

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SOTERA WIRELESS, INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

IPR2020-01082
Patent 10,255,994 B2

Before GEORGE R. HOSKINS, JENNIFER MEYER CHAGNON, and
AMANDA F. WIEKER, *Administrative Patent Judges*.

WIEKER, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background

Sotera Wireless, Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–8 (“challenged claims”) of U.S. Patent No. 10,255,994 B2 (Ex. 1001, “the ’994 patent”). Paper 1 (“Pet.”). Masimo Corporation (“Patent Owner”) filed a Preliminary Response. Paper 8 (“Prelim. Resp.”). With our authorization, Petitioner filed a Preliminary Reply (Paper 12 (“Prelim. Reply”)) and Patent Owner filed a Preliminary Sur-reply (Paper 13 (“Prelim. Sur-reply”)),¹ both directed to Patent Owner’s argument that we should exercise discretion to deny institution under 35 U.S.C. § 314(a) based on a parallel district court proceeding.²

We have authority to determine whether to institute an *inter partes* review, under 35 U.S.C. § 314 and 37 C.F.R. § 42.4. An *inter partes* review may not be instituted unless it is determined that “the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314; *see also* 37 C.F.R. § 42.4(a) (“The Board institutes the trial on behalf of the Director.”).

¹ The parties include arguments directed to the merits of the asserted grounds in their papers. *See* Prelim. Reply 7; Prelim. Sur-reply 5–7. We do not rely on these belated arguments in our determination below that Petitioner has not presented a reasonable likelihood of success on the merits (*see infra* Sections II.D–F).

² Because we deny institution on the merits of Petitioner’s asserted grounds of unpatentability, we need not address these arguments.

For the reasons provided below, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in demonstrating the unpatentability of any of the challenged claims. Accordingly, we do not institute an *inter partes* review.

B. Related Proceedings

The parties identify the following matter pending in district court and related to the '994 patent: *Masimo Corp. v. Sotera Wireless, Inc.*, Case 3:19-cv-01100 (S.D. Cal.). Pet. 2–3; Paper 7, 1. Patent Owner also identifies the following *inter partes* review proceedings involving patents asserted in the parallel district court proceeding:

IPR2020-00912, challenging U.S. Patent No. 10,213,108;
IPR2020-00954, challenging U.S. Patent No. 9,788,735;
IPR2020-00967, challenging U.S. Patent No. RE47,244;
IPR2020-01015, challenging U.S. Patent No. 9,795,300;
IPR2020-01019, challenging U.S. Patent No. RE47,353;
IPR2020-01033, challenging U.S. Patent No. RE47,249;
IPR2020-01054, challenging U.S. Patent No. 9,872,623; and
IPR2020-01078, challenging U.S. Patent No. RE47,218.

Paper 7, 2.

Patent Owner further identifies various applications that claim priority to, or share a priority claim with, the '994 patent. *Id.* at 1–2.

C. The '994 Patent

The '994 patent is titled “Physiological Parameter Alarm Delay,” and issued on April 9, 2019, from U.S. Patent Application No. 15/894,393, filed February 12, 2018. Ex. 1001, codes (21), (22), (45), (54).

The '994 patent discloses a “system configured to reduce a frequency of alarms from a physiological monitoring system” by “delay[ing] a notification of [an] alarm condition until a predetermined alarm delay period has elapsed.” *Id.* at code (57). The disclosed physiological monitoring system includes a plurality of bedside patient monitoring devices, which may include ECG sensors, acoustic sensors, or pulse oximeters, and which communicate with clinicians and other end users over a shared network. *Id.* at 8:17–58, Fig. 1 (system 100, bedside devices 110, sensors 102, network 126). Each sensor includes a processing module that “generates alarms in response to physiological parameters exceeding certain safe thresholds.” *Id.* at 8:59–9:11, Fig. 1 (processing modules 104). More specifically, an alarm condition exists when a parameter is detected to be outside a predetermined range. *Id.* at 61:54–59. In such a circumstance, “various actions can be taken. For example, the bedside medical monitor can emit an audible or visual alarm.” *Id.* at 61:59–62. The '994 patent also explains that, “after the alarm condition has persisted for some set amount of time (e.g., 5 sec.), the alarm condition can be displayed at, for example, a central patient monitoring station” and, if the alarm condition continues even longer, e.g., 10 seconds, a clinician can be notified directly through a pager or other notification device. *Id.* at 61:62–62:3.

Among other features, the '994 patent also discloses that a reporting module can use collected patient monitoring data to “simulate the alarm events that would have been detected had the patient monitoring devices . . . used a different set of alarm criteria than those that were actually used,” and can change the alarm criteria that are used thereafter based on the simulation. *Id.* at 64:40–47; *see also, e.g., id.* at 65:8–66:61 (changing,

e.g., an oxygen saturation alarm threshold from 94% to 92%), Fig. 31. The '944 patent also discloses that simulations may be conducted to evaluate changes to an alarm notification delay time between the detection of an alarm condition and the transmittal of an alarm notification to a central monitoring station or clinician. *Id.* at 71:11–26. For example, a simulation might vary the delay time from 5 seconds to 7 seconds. *Id.* at 71:37–72:56.

In some cases, if the alarm condition is only transient in nature, a relatively small lengthening of the alarm notification delay time could result in the alarm condition ceasing before an alarm notification event is generated. In this way, adjustment of the alarm notification delay time can potentially safely reduce the number of alarm notification events to which clinicians must respond. This can in turn increase the effectiveness of patient care by allowing clinicians to focus their time on attending to alarm events that are non-transient.

Id. at 72:13–28. According to the '994 patent, this ability to simulate new alarm notification delay times, without actually implementing them on live patients, is advantageous to hospitals. *Id.* at 72:34–43.

D. Illustrative Claims

Of the challenged claims, claims 1 and 5 are independent. Claims 1 and 5 are directed to a system and a method, respectively, and have similar recitations. Claims 1 and 5 are illustrative and reproduced below, with italics added to highlight the limitations on which our discussion centers.

