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reference included in any combination is not anticipatory in its own right. In particular, ResMed is currently unaware of the extent to which CleveMed will contend that certain limitations of the asserted claims are not disclosed in the art identified by ResMed as anticipatory. To the extent that an issue arises with respect to any such claim limitation, ResMed reserves the right to identify other references and combinations, which may make obvious the addition of the allegedly missing limitation to the disclosed system or method. In addition, ResMed may rely on some references under both 35 U.S.C. § 102 and 35 U.S.C. § 103. It is established law that “a rejection for obviousness under § 103 can be based on a reference which happens to anticipate the claimed subject matter.” *In re Meyer*, 599 F.2d 1026, 1031 (C.C.P.A. 1979).

Furthermore, none of ResMed’s anticipation arguments should be construed as an admission that the disclosed feature in fact practices the claim, and ResMed reserves the right to take the position that the same feature or functionality in the ResMed products accused of infringement do not practice the claims. In many cases, ResMed’s anticipation positions are based on CleveMed’s erroneous infringement allegations. However, if the same functionality is determined to practice the claim(s) in the ResMed products accused of infringement, the same functionality was also present in the prior art.

C. The PAP System Patents

1. Identification of Prior Art

The following prior art patents and published patent applications relate to the invalidity of the asserted claims of the ’921, ’284, ’029 (collectively “the PAP System Patents”). Each of the following may qualify as prior art as of an earlier date than the listed date, *e.g.*, an earlier publication or filing date. ResMed reserves the right to supplement the priority dates for the below listed references as discovery continues.

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Prior Art Patents and Published Applications	Filed Date	Issue/Publication Date	Invalidity Basis
U.S. Patent No. 6,167,258 (“Schmidt”)	10/09/1998	12/26/2000	Obviousness
U.S. Patent No. 6,644,311 (“Truitt”)	12/19/2001	11/11/2003	Obviousness
U.S. Patent Application Publication No. 2004/0129838 (“Lisy”)	1/3/2002	7/8/2004	Obviousness
U.S. Patent No. 8,187,209 (“Giuffrida”)	3/17/2005	5/29/2012	Obviousness
US 6,993,380 (“Modarres”)	6/4/2003	1/31/2006	Obviousness
U.S. Patent Application Publication No. 2016/0193437 (“Bao”)	Aug. 5, 2013	July 7, 2016	Anticipation and/or obviousness
U.S. Patent Application Publication No. 2018/0199882 (“Klee”)	June 19, 2015	July 19, 2018	Obviousness
WO 2021/152526 (“Shouldice”)	Jan. 29, 2021	Aug. 5, 2021	Obviousness
U.S. Patent Application Publication No. 2007/0161913 (“Farrell” or “Farrell-913”)	March 30, 2005	July 12, 2007	Anticipation and/or obviousness
WO 2005/096737 (“Farrell-737”)	3/30/2005	10/20/2005	Obviousness
U.S. Patent Application Publication No. 2007/0155208 (“Pirzada”)	Dec. 30, 2006	July 5, 2007	Obviousness
U.S. Patent No. 5,424,942 (“Dong”)	Aug. 10, 1993	June 13, 1995	Obviousness
U.S. Patent No. 5,704,345 (“Berthon-Jones” or “Berthon-Jones-345”)	11/4/1994	1/6/1998	Obviousness
U.S. Patent No. 6,152,129 (“Berthon-Jones-129”)	8/14/1997	11/28/2000	Obviousness
JP H5-309135 (“Emi”) ²	May 11, 1992	Nov. 22, 1993	Anticipation and/or obviousness

² These contentions rely on certified English translations of the Emi and Toge references, produced at the time of service of these Initial Contentions.

