

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VITAL CONNECT, INC.,
Petitioner,

v.

BARDY DIAGNOSTICS, INC.,
Patent Owner.

IPR2023-00381
Patent 11,051,743

DECLARATION OF DR. PER REINHALL, PH.D.

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the 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.

Dated: 4/21/2023


Dr. Per Reinhall, Ph.D.

TABLE OF CONTENTS

I. INTRODUCTION	3
II. INFORMATION AND MATERIALS CONSIDERED	3
III. EXPERIENCE AND QUALIFICATIONS	4
IV. APPLICABLE LEGAL STANDARDS	10
V. BACKGROUND OF THE '743 PATENT	10
VI. THE LEVEL OF ORDINARY SKILL IN THE ART	12
A. The Problems Encountered in the Art.	14
B. Mechanical and Electrical Engineering Skills are Required to Address the Problems Encountered in the Art.	19
C. My Experience Working With Engineers and Medical Professionals Further Supports My Opinions.	22
D. Dr. Akar's Definition of a POSITA Is Incorrect.	25
VII. CONCLUSION.....	28

I. INTRODUCTION

1. I, Dr. Per Reinhall, Ph.D., have been retained by Riley Safer Holmes & Cancilla LLP, on behalf of Bardy Diagnostics, Inc. (“Bardy”), in the matter of Case No. IPR2023-00381, which concerns U.S. Patent No. 11,051,743 (“the ’743 Patent”).

2. I am being compensated for my work in this matter at my standard hourly rate for consulting services, \$350 per hour. My compensation in no way depends on the outcome of this proceeding. I have no financial interest in any of the parties to these matters. In the previous four years, I have not testified as an expert at trial or by deposition.

II. INFORMATION AND MATERIALS CONSIDERED

3. I have been asked to provide technical expert opinions relating to the level of ordinary skill in the art at the time of the inventions of the ’743 Patent. In conducting my analyses and forming the opinions set forth in this Declaration, I have reviewed the ’743 Patent and the Declaration of Dr. Joseph Akar (Ex. 1002). I have also reviewed the following:

- International Pub. No. WO 2010/104,952 (“*Mazar*”) (Ex. 1003);
- U.S. Patent App. Pub. No. 2011/0077497 (“*Oster*”) (Ex. 1004);
- U.S. Patent No. 11,116,447 (“*Yang*”) (Ex. 1005);
- Curriculum Vitae of Dr. Joseph Akar (Ex. 1006);

- File History of the '743 Patent (Ex. 1007);
- U.S. Patent No. 5,862,803 ("*Besson*") (Ex. 1008);
- International Publication No. WO 2008/005015 ("*Shennib*") (Ex. 1013);
- U.S. Patent No. 7,206,630 ("*Tarler*") (Ex. 1014);
- U.S. Patent No. 8,611,980 ("*Choe*") (Ex. 1015);
- U.S. Patent No. 9,277,864 ("*Yang* '864") (Ex. 1019); and
- Petitioner's Exhibit Nos. 1009-1012 and 1016-1018.

III. EXPERIENCE AND QUALIFICATIONS

4. Below is a short summary of my education, training, and experience that I believe is relevant to this matter and the opinions I provide in this Declaration. A copy of my curriculum vitae is being submitted as Exhibit 2002.

5. My professional background is in mechanical engineering. I have a Bachelor of Science degree in Mechanical Engineering from the University of Washington, a Master of Science degree in Applied Mechanics from the California Institute of Technology, and a Ph.D. in Applied Mechanics from the California Institute of Technology.

6. I have more than forty years of engineering experience. I have particular interests in nonlinear dynamical systems, acoustics, biomechanics, and systems design, with a focus on the development of biomedical devices.

7. I am currently a Professor of Mechanical Engineering at the University of Washington. Over the years, I have taught many engineering classes, including the following engineering courses: Engineering in Medicine, Mechanical Engineering Analysis, Dynamics, Senior Design, Vibrations, Finite Element Analysis, and Applied Acoustics.

8. From around 2011 to 2022, I was the Chair of Mechanical Engineering at the University of Washington.

9. I am a named inventor on over 20 patents.

10. I have authored or co-authored over 150 publications on various engineering topics, including several publications related to cardiac monitoring.

