

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES AND
ABBOTT DIABETES CARE INC.,

Petitioner,

v.

ALTIVERA LLC,

Patent Owner.

Case No. IPR2024-00425
Patent No. 7,969,307 B2

DECLARATION OF STEVEN WARREN, PH.D.

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PATENT OWNER'S EXHIBITS	
Exhibit No.	Description
2001	Declaration of William Bandy, Ph.D.
2002	Declaration of John P. Peeters, Ph.D.
2003	Feb. 1, 2005 email from John Melngailis, Bates numbered GEN-AB-0003666 in <i>Gentag, Inc. v. Abbott Laboratories</i> , No. 1:23-cv-00310 (N.D. Ill.)
2004	May 6, 2003 handwritten notes by John Peeters, Bates numbered GEN-AB-00001440 in <i>Gentag, Inc. v. Abbott Laboratories</i> , No. 1:23-cv-00310 (N.D. Ill.)
2005	May 7, 2003 letter from John Peeters, Bates numbered GEN-AB-0001441-1442 in <i>Gentag, Inc. v. Abbott Laboratories</i> , No. 1:23-cv-00310 (N.D. Ill.)
2006	Aug. 19, 2003 email from John Peeters, Bates numbered GEN-AB-00002974-2977 in <i>Gentag, Inc. v. Abbott Laboratories</i> , No. 1:23-cv-00310 (N.D. Ill.)
2007	Defendants' Reply Claim Construction Brief, <i>Gentag, Inc. v. Abbott Laboratories</i> , Case No. 1:23-cv-310 (N.D. Ill. May 24, 2024), ECF No. 87
2008	Nokia 1100 User Guide
2009	Declaration of Steve Warren, Ph.D.
2010	Curriculum Vitae of Steve Warren, Ph.D.
2011	Transcript of Deposition of Dr. Majid Sarrafzadeh
2012	Nokia 1100 full phone specifications (https://www.gsmarena.com/nokia_1100-512.php)
2013	Robert Triggs, <i>A little history of Bluetooth</i> , dated Sept. 1, 2023 (https://www.androidauthority.com/history-bluetooth-explained-846345/)

PATENT OWNER'S EXHIBITS	
Exhibit No.	Description
2014	Len Ott, <i>The Evolution of Bluetooth In Wireless Medical Devices</i> , Socket Mobile (July 2010)
2015	Wikipedia, <i>Near-field communication</i> , last accessed Oct. 7, 2024
2016	Nathan Lawrentschuk & Damien M. Bolton, SYSTEMATIC REVIEW, <i>Mobile phone interference with medical equipment and its clinical relevance: a systematic review</i> , Vol. 181, No. 3 (Aug. 2004)
2017	A.A. Klein & G. N. Djaiani, JAPI, <i>Mobile Phones in the hospital – past, present and future</i> , Anesthesia (2003)
2018	ME YEOLEKAR & A SHARMA, <i>Use of Mobile Phones in ICU – Why Not Ban?</i> , Vol. 51 (Apr. 2004)
2019	Hiroshi Furuhashi, JIKEI UNIV. SCHOOL OF MEDICINE TOKYO, JP, <i>Electromagnetic Interferences of Electric Medical Equipment from hand-held radiocommunication Equipment</i>
2020	P Gilligan, et al., THE BRITISH JOURNAL OF RADIOLOGY, <i>GSM cell phones can interfere with ionizing radiation dose monitoring equipment</i> (2000)
2021	Werner E. Irnich & Rolf Tobisch, <i>Mobile Phones in Hospitals</i>
2022	Greg Knell, <i>SureCall Cell Phone Signal Booster Blog</i> (Feb. 2022), https://surecall.com/surecall-cell-phone-signal-booster-blog/cellular-phone-frequency-bands-guide-2022/

I, Dr. Steven Warren, declare as follows:

I. INTRODUCTION

1. I have been retained by counsel for Altivera LLC (“Patent Owner”) as an independent expert consultant in connection with *inter partes* review (IPR) proceeding IPR 2024-00425 concerning U.S. Patent No. 7,969,307 (the “’307 Patent”), pending before the U.S. Patent and Trademark Office, Patent Trial and Appeal Board (“Board”).

2. I have been asked to opine on whether claims 1-3, 5, 9, and 10 of the ’307 Patent (the “challenged claims”) are rendered obvious by the prior art. I have further been asked to analyze and respond to the opinions set forth in the Declaration of Dr. Majid Sarrafzadeh (EX-1003), submitted by Abbott Laboratories and Abbott Diabetes Care Inc. (“Petitioner”) in connection with their IPR Petition.

3. Along with my more than 30 years of education, research, and experience in the fields of biomedical engineering, biomedical instrumentation, and wearable/wireless sensor-based physiological monitoring systems, my opinions are based on the investigation and study of relevant materials. The materials that I evaluated in support of this Declaration include all exhibits and materials cited or referenced in this Declaration and in the Petition.

4. I may rely upon these materials, my knowledge and experience, and/or additional materials to rebut arguments raised by the Petitioner. Further, I may also

consider additional documents and information in forming any necessary opinions, including documents that may not yet have been provided to me.

5. My analysis of the materials produced in this matter is ongoing, and I will continue to review any new material as it is provided. This Declaration represents only those opinions I have formed to date. I reserve the right to revise, supplement, and/or amend my opinions stated herein based on new information and on my continuing analysis of the materials already provided.

6. I am being compensated for my time at my normal hourly consulting rate, with reimbursement for actual expenses. I have no interest in the outcome of this proceeding, and my compensation is not dependent on the content of my opinions or the outcome of this proceeding.

II. BACKGROUND AND QUALIFICATIONS

7. My educational background, career history, publications, and other relevant experience and qualifications provided herein are only a summary. My complete CV, which sets forth my education, professional appointments, publications, presentations, grant activity, courses taught, service activities, and cases in which I have testified, has been submitted as Exhibit 2010.

A. Education/Preparation

8. I received a B.S. in Electrical Engineering (Summa Cum Laude) from Kansas State University (“KSU”) in 1989, an M.S. in Electrical Engineering from

KSU in 1991 (Master's Thesis: "An Empirical Study of the Dynamic Hysteresis Characteristics of Ferromagnets"), and a Ph.D. in Electrical Engineering from The University of Texas at Austin in 1994 (graduate fellowship; laser-induced fluorescence of coronary artery and aorta; Monte Carlo simulation of light/tissue interaction; intravascular ultrasound; Dissertation: "Combined Intravascular Ultrasound and Fluorescence Spectroscopy for the Diagnosis of Atherosclerosis"). During the summers of 1989 and 1991, I was a research assistant at Lawrence Livermore National Laboratory, Livermore, CA, in the Nuclear Safety Systems Division (high-frequency magnetic hysteresis) and the Human Genome Flow Cytometry Unit (digitizer board programming; dyed chromosome measurement), respectively. Over this span from 1984 to 1994, I studied electronics, biomedical instrumentation (including device design), biomedical optics, light/tissue interaction, *in vitro* tissue analysis, computer programming, numerical computation, modeling/simulation, and engineering education. During my time as a Graduate Research Assistant at the University of Texas at Austin, I developed Monte Carlo simulation code to predict excitation and emission profiles of light (e.g., absorption, reflection, and transmission) for three-dimensional (3D) tissue geometries consisting of homogeneous media. This code was used to understand and optimize (a) separation distances between optical fiber bundle tips and tissue during fluorescence

measurements and (b) source/detector separations in reflectance-mode sensors employed for pulse oximetry (see the Sandia work below; Love Warren 1997¹).

B. Prior Professional Appointment at Sandia National Laboratories

9. From 1994 to 1999, I was employed by Sandia National Laboratories (“Sandia”), in Albuquerque, NM. I was first hired by Sandia in July 1994 as a Post-Doctoral Member of the Technical Staff (“MTS”). In March 1996, I was hired as a Senior MTS and was then promoted to a Principal MTS in November 1998. In 1994, I joined the Personal Status Monitor project—the largest internally funded biomedical project at Sandia until that time. The goal of the project was to develop wearable wireless hardware and associated software suitable to acquire and track physiological data from an ambulatory individual in a civilian or military environment. As part of that work, I (1) conducted a broad pre-1997 literature search in the areas of ambulatory health monitoring, optical sensors, pulse oximetry, and optical signal processing; (2) built and tested custom transmittance- and reflectance-mode photoplethysmographic sensors; (3) performed Monte Carlo simulations of red and near-infrared light transport in tissue for reflectance-mode sensor configurations employed for pulse oximetry, using the C programming language (Love Warren 1997); and (4) completed a comparative analysis of existing

¹ Love, Jerry T., Steve Warren, George Laguna, and Timothy J. Miller. Personal Status Monitor, Sandia Report, SAND97-0418, UC-706, February 1997, 211 pages, unlimited release (“Love Warren 1997” or “Love (1997)”).

techniques to mitigate the effects of motion artifacts in photoplethysmograms, where I wrote MATLAB scripts to support these analyses.

10. Finally, I also led a \$3.2M effort focused on (1) the economic viability of telemedicine as a new care modality and (2) a demonstration of a prototype CORBA-based telemedicine system that utilized plug-and-play interoperability standards. These biomedical projects required numerous industry interactions, workshops, and presentations. During that time, I also developed software using the C++ programming language to incorporate three-dimensional ACIS boundary representation solid models into the legacy Fortran *Integrated Tiger Series* (ITS) of coupled photon/electron Monte Carlo radiation transport codes. These ITS codes have been utilized to simulate particle transport in 3D geometries for over 35 years (Kirk 1985), including photon transport in 3D tissue structures for therapeutic dose planning, imaging system optimization, and biological parameter measurement. Current versions of the ITS transport codes still rely on ACIS geometries and upgrades to my original code to simulate particle transport in complex geometrical structures, including human tissue (Laub 2014).²

² See Bernadette Kirk, *The Integrated Tiger Series of Electron/Photon Monte Carlo Transport Codes: A User's Guide for Use on IBM Mainframes*, Prepared by Oak Ridge Nat'l Lab. (Dec. 1985) ("Kirk 1985"); Laub et al., "ITS version 6.4: The Integrated TIGER Series of Monte Carlo Electron/Photon Radiation Transport Codes," *ANS RPSD 2014 - 18th Topical Meeting of the Radiation Protection & Shielding Division of ANS* (Sept. 2014) ("Laub 2014").

C. Current Professional Appointment at Kansas State University**1. Overview**

11. From August 1999 to the present, I have been employed by the Kansas State University (“KSU”) Department of Electrical & Computer Engineering in Manhattan, KS. I am a tenured full professor, and my academic appointment has three primary facets: research, teaching, and service. My over 30 years of research and development work has addressed the broader themes of non-invasive physiological monitoring, biomedical engineering, wireless systems, embedded devices, signal processing, modeling/simulation, medical interoperability standards, and engineering education. I teach courses offered as part of the KSU Electrical Engineering, Computer Engineering, and Biomedical Engineering curricula. My service work involves engagements that benefit KSU, the local area, and the broader technical community. The following paragraphs summarize these research, teaching, and service endeavors.

2. Research and Development

12. I direct the KSU Medical Component Design Laboratory, a National Science Foundation funded research and teaching facility that supports the development of distributed health monitoring technologies. My research relates thematically to (1) wireless wearable and nearby physiological sensors coupled with signal-processing and machine-learning techniques to determine human and animal physiological status; (2) plug-and-play, point-of-care health monitoring systems that

utilize interoperability standards; and (3) the creation and assessment of technologies and techniques to streamline engineering education and enhance learning. This work highlights vulnerable populations, including children with severe disabilities, the elderly, individuals with chronic conditions who benefit from constant monitoring, and animals. These efforts include a personal investment of thousands of hours of programming in C/C++, MATLAB, Fortran, Pascal, and other languages.

13. While at KSU, I have been an investigator on 64 grant-funded efforts totaling \$14.0M that have supported basic/applied research in the overlapping biomedical and educational research arenas. Primary funding has been provided by the National Science Foundation (CAREER, EPSCoR, ITR, DUE, EEC, CRI, SIR, REESE, CCLI/TUES, CPS, and GARDE programs), with supplemental funding granted by NASA, the National Institutes of Health, the State of Kansas, private foundations, internal KSU awards, and corporate partners. This work has resulted in 154 peer-reviewed publications, three book chapters, various reports, and hundreds of workshops and presentations. I have been the major professor for 34 graduate students, supported 65 undergraduate researchers, and served on 58 graduate committees.

14. My research has addressed technical areas that include human/animal health monitoring, home care technology, human/animal telemedicine architectures, interoperability standards, assistive technology for children with severe

cognitive/developmental disabilities, designs for the disabled/elderly, nighttime monitoring tools, sensor-laden beds, acceleration-based behavior analyses, biosignals as biometrics, biomedical instrumentation, biomedical optics, light/tissue interaction, pulse oximetry, ballistocardiography, accelerometry, actigraphy, ultrasonography, wearable ambulatory devices, wireless body area networks, wearable/wireless pulse oximeters, time/frequency-domain signal processing algorithms, biosignal parameter extraction, motion artifact reduction, computational methods, and custom tools for engineering education.

3. Teaching

15. I am a Robert and Becca Reichenberger Cornerstone Teaching Scholar in the KSU Carl R. Ice College of Engineering—an endowed position that recognizes consistent excellence in pursuit of improved teaching/learning toolsets and methods. I am also the program coordinator for the new undergraduate Biomedical Engineering degree program in the KSU College of Engineering, and I help to manage the Bioengineering Option within our undergraduate Electrical Engineering curriculum. In June 2016, this new KSU Biomedical Engineering program was approved by the Kansas Board of Regents and became the first new degree program in the KSU Carl R. Ice College of Engineering in almost 35 years. After several years of curriculum management and assessment, this undergraduate Biomedical Engineering degree program received its first official ABET

accreditation in August 2024. Regarding coursework, I have taught a number of semester-long courses, including the following:

- ***BME 001 – New Student Assembly*** (6 times): KSU Biomedical Engineering courses/curriculum, facilities/resources, student organizations, internship/job opportunities, and professional development;
- ***BME 200 – Introduction to Biomedical Engineering*** (6 times): biomedical engineering, biomedical instrumentation, wearable/implantable devices, medical imaging, benchtop systems, orthotics/prosthetics, laser-tissue interaction, biomaterials, tissue engineering, biomechanics, and biomedical modeling/simulation;
- ***BME 575 – Clinical Systems Engineering*** (4 times): clinical care technology, clinical engineer roles, biomedical systems of systems, medical informatics, health information exchange, international medical interoperability standards, human factors, safety, medical ethics, training, internal review boards, clinical technician certification, and medical device regulation;
- ***ECE 512 – Linear Systems*** (37 times): continuous/discrete signals/systems, time-domain representations, convolution, Fourier series/transforms, frequency-domain spectra, sampling/aliasing, analog/digital filters, and C/MATLAB programming;
- ***ECE 571 – Introduction to Biomedical Engineering*** (20 times): biomedical application domains, telemedicine, home care, assisted living, individuals with disabilities, exercise tracking, tissue engineering resource-limited environments, emergency response, reduced gravity, military medicine, veterinary applications, medical devices, biomedical instrumentation/optics, medical imaging, biosignal processing, biomaterials, biomechanics, wearable systems, body area networks, orthotics/prosthetics, cyberphysical systems, electronic patient records, and medical ethics;
- ***ECE 636 – Introduction to Computer Graphics*** (4 times): graphics toolkits, C/C++ programming, raster depictions, view planes, scaling/rotation transformations, geometric curves/splines,

3D constructive solid geometry, 3D boundary representation models, ray tracing, 3D meshes, faceted surfaces, perspective views, and hardware acceleration;

- ***ECE 690 – Independent Design*** (9 times): wearable/wireless devices, assistive technology, and biomedical signal processing;
- ***ECE 772/773 – Theory & Techniques of Biomedical Instrumentation*** (13 times): biomedical sensors, amplifiers, electrodes, biosignals, data acquisition, electrical safety, pulse oximetry, wearable devices, imaging, X-ray radiography, ultrasound, magnetic resonance imaging, fluorescence spectroscopy, and image processing; and
- ***ECE 840 – Computer Engineering Methods for Analysis, Simulation, and Design*** (4 times): computational limits, linear systems of equations, linear least squares, interpolation, fast Fourier transforms, random number generation, eigenvalues, optimization, and numerical integration/differentiation.

