

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

Case IPR2023-00565
U.S. Patent No. 10,076,269

**PATENT OWNER'S OBJECTIONS TO EVIDENCE
UNDER 37 C.F.R. § 42.64**

Patent Owner Cleveland Medical Devices, Inc. (“CleveMed” or “Patent Owner”) objects under the Federal Rules of Evidence and 37 C.F.R. § 42.64(b)(1) to the admissibility of the following documents submitted by Petitioner ResMed Corp. (“ResMed” or “Petitioner”) in its Petition for *Inter Partes* Review. See Paper No. 1. Trial was instituted on May 6, 2024. See Paper No. 23. Thus, Patent Owner’s objections are timely under 37 C.F.R. § 42.64(b)(1). Patent Owner serves Petitioner with these objections to provide notice that Patent Owner will move to exclude the above-identified exhibits as improper evidence.

I. PETITIONER’S EVIDENCE

A. Objections to the Declaration of Dr. Jacob Sharony (Ex. 1004, the “Sharony Declaration”)

Patent Owner objects to the admissibility of the Sharony Declaration for at least the following reasons:

- Dr. Sharony’s opinions in the Sharony Declaration are inadmissible because they are conclusory, do not disclose underlying facts or data in support of his opinions, and are unreliable. Therefore, Dr. Sharony’s opinions are inadmissible under Federal Rules of Evidence (“FRE”) 702.
- The Sharony Declaration does not introduce evidence of Dr. Sharony’s personal knowledge of the subject matter of the testimony

contained therein, rendering such testimony inadmissible under FRE 602.

- The Sharony Declaration is hearsay under FRE 801 and does not fall within a hearsay exception under FRE 802 or FRE 803.
- Dr. Sharony's opinions in the Sharony Declaration are confusing, of minimal probative value, outweighed by prejudice, and/or a waste of time and therefore are inadmissible under FRE 403.

For at least these reasons, the Dr. Sharony Declaration is inadmissible under FRE 403, 602, 702, and 801-803.

B. Various Exhibits and Publications

Patent Owner objects to the admissibility of the following exhibits for at least the following reasons:

Ex.1004	Declaration of Jacob Sharony, Ph.D.
Ex.1009	Paradiso, et al., <i>Wearable Health Care System for Vital Signs Monitoring</i> , 4th Annual IEEE Conf. on Information Technology Applications in Biomedicine, 2003, at 283 ("Paradiso")
Ex. 1013	Guilleminault, et al., <i>Obstructive sleep apnea syndromes</i> , Med. Clin. N.Am. Vol. 88, No. 3 (May 1, 2004), pp.611-630. ("Guilleminault-2004").
Ex. 1014	Guilleminault, et al., <i>Clinical Overview of the Sleep Apnea Syndromes</i> , Sleep Apnea Syndromes (1978), pp.1-12. ("Guilleminault-1978").

Ex. 1015	"Sleep-Related Breathing Disorders in Adults: Recommendations for Syndrome Definition and Measurement Techniques in Clinical Research: The Report of an American Academy of Sleep Medicine Task Force," SLEEP Vol. 22, No. 5 (1999), pp.667-689 ("Chicago Criteria")
Ex.1016	Morón, et al., <i>A wireless monitoring system for pulse-oximetry sensors</i> , 2005 Systems Communications (ICW'05, ICHSN'05, ICMCS'05, SENET'05), Montreal, Quebec, August 14-17, 2005, pp.79-84
Ex.1017	Bluetooth Ver.1.0B (Parts A and B) (November 1999)
Ex.1018	Roux et al., <i>Continuous positive airway pressure: new generations</i> , Clinics in Chest Medicine, Vol. 24 (2003), pp.315-342.
Ex. 1022	Nieto et al., <i>Association of Sleep-Disordered Breathing, Sleep Apnea, and Hypertension in a Large Community-Based Study</i> , JAMA Vol. 284, No. 14 (April 12, 2000), pp.1829-1985.

- Petitioner has failed to authenticate Exhibits 1009, 1013-1018, 1022 under FRE 901 and FRE 602. Specifically, Petitioner has failed to establish that Exhibits 1009, 1013-1018, 1022 are what Petitioner claims they are, and has failed to authenticate Exhibits 1009, 1013-1018, 1022 .
- To the extent that Petitioner attempts to rely on any date that appears on Exhibits 1009, 1013-1018, 1022 to establish public accessibility of Exhibits 1009, 1013-1018, 1022 as a printed publication or prior art reference, the date is hearsay under FRE 801 and does not fall within a hearsay exception under FRE 802 and FRE 803.

- Further, the dates in Exhibits 1009, 1013-1018, 1022 have not been authenticated and are inadmissible under FRE 901.
- Exhibit 1022 is not relevant under FRE 401 because Petitioner did not rely on Exhibit 1022 in its Petition, and therefore is inadmissible under FRE 402.
- Exhibits 1009 and 1016 are not relevant under FRE 401 and inadmissible under FRE 402. Exhibit 1009 and 1016 is incomplete and thus confusing, of minimal probative value, outweighed by prejudice, and/or a waste of time and therefore inadmissible under FRE 403.

Respectfully submitted,

Dated: May 17, 2024

/James Hannah/
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Patent Owner's Objections to Evidence
IPR2023-00565 (U.S. Patent No. 10,076,269)

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(Case No. IPR2023-00565)

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CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. § 42.6(e), that
service was made on the Petitioner as detailed below.

<i>Date of service</i>	May 17, 2024
<i>Manner of service</i>	Electronic Mail (tiffany.miller@us.dlapiper.com; ed.sikorski@us.dlapiper.com; jim.heintz@us.dlapiper.com; DLA-ResMed-CleveMed-IPR@us.dlapiper.com)
<i>Documents served</i>	PATENT OWNER'S OBJECTIONS TO EVIDENCE UNDER 37 C.F.R. § 42.64
<i>Persons Served</i>	DLA Piper LLP (US) Tiffany C. Miller Edward H. Sikorski James M. Heintz

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