

Patent Owner

New York University's Slide Presentation

OCTOBER 2, 2023 ORAL ARGUMENT

IPR Nos.	Patent Nos./Issue Date
IPR2022-00988	9,108,009/August 18, 2015
IPR2022-00989	9,427,539/August 30, 2016
IPR2022-00990	9,533,115/January 3, 2017
IPR2022-00991	9,867,955/January 16, 2018
IPR2022-00992	10,384,024/August 20, 2019
IPR2022-00993	6,988,994/January 24, 2006
IPR2022-00994	9,168,344/October 27, 2015

DEMONSTRATIVE – NOT EXHIBIT

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Summary of PO's Argument

I. '994 Patent Family

II. Claim Construction

- **Support for PO's Construction**
 - Intrinsic Evidence
 - Implied Lexicography
- **Lack of Support for Petitioner's Construction**
 - Plain and ordinary meaning has no definition
 - Intrinsic evidence is ignored

III. § 102 Anticipation

IV. § 103 Obviousness

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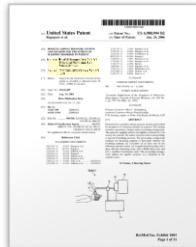
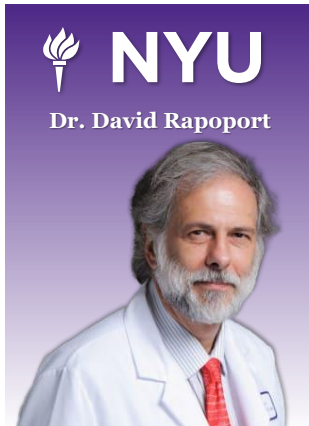
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I. '994 Patent Family

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New York University



Assignee: **New York University**, New York, NY (US)

Inventors: **David M. Rapoport**, New York, NY (US); **Robert G. Norman**, New Windsor, NY (US)

Dr. Rapoport has a **very big reputation in the field** and that reputation is - arises through his recognition in the field by his peers. This would be manifest in **multiple citations to his publications, invitations to speak at universities and at conferences**. That to me is a form of praise by others.

EX1053, 298:16-23

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Problem

PAP therapy has become the mainstay of treatment in Obstructive Sleep Disordered Breathing (OSDB), which

EX1001, '994 Patent (993 IPR), 1:47-49*

PROBLEM:

- > Discomfort due to high pressure while being awake. 993 IPR, PO Response, Paper 34, 6-7.**
- > Pressure should be applied only when the patient is asleep. 993 IPR, PO Response, Paper 34, 6-7.**
- > Has not taken asleep/awake state into account, so applies pressure unnecessarily when the patient is awake.
993 IPR, PO Response, Paper 34, 6-7**; EX1001, '994 Patent (993 IPR), 1:64-67***, 2:8-14****; EX2003, ¶¶ 42-45*****

Before the '994 Patent series, the ability to distinguish between every awake state and every sleep state was *not known*.

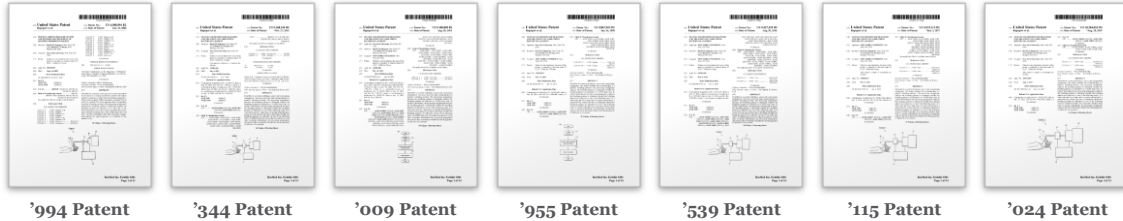
993 IPR, PO Response, Paper 34, 1; PO Sur-Reply, Paper 45, 20;***** EX1052, Bates Depo. Tr., 114:16-25-115:1-2

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- *988-992 and 994 IPR record citations: '009 Patent (988 IPR), 1:59-61; '539 Patent (989 IPR), 1:65-67; '115 Patent (990 IPR), 1:67 – 2:1-2; '955 Patent (991 IPR), 1:61-63; '024 Patent (992 IPR), 1:65-67; '344 Patent (994 IPR), 1:58-60
- **988-992 and 994 IPR record citations: 988 IPR, PO Response, Paper 27, 6; 989 IPR, PO Response, Paper 33, 7; 992 IPR, PO Response, Paper 32, 6; 994 IPR, PO Response, Paper 33, 7
- ***988-992 and 994 IPR record citations: '009 Patent (988 IPR), 2:12-14; '539 Patent (989 IPR), 2:18-21; '115 Patent (990 IPR), 2:20-23; '955 Patent (991 IPR), 2:14-17; '024 Patent (992 IPR), 2:18-21; '344 Patent (994 IPR), 2:11-13
- ****988-992 and 994 IPR record citations: '009 Patent (988 IPR), 2:24-30; '539 Patent (989 IPR), 2:29-35; '115 Patent (990 IPR), 2:31-37; '955 Patent (991 IPR), 2:26-32; '024 Patent (992 IPR), 2:29-35; '344 Patent (994 IPR), 2:22-28
- *****988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶¶ 41-44; 989 IPR, EX2005, ¶¶ 40-43; 990 IPR, EX2006, ¶¶ 41-44; 991 IPR, EX2006, ¶¶ 41-44; 992 IPR, EX2006, ¶¶ 40-43; 994 IPR, EX2006, ¶¶ 42-44
- *****988-992 and 994 IPR record citations: 988 IPR: PO Response: Paper 27, 4; PO Sur-Reply: Paper 40, 20; 989 IPR: PO Response: Paper 33, 2; PO Sur-Reply: Paper 44, 19; 990 IPR: PO Sur-reply: Paper 44, 21; 991 IPR: PO Sur-Reply: Paper 47, 20; 992 IPR: PO Response: Paper 32, 47; PO Sur-Reply: Paper 43, 20; 994 IPR: PO Response: Paper 33, 4-5; PO Sur-Reply: Paper 33, 19

'994 Patent Family



- > Includes seven patents, all continuations of U.S. Patent No. 6,988,994.
 - Priority date: August 14, 2003.
 - Lead inventor: Dr. David M. Rapoport
 - > This family addresses systems and methods for diagnosing and treating breathing disorders
- EX1001 in each IPR (challenged patents)

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988 IPR, EX2005, ¶ 26;
989 IPR, EX2005, ¶ 26;
990 IPR, EX2006, ¶ 26;
991 IPR, EX2006, ¶ 26;
992 IPR, EX2006, ¶ 26;
993 IPR, EX2003, ¶ 28;
994 IPR, EX2006, ¶ 28;

Problem Solved!

Prior art was incomplete because it did not distinguish the awake state of **troubled wakefulness from the asleep state of REM sleep.**

993 IPR, PO Response, Paper 34, 3, 8; PO Sur-Reply, Paper 45, 1; * EX1052, Bates Depo. Tr., 41:13-22; EX2003, ¶ 72**

'994 Patent recognized that the breathing patterns of troubled wakefulness (awake state) and REM (asleep state) differed in several key parameters.

993 IPR, PO Response, Paper 34, 28; PO Sur-Reply, Paper 45, 5;*** EX1001, 4:65-67 – 5:1-7****

Recognized this by analyzing both amplitude structure and temporal structure of a flow waveform.

993 IPR, PO Response, Paper 34, 28; PO Sur-Reply, Paper 45, 5;*** EX1001, 4:65-67, 5:1-7****

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*988-992 and 994 IPR record citations: 988 IPR: PO Response: Paper 27, 3, 7-8; PO Sur-Reply: Paper 40, 1; 989 IPR: PO Response: Paper 33, 4, 8; PO Sur-Reply: Paper 44, 1; 990 IPR: PO Response: Paper 33, 4, 6; PO Sur-Reply, Paper 44, 1; 991 IPR: PO Response: Paper 36, 4, 6-7; PO Sur-Reply: Paper 47, 1; 992 IPR: PO Response: Paper 32, 3, 7-8; PO Sur-Reply: Paper 43, 1; 994 IPR: PO Response: Paper 33, 3, 8; PO Sur-Reply: Paper 44, 1

**988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 78; 989 IPR, EX2005, ¶ 74; 990 IPR, EX2006, ¶ 77; 991 IPR, EX2006, ¶ 78; 992 IPR, EX2006, ¶ 73; 994 IPR, EX2006, ¶ 83;

***988-992 and 994 IPR record citations: 988 IPR: PO Response: Paper 27, 28; PO Sur-Reply: Paper 40, 5; 989 IPR: PO Sur-Reply: Paper 44, 5; 990 IPR: PO Response: Paper 33, 26; PO Sur-Reply: Paper 44, 6; 991 IPR: PO Response: Paper 36, 15; PO Sur-Reply: Paper 47, 5; 992 IPR: PO Response: Paper 32, 28; PO Sur-Reply: Paper 43, 5; 994 IPR: PO Response: Paper 33, 16; PO Sur-Reply: Paper 44, 4-5

****988-992 and 994 IPR record citations: '009 Patent, (988 IPR), 5:25-34; '539 Patent (989 IPR), 5:30-39; '115 Patent (990 IPR), 5:32-41; '955 Patent (991 IPR), 5:28-37; '024 Patent (992 IPR), 5:30-39; '344 Patent (994 IPR), 5:24-33

HOW TO: Distinguish Awake And Asleep States

> Determine a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order in which they appear in time. 993 IPR, PO Response, Paper 34, 9, 31, 37; PO Sur-Reply, Paper 45, 3-4.*

- Values of parameters: amplitude structure.

