

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,
v.

CLEVELAND MEDICAL DEVICES INC.,
Patent Owner.

Case No. IPR2023-00565
U.S. Patent No. 10,076,269

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	OVERVIEW	2
	A. Background of the Technical Field	2
	B. The ’269 Patent	4
III.	CLAIM CONSTRUCTION	7
IV.	THE BOARD SHOULD DENY THE PETITION UNDER <i>FINTIV</i>	9
	A. <i>Fintiv</i> Factor 1: There is Little to no Likelihood that a Stay Would be Granted in District Court	10
	B. <i>Fintiv</i> Factor 2: The District Court’s Scheduled Trial Date is Roughly Three Months Before the Expected Date of Any Final Written Decision.....	11
	C. <i>Fintiv</i> Factor 3: Significant Investment in the Parallel Litigation Will Have Occurred by the Time the Board’s Institution Decision is Due	13
	D. <i>Fintiv</i> Factor 4: There is Substantial Overlap Between the IPR Proceeding and the Parallel Litigation	15
	E. <i>Fintiv</i> Factor 5: Defendant is an RPI.....	18
	F. <i>Fintiv</i> Factor 6: The Petition is Without Merit and ResMed Has Abused the Process.....	19
V.	THE BOARD SHOULD DENY THE PETITION UNDER 35 U.S.C. § 325(d).....	20
	A. Advanced Bionics Step 1 (Becton, Dickinson Factors (a), (b), and (d)): The same or substantially the same prior art was previously presented to the USPTO.	21

B.	<i>Advanced Bionics</i> Step 2 (<i>Becton, Dickinson</i> Factors (c), (e), and (f)): Petitioner has made no showing of material examiner error.	24
VI.	LEVEL OF ORDINARY SKILL IN THE ART	26
VII.	THE CHALLENGED CLAIMS ARE PATENTABLE	27
A.	GROUND 1: The Challenged Claims are Patentable Over the Genger Combinations.....	27
1.	Genger in View of Westbrook Does not Disclose a CPAP Processor that Calculates Sleep Disorder Symptom Data Based on Respiratory Airflow and Pulse Oximetry Sensor Data (Claims 1-7).....	28
2.	Genger in View of Farrell Does Not Disclose an Internal Respiratory Airflow Sensor (Claims 1-4).....	30
B.	GROUND 3: The Challenged Claims are Patentable	32
1.	Stahmann does not teach or suggest a CPAP for providing a pharmaceutical agent based on the level of severity of the subject's sleep disorder symptoms."	33
C.	GROUND 6: The Challenged Claims are Patentable	35
1.	Kocinski alone or in combination with Farrell fails to teach or suggest an internal PAP airflow sensor is "adapted for measuring the respiratory airflow of a subject and outputting airflow sensor data."	36
2.	Kocinski does not teach or suggest transmitting symptom data and/or index of symptom data from the CPAP device via the base station to a remote internet site.....	37
3.	Kocinski does not teach or suggest a base station, cellular phone or PDA adapted to display the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms.....	40

VIII. CONCLUSION.....	41
-----------------------	----

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GmbH,</i> No. IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020).....	20, 21, 24, 26
<i>Apcon, Inc. v. Gigamon Inc.,</i> No. IPR2020-01583, Paper 9 (P.T.A.B. Mar. 16, 2021)	14
<i>Apple Inc. v. Fintiv, Inc.,</i> No. IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020)	passim
<i>Apple Inc. v. Optis Cellular Tech. LLC,</i> No. IPR2020-00465, Paper 13 (P.T.A.B. Sept. 17, 2020).....	16
<i>Apple v. Maxell, Ltd.,</i> No. IPR2020-00407, Paper 12 (P.T.A.B. Aug. 11, 2020).....	17
<i>BMW of North Am., LLC v. Stragent, LLC,</i> No. IPR2021-00419, Paper 21 (P.T.A.B. Mar. 12, 2022)	22
<i>Darfon Elecs. Corp. v. Shipman,</i> No. IPR2022-01008, Paper 11 (P.T.A.B. Dec. 2, 2022)	25
<i>Dir., Office of Workers' Comp. Programs, Dep't of Labor v.</i> <i>Greenwich Collieries,</i> 512 U.S. 267 (1994).....	24
<i>eClinicalWorks, LLC v. Decapolis LLC,</i> No. IPR2022-00229, Paper 10 (P.T.A.B. Apr. 13, 2022)	12
<i>Fanduel, Inc. v. Interactive Games LLC,</i> 966 F.3d 1334 (Fed. Cir. 2020)	24
<i>Forest Lab'ys, LLC v. Sigmapharm Lab'ys LLC,</i> 918 F.3d 928 (Fed. Cir. 2019)	41
<i>Gator Bio, Inc. v. Sartorius Bioanalytical Insts., Inc.,</i> No. IPR2023-00215, Paper 19 (P.T.A.B. June 20, 2023)	23, 24

<i>GlaxoSmithKline Consumer Healthcare Holdings (US) LLC v. Cipla Ltd.,</i> No. IPR2020-00371, Paper 7 (P.T.A.B. July 31, 2020)	21
<i>Immersion Sys. LLC v. Midas Green Techs., LLC,</i> No. IPR2021-01176, Paper 16 (P.T.A.B. Jan. 6, 2022)	12
<i>Next Caller Inc. v. Trusted, Inc.,</i> No. IPR2019-00961, Paper 10 (P.T.A.B. Oct. 16, 2019)	14
<i>NXP USA, Inc. v. Impinj, Inc.,</i> No. IPR2021-01556, Paper 10 (P.T.A.B. Apr. 21, 2022)	12
<i>Orthopediatrics Corp. v. K2M, Inc.,</i> No. IPR2018-01548, Paper 9 (P.T.A.B. Mar. 1, 2019)	7, 9
<i>Palo Alto Networks, Inc. v. Centripetal Networks, Inc.,</i> No. IPR2021-01270, Paper 10 (P.T.A.B. Jan. 24, 2022)	21
<i>Parus Holdings, Inc. v. Google LLC,</i> Nos. 22-1269, -1270, 2023 U.S. App. LEXIS 14543 (Fed. Cir. June 12, 2023)	31
<i>Princeton Dig. Image Corp. v. Konami Dig. Entm't Inc.,</i> No. 12-1461-LPS-CJB, 2014 WL 3819458 (D. Del. Jan. 15, 2014)	10
<i>Samsung Elecs. Co. v. Power2B Inc.,</i> No. IPR2022-01378, Paper 12 (P.T.A.B. Mar. 15, 2023)	7
<i>Samsung Electronics Co. v. California Institute of Tech.,</i> No. IPR2023-00133, Paper 10 (P.T.A.B. May 4, 2023)	18
<i>Sand Revolution II, LLC v. Cont'l Intermodal Grp. – Trucking LLC,</i> No. IPR2019-01393, Paper 24 (P.T.A.B. June 16, 2020)	11, 18
<i>SenoRx, Inc. v. Hologic, Inc.,</i> No. 12-173-LPS-CJB, 2013 WL 144255 (D. Del. Jan. 11, 2013)	13
<i>Sonos, Inc. v Google, LLC,</i> No. IPR2021-00963, Paper 9 (P.T.A.B. Nov. 9, 2021)	22
<i>Sotera Wireless, Inc., v. Masimo Corp.,</i> No. IPR2020-01019, Paper 12 (P.T.A.B. Dec. 1, 2020)	10, 17

<i>Ta Instruments-Waters LLC v. Malvern Panalytical Inc.</i> , No. IPR2021-00211, Paper 8 (P.T.A.B. May 27, 2021)	14
<i>Toshiba Samsung Storage Tech. Korea Corp. v. LG Elecs., Inc.</i> , 193 F. Supp. 3d 345 (D. Del. 2016).....	10
<i>TwinStrand Biosciences, Inc. v. Guardant Health, Inc.</i> , No. 21-1126-GBW-SRF, 2023 WL 2563179 (D. Del. Mar. 17, 2023)	10
<i>Wolfspeed, Inc. v. The Trustees of Purdue Univ.</i> , No. IPR2022-00761, Paper 9 (P.T.A.B. Nov. 8, 2022).....	25
<i>Xerox Corp. v. Bytemark, Inc.</i> , No. IPR2022-00624, Paper 9 (P.T.A.B. Aug. 24, 2022).....	39

