

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner

Case IPR2025-00158

**DECLARATION OF JASON KIRKNESS, PH.D. IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,690,512**

TABLE OF CONTENTS

I. INTRODUCTION.....	1
II. EXPERIENCE AND QUALIFICATIONS	2
III. ENGAGEMENT AS AN INDEPENDENT EXPERT.....	15
IV. UNDERSTANDING OF GOVERNING LAW.....	16
V. RELEVANT TIME PERIOD FOR THE OBVIOUSNESS ANALYSIS	19
VI. LEVEL OF ORDINARY SKILL IN THE ART.....	19
A. Legal Principles.....	19
B. Bases for Level.....	20
C. Application of POSITA Standard	21
VII. BACKGROUND	25
A. CPAP Therapy Overview.....	25
B. Remote Diagnosis and Monitoring Patients at Home versus Clinic	27
C. Telemedicine	31
D. Wearables (Wearables in Medical Technology).....	36
VIII. THE '512 PATENT.....	41
IX. OVERVIEW OF THE PRIOR ART	42
A. Ciulla (Ex. 1007).....	42
B. Orbach (Ex. 1008).....	44
C. Kumar (Ex. 1009).....	45
D. Nagai (Ex. 1010)	46

E.	Truschel (Ex. 1011).....	47
X.	CLAIM CONSTRUCTION	47
XI.	OPINIONS ON GROUND 1: CIULLA IN VIEW OF ORBACH RENDERS OBVIOUS CLAIMS 1-6, 8-17, 19, AND 20	47
A.	A POSITA Would Have Been Motivated to Combine	47
1.	Wirelessly Transferring Sleep Data from Wearable Device to a Cell Phone via Bluetooth, and from Cell Phone to Remote Site via Cell Towers [1.b], [1.e]	49
2.	Hardwiring Sensors [1.b.iii].....	58
3.	Software on Phone and Remote Site [1.a], [1.d]	61
B.	A POSITA Would Have Had a Reasonable Expectation of Success	65
C.	Independent Claim 1	68
1.	Preamble: “ <i>A sleep diagnostic data acquisition system comprising:</i> ”	68
2.	[1.a]: <i>a first software stored on a non-transitory computer readable medium and executable by a first processor, the software configured to be loaded on a cell phone or Personal Digital Assistant (“PDA”) comprising at least one first wireless transceiver and the first processor;</i>	74
a.	Teachings of Ciulla.....	75
b.	Teachings of Orbach.....	76
3.	[1.b]: “ <i>a portable, wearable patient interface box adapted to be secured to a subject at a first location and providing a single device for measuring and then wirelessly transferring sleep data from at least two</i> ”	

Declaration of Jason Kirkness, Ph.D. in Support of
Petition for *Inter Partes* Review USP No. 11,690,512

	<i>sensors used for diagnosing sleep disorders, the portable, wearable patient interface box comprising: ”</i>	81
a.	Teachings of Ciulla.....	82
b.	Teachings of Orbach.....	88
4.	[1.b.i]: <i>“an enclosure of a rigid material”</i>	91
5.	[1.b.ii]: <i>“a battery”</i>	92
6.	[1.b.iii.A]: <i>“one or more electrical components within the portable, wearable patient interface box for receiving electrical signals from the at least two sensors, the one or more electrical components include a signal processing unit for receiving the electrical signals from the sensors, [1.b.iii.B]: the at least two sensors which are attached to the subject and/or within the portable, wearable patient interface box that is secured to the subject, [1.b.iii.C]: the at least two sensors further which are hardwired to connect through at least one connector of the portable, wearable patient interface box and/or are built within the portable, wearable patient interface box, [1.b.iii.D]: the signal processing unit configured for receiving and processing the sleep data from one or more input channels; and,”</i>	94
7.	[1.b.iv.A]: <i>“a second wireless transceiver or transmitter is adapted for operating at frequencies above 2 GHz and [1.b.iv.B]: transmitting the sleep data collected with the portable, wearable patient interface box wirelessly to the at least one first wireless transceiver of the cell phone or PDA with the first software loaded;”</i>	105
8.	[1.c]: <i>“the at least two sensors are selected from a group consisting of: accelerometer(s), pulse oximeter(s) including fingertip pulse oximeter(s) and those built into the portable, wearable patient interface box, RIP belt(s), respiratory effort belt(s), pressure sensor(s),</i>	

*microphone(s), strain gauge(s), pressure transducer(s),
and transducer(s), the at least two sensors adapted: ” 109*

9. [1.c.i.A]: “*to be applied to the subject, [1.c.i.B]: a first
and a second of the at least two sensors of the portable,
wearable patient interface box when the one or more of
the sensors are built into the portable, wearable patient
interface box are adapted to be applied to a finger, arm
and/or torso of the subject; ” 111*
10. [1.c.ii]: “*to measure or derive respiratory ventilation
directly or indirectly, blood oxygenation and body
position of the subject during testing; and ” 113*
 - c. Respiratory Ventilation (Direct).....113
 - d. Respiratory Ventilation (Indirect) 114
 - e. Blood Oxygenation.....116
 - f. Body Position.....116
 - g. During Testing 116
11. [1.c.iii]: “*to be releasably connected and/or electrically
hardwired to or within the portable, wearable patient
interface box adapted to be worn by the subject; ” 116*
12. [1.d]: “*an at least second software stored on a non-
transitory computer readable medium and executable by
a computer or a second processor at one or more sites
remote to the first location; ” 117*
13. [1.e]: “*the first software, when executed by the first
processor of the cell phone or PDA, configured to
wirelessly receive and re-transmit the sleep data, or
optionally send the sleep data further processed with the
first processor of the cell phone or the PDA, with the at
least one first wireless transceiver over cell towers to the
computer or the second processor for analysis; ” 118*

Declaration of Jason Kirkness, Ph.D. in Support of
Petition for *Inter Partes* Review USP No. 11,690,512

14.	[1.f]: “the second software when executed by the computer or the second processor configured to analyze, output and/or format the sleep data at the one or more sites remote from the first location where the sleep data was collected; and”	121
15.	[1.g]: “the at least second software, when executed by the second processor or the computer, configured to display both, in part, the sleep data and/or analyzed sleep data to allow for diagnosis of a sleep disorder and, if necessary, provide a basis to modify a sleep treatment of the subject.”	123
D.	Dependent Claims 2-6, 8, 9-17, 19, and 20.....	125
1.	Claim 2: “The sleep diagnostic data acquisition system of claim 1, further comprising an at least third sensor wherein the at least third sensor is adapted for measuring respiratory ventilation such as respiratory effort and/or snore.”	125
2.	Claim 3: “The sleep diagnostic data acquisition system of claim 2, further comprising an at least fourth sensor wherein the third sensor is adapted for measuring respiratory effort and the fourth sensor is adapted for measuring snore.”	128
3.	Claim 4: “The sleep data acquisition system in claim 2, wherein the sleep data is transmitted to a remote Internet site or communication station using the at least one first wireless transceiver to transmit the sleep data over cell towers and/or the Internet for analysis.”	129
4.	Claim 5: “The sleep data acquisition system in claim 4, wherein two-way bi-directional data transmission is utilized between the second transceiver and the at least first transceiver.”	130
5.	Claim 6: “The sleep data acquisition system in claim 5, wherein the remote Internet site or communication	

	<i>station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA. ”</i>	131
6.	Claim 8: <i>“The sleep data acquisition system in claim 6, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data. ”</i>	132
7.	Claim 9: <i>“The sleep data acquisition system in claim 5, wherein the portable, wearable patient interface box further comprises an A/D converter and a digital memory for receiving the sleep data. ”</i>	136
8.	Claim 10: <i>“The sleep data acquisition system in claim 1, wherein the at least two sensors consist of a pulse oximeter and an accelerometer. ”</i>	137
a.	“Consist Of...”	137
b.	Pulse Oximeter Used For Diagnos[is], Respiratory Ventilation, and Blood Oxygenation	138
c.	“Accelerometer” Used For Diagnos[is] and Body Position	138
9.	Claim 11. <i>“The sleep data acquisition system in claim 10, wherein the sleep data is transmitted to a remote Internet site or communication station using the at least one first wireless transceiver to transmit the sleep data over cell towers and/or the Internet for analysis. ”</i>	139
10.	Claim 12. <i>“The sleep data acquisition system in claim 11, wherein two-way bi-directional data transmission is utilized between the second transceiver and the at least first transceiver. ”</i>	139
11.	Claim 13. <i>“The sleep data acquisition system in claim 12, wherein the remote Internet site or communication</i>	

station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA. ” 139

12. Claim 14. *“The sleep data acquisition system in claim 13, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data. ”* 139

13. Claim 15. *“The sleep data acquisition system in claim 1, wherein the sleep data is transmitted to a remote Internet site or communication station using the at least one first wireless transceiver to transmit the sleep data over cell towers and/or the Internet for analysis. ”* 140

14. Claim 16. *“The sleep data acquisition system in claim 15, wherein two-way bi-directional data transmission is utilized between the second transceiver and the at least first transceiver. ”* 140

15. Claim 17. *“The sleep data acquisition system in claim 16, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA. ”* 140

16. Claim 19. *“The sleep data acquisition system in claim 17, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data. ”* 140

17. Claim 20. *“The sleep data acquisition system in claim 16, wherein the portable, wearable patient interface box further comprises an A/D converter and a digital memory for receiving the sleep data. ”* 141

XII. OPINIONS ON GROUND 2: CIULLA IN VIEW OF ORBACH AND NAGAI RENDERS OBVIOUS CLAIMS 1-6, 8-17, 19, AND 20.....141

Declaration of Jason Kirkness, Ph.D. in Support of
Petition for *Inter Partes* Review USP No. 11,690,512

A.	A POSITA Would Have Been Motivated to Combine	141
B.	A POSITA Would Have Had a Reasonable Expectation of Success	144
C.	Independent Claim 1	145
D.	Dependent Claim 10.....	148
1.	Claim 10: “ <i>The sleep data acquisition system in claim 1, wherein the at least two sensors consist of a pulse oximeter and an accelerometer.</i> ”	148
a.	Only Two Sensors	148
b.	Pulse Oximeter.....	149
c.	Accelerometer.....	149
E.	Dependent Claims 2-6, 8, 9, 11-17, 19, and 20.....	150
1.	Claims 2-6, 8, and 9	150
2.	Claim 11. “ <i>The sleep data acquisition system in claim 10, wherein the sleep data is transmitted to a remote Internet site or communication station using the at least one first wireless transceiver to transmit the sleep data over cell towers and/or the Internet for analysis.</i> ”	150
3.	Claim 12. “ <i>The sleep data acquisition system in claim 11, wherein two-way bi-directional data transmission is utilized between the second transceiver and the at least first transceiver.</i> ”	150
4.	Claim 13. “ <i>The sleep data acquisition system in claim 12, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA.</i> ”	150

- 5. Claim 14. “*The sleep data acquisition system in claim 13, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data.*” 151
- 6. Claims 15-17, 19, and 20 151

XIII. OPINIONS ON GROUND 3: CIULLA IN VIEW OF ORBACH AND TRUSCHEL RENDERS OBVIOUS CLAIMS 7 AND 18.....151

- A. A POSITA Would Have Been Motivated to Combine 151
- B. A POSITA Would Have Had a Reasonable Expectation of Success 153
- C. Dependent Claims 7 and 18 153
 - 1. Claim 7. “*The sleep data acquisition system in claim 6, further comprising a software filter configured to extract a high frequency portion of a signal from one of the three sensors to obtain a snore signal.*” 153
 - 2. Claim 18. “*The sleep data acquisition system in claim 17, further comprising a software filter configured to extract a high frequency portion of a signal from one of the at least two sensors to obtain a snore signal.*” 155

XIV. OPINIONS ON GROUND 4: CIULLA IN VIEW OF ORBACH AND KUMAR RENDERS OBVIOUS CLAIMS 6, 8, 13, 14, 17, AND 19 155

- A. A POSITA Would Have Been Motivated to Combine 155
- B. A POSITA Would Have Had a Reasonable Expectation of Success 156
- C. Dependent Claims 6, 8, 13, 14, 17, and 19 156
 - 1. Claim 6: “*The sleep data acquisition system in claim 5, wherein the remote Internet site or communication station can control the sleep data transmission from the*

- at least first transceiver, and/or the first software when being executed by the cell phone or PDA. ” 156*
2. Claim 8: *“The sleep data acquisition system in claim 6, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data. ” 158*
3. Claim 13. *“The sleep data acquisition system in claim 12, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA. ” 159*
4. Claim 14. *“The sleep data acquisition system in claim 13, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data. ” 159*
5. Claim 17. *“The sleep data acquisition system in claim 16, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA. ” 159*
6. Claim 19. *“The sleep data acquisition system in claim 17, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data. ” 160*

**XV. OPINIONS ON GROUND 5: CIULLA IN VIEW OF ORBACH,
KUMAR, AND TRUSCHEL RENDERS OBVIOUS CLAIMS 7 AND
18 160**

1. Claim 7. *“The sleep data acquisition system in claim 6, further comprising a software filter configured to extract*

a high frequency portion of a signal from one of the three sensors to obtain a snore signal.” 160

2. Claim 18. “*The sleep data acquisition system in claim 17, further comprising a software filter configured to extract a high frequency portion of a signal from one of the at least two sensors to obtain a snore signal.*” 161

XVI. OPINIONS ON GROUND 6: CIULLA IN VIEW OF ORBACH, NAGAI, AND KUMAR RENDERS OBVIOUS CLAIMS 6, 8, 13, 14, 17, AND 19.....161

1. Claims 6, 8, 17, and 19 161
2. Claim 13. “*The sleep data acquisition system in claim 12, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA.*” 161
3. Claim 14. “*The sleep data acquisition system in claim 13, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data.*” 162

**XVII. OPINIONS ON GROUND 7: CIULLA IN VIEW OF ORBACH, NAGAI, AND TRUSCHEL RENDERS OBVIOUS CLAIMS 7 AND 18
162**

XVIII. OPINIONS ON GROUND 8: CIULLA IN VIEW OF ORBACH, NAGAI, AND KUMAR, AND TRUSCHEL RENDERS OBVIOUS CLAIMS 7 AND 18 162

XIX. CONCLUSION 163

I. INTRODUCTION

1. I, Jason Kirkness, Ph.D., have been retained by ResMed Corp. (“Petitioner”) to provide an analysis of the scope and content of U.S. Patent No. 11,690,512 relative to the state of the art at the time of the earliest application to which the ’512 patent claims priority. My analysis relates to claims 1-20. I have also been retained to provide analysis regarding what a person of ordinary skill in the art (“POSITA”) would have understood at the time of the earliest application underlying the ’512 patent.

2. This declaration summarizes the opinions I have formed to date. I reserve the right to modify or amend my opinions, if necessary, based on further review and analysis of information that I receive subsequent to the filing of this declaration, including in response to positions taken by Cleveland Medical Devices, Inc. (“CleveMed”) or its experts that I have not yet seen, including any secondary considerations evidence that CleveMed or its expert may consider and present.

3. It is my opinion that claims 1-20 of the ’512 patent are invalid based on the following grounds:

Ground 1	Ciulla (Ex. 1007) in view of Orbach (Ex. 1008) renders obvious claims 1-6, 8-17, 19, and 20.
Ground 2	Ciulla in view of Orbach and Nagai (Ex. 1010) renders obvious claims 1-6, 8-17, 19, and 20.
Ground 3	Ciulla in view of Orbach and Truschel (Ex. 1011) renders obvious claims 7 and 18.

Declaration of Jason Kirkness, Ph.D. in Support of
Petition for *Inter Partes* Review USP No. 11,690,512

Ground 4	Ciulla in view of Orbach and Kumar (Ex. 1009) renders obvious claims 6, 8, 13, 14, 17, and 19.
Ground 5	Ciulla in view of Orbach, Kumar, and Truschel renders obvious claims 7 and 18.
Ground 6	Ciulla in view of Orbach, Nagai, and Kumar renders obvious claims 6, 8, 13, 14, 17, and 19.
Ground 7	Ciulla in view of Orbach, Nagai, and Truschel renders obvious claims 7 and 18.
Ground 8	Ciulla in view of Orbach, Nagai, Kumar, and Truschel renders obvious claims 7 and 18.

The opinions in this declaration are based on the documents I reviewed, my knowledge and experience, and professional judgment. In forming my opinions expressed in this declaration, I have reviewed the following materials:

<u>Exhibit No.</u>	<u>Description</u>
1001	U.S. Patent No. 11,690,512 to Kayyali (“the ’512 Patent”)
1002	File History of U.S. Patent No. 11,690,512
1007	U.S. Patent Application Publication No. 2003/0199945 to Ciulla (“Ciulla”)
1008	World Intellectual Property Organization International Publication No. WO 2006/090371 to Orbach (“Orbach”)
1009	U.S. Patent Application Publication No. 2002/0198473 to Kumar (“Kumar”)

Declaration of Jason Kirkness, Ph.D. in Support of
Petition for *Inter Partes* Review USP No. 11,690,512

<u>Exhibit No.</u>	<u>Description</u>
1010	U.S. Patent Application Publication No. 2006/0173257 to Nagai (“Nagai”)
1011	U.S. Patent Application Publication No. 2003/0066529 to Truschel (“Truschel”)
1012	U.S. Patent Application Publication No. 2006/0183469 to Gadson (“Gadson”)
1013	U.S. Patent Application Publication No. 2002/0090939 to Howard (“Howard”)
1014	U.S. Patent Application Publication No. 2004/0016433 to Estes (“Estes”)
1015	U.S. Patent No. 5,947,115 to Lordo (“Lordo”)
1016	U.S. Patent No. 5,746,699 to Fredberg (“Fredberg”)
1017	Specification of the Bluetooth System, Bluetooth, v1.0 B (Dec. 1, 1999)
1018	U.S. Patent No. 5,684,460 to Scanlon (“Scanlon”)
1019	U.S. Patent Application Publication No. 2004/0034293 to Kimball (“Kimball”)
1020	U.S. Patent Application Publication No. 2008/0319277 to Bradley (“Bradely”)
1021	U.S. Patent No. 6,712,762 to Lichter (“Lichter”)

Declaration of Jason Kirkness, Ph.D. in Support of
Petition for *Inter Partes* Review USP No. 11,690,512

<u>Exhibit No.</u>	<u>Description</u>
1022	U.S. Patent Application Publication No. 2002/0032386 to Sackner (“Sackner”)
1023	U.S. Patent No. 6,083,156 to Lisiecki (“Lisiecki”)
1024	U.S. Patent No. 4,825,872 to Tan (“Tan”)
1025	U.S. Patent Application Publication No. 2006/0174871 to Jagger (“Jagger”)
1026	U.S. Patent Application Publication No. 2009/0240125 to Such (“Such”)
1027	U.S. Patent No. 5,790,040 to Kreier (“Kreier”)
1028	U.S. Patent Application Publication No. 2007/0208232 to Kovacs (“Kovacs”)
1029	Research Challenges in Wireless Networks of Biomedical Sensors, L. Schwiebert (2001), accessed at https://citeseerx.ist.psu.edu/document?repid=rep1&type=pdf&doi=200613bf402b54be0179483813f7f98a5ae053ef .
1030	U.S. Patent No. 6,236,906 to Müller (“Müller”)
1031	U.S. Patent No. 5,774,113 to Barnes (“Barnes”)
1032	U.S. Patent No. 5,002,170 to Parsons (“Parsons”)
1033	U.S. Patent Application Publication No. 2003/0163054 to Dekker (“Dekker”)

Declaration of Jason Kirkness, Ph.D. in Support of
Petition for *Inter Partes* Review USP No. 11,690,512

<u>Exhibit No.</u>	<u>Description</u>
1034	U.S. Patent No. 5,437,275 to Amundsen (“Amundsen”)
1035	U.S. Patent No. 7,575,005 to Mumford (“Mumford”)
1036	U.S. Patent Application Publication No. 2007/0208262 to Kovacs (“Kovacs”)
1037	U.S. Patent Application Publication No. 2004/0133079 to Mazar (“Mazar”)
1038	U.S. Patent No. 6,658,292 to Kroll (“Kroll”)
1039	U.S. Patent No. 7,130,689 to Turcott (“Turcott”)
1040	A. Silberschatz, “Operating System Concepts” (1994) (“Silberschatz 1994”)
1041	U.S. Patent Application Publication No. 2007/0002837 to Tan (“Tan”)
1042	U.S. Patent Application Publication No. 2006/0283446 to Chua (“Chua”)
1043	U.S. Patent Application Publication No. 2006/0224074 to Ouchi (“Ouchi”)
1044	U.S. Patent Application Publication No. 2002/0029004 to Starr (“Starr”)
1045	U.S. Patent Application Publication No. 2007/0273504 to Tran (“Tran”)
1046	S. Thompson et al., “Sleep as a Teaching Tool for Integrating Physiology and Motor Control,” <i>Advances</i>

Declaration of Jason Kirkness, Ph.D. in Support of
Petition for *Inter Partes* Review USP No. 11,690,512

<u>Exhibit No.</u>	<u>Description</u>
	in Physiology Education (2001) (“Thompson 2001”)
1047	U.S. Patent No. 5,704,345 to Berthon-Jones (“Berthon-Jones 345”)
1048	U.S. Patent No. 7,168,429 to Matthews et al. (“Matthews”)
1049	C.W. Lillebei et al., “Transistor Pacemaker for Treatment of Complete Atrioventricular Dissociation,” JAMA, 172(18): 2006 - 2010 (1960) (“Lillehei 1960”)
1050	D. Rapoport, “Methods to Stabilize the Upper Airway Using Positive Pressure,” <i>Sleep</i> 19(9): S123-S130 (1996) (“Rapoport 1996”)
1051	NASA, “Applications of Aerospace Technology in Biomedicine, Patient Monitoring” (1971) (NASA 1971)
1052	M. Weil, et al., “Experience With a Digital Computer for Study and Improved Management of the Critically Ill,” JAMA, 198:1011 - 1016 (1966) (“Weil 1966”)
1053	L. Clark et al., “Electrode Systems for Continuous Monitoring in Cardiovascular Surgery,” 29-45 (1962) (“Clark & Lyons 1962”)
1054	H. Kennedy et al., “Ambulatory (Holter) Electrocardiography Using Real-Time Analysis,” 1190-1195 (1987) (“Kennedy 1987”)
1055	S. Wilber, et. al., “Patient Monitoring and Anesthetic Management: A Physiological Communications Network,” JAMA, 191:893-898 (1965) (“Wilber 1965”)

Declaration of Jason Kirkness, Ph.D. in Support of
Petition for *Inter Partes* Review USP No. 11,690,512

<u>Exhibit No.</u>	<u>Description</u>
1056	C. Lilly, et. al., “Critical Care Telemedicine: Evolution and State of the Art,” <i>Critical Care Medicine</i> , 42:2429-2436 (2014) (“Lilly 2014”)
1057	M. Breslow, et. al., “Effect of a multiple-site intensive care unit telemedicine program on clinical and economic outcomes: An alternative paradigm for intensivist staffing,” <i>Critical Care Medicine</i> , 32:31-38 (2004) (“Breslow 2004”)
1058	K. Zundel, “Telemedicine: history, applications, and impact on librarianship,” <i>Bull Med Libr. Assoc.</i> , 84:71-79 (1996) (“Zundel 1996”)
1059	Loube, D., “Technologic Advances in the Treatment of Obstructive Sleep Apnea Syndrome,” <i>CHEST</i> , 116:1426-1433 (1999) (“Loube 1999”)
1060	A. Boudewyns, et. al., “Two months follow up of auto-CPAP treatment in patients with obstructive sleep apnoea,” <i>Thorax</i> , 54:147-149 (1999) (“Thorax 1060”)
1061	D. Lankford, “Wireless CPAP Patient Monitoring: Accuracy Study,” <i>Telemedicine Journal and e-Health</i> , 10:162-169 (2004) (“Lankford 2004”)
1062	D. Claremont et al., “Biosensors for Continuous in Vivo Glucose Sensors”, <i>IEEE Engineering In Medicine & Biology Society 10th Annual International Conference</i> , 740-741 (1988) (“Claremont 1988”)
1063	A. Berssenbrugge et al., “Mechanisms of Hypoxia-Induced Periodic Breathing During Sleep In Humans,” 343: 507-524 (“Berssenbrugge 1983”)

Declaration of Jason Kirkness, Ph.D. in Support of
Petition for *Inter Partes* Review USP No. 11,690,512

<u>Exhibit No.</u>	<u>Description</u>
1066	R. Stoohs et al., MESAM 4: “An Ambulatory Device for the Detection of Patients at Risk for Obstructive Sleep Apnea Syndrome (OSAS)”, CHEST 101(5): 1221-27 (1992) (Stoohs & Guilleminault, 1992)
1067	K. Rebrin et al., “Subcutaneous glucose predicts plasma glucose independent of insulin: implications for continuous monitoring,” 561-571 (“Rebrin 1999”)
1068	C. George, “Diagnostic Technologies in Obstructive Sleep Apnea,” 355-366 (199) (“George 1999”)
1069	N. Keijsers, “Online Monitoring of Dyskinesia in Patients with Parkinson’s Disease,” 93-103 (May/June 2003) (Keijsers 2003)

and any other material I refer to in this declaration in support of my opinions.

II. EXPERIENCE AND QUALIFICATIONS

4. My curriculum vitae (“CV”) is Exhibit 1004. I am a Voluntary Associate Professor, in the Division of Pulmonary, Critical Care and Sleep Medicine at the Miller School of Medicine, University of Miami in Miami, Florida and serve on the Board of Directors of the American Thoracic Society. My career has focused on technology and devices to diagnose, monitor, and treat chronic respiratory-related diseases and disorders, including obstructive sleep apnea, chronic obstructive airway diseases, and acute respiratory diseases. I have published dozens of papers on obstructive sleep apnea in peer-reviewed journals.

5. In 1996, I was awarded a Bachelor of Science degree in Biology from the University of Western Sydney, Kingwood, Australia.

6. In 1997, I was awarded a Bachelor of Science degree with First-Class Honors in Physiology from the University of Western Sydney, Australia.

7. In 2003, I was awarded a Ph.D. in Medicine from the University of Sydney, Camperdown, Australia. My thesis was entitled “The role of surface tension of liquid lining the upper airway in upper airway patency and the obstructive sleep apnoea hypopnoea syndrome.” This included the design and use of pressure control devices to alter upper airway patency, a crucial element in treating patients with sleep disorders.

8. While pursuing my Bachelor of Science degrees, I researched devices used to modify airway resistance in order to determine effectiveness for decreasing the occurrence of apnea, hypopnea, snoring, or inspiratory airflow limitation. The specific products were external nasal dilators that were placed over the nose to modify the mechanical properties of the nasal and subsequent nasopharyngeal airflow during wakefulness, sleep, and during exercise.

9. I have extensive experience in analyzing physiological sensor design, performance, output characteristics, and signal analysis including in assessment of sleep disordered breathing. For example, I was involved in a project examining performance of elite rowers using telemetry based ventilatory and physiological

recording in 1997 as part of a collaborative research project at Sydney Athletics Centre with NSW Institute of Sport, Department of Respiratory Medicine, Westmead Hospital and Department of Biological Sciences, University of Western Sydney, Nepean. From 1999 onward, I contributed to numerous publications examining respiratory flow measurement and diagnostics.

10. My collaborations with Westmead Hospital included work relating to the physiological impact of nasal airflow interventions and the development of devices to assess nasal wall elasticity, with research published in journals such as the Journal of Applied Physiology. This work emphasized diagnostic tools to monitor airflow dynamics, which are key to the development of effective respiratory support systems.

11. I was also involved in the development of an anatomical positioning device for assessing the therapeutic mechanism of nasal vestibule wall elasticity in response to a nasal dilator strip, which resulted in several publications, including one on nasal airflow dynamics associated with an external nasal dilator strip. (European Respiratory Journal, 2000, 15 (5): 929-936).

12. During my later thesis work, I collaborated with the Department of Physics and Biomedical Engineering at the Australian National University to create a novel instrument for determining the surface tension of microliter liquid samples from the upper airway. This research led to multiple publications, including studies

on the effect of surface tension on upper airway mechanics in anesthetized humans.
(Journal of Applied Physiology, 2003, 95 (1): 357-363).

13. I examined the biomechanical and physiological properties of airways in response to products known as exogenous surfactants. The products were known to treat the lower airways, particularly in neonates, yet it was unknown how a product that lowered airway lining liquid surface tension would impact the upper airway physiology in individuals with obstructive sleep apnea hypopnea syndrome. In order to assess surfactant product performance, I utilized airway pressure support devices to raise and lower the airway pressure via a nasal mask to generate and eliminate airway closure and reopening that occurs in patients with collapsible airways, as occurs in sleep apnea.

14. To conduct my thesis work, I was required to design and develop instrumentation to detect, quantify, monitor, display, collect, record, store, process, analyze and/or interpret physical systems and physiological responses for the purpose of characterizing the role of modifying airway surface-liquid-surface properties and their effect on upper airway collapse in sleep apnea and hypopnea.

15. I was also awarded two post-doctoral research fellowships at the Johns Hopkins School of Medicine through the Thoracic Society of Australia and New Zealand and The National Health and Medical Research Council of Australia. My 2004 fellowship was focused on neurohumoral and neuromuscular control of upper

airway patency in severe obesity and sleep apnea. This project included the design and use of specialized equipment to assess upper airway patency.

16. I was also involved in testing the design of a skin conductance monitor at Westmead Hospital in collaboration with the University of Western Sydney and the Ludwig Engel Centre for Respiratory Research. This work focused on monitoring sleep and breathing related to the sympathetic nervous system and resulted in a publication on the skin conductance response to repeated inspiration (Clinical Neurophysiology, 2005, 116 (5): 1172-1180). While at the Ludwig Engel Centre for Respiratory Research I was also involved with the design and construction of a tonometry device to assess the tone of the soft palate muscle, as part of my role as an honorary associate scientist at the Ludwig Engel Centre for Respiratory Research, Westmead Millennium Institute.

