

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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RESMED CORP.,  
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,  
Patent Owner.

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Case PGR2024-00012  
U.S. Patent No. 11,602,284

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| <b>Abbreviations</b>  | <b>Description</b>                     |
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| The '284 Patent       | U.S. Patent No. 11,602,284 (Ex. 1001)  |
| CleveMed/Patent Owner | Cleveland Medical Devices, Inc.        |
| Petitioner            | ResMed Corp.                           |
| The Challenged Claims | Claims 1–20 of the '284 Patent         |
| The '899 Application  | U.S. Patent Application No. 11/266,899 |
| RDI                   | Respiratory Disturbance Index          |
| AHI                   | Apnea-Hypopnea Index                   |
| Petition/Pet.         | PGR2024-00012, Paper 1                 |

**PATENT OWNER'S EXHIBIT LIST**

| <b>Exhibit</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2001           | Sutherland, K., et al., "Efficacy versus Effectiveness in the Treatment of Obstructive Sleep Apnea: CPAP and Oral Appliances," Journal of Dental Sleep Medicine, vol. 2, no. 4, 2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2002           | Apnea Hypopnea Index (AHI), dated December 23, 2023, available at <a href="https://www.resmed.co.in/blogs/apnea-hypopnea-index">https://www.resmed.co.in/blogs/apnea-hypopnea-index</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 2003           | Internet Archive Wayback Machine – ResLink efficacy data, dated July 8, 2003, available at <a href="https://web.archive.org/web/20030708023809/http://www.resmed.com.au/row/1031284891040.html">https://web.archive.org/web/20030708023809/http://www.resmed.com.au/row/1031284891040.html</a>                                                                                                                                                                                                                                                                                                                                                                                                         |
| 2004           | Excerpts from the Declaration of Carolyn M. D'Ambrosio, MS, MD, in Support of Plaintiff Cleveland Medical Devices Inc.'s Reply Claim Construction Brief, <i>Cleveland Medical Devices Inc. v. ResMed, Inc.</i> , Case No. 22-cv-00794-GBW, D.I. 102-1 (D. Del. June 28, 2023)                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2005           | R.B. Berry, "Ch. 9: Monitoring Respiration—Event Definitions and Examples," Fundamentals of Sleep Medicine, 2012, pp. 119-140                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2006           | M.C. Bagnato, et al., "Comparison of AutoSet and polysomnography for the detection of apnea-hypopnea events," Braz. J. Med. Biol Res., vol. 33(5), May 2000                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 2007           | 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 <a href="https://go.gale.com/ps/i.do?id=GALE%7CA12682650&amp;sid=googleScholar&amp;v=2.1&amp;it=r&amp;linkaccess=fulltext&amp;issn=00123692&amp;p=AONE&amp;sw=w&amp;userGr%E2%80%A6&amp;userGr&amp;userGroupName=anon%7E92eb47a3&amp;aty=open-web-entry">https://go.gale.com/ps/i.do?id=GALE%7CA12682650&amp;sid=googleScholar&amp;v=2.1&amp;it=r&amp;linkaccess=fulltext&amp;issn=00123692&amp;p=AONE&amp;sw=w&amp;userGr%E2%80%A6&amp;userGr&amp;userGroupName=anon%7E92eb47a3&amp;aty=open-web-entry</a> |
| 2008           | Abstract, "Polysomnography in patients with obstructive sleep apnea: an evidence-based analysis," Ont. Health Technol. Assess. Ser., 6(13), June 1, 2006, available at <a href="https://pubmed.ncbi.nlm.nih.gov/23074483/">https://pubmed.ncbi.nlm.nih.gov/23074483/</a>                                                                                                                                                                                                                                                                                                                                                                                                                               |

| <b>Exhibit</b> | <b>Description</b>                                                                                                                                                                                                                      |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2009           | Computer Hope, Are smartphones and tablets computers?, dated November 6, 2021, available at <a href="https://www.computerhope.com/issues/ch001540.htm">https://www.computerhope.com/issues/ch001540.htm</a>                             |
| 2010           | TechTarget – Definition of mobile device, dated December 17, 2023, available at <a href="https://www.techtarget.com/whatis/definition/mobile-device">https://www.techtarget.com/whatis/definition/mobile-device</a>                     |
| 2011           | Illummy - What Happened to Blackberry? The History of the Blackberry Phone, dated April 13, 2023, available at <a href="https://www.illummy.com/blackberry-phone/">https://www.illummy.com/blackberry-phone/</a>                        |
| 2012           | Bright Hub – The History of Windows Mobile, dated December 24, 2023, available at <a href="https://www.brighthub.com/computing/windows-platform/articles/1295/">https://www.brighthub.com/computing/windows-platform/articles/1295/</a> |
| 2013           | PhoneArena – Audiovox Thera, dated September 27, 2003, available at <a href="https://www.phonearena.com/news/Audiovox-Thera_id11">https://www.phonearena.com/news/Audiovox-Thera_id11</a>                                               |

The Board should deny the Petition because the '284 Patent is a pre-AIA patent and, therefore, ineligible for PGR. *See* '284 Patent at Cover (63). The '284 Patent claims priority through a series of continuation applications to the '899 Application, filed November 4, 2005, which provides written description and enablement support for the Challenged Claims. *See id.*<sup>1</sup>

## **I. INTRODUCTION**

*A rose by any other name would smell as sweet.*

- William Shakespeare, *Romeo & Juliet*

Petitioner has no basis for its PGR request because the '284 Patent describes an “index of treatment efficacy” concept throughout the specification, using different language to explain this concept. Thus, there is ample written description and enablement support for calculating an “index of treatment efficacy.” The term “index of treatment efficacy” is a term of art referring to indices that measure the efficacy of therapies. Ex. 2001 at 175; Ex. 2002 at 1-2; Ex. 2003 at 1 (collectively

