

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Abbott Diabetes Care Inc.,
Petitioner,

v.

DexCom, Inc.,
Patent Owner.

Case No. IPR2024-00861
Patent No. 9,801,541

**DECLARATION OF LANE DESBOROUGH IN SUPPORT OF PETITION
FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,801,541 UNDER 35
U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *et seq.***

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I. INTRODUCTION

1. I, Lane Desborough, have been retained by counsel to render certain opinions as an expert witness, for the above-referenced *inter partes* review (“IPR”) proceeding regarding U.S. Patent No. 9,801,541 B2 (the “’541 Patent”). In connection with my analysis, I have reviewed the ’541 Patent, the respective file history, and the documents listed in Section III, below. I have been asked to provide a declaration regarding my opinions on the patentability of claims 1-7, 9, 11, 13, 15-17 of the ’541 Patent.

2. This report sets forth the opinions I have formed in this IPR and provides the bases and reasons for those opinions. I have summarized in this section my educational background, professional experience, and publications.

3. This report is based on information currently available to me. I have personal knowledge of the facts set forth in this declaration and, if called to testify as a witness, could and would do so competently.

4. I am being compensated at my usual litigation consulting rate for my work on this matter. My compensation is in no way dependent upon my opinions or testimony or the outcome of this proceeding. To the best of my knowledge, I have no financial interest in Abbott. To the extent any mutual funds or other investments that I own have a financial interest in the Abbott, I am not aware of,

nor do I have control over, any financial interest that would affect or bias my judgment.

II. PROFESSIONAL BACKGROUND AND QUALIFICATIONS

5. I have included below a description of my professional background and qualifications. In addition, my education and professional experience are described in my curriculum vitae, Ex-1004.

Education

6. I graduated with a Bachelor of Science in Chemical Engineering from the University of Waterloo in 1990. I received a Master's degree in Chemical Engineering from Queen's University in 1992, for which my thesis was titled, "Performance Assessment Measures for Univariate Control."

7. Chemical Engineers often specialize in one of several domains: process control, heat transfer, thermodynamics, organic chemistry, physical chemistry, etc. I specialized in process control, which focuses on the application of computers to the control and monitoring of continuous process industry facilities such as oil refineries and chemical plants. The subject of my graduate work was developing methods for monitoring the performance of industrial control loops.

Relevant Employment History

8. After completing my graduate engineering studies in 1992, I started my career as a process control engineer at Nova Chemicals (then called

NOVACOR) in Joffre, Alberta, at a large petrochemical production site. I worked on a project to upgrade the control system for one of the plants. This work involved connecting sensors (transmitters) to a network of computers, which in turn connected to consoles in the control room, allowing operators to receive alarms and display graphs, thereby enhancing their ability to monitor and control the plant. During this project, I became interested in alarm systems and automation human factors.

9. I joined Honeywell International, Inc. in 1995 to pursue this interest. Honeywell was and remains one of the world's largest providers of industrial automation systems. At Honeywell, I implemented and remotely monitored automation systems at oil refineries, chemical plants, pulp mills, power plants, and mines.

10. In 1998, I led the team which created Honeywell Loop Scout, a Software as a Service ("SaaS") offering to remotely monitor and diagnose control loops. Loop Scout securely collected data from hundreds of sites, transported the data to a central server, analyzed that data, and provided reports / notifications to control engineers.

11. In 2000, I led a team which developed Alarm Scout, a remote monitoring SaaS for alarm systems which was used to identify troublesome alarms and improve overall alarm system performance at customer facilities.

12. In 2008, I left Honeywell and joined a new system engineering team at General Electric Energy Services. One of my first activities was to help redesign GE Energy Service's Remote Monitoring and Diagnostics (RM&D) system, which led one year later to a new role as Product Manager for the RM&D center. The RM&D center collected data from over a thousand gas turbine combined cycle power plants, securely transported it to a central server, generated notifications, and sent those notifications to authorized personnel who then retrieved additional diagnostic data such as graphs and trends from the server. GE was and continues to be one of the largest providers of remote monitoring and diagnostic services for various industries it serves. As of 2010, when I was product manager for the RM&D center, GE was also remotely monitoring locomotives, aircraft, wind turbines, gas turbines, and CT / MRI machines from various RM&D centers around the world.

13. During my tenure at GE, in 2009, my then-10-year-old son was diagnosed with type 1 diabetes. I am not a physician, yet our family learned very quickly that type 1 diabetes is a chronic condition requiring frequent interactions (up to many dozens daily) to manage blood glucose variation with insulin. The activities of daily life—eating, exercise, social interactions, sleep—can have a large effect on blood glucose. As an engineer, I also consider Type 1 diabetes as a data condition: insulin delivery—automated or manual—is informed by the person

with diabetes' physiological and behavioral data. Real time and historical data related to blood glucose, meals, and physical activity is used to determine the timing and magnitude of insulin injections (boluses, basal adjustments) and other therapeutic interventions (e.g., carbohydrate "rescues" or glucagon administration for hypoglycemia). For people with type 1 diabetes ("pwd"), mistakes, lapses, and errors in insulin dosing can result in severe adverse consequences.

14. The physical, cognitive, and emotional burdens of managing blood glucose which are borne by the person with diabetes can be shared remotely with care partners near and far, including parents, teachers, school nurses, and coaches of children with diabetes; partners and coworkers of adults with diabetes; and adult children of older adults with diabetes. Soon after my son's diagnosis, it became apparent to me that remote monitoring would be a helpful feature of glucose monitoring for parents of children with type 1 diabetes.

15. Shortly after my son's diagnosis, we enrolled him in a clinical trial testing the safety and efficacy of Automated Insulin Delivery ("AID"), at Stanford University under the care of Dr. Bruce Buckingham. I learned from Dr. Buckingham that Medtronic had developed but not yet commercialized a prototype remote monitoring system, mySentry. The mySentry included a "wall unit" (later called the mySentry Outpost) placed in the child's bedroom, and a remote monitor

akin to a “baby monitor,” from which parents—in a remote location such as their bedroom—could receive alarms and review glucose trends.

16. In part motivated by my knowledge of mySentry, I joined Medtronic in April 2010 as a Product Strategist, reporting to the CTO of Medtronic’s diabetes division. Medtronic was, and is, one of the largest medical device companies in the world. Medtronic developed the first commercial continuous glucose monitor (“CGM”), insulin pump, and AID system. My responsibilities as Product Strategist included evaluating how new consumer technologies and connectivity could reduce the burden for families living with type 1 diabetes.

17. Shortly after I joined Medtronic, the company permitted my family to use a prototype mySentry to remotely monitor my son’s glucose values. The mySentry CGM system included four main components: a continuous glucose sensor, a Medtronic insulin pump acting as a receiver, an Outpost that relayed the signal, and a monitor. The monitor displayed real-time insulin pump status and glucose data and conveyed audible alerts and alarms. The monitor could be used to silence these notifications for the monitor and to view current and historical glucose data.

18. The mySentry prototype allowed us to monitor my son’s glucose remotely, e.g., from our bedroom overnight. My son’s schoolteacher remotely monitored his glucose using another mySentry unit. We used mySentry for most of

the rest of 2010 and then returned it to Medtronic. Based on our experience, I began to envision building my own remote monitoring system, using commercial, off-the-shelf technologies. Medtronic's protocols were public and unencrypted, which allowed anyone with knowledge of basic wireless protocols to create systems to wirelessly receive data from Medtronic insulin pumps.

19. In early 2011, I devised and built a remote monitoring project, which I called pcSentry because it used laptop PCs. We used the pcSentry system through April 2013, when my son stopped using the Medtronic CGM and started using the Dexcom G4 CGM.

20. After my son's switch to the Dexcom product, I researched how to remotely monitor the Dexcom CGM and collaborated with others on what eventually became known as Nightscout, an open-source diabetes remote monitoring system. Nightscout was never commercialized. Instead, it was offered as "educational source code" for anyone to download and install for their own family's use. I believe that approximately fifty thousand families around the world use Nightscout. I have not personally been involved in Nightscout software development since 2013.

21. In late 2014, I left Medtronic and co-founded Bigfoot Biomedical. As Chief Engineer, I was responsible for AID algorithm and simulator development. Although Bigfoot was not focused on remote monitoring per se, we recognized that

it would be advantageous to provide remote monitoring during clinical trials, and remote monitoring was made available to the clinical staff to monitor the status of the Bigfoot system and the delivery of therapy. I have no remaining financial interest in Bigfoot Biomedical.

22. In the fall of 2019, I joined AITA Bio, which was focused on early-stage development of a novel insulin pumping mechanism for which I was providing data science support.

23. In January 2020, I co-founded Nudge BG. I am currently CEO of Nudge BG, an engineering consulting services and algorithm development company focused on the modeling, simulation, and control of physiological systems such as AID for people living with insulin-requiring diabetes. At Nudge BG, my activities related to remote monitoring have been limited to pro bono advocacy to encourage CGM companies and the FDA to allow people with diabetes to programmatically access their data in real time.

Publications and Patents

24. I am the lead or other named author on over a dozen published journal articles on topics ranging from process control to automated insulin delivery to remote monitoring and diagnostics.

25. I am a named inventor on over 30 issued U.S. patents and pending U.S. patent applications.

III. MATERIALS AND OTHER INFORMATION CONSIDERED

26. In connection with my study of this matter and reaching the opinions stated herein, I have reviewed the exhibits in the table below and any cited sources identified in this Declaration.

Exhibit	Description
1001	U.S. Patent No. 9,801,541 (the “’541 patent”)
1002	File History for U.S. Patent No. 9,801,541
1005	U.S. Patent Pub. No. 2008/0154099 (“Aspel”)
1006	U.S. Patent Pub. No. 2011/0173308 (“Gutekunst”)
1007	Breen, Christopher, <i>The iPhone Pocket Guide</i> , Sixth Ed. (Nov. 2011) (“Breen”) (scanned excerpt)
1008	U.S. Patent No. 7,301,463 (“Paterno”)
1009	U.S. Patent Pub. No. 2011/0320130 (“Valdes”)
1010	U.S. Patent Pub. No. 2012/0313785 (“Hanson”)
1011	Joint Claim Construction Chart, Doc. 107, <i>Abbott Diabetes Care Inc. et al v. DexCom, Inc.</i> , No. 1:23-cv-00239 (D. Del. Mar. 21, 2024)
1012	DexCom Inc.’s Opening Claim Construction Brief, Doc. 123, <i>Abbott Diabetes Care Inc. et al v. DexCom, Inc.</i> , No. 1:23-cv-00239 (D. Del. Apr. 18, 2024)

IV. UNDERSTANDING OF APPLICABLE LEGAL STANDARDS

27. Although I am not an attorney, I have a general understanding of the applicable legal standards pertaining to the patentability issues presented in this proceeding. I understand that, in this *inter partes* review, Petitioner has the burden of proving that each challenged claim is unpatentable by a preponderance of the evidence.

28.I understand that a patent claim is unpatentable if, at the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of the prior art to yield the patent claim.

29.I also understand that it is not required (although it is acceptable) that each element of a patent claim be found in a single reference to find a patent claim obvious. For a patent claim to be found obvious, all the elements of the patent claim may also be found in a combination of references at which a person of ordinary skill in the art would have been reasonably expected to arrive.

30.I understand that a proper analysis of whether an invention is unpatentable for obviousness includes a review of the scope and content of the prior art, the differences between the patent claims at issue and the prior art, the level of ordinary skill in the field of the invention at the time of the invention, and other objective considerations identified below.

31.I understand that a showing of obviousness requires some articulated reasoning with a rational underpinning to support the combination of the references. I understand that one of ordinary skill in the art has ordinary creativity and is not an automaton.

32.I understand that in consideration of the issue of obviousness it is important to identify whether a reason existed at the time of the invention that

would have led a person of ordinary skill in the pertinent art to combine elements of the references in a way that yields the claimed invention.

Petitioner's counsel has informed me that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered.

33. I understand that a claim may be considered unpatentable for obviousness for various reasons. I have been informed that the following exemplary rationales may support a finding of obviousness:

(A) combining prior art elements according to known methods to yield predictable results;

(B) simply substituting one known element for another to obtain predictable results;

(C) use of a known technique to improve similar devices in the same way;

(D) applying a known technique to a known device ready for improvement to yield predictable results;

(E) choosing from a finite number of identified, predictable solutions with a reasonable expectation of success;

(F) known work in a field that prompts variations in the work in the same or a different field that leads to predictable results; and

(G) some teaching, suggestion, or motivation in the prior art that would have led a person of ordinary skill in the art to modify a prior art reference or combine multiple prior art references or teachings to arrive at the claimed invention.

34. I understand that various objective or “real world” factors may be indicative of non-obviousness. I understand that such factors include: the commercial success of the claimed invention; the existence of a long-felt, unresolved need for a solution to the problem solved by the claimed invention; failed attempts to solve the problem solved by the claimed invention; copying of the claimed invention; unexpected results of the claimed invention; praise for the claimed invention by others in the relevant field; and willingness of others to accept a license under the patent because of the merits of the claimed invention.

V. LEVEL OF ORDINARY SKILL

35. A person of ordinary skill in the art (“POSITA”) as of December 2012 would have had a Bachelor’s degree in biomedical engineering, chemical engineering, mathematics, statistics, or computer science (or a related or equivalent field), and two or more years of experience researching, developing, designing and/or evaluating (or supervising the same) systems for measuring and monitoring (including remote monitoring) of a host’s analyte data, or similar data, or

equivalent experience. A person with less or different education but more relevant practical experience, or vice versa, may also meet this standard. Each of these POSITAs may be part of an interdisciplinary team with others having the relevant experience set forth above and/or with clinicians involved in diagnosing, treating, monitoring, and managing patients using medical devices.

VI. CLAIM CONSTRUCTION

36. In making this Declaration, I have been asked to consider the terms found in the claims of the '541 Patent according to their “ordinary and customary meaning” in light of the specification, a standard applied in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), for how those terms would have been understood to a POSITA at the time of the claimed invention in December 2012.

37. I have been asked to apply specific claim constructions for certain claim elements based on the constructions proposed in the copending district court litigation. I reviewed the table of proposed constructions, (Ex-1011, pp.12-13), and DexCom's Opening Claim Construction Brief, (Ex-1012, pp.12-18). Abbott argues in that proceeding that certain terms of the '541 patent are indefinite, but DexCom argues “plain and ordinary meaning.” I have been instructed for this proceeding to adopt DexCom's explanation of those terms from its claim construction brief. Ex-1012, pp.12-18.

38. I am informed Petitioner reserves the right to dispute in a different forum whether the Challenged Claims are definite under 35 U.S.C. § 112.

VII. SUMMARY OF OPINIONS

39. As addressed in detail below, it is my opinion that claims 1, 4-7, 9, 11, 13, and 15-17 would have been obvious based on Aspel in view of Gutekunst under 35 U.S.C. § 103; claims 2-3 would have been obvious based on Aspel in view of Gutekunst and Breen under 35 U.S.C. § 103; claims 1, 4-7, 9, 11, 13, and 15-17 would have been obvious based on Paterno in view of Valdes and Hanson under 35 U.S.C. § 103; and claims 2-3 would have been obvious based on Paterno in view of Valdes, Hanson, and Breen under 35 U.S.C. § 103.

VIII. TECHNOLOGY BACKGROUND

40. The following section provides an overview of relevant technology before or in 2012.

A. General Overview of Monitoring and Diagnostics Workflows and Systems

41. Based on my three decades of remote monitoring and diagnostics experience across multiple domains, “monitoring” can be thought of as refocusing attention on the aspect of the system requiring attention, based on changes in data values, while “diagnostics” is the gathering of additional contextual data to determine an appropriate course of action once attention has been refocused. *See* Desborough L., Miller R., *Increasing customer value of industrial control*

performance monitoring: Honeywell's experience. In: AIChE symposium series. American Institute of Chemical Engineers, New York, pp 169-189 (2002).

42. Monitoring and diagnostics tasks—and the systems which support them—have existed for over 60 years. One of the first remote monitoring systems for physiologic data was developed in the late 1950s during the NASA Gemini Program where astronauts' physiological data was monitored while in space by NASA officials on the ground: “Spacelabs Medical was co-founded by Ben Ettelson and James A. Reeves in 1958 for the express purpose of working with NASA and the U.S. Air Force on systems to monitor the vital signs of astronauts in space. As a prime contractor to NASA for the Gemini Program, Spacelabs Medical company manufactured and delivered prototypes of miniaturized signal conditioners to measure astronauts' temperature, respiration, and cardiac activity. This technology was first worn by astronauts James A. McDivitt and Edward H. White II during their historic Gemini IV flight—the first American spacewalk—to assure proper evaluation of their health and performance.” *See* Space-Proven Medical Monitors: The Total Patient Care Package, https://spinoff.nasa.gov/Spinoff2006/hm_2.html (2006). Spacelabs is now a leading provider of remote monitoring in healthcare. *See* Spacelabs Healthcare, <https://spacelabshealthcare.com/>; [Patents and Trademarks, https://spacelabshealthcare.com/about-us/patents-trademarks/](https://spacelabshealthcare.com/about-us/patents-trademarks/).

43. NASA / Spacelabs Medical illustrates that real time remote monitoring of health data has occurred for as long as there has been a capability to collect real time health data electronically, with radios to transport that data via wireless transmission, and computers to store, process, and present this data as notifications or visualizations.

44. Beginning in the 1960s, systems were developed to allow control room operators to monitor and control potentially hazardous industrial facilities located at a distance. For instance, at the NOVACOR site in Joffre, Alberta, Canada, there was a specialized system in the computer room, which was used to monitor remotely located pipelines for potential leaks. Even the on-site control rooms can be hundreds of meters (or more) from the process units themselves, to minimize exposure to dangerous or explosive chemicals. I was involved with a project to upgrade the control system for the Joffre plant. This involved connecting sensors (transmitters) to a network of computers, which in turn connected to consoles in the control room, allowing operators to receive alarms and display graphs, thereby facilitating their ability to monitor and control the plant. While these early monitoring efforts were not identical to the remote monitoring subject matter of the '541 patent, they illustrate the general concept of monitoring data being generated elsewhere.

B. Continuous Glucose Monitors

45. Practical, useful realtime CGMs first appeared commercially in 2007, a few years before my son was diagnosed with Type 1 diabetes. CGMs include a small sensor implanted just under the skin that transmits a wireless signal to a local receiver (or insulin pump serving as a receiver). CGMs provide data in the form of a time series of estimated glucose values (“egvs”). These measurements are referred to as *estimated* glucose values because the sensor does not directly measure glucose levels in venous or capillary blood but measures the interstitial fluid.

46. CGMs also typically provide capabilities to turn their data into events that will prompt a user to take corrective action. For example, the CGM might detect when the egv crosses a threshold indicating the possibility of low blood glucose (“hypoglycemia”), which would trigger a notification. These notifications—also referred to as alarms and alerts—help the person with diabetes or their caregiver monitor if glucose values are unsafe. The CGM can provide additional context, such as a historical egv trend graph, to help determine a proper course of action. Corrective actions include consuming additional carbohydrates, e.g., glucose tablets, to raise blood glucose or administering a bolus of additional insulin to lower blood glucose.

C. Remote Monitoring of CGM Data

47. As mentioned above, I had access in 2010 to a prototype of the Medtronic mySentry remote monitoring product. Medtronic received FDA approval for mySentry in January 2012. As stated above, mySentry was a continuous glucose-monitoring system with four primary components: a continuous glucose sensor, an insulin pump, a signal transceiver, and the mySentry remote monitoring device. Other CGM remote monitoring activity had emerged by 2011, for several reasons.

48. **CGMS were widely available but considered Class III.** The primary impediment to development of remote monitoring systems was regulatory. I am not a regulatory expert but understand that the Food and Drug Administration (“FDA”) classifies medical devices into different classes. Each class imposes a set of legal requirements on the device manufacturer to gain approval to manufacture and sell the device. The FDA pathway for Class III devices is expensive and time consuming. At the time, any device which interacted with a Class III device, including a remote monitoring system over a network connection, itself became a Class III device.

49. **CGMs used proprietary but open communications.** CGMs use radio signals to communicate glucose information from body-worn transmitters connected to a sensor to nearby receivers, including some insulin pumps. By 2012,

it was possible to gain direct access to transmissions from CGMs and insulin pumps. This enabled the development of remote monitoring systems that were based on publicly available general-purpose tools and hosting services. At the same time, Bluetooth Low Energy (BLE) had emerged as a de facto standard for low bandwidth, low energy local wireless communications.

50. **CGM data, once collected, was easily monitored.** The use of CGM remote monitoring uses general practices of data collection, data transportation, data storage, data notification, and data presentation methods, tools, and processes, because the technical requirements are low as compared, for instance, to gas turbine or aircraft or locomotive remote monitoring. Full stack software developers can and have created CGM remote monitoring systems.

51. **Smartphones with push notifications were widely available.** By 2012, it was widely recognized that smartphones were replacing other devices, including medical devices, so that users would have fewer devices to carry. I was aware of this trend while working at Medtronic. People with diabetes preferred fewer devices to buy, carry around, pair, and (re)charge. By 2012, push notifications were an accepted and necessary feature of smartphone apps to exchange data with server systems.

52. As noted above, I and other technically inclined people affected by diabetes worked to develop and use remotely monitored CGM systems. For

example, I and other volunteer engineers in the diabetes community designed and built Nightscout, a remote monitoring system using widely available software and database technologies.

53. The following table provides a summary of just some of the technological milestones related to remote monitoring.

Technology	Year	Example
Vital sign remote monitoring	1960s	NASA, Spacelabs Medical
Client-server architecture	1960s	IBM System/360
Digital SCADA systems	1970s	Honeywell
Cellular networks	1973	1G network by NTT (Japan)
Internet	1983	TCP/IP protocol adopted
Wi-Fi networks	1997	Wi-Fi Alliance founded
CGMs (real-time)	2007	Medtronic Guardian
iPhone	2007	iPhone 1
Push notifications	2009	Apple iOS 3.0
Prototype CGM remote monitoring	2009	Medtronic Diabetes
Bluetooth Low Energy (BLE)	2010	Bluetooth 4.0 specification
Smartphone with BLE	2011	iPhone 4S
Commercial CGM remote monitoring	2012	Medtronic Sentry

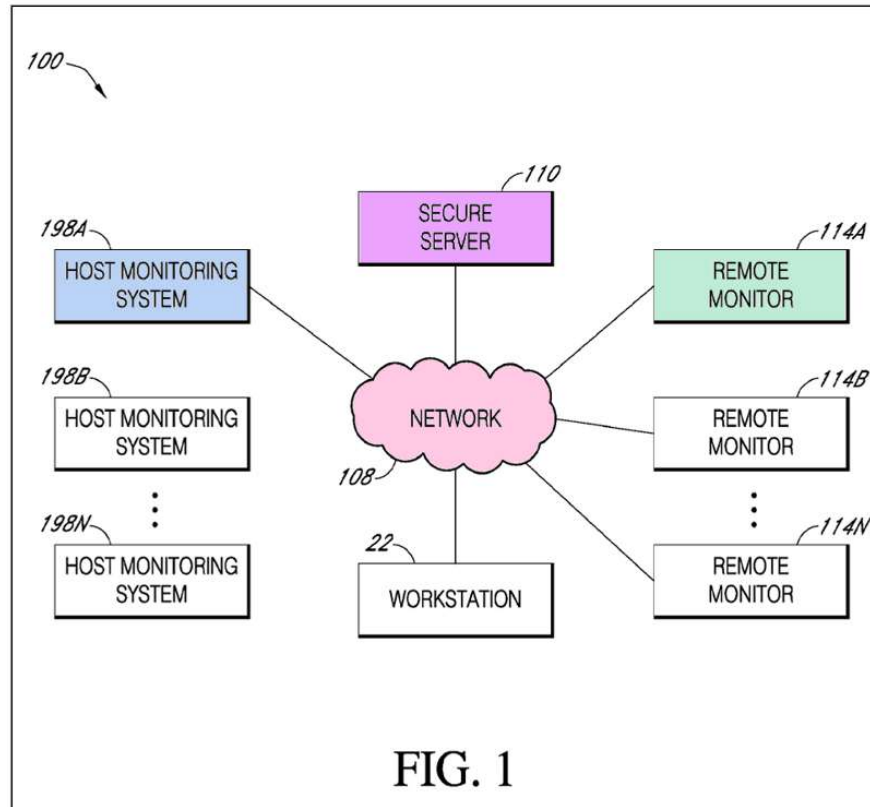
Wearable-smartphone BLE connection	2012	Fitbit One
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IX. ANALYSIS OF THE '541 PATENT

54. The '541 patent relates to methods and systems for “remote monitoring.” Ex-1001, 1:17-18. The disclosed system purports to enable “one or more caretakers (e.g., parent, spouse, or healthcare practitioner) to remotely monitor health characteristics of hosts, including an “analyte concentration of a host, such as glucose.” Ex-1001, 4:25-31. The '541 patent acknowledges that by the time of its earliest possible priority date of December 31, 2012, the following were known in the art: CGM systems; devices for remote monitoring; and the ability to transmit data from one person or device to another and between locations via wireless connectivity.

55. The '541 patent's claimed methods and systems “may include receiving, at a remote monitor, a notification message representative of an event detected, by a server, from analyte sensor data obtained from a receiver monitoring an analyte state of a host” and presenting analyte sensor data to the remote monitor. Ex-1001, 1:57-2:4. These were well-known ways of computer-automating the sending and provision of medical data to a remote device configured to modify certain settings of the host, as shown in the patent's figures.

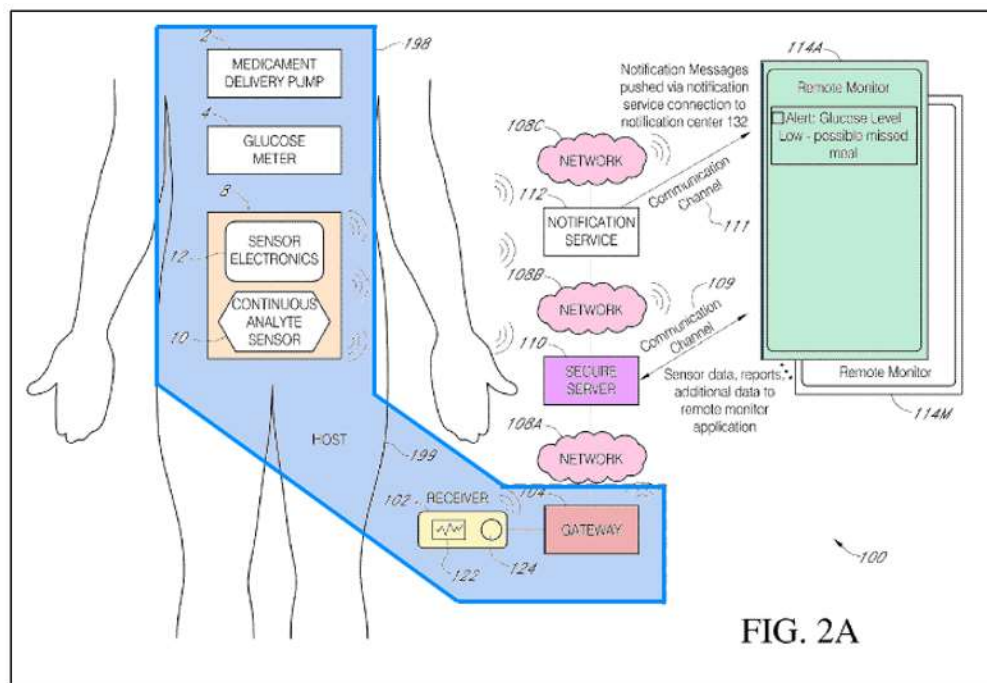
56. Figure 1, below, depicts “a high-level system architecture of an implementation of remote monitoring system 100.” Ex-1001, 5:46-47.



Ex-1001, Fig. 1.¹ Figure 1 includes a plurality of “host monitoring systems 198A-198N connected to a plurality of remote monitors 114A-114M via network 108.” Ex-1001, 5:47-50. Figure 1 also depicts “one or more servers 110 to process the health-related data received from and transmit notifications and data to one or more remote monitors 114A-114M.” Ex-1001, 5:62-6:2.

¹ All patent figures in this declaration that include color have been annotated, unless otherwise noted.

57. Figure 2A depicts a system architecture for an embodiment of remote monitoring system 100, including additional details regarding “host monitoring system 198.” Ex-1001, 3:45-47, 13:37-45.



Ex-1001, Fig. 2A. In Figure 2A above, “host monitoring system 198” includes a “sensor system 8 including a sensor electronics module 12 and a continuous analyte sensor 10” attached to “host 199,” Ex-1001, 6:48-60, a “receiver 102,” Ex-1001, 6:61-67, and a “gateway 104” comprising a “docking station 103 and a host communication device 105²,” Ex-1001, 7:1-10, 13:38-41.

² The Challenged Claims recite a *host device*. The specification refers to the “gateway 104” including either a “host device 105,” e.g., Ex-1001, 22:60–66, or “host communication device 105,” Ex-1001, 13:41–46.

A. Prosecution History

58. A brief summary of the lengthy file history of the '541 patent reflects that it was filed as Application No. 13/842,679, which was filed on March 15, 2013, claiming priority to U.S. Provisional Application No. 61/747,717, filed December 31, 2012. Ex-1001, Cover.

59. After three office actions rejecting the claims and corresponding responses, the examiner issued a final rejection of the then-pending claims on January 12, 2017. Ex-1002, 158-178. DexCom's response amended new claim 1 on April 11, 2017, as follows:

Declaration of Lane Desborough in Support of Petition for *Inter Partes*
Review of U.S. Pat. No. 9,801,541

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A method comprising:
receiving, at a wireless mobile remote monitor, an alert notification message from a server system, the alert notification message representative of an event detected by a server, the event being based on analyte concentration sensor data obtained from a receiver monitoring an analyte state of a host, the analyte concentration sensor data indicating a concentration of an analyte of the host, the wireless mobile remote monitor being remote to the host and the server system;
presenting, at the wireless mobile remote monitor, the alert notification message, wherein the wireless mobile remote monitor or a user of the wireless mobile remote monitor is configured specifically authorized by the host server to receive the alert notification message to augment the receiver monitoring of the analyte state of the host, wherein the wireless mobile remote monitor or the user of the wireless mobile remote monitor is authenticated by the server system;
receiving, at the wireless mobile remote monitor, user input indicative of acknowledgment of the presented alert notification message;
sending an acknowledgment message from the wireless mobile remote monitor to the server system indicating acknowledgement of the presented alert notification message to enable the server system to confirm that the alert notification message has been received;
after sending the acknowledgment, accessing, by the wireless mobile remote monitor, at least some of the analyte concentration sensor data from the server system, in response to the acknowledgement of the presented alert notification message; and
receiving, in response to the accessing, information the at least some of the analyte concentration sensor data including historical data, the at least some of the analyte concentration sensor data being generated by the receiver monitoring the analyte state of the host including at least the analyte sensor data,
wherein the alert notification message includes a short message and the receiving the alert notification message is over at least a first wireless connection between the remote monitor and a notification service in communication with the server, the first wireless connection comprising a persistent, encrypted connection configured to carry the short message pushed by the notification service to a notification message center at the remote monitor;
wherein the short message is structured by the notification service to be received by the remote monitor over the first wireless connection, and wherein the information is received over at least a second, different wireless connection between the remote monitor and the server, the second wireless connection comprising a momentary, encrypted connection established, in response to the accessing, to provide the information.

