) The method of claim 30, wherein the processor of the PAP or CPAP device analyzes the collected data, in part, using a time-frequency signal analysis to determine the quantified level of severity data.</p>	<p>Ex. 1002 at 32:2-16, 33:5-34:24</p>	<p>Ex. 2033 at 35:23-36:4, 38:6-17</p>
<p>Claim 40 (Substituting for Claim 28) The method of claim 30, wherein the PAP or CPAP further comprises a firmware and/or a third software which along with the first software can be updated from the remote internet site or a different remote server.</p>	<p>Ex. 1002 at 63:21-64:5</p>	
<p>Claim 41 (Substituting for Claim 29) The method of claim 30, further comprising the step of alerting the</p>	<p>Ex. 1002 at 44:20-28, 47:3-12</p>	<p>Ex. 2033 at 5:6-16.</p>

Claim Limitation	Support for Substitute Claims 30-41 in the ’715 Application	Support for Substitute Claims 30-41 in the ’899 Application
subject’s technician, clinician or physician of issues related to the therapy efficacy.		

D. The Substitute Claims are Responsive to the Grounds of Unpatentability

Pursuant to 37 C.F.R. § 42.121(a)(2)(i), CleveMed’s Motion introduces amendments that respond to Grounds 1-4. As shown in the sections that follow, the amendments introduce novel and nonobvious features that avoid the prior art and Petitioner’s proposed combinations. *Lectrosonics*, Paper 15 at 6-7.

V. PERSON OF ORDINARY SKILL IN THE ART (POSITA)

A person of ordinary skill in the art in 2005 is someone having “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, such as networked PAP machines. Additional experience could substitute for less education, and additional education could likewise substitute for less experience.” Pet. at 3-4; Ex. 2032 (“Goodrich Decl.”) at ¶¶ 29-31.

VI. THE SUBSTITUTE CLAIMS ARE PATENTABLE OVER THE INSTITUED GROUNDS

Substitute Independent Claim 30 and its dependents are responsive to and patentable over Petition Grounds 1-4.² Grounds 1 and 2 each rely on Toge (Ex. 1044) as a primary reference. Ground 1 relies on Toge in view of Kumar (Ex. 1008), and Ground 2 relies on Toge in view of Kumar and Norman (Ex. 1059). *See* Pet. at 1. Substitute Independent Claim 30 introduces the following claim features that are not disclosed in Toge, and the other asserted references do not fill in the gap because either they too lack disclosure, or a POSITA would not have been motivated to have made the combination to arrive at the claimed invention:

- “the therapy administered by the PAP or CPAP device [] configured to be adjusted by the first software on the subject’s cellular phone;”
- “a subject’s cellular phone with downloadable first software” that “using the first software further provided to receive and display” the subject’s sleep data; and
- “a remote internet site hosted on at least one server.”

² Grounds 1 and 2 challenge independent claim 15 while the other two grounds challenge claims depending from the independent claim. *See* Pet. at 1. Accordingly, the analysis herein is centered on the independent claim as challenged in Grounds 1 and 2 and which also applies to the other grounds.

Substitute Independent Claim 30 (Appendix A); *see also* Goodrich Decl. at ¶ 32.

A. The Asserted Art Does Not Disclose a Patient's Cell Phone That Adjusts the PAP or CPAP Therapy (Grounds 1 and 2)

The asserted art, including Toge, Kumar, and Norman, does not disclose a software on a patient's cell phone that is configured to adjust the therapy administered by the patient's PAP or CPAP device, as recited in substitute Independent Claim 30. *See* Appendix A, Substitute Independent Claim 30; Goodrich Decl. at ¶ 33.

This claim limitation is novel and nonobvious because no asserted art in the grounds discloses a PAP/CPAP device therapy being adjusted by the patient's cell phone. Toge discloses pushing "necessary" or "crucial" data to a physician's computer, so that the physician can remotely monitor the patient's PAP therapy and respond to medical emergencies. Toge at Abstract, ¶¶ [0001]-[0006], [0046]-[0047], [0054], [0057]. Accordingly, Toge's system includes physician-side computers and physician-side mobile terminals that allow physicians to review patient sleep data and respond to medical emergencies, if necessary. *Id.* at ¶¶ [0018]-[0019], [0039], [0047], [0054]. However, Toge's system does not include a patient's cell phone, let alone one that adjusts the PAP device. Goodrich Decl. at ¶ 34.

