

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. 10,076,296

**DECLARATION OF DR. DAVID A. BORKHOLDER
IN SUPPORT OF PATENT OWNER'S RESPONSE**

I. INTRODUCTION

I, David Borkholder, declare as follows:

1. I have been asked by Plaintiff Cleveland Medical Devices Inc. (“Plaintiff” or “CleveMed”) to submit this declaration in the matter referenced above. I have reviewed the ’269 Patent, its prosecution history, the *inter partes* review petition that Defendant ResMed Inc. (“Defendant” or “ResMed”) submitted regarding U.S. Patent No. 10,076,269 (“the ’269 Patent”), the decision to institute by the Patent Trial and Appeal Board (“PTAB”), and the art cited in those documents. I am familiar with the technology at issue and what was known in the art at the time of the earliest priority date for the ’269 Patent which is November 4, 2005.

II. EXPERIENCE AND QUALIFICATIONS

2. The details of my education, work experience, and research are summarized in my curriculum vitae (“CV”) attached to this Report as Appendix A. I have summarized some of the relevant information which is on my CV herein.

3. I hold a Ph.D and M.S. in Electrical Engineering from Stanford University, Stanford, California, and a B.S. in Microelectronic Engineering from the Rochester Institute of Technology (RIT), Rochester, New York. I have over 30 years of professional engineering experience in industry and academia.

4. Since 2004 I have taught as a professor at RIT, including as an Assistant Professor of Electrical Engineering and Microsystems Engineering, Associate Professor of Electrical and Microelectronic Engineering, and Bausch + Lomb Associate Professor and later Bausch + Lomb Professor of Microsystems Engineering. From 2016 to 2020, I also served as Director of Personalized Healthcare Technology at RIT. I oversaw undergraduate and graduate education and research in the areas of electronics, sensors, MEMs, and biomedical engineering. Courses I taught included Electronics I and II, Fundamental Electrophysiology, Biomedical Sensors and Transducers, Biomedical Instrumentation, Introduction to Nanotechnology and Microsystems, Introduction to Product Development (Honors), Reverse Engineering (Honors), and The Design Process (Honors). My research focused on Microsystems for inner ear drug delivery and fundamental studies of auditory function; non-invasive physiological monitoring; and personnel borne sensors for blast dosimetry and traumatic brain injury. During this time, I also had an appointment at the University of Rochester as an Adjunct Assistant and then Associate Professor of Otolaryngology and an Adjunct Associate Professor of Biomedical Engineering.

5. While at RIT, I became Co-Founder and Chairman of the Board of Casana (formerly Heart Health Intelligence, Inc.) (Rochester, NY), which is a technology spin-out company based on in-home cardiovascular monitoring

systems developed in the Borkholder Biomedical Microsystems Laboratory at RIT and exclusively licensed to Casana. I worked with the founder to define the company's business strategy and fundraising pitch. The company closed its first round of financing in September 2019, a Series A financing in August 2020, and a Series B financing in January 2022, for a total investment of \$46 million. From 2020 to March 2024, I worked at Casana full-time as its Chief Research Officer. Casana provides innovative healthcare delivery with a smart toilet seat that enables in-home health monitoring that is self-powered and easily accessible for the patient and provides clinically reliable data to health providers to respond to health changes in near real time. Casana's Heart Seat, which has been cleared by the FDA, uses proprietary algorithms to detect changes in heart rate and blood oxygenation to help care teams monitor patients' health trends. Casana's mission is to improve health and wellness through in-home health monitoring.

6. Also, while at RIT, from 2011 to 2021, I was Founder, Executive Chairman, and Chief Technology Officer of BlackBox Biometrics, Inc. (B3), which is the industry leader in sensor technology that instantly assesses forces that can cause traumatic brain injury. B3 formed as a technology spin-out company based on the Blast Gauge Technology (www.blastgauge.com) developed in the Borkholder Biomedical Microsystems Laboratory at RIT and licensed exclusively to B3. As part of B3, I established the leadership team, and engineering,

manufacturing, and customer service capabilities for commercialization of the Blast Gauge system. I championed efforts to treat blast overpressure exposure as an occupational hazard, which influenced congressional legislation in the FY18 and FY19 National Defense Authorization Acts, and specific brain health policies for the Department of Defense and Special Operations Command. As part of this work, I was recently interviewed for a November 27, 2023 front page New York Times article entitled “U.S. Troops Still Train on Weapons With Known Risk of Brain Injury.” One of my statements was selected as the New York Times Quotation of the Day. B3 was acquired by Airboss Defense Group in 2021.

7. Prior to becoming a professor at RIT, from 2001 to 2004, I served as Director of Hardware Engineering at ZONARE Medical Systems, Inc. (Mountain View, CA). In this role, I directed the Hardware Engineering group in the development of a portable ultrasound system utilizing non-traditional imaging techniques. My group developed three application-specific integrated circuits (ASICs), specifically analog, mixed signal, and high voltage, from concept to design, packaging and qualification, and successfully engineered a full-featured medical diagnostic imaging system following requirements of the Food and Drug Administration (FDA) and International Organization for Standards (ISO).

8. From 1998 to 2001, I worked at Cepheid (Sunnyvale, CA), which was publicly traded (on NASDAQ) from 2000 to 2016, achieving a peak market cap in

excess of \$4.5 billion. In 2016, Cepheid was acquired off the public market by Danaher Corp for \$4 billion. At Cepheid, I worked on programs for DNA analysis that were funded by the Defense Advanced Research Projects Agency (DARPA), a research and development agency of the United States Department of Defense responsible for the development of emerging technologies for use by the military. Additionally, I managed development of a ruggedized, battery powered thermal cyclor to the United States Army Medical Research Institute for Infectious Diseases (USAMRI-ID). As Director of Electronic Systems at Cepheid, I directed the development of GeneXpert, a fully automated sample processing system capable of extracting DNA from raw samples and performing DNA analysis. This platform was chosen by the United States Postal Service for screening the mail for the bioterrorism agent *Bacillus Anthracis* (Anthrax).

9. From 1989 to 1992, while obtaining my B.S. at RIT, I worked at Eastman Kodak Company on a variety of projects within the Microelectronics Technology Division involving the manufacture and characterization of charge-coupled device (CCD) image sensors. The results of this work were used to design production changes for enhanced imager sensitivity.

10. My Ph.D. dissertation at Stanford is entitled “Cell-Based Biosensors Using Microelectrodes.” For this dissertation, I designed and built microelectrode based sensors to monitor the morphology and electrophysiological activity of

cultured cells as a means for toxin detection and pharmaceutical screening. I developed microelectrode arrays, novel packaging techniques, and fluidic systems for interfacing to, and maintenance of the cultured cell systems. I created interface electronics and software for signal detection and interpretation for both action potential and impedance measurements. I also developed new signal processing techniques to improve measurement specificity and allow classification of unknown biologically active agents. While teaching at RIT, I have also advised a number of students in obtaining their Ph.D. and M.S. degrees and served as a member of dissertation panels.

11. I have also conducted extensive funded research. I have been the principal investigator on over \$21 million in research funding from federal government and industry sponsors, \$10.8 million of that in my role as a professor at RIT. As co-investigator, I have contributed to additional total research awards of \$5.4 million at RIT. The funding I have received has been provided through government agencies, such as the National Institute of Health (NIH) and National Institute on Deafness and Other Communication Disorders (NIDCD), as well as industry, such as Google.

12. I have served on numerous committees, review panels, and professional organizations. For instance, I have served on study sections for the NIH, for which I reviewed NIH grant applications as a scientific expert, including

as Chair of the NIH Bioengineering of Neuroscience, Vision and Low Vision Technologies (BNVT) study section from 2014 to 2016. I served as the Director of the Personalized Healthcare Technology Initiative at RIT from 2016 to 2020. I have been an Associate Editor of the Institute of Electrical and Electronics Engineers (IEEE) Journal of Translational Engineering in Health and Medicine from 2019 to the present and an Editorial Section Board member of the journal Micromachines from 2020 to the present . I am currently a Senior Member of the IEEE, and belong to the IEEE Engineering in Medicine and Biology Society. In 2023 I was named to the Rochester board of the American Heart Association.

13. I have received various honors in my field, including Fellow of the American Institute for Medical and Biological Engineering (2020); Distinguished Inventor of the Year - Rochester Intellectual Property Law Association (2016); and Rochester Business Journal Health Care Achievement Award: Innovation (2014) for research leading to the successful commercialization and fielding of the Blast Gauge System. I am named as an inventor on 28 issued patents.

14. I have published numerous articles and papers and spoken at various conferences and invited talks. Since March 2021, I have been serving on research task group for the North Atlantic Treaty Organization (NATO) for the Human Factors and Medicine (HFM) panel on “Guidelines to mitigate military occupational brain health risks from repetitive blast exposure,” and the NATO

HFM panel on “Blast Exposure Monitoring in Military Training and Operations.”

I have also served for a number of years on the DARPA Defense Sciences Research Council, which has run studies for DARPA to identify white space opportunities for the agency, frequently leading to new DARPA programs. I led biomedical studies such as New Tools for Neuroscience, Information in the Brain, and Towards Non-Invasive Measurement of Neural Activity in Humans.

15. My work as described above has focused on the biomedical aspect of electrical engineering. All of my research has been biomedical, and I taught courses for the biomedical option in electrical engineering at RIT. Also, Cepheid, Zonare, and Casana are all medical device companies: Cepheid is DNA diagnostics, Zonare is ultrasound, and Casana is non-invasive in-home cardiovascular monitoring. At Casana, the system is installed in the home to automatically collect physiological data. The data is captured, wirelessly transmitted to a remote cloud database, and then analyzed by cloud-based algorithms to extract key parameters from the collected sensor waveforms. These parameters are then presented to medical personnel to monitor the health of the patient.

III. COMPENSATION

16. My time is being billed at a rate of \$645 per hour, plus any direct expenses incurred. My compensation is based solely on the amount of time that I

devote to activity related to this case and is in no way affected by any opinions that I render. I receive no other compensation from work on this action. My compensation is not dependent on the outcome of this matter.

IV. LEGAL STANDARDS

17. I understand that if a patent has an effective filing date that is before March 16, 2013, the “pre-AIA” (America Invents Act) versions of 35 U.S.C. §§ 102 and 103 apply. Each of the Asserted Patents was filed before March 16, 2013 or claims priority to an application filed before March 16, 2013. § 102(a). I understand that a patent is valid under 35 U.S.C. § 102(a) (pre-AIA) unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

18. I understand that the requirement of “known or used by others in this country”, means knowledge or use which is accessible to the public. The knowledge or use relied on in a pre-AIA 35 U.S.C. 102(a) must be knowledge or use “in this country.” Prior knowledge or use which is not present in the United States, even if widespread in a foreign country, cannot be the basis of a prior art under pre-AIA 35 U.S.C. 102(a).

19. § 102 (b). I understand that a patent is valid under 35 U.S.C. § 102(b) (pre-AIA) unless the invention was patented or described in a printed publication

in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States. I understand that § 102(b) (pre-AIA) includes several distinct bars regarding the prior art status, each of which relates to activity or disclosure more than one year prior to the date of the application.

20. An invention is in “public use” under pre-AIA § 102(b) where the invention is in public use before the critical date of the application and is ready for patenting. The test for public use is whether the purported use: (1) was accessible to the public; or (2) was commercially exploited. I understand that commercial exploitation will likely require more than, for example, a secret offer for sale. I also understand that mere knowledge of the invention by the public does not necessarily constitute a bar under pre-AIA § 102(b) as the pre-AIA § 102(b) requires public use or sale, not public knowledge. An invention is “on sale” under pre-AIA § 102(b) if the invention is both (1) the subject of a commercial offer for sale not primarily for experimental purposes and (2) ready for patenting.

21. I understand that if a reference is only distributed internally within an organization and is intended to be confidential, it is not considered a “printed publication.” Further, I understand that where indexing is concerned, the reference must have been available in a way such that a person of ordinary skill in the art would be able to locate it.

