

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 MOTION TO EXCLUDE EVIDENCE

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I. INTRODUCTION

Patent Owner (“CleveMed”) requests the exclusion of the Declaration of Jacob Sharony, Ph.D., (Ex. 1004, “the Declaration”) under the Federal Rules of Evidence (“FRE”) because Dr. Sharony does not qualify as a person of ordinary skill in the art (“POSITA”) or a medical expert in this matter. Dr. Sharony admittedly does not have the type of specialized knowledge in diagnostic sensor systems or the treatment of sleep-disordered breathing that could assist the Board in this matter, which renders his opinions unreliable and inadmissible as a matter of law. CleveMed timely objected to the Declaration through its submission of “Objections to Evidence.” See Paper 25 at 1-2.

II. LEGAL STANDARD

The Federal Rules of Evidence govern the admissibility of evidence in *inter partes* review proceedings. 37 C.F.R. § 42.62(a). FRE 702 requires that a witness be “qualified in the pertinent art” to testify as an expert concerning an obviousness challenge. *HVLPO2, LLC v. Oxygen Frog, LLC*, 949 F.3d 685, 689 (Fed. Cir. 2020). It is an abuse of discretion to admit testimony “on any issue that is analyzed through the lens of an ordinarily skilled artisan” from a person who “does not have ordinary skill in the art.” *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1377-78 (Fed. Cir. 2022). “Without that skill, the witness’ opinions are neither relevant nor reliable. The opinions would not be based on any specialized

knowledge, training, or experience that would be helpful to the factfinder.” *Id.* at 1377.

III. THE BOARD SHOULD EXCLUDE DR. SHARONY'S DECLARATION

The claims of the '269 Patent relate to diagnostic sensor systems for the diagnosis and treatment of sleep-disordered breathing. *See* '269 Patent at Claims 1, 5, 8, 15. Accordingly, as Petitioner acknowledges, a POSITA must have “experience working with diagnostic sensor systems.” Pet. at 24.

Dr. Sharony has—and claims—no experience working with diagnostic sensor systems. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 588 (1993) (FRE requires an expert witness to have “knowledge, skill, experience, training, or education” in the pertinent art). His experience working with “data capture devices” does not qualify him as an expert here because such devices are not—and are not claimed to be—diagnostic sensor systems. *See* Declaration at ¶ 16 (“data capture devices” include digital imagers (bar code readers) and wireless communication devices); *Seaman v. Seacor Marine L.L.C.*, 326 F. App'x 721, 725 (5th Cir. 2009) (affirming the district court's exclusion of an oncologist's testimony concerning the cause of the plaintiff's bladder cancer because the oncologist had no “particular expertise in bladder cancer and its causes”); *see also Extreme Networks, Inc. v. Enterasys Networks, Inc.*, 395 F. App'x 709, 715 (Fed. Cir. 2010) (“General

experience in a related field may not suffice when experience and skill in specific product design are necessary to resolve patent issues.”).

Dr. Sharony also acknowledged that he has no experience in diagnosing or treating sleep-disordered breathing and is not a medical doctor:

Q. Are you a medical doctor?

A. I'm not a medical doctor.

Q. Have you ever diagnosed a patient for any disease?

A. I'm not a medical doctor, doctor. I'm not allowed to deal with patients.

Q. Have you ever treated a patient for any disease?

A. No. I'm not a medical practitioner. But this patent is about the system. It's – there is nothing about medical here. . . .

Q. Do you have any experience diagnosing sleep disorders?

A. I'm not a medical professional.

Q. Do you have any experience treating sleep disorders?

A: Same answer. I'm not a medical professional.

Q. Do you have any experience operating a CPAP machine?

A: I'm not a medical practitioner; so . . .

Q. Do you have any experience designing a CPAP machine?

A. I haven't designed CPAP machine

Ex. 2016 (Sharony Depo.) at 24:9-25:22. Petitioner acknowledges that Dr. Sharony is not qualified to testify as an expert witness, at least regarding medical matters.¹ In a post-grant review proceeding challenging a related patent, Dr. Sharony abstained from opining on matters calling for medical expertise. *See ResMed Corp. v. Cleveland Medical Devices, Inc.*, No. PGR2024-00012, Ex. 1003 at ¶¶ 57, 63 (relying on the testimony of a medical professional for an “index of treatment efficacy” as used in sleep-related breathing disorder diagnostics). The Board should—at the very least—exclude ¶¶ 120-28 of Dr. Sharony's Declaration, which purport to contain expert testimony on the subject of diagnosing sleep disorders and modifying sleep disorder treatments.

Dr. Sharony's failure to qualify as a POSITA or a medical expert renders his opinions on these subjects unreliable and inadmissible as a matter of law. *Kyocera Senco Indus.*, 22 F.4th at 1376-77 (“To offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art. Without that

¹ In a spate of recently filed IPRs and reexamination requests Petitioner did not offer any testimony from Dr. Sharony. *See generally* IPR2025-00157, -00158, -00159, -00160, -00246, and -00247 and Reexamination Control Nos. 90/019,700 and 90/019,705.

skill, the witness' opinions are neither relevant nor reliable. The opinions would not be based on any specialized knowledge, training, or experience that would be helpful to the factfinder.”). “[A]dmitting testimony from a person . . . with no skill in the pertinent art serves only to cause mischief and confuse the factfinder.” *Id.* at 1377. His testimony should, therefore, be excluded under FRE 702.

CleveMed's experts, on the other hand, have abundant education and experience in the subject matter of their testimony. Dr. Borkholder has over 25 years of experience working with diagnostic sensor systems in the medical field. Ex. 2017 at ¶ 7 (“engineered a full-featured medical diagnostic imaging system”), ¶ 15 (“[a]ll of my research has been biomedical Cepheid, Zonare, and Casana are all medical device companies: Cepheid is DNA diagnostics”), Appendix A (CV) at 2 (listing his work experience with diagnostic sensor systems in the medical field). Thus, Dr. Borkholder has specialized experience directly related to diagnostic sensor systems. CleveMed's medical expert, Dr. Patil, has specialized experience directly related to the diagnosis and treatment of sleep-disordered breathing. *See* Ex. 2018 at ¶¶ 1-9 (explaining his education and work experience in the field of sleep-disordered breathing diagnosis and treatment). Notably, Petitioner did not depose Dr. Patil on the substance of his testimony in this matter and did not otherwise challenge the substance of his testimony in its Reply.

Dr. Sharony's testimony given from the point of view of a POSITA and his testimony concerning sleep-disordered-breathing diagnostics and treatment must, therefore, be excluded under FRE 702. Even if the Board does not exclude the Declaration in its entirety, it should give the Declaration little to no weight. See *Costco Wholesale Corp. v. Robert Bosch LLC*, No. IPR2016-00041, Paper 70 at 20 (P.T.A.B. April 12, 2017) (declining to credit expert testimony in part because the expert's experience was not pertinent to the field of the claimed invention).

IV. CONCLUSION

In view of the foregoing, the Board Patent Owner respectfully requests that the Board exclude the Declaration under FRE 702.

Dated: January 13, 2025

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

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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>	January 13, 2025
<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 MOTION TO EXCLUDE EVIDENCE
<i>Persons Served</i>	DLA Piper LLP (US) Tiffany C. Miller Edward H. Sikorski James M. Heintz

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