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Prior Art Patents and Published Applications	Filed Date	Issue/Publication Date	Invalidity Basis
P2002-291889 (“Toge”)	March 29, 2001	Oct. 8, 2002	Anticipation and/or obviousness
U.S. Patent Application Publication No. 2003/0065536 (“Hansen”)	8/7/2002	4/3/2003	Obviousness
US Patent Application Publication No. 2003/0236450 (“Kocinski”).	3/20/2003	12/25/2003	Obviousness
WO 02/078775A2 (“Genger”)	4/2/2002	10/10/2002	Obviousness
WO 2005/028029 (“Stahmann”)	9/17/2004	3/31/2005	Obviousness

The following prior art non-patent publications relate to the invalidity of the asserted claims of the PAP System patents.

Prior Art Publications	Date of Publication	Invalidity Basis
Mohd Fadlee A. Rasid and Bryan Woodward, <i>Bluetooth Telemedicine Processor for Multichannel Biomedical Signal Transmission via Mobile Cellular Networks,</i> IEEE Transactions on Information Technology in Biomedicine, Vol. 9, No. 1, March 2005, at 35 (“Rasid” or “Rasid IEEE”) ³	03/2005	Obviousness
D. Alan Lankford, <i>Wireless CPAP Patient Monitoring: Accuracy Study,</i> Telemedicine Journal and e-Health, Vol. 10, No. 2, 2004, at 162 (“Lankford”)	6/1/2004	Obviousness

³ B. Woodward and M.F.A. Rasid, *Wireless Telemedicine: The Next Step*, 4th Int’l IEEE EMBS Special Topic Conference on Information Technology Applications in Biomedicine, 2003, at 43 (“Woodward”) is a 2003 disclosure by the same authors of similar work disclosed in the later 2005 Rasid publication. To the extent it is determined that Rasid is not prior art, or if CleveMed supplements its contentions with regard to conception and diligence in reduction to practice with additional facts or information, ResMed reserves the right to rely on Woodward in place of Rasid. ResMed also reserves the right to rely on similar disclosures as those provided in Farrell in an earlier publication for at least the same reasons.

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and/or also an index of a subject’s symptoms as recited in the asserted independent claims of the ’269 patent. Regardless, calculation of AHI was a well-known feature of commercial PAP devices known to a POSITA, and disclosed in the prior art.

Dr. D’Ambrosio’s opinions as to the scope of the claimed “symptom data,” “severity,” and “index” terms is in conflict with the statements made by CleveMed during prosecution of the ’269 patent. CleveMed amended the claims on March 27, 2018 to add that “calculating symptom data” was “based in part on both the respiratory airflow data and pulse oximetry sensor data.” ’116 FH, 3/27/2018 Amendment at 2, 4. CleveMed argued that the Wright reference does not teach a “*processor adapted for receiving sensor data from both the signal processing module and the airflow sensor and calculating symptom data based in part on both the respiratory airflow data and pulse oximetry sensor data of level of severity and/or an index of a level of severity of the subject’s sleep disorder symptoms,*” but “Wright uses the data collected with its system to *calculate and analyze stroke indicators not to calculate a level of severity or an index of a level of severity of the subject’s sleep disorder breathing symptoms* as claimed.” ’116 FH, 3/27/2018 Remarks at 10 (italics and underline in original, bold added). CleveMed also argued in numerous places that the Wright reference does not disclose the claimed “calculating” features, but “rather calculates and stores stroke recovery information,” citing paragraphs 30-45 of Wright. ’116 FH, 3/27/2018 Remarks at 10-11, see also page 12 (emphasis added). But a review of Wright’s paragraphs 30-45 shows that Wright described monitoring “patient health characteristics including, for example, oral and/or nasal airflow, snore, ... oximetry, pulse rate, ... and flattening index via the diagnosis unit and sensors in the blower” (¶ 34), generating “several indices” including “[o]ne such index [] based upon a functional relationship between the number of central or obstructive apneas over a particular time period” (¶¶ 35-36), and identifying an apnea (¶ 37).

like a PAP apparatus.