4. Service

16. Service is a substantive component of my appointment, and I am honored to be the recipient of three recent service-related awards: a 2022 Team Award of Excellence from the KSU Carl R. Ice College of Engineering, a 2021-2022 Outstanding Faculty Award from the KSU XIX Chapter of Mortar Board, and the 2019 Larry E. and Laurel Erickson Public Service Award offered by the KSU Carl R. Ice College of Engineering. As noted above, I am the program coordinator for the new undergraduate Biomedical Engineering degree program in the KSU College of Engineering. This program, which we proposed to the Kansas Board of Regents in 2016, was the first new undergraduate degree program in the KSU Carl R. Ice College of Engineering in almost 35 years, and as of August 2024 this program is

fully ABET accredited. I have served on numerous internal KSU committees, including the KSU Internal Review Board, where I am the senior member after a 24-year commitment. I am a faculty senator for the KSU Carl R. Ice College of Engineering and serve on the Academic Affairs committee. For several years, I occasionally traveled across Kansas to deliver lectures to high schools and community groups as part of the KSU Presidential Lecture Series.

17. Regarding service external to KSU, I am an active member of the Institute for Electrical and Electronics Engineers (“IEEE”). I act as an Associate Editor for the IEEE EMBC annual international conference, and since 2005 I have served as the founding faculty advisor for our college-wide KSU Student Chapter of the IEEE Engineering in Medicine and Biology Society. I am also the KSU college representative for the American Society for Engineering Education (“ASEE”), having recently served as the Chair of the ASEE Midwest Section and the Chair of the 2016 ASEE Midwest Section Conference. In 2017, I was honored to receive an Outstanding Service Award by the Midwest Section of the American Society for Engineering Education. I served two 3-year terms as a member of the Board of Trustees for Heartspring, Wichita, KS, and I have been engaged with a number of other industry workgroups and technical program committees. This service work has included many textbook, manuscript, and proposal reviews. Additional service as an expert witness is summarized in my CV.

III. MATERIALS CONSIDERED

18. The opinions contained in this Declaration are based on the documents I have reviewed, my professional judgment, and my education, experience, and knowledge relating to the technology at issue.

19. In forming my opinion expressed in this declaration, I reviewed the following materials:

- the '307 Patent (EX-1001);
- the prosecution history of the '307 Patent (EX-1002);
- the Petition for *inter partes* review filed by Petitioner;
- the declaration of Petitioner's expert, Majid Sarrafzadeh (EX-1003);
- the transcript of the deposition of Mr. Sarrafzadeh (EX-2011);
- the references upon which Petitioner's Grounds rely, including:
 - U.S. Patent No. 7,148,803 B2 ("Bandy") (EX-1005);
 - U.S. Patent Application Publication No. US 2002/0178126 A1 ("Beck") (EX-1007);
 - U.S. Patent No. 6,031,454 ("Lovejoy") (EX-1009);
 - World Intellectual Property Organization, International Publication No. WO 02/058537 A2 ("Heller") (EX-1016);
 - Third Report and Order, In re Revision of the Commission's Rules to Ensure Compatibility with Enhanced 911 Emergency Calling Systems, CC Docket No. 94-102, 14 FCC Rcd. 17388, 1999 WL 795989 (FCC adopted Sept. 15, 1999; released Oct. 6, 1999), http://standards.tiaonline.org/gov_affairs/fcc_filings/documents/e911rando.pdf ("FCC Report") (EX-1017);
- Patent Owner's Preliminary Response;

- Petitioner’s Reply to Patent Owner’s Preliminary Response;
- Patent Owner’s Surreply to Petitioner’s Reply;
- the Board’s decision instituting trial in this proceeding; and
- any other materials or information referenced or cited in this Declaration.

IV. SUMMARY OF OPINIONS

20. For the reasons discussed herein, it is my opinion that none of the challenged claims is rendered obvious by any combination of prior art asserted in the Petition.

V. BACKGROUND

A. Overview of the ’307 Patent

21. The invention claimed in the ’307 Patent was invented by Dr. John Peeters. Ex. 1001, Face. The patent is directed to a system for wireless diagnostics using radio frequency identification (RFID) tags that are combined with diagnostic sensors. *Id.* at 2:14–17. The technology allows a *modified* cell phone (or other wireless RFID readers) to perform diagnostic tests using RFID tags and sensors integrated with disposable skin patches. *Id.* at 2:21–24, 2:32–36, 3:54–61. For example, in one embodiment, the RFID tag and skin patch combination includes a plurality of sensors used for various diagnostic applications, measuring diagnostic parameters directly on the surface of the skin, transdermally, in skin sweat, or in blood drawn directly onto a disposable skin patch. *Id.* at 6:35–40. The “smart” patch technology described in the patent can perform any number of different diagnostic

tests on a subject, and these sensor unit and measurement data can be processed remotely by a wireless device such as a cell phone, which can interpret the sensor anywhere in the world. *Id.* at 5:42–43, 7:34–36. This technology allows on-the-spot processing of complex sensor data at a relatively low cost. *Id.* at 4:63–65.

22. For example, the technology of the '307 Patent can be utilized for monitoring blood glucose levels by individuals with diabetes. *Id.* at 8:64–9:3, Fig. 4. Prior to the invention of the '307 Patent, such a person had to regularly monitor blood glucose levels manually, such as by pricking a finger with a needle several times a day to apply blood to test strips assessed with a glucometer. The invention of the '307 Patent eliminated the need for this cumbersome process, allowing a person to instead apply an adhesive skin patch capable of sensing glucose levels in interstitial fluid then automatically communicating information regarding those glucose levels to a cell phone (or other wireless reader). This invention was prescient, as cell phone technology in 2003 was still in its infancy.

23. As illustrated below, Figures 1–2 of the '307 Patent depict a cell phone 2 serving as an RFID reader in conjunction with a disposable skin patch 4 including an RFID tag and sensor module 11. *Id.* at 5:12–16, 6:46–49. Typically, the patch 4 is composed of a thin flexible support 5 that has an adhesive surface 7. *Id.* at 6:51–52. The patch includes an RFID electronic chip 10, a sensor 12, and at least one antenna 8. *Id.* at 6:49–51. The RFID tag and sensor module 11 form an integrated

unit on a substrate disk 6. *Id.* at 6:64–65. Typically, disk 6 and sensing elements 12 are protected by at least one protective layer 20, which makes direct contact with the surface of the skin. *Id.* at 7:14–17.

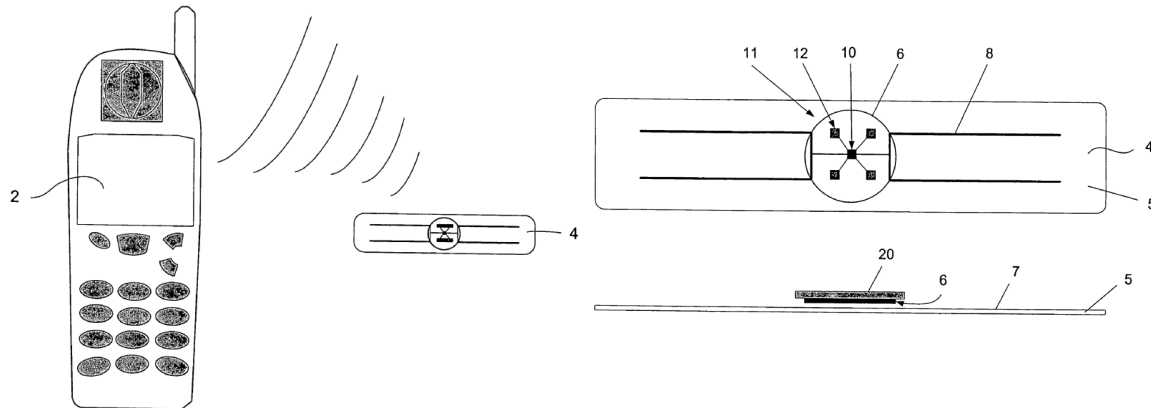


FIG. 1

FIG. 2

24. Figure 5 (reproduced below) displays the basic elements of the RFID electronic chip 10, including a power unit 60, a controller 62, an identification unit 64, a memory unit 66, a sensor table 68, a thermistor or temperature module/sensor 70, and an analog to digital converter 72. *Id.* at 9:35–39. The electronic chip 10 is coupled to an antenna 8. *Id.* at 9:24–25.

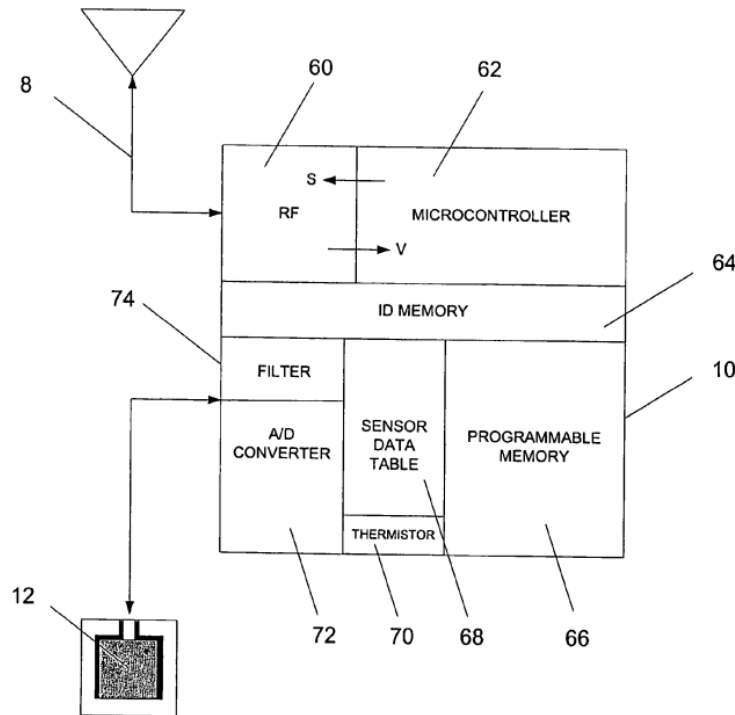


FIG. 5

25. The RFID tag provides a unique ID to the wireless device that identifies uniquely the type of sensor used. *Id.* at 7:43–45. Since each RFID tag 10 contains its own electronic identification number 64, wireless device 2 can immediately recognize the type of sensor involved. *Id.* at 12:42–45. In addition to identifying the *type* of sensor, the unique ID of the *particular* sensor facilitates downloading information related to that sensor. Ex. 1001, 11:49–60 (“downloading the correct sensor data tables from a remote location”).

26. The RFID tag and sensor module respond to a stimulus by wirelessly transmitting and receiving signals that correspond to the stimulus using the antenna. *Id.* at 2:46–48. The RFID reader can communicate over a network. *Id.* at 2:56–58. The diagnostic system may also include a remote storage/data access unit that stores

data transmitted and/or received by the RFID tag and sensor module and the RFID reader. *Id.* at 2:59–62. The patent further discloses a remote wireless device that enables access to the RFID tag and sensor module, the RFID reader, and the remote storage/data access unit from virtually any location. *Id.* at 2:62–65.

27. The '307 Patent discloses on-the-spot medical testing and self-diagnostics using smart skin patches, point-of-care analyses, food diagnostics, pathogen detection, disease-specific wireless biomarker detection, remote structural stress detection, and sensor networks for industrial or Homeland Security applications using wireless devices such as modified cell phones. *Id.*, Abstract. In some embodiments, the sensor 12 may be a chemical sensor. *Id.* at 10:24–27. As noted above, the '307 Patent describes using such a sensor to perform on-the-spot diagnostics such as blood glucose monitoring via a disposable RFID skin patch and wireless device combination. *Id.* at 8:49–52, 9:5–8, Fig. 4.

B. The State of the Art at the Relevant Time

28. Dr. Peeters' innovation, claimed in the '307 Patent, must be viewed in the context of the state of the art at the time the invention was conceived in 2003. Ex. 2001 ¶ 6; Ex. 2002 ¶¶ 12-13; Ex. 1001, Face. At that time, cell phone technology was still in its infancy. In particular, geolocation features and multiple connectivity options (i.e., connectivity other than through cellular service) were lacking in many cell phone models.

29. The Nokia 1100 (depicted below), a basic GSM mobile phone, launched in 2003 and became the world's best-selling phone handset. EX-2012, 1 (https://www.gsmarena.com/nokia_1100-512.php). The Nokia 1100, like many common cell phones at that time, did not support GPS or any other geolocation functionality and had extremely limited processing power. *Id.*; see also EX-2008 (Nokia 1100 User Guide). For context, the first iPhone was not introduced until 2007, and it did not have a GPS chip. The first Android phones followed in 2008, more than four years after the '307 Patent's priority date. Abbott's expert, ignoring this reality, treats the state of the art in 2003 and 2004 as if it were the same as the state of the art today. To the contrary, cell phones (now, years later, called "smart phones") have evolved dramatically over the past two decades. For his part, Petitioner's expert, Dr. Sarrafzadeh, acknowledged doing testing on cellular phones in the 2003 to 2005 timeframe, but he could not recall any particular model that had geolocation features. Ex. 2011, 42:8–43:6.



30. As for connectivity, the first Bluetooth phone was introduced in 2001.

EX-2013, 3 (<https://www.androidauthority.com/history-bluetooth-explained-846345/>). In 2003, the FDA approved the first Bluetooth-enabled medical device, a Serial Port Adapter (SPA) for emergency room equipment, which was designed for applications such as wireless printing of electrocardiograms or transmitting medical images. EX-2014, 1

(<https://www.techdata.ca/socketmobile/files/bluetooth%20medical%20white%20paper.pdf>). The SPA, like most early Bluetooth-enabled medical devices, used a type of Bluetooth communication referred to as the Serial Port Profile (SPP), which was designed to replace traditional cables. *Id.*

31. The SPP, however, had drawbacks. For example:

[T]he manufacturer of a Bluetooth enabled blood glucose meter would need to provide software to run on the laptop or PDA being used to capture data from the device. As a result, a Bluetooth medical device from one manufacturer has very little chance of working with a device from another manufacturer, since they probably format their data differently.

Id.

32. Near-field communication (NFC) technology employs a low-power, short-range set of communication protocols that allows electronic devices to communicate when in close proximity with one another. NFC standards are based

on radio-frequency identification (RFID) technology, which allows hardware to communicate with (and supply power to) a sensor via inductive coupling.

33. NFC was approved as an ISO/IEC standard in December of 2003, with industry players (Nokia, Philips, and Sony) establishing the NFC Forum (a non-profit industry association) in 2004. EX-2015, 2 (https://en.wikipedia.org/wiki/Near-field_communication). Nokia launched NFC shell add-ons for certain cell phone models in 2004 and 2005, releasing Nokia's 6131 phone (the first cell phone with NFC functionality) in even later. *Id.*, 2-3.

34. Even with the limited capabilities of cellular phones at the time, the '307 Patent taught a system where such phones could be used for medical diagnostic monitoring by downloading software specific to the sensor being employed.

C. The Challenged Claims

35. I understand that Petitioner is challenging claims 1-3, 5, 9, and 10 of the '307 Patent.

36. Claim 1, the sole challenged independent claim, recites:

A radio frequency (RF) addressable diagnostic sensor unit comprising:

at least one sensor element;

at least one reference sensor element;

a unique identification ID number;

a sensor interface having an analog to digital converter coupled to the at least one sensor and reference sensor element;

at least one antenna;

a substrate;

an RF power and communication interface coupled to the at least one antenna and sensor interface;

a controller coupled to the RF power and communications interface and the sensor interface; and

a memory coupled to the controller and the sensor interface;

wherein the RF addressable sensor communicates with a remote wireless device, said wireless device having multiple wireless communication means, geolocation means and a unique ID, whereby said wireless device is coupled to at least one communications network linked to [a]t least one remote server; and

wherein the wireless device communicates with the RF addressable sensor interface to obtain the ID and sensor data;

wherein the remote server authenticates said unique sensor ID associated with said unique wireless device ID and communicates to said wireless device processed information relating to said sensor data and software related to the

unique sensor ID, thereby allowing said wireless device to interpret said sensor anywhere worldwide.