Ex-1002, 117-118. The Examiner and DexCom had another interview on June 6, 2017, to discuss the claims. Ex-1002, 94. According to the documentation, DexCom agreed to “include a limitation that recited in part that the event was detected by the server based on one or more set of rules configured by the host using the receiver,

and at least one of the set being modifiable by the user of the remote monitor using the remote monitor.” Ex-1002, 94.

60. The Examiner allowed the claims on June 14, 2017. Ex-1002, 78-93. The Examiner filed corrected Notices of Allowance on August 11, 2017, and October 5, 2017. Ex-1002, 9-10, 32-77. The patent was issued on October 31, 2017. DexCom then filed a notice of correction on February 7, 2018, to address five identified errors in the specification, including two identified errors in claim 1. Ex-1002, 3-7.

X. OVERVIEW OF THE PRIOR ART

A. Aspel (Ex-1005)

61. The Aspel reference is U.S. Patent Application Publication No. 2008/0154099, titled “Health Monitoring System and Method,” to Aspel (“Aspel”). It was filed on November 6, 2007, and published on June 26, 2008. Ex-1005, p.1. I understand and am informed that Aspel qualifies as prior art to the ’541 patent.

62. Aspel discloses a “system for ongoing collection, transmission, storage, analysis, and presentation of physiological and other personal data from individuals” to “authorized system users” like “medical doctors and other Caregivers.” Ex-1005, Abstract. The system “collects data from medical and measurement devices 102 via an access point 104 ... transmits the data to a data

center 106, which securely stores that information,” and then “analyses it and provides interfaces for various users 106 [sic] to receive guidance, view and interact with that data.” Ex-1005, [0046].

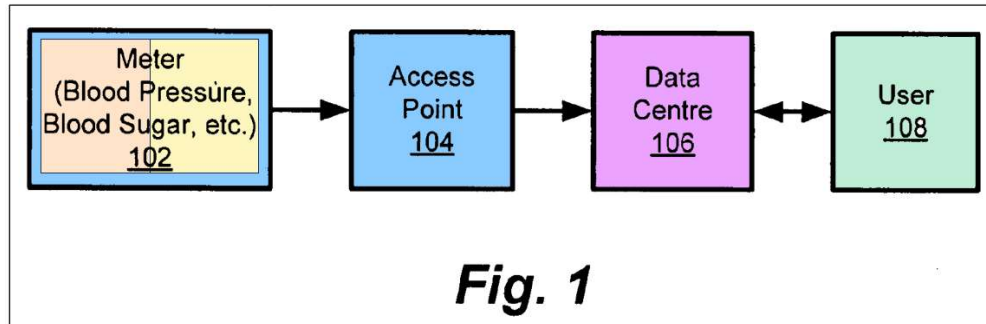
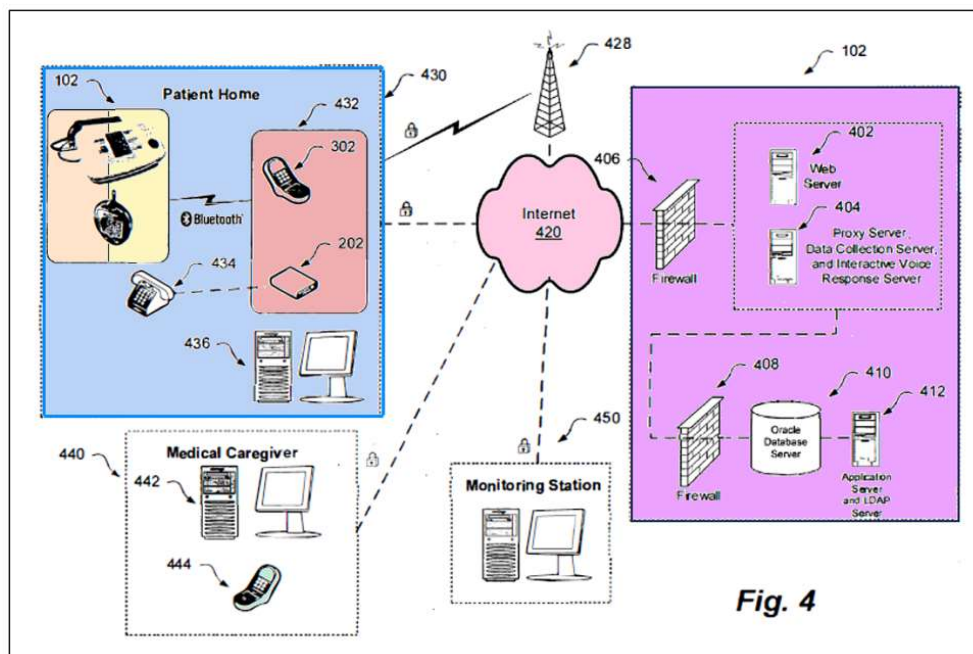


Figure 4 depicts a block diagram of Aspel’s system architecture.



63. As disclosed in the Figure, users can access the Data Centre through a stationary desktop computer, *id.*, or “[w]ireless access can be provided through a

cellular network 428 ... to a wireless device such as cellphone 302,” Ex-1005, [0052].

64. The system is also “designed to alert users and Caregivers based on the reception of certain data or the absence of data within a set time.” Ex-1005, [0089]. These data include glucose readings. Ex-1005, Fig. 17B.

1702

Fax:
Hospitalization #:
Treaty #:

Family Doctor Information
Name:
Phone:
Fax:

Equipment Serial Number
Blood Glucose Meter Serial Number:
Blood Pressure Meter Serial Number:
Note: The serial numbers are case sensitive

Description of Insulins
Insulin A:
Insulin B:

Glucose Target Range: (Units are mmol/L)
Settings for before and after meal ranges will generate the colors in the logbook, graphs, etc.

	Before	After
Hypo:		
Low:		
High:		
Hyper:		

Glucose Alerts: (Units are xxxxx/L)
An alert will be generated if there are readings above within days.
An alert will be generated if there are consecutive readings above .
An alert will be generated if there are readings within days.

FIG. 17B

65. As with the physiological sensor data, alerts can be “presented to patients, their Caregivers, designated medical professionals and monitoring centers in the web interface to the system.” Ex-1005, [0091]. This alert information “can

then be viewed along with the patient information to determine a course of action[.]” Ex-1005, [0093]. While a patient may establish “user defined alerts,” or alerts that initiate when “readings are out of a configurable set of target ranges,” Ex-1005, Abstract (explaining users include “patients, medical doctors and other Caregivers”), [0089]-[0091], a caregiver with the proper access—a “multi-Caregiver”—can also “set[] alert levels” that will trigger events based on that patient’s data, Ex-1005, [0128].

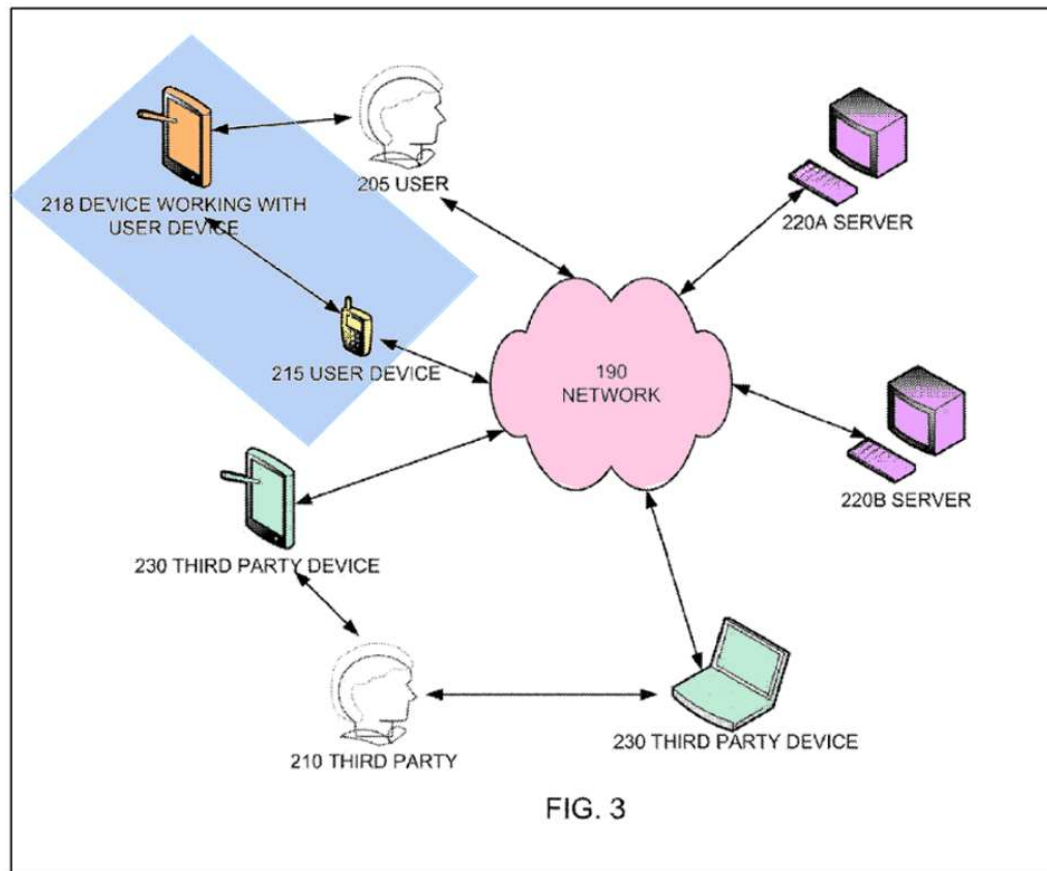
B. Gutekunst (Ex-1006)

66. The Gutekunst reference is U.S. Patent Application Publication No. 2011/0173308, titled “System and Method for Medical Surveillance through Personal Communication Device,” to Gutekunst (“Gutekunst”). It was filed on October 18, 2010, and published on July 14, 2011. Ex-1006, p.1. I understand and am informed that Gutekunst qualifies as prior art to the ’541 patent.

67. Gutekunst discloses a “medical monitoring and surveillance system [that] uses a server communicating with a general-purpose personal device running an application.” Ex-1006, Abstract. “The device may be a cellular telephone with data communication and other functionality, a personal digital organizer, a portable entertainment device, or another similar personal device.” Ex-1006, Abstract.

68. Gutekunst discloses details about how alert triggers can be configured for use in a medical monitoring system. Gutekunst discloses “embodiments [in

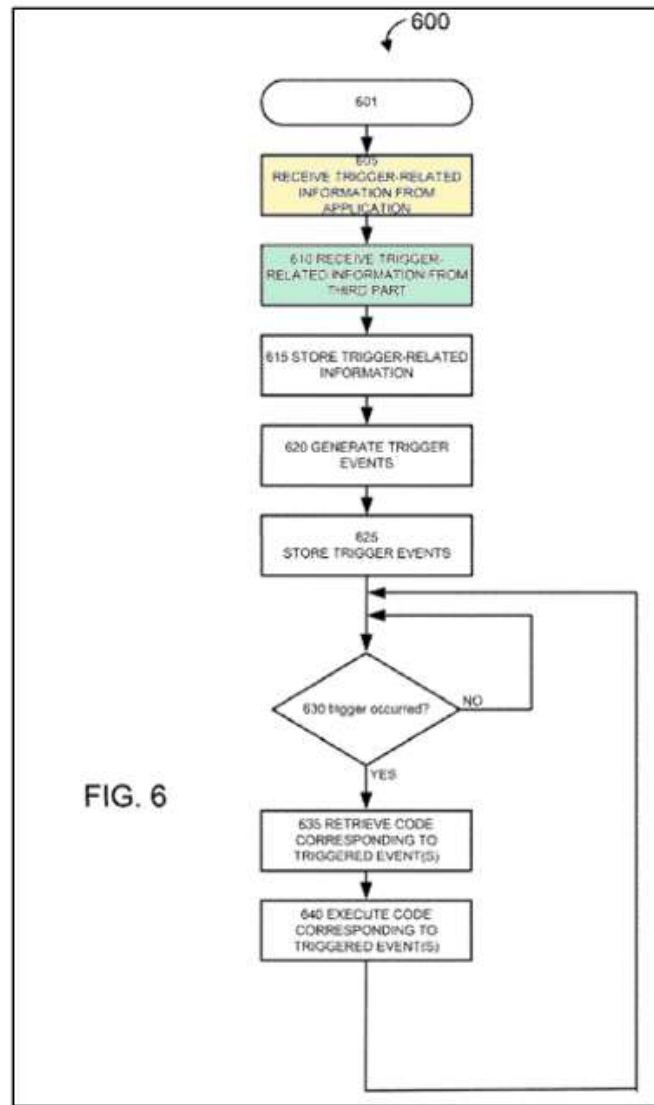
which] the server 220 enables a party (e.g., the user 220 [sic, 205], the third party 210, or yet another party) to schedule one or more trigger events to run manually or automatically at a specified time or date.” Ex-1006, [0127], Fig. 3 (below). “By accessing the server 220 through the web interface, the user 205 or the third party 210 may select from a predefined set of trigger events and build new trigger events.” Ex-1006, [0127].



69. Gutekunst discloses that “[t]he device 218 may be ... configured to communicate with the device 215 using a communication standard (such as

Bluetooth™) that operates over short distances, ... In embodiments, the device 218 may be implanted into a person's body. The device 218 may be a dedicated device designed to facilitate the gathering of the user's medical information. For example, the device 218 may be a ... a glucose monitor... The user's device 215 may receive data from the device 218, and may provide the device 218 with software and configuration data, so that the device 218 may be configured by the user 205 or by a remote device such as the server 220." Ex-1006, [0091].

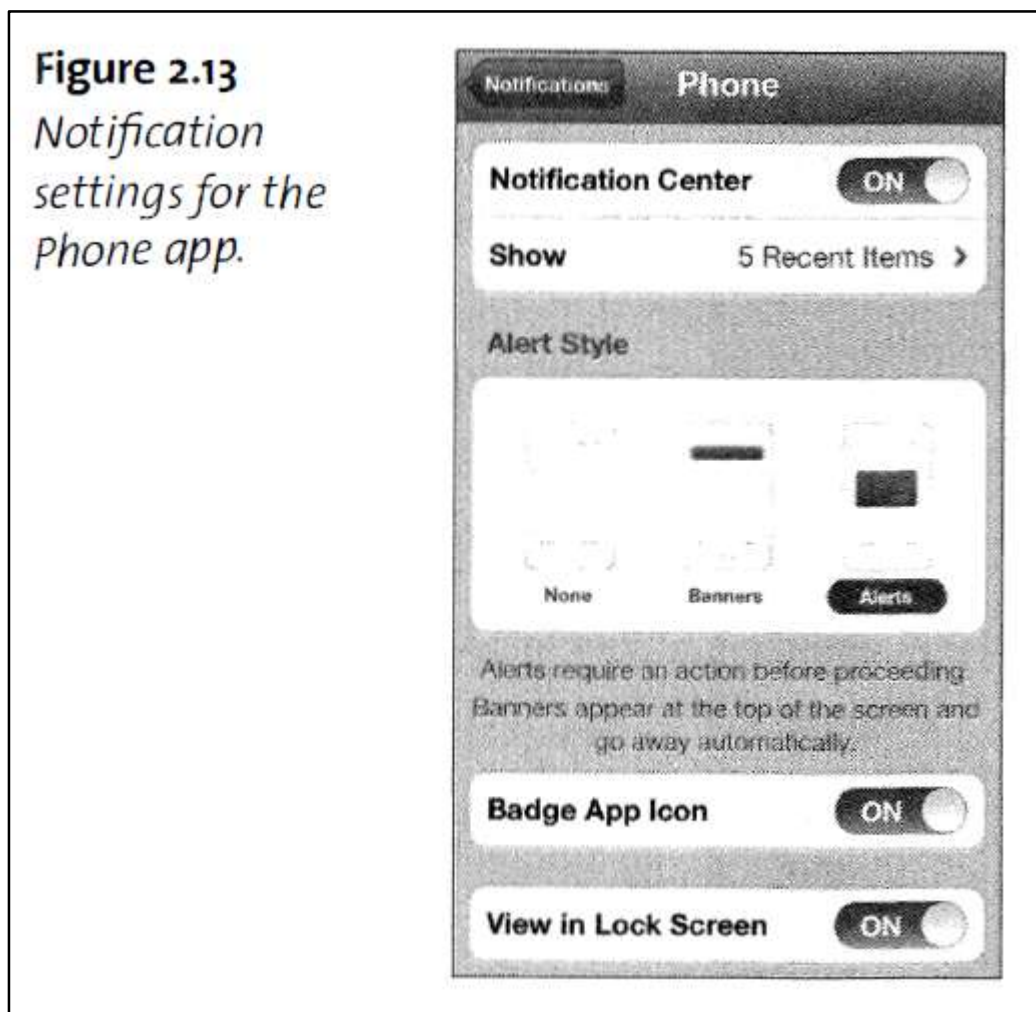
70. Gutekunst explains that "FIG. 6 illustrates selected steps and decisions of an exemplary process 600 through which the server 220 creates or modifies a trigger event, and then acts when the trigger event occurs." Ex-1006, [0156]. *See also* Ex-1006, [0128]-[0129] (a doctor or nurse "multi-Caregiver" setting alert levels using "generated HTML web pages"), [0058]-[0059] (providing details about how traffic is routed to server applications), [0063]-[0066].



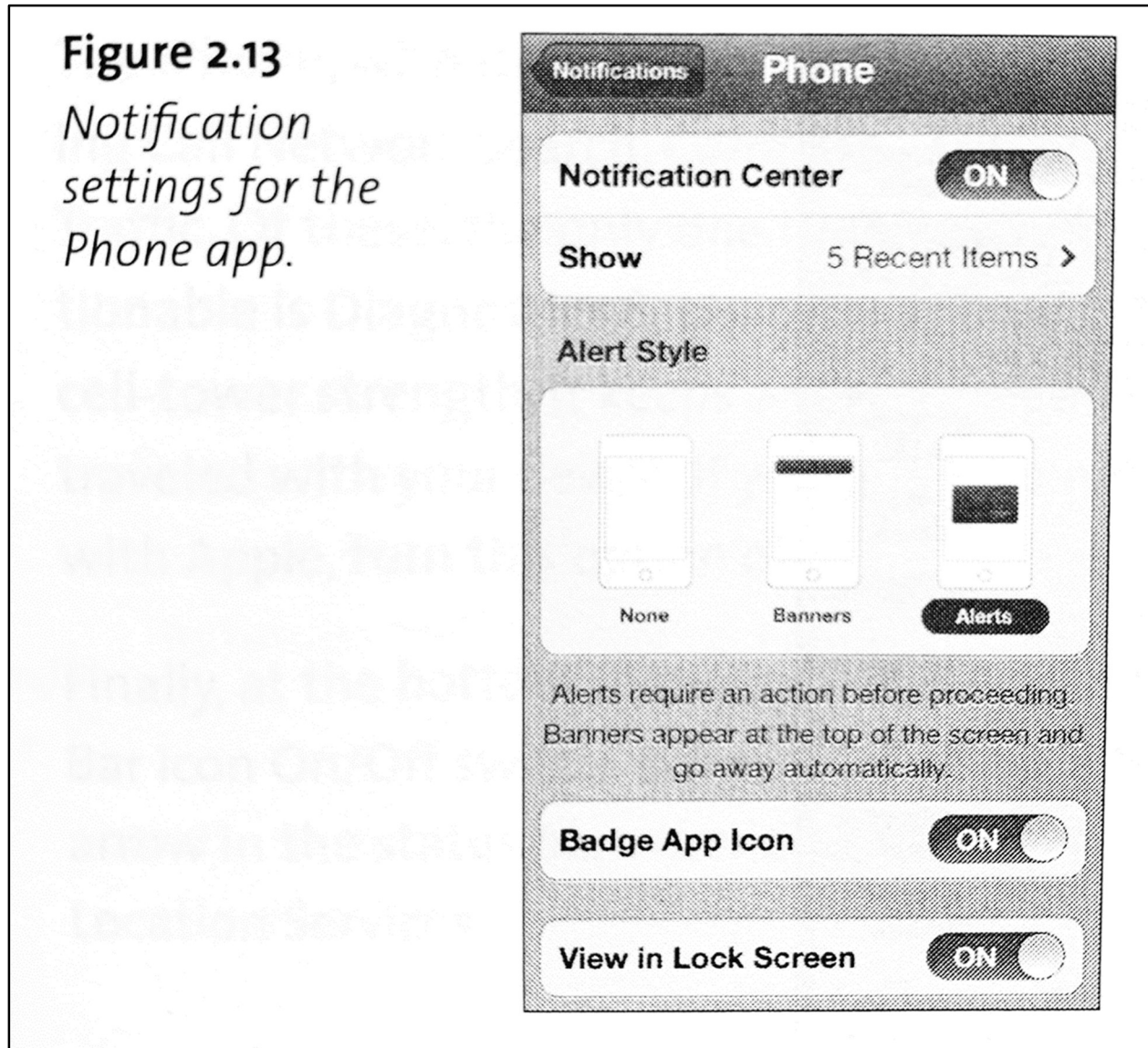
C. Breen (Ex-1007)

71. The Breen reference is *The iPhone Pocket Guide*, Sixth Edition by Christopher Breen (“Breen”). I understand and am informed that Breen was published November 30, 2011, and that Breen qualifies as prior art to the ’541 patent, which itself refers to using an iPhone.

72. Breen discloses the capabilities of Apple's iPhone running iOS 5 including its "alert styles." Ex-1007, 64-65. iOS 5 notifications are available to any "[t]hird-party applications configured to support notification." Ex-1007, 63. The Notifications settings, shown below, provide "Alert Style" optionality including "Banners" and "Alerts." Ex-1007, Fig. 2.13, 65. Figure 2.13, describes these options: "Alerts require an action before proceeding" and "Banners appear at the top of the screen and go away automatically."



73. I own a copy of the Breen book. I used my iPhone to take a photograph of Figure 2.13. The resulting image, below, improves the clarity of the “Alert Style” images and text.



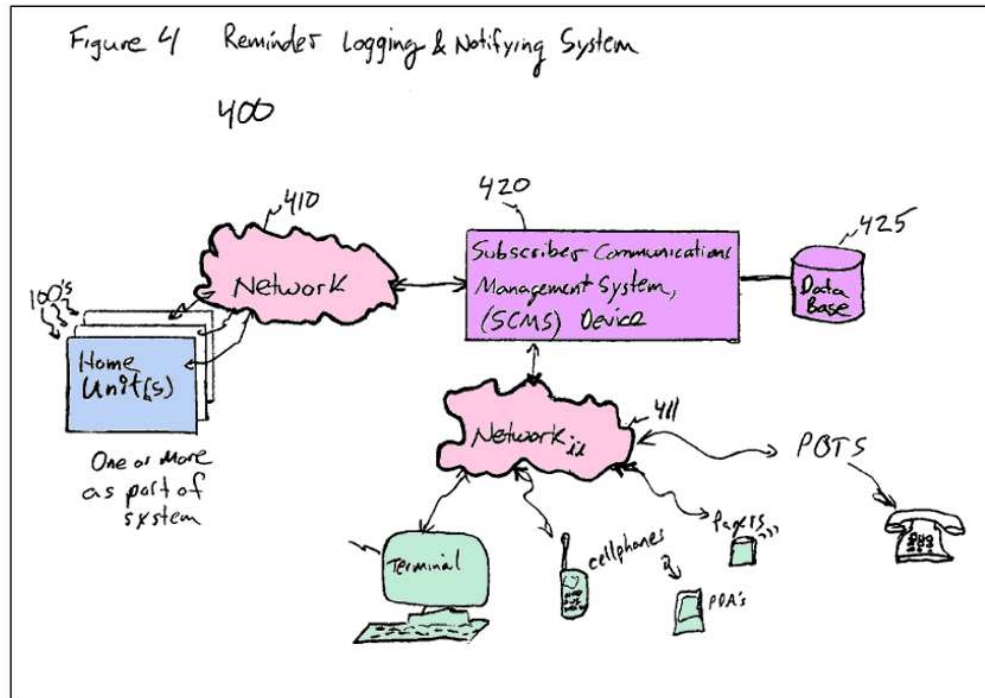
74. Breen explains that an “alert is a window that requires some action from you for it to go away—tap Accept, for example.” Ex-1007, 64. “Even after being dismissed, the Messages app can be configured to repeat an alert up to ten

times.” Ex-1007, 64. In contrast, “[a] banner appears as a short string of text (preceded by an app’s icon) that appears for a few seconds at the top of your device’s screen before disappearing.” Ex-1007, 64.

D. Paterno (Ex-1008)

75. The Paterno reference is U.S. Patent No. 7,301,463, titled “Assisting and Monitoring Method and System,” to Paterno (“Paterno”). It was filed on April 13, 2005, and issued on November 27, 2007. Ex-1008, 1. I understand and am informed that Paterno qualifies as prior art to the ’541 patent.

76. Paterno discloses an “[a]ssisting and [m]onitoring method and system” that “help[s] an individual and select caregivers of the individual track the individual’s performance of routine tasks.” Ex-1008, 1:66, 2:9-11. The disclosed system includes “network(s),” “two-way communication devices to exchange information between remotely located event logging devices,” and a central server. Ex-1008, 3:30-33. Paterno further discloses Home Units used by the individual being monitored, and (remote) “conventional messaging devices” used to monitor the individual (cellphones, PDAs, pagers, computer terminal). Ex-1008, 11:19-20; Fig. 4.



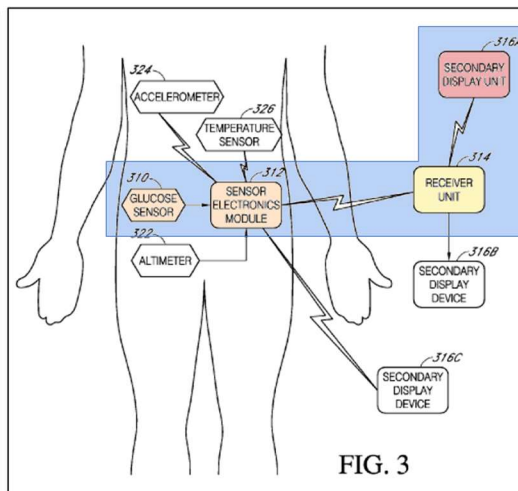
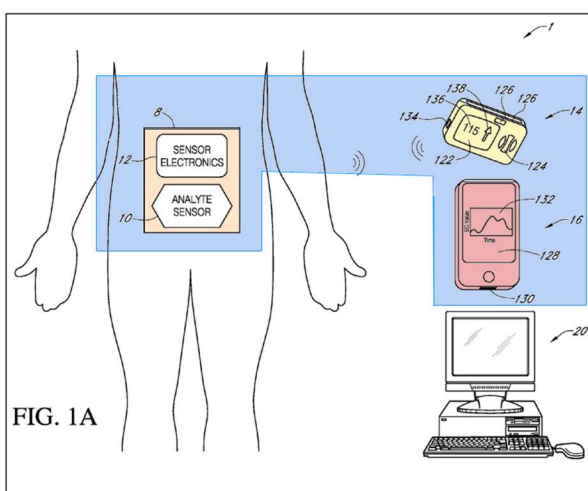
77. Ex-1008, Fig. 4 (annotated). The individual can “provide account access to one or more people” (e.g., caregivers) with “customized access permissions” to allow such individuals to make changes relating to “the programming sending of messages, alerts, ... and for setting what notifications and messages they will receive from the system[.]” Ex-1008, 3:52-63. Thus, remote caregivers can change the caregiver monitoring parameters for remotely monitoring a patient, such as “who, how, and when members of a subscribed account are notified of” different events. Ex-1008, 3:41-42,16:30-17:26.

78. Paterno discloses that “in home monitoring of critical health parameters such as blood sugar” was known in the art. Ex-1008, 1:46-48.

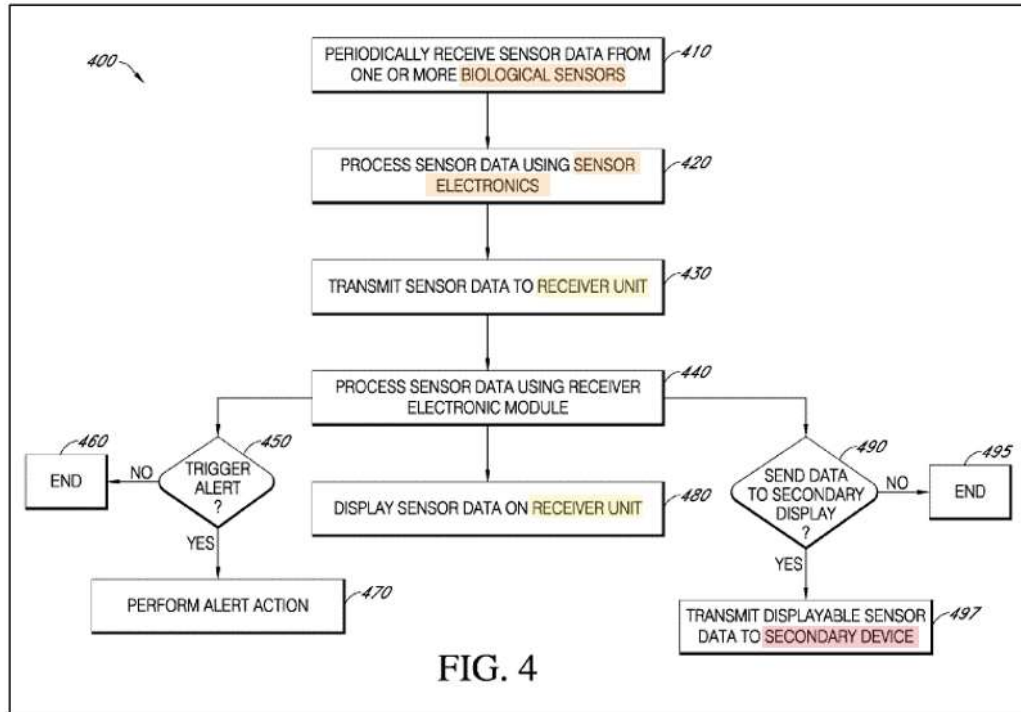
E. Valdes (Ex-1009)

79. The Valdes reference is U.S. Patent Publication No. 2011/0320130, titled “Systems and Methods for Communicating Sensor Data Between Communication Devices,” to Valdes *et al.* (“Valdes”). It was filed on June 23, 2011, and published on December 29, 2011. Ex-1009, 1. I understand and am informed that Valdes qualifies as prior art to the ’541 patent. Valdes is also admitted prior art in the specification for the ’541 patent. Ex-1001, 54:67-55:1.