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<sup>1</sup> Because all applications share a common disclosure pursuant to MPEP § 211.05, the specification of the '284 Patent is representative of all disclosures in the priority chain, including the '899 Application. *See* '284 Patent at Cover (63). Therefore, CleveMed cites the '284 Patent herein for demonstrating that the Challenged Claims are entitled to an effective filing date of November 4, 2005.

describing the AHI as measuring treatment efficacy). When the '284 Patent discloses “determin[ing] the level of severity of the subject’s sleeping disorder or symptoms” while simultaneously applying treatment, the resulting “level of severity” is an “index of treatment efficacy.” ’284 Patent at 23:36-37; *see also id.* at 3:37-39, 3:66-4:55, 19:56-57. Accordingly, while the specification does not use the term “index of treatment efficacy” *in haec verba*, it contains an equivalent description that satisfies the written description test. *See Indivior Inc. v. Dr. Reddy’s Labs., S.A.*, 930 F.3d 1325, 1349 (Fed. Cir. 2019). There is similarly no enablement problem because, as Petitioner’s expert readily admits, the procedure for calculating such indices was both disclosed in the '284 Patent and well-known to those skilled in the art in 2005.

Petitioner’s other written description arguments are similarly meritless. Given that the '284 Patent discloses an integrated diagnosis and treatment system, it is no surprise that it discloses a PAP machine can collect and calculate the very data used to determine the efficacy of the treatment and trigger real-time changes to the treatment being applied. *See* '284 Patent at 3:17-50, 3:65-4:55. The '284 Patent also discloses displaying this data on a computer, including a cell phone, and transmitting that data to a remote internet site. *Id.* at 19:7-51. Petitioner’s arguments to the contrary ignore these express disclosures and/or rely on a heightened written description that would require *in haec verba* support for every limitation, including

those that are well-known in the art and, therefore, preferably not described in the specification.

Based on these reasons and those that follow, CleveMed respectfully requests that the Board find the '284 Patent ineligible for PGR.

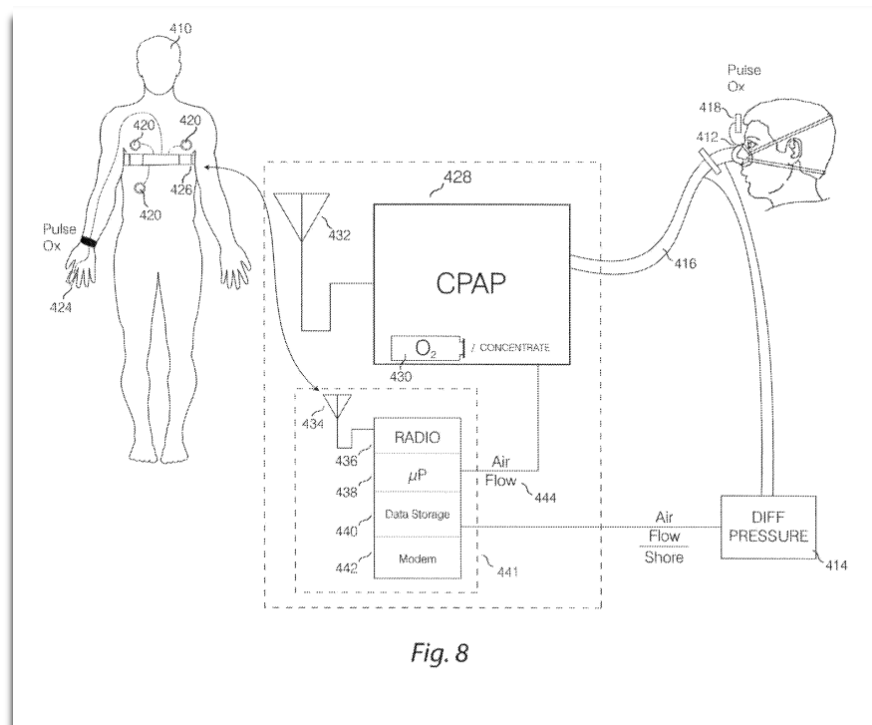
## **II. OVERVIEW OF THE '284 PATENT**

The '284 Patent discloses an integrated diagnosis and treatment device for patients suffering from sleep apnea and other sleep disorders. '284 Patent at Abstract, 1:27-31. The device monitors a patient's breathing metrics and the device's usage data while simultaneously providing a sleep-disorder treatment, such as applying continuous positive airway pressure or a pharmaceutical intervention. *Id.* at 4:6-55. The monitored breathing metrics include respiratory airflow and effort, blood oxygenation levels, and the like. *Id.* at 1:27-31; 2:46-59, 3:19-27, 3:37-40.

From these breathing metrics, the device calculates the “level of severity” of the patient's sleep-disordered breathing during treatment. *Id.* at 20:11-14, 23:26-37. That “level of severity” is, therefore, an “index of treatment efficacy . . . based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject” because it is based on breathing metrics collected while the patient is using the device. *Id.* at Claim 1. On the other hand, a “level of severity” calculated based on breathing metrics gathered while the patient is not undergoing treatment—like those gathered in an “all-night polysomnography”—are

indices that measure the severity of a patient's sleep disorder symptoms for purpose of diagnosis, but they are not indices of treatment efficacy. *See id.* at 1:59-64.

In a preferred embodiment, the '284 Patent discloses a positive airway pressure ("PAP") device with internal airflow sensors that monitor the patient's airflow. *Id.* at 6:21-7:42. An exemplary embodiment of the PAP device, shown below, includes a pressure generator, a blower, a hose, a mask or nasal cannula, a flow sensor, and a pressure sensor for measuring breathing metrics (for example, respiratory airflow), and processor(s) for collecting and processing the breathing metrics:



'284 Patent at FIG. 8; *see also id.* at 3:3-30, 23:1-49, FIG. 7. While treatment is ongoing, the PAP device also collects usage data and passes that data to the processor. *Id.* at 23:20-25; *see also id.* at 8:37-41, 19:3-17.