22. For example, the presence of a document on the Internet does not necessarily mean that the document is a printed publication because it may not be catalogued or indexed in a meaningful way or available. Rather, it must be available in a meaningful way (e.g., indexing by subject matter) such that a person interested in the art may be able to locate it.

A. Anticipation

23. I have been informed that a patent claim is anticipated if each and every limitation of that claim is disclosed in a single prior art reference or single prior art product. A limitation may be disclosed explicitly or inherently. A limitation is inherently disclosed in a prior art reference if an unstated limitation is necessarily present in the prior art. Unless all the elements are found in a single piece of prior art in exactly the same situation and united the same way to perform the identical function, there is no anticipation. In other words, if elements are disclosed in different examples and scenarios, they would not be deemed a single anticipatory reference. I have been informed that, in order for a prior art reference to anticipate a patent claim, the reference must also enable one of ordinary skill in the art to make or practice the claimed invention without undue experimentation.

B. Obviousness

24. I have been informed that if a single reference does not contain every limitation of a patent claim, it can only invalidate that claim if it would be obvious

when considered in light of other prior art references or devices without viewing the combination with hindsight bias. Only if the differences between the claimed invention and the prior art are such that the claimed invention, as a whole, would have been obvious to a person having ordinary skill in the art at the time the invention was made without the benefit of hindsight is the claim invalid. I have been informed that the types of 35 U.S.C. § 102 prior art described above can individually be a basis for invalidating a patent, or these references can be combined to show a patent is invalid as obvious under 35 U.S.C. § 103. I have been informed that the analysis of obviousness involves several factual inquiries including the scope and content of the prior art, the differences between the prior art and the claim, and the level of ordinary skill in the art at the time of the invention.

25. I have been informed that the test for analogous art is very specific. I have been informed that art is non-analogous unless it is: (1) from the same field of endeavor as the claimed invention; or (2) reasonably pertinent to the particular problem faced by the inventor. I have been informed that an art citation that is not from the same field of endeavor as a claimed invention must be “reasonably pertinent” to the problem addressed by the inventor. I have been informed that art is “reasonably pertinent” when it would “logically commend itself” to an inventor’s attention in considering his problem. Conversely, I have been informed

that when art is directed to a different purpose than a claimed invention, an inventor would have less motivation or occasion to consider it. I have been informed that the fact that prior art references all concern the same field of endeavor is not in itself sufficient rationale for making the combination. Many types of techniques and systems exist in the same field of endeavor. That fact alone would not make it obvious to combine their features. I have been informed that a proper obviousness determination must show why a person of ordinary skill in the art would have thought to combine particular available elements of knowledge, as evidenced by the prior art, to reach the claimed invention.

26. I have been informed that a party seeking to invalidate a patent on obviousness grounds must demonstrate by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.

27. I have been informed that the party seeking to invalidate a patent on obviousness bears the burden of particularly explaining (1) the primary and secondary references, (2) the missing elements supplied by the secondary references, (3) why a POSITA would have looked to the secondary reference to fill gaps in the primary reference, and (4) why adding the secondary reference's teaching would yield predictable results.

28. I have been informed that to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. I have been informed that if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious.

29. Additionally, I understand that a patent is likely to be invalid for obviousness if a person of ordinary skill in the art can implement a predictable variation or if there existed at the time of the invention a known problem for which there was an obvious solution encompassed by the patent's claims. A combination is not obvious, however, where the combination cannot be implemented without undue experimentation or when the motivation to create the combination comes from hindsight.

30. I have been informed that, even when all claim limitations can be found in a combination of prior art references, the fact-finder must consider as part of the obviousness determination not only what the prior art teaches, but whether the prior art teaches away from the claimed invention and whether there is a motivation to combine teachings from separate references in the manner claimed. I have been informed that, in assessing whether a claimed invention is obvious,

secondary considerations that may weigh towards the non-obviousness of the invention, including the following, should be considered:

- a. Whether the claimed invention satisfied a long-felt need;
- b. Whether the claimed invention was preceded by a history of failures by others to solve a problem or problems solved by such invention;
- c. Whether the claimed invention achieved a surprising or unexpected result;
- d. Whether the claimed invention exhibited performance superior to prior art devices and/or methods;
- e. Whether the claimed invention has achieved commercial success;
- f. Evidence of industry acquiescence;
- g. Licenses;
- h. Whether the claimed invention has been copied;
- i. Whether the claimed invention was the subject of skepticism by the industry; and
- j. Whether the prior art taught away from the claimed invention

31. I have been informed that there must be a nexus tying the evidence of secondary considerations to the unique characteristics of the claimed invention.

Nexus can be established via a presumption when the evidence is tied to a product that embodies and is coextensive with the claims. Even without a presumption, nexus can be shown by tying the evidence to the unique characteristics of the claimed invention. I have also been informed that nexus is not limited to only novel features, but considers the invention as a whole.

V. PERSON OF ORDINARY SKILL IN THE ART

32. I understand that for purposes of this IPR, ResMed is asserting that the person of ordinary skill in the art (“POSITA”) is someone as of November 4, 2005, the priority date of the ‘269 Patent, with 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. I use this POSITA for my opinions.

VI. GROUND 1: CLAIMS 1-3, 5 AND 7 ARE PATENTABLE OVER THE GENDER COMBINATIONS

A. Genger in View of Farrell Does not Disclose nor Render Obvious an “Airflow Sensor Internal to the PAP Device For Measuring the Respiratory Airflow Data of a Subject” (Claims 1-7)

1. Genger Does Not Disclose an Airflow Sensor Internal to the CPAP Machine

33. The Petition admits that Genger’s respiratory airflow sensor, which is located at the patient’s mask, is located outside of the CPAP machine. See Pet. at

34 (“Genger shows the airflow sensor outside the CPAP device . . .”). I understand that Dr. Sharony also stated that a POSITA would not consider airflow sensor attached to a CPAP mask or hose to be “internal” to the PAP machine with an “enclosure,” as recited in the Challenged Claims. Ex. 2016 at 44:16-45:25.

34. I agree that a POSITA would understand that an airflow sensor located at the patient’s mask is external to the CPAP machine. Figure 7 of the ‘269 Patent illustrates a CPAP device that includes a pressure generator (312), a blower, a hose (314), nasal mask (316), a flow sensor (320), and a pressure sensor (322).

35. In one embodiment of the ‘269 Patent, a patient’s respirations are measured quantitatively and directly with a pneumotachograph. See ‘269 Patent at 7:61-63. In this embodiment, the pneumotachograph consists “of a standard oxygen nasal cannula or facemask respectively connected to a pressure transducer and placed in the nares or over the subject's mouth and nose respectively.” *Id.* at 7:66-8:2. In the “more sophisticated pressure support device” described with respect to Figure 7, however, the PAP device measures a patient’s respiratory airflow with an airflow sensor, flow sensor 320, which is located within the CPAP. *Id.* at 23:7-17. This “more sophisticated” device is the subject of Claims 1 and 15, which recite “an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow data of a subject using the PAP device.” *Id.* at 23:65-67, 26:7-8.

36. Unlike Farrell's design, which discloses a pneumotachograph that measures exhalation at or near an exhaust port on the mask, the '269 Patent discloses an embodiment where the patient's respiratory airflow is measured with an airflow sensor internal to the CPAP machine.

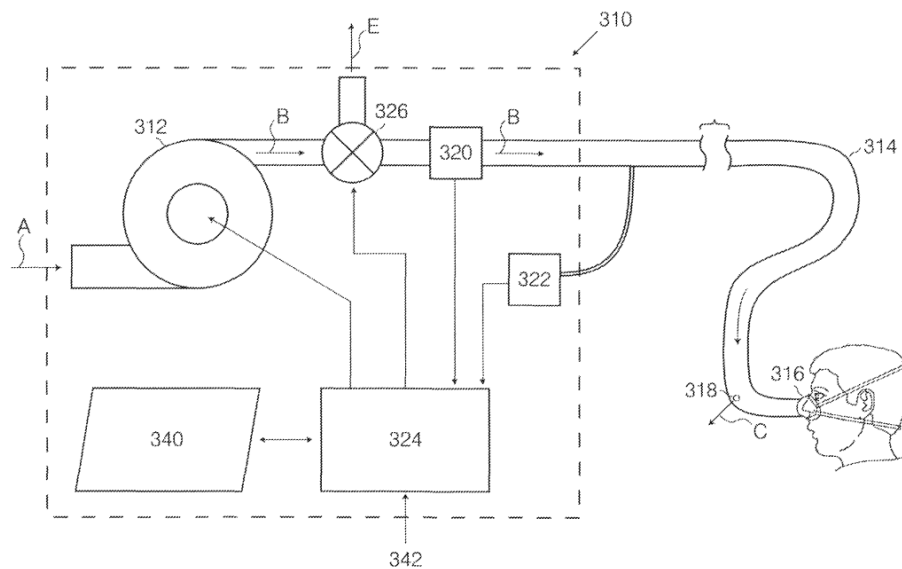


Fig. 7

'269 Patent at FIG. 7. In my opinion, the novel construction of the '269 Patent involves both the structure and functionality of the invention, whereby the airflow sensor (320) and the pressure sensor (322), located in the PAP device, can measure the respiratory airflow, before the processor generates the level of severity of the sleep disorder symptom and/or associated index and transfers the data to a remote location. '269 Patent at 23:7-17.

37. Thus, the specification supports the parties' shared understanding, along with my own, that an "internal" airflow sensor must be within the physical

enclosure of the PAP device. It cannot be outside the enclosure on the hose or the mask. In light of this agreement over proper scope of the term “internal,” there is no question that Genger’s mask-located airflow sensor is not internal to the PAP device.

38. Thus, it is my opinion that the Board should confirm the patentability of the Challenged Claims because Farrell and Berthon-Jones, which is incorporated by reference in Farrell, also do not teach or suggest an internal airflow sensor.

2. Farrell’s Sensors Incorporated in the Mask Are Not Internal to the CPAP Machine

39. I understand that the Board concluded that Farrell’s suggestion of “incorporating sensors into the mask” was sufficient to teach an internal respiratory airflow sensor. DI at 30-31. However, for the reasons discussed above, I disagree. See § V.A.1, *supra*.

40. The Farrell reference discloses a pneumotachograph for measuring a patient’s respiratory function. See DI at 27, n.7 (“A pneumotachograph is a device or apparatus for measuring the rate of the respiratory function”); see *also id.* at 49 (relying on Farrell’s pneumotachograph to conclude that the art teaches a device for measuring a subject’s respiratory airflow). In my opinion, the Board correctly recognized that Farrell’s pneumotachograph and pressure sensor are located at or near the mask DI at 30-31 (“Farrell reasonably teaches that a sensor can be

included in the mask of the CPAP device.”), 44-45. Farrell itself states that “mask pressure is measured at a pressure tap using a pressure transducer to derive a pressure signal $P_{\text{mask}}(t)$ ” where the pressure tap is located at the exhaust vent. See Ex. 1008 at 5:4-9. Thus, a POSITA would understand that Farrell’s mask-located pneumotachograph is not an airflow sensor internal to the CPAP machine.

41. It appears that neither Petitioner nor Dr. Sharony recognized that relocating Farrell’s airflow sensor within the CPAP machine would have the effect of rendering the sensor inoperable for its intended purpose. Once Farrell’s airflow sensor is moved inside the PAP device, it no longer operates as a pneumotachograph, and Dr. Sharony does not suggest that a POSITA would have had motivation to replace a pneumotachograph with a device that measures a patient’s airflow indirectly. Nor, given that it did not recognize this problem to begin with, did Petitioner recognize that its proposed modification would have required further major unaccounted-for modifications to the Genger-Farrell system, including the need to develop an algorithm that characterizes the flow characteristics of the CPAP system.

42. For at least these reasons Farrell does not cure Genger’s admitted deficiencies because it does not disclose or suggest an internal respiratory airflow sensor.