11. I have more than 20 years of engineering experience designing medical devices that include electrical components. I also have firsthand experience in clinical settings in connection with the study and development of medical devices, including those with electrical components.

12. For example, I founded the University of Washington's Engineering Innovation in Health Program ("Engineering Innovation in Health Program"). The Engineering Innovation in Health Program promotes interdisciplinary collaboration between engineering and health sciences with the goal of developing technical solutions to pressing challenges in health care. In short, medical professionals approach the Engineering Innovation in Health Program for help solving unmet

health or healthcare needs, and our engineering students (both undergraduate and graduate), along with University of Washington engineering faculty, design medical devices to address those needs. To date, we have completed over 65 projects, each of which resulted in the development of a prototype device.

13. I have supervised several projects in the Engineering Innovation in Health Program that involved designing cardiac monitoring devices. One such project involved a system that employed an electrocardiogram (“ECG”) monitor to estimate blood pressure. That system employed a patch including electrodes. The patch attached to a patient’s neck or arm, and the ECG monitor collected data, which together with pulse oximeter data were directed into an acquisition system that processed the data to estimate blood pressure via a machine learning algorithm.

14. In another project, we developed a blood flow measuring device that could be placed on a patient’s wrist. The project culminated in the development of a 3-D printed wristband that incorporated an ultrasound Doppler and PPG sensors and an ECG electrode.

15. I also have engineering experience involving cardiac monitoring devices outside of the Engineering Innovation in Health Program. For example, research in my lab at University of Washington used a patch with an acoustic sensor to monitor heart valves to study whether one could use acoustic signals to discover heart valve disease.

16. I also participated in clinical studies involving cardiac monitoring devices. By “clinical,” I mean work that involved patients (e.g., diagnosing or treating patients). For instance, I participated in a large clinical study involving implantable cardiac defibrillators. My work involved collecting data from the implantable cardiac defibrillators, developing software that organized the data, and then developing software that could predict if the device would shock a patient’s heart to prevent ventricular fibrillation. The goal was to design software that could ultimately be incorporated into the devices to warn the patient about an impending shock, so that the patient could, for example, sit down or stop driving before being shocked. The clinical study resulted in a series of articles published in the New England Journal of Medicine, Journal of the American College of Cardiology, and Heart Rhythm.

17. I also have experience teaching students about cardiac monitoring devices. I teach them about different types of devices, such as pacemakers and defibrillators, and how they work. I also teach a class in nonlinear vibrations and dynamics in which we analyze the heart, a nonlinear system. We use nonlinear time series analysis to try to detect subtle aspects of the heart’s signals, namely portions of the signal that may be the precursor of ventricular fibrillation.

18. I also have experience designing other types of medical devices. For example, I collaborated with the Veterans Administration Hospital to develop

pressure sensors for shoes and prosthetics—and ways in which to automatically modify the geometry and the material of the prosthetic interface during use—in an effort to reduce skin ulcers that can lead to the inability of using the prosthetic device. This is especially a problem for patients suffering from diabetes. I worked with both engineers and physicians on that project. The engineers were knowledgeable regarding how prosthetics were manufactured, how to digitize and model the human leg, and how human tissue behaves from an engineering perspective (i.e., in a nonlinear way). Therefore, the engineers could determine ways to better fit and form prosthetics to obtain the best possible baseline fit that could then be automatically adjusted throughout the day based on data obtained from the sensors we were developing. The physicians provided information regarding medical problems (e.g., how the ulcers form and why), about physiology (e.g., how patients suffering from diabetes may experience nerve damage that makes them less likely to feel when an ulcer is forming), and different surgical techniques

19. In collaboration with another University of Washington professor, I designed an ultrathin endoscope used to detect early onset of cancer. An endoscope is a device that is inserted into the human body and used to view body cavities and organs. They are typically tubular or hose-like in nature consisting of a bundle of a large number of optical fibers (one for each pixel) with a light and lenses at the end. However, they are generally too large in diameter to fit in many places because of

the optics and electronics that are incorporated into the device (e.g., fiberoptic bundle, lenses, wires, and mechanical devices used to control their movement). I worked with another mechanical engineer to develop an endoscope that was much thinner than the typical endoscope by reducing the bundle of optical fibers to a single fiber, enabling our endoscope to be used in places previously not possible. As part of that project, I worked with physicians, who explained the various clinical needs (i.e., an endoscope that was small enough to be inserted into parts of the body that may contain cancer or pre-cancer cells), but they did not offer any design solutions to those problems.

