

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 REQUEST FOR DIRECTOR REVIEW

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I. INTRODUCTION

Patent Owner respectfully requests that the Director vacate and remand the Board's Final Written Decision (Paper 42, "FWD") because it depends on testimony from a witness, Dr. Sharony, who does not qualify as a person of ordinary skill in the art (POSITA). Although Dr. Sharony is highly educated, he has no experience working with **diagnostic sensor systems**, like the positive air pressure ("PAP") devices disclosed and claimed in U.S. Patent No. 10,076,269 (the "'269 Patent"). The Board did not find otherwise. Instead, when considering this issue, it redefined the definition of a POSITA and found that Dr. Sharony meets the redefined standard. FWD at 16 ("The agreed-upon definition of the POSITA states that the artisan has two years of industry experience **working with sensors** and networked data systems.") (emphasis added). That is not the agreed-upon definition, and the Board did not find that Dr. Sharony meets the actual agreed-upon definition.

CleveMed also respectfully requests that the Director reverse the Board's conclusions concerning Claims 8-14 because it erroneously credited the uninformed, conclusory opinions of Dr. Sharony over those of Dr. Patil, who has over 20 years of experience in the field of sleep and respiratory medicine. Dr. Patil's unchallenged testimony explains that no medical professional would have understood Doxepin as a treatment for sleep-related breathing pathologies or adjusted the dose of Doxepin based on the severity of the patient's sleep-disordered breathing symptoms. In any

event, the Board's final conclusion that these claims would have been obvious depends on its determination that Stahmann's therapy device ***could be*** modified to achieve the claimed invention, not that a POSITA ***would have*** found it obvious to adjust ***any*** pharmaceutical treatment, as claimed.

II. LEGAL STANDARD

Under the USPTO's interim procedures, Director Review of a Board decision may be warranted to determine if it includes (a) an abuse of discretion, (b) important issues of law or policy, (c) erroneous findings of material fact, or (d) erroneous conclusions of law. USPTO, Revised Interim Director Review Process at 2.B, Availability of Director Review: AIA Trial Proceedings (last modified March 18, 2025). "The Board abuses its discretion if its decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact finding; or (4) involves a record that contains no evidence on which the Board could rationally base its decision." *Sierra Wireless, ULC v. Sisvel S.p.A.*, 130 F.4th 1019, 1024-25 (Fed. Cir. 2025) (citation omitted).

The Federal Rules of Evidence govern the admissibility of evidence in *inter partes* review proceedings. 37 C.F.R. § 42.62(a). Federal Rule of Evidence 702 governs the admissibility of expert testimony and states that a witness is qualified as an expert if petitioner demonstrates through their knowledge, skill, experience, training, or education. Fed. R. Evid. 702 (2023) (showing factors). Under Federal

Rule of Evidence (“FRE”) 702 the Board assumes a “gatekeeping role” that ensures expert testimony is properly screened for relevance and reliability. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993).

Issues of infringement and validity are analyzed “from the perspective of a person of ordinary skill in the art,” such that a witness who is “not ‘qualified as an expert by knowledge, skill, experience, training, or education’ in the pertinent art . . . [cannot] ‘assist the trier of fact to understand the evidence or to determine a fact in issue.’” *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1361-62 (Fed. Cir. 2008) (quoting FRE 702). Thus, 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, 688-89 (Fed. Cir. 2020) (citation omitted). 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 1376-77.

III. STATEMENT OF THE CASE

The ’269 Patent “relates to an integrated sleep diagnosis and treatment device”

that uses positive airway pressure (“PAP” or “CPAP”) devices to analyze a patient’s physiological condition and treat their sleep apnea symptoms based upon a quantitative measure of the severity of the detected symptoms. Paper 29 (Patent Owner Response) at 5-8; FWD at 3-6; ’269 Patent, 1:19-21. Such devices are complex and require specialized knowledge in the art of network communications (e.g., to route data between the PAP device and the patient and/or medical professional) **and** of issues related to diagnosing and treating patients with such symptoms. It is, therefore, necessary for any witness testifying from the point of view of a POSITA to have specialized knowledge of the technical and medical aspects of the claims. See ’269 Patent, Claims 1, 5, 8, and 15.