993 IPR, PO Response, Paper 34, 10; PO Sur-Reply, Paper 45, 5;** EX1052, Bates Depo. Tr., 181:11-17

- The order in which they appear in time: temporal structure.

993 IPR, PO Response, Paper 34, 8, 10; PO Sur-Reply, Paper 45, 5, 8, 16;*** EX1052, Bates Depo. Tr., 181:23-25

Amplitude	Temporal
High respiratory rates	Absence of larger breaths, especially after pauses
Low flow rates	Tendency for clustering of small breaths 993 IPR, PO Response, Paper 34, 2-3, 32; PO Sur-Reply, Paper 45, 5, 13-14;**** EX1052, 81:17-23

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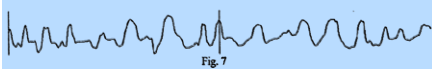
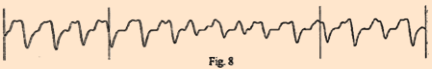
*988-992 and 994 IPR record citations: 988 IPR: PO Response: Paper 27, 9, 31-32, 37; PO Sur-Reply: Paper 40, 4; 989 IPR: PO Response: Paper 33, 10, 31, 40; PO Sur-Reply: Paper 44, 3; 990 IPR: PO Response: Paper 33, 8, 28-29, 45; PO Sur-Reply: Paper 44, 4-5; 991 IPR: PO Response: Paper 36, 8, 17-18, 35; PO Sur-Reply: Paper 47, 4; 992 IPR: PO Response: Paper 32, 9, 30-31, 36-37; PO Sur-Reply: Paper 43, 4; 994 IPR: PO Response: Paper 33, 10, 19; PO Sur-Reply: Paper 44, 3

**988-992 and 994 IPR record citations: 988 IPR: PO Response: Paper 27, 10; PO Sur-Reply: Paper 40, 5; 989 IPR: PO Response: Paper 33, 10-11; PO Sur-Reply: Paper 44, 5; 990 IPR: PO Response: Paper 33, 8-9; PO Sur-Reply: 6; 991 IPR: PO Response: Paper 36, 9; PO Sur-Reply: Paper 47, 5; 992 IPR: PO Response: Paper 32, 10; PO Sur-Reply: Paper 43, 5; 994 IPR: PO Response: Paper 33, 11; PO Sur-Reply: Paper 44, 4-5

***988-992 and 994 IPR record citations: 988 IPR: PO Response: Paper 27, 10; PO Sur-Reply: Paper 40, 5, 9; 989 IPR: PO Response: Paper 33, 10-11; PO Sur-Reply: Paper 44, 5, 8, 21; 990 IPR: PO Response: Paper 33, 8-9; PO Sur-Reply: Paper 44, 6, 9, 24-25; 991 IPR: PO Response: Paper 36, 9; PO Sur-Reply: Paper 47, 5, 8, 24; 992 IPR: PO Response: Paper 32, 10; PO Sur-Reply: Paper 43, 5, 8, 23-24; 994 IPR: PO Response: Paper 33, 11; PO Sur-Reply: Paper 44, 4-5, 8, 16

****988-992 and 994 IPR record citations: 988 IPR: PO Response: Paper 27, 4, 32; PO Sur-Reply: Paper 40, 5, 14; 989 IPR: PO Response: Paper 33, 2-3, 31-32; PO Sur-Reply: Paper 44, 5, 13-14; 990 IPR: PO Response: Paper 33, 2-3, 29-30; PO Sur-Reply: Paper 44, 6, 15; 991 IPR: PO Response: Paper 36, 3, 18-19, 22; PO Sur-Reply: Paper 47, 5, 14; 992 IPR: PO Response: Paper 32, 31-32, 47; PO Sur-Reply: Paper 43, 5, 14; 994 IPR: PO Response: Paper 33, 5, 20-21, 28-29, 37; PO Sur-Reply: Paper 44, 4-5, 13

Flow Waveforms: Troubled Wakefulness vs. REM

	Troubled Wakefulness (awake)	REM (asleep)
Flow Waveform	 Fig. 7	 Fig. 8
Sleep State	Awake	Asleep
Amplitude (vertical direction)	Peak-to-peak flow covers roughly the same range	Peak-to-peak flow covers roughly the same range
Temporal (horizontal direction)	Varies randomly throughout time in size and duration	Characteristic temporal order – big breaths followed by small breaths

EX2003, ¶¶ 64, 67-69*; EX1001, Figures 7-8

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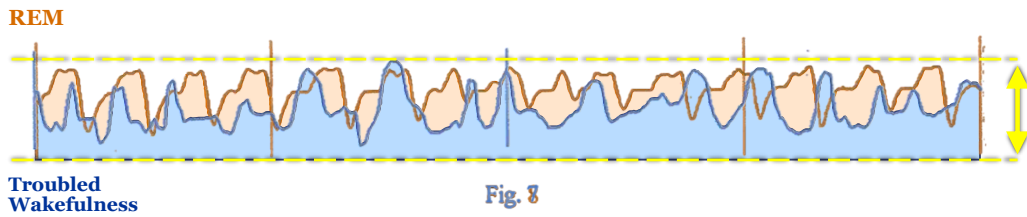
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*988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶¶ 70, 73-75; 989 IPR, EX2005, ¶¶ 66, 69-71; 990 IPR, EX2006, ¶¶ 69, 72-74; 991 IPR, EX2006, ¶¶ 70, 73-75; 992 IPR, EX2006, ¶¶ 65, 68-70; 994 IPR, EX2006, ¶¶ 75, 78-80

Amplitude

> Amplitudes of both (peak to peak) cover roughly the same range from large to small.

EX2003, ¶ 69*; Paper 45 (PO Sur-reply), 8-9**



EX1001, Figures 7-8

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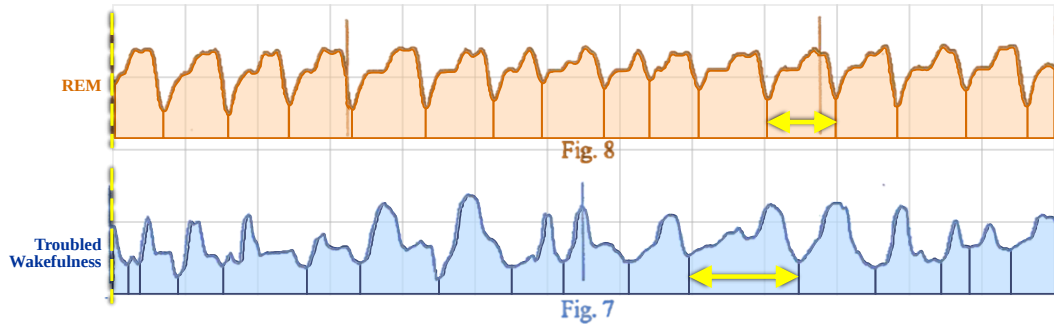
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*988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 75; 989 IPR, EX2005, ¶ 71; 990 IPR, EX2006, ¶ 74; 991 IPR, EX2006, ¶ 75; 992 IPR, EX2006, ¶ 70; 994 IPR, EX2006, ¶ 80

**988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 9-10; 989 IPR, Paper 44, Sur-Reply, 9; 990 IPR, Paper 44, Sur-Reply, 10; 991 IPR, Paper 47, Sur-Reply, 9; 992 IPR, Paper 43, Sur-Reply, 9; 994 IPR, Paper 44, Sur-Reply, 8

Temporal

- > Reordering the values of a time series does not affect its amplitude structure but DOES affect its temporal structure.



Result of reordering – a random appearance that cannot be distinguished from that of troubled wakefulness.