Statutes

35 U.S.C. § 112(6)	7, 8, 9
35 U.S.C. § 112(f).....	7
35 U.S.C. § 314(a)	1
35 U.S.C. § 325(d)	<i>passim</i>

Other Authorities

37 C.F.R. § 42.6(a)(3)	30
37 C.F.R. § 42.22(a)(2).....	31
37 C.F.R. § 42.65(a).....	39
37 C.F.R. § 42.104(b)(3).....	7, 8, 9
Consolidated Trial Practice Guide (Nov. 2019) (“CTPG”).....	7, 8

PATENT OWNER'S EXHIBIT LIST

Exhibit	Description
2001	Scheduling Order, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW, D.I. 40 (D. Del. Nov. 3, 2022)
2002	Excerpts from ResMed Inc.'s Amended Initial Invalidity Contentions, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW (D. Del. Apr. 5, 2023)
2003	Cleveland Medical Devices, Inc.'s Initial Infringement Contentions and Initial Election of Asserted Claims, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW (D. Del. Jan. 9, 2023)
2004	Oral Order Denying Stipulation to Modify Scheduling Order, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW, D.I. 56 (D. Del. Mar. 9, 2023)
2005	ResMed Inc.'s Motion for Reconsideration, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW, D.I. 61 (D. Del. Mar. 20, 2023)
2006	Email correspondence between counsel for CleveMed and counsel for ResMed, dated Feb. 15., 2023 - Exhibit 2 to ResMed Inc.'s Motion for Reconsideration, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW, D.I. 61-3 (D. Del. Mar. 20, 2023)
2007	Declaration of Benu Wells in Support of Patent Owner's Preliminary Response
2008	Joint Claim Construction Brief, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW, D.I. 96 (D. Del. June 21, 2023)

Exhibit	Description
2009	Excerpts from Defendant ResMed Inc.'s Initial Invalidity Contentions, <i>Cleveland Medical Devices Inc. v. ResMed Inc.</i> , No. 22-cv-00794-GBW (D. Del. Feb. 21, 2023)
2010	LaFrenz, C., "How the pandemic changed ResMed boss Mick Farrell" (May 21, 2021) https://www.afr.com/companies/healthcare-and-fitness/how-the-pandemic-changed-resmed-boss-mick-farrell-20210514-p57s49
2011	Thompson, H., "ResMed is disrupting connected health: Here's how" (Apr. 3, 2018) https://www.medicaldesignandoutsourcing.com/resmed-is-disrupting-connected-health-heres-how/

I. INTRODUCTION

The Board should exercise its discretion to deny *inter partes* review¹ under § 314(a) because the co-pending litigation between the parties is expected to conclude well before a Final Written Decision would be due in this case, the issues here are duplicative of those raised in the co-pending litigation—which is unlikely to be stayed given that Petitioner has challenged only one of the seven asserted patents—and Petitioner's gamesmanship (naming the District Court defendant, ResMed, Inc., as a real-party-in-interest rather than a co-petitioner) all weigh in favor of the Board exercising its discretion to deny review. Indeed, given Petitioner's tactical ploy, it is unclear whether it can offer a case-narrowing stipulation on behalf of ResMed, Inc., in order to shield this Petition from discretionary denial under *Fintiv* and the Director's Interim Guidance.

The Board should also exercise its discretion to deny the Petition under 35 U.S.C. § 325(d). Each of Petitioner's proposed grounds relies on a reference—Farrell or Stahmann—that was presented to the Office during the original prosecution of the '269 Patent, and the Office already rejected the same (or

¹ RESMED CORP., ("Petitioner") petitioned for *inter partes* review ("IPR") of U.S. Patent No. 10,076,269 (Ex. 1001, the "'269 Patent"), challenging claims 1-20 ("the Challenged Claims").

substantially the same) arguments about those references' applicability to the Challenged Claims. Petitioner neither acknowledges the overlap in arguments nor attempts to show how the Examiner erred in allowing the claims to issue.

The Board should also deny the Petition on the merits. As the Office already determined, Farrell does not disclose or suggest an airflow sensor internal to a CPAP machine that measures a patient's respiratory airflow, as recited in Claims 1 and 15, and Stahmann does not disclose a CPAP for providing a pharmaceutical agent based on the level of severity of the subject's sleep disorder symptoms. Nor does the art teach a CPAP processor that calculates sleep disorder symptom data based on the patient's respiratory airflow and pulse oximetry data, as recited in Claims 1, 5, and 15.

II. OVERVIEW

A. Background of the Technical Field

Sleep apnea refers to the cessation of breathing during sleep. A chronic sleep disorder, sleep apnea presents in three forms: obstructive sleep apnea, central sleep apnea, and mixed sleep apnea. '269 Patent at 5:43-50. These apneas disrupt normal sleep patterns and may lead to serious health consequences, including sleep deprivation, coronary artery disease, heart attack, heart failure, stroke, and an increased risk of type 2 diabetes. *Id.* at 1:27-39. Sleep deprivation can severely

degrade a person's quality of life and is responsible for an estimated \$150 billion dollars per year in excess medical and social costs. *Id.*

Doctors traditionally diagnosed sleep apnea using two methods. The first method required patients to answer questions concerning their symptoms. *Id.* at 1:40-50. Subjective diagnostic methods like these are problematic, however, because patients often underestimate their symptoms or give false responses (*e.g.*, to avoid negative consequences or obtain restricted medication). *Id.* The second traditional method for diagnosing sleep apnea involved an all-night polysomnography, commonly known as a sleep study, conducted in a lab. *Id.* at 1:51-2:10. The polysomnography would typically be followed by an all-day test, where the patient had to spend the day in a specialized sleep clinic for monitoring. *Id.* Neither of these methods effectively determined how patients were responding to their prescribed sleep therapy because they never collected quantifiable data from the patient while they are sleeping in their home environment. *Id.*

The most common method of treatment for sleep apnea at the time of filing was through the use of a continuous positive airway pressure treatment device (CPAP), which applies a constant positive pressure to the patient's airway and thereby forces the patient to breathe. *Id.* at 2:17-26. While some CPAP machines could be tuned to provide a prescribed pressure, none were adjustable on the fly

based on sleep disorder symptom data, which reflects the patient's current physiological state. *Id.* at 2:27-37.

B. The '269 Patent

The '269 Patent discloses a novel integrated diagnosis and treatment device for patients suffering from sleep apnea. The device analyzes the patient's physiological symptoms and adjusts the treatment based, at least in part, on this analysis. '269 Patent at 1:19-23; 2:38-52. The claimed invention uses a CPAP with sensors that detect the patient's physiological condition, including parameters related to a patient's breath, such as respiratory airflow and effort, and blood oxygenation levels. *Id.* at 6:10-7:30. The diagnostic readings from pulse oximeters and/or airflow sensors are combined to determine sleep disorder symptom data, which is transferred to a medical professional, displayed to the user, and/or used to adjust the patient's treatment. *See id.* at Claims 1-7 (using pulse oximetry and airflow data in combination with a CPAP); *id.* at Claims 8-14 (using a combination airflow data, pulse oximetry, and respiratory effort with a CPAP to adjust the treatment of a patient requiring chemical treatment in addition to traditional CPAP therapy); *id.* at Claims 15-20 (using airflow data and a CPAP to analyze and wirelessly send the patient's data allowing for remote adjustment the patients treatment).