37. The challenged dependent claims of the '307 Patent recite additional limitations, namely, that “said wireless device is a cell phone” (claim 2); “said sensor unit is integrated into a disposable wireless skin patch for diagnostic applications” (claim 3); “said sensor is a chemical sensor” (claim 5); “a GPS means for geolocating said system” (claim 9) and “a non-GPS geolocation means for geolocating said system” (claim 10).

D. The Alleged Prior Art

1. U.S. Patent No. 7,148,803 (“Bandy”)

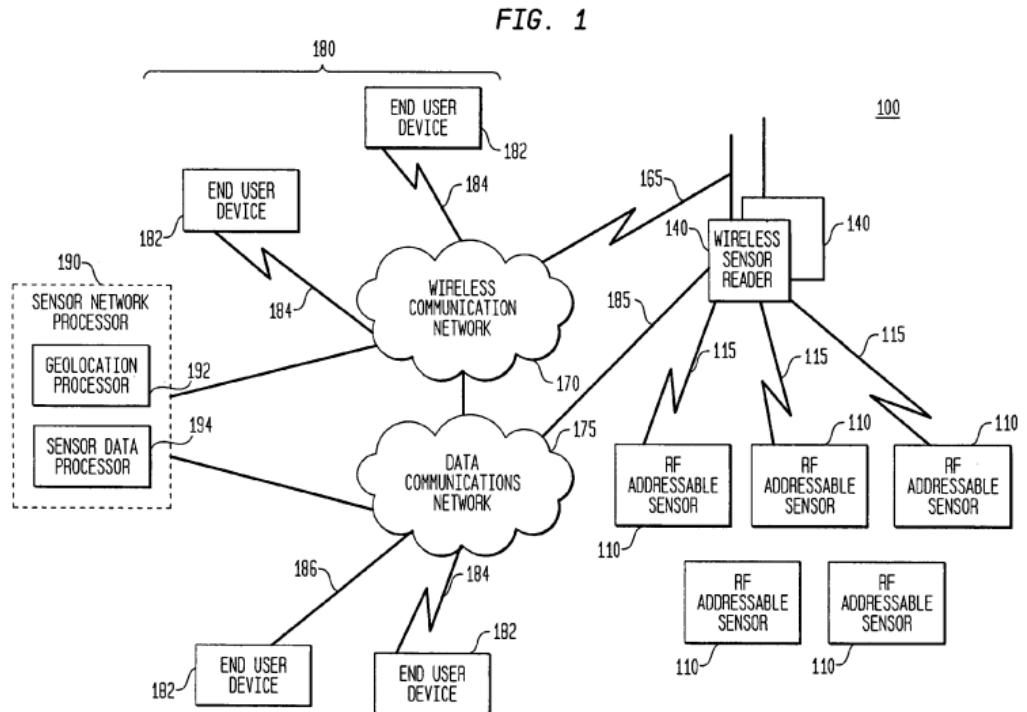
38. Bandy, the primary reference upon which Petitioner relies for Grounds 1 and 2, is listed on the '307 Patent among the “References Cited.” EX-1001, 2. During prosecution of the '307 Patent, the examiner initialed the applicant's Information Disclosure Statement corresponding to Bandy, indicating that she considered the reference. EX-1002, 383.

39. In addition, the application from which Bandy issued is discussed and incorporated by reference in the specification of the '307 Patent. EX-1001, 5:7–11 (“The underlying principles of the technology are described in more detail in U.S. patent application Ser No. 10/761,362, filed Jan. 22, 2004, entitled, ‘Radio Frequency Identification Based (RFID) Sensor Networks,’ that is incorporated

herein by reference in its entirety.”); *id.* at 5:16–19 (“As it is made clear in U.S. patent application Ser No. 10/761,362, filed Jan. 22, 2004, entitled, ‘Radio Frequency Identification Based (RFID) Sensor Networks,’ any modified wireless device can be used.”); *id.* at 9:28–33 (“The principles and operation of the RFID tag having a sensor input is described in detail in U.S. patent application Ser No. 10/761,362, filed Jan. 22, 2004, entitled, ‘Radio Frequency Identification Based (RFID) Sensor Networks,’ which is incorporated herein by reference in its entirety.”); *id.* at 14:52–58 (“The type of sensor ID is matched with data tables and processing instructions that can be downloaded directly into the cell phone. *See* U.S. patent application Ser No. 10/761,362, filed Jan. 22, 2004, entitled, ‘Radio Frequency Identification Based (RFID) Sensor Networks,’ which is incorporated herein by reference in its entirety.”). As such, Bandy was directly before the Examiner during prosecution.

40. Dr. Peeters—the sole inventor of the ’307 Patent—is one of two inventors listed on the face of Bandy. EX-1005, Face. Bandy is directed to RFID-based sensor networks. *Id.* at Abstract. The sensor network includes one or more RF addressable sensors, one or more wireless sensor readers coupled to a communications network, and one or more optional end user devices coupled to the communications network. *Id.* at 1:58–62. Figure 1, reproduced below, depicts an

illustrative RF addressable sensor network 100 for monitoring, detecting, and geolocating RF addressable sensors (*id.* at 4:33–35):



41. An RF addressable sensor includes one or more antennas for communicating with the wireless sensor reader, one or more sensor elements, an RF power and communications interface, an RFID control module, and a sensor interface. *Id.* at 2:9–13, Fig. 2. The wireless sensor reader includes one or more antennas, a user interface, a controller, a network communications module, and an RF addressable sensor logic module. *Id.* at 2:21–24, Fig. 3.

42. Bandy describes multiple applications—from detecting hazardous materials for homeland security applications to remote monitoring of shipping containers—but does not describe any patch-based diagnostic sensors or any remote

wireless device having a unique ID. In fact, Petitioner's expert recognized that some of the sensors disclosed by Bandy would not be suitable to be affixed to a person. Ex. 2011, 83:20–84:7, 85:4–22.

2. U.S. Patent App. Pub. No. US 2002/0178126 A1 (“Beck”)

43. Unlike the '307 Patent, Beck relates to remote monitoring of medical *devices* that do not include integrated sensors with unique sensor IDs. This is meaningfully different from using a cell phone or other remote wireless device to communicate with a *sensor unit that has a unique sensor ID*, as claimed by the '307 Patent. Further, unlike the disposable wireless skin patch sensor units described in the '307 patent, Beck is directed to bulky, stand-alone commercial medical devices for monitoring the biological or physiological conditions of patients, e.g., in a hospital setting. EX-1007 ¶ 2. More specifically, Beck describes systems, client computing devices, server computing devices, and methods for accessing medical devices, providing remote access to medical devices, and/or remotely accessing medical devices. *Id.*, Abstract, ¶ 4. For example, in one embodiment, client computing devices utilize protocol components that may be obtained from a server computing device via a network to communicate with medical devices using a communications protocol supported by the medical device. *Id.*, Abstract.

44. More specifically, Beck describes a system including a server computing device, a client computing device, a medical device operably coupled to

the client computing device via a communications link, and a network that operably couples the client computing device to the server computing device. *Id.* ¶ 14. The system includes a set of protocol components, which the server computing device transfers to the client computing devices. *Id.* ¶ 15. The server computing device is adapted to detect, over the network, medical devices that are operably coupled to the client computing device. *Id.* ¶ 16. Beck describes combining commercially available components and devices, including the server computing device (*id.* ¶ 17), processor (*id.* ¶ 18), storage device (*id.* ¶ 20), network interface (*id.* ¶ 21), client computing device (*id.* ¶¶ 23, 27), and medical device (*id.* ¶ 34).

45. With respect to the medical device, Beck provides little detail, noting that it is “generally operable to monitor one or more biological/physiological conditions and communicate with the client computing device.” *Id.* ¶ 34. The medical device includes a processor, memory, a communications interface, one or more user I/O devices, and a system bus. *Id.* ¶ 35. In one embodiment, the medical device includes “a glucose meter such as the glucose meters manufactured by Roche Diagnostics Corporation which are generally operable to measure blood glucose levels of blood applied to test strips.” *Id.* ¶ 34. Beck also discloses medical devices for monitoring “electrocardio-signals, brain waves, blood pressure waves” and “respiration.” *Id.* Given the examples of medical devices provided by Beck, along with the additional requirements of the remote monitoring system, it is my opinion

that a POSITA would understand the medical devices referred to by Beck to be stand-alone devices generally used in a controlled clinical setting, such as a hospital or doctor's office. *See* EX-2011, 98:23–99:24. For example, the communication ports described by Beck—such as RS-232, SCSI, USB, 1394 (EX-1007 ¶¶ 29, 30)—would normally be found on computer-based devices with operating system support (not simple mobile units with microcontroller-based implementations having minimal computational capabilities, memory, and physical space). In addition, the input/output peripherals described by Beck—such as cathode ray tubes (CRT), liquid crystal displays (LCD), and printers (*id.* ¶ 40)—also indicate use of larger computer systems. The types of system buses described by Beck—such as PCI, ISA, and PC-104 (*id.* ¶ 42)—also indicate larger computer-based devices. On the other hand, Beck does not disclose the use of mobile applications or any wearable medical devices or sensors. As discussed below, it is my opinion that Beck fails to disclose several limitations of the challenged claims of the '307 Patent. As one example, while the claims of the '307 Patent work with individual sensor units, *see, e.g.,* '307 Patent, claim 1 (“radio frequency (RF) addressable diagnostic sensor unit” comprising “a unique identification ID number”), Beck works with complete fully configured medical devices that do not include sensors with unique sensor IDs, *see, e.g.,* Ex. 1007, ¶ 65 (authentication may be based on “the serial number of the medical device”).

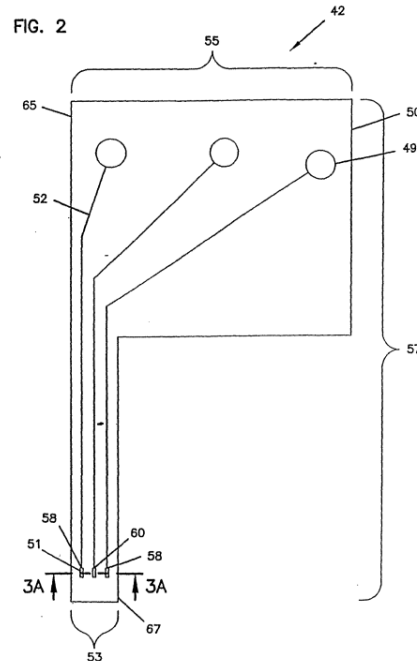
3. WIPO Pub. No. WO 02/058537 A2 (“Heller”)

46. Petitioner asserts Heller as a secondary reference in connection with Grounds 2 and 3. Unlike the ’307 Patent, which discloses a system for communicating wirelessly with a diagnostic sensor unit, Heller discloses only a particular type of sensor and an accompanying sensor control unit. Specifically, Heller discloses an analyte monitoring system using an implantable sensor for the *in vivo* determination of a concentration of an analyte (such as glucose or lactate) in a fluid. EX-1016, 1:3–7 (“The present invention is, in general, directed to devices and methods for the *in vivo* monitoring of an analyte, such as glucose or lactate. More particularly, the present invention relates to devices and methods for the *in vivo* monitoring of an analyte using an electrochemical sensor to provide information to a patient about the level of the analyte.”), 8:12–14 (“The present invention is applicable to an analyte monitoring system using an implantable sensor for the *in vivo* determination of a concentration of an analyte, such as glucose or lactate, in a fluid.”).

47. More specifically, Heller describes a sensor that is implanted under the skin of a patient (i.e., subcutaneously) for the continuous or periodic monitoring of an analyte in a patient’s interstitial fluid, which can be used to infer the glucose level in the patient’s bloodstream. *Id.* at 2:27–29 (“Generally, the present invention relates to methods and devices for the continuous and/or automatic *in vivo* monitoring of

the level of an analyte using a subcutaneously implantable sensor.”), 8:14–17 (“The sensor can be, for example, subcutaneously implanted in a patient for the continuous or periodic monitoring an analyte in a patient’s interstitial fluid. This can then be used to infer the glucose level in the patient’s bloodstream.”). Heller further describes analyte sensors “for insertion into a vein, artery, or other portion of the body containing fluid.” *Id.* at 8:17–19; *see also id.* at 10:11–12 (“implantation of the sensor may be made in the arterial or venous systems for direct testing of analyte levels in blood”), 10:22–27.

48. Heller also describes a sensor control unit having a housing adapted to receive a portion of an electrochemical sensor; conductive contacts disposed on the housing and configured for coupling to contact pads on the sensor; a transmitter disposed in the housing and coupled to the conductive contacts for transmitting data obtained using the sensor; and various optional components. *Id.* at 2:30–3:9. As seen in Figure 2 below, sensor 42 includes at least one electrode 58 formed using conductive traces 52 disposed on a substrate 50 (*id.* at 11:11–13, 11:24–25):



4. U.S. Patent No. 6,031,454 (“Lovejoy”)

49. As is the case with Bandy, Dr. Peeters, the inventor on the '307 Patent, is also an inventor on Lovejoy. EX-1009, Face. As is also the case with Bandy, Lovejoy is listed among the "References Cited" on the '307 Patent (EX-1001, 2) and the examiner initialed the applicant's Information Disclosure Statement at the row corresponding to Lovejoy, confirming her review of Lovejoy (EX-1002, 291). And Lovejoy is discussed and incorporated by reference in the specification of the '307 Patent. EX-1001, 6:10–13 ("In addition as explained in U.S. Pat. No. 6,031,454, that is incorporated herein in its entirety real time precise geolocation of the firefighter is possible."), 17:21–24 ("The reading, analysis and geolocation by GPS or non-GPS means is described in U.S. Pat. No. 6,031,454 that is included herein by reference in its entirety."), 18:38–43 ("Starting with device 800 and as explained in U.S. Pat. No.

6,031,454 and Patent Application US 2004/0119591 A1 by the present inventor that are incorporated by reference in their entirety, a wireless device such as a cell phone may be modified to accommodate any number of sensors 816, including diagnostic sensors.”). Having been listed on an IDS accompanied by the examiner’s initials, and having been repeatedly discussed in the specification, Lovejoy was before the examiner during prosecution.

50. Lovejoy is directed to a person-specific monitor that provides sensor information regarding that person’s occupational exposure to hazards, such as a radiological, chemical or other toxic agent in the environment around the person. *Id.*, Abstract, 1:25–28. Lovejoy describes a sensor module used in conjunction with an electronic monitor, which can be adapted to monitor for different types of occupational exposures (e.g., heat, humidity, noise, particles, radiation, chemicals, etc.). *Id.* at 2:28–31, 6:16–19. Lovejoy further describes base stations for reading out data from the personal monitors, for recharging the monitors, and antennae for use in the geolocation of the monitors. *Id.* at 4:38–41.

VI. PERSON OF ORDINARY SKILL IN THE ART

51. My opinions have been guided by how a person of ordinary skill in the art (“POSITA”) would have understood the state of the art, the prior art, and the claims and the specification of the ’307 Patent at the time of the invention. While I understand that Patent Owner may have evidence of an earlier conception date, I

have applied the January 27, 2004 date applied by Dr. Sarrafzadeh as the relevant timeframe for purposes of this Declaration.

52. I understand that Petitioner has set forth the following proposed definition of a POSITA in connection with this proceeding (Pet. 5):

A person of ordinary skill in the art (“POSITA”) as of January 2004 claimed priority date would have had a bachelor’s degree in computer science, electrical engineering, biomedical engineering (or a related or equivalent field), and two or more years of experience researching, developing, designing and/or evaluating systems of networked devices, such as, networked medical devices or networked embedded devices that communicate wirelessly through, for example, Radio Frequency Identification (RFID), Bluetooth, and/or cellular protocols. A person with less or different education but more relevant practical experience, or vice versa, may also meet this standard. A POSITA may be part of an interdisciplinary team with others having the relevant experience set forth above. The prior art also evidences the level of skill in the art.