ResMed Corp. (“Petitioner”) filed a Petition for inter partes review, challenging claims 1-20 of the ’269 Patent. Paper 1 (“Pet.”). That Petition relied on the testimony of Dr. Sharony in the form of a declaration. See Ex. 1004. And in recognition that the ’269 Patent concerns the medical diagnosis and treatment of patients, Petitioner represented that a POSITA would have had experience working with such “diagnostic sensor systems”:

A POSITA as of the priority date of the Challenged Patent (November 4, 2005) would have had 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. An increase in experience could compensate for less

education, and vice-versa.

Pet. at 24 (emphasis added); Paper 29 at 8.

The Board initially denied institution in consideration of the *Fintiv* factors. Paper 13 at 18. After the Director vacated that decision (so that Petitioner could address evidence concerning the district's median time-to-trial statistics), Petitioner filed a *Sotera*-style stipulation, and the Board instituted trial, citing guidance in place at the time that made such stipulations dispositive as to balance of the *Fintiv* factors. Paper 15 at 5-6; Paper 23 at 10-12.

In support of its case on the merits, CleveMed submitted declarations from two expert witnesses, whose testimony addressed Dr. Sharony's technical opinions and his testimony concerning the treatment of patients with a PAP device and other pharmaceutical agents. Dr. Borkholder has over thirty years of experience working with and developing physiological sensor systems and biomedical devices and systems. Ex. 2017. Dr. Patil is a sleep and respiratory medicine doctor whose over twenty years of experience qualifies him to testify about the proper use of medical terminology present in the '269 Patent, how to determine and treat sleep-disordered breathing symptoms, and the medical propriety of using particular drugs and therapies to treat sleep-disordered breathing symptoms. Ex. 2018.

CleveMed also argued that Dr. Sharony was not qualified to testify from the point of view of a POSITA under FRE 702 because he has no "experience working

with diagnostic sensor systems.” Paper 29 at 9 (“Dr. Sharony’s education and experience do not include any industry experience in diagnostic sensor systems in general or CPAP machines in particular. Dr. Sharony states only that he has ‘experience working with and analyzing physiological sensors’ (Ex. 1004 at ¶ 10) and with ‘bar code imagers’ (*id.* at ¶ 16), which are not diagnostic sensor systems.”).

In Reply, Petitioner pointed to Dr. Sharony’s experience with data capture devices, including “sensors [that] could be used as physiological sensors,” to suggest that this experience was sufficient to also give him experience in “diagnostic sensor systems.” Reply at 4-5. In the Sur-Reply, CleveMed argued that “Dr. Sharony does not hold the requisite work experience in ‘diagnostic sensor systems’ to testify as a POSITA in this matter” and that his “experience with ‘data capture devices’ . . . facially does not encompass diagnostic sensor systems.” Sur-Reply at 3-4.

When considering whether Dr. Sharony had the relevant experience to qualify him as a POSITA, the Board purported to adopt the parties’ agreement that a POSITA would have had experience working with diagnostic sensor systems (FWD at 15), but then it did not hold Dr. Sharony to that standard. Instead of addressing CleveMed’s argument that “Dr. Sharony does not hold the requisite work experience in ‘*diagnostic sensor systems*’” (Sur-Reply at 3) (emphasis added), the Board truncated this argument and addressed the wrong standard. FWD at 14 (“Patent Owner contends that ‘Dr. Sharony does not hold the requisite work experience in

“**diagnostic sensor[s].**” Sur-Reply at 3.”) (modification original, emphasis added).

After thus redefining the POSITA standard, the Board determined that Dr. Sharony was qualified to testify about diagnostic sensor systems, like the claimed PAP devices, in view of his experience working with sensors. FWD at 16 (“The agreed-upon definition of the POSITA states that the artisan has two years of industry experience working with sensors and networked data systems. Pet. 24; PO Resp. 8. Dr. Sharony testifies that he has 7 years’ experience working in industry with sensors and networked data systems at Motorola/Symbol. Ex. 1004 ¶ 14.”).