Once this data is collected, “[v]arious algorithms known to those skilled in the art are used to . . . then quantify the level of severity of the subject’s sleeping disorder or symptoms.” *Id.* at 20:11-14. Several exemplary algorithms are expressly disclosed in the '284 Patent, and others are—as Petitioner acknowledges—well-known to those skilled in the art. *See id.* at 1:59-63, 18:61-64, 23:26-37; Ex. 1020 (“Schwartz Decl.”) at ¶ 46 (equating the level of severity of sleep disordered breathing with sleep apnea indices).<sup>2</sup> For example, the RDI, which is explicitly disclosed in the '284 Patent and used interchangeably with AHI, is a well-known sleep-disorder index that measures the number of apnea episodes over a period of time. *See* Ex. 2004 (“D’Ambrosio Decl.”), ¶ 26; Ex. 2005 at 134 (“Definition #1 RDI = AHI”). When those apnea episodes are counted during treatment, the index

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<sup>2</sup> Sleep apnea indices are calculated based upon respiratory events (data of severity of sleep disorder symptoms) over a period of sleep time (usage of the PAP machine when a patient is sleeping). *See* D’Ambrosio Decl., ¶ 26; Schwartz Decl., ¶ 46 (Dr. Schwartz testifying that an index is based upon apnea events over a period of time)

is an index of treatment efficacy. *See* Ex. 2001 at 175; Ex. 2002 at 1-2; Ex. 2003 at 1.

After the severity and usage data are collected and calculated, that data (and/or the index of treatment efficacy calculated based on that data) is transferred to a remote internet site and downloadable on a computer for display. *See* '284 Patent at 19:3-55. That computer may be a PC, PDA, cell phone, or any other suitable computer with a processor and display capabilities. *Id.* at 19:7-51. The calculated index may also be fed back to the PAP and used to adjust the patient's treatment in real time. *See id.* at 4:6-18, 22:9-20.

### **III. LEVEL OF ORDINARY SKILL IN THE ART**

For the purpose of this preliminary proceeding only, CleveMed applies Petitioner's definition of a person of ordinary skill in the art ("POSITA" or skilled artisan), as one who "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, where an increase in experience could compensate for less education, and vice-versa. A POSITA would have worked with professionals having specialized training in related disciplines such as clinical use and operation of sleep disordered breathing treatment devices." Pet. at 15.

CleveMed reserves the right to propose its own definition of a POSITA if the Board institutes review.

#### **IV. THE '284 PATENT IS INELIGIBLE FOR PGR**

The Board should deny institution because post-grant review is only available for patents with effective filing dates on or after March 16, 2013, and the '284 Patent's effective filing date is November 4, 2005. *See* '284 Patent at 1:7-16.

Post-grant review is available only for patents that issue from applications that “contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date in section 100(i) of title 35, United States Code, that is on or after [March 16, 2013.]” Leahy-Smith America Invents Act (“AIA”), Pub L. No. 112-29, 125 Stat. 284 (2011), AIA § 3(n)(1); *Concert Pharm., Inc. v. Incyte Corp.*, No. PGR2017-00034, Paper 9 at 5-6 (P.T.A.B. Jan. 11, 2018) (finding no PGR-eligibility and denying post-grant review because the challenged claims are entitled to a priority date before March 16, 2013). “Entitlement to the benefit of an earlier date under §§ 119, 120, 121, and 365 is premised on disclosure of the claimed invention in the manner provided by § 112(a) . . . in the application for which the benefit of the earlier filing date is sought.” *Concert Pharm.*, Paper 9 at 5 (citing 35 U.S.C. §§ 119(e), 120).

The '284 Patent claims priority to a series of continuation applications, the earliest of which was filed on November 4, 2005. '284 Patent at 1:7-16. Petitioner

identifies no defects in the priority claims aside from the alleged lack of written description and enablement for several claim limitations concerning the calculation and display of an “index of treatment efficacy.” Pet. at 13-15 (alleging that the Challenged Claims of the '284 Patent are entitled to a priority date of May 26, 2022, the filing date of the '284 Patent application). However, the '284 Patent and its priority applications disclose calculating a quantitative “level of severity” of sleep-disorder symptoms while the patient is being treated, which refers to the claimed “index of treatment efficacy” in different terms.

**A. THE '284 PATENT PROVIDES WRITTEN DESCRIPTION SUPPORT FOR THE CHALLENGED CLAIMS (GROUND 1)**

The Challenged Claims are entitled to a priority date of 2005 because the '284 Patent's disclosure “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (citation omitted) (en banc); *see also Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002) (written description is found when the disclosure “allow[s] one skilled in the art to visualize or recognize the identity of the subject matter purportedly described”) (citation omitted).

**1. The '284 Patent Provides Written Description Support For  
“An Index of Treatment Efficacy”**

**(a) The '284 Patent Describes “An Index of Treatment  
Efficacy”**

Although it does not use the term *in haec verba*, the '284 Patent describes the concept of “an index of treatment efficacy” in other, equivalent terms. *See Indivior Inc.*, 930 F.3d at 1349 (expressing that “[t]he specification need not recite the claimed invention *in haec verba*” so long as the specification reasonably conveys the claimed feature to a skilled artisan) (citation omitted); *Nalpropion Pharm., Inc. v. Actavis Lab’ys FL, Inc.*, 934 F.3d 1344, 1350 (Fed. Cir. 2019) (“It is not necessary that the exact terms of a claim be used *in haec verba* in the specification, and equivalent language may be sufficient.”).

The “level of severity” of a patient’s sleep disorder symptoms, calculated from data collected while the patient is undergoing treatment, is equivalent to the claimed “index of treatment efficacy.” This term is a term of art that refers to “the ability of treatment to prevent the occurrence of obstructive breathing events during periods when the treatment is being physically applied.” Ex. 2001 at 175. “This is assessed by the number of obstructive breathing events *per hour of sleep* or apnea-hypopnea index (AHI).” *Id.* This plain and ordinary meaning of the term in the art is consistent with the language used in the Challenged Claims, which require that the index be calculated “based in part on data of severity of sleep disorder symptoms of the

subject and data of usage of the PAP device by the subject.” ’284 Patent at Claim

1. The usage data indicates, among other things, that the patient was being treated during the period that the level of severity was determined.

