

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SOTERA WIRELESS, INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

IPR2020-01078
Patent RE47,218 E

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

HOSKINS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

Sotera Wireless, Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”) pursuant to 35 U.S.C. §§ 311–319 to institute an *inter partes* review of all claims 1–10 and 12–18 of U.S. Patent No. RE47,218 E (Ex. 1001, “the ’218 patent”). Masimo Corporation (“Patent Owner”) opposes the Petition. We instituted the petitioned review (Paper 12, “Institution Decision” or “Inst. Dec.”).

Patent Owner filed a Patent Owner Response (Paper 23, “PO Resp.”) to the Petition. Petitioner filed a Reply (Paper 25, “Pet. Reply”) to the Patent Owner Response. Patent Owner filed a Sur-reply (Paper 27, “Sur-reply”) to the Reply. An oral hearing was held, for which the transcript was entered into the record (Paper 34, “Tr.”).

We have jurisdiction under 35 U.S.C. § 6(b)(4) and § 318(a). This Decision is a final written decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the patentability of claims 1–10 and 12–18 of the ’218 patent. We determine Petitioner has shown by a preponderance of the evidence that claims 1–10 and 12–18 are unpatentable.

II. BACKGROUND

A. *Real Parties-in-Interest and Related Proceedings*

Sotera Wireless, Inc. and Hon Hai Precision Industry Co., Ltd. are the real parties-in-interest for Petitioner, and Masimo Corporation is the real party-in-interest for Patent Owner. Pet. 1; Paper 5, 1. *Masimo Corp. v. Sotera Wireless, Inc. and Hon Hai Precision Industry Co. Ltd.*, Civil Action No. 3:19-cv-01100-BAS-NLS (S.D. Cal.) is a related judicial proceeding. Pet. 2; Paper 5, 1.

B. The '218 Patent

The '218 patent concerns a system for monitoring a patient's blood oxygen saturation (SpO_2), and generating an alarm if the saturation falls too low. *See* Ex. 1001, code (57), 1:34–39, 2:54–58. The system includes an optical sensor attached to the patient's finger, to emit light into the fingertip tissue and detect light that is attenuated by blood flow within the fingertip, to provide a numerical readout of oxygen saturation. *See id.* at 1:39–55.

Figure 1 of the '218 patent is reproduced here:

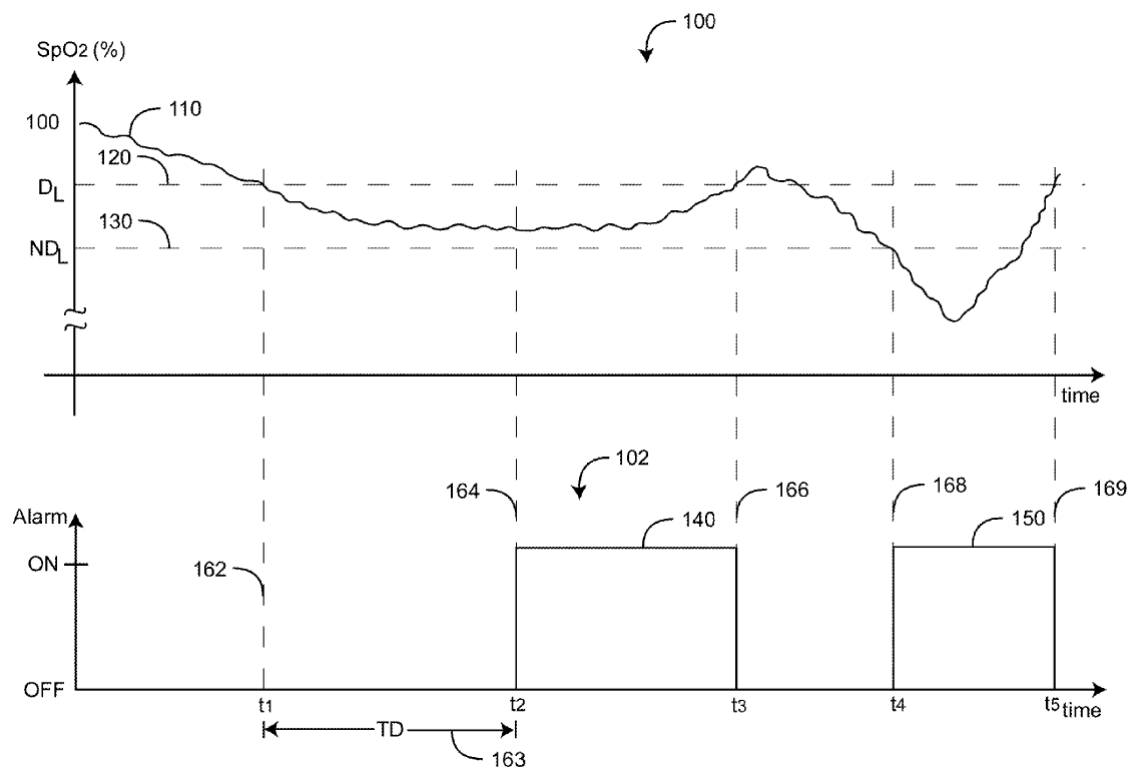


Figure 1 illustrates a prior art oxygen saturation measurement system having two “lower-limit, *fixed-threshold* alarm” schemes, at “delay” alarm threshold D_L and at “no delay” alarm threshold ND_L . *Id.* at 2:54–59 (emphasis added). If the patient's measured oxygen saturation 110 falls and stays below delay threshold D_L for a time period greater than time delay TD ,

as shown in Figure 1 from time t_1 to time t_2 , then delayed alarm 140 is triggered. *Id.* at 2:59–3:2. If the patient’s measured oxygen saturation 110 falls below no delay threshold ND_L , as shown in Figure 1 at time t_4 , then alarm 150 is triggered immediately, without delay. *Id.* at 2:61–62, 3:2–4.

According to the ’218 patent, the fixed nature of delay alarm threshold D_L undesirably leads to “a baseline drift problem,” which can generate a “nuisance” or “false” alarm. *Id.* at 2:54–56, 3:24–46 (Fig. 3). The ’218 patent therefore proposes “an adaptive alarm system,” which adjusts the delay alarm threshold downwards when an oxygen saturation baseline is established at lower values. *Id.* at 3:59–62. In this way, the inventive “alarm threshold . . . adapts to baseline drift in [oxygen saturation] and reduce[s] false alarms without a corresponding increase in missed true alarms.” *Id.* at 4:4–8.

This is illustrated in Figure 6 of the ’218 patent, reproduced here:

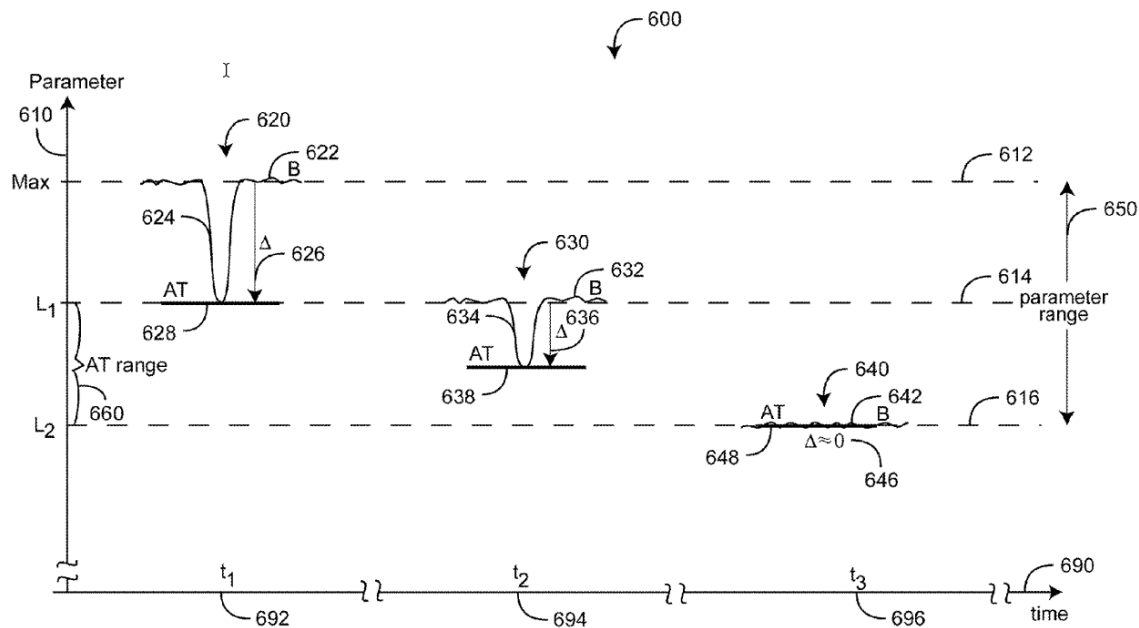


Figure 6 graphs a measured physiological parameter such as oxygen saturation (the vertical axis) over time (the horizontal axis), as generated by an alarm system having a lower limit adaptive alarm threshold AT. *Id.* at 5:34–36, 7:40–47. An adaptive alarm threshold AT is applied whenever the measured oxygen saturation falls within range 650, extending from lower limit L_2 up to maximum value Max, such as illustrated at segments 620, 630, and 640. *Id.* at 6:15–30, 7:9–67, Fig. 5B (horizontal axis values extend from L_2 to Max). The adaptive thresholds AT are constrained to lie within range 660, extending from lower limit L_2 up to limit L_1 . *Id.* at 6:15–30, 7:9–67, Fig. 5A (adaptive threshold AT line 442 is constrained between limits L_2 and L_1 along vertical axis).

In a preferred embodiment, lower limit L_2 corresponds to the value of the no delay alarm threshold ND_L of the prior art system shown in Figure 1, and limit L_1 corresponds to the value of the delay alarm threshold D_L of the prior art system. *Id.* at 5:66–6:4, 6:20–34. The fixed alarm threshold that the prior art implements at limit L_1 is replaced by adaptive alarm thresholds AT. *Id.* at 6:22–34. Each threshold AT, during a given time period such as t_1 , t_2 , or t_3 , may advantageously be implemented as a time delay alarm, as the prior art system does with its fixed delay alarm threshold D_L . *Id.* at 6:38–43.

The system determines a baseline B of the patient's oxygen saturation during different time periods t_1 , t_2 , and t_3 . *Id.* at 6:11–15, 6:44–7:8. For each different baseline B, the system applies a different adaptive alarm threshold AT. *Id.* at 6:15–19. Specifically, the system calculates delta Δ as a function of: the varying baseline B; pre-set limits L_1 and L_2 ; and maximum

value Max. *Id.* at 6:15–34 (Fig. 4A), 7:9–39 (Fig. 5B). The adaptive alarm threshold is set $AT = B - \Delta$. *Id.* at 7:27–39 (Fig. 5A), 7:53–8:6 (Fig. 6).

C. The Claims of the '218 Patent

The '218 patent lists seventeen claims, numbered 1–10 and 12–18. Ex. 1001, 1:4–9, 13:62–16:62. As a reissue patent, the claim listing in the '218 patent uses brackets to identify verbiage removed during the reissue process, and uses italics to identify verbiage added during the reissue process. *Id.* Due to the extent and nature of these reissue amendments, it is difficult to ascertain the scope of the claimed invention by simply reviewing the claim listing in the '218 patent, particularly in the three independent claims 1, 8, and 12. *Id.* at 13:62–16:62.

Accordingly, we reproduce claim 1 here, removing the bracketed verbiage and not italicizing the added verbiage, to ease readability. We also include Petitioner's labeling scheme 1(a)–1(i). *See* Pet. vii–viii.

[1(a)] 1. A system for reducing electronic alarms in a medical patient monitoring system, the system comprising:

[1(b)] an optical sensor configured to transmit optical radiation into a tissue site of a patient and detect attenuated optical radiation indicative of at least one physiological parameter of a patient; and

[1(c)] one or more hardware processors in electronic communication with the optical sensor, the one or more hardware processors configured to:

[1(d)] determine oxygen saturation values of the patient over a first period of time;

[1(e)] when at least one oxygen saturation value obtained over the first period of time exceeds a first alarm threshold, determine whether a first alarm should be triggered;

[1(f)] access a second alarm threshold to be applied during a second period of time subsequent to the first period of time, the second alarm threshold replacing the first alarm threshold,

[1(g)] wherein the second alarm threshold has a value less than the at least one oxygen saturation value and greater than a lower limit and at an offset from the at least one oxygen saturation value, wherein the offset is diminished as a difference between the at least first oxygen saturation value and the lower limit diminishes;

[1(h)] determine oxygen saturation values of the patient over the second period of time; and

[1(i)] trigger a second alarm based on at least one value of the oxygen saturation values obtained over the second period of time exceeding the second alarm threshold.

Ex. 1001, 13:62–14:40. Claim 12 recites a method comprising steps analogous to limitations 1(d)–1(i). *See id.* at 15:52–16:32.

Claim 8 is a system claim somewhat akin to claim 1. *See id.* at 15:1–39. Claim 8 differs from claim 1 most significantly in reciting that the processor is configured to “apply a time delay based on the second alarm threshold, wherein the time delay approaches zero as the at least one oxygen saturation value obtained over the first period of time approaches the lower limit.” *Id.* at 15:19–23.

D. Prior Art and Asserted Grounds

Petitioner asserts claims 1–10 and 12–18 are unpatentable, based on the following two grounds. *See Pet.* 5–6.

Claims Challenged	35 U.S.C. §	References
1–4, 7, 12–15	103	Bock ¹ , Kiani ²
5, 6, 8–10, 16–18	103	Bock, Woehrle ³ , Kiani

E. Testimonial Evidence

Petitioner relies on the testimony of George E. Yanulis, D. Eng. (Exhibit 1003) and Bryan Bergeron, M.D. (Exhibit 1040). Patent Owner relies on the testimony of Jack Goldberg (Exhibit 2011).

III. ANALYSIS

A. Statement of Law

Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter 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

¹ Ex. 1005, U.S. Patent No. 7,079,035 B2, issued July 18, 2006.

² Ex. 1006, U.S. Patent No. 6,597,933 B2, issued July 22, 2003.

³ Ex. 1007, WO 2009/093159 A1, published July 30, 2009.

(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 ordinary skill in the art; and (4) objective evidence of nonobviousness, if made available in the record (which has not occurred here). *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

*B. Level of Ordinary Skill in the Art, and
Patent Owner’s Related Challenge to Dr. Yanulis’s Testimony*

1. Level of Ordinary Skill in the Art

Petitioner contends a person having ordinary skill in the art pertaining to the ’218 patent (“POSITA”) “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.” Pet. 9–10 (citing Ex. 1003 ¶¶ 33–40). Also: “Less work experience may be compensated by a higher level of education, such as a master’s degree, and vice versa.” *Id.*

Patent Owner “does not dispute Petitioner’s characterization of the level of ordinary skill in the art,” which Patent Owner describes as “[r]elatively [l]ow.” PO Resp. 12; Ex. 2011 ¶¶ 18–19.

We conclude the parties’ agreed-upon level of ordinary skill is consistent with the ’218 patent and the asserted prior art. We, therefore, apply it here.

2. Patent Owner’s Related Challenge to Dr. Yanulis’s Testimony

Patent Owner urges us to reject Dr. Yanulis’s testimony on behalf of Petitioner concerning what a POSITA would have understood the prior art to

disclose, and what a POSITA would have been motivated to do. *See* PO Resp. 12–14. Patent Owner asserts Dr. Yanulis “admitted during his deposition that he applied the wrong legal standard” because he “based his opinions on how he personally interpreted the references, rather than what a [POSITA] would have understood.” *Id.* at 12–13 (citing Ex. 2014, 55:11–18, 57:2–6, 136:8–9). Patent Owner explains: “This is problematic because Petitioner asserts that Dr. Yanulis is an expert whose understanding exceeds that of the ordinarily skilled artisan,” so his testimony as to obviousness is based on “*extraordinary* skill and experience in the art” and is therefore “irrelevant.” *Id.* at 13–14 (emphasis by Patent Owner) (citing 35 U.S.C. § 103; *KSR*, 550 U.S. at 420 (“The question is . . . whether the combination was obvious to a person with ordinary skill in the art.”)).