EX1001, Figures 7-8

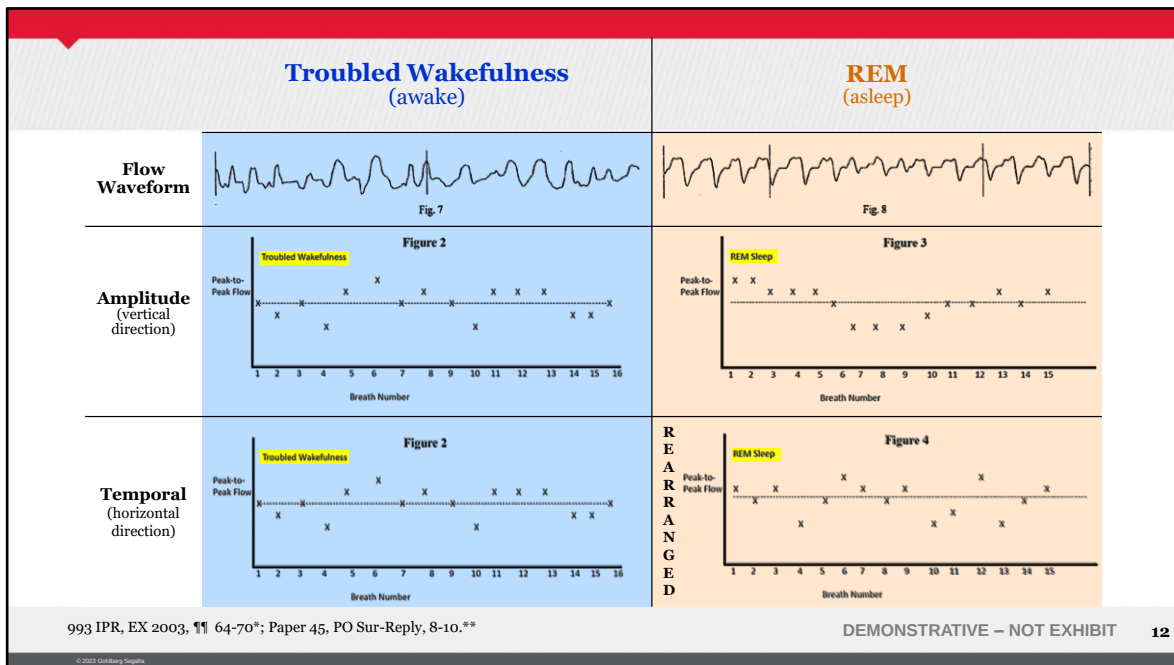
• 993 IPR, PO Response, Paper 34, 3, 37; PO Sur-Reply, Paper 45, 8, 10; * EX2003, ¶ 70**

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*988-992 and 994 IPR record citations: 988 IPR: Response: Paper 27, 3, 18; Sur-Reply: Paper 40, 9, 10; 989 IPR: Response: Paper 33, 3-4, 38; Sur-Reply: Paper 44, 8, 10; 990 IPR: Response: Paper 33, 4, 35; Sur-Reply: Paper 44, 9-11; 991 IPR: Response: Paper 36, 4, 24; Sur-Reply: Paper 47, 9-10; 992 IPR: Response: Paper 32, 37; Sur-Reply: Paper 43, 9, 10; 994 IPR: Response: Paper 32, 3, 38; Sur-Reply: Paper 44, 8-9

**988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 76, Paper 40, PO Sur-Reply, 10; 989 IPR, EX2005, ¶ 72; 990 IPR, EX2006, ¶ 75; 991 IPR, EX2006, ¶ 76; 992 IPR, EX2006, ¶ 71; 994 IPR, EX2006, ¶ 81



*988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶¶ 70-76; 989 IPR, EX2005, ¶¶ 66-72; 990 IPR, EX2006, ¶¶ 69-75; 991 IPR, EX2006, ¶¶ 70-76; 992 IPR, EX2006, ¶¶ 65-71; 994 IPR, EX2006, ¶¶ 75-81

**988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 8-11; 989 IPR, Paper 44, Sur-Reply, 8-12; 990 IPR, Paper 44, Sur-Reply, 9-14; 991 IPR, Paper 47, Sur-Reply, 8-13; 992 IPR, Paper 43, Sur-Reply, 8-13; 994 IPR, Paper 44, Sur-Reply, 8-12

II. Claim Construction

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Claim Construction

“troubled wakefulness”

Petitioner’s Construction	Patent Owner’s Construction
State in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable <i>ResMed</i>	State in which the breathing pattern is irregular indicating that the patient is awake and either anxious or uncomfortable  NYU

For purposes of this Response, Patent Owner agrees with this construction and this term is not in dispute.

993 IPR, Paper 34, PO Response, 29-30*

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*990-992 and 994 IPR record citations: 990 IPR, Paper 33, PO Response, 27-28; 991 IPR, Paper 36, PO Response, 16; 992 IPR, Paper 32, PO Response, 29; 994 IPR, Paper 33, PO Response, 17-18

Claim Construction

“analyzing the breathing patterns”*

Petitioner’s Construction	Patent Owner’s Construction
plain and ordinary meaning	determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform and examining the values of the parameters and the order in which they appear in time

ResMed

 NYU

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New York University Exhibit 2028
ResMed v. New York University
IPR2022-00991
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Claim Construction

Determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow waveform. 993 IPR, Paper 45, PO Sur-Reply, 4; EX2003, ¶ 137* **= time series**

Values of the parameters. 993 IPR, Paper 45, PO Sur-Reply, at 5; EX1052, 81:17-23** **= amplitude structure analysis**

Order in which they appear in time. 993 IPR, Paper 45, PO Sur-Reply, at 5; EX1052, 81:17-23.** **= temporal structure analysis**

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*988-994 IPR record citations: 988 IPR, Paper 40, PO Sur-Reply, 4-5; EX2005, ¶ 139; 989 IPR, Paper 44, PO Sur-Reply, 4; EX2005, ¶ 122; 990 IPR, Paper 44, PO Sur-Reply, 5; EX2006, ¶ 141 991 IPR, Paper 47, PO Sur-Reply, 4-5; EX2006, ¶ 142 992 IPR, Paper 43, PO Sur-Reply, 4-5; EX2006, ¶ 137 994 IPR, Paper 44, Sur-Reply, 4; EX2006, ¶ 148

**988-994 IPR record citations: 988 IPR, Paper 40, PO Sur-Reply, at 5; 989 IPR, Paper 44, PO Sur-Reply, 5; 990 IPR, Paper 44, Sur-Reply, 6; 991 IPR, Paper 47, Sur-Reply, 5; 992 IPR, Paper 43, Sur-Reply, 5; 993 IPR, Paper 45, PO Sur-Reply, at 5; 994 IPR, Paper 44, Sur-Reply, 4-5; EX1052, 81:17-23

Claim Construction

Q. So it's your understanding that even if the claims say awake state and an asleep state, to meet that limitation, you would still need to recognize a REM sleep state and a troubled wakefulness state, is that correct?

MR. SEIM: Objection to form.

A. **In order to make that distinction between awake and asleep reliably under every conceivable circumstance, yes. I should say every conceivable circumstance that is currently known.**

993 IPR, PO Response, Paper 34, 13, 38, 40-41, 50;* EX1052, 144:5-14

> **This construction applies to both:**

1. Claims that distinguish between awake state and asleep state and do not claim troubled wakefulness; 989 IPR, PO Response, Paper 33, 30-33.**
2. Claims that claim troubled wakefulness. 993 IPR, PO Response, Paper 34, 30-33***

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*988-992 and 994 IPR record citations: 988 IPR: PO Response, Paper 27, 13, 38; 989 IPR: PO Response, Paper 33, 37, 40, 47; 990 IPR: PO Response, Paper 33, 34, 45, 51; 991 IPR: PO Response: Paper 36, 23, 35, 42; 992 IPR: PO Response, Paper 32, 37-38, 47; 994 IPR: PO Response, Paper 33, 25, 28, 37

**988, and 990-992 IPR record citations: 988 IPR: PO Response, Paper 27, 30-34; 990 IPR: PO Response, Paper 33, 26-30; 991 IPR: PO Response, Paper 36, 15-19; 992 IPR: PO Response

***988, 990-992, and 994 IPR record citations: 988 IPR: PO Response, Paper 27, 30-34; 990 IPR: PO Response, Paper 33, 26-30; 991 IPR: PO Response, Paper 36, 15-19; 992 IPR: PO Response, Paper 32, 28-33; 994 IPR: PO Response, Paper 33, 17-22

Claim 1 With Patent Owner's Construction

a processing arrangement *determining a sequence of parameters each of which characterizes a single breath in a series of breaths from a flow wave form and examining the values of the parameters and the order which they appear in time* to determine whether the breathing patterns are indicative of one of the following patient's states: (i) a regular breathing state, (ii) a sleep disorder breathing state, (iii) a REM sleep state and (iv) a troubled wakefulness state, the processing arrangement adjusting the applied pressure as a function of the patient's state,

Paper 34, PO Response, 33*

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*988-992 and 994 IPR record citations: 988 IPR, Paper 27, PO Response, 33-34; 989 IPR, Paper 33, PO Response, 33; 992 IPR, Paper 32, PO Response, 32-33; 994 IPR, Paper 33, PO Response, 21-22

Support For Patent Owner's Construction

Intrinsic Evidence

applied. Indices of sleep disordered breathing include apnea (e.g., periods of zero airflow which are greater than 8–10 seconds alternating with large breaths), hypopnea (e.g., cyclical periods of airflow which is substantially reduced, lasting 10 or more seconds, and terminated by larger breaths), or periods of intermittent and cyclical change in the shape of the signal (e.g., characterized by flattening of the waveform, terminated by normal shaped breaths).