**3. Dr. Sharony's Conclusory Testimony Does Not Cure
Genger's and Farrell's Deficiencies**

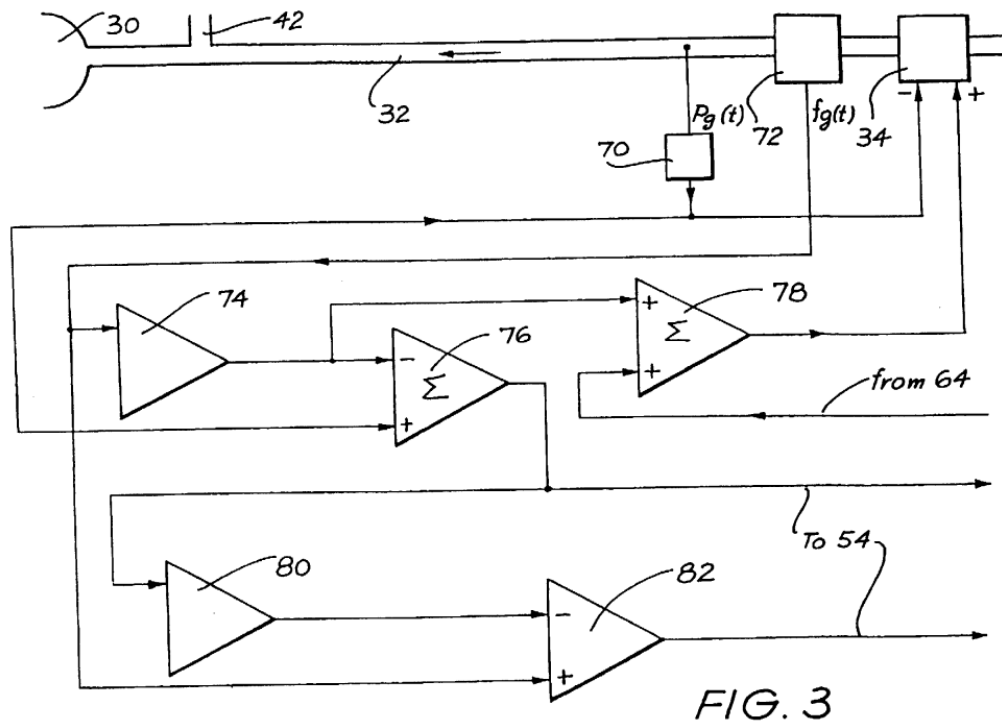
43. The Board should reject Petitioner's attempts to substantiate its claim that internal airflow sensors were "common" with testimony from Dr. Sharony because Berthon-Jones, which Dr. Sharony cites in his declaration, does not disclose an internal airflow sensor. *See* Ex. 1004 at ¶ 86.

44. Dr. Sharony's assertion that internal respiratory airflow sensors were "common" at the time of the invention is inconsistent with the Berthon-Jones reference that Dr. Sharony cites support. *See* Pet at 34 (citing Ex. 1004 at ¶ 86) (citing Ex. 2015 at 8:31-36, 7:17-24). The relevant portion of Berthon-Jones, states that the airflow sensor may measure flow through the hose near the mask or, alternatively, at a location at or near the output of the turbine, not that the airflow sensor is internal to the CPAP machine:

Further, it may not be convenient to mount the flow transducer 44 at or near the mask 30, nor to measure the mask pressure at or near the mask. An alternative arrangement, where the flow and pressure transducers are mounted at or near the air pressure generator (in the embodiment being the turbine 34) is shown in FIG. 3. The pressure $p_g(t)$ occurring at the pressure generator 34 outlet is measured by a pressure transducer 70. The flow $f_g(t)$ through tubing 32 is measured with flow sensor 72 provided at the output of the turbine 34.

Ex. 2015 at 8:31-40.

45. As illustrated in FIG. 3 of Berthon-Jones, the flow sensor is mounted to the tubing that connects the CPAP machine turbine output to the mask rather than being located internal to the machine:



Ex. 2015 at FIG. 3. As a POSITA would recognize, this hose extends between the CPAP machine and the mask, rather than being internal to the machine.

See Ex. 2020 and 2021 (images of CPAP machines); see also Ex. 2016 at 54:17-55:8 (“The pressure $p_g(t)$ occurring at the pressure generator 34 outlet is measured by a pressure transducer 70. The flow $f_g(t)$ **through tubing 32** is measured with flow sensor 72 provided at the output of the turbine 34.”) (emphasis added). A

POSITA would, therefore, understand Berthon-Jones to be disclose a flow sensor in the hose, not the enclosure.

46. Petitioner has also not established that it would have been obvious to relocate Genger's pneumotachograph based on the teachings of Berthon-Jones because Berthon-Jones' airflow sensor is not a pneumotachograph. A POSITA would recognize that pneumotachographs directly sense a patient's respiratory airflow, whereas the airflow sensor disclosed in Berthon-Jones measures respiratory airflow indirectly. Ex. 2015 at 8:31-62. Accordingly, Berthon-Jones does not establish that "POSITA would have found it obvious to locate [Genger's] airflow sensor internally" on the basis that "that location was common," as Dr. Sharony states, since that location was neither common or (without major system modifications) even possible for pneumotachographs. Ex. 1004, 86. Nor has Dr. Sharony argued that a POSITA would have been motivated to replace Genger's pneumotachograph with the non-pneumotachograph disclosed in Berthon-Jones or appreciated the challenges, drawbacks, and other system modifications associated with this proposed change.

47. Thus, it is my opinion that the Board should confirm the patentability of Claim 1 and each of the claims depending on Claim 1, which includes Claims 2-4, because Genger in light of Farrell does not teach or suggest the internal respiratory airflow sensor recited in Claim 1. As shown below, I also conclude

that Claims 15-20 are patentable because Farrell does not cure the admitted deficiencies of Kocinski for at least the same reasons that it does not cure the deficiencies of Genger. *See* § V.A-B, *supra*.

B. Genger Does Not Teach or Suggest a “Nonvolatile Memory” Being Provided “Sleep Disorder Symptom Data and/or the Index of the Level of Severity of the Subject’s symptoms” (Claim 5)

48. It is my opinion that the Genger reference does not disclose a “the processor adapted to be either part of or external to the PAP device and having a second output, the second output adapted for providing sleep disorder symptom data and/or the index of the level of severity of the subject’s symptoms to a ***nonvolatile memory*** to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject’s symptoms to a remote location.” ’269 Patent at Claim 5 (emphasis added).

49. First, Genger does not send the data to nonvolatile memory. Petitioner admits as much. Pet. At 46. This is because Genger discloses a modem that “relays” information output from a controller. *See* Ex. 1004 at 6:13-22. In these circumstances, a POSITA would recognize that Genger’s alarms and trend data would be, at best, stored in a volatile buffer memory for immediate transmission. *See* Ex. 2019 at 344, 367, 558 (definitions from Microsoft 2002 Computer Dictionary for “modem” is “[a]ny communications device that acts as an interface between a computer or terminal and a communications channel”; for

“non-volatile memory” is “[a] storage system that does not lose data when power is removed from it”; and for “volatile memory” as “[m]emory, such as RAM, that loses its data when the power is shut off”). A POSITA would know that the memory buffer is only meant to store data long enough to ensure no transmission failure has occurred. Ex. 2022 at 1.

50. My understanding is evidenced by Genger’s disclosure, specifically, when the modem and its volatile memory are used as a relay for the data. *See* Ex. 2019 at 344 (definitions from Microsoft 2002 Computer Dictionary for “modem” is “[a]ny communications device that acts as an interface between a computer or terminal and a communications channel”). Given this, a POSITA would not understand that a modem, which uses its volatile memory for a relay, would be storing the data in the volatile memory for a later transmission. Importantly, Genger discloses its alarms would be used to dispatch an ambulance to a severely disabled patient. *See* Ex. 1004 at 18:30. Given these life or death stakes, a POSITA would not have been motivated to store this critical data in nonvolatile memory *for later transmission*. *See id.*

51. To fill the gap in the disclosure, I understand that the petition relies on its expert by stating “POSITA would have found it obvious for Genger’s CPAP to put data/AHI/alarm(s) into nonvolatile memory prior to transmission by the

modem.” Pet. at 46. I disagree and believe that Dr. Sharony’s analysis was the product of hindsight. See Pet. at 46.

52. Volatile memory and non-volatile memory are used for different purposes. See *id*; see also Ex. 2019 at 367, 558 (definitions from Microsoft 2002 Computer Dictionary for “non-volatile memory” is “[a] storage system that does not lose data when power is removed from it” and for “volatile memory” as “[m]emory, such as RAM, that loses its data when the power is shut off). Indeed, there are factors that would lead a POSITA to avoid using non-volatile memory to store data intended for immediate transmission. For example, non-volatile memory is generally more expensive than volatile memory, and access speeds are generally 1000 times slower than volatile memory. Thus, incorporating non-volatile memory into the modem would not only make the system more expensive, but would also have the potential to impact speed of data transmission. A POSITA would understand these constraints and would not have been motivated to change the memory in the modem to non-volatile memory.

53. Further, a POSITA would not have been motivated to provide or add non-volatile memory in order to address communication errors. Pet. At 46. Volatile memory retains all sufficient data for re-transmission in the case of there are communication errors. Non-volatile memory was neither required nor well-suited, given its expense and relative lethargy, to fulfill this function. Thus, I do

not believe it would have been obvious to modify Genger's volatile memory with a nonvolatile memory. '269 Patent, Claim 5.

54. Nor would a POSITA have had motivation to add *additional* non-volatile memory to the system of Genger given the teachings of Westbrook, given the stated intent to *immediately* relay data to the remote location. A POSITA would not add additional cost and complexity to a system without a strong motivating factor, which is absent from Dr. Sharony's analysis. In fact, the non-volatile memory disclosed in Westbrook is used to store different data for a different reason.

55. Westbrook discloses a physiological monitoring system including a micro-controller 42, which transmits digitized sensor signals to an associated flash memory. Ex. 1007 at [0058]; [0075] ("Flash memory chips 44 provide a low cost method to **store the signals acquired** during use of the physiological monitor 12.") (emphasis added). This raw "sleep data" is then transferred to a host computer system by removing the flash card from the machine and placing it in a card reader for computer 20, which analyzes the data. *Id.* at [0054], [0077]-[0078]. Accordingly, while Westbrook suggests storing large amounts of raw sleep data in non-volatile memory, it does not provide any motivation to store Genger's *alarms and trend data in a non-volatile memory*, particularly given that Genger's goal is to relay that data to a server immediately. Ex. 1005 at 12:18-25.

56. As discussed above, Westbrook's inclusion of flash memory into the modem would make the modem more expensive, and would have the potential to negatively impact data transmission rates. Westbrook's disclosure of storing up to 40 hours of data before transferring it to the computer for analysis would plainly frustrate Genger's key objective, which is to allow for fast reactions and response times for severely disabled patients. *See* Ex. 1007 at Figure 2, 0058, 0078; Ex. 1005 at 18:30. I understand that if the intent of the Genger system is to monitor patients in hospitals, and provide alarms that can initiate dispatch of an ambulance when monitoring patients in the home, the Genger system would not be designed to accommodate capture of data over long periods prior to transmitting that data. Nor would it be designed to incorporate the claimed nonvolatile memory.

57. For at least these reasons, I conclude that Claim 5 is patentable over Genger because the petition's combination does not teach or suggest a CPAP that had nonvolatile memory to be used for later transmission of the sleep disorder symptom data and/or the index of the level of severity of the subject's symptoms to a remote location.

VII. GROUND 3: CLAIMS 8-11 AND 13 ARE PATENTABLE OVER STAHMANN IN VIEW OF EDGAR

58. Petitioner's Stahmann-Edgar combination does not disclose a "PAP apparatus comprising a controller adapted to adjust the pharmaceutical agent, at

least in part, *using the output of the level of severity of the subject's sleep disorder*" '269 Patent at Claim 8 (emphasis added). Petitioner admits that Stahmann does not disclose adjusting drug therapy in response to the level of severity of the subject's sleep disorder, suggesting only that "POSITA would have been motivated to adjust drug therapy using Figure 53 and 54's embodiments and based on AHI." Pet. at 55-56. Petitioner does not suggest that Edgar, which discloses treating a patient with a sleep-promoting medication to discourage the patient from removing the CPAP mask during treatment, cures this deficiency.