Petitioner replies that Dr. Yanulis applied the correct legal standard, because “he viewed the prior art and the [’218] patent from the perspective of a [POSITA].” Pet. Reply 1–2 (citing Ex. 1003 ¶ 33). Petitioner asserts it is not unusual for an expert witness such as Dr. Yanulis to have “credentials additional to those of a [POSITA].” *Id.* (citing Ex. 1003 ¶¶ 4–12). Petitioner does not discuss Dr. Yanulis’s deposition testimony.

Dr. Yanulis’s declaration states he has “knowledge relevant to what a person having ordinary skill in the art at the time of the invention would understand and do,” with the time of invention being “the priority date of the [’218] patent” in 2010. Ex. 1003 ¶ 33. His declaration also states that in 2010 Dr. Yanulis “had 27 years of experience in this field and was a person having ordinary skill in the art.” *Id.* Further, Dr. Yanulis concludes he is “able to read and understand the claims and specifications of the prior art and the [’218] patent in the light that a [POSITA] would read and understand

them,” and sets forth the POSITA level we have adopted above. *Id.*

¶¶ 33–34. Thus, we agree with Petitioner that Dr. Yanulis’s declaration indicates he applied the correct legal standard for obviousness, by testifying as to what a POSITA would have known and done in 2010, rather than what Dr. Yanulis personally would have known and done in 2010.

In the deposition testimony cited by Patent Owner, Dr. Yanulis was asked “I think you mentioned in your declaration or elsewhere *you have had several decades of experience in this field*. Is that right?” Ex. 2014, 55:11–16 (emphasis added). He responded: “I think that would be safe to say. Probably more close to 40 years, counselor.” *Id.* at 55:17–18.

This testimony merely reflects Dr. Yanulis’s personal experience as relevant to the ’218 patent, which qualifies him to testify concerning what a POSITA would have known and done in 2010. Dr. Yanulis did not state that his patentability opinions are premised on what he personally would have known and done in 2010, rather than what a POSITA would have known and done in 2010. *See id.* at 55:11–18.

Dr. Yanulis was later asked: “Would a person of ordinary skill in the art have *several decades of experience* as of the priority date of [the ’218] patent?” *Id.* at 56:12–14 (emphasis added). He answered: “Not necessarily,” and further alluded to the POSITA description in his declaration, which he recalled as being “at least a BS in biomedical engineering or electrical engineering, and preferably a Master’s in either; as well as at least two years of design experience and working with these devices.” *Id.* at 56:15–57:1. He then added: “I wouldn’t expect a normal [POSITA] to have that many years to completely understand what’s disclosed, not only in the Bock patent, but in the prior art[.]” *Id.* at 57:2–6.

We disagree with Patent Owner’s characterization of this testimony as establishing that Dr. Yanulis’s patentability opinions are premised on what he personally would have known and done in 2010. Instead, Dr. Yanulis acknowledged that he personally had decades of experience in the pertinent field, and then testified that such extensive experience (which is not required for a POSITA) is *not needed to understand* Bock and the other prior art at issue in this proceeding. *See id.* at 56:12–57:6. Thus, as with Dr. Yanulis’s declaration, his deposition testimony was that he applied the correct legal standard for obviousness, by testifying as to what a POSITA would have known and done in 2010. This is confirmed by his later deposition testimony: “I was referring to *what I would expect a [POSITA] should know* reviewing this challenge[d] patent and the prior art,” and “I was just reviewing based on my definition of a [POSITA]” even though “I think it’s very fair to say I have more expertise than the typical [POSITA].” *Id.* at 136:2–9 (emphases added).

Thus, after reviewing the entirety of Dr. Yanulis’s testimony cited by the parties in this proceeding, we determine he applied the correct legal standard for obviousness, by opining as to what a POSITA would have known and done in 2010.

C. Claim Construction

We interpret the ’218 patent claims “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).” 37 C.F.R. § 42.100(b). This “includ[es] 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.” *Id.*

We construe two aspects of claim 1, and then briefly address similar limitations in claims 8 and 12.

1. *Claim 1:*
“at least one oxygen saturation value,”
“the at least one oxygen saturation value,” and
“the at least first oxygen saturation value”

Claim 1 recites, in limitation 1(e), “at least one oxygen saturation value obtained over the first period of time,” wherein the value “exceeds a first alarm threshold.” Ex. 1001, 14:6–8 (italicized emphasis added). Limitation 1(g) adds “the second alarm threshold has a value less than the at least one oxygen saturation value and greater than a lower limit and at an offset from the at least one oxygen saturation value, wherein the offset is diminished as a difference between the at least first oxygen saturation value and the lower limit diminishes.” *Id.* at 14:16–30 (italicized and underlined emphases added).

In the Institution Decision, we preliminarily construed these limitations *sua sponte*. See Inst. Dec. 18–23. We also “encourage[d] both parties to state in their post-institution briefs whether they agree with [our] preliminary claim construction, and to discuss the reason(s) and support for any disagreement.” *Id.* at 23. Patent Owner accepted this invitation. See PO Resp. 29–30. Petitioner declined the invitation, until we sought clarification during the oral hearing. See Pet. Reply 10; Tr. 11:13–14:18. We now revisit our preliminary construction of these limitations, based on a full record.

First, focusing on limitation 1(g), we preliminarily concluded “the two recitations of ‘the at least one oxygen saturation value,’ and the sole recitation of ‘the at least first oxygen saturation value,’ all refer to the same value as each other.” Inst. Dec. 21. Patent Owner agrees with this preliminary construction. See PO Resp. 30. Petitioner has not taken a position as to this preliminary construction. See, e.g., Pet. Reply 10. We, therefore, discern no reason to deviate from this preliminary construction, and we continue to maintain it here. See Inst. Dec. 21 (lines 4–18).

Second, considering the inter-relationship between limitations 1(e) and 1(g), we preliminarily concluded that “the ‘one’ value in limitation 1(e) [refers] to *patient data generated by a sensor* (such as parameter segments 620, 630, and 640 in Figure 6 of the ’218 patent),” whereas “the ‘one’ or ‘first’ value in limitation 1(g) [refers] to *a value derived from the patient data* (such as baselines B in Figure 6).” Inst. Dec. 23 (emphases added); see also *id.* at 19–23 (analysis in support of preliminary construction). Patent Owner disagrees, and contends the oxygen saturation values recited in limitation 1(g) each “*refer back to*” the “*same*” oxygen saturation value in limitation 1(e). PO Resp. 30 (emphasis added). This value is patient data generated by a sensor, “not . . . a value derived from the measured parameter values.” *Id.*

During the oral hearing, Petitioner’s counsel agreed with Patent Owner’s construction of the inter-relationship between limitations 1(e) and 1(g). See Tr. 8:15–9:5, 11:13–14:18. Petitioner’s counsel stated: “I believe that our consistent position is that *the value that’s being measured from the patient at any given moment, that that is the oxygen saturation value that we’re looking at*” in both limitations. *Id.* at 12:23–13:1

(emphases added). Thus, Petitioner’s position is that all of the oxygen saturation values recited in limitations 1(e) and 1(g) refer to “measured patient value[s],” not to other values derived from measured patient values. *Id.* at 13:6–14:18. Patent Owner’s counsel confirmed Petitioner’s description of claim 1 during the oral hearing is the same as Patent Owner’s construction of claim 1. *See id.* at 31:20–32:17 (stating Patent Owner “argue[s] . . . that all of the references to the value or the first value is referring to the same thing, and so to the extent that that’s now what [Petitioner] is arguing, then I guess we would agree with that”).

Upon review of the foregoing, and based on the agreement of the parties in this regard, we construe all of the oxygen saturation values recited in limitations 1(e) and 1(g) to refer to the same value. That is, they each refer to patient data generated by a sensor, such as parameter segments 620, 630, and 640 in Figure 6 of the ’218 patent. The at least one value recited in limitation 1(e) is obtained over a first period of time such as segment 620 over time t_1 . The at least one value recited in limitation 1(g) is obtained over a second period of time, following the first period of time, such as segment 630 over time t_2 . We do not construe the oxygen saturation values recited in limitation 1(g) to refer to a value derived from the patient data, such as baselines B.

2. *Claim 1:*

“one or more hardware processors configured to . . . trigger a second alarm based on [a measured oxygen saturation value] exceeding the second alarm threshold”

Limitation 1(i) recites a processor “configured to . . . *trigger a second alarm based on* at least one value of the oxygen saturation values obtained

over the second period of time *exceeding the second alarm threshold*.”

Ex. 1001, 14:1–3, 14:34–40 (emphases added).

a) The Institution Decision’s Preliminary Construction of Limitation 1(i)

In the Institution Decision, we preliminarily construed limitation 1(i) *sua sponte*. See Inst. Dec. 18, 23–24. “[W]e conclude[d] that an oxygen saturation value exceeding the second alarm threshold must be one condition that is satisfied for the alarm to be ‘triggered . . . based on’ this condition in limitation 1(i).” *Id.* at 24. We further concluded “claim 1 is open to requiring additional conditions to be satisfied for the alarm to be triggered,” with the ’218 patent disclosing a time delay condition as one example. *Id.* at 23–24 (citing Ex. 1001, 2:54–3:1 (Fig. 1), 6:35–41 (Fig. 4A), 7:40–8:6 (Fig. 6), 14:58–62 (claim 5)).

This construction of limitation 1(i) was a significant factor in our determination, at the institution stage, that Petitioner had sufficiently established Bock discloses limitation 1(i) to justify institution of review, over objections made in Patent Owner’s Preliminary Response. See *id.* at 39–41.

b) Patent Owner’s Post-Institution Construction of Limitation 1(i)

Patent Owner argues the Institution Decision construed limitation 1(i) too broadly, and pursuant to a correct and narrower claim construction, Bock does not disclose limitation 1(i). See PO Resp. 2–3, 15–28.

Patent Owner asserts limitation 1(i) “requires that exceeding the oxygen saturation value identified as the second alarm threshold triggers the alarm (optionally in combination with other non-oxygen saturation value conditions).” *Id.* at 15; Ex. 2011 ¶¶ 47–48. A time delay is one example of

the other non-oxygen saturation value conditions permitted by this construction. *See* PO Resp. 16, 26; Sur-reply 2; Ex. 2011 ¶ 48. The critical difference between Patent Owner’s construction and the Institution Decision’s preliminary construction is that, per Patent Owner, the other conditions *cannot* be further oxygen saturation threshold values. *See* PO Resp. 15, 18 (arguing limitation 1(i) “should *not* be construed to encompass a system that triggers an alarm *only if* the patient’s oxygen saturation *exceeds a value that is more extreme than the purported ‘second alarm threshold’*” (emphasis added)); Ex. 2011 ¶¶ 47–53. Patent Owner’s construction would differentiate claim 1 from Bock, because as discussed in Section III.D.1 below, Bock triggers an alarm only if the patient’s oxygen saturation firstly exceeds tracking threshold 314—which Petitioner equates to the second alarm threshold of limitation 1(i)—and then secondly exceeds alarm limit 316. *See* PO Resp. 16–17, 20–21; Ex. 2011 ¶¶ 29–30, 36–37.

Concerning the claim language, Patent Owner argues the Institution Decision “construed the phrase ‘triggered . . . based on . . . exceeding’ but did not construe the phrase ‘second alarm threshold.’” PO Resp. 16, 18. Patent Owner construes “second alarm threshold” to mean “the most extreme (lowest) oxygen saturation value that must be exceeded to trigger the second alarm.” *Id.* at 22; Sur-reply 3–4; Ex. 2011 ¶¶ 47–53. Patent Owner’s view of the claim language is that “[i]f a purported condition requires the oxygen saturation value exceed a value more extreme than the alleged ‘second alarm threshold,’ it would not be adding a condition—it would be eliminating and replacing it,” and further “[i]f exceeding an oxygen saturation value cannot trigger an alarm, then that oxygen saturation value cannot be the claimed ‘second alarm threshold.’” PO Resp. 17 (citing

Ex. 2011 ¶¶ 47–48, 54–58, 63); *id.* at 18–19, 22–23; Sur-reply 2–3, 5 (citing *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017), as indicating “it is ‘highly disfavored’ to construe claim terms in a way that a phrase or limitation is rendered meaningless”). Patent Owner cites dictionary definitions that “define ‘threshold’ using definite articles” in support. PO Resp. 21 (citing Exs. 2012 and 2013); Ex. 2011 ¶ 52.

Claim 5 depends from claim 1 to add that the processor “wait[s] for a time delay prior to the triggering of the second alarm.” Ex. 1001, 14:58–62. Patent Owner contends claim 5 does not justify the Institution Decision’s preliminary construction. *See* PO Resp. 26–28; Ex. 2011 ¶¶ 54–64. Patent Owner argues “[a] time-delay condition is distinct from an additional oxygen saturation value-measurement condition,” so the addition of a time delay is consistent with Patent Owner’s claim construction. PO Resp. 26–27; Ex. 2011 ¶¶ 61–62. Patent Owner asserts the Institution Decision’s preliminary construction would improperly “subsume or obviate the oxygen saturation value-measurement condition” in claim 1, rendering it “meaningless,” based on the unrelated time delay condition in claim 5. PO Resp. 26–27; Sur-reply 5–6; Ex. 2011 ¶¶ 61–62. Patent Owner provides a Venn diagram to illustrate this contention. PO Resp. 27–28; Ex. 2011 ¶ 63.

Turning to the ’218 patent specification, Patent Owner asserts “each description of ‘alarm threshold’ . . . refers to the most extreme value that must be exceeded to trigger the alarm.” PO Resp. 19; Ex. 2011 ¶¶ 49–51, 59–61. Patent Owner cites several specification descriptions of alarm thresholds, including the adaptive alarm threshold AT, as supporting this assertion. PO Resp. 19–20 (citing Ex. 1001, Figs. 1 and 6, 2:58–62,

3:10–23, 3:40–42, 4:43–47, 5:5–7, 6:35–38, 7:53–8:6, 11:18–25). Patent Owner also asserts the '218 patent's usage of the claim phrase “based on” and the similar phrase “based upon” is consistent with and confirms Patent Owner's proposed construction of limitation 1(i). *Id.* at 23–24 (citing Ex. 1001, code (57), 5:5–7); Sur-reply 6; Ex. 2011 ¶¶ 59–60. Patent Owner cites *Wisconsin Alumni Research Foundation v. Apple Inc.*, 905 F.3d 1341, 1351–52 (Fed. Cir. 2018), as “rejecting a proposed construction that would improperly ‘expand the scope of the claims far beyond anything described in the specification.’” PO Resp. 26.

Patent Owner additionally contends Petitioner's witness Dr. Yanulis agrees with Patent Owner's claim construction. *See id.* at 21–22 (citing Ex. 1003 ¶¶ 26–27); *id.* at 24–25 (citing Ex. 2014, 192:3–9); Sur-reply 4–5.

c) Petitioner's Post-Institution Construction of Limitation 1(i)

Petitioner agrees with the Institution Decision's preliminary construction of limitation 1(i). *See* Pet. Reply 2–10. Thus, Petitioner contends this limitation should be construed to mean “exceeding the second alarm threshold is at least one condition required to trigger an alarm.” *Id.* at 3.

Considering the claim language, Petitioner argues Patent Owner's construction “is improperly restrictive.” *Id.* at 3, 8. According to Petitioner, “construing claim language to exclude elements is disfavored in the absence of support ‘in the words of the claim’ or through an ‘express disclaimer or independent lexicography in the written description that would justify adding that negative limitation.’” *Id.* at 3 n.1 (citing *Omega Eng'g, Inc. v. Rayteck Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003)). Petitioner argues the

claim phrase “based on” imparts a breadth to claim 1 that belies Patent Owner’s position. *Id.* at 3–4 (“Had the patentee intended the alarm to be triggered by a narrower set of conditions, it could have so stated[.]”); Ex. 1040 ¶¶ 51–53. Petitioner cites a dictionary definition of the term “base on” as meaning “to use particular ideas or facts” (plural) to make a decision, as “refut[ing] Patent Owner’s position that ‘based on’ means that other oxygen saturation conditions cannot be included.” Pet. Reply 5 (citing Ex. 1043); Ex. 1040 ¶ 52. Petitioner cites two District Court decisions that, Petitioner asserts, construed the claim phrase “based on” to be “an open-ended term.” Pet. Reply 6–7 (citing *Intellectual Ventures II LLC v. Sprint Spectrum L.P.*, No. 2:17-cv-662-JTG-RSP, 2018 WL 6018625, at *16 (E.D. Tex. Nov. 16, 2018); *Apple Inc. v. Motorola, Inc.*, No. 1:11-cv-08540, 2012 WL 12537293, at *9 (N.D. Ill. Mar. 19, 2012)).