80. Valdes discloses a “[s]ystem and method for communicating glucose concentration information between devices of a continuous glucose monitoring system.” Ex-1009, Abstract. These devices include (1) “a sensor electronics module” that “generates a glucose concentration measurement”; (2) “a receiver unit 14” that can be configured “to receive sensor data indicative of a glucose concentration in a host”; and (3) “one or more secondary display devices 16 and 20,” such as a mobile phone. Ex-1009, ¶¶ [0002], [0008], [0108]-[0109].



Ex-1009, Figs. 1A, 3 (annotated).



Ex-1009, Fig. 4.

81. Beginning with the host, a “continuous analyte sensor” provides “sensor data” to a receiver that is “directly related to the measured analyte from an analyte sensor. Ex-1009, [0062]. The “receiver unit” “can be configured to be a stand-alone device or physically connect to a secondary display device.” Ex-1009, [0002]...When the two devices are separated (annotated Figure 1A, above), the stand-alone “receiver unit” receives and processes data from the analyte sensor. Ex-1009, [0097]. The “receiver unit” then “wirelessly communicate[s]” with “one or more secondary display devices,” including “a mobile phone” and “a personal

computer.” Ex-1009, [0113]. A “secondary display device” can function as a device for use by the host, (e.g., the host receiving sensor data on a mobile phone through an application), Ex-1009, [0098], or by third-party caregivers (e.g., parents remotely monitoring “a child’s glucose levels” with “user configurable alerts”), Ex-1009, [0157]. More than one “secondary display device” may be used within a disclosed continuous glucose monitoring system.

82. Ex-1009, Fig. 4. “FIG. 4 is a flowchart illustrating one embodiment of a method 400 of using a receiver unit, such as receiver unit 14 or 314, first as a stand alone device and then used in combination with a secondary display device, such as secondary device 16, 20, 316A, 316B or 316C ... to enhance processing and displaying functionality.” Ex-1009, [0168].

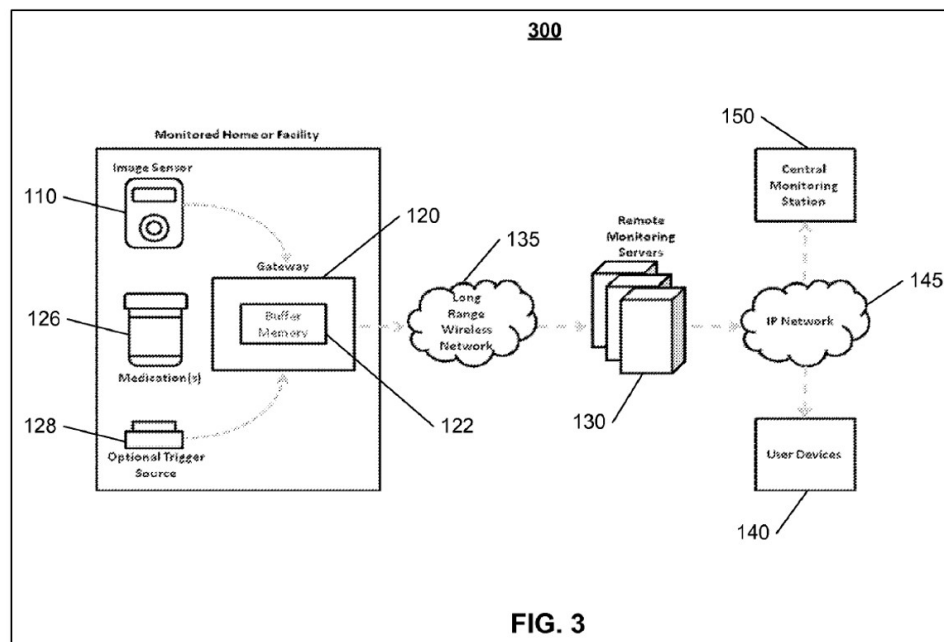
F. Hanson (Ex-1010)

83. The Hanson reference is U.S. Patent Publication No. 2012/0313785, titled “Medication Management and Reporting Technology,” to Hanson et al. (“Hanson”). It was filed on April 4, 2012, and published on December 13, 2012. I understand and am informed that Hanson qualifies as prior art to the ’541 patent.

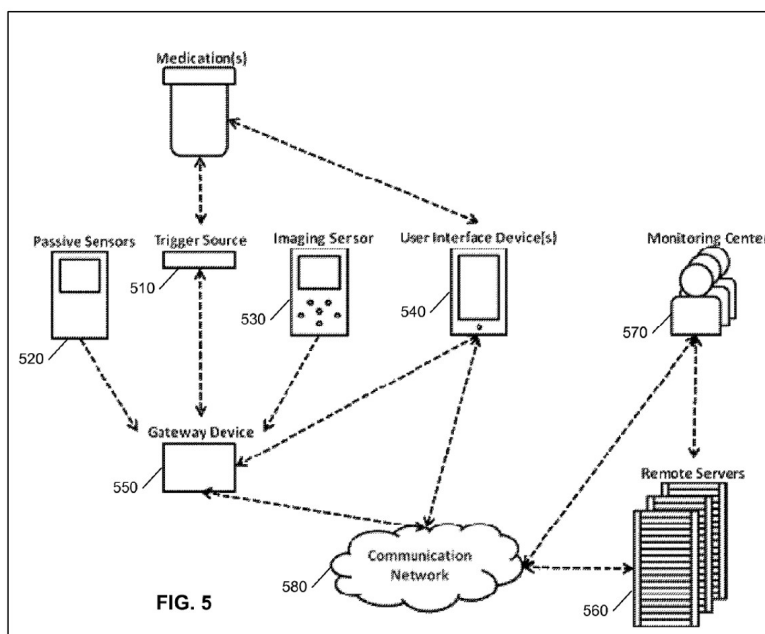
84. Hanson discloses a “medication management and reporting technology.” Ex-1010, [0002]. This system (1) uses “at least one sensor” that “analyzes” the “state of the medication”; (2) determines the “expected state of the medication” from a “schedule”; and (3) “compare[s]” the “detected state” with the

“expected state” to determine whether “the patient has departed from the schedule.” Ex-1010, Abstract. Hanson’s system “may monitor any of the sensors described throughout this disclosure,” which include “a blood sugar sensor.” Ex-1010, [0061], [0081].

85. The host-monitoring system begins with a control panel that processes sensor data, which may then send an “alert to an intermediary monitoring server that processes the alert and, potentially, relays the alert to other devices.” Ex-1010, [0037]. Such devices include “a remote device operated by a caregiver ... that is located outside of the home,” “a mobile device operated by the person ... or a mobile device operated by a family member of the person.” Ex-1010, [0037].



Ex-1010, Fig. 3.



86. Ex-1010, Fig. 5. Hanson’s system allows alert recipients to “receive information regarding the records of the patient,” but only after “the recipient of the alert ... provide[s] identification information (e.g., a user name and a password) that verifies that the recipient of the alert is authorized to view the medical records of the patient[.]” Ex-1010, [0115].

G. The Cited Prior Art is Analogous Art

87. The ’541 patent is titled “Remote Monitoring of Analyte Measurements,” Ex-1001, 1(54), and “generally relates to **remote monitoring**,” Ex-1001, 1:16-18.³ The ’541 patent explains that the “[i]mplementations described

³ Unless otherwise noted, emphasis in quoted text, as indicated by a **bold** font, has been added.

herein can include a system for one or more caretakers (e.g., a parent, spouse or healthcare practitioner) to **remotely monitor health characteristics** of one or more hosts.” Ex-1001, 4:25-28. “The health characteristics can include an analyte concentration of a host, such as glucose, or a bodily function, such as heart rate, blood pressure, temperature and the like.” Ex-1001, 4:28-31. I understand that each of the cited prior art references must be analogous art to the ’541 patent, i.e., either from the same field of endeavor as the ’541 patent, or reasonably pertinent to the particular problem addressed by the ’541 patent. Each of Aspel, Gutekunst, Paterno, Valdes, and Hanson relates to the field of remote monitoring and is at least reasonably pertinent to the ’541 patent. Breen is not in the field of remote monitoring, but it is “reasonably pertinent” to the ’541 patent because it provides teachings related to providing “push notifications” including “alerts.”

88. Aspel is titled “Health Monitoring System and Method.” Ex-1005, 1 (54). Aspel “relates generally to healthcare and medical telephony, and more specifically, to a system for and method of collecting and managing physiological and lifestyle information for use by individuals, familial and personal Caregivers, and medical professions in managing health and wellness decisions.” Ex-1005, [0002]. “It is an object of the invention to provide an **improved health monitoring and management system** and method.” Ex-1005, [0013]. The system

includes collection and display of “**glucose data**” including “a number of different blood glucose reports.” Ex-1005, [0164], [0165].

89. Gutekunst is titled “System and Method for Medical Surveillance through Personal Communication Device.” Ex-1006, 1(54). Gutekunst’s “invention relates generally to medical surveillance testing, assessing, and **monitoring**.” Ex-1006, [0002]. Gutekunst’s system configures and uses “general purpose portable communication devices.” Ex-1006, [0002]. Gutekunst discloses the system “allow[s] for **remote monitoring** and surveillance.” Ex-1006, [0010]. Gutekunst’s system includes a “medical sensor,” such as a “**glucose sensor**,” that “may be implanted into a person’s body.” Ex-1006, [0080], [0091].

90. Breen is titled *The iPhone Pocket Guide*. Breen discloses the capabilities of Apple’s iPhone running iOS 5 including its “alert styles.” Ex-1007, #. Breen explains that the iPhone’s notifications settings provide an “Alert Style” optionality including “Banners” and “Alerts.”

91. Paterno is titled “Assisting and Monitoring Method and System.” Ex-1008, 1 (54). Paterno discloses an “**Assisting and Monitoring method and system** for compliance logging and monitoring system for routine activities” and “an automated communications/notification system.” Ex-1008, 3:15-20. Paterno seeks to improve upon existing “[m]onitoring devices and systems exist that can

provide in home monitoring of **critical health parameters** such as blood sugar, pressure, heart rate and weight.” Ex-1008, 1:45-47.

92. Valdes is titled “Systems and Methods for Communicating Sensor Data Between Communication Devices,” Ex-1009, 1(54). Valdes discloses a “[s]ystem and method for communicating glucose concentration information between devices of a continuous glucose monitoring system[.]” Ex-1009, [0002]. Valdes discloses a “continuous glucose monitoring system” in which, “when an alert triggers that indicates severe hypoglycemia, the receiver unit can perform multiple actions, such as activating an alarm on the receiver unit, **transmitting a data package to a remote display device indicating activation of an alarm on the display, and transmitting a data package as a text message to a care provider.**” Ex-1009, [0106]. In addition, the ’541 patent identifies Valdes as disclosing “methods and devices suitable for use in conjunction with aspects of the preferred embodiments.” Ex-1001, 52:28-30, 55:1.

93. Hanson is titled “Medication Management and Reporting Technology,” which is also the disclosed technical field. Ex-1010, 1(54), [0002]. Hanson’s “electronic system 300” includes a “**remote monitoring** server 130” and “provides an alert to the patient’s doctor, the patient’s caregiver, or a remote monitoring station.” Ex-1010, [0046], [0112]. Hanson’s system also includes one or more sensors, which may include “a health monitoring sensor, such as ... a

blood sugar sensor ...” Ex-1010, [0061]. Systems to monitor blood glucose of pwd similarly provide medication (i.e., insulin) management by alerting the pwd when more insulin is needed (hyperglycemia) or when too much insulin was taken (hypoglycemia).

XI. APPLICATION OF PRIOR ART TO THE CHALLENGED CLAIMS

A. Ground I: Claims 1, 4-7, 9, 11, 13, and 15-17 Would Have Been Obvious Based on Aspel in view of Gutekunst

94. As shown below, claims 1, 4-7, 9, 11, 13, and 15-17 would have been obvious based on Aspel in view of Gutekunst.

95. Aspel discloses “a system for and method of collecting and managing physiological and lifestyle information for use by individuals, familial and personal Caregivers, and medical professions in managing health and wellness decisions.” Ex-1005, [0002]. Aspel discloses a “central storage server,” or *server system*,⁴ so that different users can receive an alert, or *alert notification messages*, on various devices including “wireless device 444 such as a cellphone or smartphone device,” *mobile remote monitors*. Aspel further discloses “medical and measurement devices 102,” e.g., a “glucometer,” that transfer data via a “mobile device such as cellphone 302” to “data centre 106.”

⁴ I use *italics* to indicate language from the challenged claims.



Fig. 3

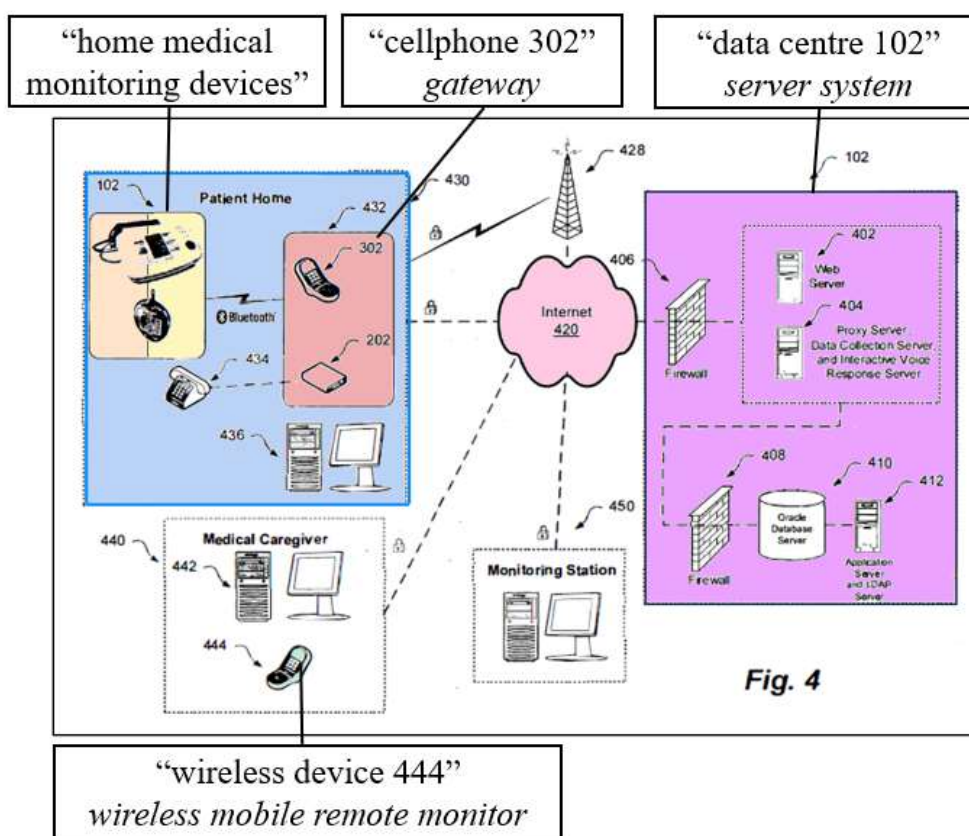
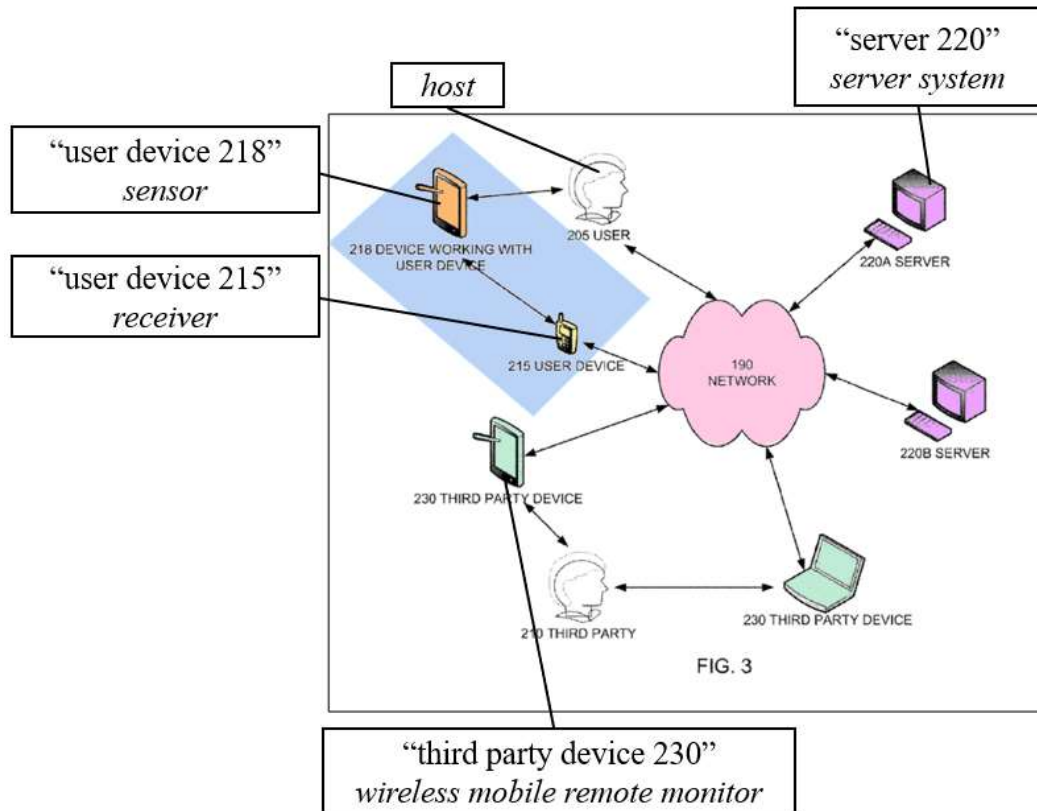


Fig. 4

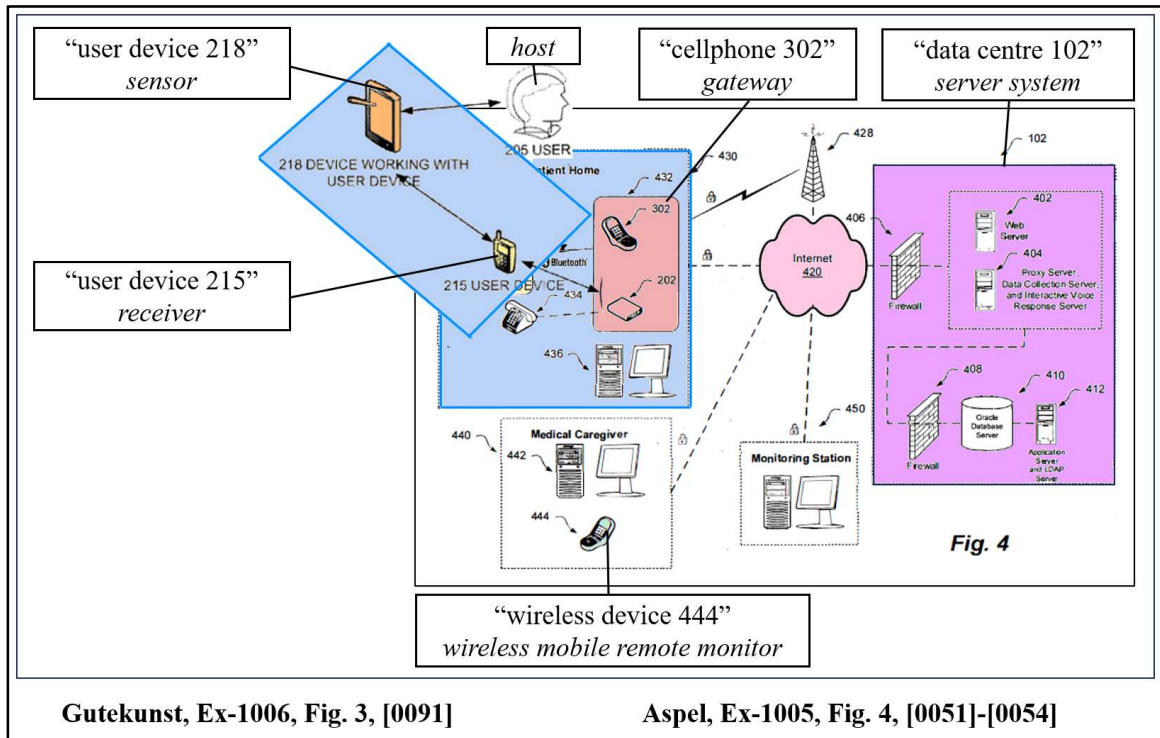
Ex-1005, Figs.3, 4.

96. Gutekunst discloses that a “medical monitoring and surveillance system uses a server communicating with a general-purpose personal device running an application.” Ex-1006, Abstract. Gutekunst discloses the personal device as “user’s device 215” communicating with “a dedicated device [218]

designed to facilitate the gathering of the user's medical information," and that "the device 218 may be implanted into a person's body" and may be "a glucose monitor." The "user's device 215 may receive data from the device 218." Ex-1006, [0091]. Thus, the "user's device 215" is a *receiver* for *analyte concentration sensor data* from the glucose monitor (device 218). This configuration is compatible with Aspel's disclosed system, substituting Gutekunst's "glucose monitor" "device 218" which "may be implanted" for the "glucometer" disclosed in Aspel. Gutekunst also provides additional disclosure regarding trigger events and how they are configured and processed by the *server system* based on the collected analyte sensor data.



97. The figure below illustrates a POSITA's understanding of the Aspel-Gutekunst combination, replacing the "home medical monitoring device" (yellow/orange) from Aspel with that of Gutekunst.



1. Motivation to combine Aspel and Gutekunst with Reasonable Expectation of Success

98. A POSITA would have been motivated to combine Aspel and Gutekunst.

Teaching, Suggestion, Motivation

99. As explained above in X.G, Aspel and Gutekunst relate to the field of remote monitoring and are at least reasonably pertinent to the '541 patent. Aspel discloses that "[t]he requirements of healthcare professionals and patients vary greatly from one application to the next. As a result, **many different user interfaces, functions and health lifestyle and wellness parameters may be required.** The invention can support all of these variations." Ex-1005, [0188].

Among these supported variants, Aspel explains that "the system can monitor and

measure a limitless variety of devices and physiological parameters ...” Ex-1005, [0188].

100. A POSITA would have recognized that Gutekunst discloses devices for monitoring and gathering a “user’s medical information,” or physiological parameters, that would complement the Aspel system. Ex-1006, [0091]. A POSITA would have understood the benefits of a CGM over sporadic point-of-care (POC), self-monitoring of blood glucose (SMBG), or blood panels from (intra)venous blood sampling. For example, Gutekunst discloses a “user device 215” that receives data from “another device 218,” which may be a “glucose monitor.” Ex-1006, [0091]. Gutekunst explains that the data on “user device 215” may be “sent or pulled (uploaded) to a remote location” using, for example, the Internet and/or a cellular network. Ex-1006, [0085], [0093], [0113]. Similarly, Aspel discloses that the disclosed server can be provided with data using a “cellular telephone” or “Ethernet or WiFi (IEEE 802.11) connectivity to the Internet.” Ex-1005, [0112], [0189]. A POSITA would thus have readily contemplated adapting Gutekunst’s “devices” to provide physiological parameters to Aspel’s monitoring system with reasonable expectation of success.

Other Factors and Reasonable Expectation of Success

101. Combining Aspel and Gutekunst would have involved combining prior art elements (i.e., a glucose monitor sensor and mobile application on a user

device) according to known methods to yield predictable results (i.e., receiving the glucose monitor sensor's data as taught in Gutekunst and providing it to the Aspel system, e.g., the Data Center 106). At the time of the alleged invention, mobile applications that interact with server systems were well-known, and both Aspel and Gutekunst disclose the use of cellular phones and the Internet to transmit data to a server. The '541 specification also references their wide use. Ex-1001, 5:2-4. Thus, a POSITA would have had a reasonable expectation of success in using Aspel and Gutekunst together to create a remote health monitoring system as discussed below. A POSITA would have been able to connect the "glucose monitor sensor" or a "mobile application on a user device" and the "patient monitor system" using well-known and standard network communication techniques present at the time, including but not limited to Bluetooth Low Energy, USB, Wi-Fi, ethernet, and cellular.

2. Independent Claim 1

a) 1[preamble]: "1. A method comprising:"

102. Aspel discloses the preamble, to the extent it is limiting.

103. Aspel discloses that "[t]he present invention relates generally to healthcare and medical telephony, and more specifically, to a system for and **method** of collecting and managing physiological and lifestyle information for use

by individuals, familial and personal Caregivers, and medical professions in managing health and wellness decisions.” Ex-1005, [0002].

- b) 1[a]: “receiving, at a wireless mobile remote monitor, an alert notification message from a server system, the alert notification message representative of a detected event,”

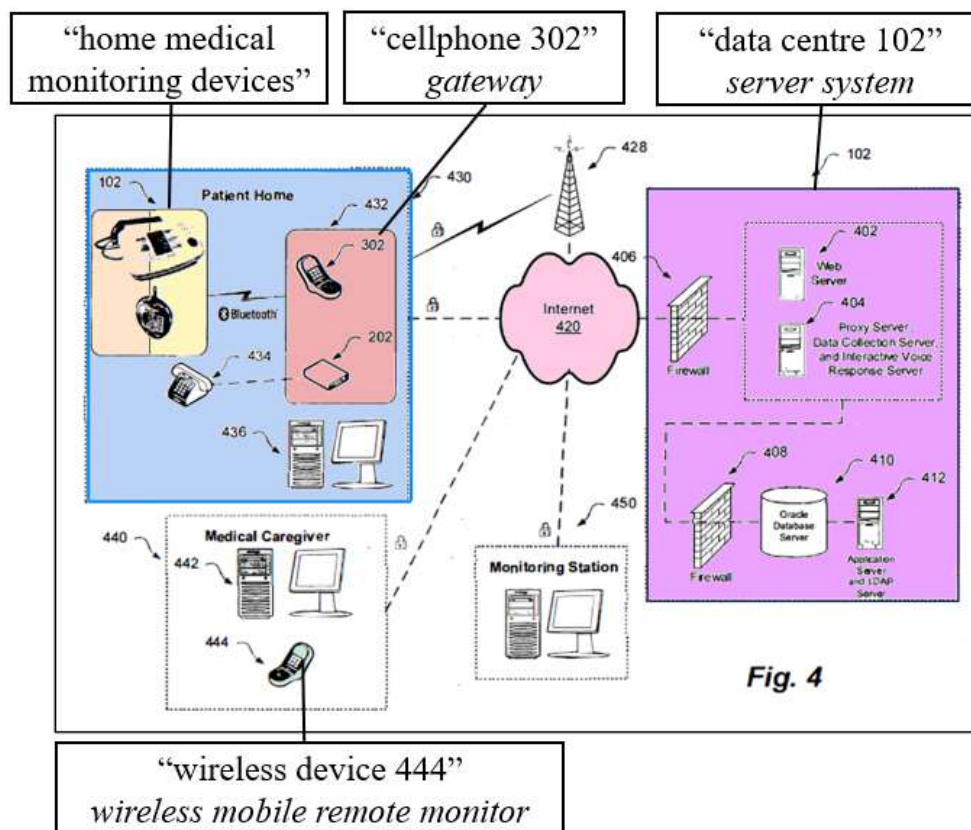
104. Aspel discloses this limitation.

105. Aspel discloses a “central storage server,” or *server system*, so that different users can receive an alert, or *alert notification messages*, at various devices including “wireless device 444 such as a cellphone or smartphone device,” or *wireless mobile remote monitor*. Alerts are generated and sent by the server when certain conditions are met such as when “readings are out of a configurable set of target ranges,” i.e., the *alert notification message representative of a detected event*. See, e.g, Ex-1005, [0156] (“Glucose Target Range”).

106. Aspel explains that “[p]atient physiological data such as ... blood sugar levels... is **collected and transmitted to a secure central storage server** which can be accessed by healthcare professionals for analysis and intervention. This data is also available to the patient for viewing purposes and to aid in self-management of their specific health condition.” Ex-1005, [0021]. “The described system has the necessary communication protocols to **enable the patient to use home medical monitoring devices such as ... a glucometer**, and all other devices

capable of collecting physiological and lifestyle data for transmission to the data center.” Ex-1005, [0044].

107. As shown in Figure 4 below, “[a] medical Caregiver 440 may access the patient data through the data centre 102 by a personal computer 442 or a **wireless device 444 such as a cellphone or smartphone device.**” Ex-1005, [0054]. **“Alerts can be generated when 1. readings are out of a configurable set of target ranges within a defined period of time; ... 4. a number of user defined alerts are detected; ...”** Ex-1005, [0090]. **“Alerts can be presented to patients, their Caregivers, designated medical professionals and monitoring centers in the web interface to the system.”** Ex-1005, [0091].



Ex-1005, Fig. 4.

108. Aspel explains that “[a]lerts can be delivered by all previously mentioned voice and data delivery systems. This allows the user to be informed of the alerts, to acknowledge alerts, and to enter additional information in response to the alerts. Alternatively, alerts can be delivered via short message service (SMS) message to a user’s cellular telephone.” Ex-1005, [0092]. “Alerts may also be delivered via e-mail, fax, phone, SMS text message or other user desired communication protocols.” Ex-1005, [0094]. *See also* Ex-1005, Fig.10, [0127]. A POSITA would have identified the benefit of substituting Gutekunst’s glucose

monitor and receiver to allow for passive, more frequent monitoring. A POSITA would have been motivated to combine Aspel and Gutekunst for at least the additional reasons set forth in XI.A.1.

- c) **1[b]: “the event being based on analyte concentration sensor data obtained from a receiver monitoring an analyte state of a host, the analyte concentration sensor data indicating a concentration of an analyte of the host,”**

109. Aspel renders this limitation obvious, alone or in view of Gutekunst.

110. Aspel discloses that its system for sending alerts when data is outside a target range, an *event* based on the *analyte state of a host*, is compatible with “all other devices capable of collecting physiological and lifestyle data,” which a POSITA would have understood to include well-known continuous glucose monitors comprising a *receiver* and *analyte sensor*. Thus, a POSITA would have understood that Aspel would send alerts based on detecting that the *analyte concentration data*, which is *indicating a concentration of an analyte of the host*, is outside of a target range, a *detected event*.