17. I was further awarded a professional society fellowship from the American Thoracic Society.

18. I became a part of the faculty at the School of Medicine at John Hopkins University in 2009, where I served as a Research Associate. I then went on to become an Assistant Professor of Medicine in 2012. I became an Adjunct Assistant Professor of Medicine in 2017.

19. From 2014 to 2016, I was the Chief Technology Officer for RespEQ, which focused on developing technology to monitor adherence to respiratory

therapies via connected devices. This included monitoring adherence to the use of pressure systems used to treat sleep and breathing disorders such as obstructive sleep apnea.

20. Between the years of 2008 and 2017, I also served as a scientific consultant for technology and medical device companies engaged in developing treatments for breathing disorders, obstructive sleep apnea, sleep disorders, and sleep disordered breathing. This included pressure support devices and systems, high flow systems, humidification systems, lifestyle and behavioral approaches, and neurostimulation.

21. In 2008, I also served as an Instructor at the University of Western Australia and assisted in the creation of sleep science educational course content.

22. I am a named inventor on two (2) patent applications for quantifying inspiratory and expiratory airflow. These patents include:

- “Apparatus for quantifying expiratory and inspiratory airflow.” U.S. Publication No. 20130345590 A1, Inventors: H. Schneider and J. P. Kirkness; Filed: September 3, 2012.
- “Whole-body plethysmography system for the continuous characterization of sleep and breathing in a mouse,” PCT Publication No. WO2013003841 A1, Inventors: A. B. Hernandez, J. Kirkness, H.

Schneider, M. Polotsky, A. Schwartz, P. Smith; W. Hernandez; Filed:
July 2, 2012.

23. I have also worked on the design of pneumotachographs for respiratory airflow measurement, which are the gold standard for short-term and specific long-term measurements. I also contributed to the development of alternative devices to address these issues, which led to the following patent applications WO2006026387A2 and WO2012122506A9.

24. Beginning in 2017, I served as the Director of Clinical Affairs at Fisher and Paykel Healthcare, a leading manufacturer, designer, and marketer of products and systems for use in respiratory care, acute care, and the treatment of obstructive sleep apnea.

25. In 2020 I became the Vice President of Medical Clinical Affairs for 4D Medical, and subsequently served as Senior Vice President of Medical and Clinical Affairs.

26. In January of 2023, I also began to serve as a Voluntary Associate Professor of Medicine at University of Miami where I am currently.

27. I have published over 50 articles in peer-reviewed journals. Throughout my career, I have published findings relating to medical devices and systems and methods for assessing the physiological characteristics of breathing during wakefulness and sleep. I have served as a peer reviewer and editorial board member

for sleep and breathing journals. I have also written several book chapters on upper airway obstruction and sleep apnea.

28. I have had several roles in chairing, creating, and presenting at international symposiums for topics that include systems, methods, and approaches for assessing, monitoring, and treating sleep disordered breathing and sleep apnea.

29. In addition, I have served on advisory and review committees as a scientific reviewer for The National Institutes of Health, The National Health and Medical Research Council of Australia, as well as other foundations and national and international grant awarding bodies. I have served as a scientific reviewer for Institutional Review Boards and the Hospital Ethics Committee.

30. I am a member of several professional societies, including the American Thoracic Society where I serve on Board of Directors, chair the Drug Device Discovery and Development Committee and serve on the Respiratory Innovation Summit Organizing Committee. I also serve on the Industry Advisory Committee for the Respiratory Compromise Institute.

III. ENGAGEMENT AS AN INDEPENDENT EXPERT

31. I am being compensated at the rate of \$700 per hour for my work related to this matter. My fee is not contingent on the outcome of this or any matter or on any position I have related to this matter.

32. I have no financial interest in ResMed. I have been informed that CleveMed claims ownership of the '512 patent. I have no financial interest in CleveMed.

IV. UNDERSTANDING OF GOVERNING LAW

33. I have been informed that statutory and judicially created standards must be considered to determine the validity of a patent claim. I am not an attorney and, consequently, will offer no opinion on the law itself. My understanding of the pertinent law is described in this section and is the result of explanations provided by counsel. I have applied this understanding in my analysis.

34. I have been informed that a patent claim is unpatentable if it is anticipated or obvious in view of the prior art. I further understand that the frame of reference for determining whether a claim is anticipated or obvious is from the perspective of a person of ordinary skill in the relevant art at the time the invention. I have been asked to assume that the effective priority date is June 16, 2006. I have not been asked to determine whether this date is appropriate.

A. Anticipation

35. I have been informed that for a patent claim to be anticipated by the prior art, each and every limitation of the claim must be found, expressly or inherently, in a single prior art reference as recited in the claim. I understand a claim limitation not expressly found in a prior art reference is inherent if the prior art

necessarily functions in accordance with, or includes, the claim limitation. Mere probability that a limitation is included is not sufficient to establish inherency.

B. Obviousness

36. In analyzing obviousness in light of the prior art I have been informed that it is important to understand the scope of the claims, the level of skill in the relevant art, the scope and content of the prior art, the differences between the prior art and the claims, and any objective indicia of non-obviousness (also called secondary considerations).

37. I have been informed that a patent claim is unpatentable for obviousness if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a POSITA to which said subject matter pertains. I have been informed that obviousness may be based on one reference or a combination of references. I have been informed that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

38. I have been informed that when a patented invention is a combination of known elements, the Board must determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue by considering the teachings of prior art references, the effects of demands known to

people working in the field or present in the marketplace, and the background knowledge possessed by a POSITA.

39. I have been informed that the Supreme Court has recognized several rationales for combining references or modifying a reference to show obviousness of the claimed subject matter. I understand that several of these rationales are: (1) combining prior art elements according to known methods to yield predictable results; (2) simple substitution of one known element for another to obtain predictable results; (3) use of a known technique to improve a similar device (method or product) in the same way; (4) applying a known technique to a known device (method or product) ready for improvement to yield predictable results; (5) choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (6) and some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

40. I have been informed that in order to prove that a claimed invention is not patentable for obviousness, a petitioner must (1) identify the differences between the claim and particular disclosures in the prior art references, singly or in combination, (2) specifically explain how the prior art references could have been combined in order to arrive at the subject matter of the claimed invention, and (3)

specifically explain why a POSITA would have had reasons to so combine the prior art references.

V. RELEVANT TIME PERIOD FOR THE OBVIOUSNESS ANALYSIS

41. I understand that the '512 patent originates from Patent Application 18/094,433 filed on January 9, 2023, which claims priority back to Patent Application No. 11/454,482 filed on June 16, 2006, through a series of continuation applications. I have arrived at my opinions in this declaration by relying on the knowledge of a POSITA as of June 16, 2006.

VI. LEVEL OF ORDINARY SKILL IN THE ART

A. Legal Principles

42. I have been informed that a person of ordinary skill in the art is a hypothetical construct used for certain analyses in patent law. I understand that the claims are construed from the viewpoint of a POSITA and the factual determinations underlying obviousness (such as the scope and content of the prior art and the differences between the prior art and the claims) are performed from the perspective a POSITA. I understand that a POSITA is presumed to be aware of all pertinent prior art, thinks along conventional wisdom in the art, and is a person of ordinary creativity.

43. I have been informed by counsel that the following five non-exclusive factors may be used to determine the level of skill in the relevant art: (1) the types

of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the educational level of active works in the field.

B. Bases for Level

44. In my opinion, a POSITA in 2006 would have had at least a bachelor's degree in mechanical engineering, electrical engineering, computer science, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience working with diagnostic sensor systems and network data systems. Additional experience could substitute for less education, and additional education could likewise substitute for less experience.

45. The five factors support this conclusion. The field of art includes "wireless data acquisition systems for data communications." Ex. 1001, 1:24-31. As Ciulla, Orbach, Nagai, Truschel, and Kumar explain, some problems in the prior art include how to improve data collection systems and how to more effectively use the data collected. Some of the solutions include making the patient more comfortable, such as using wireless sensors or observing the patient remotely from home, and providing real-time analysis of the data, such as programming algorithms to determine efficacy or real-time streaming data to the physician.

46. Given the progress and sophistication of network and wireless technology, innovations were made quickly as the availability, cost, and size of

hardware and equipment made solutions to these problems simple to implement. This also allowed many of those active in the field to quickly learn mechanical, systems, and computer engineering basics.

C. Application of POSITA Standard

47. By 2006, I met or exceeded the level of a POSITA. My background in respiratory physiology and the design and testing of diagnostic systems and therapeutic devices reflects the skills and understanding required for product design and sensor system diagnostics in respiratory and sleep medicine. My specific experience includes the following:

48. Testing the design of a skin conductance monitor at Westmead Hospital in collaboration with the University of Western Sydney and the Ludwig Engel Centre for Respiratory Research. This work focused on monitoring sleep and breathing related to the sympathetic nervous system and resulted in a publication on the skin conductance response to repeated inspiration and was also used during sleep in the development of novel indices of sleep and breathing (Clinical Neurophysiology, 2005, 116 (5): 1172-1180).

49. Collaboration with the Department of Physics and Biomedical Engineering at the Australian National University to create a novel instrument for determining the surface tension of microliter liquid samples from the upper airway. This research led to multiple publications, including studies on the effect of surface

tension on upper airway mechanics in anesthetized humans (Journal of Applied Physiology, 2003, 95 (1): 357-363) and patients with obstructive sleep apnea/hypopnea syndrome (Sleep, 2005, 28(4): 771-77).

50. Design and construction of a tonometry device to assess the tone of the soft palate muscle, as part of my role as an honorary associate scientist at the Ludwig Engel Centre for Respiratory Research, Westmead Millennium Institute.

51. Development of an anatomical positioning device for assessing the therapeutic mechanism of nasal vestibule wall elasticity in response to a nasal dilator strip. This resulted in several publications, including one on nasal airflow dynamics associated with an external nasal dilator strip (European Respiratory Journal, 2000, 15 (5): 929-936).

52. Extensive experience in analyzing physiological sensor design, performance, output characteristics, and signal analysis including in assessment of sleep disordered breathing. Since 1999 I have contributed to numerous publications examining respiratory flow measurement, diagnostic indices of sleep and breathing, and mechanisms of therapy.

53. Project examining performance of elite rowers using telemetry based ventilatory and physiological recording in 1997. I was part of a collaborative research project at Sydney Athletics Centre with NSW Institute of Sport, Department

of Respiratory Medicine, Westmead Hospital and Department of Biological Sciences, University of Western Sydney, Nepean.

54. Engagement in the design of pneumotachographs for respiratory airflow measurement, which are the gold standard for short-term and specific long-term measurements. I contributed to the development of alternative devices to address these issues, which led to patents WO2006026387A2 and WO2012122506A9.

55. Awarded a PhD in Medicine in 2003, focused on factors controlling the upper airway. This included the design and use of pressure control devices to alter upper airway patency, a crucial element in treating patients with sleep disorders.

56. Recognition through the Thoracic Society of Australia and New Zealand (TSANZ) fellowship in 2004, focusing on neurohumoral and neuromuscular control of upper airway patency in severe obesity and sleep apnea. This project included the design and use of specialized equipment to assess upper airway patency.

57. Multiple research projects on the relationship between surface tension and upper airway collapsibility, specifically addressing its impact on obstructive sleep apnea, which were published and reviewed in respected journals, establishing a foundation in diagnostic methodologies for respiratory diseases.

58. Early work with Westmead Hospital in the late 1990s on the physiological impact of nasal airflow interventions and the development of devices to assess nasal wall elasticity, with research published in journals such as the Journal of Applied Physiology. This work emphasized diagnostic tools to monitor airflow dynamics, key to the development of effective respiratory support systems.

59. I was the Chief Technology Officer for RespEQ, which focused on developing technology to monitor adherence to respiratory therapies via connected devices. This included monitoring adherence to the use of pressure systems used to treat sleep and breathing disorders such as obstructive sleep apnea.

60. These experiences collectively align with and surpass the defined POSITA requirements in 2005, demonstrating advanced knowledge in respiratory diagnostic systems, product design, and sensor application in the clinical setting.

61. My experience in design, development, validation, clinical development of medical devices in the pathogenesis, diagnosis and treatment of sleep disorders more than sufficiently substitute for specific education.

62. My opinions do not turn on this precise definition, and the claims would be unpatentable from the perspective of any reasonable POSITA.

63. For the purpose of this Declaration, and unless otherwise noted, my statements and opinions, such as those regarding my experience and understanding of a POSITA generally (and specifically related to the references I consulted) reflect

the knowledge that existed in the field as of June 16, 2006. This is true even if stated in the present tense.

VII. BACKGROUND

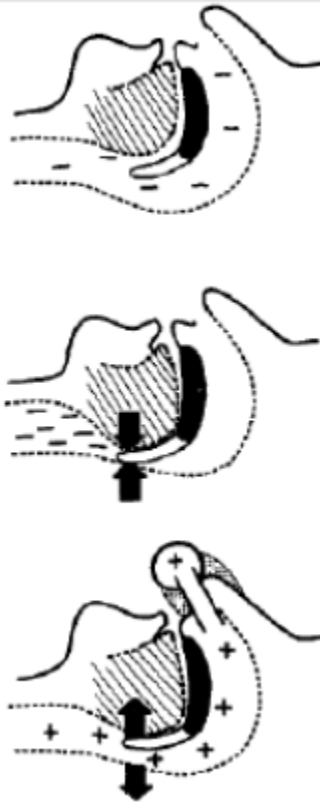
A. CPAP Therapy Overview

64. Continuous positive airway pressure (CPAP) therapy is used for patients with a spectrum of sleep apnea severity with or without symptoms. CPAP therapy involves delivering a constant supply of pressurized gas through a mask worn over the nose, mouth, or both. This pressurized air creates a “splinting” effect in the upper airway, keeping the soft tissues (such as the tongue, soft palate, and pharyngeal walls) from collapsing and blocking the airway during sleep. By maintaining an open airway, respiratory related events are reduced, allowing for uninterrupted flow of gases into the lungs and stabilizing oxygen levels during CPAP use. The mechanisms of CPAP enable improved restorative sleep and reduction of the associated symptoms.

65. The total absence of airflow, or apnea, results when the patient’s airway has completely collapsed such that air cannot pass through. *See also* Ex. 1046 at 8 (discussing reduction of muscle tone in sleep leading to upper airway narrowing or complete collapse). Because apnea, hypopnea, and heavy snoring produces decreased blood oxygenation, they are recognized causes of sleep disruption and risk

factors in certain types of heart disease. Ex. 1047 at 1:43-45; *see also id.* at 1:27-28 (“apnea leads to decreased blood oxygenation and thus to disruption of sleep”); Ex. 1048 at 1:35-38 (“Those afflicted with OSA experience sleep fragmentation and complete or nearly complete cessation of ventilation intermittently during sleep with potentially severe degrees of oxyhemoglobin desaturation”). The symptoms of obstructive sleep apnea or OSA include loud snoring, choking or gasping during sleep, impaired concentration, hypersomnolence (i.e., daytime sleepiness), and cardiovascular effects due to hypoxemia (i.e., low oxygen levels) or hypercapnia (i.e., high carbon dioxide levels).

66. To prevent collapse of the patient’s airway, PAP therapy applies positive airway pressure, which opposes the force created during inspiration (i.e., inhalation) and the gravitational effects on the tongue during expiration (i.e., exhalation). Ex. 1050 at p. 1, Fig. 1 (reproduced below).



B. Remote Diagnosis and Monitoring Patients at Home versus Clinic

67. During the 1960s, groundwork was laid for remote physiological monitoring in hospitals by anesthesiologists (Ex. 1055) and acute care physicians (Ex. 1052) by adapting process control computers—initially designed for industrial automation—to track vital signs in clinical settings. Early efforts led to the development of a computerized monitoring system at Los Angeles County General Hospital, which became operational in 1965 and allowed real-time digital transmission of physiological data within the hospital. Building on these early advances, other researchers digitized analog medical data, enabling it to be

transmitted across newly forming long-distance networks, which eventually supported nationwide remote monitoring.

68. National Aeronautics and Space Administration (NASA) early work in monitoring astronauts' physiological data remotely was instrumental in advancing telemetry technology, proving that vital signs could be reliably tracked from great distances. Ex. 1056. This capability influenced healthcare significantly, as it demonstrated how real-time physiological monitoring could assess acute changes in health, even in extreme environments. The success of these technology advancements confirmed that physiological data could be transmitted and analyzed remotely to monitor and manage patients' health status.

69. With communication technology advancements in the 1980s (such as cellular, cordless, satellite, digital switching) the ability of remote monitoring expanded further, allowing hospital and acute care settings to implement remote consultative services and collaborative care. Ex. 1056. These innovations led to trials, such as the Johns Hopkins University study using a commercially available remote monitoring platform (VisICU, Baltimore MD), which demonstrated that remote monitoring of acute care patients could effectively reduce mortality rates and healthcare costs by enabling immediate interventions and continuous oversight. Ex. 1057.

70. In the 1990s telemetry systems such as portable device designed for real-time monitoring of metabolic and respiratory parameters were deployed during exercise or field testing. Wireless data transmission enabled clinicians and scientists to track oxygen consumption, heart rate, and other physiological metrics in dynamic environments outside the laboratory in “real-world” settings. The New South Wales Institute of Sport used the COSMED K4 telemetry system monitoring elite rowers measuring exercise performance at the Penrith Regatta in 1997. Similarly, TeleDiagnostic Systems of San Francisco a home monitoring equipment vendor patented and develop a system for recording sleep patterns for all-night monitoring at the patients home rather than in a hospital. In a patent filing they described physiological parameters monitored by the TeleDiagnostics Systems to include EEG, EKG, EMG, EOG, respiration, oximetry being able to detect and monitor over ten different channels of physiological data. Ex. 1058.

71. These and other remote monitoring advancements and solutions were used and well described for quantifying the frequency and impact of breathing disturbances, health indicators and sleep quality disruptions, thus providing access to assess sleep disorder severity, guide treatment, and track therapy effectiveness.

72. By the late 1990s and early 2000s, the focus on convenience and accessibility led to the development of home-based diagnostic tools, such as portable monitors capable of recording essential parameters. These tools enabled patients to

undergo initial diagnostic studies in their own homes. Around the same time “data modules’ with CPAP systems to collect, store, and transfer treatment data for clinical review became commonplace. When connected to the flow generator through a docking mechanism, these modules recorded treatment data and, if connected to a pulse oximeter, can also capture pulse oximetry information. A removable memory card allows for automated data collection, which the patient can download and transmit to the clinic for the clinician to review. This data was then analyzed on a PC using specialized software, enabling the clinician to monitor therapy efficacy and make any necessary adjustments to the treatment plan. Ex. 1059 (see Fig 1 below).

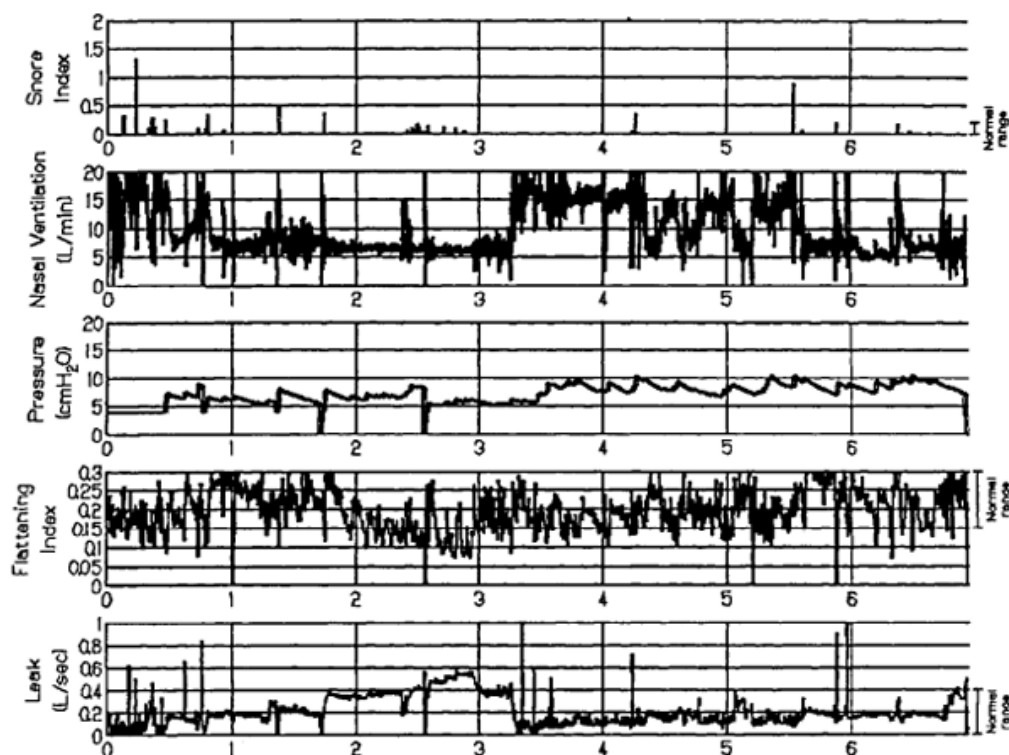


FIGURE 1. Example of cumulative overnight automatic CPAP data report for a patient with severe OSAS. Used with permission of ResMed Corporation.

CHEST / 116 / 5 / NOVEMBER, 1999

C. Telemedicine

73. The development of home sleep testing (HST) solutions began in the mid to late 1980s, with early devices focusing on ambulatory monitoring of arterial oxygen saturation and cardiopulmonary sleep studies. These initial systems were relatively primitive compared to modern standards. By the 1990s, there was a growing awareness of OSA and its health consequences, which increased the urgency to develop cost-effective diagnostic methods. This led to the creation of more reliable, portable, and user-friendly HST devices in early 2000's, allowing

patients to undergo sleep studies in their own homes. Recorded physiological data stored on the device is transferred to a personal computer through an integrated interface (FDA 510(K) K040576). These advancements made sleep testing more accessible and convenient, reducing the need for in-lab studies.

74. Prior to 2000, managing sleep disorders typically required in-person consultations at sleep clinics, with diagnoses and treatment largely reliant on traditional, lab-based polysomnography. This setup limited access to care, especially in rural areas where sleep specialists were scarce. Telehealth options were minimal, with initial consultations often occurring over the phone for basic assessments rather than the virtual, face-to-face interactions available today. Patients faced lengthy wait times for in-person appointments, and sleep studies required overnight stays, which posed logistical challenges for many.

75. In the same period, sleep apnea management with CPAP therapy required patients to regularly visit clinics for machine adjustments and adherence monitoring. Home-based sleep testing was less prevalent, and remote monitoring of CPAP data was not yet standard practice, making therapy less flexible and accessible. Symptom management strategies, such as guidance on sleep hygiene or relaxation techniques, were typically discussed only during in-office visits, and ongoing support for these interventions was limited, often resulting in inconsistent adherence and follow-up.

76. Advancements in remote management within hospital settings enabled technicians in central control room location to adjust CPAP pressure remotely and in real-time, allowing them to monitor and manage multiple patients simultaneously. Remote monitoring of the physiological and treatment data (e.g. pressure, airflow, SaO₂) from CPAP moved into the home setting. Auto-CPAP devices emerged, offering the capability to adjust CPAP pressure dynamically without the need for sleep lab titration. This innovation marked a significant shift away from hospital-based titration, allowing patients to initiate and adjust CPAP therapy at home, which eased the burden on crowded sleep labs and improved access to treatment for a larger population. This shift made therapy adjustments more efficient during the night in both hospital and home, reducing the need for continuous bedside monitoring and enabling sleep centers to treat more patients with fewer resources (more cost effective).

77. In 1999, Loube wrote that “Compensation issues may be critical to the clinical utilization of new technologies including automatic CPAP. In the United States, Medicare and most third-party payers currently will not reimburse for either attended or unattended automatic CPAP titration studies. The future trend may be for the automatic CPAP manufacturers to add additional diagnostic recording capabilities to these systems to allow for compensation as an attended

cardiorespiratory (four-channel) study monitoring airflow, respiratory effort, oxygen saturation, and heart rate.” Ex. 1059.

78. Advances in connectivity during this period improved the functionality of Auto-CPAP devices. Early networking capabilities, such as direct data transfer through memory cards or local networks, allowed therapy data to be shared within the hospital system, where healthcare providers could review and adjust treatment. Ex. 1060. This development helped facilitate timely adjustments to therapy settings and allowed clinicians to collaborate more easily in monitoring patient progress, even if they were not physically present at the bedside.

79. Methods described by Lankford 2004 for wireless data transmission attaching a transmission device (Cyracat wire-less transmitter), to the flow generator (CPAP and Auto-CPAP). Ex. 1061. Then, by accessing a secure Web site, a request for data sent from a secure sever, located centrally, through land lines to the carrier’s local transmission antenna, located within several miles of the device and location set up, where it is transmitted wirelessly to the device. Once the device received the request, the data were retrieved from the memory of the flow generator, transmitted wirelessly to a receiving antenna, located within several miles of the device. Then, through land lines back to the secure server, the data became available on the aforementioned Web site. *Id.*

80. These improvements in technology also paved the way for APAP titration outside the hospital. By allowing automatically adjusting pressure in response to patients' breathing patterns, Auto-CPAP made CPAP titration feasible in attended locations, such as home settings, minimizing the need for direct supervision. Storage of the air pressure and flow data would permit assessing both the delivered CPAP pressure and airflow fluctuations indicative of sleep disordered breathing. With early forms of remote monitoring, healthcare providers could oversee therapy progress from a distance or remote location, ensuring that patients were adhering to and benefiting from treatment.

81. The ability of Auto CPAP to adjust CPAP pressure flexibly based on real-time needs—alongside connectivity tools that enabled basic data sharing and remote oversight—expanded access to treatment, reduced costs, and supported individualized management in both hospital and home environments. These technological advances particularly helped patients with a range of severity of sleep apnea, by making sleep therapy more accessible and adaptable.

82. Remote physiological and treatment monitoring has evolved into comprehensive systems encompassing data collection, analysis, and decision-making support, for delivery of telemedicine by enhancing access to high-quality metrics that allow responsive care through real-time off-site patient monitoring. Today, advancements in telehealth and digital health technology have significantly

improved the accessibility and quality of sleep disorder management. Patients can now initiate consultations over the phone or through video calls, allowing for faster assessments and guidance on managing symptoms at home. With the development of remote monitoring and mobile apps, healthcare providers can track CPAP use and adjust therapy settings remotely, and patients have continuous access to resources for managing sleep symptoms. These technological advancements have made sleep disorder care more patient-centered and accessible, supporting better adherence and outcomes.

D. Wearables (Wearables in Medical Technology)

83. Wearable medical technology was established through a series of scientific breakthroughs and advancements that enabled the measurement and monitoring of physiological parameters in real time. In the 1960s and 1970s, the invention of biosensors provided a way to detect biological signals such as glucose levels, heart rates, and respiratory functions. Early biosensors were primarily enzyme-based, with notable advancements in glucose oxidase sensors for managing diabetes, a field that gained significant traction during this period. Ex. 1053. The concurrent development of miniaturized electronics and battery technologies allowed for portable devices that could operate for extended periods, making continuous monitoring feasible. Wireless communication systems, initially

developed for military applications, began to be adapted for healthcare, enabling remote transmission of health data to external systems.

84. Key contributions to wearable technology came from pioneers in the medical and engineering fields. Norman Holter's development of the ambulatory ECG device in 1961 enabled continuous cardiac monitoring, a breakthrough for diagnosing arrhythmias. Ex. 1054. Earl Bakken, co-founder of Medtronic, was instrumental in designing early portable pacemakers, which laid the groundwork for wearable cardiac devices. Ex. 1049. Simultaneously, NASA's efforts during the Apollo missions in the late 1960s resulted in physiological monitoring systems capable of tracking astronauts' vital signs during space travel, inspiring the development of similar devices for clinical use. Ex. 1051.

85. **Diabetes:** Wearable technology for diabetes management took its first significant steps with the development of continuous glucose monitors (CGMs) in the 1980s. Early devices, like the Biostator (Miles Laboratories), were bulky but provided the first demonstration of real-time glucose tracking. These devices relied on electrochemical sensors to measure glucose in interstitial fluid, marking a critical milestone in personalized diabetes care. Ex. 1062. Despite their limitations, such as short sensor lifespans and complex calibration requirements, these early CGMs paved the way for more compact systems by the mid-1990s, including the MiniMed CGM system, which offered improved accuracy and usability.

86. **Sleep Apnea:** The earliest wearables addressing sleep disorders, such as sleep apnea, emerged in the 1980s with devices like portable polysomnography systems. These systems used piezoelectric sensors and accelerometers to track respiratory effort, airflow, and body movements during sleep. Researchers developed simplified tools, including nasal airflow monitors and pulse oximetry sensors, to detect apneic events noninvasively. Ex. 1063. These advancements represented a shift toward more accessible diagnostic tools that could be used outside the hospital setting, laying the groundwork for modern home sleep testing devices.

87. **Neurology:** Neurological wearables gained traction in the 1990s with the development of systems to monitor tremors and motor activity in Parkinson's disease patients. Early devices used piezoelectric accelerometers to quantify tremor frequency and amplitude, providing objective data for evaluating treatment efficacy. Researchers also experimented with wearable EEG systems for monitoring seizure activity, though these were limited by the bulkiness of the equipment. Despite these challenges, such technologies demonstrated the feasibility of continuous neurological monitoring, fueling further innovation in the field.

88. **Cardiology:** Cardiac wearables saw rapid advancement with the miniaturization of ECG technology. The Holter monitor, first introduced in the 1960s, evolved significantly by the 1980s, with devices becoming smaller and more user-friendly. Advances in solid-state memory and battery efficiency allowed for

longer recording durations, facilitating the diagnosis of complex arrhythmias. By the 1990s, early external defibrillators were integrated into wearable systems for high-risk cardiac patients, enabling immediate intervention during life-threatening arrhythmias. These devices marked a critical step in preventative cardiac care.