Considering the ’218 patent specification, Petitioner asserts the patent’s usage of the term “based on” supports Petitioner’s construction. Pet. Reply 5 (citing Ex. 1001, code (57)); Ex. 1040 ¶ 51. Also according to Petitioner, the ’218 patent’s disclosure that “the alarm is triggered after falling below the adaptive threshold and *remaining below* the adaptive threshold after a time delay” further supports Petitioner’s construction. Pet. Reply 4–6 (emphasis by Petitioner) (citing Ex. 1001, 6:35–44, 9:12–20, 11:18–32, claims 5–6); Ex. 1040 ¶¶ 54–57.

Petitioner further asserts “the result of [Patent Owner’s] proposed construction is nonsensical,” because it would defeat the ’218 patent’s purpose of addressing non-actionable alarms. Pet. Reply 8. Petitioner reasons that, when a time delay is implemented as expressly contemplated in the ’218 patent, and after the time delay period begins at the moment the

patient's measured oxygen saturation value exceeds an alarm threshold, "common sense dictates that the system rechecks the patient's oxygen saturation" during the time delay period. *Id.* at 8–9 (emphasis by Petitioner); Ex. 1040 ¶¶ 54–55. Otherwise, according to Petitioner, "[i]f the alarm simply triggered at the end of the delay without rechecking oxygen saturation values" per Patent Owner's construction, "then the purpose of the delay is entirely defeated" because "nuisance alarms would not be prevented." Pet. Reply 9 (emphasis by Petitioner); Ex. 1040 ¶¶ 56–57.

Petitioner finally argues that Patent Owner's Venn diagram analysis is not persuasive, because the referenced "Other Condition" (*see* PO Resp. 28, green circle) is not identified or discussed in the record. *See* Pet. Reply 8 n.2. Petitioner concludes it is therefore "unclear what non-time delay and non-oxygen saturation value conditions [Patent Owner] proposes would satisfy its claim construction proposal." *Id.*

d) Patent Owner's Sur-reply as to Construction of Limitation 1(i)

Patent Owner replies that its proffered claim construction is not nonsensical. Sur-reply 4. In particular: "Nothing in [Patent Owner's] construction excludes verifying or 'rechecking' that the oxygen saturation exceeds *the same* 'second alarm threshold.'" *Id.* (emphasis added). The only exclusion from claim 1 proposed by Patent Owner is "exceeding a value more extreme than the 'second alarm threshold' to trigger the alarm." *Id.*

Patent Owner also argues that the dictionary definition of "base on" proffered by Petitioner supports Patent Owner's claim construction. *See id.* at 7. In Patent Owner's view, the definition "emphasizes that a decision

must be based on a ‘particular’ fact or facts,” and limitation 1(i) correspondingly “recites that the particular fact is exceeding the ‘second alarm threshold.’” *Id.*

Patent Owner asserts the two District Court decisions cited by Petitioner do not support Petitioner’s position. *See id.* at 7–8. According to Patent Owner, these decisions “stand for the unremarkable proposition that using ‘based on’ and an open-ended transition ‘comprising’ does not exclude systems that also use an additional independent condition,” and “[n]either case suggested a construction encompassing a system that replaced the claimed condition with some other more extreme condition.” *Id.*

e) Analysis and Conclusion as to Construction of Limitation 1(i)

(i) Language of Claim 1

We begin our claim construction with the claim language, which recites “one or more hardware processors configured to . . . *trigger* a second alarm *based on* at least one value of the oxygen saturation values obtained over the second period of time *exceeding the second alarm threshold*.” Ex. 1001, 14:1–3, 14:34–40 (emphases added).

This claim language does not support Patent Owner’s position that the recited “second alarm threshold” must be the *most extreme* alarm threshold that the processor determines has been exceeded by the measured oxygen saturation values to trigger the alarm. Instead, the operative verbiage is that the processor is “configured to . . . *trigger* a second alarm *based on*” the measured oxygen saturation values exceeding the second alarm threshold. The phrase “based on” requires that the processor must determine the measured oxygen saturation values exceed the second alarm threshold, as a

necessary condition precedent to the processor triggering the alarm. *See, e.g.,* Ex. 1043, 3 (defining the verb “base on” to mean “to use particular . . . facts to make a decision [or] do a calculation”).

The claim language does not exclude the processor from additionally determining that the measured oxygen saturation values further exceed a more extreme (i.e., lower) alarm threshold, as a second necessary condition precedent to the processor triggering the alarm, as Patent Owner would construe the claim. Patent Owner’s construction would re-write limitation 1(i) to recite something akin to “trigger[ing] a second alarm based on at least one value of the oxygen saturation values obtained over the second period of time exceeding the second alarm threshold, and no other more extreme threshold,” which the claim does not recite.

Patent Owner’s claim construction relies too heavily on the plain claim term “threshold.” This term reflects that *the processor must determine* the measured oxygen saturation values exceed the second alarm threshold as a *necessary condition* precedent to the processor triggering the alarm. But, it does no more than that. Patent Owner cites dictionary definitions of the term “threshold” as meaning “the magnitude or intensity that must be exceeded for a certain reaction, phenomenon, result, or condition to occur or be manifested,” and “[t]he point that must be exceeded to begin producing a given effect or result or to elicit a response.” Exs. 2012 & 2013; PO Resp. 21. Patent Owner emphasizes that both definitions begin with the definite article “the,” and argues this indicates “a ‘threshold’ does not encompass other values that *may also be exceeded along the way*” to a most extreme threshold. PO Resp. 21 (emphasis added); Ex. 2011 ¶ 52.

But, this is not what our claim construction does, because it recognizes that *the processor must determine* that the measured oxygen saturation values exceed the second alarm threshold. This comports with Patent Owner’s dictionary definitions, and gives appropriate weight to the term “threshold.” Patent Owner’s gloss on the plain term “threshold” as meaning that no further thresholds may be implemented, despite the open-ended claim term “comprising” (Ex. 1001, 13:63), is not persuasive.

Next, claim 5 depends from claim 1 to add that the processor is “further configured to *wait for a time delay prior to the triggering of the second alarm.*” Ex. 1001, 14:58–62 (emphasis added); *see also id.* at 6:38–41 (stating “the alarm . . . is triggered *after a time delay* (TD), which may be fixed or variable” (emphasis added)); *id.* at Fig. 1, 2:54–3:1 (showing and discussing delay alarm threshold D_L of a prior art alarm system, which applies time delay TD). Patent Owner accepts, based on claim 5 and the corresponding disclosures in the ’218 patent, that claim 1 is open to the processor applying additional conditions—that is, further to the measured oxygen saturation values exceeding the second alarm threshold—being required to trigger an alarm. *See* PO Resp. 15, 16, 26. Patent Owner nonetheless insists that these additional conditions cannot be further oxygen saturation value thresholds. *See id.*; Ex. 2011 ¶¶ 47–53.

However, Patent Owner’s contention is not supported by the claim language. There is nothing in claim 1 or in claim 5 that excludes the processor from applying further oxygen saturation value thresholds, so long as the processor must determine that the measured oxygen saturation values exceed the second alarm threshold as a necessary condition precedent to triggering the alarm. Based on claim 5, claim 1 is open to the processor

applying additional conditions, such as a time delay, for the alarm to be triggered. We discern nothing in claim 1 that limits the scope of the claim such that these other conditions cannot include an additional, more extreme oxygen saturation threshold also being applied by the processor.

Our construction does not eliminate, replace, or otherwise render the second alarm threshold meaningless, as Patent Owner has suggested. Instead, we recognize that the processor must determine that the measured oxygen saturation values exceed the second alarm threshold as a necessary condition precedent to triggering the alarm, even if an additional more extreme oxygen saturation threshold determination is also required.

(ii) *'218 Patent Specification*

Turning to the '218 patent specification, it is undisputed that the “second alarm threshold” of claim 1 corresponds to the adaptive threshold AT illustrated in Figure 6. *See* Ex. 1001, 6:35–38, 7:40–8:6. Further, Patent Owner is correct that the '218 patent does not disclose any embodiment in which the processor must determine the measured oxygen saturation values 620, 630, or 640 *further* exceed an *additional* and more extreme (i.e., lower) alarm threshold than alarm threshold AT to trigger an alarm. *See id.* at 4:15–18, 4:46–47, 5:5–7, 6:35–38 (Fig. 4A), 7:53–8:6 (Fig. 6). The same is true of the fixed alarm thresholds D_L and ND_L of the prior art system illustrated in Figure 1 of the '218 patent. *See id.* at 2:54–3:6, 3:32–34, 3:40–42.

Nonetheless, while our claim interpretation cannot be divorced from the '218 patent specification and the record evidence, *see Microsoft Corp. v. Proxycorr, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP*,

Inc., 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language. *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) (“The written description, however, is not a substitute for, nor can it be used to rewrite, the chosen claim language,” and “a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.” (citations omitted)). Thus, the Federal Circuit “has emphasized that the disclosure in the written description of a single embodiment does not limit the claimed invention to the features described in the disclosed embodiment,” absent a clear intention to limit claim scope by using words of manifest exclusion or restriction. *Gemstar-TV Guide Int’l Inc. v. Int’l Trade Comm’n*, 383 F.3d 1352, 1366 (Fed. Cir. 2004) (citations omitted). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

As discussed above, the language of claim 1 is broader than the single embodiment disclosed in the ’218 patent specification. Adopting Patent Owner’s claim construction would improperly import a limitation from the specification into claim 1. The verbiage of limitation 1(i) does not exclude the processor from applying additional and more extreme (i.e., lower) alarm thresholds, so long as the processor must determine that the measured oxygen saturation values exceed the second alarm threshold as a necessary condition precedent to triggering the alarm.

Patent Owner suggests our construction is overbroad, because it means that every oxygen saturation value that is passed along the way to the

most extreme alarm threshold is an “alarm threshold.” *See* PO Resp. 24–25, 37–39; Tr. 28:10–29:4. We disagree. It is, of course, true that for measured values to reach any threshold—whether the single threshold of Patent Owner’s construction, or the multiple thresholds of our construction—the measured values must pass through a domain of values leading to the threshold. For example, Figure 6 of the ’218 patent illustrates that the downward trend of transient 624 in parameter segment 620 must pass through the entire range of values from Max down to adaptive threshold AT 628 to trigger an alarm by exceeding the adaptive threshold. *See* Ex. 1001, Fig. 6, 7:53–58.

Thus, the ’218 patent states “a transient 624 having a size less than Δ 626 *does not trigger* the alarm 412.” *Id.* at 7:56–58 (emphasis added). This just means that, in the embodiment of Figure 6, the only threshold applied by the processor is adaptive threshold AT. *See id.* at 7:53–8:6. That is, in this embodiment, the only alarm-triggering oxygen saturation determination made by the processor is whether parameter segment 620, 630, or 640 exceeds its corresponding adaptive threshold AT 628, 638, or 648. Although the measured values must pass through a range of values leading down to the adaptive threshold AT to reach and then exceed the threshold, which is a matter of fact that applies to any threshold, still the processor does not determine whether parameter segment 620, 630, or 640 exceeds any one value within the range along the way. Therefore, there is no “threshold” applied above adaptive threshold AT, in the embodiment of Figure 6. But, as discussed above, this disclosure of a single embodiment is not inconsistent with the broad language of claim 1 covering other embodiments, in which the processor triggers an alarm based on multiple

threshold-exceeding determinations rather than the single threshold-exceeding determination of Figure 6.

(iii) *'218 Patent Prosecution History*

Patent Owner does not rely, in its briefs, on the '218 patent prosecution history to support its claim construction. *See* PO Resp. 15–28; Sur-reply 2–8; Ex. 2011 ¶¶ 53, 64.

Petitioner's Reply argues Patent Owner's claim construction "ignores the very amendments that [Patent Owner] was required to make in order to obtain allowance" of the '218 patent. Pet. Reply 1. The Reply particularly asserts "the original claims" demonstrate Patent Owner could have claimed the "narrower set of conditions" for triggering an alarm that Patent Owner now seeks to incorporate into claim 1 via an improperly narrow claim construction. *Id.* at 4. The Reply indicates the details are "discussed below" (*id.*), but the Reply does not compare the original limitation 1(i) to the final limitation 1(i) set forth in the '218 patent. *See id.* at 4–10.

Petitioner provided the comparison during the oral hearing. *See* Tr. 10:9–11:12, 15:3–4; Paper 32 (slides 8 & 13). Patent Owner objected to this as improperly presenting new argument during the hearing (*see* Tr. 26:21–25), and also argued the amendments to limitation 1(i) during prosecution of the '218 patent did not materially change the scope of the claim as it applies to Bock (*see id.* at 26:26–28:5; Ex. 2016 (slides 11 & 13)). Petitioner responded that its oral hearing argument was presented timely, because it responded to the claim construction position taken in the Patent Owner Response. *See* Tr. 33:21–34:5.

We conclude Petitioner’s oral hearing argument did not expand improperly on arguments made in the Reply in response to Patent Owner’s claim construction. The Reply expressly refers to changes made to “the original claims” during prosecution of the ’218 patent, even though the specific changes were not identified in the Reply. *See* Pet. Reply 4. The application that became the ’218 patent was for a reissue of U.S. Patent No. 9,775,570 B2 (“the ’570 patent”). *See* Ex. 1001, code (64); Ex. 1014 (the ’570 patent). Because limitation 1(i) is the limitation at issue here, Petitioner’s comparison of limitation 1(i) in the ’570 patent (Ex. 1014, 14:17–22) to limitation 1(i) in the ’218 patent (Ex. 1001, 14:34–40) was not out of bounds.

However, we do not rely on the changes made to limitation 1(i) during prosecution of the ’218 patent to support our claim construction. Petitioner first suggests that, because the application that became the ’218 patent was filed within 2 years of the ’570 patent being issued,⁴ limitation 1(i) was necessarily broadened during prosecution. *See* Tr. 11:7–12 (“So it’s necessarily more broad. We know that because it’s a broadening reissue.”). We disagree. Although filing within this 2-year period permits an applicant to enlarge the scope of the claims, it does not require it. *See, e.g.*, 35 U.S.C. § 251(d) (“No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.”).

⁴ The ’570 patent issued on October 3, 2017, and the application that became the ’218 patent was filed on January 26, 2018. *See* Ex. 1014, code (45); Ex. 1001, code (22).

Turning then to the amendments at issue, limitation 1(i) in the '570 patent recites “one or more hardware processors configured to . . . *determine whether a second alarm should be triggered by determining if at least one oxygen saturation value obtained during the second period of time exceeds the second alarm threshold and triggering an alarm if it is determined the second alarm should be triggered.*” Ex. 1014, 13:51–53, 14:17–22 (emphasis added). Limitation 1(i) in the '218 patent recites “one or more hardware processors configured to . . . *trigger a second alarm based on at least one value of the oxygen saturation values obtained over the second period of time exceeding the second alarm threshold.*” Ex. 1001, 14:1–3, 14:34–40 (emphases added).

It might be, as Petitioner contends, that the original version of limitation 1(i) is limited in the way that Patent Owner now proposes we should construe the reissued version of limitation 1(i), and the reissued version is not so limited. However, Petitioner does not identify any action taken or any representations made during prosecution of the '218 patent to indicate limitation 1(i) was construed in this specific fashion. *See, e.g.*, Pet. Reply 1, 4. Therefore, the prosecution history has little impact on our decision as to the scope of the reissued version of limitation 1(i). The issue we must decide here is the scope of claim 1 in the '218 patent, not the scope of claim 1 in the '570 patent. Comparing the two versions of limitation 1(i) is an academic exercise that does not help us resolve this case. We therefore do not assess the parties' competing comparisons. *See, e.g.*, Tr. 10:9–11:12, 15:3–4, 26:21–28:5; Paper 32 (slides 8 & 13); Ex. 2016 (slides 11 & 13).

(iv) *Extrinsic Evidence*

We are not persuaded by Patent Owner's contention that Petitioner's witness Dr. Yanulis agrees with Patent Owner's claim construction.

