

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Al-Ali et al.
U.S. Patent No.: 8,190,223 Attorney Docket No. 50095-0132IP2
Issue Date: May 29, 2012
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Title: NONINVASIVE MULTI-PARAMETER PATIENT MONITOR

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**PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT
NO. 8,190,223 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42**

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LIST OF EXHIBITS

APPLE-1001	U.S. Patent No. 8,190,223 (“the ’223 Patent”)
APPLE-1002	U.S. Patent No. 8,190,223 File History
APPLE-1003	Declaration of Dr. Cockburn
APPLE-1004	U.S. Patent No. 6,707,476 (“Hochstedler”)
APPLE-1005	U.S. Patent Pub. No. 2002/0184055 (“Naghavi”)
APPLE-1006	U.S. Patent Pub. No. 2006/0064020 (“Burnes”)
APPLE-1007	U.S. Patent No. 6,151,518 (“Hayashi”)
APPLE-1008	U.S. Patent No. 5,842,979 (“Jarman”)
APPLE-1009	U.S. Patent No. 6,385,471 (“Mortz”)
APPLE-1010	U.S. Patent No. 6,584,336 (“Al-Ali-336”)
APPLE-1011	U.S. Patent Pub. No. 2003/0181798 (“Al-Ali-798”)
APPLE-1012	U.S. Patent Pub. No. 2003/0009119 (“Kamm”)
APPLE-1013	U.S. Patent Pub. No. 2003/0145852 (“Schmidt”)
APPLE-1014	U.S. Patent Pub. No. 2004/0204637 (“Diab-637”)
APPLE-1015	U.S. Patent No. 6,654,624 (“Diab”)
APPLE-1016	U.S. Patent No. 5,331,549 (“Crawford”)
APPLE-1017	U.S. Patent Pub. No. 2003/0092974 (“Santoso”)

APPLE-1018	U.S. Patent No. 6,912,413 (“Rantala”)
APPLE-1019	U.S. Patent No. 6,658,276 (“Kianl”)
APPLE-1020	U.S. Re-examination No. 90/012,559 File History
APPLE-1021-1059	RESERVED
APPLE-1060	Combined Civil and Criminal Federal Court Management Statistics (Sep. 30, 2023) United States Courts (uscourts.gov), available at: https://www.uscourts.gov/sites/default/files/fcms_na_distprofile0930.2023.pdf
APPLE-1061	Memorandum, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (USPTO June 21, 2022) (“ <i>Director’s Guidance</i> ”)
APPLE-1062	Apple’s Complaint for Patent Infringement (Design), <i>Apple Inc., v Masimo Corporation, et al.</i> , Case No. 1-22-cv-01377 (D. Del. Oct. 20, 2022)
APPLE-1063	Apple’s Complaint for Patent Infringement (Utility), <i>Apple Inc., v Masimo Corporation, et al.</i> , Case No. 1-22-cv-01378 (D. Del. Oct. 20, 2022)
APPLE-1064	Defendant Masimo Corporation’s Answer to Complaint and Counterclaims, <i>Apple Inc., v Masimo Corporation, et al.</i> , Case No. 1-22-cv-01378 (D. Del. Dec. 12, 2022)
APPLE-1065	Order Granting Joint Motion to Amend the Case Schedule, <i>Apple Inc., v Masimo Corporation, et al.</i> , Case No. 1-22-cv-01378 (D. Del. Sep. 21, 2023)
APPLE-1066	Stipulation by Apple Inc.
APPLE-1067	Email Identifying Masimo’s District Court Invalidity Grounds (Nov. 16, 2023)

APPLE-1068 Excerpt of Apple's District Court Expert Invalidity Report, *Apple Inc., v Masimo Corporation, et al.*, Case No. 1-22-cv-01378 (Nov. 22, 2023)

APPLE-1069 Order Granting Unopposed Motion to Stay Certain Patent Counterclaims, *Apple Inc., v Masimo Corporation, et al.*, Case No. 1-22-cv-01378 (Jan. 10, 2023)

CLAIM LISTING

Limitation	Claim Language
[1pre]	A patient monitor capable of measuring at least two physiological parameters,
[1a]	the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information
[1b]	wherein in the common display area, the display of one of the measured values of the first or second physiological parameter is replaced with the other of the measured values based on an occurrence of an event,
[1c]	the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.
[2]	The patient monitor of claim 1, wherein the first display area and the second display area comprise the common display area.
[3]	The patient monitor of claim 1, wherein activation of a user input causes the common display area to replace one of the measured value of the first or second physiological parameter with the other of the measured value of the first or second physiological parameter.
[4]	The patient monitor of claim 1, wherein the common display area is configured to default to displaying one of the measured values of the first or second physiological parameters.
[6]	The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises a non-invasively measured value.
[11]	The patient monitor of claim 1, wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters.

Limitation	Claim Language
[12]	The patient monitor of claim 11, wherein the aspect that changes comprises a display color.
[13pre]	A patient monitor capable of measuring at least two physiological parameters,
[13a]	the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information,
[13b]	wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event,
[13c]	the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient,
[13d]	wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters, wherein the aspect that changes comprises a display size.
[14]	The patient monitor of claim 11, wherein the aspect that changes comprises a display intensity.
[15pre]	A patient monitor capable of measuring at least two physiological parameters,
[15a]	the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information,

Limitation	Claim Language
[15b]	where in the common display area, the display of one of the measured values of the first or second physiological parameter is replaced with the other of the measured values of the first or second physiological parameters based on an occurrence of an event,
[15c]	the event being one of the measured values of the first or second physiological parameters alarming.
[16]	The patient monitor of claim 15, wherein an aspect of an alarm changes when the common display area changes from displaying one of the measured values of the first or second physiological parameters.
[17]	The patient monitor of claim 16, wherein the aspect that changes comprises a display color.
[18pre]	A patient monitor capable of measuring at least two physiological parameters,
[18a]	the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information,
[18b]	wherein in the common display area, the display of one of the measured values of the first or second physiological parameters is replaced with the other of the measured values of the first or second physiological parameters automatically based on which is a more critical one of the measured values of the first or second physiological parameters.
[19]	The patient monitor of claim 18, wherein measured values of the first and second physiological parameters are determined using an output signal of a light sensitive detector capable of detecting light attenuated by the body tissue.
[20]	The patient monitor of claim 18, wherein at least one of measured physiological parameters is determined noninvasively.

Limitation	Claim Language
[21pre]	A method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device, the display location being generally capable of displaying a single physiological parameter measurement, the method comprising:
[21a]	displaying a measured value of a first physiological parameter in a display location of an electronic display; and
[21b]	replacing the display of the measured value of the first physiological parameter with a display of a measured value of a second physiological parameter in the display location when a change in the measurement of the second physiological parameter indicates a worsening state of the patient.
[22]	The method of claim 21, wherein the indication of the worsening state comprises an alarm condition.
[27pre]	A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:
[27a]	a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and
[27b]	a user input button, the activation of which replaces the display of the measured value of the first blood parameter with the measured value of the second blood parameter,
[27c]	wherein the display of the measured value of the first blood parameter is replaced by the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,
[27d]	wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.

Limitation	Claim Language
[28pre]	A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:
[28a]	a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue, and
[28b]	a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter,
[28c]	wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,
[28d]	wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue,
[28e]	wherein the display shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter.
[32]	The patient monitor of claim 27, wherein the attached sensor can provide data through the output signal and through a memory device.
[34]	The patient monitor of claim 27, further comprising a memory for storing trend data on one or more of the first and second blood parameters.
[36]	The patient monitor of claim 27, further comprising an alarm corresponding to either of the measured values of the first and second blood parameters falling below predetermined associated threshold values.
[37]	The patient monitor of claim 36, wherein the alarm comprises at least one of an audio or visual alarm.

Limitation	Claim Language
[42]	The patient monitor of claim 27, wherein the display comprises a first display and the patient monitor further comprises a second display capable of displaying a pulse rate.
[43]	The patient monitor of claim 42, wherein the second display is capable of displaying the pulse rate when the first display displays the measured value of the first blood parameter.
[44]	The patient monitor of claim 42, wherein the second display is capable of displaying indicia identifying the second blood parameter when the first display displays the measured value of the second blood parameter.

Apple Inc. (“Petitioner”) petitions for IPR of claims 1-4, 6, 11-22, 27-28, 32, 34, 36-37, and 42-44 (“Challenged Claims”) of U.S. Patent No. 8,190,223 (“the ’223 Patent”).

I. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104

A. Standing

Petitioner certifies that the ’223 Patent is available for IPR. Petitioner is not estopped from requesting IPR.

B. Challenge and Relief Requested

Petitioner requests IPR of the Challenged Claims on the following grounds, supported by the Declaration of Dr. Cockburn. APPLE-1003, ¶¶1-229.

Ground	Claims	Basis for Rejection
1A	1-4, 6, 11-18, 20-22	§103: Naghavi-Hochstedler-Burnes
1B	19, 27-28, 32, 34, 36-37, 42-43	§103: Naghavi-Hochstedler-Burnes-Hayashi
1C	42-44	§103: Naghavi-Hochstedler-Burnes-Hayashi-Mortz

The ’223 Patent claims earliest priority to an application filed March 1, 2005 (“Critical Date”). Petitioner does not take a position as to whether the ’223 Patent is entitled to this priority, but has applied references that pre-date the Critical Date and qualify as prior art:

Reference	Date	Section
Hochstedler	7/5/2000 (filed) 3/16/2004 (patented)	102(a), 102(e)
Naghavi	12/2/2002 (published)	102(b)
Burnes	9/20/2004 (filed) 3/3/2006 (published)	102(e)
Hayashi	11/21/2000 (patented)	102(b)
Mortz	5/7/2002 (patented)	102(b)

II. SUMMARY OF THE '223 PATENT

A. Brief Description

The '223 Patent relates to “patient monitors” “displaying measurements derived using signals from optical sensors.” APPLE-1001, 1:54-57.

B. Prosecution History

The '223 Patent was allowed after an anticipation rejection over Nielsen (US2003/0120164) or Simond (US2004/0262046). APPLE-1002, 431-446. An Examiner Interview Summary stated that “Nielsen et al. do not teach changing output based on alarm threshold or an evaluation of the relative criticality of measured parameters.” *Id.*, 429.

After issuance, an *ex parte* reexamination request was filed (APPLE-1020, 309-372) and granted with the statement that “Al-Ali [US2002/0082488] provides

a new teaching of changing the parameters that are displayed based on a change in the patient's condition based on measured values of parameters.” *Id.*, 633-644. Responsive to a rejection over Al-Ali (*id.*, 91-100), Patent Owner amended certain claims “to more specifically claim a first display element is being replaced by a second display element.” *Id.*, 56-80. A reexamination certificate was issued. *Id.*, 1-10.

C. Claim Construction

All claim terms should be construed according to the *Phillips* standard. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005); 37 C.F.R. §42.100. Apple submits that no claim terms need be construed to resolve issues of controversy in the present Petition. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011).

III. THE CHALLENGED CLAIMS ARE UNPATENTABLE

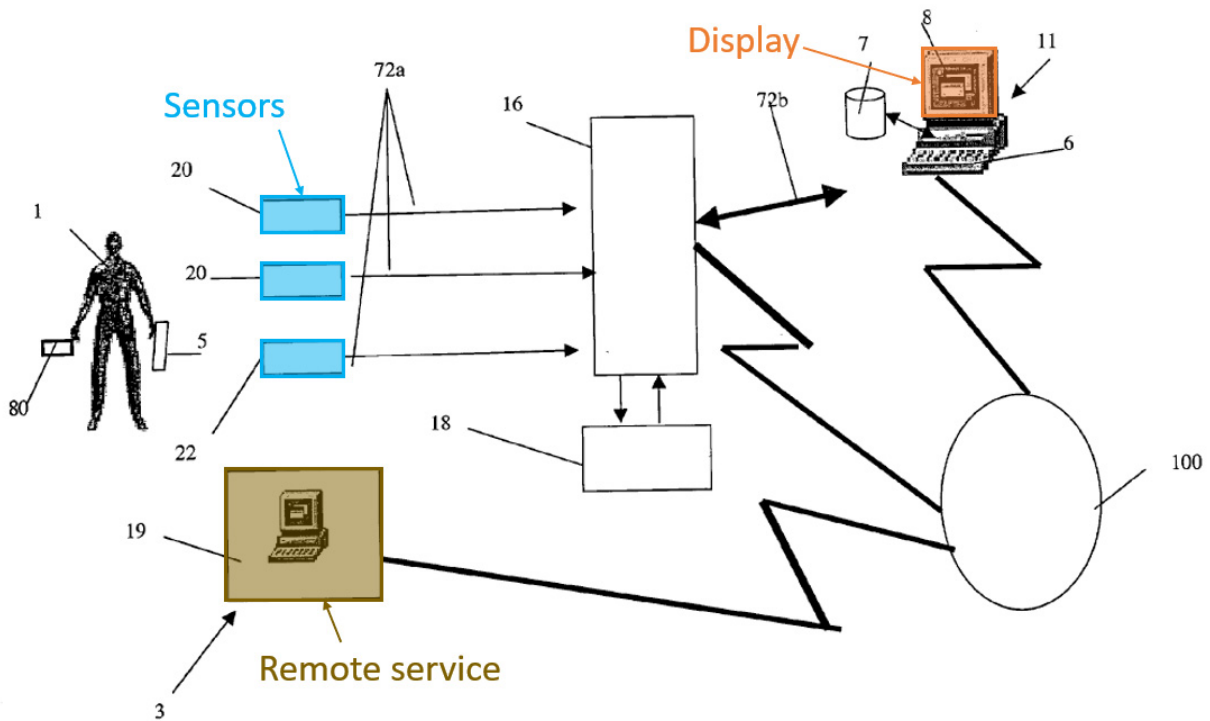
A. [GROUND 1A] – CLAIMS 1-4, 6, 11-18, 20-22 ARE OBVIOUS OVER NAGHAVI-HOCHSTEDLER-BURNES

1. Overview of Naghavi¹

Naghavi describes a flexible “[p]ersonal healthcare management system” for “managing and risk stratifying of patients.” APPLE-1005, [0024]. Naghavi’s

¹ Descriptions of references and combinations thereof are incorporated into each mapping having citations to these references.

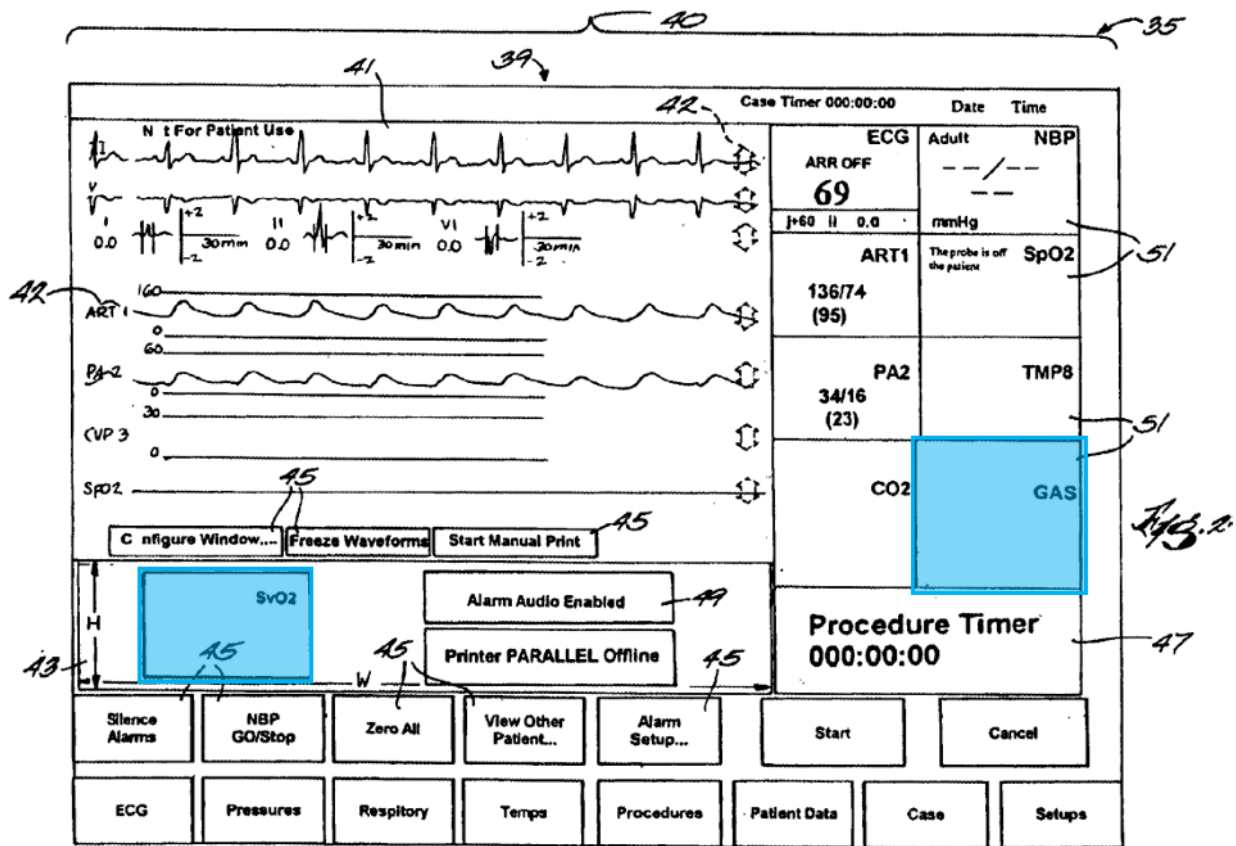
system acquires data from medical devices and sensors (blue in FIG. 1, *infra*). *Id.*, [0029]-[0030], [0032]. It “employs a[] ... healthcare specific graphical user interface, GUI 80,” displayed on an “output device 8 such as a monitor,” orange. APPLE-1005, [0025], [0056]. Alternatively/additionally, the system “may be accessible through data network ... to a clinical location such as [a] hospital” as a “remote service 3,” brown. APPLE-1005, [0044]. The GUI “permits taking in information without reading” by “arranging icons and menus in a display area,” and it “change[s] and show[s] different types of icons and health objects according to different diseases and/or other physical conditions of patient 1,” *e.g.*, by changing “color, shape, order, or other mutable attribute according to ... severity or degree of some findings” related to “current health status” of the patient. *Id.*, [0059]. Specifically, it “automatically detect[s] changes in health status and automatically react[s] and rearrange[s] the available options to best suit the condition of patient 1.” *Id.*, [0063]. Notably, Naghavi does not limit its disclosure to a particular display layout/configuration or set/arrangement of display icons, nor does Naghavi limit the detected patient health changes/conditions to which it responds with display changes. APPLE-1003, ¶¶25-27.



Naghavi, FIG. 1 (annotated)

2. Overview of Hochstedler

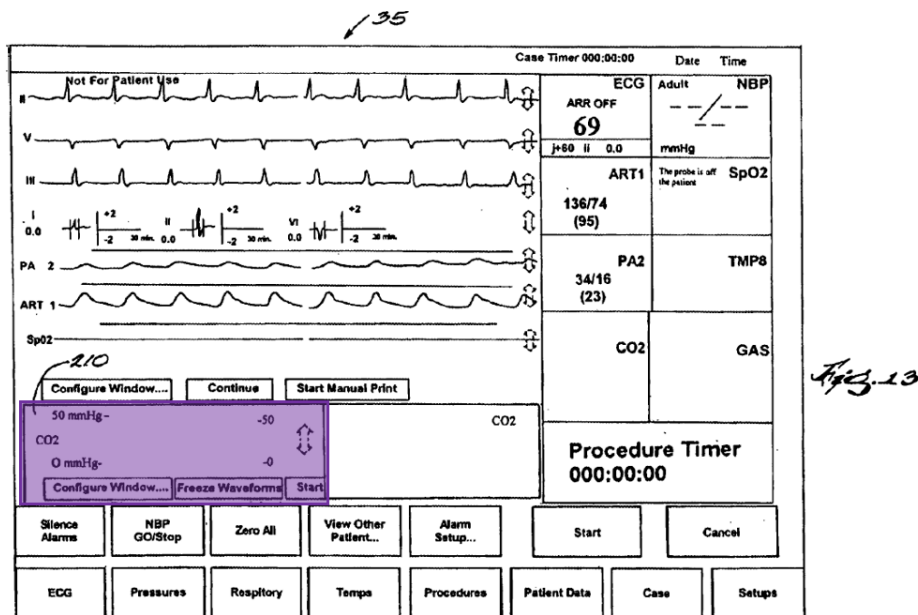
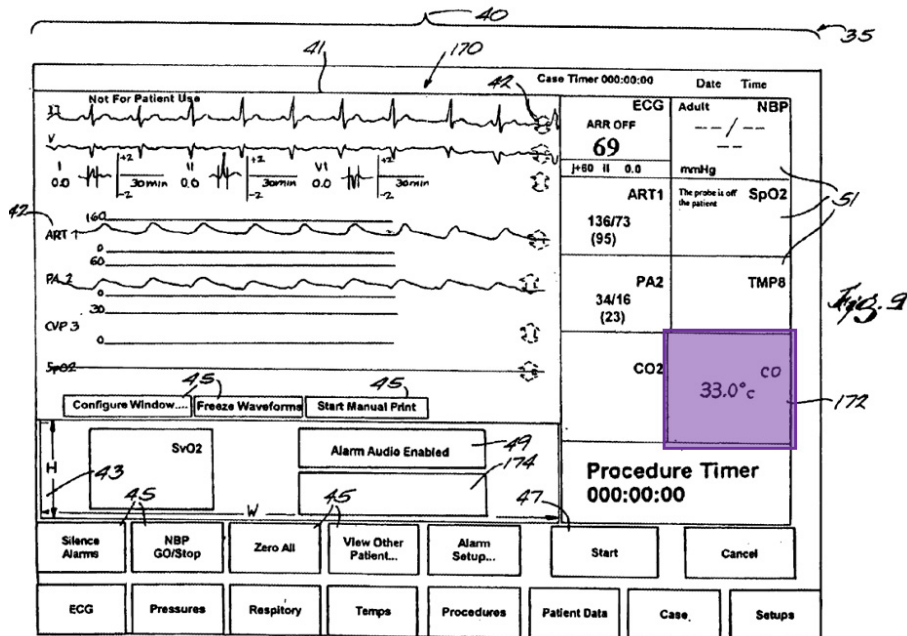
In the context of “a patient monitoring system,” Hochstedler offers a graphical user interface (GUI) including “components that are used to build or construct a layout” for displaying information from sensors, and Hochstedler also contemplates reconfiguring its display based on external inputs. *Id.*, 3:6-7, 3:27-29. An example GUI layout (*see* FIG. 2) has components including parameter blocks 51 that “display real-time information about patient vital signs,” including ECG, SpO₂, and GAS (blue). *Id.*, Fig. 2; 1:20-21; *see* 3:31-40. It also includes a “sub-layout 43” including an SvO₂ block (also blue). APPLE-1004, 1:20-21, 4:7; *see* 3:38-40; APPLE-1003, ¶¶28-29.



