

UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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*Ex parte* ROBERT G. NORMAN and DAVID M. RAPOPORT

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Appeal 2008-3513  
Application 10/862,067  
Technology Center 3700

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Decided: August 19, 2008

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Before TONI R. SCHEINER, LORA M. GREEN, and  
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

**DECISION ON APPEAL**

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1, 3-16, 18-28, 30-33, and 35-48. We have jurisdiction under 35 U.S.C. § 6(b).

## STATEMENT OF THE CASE

According to the Specification, “[o]bstructive sleep apnea/hypopnea syndrome (OSAHS) is a well recognized disorder which may affect as much as 1-5% of the adult population.” (Spec. 1.) While the pathophysiology of the disorder is not fully understood, “it is now well recognized that obstruction of the upper airway during sleep is in part due to collapsible behavior of the supraglottic segment of the respiratory airway during the negative intraluminal pressure generated by inspiratory effort.” (*Id.*)

“[P]ositive airway pressure (‘PAP’) applied by a tightly fitted nasal mask worn during sleep has evolved to become the most effective treatment for this disorder, and is now the standard of care.” (*Id.* at 2.) “PAP therapy is directed to maintaining pressure in the collapsible portion of the airway at or above the critical ‘tissue pressure’ at all times. This goal is achieved by raising the airway pressure in the entire respiratory system to a level higher than this critical pressure.” (*Id.* at 2-3.)

The Specification teaches that

the determination of the appropriate pressure for therapy, referred to as PAP titration, is normally performed in a sleep laboratory where a specific treatment pressure is determined. However, during the first week of treatment the necessary pressure to treat the OSDB may decrease, which results in a prescribed pressure that is too high and may compromise patient compliance. In addition, the patient may assume body positions or sleep stages, other than those occurring in the sleep laboratory that may change the therapeutic pressure. Finally, patients may require periodic retitration following changes in condition, such as weight gain or loss. Retitration of the PAP in the laboratory is usually expensive and is not part of the usual standard of care. Thus, there is a need for a system and

method that would provide initial PAP titration and retitration to patients as required during subsequent treatments.

(*Id.* at 3.)

The claims are directed to a system for providing air pressure to a patient's airway having a titration device that determines the number of abnormal respiratory events, as well as methods of using the system. Claim 1 is representative of the claims on appeal, and reads as follows:

1. A system, comprising:

an air pressure supply arrangement providing air pressure to a patient's airways;

a sensor detecting input data corresponding to a patient's breathing patterns for a plurality of breaths for at least one time period; and

a titration device receiving and analyzing the input data to determine a number of abnormal respiratory events during the at least one time period and generating output data for adjusting the air pressure supplied to the patient as a function of the number of abnormal respiratory events during the at least one time period.

The Examiner relies on the following references:

Remmers	US 5,645,053	Jul. 8, 1997
Wright	US 6,832,609 B2	Dec. 21, 2004

We affirm.

#### ISSUE (ANTICIPATION)

The Examiner contends that claims 1, 3-5, 7-11, 13-16, 18-21, 23-27, 37-45, 47, and 48 are anticipated by Remmers (Ans. 3).

Appellants contend that "Remmers does not disclose or suggest 'a titration device receiving and analyzing the input data to determine a number of abnormal respiratory events during the at least one time period and

generating output data for adjusting the air pressure supplied to the patient as a function of the number of abnormal respiratory events during the at least one time period' as recited in claim 1.” (App. Br. 8.)

Thus, the issue on Appeal is: Has the Examiner established that Remmers teaches “a titration device receiving and analyzing the input data to determine a number of abnormal respiratory events during the at least one time period and generating output data for adjusting the air pressure supplied to the patient as a function of the number of abnormal respiratory events during the at least one time period”?

#### FINDINGS OF FACT

FF1. Claims 1, 3-5, 7-11, 13-16, 18-21, 23-27, 37-45, 47, and 48 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Remmers (Ans. 3).