This conclusion is consistent with the inventors’ description that one of the key benefits of the ’284 Patent is that the level of severity of a patient’s sleep disorder systems can be used to adjust, in real-time, the treatment being provided to the patient based on their current physiological symptoms:

The present invention is envisioned to be particularly valuable in the treatment of sleep apneas. With the present invention, it is envisioned that **modifications can be made to a subject’s treatment regiment as the severity or level of the subject’s symptoms increase or decrease** better regulating the therapeutic treatment of the subject’s sleeping disorder. For example, with a subject who has sleep apnea, delivery of a physical treatment such as CPAP can be **adjusted during the treatment based on the sleep diagnosis results.**

’284 Patent at 22:37-45 (emphasis added); *see also id.* at 2:35-37 (“None of the devices on the market can be used to adjust a patient's treatment, whether physical or chemical, based on the patient's current physiological state.”). In this context—where the level of severity is determined during treatment (not to mention used to adjust that treatment)—the level of severity is just another name for an index of treatment efficacy.

This conclusion is also consistent with the requirement that the index of treatment efficacy is “based in part on data of severity of sleep disorder symptoms of the subject and data of usage of the PAP device by the subject.” ’284 Patent at Claim 1. Although the ’284 Patent discloses that “[v]arious algorithms known to those skilled in the art are used to... quantify the level of severity of the subject's sleeping disorder or symptoms,” it calls one out by name: the well-known respiratory disturbance index (“RDI”). *Id.* at 1:59-62; 20:11-14. A skilled artisan understands that in the context of sleep apnea the term “index” is calculated by evaluating breathing metrics to determine the number of sleep disordered breathing events that occur over a period of time (for example, usage of the PAP machine when sleeping). *See id.* at 1:59-63;<sup>3</sup> *see also* D’Ambrosio Decl., ¶ 26; Schwartz Decl., ¶ 46 (Dr. Schwartz testifying that an index is based upon apnea events over a period of time).

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<sup>3</sup> The breathing metrics, such as the patient’s respiratory airflow data, characterize apnea events, hypopnea events, and the like. *See* Ex. 2006 at 516 (“The criteria adopted to define respiratory events were a) apneas characterized by absence of, or drop in, airflow higher than 80% in relation to basal values, associated or not with alterations in chest and abdominal movements for more than 10 s; b) hypopneas, characterized by a drop in airflow between 50 and 80% of basal values, for more than 10 s, associated with an oxygen destruction of  $\geq 4\%$  or arousal”); Ex. 2007 at 6.

The term RDI is used interchangeably with the apnea-hypopnea index (AHI), which also evaluates the severity of the patient's sleep apnea disorder. *See* Ex. 2008 at 1; Ex. 2005 at 134 ("Definition #1 RDI = AHI").

The petitioner's expert confirms that these well-known sleep apnea indices represent the level of severity of the patient's sleep disordered breathing. Schwartz Decl., ¶ 46 (equating the level of severity of sleep disordered breathing with sleep apnea indices). This fact is also confirmed by contemporaneous expert testimony in *Cleveland Medical Devices Inc. v. ResMed, Inc.*, No. 22-794-GBW (D. Del. June, 28, 2023). *See* D'Ambrosio Decl., ¶ 26 (stating that the "level of severity" represents sleep apnea indices such as AHI which indicate "how dire a patient's calculated symptom data may be.").

In accordance with these undisputed facts, the '284 Patent discloses collecting usage data and data representing breathing metrics, including a patient's airflow pressure, nasal pressure, respiratory effort, pulse oximetry, oxygenation and ventilation, and the like. '284 Patent at 3:21-27, 5:42-52, 7:38-54, 23:20-25. These breathing metrics, collected while the patient is being treated, are used to determine a level of severity of the patient's symptoms while being treated to diagnose and treat the patient in real-time. *See id.* at 3:19-27, 3:37-38, 5:42-52, 7:38-54, 20:11-22. Accordingly, the '284 Patent discloses calculating an index of treatment efficacy based on the severity data and usage data because it calculates a level of severity of

the patient's symptoms while the patient is using the treatment device. *See id.* at 3:19-27, 3:37-38, 5:42-52, 7:38-54, 20:11-22, 23:1-35.

Petitioner's own documents further demonstrate that the well-known AHI and RDI indices are indices of treatment efficacy. *See, e.g.,* Ex. 2002 at 1-2 (describing that AHI "helps you assess ***how well your treatment*** with the CPAP machine is working" and "through it, you can track ***the effectiveness of your treatment.***") (emphasis added); Ex. 2003 at 1 ("ResLink provides valuable insights ***into treatment efficacy*** by reporting on significant parameters such as . . . AHI") (emphasis added). For instance, the treatment efficacy for obstructive sleep apnea (OSA) is measured based on AHI:

Efficacy, in the context of OSA, reflects the ability of treatment to prevent the occurrence of obstructive breathing events during periods when the treatment is being physically applied. This is assessed by the number of obstructive breathing events *per hour of sleep* or apnea-hypopnea index (AHI).

Ex. 2001 at 175. In this regard, sleep apnea indices based on breathing metric data tracked over sleep time is one way to quantify treatment efficacy for sleep apnea. *See* D'Ambrosio Decl., ¶ 26.

Given these express disclosures, a skilled artisan would recognize that "an index of treatment efficacy" is just another term for the level of severity of a patient's symptoms determined while the patient is being treated. The '284 Patent, therefore,

more than reasonably conveys to those skilled in the art that the inventors were in possession of “an index of treatment efficacy” at the time of filing the original disclosure.