Hochstedler, FIG. 2 (annotated)

Like Naghavi, Hochstedler contemplates changing its GUI layout responsive to external input, though the external inputs described by Hochstedler are “changes in the system’s capabilities (e.g., an additional sensor is added) or changes in the system’s environment (e.g., a switch is made from one medical procedure to another).” APPLE-1004, 1:54-60. Also similar to Naghavi, Hochstedler describes changing its layout “automatic[ally],” though it recognizes that such changes could be made “after prompting the user for approval.” *Id.*, 5:42-45; APPLE-1003, ¶30.

Hochstedler's FIG. 9, *infra*, shows an example layout that has been changed relative to that of FIG. 2 in that it "contains a different parameter block 172," purple, replacing the GAS block of FIG. 2's layout. *Id.*, 8:40-42. FIG. 13, *infra*, shows another example layout that has been changed differently relative to that of FIG. 2, with FIG. 2's sub-layout 43 replaced with "a sub layout 210" containing a CO2 block, purple. APPLE-1003, ¶31.



Hochstedler, FIGS. 9 and 13 (annotated)

3. Overview of Burnes

Similar to Hochstedler, in the context of a “patient monitoring system,” Burnes describes a configurable GUI, though Burnes (like Naghavi) confirms

POSITA contemplation of triggering changes to GUI configuration based on detected changes to monitored patient status. Burnes categorizes parameter values for monitored patients “according to predefined thresholds or ranges” and it discloses a GUI “that displays a summary table of categorized parameter values,” indicating a relationship of parameters to corresponding normative thresholds. APPLE-1006, Abstract; *see* [0030]-[0031], [0037]. To this end, Burnes categorizes a parameter as “out of range” if its “value [] has crossed a predetermined threshold,” or as “near out of range” if “its value has come within some predetermined range or percentage of ... the ‘out of range’ boundary.” *Id.*, [0038]-[0040]. Based on this categorization, Burnes describes automatic changes to its GUI: “[a]larm or warning messages may be displayed based on summary parameter values.” *Id.*, [0043]. And Burnes further describes “differentiat[ing] between categories” using “different symbols, color, font, highlighting, shading, or other formatting schemes” within its GUI. *Id.*, [0035]; APPLE-1003, ¶¶32-33.

4. Naghavi-Hochstedler-Burnes combination

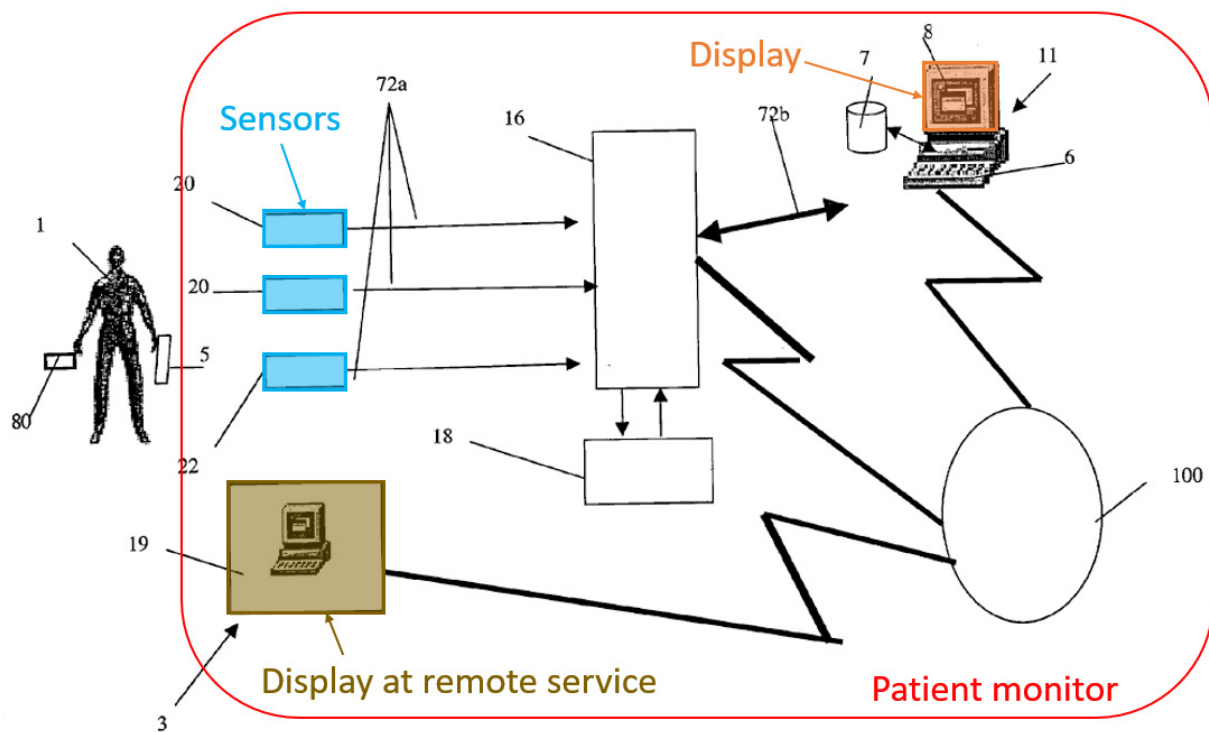
A POSITA² would have found it obvious to implement a Naghavi-Hochstedler-Burnes patient monitoring system that “acquire[s] data” from medical devices/sensors, *blue infra*, for monitoring physiological parameters of a patient.

²*See* APPLE-1003, ¶22.

APPLE-1005, [0029]-[0030], [0032]; APPLE-1003, ¶34. Generally, as taught by each of Naghavi, Hochstedler, and Burnes, parameters monitored by sensors are displayed on a GUI, and changes are made automatically to the display responsive to changes in patient health status. *See* APPLE-1005, [0059], [0099]; APPLE-1003, ¶¶34-35. While these references do not limit the configuration of disclosed GUIs, Hochstedler offers examples of GUI configurations and changes consistent with those recited by the claims, and Burnes reinforces the obviousness of making such changes based on detected changes in patient condition, as contemplated by Naghavi. APPLE-1004, 1:54-60, 5:26-45; APPLE-1006, [0035]-[0040]; APPLE-1003, ¶¶34-38. For instance, the specific implementation of the GUI and its changes are based on Hochstedler, and examples of changes in parameters triggering this display change are based on Burnes. APPLE-1003, ¶¶34-38

Through the combination, a POSITA would find it obvious to display patient health parameters as “icons and health objects” of a GUI implemented on an “output device 8 such as a monitor,” orange, and/or on a display of a “remote service,” brown. APPLE-1005, [0025], [0044], [0056], [0059]; APPLE-1003, ¶35. And, using the combination system, a POSITA would find it obvious to “detect[s] changes in health status” of the monitored patient and “automatically react and rearrange the available options to best suit the condition of” the patient. APPLE-1005, [0063]; APPLE-1003, ¶35. This would be obvious from either of Naghavi

or Burnes, and certainly from their combination, as Naghavi discloses monitoring and triggering GUI changes in response to changes in the “severity” of patient health, and Burnes similarly discloses making automated changes to the GUI when parameter values become “out of range” or “near out of range.” APPLE-1005, [0059]; APPLE-1006, [0038]-[0039]; APPLE-1003, ¶¶35-38.



Naghavi-Hochstedler-Burnes

More, based on Hochstedler, a POSITA would have found obvious not only the display of “real-time information about patient vital signs,” but the use of “icons and health objects” within blocks and/or sub-layouts of the GUI. APPLE-1005, [0056]-[0057]; APPLE-1004, 1:20-21; *see* APPLE-1004, 3:27-33, FIGS. 2, 8-13; APPLE-1003, ¶¶36-37. And, with each of Hochstedler, Naghavi and Burnes

contemplating GUI updates in response to external input, it would have been obvious to replace displayed GUI icons/health objects based on “changes in health status,” based on, *e.g.*, Naghavi and Burnes, *e.g.*, to display different parameter blocks or sub-layouts (based on Hochstedler) when health changes are detected. *See* APPLE-1004, 1:54-60, 5:26-45; APPLE-1003, ¶¶35-38.

Based on Naghavi’s disclosure of GUI changes triggered based on the “severity” of “changes in [patient] health status” related to the monitored parameters, it would have been obvious for a POSITA to make changes within the combined system to GUI objects corresponding to parameter “values found to be ‘out of range’” or “near out of range,” as disclosed by Burnes. APPLE-1005, [0059]; APPLE-1006, [0038]-[0039]; APPLE-1003, ¶38. For example, in the combination, when a parameter that is not displayed in a current layout becomes (near) out of range, it would have been obvious to change the layout to include a block for that parameter, as shown by Hochstedler. APPLE-1006, [0038]-[0039]; *see* APPLE-1005, [0059]; APPLE-1003, ¶¶38-39. In this way, “the layout is switched” from one like Hochstedler’s FIG. 2 to one like its FIG. 9, which “contains a different parameter block 172,” or FIG. 13, which contains a different “sub layout 210,” responsive to the parameter represented in block 172 or sub layout 210, respectively, changing in “severity” to become “out of range” or “near out of range.” APPLE-1004, 8:28-41, 8:56-65; APPLE-1005, [0059]; APPLE-

1006, [0038]-[0039]; APPLE-1003, ¶39. In addition or as an obvious alternative, based on Burnes, it would have been obvious to react to a health parameter value that changes in severity by “highlight[ing] or display[ing] [that parameter value] in a particular color” or offering an “alert symbol” in the parameter block. APPLE-1006, [0050], [0057]; APPLE-1003, ¶40.

5. Reasons for the combination

Display of icons and health objects according to layouts such as Hochstedler’s

A POSITA would have been motivated to display icons/health objects in layouts, *e.g.*, according to Hochstedler. APPLE-1003, ¶¶41-46.

First, automatic replacement of a layout advantageously allows “the layout of the GUI [to] change[] with the needs of users and the stage of medical treatment,” thus helping ensure display of clinically relevant information. APPLE-1004, 1:49-50; APPLE-1003, ¶¶42-43. This dynamic change is consistent with Naghavi’s approach to changing a GUI responsive to patient health status. *See* APPLE-1005, [0059], [0099]; *see* claim 1. Moreover, concurrent display of multiple parameters at the “remote service” (APPLE-1005, [0069]), and the Hochstedler-based layout replacement, provides the remote service operator with a volume of clinically relevant information suitable for their role as a medical professional, without concerns over obfuscation. *See* APPLE-1003, ¶¶42-43.

Second, automatic layout replacement provides prioritized display of important information rather than other, less relevant information. *See* APPLE-1004, 1:49-50; APPLE-1005, [0063]; APPLE-1003, ¶44.

Third, this implementation is merely the application of known techniques (multiparameter display) by a known system (a medical monitoring system) to yield predictable results (multiparameter display in a medical monitoring system). APPLE-1003, ¶45; *see KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

A POSITA would have expected success because integration of display techniques with a medical monitoring device is predictable. APPLE-1003, ¶46.

Change in severity of a parameter triggering a display layout change

A POSITA would have been motivated to switch the layout responsive to a parameter value changing to become (near or) out of range, *e.g.*, based on Burnes. APPLE-1003, ¶¶47-52.

First, as recognized by Naghavi and Burnes, this implementation would provide a display that “best suit[s] the condition of [the] patient.” APPLE-1005, [0063]; APPLE-1003, ¶¶48-49. A change in the severity of parameter can indicate a health status change that may require close monitoring, and automatic layout switching would enable caregiver monitoring of changing parameters even if they are not displayed on a main screen. APPLE-1003, ¶¶48-49.

Second, this implementation would “relieve the data analysis burden placed on the clinician while enabling the clinician to maintain thorough patient care.”

APPLE-1006, [0004]; APPLE-1003, ¶50. A POSITA would have recognized that not all parameters must be displayed on a main layout, nor should they crowd a single layout, so long as those parameters that change in severity can be displayed/highlighted to the clinician to enable proper attention and care to be timely provided to the patient. *See* APPLE-1006, [0004]; APPLE-1003, ¶50. By displaying certain parameters only when necessary, the amount of displayed information is maintained at a manageable level while still providing a mechanism to inform the clinician about relevant parameters. APPLE-1006, [0004]; APPLE-1003, ¶50.

Third, this implementation is merely the application of known techniques (changing a parameter display responsive to a change in parameter status) by a known system (a multiparameter monitoring and display system) to yield predictable results (a multiparameter monitoring and display system in which the parameter display changes responsive to a parameter change). APPLE-1003, ¶51; *see KSR*, 550 U.S. at 417.

A POSITA would have expected success because systems in which a parameter change triggers a display change were conventional, predictable technologies. APPLE-1003, ¶52.

Colors or alert symbols to indicate parameter severity

A POSITA would have been motivated to display parameters in different colors or with different symbols to indicate severity, *e.g.*, based on Burnes.

APPLE-1003, ¶¶53-57.

First, this implementation would “allow a parameter value category”—*e.g.*, out of range or near out of range—“to be recognized,” making the GUI easier to understand. APPLE-1006, [0007]; *see* [0035] (“values that ... are of particular clinical concern may be formatted for display in a conspicuous manner to draw the attention of a clinician or other user”), [0042] (“icons or color-coded symbols ... which allows a clinician or other user to easily distinguish between parameter value categories”); APPLE-1003, ¶54.

Second, the use of color and/or alert symbols to indicate parameter status was well-established in the context of multi-parameter displays. APPLE-1003, ¶55, citing APPLE-1016, 6:3-27.

Third, this implementation is merely the application of known techniques (use of color and/or symbols to indicate parameter status) by a known system (a multiparameter monitoring and display system) to yield predictable results (a multiparameter monitoring and display system employing color and/or symbols). APPLE-1003, ¶56; *see KSR*, 550 U.S. at 417.

A POSITA would have expected success because display technology was predictable, and adjusting display characteristics to reflect parameter status was common and well-understood. *See* APPLE-1001, 17:22-32; APPLE-1003, ¶57.

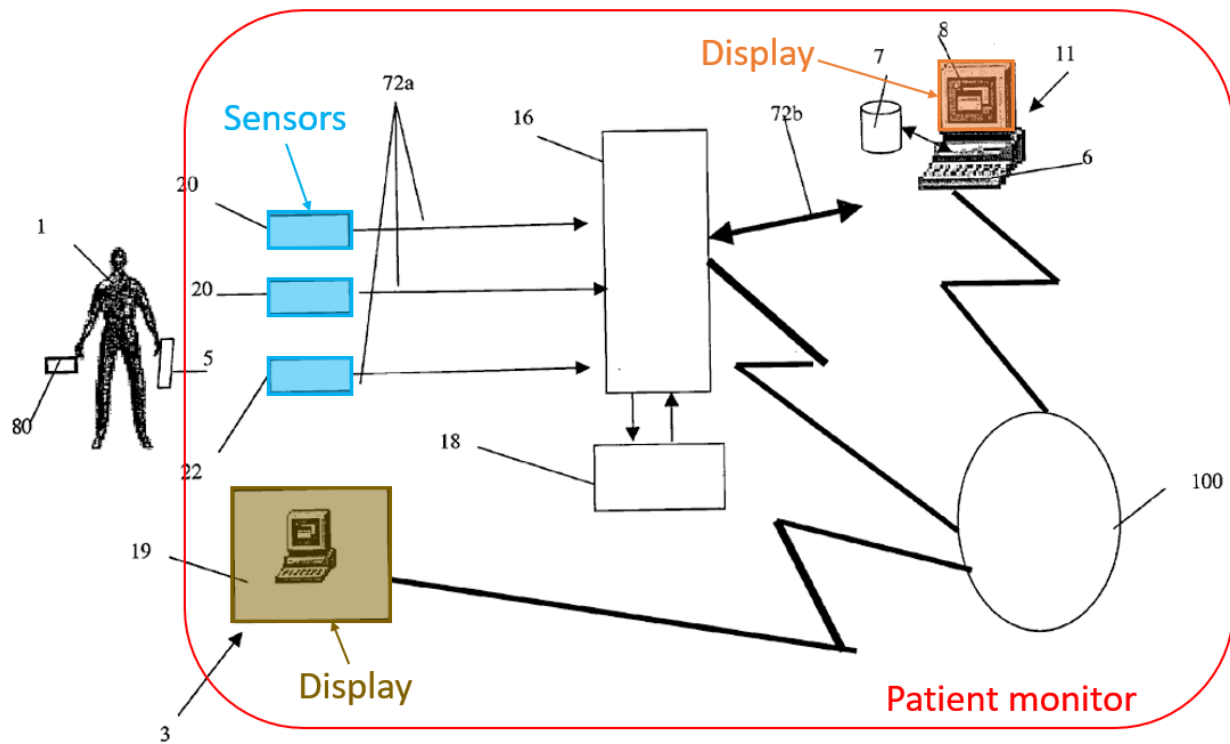
6. Analysis

(i) Claim 1

[1pre]

To the extent the preamble is deemed to be limiting, Naghavi-Hochstedler-Burnes renders it obvious. APPLE-1003, ¶¶58-60.

The combination, *infra*, is “a personal healthcare management system,” *e.g.*, **a patient monitor**, at least because it includes sensors, blue, for patient monitoring. APPLE-1005, [0025]; *see* [0033]; APPLE-1003, ¶59.



Naghavi-Hochstedler-Burnes

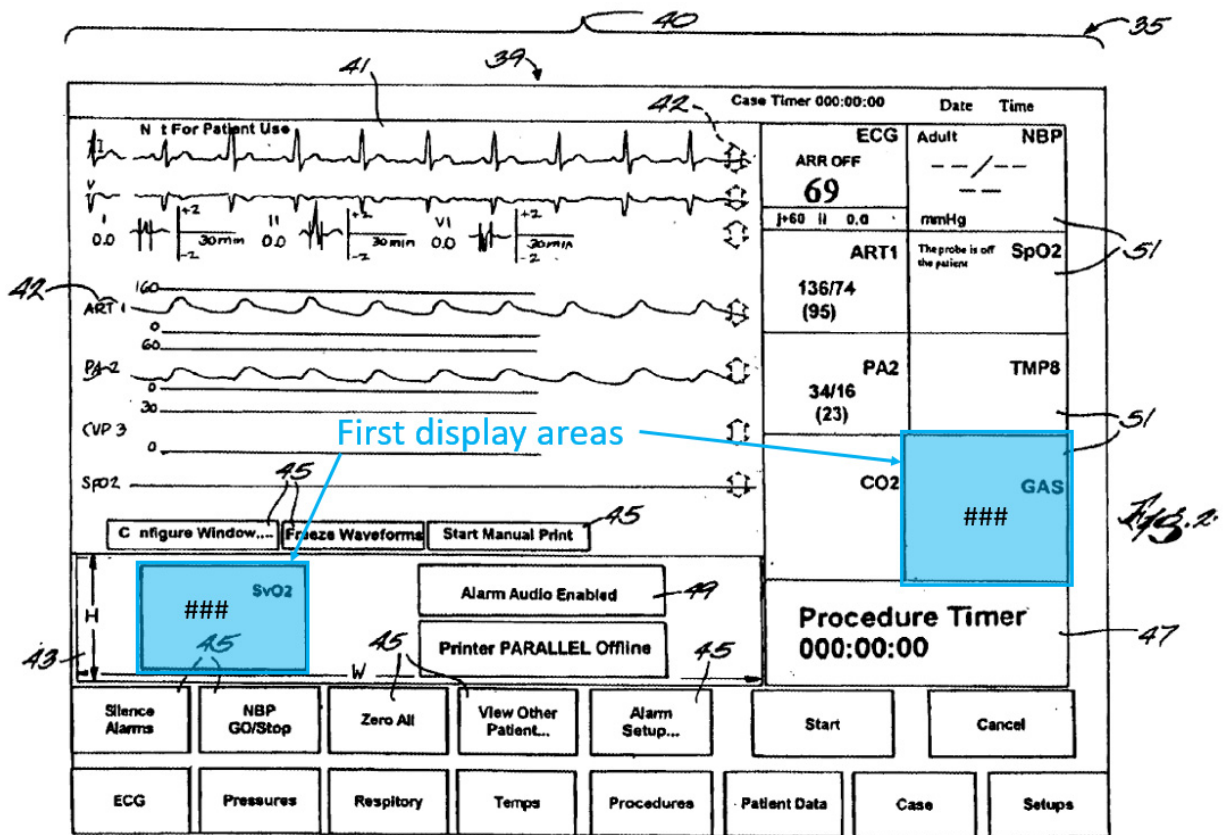
The combination monitor is **capable of measuring at least two physiological parameters**. APPLE-1003, ¶60. Based on Naghavi, the monitoring system includes multiple (**at least two**) sensors, each measuring a physiological parameter; *e.g.*, “biophysical, biomechanical, physiological, biochemical, and electromechanical parameters.” APPLE-1005, [0033]; *see* APPLE-1004, 3:14-18, 3:42-46; APPLE-1003, ¶60.