Technological Evolution

89. The evolution of wearable medical devices from basic prototypes to functional tools capable of continuous monitoring was shaped by advancements in sensor technology, miniaturization, and connectivity. In the 1980s, the integration of piezoelectric and electrochemical sensors enabled more precise and reliable monitoring of physiological parameters. For example, advancements in enzymatic sensors for glucose monitoring improved the accuracy and durability of early CGMs. Ex. 1067. During the same period, the application of microprocessor technology allowed for data processing within the wearable device itself, reducing reliance on external computing systems and enhancing portability.

90. Sleep monitoring devices also underwent significant changes during this time. Early polysomnography systems were cumbersome and required laboratory settings, but innovations in sensor technology led to the development of portable sleep trackers. These devices incorporated accelerometers to detect sleep position and movement, as well as pulse oximeters for assessing blood oxygen

saturation. By the late 1990s, these systems had become compact enough for home use, enabling more widespread screening for sleep apnea. Ex. 1068.

91. Neurological wearables advanced through the incorporation of more sophisticated motion-sensing technologies. Early accelerometer-based devices were complemented by gyroscopic sensors in the 1990s, providing three-dimensional tracking of tremor activity in conditions like Parkinson's disease. Ex. 1069. These developments allowed researchers to quantify motor impairments more accurately, providing valuable insights into disease progression and the effects of treatments.

92. In cardiology, the introduction of solid-state electronics transformed ECG wearables. The shift from analog to digital recording improved data quality and storage capacity, enabling devices like the Holter monitor to record uninterrupted for 48 hours or more. Concurrently, the development of wearable external defibrillators provided a safety net for patients at risk of sudden cardiac arrest, offering a life-saving intervention in out-of-hospital settings.

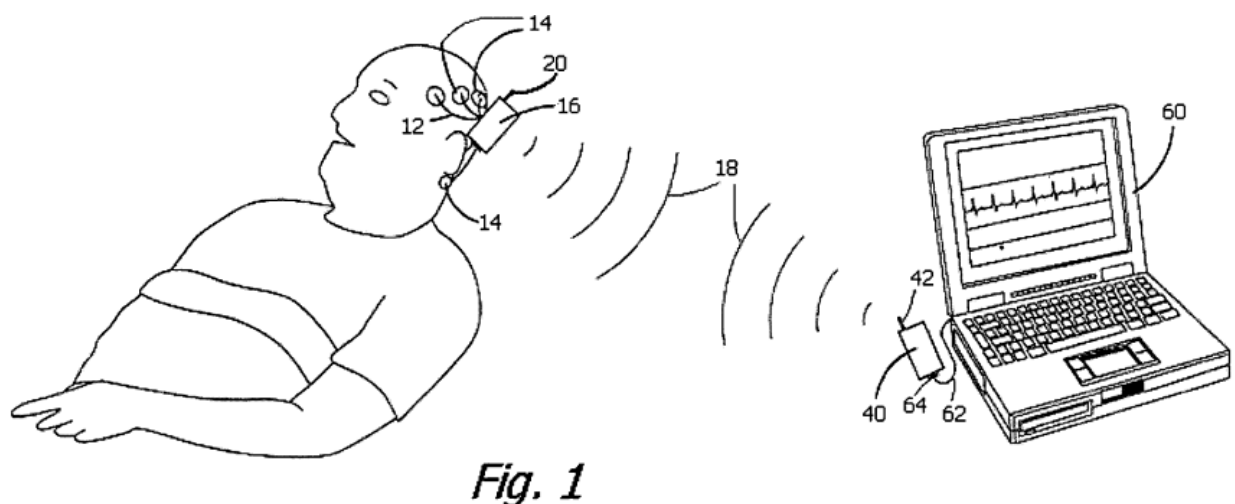
Health Applications and Sleep Monitoring

93. Wearable sensor technology has transformed health monitoring across various medical fields, demonstrating versatility in applications such as improving athletic performance, detecting illnesses, and facilitating treatment. Examples include insulin pumps for diabetes management and brain implants enabling communication for speech-incapable patients. Originally developed for military

purposes, wearable systems like the Personnel Status Monitor predicted fatigue and injuries in soldiers, while neck-mounted acoustic sensors monitored physiological signals such as blood flow, respiration, and mobility, with minimal interference from ambient noise. These advances have paved the way for their use in sleep diagnostics, where devices like the MESAM 4 offered low-cost, multi-channel recordings of oxygen saturation, heart rate, snoring, and body position, providing validated alternatives to traditional polysomnography for diagnosing obstructive sleep apnea (OSA). Ex. 1066. This progression highlights the adaptability of wearable sensors and their pivotal role in advancing both general health monitoring and specialized applications like sleep disorder diagnostics.

VIII. THE '512 PATENT

94. The '512 Patent describes a well-known approach for acquiring physiological data from patients. Ex. 1001, Abstract, FIG. 1, 16:8-61.



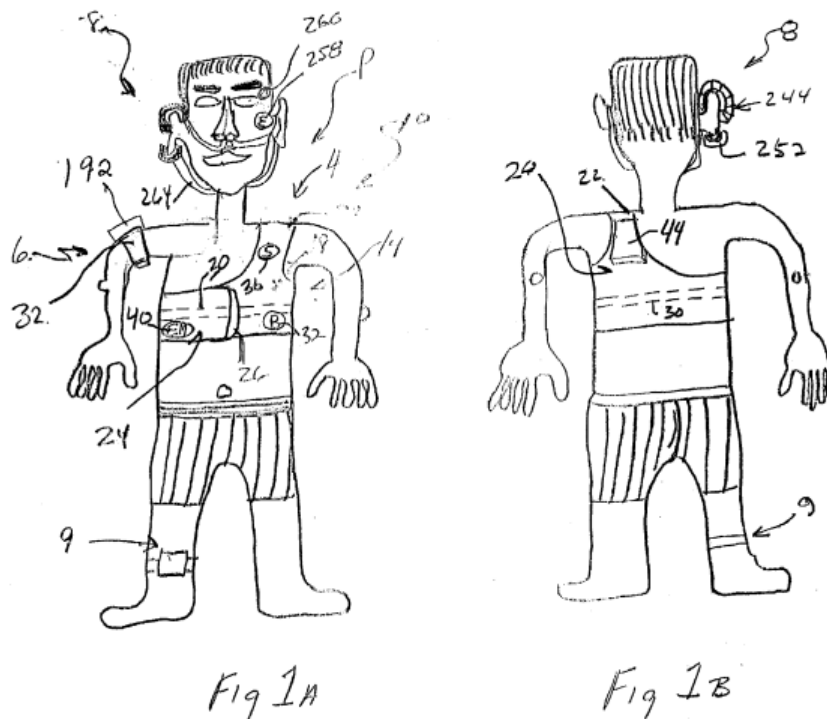
Various sensors 14 (such as an EEG electrode) are attached to a subject. *Id.*, 16:8-61. According to the '512 Patent, such sensors can include electro-physiological electrodes (*id.*, 7:42-51, 7:61-8:60), magnetic sensors (*id.*, 7:52-60), respiration belt (*id.*, 9:10-26), nasal cannula or face mask (*id.*, 9:27-56), pulse oximeter (*id.*, 9:57-10:4), or additional sensors such as accelerometers and “potentially any transducer type sensor, that is any sensor that outputs an electrical signal, can be used with the system” (*id.*, 10:5-14, *see also* 8:61-67).

95. These sensors measure various physiological parameters of the patient (*id.*, 8:67-9:9), and provide inputs 12 to a module 16, which wirelessly transmits a signal 18 (encoded with data corresponding to the inputs 12) to a base station 40, such as over “Bluetooth, WiFi, IEEE 802.11, and the like.” *Id.*, 16:8-61, 10:45-53. The base station can be a “cell phone, which receives the physiological data transmission, optionally re-processes the information, and re-transmits the information via cell towers... to a remote site for analysis.” *Id.*, 39-44.

IX. OVERVIEW OF THE PRIOR ART

A. Ciulla (Ex. 1007)

96. Ciulla discloses a patient-wearable device for diagnosing sleep disordered breathing. Ex. 1007, Abstract, [0095]-[0106], [0219], [0078]-[0079], FIGs. 1A, 1B. The system can also be used to treat sleep ordered breathing. *Id.*



The device includes a “main module 44 [] disposed on the back of the patient” that receives signals from sensors, including an oximeter 252, “chest sensor 30, snoring sensor 36, breathing sensor 32, and EMG sensor 40.” *Id.*, [0100], [0117]-[0122], FIG. 8. These sensors can be hard-wired to the main back module 44, communicate wirelessly with module 44. *Id.*, [0100], [0106], [0124], [0145]. The sensor also “may be designed to be incorporated within the main back module as a part thereof, and as such, would be connected to the main back module for a hard-wired connection.” *Id.*, [0100], [0106], [0124], [0145]. An “attitude sensor is made a part of the CPU containing main module” and “determine[es] the patient’s sleeping position (e.g. on back, on side, etc.).” *Id.*, [0143], [0121], [0124], [0139], [0202].

97. After receiving signals from the sensors, the microprocessor within Ciulla's wearable device "process[es] the input so received, generat[es] commands, and transmit[s] those commands to various output devices." *Id.*, [0126], [0172] ("microprocessor [] analyzes its multi-sensor inputs to detect faulty or obstructed breathing"), [0202]. The device also has "[a] clinical trial version [] designed to transmit the multiple sensors' outputs wirelessly (RF, BlueTooth, WAN, LAN, IT Ethernet Modem or other)" and "incorporate[s] a wireless receiver allowing the researcher to... observ[e] the patient's responses in a montage display format on the receiving computer's screen." *Id.*, [0213]. Moreover, the device's microprocessor can "directly transmit [analysis] reports by IT to the therapist's computer and/or the company's main frame system for further analysis, research or documentation." *Id.*, [0214].

B. Orbach (Ex. 1008)

98. Orbach discloses wearable sensor modules that sense physiological parameter data of a user/patient, and a mobile monitor that can receive such data from the sensor modules for subsequent transmission to a remote server. Ex. 1008, Abstract, FIG. 1, 13:21-14:2. Among other features, the mobile monitor 120 is a "cellular phone or a Personal Digital Assistant (PDA)," which is also illustrated below in Figure 1. *Id.*, 13:14-27, 14:3-15:15, 22:3-27.

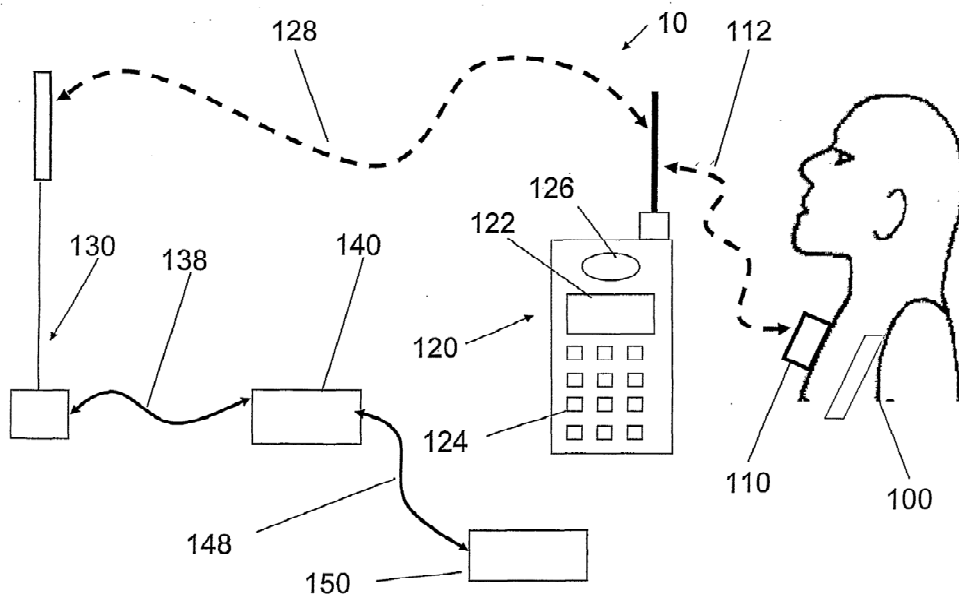


Fig. 1

Id., FIG. 1.

99. Orbach's cellular phone is "equipped with...means to communicate with both [the] sensor module and remote server" wirelessly. *Id.*, 13:14-27, 16:13-20, 22:4-27. When the remote server receives the sensor data from the user/patient sensing module, an expert can review the data to "help identify and possibly correct sleep disorders." Ex. 1008, 13:14-14:2, 22:20-23:4, 41:25-27, 44:1-11.

C. Kumar (Ex. 1009)

100. Kumar discloses a patient side device that senses sleep information. Ex. 1009, [0071], [0015], [0068], [0239]-[0241]. A provider can remotely control a readout of the patient sensor data via a stream manager running on a user's PDA or wireless telephone. *Id.*, [0015] ("Further, the provider may remotely control the

client-side device. For example, when the patient is sleeping in his/her home with EKG and blood pressure devices connected, the provider can start these devices remotely to read the data periodically or whenever needed.”), [0080] (“Using optional remote control features built in to the system, remote providers can control the software on the patient’s end. Thus, patients do not need to know how to operate the software.”), [0085] (“A remote client module (not shown) allows remote hosts to view the data being streamed in real time. The remote client module can also control the software being run on the patient’s and/or provider’s end. Multiple remote client modules can run concurrently, allowing multiple remote providers to view data form one device.”).

D. Nagai (Ex. 1010)

101. Nagai discloses methods “for evaluating sleep of subjects in diagnosing sleep” disorders. Ex. 1010, [0003]. Nagai further discloses “body position detector 12,” which “detects a body position of the subject in terms of angle information.” *Id.*, [0047], [0049], FIG. 1. The body position detector uses “a three-axis acceleration sensor” comprising a sensor body 220 comprising piezoresistive devices 224. *Id.*, [0049], [0070]. [0071]. Nagai discloses that pulse oximeter information can also be considered with such body position information to determine a “correlation between apnea and body position of the subject in sleep.” *Id.*, [0172], [0142]-[0145].

E. Truschel (Ex. 1011)

102. Truschel discloses a dynamic software-based filtering process for snore detection. Specifically, Truschel uses a “pressure sensor 48 as a microphone” which “is capable of converting a snore pressure wave into a proportional analog signal.” Ex. 1011, [0045]. The system includes a “snore analysis device 64” and a “digital band pass filter 58,” which are implemented within a controller 50 using “suitable programming.” *Id.*, [0043], [0046] (“programmed to function as a snore detection device”). The filter obtains a snore signal from a sensed pressure signal. *Id.*, [0043], [0045]-[0046], [0050], [0068] (“first checking for vibrations in pressure signal 72 within a broad range of 40 to 160 Hz”), [0053].

X. CLAIM CONSTRUCTION

103. I have applied the plain meaning of the terms and phrases in the claims in my analysis, as a POSITA would have understood those terms and phrases at the relevant time (around 2006).

**XI. OPINIONS ON GROUND 1: CIULLA IN VIEW OF ORBACH
RENDERS OBVIOUS CLAIMS 1-6, 8-17, 19, AND 20**

A. A POSITA Would Have Been Motivated to Combine

104. It is my opinion that a POSITA would have found it obvious to modify the *sleep diagnostic data acquisition system* in Ciulla (*see* Section XI.C.1) to send its sensor data through a mobile phone or PDA to a remote computer for diagnosing

transceivers in both the wearable device and the cell phone, with communication between the cell phone and a remote computer via cell towers for display, analysis, diagnosis, and/or treatment adjustments, consistent with what the '512 Patent claims.

106. A POSITA, as a part of the Ciulla-Orbach combination, would have been motivated to implement and would have found it obvious to make the following modifications to Ciulla prior to the alleged time of invention.

1. Wirelessly Transferring Sleep Data from Wearable Device to a Cell Phone via Bluetooth, and from Cell Phone to Remote Site via Cell Towers [1.b], [1.e]

107. Ciulla's main module 44 features "a radio frequency transmitter and receiver for wireless communication":

Additional componentry can include a voice chip, a non-volatile memory, such as a smart card, and various cableing and wires to provide communication, along with a radio frequency transmitter and receiver for wireless communication. A power source, such as a plurality of batteries provide the power for the main module 44 to operate.

....

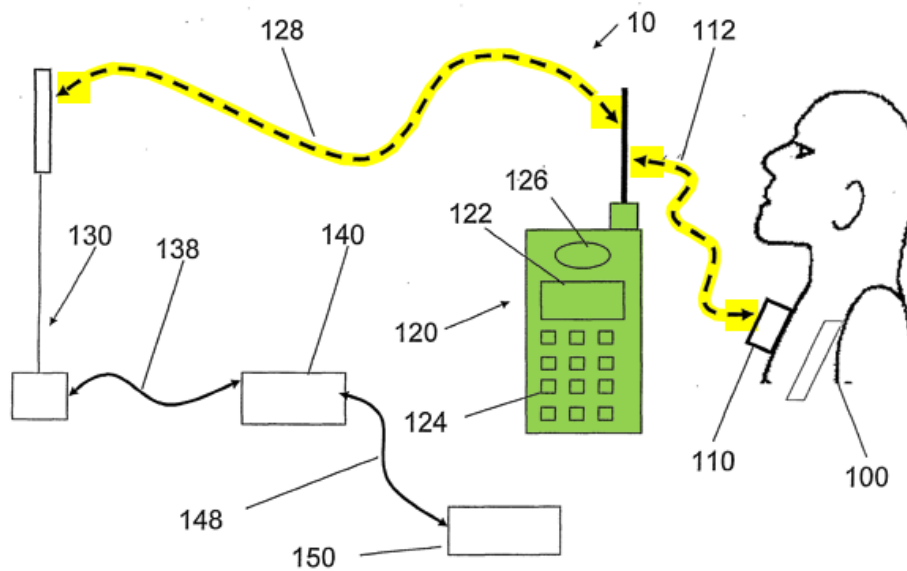
An internal, transmitter/receiver/ antenna 92 is provided for enabling the main module 44 to communicate wirelessly with the various sensors and output devices of the present invention. A plurality of jacks and/or plug receivers and/or ports (collectively referred to herein as "ports") 96 are provided on the main module 94 for

enabling the main module 44 to be hard-wired to various sensor-type input devices and/or output devices.

Ex. 1007, [0102], [0106], FIGs. 1A-1B, 8. Moreover, Ciulla discloses “transmit[ting]...multiple sensors’ outputs wirelessly”:

The device of the present invention can be modified to add additional outputs and additional reporting capabilities to better adapt the device for use by trained technicians during attended sleep studies. This clinical trial version can be designed to transmit the multiple sensors' outputs wirelessly (RF, BlueTooth, WAN, LAN, IT Ethernet Modem or other) along with video cam images of the sleeping patient.

Id., [0213]; *see also id.*, [0219], [0221], [0230]. Ciulla does not explicitly state that its main module 44 wirelessly transmits received sensor data to a cell phone and then from the cell phone to a remote site. Nonetheless, it is my opinion that such functionalities and features would have been obvious in light of Orbach.. Ex. 1008, FIG. 1, 13:21-27 (“A communication link is used to transfer data from the [sensor] module 110 to a mobile monitor 120.... [C]ommunication link 128 is used to connect the mobile monitor 120 to a remote server 140 where in-depth analysis of data obtained by the sensor unit 110 may be done....[C]ommunication link 112 is a Bluetooth link, and communication link 128 is cellular RF link to a cellular base station .”), 22:4-13, 22:20-23:4 (“Remote servers may provide additional processing of the sensor’s data.”); Sections XI.C.2-3.



Ex. 1008, FIG. 1 (annotated) (depicting wireless sensor data communication through a cell phone).

108. First, implementing Orbach's sensor communication techniques into the Ciulla system would have facilitated continuous, real-time data communication, providing healthcare providers and users with more personalized and timely interventions. Indeed, Orbach explicitly discloses such applications:

Optionally, an additional data link 148 such as Local Area Network (LAN) or Internet networking or RF cellular link connects the remote server 140 to a viewing station 150 where a human expert may provide interpretation of the data and transmit recommendations to the user.

....

Instructions and commands may be initiated by the remote server 140 or expert station 150 and relayed to sensor module 110 through mobile monitor 120.

....

The users can receive feedback in real time directly from the system by audio-visual feedback in real time, and at the same time the system can transmit the information to an expert or coach who can help them improve their reactions. This can be relevant for health issues—*e.g.* a child with asthma who can get feedback in real time from the system and/or physician, or an athlete receiving feedback to improve his performance.

....

“The system may be programmed to alert the user or someone else when certain conditions occur.”²

Ex. 1008, 13:28-14:2, 17:19-20, 25:27-26:2, 38:24-27.

109. Second, Orbach discloses techniques that allow patients to remotely track and conveniently report their health data using a common portable device, such as a cell phone or PDA. Accordingly Orbach improves early detection of potential health issues while reducing patient healthcare costs, including for example by reducing doctor visits and hospital stays or requiring extra networked hardware. Ex. 1008, FIG. 1. Such a configuration would not require an additional or expensive custom device to transmit sensor data, as the relevant software would simply be

² Emphasis is added in this Declaration unless stated otherwise.

downloaded to the user's mobile device, as suggested by Orbach in the following exemplary passages:

Specific programs necessary for interfacing with the sensor module and for providing feedback to the user may be uploaded by the user. For example, the program may be loaded into a cellular phone wirelessly in the same way a new game or ring tone is loaded.

....

In the case where the mobile unit 120 is a cellular phone, the data analysis and screen display may be created by an application loaded into the cellular phone memory and executed by the processor within the cellular phone.

Ex. 1008, 22:10-13, 33:24-27. It is my opinion that a POSITA would have appreciated that cell phones and similar mobile devices were growing in popularity and connectivity during the relevant time, which would have further motivated such data transmission disclosed by Orbach. This convenience would have been particularly beneficial for individuals in rural or underserved areas, where access to healthcare providers is limited, thus enhancing overall healthcare accessibility.

110. Orbach discloses that sensor data is transmitted over a “cellular RF link to a cellular base station 130” in a corresponding “cellular network”:

The mobile unit may be a cellular telephone and communication between the mobile monitor and the remote server may be over a cellular communication network.

....

Optionally, a communication link 128 is used to connect the mobile monitor 120 to a remote server 140 where in-depth analysis of data obtained by the sensor unit 110 may be done and, optionally, data can be transmitted to an expert or another user. In the exemplary embodiment of Fig. 1, the mobile monitor 130 is a cellular phone, communication link 112 is a Bluetooth link, and communication link 128 is cellular RF link to a cellular base station 130 which is linked to a remote server 140 by a data link 138. Optionally, an additional data link 148 such as Local Area Network (LAN) or Internet networking or RF cellular link connects the remote server 140 to a viewing station 150 where a human expert may provide interpretation of the data and transmit recommendations to the user.

....

The communication range of the sensor module is limited due to its small size and low battery capacity to few meters or up to almost 100 meters using Bluetooth. In contrast, the Mobile monitor is equipped with means to connect to a remote server wirelessly over the cell network, preferably using the Internet. For example, cellular phone may be connected using one of the cellular data exchange protocols such as GPRS. Other standard and proprietary protocols may be used such a wired connection to a phone line using a modem or an Asymmetric Digital Subscriber Line (ADSL), a Local Area Network (LAN) Wireless LAN (WAN), etc.

....

The data logged on the mobile unit may be transmitted to a remote server for further analysis. For example data may be sent to via the cellular network using a data exchange protocol such as GSM, GPRS or 3G. Alternatively or additionally, data may be transferred to a PC or a laptop computer using a cable such as USB cable, Bluetooth RF communication or Infrared (IR) communication.

Ex. 1008, 5:3-5, 13:21-14:2, 22:20-27, 33:27-34:2 (“data may be sent to via the cellular network using a data exchange protocol such as GSM, GPRS or 3G”).

111. Third, integrating Orbach’s sensor communication techniques into the Ciulla system would have also fostered greater patient engagement, resulting in improved outcomes and higher satisfaction with care as individuals took a more active role in managing their health.

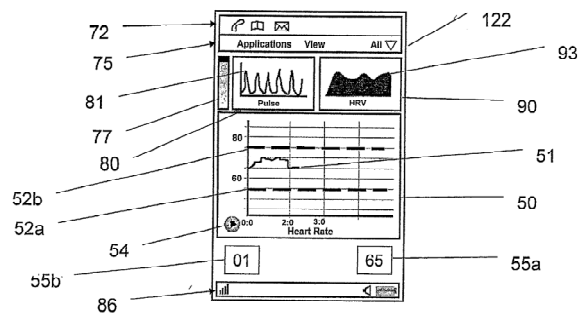
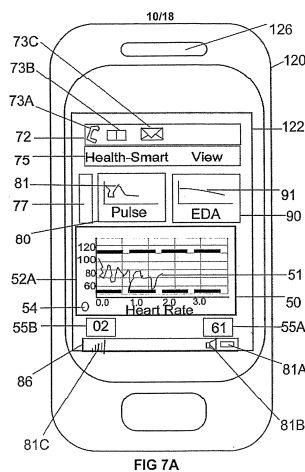


Fig. 7b

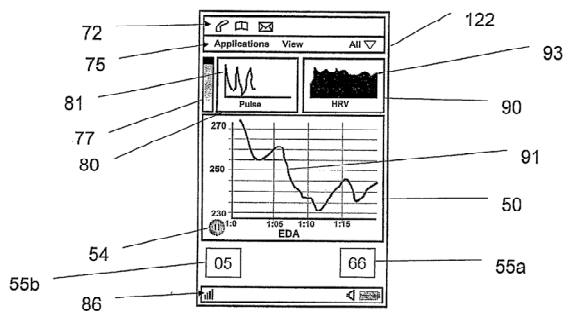


Fig. 7c

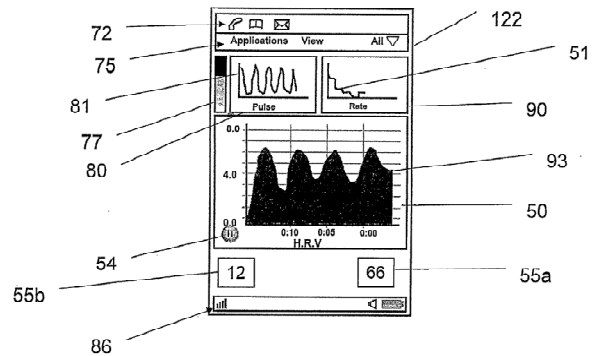


Fig. 7d

Ex. 1008, FIGs. 7a-7d (illustrating various interfaces for users to manage their health information). By leveraging wireless communication via cell phones, patients would have real-time access to sensor data, enabling them to track their sleep patterns or other health metrics continuously. This constant stream of information would empower individuals to take a more proactive approach to managing their health, rather than relying solely on periodic doctor visits or assessments.

112. It is my opinion that to the extent not explicitly disclosed, communications over “*cell towers*” in the cellular network described by Orbach would have been obvious, for instance in order for the Ciulla-Orbach system to operate in accordance with standard cell tower-based networks and increase usability and reach, or to obtain the benefit of allowing the Ciulla-Orbach system to send data to the remote server from multiple locations over an existing network. Thus a POSITA would have appreciated that the configuration would need to integrate with

mobile network infrastructure cell towers, allowing seamless data transmission to a remote server via existing cellular networks. By leveraging existing mobile networks, the system would also support real-time monitoring, enabling healthcare providers to track patient data and adjust treatment plans remotely, without geographic limitations. This existing network approach would reduce costs, improve efficiency, and enhance both patient care and system scalability. Such understanding is all consistent with a POSITA's understanding of such systems before the alleged time of invention and as expressed in the following passages:

Cellular telephones work by transmitting radio signals to cellular towers. These towers vary in their capability to receive cellular telephone signals. Some towers can receive signals from distances of only 1.5 to 2.4 km (1.0 to 1.5 mi), while others can receive signals from distances as far as 48 to 56 km (30 to 35 mi). The area a tower can cover is referred to as a cell. However, more than one tower may exist in a given cell area. The cells overlap so that the system can handle increased telephone traffic volume. The towers within these cells are networked to a central switching station, usually by wire, fiber-optic cable, or microwave.

Ex. 1041, [0007].

Cellular telephone systems are well known in the art, and minimally include an array of cell towers, each tower facilitating duplex communication of cellular tele phone customers within a defined region called a “cell.”

Ex. 1012, [0004]; Ex. 1013, [0011] (“[C]ellular networks...require cellular towers.”).

2. Hardwiring Sensors [1.b.iii]

113. It is my opinion that it would have been obvious to use standard wired sensors for Ciulla's fingertip pulse oximeter and nasal-cannula sensor components, hardwired to Ciulla's main module 44 through a connector (*e.g.*, a jack, port, etc.), to the extent Ciulla does not explicitly disclose such a configuration. *See* Section XI.C.6. Ciulla discloses that its sleep device "can be constructed using off-the-shelf sensor inputs," and that the use of such "standard" sensors would "help reduce production costs":

An additional feature of the present invention is that the sensor and stimulator components can be designed to be miniaturized, reliable, and convenient....To help reduce production costs, standard sensors and stimulators can be used, along with micro-electro mechanical system technology, that can be programmed and designed to work with the present invention. The components can be made small enough to be used on very young children, yet powerful enough to be used on very large, or obese adults.

....

The device can be constructed using off-the-shelf sensor inputs with the main module containing prefilters, and an analog to digital converter. Alternately, digital acquisition may be used followed by digital filtration prior to analysis and digital storage (DDD technology) for greater accuracy, if required or desired. Standard 50 Hz and 60 Hz filtration will remove powerline frequencies. Appropriate filtration to insure accurate detection of HR, snore vibrations, breath sounds, etc., is included in the system.