1. A system configured to reduce a frequency of alarms from a physiological monitoring system, the system comprising:
a physiological sensor configured to detect signals representative of a physiological condition of a patient;
one or more processors configured to receive the detected signals and determine a physiological parameter of the patient, the one or more processors further configured to detect an alarm condition for the physiological parameter and delay a notification

of the alarm condition until the alarm condition persists for a predetermined alarm notification delay time, wherein said one or more processors are configured to provide a notification of the alarm condition responsive to the alarm condition persisting through the alarm notification delay time, the one or more processors being associated with a care unit; and

a reporting module configured to simulate, using measurements obtained from the care unit, different alarm notification delay times to determine whether any of the different alarm notification delay times would have resulted in an alarm notification event, the alarm notification event for each different alarm notification delay time indicating that an alarm condition persisted for at least that alarm notification delay time, and to provide an indicator of the effect of a change in alarm notification delay time on frequency of alarm notification events; wherein the indicator is indicative of a change in the alarm notification delay time that is effective to reduce the frequency of transient or false alarms and wherein the indicator is configured to be used to program one or more physiological monitoring systems with alarm notification delay times.

5. A method of reducing a frequency of alarms, the method comprising:

collecting signals representative of a physiological condition of a patient;

determining a physiological parameter of the patient;

detecting an alarm condition for the physiological parameter;

delaying notification of the alarm condition until the alarm condition persists for a predetermined alarm notification delay time;

providing a notification of the alarm condition responsive to the alarm condition persisting through the alarm notification delay time;

simulating, using measurements obtained from a care unit, different alarm notification delay times to determine whether any of the different alarm notification delay times would have resulted in an alarm notification event, the alarm notification event for each different alarm notification delay time

indicating that an alarm condition persisted for at least that alarm notification delay time; and

providing an indicator of the effect of a change in alarm notification delay time on frequency of alarm notification events; wherein the indicator is indicative of a change in the alarm notification delay time that is effective to reduce the frequency of transient or false alarms and wherein the indicator is configured to be used to program one or more physiological monitoring systems with alarm notification delay times.

Ex. 1001, 75:35–76:9, 76:20–48 (emphases added).

E. Applied References

Petitioner relies upon the following references:

Lynn, U.S. Patent Application Publication No. 2008/0287756 A1, filed May 16, 2008, published Nov. 20, 2008 (Ex. 1010, “Lynn”);

Batchelder et al., U.S. Patent Application Publication No. 2009/0247851 A1, filed Mar. 24, 2009, published Oct. 1, 2009 (Ex. 1011, “Batchelder”);

Wang et al., U.S. Patent Application Publication No. 2009/0326340 A1, filed June 30, 2008, published Dec. 31, 2009 (Ex. 1012, “Wang”); and

A.T. Rheineck-Leyssius and C.J. Kalkman, *Influence of Pulse Oximeter Lower Alarm Limit on the Incidence of Hypoxaemia in the Recovery Room*, 79 British J. of Anaesthesia 460–464 (1997) (Ex. 1013, “Kalkman”).

Pet. 7–8. Petitioner submits the Declaration of George E. Yanulis (Ex. 1003). Patent Owner does not submit declaratory evidence.

F. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–8 of the ’994 patent based on the following grounds. Pet. 8.

Claims Challenged	35 U.S.C. §	References/Basis
1–3, 5–7	103	Lynn, Kalkman

Claims Challenged	35 U.S.C. §	References/Basis
3, 4, 7, 8	103	Lynn, Kalkman, Wang
1–8	103	Wang, Batchelder, Kalkman

II. DISCUSSION

A. Claim Construction

For petitions filed on or after November 13, 2018, a claim shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. 37 C.F.R. § 42.100(b). The Petition was filed June 11, 2020. Thus, we apply the claim construction standard as set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

Only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

Although the record reflects certain disputes regarding the claim language, it is not necessary for us to resolve those disputes in order to determine whether Petitioner has satisfied its burden of demonstrating a reasonable likelihood of prevailing. *See also* Pet. 16–19 (construing the claim terms “alarm condition” and “alarm notification delay time,” but stating that the “Board need not construe these terms because the claims are invalid under either [parties’ proposed] interpretation”); Prelim. Resp. 27–31 (agreeing that “the Board does not need to construe any claim terms for purposes of deciding whether to institute the Petition,” but also arguing that

Petitioner failed to identify corresponding structure for the purported means-plus-function term, “reporting module”). Accordingly, we determine that no claim term requires express construction for purposes of this Decision.

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103 if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of non-obviousness.³ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also “determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of prior art elements would have produced a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

In an *inter partes* review, the petitioner must show with particularity why each challenged claim is unpatentable. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); 37 C.F.R. § 42.104(b). The

³ Patent Owner has not presented objective evidence of non-obviousness.

burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art “would have been a person with at least a B.S. degree in electrical or biomedical engineering or a related field with at least two years’ experience designing patient monitoring systems,” wherein “[l]ess work experience may be compensated by a higher level of education, such as a master’s degree, and vice versa.” Pet. 15 (citing Ex. 1003 ¶¶ 41–43). Patent Owner does not offer a position as to the level of ordinary skill in the art. *See generally* Prelim. Resp.

For purposes of this Decision, we adopt Petitioner’s assessment, which appears consistent with the level of skill reflected in the Specification and asserted prior art.

D. Obviousness over Lynn and Kalkman

Petitioner contends that claims 1–3 and 5–7 of the ’994 patent are unpatentable as obvious over the combined teachings of Lynn and Kalkman. Pet. 29–50. Patent Owner disagrees. Prelim. Resp. 38–48.

1. Overview of Lynn (Ex. 1010)

Lynn is a U.S. Patent Application Publication titled “Pulse Oximetry Relational Alarm System for Early Recognition of Instability and Catastrophic Occurrences.” Ex. 1010, code (54).

Lynn discloses a relational alarm system for detecting patterns in monitored physiological parameters. *Id.* ¶ 30. Lynn’s system includes a

portable bedside monitor that includes a pulse oximeter. *Id.* The system monitors oxygen saturation and pulse rate, and sounds an alarm if either parameter falls below a threshold, e.g., if oxygen saturation falls below 85% or if pulse rate falls below 50 beats per minute. *Id.* ¶ 31. Lynn discloses that the system also monitors for “a relational output suggestive of an adverse event,” which the ’994 describes as occurring when a “primary threshold is not reached but a secondary threshold is reached,” e.g., when, within 45 seconds, the system detects a fall of 5% in oxygen saturation and a concurrent fall of 8 beats per minute in heart rate, where both parameters fell at or about the same time. *Id.* In such a case, the alarm sounds. *Id.*; *see also id.* ¶ 32 (explaining that relational patterns can be customized and providing an example “defined by a fall in oxygen saturation of X (say greater than or equal to 8%) coupled with a rise in respiration rate of Y (say 50% or more) lasting for at least Z (say 5–10 minutes)”).

