

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 B1

**PETITIONER'S OPPOSITION TO
PATENT OWNER'S MOTION TO EXCLUDE**

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I. INTRODUCTION

Dr. Sharony's education and professional experience, including "experience working with diagnostic sensor systems," meets the undisputed definition of a person of ordinary skill as one having "a bachelor's degree in mechanical engineering, electrical engineering, computer science, or an equivalent field and two years of industry experience working with diagnostic sensor systems and networked data systems." Pet., 24; POR, 8; EX1004, ¶70. CleveMed's argument that Dr. Sharony lacks "experience working with diagnostic sensor systems" is squarely contradicted by the evidence. And, even if Dr. Sharony lacks experience (he does not), the undisputed definition of a person of ordinary skill (POSA) also states that "[a]n increase in experience could compensate for less education, and vice-versa." Moreover, CleveMed's Motion is untimely and should be denied on that basis alone. Regardless of the definitional constraints for a POSA, Dr. Sharony's demonstrated knowledge, skill, and experience are helpful to understand the evidence. Thus, the Board should deny Patent Owner's Motion to Exclude (Paper 35, "Mot.").

II. LEGAL STANDARD

The Federal Rules of Evidence govern the admissibility of evidence in an *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). “[A] declarant’s expertise and experience need not match perfectly the experience and education of a person of ordinary skill in the art in order to provide testimony so long as there is an adequate relationship between the declarant’s education and experience when compared to the claimed invention.” *Cardiovascular Systems, Inc. v. Shockwave Medical, Inc.*, No. IPR2019-00405, Paper 99 at 21 (P.T.A.B. Feb. 2, 2023) (citing *SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010)); *see also AVX Corp. v. Greatbatch, Ltd.*, No. IPR2014-0697, Paper 57 at 24 (P.T.A.B. Oct. 21, 2015). The declarant must, instead, have sufficient “knowledge, skill, experience, training, [and] education” of such specialized nature to assist the trier of fact to understand the evidence. *SEB*, 594 F.3d at 1373 (quoting Fed. R. Evid. 702).

III. CLEVEMED’S MOTION TO EXCLUDE IS UNTIMELY

CleveMed’s Motion to Exclude under FRE 702 based on Dr. Sharony’s qualification as a person of ordinary skill is not timely because CleveMed did not file an objection on this basis in compliance with the Board’s procedures. *See Consolidated Trial Practice Guide* at 78-79; 37 C.F.R. § 42.64(b)(1). CleveMed’s only objections under FRE 702 were that Dr. Sharony’s opinions “are conclusory, do not disclose underlying facts or data in support of his opinions, and are unreliable.” *See Patent Owner’s Objections to Evidence* (Paper 25) at 1-2. This

conclusory statement fails to object to Dr. Sharony's qualification as a person of ordinary skill, which is the basis of CleveMed's Motion to Exclude. Thus, the Motion is untimely and should be denied.

IV. DR. SHARONY IS A POSITA AND QUALIFIED TO ASSIST ON RELEVANT ISSUES

Dr. Sharony's extensive education and 35+ years of professional experience including "experience working with diagnostic sensor systems" meets the undisputed definition of a person of ordinary skill as one having "a bachelor's degree in mechanical engineering, electrical engineering, computer science, or an equivalent field and two years of industry experience working with diagnostic sensor systems and networked data systems." Pet., 24; POR, 8.

CleveMed's Motion does not dispute that Dr. Sharony meets the educational portion of the POSITA definition or that Dr. Sharony possesses "two years of industry experience working with ... networked data systems." EX1004, ¶11 (listing Dr. Sharony's Bachelor's Degree, Master's Degree, M.Phil., and Ph.D. in Electrical Engineering); *see also id.*, ¶12-14 (describing "substantial experience" in "wireless networking and architecture solutions."). CleveMed's only basis for exclusion is CleveMed's conclusory and unfounded argument that Dr. Sharony has "no experience working with diagnostic sensor systems." Mot., 2. CleveMed is wrong. As explained in Petitioner's Reply, Dr. Sharony has "several years" of experience with data capture devices, including "sensors [that] could be used as

physiological sensors to sense changes in blood oxygen saturation or blood vessels volume and detect various vital signs” as well as “physiological sensors, including but not limited to human activity sensors, heart rate and pulse sensors, and environmental sensors (*e.g.*, proximity, temperature).” EX1004, ¶¶10, 14, 16. CleveMed’s suggestion that Dr. Sharony only has experience with “digital imagers (bar code readers) and wireless communication devices” (Mot., 2) is thus unfounded.

CleveMed attempts to minimize Dr. Sharony’s experience by arguing that his experience with data capture devices “does not qualify him as an expert” because “such devices are not ... diagnostic sensor systems.” Mot., 2. But Dr. Sharony’s experience with physiological sensors used in diagnostic sensor systems for sensing blood oxygen saturation, blood vessels volume, vital signs, human activity, heart rate, and pulse is directly relevant to the claims of the ’269 patent that recite electronics, processors, and transceivers adapted for measuring, filtering, processing, and transmitting signals from “a pulse oximeter” and other sensors, as well as the electronic connections between those sensors, processors, electronics, transceivers, and a PAP device. *See, e.g.*, EX1001, 23:53-57 (“a signal processing module comprising a first input adapted for connecting to a pulse oximeter sensor with a signal, electronics adapted for filtering and processing the signal, and an output adapted for outputting pulse oximetry sensor data.”).