20. I also designed devices that led to the creation of two active companies, VICIS and Marine Construction Technologies. VICIS manufactures football helmets that provide market-leading protection against concussions. I was the co-founder and its initial Chief Technology Officer. Marine Construction Technologies designs and develops technology used in marine construction to remove 90% of the noise created during pile driving. I am currently the Chief Technology Officer for Marine Construction Technologies.

21. Recently, in collaboration with a colleague, I also started a medical device company that is developing a device for extracting biopsies for better imaging of tissue

IV. APPLICABLE LEGAL STANDARDS

22. I am a mechanical engineer by training and profession. I was involved as a technical expert in two previous patent matters and have been named as an inventor on more twenty patents, but I am not an expert in patent law. Therefore, I have been advised of certain aspects of patent law applicable in this matter, namely with respect to the principles regarding a person of ordinary skill in the art, as expressed in this Section.

23. I understand that to determine the level of ordinary skill in the art, the following factors may be considered: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. I understand that these factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art. I also understand that not every factor may be present in a given case, and one or more of the factors may predominate.

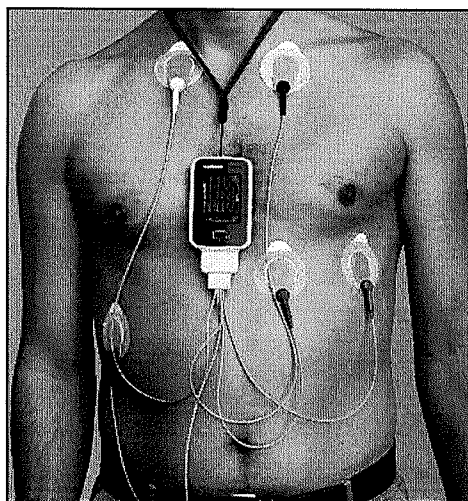
24. I also understand that the level of ordinary skill in the art must be the level of skill in the art at the time of the invention.

V. BACKGROUND OF THE '743 PATENT

25. The '743 Patent is titled "Electrocardiographic Patch." (Ex. 1001.) As explained in the '743 Patent, an electrocardiogram ("ECG") is used to detect and

depict the electrical signals of a patient's heart and can be used by physicians to diagnose heart problems and other potential health concerns. (*See id.* at 1:27–49.) According to the '743 patent, conventionally, ECGs are generated by ECG machines connected to 12 electrical leads that are placed in “well-established traditional chest locations.” (*See id.* at 1:31–37.) The '743 Patent explains that long-term ECG monitoring has benefits over short-term monitoring, but the design of ECG monitoring devices can be “arduous to employ, cumbersome to the patient, and excessively costly,” which can prevent successful long-term monitoring. (*See id.* at 1:60–2:8.)

26. The '743 Patent describes Holter monitors as being a conventional solution for outside-the-clinic, portable ECG monitoring, but their design typically limits their use to 24-48 hours in practice. (*See id.* at 2:36–41; *see also id.* at 1:51–53.) Through my professional experience, I am familiar with Holter monitors. The following shows a representative Holter monitor on a patient:



(https://commons.wikimedia.org/wiki/File:Alex_CM4000.jpg).)

27. The '743 Patent also explains that “wearable stick-on monitoring devices” had been developed and commercialized into two products manufactured by iRhythm Tech., Inc. (Ex. 1001 at 2:58–62.)

28. The '743 Patent identified several problems with these products and noted that there “remains a need for an extended wear continuously recording ECG monitor practicably capable of being worn for a long period of time in both men and women and capable of recording atrial signals reliably.” (*Id.* at 3:36–39.) I discuss these problems in more detail below.

VI. THE LEVEL OF ORDINARY SKILL IN THE ART

29. The field of art relevant to the '743 Patent is electrocardiographic monitoring and, in particular, electrocardiography patches. (Ex. 1001 at 1:20-23.)

30. For purposes of this Declaration, I am considering the time of the invention to be the earliest date to which the application giving rise to the '743 Patent claims priority: September 25, 2013. I understand that the '743 Patent also claims priority to several patent applications filed on November 14 or 15, 2013, and the opinions I give in this Declaration would be the same to the extent November 14 or 15, 2013, was considered the time of the invention.