111. Aspel explains, “[p]atient physiological data such as ... **blood sugar levels**, ... is collected and transmitted to a secure central storage server ...” Ex-1005, [0021]. “The described system has the necessary communication protocols to enable the patient to use home medical monitoring devices such as ..., a **glucometer, and all other devices capable of collecting physiological and**

lifestyle data for transmission to the data center. Readings are taken in the same fashion as any patient currently using these devices would.” Ex-1005, [0044]. *See also* Ex-1005, [0046]. Aspel further discloses sending alerts, *events*, based on blood sugar levels, *an analyte state of a host*, being outside of “target ranges.” *See, e.g.*, Ex-1005, [0090], [0156], [0157], [0166].

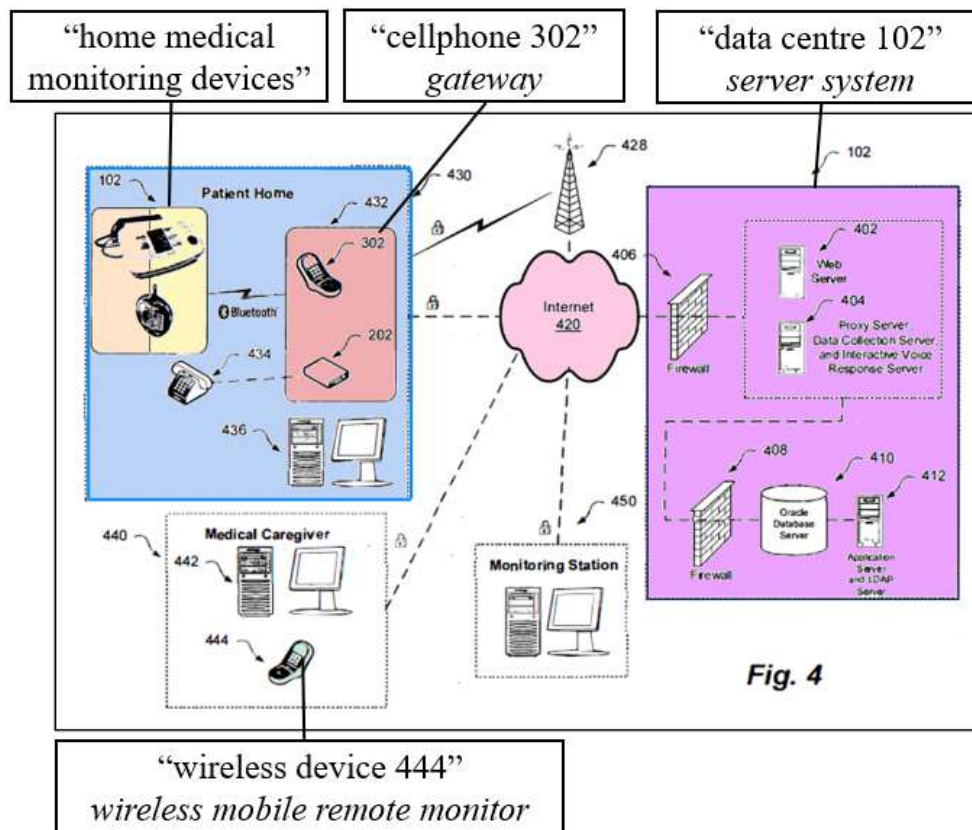
112. Gutekunst discloses a “device 218,” an *analyte concentration sensor*, and a “device 215,” or *receiver*. Gutekunst explains that “[t]he device 218 may be plugged into the device 215; connected to the device 215 through a short cable ... or **configured to communicate with the device 215 using a communication standard (such as Bluetooth™)** that operates over short distances, ... In embodiments, **the device 218 may be implanted into a person’s body. The device 218 may be a dedicated device designed to facilitate the gathering of the user’s medical information.** For example, the device 218 may be a blood pressure gauge, a heart rate monitor, or a **glucose monitor...**” Ex-1006, [0091]. A POSITA would have understood that Gutekunst’s “glucose sensor” and “glucose monitor” provide *analyte concentration sensor data indicating a concentration of an analyte of the host*. A POSITA would have understood the benefit of combining existing technology – electronic transport of glucose values, and continuous glucose monitors – to provide real time remote monitoring of glucose values. In the Aspel-Gutekunst combination, this glucose monitor and its *receiver* (device 215) is

substituted for the “glucometer” to monitor the analyte concentration of the host and obtain *analyte concentration sensor data* that is used in determining the *event* on which an alert will be based. A POSITA would have been motivated to combine Aspel and Gutekunst for at least the additional reasons set forth in XI.A.1.

d) 1[c]: “the wireless mobile remote monitor being remote to the host and the server system;”

113. Aspel discloses this limitation.

114. Aspel discloses (and depicts in Figure 4) a medical caregiver’s “wireless device 444 such as a cellphone or smartphone device,” or *wireless mobile remote monitor*, that is remote to the *pwd*, or *host*, and the “central storage server,” or *server system*.



Ex-1005, Fig. 4.

115. Aspel discloses a flexible system of delivering alerts including e-mail, fax, phone, SMS text message, or other communication protocols. Aspel discloses “[b]roadly, the system provides a **remote patient monitoring service that enables continuous feedback between patients and their Caregivers.**” Ex-1005, [0193]. Aspel explains that a “medical Caregiver 440 may access the patient data through the data centre 102 by a personal computer 442 or a wireless device 444 such as a cellphone or smartphone device.” Ex-1005, [0054]. “Alerts can be delivered by all previously mentioned voice and data delivery systems. This allows the user to be

informed of the alerts, to acknowledge alerts, and to enter additional information in response to the alerts. Alternatively, alerts can be delivered via short message service (SMS) message to a user's cellular telephone." Ex-1005, [0092]. "Alerts may also be delivered via e-mail, fax, phone, SMS text message or other user desired communication protocols." Ex-1005, [0094].

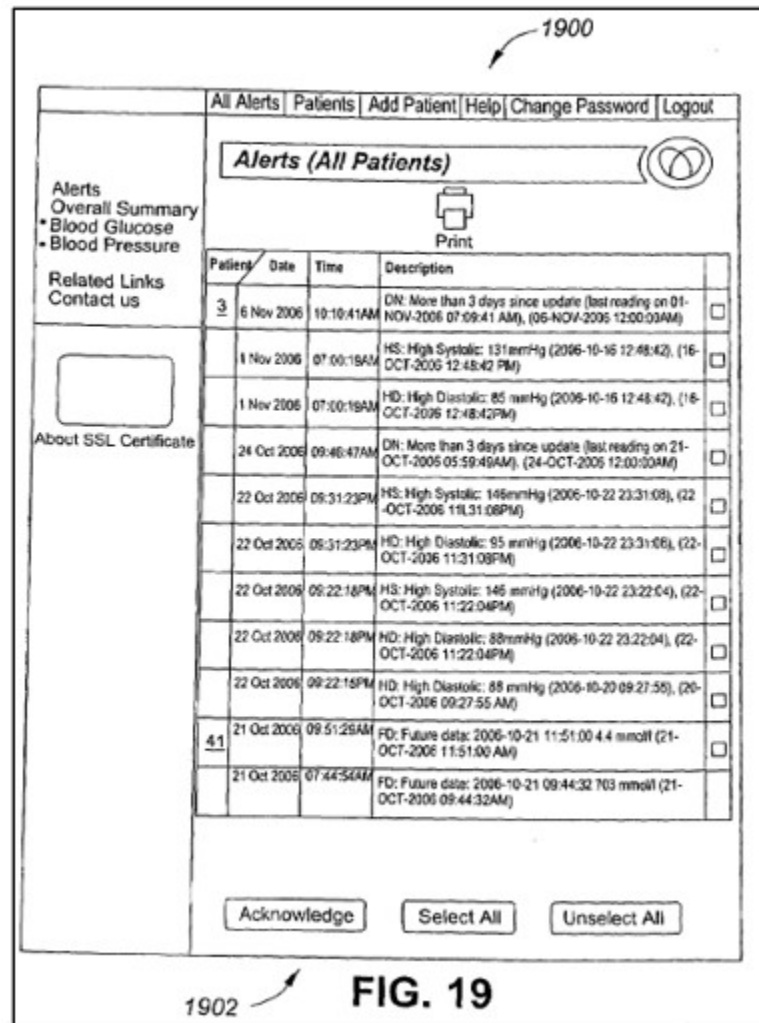
e) 1[d]: "presenting, at the wireless mobile remote monitor, the alert notification message,"

116. Aspel discloses this limitation.

117. As explained above, Aspel discloses that "[a]lerts can be presented to patients, their Caregivers, designated medical professionals and monitoring centers in the web interface to the system. Once logged in, the user may see all alerts pertaining to them and persons within their care." Ex-1005, [0091]. "Alerts can be delivered by all previously mentioned voice and data delivery systems. This allows the user to be informed of the alerts, to acknowledge alerts, and to enter additional information in response to the alerts. Alternatively, alerts can be delivered via short message service (SMS) message to a user's cellular telephone." Ex-1005, [0092]. In this way, alert notification messages are presented at the wireless mobile remote monitor.

118. Aspel further discloses accessing an "All Alerts" report for caregivers, which displays an *alert notification message*, presented at a "wireless device 444 such as a cellphone or smartphone device," or *wireless remote monitor*. Aspel

explains that a “medical Caregiver 440 may access the patient data through the data centre 102 by a personal computer 442 or **a wireless device 444 such as a cellphone or smartphone device.**” Ex-1005, [0054]. ““All Alerts’—clicking on this selection presents the user with a list of all alerts that this particular user is entitled to view. If the user is a patient, this will be limited to their personal alerts, while **if the user is a medical doctor, it may list the alerts for all of their patients.** FIG. 19 presents an exemplary screen capture of an ‘all alert’ report for a Caregiver with multiple patients.” Ex-1005, [0135].



119. In this way, alert notification messages are presented at the wireless mobile remote monitor.

- f) 1[e]: “wherein the wireless mobile remote monitor or a user of the wireless mobile remote monitor is specifically authorized by the host to receive the alert notification message to augment the receiver monitoring of the analyte state of the host, wherein the wireless mobile remote monitor or the user of the wireless mobile remote monitor is authenticated by the server system;”

120. Aspel discloses this limitation or renders this limitation obvious.

121. Aspel discloses “reports and alerts that may be presented through various interfaces to **authorized system users, including patients, medical doctors and other Caregivers.**” Ex-1005, Abstract. In Aspel’s system, “patient data ... is only resolved when securely accessed by an **authorized user.**” Ex-1005, [0024]. Aspel explains that the “Web interface allows **authorized users** to add and delete users, view data and delegate access to data based on user roles.” Ex-1005, [0063]. Thus, Aspel discloses that *a user (e.g., a “Caregiver”) of the wireless mobile remote monitor is specifically authorized by the host to receive the alert notification message.*

122. To the extent the language to augment the receiver monitoring of the analyte state of the host is a claim limitation, Aspel discloses it.⁵ Aspel’s system “closes the feedback loop between the client (patient) and Caregiver (professional or loved one)” in part by alerting Caregivers. Ex-1005, [0017], [0089]-[0094]. Thus, Aspel discloses or renders obvious providing *alert notification messages* in order *to augment the receiver monitoring of the analyte state of the host.* “Closing

⁵ I have been informed that DexCom contends this limitation is met inherently by the use of a remote monitor in addition to the host’s own receiver monitoring. Therefore, under DexCom’s apparent construction, this limitation is inherently met by Aspel.

the feedback loop between the client and the Caregiver improves the efficiency and effectiveness of providing healthcare services: increased quality and length of life, decreased travel and hospital time, reduced comorbidities associated with chronic and acute illnesses and lifestyle concerns for patients/clients. It also provides professional Caregivers with the information they require to properly manage their clients' illnesses without actually having to see the patient in person." Ex-1005, [0014].

123. Additionally, as explained above in XI.A.2.b,e, a "designated medical professional" uses a "wireless device," *mobile remote monitor*, to receive an alert, *alert notification message*. A POSITA would have understood that a "**designated** medical professional" is *specifically authorized by the host to receive the alert notification message to augment the receiver monitoring of the analyte state of the host*. It was obvious to a POSITA that to comply with Health Insurance Portability and Accountability Act ("HIPAA"), authorization and security measures are necessary components of a CGM remote monitoring system. HIPAA aims to protect individually identifiable health information of patients. For systems which involved collecting patient health data remotely (e.g., estimated glucose values from a CGM) and transmitting it to care partners / HCP's, HIPAA compliance was mandatory. Generally, HIPAA requires a patient's written authorization before using or disclosing their Personal Health Information (PHI) for most purposes.

HIPAA mandates that covered entities such as providers of remote monitoring systems implement appropriate security measures to safeguard PHI, such as access controls and encryption of data during transmission. “Alerts can be presented to patients, their Caregivers, **designated medical professionals** and monitoring centers in the web interface to the system. **Once logged in, the user may see all alerts pertaining to them and persons within their care.**” Ex-1005, [0091]. “The web application is designed for the patient to view their data along with a number of other persons simultaneously. **The persons who are able to view the data in addition to the patient are configurable within the web application.**” Ex-1005, [0065].

g) **1[f]: “receiving, at the wireless mobile remote monitor, user input indicative of acknowledgment of the presented alert notification message;”**

124. Aspel discloses this limitation.

125. Aspel expressly discloses acknowledgement by the user. Aspel explains that the user displays an alert list, *alert notification message*, to the user of a “wireless device,” a *mobile remote monitor*, and that the user can use a “tick box” to “acknowledge alerts,” *receiving ... user input indicative of an acknowledgment of the presented alert notification message*. Aspel discloses that “[a]lerts can be delivered by all previously mentioned voice and data delivery systems. This allows the user to be informed of the alerts, **to acknowledge alerts**,

and to enter additional information in response to the alerts.” Ex-1005, [0092]. For example, Aspel explains that “FIG. 19 presents an ‘all alerts’ report 1900 for a Caregiver with multiple patients. The report includes a table with columns listing **patient, date of the alert, time of the alert and description of the alert**. The user may click on the patient entry to link to the particular patient’s main page, or to other reports/pages corresponding to that patient.” Ex-1005, [0162]. The report is provided as an interface to the user. **“Each event also includes a tick box, allowing the user to select particular records so they can be ‘acknowledged’** (1902) and have them removed from the report.” Ex-1005, [0163]. The user acknowledges an alert with the interface by clicking the “tick box” corresponding to particular alert records. Ex-1005, [0163].

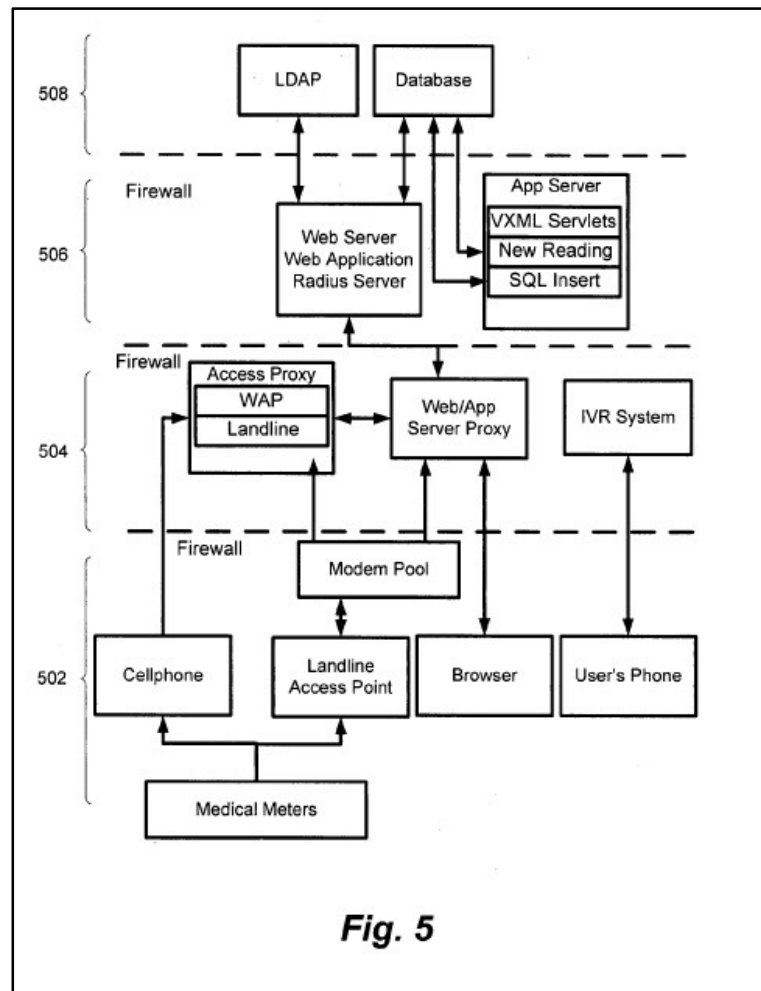
- h) **1[g]: “sending an acknowledgment message from the wireless mobile remote monitor to the server system indicating acknowledgement of the presented alert notification message to enable the server system to confirm that the alert notification message has been received;”**

126. Aspel discloses this limitation or renders this limitation obvious.

127. Aspel Fig. 19 and paragraph [0163] disclose that using the “tick box” to acknowledge an alert results in the alert being removed from the alert list. For example, Aspel discloses, with reference to Figure 19, that “[e]ach event also includes a tick box, allowing the user to select particular records so they can be ‘acknowledged’ (1902) and have them removed from the report. For convenience,

‘select all’ and ‘unselect all’ tabs are also provided. The report may also be printed out by clicking on the ‘print’ icon.” Ex-1005, [0163].

128. Figure 5 depicts the structure and operation of the Aspel system, from which a POSITA would have recognized that Aspel’s acknowledgment is sent from its wireless device (layer 502) to the server (layer 506).



129. “FIG. 5 presents a block diagram of the overall system architecture in an embodiment of the invention.” Ex-1005, [0032]. “The first layer 502 consists of medical devices, access devices and a modem pool with a toll free number. This

layer allows: 1. the user's medical devices to transmit data using a cellular telephone or landline access point and modem; ..." Ex-1005, [0056]. "The second layer 504 proxies traffic to the appropriate software applications in the third layer." Ex-1005, [0059]. "The third layer 506 holds the main logic of the system. It controls access to the information stored in the LDAP and Central Database of the fourth layer, inserts data into the Central Database, and provides presentation services for content in the Central Database." Ex-1005, [0060].

130. A POSITA would have recognized that, for the acknowledgment to result in removing the alert from the report, it would necessitate the recited *sending an acknowledgement message from the wireless mobile remote monitor to the server system indicating acknowledgement of the presented alert notification message to confirm that the alert notification message has been received*. Aspel's acknowledgment would necessarily be sent from the "wireless device 444" to the server. In the alternative, it would have been obvious to implement Aspel's system such that selecting the "tick box" sends an acknowledgement message to the server, which then confirms receipt of the alert notification message and removes the alert from the alert list.

- i) **1[h]: "after sending the acknowledgment accessing, by the wireless mobile remote monitor, at least some of the analyte concentration sensor data from the server system; and"**

131. Aspel discloses this limitation.

132. Aspel discloses a system and method that allows caregivers and medical professionals to access blood glucose data (*analyte concentration sensor data*) from the *server system*. The temporal limitation for “after” is being subsequent to sending the acknowledgement, i.e., resulting from clicking the “tick box” in the alert rules list (Ex-1005, [0163]; *see* XI.A.2.h). In Aspel’s system, a medical caregiver would use “wireless device 444,” or *wireless mobile remote monitor*, to access patient data, including *analyte concentration sensor data*, from the data center, or *server system*.

133. Aspel discloses that a “medical Caregiver 440 may access the patient data through the data centre [sic]102 by a personal computer 442 or a wireless device 444 such as a cellphone or smartphone device.” Ex-1005, [0054]. For example, “FIG. 21 presents a screen capture of an exemplary summary report 2100. Clicking on the ‘Summary’ tab of the ‘Blood Glucose’ menu causes the system to collect data for the current patient and generate the report as shown, which includes: title, patient name and a table with minimum, maximum, average glucose levels and counts for various time periods (two weeks, four weeks and ‘all’, in this example).” Ex-1005, [0168].

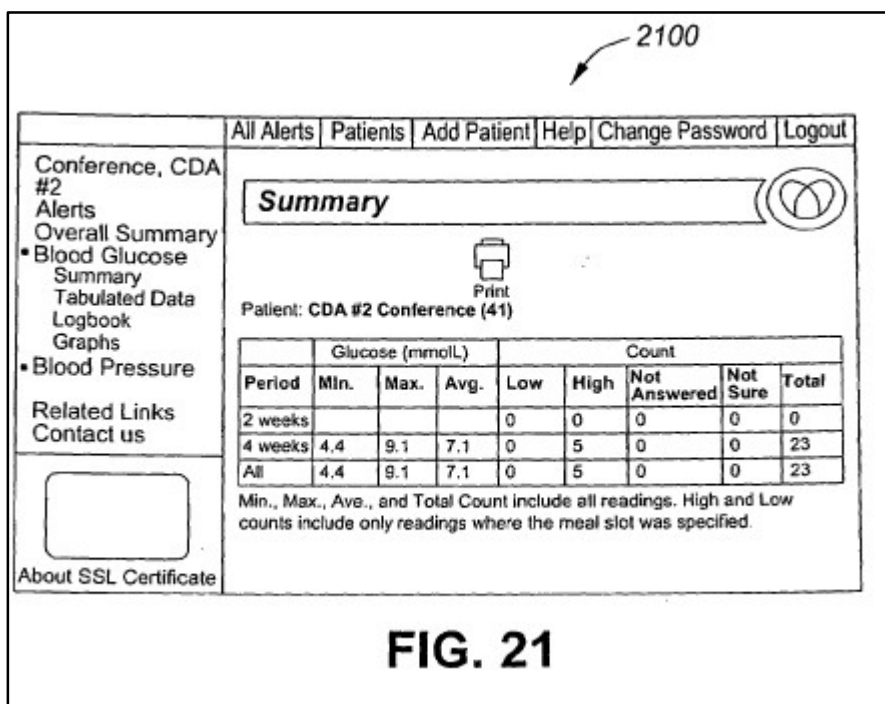


FIG. 21

134. In Aspel’s system a caregiver would access patient data in the form of “reports” provided by the system. *See, e.g.,* Ex-1005, [0165]-[0169]. As a result, a caregiver using a *wireless mobile remote monitor* would access *at least some of the analyte concentration sensor data from the server system* sometime after sending *the acknowledgment*.

- j) 1[i]: “receiving, in response to the accessing, the at least some of the analyte concentration sensor data including historical data, the at least some of the analyte concentration sensor data being generated by the receiver monitoring the analyte state of the host;”

135. Aspel discloses this limitation.

136. Aspel discloses *receiving, in response to the accessing*, “a number of different blood glucose reports” with customizable “time ranges,” *analyte*

concentration sensor data including historical data, based on the “[p]atient physiological data such as ... blood sugar levels ...” that was “collected and transmitted” to the server by the *receiver monitoring the analyte state of the host*. Aspel discloses that “[p]atient physiological data such as ... blood sugar levels ... is collected and transmitted to a **secure central storage server which can be accessed by healthcare professionals for analysis and intervention.**” “A medical Caregiver 440 may access the patient data through the data centre [sic] 102 by a personal computer 442 or a wireless device 444 such as a cellphone or smartphone device.” Ex-1005, [0054].

137. As explained in XI.A.2.i, a number of different reports are available for viewing. “The time ranges on these reports are typically customizable, allowing Caregivers to tailor the service particular to the patients [sic] individual situation.” Ex-1005, [0167]. For example, Figures 21 depicts a “screen capture of an exemplary summary report 2100. Clicking on the ‘Summary’ tab of the ‘Blood Glucose’ menu causes the system to collect data for the current patient and generate the report as shown, which includes: title, patient name and a table with minimum, maximum, average glucose levels and counts **for various time periods [i.e., historical data]**.” Ex-1005, [0168]. The “Tabulated Data” selection of the “Blood Glucose” menu prompts the user for the parameters to generate a tabulated data report. “**As shown, the user is required to specify the start period and end**

period by date, using the interactive calendar utility, or by clicking on the ‘last week’, ‘last 2 weeks’, ‘last 30 days’ or ‘all’ tabs... . Clicking on ‘view report’ tab causes the system to collect and compile the data, presenting it in a report 2300 as shown in FIG. 23.” Ex-1005, [0169]. *See generally* Aspel at Figs. 14-36.

The generated reports are available for “downloading,” (Ex-1005, [0130]), and printing, (Ex-1005, [0170]). Thus, the browser application running on the *wireless mobile remote monitor* downloads, i.e., receives, data in response to a request from the *wireless mobile remote monitor*.

- k) 1[j]: “wherein the event is detected by the server system based on one or more sets of recommended alert rules settings configured by the host using the receiver, at least one of the sets of recommended alert rules settings being modifiable by the user of the wireless mobile remote monitor using the wireless mobile remote monitor.”

138. Aspel renders this limitation obvious in view of Gutekunst.

139. Aspel discloses a system with a data center, *server system*, that analyzes data and compares data to target values, or *alert rules settings*, to create alerts, *i.e., the event is detected by the server system*. Ex-1005, [0089]-[0090]. Aspel’s system allows the user to configure target ranges and define alerts generally.

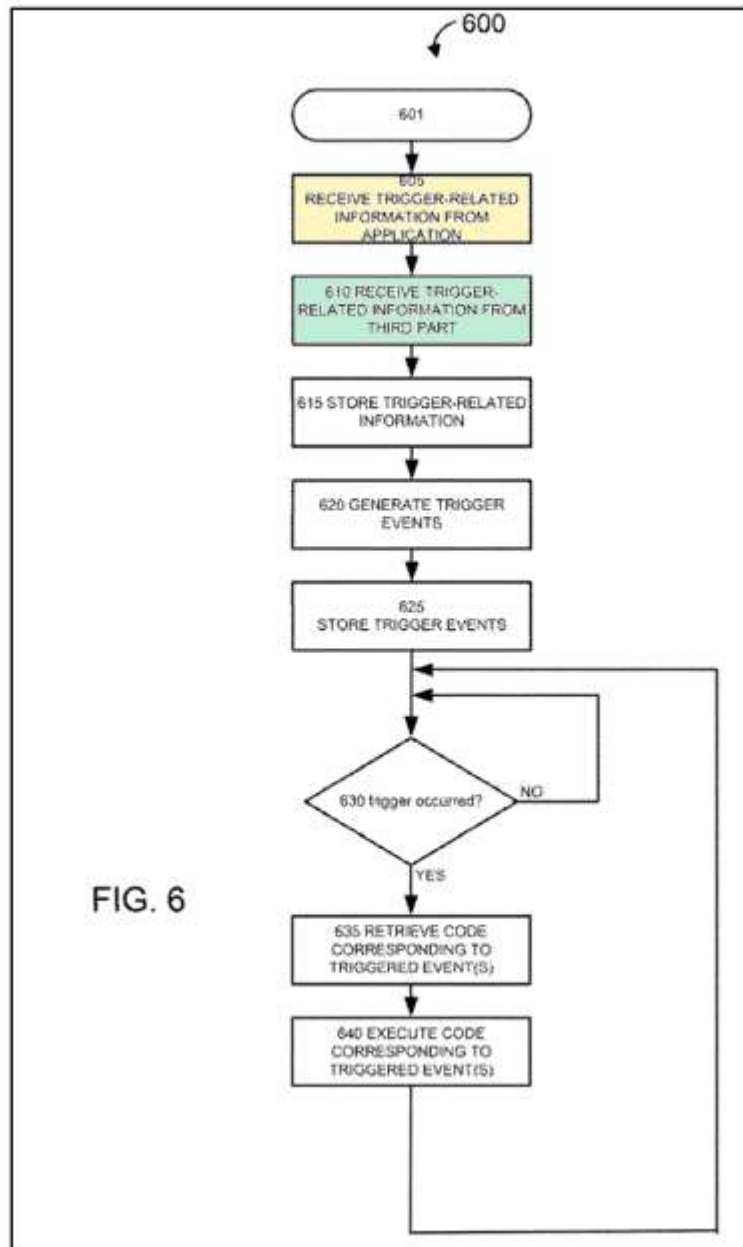
140. Gutekunst discloses alert rule settings being created or modified by the remote monitor. Gutekunst explains that a “medical monitoring and

surveillance system uses a server communicating with a general-purpose personal device running an application.” Ex-1006, Abstract. Gutekunst further describes the “user device 215,” or *receiver*, including an application that can be used to create or modify trigger events, or *alert rule settings*. Gutekunst discloses, with reference to Figure 6, how the *server* uses trigger events, or *alert rule settings, configured by the host* using “user device 215,” or *receiver*, and combines them with trigger events, or *alert rule settings*, from a “third party,” or *wireless mobile remote monitor*.

141. Gutekunst discloses details about how alert triggers can be configured for use in a medical monitoring system, such as the one described by Aspel. Gutekunst discloses “embodiments [in which] **the server 220 enables a party (e.g., the user 220, 205, the third party 210, or yet another party) to schedule one or more trigger events** to run manually or automatically at a specified time or date... A task may include searching, filtering, or some other evaluation or utilization of data that, if meeting certain parameters, triggers a subsequent (different) task. By accessing the server 220 through the web interface, **the user 205 or the third party 210 may select from a predefined set of trigger events and build new trigger events.**” Ex-1006, [0127].

142. Gutekunst additionally explains a method in which a user’s “trigger-related information,” or *alert rules settings configured by the host using the*

receiver (depicted in Fig. 6 block 605) is combined and stored with “trigger-related information from third party,” or *alert rules settings being modifiable by the user of the wireless mobile remote monitor*, (depicted in Fig. 6 block 610) for evaluation by a decision block 630. This allows a third-party user of a *wireless remote monitor*, e.g., a caregiver or medical professional, to modify *recommended alert rule settings*. “FIG. 6 illustrates selected steps and decisions of an exemplary process 600 through which the server 220 creates or modifies a trigger event, and then acts when the trigger event occurs.” Ex-1006, [0156]. *See also* Ex-1006, [0128]-[0129] (a doctor or nurse "multi-Caregiver" setting alert levels using “generated HTML web pages”), [0058]-[0059] (providing details about how traffic is routed to server applications), [0063]-[0066].