Kumar and Norman also do not disclose PAP therapy adjustment by a patient's cell device. Nowhere do these references discuss the use of a patient's cell phone to modify a CPAP/PAP device therapy treatment. Although Kumar discloses

a patient-side computing device, this device simply manages the transmission of data between the patient-side medical device and the web server. *See* Kumar at ¶¶ [0018], [0072], Claims 5, 9. And rather than a patient or medical provider adjusting the therapy of a PAP device, Norman discloses a PAP device that automatically adjusts its own treatment pressure in response to sensor data. *See* Norman at Title, Abstract, ¶¶ [0007], [0023]. Thus, neither of these references use a patient's cell phone to adjust the PAP device's treatment therapy. Goodrich Decl. at ¶ 35.¶

For at least these reasons, substitute Independent Claim 30 and its dependents are patentable over Toge, Kumar, and Norman. *Id.* at ¶ 36.

B. Toge in View of Kumar Does Not Teach a Patient's Cell Phone with Downloadable Software That Receives and Displays Patient's Sleep Data (Grounds 1 and 2)

Toge in view of Kumar does not teach the claim features of a patient's cell phone with downloadable first software receiving and displaying sleep data as recited in substitute Independent Claim 30. This claim feature is novel and nonobvious because Toge does not disclose the use of patient's cell phone in its system, and a POSITA would not have been motivated to add a patient's cell phone to Toge's system because Toge is directed to the physician so there was no problem that needed solving that would have motivated this modification. Goodrich Decl. at ¶ 37.

Toge does not disclose a patient's cell phone, let alone any claimed associated features, because its system is directed to solving the problem related to a physician's remote monitoring, as discussed above. Toge at Abstract (“[e]nabling remote monitoring of the patient's condition”), ¶ [0018] (“*Medical institution personnel such as physicians and nurses can access the transmitted data* using the physician-side computer 4.”), ¶ [0047] (“[I]f the oxygen saturation, for example, falls below 90%, *physicians can take emergency measures . . .*”) (emphases added); *see also id.* at ¶¶ [0039], [0055]; Goodrich Decl. at ¶ 38.

Because Toge's system already independently operates effectively for its purpose, there is no reason to add a patient's cell phone with downloadable software. *See Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1369 (Fed. Cir. 2012) (“Because each device independently operates effectively, a person having ordinary skill in the art, who was merely seeking to create a better device . . . would have no reason to combine the features of both devices into a single device”). In fact, Toge's PAP device includes a PAP display screen that already allows a patient to view their sleep data. Petitioner does not dispute this. *See ResMed Corp. v. Cleveland Med. Devices, Inc.*, No. IPR2025-00160 (the “-00160 IPR”), Paper 1 at 33 (P.T.A.B. Dec. 6, 2024) (arguing that a PAP device as in Toge includes “a screen suitable for displaying data to the patient”). Thus, aside from there being no need

for a patient's cell phone, it would also have been completely unnecessary because of the display screen. Goodrich Decl. at ¶¶ 39-40.

For at least this reason, substitute Independent Claim 30 and its dependents are patentable over Toge, Kumar, and Norman.

C. Toge Alone or in View of Kumar Does Not Teach a “Remote Internet Site” That is “Hosted on At Least One Server”

Toge in view of Kumar does not teach the “remote internet site hosted on at least one server” features as recited in substitute Independent Claim 30. Toge does not disclose “a remote internet site” that is “hosted on at least one server,” as conceded in its co-pending IPR challenge against related U.S. Patent No. 11,786,680 (the “’680 Patent”). -00160 IPR, Paper 1 at 45-46. Kumar does not resolve Toge's deficiency. In the Petition, Petitioner modifies Toge's system with Kumar's web server (hosting a browser-based engine) accessible via a web page. *See* Pet. at 23-25. However, a POSITA would not have found it obvious to make such a modification because it would have interfered with Toge's purpose of pushing crucial treatment data to the physician-side devices. Goodrich Decl. at ¶¶ 41-48.