Moreover, the PAP System Patents’ disclosure copied its only mention of a cell phone directly from U.S. Patent No. 8,187,209 (or at least application no. 11/082,668) (“Giuffrida”) that issued May 29, 2012 from an application filed March 17, 2005. *See, e.g.*, RMD-305981 at 13:5-36. For example, the asserted claims of the ’921, ’284, and ’029 patents recite a cellular phone, which appears to rely solely on the copied text from Giuffrida for the requirements of 35 U.S.C. § 112, first paragraph.

With regard to claims that specifically recite the use of Bluetooth, the PAP System Patents fail to identify any specific advancement by using the “Bluetooth wireless protocol,” mentioning Bluetooth only once and only generally stating that “IR or Bluetooth wireless technology can be used for data transmission.” ’921 patent, 8:39-48. Thus, the patent disclosure appears to rely on the knowledge of a POSITA to apply Bluetooth wireless technology generally to the disclosed system. As established above and in the attached exhibits, a POSITA would have found it at least obvious to similarly use their knowledge of Bluetooth wireless technology to arrive at the claimed system. A POSITA would have been motivated to do so, for example, because of Bluetooth’s ubiquity in the art, low operating power, and design to avoid interference.

All of the reasons discussed above for combining references are incorporated by reference into the claim charts whether or not specifically stated.

D. The Integrated PAP and Diagnosis System Patents

1. Identification of Prior Art

The following prior art patents and published patent applications relate to the invalidity of the asserted claims of the ’333 and ’680 patents (collectively “the Integrated PAP and Diagnosis System Patents”). Each of the following may qualify as prior art as of an earlier date than the listed date, *e.g.*, an earlier publication or filing date. ResMed reserves the right to

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supplement the priority dates for the below listed references as discovery continues.

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U.S. Patent No. 6,167,258 (“Schmidt”)	10/09/1998	12/26/2000	Obviousness
U.S. Patent No. 6,644,311 (“Truitt”)	12/19/2001	11/11/2003	Obviousness
U.S. Patent Application Publication No. 2004/0129838 (“Lisy”)	1/3/2002	7/8/2004	Obviousness
U.S. Patent No. 8,187,209 (“Giuffrida”)	3/17/2005	5/29/2012	Obviousness
US 6,993,380 (“Modarres”)	6/4/2003	1/31/2006	Obviousness
U.S. Patent Application Publication No. 2016/0193437 (“Bao”)	Aug. 5, 2013	July 7, 2016	Anticipation and/or obviousness
U.S. Patent Application Publication No. 2018/0199882 (“Klee”)	June 19, 2015	July 19, 2018	Obviousness
WO 2021/152526 (“Shouldice”)	Jan. 29, 2021	Aug. 5, 2021	Obviousness
U.S. Patent Application Publication No. 2007/0161913 (“Farrell” or “Farrell-913”)	March 30, 2005	July 12, 2007	Anticipation and/or obviousness
WO 2005/096737 (“Farrell-737”)	3/30/2005	10/20/2005	Obviousness
U.S. Patent Application Publication No. 2007/0155208 (“Pirzada”)	Dec. 30, 2006	July 5, 2007	Obviousness
U.S. Patent No. 5,424,942 (“Dong”)	Aug. 10, 1993	June 13, 1995	Obviousness
U.S. Patent No. 5,704,345 (“Berthon-Jones” or “Berthon-Jones-345”)	11/4/1994	1/6/1998	Obviousness
U.S. Patent No. 6,152,129 (“Berthon-Jones-129”)	8/14/1997	11/28/2000	Obviousness
JP H5-309135 (“Emi”)	May 11, 1992	Nov. 22, 1993	Anticipation and/or obviousness
P2002-291889 (“Toge”)	March 29, 2001	Oct. 8, 2002	Anticipation and/or obviousness