143. In the Aspel-Gutekunst combination, the Aspel *server system* would incorporate Gutekunst’s “trigger events,” which include “trigger-related information” from the *receiver* and the *wireless mobile remote monitor*, in order to detect events. A POSITA would have been motivated to combine Aspel and Gutekunst for the reasons explained above in XI.A.1.

3. **Claim 4**

- a) **“The method of claim 1, wherein at least one of the wireless mobile remote monitor and the receiver comprise one or more of a mobile station, a wireless terminal, a tablet, a smart phone, a multi-mode wireless device, and a computer.”**

144. Aspel discloses this limitation.

145. As explained above in Section XI.A.2.b, Aspel discloses a *wireless mobile remote monitor* that is “a **wireless device 444** such as a cellphone or **smartphone device.**” Ex-1005, [0054].

4. **Claim 5**

- a) **“The method of claim 1, wherein the server system comprises at least one processor configured to receive analyte sensor data from the receiver, process the analyte sensor data to detect the event, and forward, when the event is detected, the alert notification message to the wireless mobile remote monitor based on one or more rules mapping the event to the wireless mobile remote monitor designated to receive alert messages related to the detected event.”**

146. Aspel discloses this limitation or renders it obvious in view of Gutekunst.

147. Aspel discloses that “physiological data,” including *analyte sensor data from the receiver*, is sent to the “secure central storage server,” or *server system*, that includes a “computer processor,” or *processor*. Aspel expressly discloses that “[t]he embodiments of the invention may be executed by a

computer processor or similar device programmed in the manner of method steps, or may be executed by an electronic system which is provided with means for executing these steps.” Ex-1005, [0192]. “**Patient physiological data such as ... blood sugar levels ... is collected and transmitted to a secure central storage server** which can be accessed by healthcare professionals for analysis and intervention. This data is also available to the patient for viewing purposes and to aid in self-management of their specific health condition.” Ex-1005, Fig. 1, [0021]. “FIG.1 presents a process flow diagram of the system at a high level. In its essence, the system collects data from medical and measurement devices 102 via an access point 104 that is local to the patient and devices 102. The access point 104 in turn, transmits the data to a data center 106 which securely stores that information, analyses it and provides interfaces for various users 106 to receive guidance, view and interact with that data.” Ex-1005, [0046].

148. In addition, a POSITA would have understood that the various servers described by Aspel include traditional computer components such as processors and memory.

149. Gutekunst explains, in the context of Figure 6, that “the server 220 receives trigger-related information from the third party 205 (or its device 230, or yet another device).” Ex-1006, [0159]. The received information is processed by a “trigger generator” to “generate trigger events” that are used by the server to create

notifications. Ex-1006, [0161]-[0165]. Thus, *the alert notification message to the wireless mobile remote monitor is based on one or more rules mapping the event to the wireless mobile remote monitor designated to receive alert messages related to the detected event.* Aspel's and Gutekunst's disclosure of these and other claim limitations is discussed above in XI.A.2.b-d. A POSITA would have been motivated to combine Aspel and Gutekunst for the reasons explained in XI.A.1, above.

5. Claim 6

- a) **“The method of claim 1, further comprising detecting, based on a first set of rules at the server system, the event, wherein the first set of rules used to generate the alert notification message are different from a second set of rules used to generate alerts to be sent to the receiver coupled to a sensor system at the host.”**

150. Aspel renders this limitation obvious in view of Gutekunst.

151. Aspel discloses a first set of rules is used to generate the alert notification message, as explained above in XI.A.2.c. These rules can be modified to create a *second set of rules used to generate alerts* as explained in XI.A.2.k. In addition, Gutekunst explains that the server receives “trigger-related information from the application” for “user 205”—*a second set of rules to generate alerts to be sent to the receiver* (user device 215) *coupled to the sensor system* (device 218) *at the host* (user 205)—and in a second step receives “trigger-related information from the third party [210] (or its device 230, or yet another device)” —*the first set*

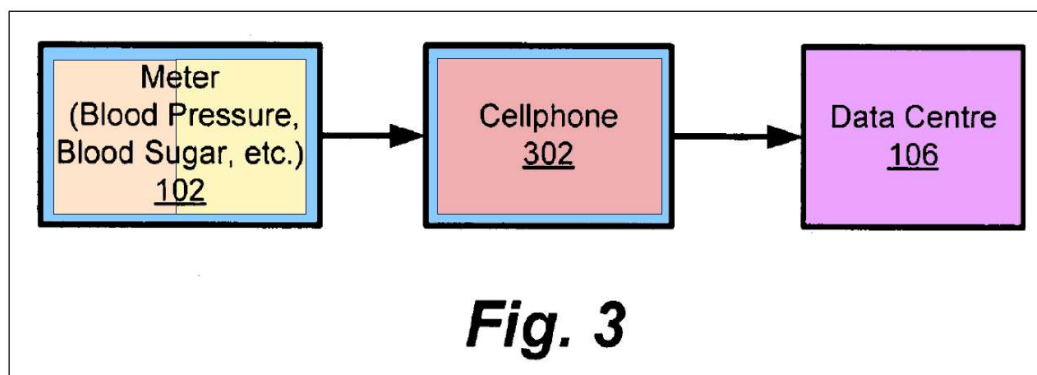
of rules used to generate the alert notification message (for third party 210 and device 230, a *wireless mobile remote monitor*). Ex-1006, [0158]-[0159]. A POSITA would have been motivated to combine Aspel and Gutekunst for the reasons explained in XI.A.1, above.

6. Claim 7

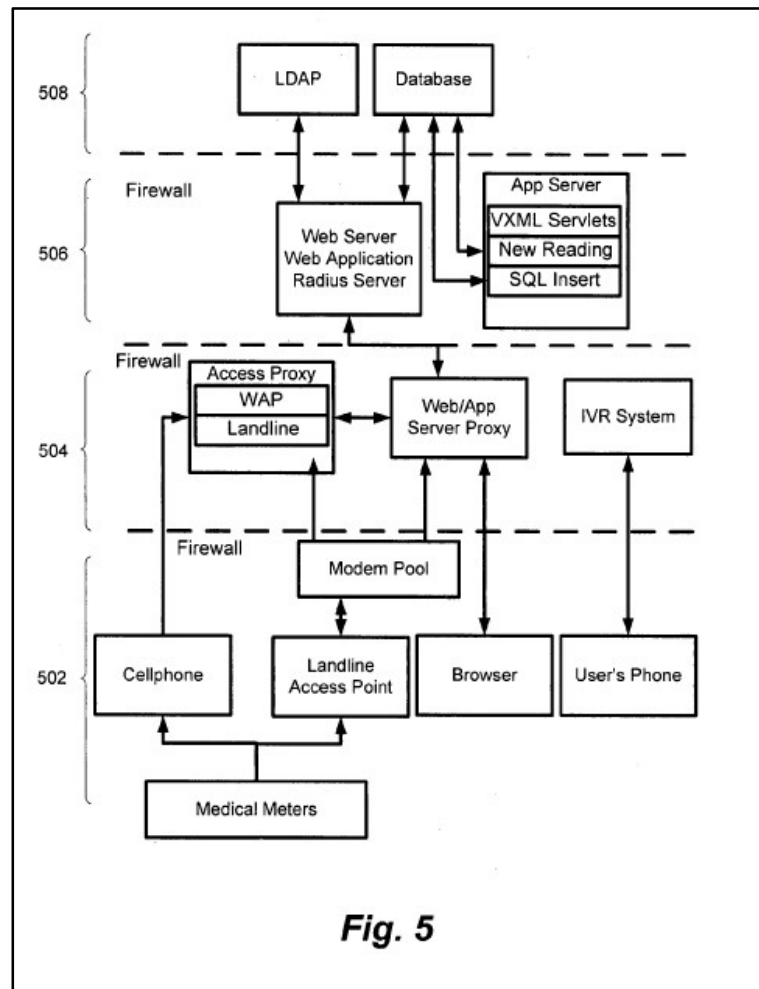
- a) **“The method of claim 1, wherein the receiver includes, or couples to, a gateway interfacing a wireless connection to a public land mobile network and the server system.”**

152. Aspel discloses this limitation.

153. Aspel discloses using a cellphone and its wireless cellular network, *a wireless connection to a public land mobile network*, to upload data from the receiver to the *server system*, using the “WAP gateway,” or *gateway*. Ex-1005, [0119]. “FIG. 3 presents a process flow diagram of the data transfer from a remote device through to the data centre [sic], via a wireless cellular network, in an embodiment of the invention.” Ex-1005, [0030]. A POSITA would have known that a “wireless cellular network” is a *public land mobile network*.



154. Aspel further discloses “[a]s an alternative to the landline access point, medical device readings may be received and forwarded to the central database via a Bluetooth-enabled cellular telephone as presented in the block diagram of FIG. 4. Many existing cellular telephones already have hardware support for such functionality.” Ex-1005, [0112]. “The cellular telephone reformats the medical reading data and lifestyle questions into the dedicated XML specification at step 814. The cellular telephone then transmits the medical reading to the data collection servlet (SQL insert) using the **WAP gateway** and web/app server proxy in the data centre [sic] (using 128 bit SSL encryption) at step 816.” Ex-1005, [0119].



7. Claim 9

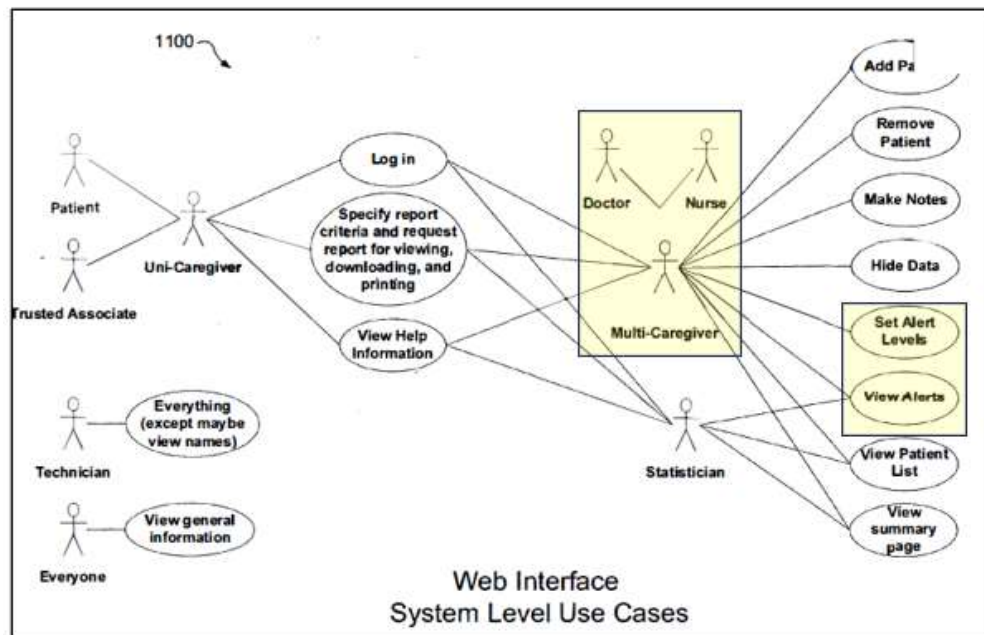
- a) **“The method of claim 1, further comprising configuring, by the wireless mobile remote monitor, at least one rule including a trigger that when triggered causes an alert to be sent by the server system to the receiver.”**

155. Aspel renders this limitation obvious in view of Gutekunst.

156. Aspel discloses a “web interface” that in combination with Gutekunst, allows a user to set alert levels, or *configuring at least one rule including a trigger*, the alerts are sent by the *server system to the receiver*, as explained above in

XI.A.2.c,k. The “web interface” can be accessed and used from a “cellphone,” or *wireless mobile remote monitor*, as depicted in Figure 5.

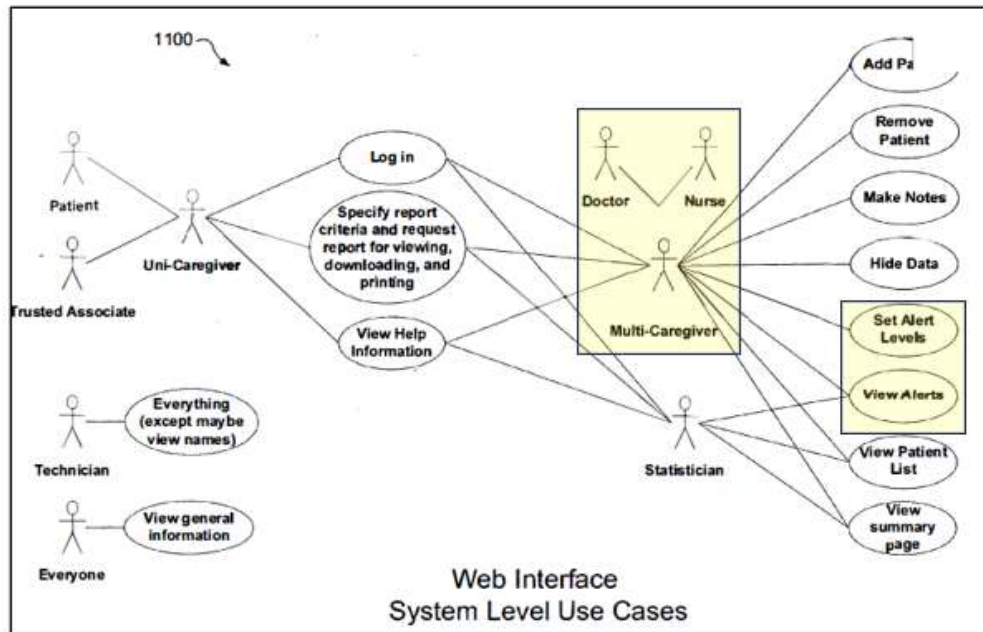
157. Aspel Figure 11 “presents a web interface structure 1100 showing system level use cases generated by the data centre [sic] in connection with FIGS. 14 to 36... The multi-Caregiver has access to functionality such as adding a patient, removing a patient, making notes, hiding data, **setting alert levels**, viewing alert levels, view patient list, or view summary page.” Ex-1005, [0128].



158. Gutekunst discloses a “user device 215,” or *receiver*, with a software application that can receive an alert based on a *rule* configured by *the wireless remote monitor*. Gutekunst discloses a process that includes trigger events configured by a third party, as explained above in XI.A.2.k. In particular, Gutekunst discloses that “[a] triggering task may be paired with an action task.

The server 220 and/or the device 215 can then initiate an action task in response to predetermined parameters being met or not met. An action task may include, for example, code for performing **notifications** and other actions, including these:” Ex-1006, [0133]. “Notification of **a party (e.g., the user 205 and/or the third party 210)** in response to change(s) in an application’s configuration;” Ex-1006, [0134]. “**Notification of a party if one or more predetermined results from an application are above a predetermined threshold, below a predetermined threshold, within a predetermined range, or otherwise meet(s) one or more predetermined criteria.**” Ex-1006, [0135].

159. “FIG. 11 presents a web interface structure 1100 showing system level use cases generated by the data centre [sic] in connection with FIGS. 14 to 36... The multi-Caregiver has access to functionality such as adding a patient, removing a patient, making notes, hiding data, **setting alert levels**, viewing alert levels, view patient list, or view summary page.” Ex-1005, [0128].



160. Gutekunst thus discloses “server 220” which has a “triggering task,” *at least one rule* (predetermined results ... are above a predetermined threshold) *including a trigger that when triggered*, may be paired with an “action task” including “performing notifications.” This in turn *causes an alert to be sent by the server system to*, “a party (e.g., the user 205 ...),” who has “215 user device,” *the receiver*. See Ex-1006, [0133]-[0135]. A POSITA would have been motivated to combine Aspel and Gutekunst for the reasons explained in XI.A.1, above.

8. Claim 11

- a) **“The method of claim 1, further comprising sending, to the server system, a message acknowledging a receipt of the alert notification message.”**

161. Aspel discloses this limitation as explained above in XI.A.2.h.

9. **Claim 13**

- a) **“The method of claim 1, wherein the presenting the alert notification message comprises opening a monitoring application on the wireless mobile remote monitor, and the monitoring application initiating the accessing the at least some of the analyte concentration sensor data from the server system.”**

162. Aspel renders this limitation obvious in view of Gutekunst.

163. Aspel discloses *presenting the alert notification message* using a web browser application, or *monitoring application*, on the *wireless mobile remote monitor* as explained above in XI.A.2.e. For example, Aspel depicts an “‘all alert’ report” in Figure 19. Ex-1005, Fig. 19, [0162]. This report includes a “description” for each alert entry in the report. Ex-1005, [0163]. The exemplary alert entries in Figure 19 demonstrate that the “description” field includes at least some of the data used to generate the alert, e.g., “HS: High Systolic: 131 mmHg.” Thus, *presenting* this report includes *the monitoring application initiating the accessing the at least some of the analyte concentration sensor data from the server system*.

164. Gutekunst further describes a specific type of “medical application” for operating on mobile devices, such as an iPhone. A POSITA would have readily contemplated using a specific application instead of a general purpose web browser, as disclosed in Aspel. Gutekunst’s medical application is a monitoring application, in that “[t]he expression ‘**medical application**’ refers to a **software application** (such as an iPhone® application and analogous applications) for

performing or facilitating at least some part of a medical or health-related diagnostic assessment, medical or health-related test, **medical or health-oriented monitoring protocol**, medical or health-related surveillance protocol, and similar activities related to provision of healthcare and health maintenance services to a user of the application, or to another person... . For example, a software application for **monitoring** a person's blood pressure or **serum glucose level** would be both an 'application' and a 'medical application' as defined herein." Ex-1006, [0079]. Thus, Gutekunst discloses that a "medical application," or *monitoring application*, is "an iPhone® application and analogous applications," i.e., *on the wireless mobile remote monitor*, an "application for monitoring a person's ... serum glucose level." A POSITA would have been motivated to combine Aspel and Gutekunst for the reasons explained in XI.A.1, above.

10. Independent Claim 15

a) 15[preamble]: "A method comprising"

165. Aspel discloses this limitation. *See* Section XI.A.2.a above.

b) 15[a]: "providing, by a wireless mobile remote monitor to a server system, one or more sets of alert rules including at least one analyte concentration level threshold, the one or more sets of rules being specifically associated with the wireless mobile remote monitor and a host,"

166. Aspel discloses this limitation. *See* Sections XI.A.7 and XI.A.2.b-c,k above.

- c) **15[b]: “wherein the wireless mobile remote monitor or a user of the wireless mobile remote monitor is specifically authorized by the host to receive an alert notification message,”**

167. Aspel discloses this limitation or renders this limitation obvious in view of Gutekunst. *See* Section XI.A.2.f above.

- d) **15[c]: “wherein the wireless mobile remote monitor or the user of the wireless mobile remote monitor is authenticated by the server system;”**

168. Aspel discloses this limitation or renders this limitation obvious in view of Gutekunst. *See* Section XI.A.2.f above.

- e) **15[d]: “receiving, at the wireless mobile remote monitor, an alert notification message from the server system,”**

169. Aspel discloses this limitation. *See* Section XI.A.2.b above.

- f) **15[e]: “the alert notification message indicating that analyte concentration sensor data associated with the host has exceeded or fallen below the at least one analyte concentration level threshold,”**

170. Aspel discloses this limitation or renders this limitation obvious in view of Gutekunst. *See* Section XI.A.2.c above. Gutekunst further discloses “[i]n variants, the server 220 transmits the data to the third party 210 in response to **some datum being equal to a trigger, exceeding a trigger, or being less than a trigger ...**,” where the data can be glucose data, i.e., data exceeding or falling below an analyte concentration threshold. Ex-1006, [0126].

- g) **15[f]: “the analyte concentration sensor data being received by the server system from a receiver monitoring an analyte concentration state of the host,”**

171. Aspel discloses this limitation or renders this limitation obvious in view of Gutekunst. *See* Section XI.A.2.c above.

- h) **15[g]: “the wireless mobile remote monitor being remote to the host and the server system;”**

172. Aspel discloses this limitation. *See* Section XI.A.2.d above.

- i) **15[h]: “presenting, at the wireless mobile remote monitor, the alert notification message;”**

173. Aspel discloses this limitation. *See* Section XI.A.2.e above.

- j) **15[i]: “receiving, at the wireless mobile remote monitor, user input indicative of acknowledgment of the presented alert notification message;”**

174. Aspel discloses this limitation. *See* Section XI.A.2.g above.

- k) **15[j]: “sending an acknowledgment message from the wireless mobile remote monitor to the server system indicating acknowledgment of the presented alert notification message to enable the server system to confirm that the alert notification message has been received;”**

175. Aspel discloses this limitation. *See* Section XI.A.2.h above.

- l) **15[k]: “accessing, by the wireless mobile remote monitor, the server system using a remote monitoring**

software application running on the wireless mobile remote monitor; and”

176. Aspel discloses this limitation or renders this limitation obvious in view of Gutekunst. *See* Section XI.A.9 and XI.A.2.h above.

- m) 15[l]: “receiving from the server system, at the wireless mobile remote monitor, information including at least some of the analyte concentration sensor data;”**

177. Aspel discloses this limitation or renders this limitation obvious in view of Gutekunst. *See* Section XI.A.2.j above.

- n) 15[m]: “wherein at least one of the sets of alert rules is configured by the host using the receiver, said at least one set configured by the host being modifiable by the user of the wireless mobile remote monitor using the wireless mobile remote monitor.”**

178. Aspel discloses this limitation or renders this limitation obvious in view of Gutekunst. *See* Section XI.A.2.k above.

11. Independent Claim 16

- a) 16[preamble]: “A wireless mobile remote system comprising:”**

179. Aspel discloses this limitation. *See* Section XI.A.2.a,b above.

- b) 16[a]: “at least one processor; and memory, the memory including instructions to configure the processor to:”**

180. Aspel discloses this limitation.

181. Aspel discloses a “personal computer 442 or a wireless device 444 such as a cellphone or smartphone device,” or *wireless mobile remote system*, and explains at paragraph 192 that embodiments can be executed by a “computer processor or similar device,” *processor*, and an “electronic memory medium,” *memory*, “programmed to execute such method steps,” i.e., *including instructions to configure the processor*. Aspel explains that “[t]he method steps of the invention may be embodied in sets of executable machine code stored in a variety of formats such as object code or source code. Such code is described generically herein as programming code, or a computer program for simplification. Clearly, the executable machine code or portions of the code may be integrated with the code of other programs, implemented as subroutines, plug-ins, add-ons, software agents, by external program calls, in firmware or by other techniques as known in the art.” Ex-1005, [0191]. “The embodiments of the invention **may be executed by a computer processor** or similar device programmed in the manner of method steps, or may be executed by an electronic system which is provided with means for executing these steps. Similarly, **an electronic memory medium such computer diskettes, CD-ROMs, Random Access Memory (RAM), Read Only Memory (ROM) or similar computer software storage media known in the art, may be programmed to execute such method steps**. As well, electronic signals representing these method steps may also be transmitted via a communication

network.” Ex-1005, [0192]. “A medical Caregiver 440 may access the patient data through the data centre [sic] 102 by a personal computer 442 **or a wireless device 444 such as a cellphone or smartphone device**. The medical Caregiver is contacted by a monitoring agent whenever medical attention is required by the patient.” Ex-1005, [0054].

- c) **16[b]: “receive an alert notification message from the server system,”**

182. Aspel discloses this limitation. *See* Section XI.A.2.b above.

- d) **16[c]: “the alert notification message representative of a detected event,”**

183. Aspel discloses this limitation. *See* Section XI.A.2.b above.

- e) **16[d]: “the event being based on analyte concentration sensor data obtained from a receiver monitoring an analyte state of a host, the analyte concentration sensor data indicating a concentration of an analyte of the host;”**

184. Aspel discloses this limitation or renders this limitation obvious in view of Gutekunst. *See* Section XI.A.2.c above.

- f) **16[e]: “present the alert notification message,”**

185. Aspel discloses this limitation. *See* Section XI.A.2.e above.

- g) **16[f]: “wherein the wireless mobile remote system or a user of the wireless mobile remote system is**

specifically authorized by the host to receive the alert notification message”

186. Aspel discloses this limitation or renders this limitation obvious in view of Gutekunst. *See* Section XI.A.2.f above.

h) 16[g]: “to augment the receiver monitoring of the analyte state of the host,”

187. Aspel discloses this limitation or renders this limitation obvious in view of Gutekunst. *See* Section XI.A.2.f above.

i) 16[h]: “wherein the wireless mobile remote system or the user of the wireless mobile remote system is authenticated by the server system;”

188. Aspel discloses this limitation or renders this limitation obvious in view of Gutekunst. *See* Section XI.A.2.f above.

j) 16[i]: “receive user input indicative of acknowledgement of the presented alert notification message;”

189. Aspel discloses this limitation. *See* Section XI.A.2.g above.

k) 16[j]: “send an acknowledgment message to the server system indicating acknowledgment of the presented alert notification message to enable the server system to confirm that the alert notification message has been received;”

190. Aspel discloses this limitation. *See* Section XI.A.2.h above.

l) 16[k]: “after sending the acknowledgment, access at least some of the analyte concentration sensor data from the server system; and”

191. Aspel discloses this limitation. *See* Section XI.A.2.i above.

- m) **16[l]: “receive the at least some of the analyte concentration sensor data including historical data from the receiver monitoring the analyte state of the host;”**

192. Aspel discloses this limitation. *See* Section XI.A.2.j above.

- n) **16[m]: “wherein the event is detected by the server based on one or more sets of recommended alert rules settings configured by the host using the receiver, at least one of the sets of recommended alert rules settings being modification by the user of the wireless mobile remote system using the wireless mobile remote system.”**

193. Aspel discloses this limitation or renders this limitation obvious in view of Gutekunst. *See* Section XI.A.2.k above.

12. Independent Claim 17

- a) **17[preamble]: “A non-transitory computer readable medium comprising executable instructions, the executable instructions being executable by a processor to perform a method, the method comprising:”**

194. Aspel discloses this limitation. *See* Section XI.A.11.b above.

- b) **17[a]: “receiving an alert notification message from a server system,”**

195. Aspel discloses this limitation. *See* Section XI.A.2.b above.

- c) **17[b]: “the alert notification message representative of a detected event,”**

196. Aspel discloses this limitation. *See* Section XI.A.2.b above.

- d) **17[c]: “the event being based on analyte concentration sensor data obtained from a receiver monitoring an**

**analyte state of a host, the analyte concentration
sensor data indicating a concentration of an analyte of
the host;”**

197. Aspel discloses this limitation or renders this limitation obvious in
view of Gutekunst. *See* Section XI.A.2.c above.

e) 17[d]: “presenting the alert notification message,”

198. Aspel discloses this limitation. *See* Section XI.A.2.e above.

**f) 17[e]: “wherein a digital device executing the
instructions or a user associated with the digital
device is specifically authorized by the host to receive
the alert notification message”**

199. Aspel discloses this limitation or renders this limitation obvious in
view of Gutekunst. *See* Section XI.A.2.f above.

**g) 17[f]: “to augment the receiver monitoring of the
analyte state of the host,”**

200. Aspel discloses this limitation or renders this limitation obvious in
view of Gutekunst. *See* Section XI.A.2.f above.

**h) 17[g]: “wherein the digital device or the user of the
digital device is authenticated by the server system;”**

201. Aspel discloses this limitation or renders this limitation obvious in
view of Gutekunst. *See* Section XI.A.2.f above.

**i) 17[h]: “receiving user input indicative of
acknowledgment of the presented alert notification
message;”**

202. Aspel discloses this limitation. *See* Section XI.A.2.g above.

- j) **17[i]: “sending an acknowledgment message to the server system indicating acknowledgement of the presented alert notification message to enable the server system to confirm that the alert notification message has been received;”**

203. Aspel discloses this limitation. *See* Section XI.A.2.h above.

- k) **17[j]: “after sending the acknowledgment, accessing at least some of the analyte concentration sensor data from the server system;”**

204. Aspel discloses this limitation. *See* Section XI.A.2.i above.

- l) **17[k]: “receiving the at least some of the analyte concentration sensor data including historical data, the at least some of the analyte concentration sensor data being generated by the receiver monitoring the analyte state of the host;”**

205. Aspel discloses this limitation. *See* Section XI.A.2.j above.

- m) **17[l]: “wherein the event is detected by the server system based on one or more sets of recommended alert rules settings configured by the host using the receiver, at least one of the sets of recommended alert rules settings being modifiable by the user of the digital device using the digital device.”**

206. Aspel discloses this limitation or renders this limitation obvious in view of Gutekunst. *See* Section XI.A.2.k above.

B. Ground II: Claims 2 and 3 Would Have Been Obvious Based on Aspel in view of Gutekunst and Breen

207. Aspel discloses a health monitoring system and method, as explained above X.A. Gutekunst provides additional implementation details for a medical monitoring and surveillance system that uses a server communicating with a

general-purpose personal device running an application. *See* Section XI.A.1. Breen provides additional details about display of alert notifications. *See* Section X.C. Breen describes a “Notification” settings panel running on iOS 5 on an iPhone device—including the iPhone 4 referenced in the ’541 patent—that allows a user to configure notifications, including “Banners” or “Alerts” alert styles, for “[t]hird-party applications configured to support notifications.”

1. Motivation to Combine Aspel, Gutekunst, and Breen with Reasonable Expectation of Success

208. A POSITA would have been motivated to combine Aspel with Gutekunst as explained in XI.A.1. Breen provides additional disclosures regarding sending notifications to a mobile device, which is an important function of the Aspel-Gutekunst combination, and wherein both Aspel and Gutekunst expressly reference cellular phones, with Gutekunst specifying the iPhone.

Teaching, Suggestion, Motivation

209. As explained above in X.G, Breen provides “reasonably pertinent” disclosures regarding notifications as used in Aspel and Gutekunst. Aspel discloses “exemplary screen captures of various graphic user interfaces (GUIs)” that “are presented to the user via HTML in a web browser but **may also be implemented in a software application ...**” Ex-1005, [0131]. Similarly, Gutekunst describes a “medical application,” which “refers to a software application” “such as an **iPhone® application.**” Ex-1006, [0079].

210. A POSITA would have understood Breen's disclosures regarding the operation of an iPhone to provide details about a "software application" with a user interface that implements the features described by Aspel and Gutekunst. Thus, a POSITA would have understood that combining the notification and user interface elements of Breen with the monitoring system disclosed by Aspel and Gutekunst would enable implementation of their features.

Other Factors and Reasonable Expectation of Success

211. Combining Aspel and Gutekunst with Breen would have involved combining prior art elements (i.e., adding to the Aspel-Gutekunst software application the notification system and user interface elements taught by Breen for iPhone applications) according to known methods to yield predictable results (i.e., an iPhone app for handling notifications and interacting with a server). At the time of the alleged invention, mobile applications that interact with server systems were well-known. Thus, a POSITA would have had a reasonable expectation of success in using Breen's disclosures regarding notifications with the Aspel-Gutekunst system. Claims 2 and 3 appear to simply claim the two options for "Alert Style" provided by iPhone Notification settings.