IPR2022-00993, EX1001 at 4:12-19*

- > Defines breathing patterns in terms of both amplitude (parameter values) and temporal structures (the order in which they appear in time).

EX2003, ¶ 135**

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*988-992 and 994 IPR record citations: '009 Patent (988 IPR), 4:39-46; '539 Patent (989 IPR), 4:44-51; '115 Patent (990 IPR), 4:46-53; '955 Patent (991 IPR), 4:40-49; '024 Patent (992 IPR), 4:44-51; '344 Patent (994 IPR), 4:37-45

**988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 138; 989 IPR, EX2005, ¶ 120; 990 IPR, EX2006, ¶ 139; 991 IPR, EX2006, ¶ 140; 992 IPR, EX2006, ¶ 135; 994 IPR, EX2006, ¶ 146

Support For Patent Owner's Construction

Intrinsic Evidence

pressure, etc). FIG. 7 shows a period of such troubled wakefulness in which the breathing pattern is characterized by irregularly variations in the size and/or frequency of breaths and/or irregular variation in the shapes of the patient's airflow tracing indicating that the patient is awake and either anxious or uncomfortable. There is, however, no **cyclical change** (e.g., a periodic irregularity) in breath size, such as would be seen during apnea and hypopnea sleep events. One of the ways to increase the patient's comfort is

IPR2022-00993, EX1001 at 4:27-35*

- > Describes both amplitude and temporal structures when examining flow waveforms, such as in FIG. 7.

EX2003, ¶¶ 136-37**

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*988-992 and 994 IPR record citations: '009 Patent (988 IPR), 4:54-61; '539 Patent (989 IPR), 4:59-66; '115 Patent (990 IPR), 4:61 – 5:1; '955 Patent (991 IPR), 4:55-64; '024 Patent (992 IPR), 4:59-66; '344 Patent (994 IPR), 4:53-60

**988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 139; 989 IPR, EX2005, ¶¶ 121-122; 990 IPR, EX2006, ¶¶ 140-141; 991 IPR, EX2006, ¶¶ 141-142; 992 IPR, EX2006, ¶¶ 136-137; 994 IPR, EX2006, ¶¶ 147-148;

Support For Patent Owner's Construction

Intrinsic Evidence

be maintained (i.e., not reduced as during wakefulness). The type of irregularity seen during REM differs from that seen in wakefulness in several key parameters. This REM associated pattern of breathing may include, e.g., the absence of larger breaths, especially after pauses, generally high respiratory rates and low flow rates, and a tendency for clustering of small breaths. These differences in the pattern of the respiratory airflow signal from those seen during troubled wakefulness allow the separation of these states and can be used to make a change in the applied pressure.

IPR2022-00993, EX1001 at 4:65-5:7*

Key:

Blue = Temporal | Yellow = Amplitude

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*988-992 and 994 IPR record citations: '009 Patent (988 IPR), 5:25-34; '539 Patent (989 IPR), 5:30-39; '115 Patent (990 IPR), 5:32-41; '955 Patent (991 IPR), 5:28-37; '024 Patent (992 IPR), 5:30-39; '344 Patent (994 IPR), 5:24-33

Support For Patent Owner's Construction

Intrinsic Evidence

One of the advantages of the system 1 according to the present invention is that the pressure supplied to the patient is adjusted (e.g., **reduced to zero or a preset low level**) when the patient has an irregular breathing pattern that suggests that he is **awake and anxious**. When breathing is either regular (e.g., suggesting sleep) or shows sleep disorder breathing events, the pressure may be maintained or increased.

IPR2022-00993, EX1001 at 6:7-13*

- > This precise construction accounts for decreasing the pressure when the patient is awake and anxious.

993 IPR, Paper 45, PO Sur-Reply, 6**; see also *id.* at 6-7.***

DEMONSTRATIVE – NOT EXHIBIT

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*988-992 and 994 IPR record citations: '009 Patent (988 IPR), 6:33-39; '539 Patent (989 IPR), 6:41-48; '115 Patent (990 IPR), 6:41-48; '955 Patent (991 IPR), 6:38-45; '024 Patent (992 IPR), 6:41-48; '344 Patent (994 IPR), 6:33-39

**988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 6; 989 IPR, Paper 44, Sur-Reply, 6; 990 IPR, Paper 44, Sur-Reply, 7; 991 IPR, Paper 47, Sur-Reply, 6; 992 IPR, Paper 43, Sur-Reply, 6; 994 IPR, Paper 44, Sur-Reply, 5-6

***988-992 and 994 IPR record citations: 988 IPR, Paper 40, PO Sur-Reply, 7-8; 989 IPR, Paper 44, PO Sur-Reply, 6-7; 990 IPR, Paper 44, PO Sur-Reply, 8-9; 991 IPR, Paper 47, PO Sur-Reply, 7-8; 992 IPR, Paper 43, PO Sur-Reply, 7-8; 994 IPR, Paper 44, PO Sur-Reply, 6-7

Support For Patent Owner's Construction

Implied Lexicography



Lexicography does not require a statement in the form “I define ____ to mean ____”.

AstraZeneca AB v. Mut. Pharm. Co., 384 F.3d 1333, 1339 (Fed. Cir. 2004)

'994 Patent implies:

- Measurement of certain parameters.
988 IPR, Paper 40, PO Sur-Reply, 7-8* (citing EX1052, 44:6-20)
- That the asleep and awake states can be separated from one another.
988 IPR, Paper 40, PO Sur-Reply, 7-8* (EX1052, 178:24-25, 179:1-22)
- Separation done by analysis of amplitude and temporal structures.
988 IPR, Paper 40, PO Sur-Reply, 7-8* (EX1052, 178:24-25, 179:1-22)

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*989-994 IPR record citations: 989 IPR, Paper 44, PO Sur-Reply, 6-7; 990 IPR, Paper 44, PO Sur-Reply, 8-9; 991 IPR, Paper 47, PO Sur-Reply, 7-8; 992 IPR, Paper 43, PO Sur-Reply, 7-8; 993 IPR, Paper 45, PO Sur-Reply, 6-7; 994 IPR, Paper 44, PO Sur-Reply, 6-7

Problems With Petitioner's Construction

"Plain and ordinary meaning"

1. What is "plain and ordinary meaning"?

Paper 45, PO Sur-Reply, 12-13*

2. Ignores specification disclosures.

Paper 45, PO Sur-Reply, 13-14**

3. Dependent claims narrow the independent claims.

Paper 45, PO Sur-Reply, 14-15***

4. Petitioner's construction could result in incorrect pressure.

Paper 45, PO Sur-Reply, 6****

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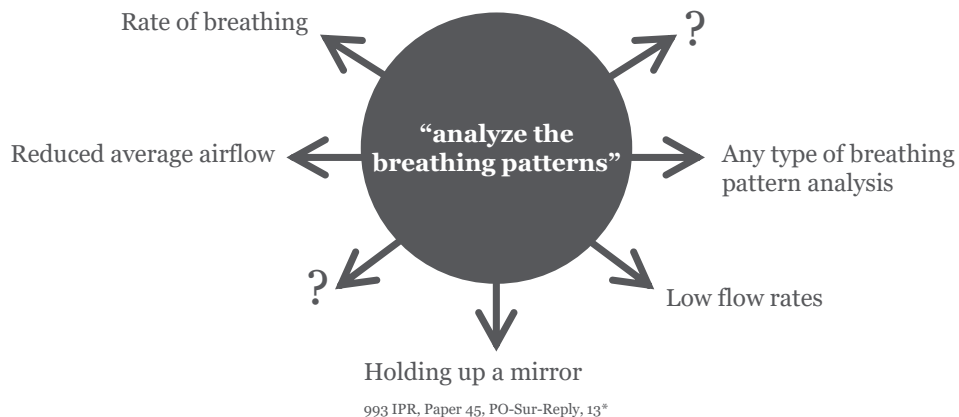
*988-992 and 994 IPR record citations: 988 IPR, Paper 40, PO Sur-Reply, 13; 989 IPR, Paper 44, PO Sur-Reply, 12-13; 990 IPR, Paper 44, PO Sur-Reply, 14; 991 IPR, Paper 47, PO Sur-Reply, 13; 992 IPR, Paper 43, PO Sur-Reply, 13; 994 IPR, Paper 44, PO Sur-Reply, 12