**(b) Petitioner Applies the Wrong Standard With its Own Arguments and Evidence Demonstrating Written Description Support**

Petitioner's arguments to the contrary fail as a matter of law because they are predicated upon a written description standard that requires *in haec verba* disclosure. *See* Pet. at 18 (asserting that “[t]he term ‘efficacy’ does **not appear** in the ’284 patent’s specification, let alone an ‘index of treatment efficacy.’”) (emphasis added); *id.* at 18-19 (asserting that “**there is no disclosure** of any other parameter, whether or not referred to as an index, . . . ‘based in part on data of severity of sleep disorder symptoms of the subject *and* data of usage of the PAP device by the subject’”) (emphasis added). As discussed above, although the term is not recited *in haec verba*, a POSITA would have recognized that the ’284 Patent discloses the same concept using different language. *See* § IV.A.1.a, *supra*. Thus, Petitioner's assertion that there is no “disclosure of any other parameter” is meritless. *See* Pet. at 18-19.

Nevertheless, even granting the premise that an “index of treatment efficacy” is not expressly disclosed, that fact would still not establish lack of written description because the patent specification is also “written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come

before.” *Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1167 (Fed. Cir. 2012) (citation omitted); *see also Capon v. Eshhar*, 418 F.3d 1349, 1357-58 (Fed. Cir. 2005) (“The ‘written description’ requirement must be applied in the context of the particular invention and the state of the knowledge [in the art].”); *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1365 (Fed. Cir. 2006) (“[A] patent need not teach, and preferably omits, what is well known in the art.”) (citation omitted).

Petitioner readily admits that calculating an “index of treatment efficacy” was known in the art. Pet. at 36 (asserting that determining an “index of treatment efficacy” is “merely applying a known technique.”); Schwartz Decl., ¶ 45 (admitting that “‘efficacy’ of treatment” is determinable if it is known what is “being detected, evaluated, or treated”). Petitioner concedes, therefore, that the term “index of treatment efficacy” has a well-understood meaning in the context of sleep apnea and a skilled artisan knows how to calculate the index. Accordingly, by Petitioner’s own concession, the ’284 Patent reasonably conveys to skilled artisans that the inventors had possession of an index of treatment efficacy at the time of filing.

The ’284 Patent claims require treating a patient’s “sleep disorder,” and the specification describes the treatment as related to sleep apnea disorders. ’284 Patent at Abstract (describing the claimed invention as directed to “an integrated apnea diagnosis and treatment device”) (emphasis added); *see also id.* at 1:27-29 (describing “an integrated apnea diagnosis and treatment device”) (emphasis

added), 2:63-65, 5:37-39 (same), 22:37-40 (“The present invention is envisioned to be particularly valuable in the treatment of sleep apneas.”) (emphasis added). Given that the treatment is for sleep apnea disorders, Dr. Schwartz concedes that a skilled artisan would know how to determine indices of treatment efficacy for sleep apnea.

Dr. Schwartz also admits that a skilled artisan comes to the '284 Patent with the knowledge that sleep apnea indices are generated using standard breathing metrics, such as those disclosed in the '284 Patent. Schwartz Decl., ¶ 46 (acknowledging that standard breathing metrics, including the patient's airflow, were used “long before” the claimed invention as indicators of the “type and severity of sleep-disordered breathing” (such as sleep apnea indices)). Thus, Dr. Schwartz concedes and demonstrates that a skilled artisan would know how to calculate indices of treatment efficacy for sleep apnea based on the disclosed breathing metrics (for example, respiratory airflow) and usage of the PAP device. *See Pozen Inc.*, 696 F.3d at 1167; *see also* § IV.A.1.a, *supra* (establishing that an “index” in the context of sleep apnea is based on breathing metric data over a period of time).

In view of the above, Petitioner's arguments and evidence only solidifies that a skilled artisan would understand that the inventors were in possession of “an index of treatment efficacy” at the time of filing the original disclosure.

**2. The '284 Patent Provides Written Description Support For “the Data of Severity of Sleep Disorder Symptoms of the Subject and the Data of Usage of the PAP Device By the Subject Both Calculated By the PAP Device”**

The '284 Patent provides more than sufficient support for this claim limitation. Petitioner's dispute appears to rest on the term “data of usage” as it alleges that the term does not “appear in the '284 patent's specification.” Pet. at 20 (“The term ‘data of usage’ does not appear in the '284 patent's specification”). Again, the disclosure does “not have to provide *in haec verba* support for the claimed subject matter at issue.” *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (citation omitted). Rather, it must reasonably convey to those skilled in the art that the inventors were in possession of the subject matter. *Ariad Pharm.*, 598 F.3d at 1351. The '284 Patent disclosure does just that.

The '284 Patent specification describes that information collected from the sensors is used to “monitor the usage of the pressure support device” (the PAP device), which a skilled artisan would appreciate requires calculating. '284 Patent at 23:20-25. Petitioner acknowledges this very passage; however, it asserts that the passage does not disclose “calculating” the “‘data of usage’ by the PAP device.” Pet. at 20 (alleging that “there is simply no disclosure or suggestion of ‘calculating’ ‘data of usage.’”). But what matters is what the disclosure reasonably conveys to a skilled artisan, not what it does or does not explicitly discloses. Here, a skilled artisan would immediately discern that to monitor the usage of the PAP device, the

usage data is calculated by the PAP device. '284 Patent at 23:20-25. That is, monitoring the usage of the PAP device entails the PAP device collecting and processing a patient's PAP device usage data from the sensors. *Id.* ("The information from the flow sensor 320 . . . is used, for example, to . . . monitor the usage of the pressure support device."); *see also id.* at 8:37-41, 19:3-17.