Lynn also discloses an oximeter testing apparatus with a processor in connection with a dynamic simulator, which interfaces with the probe of an oximeter to be tested. *Id.* ¶¶ 33, 35. The processor is “programmed to simulate the time series of arterial oxygen saturation and one or more additional parameters, which are generated in association with the occurrence of a precipitous apnea or respiratory arrest.” *Id.* ¶ 33. Lynn’s processor begins the simulation of the respiratory arrest and “sets the clock at the onset” of the simulation. *Id.* ¶ 34. When the oximeter detects the respiratory arrest, it outputs an alarm and records the time of alarm occurrence. *Id.* The difference in recorded time between the onset of the simulated respiratory arrest and the onset of the alarm is termed “T-Arrest”

and “is a single number used to provide evidence of the performance of the oximeter as an early warning device.” *Id.* ¶ 35.

2. Overview of *Kalkman* (Ex. 1013)

Kalkman is an article published in the British Journal of Anaesthesia titled “Influence of Pulse Oximeter Lower Alarm Limit on the Incidence of Hypoxaemia in the Recovery Room.” Ex. 1013, 1.

Kalkman describes a study that investigated the effects of two oximeter lower alarm limit (“LAL”) settings—85% oxygen saturation and 90% oxygen saturation—and the effect of introducing a time delay of 0 to 60 seconds between the onset of an alarm condition and the triggering of an alarm, in the 90% LAL group. *Id.* at 1, 2 (delay). The study classified alarms “as either true positive (generated by hypoxaemia) or false positive (generated by artifact).” *Id.* at 2. The study concluded that the incidence of hypoxaemia was greater in the 85% LAL group. *Id.* The study also concluded that “[m]aintaining the LAL at 90% and instituting a 15 s[econd] time delay before triggering the audible alarm is an equally effective approach to reduce the frequency of alarms that might not hamper rapid detection of hypoxaemia.” *Id.* at 4.

3. Analysis

Independent claim 1 recites, *inter alia*, “a reporting module configured to simulate, using measurements obtained from the care unit, different alarm notification delay times to determine whether any of the different alarm notification delay times would have resulted in an alarm notification event” Ex. 1001, 75:52–76:9. Independent claim 5 contains a similar recitation, but in method form and without “a reporting module.” *Id.* at 76:32–48.

Petitioner makes alternate contentions regarding these limitations, to account for different claim constructions of “alarm notification delay time.”

i. Lynn

Pre-Alarm Delays

Petitioner’s first contention applies “to the extent [Patent Owner] contends the simulation of ‘alarm notification delay times’ refers to pre-alarm delays,” i.e., “the amount of time between when a physiological parameter measurement exceeds an alarm threshold before an alarm sounds.”⁴ Pet. 17, 38.

According to Petitioner, Lynn discloses a relational alarm system with both pre-alarm delays and alarm notification delays, and an oximeter testing apparatus that includes a processor in conjunction with a dynamic simulator. *Id.* at 36–37. Petitioner contends that “Lynn teaches the processor ‘may be programmed to simulate the time series of arterial oxygen saturation and one or more additional parameters, which are generated in association with the occurrence of a precipitous apnea or respiratory arrest as from functional residual capacity.’” *Id.* According to Petitioner, “[w]hen the monitor being tested determines the physiological value exceeds the alarm criteria and sounds an alarm,” the simulation records the time of the alarm occurrence. *Id.* Then, the “difference between the time of onset of the simulation of the respiratory arrest and the onset of the alarm occurrence is calculated by the processor and outputted as the ‘TA’ or ‘T-Arrest’ value (given in seconds).”

⁴ As noted in the Claim Construction section, we do not construe “alarm notification delay times.” For sake of argument, we consider Petitioner’s application of the prior art to the claim language under this presumed construction of “alarm notification delay time” in claim 1.

Id. (quoting Ex. 1010 ¶ 34). In light of this teaching, Petitioner contends that an ordinarily skilled artisan “would understand Lynn to teach a processor configured to conduct simulations, using measurements from the care unit, that determine the delay time between the onset of a physiological condition and triggering of the alarm and to provide an indication of such delay (i.e., a ‘TA value’).” *Id.* at 38; *see also id.* at 49 (analysis of claim 5, incorporating analysis of claim 1).

We are not persuaded by Petitioner’s contentions. As an initial matter, the Petition does not identify what structure in Lynn is relied upon as the “reporting module” of claim 1. The Petition fails to specify whether it relies upon Lynn’s “relational alarm system,” Lynn’s “oximeter testing apparatus,” or Lynn’s “processor in conjunction with a ‘dynamic simulator’” to satisfy the recited “reporting module.” Pet. 36–37. Moreover, we disagree with the testimony of Petitioner’s declarant, Dr. Yanulis, that this claim limitation “is broadly *directed to a result* that is taught by the prior art.” Ex. 1003 ¶ 101 (emphasis added).⁵ To the contrary, claim 1 recites a system comprised of structures including “a reporting module.” It is Petitioner’s burden to identify what element of the prior art it contends anticipates or renders obvious this limitation. With respect to its contentions regarding Lynn, Petitioner has failed to do so. *See* Pet. 36–37.⁶

⁵ In this proceeding, Petitioner did not allege that this limitation is written in means-plus-function format, pursuant to 35 U.S.C. § 112 ¶ 6, despite having taken that position in district court. *See* Prelim. Resp. 27–33.

⁶ Our conclusion regarding the “reporting module” applies equally to the “notification delay” alternative. *See infra* § II.D.3.i.Notification Delays.

Moreover, we are not persuaded that Lynn discloses “simulat[ing] . . . different alarm notification delay times” as required by independent claims 1 and 5. Rather than simulating alarm notification delay times, Lynn discloses simulating a respiratory arrest event in order to test the responsiveness of an oximeter. Specifically, Lynn discloses oximeter testing apparatus 10, which includes processor 12 and dynamic simulator 14. Ex. 1010 ¶ 33, Fig. 3.⁷ Lynn explains that the processor is programed to simulate “the occurrence of a precipitous apnea or respiratory arrest,” e.g., to simulate a patient having stopped breathing. *Id.* ¶¶ 33–34. “The processor sets the clock at the onset of the simulated respiratory arrest,” and then identifies the time at which an alarm sounds to indicate that the oximeter detected the simulated respiratory arrest. *Id.* ¶ 34. This difference in time values, i.e., “[t]he time from the onset of a standardized respiratory arrest simulation to the onset of the alarm,” is identified as “T-Arrest” and “is a single number used to provide evidence of the performance of the oximeter as an early warning device.” *Id.* ¶ 35.