A. Stahmann Does Not Disclose Adjusting a Pharmaceutical Agent Based on the Level of Severity of the Subject's Sleep Disorder

59. It is my opinion, Stahmann does not disclose "a controller adapted to adjust the pharmaceutical agent, at least in part, using the output of the level of severity of the subject's sleep disorder from the data acquisition system," and Petitioner does not suggest that it does. See Pet. at 53-57 (acknowledging that Stahmann does not disclose this aspect of the claimed invention); Ex. 2016 at 62:14-65:12 (same). I disagree that a POSITA would have reached this conclusion.

60. The integrated diagnostic and treatment device disclosed in the '269 Patent includes a number of sensors, including respiratory airflow and pulse oximetry sensors, which collect data reflecting the patient's physiological state

while receiving treatment for a sleeping disorder. '269 Patent at 6:10-25 (sensors for EEG, ECG, EMG, EOG and alike), 7:27-8:30 (sensors for pulse oximetry, and respiration). This disclosed data is provided to a microprocessor that determines “a level of severity of the subject’s sleeping disorder or symptoms.” *Id.* at 23:27-33. The severity of the subject’s sleep disorder symptoms and/or its associated index is then used to adjust different aspects of the patient’s treatment, including the air pressure provided by the CPAP machine, oxygen from a connected O₂ tank, and/or medication, such as a pharmaceutical agent, from a connected nebulizer. *Id.* at 23:33-41. Accordingly, I understand that the integrated diagnosis and treatment system disclosed and claimed in the '269 Patent does not merely administer a pharmaceutical agent upon detection of a sleep disorder, the '269 Patent’s claimed system uses a controller to adjust the pharmaceutical agent based on the level of severity of the patient’s sleep disorder.

61. In one embodiment, rather than disclosing a controller, like the '269 Patent’s controller, that adjusts a pharmaceutical agent based on the level of severity of a patient’s sleep disorder systems, Stahmann discloses releasing carbon dioxide each time an apnea is detected. Ex. 1010 at 22:29-31, 309:25-27. However, the Stahmann system of using single apnea events does not reach the disclosure of “a level of severity of the subject’s sleep disorder” as found in the '269 Patent. Further, the petition does not suggest that they do. *See* Pet. at 53-57

(not providing any reference to the Stahmann disclosure); DI at 39-40 (providing the Stahmann disclosure).

62. Accordingly, the Board’s factual determination that “Stahmann reasonably suggests detecting sleep events including arousals from sleep” does not read on the language of the claims. *See* DI at 39-41. Specifically, the ’269 Patent’s Claim 8 requires *adjusting* a pharmaceutical agent based on a *level of severity* of a patient’s sleep disorder rather than administering a therapy whenever a central apnea is detected. *See id.* Indeed, the Examiner noted this very deficiency during the original prosecution of the ’269 Patent. Ex. 1002 at 283 (“Stahmann nor the prior art of record teaches the device of [claim 8], including . . . a pharmaceutical agent [] which can be adjusted at least in part using the output of the level of severity of the subject’s sleep disorder”).

63. Petitioner also recognizes this deficiency in the Stahmann reference. Pet. at 55-56. Attempting to fill this missing limitation, the petition alleges, with no analysis or any other evidentiary support, that a POSITA would have been motivated to adjust drug therapy based on AHI. *See* Pet. at 55-56. The only support for this argument comes from the testimony of Dr. Sharony, who admitted that he never designed or operated a CPAP machine. *See* Ex. 2016 at 24:9-27:25 (testifying he has not designed a CPAP machine, has no experience treating sleep disorders and has no experience operating a CPAP machine.)

64. Because the Stahmann reference also does not disclose or teach a controller for adjusting a pharmaceutical agent based on the level of severity of the patient's symptoms, I conclude that the Board should confirm the patentability of Claim 8 and Claims 8-11 and 13, which are dependent claims of Claim 8.

B. Stahmann in View of Edgar Does Not Teach Treating Sleeping Disorders or Symptoms with a Pharmaceutical Agent

65. It is my opinion that Stahmann's system provides for the treatment of sleeping disorders using a positive airway pressure device and the treatment of other respiratory issues, such as asthma, using a pharmaceutical agent. See Ex. 1010 at 224:15-17 ("Asthma may be treated with a nebulizer"). I can conclusively say that Asthma is not (and the petition has not alleged that it is) a sleep disorder. Pet. at 53-57 (not providing any reference to Stahmann's disclosure of Asthma). In light of Stahmann's acknowledged deficiencies, Petitioner cites Edgar, but Edgar discloses providing a sleep-promoting agent in order to increase the chance that the patient leaves the CPAP mask on during the night, not to treat a sleep disorder or its symptoms. See Pet. at 56-57 ("Stahmann does not limit the type of drug therapy, but Edgar teaches a system for providing a pharmaceutical compound...").

66. Edgar discloses using a CPAP machine to treat a patient with a pharmaceutical compound to promote sleep. See Ex. 1011 at ¶¶[0406]–[0408].

However, like Stahmann, Edgar's treatment is unrelated to "the output of the level of severity of the subject's sleep disorder." '269 Patent at Claim 8. Instead, Edgar discloses supplementing normal CPAP treatment with a sleeping agent to prevent the patient from removing the mask during the night:

[M]any patients *cannot tolerate the [CPAP] apparatus or pressure and refuse treatment*. Moreover, recent covert monitoring studies demonstrated that long-term compliance with CPAP treatment is very poor. *It is known that patients remove their masks while sleeping*.

In one aspect, the compound of the invention is administered in conjunction with a CPAP device *to promote sleep*. In another aspect, the compound of the invention is administered in conjunction with a CPAP device to improve sleep. In another aspect, the compound of the invention is administered in conjunction with a CPAP device to improve compliance regarding with CPAP treatment. Without wishing to be bound by theory, it is thought that by administering an effective amount of a sleep promoting compound of the invention to a patient in conjunction with CPAP treatment, the patient will sleep better and more soundly and therefore, *not be as likely to remove the mask*.

Ex. 1011 at ¶¶ 0406-0407 (disclosing that the "sleep promoting compound" is used to keep the mask on and allow the CPAP machine to effectively operate on the

patient rather than the subject not being able to receive treatment due to the uncomfortable nature of the CPAP and its mask).

67. Accordingly, Edgar does not disclose treating the subject's sleep disorder or symptoms with a pharmaceutical agent, it discloses the "promoting of sleep" in order to ensure that the subject does not remove the mask. See Ex. 1011 at ¶¶ 392-393. In other words, Edgar teaches the use of a pharmaceutical agent to ensure that a *different* therapy, i.e. continuous positive air pressure, remains effective. Ex. 1011 at ¶¶ 0406-0408.

68. For at least these reasons, it is my opinion that Claim 8 is patentable over Stahmann in view of Edgar because the combination does not teach or suggest a CPAP for providing a pharmaceutical agent based on the level of severity of the subject's sleep disorder symptoms.

VIII. GROUND 6: CLAIMS 15-16 AND 18-19 ARE PATENTABLE OVER KOCINSKI IN VIEW OF FARRELL AND BLUETOOTH

A. Kocinski in View of Farrell Does Not Render Obvious an "Airflow Sensor Internal to the PAP Device For Measuring the Respiratory Airflow Data of a Subject" (Claims 15-20)

69. It is my opinion that Claims 15-20 are patentable at least because the combination of Kocinski, Farrell, and Bluetooth does not disclose "an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject." '269 Patent at Claim 15.

70. Kocinski is not alleged to disclose a respiratory airflow sensor, and I agree. Kocinski discloses a pressure transducer responsible for controlling the blower pressure provided to the subject. Ex. 1012 (“Kocinski”) at ¶ 0046. This pressure transducer, as described in ¶0046 does not measure the subject’s respiratory airflow. See Ex. 1012 at ¶0046. It is my opinion that Farrell does not cure the deficiency of Kocinski for the reasons discussed in detail above. See Sections VI.A, 2-3, *supra*.

71. In view of the foregoing reasons, Kocinski taken alone or in combination with Farrell does not teach or suggest an airflow sensor internal to the PAP device adapted for measuring the respiratory airflow of a subject while using the PAP and outputting airflow sensor data.

B. Kocinski does not teach or suggest transmitting symptom data and/or index of symptom data from the CPAP device via the base station to a remote internet site

72. It is my opinion that Kocinski fails to teach or suggest “transmitting the symptom data of the severity of the subject’s sleep disorder symptoms and/or an index of a subject’s symptoms measuring during use of the PAP device” or “retransmit[ting] the symptom data of the severity of the subject’s sleep disorder symptoms and/or the index of the subject’s symptoms and the data of usage received from the PAP device to a remote internet site.” ’269 Patent Claim 15.

73. I understand that the petition relies on Kocinski, paragraphs 28 and 31, for the transmission of the symptom data and/or index of symptom data both from the CPAP device to the base station and from the base station to a remote internet site. See Pet. at 71. Rather than transmitting symptom data (which the petition alleges is Apnea events, Hypopnea events, or counts) or an index of symptom data (which the petition alleges is AI, HI, AHI), Kocinski only transmits alerts when the number of apnea/hypopnea events exceeds a threshold value. Ex. 1012 at ¶ 0028 (“The CPAP apparatus may be programmed, for example, to send a *message* to the central database server, which is *relayed* to the medical professional if the number of apnea events per hour exceeds the programmed threshold, or if the number of hypoapnea [sic] events per hour exceeds a programmed threshold, or if the blood desaturation exceeds a programmed threshold.” (emphasis added)); see also Ex. 1012 at ¶¶ [0029], [0031] (triggering the unexpected transmission of the email notification if the subject is experiencing too many abnormal sleep events to alert the medical professional). The data transfer referenced in Kocinski ¶ 0031 is restricted to usage compliance data (Kocinski ¶ 0035) and reports (Kocinski ¶ 0039) rather than the underlying symptom data or an index of the subject’s systems. See Kocinski ¶¶ 0031, 0035, 0039.

74. I understand the petition relies on Farrell in an attempt to cure Kocinski’s deficiency. See Pet. at 66-67. However, Farrell also does not disclose

the transmission of any symptom data to its hand-held device for display or re-transmission to a remote location. The citation that the petition references only provides that, “[t]he apparatus preferably also includes a communication port or module, for example, a wireless communication transceiver and/or a network card, for communication with other devices or computers such as a held-held display and control devices.” Ex. 1008 at 5:28-31, Fig. 1. As evidenced by the full recitation of the referenced citation, however, Farrell does not disclose the transmission of symptom data nor its related indexes to the hand-held device, let alone displaying or retransmitting that data to a remote location. Ex. 1008 at 7:35-8:3.

75. For at least this reason, it is my opinion that Kocinski does not meet independent claim 15.f nor 15.g.2 because of its lack of transmission of the subject’s symptom data and/or the index of the subject’s symptom data.

C. Kocinski does not teach or suggest a base station, cellular phone or PDA adapted to display the symptom data of the severity of the subject’s sleep disorder symptoms and/or the index of the subject’s symptoms

76. As established in my opinions above, it is my opinion that Kocinski fails to teach or suggest an internal airflow sensor adapted for measuring the respiratory airflow of a subject and outputting airflow sensor data. Kocinski’s

Figure 10 does not display either the subject's sleep disorder symptom data or the index of the subject's symptoms.

77. It is my opinion that the petition provides a conclusory argument that it would have been obvious to display symptom and/or index data at a local base station, cellular phone, or PDA. Pet. at 74. A POSITA would disagree because the relevant data is not even re-transmitted to a remote location using the Kocinski system. See § VIII.B, *supra*. As such, a POSITA would not find it obvious to display data that is never transmitted to “the patient, patient’s family, and visiting medical professionals to see the patient’s data on-site,” absent the benefit of hindsight. Pet. at 74. Kocinski’s “two-way” software does not provide any additional evidence that it would have been obvious to display any data at the its alleged “base-station” because it stores data for *other* devices to retrieve and display. Kocinski, [0035]-[0039], [0049], Figure 12. EX1004, ¶149.