FF2. As to the contested limitation, the Examiner finds that Remmers teaches “a titration device 10 and 12 (see figure 1A) receiving and analyzing the input data to determine a number of abnormal respiratory events during the at least one time period and generating output data for adjusting the air pressure supplied to the patient as a function of the number of abnormal respiratory events during the at least one time period (see column 6 lines 15-33).” (Ans. 3-4.)

FF3. The Examiner finds further:

In Remmers the titration device is defined as an adaptive control system 10 (see column 4 lines 58-67) which receives and analyzes the input data to determine a number of abnormal respiratory events. Remmers defines abnormal respiratory events as OSA (Obstructive Sleep Apnea) or other sleeping disorders (see background of the invention; column 1 lines 15-

20). During the at least one time period (time period in a broad sense is defined as 5 to 10 breaths as stated in Remmers; see column 6 lines 15-30) and generating output data (see column 6 lines 20-67; hypoventilation is defined as means inspiratory flow being less than 40% of the predicted awake supine means inspiratory flow within five breaths (time period) and apnea is defined as a 10 seconds duration of no change in respiratory phase within five breaths (time period) and if these events occur with the time period, the device would correct the air pressure supplied to the patient) for adjusting the air pressure supplied to the patient as a function of the number of abnormal respiratory events during the at least one time period.

(Ans. 9-10 (emphasis removed).)

FF4. Remmers is drawn to

systems and methods for adaptively providing continuous positive airway pressure [CPAP] to an upper airway system by detecting airflow data in the upper airway system at predetermined increments of time; averaging said airflow data over a second period of time which includes a plurality of said predetermined time increments; determining non-respiratory airflow using said averaged data; identifying periods of inspiration and expiration using said non-respiratory airflow data; extracting information or features from said airflow data; and continuously adjusting pressure in said upper airway system.

(Remmers col. 2, ll. 43-53.)

FF5. An adaptive control operator is part of the system, and serves as an overseer that has access to the feature extractor (which monitors the patient's breathing) at all times (Remmers col. 5, ll. 58-65; col. 7, ll. 31-36).

FF6. During both testing and non-testing periods, "the adaptive control system continuously monitors breathing variations, hypoventilation, apnea,

and signs that the threshold detection mechanism has not been properly adjusted for leaks.” (Remmers col. 6, ll. 48-52.)

FF7. The adaptive control system

generates an optimal desired (i.e., command) pressure by averaging airflow data over a predetermined period of time, partitioning airflow data into respiratory and non-respiratory components, identifying periods of inspiration and expiration using the non-respiratory component, and extracting information or features from airflow data. Using this information, the adaptive control system identifies a critical pressure ( $P_{crit}$ ) at which a significant obstruction occurs during inspiration. More particularly,  $P_{crit}$  corresponds to a lower limit of mask pressure associated with a significant decrease in peak inspiratory airflow and/or significant (i.e., critical) airflow limitation. After determining  $P_{crit}$ , the adaptive control system identifies an optimum (i.e., minimum) effective CPAP ( $P_{opt}$ ) for eliminating the obstruction during inspiration.

(Remmers col. 5, ll. 8-23.)

FF8. Testing periods are used to determine  $P_{crit}$  and  $P_{opt}$  (Remmers col. 11, ll. 45-54).

FF9. If during testing an apnea, hypoventilation, or respiratory variation error is detected, the testing mode is exited and the system returns to the previous holding pressure (col. 12, 11. 62-65).

FF10. In operation of the system, after start-up, the adaptive control system operator enters a non-testing mode (col. 16, ll. 35-37). An interval count is used to keep track of the number of breaths, in which each interval count represents ten breaths (col. 16, ll. 45-46). After two intervals, the testing protocol is entered if there are no breathing instabilities (i.e., apnea, hypoventilation, variable breathing) (col. 16, ll. 53-55). If breathing

instabilities are detected, the testing protocol may be delayed up to three more interval counts (30 breaths) (col. 16, ll. 55-61). If breathing instabilities are determined after 50 breaths, the consistency of the instability is sufficient to start the testing protocol (col. 16, ll. 62-67).