An exemplary embodiment of the CPAP device, shown below, includes pressure generator 312, a blower, hose 314, mask or nasal cannula 316, flow sensor 320, and pressure sensor 322:

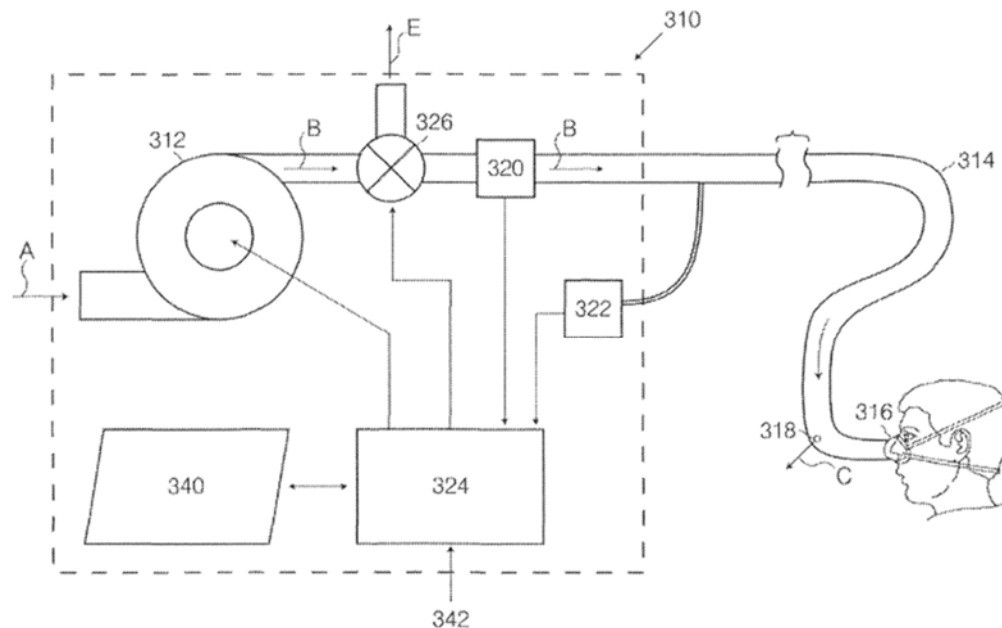


Fig. 7

The information from flow sensor 320 and/or pressure sensor 322 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 23:7-17.

In some claimed embodiments, the CPAP machine measures a patient's respiratory airflow using a pressure sensor located within the device. *Id.* at 7:27-42. Unlike the prior art, this airflow sensor is placed within the CPAP device, not attached to the hose or the patient's mask. This measurement is from the flow sensor

320 and pressure sensor 322, which monitors the condition of the subject, monitors the usage of the pressure support device, and controls the blower. *Id.* at 23:7-17. The device is capable of analyzing fluctuations on the pressure transducer in a breath-by-breath manner. *Id.* at 8:2-6. Another sensor claimed is a pulse oximeter that can measure the oxygenation of the subject's blood by producing a source of light in two wavelengths that originate from the oximeter. *Id.* at 8:13-25. This allows certain embodiments to use the oxygen saturation in the patient's blood as another indicator of sleep apnea. *Id.*

The signals from the sensors are sent to the device where the processor can analyze the signals. *Id.* at 8:27-30. The inventions use a data acquisition system or signal processing module to receive the inputs from the external sensors and relay that data to the processor where it is combined with the internally derived signals. *Id.* at 8:31-42. Quantitative methods for estimating the severity of a patient's sleeping disorder or symptoms based upon the physiological signals include a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, and a wavelet analysis. *Id.* at 19:46-21:67.

Data indicating the severity of a patient's sleeping disorder is then transferred wirelessly to a wireless communications module, which sends it to a remote location, such as a doctor's office. *Id.* at 8:63-9:45.

III. CLAIM CONSTRUCTION

37 C.F.R. § 42.104(b)(3) requires that “[w]here the claim to be construed contains a means-plus-function or step-plus-function limitation as permitted under 35 U.S.C. [§] 112(f), the construction of the claim must identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function.” If a petitioner does not satisfy this obligation, the Board generally denies the petition. *See Samsung Elecs. Co. v. Power2B Inc.*, No. IPR2022-01378, Paper 12 at 11-14 (P.T.A.B. Mar. 15, 2023); *see also* Consolidated Trial Practice Guide (Nov. 2019) (“CTPG”) at 45 (“A petitioner who chooses not to address construction under § 112(f) risks failing to satisfy the requirement of 37 C.F.R. § 42.104(b)(3).”).

Petitioner’s burden to construe means-plus-function limitations extends to all terms that “may” be construed according to 35 U.S.C. § 112(6)²:

Where claim language *may* be construed according to 35 U.S.C. § 112(f), a petitioner *must* provide a construction that includes both the claimed function and the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function.

² 35 U.S.C. sections refer to the pre-AIA version of the statute.

Samsung, Paper 12 at 11 (emphasis added) (citing CTPG at 45); *see also Orthopediatrics Corp. v. K2M, Inc.*, No. IPR2018-01548, Paper 9 at 10-11 (P.T.A.B. Mar. 1, 2019) (denying a petition under 37 C.F.R. § 42.104(b)(3) where Petitioner advocated for a means-plus-function construction in the related district court litigation and took the opposition position in the IPR petition).

Roughly one week ago, Real Party-in-Interest (“RPI”), ResMed Inc., told the District Court that three different claim limitations in the ’269 Patent should be construed according to 35 U.S.C. § 112(6):³

Term 4: “a processor adapted for receiving the airflow sensor data and calculating both symptom data of a severity of the subject’s sleep disorder symptoms and/or an index of a subject’s symptoms measured during use of the PAP device and data of usage of the PAP device” (’269 Patent, Claim 15).

Term 5: “a processor adapted for receiving the pulse oximetry sensor data from the second input and the respiratory airflow data from the airflow sensor and calculating, based in part on both the respiratory airflow data and the pulse oximetry sensor data, sleep disorder symptom data of a level of severity and/or an index of a level of severity

³ It is CleveMed’s position in both proceedings that no terms of the ’269 Patent should be construed according to 35 U.S.C. § 112(6). *See* Ex. 2008 at 52-57, 63-67.

of the subject's sleep disorder symptoms measured during use of the PAP device" ('269 Patent, Claim 1).

Term 6: "the processor further adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms measured during the subject's use of the PAP device" ('269 Patent, Claim 5).

Ex. 2008 at 48-49, 57-60. In these circumstances, "Petitioner should have either provided reasons why these limitations are not governed by 35 U.S.C. § 112 ¶ 6, or Petitioner should have provided an explicit claim construction as required by [the] rules." *Orthopediatrics*, Paper 9 at 10. Because it did neither, the Board should deny the Petition under 37 C.F.R. § 42.104(b)(3). *Id.* at 11.

IV. THE BOARD SHOULD DENY THE PETITION UNDER *FINTIV*

The Board should deny this Petition under *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (precedential) because the co-pending litigation is at an advanced stage and will terminate before a Final Written Decision is scheduled issue in this case, the Court is unlikely to grant a stay of the co-pending proceeding because ResMed has only petitioned for IPR of one of the seven asserted patents, and the merits of the case are weak.

Exacerbating these facts, which are already sufficient to support discretionary denial under *Fintiv*, Petitioner has engaged in transparent gamesmanship that undermines the goals of the AIA and the *Inter Partes* Review framework. Petitioner,

ResMed Corp., is the subsidiary of ResMed, Inc., which is the Defendant in the co-pending litigation. It appears that Petitioner chose to file this proceeding as an end-run around *Fintiv*. Pet. at 5 (“Also, importantly, Petitioner is **not** party to parallel litigation—the suit identified above (Section I.B.) was filed against a separate entity, ResMed Inc.—so the *Fintiv* factors should all weigh against discretionary denial.”). Petitioner simultaneously acknowledges, however, that ResMed, Inc., is a real-party-in-interest and, therefore, that the Petition was filed on ResMed, Inc.’s behalf. *Id.* The Board should not countenance such chicanery. One notable consequence of Petitioner’s tactics is that it has not made any case-narrowing stipulations (*e.g.*, a *Sotera*-type stipulation).

All of the *Fintiv* factors weigh strongly in favor of a discretionary denial of ResMed’s petition. *Fintiv*, Paper 11 at 6.

A. *Fintiv* Factor 1: There is Little to no Likelihood that a Stay Would be Granted in District Court

Factor 1 favors discretionary denial of the Petition because Petitioner has not filed a Motion to Stay the co-pending litigation in view of this Petition.

Any request to stay the case is unlikely to be successful because Petitioner has only challenged one of the seven asserted patents. *TwinStrand Biosciences, Inc. v. Guardant Health, Inc.*, No. 21-1126-GBW-SRF, 2023 WL 2563179, *2-4 (D. Del. Mar. 17, 2023) (denying a motion to stay pending IPR where the Board would only address two of eight asserted patents); *Toshiba Samsung Storage Tech. Korea Corp.*

v. LG Elecs., Inc., 193 F. Supp. 3d 345, 349-50 (D. Del. 2016) (concluding that the outcome of an IPR addressing 13 of 43 asserted claims would not significantly simplify the action); *Princeton Dig. Image Corp. v. Konami Dig. Entm't Inc.*, No. 12-1461-LPS-CJB, 2014 WL 3819458, at *3 (D. Del. Jan. 15, 2014) (“The more that the scope of the issues to be resolved during the litigation exceeds the scope of the issues that can be examined during IPR, the greater this cuts against a finding that an IPR proceeding will lead to great simplification of the issues at play [in the litigation].”) (citations omitted).