53. I understand that, for purposes of the Patent Owner Response, Patent Owner does not dispute this proposed definition of a POSITA.

VII. CLAIM CONSTRUCTION

A. **“the remote server authenticates said unique sensor ID associated with said unique wireless device ID”**

54. I understand that the Board preliminarily construed the claim phrase “the remote server authenticates said unique sensor ID associated with said unique wireless device ID” as not requiring authentication of the unique wireless device ID or authentication using the unique wireless ID. Inst. Dec. 9–10. It is my opinion, however, that a POSITA reading the ’307 Patent at the relevant time—particularly in light of the prosecution history—would have understood that, because the claim requires an association between the unique sensor ID and the unique wireless device ID, the authentication of the sensor ID necessarily requires the unique wireless ID be a part of the authentication process. Thus, as discussed below, it is my opinion that the proper construction of this limitation is “the remote server authenticates the unique sensor ID and the associated unique wireless device ID.”

55. The plain meaning of the claim term is that the remote server authenticates the unique sensor ID and that such unique sensor ID is associated with a unique wireless device ID.

56. A POSITA would have understood that the unique sensor ID could not be authenticated in a vacuum, i.e., without reference to the unique wireless device ID. To the contrary, a POSITA would have understood the claim language to require

that the unique sensor ID and unique wireless device ID are associated with each other and authenticated by the remote server.

57. Requiring an association between the unique wireless device ID and the unique sensor ID in the claim would have been meaningless unless the unique wireless ID was part of the authentication process, i.e., it would have served no purpose if not needed for authentication. A POSITA would have understood that such device information was necessary for security and privacy of the system as well as the integrity of any subsequently stored and processed information/data. In the context of the patent, a sensor ID could not be authenticated on its own. Importantly, a POSITA would have understood that the sensor ID could have been read by any RFID reader in range of the sensor (e.g., a nearby pedestrian's mobile phone) unless both the sensor and the particular wireless reader were authenticated.

58. Authenticating the sensor ID “associated with” the wireless ID ensures a person's confidential health information is not stolen or misused. A couple of use cases make this clear. Consider a bad actor traversing a crowd, scanning sensors with a wireless device. This is referred to as RFID “skimming,” and is a major problem for RFID-enabled credit cards. If the claim required only authenticating the sensor ID, this skimming would allow the bad actor to access the health information of the person wearing a sensor, including at least “processed information relating to said sensor data.” But by requiring—as claim 1 of the '307 Patent does—that the

authentication is of the sensor ID “associated with” the wireless device ID, only the true user (using the associated authorized wireless device) would have such access. As another more innocent, but still potentially problematic, example: a married couple may both be using diagnostic sensor units covered by the claims of the ’307 Patent. It would be important to make sure that each person’s wireless device was reading the data from their respective sensor, and not accidentally reading from their spouse’s sensor, even when they are in close proximity to each other, such as in bed. The unique sensor ID and the unique wireless device ID must, at some point, both be authenticated because the remote server is not plausibly going to send software to operate a trusted sensor to a wireless device that is not itself trusted. That would break the chain of trust and taint the reliability and verifiability of the resulting data ultimately stored in the remote database.

59. The prosecution history also supports the requirement that both the sensor ID and the wireless device ID are transmitted to the remote server. In a section cited by Petitioner, Pet. 4, and analyzed by Petitioner’s expert, EX-1003, ¶ 61, the Applicant distinguished prior art by noting that pending claim 65 (issued as claim 1) “actively recites limitation wherein the remote [wireless] device communicates the unique sensor ID *and* unique wireless ID to a remote server....” EX-1002, 65. In fact, according to Petitioner’s expert, “[t]he Applicant confirmed that the remote server ‘uses’ *the received unique sensor/wireless ID* to send the

necessary software.” EX-1003, ¶ 61 (emphasis added). Dr. Sarrafzadeh confirmed this understanding at his deposition. EX-2011, 59:6–20. Therefore, both the Applicant and Examiner clearly understood that “the remote server authenticates said unique sensor ID associated with said unique wireless device ID,” which existed in the pending claim, EX-1002, 52, meant that the wireless device was transmitting both the unique sensor ID and the unique wireless device ID to the remote server.

60. Even if a POSITA’s understanding and the Applicant’s statements made during prosecution are ignored, there *still* must be an association between the unique sensor ID and the unique wireless ID. Under the Board’s preliminary view, “‘associated with said unique wireless device ID’ serves to further describe the unique sensor ID, specifically, that the unique sensor ID is associated with the unique wireless device ID.” Inst. Dec. 10. Thus, the Board recognized that an association between the unique sensor ID and the unique wireless device ID must exist, even if only the unique sensor ID is authenticated by the remote server. Nowhere does Petitioner map *anything* in any prior-art reference to this “association” requirement of the claims. Thus, even if Patent Owner’s proposed construction is not fully adopted, Petitioner has failed to show that this limitation is met in any ground.

61. Petitioner inserts into the limitation requirements not supported by the intrinsic record. In particular, Petitioner asserts that the processed information and

software are sent from the remote server to the wireless device “in response to the authentication.” Pet. 6. While the determination of whether the wireless device ID is transmitted as part of authentication is relevant to this proceeding—because Petitioner has not shown that feature disclosed in any prior art reference—whether the processed information and software are sent “in response to” authentication is irrelevant.

62. Petitioner’s proposed claim construction should be rejected. To be clear, Petitioner is asserting more than just that the authentication must occur before software is downloaded. Petitioner’s proposed construction requires more than just one action happening after the other. In particular, Petitioner’s proposed construction requires the software to be downloaded *in response to* the authentication. Nothing in the claim language requires this limitation, and a POSITA would not have read such a requirement into the claim. Nor does Petitioner’s construction indicate what it means by “in response to”: Is there a temporal limitation? Can there be intervening activities? Must the computer code be written in a specific way to meet Petitioner’s “in response to” language? During his deposition, Dr. Sarrafzadeh was unable to provide *any* additional details of what was required by “in response to” beyond one event happening after the other. Ex. 2011, 50:20–56:13.

63. Further, “request” and “response” are terms of art related to a particular communication paradigm, such as used in standard Internet communication. Does

Petitioner's additional requirement mean that the communication of processed information and software must be provided in a "response" to an authentication "request?" While Dr. Sarrafzadeh acknowledged he was familiar with this paradigm, he failed to analyze his own proposed claim construction in that context. Ex. 2011, 32:21–33:5, 36:12–37:3. Regardless, introducing this confusion is unnecessary, as the claim language includes no such requirement.

64. Contrary to Dr. Sarrafzadeh's opinion, the wording in the claim limitation does not force a temporal cause-and-effect relationship between the steps of authentication and communication. Rather, the claim language states that both authentication *and* communication must occur. Some amount of communication from the remote server to the wireless reader can plausibly occur before the authentication of the unique sensor ID. For example, based on an initial communication with the RFID sensor, the wireless reader can understand/predict that it has a certain type of sensor without "authenticating" that sensor unique ID. The wireless reader can then send messages to the remote server stating that the wireless reader believes it has a certain type of sensor, and without authenticating the sensor unique ID first, the remote server can send software to the wireless reader that allows it to control the RFID sensor and obtain data from the sensor that it can then parse. At that point, when the sensor seeks to upload data to the remote server, the remote server can receive those parsed data and authenticate the sensor unique

ID based on the ID itself plus the contents of the data stream. If the unique sensor ID is successfully authenticated, then the remote server can store those data at that point and return processed information related to those sensor data to the wireless reader. Other such scenarios are possible that do not mandate that the communication of processed information and software from the remote server occur only *in response to* authentication of the sensor unique ID.

65. Such an authentication process might also be a two-stage process that involves both the verification of the sensor unique ID itself and the confirmation of the format/content of the data provided by the sensor. In order to accomplish the latter, the remote server may need to first provide software to the wireless reader that allows the wireless reader to sensibly activate the sensor and acquire/parse its data. Using such a protocol, where the parsed data are subsequently sent from the wireless reader to the remote server prior to the authentication of the sensor unique ID, the sensor unique ID is still authenticated prior to the processing and/or storage of any patient-related data to the remote database. Such a two-stage authentication process is similar in nature to a user name + password authentication, where the user provides what they have (a user name) + what they know (a password). Such a process is not bound by the “in response to” temporal cause-and-effect wording proposed by Dr. Sarrafzadeh.

66. Dr. Sarrafzadeh’s narrative regarding the claim language, EX-1003 ¶ 57, improperly assumes that the communication of processed information and the communication of software occur at the same time. But this can be an iterative process consistent of multiple rounds of data, information, and software transfers.

67. Dr. Sarrafzadeh’s opinion that the claim language “plainly requires a causal relationship,” EX-1003 ¶ 57, is incorrect for at least two reasons. First, as discussed above, some level of data interpretation may be required as part of the authentication process. Second, this statement ignores the claim language that addresses communication of software, which may need to occur prior to the authentication of the sensor unique ID.

68. Dr. Sarrafzadeh’s statement that without “download of ‘processed information’ and ‘software,’ the wireless device cannot interpret said sensor,” EX-1003 ¶ 57, is also incorrect. The wireless reader does not need to receive processed information before it can interpret said sensor. The receipt of processed information can occur late in the process, at which point the wireless device has already “interpreted” the sensor and is now receiving processed information from the remote server based on sensor data.

69. Dr. Sarrafzadeh’s interpretation of Figure 22 of the ’307 Patent, EX-1003 ¶¶ 58-59, is also flawed. Dr. Sarrafzadeh cites Step 708 (“Tag Recognized by Reader?”) of Figure 22 as occurring prior to Step 738 (“Download Software”). It is

important to note, however, that the recognition of the tag by the wireless reader in Step 708 is *not* the same thing as the authentication of the sensor unique ID. Additionally, the ID match functionality in step 730 is also not the same thing as the authentication of the sensor unique ID by the remote server. Such an authentication may involve additional steps/information.

70. Further, Dr. Sarrafzadeh incorrectly states that, based on Figure 22, “if authentication does not take place, or authentication is attempted and fails,” “no software related to said sensor ID is communicated to the wireless device.” EX-1003 ¶ 60. No such scenario is indicated in Figure 22 and its accompanying text, because Step 730 (“ID Match”) is not followed by a Yes/No set of decision boxes as are Steps 708 and 716.

71. Petitioner also relies on the word “thereby” in the final clause as “reaffirm[ing]” a “cause and effect” relationship between authentication and communication. Pet. 7. But, importantly, the word “thereby” follows the “communicates” limitation and precedes the “worldwide” limitation. Thus, to the extent “thereby” indicates any cause-and-effect relationship—and Petitioner provides no support for that assertion—Petitioner’s mapping of cause and effect is inconsistent with the language of the claim. Indeed, the proper reading of the claim is that the “cause” is communicating processed information and software, and the “effect” is interpreting the sensor worldwide. Petitioner’s reading, conversely, is

nonsensical, because both the purported “cause” (authentication) and the purported “effect” (communicating processed information and software) are recited before the word “thereby.” Petitioner’s argument could make sense if the claim recited *the remote sensor authenticates said unique sensor ID associated with said unique wireless device ID, **thereby** communicating to said wireless device...*, but that is not the language recited in the claim.

B. Means-Plus-Function Limitations

72. It is my understanding that for purposes of the Patent Owner Response, Patent Owner does not contest Petitioner’s proposed constructions of the means-plus function limitations. It is my opinion that even applying Petitioner’s proposed constructions, the Petition fails to show that any of the challenged claims is unpatentable.

VIII. LEGAL STANDARDS

73. I am not an attorney and thus do not provide any legal opinions. Counsel has notified me of the legal principles that apply in assessing whether patent claims are obvious and unpatentable. Throughout my work, I have studied and analyzed patents and patent claims from the perspective of a person skilled in the art. My understanding of the law is as follows:

74. I have been informed that in *inter partes* review proceedings, the Petitioner bears the burden of proof to prove that the claims that were challenged in

the Petition and for which the Board instituted review are unpatentable. It is my understanding that the Petitioner also bears the burden to prove a proposition of unpatentability by a preponderance of the evidence.

75. It is my understanding that based on the '307 Patent filing date, the America Invents Act ("AIA") does not apply to the determination of invalidity of the '307 Patent, but rather the pre-AIA version of 35 U.S.C. § 103 applies.

76. Patent Owner's counsel has informed me that a claim may be unpatentable as obvious under § 103 if the subject matter described in the claim as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

77. I have been informed that, prior to considering the prior art, the claims are first analyzed to determine what subject matter the claims cover. I understand that the claims are read from a POSITA's perspective at the time of the alleged invention. I understand that the words of a claim are generally given their ordinary and customary meaning as understood by a POSITA in view of the entire patent specification in which they are present and the prosecution history of the patent.

78. I understand that a claim's words may nevertheless be given a meaning different than their plain and ordinary meaning if: (1) a patentee explicitly and unambiguously defines a term in a different manner as compared to its plain

meaning; or (2) a patentee “disclaims” the full scope of a claim term’s plain meaning, such as, by clearly and unambiguously stating during prosecution that a claim term does or does not encompass certain subject matter that may otherwise be encompassed by the plain words of the claim.

79. I have been informed that, after construing the claims, the teachings of the prior art are evaluated. I understand the information that is used to evaluate whether an invention is new and not obvious is generally referred to as “prior art” and generally includes patents and printed publications (e.g., books, journal publications, articles on websites, product manuals, etc.).

80. I understand that although the ultimate question of an obviousness analysis is a legal determination, obviousness is based on many factual inquiries, including: the prior art’s scope and content, the distinctions between the claimed subject matter and the prior art, the level of ordinary skill in the art at the time of the invention, and any “objective indicia” or “secondary considerations” of non-obviousness, which must all be considered.

81. I have been informed that, in ascertaining the scope and content of the prior art, a prior-art reference is deemed relevant if it falls within the field of the inventor’s endeavor, or if it is reasonably pertinent to the particular problem that the inventor was attempting to solve. I understand that a reference is reasonably

pertinent if it logically caught an inventor's attention in considering the problem sought to be solved.

82. I have been informed that, to evaluate the differences between the prior-art references and the claimed subject matter, the claimed invention must be considered as a whole. I understand that this involves demonstrating that a POSITA, facing the same problems as the inventor and without knowledge of the claimed invention, would have recognized the elements in the prior art and combined them in the claimed manner.

83. I understand that there are many rationales for combining prior-art references. For example, I have been informed that it is considered obvious to:

- combine prior-art elements according to known methods to yield predictable results;
- substitute one known element for another to obtain predictable results;
- use the prior-art elements in a predictable way according to their established functions;
- apply a known technique to a known device (method or product) ready for improvement to yield predictable results;
- choose from a finite number of identified, predictable solutions, with a reasonable expectation of success;

- or if there is some teaching, suggestion, or motivation in the prior art that would have led a POSITA to modify a prior-art reference or combine prior-art teachings to arrive at the claimed invention.

84. I understand, however, that a POSITA can come to the claimed invention for completely different reasons than the inventors and therefore does not need to have the same motivations or reasons to combine the prior art as the inventors.

85. I understand that when reviewing the prior art, the prior art cannot be combined or modified with “hindsight.” I have been informed that hindsight designates scenarios when the asserted patent is employed as a framework to pick and choose aspects from the prior art to arrive at the claims. I understand that hindsight also occurs when rationales are adopted that are identified by the patent-at-issue but would not have been recognized by those in the art. Alternatively, I have been informed that the obviousness analysis is evaluated from the perspective of a POSITA, as of the critical date of the patent-at-issue and with all the prior art before them. I also understand that with this in mind, the analysis includes determining whether the POSITA would have independently arrived at the claimed invention without the help of the patent-at-issue for guidance.

86. I understand that to evaluate obviousness, “objective indicia” or “secondary considerations” of non-obviousness must also be considered and

include, among a few others, whether: (1) there was a long-felt need for the claimed invention; (2) the claimed invention has attained commercial success; (3) others have copied the claimed invention; (4) others have attempted but failed to create the alleged invention; (5) there was praise of the invention in the field; and (6) there was skepticism the claimed invention could be achieved.