**988-992 and 994 IPR record citations: 988 IPR, Paper 40, PO Sur-Reply, 13-14; 989 IPR, Paper 44, PO Sur-Reply, 13-14; 990 IPR, Paper 44, PO Sur-Reply, 15; 991 IPR, Paper 47, PO Sur-Reply, 14; 992 IPR, Paper 43, PO Sur-Reply, 14; 994 IPR, Paper 44, PO Sur-Reply, 13

***988-992 and 994 IPR record citations: 988 IPR, Paper 40, PO Sur-Reply, 15; 989 IPR, Paper 44, PO Sur-Reply, 14-15; 990 IPR, Paper 44, PO Sur-Reply, 15-16; 991 IPR, Paper 47, PO Sur-Reply, 14-15; 992 IPR, Paper 43, PO Sur-Reply, 14-15; 994 IPR, Paper 44, PO Sur-Reply, 14-15

****988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 6; 989 IPR, Paper 44, Sur-Reply, 6; 990 IPR, Paper 44, Sur-Reply, 7; 991 IPR, Paper 47, Sur-Reply, 6; 992 IPR, Paper 43, Sur-Reply, 6; 994 IPR, Paper 44, Sur-Reply, 6

1. What is “plain and ordinary meaning”?



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*988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 13; 989 IPR, Paper 44, Sur-Reply, 13; 990 IPR, Paper 44, Sur-Reply, 14; 991 IPR, Paper 47, Sur-Reply, 13; 992 IPR, Paper 43, Sur-Reply, 13; 994 IPR, Paper 44, Sur-Reply, 12

1. What is “plain and ordinary meaning”?

Dr. Bates – “breathing pattern” has no ordinary meaning.

Q. So it's your opinion that the '994 patent family does not use the term “breathing pattern” in its ordinary meaning?

MR. SEIM: Objection to form.

A. **There is no ordinary meaning.** Breathing pattern is an extremely general term and it can be leveraged in whatever way is appropriate for the circumstances at hand.

EX1052, Bates Depo. Tr. 108:25 – 109:1-7; Paper 45, PO Sur-Reply, 13*

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*988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 13; 989 IPR, Paper 44, Sur-Reply, 13; 990 IPR, Paper 44, Sur-Reply, 14-15; 991 IPR, Paper 47, Sur-Reply, 13-14; 992 IPR, Paper 43, Sur-Reply, 13-14; 994 IPR, Paper 44, Sur-Reply, 12-13

Practical Results of Applying “Plain and Ordinary Meaning”

IF:
“analyze breathing patterns” is construed as “plain and ordinary meaning” which is construed as “any” type of breathing pattern analysis,

EX1051, ¶ 16



THEN:
any invention claiming a new way of analyzing breathing patterns



Including ResMed's own inventions



**because
“plain and ordinary meaning”
covers everything**

993 IPR, PO Sur-Reply, Paper 45, 12-13*

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*988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 13; 989 IPR, Paper 44, Sur-Reply, 12-13; 990 IPR, Paper 44, Sur-Reply, 14; 991 IPR, Paper 47, Sur-Reply, 13; 992 IPR, Paper 43, Sur-Reply, 13; 994 IPR, Paper 44, Sur-Reply, 12

Practical Results of Applying “Plain and Ordinary Meaning”

> If “plain and ordinary meaning” is construed to only include analysis of amplitude structure:

- Board would be adopting a construction that does not enable the challenged patents. 993 IPR, Paper 45, PO Sur-Reply, 2.*
- Claims including analysis of breathing patterns, without troubled wakefulness, are invalid. 993 IPR, Paper 45, PO Sur-Reply, 6.*
- Claims including troubled wakefulness survive, because troubled wakefulness cannot be determined without analyzing both amplitude and temporal structure of a flow waveform. 993 IPR, Paper 45, PO-Sur-Reply, 13-14.***

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*988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply 3; 989 IPR, Paper 44, Sur-Reply 2; 990 IPR, Paper 44, Sur-Reply 3; 991 IPR, Paper 47, Sur-Reply 3; 992 IPR, Paper 43, Sur-Reply 3; 994 IPR, Paper 44, Sur-Reply, 2

*988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 6; 989 IPR, Paper 44, Sur-Reply, 6; 990 IPR, Paper 44, Sur-Reply, 7; 991 IPR, Paper 47, Sur-Reply, 6; 992 IPR, Paper 43, Sur-Reply, 6; 994 IPR, Paper 44, Sur-Reply, 6

***988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 14; 989 IPR, Paper 44, Sur-Reply, 13-14; 990 IPR, Paper 44, Sur-Reply, 15; 991 IPR, Paper 47, Sur-Reply, 14; 992 IPR, Paper 43, Sur-Reply, 14; 994 IPR, Paper 44, Sur-Reply, 13

2. Specification Ignored

- > Specification discloses both amplitude and temporal structural analysis.
993 IPR, Paper 45, PO Sur-Reply, 3-5, 13-14.*
- > Petitioner adopts the amplitude structure, but ignores the temporal structure disclosures. 993 IPR, Paper 45, PO Sur-Reply, 3.**

Amplitude	Temporal
High respiratory rates	Absence of larger breaths, especially after pauses
Low flow rates	Tendency for clustering of small breaths EX1052, 81:17-23

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*988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 3-5 13-14; 989 IPR, Paper 44, Sur-Reply, 3-5, 13-14; 990 IPR, Paper 44, Sur-Reply, 4-6, 14-15; 991 IPR, Paper 47, Sur-Reply, 3-5, 13-14; 992 IPR, Paper 43, Sur-Reply, 3-5, 13-14; 994 IPR, Paper 44, Sur-Reply, 3-5, 13

**988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 3; 989 IPR, Paper 44, Sur-Reply, 3; 990 IPR, Paper 44, Sur-Reply, 4; 991 IPR, Paper 47, Sur-Reply, 3; 992 IPR, Paper 43, Sur-Reply, 3; 994 IPR, Paper 44, Sur-Reply, 3

3. Dependent Claims



“...[D]ependent claims ... are only an aid to interpretation and are not conclusive.”

N. Am. Vaccine, Inc. v. Am. Cyanamid Co., 7 F.3d 1571, 1577 (Fed. Cir. 1993)

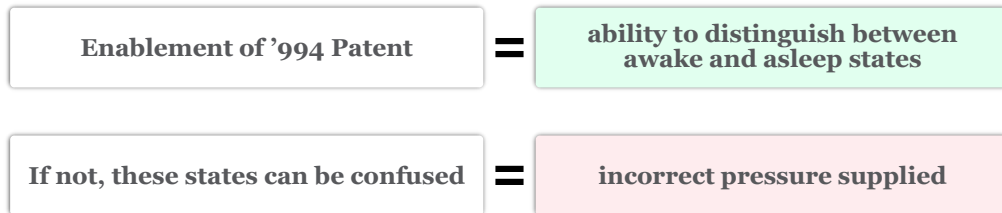
988 IPR, Paper 45, PO Sur-Reply, 14-15*

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*988-992 and 994 IPR record citations: 988 IPR, Paper 40, PO Sur-Reply, 14-15; 989 IPR, Paper 44, PO Sur-Reply, 14; 990 IPR, Paper 44, PO Sur-Reply, 15-16; 991 IPR, Paper 47, PO Sur-Reply, 14-15; 992 IPR, Paper 43, PO Sur-Reply, 14-15; 994 IPR, Paper 44, PO Sur-Reply, 14

4. Petitioner's Construction Could Result in Incorrect Pressure



Paper 45, PO Sur-Reply, 6*

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*988-992 and 994 IPR record citations: 988 IPR, Paper 40, PO Sur-Reply, 6; 989 IPR, Paper 44, PO Sur-Reply, 6; 990 IPR, Paper 44, PO Sur-Reply, 7; 991 IPR, Paper 47, PO Sur-Reply, 6; 992 IPR, Paper 43, PO Sur-Reply, 6; 994 IPR, Paper 44, PO Sur-Reply, 5-6

III. § 102 Anticipation

DEMONSTRATIVE – NOT EXHIBIT

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§ 102 Anticipation

Sullivan⁹⁹⁵ (989, 993, 994 IPRs)	Rapoport⁵⁰² (989 IPR)
Petitioner admits this does not explicitly disclose REM and troubled wakefulness breathing patterns. EX2003, ¶¶ 292; EX1003, ¶ 209*	Petitioner admits this does not disclose determining whether breathing patterns indicate an awake state. 989 IPR, EX2005, ¶ 251, citing EX1003, ¶ 254
Petitioner admits this does not explicitly disclose awake state breathing pattern. EX2003, ¶ 293; EX2012, 89:18-20**	Petitioner admits this does not explicitly disclose certain breathing patterns. 989 IPR, EX2005, ¶ 252, citing EX2015, 134:4-8
Infringement allegations cannot support anticipation. EX2003, ¶¶ 295-296; PO Sur-Reply, 25***	Infringement allegations cannot support anticipation. 989 IPR, EX2005, ¶¶ 253-55; 989 IPR PO Sur-Reply, 24-25

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*989 and 994 IPR record citations: 989 IPR: EX2005, ¶ 245; EX1003, at ¶¶ 122, 129, 166
994 IPR: EX2006, ¶ 211; EX1003, at ¶ 194

**989 and 994 IPR record citations: 989 IPR: EX2005, ¶ 246; EX2014, 89:18-20
994 IPR: EX2006, ¶ 233; EX2015, 89:18-20

***989 and 994 IPR record citations: 989 IPR: EX2005, ¶¶ 247-248, 253-254; Paper 44,
PO Sur-Reply, 24-25
994 IPR: EX2006, ¶¶ 235-236; Paper 44, PO Sur-Reply, 24-25

§ 102 Anticipation – What Petitioner did not do

> NO limitation-by-limitation analysis of all claims.