Plainly, simulating a respiratory arrest is *not* simulating different alarm notification delay times. *See* Prelim. Resp. 40–43. To be sure, Lynn’s T-Arrest number is calculated after the simulated respiratory arrest, and provides an indication of the time it took the oximeter to recognize the simulated respiratory arrest, i.e., the oximeter’s “delay” in recognizing the simulated respiratory arrest. However, that is not what claims 1 and 5

⁷ In an apparent typographical error, the reference numbers appearing in Figure 3 of Lynn include an additional zero as compared to the reference numbers in the Specification, e.g., Figure 3 identifies the oximeter testing apparatus as “100,” the processor as “120,” and the dynamic simulator as “140.”

require. *See* Ex. 1001, 75:52–76:9, 76:32–48. Similarly, Petitioner’s contention that an ordinarily skilled artisan “would understand Lynn to teach a processor configured to *conduct simulations . . . that determine the delay time*” does not address the pertinent claim language of “*simulat[ing]* different alarm notification delay times.” Pet. 38 (emphasis added); *see also* Ex. 1003 ¶ 103 (testifying that Lynn performs “simulations of alarm criteria . . . to determine the delay time”).

For this reason, we are not persuaded by Petitioner’s contentions.

Notification Delays

Petitioner’s second contention applies “[t]o the extent ‘alarm notification delay times’ is properly construed to mean delaying notification of an active bedside alarm to a remote location” as proposed by Petitioner, i.e., “the elapsed time between alarm condition^[8] and transmission of notification.”⁹ Pet. 18, 38. According to Petitioner, “Lynn teaches that, in an alternative configuration, the simulator can include a transmitter to simulate the delay between onset of the alarm condition and transmission of the alarm notification.” *Id.* Petitioner relies upon the following portion of Lynn’s disclosure:

In some situations, the oximeter under test may also include a transmitter, which transmits the oxygen saturation output back to a central nursing station where the alarm will sound. Since such transmissions also may include averaging intervals or long

⁸ Petitioner argues “‘alarm condition’ is a patient condition that satisfies all alarm criteria resulting in a triggered alert,” e.g., “at the bedside monitor.” Pet. 16.

⁹ Again, for sake of argument, we consider Petitioner’s application of the prior art to the claim language under this presumed construction of “alarm notification delay time” in claim 1.

intervals (20 seconds) between sample transmissions, the effect of this delay can also be determined by this system 100. The system 100 can be used for spot (surprise) checks of the alarm response times in a nursing ward where all of the factors: patient physiologic delay, signal processing delay, transmission delay, alarm output delay, personnel response delay, and the delay associated with the time to reach the bedside (where the nurse inputs the endpoint) are automatically included, providing a true index of the effective hospital response to an actual alarm indicative of a life threatening event.

Id. at 38–39 (quoting Ex. 1010 ¶ 38); *see also id.* at 49 (analysis of claim 5, incorporating analysis of claim 1).

We are not persuaded that this disclosure satisfies the limitations of claims 1 and 5 reciting, “simulat[ing] . . . different alarm notification delay times.” At the cited passage, Lynn explains that *the oximeter* being tested may include a transmitter for conveying measured oxygen saturation levels to a central nursing station, where an alarm will sound after respiratory arrest is detected by the oximeter. Ex. 1010 ¶ 38 (“[T]he oximeter under test may also include a transmitter.”); *see also id.* ¶ 34. No portion of the cited disclosure supports Petitioner’s statement that Lynn’s “*simulator* can include a transmitter to simulate the delay.” *Id.* ¶ 38; Pet. 38 (emphasis added).

Moreover, the passage explains that some delay is innately involved in the detection and transmission of oxygen saturation levels from the patient to the oximeter to the nursing station, including “patient physiologic delay, signal processing delay, transmission delay, alarm output delay, personnel response delay, and the delay associated with the time to reach the bedside.” Ex. 1010 ¶ 38. Neither Petitioner nor Dr. Yanulis explain, however, how these innate delays associated with the capture of physiological parameters, signal processing, transmission, alarm recognition, or personnel response

relate to the claim requirement of *simulating* different alarm notification delay times. Pet. 38–39. Instead, Lynn explains that the system can be used for “spot (surprise) checks of the alarm response times in a nursing ward where all of the[se] factors . . . are automatically included providing a true index of the effective hospital response to an actual alarm indicative of a life threatening event.” Ex. 1010 ¶ 103. Notably, no part of the cited disclosure concerns simulating anything other than respiratory arrest.

For this reason, we are not persuaded by Petitioner’s contentions.

ii. Lynn and Kalkman

Next, Petitioner contends that a person of ordinary skill in the art would have been motivated to modify Lynn in view of Kalkman. According to Petitioner,

To the extent Lynn does not expressly inform a [person of ordinary skill in the art] how to simulate pre-alarm delays and alarm notification delays using measurements from a case unit, or how to use those simulations to “provide an indicator of the effect of a change on the alarm notification delay time on frequency of alarm notification events; wherein the indicator is indicative of a change in the alarm notification delay time that is effective to reduce the frequency of transient or false alarms” and to use the indicator to “program one or more physiological monitoring systems with alarm notification delay times,” a [person of ordinary skill in the art] would have been motivated to modify Lynn . . . in view of Kalkman.

Pet. 39 (citing Ex. 1003 ¶ 104). Again, Petitioner makes different contentions to account for different claim constructions.

Pre-Alarm Delays

Regarding “pre-alarm delays,” Petitioner contends that Kalkman describes a study that “simulate[d] theoretical pre-alarm delays and output[ted] a graph indicating the effect of the theoretical delays on the

number of alarms generated, and in particular, [found] the optimal pre-alarm delay to reduce transient and false alarms.” Pet. 39–40, 42 (introducing an alarm delay “eliminates short-lasting alarms”). According to Petitioner, Kalkman discloses that these simulations were performed using a “PC (i.e., ‘a reporting module’).” *Id.* at 40–41.