Accordingly, Factor 1 weighs in favor of denying institution because there is little to no likelihood that the District Court will stay the co-pending litigation. At the very least, the Board should find this factor neutral. *See Sand Revolution II, LLC v. Cont'l Intermodal Grp. – Trucking LLC*, No. IPR2019-01393, Paper 24 at 7 (P.T.A.B. June 16, 2020) (informative).

B. *Fintiv* Factor 2: The District Court's Scheduled Trial Date is Roughly Three Months Before the Expected Date of Any Final Written Decision

Fintiv Factor 2 weighs in favor of discretionary denial because trial is scheduled in the co-pending litigation for August 26, 2024, which is three months before a final written decision is due in this case.

Petitioner delayed filing this Petition until after the District Court denied its Motion to modify the stipulated scheduling order and assert more than ten prior art

references against the '269 Patent, the co-pending litigation will be completed well before any final written decision is expected in this case. Accordingly, the Board should exercise its discretion to deny institution in order to avoid duplication of efforts and “potentially conflicting outcomes.” Ex. 1021 (June 21, 2022 PTAB Interim Procedure for Discretionary Denials) at 5.

The Board routinely exercises its discretion to deny institution in circumstances where the period between the scheduled trial date and the projected deadline for a final written decision is less than the three-month period in this case. *See, e.g., NXP USA, Inc. v. Impinj, Inc.*, No. IPR2021-01556, Paper 10 at 8 (P.T.A.B. Apr. 21, 2022) (determining that two months between the scheduled trial and the deadline to reach a final written decision weighed in favor of discretionary denial); *eClinicalWorks, LLC v. Decapolis LLC*, No. IPR2022-00229, Paper 10 at 9 (P.T.A.B. Apr. 13, 2022) (determining that one to two months between the scheduled jury trial and the deadline to reach a final decision weighed in favor of denial); *Immersion Sys. LLC v. Midas Green Techs., LLC*, No. IPR2021-01176, Paper 16 at 13 (P.T.A.B. Jan. 6, 2022) (determining that three months between the scheduled trial date and the deadline to reach a final decision weighed in favor of exercising discretionary denial).

Because the trial is scheduled to begin well before the Board's deadline to reach a final written decision, it would make no sense to have the Board address

patentability when it will have already been addressed at the District Court trial particularly given the possibility of conflicting outcomes. Therefore, *Fintiv* factor 2 weighs in favor of the Board exercising its discretion to deny institution.

C. *Fintiv* Factor 3: Significant Investment in the Parallel Litigation Will Have Occurred by the Time the Board's Institution Decision is Due

The Board should deny institution because the District Court case will be nearly complete “at the time of the institution decision.” *See Fintiv*, Paper 11 at 9-10. By August 1, 2023, the parties will have already exchanged preliminary infringement and invalidity contentions, completed *Markman* briefs, conducted a *Markman* hearing, surpassed its substantial completion of document production, and begun taking fact depositions. *See* Ex. 2001 at 17 (“Scheduling Order”). Fact discovery closes on September 26, 2023, and opening expert reports are due November 2, 2023. *Id.* This amount of work is substantial as the parties have presently submitted 40 interrogatories, 166 requests for production, produced 41,250 documents totaling over 260,000 pages, and will have conducted numerous depositions by the time of the institution decision. *See* Ex. 2007 at ¶¶ 2-3 (“Wells Decl.”); *SenoRx, Inc. v. Hologic, Inc.*, No. 12-173-LPS-CJB, 2013 WL 144255, at *5-6 (D. Del. Jan. 11, 2013) (“[Once] the Court and the parties have already expended significant resources . . . the principle of maximizing the use of judicial and litigant resources is best served by seeing the case through to its conclusion.”).

The Board has found Factor 3 to weigh in favor of discretionary denial in cases like this, where contentions have been served, claim construction has been fully briefed, and fact discovery and opening expert reports completed before the expected institution decision deadline. *See Ta Instruments-Waters LLC v. Malvern Panalytical Inc.*, No. IPR2021-00211, Paper 8 at 12-13 (P.T.A.B. May 27, 2021) (determining that factor 3 weighed in favor of denial because of the substantial investment that had already occurred in the parallel litigation, as fact discovery, claim construction briefing and hearing, and opening and rebuttable expert reports were to be completed); *Apcon, Inc. v. Gigamon Inc.*, No. IPR2020-01583, Paper 9 at 11-12 (P.T.A.B. Mar. 16, 2021) (determining that factor 3 weighed in favor of denial given that substantial investment had already occurred as the parties had served contentions, completed the claim construction briefings, and completed fact and expert discovery).

Petitioner's conduct in filing the Petition only after the District Court ordered their narrowing of references also favors denial under Factor 3. Ex. 2004; Ex. 2001 at 3. The Board regularly holds that delays in filing the Petition weigh in favor of denial where the petitioner is "aware or could have reasonably been aware of the prior art asserted in the challenges set forth in the instant proceeding." *Next Caller Inc. v. Trusted, Inc.*, No. IPR2019-00961, Paper 10 at 15-16 (P.T.A.B. Oct. 16, 2019) (finding that petitioner's delay in filing its petition weighed in favor of the Board

exercising discretionary denial as petitioner could have filed the petition concurrently with another petition asserting the same art).

Here, Petitioner served its preliminary invalidity contentions including the same art asserted in this Petition among the 33 number of references, on February 21, 2023. *See generally*, Ex. 2009 at 17-20 (Initial invalidity contentions). Accordingly, rather than file the Petition concurrently with its preliminary invalidity contentions, Petitioner waited until the District Court ordered its compliance with the per patent limitations. Petitioner filed this IPR shortly before its motion for reconsideration of the order requiring them to narrow the number of asserted invalidity references in hopes of buying as much time as possible before narrowing its ridiculous number of references in District Court.

In view of the substantial time and resources that have been and continue to be invested in the parallel litigation, particularly in view of Petitioner's dilatory conduct, *Fintiv* Factor 3 weighs in favor of discretionary denial.

D. *Fintiv* Factor 4: There is Substantial Overlap Between the IPR Proceeding and the Parallel Litigation

Fintiv factor 4 weighs in favor of discretionary denial. This factor looks at “whether all or some of the claims challenged in the petition are also at issue in district court,” and whether the “petition includes the same or substantially the same claims, grounds, arguments, and evidence” as included in the parallel District Court litigation. *Fintiv*, Paper 11 at 12-13. Here, Petitioner challenges all the claims

asserted in the parallel District Court litigation. *Compare* Ex. 2002 at 1, 17-20 (Amended Invalidity Contentions) *with* Pet. at 3-4.

The Petition also “includes the same or substantially the same claims, grounds, arguments, and evidence” because there is substantial overlap between the primary references and arguments asserted in both forums. *Fintiv*, Paper 11 at 12-13. For example, in both proceedings, Petitioner points to Genger, Kocinski, and Stahmann as three of the five primary references against the '269 Patent, one of which is a system. Accordingly, there is “substantial overlap of issues concerning the prior art” because the primary references are the same and the arguments substantially similar in both proceedings. *See Apple Inc. v. Optis Cellular Tech. LLC*, No. IPR2020-00465, Paper 13 at 20-21 (P.T.A.B. Sept. 17, 2020) (finding that factor 4 weighed in favor of discretionary denial as there was a “substantial overlap of issues concerning the prior art” even though “the combinations of four references asserted by Petitioner at [District Court] and in the Petition are different, two of the references, including the primary reference [], are the same in both combinations.”).