[1a]

The combination monitor includes **a display**, *e.g.*, based on Naghavi’s “output device 8 such as a monitor,” orange in the figure in [1pre]; or a display at a “remote service” (brown) providing healthcare monitoring services. APPLE-1005,

[0025], [0044]; *see* [0027], [0038], [0057], [0069]; APPLE-1003, ¶61. A GUI of the display displays information measured by the sensors using “icons and health objects.” APPLE-1005, [0056]-[0057]; APPLE-1003, ¶61.

The GUI is implemented based on Hochstedler to “include[] a number of components that are used to build or construct a layout.” APPLE-1004, 3:26-34, FIG. 2 *infra*; *see* Abstract (“Layouts are sets of graphical components that are associated with monitored or sensed activities”), 1:5-7 (“the invention relates to the display of information using configurable arrangements of interface components”), 3:6-8, 3:22-23, FIGS. 1-2, 8-13; APPLE-1003, ¶62.



Based on Hochstedler, FIG. 2

The GUI is **capable of displaying measurements of physiological parameters of body tissue of a monitored patient**: “the information from the sensors” of the combination monitor “is displayed” in “parameter blocks” which “display real-time information about patient vital signs.” APPLE-1004, 3:40-41, 1:19-23; *see* 3:21-23; APPLE-1003, ¶63. The sensors measure physiological parameters, and thus the display of information from the sensors (*e.g.*, information about patient vital signs) is display of those physiological parameter measurements. *See* [1pre].

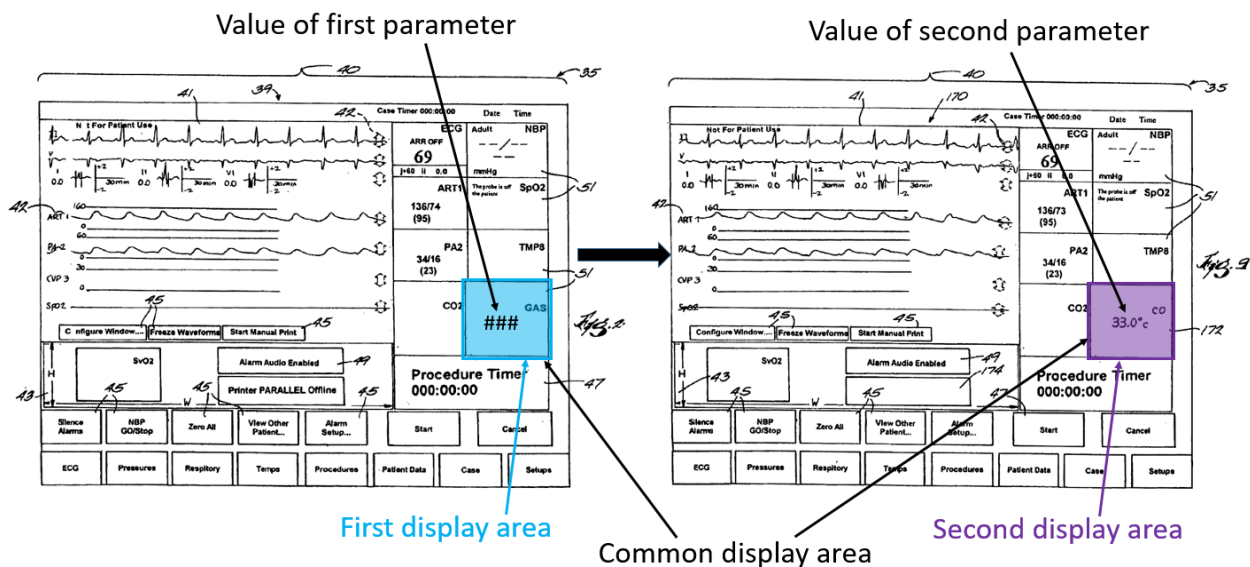
As an example, illustrated *supra*, the parameter blocks and sub-layout in Hochstedler's FIG. 2 GUI display measurements of physiological parameters. *See* APPLE-1004, 1:20-21, 3:31-40, 4:7; APPLE-1003, ¶64. Each parameter is a **first physiological parameter of body tissue of the patient**. APPLE-1003, ¶65. The parameter block for each parameter is a **first display area** for display of a measurement of the respective parameter. *See* APPLE-1004, 1:19-23; APPLE-1003, ¶65. In the figure *supra*, two example first display areas are in blue; other blocks are other examples of first display areas. APPLE-1003, ¶65.

A **measured value of the first physiological parameter** is displayed in the respective parameter block, *e.g.*, **in the first display area**. *See* APPLE-1004, FIG.2; APPLE-1003, ¶66. As illustrated *supra*, measured numeric values are displayed in the ECG, ART1, and PA2 blocks. Although Hochstedler's FIG. 2 does not illustrate values displayed in the other blocks, a POSITA would have understood, or at least found obvious, that the display is **capable of displaying measured values** (depicted as “###” in the blue-highlighted blocks *supra*) of parameters in respective blocks (*e.g.*, in the first display areas), given the purpose of the parameter blocks (to “display real-time information about patient vital signs”) and given that vital signs information is often in the form of measured values. APPLE-1004, 1:19-23; *see* APPLE-1006, [0007]; APPLE-1003, ¶66.

In the combination, the display layout changes responsive to a change in severity of a parameter. *See* APPLE-1004, 1:54-60, 5:26-37; APPLE-1005, [0059], [0063], claim 1; APPLE-1006, [0038]-[0039]; *see* [1c], *infra*; APPLE-1003, ¶67. Based on Hochstedler, a block in the initial layout (*e.g.*, the layout of Hochstedler's FIG. 2, *supra*) is replaced by a block for a different physiological parameter, *e.g.*, the parameter changing in severity. *See* APPLE-1004, 8:40-41 ("the layout is switched to a layout 170 shown in FIG. 9. The layout 170 contains a different parameter block 172"), 8:64-65 ("the sub layout 43 is replaced by a sub layout 210"), FIGS. 9 and 13; APPLE-1003, ¶68. Each block in the new layout is **a second display area** for display of a measurement of a respective **second physiological parameter of the body tissue of the patient**, *e.g.*, the same patient for whom the first parameter was measured. APPLE-1003, ¶68. Moreover, for the reasons discussed *supra*, **a measured value of the second physiological parameter** is displayed in the respective block, *e.g.*, **in the second display area**, or at least a POSITA would have understood the display to be **capable of displaying measured values** of the parameters in the respective blocks. *See* APPLE-1004, 1:19-23; APPLE-1003, ¶68.

In one example, the layout of Hochstedler's FIG. 2, at left *infra*, "is switched to a layout" of FIG. 9 that "contains a different block 172," purple in FIG. 9 at right *infra*. APPLE-1004, 8:40-41; APPLE-1003, ¶69. The block 172 is **a second**

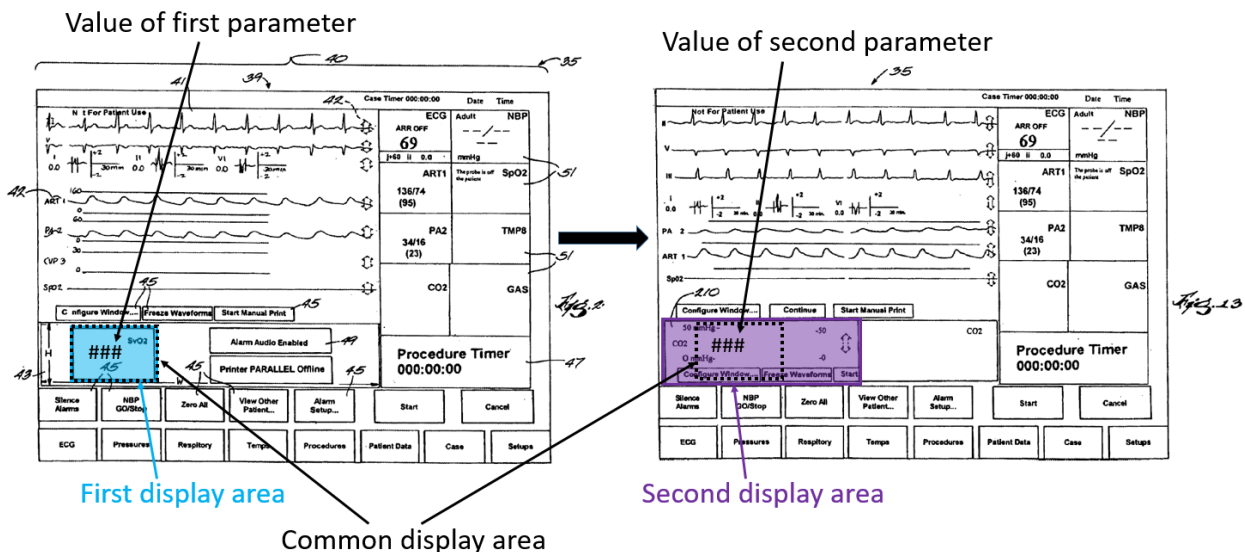
display area in which is displayed a measured value (“33.0°C”) of a second physiological parameter, *i.e.*, the parameter represented by that block. *See* APPLE-1004, FIG. 9; APPLE-1003, ¶69. The “GAS” block from the original layout and the “CO” block in the new layout are located in the same position, and thus the area occupied by these two blocks (the **first display area**, blue; and the **second display area**, purple) is substantially the same: a **common display area** capable of displaying information (*e.g.*, measured values of parameters). *See* APPLE-1004, FIGS. 2 and 9; APPLE-1003, ¶69.



Based on Hochstedler's FIGS. 2 and 9

In another example, “the sub layout 43” of Hochstedler’s FIG. 2, at left *infra*, “is replaced by a sub layout 210,” purple at right *infra*. APPLE-1004, 8:64-65; APPLE-1003, ¶70. The sub layout 210 is a **second display area** in which is displayed a measured value of a second physiological parameter, *i.e.*, the

parameter (“CO2”) represented by the sub layout 210. *See* APPLE-1004, FIG. 11; APPLE-1003, ¶70. The **second display area** (purple) occupied by sub layout 210 overlaps and encompasses the **first display area** (blue) occupied by the SvO2 block in sub layout 43: this overlapping area, which is **capable of displaying information** (e.g., measured values of parameters) is a **common display area**. *See* APPLE-1004, FIGS. 2 and 11; APPLE-1003, ¶70.



Based on Hochstedler's FIGS. 2 and 13

A POSITA would have understood, or at least found obvious, that the blocks and sub layouts can display information about parameters other than those specifically illustrated. APPLE-1003, ¶71. Hochstedler states that “[t]he number and type of sensors used in the system 10 changes based on the type of information that an end user desires to see,” and in this context, a POSITA would have expected corresponding flexibility in which parameters are displayed. APPLE-

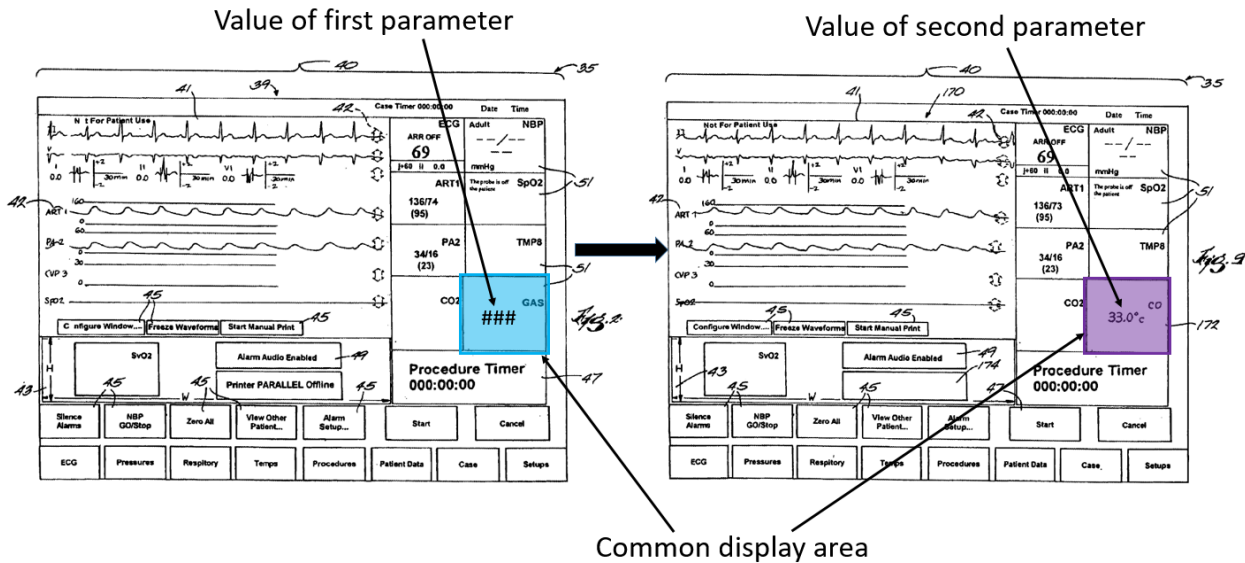
1004, 3:42-44; APPLE-1003, ¶71. Moreover, a POSITA also would have understood, or at least found obvious, that blocks and sub layouts can be displayed other than those highlighted *supra*, e.g., depending on the environment (e.g., on patient health status). See APPLE-1004, 1:49-66; APPLE-1003, ¶71.

[1b]

In the combination, the layout changes responsive to a change in a monitored parameter; when this occurs, **the display of the measured value of one parameter is replaced with the measured value of the other parameter.** See APPLE-1004, 1:54-60, 5:26-37; APPLE-1005, [0059], [0063]; APPLE-1006, [0038]-[0039]; APPLE-1003, ¶72.

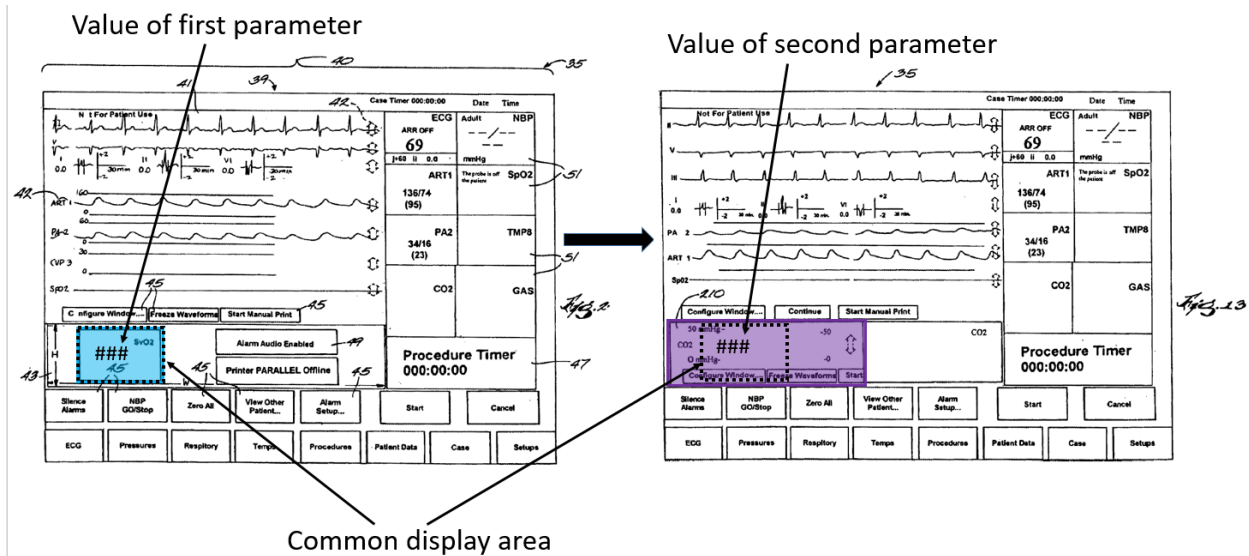
In one example, illustrated *infra*, a layout such as that of Hochstedler's FIG. 2 "is switched to a layout 170 shown in FIG. 9." APPLE-1004, 8:40-42. The FIG. 2 layout includes block 51, blue, for display of the measured value of one parameter ("GAS"). The new FIG. 9 layout "contains a different parameter block 172," purple, for display of the measured value of a different parameter ("CO"). *Id.*, 8:40-42. The purple block 172 in the new layout takes the place of (replaces) the blue block 51 in the original layout: **the display of the measured value of the first physiological parameter (in the blue-highlighted block) is replaced with the measured value of the second physiological parameter (in the purple-highlighted block).** APPLE-1003, ¶73. This replacement occurs **in the common**

display area at least because the blue-highlighted and purple-highlighted blocks both occupy the common display area. *See* [1a]; APPLE-1003, ¶73.



Based on Hochstedler's FIGS. 2 and 9

In another example, *infra*, a layout based on Hochstedler's FIG. 2 and including a "sub layout 43," blue, ***is replaced by*** a sub layout 210," purple, in a new layout based on Hochstedler's FIG. 11: **the display of the measured value of the first physiological parameter (in the blue-highlighted sub layout) is replaced with the measured value of the second physiological parameter (in the purple-highlighted sub layout).** This replacement occurs **in the common display area** at least because the blue-highlighted and the purple-highlighted blocks both occupy the common display area. *See* [1a]; APPLE-1004, 8:64-65; APPLE-1003, ¶74.



Based on Hochstedler's FIGS. 2 and 13

In either example, the replacement is **based on the occurrence of an event**, as discussed in the following paragraphs. APPLE-1003, ¶¶75-78.

First, the display layout is switched (display of one parameter value is replaced with another) responsive to “changes in health status” of the patient. APPLE-1005, [0063]; *see id.*, [0059] (“GUI 80 may further change and show different types of icons and health objects according to different diseases and/or physical conditions of the patient”), [0063] (“GUI 80 ... [may] automatically react and rearrange the available options to best suit the condition of patient 1”), claim 1; APPLE-1004, 5:31-37 (“A second type of change ... relates to a change in the system environment (such as ... change in the phase of the case ... change in the type of medical procedure being carried out, or other similar change”); APPLE-1003, ¶76.

The “changes in health status” triggering the display change relate to “severity” of a monitored parameter. APPLE-1005, [0059]; *see id.* (“The icons and health objects may change in color, shape, order, or other mutable attribute according to ...severity or degree of some findings”); APPLE-1003, ¶77. Specifically, the layout change occurs when a parameter’s severity changes, *e.g.*, to become out of range or near out of range. APPLE-1006, [0038]-[0039]; *see id.* [0038] (“any parameter values found to be ‘out of range’ are formatted for display as an ‘alert symbol,’ and “[c]ategorizing a parameter value in the ‘alert’ category may trigger an alarm”), [0039] (“any parameter values found to be ‘near out of range’ are assigned a ‘warning’ symbol to be displayed as the parameter value”), [0043]; APPLE-1003, ¶77. This change in severity is **the occurrence of an event** causing display of one parameter value to be replaced with display of another—specifically, with display of the parameter whose value has become (near) out of range. APPLE-1003, ¶77.

The initial layout includes blocks/sub-layouts for display of measured values of various parameters, including the first parameter. *See* [1a]; APPLE-1004, 1:20-21, 3:38-40, FIG. 2; APPLE-1003, ¶78. When a parameter that is not displayed in that initial layout (*e.g.*, the second parameter) changes in severity, the layout changes such that the value of that second parameter is displayed, thus serving as

an alarm bringing the parameter change to the attention of clinical staff. *See* APPLE-1004, 1:54-60, 5:26-45, 8:40-65; APPLE-1003, ¶78.

