

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

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

PATENT OWNER'S SUR-REPLY

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. GROUNDS 1 & 3: The CHALLENGED CLAIMS ARE PATENTABLE OVER TOGE IN VIEW OF KUMAR	2
A. The Board Should Terminate This Proceeding Under <i>Tesla</i>	2
B. ResMed Has Not Met its Burden to Construe the Claims, and its Tacit Interpretation is Manifestly Overbroad	3
C. Toge Does Not Disclose a “Quantified Level of Severity Data” Under the Plain and Ordinary Meaning as Properly Defined	7
III. GROUNDS 2 & 4: CHALLENGED CLAIM 15 AND ITS DEPENDENTS ARE PATENTABLE OVER TOGE IN VIEW OF KUMAR AND NORMAN	9
A. The Plain Language of “Integrated Into” Means Inside the “PAP/CPAP Device”	10
B. ResMed Fails to Show Why a POSITA Would Have Combined the Elements of Toge and Norman in a Way that Achieves the Claimed Invention	11
IV. CONCLUSION.....	13

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.</i> , 694 F.3d 1312 (Fed. Cir. 2012)	12
<i>In re Entresto</i> , 125 F.4th 1090 (Fed. Cir. 2025)	6
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	11
<i>Tesla, Inc. v. Intell. Ventures II LLC</i> , No. IPR2025-00340, Paper 18 (Squires, Nov. 5, 2025).....	2
<i>TIP Systems, LLC v. Phillips & Brooks/Gladwin, Inc.</i> , 529 F.3d 1364 (Fed. Cir. 2008)	10
<i>Trading Techs. Int’l, Inc. v. Open E Cry, LLC</i> , 728 F.3d 1309 (Fed. Cir. 2013)	6, 7
Other Authorities	
37 C.F.R. § 42.104(b)(3).....	3
37 C.F.R. § 42.104(b)(4).....	3

I. INTRODUCTION

The Challenged Claims are patentable because Toge does not disclose determining “a quantified level of severity data based on the subject’s sleep apnea symptoms during the therapy” (Grounds 1 and 3), and the combination of Toge and Norman does not determine “a quantified level of severity” with a “processor . . . integrated into a PAP or CPAP device” (Grounds 2 and 4). Ex. 1001 (“’333 Patent”) at Claim 15.

Toge’s tidal volume is not a “quantified level of severity data” under the plain and ordinary meaning of the term, which is *a calculated value that represents how dire a patient’s symptoms are*. The broad interpretation ResMed advances in this case is inconsistent with the plain language of the claims and its own expert’s testimony in a related PGR proceeding. Ex. 2026 at ¶ 47 (testifying that the “level of severity” is not “mere[] statistics of the measured conditions alone, such as pressure, leak, airflow, pulse rate, or oxygen saturation (e.g., SaO₂ or SpO₂), snore, or flattening index”). Toge’s tidal volume is a “statistic[] of the measured [respiratory] condition[]” used to identify a patient’s symptoms, not a calculated value that represents how dire those symptoms are. *Id.*; Ex. 2028 at 11.

The Challenged Claims are also patentable because the combination of Toge, Kumar, and Norman system does not include a “processor . . . integrated into a PAP or CPAP device” that determines a “quantified level of severity data.” In Toge and

Norman, analysis of collected sleep data is performed at a computer separate from the PAP/CPAP device, and ResMed does not argue, let alone demonstrate, that it would have been obvious to calculate a “quantified level of severity data” using a processor of the PAP device.

II. GROUNDS 1 & 3: THE CHALLENGED CLAIMS ARE PATENTABLE OVER TOGE IN VIEW OF KUMAR

The plain and ordinary meaning of “a quantified level of severity data based on the subject’s sleep apnea symptoms during the therapy” is *a calculated value that represents how dire a patient’s symptoms are*. Paper 27 (“POR”) at 8-9. This interpretation represents the plain and ordinary meaning of the term and reflects that claim languages recites that the “quantified level of severity” is “based on the subject’s sleep apnea symptoms during the therapy.” *Id.* To the extent that ResMed’s interpretation is intelligible, it is inconsistent with the plain language of the claims and both parties’ experts’ testimony and the position it is maintaining in the District Court litigation.

A. The Board Should Terminate This Proceeding Under *Tesla*

First, the Board should terminate this case because ResMed advances a different construction for this term in this case than it did in the District Court, where it maintains that the term is indefinite. *Tesla, Inc. v. Intell. Ventures II LLC*, No. IPR2025-00340, Paper 18 at 3-4 (Squires, Nov. 5, 2025) (informative) (vacating the institution decision and terminating a proceeding where petitioner argued the claims

were indefinite in district court but the plain and ordinary meaning before the PTAB and did not show why different positions were warranted). Ex. 1058 at ¶ 28.