87. Additionally, I have been informed that a petition must identify, for any terms with means-plus-function limitations, the particular portions of the specification that describe the structure, material, or acts corresponding to each claimed function. I also understand that a rebuttable presumption exists that without use of the term, “means,” a claim term is not interpreted as means-plus-function. However, I have been informed that other nonce words like “component” have been found to satisfy the rebuttable presumption and invoke a means-plus-function claim construction of such a claim term.

88. I have been informed that a petitioner seeking to demonstrate that the prior art discloses a means-plus-function limitation must prove that the corresponding structure—or an equivalent—was present in the prior art and performing the same claimed function.

89. I understand that proving structural equivalence does not require a component-by-component analysis. I have been informed that it is sufficient to show structure, materials, or acts that perform the claimed function in substantially the

same way to achieve substantially the same result because the claim limitation is the overall structure corresponding to the claimed function and not individual components.

90. I have been informed that the standard for determining whether the prior art discloses the corresponding structure or an equivalent is whether there are insubstantial differences, which means that if the assertedly equivalent structure performs the claimed function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification, it is equivalent.

91. Lastly, I understand that in *inter partes* review proceedings, the Petitioner must demonstrate the obviousness of a claim by “a preponderance of the evidence.” I have been informed that the preponderance of the evidence standard requires that a reasonable factfinder would find a material fact more probable than the nonexistence of that fact. I understand that this standard does not permit speculation concerning particular facts and is rather focused on whether the evidence more likely than not demonstrates the existence or non-existence of particular material facts. I have been informed that “preponderance of the evidence” is a lower standard than “clear and convincing evidence” (which requires a fact to be substantially more likely to be true than untrue), or “beyond a reasonable doubt”

(which is an exceedingly high standard that I understand is usually used in criminal matters).

92. Throughout my Declaration, I have applied the “preponderance of the evidence” standard.

IX. GROUND 1: BANDY

A. “unique ID” of the remote wireless device

93. Claim 1 requires that the wireless device has a “unique ID” and that the unique sensor ID is “associated with said unique wireless device ID.” None of Petitioner’s references discloses this limitation, but Petitioner nonetheless asserts that the unique wireless device ID limitation is met based on a POSITA’s knowledge of a Media Access Control (MAC) address and/or an International Mobile Equipment Identity (IMEI) number used for wireless phones. Pet. 26-27 (citing EX-1003 ¶¶ 184–85).

94. Notably, Petitioner’s argument relies on features not even discussed in Bandy (e.g., IMEI numbers and MAC addresses). Further, claim 1 of the ’307 Patent recites that “the remote server authenticates said unique sensor ID associated with said unique wireless device ID.” It is my opinion, therefore, that Petitioner fails to show that this limitation is met by Bandy.

95. Even if a POSITA would have understood Bandy to disclose a wireless device with a unique identifier, Petitioner has failed to assert any association

between that identifier and the unique identifier of a sensor. As recognized by the Board in its preliminary claim construction of “remote server authenticates said unique sensor ID associated with said unique wireless device ID,” “the last portion of the limitation reciting ‘associated with said unique wireless device ID’ serves to further describe the unique sensor ID, specifically, that the unique sensor ID is associated with the unique wireless device ID.” Inst. Dec. 10.³ But Petitioner’s argument is limited to purportedly showing that Bandy discloses (1) a unique wireless ID and (2) authentication based on the unique sensor ID. Pet. 30–31. Petitioner even points out that Bandy discloses that “*only the ID of the RFID-sensor is necessary....*” *Id.* (citing Bandy, 10:37–41) (emphasis Petitioner’s). Nowhere does Petitioner even attempt to show that “the unique sensor ID is *associated* with the unique wireless device ID.”

B. “the remote server authenticates said unique sensor ID associated with said unique wireless device ID and communicates to said wireless device processed information relating to said sensor data and software related to the unique sensor ID”

96. Claim 1 further requires that “the remote server authenticates said unique sensor ID associated with said unique wireless device ID and communicates

³ As discussed above, I provide a different proposed construction. But I agree that the claims require that the unique sensor ID be associated with the unique wireless device ID. Therefore, it is my opinion that this limitation is not met by Bandy, whether or not the Board adopts Patent Owner’s proposed construction of the authentication limitation.

to said wireless device processed information relating to said sensor data and software related to the unique sensor ID....” As discussed above, the plain language, specification, and prosecution history requires the remote server to authenticate based on the “unique sensor ID” in association with the “unique wireless device ID.” It is my opinion that the portions of Bandy cited by Petitioner do not disclose these features.

97. First, Petitioner quotes Bandy’s disclosure that “some or all of the necessary information to handle and analyze the sensor is retrieved from processor 190.” Pet. 30 (quoting EX-1005, 10:29–32). But this says nothing about either the “unique sensor ID” or the “unique wireless device ID.”

98. Second, Petitioner quotes Bandy’s disclosure that “when a sensor 110 having data table 258 is activated by wireless sensor reader 140, the sensor 110 identifies itself (e.g., by providing its [i.e., the sensor’s] identification number) and provides the cell phone reader with the necessary information for analyzing the sensor output.” Pet. 30 (quoting EX-1005, 10:19–24). But this disclosure refers to a communication between the sensor and the wireless sensor reader. It does not refer to authentication, and it does not refer to any remote server, both of which are required by the cited limitation.

99. Third, Petitioner’s other citations (Pet. 30-31 (quoting “Software may also be downloaded directly and transparently into the cell phone or reader 140 to

‘train’ the wireless device to recognize and analyze that given type of RFID sensor” (Ex. 1005, 10:14-51); “When the necessary processing and analysis information is downloaded from a remote location, only the ID of the RFID-sensor is necessary, providing a highly streamlined solution for universal sensor analyses for wireless devices such as cell phones” (Ex. 1005, 10:37-41); *id.*, claims 29, 39, 40)) relate only to what is communicated *from* the server. These citations do not disclose sending anything *to* the server for authentication.

100. Finally, Petitioner cites Bandy’s statement that “*only the ID of the RFID-sensor* is necessary,” completely undermining its argument. Pet. 30 (citing Ex. 1005, 10:37-41) (emphasis Petitioner’s). As discussed above, authentication—as claimed by the ’307 Patent—requires the sensor ID to be associated with the wireless device ID. Authentication based only on the sensor ID does not meet the “associated with” limitation.

C. Petitioner Fails to Show that Bandy Renders Obvious Dependent Claims 2, 5, 9, and 10

101. As Petitioner has failed to establish that Bandy is prior art or meets all limitations of claim 1, it likewise cannot prevail on dependent claims 2, 5, 9, and 10.

X. GROUND 2: BANDY + HELLER

102. Ground 2 of the Petition challenges only claim 3, which recites “[t]he system according to claim 1 wherein said sensor unit is integrated into a disposable

wireless skin patch for diagnostic applications.” Petitioner does not assert that this limitation is met by Bandy, instead relying on Heller’s disclosure of an “on-skin sensor control unit.” Pet. 37. Petitioner makes the conclusory argument that “[a] POSITA would have been motivated to use the same or similar technique (use of an adhesive skin patch) to affix Bandy’s RF addressable sensor proximate to the surface of the skin of an individual,” without even attempting to explain *why* a POSITA would have been so motivated. *Id.* Petitioner’s proffered expert likewise provides no explanation as to *why* a POSITA would have been motivated to combine Bandy and Heller. *See generally* EX-1003 ¶¶ 222–23. In my opinion, this plainly fails to demonstrate a motivation to combine the asserted references.

103. Bandy describes diagnostic monitoring via *externally* positioned “smart cards” or “badges.” EX-1005, 19:59–61 & Fig. 11. Heller discloses *implantable* sensors (i.e., a skin-insertion mechanism). EX-1016, 2:27–29 (“Generally, the present invention relates to methods and devices for the continuous and/or automatic *in vivo* monitoring of the level of an analyte using a subcutaneously implantable sensor.”); 8:12–13 (“The present invention is applicable to an analyte monitoring system using an implantable sensor....”). In my opinion, Petitioner fails to demonstrate that a POSITA would have been motivated to use Heller’s implantable sensors in Bandy’s unrelated system directed to external cards or badges. When pressed, Petitioner’s expert pointed only to sensors disclosed by Bandy for purposes

other than diagnostic monitoring. EX-2011, 83:20–85:22 (citing EX-1003 ¶ 130).

Further, Dr. Sarrafzadeh’s testimony regarding the form factor of Bandy’s gas and chemical sensors shows a POSITA would not have been motivated to include them in a skin patch. *Id.* Only hindsight could provide such a strained motivation. Indeed, nothing in either cited reference suggests their compatibility. In my opinion, this failure of proof is fatal to Petitioner’s argument.

XI. GROUND 3: BECK + LOVEJOY + HELLER

A. Petitioner Fails to Show That a POSITA Would Have Been Motivated to Combine Beck with Heller and/or Lovejoy

104. In my opinion, Petitioner fails to show that a POSITA would have been motivated to combine Beck, Heller, and Lovejoy. Beck is directed to creating secure systems by integrating various commercially available stand-alone devices, i.e., networking various off-the-shelf medical devices so that they can communicate with one another. A medical device of Beck includes “one or more user I/O devices 137, and a system bus 138.” Ex. 1007 ¶ 35. Beck describes the I/O devices as including, e.g., “mechanisms for entering information into the medical device ..., receiving information from the medical device ..., and/or controlling the operation of the medical device.” *Id.* ¶ 40. For example, the user I/O device may include “cathode ray tubes (CRT), liquid crystal displays (LCD), light emitting diodes (LED), printers, and/or other output devices that are operable to visually present information to a user”; “sound cards, wave generators, sequencers, mixers, speakers, and/or other

audio devices that are used to audibly present information to a user”; and “a mouse, a keyboard, a touch pad, a push button, a scanner, a stylus, a touch screen, and/or another input device that provides a user of the exemplary medical device ... with an interface to directly control the operation of the exemplary medical device.” *Id.* ¶¶ 40–41.

105. The medical devices of Beck are thus large and bulky—far from disposable, wireless skin patches. Petitioner’s suggestion that it would have been obvious to a POSITA to transition from Beck’s collection of bulky, stand-alone medical devices to a disposable patch is nonsensical. While the Board noted in its Institution Decision (at 19) that “it is not regarded as inventive to merely make an old device portable or movable without producing any new and unexpected result,” the ’307 Patent *does not* merely make a Beck-like system portable; rather, it employs an entirely different technology, in a different setting, for a different purpose, in a different manner.

106. In addition, Beck describes a networked, wired medical system and makes no reference to RFID (or any other wireless protocol or standard). In particular, Beck states “a standard RS-232 serial port” would be used to connect the medical device to the client computing device. Ex. 1007 ¶ 29. The RS-232 standard was one of the first serial port protocols, introduced in 1960. It originally used a 25-

pin connector, but more modern implementations use a 9-pin connector, such as that of the connector cable shown below.



<https://www.campbellsci.com/35688>

107. A POSITA would have known that such serial connections are meant for semi-permanent connections between a computer and a peripheral device, such as a printer or, in the case of Beck, a medical device. While Beck refers to other wired connections, and makes a passing reference to wireless (with no detail), a POSITA would have understood that such connections were intended for extended durations. Notably, even for the wireless connections, Beck describes using them to “establish the physical communications link 140 between the client computing device 120 and the medical device 130.” Ex. 1007 ¶ 30. In my opinion, a POSITA would have understood these connections as providing communication for ongoing, continuous monitoring of a patient, such as in a hospital setting. On the other hand, the ’307 Patent describes an RFID system, where a sensor is intermittently checked—not continuously monitored—by a wireless device. Unlike Beck, the ’307

Patent's system facilitates use in a distributed, dynamic, even ambulatory setting. Indeed, the '307 Patent describes using a cell phone or PDA to read the sensor information "anywhere in the world." Ex. 1001, 5:40–43.

1. Petitioner Fails to Show That a POSITA Would Have Been Motivated to Combine Beck with Heller

108. It is my opinion that Petitioner fails to show that a POSITA would have been motivated to combine Beck with Heller, or that the resulting combination—even when combined with Lovejoy—would meet all the limitations of the identified claims. Petitioner asserts that Beck and Heller “are both directed to medical/diagnostic sensing systems, including systems with chemical sensors for measuring glucose,” and that “Heller provides use of known techniques that can be used implement [sic] and improve Beck’s medical devices.” Pet. 41 (citing EX-1003 ¶ 225). This conclusory argument is insufficient to establish a motivation to combine.

109. Beck teaches remote access to medical devices through the networked integration of client computing devices, each of which interfaces to a medical device. A client computing device in this context is a computer-based host that incorporates standard operating-system support and built-in network communication interfaces, and a medical device in this context exists in the form of a stand-alone commercial-off-the-shelf (COTS) medical device with built-in interface support. The Beck specification does not contemplate small, wearable, patch-like devices, such as the

embodiments of the device disclosed in Heller, which would not offer the standard interface support and other features to connect to a client computing device host. Nor does Beck contemplate communication by the client computing device directly with a sensor unit, as opposed to with a medical device as a whole. Further, Beck's medical device incorporates user I/O functionality that allows a patient or physician to manually control the medical device settings and directly view the resulting data on the medical device itself. Heller's sensor control unit offers no such capabilities for direct user interaction and would therefore constitute a functional mismatch in the context of the Beck system and its expectations for on-board medical device functionality.

110. Beck merely discloses an aggregation of pre-designed, off-the-shelf medical devices for use in a hospital setting (i.e., non-ambulatory devices). EX-1007 ¶ 34. Beck *never* mentions mobile/wearable applications (e.g., terms such as “wearable,” “worn,” “mobile,” “ambulatory,” “patch,” “portable,” “battery,” “light,” “small,” and “RFID” are not found in the specification). Notably, any reference to “remote” access to medical device data does not imply “mobile” monitoring. Beck offers application examples and technology listings that are suited only to stand-alone devices that already incorporate interface/port support from the manufacturer, not to wireless disposable skin-patch formats that must utilize RFID to properly function.

111. In fact, the proposed combination of Beck and Heller necessarily involves a connection to a bulky device in a hospital setting. Heller, however, disparages—and therefore explicitly teaches away from—“large, bulky, and/or inflexible” devices. EX-1016, 2:4–6. The entire purpose of Heller was to provide a system that could be “used effectively outside of a controlled medical facility, such as a hospital or doctor’s office....” *Id.* Thus, a POSITA would have considered Heller’s system antithetical to—not compatible with—Beck’s system.

112. The particular combination proposed by Petitioner involves using Heller’s glucose sensor in Beck’s system. But in doing so, Petitioner ignores the difference between a medical device and a sensor. The distinction between sensor and device is critically important in the analysis of the (lack of) motivation to combine Beck and Heller. Beck discloses remote access to medical devices. EX-1007, Abstract. Beck does not disclose remote monitoring and control of medical sensors. The glucose meter disclosed by Beck “measure[s] blood glucose levels of blood applied to test strips.” Ex. 1007, [0034]. It is the test strips that are the glucose sensors, as a test strip contains, e.g., enzymes that chemically react with glucose to create carriers in the form of an electrical current. And Beck nowhere discloses these test strips as having unique identifiers. A POSITA would understand that Heller’s “sensor control unit” or “on-skin sensor unit” would have been incompatible with the glucose meter disclosed by Beck, which uses test strips. Petitioner’s problem is

laid bare in Dr. Sarrafzadeh's opinion. In arguing that a POSITA would have been motivated to combine Beck with Heller, Dr. Sarrafzadeh refers to the glucose meter as a "medical sensor." Ex. 1003, ¶ 226. But that is inaccurate. Again, the glucose meter is a medical device, and it is the test strips that are the glucose sensors. Even Dr. Sarrafzadeh recognized that the test strips were part of the sensing system. Ex. 2011, 32:12–16. The only way to combine Beck with Heller would have been to replace the entire test-strip glucose meter from Beck with the entire device disclosed by Heller, which includes a display unit or other data analyzer that receives data from the sensor control unit. Ex. 1016, 4:17-30, 86:6-10. But that combination would not meet the limitations of the challenged claims because it would not include, *inter alia*, a unique identifier for the **sensor**. In other words, Petitioner is trying to have its cake and eat it too. It wants to use the **sensor** from Heller and the serial number of the **device** from Beck, but that combination makes no sense.