[1c]

The **event** is the change in a parameter's severity, and specifically the change in a parameter value (*e.g.*, the second parameter value; *see* [1b]) to become "out of range" or "near out of range." *See* APPLE-1005, [0059], [0063], claim 1; APPLE-1006, [0038]-[0039], [0043]; APPLE-1003, ¶79.

Burnes describes that a parameter value becoming "near out of range" is "a value that has come within some predetermined range or percentage of a threshold defining the 'out of range' boundary.'" APPLE-1006, [0039]. That is, a parameter value that has become near out of range is a parameter value that is **approaching a threshold value**, specifically, approaching the "threshold defining the 'out of range' boundary." *Id.*; APPLE-1003, ¶80.

The "out of range" boundary is a **threshold value indicative of a worsening state of the patient**: "An 'out of range' value is a value that has crossed a predetermined threshold ... and is *an indication that the patient may require clinical attention*." APPLE-1006, [0038]; *see* [0048] ("patients having one or more summary parameters categorized as 'out of range' ... or otherwise are determined to have an indication that warrants medical attention"), [0037]; APPLE-1003, ¶81. A patient whose physiological parameter has changed to

require clinical attention is a patient whose state is worsening, thus the “out of range boundary” threshold is **indicative of a worsening state of the patient**.

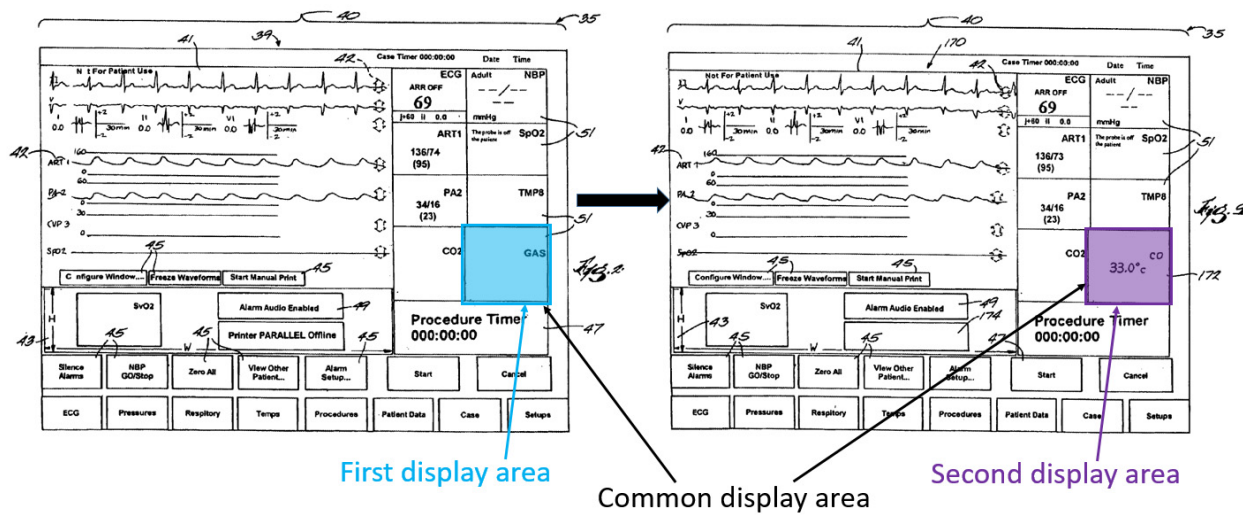
APPLE-1003, ¶81.

Moreover, the parameter becoming “near out of range,” and thus approaching the threshold value, is also **indicative of a worsening state of the patient**, *e.g.*, indicative that “the patient may soon require medical attention based on the corresponding parameter value.” APPLE-1006, [0039]; *see* [0048], [0037]; APPLE-1003, ¶82.

(ii) **Claim 2**

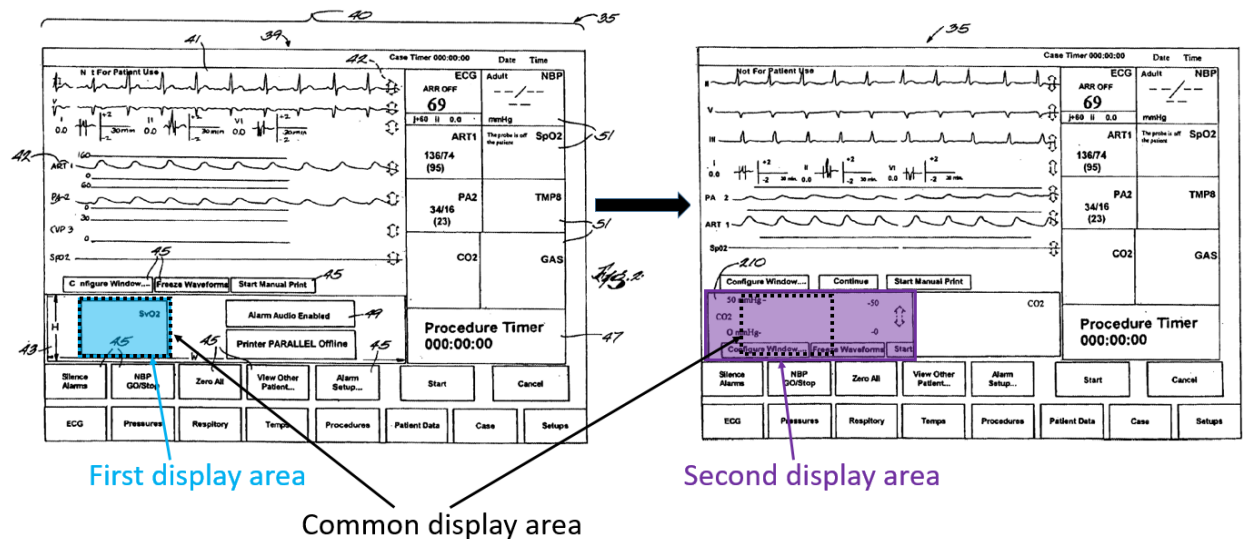
[2]

See [1a]-[1b]. When the layout is changed to replace one block with another (*e.g.*, from Hochstedler’s FIG. 2 layout to the FIG. 9 layout, illustrated *infra*), the first and second display areas occupy substantially the same display area, and thus they **include the common display area**. APPLE-1003, ¶83.



Based on Hochstedler's FIGS. 2 and 9

Alternatively/additionally, *infra*, when one sub-layout replaces another, the common display area falls entirely within both first and second display areas, *e.g.*, both display areas **include the common display area**. APPLE-1003, ¶84.



Based on Hochstedler's FIGS. 2 and 13

(iii) **Claim 3**

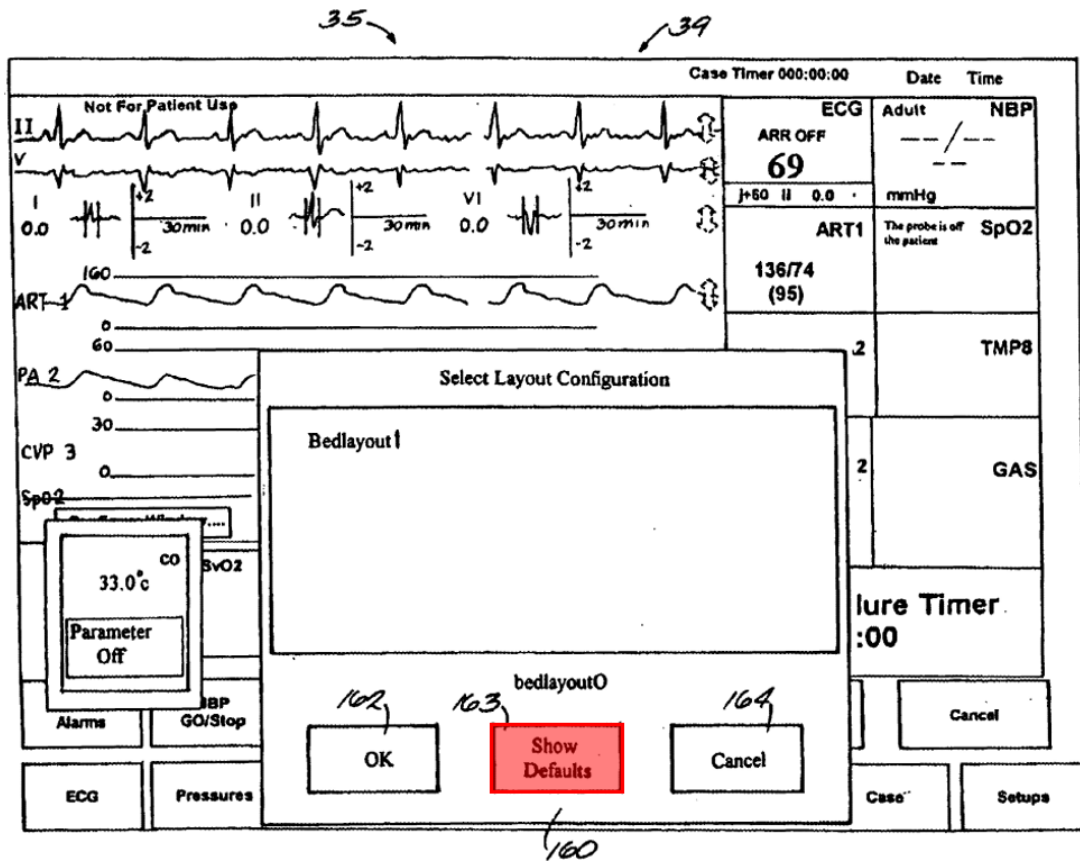
[3]

In the combination, Hochstedler describes that the layout change (**replacement**; *see* [1b]) can be “an automatic layout switch [that] occur[s] after prompting the user for approval of the proposed change.” APPLE-1004, 5:42-45; *see* 1:63-67, 8:39-42, FIG. 8. Receipt of user approval is **activation of a user input that causes the replacement**. APPLE-1003, ¶85.

(iv) **Claim 4**

[4]

In the combination, a dialog box for layout selection (FIG. 8, *infra*) includes “a default selection button” (red). APPLE-1004, 8:30-38. In this context, a POSITA would have understood, or at least found to be obvious, that the GUI has a default layout. *See id.*, 8:36-38; APPLE-1003, ¶86. When the layout displaying the measured value of the first or second parameter is the default, **the common display area is configured to default to displaying the measured value of the first or second parameter**, respectively. *See* [1a]; APPLE-1003, ¶87.



Hochstedler, FIG. 8 (annotated)

(v) **Claim 6**

[6]

In the combination, physiological parameters are measured using, *e.g.*, blood-pressure, temperature, ECG, blood oxygen, or respiratory sensors. *See* APPLE-1004, 3:14-17. Parameter values measured by these sensors are **non-invasively measured values** because the sensors perform non-invasive (*e.g.*, external) measurements. APPLE-1003, ¶88.

(vi) **Claim 11**

[11]

In the combination, the layout is switched based on a parameter's "*severity*," *e.g.*, the layout is switched to display the second parameter responsive to a change in the second parameter's severity. APPLE-1005, [0059]; *see* [0063]; *see* [1b]; APPLE-1003, ¶89. The layout is **an aspect of the display that changes to illustrate a change in the severity** of the second parameter value.

Alternatively/additionally, the "color, shape, ... or other mutable attribute" is each **an aspect of the display that changes to illustrate a change in the severity** of the second parameter value. APPLE-1005, [0059]; APPLE-1003, ¶90. Specifically, based on Burnes, when the layout is switched responsive to the second parameter value becoming "out of range" or "near out of range" (*see* [1c]), the displayed second parameter value is "highlighted or displayed in particular color, such as red" or "yellow," respectively. APPLE-1006, [0057]; *see* [0007], [0035]; APPLE-1003, ¶90. Color of the displayed parameter value is **an aspect of the display that changes to illustrate a change in the severity** of the parameter value.

Still alternatively/additionally, when the layout is switched, "a red symbol may be used as an alert symbol" or "a yellow symbol [is used as] a warning symbol" for the second parameter. APPLE-1006, [0050]; *see* [0038]-[0039],

[0008], [0035], [0042], [0056], FIG. 6, claim 11; APPLE-1003, ¶91. Display of a symbol is **an aspect of the display that changes to illustrate a change in the severity** of the parameter value.

(vii) **Claim 12**

[12]

See [11]. Based on Burnes, **the display color** of the displayed parameter value changes. *See* APPLE-1006, [0007]-[0008], [0042], [0050], [0057]; APPLE-1003, ¶92.

(viii) **Claim 13**

[13pre]-[13a]

See [1pre]-[1a]; APPLE-1003, ¶¶93-94.

[13b]

See [1b]. **Based on an occurrence of an event**, the layout is switched, replacing display of the first parameter value with the second parameter value. *See* APPLE-1004, 1:54-60, 5:26-45; APPLE-1003, ¶95. When this occurs, **the common display area changes from displaying the measured value of the first physiological parameter** (*e.g.*, in the blue-highlighted area based on Hochstedler's FIG. 2) **to displaying the measured value of the second physiological parameter** (in the purple-highlighted area based on Hochstedler's FIG. 9 or 13). *See* APPLE-1004, 1:54-60, 5:26-45; APPLE-1003, ¶95.

[13c]

See [1c]; ¶96.

[13d]

In the combination, **an aspect of the display changes to illustrate a change in the severity** of the second parameter value. *See* APPLE-1005, [0059], [0063]; APPLE-1006, [0007], [0035], [0057], *see* [1b], [11]. Naghavi describes that “**size** ... of each icon can change according to a current health status ... of patient 1.” APPLE-1005, [0059]. In the combination, when the layout is switched responsive to the second parameter value becoming “out of range” (APPLE-1006, [0057]; *see* [1c], *supra*), the display of the second parameter changes in size, based on Naghavi. APPLE-1003, ¶97.

(ix) **Claim 14**

[14]

See [11]. In the combination, when the layout is switched to display the second parameter value (*see* [1c], *supra*), the displayed second parameter value “may be **highlighted** or displayed in particular color, such as red” or “yellow,” respectively. APPLE-1006, [0057]; *see* [0035] (“**font, highlighting**, shading, or other formatting schemes may be used to differentiate between categories [of parameter values].”), [0007]; APPLE-1003, ¶98. Highlighting or change in font is **a display intensity**. APPLE-1003, ¶98.

(x) **Claim 15**

[15pre]-[15b]

See [1pre]-[1b]; APPLE-1003, ¶¶99-101.

[15c]

The **event** is the second parameter value changing to become “out of range” or “near out of range.” *See* [1c]; *see* APPLE-1006, [0038]-[0039]. This change in the second parameter (**the event**) is **the measured value of the second parameter alarming** at least because the parameter change causes a display change (*e.g.*, causes the second parameter value to be displayed) that acts as an alarm, alerting clinical staff of the change. *See* APPLE-1006, [0007]-[0008], [0034]-[0035], [0037]-[0039]; APPLE-1003, ¶102.

Alternatively/additionally, the second parameter value changing to become “out of range” or “near out of range” (**the event**) is itself **the measured value of the second parameter alarming**. APPLE-1006, [0038]-[0039]. The value of the parameter becoming “out of range” is the value **alarming** at least because this change indicates “that the patient may require clinical attention” and “may trigger an alarm.” APPLE-1006, [0038]; *see* [0037] (“an ‘alarm’ category, indicating the patient may require medical attention based on the parameter value”), [0007]-[0008], [0034]-[0035], [0038]-[0039]; APPLE-1003, ¶103. Specifically, a parameter becomes “out of range” when it “has crossed a predetermined threshold

or fallen outside a normally accepted range.” APPLE-1006, [0038]; *see* [0039].

The second parameter value crossing a threshold is **the measured value of the second parameter alarming**, *e.g.*, because crossing the threshold triggers an alarm (a display change). APPLE-1003, ¶103.

(xi) **Claim 16**

[16]

The change from one display layout to another such that **the common display area changes from displaying the measured value of the first parameter** to displaying the measured second parameter value is **an aspect of an alarm**. *See* [1b], [15c]; APPLE-1004, 1:54-60, 5:26-37, 8:40-65; APPLE-1003, ¶104.

Color of the displayed parameter value is **an aspect of an alarm that changes**. *See* [11]; APPLE-1006, [0007], [0035], [0057]; APPLE-1003, ¶105. Alternatively/additionally, display of a symbol in a block or sub-layout is **an aspect of an alarm that changes**. *See* [11]; APPLE-1006, [0008], [0035], [0038]-[0039], [0042], [0050], [0056], FIG. 6, claim 11; APPLE-1003, ¶105. Each of these is **an aspect of the alarm** because it is an aspect (color or symbol) of the display change triggered by the measured second parameter value alarming. *See* [15c]; APPLE-1003, ¶105.

(xii) **Claim 17**

[17]

See [12], [16]; APPLE-1003, ¶106.

(xiii) **Claim 18**

[18pre]-[18a]

See [1pre]-[1a]; APPLE-1003, ¶¶107-108.

[18b]

In the combination, **in the common display area, the display of one of the measured values of the first or second physiological parameters is replaced with the other of the measured values of the first or second physiological parameters** when a parameter changes to become “out of range” or “near out of range.” *See* [1b]-[1c]; APPLE-1005, [0059], [0063]; APPLE-1006, [0038]-[0039], [0043]. A parameter (*e.g.*, the second parameter) becoming (near) out of range indicates that the second parameter is **a more critical one** of the parameters, *e.g.*, compared to a parameter that has not changed. APPLE-1003, ¶109. Moreover, the replacement is **automatic**. *See* APPLE-1004, 5:42-45 (describing that the change in layout can be “an automatic layout switch”); APPLE-1005, [0063] (“GUI ... may automatically detect changes in health status and health plan for patient 1 and automatically react and rearrange the available options”); APPLE-1003, ¶109.

(xiv) **Claim 20**

[20]

See [6]; APPLE-1003, ¶110.

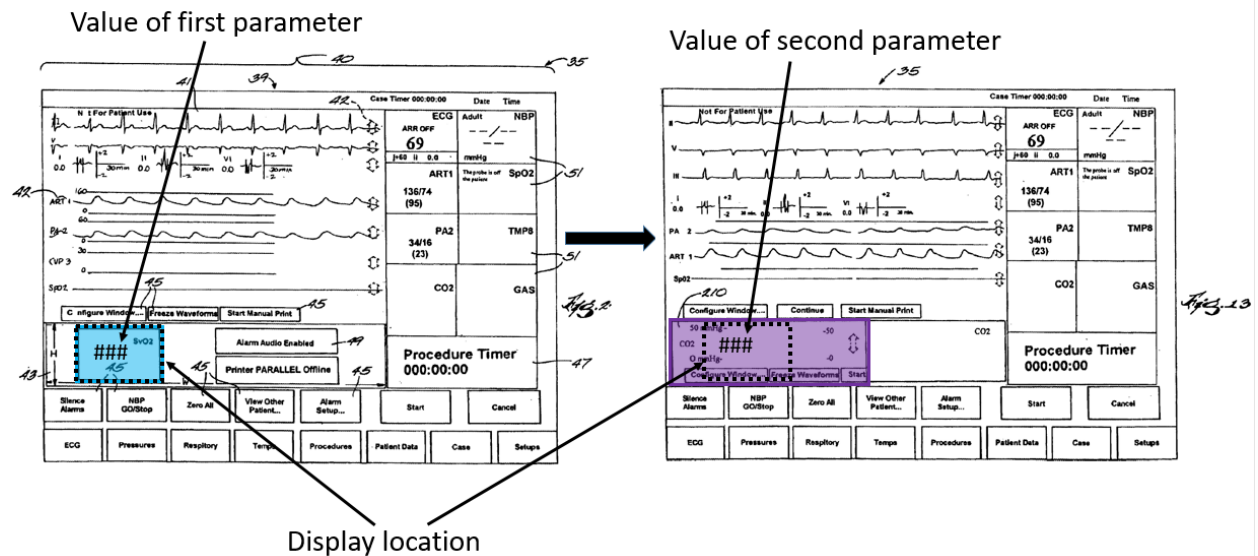
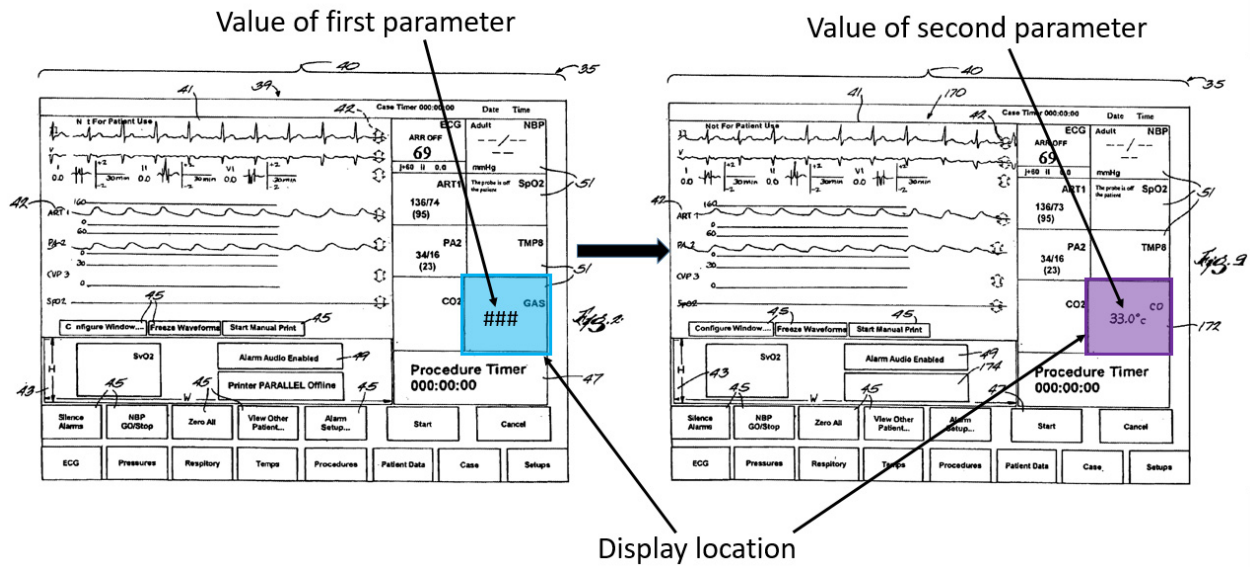
(xv) **Claim 21**

[21pre]

To the extent the preamble is deemed to be limiting, Naghavi-Hochstedler-Burnes renders it obvious. APPLE-1003, ¶¶111-113.