B. ResMed Has Not Met its Burden to Construe the Claims, and its Tacit Interpretation is Manifestly Overbroad

In the event that this proceeding is not terminated, the Board should find the Challenged Claims patentable because ResMed has not met its burden construe the claims and explain how the claims are unpatentable as properly construed. 37 C.F.R. § 42.104(b)(3)-(4). Although ResMed purports to apply the “plain and ordinary meaning” of the term, it does not say what that meaning is. Paper 30 (“Reply”) at 2-6.

To the extent that ResMed’s interpretation of this term is intelligible, it is inconsistent with the plain language of the claims and the sworn testimony of both parties’ experts. According to ResMed, Toge’s tidal volume is a “quantified level of severity” because it “represents the ‘level [or “severity”] of airway obstruction the patient experiences during the sleep apnea treatment using the PAP device.”” Reply at 1. This argument conflates the severity of the subject’s airway obstruction with severity of the subject’s apnea symptoms. As ResMed explained in the Petition, total obstruction of the airway, “zero milliliters per breath” corresponds to an apnea, so tidal volume data may be analyzed to identify apneas (or hypopneas or snores). Paper 1 (“Pet.”) at 16. The tidal volume is, therefore, not a quantified level of

severity “based on the subject’s sleep apnea symptoms,” it is breathing metric data that could be analyzed to detect those symptoms in the first place.

Tidal volume data is, therefore, at least two steps removed from the claimed “quantified level of severity. To determine a quantified the level of severity “based on the subject’s sleep apnea symptoms,” Toge’s tidal volume would have to be analyzed to detect the subject’s apneas. Then the subject’s apneas would have to be analyzed to determine the quantified level of severity “based on the subject’s sleep apnea symptoms.” POR at 10-11 (citing Ex. 2028 at 13-14; Ex. 2029 at 1). Tidal volume is not, therefore, the claimed quantified level of severity.

Both parties’ experts agree. Dr. D’Ambrosio, CleveMed’s expert in its *Markman* briefing in the parallel district court proceeding, testified that the ordinary meaning of “level of severity” is “how dire a patient’s calculated symptom data may be” (for example, as indicated by indices calculated from symptom data). Ex. 1058 at ¶ 32 (describing AHI and RDI indices). Dr. Schwartz, ResMed’s expert in a related PGR proceeding, likewise testified that indices are “well validated indicators of the type and *severity* of sleep disordered breathing.” Ex. 2026 at ¶ 46 (emphasis added).

Dr. Schwartz also explained what is *not* encompassed within the scope of the term: “mere[] statistics of measured conditions alone, such as . . . airflow.” *Id.* at ¶ 47 (opining that that the “level of severity” is not “merely statistics of the measured

conditions alone, such as pressure, leak, airflow, pulse rate, or oxygen saturation (e.g., SaO₂ or SpO₂), snore, or flattening index).¹ This testimony directly refutes ResMed's attempt to broaden the meaning of the term "quantified level of severity" to include tidal volume, which *is* a merely statistic of measured respiration (airflow). *See, e.g.*, Ex. 1044 ("Toge") at ¶ [0033] ("[T]he measured value from this flow meter is used for the patient's tidal volume Fp."). Thus, both parties' experts have agreed that a quantified level of severity refers to how dire the subject's symptoms, and common indices like AHI and RDI quantify how dire the subject's symptoms are.

ResMed does not dispute the expert testimony. Instead, ResMed argues that CleveMed's construction improperly limits the "quantified level of severity" to indices. Reply at 5-7. That is not true. CleveMed's construction encompasses known indices, like AHI and RDI, without limiting the claims to any specific index or indices in general. Reply at 5-6; POR at 9 (arguing that "[a]n index such as AHI or RDI" is example of a quantified level of severity); Ex. 1058 at ¶ 32 (listing AHI and RDIs as examples of quantified levels of severity). CleveMed's construction in this case is, therefore, entirely consistent with the testimony of both parties' experts.

¹ ResMed's assertion that Dr. Schwartz's testimony related to "index of treatment efficacy" is at odds with his actual testimony related to *the* "level of severity." Reply at 5.

Nor is it relevant that Dr. Schwartz's testimony interpreting this limitation arose in the context of a written description argument. Reply at 3-5; *In re Entresto*, 125 F.4th 1090, 1097-98 (Fed. Cir. 2025) (“[T]he invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed” and the “scope of what is claimed (and must be adequately described) is, in turn, determined through claim construction.”) (citation modified). Indeed, Dr. Schwartz's testimony interpreting this term was based in part on his evaluation of the inventors' statements to the Office during prosecution, which is a quintessential technique for construing the claims. Ex. 2026 at ¶ 46 (evaluating remarks made “during prosecution of the '116 application”); *id.* at ¶ 47 (“Thus, a POSITA, having considered these statements, would understand that the . . . ‘level of severity’ . . . are not merely statistics of measured conditions alone”).