113. A POSITA would not have been motivated to replace the client computing device of Beck, meant to interface to a wide variety of COTS medical devices, with a device designed to interface to a particular sensor, such as the sensor control unit disclosed by Heller. Numerous excerpts from Beck confirm the goal of self-contained, COTS medical devices, e.g.:

- "In general, the system 100 automatically or semi-automatically configures the client computing devices 120 for communication with **medical devices 130 that utilize different communications protocols**, and provides the server computing device 110 remote access to the medical devices 130 via the

client computing devices 120 and the network 150.” Ex. 1007 ¶ 14 (emphasis added).

- “Each protocol component 204 configures the client computing devices 120 for communication with a **specific set of medical device models or types of medical devices 130.**” *Id.* ¶ 15 (emphasis added).
- “More Specifically, each protocol component 204 in the exemplary embodiment is adapted to configure the client computing devices 120 to send **medical device configuration information, medical device version information, medical device setup information, and medical device measurement data** to the server computing device 110.” *Id.* (emphasis added).
- “The server computing device 110 is adapted to detect, over the network 150, medical devices 130 that are operably coupled to the client computing devices 120. Illustratively, the server computing device 110 is adapted to query the connected medical devices 130 for **medical device version information, medical device configuration information, medical device setup information, and medical device measurement data.**” *Id.* ¶ 16 (emphasis added).
- “More specifically, the processor 122 as a result of executing software and/or firmware routines of the memory 123 is generally operable to **configure the client computing device 120 for communication with the medical devices 130.** Further, the processor 122 as a result of executing the software and/or firmware routines of the memory 123 is generally operable to configure the client computing device 120 to **determine the medical device type of a medical device 130 operably coupled thereto**, obtain from the server computing device 110 a protocol component 204 (See, FIG. 2.) suited for communicating with the medical device 130 operably coupled thereto, and/or communicate with the medical device 130 via the protocol component 204.” *Id.* ¶ 24 (emphasis added).
- “As shown, the exemplary client computing device 120 further includes the device interface 126. The device interface 126 is generally operable to establish a physical communications link 140 between the client computing device 120 and the medical device 130. To this end, the device interface 126 of the exemplary client computing device 120 includes a **standard RS-232 serial port to which the medical device 130 may be operably coupled via an RS-232 cable.**” *Id.* ¶ 29 (emphasis added).
- “However, the device interface 126 may alternatively, or in addition, include other communications mechanisms such as a **parallel port, a SCSI port, a USB port, a 1394 port (i.e. FireWire or I-Link port), a Fibre Channel**

port, a network interface controller, or some other type of communications port to which a user may couple a corresponding communications port of the medical device 130 via an appropriate cable or connector. The device interface 126 may alternatively, or in addition, include wireless technologies such as RF and/or IR transmitter/receivers to establish the physical communications link 140 between the client computing device 120 and the medical device 130. *Id.* ¶ 30 (emphasis added).

- “As shown, the system 100 further includes a medical device 130. The medical device 130 of the system 100 is generally operable to monitor one or more biological/physiological conditions and communicate with the client computing device 120 via the physical communications link 140 established between the client computing device 120 and the medical device 130. In an exemplary embodiment, the medical device 130 includes a **glucose meter such as the glucose meters manufactured by Roche Diagnostics Corporation which are generally operable to measure blood glucose levels of blood applied to test strips**. While the medical device 130 of the exemplary embodiment includes a glucose meter, the medical device 130 could be implemented to monitor and/or analyze other biological/physiological parameters or conditions such as **body fluids or bodily functions (e.g. blood, urine, saliva), bodily signals (e.g. electrocardio-signals, brain waves, blood pressure waves), and/or other bodily stimuli (e.g. respiration) to obtain measurements of blood pressure, blood gases, blood coagulation, electrolytes, cardiovascular activity, drug levels, respiration rate, stress, etc.**” *Id.* ¶ 34 (emphasis added).
- “As can be seen from FIG. 1, the exemplary medical device 130 includes a processor 132, memory 133, a communications interface 136, **one or more user I/O devices** 137, and a system bus 138.” *Id.* ¶ 35 (emphasis added).
- “Further, the processor 132 as a result of executing the software and/or firmware routines of the memory 133 is generally operable to control communication between the client computing device 120 and the medical device 130 in accordance with a **particular communications protocol which may be specific to the medical device 130**. In an exemplary embodiment, the system 100 supports **several different models and/or types of medical devices 130 which may use different communications protocols**. In general, these different models and/or types of medical devices 130 may utilize protocols that define different procedures for formatting data and the procedure used to transfer the data. For example, different medical devices 130 may utilize (i) a different message or packet format, (ii) a different transfer rate, (iii) a different error detection scheme, (iv) a different error

correction scheme, (v) a different command set, and/or (vi) a different compression scheme to name a few.” *Id.* ¶ 36 (emphasis added).

- “As shown, the exemplary medical device 130 further includes the communications interface 136. The communications interface 136 is generally operable to establish the physical communications link 140 between the client computing device 120 and the medical device 130. To this end, the communications interface 136 of the exemplary medical device 130 includes **a standard RS-232 serial port to which the client computing device 120 may be operably coupled via an RS-232 cable.**” *Id.* ¶ 38 (emphasis added).
- “The communications interface 136, however, may alternatively, or in addition, include other communications mechanisms. such as a **parallel port, a SCSI port, a USB port, a 1394 port (i.e. FireWire or I-Link port), a Fibre Channel port, a network interface controller**, or some other type of communications port to which a user may couple a corresponding communications port of the client computing device 120 via an appropriate cable or connector. The communications interface 136 may alternatively, or in addition, include wireless technologies such as RF and/or IR transmitter/receivers to establish the physical communications link 140 between the client computing device 120 and the medical device 130.” *Id.* ¶ 39 (emphasis added).
- “The medical device 130 further includes one or more user I/O devices 137. The user I/O devices 137 in general provide a user of the medical device 130 with **mechanisms for entering information into the medical device 130**, receiving information from the medical device 130, and/or **controlling the operation of the medical device 130**. For example, the user I/O devices 137 may include **cathode ray tubes (CRT), liquid crystal displays (LCD)**, light emitting diodes (LED), **printers**, and/or other output devices that are operable to visually present information to a user of the exemplary medical device 130. The user I/O devices 137 may also include **sound cards, wave generators, sequencers, mixers, speakers, and/or other audio devices** that are used to audibly present information to a user of the exemplary medical device 130.” *Id.* ¶ 0040 (emphasis added).
- “Further, the user I/O devices 137 of the medical device 130 may include a **mouse, a keyboard, a touch pad, a push button, a scanner, a stylus, a touch screen**, and/or another input device that provides a user of the exemplary medical device 130 with an interface to directly control the operation of the exemplary medical device 130. The medical device 130 may also be implemented with no user I/O devices 137, and simply leverage the user I/O devices 127 of the client computing device 120. However, even a medical device 130 that highly leverages the user I/O devices 127 of the client

computing device 120 will usually still have a few user I/O devices 137 such as an LED that provides visual feedback that the medical device 130 is powered, an LED that provides visual feedback that the physical communications link 140 has been established, and/or a button or switch to power the medical device 130 on or off.” *Id.* ¶ 41 (emphasis added).

- “Furthermore, the system bus 138 may be implemented with one or more buses utilizing one or more bus architectures such as **PCI, ISA, VME, and PC-104.**” *Id.* ¶ 42 (emphasis added).
- “In the exemplary embodiment, the protocol components 204 are implemented as **ActiveX components** which can be downloaded and executed by the client computing device 120 via a web browser. However, the protocol components 204 may also be implemented using other software technologies such as **COM, DCOM, Java, JavaScript, VBScript, Perl, Python,** as well as native applications written in the language of the developers choice which could be executed on the client computing device 120 via various RPC techniques.” *Id.* ¶ 49 (emphasis added).
- “Besides merely scanning a predetermined port for the medical device 130, the device identification component 214 may allow a user to specify via the user interface 210 to which port the medical device 130 is operably coupled. Further, the identification component 214 could simply scan all ports of a particular type (e.g. all **USB ports, all SCSI ports, all parallel ports, wireless interfaces, etc**) or scan a user-definable set of ports.” *Id.* ¶ 56 (emphasis added).
- “In an exemplary embodiment, the protocol components 204 comprise software such as **Java Applets, JavaScripts, ActiveX Controls,** etc. which is executed by the client computing device 130 in response to information received from the server computing device 110.” *Id.* ¶ 62 (emphasis added).
- “A flowchart depicting an exemplary method of operation 300 is illustrated in FIG. 3. As illustrated, the exemplary method 300 begins in step 302 with establishing a physical communications link 140 between the client computing device 120 and the medical device 130. In an exemplary embodiment, a user of the system establishes the physical communications link 140 by **coupling a interface cable between a port (e.g. serial I/O port) of the medical device 130 and a corresponding port (e.g. COM port 1) of the client computing device 120.** However, if the medical device 130 includes a wireless communication mechanism such as IR and/or RF transmitters/receivers, then the physical communications link 140 is established by simply placing the medical device 130 within transmission range of the corresponding IR and/or RF transmitters/receivers of the client

computing device 120.” *Id.* ¶ 63 (emphasis added).

- “In an exemplary embodiment, the server computing device 110 merely transfers to the client computing device 120 an HTML document that includes a reference to the proper **ActiveX Control for the client computing device 120 to execute in order to communicate with the medical device 130.**” *Id.* ¶ 69 (emphasis added).
- “In particular, the user in the exemplary embodiment requests via a web browser of the user interface 210 that the web browser connect to a particular server computing device 110 and associated transport agent 202 identified by a **particular URI (Universal Resource Identifier), URL (Universal Resource Locator), PURL (Persistent Uniform Resource Locator) and/or URN (Universal Resource Name) which services medical devices 130 of a particular family or type.** By utilizing **different URLs for different models of medical devices 130,** different types of medical devices 130, different classes of medical devices 130, and/or different manufacturers of medical devices 130, the URL essentially provides a mechanism to identify or partially identify the medical device 130 attached to the client computer system 120. **For example, a first URL may be defined for a first model of glucose meters, a second URL may be defined for a class of glucose meters which have similar capabilities, and a third URL may be defined for all cholesterol meters of a certain manufacturer.**” *Id.* ¶ 79 (emphasis added).
- “By utilizing different URLs for different models, different types, different classes, and/or different manufacturers of medical devices 130, the URL essentially provides a mechanism to identify or partially identify the medical device 130 attached to the client computer system 120. **For example, a first URL may be defined for a first model of glucose meters, a second URL may be defined for a class of glucose meters which have similar capabilities, and a third URL may be defined for all cholesterol meters of a certain manufacturer.**” *Id.* ¶ 90 (emphasis added).
- “It should be appreciated that the client computing device 120 has essentially identified the model, type, class, and/or manufacturer of the medical device 130 in step 504 **via the particular URI, URL, PURL, and/or URN.**” *Id.* ¶ 92 (emphasis added).

114. Beck focuses on methods to connect these medical devices to the overall network via the use of client computing devices. *Id.* ¶ 35. Beck is not directed to device construction or optimization, and a POSITA would not have been

motivated to make improvements to an isolated Beck device using the teachings of Heller (which describes a small, wearable, ambulatory device). Rather, a POSITA would have been interested in utilizing the teachings in Beck to implement multi-device systems comprised of already assembled, commercially available products. A POSITA would not have been motivated to use the unrelated implantable sensor disclosed by Heller with the system of Beck.

115. For example, Beck describes software protocol components, such as ActiveX and HTTP/HTML. EX-1007 ¶¶ 49, 53. Heller, conversely, describes a rudimentary communication system using frequency modulation (FM) transmissions. Heller, 75:3-16. Nothing would have motivated a POSITA to add the high-level protocols described in Beck to the sensor described in Heller.

116. In short, Beck describes a network of medical devices that are essentially stand-alone commercial-off-the-shelf (COTS) devices with standard cable interfaces to the outside world (e.g., an RS-232 port, a parallel port, a SCSI port, a USB port, a 1394 port, a Fibre channel port, a network interface controller, wireless links, etc.), user I/O interfaces (at least one per device, such as a CRT, an LCD, LEDs, a printer, a mouse, a keyboard, a touch pad, a push button, a scanner, a stylus, a touch screen, etc.), bus architectures (e.g., PCI, ISA, VME, and PC-104), support for component technologies such as ActiveX, COM, DCOM, Java applets, etc.), and possibly access via a URL. A specific example of a Roche glucose meter

is mentioned in Beck. This is a device that is fully functional on its own and provides a user interface and a data display.

117. Heller, on the other hand, describes an electrode-based sensor encapsulated in a sensor control unit (SCU), where the SCU contains limited memory, processing, etc. and is intended to be small, low-power, disposable, and limited to short-range RF links. Heller's SCU does not support standard cable connectivity, user I/O interfaces, bus architectures, and component technologies. In contrast with the medical device in Beck's network, a user cannot control Heller's SCU directly or visualize its data because a display does not exist on the SCU. Rather, Heller's SCU requires a remote receiver and display unit to be useful, and Dr. Sarrafzadeh does not mention Heller's small/large receiver and display units as playing any role whatsoever in any asserted Beck/Heller combination. Overall, Heller's sensor control unit is a small embedded subsystem that is much too lightweight to function on its own and therefore in Beck's device network, and a POSITA would not naturally attempt to force such a combination between Beck and Heller.

118. Heller's device does not incorporate, e.g., user I/O capabilities or bus technologies. Heller's device can only communicate with the outside world via a small, low-power telemetry link, meaning Heller's small, disposable sensor control unit is designed to push measured data outward. It is not designed for any user

interaction, bus capability, or other physical interfacing options and is therefore a device that is very different from the medical devices described in Beck.

119. While Heller focuses on details of certain low-level features of specific wearable sensors, Beck discusses the networking of various devices at a high level. This disparity in the scope and purpose of the references would not provide a motivation to combine Beck's teachings with Heller's teachings. Rather, only improper hindsight, based on the '307 Patent's disclosure, could provide such a motivation.

120. I also disagree with Dr. Sarrafzadeh's statement that Heller provides "techniques for improving sensor devices like those used in Beck's system." EX-1003, ¶ 225. First, Heller relates only to glucose monitoring, and Beck lists a glucose meter as only one example of many medical devices. Second, in my opinion, there is nothing disclosed in Heller that would improve on Beck's medical devices. In fact, in my opinion the medical devices disclosed by Beck are each more capable than the device disclosed by Heller. There are reasons to preferentially use test strips over the type of sensor disclosed by Heller. For example, in some cases, test strips may provide more accurate results, and implantable glucose sensors put the patient at greater risk for infection and can experience sensor degradation over time.

121. Beck relates to the networking of COTS medical devices that can each operate on their own. These teachings are not "improved" by small details in a given

sensor that are never mentioned in, or motivated by, the Beck specification. If a POSITA were to improve Beck's system, such an improvement might include a connectivity standard that allows more rapid device pairings or improved data throughput, because the network level is the level of focus in Beck. Beck does not, in any way, address the minutia of individual sensor design.

122. Dr. Sarrafzadeh obfuscates the issue of obviousness by seeking to draw a parallel between a medical *device* of Beck and a *sensor* of Heller. A Beck device is not reasonably replaced with a Heller sensor. Additionally, a Beck device is also not reasonably replaced with a Heller sensor control unit (SCU) because, as noted above, a Beck medical device is a capable, stand-alone unit with user I/O capabilities, display mechanisms, standard interface connectivity with the outside world (e.g., a network), etc. Heller's SCU is not such a unit. Beck's teachings do not address any specific sensing elements within a given medical device; such details are abstracted out. Therefore, a POSITA would not naturally seek to improve upon Beck by combining Beck with specific sensor upgrades.

123. Dr. Sarrafzadeh also misstates that a glucose meter is an example of a medical sensor. EX-1003, ¶ 226. The glucose meter is a medical device, which uses test strips that are sensors.