....

Standard sensors and stimulators, or MEMS (micro-electrical mechanical systems) technology can be employed for miniaturization and convenience.

Ex. 1007, [0072], [0204], [0226]. Wired fingertip pulse oximeters and nasal cannula/pressure sensors were standard and ubiquitous prior to the alleged date of invention. *See, e.g.*, Ex. 1021, 11:16-38 (“The pulse oximeter finger clip 98 is connected...via a pulse oximeter cable 101....”); Ex. 1025, [0092] (“[N]asal pressure sensor input 190 are wires....”); *see* Section XI.C.6.

114. Consistent with that known in the art, a POSITA would have been motivated to implement the fingertip-based pulse oximeter and nasal cannula-type sensors as standard hardwired sensors connected via a connector to main module 44. As I discussed previously, Ciulla suggests such a configuration, explicitly noting that “it would be more cost effective to hardwire” sensors of the device to the main module 44. Ex. 1007, [0145], [0072] (“standard” sensors would “help reduce production costs”). Consistent with Ciulla, a POSITA would have recognized that using wired sensors, as claimed and known, would have reduced sensor connection complexity, noise, battery bulk, cost, and charging inconveniences, offering clear benefits, advantages, and/or utility over wireless alternatives. Ex. 1026, [0030], [0032] (“The battery 34 is the most bulky component of the wireless pulse oximetry embodiment....”); Ex. 1027, 1:23-21 (“Wireless sensors are typically larger and more

costly than their hard-wired counterparts. Unlike hard-wired sensors, wireless sensors must house an RF transmitter and its associated circuitry, as well as a local battery source that is sufficient to provide the required power.”); Ex. 1028, [0102] (“[A] wired connection may be used to minimize cost or unwanted RF radiation.”), [0116] (“Adding wireless transmission circuitry to the physiologic monitor can add significant complexity, power losses, and noise to the system.”). Moreover, the specific use of a “limited wired connection” in combination with a wireless main module 44 was known to be advantageous in that it “would allow for the sensor node to sense and process some data while the communication node could then send out this processed information,” thereby allowing the communication node to “use its energy explicitly for sending or receiving data, yielding a longer time before the necessary recharge.” Ex. 1029, p. 5 (Section 3.2).

115. A POSITA would have taken into account trade-offs associated with different design options for implementing such a modification, including factors like design constraints, cost, user convenience, and others. Although Ciulla mentions that some sensors “would likely receive and/or transmit...their signals...wirelessly” (Ex. 1007, [0125]), such qualified language (“likely”) does not preclude a wired sensor version, nor does it remotely suggest avoiding the known and advantageous and suitable configuration. It is my opinion that a POSITA would have appreciated that a given course of action often has simultaneous advantages and disadvantages,

and this does not necessarily obviate motivation to combine. And it is clear that wired sensors would have been a suitable option in the Ciulla system. Such a modification thus would have been no more than an obvious and predictable substitution of one known sensor type for another with a reasonable expectation of success. Indeed, the combination of familiar elements like that discussed here according to known methods is likely to be obvious when it does no more than yield predictable results. A simple substitution of one known element for another is obvious and it would have been obvious to try finite number of identified, predictable solutions (wired versus wireless connection)). The known interchangeability of wired and wireless devices was obvious and well-understood before the relevant time of invention.

3. Software on Phone and Remote Site [1.a], [1.d]

116. Orbach discloses that a cell phone device forwards sensor data to a “remote server” 140 that is connected to a viewing station 150. Ex. 1008, 3:19-23, 5:3-5, 8:11-15, 13:21-14:2, 22:20-27, 33:27-34:2, FIG. 1. Orbach additionally discloses that the remote server is “equipped with programmable data processing power” and includes storage for “acquiring and storing...records”:

When the system of the present invention may be equipped with programmable data processing power and flexible output means, numerous applications and uses may be adopted and used, optionally simultaneously and in

combinations. A few exemplary applications will be described below.

....

According to another embodiment of the invention, the system may be used to record physiological readings during sports training. In contrast to available devices that display only moving AHR, the system of the invention is capable of recording and storing virtually a record of each individual heartbeat and breath. Data compression, large memory capacity in the mobile monitor and mass storage in the remote server enable acquiring and storing these records over long periods of use. Because the sensors are small and transmit the data wirelessly-either using the Bluetooth protocol or the mobile network communication services- an expert coach can view and monitor the physiological parameters, the emotional- arousal states and the performance of the athlete, and coach him in real time to improve his reactions and performance. The data can be also saved for analysis later on. An athlete can also rehearse at his home or office using the invention, with either a multimedia mobile phone or PC or PDA (personal digital device) while he is viewing his performance, and simulating his emotional and physiological conditions, as in a real competition. By using several of the sensors simultaneously (e.g. heart rate, HRV, breathing, EDA EMG), the user learns to tune not only his physiology but also his attitude, arousal level etc, and to achieve his best performance.

Id., 38:19-22, 41:8-24. Similarly, and as I discussed previously, Orbach's cell phone includes an "application loaded into the cellular phone memory and executed by the processor within the cellular phone" and/or "specific programs necessary for

interfacing with the sensor module.” *Id.*, 22:4-13, 33:24-26. The cell phone also includes helpful graphic interfaces that allow the user to see breathing and other logged data. Ex. 1008, 32:9-30, 33:24-26, 34:3-16, 35:28-36:16, FIGs. 7A-7D.

117. Given the functions and teachings of Orbach’s remote server and cell phone, a POSITA would have found it obvious for Orbach’s remote server and cell phone to include conventional ***executable software stored on a non-transitory computer readable medium*** and corresponding cell phone graphical interfaces like that disclosed by Orbach. *See* Section XI.C.12, XI.D.6. A POSITA, when designing or improving such a system, would recognize that executable software is a standard and necessary component for enabling the required functionality. The software would be responsible for processing, analyzing, and managing the sensor data, facilitating communication between the devices, and ensuring the smooth operation of the entire system. In the context of modern technology, storing executable software on a non-transitory computer-readable medium (such as flash memory, hard drives, or solid-state drives) is a conventional and efficient approach. Non-transitory media offer the reliability and permanence needed for software storage, as they do not lose data when power is lost (unlike transitory media like RAM). Thus, a POSITA would understand that integrating such software on a non-transitory medium in both the remote server and cell phone would be both a practical and well-established solution. Moreover, the use of non-transitory computer-readable media

to store executable software is common practice in similar systems involving mobile devices and remote servers. This approach ensures that the software is easily accessible, can be updated as needed, and can be executed efficiently by the hardware. Given the widespread use of such media in the industry, a POSITA would naturally consider it an obvious choice to include this type of software in the Orbach system for optimal performance and functionality. By combining the remote server, cell phone, and executable software on non-transitory media, the system would efficiently handle the required tasks—such as data collection, transmission, processing, and feedback—without introducing unnecessary complexity or reliance on less reliable alternatives. As a result, this combination would not only enhance the system’s reliability but also align with common practices in the field, making it an obvious choice for a POSITA to implement. Moreover, a processor similar to Orbach processing elements is ubiquitously the part of a computer that executes software program instructions to perform functions, such as processing and analyzing sensor data, like that described by Orbach. The processor communicates with non-transitory memory (e.g., a hard disk) to load the software programs that it will execute. *E.g.*, Ex. 1040, 29-30 (explaining a “computer system consists of a CPU and a number of device controllers that are connected through a common bus that provides access to shared memory”), 37 (stressing that for a computer “to do its job of executing programs,” the programs must be stored in memory). Thus, it would

have been obvious for Orbach's remote server and cell phone to execute memory-stored instructions that comprise the software programs described in Orbach, like that conventionally understood in the art. Such a skilled person would have understood that Orbach's software would have been stored in non-transitory memory for several good reasons, including, for instance, to allow the system to remain functional even if powered off and on again (*i.e.*, power cycled).

B. A POSITA Would Have Had a Reasonable Expectation of Success

118. A POSITA would have had a reasonable expectation of success in modifying the Ciulla system to wirelessly transmit sleep sensor data to a remote computer for sleep disorder diagnosis via a cell phone, hardwire sensors, and implement software on the cell phone and remote computer.

119. First, Ciulla already expressly contemplates an environment where its sleep device 10 would send sleep data to a remote location for human analysis. Ex. 1007, [0213] (“[A]dditional outputs and additional reporting capabilities” can be added to the user’s sleep device so that “[a]ll sensory data and responses...can be recorded and analyzed by [a] researcher and/or medical practitioner.”), [0219] (“The device of the present invention...can be employed and will record and report untreated SDB events. Thus the device can be adjust to serve as a diagnostic or screening device for SDB.”), [0221] (“The system’s treatment mode can be

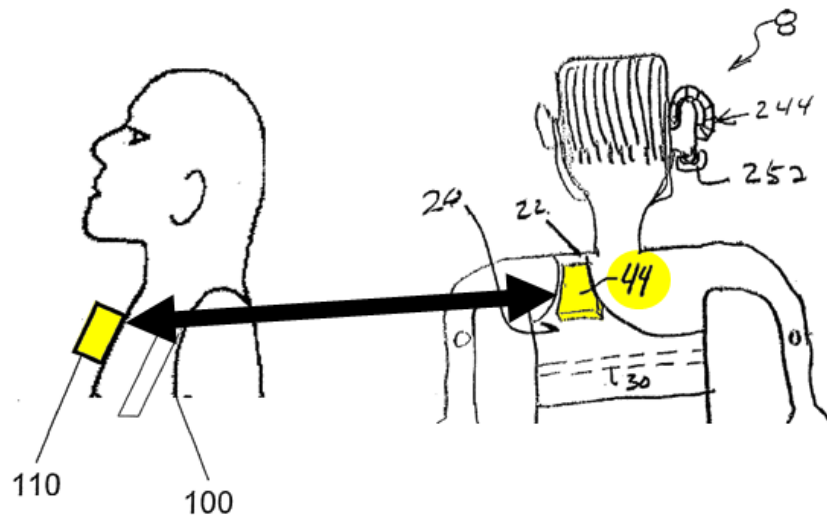
disabled...turning it into a full SDB home screening device generating only its data report of events.”). Indeed, Ciulla expresses the following:

The system is also designed to permit total monitoring, control and analyses to be performed in a different location from where the patient is sleeping by being capable of transmitting data it obtains at any distance, either wirelessly or by a modem.

Id., [0230]. A POSITA therefore would have had a reasonable expectation of success in implementing such a suggested, contemplated, and known configuration like that disclosed by Orbach. Ex. 1008, Abstract, 13:28-14:2, FIG. 1. Cell phone-based telehealth systems and software were known and common. Ex. 1045, [0217] (“If the wearable appliance detects a cell phone that is mesh network compatible, the wearable appliance communicates with the cell phone and provides information to the server 200 using the cellular connection.”); Ex. 1009, [0072] (“The patient-side device may then be connected via...handheld devices such as personal digital assistants (PDAs)..., wireless telephone, or any other computing device.”). Wired sensor connections were also well-known and straightforward to implement. *E.g.*, Ex. 1028, [0102], [0116].

120. Second, Ciulla and Orbach are analogous art and disclose readily combinable teachings and applications. Indeed, both references describe sensor monitoring systems and relate to “wireless data acquisition systems for data

communications,” which the ’512 Patent identifies as a field of the invention. *E.g.*, Ex. 1007, Abstract, [0213] (“designed to transmit the multiple sensors’ outputs wirelessly (RF, BlueTooth, WAN, LAN, IT Ethernet Modem or other)”), FIGs. 1A-B, 8; Ex. 1008, Abstract, 13:19-27, FIG. 1; Ex. 1001, 1:24-30. Both references moreover disclose wearable modules (main module 44; sensor module 110) that receive sleep sensor data from sensors, further confirming their compatible teachings. Ex. 1007, FIGs. 1B and 8, [0100] (“The main module 44 is disposed on the back of the patient”), [0126] (“[T]he microprocessor that is contained within the shoulder unit, is the ‘heart and brains’ of the device, that is provided for receiving a wide variety of inputs from various sensors”); Ex. 1008, 13:14-15:29 (“A sensor module 110 is attached to a user 100.”), FIG. 1.



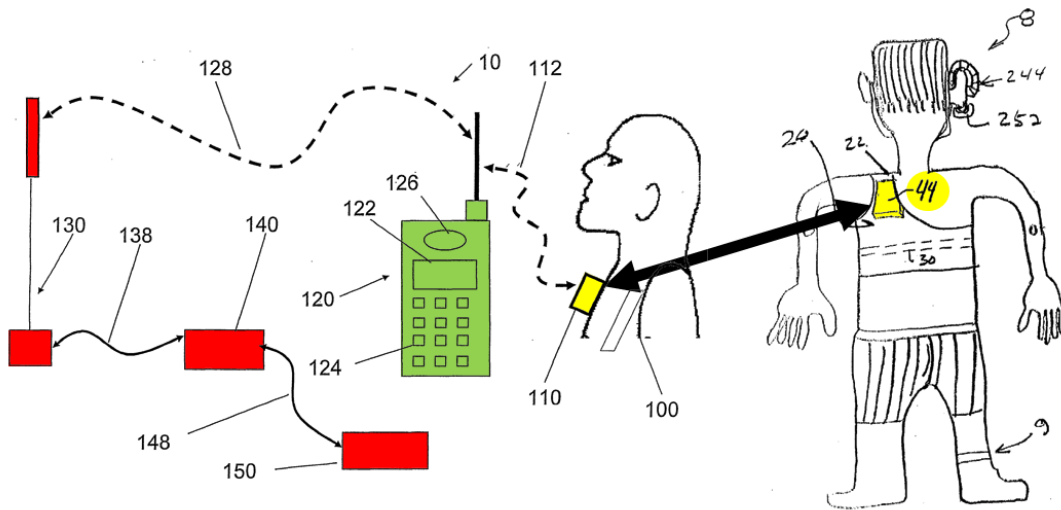
Ex. 1008, FIG. 1 (annotated and excerpted) (left); Ex. 1007, FIG. 1B (annotated and excerpted) (right).

121. It is my opinion that the Ciulla-Orbach sleep diagnostic data acquisition system would have been a predictable combination of known components according to known methods (*e.g.*, communication and data processing methods). The configured system would have produced the predictable result of a cell phone that can send sleep sensor data to a remote location for processing like that claimed.

C. Independent Claim 1

1. **Preamble:** “*A sleep diagnostic data acquisition system comprising:*”

122. I have been asked to assume a scenario where the preamble is limiting. In that scenario, it is my opinion that Ciulla alone or in view of Orbach discloses the preamble. As an overview, this Ground combines Ciulla’s wearable sleep data acquisition system (*e.g.*, Ex. 1007, FIGs. 1A-1B, 8) with Orbach’s communication system including a cell phone to transmit sleep sensor data to a remote computer for processing (*e.g.*, Ex. 1008, FIG. 1). An example of such a configuration follows.



Ex. 1008 (Orbach), FIG. 1 (left) (annotated); Ex. 1007 (Ciulla), FIG. 1B (right) (annotated).

123. Starting with Ciulla, Ciulla discloses a wearable “sleep disordered breathing (SDB) treatment device 10” that includes various sleep sensors. Ex. 1007, [0095], FIGs. 1A-1B, 8. Sensors such as a “breathing sensor” 32 and a “snoring sensor” 36 monitor user vitals and other sleep related information:

A plurality of sensors are fixedly coupled to the chest engaging shoulder wrap 14. The sensors can be permanently affixed to the shoulder wrap 14, or alternately can be removeably coupled, such as through a snap member, to permit the sensors to be replaced when necessary. The sensors include a chest expansion sensor 30, that essentially comprises a tubular member that extends around the chest, and is utilized to measure the expansion of the chest, which provides an indication of the breathing, (or lack thereof) being performed by the patient.

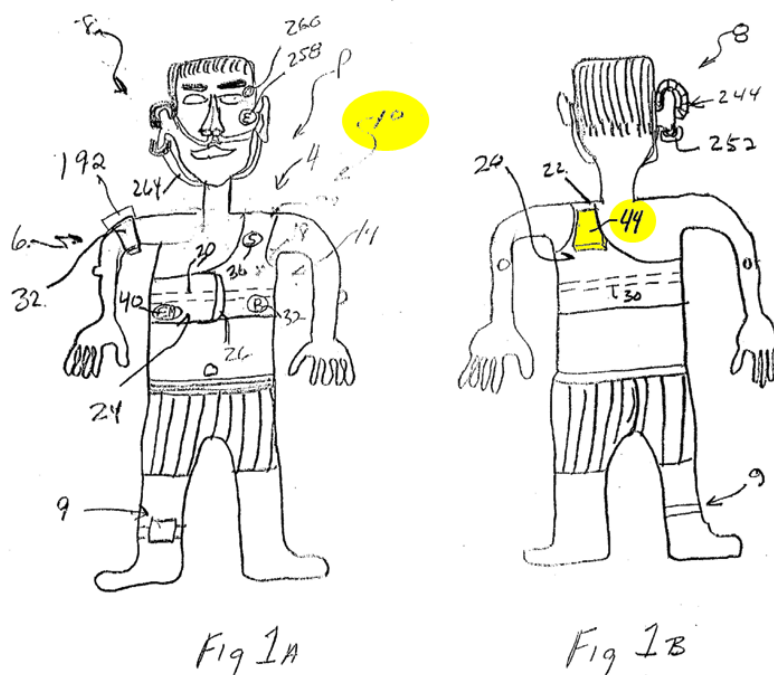
A breathing sensor 32 is positioned adjacent to the chest cavity of the patient, and functions similarly to a stethoscope, insofar as it senses breathing sounds. A snoring sensor 36 is positioned on the shoulder portion 22, to detect snoring sounds and breathing sounds emitted from the mouth and nose of the patient. Snoring sensor 36 essentially comprises a microphone. An EMG sensor 40 may be placed upon the chest or strap portion.

Each of the sensors described above, including chest sensor 30, snoring sensor 36, breathing sensor 32 and EMG sensor 40 are provided with either a hard wire or wireless communication, to provide input to the main module 44 of the device 10. The main module 44 is disposed on the back of the patient, and is best shown in FIG. 8.

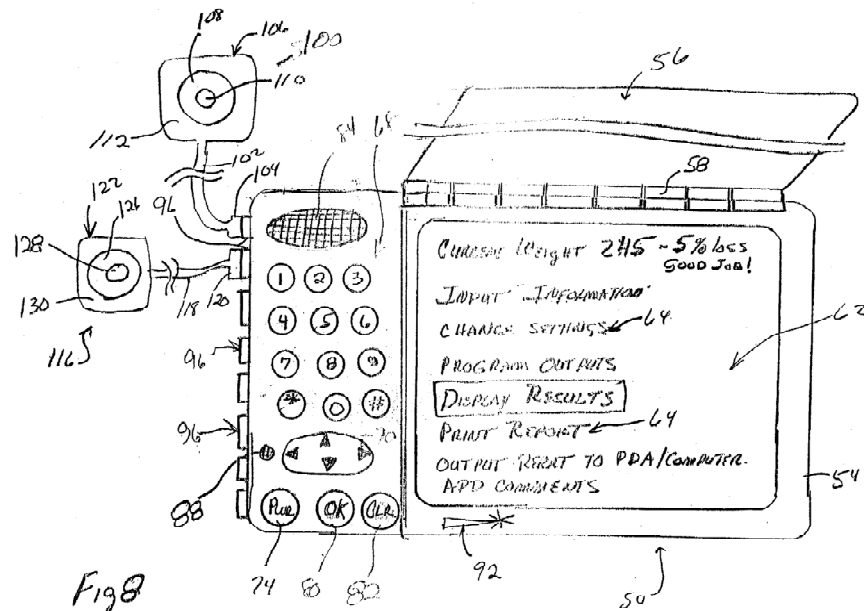
The main module 44 includes a case 50 having a base portion 54 and flip top lid 56 that is hingedly connected to the base portion 54 by a hinge arrangement 58, that can comprise a conventional piano-type hinge, as shown in the drawings, or alternately, a less expensive living hinge. The case 50 houses the electronic circuitry that comprises the “brains” of the device 10, the most component of which is the processor.

Id., [0098]-[0101]. Sensors also include an oximeter 252 that “is provided for sensing the oxygen saturation of the user’s blood,” a sensor for detecting a “patient’s sleeping position (*e.g.* on back, on side, etc.).”. Ex. 1007, FIGs. 1A-1B, [0100], [0118], [0143]. As highlighted above, main module 44 includes “the electronic circuitry that comprises the ‘brains’ of the device 10.” Ex. 1007, [0101], FIG. 8.

Additional features of Ciulla's sleep device 10 are illustrated below in Figures 1A-1B and 8 and provide additional context for the described system.



Ex. 1007, FIGs. 1A-1B (annotated).



Ex. 1007, FIG. 8, [0090] (“FIG. 8 is front, somewhat schematic view of a main module [44] of the present invention.”).

124. Ciulla’s sleep device 10 reports sleep data and “serve[s] as a diagnostic or screening device for [Sleep Disordered Breathing],” such that the sleep device and related features (as modified by Orbach) are *[a] sleep diagnostic data acquisition system:*

The device of the present invention can also contain a disabler of the treatment mode and the device so that the device can be employed and will record and report untreated SDB events. Thus the device can be adjust to serve as a diagnostic or screening device for SDB. Such an embodiment probably would have the oximeter option added. This treatment-disabled mode is useable to evaluate the patient’s response to compliance. Reports of these non-treatment nights can be used to encourage or praise life style improvements with the patient.

....

The device comprises an interactive, rehabilitative robotic for the holistic treatment of all Sleep Disordered Breathing (SDB) syndromes, and simple snoring, which system functions like two separate devices to accomplish said treatment, both using operant and respondent deconditioning and reconditioning processes, and motivational processes. The system's treatment mode can be disabled (becoming a third device) turning it into a full SDB home screening device generating only its data report of events. The treatment system uniquely incorporates humanoid intercessions, intelligently blended with various electronic cues and stimuli, to correct breathing faults, and preserve oxygen saturation, without requiring any uncomfortable equipment on the face or anterior neck.

....

The system is also designed to permit total monitoring, control and analyses to be performed in a different location from where the patient is sleeping by being capable of transmitting data it obtains at any distance, either wirelessly or by a modem.

Ex. 1007, [0219], [0221], [0230]; *see also id.*, FIGs. 1A-1B, 8, Abstract, [0095]-[0108], [0120]-[0125] (describing various features of the sleep device). According to Ciulla, “additional outputs and additional reporting capabilities” can be added so that “[a]ll sensory data and responses...can be recorded and analyzed by [a] researcher and/or medical practitioner.” Ex. 1007, [0213], [0230].

125. As I explain in the following sections of this declaration, the Ciulla-Orbach combination discloses the following additional features of the *sleep diagnostic data acquisition system*. For instance, Ciulla's main module 44 wirelessly communicates sleep sensor data (e.g., blood oxygenation, body position, breathing data) with a cell phone 120 using appropriate software and hardware in the combination. *See* Sections XI.C.2-11. From there, the cell phone transmits the sleep sensor data via a cellular network to a remote server, where a practitioner processes and analyzes the sleep data of a user that is being monitored, analyzed, etc. *See* Sections XI.C.12-15. The combination moreover includes Bluetooth wireless transceivers in the wearable device and cell phone, enabling communication via cell towers between the cell phone and a remote computer for purposes such as display, analysis, diagnosis, and treatment modification. Sections XI.A-C. The specific disclosures discussed below are combined and supported by the motivations to combine and reasonable expectation of success analysis in Sections XI.A-B

2. **[1.a]:** *a first software stored on a non-transitory computer readable medium and executable by a first processor, the software configured to be loaded on a cell phone or Personal Digital Assistant ("PDA") comprising at least one first wireless transceiver and the first processor;*

126. In my opinion, Ciulla in view of Orbach discloses this limitation as I explain in the following analysis.

a. Teachings of Ciulla

127. Ciulla, as I explained previously, discloses that its sleep device 10 is configured to transmit sensor data to a researcher or medical practitioner. *See* Section XI.C.1; Ex. 1007, [0213] (“[A]dditional outputs and additional reporting capabilities” can be added to the user’s sleep device so that “[a]ll sensory data and responses...can be recorded and analyzed by [a] researcher and/or medical practitioner.”), [0219] (“The device of the present invention...can be employed and will record and report untreated SDB events. Thus the device can be adjust to serve as a diagnostic or screening device for SDB.”), [0221] (“The system’s treatment mode can be disabled...turning it into a full SDB home screening device generating only its data report of events.”), [0230].

128. These teachings (with a POSITA’s understanding that there were various ways and benefits for remotely sharing sleep data) would have motivated a POSITA to look to the art for implementing ways to communicate the sleep data to a remote location. While Ciulla does not explicitly disclose the details of these communications, a POSITA would have looked to Orbach for its teachings of a cell phone or PDA with software and corresponding hardware including a first wireless transceiver and a first processor, for receiving sleep data and transmitting it to the remote site. XI.A-B.

b. Teachings of Orbach

129. Orbach, similar to Ciulla, discloses a system for the communication of sensor data. Both systems focus on capturing and transmitting sensor data for various applications, with Orbach emphasizing the use of mobile devices, such as cell phones, to wirelessly transmit sensor information to a remote server for processing.

130. For instance, Orbach discloses “one or more wearable sensor modules sensing...one or more physiological parameters.” Ex. 1008, Abstract. A sensor module 110 is “attached to a user 100” and configured to transmit sensor data to a mobile monitor 120 (which is a “cellular phone or a Personal Digital Assistant (PDA)”) (the claimed *cell phone or PDA*)³ via a wireless communication link 112, as illustrated below in Figure 1 and described in the following passages:

A sensor module 110 is attached to a user 100. A communication link 112 is used to transfer data from the module 110 to a mobile monitor 120. Based on the transferred data the mobile monitor 120 provides visual biofeedback to the user by means of a display 122 and

³ Orbach discloses the mobile monitor 120 is a cell phone or PDA. I primarily rely on Orbach’s cell phone teachings, but it is my opinion that a POSITA would have understood that Orbach’s teachings applicable to the mobile monitor 120 or cell phone would have also applied to a PDA. Ex. 1008, 22:3-23:4.

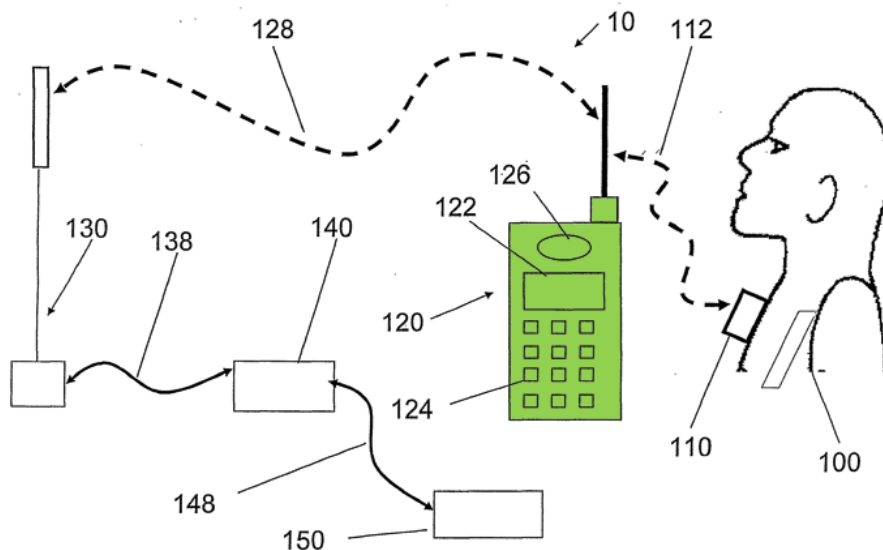
optionally an audio biofeedback to the user by means of speaker 126. Optionally, a keypad 124 is used to control the operation of the mobile monitor 120, sensor module 110, or both. Optionally the user can control the operation using voice recognition methods. Optionally, a communication link 128 is used to connect the mobile monitor 120 to a remote server 140 where in-depth analysis of data obtained by the sensor unit 110 may be done and, optionally, data can be transmitted to an expert or another user. In the exemplary embodiment of Fig. 1, the mobile monitor 130 is a cellular phone, communication link 112 is a Bluetooth link, and communication link 128 is cellular RF link to a cellular base station 130 which is linked to a remote server 140 by a data link 138.

....

In an embodiment of the current invention the sensor module 110 is connected by communication link 112 to a mobile monitor 120. In one preferred embodiment, the mobile monitor 120 is a cellular phone or a Personal Digital Assistant (PDA) equipped with a processor to perform data analysis, memory, a display, Audio output, input means such as keypad, and microphone and sketchpad and means to communicate with both sensor module and remote server. Specific programs necessary for interfacing with the sensor module and for providing feedback to the user may be uploaded by the user. For example, the program may be loaded into a cellular phone wirelessly in the same way a new game or ring tone is loaded. Alternatively, other personal computing devices may be used as mobile monitors, for example a Laptop Personal Computer LPT or a media player such as Apple iPOD®, pocket PC or an electronic note-book.

Alternatively, a standard PC may be used if the user wants to execute a training session without moving around or if the user wants to download data stored in the sensor module periodically or to reprogram the sensor. The communication range of the sensor module is limited due to its small size and low battery capacity to few meters or up to almost 100 meters using Bluetooth. In contrast, the Mobile monitor is equipped with means to connect to a remote server wirelessly over the cell network, preferably using the Internet. For example, cellular phone may be connected using one of the cellular data exchange protocols such as GPRS. Other standard and proprietary protocols may be used such a wired connection to a phone line using a modem or an Asymmetric Digital Subscriber Line (ADSL), a Local Area Network (LAN) Wireless LAN (WAN), etc.

Id., 13:14-27, 22:3-27; *see also id.*, 14:3-15:15.



Id., FIG. 1 (annotated).