In light of these teachings, Petitioner contends that a person of ordinary skill in the art “would have been motivated to implement Kalkman’s simulation method using real patient data to find the optimal ‘Z’ delay period for Lynn.” *Id.* at 42. Petitioner also asserts that such a person “would have been motivated to modify the system of Lynn to use the pre-alarm delay time simulation of Kalkman to achieve the predictable result of optimizing pre-alarm delay times and reducing false and transient alarms that can lead to ‘alarm fatigue’” and “to customize pre-alarm delay times for different care units treating patients in different physiological conditions . . . [which] would have predictably resulted in a system that considers and finds an optimal pre-alarm delay for a particular subset of patients.” *Id.* at 42–44; *see also id.* at 49 (analysis of claim 5, incorporating analysis of claim 1).

We are unpersuaded by Petitioner’s contentions. First, as above, the Petition fails to identify clearly what structure is relied upon as the “reporting module” of claim 1, in the proposed combination of Lynn and Kalkman.¹⁰ Although the Petition refers to Kalkman’s PC as a “reporting module,” *see* Pet. 40–41, Petitioner proposes modifying Lynn’s system to incorporate Kalkman’s simulations of different alarm delay notification times, and does *not* propose modifying Lynn to incorporate Kalkman’s PC.

¹⁰ Our reasoning regarding the “reporting module” applies equally to the “notification delay” alternative. *See infra* § II.D.3.ii.Notification Delays.

Id. at 42–43 (proposing to “modify the system of Lynn to use the pre-alarm delay time simulation of Kalkman”), 43–44 (proposing to “use Kalkman’s simulation”). As such, Petitioner fails to identify a “reporting module,” as recited in claim 1, in the combination of prior art upon which Petitioner relies.

Moreover, we are not persuaded that the combined teachings of Lynn and Kalkman satisfy the limitations of claims 1 and 5 that require simulating different alarm notification delay times. Petitioner contends that Lynn, like Kalkman’s disclosure of simulating pre-alarm delays, “also describes a pulse oximetry monitor that simulates pre-alarm delays and alarm notification delay times.” Pet. 40. As discussed above, however, Lynn simulates respiratory arrest, not alarm notification delay times. Ex. 1010 ¶¶ 33–35. Thus, we agree with Patent Owner that Lynn and Kalkman are directed to different concepts. Prelim. Resp. 45–46.

Moreover, Petitioner provides insufficient reasoning to show that a skilled artisan would have been motivated to modify Lynn’s system to implement Kalkman’s simulation. We agree with Patent Owner that such a modification would render Lynn unsuitable for its intended purpose as an oximeter testing apparatus. Prelim. Resp. 46–47. For example, Petitioner does not explain how Lynn’s system would achieve its intended purpose of testing the responsiveness of an oximeter if the system were modified to simulate pre-alarm delay times instead of respiratory arrest. *See, e.g.*, Pet. 43 (“[A] PHOSITA would have been motivated to modify the system of Lynn to use the pre-alarm delay time simulation of Kalkman to achieve the predictable result of optimizing pre-alarm delay times and reducing false and transient alarms.”). Neither Petitioner nor Dr. Yanulis explain why a person

of ordinary skill in the art would have been motivated to abandon Lynn's intended purpose as an oximeter testing apparatus, *even if* such a combination would have resulted in the optimization of pre-alarm delay times, as Petitioner contends. Pet. 42–44; Ex. 1003 ¶¶ 110–113. Petitioner does not discuss this trade-off in functionality or intended purpose at all.

For these reasons, we are not persuaded by Petitioner's contentions.

Notification Delays

Regarding notification delays, Petitioner contends that, if the phrase “alarm notification delay times” is understood to mean “delaying notification of an active alarm condition to a remote location, a [person of ordinary skill in the art] would have been motivated to [further] modify the teachings of Kalkman to include the simulation of such alarm notification delays,” for similar reasons as discussed above regarding pre-alarm delays.

Pet. 44. According to Petitioner,

In both instances, the PC uses collected data to simulate the length of a delay between two events—the time between when a physiological value crosses a threshold and the time at which an alert sounds (pre-alarm delays), or the time between the activation of a bedside alarm and transmission of the alarm notification to a remote location (alarm notification delays). The implementation would likewise achieve predicable results—namely reducing the number of transient/false alarms and alarm notifications, respectively, to which a clinician must respond. Both pre-alarm delays and alarm notification delays use time to confirm an alarm condition before notifying a clinician (either locally or remotely). Thus, Kalkman's simulation would similarly help find an optimal alarm notification delay time before remotely notifying a clinician of an alarm, by simply further considering whether alarms are locally addressed, as taught by Lynn.

Id. at 44–45 (citations omitted). Petitioner contends that a person of ordinary skill in the art “would have been motivated to modify Lynn’s system to use the same simulation method of Kalkman because Lynn already compiles the data necessary to simulate the effect of alarm notification delays”—e.g., transmission delay and alarm output delay (Ex. 1010 ¶ 38)—“and it would be advantageous to implement custom alarm notification delays because the staffing and physical layout of each care unit are unique.” *Id.* at 45; *see also id.* at 49 (analysis of claim 5, incorporating analysis of claim 1).

Petitioner’s contentions in this regard fail for the same reasons discussed above regarding pre-alarm delays. Petitioner does not present persuasive reasoning to show that a skilled artisan would have found it obvious to modify Lynn’s system to simulate different alarm notification delay times, instead of simulating respiratory arrest, where such a modification would have rendered Lynn unsuitable for its intended purpose as an oximeter testing apparatus.

For these reasons, we are not persuaded by Petitioner’s contentions.

4. Summary

For the foregoing reasons, Petitioner has not shown a reasonable likelihood of prevailing with respect to independent claims 1 or 5. Petitioner’s additional contentions regarding dependent claims 2, 3, 6, and 7 do not cure these deficiencies regarding claims 1 and 5, and fail for the same reasons.

E. Obviousness over Lynn, Kalkman, and Wang

Each of claims 3, 4, 7, and 8 depend from either claim 1 or claim 5. Regarding these claims, Petitioner additionally relies upon Wang. Pet. 51–

52. For the same reasons discussed above, *see supra* § II.D.3, Petitioner has not demonstrated a reasonable likelihood of prevailing with respect to independent claims 1 or 5. Petitioner’s contentions regarding Wang do not cure the deficiencies regarding claims 1 or 5. Accordingly, for the same reasons, Petitioner has not shown a reasonable likelihood of prevailing with respect to claims 3, 4, 7, and 8.

