

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CLEVELAND MEDICAL DEVICES INC.,	)	
an Ohio Corporation,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 22-cv-00794-GBW
v.	)	
	)	
RESMED, INC., a Delaware Corporation,	)	
	)	
Defendant.	)	
	)	
	)	

**DECLARATION OF CAROLYN M. D’AMBROSIO, MS, MD, IN SUPPORT OF
PLAINTIFF CLEVELAND MEDICAL DEVICES INC.’S
REPLY CLAIM CONSTRUCTION BRIEF**

I, Carolyn M. D’Ambrosio, MS, MD, hereby declare that:

1. I make this Declaration based upon my own personal knowledge, information, and belief, and I would and could competently testify to the matters set forth herein if called upon to do so.

2. I understand that I am submitting this Declaration to assist the Court in determining the proper construction of certain terms used in the asserted claims of the patents being asserted in the above-referenced action.

I. BACKGROUND, EXPERIENCE, AND QUALIFICATIONS

3. A list of my qualification and experience is listed on my curriculum vitae attached hereto as Exhibit A.

4. I hold a B.A. in Biological Sciences from Cornell University, and a M.S. in physiology and a M.D. from George Washington University. I am currently an Associate Professor at Yale School of Medicine’s Department of Internal Medicine, Section of Pulmonary, Clinical Care and Sleep Medicine, Clinician Educator Track.

attempt to sleep. I have personally used this term when discussing the diagnosis and treatment of a patient's sleeping disorder with colleagues in various clinical settings.

25. The different sensors used to monitor and diagnose a patient result in different types of symptom data that is calculable. '269 Patent at 3:9-28; 6:10-8:30. For example, based on Claim 15's use of an internal airflow sensor, one would use the term "symptom data" to refer to at least the patient's: airflow, inhalation pressure, exhalation pressure, apnea events, hypopnea events, I:E ratio. See '269 Patent at Claim 15; '269 Patent at 7:61-8:12. When looking at Claims 1 and 5, "symptom data" would refer to those data points identified above and also include pulse and SpO₂ due to the inclusion of the pulse oximeter into the system. '269 Patent at Claims 1, 5; '269 Patent at 8:13-25.

26. Based upon the disclosures in the '269 Patent, a POSITA understands how to calculate the symptom data in order to derive the severity of the patient's symptoms. '269 Patent at 18:51-21:67. A commonly used term within the clinical sleep setting is "level of severity" which clinicians understand to represent the how dire a patient's calculated symptom data may be. For example, a clinician would recognize a patient's symptom's as severe if their data shows a respiratory disturbance index (RDI) or apnea-hypopnea index(AHI) of greater than or equal to 30 events per hour of sleep. The RDI is the sum of all the apneas, hypopneas, and Respiratory Effort Related Arousals (RERAs) divided by total sleep time. The AHI is the sum of all the apneas and hypopneas divided by the total sleep time. RERAs include arousals from sleep in the definition. Hypopneas include oxygen desaturation of equal to or greater than 4% from the baseline oxygen saturation associated with a reduction in airflow limitation. Clinically, both the RDI and AHI can be used to determine severity but Medicare only recognizes AHI. The denominator in these indices is total sleep time. Any of the measures

themselves can be of concern and indicate severity of illness. Severe reduction in airflow, very high numbers of obstructive apneas, oxygen saturations below 88% sustained for 5 minutes or greater are all concerns for severe symptoms. However, they are most often considered together to evaluate severity of illness.

27. Another calculation a sleep clinician would commonly expect the symptom data to be compiled and presented is in the form of an “index.” ’269 Patent at Claims 1, 5, 15. An index takes individual and combined symptom data points and averages them over a one-hour period of sleep. For example, if a patient sleeps seven hours and has 70 total instances where they cease breathing (apnea events) or present shallow breathing (hypopnea), they would have an apnea-hypopnea index (AHI) of 10, which a sleep clinician interpret as being mildly elevated but some clinicians would consider this still in the normal range. If instead that patient had 175 total apnea and hypopnea events in seven hours of sleep, a sleep clinician would understand the patient’s AHI to be 25 and in a moderate severity range.

28. Therefore, it is my opinion these claim limitations are definite because a person of skill within the sleep industry would understand each of these claim terms and their calculations with reasonable certainty in order to ascertain the scope of the claimed invention.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on May 31, 2023, in New Haven, Connecticut.



Carolyn M. D'Ambrosio, MS, MD

CERTIFICATE OF SERVICE

I hereby certify that on May 31, 2023, a copy of the foregoing **DECLARATION OF CAROLYN M. D'AMBROSIO, MS, MD, IN SUPPORT OF PLAINTIFF CLEVELAND MEDICAL DEVICES INC.'S REPLY CLAIM CONSTRUCTION BRIEF** was served via electronic mail upon the following counsel of record for Defendant ResMed Inc.:

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