Dr. Yanulis pertinently provides an "OVERVIEW" of the '218 patent. *See* Ex. 1003, pg. 7 (Title IV), ¶¶ 20–30. As part of this overview, Dr. Yanulis states the "*claims* are directed to a system" including a processor that "triggers an alarm *if* a second SpO₂ measurement falls below the second threshold." *Id.* ¶ 26 (emphases added). Dr. Yanulis also states dependent claim 5 "add[s] in the concept of introducing a time delay into the second alarm threshold," wherein "*if* an SpO₂ measurement exceeds an alarm threshold, the SpO₂ measurement must remain below the threshold for a predetermined amount of time before an alarm is generated." *Id.* ¶ 27 (emphasis added). According to Patent Owner, these "statements that the alarm is triggered 'if' the oxygen saturation level falls below the second alarm threshold (or remains below for an amount of time) *confirms there cannot be an even lower value that must be exceeded to trigger the alarm.*" PO Resp. 21–22 (emphasis added).

We disagree, for at least two reasons. First, Dr. Yanulis's statements provided an overview of the '218 patent including its claims, not a rigorous claim construction analysis. *See* Ex. 1003, pg. 7 (Title IV), ¶¶ 42–43. For example, he does not address the verbiage of limitation 1(i) in a claim construction context. *See id.* ¶¶ 26–27.

Second, Dr. Yanulis's testimony is not inconsistent with our construction of claim 1, even if it is re-cast to the verbiage used in claim 1. Specifically, describing an alarm as being triggered "if" the measured oxygen saturation values exceed an alarm threshold is consistent with our

construction that the processor must determine the measured oxygen saturation values exceed the second alarm threshold as a necessary condition precedent to triggering the alarm.

Patent Owner further relies on Dr. Yanulis's deposition testimony concerning Bock's disclosure, as confirming Patent Owner's claim construction. Here, Dr. Yanulis was asked: "Is it correct that in Figure 2, Bock does not disclose triggering the alarm based on the acquired data merely exceeding heart rate value of 150?" Ex. 2014, 192:3–6. He answered: "That would -- I would agree with that. It has to get to a certain value before you are triggering the alarm." *Id.* at 192:7–9. According to Patent Owner, this testimony confirms the Institution Decision's preliminary construction is overbroad and Patent Owner's narrower construction is correct, because in Bock's Figure 2 the heart rate value of 150 "is necessarily exceeded . . . before and during the triggering of the alarm." PO Resp. 25; Sur-reply 4–5.

As already discussed in Section III.C.2(e)(ii) above, the measured oxygen saturation values must pass through a domain of values leading to a threshold in order to trigger an alarm based on exceeding the threshold, regardless of whether a single threshold is applied per Patent Owner's construction or multiple thresholds are applied per our construction. In referring to the measurements needing "to get to a certain value before you are triggering the alarm," Dr. Yanulis merely acknowledged that the threshold must be reached. He did not agree with Patent Owner's construction that would require the second alarm threshold of claim 1 to be the most extreme threshold applied by the processor.

(v) *Construction of Limitation 1(i)*

We construe limitation 1(i) to require that the processor must determine that the measured oxygen saturation values exceed the second alarm threshold as a necessary condition precedent to triggering the alarm. However, the second alarm threshold need not be the most extreme alarm threshold applied by the processor. Claim 1 is open to additional alarm thresholds also being applied by the processor, which are more extreme than the second alarm threshold, so long as the second alarm threshold determination is made by the processor.

3. *Claims 8 and 12*

Independent claims 8 and 12 each contain limitations that are substantially identical to limitation 1(i) in claim 1. *See* Ex. 1001, 15:28–33 (claim 8), 16:26–32 (claim 12). Patent Owner argues we “should apply the construction of [l]imitation 1(i)” to these limitations in claims 8 and 12. PO Resp. 28–29; Ex. 2011 ¶ 65. We agree. Therefore, we construe these limitations in the same fashion as limitation 1(i). *See supra* Section III.C.2(e)(v).

4. *Other Claim Terms*

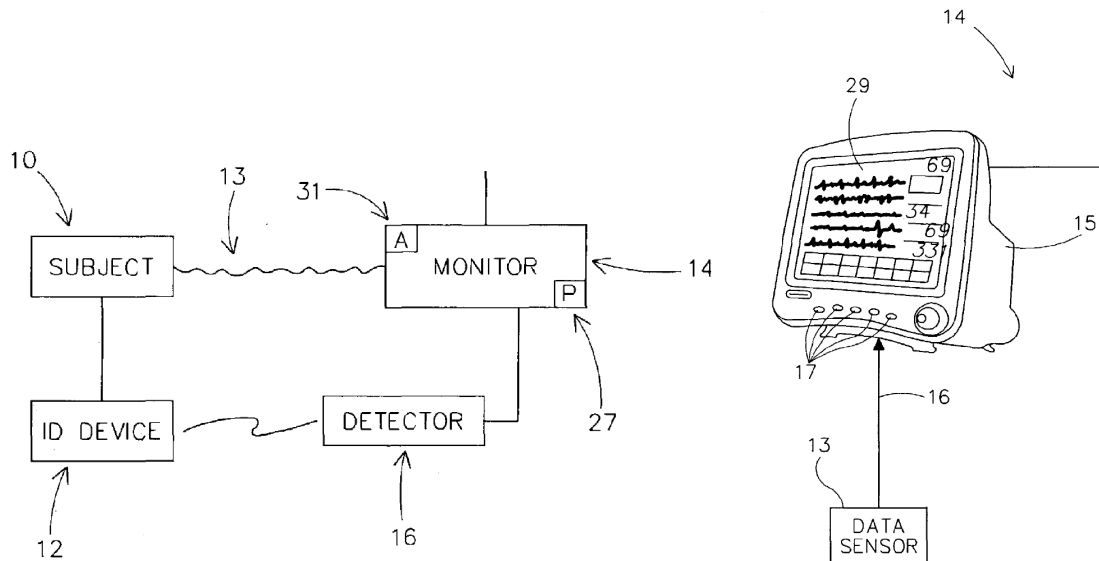
We determine no further explicit construction of any claim term is needed to resolve the issues presented by the arguments and evidence. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (per curiam) (claim terms need to be construed “only to the extent necessary to resolve the controversy” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

D. Obviousness over Bock and Kiani

Petitioner asserts claims 1–4, 7, and 12–15 of the '218 patent are unpatentable as having been obvious over Bock and Kiani. Pet. 21–43. Patent Owner opposes. PO Resp. 30–42. We have reviewed Petitioner's and Patent Owner's arguments, and the evidence of record. We conclude a preponderance of the evidence supports Petitioner's assertions as to all challenged claims 1–4, 7, and 12–15. We begin our analysis with brief summaries of Bock and Kiani, then we address the parties' contentions as to obviousness.

1. Bock Disclosure

Bock discloses a system and method for monitoring a patient's physiological characteristics, and “dynamically adjusting an alarm limit based on” the monitored data. Ex. 1005, code (57), 1:50–64, 5:8–13. Excerpts from Figures 1 and 4 of Bock are reproduced here:



Figures 1 and 4 illustrate data acquisition device or sensor 13, which acquires physiological data such as heart rate or blood oxygen saturation (SpO₂) from patient 10, and transmits the acquired data to monitor 14 to be illustrated on display 29. *Id.* at 3:30, 5:3–21. Monitor 14 includes processor 27, which analyzes the acquired data to implement Bock’s alarm scheme, by initiating alarm 31 pursuant to the scheme. *Id.* at 3:3–40, 9:9–11.

Figure 2 of Bock illustrates Bock’s alarm scheme, and is reproduced here.

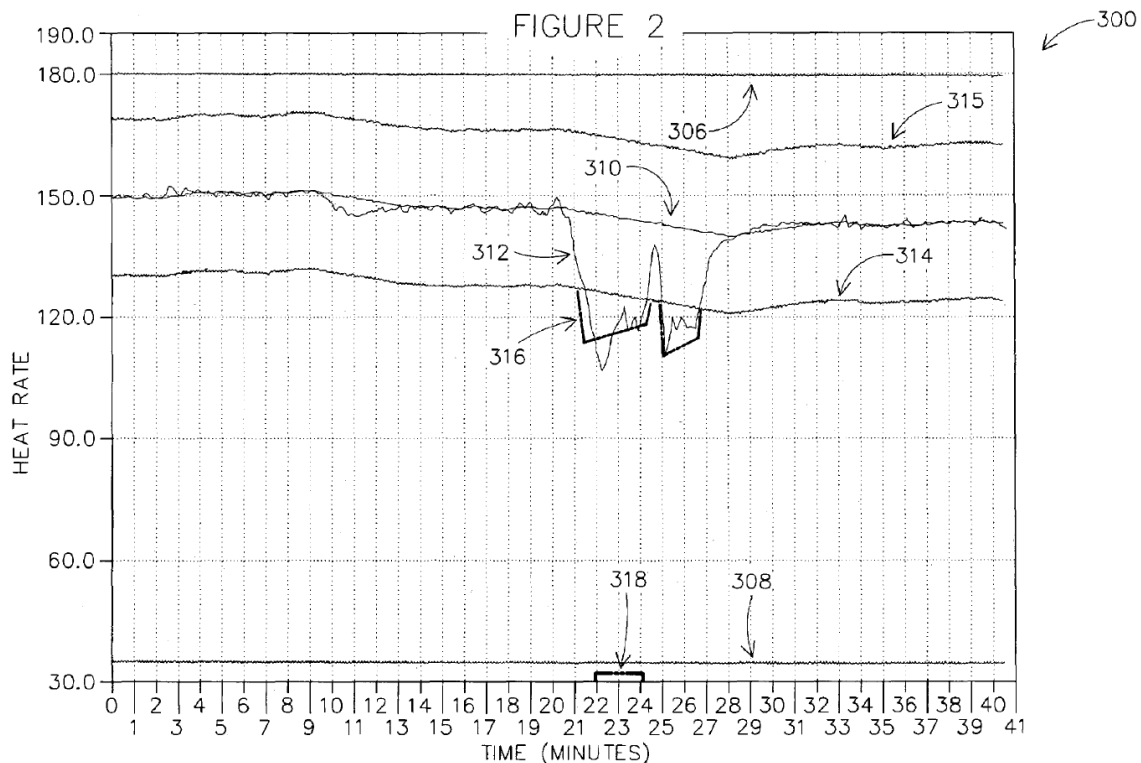


Figure 2 “is an illustration of alarm limits as alarm criteria where the limits are dynamically adjusted,” in the context of monitoring a patient’s heart rate (vertical axis) over time (horizontal axis). *Id.* at 2:47–49, 3:41–45.

Acquired data stream 312 reflects the patient's physiological data as acquired by Bock's sensor 13. *Id.* at 3:41–47, 5:8–13.

Extremity limit 308 represents an extreme lower value for the monitored characteristic, requiring immediate attention if it is exceeded by acquired data stream 312, so Bock's processor 27 generates an immediate alarm when this occurs. *Id.* at 3:50–58, 6:7–15 (describing Fig. 5, blocks 104 and 106).

Calculated representative value 310 is generated by Bock's processor 27 based on acquired data stream 312, and “represents a typical value for the patient for the characteristic being monitored” over time. *Id.* at 1:52–57, 3:46–47, 3:59–4:3, 5:55–6:6 (describing Fig. 5, block 102), 7:4–33 (describing Fig. 5, block 116).

Lower tracking threshold 314 “is set based on calculated representative value 310,” for example threshold 314 can be a pre-set percentage difference less than calculated representative value 310. *Id.* at 4:4–7, Fig. 2. In use: “Alarm limit 316 is set when acquired data 312 crosses tracking threshold 314.” *Id.* at 4:15–16, Fig. 2; *id.* at 6:20–23, 6:43–54 (describing Fig. 5, blocks 110 and 112). The initial value of alarm limit 316 “can be based on calculated representative value 310, tracking threshold 314, and/or any other value,” and then alarm limit 316 decreases over time as shown in Figure 2 between minutes 21.5 and 24.5. *Id.* at 4:17–25. “Once alarm limit 316 is set, if acquired data 312 crosses alarm limit 316 an alarm is generated as represented by bar 318” in Figure 2 between minutes 22 and 22.8, and again at about minute 23.3 and about minute 24. *Id.* at 4:26–30; *id.* at 6:43–45, 6:64–65 (describing Fig. 5, blocks 112 and 106).

2. *Kiani Disclosure*

Kiani discloses: “A pulse oximetry system [that] consists of a sensor attached to a patient, a monitor, and a cable connecting the sensor and monitor.” Ex. 1006, 1:19–21. The sensor is attached to a patient’s finger, and includes emitters that emit red and infrared light through a patient’s fingernail and into the blood vessels and capillaries, as well as a photodiode detector that detects the emitted light as it emerges from the finger tissue. *Id.* at 1:22–30. The monitor analyzes the data to determine oxygen saturation in the patient’s blood. *Id.* at 1:31–43.

3. *Claim 1*

Petitioner provides arguments and evidence, including testimony from Dr. Yanulis and Dr. Bergeron, in support of contending claim 1 is unpatentable as having been obvious over Bock and Kiani. Pet. 21–38; Pet. Reply 10–14; Ex. 1003 ¶¶ 71–115; Ex. 1040 ¶¶ 58–59, 61–75. Patent Owner provides arguments and evidence in opposition, including testimony from Mr. Goldberg. PO Resp. 30–41; Ex. 2011 ¶¶ 27–40, 67–80.

a) *[1(a)] 1. A system for reducing electronic alarms in a medical patient monitoring system, the system comprising:*

[1(b)] an optical sensor configured to transmit optical radiation into a tissue site of a patient and detect attenuated optical radiation indicative of at least one physiological parameter of a patient

Petitioner addresses claim 1’s preamble 1(a) and limitation 1(b) by contending Bock’s patient monitor 14 reduces alarms when monitoring a patient, and Bock’s sensor 13 monitors the patient to generate data indicative of a physiological parameter of the patient, i.e., oxygen saturation. *See*

Pet. 12, 21–23 (citing Ex. 1005, code (57), 1:8–20, 5:3–16, Fig. 4); Ex. 1003 ¶¶ 44–46, 73–76. Petitioner concedes Bock’s sensor 13 is not expressly disclosed to be an “optical” sensor, as is required by limitation 1(b). *See* Pet. 21, 24; Ex. 1003 ¶¶ 71–72, 77, 80.

Patent Owner does not challenge these contentions, and we determine they are supported by a preponderance of the evidence cited by Petitioner. *See, e.g.*, Ex. 1005, code (57), 1:8–20, 5:3–16 (Fig. 4); Ex. 1003 ¶¶ 44, 46, 74–77.

Petitioner next asserts Kiani discloses an optical sensor, which senses oxygen saturation by transmitting and detecting optical radiation passing through the patient’s tissue, as is required by limitation 1(b). *See* Pet. 17–18, 23–24 (citing Ex. 1006, 1:12–45); Ex. 1003 ¶¶ 53–56, 79. Petitioner further asserts it was well known at the time the ’218 patent was filed that oxygen saturation “was generally measured externally for a patient” using optical sensors. Pet. 23 (citing Ex. 1003 ¶¶ 77–78; Ex. 1001, 1:39–55). Petitioner asserts a person of ordinary skill in the art “would have been motivated to substitute the optical sensor of Kiani for [Bock’s sensor,] because optical sensors measure oxygen saturation and pulse rate non-invasively, which provides more comfort to the patient and enables easy application and removal of the sensor on a patient.” *Id.* at 24 (citing Ex. 1005, 1:8–20, 5:3–5; Ex. 1006, 1:17–19); Ex. 1003 ¶¶ 71–72, 77–81. This substitution, in Petitioner’s view, “is a simple substitution of one known element for another yielding predictable results.” Pet. 24; Ex. 1003 ¶¶ 80–81.

Patent Owner does not challenge these contentions, and we determine they are supported by a preponderance of the evidence cited by Petitioner. Specifically, Kiani discloses a sensor that emits optical radiation (i.e., red

light) through an adult patient's finger, and then detects the attenuated light, to measure the patient's blood oxygen saturation level. *See* Ex. 1006, 1:10–45. The summary nature of Kiani's description of optical oxygen saturation sensors, as the “BACKGROUND” to Kiani's invention, suggests this technology was well developed and well known at the time of Kiani's invention in July 2003—almost seven years before the '218 patent's March 2010 earliest-possible priority date. *See id.*; *id.* at code (45); Ex. 1001, code (60). The '218 patent's “BACKGROUND” section, similarly, suggests optical oxygen saturation sensors were well developed and well known at the time of the '218 patent's invention. Ex. 1001, 1:32–55. Dr. Yanulis's testimony is to a similar effect. Ex. 1003 ¶¶ 36–37, 52, 54, 56, 77–79. Mr. Goldberg does not contest this testimony from Dr. Yanulis. *See, e.g.*, Ex. 2011 ¶¶ 66–80.

