

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

RESMED CORP.,	)	
	)	
<i>Plaintiff / Counterclaim-</i>	)	
<i>Defendant,</i>	)	
	)	
v.	)	C.A. No. 1:23-cv-02221-BMB
	)	
CLEVELAND MEDICAL DEVICES, INC.,	)	
<i>Defendant / Counterclaim</i>	)	
<i>Plaintiff.</i>	)	
	)	
	)	

**PLAINTIFF AND COUNTERCLAIM DEFENDANT RESMED CORP.’S
INITIAL INVALIDITY AND UNENFORCEABILITY CONTENTIONS**

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.

HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY

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.

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).

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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/s/ Angela C. Whitesell
Michael R. Reed (0063995) Trial Attorney
Elise K. Yarnell (0093996)
HAHN LOESER & PARKS LLP
65 East State Street, Suite 1400
Columbus, Ohio 43215
Tel. (614) 221-0240
Fax: (614) 221-5909
mreed@hahnlaw.com
eyarnell@hahnlaw.com

OF COUNSEL:

Sean Cunningham (admitted *Pro Hac Vice*)
Tiffany Miller (admitted *Pro Hac Vice*)
David R. Knudson (admitted *Pro Hac Vice*)
DLA PIPER LLP (US)
4365 Executive Drive, Suite 1100
San Diego, CA 92121-2133
Telephone: 858-677-1400
sean.cunningham@dlapiper.com
tiffany.miller@dlapiper.com
david.knudson@dlapiper.com

Angela C. Whitesell (admitted *Pro Hac Vice*)
DLA PIPER LLP (US)
1201 N. Market Street, Suite 2100
Wilmington, DE 19801-1147
Telephone: 302-468-5711
angela.whitesell@dlapiper.com

***Attorneys for Plaintiff / Counterclaim-
Defendant ResMed Corp.***

CERTIFICATE OF SERVICE

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

PLAINTIFF AND COUNTERCLAIM DEFENDANT'S INITIAL INVALIDITY AND

UNENFORCEABILITY CONTENTIONS were served upon the following counsel of record

via electronic mail:

Lisa Kobialka
Charles Keller
James R. Hannah
Jennifer L. Gilbert
Melissa T.G. Brenner
Michael H. Lee
Paul J. Andre
Sabah S. Khokhar
Timothy J. Layden
**KRAMER LEVIN NAFTALIS &
FRANKEL LLP**
Redwood Shores
Ste. 700
333 Twin Dolphin Drive
Redwood Shores, CA 94065
Telephone: (650) 752-1711
Facsimile: (650) 752-1800
lkobialka@kramerlevin.com
ckeller@kramerlevin.com
jhannah@kramerlevin.com
jgilbert@kramerlevin.com
missy.brenner@hogefenton.com
mhlee@kramerelevin.com
pandre@kramerlevin.com
skhokhar@kramerlevin.com
tlayden@kramerlevin.com

Joshua A. Friedman
**CALFEE, HALTER & GRISWOLD-
CLEVELAND**
The Calfee Building
1405 East Sixth Street
Cleveland, OH 44114-1607
Telephone: (216) 622-8200
Facsimile: (216) 241-0816
jfriedman@calfee.com

Benu Wells
**KRAMER LEVIN NAFTALIS &
FRANKEL LLP**
Red Bank
1177 Avenue of The Americas
Red Bank, NH 07701
Telephone: (212) 715-7590
bwells@kramerlevin.com

/s/ Angela C. Whitesell
Angela C. Whitesell (pro hac vice)