2. Petitioner Fails to Show That a POSITA Would Have Been Motivated to Combine Beck with Lovejoy

124. Petitioner's assertions regarding an alleged motivation to combine Beck and Lovejoy are even flimsier: "both disclosures are directed to mobile sensing systems" (Pet. 45). Beck does not, however, disclose a mobile sensing system. Instead, Beck discloses only remote access to medical devices, which is not equivalent to either mobile access to sensors or access to mobile sensors. Beck achieves remote access via a server connected to a network. EX-1007 ¶ 14. Remote access is further enabled in Beck because each medical device is connected to a client computing device. Importantly, Beck does not disclose that the client computing device connected to a medical device is mobile, nor does Beck disclose that a medical device is itself mobile. While Beck discloses, in passing, wireless communication, a POSITA would have understood such wireless communication as an option to avoid physical cable clutter. A POSITA would not have understood Beck's system to suggest placing a sensor on an ambulatory patient.

125. Even if Beck had disclosed a mobile sensing system, that would not have provided a POSITA with motivation to combine Beck with Lovejoy. Mobile sensing is not a defined domain, and what would potentially be included in that definition is unclear. Importantly, Beck and Lovejoy are directed to unrelated domains. Beck is directed to medical devices which monitor and/or analyze patients. EX-1007 ¶ 2. Lovejoy is unrelated to medical or diagnostic testing. Instead, Lovejoy

discloses monitoring occupational exposures using a wearable external device (on clothing) that does not interact with the user's biology. EX-1009, 1:25-35; 4:44-50.

126. Petitioner and Petitioner's expert rely heavily on Beck's disclosure that the client computing device can be implemented as a cellular phone to argue a POSITA would have been motivated to integrate geolocation functionality into the phone. Pet. 45–46; EX-1003 ¶ 242. According to Petitioner's expert, "[l]ocation information can provide vital information about an individual to allow timely responses. For example, it can help in identifying the location of an individual in case of emergency." EX-1003 ¶ 242. But this is a red herring and completely mischaracterizes the disclosure of Beck and the role of its client computing device. As discussed above, Beck is focused on medical monitoring in, for example, a hospital setting. In such a situation, a POSITA would have understood that patient location is obviously known. And to the extent that patient location is not known, geolocation in the client computing device—potentially in the location of the medical professional—would not be helpful in locating the patient.

127. Beck does not mention—or even imply—the need to locate a device, as taught in Lovejoy. Beck's two references to cell phones are solely in the context of connecting a cell phone to a client computing device:

- “The exemplary client computing device 120 may alternatively be implemented such that **the same hardware components that implement the memory 123 also implement the storage device 124**. For example, the exemplary client computing device 120 may be implemented with memory

chips that implement both the functionality of the memory 123 and the storage device 124. Many special purpose computing devices such as handheld computing devices (e.g. PalmPilots) and **Internet enabled cellular phones** which could be used to implement the client computing device 120 are implemented in such a manner.” Ex. 1007 ¶ 27 (emphasis added).

- “In other words, the server computing device 110 may be efficiently implemented to supported [sic] a wide range of client computing devices 110 (e.g. computer systems using the McIntosh, Windows, and/or Linux operating systems, Palm Pilots, Handspring Visors, **Internet enabled cellular phones**, etc.).” *Id.* ¶ 49 (emphasis added).

128. Importantly, Lovejoy refers to an entirely different application domain.

Lovejoy is focused on applications such as accumulated radiation monitoring for exposure to hazards, not on physiological monitoring as disclosed in Beck. In my opinion, a POSITA would not have been motivated—for any reason—to combine the two references.

129. Additionally, the location capabilities taught in Lovejoy refer to the location of the radiation-monitoring security badge (the device worn by the user), not to the location of the interrogator (e.g., an RFID reader) that receives the data from the badge. Thus, Lovejoy’s location capabilities are completely unrelated to the geolocation limitations recited in the ’307 patent, which are directed to the *remote wireless device*, not to a badge or sensor element. For example:

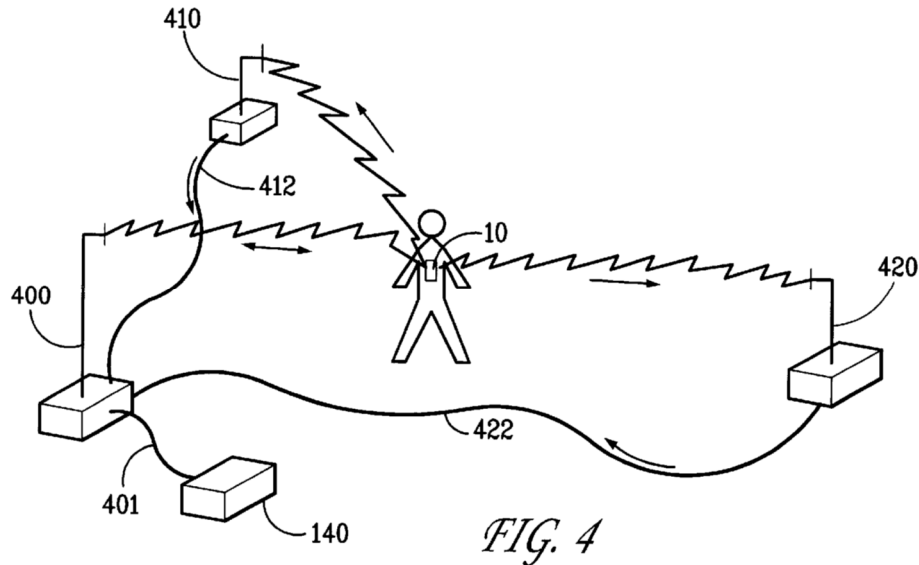
- “None of these prior art patents discloses a **monitor or security badge** which combines in a highly compact unit an **accurate positional capability** which works within buildings with a capability to monitor for any type of chemical/physical exposure or combination of exposures.” Ex. 1009, 2:15–19 (emphasis added).
- “The monitor also includes an optional highly accurate **positional capability** for large industrial sites, buildings, or other places of limited vision, to allow

exposures to be pinpointed to a given location and allow an overall exposure picture to be automatically drawn across an entire plant or factory. Conversely, the positional capability can **notify the worker when he enters** an exclusion or dangerous area. In addition, in case of an emergency, a worker can press an **emergency call button on the monitor which allows the worker to be precisely located** and allow for effective intervention. Finally the positional capability combined with an external chemical sensing capability (which can be specifically tailored for any type of chemical) allows this **monitor to be used as a security badge** for sensitive security jobs such as airplane maintenance crews or workers in nuclear facilities.” *Id.* at 2:42–56 (emphasis added).

- “However, in situations where **line-of-sight to 4 GPS satellites** can be guaranteed and **greater size and weight are acceptable**, GPS can be utilized for geolocating. With GPS locating, reduced cost in the locating infrastructure is realized. When reduced weight and size are important and when geolocating in buildings is important, a local geolocating infrastructure is required. Although greater cost is required for the infrastructure itself, greatly reduced cost of the tagging units is realized. With this system interrogators that prompt the tag unit for a response are strategically located in the area of interest. With simultaneous reception of the tag transmission, **precision geolocating can be performed.**” *Id.*, 9:4–15 (emphasis added).

130. Lovejoy Figures 3 and 4 (and their accompanying text), confirm that the location of the tag, and not the location of the interrogator, is determined. *Id.* at Figs. 3 & 4, 9:41–10:17.

131. Petitioner conveniently paints over the details of Lovejoy’s disclosure in its attempt to show a motivation to combine. Lovejoy discloses a wearable “monitor” and an “interrogator system,” which provides two functions: geolocation of the monitor and data transfer to and from the monitor. EX-1009, 9:17–40. The geolocation aspect is depicted in Figure 4 of Lovejoy, reproduced below. *Id.* at 4:17–19.



132. Petitioner’s arguments for incorporating geolocation into Beck based on the teaching of Lovejoy are flawed. Petitioner points to a disclosure in Lovejoy regarding geolocation of the monitor to purportedly meet the geolocation-means limitation. Pet. 60–61. This is misplaced. To the extent Lovejoy would have motivated any revision to Beck, the revision would have entailed adding geolocation to the medical device monitoring the patient (which is akin to the claimed sensor, not to the claimed wireless reader). In such a situation, if a medical device signals an emergency, a crash team could theoretically be dispatched to the location of the medical device.

133. Petitioner argues that “both disclosures are directed to mobile sensing systems” and that Beck discloses that its client computing device can be wireless and implemented as a cell phone. This, Petitioner argues, “would prompt a POSITA to implement such a cell phone with features normally found on cell phones”

including GPS and non-GPS geolocation features such as those described in Lovejoy. Pet. 45–47. According to Petitioner, this “would enable the provision of emergency response to users of Beck’s system in the event that the medical device detects a dangerous condition.” *Id.* at 47. But this makes no sense. Indeed, sending a crash team to the location of the client computing device—presumably in the possession of a nurse or doctor—would be pointless when the patient at issue would likely be in a different location. This is especially true in the embodiment of a client computing device Petitioner focuses on: a cellular phone. Thus, the location of the client computing device (i.e., where the medical professional is reading the output of the medical device) is irrelevant to sending an emergency response to the location of the medical device (i.e., where the patient is located). Hospitals rely on their own networks, IT systems, and record-management systems to locate patients by their hospital room ID. No reason existed to use a geolocation process (which, at the time, would have been imprecise) to locate a patient when healthcare providers would already have known the exact location of the patient/device.

134. A POSITA would also have been dissuaded from using a cellular phone in the hospital setting of Beck for practical reasons. At the time of invention of the ’307 Patent, hospitals typically restricted the use of cellular phones due to concerns regarding electromagnetic interference with medical equipment and devices. For example, a concern at the time was that cellular phones could cause magnetic

interference with implantable devices such as pacemakers. *See, e.g.*, EX-2016

(Lawrentschuk 2004 – Mobile phone interference with medical equipment;

<https://pubmed.ncbi.nlm.nih.gov/15287832/>;

<https://onlinelibrary.wiley.com/doi/epdf/10.5694/j.1326-5377.2004.tb06205.x>);

EX-2017 (Klein 2003 – Mobile phones in the hospital,

<https://pubmed.ncbi.nlm.nih.gov/12648117/>; [https://associationofanaesthetists-](https://associationofanaesthetists-publications.onlinelibrary.wiley.com/doi/full/10.1046/j.1365-)

[publications.onlinelibrary.wiley.com/doi/full/10.1046/j.1365-](https://associationofanaesthetists-publications.onlinelibrary.wiley.com/doi/full/10.1046/j.1365-)

[2044.2003.03079.x?sid=nlm%3Apubmed](https://associationofanaesthetists-publications.onlinelibrary.wiley.com/doi/full/10.1046/j.1365-2044.2003.03079.x?sid=nlm%3Apubmed)); EX-2018 (Yeolekar 2004 – Use of

Mobile Phones in ICU – Why Not Ban?,

<https://pubmed.ncbi.nlm.nih.gov/15636335/>). Cell phones also had documented

effects on the operation of electrical medical equipment, such as

electrocardiographic equipment (including EKG machines), anesthetic equipment,

ventilators, syringe pumps, ionizing radiation dose monitoring equipment, and

myriad other types of devices. See EX-2019 (Furuhata 1999 EMI and Electric

Medical Equipment,

<https://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=801366>); EX-2020

(Gilligan 2000 GSM Cell Phone Interference); EX-2016 (Lawrentschuk 2004 -

Mobile phone interference with medical equipment;

<https://onlinelibrary.wiley.com/doi/epdf/10.5694/j.1326-5377.2004.tb06205.x>) ;

EX-2021 (Irnich 1999 Mobile Phones in Hospitals;

[https://www.researchgate.net/profile/Werner-](https://www.researchgate.net/profile/Werner-Irnich/publication/13223913_Mobile_phones_in_Hospitals/links/5e00af88299bf10bc371ec7f/Mobile-phones-in-Hospitals.pdf)

[Irnich/publication/13223913_Mobile_phones_in_Hospitals/links/5e00af88299bf10bc371ec7f/Mobile-phones-in-Hospitals.pdf](https://www.researchgate.net/profile/Werner-Irnich/publication/13223913_Mobile_phones_in_Hospitals/links/5e00af88299bf10bc371ec7f/Mobile-phones-in-Hospitals.pdf)). Considering these concerns, it was recommended that cellular phones not be brought within close proximity of medical equipment and devices.

135. Hospitals at that time were also notoriously RF-impervious structures, as they necessarily included areas with thick walls to prevent penetration by X-rays, or walls with embedded screens (i.e., Faraday cages) to provide RF protection for equipment such as MRI systems whose images were susceptible to RF interference, or the converse situation where proper operation of a given medical device was susceptible to RF interference emitted by the MRI unit itself. This made cellular phone use—to the extent permitted—inconsistent and unreliable, as cellular phone signals could not pass through such structures. Healthcare providers thus typically used pagers, which communicate with generally lower-frequency radio signals (carrier frequencies in VHF, UHF, and 900 MHz bands) when compared to cell phones (carrier frequencies from 600 MHz to 39 GHz). *See, e.g.*, “Why doctors still use pagers (it’s not what you thought)” at <https://www.youtube.com/watch?v=uAwW9arTxGo>; EX-2022 (“Cell Phone Frequency Bands Guide” at <https://surecall.com/surecall-cell-phone-signal-boosters-blog/cellular-phone-frequency-bands-guide-2022/>). The use of pagers also reduced

the chance of security breaches or accidental transmission of confidential patient information, as pagers transmit only numeric messages or very basic text messages. Pagers also had much longer battery life than cell phones, making it less likely for a healthcare provider to lose power, which could interfere with communications and put patients at risk. Given all the benefits of pagers over cellular phones in the hospital setting at the time of Beck—and the climate of concern regarding cellular phones in hospitals at that time—a POSITA would not have been motivated to incorporate a cell phone into Beck’s system.

136. In addition, at that time, geolocation in hospitals could not use triangulation, in part for the reasons addressed above; rather, patient location tracking was accomplished with a combination of patient ID, room ID and medical device ID (all of which were specific to a given hospital). Therefore, the idea that Lovejoy discloses geolocation of the “monitor” (i.e., sensor unit) is irrelevant to teaching geolocation of a wireless device that reads the monitor, as required by the ’307 Patent claim language, and this idea would not have motivated a POSITA to add such geolocation into Beck’s client computing device.

137. In my opinion, differences also exist between Beck’s medical devices and Lovejoy’s monitor that would have prevented a POSITA from combining the references. Lovejoy’s monitor device is intended to be worn for years. EX-1009, 2:57–65. The wearability and occupational-hazard applications for this device are

different in intent from Beck, which discloses the aggregation of a collection of off-the-shelf medical devices that are static in their application (e.g., bedside devices), not wearable units. EX-1007 ¶¶ 29–30 (describing physical connections using cables), ¶¶ 34, 40 (describing glucose meter manufactured by Roche Diagnostics Corporation). A POSITA thus would not have been motivated to combine the device of Lovejoy with the system of Beck, nor would such a combination have resulted in the claimed diagnostic-sensor unit.

3. The FCC Report Does Not Fill in the Holes in Petitioner’s Asserted Combination

138. Petitioner’s reliance on the FCC Report is also misplaced. *See* Pet. 46. In particular, Petitioner fails to show that the disclosure of the FCC Report was inherent in the disclosure of Lovejoy or that a POSITA would have been motivated to combine Lovejoy with the FCC Report. Indeed, Petitioner does not make *any* arguments regarding a motivation to combine the FCC Report with any other art.

139. While the Board previously indicated that Petitioner is merely using the FCC Report “as evidence of what was known in the art” (Inst. Dec. 23), the FCC Report does not establish that geolocation, as used in the sense of the ’307 Patent, was a common cellular-phone feature at the time of the invention. Further, Petitioner’s statement that “geolocation features” were “normally found on cell phones,” Pet. 45, is unsupported. While the FCC Report revises certain rules, it does not establish that all (or even any) cell phones were *in compliance* with those rules

(or included the claimed geolocation means) at the relevant time. Indeed, if all cell phones already included this feature, no need would have existed for the FCC Report to establish *target deadlines for compliance* with the revised rules. When confronted with the particulars of the FCC Report, Dr. Sarrafzadeh downplayed the importance of the FCC Report, only saying that it showed that it would have been obvious to a POSITA to include geolocation features in cellular phone. EX-2011, 41:20–42:4, 77:17–22. But Dr. Sarrafzadeh could not distinguish between network-based geolocation and handset-based geolocation. *Id.*, 66:2–10, 68:22–71:5. That distinction is key.