Further, Bock discloses its sensor 13 and monitor 14 may be used to monitor a patient's blood oxygen saturation (SpO_2), but Bock does not provide any details concerning how sensor 13 would do so. *See* Ex. 1005, 5:3–16 (Fig. 4). We agree with Petitioner's contention that it would have been obvious to use an optical oxygen saturation sensor in Bock's system, based on Kiani and the well developed status of such sensors at the time of the '218 patent's invention, as a non-invasive measurement technique which provides more comfort to the patient and enables easy application and removal of the sensor on a patient. *See* Pet. 23–24; Ex. 1003 ¶¶ 77–81. Thus, we determine Petitioner's contentions as to the preamble 1(a) and limitation 1(b) are supported by a preponderance of the evidence.

b) [1(c)] one or more hardware processors in electronic communication with the optical sensor, the one or more hardware processors configured to: . . .

Petitioner contends Bock’s patient monitor 14 is in electronic communication with the optical sensor of Bock and Kiani, in order to receive physiological data from the sensor. *See* Pet. 25–26 (citing Ex. 1005, Fig. 1, 3:31–39, 5:3–16); Ex. 1003 ¶¶ 82–83. Petitioner further contends patient monitor 14 includes processor 27 which performs the data analyses disclosed in Bock. *See* Pet. 26 (citing Ex. 1005, 3:31–39); Ex. 1003 ¶¶ 82–83.

Patent Owner argues “Bock fails to disclose ‘one or more processors configured’ to perform the claimed triggering.” PO Resp. 40 (section title modified to lowercase letters). Patent Owner here quotes limitation 1(c) as the limitation at issue, but then argues “Petitioner fails to demonstrate that Bock discloses a ‘second alarm threshold’ . . . or ‘trigger[ing] a second alarm based on [an oxygen saturation value] exceeding the second alarm threshold[.]’” as recited in limitation 1(i). *Id.* In other words, Patent Owner does not dispute that Bock discloses a processor, or that Bock’s processor implements an oxygen saturation level alarm scheme. *See id.* at 40–41. Instead, Patent Owner’s objection is that the alarm scheme implemented by Bock’s processor is different from the scheme required by limitation 1(i). We address this argument below in Section III.D.3(h).

As to limitation 1(c), we find a preponderance of the evidence supports Petitioner’s contention that Bock discloses one or more hardware processors in electronic communication with an oxygen saturation sensor, and configured to implement an alarm scheme based on the sensor readings. In particular, Bock’s patient monitor 14 includes processor 27 in

communication with sensor 13 which measures the oxygen saturation (SpO_2) of patient 10. *See* Ex. 1005, Figs. 1 and 4, 3:29–34, 5:3–16; Ex. 1003

¶¶ 82–83. Further, as we found in the Institution Decision, in Bock “the data processing may be performed by processor 27 of monitor 14, or by another processor 26 via a network connection to monitor 14.” Inst. Dec. 33 n.7 (citing Ex. 1005, Fig. 1, 3:31–39, 5:3–16). Patent Owner does not challenge these findings. *See, e.g.*, PO Resp. 40–41.

c) [1(d)] determine oxygen saturation values of the patient over a first period of time

Petitioner contends Bock’s processor 27 determines oxygen saturation values of the patient over a first period of time, which Petitioner equates to minute 0 to minute 21 in Bock’s Figure 2. Pet. 26–27 (citing Ex. 1005, 5:3–16, 5:52–6:6); Ex. 1003 ¶¶ 84–86. Petitioner asserts these values appear in Figure 2 as acquired data stream 312, which in Figure 2 are heart rate values, but “the same concepts apply to [oxygen saturation] measurements” when Bock’s system monitors oxygen saturation, as is disclosed in Bock. Pet. 13, 26–27 (citing Ex. 1005, 5:10–13, 5:52–6:6); Ex. 1003 ¶¶ 46, 84–86.

Patent Owner does not challenge these contentions, and we determine they are supported by a preponderance of the evidence cited by Petitioner. *See, e.g.*, Ex. 1005, 5:3–16 (Fig. 4), 5:52–6:6 (Fig. 5); Ex. 1003 ¶¶ 46, 84–86.

d) [1(e)] when at least one oxygen saturation value obtained over the first period of time exceeds a first alarm threshold, determine whether a first alarm should be triggered

We have construed the “one” oxygen saturation value in limitation 1(e) to refer to one value of the patient data generated by a sensor

during the first period of time. *See supra* Section III.C.1. Petitioner equates this, in Bock, to one value of acquired data stream 312, during minute 0 to minute 21 in Bock’s Figure 2. Pet. 27–28.

Petitioner particularly contends Bock’s processor 27 determines whether acquired data stream 312 “exceeds the tracking threshold [314] and alarm limit [316] . . . and, if so, an alarm is triggered,” as is shown in Figure 5 at blocks 110, 112, and 106. *Id.* (citing Ex. 1005, 6:20–54, 6:64–7:3); *id.* at 13 & n.3 (“If the patient data [312] exceeds the threshold [314] (this event is called an alarm limit 316), then an alarm is triggered.”) (further citing Ex. 1005, 2:23–28, 4:4–28, 5:3–16); Ex. 1003 ¶¶ 46–47, 49, 87–88. Petitioner contends that, while Figure 2 does not illustrate the alarm being triggered during the first period of time from minute 0 to minute 21, nonetheless acquired data stream 312 is monitored during the first period of time, and an alarm would be triggered if the data were to cross tracking threshold 314 and then alarm limit 316, as is shown in Figure 2 “at the 22–24 minute mark.” Pet. 27–28; Ex. 1003 ¶¶ 87–88.

Patent Owner does not challenge these contentions, and we determine they are supported by a preponderance of the evidence cited by Petitioner. *See, e.g.*, Ex. 1005, 2:23–28, 4:4–28 (Fig. 2), 6:20–54 (Fig. 5), 6:64–65; Ex. 1003 ¶¶ 46–47, 49, 87–88.

- e) *[1(f)] access a second alarm threshold to be applied during a second period of time subsequent to the first period of time, the second alarm threshold replacing the first alarm threshold*

Petitioner contends Bock’s processor 27 accesses a second alarm threshold, which is tracking threshold 314, to be applied during a second period of time, which includes minute 28 in Bock’s Figure 2. Pet. 14–15,

28–31 (citing Ex. 1005, 3:40–48, 3:59–4:25, 7:4–26); Ex. 1003 ¶¶ 47, 89–96. Petitioner asserts Bock replaces the first alarm threshold, which is tracking threshold 314 during the first period of time, with the second alarm threshold, which is tracking threshold 314 during the second period of time, because this is how a computer’s processor and memory operate. Pet. 28–30 (citing Ex. 1005, code (57), 3:31–40, 4:4–25, 7:19–26, 7:61–8:2, 8:25–27); Ex. 1003 ¶¶ 89–91. In particular, according to Petitioner, “Bock teaches that new tracking thresholds [314] are calculated based on the calculated representative value 310,” which changes over time as acquired data stream 312 changes. Pet. 29–31 (citing Ex. 1005, 3:31–40, 4:4–25, 7:19–26, 8:25–27); Ex. 1003 ¶¶ 92–93, 95–96.

Patent Owner does not challenge these contentions, and we determine they are supported by a preponderance of the evidence cited by Petitioner. *See, e.g.*, Ex. 1005, code (57), 3:31–48 (Fig. 1), 3:59–4:25 (Fig. 2), 7:4–8:27 (Fig. 5); Ex. 1003 ¶¶ 47, 92–93, 95–96.

f) [1(g)] wherein the second alarm threshold has a value less than the at least one oxygen saturation value and greater than a lower limit and at an offset from the at least one oxygen saturation value, wherein the offset is diminished as a difference between the at least first oxygen saturation value and the lower limit diminishes

We have construed the “one” and the “first” oxygen saturation values in limitation 1(g) to refer to the same value, which is one value of the patient data generated by a sensor during the second period of time. *See supra* Section III.C.1.

In the Institution Decision, we concluded “Petitioner appears to equate” the oxygen saturation value in limitation 1(g) “to *calculated representative value 310*, after minute 21 in Figure 2.” Inst. Dec. 36

(emphasis added) (citing Pet. 31–37; Ex. 1003 ¶¶ 97–112). However, we recognized “Petitioner’s analysis here lacks clarity, because it largely abstains from analyzing the allegedly ‘long and wordy’ claim language in favor of what Petitioner describes as the ‘[e]ssential[]’ ‘concept’ of limitation 1(g).” *Id.* (citing Pet. 31; Ex. 1003 ¶¶ 97–99). In particular, we concluded “[t]he Petition . . . refers repeatedly to a ‘measured parameter’ or a ‘measured value’ in Bock, *sometimes referencing acquired data stream 312, and other times referencing calculated representative value 310.*” *Id.* (emphases added) (citing Pet. 31–37).

The post-institution briefing (the Patent Owner Response, the Petitioner Reply, and the Patent Owner Sur-reply) does not address the Petition’s reliance on Bock as disclosing limitation 1(g), or the Institution Decision’s preliminary reading of the Petition in this regard.

When Petitioner’s counsel was questioned during the oral hearing about Petitioner’s contentions in this regard, counsel stated: “I believe that our consistent position is that *the value that’s being measured from the patient at any given moment*” in Bock, “that *that is the oxygen saturation value that we’re looking at*” as being the oxygen saturation value in limitation 1(g). Tr. 12:23–13:5 (emphases added). Thus, Petitioner’s position is that Bock’s “measured patient value” (i.e., acquired data stream 312) corresponds to the oxygen saturation value identified in limitation 1(g). *Id.* at 13:6–14:18.

Patent Owner’s counsel then argued: “[T]o the extent that [Petitioner’s] initial analysis took a different approach and identified different things in Bock [as satisfying limitation 1(g)], then I think there may still be a deficiency in [Petitioner’s] grounds.” *Id.* at 31:20–32:25.

However, Patent Owner's counsel did not explain what the deficiency might be, or identify any specific passage(s) in the Petition that would limit Petitioner's contentions to relying on Bock's calculated representative value 310 as the oxygen saturation value recited in limitation 1(g). *See id.*

Based on the entirety of the record, we now understand Petitioner contends Bock's acquired data stream 312, and *not* Bock's calculated representative value 310, corresponds to the oxygen saturation value in limitation 1(g). Further, we understand Petitioner contends Bock's tracking threshold 314 is a second alarm threshold that is less than acquired data stream 312, and is greater than a lower limit, which is lower extremity limit 308. Pet. 33–35 (citing Ex. 1005, code (57), Figs. 2, 3, and 5, 1:25–31, 3:40–49, 4:4–25, 5:52–6:6, 7:4–26, 8:28–34, 9:28–37); Ex. 1003 ¶¶ 101–105. Petitioner also contends Bock's tracking threshold 314 is at an offset from acquired data stream 312, because threshold 314 is set as a percentage of calculated representative value 310, which is adjusted to represent acquired data stream 312 over time. Pet. 34–35 (citing Ex. 1005, 3:40–49, 4:4–25, 7:4–26, 8:28–34, 9:28–37); Ex. 1003 ¶¶ 104–107. According to Petitioner, based on this percentage relationship, it necessarily follows that the offset is diminished as a difference between acquired data stream 312 and lower extremity limit 308 diminishes. Pet. 16 & n.4; *id.* at 32–33, 35; Ex. 1003 ¶¶ 50–51, 99–100, 104–107.

Patent Owner does not challenge these contentions, and we determine they are supported by a preponderance of the evidence cited by Petitioner.⁵

⁵ Petitioner also argues Bock's disclosure of "tightening" alarm criteria "is the same concept as the claimed 'diminishing' threshold." Pet. 36–37 (citing

See, e.g., Ex. 1005, code (57), Figs. 2 and 5, 3:40–49, 4:4–25, 5:52–6:6, 7:4–26, 8:28–47; Ex. 1003 ¶¶ 50–51, 99–107.

g) [1(h)] determine oxygen saturation values of the patient over the second period of time

Petitioner contends Bock’s processor 27 determines oxygen saturation values of the patient over the second period of time, which (as discussed above) is after minute 21 in Bock’s Figure 2. Pet. 37–38 (citing Ex. 1005, 1:32–44, 2:23–28, 5:3–16, 8:3–19); Ex. 1003 ¶ 113.

Patent Owner does not challenge this contention, and we determine it is supported by a preponderance of the evidence cited by Petitioner. *See, e.g.,* Ex. 1005, 2:23–28, 5:3–16, 8:3–19; Ex. 1003 ¶ 113.

h) [1(i)] trigger a second alarm based on at least one value of the oxygen saturation values obtained over the second period of time exceeding the second alarm threshold

Petitioner contends Bock’s processor 27 triggers a second alarm based on at least one oxygen saturation value obtained over the second period of time exceeding the second alarm threshold. Pet. 38 (citing Ex. 1005, Fig. 5, 2:23–28, 5:3–16, 8:3–27); Ex. 1003 ¶ 114. As discussed above, Petitioner equates the claimed second alarm threshold over a second period of time, in Bock, to tracking threshold 314 after minute 21 in Figure 2.

Patent Owner firstly argues Petitioner errs in relying on Bock’s tracking threshold 314 as the “second alarm threshold” of claim 1, because threshold 314 is not the most extreme (lowest) oxygen saturation value that

Ex. 1005, Fig. 3, 1:19–44, 6:36–42, 6:55–63, 8:3–34, 9:28–34); Ex. 1003 ¶¶ 109–111. We do not rely on this position as a basis for our present Decision.

must be exceeded to trigger an alarm, which instead is Bock's alarm limit 316. *See* PO Resp. 7–11, 30–34; Ex. 2011 ¶¶ 27–38, 68–74. This argument is premised on Patent Owner's construction of limitation 1(i), which we have determined is not persuasive. *See supra* Section III.C.2. Therefore, Patent Owner's application of its claim construction to Bock also is not persuasive.

We find Bock's tracking threshold 314 is an “alarm threshold” as recited in claim 1, because Bock's processor 27 must determine acquired data stream 312 exceeds (falls below) tracking threshold 314 as a necessary condition precedent to triggering the alarm at alarm limit 316. *See supra* Section III.C.2 (claim construction). Specifically, acquired data stream 312 falling below tracking threshold 314 “set[s]” alarm limit 316, to a value which can be “based on” tracking threshold 314. Ex. 1005, 4:15–28, Fig. 2 (showing acquired data stream 312 crossing tracking threshold 314 at minute 21.5, which sets alarm limit 316 at about 113 heart beats per minute, and alarm limit 316 thereafter decreases over time). If acquired data stream 312 does not fall below tracking threshold 314, then alarm limit 316 is not set, and alarm indicator 318 cannot be triggered by acquired data stream 312 falling below alarm limit 316. *Id.*; *see also id.* at 6:43–47 (in Figure 5, “[i]f the data [312] does cross the tracking threshold [314] at block 110, a determination is made at block 112 as to whether the data meets an alarm criteria [i.e. alarm limit 316] at block 112,” and “[t]he alarm criteria of block 112 is preferably affected by the fact that the data [312] crossed the tracking threshold [314] at block 110” (emphasis added)). In this way, acquired data stream 312 falling below tracking threshold 314 is

one necessary condition precedent that must be satisfied for alarm 318 to be triggered at alarm limit 316.

Dr. Yanulis, Dr. Bergeron, and Mr. Goldberg all agree that this is how Bock operates to trigger an alarm at alarm limit 316, based on data 312 firstly crossing threshold 314 to set limit 316. *See* Ex. 1003 ¶¶ 46–49, 87–88, 114; Ex. 2014, 158:12–163:14 (Dr. Yanulis correcting and clarifying statements he made in Ex. 1003 ¶ 114); Ex. 1040 ¶¶ 62–64, 75; Ex. 2011 ¶¶ 29–32, 35–37, 70–73.

This finding that Bock’s tracking threshold 314 is an “alarm threshold” as recited in claim 1 means that we need not reach a few alternative arguments presented by both parties. Thus, we do not reach Petitioner’s arguments that Bock discloses alarm limit 316 may either: be *set* equal to tracking threshold 314 in some circumstances; or *decay* to be equal to tracking threshold 314 in other circumstances.⁶ *See* Pet. Reply 10–14; Ex. 1040 ¶¶ 63–75. We also do not reach Patent Owner’s argument that Petitioner does not and cannot “assert that any other value disclosed in Bock is the claimed ‘second alarm threshold,’” such as Bock’s alarm limit 316. *See* PO Resp. 33 (lines 5–19).