The combination provides **a method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device**, illustrated *infra*. *See* [1pre]-[1a]; APPLE-1003, ¶112.

The **display location** (the area where a parameter value is displayed) is **generally capable of displaying a single physiological parameter measurement**: the value for the parameter represented by the block or sub-layout. *See* [1a]; APPLE-1004, 1:54-60, 5:26-37, 8:40-65, FIG. 1, FIG. 9, FIG. 13; APPLE-1003, ¶113. The display location (blue at left *infra*) displays the value of the first physiological parameter; when the layout changes, the display location (purple at right *infra*) displays the value of the second physiological parameter. *See* [1a]; APPLE-1003, ¶113.



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[21a]

See [1a]. The combination patient monitor includes **an electronic display**, e.g., based on Naghavi's "output device 8 such as a monitor" or implemented as a display at a "remote service." APPLE-1005, [0025], [0044]; see [0027], [0038], [0057], [0069]; APPLE-1003, ¶114. In the combination, **a measured value of a**

first physiological parameter is displayed in a display location of the electronic display, *e.g.*, in the blue-highlighted block or sub-layout in the figures in [21pre].

See [1a]; APPLE-1003, ¶114.

[21b]

See [1b]. In the combination, **the display of the measured value of the first physiological parameter is replaced with a display of a measured value of a second physiological parameter in the display location**, *e.g.*, the first parameter value displayed in the blue-highlighted block/sub-layout in the initial layout is replaced with the value of a second parameter displayed in the purple-highlighted block/sub-layout, at right in the figures in [21pre]. *See* APPLE-1004, 1:54-60, 5:26-37, 8:40-65; APPLE-1003, ¶115.

This replacement occurs **when the measured value of the second parameter changes** in severity, *e.g.*, to become “out of range” or “near out of range,” which **indicates a worsening state of the patient**. *See* [1c]; APPLE-1005, [0059], [0063]; APPLE-1006, [0037]-[0039], [0043], [0048]; APPLE-1003, ¶116.

(xvi) **Claim 22**

[22]

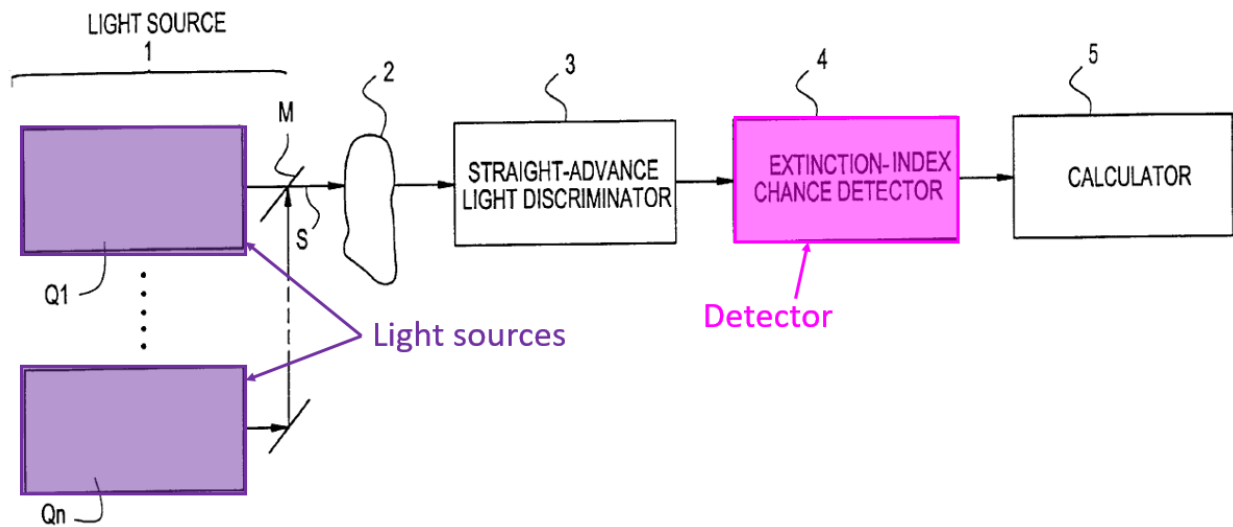
In the combination, the measured second parameter value changing to become “out of range” or “near out of range” **(the indication of the worsening**

state; *see* [21b], [1c]) is the measured second parameter value alarming, *e.g.*, **an alarm condition**. *See* [15c]; APPLE-1006, [0037]-[0039]; APPLE-1003, ¶117.

B. [GROUND 1B] – CLAIMS 19, 27-28, 32, 34, 36-37, AND 42-43 ARE OBVIOUS OVER NAGHAVI-HOCHSTEDLER-BURNES-HAYASHI

1. Overview of Hayashi

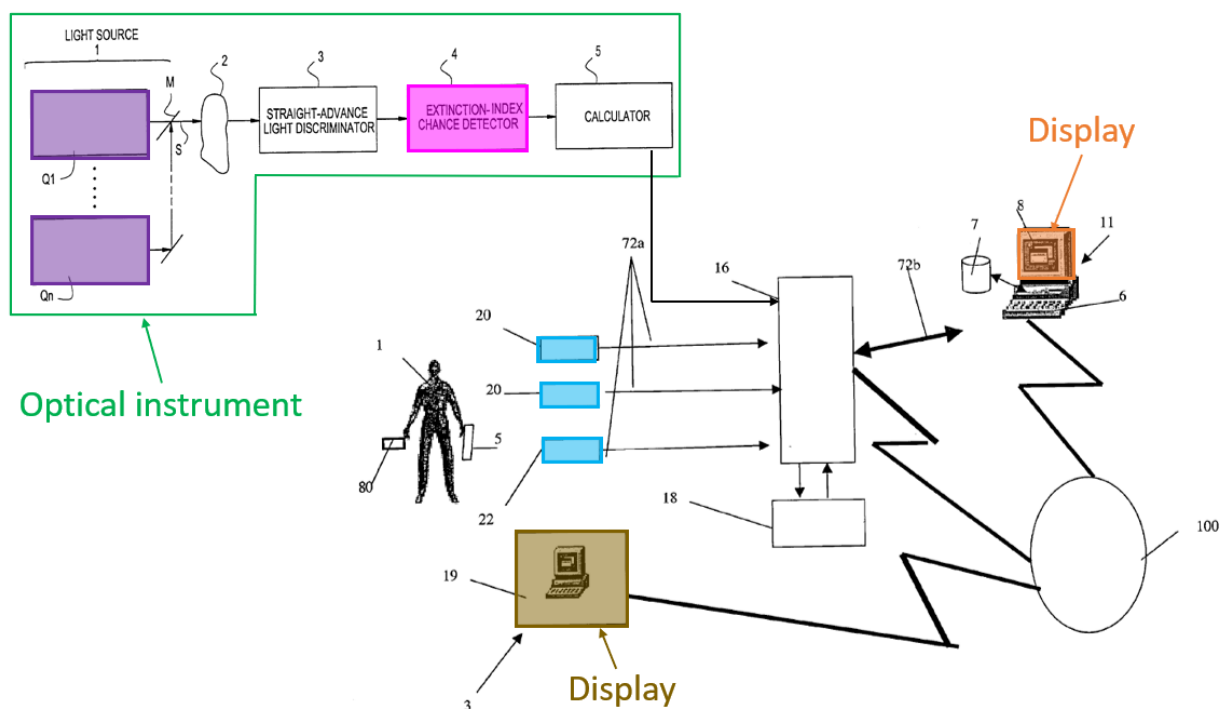
Hayashi describes an instrument for “measuring concentrations of the constituent parts of blood without invading tissue,” *e.g.*, “hemoglobin (oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, methemoglobin, etc.).” APPLE-1007, Abstract, 1:10-14. Light from light sources emitting at different wavelengths (purple in FIG. 1, *infra*) is incident on tissue and is “attenuated” by “absorption and scattering ... in the tissue.” *Id.*, 4:32-36, 4:63-66. A “optical detector,” pink, “detects the light of respective wavelengths” after attenuation by the tissue. *Id.*, 7:19-23; *see* 5:3-8, FIG. 4. Oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, methemoglobin, and/or bilirubin concentrations are calculated based on the detected signals. *Id.*, 5:8-40; *see* 7:31-40; APPLE-1003, ¶¶119-120.



Hayashi, FIG. 1 (annotated)

2. Naghavi-Hochstedler-Burnes-Hayashi combination

The Naghavi-Hochstedler-Burnes-Hayashi patient monitor incorporates a Hayashi-based instrument (green *infra*) “for optically measuring” “the concentration of the hemoglobin (oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, methemoglobin, etc.) in blood,” in addition to (as illustrated) or instead of other sensors (blue). APPLE-1007, 1:7-14; *see* APPLE-1005, [0029]-[0030], [0032]; APPLE-1003, ¶¶121-122. Concentrations of blood constituents measured by the optical instrument are displayed in respective blocks in layouts of the Naghavi-Hochstedler-Burnes display (orange or brown). *See* APPLE-1007, 7:32-40; APPLE-1004, 1:20-21, 3:38-40; APPLE-1003, ¶¶121-123.



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3. Reasons for the combination

A POSITA would have been motivated to implement the Naghavi-Hochstedler-Burnes-Hayashi combination. APPLE-1003, ¶¶124-129.

First, a POSITA would have been motivated to pursue this implementation because of the clinical utility of monitoring concentrations of specific blood constituents. Hemoglobin concentrations provide clinically actionable details of the oxygen concentration in a patient's tissue. APPLE-1007, 1:17-19; *see id.*, 1:46-47; APPLE-1008, 1:23-37; APPLE-1003, ¶125.

Second, a POSITA would have been motivated to pursue this implementation because of the advantages of non-invasive (*e.g.*, optical)

monitoring of blood constituents. APPLE-1003, ¶126; *see* APPLE-1007, 3:22-28. Non-invasive instruments present a low risk of infection or injury. APPLE-1003, ¶126.

Third, to the extent an instrument having the specific configuration described by Hayashi is implemented, a POSITA would have been motivated to pursue this configuration because this instrument “is capable of accurately measuring the concentrations of various constituent parts of blood.” APPLE-1007, 3:24-25; *see* 4:29-31, 5:40-46, 8:67-9:3; APPLE-1003, ¶127.

Fourth, this implementation is merely the application of known techniques (optical monitoring of blood constituent concentrations) by a known system (the Naghavi-Hochstedler-Burnes monitor) to yield predictable results (a multi-parameter monitor with capability to monitor blood constituent concentrations). APPLE-1003, ¶128; *see KSR*, 550 U.S. at 417.

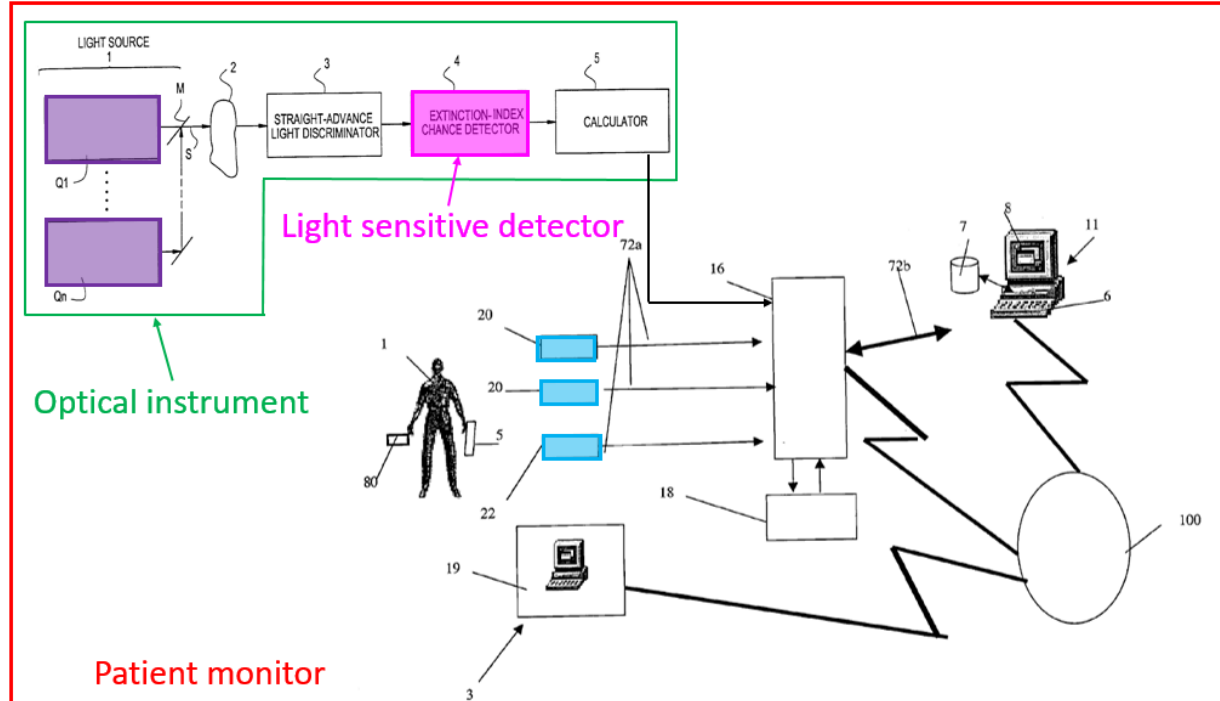
A POSITA would have expected success given that monitoring of the concentration of blood constituents was common. APPLE-1003, ¶129, citing APPLE-1008, Abstract. Additionally, a POSITA would have expected success because of Naghavi’s flexibility with regard to the type of attached sensors in the system, and Hochstedler’s similar flexibility with regard to sensor data to be displayed. *See* APPLE-1005, [0033]; APPLE-1004, 3:17-19; APPLE-1003, ¶129.

4. Analysis

(i) **Claim 19**

[19]

The Naghavi-Hochstedler-Burnes-Hayashi combination includes an optical instrument, green *infra*, “for optically measuring the concentration of the constituent parts of the blood of a living organism,” including “the hemoglobin concentration in blood (e.g., oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, and methemoglobin concentrations).” APPLE-1007, 1:7-14, 3:23-27; *see* Abstract; APPLE-1003, ¶130. Each of these concentrations is a **measured value of a physiological parameter.**



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The optical instrument includes an “extinction-index change detection means,” pink, which is **a light sensitive detector** at least because it includes an “*optical detector*” that “detects the light of respective wavelengths emitted by the light sources,” purple. APPLE-1007, 5:4-8, 6:26-32, 7:19-23; *see* 3:33-44, 5:4-6, 4:19-23, 3:66-4:66, 9:47-51, Abstract, claim 1, claim 14; APPLE-1003, ¶131.

The detector is **capable of detecting light attenuated by body tissue**. APPLE-1003, ¶132. Hayashi describes light incident on tissue is “*attenuated*” due to “absorption and scattering ... in the tissue,” and that “the intensity of the emergent light” (*e.g.*, the attenuated light) “is observed.” APPLE-1007, 3:64-66; *see* 4:52, 5:4-17, 8:5-57 APPLE-1003, ¶132.

In the combination, **measured values of the physiological parameters** (blood constituent concentrations) **are determined using an output signal of the light sensitive detector**. APPLE-1003, ¶133. Hayashi describes “calculating the concentrations” of blood constituents based on detected “extinction index changes”, *e.g.*, **using an output of the detector**. APPLE-1007, 5:27-42; *see* Abstract (“Calculation means (5) calculates concentrations of the constituent parts of the blood, based on the extinction index change for each wavelength component of the measuring light”), 3:44-47, 4:6-10; APPLE-1003, ¶133. For instance, the optical detector “detects the light of respective wavelengths emitted by the light sources 101~106, and the aforementioned beat signal ... is obtained as an

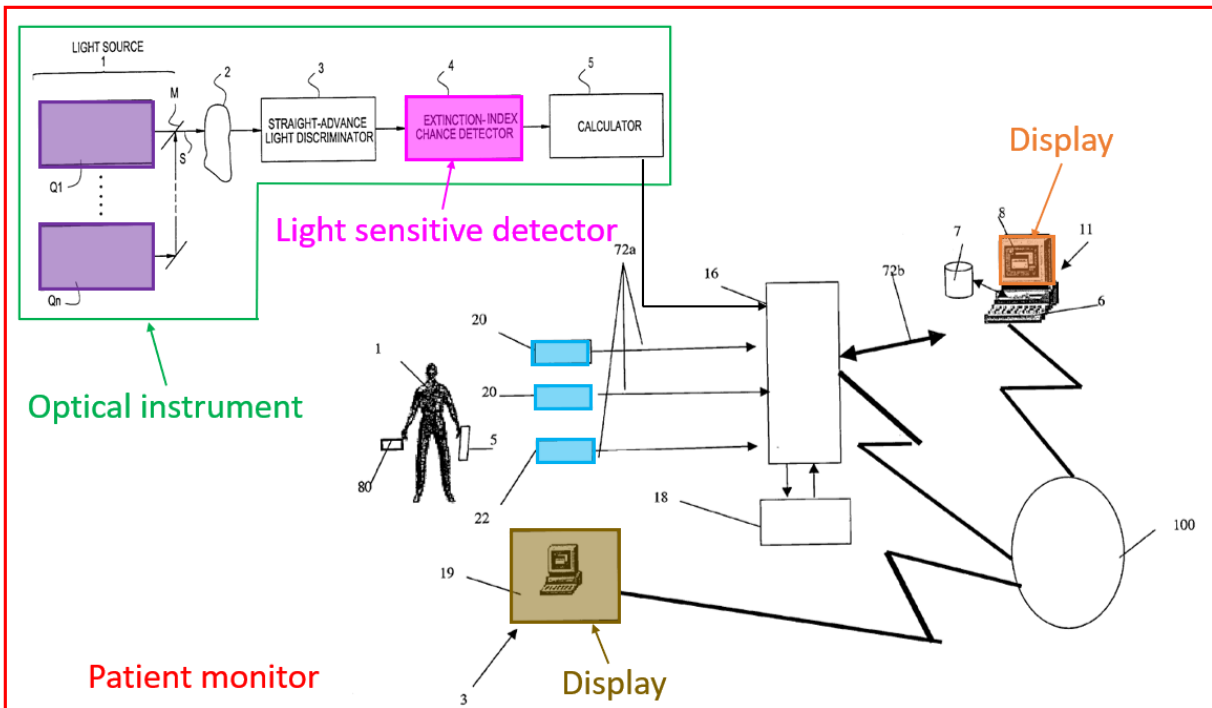
extinction-index signal,” from which blood constituent concentrations are determined. APPLE-1007, 7:21-40; APPLE-1003, ¶133.

(ii) **Claim 27**

[27pre]

To the extent the preamble is deemed to be limiting, Naghavi-Hochstedler-Burnes-Hayashi renders obvious **a patient monitor capable of determining a plurality of physiological parameters** (*e.g.*, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, methemoglobin concentrations). *See* [1pre], [19]; APPLE-1007, 1:11-13, 3:21-28; APPLE-1003, ¶134.

The combination monitor includes an optical instrument, green *infra*, which includes **a light sensitive detector capable of detecting light attenuated by body tissue**: the optical detector (pink). *See* [19]; APPLE-1007, 3:33-34, 6:26-32, 7:19-23; APPLE-1003, ¶135. The measured values **of the first and second physiological parameters** (*e.g.*, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, methemoglobin concentrations) **are determined from an output signal of the light sensitive detector**. *See* [19]; *see* APPLE-1007, 3:44-47, 4:6-10, 5:27-42, 7:21-40 Abstract; APPLE-1003, ¶135.