31. Based on the problems encountered in the prior art, the level of skill reflected by the '743 Patent and the prior art, and my engineering experience,

including my experience working with others, a person of ordinary skill in the art at the time of the of the '743 Patent's inventions (a "POSITA") would be (a) a person with a degree in mechanical engineering, electrical engineering, or an equivalent degree¹, with at least six months' experience designing medical devices that include electrical components (hereafter "e-medical devices"); or (b) a person without the foregoing engineering education, but who achieved similar knowledge through approximately five years' experience designing e-medical devices.

32. I possess the qualifications of the POSITA, now and at the time of the inventions of the '743 Patent. Also, as a professor and through my other professional experience, I have worked with many others who have the qualifications of a POSITA, so I have an understanding of their capabilities and skillsets. I have also worked with many physicians and other medical practitioners (e.g., nurses), so I have an understanding of their capabilities and skillsets as well.

¹ For example, a biomedical engineering degree may be equivalent to a mechanical or electrical engineering degree. The boundaries of the engineering disciplines are not set in stone, and mechanical engineers, electrical engineers, and biomedical engineers can have significant overlap in their education depending on how a particular university structures its curriculum.

A. The Problems Encountered in the Art.

33. My opinions regarding the level of skill in the art at the time of the inventions of the '743 Patent are supported by the problems encountered in the prior art. First, the '743 Patent identifies several problems encountered in the art, and they are engineering problems involving issues such as compressional, tensile, torsional, and shear forces; material properties; adhesives; electrical power consumption; circuits; and electrical hardware architectures, and component configurations, layouts, and fabrication

1. The Problems in the Art Identified in the '743 Patent.

34. The '743 Patent criticizes prior art cardiac monitoring devices for being arduous to employ, cumbersome, and expensive. (Ex. 1001 at 1:6-2:2, 2:50-57.) These are problems that go to the shapes of the devices, the layouts and configurations of components on the device, their electrical hardware architectures, and the types of hardware components utilized. For example, different types of hardware have different sizes and mass, and the components' positions and layouts relative to each other can affect the surface area covered by the device or how far from the patient's skin the device protrudes. Generally speaking, larger memory capacity, increased processing power, and longer battery life equates to larger, more expensive hardware and support structures.

35. The '743 Patent also describes problems with prior art ECG monitoring devices lacking adequate battery capacity. (Ex. 1001 at 3:8-11.) Lack of adequate battery capacity arises from, among other things, size constraints in the devices, hardware selection, the layout of the circuitry, sampling rate, and the amount and frequency of power being drawn from the battery by the various components that require power. Typically, battery energy storage capacity is tied to the physical volume of the battery (for batteries of the same type) because batteries are chemical devices, and the more chemicals (i.e., electrolytes) contained in the battery, the higher the battery power. But, a higher capacity battery (and thus a larger battery) may make the devices bulkier and heavier, and would result in larger forces being applied to the adhesive when the patient moves, increasing the risk of dislodgment. Circuitry layout also affects power consumption, as longer electrical and thinner paths generally increase the amount of energy loss as the current flows through the circuit. In addition, the types and amounts of components drawing power from the battery impacts battery life. Moreover, components that frequently or continuously draw power from the battery generally will deplete the battery faster than if the components periodically drew power.

36. The '743 Patent describes problems with prior art ECG monitoring devices not being adequately waterproofed. (Ex. 1001 at 3:11-14.) Waterproofing electronics generally involves whether or how the electronics are housed. For

example, if the devices contemplate removal and replacement of components, connections to those components or the need to open a housing may create vulnerabilities where water or moisture may infiltrate.

37. The '743 Patent also recognizes that "a need remains for an extended wear continuously recording ECG monitor practically capable of being worn for a long period of time in both men and women" and for integrating "wider-ranging physiological and 'life tracking'-type data into long-term ECG and physiological data monitoring." (Ex. 1001 at 1:36-42.) Addressing those needs presents challenging engineering problems because extending the sensing time of an ECG monitor is at odds with adding sensing and processing capabilities and memory capacity, as those functions require more, not less, energy consumption. Plus, adding sensing and processing capabilities and memory capacity would likely mean using additional components or components of larger sizes and masses, which increases the forces that must be withstood to maintain adhesion of the device to the patient.