At the outset of the co-pending litigation, the parties negotiated a scheduling order that limited CleveMed to assert no more than ten claims per patent and for Petitioner to assert no more than ten invalidity references per patent. Ex. 2001 at 3. On January 9, 2023, CleveMed served its initial infringement contentions which complied with the District Court's limitations and asserted no more than ten claims

per patent. Ex. 2001 at 3; Ex. 2003 at 2 (Initial Infringement Contentions). After reviewing CleveMed's contentions for nearly a month, the district court Defendant requested they be allowed to assert twenty-five invalidity references against the '269 Patent because it contains a purportedly excessive number (4) of independent claims. Ex. 2006 at 3-4. Although CleveMed agreed to lift the per-patent cap, the District Court did not and instructed Petitioner to narrow its list of asserted references to no more than ten. Ex. 2004 (citing to Scheduling Order (Ex. 2001 at 3 filed herewith)).

Rather than comply with the District Court's Order, Petitioner requested reconsideration of the District Court's order and filed this Petition, raising ten different references against the Challenged Claims. Petitioner's motion for reconsideration of the District Court's Order remains pending. Ex. 2005. Accordingly, instead of filing this IPR as an alternative to the litigation in the district court, Petitioner filed this Petition as an adjunct. This tactic raises "concerns of duplicative efforts and potentially conflicting decisions," and appears calculated to multiply rather than streamline proceedings. *Sotera Wireless, Inc., v. Masimo Corp.*, No. IPR2020-01019, Paper 12 at 19 (P.T.A.B. Dec. 1, 2020).

Petitioner has not provided any case-narrowing stipulation in this case, and because of Petitioner's gamesmanship, it is not clear whether such a stipulation is even possible. Nevertheless, Petitioner's failure to provide a *Sotera* stipulation will result "in duplication of work and create the potential for inconsistent decisions."

Apple v. Maxell, Ltd., No. IPR2020-00407, Paper 12 at 12 (P.T.A.B. Aug. 11, 2020).

The co-pending litigation is proceeding at full pace, and each of the alleged prior art references asserted in the Petition are part of the case or cumulative of those asserted in District Court. And in the event that Petitioner agrees (and has the power to agree) not to raise the *same* grounds raised in the Petition (a *Sand Revolution II* stipulation), such a stipulation would only weigh modestly against the Board's exercising its discretion to deny institution. *Samsung Electronics Co. v. California Institute of Tech.*, No. IPR2023-00133, Paper 10 at 14-15 (P.T.A.B. May 4, 2023).

In view of the foregoing, *Fintiv* Factor 4 weighs strongly in favor of the Board exercising its discretion to deny institution.

E. *Fintiv* Factor 5: Defendant is an RPI

Fintiv factor 5 weighs in favor of exercising discretionary denial because the parties are related. *Fintiv*, Paper 11 at 13-14 (determining that Factor 5 may weigh in favor of institution if the parties are "unrelated"). Petitioner is a subsidiary of ResMed Inc., which is the defendant in the parallel litigation proceeding. *See* Pet. at 1; *id.* at 5 (acknowledging that ResMed Inc. is an RPI). Thus, while Petitioner and defendant in District Court are not the "same," factor 5 weighs in favor of discretionary denial because they are intimately related. *See Fintiv*, Paper 11 at 13-14.

F. *Fintiv* Factor 6: The Petition is Without Merit and ResMed Has Abused the Process

Fintiv factor 6 weighs in favor of discretionary denial. As explained in detail in Section 7, *infra*, Petitioner fails to present a likelihood of success, much less “compelling evidence of unpatentability.” Ex. 1021 (June 21, 2022 PTAB Interim Procedure for Discretionary Denials) at 4-5, 9. Because Petitioner’s arguments and evidence presented in the Petition fail to show a reasonable likelihood of success that the nine Asserted References render obvious any of the Challenged Claims, the Board “has authority . . . to exercise discretion to deny institution.” *Id.* at 4.

Petitioner has not demonstrated a reasonable likelihood that any Challenged Claim is unpatentable, let alone “compelling merits” necessary to overcome discretionary denial of the Petition under *Fintiv*. Ex. 1021 at 4 (explaining that where the information presented at the institution stage is “merely sufficient to meet the statutory institution threshold,” the Board may deny institution based on the other *Fintiv* factors). As established above, the other *Fintiv* factors overwhelmingly support denying institution. Moreover, the Board “retains discretion to deny institution for proceedings where abuse has been demonstrated.” *Id.* ResMed’s pattern of abuse began early in the litigation and has continued to date. Based on “abuse of process by [ResMed],” the Board should exercise its discretion to deny institution. *Id.* at 9.

For example, ResMed has taken inconsistent positions regarding the scope of the '269 Patent. Its proposed constructions to the District Court conflict with its positions in its Petition regarding the scope of the Challenged Claims. *See* § III, *supra*. ResMed seeks to have the terms of the '269 Patent construed as broadly as possible when attempting to substantiate its invalidity arguments before the Board while simultaneously arguing that several key terms should be construed as means-plus-function limitations in District Court. *See generally* Ex. 2008 at §§ II.D, F, K (Joint Claim Construction brief). Petitioner's gamesmanship regarding the proper construction of the claims is another reason to deny its Petition under the *Fintiv* factors.

V. THE BOARD SHOULD DENY THE PETITION UNDER 35 U.S.C. § 325(d)

The Board “may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). As the Board explained in *Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GmbH* (“*Advanced Bionics*”):

[U]nder § 325(d), the Board uses the following two-part framework: (1) whether the same or substantially similar art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated

that the Office erred in a manner material to the patentability of the challenged claims.[] If a condition in the first part of the framework is satisfied and the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute *inter partes* review.

No. IPR2019-01469, Paper 6 at 8-9 (P.T.A.B. Feb. 13, 2020) (precedential). “At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9.

A. Advanced Bionics Step 1 (Becton, Dickinson Factors (a), (b), and (d)): The same or substantially the same prior art was previously presented to the USPTO.

The first prong of the *Advanced Bionics* framework is satisfied because Petitioner's arguments regarding the Farrell and Stahmann—both critical to at least one ground raised in the Petition—were traversed during the prosecution of the application that led to the '269 Patent as well as its parent U.S. Patent No. 8,172,766. *See Advanced Bionics*, Paper 6 at 7-8 (“Previously presented art includes . . . art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent.”).

The first prong of the *Advanced Bionics* framework is satisfied where an examiner signs an IDS indicating that the art and arguments were considered. *See Palo Alto Networks, Inc. v. Centripetal Networks, Inc.*, No. IPR2021-01270, Paper 10 at 13-14 (P.T.A.B. Jan. 24, 2022) (denying institution because the examiner's

signature on the IDS indicated that the examiner had considered the previous IPR petitions including the same art and arguments); *GlaxoSmithKline Consumer Healthcare Holdings (US) LLC v. Cipla Ltd.*, No. IPR2020-00371, Paper 7 at 12-14 (P.T.A.B. July 31, 2020) (denying institution based in part on an IDS listing a previous IPR petition, which included the same art, that the examiner considered); *see also BMW of North Am., LLC v. Stragent, LLC*, No. IPR2021-00419, Paper 21 at 5 (P.T.A.B. Mar. 12, 2022) (denying petitioner's request for rehearing because the examiner's signature of the IDS indicated that the references were considered); *Sonos, Inc. v Google, LLC*, No. IPR2021-00963, Paper 9 at 9-10 (P.T.A.B. Nov. 9, 2021) (denying institution because the examiner's signature on the IDS indicated that the references were considered).

Here, the same art and arguments relied on in the Petition were presented to and considered by the Office. The '269 Patent lists among its References Cited U.S. Patent No. 7,878,198 titled Methods And Apparatus For Monitoring The Cardiovascular Condition Of Patients With Sleep Disordered Breathing. Ex. 1008 ("Farrell"). This reference cited by the Examiner has the same title, inventors, and disclosures as the Farrell reference cited in the Petition because they stem from the same provisional application No. 60/557,846, filed on March 31, 2004. In fact, the Petition admits that this is just the WIPO publication of the U.S. patent reviewed and cited in the prosecution of the '269 Patent.

The argument that Farrell is shielded from § 325(d) scrutiny because it is being used here as “a secondary reference” fails because the Office does not distinguish between “primary” and “secondary” references in its obviousness analyses, and the Office already rejected the substantially the same arguments made concerning Farrell. For example, the Petition uses Farrell as motivation to allegedly modify Genger, Schmidt, or Kocinski to achieve an internal airflow sensor for measuring the respiratory airflow of the subject but the Examiner already considered this disclosure in Farrell. Ex. 1002 ('269 Patent File History (Part 2)) at 372. There the Examiner concluded that Farrell teaches “a traditional device” that uses an optional “diagnosis unit” that is separate from the device for collection of patient data and the pressure and flow sensors in Farrell are used just for determination of the delivered air to the patient. Thus, the sensors in Farrell have already been determined not to detect physiological information, such as a patient's respiratory airflow.