The Board also relied on Dr. Sharony’s opinions to determine that it would have been obvious to treat a patient with sleep-disordered breathing symptoms with a particular drug, Doxepin, based on the severity of the patient’s symptoms. See FWD at 75-76. Despite Dr. Sharony plainly having no relevant specialized knowledge in this area, the Board credited this testimony over that of Dr. Patil, who explained (1) why Doxepin, a drug used to treat insomnia, would not be used to treat sleep-disordered **breathing** symptoms **and** (2) that there is no evidence to support Dr. Sharony’s unsupported contention that it would have been obvious to adjust the dose based on a measure of severity like the apnea-hypopnea index (“AHI”). *Id.* at 67-82. Eventually, the Board found the claims obvious by focusing on the fact that Stahmann **could be** used to perform the requirements of Claim 8, not that it **would have been** obvious, as required under Federal Circuit precedent. *Id.* at 82.

IV. ARGUMENT

A. Dr. Sharony is Not a Person of Ordinary Skill in the Art

Dr. Sharony is not qualified to testify from the point of view of a POSITA because he does not have the requisite experience working with diagnostic sensor systems. FWD at 12, 15-17; *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986) (stating that the critical question in determining obviousness is whether the claimed invention was obvious to a person of ordinary skill in the art, not a layman or those skilled in remote arts). Patent Owner, therefore, respectfully requests that the Director reverse the Board's decision denying the Motion to Exclude Dr. Sharony's testimony and vacate the FWD, which relies on that testimony for its ultimate conclusions.

Initially, the Board recognized that Dr. Sharony's background and expertise are in the field of "data networks and mobile and wireless technologies," not systems that sense, diagnose, and treat medical ailments. FWD at 15-17. While that background and knowledge may be relevant to some aspects of the '269 Patent, it does not qualify him as a POSITA, who also would have had experience working with "diagnostic sensor systems," like the claimed PAP device, because that is the subject matter of the invention. *See State Cont. & Eng'g Corp. v. Condotte Am., Inc.*, 346 F.3d 1057, 1069 (Fed. Cir. 2003). There is no dispute that the '269 Patent "relates to an integrated sleep diagnosis and treatment device." '269 Patent, 1:19-

21. It discloses PAP devices that analyze a patient's physiological condition to detect and treat symptoms of sleep apnea based upon a quantitative measure of the severity of the detected symptoms. Paper 29 at 5-8; FWD at 3-6. Indeed, Dr. Sharony testified that he understood the '269 Patent "field of endeavor" as being "CPAP devices and sensors." Ex. 2016 at 20:2-21:23.

In view of the foregoing, the Board properly adopted the parties' agreed understanding that a POSITA requires at least "two years of industry experience working with diagnostic sensor systems and networked data systems." FWD at 12-17. However, at the Oral Hearing, the Board began questioning whether the requisite experience in "diagnostic sensor systems" could be satisfied by experience with "a temperature probe" or "a car":

That's what an electrical engineer does. Sure, I mean, ***does it matter that he's working on a CPAP device or on a car?*** I'm not so sure. I think they could work on both, because they know how the information gets transported and how sensors work.

Paper 41 at 26:14-27:12 (emphasis added); FWD at 16. Of course, it matters that Dr. Sharony has no experience working on diagnostic sensor systems, like diagnostic PAP devices. *Kyocera*, 22 F.4th at 1377 ("Admitting testimony from a person . . . with no skill in the pertinent art serves only to cause mischief and confuse the factfinder.") (citation omitted). Barring relevant experience, testimony "amount[s] to nothing more than advocacy from the witness stand." *Id.* at 1364-65 (citation

omitted).

Dr. Sharony's experience in data networks and wireless technologies renders him no more of a POSITA than the car mechanic mentioned during the Oral Hearing. The Board did not find otherwise: Rather than finding that Dr. Sharony has the requisite experience working with "diagnostic sensor systems," it determined that he qualifies as a POSITA because "he has 'experience working with and analyzing physiological **sensors**, including but not limited to human activity **sensors**, heart rate and pulse sensors, and environmental sensors (e.g., proximity, temperature).'" FWD at 17; *see also id.* at 16 ("The agreed-upon definition of the POSITA states that the artisan has two years of industry experience **working with sensors** and networked data systems.") (emphasis added). This misstatement of the POSITA standard mirrors the Board's misstatement of CleveMed's argument. *Compare* FWD at 14 ("Patent Owner contends that 'Dr. Sharony does not hold the requisite work experience in "diagnostic sensor[s].'" Sur-Reply at 3.") *with* Sur-Reply at 3 ("Dr. Sharony does not hold the requisite work experience in 'diagnostic sensor systems.'").