131. Orbach (including as modified) discloses a first software stored on a non-transitory computer readable medium and executable by a first processor, the software configured to be loaded on a cell phone or PDA. Similar to my above explanations, Orbach discloses the cell phone is “loaded” with “specific programs necessary for interfacing with the sensor module” (Ex. 1008, 22:4-13), which includes wirelessly receiving sleep data from the sensors (see [1.e]). There is “an application” (together with the programs, forming the first software) that is “loaded into the cellular phone memory” (the claimed non-transitory computer readable medium) and “executed by the processor within the cellular phone” (the claimed first processor). *Id.*, 33:24-26, 22:4-9; *see also id.*, 38:19-22 (stating that the system is “equipped with programmable data processing power”). As configured, it is my opinion that the “application” and programs are “loaded” and therefore also stored in the cell phone’s memory, and are executable by the first processor.

132. Orbach further discloses that *the cell phone* comprises *at least one first wireless transceiver and the first processor*. Orbach recites that its processor is “within” *the cell phone*, meaning the phone comprises *the first processor*:

In the case where the mobile unit 120 is a cellular phone, the data analysis and 25 screen display may be created by an application loaded into the cellular phone memory and executed by the processor within the cellular phone.

Ex. 1008, 33:24-26. Orbach's *cell phone* is "equipped with...means to communicate with both sensor module and remote server," which corresponds to the *first wireless transceiver*. Ex. 1008, 22:4-9. As the POSITA would have understood, such a communications means is a *first wireless transceiver*, which is confirmed by Orbach's depiction in Figure 1 of an antenna as part of the mobile monitor 120. *Id.*, FIG. 1 (*see above*). Orbach's *cell phone* hardware includes a *first wireless transceiver* to enable it to communicate and transmit/receive data over the "Bluetooth" communication link 112 with the sensor module 110, and over the "cellular RF" communication link 128 to a remote server 140:

Optionally, a communication link 128 is used to connect the mobile monitor 120 to a remote server 140 where in-depth analysis of data obtained by the sensor unit 110 may be done and, optionally, data can be transmitted to an expert or another user. In the exemplary embodiment of Fig. 1, the mobile monitor 130 is a cellular phone, communication link 112 is a Bluetooth link, and communication link 128 is cellular RF link to a cellular base station 130 which is linked to a remote server 140 by a data link 138.

....

The communication link 112 is preferably bidirectional and continues while the sensor module is in operation. In such cases, the sensor module transmits information 15 indicative of the user's physiological state to the mobile monitor for display and processing and receives commands and instructions from said mobile module.

Such commands and instruction may control the operation mode of the sensor module. For example, the data sampling rate may be changed by such a command. Additionally or alternatively, data sampling accuracy or range may be changed by such commands. 20 Programs executed by processor 340 may be uploaded and stored in the memory 342.

....

The communication range of the sensor module is limited due to its small size and low battery capacity to few meters or up to almost 100 meters using Bluetooth. In contrast, the Mobile monitor is equipped with means to connect to a remote server wirelessly over the cell network, preferably using the Internet. For example, cellular phone may be connected using one of the cellular data exchange protocols such as GPRS. Other standard and proprietary protocols may be used such a wired connection to a phone line using a modem or an Asymmetric Digital Subscriber Line (ADSL), a Local Area Network (LAN) Wireless LAN (WAN), etc.

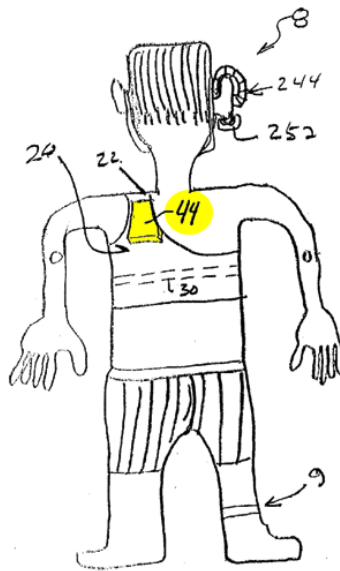
Ex. 1008, 13:14-27, 16:13-20, 22:20-27, FIG. 1.

3. **[1.b]:** *“a portable, wearable patient interface box adapted to be secured to a subject at a first location and providing a single device for measuring and then wirelessly transferring sleep data from at least two sensors used for diagnosing sleep disorders, the portable, wearable patient interface box comprising:”*

133. It is my opinion that Ciulla alone or in view of Orbach discloses this limitation as I explain in the following analysis.

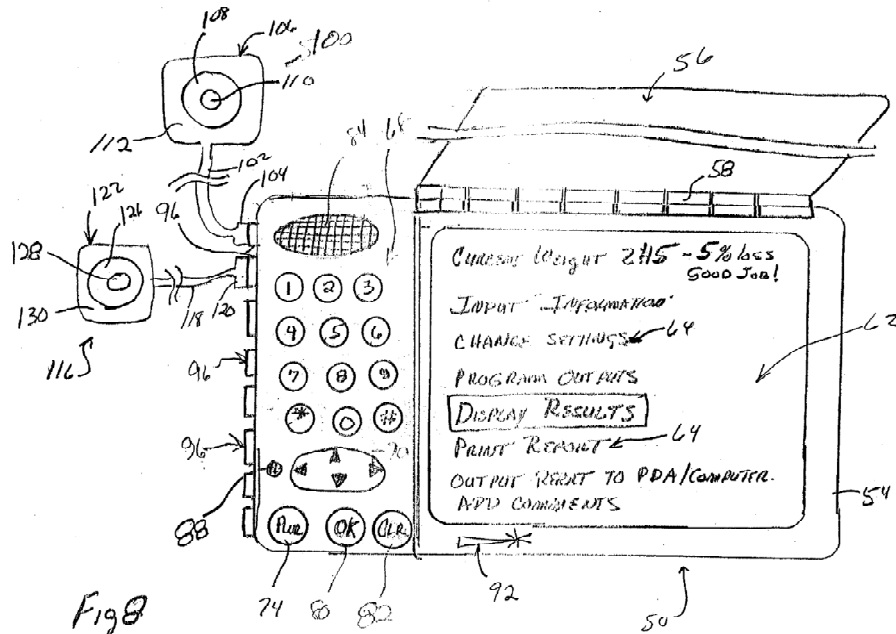
a. Teachings of Ciulla

134. Ciulla's sleep device 10 includes "main module 44," which is *a portable, wearable patient interface box*. Ex. 1007, [0095], [0100], FIGs. 1B, 8.



Ex. 1007, FIG. 1B (annotated). Main module 44 is *portable, wearable, and adapted to be secured to a subject* because it includes "batteries" and can be worn "on the back of the patient" as the patient sleeps, walks around, and otherwise goes about their day. Ex. 1007, [0078]-[0079], [0095], [0100] ("[M]ain module 44 is disposed on the back of the patient."), [0102] ("[B]atteries provide the power for the main module 44 to operate."), [0183], [0185] ("The device [] does not need to be removed if the patient gets up, walks around, or changes the place they are sleeping in. Patients can sit in their living room and watch television or read, etc. and not worry

about falling asleep without having their SDB treatment device on and activated.”),
FIGs. 1A-1B.



Ex. 1007, FIG. 8, [0090] (“FIG. 8 is front, somewhat schematic view of a main module [44] of the present invention.”).

135. It is my opinion that Ciulla’s main module 44 is a *patient interface box* just like that claimed. For additional context, the ’512 Patent discloses that an interface box includes a device that protects electrical components, allows the connection of various sensors, and can be secured to or held by a subject:

[A]n interface box which is preferably used to protect one or more electrical components and allow for the connection of various sensors to the electrical components inside the interface box. The interface box is preferably intended to be secured to or held by the subject. The box will preferably have electrical connectors incorporated in

to the structure of the interface box, so that various sensors can be connected to the box and through to the electrical components inside the interface box.

Ex. 1001, 7:15-24. Just like that described by the '512 Patent, Ciulla's main module 44 includes a case 50 that protects and "houses the electronic circuitry that comprises the 'brains'" of sleep device 10. Ex. 1007, [0101], [0126]. The main module also contains sensor data processing circuits, along with communication jacks and ports, enabling the user (*patient*) to connect and *interface* various sensors to the internal electrical components for interaction with the system. *Id.*, [0101]-[0107], [0112], [0121]-[0123], [0126]-[0128], FIGs. 1B, 8. Additionally, the main module 44 is equipped with an input device 66, buttons, and an LCD display, which together offer a *patient interface*, allowing the user to control the sleep system. *Id.*, [0101]-[0107], [0112], [0121]-[0123], [0126]-[0128], FIGs. 1B, 8.

136. In my opinion, Ciulla's main module 44 (*box*) *provid[es] a single device for measuring and wirelessly transferring* like that claimed. Ex. 1007, FIGs. 1B, 8, [0079], [0090], [0100], [0123], [0126], [0128]. Ciulla depicts and describes the main module 44 as a *single device*. Ex. 1007, [0079], [0090], [0100], [0176] ("a single device to be used with a series of many patients"), FIGs. 1B, 8. Main module 44 also is *for measuring...sleep data from at least two sensors*. For instance, main module 44 is connected to *at least two sensors* (e.g., an attitude sensor; a breathing sensor 32; a snoring sensor 36; an oximeter; nasal cannula-type sensor 264; heart

rate monitor), which sense data while the user is sleeping (***sleep data from at least two sensors***) and communicate the sensed data to the main module 44. Ex. 1007, [0100], [0106]-[0107], [0118]-[0119], [0121], [0123]-[0126], [0128] (“downloading data...about the condition of a patient during a sleeping episode. This information can include...the information sensed from the patient”), [0143], [0202], [0219], [0230] (“total monitoring, control and analyses to be performed in a different location from where the patient is sleeping”), [0145], FIGs. 1A-1B, 8; *see* Section XI.C.1. The main module 44 ***measur[es]*** ***sleep data*** by converting analog sensor data to digital data and/or “processing the information sensed” to, for instance, “distinguish[] between snoring...[and] total obstruction.” Ex. 1007, [0060], [0067], [0073], [0123], [0126], [0128], [0204] (“analog to digital converter”). Moreover, main module 44 receives and ***measur[es]*** the ***sleep data*** (Ex. 1007, Abstract, [0060], [0106], [0123], [0126]), which is consistent with the ’512 Patent’s generic description that the system’s sensors measure various physiological parameters that are then transmitted to an interface box that also measures the data (Ex. 1001, 3:23-24 (“one or more sensors for measuring”), 8:67-9:9 (“These sensors or devices, also preferably measure....”), 10:5-6 (“Other sensors can be used to measure various parameters of a subject’s physiological condition.”), 20:57-67 (“two sensors adapted . . . to measure”)). Thus, Ciulla’s main module 44 ***measures*** sleep data from various sensor inputs as a ***single device***, just like the single device the ’512 Patent describes.

Ex. 1001, FIG. 2, 16:62-17:48 (“The present invention provides a single device for measuring such widely disparate signal types...”). Indeed, the single device disclosed by Ciulla can be hardwired to other sensors, just like that claimed in the ’512 Patent. *See, e.g.*, [1.b.iii] (“the portable, wearable patient interface box comprising...at least two sensors further which are hardwired to connect through at least one connector of the portable, wearable patient interface box”); *infra*, XI.C.6.

137. In Ciulla, the *sleep data* and *sensors* are *used for diagnosing sleep disorders*. Ex. 1007, [0123], [0128], [0200], [0202], [0219], [0230]. For instance, Ciulla discloses that the sensor data is recorded and reported and that the device “serve[s] as a diagnostic or screening device for SDB” (Sleep Disordered Breathing). Ex. 1007, [0219]; *see also id.*, [0126], [0128], [0200], [0213], [0221], [0230].

138. Next turning to *wirelessly transferring* the *sleep data*, Ciulla’s main module 44 includes “a radio frequency transmitter and receiver for wireless communication”:

Additional componentry can include a voice chip, a non-volatile memory, such as a smart card, and various cableing and wires to provide communication, along with a radio frequency transmitter and receiver for wireless communication. A power source, such as a plurality of batteries provide the power for the main module 44 to operate.

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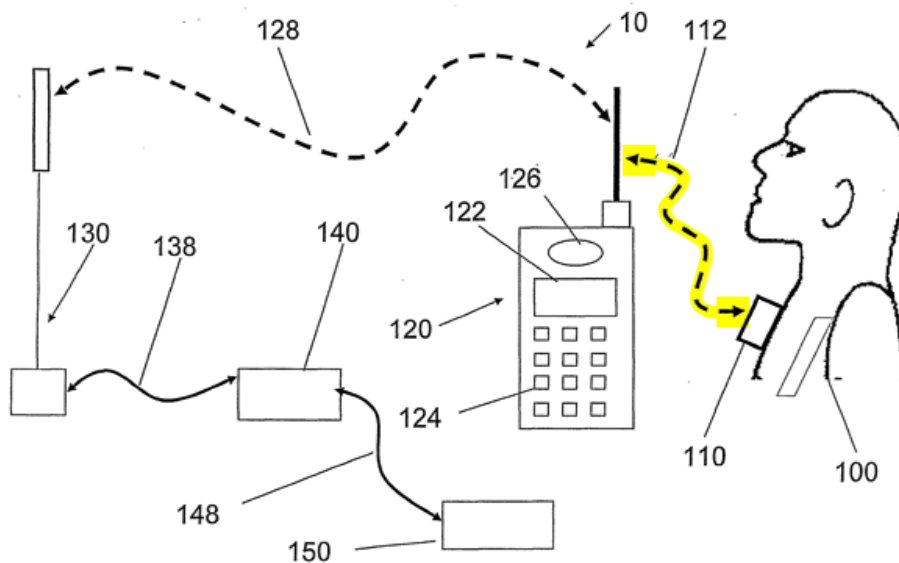
An internal, transmitter/receiver/ antenna 92 is provided for enabling the main module 44 to communicate wirelessly with the various sensors and output devices of the present invention. A plurality of jacks and/or plug receivers and/or ports (collectively referred to herein as “ports”) 96 are provided on the main module 94 for enabling the main module 44 to be hard-wired to various sensor-type input devices and/or output devices.

Ex. 1007, [0102], [0106], FIGs. 1A-1B, 8. Ciulla’s device, which in my opinion a POSITA would have understood to be the main module 44, “transmit[s] the multiple sensors’ outputs wirelessly (RF, BlueTooth, WAN, LAN, IT Ethernet Modem or other).” Ex. 1007, [0213]; *see also id.*, [0219], [0221], [0230]. “The system is also designed to permit total monitoring, control and analyses to be performed in a different location from where the patient is sleeping by being capable of transmitting data it obtains at any distance...wirelessly.” *Id.*, [0230]. Thus, a POSITA would have understood that Ciulla’s main module 44 **wirelessly transfer[s] sleep data** just like that claimed. Ex. 1007, [0102], [0106], [0123], [0126], [0128], [0213], [0219], [0221], [0230]; *see* Section XI.C.1.

139. I have also been asked to assume a scenario wherein Ciulla does not explicitly disclose **wirelessly transferring sleep data or a portable, wearable patient interface box** like that claimed. As to that scenario, it is my opinion that this feature would have been obvious in view of Orbach.

b. Teachings of Orbach

140. Orbach's sensor module 110, which is similar to Ciulla's main module 44 (see Section XI.B), transmits sensor data wirelessly over a "Bluetooth" communication link 112 to a cell phone (*wirelessly transferring*) as I discussed previously. Ex. 1008, 13:14-27 ("communication link 112 is a Bluetooth link"), 15:9-15 ("a wireless communication link is used...."blue-tooth" RF bidirectional wireless communication"), 16:9-20 ("sensor module transmits information indicative of the user's physiological state to the mobile monitor"), 22:20-27, 41:13-15, FIG. 1; Section XI.C.2.



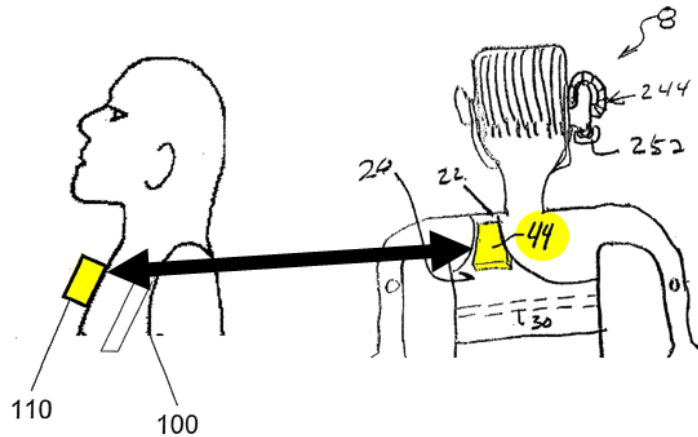
Ex. 1008, FIG. 1 (illustrating wireless communication between cell phone 120 and sensor module 110). The data is used to "help identify and possibly correct sleep disorders" as *sleep data*:

According to another embodiment of the invention, the system may be used to record physiological reading while the user is sleeping in order to help identify and possibly correct sleep disorders.

Ex. 1008, 41:25-27, FIG. 1.

141. Orbach's sensor module 110, just like Ciulla's main module 44, is ***a portable, wearable patient interface box***. The device 110, as depicted in Figures 1 and 2 on the user's chest (but can also be attached to another part of the body), is designed to be worn by the user (***wearable***) as a single unit, making it convenient and comfortable for continuous monitoring. The user can wear the device on various parts of the body, depending on the specific design and intended function. Ex. 1008, FIGs. 1-3, 13:14-16:20. As to ***portable*** features, the inclusion of a battery 360 makes the device portable, allowing it to be used without needing to be plugged into a power source. *Id.* This portability is crucial, as it ensures that the device can be worn continuously throughout the day or night, enabling real-time data collection without interruptions. *Id.* The battery allows the device to function independently, providing flexibility in its usage, whether the user is at home, at work, or traveling. *Id.* Overall, the combination of a single wearable design and a portable battery makes device 110 highly practical for users who need ongoing, non-invasive monitoring in various settings. *Id.* The module 110 is coupled to various sensors, including a Plethysmograph Electronics 320 and "additional sensors 372," "to

monitor one or more additional physiological signals” of a monitored user as a *patient interface* and “measur[e]” blood flow by optical reflectance, etc. that is wireless transmitted as I explained previously (*measuring and then wirelessly transferring*). Ex. 1008, FIGs. 1-3, 13:14-16:20, 13:14-27, 15:9-15, 16:9-20, 22:20-27, 41:13-15. Orbach further discloses that the sensor module 110 **box** includes an indicator 380 that “provides visual or audio indication as to the status of the module” to the monitored patient (“*patient interface*”). Ex. 1008, 15:4-8.



Ex. 1008, FIG. 1 (annotated and excerpted) (left); Ex. 1007, FIG. 1B (annotated and excerpted) (right).

* * *

142. It is my opinion that Ciulla’s **box** (including as modified by Orbach) further comprises limitations 1.b.i-1.b.iv as I explain in the following sections.

discourage supine position which promotes snoring.” Ex. 1007, [0143], FIG. 1B. When such electronics are placed on the shoulder area, a POSITA would have understood that a ***rigid enclosure*** would have discouraged sleeping in the supine position, and that only a ***rigid*** construction would have prevented the module from flattening and crushing or breaking the circuitry. A POSITA would have understood the case 50 is a ***rigid enclosure*** at least because it has a “flip top lid 56 that is hingedly connected to the base portion 54” by a “piano-type hinge.” Ex. 1007, [0101]. Moreover, a ***rigid enclosure*** would have been obvious in view of the main module 44 housing an LCD display and a keypad. Ex. 1007, [0101], [0103]-[0104], FIG. 8. A POSITA, for example, would have understood that ***enclosures*** for a conventional LCD screen and keypad are ***rigid***, and that a hinge implies the ***enclosure*** is rigid, as a lack of rigidity for the screen, keypad, or hinge would reduce the performance of each. Ex. 1007, [0101], [0103]-[0104], FIG. 8.

5. [1.b.ii]: “a battery”

145. It is my opinion that Ciulla alone or in view of Orbach discloses this limitation. For instance, Ciulla discloses that “batteries” power main module 44:

The main module 44 includes a case 50 having a base portion 54 and flip top lid 56 that is hingedly connected to the base portion 54 by a hinge arrangement 58, that can comprise a conventional piano-type hinge, as shown in the drawings, or alternately, a less expensive living hinge. The case 50 houses the electronic circuitry that comprises the

“brains” of the device 10, the most component of which is the processor.

Additional componentry can include a voice chip, a non-volatile memory, such as a smart card, and various cableing and wires to provide communication, along with a radio frequency transmitter and receiver for wireless communication. A power source, such as a plurality of batteries provide the power for the main module 44 to operate.

Ex. 1007, [0101]-[0102], FIGs. 1, 8. Indeed, Ciulla’s **box** includes **batteries** that allow the main module 44 to operate, which is consistent with that illustrated in Figures 1B and 8 that do not illustrate externally accessible batteries. *Id.*, [0101]-[0102], FIGs. 1B, 8.

146. To the extent Ciulla does not explicitly disclose a **battery** within the **box**, it is clear that the conventional configuration would have been obvious. For example, a POSITA would have understood that Ciulla’s **batteries** are an example of “[a]dditional componentry” that is “house[d]” within the case 50. Ex. 1007, [0101]-[0102]. Moreover, Orbach’s FIGs. 2-3 depict a battery 360 as part of the “sensor module.” Ex. 1008, FIGs. 2-3, 14:4-16:2. A POSITA would have found an internal battery obvious and had a reasonable expectation of success in implementing such a standard battery configuration. For instance, a POSITA would have appreciated that there are recognized medical device consensus standards, such as IEC 60529, which have been developed to rate and grade the resistance of

enclosures of electric and electronic devices against the intrusion of dust and liquids. It also rates how easy it is for individuals to access the potentially hazardous parts within the enclosure. The first edition of IEC 60529 was published in 1976 with the aim of creating a single document to bring together all requirements regarding protection by enclosures, including enclosed battery configurations. It is my opinion that it would have been obvious to implement such a well-known and beneficial configuration. Moreover, a POSITA would have appreciated that an internal **battery** would have avoided disadvantages associated with an external battery, such as susceptibility of being disconnected due to the user's movement. An internal **battery** would have therefore increased the wearability of main module 44, and protected the battery from the user and external environment, consistent with known configurations and medical standards.

6. **[1.b.iii.A]:** *“one or more electrical components within the portable, wearable patient interface box for receiving electrical signals from the at least two sensors, the one or more electrical components include a signal processing unit for receiving the electrical signals from the sensors, [1.b.iii.B]: the at least two sensors which are attached to the subject and/or within the portable, wearable patient interface box that is secured to the subject, [1.b.iii.C]: the at least two sensors further which are hardwired to connect through at least one connector of the portable, wearable patient interface box and/or are built within the portable, wearable patient interface box, [1.b.iii.D]: the signal processing unit configured for receiving and processing*

the sleep data from one or more input channels; and,”

147. It is my opinion that Ciulla alone or in combination with the knowledge of a POSITA discloses this limitation as I describe in the following analysis.

148. For [1.b.iii.A], Ciulla discloses one or more electrical components within the main module 44 (box, see my above discussions in Section XI.C.3) for receiving electrical signals from various sensors (the at least two sensors, see Section XI.C.3), *the one or more electrical components include a signal processing unit for receiving the electrical signals from the sensors*. Ciulla discloses that main module 44 “houses electronic circuitry that comprises the ‘brains’ of the device 10”:

The main module 44 includes a case 50 having a base portion 54 and flip top lid 56 that is hingedly connected to the base portion 54 by a hinge arrangement 58, that can comprise a conventional piano-type hinge, as shown in the drawings, or alternately, a less expensive living hinge. The case 50 houses the electronic circuitry that comprises the “brains” of the device 10, the most component of which is the processor.

Ex. 1007, [0101]; *see also id.*, [0100]-[0102], [0121], [0126]. A “microprocessor” (*one or more electrical components includ[ing] a signal processing unit*) within main module 44 *receiv[es] electrical signals from the [at least two] sensors* because it “receiv[es] a wide variety of inputs from various sensors.” Ex. 1007, [0126]; *see also id.*, [0101], [0120]-[0121] (“The device includes a plurality of sensors that transmit information into the main back module, that relate to the various conditions

of the patient.”), [0123] (“The main back module includes a microprocessor for processing the information sensed by the sensor...”), [0202], FIGs. 1B, 8.

149. Ciulla’s microprocessor (which Ciulla interchangeably refers to as a CPU or processor) is an *electrical component* like that claimed and includes *a signal processing unit* at least because it “*process[es]* the information sensed by [a] sensor,” which a POSITA would have understood to include *signals*. Ex. 1007, [0123]; *see also id.*, [0060] (“a processor for receiving sensor inputs, processing the received sensor inputs, and generating commands”), [0116] (describing signals received from various sensors), [0125]-[0128], [0142], [0172], [0202].

150. For [1.b.iii.B], Ciulla discloses *the at least two sensors which are attached to the subject and/or within the portable, wearable patient interface box that is secured to the subject*.⁴

⁴ I understand here that this disjunctive “or” included in this claim limitation specifies the claim limitation is met if the at least two sensors are A) *attached to the subject* or B) *within the portable, wearable patient interface box*. It is my understanding that a plain reading of the claims is that the backslash means “and” or “or.”

151. Ciulla discloses both configurations. Ciulla discloses that the various sleep sensors of the system (*at least two sensors*) are *attached to the subject*. For example, an oximeter is attached to an “earlobe” or “finger”:

The sensors that can be coupled to the ear-engaging processing unit 238 include an earlobe oximeter 252, that is provided for sensing the oxygen saturation of the user’s blood. An EMG sensor 256 can also be coupled to the ear-engageable processing unit. An EEG sensing electrode 258 is used alone, or in tandem with a combination EOG+EEG sensor 260 can be provided for sensing brain wave information of the user. An EOG sensor is also provided as a part of the combined EOG and EEG sensor.

....

The main sensor inputs analyzed by the microprocessor to accomplish the device’s purposes include, preferably, a piezo-electric snore monitor, a small breath sounds microphone, a heart rate sensor, an attitude monitor, and an upper chest expansion sensor (either strain gauge, piezo, pneumatic tubing or other), all of which are well known in the art and commercially available. Additional options that can be included in various embodiments of the design can include an EMG muscle tension probe (either on the inferior portion of the sternocleidomastoid or the lateral intercostal area above the diaphragm), a thin non-obtrusive oral nasal airflow canula (such as the canula sold by ProTech) with the transducer in the shoulder module, an oximeter (with probe on finger, earlobe, or toe)....

Ex. 1007, [0118], [0202], FIG. 1B. A snore sensor 36 is “secured on the chest”:

Preliminary investigations indicate that lateral tracheal placement of those small sensors is avoidable, and the upper anterior chest wall provides reliable detection of snoring. This snore sensor is also secured on the chest by the Velcro harness. A small microphone is also connected to the CPU, and can be placed on the anterior chest or on the lateral subaxillary chest wall. The microphone is also directly wired to the CPU and secured by the harness. An attitude monitor for determining the patient's sleeping position (e.g. on back, on side, etc.) is also placed preferably over the scapular as opposed to the arm, as such placement helps to discourage supine sleeping which promotes snoring. Preferably the attitude sensor is made a part of the CPU containing main module. The sensor used to monitor upper chest expansion is either built into the harness, or is separate, but is securely held down onto the patient by the harness.

Id., [0143]. An attitude sensor is placed “over the scapular.” *Id.* Ciulla further discloses that a breathing sensor 32 is attached to the chest of the subject by a shoulder strap. *Id.*, [0098]-[0099], FIG. 1A. Figures 1A and 1B and their descriptions also describe several other sensors that are attached to the subject, including elements 30, 40, 252, 258, and 260. *Id.*, FIGs. 1A-1B, [0098]-[0099], [0118]-[0119], [0144]. For the ***within...the box*** claim limitation, Ciulla also discloses that the attitude sensor or other sensors (*e.g.*, breath sounds monitor, snore monitor, heart rate monitor, and/or chest expansion module) are “designed to be incorporated within the main back module”:

It is likely that the proximity between the main back module and the shoulder vibrator, and shoulder stimulator will likely cause these to be connected to the main back module through a hard-wired connection. Additionally, breath sounds monitor, snore monitor, heart rate monitor an attitude indicator, and/or chest expansion module, may be designed to be incorporated within the main back module as a part thereof, and as such, would be connected to the main back module for a hard-wired connection.

....

Preliminary investigations indicate that lateral tracheal placement of those small sensors is avoidable, and the upper anterior chest wall provides reliable detection of snoring. This snore sensor is also secured on the chest by the Velcro harness. A small microphone is also connected to the CPU, and can be placed on the anterior chest or on the lateral subaxillary chest wall. The microphone is also directly wired to the CPU and secured by the harness. An attitude monitor for determining the patient's sleeping position (e.g. on back, on side, etc.) is also placed preferably over the scapular as opposed to the arm, as such placement helps to discourage supine sleeping which promotes snoring. Preferably the attitude sensor is made a part of the CPU containing main module. The sensor used to monitor upper chest expansion is either built into the harness, or is separate, but is securely held down onto the patient by the harness.

Id., [0124], [0143] (“a part of the CPU containing main module”). In this configuration, such a sensor would be within the main module 44 (**box**). *Id.*, [0101], [0124], [0126], [0142], FIGs. 1B, 8. As I explained for limitation [1.b], the **box** is

secured to the subject because it is attached to the patient's shoulder area. *Id.*, [0095]-[0098], FIG. 1B.

152. For [1.b.iii.C], it is my opinion that Ciulla further discloses the at least two sensors further which are hardwired to connect through at least one connector of the portable, wearable patient interface box and/or are built within the portable, wearable patient interface box.⁵ Ciulla discloses both of these configurations.