Further, the Stahmann (Ex. 1010) reference relied on in the Petition cites to the same disclosures that were present in the Stahmann publication (Ex. 1019) considered by the Office. By Petitioner's own admission, the same figures and embodiments in the allegedly more expansive Stahmann disclosure contain the same figures and embodiments considered by the Examiner. Pet. at 6-7. In fact, Petitioners point to nothing in the allegedly more expansive Stahmann disclosures

that is not in the reference considered by the Examiner, as all of their citations are present in the Examiner-reviewed reference. *Gator Bio, Inc. v. Sartorius Bioanalytical Insts., Inc.*, No. IPR2023-00215, Paper 19 at 17-19, 22 (P.T.A.B. June 20, 2023) (denying institution where the challenges set forth in the Petition are based on the same or substantially the same prior art or arguments previously presented to the Office during patent examination for each of the asserted grounds). Thus, the first prong of the *Advanced Bionics* framework is satisfied.

B. *Advanced Bionics* Step 2 (*Becton, Dickinson* Factors (c), (e), and (f)): Petitioner has made no showing of material examiner error.

The second prong of *Advanced Bionics* is satisfied because Petitioner does not show that the Examiner erred in a manner material to patentability. Petition at 6-7; *see also Gator Bio*, Paper 19 at 7-8, 17-22. It is the Petitioner's burden to affirmatively demonstrate that the Office committed material error in issuing the challenged patent. *See, e.g., Dir., Office of Workers' Comp. Programs, Dep't of Labor v. Greenwich Collieries*, 512 U.S. 267, 276 (1994) (consistent with the Administrative Procedure Act (APA), the proponent of a claim has the burden of persuasion); *Fanduel, Inc. v. Interactive Games LLC*, 966 F.3d 1334, 1341 (Fed. Cir. 2020) ("the burden of proving invalidity in an IPR remains on the petitioner throughout the proceeding") (citations omitted).

Petitioner alleges no error by the Office, let alone material error. Pet. at 9. The Board should, therefore, defer to the Examiner's evaluation of the same

evidence asserted here and exercise its discretion to deny institution. *Advanced Bionics*, Paper 6 at 8-9 (indicating that the Board should exercise discretion to deny institution if the petitioner fails to make a showing of material error because “this framework reflects a commitment to defer to previous Office evaluations of the evidence of record”).

The Board consistently exercises its discretion to deny institution in circumstances where a petitioner does not address whether the Office materially erred. *See Wolfspeed, Inc. v. The Trustees of Purdue Univ.*, No. IPR2022-00761, Paper 9 at 14-15 (P.T.A.B. Nov. 8, 2022) (exercising its discretion under Section 325(d) to not institute IPR because the proffered art was cumulative to or substantially the same as art previously presented to the Office and petitioner did not address whether the Office materially erred); *see also Darfon Elecs. Corp. v. Shipman*, No. IPR2022-01008, Paper 11 at 14 (P.T.A.B. Dec. 2, 2022) (same). In *Wolfspeed*, for example, the petitioner asserted the same prior art as presented in a previous IPR petition. *Wolfspeed*, Paper 9 at 14.

While the petitioner addressed Section 325(d), the Board nonetheless denied institution because petitioner did not identify any material error in the prior decision. *Id.* at 15 (exercising its discretion under petitioner “stop[ped] short of identifying any error, much less a material error, in the prior decision.”). Likewise, Petitioner acknowledges that the Farrell and Stahmann references were presented to and

considered by the Office while failing to identifying any error. *See* Petition at 6-7. Petitioner's lone, passing, and conclusory comment that the Examiner somehow materially erred does not pass muster as an explanation of why Stahmann is not "substantially the same" as that previously considered by the Examiner, let alone why the Examiner material erred in considering the art to not be invalidating. *Id.*

Because the Petition presents only the same and substantially the same prior art as previously presented during prosecution, and because Petitioner has failed to make any showing of error by the USPTO, the Board should exercise its discretion and deny institution under 35 U.S.C. § 325(d). *See Advanced Bionics*, Paper 6 at 7-9 (describing a two-part framework that demonstrates "a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown").

VI. LEVEL OF ORDINARY SKILL IN THE ART

A POSITA as of the priority date of the Challenged Patent (November 4, 2005) would have had a bachelor's degree in mechanical engineering, electrical engineering, computer science, or an equivalent field and two years of industry experience working with diagnostic sensor systems and networked data systems. Additional experience could compensate for less education, and vice-versa.

VII. 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 (let alone compelling merits) that any Challenged Claim is obvious.

A. GROUND 1: The Challenged Claims are Patentable Over the Genger Combinations⁴

Independent Claims 1 and 5 are patentable at least because the combination of Genger, Schmidt, Westbrook, and Farrell does not disclose a CPAP processor that calculates sleep disorder data based on respiratory airflow and pulse oximetry data. Claim 1 is also patentable because the combination of references does not disclose “an airflow sensor *internal* to the PAP device adapted for *measuring the respiratory airflow of a subject*.” Rather than measure the respiratory airflow of a subject using an internal sensor, Genger’s respiratory airflow sensor is admittedly located outside of the CPAP machine. Farrell, which was considered extensively during original prosecution of the ’269 Patent, discloses an airflow sensor that measures the *blower*

⁴ In this ground, Petitioner relies on Genger (Ex. 1005) combinations to challenge claims 1-3, 5, and 7. Pet. at 3-4. Ground 2 challenges claims 4 and 6, depending on Independent Claims 1 and 5, accordingly Ground 2 fails for the same reasons as Ground 1. *Id.*

output but provides no motivation to move Genger's respiratory airflow sensor within the CPAP machine.

1. Genger in View of Westbrook Does not Disclose a CPAP Processor that Calculates Sleep Disorder Symptom Data Based on Respiratory Airflow and Pulse Oximetry Sensor Data (Claims 1-7)

Genger, alone or in combination with Westbrook, fails to teach or suggest a “processor adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors, sleep disorder symptom data of a level of severity and/or index of a level of severity of the subject's symptoms” ’269 Patent at Claim 5.

Genger discloses sampling data received from individual sensors to generate “trend data” indicative of the sensors' readings over time. Ex. 1005 at 12:27-30. However, Genger does not disclose using this trend data to calculate sleep disorder symptom data.” *See id.* at 13:4-6 (disclosing that “the oxygen saturation may be averaged over a certain time or the number of apneas in a predetermined period may be determined as trend data”). As a result, Genger does not disclose a CPAP processor that calculates sleep disorder symptom data based on data from respiratory airflow and pulse oximetry sensors.

Westbrook does not cure this deficiency because Westbrook also does not disclose a CPAP processor that calculates sleep disorder data based on data from both the respiratory airflow and pulse oximetry sensors. Instead, Westbrook

discloses a screening device for sleep diagnostics having software that “quantif[ies] the physiological signals in combination with automated pattern recognition.” Ex. 1007 at ¶ 0140. This automated analysis is not done on the CPAP machine. It is done on a computer using the ARES system. The reason is the analysis requires that expert logic is “applied to combine summary results from the analysis of the physiological signals with results from the ARES Profile analysis.”

For Westbrook's calculation to be based in part on both data from the respiratory airflow and pulse oximetry sensors, Westbrook requires the consultation of an expert using a computer to derive the calculation rather than simply being done on the PAP's processor as claimed in the '269 patent. In fact, Westbrook's system requires the intervention of a doctor in order for the system to have the calculations based in part on both respiratory airflow data and pulse oximetry data. *See* Ex. 1007 at ¶¶ 0157-0158. As a result, Genger and the Genger-Westbrook combination does not teach or suggest a CPAP processor adapted for calculating sleep disorder data based in part on both data from the respiratory airflow and pulse oximetry sensors.

In view of the foregoing reasons, Genger taken alone or in combination with Westbrook does not teach or suggest a processor adapted for calculating, based in part on both data from the respiratory airflow and pulse oximetry sensors.

2. Genger in View of Farrell Does Not Disclose an Internal Respiratory Airflow Sensor (Claims 1-4)

Genger, alone or in combination with Farrell, fails to teach or suggest an internal airflow sensor adapted for measuring the respiratory airflow of a subject and outputting airflow sensor data.