38. Furthermore, the '743 Patent describes the problems arising from "various compressional, tensile, and torsional forces" that can dislodge electrodes. (Ex. 1001 at 2:9-23.) Addressing those forces is an engineering problem that is particularly complex in light of the dynamic environmental and physical conditions presented by the device being attached to skin. For example, skin wants to stretch and change shape when a person moves, which together with the friction of the

clothing and inertial effects due to movements applies numerous and varying forces (stresses) to the electrodes attached to the skin. In addition, contaminants such as sweat, oil, dead skin, and water (e.g., from showering) come between the skin and the part of cardiac monitoring devices attached to the skin. Those contaminants affect the level of adhesion over time. In addition, everyone is different: people move differently, their skin stretches and folds differently, people sweat differently, and more. So, maintaining electrodes on the skin, particularly over a long period of time, presents challenging engineering problems.

2. The Problems Identified in the Prior Art.

39. I understand that several prior art patents and publications have been made of record in this proceeding. That prior art also identifies technical, engineering problems regarding monitoring devices.

40. For Example, International Publication No. WO 2010/104952 (“*Mazar*”) criticizes prior art monitoring devices for being “bulky and uncomfortable,” “cumbersome,” having “excessive weight,” being stiff, and unadhering from the patient during use. (Ex. 1003 at ¶¶ [0003]-[0004].) As discussed above, these are problems with the configurations of the device, plus problems associated with the materials and mechanical properties of the prior art devices, and the resulting challenges posed by the forces being applied to them during use.

41. *Mazar* further identifies that monitoring devices have problems with “energy consumption.” (Ex. 1003 at ¶ [0004].) That can relate to difficulties in balancing the energy demands—desired for continuous monitoring, processing power, and the length of use—with the physical constraints of the devices, such as their sizes and shapes, plus the difficulties in keeping the device attached to the patient, which is impacted by the size of the power source. (Ex. 1003 at ¶ [0004].)

42. U.S. Patent No. 11,116,447 (“*Yang*”) explains that ECG monitoring devices “are subject to repeated use and high wear and tear,” which is caused at least in part by various forces being applied by the device over time as a result of, for example, movement of the patient. (Ex. 1005 at 1:27-37.)

43. U.S. Patent No. 5,862,803 (“*Besson*”) describes problematic device layouts and their failures to withstand the forces applied during use. Specifically, *Besson* describes prior art cardiac monitoring devices having cables that “obstruct the patient and highly limit his or her freedom of movement” and, “due to the stiffness of the cables and the lever forces connected therewith, the cables become easily detached particularly when the patient moves.” (Ex. 1008 at 1:46-52)

44. *Besson* also describes problems with battery life due to the demands on the battery from the processing, recording, and transmitting components. (*Id.* at 2:44-49.)

45. International Publication No. WO 2008/005015 (“*Shennib*”) describes the problem of prior art devices being unable to provide power for extended use. (Ex. 1013 at ¶ [0011].)

46. *Shennib* also calls prior art cardiac monitoring devices “bulky,” expensive, and uncomfortable. (Ex. 1013 ¶¶ [0009]–[0010].) As discussed above, that recognizes problems with their layouts and configurations.

47. U.S. Patent No. 7,206,630 (“*Tarler*”) describes drawbacks in prior art devices arising from their device layouts and configurations, material properties, and “unique power requirements.” (Ex. 1014 at 2:51–3:3.) Specifically, *Tarler* describes the rigidity of the devices preventing “good electrode contact,” device cumbersomeness, and problems delivering sufficient power to all desired components. (*Id.*)

B. Mechanical and Electrical Engineering Skills are Required to Address the Problems Encountered in the Art.

48. The problems encountered in the art at the time of the inventions of the ’743 Patent are engineering problems specific to the mechanical and electrical aspects of devices. Based on my personal experience designing e-medical devices, and my years of experience working with students, engineers, and medical professionals, it is my opinion that engineering skills are necessary to address the problems encountered in the art here.

49. Based on my experience as a professor of engineering and as a prior Chair of the Department of Mechanical Engineering at the University of Washington, I know that mechanical and electrical engineers receive specific education and training in mechanics, material properties, power consumption, circuitry, and electrical hardware architectures, and they could apply that education and training to try to develop solutions to the problems encountered in art, particularly after obtaining some experience designing e-medical devices, such as cardiac monitoring devices.