Further, although a heading in the Petition also appears to challenge whether "the data of severity of sleep disorder symptoms . . . calculated by the PAP device" finds written description support in the '284 Patent, Petitioner does not mention this limitation in its argument. *See* Pet. at 19-20; *Trading Techs. Int'l, Inc. v. IBG LLC*, 921 F.3d 1378, 1385 (Fed. Cir. 2019) (holding that a conclusory assertion with no analysis was not adequately developed); *Novartis AG v. Torrent Pharm., Ltd.*, 853 F.3d 1316, 1326 n.2 (Fed. Cir. 2017) (finding that an argument presented in one conclusory sentence and a string cite was "far from sufficient to raise a meaningful challenge" and "amount[ed] to little more than a request that the Board peruse the cited evidence and piece together a coherent argument on Novartis' behalf"). Petitioner's superficial treatment of the term amounts to requesting the Board to pursue a lack of written description argument on Petitioner's behalf, which does not rise to a meaningful challenge.

Nevertheless, the '284 Patent specification also conveys to a skilled artisan that the inventors had possession of calculating the data of severity of sleep disorder

symptoms by the PAP device. Specifically, the specification discloses that the PAP device collects and processes the patient's breathing metrics, respiratory airflow, and the like, for indicating data of the severity of the patient's sleep disorder symptoms, for example, apnea and hypopnea events.<sup>4</sup> '284 Patent at 20:11-14 ("Various algorithms known to those skilled in the art are used to filter out noise from the signal or data, and to then quantify the level of severity of the subject's sleeping disorder or symptoms"), 23:26-37 (describing that the microprocessor "process[es] the data or signals to determine a level of severity of the subject's sleeping disorder or symptoms."); 19:7-14; *see also id.* at 3:19-27, 3:37-38 (disclosing that breathing metrics include a patient's airflow, respiratory effort, oxygenation, and ventilation, etc.). For instance, by collecting and processing respiratory airflow, the PAP device calculates sleep disordered breathing episodes such as apnea events, which a skilled artisan understands is used along with the data of usage to determine sleep apnea indices/level of severity of sleep disordered breathing, as discussed in detail above. *See* § IV.A.1.a, *supra*.

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<sup>4</sup> A skilled artisan would know that apnea and hypopnea events, which are indicated based on breathing metrics, represent data of severity of the patient's sleep disorder symptoms. *See* Ex. 2006 at 516 (describing that apnea events are indicated based on "the absence of, or drop in, airflow" for more than 10 seconds).

In view of the foregoing, the '284 Patent specification provides sufficient written description support for calculating both the “data of usage” and “data of severity of sleep disorder symptoms.”

**3. The '284 Patent Provides Written Description Support For “Non-Transitory Computer Readable Medium Comprising a First Software Executable By a First Processor and Configured to Be Used With a Cell Phone to Display to a Subject For Viewing on the Cell Phone on to Which the First Software is Downloaded an Index of Treatment Efficacy of the Subject Using a PAP Device”**

The '284 Patent specification provides more than sufficient support for this claim limitation at issue. Petitioner's dispute here centers around the claim requirement of software downloadable on a cell phone for displaying an index of treatment efficacy. *See* Pet. at 21.

As a preliminary matter, the '284 Patent reasonably conveys to a skilled artisan that the inventors had possession of the “index of treatment efficacy” at the time of filing. *See* § V.A.1, *supra*. The '284 Patent specification also reasonably conveys to a skilled artisan that the inventors possessed software downloadable on a cell phone for displaying data or records as disclosed in the specification.

The specification provides specific examples of remote communication systems that display data and records that provide sufficient support for the claimed cell phone. The '284 Patent specification describes a remote communications system as a “PDA, computer or cell phone, which receives the physiological data

transmission, optionally re-processes the information, and re-transmits the information.” ’284 Patent at 19:45-49; *see also id.* at 19:14-17. In one example, the remote communications system is “a computer or processor, which receives the data transmission and displays the data or records it on some recording medium.” *Id.* at 19:51-55. In this regard, the ’284 Patent provides specific examples of what a remote communication system is (for example, a cell phone) and the functions the system performs (for example, receiving and displaying data).

Petitioner provides no basis for its apparent argument that a cell phone is not a computing device that displays data. *See* Pet. at 22. A skilled artisan appreciates that cell phones are considered such devices. *See* Ex. 2009; Ex. 2010. In fact, by 2005, cell phones, such as those offered by Blackberry, Verizon, and Microsoft, had their own operating systems and processors that offered various mobile applications that display data. *See* Ex. 2011 at 3; Ex. 2012 at 10; Ex. 2013 at 2.

For at least the foregoing reasons, the ’284 Patent specification supports software downloadable on a cell phone for displaying data, such as an index of treatment efficacy.

**4. The '284 Patent Provides Written Description Support For “the Remote Internet Site is Configured to Retransmit to the First Radio Frequency Wireless Transceiver on the Cell Phone the Data of the Severity of the Symptoms of the Subject, the Index, a Second Index and/or the Data of Usage Related to the Subject’s Treatment and the Treatment Efficacy, in Whole or Part, Calculated by the PAP Device.” (Dependent Claims 10 and 14)**

The '284 Patent specification also provides more than sufficient support for this claim limitation at issue. Petitioner's dispute focuses on the transmission of data to a radio frequency wireless transceiver on a cell phone. See Pet. at 23. In particular, Petitioner alleges in one sentence that the retransmission of data to a cell phone is not disclosed in the '284 Patent. *Id.* (merely alleging that the retransmission of any data, including a “second index” to a radio frequency wireless transceiver on a cell phone is not disclosed in the specification). Here, again, an argument presented in one conclusory sentence is “far from sufficient to raise a meaningful challenge.” *Novartis AG*, 853 F.3d at 1326 n.2; see also *Trading Techs.*, 921 F.3d at 1385 (holding that a conclusory assertion with no analysis was not adequately developed).

Nonetheless, the '284 Patent specification adequately conveys to a skilled artisan that the inventors possessed a cell phone that receives the retransmission of data, including indices. As discussed above, the specification provides specific examples of a remote communication system (e.g., cell phone) that in addition to displaying data may receive data from another remote communication system:

The remote communication station or base station ***can be any device known to receive RF transmissions***. . . . The remote communication station or base station by way of example but not limitation can include a communications device for relaying the transmission, a communications device for re-processing the transmission, a communications device for ***re-processing the transmission then relaying it to another remote communication station*** . . . . [For example,] ***the remote communication system is a PDA, computer or cell phone, which receives the physiological data transmission, optionally re-processes the information, and re-transmits the information via cell towers, land phone lines, satellite, radio frequencies or cable to a remote site for analysis.***

'284 Patent at 19:20-51 (emphasis added).