78. Petitioner also cites no evidence that it was known or otherwise obvious to display symptom data to such parties. Indeed, ResMed’s CEO credited this feature with an unexpectedly large increase in compliance rates over prior systems (like Kocinski), which only displayed the patient’s compliance data. Ex. 2010 at 5 (Patients’ visibility into their own sleep data “significantly improve[d] their adherence to sleep therapy”); Ex. 2011 at 3-4 (crediting the AirView and myAir platforms for improving compliance to more than 87% adherence). I

believe these “surprising and unexpected” results undermine Dr. Sharony’s conclusory assertion that it would have been obvious to display this data at the claimed base station.

79. For at least this reason, I conclude that Kocinski does not meet independent claim 15.g.2 because of its lack of transmission of the subject’s symptom data and/or the index of the subject’s symptom data which results in the inability to display the data on the base station, cellular phone or PDA.

IX. GROUND 2: CLAIMS 4 AND 6 ARE PATENTABLE OVER GENDER IN VIEW OF SCHMIDT, WESTBROOK, FARRELL, AND PARADISO

80. As established above, it is my opinion that the petition fails to demonstrate by a preponderance of the evidence that Claims 1 and 5 are obvious over Genger, Schmidt, Westbrook, and Farrell, and Paradiso to cure any of the deficiencies as set forth above. *See* § VI.A-B, *supra*.

81. Therefore, it is my opinion that the petition also fails to show by a preponderance of the evidence that the cited combination renders obvious Claims 4 and 6, which depend on Independent Claims 1 and 5.

X. GROUND 4: CLAIM 12 IS PATENTABLE OVER STAHMANN, EDGAR AND SCHMIDT

82. As established above, it is my opinion that the petition fails to demonstrate by a preponderance of the evidence that Claim 8 is obvious over

Stahmann and Edgar, and Schmidt to cure any of the deficiencies as set forth above. *See* § VII.A-B, *supra*.

83. Therefore, it is my opinion that the petition also fails to show by a preponderance of the evidence that the combination renders obvious Claim 12, which depends from Independent Claim 8.

XI. GROUND 5: CLAIM 14 IS PATENTABLE OVER STAHMANN, EDGAR AND PARADISO

84. As established above, it is my opinion that the petition fails to demonstrate by a preponderance of the evidence that Claims 8-11 and 13 are obvious over Stahmann and Edgar, and Paradiso to cure any of the deficiencies as set forth above. *See* § VII.A-B, *supra*.

85. Therefore, it is my opinion that the petition also fails to show by a preponderance of the evidence that the combination renders obvious Claim 14, which depends on Independent Claim 8.

XII. GROUND 7: CLAIM 17 IS PATENTABLE OVER KOCINSKI, FARRELL, BLUETOOTH, GUILLEMINAULT-2004, AND WESTBROOK

86. As established above, it is my opinion that the petition fails to demonstrate by a preponderance of the evidence that Claim 15 is obvious over Kocinski Farrell, and Bluetooth, and Guillminault-2004, and Westbrook to cure any of the deficiencies as set forth above. *See* § VIII.A-C, *supra*.

87. Therefore, it is my opinion that the petition also fails to show by a preponderance of the evidence that the combination renders obvious Claim 17, which depends on Independent Claim 15.

XIII. GROUND 8: CLAIM 20 IS PATENTABLE OVER KOCINSKI, FARRELL, BLUETOOTH, AND PARADISO

88. As established above, it is my opinion that the petition fails to demonstrate by a preponderance of the evidence that Claim 15 is obvious over Kocinski, Farrell, Bluetooth, and Paradiso to cure any of the deficiencies as set forth above. *See* § VIII.A-C, *supra*.

89. Therefore, it is my opinion that the petition also fails to show by a preponderance of the evidence that the combination renders obvious Claim 20, which depends on Independent Claim 15.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code.

Declaration of Dr. David A. Borkholder
IPR2023-00565 (U.S. Patent No. 10,076,269)

Executed on July 29, 2024, in Canandaigua, NY.

A handwritten signature in blue ink, appearing to read "David Borkholder", is positioned above a horizontal line.

David Borkholder, Ph.D.

APPENDIX A

David A. Borkholder

e-mail: dborkholder@gmail.com

EDUCATION

Stanford University

Stanford, CA

Ph.D. in Electrical Engineering (1999)

MS in Electrical Engineering (1994)

Rochester Institute of Technology

Rochester, NY

BS in Microelectronic Engineering (1992)

PROFESSIONAL EXPERIENCE

Casana (formerly Heart Health Intelligence, Inc)

Rochester, NY

2020 – 2024 *Chief Research Officer*

2018 – 2020 *Co-Founder, Chairman of the Board*

Technology spin-out company based on in-home cardiovascular monitoring systems developed in the Borkholder laboratory at RIT and exclusively licensed to Casana. Worked with founder to define business strategy and fundraising pitch. The company closed its first round of financing in September 2019, a Series A financing in August 2020, and a Series B financing in January 2022, for a total investment of \$46 million. Led organization elements including research, electrical and mechanical hardware engineering, clinical affairs, and supply chain / manufacturing.

Rochester Institute of Technology

Rochester, NY

2016 – 2020 *Director, Personalized Healthcare Technology*

2015 – Present *Bausch + Lomb Professor, Microsystems Engineering*

2012 – 2015 *Bausch + Lomb Associate Professor, Microsystems Eng*

2007 – 2015 *Associate Professor, Electrical and Microelectronic Eng*

2007 – 2012 *Associate Professor, Microsystems Engineering*

2006 – 2007 *Assistant Professor, Microsystems Engineering*

2004 – 2007 *Assistant Professor, Electrical Engineering*

Undergraduate and graduate education and research in the areas of electronics, sensors, MEMs, and biomedical engineering. Course taught include Electronics I and II, Fundamental Electrophysiology, Biomedical Sensors and Transducers, Biomedical Instrumentation, Introduction to Nanotechnology and Microsystems, Introduction to Product Development (Honors), Reverse Engineering (Honors), and The Design Process (Honors). Research focused on Microsystems for inner ear drug delivery and fundamental studies of auditory function; non-invasive physiological monitoring; and personnel borne sensors for blast dosimetry and traumatic brain injury.

University of Rochester

Rochester, NY

September 2007 – 2020 *Adjunct Associate Professor, Biomedical Engineering*

September 2007 – 2020 *Adjunct Associate Professor, Otolaryngology*

September 2006 – 2007 *Adjunct Assistant Professor, Otolaryngology*

BlackBox Biometrics, Inc (B3)

Rochester, NY

2011 – 2021 *Founder, Executive Chairman, Chief Technology Officer*

Technology spin-out company based on the Blast Gauge Technology (www.blastgauge.com) developed in the Borkholder laboratory at RIT and licensed exclusively to B3. Established leadership team, engineering, manufacturing, and customer service capabilities for commercialization of the Blast Gauge system. Championed efforts to treat blast overpressure exposure as an occupational hazard influencing congressional legislation in the FY18 and FY19 National Defense Authorization Acts, and specific brain health policies for the Department of Defense and Special Operations Command. As part of this work I was interviewed for a Nov 27, 2023 front page New York Times article entitled "US Troops Still Train on Weapons with Known Risk of Brain Injury." One of my statements was selected as the New York Times Quotation of the Day. The company was acquired by Airboss Defense Group in 2021.

ZONARE Medical Systems, Inc.

Mountain View, CA

2001 –2004 *Director, Hardware Engineering*

Directed the Hardware Engineering group in the development of a portable ultrasound system utilizing non-traditional imaging techniques. Team responsibilities included analog, digital and power board design, FPGA programming, ASIC development, thermal management, integration, design verification and environmental testing. Resources, budgets, schedules, equipment, laboratory space, and all related projects for these disciplines were managed.

Results: *Resourced and developed the hardware engineering team to meet business objectives. Managed consulting resources for outsourced design engineering. Developed three ASICs (analog, mixed signal and high voltage) from concept, to design, packaging, and qualification. Successfully engineered a full featured medical diagnostic imaging system following ISO / FDA requirements.*

Cepheid

(July 1998 – September 2001)

Sunnyvale, CA

2000 –2001 *Director, Electronic Systems*

Directed Electrical and Test Engineering groups in development of advanced DNA analysis systems. Responsible for development of all electronic systems and components, design verification and environmental testing of subsystems and instruments, and development of electronic, mechanical and optical test systems for both engineering and manufacturing. Systems included embedded microcontrollers, sensitive analog electronics for optical detection, thermal control, motion control, and ultrasonics. All work was performed according to ISO / FDA requirements. Managed resources, budgets, equipment, laboratory space, and projects for these disciplines.

In addition, was Technical Lead for development and commercialization of the GeneXpert, a fully automated sample processing system capable of extracting DNA from raw samples and performing DNA analysis. Responsibilities included understanding marketing constraints, driving critical path, managing system integration and interdisciplinary conflicts, and management of personnel in electrical, mechanical, and software engineering, molecular biology, precision injection molded disposables, and lyophilized PCR reagents.

Results: *Successfully developed technologies, equipment, disposables, and reagents required for automated DNA extraction and analysis from liquid samples. This GeneXpert platform was chosen by the United States Postal Service for screening the mail for the bioterrorism agent Bacillus Anthracis (Anthrax). CPHD was publicly traded (NASDAQ) from 2000 to 2016, achieving a peak market cap in excess of \$4.5 billion. In 2016, Cepheid was acquired off the public market by Danaher Corp for \$4 billion.*

1998 –2000

Senior Scientist

Managed DARPA funded programs for DNA analysis including sample preparation and detection of PCR product in a multiplexed format. Technology development included high voltage electronics, optical systems for fluorescence measurements, microfluidics, micromachined structures for DNA capture, capillary electrophoresis, and isoelectric focusing. Scanning detection strategies coupled with microfluidics and custom electronics allowed miniaturized, low power systems to be realized

Program managed development of a ruggedized (MIL STD 810E) thermal cycler for rapid, field deployable DNA analysis. Technology development included an uninterruptable power system, smart batteries, a custom graphical user interface, protection against humidity, and mechanical isolation for shock and vibration. Responsibilities included customer interface, product definition, technical engineering lead, and project management.

Results: *Successfully demonstrated a prototype system for doing electrophoretically based separation of DNA and proteins. Delivered a ruggedized, battery powered thermal cycler to the United States Army Medical Research Institute for Infectious Diseases (USAMRIID).*

Eastman Kodak Company

Rochester, NY

1989-1992

Microelectronic Engineer (part time)

Worked on a variety of projects within the Microelectronics Technology Division involving the manufacture and characterization of CCD image sensors. Manufacturing work involved the use of statistically designed experiments to optimize both lithographic and plasma processes. Characterization work required electronics design and development, instrument interfacing and programming, and measurements on both infrared and visible image sensors. The resulting analyses were used to design production changes for enhanced imager sensitivity.

ACADEMIC EXPERIENCE

Stanford University

Stanford, CA

1992-2000

January, 1999 – January 2000

Visiting Scholar:

Advised students developing cell based sensor technologies and formulated and prepared research proposals. Project involvement included:

- Exploration of dose-response curves for toxins using various cell-lines.
- Development of a hand-held, field-operable military chem/bio warfare sensor.
- Development of advanced structures for improved cell / electrode coupling.

January, 1994 – January, 1999

Doctoral Candidate

Designed and built microelectrode based sensors to monitor the morphology and electrophysiological activity of cultured cells as a means for toxin detection and pharmaceutical screening. Microelectrode arrays, novel packaging techniques, and fluidic systems were developed for interfacing to, and maintenance of the cultured cell systems. Created interface electronics for signal detection and interpretation for both action potential and impedance measurements. Developed new signal processing techniques to improve measurement specificity and allow classification of unknown biologically active agents.