⁶ Petitioner has further disavowed any argument that it might have been obvious to modify Bock to implement limitation 1(i), if it is not expressly disclosed in Bock, unless we adopt Patent Owner’s claim construction. *See* Pet. Reply 10–14 (“[S]hould the Board adopt [Patent Owner’s] proposed constructions, Bock still renders the claims obvious.”); Tr. 17:20–18:16 (Petitioner’s counsel stated “the only modification that we argued with respect to Bock in Ground 1 is the replacement of the sensor with the optical sensor of Kiani,” and “[w]e are not arguing that the tracking threshold or the alarm limit have to be modified”).

Patent Owner secondly argues that, even if Bock's tracking threshold 314 is an "alarm threshold" as recited in claim 1, Bock does not disclose *triggering* a second alarm based on an oxygen saturation value *exceeding* tracking threshold 314 as is further claimed. *See id.* at 7–11, 34–40. In particular, according to Patent Owner, "Bock discloses that exceeding tracking threshold 314 does not, alone or in combination with a time delay, trigger an alarm," because Bock's alarm limit 316 must also be exceeded to trigger an alarm. *Id.* at 34–36 (citing Ex. 1005, Fig. 5 (steps 110, 112, and 106), 6:20–24); Ex. 2011 ¶¶ 75–80.

These arguments are not persuasive, for reasons provided above. They again rely on Patent Owner's proffered claim construction, which is not persuasive. *See supra* Section III.C.2 (claim construction). And, we find that Bock's processor 27 triggers an alarm based on acquired data stream 312 falling below tracking threshold 314, because the processor must first determine this event occurs before alarm limit 316 is set to cause the triggering of an alarm when acquired data stream 312 exceeds limit 316.

Patent Owner thirdly contends that Dr. Yanulis admitted during his deposition that his declaration was mistaken in stating that "Bock teaches the processor trigger[s] an alarm anytime [an] oxygen saturation value[] exceeds a threshold," and "Bock teaches that if the data [312] dipped below the tracking threshold 314 at a period of time subsequent to the 24 minute mark, another alarm would be triggered." Ex. 1003 ¶ 114; PO Resp. 36 (citing Ex. 2014, 162:11–163:13). We agree that Dr. Yanulis admitted these two sentences were mistaken. *See* Ex. 2014, 163:3–13.

However, in context, Dr. Yanulis testified that Bock's processor 27 triggers an alarm based on acquired data stream 312 falling below tracking

threshold 314, because the processor must first determine this event occurs before alarm limit 316 is set to cause the triggering of an alarm when acquired data stream 312 exceeds limit 316. *See id.* at 158:12–163:14. For example, Dr. Yanulis stated: “The tracking threshold . . . is just one condition for triggering the alarm, or if an alarm is triggered.” *Id.* at 159:1–3. Dr. Yanulis further acknowledged that Figure 2 of Bock does not illustrate an alarm being triggered after minute 24, despite acquired data stream 312 falling below tracking threshold 314 at minute 25, which causes the processor to set a second alarm limit 316 that persists from minute 25 to minute 27. *Id.* at 161:3–163:1. But, he added “[t]hat doesn’t mean another alarm won’t eventually present itself as an event.” *Id.* at 161:15–16. Thus, according to Dr. Yanulis, Bock’s system would have triggered an alarm between minutes 25 and 27 if acquired data stream 312 had passed below the second alarm limit 316 that was set when data 312 exceeded tracking threshold 314 at minute 25, but because that second alarm condition did not actually occur no alarm was triggered.

Patent Owner further asserts Dr. Yanulis agreed “that Bock does not disclose triggering an alarm based on exceeding the tracking threshold” 314. PO Resp. 37 (quoting Ex. 2014, 89:17–22). Patent Owner’s selective quotation here of the deposition transcript at page 89, lines 17–22 omits the introductory line 16, “I’m looking at minutes 25 to 27” (Ex. 2014, 89:16–22). This cabined Dr. Yanulis’s statement to that portion of Bock’s Figure 2 where no alarm was triggered because acquired data stream 312 did not exceed the second alarm limit 316 that was set when data 312 exceeded tracking threshold 314 at minute 25. This does not change the fact that Bock’s processor does not set *any* alarm limit 316 until the processor

determines acquired data stream 312 falls below tracking threshold 314. This fact establishes Bock's processor triggers an alarm based on acquired data stream 312 exceeding tracking threshold 314, as broadly recited in claim 1, even though data 312 must additionally exceed the corresponding alarm limit 316 for an alarm to be triggered.

i) Conclusion as to Claim 1

Based on the foregoing arguments and evidence, we conclude Petitioner has demonstrated by a preponderance of the evidence that claim 1 is unpatentable as having been obvious over Bock and Kiani.

4. Claim 7

Claim 7 recites: "The system of claim 1, wherein the first alarm threshold is *predetermined*." Ex. 1001, 14:66–67 (emphasis added).

Petitioner contends "Bock teaches that the alarm threshold may be predetermined." Pet. 40. Petitioner cites Bock's disclosure that: "The tracking threshold [314] can be a preset amount different than the calculated representative value [310]." *Id.* (quoting Ex. 1005, 6:23–24, and citing *id.* at 6:20–42); Ex. 1003 ¶ 122.

Patent Owner argues Bock's tracking threshold 314 is not predetermined. *See* PO Resp. 41–42. Patent Owner asserts "Bock calculates the representative value [310] *after* acquiring patient data [312]," which "is not predetermining the tracking threshold [314]." *Id.* at 41 (emphasis added) (citing Ex. 1005, 5:52–56); Ex. 2011 ¶ 82. To satisfy claim 7, Patent Owner argues Bock must determine tracking threshold 314 "*prior to acquiring* patient data." PO Resp. 41 (emphasis added); Ex. 2011 ¶ 82.

Petitioner replies that “claim 7 does not state when or how the tracking threshold must be ‘predetermined.’” Pet. Reply 15. Petitioner asserts Bock’s tracking threshold 314 “is predetermined because it is not a diminishing or changing threshold, but one that is set at a difference from the calculated representative value” 310, wherein the difference is predetermined. *Id.* (citing Ex. 1005, 6:20–42; Ex. 1003 ¶ 122); Ex. 1040 ¶ 77.

Patent Owner replies that, although Bock does calculate tracking threshold 314 as a *predetermined difference* from calculated representative value 310, threshold 314 is not predetermined as recited in claim 7 because value 310 “changes over time” and threshold 314 changes with it. Sur-reply 20 (citing Ex. 1005, Fig. 2).

Resolution of the parties’ dispute as to claim 7 turns on claim construction. Specifically: Does the term “predetermined” require that the alarm threshold *value* is determined prior to acquiring patient data (as Patent Owner contends), or that the alarm threshold *calculation* is determined prior to acquiring patient data, and may change as the patient data changes (as Petitioner contends)? We conclude Petitioner has the better position. Claim 1, from which claim 7 depends, recites a first alarm threshold applied during a first period of time and a second alarm threshold applied during a second period of time, wherein the latter “replace[s]” the former. *See* Ex. 1001, 14:6–9 (first alarm threshold), 14:13–16 (second alarm threshold). It is undisputed that both of these alarm thresholds correspond to an adaptive threshold AT applied at different times, as illustrated in Figure 6 of the ’218 patent. *See id.* at Fig. 6, 6:35–38, 7:40–8:6. Therefore, Patent Owner’s

position is inconsistent with the '218 patent specification, and Petitioner's position is consistent with the '218 patent specification.

Applying Petitioner's claim construction, we find Bock's tracking threshold 314 is a predetermined alarm threshold, because its calculation is determined prior to acquiring patient data. Specifically, Bock predetermines that tracking threshold 314 is "a preset amount different than the calculated representative value [310]," such as a constant percentage lower than calculated representative value 310. Ex. 1005, Fig. 2, 4:4–14, 6:23–25.

We conclude Petitioner has demonstrated by a preponderance of the evidence that claim 7 is unpatentable as having been obvious over Bock and Kiani.

5. *Claims 2–4 and 12–15*

Petitioner provides arguments and evidence, including testimony from Dr. Yanulis, in support of contending claims 2–4 and 12–15 are unpatentable as having been obvious over Bock and Kiani. Pet. 38–43; Ex. 1003 ¶¶ 116–121, 123–133. In defense of these claims, Patent Owner relies solely on arguments relating to claim 1. *See, e.g.*, PO Resp. 34, 39–40, 41. For the reasons provided in Section III.D.3 above in the context of claim 1, we conclude Patent Owner's defense is not persuasive. Our analysis of claim 1 applies equally well to independent claim 12.

We further find a preponderance of the evidence supports Petitioner's contention that Bock discloses the limitations recited in dependent claims 2–4 and 13–15, for the following reasons.

Concerning claims 2 and 13, Bock's representative value 310 is a "baseline measurement" calculated from acquired data stream 312 over the

first period of time, which Petitioner equates to minutes 0–21 in Bock’s Figure 2. *See* Ex. 1001, 14:41–47 (claim 2), 16:33–40 (claim 13); *supra* Section III.D.3(c). Concerning claims 3 and 14, Bock’s representative value 310 is also a “baseline measurement” calculated from acquired data stream 312 over the second period of time, which Petitioner equates to after minute 21 in Bock’s Figure 2. *See* Ex. 1001, 14:48–54 (claim 3), 16:41–48 (claim 14); Pet. 39 (stating “the second period of time” in Bock is “after minute 21”). Specifically, Bock’s representative value 310 is adjusted to represent acquired data stream 312 over time. Ex. 1005, Fig. 2, 3:44–4:3, 5:52–6:6; *see* Pet. 38–39, 43; Ex. 1003 ¶¶ 116, 118, 131–132.

Concerning claims 4 and 15, Bock’s “lower limit” (i.e., lower extremity limit 308 in Figure 2) “is predetermined and corresponds to a minimum parameter value for oxygen saturation.” *See* Ex. 1001, 14:55–57 (claim 4), 16:49–51 (claim 15). Specifically, Bock’s lower extremity limit 308 represents a value that is “extreme for the characteristic being monitored,” and “may represent a value for the characteristic that is unlikely to be acquired from a patient who does not require immediate attention.” Ex. 1005, 3:50–58, 6:7–15; *see* Pet. 40, 43; Ex. 1003 ¶¶ 120, 133.

Thus, we conclude Petitioner has demonstrated by a preponderance of the evidence that claims 2–4 and 12–15 are unpatentable as having been obvious over Bock and Kiani.

E. Obviousness over Bock, Woehrle, and Kiani

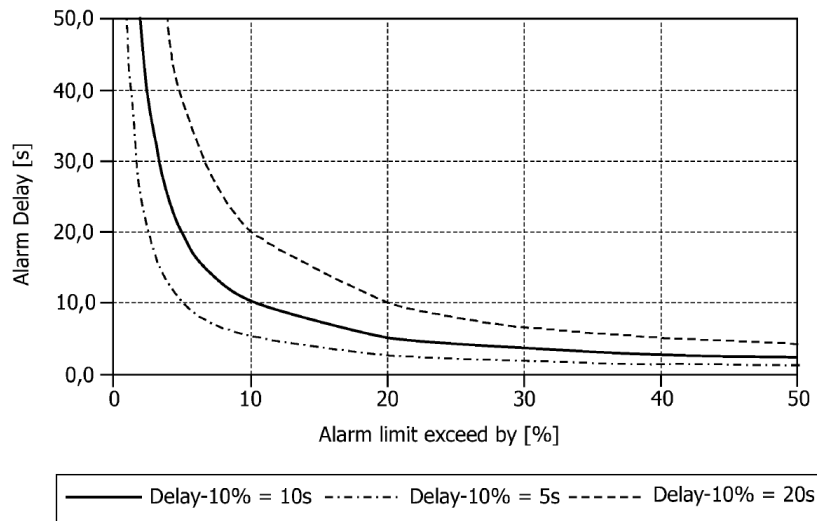
Petitioner asserts claims 5, 6, 8–10, and 16–18 of the ’218 patent are unpatentable as having been obvious over Bock, Woehrle, and Kiani. Pet. 44–50. Patent Owner opposes. PO Resp. 42–52. We have reviewed

Petitioner’s and Patent Owner’s arguments, and the evidence of record. We conclude a preponderance of the evidence supports Petitioner’s assertions as to all challenged claims 5, 6, 8–10, and 16–18. We first briefly summarize Woehrle, then we address the parties’ contentions as to obviousness.

1. *Woehrle Disclosure*

Woehrle discloses “a method for controlling an alarm in a medical instrument or system . . . detecting at least one physiological parameter of the patient,” such as oxygen saturation. Ex. 1007, code (57), 2:11–14.⁷ Woehrle indicates “in order to avoid nuisance alarms it is known to use an *alarm delay* between the event of exceeding or under-running a preset limit and the actual generation of the alarm,” and Woehrle’s method seeks to “avoid generating nuisance alarms to a high degree.” *Id.* at 2:15–20, 3:6–9 (emphasis added).

Figure 1 of Woehrle is reproduced here.



⁷ Our citations to Woehrle (Exhibit 1007) refer to the page numbers added by Petitioner to the bottom of each page, as is done in the Petition.

Figure 1 illustrates how, in Woehrle, an alarm delay (the vertical axis) is determined as a function of the degree by which a measured oxygen saturation value exceeds an alarm limit (the horizontal axis) which triggers the alarm. *Id.* at 3:15–21, 3:27–31, 4:12–19, 7:15–27. As shown, “the function yields a longer alarm delay for a lesser degree of exceeding or under-running the predefined threshold, respectively, and vice versa,” so “the more the present value exceeds or under-runs the predefined threshold the earlier an alarm is generated.” *Id.* at 4:12–19. A look-up table may be used instead of the continuous function shown in Figure 1. *Id.* at 8:31–9:1.

2. Claim 5

Claim 5 recites: “The system of claim 1, wherein the one or more hardware processors are further configured to *wait for a time delay* prior to the triggering of the second alarm, and wherein *the time delay is a function of the second alarm threshold.*” Ex. 1001, 14:58–62 (emphasis added).

Petitioner provides arguments and evidence, including testimony from Dr. Yanulis and Dr. Bergeron, in support of contending claim 5 is unpatentable as having been obvious over Bock, Woehrle, and Kiani. Pet. 44–47; Pet. Reply 15–20; Ex. 1003 ¶¶ 134–142; Ex. 1040 ¶¶ 79–92. Patent Owner provides arguments and evidence in opposition, including testimony from Mr. Goldberg. PO Resp. 42–51; Ex. 2011 ¶¶ 85–98.

a) Petitioner’s Case

Petitioner relies on Bock and Kiani for the obviousness of parent claim 1. *See supra* Section III.D.3; Pet. 44–45; Ex. 1003 ¶ 137. As already discussed, we agree with Petitioner here over Patent Owner’s objections. *See supra* Section III.D.3; PO Resp. 42–43; Ex. 2011 ¶¶ 86–88.

Petitioner then relies on Woehrle as disclosing the time delay limitation of claim 5. Pet. 44, 45–46; Ex. 1003 ¶¶ 134–140; Ex. 1040 ¶ 80. Petitioner cites the time delay schemes shown in Woehrle’s Figure 1, and in Woehrle’s similar look-up table, as “setting a time delay for the alarm based on the deviation between the measured values of the patient and the normal value (or second threshold).” Pet. 45–46 (citing Ex. 1007, 3:10–4:3, 7:15–9:14); Pet. Reply 15–16 (same); Ex. 1003 ¶¶ 138–140. Patent Owner does not challenge these contentions, and we determine they are supported by a preponderance of the evidence cited by Petitioner. *See* Ex. 1007, 3:27–31 (“[I]t is an important idea of the invention to consider the present situation of the physiological parameter in order to determine the alarm delay in such a way that in case of decreasing abnormalities of the detected values a longer alarm delay is determined and vice versa” so “a present alarm delay is extended if the patient’s condition starts to improve again.”), 7:15–8:1 (Fig. 1), 8:31–9:1 (look-up table).