In this context, the '284 Patent expressly discloses that a cell phone receives physiological data including data of the severity of symptoms, indices, and/or the data of usage from another remote communications system. A skilled artisan would readily discern that the received data may include first and second indices that, calculated over different periods of usage of the PAP device, assess the efficacy of treatment over time.

Accordingly, the '284 Patent specification provides sufficient written description support for the retransmission of data to a radio frequency wireless transceiver on a cell phone.

\* \* \*

In view of the foregoing, Petitioner fails to show that it is more likely than not that the '284 Patent lacks written description support for the Challenged Claims. Because the Challenged Claims are entitled to an effective filing date of November 4, 2005, the '284 Patent is not eligible for post-grant review.

**B. THE '284 PATENT ENABLES THE CHALLENGED CLAIMS  
(GROUND 2)**

Petitioner's non-enablement challenge is largely a repeat of its written description challenge. *See* Pet. at 25. Accordingly, just like its written description challenge, Petitioner's lack of enablement challenge fails, as does its argument that the alleged lack of enablement limits the Challenged Claims to a PGR-eligible May 26, 2022 filing date. *See id.* at 1-2, 24-26; *Concert Pharm.*, Paper 9 at 11-13 (finding no PGR-eligibility based on non-enablement).

To establish a lack of enablement, "a challenger must show 'that a person of ordinary skill in the art would not be able to practice the claimed invention without undue experimentation.'" *China Lithium Battery Tech. Co. v. Contemporary Amperex Tech. Co.*, No. PGR2022-00008, Paper 8 at 22 (P.T.A.B. Jun. 6, 2022) (citing *Enzo Life Sciences, Inc. v. Roche Molecular Sys., Inc.*, 928 F.3d 1340, 1345 (Fed. Cir. 2019)); *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.").

Here, Petitioner fails to demonstrate that any experimentation would have been “undue” in view of the *Wands* factors:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (citation omitted); *see also* Pet. at 24-26 (citing *In re Wands*).

**1. The '284 Patent Enables the “Index of Treatment Efficacy”**

In light of the *Wands* factors discussed as follows, the claimed “index of treatment efficacy” is adequately enabled.

***The quantity of experimentation necessary, nature of the invention, the state of the prior art, relative skill of those in the art, predictability of the art (Wands Factors 1, 4, 5, 6, 7).*** The field of the invention relates to an “integrated apnea diagnosis and treatment device,” which is a well-developed art, and the apnea disorder diagnosis and treatment subject matter behaves in a predictable manner such that a significant amount of experimentation is not required. *See* '284 Patent at Abstract, 2:63-65, 5:37-39.

Those skilled in the art would work alongside those with “specialized training” in the field of sleep apnea disorders and treatments. *See* Schwartz Decl., ¶

39 (asserting that a POSITA “refers[s] to the perspective of a” clinician who has “**specialized training** in the field of sleep and breathing disorders and related treatments.”) (emphasis added); Pet. at 15 (asserting that those skilled in the art “worked with professionals having **specialized training** in related disciplines such as clinical use and operation of sleep disordered breathing treatment devices”) (emphasis added). Given this “specialized training,” skilled artisans would readily know how to determine indices of treatment efficacy without any experimentation, let alone undue. Dr. Schwartz and Petitioner confirm this.

Dr. Schwartz testifies that the efficacy of treatment is determinable if the disorder was known. Schwartz Decl., ¶ 45. In the context of the '284 Patent, the disorder relates to sleep apnea. *See* § V.A.1.b, *supra* (describing the '284 Patent's disclosure of treating sleep apnea). Petitioner also acknowledges that determining treatment efficacies was merely applying a known technique. *See* Pet. at 36 (asserting that “determining treatment efficacy” was “merely applying a known technique.”). Thus, both Dr. Schwartz and Petitioner demonstrate the predictable nature and lack of experimentation required in determining treatment efficacy for sleep apnea disorders.

Indeed, it was well-known in the art of how to determine indices of treatment efficacy based on breathing metric data over a period of time. *See, e.g.*, Ex. 2001 at 175; Ex. 2002 at 1-2; Ex. 2003 at 1. Accordingly, Petitioner and Dr. Schwartz's

admissions coupled with the record evidence plainly contradict the Petition's conclusory allegation that sleep disorder treatment is "unpredictable [in] nature" and that "a significant amount of experimentation would be needed." *See* Pet. at 25 (citing *Wands* Factors 1, 4, and 7; Schwartz Decl., ¶¶ 50-56).

***The amount of direction or guidance presented, the presence or absence of working examples (Wands Factors 2 and 3).*** The specification's disclosure of sleep indices and the corresponding level of severity of sleep disordered breathing provides to skilled artisans (*i.e.* those specially trained in the field) ample guidance and working examples on how to generate the "index of treatment efficacy;" a known term of art that is directly connected to these terms. *See* § V.A.1.a, *supra*.

For instance, the specification discloses that breathing metrics such as respiratory airflow are used in the indication of the level of severity. *See* '284 Patent at 3:19-27, 7:38-48, 20:19-22; Schwartz Decl. ¶ 46 (stating that standard breathing metrics are used to indicate the level of severity, *i.e.* indices). The '284 Patent describes that the breathing metrics are collected and processed for determining quantitative values of the patient's sleep disorder symptoms (*e.g.*, apnea events, hypopnea events, and the like), with the level of severity indicated based in part on these values. *See* '284 Patent at 7:38-8:36, 18:61-64, 23:32-37. In connection with the level of severity, the '284 Patent discloses sleep apnea indices, such as RDI/AHI, which a skilled artisan knows is calculated based on apnea and hypopnea events over

a period of time. *Id.* at 1:59-62; *see also* Ex. 2005 at 134 (“Definition #1 RDI = AHI”); D’Ambrosio Decl., ¶ 26. Accordingly, these express disclosures provide guidance and examples on how to determine the level of severity/sleep apnea indices, and therefore also indices of treatment efficacy.