After amending the agreed-upon POSITA standard to require experience with "diagnostic sensor[s]" instead of "diagnostic sensor systems," the Board found that Dr. Sharony's development of bar code imagers and wireless networking satisfied the requisite work since "[s]uch image sensors **could be used** as physiological

sensors.” FWD at 15-16 (emphasis added). However, whether any sensor that Dr. Sharony previously worked with “could be used” as a physiological sensor is irrelevant to whether or not he has experience working with **diagnostic sensor systems** that incorporate such sensors to diagnose and treat a patient.

CleveMed, therefore, respectfully requests that the Director reverse the Board’s decision denying the Motion to Exclude the testimony of Dr. Sharony because he does not have the required “knowledge, skill, experience, training, or education” in the pertinent art to testify as an expert in this case from the point of view of a POSITA. *Daubert*, 509 U.S. at 588 (quoting FRE 702); *Kyocera*, 22 F.4th at 1376-77 (in patent cases-particularly those involving validity, a witness must at least have ordinary skill in the relevant art).

B. The Board Erred in Admitting Dr. Sharony’s Testimony Concerning Pharmaceutical Treatments and Improperly Weighing Dr. Patil’s Rebuttal Testimony and Evidence

The Board also failed in its gatekeeping role under FRE 702 by relying upon the testimony of Dr. Sharony to conclude how diagnostic sensor systems (CPAPs) are designed and used in the diagnosis and treatment of sleep-disordered breathing pathologies. This failure is further exacerbated by simultaneously disregarding the rebuttal testimony of Dr. Patil, a respiratory and sleep medicine doctor of over 20 years on these issues. FWD at 15-20; *see also* ’269 Patent at Claims 1, 5, 8, 15; *Daubert*, 509 U.S. at 588 (FRE 702 requires an expert witness to have “knowledge,

skill, experience, training, or education” in the pertinent art) (quoting FRE 702). As gatekeeper, the Board had three duties: “(1) confirm the witness is a qualified expert; (2) check the proposed testimony is reliable and relates to matters requiring scientific, technical, or specialized knowledge; and (3) ensure the expert’s testimony is ‘sufficiently tied to the facts of the case,’ so that it ‘fits’ the dispute and will assist the trier of fact.” *See UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 832 (3d Cir. 2020) (citing *Daubert*, 509 U.S. at 591).

The Board erred in relying on Dr. Sharony’s opinion that since “awakening is a symptom of apnea or hypopnea,” a POSITA would be motivated to treat that condition with “doxepin.” Ex. 2016 at 28:17-29:13; FWD at 75-76 (citing Ex. 1004 at ¶¶ 34-36). **Regardless** of whether he qualifies as a POSITA in this case, Dr. Sharony plainly lacks the type of “specialized knowledge” in treating patients suffering from sleep apnea to testify on this subject. *Daubert*, 509 U.S. at 588, 591; *see also Flex-Rest, LLC v. Steelcase, Inc.*, 455 F.3d 1351, 1360 (Fed. Cir. 2006). Notably, when offering opinions in PGR2024-00012—a post-grant review petition challenging a related patent—Dr. Sharony abstained from opining on sleep-related diagnostics because he believed it called for testimony outside his expertise. *See ResMed Corp. v. Cleveland Med. Devices, Inc.*, No. PGR2024-00012, Ex. 1003 at ¶¶ 57, 63 (P.T.A.B. Dec. 13, 2023) (relying on the testimony of a medical professional for an “index of treatment efficacy” where it is used in sleep-related

breathing disorder diagnostics).

Thus, the Board decided that Dr. Sharony was better suited to opine on sleeping disorder symptoms and the drugs used to treat them than Dr. Patil, who has over twenty years of treating patients in sleep medicine. *See* FWD at 79. Contradicting Dr. Sharony's conclusory and unsupported testimony concerning the use and effects of doxepin, Dr. Patil testified that Doxepin is not used to treat sleep-related breathing disorders: It is used to promote sleep so that the patient keeps the PAP mask on throughout the night and **would not** be adjusted based on a measure of the severity of the patient's sleep-disorder symptoms. *See id.* at 79 (“[D]oxepin could be administered to improve the likelihood that the patient kept the mask on all night. . . . In this case, the treatment for the patient's sleep disorder or symptoms was the positive pressure provided by the CPAP, not the doxepin.”) (quoting Ex. 2018 at ¶ 31).