The claims are further directed to a PAP device with data acquisition components and sensors “known to those skilled in the art” (EX1001, 6:10-11), and transmission of acquired data—issues that are well within the purview of an electrical engineer with 35+ years of experience in communication technology. For example, in the claimed system of sensors, mask, hose, and device supplying pressurized air (PAP device) using a blower, the location of a sensor within that system is well within the purview of an engineer. *See* POR, 9-10; EX2016, 59:3-15 (testifying that the location of the airflow sensor is “a matter of engineering”), 51:16-21 (“it’s a matter of implementation. That[’s] what we engineers really do.”), 53:7-12 (explaining that “you can put the sensor in [a] different location, like near the mask or near the generator as long as you take in account what kind of flow is or leakage through the mask. So it’s a matter of implementation.”).

Further, the undisputed definition of a POSITA recites that “[a]n increase in experience could compensate for less education, and vice-versa.” Pet., 24; POR, 8. Thus, even if Dr. Sharony lacked experience with diagnostic sensors (he does not), his Master’s Degree, M.Phil., and Ph.D. in Electrical Engineering compensates for this. *Medtronic, Inc. v. Teleflex Life Scis. Ltd.*, No. IPR2020-01343, 2022 WL 557277, at *8 (P.T.A.B. Feb. 23, 2022) (rejecting argument that Petitioner’s expert did not meet the definition POSITA where “it is undisputed that ‘[e]xtensive experience and technical training might substitute for education.’”).

Notably, CleveMed fails to address this portion of the POSITA definition. Indeed, this built-in flexibility in the definition distinguishes this case from the *Kyocera* case CleveMed relies on. Unlike this IPR, the POSITA definitions in *Kyocera* did not allow for experience to compensate for education and vice-versa. *See Kyocera Senco Indus. Tools, Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1376-77 (Fed. Cir. 2022).

Moreover, CleveMed's argument that Dr. Sharony has "no experience in diagnosing or treating sleep-disordered breathing and is not a medical doctor" (Mot., 3-5) is irrelevant—the undisputed definition of a person of ordinary skill does not require a medical degree or experience diagnosing or treating sleep-disordered breathing. The only specific paragraphs CleveMed points to in Dr. Sharony's report pertaining to diagnostic or medical knowledge are paragraphs 120-28, but the technical analysis in these paragraphs is well within the purview of Dr. Sharony's education and experience with physiological sensors such as pulse oximeters. *E.g.*, EX1004, ¶¶121-22 (discussing feedback and event detection signals). And Dr. Sharony made it clear at his deposition that he was testifying from the perspective of an engineer on the implementation of engineering concepts. EX2016, 51:16-21 ("it's a matter of implementation. That[']s what we engineers really do.").

Also, CleveMed relies almost exclusively on the opinions of Dr. Borkholder—an engineer who has no experience designing or developing PAP devices. *See* EX2017, ¶¶2-15; EX1029, 15:25-22:5. Like Dr. Sharony, Dr. Borkholder has experience with diagnostic imaging systems. EX2017, ¶7. Although CleveMed cites to a declaration from Dr. Patil, a medical doctor, Dr. Patil opines only on the FDA approval process and specific aspects of Stahmann and Edgar, leaving Dr. Borkholder for all other opinions in this matter. EX2018, ¶¶23-31. CleveMed and its experts do not point to any medical reason why Dr. Sharony's opinions on the engineering aspects of the claimed systems are purportedly incorrect. Indeed, Dr. Borkholder testifies in paragraphs 58-68 on the same matters that CleveMed seeks to exclude from Dr. Sharony's Declaration in paragraphs 120-28. Dr. Borkholder does not cite to Dr. Patil or claim to have reviewed his opinions, and vice-versa, and therefore none of Dr. Borkholder's opinions are supported by Dr. Patil. *E.g.*, EX1029, 11:10-12:15. Thus, to the extent CleveMed argues that the Board should exclude any of Dr. Sharony's opinions because he is not a medical doctor (it should not), the Board should—by that same logic—also exclude Dr. Borkholder's opinions.

Furthermore, Dr. Sharony's experience with digital imagers and mobile and wireless communication technologies is also highly relevant to the claims of the '269 patent, including, *e.g.*, claim 1's "module transceiver," claim 5's "nonvolatile

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memory” and “transmission ... to a remote location,” and claim 15’s wireless communication features. See Exhibit 1004, ¶¶ 12, 14, 15. CleveMed does not, and cannot, dispute that Dr. Sharony has sufficient knowledge, skill, experience, training, and education on such relevant topics so as to be helpful to the Board.

V. CONCLUSION

Petitioner respectfully requests that the Board deny Patent Owner’s Motion to Exclude.

Respectfully submitted,

Dated: January 21, 2025

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CERTIFICATE OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b) on the Patent Owner by **Electronic Mail** of this Petitioner's Opposition to Patent Owner's Motion to Exclude.

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