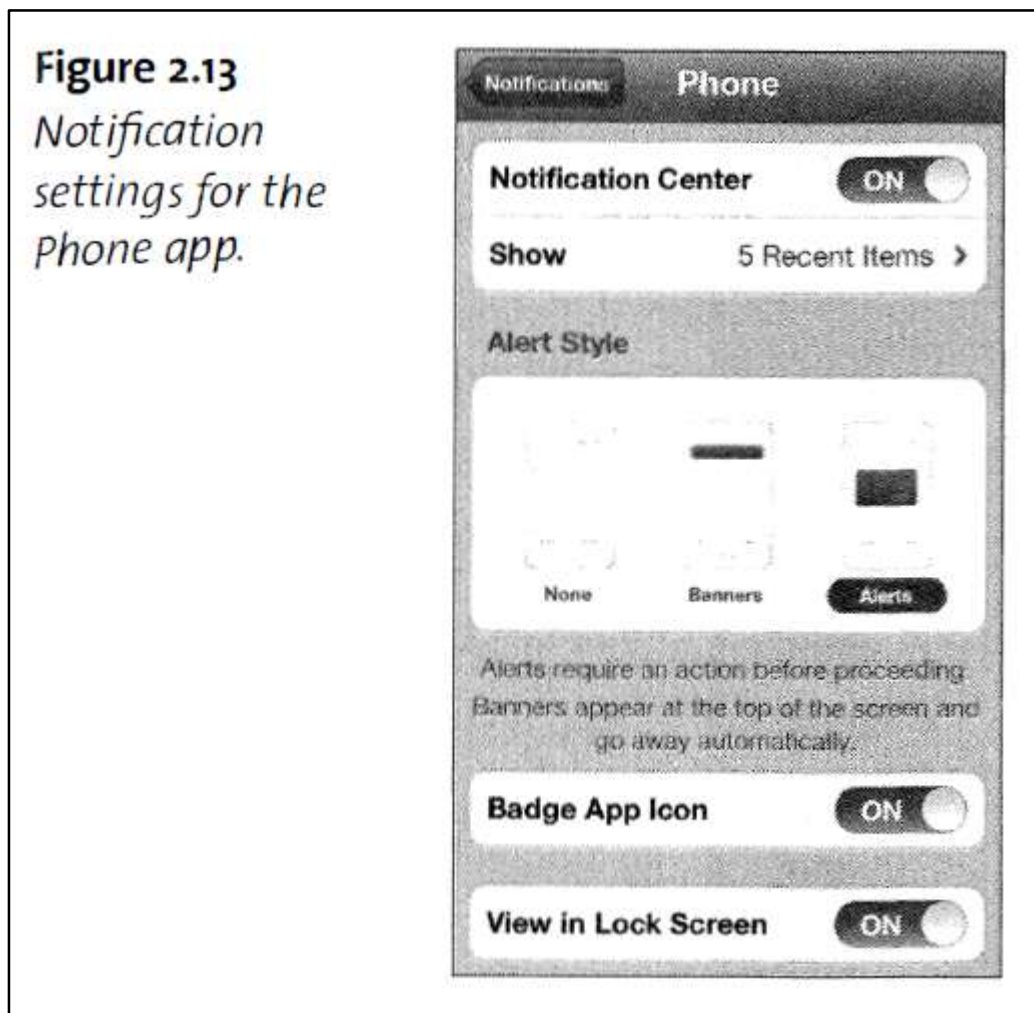
2. Claim 2

- a) **"The method of claim 1, wherein the presenting further comprises inhibiting access to one or more applications at the wireless mobile remote monitor until an action at the wireless mobile remote monitor"**

is detected to indicate an interaction by the user with the alert notification message.”

212. Aspel renders this limitation obvious in view of Gutekunst and Breen.

213. Aspel discloses that “[a]lerts may also be delivered via e-mail, fax, phone, SMS text message or other user desired communication protocols.” Ex-1005, [0094]. Aspel further describes presenting a list of alerts as explained in XI.A.2.e. Breen discloses different visual presentations for an alert notification, the “Alert Style.” Ex-1007, 63-65.



Ex-1007, Fig 2.13, 65. Breen explains that the application can choose to display “Alerts” for notifications, which “require an action before proceeding.” Ex-1007, Fig. 2.13, 64-65. A POSITA would have understood that “requiring an action before proceeding” involves *inhibiting access to one or more applications* until the user performs some action such as “tap Accept,” i.e., *an action at the wireless remote monitor*.

214. In the Aspel-Gutekunst-Breen combination, at least some of the alerts would result in displaying an “Alert,” (“a window that requires some action from you for it to go away”) which would result in the wireless remote monitor *inhibiting access to one or more applications at the wireless mobile remote monitor until an action (“tap Accept”) at the wireless mobile remote monitor is detected to indicate an interaction by the user with the alert notification message*.

215. A POSITA would have combined Aspel with Gutekunst and Breen for at least the reasons described above in Sections XI.B.1 and XI.A.1.

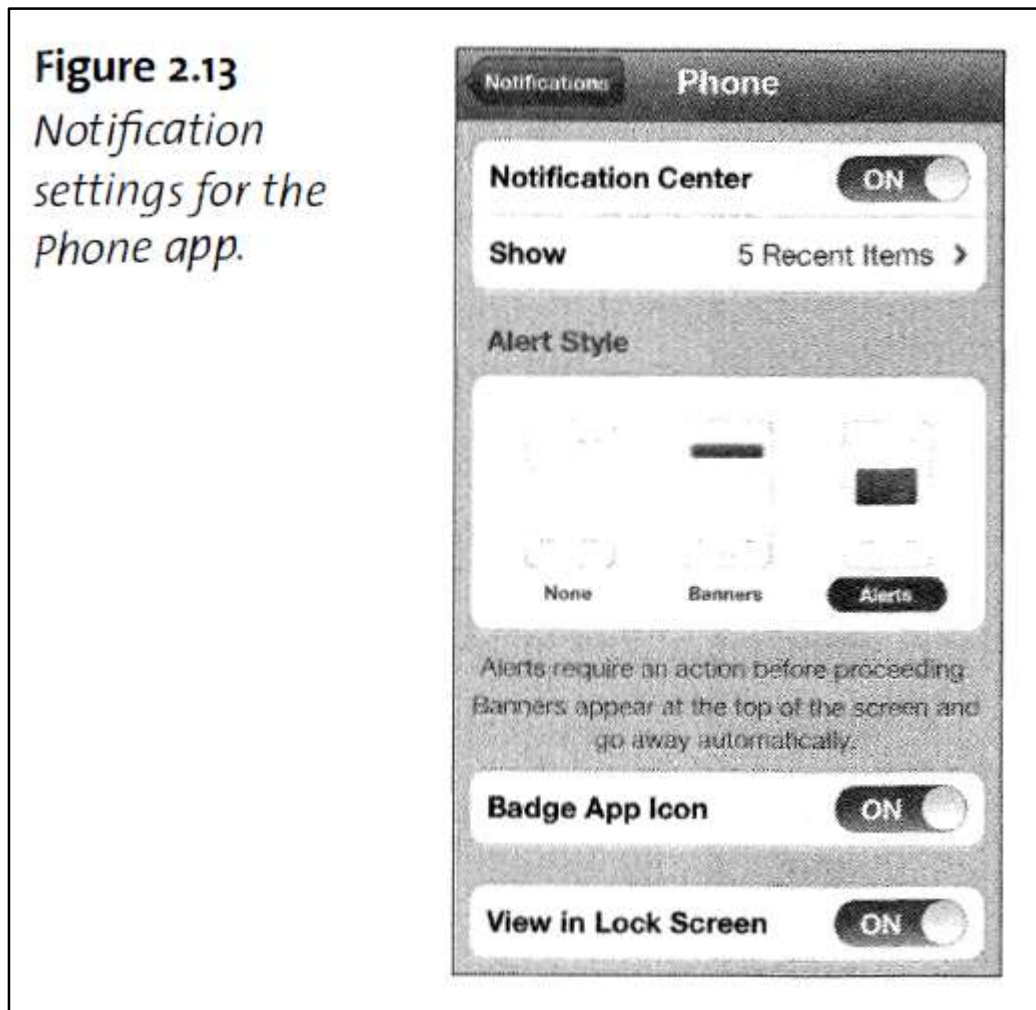
3. Claim 3

a) **“The method of claim 1, wherein the presenting further comprises presenting the alert notification message as a momentary message on a display at the wireless mobile remote monitor.”**

216. Aspel renders this limitation obvious in view of Gutekunst and Breen.

217. Aspel discloses that “[a]lerts may also be delivered via e-mail, fax, phone, SMS text message or other user desired communication protocols.” Ex-

1005, [0094]. Aspel further describes presenting a list of alerts as explained in XI.A.2.e. Breen discloses the visual presentation of a notification with “Banners” “that appear[] for a few seconds at the top of the device’s screen before disappearing,” i.e., *a momentary message on a display at the wireless remote monitor*.



Ex-1007, Fig. 2.13, 65. Breen explains that the application can choose to display “Banners” for notifications. “A banner appears as a short string of text (preceded by

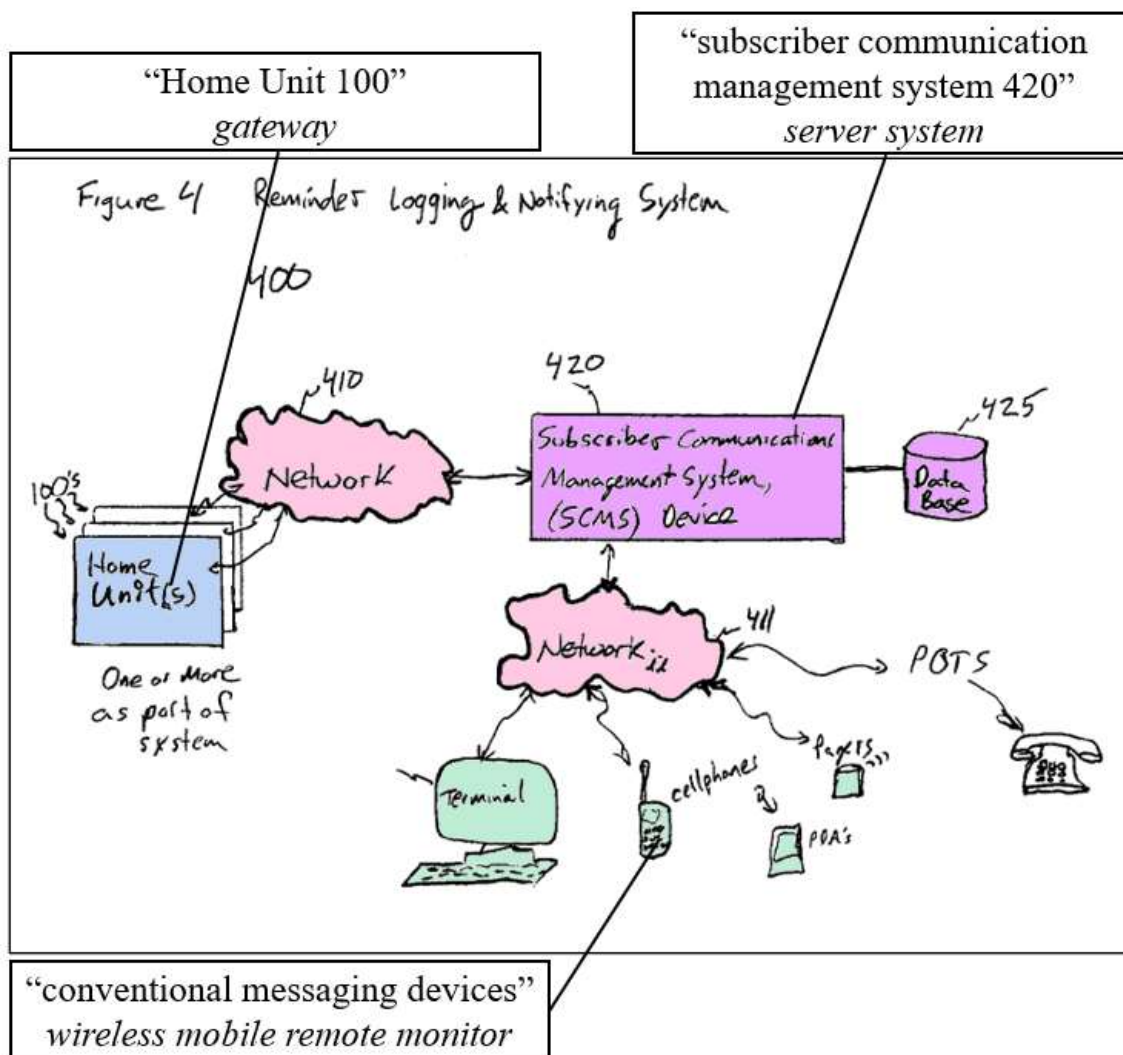
an app's icon) that appears for a few seconds at the top of your device's screen before disappearing." Ex-1007, 64-65.

218. In the Aspel-Gutekunst-Breen combination, at least some of the alerts would result in the *wireless mobile remote monitor* displaying a "Banner" that would "appear[] for a few seconds at the top of [the] device's screen before disappearing," which is *a momentary message on a display at the wireless mobile remote monitor*. This notification and the other type of notification recited in claim 2 are alternatives described in Breen, and thus both equally obvious.

219. A POSITA would have combined Aspel with Gutekunst and Breen for at least the reasons described above in Sections XI.B.1 and XI.A.1.

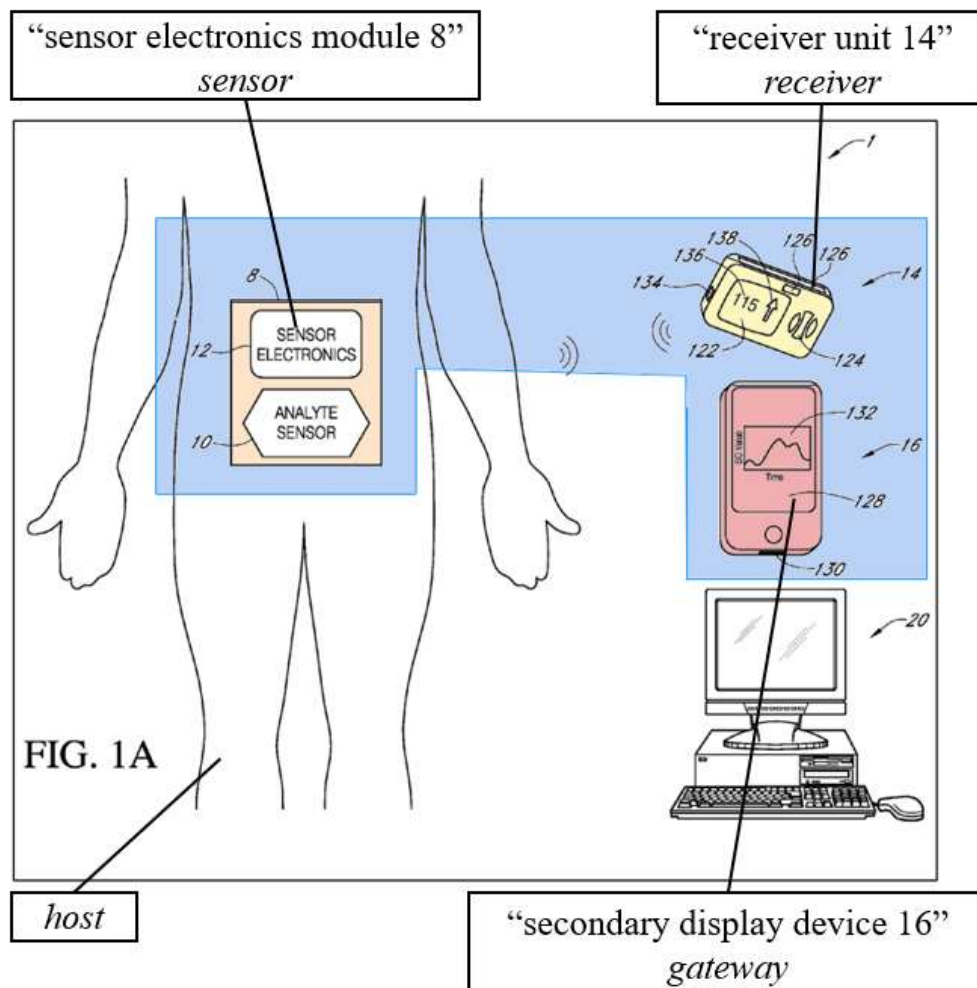
C. Ground III: Claims 1, 4-7, 9, 11, 13, and 15-17 Would Have Been Obvious Based on Paterno in view of Valdes and Hanson

220. As shown below, claims 1, 4-7, 9, 11, 13, and 15-17 would have been obvious based on Paterno in view of Valdes and Hanson. Paterno discloses "[a]n Assisting and Monitoring method and system for compliance logging and monitoring system." Paterno discloses that a "monitoring and notification service provider may offer to subscribers an ability to remotely deliver messages and scheduled event reminders" and a "Home unit" at a patient's location for providing reminders and logging and a server, its SCMS.



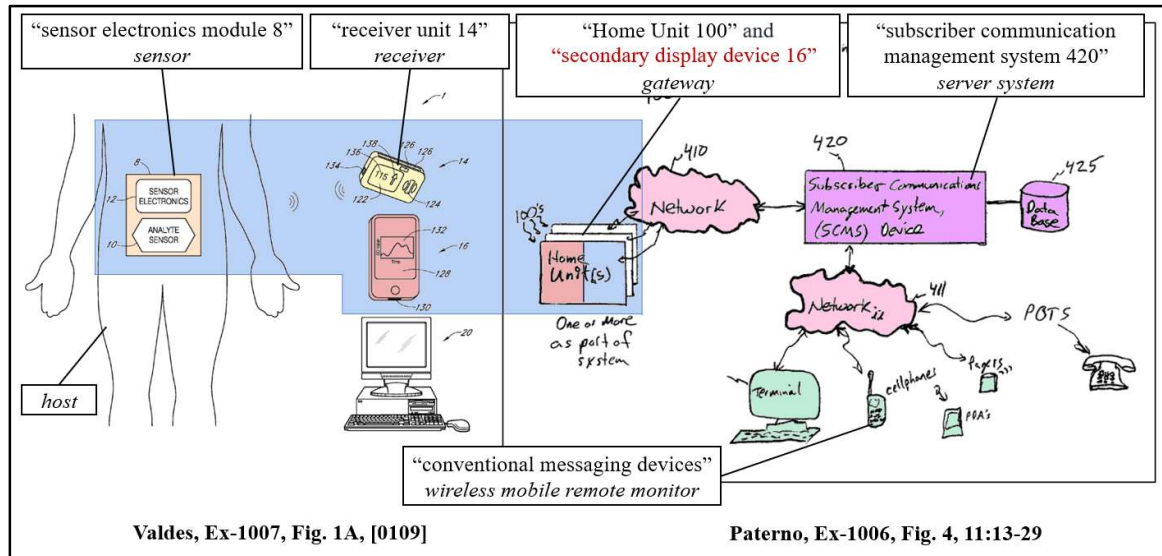
221. Paterno acknowledges the prior art of monitoring systems and devices for “in-home monitoring ... of blood sugar”. Ex-1007, 1:45-47. Using a glucose monitoring system to monitor blood glucose was well known in the prior art, and a POSITA would have considered it obvious to use such a monitoring system for the “in-home monitoring ... of blood sugar” taught by Paterno.

222. Valdes discloses a glucose monitor including a sensor for measuring *analyte concentration sensor data* and a *receiver* to gather the data.



223. Ex-1009, Figs. 1, 3 (annotated). Valdes also provides the capability for the *receiver* to interact with a “secondary device” in order to provide data. A POSITA would have recognized that in the Paterno-Valdes-Hanson combination Paterno’s Home Unit could incorporate a software modification to readily operate as a secondary device to collect data and other information from the *receiver*. Valdes also discloses setting alert rules based on the *analyte concentration sensor data*. A POSITA would have understood that Paterno’s system would incorporate these rules for evaluation by the SCMS, or *server*.

224. The figure below depicts the result of combining Paterno with Valdes as in the proposed combination.



225. Hanson discloses “medication management and reporting technology.” Hanson discloses incorporating additional alert rules into the *server* and provides details about the sequence of interaction between the *wireless remote monitor* and the *server* when alerts occur. For example, Hanson discloses *sending an acknowledgement message* that an alert has been received. In the Paterno-Valdes-Hanson combination, Hanson’s disclosures regarding networking communications would be incorporated into the *server system* and the *wireless mobile remote monitor*.

1. Motivation to combine Paterno, Valdes, and Hanson with Reasonable Expectation of Success

226. Paterno in combination with Valdes renders *a receiver monitoring an analyte state of a host*, and related limitations, obvious, as explained in more detail below. A POSITA implementing Paterno's system would have been motivated to use Valdes' "continuous analyte sensor," "receiver unit," and "secondary display unit" with Paterno's system for providing additional patient data for use in the system, and thereby implement the "in-home monitoring of ... of blood sugar" taught by Paterno. Similarly, Paterno discloses providing *alert notification messages to a wireless remote monitor from a server system*, and Hanson provides additional details regarding the alert process and operation of a wireless remote monitor that would be beneficial for a POSITA implementing Paterno's remote monitoring system. Both Paterno and Hanson include example alerts related to medication.

Teaching, Suggestion, Motivation

227. As explained above in X.G, these references relate to the field of remote monitoring and are at least reasonably pertinent to the '541 patent. In addition, Paterno discloses that "Home Unit(s) 100 are part of a reminding, logging and notification system 400..." Ex-1008, 6:6-10. Paterno further discloses that "monitoring devices and systems exist that can provide in home monitoring of critical health parameters such as blood sugar ..." Ex-1008, 1:46-48. Paterno

discloses that “[t]he SCMS 7000 ... can support numerous data analysis and reporting tools for the information collected by the Home Units, CPTBs, and connected communications tools of the account group members.” Ex-1008, 15:17-27.

228. A POSITA would have understood that one way to monitor “blood sugar” is using a CGM, such as disclosed by Valdes. A POSITA would have understood that for patients with diabetes mellitus, a continuous glucose monitor offers certain advantages. For example, Valdes explains that when “time intervals are spread so far apart ... the diabetic will likely find out too late, sometimes incurring dangerous side effects, of a hyperglycemic or hypoglycemic condition.” Ex-1009, [0004]. “In fact, it is not only unlikely that a diabetic will take a timely SMBG value, but additionally the diabetic will not know if his blood glucose value is going up (higher) or down (lower) based on conventional methods.” Ex-1009, [0004]. Thus, a POSITA would have understood that combining the continuous glucose monitor disclosed by Valdes with the monitoring system disclosed by Paterno would be advantageous for patients with diabetes mellitus.

229. Paterno discloses providing alert messages from its “SCMS,” *server system*, to a caregiver’s “cellphones” or “PDA’s,” *wireless remote monitors*. For example, Paterno describes “Jane receiv[ing] a notification message that Betty has not responded to reminder prompts...” Ex-1008, 16:59-17:4. In addition, Paterno

describes multiple caregivers receiving notifications regarding Betty. Ex-1008, 17:5-17:14. A POSITA would have considered Hanson's disclosures regarding alert messages to be beneficial to Paterno's system because they would allow for more advanced notification rules.

230. Hanson discloses "medication management and reporting technology," incorporating additional alert rules into the *server*. Hanson discloses "providing a remote alert to a remote device" using a variety of "notification mechanisms (e.g., IVR, SMS, email, etc.)." Ex-1010, [0018], [0062]. Hanson describes "alert interfaces" that "enable[] a recipient of the alert (e.g., a doctor, a caregiver, etc.) to receive information regarding the records of the patient." Ex-1010, [0115]. A POSITA would have considered Hanson's disclosures regarding alert messages to benefit Paterno's system by allowing additional notification rules.

Other Factors and Reasonable Expectation of Success

231. Combining Paterno and Valdes would have been combining prior art elements (i.e., adding Valdes's CGM for "monitoring of ... blood sugar" to Paterno's system) according to known methods to yield predictable results (i.e., continuous measurement of the blood glucose level of a host).

232. CGMs, such as Valdes, were well known in the art to yield predictable results. In addition, Valdes discloses using well-known "direct wireless

communication” protocols to send a “data package” using a number of standard protocols “including radio frequency, Bluetooth, universal serial bus, any of the wireless local area network (WLAN) communication standards, including the IEEE 802.11, 802.15, 802.20, 802.22 and other 802 communication protocols, and/or a proprietary communication protocol.” Ex-1009, [0092]-[0093]. Paterno, in turn, describes communication by “wireless means” or “wireless network” throughout. *See, e.g.*, Ex. 1008, 6:10-12, 20:28-34. Because the technology used by Valdes was well-known and in some cases industry standard, a POSITA would have had a reasonable expectation of success in using Valdes’s CGM to generate data and transmit it to Paterno’s Home Unit for use in Paterno’s monitoring system. A POSITA would have known that by 2012, for instance, Medtronic used a wireless network to share glucose information between continuous glucose monitors (Guardian), glucometers (Bayer Contour Next Link), insulin pumps (Revel), remote monitors (mySentry), personal computer software applications (Carelink Professional), and cloud-based systems (Carelink Personal).

233. Adding Hanson to the Paterno-Valdes combination would have been combining prior art elements (i.e., adding Hanson’s mobile application) according to known methods to yield predictable results (i.e., a custom mobile application for interacting with a server). Hanson discloses using “native applications” on “a mobile device” such as a “smart phone, tablet PC, [or] personal digital assistant

(‘PDA’))” to enable more advanced interactions with the monitoring system. Ex-1010, [0055]-[0056]. A POSITA would have readily appreciated the convenience and special features of a native application.

234. Because the transition from a cross-platform website to mobile applications was a common occurrence prior to the priority date of the ’541 patent, a POSITA would have had a reasonable expectation of success.

2. Independent Claim 1

a) 1[preamble]: “1. A method comprising:”

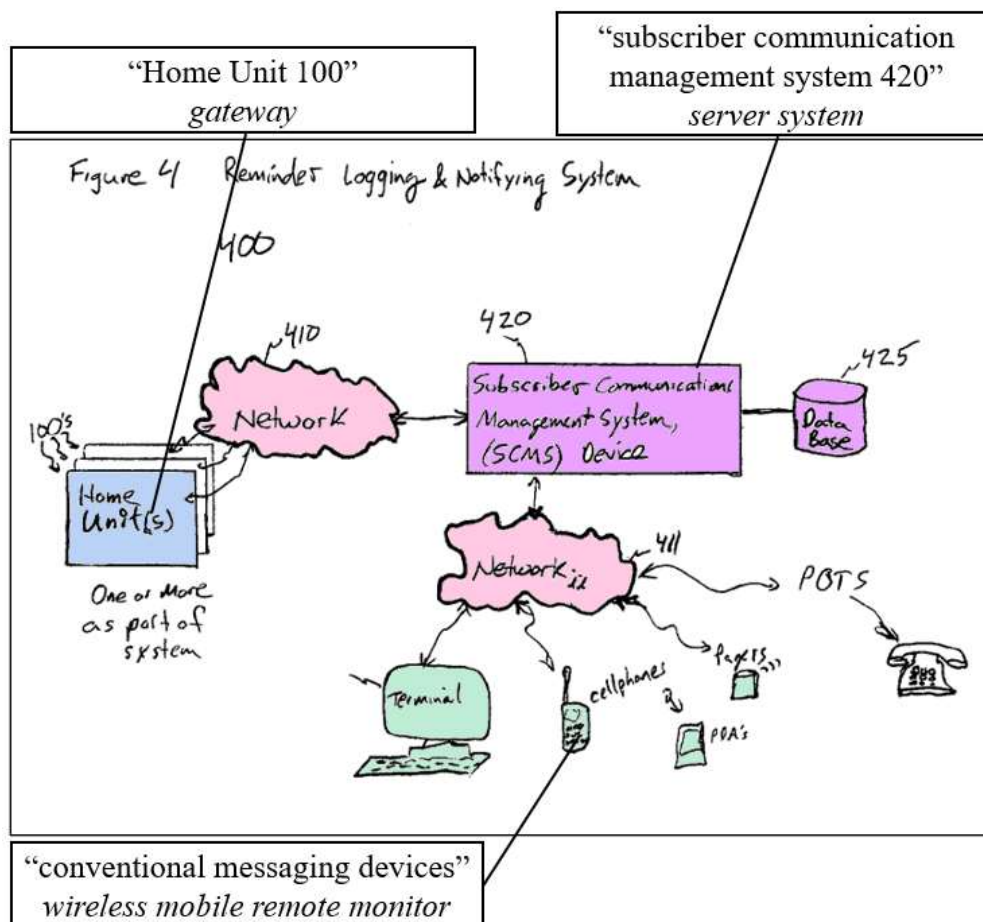
235. Paterno discloses the preamble, to the extent limiting.

236. Paterno explains that “[t]his invention relates to providing convenience reminders, improving compliance to performing routine tasks, and providing automated communications between a person and his or her caregiver(s).” Ex-1008, 1:42-45. Paterno discloses “[a]n Assisting and Monitoring **method** and system for compliance logging and monitoring system for routine activities is presented as well as an automated communications/notification system that can relay the activity and/or inactivity recorded by a Home Unit device to other systems and/or specifically designated people.” Ex-1008, 1:66-2:4.

b) 1[a]: “receiving, at a wireless mobile remote monitor, an alert notification message from a server system, the alert notification message representative of a detected event,”

237. Paterno discloses this limitation.

238. Paterno discloses “conventional messaging devices,” or *wireless mobile remote monitor*, and a “Subscriber Communications Management System, SCMS,” or *server system* sending notification messages (*alert notification messages*) to the wireless mobile remote monitor. For example, Paterno depicts “in FIG. 4 Home Unit(s) 100 are part of a reminding, logging and notification system 400 where the Home Units are remotely located from **a central Subscriber Communications Management System, SCMS. 420. The SCMS is a computer based system with an internal or external database 425**, and it communicates over wired and/or wireless network(s) 411, with **the conventional messaging devices of the caregivers** associated with the Home Unit (reminder & logging) system subscribers.” Ex-1008, Fig. 4, 11:13-29.