F. Obviousness over Wang, Batchelder, and Kalkman

Petitioner contends that claims 1–8 of the ’994 patent are unpatentable as obvious over the combined teachings of Wang, Batchelder, and Kalkman. Pet. 52–75. Patent Owner disagrees. Prelim. Resp. 36–37, 49–64.

1. Overview of Wang (Ex. 1012)

Wang is a U.S. Patent Application Publication titled “Patient Monitor Alarm System and Method.” Ex. 1012, code (54).

Wang discloses a patient monitoring alarm escalation system that generates alarms related to various monitored patient conditions. *Id.* ¶ 13, Fig. 1. Wang explains that “[w]hen alarm conditions are detected, the system 10 may emit alarm signals from any one of the monitors 12, the central management system 16, and/or the alarm paging system [18]. Further, if the alarm is not acknowledged, the monitoring system 10 may escalate the alarm.” *Id.* ¶ 15. As an example, Wang explains that upon detecting an alarm condition the system will generate a primary alarm at the patient bedside monitor and at the central management station. *Id.* If that alarm is not acknowledged within a predefined amount of time, the system will send a second alarm to a wireless device of the caregiver. *Id.* Additionally, Wang explains that if “the second alarm remains unacknowledged for a predefined amount of time (e.g., half of the time

allotted to acknowledge the primary alarm), a third alarm may be sent to an additional wireless device . . . and so forth.” *Id.*; *see also id.* at Fig. 4.

Wang discloses a pulse oximeter as an example of a patient monitor. *Id.* ¶ 16, Fig. 2. Wang’s pulse oximeter provides alarms when monitored parameters cross certain thresholds, which “may be designated by set points or by designating patterns of values (e.g., patterns in an SpO₂ trend) or limits that can be entered via adjustment buttons.” *Id.* ¶ 22. Wang also discloses that, “in some embodiments, the alarm system employs SatSeconds by Nellcor Puritan Bennett, incorporated, to detect alarms and manage nuisance alarms. SatSeconds may include alarming based on an integral of time and depth of a desaturation event.” *Id.*

2. Overview of Batchelder (Ex. 1011)

Batchelder is a U.S. Patent Application Publication titled “Graphical User Interface for Alarm Management.” Ex. 1011, code (54).

Batchelder describes an alarm integration method that reduces nuisance alarms on patient monitors. *Id.* ¶ 15. “An exemplary alarm management system may be the SatSeconds™ alarm management technology.” *Id.* Batchelder’s Figure 1 is reproduced below.

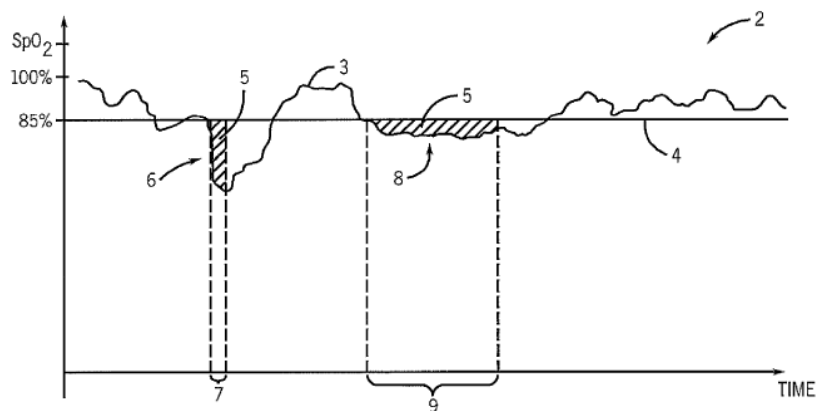
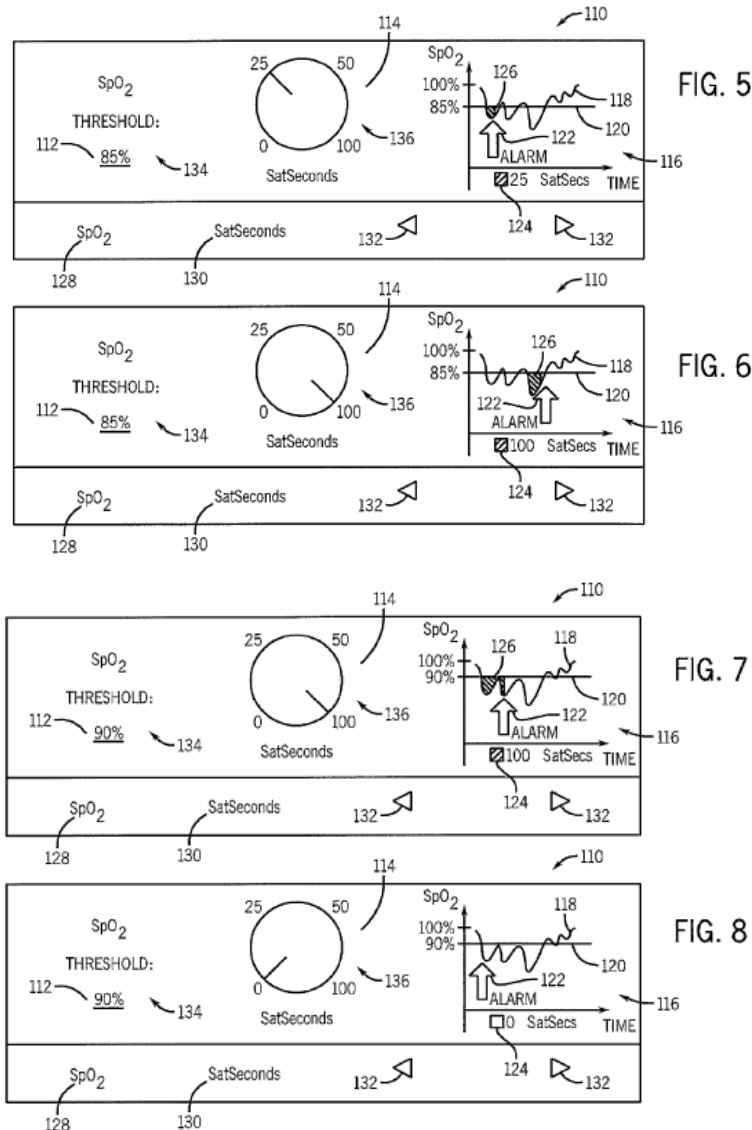