153. For the *hardwired* configuration, Ciulla discloses “hard wir[ing]” sensors (such as breathing sensor 32 and snore sensor 36) through “jacks” or “ports” 96 (*connector*) of main module 44 (*box*). Ex. 1007, [0100], [0106], [0145], FIGS. 1A-1B, 8. For the *built within the... box* configuration, Ciulla also discloses that the attitude sensor ⁶ or other sensors are “incorporated within the main back module” or placed “over the scapular.” *Id.*, [0124], [0143]; *see also id.*, [0143] (“a part of the CPU containing main module”).

154. I have been asked to assume a scenario wherein Ciulla does not explicitly disclose hardwiring the fingertip-based pulse oximeter or nasal cannula-

⁵ *See supra* n.3.

⁶ Ciulla interchangeably refers to an “attitude indicator,” an “attitude monitor,” and an “attitude sensor.” Ex. 1007, [0121], [0139], [0143]. My Declaration refers to any of these as an attitude sensor.

type sensor 264 to *connect through at least one connector of the...box*. See also my below discussions in XI.C.8. As to that scenario, it would have been obvious to use standard wired sensors, hardwired to the main module 44 through a connector (e.g., a jack, port, etc.). As I discussed previously, Ciulla discloses that its sleep device “can be constructed using off-the-shelf sensor inputs,” and that the use of such “standard” sensors would “help reduce production costs.” Ex. 1007, [0204], [0072], [0226] (“Standard sensors...can be employed for miniaturization and convenience.”). Moreover, wired fingertip pulse oximeters and nasal cannula/pressure sensors were standard and ubiquitous prior to the alleged date of invention. Indeed, the configuration, exemplified with the below passages, was well-understood before the alleged time of invention:

A schematic representation of a pulse oximeter system 100 attached to a patient's fingertip 102 is presented in FIG. 1. The patient's hand 104 is typically not immobilized and is free to move throughout the measurement time interval. The sensor head 106 containing the LEDs and detector is attached to the patient's fingertip 102. The sensing head 106 is coupled to the main signal processing unit 108 by an interconnect 110. The interconnect 110 may be electrical or optical. The system may include a data display 112 for displaying the measured level of hemoglobin oxygen saturation, and any other information.

Ex. 1019, FIG. 1, [0035].

As shown in FIG. 1, the present invention is comprised of a portable or wearable processing and recording unit 10 that can be worn by a subject on the chest (as shown) or elsewhere on the Subject. The processing and recording unit 10 can be connected to sensing devices. Such as a microphone 12 for sampling Snoring/breathing Sounds, a nasal cannula 14 for sensing airflow, a SpO2/pulse finger sensor 16 for measuring pulse and blood oxygen saturation, and respiratory effort sensors 18 and 20 for measuring chest and abdominal respiratory effort, respectively. Processing and recording unit 10 can be affixed to the subject, or attached to the subject via a strap that goes through the gull wings 22 and around the Subject's thorax, or arm or other extremity.

....

[C]onnector 32 is used to connect a nasal or nasal/oral cannula 14 to the processing and recording unit 10. When a subject wearing nasal or nasal/oral cannula 14 inhales or exhales, the air pressure at the nose, or nose and mouth, is transmitted to a pressure conducting tube 44 which is connected to the internal pressure sensor module 72. The pressure measurements measured by the internal pressure sensor module 72 are used by the microprocessor to indicate airflow and to derive airflow output.

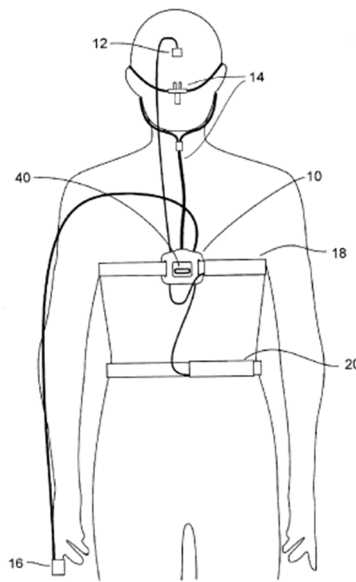


Fig. 1

Ex. 1020, [0024], [0040] FIG. 1.

FIG. 7 illustrates a perspective view of a pulse oximeter finger clip 98 connected to a hand 87 of a user. The pulse oximeter finger clip 98 is connected to the supplemental circuit board 130 via a pulse oximeter cable 101.

....

A nasal canula/thermistor 246 measures breathing through a patient's nose, and the data therefrom is input into a pressure.

Ex. 1021, 11:16-38, 12:53-56, FIGs. 7, 10.

Further, any transdermal sensor may be incorporated into the illustrated monitoring apparatus. Such sensors may include pulse oximeters, which measure hemoglobin saturation in a finger, blood pressure sensors of various types, transdermal sensors indicative of blood chemistry, for example, blood glucose sensors or sweat electrolyte sensors, and so forth. signals from these sensors may reach

micro processor module 17 over signal cable 16. Preferably, these sensors will present a standard interface to the microprocessor module, for example an RS-232 or more modem serial interface. Further, it may be advantageous to obtain more complete ECG information, such as by receiving signals from 7 or 12 leads placed in manners well known in the art. A further additional sensor may be a throat micro phone, which is useful for detecting Snoring during sleep and talking during wakefulness. Detection of snoring during sleep is a valuable indication of incipient or actual upper airway obstruction useful in sleep apnea studies. In such an embodiment, the microprocessor module may accumulate information reflecting a broad array of transdermally measurable physiological parameters in a scandalized ??? [sic] manner and in a standardized format.

Ex. 1022, [0086]; Ex. 1023, 7:5-9, FIG. 2; Ex. 1024, 1:9-19, FIG. 1, 2:65-3:3; Ex. 1025, [0092], [0106] (describing wire connected to a nasal pressure sensor).

155. For [1.b.iii.D], Ciulla discloses the signal processing unit configured for receiving and processing the sleep data from one or more input channels. The main module 44 processor (signal processing unit) receives the sensor data (sleep data) from the various sensors of Ciulla's sleep device 10. Ex. 1007, [0126] ("the microprocessor that is contained within the shoulder unit, is the 'heart and brains' of the device, that is provided for receiving a wide variety of inputs from various sensors"); *see also id.*, [0060] ("a processor for receiving sensor inputs, processing the received sensor inputs, and generating commands"), [0101], [0121] ("The device

includes a plurality of sensors that transmit information into the main back module, that relate to the various conditions of the patient.”), [0127]-[0128], [0142], [0172], [0202].

156. Moreover, Ciulla’s processor (*signal processing unit*) within the main back module is “for processing the information sensed by the sensor” (*id.*, [0123]) and “process[es] the received sensor inputs (*id.*, [0060]). This information corresponds to the patient’s *sleep data* because it is sensor data measured during sleep, and is input *from input channels such as* an input jack, “two channel EEG leads,” or another *input channel* for sensed oximeter or attitude data. Ex. 1007, [0101], [0118], [0121], [0123], [0124], [0126], [0128], [0143], [0202], [0230]. Indeed, the main module 44 *receives* and *processes* sensor inputs from various communication channels. *Id.*, FIG. 8, [0106], [0124], [0143], [0202], [0219], [0230]. As a POSITA would have readily understood, each sensor has at least one *input channel*, over which the *sleep data* is *received* by the processor.

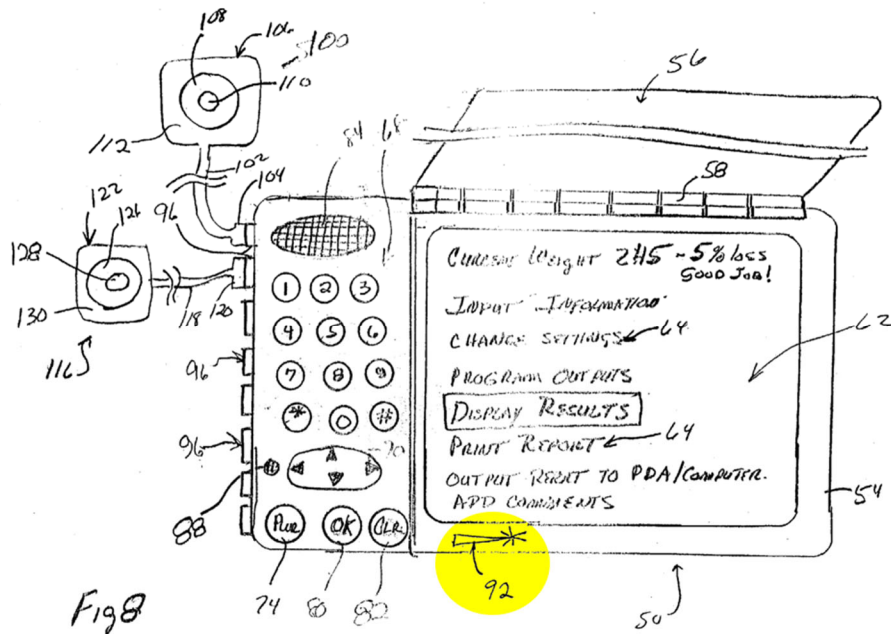
7. [1.b.iv.A]: “a second wireless transceiver or transmitter is adapted for operating at frequencies above 2 GHz and
[1.b.iv.B]: transmitting the sleep data collected with the portable, wearable patient interface box wirelessly to the at least one first wireless transceiver of the cell phone or PDA with the first software loaded;”

157. It is my opinion that Ciulla in view of Orbach discloses this limitation.

158. For [1.b.iv.A], main module 44 (*box*, see Section XI.C.3) includes antenna 92 and associated hardware (*second wireless transceiver or transmitter*) that “enabl[es] the main module 44 to communicate wirelessly”:

An internal, transmitter/receiver/ antenna 92 is provided for enabling the main module 44 to communicate wirelessly with the various sensors and output devices of the present invention. A plurality of jacks and/or plug receivers and/or ports (collectively referred to herein as “ports”) 96 are provided on the main module 94 for enabling the main module 44 to be hard-wired to various sensor-type input devices and/or output devices.

Ex. 1007, [0106], FIG. 8; *see also id.*, [0100] (“wireless communication, to provide input to the main module 44 of the device 10”), [0125] (“wireless transmitter/receiver within the main back module could be used to transfer data”). The main module 44 uses its *wireless transceiver or transmitter* to transmit information over “Bluetooth.” Ex. 1007, [0144] (“receives...wirelessly (regular RF, Bluetooth, or other) from the CPU in the main module”); Section XI.A-B, XI.C.2-3.

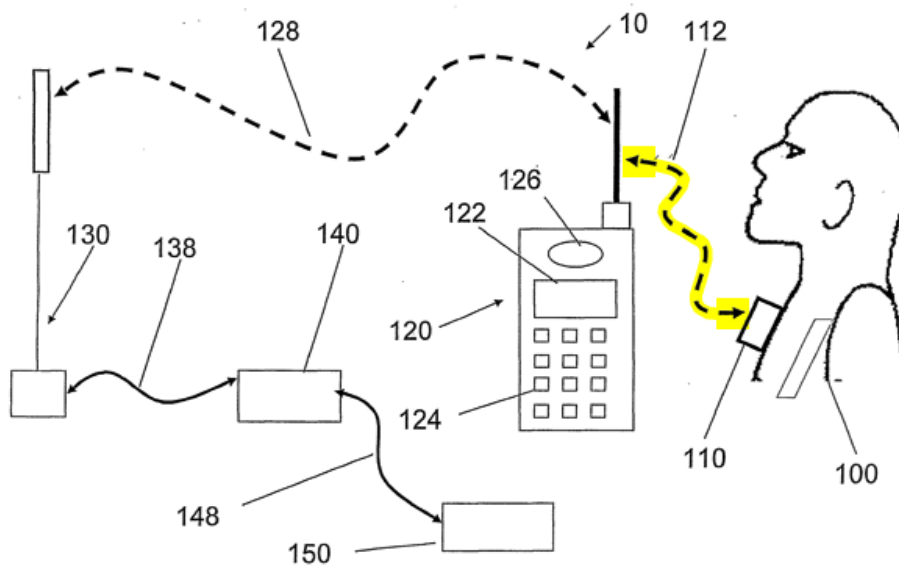


Ex. 1007, FIG. 8 (annotated to highlight antenna 92). As a POSITA would have understood, Bluetooth operates around 2.4 GHz, which means that Ciulla's *second wireless transceiver or transmitter is adapted for operating at frequencies above 2 GHz*. See generally Ex. 1017, 18 (describing Bluetooth “operating in the 2.4 GHz ISM band.”). For instance, Bluetooth technology operates in the 2.4 GHz frequency range, specifically within the globally unlicensed Industrial, Scientific, and Medical (ISM) band. This frequency range is chosen because it allows for worldwide compatibility, eliminating the need for region-specific adaptations. The 2.4 GHz band also supports robust communication over short ranges, typically within 10 to 100 meters, depending on the Bluetooth class and environmental factors. Bluetooth’s use of this frequency enables reliable wireless communication for a wide range of devices, including wearable sensors, smartphones, and other portable

electronics. The 2.4 GHz band is particularly suited for low-power devices, making it an ideal choice for battery-operated systems like those in sleep monitoring or medical applications. This frequency range's widespread adoption and efficiency ensure compatibility between Bluetooth-enabled devices and enable seamless data exchange, a critical feature for applications such as transmitting sensor data from a wearable device to a smartphone or remote server.

159. For [1.b.iv.B], and as I explained for [1.b], the main module 44's *second wireless transceiver or transmitter* wirelessly transfers *(transmits...wirelessly) the sleep data*. See Section XI.C.3; Ex. 1007, [0100], [0106], [0125], [0144]. As explained for [1.b.iii], the *box's* processor receives the *sleep data*, which means the *sleep data* is *collected with the...box*. See Section XI.C.6.

160. In the combination with Orbach as I discussed previously, Ciulla's main module 44 wirelessly transfers and therefore *transmits* the sensor data (*sleep data*) to Orbach's communication means (*the at least one first wireless transceiver of the cell phone with the first software loaded*). See Sections XI.A-B, XI.C.2-3; Ex. 1007, [0102], [0106], [0123], [0126], [0128], [0213], [0219], [0221], [0230]; Ex. 1008, 13:14-27, 15:9-15, 16:9-20 ("sensor module transmits information indicative of the user's physiological state to the mobile monitor"), 22:20-27, 41:13-15.



Ex. 1008, FIG. 1 (illustrating wireless communication between cell phone 120 and sensor module 110).

8. [1.c]: “the at least two sensors are selected from a group consisting of: accelerometer(s), pulse oximeter(s) including fingertip pulse oximeter(s) and those built into the portable, wearable patient interface box, RIP belt(s), respiratory effort belt(s), pressure sensor(s), microphone(s), strain gauge(s), pressure transducer(s), and transducer(s), the at least two sensors adapted:”

161. It is my opinion that Ciulla discloses this limitation. Ciulla’s various sensors (*the at least two sensors*) include the listed sensors in [1.c] and correspond to any two of the first, second, third, fourth, and additional sensors, described below. For instance, Ciulla’s “oximeter” (first *sensor*) is attached to a “finger” “for sensing the oxygen saturation of the user’s blood,” and is therefore a *pulse oximeter including fingertip pulse oximeter*. Ex. 1007, [0118], [0202], FIG. 1B. This understanding is consistent with the 512 Patent’s discussion of what a pulse oximeter

can be. Ex. 1001, 9:59-62 (“The pulse oximeter can measure the oxygenation of the subject’s blood....”). Moreover, it is also consistent with the state of the art, as a POSITA would have readily appreciated that pulse oximeters can measure blood saturation like that disclosed by Ciulla and can sometimes or optionally measure heart rate. Ex. 1033, [0006] (“Pulse oximeters typically provide as outputs blood oxygen saturation values and, sometimes, a heart rate....”); Ex. 1034, 1:11-21 (“In pulse oximetry, light is passed through a portion of a patient’s body....to determine the arterial oxygen saturation and/or pulse rates.”). In addition, a POSITA would have understood that Ciulla’s attitude sensor (second *sensor*) is a “*transducer*.” Ex. 1007, [0121], [0124], [0143]; Ex. 1030, 5:46-49 (an attitude transducer senses angle and position); Ex. 1031, 11:20-22 (transducers indicating attitude); Ex. 1032, 11:56-57 (arranging a transducer to observe attitude). A POSITA would have also understood to implement Ciulla’s attitude sensor as an *accelerometer*, especially when considering how well-understood accelerometer-based position sensors were for patient monitoring by 2006. Ex. 1039, 15:63-16:4; Ex. 1035, 2:18-21; Ex. 1045, [0248]; Ex. 1036, [0035]; Ex. 1037, [0005]; Ex. 1038, Title (all describing accelerometers for sensing body position). Moreover, Ciulla’s snore sensor 36, breathing sensor 32, nasal cannula-type sensor 264, and chest expansion sensor 30 are implemented as microphones, pressure devices, and/or piezo-electric devices (additional third, fourth, etc. *sensors*) (“*pressure sensor(s)*, *microphone(s)*,”

“pressure transducer(s),” and/or *“transducer(s)”*). Ex. 1007, [0098]-[0099], [0119], [0139], [0143], [0202]; Ex. 1014, [0034] (“a pressure transducer, for instance, a microphone located within or near the patient’s respiratory interface”); Ex. 1015, 7:66-67 (“the pressure transducer 26 is an audio transducer or microphone”); Ex. 1016, Abstract (“pressure wave sensing transducers, such as microphones”); Ex. 1018, 4:12-13 (“pressure transducer 14 may be a microphone”). It is my opinion that the *at least two sensors* can be any two of the first, second, third, fourth, etc. sensors.

162. I have also been asked to assume a scenario wherein a “pulse oximeter” must determine heart rate in contrast with the disclosure of the ’512 Patent (which specifies that a pulse oximeter measures blood oxygenation (Ex. 1001, 9:59-62)) As to that scenario, it would have been obvious for Ciulla to include a pulse oximeter that measures both blood oxygenation and heart rate as discussed in the [1.c.ii] analysis. *See* Section XI.C.10.

163. As I explain below, Ciulla’s sensors are adapted to perform limitation 1.c.i-1.c.iii.

9. [1.c.i.A]: *“to be applied to the subject, [1.c.i.B]: a first and a second of the at least two sensors of the portable, wearable patient interface box when the one or more of the sensors are built into the portable, wearable patient interface box are adapted to be applied to a finger, arm and/or torso of the*

subject;”

164. It is my opinion that Ciulla discloses this limitation. For [1.c.i.A], Ciulla’s sensors are ***applied to the subject***. For example, nasal cannula-type sensor 264 is secured to the head, mouth, and/or nose (***applied to the subject***). Ex. 1007, [0119], FIG. 1A. Other sensors are also ***applied to the subject***, including the ***pulse oximeter, microphones, pressure sensors, pressure transducers, and transducers***, as explained for [1.c], and further explained below.

165. For [1.c.i.B], I understand that the remaining claim language (the ***sensors...are adapted to be applied to a finger, arm and/or torso of the subject***) is conditional (“***when***”) and is not required, specifically when none of the sensors are ***built into the...box***. See Section XI.C.6. Nonetheless, several sensors in Ciulla are ***applied to the subject*** and are further ***adapted to be applied to a finger, arm and/or torso of the subject*** when built into the box. For instance, Ciulla discloses that snore and breathing monitors are “incorporated within the main back module”

It is likely that the proximity between the main back module and the shoulder vibrator, and shoulder stimulator will likely cause these to be connected to the main back module through a hard-wired connection. Additionally, breath sounds monitor, snore monitor, heart rate monitor an attitude indicator, and/or chest expansion module, may be designed to be incorporated within the main back module as a part thereof, and as such, would be connected to the main back module for a hard-wired connection.

Ex. 1007, [0124], FIG. 8. The attitude sensor similarly is ***built into the...box*** because it is “designed to be incorporated within the main back module.” Ex. 1007, [0124], [0143] (“a part of the CPU containing main module”), FIG. 8, [0095]-[0098]. The attitude sensor is also placed “over the scapular” and is therefore also ***applied to a torso*** to detect the user’s body position. Ex. 1007, [0143]. Ex. 1007, [0100], [0124], [0143], [0145], [0205], FIG. 8. Therefore, in Ciulla, ***when*** a sensor is ***built into the...box***, it is ***adapted to be applied to a torso of the subject***. Because the ***box*** is mounted to the user’s scapular, any sensors that are ***built into the...box*** are ***adapted to be applied to a torso of the subject***. Ex. 1007, [0100], [0124], [0143], [0145], [0205], FIG. 8.

10. [1.c.ii]: “*to measure or derive respiratory ventilation directly or indirectly, blood oxygenation and body position of the subject during testing; and*”

166. It is my opinion that Ciulla alone or in view of Orbach discloses this limitation. Ciulla’s ***sensors*** make measurements or derivations ***of the subject*** and their breathing, position, etc. as I explained above and below.

c. Respiratory Ventilation (Direct)

167. For ***measur[ing] or deriv[ing] respiratory ventilation directly during testing***, the breathing sensor 32, snore sensor 36, and nasal cannula-type sensor 264 ***directly*** measure the subject’s snore and breathing parameters. *See* dependent claims 2 and 3 stating snore is a type of ***respiratory ventilation***; Ex. 1007, [0098]-[0099],

[0119], [0121], [0124], [0139], [0143], [0202]. Specifically, breathing sensor 32 senses breathing sounds from the chest, and snoring sensor 36 senses snoring and breathing sounds from the nose or mouth. Ex. 1007, [0099]. Nasal cannula-type sensor 264 senses “breath sounds and/or pressure” from nose or mouth of the subject.⁷ Ex. 1007, [0119]. Each of these is a **direct** measurement or derivation of respiratory ventilation because snoring and breathing sounds and pressure relate to the process of respiratory breathing.

d. Respiratory Ventilation (Indirect)

168. It would have been obvious for Ciulla’s oximeter to ***measure or derive respiratory ventilation indirectly during testing*** in light of Orbach’s pulse oximeter teachings. Ciulla discloses a pulse oximeter as explained for [1.c]. Section XI.C.8. Orbach discloses a similar conventional pulse oximeter including “Plethysmograph Electronics 320,” and a light source 322 and detector 328, and determines heart activity from intensity of scattered light. *Id.*, 14:11-16, 17:27-18:15, FIG. 3. A POSITA would have appreciated that pulse oximeters use light to determine arterial oxygen saturation and/or pulse rate. Ex. 1034, 1:11-21.

⁷ A POSITA would have understood that the nasal cannula-type sensor 264 senses the ventilation flow path of the canula for sensing pressure.

169. Orbach analyzes “optical signals from detector 328” to determine parameters like Heart Rate (HR) and Heart Rate Variability (HRV). Ex. 1008, 14:11-16, 16:29-17:3, 27:27-29, 28:5-17, 28:24-29:2, 29:27-30:4, FIG.3. With HR and HRV, Orbach then calculates “Breathing Depth (BD)” and “Breathing Rate (BR)” (*respiratory ventilation* data). *Id.*, 8:23-27, 16:29-17:3, 29:27-30:4. By calculating BD and BR from the direct pulse oximeter measurements, Orbach *indirectly measure[s] or derive[s] respiratory ventilation*.

170. Separately, the system *indirectly measure[s] or derive[s] respiratory ventilation* information *during testing* by displaying “a bar having a length indicative of the breathing activity,” which varies based on lung volume and is *respiratory ventilation*. Ex. 1008, 32:8-30, 56:8-9.

171. It is my opinion that a POSITA would have been motivated to infer such user breathing vitals using a single pulse oximeter (measuring blood oxygenation and heart rate) to increase user comfort over “cumbersome and uncomfortable” conventional breathing monitors and to decrease the number of sensors in Ciulla, allowing for cost savings and increased power efficiency. Ex. 1008, 29:23-26; Ex. 1007, [0119]; *see also* XII.A-B. A POSITA would have had a reasonable expectation of success in combining the oximeter teachings Ciulla and Orbach, given the similar structures in both references, and that Orbach expressly discloses deriving breathing data from blood data.

e. Blood Oxygenation

172. As explained for [1.c] (Section XI.C.8), Ciulla's oximeter senses blood oxygen saturation *during testing*, which is *blood oxygenation*. Ex. 1007, [0118], [0202], FIG. 1B.

f. Body Position

173. Ciulla's attitude sensor "determin[es] the patient's sleeping position (e.g. on back, on side, etc.)" *during testing*, which is *measur[ing] or deriv[ing]...body position*. Ex. 1007, [0143].

g. During Testing

174. In Ciulla, these measurements are performed *during testing* because the sensors are applied during sleep monitoring or analysis, and during "tests conducted." Ex. 1007, [0150], *see also* [0128], [0143], [0230]. To the extent *during testing* is not met by Ciulla alone, a POSITA would have known to *test[]* the data acquisition system, especially in view of Orbach's disclosure of using the distributed system for identifying sleep disorders "in the practice or *testing* of the present invention," which are a part of the Ciulla-Orbach combination. Ex. 1008, 11:8-10, 41:25-27, FIG. 1; XI.A-B.

11. **[1.c.iii]:** *"to be releasably connected and/or electrically hardwired to or within the portable, wearable patient interface*

box adapted to be worn by the subject;”

175. As I explained for [1.b.iii], Ciulla’s *sensors* are ***hardwired to*** or ***within the... box***. See Section XI.C.6. A POSITA would have understood by design that such hardwired configuration comprises ***electrical***[] connections for transmitting signals and data across wires, etc. like that understood in the art. Moreover, as I explained for [1.b], Ciulla’s ***subject*** wears main module 44 on his/her back, which means the *box* is ***adapted to be worn by the subject***. Ex. 1007, [0100], FIG. 8; see Section XI.C.3.

12. [1.d]: “*an at least second software stored on a non-transitory computer readable medium and executable by a computer or a second processor at one or more sites remote to the first location;*”

176. It is my opinion that Ciulla in view of Orbach discloses this limitation. As one example, Orbach’s cell phone forwards sensor data to a “remote server” 140 that is connected to a viewing station 150. Ex. 1008, 3:19-23, 5:3-5, 8:11-15, 13:21-14:2, 22:20-27, 33:27-34:2. The remote server with a viewing station (either being the ***computer***) has a “second processor” (***second processor***) that “provide[s] additional processing” of received “sensor[] data.” Ex. 1008, 3:19-23, 22:28-23:4.

177. A POSITA, in my opinion, would have found it obvious for Orbach’s server to include ***second software stored on a non-transitory computer readable medium and executable by*** the remote server, viewing station, or corresponding

processor, as these components are programmed to process sensor data and output data. Ex. 1008, 38:19-22, 41:8-24. Indeed, as I explained in Section XI.A.3, such software was standard, fundamental, and well-known to operate as described.

178. Orbach's remote sensor, viewing station, and second processor (*computer or second processor*) are *at one or more sites remote to the first location*. For instance, Orbach's server is "remote," and is therefore at a *site remote to the first location*, where the user is located. Ex. 1008, 3:19-23, 5:3-5, 8:11-15, 13:21-14:2, 22:20-27, 33:27-34:2. The user at *the first location* sends data to the remote server using a "cellular RF link," which allows an expert to process and interpret the sensor data and "transmit recommendations to the user." Ex. 1008, 3:19-23, 5:3-5, 8:11-15, 13:21-14:2, 22:20-27, 33:27-34:2.

13. [1.e]: "*the first software, when executed by the first processor of the cell phone or PDA, configured to wirelessly receive and re-transmit the sleep data, or optionally send the sleep data further processed with the first processor of the cell phone or the PDA, with the at least one first wireless transceiver over cell towers to the computer or the second processor for analysis;*"

179. It is my opinion that Ciulla in view of Orbach discloses this limitation. As I explained previously, it would have been obvious to a POSITA in view of Orbach to modify Ciulla (Ex. 1007, FIGs. 1A-1B, 8) to transmit sensor data via a cell phone to a practitioner at a remote computer for purposes of sleep disorder diagnosis. See Sections XI.A-B, XI.C.3.

180. As I explained for [1.a], Orbach's application and programs (*first software*) is *executed by* a cell phone processor (*first processor of the cell phone*). See Section XI.C.2. The programs include those "necessary for interfacing with the sensor module":

In an embodiment of the current invention the sensor module 110 is connected by communication link 112 to a mobile monitor 120. In one preferred embodiment, the mobile monitor 120 is a cellular phone or a Personal Digital Assistant (PDA) equipped with a processor to perform data analysis, memory, a display, Audio output, input means such as keypad, and microphone and sketchpad and means to communicate with both sensor module and remote server. Specific programs necessary for interfacing with the sensor module and for providing feedback to the user may be uploaded by the user. For example, the program may be loaded into a cellular phone wirelessly in the same way a new game or ring tone is loaded.

Ex. 1008, 22:4-13. This which means the *first software* is *configured to wirelessly receive...the sleep data* from the sensors. See Section XI.C.2. Regarding the *wirelessly re-transmit[ting]* aspect, Orbach's *software* also causes the cell phone to "transmit[]" the same sensor data (*re-transmit*) to the remote server, viewing station, or processor (*the computer or the second processor*). Ex. 1008, 13:21-27 ("[C]ommunication link 128 is used to connect the mobile monitor 120 to a remote server 140 where in-depth analysis of data obtained by the sensor unit 110 may be

done and, optionally, data can be transmitted to an expert or another user.”), 16:8-12, 22:4-13, 22:20-23:4 (“Remote servers may provide additional processing of the sensor’s data.”), 41:25-27, FIG. 1; *See* Sections XI.C.2-3, XI.C.6-7. Orbach also discloses that *optionally*, the *cell phone processor send[s] the sleep data further processed*, by stating the sensed data may be “analy[zed],” “compressed,” used to calculate user vitals, or processed as an alert sent to the server. Ex. 1008, 7:12-16, 22:4-9, 33:24-34:2, 38:23-39:16, 41:11-13 (“Data compression, large memory capacity in the mobile monitor....”). In this case, the cell phone processor performs *further process[ing]* on the *sleep data* before *send[ing]* it to the *computer or second processor*.