For obviousness, Petitioner contends both Bock and Woehrle are directed to avoiding nuisance alarms in patient oxygen saturation monitoring devices. Pet. 44, 46–47; Ex. 1003 ¶¶ 135–136, 140. Petitioner asserts a POSITA would have been motivated to modify Bock’s system by adding an alarm time delay, such as disclosed by Woehrle, to provide an “additional” method of reducing nuisance alarms in Bock. Pet. 44, 46; Ex. 1003 ¶¶ 136, 140. Petitioner argues this would have used a known technique to improve a similar device in a similar way, by reducing nuisance alarms and providing delays in the alarm when an oxygen saturation alarm limit has been exceeded for some set period of time. Pet. 46–47; Ex. 1003 ¶¶ 140–141. This would have improved Bock’s alarm by “predictably reduc[ing]

nuisance alarms in *two ways*,” according to Petitioner. Pet. 47 (emphasis added) (citing Ex. 1003 ¶ 142). Dr. Yanulis identifies these as: (1) from Bock, customizing alarm thresholds based on the patient’s measured oxygen saturation levels, rather than a default or standard threshold; and (2) from Woehrle, “utilizing pre-alarm delays to prevent activation of alarms until and unless the physiological parameter measurement exceeds a threshold for a period of time to ensure it is not transient and requires medical intervention.” Ex. 1003 ¶ 142.

Petitioner’s Reply expounds on Dr. Yanulis’s second way that combining Bock and Woehrle would predictably reduce nuisance alarms. *See* Pet. Reply 18–20. Petitioner and Dr. Bergeron here describe Bock’s use of tracking threshold 314 and alarm limit 316 as “an *effective* delay” in triggering an alarm, due in part to the decaying nature of alarm limit 316. *Id.* at 18–19 (emphasis added); Ex. 1040 ¶¶ 74, 87–88; *see also* Ex. 1005, Figs. 2–3, 4:41–5:2 (illustrating and describing the decay of alarm limit 316). According to Dr. Bergeron: “In critical conditions, a caregiver wants more certainty [than Bock’s alarm limit 316 provides] in how long the effective delay would be,” and this desire would motivate a POSITA “to *replace* the effective delay [of Bock’s alarm limit 316] with a preset delay” as disclosed by Woehrle. Ex. 1040 ¶¶ 88–89 (emphasis added); Pet. Reply 19 (also citing Ex. 1003 ¶¶ 138, 142, 146). Dr. Bergeron concludes this is “merely . . . *substituting* one known option for another to predictably yield a system with time delays that are not dependent on a patient’s measured parameter after starting the delay period.” Ex. 1040 ¶ 90 (emphasis added); Pet. Reply 19–20 (citing *KSR*, 550 U.S. at 418).

b) Whether the Reply Improperly Presents New Argument

Patent Owner argues Petitioner’s Reply provides a “belated explanation” of obviousness in a “new argument[] . . . exceeding the proper scope of a reply.” Sur-reply 9–10, 21–22 (citing Inst. Dec. 48; PTAB Consolidated Trial Practice Guide (Nov. 2019) (CTPG)⁸, 73–74; 37 C.F.R. § 42.23). Patent Owner particularly asserts the Reply’s description of Bock’s alarm limit 316 as “effectively an alarm delay” (Pet. Reply 18–19) is “absent from the Petition,” which in fact “argued the opposite” because the Petition relied on Woehrle and not Bock as disclosing the time delay of claim 5. *Id.* (citing Pet. 13, 44–50; Ex. 1003 ¶ 52; Inst. Dec. 41 n.9).

Our rules require that the Petition must provide “[a]ll arguments for the relief requested,” and that the Reply “may only respond to arguments raised in the . . . patent owner response.” 37 C.F.R. § 42.23(b); CTPG 73–74. Thus, “Petitioner may not submit new evidence or argument in reply that it could have presented earlier, e.g. to make out a prima facie case of unpatentability,” but Petitioner “may submit rebuttal evidence in support of its reply.” CTPG 73–75 (citations omitted).

We conclude the Reply does not improperly present new argument or evidence. The Petition states: “The combination of Bock . . . and Woehrle would have predictably reduced nuisance alarms in two ways.” Pet. 47 (citing Ex. 1003 ¶ 142). While the Petition does not spell out the “two ways” (*id.*), the cited testimony from Dr. Yanulis does (Ex. 1003 ¶ 142). Dr. Yanulis here cites Woehrle as evidencing the benefits provided by “utilizing pre-alarm delays to prevent activation of alarms *until and unless*

⁸ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

the physiological parameter measurement exceeds a threshold for a period of time to ensure it is not transient and requires medical intervention.”

Ex. 1003 ¶ 142 (emphasis added); *id.* ¶¶ 138–142 (discussed at Pet. 45–47).

This argument and evidence sufficiently support the positions taken in the Reply as to the obviousness of *replacing* Bock’s alarm limit 316 with Woehrle’s preset time delay, to avoid the Board’s proscription against raising new arguments in the Reply.

No doubt, the Reply’s specific discussion of Bock’s alarm limit 316 being “effectively an alarm delay” (Pet. Reply 18–19) and portions of Dr. Bergeron’s corresponding testimony (Ex. 1040 ¶¶ 81, 87–91) are not reflected in the Petition. Nonetheless, Petitioner’s obviousness theory remains the same—it would have been obvious to replace Bock’s alarm limit 316 with Woehrle’s preset time delay. *Compare* Pet. 44–48 and Ex. 1003 ¶¶ 134–146, *with* Pet. Reply 18–20 and Ex. 1040 ¶¶ 79–81, 85, 87–90. The Reply’s additional focus on Bock’s pertinent disclosures, and relating them to Woehrle’s pertinent disclosures, is a permissible reply to the Patent Owner Response’s opposition to Petitioner’s contentions of obviousness. Thus, we have considered Petitioner’s Reply as part of reaching our present Decision.

c) Patent Owner’s Opposition on the Merits

On the merits, Patent Owner attacks Petitioner’s case for a motivation to combine Bock and Woehrle, and for a reasonable expectation of success, leading to the invention of claim 5. *See* PO Resp. 42–51; Ex. 2011 ¶¶ 85–98. We consider each issue in turn.

d) Motivation to Combine

Patent Owner argues the Petition fails to establish a motivation for combining the alarm method of Bock with the time delay of Woehrle. PO Resp. 43–48; Ex. 2011 ¶¶ 89–94. Patent Owner asserts: “[B]y arguing that both Bock and Woehrle describe ways to reduce nuisance alarms, Petitioner is merely contending that the references are directed to the same field of endeavor,” which “is not sufficient to establish a motivation to combine.” PO Resp. 44 (citations omitted). Also: “Petitioner fails to identify why one of ordinary skill would have been motivated to combine the respective approaches to reducing alarms taken by Bock and Woehrle.” *Id.* at 45; Ex. 2011 ¶ 90. Indeed, according to Patent Owner and Mr. Goldberg, a POSITA “would have expected that layering multiple approaches to reducing alarms would materially increase the risk of missing a patient’s life threatening emergency because multiple layers of alarm reduction could suppress actionable alarms,” so a POSITA would have been dissuaded “from layering Woehrle’s time delay approach on top of Bock’s alarm system.” PO Resp. 45–46; Ex. 2011 ¶ 90 (citing Ex. 1005, 1:18–20; Ex. 1007, 2:15–20).

Patent Owner further points out that claim 5 recites the time delay “is a function of the second alarm threshold”—which, in Bock, is tracking threshold 314. PO Resp. 46–47; Ex. 2011 ¶ 91. Patent Owner asserts Petitioner fails to explain why a POSITA would have applied a time delay to Bock’s use of tracking threshold 314, given that “exceeding tracking threshold 314 sets the alarm limit 316, it does not trigger an alarm.” PO Resp. 46–47; Ex. 2011 ¶ 91. Mr. Goldberg testifies: “Adding a time delay to Bock’s tracking threshold 314 would thus mean that the acquired data 312

would have to exceed the tracking threshold 314 for some amount of time before the alarm limit 316 would be created,” which “would not . . . delay an alarm ‘based on the degree of deviation from the normal value’ of a parameter, as Dr. Yanulis characterizes the teachings of Woehrle.” Ex. 2011 ¶ 91 (citing Ex. 1003 ¶ 140). Mr. Goldberg further opines a POSITA “would not have expected a potential benefit from adding a time delay after the measured data [312] crosses Bock’s tracking threshold [314],” because “Woehrle’s time delay is applied after an alarm otherwise would have been triggered,” whereas crossing Bock’s tracking threshold 314 merely “establishes the alarm limit 316.” *Id.* ¶ 92.

Petitioner replies that “[t]he Petition adequately set out the motivation to combine” by describing “how the Woehrle system reduces alarms using time delays based on the deviation between the measured values of the patient and the normal (or second threshold) value.” Pet. Reply 15–16 (citing Pet. 45–46). Petitioner insists: “Using these time delays in [Bock] provides another way for the tightening thresholds to be implemented.” *Id.* (citing Ex. 1003 ¶ 146; Ex. 1040 ¶ 80). In particular, according to Petitioner, a POSITA “would have known various ways to delay alarms including delaying them based on the dynamic thresholds of Bock or the predetermined alarm delays of Woehrle that decrease in duration as a parameter measurement gets further out-of-limits.” *Id.* at 16; Ex. 1040 ¶ 81. Thus, Petitioner argues Dr. Yanulis’s reasoning for motivation to combine “goes far beyond simply stating the prior art is direct[ed] to the same field of endeavor,” thereby distinguishing case law cited by Patent Owner. Pet. Reply 16–17 (citing Ex. 1003 ¶¶ 137–142). Petitioner finally asserts: “Nothing about the combination causes a risk of missing a true alarm,”

because this “is a risk in any system designed to minimize nuisance alarms, and is one that a [POSITA] would anticipate and avoid,” such as “by simply adjusting parameters, e.g. shortening alarm delay periods” or relying on Bock’s extremity limit 308. *Id.* at 17–18 (citing Ex. 1003 ¶¶ 39, 141–142, 146; Ex. 1040 ¶¶ 81–86; Ex. 1042, 16:8–19).

We conclude Petitioner has established, by a preponderance of the evidence, a sufficient motivation for the proposed obviousness of replacing Bock’s alarm limit 316 with Woehrle’s preset time delay. Dr. Yanulis testifies, and Patent Owner does not dispute, that Bock and Woehrle both disclose oxygen saturation monitoring systems that seek to avoid nuisance alarms. *See* Ex. 1003 ¶ 60 (citing Ex. 1007, 3:7–31, 8:31–9:1); *id.* ¶ 74 (citing Ex. 1005, 1:8–20); *id.* ¶¶ 135–136, 140. Dr. Yanulis describes how Bock and Woehrle seek to achieve this goal in different ways, with Bock “basing alarm thresholds on a patient’s actual physiological parameter measurements” (*id.* ¶ 140), and Woehrle “configuring a processor to wait for a time delay . . . prior to triggering a second alarm” with the delay being “a function of the second alarm threshold” (*id.* ¶ 138). Further according to Dr. Yanulis, Woehrle “explains the need for alarm delays based on the degree of deviation from the normal value for that parameter to reduce false alarms while also generating alarms more quickly for more severe parameter measurements requiring quicker medical intervention.” *Id.* ¶ 140. Thus, Dr. Yanulis’s view is that adding Woehrle’s preset time delay to Bock’s system would advantageously provide an additional means of reducing nuisance alarms in Bock. *Id.* ¶¶ 140–142.

Dr. Bergeron’s testimony is to the same effect, and is persuasive. Dr. Bergeron concludes that replacing Bock’s alarm limit 316, which is an

effective delay in triggering an alarm, with Woehrle's preset time delay is the simple substitution of one delay for another delay, and would have been advantageous. Ex. 1040 ¶¶ 87–90. The advantage is that, “[i]n critical conditions,” Woehrle's preset time delay provides “more certainty” because it is independent of “the patient's measured” oxygen saturation, whereas in Bock the effective delay requires acquired data stream 312 to drop below alarm limit 316. *Id.*

Dr. Bergeron also persuasively explains how replacing Bock's alarm limit 316 with Woehrle's preset time delay would not materially increase the risk of the alarm system missing true alarm, or life threatening, situations. Dr. Bergeron acknowledges that “[m]issing a true alarm is a risk in any system designed to minimize nuisance alarms,” which both Bock and Woehrle attempt to do. Ex. 1040 ¶ 82. Nonetheless, Dr. Bergeron testifies a POSITA would have known that “[t]hese risks can be greatly offset by simply adjusting parameters, such as shortening alarm delay periods.” *Id.* ¶¶ 83–84. Dr. Bergeron explains that Bock's extremity limit 308 provides further insurance against the alarm system missing life threatening situations. *See id.* ¶ 86; Ex. 1005, Fig. 2, 3:50–58, 6:7–15 (discussing how extremity limit 308 represents an extreme lower value for the monitored characteristic, requiring immediate attention if it is exceeded by acquired data stream 312, so Bock's processor 27 generates an immediate alarm when this occurs).

Patent Owner's opposition is premised largely on there being no reason to implement a time delay along with Bock's alarm limit 316. However, as discussed above, Petitioner proposes replacing Bock's alarm limit 316 with Woehrle's preset time delay.

Mr. Goldberg's contrary testimony also is not persuasive. He does not explain the reasons behind his conclusion that the risk of missing true alarm situations would have led a POSITA away from using Woehrle's preset time delay in Bock's alarm system. Ex. 2011 ¶ 90. The disclosures of Bock and of Woehrle cited by Mr. Goldberg establish that designing an oxygen saturation monitoring system presents a Goldilocks design challenge: the system needs to trigger alarms for significant patient events, but not trigger alarms for non-significant patient events. *See* Ex. 1005, 1:18–20; Ex. 1007, 2:15–20 (implementing alarm delays “is often a compromise between warning the clinical staff fast enough about a change in the patient's condition on the one hand and generation of too many unjustified and, thus, nuisance alarms which detract the clinical staff from other work, especially more important alarms, on the other hand”). Nonetheless, the prior art establishes that using a preset time delay was one tool that could be used to avoid nuisance alarms, if managed appropriately as a POSITA would have known how to do. *See* Ex. 1007, 2:15–20 (“[I]n order to avoid nuisance alarms it is known to use an alarm delay between the event of exceeding or under-running a preset limit and the actual generation of the alarm.”). Mr. Goldberg does not persuasively explain why this routine design challenge would have dissuaded a POSITA from implementing Woehrle's preset time delay in Bock's alarm system.

Patent Owner's argument that Petitioner fails to address claim 5's requirement that “the time delay is a function of the second alarm threshold” (Ex. 1001, 14:61–62) also is not persuasive. Woehrle's preset time delay satisfies this claim requirement. *See, e.g.*, Pet. 45–46; Pet. Reply 15–16; Ex. 1003 ¶¶ 138–139; Ex. 1040 ¶¶ 80–81, 88. In particular, Woehrle states

it is “important . . . *to consider the present situation of the physiological parameter* in order to determine the alarm delay in such a way that *in case of decreasing abnormalities of the detected values a longer alarm delay is determined and vice versa.*” Ex. 1007, 3:27–31 (emphases added). Thus, according to Woehrle’s time delay method, the time delay period is preset to be “*longer . . . for a lesser degree of exceeding*” an alarm threshold, and shorter for a greater degree of exceeding an alarm threshold. *Id.* at 4:12–19 (emphasis added), 7:15–8:1 (Fig. 1), 8:31–9:1 (look-up table). Thus, Petitioner’s proposal to replace Bock’s alarm limit 316 with Woehrle’s present time delay leads to the invention of claim 5, based on Woehrle’s disclosure that the time delay should be preset as a function of the degree to which acquired data stream 312 exceeds tracking threshold 314.

Thus, we conclude Petitioner has established, by a preponderance of the evidence, a sufficient motivation for the proposed obviousness of replacing Bock’s alarm limit 316 with Woehrle’s preset time delay.

e) Reasonable Expectation of Success

Patent Owner argues the Petition fails to establish a reasonable expectation of success in combining the alarm method of Bock with the preset time delay of Woehrle, to reach the invention of claim 5. PO Resp. 48–51; Ex. 2011 ¶¶ 95–98. Patent Owner first relies on the reasoning we provided in the Institution Decision, where we concluded “Patent Owner may have a valid point” in attacking reasonable expectation of success. *See* PO Resp. 48–49; Inst. Dec. 47–48. Patent Owner particularly asserts a POSITA “would not have reasonably understood how to successfully incorporate Woehrle’s time delay into Bock’s alarm scheme as a function of,

or based on, tracking threshold 314,” which Petitioner equates to the “second alarm threshold” of claims 1 and 5. PO Resp. 49–50; Ex. 2011 ¶¶ 95–97.