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Prior Art Patents and Published Applications	Filed Date	Issue/Publication Date	Invalidity Basis
U.S. Patent Application Publication No. 2003/0065536 (“Hansen”)	8/7/2002	4/3/2003	Obviousness
U.S. Patent No. 5,953,713 (“Behbehani”)	9/12/1997	9/14/1999	Obviousness
WO 2004/032719 (“Burton”)	10/9/2003	4/22/2004	Obviousness
U.S. Patent No. 6,889,691 (“Eklund”)	9/27/2001	5/10/2005	Obviousness
US Patent Application Publication No. 2004/0040560 (“Euliano”).	8/29/2003	3/4/2004	Obviousness
U.S. Patent Application Publication No. 2002/0143576 (“Nolvak”)	March 28, 2001	Oct. 3, 2002	Obviousness
U.S. Patent Application No. 2004/0106855 (“Brown”)	Oct. 7, 2003	June 3, 2004	Obviousness
U.S. Patent No. 6,605,038 (“Teller”)	June 23, 2000	August 12, 2003	Obviousness
U.S. Patent Application Publication No. 2008/0214903 (“Orbach”)	Feb. 22, 2006	Sept. 4, 2008	Obviousness
US 2002/0022973 (“Sun”)	Mar. 21, 2001	Feb. 21, 2002	Obviousness
US 2005/0211249 (“Wagner”)	May 19, 2005	Sept. 29, 2005	Obviousness
WO 2005/028029 (“Stahmann”)	Sept. 17, 2004	Mar. 31, 2005	Obviousness
WO 02/078775 (“Genger”)	April 2, 2002	Oct. 10, 2002	Obviousness

The following prior art non-patent publications relate to the invalidity of the asserted claims of the Integrated PAP and Diagnosis System patents.

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Initial Contentions.

Exhibit	Description of Charts for '680 Patent	Invalidity Theory
D01	P2002-291889 (“Toge”)	Anticipation (1-5, 7, 11-13, 16-18, 20-28), Obviousness (1-5, 7, 8, 10-13, 15-18, 20-31)
D02	ResMed ResTraxx Prior Art	Anticipation (1, 2, 4, 5, 12, 13, 15, 16, 17, 20, 22-28, 30), Obviousness (1-5, 7, 8, 10-13, 15-18, 20-31)
D03	U.S. Patent Application Publication No. 2007/0161913 (“Farrell”)	Anticipation (1-5, 7, 11-13, 16-18, 20-28), Obviousness (1-5, 7, 8, 10-13, 15-18, 20-31)
D04	JP H5-309135 (“Emi”)	Obviousness (1-5, 7, 8, 10-13, 15-18, 20-31)

Exhibit	Description of Charts for '333 Patent	Invalidity Theory
E01	P2002-291889 (“Toge”)	Anticipation (15-20, 22, 24-25, 27, 29), Obviousness (15-20, 22, 24-27, 29)
E02	ResMed ResTraxx Prior Art	Anticipation (15, 17-20, 22, 25-27), Obviousness (15-20, 22, 24-27, 29)
E03	U.S. Patent Application Publication No. 2007/0161913 (“Farrell”)	Anticipation (15-20, 22, 24-25, 27, 29), Obviousness (15-20, 22, 24-27, 29)
E04	JP H5-309135 (“Emi”)	Obviousness (15-20, 22, 24-27, 29)

The following analysis applies to the attached Exhibits D01-E04 in addition to the motivations identified above and expressly in the exhibits.

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IX. PRIOR ART DOCUMENT PRODUCTION

Pursuant to LPR 3.6 and the Scheduling Order, ResMed produces prior art documentation accompanying these invalidity and unenforceability contentions. Some of the produced prior art documents are highly confidential and are being produced on an outside attorneys’ eyes only basis (HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY) pursuant to the Stipulated Protective Order entered in this matter. (*See* D.I. 23-2221).

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CERTIFICATE OF SERVICE

I, Angela C. Whitesell, do hereby certify that on this 15th day of July, 2024, the attached

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UNENFORCEABILITY CONTENTIONS were served upon the following counsel of record

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