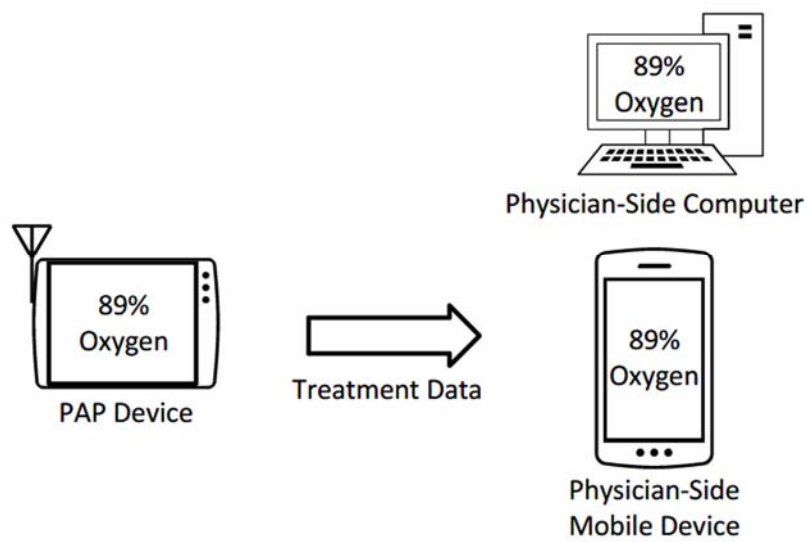
1. Toge Does Not Disclose a “Remote Internet Site” That is “Hosted on At Least One Server”

Toge does not disclose “remote internet site” that is “hosted on at least one server,” Petitioner does not dispute this in the co-pending -00160 IPR. *See* -00160

IPR, Paper 1 at 45-46 (relying on Kumar's web server for similar claim limitations in the '680 Patent); Goodrich Decl. at ¶ 42.

Instead of including a remote internet site hosted on a server, where data is stored, further analyzed, and provided upon request as in the '333 Patent, Toge's system pushes patient data to the doctor's computer and mobile device for analysis and without request. *Compare* '333 Patent at 51:38-63, Substitute Independent Claim 30 *with* Toge at ¶¶ [0050]-[0054].³ The physician's devices, therefore, automatically receive "necessary" and "crucial" treatment data (e.g., oxygen saturation of 89%) so that they can analyze the data and take emergency measures. *See* Toge at ¶¶ [0019], [0047], [0054]; Goodrich Decl. at ¶ 43.

³ Toge's system implements a push protocol as the physician-side devices passively accepts the data without making any request. Ex. 2019 at 25-26 (describing that in a push protocol, the "receiver[] *passively accept[s]* whatever the sender[] push[es]to them") (emphasis added).



Goodrich Decl. at ¶ 43 (providing a rendition of Toge's Figure 1 where the relay device is incorporated within the PAP device such that treatment data is transferred directly to the physician-side devices as in one embodiment) (citing Toge at Fig. 1, ¶¶ [0060]-[0061]). Even in the embodiment where the relay device is separate from the PAP device, this “necessary” or “crucial” treatment data is still pushed to the physician-side devices. Toge at ¶¶ [0016], [0054].

There is no “remote internet site” in Toge's system, expressly or inherently, because patient data is pushed to the necessary physician-side devices without traversing any such site. *See id.* at ¶ [0009]. In fact, changing Toge's system to require client devices to request data from a web server—which uses a pull protocol instead of a push protocol—would have interfered with Toge's ability to push crucial treatment data to the physician-side devices. *See* Goodrich Decl. at ¶ 44 (citing Ex.

2020 at 2-3 (describing that “HTTP is a pull protocol” as “information can only be pulled from a web server after a client’s request”).

In view of the foregoing, Toge does not disclose a “remote internet site” that is “hosted on at least one server.” Goodrich Decl. at ¶ 45.