Genger's respiratory airflow sensor is admittedly located outside of the CPAP machine. Pet. at 34 ("Genger shows the airflow sensor outside the CPAP device . . ."). In an attempt to cure this deficiency, Petitioner argues that "POSITA would have found it obvious to locate the airflow sensor *internally* because that location was common." *Id.* (emphasis original). However, neither Farrell nor Berthon-Jones⁵ expressly discloses locating a respiratory airflow sensor within a CPAP machine, let alone state that such a location was "common." *Id.*

As Petitioner acknowledges, Farrell does not disclose that the relevant sensors are "internal" to the CPAP machine, given Farrell's that "Sensors 4f and 4p 'have only been shown symbolically in FIG. 1.'" Pet. at 35 (quoting Ex. 1008 at 5:9-11). Berthon-Jones, which is referenced in Dr. Sharony's declaration but not in the Petition, only states that it may be convenient to measure airflow through the air delivery tube at the location where the tube connects to the "output of the turbine,"

⁵ Farrell incorporates Berthon-Jones by reference. Ex. 1008 at 2:5-6.

which Petitioner has not shown or alleged to be “internal” to the CPAP machine. Accordingly, to the extent that Petitioner’s argument relies on Berthon-Jones, the Board should deny the Petition because its argument is improperly incorporated by reference pursuant to 37 C.F.R. § 42.6(a)(3) because Petitioner has not provided “a detailed explanation of the significance of the evidence including material facts” pursuant to 37 C.F.R. § 42.22(a)(2). *See Parus Holdings, Inc. v. Google LLC*, Nos. 22-1269, -1270, 2023 U.S. App. LEXIS 14543, at *9 (Fed. Cir. June 12, 2023) (citation omitted).

Farrell also does not cure Genger’s deficiencies because Farrell’s pressure sensor measures the output of the CPAP machine’s blower rather than the respiratory airflow of the subject. This is evidenced by Farrell’s statement that the Flow $F(t)$ (the value derived from the flow sensor) and pressure $P_{\text{mask}}(t)$ (the value derived from the pressure sensor) are sent to the controller responsible for delivering “different pressure treatment therapies simply by adjusting the pressure delivery equation that is used to set the speed of the blower or manipulate the venting with the release valve.” Ex. 1008 at 5:25-27. And as persuasively argued during prosecution, “Farrell makes clear that flow and pressure measurements of the delivered are used to adjust the PAP device – not [the subject’s] respiratory effort.” Ex. 1002 at 372. As a result, Genger and the Genger-Farrell combination never teaches or suggests an internal airflow sensor for measuring the patient’s respiratory airflow.

In view of the foregoing, Genger taken alone or in combination with Farrell does not teach or suggest an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data to the PAP device.

B. GROUND 3: The Challenged Claims are Patentable⁶

Independent Claim 8 is patentable at least because the combination of Stahmann-Edgar does not disclose “PAP apparatus comprising a controller adapted to adjust the pharmaceutical agent, at least in part, *using the output of the level of severity of the subject’s sleep disorder from the data acquisition system.*” ’269 Patent at Claim 8. Rather than adjust the pharmaceutical agent based on the output of the level of the severity of the subject’s sleep disorder, Stahmann discloses a system of moderating therapy during sleep using “physiologic data acquired during non-sleep.” Edgar does not cure Stahmann’s deficiencies because it does not disclose or suggest a controller adapted to adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject’s sleep disorder from

⁶ In this ground, Petitioner relies on Stahmann combinations to challenge claims 8-11, and 13. Pet. at 3-4. Ground 4 challenges claim 12 and Ground 5 challenges claim 14, both depending on Independent Claim 8, accordingly Ground 4 and 5 fails for the same reasons as Ground 3. *Id.*

the data acquisition system because the adjustments occur to treat disordered breathing such as the treatment of asthma and not a sleep disorder.

1. Stahmann does not teach or suggest a CPAP for providing a pharmaceutical agent based on the level of severity of the subject's sleep disorder symptoms."

Stahmann fails to teach or suggest a CPAP for providing a pharmaceutical agent based on the level of severity of the subject's sleep disorder symptoms. The reference teaches a CPAP apparatus, but the CPAP apparatus described in Stahmann does not provide drug therapy for sleep-related disorders where the dosing of the pharmaceutical agent is based on the level of severity of the subject's sleep disorder symptoms. Ex. 1010 at 222:15-18.

Stahmann's system provides for the treatment of sleeping disorders using a positive airway pressure device and the treatment of *other* respiratory issues, such as asthma, using a pharmaceutical agent. See Ex. 1010 at 222 15-17 ("Asthma may be treated with a nebulizer). Asthma is not (and Petitioner has not alleged that it is) a sleep disorder. Nor has Petitioner alleged that the drug treatment is adjusted "using the output of the level of severity of the subject's sleep disorder or symptoms," as claimed. Pet. at 55-56. The Examiner noted this very deficiency during original prosecution of the '269 Patent. Ex. 1001 ("'269 Patent File History (Part 1)") at 283 ("Stahmann nor the prior art of record teaches the device of [claim 8].").

In an effort to cure these deficiencies in Stahmann, Petitioner cites Edgar (Ex. 1011). Edgar discloses using a CPAP machine to treat a patient with a pharmaceutical compound to promote sleep. However, like Stahmann, Edgar's treatment is unrelated to "the output of the level of severity of the subject's sleep disorder." '269 Patent at Claim 8. Instead, Edgar discloses supplementing normal CPAP treatment with a sleeping agent to prevent the patient from removing the mask during the night:

[M]any patients cannot tolerate the [CPAP] apparatus or pressure and refuse treatment. Moreover, recent covert monitoring studies demonstrated that long-term compliance with CPAP treatment is very poor. It is known that patients remove their masks while sleeping.

Ex. 1011 at ¶ 406.

Edgar discloses the "promoting of sleep" in order to ensure that the subject does not remove the mask, not treating the subject's sleep disorder through the pharmaceutical agent. To this point, Petitioner references paragraphs 392 and 393 as a means to chemically dose the patient such that compliance occurs rather than treating the subject's sleep disorder through the use of a pharmaceutical agent. Further, Edgar teaches or suggests an invention involving "a need for improved pharmaceutical treatments for maintaining sleep in subjects in need of [insomnia] treatment." Ex. 1011 at ¶ 0006. Thus, Edgar discloses ensuring that the subject

stays asleep using a pharmaceutical agent rather than treating the subject's sleep disorder as referenced in the claim language.

For at least these reasons, Claim 8 is patentable over Stahmann in view of Edgar because the combination does not teach or suggest a CPAP for providing a pharmaceutical agent based on the level of severity of the subject's sleep disorder symptoms.

C. GROUND 6: The Challenged Claims are Patentable⁷

Independent Claim 15 is patentable at least because the combination of Kocinski, Farrell, and Bluetooth does not disclose “an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject.” ’269 Patent at Claim 15. Rather than measure the respiratory airflow of a subject, both Kocinski and Farrell disclose pressure sensors that measure the pressure that the CPAP machine provides to the patient. The combination of references asserted as part of Ground 6 also does not disclose or suggest the display or transmission of the subject's sleep disorder symptom data and/or an associated index.

⁷ In this ground, Petitioner relies on Kocinski combinations to challenge claims 15-16, and 18-19. Pet. at 3-4. Ground 7 challenges claim 17 and Ground 8 challenges claim 20, both depending on Independent Claim 15, accordingly Ground 7 and 8 fails for the same reasons as Ground 6. *Id.*

1. Kocinski alone or in combination with Farrell fails to teach or suggest an internal PAP airflow sensor is “adapted for measuring the respiratory airflow of a subject and outputting airflow sensor data.”

Kocinski, alone or in combination with Farrell, fails to teach or suggest an internal airflow sensor adapted for measuring the respiratory airflow of a subject and outputting airflow sensor data. Both references disclose pressure sensors, but they measure the pressure output by the CPAP machine, not the patient's respiratory airflow.

Kocinski's internal pressure transducer is responsible for controlling the blower pressure provided to the subject as an internal airflow sensor tasked with measuring the respiratory airflow of the subject while using the PAP and outputting airflow sensor data. Ex. 1012 (“Kocinski”) at ¶ 0046. The referenced internal pressure transducer does not measure the respiratory airflow of the subject nor output the subject's airflow data.