989 IPR, Institution Decision, Paper 16, 38; 993 IPR, PO Response, Paper 34, 54-55; 994 IPR, PO Response, Paper 33, 42-44.

- **This failure was noted by the Board:**

construction advanced by Patent Owner in district court. *Id.* Petitioner provides no limitation-by-limitation analysis of any challenged claim, and instead focuses much of its short discussion on allegations made by Patent Owner in district court. *Id.* According to Petitioner, Sullivan⁹⁹⁵ and 989 IPR, Institution Decision, Paper 16, 38

> **Petitioner only points to PO's complaint regarding the ResMed Air Solutions brochure, copyright 2015.** 989 IPR, Paper 11, 69 (citing EX1033), Exhibit 8 to complaint).*

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*993 and 994 IPR record citations: 993 IPR, Corrected Petition, Paper 12, 80; 994 IPR, Corrected Petition, Paper 12, 8

§ 102 Anticipation – What Petitioner did not do

> **NO** independent infringement analysis done by its expert.

EX1003, ¶ 45; EX2012, 89:20-21.*

> **NO** disclosure to the Board that Sullivan995 was considered by the PTO during prosecution of the '994 Parent Patent.

993 IPR, Corrected Petition, Paper 12, 77-81.**

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*989 and 994 IPR record citations: 989 IPR, EX2014, 89:20-21; 994 IPR, EX2015, 89:20-21

**988-992 and 994 IPR record citations: 989 IPR, Corrected Petition, Paper 11, 68-69; 994 IPR, Corrected Petition, Paper 12, 62-66

IV. § 103 Obviousness

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No Motivation to Combine

Motivation to Combine

=

Recognition of a Problem

+

Combine Prior Art References
to Solve the Problem

> PROBLEM:

Failure of CPAP devices to distinguish between awake and asleep states, because the awake state of troubled wakefulness was not known, as recognized by the PTO during prosecution of the '994 Parent Patent.

993 IPR, EX2003, ¶ 55, citing EX1002, 120.*

As to independent claim 1, the prior art of record **does not teach** a positive airway pressure system comprising a processing arrangement analyzing the breathing patterns to determine whether the breathing patterns are indicative of (iv) **a troubled wakefulness state**, the processing arrangement adjusting the applied pressure as a function of the patient's state, wherein when the breathing patterns indicate a troubled wakefulness state, the processing arrangement controls the generator to adjust the pressure to a second value.

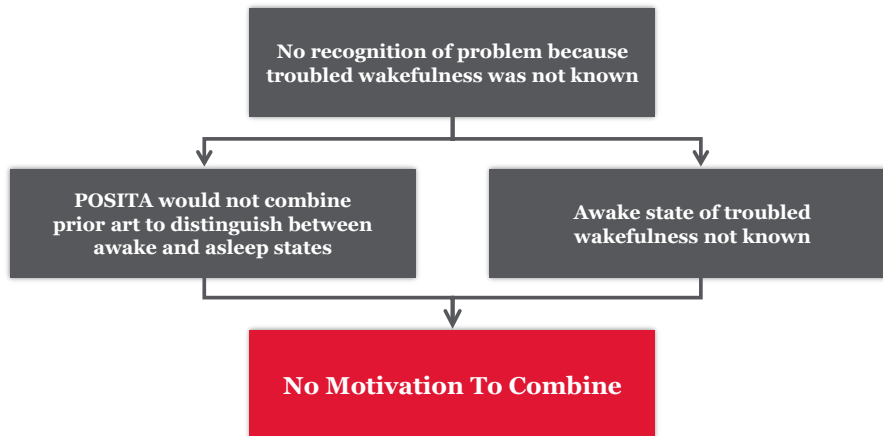
EX1002 at 120

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*988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 61; 989 IPR, EX2005, ¶ 57; 990 IPR, EX2006, ¶ 60; 991 IPR, EX2006, ¶ 61; 992 IPR, EX2006, ¶ 56; 994 IPR, EX2006, ¶ 66

No Motivation to Combine



EX2003, ¶¶ 163-166*; 221-224**

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*988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶¶ 236-237, 247, 252, 256; 989 IPR, EX2005, ¶¶ 196-197; 990 IPR, EX2006, ¶¶ 262-268; 991 IPR, EX2006, ¶¶ 346-352; 992 IPR, EX2006, ¶¶ 249-255; 994 IPR, EX2006, ¶¶ 174-177

**988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶¶ 144-145, 171, 176-178, 185-187; 989 IPR, EX2005, ¶¶ 126-127; 990 IPR, EX2006, ¶¶ 205-206; 991 IPR, EX2006, ¶¶ 266-267; 992 IPR, EX2006, ¶¶ 203-204; 994 IPR, EX2006, ¶¶ 213-216

No Motivation to Combine

- > No motivation to combine with Sullivan460 because it is not enabling.
 - **Petitioner failed to address this issue.**

993 IPR, PO Sur-Reply, Paper 45, 19.*

- > Combining these references requires undue experimentation, because analyzing both amplitude and temporal structures to determine asleep/awake states was not known.

993 IPR, PO Sur-Reply, Paper 45, 20.**

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*988-992 and 994 IPR record citations: 988 IPR, PO Sur-Reply, Paper 40, 19-20; 989 IPR, PO Sur-Reply, Paper 44, 18-19; 990 IPR, PO Sur-Reply, Paper 44, 20; 991 IPR, PO Sur-Reply, Paper 47, 19-20; 992 IPR, PO Sur-Reply, Paper 43, 19; 994 IPR, PO Sur-Reply, Paper 44, 18-19

**988-992 and 994 IPR record citations: 988 IPR, PO Sur-Reply, Paper 40, 20; 989 IPR, PO Sur-Reply, Paper 44, 19; 990 IPR, PO Sur-Reply, Paper 44, 21; 991 IPR, PO Sur-Reply, Paper 47, 20; 992 IPR, PO Sur-Reply, Paper 43, 20; 994 IPR, PO Sur-Reply, Paper 44, 19

No Reasonable Expectation of Success

- > No reasonable expectation of success in lowering the pressure upon detecting a troubled wakefulness state, because determining this state is not taught in the prior art.

993 IPR, PO Response, Paper 34, 45;* 993 IPR, EX2003, ¶ 145**

- > Modifying existing systems to distinguish the troubled wakefulness awake state from the REM asleep state is not a simple change in programming.

993 IPR, PO Response, Paper 34, 45-46; PO Sur-Reply, Paper 45, 18;*** 993 IPR, EX2003, ¶¶ 214-215.**** EX2003, ¶ 215***** ¶ 146*****, 228*****

But in fact, they would have been **unsuccessful** in creating a device that could actually do that [sense whether the patient is asleep] because they would not have the means to unambiguously determine whether the patient was awake or asleep because prior to the Rapoport '994 patent, yes, that sequence of patents – and this is the critical thing – it was not known how to distinguish between troubled wakefulness versus REM sleep ... those two could have been confused . . .