Trading Techs. Int'l, Inc. v. Open E Cry, LLC, 728 F.3d 1309 (Fed. Cir. 2013) is inapposite. Reply at 4-5. In *Trading Techs.*, the district court relied on the Federal Circuit's claim construction of the term “static” to find that a “non-‘static’ display” term had written description support. 728 F.3d at 1318-20. The Federal Circuit rejected such reliance because it had not in its prior opinion “determine[d] whether the same written description would also support different claims drawn to non-‘static’ display.” *Id.* at 1320. That is, the district court relied on the claim scope of a different claim term to define the boundaries of another term for written

description. *Id.* Here, Dr. Schwartz's claim scope-related testimony is relied on for the same "level of severity term" having the same boundaries and scope.

Accordingly, for all these reasons and those in the POR, the Board should adopt CleveMed's plain and ordinary meaning, which is *a calculated value that represents how dire a patient's symptoms are.*

C. Toge Does Not Disclose a "Quantified Level of Severity Data" Under the Plain and Ordinary Meaning as Properly Defined

The Board should hold the Challenged Claims patentable because Toge does not disclose "a quantified level of severity data" under the plain and ordinary meaning, which *is* a calculated value representing how dire a patient's symptoms are. POR at 10-12. Despite ResMed's argument to the contrary, its own expert's testimony directly refutes any notion that tidal volume is a "quantified level of severity." Instead, it is statistical data outside the scope of the claim. Reply at 6-8.

As discussed above, Dr. Schwartz—ResMed's own expert—testified that the claimed "level of severity" is *not* "merely statistics of the measured conditions alone, such as . . . airflow." Ex. 2026 at ¶ 47. Tidal volume *is* the mere statistic of the measured respiratory condition. Ex. 2028 at 11 ("Respiration = airflow or tidal volume."); *id.* at 13 ("Tidal volume refers to the volume of air that is inspired or expired during a respiratory cycle."). Accordingly, ResMed's expert's claim scope-related testimony confirms that tidal volume is not a "level of severity" under the plain and ordinary meaning.

ResMed's assertion that tidal volume can be calculated does not change the determinative fact. Reply at 7. Toge explains that a flow meter provided at a patient's mask collects the patient's tidal volume (respiratory airflow), but if the flow meter is not provided then tidal volume can be determined using a formula. Toge at ¶¶ [0033]-[0034]. Regardless of whether it is derived directly from the flow mask or through a formula, the tidal volume remains a mere statistic of the measured respiratory airflow, which falls outside the claim scope of a "quantified level of severity."

Dr. Schwartz's testimony that a statistic of a measured condition is not a "level of severity" supports CleveMed's position arguing the same although in different form, particularly that tidal volume is a breathing metric. POR at 10-11 (tidal volume is not a "quantified level of severity data,' it is a breathing metric.")² ResMed's attempt at rebutting CleveMed's position is based on the faulty premise that only indices represent the level of severity under CleveMed's plain and ordinary definition. Reply at 7-8. To the contrary, indices are but an example of a "level of

² While ResMed asserts that Dr. Schwartz labels breathing metrics as indicators of severity in paragraph 46, ResMed ignores Dr. Schwartz's testimony in the next paragraph excluding tidal volume from the claimed "level of severity" scope. Ex. 2026 at ¶ 47; Reply at 8.

severity” (for example, AHI is commonly used to represent the “severity of sleep apnea”). Ex. 2029 at 1. While the claimed “quantified level of severity data” encompasses indices, it excludes mere statistics (or otherwise breathing metric data) such as tidal volume.

Accordingly, because Toge’s tidal volume is a statistic of the measured respiratory condition, it does not fall within the definition and scope of the claimed “quantified level of severity.” Consequently, ResMed fails to demonstrate that Toge in view of Kumar renders obvious the Challenged Claims.

III. GROUNDS 2 & 4: CHALLENGED CLAIM 15 AND ITS DEPENDENTS ARE PATENTABLE OVER TOGE IN VIEW OF KUMAR AND NORMAN

The Board should hold the Challenged Claims patentable because the Toge-Norman combination does not achieve determining a “quantified level of severity data” by a “processor . . . integrated into the PAP or CPAP device.” ’333 Patent at Claim 15. As established above, because Toge’s tidal volume is not “a quantified level of severity data,” Toge’s control unit 250 does not determine “a quantified level of severity data.” Norman also does not teach the claim limitation because its “processor” is not “*integrated into* the PAP or CPAP device.” Instead, its processing device is located outside the PAP/CPAP device. Thus, neither reference teaches a processor that “integrated into the PAP or CPAP device” determines a “quantified level of severity data,” and ResMed does identify a reason a POSITA would have

modified Toge's system based on the elements of the references to achieve the claimed invention.