March, 1993 - January, 1994

Research Assistant

Developed innovative lamination based microfabrication processes allowing fabrication of electroplated pillars 100 μm tall (10:1 aspect ratio) on electrostatically deflectable cantilever beams.

September, 1992 – March, 1993

Research Assistant

Investigated 1X photolithographic masks for deep UV lithography with patterns approaching 10 nm. Examined aluminum grain size, reflectivity, and dry etch characteristics. Masks were used for optical lithography with quarter-micron image resolution.

FUNDED RESEARCH

Professor Borkholder has been the PI on over \$21MM in research funding from federal and industrial sponsors, \$10.8MM of that in his role as a professor at RIT. As Co-I, he has contributed to additional total research awards of \$5.4MM at RIT.

RIT

6/18/2020 - 10/31/2020

Role: PI (transitioned grant to Wang in Oct 2020 during transition from RIT). \$2,990,975

Inconspicuous Daily Monitoring to Reduce Heart Failure Hospitalizations this research aims to demonstrate that heart failure patient hospitalization rates and duration of stay can be significantly reduced through inconspicuous in-home monitoring and early intervention enabled with a cardiovascular monitoring toilet seat.

USAF STTR

7/1/2016-3/31/2018

Role: PI (Subcontract under Quest Integrated, LLC)

\$65,993

Printed Skin (pSkin) for Aircraft Sensing and Testing This research aims to develop printed sensor technology smart skins for aircraft sensing of pressure and strain.

RIT 4/1/16-4/14/2021
Role: PI \$1,000,000

Signature Interdisciplinary Research Area in Personalized Healthcare Technology This research aims to enhance patient care and access through intelligent, interactive, mobile, and wearable technologies that integrate new media design and leverage data, behavioral, and social sciences.

NYS Empire State Development 6/1/2015-6/30/2020
Role: Co-I (Cormier PI) \$4,260,550

AMPrint Center for Advanced Technology This is an Additive Manufacturing and Multi-Functional Printing (AMPrint) Center intended to help catalyze growth of New York State's 3D printing and additive manufacturing industry.

1R01DC014568 4/1/2015-3/31/2020
NIDCD / NIH \$2,716,030
Role: PI

Enabling Microsystem Technologies for Advanced Drug Delivery This research aims to develop novel micropumps for drug delivery, determine pump parameters and functional characteristics with a unique interplay of quantitative modeling and μ CT scan biomedical imaging, and test the micropumps *in vivo* by infusion of salicylate.

Google 7/15/2014-1/31/2016
Role: PI \$1,474,821

Inconspicuous Daily Medical Analyses The purpose of this research is to develop new technologies enabling extraction of key cardiac parameters from non-invasive physiology measures. System validation includes normative subjects and heart failure patients in the clinic and the home.

PEO Soldier (ARMY) 9/30/2013-10/1/2014
Role: PI (BlackBox Biometrics, Inc - Subcontract to BAE Systems) \$177,600

Blast Gauge for the Integrated Soldier Sensor Suite The purpose of this research is to develop an advanced Blast Gauge platform that integrates with a third generation HEADS system and a physiologic monitor for the next generation soldier sensor system.

M67854-13-C-6513 2/1/2013-5/1/2014
Marine Corps Systems Command \$149,903
Role: PI (BlackBox Biometrics, Inc)

Blast Dosimeter for Monitoring and Documenting Blast Exposure for Breacher and Route Clearance Personnel The purpose of this research is to develop a portable, cost-efficient blast force monitoring device that can be easily deployed by Marines and other ground forces in the theater of operations to measure, record, and display overpressure and force acceleration data from varying blast type events to which these troops are exposed.

IIP-1237761 9/1/2012-8/31/2015
NSF PFI \$599,389
Role: Co-I (Cormier PI)

Partnerships for Innovation in Printed Devices and Materials This research seeks to build innovation capacity pertaining to printed devices and materials (e.g., sensors, actuators, displays) through a partnership between RIT researchers and three small business knowledge enhancement partners: Intrinsiq Materials (nano-inks), Optomec (printing technology), and NovaCentrix (sintering).

11P-1237699 9/1/2012-8/31/2014
NSF PFI \$599,800

Role: Co-I (McGrath PI - UofR)

Partnership for Nanomembranes in Microscale Biodevices This research aims to apply porous nanocrystalline silicon (pnc-Si) membranes to microscale preparative and analytical systems. First principle theory and modeling of ultra-thin nanoporous membranes for low flow rate electroosmotic pumps.

HR0011-11-9-0006 7/29/2011–7/30/2013
DARPA MTO \$9,901,025

Role: PI (BlackBox Biometrics, Inc)

Blast Gauge Field Research Studies This research aimed to pilot deployment of the Blast Gauge in Afghanistan to validate device performance, refine distribution and recovery logistics, and evaluate wearability of the device.

CBET-0967732 8/15/2010-8/14/2014
NSF RAPD \$300,867

Role: PI

Adaptive User-Guided Assistive Listening System This research aims to test the hypothesis that an assistive listening system with dynamic, user-controlled directional characteristics will improve communication for the hearing impaired significantly relative to traditional fixed-directional systems.

HR0011-10-C-0095 4/14/2010 –10/1/2011
DARPA MTO \$1,200,097

Role: PI

Soldier Wearable Blast Dosimeter This research aims to address a critical need for measurement of blast exposure and resulting head acceleration in combat troops through development of a helmet mounted dosimeter system.

Blue Highway 10/1/2009 –6/30/2010
Role: PI \$88,118

Continuous Glucose Detection with Nanoscale Sensors

National Semiconductor 10/1/2009-9/30/2011
Role: PI \$130,000

Integrated, Non-Invasive, Continuous Blood Pressure Monitor

5K25-DC008291-02 7/1/2006 – 6/30/2011
NIDCD / NIH \$922,048

Role: PI

Improved Micro-Technologies for Inner Ear Drug Delivery: This Mentored Career Development Award aims to optimize intra-cochlear dosing profiles for gene therapy studies in the mouse model system while preserving cochlear function. Implantable micropump development is targeted at expanding drug delivery capabilities, allowing repetitive cochlear infusions of multiple agents over extended periods for more complex deafness therapies. This work is in collaboration with Dr. Robert D. Frisina at the University of Rochester.

FEDERAL GOVERNMENT REVIEW PANELS

2019	MRMC Extramural Medical Research on the Medical Simulation and Information Sciences (MSIS) panel
2018-2019	NIH, CSR: Bioengineering of Neuroscience, Vision, and Low Vision Technologies (BNVT) study section (Ad Hoc)
2014	Army Rapid Innovation Fund – Traumatic Brain Injury Assessment and Treatment
2012-2016	NIH, CSR: Bioengineering of Neuroscience, Vision, and Low Vision Technologies (BNVT) study section (Chair June 2014 – June 2016)
2010-2011:	Defense Threat Reduction Agency
2010:	Swiss National Science Foundation
2009:	NSF: Research to Aid People with Disabilities
2008:	Office of Naval Research (ONR) Force Health Protection Initiative BAA 08-001 Proposals
2007-2011:	NIH, CSR: Neurotechnology (NT) study section (Ad Hoc)
2007:	Ad hoc Reviewer, NIH, CSR ZRG1 IFCN-G 10 B, Small Business: Ear
2002-2007:	NIH, CSR: Neurotech/Engineering Special Emphasis Study Section Panel

GOVERNMENT SERVICE

2021 – Present	Member, NATO HMF-338 Human Factors and Medicine Panel on “Guidelines to mitigate military occupational brain health risks from repetitive blast exposure.”
2023 – Present	Member, NATO HFM-371 RSM Human Factors and Medicine Research Specialists Meeting on “Blast Exposure Monitoring in Military Training and Operations.”
2012 – 2016	NIH Bioengineering of Neuroscience, Vision and Low Vision Technologies (BNVT) study section (served as the Chair 2014-2016).
2009 - 2015	Defense Sciences Research Council (DSRC)

INSTITUTE SERVICE

2016-2020	Director, Personalized Healthcare Technology Initiative
2016-2017	RIT / Rochester Regional Health Strategic Planning Committee
2015-2016	RIT Kate Gleason College of Engineering Dean Search Committee co-chair
2014-2019	RIT Long Range Planning and Environment Committee
2014	Acting Director, Microsystems Engineering PhD Program
2013-2014	RIT Long Range Planning Committee
2013	RIT Nanopower Research Lab Director Search Committee
2011	RIT VP/Dean Institute for Health Sciences and Tech Search Committee
2010-2012	RIT Research Advisory Board
2010-2012	Research at RIT Editorial Advisory Board
2009-2011	RIT / RGHS Education and Research Committees
2009	RIT / RGHS Strategic Steering Committee
2008-2013	RIT KGCOE Ethics Program founding co-chair
2006-2007	RIT Presidential Search Committee

PROFESSIONAL SERVICE

2023 – Present	Member American Heart Association Board, Rochester
2019 – Present	Associate Editor, IEEE Journal of Translational Engineering in Health and Medicine (JTEHM)
2020 – Present	Editorial Section Board member, Micromachines
2014 - 2020	Board of Directors, RedSky (Biomedical Institute of the Americas)
2013	Transducers 2013 Technical Program Committee
2010	UNYBECC 2010 Conference organizer, Translational Research Session moderator. Upstate New York Biomedical Engineering Career Conference
2006 – 2020	Journal reviewer for numerous engineering and medical journals.

OUTREACH ACTIVITIES

- 2015 Midlakes Middle School – Presentations to grades 3-6 on “Innovation - Thoughts for Young Inventors”
- 2010-2011 BOCES-2 Project ADEPT Explorations Engineering outreach to 4th-6th graders.

PROFESSIONAL AFFILIATIONS AND DATES OF ADMITTANCE

- 2020 American Institute for Medical and Biological Engineering
- 2018 American Heart Association
- 2007 Biomedical Engineering Society (BMES)
- 2006 **Senior Member**, Institute of Electrical and Electronics Engineers (IEEE)
- 2006 Association for Research in Otolaryngology
- 2005 IEEE Engineering in Medicine and Biology Society
- 2005 American Association for Engineering Education (ASEE)
- 1991 IEEE
- 1991 Tau Beta Pi (Engineering Honor Society)
- 1991 Eta Kappa Nu (Electrical and Computer Engineering Honor Society)
- 1991 Phi Kappa Phi (Honor Society)

SELECTED HONORS

- Fellow of the American Institute for Medical and Biological Engineering (2020)
- Distinguished Inventor of the Year - Rochester Intellectual Property Law Association (2016).
- Rochester Business Journal Health Care Achievement Award: Innovation (2014) for research leading to the successful commercialization and fielding of the Blast Gauge System.
- Admission to the 2007 MBL course, *Biology of the Inner Ear: Experimental & Analytical Approaches* at the Marine Biological Laboratory in Woods Hole, MA.
- United States Air Force Laboratory Graduate Fellowship, 1993-1996.
- Rochester Engineering Society David Fergusson Scholarship, 1991.
- RIT Award for Outstanding Undergraduate Scholarship, 1990.
- Nathaniel Rochester Society Scholarship, 1991
- Tau Beta Pi Engineering Honor Society, 1991
- Eta Kappa Nu Electrical and Computer Engineering Honor Society, 1991
- Phi Kappa Phi Honor Society, 1991
- Frank Horton Scholarship, 1990.

GRADUATE STUDENT ADVISING

Current PhD

- 18-2020 **Advisor** (transition to Prof Abhyankar, Oct 2020), Nuzhet Nihaar Nasir Ahamed, PhD Microsystems Engineering, RIT.
- 15-2020 **Advisor** (transition to Prof Abhyankar, Oct 2020), Meng-Chun Hsu, PhD Microsystems Engineering, RIT.