Eventually, the Board did not even determine that **it would have been obvious** to treat a patient's sleep-disordered breathing symptoms with Doxepin based on AHI. FWD at 82-83. Instead, it recognized that Stahmann teaches adjusting “suggests evaluating the effectiveness of **therapy** . . . in conjunction with AHI” and determined that “Stahmann '029 reasonably suggests detecting sleep events including arousal from sleep and supplying medicines, indicating that the device disclosed in Stahmann '029 **can perform the function** as recited

in element 8b.” FWD at 82 (emphasis added). But whether or not Stahmann’s device **could** perform the claimed function is facially insufficient to demonstrate what a POSITA **would have** done at the time of the invention. *ActiveVideo Networks, Inc. v. Verizon Commc’ns*, 694 F.3d 1312, 1327-28 (Fed. Cir. 2012) (the obviousness inquiry focuses on what a POSITA “would have” done).

There is, therefore, no medical, evidentiary, or legal basis for the Board’s conclusion that it was known or obvious to adjust a pharmaceutical agent to treat a patient’s sleep-disordered breathing symptoms based on the severity of those symptoms. CleveMed respectfully requests, that the Director reverse the FWD, at least with respect to Claim 8 and Claims 9-14, which depend therefrom.

C. The Board’s Errors Were Not Harmless

It is “not harmless” error to use an incorrect POSITA perspective where it “affects the ultimate conclusion” of unpatentability. *Innovation Toys, LLC v. MGA Ent., Inc.*, 637 F.3d 1314, 1323-24 (Fed. Cir. 2011) (reversing obviousness finding “based on an inappropriately low level of skill in the art”) (citation omitted). The Board relied on Dr. Sharony’s opinions as its primary support throughout its decision. *See, e.g.*, FWD at 33 (relying on Dr. Sharony to show that “the combination of Genger, Schmidt, Westbrook, and Farrell ’737 teaches the positive pressure airway (PAP) device as recited in claims 1 and 5”); *id.* at 48 (relying on Dr. Sharony’s to show that “the combination of Kocinski, Farrell ’737

and Bluetooth teaches the positive pressure airway (PAP) device as recited in claim 15”); *id.* at 34-35, 50 (using Dr. Sharony to support modifying the location of the airflow sensor to within the CPAP based upon his understanding of prior art); *id.* at 37, 51-52 (relying on Ex. 1004 ¶ 86 to support that the location of the airflow sensor is immaterial and consistent with prior art devices so long as it measures correctly); FWD at 48-49 (relying on Dr. Sharony for the motivation to replace a prior art pressure transducer with a flow sensor and house it within a CPAP device); *id.* at 75 (“Awakening is a symptom of apnea or hypopnea, which are sleep disorders.”); *see also id.* at 53 (citing Pet. at 71 which relies on Dr. Sharony for concluding that the observation of abnormal sleep events is symptom data).

Given Dr. Sharony’s lack of specialized skill and experience in the relevant art, it was error for the Board to admit, let alone rely, on that testimony. *In re Chapman*, 595 F.3d 1330, 1339-40 (Fed. Cir. 2010) (vacating obviousness determination because the Board’s misunderstanding of the prior art, which lead to its obviousness determination, was not harmless error).

V. CONCLUSION

Patent Owner respectfully requests that the Director grant its request for Director Review of the Final Written Decision, reverse the portion of the decision denying CleveMed’s Motion to Exclude, vacate the FWD, and/or reverse the FWD with respect to Claims 8-14.

Patent Owner's Request for Director Review
IPR2023-00565 (U.S. Patent No. 10,076,269)

Respectfully submitted,

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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>	June 2, 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 REQUEST FOR DIRECTOR REVIEW
<i>Persons Served</i>	DLA Piper LLP (US) Tiffany C. Miller Edward H. Sikorski James M. Heintz

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