2. Modifying Toge With Kumar Would Have Interfered with Toge’s Purpose

Kumar’s web server teaching does not cure the Toge deficiency because Kumar’s web server would interfere with Toge’s purpose. *See* Goodrich Decl. at ¶ 46; *Medtronic, Inc. v. Teleflex Innovations S.à.r.l.*, 69 F.4th 1341, 1349-50 (Fed. Cir. 2023) (it would have been “error for the Board to ignore evidence that a proposed modification would interfere with a reference’s stated purpose” and affirming the Board’s finding that challenged patent was non-obvious because “the destruction of [a prior art reference’s] ‘entire premise’ ‘counsel[ed] strongly against’ obviousness”).

The purpose of Toge’s system is to push “necessary” or “crucial” data to physician-side devices so that physicians can monitor their patients and take emergency action when needed. *See* Toge at Abstract, ¶¶ [0001]-[0006], [0046]-[0047], [0054], [0057]. Toge explains that by setting a threshold (for example, 90% oxygen saturation), the physician-side devices are pushed “crucial data” when the threshold is met such that physicians “can take emergency measures” (adjusting the pressure of the PAP device, for example). *Id.* at ¶ [0047]; *see also id.* at ¶¶ [0039],

[0054] (“[I]t becomes possible to selectively transmit only the necessary or crucial data to the physician-side computer 4 or portable device 5.”).⁴ In this way, physicians can care for their patients who are in critical condition without having to log into a web page and make requests for data. Goodrich Decl. at ¶ 47.

Implementing a web server that transmits the data upon a client request would interfere with Toge's purpose. In the client/server-model, a physician would request the data from the web server instead of the data being pushed to the physician. Goodrich Decl. at ¶ 48; Ex. 1005 at ¶¶ 32-34 (explaining how a web server stores the Internet's data and provides the data to clients upon a HTTP request); Ex. 2034, Ex. 2035 at 2-3. Because data is pulled only upon request, Toge's purpose of pushing, without request, “necessary” or “crucial” (Toge at ¶ [0054]) treatment data would be interfered with. Ex. 2019 at 25-26; Ex. 2020 at 2-3.

* * *

For at least these reasons, substitute Independent Claim 30 and its dependents are patentable over Toge, Kumar, and Norman.

⁴ A push protocol is where “a sender can deliver traffic *at will* to a receiver” and the “receiver[] *passively accept[s]* whatever the sender[] push[es] to them.” Ex. 2019 at 25-26 (emphases added).

VII. CONCLUSION

In view of the foregoing, CleveMed respectfully requests that the Board grant the Motion, cancel claims 15-29 and substitute claims 30-41 as set forth in Appendix A.

Respectfully submitted,

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(Case No. IPR2025-00246)

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APPENDIX A

Listing of Claims

CleveMed presents the following contingent substitute claims for claims 15-29. Pursuant to 37 C.F.R. § 1.121(c)(2), the use of strikethroughs/double brackets indicate deleted text and underlining indicates inserted text.

Claims 1-14 (not challenged)

Claims 15-29. (Canceled).

[[15.]] 30. (Proposed Substitute for Claim 15) A method of treating a subject's sleep apnea comprising steps of:

providing a therapy to a subject using a PAP or CPAP device while sleeping, the PAP or CPAP comprising a flow or pressure sensor, and a processor both which are integrated into the PAP or CPAP device;

collecting data with the PAP or CPAP device from the flow or pressure sensor during a time period of the therapy;

analyzing with the processor the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy;

transmitting, in either order, both 1) the collected data and/or the quantified level of severity data to a subject's cellular phone with downloadable first software via a radio frequency wireless link; and 2) the collected data and/or the quantified level of severity data to a remote internet site hosted on at least one server ~~the remote~~

~~station~~ from either a) the PAP or CPAP device via a cellular system, or b) the subject's cellular phone to the remote internet site ~~a remote station~~ via the cellular system or ~~[[the]]~~ Internet for further analysis with a second processor on the at least one server ~~or a server at the remote station~~ and review of the collected data, the quantified level of severity and/or this analysis by a clinician, technician, or physician at a remote computer; ~~[[and]]~~

further determining ~~[[the]]~~ therapy efficacy data with either the processor of the PAP or CPAP device, the second processor ~~or server~~ configured with a second software stored on a computer readable medium at the at least one server ~~at the remote station~~, or the subject's cellular phone using the first software further provided to receive and display the quantified level of severity data and/or therapy efficacy data to the subject ~~or a care provider~~; and

wherein the therapy administered by the PAP or CPAP device is configured to be adjusted by the first software on the subject's cellular phone and the remote computer of the clinician, technician, or physician based on the wirelessly transmitted collected data, quantified level of severity data, or the therapy efficacy data.