Figure 1 “is a graph illustrating a patient’s measured SpO₂ versus time.” *Id.* ¶ 9. Line 4 represents a threshold SpO₂ value. *Id.* ¶ 15. “Rather than sounding an alarm as soon as the patient’s measured SpO₂ (plot 3) drops below the threshold value (line 4), the SatSeconds system measures [] area 5 (shaded in FIG. 1) by integrating the difference between [] plot 3 and [] line 4 when [] plot 3 is below [] line 4.” *Id.* “[S]ignificant desaturation event 6 (e.g., a large drop in SpO₂) may cause the alarm to activate quickly because the SatSeconds threshold value may be exceeded in [] short period of time 7.” *Id.* “In contrast, [] minor desaturation event 8 . . . may not cause the alarm to be activated quickly. That is, [] minor desaturation event 8 may continue for [] relatively long period of time 9 before the SatSeconds threshold value is exceeded.” *Id.*

Batchelder explains that, “[b]ecause the SatSeconds technology is relatively new in the medical field, it may be desirable to assist the caregiver in efficiently determining the desired SatSeconds threshold value. Accordingly, a patient monitoring system in accordance with embodiments of the present disclosure may include one or more user interfaces which enable the caregiver to change the SatSeconds threshold value and/or the SpO₂ threshold value.” *Id.* ¶ 16. Batchelder describes a monitor device including a display, a speaker, and user inputs. *See id.* ¶ 24. The user inputs enable the caregiver to change the SpO₂ and SatSeconds threshold values. *Id.* ¶¶ 25, 26. “For example, [] SpO₂ thresholds 112 may be adjusted in increments of 1% while [] SatSeconds thresholds 114 may be adjusted in increments of 25. A number of discreet values may be available for [] thresholds 112 and 114, or the value adjustment may be continuous.” *Id.* ¶ 28.

Figures 5–8, reproduced below, illustrate how changes in SpO₂ and SatSeconds thresholds effect the alarm settings.



Figures 5–8 illustrate a graphical user interface of a pulse oximeter. *Id.* ¶ 12. These figures depict, e.g., a change in SatSeconds threshold 114 from 25 (see Fig. 5) to 100 (see Figs. 6–7).¹¹ *Id.* ¶ 30. Likewise, the figures depicts

¹¹ Batchelder’s description of these figures in paragraphs 30–32 appears to incorrectly describe the content of the figures. *Compare, e.g.,* Ex. 1011 ¶ 30 (describing Figure 5 as showing an increased SatSeconds threshold 114 of

a change in SpO₂ threshold 112 from 85% (*see* Figs. 5–6) to 90% (*see* Fig. 7–8). *Id.* ¶ 31. The figures depict changes in alarm indicator 122 and shaded area 126 as SatSeconds threshold 114 and SpO₂ threshold change. For example, SatSeconds threshold 114 is reached earlier in Figure 7 than in Figure 6, thereby activating the alarm earlier, as the SpO₂ threshold increases from 85% to 90%. *Id.* ¶ 31. Additionally, in Figure 8, SatSeconds threshold 114 is set to 0, so that “the alarm will be activated as soon as [] SpO₂ plot 118 falls below [] threshold line 120 as indicated at 122.” *Id.* ¶ 32.

3. Analysis

Again, we focus on the language of independent claim 1 that recites “a reporting module configured to simulate, using measurements obtained from the care unit, different alarm notification delay times . . .” (Ex. 1001, 75:52–76:9) and the similar method claim recitation of independent claim 5 (*id.* at 76:32–48 (but lacking a “a reporting module”)).

Petitioner again makes alternate contentions to account for different claim constructions of “alarm notification delay time.”

Pre-Alarm Delays

Petitioner’s first contention applies to the construction of “alarm notification delay times” as referring to “pre-alarm delays,” i.e., “the amount

100), *with id.* Fig. 5 (depicting a SatSeconds threshold 114 of 25). Our description reflects the content of the figures as depicted.

of time between when a physiological parameter measurement exceeds an alarm threshold before an alarm sounds.”¹² Pet. 17, 62–68.

According to Petitioner “Wang teaches the use of SatSeconds (time + severity) for implementing pre-alarm delays, and Batchelder teaches that a medical monitor’s user interface assists in setting an optimal alarm delay by simulating different threshold values on data received by the medical monitor.” Pet. 62. Petitioner contends that Batchelder teaches that a clinician can change the pre-alarm delay by varying either the oxygen saturation threshold or the SatSeconds threshold, and can thereby optimize the pre-alarm delay time through simulations that determine “how the changes in thresholds affected the plotted data . . . [,] whether alarms would have triggered[,], and the amount of pre-alarm delay in the plotted data.” *Id.* at 62–64. “Thus, Batchelder’s monitor 14 simulates, using measurements obtained from the monitor, different pre-alarm delay times (e.g., through changes to the SatSeconds and SpO₂ thresholds) to determine whether any of the different pre-alarm delay times would have resulted in an alarm notification event.” *Id.* at 64.

Petitioner further relies upon Kalkman as teaching simulations across a care unit. *Id.* at 64–67. According to Petitioner, “Wang/Batchelder in view of Kalkman provides the motivation to simulate different SatSeconds thresholds, and thereby different alarm delays, across an entire care unit,” wherein this combination “applies a known technique (simulating across a care unit) to a known device (Wang/Batchelder’s monitor 14) ready for

¹² Again, for sake of argument, we consider Petitioner’s application of the prior art to the claim language under this presumed construction of “alarm notification delay time” in claim 1.

improvement to yield predictable results,” such as “finding . . . an optimal integral threshold setting for a care unit, which could be used as a default value programmed into the monitor’s processor, while still allowing for further adjustment at the individual level, as taught by Batchelder.” *Id.* at 66; *see also id.* at 73 (analysis of claim 5, incorporating analysis of claim 1).

We are unpersuaded by Petitioner’s contentions. First, as above, Petitioner has not identified what prior art structure is relied upon as the “reporting module” of claim 1.¹³ In this Ground, Petitioner mentions “reporting module” once, in reference to Kalkman’s PC. Pet. 65 (“Database software running on processors in a PC (i.e., a ‘reporting module’).”). As Patent Owner notes, however, Petitioner does not propose incorporating Kalkman’s PC into the combined Wang/Batchelder system. Pet. 64 (“Kalkman provides the motivation to further simulate data across a care unit.”), 66 (“Wang/Batchelder in view of Kalkman provides the motivation to simulate different SatSeconds thresholds, and thereby different alarm delays, across an entire care unit.”); Prelim. Resp. 49–50; *cf. supra* § II.D.3.ii.Pre-Alarm Delays. Thus, Petitioner fails to identify a “reporting module,” as recited in claim 1, in the combination of prior art upon which Petitioner relies.