50. For example, mechanical engineers typically receive education and training in dynamics and vibrations so that they learn about how structures move when forces are applied. They also typically receive education and training in engineering materials (e.g., polymers and adhesives), structural analysis, energy and energy storage (including batteries), thermal management, sensors, actuators, and software engineering. They also typically receive education and training in mechatronics, which is how to couple mechanics with electronics.

51. Electrical engineers typically receive education and training in computer engineering, software engineering, and circuit design, which includes powering electrical components and energy storage. They also receive education in dynamics and mechatronics.

52. Thus, mechanical and electrical engineers, especially those who have some experience designing e-medical devices, are likely to receive specific education and training as to what impacts energy efficiency in electrical devices and the fundamental engineering principles that can be applied to increase energy efficiency and reduce unnecessary power losses. They are also likely to receive specific education and training in physics and mechanics that can be used to identify, calculate, and reduce the effects of forces applied to structures during use. They also generally obtain skills through their engineering education and training regarding how to determine whether materials are suitable for use in medical devices, and how to waterproof and configure engineering systems and components. They likely also receive education and training in manufacturing processes for mechanical and electrical systems.

53. Here, some post-undergraduate experience designing e-medical devices is necessary to address the problems in the art, and education alone would not be sufficient. Based on my decades of experience teaching undergraduate students, a person who just received his or her undergraduate degree is a novice. After they land their first job, the person will begin on-the-job training in order to obtain the real-world skills necessary to perform the basics of a practicing engineer. In the context of designing e-medical devices, it is my experience that this introductory training period lasts at least six months.

54. Therefore, in my opinion, the technical knowledge gained from an engineering education—plus at least six months designing e-medical devices—or real-world design experience that would provide similar technical know-how in e-medical devices, would be necessary for a person to be able to address the engineering problems identified by the '743 Patent and the prior art.

C. My Experience Working With Engineers and Medical Professionals Further Supports My Opinions.

55. My opinions are also supported by my own experience, including my engineering work, including in the field cardiac monitoring; my experience teaching others; and my experience collaborating with other engineers and medical professionals in connection with the development and design of medical devices.

56. In the Engineering Innovation in Health Program, I work together with other engineering faculty members and my engineering students to develop medical devices that address the problems and needs of medical professionals from the University of Washington's School of Medicine and elsewhere.

57. Since its founding, I and my colleagues in the program have overseen over 65 medical device design projects, all of which resulted in the development of a prototype device. For each of those projects, a medical professional approaches the engineering department at the University of Washington for help addressing a problem or unmet need in their medical practice.

58. In my experience in the program, without exception, the medical professionals who lack extensive experience designing medical devices do not provide design solutions because they lack the skills necessary to do so. The medical professionals provide valuable clinical and medical information and background information on the problem or need or what has been done in the past. But, they turn to engineers for all aspects of the design of the devices. This interplay between the clinical need from the medical professional and the design of the device by the engineer is why I thought it was imperative to start the Engineering in Health program at the University of Washington.

59. For instance, an intestinal surgeon approached the Engineering Innovation in Health Program after noticing that reconnecting intestines via stitching was time consuming and sometimes resulted in inadequate connections that leaked, leading to infections. The surgeon asked for help developing an alternative way to reattach intestines that did not involve stitching. While the surgeon understood what the human body could withstand, where risks of infections may arise, how the intestines heal over time, existing techniques and devices, and other medical and biological information, he lacked knowledge in engineering fundamentals and the basic engineering skills that were necessary to design a device that could act as an alternative to stitches. As a result, he did not provide any design solutions during the pendency of the project. In contrast, I, along with other members of the engineering

faculty, and my engineering students developed a prototype device that was faster, safer, and more effective than stitching. Notably, this project involved a pure mechanical device with no electrical components. When electrical components are involved, even more engineering skills are necessary.