Naghavi-Hochstedler-Burnes-Hayashi

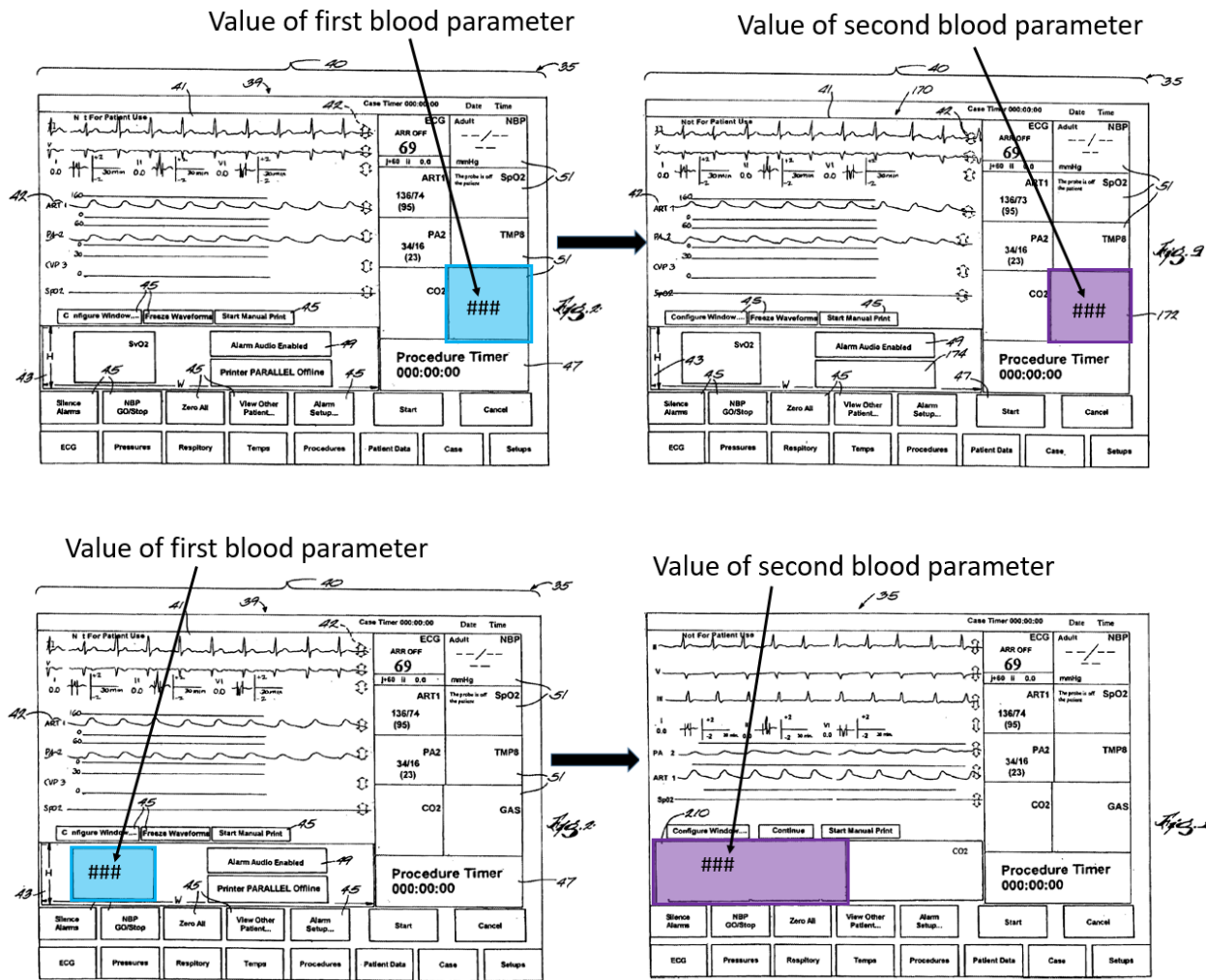
[27a]

In the combination, the measured blood analyte concentrations (oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, methemoglobin concentrations) are **blood parameters** because they are measured concentrations of blood constituents. *See* APPLE-1007, 1:12-13, 3:21-28; APPLE-1003, ¶136.

In the combination, the **display** (orange or brown in [27pre]) is **capable of displaying a measured value of a first blood parameter** (*e.g.*, displaying a blood analyte concentration in a block of a layout based on Hochstedler's FIG. 2) **or displaying a measured value of a second blood parameter** (*e.g.*, displaying a

different blood analyte concentration in a block of a different layout). *See* [1a]; *see* APPLE-1004, 1:19-23, 3:40-41; APPLE-1003, ¶137.

Two examples of layouts are *infra*. In both examples, an initial layout (at left) based on Hochstedler's FIG. 2 includes a block or sublayout (blue) capable of displaying a measured value of a first blood parameter (a blood concentration). *See* APPLE-1004, 3:38-40; APPLE-1003, ¶¶138-139. Responsive to a change in severity of a second blood parameter), the layout is replaced with a layout (at right), *e.g.*, based on Hochstedler's FIG. 9 or 13. *See* [1a]-[1b]; APPLE-1004, 1:54-60, 5:26-37, 8:41-65; APPLE-1003, ¶139. The new layout includes a block or sublayout (purple) capable of displaying a measured value of a second blood parameter (a different blood concentration). *See* [1a]-[1b]; APPLE-1004, 8:41-42, 8:64-65; APPLE-1003, ¶139.



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Each layout includes multiple blocks for display of parameter values. *See* APPLE-1004, 1:54-60, FIG. 2, FIG. 9, FIG. 13; APPLE-1003, ¶140. A POSITA would have found it obvious for some blood parameters to be displayed in one layout while others are displayed in another layout, *e.g.*, such that the display is capable of displaying the measured value of one blood parameter **or** another blood parameter, as discussed in the following paragraphs. APPLE-1003, ¶140.

First, Hochstedler describes that the layouts are set according to user input: “[h]ow the system 10 displays information may be modified through the controls 42 and buttons 45” to “adjust[] the display of information to suit that user’s preferences or needs.” APPLE-1004, 3:55-59; APPLE-1003, ¶141. Which blood parameters are displayed on which layout is a user preference. APPLE-1003, ¶141. A POSITA would have recognized that in certain situations, it would make sense to display certain blood parameters in one layout and others in a different layout, *e.g.*, depending on patient condition or medical issues. *Id.*

Alternatively/additionally, a POSITA would have been motivated to implement the combination layout such that some blood parameters are displayed in one layout while others are displayed in another layout because the display arrangement of parameters is merely the non-inventive rearrangement of parts and as such, is an obvious design choice. APPLE-1003, ¶142. Which parameter is displayed in which location and in which layout provides no unexpected results. *Id.*; *see In re Kuhle*, 526 F.2d 553, 555 (CCPA 1975) (use of claimed feature solves no stated problem and presents no unexpected result and “would be an obvious matter of design choice within the skill of the art”). Moreover, the location of each parameter’s display has no impact on function of the patient monitor: the display is capable of replacing display of one parameter value with another regardless of the identity of the parameters themselves. APPLE-1003,

¶142; *see In re Chu*, 66 F.3d 292, 298-99 (Fed. Cir. 1995) (“design choice” is appropriate where the applicant fails to set forth any reasons why the differences between the claimed invention and the prior art would result in a different function).

[27b]

The layout switch is **replacing the display of the measured value of one parameter with the measured value of another parameter**. *See* [1b], [27a]; APPLE-1004, 1:54-60, 5:26-37, 8:40-65; APPLE-1003, ¶143.

In the combination, Hochstedler describes that the layout change (the replacement) is “an automatic layout switch [that] occur[s] *after prompting the user for approval of the proposed change*,” *e.g.*, user input causes the replacement. APPLE-1004, 5:42-45; *see* 6:1-3, 1:63-67, 8:39-42 (“*If the user selects the OK button 162*, the layout is switched”), FIG. 5, FIG. 8; APPLE-1003, ¶144. Specifically, the user is prompted for approval of the display change responsive to detection of “changes in health status” of the monitored patient that warrants the display change. *See* [1b]-[1c]; APPLE-1004, 1:54-60, 5:26-45; APPLE-1005, [0059], [0063]; APPLE-1006, [0038]-[0039]; APPLE-1003, ¶144. In the combination, Hochstedler’s “OK button” (*e.g.*, as a displayed button icon or as a physical button, as explained by Dr. Cockburn) corresponds to a user input button, and **activating of the user input button** (*e.g.*, user selection of the button)

results in the layout being switched, *i.e.*, **replaces the display of the measured value of the first blood parameter with the measured value of the second blood parameter.** *See* APPLE-1004, 1:54-60, 5:26-45, 8:40-65; APPLE-1003, ¶¶144-151.

[27c]

The layout is switched, thus **replacing the display of the measured value of the first blood parameter with the value of the second blood parameter** responsive to detection of “changes in health status” of the monitored patient, and specifically when the second parameter changes to become “out of range” or “near out of range.” *See* [1c]; APPLE-1005, [0059], [0063]; APPLE-1006, [0038]-[0039], [0043]; APPLE-1003, ¶152. As discussed for [27b], this change in the value of the second parameter triggers the system to “prompt the user to change the layout.” APPLE-1004, 1:63-67; *see* 5:42-45; APPLE-1003, ¶152.

The second parameter changing to become “out of range” is that parameter **passing an alarm threshold.** *See* [15c]; APPLE-1006, [0038] (“An ‘out of range’ value is a value that *has crossed a predetermined threshold*”), [0039]; APPLE-1003, ¶152. The second parameter changing to become “near out of range” is also that parameter **passing an alarm threshold**, *e.g.*, because the second parameter value has changed to beyond a threshold that triggers an alarm. *See* [15c]; APPLE-1006, [0039]; APPLE-1003, ¶152. These thresholds are specifically **alarm**

thresholds at least because the second parameter value exceeding that threshold

“may trigger an alarm.” APPLE-1006, [0038]; *see* [0007]-[0008], [0034]-[0035], [0037], [0039]; *see* [1c], [15c]; APPLE-1003, ¶152.

[27d]

The **measured values of the first and second blood parameters**—*e.g.*, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, methemoglobin, bilirubin (*see* [27a])—**are determined using an output signal of a light sensitive detector capable of detecting light attenuated by the body tissue.** *See* [19], [27pre]; *see* APPLE-1007, 3:33-34, 6:26-32, 7:19-23; APPLE-1003, ¶153. The light sensitive detector is **noninvasive** because it operates external to the body. APPLE-1003, ¶153.

(iii) **Claim 28**

[28pre]-[28a]

See [27pre]-[27a]; APPLE-1003, ¶¶154-155.

[28b]

See [27b]. The combination includes **a user input button, the activation of which** results in “an automatic layout switch,” replacing the display of one parameter value with another, *e.g.*, **causes the display to change from displaying the measured value of the first blood parameter to displaying the measured**

value of the second blood parameter. APPLE-1004, 5:42-45; *see* 1:54-60, 5:26-45, 8:40-65; *see* [13b]; APPLE-1003, ¶156.

[28c]

In the combination, display of one parameter value is replaced by another (*e.g.*, the display changes from displaying the measured first parameter value to displaying the measured second parameter value; *see* [28b]) **when the second blood parameter passes an alarm threshold.** *See* [27c]; APPLE-1005, [0059]; APPLE-1006, [0007]-[0008], [0034]-[0035], [0037]-[0039]; APPLE-1003, ¶157.

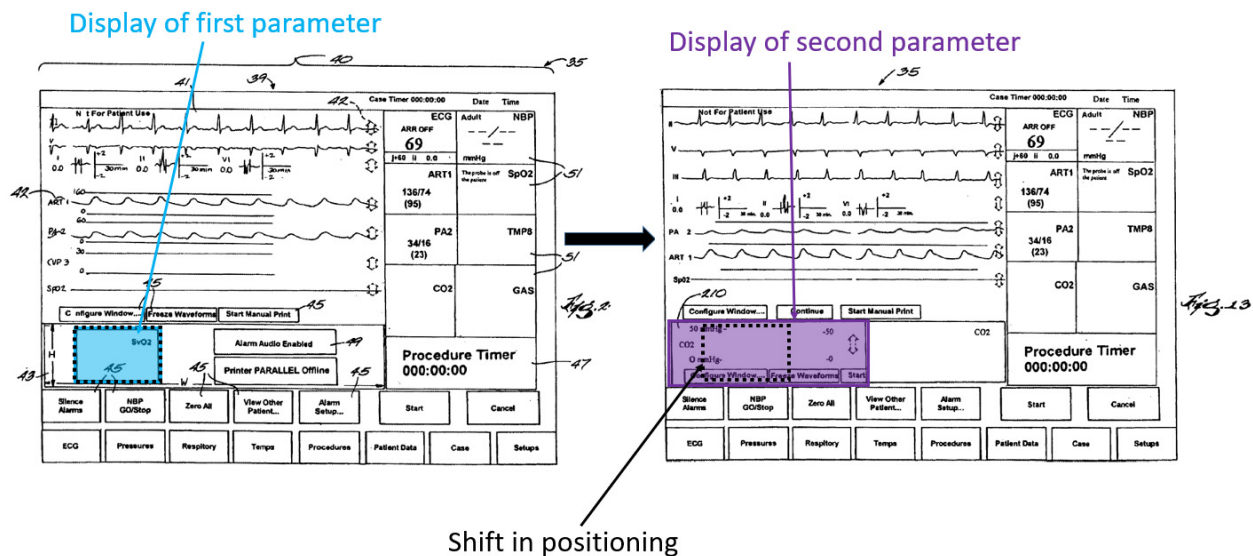
[28d]

See [27d]; APPLE-1003, ¶158.

[28e]

As illustrated *infra*, a POSITA would have found obvious that when a display layout based on Hochstedler's FIG. 2 is replaced with a display layout based on Hochstedler's FIG. 13, **a positioning of the display of the second blood parameter is shifted with respect to a positioning of the display of the first blood parameter.** APPLE-1003, ¶¶159-161. The display area for the second parameter (purple at right) occupies a space encompassing and extending beyond the display area for the first parameter (blue at left): the display area for the second parameter is shifted with respect to the display area for the first parameter. *Id.* Alternatively/additionally, a POSITA would have recognized that in many

implementations of these two layouts, the positioning of the display of the second parameter value itself within its sub-layout is shifted relative to the positioning of the display of the first parameter value within its (smaller) sub-layout, *e.g.*, given the different spaces available for display of each parameter. *Id.* For instance, display of each parameter value in the center of, or aligned with the same edge of, its respective sub-layout, would cause display of one parameter value to be shifted relative to display of the other. *Id.* And as illustrated in Hochstedler's FIG. 2 and FIG. 13, parameter values in different layouts can be displayed in different locations relative to one another.



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Moreover, there is nothing inventive about the specific positioning of each blood parameter value within its respective sub-layout. The positioning of the display of each blood parameter (*e.g.*, the display of the value of each blood

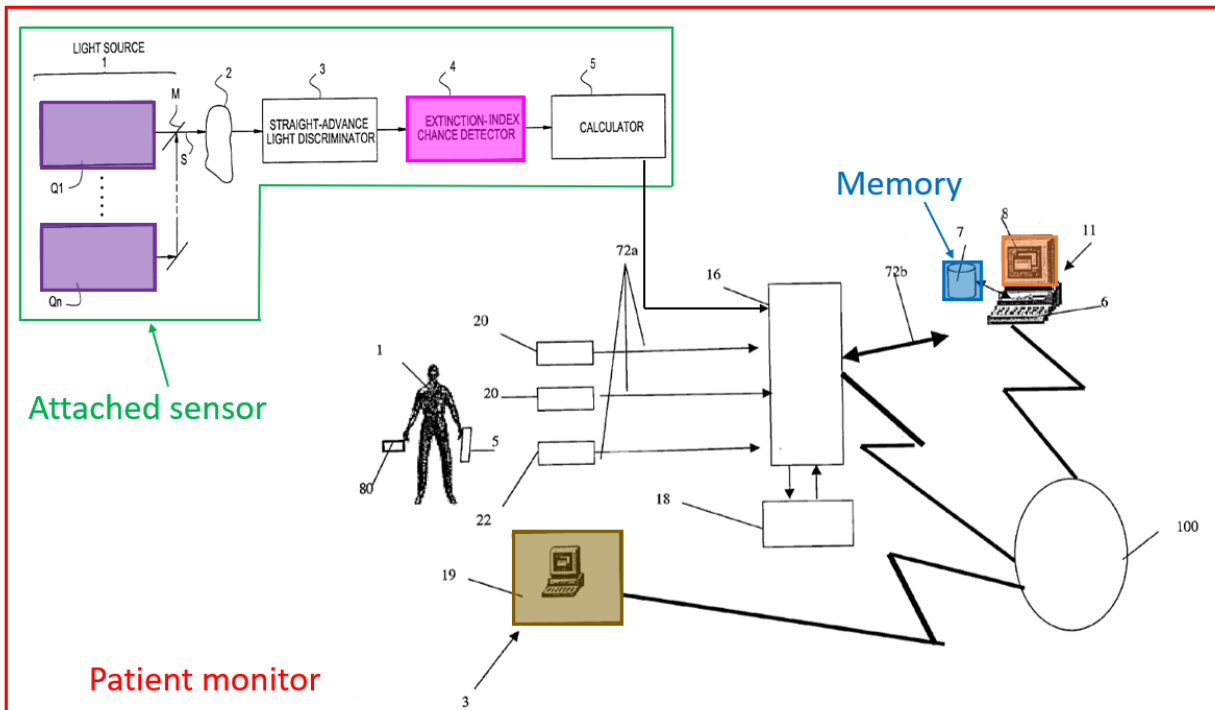
parameter) within their respective sub-layout is mere rearrangement of parts that presents no unexpected results, and as such, is an obvious design choice. APPLE-1003, ¶160; *see In re Kuhle*, 526 F.2d 553, 555 (CCPA 1975). Importantly, too, the particular position of each parameter value within its sub-layout has no impact on function of the patient monitor: the display of the patient monitor is capable of replacing display of one parameter sub-layout with another regardless of the display position of the parameter values within the respective sub-layouts. APPLE-1003, ¶160; *see In re Chu*, 66 F.3d 292, 298-99 (Fed. Cir. 1995).

(iv) **Claim 32**

[32]³

In the combination, the Hayashi-based optical instrument, green *infra*, is **an attached sensor** providing data from which the second blood parameter value (a blood concentration) is determined. *See* APPLE-1007, 1:12-13, 3:21-28, 4:32-5:8; *see* [27pre]; APPLE-1003, ¶162. This **attached sensor can provide data through the output signal** (the output signal of the detector, pink; *see* [19], [27pre]). *See* APPLE-1007, Abstract, 3:44-47, 4:6-10, 5:27-42, 7:21-40; APPLE-1003, ¶162.

³ Petitioner notes the lack of antecedent basis for the phrase “the attached sensor.”



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In the combination, Naghavi's "personal healthcare management system" includes "memory such as RAM memory, and persistent data store 7 [dark blue *supra*] such as a fixed or removable electronic, magnetic, and/or optical medium." Naghavi, [0027]; *see* [0068]. The RAM and/or persistent data store is a **memory**. APPLE-1003, ¶163.

Furthermore, in the combination, Burnes describes a "central database" which receives data from "external medical devices used in monitoring or treating" a patient, and "processing unit 34 for analyzing data received by the central database." APPLE-1006, [0031]; *see* FIG. 4; APPLE-1003, ¶164. Based on Burnes, the **memory** of the combination receives data from the optical instrument

and provides data to a processor for analysis: the **attached sensor** (green) **can provide data through a memory device** (dark blue), where the signal is processed. *See* APPLE-1006, [0031]; APPLE-1005, [0027]; APPLE-1003, ¶¶164-165.

(v) **Claim 34**

[34]

In the combination, Burnes describes that “any cell [of a display] may be selectable by a user for causing a more detailed display of data related to the respective parameter value,” where “[s]uch detailed displays may include histograms, strip chart like recordings, long term parameter trends, data plots or other graphical displays and/or tabular lists of data.” APPLE-1006, [0065]; *see* [0067] (“A HF symptoms trends button 366 may be selected to review a chronological listing or other tabular or graphical display of clinical data ... A pressure trends button 368 may be selected to review a graphical or tabular display of blood pressure measurements or other hemodynamic measurements or changes over time”). In the combination, a displayed parameter value is “selectable by a user” to access “detailed displays” such as “histograms ... [or] long term parameter trends.” APPLE-1006, [0065]; APPLE-1003, ¶¶166-167. This information is **trend data on one or more of the first and second blood parameters**. APPLE-1003, ¶167.

A POSITA would have understood, or at least found to be obvious that the **memory** in the combination (dark blue in the figure *supra* in [33]) is **for storing trend data on the blood parameters**, *e.g.*, to enable display of trend information. *See* APPLE-1006, [0065], [0067]; APPLE-1005 (Naghavi), [0027], [0068]; APPLE-1003, ¶168. Trend data relate to previously measured values. A POSITA would have understood those previously measured values (**trend data**) to be stored in memory such that the trend history can be determined and displayed. APPLE-1006, [0065]; APPLE-1003, ¶168.

A POSITA would have been motivated to have the combination patient monitor store trend data. APPLE-1003, ¶¶169-173.

First, a POSITA would have recognized that storing/displaying trend data provides the clinician with clinically valuable information about patient health beyond current parameter values. APPLE-1003, ¶170.

Second, a POSITA would have been motivated to store trend data so that such data can be incorporated into the patient's medical record. APPLE-1003, ¶171.