239. Paterno’s SCMS “determines when, how, and what notifications to send” based on “customized conditions,” i.e., *detected events*. Namely, Paterno discloses that a “monitoring and notification service provider may offer to subscribers an ability ... to **receive convenient notifications based on customized conditions** related to the logging of activities associated with the scheduled events.” Ex-1008, 11:13-37. In the disclosed system, the “SCMS controller 7010 scans the profile records 9000 of every profile, 8010-8050 and **determines when, how and what notification messages should be delivered** to each member or integrated service system of each subscriber account profile 8010-

8050.” Ex-1008, 16:34-39. Paterno explains, for example, that a caregiver “may specify in the notification parameters that she wants an email sent to her every time the SCMS device 420 receives an update from [the host’s] Home Unit 100.” Ex-1008, 16:50-58. In the Paterno-Valdes combination, the notification may also be based on monitoring *data indicating a concentration of an analyte of the host*, as explained below.

- c) **1[b]: “the event being based on analyte concentration sensor data obtained from a receiver monitoring an analyte state of a host, the analyte concentration sensor data indicating a concentration of an analyte of the host,”**

240. Paterno renders this limitation obvious in view of Valdes.

241. Paterno discloses a system for detecting events, including associated with “in-home monitoring of ... blood sugar,” as explained above, but does not specifically disclose a *receiver* monitoring the *analyte state of a host* to generate *analyte concentration sensor data*. Valdes discloses a CGM that includes a “receiver unit,” or *receiver*, and a “sensor module that generates glucose concentration measurement data,” or *analyte concentration sensor data indicating a concentration of an analyte of the host*. Valdes further discloses different types of “predetermined events” based on the sensor data.

242. In particular, Valdes discloses a “[s]ystem and method for communicating glucose concentration information between devices of a

continuous glucose monitoring system is provided. The **continuous glucose monitoring system can include a sensor module that generates glucose concentration measurement data and transmits the data to one or more further devices of the continuous glucose monitoring system. The further devices can include a receiver unit** and one or more secondary display devices.” Ex-1009, [0002].

243. Valdes further discloses “a software program stored in the computer memory, the software program comprising instructions configured to perform: **receiving sensor data from the substantially continuous glucose sensor,** processing the received sensor data, the processing comprising generating displayable sensor data, displaying an indication of the displayable sensor data on the display, and transmitting the displayable sensor data to a secondary device via the first communication port.” Ex-1009, [0008]. “[T]he software further comprises instructions for determining an occurrence of **a predetermined event based on the processed received sensor data, and for initiating an alert upon the occurrence of the predetermined event,** the alert comprising one or more of an audible alert, a vibratory alert or a visual alert, each of the alerts being performed using a communication unit user interface, wherein **the predetermined event comprises an event selected from the group consisting of exceeding a hypoglycemia threshold, exceeding a hyperglycemia threshold, exceeding an**

approaching hypoglycemia threshold, exceeding an approaching

hyperglycemia threshold, and exceeding a glucose concentration rate-of-

change threshold.” Ex-1009, [0017]. Valdes discloses that “receiver module 200

automatically transmits (‘pushes’) sensor data to secondary display device 16, 20

using telemetry module 232. In this manner, a parent having secondary display

device 16, 20 can remotely monitor a child’s glucose levels. Secondary display

device 16, 20 can additionally have user configurable alerts to alert a parent of a

child’s glucose level... The secondary display device 14, 20 can also be used to

send messages to a child via the child’s receiver unit 14, such messaging including

reminders for the child to eat, calibrate, administer insulin and the like.” Ex-1009,

[0157]. A POSITA would have been motivated to combine Paterno and Valdes for

at least the additional reasons set forth in XI.C.1.

**d) 1[c]: “the wireless mobile remote monitor being
remote to the host and the server system;”**

244. Paterno discloses or renders obvious this limitation.

245. Paterno discloses “conventional messaging devices,” or *wireless mobile remote monitors*, that are remote to the “Home Unit,” located with the *host*, and remote to the SCMS, or *server system*. For example, Paterno depicts “in FIG. 4 Home Unit(s) 100 are part of a reminding, logging and notification system 400 where the Home Units are **remotely located** from a central Subscriber Communications Management System, SCMS. 420. **The SCMS is a computer**

based system with an internal or external database 425, and it communicates over wired and/or wireless network(s) 411, with the conventional messaging devices of the caregivers associated with the Home Unit (reminder & logging) system subscribers. The SCMS provides the interfaces for convenient programming of the Home Unit 100, by Home Unit user, by the caregiver(s) of the user, or any individual or organization authorized by the Subscriber.” Ex-1008, 11:13-29.

246. A POSITA would have been motivated to combine Paterno and Valdes for at least the additional reasons set forth in XI.C.1.

e) 1[d]: “presenting, at the wireless mobile remote monitor, the alert notification message,”

247. Paterno discloses this limitation.

248. Paterno discloses that the “SCMS,” or *server*, sends “notification messages,” or *alert notification messages*, to “communications tools of the caregivers,” or *wireless mobile remote monitor* and those messages are *presented*. Paterno discloses that “Each Home Unit has associated with it an account record in the SCMS. Each account record associated with a Home Unit user account contains pertinent subscriber profile information that includes records of who can access the account, and of the people that can access it, what permissions if any they have to make account profile changes.” Ex-1008, 3:29-42. Paterno’s Home

Unit parameters may include **“how and when members of a subscriber account are notified of Home Unit generated information.”** Ex-1008, 3:29-42.

249. Paterno discloses “[t]he second key function of the SCMS device 420 is to **generate and deliver timely notification messages to the communications tools of the caregivers** and integrated service systems associated with each of the Home Unit/subscriber account profiles 8010-8050. The SCMS controller 7010 scans the profile records 9000 of every profile, 8010-8050 and determines when, how and what notification messages should be delivered to each member or integrated service system of each subscriber account profile 8010-8050.” Ex-1008, 16:30-41. For example, Paterno discloses “[t]he primary caregiver, daughter Jane, may specify in the notification parameters that she wants an email sent to her every time the SCMS device 420 receives an update from Betty’s Home Unit 100, and a text message to her cell phone any time the SCMS receives an immediate action initiated communication from the Home Unit, and after 5 AM any time the SCMS does not receive the expected daily communication (between 2 AM and 4 AM).” Ex-1008, 16:50-58. In the Paterno-Valdes-Hanson combination, the “conventional message devices of the caregivers,” or *wireless mobile remote monitors*, are responsible for *presenting* “notification messages” based on a detected event, or *alert notification messages*. A POSITA would have been motivated to combine

Paterno with Valdes and Hanson for at least the additional reasons set forth in

XI.C.1.

- f) **1[e]: “wherein the wireless mobile remote monitor or a user of the wireless mobile remote monitor is specifically authorized by the host to receive the alert notification message to augment the receiver monitoring of the analyte state of the host, wherein the wireless mobile remote monitor or the user of the wireless mobile remote monitor is authenticated by the server system;”**

250. Paterno renders this limitation obvious in view of Valdes and Hanson.

251. Paterno discloses “subscribers,” the *host*, authorizing “caregivers” to receive “notifications,” or *alert notification message*. Hanson discloses additional details about how the *wireless mobile remote monitor or the user of the wireless mobile remote monitor* is given privileges, i.e., *authorized*, for receiving messages. “The **subscriber can further request customized access permissions by person in the account group**. For instance, **subscribers can specify specific privileges by group member** for both the programming sending of messages, alerts, and alert Schedule updates to the Home Unit in that account, and for setting what notifications and messages they will receive from the system based on the communications from the Home Unit associated with their account.” Ex-1008, 3:52-63.

252. To the extent the language *to augment the receiver monitoring of the analyte state of the host* is a claim limitation,⁶ a POSITA would have understood from Paterno, Valdes, and Hanson that *alert notification messages* sent by the system *augment the receiver monitoring of the analyte state of the host*. Valdes describes benefits for parents who remotely monitor children with diabetes. Ex-1009, [0107]. Hanson describes increased automated monitoring of the patient. Ex-1010, [0116].

253. Hanson further discloses how the user of a *remote monitor* is *authenticated*. For example, Hanson explains that “[t]he first alert interface 1210 also includes a view records input control 1212 that enables a recipient of the alert (e.g., a doctor, a caregiver, etc.) to receive information regarding the records of the patient. For instance, the recipient of the alert may select the view records input control 1212 and, based on the selection, the system 300 retrieves the medical records of the patient from a remote database and displays the retrieved medical records to the recipient of the alert. The recipient of the alert reviews the records of the patient and makes a determination of how to handle the alert. In some implementations, **the system 300 may require the recipient of the alert to provide identification information (e.g., a user name and a password) that**

⁶ See Section XI.A.2.f; Ex-1012, p.15.

verifies that the recipient of the alert is authorized to view the medical records of the patient prior to allowing the recipient of the alert to view the medical records.” Ex-1010, [0115]. A POSITA would have been motivated to combine Paterno with Valdes and Hanson for at least the additional reasons set forth in XI.C.1.

g) 1[f]: “receiving, at the wireless mobile remote monitor, user input indicative of acknowledgment of the presented alert notification message;”

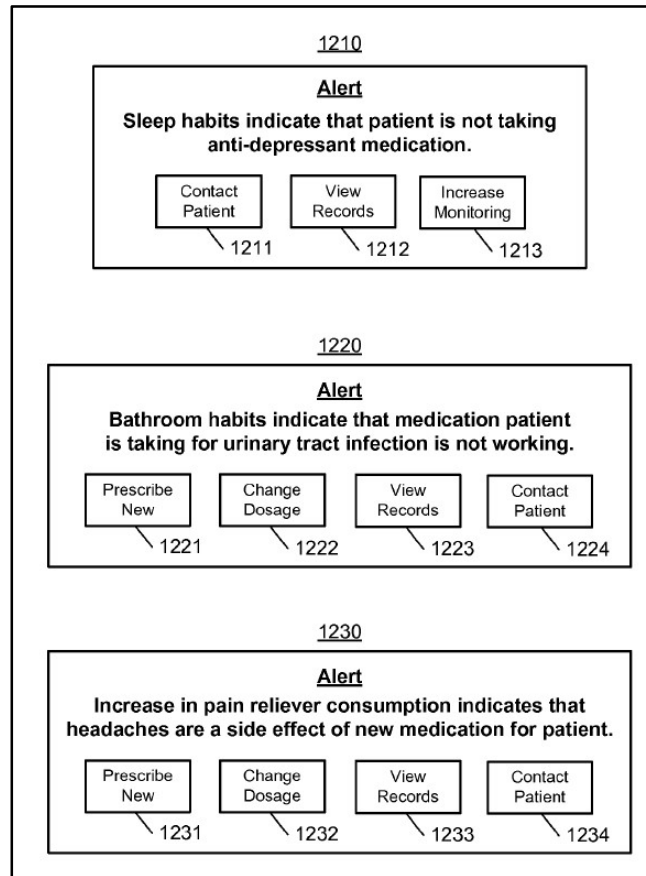
254. Paterno renders this limitation obvious in view of Hanson.

255. Paterno discloses communicating with the *wireless mobile remote monitor*, but does not expressly illustrate the user interface interaction in response to the *alert notification message*. Paterno discloses “initiating communication, receiving acknowledgement that the desired receiving device or system has been reached, transmitting the appropriate data as specified in the memory parameters 200 and receiving confirmation that the transmitted data was received.” Ex-1008, 10:9-14.

256. Hanson discloses “providing an alert to a remote device,” or *wireless mobile remote monitor*, that displays exemplary alert notification dialogs that include “input controls” that “receive input,” *user input indicative of acknowledgement*. These examples relate to alerts for medication, but a POSITA would have readily adapted these examples to the types of alerts discussed above

in XI.C.2.c. Hanson discloses “the system 300 may **provide an alert to a remote device (e.g., mobile phone) of the patient’s doctor, the patient’s caregiver**, or a remote monitoring station to alert the patient’s doctor, the patient’s caregiver, or the remote monitoring station to the issue related to the patient’s taking of the medication.” Ex-1010, [0112]. “The **system 300 sends the alert that causes display of the second alert interface 1220 ...**” Ex-1010, [0119].

257. Hanson explains how the second alert interface operates to alert a recipient to handle the alert. “The second alert interface 1220 provides several **user input controls that help a recipient of the alert (e.g., a doctor, a caregiver, etc.) evaluate and handle the alert.**” Ex-1010, [0120]. “The second **alert interface 1220 also includes a change dosage input control 1222** that allows the recipient of the alert to change a dosage at which the patient is currently taking the medication. **In response to receiving user input selecting the change dosage input control 1222, the system 300 displays an interface that allows the recipient of the alert to select a new dosage for the medication. In response to receiving input selecting the new dosage, the system 300 automatically provides the patient or the patient’s caregiver with a message indicating that the patient’s doctor has set a new dosage for the medication the patient is taking ...**” Ex-1010, [0121].



258. In the Paterno-Valdes-Hanson combination, Hanson's "alert interface" would be used on Paterno's "conventional messaging devices," or *wireless mobile remote monitor*, to provide *presenting an alert notificaiton message and receiving user input indicative of acknowledgment of the message*. A POSITA would have been motivated to combine Paterno with Valdes and Hanson for at least the additional reasons set forth in XI.C.1.

- h) **1[g]: "sending an acknowledgment message from the wireless mobile remote monitor to the server system indicating acknowledgement of the presented alert notification message to enable the server system to**

confirm that the alert notification message has been received;”

259. Paterno renders this limitation obvious in view of Hanson.

260. Paterno discloses “receiving confirmation that the transmitted data was received and deemed complete by embedded data consistency checks,” after “initiating communication, receiving acknowledgement that the desired receiving device or system has been reached, transmitting the appropriate data as specified in the memory parameters 200.” Ex-1008, 10:9-14.

261. Hanson discloses using the second alert interface to acknowledge the *presented alert notification message*. For example, Hanson Figure 12 further discloses “receiving input selecting the new dosage” and then changing the dosage of the medication in the system (i.e., a form of acknowledgment), namely, “The second alert interface 1220 also includes a change dosage input control 1222 that allows the recipient of the alert to change a dosage at which the patient is currently taking the medication. **In response to receiving user input selecting the change dosage input control 1222, the system 300 displays an interface that allows the recipient of the alert to select a new dosage for the medication. In response to receiving input selecting the new dosage, the system 300 automatically provides the patient or the patient’s caregiver with a message indicating that the patient’s doctor has set a new dosage for the medication the patient is taking... In some implementations, the system 300 may require the recipient**

of the alert to provide identification information (e.g., a user name and a password) that verifies that the recipient of the alert is the patient's doctor prior to allowing the recipient of the alert to change the dosage for the patient's medication." Ex-1010, [0121]. *See also id.* [0018] (describing "confirmation" from the remote device "in response to the local alert"). A POSITA would have understood that Hanson's acknowledgement (change of prescription) could be applied to glucose alerts in Paterno's system. A POSITA would have been motivated to combine Paterno with Hanson for at least the additional reasons set forth in XI.C.1.

- i) **1[h]: "after sending the acknowledgment accessing, by the wireless mobile remote monitor, at least some of the analyte concentration sensor data from the server system; and"**

262. Paterno renders this limitation obvious in view of Valdes and Hanson.

263. Valdes discloses the *analyte concentration sensor data* and Hanson Fig. 12 discloses the user receiving an alert *accessing* records of such data using the first alert interface. Hanson explains that "the recipient of the alert **may select the view records input control 1212** and, based on the selection, the system 300 **retrieves the medical records of the patient from a remote database** and displays the retrieved medical records to the recipient of the alert." Ex-1010, [0115].

264. Hanson further discloses that the medical records include blood sugar sensor data. Ex-1010, [0061] (“The sensors further may include ... a blood sugar sensor”). “The second alert interface 1220 further includes a view records input control 1223 that enables a recipient of the alert (e.g., a doctor, a caregiver, etc.) to receive information regarding the records of the patient. For instance, **the recipient of the alert may select the view records input control 1223 and, based on the selection, the system 300 retrieves the medical records of the patient from a remote database and displays the retrieved medical records to the recipient of the alert.**” Ex-1010, [0122].

265. In the Paterno-Valdes-Hanson combination, the recipient’s selection of the “view records input control” using a “conventional messaging devices,” the *wireless mobile remote monitor*, is *accessing at least some of the analyte concentration sensor data from the server system*. A POSITA would have been motivated to combine Paterno with Valdes and Hanson for at least the additional reasons set forth in XI.C.1.

- j) **1[i]: “receiving, in response to the accessing, information the at least some of the analyte concentration sensor data including historical data, the at least some of the analyte concentration sensor data being generated by the receiver monitoring the analyte state of the host;”**

266. Paterno renders this limitation obvious in view of Valdes and Hanson.

267. Hanson Fig. 12 discloses *receiving* medical records in response to *accessing* them. “The first alert interface 1210 also includes a view records input control 1212 that enables a recipient of the alert (e.g., a doctor, a caregiver, etc.) to receive information regarding the records of the patient. For instance, the recipient of the alert may select the view records input control 1212 and, based on the selection, the system 300 **retrieves the medical records of the patient from a remote database** and displays the retrieved medical records to the recipient of the alert.” Ex-1010, [0115]. Hanson discloses that the medical records include blood sugar sensor data. Ex-1010, [0061] (“The sensors further may include ... a blood sugar sensor”).

268. Valdes discloses providing *analyte concentration sensor data* to the server system so that it becomes part of the medical records that can be first accessed and then received, as explained above in XI.C.2.c.

269. In the Paterno-Valdes-Hanson combination, in response to the recipient’s selection of the “view records input control,” the system “retrieves the medical records of the patient from a remote database,” thereby *receiving information the at least some of the analyte concentration sensor data including historical data*. This data would include *at least some of the analyte concentration sensor data being generated by the receiver monitoring the analyte state of the host* because the Valdes “receiver unit 14” uploads the analyte concentration

sensor data to the database. A POSITA would have been motivated to combine Paterno with Valdes and Hanson for at least the additional reasons set forth in XI.C.1.

- k) 1[j]: “wherein the event is detected by the server system based on one or more sets of recommended alert rules settings configured by the host using the receiver, at least one of the sets of recommended alert rules settings being modifiable by the user of the wireless mobile remote monitor using the wireless mobile remote monitor.”

270. Paterno renders this limitation obvious in view of Valdes.

271. Paterno discloses an “SCMS,” or *server system*, that “generates and delivers timely notification messages,” i.e., when *the event is detected by the server system based on one or more sets of recommended alert rules settings*. Paterno further discloses that a “caregiver” can customize “notification parameters,” i.e., *at least one of the sets of recommended alert rules settings being modifiable by the user of the wireless mobile remote monitor using the wireless mobile remote monitor*. Valdes discloses a *host* “configuring alert settings of a glucose monitoring system,” i.e., *one or more sets of recommended alert rules settings configured by the host using the receiver*. A POSITA would readily have incorporated the “alert settings” disclosed by Valdes into the notification system disclosed by Paterno with expectation of success.

272. Paterno discloses users of wireless remote monitors may modify alert rules settings: “subscribers can specify specific privileges by group member for both the programming sending of messages, alerts, and alert schedule updates to the Home Unit in that account, and for setting what notifications and messages they will receive from the system based on the communications from the Home Unit associated with their account.” Ex-1008, 3:57-63. For example, Paterno explains that “[t]he **primary caregiver, daughter Jane, may specify in the notification parameters** that she wants an email sent to her every time the SCMS device 420 receives an update from Betty’s Home Unit 100, and a text message to her cell phone any time the SCMS receives an immediate action initiated communication from the Home Unit, and after 5 AM any time the SCMS does not receive the expected daily communication (between 2 AM and 4 AM).” Ex-1008, 16:50-58.

273. Valdes discloses *one or more sets of recommended alert rules settings* are “configured by the host using the receiver,” as required by this limitation. Valdes discloses that “**the receiver unit 14 has a set of configurable alert settings, wherein the set of alert settings can be initially set to a first, configuration (such as a default configuration set by a manufacturer), but modified to a second, different configuration.** Display device 16 or 20 can receive user input via a user interface (e.g., via one or more buttons, a keypad,

voice recognition software, touch-sensitive display, etc. incorporated into the display device) indicative of modifying the alert settings and send a data message to the receiver unit 14 indicative of the modifications. Alternatively, **the receiver unit 14 can allow a user to modify the alert setting using the user interface of the receiver unit. The receiver unit 14 can then modify the current settings according to the user input.** The set of settings can include a hypoglycemic setting, a hyperglycemic setting, a rate-of-change setting and a calibration setting.” Ex-1009, [0124].

274. In the Paterno-Valdes-Hanson combination, the Paterno system would detect an *event* based on data received from the Valdes “receiver unit 14,” and the detected events would be based on an “alert setting,” *one or more sets of recommended alert rule settings*, that the *host configured* using “receiver unit 14”, *the receiver*. Further, Paterno discloses a caregiver, or *user*, could use “conventional messaging devices,” a *wireless mobile remote monitor*, to modify these settings making them *modifiable by the user of the wireless mobile remote monitor using the wireless mobile remote monitor*. A POSITA would have been motivated to combine Paterno with Valdes and Hanson for at least the additional reasons set forth in XI.C.1.

3. Claim 4

- a) **“The method of claim 1, wherein at least one of the wireless mobile remote monitor and the receiver**

comprise one or more of a mobile station, a wireless terminal, a tablet, a smart phone, a multi-mode wireless device, and a computer.”

275. Paterno discloses this limitation.

276. As explained above in XI.C.2.b, Paterno discloses “conventional messaging devices,” which each are a *wireless mobile remote monitor*. Figure 4 depicts, for example, cellphones, PDA’s, and pagers. Ex-1008, Fig.4.

4. Claim 5

- a) **“The method of claim 1, wherein the server system comprises at least one processor configured to receive analyte sensor data from the receiver, process the analyte sensor data to detect the event, and forward, when the event is detected, the alert notification message to the wireless mobile remote monitor based on one or more rules mapping the event to the wireless mobile remote monitor designated to receive alert messages related to the detected event.”**

277. Paterno renders this limitation obvious in view of Valdes.

278. Paterno discloses an SCMS device, or *server*. “The SCMS device 420 performs its three key functions: communicates with Home Units 100 and CPTBs, generates custom notification messages to the communications tools of the caregivers and integrated service systems associated with each Subscriber account, and provides convenient method(s) of updating event schedules, messages, reminder parameters, reminder contents, and operational parameters of the Home Units and CPTBs, as directed by each of the subscriber account profiles 8010-

8050.” Ex-1008, 15:44-53. A POSITA would have understood that the SCMS device performs the functions of and includes at least one *processor*. *See also, e.g.*, Ex-1008, 4:32-36 (“**processed** according to pre-configured logical operations”). As explained above, in XI.C.2.b-d, the SCMS device is configured to perform these limitations in combination with the glucose monitor system of Valdes.

279. In the Paterno-Valdes-Hanson combination, Paterno discloses that the SCMS, *secure server*, controller 7010 scans the profile records 9000 of every profile, 8010-8050 and determines when, how and what notification messages should be delivered to each member,” Ex-1008, 16:30-41, i.e., the recited *one or more rules mapping the event to the wireless mobile remote monitor designated to receive alert messages related to the detected event*. A POSITA would have been motivated to combine Paterno with Valdes for at least the additional reasons set forth in XI.C.1.

5. Claim 6

- a) **“The method of claim 1, further comprising detecting, based on a first set of rules at the server system, the event, wherein the first set of rules used to generate the alert notification message are different from a second set of rules used to generate alerts to be sent to the receiver coupled to a sensor system at the host.”**

280. Paterno renders this limitation obvious in view of Valdes.

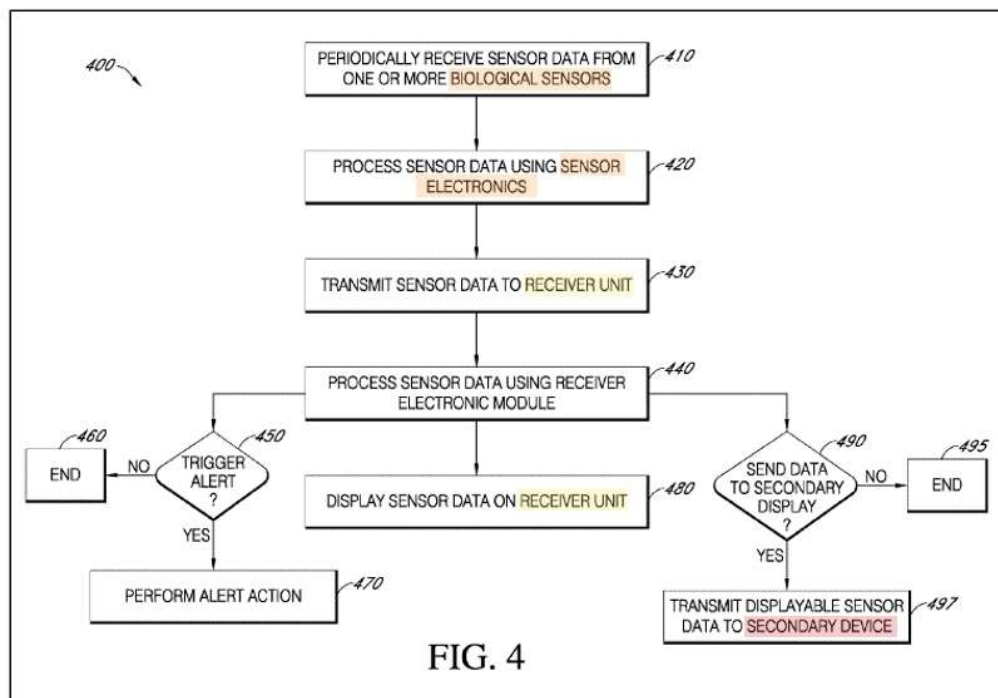
281. Paterno discloses an SCMS device, or *server*, that processes a *first set of rules used to generate the alert notification message* to the remote monitor, as

explained above in XI.C.2.c. “The second key function of the SCMS device 420 is to generate and deliver timely notification messages to the communications tools of the caregivers and integrated service systems associated with each of the Home Unit/subscriber account profiles 8010-8050. **The SCMS controller 7010 scans the profile records 9000 of every profile, 8010-8050 and determines when, how and what notification messages should be delivered to each member or integrated service system of each subscriber account profile 8010-8050.**” Ex-1008, 16:30-16:39.

282. Once the SCMS determines when, how and what notification messages should be delivered, “[t]he SCMS device 420 performs a notification process that is appropriate for each of the notification methods.” Ex-1008, 16:40-41. Paterno includes exemplary notifications messages. “For instance, one profile 8010 may have an event schedule 9020 of tasks with associated reminder alerts that are 2 to 4 per day, depending on day of the week, and a communication schedule 9040 that is daily between 2 AM and 4 AM and after any reminder alert that is not answered after the maximum retries with the user logged “Home”. Further, the account member information 9050 contents of this profile 8010 may also include four caregivers associated with the one Home Unit at Betty’s house. The primary caregiver, daughter Jane, may specify in the notification parameters that she wants an email sent to her every time the SCMS device 420 receives an

update from Betty's Home Unit 100, and a text message to her cell phone any time the SCMS receives an immediate action initiated communication from the Home Unit, and after 5 AM any time the SCMS does not receive the expected daily communication (between 2 AM and 4 AM).” Ex-1008, 16:42-58.

283. Valdes discloses a second set of rules used to generate alerts to be sent to the receiver coupled to a sensor system at the host. Valdes explains the process of using the receiver with a secondary display device with reference to Figure 4.



Ex-1010, Fig. 4. Figure 4 “is a flowchart illustrating one embodiment of a method 400 of using a receiver unit, such as receiver unit 14 or 314, first as a stand alone device and then used in combination with a secondary display device, such as

secondary device 16, 20, 316A, 316B or 316C.” Ex-1009, [0168]. “In block 440, the receiver unit 14, 314 processes the **sensor data received from the sensor electronics unit 12, 312**. The processing performed by the receiver unit 14, 314 can include any of the processing described herein.” Ex-1009, [0172].

284. Valdes provides examples of alerts, including examples that use slightly different alert conditions. “**A first branch proceeds to decision block 450, which decides whether to trigger an alert.** As noted above, each alert can be associated with one or more alert conditions that must be met in order for the respective alert to trigger. **The alert conditions could be any characteristic of the sensor data, transformed sensor data, a display device, a host, or an operator of a display device, along with other characteristics.** For example, two different alerts that are each related to the host reaching a hypoglycemic glucose level may have slightly different alert conditions that must be satisfied in order to trigger the alerts. For example, a first hypoglycemic alert may require that the host’s glucose level is below a first threshold and that a temperature of the host is above a certain threshold, while a second hypoglycemic alert may only require that the host’s glucose level is below a second threshold (which may be slightly lower than the first threshold)... As discussed above, alerts may be triggered based on raw sensor data, transformed sensor data (e.g., calibrated and/or filtered data), or any other data from one or more sensors.” Ex-1009, [0174]. Valdes further

discloses configurations in which its receiver is physically connected to a mobile phone, Ex-1009, [0098].