A. The Plain Language of “Integrated Into” Means Inside the “PAP/CPAP Device”

The plain language of a “processor . . . integrated into the PAP or CPAP device” means that the processor is inside the “PAP or CPAP device.” POR at 13 (citing Ex. 2030 at 1 (defining “into” as “the inside . . . of a place”)). ResMed's does not dispute that “integrated *into*” means “inside.” Instead, ResMed's conflates “the PAP or CPAP *device*” recited in the claims with Norman's CPAP “system,” which includes a CPAP device and other separate components. Reply at 11 (“Norman explicitly states that the titration device/processing unit is ‘built into’ (i.e., ‘integrated into’) the *CPAP system*”) (emphasis added)). ResMed's allegations, therefore, facially do not reach the express language of the Challenged Claims.

The Board should also reject ResMed's attempt to broaden the plain language of the claims simply because the specification also teaches an embodiment where the quantified level of severity is calculated using a processor other than one integrated into a PAP or CPAP device. See *TIP Systems, LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008) (“[T]he mere fact that there is an alternative embodiment disclosed in the . . . patent that is not encompassed by district court's claim construction does not outweigh the language of the claim.”); Reply at 11-12 (citing '333 Patent, Fig. 8).

B. ResMed Fails to Show Why a POSITA Would Have Combined the Elements of Toge and Norman in a Way that Achieves the Claimed Invention

ResMed does not identify a reason a POSITA would have modified Toge's system such that "a quantified level of severity" is determined at a "processor" inside the "PAP or CPAP device." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) ("[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."); POR at 15.

As an initial matter, ResMed mischaracterizes the POR as taking the position that Toge does not disclose its control unit 250 inside a PAP device. Reply at 13 (citing POR at 15). Although Toge discloses a processor within the PAP device, it does not determine "quantified level of severity data." POR at 12, 15-16 (asserting that "to the extent [] severity analysis occurs in Toge's system, that activity is performed at the physician's device."). As indicated above, tidal volume is simply a statistic of a measured condition that is sent to a physician-side computer where trend data is reviewed and any further analysis would be performed. Toge at ¶ [0039] (describing a physician evaluating "decreasing trend in the tidal volume" that could require "adjusting the prescription pressure to a higher level"); *id.* at ¶ [0051] (sending tidal volume data to the physician-side device).

Like Toge, Norman discloses analyzing data at a processing device located outside the PAP/CPAP device. *See* POR at 13-14 (“Norman’s processing arrangement 24 and titration device 26 (identified as the claimed “processor”) are external to the PAP/CPAP Device componentry”). ResMed does not argue otherwise. Reply at 11 (removing “integrated into the PAP or CPAP device” claim language when referencing Norman).

Accordingly, neither reference teaches the claim limitation, and ResMed fails to explain why a POSITA would have modified Toge’s system to perform Norman’s analysis at Toge’s control unit rather than at the physician-side computer. POR at 15-16. Instead, ResMed states that the “Petition describes *generally* why a POSITA would have been motivated to further combine Norman’s automated titration CPAP device with the Toge and Kumar system.” Reply at 12-13 (citing Pet at 49-50) (emphasis added). This generic rationale “bears no relation to any specific combination of prior art elements” and does not “explain why a person of ordinary skill in the art would have combined elements from specific references *in the way the claimed invention does.*” *ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012).

Based on at least the foregoing reasons, a POSITA would not have modified Toge’s system based on Norman to arrive at a “quantified level of severity data” determined at “processor” that is “integrated into the PAP or CPAP device.”

Consequently, ResMed fails to demonstrate that Toge in view of Kumar and Norman renders obvious the Challenged Claims.

IV. CONCLUSION

For the reasons discussed herein and in the POR, the Board should hold patentable the Challenged Claims.

Respectfully submitted,

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

The undersigned hereby certifies that the portions of the above-captioned **PATENT OWNER'S SUR-REPLY** specified in 37 C.F.R. § 42.24 has 2,948 words in compliance with the 5,600 word limit set forth in 37 C.F.R. § 42.24(c)(4). This word count was prepared using the Microsoft Word word-processing system used to prepare this paper.

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CERTIFICATE OF SERVICE

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

<i>Date of service</i>	February 25, 2026
<i>Manner of service</i>	Electronic Filing and Electronic Mail (PH-ResMed-CleveMed@paulhastings.com)
<i>Documents served</i>	PATENT OWNER'S SUR-REPLY
<i>Persons Served</i>	Paul Hastings LLP Lisa K. Nguyen David M. Tennant Grace Wang Eric E. Lancaster Howard Herr Kamilah Alexander Maksim Mints Rachel Wu Hankinson

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