Third, this implementation is merely the application of known techniques (storage and display of patient trends) by a known system (the combination monitor) to yield predictable results (a patient monitor that stores and displays trends). APPLE-1003, ¶172; *see KSR*, 550 U.S. at 417.

A POSITA would have expected success because storage of already-collected data in a monitoring system is predictable, and because Naghavi already contemplates storage of medical history and trend data. *See* APPLE-1005, [0070]-[0071]; APPLE-1003, ¶173.

(vi) **Claim 36**

[36]

The replacement of one layout with another is **an alarm**, *e.g.*, because the display change alerts staff of a change in the patient's status. *See* APPLE-1006, [0007]-[0008], [0034]-[0035], [0037]-[0039]; APPLE-1003, ¶174. In the combination, a parameter changing to become “out of range” or “near out of range” causes the display layout change, *e.g.*, triggers the **alarm**. APPLE-1006, [0038]-[0039]; APPLE-1003, ¶174. A parameter becoming “out of range” or “near out of range” occurs when its value has “***crossed a predetermined threshold***,” *e.g.*, the **alarm corresponds to the measured value of a parameter** crossing a **threshold**. *See* [27c]; APPLE-1006, [0038]; APPLE-1003, ¶174.

A POSITA would have understood that a parameter that “crosse[s] a predetermined threshold” can either exceed or fall below the threshold, depending on the parameter. The threshold for oxyhemoglobin or deoxyhemoglobin concentration triggers an alarm if the measured concentration falls below a threshold indicating a low blood oxygen level. *See* APPLE-1003, ¶175, citing

APPLE-1018, [0003]. Thus, at least when oxyhemoglobin or deoxyhemoglobin is the second blood parameter, **the alarm** (the display layout change) **corresponds to the value of the second blood parameter falling below its threshold value.**

APPLE-1003, ¶175.

(vii) **Claim 37**

[37]

See [36]. **The alarm is a visual alarm**, *e.g.*, because the display change is a **visual** representation of the parameter whose value fell below its threshold. *See* APPLE-1004, 1:54-60, 5:26-37, 8:40-65; APPLE-1006, [0038]-[0039]; APPLE-1003, ¶176.

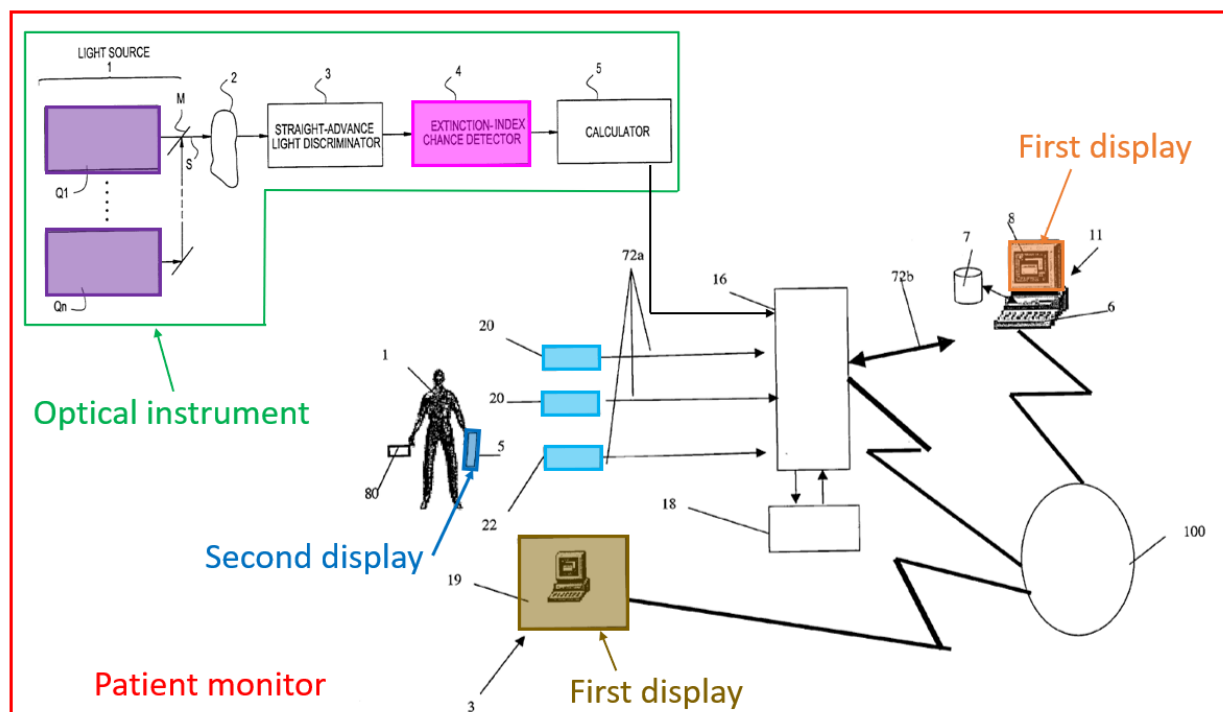
Alternatively/additionally, the combination monitor includes an **audio alarm** based on Hochstedler. *See* APPLE-1004, FIG. 2 (“Alarm Audio Enabled”), FIG. 9, FIG. 11; APPLE-1003, ¶177. A POSITA would have found obvious for **an audio alarm** to be sounded when a parameter falls below its threshold, consistent with Burnes’s teachings that a parameter becoming “out of range” “may trigger an alarm.” APPLE-1006, [0038]; APPLE-1003, ¶177.

(viii) **Claim 42**

[42]

In the combination, the display based on Naghavi’s monitor 8 (orange) and/or a display of the remote service (brown) is a display with multiple display

states, and corresponds to a **first display**. See [1a]. Also based on Naghavi, an “interactive user control module 5” (dark blue *infra*) that “facilitates access to one or more predefined functions” of the system and which can be implemented as “a touch screen” corresponds to a **second display**. APPLE-1005, [0035]; see [0036]-[0037]; APPLE-1003, ¶¶178-179.



Naghavi-Hochstedler-Burnes-Hayashi

A display, such as a display state of Naghavi’s monitor or of the remote service, or the touch screen implementation of the user control module, is **capable** of displaying data (*e.g.*, **capable of displaying a pulse rate**): this is the nature of displays. APPLE-1003, ¶180.

To the extent the claim is interpreted as requiring detection of pulse rate, a POSITA would have found obvious for the combination system to detect pulse rate, *e.g.*, for one of the sensors to be a pulse rate sensor. APPLE-1003, ¶181. Generally, patient monitors, *e.g.*, pulse oximeters, detecting displaying pulse rate were common, *e.g.*, as evidenced by Mortz. *See* APPLE-1009, 5:17-20, 9:65-66; APPLE-1003, ¶182, citing APPLE-1010, 1:27-34; APPLE-1012, 1:28-35; APPLE-1014, [0062]. Moreover, Naghavi is flexible with respect to the type of attached sensors (blue in the figure *supra*). *See* APPLE-1005, [0033]; APPLE-1003, ¶182. A POSITA thus would have found obvious to implement one of these sensors as a conventional pulse rate sensor. APPLE-1003, ¶182.

In this context, a POSITA would have found it obvious for the user control module (**the second display**) to **display a pulse rate** to facilitate user access to this basic parameter, particularly given Naghavi's indication that this user control module is specifically designed to "facilitate interaction between" the patient and an otherwise relatively complex system. APPLE-1005, [0035]; APPLE-1003, ¶183. Moreover, a POSITA would have been motivated to monitor and display pulse rate because of the various advantages of pulse rate monitoring. APPLE-1003, ¶¶184-188.

First, monitoring and displaying a patient's pulse rate has clinical advantages. APPLE-1003, ¶185. A patient's pulse rate can indicate and/or cause a

medical issue, and displaying pulse rate enables early warning of the development of such issues, *e.g.*, so that the patient can reach out to clinical staff for prompt treatment. APPLE-1003, ¶185.

Second, because pulse oximeters are “relatively inexpensive,” they provide a simple way to monitor pulse rate—a clinically relevant parameter. APPLE-1007, 1:63-65; APPLE-1003, ¶186.

Third, this implementation is merely the application of known techniques (pulse rate monitoring) by a known system (the Naghavi-Hochstedler-Burnes monitor) to yield predictable results (a patient monitor having pulse rate monitoring capability). APPLE-1003, ¶187; *see KSR*, 550 U.S. at 417.

A POSITA would have expected success because use of pulse oximeters in patient monitoring systems was common. *See* APPLE-1003, ¶188. Additionally, a POSITA would have expected success because of Naghavi’s and Hochstedler’s flexibility with regard to the type of sensors and sensor data, as discussed *supra*. *See* APPLE-1005, [0033]; APPLE-1004, 3:17-19; APPLE-1003, ¶188.

(ix) **Claim 43**

[43]

In the combination, **the second display is capable of displaying the pulse rate.** *See* [42]. **The first display displays the measured value of the first blood**

parameter, *e.g.*, the value of a blood analyte concentration measured by the Hayashi-based instrument. *See* [27a]; APPLE-1003, ¶189.

The first and second displays are distinct displays (*e.g.*, display states or physical displays) and thus they are capable of displaying different data concurrently, *e.g.*, one display displaying one type of data (*e.g.*, pulse rate) **when** the other display displays another type of data (*e.g.*, a blood parameter). APPLE-1003, ¶190. That is, **the second display is capable of displaying the pulse rate when the first display displays the measured value of the first blood parameter.** *Id.*

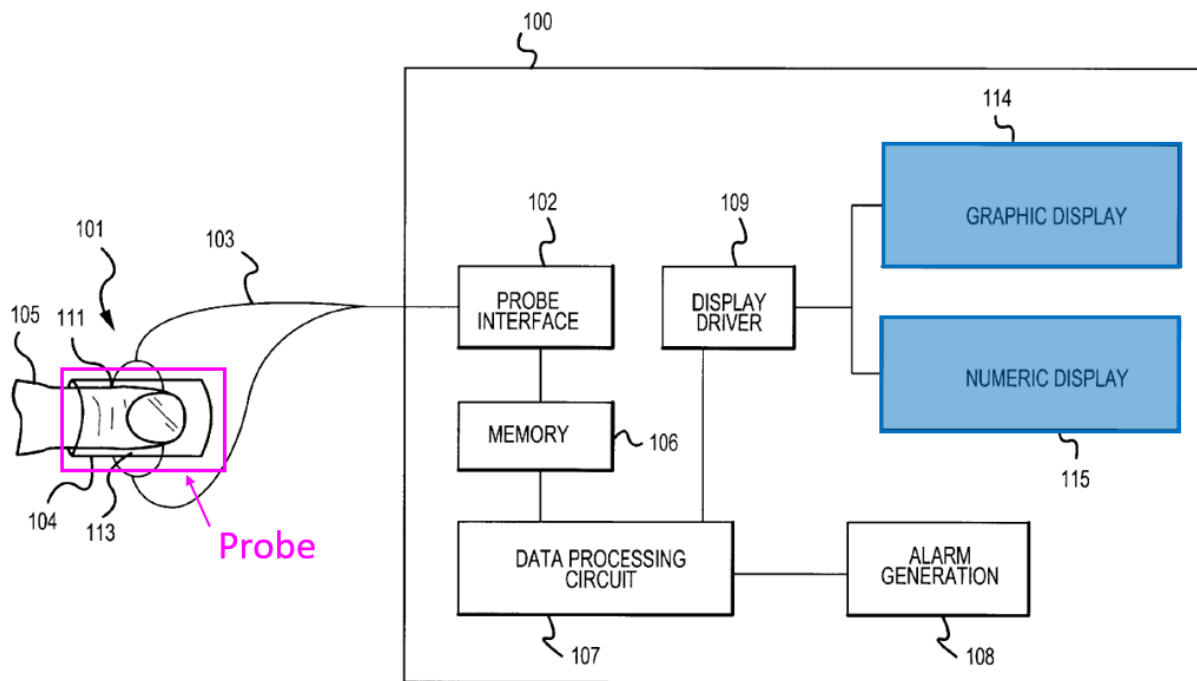
Alternatively/additionally, a POSITA would have found this capability to be obvious, *e.g.*, given advantages of displaying different data concurrently on different displays. APPLE-1003, ¶191. Displaying pulse rate on one display and a blood analyte concentration on another display enables a medical professional to quickly access multiple types of information relevant to patient care. *Id.*

Moreover, displaying different data concurrently on different displays was well-known in the context of patient monitors. *Id.*, citing APPLE-1010, 6:2-18, FIGS. 2-3; APPLE-1011, [0003], [0026]-[0030], FIGS. 3-4.

**C. [GROUND 1C] – CLAIMS 32 AND 42-44 ARE OBVIOUS
OVER NAGHAVI-HOCHSTEDLER-BURNES-
HAYASHI-MORTZ**

1. Overview of Mortz

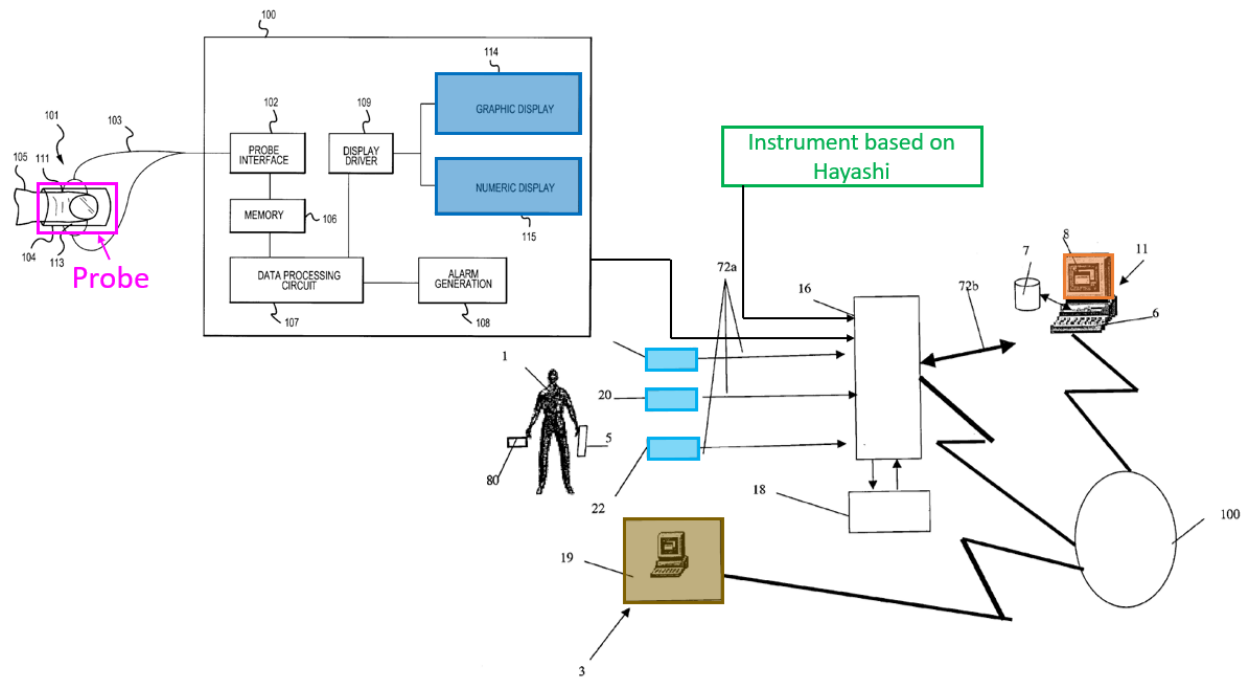
Mortz describes a pulse oximeter probe 101, pink in FIG. 1, *infra*, that includes “a pair of light emitting diodes 111, 112 and at least one corresponding light detector 113.” APPLE-1009, 4:51-59. Signals received from the light detector are processed “to compute the oxygenation level of the hemoglobin in the arterial blood in tissue 105” and “the pulse rate,” and “[t]he results ... are displayed” on “the associated display 114, 115 [dark blue]” of a probe monitor 100. *Id.*, 5:17-20; APPLE-1003, ¶193.



Mortz, FIG. 1 (annotated)

2. Naghavi-Hochstedler-Burnes-Hayashi-Mortz combination

The Naghavi-Hochstedler-Burnes-Hayashi-Mortz patient monitor incorporates a Mortz-based pulse oximeter probe (pink *infra*), along with the Hayashi-based optical instrument (green; *see* §IV.C.2) and, optionally, other sensors (light blue). *See* APPLE-1009, 4:51-59; APPLE-1007, 1:10-14; APPLE-1005, [0029]-[0030], [0032]; APPLE-1003, ¶194. Signal data from the probe is processed to determine at least pulse rate. *See* APPLE-1009, 4:4-17. The numeric and/or graphic display (dark blue) of the probe monitor displays numeric pulse rate and/or a plethysmographic waveform. *See id.*, 5:17-20; APPLE-1003, ¶194.



Naghavi-Hochstedler-Burnes-Hayashi-Mortz

3. Reasons for the combination

A POSITA would have been motivated to implement pulse rate detection/display in the combination. APPLE-1003, ¶¶195-201.

First, pulse rate monitoring is common and has clinical advantages, and pulse oximeters are simple and inexpensive, as discussed in [42], *supra*; APPLE-1003, ¶¶196-198.

Second, to the extent Mortz's specific pulse oximeter and data processing approach is implemented, a POSITA would have been motivated to proceed because of its speed and performance advantages. See APPLE-1009, Abstract ("The minimum size of the data set required for high confidence calculations using

this apparatus is significantly smaller than the a pulse period and permits faster response to changing input data”), 2:22-26; APPLE-1003, ¶199.

Third, this implementation is merely the application of known techniques (pulse rate monitoring) by a known system (the Naghavi-Hochstedler-Burnes-Hayashi monitor) to yield predictable results (a patient monitor implementing pulse rate monitoring). APPLE-1003, ¶200; *see KSR*, 550 U.S. at 417.

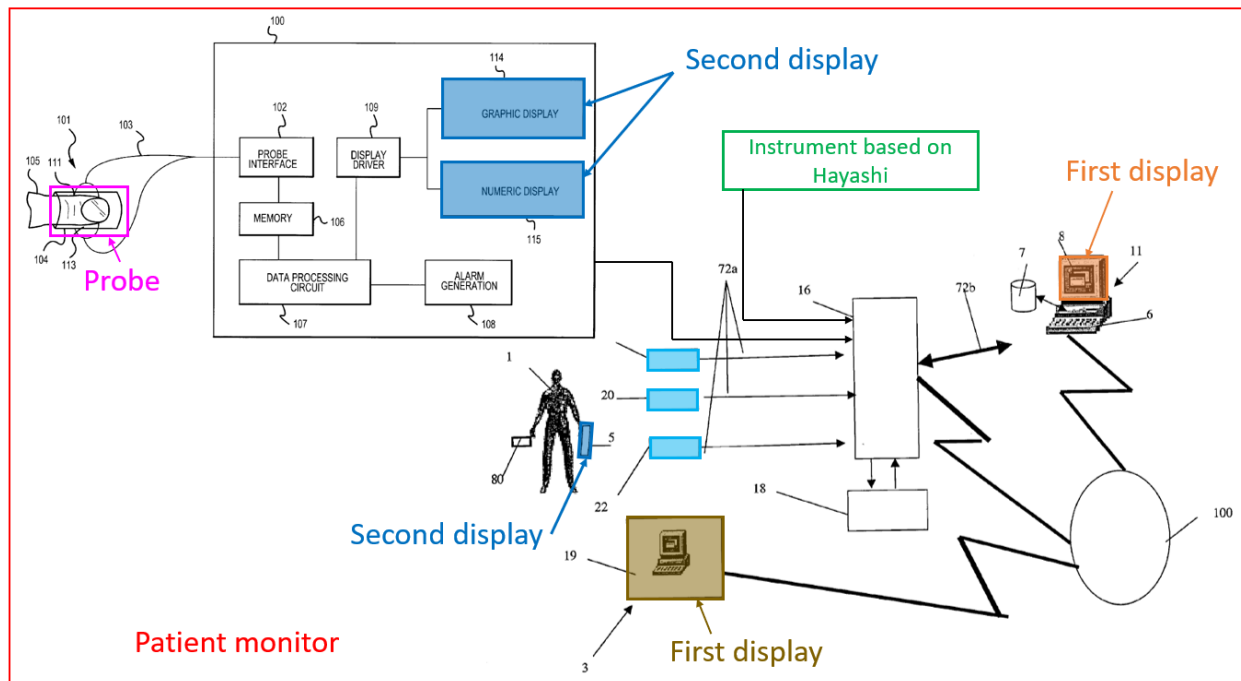
A POSITA would have expected success because pulse oximeters in patient monitoring systems were common, and because of Naghavi’s and Hochstedler’s flexibility, discussed *supra* in [42]. APPLE-1003, ¶201.

4. Analysis

(i) Claim 42

[42]

In the combination, the display based on Naghavi’s monitor (orange) and/or remote service display (brown) is **a first display**. *See* [1a]. The combination includes **a second display** (dark blue), *e.g.*, graphic or numeric display of the Mortz-based probe monitor and/or a Naghavi-based touch screen user control module. *See* APPLE-1009, 5:17-20, APPLE-1005, [0035]-[0037]; *see* [42] of Ground 1C; APPLE-1003, ¶202.