181. Orbach further discloses that the sleep data is re-transmitted or sent *with the at least one first wireless transceiver over cell towers to the computer or the second processor for analysis*. For instance, and as I explained for [1.a], Orbach’s phone uses its communication means (*first wireless transceiver*) to “communicate with...remote server.” *See* Section XI.C.2. In Orbach, this communication occurs over a “cellular RF link to a cellular base station 130” in a corresponding “cellular network,” which a POSITA would have understood to include communication over *cell towers to the* remote server, viewing station, and processor (*computer or second processor*). Ex. 1008, 5:3-5, 13:21-14:2, 22:20-27, 33:27-34:2 (“data may be sent to via the cellular network using a data exchange protocol such as GSM, GPRS or

3G”); *e.g.*, Ex. 1041, [0007] (“Cellular telephones work by transmitting radio signals to cellular towers.”); Ex. 1012, [0004] (“Cellular telephone systems are well known in the art, and minimally include an array of cell towers.”); Ex. 1013, [0011] (“cellular networks...require cellular towers”). To the extent not explicitly disclosed, such communications over cell towers would have been obvious as I explained previously. For instance, the configuration would have allowed the Ciulla-Orbach system to operate in accordance with standard cell tower-based networks of the time to increase usability and reach, as well as to obtain the beneficial result of allowing the Ciulla-Orbach system to send data to the remote server from multiple locations over an existing network. Ex. 1041, [0007]; Ex. 1012, [0004]; Ex. 1013, [0011].

182. Finally, regarding the *for analysis* aspect of the claim, Orbach’s remote server, viewing station, and processor (*computer or second processor*) receive the sleep data *for analysis* by an expert or the processor. Ex. 1008, 3:19-4:4 (“analysis”), 5:3-5, 8:11-15, 13:21-14:2 (“in-depth analysis”).

14. [1.f]: “*the second software when executed by the computer or the second processor configured to analyze, output and/or format the sleep data at the one or more sites remote from the first location where the sleep data was collected; and*”

183. In my opinion Ciulla in view of Orbach discloses this limitation. As I explained for [1.d-e], Orbach’s remote server with a processor (*computer or the second processor*) executes the *second software* to receive and process *sleep data*

(see Section XI.C.12-13) from the patient sensors (see Sections XI.A-B, XI.C.7, XIC.13). Such processing includes *analyz[ing]* it:

The system of the invention may further comprise a remote server capable of communication with said mobile monitor, the remote server receiving second signals from the mobile monitor, the remote server associated with a viewing station having a second processor, the remote server being configured to perform at least one of the following: (a) transmitting the second signals to a viewing station for analysis, the analysis; (b) accessing historical data relating to the subject; (c) transmitting the historical data to the viewing station; (d) receiving from the viewing station results of the analysis; (e) transmitting the results of the analysis to the mobile unit; the analysis being based upon the second signals, and one or more of the historical data, expert knowledge and computerised protocols.

Ex. 1008, 3:19-4:4; *see also id.*, 5:3-5, 8:11-15, 13:21-14:2 (“[C]ommunication link 128 is used to connect the mobile monitor 120 to a remote server 140 where in-depth analysis of data obtained by the sensor unit 110 may be done and, optionally, data can be transmitted to an expert or another user.”), 16:8-12, 22:4-13, 22:20-23:4 (“Remote servers may provide additional processing of the sensor’s data.”), 41:25-27, FIG. 1. Moreover, Orbach also *output[s]* the *sleep data* to the “viewing station” or *format[s]* it for an expert to review *at the one or more sites remote from the first location where the sleep data was collected*. Ex. 1008, 3:19-4:4, 5:3-5, 8:11-15, 13:21-14:2, 16:8-12, 22:4-13, 22:20-23:4, 41:25-27, FIG. 1.

15. [1.g]: “*the at least second software, when executed by the second processor or the computer, configured to display both, in part, the sleep data and/or analyzed sleep data to allow for diagnosis of a sleep disorder and, if necessary, provide a basis to modify a sleep treatment of the subject.*”

184. In my opinion Ciulla in view of Orbach discloses this limitation. Orbach’s remote server, viewing station, and processor (*computer or the second processor*) *execut[es]* the *second software* (see Sections XI.C.12-13) to *display the sleep data* (see Section XI.C.12-13) on a “viewing station.” Ex. 1008, 3:19-4:4, 5:3-5, 8:11-15, 13:21-14:2 (“[A]n additional data link 148...connects the remote server 140 to a viewing station 150 where a human expert may provide interpretation of the data and transmit recommendations to the user.”), 16:8-12, 22:4-13, 22:20-23:4 (“Remote servers may provide additional processing of the sensor’s data.”), 41:25-27, FIG. 1. As the POSITA would have understood, the viewing station would have also displayed the *analyzed sleep data*, as this would have allowed the expert to efficiently interpret the data, if the sleep data is analyzed at the remote site. The expert can thus “provide interpretation of the data and transmit recommendations to the use,” to thereby “help identify and possibly correct sleep disorders” as needed and disclosed by Orbach, where identifying the sleep disorder is *allow[ing] for diagnosis of a sleep disorder*, and possibly correcting the sleep disorder is *if necessary, provid[ing] a basis to modify a sleep treatment of the subject*. Ex. 1008, 2:22-24, 8:11-15, 13:21-14:2, 41:25-27, 44:1-11, FIG. 1.

185. Similarly, Ciulla also discloses *allow[ing] for diagnosis of a sleep disorder*, and possibly correcting the sleep disorder *if necessary, provid[ing] a basis to modify a sleep treatment of the subject*. Ciulla discloses “[a] clinical trial version [] designed to transmit the multiple sensors’ outputs wirelessly (RF, BlueTooth, WAN, LAN, IT Ethernet Modem or other)” and “incorporate[s] a wireless receiver allowing the researcher to... observ[e] the patient’s responses in a montage display format on the receiving computer’s screen.” Ex. 1007, [0213]. A person of ordinary skill in the art would have understood that the researcher is observing the patient’s responses in order to determine the most effective treatment.

186. Moreover, the device’s microprocessor can “directly transmit [analysis] reports by IT to the therapist’s computer and/or the company’s main frame system for further analysis, research or documentation.” *Id.*, [0214]. Again, a person of ordinary skill in the art would understand that this analysis would have included adjusting sleep treatment, particular given Ciulla’s emphasis on diagnosing and treating sleep disordered breathing. As Ciulla explains, “[o]ne object of the present invention and its mode of implementation is to offer another alternative to CPAP and other current treatments that aim to achieve a higher compliance rate and an active participation of the patient for compliance with other health promoting issues. At minimum, the present invention provides oxygen saturation preserving treatment

for already diagnosed patients who have given up on CPAP, or refuse to start.” Ex. 1007, [0021].

D. Dependent Claims 2-6, 8, 9-17, 19, and 20

1. **Claim 2:** “*The sleep diagnostic data acquisition system of claim 1, further comprising an at least third sensor wherein the at least third sensor is adapted for measuring respiratory ventilation such as respiratory effort and/or snore.*”

187. In my opinion, Ciulla in view of Orbach discloses this limitation. See Section XI.C (Claim 1). Relevant here is Ciulla’s disclosure regarding additional sensors. Specifically, for example, Ciulla’s disclosure describes a “nasal cannula-type sensor 264” (*third sensor*):

Finally, a nasal cannula- type sensor 264 can be provided for sensing nasal and mouth emitted breath sounds and/or pressure, or for inducing a flow of air into the patient's nostrils and/or mouth. However, to induce such a flow of air, it is likely that the nasal cannula 264 would be better served by being connected to an air pump or CPAP-type device that is capable of creating a flow of air that can flow through the cannula 264. A volume knob 244 is provided for enabling the user to adjust the volume of sound emitted from the earphone 246, to accommodate patients having different degrees of hearing acuity.

Ex. 1007, [0119]. By sensing the emitted breath sounds and the flow of air into the patient’s nostrils and/or mouth, the sensor can measure respiratory effort. And Ciulla also teaches a “breathing sensor 32” (which in my opinion is also a *third*

sensor) that “senses breathing sounds” and helps detect “faulty or obstructed breathing” conditions, among other information:

A breathing sensor 32 is positioned adjacent to the chest cavity of the patient, and functions Similarly to a stethoscope, insofar as it senses breathing Sounds. A snoring sensor 36 is positioned on the shoulder portion 22, to detect snoring sounds and breathing sounds emitted from the mouth and nose of the patient. Snoring Sensor 36 essentially comprises a microphone. An EMG sensor 40 may be placed upon the chest or Strap portion.

Ex. 1007, [0099]; *see also id.*, [0121] (“The device includes a plurality of sensors that transmit information into the main back module, that relate to the various conditions of the patient.”), [0124] (“breath Sounds monitor”), [0172] (“A device includes a microprocessor that analyzes its multi-sensor inputs to detect faulty or obstructed breathing....”), FIG. 1A.

188. Because Ciulla discloses a microphone and/or a pressure sensor (*see* Section XI.C.8) that are connected to main module 44 for processing, a POSITA would have understood that the nasal cannula-type sensor 264 and breathing sensor 32 are *adapted for measuring respiratory ventilation such as respiratory effort and/or snore* because they “sens[e] nasal and mouth emitted breath sounds and/or pressure.” Ex. 1007, [0119], *see also* [0099], [0101], [0121], [0123], [0124], [0126], [0128]. Ciulla discloses such inputs:

The probable main inputs are simple snore piezo transducer, upper chest expansion (Strain gauge, pneumatic tubing, or other), and actual breath Sounds mike (probably filtered below 200Hz to eliminate vascular sounds), HR and an attitude monitor.

Id., [0139]; *see also id.*, [0172]. Ciulla further discloses such analysis:

The main sensor inputs analyzed by the microprocessor to accomplish the device's purposes include preferably, a piezo-electric snore monitor, a small breath sounds microphone, a heart rate sensor, an attitude monitor, and an upper chest expansion sensor (either strain gauge, piezo, pneumatic tubing or other), all of which are well known in the art and commercially available.

Id., [0202]. Moreover, Ciulla discloses a “sensor positionable for receiving information to the amount of chest expansion of a patient.” Ex. 1007, Claim 1. Such a chest expansion sensor also would have sensed ***respiratory effort***.

189. The '512 Patent and other publications disclose that transducers can measure pressure, consistent with Ciulla's disclosures. *See* Ex. 1001, 3:25-27 (“pressure transducers, are used to measure”), 9:4-5 (“respiratory effort is preferably measured by esophageal pressure”); Ex. 1014, [0034] (“a pressure transducer, for instance, a microphone located within or near the patient's respiratory interface”); Ex. 1015, 7:66-67 (“the pressure transducer 26 is an audio transducer or microphone”); Ex. 1016, Abstract (“pressure wave sensing transducers, such as microphones”); Ex. 1018, 4:12-13 (“pressure transducer 14 may be a microphone”).

190. Moreover, Ciulla's chest expansion sensor (disclosed in claim 1) also would have *measur[ed] respiratory ventilation such as respiratory effort* because it is used "to measure the expansion of the chest, which provides an indication of the breathing, (or lack thereof) being performed by the patient." Ex. 1007, [0098]. A POSITA would have appreciated that respiratory effort can be measured in a variety of ways, including by visual observation, chest movement measurement, and more invasive esophageal pressure techniques.

2. **Claim 3:** "*The sleep diagnostic data acquisition system of claim 2, further comprising an at least fourth sensor wherein the third sensor is adapted for measuring respiratory effort and the fourth sensor is adapted for measuring snore.*"

191. In my opinion, Ciulla discloses this limitation. See Section XI.D.1 (Claim 2). As I explained for Claim 2, the Ciulla-Orbach combination discloses a *third sensor is adapted for measuring respiratory effort*. See Section XI.D.1. Ciulla's "snoring sensor 36" (*fourth sensor*) "is positioned on the shoulder portion 22, to detect snoring sounds and breathing sounds emitted from the mouth and nose of the patient." Ex. 1007, [0099], FIG. 1A. Ciulla's *fourth sensor* (see Section XI.C.8) is *adapted for measuring snore* by detecting snoring and breathing sounds. Ex. 1007, [0099]. Ciulla discloses such sensors:

Each of the sensors described above, including chest sensor 30, snoring Sensor 36, breathing sensor 32 and EMG sensor 40 are provided with either a hard wire or wireless communication, to provide input to the main

module 44 of the device 10. The main module 44 is disposed on the back of the patient, and is best shown in FIG.

Id., [0100]; *see also id.*, [0123], [0126]; Ex. 1001, 3:25-27 (“pressure transducers, are used to measure...snore parameters”); *see* Section XI.D.1.

3. **Claim 4:** “*The sleep data acquisition system in claim 2, wherein the sleep data is transmitted to a remote Internet site or communication station using the at least one first wireless transceiver to transmit the sleep data over cell towers and/or the Internet for analysis.*”

192. In my opinion, Ciulla in view of Orbach discloses this limitation. *See* Section XI.D.1 (Claim 2). The ’512 Patent discloses that a ***communication station*** may refer to any “computer with wireless capabilities,” a device that can “receive RF transmissions,” or even just a “processor.” Ex. 1001, 15:16-28 (“The base station, remote communication station or the like of various embodiments of the present invention can be any device known to receive RF transmissions.... The...remote communication station...can include...a computer with wireless capabilities [or] a processor....”).

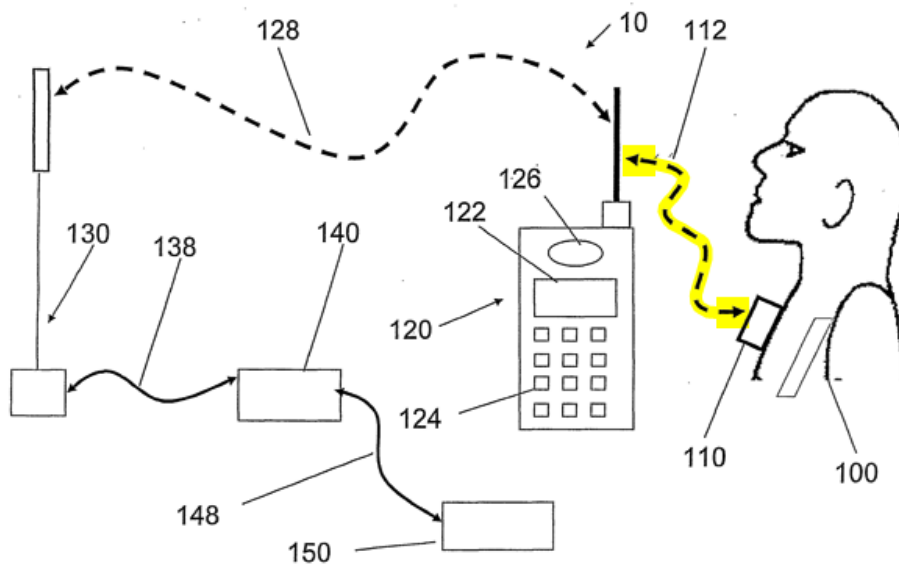
193. Orbach’s “remote server” is a ***communication station*** because it is a computer or processor with wireless capabilities that receives RF transmissions. The remote server connects to a viewing station via an “RF link” (which is a wireless link) for data exchange. Ex. 1008, 13:21-14:2, 52:14-26 (viewing station and remote server exchange data).

194. As I explained for [1.e], the cell phone's communication means (*first wireless transceiver*) is used so that *the sleep data is transmitted* to the *communication station...over cell towers... for analysis*. Ex. 1008, 13:21-14:2 (“[C]ommunication link 128 is used to connect the mobile monitor 120 to a remote server 140 where in-depth analysis of data obtained by the sensor unit 110 may be done and, optionally, data can be transmitted to an expert or another user.”), 22:20-23:4, FIG. 1; see Sections XI.C.12-14.

4. **Claim 5:** “*The sleep data acquisition system in claim 4, wherein two-way bi-directional data transmission is utilized between the second transceiver and the at least first transceiver.*”

195. In my opinion, Ciulla in view of Orbach discloses this limitation. See Section XI.D.3 (Claim 4). As I explained for limitations [1.a] and [1.b.iv], Orbach's cell phone's communication discloses a *first transceiver*, and Ciulla's antenna 92 and associated hardware on main module 44 discloses a *second transceiver*. See Sections XI.C.2.a, XI.C.7. In the Ciulla-Orbach combination, data communication between the wearable device and the cell phone is *two-way* and “*bi-directional*” because the cell phone's *first transceiver* (i) receives sensor data from sensor module 110's (analogous to Ciulla's main module 44) *second transceiver* and (ii) transmits alerts and other data to the sensor module 110 (analogous to Ciulla's main module 44 and the *second transceiver*) over communication link 112. Ex. 1008, 13:14-14:2,

16:13-20 (“The communication link 112 is preferably bidirectional....transmits...and receives....”), 17:19-26; Sections XI.A-B, XI.C.2.a, XI.C.7. Orbach’s Figure 1 (illustrated below) discloses *two-way bi-directional* communications between the two transceivers. Ex. 1008, FIG. 1. In the Ciulla-Orbach combination, *two-way bi-directional data transmission is utilized between* Ciulla’s main module 44 (analogous to Orbach’s sensor module 110 and the *second transceiver*) and Orbach’s cell phone (*first transceiver*).



Ex. 1008, FIG. 1 (illustrating two-way data communication between cell phone 120 and sensor module 110).

5. **Claim 6:** “The sleep data acquisition system in claim 5, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by

the cell phone or PDA.”

196. In my opinion, Ciulla in view of Orbach discloses this limitation. See Section XI.D.4 (Claim 5). As I explained for limitation [1.a] and claim 4, Orbach’s remote server (*communication station*) interfaces with a cell phone having a *first transceiver* and *first software*. See Sections XI.C.2 ([1.a]), XI.D.3 (Claim 4). Orbach’s the remote server (*communication station*) sends “[i]nstructions and commands” “to sensor module 110 through mobile monitor 120.” Ex. 1008, 17:19-26, FIG. 1. These instructions and commands change the “sampling rate” or “sampling accuracy or range” of sensor data, which a POSITA would have understood to include the sampling parameters of the sensor data for transmission. Ex. 1008, 13:13-14:2, 16:13-20, 17:19-26, 22:20-23:4 (“Remote servers may provide additional processing of the sensor’s data.”). Thus, Orbach’s remote server is involved in the *control* of *the sleep data transmission* from the phone to the server, which a POSITA would have understood is implemented by the *first software* on the phone *when being executed by the cell phone*. Ex. 1008, 13:13-14:2, 16:13-20, 17:19-26, 22:20-23:4; see Sections XI.C.2, 13.

6. **Claim 8:** “*The sleep data acquisition system in claim 6, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume,*

ventilation rate and snore detection from the sleep data.”

197. In my opinion, Ciulla in view of Orbach discloses this limitation. *See* Section XI.D.5 (Claim 6). Ciulla-Orbach discloses this limitation in at least two ways.

198. First, Ciulla-Orbach discloses a software filter that determine[s] one or more of airflow, tidal volume, ventilation rate and snore detection from heart beat data of the sleep data. The '512 Patent discloses that software filtering may allow a system to extract different types of sleep data from a single sensor. Ex. 1001, 2:31-42, 9:44-51. The Ciulla-Orbach pulse oximeter, which as I explained for [1.c.ii], detects both heart rate information and blood oxygenation and infers various breathing parameters like BD or BR. *See* Section XI.C.10.

199. Orbach discloses using such heart rate sensor data and a software filter to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data as claimed. Orbach's heart sensor detects a user's "Heart Rate (HR)" or "Heart Rate Variability (HRV)." Ex. 1008, 8:23-27, 14:11-16, 16:29-17:3, FIG. 3. With the HR and HRV information, "Breathing Depth (BD)" (tidal volume) or a "Breathing Rate (BR)" (airflow or ventilation rate) are calculated or detected:

In an embodiment of the invention, values of instantaneous HR(t) determined for example from optical signals or from ECG signals are analyzed and the

breathing cycles are determined. This can be done by identifying the peaks, the valleys or zero crossings in the HR sequence, by performing auto correlation or using FFT analy by wavelet analysis. Each breathing cycle may be analyzed for Breathing Rate (BR), Breathing Depth (BD) and the Ratio of Exhale over Inhale duration (REI).

Id., 29:27-30:4. The Breathing Depth (BD) corresponds to ***tidal volume*** because it refers to the amount of air inhaled or exhaled during a breath. Similarly, the Breathing Rate (BR) corresponds to ***airflow*** or ***ventilation rate*** because it refers to the rate at which a person breaths air. As I explained for [1.a-b, 1.e], the sensed data is monitored for sleep diagnostic purposes (from the sleep data). *See* Ex. 1008, 41:25-27 (“[T]he system may be used to record physiological reading while the user is sleeping in order to help identify and possibly correct sleep disorders.”); Sections XI.C.2-3, 6-7, 13.

200. A ***software filter*** in Orbach’s cell phone is ***adapted to determine*** the ***airflow, tidal volume, and ventilation rate*** from the heart sensor data (included in the ***sleep data***). Orbach’s analysis of BD (***tidal volume***) and BR (***airflow*** or ***ventilation rate***) values are “done at the mobile monitor,” which is the cell phone, loaded with a corresponding section of an “application” or “program” (***software filter***). Ex. 1008, 13:14-14:2, 22:10-13 (“program may be loaded into a cellular phone”), 29:27-30:9, 30:10-12 (“[T]he breathing analysis may be done at the mobile monitor.”), 32:9-30, 33:24-26, FIG. 1.

201. Second, Ciulla-Orbach discloses a *software filter* that *determine[s] one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data* based on the system's selective display of a "breathing bar" on a user's phone. Orbach further discloses that the cell phone application software also selectively displays an animation based on the BR (*software filter*):

Static or moving animations may "also be displayed according to the interpretation of the physiological data. For example, a happy "smiley face " may be displayed when the state of the user is relaxed and sad face when the user is in a state of anxiety. The speed of the motion of the animation may be correlated with vital parameters such as HR or BR. A pulsing heart or breathing lungs may be displayed and animated to follow the cycles of the user. Music and musical tones may also be used as indicators, for example the pitch or intensity may be correlated with HR and BR and the user may train to achieve and maintain low quiet sound.

Ex. 1008, 36:8-16; *see also id*, 2:10-13, 33:24-26, 34:3-9, 35:28-36:8. Orbach discloses the cell phone application software calculates the respiration/breathing rate or lung volume (*tidal volume*) to selectively display a user friendly "breathing bar" via a corresponding *software filter*.

In the graphical bar display, the breathing bar length may vary, for example, in accordance with the user's respiration rate or the duration of the inspiratory or expiratory phase of the respiration cycle...As another example, the breathing bar length may vary in accordance with the lung volume of the user, increasing in length as the user inhales

and decreasing as he exhales... Alternatively, the breathing bar may change color according to the phase of the breathing cycle.

Ex. 1008, 32:9-30, *see also id*, 33:24-26, 34:3-16. The user's cell phone displays such data to the user based on real-time data or previously acquired and stored data.

Ex. 1008, 35:28-36:16.

7. **Claim 9:** *“The sleep data acquisition system in claim 5, wherein the portable, wearable patient interface box further comprises an A/D converter and a digital memory for receiving the sleep data.”*

202. In my opinion, Ciulla discloses this limitation. *See* Section XI.D.4 (Claim 5). Ciulla's main module 44 (**box**) is “constructed using off the shelf components,” including an “analog to digital converter” (**A/D converter**). Ex. 1007, [0204].

203. Ciulla's sensing system is a “digital processing system,” and the micro-processor of the main module 44 (**box**) is configured for “digitally analyzing and storing data.” Ex. 1007, [0073]-[0074], Abstract, [0101], [0123] (“The main back module includes a microprocessor for processing the information sensed by the sensor, as directed by the input device, that tells the processor what to do with the sensed information.”). Ciulla disclose **digital memory** because the main module 44 comprises a “non-volatile memory, such as a smart card” that serves as a “repository of data collected” by sensors of the system, which is the system sleep data. Ex. 1007,

[0102], [0127]-[0128], FIGs. 1A-1B, 8; *see also* Sections XI.C.2-3, XI.C.13. The smart card is a “digital storage” device. Ex. 1007, [0230]. A POSITA would have understood that Ciulla’s main module 44 *comprises* a non-volatile *digital memory for receiving the sleep data* from the sensors.

8. **Claim 10:** “*The sleep data acquisition system in claim 1, wherein the at least two sensors consist of a pulse oximeter and an accelerometer.*”

204. In my opinion, Ciulla in view of Orbach discloses this limitation.

a. “**Consist Of...**”

205. Claim 10 depends from claim 1, which recites “A...system *comprising*...at least two sensors.” (emphasis added). The ’512 Patent does not disclose any embodiment limited to a pulse oximeter and accelerometer as the only two sensors. The sensors in the Ciulla-Orbach combination meet this limitation because the *pulse oximeter* and *accelerometer* in the combination meet [1.b] (*used for diagnosing sleep disorders*) and [1.c.ii] (*measure or derive respiratory ventilation..., blood oxygenation and body position of the subject during testing*).⁸

⁸ As explained for [1.c.i] and [1.c.iii], these limitations are met by all sensors in the Ciulla-Orbach combination, and are not re-mapped here.

b. Pulse Oximeter Used For Diagnos[is], Respiratory Ventilation, and Blood Oxygenation

206. As explained for [1.c], the combination's oximeter is a *pulse oximeter*. Section XI.C.8. As explained for [1.c.ii] (for *indirect* determination of *respiratory ventilation*), the combination's oximeter *measure[s] or derive[s] respiratory ventilation indirectly*. Section XI.C.10. Also, as explained for [1.c.ii] (for *blood oxygenation*), the combination's oximeter measures *blood oxygenation*. Section XI.C.10.

207. For *diagnosing sleep disorders*, the combination's oximeter data is used to *diagnos[e] sleep disorders* because the pulse oximeter data is collected as a part of the SDB diagnosis process explained previously. Ex. 1007, [0118], [0202], [0219], [0230]; Sections XI.C.1, 3, 15.

c. "Accelerometer" Used For Diagnos[is] and Body Position

208. As explained for [1.c], a POSITA would have known that Ciulla's attitude sensor is an *accelerometer*. Section VII.C.8. As explained for [1.c.ii] (for *body position*), Ciulla's attitude sensor *measure[s] or derive[s]...body position*. Section XI.C.10.

209. For *diagnosing sleep disorders*, the attitude sensor is used to *diagnos[e] sleep disorders* because the body position data is collected as a part of

the SDB diagnosis process explained previously. Ex. 1007, [0143], [0219], [0230];
Sections XI.C.1, 3, 15.

9. **Claim 11.** *“The sleep data acquisition system in claim 10, wherein the sleep data is transmitted to a remote Internet site or communication station using the at least one first wireless transceiver to transmit the sleep data over cell towers and/or the Internet for analysis.”*

210. In my opinion, Ciulla in view of Orbach discloses this limitation. See
Sections XI.D.8 (Ground 1, Claim 10), XI.D.3 (Claim 4).

10. **Claim 12.** *“The sleep data acquisition system in claim 11, wherein two-way bi-directional data transmission is utilized between the second transceiver and the at least first transceiver.”*

211. In my opinion, Ciulla in view of Orbach discloses this limitation. See
Section XI.D.9 (Ground 1, Claim 11), XI.D.4 (Ground 1, Claim 5).

11. **Claim 13.** *“The sleep data acquisition system in claim 12, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA.”*

212. In my opinion, Ciulla in view of Orbach discloses this limitation. See
Section XI.D.10 (Ground 1, Claim 12), XI.D.5 (Ground 1, Claim 6).

12. **Claim 14.** *“The sleep data acquisition system in claim 13, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume,*

ventilation rate and snore detection from the sleep data.”

213. In my opinion, Ciulla in view of Orbach discloses this limitation. See Sections XI.D.11 (Ground 1, Claim 13), XI.D.6 (Ground 1, Claim 8).

13. **Claim 15.** *“The sleep data acquisition system in claim 1, wherein the sleep data is transmitted to a remote Internet site or communication station using the at least one first wireless transceiver to transmit the sleep data over cell towers and/or the Internet for analysis.”*

214. In my opinion, Ciulla in view of Orbach discloses this limitation. See Section XI.D.3 (Ground 1, Claim 4), XI.C (Ground 1, Claim 1).

14. **Claim 16.** *“The sleep data acquisition system in claim 15, wherein two-way bi-directional data transmission is utilized between the second transceiver and the at least first transceiver.”*

215. In my opinion, Ciulla in view of Orbach discloses this limitation. See Section XI.D.13 (Ground 1, Claim 15), XI.D.4 (Ground 1, Claim 5).

15. **Claim 17.** *“The sleep data acquisition system in claim 16, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA.”*

216. In my opinion, Ciulla in view of Orbach discloses this limitation. See Section XI.D.14 (Ground 1, Claim 16), XI.D.5 (Ground 1, Claim 6).

16. **Claim 19.** *“The sleep data acquisition system in claim 17, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume,*

ventilation rate and snore detection from the sleep data.”

217. In my opinion, Ciulla in view of Orbach discloses this limitation. *See* Sections XI.D.15 (Ground 1, Claim 17), XI.D.6 (Ground 1, Claim 8).

17. **Claim 20.** “*The sleep data acquisition system in claim 16, wherein the portable, wearable patient interface box further comprises an A/D converter and a digital memory for receiving the sleep data.*”

218. In my opinion, Ciulla in view of Orbach discloses this limitation. *See* Sections XI.D.14 (Ground 1, Claim 16), XI.D.7 (Ground 1, Claim 9).

XII. OPINIONS ON GROUND 2: CIULLA IN VIEW OF ORBACH AND NAGAI RENDERS OBVIOUS CLAIMS 1-6, 8-17, 19, AND 20

A. A POSITA Would Have Been Motivated to Combine

219. It is my opinion that Ground 1 specifies how Claim 1 would have been obvious. Nonetheless I have been asked to assume a scenario where this is not that case. As to that scenario, Ground 2 incorporates Ground 1 and modifies the Ciulla-Orbach system with Nagai’s *hard-wiring* or *releasably connect[ing]* of a pulse oximeter sensor (for [1.b.iii.C] or [1.c.iii]) and/or with Nagai’s teaching of sensors *consist[ing] of a pulse oximeter and an accelerometer* for [1.c] and claim 10. For claim 10, this Ground additionally relies on Nagai’s teaching of a system limited to two sensors, to the extent required by Claim 10.