993 IPR, PO Sur-Reply, Paper 45, 20;***** EX1052, 200:3-15

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*988-992 and 994 IPR record citations: 988 IPR: PO Response, Paper 27, 49-50; 989 IPR: PO Response, Paper 33, 51-52; 990 IPR: PO Response, Paper 33, 49, 56; 991 IPR: PO Response, Paper 36, 46; 992 IPR: PO Response, Paper 32, 42, 47-48; 994 IPR: Paper 33, 32

**988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶¶ 218, 287; 989 IPR, EX2005, ¶¶ 129, 225; 990 IPR, EX2006, ¶¶ 208, 270; 991 IPR, EX2006, ¶¶ 269, 352-354; 992 IPR, EX2006, ¶¶ 206, 257; 994 IPR, EX2006, ¶¶ 156, 206

***988-992 and 994 IPR record citations: 988 IPR: PO Response, Paper 27, 50, 53, 57; Sur-Reply: Paper 40, 23-24; 990 IPR: Response: Paper 33, 56-57; 991 IPR: Response: Paper 36, 46-47; 992 IPR: Response: Paper 32, 42, 51, 53; 994 IPR: Response: Paper 33, 33; Sur-Reply: Paper 44, 18

****988, 990-992 and 994 IPR record citations: 988 IPR, EX2005, ¶¶ 218-219; 990 IPR, EX2006, ¶¶ 270-271; 991 IPR, EX2006, ¶¶ 269-270; 992 IPR, EX2006, ¶¶ 257-258; 994 IPR, EX2006, ¶¶ 174-175

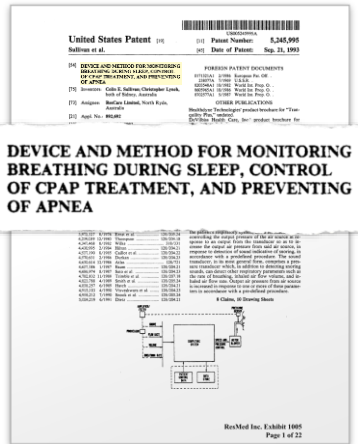
*****988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 219, 288; 989 IPR, EX2005, ¶ 200; 990 IPR, EX2006, ¶ 271; 991 IPR, EX2006, ¶ 355-356; 992 IPR, EX2006, ¶ 256-259; 994 IPR, EX2006, ¶ 158, 195

*****988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 283; 990 IPR, EX2006, ¶ 265-267; 991 IPR, EX2006, ¶ 349-350; 992 IPR, EX2006, ¶ 258-259; 994 IPR, EX2006, ¶ 157

*****988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 235; 989 IPR, EX2005, ¶ 129, 131, 140, 150, 167, 176; 990 IPR, EX2006, ¶ 150-151; 991 IPR, EX2006, ¶ 270; 992 IPR, EX2006, ¶ 146-148; 994 IPR, EX2006, ¶ 219

*****988-992 and 994 IPR record citations: 988 IPR: PO Sur-Reply, Paper 40, 20-21; 989 IPR: PO Sur-Reply, Paper 44, 20; 990 IPR: PO Sur-Reply, Paper 44, 21-22; 991 IPR: PO Sur-Reply, Paper 47, 20-21; 992 IPR: PO Sur-Reply, Paper 43, 20; 993 IPR, PO Sur-Reply, Paper 45, 20; 994 IPR: PO Sur-Reply, Paper 44, 20

Sullivan995



Detects sleep apnea on the basis of snoring sounds.

EX2003, ¶ 106(a)*

Missing Limitations:

- Analyzing breathing patterns. EX2003, ¶ 217**
- Awake state and transition from an asleep state to an awake state. EX2003, ¶ 106(e)**
- Troubled wakefulness. EX2003, ¶ 106(e)***

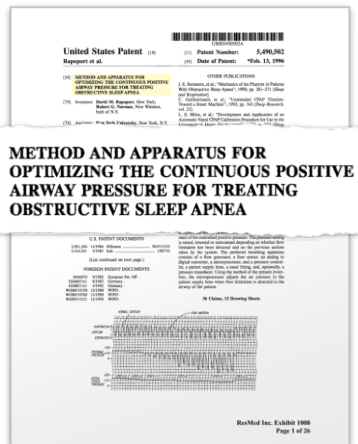
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*988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 112(a); 989 IPR, EX2005, ¶ 108(a); 990 IPR, EX2006, ¶ 111(a); 991 IPR, EX2006, ¶ 112(a); 992 IPR, EX2006, ¶ 107(a); 994 IPR, EX2006, ¶ 117(a)

**988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 221; 989 IPR, EX2005, ¶ 134, 161; 990 IPR, EX2006, ¶ 157; 991 IPR, EX2006, ¶ 157, 211; 992 IPR, EX2006, ¶ 147-148; 994 IPR, EX2006, ¶ 209

***988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 112(e); 989 IPR, EX2005, ¶ 108(e); 990 IPR, EX2006, ¶ 111(e); 991 IPR, EX2006, ¶ 112(e); 992 IPR, EX2006, ¶ 107(e); 994 IPR, EX2006, ¶ 117(e);



Adjusts CPAP pressure by detecting flow limitation of a single breath.

EX2003, ¶¶ 73, 81(a)*

Missing Limitations:

- **Analyzing breathing patterns.** EX2003, ¶ 150**
- **Awake state and transition between awake and asleep state.** EX2003, ¶ 81(a)**
- **Fails to disclose troubled wakefulness state.** EX2003, ¶ 81(a)***

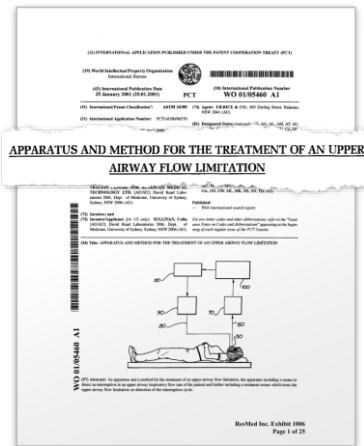
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*988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶¶ 79, 87(a); 989 IPR, EX2005, ¶¶ 75, 83(a); 990 IPR, EX2006, ¶¶ 78, 86(a); 991 IPR, EX2006, ¶¶ 79, 87(a); 992 IPR, EX2006, ¶¶ 74, 82(a); 994 IPR, EX2006, ¶¶ 84, 92(a)

**988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 291; 989 IPR, EX2005, ¶ 196-197; 990 IPR, EX2006, ¶ 264; 991 IPR, EX2006, ¶ 306, 309, 312; 992 IPR, EX2006, ¶ 249-250; 994 IPR, EX2006, ¶ 161

***988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 87(a); 989 IPR, EX2005, ¶ 83(a); 990 IPR, EX2006, ¶ 86(a); 991 IPR, EX2006, ¶ 87(a); 992 IPR, EX2006, ¶ 82(a); 994 IPR, EX2006, ¶ 92(a)

Sullivan460



Detects upper airway flow limitation on a breath-by-breath basis from the shape of the inspiratory flow waveform.

EX2003, ¶ 88(a)*

Missing Limitations:

- Analyzing breathing patterns. EX2003, ¶ 153**
- Not enabled because does not describe how to determine the preset flow rate. EX2003, ¶ 88(a)(i)***
- Fails to disclose troubled wakefulness. EX2003, ¶ 88(c)****

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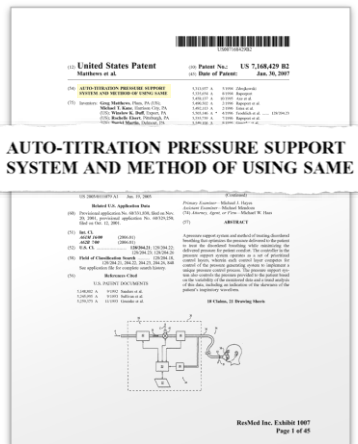
*988-992 and 994 IPR record citations: 988 IPR, EX2005, EX2003, ¶ 94(a); 989 IPR, EX2005, ¶ 90(a); 990 IPR, EX2006, ¶ 93(a); 991 IPR, EX2006, ¶ 94(a); 992 IPR, EX2006, ¶ 89(a); 994 IPR, EX2006, ¶ 99(a)

**988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 290-291; 989 IPR, EX2005, ¶ 137; 990 IPR, EX2006, ¶ 262; 991 IPR, EX2006, ¶ 358-359; 992 IPR, EX2006, ¶ 257; 994 IPR, EX2006, ¶ 164

***988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 94(a)(i); 989 IPR, EX2005, ¶ 90(a)(i); 990 IPR, EX2006, ¶ 93(a)(i); 991 IPR, EX2006, ¶ 94(a)(i); 992 IPR, EX2006, ¶ 89(a)(i); 994 IPR, EX2006, ¶ 99(a)(i)

****988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 94(c); 989 IPR, EX2005, ¶ 90(c); 990 IPR, EX2006, ¶ 93(c); 991 IPR, EX2006, ¶ 94(c); 992 IPR, EX2006, ¶ 89(c); 994 IPR, EX2006, ¶ 99(c)

Matthews



Uses an equation to detect erratic breathing to adjust CPAP pressure.

Missing Limitations:

- Analyzing breathing patterns. 993 IPR, EX2003, ¶ 153*
- Asleep vs. awake states. EX1052, Bates Depo. Tr., 173:12-22
- Troubled wakefulness, because troubled wakefulness ≠ erratic breathing.

Q. And would you say that the way that Matthews uses the term “erratic” is different than how you understand the word “irregular” to mean in the ‘994 patent family?

MR. SIEM: Objection to form.