Graduated PhD

- 2023 **Advisor** (transition to Prof Day, Oct 2020), Krittika Goyal, PhD Microsystems Engineering, RIT.
- 2022 **Co-Advisor**, Sanketh Moudgalya , PhD Imaging Science, RIT.
Thesis title: *Cochlear Compartments Segmentation and Pharmacokinetics using Micro Computed Tomography Images*
- 2019 **Member**, Dissertation Committee, Yashar Seyed Vahedein, PhD Engineering, RIT.
Thesis title: *Development and Application of Direct and Inverse Models for Noninvasive Measurement and Diagnostics in Cardiovascular Circulatory System.*
- 2019 **Advisor**, Farzad Forouzandeh, PhD Microsystem Engineering, RIT. Thesis title:

Implantable Microsystem Technologies For Nanoliter- Resolution Inner Ear Drug Delivery.

- 2019 **Member**, Dissertation Committee, Chaitanya Mohajan, PhD Engineering, RIT. Thesis title: *Three Dimensional Digital Alloying with Reactive Metal Inks.*
- 2018 **Advisor**, Jing Ouyang, PhD Microsystems Engineering, RIT. Thesis title: *Enhanced Piezoelectric Performance of Printed PZT Films on Low Temperature Substrates.*
- 2017 **Advisor**, Jeff Lillie, PhD Microsystems Engineering, RIT. Thesis title: *Non-invasive Continuous Blood Pressure Monitor.*
- 2016 **Advisor**, Nicholas Conn, PhD Microsystems Engineering, RIT. Thesis title: *Robust Algorithms for Unattended Monitoring of Cardiovascular Health*
- 2015 **Advisor**, Jirachai Getpreechawsawas, PhD Microsystems Engineering, RIT. Thesis title: *Low-Power, Low-Voltage Electroosmotic Actuator for an Implantable Micropumping System Intended for Drug Delivery Applications*
- 2013 **Advisor**, Dean Johnson, PhD Microsystems Engineering, RIT. Thesis title: *Integration Technologies for Implantable Microsystems.*
- 2011 **Member**, Dissertation Committee, Ivan Puchades, PhD Microsystems Engineering, RIT. Thesis title: *A thermally actuated MEMS Device for Measuring Viscosity.*
- 2011 **Member**, Dissertation Committee, Mark Pude, PhD Microsystems Engineering, RIT. Thesis title: *Circuit Solutions for Device Degradation in Scaled Analog Design.*
- 2008 **Member**, Dissertation Committee, Marie Yvanoff, PhD Microsystems Engineering, RIT. Thesis title: *Implantable Micro-Transceiver Wireless Link for Biomedical Applications.*
- 2006 **Member** of Dissertation Committee, Tejasvi Das, PhD Microsystems Engineering, RIT. Thesis title: *Fault-Tolerant design of RF front-end circuits.*

Graduated MS

- 2018 **Advisor**, Kevin Wilson, MS EE, RIT. Thesis title: *Modeling and Extraction of Transport Parameters to Simulate Drug Delivery in the Murine Cochlea*
- 2018 **Member** Dissertation Committee, Elise Wilcocks, MS Public Policy, RIT. Thesis title: *Evaluation of the Implementation of the New York State (NYS) Concussion Management and Awareness Act.*
- 2017 **Advisor**, Joseph Kubek, MS EE, RIT. Project title: *Inconspicuous Daily Weight Tracking Using an Artificial Neural Network.*
- 2016 **Advisor**, Danielle Walters, MS EE, RIT. Project title: *RF Energy Harvesting*
- 2016 **Advisor**, Terence Binotto, MS EE, RIT. Project title: *Direct write integration of commercial off the shelf electronics on non-traditional substrates*
- 2015 **Member**, Dissertation Committee, Siddharth Dasgupta, MS Mechanical Engineering, RIT. Thesis title: *An Experimental Study of Dispersion in Oscillating Flows in Cylindrical Tubes.*
- 2014 **Advisor**, Matthew Kelly, MS EE, RIT. Project title: *The Focal Index as a Singular Metric for Beamforming Effectiveness*
- 2014 **Advisor**, Cody Czesler, MS CE, RIT. Thesis title: *Using Least Variance for Robust Extraction of Systolic Time Intervals*
- 2014 **Member** Dissertation Committee, Kyle Tomsic, EE, RIT. Thesis title: *Analysis of*

- the Effects of Pre- and Post-Processing Methods on vPPG*
- 2012 **Advisor**, Nicholas Conn, MS EE, RIT. Project title: *Compressed Sensing for Power Efficient Physiological Monitoring*
- 2012 **Member** Dissertation Committee, Jean-Jacques DeLisle, MS EE. Thesis title: *Design and Analysis of a UHF Transmission Line Coupler for Telemetry and Power Harvesting in a Passive Sensor System*
- 2011 **Advisor**, Matt Kenyon, MS EE, RIT. Project title: *Photonic Neural Stimulator*
- 2011 **Co-Advisor**, Miriam Gladstone, PhD BME, UofR. Thesis title: *Gene Therapy in the Inner Ear via Intracochlear Infusion into the Mouse Cochlea*.
- 2009 **Advisor**, Mathew Waldren, MS EE, RIT. Thesis title: *Low Power Flow Rate Sensors for Biomedical Applications*.
- 2009 **Advisor**, Sean O'Brien, MS MicroE, RIT. Thesis title: *Low Voltage Actuation Mechanism for Micropump Applications*.
- 2009 **Advisor**, Jesse Steiner, MS EE, RIT. Project title: *A Self-Contained Bicycle Power Center*.
- 2008 **Advisor**, Murtuza Quaizar, MS EE, RIT. Project title: *Simulation of a User Guided Acoustic Beamforming Assistive Listening System*.
- 2008 **Member** Dissertation Committee, Todd Simon, MS EE, RIT. Thesis title: *Microgripper Force Feedback Integration using Piezoresistive Cantilever Structure*.
- 2007 **Advisor**, Avery Sonnenberg, MS EE, RIT. Project title: *Single-Actuator Peristaltic Micropump*.

POST-DOCTORAL MENTORING

- 2016-2019 Nicholas Conn
- 2019-2020 Farzad Forouzandeh
- 2018-2019 Armando Arpys Arevalo Carreno
- 2016-2018 Ahmed Alfadhel
- 2012-2015 Masoumeh Haghpanahi

ISSUED PATENTS (28 TOTAL)

David A. Borkholder, and Hamed Shamkhalichenar. "Systems, devices, and methods for measuring body temperature of a subject using characterization of feces and/or urine." U.S. Patent No. 11,969,229. Issued Apr 30, 2024.

David A. Borkholder, Nicholas J. Conn, Masoumeh Haghpanahi, "Apparatus, System and method for medical analyses of seated individual." US Patent 12,036,044, Issued July 16, 2024.

David A. Borkholder, Austin McChord, Nicholas Joseph Conn, Steve Petrucelli. "Systems, Devices, and Methods for Monitoring Loads and Forces of a Seated Subject Using Scale Devices." US Patent 11,650,094, Issued May 16, 2023.

David A. Borkholder, Alexander S. Liberson, Jeffrey S. Lillie, Steven W. Day. "Pulse wave velocity, arterial compliance, and blood pressure." U.S. Patent 11,622,730, Issued April 11, 2023

Chaitanya G Mahajan, Denis Cormier, Mark Irving, Scott Williams, **David Borkholder**, Ahmed Alfadhel. "Magnetic field patterning of nickel nanofibers using precursor ink." U.S. Patent 11,254,156, Issued February 22, 2022.

David A. Borkholder, Nicholas J. Conn, Masoumeh Haghpanahi. "Apparatus, System, and Method for Medical Analyses of Seated Individual." U.S. Patent 11,234,651, Issued February 1, 2022.

Ahmed Alfadhel, Meng-Chun Hsu, **David A Borkholder**. "Capsule, in-line magnetic valve system and method." U.S. Patent 11,035,498, Issued June 15, 2021

David A Borkholder, Farzad Forouzandeh, Robert Nash Carter, Denis Roger Cormier, Joseph P Walton, Robert Dana Frisina. "Peristaltic micropumps and fluid delivery devices that incorporate them." U.S. Patent 11020524, Issued June 1, 2021.

Borkholder, David A., Matthew Kenyon, Ryan Ramplin, Michael H. Ostertag, Kim Sherman, Matthew Wellman, and Micah Harrison. "Device packaging for an impact detection device." U.S. Patent 10,561,341, issued February 18, 2020.

Borkholder, David A., Nicholas J. Conn, and Masoumeh Haghpanahi. "Apparatus, System and Method for Medical Analyses of Seated Individual." U.S. Patent No 10,292,658, issued May 21, 2019.

Borkholder, David A., Werner Fassler, Andrew Blair, Kim Sherman, and Derek Debusschere. "Event monitoring dosimetry apparatuses and methods thereof." U.S. Patent No 10,292,445, issued May 21, 2019.

Borkholder DA, DeBusschere D, "Methods for Monitoring Exposure to an Event and Devices Thereof," CA 2824597, issued May 21, 2019

Getpreecharsawas, Jirachai, and **David A. Borkholder**. "Ultra-thin nanometer scale polymeric membranes." U.S. Patent No 10,086,336, issued 2 Oct 2018.

Eddins DA, **Borkholder DA**, Amuso, VJ., "System and method for listener controlled beamforming," US Patent No 9,729,994B1, issued 8 August 2017.

Borkholder, David A., Gregory TA Kovacs, and Jeffrey Rogers. "Event Dosimeter Device and Methods Thereof." U.S. Patent No 9,668,689 B2, issued 6 June 2017.

Borkholder DA, Kenyon M, Ramplin R, Ostertag MH, Sherman K, Wellman M, Harrison M, "Devices, systems and methods for detecting and evaluating impact events." US Patent No 9,380,961, issued 5 July 2016.

Borkholder DA, DeBusschere D, "Methods for Monitoring Exposure to an Event and Devices Thereof," AU 2012222109, issued April 21, 2016.

Borkholder, David A., Gregory TA Kovacs, and Jeffrey Rogers. "Event dosimeter devices and methods thereof." U.S. Patent No. 9,339,224. issued 17 May 2016.

Borkholder DA, Kenyon M, Ramplin R, Sherman K, Wellman M, and Harrison M, "Device for Detecting an Impact Event," US D743,822, issued November 24, 2015.

Borkholder DA, DeBusschere BD, "Method for Monitoring Exposure to an Event and Device Thereof." US 9,138,172, issued September 22, 2015.

Borkholder DA, Kovacs GTA, Rogers J, "Event Dosimeter Device and Methods Thereof," AU 2012222110, Issued August 6, 2015.

Borkholder DA, Fassler W, Blair A, Sherman K, DeBusschere D, "Event Monitoring Dosimetry Apparatuses and Methods Thereof," AU 2012222107, Issued June 11, 2015.

McMillan WA, Christel LA, **Borkholder DA**, and Young SJ, "Apparatus for analysis of a nucleic acid amplification reaction," US 6,942,971, Issued September 13, 2005.

McMillan WA, Christel LA, **Borkholder DA**, and Young SJ, "Method for quantitative analysis of a nucleic acid amplification reaction" US 6,911,327, Issued June 28, 2005.

McMillan WA, Christel LA, **Borkholder DA**, and Young SJ, "Methods for Quantitative Analysis of

Nucleic Acid Amplification Reaction," US 6,783,934, Issued August 31, 2004.

McMillan WA, Christel LA, **Borkholder DA**, and Young SJ, "Apparatus for Quantitative Analysis of a nucleic acid amplification reaction," US 6,713,297, Issued March 30, 2004.

Borkholder DA, "Classification of Biological Agents According to the Spectral Density Signature of Evoked Changes in Cellular Electric Potential," US 6,377,057, Issued Apr 23, 2002.

Kovacs GTA, and **Borkholder DA**, "Hybrid Biosensors," US 6,051,422, Issued April 18, 2000.

Kovacs GTA, and **Borkholder DA**, "Hybrid Biosensors," US 5,981,268, Issued November 9, 1999.

JOURNAL PUBLICATIONS (48 TOTAL)

Goyal, Krittika, **David A. Borkholder**, and Steven W. Day. "Dependence of skin-electrode contact impedance on material and skin hydration." *Sensors* 22, no. 21 (2022): 8510.