Additionally, Petitioner does not contend that Wang discloses the claim limitations of “simulat[ing] different alarm notification delay times.” Pet. 62–64. Even accepting Petitioner’s contention that Batchelder discloses such simulations, Petitioner has not shown that a skilled artisan would have been motivated to incorporate those simulations into Wang. Specifically,

¹³ Our reasoning regarding the “reporting module” applies equally to the “notification delay” alternative. *See infra* § II.F.3.Notification Delays.

Petitioner acknowledges that it is Batchelder's monitor and user interface that perform the simulations. *Id.* at 64 (“Batchelder’s monitor 14 simulates, using measurements obtained from the monitor, different pre-alarm delay times.”). However, Petitioner does not propose modifying Wang to incorporate Batchelder’s monitor and user interface, or the simulations it performs. *See, e.g., id.* at 54 (“Combining Wang and Batchelder does not modify the teachings of Wang.”).

To the contrary, Petitioner explains that both Wang and Batchelder disclose use of the same SatSeconds technology, “which causes ‘alarming based on an integral of time and depth of a desaturation event.’” *Id.* at 53–54 (quoting Ex. 1012 ¶ 22) (also noting that both Wang and Batchelder use “‘SatSeconds’ technology sold by ‘Nellcor Puritan Bennett’”) (citing Ex. 1011 ¶ 15; Ex. 1012 ¶ 22). According to Petitioner,

Batchelder merely represents common knowledge in the art or well-known prior art techniques. Combining Wang and Batchelder *does not modify the teachings of Wang*, but rather expressly states features Wang infers (i.e., a detailed description of “SatSeconds” commercial technology) because they were unnecessary to enable his invention. The combination of Wang and Batchelder is proper because *Batchelder expressly discloses that which Wang implicitly teaches—a caregiver may use SatSeconds technology to implement various pre-alarm delay[] periods* based on the severity of a parameter measurement or the value of a SatSeconds integration threshold, which in turn reduces false or transient alarms.

Id. at 54–55 (citing Ex. 1003 ¶ 139 (substantially identical)) (emphasis added). Thus, Petitioner’s proposed modification of Wang incorporates Batchelder’s express disclosure of “us[ing] SatSeconds technology to *implement various pre-alarm delay[] periods*,” but does not incorporate Batchelder’s disclosure of simulating different alarm notification delay

times. Ex. 1011 ¶ 16 (“Because the SatSeconds technology is relatively new in the medical field, it may be desirable to assist the caregiver in efficiently determining the desired SatSeconds threshold value. Accordingly, a patient monitoring system in accordance with embodiments of the present disclosure may include one or more user interfaces which enable the caregiver to change the SatSeconds threshold value and/or the SpO₂ threshold value.”); *see also* Prelim. Resp. 36–37.

For these reasons, we are not persuaded by Petitioner’s contentions.

Notification Delays

Petitioner’s second contention applies to the construction of “alarm notification delay times” as referring to “delaying notification of an active bedside alarm to a remote location” as proposed by Petitioner, i.e., “the elapsed time between alarm condition and transmission of notification.”¹⁴ Pet. 18, 67–70.

Petitioner relies on Wang’s alarm escalation method in which Wang’s system delays transmission of an alarm notification to, e.g., a central nursing station or clinician. *See id.* at 55, 68; Ex. 1012 ¶¶ 26–27. According to Petitioner, an ordinarily skilled artisan “would have been motivated to modify the system taught in Wang/Batchelder to simulate theoretical alarm notification delays using the same simulation method taught in Kalkman and based on the alarm history data collected by the monitoring system of Wang.” Pet. 69 (citing Ex. 1003 ¶ 161). Petitioner contends this further modification would have “reduc[ed] the number of alarms generally and . . .

¹⁴ Again, for sake of argument, we consider Petitioner’s application of the prior art to the claim language under this presumed construction of “alarm notification delay time” in claim 1.

decrease[d] the number of nuisance or false alarms.” *Id.* Additionally, Petitioner contends that simulating notification delay times is a safe option. *Id.* at 69–70; *see also id.* at 73 (analysis of claim 5, incorporating analysis of claim 1).

Petitioner’s contentions in this regard fail for the same reasons discussed above. Namely, Petitioner’s contentions turn on the premise that the combined Wang/Batchelder system simulates pre-alarm delays and that it would have been obvious to modify that system to simulate notification delays in the same manner. Pet. 68–69. However, as discussed above regarding pre-alarm delays, Petitioner has not established that “the system taught in Wang/Batchelder” simulates *anything* because Petitioner has not shown that a person of ordinary skill in the art would have been motivated to incorporate Batchelder’s simulations, or Batchelder’s monitor and user interface (which conduct the simulations), with Wang’s system. Therefore, Petitioner has not demonstrated persuasively that a person of ordinary skill in the art would have been motivated to modify this system to “simulate theoretical alarm notification delays.” *Id.* at 69. For example, Petitioner fails to explain how Wang’s system (modified by Batchelder to include its express SatSeconds disclosures, but no simulations) would have been modified to conduct simulations of notification delay times. *Id.* at 68–70.

4. Summary

For the foregoing reasons, Petitioner has not shown a reasonable likelihood of prevailing with respect to independent claims 1 or 5. Petitioner’s additional contentions regarding dependent claims 2–4 and 6–8 do not cure these deficiencies regarding claims 1 and 5, and fail for the same reasons.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not demonstrated a reasonable likelihood it would prevail in establishing the unpatentability of any challenged claim of the '994 patent. Accordingly, we deny institution of an *inter partes* review.

IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that the Petition is *denied* as to all challenged claims, and no trial is instituted.

PETITIONER:

Rudolph A. Telscher, Jr.
Daisy Manning
Nathan P. Sportel
HUSCH BLACKWELL LLP
PTAB-RTelscher@huschblackwell.com
PTAB-DManning@huschblackwell.com
Nathan.Sportel@huschblackwell.com

PATENT OWNER:

Benjamin A. Katzenellenbogen
Irfan A. Lateef
Brian C. Claassen
KNOBBE, MARTENS, OLSON, & BEAR, LLP
2bak@knobbe.com
2ial@knobbe.com
2bcc@knobbe.com