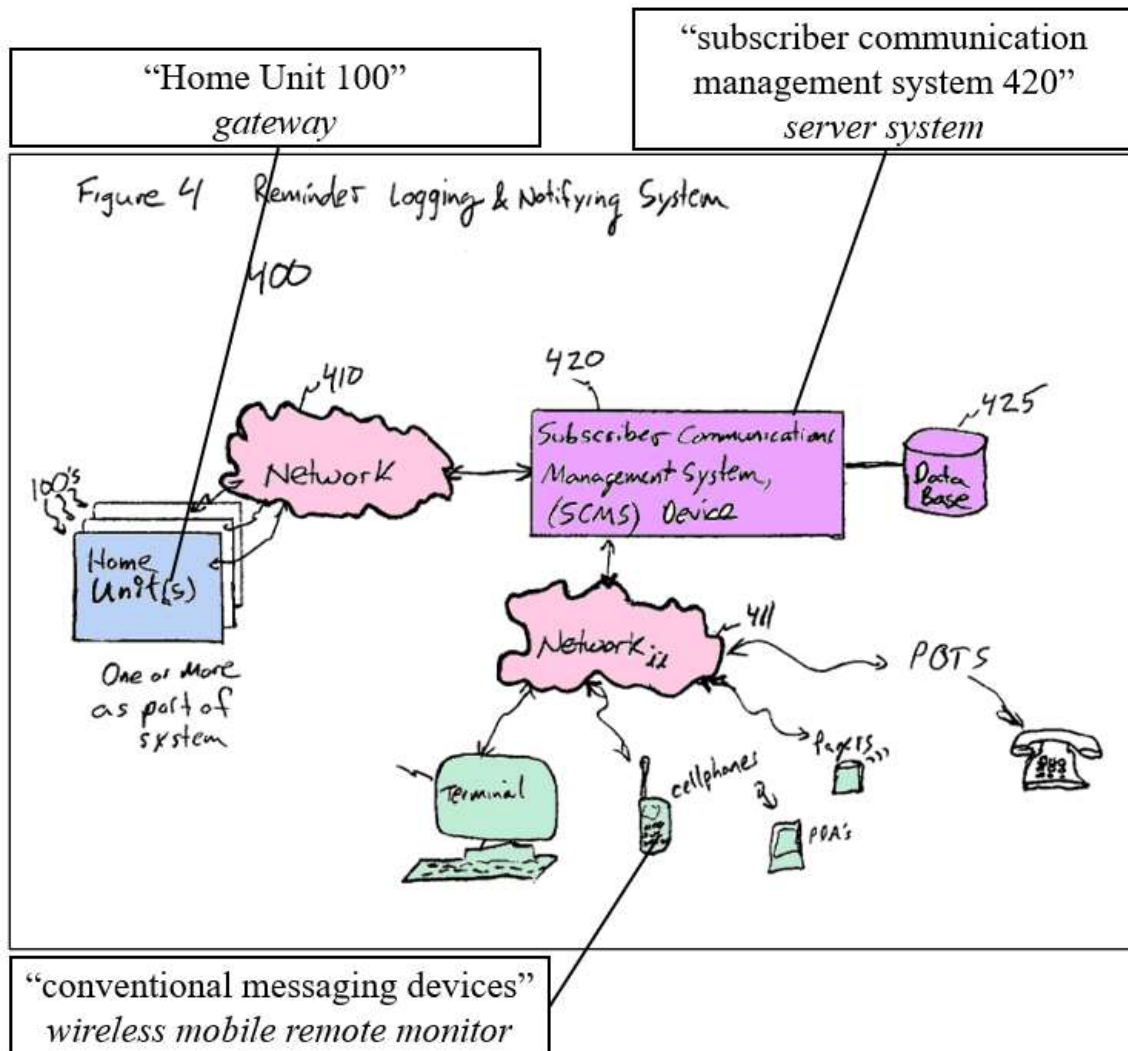
285. In the Paterno-Valdes-Hanson combination, Paterno's "SCMS controller 7010," the *server system*, detects events by scanning "profile records 9000," *a first set of rules at the server system*, and Valdes teaches *a second set of rules used to generate alerts to be sent to the receiver* ("receiver unit 14") *coupled to a sensor system* ("sensor electronics 12") *at the host*. A POSITA would have been motivated to combine Paterno with Valdes for at least the additional reasons set forth in XI.C.1.

6. Claim 7

- a) "The method of claim 1, wherein the receiver includes, or couples to, a gateway interfacing a wireless connection to a public land mobile network and the server system."**

286. Paterno renders this limitation obvious in view of Valdes.

287. Paterno discloses an SCMS device, or *server system* that is accessible via "Network," *a wireless connection to a public land mobile network*.



288. Paterno discloses a gateway in its Home Unit that “includes network(s) and two-way communication devices to exchange information between remotely located event logging devices, (Home Units), and a central Subscriber Communications Management System, (SCMS).” Ex-1008, 3:29-33. “Shown in FIG. 4 Home Unit(s) 100 are part of a reminding, logging and notification system 400 where the Home Units are remotely located from a central Subscriber Communications Management System, SCMS, 420. The SCMS is a computer

based system with an internal or external database 425, and it communicates over wired and/or wireless network(s) 411, with the conventional messaging devices of the caregivers associated with the Home Unit (reminder & logging) system subscribers...” Ex-1008, 11:13-28.

289. Valdes expressly discloses a *gateway* to access the wireless network. “In some embodiments, **a gateway can be included in the glucose monitoring system 1**. The gateway can receive a data packet transmission containing sensor-related data from sensor electronics 12 or receiver 14, for example, in a first data format (e.g., format used with ANT or Bluetooth enabled devices), convert the data packet transmission into a second data format (e.g., format compatible with Wi-Fi enabled devices), and transmit the converted data packet. **The converted data packet can be transmitted over the Internet to a remote storage device or remote computing system for further processing**, for example, or to a receiver unit 14 over a Wi-Fi network.” Ex-1009, [0162].

290. In the Paterno-Valdes-Hanson combination, Paterno’s “Home Unit 100” acts as Valdes’s *gateway* and is used by the “receiver unit 14” in order to upload data “to a remote storage device or remote computing system,” Paterno’s SCMS, the *server system*. A POSITA would have been motivated to combine Paterno with Valdes for at least the additional reasons set forth in XI.C.1.

7. **Claim 9**

- a) **“The method of claim 1, further comprising configuring, by the wireless mobile remote monitor, at least one rule including a trigger that when triggered causes an alert to be sent by the server system to the receiver.”**

291. Paterno renders this limitation obvious in view of Valdes and Hanson.

292. In the Paterno-Valdes-Hanson combination, Paterno’s notification system allows caregivers to use “conventional messaging devices,” *wireless mobile remote monitors*, to modify notification settings such as a blood glucose alert as taught by Valdes, *at least one rule including a trigger that when triggered causes an alert to be sent by the server system to the receiver*. Hanson further describes setting the server’s notification settings so that a notification is sent to a patient’s, or *host’s*, “user interface mechanism,” such as Valdes’s “receiver unit 14,” or *receiver*.

293. Paterno discloses a *wireless mobile remote monitor* that can configure *at least one rule including a trigger*. Paterno discloses that “[t]he SCMS 7000 performs three key functions: communicates with Home Units 100 and CPTBs, generates custom notification messages to the communications tools of the caregivers and integrated service systems associated with each subscriber account, and provides convenient method(s) of updating event schedules, messages, reminder parameters, reminder contents, and operational parameters of the Home

Units and CPTBs. Additionally, it can support numerous data analysis and reporting tools for the information collected by the Home Units, CPTBs, and connected communications tools of the account group members.” Ex-1008, 15:17-27.

294. Paterno further discloses that “[t]he profile 8010 associated with Betty’s Home Unit 100, may further include a Health care provider in the account member information. For Betty’s situation, it may not be desired for the health care provider to receive notifications, but rather to have access to history records, such as trend charts of task completion compliance associated with Betty’s Home Unit recorded event logs. The profile 8010 associated with Betty’s Home Unit 100, may further include a Health care provider in the account member information. For Betty’s situation, it may not be desired for the health care provider to receive notifications, but rather to have access to history records, such as trend charts of task completion compliance associated with Betty’s Home Unit recorded event logs. Further, it may be desired and stored in the profile record 8010 that this health care provider has permission to change the schedule of events and event reminder message contents, and that when any such changes are made, a summary report of the changes is delivered electronically to all caregivers by the methods also specified in the profile 8010.” Ex-1008, 17:27-39. Paterno also describes

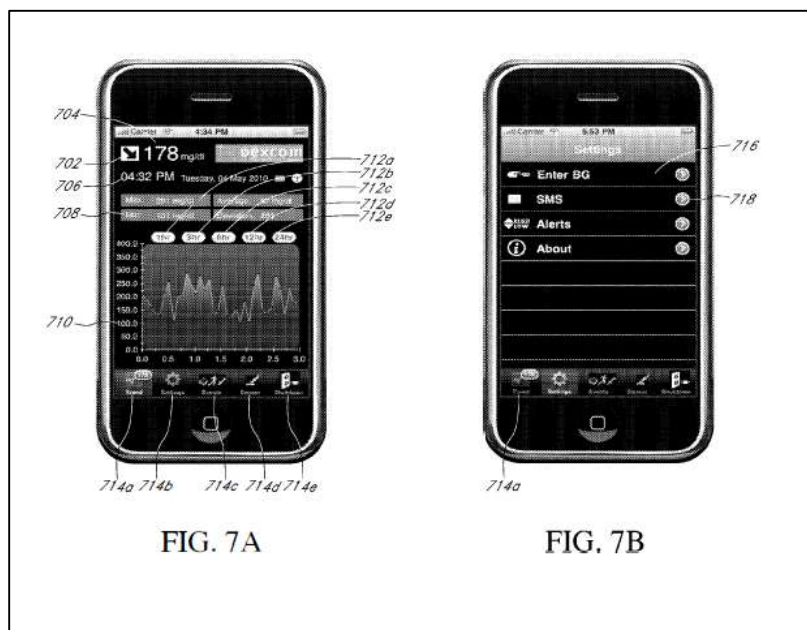
“input types” with “special influences” on controller function, causing “immediate special action, such as triggering an emergency call.” Ex-1008, 5:39-46.

295. Hanson discloses storing sensor data on the *server* and using it to generate a message to the host. Hanson discloses that “[t]he first alert interface 1210 further includes an increase monitoring input control 1213 that enables a recipient of the alert (e.g., a doctor, a caregiver, etc.) to cause an increase in the monitoring procedures used to verify whether the patient is properly taking his or her anti-depressant medication. Because the patient is expected to be failing to comply with his or her medication schedule, the recipient of the alert may determine that increased monitoring of the patient’s medication schedule would be beneficial to confirm whether or not the patient is failing to comply with his or her medication schedule. For example, the increase monitoring input control 1213 may cause the system 300 to increase automated monitoring for whether the patient is complying with the medication schedule. In this example, the system 300 may increase the frequency with which the system 300 takes images of the patient’s medication to get a more accurate timing of when medication is being removed from the patient’s medication tray or other container.” Ex-1010, [0116].

296. Hanson explains, with reference to Figure 6, how the system 300 performs reporting. “[T]he system 300 performs reporting related to one or more medication events (650). Data (including images) from sensors, trigger sources,

user interface devices, monitoring centers can be securely stored on the remote servers or immediately forwarded to the patient, caregivers, or monitoring center. The remote servers, monitoring center, or user interface device can initiate communication to the patient, caregivers, or other trusted parties. Communication can take the form of email, text message, automated or human telephone call, push notification, or other user interface mechanism. Communication can be established based on rules established by the patient, caregivers, monitoring center, or set by default. Rules can be applied to raw or processed data and initiate preemptive action (e.g., reminders) or post medication event action. Processing can also be used to score patients on their compliance level. Scores can be compared to patient historic data or various population scores.” Ex-1010, [0129].

297. Valdes discloses a *receiver* that can display an *alert*. Valdes further discloses “modifying the one or more configurable alert settings in accordance with the user input into a second configuration that is different than the first, default configuration.” Ex-1010, [0032].



298. Valdes includes exemplary user interface images in Figures 7A and 7B. “Further to FIG. 7B, the user interface 700 can include a settings screen that allows a user to select and modify settings of a glucose monitoring system. These settings can be related to settings of the glucose monitoring system 1, such as a receiver unit 14, secondary display device 16, 20, sensor electronics module 8, or other devices associated with the monitoring system like an insulin pump. In the exemplary settings screen of FIG. 7B, the user interface 700 can include a menu of a plurality of selectable items. Functions associated with the plurality of selectable items include: inputting a blood glucose (BG) reference value for use with calibrating continuous glucose sensor data, for example; modifying settings relating to sending SMS alerts; modifying high and low blood glucose threshold alerts; and an “about” setting that can initiate a ‘help’ process that allows a user to

query for information related to the glucose monitoring system 1.” Ex-1009, [0198]. A POSITA would have been motivated to combine Paterno with Valdes and Hanson for at least the additional reasons set forth in XI.C.1.

8. Claim 11

- a) **“The method of claim 1, further comprising sending, to the server system, a message acknowledging a receipt of the alert notification message.”**

299. Paterno renders this limitation obvious in view of Valdes and Hanson as explained above in XI.C.2.h.

9. Claim 13

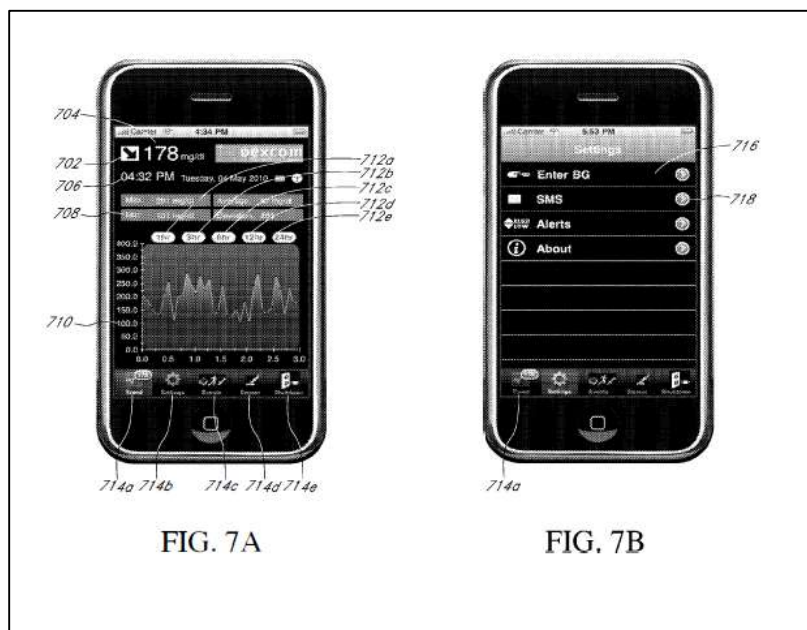
- a) **“The method of claim 1, wherein the presenting the alert notification message comprises opening a monitoring application on the wireless mobile remote monitor, and the monitoring application initiating the accessing the at least some of the analyte concentration sensor data from the server system.”**

300. Paterno renders this limitation obvious in view of Valdes and Hanson.

301. Paterno discloses “cellphones” and “PDA’s” as *wireless mobile remote monitors*. Valdes discloses an application running on a “secondary display device” “such as a mobile telephone, personal digital assistant (PDA), MP3 player or the like.” A POSITA would have readily understood that the application on the “secondary display device” that “provides alerts” could be adapted as a monitoring application for the caregiver “cellphones” and “PDA’s” (*wireless mobile remote monitor*) that Paterno describes.

302. “Furthermore, a low cost Home Unit and communications tool is needed to empower the elderly person to perform his tasks and automatically **send messages related to his activity to the common communication tools of informal caregivers.**” Ex-1008, 1:45-62.

303. Valdes discloses a “continuous glucose monitoring system can include a sensor module that generates glucose concentration measurement data and transmits the data to one or more further devices of the continuous glucose monitoring system. The further devices can include a receiver unit and one or more secondary display devices... A user interface can also be provided that provides enhanced functionality for using the continuous glucose monitoring system.” Ex-1009, [0002]. “In one embodiment, the receiver unit is a computer processor-based device that can be physically and electrically coupled to **a secondary display device having a larger display, such as a mobile telephone, personal digital assistant (PDA), MP3 player or the like.**” Ex-1009, [0098].



Ex-1009, Fig. 7.

304. Valdes discloses a software program with a “user interface software module” that can be used to review glucose readings, *accessing the at least some of the analyte concentration sensor data*. See Ex-1009, Figs. 7A-7E, [0192]-[0193]. According to Valdes, a similar user interface could be provided to clinicians for use on their remote devices. See Ex-1009, [0206] (“connect with a device of the clinician, which may have a similar user interface as user interface 700”). Valdes discloses that the sensor data could be sent to the clinician for display on the clinician’s device. See Ex-1009, [0209] (“[T]he user interface 700 can be used to select sensor data and **transmit the selected data to the clinician for display on the clinician’s device ...**”).

305. Hanson also discloses “user devices” including “a smart phone, a tablet PC, a personal digital assistant (‘PDA’)” that “may include a native medication monitoring and reporting application.” Ex-1010, [0055]-[0056].

306. In the Paterno-Valdes-Hanson combination, Paterno’s “cellphones” and “PDA’s” as *wireless mobile remote monitors* would include opening Valdes’s disclosed “application,” Ex-1007, [0192]-[0193], *monitoring application*, including “user interface 700” that would display Hanson’s “Alert” with the ability to “View Records,” *initiating the accessing the at least some of the analyte concentration sensor data from the server system*. A POSITA would have been motivated to combine Paterno with Valdes and Hanson for at least the additional reasons set forth in XI.C.1.

10. Independent Claim 15

a) 15[preamble]: “A method comprising”

307. Paterno discloses this limitation, to the extent it is limiting. *See* Section XI.C.2.a above.

b) 15[a]: “providing, by a wireless mobile remote monitor to a server system, one or more sets of alert rules including at least one analyte concentration level threshold, the one or more sets of rules being specifically associated with the wireless mobile remote monitor and a host,”

308. Paterno discloses this limitation or renders this limitation obvious in view of Valdes and Hanson. *See* Sections XI.C.7 and XI.C.2.b-c,k above.

- c) **15[b]: “wherein the wireless mobile remote monitor or a user of the wireless mobile remote monitor is specifically authorized by the host to receive an alert notification message,”**

309. Paterno discloses this limitation or renders this limitation obvious in view of Valdes and Hanson. *See* Section XI.C.2.f above.

- d) **15[c]: “wherein the wireless mobile remote monitor or the user of the wireless mobile remote monitor is authenticated by the server system;”**

310. Paterno discloses this limitation. *See* Section XI.C.2.f above.

- e) **15[d]: “receiving, at the wireless mobile remote monitor, an alert notification message from the server system,”**

311. Paterno discloses this limitation or renders this limitation obvious in view of Valdes and Hanson. *See* Section XI.C.2.b above.

- f) **15[e]: “the alert notification message indicating that analyte concentration sensor data associated with the host has exceeded or fallen below the at least one analyte concentration level threshold,”**

312. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.C.2.c above. Valdes further discloses “the predetermined event comprises an event selected from the group consisting of exceeding a hypoglycemia threshold, **exceeding a hyperglycemia threshold,** **exceeding an approaching hypoglycemia threshold,** exceeding an approaching hyperglycemia threshold, and exceeding a glucose concentration rate-of-change

threshold.” Ex-1009, [0017]. *See also* Ex-1009, [0034], [201]. A POSITA would have been motivated to combine Paterno with Valdes and Hanson for at least the additional reasons set forth in XI.C.1.

- g) **15[f]: “the analyte concentration sensor data being received by the server system from a receiver monitoring an analyte concentration state of the host,”**

313. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.C.2.c above.

- h) **15[g]: “the wireless mobile remote monitor being remote to the host and the server system;”**

314. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.C.2.d above.

- i) **15[h]: “presenting, at the wireless mobile remote monitor, the alert notification message;”**

315. Paterno discloses this limitation. *See* Section XI.C.2.e above.

- j) **15[i]: “receiving, at the wireless mobile remote monitor, user input indicative of acknowledgment of the presented alert notification message;”**

316. Paterno discloses this limitation or renders this limitation obvious in view of Hanson. *See* Section XI.C.2.g above.

- k) **15[j]: “sending an acknowledgment message from the wireless mobile remote monitor to the server system indicating acknowledgment of the presented alert notification message to enable the server system to**

confirm that the alert notification message has been received;”

317. Paterno discloses this limitation or renders this limitation obvious in view of Hanson. *See* Section XI.C.2.h above.

l) 15[k]: “accessing, by the wireless mobile remote monitor, the server system using a remote monitoring software application running on the wireless mobile remote monitor; and”

318. Paterno discloses this limitation or renders this limitation obvious in view of Valdes and Hanson. *See* Section XI.C.9 above.

m) 15[l]: “receiving from the server system, at the wireless mobile remote monitor, information including at least some of the analyte concentration sensor data;”

319. Paterno discloses this limitation or renders this limitation obvious in view of Valdes and Hanson. *See* Section XI.C.2.j above.

n) 15[m]: “wherein at least one of the sets of alert rules is configured by the host using the receiver, said at least one set configured by the host being modifiable by the user of the wireless mobile remote monitor using the wireless mobile remote monitor.”

320. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.C.2.k above.

11. Independent Claim 16

a) 16[preamble]: “A wireless mobile remote system comprising:”

321. Paterno discloses this limitation. *See* Section XI.C.2.a,b above.

b) 16[a]: “at least one processor; and memory, the memory including instructions to configure the processor to:”

322. Paterno discloses this limitation.

323. Paterno discloses “conventional messaging devices,” or *wireless mobile remote systems*. For example, Paterno depicts “in FIG. 4 Home Unit(s) 100 are part of a reminding, logging and notification system 400 where the Home Units are remotely located from a central Subscriber Communications Management System, SCMS. 420. The SCMS is a computer based system with an internal or external database 425, and it communicates over wired and/or wireless network(s) 411, with **the conventional messaging devices of the caregivers** associated with the Home Unit (reminder & logging) system subscribers.” Ex-1008, 11:13-29.

324. A POSITA would have understood that “conventional messaging devices,” for example “cellphones” and “PDA’s,” include at least one processor, memory, and instructions to configure the processor.

c) 16[b]: “receive an alert notification message from the server system,”

325. Paterno discloses this limitation. *See* Section XI.C.2.b above.

d) 16[c]: “the alert notification message representative of a detected event,”

326. Paterno discloses this limitation. *See* Section XI.C.2.b above.

e) 16[d]: “the event being based on analyte concentration sensor data obtained from a receiver

monitoring an analyte state of a host, the analyte concentration sensor data indicating a concentration of an analyte of the host;”

327. Paterno discloses this limitation and/or renders this limitation obvious in view of Valdes. *See* Section XI.C.2.c above.

f) 16[e]: “present the alert notification message,”

328. Paterno discloses this limitation. *See* Section XI.C.2.e above.

g) 16[f]: “wherein the wireless mobile remote system or a user of the wireless mobile remote system is specifically authorized by the host to receive the alert notification message”

329. Paterno discloses this limitation and/or renders this limitation obvious in view of Valdes and Hanson. *See* Section XI.C.2.f above.

h) 16[g]: “to augment the receiver monitoring of the analyte state of the host,”

330. Paterno discloses this limitation and/or renders this limitation obvious in view of Valdes and Hanson. *See* Section XI.C.2.f above.

i) 16[h]: “wherein the wireless mobile remote system or the user of the wireless mobile remote system is authenticated by the server system;”

331. Paterno discloses this limitation and/or renders this limitation obvious in view of Valdes and Hanson. *See* Section XI.C.2.f above.

- j) **16[i]: “receive user input indicative of acknowledgement of the presented alert notification message;”**

332. Paterno discloses this limitation and/or renders this limitation obvious in view of Hanson. *See* Section XI.C.2.g above.

- k) **16[j]: “send an acknowledgment message to the server system indicating acknowledgment of the presented alert notification message to enable the server system to confirm that the alert notification message has been received;”**

333. Paterno discloses this limitation and/or renders this limitation obvious in view of Hanson. *See* Section XI.C.2.h above.

- l) **16[k]: “after sending the acknowledgment, access at least some of the analyte concentration sensor data from the server system; and”**

334. Paterno discloses this limitation and/or renders this limitation obvious in view of Valdes and Hanson. *See* Section XI.C.2.i above.

- m) **16[l]: “receive the at least some of the analyte concentration sensor data including historical data from the receiver monitoring the analyte state of the host;”**

335. Paterno discloses this limitation or renders this limitation obvious in view of Valdes and Hanson. *See* Section XI.C.2.j above.

- n) **16[m]: “wherein the event is detected by the server based on one or more sets of recommended alert rules settings configured by the host using the receiver, at least one of the sets of recommended alert rules settings being modification by the user of the wireless**

**mobile remote system using the wireless mobile
remote system.”**

336. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.C.2.k above.

12. Independent Claim 17

- a) **17[preamble]: “A non-transitory computer readable medium comprising executable instructions, the executable instructions being executable by a processor to perform a method, the method comprising:”**

337. Paterno discloses this limitation. *See* Section XI.C.11.b above.

- b) **17[a]: “receiving an alert notification message from a server system,”**

338. Paterno discloses this limitation. *See* Section XI.C.2.b above.

- c) **17[b]: “the alert notification message representative of a detected event,”**

339. Paterno discloses this limitation. *See* Section XI.C.2.b above.

- d) **17[c]: “the event being based on analyte concentration sensor data obtained from a receiver monitoring an analyte state of a host, the analyte concentration sensor data indicating a concentration of an analyte of the host;”**

340. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.C.2.c above.

- e) **17[d]: “presenting the alert notification message,”**

341. Paterno discloses this limitation. *See* Section XI.C.2.e above.

- f) **17[e]: “wherein a digital device executing the instructions or a user associated with the digital device is specifically authorized by the host to receive the alert notification message”**

342. Paterno discloses this limitation or renders this limitation obvious in view of Valdes and Hanson. *See* Section XI.C.2.f above.

- g) **17[f]: “to augment the receiver monitoring of the analyte state of the host,”**

343. Paterno discloses this limitation or renders this limitation obvious in view of Valdes and Hanson. *See* Section XI.C.2.f above.

- h) **17[g]: “wherein the digital device or the user of the digital device is authenticated by the server system;”**

344. Paterno discloses this limitation or renders this limitation obvious in view of Hanson. *See* Section XI.C.2.f above.

- i) **17[h]: “receiving user input indicative of acknowledgment of the presented alert notification message;”**

345. Paterno discloses this limitation or renders this limitation obvious in view of Hanson. *See* Section XI.C.2.g above.

- j) **17[i]: “sending an acknowledgment message to the server system indicating acknowledgement of the presented alert notification message to enable the server system to confirm that the alert notification message has been received;”**

346. Paterno discloses this limitation or renders this limitation obvious in view of Hanson. *See* Section XI.C.2.h above.

- k) **17[j]: “after sending the acknowledgment, accessing at least some of the analyte concentration sensor data from the server system;”**

347. Paterno discloses this limitation or renders this limitation obvious in view of Valdes and Hanson. *See* Section XI.C.2.i above.

- l) **17[k]: “receiving the at least some of the analyte concentration sensor data including historical data, the at least some of the analyte concentration sensor data being generated by the receiver monitoring the analyte state of the host;”**

348. Paterno discloses this limitation or renders this limitation obvious in view of Valdes and Hanson. *See* Section XI.C.2.j above.

- m) **17[l]: “wherein the event is detected by the server system based on one or more sets of recommended alert rules settings configured by the host using the receiver, at least one of the sets of recommended alert rules settings being modifiable by the user of the digital device using the digital device.”**

349. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.C.2.k above.

D. Ground IV: Claims 2 and 3 Would Have Been Obvious Based on Paterno in view of Valdes, Hanson, and Breen

350. Paterno discloses a health monitoring system and method, as explained above X.D. Valdes discloses a glucose monitor receiver and associated alert rules, as explained above in XI.C.1. Hanson provides additional details regarding authorization and authentication for the health monitoring system, as

explained above XI.C.1. Breen supplies user interface details regarding displaying alerts at the *wireless remote monitor*. Breen describes a “Notification” settings panel running on iOS 5 on an iPhone device—including the iPhone 4 referenced in the ’541 patent—that allows a user to configure notifications for “[t]hird-party applications configured to support notifications,” including “Banners” or “Alerts” alert styles.

1. Motivation to Combine Paterno, Valdes, Hanson, and Breen with Reasonable Expectation of Success

351. As discussed above in XI.C.1, a POSITA would have been motivated to combine Paterno with Valdes (CGM) and Hanson (mobile application for remote monitoring). Breen provides additional disclosures regarding sending notifications to a mobile device (an iPhone), which is an important function of the Paterno combination.

Teaching, Suggestion, Motivation

352. As explained above in X.G, Breen provides “reasonably pertinent” disclosures regarding notifications as used in Paterno, Valdes, and Hanson. Hanson states that its “native medication monitoring and reporting application refers to a software/firmware program running on the corresponding mobile device.” Ex-1010, [0056].

353. A POSITA would have understood Breen’s disclosures of user interfaces for “notifications” to beneficially provide an application user interface

that implements Hanson's features. Thus, a POSITA would have understood that combining the user interface elements of Breen with the monitoring system disclosed by Paterno in combination with Valdes and Hanson would be advantageous for implementing the features discussed in the references.

Other Factors and Reasonable Expectation of Success

354. Combining Paterno, Valdes, and Hanson with Breen would have involved combining prior art elements (i.e., adding to Paterno, Valdes, and Hanson the user interface elements taught by Breen) according to known methods to yield predictable results (i.e., a native monitoring application for handling alerts and interacting with the server). At the time of the alleged invention, mobile applications that interact with server systems were well-known, for example as explained in Breen. Thus, a POSITA would have had a reasonable expectation of success in using Breen's disclosures regarding notifications with Paterno, Hanson, and Valdes.

2. Claim 2

- a) **"The method of claim 1, wherein the presenting further comprises inhibiting access to one or more applications at the wireless mobile remote monitor until an action at the wireless mobile remote monitor is detected to indicate an interaction by the user with the alert notification message."**

355. Paterno renders this limitation obvious in view of Valdes, Hanson, and Breen.

356. Paterno discloses sending alerts to a *wireless mobile remote monitor* as explained in XI.C.2.b,e. As explained above in XI.B.1, Breen discloses notification settings for displaying an “Alert” meeting the limitations of this claim. Breen explains that the application can choose to display “Alerts” for notifications, which “require an action before proceeding.” Ex-1007, Fig. 2.13, 64-65. In the Paterno-Valdes-Hanson-Breen combination, at least some of the alerts would result in the *wireless mobile remote monitor* displaying an “Alert” (“a window that requires some action from you for it to go away”), which would result in the wireless mobile remote monitor *inhibiting access to one or more applications at the wireless mobile remote monitor until an action* (“tap Accept”) *at the wireless mobile remote monitor is detected to indicate an interaction by the user with the alert notification message.*

357. A POSITA would have combined Paterno with Valdes, Hanson, and Breen for at least the reasons described above in Section XI.D.1 and XI.C.1.

3. Claim 3

- a) **“The method of claim 1, wherein the presenting further comprises presenting the alert notification message as a momentary message on a display at the wireless mobile remote monitor.”**

358. Paterno renders this limitation obvious in view of Valdes, Hanson, and Breen.

359. Paterno discloses sending alerts to a *wireless mobile remote monitor* as explained in XI.C.2.b,e. As explained above in XI.B.2, Breen discloses a notification with “Banners” meeting the limitations of this claim. “A banner appears as a short string of text (preceded by an app’s icon) that appears for a few seconds at the top of your device’s screen before disappearing.” Ex-1007, 64-65. In the Paterno-Valdes-Hanson-Breen combination, at least some of the alerts would result in the *wireless mobile remote monitor* displaying a “Banner” that would “appear[] for a few seconds at the top of [the] device’s screen before disappearing,” which is *a momentary message on a display at the wireless mobile remote monitor*. This notification and the other type of notification recited in claim 2 are alternative options that are both described in Breen, and thus both equally obvious.

360. A POSITA would have combined Paterno with Valdes, Hanson, and Breen for at least the reasons described above in Section XI.D.1 and XI.C.1.

XII. CONCLUSION

All of the statements made in this declaration of my own knowledge are true. All statements made on information and belief are believed to be true. These statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code.

Declaration of Lane Desborough in Support of Petition for *Inter Partes*
Review of U.S. Pat. No. 9,801,541

Dated: May 8, 2024

Respectfully submitted,

By: _____