60. A pertinent example of a project involving the design of an e-medical device is the ultrathin endoscope project I discussed earlier in this Declaration. That project involved trying to reduce the size of an endoscope—a challenging engineering problem that involved mechanical and electrical aspects of the device. Existing devices employed many fiberoptic cables, which required a relatively large diameter housing. I worked with another mechanical engineer to develop an endoscope that was much thinner than the typical endoscope by reducing the number of fiberoptic cables to a single cable. The physicians with whom we worked on that project were aware of the problems with existing endoscopes and explained what they needed (i.e., an endoscope that was small enough to be inserted into parts of the body that may contain cancerous portions), but they did not offer any workable design solutions to those problems because they lacked the necessary engineering skills. For example, despite having knowledge of endoscopes and how they worked, the physicians did not know how to reconfigure or change electrical components of an endoscope to make the endoscope thinner. An engineering education and design experience was needed to come up with an improved endoscope that effectively

addressed the problem, particularly with respect to reworking the electrical and optical components.

61. Through my experience with the Engineering Innovation in Health Program and in my collaboration with hospitals and medical device companies, physicians and other medical professionals are important to identify problems and unmet needs. However, I have seen firsthand that physicians and other medical professionals who do not have education and training in engineering lack the necessary skills to come up with engineering solutions to the problems. That is the very reason they approach the Engineering Innovation in Health Program (and me) in the first place.

62. Physicians and other medical professionals need the help of engineers to develop improvements or design new mechanical and electrical aspects of devices because they lack the skills to do so themselves. If a physician becomes part of the team working to develop or improve devices, their involvement is typically limited to providing clinical information and insight into patient preferences and treatment needs.

D. Dr. Akar's Definition of a POSITA Is Incorrect.

63. Dr. Akar's primary and alternative definitions of a POSITA are incorrect. Notably, neither of Dr. Akar's definitions require any experience designing devices of any kind.

64. With respect to Dr. Akar's primary definition, I have never heard of "a bachelor's degree in cardiovascular medicine, electrophysiology, [or] internal medicine." (Ex. 1002 ¶ 43.) To my knowledge, no such bachelor's degrees exist. Instead, cardiovascular medicine, electrophysiology, and internal medicine are specialty areas of study pursued as part of or after completing medical school.

65. In any event, "two to three years of clinical experience in the field of biomedical engineering" would not have provided a non-engineer with skills necessary to address the problems encountered in the art at the time of the invention here. I have first-hand knowledge of clinical work. Clinical work involves working directly with patients in a diagnostic or treatment setting to provide patient care.

66. Clinical experience does not confer engineering skills on non-engineers. For example, a physician with clinical experience with cardiac monitoring devices may understand how to use the devices, how the patients tolerate the devices, the medical need for the devices, and how the devices may facilitate medical treatment. But, there is no engineering occurring in the clinic. In other words, clinical experience may give a physician experience in using a device, but not in designing or developing one—particularly ones with internal electrical components.

67. Thus, Dr. Akar's primary definition of a POSITA is too broad because it includes people who have no engineering education or training and no experience

designing devices of any kind. That does not reflect the level of skill necessary to address the problems encountered in the art.

68. Furthermore, “the field of biomedical engineering” is vast, and clinical experience in one part of the field of biomedical engineering would not necessarily confer any skills applicable to the problems in the art here. For instance, biomedical engineering spans disparate technologies such as tissue engineering, artificial organs, bone implants, stem cell development, and medical imaging (e.g., x-rays). Clinical experience that is limited to tissue engineering would not impart onto a physician any of the mechanical and electrical engineering skills that are necessary to address the problems encountered in the art here.

69. Dr. Akar’s alternative definition is also too broad. The definition merely requires a medical worker “with knowledge of the electronic design and operation of cardiac monitoring technologies.” Essentially any nurse or physician in the United States who uses cardiac monitoring technologies in their daily practice would have knowledge of their general design and operation. For example, they would know the general configuration of the major components and how the device works. However, that knowledge is not enough to improve the device or design a new device. For example, a nurse or physician would not know how to make a cardiac monitoring device more energy efficient just because the nurse or physician had knowledge of where a battery in the device was located and that the battery

supplied power to the device's electrical components. In sum, a physician or medical worker with no experience designing devices may understand the need to improve existing devices, but they would not have sufficient understanding or skills to address the problems in the art described in the '743 Patent or the prior art.

VII. CONCLUSION

70. For the foregoing reasons, a person of ordinary skill in the art at the time of the of the '743 Patent's inventions would be (a) a person with a degree in mechanical engineering, electrical engineering, or an equivalent degree, with at least six months' experience designing e-medical devices; or (b) a person without the foregoing engineering education, but who achieved similar knowledge through approximately five years' experience designing e-medical devices.