[[16.]] 31. (Proposed Substitute for Claim 16) The method of claim ~~[[15]]~~ 30, wherein the subject's cellular phone and the PAP or CPAP device each have a

Bluetooth standard wireless RF connection and can communicate directly with each other through the wireless connection in real time.

[[19.]] 32. (Proposed Substitute for Claim 19) The method of claim [[15]] 30, wherein the steps of the method can be used to train the PAP or CPAP to adjust or titrate itself to better identify and distinguish between obstructive, central and complex sleep apneas during a second time period with data from the first sensor.

[[21.]] 33. (Proposed Substitute for Claim 21) The method of claim [[20]] 30, wherein the PAP or CPAP is adjusted or titrated in real-time by the technician, clinician or physician from the remote computer ~~a remote location~~.

[[22.]] 34. (Proposed Substitute for Claim 22) The method of claim [[15]] 30, including the step of storing the collected data, the quantified level of severity data from either the PAP or CPAP device transmitted to the ~~remote station~~ remote internet site, and/or data based on the transferred data on a database with similar data from treatments of many other subjects.

[[23.]] 35. (Proposed Substitute for Claim 23) The method of claim [[22]] 34, wherein the database is stored on the at least one server, which consists of either a central server or on a group of servers remote to the test location, the central server[[s]] or the group of servers and upon which the second software is stored on a computer readable medium and executed by the central server or the group of servers.

[[24.]] 36. (Proposed Substitute for Claim 24) The method of claim [[23]] 34, including the step of analyzing the data on the database with a relationship algorithm or a neural network to determine an optimal treatment for the subject.

[[25.]] 37. (Proposed Substitute for Claim 25) The method of claim [[23]] 30, wherein the PAP or CPAP device, the software on the subject's cellular phone or the remote internet site ~~remote station~~ determines a total sleep time.

[[26.]] 38. (Proposed Substitute for Claim 26) The method of claim [[23]] 30, wherein the processor of the PAP or CPAP device analyzes the collected data, in part, using one or more of a Short-Time Fourier Transform, a Discrete Fourier Transform, a Fast Fourier Transform, a recursively identified system model, a standard deviation technique, a time-frequency signal analysis and/or a Wavelet signal analysis to determine the quantified level of severity data.

[[27.]] 39. (Proposed Substitute for Claim 27) The method of claim [[23]] 30, wherein the processor of the PAP or CPAP device analyzes the collected data, in part, using a time-frequency signal analysis to determine the quantified level of severity data.

[[28.]] 40. (Proposed Substitute for Claim 28) The method of claim [[15]] 30, wherein the PAP or CPAP further comprises a firmware and/or a third software which along with the first software can be updated from the remote internet site ~~remote station~~ or a different remote server.

[[29.]] 41. (Proposed Substitute for Claim 29) The method of claim [[15]] 30, further comprising the step of alerting the subject's technician, clinician or physician of issues related to the therapy efficacy.

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), service was made on the Petitioner as detailed below.

<i>Date of service</i>	October 29, 2025
<i>Manner of service</i>	Electronic Filing and Electronic Mail (PH-ResMed-CleveMed@paulhastings.com)
<i>Documents served</i>	PATENT OWNER'S CONTINGENT MOTION TO AMEND AND REQUEST FOR PRELIMINARY GUIDANCE
<i>Persons Served</i>	Paul Hastings LLP Lisa K. Nguyen David M. Tennant Eric E. Lancaster Grace Wang Howard Herr Kamilah Alexander Maksim Mints Rachel Wu Hankinson

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