140. The FCC Report specifically states that the Phase II requirements, on which the Petitioner relies, would “only permit network-based solutions” because it was not “economically or logistically feasible to expect or require that all current handsets be upgraded or replaced to meet that date.” EX-1017, 4. The FCC updated its rules to “permit” (but not require) handset-based solutions. *Id.* Notably, the FCC also recognized that “handset approaches will generally require a longer phase-in period....” *Id.*, 5; *see also id.* at 19-20 (“Commenters universally agree that some transition past October 1, 2001, is necessary to deploy a handset-based or hybrid technology....”).

141. Regardless, Petitioner has offered no evidence that any, much less all, cell phones included the claimed geolocation means *as of the priority date*. The FCC

Report further describes handset-location features as being planned by various manufacturers for the future, not as already incorporated into any currently available device. *Id.* at 15. Indeed, the FCC Report itself expressly acknowledges that its actions were “ambitious” and that “we may confront challenges as we move forward.” *Id.* at 5. The FCC Report also recognized significant problems in achieving universal coverage through handset-based solutions. *Id.* at 17. Even the FCC’s forward-looking goal set a date of December 31, 2004—almost a year after the priority date of the ’307 Patent—for carriers to make reasonable efforts to ensure that all customers’ handsets were location-capable. *Id.*, 25. The FCC acknowledged this was an “aggressive schedule.” *Id.* at 26.

142. Moreover, the FCC Report does not teach “geolocation” as taught in the ’307 Patent. At the time of the FCC Report, commercial implementations of GPS did not allow for precise geolocation. EX-1017, 2 (“[W]hen a 911 call is placed using a wireless handset, the dispatcher at the 911 Public Safety Answering Point (PSAP) does not know where the caller is.... Wireless calls may be received by the carrier at an antenna some distance away from where the call is actually placed, because of the vagaries of radio transmission, terrain, or network congestion.”); *id.* at 3 (“PSAPs do not know the location of wireless callers, except in a very general way in those PSAPs where Phase I (providing cell site or cell sector information) has been deployed.”). While technology available to the public (i.e., technology that was not

classified by the government due to safety or security concerns) could provide information regarding the general area of a target (e.g., the zip code), such geolocation was not precise enough to be useful for the applications contemplated by the '307 Patent. Indeed, even the changes contemplated by the FCC Report would not have allowed precise geolocation:

- We adopt the following revised standards for Phase II location accuracy and reliability:
 - For network-based solutions: 100 meters for 67 percent of calls, 300 meters for 95 percent of calls;
 - For handset-based solutions: 50 meters for 67 percent of calls, 150 meters for 95 percent of calls.

EX-1017, 7. *Even if* these standards were achieved by the time of the priority date, their imprecision would not have constituted “geolocation” as contemplated by the '307 Patent.

4. A POSITA Would Not Have Had a Reasonable Expectation of Success

143. I understand that an obviousness determination requires finding both ‘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. As to how the individual teachings of Beck, Heller, and Lovejoy would have been combined into an operable system or would have had a reasonable expectation of success, the Petition provides no explanation, instead relying on the *ipse dixit* of its expert. And

when asked, Dr. Sarrafzadeh refused to provide any details about the purported combination, such as what components it would include. EX-2011, 87:23–90:25, 95:15–96:17. In my opinion, this is insufficient, and demonstrates the proposed combination is based purely on hindsight.

B. The Petition Fails to Show that the Challenged Claims Are Rendered Obvious by Beck in View of Heller and Lovejoy

144. Even if there was sufficient motivation to combine Beck with Heller and Lovejoy, the resulting combination would not meet all the limitations of the challenged claims. What Dr. Sarrafzadeh ignores, and failed to explain in deposition, is that Heller’s device includes not only a “sensor control unit,” but also a “receiver/display unit.” Ex. 1016, 10:30–33. That component receives data from the sensor control unit. *Id.*, 3:20–23. To the extent a POSITA would combine Beck and Heller, such a combination would include that receiver/display unit, and it is that component that would communicate with Beck’s client computing device. But Dr. Sarrafzadeh refused to say what components would be included in his proposed combination, or whether the combination would include Heller’s receiver/display unit. Ex. 2011, 87:23–90:25, 95:15–96:17.

2. “unique identification ID number”

145. Claim 1 recites a diagnostic sensor unit comprising “a unique identification ID number.” This is consistent with the specification of the ’307

Patent, which describes downloading software related to a particular sensor. EX-1001, 11:49–60. If the cited ID number merely identifies a *type* of sensor, or the *medical device* used with that sensor, this is insufficient to meet the claim limitation. Beck discloses, at most, identification numbers for the entire medical device. Petitioner’s assertion is limited to a single paragraph and irrelevant cites regarding Beck’s disclosure of “identification codes” and “serial number[s]” “for the *medical device*”—not a sensor unit as required by the claim. Pet. 51 (emphasis added). But a medical device is not a sensor unit, and the difference dooms Petitioner’s invalidity ground. The invention of the ’307 Patent, as described in its specification, involves a wireless device reading data directly from a sensor module. *See, e.g.*, 2:66–3:5. Each sensor having a unique identifier is what ultimately allows the proper identification, retrieval, and downloading of the claimed software. *Id.*, 4:67–5:2; claim 1 (“software related to the unique sensor ID”). Note that such software identification, retrieval, and download can occur either *before* or *after* the unique sensor ID is formally authenticated by the remote server, since sensor “identification” and “authentication” are two different processes. This is contrary to the messaging repeatedly put forth by Dr. Sarrafzadeh in his declaration and deposition testimony, which errantly requires the “condition precedent” or “causal relationship” that unique sensor ID authentication must occur prior to any communication of processed information and software. EX-1003, ¶ 57; EX-2011,

52:3-19, 54:8-17, 55:4-9, and 55:21-56:13. Such a message from Dr. Sarrafzadeh is inconsistent with the plain meaning of the claim language. Notably, the Beck system operates under a completely different set of guidelines anyway. Because the Beck architecture works at the level of granularity of the medical device—and not the underlying sensors—it has no need for the sensors to have unique identifiers (and does not teach that they do).

146. As disclosed by Beck, a medical device could be, for example, a glucose meter. Ex. 1007, [0034]. But the glucose meter is not a sensor or a diagnostic sensor unit. The glucose meter uses test strips, which are the sensors that detect the glucose levels. Even Dr. Sarrafzadeh acknowledged that that “the test strip [is] part of the sensing system.” Ex. 2011, 32:12–16. Petitioner does not assert, and Beck does not disclose, that each individual test strip, or any other sensor for the glucose meter, has a unique identification ID number.

147. As another example, Beck discloses a medical device that monitors electrocardio-signals. Ex. 1007, [0034]. As acknowledged by Dr. Sarrafzadeh, a POSITA would know this as an EKG. EX-2011, 28:8–13. Dr. Sarrafzadeh also acknowledged that the electrodes and/or leads that are connected to the EKG are the sensors used by the EKG. EX-2011, 23:10–16, 30:17–19. Even if the EKG machine has a serial number, nowhere does Beck disclose that the electrodes/leads (sensors) each have a unique identification ID number. The leads are detachable from the EKG

unit, and replacing them with other leads would not change the serial number of the EKG itself.

148. Without identifying any disclosure of unique identification ID numbers of any sensors (as opposed to medical devices), Petitioner has failed to show this limitation is met for this ground.

3. “said wireless device having...a unique ID,” “wherein the remote server authenticates said unique sensor ID associated with said unique wireless device ID”

149. Claim 1 recites “said wireless device having...a unique ID” and later requires authentication of the “unique sensor ID associated with said unique wireless device ID.” Petitioner fails to show that either of these limitations is met. For the wireless device allegedly having a unique ID, Petitioner relies on Beck’s disclosure that authentication can include using a network address. Pet. 60; EX-1007 ¶ 65. But the paragraph cited by Petitioner does not refer to any particular type of network address. Pet. 60; EX-1007 ¶ 65. And a POSITA would understand that some network addresses might be unique, but others, such as internal IP addresses, which identify devices on a private network, may not be unique. As with Bandy in Ground 1, Petitioner’s argument relies on features not discussed anywhere in Beck (e.g., IMEI numbers and MAC addresses).

150. Petitioner makes the same fatal mistake as with Ground 1, citing only that “the serial number of the medical device” (i.e., the purported unique ID of the

sensor unit) is used in authentication (Pet. 62), while ignoring that the limitation requires authentication of “said unique sensor ID associated with *said unique wireless device ID*” (EX-1001, claim 1) (emphasis added). Under my proposed claim construction, that limitation requires receipt by the remote server of the unique wireless device ID. Even under the Board’s preliminary claim construction, Petitioner must show that the unique sensor ID is “associated with the unique wireless device ID.” Nowhere does Petitioner provide any disclosure in the prior art of either requirement.

4. “geolocation means”

151. Claim 1 recites a “wireless device having...geolocation means....” Petitioner argues that this limitation is met because (1) “Beck discloses...an internet enabled cellular phone” and (2) “a POSITA would have been motivated to modify Beck’s client computing device to add geolocation disclosed by Lovejoy....” Pet. 60. Neither of these arguments holds water.

152. First, as discussed above, Petitioner’s assertion that a POSITA would have been motivated to combine Beck and Lovejoy is flawed and based entirely on hindsight.

153. Second, Petitioner has failed to show how the existence of a cellular phone necessarily includes the particular structure (or an equivalent structure) disclosed by the ’307 Patent for performing geolocation. While Petitioner asserts

that an “internet cellular phone” would have been “required to have GPS and non-GPS geolocation capability before the priority date of the ’307 patent,” that is patently false. Pet. 60. For this assertion, Petitioner cites the FCC Report. Pet. 60, citing EX-1017. But Petitioner and its expert ignore that ways existed to geolocate a device that did not require any structure for geolocation in the device itself.

154. Indeed, the FCC Report explicitly recognizes both “network-based solutions,” which do not require implementation of a geolocation component in the wireless device itself, and “handset-based solutions,” which would require such an implementation. *See, e.g.*, EX-1017, 4. Importantly, the entire purpose of the FCC Report was to address the lack of “handset-based solutions” for geolocation (i.e., the cellular phones at issue did not include internal geolocation features). *Id.* (“The Commission’s current rules, however, as a practical matter only permit network-based solutions....”). Thus, the FCC Report in no way supports that the vaguely described “Internet enabled cellular phone” in Beck would have included internal geolocation components. If anything, it suggests the opposite. And the “network-based solutions” disclosed in the FCC Report cannot meet the “geolocation means” limitation because they do not include a geolocation component in the wireless device, as claimed.

155. Further, while the FCC Report revises certain rules, it does not establish that all (or any) cell phones were *in compliance* with those rules (or met the

geolocation limitation) at the relevant time. Indeed, the revision of the rules was necessary because the rules in place at the time were preventing service providers from including geolocation features in handsets. EX-1017, 4. And the FCC recognized that it was not “economically or logistically feasible to expect or require that all current handsets be upgraded or replaced to meet [the target date].” *Id.* Regardless, Petitioner has offered no evidence that all cellular phones included a geolocation means or that such a means was inherent in the disclosure of Beck. Petitioner’s reliance on the FCC Report as allegedly requiring geolocation in cellular phones before the ’307 Patent’s priority date (Pet. 45–46) is also undermined by the testimony of its own expert. When presented with the fact that the FCC Report did not require all handsets sold as of March 1, 2001 to have geolocation capability, Dr. Sarrafzadeh retreated by saying his opinion was that it would have been obvious to include geolocation capabilities, and never said that such geolocation capabilities were necessarily included. EX-2011, 77:17–22. But that is contrary to the position he took in his declaration in support of the IPR petition. EX-1003, ¶246 (“[T]he inclusion of geolocation features was required by the FCC well before the priority date of the ’307 patent....”). Further, Dr. Sarrafzadeh, who did testing on cellular phones around the time of the invention, could not recall if any of the phones he tested had geolocation capabilities. EX-2011, 42:19–43:6.

156. Third, even combining Beck, Heller, and Lovejoy (with or without the FCC Report), the resulting system still does not meet the “geolocation means” limitation. Petitioner is relying on a disclosure from Lovejoy related to geolocation of Lovejoy’s *personal monitors*—the components, worn by the subjects, that measure the exposure to hazards of those subjects. This maps—if at all—to the diagnostic *sensor* of claim 1. But it is the claimed *wireless device* that includes the geolocation means, not the sensor. Petitioner does not even attempt to show that any portion of Lovejoy discloses a wireless device having a geolocation means (because it does not).

157. While Beck includes an embodiment where an “Internet enabled cellular phone” is used as a reader, adding a geolocation means to Beck’s reader would have been nonsensical, as such means would only indicate where the reader (or person performing the reading, such as a nurse) is located—not where the sensor (or the patient wearing such a sensor who may be remote from the reader) is located. In the case of an emergency, this would result in routing a crash cart to the nurse, not the patient. Including the geolocation means in the claimed wireless device of the ’307 Patent, conversely, makes sense because the user of the wireless device *is also the patient* wearing the sensor (i.e., they are in the same location, as evidenced by the use of the short-range wireless techniques upon which RFID tags in the ’307 Patent are predicated). Beck’s system is simply unrelated to the claimed system.

5. “a sensor interface having an analog to digital converter coupled to the at least one sensor and reference sensor element”

158. Claim 1 recites a radio frequency (RF) addressable diagnostic sensor unit comprising “a sensor interface having an analog to digital converter coupled to the at least one sensor and reference sensor element.” Petitioner argues that Beck, alone or in view of Heller, renders this limitation obvious because (1) a POSITA would have understood that collected “measurement data” would be analog, and (2) the “analog data must be converted into a digital signal for processing by processor 132 of the medical device 130.” Pet. 51–52. Petitioner focuses on Beck’s general disclaimer that the software components shown in Figure 2 can be replaced with hardware components, including “analog/digital hybrid circuits.” *Id.*; EX-1007 ¶ 44. But Petitioner fails to indicate which portion of Figure 2 discloses a “sensor interface,” “sensor,” or “reference sensor element.” In fact, for the “reference sensor” limitation, Petitioner relies on Heller, not Figure 2 (or any other part) of Beck, and this limitation is absent from Beck. Pet. 49–51.

159. Beck’s lack of disclosure of this limitation is unsurprising. As discussed above, Beck discloses a system that connects to commercially available medical devices. Beck does not disclose the internal operation of any of those medical devices.

160. Nor is this limitation inherent in the disclosure of Beck. To the extent Beck and/or Heller disclose an analog sensor and an analog reference sensor—and Petitioner has provided no evidence that is the case—there are ways to calculate a value based on those two sensors without first converting them to digital values. In doing so, neither sensor would be coupled to any analog to digital converter. And Petitioner, which has the burden of proving unpatentability, has not demonstrated otherwise.

C. Petitioner Fails to Show that the Asserted Combination Renders Obvious Dependent Claims 2, 3, 5, 9, and 10

161. As Petitioner has failed to establish that claim 1 is not patentable, it likewise cannot prevail on dependent claims 2, 3, 5, 9, and 10.

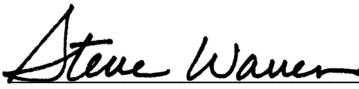
162. In addition to the reasons set forth above, the Petition makes no attempt to show that the asserted prior art satisfies the additional requirements of dependent claims 9 and 10. The Board has construed those claims as means-plus-function claims requiring a structure of “GPS methods or processing logic for determining a geographic position of an object” (claim 9) or “non-GPS triangulation methods or processing logic for determining a geographic position of an object” (claim 10). Inst. Dec. 12–13. Petitioner has not identified any structure of this type in the disclosures of the asserted prior art, and Petitioner has failed to demonstrate that these structures were common cell phone features as of the priority date.

XII. CONCLUSION

163. For the reasons discussed herein, it is my opinion that Petition has not met its burden of demonstrating the unpatentability of any challenged claim.

164. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and 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: October 15, 2024

By: 
Steven Warren, Ph.D.