Farrell does not cure the deficiency of Kocinski because Farrell's pressure sensor also measures the output of the CPAP machine's blower rather than the respiratory airflow of the subject. This is evidenced by Farrell's statement that the Flow $F(t)$ (the value derived from the flow sensor) and pressure $P_{\text{mask}}(t)$ (the value derived from the pressure sensor) are sent to the controller responsible for delivering “different pressure treatment therapies simply by adjusting the pressure delivery equation that is used to set the speed of the blower or manipulate the venting with

the release valve.” Ex. 1008 at 5:25-27. As persuasively argued during prosecution, “Farrell makes clear that flow and pressure measurements of the delivered are used to adjust the PAP device – not [the subject’s] respiratory effort.” Ex. 1002 at 372. As a result, Kocinski and the Kocinski-Farrell combination never teaches or suggests an internal pressure transducer capable of measuring the airflow from the subject.

In view of the foregoing reasons, Kocinski taken alone or in combination with Farrell does not teach or suggest an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data.

2. Kocinski does not teach or suggest transmitting symptom data and/or index of symptom data from the CPAP device via the base station to a remote internet site

Kocinski fails to teach or suggest “transmitting the symptom data of the severity of the subject’s sleep disorder symptoms and/or an index of a subject’s symptoms measuring during use of the PAP device” or “retransmit[ting] the symptom data of the severity of the subject’s sleep disorder symptoms and/or the index of the subject’s symptoms and the data of usage received from the PAP device to a remote internet site.”

Petitioner relies on Kocinski, paragraphs 28 and 31, for the transmission of the symptom data and/or index of symptom data both from the CPAP device to the base station and from the base station to a remote internet site. Pet. at 71. However,

Kocinski does not transmit symptom data (which Petitioner alleges is Apnea events, Hypopnea events, or counts) or an index of symptom data (which Petitioner alleges is AI, HI, AHI). Rather, Kocinski simply provides an email notification to the medical professional if the number of apnea events or hypopnea per hour exceed[s] a programmed threshold. Ex. 1012 at ¶ 0028. Specifically, the email only informs that the threshold has been exceeded and does not provide symptom data such as the apnea event count to the medical professional nor its associated index. Similarly, in paragraph 31, Kocinski's CPAP apparatus discloses the ability to trigger the unexpected transmission of the email notification if the subject is experiencing too many abnormal sleep events to alert the medical professional.

Petitioner relies on Farrell in an attempt to cure Kocinski's deficiency. See Pet. at 66-67. However, Farrell also does not disclose the transmission of any symptom data, either to its hand-held device for display or to a remote location. The citation that Petitioner points to only provides that, "[t]he apparatus preferably also includes a communication port or module, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as a held-held display and control devices." Ex. 1008 at 5:28-31, Fig. 1. As evidenced by the full recitation of the referenced citation, however, Farrell does not disclose the transmission of symptom data nor its related indexes to the

hand-held device. Rather, Farrell discloses that this data is merely “recorded for analysis.” Ex. 1008 at 7:35-8:3.

Petitioner also asserts, with no underlying evidentiary support, that the Farrell and Kocinski combination would not only allow for the viewing of the information but also the transmission of data to a remote location. These assertions are not supported by either the Kocinski or Farrell reference. To cure this lack of supporting evidence, Petitioner cites Declarant, Dr. Jacob Sharony. However, Dr. Sharony's expert opinion is nothing more than a perfect verbatim recitation of the unsupported position asserted in the Petition. Dr. Sharony's testimony on this combination should be given little to no weight as it does not disclose any underlying facts or data on which the opinion is based. *See* 37 C.F.R. § 42.65(a); *see also Xerox Corp. v. Bytemark, Inc.*, No. IPR2022-00624, Paper 9 at 15 (P.T.A.B. Aug. 24, 2022) (precedential) (concluding when the expert simply repeated verbatim the conclusory allegations provided in the opinion, the expert's opinion should be given little to no weight).

For at least this reason, Kocinski does not meet independent claim 15.f nor 15.g.2 because of its lack of transmission of the subject's symptom data and/or the index of the subject's symptom data.

3. Kocinski does not teach or suggest a base station, cellular phone or PDA adapted to display the symptom data of the severity of the subject's sleep disorder symptoms and/or the index of the subject's symptoms

As established above, Kocinski fails to teach or suggest an internal airflow sensor adapted for measuring the respiratory airflow of a subject and outputting airflow sensor data. Kocinski's figure 10 does not display either the subject's sleep disorder symptom data nor the index of the subject's symptoms. Kocinski does not display this data because "the pressures and sleep events may be made available only to the medical professional since others do not need this information," and in Kocinski's system, the medical professional is remote. Kocinski at ¶ [0028].

Petitioner's conclusory argument that it would have been obvious to display symptom data to "the patient, patient's family, and visiting medical professionals to see the patient's data on-site" is entirely conclusory and contradicts Kocinski's express disclosure. Pet. at 74. Prior to the '269 Patent, it was not known to display symptom data to such parties, and Petitioner cites no evidence that it was. Indeed, ResMed's CEO credited this feature with an unexpectedly large increase in compliance rates over prior systems (like Kocinski), which only displayed the patient's compliance data. Ex. 2010 at 5 (Patients' visibility into their own sleep data "significantly improve[d] their adherence to sleep therapy"); Ex. 2011 at 3-4 (crediting the AirView and myAir platforms for improving compliance to more than 87% adherence). These "surprising and unexpected" results related to displaying

the patient's symptom data belie Petitioner's conclusory assertion that it would have been obvious to display this data. *Forest Lab's, LLC v. Sigmapharm Lab's LLC*, 918 F.3d 928, 937 (Fed. Cir. 2019).

For at least this reason, Kocinski does not meet independent claim 15.g.2 because of its lack of transmission of the subject's symptom data and/or the index of the subject's symptom data which results in the inability to display the data on the base station, cellular phone or PDA.

VIII. 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 '269 Patent.

Patent Owner's Preliminary Response
IPR2023-00565 (U.S. Patent No. 10,076,269)

Respectfully submitted,

Dated: June 28, 2023

/James Hannah/

James Hannah (Reg. No. 56,369)
Jenna Fuller (Reg. No. 74,212)
Kramer Levin Naftalis & Frankel LLP
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065
Telephone: (650) 752-1700
Facsimile: (650) 752-1800
jhannah@kramerlevin.com
jfuller@kramerlevin.com

Jeffrey H. Price (Reg. No. 69,141)
Kramer Levin Naftalis & Frankel LLP
1177 Avenue of the Americas
New York, NY 10036
Telephone: (212) 715-7502
Facsimile: (212) 715-8302
jprice@kramerlevin.com

Attorneys for Patent Owner
Cleveland Medical Devices Inc.

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

The undersigned hereby certifies that the portions of the foregoing
PATENT OWNER'S PRELIMINARY RESPONSE specified in 37 C.F.R. §
42.24 has 9,288 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: June 28, 2023

/James Hannah/

James Hannah (Reg. No. 56,369)
Jenna Fuller (Reg. No. 74,212)
Kramer Levin Naftalis & Frankel LLP
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065
Telephone: (650) 752-1700
Facsimile: (650) 752-1800
jhannah@kramerlevin.com
jfuller@kramerlevin.com

Jeffrey H. Price (Reg. No. 69,141)
Kramer Levin Naftalis & Frankel LLP
1177 Avenue of the Americas
New York, NY 10036
Telephone: (212) 715-7502
Facsimile: (212) 715-8302
jprice@kramerlevin.com

Attorneys for Patent Owner
Cleveland Medical Devices Inc.

CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. § 42.6(e), that service was made on the Petitioner as detailed below.

<i>Date of service</i>	June 28, 2023
<i>Manner of service</i>	Electronic Mail (tiffany.miller@us.dlapiper.com; ed.sikorski@us.dlapiper.com; jim.heintz@us.dlapiper.com DLA-ResMed-CleveMed-IPR@us.dlapiper.com)
<i>Documents served</i>	PATENT OWNER'S PRELIMINARY RESPONSE
<i>Persons Served</i>	DLA Piper LLP (US) Tiffany C. Miller Edward H. Sikorski James M. Heintz

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