220. First, it would have been obvious to *hardwire* a standard wired pulse oximeter to the main module 44 through a connector (e.g., a jack, port, etc.) (as

compared to a wireless pulse oximeter) (“***hardwired to connect through at least one connector of the portable, wearable patient interface box***”; “***releasably connected and/or electrically hardwired to***”) for reasons previously explained for limitations [1.b.iii] and [1.c.iii]. See Sections XI.C.6, XI.C.11, XI.A.2.

221. Second, with Nagai’s use of ***accelerometer***-based body position and ***pulse oximeter*** data (explained below), a POSITA would have been motivated to implement Ciulla’s various sensors to only include or at least include an ***accelerometer*** and a ***pulse oximeter***, and would have implemented Ciulla’s body position sensor using a standard ***accelerometer*** and ***pulse oximeter*** in view of Nagai, as well-understood in the art and for the same reasons explained previously in [1.c]. See Sections XI.C.3, 8. Ciulla contemplates such a well-known configuration by explicitly noting that its system “can be constructed using off-the-shelf sensor inputs,” and that the use of such “standard” sensors would “help reduce production costs.” Ex. 1007, [0204], [0072], [0226] (“Standard sensors...can be employed for miniaturization and convenience.”).

222. Consistent with the Ciulla system’s purpose of monitoring sleep data for treatment and analysis purposes, a POSITA would have appreciated that implementing such a configuration would have helped prevent sleep issues:

With this method, the body position of the subject in sleep can be measured in terms of body angle, which is a minute parameter, in place of body direction, which is a rough

parameter. Such as supine position or lateral decubitus position, and the blood oxygen Saturation can be concurrently measured with the body angle. Accordingly, a correlation between apnea and body position of the subject in sleep can be accurately obtained.

The correlation between apnea and body position of the subject is obtained by way of a relation between apnea and body angle, which represents how much the body of the subject is tilted with respect to a reference plane in terms of angle, in place of a relation between apnea and body direction, which is a rough parameter as detected in the conventional art. This enables to securely acquire a causal relation between apnea and body position of the subject. Accordingly, the subject i.e. individual SAS patients are provided with a proper treatment having dependence on body position.

Ex. 1010, [0172]-[0173]; *see also id.*, [0183]-[0189], [0209], [0211]; Section XI.A.

The configuration would have allowed the system to be able to eliminate data that is not actually sleep data or prevent the analysis of non-sleep data based on the position of the patient (*i.e.*, because the user is “seated,” etc.), thereby increasing system and diagnostic efficiency. Ex. 1010, [0198]-[0199].

223. Third, to the extent this claim is interpreted to cover a two-sensor system including a pulse oximeter and accelerometer, and no other sensor, this also would have been obvious. When only two sensors are used as disclosed by Nagai (as compared to a system that can include multiple sensors like that disclosed by Ciulla), a POSITA would have appreciated that the reduction in the number sensors

would have helped reduced costs and complexity of the Ciulla system. For example, fewer sensors would have meant less investment in purchasing, installing, and maintaining additional hardware. There would have been reduced power consumption and maintenance requirements in such a configuration. Further, a POSITA would have appreciated that two sensors would have simplified the data acquisition process and reduced the computational burden in Ciulla. Especially in applications like sleep studies or wearable health monitoring like that disclosed by Nagai and Ciulla, minimizing the number of sensors would have improved user comfort and compliance with the Ciulla system, as it would have reduced obtrusiveness. A POSITA would have considered tradeoffs relating to various design options available to facilitate such a modification (*e.g.*, design constraints, cost, user convenience, etc.).

B. A POSITA Would Have Had a Reasonable Expectation of Success

224. A POSITA would have had a reasonable expectation of success in modifying Ciulla-Orbach with Nagai. First, like Ciulla and Orbach, Nagai is analogous art by pertaining to sleep monitoring systems:

The present invention relates to a method and a system for evaluating sleep of Subjects in diagnosing sleep apnea syndrome (hereinafter, called as “SAS”), and more particularly to a sleep evaluation method and a sleep evaluation system capable of accurately obtaining a

correlation between apnea and body position of a Subject
in sleep.

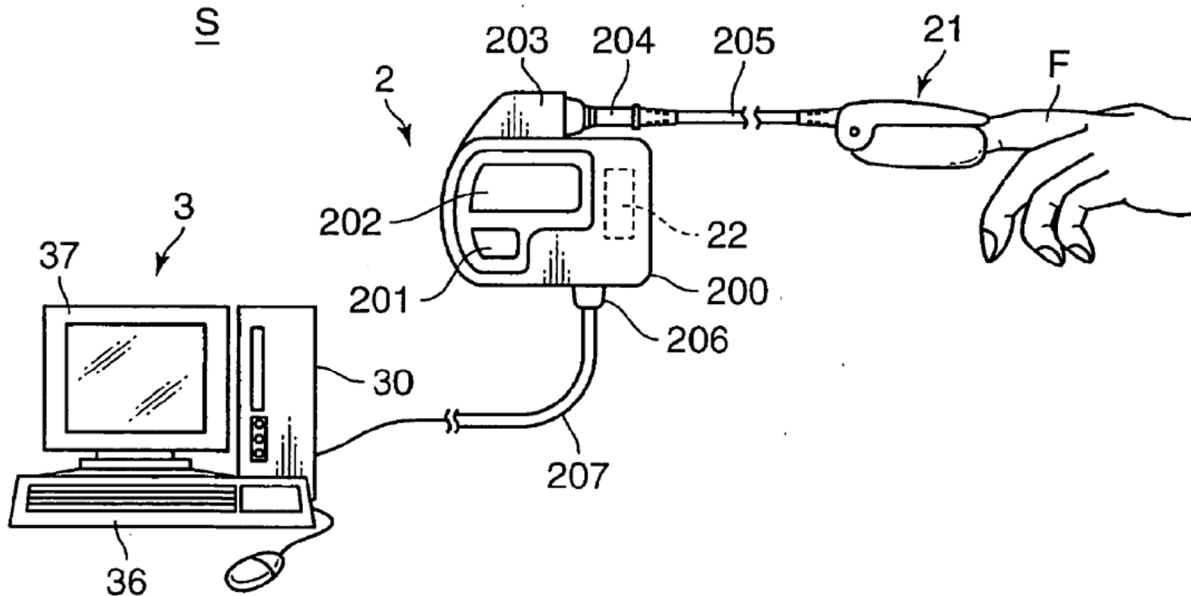
Ex. 1010, [0003], *see also id.*, Abstract; Section XI.B. Second, such a modification would have been no more than an obvious and predictable integration of known hardwired pulse oximeters and accelerometers, and simple two-sensor sleep evaluation systems, using known circuit integration methods with a reasonable expectation of success, at least due to how well-known the configuration was. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

C. Independent Claim 1

225. This Ground incorporates Ground 1, and adds Nagai's teachings for hardwiring a pulse oximeter like that claimed. See [1.b.iii] ("the at least two sensors further which are hardwired to connect through at least one connector of the portable, wearable patient interface box"), [1.c.iii] ("releasably connected and/or electrically hardwired to or within the portable, wearable patient interface box").

226. Ciulla-Orbach in view of Nagai discloses the claimed hardwired configuration of claim 1. Nagai discloses a "sleep evaluation system":

FIG.2

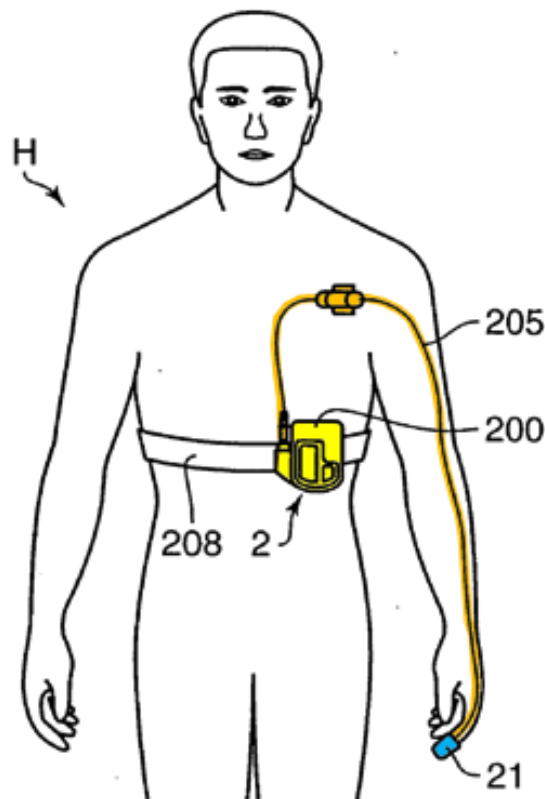


Id., FIG. 2, [0057] (“FIG. 2 is an illustration showing an example of a sleep evaluation system S having the hardware construction.” Nagai discloses that “[t]he sleep evaluation system S includes a pulse oximeter 2 for concurrently or simultaneously measuring a blood oxygen saturation.” *Id.* Nagai describes the components of the system:

The pulse oximeter 2 has a main body 200 and a probe 21. The oximeter main body 200 and the probe 21 are electrically connected by a probe cable 205 equipped with a connector 204...The probe 21 has a paper-clip like shape capable of securely holding a finger F of a subject to measure the blood oxygen saturation of the subject...Also, the probe 21 is fixedly attached to the finger F of the subject H for measurement. Thereafter, the oximeter main

body 200 and the probe 21 are connected to each other by way of the probe cable 205.

Id., [0058]-[0060]. The main body 200 and the oximeter probe 21 are electrically connected by a “probe cable 205” (*releasably connected and/or electrically hardwired*) equipped with a connector 204 that connects to a connecting portion of the main body (such as 206) (*to connect through at least one connector*). Nagai illustrates the connection between the oximeter main body 200 and the probe 21:



Id., FIG. 3 (excerpted and annotated to highlight standard pulse oximeter probe 21 in blue, a hardwired probe cable 205 and connector in orange, and a main body 200).

227. Ciulla in view of Orbach and Nagai discloses the remaining limitations of claim 1 for the same reasons discussed in Ground 1. *See* Section XI.C (Ground

1, Claim 1). The modification of the Ciulla-Orbach combination in view of Nagai does not materially affect the combination's disclosure of claim 1 as discussed in Ground 1.

D. Dependent Claim 10

1. **Claim 10:** *"The sleep data acquisition system in claim 1, wherein the at least two sensors consist of a pulse oximeter and an accelerometer."*

228. Ciulla-Orbach in view of Nagai discloses this limitation. *See* Section XI (Claim 1).

a. Only Two Sensors

229. Assuming a scenario where the Claim 10 system is limited to two sensors (accelerometer and pulse oximeter), it is my opinion that such a system would have been obvious from Nagai's express teaching of a two-sensor system for detecting and treating sleep disorders. Nagai considers pulse oximeter information with body position information (sensed by an accelerometer) to determine a "correlation between apnea and body position of the subject in sleep." Ex. 1010, [0172], [0142]-[0145].

FIG.21C

RELATION BETWEEN BODY
POSITION AND BODY ANGLE

PRONE POSITION	-135° TO -180° OR 135° TO 180°
RIGHT LATERAL DECUBITUS POSITION	-45° TO -135°
SUPINE POSITION	-45° TO 45°
LEFT LATERAL DECUBITUS POSITION	45° TO 135°

Id., FIG. 21C, [0135]. According to Nagai, the acceleration sensor and pulse oximeter are sufficient for evaluating sleep. *Id.*, [0048]-[0049], [0054]-[0055], [0058], FIGs. 2, 11, claims 2, 7, 9.

b. Pulse Oximeter

230. To the extent Ciulla-Orbach do not explicitly disclose a *pulse oximeter*, this would have been obvious in view of Nagai's explicit teachings of a *pulse oximeter* as "measuring the blood oxygenation saturation," which is consistent with the disclosures in Ciulla and Orbach. Sections XI.C.8, 10.

c. Accelerometer

231. To the extent Ciulla-Orbach do not explicitly disclose an *accelerometer*, it would have been obvious to implement Ciulla's attitude sensor as Nagai's "acceleration sensor," which is an *accelerometer*. Ex. 1010, [0049], [0070]-[0071]. Nagai's "acceleration sensor" is used as a "body position detector 12," which "detects a body position of the subject in terms of angle information." *Id.*, [0047], [0049], FIG. 1. Nagai's "acceleration sensor" is an *accelerometer*, at least

because it has a sensor body 220 comprising piezoresistive devices 224. *Id.*, [0049], [0070]-[0071]. As Nagai describes, the *accelerometer* provides angle information for detecting the subject's position (*e.g.*, prone, supine). *Id.*, [0081]-[0082], [0135], [0183].

E. Dependent Claims 2-6, 8, 9, 11-17, 19, and 20

1. Claims 2-6, 8, and 9

232. In my opinion, Ciulla in view of Orbach and Nagai discloses claims 2-6, 8, and 9 for the same reasons discussed in Ground 1. *See* Section XI.D. The modification of the Ciulla-Orbach combination in view of Nagai does not materially affect the combination's disclosure of these claims as discussed in Ground 1.

2. **Claim 11.** *"The sleep data acquisition system in claim 10, wherein the sleep data is transmitted to a remote Internet site or communication station using the at least one first wireless transceiver to transmit the sleep data over cell towers and/or the Internet for analysis."*

233. In my opinion, Ciulla in view of Orbach and Nagai discloses this limitation. *See* Sections XII.D.1 (Ground 2, Claim 10), XI.D.3 (Claim 4).

3. **Claim 12.** *"The sleep data acquisition system in claim 11, wherein two-way bi-directional data transmission is utilized between the second transceiver and the at least first transceiver."*

234. In my opinion, Ciulla in view of Orbach and Nagai discloses this limitation. *See* Section XII.E.2 (Ground 2, Claim 11), XI.D.4 (Ground 1, Claim 5).

4. **Claim 13.** *"The sleep data acquisition system in claim 12,*

wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA.”

235. In my opinion, Ciulla in view of Orbach and Nagai discloses this limitation. *See* Section XII.E.3 (Ground 2, Claim 12), XI.D.5 (Ground 1, Claim 6).

5. **Claim 14.** *“The sleep data acquisition system in claim 13, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data.”*

236. In my opinion, Ciulla in view of Orbach and Nagai discloses this limitation. *See* Sections XII.E.4 (Ground 2, Claim 13), XI.D.6 (Ground 1, Claim 8).

6. **Claims 15-17, 19, and 20**

237. In my opinion, Ciulla in view of Orbach and Nagai discloses claims 15-17, 19, and 20 for the same reasons discussed in Ground 1. *See* Section XI.D. The modification of the Ciulla-Orbach combination in view of Nagai does not materially affect the combination’s disclosure of these claims as discussed in Ground 1.

XIII. OPINIONS ON GROUND 3: CIULLA IN VIEW OF ORBACH AND TRUSCHEL RENDERS OBVIOUS CLAIMS 7 AND 18

A. A POSITA Would Have Been Motivated to Combine

238. Ground 3 incorporates Ground 1 and modifies the Ciulla-Orbach system with Truschel’s high-frequency and dynamic snore filtering process. Ciulla discloses that its device includes a snoring sensor 36, and functionally suggests that some kind of signal filtering would be “appropriate” for detecting snoring. Ex. 1007,

[0142] (“The snore and breath sounds sensors are to be placed...with appropriate gain and filtering.”), [0204] (“Appropriate filtration to insure accurate detection of HR, snore vibrations, breath sounds, etc., is included in the system.”).

239. Truschel’s software filtering technique would have improved the Ciulla system to better detect snoring:

Digital signal 70 is then passed, relayed, or transmitted to a digital band pass filter 58, which is preferably implemented by a floating or fixed point computer contained in the controller 50. Digital band pass filter 58 filters digital signal 70 to obtain a filtered digital signal 72 containing qualifying frequencies in a range of about 40-160 Hz. The approximate qualifying frequency range represents the approximate range of frequencies produced during snoring and takes into account factors, Such as the age, gender, or health of a patient.

Ex. 1011, [0050]. A POSITA would have been motivated to use Truschel for the Ciulla system to avoid detecting “false snore indications” by failing to “take into account dynamic background noise” and “other noise:”

In addition to filtering unwanted audible frequencies, the present invention contemplates modifying digital band pass filter 58 to further limit the qualifying range to a specific frequency range tailored for a particular patient. For example, it has been found that Snoring males tend to produce lower audible frequencies and Snoring females tend to snore at higher audible frequencies. Moreover, the present invention can be used to archive sample snores for a given patient and further tailor the qualifying frequency

range to an even narrower, individualized qualifying range of frequencies.

Id., [0051]. By dynamically adjusting snore calculations, a POSITA would have been motivated to better equip the Ciulla system to handle changes in “background noise and patient noises.” Ex. 1011, [0052]-[0054], [0068], FIG. 3.

B. A POSITA Would Have Had a Reasonable Expectation of Success

240. In my opinion, a POSITA would have had a reasonable expectation of success in modifying Ciulla combinations with the teachings of Truschel. First, Ciulla, Orbach, and Truschel are analogous art. Both references, for instance, describe sensors and processors for processing sleep data. Section XI.A-B; Ex. 1010, Abstract, [0005]-[0007], [0041]. Second, the proposed modification would have involved a simple and understood change in a programming algorithm, which was nothing more than a combination of known prior art elements according to known methods and known techniques (programming a processor based on signals from snore sensors and/or user information) to yield predictable results (dynamically filtering snore data).

C. Dependent Claims 7 and 18

1. **Claim 7.** “*The sleep data acquisition system in claim 6, further comprising a software filter configured to extract a high frequency portion of a signal from one of the three sensors to*

obtain a snore signal.”

241. Truschel discloses a dynamic software-based filtering process for better detecting snoring. Similar to Ciulla, Truschel discloses using a “pressure sensor 48 as a microphone” which “is capable of converting a snore pressure wave into a proportional analog signal.” Ex. 1011, [0045]. The system includes a “snore analysis device 64” and a “digital band pass filter 58,” which are implemented within a controller 50 using “suitable programming” (*software filter*). *Id.*, [0043], [0046] (“programmed to function as a snore detection device”).

242. The filter obtains a snore signal from a sensed pressure signal (*a software filter configured to extract...a signal from one of the three sensors to obtain a snore signal*). Ex. 1011, [0043], [0045]-[0046], [0050], [0068] (“first checking for vibrations in pressure signal 72 within a broad range of 40 to 160 Hz”), [0053] (“Digital band pass filter 58 filters...frequencies in a range of about 40-160 Hz. The approximate qualifying frequency range represents the approximate range of frequencies produced during snoring and takes into account factors, such as the age, gender, or health of a patient.”).

243. A POSITA would have understood that extracting a 40-160 Hz range snore signal comprises *extract[ing] a high frequency portion* of a monitored breathing signal like that claimed. *See, e.g.*, Ex. 1042, [0058] (“a filter circuit which filters out the higher frequency components, that is, any snoring component 110s in

the 10 Hz-300 Hz range, from the input respiration signal 110”); Ex. 1043, [0044] (“snoring waveform data...frequencies of 5 Hz or more”), [0045] (“high-frequency band indicating snoring”); Ex. 1044, [0091] (“the relatively high frequency snore”).

2. **CLAIM 18.** *“The sleep data acquisition system in claim 17, further comprising a software filter configured to extract a high frequency portion of a signal from one of the at least two sensors to obtain a snore signal.”*

244. In my opinion, Ciulla in view of Orbach and Truschel discloses this limitation. *See* Sections XI.D.15 (Ground 1, Claim 17), XIII.C.1 (Ground 3, Claim 7).

XIV. OPINIONS ON GROUND 4: CIULLA IN VIEW OF ORBACH AND KUMAR RENDERS OBVIOUS CLAIMS 6, 8, 13, 14, 17, AND 19

A. A POSITA Would Have Been Motivated to Combine

245. It is my opinion that Ground 1 specifies how Claims 6, 8, 13, 14, 17, and 19 are obvious. Nonetheless I have been asked to assume a scenario where this is not that case. As to that scenario, Ground 4 incorporates Ground 1 and modifies the Ciulla-Orbach system with Kumar’s teachings regarding the use of a remote practitioner site to control a user sensor and corresponding transmitted data (via a cell phone, PDA, etc. of Ciulla-Orbach) like that claimed. Such remote sensing control features would have reduced burden on and confusion of patients when operating at-home sleep equipment by allowing their doctors or a practitioner to directly control the sensing hardware. Ex. 1009, [0080], [0085]. A POSITA would

have recognized that the modification would have allowed the system to be used for remote troubleshooting to reduce problems when a user uses such sleep monitoring equipment, thereby improving the user experience and allowing the system to better develop. Ex. 1009, [0258]-[0259].

B. A POSITA Would Have Had a Reasonable Expectation of Success

246. A POSITA would have had a reasonable expectation of success in modifying Ciulla combinations with the teachings of Kumar. First, Ciulla and Kumar are analogous art, both pertaining to sleep monitoring systems. Section XI.B; Ex. 1009, [0015], [0068], [0239]-[0241] (“A system allows remote monitoring of such devices by providing in-home monitoring utilizing polysomnography and Oximetry with newer portable and/or disposable devices with on line live monitoring.”), Abstract. Second, such a modification would have been no more than an obvious and predictable integration of known methods for enabling a doctor/practitioner to control user/patient sensing equipment with a reasonable expectation of success. Implementing such changes in software described by Kumar with the given Ciulla-Orbach hardware configuration would have been well within the skill and capability of a POSITA before the alleged priority date. Ex. 1009, [0080], [0085], [0191].

C. Dependent Claims 6, 8, 13, 14, 17, and 19

1. **Claim 6:** “*The sleep data acquisition system in claim 5,*

wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA.”

247. Kumar discloses a patient side device that generates sensed sleep information (***sleep data***). Ex. 1009, [0015], [0068], [0071] (“The patient-side device is located with a patient and can be any device that gathers physiological data from the patient.”), [0239]-[0241]. A POSITA would have understood that a medical provider receives such sensed information from a stream manager program running on a patient computing device (e.g., PDA, “wireless telephone,” etc.) (***first software when being executed by the cell phone or PDA***), which receives sensor data from the patient-side device via wireless communication hardware (***first transceiver***). Ex. 1009, [0089] (“The sensors are coupled to a medical and/or biofeedback patient-side device that is in wireless or wired communication with a computing device.”), [0071]-[0072], [0080]-[0081], [0085], [0191].

248. A provider in the Kumar system can remotely control the readout of the patient’s sensor data via the stream manager running on the user’s PDA or wireless telephone (***remote Internet site or communication station can control the sleep data transmission***). Ex. 1009, [0015] (“Further, the provider may remotely control the client-side device. For example, when the patient is sleeping in his/her home with EKG and blood pressure devices connected, the provider can start these devices

remotely to read the data periodically or whenever needed.”), [0080] (“Using optional remote control features built in to the system, remote providers can control the software on the patient’s end. Thus, patients do not need to know how to operate the software.”), [0085] (“A remote client module (not shown) allows remote hosts to view the data being streamed in real time. The remote client module can also control the software being run on the patient’s and/or provider’s end. Multiple remote client modules can run concurrently, allowing multiple remote providers to view data form one device.”).

249. Because the remote provider receives sleep data from the cell phone/computing device’s stream manager, a POSITA would have understood that Kumar describes that a *remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA* when the remote practitioner device remotely reads, periodically starts, or otherwise controls sensor measurements that are received from the PDA or wireless telephone as described by Kumar. From Kumar’s teachings, a POSITA would have found it obvious to implement Orbach’s remote server (*communication station*) to also *control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA*.

2. **Claim 8:** “*The sleep data acquisition system in claim 6, further*

comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data.”

250. In my opinion, Ciulla in view of Orbach and Kumar discloses this limitation. *See* Sections XIV.C.1 (Ground 4, Claim 6), XI.D.6 (Ground 1, Claim 8).

3. **Claim 13.** *“The sleep data acquisition system in claim 12, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by the cell phone or PDA.”*

251. In my opinion, Ciulla in view of Orbach and Kumar discloses this limitation. *See* Section XIV.C.1 (Ground 4, Claim 6), XI.D.10 (Ground 1, Claim 12).

4. **Claim 14.** *“The sleep data acquisition system in claim 13, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data.”*

252. In my opinion, Ciulla in view of Orbach and Kumar discloses this limitation. *See* Sections XIV.C.3 (Ground 4, Claim 13), XI.D.6 (Ground 1, Claim 8).

5. **Claim 17.** *“The sleep data acquisition system in claim 16, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by*

the cell phone or PDA.”

253. In my opinion, Ciulla in view of Orbach and Kumar discloses this limitation. *See* Sections XI.D.14 (Ground 1, Claim 16), XIV.C.1 (Ground 4, Claim 6).

6. **Claim 19.** *“The sleep data acquisition system in claim 17, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data.”*

254. In my opinion, Ciulla in view of Orbach and Kumar discloses this limitation. *See* Sections XIV.C.5 (Ground 4, Claim 17), XI.D.6 (Ground 1, Claim 8).

XV. OPINIONS ON GROUND 5: CIULLA IN VIEW OF ORBACH, KUMAR, AND TRUSCHEL RENDERS OBVIOUS CLAIMS 7 AND 18

255. This Ground incorporates Ground 3 for the combination of Ciulla, Orbach, and Truschel, and incorporates Ground 4 for adding Kumar’s teachings to modify the Ciulla-Orbach-Truschel system in the same manner for claims 7/18. *See* Sections XIV.C (Ground 4, Claim 6/17), XIII.C (Ground 3, Claim 7/18). The addition of Kumar does not change how a POSITA would consider the combination of Ciulla-Orbach-Truschel.

1. **Claim 7.** *“The sleep data acquisition system in claim 6, further comprising a software filter configured to extract a high frequency portion of a signal from one of the three sensors to*

obtain a snore signal.”

256. In my opinion, Ciulla in view of Orbach, Kumar, and Truschel discloses this limitation. *See* Sections XIV.C.1 (Ground 4, Claim 6), XIII.C.1 (Ground 3, Claim 7).

2. **Claim 18.** *“The sleep data acquisition system in claim 17, further comprising a software filter configured to extract a high frequency portion of a signal from one of the at least two sensors to obtain a snore signal.”*

257. In my opinion, Ciulla in view of Orbach, Kumar, and Truschel discloses this limitation. *See* Sections XIV.C.5 (Ground 4, Claim 17), XIII.C.1 (Ground 3, Claim 7).

XVI. OPINIONS ON GROUND 6: CIULLA IN VIEW OF ORBACH, NAGAI, AND KUMAR RENDERS OBVIOUS CLAIMS 6, 8, 13, 14, 17, AND 19

1. **Claims 6, 8, 17, and 19**

258. In my opinion, Ciulla in view of Orbach, Nagai, and Kumar discloses claims 6, 8, 17, and 19 for the same reasons discussed in Ground 4. *See* Section XIV. The modification of the Ciulla-Orbach-Kumar combination in view of Nagai does not materially affect the combination’s disclosure of these claims as discussed in Ground 4.

2. **Claim 13.** *“The sleep data acquisition system in claim 12, wherein the remote Internet site or communication station can control the sleep data transmission from the at least first transceiver, and/or the first software when being executed by*

the cell phone or PDA.”

259. In my opinion, Ciulla in view of Orbach, Nagai and Kumar discloses this limitation. *See* Sections XII.E.3 (Ground 2, Claim 12), XIV.C.1 (Ground 4, Claim 6).

3. **Claim 14.** *“The sleep data acquisition system in claim 13, further comprising a software filter wherein the software filter is adapted to determine one or more of airflow, tidal volume, ventilation rate and snore detection from the sleep data.”*

260. In my opinion, Ciulla in view of Orbach, Nagai and Kumar discloses this limitation. *See* Sections XVI.2 (Ground 6, Claim 13), XI.D.6 (Ground 1, Claim 8).

XVII. OPINIONS ON GROUND 7: CIULLA IN VIEW OF ORBACH, NAGAI, AND TRUSCHEL RENDERS OBVIOUS CLAIMS 7 AND 18

261. This Ground incorporates Ground 2 for the combination of Ciulla, Orbach, and Nagai, and incorporates Ground 3 for adding Truschel’s teachings to modify the Ciulla-Orbach-Nagai system in the same manner for claims 7/18. *See* Sections XII, XIII. In my opinion, the addition of Truschel does not change how a POSITA would consider the combination of Ciulla-Orbach-Nagai.

XVIII. OPINIONS ON GROUND 8: CIULLA IN VIEW OF ORBACH, NAGAI, AND KUMAR, AND TRUSCHEL RENDERS OBVIOUS CLAIMS 7 AND 18

262. This Ground incorporates Ground 6 for the combination of Ciulla, Orbach, Nagai, and Kumar, and incorporates Ground 3 for adding Truschel’s

teachings to modify the Ciulla-Orbach-Nagai-Kumar system in the same manner for claims 7/18. *See* Sections XIII, XVI. In my opinion, the addition of Truschel does not change how a POSITA would consider the combination of Ciulla-Orbach-Nagai-Kumar.

XIX. CONCLUSION

263. For all the reasons stated above, it is my opinion that the challenged claims of the '512 Patent are unpatentable.

Declaration of Jason Kirkness, Ph.D. in Support of
Petition for *Inter Partes* Review USP No. 11,690,512

This declaration and my opinions are made to the best of my knowledge and understanding, and based on the material available to me at the time of signing this declaration. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true. Further, I am aware that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001. I declare under penalty of perjury that the foregoing is true and correct.

Executed on December 6, 2024.