A. They are – they are not the same thing.

EX1052, Bates Depo. Tr., 174:18-23; see also 988 IPR, Paper 27, PO Response, 28**

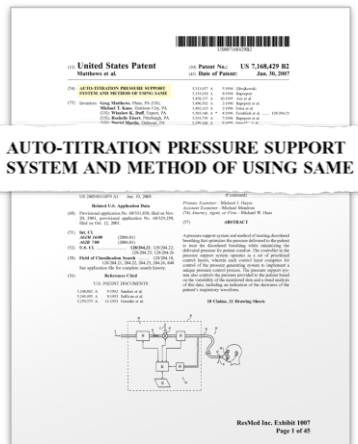
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*988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 290-291; 989 IPR, EX2005, ¶ 137; 990 IPR, EX2006, ¶ 262; 991 IPR, EX2006, ¶ 358-359; 992 IPR, EX2006, ¶ 257; 994 IPR, EX2006, ¶ 164

**990-994 IPR record citations: 990 IPR, Paper 33, PO Response, 26; 991 IPR, Paper 36, PO Response, 15; 992 IPR, Paper 32, PO Response, 28; 993 IPR, Paper 34, PO Response, 28; 994 IPR, Paper 33, PO Response, 16

Matthews



Upon detection of erratic breathing, teaches alteration of pressure based on prior pressure. 993 IPR, PO Response, Paper 34, 26-28, 42-43; PO Sur-Reply, Paper 45, 18.*

- If pressure **increased**  during prior period, pressure then **decreased**. 
- If pressure **decreased**  during prior period, pressure then **increased**. 

OPPOSITE of '994 Patent family – troubled wakefulness = decrease the pressure.

993 IPR, PO Response, Paper 34, 42-43; PO Sur-Reply, Paper 45, 17-18; ** EX2003, ¶ 142**

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*988-992 and 994 IPR record citations: 988 IPR: Response: Paper 27, 26-28; Sur-Reply: Paper 40, 21; 990 IPR: Response: Paper 33, 23-25, 54; Sur-Reply: Paper 44, 22; 991 IPR: Response: Paper 36, 12-13, 44; Sur-Reply: Paper 47, 21; 992 IPR: Response: Paper 32, 25-27, 53; Sur-Reply: Paper 43, 21; 994 IPR: Response: Paper 33, 14-15, 30; Sur-Reply: Paper 44, 17-18

**988-992 and 994 IPR record citations: 988 IPR: Response: Paper 27, 56; Sur-Reply: 21-23; 990 IPR: Response: Paper 33, 54; Sur-Reply: Paper 44, 22; 991 IPR: Response: Paper 36, 44; Sur-Reply: Paper 47, 21; 992 IPR: Response: Paper 32, 53; Sur-Reply: Paper 43, 21; 993 IPR, Paper 34, 42-43; PO Sur-Reply, Paper 45, 17-18; 994 IPR: Response: Paper 33, 30-31; Sur-Reply: Paper 44, 17

***988, 990-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 282-283; 990 IPR, EX2006, ¶ 266; 991 IPR, EX2006, ¶ 350; 992 IPR, EX2006, ¶ 253; 994 IPR, EX2006, ¶ 153

Temporal Structure Analysis is Not Disclosed

ResMed	Petitioner's Argument	NYU	PO's Argument
	Prior art references disclose temporal structures of a time series. 993 IPR, Petitioner's Reply, Paper 42, 18-20.*		None of these references disclose temporal structure analysis. 993 IPR, EX2003, ¶ 66.**
	Temporal structure analysis = chronological sequence of events. 993 IPR, EX1051, ¶ 43.		This is a time series, not a temporal structure analysis. 993 IPR, PO Sur-Reply, Paper 45, 21.***
	"Reduced average airflow" in Sullivan460 implies temporal structure analysis. 993 IPR, EX1051, ¶¶ 41-43.		"Reduced average airflow" only examines amplitude structure. 993 IPR, EX2003, ¶ 66. Petitioner earlier argued this does not include temporal structure. 993 IPR, Petitioner's Reply, Paper 42, 4.****
	Flow limitation and upper airway vibrations involve temporal structure analysis. 993 IPR, EX1051, ¶¶ 41-43.		This analysis only described temporal structure of a single inspiration, not a full breathing pattern. EX1052, 46:15-18; 119:7-25 – 12:1; EX2003, ¶¶ 82, 98.*****
	Interruption cycles in Sullivan460 include analysis of temporal structures. EX1051, ¶ 41.		These involve repetitive events with no consideration given to the order in which these occur in time. 993 IPR, PO Sur-Reply, Paper 45, 21-23.*****
	Three figures in Matthews reveal temporal structures. EX1051, ¶ 47.		No analysis is included for the basis of this claim. Dr. Bates testified that Matthews did not disclose temporal structure analysis. 993 IPR, PO Sur-Reply, Paper 45, 23.*****

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*988-992 and 994 IPR record citations: 988 IPR, Paper 37, Petitioner's Reply, 13-14; 989 IPR, Paper 41, Petitioner's Reply, 13-14; 990 IPR, Paper 41, Petitioner's Reply, 12-13; 991 IPR, Paper 44, Petitioner's Reply, 12-13; 992 IPR, Paper 40, Petitioner's Reply, 12-14; 994 IPR, Paper 41, Petitioner's Reply, 19-21

**988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 72; 989 IPR, EX2005, ¶ 68; 990 IPR, EX2006, ¶ 71; 991 IPR, EX2006, ¶ 72; 992 IPR, EX2006, ¶ 67; 994 IPR, EX2006, ¶ 77

***988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 17; 989 IPR, Paper 44, Sur-Reply, 16; 990 IPR, Paper 44, Sur-Reply, 18; 991 IPR, Paper 47, Sur-Reply, 17; 992 IPR, Paper 43, Sur-Reply, 17; 994 IPR, Paper 44, Sur-Reply, 21

****988-992 and 994 IPR record citations: 988 IPR, Paper 37, Petitioner's Reply, 4-5; 989 IPR, Paper 41, Petitioner's Reply, 4-5; 990 IPR, Paper 41, Petitioner's Reply, 4; 991 IPR, Paper 44, Petitioner's Reply, 4; 992 IPR, Paper 40, Petitioner's Reply, 4; 994 IPR, Paper 41, Petitioner's Reply, 4

*****988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶¶ 88, 104; 989 IPR, EX2005, ¶¶ 84, 100; 990 IPR, EX2006, ¶¶ 87, 103; 991 IPR, EX2006, ¶¶ 88, 104; 992 IPR, EX2006, ¶¶ 83, 99; 994 IPR, EX2006, ¶¶ 93, 109

*****988-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 17-19; 989 IPR, Paper 44, Sur-Reply, 16-18; 990 IPR, Paper 44, Sur-Reply, 17-19; 991 IPR, Paper 47, Sur-Reply, 16-18; 992 IPR, Paper 43, Sur-Reply, 16-18; 994 IPR, Paper 44, Sur-Reply, 21-22

*****988, 990-992 and 994 IPR record citations: 988 IPR, Paper 40, Sur-Reply, 22; 990 IPR, Paper 44, Sur-Reply, 22-23; 991 IPR, Paper 47, Sur-Reply, 22; 992 IPR, Paper 43, Sur-Reply, 21-22; 994 IPR, Paper 44, Sur-Reply, 23

Temporal Structure Analysis is Not Disclosed

71. The prior art discloses only the analysis of the amplitude structure of the time series, i.e., how to make decisions based on mean values derived from inspiratory flow within a single breath and the standard deviation of such quantities [Sullivan460, p. 7, lines 18-19; Matthews, col. 22, Equation (1)]. Kirkness agrees

Ex2003 at ¶71*

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*988-992 and 994 IPR record citations: 988 IPR, EX2005, ¶ 77; 989 IPR, EX2005, ¶ 73; 990 IPR, EX2006, ¶ 76; 991 IPR, EX2006, ¶ 77; 992 IPR, EX2006, ¶ 72; 994 IPR, EX2006, ¶ 82

Secondary Considerations

[T]here is a need to -- there was at the time of the patent a well-recognized and long-felt need to deal with the fact that patients on CPAP, when they're awake, are somehow -- use the word in a general sense -- uncomfortable and thus have difficulty falling asleep if the CPAP pressure is above a certain very minimal level.

And so the long-felt need was how do you control the CPAP in a way that delivers it when it's needed therapeutically, but does not deliver it in circumstances where it's going to prevent it from being used when it's needed therapeutically and I say particularly interfering with the patient's ability to fall asleep. This was, I believe, mentioned in at least one of the prior art patents and so this was clearly a long-felt but unresolved need in the sleep medicine community.

And the '994 patent family of patents, by recognizing for the first time this breathing pattern of troubled wakefulness and in addition, specifying how that is uniquely determined as distinct from the other breathing pattern or the other state that it could be confused with, which is REM sleep, provides a way of determining unambiguously when the patient is awake and when the patient is asleep. And until you can do that, you can't have a machine that knows for sure when it should be potentially applying CPAP, potentially when the subject is asleep, and when it should under no circumstances be applying CPAP when the patient is awake.

EX 1052, 296:24 - 298:4

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