FF11. Remmers teaches:

During a testing mode, a search is first made for  $P_{crit}$ . Once  $P_{crit}$  has been determined, a search is made for  $P_{opt}$ . In the testing mode, the system continuously checks for apnea, hypoventilation and/or variable breathing (blocks 70, 72 and 74). If any of these instabilities are detected (or any changes in these values are detected in the case where the test mode was entered after 50 breaths), testing is stopped (block 76). The non-test interval count is reset to zero (block 78) and the system returns to a non-test mode.

(Col. 17, ll. 1-9.)

FF12. In the system of Remmers, therefore, the adaptive control system (referred to as the titration device in the appealed claims) analyzes input data, and during a testing period, determines a number of abnormal respiratory events. If the number of respiratory events is zero, a new optimum effective continuous positive airway pressure is determined and adopted. If the number of respiratory events is one or more, the testing period is halted and the system reverts to the previous effective continuous positive airway pressure.

## PRINCIPLES OF LAW

To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim.

*Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001).

In addition, during prosecution before the Office, claims are to be given their broadest reasonable interpretation consistent with the Specification as it would be interpreted by one of ordinary skill in the art. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). “An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.” *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989). Moreover, it is during prosecution that applicants have “the opportunity to amend the claims to obtain more precise claim coverage.” *American Academy*, 367 F.3d at 1364.

## ANALYSIS

As to claim 1, Appellants argue that Remmers teaches “an adaptive control system 10 that utilizes a testing mode to determine a critical pressure . . . at which airway obstruction occurs during inspiration and an optimum pressure . . . for eliminating the obstruction during inspiration.” (App. Br. 6.) According to Appellants, during the non-testing mode, the optimum pressure is delivered to the patient (*id.* at 6-7).

Appellants argue further that Remmers teaches that the testing mode is utilized only “when there is ‘(1) a low to moderate level of variation in respiratory features, (2) no hypoventilation and (3) no apnea.’” (App. Br. 7 (quoting Remmers col. 6, ll. 7-11).) Appellants assert that Remmers teaches that a detection of any of the above events ends the analysis and the system determines whether to enter/continue the testing mode “based on a singular instance of one of these events and does not disclose or suggest determining a number of such events during a time period, and clearly neither shows nor suggests adjusting any pressure based on such a number of events.” (App. Br. 7.)

Appellants’ arguments are not found to be convincing. Claim 1 requires “a titration device receiving and analyzing the input data to determine a number of abnormal respiratory events during the at least one time period and generating output data for adjusting the air pressure supplied to the patient as a function of the number of abnormal respiratory events during the at least one time period.” As noted above (FF12), Remmers teaches an adaptive control system (“the titration device”) which analyzes input data during a testing period, and determines a number of abnormal respiratory events. If the number of respiratory events is zero, a new optimum effective continuous positive airway pressure is determined and adopted. If the number of respiratory events is one or more, the testing period is halted and the system reverts to the previous effective continuous positive airway pressure (FF9). Thus, depending on the number of abnormal respiratory events, in the case of Remmers, zero or one, the adaptive control system adjusts the air supply supplied to the patient. Note that there is

nothing in claim 1 that excludes the number of abnormal respiratory events being zero or one.

### CONCLUSION

Thus, we find that Remmers anticipates claim 1, and as Appellants do not offer any additional arguments as to the other rejected claims, *i.e.*, claims 3-5, 7-11, 13-16, 18-21, 23-27, 37-45, 47, and 48,<sup>1</sup> the rejection is affirmed as to those claims as well. 37 C.F.R. § 41.37(c)(1)(vii).

Moreover, the Examiner rejected claims 6, 12, 22, 28, 20-33, 35, 36, and 46 under 35 U.S.C. § 103(a) as being obvious over the combination of Remmers and Wright. As Appellants only argue that Wright does not cure the deficiencies of Remmers, the rejection is affirmed for the reasons set forth above with respect to the anticipation rejection over Remmers.

### TIME LIMITS

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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<sup>1</sup> As to independent claims 13 and 28, Appellants merely reiterate their arguments as to claim 1 (App. Br. 8-9).

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