Naghavi-Hochstedler-Burnes-Hayashi-Mortz

The **second display is capable of displaying a pulse rate**: signals from a Mortz-based probe (pink) are processed to determine “pulse rate,” and the “*pulse rate [is] displayed numerically (115)* via ... the associated display 114, 115 while the *plethysmographic waveform is typically displayed graphically* via display 114,” or is displayed on the touch screen display of the user control module.

APPLE-1009, 5:17-20; *see* 9:65-66, FIG. 1; APPLE-1003, ¶203.

(ii) **Claim 43**

[43]

In the combination, **the second display is capable of displaying the pulse rate**. *See* [42]. **The first display displays the measured value of the first blood**

parameter, *e.g.*, the value of a blood analyte concentration. *See* [27a]; APPLE-1003, ¶204.

The first and second displays are distinct displays and thus capable of displaying different data concurrently, and/or a POSITA would have found this capability to be obvious given advantages of displaying different data concurrently on different displays, *e.g.*, **the second display is capable of displaying the pulse rate when the first display displays the measured value of the first blood parameter**. *See* [42] of Ground 1C, *supra*; APPLE-1003, ¶205.

(iii) **Claim 44**

[44]

In the combination, **the first display displays the measured value of the first blood parameter**. *See* [27a], [43]; APPLE-1003, ¶206.

Also in the combination, “[b]lood analyte concentrations” (**indicia identifying the blood parameters**) “may then be displayed via ... graphic display 114 and/or numeric display 115,” *e.g.*, **the second display is capable of displaying indicia identifying the second blood parameter**. APPLE-1009, 4:44-46; *see* [27a], [42]; APPLE-1003, ¶207.

Alternatively/additionally, a POSITA would have found this capability to be obvious given the importance of providing an identifier of a displayed value, *e.g.*, to inform the user of which blood analyte concentration measurement is displayed,

and given that displaying indicia identifying parameters in a multi-parameter measurement system was well-known. APPLE-1003, ¶208.

The first and second displays are two distinct displays, and thus, a POSITA would have understood, or at least found to be obvious, that they are capable of displaying different data concurrently, *e.g.*, that **the second display is capable of displaying indicia identifying the second blood parameter when the first display displays the measured value of the second blood parameter.** *See* [43]; APPLE-1003, ¶209.

IV. PTAB DISCRETION SHOULD NOT PRECLUDE INSTITUTION

A. 314(a) – *Fintiv*

Consistent with Congressional intent, the goals of *Fintiv*, and the Interim Guidance issued by Director Vidal on June 21, 2022 (“*Director’s Guidance*”), Petitioner respectfully asks the Board to reach the merits of the challenges raised in this Petition. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, 6 (PTAB Mar. 20, 2020)(precedential)(“*Fintiv*”); APPLE-1032, 6-7, 9. As demonstrated below, a holistic analysis of the *Fintiv* framework favors institution.

The concerns addressed by *Fintiv* are simply not present. Not only will the Final Written Decision (“FWD”) be rendered well in advance of trial in co-pending District Court proceedings based on median time-to-trial statistics, but Apple has

doubled-down with a comprehensive institution-invoked stipulation to ensure that there can be no redundancy between art considered in this IPR and art asserted in the District Court. *Director's Guidance*, 9; APPLE-1060, 14; APPLE-1066, 1.

The present grounds are premised on Dr. Cockburn's robustly corroborated testimony, which if unrebutted at trial, would compel a conclusion that the Challenged Claims are unpatentable by a preponderance of the evidence. For at least that additional reason, "the PTAB should not discretionarily deny institution under *Fintiv*." APPLE-1032 (*Director's Guidance*), 3-5, 9; IPR2022-01242 Pap. 23 at 3, 5-6 (PTAB Feb. 27, 2023)(precedential)("Commscope").

1. Factor 1: Neither Party has yet Requested a Stay with Respect to the '223 Patent

Factor 1 does not favor denial. Neither party has indicated a lack of intent to request a stay of the related litigation with respect to the '223 Patent⁴, and the Board has indicated that it "will not attempt to predict" how a district court might adjudicate a future motion to stay, if/when filed. *See Fintiv*, 12; *Sand Revolution II, LLC v. Cont'l Intermodal Group – Trucking LLC*, IPR2019-01393, Pap. 24, 7

⁴ Notably, Judge Noreika granted a stay of Masimo counterclaims asserting U.S. Patent Nos. 10,912,501, 10,912,502, 10,945,648, 10,687,745, and 7,761,127, until conclusion of an ongoing ITC matter, including all appeals. APPLE-1069, 1.

(June 16, 2020)(“*Sand Revolution*”)(informative); *Sotera Wireless Inc. v. Masimo Corp.*, IPR2020-01019 Pap. 12, 14 (PTAB Dec. 1, 2020)(“*Sotera*”)(precedential).

2. Factor 2: The Board and Parties can Only Speculate as to the Trial Date, and Statistics Disfavor Denial

As the Director recognizes, “scheduled trial dates are unreliable and often change.” *Director’s Guidance*, 8. Thus, the “PTAB will weigh this factor against exercising discretion to deny institution...if the median time-to-trial is...after the projected statutory deadline for the PTAB’s [FWD].” *Id.*, 9. Indeed, the Delaware District Court, which presides over the related litigation and which is one of the country’s busiest patent courts, recently granted a joint motion to amend the case schedule that moved the case management conference back by approximately two months, but has not yet set an estimated trial date. *See* APPLE-1065, 3 (indicating a “New Deadline” for “Trial” of “TBD”).

Based on the October 20, 2022 filing date of Apple’s original complaint, an average time-to-trial of 37.8 months, and the 18-month IPR schedule, the Board is expected to issue its FWD in June or July, 2025, nearly six months ahead of the statistically indicated December, 2025 district court trial date. APPLE-1060, 14.

Accordingly, Factor 2 disfavors denial. *Director’s Guidance*, 9; *see also Masimo Corp. v. Apple Inc.*, IPR2023-00634 Pap. 1, 108 (Feb. 27, 2023)(Petition)(arguing against denial based on “published statistics indicat[ing]

that the median time to trial for a civil action in the District of Delaware is almost three years”).

More, in this case, several factors contribute to uncertainty with respect to the yet-scheduled trial date, including, for example, whether a single trial will be conducted to address all 6 of Apple’s asserted utility patents, all 4 of Apple’s asserted design patents, and all 5 of Masimo’s counter-asserted utility patents (including the ’223 patent). *See, generally*, APPLE-1062-1065, APPLE-1069. For example, it remains unclear whether the 5 Masimo patents that are subject to stay until conclusion of the related ITC matter, including all appeals, will eventually be tried together with the 5 additional Masimo patents that are not subject to stay, or if separate trials addressing those two sets of patents might instead be conducted in sequence. *See* APPLE-1069, 1.

For at least these reasons, Factor 2 disfavors denial.⁵ *See Director’s Guidance*, 9.

⁵ Moreover, Apple has been diligent. Patent Owner filed its D. Del. counterclaims asserting 10 patents, including the ’223 Patent, in the context of ongoing complex litigation, initiated by Masimo on January 9, 2020 by its C. D. Cal. complaint, that has thus far involved 37 patents and, in addition to the PTAB, forums including

3. Factor 3: Petitioner's Diligence and Investment in IPR Disfavors Denial

Factor 3 disfavors denial. Apple's substantial investment in petitions addressing the 10 patents asserted by Patent Owner in District Court Litigation (including the 5 patents reasserted from ITC litigation) should counterbalance—and frankly outweigh—the resources invested in the co-pending District Court Litigation. It would be unjust to consider resources expended in District Court (equally by both parties), without considering Apple resources expended to prepare petitions that would be irretrievably lost without consideration on the merits.

For example, as explained below with respect to Factor 4, to ensure that an IPR proceeding instituted on the basis of this Petition will be a true alternative to

C.D. Cal., ITC, D. Del., and the Fed. Cir. In addition to today's filings, Apple has demonstrated at least a reasonable likelihood of success in proving unpatentability of 22 of these patents at the PTAB, and has indeed been found to have demonstrated unpatentability of claims in 18 of the corresponding 20 FWDs that have issued thus far. For at least that additional reason, Factor 2 favors institution. *See Apple Inc. v. Seven Networks, LLC*, IPR2020-00156, Pap. 10, 9 & n.8 (June 15, 2020)(“*Seven Networks*”)(factor 2 should be analyzed on a sliding scale based on petitioner diligence and relative trial dates).

district court litigation that might otherwise address overlapping issues, Apple stipulates that, if the Board institutes this IPR, Apple will not, for the instituted claims, seek resolution in the co-pending Delaware District Court proceeding of any ground of invalidity that utilizes any of the prior art asserted in this petition, *i.e.*, Naghavi, Hochstedler, Burnes, Hayashi, or Mortz. APPLE-1066. Consistent with Apple's stipulation, Apple's district court expert invalidity report does not include any of Naghavi, Hochstedler, Burnes, Hayashi, or Mortz. APPLE-1068. As such, discretionary denial of the instant petition would prevent Apple from being heard, not only by the PTAB, but also by the District Court, both with respect to the compellingly meritorious grounds presented within this petition, and also with respect to any ground of invalidity utilizing any of Naghavi, Hochstedler, Burnes, Hayashi, or Mortz. *Id.*

In this way, Apple's stipulation is broader in several dimensions than a *Sotera* stipulation, at least according to Masimo. For instance, despite offering a *Sotera* stipulation in support of its petitions, after institution, Masimo advances in district court invalidity grounds the same references that it applied within its instituted IPR petitions.⁶

⁶ For example, the Board instituted Masimo's *Sotera*-backed petition challenging

For at least these reasons, *Fintiv* factor 3 disfavors denial. *See Seven Networks*, 11-12; *Sotera*, 16-17; *Snap, Inc. v. SRK Technology LLC*, IPR2020-00820, Pap. 15, 11-13 (Oct. 21, 2020)(“*Snap*”)(precedential).

4. Factor 4: The Petition’s Grounds are Materially Different from Any that Might be Raised in Litigation

Factor 4 strongly disfavors denial. First, Patent Owner asserts only ’223 Patent claims 15, 21, 22, 27, 28, 34, 36, 43, and this Petition challenges additional ’223 Patent claims beyond the asserted claims. Accordingly, a material number of

Apple’s D. Del.-asserted ’257 patent, and Masimo has since revealed that it relies for its district court invalidity grounds on the same Markel and Mills references applied in that petition, further combined with product art. *Masimo Corp. v. Apple Inc.*, IPR2023-00745 Pap. 1, 12-13, 85 (Mar. 22, 2023); APPLE-1067, 1.

Similarly, Masimo relies in district court on the same Chae reference applied in its now-instituted and *Sotera*-backed ’352 patent petition, further combined with product art. *Masimo Corp. v. Apple Inc.*, IPR2023-00664 Pap. 1, 33, 94 (Mar. 6, 2023); APPLE-1067, 1. Finally, Masimo relies in district court on the same Kotanagi reference applied in its now-instituted and *Sotera*-backed ’783 patent petition, further combined with product art. *Masimo Corp. v. Apple Inc.*, IPR2023-00634 Pap. 1, 6, 109 (Feb. 27, 2023); APPLE-1067, 1.

the Challenged Claims will be left unaddressed in District Court Litigation. *See Seven Networks*, 21.

Second, to eliminate any doubt as to the absence of meaningful overlap between the District Court Litigation and IPR, Apple stipulates that, if the Board institutes this IPR, Apple will not, for the instituted claims, seek resolution in the co-pending District Court proceeding of any ground of invalidity that utilizes any of Naghavi, Hochstedler, Burnes, Hayashi, or Mortz. APPLE-1066.

By this stipulation, Factor 4 strongly disfavors denial, at least because Apple's stipulation guarantees that the prior art relied on in this IPR will not be relitigated/otherwise litigated in the co-pending District Court proceeding. *See Apple Inc. v. AliveCor, Inc.*, IPR2021-00972 Pap. 10, 13-16 (PTAB Dec. 8 2021)(“*AliveCor*”); APPLE-1068 (demonstrating that Apple's district court expert invalidity report does not leverage Naghavi, Hochstedler, Burnes, Hayashi, or Mortz).

Notably, Apple's stipulation is substantially more robust than a *Sand Revolution* stipulation, by which a petitioner pledges not to pursue the same grounds of invalidity in district court litigation, while leaving open the possibility of the same references applied within a petition being reasserted by the same petitioner in different district court invalidity grounds. *See Sand Revolution* at 11-12. For at least that reason, Apple respectfully submits that ***Apple's stipulation***,

which *guarantees that there will be no overlap* between the prior art relied on in this IPR and the prior art relied on in the District Court proceeding, should be accorded substantially more weight than a *Sand Revolution* stipulation. *Cf. Sand Revolution* at 12.

Further, and as noted above with respect to Factor 3, Apple's stipulation is also broader than a *Sotera* stipulation, at least insofar as it is apparently Masimo's position that a *Sotera* stipulation leaves open the possibility of the same references applied within an instituted IPR petition being reasserted by the same petitioner in district court invalidity grounds that could not reasonably have been raised in that petition. *See Sotera*, 13-14, 19; 35 U.S.C § 315(e)(2). More specifically, Masimo's Delaware District Court invalidity positions with respect to Apple's '257, '352, and '783 patents rely on many of the same references already applied within Masimo's *Sotera*-backed and earlier-instituted IPR petitions, further combined with product art that is not eligible for PTAB consideration. *See* APPLE-1067, 1; IPR2023-00745 Pap. 1, 12-13, 85; IPR2023-00664 Pap. 1, 33, 94; IPR2023-00634 Pap. 1, 6, 109.

Whether the District of Delaware will allow Masimo to proceed in this manner remains to be seen, but recent decisions treating language of the § 315(e)(2) estoppel provision that is co-extensive with *Sotera* suggest that it might. *See Sotera*, 19; 35 U.S.C § 315(e)(2). For example, a recent D. Del. decision held

that so long as printed publications are used in combination with product or system art such that the “combination is substantively different from the grounds that were raised or reasonably could have been raised” in the IPR, IPR estoppel does not apply. *Ioengine, LLC v. PayPal Holdings, Inc.* 607 F. Supp. 3d 464, 513 (D. Del. Jun. 15, 2022) (Bryson); *see also Chemours Co. FC, LLC v. Daikin Indus. Ltd.*, No. 1:17-cv-01612, 2022 WL 2643517, at *1 (D. Del. Jul. 8, 2022) (Noreika) (holding that IPR estoppel does not apply to prior art products, even if cumulative to references asserted in IPR).

In stark contrast with Masimo’s *Sotera* stipulations and Masimo’s reliance on overlapping references applied in IPR and the District Court Litigation, Apple’s stipulation extinguishes the possibility of ***any overlap*** in prior art between this IPR and grounds resolved in counterpart D. Del. proceedings, thereby ensuring that IPR is a true alternative to the District Court Litigation with respect to that art.

Moreover, Masimo asserts only a small subset of the claims challenged in this IPR (8 of 26). Further, official statistics indicate that the Board will issue its FWD months in advance of the District Court trial. APPLE-1060, 14

At least because ***the invalidity grounds to be resolved in the District Court Litigation involve no overlap in prior art and only a small subset of the Challenged Claims***, Factor 4 strongly disfavors denial. *See AliveCor*, 16; *Seven Networks*, 21.

5. Factor 5: The PTAB Parties are Not Different Than District Court Parties

Factor 5 should, at worst, be neutral. The Litigation involves the same parties. However, the *Fintiv* decision says nothing about weighing Factor 5 in favor of denial when the petitioner and the defendant in the parallel proceeding are the same; with respect to Factor 5, *Fintiv* instead notes that “if a petitioner is unrelated” the Board has weighed that “fact against exercising discretion to deny institution.” *Fintiv*, 13-14; *see also Cisco Systems, Inc. v. Ramot at Tel Aviv University Ltd.*, IPR2020-00122, Pap. 15, 10 (Crumbley, dissenting).

Neither the grounds of unpatentability advanced by the instant Petition nor the prior art itself will be addressed in the District Court Litigation, as the invalidity contentions omit the petitioned prior art. APPLE-1068. Presented with a similar situation, the Board in *Snap* resolved “the fifth *Fintiv* factor as neutral or, at most, weighing slightly in favor of exercising discretion to deny institution”. *Snap*, 16.

6. Factor 6: The Merits of this Petition Compel Institution

Factor 6 strongly disfavors denial. Here, the strength of the merits alone outweighs any potential inefficiencies, regardless of whether the timing of the District Court Litigation is thought relevant (it is not, as demonstrated with respect to Factors 1-5). *Fintiv*, 14-15 (noting under Factor 6 that “if the merits of a ground

raised in the petition seem particularly strong...institution of a trial may serve...overall system efficiency and integrity”).

With Factors 2, 3, 4, and 6 disfavoring denial, and with remaining Factors 1 and 5 otherwise neutral, discretion should not be exercised to deny institution (and thus, substantive consideration on the merits). *Fintiv*, 19 (declining to deny institution based on a “holistic” balancing of “all of the *Fintiv* factors”).

Moreover, Director Vidal has further explained that “where the PTAB determines that the information presented at the institution stage presents a compelling unpatentability challenge, that determination alone demonstrates that the PTAB should not discretionarily deny institution under *Fintiv*.” *Director’s Guidance*, 4-5. More specifically, the PTAB will not discretionarily deny institution if “the Petition presents challenges ‘in which the evidence, if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence.’” *Commscope*, 3 (quoting *Director’s Guidance*, 4); *Director’s Guidance*, 3-5, 9.

The merits of this Petition are compelling. As the instant Petition demonstrates, evidence including the applied references and Dr. Cockburn’s robustly corroborated testimony, if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence.

Both because a holistic analysis of the *Fintiv* factors disfavors denial, and because the merits of the instant Petition are compelling, Apple respectfully submits that the Board should not discretionarily deny institution under *Fintiv*.⁷ *Fintiv*, 19; *Director's Guidance*, 3-5, 9; *Commscope*, 3.

B. 325(d) – *Advanced Bionics*

Advanced Bionics strongly favors institution. *Advanced Bionics*, IPR2019-01469 Pap. 6. Under *Advanced Bionics*, discretionary denial under Section 325(d) is appropriate only if a condition in the framework's first prong is satisfied, and if there is no showing of material error under the second prong. IPR2019-01469 Pap. 6 (PTAB Feb. 13, 2020).

First, there is no indication in the file history that the examiner was aware of, let alone considered, Naghavi, Hochstedler, or Burnes.

Moreover, while Hayashi and a parent of the applied Mortz reference are listed on the face of the '223 Patent, each is merely one of the hundreds references that were cited to the Examiner and, critically, was not applied or discussed by the

⁷ Apart from Petitioners' showing that *Fintiv* favors institution, the *Fintiv* framework should not be followed because it is legally invalid. The framework (1) exceeds the Director's authority, (2) is arbitrary and capricious, and (3) was adopted without notice-and-comment rulemaking.

Examiner in any capacity during prosecution. *See generally* APPLE-1002. Simply citing a reference on an information disclosure statement, with nothing more, does not favor denial of institution. *See Navistar, Inc. v. Fatigue Fracture Tech., LLC*, IPR2018-00853, Paper 13 at 16-17 (PTAB Sept. 12, 2018) (“[T]he fact that [references] were of record, but not applied in any rejection by the Examiner . . . provides little impetus for us to exercise our discretion to deny institution under §325(d).”).

Further, the instant Petition’s art and arguments cannot be said to be the same as, or substantially similar to, art and arguments previously presented to the Office in connection with the ’223 Patent. *See generally* APPLE-1002.

V. PAYMENT OF FEES – 37 C.F.R. § 42.103

Petitioner authorizes the Office to charge Deposit Account No. 06-1050 for the petition fee set in 37 C.F.R. §42.15(a) and for any other required fees.

VI. CONCLUSION

Petitioner respectfully requests institution of an IPR for the Challenged Claims.

VII. MANDATORY NOTICES UNDER 37 C.F.R § 42.8(a)(1)

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Apple Inc., is the petitioner and real party-in-interest.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

Petitioner is not aware of any disclaimers or petitions for inter partes review for the '223 Patent. An ex parte reexamination certificate number was issued for the '223 Patent on April 24, 2013, based on Reexamination Request No. 90/012,559. The '223 Patent is the subject of *Apple Inc. v. Masimo Corporation et al.* 1-22-cv-01378 (DDE) filed October 20, 2022.

C. Lead And Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioner provides the following designation of counsel.

LEAD COUNSEL	BACK-UP COUNSEL
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D. Service Information

Please address all correspondence and service to the address listed above.

Petitioner consents to electronic service by email at IPR50095-0132IP2@fr.com.

Respectfully submitted,

Dated: December 12, 2023

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(Control No. IPR2024-00290)

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CERTIFICATION UNDER 37 CFR § 42.24

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter Partes* Review totals 13,997 words, which is less than the 14,000 allowed under 37 CFR § 42.24.

Dated: December 12, 2023

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on December 12, 2023, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits were provided via Federal Express, to the Patent Owner by serving the correspondence address of record as follows:

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