Petitioner and Dr. Schwartz’s arguments that “[t]he specification provides absolutely *no* direction or guidance” do not take into account the express disclosures and are contradicted by their statements made elsewhere. *See* Pet. at 24-25 (citing *Wands* Factors 2-3); Schwartz Decl., ¶ 52. For instance, Dr. Schwartz and Petitioner readily admit that “determining treatment efficacy based on multiple factors” was “merely applying a known technique.” Pet. at 36; Schwartz Decl., ¶ 45. Dr. Schwartz further elaborates that this known technique includes the use of standard breathing metrics to indicate the level of severity/indices. Schwartz Decl., ¶ 46. In fact, Dr. Schwartz recognizes that the disclosed level of severity is used as an “output” to help adjust the treatment of sleep apnea disorders. *Id.* at ¶ 54 (citing ’284 Patent at 22:9-14). In this regard, Dr. Schwartz acknowledges that the ’284 Patent provides guidance and examples on generating “output” data, including indices.

Dr. Schwartz’s statement, however, that “AHI does not alone provide information on the type of apnea” is irrelevant to the claimed “index on the treatment efficacy” and belied by his testimony indicating otherwise. *Id.* Dr. Schwartz

acknowledges that the claimed “index of treatment efficacy” is directed to the treatment of the sleep apnea disorder, not the diagnosis of the type of sleep apnea. *Id.* at ¶ 43 (“The independent claim does not mention diagnosis and instead is directed to a ‘treatment system.’”). Dr. Schwartz also acknowledges that standard breathing metrics are and “were well validated indicators of the type and severity of sleep disordered breathing long before the ’269 patent” (the parent of the ’284 Patent). *Id.* at ¶ 46 (describing an index that is “based upon a functional relationship between the number of central or obstructive apneas over a particular time period”) (emphasis added). In this manner, Dr. Schwartz submits that the “type and severity” of the sleep apnea disorder is outputted in a way useful for treatment.

***Breadth of the claims (Wand Factor 8).*** Petitioner’s argument here is dependent on guidance in the specification. Pet. at 26 (alleging that the claim terms broadly claim an “index of treatment efficacy” “but there is no guidance in the specification to enable these claimed elements.”). As established above, the specification provides guidance and examples directed to the “index of treatment efficacy,” therefore the breadth of the claims is commensurate in scope with the specification.

\* \* \*

Overall, in view of the predictable art, the specialized training required, what was well-known in the, the guidance and examples provided in the specification, and

the claims being commensurate with the disclosure, the '284 Patent enables the Challenged Claims. Accordingly, Petitioner fails to show it is more likely than not that the "index of treatment efficacy" is not enabled, and likewise that the alleged lack of enablement limits the Challenged Claims to a PGR-eligible filing date.

## **2. The '284 Patent Enables the Other Claim Limitations**

To the extent that Petitioner also alleges lack of enablement for the other claim limitations, Petitioner's arguments are blanket repeats of its written description arguments. See Pet. at 25 (the Petition's enablement section alleges that there is no disclosure for the other claim limitations challenged in the written description section). As established above, Petitioner does not meet its burden showing a lack of written description, and here provides no further analysis for its alleged non-enablement concerning whether any experimentation necessary to make and use the full scope of the claimed invention is undue. *Microbiotica, Ltd. v. Board of Regents, the Univ. of Texas Sys.*, No. PGR2023-00026, Paper 12 at 27-28 (P.T.A.B. Nov. 21, 2023) (denying institution based in part on the petitioner's failure to show that the claims were not enabled because its non-enablement analysis was merely a repeat of its lack of written description analysis).

## **V. PETITIONER'S GROUNDS 3-10 ALL FAIL BECAUSE THE '284 PATENT IS NOT PGR-ELIGIBLE**

The Petition's Obviousness Grounds 3-10 are based on the assumption that the Challenged Claims are not entitled to an effective filing date earlier than May

26, 2022. *See* Pet. at 15; *see also id.* at 7-8. However, because Petitioner fails to carry its burden to show lack of written description or non-enablement, it failed to establish that the '284 Patent is PGR-eligible for and that the references (*e.g.*, Bao, Klee, and Pirzada)<sup>5</sup> are prior art. *See Concert Pharm.*, Paper 9 at 4, 13 (declining to consider the petition's anticipation ground because the petitioner failed to demonstrate that the patent was PGR-eligible and that the reference was prior art).

## VI. CONCLUSION

For the foregoing reasons, CleveMed respectfully requests that the Board deny institution of post grant review of the Challenged Claims of the '284 Patent.

Respectfully submitted,

Date: March 29, 2024

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<sup>5</sup> Bao (Ex. 1009), Klee (Ex. 1010), and Pirzada (Ex. 1013) were filed after the '284 Patent's priority date of November 4, 2005. *See* Bao at Cover; Klee at Cover; Pirzada at Cover.

Patent Owner's Preliminary Response  
PGR2024-00012 (U.S. Patent No. 11,602,284)

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(Case No. PGR2024-00012)

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**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 7,145 words in compliance with the 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: March 29, 2024

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**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>   | March 29, 2024                                                                                                                                                            |
| <i>Manner of service</i> | Electronic Mail<br>(tiffany.miller@us.dlapiper.com;<br>gianni.minutoli@us.dlapiper.com;<br>matthew.middleton@us.dlapiper.com;<br>DLA-ResMed-CleveMed-PGR@us.dlapiper.com) |
| <i>Documents served</i>  | PATENT OWNER'S PRELIMINARY RESPONSE                                                                                                                                       |
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