According to Mr. Goldberg: “Because exceeding tracking threshold 314 does not trigger alarm 318, it would be unclear to a [POSITA] how a time delay would even relate to tracking threshold 314” or “when such a time delay would even start in Bock’s systems.” Ex. 2011 ¶ 96. Patent Owner adds that Petitioner fails to explain how adding a time delay to Bock’s setting of alarm limit 316 after acquired data stream 312 crosses alarm threshold 314 corresponds to claim 5’s requirements of “wait[ing] for a time delay *prior to the triggering* of the second alarm,” and “*the time delay is a function of*” threshold 314. PO Resp. 50 (emphasis added to claim language); Ex. 2011 ¶ 97.

Petitioner replies that replacing Bock’s alarm limit 316 with Woehrle’s preset time delay would have been within the capabilities of a POSITA. Pet. Reply 20; Ex. 1040 ¶¶ 91–92 (“[I]mplementing a time delay would be known to a [POSITA].”). In support, Petitioner asserts the ’218 patent “does not describe how claim 5 is implemented because it would have been known to a [POSITA], and therefore is unnecessary to describe in detail.” Pet. Reply 20; Ex. 1040 ¶ 91.

Patent Owner responds that Petitioner has failed to establish a reasonable expectation of success in replacing Bock’s alarm limit 316 with Woehrle’s preset time delay. Sur-reply 22–23. Patent Owner argues “Bock’s alarm limit [316] is a parameter value at which an alarm will trigger—not a time delay,” so Petitioner’s proposal to replace alarm limit 316 with Woehrle’s preset time delay is not the substitution of a known equivalent as Petitioner would have it. *Id.* at 9, 23 (citing Ex. 1005, Fig. 2,

4:26–28); Ex. 2011 ¶¶ 32, 37–38, 93–94. Patent Owner further asserts replacing Bock’s alarm limit 316 with Woehrle’s preset time delay “would leave nothing to trigger an alarm.” Sur-reply 23 (citing Ex. 1005, 4:26–28). Petitioner’s theory for obviousness would also improperly “fundamentally change Bock’s principle of operation,” according to Patent Owner, which is “the interaction . . . between the tracking threshold 314 and the alarm limit 316.” *Id.*; Tr. 31:1–7 (citing Ex. 1005, 1:16–20).

We conclude Petitioner has established, by a preponderance of the evidence, that a POSITA would have had a reasonable expectation of success in replacing Bock’s alarm limit 316 with Woehrle’s preset time delay. The evidence shows that preset time delays were a well developed tool in the context of oxygen saturation monitoring systems at the time of the ’218 patent’s invention. For example, the ’218 patent describes time delays as being known in the art prior to the ’218 patent’s invention. *See* Ex. 1001, Fig. 1, 2:54–3:2 (illustrating and describing a prior art oxygen saturation measurement system incorporating delay alarm threshold D_L with time delay TD); *id.* at 3:24–59 (disclosing that the ’218 patent’s adaptive alarm system overcomes a baseline drift problem that occurs in the system of Figure 1), 6:20–23 (referring to the “*conventional* fixed alarm thresholds with and without an alarm time delay” shown in Figure 1 (emphasis added)). Woehrle similarly describes time delays as being previously known, and discusses one previously known alarm scheme employing a time delay. *See* Ex. 1007, 2:15–30. Thus, implementing time delays was a known technology to a POSITA prior to the ’218 patent.

Patent Owner’s opposition is unpersuasive, largely because it misconstrues the nature of Petitioner’s proposed obviousness. Petitioner

proposes to *replace* Bock’s alarm limit 316 with Woehrle’s preset time delay. *See, e.g.*, Pet. 44–48; Pet. Reply 18–20; Ex. 1003 ¶¶ 134–146; Ex. 1040 ¶¶ 79–81, 85, 87–90. Thus, Patent Owner’s and Mr. Goldberg’s various discussions of the difficulty of implementing a preset time delay *with* Bock’s alarm limit 316 are not pertinent to Petitioner’s theory of obviousness. *See* PO Resp. 48–50; Ex. 2011 ¶¶ 95–98. Applying Petitioner’s theory, it would have been well within the capabilities of POSITA to incorporate a preset time delay in Bock’s alarm scheme, wherein the delay period begins at the time acquired data stream 312 crosses tracking threshold 314, based on Woehrle’s discussion of implementing time delays based on a “predefined threshold defining an upper or lower limit for a normal range of the physiological parameter.” Ex. 1007, 4:12–19, 7:15–8:1 (Fig. 1), 8:31–9:1 (look-up table).

When instituting the present review, we stated “we do not ascertain any discussion in the Petition explaining how [claim 5] would be satisfied by incorporating a time delay into Bock’s alarm scheme.” Inst. Dec. 48 (citing Pet. 44–47). Now, based on the record as fully developed during trial, we understand Petitioner proposes to replace Bock’s alarm limit 316 with Woehrle’s preset time delay, as set forth above.

Finally, we disagree with Patent Owner’s position that replacing Bock’s alarm limit 316 with Woehrle’s preset time delay would fundamentally change Bock’s principle of operation. Bock’s principle of operation is to reduce nuisance alarms in an oxygen saturation monitoring system, specifically “to avoid registering false positives, while avoiding false negatives (not registering the occurrence of a significant event).” Ex. 1005, 1:16–20. As discussed in detail above, the principle remains the

same even after Bock is modified to include Woehrle's preset time delay, which is another tool to employ when addressing this Goldilocks design objective.

Thus, we conclude Petitioner has established, by a preponderance of the evidence, that a POSITA would have had a reasonable expectation of success in replacing Bock's alarm limit 316 with Woehrle's preset time delay.

f) Conclusion as to Claim 5

Based on the foregoing arguments and evidence, we conclude Petitioner has demonstrated by a preponderance of the evidence that claim 5 is unpatentable as having been obvious over Bock, Woehrle, and Kiani.

3. Claims 6 and 8

Claim 6 recites: "The system of claim 5, wherein the time delay decreases as the difference between the at least one value and the lower limit diminishes." Ex. 1001, 14:63–65. Claim 8 is an independent claim that is similar to claim 1, except that claim 8 recites that the processor is "configured to . . . apply a time delay based on the second alarm threshold, wherein the time delay approaches zero as the at least one oxygen saturation value obtained over the first period of time approaches the lower limit." *Id.* at 15:1–39.

Petitioner provides arguments and evidence, including testimony from Dr. Yanulis, in support of contending claims 6 and 8 are unpatentable as having been obvious over Bock, Woehrle, and Kiani. Pet. 47–48 (claim 6), 48–50 (claim 8); Ex. 1003 ¶¶ 143–154. In defense of these claims, Patent Owner relies solely on arguments relating to claim 5. *See, e.g.*, PO Resp. 48.

For the reasons provided in Section III.E.2 above in the context of claim 5, we conclude Patent Owner's defense is not persuasive.

We further find a preponderance of the evidence supports Petitioner's contention that Woehrle discloses the time delay limitations recited in claims 6 and 8. *See* Pet. 47–48 (claim 6), 49 (claim 8). In particular, Woehrle states that “the function for determining the alarm delay considers the degree by which the present value exceeds or under-runs at least one predefined threshold” so that “*the function yields a longer alarm delay for a lesser degree of exceeding or under-running the predefined threshold, respectively, and vice versa.*” Ex. 1007, 4:12–17 (emphasis added); Ex. 1003 ¶ 143. This is shown, for example, in Figure 1 of Woehrle, which shows an inverse relationship between the degree by which the measured values exceed a predefined alarm threshold (horizontal axis) and the alarm delay (vertical axis). *See* Ex. 1007, Fig. 1, 7:15–27. This is also shown in the look-up table cited by Petitioner and Dr. Yanulis. *See id.* at 8:31–9:1; Pet. 47–48; Ex. 1003 ¶¶ 144–145.

Dr. Yanulis testifies, and we agree, that these disclosures “teach[] the pre-alarm time delay gets shorter as the difference between the measured SpO₂ measurement gets more severe and gets closer to a lower limit.” Ex. 1003 ¶ 143; Pet. 47. In particular, in relation to claim 6, Woehrle's Figure 1 shows that the time delay decreases (lower on the vertical axis) as the difference between the measured oxygen saturation values and a lower limit diminishes (to the right on the horizontal axis). We acknowledge that Woehrle's horizontal axis does not reflect, directly, the difference between measured oxygen saturation values and a lower limit, which is the characteristic recited in claim 6.

Nonetheless, when the teachings of Woehrle's Figure 1 are applied within the context of Bock's Figure 2, it is apparent that the combination leads to the subject matter recited in claim 6. This is illustrated by our annotations here to Bock's Figure 2:

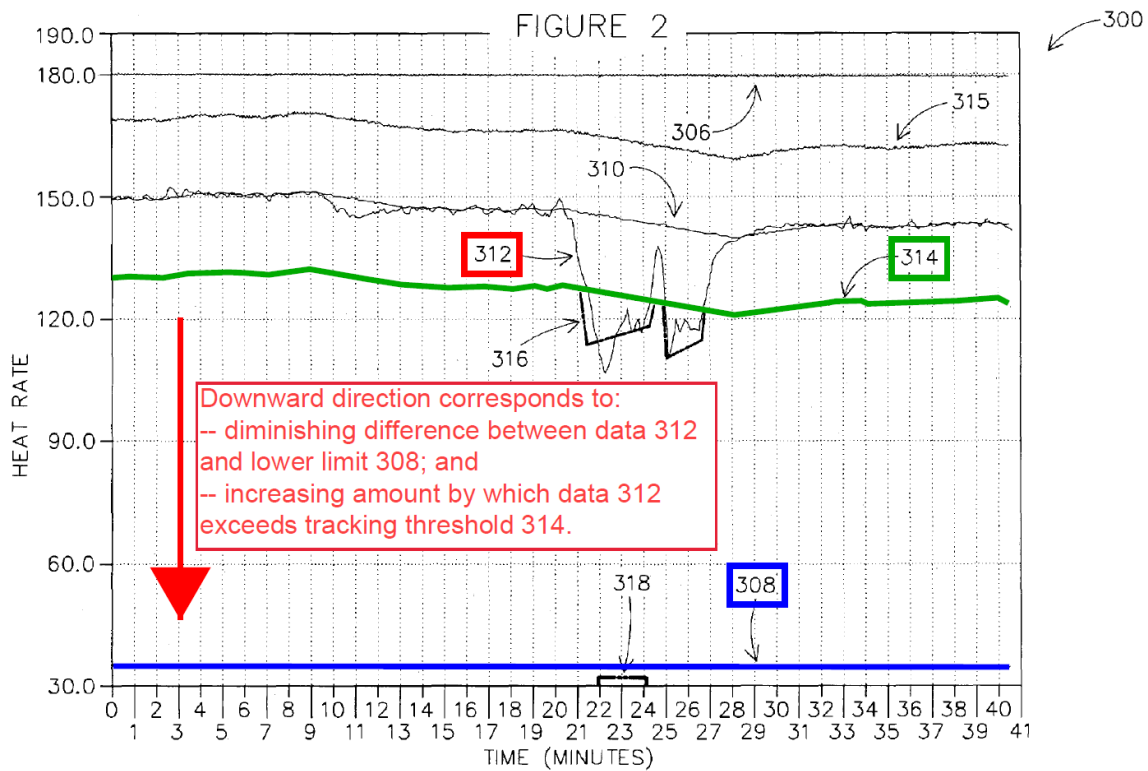


Figure 2 illustrates Bock's alarm scheme, and our annotations reflect how, within the region between tracking threshold 314 (green) and lower limit 308 (blue), a diminishing difference between measured data 312 and lower limit 308 per claim 6 corresponds to an increasing amount by which measured data 312 exceeds or drops below tracking threshold 314 per Woehrle's horizontal axis. *See, e.g., Ex. 1003 ¶¶ 145–146.* Thus, Woehrle teaches that, when a preset time delay is applied to Bock's system, it would be beneficial to *shorten* the delay time when acquired data stream 312 gets *more critical* by exceeding (dropping below) tracking threshold 314 by a

greater amount. *See id.* Stated another way, Woehrle teaches that it would be beneficial to *lengthen* the delay time when acquired data stream 312 gets *less critical* by exceeding (dropping below) tracking threshold 314 by a *lesser* amount, to reduce nuisance alarms. *See id.*

In relation to claim 8, Woehrle's Figure 1 shows that the time delay approaches zero (lower on the vertical axis) as the measured oxygen saturation values approach the lower limit (to the right on the horizontal axis). As with claim 6 discussed above, it is apparent from Bock's Figure 2 that data 312 approaching lower limit 308, per claim 8, corresponds to an *increase* in the amount by which data 312 exceeds (drops below) tracking threshold 312, and hence leads to the time delay approaching zero as required by claim 8 by applying Woehrle's teachings. *See, e.g.,* Ex. 1003 ¶ 151.

We conclude Petitioner has demonstrated by a preponderance of the evidence that claims 6 and 8 are unpatentable as having been obvious over Bock, Woehrle, and Kiani.

4. *Claims 9 and 18*

Claim 9 recites: "The system of claim 8, wherein the first alarm threshold is *predetermined*." Ex. 1001, 15:40–41 (emphasis added). Claim 18 depends from claim 12 to add the same limitation as claim 9. *Id.* at 16:61–62.

Petitioner contends "Bock teaches that the alarm threshold may be predetermined," as discussed above in relation to claim 7 and Petitioner's first ground. Pet. 40, 50. Patent Owner argues Bock's tracking

threshold 314 is not predetermined, as discussed above in relation to claim 7 and Petitioner's first ground. *See* PO Resp. 41–42, 51–52.

As discussed above in relation to claim 7 and Petitioner's first ground, resolution of this dispute turns principally on claim construction of the term “predetermined,” and Petitioner has the better position. *See supra* Section III.D.4. Therefore, we conclude Petitioner has demonstrated by a preponderance of the evidence that claims 9 and 18 are unpatentable as having been obvious over Bock, Woehrle, and Kiani.

5. *Claims 10, 16, and 17*

Petitioner provides arguments and evidence, including testimony from Dr. Yanulis, in support of contending dependent claims 10, 16, and 17 are unpatentable as having been obvious over Bock, Woehrle, and Kiani. Pet. 50 (referring back to previous sections of the Petition); Ex. 1003 ¶¶ 156–157. Patent Owner does not address these dependent claims separately from their respective parent independent claims 8 and 12. *See, e.g.*, PO Resp. 48.

Concerning claim 10, Bock's “lower limit” (i.e., lower extremity limit 308 in Figure 2) “is predetermined and corresponds to a minimum parameter value for oxygen saturation.” *See* Ex. 1001, 15:42–44 (claim 10); *supra* Section III.D.5 (discussing corresponding limitation in claim 4). Thus, in combination with the established obviousness of the parent claim 8 (*see supra* Section III.E.3), we conclude Petitioner has demonstrated by a preponderance of the evidence that claim 10 is unpatentable as having been obvious over Bock, Woehrle, and Kiani.

Claim 16 depends from claim 12 to add “waiting for a time delay prior to the triggering of the second alarm, and wherein the time delay is a function of the second alarm threshold.” Ex. 1001, 16:52–57. Claim 17 depends from claim 16 and adds “the time delay decreases as the difference between the at least one oxygen saturation value and the lower limit diminishes.” *Id.* at 16:58–60. Thus, our previous discussions as to the obviousness of claims 5 and 6 apply here too. *See supra* Sections III.E.2–3. We conclude Petitioner has demonstrated by a preponderance of the evidence that claims 16 and 17 are unpatentable as having been obvious over Bock, Woehrle, and Kiani.

IV. SUMMARY OF CONCLUSIONS

In summary, we determine a preponderance of the evidence establishes claims 1–10 and 12–18 of the ’218 patent are unpatentable, as shown in the following table:⁹

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–4, 7, 12–15	103	Bock, Kiani	1–4, 7, 12–15	

⁹ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
5, 6, 8–10, 16–18	103	Bock, Woehrle, Kiani	5, 6, 8–10, 16–18	
Overall Outcome			1–10, 12–18	

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–10 and 12–18 of the '218 patent have been proven by a preponderance of the evidence to be unpatentable; and

FURTHER ORDERED that, because this is a final written decision, parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2). We are already aware of Application Nos. 16/184,908 and 16/800,971.

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