Goyal, Krittika, **David A. Borkholder**, and Steven W. Day. "A biomimetic skin phantom for characterizing wearable electrodes in the low-frequency regime." *Sensors and Actuators A: Physical* 340 (2022): 113513.

Hsu, Meng-Chun, Mansouri, Mehran, Ahamed, Nuzhet, N. N., Larson, Stephen M., Joshi, Indranil M., Ahmed, Adeel, **Borkholder, David A.**, and Abyankar, Vinay V. A miniaturized 3D printed pressure regulator (μ PR) for microfluidic cell culture applications. *Sci Rep* 12, 10769 (2022).

Forouzandeh, Farzad, Nuzhet N. Ahamed, Xiaoxia Zhu, Parveen Bazard, Krittika Goyal, Joseph P. Walton, Robert D. Frisina, and **David A. Borkholder**. "A Wirelessly Controlled Scalable 3D-Printed Microsystem for Drug Delivery." *Pharmaceuticals* 14, no. 6 (2021): 538. doi.org/10.3390/ph14060538.

Ahmed, A., Joshi, I. M., Larson, S., Mansouri, M., Gholizadeh, S., Allahyari, Z., Forouzandeh, F., **Borkholder, D. A.**, Gaborski, T. R., Abhyankar, V. V., "Microengineered 3D Collagen Gels with Independently Tunable Fiber Anisotropy and Directionality". *Adv. Mater. Technol.* (2021) DOI:10.1002/admt.202001186

Forouzandeh, Farzad, Arpys Arevalo, Ahmed Alfadhel, and **David A. Borkholder**. "A review of peristaltic micropumps." *Sensors and Actuators A: Physical* (2021): 112602. DOI:10.1016/j.sna.2021.112602

Forouzandeh, Farzad, and **David A. Borkholder**. "Microtechnologies for inner ear drug delivery." *Current Opinion in Otolaryngology & Head and Neck Surgery* 28, no. 5 (2020): 323-328.

Forouzandeh, Farzad, Nuzhet N. Ahamed, Meng-Chun Hsu, Joseph P. Walton, Robert D. Frisina, and **David A. Borkholder**. "A 3D-printed modular microreservoir for drug delivery." *Micromachines* 11, no. 7 (2020): 648.

Sanketh S. Moudgalya, Kevin Wilson, Xiaoxia Zhu, Mikalai M. Budzevich, Joseph P. Walton, Nathan D. Cahill, Robert D. Frisina, **David A. Borkholder**, "Cochlear Pharmacokinetics - Micro-Computed Tomography and Learning-Prediction Modeling for Transport Parameter Determination." *Hearing Research*, 380:46-59 (2019). **Featured as the cover article.**

Conn, Nicholas J., Karl Q. Schwarz, and **David A. Borkholder**. "In-Home Cardiovascular Monitoring System for Heart Failure: Comparative Study." *JMIR mHealth and uHealth* 7, no. 1 (2019): e12419. DOI: 10.2196/12419

Mahajan, Chaitanya G., Ahmed Alfadhel, Mark Irving, Bruce E. Kahn, **David A. Borkholder**, Scott A. Williams, and Denis Cormier. "Magnetic Field Patterning of Nickel Nanowire Film Realized by Printed Precursor Inks." *Materials* 12, no. 6 (2019): 928. DOI: 10.3390/ma12060928

Forouzandeh, Farzad, Xiaoxia Zhu, Ahmed Alfadhel, Bo Ding, Joseph P. Walton, Denis Cormier, Robert D. Frisina, and **David A. Borkholder**. "A nanoliter resolution implantable micropump for murine inner ear drug delivery." *Journal of Controlled Release* 298 (2019): 27-37. DOI: 10.1016/j.jconrel.2019.01.032

Ouyang, Jing, Denis Cormier, and *David A. Borkholder*. "Piezoelectric Property Enhancement of PZT Thick Film via Pulsed Flash Poling during Sintering." *ACS Applied Energy Materials* 2, no. 1 (2018): 338-343.

Conn, Nicholas J., Karl Q. Schwarz, and **David A. Borkholder**. "Nontraditional Electrocardiogram and Algorithms for Inconspicuous In-Home Monitoring: Comparative Study." *JMIR mHealth and uHealth* 6, no. 5 (2018).

Alfadhel, Ahmed, Jing Ouyang, Chaitanya G. Mahajan, Farzad Forouzandeh, Denis Cormier, and **David A. Borkholder**. "Inkjet printed polyethylene glycol as a fugitive ink for the fabrication of flexible microfluidic systems." *Materials & Design* 150 (2018): 182-187.

Antoine, Michelle W., Xiaoxia Zhu, Marianne Dieterich, Thomas Brandt, Sarath Vijayakumar, Nicholas McKeehan, Joseph C. Arezzo, R. Suzanne Zukin, **David A. Borkholder**, Sherri M. Jones, Robert D. Frisina, Jean M. Hébert. "Early uneven ear input induces long-lasting differences in left-right motor function." *PLoS biology* 16, no. 3 (2018): e2002988.

Hsu, Meng-Chun, Ahmed Alfadhel, Farzad Forouzandeh, and **David A. Borkholder**. "Biocompatible magnetic nanocomposite microcapsules as microfluidic one-way diffusion blocking valves with ultra-low opening pressure." *Materials & Design* 150 (2018): 86-93.

Frisina, R. D., M. Budzevich, X. Zhu, G. V. Martinez, J. P. Walton, and **D. A. Borkholder**. "Animal model studies yield translational solutions for cochlear drug delivery." *Hearing Research* (2018).

Liberson, A. S., Y. Seyed Vahedein, and **D. A. Borkholder**. "Application of Variational Principle to Form Reduced Fluid-Structure Interaction Models in Bifurcated." *Journal of Fluid Flow, Heat and Mass Transfer* 4, no. 1 (2017): 1-9.

Johnson, Dean G., and **David A. Borkholder**. "Towards an implantable, low flow micropump that uses no power in the blocked-flow state." *Micromachines* 7, no. 6 (2016): 99.

Lillie, Jeffrey S., Alexander S. Liberson, and **David A. Borkholder**. "Quantification of hemodynamic pulse wave velocity based on a thick wall multi-layer model for blood vessels." *Journal of Fluid Flow, Heat and Mass Transfer* 3 (2016).

Ouyang, Jing, Denis Cormier, Scott A. Williams, and **David A. Borkholder**. "Photonic sintering of aerosol jet printed lead zirconate titanate (PZT) thick films." *Journal of the American Ceramic Society* 99, no. 8 (2016): 2569-2577.

Lillie, Jeffrey S., Alexander S. Liberson, and **David A. Borkholder**. "Improved Blood Pressure Prediction Using Systolic Flow Correction of Pulse Wave Velocity." *Cardiovascular Engineering and Technology* (2016): 1-9. DOI: 10.1007/s13239-016-0281-y

Liberson, Alexander S., Jeffrey S. Lillie, Steven W. Day, and **David A. Borkholder**. "A physics based approach to the pulse wave velocity prediction in compliant arterial segments." *Journal of Biomechanics* 49, no. 14 (2016): 3460-3466. DOI: 10.1016/j.jbiomech.2016.09.013

Johnson, Dean G., and **David A. Borkholder**. "Towards an Implantable, Low Flow Micropump That Uses No Power in the Blocked-Flow State." *Micromachines* 7.6 (2016): 99.

Lillie, Jeffrey S., Alexander S. Liberson, and **David A. Borkholder**. "Quantification of Hemodynamic Pulse Wave Velocity Based on a Thick Wall Multi-Layer Model for Blood Vessels." *Journal of Fluid Flow* 3 (2016).

Getpreecharsawas J, McGrath J, **Borkholder DA**, The electric field strength in orifice-like nanopores of ultrathin membranes. *Nanotechnology*, 26(4) (2015): 045704. DOI: 10.1088/0957-4484/26/4/045704

Lillie JS, Liberson AS, Mix D, Schwarz QS, Chandra A, Phillips DB, Day SW, **Borkholder, DA**, Pulse wave velocity prediction and compliance assessment in elastic arterial segments. *Cardiovascular Engineering and Technology*, 6(1):49-58 (2015): DOI:10.1007/s13239-014-0202-x.

Matthew Kelly, Vincent Amuso, David Eddins, and **David A Borkholder**, "The Focal Index as a Singular Metric for Beamforming Effectiveness," *Journal of the Acoustical Society of America*, 136.5 (2014): 2654-2664.

Liberson A., Lillie J, **Borkholder DA**, "Numerical Solution for the Boussinesq Type Models with Application to Arterial Flow," *Journal of Fluid Flow*, 1 (2014).

Haghpanahi, Masoumeh, and **David A. Borkholder**. "Fetal QRS extraction from abdominal recordings via model-based signal processing and intelligent signal merging." *Physiological measurement* 35.8 (2014): 1591.

David A. Borkholder, XiaoXia Zhu, Robert D. Frisina, "Round Window Membrane Intracochlear Drug Delivery Enhanced by Induced Advection," *Journal of Controlled Release*, 174:171-176 (2013).

Jessica L. Snyder, Jirachai Getpreecharsawas, David Z. Fang, Thomas R. Gaborski, Christopher C. Striemer, Philippe M. Fauchet, **David A. Borkholder**, and James L. McGrath, "High-performance, low-voltage electroosmotic pumps with molecularly thin silicon nanomembranes," *Proceedings of the National Academies of Sciences*, 110(46):18425-18430 (2013).

Haghpanahi M, Gladstone MB, Zhu XX, Frisina RD, **Borkholder DA**, "Noninvasive Technique for Monitoring Drug Transport Through the Murine Cochlea using Micro-Computed Tomography," *Ann Biomed Eng*, 41:2130-2142 (2013) DOI 10.1007/s10439-013-0816-4.

Leary Pararas EE, **Borkholder DA**, Borenstein JT, "Microsystems technologies for drug delivery to the inner ear," *Advanced Drug Delivery Reviews*, *Advanced Drug Delivery Reviews*, 64(14):1650-1660, (2012).

Johnson, D., Frisina, R., **Borkholder, D.A.**, "In-Plane Biocompatible Microfluidic Interconnects for Implantable Microsystems," *IEEE Transactions on Biomedical Engineering*, 58(4):943-948 (2011).

Borkholder, D.A., Xiaoxia Zhu, Brad T. Hyatt, Alfredo S. Archilla, William J. Livingston III, and Robert D. Frisina, "Murine intracochlear drug delivery: Reducing concentration gradients within the cochlea," *Hearing Research*, 268(1-2):2-11 (2010).

Borkholder, D.A., "State-of-the-art mechanisms of intracochlear drug delivery," *Current Opinions in Otolaryngology & Head and Neck Surgery*, 16:472-477 (2008).

Raisi, F., Belgrader, P., **Borkholder, D. A.**, Herr, A. E., Kintz, G. J., Pourhamadi, F., Taylor, M. T., and Northrup, M. A., "Microchip Isoelectric Focusing Using a Miniature Scanning Detection System," *Electrophoresis*, 22(11):2291-2295 (2001).

Belgrader, P., Okuzumi, M., Pourahmadi, F., **Borkholder, D.A.**, and Northrup, M.A., "A Microfluidic Cartridge to Prepare Spores for PCR Analysis," *Biosensors & Bioelectronics* 14:849-852 (2000).

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INVITED TALKS

Ahmed Alfadhel, Jing Ouyang, Chaitanya Mahajan, Denis Cormier, **David A. Borkholder**, “Towards the Realization of Flexible and Wearable Microfluidic Electronics,” KAUST-NSF Research Conference On Interactive Electronics, January 2017.

Borkholder DA, “Concept to Commercialization of a MEMS-based System- Having a Blast,” Marquette University, April 14 (2015).

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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>	July 29, 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>	DECLARATION OF DR. DAVID A. BORKHOLDER IN SUPPORT OF PATENT OWNER'S RESPONSE
<i>Persons Served</i>	DLA Piper LLP (US) Tiffany C. Miller Edward H. Sikorski James M. Heintz

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